

CLINICAL ETHICS

“If you think you’ve got a lump, they’ll screen you.” Informed consent, health promotion, and breast cancer

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A great deal has been written about information that is or should be provided when seeking consent to medical research and treatment. Relatively little attention has been paid to information describing health promotion interventions. This paper critically examines some information material describing three different methods of encouraging early presentation of breast cancer in the UK: the NHS breast screening programme, breast self examination, and breast awareness. Findings from a content analysis of printed material and a series of focus group discussions that included women who speak little or no English were organised around the Department of Health’s recommendations about the information which should be provided when seeking consent to treatment and research. They exposed inconsistencies, ambiguities, and gaps, which when taken together suggest both compliance and non-compliance are being achieved in the absence of informed consent. The findings also provide a starting point for a discussion about how informed consent to health promotion might be sought.

INTRODUCTION

There is nothing women can do to reduce their risk of breast cancer. The aim of health promotion interventions is to encourage presentation of the disease in its early stages. Three methods are currently in use. Introduced in the 1970s, breast self examination (BSE) is the oldest one. As the term “self examination” suggests, it is a diagnostic technique borrowed from medicine which women must be taught how to do. Instructions are given either by a healthcare professional or through illustrated (photos and diagrams) leaflets.

The National Health Service Breast Screening Programme (NHSBSP), a call and recall system of screening mammography, was set up in 1987 on the recommendation of an official working party.¹ Every three years, the names and addresses of women aged 50–64 years are taken from general practitioners’ lists of patients and, if they fulfil the programme’s other eligibility criteria, they are sent a letter of invitation to attend one of the 90 or so mammography screening units in the country.

Breast awareness (BA) was introduced in 1991. BA is not a medical technique; it is “a part of general body awareness ... a process of getting to know your own breasts and becoming familiar with their appearance”.² Women are urged to be on the look out for anything unusual about their breasts whilst bathing, showering, and dressing.

Using as a framework the Department of Health’s criteria for essential information which should be provided when seeking consent to research and treatment, the research described here set out to evaluate critically some information provided to women about these different methods.

METHODS

Two methods were used. First, the contents of some leaflets and websites in which the three methods mentioned above are described were analysed. Information about BA was found in *Be breast aware*²; information about the NHSBSP was found in *Breast screening: the facts*,³ and on the websites of the NHSBSP⁴ and Cancer Research UK.⁵ BSE was officially repudiated in the UK in 1991. Therefore information about it is not provided by official organisations in the UK, although it is offered by other sources of health related

information such as pharmaceutical companies, women’s magazines, and official US websites. The material discussed here represents the tip of a very large mountain of information.

What women make of the information was ascertained during 20 focus group discussions; six were held in English and 12 in other languages. These were held to investigate women’s understandings of breast cancer and the three methods encouraging early diagnosis (the methodology is described in detail elsewhere⁶). The research was reviewed and approved by the East London and City Health Authority Research Ethics Committee. Women who had never had a diagnosis of breast cancer were recruited in Hackney, an inner-London borough which scores high on social deprivation indicators and has a diverse population. In the focus groups, women were invited to discuss their understanding of breast cancer, its diagnosis and treatment, and they were asked to comment on leaflets produced by the NHSBSP in several different languages.

Findings from the research methods have been organised below under the following themes: what the procedures involve, benefits and risks, and alternatives. According to the Department of Health, these themes are the minimum requirements demanded of information about research and treatment.⁷

RESULTS

What the procedure involves

The different practical demands on women made by the three methods are described in table 1.

Compliance with the NHSBSP is a public act; place and timing are decided by local administrators. In practical terms, attending an NHS screening mammography centre makes similar demands on women as those of attending a hospital outpatient clinic (ambulatory centre). Women are required to undertake a journey to a screening unit and, on their arrival, undress, and allow their breast to be manipulated by healthcare professionals. *Breast screening: the facts* includes

Abbreviations: BA, breast awareness; BSE, breast self examination; NHSBSP, National Health Service Breast Screening Programme

Table 1 Comparative analysis of breast self examination (BSE), breast awareness (BA), and the NHS Breast Screening Programme (NHSBSP)

	Frequency	What to look out for	Who does it?	Where?	How?	Concept of normality and target
BSE	Monthly	Lumps, thickening, etc, that can be seen and felt	Woman	Lying on a bed, in the bath, etc	Systematic looking and feeling, as taught	Clinical individual
BA	Daily	Changes “unusual for you” that can be seen and felt	Woman	During personal hygiene (bath, shower, while dressing)	Looking and feeling (including sensations of discomfort)	Personal individual
NHSBSP	Every three years, women aged 50–64 who fulfil eligibility criteria	“small changes” invisible to women	Radiographer	NHS screening unit	X ray	Cellular population

instructions on self-presentation (for example, women are advised to wear a separate top) and warnings of what might happen (for example, the procedure can be uncomfortable, even painful).

Because both BSE and BA are carried out by women in the privacy of their own home, information about them focuses on technique. Although both involve “looking” and “feeling”, their performance requires different frames of mind: in carrying out BSE, women stand in for healthcare professionals; BA requires a state of mind similar to that adopted to ward off threats to moral hygiene such as excessive food consumption. It entails a state of vigilance in which women are on the look out for untoward developments which might signal something sinister is afoot. Unlike BSE, which uses objective clinical criteria of normality, BA asks women to think in terms of “what is normal for them”.

Not one focus group participant said she was confident she knew what to look for. One reason for this, almost without exception, is that information material is illustrated by healthy breasts, free of any signs of cancer. Guidance on what to look for is addressed exclusively to white women. A black woman pointed this out by saying, “Some people say it’s the colouring of the breast but in black women it’s a bit hard to talk about colouring.”

Guidance on “feeling” instructs women how to spot sinister changes in the skin and texture of the flesh of the breast, described as “thickening”, “puckering”, and “lumps”. In envisaging what these might feel like, women allude to familiar foodstuffs. However, food is a crucial marker of ethnicity and, because the focus group respondents were drawn from a very diverse population, different kinds of food were evoked. For example, a woman who cooked traditional English food said “lumps” made her think of custard and gravy powders. Several women thought a lump would feel like a pea because they had attended classes on BSE where a “beanbag” fabric breast with hard lumps in it had been used to teach women what to feel for. A Bangladeshi woman said “thickening” brought to mind ghee (clarified butter); “puckering” reminded one woman of raw chicken skin.

“Feeling” can also mean how having breast cancer might feel. Although a few women appreciated the difference between early, silent signs and later manifestations of breast cancer, many found it difficult to accept that such a serious disease could be painless at any stage. In information about the three methods, different stands are taken on the significance of feeling. Guidance on BSE tends to dismiss tenderness in the breast as a normal part of the menstrual cycle. According to the leaflet *Be breast aware*, one of the “Changes to look out for”, is “Discomfort or pain in one breast that is different from normal, particularly if new and persistent”. The website of Cancer Research UK tells women to be on the look out for unusual pain or discomfort, and

then qualifies the message by saying that pain without other symptoms is extremely unlikely to be due to cancer.

Although presentation of breast cancer in its early stages is what is being promoted, the natural history of breast cancer is never described. Does it emerge suddenly? Does it progress rapidly or slowly? Currently, there is a lack of knowledge about the aetiology of breast cancer—a highly complex disease. Yet BA demands a 24/7 state of vigilance whereas, in sending out invitations every three years, the NHSBSP suggests a different time frame is important. Women found these conflicting messages about the significance of time confusing. Indeed, some women referred to them in their explanations of why they lacked confidence in all three methods.

Participants were uncertain which messages about early presentation were meant for them. Each method appears to be addressed to a different target audience. Women are advised that breast cancer is rare in women under 40, and that risk of the disease rises sharply after the menopause. However, despite declarations to the contrary, in subtle ways, information about the different methods conveys the impression that the disease strikes mostly younger women. Although half of all breast cancers are found in women over 65, they are ineligible for the NHSBSP which invites only women aged between 50 and 64 (the upper age limit is being extended to 70 by 2004, but average life expectancy in women is reaching 80). The NHSBSP informs women aged over 65 that they will not automatically be invited for screening but they can ask for it: advice which fails to convey urgency. In insisting women perform BSE monthly, a few days after menstruation has begun, the impression has been conveyed for more than 20 years that breast cancer is somehow related to menstruation. Paradoxically, although women are advised the risk of breast cancer increases sharply after the menopause, the information examined fails to engage with the ageing body. Illustrations invariably show firm and pert breasts wholly unlike those of older women. Another failure in communication emerged when a focus group participant insisted information about BA was not meant for her. She had been “going through” the menopause for several years. However, as she pointed out, references to the menopause suggest it takes place overnight: breasts are described before or after but never during. And no guidance is offered to the many women taking hormone replacement therapy, although sex hormones undoubtedly affect the consistency of breasts.

In finding out what women from a variety of backgrounds make of information about early diagnosis of breast cancer, implicit messages have been exposed, confusions identified, and gaps in information highlighted. To sum these up: instructions on how to carry out BSE and BA are unclear and confusing partly because idiom and metaphor have been used

uncritically. Despite declarations to the contrary, messages appear to be targeted at white women and at younger women whose risk of breast cancer is relatively low; the bodies of menopausal, older, and non-white, women are largely absent.

Benefits and risk

Different standards of proof of benefit are demanded of the three methods. In his speech launching BA, Kenneth Calman, then Chief Medical Officer of Health, said the method was meant to replace BSE which had been discredited when research had failed to find evidence that “a formally taught, ritual self examination, performed at the same time each month, reduces the death rate from breast cancer”.⁸ BSE also stands accused of being responsible for a high rate of false positive diagnoses made by women.⁹ Yet in the UK, it continues to enjoy the support of unofficial sources of health promotion information, and, in the USA, it is still officially endorsed: it is described on the website of the American Cancer Society.¹⁰

Paradoxically, despite its commendation by the Department of Health, the efficacy of BA has not been scientifically tested. Instead, women are told it has “strong support from nursing and medical professions”.¹¹ The NHSBSP has been evaluated in several ways including technical performance of equipment, rate of cancers detected, uptake (numbers of women who accept the invitation as a proportion of invitations sent out) and epidemiological data on numbers of lives saved. The last statistic is hotly disputed.

There is a lack of clarity about the value of early detection: Does it save lives, guarantee less heroic treatment, or both? On its website, the NHSBSP claims currently to be saving around 300 lives each year. *Breast screening: the facts* puts the figure at 1250 lives saved although this is the target for 2010. The NHSBSP also advises women that, if found early, removal of the cancer may not entail removal of the whole breast. The leaflet on BA suggests the purpose of early detection is primarily less heroic treatment. It states, “[I]f there is a cancer present, the sooner it is reported, the more simple treatment is likely to be. This offers greater prospects of benefit in terms of quality of life.”

Muddying the waters further is the dispute between advocates of the NHSBSP and clinicians who say the programme should be abandoned and its resources channelled into research on treatment which they claim is relatively ineffective. In particular, there are uncertainties about how best to manage the disease in its very early stages, the stages only the NHSBSP can identify. In calling its leaflet *Breast screening: the facts*, the NHSBSP is flouting but not acknowledging the arguments of its critics and ignoring their uncertainties. But the NHSBSP does not control the public sphere: the protagonists regularly fight in public and their dispute was mentioned by several focus group participants.

Deficiencies in the quality of treatment of breast cancer are recognised in policy making circles. For example, the postcode lottery in breast cancer treatments is currently being addressed in *The NHS Cancer Plan*.¹² Availability of an effective treatment, and facilities for all those diagnosed to receive prompt treatment, are two of the essential attributes of a screening programme laid down for the World Health Organization (WHO) in 1968.¹³ They were also a concern of the focus group participants several of whom explained how the wide publicity given to the failings of the NHS combined with personal experience of its inadequacies in relation to breast cancer were undermining their faith in the quality of the care they might receive should it be diagnosed. Yet the NHSBSP assures women that, if a cancer is discovered, they will “receive the best care and treatment at all times”. It is possible to arm women with appropriate information about quality of care: *Breast cancer: how to help yourself*,¹⁴ published by

the Macmillan Breast Cancer Campaign in 1994 includes 10 minimum standards of care which every woman should expect and demand.

None of the information material examined describes how breast cancer is treated. Yet treatment is uppermost in women’s minds when they think about the disease. Women are understandably fearful of mastectomy: the loss of a breast threatens both a woman’s self-esteem and her eligibility in the collective of women. Indeed, in the focus groups, several women from different backgrounds said heroic treatment makes breast cancer a serious disease.

According to *Breast screening: the facts*, one in nine women in the UK develops breast cancer at some time in her life. Population risk, however, is not the same as personal risk, which is unknown. Data on population risk have been found to influence policy makers and healthcare purchasers.¹⁵ However, there is no explanation of why they are relevant to individual women.

The risk of both physical and emotional iatrogenesis have been considered at length by healthcare professionals. These include the distress of a false positive diagnosis, the possibility that radiation from mammography may initiate breast cancer and that screening itself may provoke high levels anxiety in women. Through their experience of other kinds of screening especially for cervical cancer which has had some negative publicity and media attention to the debates about the value of mammography, women are aware of the possibility of iatrogenesis and asked for information about it.

To sum up, in failing to acknowledge the different standards of evidence of efficacy and the controversies about them, information about the benefits of early diagnosis of breast cancer must be judged partial and misleading. Although undoubtedly difficult to convey, a clear account of risks, including those women most fear, is absent. Unrealistic reassurances about the quality of care provided by the NHS provoke distrust in women who hear daily about its failings.

Alternatives

In seeking consent to treatment and research, the Department of Health requires information about alternatives to be provided. Currently, the relationship between them is either of rivals (NHSBSP and BA v BSE) or master/servant (NHSBSP and BA). Because ostensibly they share the same objective, women assume they are interchangeable; in practice, there is considerable traffic between the three methods—for example, one participant claimed, “If you think you’ve got a lump then they’ll screen you”.

In presenting the three methods as alternatives, crucial differences between them are clarified. Each is framed by an unacknowledged commitment to a different branch of medicine. BSE is a diagnostic technique derived from and informed by clinical pathology; BA appeals to an intuitive sense of body self-awareness, similar to that found within types of alternative and complementary therapy which subscribe to a holistic relationship of body and mind; epidemiology and radiology are largely responsible for the NHSBSP. Each is concerned with a different time frame: BA and BSE investigate current state whereas the NHSBSP seeks omens of the future. Women could be told about the different outcomes sought—that is, the NHSBSP seeks a population effect whereas BSE and BA seek to foster wellbeing in individual women. Finally, the different criteria of efficacy, including the risk of false positive and false negative, could be explained.

A crucial difference between the methods which matters to women is, who does the worrying about their breasts? BSE and BA require women to take responsibility for themselves,

whereas the NHSBSP does it for them. This difference is implicit yet strong preferences for one or the other emerged in the focus groups: some women said they found peace of mind in an official reassurance whereas others preferred to be agents of their own destiny.

DISCUSSION

One and a half million women currently accept their invitation to attend the NHSBSP, around 500 000 do not, and unknown numbers of women carry out BSE or are breast aware. Does it matter if, as this paper suggests, their reasons for compliance or non-compliance do not amount to informed consent? If the procedures were part of treatment or research then the answer would be yes, and a host of guidelines, official and unofficial, legal and ethical might be called upon in support of it. However, a confident response is less likely in relation to health promotion interventions because surprisingly little attention has been paid to whether and how to seek informed consent to them.

The now classic and highly influential principles by which the ethics of screening programmes for adults are evaluated were developed for the WHO in 1968. They were addressed to policy makers faced with a decision whether or not to support a population screening programme. For example, they were referred to in the report of the working party responsible for the setting up of the NHSBSP, and they have been cited by the Department of Health in its explanation of why it decided against introducing a screening programme for prostate cancer.¹⁶ However, the issue of informed consent was not considered in the guidelines perhaps because, in the 1960s, the doctrine was less clearly articulated and paternalism in health care had not yet begun to be questioned.

There is no good reason why informed consent should not now be sought for health promotion interventions: they are neither neutral nor anodyne and blind compliance or non-compliance fails to respect human rights. However, if the Department of Health's criteria for informed consent are applied to health promotion interventions, then, as this paper suggests, a radical shift in thinking about information about them would have to take place: the requirements of information provided for the purpose of seeking consent are wholly different from those used in health education or publicity. In making this shift, many challenges would emerge, but it might lead to the production of information which is more credible and relevant to its target audience.

Findings from the research presented here suggest some of the advantages to be gained. In thinking carefully about what might constitute clear and relevant information about procedures, especially those which women must perform themselves, attention is drawn to their demographic and physical attributes. It would encourage engagement with women's bodies which are notorious for their radical

instability—that is, for undergoing repeated change. Women lead complex and busy lives and inhabit a variety of different places—for example, how many enjoy the time and privacy some procedures demand? Women think in culturally bounded ways, often using food as an imaginative resource. Sensitivity to idiom and metaphor can provide simple and effective ways of explaining complex issues. For example, in explaining the difference between a population and a clinical intervention, a health promotion officer who works with the Bangladeshi community draws an analogy between population screening and picking over of lentils to identify the bad ones.

In presenting the three methods as alternatives, the traffic women conduct between them is acknowledged and can be tackled. By exposing crucial differences between the different methods, such as inconsistencies in their evidence base, women can be helped to make an informed choice about them; a graphic contrast might also force their proponents to give an honest account of why they promote them. Above all else, in providing women with information they want and need in order to give their informed consent, they can become equal partners in interventions intended to save or improve the quality of their lives.

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