

## There should be only one priority in clinical research – to put the needs of the consumer first

“... it will represent another missed opportunity for research to connect with its public ...”

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A new publicly led campaign entitled ‘Patients Included’ highlights how ‘nothing has changed and yet everything is different’ [1] in clinical research when it comes to its relationship with patients.

‘Patients Included’ has its origins in the stand taken some years ago by Lucien Engelen [2]. This innovation expert became patient advocate and agitator when the author realized that the many technology and medical conferences the author attended and which purported to be about what patients wanted did not have a patient in sight. In fact, in some cases, their presence was actively discouraged. So the author decided that if such events did not have patients in the audience and on the speaker’s platform the author would not show up [3].

This ‘one-man stand’ has now been taken up by fellow patient advocates with strong backing from the BMJ. On 1 May they launched a ‘Charter for Conferences’ with organizers able to self-accredit themselves as ‘Patients Included’ if they meet the five principles set out in the charter. It has already created a social media buzz among patient activists and those who support them [4]. Whether it will change attitudes and practices on the lucrative conference circuit remains to be seen; which is my point.

On the one hand ‘Patients Included’ is an exemplar for how the patient voice is becoming ever louder and more assertive in the world of health research. On the other, it shows just how far we still have to go just to be part of the conversation. Three decades

on from the beginnings of public activism in research it can still feel that we are having to thump on the closed and heavy door of the medical research establishment.

But it would be wrong to tar everyone with the same brush. Whether it is the innovative and exciting PatientsLikeMe [5] or user-driven charities such as Parkinson’s UK and Alzheimer’s Society, there is increasing evidence of patients and carers, clinicians and researchers working together to vigorously pursue outcomes that matter to patients.

Many international government funding bodies are also now stepping in to correct the long-standing market failure of clinical research to put the needs of its consumers first. From the impressive Patient Centered Outcomes Research Initiative [6] in the USA, to the Canadian Institutes of Health Research which has been steadily establishing Support for Patient Orientated Research [7] units in each province with public involvement at their core.

The National Institute for Health Research (NIHR) in the UK – the research arm of the National Health Service – has arguably set the pace internationally for how research funders should set about the task of working with the public to deliver research excellence. As a recent strategic review of NIHR’s approach states: ‘No researcher or institution who applies to the NIHR for funding can expect to be successful without a plan for public involvement that lay reviewers have scrutinized. Its James Lind Alliance Priority Setting Partnerships lead the way in enabling



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patients, carers, clinicians and others to identify research priorities for future funding. Public involvement plays a vital role in strengthening the effectiveness and efficiency of the NIHR's Clinical Research Networks in recruiting people to studies.'

The 'Going the extra mile' report goes on to set a new ambition for NIHR - to make public involvement as important to health research as accurate measurement: 'In this future scenario, research without evidence of public involvement would be considered flawed, the openness and transparency with which it is conducted, vital to maintaining public confidence in research and their belief in its ability to improve their health and that of their neighbor.' The Director General, Research and Development and Chief Medical Officer Professor Dame Sally Davies, is expected to respond formally to

**"From the anticipated comprehensive spending review of the new British government to the need to convince the population of the merits of the sharing data."**

the report [8].

However, evidence of what is happening across the wider health research system, points to medical research charities, universities and the research councils being behind the curve when it comes to public involvement, even if things have undoubtedly improved in these sectors over the last 2 years.

A joint report by INVOLVE and the Health Research Authority published this year showed that 47% of charity funded research applications to ethics committees in 2012 included plans for public involvement up from 32% in 2010 [9]. But this looks poor in comparison to the NIHR figure of 87%. Commercially funded applications come out even worse with only 5% of applications reporting public involvement (up from 2% 2 years before) [10]. It is small wonder that leading researchers and others have observed that this detachment from the public leads to research that is ultimately of poor value to its end users. [11]

What is perhaps more worrisome is the extent to which the patient voice is often used to give legitimacy to initiatives that are more about unleashing science than promoting the patient and public interest. Campaigns that, when you scratch the surface, are unable to demonstrate anything other than a cursory involvement of patients and the public in their development. It will be a key test of the 'Innovative Medicines and Medical Technology Review' announced by the British government just before the General Election whether it can avoid this charge (1210). Talked-up beforehand by the Life Sciences Minister, George Freeman MP, as a significant step towards making patient empowerment a key driver of innovation in the UK, one of

the review's cross-cutting themes of work will now be an examination of the role public engagement and involvement can and should play as part of the innovation and diffusion agenda. It must engage widely and constructively with the many voices who have much to contribute on this subject.

If not, it will represent another missed opportunity for research to connect with its public (or, more accurately, its publics) at a time when research will need public support to ensure that it emerges from the current political and economic climate in good health. From the anticipated comprehensive spending review of the new British government to the need to convince the population of the merits of the sharing data.

A key example will be the 100,000 Genome Project in the National Health Service which will conclude in 2017 but anticipated to leave a strong legacy for how this science and the healthcare interventions that stem from it can be embedded in the National Health Service. Life will be more difficult for all of us – researchers, doctors, other health professionals and patients – without the public alongside us [13].

The Health Research Authority – which itself has done much to champion public involvement in research in its short life thus far – published its latest round of public survey data in March. It showed the strong and instinctive public support for health research that has been a long-standing feature of our society and culture in the UK. But it also pointed to the degree of confidence that the public draws from knowing that people just like them have been involved in how research is designed and conducted. It is this sweet spot in the relationship between research and citizens that we must continue to nurture, that we become complacent about at our peril [14].

'Patients Included' would not be a bad mantra for us all to adopt in UK research as we face the challenges of the future.

## Conflicts

S Denegri is the NIHR National Director for Patients and the Public in Research and Chair, INVOLVE and his post is hosted by University College London. The author was Chair of the 'Breaking Boundaries' review of public involvement in NIHR which published its findings in the report entitled 'Going the Extra Mile.' The author has advised the Canadian Institute of Health Research on its approach to public involvement and is on the panel which reviews provincial applications to run SPOR units.

## Financial & competing interests disclosure

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honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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