



EDITORIALS

Patients' roles and rights in research

Full partnership with patients is essential to any modern research enterprise

Paul Wicks *vice president of patient innovation*¹, Tessa Richards *patient partnership editor*², Simon Denegri *NIHR national director for patients, carers and the public*³, Fiona Godlee *editor in chief*²

¹PatientsLikeMe, Cambridge, MA, USA; ²The BMJ, London UK; ³National Institute for Health Research, London UK; Correspondence to: P Wicks pwicks@patientslikeme.com

Patient and public involvement in research is becoming a mainstream activity thanks to recognition by everyone in the research process from funders and regulators to conference organisers and publishers that it helps them do a better job. There is certainly a strong case for increasing the value to patients and the public from the billions spent on biomedical research. The exponential rise in research output has seen a decline in quality¹ and mounting concern about high levels of waste, bias, inefficiency, and error.² A collaborative effort is needed to reform the research enterprise, and patients and the public have a leading part to play.³

Including patients and the public as partners in research is accepted best practice in several Western countries, and some funders make it mandatory. *The BMJ* supports this by requiring authors to report the extent of patient and public involvement in all submitted research.⁴ It is clear, however, that some researchers struggle to differentiate between qualitative research (when patients' experiences are sought and used as data) and including patients as true research partners (when their views and experience contribute to decisions about the research agenda and the design, conduct, and reporting of studies).⁵

Critical voices, including some patient advocates, have likened current approaches to patient involvement to "virtue signalling."^{6,7} They point to an enterprise which remains skewed to serving the vested interests of professionals and industry—not patients.⁸ Some patients even independently fund and conduct their own research out of frustration with the system.⁹

A recent study of 11 research funding organisations found that, with the exception of UK National Institute of Health Research (NIHR) and the Netherlands Organisation for Health Research and Development, grant funding committees remain dominated by academics and clinicians, with limited or no involvement of patients or the public.¹⁰ The design and conduct of clinical trials often fail to take account of patients' experiences or realise the potential of working collaboratively with them and their networked communities.¹¹

The failure to enshrine collaborative working with patients perpetuates a status quo that focuses more on developing new (patentable) products than developing better services that deliver "kind, careful, minimally disruptive care."¹² Also neglected are initiatives to ensure that patient communities can access and understand research findings, identify what they add to previous

evidence, and use them to inform therapeutic decisions.¹³ People in low income countries, where many drug trials are conducted (and ethical standards vary), are particularly side-lined—not least because many cannot afford the medicines they helped to evaluate.

The benefits of patient involvement are increasingly accepted by drug companies, which are actively working with patients¹⁴ and realising returns on this investment.¹⁵ Simplifying protocols by minimising burdensome procedures or study visits can reduce research costs and increase recruitment; including patients in the design of recruitment materials can shorten enrolment periods; focusing on what matters to patients can avoid costly protocol amendments or problematic switching of outcomes.¹⁶

One of the main stumbling blocks to "coproduction" of research with patients and the public is that professionals lack knowledge, skills, and experience on how best to do it. Although guidance is available from organisations like NIHR and the Patient-Centered Outcomes Research Institute (PCORI),^{17,18} adapting this to specific situations can be challenging. An enthusiastic and committed lead researcher is often needed to see such work through. Some organisations and research networks are making progress,¹⁸ but their work needs to be more widely replicated and disseminated internationally.¹⁸

One particular challenge is to ensure diversity within collaborations so the interests of the well-educated white middle classes in rich countries do not dominate.¹⁹ Patient leaders must be supported and empowered to engage diverse communities from the outset. The Food and Drug Administration's patient focused drug development programme, for example, started by running in-person meetings around Washington DC but now provides standards for advocacy organisations to contribute virtually. Non-profit organisations such as the Amyotrophic Lateral Sclerosis Association have surveyed patients online, giving voice to those unable to attend meetings.²⁰

Giving real power to patients and those who care for them will entail shaking up existing research hierarchies, not merely smoothing out a few bumps in current practice. Senior researchers should lead by example and embrace this essential culture change. Coproduction of research must go beyond a handful of enlightened practitioners responding only to the most vocal (and well funded) patient communities, to become the new global norm for clinical research.

To advance this move, the BMJ is extending its current requirement to report how patients and the public were included in the design, conduct, and reporting of clinical research studies across its portfolio of journals.²¹ In addition, from January 2019 onwards we will require authors of clinical research papers to provide details of how they intend to disseminate results to participants and relevant communities. We have also pledged to work with others to define and enshrine best methods for coproduction of research.

This is a critical point in the development of patient and public involvement: appraisal of the fundamental rights—or lack of them—that underpin patient, carer, and public inclusion in research as both participants and coproducers is timely. Later this year, we will host a meeting to examine the issues raised in this editorial and set the agenda for further debate. We invite comment and thought on the current state and future path of patients' rights and roles in research.

We thank the members of *The BMJ's* patient panel for thoughtful comments on this piece.

Competing interests: We have read and understood BMJ policy on declaration of interests and have no relevant interests to declare.

Provenance and peer review: Commissioned; not externally peer reviewed.

- 1 Sarewitz D. The pressure to publish pushes down quality. *Nature* 2016;533:147. 10.1038/533147a 27172010
- 2 Macleod MR, Michie S, Roberts I, et al. Biomedical research: increasing value, reducing waste. *Lancet* 2014;383:101-4. 10.1016/S0140-6736(13)62329-6 24411643
- 3 Heneghan C, Mahtani KR, Goldacre B, Godlee F, Macdonald H, Jarvies D. Evidence based medicine manifesto for better healthcare. *BMJ* 2017;357:j2973. 10.1136/bmj.j2973 28634227
- 4 Price A, Schroter S, Snow R, et al. Frequency of reporting on patient and public involvement (PPI) in research studies published in a general medical journal: a descriptive study. *BMJ Open* 2018;8:e020452. 10.1136/bmjopen-2017-020452 29572398

- 5 Liabo K, Boddy K, Burchmore H, Cockcroft E, Britten N. Clarifying the roles of patients in research. *BMJ* 2018;361:k1463. 10.1136/bmj.k1463 29636343
- 6 Madden M, Speed E. Beware zombies and unicorns: toward critical patient and public involvement in health research in a neoliberal context. *Frontiers in Sociology* 2017;2:7. 10.3389/fsoc.2017.00007.
- 7 Johannessen J. Exploring the purpose and meaning of patient engagement in pediatric neurodisability research. 8 Nov 2017. <http://johannessen.ca/2017/11/exploring-purpose-meaning-patient-engagement-pediatric-neurodisability-research/>
- 8 Stecher B. Rewiring neuroscience: letter to a young researcher. 7 Aug 2017. <https://tmrwedition.com/2017/08/07/rewiring-neuroscience-letter-to-a-young-researcher/>
- 9 Omer T. Empowered citizen 'health hackers' who are not waiting. *BMC Med* 2016;14:118. 10.1186/s12916-016-0670-y 27530970
- 10 Nasser M, Clarke M, Chalmers I, et al. What are funders doing to minimise waste in research? *Lancet* 2017;389:1006-7. 10.1016/S0140-6736(17)30657-8 28290987
- 11 Wicks P. How to design a better clinical trial with the patient experience in mind. *Newsweek* 2017 Jul 21. <http://www.newsweek.com/cancer-patients-clinical-trials-design-better-experience-639310>
- 12 Montori V. *Why we revolt: A patient revolution for careful and kind care*. Patient Revolution, 2017.
- 13 Schoter S, Price A, Malicki M, et al. Frequency and format of clinical trial results disseminated to participants: a survey of trialists. Peer Review Congress 2017 <https://peerreviewcongress.org/pdf/2017/prc8-poster-complete.pdf>
- 14 Yeoman G, Furlong P, Seres M, et al. Defining patient centricity with patients for patients and caregivers: a collaborative endeavour. *BMJ Innov* 2017;3:76-83. 10.1136/bmjinnov-2016-000157 28890797
- 15 Getz KA. Establishing return-on-investment expectations for patient-centric initiatives. *The Innov Regul Sci* 2015;49:745-9. 10.1177/2168479015579521
- 16 Getz K. Improving protocol design feasibility to drive drug development economics and performance. *Int J Environ Res Public Health* 2014;11:5069-80. 10.3390/ijerph110505069 24823665
- 17 NIHR Research Design Service. How to do patient and public involvement. <https://www.rds-london.nihr.ac.uk/Patient-Public-Involvement/Resources.aspx>
- 18 Patient-Centered Outcomes Research Institute. Engagement rubric. 2014. <https://www.pcori.org/sites/default/files/Engagement-Rubric.pdf>
- 19 Richards T. Patient and public involvement in research goes global. *BMJ Blogs* 20 Nov 2017. <https://blogs.bmj.com/bmj/2017/11/30/tessa-richards-patient-and-public-involvement-in-research-goes-global/>
- 20 Charpentier B, Petrillo J, Laverdiere A, et al. CLT-03 People living with ALS and their caregiver's input into drug development. *Amyotroph Lateral Scler Other Motor Neuron Disord* 2017;18(suppl 2):229. 10.1080/21678421.2017.1374609
- 21 BMJ. Reporting patient and public involvement in research. <https://drive.google.com/file/d/14vnXwtJ2CDn2KQsuNpuEnSwad69gc7dR/view>

Published by the BMJ Publishing Group Limited. For permission to use (where not already granted under a licence) please go to <http://group.bmj.com/group/rights-licensing/permissions>