26

Chapter 26

What should be the RCOG's relationship with older women?

Donna Dickenson

Introduction

A 'should' question normally signals work for an ethicist but this ethicist's task is complicated by the normative dimension of all the chapters in this volume. Each author was asked to come up with three recommendations from their own subject area – 'should' statements deriving from the 'is' analysis that they present. If those prescriptions cover the relevant topics, what more is there for an ethicist to do?

I have had a personal interest in obstetricians' relationship with 'older women' since being classified as an 'elderly primigravida' at the superannuated age of 26 years. Apart from that, however, what original contribution can I make? The convenors of the 56th RCOG Study Group gave me plentiful suggestions – perhaps a little too plentiful:

> How should the RCOG approach its constituencies, medical ethics, regulation and its relationship to government and the rest of the medical profession, i.e. the NHS and the market, vested interests, individuals or consumers, families, the unborn, doctors, drug companies, surrogacy, the unborn, trafficking, global adoption, law, research?

I have to admit this was just too much for me. Instead, I want to argue for what may seem a self-evidently simple point. The RCOG describes its mission as 'setting standards to improve women's health' – presumably all women. In the 6 years that I have served on the RCOG Ethics Committee, however, we have almost always been concerned with that minority of the female population who are of reproductive age. There are two things wrong with that slant: it defines women in terms of their reproductive role alone and it risks allowing women above that age (or, indeed, girls below puberty) to vanish from our scrutiny.

I did say my point was self-evidently simple, perhaps even simplistic. The organisers of the Study Group were clearly fully aware of it, since their brief is to expand our awareness. What I want to do is to elaborate on why the narrower concentration is not only professionally blinkered but also morally wrong – and there my background as an ethicist is indeed relevant, particularly as a feminist ethicist. I also want to make three recommendations of my own, which I hope will contribute towards 'consciousness-raising' – itself a feminist method – about older women.

Feminist ethics and reproduction

In the early days of what has come to be called 'second-wave' feminism – that is, the Women's Liberation movement of the late 1960s – feminist activists and academics had plenty to do in asserting women's autonomy and rights in the reproductive context. The popular starting point was probably the collective volume *Our Bodies, Ourselves*,[1] which reads in retrospect as both familiar and strange – familiar because the assertion that women have the right to control their own bodies seems like a platitude to all but militant anti-abortionists, strange because practice in obstetrics and gynaecology has evolved so far away, in most instances, from the taken-for-granted medical paternalism of the earlier period.

In the area of new reproductive technologies, however, feminists came up against not just medical paternalism but also the technological imperative. The cover of the 1984 collection *Test-Tube Women: What Future for Motherhood?*[2] shows a naked and heavily pregnant woman trapped in what looks like a padded cell, with a ludicrously gaudy collection of wires extruding from her stomach. The villain of the piece is the white-coated male doctor whom she's trying in vain to push away. A great deal of feminist concern, much of it quite prophetic, was raised in that book about areas where ethical debates still rage: 'designer genes', for example, as well as surrogacy, egg harvesting, abortion of female fetuses and disability. Reacting against media descriptions of the new reproductive technologies as enabling all women to fulfil their supposedly deepest desire, motherhood, the writers in *Test-Tube Women* typified second-wave feminism's scepticism about whether these new developments were necessarily liberating for women.

That work of challenging the ethical basis of assisted reproductive technologies was, and continues to be, necessary but, ironically, it risks becoming caught up in a sexist stereotype: that reproductive issues, whether 'natural' or 'artificial', are the only rightful concern of feminist ethics. Some feminist ethicists, such as Francoise Baylis and Susan Sherwin, expanded their concerns to power in the doctor–patient relationship more generally, even though the immediate theatre of their concern was pregnancy. In their 2002 essay 'Judgements of non-compliance in pregnancy',[3] the two Canadian professors use pregnancy as a fulcrum, expanding their ethical concerns to:

> ... understanding what is problematic in the circumstances that elicit judgements of patient non-compliance from the perspectives of both the physician and the patient ... We suggest that a subset of the behaviours and choices that the language of non-compliance now captures are not inherently problematic. They ought not to be construed as non-compliance, but rather as informed or uninformed refusals ... A commitment to provide respectful health care requires that these situations be dealt with in a way that enhances, rather than undermines, autonomy-respecting, integrity-preserving patient–physician interactions.

In other words, Baylis and Sherwin broadened feminist concerns to power in the doctor–patient relationship: the power doctors have to brand women who refuse what they recommend as 'non-compliant'. Pregnant women, in their view, should not be treated any differently from other patients who make an informed refusal to consent to a procedure. By implication, this anti-paternalistic position, which might be a truism in relation to other patients, still has to be fought for where pregnant women are concerned. Here feminist ethicists pursue a patient's rights position that applies across the board, to women past reproductive age, and to men as well, even if their starting point is pregnancy.

Other feminist ethicists have left pregnancy behind completely, concentrating instead on developing feminist approaches to such tried-but-not-necessarily-true concepts in medical ethics as autonomy, freedom and property in the body. The concept of 'relational autonomy', for example, has been developed by a number of authors to make up for obvious deficiencies in the 'knee-jerk' standard view that autonomy equals whatever the patient wants. A concept of 'relational autonomy', in contrast, requires both physician and patient to stand back and consider the wider nexus of relationships, both personal and professional, within which autonomy is exercised.[4–6] Of course, relational autonomy may and should be exercised within the patient–obstetrician relationship as well but it is not exclusive to pregnancy and childbirth, although the relationship with the developing fetus may add a further set of considerations.[7,8]

Rethinking the universal concept of autonomy clearly expands our ethical analysis beyond younger women of reproductive age to include older women and men of all ages. Similarly, in my own recent works, the academic book *Property in the Body*[9] and its popular-science sister *Body Shopping*,[10] I have argued that all bodies are in a sense 'open-access' now, as women's bodies were traditionally construed. To that extent, all bodies are 'feminised'. Here I develop and apply the economic, legal and political concepts of property and 'commodification', the process by which we attribute monetary value to something previously outside the market system. Although women's tissue is particularly prone to commodification – think of the huge US market for human eggs – all human tissue is becoming a commodity like any other, when one in five human genes is the subject of a patent, for example. The ethical, economic and political questions which that development raises certainly do not only concern women of reproductive age, although many of the unexpected commercial developments do – private umbilical cord blood banking for one.

Reproductive rights, then, remain 'one of the most important issues for different kinds and different phases of women's movements'[11] but they do not exhaust the ethical concerns of moral philosophers concerned about women's position, any more than they do the range of concerns proper to the RCOG. What else is there, one might ask? Actually, that would be the wrong question because it still prioritises reproduction by reducing everything else to 'else'. Of course, there are many other concerns involving women past reproductive age, such as menopause, hormone replacement therapy, postmenopausal *in vitro* fertilisation, breast, cervical and ovarian cancer screening, sexual disease transmission in older women, incontinence, cosmetic surgery and osteoporosis. My three specific recommendations at the end of this chapter will touch on some of these areas.

However, I want to argue that the RCOG should not adopt a 'scattergun' or 'pick-and-mix' approach to its relationship with older women. There is one particular point that it should concentrate on: preventing the syndrome I have elsewhere called 'the lady vanishes'. Our primary task should be to make sure that the lady does not vanish from public, political and professional sight when she is no longer able to bear children.

The lady vanishes

I first used the term 'the lady vanishes' (apologies to Alfred Hitchcock) to describe public discussion of the ethical issues in stem cell research, where only the status of the embryo seemed to count. Yet because ova are crucial to the somatic cell nuclear transfer variant of stem cell research, there are also important regulatory issues concerning the protection of women from whom ova are taken.[12–14] In most

commentaries and debates, however, the women from whom the ova are taken had virtually disappeared from view.

This phenomenon was most evident at the time of the near-universal jubilation over the supposed success of Hwang Woo Suk in creating tissue-matched stem cell lines.[15,16] We now know that Hwang used over 2200 human eggs, many taken from his junior researchers in breach of the Helsinki Declaration, others bought through an international commercial agency in violation of Korean law. In announcing his 'success', however, Hwang claimed to have used less than one-tenth of that number of eggs to create eleven patient-matched cell lines. The few commentators who picked up on that number – or on the very fact that human eggs were involved at all – expressed a degree of incredulity at Hwang's figures, which were wildly out of line with the figure of 400 sheep eggs required to produce one 'Dolly' in the similar reproductive cloning method. But we were drowned out by the far louder and more numerous voices of congratulation. Where there was ethical debate, it focused almost exclusively on the early-stage embryos from which blastocysts had been extracted to create the alleged stem cell lines.

It took the efforts of a collective grouping of Korean feminists known as Korean Womenlink to bring to light the facts about the unethical methods that Hwang had used to collect his eggs and the sheer number of women who had 'contributed'.* Disquiet at those initial findings led Hwang's US collaborator Gerard Schatten to resign publicly from the team and eventually brought the whole flimsy edifice tumbling down. So by ensuring that the lady did not vanish, Korean feminists performed a valuable service for both ethics and science, unwelcome though it was in certain quarters.

The recent ructions in the UK Parliament over the question of human-admixed embryos, or cybrids, in which an enucleated animal egg is substituted for a human one in somatic cell nuclear transfer research, reflect the success of those voices determined to ensure that the very real risks to women in egg donation do not vanish altogether from public sight. Although some of the scientists pressing for cybrid legalisation have made it clear that they hope to move on to using women's eggs if a reasonable success rate can be achieved with animal ones, at least the availability of women's eggs has become a highly public, practical and ethical issue. It is no longer simply taken for granted.

The egg-donating variety of vanishing lady is of reproductive age, of course, but the point about women's invisibility also applies to research involving both younger and older women. Inappropriate experimentation on women of reproductive age has long been a feminist concern. For example, in one birth control study, women seeking contraception were divided into experimental and placebo arms, with 10 of 76 women receiving the placebo becoming pregnant against their wishes.[17] This study gives a whole new meaning to the phrase 'therapeutic misconception' – the way in which control arm participants wrongly believe that by taking part in the experiment, they are assuring themselves of the right to try the new drug.

However, it is the lack of research trials and data on women of reproductive age that is more germane to our subject here – wrongful exclusion rather than wrongful inclusion. Inappropriate generalisation to women from trials only performed on men has led to mismatched drug regimens as well as inaccurate advice about symptoms of major diseases, such as cardiac disease, where signs of an impending heart attack differ markedly between the sexes. Yet equality is difficult to achieve. Although a 2007 study on myocardial infarction found that women showed lower distrust of medical researchers than men, men demonstrated 15% greater willingness to participate in

* For further details, see chapter 4 in *Body Shopping*.[10]

clinical trials than women.[18] Perhaps the popular perception that women are less at risk of heart attack than men lies behind this phenomenon – another instance of the vanishing lady over a certain age, since that benefit essentially ends at menopause.

The disastrous teratogenic effects of thalidomide impelled the US Food and Drug Administration to ban women of reproductive age from early clinical trials in the 1970s but the practice soon spread to women in older age groups as well. With the exception of sex-specific drugs such as hormone replacement therapy, the practice of recruiting only men for trials became so prevalent that many drugs licensed for use in the USA had never been tested on women.[19] All new drug applications in the USA must now include analysis of differential impact on subjects of varying ages, genders, ethnicity and class. Nevertheless, a 2002 meta-analysis concerning representation of women, elderly men and minority ethnic groups found that clinical trials continue to focus on a relatively small percentage of the population at risk of heart failure. Reviewing MEDLINE studies from as far back as 1989, Helat *et al.*[20] concluded that patients in randomised clinical trials were younger, whiter and more commonly male. There was no improvement in representation from the period of the late 1980s into the 21st century. The lady was still conspicuous by her absence.

Three recommendations and a preliminary warning

I hope I have demonstrated that there are clinical reasons and arguments from gender justice for the RCOG to make a priority of preventing the lady of a certain age from vanishing. The three recommendations I propose all have that goal. But before I present them, I want to raise and then dispel a preliminary objection. If we are concerned to treat women equally, do we need to make them a special case? Is it not patronising to assume that older women need an organisation to speak for them? Does it not smack of the worst kind of medical paternalism? And if we believe in equal treatment of the sexes, what do we make of the fact that men have no Royal College specifically dedicated to their interests?

These sorts of objections are commonly made in all contexts where positive discrimination is an issue. Even if they are well-intentioned – in some cases I think they are just a front for status quo interests – they make one common mistake. They fail to distinguish the more powerful groups from the less powerful. In creating a situation of equality from a situation where one group has more power than another, or is simply more visible than another, we do need to give 'special treatment' to the weaker group, if only to bring them up to a position where they can then function equally well without any further assistance. That is not an insult to women's autonomy or integrity: merely a realistic assessment of the situation. As Catharine MacKinnon wrote in 1989,[21] demands for change in the distribution of power appear to favoured groups to be demands for special protection, but they are really just demands for no group to be more special than any other.

It is precisely because the lady vanishes all too readily that it is incumbent on those concerned for gender justice to advocate for her. We are extraordinarily lucky that the RCOG already exists, with its motto of 'setting standards to improve women's health' and its particular brief to act for women. The recommendations I am proposing are in concord with that mission and with my analysis thus far. The RCOG should do the following:

1. lobby for a lower breast cancer screening age and for genetic testing enabling a more targeted approach, while opposing the growing commercialisation of genetic testing

2. oppose genetic patents that particularly affect women, for example patents on the *BRCA1*, *BRCA2* and *HER2* genes
3. back a safe sex campaign and more funding for sexual health clinics aimed at women over reproductive age.

1. Breast cancer screening and genetic testing

It might appear that the UK's national breast cancer screening programme for women aged 50–71 years is one of the few instances in which the lady has not vanished. That achievement is certainly considerable but it can be improved, particularly in light of the June 2008 findings published in the *New England Journal of Medicine* by Paul Pharaoh *et al.*[22] in a paper entitled 'Polygenes, risk prediction and targeted prevention of breast cancer'. The concept of genetic risk stratification needs to be embedded in public health practice, they argue, replacing the one-size-fits-all approach of a national screening programme directed at all women over any particular age, irrespective of family history. (The National Institute for Health and Clinical Excellence [NICE] guidelines in the UK do recommend mammographic screening for women aged 40 years or over if their 10-year risk is over 3% on the basis of family history.)

Individual genes linked to inherited breast cancer, such as *BRCA1* and *BRCA2*, are relatively rare, with a combined carrier frequency of about 0.003 in the general UK population, where there are no common 'founder mutations'. They account for less than 25% of the inherited component of breast cancer.[23] That might not seem sufficient reason to single out women at familial risk in a national screening programme, given that a screening programme to detect and treat carriers would reduce the disease burden in the population by only 0.7%.[22]

Genome-wide association studies, however, have pinpointed a number of more common alleles increasing breast cancer susceptibility, which seem to act in a multiplicative fashion. Profiling women for combinations of these alleles would enable more useful discrimination between higher- and lower-risk groups in the context of population screening. Women's overall risk of breast cancer can vary approximately six-fold when this multiplicative model is converted into absolute risk over a specified time period.

Although risk profiling based on genetic susceptibility is not productive at the individual clinical level, it would provide enough information at the population level to warrant targeted screening programmes for women at greatest risk according to genotype. Currently the 10-year risk for all women aged 50 years is calculated at around 2.3%. If genetic screening were used to stratify the UK population in this fashion, around 20% of women would be classified as low risk and below this level. However, the top 5% of women at highest risk would hit the 2.3% risk level nearly 10 years earlier, at only 41 years of age.[24]

The study by Pharaoh *et al.*[22] was the first to apply individual risk calculations to population screening. It has not yet reached a wider popular audience but, when and if it does, it will almost certainly trigger a rush of personalised genetic screening services offered by commercial companies to women who fear they may be in the high-risk bracket. Although Pharaoh and his colleagues were careful to state that they did not view risk profiling at the individual level as useful, commercial gene-profiling services will probably disregard that injunction. Without adequate counselling and follow-up services, these genetic profiling 'products' can be seen as preying on older women's understandable anxiety, as accentuating the popular tendency to believe in genetic determination of disease, and as cashing in on the glamour of 'the new genetics'. They may even result in a rash of elective mastectomies, given the publicity which has been given to the stories of women with the much more lethal *BRCA1* gene who have decided to go down that painful route. In the USA, where ancestry tracing is a popular hobby and genetic profiling already much bigger business, such concerns have provoked at least one state, California, to serve 'cease and desist' orders on a score of gene profile companies as a hazard to public health, and to pass a statute banning any new attempts to offer such 'services'.

The RCOG should consider advocating a national programme of genetically stratified breast cancer susceptibility screening, while simultaneously calling for legislation to bar commercial firms from offering breast cancer susceptibility 'profiles'. Admittedly, the efficacy of breast cancer screening may be less good in premenopausal women and the full range of risk factors for breast cancer is not yet established. These new findings, however, do strengthen the case for a genetically stratified risk screening programme to be undertaken by the NHS – not by the commercial gene testing companies that will doubtless spring up soon in the UK, as they already have in the USA. Prohibiting commercial genetic testing is particularly important for women, not only because they are affected by breast cancer, but also because women are more likely than men to be offered and to undergo genetic testing.[25]

2. Genetic patents

Roughly one in five human genes is now the subject of a patent, with the majority in the hands of commercial firms such as pharmaceutical companies.[26] One company, Sciona, holds patents on 2300 genes. This phenomenon is not just some abstract fact of interest only to pedants: it affects daily clinical care. Although the rationale of patenting is to allow researchers and funders a temporary monopoly as an incentive to make scientific discoveries, misuse of genetic patents impairs medical progress and harms patients, particularly the abuses of 'defensive patenting' and restrictive licensing agreements.

These are strong statements, at first glance: what proof do we have that they are true? Two cases particularly affecting older women prove the relevance of these accusations. One of the most worrying cases of restrictive patenting has involved fees for diagnostic tests on the *BRCA1* and *BRCA2* genes, levied by the biotechnology firm holding US patents on these genes, Myriad Genetics. Although the genes were discovered through publicly funded international collaboration, Myriad patented them in 1994 and has enforced its patent rights 'rather aggressively'.[27] Refusing to license any other laboratories than its own US-based operations, Myriad charged a substantial fee for diagnostic testing (up to US$3,000 in the USA) and pursued its rights in court when a strong opposition grew up in Europe. The European Patent Court granted Myriad patents on *BRCA1* in 2001 but subsequently revoked one patent and severely limited the scope of the other two, later amending its similar judgement on *BRCA2* as well.[28] Myriad is still appealing against the judgement, leaving European laboratories who continue to perform the test living in fear of infringement suits. Myriad also challenged Cancer Research UK when the organisation tried to protect its rights to make the genetic test freely available for public health services.

In the USA, where its patents are still valid, Myriad has launched direct mail shots urging women to ask their doctors for a diagnostic test. This attempt to 'grow the market' plays on patients' understandable confusion about the effect of the genes: although the vast majority of women with the *BRCA1* and *BRCA2* genes will develop breast cancer, most breast cancers are not caused by the genes. Urging older women to undergo an expensive genetic test for their supposed peace of mind raises both

false alarm and false hope: false alarm because the gene mutations are comparatively rare, false hope because even if a woman tests negatively for the mutation, she can still develop breast cancer.

When a firm holds a patent not just on the diagnostic test kit or drug but on the gene itself, it is very difficult or even impossible to 'invent around' the patent, as is usually feasible with other inventions. The stifling impact of genetic patents on alternative, cheaper treatments was equally evident in the case of the drug Herceptin® (trastuzumab; Roche), which has innovative therapeutic uses against cancer cell production in women with certain genetic predispositions to breast cancer. Herceptin acts on the human epidermal growth factor receptor-2 gene (*HER2*) and increases survival rates in women who have the version of the gene making them prone to some forms of breast cancer. (About 20–25% of all breast cancers are *HER2* positive.) The patent holder of Herceptin, Genentech, also holds multiple patents related to the *HER2* gene itself. Any researcher or drug company wishing to develop an alternative, cheaper drug must obtain permission from Genentech – which it is unlikely to give, for obvious reasons of commercial competition – or risk being sued for patent infringement. It was this monopoly that drove the price of the drug up to such high levels that NICE initially had to restrict its use on the NHS in England and Wales, until a public outcry forced the authority to rethink the decision in 2006. At that time, the NHS Confederation warned that the £100 million annual cost of providing Herceptin – at a price inflated by the monopoly patent – would mean cutbacks elsewhere.

The RCOG has the expertise and the credibility to expose the abuses caused by monopoly patents. It could and should concentrate its skills and authority on supporting the European Patent Court resistance and on making women more widely aware of the way in which the medications they may need are more expensive than necessary because of restrictive licences and monopoly patenting of the genes themselves. There is a growing popular awareness of the 'great genome grab', making RCOG intervention both timely and potentially very influential.

3. Sexual health

Although male celebrities over a certain age evidently have sex – witness new fathers in their 60s such as Jonathan Dimbleby – the soft-porn MTV-generation media still seem uncomfortable with the fact that older women do too. This is a prime case of the vanishing (older) lady: sexualised female bodies are inevitably young female bodies. Much more could be done to get across the 'safe sex' message for older women, and much more needs to be done, since the incidence of sexual diseases among the over-45s has doubled in the past 8 years, according to a Birmingham study of 4445 cases of sexually transmitted infections.[29] Cases of chlamydia, herpes, genital warts, gonorrhea and syphilis all rose, with the overall infection rate per 100 000 people up from 16.7 to 36.3.

Older men and women who are divorced and beginning new relationships may be less likely to use condoms to prevent transmission of sexual diseases, since there is less risk of pregnancy. Other factors include the rise of internet dating and the ready availability of Viagra®. More open mores do mean that older women can now visit sexual health clinics without fear of stigmatisation but the rise in their attendance is still not proportional to the rate of disease incidence increase. This, too, is an area in which the RCOG could take a lead, in line with the call from the Health Protection Agency for a safe sex campaign aimed at the middle-aged.

Conclusion

In these three cases, older women do constitute a group with common interests in safer sex, in more targeted screening for breast cancer and in cheaper drugs for the treatment of that disease. Where they are blocked by lack of awareness of statistically complex scientific studies such as Pharaoh's,[22] for example, it is perfectly right and proper for an organisation dedicated to their health to act on their behalf.

It is neither patronising nor paternalistic for the RCOG to use its specialist knowledge, legitimacy and 'clout' to prevent the lady from vanishing.

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