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Patient and public involvement in NIHR research 2006-2019: policy intentions, progress and themes

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Plain English summary

This report explores the development of NIHR's policy for involving patients and the public in health research. The report was commissioned because NIHR wished to know more about the impact of its patient and public involvement (PPI) policy, and in order to assess impact, a first step was to better understand policy intentions and how these intentions have been interpreted since NIHR was established in 2006.

We undertook interviews with key people involved in policy development at NIHR, and reviewed NIHR policy and strategy documents. We also reviewed published literature on the topic of PPI in health research, and the database produced by healthtalk.org on people's experiences of PPI.

We analysed the data we collected from these sources, identifying six key themes:

1. The NIHR's policy on PPI encompasses many different purposes and goals. For some the key purpose of PPI is to improve the quality of research; for others the primary concern is public involvement as a democratic right.
2. There is much emphasis on what we refer to as the 'hardware' of PPI; in other words, the structures and mechanisms for involving patients and the public in research, such as training workshops and PPI facilitator posts. There has been less emphasis on the equally important 'softer' aspects of PPI to do with changing people's value systems and organisational culture, although there is some evidence that this has begun to change.
3. There is some, but limited, evidence on the impact of PPI policies in research settings.
4. An ongoing need exists to recognise and address issues of power between the scientific community and the public.
5. The potential 'dis-benefits' of involvement have tended to be overlooked and under-reported.
6. Tokenism and difficulties of representativeness are widely-recognised problems in PPI policy and practice.

Our findings suggest that there are no straightforward answers to questions about the early intentions of NIHR PPI policy and how they have developed over time. Rather, our report highlights the complexity of involving patients and the public in research, and provides a starting point for opening up thinking about the assessment of NIHR's PPI policy in its next phase of development.

Executive summary

This report takes a historical look at the National Institute for Health Research (NIHR) patient and public involvement (PPI) policy, exploring early policy intentions, and discernible shifts over the past 12 years. It was commissioned by the Impact Team at NIHR Central Commissioning Facility (CCF) with the purpose of establishing a baseline for future in-depth work on the impact of NIHR's PPI policy.

The report presents an interpretive policy analysis of NIHR policy and strategy documents, published literature, the healthtalk.org database of people's experiences of involvement in health research, and interviews with key informants. It identifies six overarching narratives to emerge from NIHR PPI policy as it has developed since 2006: [1] the diversity of purposes and goals of PPI policy, [2] the need to balance the emphasis on the 'hardware' of PPI (the structures and mechanisms) with a focus on the 'software' of underpinning values and cultural aspects of PPI, [3] the ongoing search for better evidence of the impact of PPI, [4] negotiation of the power dynamic between researchers and the public, [5] the potential dis-benefits of involvement, and [6] the persistence of concerns about tokenism and representativeness.

These narratives highlight the richness and complexity of the NIHR's PPI policy, and serve to caution against simplistic or formulaic approaches to exploring policy intentions and impact. The findings and discussions presented in this report offer a starting point for opening up thinking about the assessment of PPI policy impact in the NIHR's next phase of development.

Introduction and background

Patient and public involvement in research (PPI) have been central to the National Institute for Health Research's (NIHR) mission since it was established in 2006. As NIHR enters the next phase of its development, with the publication in 2015 of the landmark report 'Going the Extra Mile' on improving the nation's health and wellbeing through public involvement (PPI) in research (Denegri, 2015), followed in 2018 by the setting of national standards for PPI (National Institute for Health Research, 2018), it is timely to take stock and consider how the focus on PPI emerged and developed historically. The thinking behind the commissioning of this study was that "*if we're going to assess the impact of 'Going the Extra Mile', we need a baseline. What was expected from PPI in the first place back in 2006? … What were the original intentions at policy level? What was the intended impact of PPI and what have we learned from the first twelve years?"* (extract from interview notes).

The field of policy studies reminds us that exploring such questions is far from straightforward (Parsons, 1995). Despite the simple allure of an 'instrumental-rational' logic model of policymaking that implies a linear relationship between objectives, activities and outcomes (Yanow, 2015), policy development in practice has repeatedly proved to be a more diffuse, indeterminate and ambiguous affair (Fischer & Gottweis, 2012; Maybin, 2013). The phrase 'muddling through' has long been used to describe the messiness of real world policymaking (Lindblom, 1959). From this perspective, the assumption that there was a discernible 'baseline', or a unitary, identifiable set of expectations and intentions, is questionable.

A more plausible theory to help explain how PPI policy developed at NIHR is one that highlights how policy emerges from continual debate and struggles over different ideas; how what is written down in formal guidance gets variously interpreted and shaped by multiple stakeholders; and how policy developments are influenced by a difficult to disentangle back-and-forth between policy and sense-making practices (Greenhalgh & Russell, 2009; Weiss, 1977). A defining feature of NIHR PPI policy is its richly multi-faceted nature. From the outset, this policy has had different intentions and meant different things to different people in different contexts. Additionally, NIHR is itself a diverse network of organisations and programmes, each with their own set of policies and ways of working.

In setting the scene for this report, it is important to acknowledge that NIHR PPI policy was not developed from scratch in 2006; rather, when NIHR was set up it inherited an already well-established set of policies, frameworks and ideas about involvement and engagement from the organisations assimilated under its umbrella. These organisations included the Health Technology Assessment (HTA) programme, established in 1993, and INVOLVE, established in 1996 (known as Consumers in NHS Research from 1996 – 2003). By the time NIHR was established in 2006, the HTA programme had published an extensive review of evidence of involving consumers in research and development agenda setting for the NHS (Oliver et al., 2004), and INVOLVE already had 10 years' experience of developing PPI initiatives.

An exploration of the provenance of NIHR PPI policy also needs to acknowledge the broader policy context within which NIHR policy has developed. Beyond NIHR, over the past 25 years or so, PPI has become a major focus of activity in the NHS, in charity sector organisations such as the MS Society, other funding bodies such as the UK Research Councils and the Wellcome Trust, and more recently bodies such as the National Cancer Research Institute and the UK Clinical Research Collaboration (Wicks et al, 2018). As one respondent for this study put it, PPI has become *"part of the zeitgeist"*. Broader policy trends that have intertwined with NIHR policy developments include: the shift of emphasis from knowledge production to knowledge mobilisation in UK R&D policy (Walshe & Davies, 2013); an increased focus on societal impact of research in the Research Excellence Framework for higher education (Greenhalgh et al., 2015); the setting up of the National Coordinating Centre for Public Engagement in 2008; political initiatives such as David Cameron's notion of the 'big society' and 'active citizens'; and social movements, particularly those of disabled people and mental health service users, who have long pushed for greater participation in public services and research from a democratic perspective (Beresford, 2002).

NIHR PPI policy is therefore part of a complex jigsaw of policies and practice to do with involving and engaging the public. Kingdon's theory of agenda setting is of relevance here. He suggests that policy developments occur when certain conditions (referred to as 'problem', 'policy' and 'political' streams) come together to open up 'policy windows' for change (Kingdon, 1984). Arguably, when NIHR was established and Best Research for Best Health (the document which set the ground for the development of NIHR's PPI policy) was published in 2006, the 'problem' of PPI had

already been identified as amenable to policy action, viable strategies for change were evident, and PPI in research was attracting widespread political support, with its embodiment of dominant societal values such as consumerism and citizen involvement (Salter, 2003).

This project was commissioned by the Impact Team at the NIHR CCF, as a preliminary piece of work to inform a subsequent, wider exploration of the impact of NIHR PPI policy. In considering any future work, it will be important to recognise the significant body of work that has been undertaken to date on the impact of PPI in research. There exists a number of systematic reviews exploring methods and impact of PPI in research (for example, Brett et al., 2010; Crocker et al., 2018; Domecq et al., 2014; Mathie et al., 2014; Mockford et al., 2012; Nilsen et al., 2006; Shippee et al., 2015; Staley, 2009). Realist evaluations of the context, processes, mechanisms and impact of PPI in health research have also been undertaken (Evans et al, 2014; Wilson et al., 2015). Other researchers have explored stakeholder views about the impact of PPI in research (Barber et al., 2012; Bekkum & Hilton, 2014); some studies have developed practical guidance for researchers to incorporate assessment of the impact of public involvement in their research (Popay & Collins, 2014), while others have suggested conceptual frameworks for exploring the nature and impact of public involvement in research (Greenhalgh et al., 2018; Oliver et al., 2008; Oliver et al., 2015). Most recently, NIHR has established a public involvement impact working group, chaired by Simon Denegri, and the Cabinet Office is undertaking an audit of progress with implementing ‘Going the Extra Mile’ (Denegri, 2018a).

It is beyond the remit of this project to report on the findings of these studies in any depth, but salient findings are flagged in subsequent sections of this report. Overall, published studies highlight [a] how complex and difficult the task of assessing impact is, [b] the contested conceptualisation of the phenomena under study, and [c] the continued scarcity of what is considered to be robust evidence. Despite these limitations, the overall message to emerge is that PPI can have positive impacts on the research process, users, researchers, and wider stakeholders. At the same time, PPI can have unintended negative consequences (see Section 5), an aspect of PPI that tends to be both overlooked and under-reported (Barber et al., 2012; Brett et al., 2010; Staniszewska et al., 2011).

In the following sections, we draw on our interpretive policy analysis of NIHR policy/strategy documents, interviews with key informants, published literature, and the healthtalk database of interviews with people who have been involved in health research (healthtalk.org, 2016) to identify six overarching narratives to emerge from NIHR PPI policy as it has developed since 2006. These narratives serve to [a] explore what key stakeholders were expecting from PPI policy when NIHR was established in 2006 (while acknowledging the limitations of asking respondents to reflect back on expectations held over 12 years ago), [b] capture persistent themes in NIHR PPI policy development over the past 12 years, and [c] provide pointers for thinking about the assessment of policy impact in the NIHR's next phase of development. Appendix 1 contains further details of our interpretive policy analysis and the methods used.

Our report will be of interest primarily to those who commissioned and took part in the review from within and beyond the NIHR infrastructure, to consolidate and progress thinking on the impact of PPI in health research. We also anticipate that our findings will be of interest to a wider audience, given NIHR's reputation nationally and internationally as an exemplar of involving patients and the public in health research.

Policy narratives

1. The diversity of purposes and goals of PPI policy

A review of NIHR policy documents reveals a diverse set of suggested purposes and goals of PPI. Best Research for Best Health (BRBH) suggests that *"patients and the public must be involved in all stages of the research process: priority setting; defining research outcomes; selecting research methodology; patient recruitment; interpretation of findings and dissemination of results"* (Department of Health, 2006). The document includes what, according to one respondent, is colloquially referred to as the 'NIHR dartboard': a diagram of the NIHR infrastructure, programmes and systems, with patients and the public at the centre, *"at the heart of everything we do"*. BRBH does not explicitly identify the goals of PPI, but states that: *"We know from our experience that engaging patients and members of the public leads to research that is more relevant to people's needs and concerns, more reliable and more likely to be put into practice".* BRBH also says *"We will work with patients and the public to improve our mutual understanding of the wider societal issues that determine the success of the health research endeavour"*, although there is no elaboration of what this might mean in practice. BRBH places considerable

emphasis on the need to increase participation of patients in clinical trials, although statements such as: *"We believe all patients and professionals across England should be able to participate in appropriate clinical studies when they wish to",* present this need more in terms of opening up patient access to trials, than the need for researchers to achieve higher recruitment rates.

Subsequent documents refer to a variety of benefits and goals of PPI. In a foreword to a review of research on the impact of public involvement undertaken by INVOLVE, Sally Davies says: *"No matter how complicated the research, or how brilliant the researcher, patients and the public always offer unique, invaluable insights. Their advice when designing, implementing and evaluating research invariably makes studies more effective, more credible and often more cost efficient as well"* (Staley, 2009). And the NIHR website states that *"involving patients and members of the public in research can lead to better research, clearer outcomes, and faster uptake of new evidence"* (NIHR, 2013). One respondent suggested that an early influence on NIHR policy was work by Ian Chalmers and colleagues published in the Lancet, drawing attention to waste in the production and reporting of research evidence, for example, unnecessary research, research that addresses the wrong questions, is poorly designed, or remains unused. They argued that much waste could be avoided by greater involvement of patients and the public in research to help define questions of most relevance and importance to populations rather than to researchers (Chalmers & Glasziou, 2009). Another respondent, reflecting back on pre-NIHR days, commented that *"too often researchers were following an entirely academic led agenda. As opposed to where patient need for research was. From the outset NIHR was about making sure applied research is relevant to people".*

From a theoretical perspective, the goals and purposes of PPI discussed so far could all be categorised under the heading of instrumental or 'benefits-based' reasons for policy development (Beresford, 2002). They position PPI as a means to the end of achieving better research, and suggest that studies of impact of PPI policy focus on the research process itself (for example the quality, validity, relevance and utility of research) (Boote, Wong, & Booth, 2015). Several respondents suggested that this technocratic framing of PPI purpose has tended to dominate NIHR policy development, perhaps unsurprisingly, given that instrumental arguments are the ones most likely to sway researchers to include PPI in their work. As one respondent commented: *"I'm interested in it [PPI] as a hard-nosed research manager. PPI leads to better research, full stop".*

However, running alongside this framing of PPI is a contrasting, 'democratic' or 'rights-based' perspective, suggesting that *"defining consumer involvement outcomes solely in terms of research quality ignores the rights of those being researched or likely to benefit from the research"* (Mathie et al., 2014). A democratic framing of PPI draws on philosophies of human rights and empowerment, seeing involvement and engagement as ends in themselves (Green, 2016). It is *"primarily concerned with people having more say in agencies, organisations, and institutions which impact upon them and being able to exert more control over their own lives"* (Beresford, 2002). It is also concerned with public accountability and transparency, given that research is funded from the public purse (Ives, Damery and Redwod, 2013).

This conceptualisation of PPI shifts the attention of impact studies from the research endeavour to patients and the public and the wider community. Some argue that if involvement is considered a democratic right, with intrinsic value, there is not necessarily any further need for evaluation of impact (Edelman & Barron, 2016). Furthermore, others have suggested that it is inappropriate to consider PPI in research as an intervention with measurable impacts, questioning "*the appropriateness of applying scientific enquiry to a social, collaborative partnership, where mutual learning takes place during personal interactions"* (Barber et al., 2012).

Thus, a key narrative running through NIHR policy documents and our interviews with respondents is the diversity of purpose of PPI. For some, with backgrounds rooted in participatory movements, the fundamental motivation for PPI is a moral and ideological one, concerned with addressing democratic deficits in societal processes. For others, the motivations are more pragmatic – they are concerned with the transactional relationship between researcher and researched, and how improving this can lead to better quality research. Of course, this is not to suggest that people's motivations can be divided neatly into democratic or practical; the reality is likely to be more nuanced. Nonetheless, the advice the Cheshire Cat gave to Alice when she asked which way she ought to go from here – *"that depends a great deal on where you want to get to"* – is a useful reminder for those concerned with studying the impact of PPI policy. In their critique of the recently published national standards for public involvement in research, McCoy and colleagues argue that PPI work must always be firmly tethered to questions about why, when and with whom. The danger otherwise, they suggest, is that:

> *"…the Standards promote an unreflective 'more the merrier' attitude in relation to involvement. While promoting involvement in research is important,*

> *promoting uncritical involvement has the potential to squander resources, frustrate involved persons and even do harm".* (McCoy et al, 2018)

Returning to the fundamental question prompting this study: what were those involved expecting of NIHR PPI policy back in 2006? Beyond the diverse motivations described here, also lay some simpler concerns – the need to convince researchers of the value of PPI. As one respondent put it: *"the problem that NIHR PPI policy was trying to solve was to convince researchers, mostly clinical and biomedical researchers who weren't used to involving patients and the public, of the need to do so".* 12 years on, this is something our respondents thought had by and large been achieved (although some published accounts are less optimistic, see Section 4). In general, patients interviewed by healthtalk.org also thought that the priority researchers give to PPI has changed significantly, with one patient suggesting: *"The fact that it is so accepted now, I think the work that NIHR has done has been really ground-breaking for the whole patient involvement community…."* At the same time, patients have expressed concern that, with some recent policy developments, *"we might actually be taking a step back rather than forward in terms of patient involvement"*. The danger, one patient suggested, is that *"the advent of academic health science networks and the reorganisation of clinical research networks might actually distance the whole research process from the health and social care needs of the population…. And particularly when the research community is being told that the main driver for health research is economic success…"* (healthtalk.org, 2016).

2. The hardware and software of PPI

Wilsdon and colleagues argue that in public policy the focus on *"the 'hardware' of engagement – the methods, the focus groups, the citizens' juries that can give the*

public a voice in science policy and decision-making" has too often been at the expense of *"the 'software' – the codes, values and norms that govern scientific practice, but which are far harder to access and change"* (Wilsdon et al, 2005). Arguably, this has been the case with NIHR PPI policy, with several respondents noting the overriding emphasis on mechanisms and structures for PPI, particularly in the early days of NIHR, with considerably less attention paid to the underlying values of PPI and the need for accompanying cultural change.

Best Research for Best Health set the scene in 2006, announcing that *"We have established structures and mechanisms to facilitate increased involvement of patients and the public in all … stages of NHS R&D"* (Department of Health, 2006). Subsequent NIHR annual reports primarily focus on PPI as a technical process and practical endeavour, reporting for example on the number of training workshops and conferences held each year, the number of people employed as public involvement leads, facilitators and advisers, quantifying the work of the Research Design Service, identifying structures such as the People in Research website, the involvement cost calculator, the James Lind Alliance priority setting partnerships, and so on (National Institute for Health Research, 2012, 2013, 2014, 2015, 2016). The overall impression is of the development of a large public involvement infrastructure, described in the Going the Extra Mile report as *"a frenzy of activity"* (Denegri, 2015). Our respondents noted how NIHR reporting on PPI activity has been *"very much numbers based, all about formal metrics"*. One respondent described PPI as *"a massive managerialist and administrative machine"* and patients referred to *"the PPI industry"* (healthtalk.org, 2016). More critically, Madden and Speed (2017) have described PPI as *"a form of busywork in which the politics of social movements are entirely*

displaced by technocratic discourses of managerialism", although such comments have been criticised for being *"deeply unfair and disrespectful"* (Denegri, 2018a).

In their public involvement impact assessment framework guidance (PiiAF), Popay and colleagues argue that the values people hold about public involvement can be a powerful influence on the process of involvement and the impacts it can have, and thus that explicit awareness of the different values underpinning PPI should be the *starting point* of any work (Popay & Collins, 2014). Although BRBH states that a key objective of the BRBH strategy is to *"behave with integrity, expressing our values in the way we behave – from developing and implementing our strategy to how we work with our partners and key stakeholders"*, the document makes no further explicit reference to values (Department of Health, 2006). Likewise, our review of NIHR annual reports and strategy documents revealed scant attention to the underpinning values guiding PPI.

In 2015, however, INVOLVE published a values and principles framework for public involvement in research (INVOLVE, 2015), indicating increased attention to making explicit the significance of values underpinning PPI in research. The document includes a self-assessment from various parts of NIHR (the CFF, the Horizon Scanning Research and Intelligence Centre, the Trainees Coordinating Centre (TCC), and the Evaluation, Trials and Studies Coordinating Centre (NETSCC)), giving examples of how specified values (respect, support, transparency, responsiveness, fairness of opportunity and accountability) are evident in everyday work practices. Arguably, the six values identified in this document represent a restricted set of values compared with those identified by Gradinger and colleagues

in their narrative review of values explored in PPI literature (which include, for example, the values of empowerment, human rights, social justice, and transformation of power relations, see Section 4 (Gradinger et al., 2015)).

Going the Extra Mile, published by NIHR in the same year, pays more attention to such normative values. There is a discernible shift in language and intention from earlier NIHR strategy documents, particularly BRBH. As one respondent put it, *"BRBH is a fairly dry document, it's process oriented, with a fairly narrow focus. No lofty ambitions there. It's only in the last few years that we've broken out of the BRBH mindset and set ourselves a more ambitious agenda"*. In Going the Extra Mile concepts such as empowerment and the need for cultural change are commonplace, with endorsement of the principles of co-production (Denegri, 2015).

In summary, whilst the 'hardware' of PPI in research remains as important as ever, there appears to be increasing recognition of the need for NIHR to focus on the 'software' of cultural change. This is an area where expectations have clearly shifted over the past 12 years. A challenge for the next phase of NIHR's development will be finding ways to assess and record such cultural change. As our respondents noted, it is much easier to count and measure tangible things (the 'hardware'), much harder to pin down the softer, but equally important, attributes of PPI.

3. The ongoing search for evidence of impact of PPI

A documentary analysis of English R&D policy documents between 1991 and 2010 concluded that *"Overall, R&D policy documents have made little attempt to justify the policy of PPI in research beyond simple assertions that it is beneficial without citing*

evidence" (Evans, 2014). An example is evident in BRBH (quoted above): *"We know from our experience that engaging patients and members of the public leads to research that is more relevant to people's needs and concerns, more reliable and more likely to be put into practice"* (Department of Health, 2006). The use of the word 'experience' here is surprising in a cultural environment that has long emphasised the importance of evidence-based policy.

However, since the publication of BRBH in 2006 increased attention has been paid to improving the evidence base to justify PPI activity. As indicated in the introductory section of this report, a number of reviews of evidence of impact of PPI in research have been undertaken, some commissioned by NIHR (Brett et al., 2010; Crocker et al., 2018; Domecq et al., 2014; Mathie et al., 2014; Mockford et al., 2012; Nilsen et al., 2006; Shippee et al., 2015; Staley, 2009). Somewhat paradoxically, the overall narratives to emerge from these reviews point to the dearth of robust evidence and the need for better methods and instruments to capture and measure impact of PPI, and at the same time, to the substantial amount that is now known about the impact of PPI: for example, how PPI improves recruitment to research trials, makes research more relevant and appropriate for users, improves the quality of the research, and improves relationships between researchers and communities.

Despite this emerging evidence base, the INVOLVE Advisory Group Members' submission to NIHR Breaking Boundaries review of public involvement in 2014 concurred with Evans' analysis quoted at the beginning of this section, noting that:

> *"Continuing efforts need to be made to gather evidence on the impact of public involvement to demonstrate how routinely using public involvement to inform research priorities, improve research methods, manage and disseminate research adds value to research outcomes and enhances*

> *patient benefit. This evidence should be used more proactively to tackle the evident scepticism and resistance to public involvement that is still influential in the health research community. Across the NIHR, there needs to a strategic approach to evidence, with greater understanding of audiences, key concerns and how evidence addresses these concerns".* (INVOLVE, 2014)

In our interviews, one respondent described the scarcity of robust evidence of impact as *"a major vulnerability of PPI"*. Another commented: *"it's an area we've not spent enough attention on. NIHR has not invested in developing the evidence base as much as it should have"*. The overall sense to emerge from interviews was that NIHR *"started out from base zero"* with little evidence of impact, and whilst significant progress has been made over the past 12 years, it still has *"a long way to go".*

Evidencing the impact of PPI is widely recognised to be problematic. In part the problems are conceptual – the diverse, complex and diffuse nature of PPI means that it is difficult to pinpoint, track and generalise across research projects. And, as indicated earlier, there is a view that if PPI is considered as an ongoing dialogue and difficult to capture, subtle social interactions between researchers and researched, the notion of measuring impact is arguably an inappropriate one (Barber et al., 2012). In their Delphi study exploring barriers and potential for assessing impact of PPI, Snape and colleagues reported that *"many panellists expressed the view that the process of involvement, when carried out well, is often difficult to deconstruct in order to evaluate discrete elements of the PI contribution and/or impact"* (Snape et al., 2014). Patients too have noted that the impact of their involvement may not be easy to identify. By being present they may change the course of a discussion or attitudes to an issue in significant but subtle and hard to measure ways (healthtalk.org, 2016).

There is also the view that too much emphasis has been placed on the search for hard, quantitative measures, with a concomitant undervaluing of qualitative and particularly narrative data on impact, which it is argued can provide rich learning. In her review of the impact of PPI in research, Staley concludes that:

> *"…very powerful and convincing evidence can come from simply telling the story of involvement. Strengthening the evidence base may therefore not only be about finding the most robust and rigorous ways of assessing impact, but also about helping researchers and the public to find the most useful and consistent way of telling their stories."* (Staley, 2009)

The problems of evidencing impact are also seen as practical, with researchers indicating lack of time and resources to adequately investigate and report on the impact of their PPI work (Snape et al., 2014). Nonetheless, there now exist a number of published accounts of how PPI has impacted on specific research projects (Buck et al., 2014; Mann et al., 2018), and tools are available to help researchers improve the reporting of PPI in research (Popay & Collins, 2014; Staniszewska et al., 2017).

Several respondents made suggestions of how NIHR could and should be gathering more evidence internally to assess the impact of its PPI processes. For example, one suggestion was for in-depth analysis of funding panel meetings and minutes to explore how the views of PPI representatives were taken account of and influenced decision-making. NETSCC has in fact undertaken some recent research on this topic, interviewing committee members, including public members and chairs from NIHR research funding programmes, and is expected to publish the results shortly (Tembo, 2019; personal communication). Another comment concerned the need to evaluate a recent change in the format of NIHR funding application forms:

> *"We started with a PPI box on our application forms, so in some sense you could interpret that as PPI just being one component, ghettoised. But on the most recent forms we've removed the box, so now we've moved to a situation where PPI is part and parcel of everything about a research proposal. This is an attempt to normalise and integrate it. It's a bit of an experiment, we need to survey our PPI members and build an evidence base to see the impact of that policy"*[1].

In summary, despite a growing evidence base on the impact of PPI in research, the search for more 'robust' evidence of impact remains a holy grail. Denegri has suggested that perhaps ultimately the debate about impact *"is an issue which has no solution. Rather it's a question that can only be answered by asking lots of other questions. Which lead to further questions"* (Denegri, 2018). This line of thinking connects with Tsoukas' argument that the predominant scientific paradigm encourages reductionist theorising: it aims to abstract and simplify, rather than engaging with the complexity of social phenomena such as patient and public involvement (Tsoukas, 2016). Greenhalgh and Papoutsi (2018) suggest that we need new ways of thinking and theorising about the study of impact of policies and interventions such as PPI, in order to embrace the characteristics of complexity (for example, unpredictability, multiple interacting influences, inherent and dynamic tensions.

4. Negotiating the power dynamic between researchers and the public

For many of our respondents, one of the most significant trends over the past 12 years of NIHR policy development has been greater recognition of the need to shift the power dynamic between researchers and the public. According to one respondent there has already been, and continues to be *"a huge increase in the*

[1] NIHR reports that it is currently researching this topic.

democratisation of research". For another, comparing NIHR in 2006 and 2018, *"the language is much less 'them and us' now. We're making research an enterprise done 'with or by' patients and the public, rather than 'about or for' them".*

Commentators such as Green are not so confident that there has been any fundamental shift in power relations from the scientific community to the public. From her analysis of NIHR activity, she argues that, despite an increasingly progressive rhetoric, as evidenced for example in the attention given to methods of co-production in Going the Extra Mile, and despite a body of evidence demonstrating that it is increasingly the norm for the public voice to be incorporated into various stages of the research process, "*there has not, however, been a concomitant transformation of the social relations of research, as envisaged by the emancipatory research movement*" (Green, 2016). And Boaz and colleagues' interview study of researchers involved with NIHR Biomedical Research Centres concluded that despite *"changing currents on the surface"*, there remained active resistance to sharing power and control in the process of knowledge generation (Boaz, Biri, & Mckevitt, 2016). Similarly, one of our interview respondents argued *"we're still not brave enough in NIHR to address power issues… scope has been limited for people to really challenge the power dynamic around research".*

Empowerment is a frequently used word in the PPI field. BRBH talks about empowering people to play an active role in research, and in 'Going the Extra Mile' it is suggested that: *"The public, researchers and health professionals should be empowered and supported better to work together in the future"* (Denegri, 2015). The 'OK to Ask' initiative, launched by NIHR in 2015, is described as a patient

empowerment campaign, encouraging patients and their carers *"to ask their doctors about clinical research and whether it is right for them"* (NIHR, 2013).

But empowerment is a slippery word that means different things to different people. Inglis draws a helpful distinction between the terms empowerment and emancipation, the former involving people developing capacities to act successfully *within* the existing system and structures of power, whilst emancipation, he argues, concerns critically analysing, resisting and challenging structures of power (Inglis, 1997). In other words, an emancipatory conceptualistion of empowerment is oriented to the macro-politics of the social relations of research production rather than, as with more mainstream uses of the term empowerment, the micro-politics of research processes (Beresford, 2002).

In line with these ideas, Fudge and colleagues argue that despite a progressive rhetoric, NIHR policy can be characterised as encouraging patients and the public to 'play by the rules of the game', rather than fundamentally challenging the rules (Komporozos-Athanasiou et al, 2016; Fudge et al, 2008). An example here, suggested by one of our respondents, is work supported by NIHR looking at how PPI can increase recruitment and retention in surgical trials (Kearney et al., 2017). Our respondent commented: *"What this research doesn't do is raise questions about whether patients necessarily think an RCT is the best way to go about researching something. It assumes that the RCT is the gold standard, and then PPI starts from that assumption. So it's still very researcher-led".*

Fudge draws on scholars who have analysed policy from an anthropological perspective to suggest that, rather than necessarily seeing policy as having a specific means to an end (for example improving research quality), it is perhaps as much about shaping citizens and directing people as to how they should behave (Fudge, 2013; Shore & Wright, 1997). From this perspective, PPI policies 'empower' people to become responsible 'active citizens' who contribute to the national research endeavour (Martin, 2008) (although arguably the policy fails in this regard because the people who get involved tend to be those who are already health aware, active citizens in the community (Fudge, 2013)).

Fudge identifies a shift in NIHR PPI research policy towards PPI increasingly being presented as a responsibility or even a duty of citizenship. The strategic goal of NIHR policy identified in 'Going the Extra Mile' is by 2025 for everyone using health and social care *"to choose to contribute to research"*. The public are to be empowered to 'seize the opportunities' to engage and become actively involved in research:

> *"By 2025 we expect all people using health and social care, and increasing numbers of the public, to be aware of and choosing to contribute to research by:*
> - *Identifying future research priorities and research questions*
> - *Informing the design and development of innovations*
> - *Participating in research studies*
> - *Advocating for the adoption and implementation of research in the NHS"* (Denegri, 2015)

Of note here is that participating as a subject of research, which typically is not considered to constitute involvement as defined in the PPI field, has been subsumed under the involvement umbrella.

Overall, as with other themes identified in this report, it seems that there are two parallel, contradictory narratives – it is thought that the last 12 years has seen a significant shift in the fundamental power dynamic between researchers and the public towards greater equality; at the same time, there is a questioning of how much cultural change towards the democratisation of research has really occurred.

5. The dis-benefits of PPI

While the general assumption in NIHR policy is that involvement in research is positive and empowering, some commentators have pointed to the dis-benefits and opportunity costs of involvement (Popay & Collins, 2014), highlighting the possibility of PPI having the unintended effect of disempowerment. This was also an issue raised by some of our respondents and those interviewed for healthtalk.org.

Research studies have identified a range of negative impacts of involvement: feelings of overwork and frustration at the limited opportunities to influence the direction of research (with one person commenting: *"there is a potential emotional toll but I think it's more to do with whether you're listened to really"* (healthtalk.org, 2016); feelings of being marginalised, confusion and conflict due to lack of clarity about the lay role, the burden of responsibility and duty, as well as time and financial burdens (Barber et al., 2012; Brett et al., 2010; Cotterell et al., 2011). Patients have talked about how involvement can stir up strong emotions that may be difficult to express and/or contain within the context of a formal committee meeting (healthtalk.org, 2016). Some commentators have suggested PPI can impact

negatively on the 'science' of research; Bekkum and Hilton for example found *"numerous and sometimes conflicting concerns about public knowledge deficits and their biases, emotions and personal interests potentially damaging the integrity of science"* (Bekkum & Hilton, 2014).

Staniszewska and colleagues note the tendency for negative impacts, including those on researchers, to be under-reported in studies exploring impact (Staniszewska *et al.*, 2011), and one of our respondents found there was sometimes a reluctance among stakeholders to explore situations where PPI did not appear to add value. The idea that the public necessarily want to be involved in research has also been questioned; Ward et al suggest a tendency in PPI policy towards 'researchism' or the veneration of research, with concepts such as 'research literacy' implying that the public need to be better educated about research (Ward et al., 2010).

6. Concerns about tokenism and representativeness

A key storyline running through our interviews, policy documents, academic literature, and patients' reported experiences was the danger and problem of tokenism (see below for definition) in PPI. Whereas the general sense from our interviews was that concerns about tokenism are less prevalent now than in 2006 when NIHR was established, reports from published literature convey a different picture – emphasising the persistence of stakeholders' anxieties about tokenism. For example, a systematic review of PPI in research found that one of the key challenges facing researchers is an overarching worry about tokenism (Domecq et

al., 2014), and other studies have similarly reported tokenism as an ongoing concern (Buck et al., 2014; Snape et al., 2014).

A number of different interpretations of tokenism can be identified. For Arnstein, whose 'ladder of participation' is one of the most widely referred to conceptual frameworks in the PPI field, tokenism references a lack of power sharing between researchers and the public. Activities such as consultation and informing, she suggests, are forms of tokenism, whereas higher up rungs on the ladder of citizen participation, such as partnership and delegated power, represent varying degrees of citizen control (Arnstein, 1969).

The term tokenism is also used to describe the way in which PPI can become a 'tick box' exercise, with researchers going through the motions of involvement to satisfy funding bodies and ethics committees, rather than engaging with the process in a meaningful and robust way. As one patient expressed it: *"You've got to tick the box because you won't get the money at all if you don't… And that's the real worry because then my experience has been that researchers are rushing around finding, retrospectively, some engagement with patients, and that's not terribly helpful"* (healthtalk.org, 2016). Snape and colleagues argue that PPI tokenism presents itself as a self-fulfilling prophecy: *"PI when under-valued leads to tokenism in involvement practice; tokenistic practice fails to demonstrate the value of PI; hence, PI is therefore perceived as not adding value to health and social care research"* (Snape *et al.*, 2014). As mentioned above, one of our respondents noted how having a specific PPI box on NIHR application forms risked 'ghettoising' it, hence the policy

change of expecting applicants to refer to PPI throughout their proposals rather than marginalise it in one box.

Tokenism can also refer to the nature of representation in PPI work. Some PPI initiatives are seen as tokenistic in their inclusion of one or two members of the public on a research advisory group for example, with these members assumed to somehow 'represent' the public view. Some patients make the point that they see themselves as 'a patient representative' rather than 'a representative patient' (healthtalk.org, 2016). A common concern is that the people involved are an 'unrepresentative minority' (Maguire & Britten, 2017), or in the words of one of our respondents, *"a very self-selecting bunch"*. The healthtalk.org website notes that *"the profile of people who get involved tends to be white, middle class, retired people, quite often with some form of health or research background. Having time to get involved, but also a certain level of education and confidence to engage with high-powered scientists, may make involvement easier for such people"* (healthtalk.org, 2016). In Going the Extra Mile NIHR indicates that its PPI needs to be more inclusive and diverse, suggesting that *"if leaders and role models were promoted and recruited from varied backgrounds, this would encourage more people to become involved"* (Denegri, 2015).

However, theoretical literature and empirical studies on representation in PPI work caution us to be wary of all too easy criticisms of representativeness and accusations of tokenism. Forms of representation, it is argued, are always contestable. At the heart of the concept of representativeness lies a fundamental dualism: being a representative is to make present someone or something which

may not be there, making them both absent and present (Maguire & Britten, 2017). Renedo and colleagues describe how this paradox is played out in PPI initiatives, with patients being *"simultaneously asked to be nobody (by silencing their personal lived experiences and putting aside their own idiosyncrasies) and everybody (by having embodied broad experiences or views that are representative of others)"* (Renedo, Komporozos-Athanasiou, & Marston, 2017). These contradictory demands on patients can also be seen as a manifestation of broader tensions between biomedical (evidence-based) and experiential knowledge systems.

Conclusion

From the outset, NIHR PPI policy has had different intentions and meant different things to different people in different contexts. Notwithstanding this diversity, a number of common narratives emerge from our interpretive policy analysis: [1] pragmatic 'benefits-based' and moral 'rights-based' arguments have both been powerful drivers in the development of PPI, [2] emphasis on the 'hardware' of PPI (structures and mechanisms) has begun to be balanced by a focus on the 'softer' aspects of PPI (underlying values and cultural changes), [3] there exists a widespread perception that there is a dearth of robust evidence on the impact of PPI persists, despite an emerging literature evidencing the substantial amount that is now known about the impact of PPI, [4] beyond the commonly held assumption that PPI 'empowers' lie complex questions about power imbalances between researchers and the researched, [5] potential dis-benefits and even disempowering effects of PPI can be overlooked and under-reported, and [6] there exists continuing concerns about the dangers of tokenism in PPI.

These narratives highlight the richness and complexity of PPI policy, and serve to caution against simplistic or formulaic approaches to exploring policy intentions and impact. They suggest that there are no straightforward answers to questions such as ‘what were the original intentions of NIHR PPI policy? Rather, the hope is that the findings and discussions presented in this report offer a starting point for opening up thinking about the assessment of PPI policy impact in the NIHR’s next phase of development.

References

Arnstein, S. R. (1969) A Ladder Of Citizen Participation. *Journal of the American Institute of Planners*, *35*(4), 216–224.

Bacchi, C. L. (2009) *Analysing policy: what's the problem represented to be?* Frenchs Forest, N.S.W: Pearson Education.

Barber, R., Boote, J. D., Parry, G. D., Cooper, C. L., Yeeles, P., & Cook, S. (2012) Can the impact of public involvement on research be evaluated? A mixed methods study. *Health Expectations*, *15*(3), 229–241.

Bekkum, J. E. van, & Hilton, S. (2014) UK research funding bodies' views towards public participation in health-related research decisions: an exploratory study. *BMC Health Services Research*, *14*(318).

Beresford, P. (2002) User involvement in research and evaluation: liberation or regulation? *Social Policy and Society*, *1*(02), 95–105.

Boaz, A., Biri, D., & Mckevitt, C. (2016) Rethinking the relationship between science and society: Has there been a shift in attitudes to Patient and Public Involvement and Public Engagement in Science in the United Kingdom? *Health Expectations*, *19*(3), 592–601.

Boote, J., Wong, R., & Booth, A. (2015). "Talking the talk or walking the walk?" A bibliometric review of the literature on public involvement in health research published between 1995 and 2009. *Health Expect*, *18*(1), 44–57.

Brett, J., Staniszewska, S., Mockford, C., Seers, K., Herron-marx, S., & Bayliss, H. (2010). *The PIRICOM Study : A systematic review of the conceptualisation, measurement, impact and outcomes of patients and public involvement in health and social care research*. University of Warwick.

Buck, D., Gamble, C., Dudley, L., Preston, J., Hanley, B., Williamson, P. R., Walker, A. (2014). From plans to actions in patient and public involvement: Qualitative study of documented plans and the accounts of researchers and patients sampled from a cohort of clinical trials. *BMJ Open*, *4*(12). https://doi.org/10.1136/bmjopen-2014-006400

Bullock, H., Mountford, J., & Stanley, R. (2001). *Better policy making*. London: Centre for Management and Policy Making, Cabinet Office.

Chalmers, I., & Glasziou, P. (2009). Avoidable waste in the production and reporting of research evidence. *The Lancet*, *374*(9683), 86–89.

Conklin, A., Morris, Z., & Nolte, E. (2015). What is the evidence base for public involvement in health-care policy?: Results of a systematic scoping review. *Health Expectations*, *18*(2), 153–165.

Cotterell, P., Harlow, G., Morris, C., Beresford, P., Hanley, B., Sargeant, A., Staley, K. (2011). Service user involvement in cancer care: The impact on service users. *Health Expectations*, *14*(2), 159–169.

Cowden, S., & Singh, G. (2007). The'User': Friend, foe or fetish?: A critical exploration of user involvement in health and social care. *Critical Social Policy*, *27*(1), 5.

Crocker, J., Ricci-Cabello, I., Parker, A., Hirst, J., Chant, A., Petit-Zeman, S., Rees, S. (2018). Assessing the impact of patient and public involvement on recruitment and retention in clinical trials: a systematic review. *British Medical Journal*, *363*, https://doi.org/10.1136/bmj.k4738

Denegri, S. (2015). *Going the extra mile: Improving the nation's health and wellbeing through public involvement in research*. London: INVOLVE.

Denegri, S. (2017). *NIHR and the national strategy for public involvement*. Second RDS/INVOLVE SE Partnership event NIHR PPI Leads Meeting, Royal Society, 19th June.

Denegri, S. (2018). *Monsters Inc holds the key to assessing research impact.* Simon Denegri's lay review. Retrieved July 2, 2018, from https://simondenegri.com/2018/06/25/monsters-inc-holds-the-key-to-assessing-research-impact-ref2021-oxfordimpact/

Denegri, S. (2018a) *Public involvement in research: it's academic isn't it? (notes from a growing movement).* Simon Denegri's lay review. Retrieved Feb 5, 2019, from https://simondenegri.com/2018/11/26/public-involvement-in-research-its-academic-isnt-it-notes-from-a-growing-movement/

Department of Health. (2006). Best Research for Best Health. *A New National Health Research Strategy. The NHS Contribution to Health Research in England.*, *17*(Suppl.1), 11–315. London, Department of Health.

Domecq, J. P., Prutsky, G., Elraiyah, T., Wang, Z., Nabhan, M., Shippee, N., Murad, M. H. (2014). Patient engagement in research: A systematic review. *BMC Health Services Research*. https://doi.org/10.1186/1472-6963-14-89

Edelman, N., & Barron, D. (2016). Evaluation of public involvement in research: time for a major re-think? *Journal of Health Services Research & Policy*, *21*(3), 209–211.

Evans, D. (2014). Patient and public involvement in research in the English NHS: a documentary analysis of the complex interplay of evidence and policy. *Evidence & Policy: A Journal of Research, Debate and Practice*, *10*(3), 361–377.

Evans, D. *et al.* (2014) 'Public involvement in research: assessing impact through a realist evaluation', *Health Services and Delivery Research*, 2(36), pp. 1–128. doi: 10.3310/hsdr02360.

Fischer, F., & Gottweis, H. (2012). *The argumentative turn revisited: public policy as communicative practice*. Durham, NC: Duke University Press.

Fudge, N. (2013) The participation of stroke survivors in service development and research: an ethnographic study. PhD thesis. London: King's College London

Fudge N, Wolfe CDA, McKevitt C. (2008) Assessing the promise of user involvement in health service development: ethnographic study. *BMJ.* 336(7639): 313-7.

Gradinger, F., Britten, N., Wyatt, K., Froggatt, K., Gibson, A., Jacoby, A., Popay, J. (2015). Values associated with public involvement in health and social care research: A narrative review. *Health Expectations*, *18*(5), 661–675.

Green, G. (2016). Power to the people: To what extent has public involvement in applied health research achieved this? *Research Involvement and Engagement*, *2*(1), 28.

Greenhalgh, T., Fahy, N., Walshe, K., Davies, H., Glasziou, P., Altman, D., Cattan, M. (2015). Research impact in the community-based health sciences: an analysis of 162 case studies from the 2014 UK Research Excellence Framework. *BMC Medicine*. https://doi.org/10.1186/s12916-015-0467-4

Greenhalgh, T., & Russell, J. (2009). Evidence-based policymaking: a critique. *Perspect Biol Med*, *52*(2), 304–318.

Greenhalgh, T., & Russell, J. (2010). Why do evaluations of eHealth programs fail? An alternative set of guiding principles. *PLoS Med*, *7*(11), e1000360.

Greenhalgh, T., Hinton, L., Finlay, T., & Macfarlane, A. (2018) Frameworks for supporting patient and public involvement in research: systematic review and design pilot. *British Medical Journal (under review)*.

Greenhalgh, T., & Papoutsi, C. (2018). Studying complexity in health services research: Desperately seeking an overdue paradigm shift. *BMC Medicine*, *16*(1), 4–9. https://doi.org/10.1186/s12916-018-1089-4

healthtalk (2016) Patient and public involvement in research. Available from: http://healthtalk.org

Inglis, T. (1997). Empowerment and emancipation. *Adult Education Quarterly*, *48*(1), 3–17.

Involve. (2014). *INVOLVE work plan 2013 – 2016 Update August 2014*. *INVOLVE website*.

INVOLVE. (2012). *INVOLVE Strategy 2012 – 2015: Putting people first in research*. *INVOLVE website*.

INVOLVE. (2014). *INVOLVE Advisory Group Members' submission to NIHR Breaking Boundaries review of public involvement*.

INVOLVE. (2015). Public involvement in research : values and principles framework, INVOLVE?NIHR.

Ives, J., Damery, S. and Redwod, S. (2013) 'PPI, paradoxes and Plato: Who's sailing the ship?', *Journal of Medical Ethics*, 39(3), pp. 181–185. doi: 10.1136/medethics-2011-100150.

Kearney, A., Williamson, P., Young, B., Bagley, H., Gamble, C., Denegri, S., Woolfall, K. (2017). Priorities for methodological research on patient and public involvement in clinical trials: A modified Delphi process. *Health Expect*. https://doi.org/10.1111/hex.12583

Kingdon, J. (1984). *Agendas, alternatives and public policy*. Boston: Little Brown.

Komporozos-Athanasiou, A., Fudge, N., Adams, M., & McKevitt, C. (2018). Citizen Participation as Political Ritual: Towards a Sociological Theorizing of 'Health Citizenship.' *Sociology*, *52*(4), 744–761.

Kushner, S. (2002). The Object of One's Passion: Engagement and Community in Democratic Evaluation. *Evaluation Journal of Australasia*, *2*(2), 16–22.

Lindblom, C. (1959). The science of muddling through. *Public Administration Review*, *19*(2), 79–88.

Madden, M. and Speed, E. (2017) 'Beware Zombies and Unicorns: Toward Critical Patient and Public Involvement in Health Research in a Neoliberal Context', *Frontiers in Sociology*, 2(June), pp. 1–6. doi: 10.3389/fsoc.2017.00007.

Maguire, K., & Britten, N. (2017). "How can anybody be representative for those kind of people?" Forms of patient representation in health research, and why it is always contestable. *Social Science and Medicine*, *183*, 62–69.

Mann, C., Chilcott, S., Plumb, K., Brooks, E., Man, M.-S., & Uk, C. (2018). Reporting and appraising the context, process and impact of PPI on contributors, researchers and the trial during a randomised controlled trial -the 3D study, 1–12.

Martin, G. P. (2008). "Ordinary people only": Knowledge, representativeness, and the publics of public participation in healthcare. *Sociology of Health and Illness*, *30*(1), 35–54.

Mathie, E., Wilson, P., Poland, F., Mcneilly, E., Howe, A., Staniszewska, S.,

Goodman, C. (2014). Consumer involvement in health research: A UK scoping and survey. *International Journal of Consumer Studies*, *38*(1), 35–44.

Maybin, J. (2013). *Knowledge and Knowing in Policy Work: A case study of civil servants in England's Department of Health. PhD thesis*. Edinburgh: University of Edinburgh.

McCoy, M. S. *et al.* (2018) 'National Standards for Public Involvement in Research: missing the forest for the trees', *Journal of Medical Ethics*, p. medethics-2018-105088. doi: 10.1136/medethics-2018-105088.

Mockford, C., Staniszewska, S., Griffiths, F., & Herron-marx, S. (2012). The impact of patient and public involvement on UK NHS health care: a systematic review, *International Journal for Quality in Health Care 24*(1), 28–38.

National Institute for Health Research. (2012). *NIHR Annual Report 2011 / 12*.

National Institute for Health Research. (2013). NIHR Annual Report 2012-13, (April)

National Institute for Health Research. (2014). *NIHR annual report 2013/14*. Retrieved from http://www.nihr.ac.uk/documents/about-NIHR/NIHR-Publications/NIHR-Annual-Reports/NIHR Annual Report 2014-2015.pdf

National Institute for Health Research. (2015). *NIHR Report Annual 2014/15*.

National Institute for Health Research. (2016). NIHR Annual Report 2015-16. Retrieved from https://www.nihr.ac.uk/about-us/documents/CRN performance reports/2015-16 NIHR CRN High Level Objectives Annual Report_v1.0Public.pdf

National Institute for Health Research. (2018). *National standards for public involvement in research*. London. Retrieved from http://www.invo.org.uk/wp-content/uploads/2014/11/Draft-Values-principles-and-standards-framework-071114.pdf

NIHR. (2013). *" OK to ask " campaign: Summary report*.

NIHR. (2017). Standards for Public Involvement in Research : Consultation 2017

Nilsen, E. S., Myrhaug, H. T., Johansen, M., Oliver, S., & Oxman, A. D. (2006). Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material. *Cochrane Database Syst Rev.*

Oliver, S., Clarke-Jones, L., Rees, R., Milne, R., Buchanan, P., Gabbay, J., Stein, K. (2004). Involving consumers in research and development agenda setting for the NHS: Developing an evidence-based approach. *Health Technology Assessment*, *8*(15).

Oliver, S. R., Rees, R. W., Clarke-Jones, L., Milne, R., Oakley, A. R., Gabbay, J., Gyte, G. (2008). A multidimensional conceptual framework for analysing public involvement in health services research. *Health Expectations*, *11*(1), 72–84.

Oliver, S. *et al.* (2015) 'Public involvement in research: making sense of the diversity', *Journal of Health Services Research & Policy*, 20(1), pp. 45–51. doi: 10.1177/1355819614551848.

Parsons, D. W. (1995). *Public policy: an introduction to the theory and practice of policy analysis*. Aldershot: Edward Elgar.

Popay, J., & Collins, M. (2014). *PiiAF The Public Involvement Impact Assessment Framework Guidance,* Lancaster, Lancaster University.

Renedo, A., Komporozos-Athanasiou, A., & Marston, C. (2017). Experience as Evidence: The Dialogic Construction of Health Professional Knowledge through Patient Involvement. *Sociology*, 003803851668245.

https://doi.org/10.1177/0038038516682457

Salter, B. (2003). Patients and doctors: Reformulating the UK health policy community? *Social Science and Medicine*, *57*(5), 927–936.

Shippee, N. D., Domecq Garces, J. P., Prutsky Lopez, G. J., Wang, Z., Elraiyah, T. A., Nabhan, M., Murad, M. H. (2015). Patient and service user engagement in research: A systematic review and synthesized framework. *Health Expectations*, *18*(5), 1151–1166.

Shore, C., & Wright, S. (1997). *Anthropology of policy: critical perspectives on governance and power*. Routledge.

Snape, D., Kirkham, J., Britten, N., Froggatt, K., Gradinger, F., Lobban, F., Jacoby, A. (2014). Exploring perceived barriers, drivers, impacts and the need for evaluation of public involvement in health and social care research: a modified Delphi study. *BMJ Open*, *4*(6), e004943.

Snape, D., Kirkham, J., Britten, N., Froggatt, K., Gradinger, F., Lobban, F., Jacoby, A. (2014). Exploring perceived barriers, drivers, impacts and the need for evaluation of public involvement in health and social care research: A modified Delphi study. *BMJ Open*, *4*(6). https://doi.org/10.1136/bmjopen-2014-004943

Staley, K. (2009). *Exploring Impact: Public involvement in NHS, public health and social care research*. INVOLVE/NIHR.

Staley, K., Buckland, S. A., Hayes, H., & Tarpey, M. (2014). "The missing links": understanding how context and mechanism influence the impact of public involvement in research. *Health Expect*, *17*(6), 755–764.

Staniszewska, S., Adebajo, A., Barber, R., Beresford, P., Brady, L.-M., Brett, J., Jones, D. (2011). Developing the evidence base of patient and public involvement in health and social care research: the case for measuring impact. *International Journal of Consumer Studies*, *35*(6), 628–632.

Staniszewska, S., Brett, J., Simera, I., Seers, K., Mockford, C., Goodlad, S., Tysall, C. (2017). GRIPP2 reporting checklists: Tools to improve reporting of patient and public involvement in research. *BMJ (Online)*, *358*. https://doi.org/10.1136/bmj.j3453

Staniszewska, S., Mockford, C., Gibson, A., Herron-Marx, S., & Putz, B. (2011). Moving forward: understanding the negative experiences and impacts of patient and public involvement in health service planning, development and evaluation. In M. Barnes & P. Cotterrell (Eds.), *Critical Perspectives on User Involvement*. Bristol: Policy Press.

Tsoukas, H. (2017). Don't Simplify, Complexify: From Disjunctive to Conjunctive Theorizing in Organization and Management Studies. *Journal of Management Studies*, *54*(2), 132–153. https://doi.org/10.1111/joms.12219.

Walshe, K., & Davies, H. T. (2013). Health research, development and innovation in England from 1988 to 2013: From research production to knowledge mobilization. *Journal of Health Services Research & Policy*, *18*(3), 1–12.

Ward, P. R., Thompson, J., Barber, R., Armitage, C. J., Boote, J. D., Cooper, C. L., & Jones, G. L. (2010). Critical perspectives on "consumer involvement" in health research: Epistemological dissonance and the know-do gap. *Journal of Sociology*, *46*(1), 63–82.

Weiss, C. (1977). The many meanings of research utilization. *Public Administration Review*, *39*, 426–431.

Wicks, P. *et al.* (2018) 'Patients' roles and rights in research', *BMJ (Online)*,

362(July), pp. 1–2. doi: 10.1136/bmj.k3193.

Wilsdon, J., Wynne, B., & Stilgoe, J. (2005). *The Public Value of Science: Or how to ensure that science really matters*. *Demos*.

Wilson, P., Mathie, E., Keenan, J., McNeilly, E., Goodman, C., Howe, A., … Peckham, S. (2015). ReseArch with Patient and Public invOlvement: a RealisT evaluation – the RAPPORT study. *Health Services and Delivery Research*, *3*(38), 1–176.

Yanow, D. (2015). Making sense of policy practices: interpretation and meaning. (D. Torgerson, A. Durnova, M. Orsini, & F. Fischer, Eds.), *Handbook of Critical Policy Studies*. Cheltenham, Glos.: Edward Elgar Publishing.

Appendix 1: Method

This project comprised three overlapping stages of work.

In Stage 1 we undertook a literature review and analysis of relevant policy/strategy documents. We also explored the healthtalk.org database of interviews with patients and the public about their experiences of involvement in health care research.

Stage 2 comprised interviews and conversations with key informants. People to interview were suggested by Mark Taylor, who commissioned the research, by respondents, or who we knew to have an interest in the area under investigation. Seven respondents were interviewed (all except one were undertaken by phone):

- Russell Hamilton (Director of R&D, Department of Health 2004 - 16)
- Simon Denegri (National Director for Patients, Carers and the Public, previously chair of INVOLVE)
- Nina Fudge (Research Associate, QMUL, with a particular interest in the role of patients in research implementation)
- Tom Walley (Director NIHR Health Technology Assessment programme)
- Jon Cole (Assistant Director, Public Involvement and External Engagement, NIHR Evaluations Trials and Studies Coordinating Centre)
- Doreen Tembo (Senior Research Manager PPI and External Review, NIHR Evaluations Trials and Studies Coordinating Centre)
- Sophie Olszowski (previously Director of Patient Involvement, NIHR Oxford Biomedical Research Centre)

The following questions were discussed with respondents:

- The original intentions of PPI policy when NIHR was established. One way of thinking about policy analysis is to ask what is the 'problem' that a particular policy is trying to 'solve'. What would you say is the problem to which PPI is a solution?
- How has NIHR PPI policy evolved over the last 12 years? What have been the critical stages in its evolution? How has the language/focus changed over the past 12 years? How has the nature of the partnership with the public changed?
- What is the evidence base for NIHR PPI policy?
- What have been the key influences/drivers/contextual factors on PPI policy development? Have there been key individuals who have influenced policy? In what way/direction?
- What would you say are the defining characteristics of NIHR PPI policy in 2018?

Stage 3 comprised analysis and synthesis of findings. The methodology for this investigation drew on the principles of interpretive policy analysis. This meant that we were interested in the different representations of 'the problem' of PPI, and the assumptions and presuppositions underpinning policy statements and developments. We were attentive to the language used by our respondents and in policy documents, attempting to tease out the meaning that words conveyed. Interpretive policy analysis is concerned with both the historical contexts and 'situated meanings' of issues under investigation (Bacchi, 2009; Yanow, 2015).