Clinical trials – A brave new partnership: A new doctor–patient working relationship in research

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ABSTRACT

An outline of the development of a “brave new partnership” in clinical trials is provided in this specific personal account. This paper was one of several delivered in November 2007 by colleagues deemed to have contributed to the distinguished career of Professor Michael Baum, at a Festschrift convened to honour him. This account describes this strange, new doctor–patient relationship in the research process that we developed, both in our dialogues and in the work of the Consumers’ Advisory Group for Clinical Trials (CAG-CT) that we jointly founded. This work formed but one facet of his outstanding contribution to society and academe, in the fields of medicine, ethics and science.

“Thus not only morality but also scientific self-interest combine to urge the ‘brave new partnership’ between clinical trialists and patients advocated by Mrs. Thornton. Like all partnerships it requires understanding by each partner of the interests and objectives of the other when those interests and objectives are perceived to conflict.”

Raanon Gillon.

“Recruitment for clinical trials: the need for public-professional co-operation”.1

1. Introduction

I’m delighted to have this wonderful opportunity to participate in Michael Baum’s Festschrift. It is an honour to be numbered amongst those colleagues deemed to have contributed to his distinguished career. He acknowledged this contribution when giving his acceptance speech in St. Gallen in March this year when he received the prestigious St. Gallen Lifetime Achievement Award for Advancement in Breast Cancer Research which he dedicated “to the amazing people I have worked with over the years and to the many thousands of patients and their families who have in some way benefited from the great advances in research and treatment”.2 It was a very moving occasion for everyone present, but particularly for me when he mentioned my name.

I hope now to be able to convey to you some of his particular qualities and attributes that I discovered and appreciated as we explored and developed this “brave new partnership”, this strange, new doctor–patient relationship in the research process which formed but one facet of his outstanding contribution to society and academe, in the fields of medicine, ethics and science.

2. The nature of the relationship

“Scientists and patient advocates have always enjoyed a delicate relationship”.3

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What then does it take to create an unlikely, lasting, productive “brave new partnership” between two apparently unmatched individuals? Two TV programmes, shown one after the other in August this year, depicting two extraordinary relationships, provide modern and Victorian parables. The first was a visually stunning documentary showing TV presenter and novice rock-climber, Julia Bradbury, tackling one of Britain’s most dangerous ascents of the Old Man of Stoer, a 60 m sandstone sea stack on the Scottish Sutherland coast, in the company of professional rock-climber, Tim Emmett. The second was the acclaimed film Mrs. Brown, in which the story is told of the summoning by Queen Victoria’s Secretary, Sir Henry Ponsonby, of servant John Brown from Scotland, a favourite riding companion of Prince Albert, to help lift the Queen’s prolonged depression after Prince Albert’s death.

The rock-climbing partnership vividly demonstrated a relationship in which all the energies and efforts of both people were concentrated solely on the identified common goal to which they had committed themselves – no turning back was possible. No time was wasted on unrelated, un-essential facets of each other’s lives that had no bearing on the task in hand. It was a working relationship that demanded complete and full concentration solely on the necessary elements of the challenging undertaking. But, as one could see, there was a strong rapport and intensity of purpose, evidently based on trust in each other, and confidence in the skills and personal characteristics of each person for the other. A paring down to vital practical and personal essentials, with economy of expression and measured pace: novice and expert roped together to reach the summit!

The John Brown/Queen Victoria relationship flew in the face of the conventions of the time and was frowned on by the pillars of society – and the servants. They were as far removed from each other as could be in wealth and status. Servants did not speak unless spoken to. But Servant and Queen were equally strong-willed, stubborn and determined when it came to a goal worth fighting for! ‘Politically correct’ barriers of etiquette were pushed, broached and surmounted. A strong rapport was evident. The aim was achieved.

To return to our “brave new partnership”: there was never any time wasted, right from the start: communication was direct, to the point and lively – indeed, one could say, provocative and challenging; hence its productiveness. For me, it was informative, stimulating and inspirational: never oppressive or coercive. Sometimes with the gloves really off! He exhibited immense patience with my ignorance of many subjects, gently and gradually leading me to the literature. By inviting me to attend the Royal Marsden Hospital weekly Breast Unit Meetings, and copying me in to various correspondences, he led me to identification of leading players in the forefront of thought about the moral obligation of patients to join randomised trials, but leaving me to take the initiative to respond or approach them. Just such a letter was one to Dr. William Silverman about his pending visit to Oxford to give the Archie Cochrane “Effectiveness and Efficiency” Anniversary Lecture, 17th March 1994.

3. ‘Matchmaking’ and meeting

Our first meeting took place at the Royal Marsden Hospital, Fulham Road (and a Thai restaurant on the corner with Sidney Street!), 9th April 1992. That corner is where he left me, waving a hand up at the Royal Marsden Hospital façade, saying “There are professors in there who would give their eye teeth to have a paper published in the Viewpoint section of The Lancet.” I replied that I hadn’t even seen a copy of The Lancet at the time I wrote my piece. Early on he told me that I should write – but I wondered then what I should write about!

“How did you meet?” “Where did you meet?” “Who introduced you?” are questions that people like to ask, but may be too reticent to voice, particularly if (as one can frequently observe – no exception in this case!) partners seem to be an unlikely match. The ‘matchmaker’ in this case was Mr. Neil Orr, my breast surgeon in Colchester, Head of the Breast Unit Team. This happened in November 1991, a couple of months after I declined to participate in the UK DCIS Trial. After being diagnosed, operated on and invited to join this trial in September 1991, and had had time to research a little about trials, about DCIS, about informed consent, and think about these things, I had sent Neil Orr a summary of the practical, moral and ethical reasons why I had not agreed to participate. Neil Orr replied by return, telling me that he had taken the liberty of photocopying what I had written and had sent it to Professor Michael Baum and Professor Roger Blamey.

I now want you to try to imagine how I felt, as a very ordinary lay member of the public, when I received a letter the following month from Michael Baum, the day before Christmas Eve. He stated that he “would enjoy continuing this dialogue’’ with me by exchange of correspondence, and, as Chairman of the Breast Cancer Trials Co-ordinating Committee, he “would be very happy to meet me in Town to discuss the matter in greater detail” having agreed with me about the inadequacy of information for trial participants.

It thus took the bold and decisive action of two breast surgeons, stepping outside their usual remit, having identified potential for improvement to the process of seeking patients’ consent in research, to take personal initiatives to provide the means for dialogue and action between two people from very different backgrounds who were both concerned about this. This action has to be set against the prevailing culture of the time, when it was not normal to make this kind of approach to a patient, when it might even be looked at askance by some medical colleagues. It took a particular kind of physician to identify the potential in this new alliance and pursue it without hesitation or fear of criticism.

But I had kept something up my sleeve. When Michael Baum wrote to me in December, he did not know that, when I had written to Neil Orr in November, I had also sent a copy of my piece to all the members of the DCIS Trial Steering Group, and to several medical journals, not knowing, of course, that this was not how things were done! The first acceptance of my piece came from The Lancet on 27th November 1991. They offered to publish it in the Viewpoint section of the journal. Imogen Evans, the Senior Editor there, commented “Many of the arguments that you raise cast a completely
different light on the subject – and not before time.” Again, we see in this bold move, people taking unusual initiative – a departure from the norm of that time; recognition of the benefits of a new approach; a possible new contributory relationship between doctor and patient for the improvement of the research process. Little did I think then that I would, one day, co-author a book with Imogen Evans and Iain Chalmers that added to this continued striving to educate the public about the need for them to understand and be involved in testing treatments, advocating for better research to achieve better healthcare.11


Michael Baum chaired the full morning session of The Lancet ‘Challenge of Breast Cancer’ conference in Brugge 22nd April 1994. Imogen Evans chaired the first session of the morning – “The patient’s role in research”, in which I shared a platform with Susan Love and Kay Dickersin. This was a prime opportunity for me to advocate to the assembled international breast cancer specialists for sharing the responsibility to test treatments.12 Subsequently, Michael was keen for me to establish a constituency to take this forward. So, in September that year, 1994, we held the first meeting of our jointly founded Consumers’ Advisory Group for Clinical Trials (CAG-CT). The group immediately went to work on a draft protocol for a randomised controlled trial; set about registering ourselves as a charity; worked up our successful bid for funding from the NHS R&D Cancer Programme to explore the use of a Consumers’ Advisory Group to increase accrual into trials; and drafted the first version of our leaflet outlining our aims and objectives.

5. Conclusion

Historical events are placed in context by dates.13 Detailing and appreciation of strict chronological order are necessary if proper and accurate interpretation of any event in its wider context is to be undertaken. Leading dramatis personae need patience and doggedness14; history cannot be hurried. Timing of important events may be exquisitely precise; pace of events will vary; long lapse of time is usually needed in order to be able to draw reasonable inferences. Induction, deduction and interpretation follow inexorably in sequence, rolling relentlessly against the broad background of contiguous events.

At this celebration of Michael Baum’s lifework, we have seen this to be so. He is a man of many skills, expertises and talents. That he should have identified the potential in a continued dialogue and relationship with me, come what may, through thick and thin, in pursuit of a common goal that stood to benefit the lives of countless thousands of women, and also improve the relationship between health professionals and involved patients and public in testing treatments, whatever their race, creed, colour or individual circumstances, is testimony both to his wide vision and to his courage. We were allies, even though “diametrically opposed” as he had said in our first published debate.15,16 We had emerged “from the two distinct cultures of our society, with differing backgrounds in the liberal arts and the biological sciences”. He relished dissent within the scientific process, for, as he said, “without dissent there can be no progress.” He pushed the boundaries with his 1993 Lancet paper “new approach for recruitment to randomised trials”17; this was met with excitement in my editorial commentary, but also with robust challenge.18 It led on to organised, productive, brave new partnerships in research, not just in breast cancer,19 but also generally.

Conflict of interest statement
The author has no conflict of interest.

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REFERENCES

4. http://www.grough.co.uk/content/view/555/2/.
6. Thornton H. Green College, Oxford. Seminar: “Is there a moral obligation for patients to join randomised controlled trials?” To members of the Clinical Trials Service Unit, Oxford, and Cochrane Centre staff. At the invitation of Dr. Iain Chalmers, Director, Cochrane Centre; 19th October 1993.
8. Baum M. Personal communication; 11th December 1991.

[Ductal Carcinoma In Situ (DCIS)]

"It is much easier to write upon disease than upon a remedy. The former is in the hands of nature, and a faithful observer, with an eye of tolerable judgement, cannot fail to delineate a likeness. The latter will ever be subject to the whims, the inaccuracies, and the blunders of mankind".20 W. Witherington. 1785.


