How Public Contributors can manage overlapping roles in health research

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Introduction and scope

People with lived experience of a health condition or disability are often called 'experts by experience' and sometimes find that they have multiple roles that overlap. This paper seeks to name and then discuss some of these overlapping roles as they might be experienced by a single person. Possibilities include:

- Serving as a research participant (this used to be termed a research subject) on more than one study, either consecutively or concurrently.
- Expert by experience and member of the Lived Experience Advisory Panel (LEAP)
- Serving as a research participant and a member of the LEAP for the same study.
- Serving as a LEAP member while belonging to a relevant campaigning group
- Serving as LEAP member in multiple research studies, either consecutively or concurrently.

- Experiencing the health condition under investigation in a research study and working as a researcher or clinician on that same study – often known as a peer researcher or peer worker.
- Working as a peer researcher and serving as a LEAP member on the same or a different study.

Some people occupy more than two roles and so the complexities increase exponentially, as with the person who brings lived experience to their clinical role whilst also working as a researcher. In order to keep the discussion as clear as possible, each section below will refer to a simple pair of overlapping roles. For brevity, Issues are named only once in this paper, even where they apply to several situations, so readers should consider the whole document when thinking through their circumstances.

This paper considers the circumstances where a single person occupies multiple roles and may be subject to a conflict of interest; it does not consider how roles held by different people may overlap and cause conflict between those persons. A conflict of interest has been defined as '*circumstances that create a risk that… judgments or actions regarding a primary interest will be unduly influenced by a secondary interest.*'[1] Primary interests are concerned with general patient benefit and the integrity of research, while secondary interests include financial gain and advancement for the person, friends or a particular subgroup of society. Conflicts of interest vary according to four factors

- the **reach** of the person's power and influence and so the range of decisions that may be affected
- the **likelihood** that the conflict of interest will change the decision that is being taken
- the **proximity** of the secondary interest to the primary interest – as a conflict may be more difficult to detect and manage if the secondary interest is closely related to the primary interest
- the scale of **harm** that may occur.

Critics sometimes declare that overlapping roles should be outlawed, but rarely seem able to explain what they mean by their vague reference to conflicts of interest. Most take a preventative approach, preferring to minimise opportunity rather than repair damage after it has occurred. It must be stated that the recognition of a potential conflict of interest does not suggest that the person has behaved in an unethical manner.

The harms that may occur as a result of conflicts of interest include:

- Loss of objectivity. One study found an asymmetric effect, in that a financial relationship with a drug manufacturer did not result in academics inflating positive research findings, but did make them less likely to report negative qualitative results[2].
- Reordering of priorities
- Degradation of the quality of scientific endeavour
- Secrecy rather than openness and transparency across the whole team
- Exploitation of others
- Misallocation of time, effort, and publicity
- Loss of public trust

The discussion set out in this Guide assumes that most citizens live with multiple, overlapping roles every day of their lives, constantly juggling the conflict of interest between their identity as employee and homemaker, neighbour and parent, and so on. In the workplace or in leisure activities, it is normal for some people to hold multiple roles and pursue a variety of interests. As

discussions of work/life balance illustrate, it can be helpful to explore how competing roles interact, try to pin down the nature of the threats involved and adopt practices that mitigate the risks. This *How To* guide therefore attempts to identify the value of involving Public Contributors in research who occupy multiple roles within the research community, appraises the potential risks, proposes ways to mitigate them, and embraces people with multiple roles, identities and relationships.

In general, the following paragraphs address overlapping roles which all occur within the research world. Others may wish to explore the potential for conflicts to occur between research activities and other activities. For example, when recruiting a 'Patient and Public Voice' representative, NHS Improvement ask for a declaration of all employment, commercial sponsorship and volunteering as they expect that these activities may cause a conflict of interest to arise[3].

Research participant on concurrent studies

Getting involved in a second research study whilst already participating in the first study is usually going to confound the results and so is generally avoided. However, one study[4] in 2007 found 10% of research participants in their sample admitted to dual enrolment, which undermines the view that *all* participants are motivated entirely by altruism.

Research participant on consecutive studies

Some participants in drug trials are prohibited from joining a second research project until a washout period has elapsed, so that the intervention from the earlier study does not impact the baseline measurements taken for the later study, or the combination of pharmacological interventions cause harm. In the UK, the Health Research Authority maintain a register[5] of research participants called TOPS in order to prevent participants from engaging in two or more concurrent studies and ensure that the washout requirement is met.

We might discern a principle at work here. TOPS is not applicable to all research studies but is confined to a small group where the risk of harm is highest. TOPS is used solely in Phase 1 research, which means:

- drug trials rather than all research
- the first time that the new drug is tested on humans, so the risk of harm is greatest
- the drug is tested on healthy people who will gain no therapeutic benefit if it works
- to drug trials where payments to research participants are highest, and so there is the greatest risk that people will see the money and choose to ignore advice.

Beyond this specific situation, there is no national register, so the Health Research Authority has considered that the risks which attend participation in concurrent or consecutive studies do not need such stringent controls. Instead, rules appear in the guidance from Ethics Committees, are set out in exclusion criteria for individual studies and considered by the patient's clinician and through a stringent process of informed consent. So it seems fair to conclude that risk associated with participation in concurrent or consecutive research projects must vary by context and so must be individually defined, evaluated and mitigated. Even in TOPS, there is no standard duration for a washout period, as it varies according to the way in which the drug is metabolised and how long it remains in the body.

Expert by experience and LEAP member

Forming a new Lived Experience Advisory Panel of people with lived experience of the relevant health condition and then consulting with them about decisions throughout the project (design, funding application process, recruitment of staff and research participants, data collection, analysis and dissemination of findings) is only one way to organise the partnership with patients and the public, but it will be used in this paper to represent all the varying forms of research coproduction.

Experts by experience will be anything but neutral about the outcome of the research, generally taking a passionate and committed view on the importance of finding ways to improve patient care for the individuals affected by the condition under examination. In one example, the LEAP considered that a treatment would be worth it, even if, irrespective of cost, just one patient benefited, setting them at odds with the funder who may decide to close down the study if the cost outweighed benefits. Indeed, it is this passion for patient benefit that is perhaps the unique value which the LEAP can add to a study, but there may be other specific decision points during the course of the study where this passion could come into conflict with academic priorities.

Research participant and LEAP member

Some experts by experience wish to sign up to the study as research participants, so this creates a specific subset of the previous section. In 2018, Vale and colleagues[6] recommended that research participants should be routinely included in a LEAP and went on to explore why this should be so, and the potential safeguards that may be needed. This recommendation was set out in direct contradiction to the advice[7] available at the time from NIHR INVOLVE, which, save for participants in action research studies, worried that involvement of trial participants would generate an unspecified conflict of interest.

In the early design stages of a research project, no-one has yet participated in the research, so limiting membership of the LEAP to participants is impractical. At the other end of that spectrum lies the possibility that it might be hard to find potential LEAP members who have not participated in the research project, perhaps because it is a rare condition or an action research methodology is being used.

A research participant will add value by bringing their knowledge of the condition being treated and the precise details and experience of participation to the LEAP. Their personal experience of receiving the treatment will enrich LEAP discussions and help to suggest improvements to protocols and patient care throughout the study, thus sharpening the focus of the research and enhancing adherence and retention, so that fewer participants drop out. They will be powerful communicators of the research findings, able to blend their personal experience of the condition and the relevance of the treatment as well as their knowledge of the overall project acquired through participation in the LEAP.

Alternatively, an established LEAP member may subsequently enrol as a research participant on the same study and would then bring their commitment to the study gained through the LEAP into their role as participant. However, they will be much more knowledgeable than other participants, potentially distorting their responses. They may also be ‘unblinded’, using their knowledge of the research method to work out whether they have received the intervention or ‘treatment as usual’, and data may be contaminated by their belief about which intervention they received.

If the research intervention is attractive and seems to be of value to the LEAP members, there is a possibility that they may seek preferential access to it because of their contribution to the overall study. For example, it took some time for one LEAP member who was unemployed to fully understand that he was not eligible for the employment support that was being evaluated through the study.

Rules of confidentiality are likely to vary between roles, with duties towards the trial participant being stricter than the rules that apply to LEAP members, although, in Europe, the General Data Protection Regulation covers all.

Both trial and LEAP participation may attract financial or other rewards and people eligible to receive something from both systems will need to understand the separate basis for each financial transaction. Similarly, publicity, marketing activities and selection processes must be entirely clear, so that people who participate in both understand the basis on which they attend each event. There is potential for some people to be confused at this point, and to offer or expect the rewards associated with the LEAP activities to apply to trial participation, and vice versa.

Whilst the LEAP will want to conduct its business in an ethical manner, it is not subject to the local regulation of the Research Ethics Committee, in contrast to the study's engagement with research participants which is closely regulated. Nevertheless, local ethics committees will have an overall view on how Patient and Public Involvement is woven into the fabric of the whole research project, as will the funding body.

Trial Steering Committee member

The UK's National Institute of Health Research appoints members to the Trial Steering Committee for research projects that it has funded[8]. Membership must include "at least one individual who is able to contribute a patient and/or wider public perspective." The purpose of this group is to provide an independent view on the progress of the research and, if necessary, to recommend its early closure if it becomes clear that there is little value in continuing. In order to achieve independence, the Public Contributor who is part of the Trial Steering Committee should not be involved in any other role in this particular research study. Members are required to sign a 'conflict of interests' declaration.

Data Management and Ethics Committee (DMEC) member

While it is not an NIHR requirement[9] for the DMEC to include a Public Contributor, this sometimes happens. DMEC members may be invited to view the data gathered during the research and can do so 'unblinded', therefore potentially seeing confidential and identifiable information about research participants. For this reason, Public Contributors who become DMEC members should not be involved in any other role in this particular research study. Members are required to sign a 'conflict of interests' declaration.

Research Ethics Committee lay member

All research proposals in the UK must be reviewed by a Research Ethics Committee which includes lay members. While the Health Research Authority uses the term 'lay member' to refer to people with professional training which is not a health profession, some RECs do include Public

Contributors. The practices designed by the Health Research Authority and adopted by RECs help to ensure that conflicts of interest within the REC are managed appropriately, and so a Public Contributor who had any involvement with a particular research proposal would need to declare the fact to the chair of the REC and take mitigating actions as advised. However, it is less certain that a lay member of a REC who subsequently became involved with a research study would be under similar obligations. At worst, the research proposal could be unhelpfully distorted by efforts to shape it according to a belief about what would be acceptable to the Committee, rather than simply presenting the proposal with integrity. These hazards are, of course, equally present for researchers, but it is perhaps more likely that the research team will know that a particular academic sits or has sat on a REC, while lay membership may be less well known.

Campaigner as a LEAP member

Steffens et al (2019)[10] report on the impact of anti-vaccine campaigners on the work of agencies promoting vaccination and propose actions to mitigate the harm done by misinformation. In this account, campaigners deliberately sought to unseat others, using manipulative and aggressive strategies to cause harm. While in this example the campaigners are separate persons in conflict with research teams, it illustrates the potential for campaigners to bring entirely divergent views into the LEAP, or for LEAP members to be under pressure from these views as presented by other members of the lived experience constituency.

LEAP member on concurrent studies

Early career researchers may find themselves fully occupied by the work associated with a single study, while their more experienced counterparts commonly have involvement in multiple research projects. Some LEAP members may quickly become involved in several studies at the same time, either where the LEAP is a generic panel covering a group of research projects, or where experts by experience join more than one LEAP. In this event, the fit between their life experience and the subject of the research begins to vary, as they are likely to have a more tenuous connection with one study rather than another.

Involvement in two or more studies can accelerate the LEAP member's learning about research methods and enrich their contribution as they bring insights from other studies. However, the LEAP member quickly loses their naivety as they acquire an understanding of jargon and becomes skilled in navigating relationships with academics and clinicians. This means that their contribution as an outsider to the research community, bringing fresh perspectives and challenging the status quo, will be a diminishing asset, while their ability to target key issues because they are familiar with research processes, will grow over time[11].

Peer Researcher

The peer researcher has lived experience and is employed as a researcher. They may have been employed as a researcher first and then experienced the health condition; they may have lived with the health condition on a lifelong basis and subsequently obtained employment as a researcher; they may have responded to an advert that specifically sought to appoint people with this sort of 'dual identity'. Guidance is available on taking your lived experience to work[12].

Alison Faulkner has helpfully pointed out[13] that organisations that employ people with lived experience may start to think that the task of coproduction is now accomplished and stop listening to or even providing funding support to independent 'user led' groups. This approach, of course, pays scant attention to the conflicts of interest that could silence the peer researcher or tame their challenges. Even where there are amicable relationships between the employee and the organisation, it can be argued that the employee already has a voice and an opportunity to declare their view, so consultation and engagement processes should reach beyond staff in order to hear the views of other citizens.

Peer researcher as a LEAP member

Emma Sutton[14] lists the following barriers that might prevent her as a physiotherapist and researcher with lived experience joining a Lived Experience Advisory Group for a research project:

- "I may not be able to contribute my views while simultaneously enabling others to speak because my professional authority could predominate. Perhaps others would worry about this too and I may not have permission to join a PPI team at all. When discussing a subject which is clearly emotive for me as a patient, I might not be able to avoid asserting the power that my professional knowledge as a clinician and researcher brings." This could lead to other members being accidentally disenfranchised.
- "What if exposing my own experience as a patient could affect my academic career?" This is particularly relevant for conditions that are stigmatised or associated with fluctuations in performance such as some mental health issues, chronic pain or fatigue. Assumptions and stereotypes held by managers and occupational health departments may result in disclosure being a career-limiting move.

If the advice needed from the Lived Experience Advisory Group is mostly concerned with improving communications with patients who do not understand clinical interventions, research methods or jargon, then a peer researcher will not be much use, as they know too much about such matters. On the other hand, if the goal is to generate ideas for service improvement, then understanding the mechanisms of evidence-based improvement science would be an asset to the LEAP.

A further consideration is one of power. Paul Radin[15] has argued that the overall research team is heavily populated by powerful people, and therefore the small number of places on the LEAP should not be wasted by filling them with professionals who already have a voice. Rather, these places should be occupied by patients who do not otherwise have a way to be heard.

Peer Clinician

Professor Trisha Greenhalgh and Dr Liz O'Riordan have reported on the difference it has made to their work to live through breast cancer themselves, rather than just undertake research and treat patients. Similarly, Emma Sutton has reported[16] on the difference it has made to live through healthcare interventions as a patient as well as work as a physiotherapist and researcher.

While lived experience has the potential to make the clinician more empathic, this is not inevitable, as some may assume that every patient has had the same experience as themselves. If the peer clinician discloses their experience, then this may help the patient to feel understood, or it may damage the confidence that the patient has that the clinician will be available next time they are needed. That 'availability' includes both physical presence, where the clinician is at work rather than

relapsing and taking time off for health reasons; and mindfulness, as the patient needs the clinician to be emotionally and psychologically present rather than revisiting their own experience. For that matter, if the clinician's disclosure in the LEAP meeting or elsewhere became known to their patients, the tables could be turned and the patient may use the clinical interview to offer help and comfort to the worker. These hazards are exacerbated where either party expect the clinician to be a faceless technician rather an someone with whom they share a common humanity.

Managing conflicts of interest

In organisational governance, it has long been recognised that Trustees or Board members may find themselves in a situation where they have a conflict of interest. The usual way to address these matters consists of a combination of the following components:

- A clear ethical position, set out in writing, that specifies what these influences may be and that promotes a culture of freedom from undue influence upon decision-making. This is usually set out in a policy that meets legal obligations in respect of bribery and corruption as well as organisational rules regarding gifts and hospitality. Unfortunately, researchers are not always sufficiently aware of these issues for their own practice[17] and can be guilty of self-deception[18], so cannot be relied upon to carry the ethical burden for Public Contributors.
- An obligation laid on all participants to be diligent in recognising and acknowledging any conflict of interest that may arise from time to time.
- A recruitment policy that balances the need to engage the right people with the need to exclude persons who are unfit to serve due to a profound conflict of interest[19].
- An opportunity to declare any conflict of interest that is relevant to a particular discussion.
- A register which records any conflicts of interest that are declared from time to time.
- Permission to withdraw from a particular discussion or resign entirely, should a conflict of interest overwhelm the person's capacity to add value and be seen as independent.

Arrangements should be proportionate to the threat, fair to all, transparent and open to scrutiny, and accountable, so that implementation arrangements can be challenged. It would appear that the discussion about conflicts of interest in public involvement in research has not yet adopted this approach and largely confines itself to discussions of unsuitability, rather than positive recognition and mitigating action. More needs to be done.

Conclusion

Care is needed to navigate the ethics of these arrangements, but it can be done by clearly identifying potential benefits and harm and ensuring that these risk factors are clearly evaluated and reported.

What is the status of this paper?

Most of the documents we read are finished pieces of work, carefully crafted and edited in private before being shared with anyone else. This is a different kind of paper – it was shared online here from the first day, when the initial handful of ideas were incomplete, poorly phrased and tactless. I hope that the work will be edited many times, and on each occasion a revised version will replace the earlier material online. This process has hardly yet begun and so this paper may still be lacking

crucial concepts, evidence, structure and grammar[20]. As readers continue to provide feedback[21], further insights will be used to update it, so please contact peter.bates@ndti.org.uk with your contributions[22].

It is one of a suite of documents that try to open up debate about how to empower disabled people and share decision-making in health and social care services – in research, implementation and evaluation.

This way of writing is risky, as it opens opportunities to those who may misunderstand, mistake the stopping points on the journey for the destination, and misuse or distort the material. This way of writing requires courage, as an early version can damage the reputation of the author or any of its contributors. At least, it can harm those who insist on showing only their 'best side' to the camera, who want others to believe that their insights appear fully formed, complete and beautiful in their simplicity. It can harm those who are gagged by their employer or the workplace culture, lest they say something in a discussion that is not the agreed party line. It can harm those who want to profit from their writing, either financially or by having their material accepted by academic journals.

In contrast, this way of writing can engage people who are not invited to a meeting or asked for their view until the power holders have agreed on the 'right message'. It can draw in unexpected perspectives, stimulate debate and crowdsource wisdom. It can provide free, leading edge resources.

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[1] Institute of Medicine (US) Committee on Conflict of Interest in Medical Research, Education, and Practice; Lo B, Field MJ (eds) (2009). *Conflict of Interest in Medical Research, Education, and Practice.* Washington (DC): National Academies Press (US). Available at https://www.ncbi.nlm.nih.gov/books/NBK22926/#a2001902bddd00014

[2] Friedberg, M., B. Saffran, et al. (1999). "Evaluation of Conflict of Interest in Economic Analyses of New Drugs Used in Oncology." *JAMA* 282(15): 1453-1457.

[3] See NHS Improvement (2017) *NHS England Patient and Public Voice Partners Policy* Section 13, page 26. Available at https://www.england.nhs.uk/wp-content/uploads/2017/08/patient-and-public-voice-partners-policy-july-2017.pdf

[4] Kass NE, Myers R, Fuchs EJ, Carson KA, Flexner C. (2007) Balancing justice and autonomy in clinical research with healthy volunteers. *Clinical Pharmacology & Therapeutics*; 82:219–227.

[5] See https://www.hra.nhs.uk/about-us/committees-and-services/the-over-volunteering-prevention-system/. This is used for Phase 1 studies, which test new drugs on healthy volunteers. As there is no therapeutic benefit to these citizens they are at risk if the drug has unintended consequences, and payments are made to these volunteers for their participation, extra safeguards need to be set in place, as represented by TOPS. Participation in other kinds of health and social care research is regulated through Ethics Committees, recommendations by the patient's doctor, robust patient information and the process of gaining informed consent. There is no fixed washout time, as this depends upon how the drug is metabolised, so TOPS record the date of the last dose and the follow up appointment to ensure that a new trial does not start until these dates are past.

[6] Vale, C.L., Cragg, W.J., Cromarty, B. *et al.* (2018) When participants get involved: reconsidering patient and public involvement in clinical trials at the MRC Clinical Trials Unit at UCL. *Trials* **19,** 95. doi:10.1186/s13063-018-2471-4.

[7] See http://www.invo.org.uk/find-out-more/what-is-public-involvement-in-research/.

[8] See https://www.nihr.ac.uk/documents/research-governance-guidelines/12154

[9] See https://www.nihr.ac.uk/documents/research-governance-guidelines/12154

[10] Steffens, M.S., Dunn, A.G., Wiley, K.E. *et al.* How organisations promoting vaccination respond to misinformation on social media: a qualitative investigation. *BMC Public Health* **19,** 1348 (2019) doi:10.1186/s12889-019-7659-3.

[11] See Johansson V. From Subjects to Experts - On the Current Transition of Patient Participation In Research. The American Journal of Bioethics. 2014;14(6):29-31. Also Lough S. Need to define patient engagement in research. CMAJ. 2015;187(12):385-6. Also Ocloo J, Matthews R. From tokenism to empowerment: progressing patient and public involvement in healthcare improvement. BMJ Quality & Safety. 2016;25(8):626-32.

[12] See How to take your lived experience to work.

[13] See https://www.nsun.org.uk/blog/the-inconvenient-complications-of-peer-support

[14] https://blogs.bmj.com/bmj/2019/10/29/emma-sutton-the-problem-of-too-many-hats-involving-clinician-patients-in-ppi/?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+bmj%2Fblogs+%28Latest+BMJ+blogs%29&g=w_bmj-com

[15] Personal communication, 2018.

[16] https://blogs.bmj.com/bmj/2019/10/29/emma-sutton-the-problem-of-too-many-hats-involving-clinician-patients-in-ppi/?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+bmj%2Fblogs+%28Latest+BMJ+blogs%29&g=w_bmj-com

[17] Zeynep G. Aytug, Hannah R. Rothstein, Mary C. Kern & Zhu Zhu (2019) Is There Social Consensus Regarding Researcher Conflicts of Interest?, *Ethics & Behavior*, 29:2, 101-140, DOI:10.1080/10508422.2017.1402683.

[18] Boyd EA, Cho MK, et al. (2003). "Financial Conflict-of-Interest Policies in Clinical Research: Issues for Clinical Investigators." *Acad Med* 78(8): 769-774.

[19] NHS Improvement has prepared a role description for the Patient and Public Voice members of its National Patient Safety Alert Committee. This role description requires PPV candidates to declare any conflict of interest, but the document itself does not provide any guidance on what a conflict of interest might consist of and what would be done should it arise. See https://www.thurrockccg.nhs.uk/your-health/information-leaflets/information-leaflets-2018/4469-patient-and-public-voice-representative-role-description/file

[20] As a result, the author assumes no responsibility or liability for any errors or omissions in the content of this paper. The information contained is provided on an “as is” basis with no guarantees of completeness, accuracy, usefulness or timeliness.

[21] Contributions and challenges to elements of this discussion have been kindly offered by the following people, who bear no responsibility whatsoever for the contents of this paper – Abe Schwab, Harsh Suri.. The following people have been invited to comment: Tom Latten, Joseph B. Zwischenberger. An old but useful annotated bibliography can be found at https://ori.hhs.gov/education/products/ucla/chapter4/Chapter4.pdf.

[22] This document was begun on 3 November 2019. Undated or early versions should be replaced with the most recent, available here.