

# OCCASIONAL COMMUNICATIONS

## THE INFORMED PATIENT\*

H Thornton, Honorary Visiting Fellow, Department of Health Sciences, University of Leicester

### INTRODUCTION

Your patient has no more right to all the truth you know than he has to all the medicine in your saddlebags . . . He should get only just so much as is good for him.

Oliver Wendell Holmes, 1871

Going back to 1760, more than a century before Oliver Wendell Holmes, one should doubt whether the news about James Lind's controlled trial, undertaken at sea' ([www.jameslindlibrary.org](http://www.jameslindlibrary.org)), had reached the ears of Dr Mylock Pheyaro, who placed the following advertisement in Essex:<sup>2</sup>

Doctor Mylock Pheyaro informs the Publick that he has removed from the King's Arms in Colchester to the Crown in Maldon, Essex, where he continues to cure (under the blessing of God) Cancerous Complaints, Fustulas, King's Evil, Ulcers in legs and other extremities, Scurvy breaking out in all part of the Body, Pimples in the Face, St. Anthony's Fire, Scald Heads, Itch, Gout, Rheumatism, and many other Disorders, too tedious to mention. What I have already done at Colchester, Manningtree, Wyvenhoe, Saxmundham, Woodbridge and Hadleigh in Suffolk, since June last, is a sufficient testimony of my ability, and those who need my assistance may, with good effect, through the help of God, apply to their friend and humble servant, Nov. 1760.

Direct-to-consumer advertising was evidently allowed at that time! The ailing individual was asked to rely only on evidence of the doctor's past accomplishments and God's help.

The doctor's recognition as a 'friend and humble servant' is rather appealing: perhaps he had good communication skills, even if he had little in his saddlebag that could be offered as cure, or lacked more solid evidence of the 'truth' about the effectiveness of his medicines and ministrations. One wonders what questions these patients might have asked of him, what information they brought to help support their treatment decisions and what degree of concordance<sup>3</sup> they reached.

### WHAT IS A PATIENT?

When considering the notion of 'the informed patient'

today, who is as vulnerable as his or her counterpart in Dr Pheyaro's time, it is necessary to wonder first just who are and who are not patients, and what a patient is. When Richard Smith says: 'the problem lies in medicine's difficulties in defining normality',<sup>4</sup> he is musing on the intense marketing in the US of whole-body scanning.<sup>5</sup> The antidote he suggests to the prospect 'that soon none of us will be normal' is the economist's one of 'rational ignorance' because it simply is not 'sensible' to try to know everything.

In Lind's time, people went to the doctor when they were ill. Today, in the developed world, citizens are bombarded with healthcare advice and education and are subjected to promotions and promises to 'find it early' for serious conditions. These interventions might require treatment decisions for drugs and therapies to prevent diseases<sup>6</sup> rather than to alleviate or cure them, or even to make patients look and feel better. Huge quantities of powerful drugs such as hormone replacement therapy (HRT), for example, are taken by women not just for relief of menopausal symptoms or osteoporosis, but to 'prevent' ageing, i.e. for cosmetic reasons. Following a headline in the *Independent* in early October 2003: 'HRT the new thalidomide',<sup>7</sup> a reader was moved to write<sup>8</sup> that she had visited her GP again, following being criticised some time before for being uncooperative. Her reasoned decision on the evidence as it stood then, was not to take HRT, having decided that the risks and potential harms, for her, outweighed any possible benefits. On this occasion, when she referred her GP to the latest evidence<sup>9</sup> and reminded him of their last exchange, her GP said: 'Oh well, things change!'

It is unpopular but regrettably apt that the word 'consumer' is regularly applied in settings where medicine has become an industry, and where an endless stream of technical innovations has led to rationing – no matter how affluent the setting. The gulf between the haves and the have-nots is widening, both within affluent nations and between them and less well-developed countries. But plenty of 'real' patients do still exist and are now being encouraged to become well informed. Last summer, John Reid, Secretary of State for Health, encouraged NHS conference delegates to 'help every patient to be an informed patient'.<sup>10,11</sup> This report did not advise if anyone might have raised a dissenting hand to suggest that not every patient wants to be an informed patient.

The borderline between citizen and patient is very indistinct in those societies where healthcare is a commodity; where industry 'invents' illnesses because it can provide more remedies than there are illnesses;<sup>12</sup> where length of life is striven for at great cost and is often the main endpoint sought both in trials and in routine care. Expensive public health measures and private initiatives encourage citizens to 'behave responsibly', thereby often causing them to inadvertently cross the line from healthy citizen to iatrogenic patient, labelled with a disease or its precursor, or a 'raised level' on some scale of biochemical or other measurement. These citizens-turned-patients then go on to consume resources that might be better allocated to people with real diseases and far greater needs.

Where are these people to go for information to support their treatment decisions if they suddenly find they have been labelled as a patient? The evidence for the benefits and harms of engaging in these programmes is often hotly disputed and usually disregarded by profession and public alike.<sup>13</sup> But, as Barron Lerner describes so clearly in his gripping medical and cultural history of breast cancer in twentieth-century America, it is social and cultural factors that influence interpretations of scientific data, where belief – both of health professionals and of the public – holds greater sway than evidence. He cites belief in Halsted's radical mastectomy, which kept the procedure going for three-quarters of a century – even though mortality statistics had remained unchanged, and mid-century challenges, and then evidence, demonstrated equal mortality when compared with lumpectomy plus radiation therapy. As many of us have experienced, as in this case, it can take the other quarter of a century for evidence-based challenges to begin to affect practice.

## **THE INFORMED, 'ACTIVIST' PATIENT**

An American breast cancer patient, Rose Kushner, contributed to this debate by a conspicuous and very vocal challenge to the traditional authoritarian physician-patient relationship, to radical surgery and the one-step procedure, in a vigorous, intelligent and well-researched campaign in the early 1970s.<sup>14</sup> She was not prepared to be the passive recipient of 'only so much of the truth as is good for her' that Halsted and colleagues had in their saddlebags! Activism was born.

Concurrently, in the UK, Betty Westgate was diagnosed with breast cancer in 1968. Her unhappy experience led to her founding the Cancer Education Voluntary Service in 1972. Her passion for information, education and empowerment led to her setting up the Mastectomy Association, based at her home in Croydon from 1973–81. It is now flourishing as Breast Cancer Care in London, with branches in Scotland and Wales, providing thousands of women with information and support.<sup>15</sup>

Also in the UK, CancerBACUP was set up by Dr Vicky Clement Jones as a national charity in 1985. Her own experience of cancer taught her that patients were in desperate need of good-quality information, practical advice and emotional support. All too often, it was not available. Today, CancerBACUP and their cancer specialist nurses provide this service for nearly 50,000 people each year. They do this through their telephone helpline, by letter and by e-mail. CancerBACUP also provides 60 booklets and 200 fact sheets on every aspect of cancer.<sup>16</sup>

These three remarkable women's passion for information, not just for themselves but for others, led to the improvement of millions of people's lives, not through legislation or guidelines, but by exercise of the responsibility they recognised to their fellow human beings. They initiated and led voluntary organisations that have played their part through collective involvement in the needs of society.

## **WHEN SHOULD PATIENTS BECOME INFORMED?**

It could be argued that it is too late to wait to become informed until you become a patient, or until you are turned into one by a preventive programme, or until you have succumbed to seductive advertising, or until you become a trial participant as a healthy individual in a 'prevention' trial. It is preferable to become informed before attempting to give consent to interventions that might seem to be, or are sold to us as, worthwhile and effective interventions, either by GPs, trial investigators, for-profit health concerns, public health programmes or by industry. As Richard Smith says, it just is not sensible to try to know everything. There is much truth in the saying that 'ignorance is bliss', and more contentment perhaps in believing that 'what the eye doesn't see, the heart doesn't grieve over'. There is also much comfort to be obtained from having faith in a reliable, up-to-date health professional whom one can trust, and who might be our 'friend and humble servant'.

## **WHAT DO WE NEED TO LEARN?**

We must therefore learn what and whom to choose; learn how to live;<sup>17,18</sup> learn how to live with uncertainty;<sup>19</sup> learn how to learn; learn what we need to learn;<sup>20</sup> learn where good sources of good quality information are;<sup>21</sup> learn to be sceptics; and learn to be passionate advocates of good common sense and of the teaching of critical appraisal skills from an early age.<sup>22</sup> Learning about risk assessment<sup>23</sup> and how to negotiate and make shared decisions<sup>24</sup> are other absolutely necessary skills.

## **WHY SHOULD PATIENTS BE INFORMED?**

Patients need or seek to become informed for many reasons. Many, but not all, want and need to do so because they want to become involved in decisions about the management of the disease that ails them. They are motivated by the desire to share the

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responsibility for their healthcare with their doctor, and/or to feel some sense of control over, and understanding of, their disease. Many are pushed rather too fast along the fact-finding route because they have been invited to take part in a controlled clinical trial,<sup>25</sup> when they need to decide whether to participate or not, because the 'informing' process started rather too late in their journey.

## HOW MUCH INFORMATION?

There are huge differences in preferences for the amount or 'level' of information wanted. Each patient who seeks information for himself or herself will come with different and variable quality information and will use it in different ways. 'Informed patient' also sounds rather more passive than 'a patient with information'.

Some will have been given information and may or may not have been helped to understand it; others will also have sought their own. What is certain is that there is no dearth of information. Quite the contrary, in fact: there is more than anyone can hope to access or understand. Of more importance are the following questions: is it any use to them; what is its quality; how reliable is it; and how much have they understood?

## THE INFORMED CONSENT PROCESS

It has been said, and I strongly agree, that the informed consent process begins for the citizen or patient with the first encounter with the medical profession, and is an ongoing process throughout that patient's experience of a particular condition. Mark Hockhauser described it well in a letter posted on [www.bmj.com](http://www.bmj.com) in early October 2003 as: 'consent delayed is consent denied'.<sup>26</sup> This was after attending (in the US) his 'first mid-life colonoscopy'.

This fact needs to be recognised and accepted by practitioners in healthcare and shared across the barriers that divide department from department, or public health practitioners from practising clinicians and trialists. It can often appear that they work in isolation and have little concept of the need for a common accountability and shared responsibility for ensuring a timely and seamless route for the patient's information needs.<sup>27</sup> Mark Hockhauser cogently argues that adequate information should be provided at the time of offering screening and prevention. This should cover possible known consequences of accepting the invitation, and should not be provided when the patient is too drugged to competently discuss the pros and cons, just before signing the consent form on the colonoscopy table. (Hockhauser is a psychologist in Minnesota who researches, writes and consults on document readability and writing style.)

Information should be amplified in patient information sheets by the clinical trialists devising trials for

management of conditions found, and re-iterated by those in the clinics attempting to offer choices.

## IBIS II BREAST CANCER PREVENTION TRIAL FOR WOMEN AT HIGH RISK OR WITH DCIS<sup>28</sup>

This ongoing process for providing information to patients has not been observed in the latest breast cancer prevention trial, IBIS II, launched in early October 2003 amidst much razzamatazz about the latest wonder drug for breast cancer, anastrozole (Arimidex).<sup>29</sup>

This trial is seeking 6,000 healthy but high-risk participants and 4,000 participants with ductal carcinoma *in situ* (DCIS). The obligation for taking responsibility to inform the 'patients' about DCIS is being fielded like a hot potato. The screeners have repeatedly defended their decision not to mention DCIS in the invitation leaflets because, they say, research they undertook showed that 'women don't want it'.<sup>30,31</sup> What about the screeners' obligations – the 'ought'? We must question whether undertaking research in focus groups of women who have not got DCIS, and who may not have heard of DCIS until that moment, is the right use of resources, or the right way of exploring this issue, in order to justify excluding mention of DCIS in the screening invitation information leaflet. This is contrary to General Medical Council (GMC) 1998 guidelines that describe clearly what citizens ought to be told.<sup>32</sup> That 'women don't want it' is still evidently the party line in the NHS Breast Screening Programme, even though they are currently drafting a booklet of supplementary information that will be available to women (but only those who ask for it) before attending for screening, which does cover DCIS.

The IBIS II lead investigator passed the buck in June 2003 by telling me that the clinicians will have already informed the potential DCIS participants,<sup>33</sup> or, more recently in the *Lancet*, responding to concerns I had raised in that journal,<sup>34,35</sup> that they 'would suggest the BACUP website as a source' whilst agreeing that 'more information about DCIS should be made available to women involved in screening'.<sup>36</sup> Actions would speak louder than words;<sup>37</sup> one must remember that recruitment to the DCIS arm of this trial is dependent on the screening programme for potential participants who have not been properly informed or consented – a curious symbiotic arrangement. Meanwhile, in the clinics, clinicians spend an inordinate amount of time attempting to explain the enigmatic condition of DCIS to the 2,000 women per annum sent to them via the national screening programme in the UK, who were not told of this possibility – even though one out of five women diagnosed with 'cancer' in the screening programme will have it.<sup>38</sup>

What is sure is that we already have increasing numbers of iatrogenically created patients, suffering personal,

social, financial<sup>39, 40</sup> and psychological consequences,<sup>41</sup> some of whom may have avoided that fate if they had not been lured as citizens by poor-quality, coercive and biased information.<sup>42</sup> At times, it can seem as though public health medicine is trying hard to make patients of us all. Citizens-turned-probable-patients perhaps have one of the most difficult tasks. They went for reassurance but some got more than they bargained for. This is a difficult enough dilemma for an individual even if they are being screened for a *single* condition, but it challenges imagination to consider the difficulties for both patient and health professional, and providers, if minute manifestations are identified in several different organs in the current vogue for whole-body scans. Dr Harvey Eisenberg, who runs a scanning service in Newport, California, said he referred 80% of the clients he screened for further hospital checks. He said: 'Emerging pathologies are almost always present. In 25,000 patients, I have seen maybe 10 that were completely normal.'<sup>43</sup> This surely indicates a pressing need to educate citizens and children<sup>21, 44</sup> in critical appraisal skills; about research; about risk assessment;<sup>45, 46</sup> and in decision-making skills,<sup>47</sup> so that they feel equipped to begin to learn how to make trade-offs, and grapple with all the uncertainties<sup>16</sup> that form the most difficult aspect for citizens, for patients and indeed for healthcare professionals.

## HOW CAN INFORMED PATIENTS CONTRIBUTE TO ACHIEVING BETTER QUALITY HEALTHCARE?

The passion for availability of accessible, good-quality information led three breast cancer patients to set up information and support organisations that are used as a resource by patients and health professionals alike. There are now many opportunities for more low-profile but valuable ways of fulfilment through voluntary social involvement – satisfying for volunteer and recipients alike. These communitarian activities constitute a bridge from individuals to the powers-that-be, aside from the inherent value of their work. Jonathan Sacks defines autonomy as 'the capacity to act and choose in the consciousness of alternatives – it is a late stage in moral development'.<sup>48</sup> The action and choices of these individuals surely represents a glorious manifestation of autonomous action.

## IN PARTNERSHIP WITH HEALTH PROFESSIONALS

In a culture of rising expectations and limitless demands, informed patients have increasing opportunities to work together with health professionals to encourage review of wasteful systems of healthcare provision or profligate prescription 'on demand' for unproven treatments, and to have a say in research affairs. The Cochrane Collaboration has welcomed and encouraged patient participation from its beginning in 1992. The Royal Colleges, the Medical Research Council (MRC) and other institutions have set up Consumer Liaison Groups. The NHS set up a Consumers in Research initiative in 1995 ([www.invo.org.uk](http://www.invo.org.uk)).

## WHERE NOW? WHAT ROLE FOR THE 'INFORMED PATIENT'?

Self-restraint, self-reliance, thrift and frugality – seen as virtues before the birth of the NHS mid-twentieth century – have been replaced by a consumerist, throw-away society where any benefit from a welfare state is viewed by some, not as a privilege, but as an entitlement to be claimed as a right. By definition, involved informed patients have wider interests at heart than their own individual healthcare, are less likely to have vested economic interests and are best placed to encourage a shift in emphasis away from this uncaring, individualistic clamour. They must encourage the replacement of an ethos of 'demands for rights' with one that emphasises 'recognition of duties'.<sup>43</sup> They must use their newly found (and endorsed<sup>49</sup>) opportunity to be involved in evaluating healthcare interventions to see that money is spent on trials that are needed by patients and have endpoints that mean something and matter to patients, and that a more equitable and just provision is achieved.

As the MRC report *Clinical trials for tomorrow* stated in its concluding paragraph about working with the public: 'The ultimate objective of any trial is to provide patients with better evidence about options in healthcare.' It reaffirmed its commitment to working with the public to promote understanding of, and engagement with, clinical trials through encouraging 'soundly based research'.

The informed patient is probably better placed than the concerned clinician to encourage working together for the afflicted, the vulnerable, those who have no access to even the most basic healthcare and those without power. They can work to uphold the dignity of the individual in a world 'destitute of social cohesion'.<sup>46</sup> Health must be a global concern. Distributive justice becomes less and less attainable as the gulf continues to widen between rich and poor,<sup>50</sup> and the means to tackle this problem eludes those who would tackle it. Informed patients can also work on behalf of those lucky enough to have access to healthcare, but who may not want or understand information needed to make 'informed' decisions. They can work for those who have to give 'informed' consent as citizens or patients, to see that they are not used and are treated with the dignity due to every individual. They can work to see that understandable 'neutral' information is available and accessible for any who want access to it.

To provide inadequate, biased, incomplete, persuasive or coercive patient information is not only patronising but offends ethically and morally. Unavailability of good-quality information from the moment of first encounter with the health profession, in whatever circumstance that may be, prevents true informed choice in all treatment decisions.

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