

## **Research Network Patient Information Conference June 16 2010 - Stirling**

### **Personal experience of participating in research**

Thank you very much for inviting me to give this talk. My story begins a long time ago: 23 and a half years ago in fact, when I was diagnosed with breast cancer in November 1986. Why is it relevant now? Well, I think that our experience of the notorious study of women who attended the Bristol Cancer Help Centre for complementary care was something of a turning point in medical research. To our knowledge it was the first time that the guinea-pigs found a voice and challenged the results of the research in which they had taken part. And from that time, the voice of the guinea pig has been taken seriously, and for about the last 10 years patient partnership has become *de rigueur*.

### **Title slide (Embracing Patient Partnership)**

But at the time it was a shocking business.

First, I should give you some personal background. As you can guess, I am an asylum seeker from England – West Sussex in fact – I've only been living in Edinburgh for the last 7 years. At the age of 55, after a career in academic publishing, I was diagnosed with breast cancer. I was a typical breast cancer patient, with a standard collection of risk factors. I did not have a good prognosis.

### **Slide 1 (Risk factors) Slide 2 (Pathology)**

Finding adequate and prompt surgical and medical treatment but no psychological support in my home town (in those days there were no breast care nurses, no counsellors) I went to the Bristol Cancer Help Centre for complementary care, initially only for a day visit in January 1987. The Bristol programme was a holistic one, with equal emphasis on body, mind, and spirit. I benefited greatly, together with my husband. I believe that the Bristol centre helped me to survive. I made several more visits to the centre that year.

### **Slide 3 (Bristol Cancer Help Centre)**

I should add that in those days following an instruction to eat organic vegetables and fruit was much more difficult than it is now, when they are available in every supermarket. You had to be really persistent to track down some misshapen organic carrots down some muddy lane. Now even Scotmid has them, perfectly formed and scrubbed clean.

While at Bristol, I was recruited into a five-year study of breast cancer patients, in which women visiting the Bristol Centre for complementary care, in addition to orthodox treatment, were to be compared with women receiving orthodox treatment only. We were told that both our survival and our quality of life were

to be studied. I enrolled in the study enthusiastically, and conscientiously filled in annual questionnaires for the following three years.

Then in September 1990 came the shocking news, broadcast to the nation on television and radio, and in every newspaper, that 'women who go to Bristol are twice as likely to die, and three times as likely to relapse' as women receiving orthodox therapy only. These were typical headlines:

#### **Slide 4 (press headlines)**

I like the last one, from the BMJ: 'Death from complementary medicine'!

How had this happened? It seemed that the study we had taken part in, which was supposed to last for five years, had already been reported on in the Lancet, after only two years' data had been collected. The sponsoring cancer charities, the ICRF and the CRC, now amalgamated into Cancer Research UK, had broadcast the news to the world by means of a major press conference. The women in the study had not been notified beforehand: it was quite a shock.

#### **Slide 5 (Lancet paper)**

When I read the paper, I was appalled. It was quite clear even to me, a non-scientist, that it was grossly flawed. Like had not been compared with like, there were internal inconsistencies, and no use had been made of the data we had given the researchers in our questionnaires. As an editor, I would not have passed it for press. I wrote to the Lancet: the editor did not publish my letter, but he did publish a number of others from doctors and statisticians, all highly critical of the paper. They made the following points:

#### **Slide 6 and 7 (criticisms made in letters to the Lancet)**

The authors too wrote in response, acknowledging some of the points made, and Sir Walter Bodmer of the Imperial Cancer Research Fund, who had sponsored the study, wrote to say: 'Our own evaluation is that the study's results can be explained by the fact that women going to Bristol had more severe disease than control women.'

In fact, like had not been compared with like.

However, the problem was that this conclusion was not widely reported in the media. Also, the researchers themselves refused to acknowledge that their errors made any difference to their conclusions: they still said that their research showed no survival advantage for the Bristol women. We entered a Kafkaesque world. This is a quote from *The Castle*:

'Is there a Control Authority? There are only control authorities. Frankly, it isn't their function to hunt out errors in the vulgar sense, for errors don't happen, and even when once in a while an error does happen, as in your case, who can say finally that it is an error?'

At this point, advocacy took over. Some of the women in the study contacted each other on the self-help grapevine, and formed a support group, which we called the Bristol Survey Support Group. We drew up our aims and objectives. It was the first time in the UK that a group of patients had challenged the results of research in which they had taken part. As we worked away to try to understand what had gone wrong, the Bristol Centre itself nearly had to close, since it was rapidly losing both patients and funding. The correspondence in the Lancet made no impact on the general public since it had relatively little coverage in the lay press.

Our researches uncovered further problems with the Lancet paper.

### **Slide 8 (The Bristol Survey: was like being compared with like?)**

The differences between the two groups were pretty striking. We still don't know how many of the controls died during the period of the study. The following graphs illustrate the main differences between the cases and the controls.

### **Slides 9 (menopausal status), 10 (age group), 11 (surgical treatment of primary)**

We were not in a position to criticise the science: we were not scientists, nor did we have access to the original data. But we consulted experts – for example, my husband was an actuary so could beat most scientists at statistics. We then drew up a formal complaint to the UK Charity Commission about the conduct of the cancer charities who had sponsored the study and publicized it, in our view irresponsibly. In our submission, neither the Cancer Research Campaign nor the Imperial Cancer Research Fund had exercised proper supervision over the application of their funds for charitable purposes.

We also made a film for the public-access series on Channel 4 television called 'Free for All'. Our film had the ironic title CANCER POSITIVE. The film company, FILMIT, supplied us with a production team: we were responsible for the content. The film took six weeks to make, and the whole group took part in the filming. The co-founder of the group, Isla Bourke and I, hammered out the script and did the interviewing, including a satisfying encounter with the heads of the two giant cancer charities, from whom we secured an apology on film. It was very hard work – on top of all our normal commitments. This film was shown twice at peak time in 1992 and made quite an impact. It has since been used for medical education.

The Charity Commission, after considering our 300-page dossier for 19 months, upheld our complaint. In January 1994 they reported that the charities 'lent their names to the publication of the research without ensuring that it was soundly based', and that 'their procedures for the supervision of research were insufficient to ensure that charity funds guaranteed to independent researchers were properly controlled'.

## **Slide 12 (Funding of medical research by charities)**

With the publication of this report, the fortunes of the Bristol Centre took an upward turn, and they are now seriously back in business. They now have a new name, Penny Brohn Cancer Care, and large new premises outside Bristol. But they themselves are the first to acknowledge that they owe their survival to the patients who fought so hard to set the record straight. Some of the women's personal stories are told in the book *Fighting Spirit*, with a foreword by the actress Sheila Hancock, one of the women who went to Bristol, and edited by myself. It was published in 1996 by Scarlet Press. (1)

The women in the Bristol study felt doubly cheated because the researchers did not carry out the promised quality-of-life study, concentrating merely on survival. Instruments to measure Quality of Life have improved recently, focusing more on the individual's own values, but there are still problems, which are illustrated by the current START trial (Standardization of Radiotherapy: led by John Yarnold from the Royal Marsden Hospital). In fact, another group I belong to, dealing with long-term adverse effects of radiotherapy, has commented on this in the July issue of *Lancet Oncology*: watch this space! (2)

After the publication of the Charity Commission report in 1994, the medical press began to take an interest in the affair once more. At the time I was Secretary of the Bristol Survey Support Group. A letter I then wrote to the *British Medical Journal* aroused interest from the Editor, and he asked me to join him in writing an editorial. We said in our piece with the title 'The rights of patients in research':

## **Slide 13 (Patients should help to set the research agenda)**

### **Patients should help to set the research agenda**

The first way that patients and the public can be involved in research is by helping to set the research agenda, and in Britain the NHS research and development programme is committed to trying to reflect the concerns of consumers throughout its work. The concerns of patients are not the same as those of researchers. For instance, women with breast cancer want more research on quality of life, environmental and psychosocial issues, and the optimum dose of radiotherapy to control the tumour but cause minimal damage to healthy tissues. (3)

My experience as a guinea-pig in this study inspired me to become an advocate, a founder member of the UK Breast Cancer Coalition in 1995, and Chair of its Research Committee. I was also appointed to the Editorial Board of the *BMJ* in 1995 as its only lay member, and the final accolade for the former Bristol Survey Support Group came with a favourable review of the book *Fighting Spirit* in the journal in 1996. Remember the *BMJ* headline 'Death from complementary medicine'? The wheel had come full circle, and we had become 'respectable'. And now of course no self-respecting cancer treatment centre is without its adjoining department of complementary care, its Maggie's Centre, and also, no research committee or clinical trial is without its patient representatives. The

organization 'Consumers in NHS Research' was set up, later changing its name to 'Involve', and it is now understood that patients can help not just with checking consent forms but also in the actual design of trials in the first place. This was prophesied back in 1994 in the Lancet:

#### **Slide 14 (Patients and cancer research)**

'Women with breast cancer have led the way in showing how patients can contribute to many aspects of research, from trial design and participation to the raising of awareness and of funds ...'

Yes, funds: that's quite important!

And the quote from Susan Love is also interesting:

'The cure for breast cancer is political action'.

According to the Nottingham Prognostic Index I should have been dead long ago. But at the age of nearly 79 I have had no recurrences, and I still don't seem to be able to keep away from involvement in NHS matters and clinical research. I am still a 'consumer reviewer' for the Cochrane Collaboration and the Health Technology Assessment Programme. In Scotland I seem to have left cancer behind me, but after my husband had a stroke two years ago I am now involved in the Stroke Managed Clinical Network, and also the third International Stroke Trial as a carer representative. And as a member of the Women's Environmental Network Scotland I am interested in research on environmental toxins and their effect on health.

Perhaps this also illustrates the point sometimes forgotten by healthcare professionals: patients are not just patients, or clinical trial fodder. They aren't just 'the mastectomy in the third bed on the right'. They have minds, as well as bodies to be experimented upon. They may have had distinguished careers in other fields. They may even be scientists, or doctors. They can contribute a great deal to medical research. A piece of research I undertook myself on 'Improving Cancer Care' in Sussex, with a colleague who did have a scientific background, found that healthcare professionals with personal experience of the disease were those with the strongest opinions about reform of the service. (4) Sometimes the 'establishment' relies on 'consumers' to blow the whistle and say those things that it feels awkward for them to say themselves. What's more, you don't even have to pay us!

My final slide is a letter I wrote to the BMJ asking for the paper on the Bristol study to be withdrawn. It never has been, but it has certainly been discredited, and lessons have been learnt.

#### **Slide 15 (The scandal of poor medical research) (5)**

Thank you for listening.

## References

1. Goodare H. (ed.) *Fighting Spirit: the stories of women in the Bristol breast cancer survey* (London: Scarlet Press, 1996)
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4. Goodare H, Nadim L M. Improving cancer care: a partnership project between service users and healthcare professionals to identify potential improvements to cancer services. *Journal of Holistic Healthcare* 2006: 3 (4): 24-31.
5. Goodare H. Wrong results should be withdrawn (letter). *BMJ* 308: 591 (26 February 1994).