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The ethics of Patient and Public Involvement across the research process: Towards partnership with people with aphasia.

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The ethics of Patient and Public Involvement across the research process: Towards partnership with people with aphasia.

Abstract

Background: Conducting *Patient and Public Involvement* (PPI) in health research is a way of building knowledge that incorporates the experience of service users, adds research impact, and helps avoid wasting resources on findings that have little relevance to people or cannot be implemented. We argue there is a need to extend ethical considerations currently focused on research *participants* with aphasia to encompass and guide expectations of *involvement in partnerships* with people with aphasia across the research lifecycle.

Method: We use the 2018 revision of the Australian *National Statement on Ethical Conduct in Human Research* (2007) as the framework for this article. The *National Statement* is underpinned by values based on respect for human beings, research merit and integrity, justice, and beneficence. While it outlines the ethical standards for conducting human research with research participants in Australia, the ideas and principles within it draw on international norms. Building on the seven elements of the research process introduced in Chapter 3 of the *National Statement*, we develop a model for examining ethics and PPI across the research lifecycle. This model revolves around an extra phase, Element Zero, required for the preparation of PPI for both researchers and research partners with aphasia.

Results: There are many ethical considerations when involving patients and members of the public across the research lifecycle. Ethical questions that arise in relation to patients and the public as *partners* (whether in a role of consultant, advisor, collaborator or within user-controlled projects) may differ from those associated with *participants*. The nature of the relationships built through the process of PPI requires a clear extension of the remit for

research ethics to encompass ethical reflection both before the design of a project and after a project has ended as represented by the *Ethics and PPI Research Lifecycle Model*.

Conclusion: The role of people with aphasia as *partners* in research recognises their expertise and potential to improve the relevance and impact of research endeavours.

Reflecting on the ethical implications of this is crucial, protecting, empowering and enabling both researchers and partners with aphasia to engage with each other through respectful and positive research relationships.

Key Words: aphasia, ethics, research, involvement, engagement.

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Introduction

Research ethics in human research traditionally focuses on the relationship between researchers and research participants, particularly on protecting participant rights, and ensuring that they are treated properly. Judgements of what is good or morally appropriate are often based on a conventional set of ethical principles (Beauchamp & Childress, 2019) as outlined in the Belmont Report (1979): respect for autonomy (self-determination), beneficence (doing good), non-maleficence (avoiding harm), and justice (fairness). These are used to frame the ethics of the research interaction and its immediate aftermath. There are a range of other approaches such as deontology (following moral laws or universal rules), teleological or consequentialist ethics, casuistry (case based ethics), those grounded in feminism and the ethics of care, or virtue-based, indigenous, post-modern or postcolonial notions of ethics (Israel, 2015). Research ethics encompasses the practices and judgements involved across the research process and includes the bureaucratic systems that regulate them (Sieber & Tolich, 2013). Many countries have national ethics guidelines, statements or codes to guide researchers from some or all disciplines as well as national, regional, local, specialist and institutional ethics committees who review individual ethics applications. Different countries use various terms to refer to local ethics review bodies – for example, Institutional Review Boards (IRBs) (United States), Research Ethics Boards (Canada), and Human Research Ethics Committees (Australia). We use the term research ethics committees to cover the collective group.

In this article, we explore how accepted ethics guidelines, directed to protecting the rights of participants, might apply to people with aphasia in research beyond their role as participants. This role could be consultative, advisory, as a collaborator, or where studies are

user-controlled. In this Special Issue, Isaksen et al. (in press) discuss the different levels of involvement that people with aphasia have had within the research process, and further examples can be found elsewhere in this volume. We suggest that Patient and Public Involvement (PPI) challenges current ethics frameworks in two respects. First, PPI extends the remit for research ethics in both directions: raising ethical questions early, even before the design of a project; and having effects on the public long after a project has ended. Second, during this extended period, the ethical questions and choices that arise in relation to patients and the public as *partners* in a study (we are using the term *partner* throughout this paper to encompass all roles and levels of involvement) may vary from those associated with individuals who are *participants*. The distinction between research participants (those who are recruited to a study to contribute data) and research partners (those who are part of the research team in some capacity or are involved at some level to inform the research, for example, the design, process, reporting or research translation) is an important one (Pandya-Wood, Barron & Elliot, 2017). As we note later, people can change roles within a study and when they do so, there may be different ethical obligations. This article therefore justifies both a lengthening and a deepening of consideration of research ethics when planning for, or conducting, PPI and offers a model for examining ethics and PPI across the research lifecycle.

Conducting health research *with* patients and members of the public is a way of building knowledge that incorporates their unique experiential perspective. This approach can ensure that the research is meaningful to end users, is targeting their most important research questions, uses research designs and procedures that are acceptable, and positively influences implementation, uptake and impact of the research (Phipps et al., 2016). As such, there are moral and ethical reasons for adopting PPI in research; for example, that patients or the public have a legitimate expectation that they should be able to influence the development of

services on which they depend. Theoretical developments in the ethics of disability (Barnes, 2009; Oliver, 1992; Zarb, 1992) highlight that involvement empowers those who may be marginalised or silenced by their disabilities or situations (Ocloo & Matthews, 2016). These notions challenge researchers to transgress traditional boundaries delimiting how people with disabilities such as aphasia are involved in research. PPI also helps avoid wasting resources on findings that have little relevance to people or cannot be implemented (Greenhalgh et al., 2016). As such, engaging with PPI is a way of making research more ethical (Health Research Authority/INVOLVE, 2016), relevant, useful and beneficial, helping to define what is acceptable to participants, improving their experience of research participation, enhancing the process of informed consent, and the dissemination of findings (Ives et al., 2013). Adopting PPI highlights a focus on justice – both *procedural*, in relation to fair treatment during the research, and *distributive*, in terms of fair allocation of the benefits and possible burdens of research.

PPI is increasingly expected and is, in some countries, a bureaucratic prerequisite for research to occur at all. For example, within the United Kingdom (UK) evidence of PPI is either essential (National Institute for Health Research (NIHR)) or advantageous (The Stroke Association) for grant applications for funding of contemporary health research. However, other countries, for example, low- and middle-income countries, may not expect PPI as a requirement for research funding. Cook et al. (2019) found that while there are examples of PPI in these countries, the terminology used for involvement varies greatly, and few details are reported in publications. They suggested that research funders and journal publishers should make PPI an explicit requirement to increase its adoption. Clearly, there are implications for researchers who cannot demonstrate PPI but wish to publish in a journal such as the *British Medical Journal Open*, which requires authors to report on PPI in any

submitted manuscripts.¹ As a reflection of prioritising PPI, the NIHR has established an advisory body, INVOLVE, to support public involvement in National Health Service (NHS), public health and social care research in the United Kingdom. Similarly, in Australia, the National Health and Medical Research Council (NHMRC) and the Consumer Health Forum of Australia have developed the *Statement on Consumer and Community Involvement in Health and Medical Research* (2016). This document commits these bodies to building greater research literacy and the capacity of consumers to help achieve quality, relevance and greater public confidence in research, as well as better translation of research to improve health outcomes.²

In this article, we explore the relationship between PPI and ethics, an issue which is relatively new to ethics review:

...most of the ethical questions that IRBs are asked to adjudicate are directed at safeguarding individual participants and evaluating the ethics of what they will be asked to do in the proposed research... The focus is on ensuring anonymity and confidentiality. Partnership ethics raises a different set of questions: What happens when a whole community is the focus of research, when community researchers may be collecting data about people with whom they are familiar, or on questions of the ethics of who owns the data and how the data will be used? (Silka, 2009, p.346)

Our focus is on exploring the additional ethical considerations when working with partners who have aphasia, an acquired language disorder following brain injury, such as from stroke. Loss of language skills is highly variable but can impact on comprehension of what is said by others, the ability to express oneself, as well as reading, writing and numeracy (Papathanasiou & Coppens, 2017). While aphasia does not in itself impact on intelligence or capacity to inform decision-making, stroke or brain injury may result in a range of co-morbidities such as physical, visual, cognitive or executive function changes. Nevertheless, people with aphasia can and do contribute positively to research, bringing their lived

¹ https://bmjopen.bmj.com/pages/authors/#reporting_patient_and_public_involvement_in_research

² Unfortunately, this is no longer referred to in the 2018 version of the *Australian Code for the Responsible Conduct of Research* (see Allen & Ehrlich, 2019).

experience and expertise in order to deliver the beneficial aspects of PPI identified by INVOLVE to research. People with aphasia have been involved in the design and direction of research studies (Herbert et al., 2019; Hinckley et al., 2014; Kearns et al., 2020; Mc Menamin et al., 2018; Pound et al., 2011). Researchers and organisations have developed guidelines to support the application of PPI in aphasia research (Swinburn et al., 2007), and have called for closer working relationships between researchers, clinicians and people with aphasia (Shrubsole et al., 2019). Simmons-Mackie et al. (2020) outlined the need for an international, coordinated research agenda that embeds partnership or co-design so that aphasia awareness campaigns, essential to improving living with aphasia, are devised and driven with people with aphasia. Moreover, achieving meaningful *Knowledge Transfer and Exchange* (KTE) needs to include people with aphasia as well as service providers in the co-creation of knowledge (Kagan et al., 2010).

The ethical issues raised in this article move beyond viewing people with aphasia as *participants* and considers their role as *partners* in research. What are the risks and benefits for them in these roles? Parallels can be drawn from the more frequent discussions in the aphasiology literature focused on adaptations required to enable people with aphasia to be participants: developing accessible information and consent forms (Braunack-Mayer & Hersh, 2001; Jayes & Palmer, 2014; Kagan & Kimelman, 1995; Penn et al., 2009); minimising fatigue or reducing load on memory (Pearl & Cruice, 2017); and developing communicatively accessible resources (Pearl & Cruice, 2017). As partners, people with aphasia still need to agree or consent to the demands of their involvement and may require adapted schedules and accessible resources and materials. How are these considered by researchers, particularly those lacking experience working with people with aphasia or making materials and processes accessible? How is the time needed to adapt research

designs, procedures and materials allocated in workloads, and how is inclusive practice incentivised and regulated?

These considerations are important because aphasia may otherwise prevent involvement in PPI just as it has so often contributed to exclusion from research participation due to assumptions that people with aphasia lack capacity to consent (Braunack-Mayer & Hersh, 2001) or that participation lies beyond their capability (Brady et al., 2013; Hersh, 2014; Hersh et al., 2018; Jayes & Palmer, 2014; Townend et al., 2007). These misconceptions are often perpetuated such that people with more severe or complex difficulties face greater exclusion. Many healthcare professionals report that they find mental capacity assessments with people with communication difficulties challenging (Borrett & Gould, 2020) and would benefit from additional support (Jayes et al., 2017). People with aphasia may be deemed 'vulnerable' by law in some countries which may inadvertently add to the barriers to involvement which they already face. Compounded, these issues act to exclude people with aphasia from involvement in research. Not only can such exclusion skew the findings of research studies, but it also perpetuates the situation where those with high and complex needs have a poorer evidence base (Brady et al., 2013) and are denied their basic human right to have their voices heard (Hersh, 2018; Taylor & Balandin, 2020). Exclusion of people with aphasia as research participants arguably reinforces or perpetuates their potential exclusion as research partners.

While researchers recognise the value of ethics to guide them (Gillam & Guillemin, 2018), ethical regulations on how research is conducted (protection of participants, consent procedures, participant rights, confidentiality, data storage, and so on) are often viewed as a stage, where practical concerns dominate managing the bureaucracy of ethics review and of gaining ethics approval before any actual research can begin (Israel, 2015). We suggest the shift towards acceptance and expectation of PPI in aphasia research demands that ethical

practice is not simply a stage but rather an orientation across the research process, permeating research practice, and starting well before the formal ethics process begins. We argue there is a need to extend ethical considerations currently limited to research *participants* with aphasia to encompass and guide expectations of *involvement in partnerships* with people with aphasia, so enabling both participation and partnership, and considering the methodologies to which this might apply.

Embedding PPI across the research cycle

Writing about *partnership ethics*, Silka (2009) suggested looking at predictable points in a research cycle where ethical issues might arise. For example, at the start there may be difficult negotiations about the research direction. Midway, there might be discussions about implementation and interpretation of data. Towards the end, there may be issues of data ownership, and dissemination. She wrote:

...even as research partnerships become a means for addressing past ethical problems resulting from unequal distributions of power, this partnership approach also raises new ethical issues and challenges. (Silka, 2009, p.350)

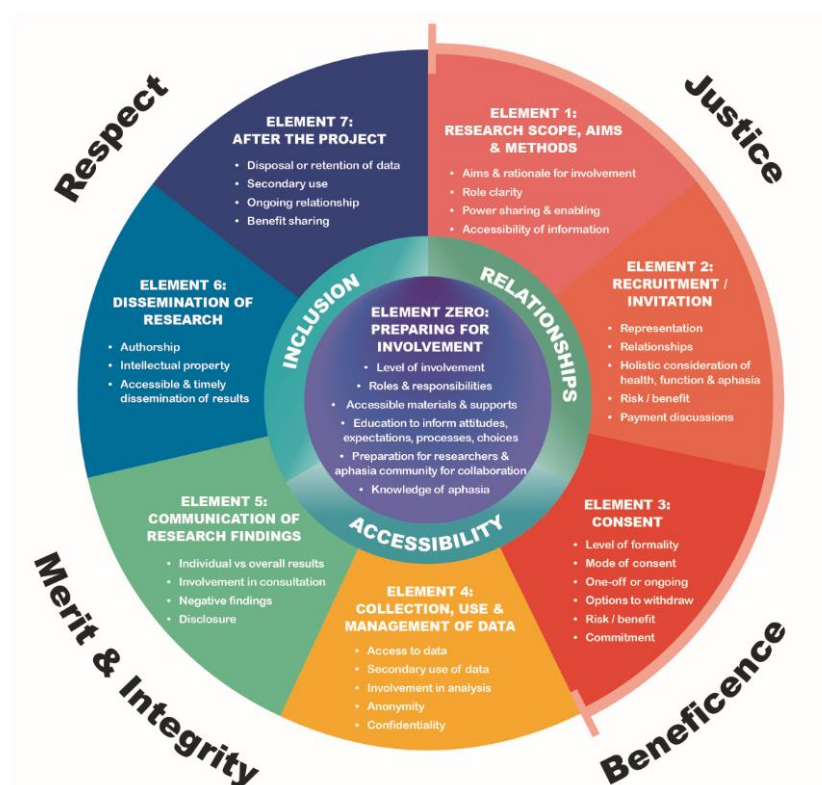
We have drawn on Silka's use of the research cycle to frame ethical considerations in order to discuss PPI in aphasia. In doing so, as a guide for this paper, we adopt the more detailed research lifecycle introduced in the 2018 revision of the Australian *National Statement on Ethical Conduct in Human Research* (2007). While the National Statement outlines the ethical standards for conducting human research in Australia, some of the ideas and principles within it are applicable internationally. The seven *elements*, or stages in the research lifecycle, in Chapter 3 of the National Statement are:

- Element 1: Research Scope, Aims, Themes, Questions and Methods
- Element 2: Recruitment
- Element 3: Consent
- Element 4: Collection, Use and Management of Data and Information
- Element 5: Communication of Research Findings or Results to Participants

- Element 6: Dissemination of Research Outputs and Outcomes
- Element 7: After the Project

We use these elements to extend thinking about the ethics of research involving people with aphasia beyond their role as *participants* in order to consider their involvement as *partners* across the research lifecycle. We propose expanding the National Statement framework by including an additional element, ‘Element Zero’, which underpins PPI and prepares both researchers and individual partners (and their communities) for the research relationship. This may be particularly important in the context of aphasia where language issues for partners complicate communication and information exchange. In Figure 1, we illustrate how we have adapted this framework, both in length and depth, to make it applicable to PPI with people with aphasia in research. The *Ethics and PPI Research Lifecycle Model* will help to structure the rest of this article where we explore ethical considerations across the research lifecycle.

Figure 1: Ethics and PPI Research Lifecycle Model



Element Zero: Preparing for PPI

There are good reasons to take a step back to include an 'Element Zero' because PPI raises ethical implications depending on existing expectations, attitudes and motivations and it challenges traditional expectations of research relationships. In Figure 1, Element Zero takes a central position influencing each of the other seven elements of the research cycle. It involves educational and attitudinal preparation for both researchers and people with aphasia to work together. It enables a perspective that people with aphasia are competent adults and have the capacity to contribute actively to the research process, and highlights groundwork required to allow PPI to occur successfully in the context of aphasia. Until recently, despite PPI being a policy requirement and expectation, limited detail about the practices or impact of PPI has been reported in research documents and articles (Mathie et al., 2014). Little work has been done to find out how researchers feel about moving to a different way of working or what their understanding of PPI might be. Boylan et al. (2019) commented: "The privileging of scientific expertise over lay experience has been remarkably resilient, and it has been noted that researchers are reluctant to cede control over research" (p.722). They warned that sceptical researchers unconvinced about the benefits of PPI will adopt it superficially "reinforcing their belief that it makes little difference" (p.722). Tokenism risks causing harm (for example by wasting people's time and effort) and runs counter to notions of integrity and respect. Tembo et al. (2019) found a continuum of implementation in PPI from "ineffectual tokenism to meaningful co-creation of knowledge" (p.6). They concluded that while it was not uncommon for researchers to ask patients for their views about priorities for projects, this rarely extended beyond the initial questioning, with lack of clarity about how to translate this work into shared decisions, and limited awareness of how practices, systems and cultures contributed to meaningful inclusion. Similarly, Price et al. (2018) conducted an overview of systematic reviews of PPI in clinical trials design. They found PPI was used mainly in setting

agendas, and as part of advisory or steering committees, ethics review, protocol development, piloting, and some evidence of PPI in dissemination. However, they discovered little involvement in data collection, analysis, or manuscript authoring. Boylan and colleagues (2019) interviewed 36 health researchers in the UK about their experiences of PPI and found a complex mix of ambivalence, cynicism and enthusiasm. Some researchers felt their expertise was threatened by the process, some that PPI was appropriate to qualitative studies with a focus on lived experience, but not those of a more quantitative nature. The attitude of research leaders was important, either creating an environment where PPI was expected or, alternatively, making researchers feel that pursuing PPI was “going against the tide and damaging their careers” (Boylan et al., 2019, p. 728). These studies suggest more groundwork is required to prepare researchers to understand and take full advantage of PPI.

De Wit et al. (2018) highlighted that preparation to enable patients or the public to be involved in research has received some attention (for example, through the European Union training course for patients interested in involvement in medicines research (<https://eupati.eu/>; Klingmann et al., 2018) or training run through INVOLVE (<http://www.invo.org.uk/>)) but they suggested that less has been written regarding researcher training in the area. Therefore, de Wit et al. (2018) developed a programme of PPI coaching which ran in the Netherlands over 18 months offering a range of Masterclass sessions, individual assignments, group coaching sessions and individual coaching sessions as requested. Using action research, they encouraged “a critical though supportive attitude towards PPI” (p.753), the skills to implement it, and the establishment of a PPI community of practice. Another example of a tool to prepare for PPI and support the process is the Involvement Matrix co-created by Smits et al. (2020) with stakeholders. This tool was designed to support discussion between researchers and partners about roles of involvement across different phases of a project and, in doing so, foster sustainable research partnerships.

Greenhalgh and colleagues (2019), through their systematic review, summarise the numerous frameworks for PPI in research which include those to help prepare for and support it. They found 65 frameworks, including 17 that they classed as having a focus on partnership which entailed transparency, accountability, power-sharing arrangements, good communication, training and capacity-building. Greenhalgh et al. (2019) concluded that a “one-size-fits-all” approach was unhelpful in supporting PPI. While they suggested researchers should explore existing frameworks, they said they should be prepared to adapt them to suit a particular project or develop a tailored framework.

Specific training and opportunities to explore attitudes to PPI, as well as practical issues of implementation, are therefore important. As Silka (2009) noted, partnerships in research involve shared decisions and extend over time, and advice to simply ‘share decisions’ is not always easily applicable to situations where researchers are working with lay consumers.

Therefore, we view Element Zero as important preparation for both researchers and potential partners, and notably, as illustrated in Figure 1, *relationships*, *accessibility* and *inclusion* are wrapped around it. Research teams need to reflect in detail on their model of PPI and the nature of the roles within it. They could consider levels of involvement; whether their research benefits from *consultation* (asking for views and opinions, perhaps at a particular stage in the research), *collaboration* (working together as co-researchers more deeply embedded in the project over time), or a *user-controlled* approach (where a community sets an agenda and also enrolls researchers to work with it) (Harrison & Palmer, 2015; Health Research Authority/INVOLVE, 2016; Ocloo & Matthews, 2016). Potential roles and responsibilities in any collaborative engagement need to be clear (Isaksen et al., in press; Shiggins et al., in press) avoiding discrepancies in PPI terminology, or misinterpretations of involvement. Even consciously considering the implied meanings

behind words like *patients*, *participants* and *partners* is important. For example, the word *patient* still denotes compliance and passive acceptance of care (in the same way that research *subject* might) (Hersh, 2014; McLaughlin, 2009), which can cause confusion about the expectations of a patient's potential role in research. Liabo et al. (2018) used a different typology with *engagement* (for example, raising awareness), *participation* (contribution of data to a project) and *involvement* (being more actively involved in a project or research organisation). They distinguished between patients as participants in a research study who contribute data, and patients as active partners included in the full research process – design, conduct, analysis and reporting:

Failure to clarify roles early on risks stigmatising and alienating the people who make all medical research possible. Providers of data and active partners are both crucial to health research, and conflating the two is counterproductive to ethical, valid, and patient focused research (Liabo et al., 2018, p.1).

While this distinction is useful, there can still be grey areas across different research methodologies (Price et al., 2018; Salway et al., 2015) with the need to explore why stakeholders wish to engage with research and whether their expectations may be met. For example, in health research, partners or co-designers sometimes seek to benefit therapeutically from involvement in PPI (Ives et al., 2013), which may not be the intended outcome or a realistic result of their partnership in the research process (Ives et al., 2013). It may be reasonable for *participants* to have preferential access to the benefits of a study as part of an approach to risks and potential benefits based on distributive justice (Beauchamp and Childress, 2019; Hugman et al., 2011), but if this extends to *partners* such as community advisory groups, this might compromise any advice they could give. By agreeing aims clearly at the beginning of the process, roles can be clarified along with responsibilities, decisions, rights and stakeholder expectations (Mc Menamin et al., in press). These considerations are all needed to avoid tokenism or the risk of including people superficially who are then not fully supported and may experience more harm than benefit from PPI.

Element Zero includes the notion of preparing people with aphasia for PPI either individually or through community aphasia groups or aphasia organisations. This work gives people confidence to act as representatives and advocates on projects (Mc Menamin et al., 2018; Mc Menamin & Pound, 2019). Empowering people to have a say and being prepared to take partnership roles in research respects their autonomy and human right to have a positive impact on service provision and life quality. When research is conducted on this basis it might contribute to a broader political agenda of 'decolonising methodologies' (Smith, 2012), a stimulus for critiquing how dominant cultures shape what and who are deemed worthy of research and funding, what knowledges are privileged, what relationships between researcher and researched are acceptable, and to whom researchers and their institutions should be accountable. While Smith, like others (AIATSIS, 2020), use the concept of decolonisation to enable indigenous peoples to assert control over ways of knowing and being, the decolonising project is also part of global disability studies (Connell, 2011). Indeed, at the intersection, it has been initiated in disability research (Gilroy et al., 2018) and aphasia research in partnership with indigenous communities (Brewer et al., 2019; Penn et al., 2017) in accordance with the expectations of some national guidelines (Tri-Council Policy Statement, 2018 in Canada; National Statement (NHMRC, 2007, updated 2018) in Australia). Aphasia researchers have used empowering and emancipatory approaches to involve and accommodate people with aphasia (including those with higher levels of severity) in different roles in research partnerships (Mc Menamin & Pound, 2019; Swinburn et al., 2007).

Element Zero supports merit and integrity, a genuine rationale for using PPI rather than simply to satisfy future funders or research ethics committees. It gives attention to the need for research teams to discuss expectations, attitudes, benefits and challenges in relation to PPI and choices within potential research studies. Keenan et al. (2019) found PPI was better embedded in projects where researchers understood its potential: the promotion of a

democratic process; increased accountability and research transparency, and an enhanced opportunity to learn from patients and the public about their use and their opinions of healthcare (Department of Health, 2006; ~~World Health Organization, 1978~~). Conducting PPI in a meaningful way can be time consuming, particularly when working with people with aphasia (Cruice et al., in press; Shiggins et al., in press) and, therefore, researchers must believe the benefits of PPI are worth investing the extra time needed (Mathie et al., 2014; Shiggins et al. in press). Mathie et al. (2014) reported researchers also found it hard to know how to invite people who were able to represent other service users and, of relevance to aphasia research, how to communicate with and make their research accessible for lay people. We suggest researchers should engage with the PPI literature and reflect on their own attitudes towards PPI and motivations for conducting it. This should occur in the early stages of developing ideas about research projects related to aphasia, prior to applications for funding. Discussions need to extend to attitudes towards involving people with aphasia, and how they might contribute, particularly for researchers who are not aphasia clinicians, or who do not have experience with people with aphasia or supported communication (Pearl & Cruice, 2017; Swinburn et al., 2007). Reflection on attitudes about aphasia itself are crucial. If, for example, aphasia is viewed as a disorder of *masked competence* (Kagan, 1998) then researchers need to use conversation supports that reveal competence. This implies that at least some team members must have the skills to use supported conversation and to adapt processes and documents to an aphasia-friendly format (Rose et al., 2011). Underpinning these efforts towards accessibility is the understanding that they permit a truly respectful research partnership, two-way learning and mutual benefit.

Element 1: Research scope, aims, themes, questions and methods

Where Element Zero underpins preparation for PPI, Element 1 addresses issues that arise once a project has been identified. It considers the aims of the chosen project and the

rationale for PPI within it, the type of involvement (consultation, collaboration or user-controlled), role clarity, notions of power-sharing and how people with aphasia can be enabled to contribute, including their access to project documentation and design. Figure 1 shows Element 1 linking closely with Elements 2 and 3. Unlike the clear stages of project planning, recruitment and consent for participants, in the context of PPI, partners to the project should be part of the design and planning of Element 1, so their invitation, understanding and agreement to involvement, means there some merging of Elements 1, 2 and 3.

Genuine PPI occurs from the very start of a research initiative, when research aims and questions are identified, issues are prioritised and funding is sought (Tembo et al., 2019). While some funding bodies, like the UK Stroke Association, emphasise preparation for PPI in the grant application stage, this process can be harder to achieve where funding bodies do not promote PPI. If a research team is submitting a grant application, is that application based on discussions with people with aphasia? If so, in that early stage, how might these partners have been prepared, invited, involved and perhaps paid for their time considering the grant application itself was still in preparation? Discussion about role is important here too – so for example, do collaborative partners' names go on the grant application where perhaps an advisor or consultant may not?

Some health researchers only involve partners (who may be patients) after they have received ethics approval for a project. In the United Kingdom, Pandya-Wood et al. (2017) expressed frustration that ethics review skipped over research preparation. This meant not only might research ethics review occur late in the process but also that little guidance was offered to researchers on the ethics of designing research in a way that might be shaped by the insights of the public. The need to attend to ethical considerations that might arise at the point of research design was noted in the recommendations of the *Going the Extra Mile*

report published by the NIHR (2015). Subsequent iterations of the national policy framework (Health Research Authority, 2020) committed the Health Research Authority and the United Kingdom Health Departments to an environment where patients, service users and the public had opportunities to be involved in the design of research, but the framework remained silent on the ethics of doing so. As a result, some researchers confuse consultation on design with data collection and either unwittingly gather data prior to research ethics review or avoid early consultation for fear that they would need ethics approval for that. The framework of ten ethical issues for the design stage of research described by Pandya-Wood et al., (2017) is very helpful here. More recently, Ní Shé et al. (2020) suggested that PPI should be grounded at the pre-commencement stage of research projects in a culture characterised by the values of respect, openness, reciprocity and flexibility in order to underpin a successful process in subsequent stages.

At this stage, many decisions need to be made about a project – for example, the scope, duration, potential sources of funding and methodological approaches. Price et al. (2018) found that PPI in clinical trials required meaningful involvement; however, patients were: “worried about inappropriate conclusions from composite outcomes but lacked opportunity to share these concerns and noted they would benefit from research methods training” (p.248). Equally, researchers worried that the research design adaptations they were making threatened their methodological rigour and focus. Price and colleagues recommended involvement at all levels early on with consistent levels of support and feedback: “The best impact was obtained where resources, preparation, training, flexibility, and time were designated for PPI and where communication channels were transparent” (p. 249). Careful negotiation may be needed with partners with aphasia because of the complexities of research design and the extra efforts required to achieve the clear, accessible communication that underpins successful PPI with people with aphasia.

Element 2: Recruitment of people with aphasia to be involved in research

When building a research team, there are considerations around who to include: the role each person will have, what experience and knowledge they bring, what part of the project they will work on, their responsibilities and expectations. PPI adds another layer to the complexities of constructing a team because there are various levels of involvement (Mathie et al., 2014; Ocloo & Matthews, 2016), different relationships, and issues such as payment for contribution which are sensitive. While we have included the term *Recruitment* for Element 2 to reflect the wording in the National Statement, we recognise that the nature of a relationship with a research partner differs from that of a participant and that partners are being *invited* to join the collaboration. However, planning invitations can be complex. There may be a lack of relevant networks through which to approach and invite partners (Price et al., 2018). The information used to invite partners also needs to be clear, informative and accessible and may require advanced knowledge about how to reach people. In addition, the timing is important because PPI requires early engagement. While research ethics committees scrutinise projects before recruitment of *participants* starts and require information about how potential participants will be identified, screened or excluded, invitations to *partners* may need to be organised prior to ethics approval. The literature on the ethics of recruitment of participants is well developed but the literature on the ethics of invitation to PPI is not.

Research involvement should rest on justice and respect. The choice of whether to be involved must be voluntary – neither coerced nor manipulated. Yet, there are difficulties reported with ethical recruitment and retention of people with disabilities (Banas et al., 2019) which are relevant to both participants and partners in health research. For example, research ethics committees might reject inclusion of people deemed to be unable to make decisions for themselves because of concerns that they will be coerced into participating. In the context of aphasia, an ethics application may then need to explain thoroughly how people with aphasia

can be supported, not only to contribute to research as participants, but also as partners. In relation to recruitment of participants, Banas et al. (2019) note that researchers are often time-poor and may over-sample convenient or easy-to-reach individuals thereby missing others. Additionally, they could lose potential participants because of transport issues, geographical distance from a site or mobility challenges; fatigue; excessive demands on time; and low literacy or access to online media recruitment information. All these concerns could equally impact on inviting research partners with aphasia, who often live with other post-stroke comorbidities, potentially experiencing all these issues as barriers to involvement.

In their survey of consumer involvement in health research, Mathie et al. (2014) found half of the partners involved in studies were already known to the researcher/clinician. Partners were invited through voluntary organisations (40%) or service user groups (35%); only 25% had replied to an open invitation (respondents could answer more than one category). To illustrate this point, Keenan et al. (2019) reported that one of the “salient actions for effective PPI” was “relationships maintained over time” (p.4) between the research team and PPI partners, so long-term relationships with strong rapport may be beneficial to the process, even enhance it. In contrast, Ocloo and Matthews (2016) raised concerns that “PPI often involves a narrow group of individuals, with the handpicking of just one or two ‘appropriate’ or ‘acquiescent’ patient representatives” (p.629). They wrote:

The consequences of narrow PPI selection processes mean that those with most to gain are most excluded from healthcare decision-making. This restricts the pool of ideas from improvement and limits the opportunity to break cycles of suboptimal care and services. (p.629)

Relationships can also be complicated when research teams recruit either participants or partners through clinicians. Larsen and McMillin (2011), paediatric speech-language pathologists, described ethical difficulties recruiting research *participants* from their client base when working closely with researchers. Clinician-researcher partnerships can result in

collaboration with research design and studies of direct relevance to clinical practice. However, Larsen and McMillin noted three areas where ethics guidelines on recruitment of *participants* required attention. The first is *therapeutic misconception*, where clients might believe that participating in a study would directly benefit them even if the consent forms state otherwise, a belief perhaps strengthened by the enthusiasm clinicians might convey when recruiting on behalf of research colleagues. The second is the *clinician-client relationship* and its potential impact on recruitment: “a client is at increased risk of implicit coercion to do what the clinician says, trusting that it will be in their best interest” (p.341). Third is *client vulnerability*, not only due to communication impairment but also when making decisions to be involved in a context of grieving, loss and hoping for a breakthrough to assist their condition. These cautions about recruiting participants have direct relevance to inviting people who are or have been patients or clients as research partners. In aphasiology, researchers often approach clinicians to help them to invite people with aphasia to be involved in research, and clinicians are likely to approach clients or previous clients they know well. While this existing rapport can contribute to the effectiveness of PPI (Keenan et al., 2019), researchers need to consider how to reach those with diverse perspectives and not overburden the same people. In the National Statement, a focus in Element 2 is on having clear inclusion and exclusion criteria for participants. In Figure 1, we have instead used *representation* to capture the issues around who becomes a partner in a research project, how they are invited, and how best to clarify their role.

Mathie et al. (2014) found that some partners came for personal benefit rather than to represent the views of others – so there may be tensions between different motivations for PPI. Harrison and Palmer (2015) noted some stroke survivors and carers reported benefits of involvement in PPI such as developing supportive relationships through the process, giving back, gaining confidence, feeling valued and intellectual stimulation. People with aphasia

have reported that being part of research helped them to feel well and provided them with opportunities for participation (Shiggins et al., 2020). These findings suggest people gain more than simply therapeutic benefit through involvement in research. Finally, there is the complex issue of payment for involvement (INVOLVE, 2010). Covering expenses, such as transport or any out-of-pockets costs, is quite separate from payment for time, skill and expertise. Both these aspects are viewed as supporting inclusion, reducing barriers to involvement, clarifying expectations and responsibilities, and furthering equity in partnerships. In the British context, INVOLVE (2010) notes a range of practical issues around payment such as whether the arrangement is for one-off payments, gifts or ongoing payments, how a rate is set, potential impacts on any government benefit payments, and whether arrangements are stated in informal agreements or formal contracts. Where people with aphasia are involved as partners, extra care is needed to ensure these complex issues are transparent, accessible and agreed.

Element 3: Consent

Informed consent is about ensuring full understanding of the implications of participating in research, agreeing voluntarily and without coercion, and being able to explicitly communicate a choice (Faden & Beauchamp, 1986). Participants should be autonomous and have the right to ask questions and withdraw at any point. We can learn from work on gaining and maintaining informed consent to *participate* in studies and examine its relevance for PPI contexts. For example, is the degree of formality different along with the mode of consent (verbal or written)? Should partners need to sign a consent form at all, particularly as this requirement would not apply to other team members, and that involvement may precede ethics approval for the study (Ives et al., 2013)? Should consent be an ongoing notion, a dynamic process of consent (Sieber & Tolich, 2013) rather than a one-off signing (Wynn & Israel, 2018), with options to withdraw through the study? This requires

researchers to check repeatedly whether participants or partners are willing to continue. Do partners understand at the start what the commitment is to involvement across a full study; do they recognise that timelines and parameters may change over the span of a study? How well can any risks or benefits be anticipated early on, for example, before funding (including payment for involvement as partners) is secured and before the design is fully established?

As is well recognised for participants, the very nature of aphasia may require considerable additional effort when negotiating complex matters (Casella and Aliotta, 2014). Kagan and Kimelman (1995), Jayes and Palmer (2014) and Braunack-Mayer and Hersh (2001) called for modification of traditional consent materials, augmenting text-based consent forms with images, as well as talking through the consent process with potential participants. Swinburn et al. (2007) also included examples of such resources. Penn et al. (2009) used an aphasia-friendly document but in addition focused on *how* participants were encouraged to ask questions throughout the recruitment interview. Those approached in their study were given time to consider whether they wanted to participate and to consult with family, friends and health professionals before reaching a decision. Nevertheless, for some people with aphasia, maintaining focus or establishing a comprehensive understanding of what participation might entail proved difficult.

These findings should alert researchers to the complexities of negotiating roles and implications for potential partners in projects, particularly when efforts are made to include those with more than mild aphasia. Commonly, in a research project, researchers seek consent from participants for an already established process; this might involve collecting specific forms of data for a defined purpose using an identified methodology. By contrast, potential PPI partners may be asked to join an initiative that does not yet have an established approach; consequently, it may be unclear what partners are being asked to do. As co-creators, they may be part of establishing the definitions and purpose of the study, and this

will vary with the range of research designs, whether qualitative or quantitative (Hannigan, 2018; Price et al., 2018). The consent process for participants could be developed with input from partners (Kane et al., 2006). Some designs may well be emergent, resulting from an iterative engagement between researchers and participants. This is often the case in community-based participant action research and some ethnography, for example, and may also be part of the broader processes of collective consent expected when working with indigenous communities (Israel, 2015; United Nations, 2007). It is therefore worth examining ways of negotiating agreement in those contexts to identify its relevance for PPI.

In summary, involving people with aphasia as partners in research requires clear information to enable informed negotiations about the nature and commitment to a project, including rolling or dynamic agreement to work together, so that people understand what they are taking on and can express voluntary choices, particularly in light of the risks of therapeutic misconception, implicit coercion and vulnerability noted earlier. They should be able to revisit their decision and end their involvement at any point (Pandya-Wood et al., 2017). Accessible information and documentation to help support comprehension and memory include supported exchanges, agendas, minutes and updates, all part of the process of ensuring voluntary and informed engagement.

Element 4: Collection, use and management of data and information

The ethics of data collection and its management by research teams encompasses access to data, anonymity, confidentiality, analysis, and ongoing use of the data. PPI raises similar issues for partners if a study involves their input at this point in the research cycle. If so, their role in data management and analysis needs to be understood early. For example, might partners with aphasia see interview transcripts or hear audio-recordings; might they be asked to comment on aggregated findings only, and how these might be presented?

Ives et al. (2013) suggest that as the “lay” perspective in PPI brings an outsider, service-user view, then formal training in contributing to the conduct of research (data analysis or management) could compromise the lay perspective so valuable in PPI. They wrote of a “professionalisation paradox”, proposing that PPI is less useful at this point in the research cycle because of the specific skills required:

The appropriate response is not to abandon PPI, but to recognise that the best place for a cooperative model is not during the conduct of research, but at the funding, reviewing and dissemination stages, for which specialist knowledge and training are not necessary and in which the democratic/cooperative ideal can be fully expressed, because at these stages genuine ‘layness’ is not a barrier to inclusion in the way that it is in the research process. (Ives et al., 2013, p. 183)

This perspective is interesting because in any team, not every co-researcher is involved in all aspects of analysis whether qualitative or quantitative (Hannigan, 2018) and this reflects the findings of Price et al. (2018) that PPI was far less frequent in “hands-on research tasks” (p.244). However, these issues need consideration and clarification early because different types of projects may be variably conducive to incorporating PPI at the analysis stage. Indeed, Staley (2013) refutes the very notion of the professionalisation paradox and argues that providing training for partners in conducting research does not diminish the value of their perspective: “When done properly, such training equips the lay person to conduct high-quality research and also prepares them to use their lay status to maximum advantage” (p.186). She cites the example of using peer interviewers in projects where partners are given specific research training in data collection.

PPI partners need to understand what their level of involvement is likely to be at the different stages of a project. There are examples of people with aphasia being successfully involved as partners at the stage of data management and analysis when their involvement is carefully built into the project design. One study used accessible co-design techniques (Wilson et al., 2015). The team created what they termed “tangible design languages”, a

range of ways of using different modalities, rather than just verbal exchanges, to make participation possible.

Confidentiality and anonymity are also significant issues at this stage in the research cycle. In most clinical studies, participants are granted anonymity and their data is kept confidential. However, this may not be appropriate for those engaged in PPI. Where people with aphasia become involved in research, they may regard it as a lack of respect for their contribution not to be acknowledged by name. Where they are involved as advisors or experts, they may have been invited into the project precisely because they already have a public profile as advocates or activists. Boyle and Lombard, co-leaders of an aphasia support group in Florida and spouses of people with aphasia, have their support group named and are listed as authors in Hinckley et al. (2014). Alternatively, there may be good reason for partners' names not to be listed, for example, where a partner shifts role by enrolling as a participant in a project. Protecting their identity as a partner may be the only way of protecting their identity as participant (Øye et al., 2019). Equally, some people may be known to clinician-researchers initially as patients and then be recruited as partners. That may increase the chance that these partners can infer the identity of participants in a study. To complicate matters, research teams may wish to avoid situations where a partner representing a community, like an aphasia group, might recognise participants from their data, or might feel conflicted by the material they view. In this case, external confidentiality may be secured but not internal confidentiality (Tolich, 2004). In other words, participants' identity might be protected from people outside but not from people within the group. In such a case, if the partner's identity were disclosed, the group and then its members might be more easily identifiable (Scheper-Hughes, 2000). Tolich recommends "taking time to learn from insiders what information is potentially damaging if read by another insider, and which information is innocuous" (2004, p. 105). He suggests using clearer notions of confidentiality to consider

both external and internal risks, which would allow more explicit discussion and reflection with partners.

Element 5: Communication of Research Findings or Results

Ethical considerations for PPI in this element include what results partners have access to, for example, individual participants' data or aggregated data only, how much they are involved in discussions about dissemination of results and whether findings are also disclosed to third parties. The National Statement points out that the provision of research findings or results to participants can be both a benefit, but also a risk, perhaps from a psychological, social or legal perspective. Similarly, partners may benefit from hearing about results but could also be distressed by them, considering they have a representative role and common experiences with participants. Working in partnership should enable ways of identifying, assessing and managing risks, and responding to potential harm. There could be sensitive and early discussions, for example, about what happens if an intervention does not work or if the findings are not what is expected. For partners with aphasia, this process would need to be supported and accessible. In addition, empowering stakeholders as partners may mean that they are more willing to assume risks as a trade-off for potential benefits that they themselves have played a role in defining.

We have moved discussion of negative findings, placed in Element 6 in the National Statement, into Element 5 because partners should be party to study results prior to dissemination of the research beyond the team. Mathie et al. (2018) found researchers often failed to let PPI partners know about the research findings including whether and how their contributions were useful to the outcomes of the research. Partners considered feedback could range from an acknowledgement of their contribution through to details about the impact of their involvement, study progress, success and outcome. Considering the importance of the relationship between researchers and those undertaking PPI, lack of feedback negatively

affected motivation for further involvement. Conversely, giving feedback and discussing results with partners made them feel appreciated and valued, and supported learning and reflection for both parties. This point demonstrates an overlap with Element 7, contributing to positive and ongoing research partnerships.

Element 6: Dissemination of Research Outputs and Outcomes

In this Element, we locate PPI in relation to authorship, intellectual property, and the accessible and timely dissemination of results. Even for those with a collaborative or user-controlled PPI role, authorship can be problematic in aphasia research because of acquired reading and writing deficits. This could mean the contribution of partners, who may have provided input to the intellectual direction of a manuscript, but not actually the drafting itself, is not always acknowledged and, in the language of publication ethics, they become ‘ghost’ authors (Rennie & Flanagan, 1994). Sometimes, this reflects traditional practice by academic researchers who assume authorship; however, sometimes attempts to be inclusive may be thwarted by ethics guidelines that are poorly attuned to the practices of PPI. This might include the notion that PPI contributors remain anonymous in projects just as a participant would. In the internationally persuasive *Singapore Statement on Research Integrity*, Wager and Kleinert (2011) stated what should be non-contestable: “authorship of research publications should... accurately reflect individuals’ contributions to the work and its reporting” (s.6.1). So, those that contributed sufficiently should be listed as authors and, where that is not appropriate, be acknowledged in another way; conversely, those who did not contribute sufficiently should not be listed.

The International Committee of Medical Journal Editors (ICMJE) developed criteria for authorship (last updated in 2019). These require four conditions must be met in order to be included as an author: “substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work”; “drafting the work or

revising it critically for important intellectual content”; “final approval of the version to be published”; “agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved” (ICMJE, 2019, p.2).

However, the ICMJE criteria have not been universally adopted and many national codes require something less than all four conditions. For instance, the 2019 guide for authorship that accompanies the Australian Code for the Responsible Conduct of Research requires authors to have “made a significant intellectual or scholarly contribution to research and its output” (National Health and Medical Research Council et al., 2019, p.1). This is interpreted as meaning one or a combination of activities that may fall short of the first two conditions in ICMJE.

The difference may be critical for community-based research partners (Castleden et al., 2010). For example, community partners in PPI may not always be involved in conceiving or designing work where researchers who have already secured funding subsequently approach a potential community partner. Again, some partners may struggle to be involved in drafting articles. Of course, there are examples where the ICMJE criteria can be met in community-based participatory aphasia research. Good illustrations of co-authorship can be found in this Special Issue (Cruice et al., in press; Horton et al., in press; Shiggins et al., in press; Mc Menamin et al., in press) as well as in Hinckley et al. (2014). Authorship has been ascribed to community disability groups acting by themselves (Scottish Dementia Working Group Research Sub-Group, 2014). In some cases, this might allow actual participants to retain anonymity while still receiving credit as partners within a collective. We have also seen a shift at academic and consumer conferences, with both poster and oral presentations led or co-presented by people with aphasia, and people with aphasia

presenting at a launch of a co-produced project (e.g. Shiggins et al., in press) or at community engagement events.

The ethics of dissemination are not limited to authorship, and academic and community-based research partners have often struggled to identify let alone tackle them. In dementia research, for example, Swaffer (2016) maintained "...the moral and ethical considerations of engaging consumers with dementia and co-production with them have been overlooked" (p.1321). Swaffer, a person with early dementia involved in research, recognised the positive shift towards PPI in that involvement of people with dementia is often required for research to go ahead at all, but she reported that this does not address the issue of intellectual or creative copyright or ownership. She noted that people with dementia report they are made to feel special by research groups but are then often dropped when the relationship is over. As a result, their contribution is inadequately recognised when results are disseminated publicly. However, she highlighted positive shifts in an article written on behalf of the Scottish Dementia Working Group Sub-Group (2014) which contains comprehensive guidelines for involving people with dementia in research.

Element 7: After the Project

While publication is conventionally viewed as the end of a research project, ethical considerations can continue to arise well beyond that point. This final element covers issues such as disposal or retention of data, secondary use of data by other researchers (Morrow et al., 2014) and misuse of results. For example, researchers and partners may need to engage in discussions about what, how, with whom and under what conditions data might be shared. It also includes sharing benefits that might flow from the research with, in this case, the aphasia community – people with aphasia as well as their families, clinicians and other stakeholders. Partners may not be aware of these issues, of where their ideas or intellectual property is stored, or used by others (Swaffer, 2016). It is important that those who have contributed to a

study are kept informed about that study, any impacts from its findings, and how its outcomes may be implemented in practice.

Ideally, research will be of public benefit. In such cases, distribution of such benefits can become a source of contention (Arnason & Schroeder, 2013). Unfortunately, as Israel and Fozdar (2019) have noted, the art of benefit-sharing can prove to be complex. First, it is not always clear what constitutes a benefit to a community. Second, communities may struggle to identify a fair way of sharing benefits. Third, some researchers may simply be unable to ensure benefits do flow to a particular community. Finally, not all stakeholders nor even all governments accept the basic premises of benefit-sharing even when formalised in international agreements and statements such as the Declaration of Helsinki (Macklin, 2004; World Medical Association, 2013). Within an aphasia context, researchers are often driven by a desire for the work to make tangible differences to people with aphasia, and PPI is one way to ensure that this occurs (Brewer et al., 2019; Cruice et al., in press; Kearns et al., 2020). There are examples where co-created research projects have resulted in new resources of direct value to people with aphasia, such as by Neate et al. (2020) for the development of CreaTable; Neate et al. (2019) for co-creating personas in the co-design process; Kearns et al. (2020) for the development of a feedback questionnaire for ICT-delivered aphasia rehabilitation; the PPI aphasia research resources created by Pearl and Cruice (2017); and papers within this Special Issue. A range of channels of communication – newsletters and websites, presentations at aphasia conferences and seminars – can be used to explain how research may benefit people with aphasia. For example, the Australian Aphasia Association creates aphasia-friendly summaries of relevant publications and makes them available to people with aphasia and their families via social media. We need to demonstrate respect for people's involvement through regular communication and engagement with communities. People with aphasia are often keen to 'give back' after their experiences in rehabilitation;

they may want to be involved with students and with research as participants or partners (Worrall et al., 2011; Shiggins et al, 2020; Horton et al., in press). Involvement in research can counter the isolation experienced after stroke with incentives to be involved as for other groups of PPI contributors (Swaffer, 2016). For this reason, and because relationships between researchers and partners are often important and longstanding, what happens after the project may be critical. Continuing and then finishing those relationships should be done sensitively, respectfully, and in a way that maintains people's feelings of being appreciated and valued rather than feeling used or exploited.

Conclusion

This article does not solve the ethics of PPI – it does not even attempt to do so. Instead, it uses the Australian National Statement to underpin our *Ethics and PPI Research Lifecycle Model* and map ethical questions across the research enterprise. We point out how research ethics guidelines, developed to protect research participants, can be used as a starting point to consider ethical issues for partners in research. Ethical considerations for partners are not the same as for participants, but to understand the former requires both a lengthening and deepening of ethical analysis across the research lifecycle. In aphasia research, we suggest careful preparation is needed for both researchers and partners, as outlined in our Element Zero and beyond. This preparation ensures accessibility where partners are fully informed throughout a project, can exercise their autonomy, share their expertise of living with aphasia to benefit others in the aphasia community, and are neither exploited nor unfairly advantaged in the distribution of resources that might flow from a project. Researchers should also maintain positive and respectful relationships with their research partners, whether consultants or collaborators, after a project is finished.

PPI should be an ethical and political project. At its heart, it should be contributing to the shift in research agendas, methodologies and relationships from work *on* to work *with, for*

and *by* people with aphasia (INVOLVE, n.d.). PPI could stand with community-based participatory action research and decolonising methodologies in challenging the gaze of conventional researchers and supporting them to consider new opportunities to build PPI into their research plans. It can also reshape the politics and ethics of aphasiology's relationship with its consumers, clients, patients and communities. As Mathie and her colleagues (2014) emphasise, how an area engages in PPI may actually reflect how we engage more generally; PPI may be "a proxy measure of disciplines' commitment to public understanding, patient engagement and involvement in decision making" (p.42). In other words, the commitment to getting relationships right for PPI may then mirror how well we are applying principles such as respect, inclusion, and accessibility, not only with research participants, but also across related clinical, professional development or policy domains.

In aphasiology, we suggest there is a desire to re-evaluate research relationships and build on the momentum where people with aphasia have shifted from subjects to participants and then to partners in research (Hersh, 2014). This recognises their expertise and potential to improve the relevance and impact of research endeavours. Reflecting on the ethical implications of this, in the complex context of communication disability, is helpful for research ethics committees and funding bodies, and crucial for protecting, empowering and enabling both researchers and partners with aphasia to engage with each other through respectful and positive research relationships.

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