Evaluating the impact of patient and public involvement on cancer research outcomes: A UK mixed methods study

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Abstract

Interest in patient and public involvement (PPI) in healthcare research has been growing. In the UK and internationally there is increasing demand for researchers to demonstrate the value of PPI both in their work and to funding bodies. Existing evidence demonstrates that reporting of PPI has been limited and inconsistent. In particular, whilst there is growing evidence about the use and efficacy of PPI in research *processes*, little is known about how to evaluate the impact of PPI on research *outcomes*. The aim of this research was therefore to evaluate the impact of PPI on cancer research outcomes.

An interpretivist and pragmatist methodology was adopted to explore how the impact of PPI on cancer research outcomes can be evaluated, using a mixed methods sequential design. In phase one, 23 in-depth interviews were conducted with patients, researchers and stakeholders from the East Midlands region to explore perceptions of the impact of PPI on research outcomes and their experiences of involving patients and the public in research outcomes. In phase two, a modified Delphi study was conducted with 35 experts across England in order to refine and enhance knowledge about the impact of PPI on research outcomes. Data were analysed using Braun and Clarke (2006). End user involvement was embedded in the study at key stages and evaluated using the GRIPP 2 checklist (Staniszewska 2017). Limitations to this research study included the paucity of black and minority ethnic participants and being only East Midlands focused in phase 1.

Findings from the interviews and the Delphi study demonstrated that there are several factors which shape the impact of PPI on research outcomes. These are: PPI in commissioning; PPI in research processes; PPI in dissemination; PPI in implementation; information and communication technology; power and leadership; resources and the political context; networks; and wanting to make a difference. Data show that the evaluation of the impact of PPI on research outcomes was achievable at four stages: pre-implementation, partial-implementation, during-implementation and post-implementation. Reflexive analysis of the use of end user involvement within the study included a consideration of the challenges of involvement for PhD researchers.

Drawing on theoretical insights about PPI in research and work from the field of implementation science, this thesis makes an original contribution by arguing three main points. First, that PPI can be considered as a complex intervention (Craig et al. 2008).

Second, that as a complex intervention, the impact of PPI on research outcomes can therefore be evaluated using the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al. 2009). Third, using the CFIR, particularly the domain of ‘process of implementation’, enhances understanding about the success or failure of the implementation of PPI in practice. The data highlight particular attention should be given to the time and resource implications required to conduct effective evaluation of the impact of PPI on research outcomes.

Dedication

This thesis is dedicated to a number of people. Firstly, to my feminist aunt Indira Mears. She had no children but was like a mother (and a friend) to me. Benki auntie (as we called her) instilled a feminist streak in me, which later inspired me to study for a PhD. Benki auntie had trained as a social worker, she taught me the importance of taking pride in our background, and to question everything. These ideas have no doubt contributed towards my shaping as a researcher. I know that if she was alive today, she would be one of the first people to read this PhD in its entirely, quizzing and perhaps prepping me for the viva.

This thesis is for my mum and dad, Asha and Dinker, who have done everything in their power to support me throughout life, not just in this PhD venture. There will hopefully be a 'doctor' in the Pandya family, dad, just not the medical sort! Thank you Bro Kam also.

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Thank you, Susan Naylor from the Study Skills Support centre, for the dyslexia support and helping me to think harder about how to convey thoughts into writing.

Away from the institutions, thanks need to be expressed to people in the home environment, where the writing took place because they allowed me to have peace of mind that everything was taken care of. Giving birth, twice, during this study was the easy part (well sort of!) because they say it takes a village to raise children. I say yes to that. My parents, in-laws, friends, neighbours, the schools and nurseries have all, over the last few years helped out with Jasmine and Roisin in one way or another, while I locked myself away upstairs, to write. As a result of their help, Jasmine and Roisin are polite, kind and confident little girls. I cannot take credit for them entirely, because balancing a PhD part time, with a demanding career, and being a mother, altogether in one concentrated space of time is inexplicably challenging, and the truth is, these two girls are what they are because of help and support from others around me – for which I will always be beholden for.

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provoking discussion with me most evenings, inspired and challenged my ideas and assumptions and most importantly - taken care of me. Every day he has provided me with nutrition, comfort and serenity while I wrote. Anybody who has written a PhD, under similar circumstances will know that self-comfort becomes a low priority, not intentionally, but because (apart from the kids) nothing offers comfort like a well written chapter, especially in the last year. Jason whilst looking after the children (and me) did all the shopping, cooking, cleaning, gardening… he has done everything. His love, patience and faith in me has carried me through some of the hardest days. I love you Jason, you deserve a gold medal for spurring me through this.

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Lastly and most importantly, I want to offer my deepest and sincerest thanks to all the participants, without whom this thesis would not have been possible. I hope I have done your views justice.

Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ARCs	Applied Research Collaborations
BME	Black and Minority Ethnic
BMJ	British Medical Journal
CHC	Community Health Councils
CLAHRC	Collaborative Leadership of Applied Health Research and Care
CPPIh	Commission for Patient and Public Involvement in Health
CTAAC	Clinical Trials Awards and Advisory Committee
DH/DHSC	Department of Health (and Social Care)
EuPATI	European Patient's Academy for Therapeutic Intervention
GP	General Practitioner
HEFCE	Higher Education Funding Council for England
HIV	Human Immune Virus
HTA	Health Technology Assessment
ICT	Information and Communication Technology
LGBT	Lesbian Gay Bisexual Transgender
LINks	Local Involvement Networks
MP	Minister of Parliament
MRC	Medical Research Council
NCRI	National Clinical Research Institute
NHS	National Health Service
NICE	National Institute of Health and Clinical Excellence
NIHR	National Institute for Health Research
NVIVO	Name of a data software used to help with qualitative research analysis
PALs	Patient Advisory Liaison Services
PCT	Primary Care Trust
PhD	Doctor of Philosophy
PPI	Patient and Public Involvement
PROMs	Patient Reported Outcome Measures
RCTs	Randomised Controlled Trial
RCUK	Research Council United Kingdom
RDS	Research Design Service
REF	Research Excellence Framework
RfPB	Research for Patient Benefit
UK	United Kingdom
USA	United States of America
WT	Wellcome Trust

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Chapter One: Introduction

Introduction

Patient and public involvement (PPI) in healthcare research has taken centre stage in the research landscape in recent years and this is a thesis that aims to explore how its impact might be evaluated. PPI in research is defined as *'doing research with or by people, not to, about, or for them'* (INVOLVE 2012). Whilst a great deal of attention has been given to evaluation of PPI in and on research processes, less attention has been paid to how involving patients and the public in research might shape its outcomes. It has been suggested that post research plans frequently fail because the use of PPI is underdeveloped in implementation programmes (Savory 2010). Similarly, understandings about the impact of PPI on research outcomes are underdeveloped in part because of not knowing what and how to evaluate such impact.

This thesis draws on concepts from implementation science to explore the impact of PPI on research outcomes. Implementation science is defined as the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and hence, to improve the quality and effectiveness of health services and care (Eccles and Mittman 2006). Implementation research attempts to understand what implementation plans work for whom and in what context. It uses theoretical frameworks that can help to guide data collection, analysis, and interpretation of implementation processes (Kirk et al. 2015). Therefore, a question at the heart of this study is whether the impact of PPI on research outcomes is evaluable using implementation theory.

This chapter establishes the themes that underpin this study. It will introduce PPI in healthcare research, how PPI came about, and how it operates in the UK context. This is followed by a discussion about research impact and the gap between research and practice. Observations are made about the researcher's practitioner role, which triggered ideas for the current PhD study and its particular focus on cancer research. Finally, the

chapter offers insights into the end user involvement present throughout this study, a justification, the aims and objectives. Lastly it offers a chapter by chapter synopsis.

What is 'PPI' in 'healthcare' and 'research'?

It is important to carefully consider the terms applied throughout this thesis and a brief overview is offered here, before terminology is considered in more detail in the next chapter. Terms of particular significance (and already used here) are: 'patient and public', 'involvement' and 'healthcare research'. In this study 'patient and public' broadly refers to 'non-specialist' input in healthcare decisions (Frederikkson and Tritter 2017). The word 'involvement' draws from the INVOLVE (2012) definition, set out above. This definition encompasses an active input that people have in the research process. Finally, 'healthcare research' is considered as the NIHR definition:

> Research is about finding out new knowledge that could lead to changes in treatments, policies or care. There are many different types of research from studies in a scientific laboratory to those that observe and examine people with different conditions or develop new treatments. Research might be concerned with preventing disease and promoting good health or finding out people's experience of different services and support in the community.
>
> (NIHR 2018, para. 1)

PPI in healthcare research: an evolving phenomenon

PPI has been set as a global policy imperative by the World Health Organisation (WHO). The declaration of Alma Ata (1978) stated that: '*…people have the right and the duty to participate individually and collectively in their health care'* (WHO Alma Ata Declaration 1978 [no page number listed]). Yet in the UK, PPI was not implemented with conviction until serious clinical and health service failings occurred (Kennedy Report 2001). These clinical breakdowns highlighted that PPI could be one way of delivering safer care and a method of improving health service accountability via a move away from paternalism towards patient empowerment (Ocloo and Fulop 2011). Within the UK, the government embraced the following principle from the NHS constitution: '*The patient will be at the heart of everything the NHS does'* (Department of Health 2009). Many other countries also involve the patients and the public in healthcare governance and decision-

making, including Australia (Todd and Nutbeam 2018), North America (Frank et al. 2014), Canada (Boivin et al. 2014) and countries across Europe (Brett et al. 2010).

Research involving patients and the public will affect all disease areas. PPI can be non-disease-specific too, e.g. in routine healthcare planning and development or in accident and emergency settings (Bridges 2010). PPI operates in primary care (Coulter 2005), in secondary care (Doherty and Doherty 2005), and in tertiary care (Carlet et al. 2004). It can be found in healthcare audit (Le Var 2002), healthcare evaluation (Gagliardi et al. 2008) and in healthcare research (Brett et al. 2014). This thesis specifically addresses PPI in healthcare research and research evaluation.

Since 1997, the discourse and direction of PPI in UK healthcare has evolved considerably (explored in chapter two). PPI has been politicised as a way of servicing a spectrum of needs for government, for the patients, and for the public. These needs range from increasing peoples' democratic rights, through to legitimising healthcare services to help address public concerns (Forster and Gabe 2008).

In parallel to these wider developments, PPI has become commonplace in research. PPI in research is underpinned by what Snape et al. (2014a) defined as 'intrinsic values'. The public have an entitlement to be involved in the research process, they have the right to say what research is undertaken and importantly, for this research, they have the right to shape how research is used. If we acknowledge that different types of knowledge are important, then members of the public will have a unique knowledge to offer healthcare practice (Snape et al. 2014).

PPI in research embraces a variety of activities carried out with patients and the public (Pandya-Wood and Robinson 2014). Involvement might include participation in one or more ways of helping to set a research question (Batchelor et al. 2013), developing a research design (Walker and Pandya-Wood 2013), collecting and analysing data (Brett et al. 2010; Pandya 2007), and disseminating research and planning for implementation (Gray-Burrows et al. 2018; Rivas and Pandya-Wood 2014). These activities are often

carried out at different levels with patients and the public, ranging from consultation through to deep collaboration or even user-led work (Fleming and Hudson 2007). PPI can be '*spontaneous or planned…invited or sponsored… [people engage in a range of ways], by gathering data through to challenging theory'* (Madden and Speed 2017 p1). Despite all the different ways that research studies involve people, and the extent to which this is meaningful, PPI can run the risk of being '*insignificant, tokenistic, and overly managerialist'* (ibid p.2). Consequently, some studies will thrive whilst others will fail, and in some cases, this may be on account of the extent to which PPI is meaningful and impactful. This study seeks to better understand what factors might allow for such success or failure.

The research impact agenda

Through investment in research, development and innovation, the UK aspires to be a world class research facility. In 2016 alone, the Office of National Statistics (ONS) indicated that expenditure on research and development reached its highest level on record at £31.8bn[1]. At the same time, some £1.37bn was spent by the National Institute for Health Research (NIHR) (NIHR 2016), which is the research arm of the National Health Service (NHS). In 2017, this figure was supplemented by a research spend of £816m for health and social care research managed by the Department of Health and Social Care (DHSC 2016).

Health research, by its very nature, is focused on impact and alongside the shift towards PPI in research, every funded healthcare research study must now include an impact plan that involves patients and the public. To assess the impact of funded research and avoid waste, the NIHR uses the Added Value Framework (Chalmers and Glasziou 2009). From investigating digital and technological solutions to developing new drugs to perform precision medicine, the work of the NIHR is focused on funding health and social care research and translating discoveries into practical products, treatments, devices and procedures, whilst involving the patients and the public in all of its work (NIHR 2018).

[1] Research expenditure https://www.ons.gov.uk/economy/governmentpublicsectorandtaxes/researchanddevelopmentexpenditure/bulletins/ukgrossdomesticexpenditureonresearchanddevelopment/2016

The routine involvement of patients and the public affected by the research (or the work carried out in research centres) is therefore compulsory for NIHR-funded research. Other UK research funding bodies including Wellcome Trust, the Research Council United Kingdom (RCUK) and specialist research charities such as Cancer Research UK have all dramatically increased their emphasis on the need for PPI (Hughes and Duffy 2018) and the need for demonstrating research impact (ibid).

The Higher Education Funding Council for England's (HEFCE) Research Excellence Framework (REF) set out new expectations that academic research needed to demonstrate 'impact', defined as: '*an effect on, change or benefit to the economy, society, culture, public policy or services, health, the environment or quality of life, beyond academia*' (HEFCE 2011). It was clear that REF impact and the impact of PPI on research outcomes concerned similar issues, i.e. the impact of research at an implementation level in healthcare (beyond the research dissemination stage).

However, despite the emphasis on impact, REF has posed a challenge for understanding the contribution of PPI, notably since knowledge on PPI outcomes is limited (Caress 2014). There are also methodological problems in trying to attribute research outcomes to the involvement of patients and the public. This present study is therefore exploratory in nature, it does not seek to prove a causal link.

The working definition of impact used within this study is any effect or outcome outside the research which occurs as a result of the research, usually after some form of dissemination has taken place (Rivas and Pandya-Wood).

The research and practice gap and PPI

Understanding the impact of completed research studies on health and social care services is generally unclear (Morris et al. 2011; Butler 2008; Norman 2010; Bero et al. 1998). Implementation science attempts to investigate and address this gap, offering researchers a plethora of informed and evidence-based ways for mapping how to instigate change in the complex and dynamic healthcare environment made up of interacting components of context, people and processes (Campbell et al. 2007). Whilst implementation processes

attempt to help close the research and practice gap, there continues to be a challenge. This gulf between research and practice mirrors a *general* implementation problem globally, i.e. the 'know-do gap' (Pablos-Mandez and Shademani 2006). *Specifically*, for PPI in research, the gap highlights that whilst the literature suggests that PPI helps the research process by prioritising what to research, how to research, what the findings mean and how they might be communicated (Staley 2009), we know very little about the impact of PPI on research outcomes (Brett et al. 2010). Meanwhile, the patients and the public who might have helped during the research processes, and who invested their time, do not always see change.

There continues to be little evidence on how PPI makes any difference to the outcomes of health research (Shippee et al. 2013; Snape et al. 2014; Mockford et al. 2011, Mathie et al. 2014; Evans et al. 2014; Brett et al. 2014). Researchers have begun to highlight that this apparent lack of evidence may be due to poor quality reporting of PPI in research (Staniszewska et al. 2011). Some researchers question whether PPI is really worth the effort if it does not achieve anything (Petit-Zeman and Locock 2013). As a result, PPI could become vulnerable to poor practice or tokenistic use.

Conceptualisation of this study and the researcher's role

The research idea at the heart of this study first emerged in 2008, when the author was new in post working as a PPI in Research Advisor as part of the NIHR-funded regional Research Design Service[2] based in the Centre for Social Action at De Montfort University (a role still held but now based at the University of Leicester). It was felt during frontline advising that public sector researchers were yet to fully embrace involvement ideas because frequently during PPI advising sessions, researchers would be concerned about the added time and resource implications.

Being new in the public-sector role, with a background in community research and development (in HIV and substance abuse), it was observed that PPI in research was seen

[2] The NIHR funds roles such as the current researcher's, which focus specifically on 'front line advising' on PPI in research design and helping researchers to prepare research grant applications for national peer-reviewed funding competitions. with members of the public and patients to gain mutual understanding about how PPI can enhance particular research studies.

as a burden for some clinical researchers. Although there was an expectation from the then Department of Health (DH), now Department of Health and Social Care (DHSC), that all researchers were intrinsically in favour of its values (Harrison and Mort 1998), this was not always the case in practice. Taking aside the rich value base that underpins PPI, for clinical researchers, involving patients and the public was often seen as something of an inconvenience (Madden and Speed 2017). Thus, not only were clinical researchers having to demonstrate PPI in the planning of research to convince those peer-reviewing their research application on funding panels, they were also expected to accept the ethos of PPI seemingly without question. Some researchers entertained the idea of PPI because it was a mandatory requirement, not because they necessarily believed in it, nor that they saw its value.

It was decided after these observations that a research study was necessary. Following extensive conversations, which were later understood to be consultation work (Fleming and Hudson 2007) with public members and academic researchers in social action and health, the topic of cancer was deemed as an appropriate area of health and illness as a context for the current study. This was appropriate for a number of reasons. Firstly, more than one in three people will be diagnosed with a cancer in their lifetime and cancer research translation remains an important NHS priority (Cancer Research UK 2011). Secondly, cancer research is one area where PPI is already advanced (Stewart et al. 2011; Hubbard et al. 2007), meaning there are a plethora of completed research study examples with PPI. Thirdly, the choice of cancer as the topic would allow for targeted data collection. Finally, the focus on one disease also allowed the current researcher some rigour and replicability, as empirical work would be richer, fuller and more detailed, building understandings of perceptions and accounts of involvement that professionals, patients and the public offered.

Given this PhD was a study about PPI, it was important to involve people who were potential end users, such as researchers/academics, healthcare professionals, and patients and the public. Inviting input from these groups at key stages offered an opportunity to ask important questions about how PPI in research and implementation are connected. To keep the work focused on the aims (which are identified below), this study has had

deliberation embedded in its design (explained in depth in chapters four and nine). Suitable researchers and academics were involved via university research networks. Patients and the public were found through working in the PPI role. When involvement was planned with patients and the public, the opportunity to input this work was made possible by patient forums the researcher had set up in her professional work. Thus, members of the public and patients were already interested in the impact of PPI and this research. Some were affected by cancer research themselves, they were all geographically close in proximity, willing to help, interested in the study and available to offer comments at a given time (Dörnyei 2007). A variety of end users were invited to offer their input during research design and analysis. Towards the end of the study, end user workshops were also held to help untangle the originality of the study. A journal was kept of key influences of encounters with end users. No funds were available to carry out the end user involvement, but the researcher felt that input from end users has been invaluable to this study, by adding a layer of scrutiny and reflection. Further reflections on involvement in this study are explored in chapter nine.

End user involvement has taken place throughout this study. To demonstrate how the involvement has shaped the process of research and when, a table in chapter 4. draws on the Guidelines for Reporting Involvement of Patients and Public 2. Model (Staniszewska et al. 2017). The table 6 explains who was involved, the stage of the study, the level of involvement, the nature of involvement, what was raised by end users, what was used in the study, and finally, the context and the application of theory influencing end user involvement.

Additionally, in chapters one, four, five, six, seven and eight, a text box has been included to show how involvement influenced that particular stage of the research. Finally, chapter nine is dedicated entirely to providing a reflection of the dilemmas experienced in relation to end user involvement in this study.

Justification of this research

As this chapter has shown, interest in PPI in healthcare research has grown significantly. At the same time, there has been increasing demand for researchers to articulate and demonstrate the value of PPI to national funding bodies. While there is now evidence

about the benefits of public involvement on the *process* of research (Staley 2009), we still do not know specifically whether and how PPI makes a difference to research *outcomes* (Mockford et al. 2011), nor do we have sufficient understanding of the types of issues which affect the implementation of PPI informed research findings into policy and practice (Staniszewska 2011).

There is a dearth of published high-quality research assessing the impact of PPI (Staniszewska et al. 2017) and the possible reasons for this include that evaluation may be too difficult and that PPI is thought to be of intrinsic value and therefore needs no further justification (Snape et al. 2014). At an implementation level, difficulties exist for clinicians, patients and managers in healthcare settings in transferring research into policy and/or practice (Forbat et al. 2009). The present study was therefore designed to address these knowledge gaps.

Aims and objectives

This exploratory and inductive social science research study aims to advance knowledge about how to evaluate the impact of PPI on cancer research outcomes. The objectives are:

1. To explore perceptions and experiences relating to the impact of PPI on research outcomes amongst patients, researchers and stakeholders involved in cancer research
2. To identify factors which affect the implementation of PPI informed research findings in policy and practice
3. To enhance and refine understandings of factors that shape the impact of PPI
4. To enhance knowledge and understanding about the link between implementation theory and how evaluation of impact of PPI on research outcomes might be achieved.

Structure of the thesis

This thesis is organised into ten chapters including this one. Chapter two presents a policy overview of PPI in UK health research, clarifying terminology and exploring debates on what PPI in healthcare and research seeks to achieve. It describes the underlying

ideologies (democratic and technocratic) that have shaped the politics of PPI. Relevant social and healthcare policies are reviewed, leading the author to conclude that PPI sits both within a neoliberal agenda but also poses challenging questions for neoliberalism.

Chapter three presents a critical narrative review of what is understood by 'research impact' along with the 'impact of PPI on research process and outcomes'. This chapter leads the author to argue that progress has been made to understand the impact of PPI on research processes, but not on the outcomes. It is argued that implementation science, as a field of activity, could advance thinking for the current research question.

Chapter four is a methodological chapter in which the study design, methods selected and ethical issues and are discussed. The involvement of end users is described in detail and a snapshot of the sample is offered along with information concerning their demographic profile.

Chapter five is the first findings chapter, exploring how participants gave meaning to the impact of PPI on research outcomes. The chapter presents seven factors thought to shape PPI on research outcomes, drawing on 23 interviews conducted with patients and the public, researchers and stakeholders. The chapter explores how these factors acted as barriers or facilitators towards achieving the impact of PPI on research outcomes and identified the importance of context and processes in shaping outcomes.

Chapter six presents the findings drawn from a three-round Delphi survey with 35 panellists. During the Delphi survey, panellists reviewed and enhanced the seven factors set out in chapter five and introduced a further two factors. The collective nine factors of PPI were then situated at micro, meso and macro levels and a definition of the impact of PPI was formed offering insights into what impact of PPI is enveloped by.

Chapter seven presents six examples drawn from the data. This chapter explores: a) what PPI activity enabled the impact within the example; b) why participants felt that factors

of PPI influenced the ability to have this impact; and; c) how PPI on research process and outcomes are conceptualised for evaluation.

Chapter eight, the discussion, draws the findings together and sets out the original contribution to knowledge. The chapter positions PPI as a complex intervention (Craig et al. 2008) and one which can be subjected to evaluation as such using Damschroder et al.'s (2009) Consolidated Framework Implementation Research (CFIR). This original contribution offers new ideas that support the evaluation of PPI and highlights challenges for addressing the impact of PPI. It demonstrates that the current study findings can be mapped out using the domains of CFIR: intervention characteristics, outer settings, inner settings, characteristics of individuals involved, and the process of implementation, but pays particular attention to the latter domain.

Chapter nine is a critical reflection of conducting PPI in this PhD study. It explores the epistemological tensions of doing PPI in the context of a doctoral research study and considers how barriers were overcome.

Chapter ten, the conclusion, describes how the aims have been achieved and the implications of the study. The chapter also sets out the limitations of the study. It identifies further research and recommendations in the field and argues that the current study has advanced the field of PPI evaluation and PPI in implementation.

End user involvement influencing this phase/chapter

December 2009 - Conceptualisation of the study. Involvement in the form of **consultation** took place **on a one-to-one basis** with 6 people: researchers, PPI staff, patients and public. These conversations took place following a national meeting about PPI and impact. This led to the development and refining of the objectives of the current research and the need to have a specific health area (cancer) as a focus for the study.

April 2011 - Conceptualisation of the study. Involvement in the form of **collaboration** via a workshop with 8 academics at De Montfort University. This led to understanding the need for having PPI in the study itself.

Chapter Two: Overview of PPI in health and research in England

Introduction

There are two literature chapters in this thesis. This chapter is a policy overview of PPI in health research and the next literature chapter is a critical thematic narrative review. The focus of this chapter is on the policy, practice and theory of patient and public involvement (PPI) in healthcare services and research in the UK. The purpose is to contextualise the recent and rich evolution of PPI from healthcare to research within the political and theoretical landscape[1].

There are four broad sections in this chapter which help to set the context for the thesis. The first section draws attention to the terms used across the literature and helps to set the scene about the roots of PPI and how policy (and with it) terminology has evolved. The second section offers understandings about the rationale and ideology of patient and public involvement in healthcare arguing that democratic and technocratic principles guide involvement policies. The third section of this chapter traces neoliberalism in PPI in healthcare policy. The idea of PPI is critiqued, as is the rhetoric used by politicians. The fourth section focuses specifically on research policy concerning PPI and offers a critique of the *Going the Extra Mile* (GEM, 2015) recommendations. Through the critique, issues about the quality and power-sharing of PPI in research are raised by considering theory-based models such as the commonly used Arnstein's Ladder of Participation (1969). The critical theory of Habermas (1987) has been threaded in to this last section, as it helps to analyse the GEM report recommendations. It is worthy of note that this fourth section is long but highly necessary because the GEM policy is the only PPI specific research policy that situates the government's thinking relating to the current thesis. The GEM report recommendations will be analysed to help gain a sense of PPI principles and the values placed on PPI in research. Analysing each recommendation

[1] The discussion in this chapter uses materials from a mix of sources including select papers from the critical thematic narrative review (next chapter), recent policy documents, critical theoretical literature from books, funding websites and grey literature from conference proceedings.

offers insights into context and process of PPI in research (context and process are running themes in the entire thesis).

By collectively exploring these entwined four sections concerning PPI, a concluding summary is offered at the end, in which it is argued that PPI in research practice is steadier than in health services. It also concludes that the 'impact of PPI' question stems from neoliberal thinking but also threatens neoliberalism.

Section 1. Terms used in PPI

This study uses the widely accepted term 'patient and public' but it is important to clarify that within the literature sources used, different terminology was referred to for patients and the public involved in healthcare and research. Whilst placing people in neat categories is not the purpose of the study, it is important to acknowledge the difference between those who are professionally involved in health research, i.e. salaried workers in healthcare versus those who are people involved in the research because of their illness and experience. Thus, a critique is offered about some of the assumptions and connotations which are associated with the terms.

Commonly used terms found in the literature included consumer, service user, user, client, lay person, expert by experience and expert patient. There were other labels too, but these ones particularly were frequently referred to. Each label listed here has positives and negatives associated with it and while the label may define someone's status it also carries weight beyond its definition. The term 'consumer', whilst implying choice of care, has been critiqued as suggesting a market-based consciousness that the patient is a customer, that the NHS is a market and the doctor is a provider (Boote et al. 2002). 'User' or 'service user' similarly, at face value, implied ensuring the suitability of the service (DH 1998). However, it would commonly be associated only with those who had a history of substance abuse or mental health (McLaughlin 2008) leading to confusion about its transferability. The name 'client' was widely used in the UK to describe a social work relationship between social workers (including hospital social workers) and the people they protect (McDonald 2006 in McLaughlin 2009). However, client has negative constructions associated with it too, mainly to suggest those who are clients are often in

need of something (McLaughlin 2008). The label 'lay person' may distinguish from someone who is not a professional in healthcare, but it also suggests the person is present with less knowledge, even though they may have another profession (Thompson 2009). Despite this, in the absence of universally accepted terminology, occasionally 'lay' will be used in this thesis mainly to distinguish between healthcare professionals who are salaried workers versus those who are there because of their lived experience. 'Expert by experience' or 'expert patient' are the final terms scrutinised because it makes a claim for specialist knowledge about a health condition which is framed from the view of the patient with the lived experience (McLaughlin 2008). The term 'expert patient' has gained currency via the government over the last few years, e.g. the Expert Patient Programme (Donaldson 3003). The name implies that '…*[they] have the confidence, skills, information and knowledge to play a central role in the management of life with chronic diseases'* (DOH 2001 page no unavailable). The problem with this term however is that it paints a picture of a patient who has researched their illness and demands improved treatment, which is expensive, unsuitable and one that the clinician does not know about (Shaw 2004). But, the term also suggests a degree of power that the other terms do not quite capture. In this work 'expert patient' will be used in the methodology chapter and in the findings (chapter six) to distinguish patient participants from other 'expert' participants.

Summary of section 1. Terms used in PPI

In this first section terminology concerning PPI has been explored. Ultimately what each of these terms describe is the unequal relationship between those in power and those outside it. They demonstrate that terms range from those which are passive to those which imply levels of knowledge about health and disease. In the previous chapter a summary of key terms used in this thesis and their definitions has been offered. Paying attention to terminology matters because underpinning the discourse of labels and names are questions concerning ideology, to which we now turn our attention.

Section 2. The rationale and ideology behind patient and public involvement in healthcare

Since the 1970s, UK governments have pursued various policies to enable PPI in healthcare underpinned by a combination of two stances: democratic (attempting to legitimise services), and technocratic (improving services to suit people better).

Democratic

Abelson et al. (2003) argue that involvement improves the accountability of public services, and in turn contributes to addressing a wider but contentious 'democratic deficit' in public life (Flinders 2015; Warren 2009; Wood 2010). By improving accountability, PPI offers a democratising influence, and enhances the legitimacy of public services and administration. This accountability in turn offers engagement as a means of tackling often entrenched policy problems. Abelson et al. (2003) argue that the trend of involvement in governance suggests policymakers want a more sceptical and critical public, where involvement provides a way to harness popular rejection of paternalistic healthcare models of governing. This basis for involvement would appeal to the principles of individualism and autonomy whereby people become self-governing and rely less on the state (Schofield 2002), echoing the neoliberal challenge to professional power. Such principles are in tension with collectivism. Consumerism, choice and meeting the needs of a demanding public in healthcare are framed in 'market' terms, rejecting the 'one size fits all' approach to healthcare provision (Clarke et al. 2007). As a result, participation offers both co-operation between services and the 'demanding public', and serves as an instrument for self-governance within communities (Schofield 2002).

Technocratic

In contrast, a technocratic rationale for improving PPI in healthcare, as Beresford (2005) argues, concerns the intimate link between people's personal experience of a health condition and having a greater say in controlling their own lives. The ideological characteristics of this concern the struggles experienced by people regarding unequal access to services (a thread running through this chapter), a point which is important because it suggests that activism and agency can improve services. The driving factors for change are therefore equality and empowerment (Barnes et al. 2004), but the focus on service improvement is technocratic by nature.

The welfare state has faced criticism as being inflexible and bureaucratic (Hogg 2009), and from the 1970s onwards, became increasingly challenged by equality-based movements, for example disability activism (Barnes 2003). People's experiences and experiential knowledge became important in offering medicine the lay perspective (Popay and Williams 1996: Epstien 1996) but with the issues of lay and professional knowledge came questions of who has the power (Milewa et al. 1999).

Both the democratic and technocratic stances have seen a rise in the public becoming sceptical because of changing (healthcare) structures and expectations in society (Giddens 1991). Some public doubt probably comes from the rising and falling of patient- and public-focused organisations such as the Community Health Councils (CHCs) and Patient and Public Involvement Forum(s) (PPIF) (discussed later). But being involved in government dealings beyond voting is attractive to sections of the public and to some extent the government too (Martin 2007). Each rationale suggests different outcomes attributable to involvement (Montpetit 2008) and people will have different motivations for engaging.

Democratically driven involvement expects improved accountability and individualistic responsibility (Truman and Raine 2002). In contrast technocratically driven policy characteristics concern improving the quality of a service by using people's experiences, ideas and knowledge (Prior 2003). In healthcare research, as the chapter will move onto later, the ideas of these rationales extend to the person(s) involved being the co-producer(s) of research (Greenalgh et al. 2016), as they help to generate useful questions to address healthcare problems and potentially improve translation of research into practice (Rycroft-Malone et al. 2016).

To whom PPI policies appeal to

The people to whom technocratically driven policies appeal may well be different from those who respond better to the democratically driven ones. In both cases though, the issue of representativeness and whose knowledge is being used to inform the services is often inadequately addressed (Crawford et al. 2003). Some involvement plans expect

elected members of the public, some random selection, and some stratified selection, which guarantees *'representation of different demographic groups, for example those of different ethnicities, socio-economic (backgrounds and ages) and election'* (Martin 2009a p4). Each of the approaches to representativeness comes with problems of whose views are being used and whose views are trustworthy (Martin 2009b).

The democratic ideology is a mixed spectrum of genuine democracy on the one hand and a challenge to the effectiveness and efficiency of services on the other. The technocratic ideology concerns improving the integrity of healthcare services using people's daily experience and knowledge of struggles. Despite their differences, both ideologies of involvement contain within them notions of 'democracy' in healthcare services. However, this presents one acute challenge, that of 'representativeness'.

Involvement opportunities are often undermined or controlled by the powerful (Beresford and Campbell 1994) and as a result involvement can often be merely an act of tokenism, manipulating PPI processes to advance professional interests (Milewa et al. 1999). Martin (2008a) has argued that because involvement initiatives are not representative, they could be understood as a distortion of participation policy whereby outcomes of who gets involved will be contingent on micro-level negotiations. The problem of legitimacy of knowledge begins at self-selection because those that come forward are often from middle-class cross-sections of society (Church et al. 2002) or 'pale, male, and stale' (Flinders et al. 2011). Harrison and Mort (1998) call the legitimacy issue a 'technology of legitimation', implying professionals use certain voices over others to suit their own agendas and yet at the same time reject certain views, claiming those voices are rejected because they are 'unrepresentative' (Barnes 1999. p79). Martin (2008b, p.1758) argues that this is a case of 'acute hypocrisy' using Beresford and Campbell's (1994) work to confirm his own analysis of representativeness, arguing that this is a 'no win' situation. Learmonth et al. (2009) summarise this paradoxical situation that people have to be 'ordinary' to represent their community but if they are ordinary, they cannot effectively represent their community.

As already discussed, PPI is delivered via a complex infrastructure of services in England. The third sector is a significant contributor to healthcare. Patients and the public

contribute to the shaping of health care via the third sector in a number of ways, including contributing to the development of health policies and campaigns and by setting research priorities and resource planning. Patient groups, set up by the third sector, are also involved in identifying ethical and best practice in treating particular diseases (Baggott and Jones 2018). However, whilst these tasks and roles are important in the running of health services, questions remain about whom these individuals and organisations represent and precisely who holds power to exert influence.

Community participation in the third sector offers a way for people and groups to legitimise their own knowledge claims and experience of health and disease (Renedo and Marston 2011). They may do this for technocratic or democratic reasons, or a combination of both, which in turn can potentially lead to disagreement amongst advocacy groups. For example, groups might seek to draw on combined experiences of a disease or prioritise the needs of an individual citizen with their unique experience of disease. Further, Baggott and Jones (2018) suggest that some patient groups may not be representative in the absence of formal membership processes. Yet, if such groups can draw on the solidarity, expertise and support from the wider public, their knowledge claims will be considered more authoritive or legitimate when exerting power and influence. Researchers therefore need to be mindful of 'whose voice' is represented through third sector PPI. Through considering third sector organisations, we can identify challenges of representativeness that are very similar to those found in debates within the public sector.

Summary of section 2. The rationale and ideology of patient and public involvement in healthcare

In this section of critiquing democracy in healthcare services, the drivers of democratic and technocratic policy understandings have been formed. On the one hand problem policy attempts to fix a democratic deficit and on the other it serves a purpose to legitimise healthcare. The problem of representativeness has been summarised. It is argued that people involved may not have the organic (and networked) connections that healthcare needs thus people are not representative of the populations affected by the problem issue. This may further exacerbate any democratic deficit and health inequalities (later it will

be argued that a similar problem exists in healthcare research). In the next section the policies and rhetoric around PPI initiatives are considered to understand the evolution and reshuffling of such initiatives in England, leading to a claim that a strong neoliberal undercurrent runs though policy.

Section 3. Tracing patient and public involvement in healthcare policy

The government's ambition for the health service when it was first set up was to have a centrally controlled public service, but policy concerning PPI was limited before 1973 (Toth 1996). Healthcare began as a collective movement but ended up turning into an individualism agenda, resulting in a weaker universal healthcare system, and in turn valuing a neoliberal agenda.

Thatcher

Local authorities managed community health services until 1974. After this point, under Prime Minister Wilson, Community Health Councils (CHCs) were introduced in England (and Wales) to endorse local community input in health-related matters. When Thatcher's premiership began in 1979, she had 'different ideas' about how to tackle the problems in the NHS and its relationship to the people using the service (Hogg 2009 p.3). She introduced 'New Public Management' ideas to healthcare and an internal market, notable for its purchaser/provider split). As a result, involvement was increasingly beginning to take place within a consumerist health care agenda. In this new model of health delivery, CHCs were becoming redundant and health authorities became the 'consumer champion' (Hogg 1999). Milewa et al. (1999) argue that health authorities in the Thatcher era were believed to have all the knowledge about what the public needed and wanted from services, but they failed to state who had claimed this position. Thatcher's government saw the possibilities of using individual people to manoeuvre change in her proposed business model of the NHS and the language of 'consumerism' became fashionable. These consumers were understood to help local authorities by expressing their dissatisfaction about the quality of services they were receiving. The consumerist focus (technocratic ideology) therefore dominated over a democratic focus.

Also, during this time, there was a notable move towards people taking responsibility for their own health, a direct challenge to state responsibility for collective healthcare. This permeated different public-sector policies and began to undermine the collectivist and social rights principles of citizenship (Heater 2004). The social rights discourse in citizenship enables a relationship of accountability between public service providers and their users (Barnes 1999). Consumerist ideologies raise questions of how equal access to services and treatments are safeguarded for *all* users because individual consumers are likely to inhibit or prevent collective approaches (Steen et al. 2018). Steen et al. (2018) argue that the employment of individualistic policies by government act as a cover-up for *'minimizing governments' responsibilities and accountability in a context of scarcity of financial resources […and] in social and health care services most specifically'* (p285). Over time, the continual undermining of collectivism has, according to some authors, resulted in increased social inequalities and the reinforcement of ideas about the 'deserving' and 'undeserving poor' (Hogg 2009; Bambra et al. 2010).

Major

The turn towards individualism continued under John Major's leadership of the Conservative government in the 1990s, with an increasing focus on individual responsibility underpinned by a liberal economic agenda. Government interest in community development around this time fitted effortless with its broader aims of decentralisation, voluntarism and consumerism (Farrant 1991). As care in the community healthcare reforms took hold, so too did new codes of practice.

In 1991, a passive Patient's Charter was introduced with the aim of defining rights and standards that the public could expect from the healthcare they received. This was situated as a way for people to be informed about what to expect in order to better benchmark their satisfaction (Coulter 1997). Then in 1992, further attempts were made to strengthen the purpose of involvement, which outlined plans for how health commissioners could involve local people in purchasing agreements (Rhodes and Nacon 1998). This approach continued for five years until the announcement was made to reform local commissioning under New Labour (see below), and Primary Care Groups were established with commissioning responsibilities (Rhodes and Nocon 1998). Public confidence in

healthcare was low by this point, but expectations were rising. Perhaps one contributing factor for low public confidence might have been the serious clinical failings at Bristol Royal Infirmary where 29 babies had died during or after heart surgery (Dyer 1998).

Blair

When New Labour was elected in 1997, Tony Blair's agenda for health became one concerning 'modernisation' of healthcare alongside significant financial investment. The term 'user involvement' started to gain currency, and many of the reforms were arguably a continuation of individualism enacted under Thatcher and Major. Engaging with all citizens, and people understanding their social rights, became guiding policy themes. Amongst many plans, New Labour introduced Health Action Zones to involve local people in decision-making about local health services (Rhodes and Nocan 1998).

Blair's plans were sometimes controversial, for example replacing, in 2003, 185 CHCs with 572 Patient and Public Involvement Forums (PPIF) and Patient Advisory Liaison Services (PALS) (Baggott 2005). The reason for the abolition of CHCs rested in fears that they attracted the 'usual suspects', implying the same people were repeatedly coming forward to represent everyone in society (Hogg 2009). Unlike the CHCs, the PPIFs were linked to institutions, NHS trusts and Primary Care Trusts. Their stated aim was to improve public engagement in NHS organisations but whether and how this happened was unclear. Also, in 2003, the Commission for Patient and Public Involvement in Health (CPPIH) was set up as a non-departmental public body with many responsibilities, including undertaking national reviews of policies and services. However, after just 18 months the closure of the CPPIH was announced. This was because there were concerns about the way in which the CPPIH approached public involvement. Meanwhile PPIFs were criticised for not accurately communicating with or reflecting the views of local communities (Baggott 2005: Forster and Gabe 2008: Tritter 2009). Then in 2006, another new announcement was made that 151 Local Involvement Networks (LINks) would replace the 572 PPIFs. LINks were developed to engage with the local communities and the voluntary sector organisations, but they had no statutory rights (Hogg 2009). LINks focused on commissioning rather than providing services: funding was channelled

through local authorities, which commissioned a local organisation to act as a host for the relationship to be made with people in that locality.

These numerous and rapid reshuffles could have been interpreted as indicating that something odd and unclear was guiding involvement initiatives, perhaps by destabilising the structures representing people using healthcare. The changes also destabilised public understandings of what government was trying to achieve during this period.

Brown

For Gordon Brown's premiership in 2007, the concept of 'engagement' became commonplace. However, inequalities in participation persisted and relatively few people participated in established health forums. More work needed to be done to engage 'hard-to-reach' people. The *Darzi Review* (2007) emphasised the need to give patients and the public better information and more control and influence. However, soon after in 2008, the world financial crisis took hold, followed by a sustained global recession. It was a time of the economic downturn and consequent restrictions to public funds. Austerity took hold with an aim of reducing the budget deficit.

Cameron

In 2010 David Cameron, who had formed a Coalition government between the Conservatives and Liberal Democrats, introduced the 'Big Society' agenda and a number of reforms designed to stimulate 'localism'. For Cameron:

> The Big Society is about a huge culture change, where people, in their everyday lives, in their homes, in their neighbourhoods, in their workplace, don't always turn to officials, local authorities or central government for answers to the problems they face but instead feel both free and powerful enough to help themselves and their own communities.
>
> (Cameron 2010)

Built on his perception of a 'broken Britain', the ideas underpinning the Big Society echoed a return to individual responsibility, rather than state responsibility. A reduction in state 'interference' would mean that individuals and communities would need to work out issues for themselves, with emphasis on civil society rather than the state (Hogg and

Baines 2011). The accompanying localism agenda worked to decentralise power with expectation that local governments and communities would take responsibility, yet no funds were provided for this ambition. The ideology of the Big Society underpins the *Liberating the NHS* white paper, where decentralisation plans are clear: *'Too many decisions have been made nationally, rather than locally, without enough public involvement.'* (Department of Health 2010b). *Liberating the NHS* led to the abolition of LINks, replacing them with 152 local HealthWatch organisations, one for each local authority. HealthWatch England was designed to support the work of the local HealthWatch organisations and recommended inspections of services which appeared to be failing. Reference to HealthWatch was included in the Health and Social Care Act 2012 too, which was developed to help strengthen public power and involvement in health and social care. HealthWatch became established in 2013. After 2013, no public speeches mentioned the Big Society (Levitas 2012), suggesting the agenda has failed to gain public traction.

May

After the resignation of Cameron in 2016, Theresa May became Prime Minister of the Conservative government and to date the NHS remains financially unstable and continues to dominate public policy debate about its funding and priorities. The Brexit negotiations dominate political discourse and meanwhile other social policy has taken a back seat. The language of consumerism remains present (e.g. McCartney 2017), thus maintaining neoliberal thinking.

Summary of section 3 Tracing patient and public involvement in healthcare policy

The purpose of introducing the selected PPI policy initiatives by each government is not to 'skate over' the different structures of involvement at local, regional and national levels. Rather, it demonstrates the continuity and changes in language used and the cycle of centrally driven reform, without clarity, by whosoever sits in power. At best, involvement policy is confused and muddled (Forbat et al. 2009). Ideological difference is demonstrated in tensions between how a policy issue is communicated to the public and how the policy issue is achieved. Instability is clearly exemplified between 2003 - 2013 with three major reorganisations for patient-focused organisations. It seems that no structure could stay for too long, in case it become powerful or genuinely questioning of

decisions on healthcare. Rather than address any democratic deficit, changes could ultimately exacerbate problems of participation. Thatcher's neoliberal ideology was subsequently strengthened and more firmly embedded by her successors (McKee and Stuckler 2011). In the next section the literature focuses on healthcare research, the focus of the current thesis.

Section 4. Tracing policy for patient and public involvement in *research*

Despite the enduring climate of financial austerity, there continues to be an economic imperative to support the development of the UK research and knowledge industry (Carter et al. 2013). Legislative developments, such as the Health and Social Care Act 2012 (DH 2012), have opened the door to the NIHR, working with NHS England and others, to increase opportunities for the public to contribute to research (NIHR 2018). The origins and development of PPI in research policy shall be the focus of this last section in this chapter.

What is PPI in research?

It is now commonly accepted that it may be appropriate to involve people in all stages of the research process, depending on the research project. There are various points where PPI can take place in the research cycle (as shown in figure 1 below).

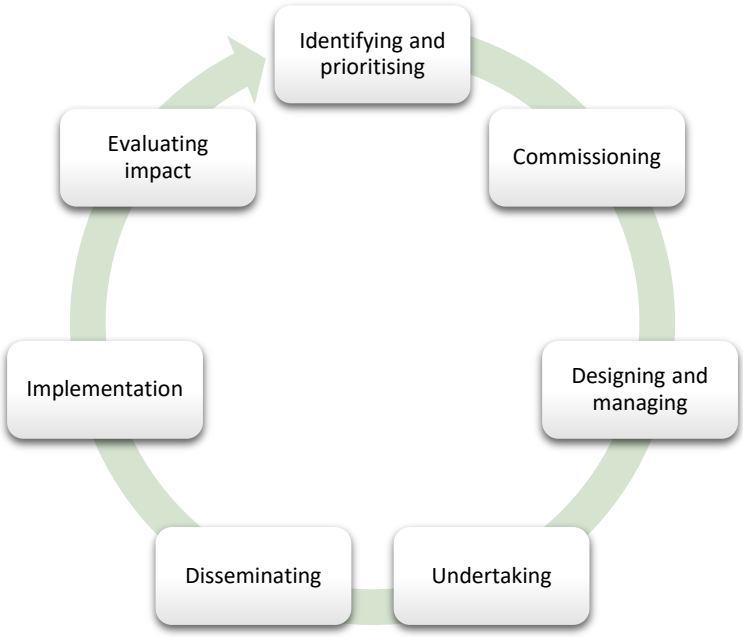

Figure 1 - Research cycle of patient and public involvement

(Pandya-Wood and Robinson 2014)

The extent to which people are involved can vary significantly, from consultative, through collaborative and ultimately to user-controlled involvement (Fleming and Hudson 2009). Whichever stages of the research cycle the involvement takes place(s) in, it is important to clarify the purpose and identify suitable resources (Boaz et al. 2018). There is a growing field of spectra (Hanley et al. 2003), frameworks (Shippee et al. 2013) and models (Forbat et al. 2009) to help understand characteristics of PPI in research. PPI has been documented in a variety of healthcare research areas to have positive outcomes on different stages of the research, for example: winning funding for the research, designing, recruitment, and selecting outcomes (Domecq et al. 2014). In chapter three, the impact on all of the stages of the research cycle is considered in more depth, including the potential for negative impact.

Although from an outsider's point of view it would seem that PPI has been carefully considered and works well in research, at a closer level of scrutiny there are problems of delivery (explained later). Prior to this, a brief history of PPI in research is offered to help situate involvement in research in healthcare in England.

How did PPI in research start?

State funded medical research in England began in 1919 (Medical Research Council 2017) but involvement of patients in research only really started 80 or so years later. In England, clinical trials were inviting patient input around the mid-1990s (see Partridge's contributions in Consumers in NHS Research (now known as INVOLVE) (2000)). According to Thornton (2008), AIDS patients had challenged researchers conducting trials that overlooked patients' preferences of outcomes. Thornton (2008) also argues that in 1997, after an international conference on breast cancer advocacy, there was a notable shift towards 'consumer participation' in the UK. Thornton (2008) identified that 1995 was an important time for PPI in research, as a Health Select Committee report on breast cancer services had faithfully offered an entire section to *'involving patients in research'*. Select Committee members believed that their recommendations would help to improve the standard of care for women in the UK with breast cancer. They also hoped that '*as other specialties follow the lead, they may help to raise the standard of care for all cancer patients'* (Thornton 2008, p904). Since the mid 1990s, government policy documents referring to involvement in research have steadily established the concept of PPI in research (Evans 2014).

Best research for best health policy

An important research policy set out by the DH was *Best Research for Best Health* (2006). The DH endorsed PPI by suggesting that they knew that PPI in research made research more relevant to the needs of the people the research affected. That more reliable knowledge was formed thus more likely to be applied into practice (DH 2006). But people needed to be involved in all stages of the research:

> priority setting, defining research outcomes, selecting research methodology, patient recruitment, interpretation of findings and dissemination of results. We have established structures and mechanisms to facilitate increased involvement of patients and the public in all these stages of NHS Research and Development. […] We will continue funding and developing INVOLVE […]
>
> (Department of Health 2006)

A blanket expectation of involvement throughout the research process has been critiqued on the frontline by researchers because of premature understandings within the policy about what is deemed appropriate and meaningful to achieve a useful contribution for a study (Bagley et al. 2015).

As the statement above suggests the DH promised to support INVOLVE - established in 1996. INVOLVE describes itself as world leading for PPI in research and is one of the few government funded programmes of its kind globally. They have a national advisory group and their role is to bring together insights, expertise and experience to ensure PPI is an essential component to research (INVOLVE 2018). As outlined in the introduction INVOLVE (2018) defines PPI as: *'Doing research with or by people, not to about or for them'*. This definition appeared in over half of the journal papers appraised (in the next chapter), suggesting acceptance amongst scholars in the field. Linked to the INVOLVE, the DH set up the NIHR.

The NIHR is funded by taxation, and as a result, PPI in research retains an important place in healthcare funding. The DH has invested considerably in policy for PPI in health research: the NIHR is a large, multi-faceted and nationally distributed organisation (Harvey et al. 2011). The NIHR vision is: *'To improve the health and wealth of the nation through research'* (NIHR 2013). Its mission is: *'To provide a health research system in which the NHS supports outstanding individuals working in world-class facilities, conducting leading-edge research focused on the needs of patients and the public'*. The NIHR's aims are to:

1. *Establish the NHS as an internationally recognised centre of research excellence;*
2. *Attract, develop and retain the best research professionals to conduct people-based research;*
3. *Commission research focused on improving health and social care;*
4. *Strengthen and streamline systems for research management and governance;*
5. *Increase the opportunities for patients and the public to participate in, and benefit from, research;*
6. *Promote and protect the interests of patients and the public in health research;*

7. *Drive faster translation of scientific discoveries into tangible benefits for patients;*
8. *Maximise the research potential of the NHS to contribute to the economic growth of the country through the life sciences industry; and*
9. *Act as sound custodians of public money for the public good.*

(NIHR 2013)

The NIHR is designed around patients and the public (Green 2015). The target diagram (Figure 2) demonstrates that the different components of the NIHR (faculty, infrastructure and research) all carry out their work plans with the patients and the public at the heart of everything they do. The NIHR's facilities and systems represent an integrated clinical research system and, since its establishment, claims itself to have increased the volume of applied health research for the benefit of patients and the public, driven faster translation of basic science discoveries into definite benefits for patients and the economy, and to have developed and supported the people who conduct and contribute to applied health research (NIHR 2015).

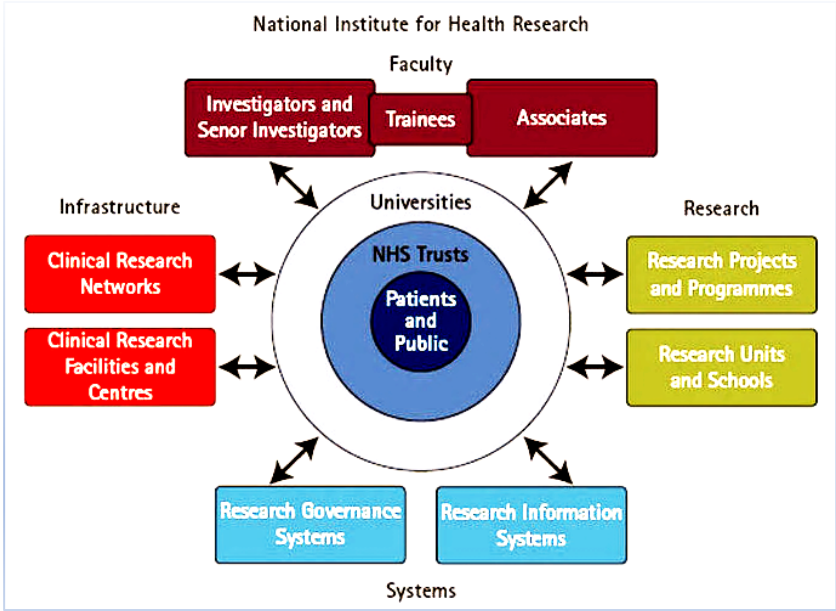

Figure 2 - NIHR Target diagram

To scrutinise just one section of the target diagram helps us to understand the PPI agenda. Under the infrastructure organisations, for example, sit the Research Design Services

(RDS). As mentioned in the introduction chapter the author works in an RDS as a PPI lead. RDS' have a strong but recent foundation in the NIHR. In February 2016, the Department of Health and Social Care (DHSC) via the NIHR, initiated a partnership between the RDS and INVOLVE because it was believed that RDS' had the ability to draw on the expertise of research advisers working on the ground with researchers doing PPI and using real-world examples. NIHR believed the partnership would help inform the development of national policy and guidance, which was technically INVOLVE's sole role before this period. In addition, NIHR believed that the partnership would have the ability to rapidly convey new national policy issues to local researchers.

The ten RDS are split by England's regions and were set up to help researchers to submit high quality research applications for national, peer-reviewed funding (NIHR RDS 2018). A major work stream for all RDS' is to help researchers consider PPI at research design stage. RDS' have facilitated this via a 'Public Involvement Fund' to help pay for early involvement of the patients and public in research design work (Walker and Pandya-Wood 2013). The work of the RDS raises awareness of what good practice at research design stage might look like, with the research community, by considering ethical boundaries and the consequences of close patient contact with researchers before formal ethical approval has been obtained (Pandya-Wood et al. 2017a). They also identify and assist with the types of issues to consider when inviting the input of public co-applicants to help with planning, conducting and disseminating the research study. However, the legal position of involving the (lay) public as co-applicants in research and how these people will be adequately paid, trained and mentored (like the rest of the research team) is under-developed (Pandya-Wood et al. 2017b).

Anticipating the progress made and challenges ahead in PPI in research, and to help plan for the next decade, in 2014 an independent panel conducted a review of PPI in research to help form an overarching PPI in research policy for the NIHR. The consultation with hundreds of public and patients and over 80 national and international organisations, provided evidence and helped to scan the horizons of PPI in research for the NIHR to consider. The consultation's name '*Breaking Boundaries*' implied that the NIHR was aware of the barriers that existed between researchers and PPI. What followed was a

policy report called *'Going the Extra Mile'* (NIHR 2015) outlining a new vision, mission and set of goals for the next ten years specifically to address research-related PPI complexities.

Going the Extra Mile

Going the Extra Mile (GEM) raised 11 recommendations, each of which are explored here, along with a short critical appraisal of what may have been at the heart of the issue that the recommendation is addressing. Critiquing the recommendations individually helps to locate arguments and gaps in knowledge about representativeness, equalities, resources and leadership around PPI in research that the current study will address.

Recommendation one: Information and communication

To improve the ways in which the public can learn about and become involved in research, the NIHR will work with partners.

(GEM 2015)

The problem of representativeness and poor communication sits behind this dual recommendation. The field of PPI has been described on the ground by frontline workers as a 'battle ground' of competing interests concerning the diverse needs of a society characterised by differences of race, religion, class, disability, sexuality and gender. The technocratic and democratic ideas that all these differences can work together to service research are nothing short of utopianism (Gibson et al. 2012). But by applying newer ways to address the long-standing issue of having the same people come forward, and perhaps making it easier for the public to get involved via better communication in a more tailored way, helps to address inclusiveness as a democratic value (Bochel et al. 2008).

Perhaps the issue of 'communication' could be fostered as a dialogic process, helping to harness understandings about people's motivations of involvement. Bissell et al. (2018) argue, in their paper about PPI work in the cancer research setting, that Habermas' (1987) work on communicative rationality and avoiding colonisation of the lifeworld by the forces of capitalism and the state is a useful way to help pave mutual understanding between those inside and outside of systems. Patients and the public are outside of

systems and their lifeworld is governed by communicative rationality, orientated towards reasoning and achieving mutual understanding. This recommendation of GEM is an opportune way to consider these different but entwined issues.

Recommendation two: Culture (a)

> The NIHR will commission the development of a set of values, principles and standards for public involvement, to be co-produced with the public and other partners.
>
> (GEM 2015).

This recommendation addresses the thorny issue of tokenism. Researchers can sometimes be suspicious, unwilling to cede control and are dubious about involvement (Carter 2013). Having principles and standards can help to overcome challenges such as tokenism. More importantly, standards of good practice can clarify for those involved, the expectations from both sides. Arnstein's (1969) ladder of citizen participation focused on power and has been used to conceptualise the extent of involvement in research (Tritter and McCallum 2006; Gibson et al. 2012; Mc Laughlin 2009; Oliver et al. 2008). The eight rungs of the ladder are: *manipulation, therapy, informing, consultation, placation, partnership, delegated power* and *citizen controlled*. The model demonstrates that participation does not come without democratic and technocratic concerns and implies that participation processes may often be little more than manipulation. For Arnstein, participation was concerned with the power to make decisions and the seizing of this power. Each rung relates directly to the degree to which citizens had achieved decision-making power. Arnstein's work has been critiqued for being too linear, missing rungs, and for focusing too much on one type of power without looking at the dynamics of involvement (Tritter and McCallum 2006). The model has been adapted to include Mullen et al.'s (1984) reactive and proactive involvement and to help create a matrix of involvement (Oliver et al. 2008). McLaughlin (2009) argues that the ladder fails to appreciate that involvement evolves in projects, outlining that involvement of the public at research application stage will not have the same level of input as at write-up stage. The linearity is problematic as it may lead people to be swayed to either starting at the highest or lowest points of the ladder rungs, opening potential for tokenism in practice.

The ladder analysis demonstrates that since 1969, the application of the ladder specifically for research in healthcare is unhelpful, but scholars appreciate it as a starting point for addressing principles and standards in of PPI research.

More recently, a Medical Research Council (MRC) study (Gradinger 2015) on values associated with PPI, found that there were three value sets. One, normative values concerned ethical and political values associated with empowerment, change, accountability and transparency. Two, substantive values concerned with consequences of PPI in research e.g. quality, validity, relevance, reliability, representativeness and evidence. The third set of values concerned processes, e.g. partnership, trust, clarity and respect.

Therefore, broad principles and standards of involvement, as the recommendation states, offers a common new starting point for researchers and the patients and public involved to consider aspects such as decision making, power and the avoidance of tokenism. Subsequent to this recommendation, six principles have been developed and are being piloted for wider use, covering: *respect*, *support*, *transparency*, *responsiveness*, *diversity* and *accountability*, and six standards which comprise: *Inclusive opportunities*, *working together*, *support and learning*, *communications*, *impact* and *governance* (NIHR 2017).

Recommendation three: Culture (b)

Strategic goals identified in the report will be included in the NIHR overall strategic plan and become the objectives against which public involvement, engagement and participation are planned and reported across the NIHR,

(GEM 2015)

This recommendation concerns making PPI and engagement meaningful in routine research practice. Such an approach would foster a culture which values and encourages questions and dialogue between professionals and the lay public. In the report, the strategic goal to use and apply people's knowledge gained through their experience of health and social care and research is believed to be a vital component to developing treatments, interventions and services required to tackle the health needs and priorities of

the population (GEM 2015). This recommendation builds on the previous recommendation of culture and the formation of national standards, by creating a culture that values lay knowledge working with professional knowledge. This is an important point because current systems of lay input into healthcare research do not always function well, e.g. people involved are sometimes barely able to express their views (Renedo et al. 2015). One PhD study, on the impact of PPI in the cancer research context (Thompson 2009), found that participants highlighted specific forms of expertise in their accounts about involvement. These accounts suggested professionalisation of patients, above and beyond what may have been regarded as experiential expertise. This professionalisation legitimatised their credibility in PPI roles (Thompson et al. 2012). In a further publication, Thompson et al. (2014) argued using Habermas' (1987) systems and lifeworld analogy, that in health systems, such as the NIHR, certain rules and practices are more or less codified and organised in meaningful ways to deliver outcomes for both professional and lay groups. Thus, Bissell et al. (2018) argue that involvement (in cancer research settings) is less about the use of experience, and more about lay people watching or supporting the professional researchers at work. Despite this criticism, recommendation three in the GEM report is commendable, if ambitious.

Recommendation four: Continuous Improvement (a)

> INVOLVE will provide leadership and co-ordination across the NIHR, ensuring that the public and researchers are better supported to do public involvement. NIHR leaders, researchers and staff will receive an induction in public involvement and leads across the NIHR will have their own leadership and development programme as well as opportunities to share good practice.

(GEM 2015)

The NIHR has recognised that PPI in research requires long-term investment, leadership and co-ordination. This recommendation echoes the general concerns about leadership found in wider literature around research impact and implementation (e.g. Kuruvilla et al. 2006) as well as PPI literature (e.g. Jinks et al. 2016). Trust between researchers, patients and the public, and staff in PPI leadership roles requires investment. Learning about what approaches in PPI work best in different healthcare research settings requires detailed understandings about the complex interplay of involvement dynamics. Concerns

include: clarity of purpose, defined roles and relationships, organised support and a strongly funded infrastructure, which are all components believed to create the spaces for strong and supported PPI in research (Jinks et al. 2016).

Since this recommendation, a leadership survey took place between June 2017-January 2018 amongst PPI leads across the RDS network, which demonstrated that a considerable mix of skills and knowledge is needed for those working on the ground, supporting researchers and patients and public. The synthesised set of knowledge and skills spans academia, management, community development work, healthcare and nursing. This implies that the staff leading in PPI roles need to be highly trained and invested in, to help them in PPI in research work duties. (Williamson et al. 2018).

Recommendation five: Continuous improvement (b)

> The NIHR will measure success along these indices: Reach: the extent to which people and communities are engaged, participating and involved in NIHR research including the diversity of this population. Relevance: the extent to which public priorities for research are reflected in NIHR funding and activities. Refinement and improvement: how public involvement is adding value to research excellence as funded by the NIHR. Relationships: collaborative working for the advancement of public involvement across NIHR.
>
> (GEM 2015)

General research impact has been defined by similar characteristics such as reaching out, being responsive, being relevant, disseminating appropriately and ensuring appropriate impact (Oliver et al. 2004: Haines et al. 2004). The focus of this study applies especially to this point and the entire next chapter addresses impact. After this recommendation was set, a 'public involvement impact working group' was developed by the DH to explore the usability of such terms in assessing impact of PPI.

Recommendation six: Co-production

> The public, researchers and health professionals will be empowered and supported better to work together in the future using the principles of co-production.
>
> (GEM 2015)

Co-production is a 'buzz word' that has gained increasing popularity in the field of PPI. Maguire and Britton (2017) explore a Habermasian understanding of the metaphor 'spaces' between professionals and the public (the potential co-producers). They argue that it is difficult to keep a productive relationship between those who run the research agenda and the people who get involved. Institutions will have an instrumental purpose (i.e. pre-set goals), whereas patients and the public will have their own goals, but their goals will only be known if they communicate appropriately in the space for sharing their experience. Some people involved may be forceful or better communicators, others may lack confidence to speak up. Some may speak different languages (literally) or have arrived with previous life events which may not fit easily in the knowledge space available in a particular setting. Positioning these knowledge spaces in the landscape between 'lifeworld' and 'system' (Habermas 1987) offers understanding towards the complex nature of internal and external pressures of PPI in research. Whilst the idea of co-production is something of admirable quality, the co-production agenda to some extent glosses over and suppresses the heart of the problem that:

> They [spaces] not only connect different worlds, different ways of thinking and being, they have often come into existence, like blisters, where these worlds rub against each other, or like bruises, where they have collided.
>
> (Maguire and Britton 2017: 13)

The quotation above suggests a difficult and tense relationship between two clashing agendas sharing the space. Despite this, the co-production recommendation challenges epistemic values for those on the ground. However, an INVOLVE-led piece of work has resulted in the newly formed *Guidance on Co-producing Research Projects* (2018).

Recommendation seven: Connectivity

> NIHR will support work that is locally inspired and driven whilst strategically consistent with the NIHR overall goals.
>
> (GEM 2015)

Recommendation seven concerns staying grounded locally amidst a fast pace of evolving healthcare needs. PPI is not a homogeneous entity and to work with groups of needs, an

organised and collective voice, holds weight. Gibson et al. (2012) and Locock et al. (2017) have described Nancy Fraser's work (1990) on weak and strong publics to help understand the strength of organised and collective voices. A weak public is when people have little power, whereas a strong public exerts influence. Making efforts to explore strong publics or groups chimes with Kelleher's (2001) work on 'New Social Movements' which used Habermas (1987) to analyse self-help groups and to study the 'way of life' that these groups captured when describing their daily struggles. Kelleher (2001) argues that language has an important function in the analysis of the activities of these self-help groups. In his work, Kelleher discusses narrative reconstructions of networks and groups, arguing that when people engage in groups, not only will 'people let off steam' (own experiences) but they will allow people to gain new knowledge by listening to others. Such interactions give people confidence, to express themselves but more importantly, altering their identity by perhaps considering what doctors think, hence balancing and taking forward a collective voice (Kelleher 2001). This recommendation attaches appropriate weight to 'connectedness' because it offers a lens into some of the wider groups of society and how some of these are affected by health issues that are the focus of research.

Recommendation eight: Co-ordination (a)

> Leadership and appropriate governance structures will ensure that the future development of public involvement in the NIHR has a clear sense of direction and is accountable. The NIHR National Director for Patients and the Public in Research will establish a leadership group to provide strategic leadership for public involvement, engagement and participation activities across NIHR and identify clear priorities for resourcing.
>
> (GEM 2015)

This recommendation concerns strategic direction from central government, which is essential for the success of PPI in research. If the government distances itself too much, then values for PPI in research might dissolve, and progress and momentum may slow down. Therefore, the lead must come centrally, and must be embedded in the structure of the NIHR. Subsequently, priorities have been developed and include the following: making more help and support available to the lay public and researchers, encouraging

local innovation and creativity in PPI, and facilitating greater collaboration in PPI including regional ‘patient voice’ forums.

One example of a piece of work supported locally by the NIHR was the Sharebank initiative in the East Midlands, focusing on training in PPI (Horobin et al. 2017), which is, at the time of writing, being piloted for roll-out across England. The essence of the project is to train the lay public in research issues so that they are better equipped to challenge researchers and articulate their concerns. Traditionally people have been passive recipients of healthcare research, but Sharebank is unique in that the patients and public are being upskilled to challenge the medical voice, perhaps as Habermas might argue, taking steps towards reigniting the vision of the bourgeois public sphere (1962). The public sphere was understood to be a public realm which co-existed with authority (i.e. the police, the church and royalty). It was a place where people were seen in public such as salons, coffee houses and clubs where there was a shared sense of belonging, and people discussed life politics cohesively as equals. Habermas (1962) was inspired by the conditions and dialogue of the public sphere, and he attributed the death of open discussions to a negatively changing ethos. As certain people became more authoritative and influential, unconstrained dialogue and debate was lost. However, it could be argued that internet-based platforms such as social media, online forums and blogs offer a new way to help re-imagine the public sphere and dialogue (Kellner 2014). Little is known about how involvement initiatives can take advantage of such online platforms but for now the strategic goals of the NIHR are reasonably flexible to accommodate this newer technology – a recent guide addresses PPI in the digital age (Dumper 2018), suggesting increased understandings are forming.

Recommendation nine: Co-ordination (b)

All NIHR Coordinating Centres and infrastructure organisations will have a strategy, framework or plan that covers the promotion and advancement of public involvement, participation and engagement in research. Leadership accountability and funding for this agenda within organisations will be clear and transparent. Progress should be reported annually, made publicly available and an overview included in the NIHRs annual report.

(GEM 2015)

This recommendation links to democracy and reiterates that by involving the patients and the public, transparency in research infrastructure becomes more observable, resulting in increased research value and a reduction of waste in research as argued eloquently by Chalmers et al. (2014). This is discussed further in chapter three.

Recommendation ten: Diversity

A diverse and inclusive public involvement community is essential if research is relevant to population needs and provides better health.

(GEM 2015)

Although concealed, recommendation ten seeks to address problems of class, power and health inequalities. The involvement of underrepresented voices is undermined by insufficient mobilisation efforts and a lack of resources to meet the diverse range of needs of the population (de Freitas and Martin 2015). The number of 'how to involve' manuals is plentiful (Beresford 2002: Reed et al. 2004: and Goodare and Lockwood 1999) and yet many initiatives fail to reflect the voices of seldom-heard sections of society, and in turn may exacerbate inequalities (de Freitas and Martin 2015). The work of Renedo and Marston (2011) discusses inclusive participation, community participation and bottom-up approaches to participation. The authors argue that patients and public struggle to assert their identities, that as outsiders of the expert-led system they find it difficult to negotiate or even 'survive'. Further, the lay public are adapting their individual agency to a top-down model and have to cope with threats of moving away from their own sense of identity. This could be viewed as Habermas' (1987) understanding of 'uncoupling' and reflects the professionalisation dilemma discussed above.

Scambler (2001) argues that in the past, social and health policies have failed to reduce health inequalities in the UK, signalling the strength of the 'power elite' or what he calls 'greedy bastards hypothesis (GBH)'. From this perspective, inequalities are interpreted as indirect and unintentional by the capitalist elite. Scambler (2001, p91) applies Habermas' understanding of Marx's theory of class which sits between 'defensible

revision and premature displacement' (Scambler 2001, p92). Scambler argues that Habermas' study of the uncoupling of system and lifeworld in society has prematurely rejected the Marxian claims on the importance of relations of class.

> Habermas (1984, 1987) […] distinguish[es] between the system – comprising the economy (which generates money) and the state (which generates power), and which is characterized by strategic action (or action oriented to success) – and the lifeworld – comprising the private sphere (which generates commitment) and the public sphere (which generates influence), and which is characterized by communicative action (or action oriented to understanding). He maintains that social differentiation has led to an uncoupling of system and lifeworld, and to an excessive rationalization of the former at the cost of a colonization of the latter.
>
> (Scambler 2001, p92)

Scambler argues that Habermas' 'colonisation of the lifeworld' thesis somewhat addresses issues of class, power and inequalities but without due attention to Marxist thinking. What Habermas does offer is a way to study the complex systemic problems experienced by people and exercised by the state:

> The intention in the GBH is not to 'test' this complex and awkward hypothesis, which would be premature, but rather to explore the conditions and extent of its plausibility, and to reflect on how effective empirical procedures to test it might be devised.
>
> (Scambler 2001, p92)

Returning to the GEM (2015) report, the importance of diversity and inclusiveness being stated as a national recommendation will no doubt be carefully watched and studied. It will be of interest to see to what extent the recommendation has made steps to represent the research users and to reduce class, power and health inequalities.

Recommendation eleven: Review

> An independent review will be commissioned by the NIHR in three years' time to assess the progress made in taking forward the recommendations in this report.
>
> (GEM 2015)

Making progress is the what this last recommendation addresses. The expectations for PPI in research continues to confuse those working on the ground. Whether the ambition of PPI in research is 'fit for purpose' with its plans, initiatives, pressures, demands, influences, facts and folklores constantly evolving (Gibson et al. 2012) is an important question and currently the idea of review relates to this agenda. PPI is gaining fast recognition in a critically constructive manner (Madden and Speed 2017). The 11th recommendation of the review seeks to ensure that involvement initiatives stay true to the people that research affects the most: the patients and the public.

Summary of section 4.

Under this section the recent context of PPI in research has been described by examining specifically what PPI in research is, how it is considered to help research and when and why it started. The section referred to *Best Research for Best Health,* the establishment of INVOLVE and the NIHR. The first and only PPI in research policy *GEM* was scrutinised at depth. The eleven recommendations have demonstrated and situated the deep problem points for PPI in research.

The earlier part of this chapter focused on understanding conceptual and theoretical ideas about patient and public involvement (PPI) in healthcare more generally, considering the democratic and technocratic rationales. The knowledge economy has been stable organisationally, in terms of infrastructure to address some of the challenges found in PPI in healthcare. Thus, borrowed arguments which apply in research amongst many, include representation problems, failing to adequately bring the patients and public perspectives into healthcare problems. By focusing on theory offered by Arnstein (1969) and Habermas (1987), arguments concerning power were demonstrated as a core reason for common failures well known in PPI in healthcare. It is hoped that similar problems can be avoided in healthcare research. Thus, involvement in healthcare research is, we can conclude, steadier and better invested in than healthcare services.

Concluding chapter summary

This chapter aimed to orient the reader to PPI by sewing together four salient debates from healthcare to healthcare research. Section 1. demonstrated that terms for patients and the public have evolved and helps to draw attention to the power imbalance between professionals and the lay unpaid public who get involved and suggest that evolving terms are slowing recognising that people involved are becoming 'experts' of their disease, rather than just passive patients. Section 2. has drawn on ideology to understand rationales to help conceptualise arguments concerning democratic and technocratic knowledge: the two driving forces for PPI in healthcare (which can be applied to serve the research purpose too). The democratic ideology for involvement is a mixed spectrum of genuine democracy on the one hand and legitimisation of services on the other. A critique of democracy in healthcare services found that the problem of representativeness can be summarised as lacking organic connection, meaning those who get involved are often not representative. By carefully observing PPI in healthcare policy, it was made possible to see that healthcare development in PPI has been subject to mass restructuring, resulting in loss of direction and lack of public trust. Healthcare policies and rhetoric connected with PPI initiatives highlighted the dominance of neoliberal thinking.

In section it was argued that most governmental activity is framed within neoliberalism. Liberalism concerns choice and economic gains, while democracy concerns equality and collectivism. Both ideological positions appeal to individuals in the growing neoliberal population. These ideological positions are reflected in the language used by politicians too, to strike appeal across the population. The differing ideological beliefs of each political party fall under the principles of conservativism, liberalism and socialism but have merged into a culmination of neoliberalism.

In section 4. the focus was offered to PPI in healthcare research examining what the research process with PPI looks like, when it all started and how government has invested in it. The focus on one particular policy – GEM – enabled a critical review of some of the challenges faced in PPI and research.

Politics is sometimes described as *'the deliberate shaping of future society'* (Dorlen 1998, p129) and what the policy overview presented here means for current study is that politically there is an ideological constraint between the governing force and those being governed which can destabilise healthcare. Underpinning the governing force is the desire to carefully manipulate and, only at certain opportunities, encourage public input into health and research decision-making. But a desired behaviour can only be reached if the governing forces can relate to its people on the ground, e.g. meet the diversity and co-production challenges, and have transparent and open conversations about what matters to public. There are some fundamental gaps and challenges that this policy review has highlighted. What we have yet to understand is the role the lay public have in shaping healthcare after research ends and how government policy affects the impact of PPI on research outcomes. This policy overview suggests that PPI in research is a blend of democratic and technocratic ideology. PPI in research is regarded as something relatively new but appears to be an extension of government promoting new approaches to citizenship (Barnes et al. 2004) and at the same time intended to shape and improve the organisation and delivery within the health service (Tritter and Lutfey 2009). The policy cycle shows great fluctuation and potential tension for the development of PPI, as we have seen from the various healthcare PPI initiatives. However, within healthcare research, notably through the GEM policy, it appears that ambitions are well intended. Moving on from the foundations of this work, the next chapter considers questions of impact of PPI in healthcare research.

Chapter Three: Understanding the impact of research and the impact of PPI on research outcomes: a critical narrative review

Introduction

This chapter aims to review key literature on the impact of research generally, as well as on the impact of PPI on research. The literature is presented in a form of a critical narrative review (Culley et al. 2013), which allows for different themes to be discussed and interpreted from a range of disciplines and which considers qualitative, quantitative and mixed methods research. The review asks the following questions: What is the current state of evidence on the impact of research in general? What is the current state of evidence on the impact of PPI?

Background

The question of whether PPI has any effect on health research first began to be asked by scholars as early as 2002 (Boote et al. 2002). More recent insights have considered how we might evaluate the impact of PPI on research outcomes (Brett et al. 2010) including how context, process and mechanism shape impact (Staley 2014). The last eight years have been witness to high quality funded research on the impact of PPI e.g.: how to measure the impact of service user involvement by taking consideration of values (MRC study, Grant ID:G0902155, awarded to Popay); evaluating CLAHRCs in action (NIHR study, Grant ID HS&DR/09/1809/1072 awarded to Rycroft-Malone); two studies applying realist evaluation (Pawson and Tilley 2004) to PPI (both NIHR, Grant ID: HS&DR/10/2001/41 awarded to Evans, and Grant ID: HS&DR/10/2001/36 awarded to Wilson); then a further study to optimise methods of PPI in clinical trials in HTA (NIHR Grant ID: HS&DR/10/2001/29, awarded to Gamble); and most recently, to understand knowledge mobilisation concerning PPI and the gap between knowledge generation and its implementation in practice (Grant ID: KMRF-2016-05-014, awarded to Maguire).

These studies matter because PPI in research has been suggested as one way to address the gap between knowledge generation with PPI and research implementation in practice (Savory 2010; Boaz et al 2018). Links between PPI impact and impact of research are very recently starting to form in literature reviews (Hughs and Duffy 2018). Hughs and

Duffy formed a concept analysis (a way of formally defining attributes to a concept) to link understandings about the impact of research and the impact of PPI, Other than their work, and anecdotal observations about dominant structures of impact and how they may relate to PPI (McKenna 2015), few scholars have explicitly in the PPI literature formed any links between the two bodies of knowledge.

To date, no review has explicitly explored how the two aspects come together: 1, the distinct academic literature on research impact and: 2, the role that PPI as a phenomenon has on research outcomes of PPI. Including the two areas under one review will help to map out newer understandings about the most recent thinking about how they might link. Therefore, the two questions for the current critical narrative review are: 1) What is the current state of evidence on the impact of research in general? (are there explicit or applicable connections to understanding the impact of PPI on research outcomes?) and 2): Can any knowledge be applied from the impact of research and implementation science literature (concerned with knowledge translation) help to form newer understandings about the impact of PPI on research outcomes?).

Together these two questions will help to address the current state of evidence on the impact of PPI on research outcomes.

Methods

To address the two review questions, the critical narrative review method of reviewing literature was used. This involves: interpreting the knowledge gained; and acknowledging the diversity of studies from a range of disciplines from both qualitative and quantitative research (Culley et al. 2013). Inclusion and exclusion criteria, and search screening and selection will be considered next.

Electronic search strategy

The first challenge faced when conducting the electronic searches was ensuring to use the correct terminology because, as described in the previous chapter, there is a debate of terminology (McLaughlin 2009). With personal experience of working in the field of PPI and reading around the topic as advocated by Harlem and Schlapp (1998), it became clear that certain terminology was used more widely (Aveyard 2010). Therefore, the following

terms, in common usage by healthcare researchers and professionals, were included: ‘user’, ‘patient’, ‘carer’, ‘lay’, ‘public’, ‘client’, ‘consumer’, ‘citizen’, ‘stakeholder’ ‘participation’, ‘involvement’, ‘engagement’, ‘research’ and ‘impact’. Conducting literature searches on such ambiguous concepts also meant that search results covered a mix of professional settings, ranging from social work research to laboratory-based scientific health research. Additionally, impact was variously defined: for example, from individual impact on a person, through to impact on healthcare service delivery. Special attention was applied to health research, as principally the focus of this research was concerning research in the NHS which had PPI. Electronic searches were conducted in specialist databases: Medline, Scopus, Cumulative Index of Nursing & Allied Health Literature (CINAHL) (NHS), PubMed, Health Management Information Consortium (HMIC) (NHS), ASSIA, Web of Science and PsycINFO.

A second stage for literature searching was also applied, a point supported by Greenhalgh and Peacock (2005) who argue that electronic robotic methods are not sufficient and that other systems are necessary to add scrutiny in generating results. Thus, five tiers were added as follows:

1. Reference chaining using the articles generated from the electronic searches.
2. Known academic and professional contacts were emailed asking for particularly relevant sources for the current study.
3. Relevant websites which had a focus on public involvement in research were checked regularly for any new reports, e.g. the INVOLVE and NIHR websites.
4. Zetoc alerts and Google Scholar alerts were set up from 2010 to help keep abreast of any new articles about the topic. Both alerts were particularly useful when a new journal entry was added on the World Wide Web. These alerts are without charge and were sent once a week, every week during the course of study
5. University libraries (DMU and Leicester) were searched for suitable books. Particularly where the focus of the content matched the current research, e.g. impact of PPI on research outcomes, theorising PPI on research and/or impact of PPI on research.

Inclusion and exclusion criteria

The inclusion and exclusion criteria set in table 1 were adopted.

Table 1 - Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Peer reviewed and focusing on patient and public involvement theory, practice, policy and research	Training and Patient Reported Outcomes Measures (PROMs)
Since 1997 unless reference chained	Pre-dates 1997 unless found via chaining
Research policy focused websites on patient and public involvement in research policy such as INVOLVE, Department of Health, NIHR and RCUK	Not NHS or research-focused websites discussing patient and public involvement in research
Books and PhDs with a focus on impact of patient and public involvement in cancer research (identified by known contacts)	PhDs which focused on involving patients and the public outside of cancer research
Any other information building understandings to help conduct the current work found through reference chaining	Anything outside of social sciences, health sciences and implementation sciences fields e.g. business and commerce

Eligibility of sources

Sources discussing: training, service development, PROMs, or participation in trials were not relevant. These foci were beyond the scope of the study and these articles were rejected.

Results

A total n=704 sources were identified from the combined searches. Duplicates were removed and upon reading the titles and keywords it became clear that some of the articles were not relevant to the current study. This process brought the number down to n=386 sources. However, Evans (2002) noted that journal article titles would not always accurately reflect the content covered, therefore important articles could have been missed out, for example studies describing ‘co-production’ or ‘community-led’ research. Special efforts were made to keep up to date and scan carefully.

Table 2 - Literature search stages

Stages	Number of sources found
Stage 1 to search: Medline, CINAHL (NHS) HMIC (NHS) ASSIA Web of Science PsychINFO SCOPUS	*n*=704 Duplicates found and removed (n=182) (n=704 - n=182 = n=522) Non-relevant articles found and removed (*n*=214) (n=522 – n=214 = n=308) Sources to be longlisted *n*=308
Stage 2 Five-tiered system: o Reference chaining o Emailed known contacts o Websites checked o Zetoc alerts o Library searches for books and PhD's	Sources to be longlisted *n*=78
Total number of longlisted articles Which involved checking abstracts and keywords and content scrutiny	n=308 + n=78 = *n*=386 251 articles removed in this process
Total number of shortlisted articles to include	**n=135 to include**

Characteristics of sources

Of the *n=135* sources identified, the earliest sources dated from 1997, and *n=47* studies had been published since 2014. Publishing output increased, which suggests literature was starting to gain recognition about PPI and impact. A database was created and updated on an ongoing basis/as required so that the topic, type of involvement, the type of impact (process or outcome), methodology, theoretical position and key messages could be assessed and recorded. The headings in the database created were:

- *Source, author, date and title;*
- *the topic or health condition the article was discussing;*
- *sort type of involvement that had taken place being described in the article (consultation, collaboration or user controlled);*

- *whether the authors were discussing the impact of public involvement on the research process or outcomes;*
- *any mention of research impact generally;*
- *the methodology that was employed to help understand the topic;*
- *theoretical position applied; and*
- *any key messages.*

Table 3 - Grouping of 135 sources

Sources categorised	From n=135
Empirical studies on the impact of PPI	n=55
Evaluations of PPI	n=14
Opinion pieces and commentaries on impact of PPI	n=13
Generalisable lessons on PPI (and theory)	n=13
Policy of PPI (the majority of which were used for the previous literature chapter)	n=10
Research impact and implementation science	n=11
Book chapters on health policy and Habermas (some sources were used in the previous chapter)	n=8
Systematic reviews on PPI	n=7
PPI related websites (all three used for the previous chapter)	n=3
PhD Studies (PPI related) (used in the previous chapter)	n=1

It became clearer after developing a database (see table 3) that the impact of research literature (n=11) focused on four issues. 1) Defining impact 2)'Research context' within which research problems are defined, 3) the 'application of new knowledge' and how it is applied, 4) 'Research evaluation-tracing tools' these are impact tracing ideas, and 5) that implementation theories help to tie context, process and outcomes together to help 'implementers' apply new knowledge to real-world issues.

Of the remaining n=124 articles the majority of sources (n=87) were discussing not just one but multiple types of impact of PPI. Further, that various health conditions spanned the content, in the body of the article e.g. in systematic reviews about impact of PPI or when a study was focusing on a combination health conditions and groups such as: arthritis and older people, sport and exercise in young people, and palliative care in the community. However, some articles had a clear focus on PPI and impact, for example

n=9 mental health, n=10 cancer, n=5 children and maternity, n=6 health networks, n=2 dermatology, n=8 clinical trials and n=3 primary care.

Hence two related but academically distinct bodies of literature inform this chapter. One concerned 'the impact of research' and the other concerned 'impact of PPI on research healthcare and process and outcomes'. What was most striking from looking at the two bodies of literature was that impact of PPI was never explicitly discussed in the impact of research literature, although input of 'end users' or 'stakeholders' was. Similarly, in the impact of PPI on healthcare research process and outcomes literature, the dominance of higher education impact strategies such as Research Excellence Framework (REF) were largely absent.

Table 4 - Critical Narrative Review content summary

Summary of two bodies of literature found	Impact of research	Impact of PPI on research process and outcomes on healthcare research
Type of source	Empirical studies Systematic reviews	Literature reviews (Systematic, policy) empirical studies
Countries of origin	UK-based (n=3), American (n=2), Canadian (n=2), European countries (n=2) and Australia (n=1).	Mainly from the UK (n=118), from Europe (n=4) and Canada (n=3).
Aimed at	Policy makers, university leaders, healthcare managers and commissioners	Researchers, policy makers and scholars
Themes of evidence	1)Meaning of impact 2)Research Context 3)Application of new knowledge, Research evaluation tracing 4)Implementation science and Summary of gaps	1)The impact of PPI on healthcare research 2)The impact of PPI on research processes 3)The impact of PPI on people involved in the research process 4)Impact of PPI on research outcomes 5)Poor quality reporting on PPI
Absence of evidence on	Discussion of PPI in research during implementation	Discussion of PPI on impact of research (outcomes)

Findings

Body of evidence 1: 'The impact of research'

Introduction

From 'the impact of research' body of literature (review question one), articles came from: UK (n=3), America (n=2), Canada (n=2), European countries (n=2), and Australia (n=1). It was noticeable that the information was aimed at policy makers, university leaders, and healthcare leaders. Almost every article since 2013 discussed the words 'impact' and 'REF', indicating their emerging importance. The content described in the literature often consisted of comparisons of existing and/or new models/frameworks developed by authors to help assess impact, based on empirical work (e.g. Rivera et al. 2017). Content also spanned implementation theory (e.g. Damschroder et al. 2009). Impact of research papers confirmed the gap between research and policy (Haines et al. 2003), needing more research on impact of research itself (Penfield et al. 2014) and other factors affecting impact of research, such as the media (Eysenbach 2011) or political agendas affecting decision-making (Gold 2016). Competing local priorities (Brownson et al. 2017), conflicting expert opinion (Milat et al. 2015), and powerful lobbying groups were also discussed (Campbell et al. 2007) as affecting the impact of research. There was only very recent evidence about the role that stakeholders can have in implementation work (Boaz et al. 2018) and evidence from Kirk et al. (2016) to suggest that Damschroder et al's. (2009) implementation theory was flexible enough to help evaluate implementation processes. One very early government report referred to PPI as a complex intervention (Farrell 2004). These aspects will now be discussed in turn.

Meaning of impact

The word 'impact' is defined as *'marked effect or influence'* (Oxford English Dictionary 2004). Internationally, there is a growing interest in demonstrating the impact of research (Morrow et al. 2017). Demonstrating impact is important because it helps to minimise research waste (Ioannidis et al. 2014), helps allocate resources efficiently (Pang et al. 2003), and maximises the benefits of research (Rivera et al. 2017). But there is a difference between 'academic impact', assumed as the intellectual contribution to one's field of study within academia, and 'external (socio-economic) impact' beyond academia

(Penfield et al. 2014). Exploring impact in the context of research verses practice showed that the word impact was generally understood to mean the consequences of research (Donovan 2011), implying effect, change or influence of research on various complex phenomena, including policy (Oliver et al. 2014), society (Bornmann 2013) and/or the economy (Deloitte Access Economics 2011). The impact of research has also been explicitly defined by REF as *'any identifiable benefit to, or positive influence on, the economy, society, public policy or services, health, the environment, quality of life, or academia'* (HEFCE 2011). But evaluating this type of impact is complicated. The definition above given by HEFCE to some extent implies linearity, similar to the Research Council United Kingdom (RCUK) definition which discussed the contribution that research makes to society and the economy, embracing a diversity of ways that research affected individuals, institutions and different countries, including:

> fostering global economic performance, and specifically the economic competitiveness of the United Kingdom; increasing the effectiveness of public services and policy; enhancing quality of life, health and creative output.
>
> (RCUK 2013)

The most important aspect of RCUK's definition was that impact needed to be demonstrable. However, RCUK also acknowledged that policy and service development from social science research is not direct or linear, contradicting its impact statement by suggesting that impact is not straightforward and policy processes are not linear either which they said made it: *'difficult to pin down the role that an individual piece of research has played'* (RCUK 2013). They argued that the timing of evaluation also presented problems because after research has ended it may be too soon to judge whether impact has yet to fully develop. Conversely, it can be too late, when impact may no longer be traceable as people involved had moved on (RCUK 2013). But Davies et al. (2005) suggest that problems arise when trying to track and demonstrate immediate impact of research because research can directly influence or indirectly influence policy, practice and behaviour. More subtly, impact can help to change *'peoples knowledge, attitudes and understandings towards social issues' (p2).* They finished by saying that: *'Tracking these subtle changes can be difficult, but it is perhaps more important in the long run' (p2)* and that extra problems arise about:

> knowing where to look, for research impacts (who are the research users?); knowing when to look for these impacts (how long is sufficient for research to take effect?); and knowing how to assess the specific contributions made by research (was the research really the key factor in any changes observed?).
>
> (Davies et al. 2005p2)

The statements above help to describe the sensitive nuances of trailing impact of research. The quotations set the tone of three aspects concerning impact of research: the research context; the application of new knowledge; and evaluation tools.

Research context

The literature showed that the research context needs to be advantageous for the investigation issue (Owen et al. 2012) and is necessary for impact to generate. An advantageous research context concerns favourable conditions for research collaboration to occur, i.e. recognition of the problem, question or issue (Morrow et al. 2017), along with alignment with the wider socio-economic and political factors which are usually important influences for the *'research design stage and providing momentum for research that was underway' (p420).* They concluded that:

> Political, professional or public agendas had helped to promote research studies by directly linking research outputs to political figures or campaigns by professional bodies on issues.
>
> (Morrow et al. 2017 p420)

Morrow et al. (2017) argue that research design and conduct is sensitive to the political climate that the research is conducted within. However, Eccles et al. (2009) have argued that there are uncertainties about the relationship between the context and intervention. The challenge of the actual context for some researchers may lean against prevailing orthodoxies of political priorities which are pre-set. Guthrie et al. (2013) argued that the wider political, economic and social context must suit the climate at the time new knowledge is shared, implying that impact of research is dependent on its end users and the likelihood of them adopting the new research evidence or products (Boaz et al. 2009). Thus, individuals, groups and organisations need to 'buy in' and value the new information, in order to adapt and apply it. Thus, Guthrie et al. (2013) is pointing to the

context after the research has finished, which Morris et al. (2011) argued would be on average 17 years for impact to be experienced.

The literature on impact of research 'context' failed to connect how PPI affects the context of research. The question the current study is addressing, the impact of PPI on research outcomes, requires us to address how the research context assists or limits alignment from 'bench to bedside' (Callard et al. 2011). The rationales (described in the previous chapter) outline common drivers for PPI in research. It can be argued that alignment ensures that research is patient-centred (Martin 2008a; Greenalgh et al. 2016) and thus findings generated will be convertible into relevant answers for users (Gold 2016). Further, the importance of a live dialogue about what patient and public users, and professional users, want from the research findings, will aid its potential application.

Application of new knowledge

According to Graham et al. (2006), there are at least 29 terms that refer to acting on findings. This presents a challenge for researchers and policy makers in applying new knowledge because no single term is used post-dissemination. For example, in the literature the terms 'knowledge creation' (Nonaka 2000), 'knowledge brokerage' (Van Kammen et al. 2006) and 'knowledge mobilisation' (Levin 2008) were found. Though, the three main terms found in literature were 'knowledge translation', 'knowledge exchange' and 'knowledge transfer'. Knowledge translation concerns a dynamic and iterative process that includes synthesis, exchange and application of knowledge to improve and provide more effective health services and products and strengthen the healthcare system (Straus et al. 2009). 'Knowledge exchange' involves collaborative problem-solving between researchers and decision makers, which happens through linkage and exchange of knowledge. Effective knowledge results in mutual learning through the process of planning, producing, disseminating and applying existing or new research in decision making (Lomas et al. 2005). The third term to consider was 'knowledge transfer', which is used to represent the process of moving research-based knowledge or ideas from one area to another, supporting a culture of evidence-based decision making in healthcare (LoBiondo-Wood and Haber 2005). However, a problem with this term is that it suggests that knowledge can be 'rolled out'. Moreover, the

applicability and usefulness of the term 'knowledge transfer' is increasingly being questioned because the knowledge-base is itself diverse and the agents or professionals who are supposedly using new knowledge are also diverse. The agents cut across sectors from health research to health management, health policy makers, through to clinicians, service users and the public, and the nature of these 'agents' is fragmented across healthcare (Walker 2007). There are two reasons that have been offered to why knowledge transfer can present difficulties. Firstly, knowledge messages can be 'sticky' or difficult to share beyond the immediate setting (Szulanski 1996; 2000). Secondly, this sticky knowledge may also lead to problems associated with 'absorptive capacity' when trying to transfer the knowledge to healthcare staff to maximise the new knowledge (Cohen and Levinthal 1990), implying the new knowledge may not suit the staff or the setting it which it is being offered.

Each term described acting on findings after dissemination. Yet, introducing the three main terms, which have very slight difference in meaning is important as it helps to highlight that language is inconsistent across the sectors. It was also documented in the literature that research knowledge will depreciate significantly before it makes its way into real life (Hanney et al. 2004). Some argued that knowledge will slowly 'creep' into a decision maker's mind (Pawson et al. 2005). The subtle issue such as knowledge 'creep' is largely invisible and therefore impact-tracing becomes even harder to assess (Molas-Gallart 2004). Consideration of how completed research study findings are applied into real healthcare settings demonstrates that difficulties already exist in trying to understand how new knowledge is used or even described in its use. Therefore, attempting to assess the impact of PPI presents further difficulties.

However, to plan for the application of new knowledge, research funders increasingly expect researchers to submit impact plans as part of their proposals (Lyall et al. 2015; Smith et al. 2011). Typically, researchers include in their impact plans: forums for debate (Walshe and Davies, 2013), public engagement (Grand et al. 2015), dissemination and communication plans for different audiences (Rivas and Pandya-Wood 2014), or partnerships with research users to implement research evidence in practice (Meagher et al. 2008). Some argue that impact of research is generated through multiple processes,

including knowledge creation, exchange, transfer and translation between researchers and research 'end users' (Donovan and Hanney, 2011; Kuruvilla et al. 2006). Yet, interestingly no funders explicitly required researchers to demonstrate plans for the involvement of patients and the public at implementation stage nor how research impact will be traced.

Research evaluation tracing

There was an array of ways to assess the impact of research. In some cases, assessing impact was described as burdensome and intrusive and there was no overall consensus as to which evaluation tool should be used (Martin 2011). In a recent systematic review conducted by Rivera et al. (2017), the authors summarised n=24 health research impact frameworks to help researchers and policy makers understand how a research study might examine impact. Rivera et al. considered assessing ways to study impact and at which point potential impacts could be assessed. They generated a research impact framework which focused on academia, society, economy, and cultural outputs using narrative and quantitative metrics. Assessment approaches included: using a combination of interaction processes between stakeholders and researchers; the use and importance of partnerships between researchers and policy makers; understanding the pathways to impact; as well as the ability of health technology assessments to influence efficiency of healthcare systems (Raftery et al. 2016). Rivera et al. (2017) identified through their data synthesis five tiers across a range of short-, medium- and long-term time periods, although they do not explicitly state how many years each tier could take. The time taken in each tier is potentially highly important when considering that some research funders, e.g. Research for Patient Benefit (RFPB) fund, who explicitly stated once that impact should be demonstrable five years post completion of study (Ashby 2017). The first-tier proposed by Rivera et al. (2017) was primary-research related impact, which the authors argued were immediate research outcomes. Their second tier focused on influencing policy; the third tier involved health systems impact; the fourth tier was health-related and societal impact; and the fifth tier was broader economic impact. Their framework is summarised in table 5.

Table 5 - Tiers of impact

Tiers of impact and their focus	***Subgroups of impact***	Time
1) Primary research-related-impact	*Research and innovation outcomes (publication and citation rates)* *Dissemination and knowledge transfer (talks, media coverage)* *Capacity building, training, and leadership (further research)* *Academic collaborations, research networks and data sharing*	Short term
2) Influence and involvement in policy making	*Type and nature of policy impact (presentations to decision makers)* *Level of policy impact (influencing policy makers, changes in legislation)* *Policy networks (collaborations between policy and industry)*	Medium term
3) Health and health systems impact	*Quality of care and service delivery (improved prognosis/diagnosis)* *Evidence-based practice (improved patient experience)* *Improved information and health information management* *Cost containment and cost-effectiveness* *Resource allocation (targeted)* *Health workforce (fewer days of loss of earnings)*	Long term
4) Health-related and societal Impacts	*Health knowledge, attitudes and behaviours (public engagement)* *Improved equity inclusion, cohesion and human rights* *Health literacy (changed behaviours for the better)*	
5) Broader economic impacts	*Attracting research investment* *Income from intellectual property* *Spin-out companies*	

Adapted from Rivera et al. (2017)

Rivera et al's. (2017) work is helpful in offering an overview of impact categories but challenges are presented when considering the research context, and the application of knowledge and tools for evaluating impact. Rivera et al. (2017) advances from short- to long-term impact without the explicit mention of PPI. There was mention of 'end users'

at an engagement level, but engagement does not constitute involvement because public engagement is arguably often concerned with informing the public about something, rather than seeking their active involvement in research outcomes. Thus, tools for evaluating impact of research has revealed a gap that overt PPI in the process of research evaluation was a missing link because the n=24 impact assessments had failed to identify the use of patients and the public for long term impact, thus missing it out as a thread running through their entire framework. There could be many reasons for this: 1. that others may have implied though the term 'end users' that all stakeholders, including the patients and the public, fall under this category; 2. that Rivera et al. (2017) may not have explicitly considered the practical knowledge of patient and public in their work, hence they had chosen not to comment; 3: because there is limited evidence about PPI in shaping healthcare policy and practice (Mockford et al. 2011), the issue did not translate fully into the work of Rivera et al. (2017).

Yet, if we look at the core goals of PPI, it is associated with improvement beyond the medium term. Such improvements include reducing health inequalities (see Greenhalgh 2009); improving patient safety (Gauvin et al. 2010); making better use of resources (Minogue and Wells 2016, Fudge et al. 2007); and the better management of healthcare knowledge by both the professionals and the public (Garfield et al. 2003, Greenhalgh 2009). These examples all comfortably rest on the fourth tier of the Rivera et al.'s (2017) framework, so the absence of PPI as a thread running through their framework implies a gap in knowledge. Having PPI in the five tiers could alleviate some of the challenges between research and practice (including understanding negative research and why the research should not be applied (Chalmers 1995; Goldacre 2014). After all, the ultimate goal of healthcare research is: *'to advance knowledge for the good of society; to improve the health of people worldwide; or to find better ways to treat and prevent disease'* (The Lancet 2013 p1315).

However, it is of interest that the field of implementation science has paid attention to the people and processes that affect the routine uptake of knowledge; this is explored next.

Implementation science

Implementation science is a growing field of activity which attempts to study the processes promoting the uptake of research and evidence into routine practice as described by Eccles and Mittman (2006). In a recent review about engaging stakeholders to support improvement, the study focused on multiple stakeholders, which included patient and public, but not exclusively. Boaz et al. (2018) produced a set of indicators which could be used to identify stakeholder engagement with the potential for impact. Boaz et al.'s (2018) work is the only study which partially comes close to what the current thesis is examining about the impact of PPI on research outcomes. They found organisational factors, values and practices for future researchers. Their study reports on 15 indicators which were observable for stakeholder engagement impact. They did not consider implementation processes specifically for patients and the public. Also, the work of Damschroder et al. (2009) is of significant value because they analysed 19 existing theories on implementation of research into practice and created a meta-framework which they called 'The Consolidated Framework for Implementation Research (CFIR)'. They identified five domains in this meta framework: These where:

1. the intervention that the research focused on needs adapting to the setting;
2. the inner settings must recognise that people on the ground will be affected by the issue, therefore policies must be ready for change;
3. the outer settings (contextual aspects e.g. politico-social issues) need to be aligned to the inner settings;
4. the individuals involved in making the change must include all end users;
5. careful thought must be offered to the process by which implementation is accomplished.

(Damschroder et al. 2009)

Together the five domains of Damschroder et al. (2009) are home to list 36 conceptual definitions which they call constructs. The use of the CFIR (Damschroder et al. 2009) in implementation processes and research was reviewed by Kirk et al (2015). Their review attempted to address three objectives: 1. to determine the type of studies which use the CFIR, 2. how the CFIR has been applied (including depth of application), and 3. to

determine the contribution of the CFIR to implementation research. 26 studies met their inclusion criteria for their review. The range of studies included came from a mix of qualitative (n=10), quantitative (n=3) and mixed methods (n=13) implementation research. They found that the CFIR was applied at pre (n=2), during (n=8), and post (n=15) implementation phases. Almost every study focused on facets of implementation where the intervention had already been developed and tested for feasibility and effectiveness.

They found that the objective of more than two thirds of these studies (73.1%) was to gain insights of practitioners' experiences into barriers and facilitators of implementation. This is potentially important for the current study. The settings in which the CFIR was adopted in was healthcare delivery, health promotion, the management of disease and process redesigns. Once again, for the current study, this is important as it suggests flexibility in the model's applicability. The topics of health covered in the CFIR ranged from mental health to obesity. In n=20 of the studies reviewed by Kirk et al. (2016), analysis occurred within the healthcare system, healthcare programmes (n=2), departments (n=2) and the patients (n=2). Of these 26 studies, n=15 stated specific constructs of the CFIR that were used for implementation. While n=9 studies specified only the domains, n=3 reported using domains and constructs and n=2 studies specified no domains or constructs. Some studies used the constructs to guide interviews whilst others used the CFIR as coding templates, though a disadvantage raised was unmeasured implementation factors. Different authors who used CFIR raised advantages such as it acting as an aid memoir. But Kirk et al. (2016) found that little attention was offered by other researchers using the CFIR, about the terminology in the CFIR. They found that Ilott et al. (2013) critiqued the implementation process domain for prematurity as it failed to take account of longer-term change. Kirk et al. (2016) offered a short discussion on how the CFIR might advance theoretical direction, and they argued that further research was needed to develop measures to propose and test models that predict implementation they concluded by saying that the CFIR acted as a foundational strategy for implementation.

What Kirk et al.'s (2016) review conveys to the current researcher is that the CFIR is useful in a variety of settings and more importantly all domains and constructs are useable across different areas of health and units of analysis (e.g. departments, projects and programmes). However, it does not tell us how the CFIR can be used specifically towards evaluating the impact of PPI on research outcomes. None of the studies reviewed by Kirk et al. demonstrated its usability for understanding the impact of PPI. But the review of Kirk et al (2016). tells us that the CFIR is potentially a valuable tool to help understand PPI on research outcomes and understanding its complexities.

In an early DH report concerning PPI and implementation, Farrell (2004) offered a diverse look at the nuances of implementation in healthcare projects which had PPI. Of the n=12 PPI projects reviewed, Farrell reported four ingredients to successful outcomes:

1. enhancing communication and interaction between professionals and patients;
2. recognition and clarification of the problem, by specifically stating questions and comments about a particular research project and its benefits and problems;
3. preparing for difficult situations, particularly relating to resource allocation decision-making and;
4. building relationships and partnerships so that local partners can be aware and help to share the knowledge.

Farrell's four ingredients link to aspects of the CFIR, because Farrell (2004) suggested that PPI is a 'complex intervention'. A complex intervention, according to Brett et al. (2014 p388), is '*where impact needs to be evaluated alongside broader factors, in order to identify what works, for whom and in what circumstances'*. Understanding such complexity helps to shed light on why some studies thrive whilst others fail. Snape et al. (2014) also formed consensus in their work on impact barriers and drivers that are central components to implementation work with PPI which required research team cohesion and suitable resources. Thus, implementation processes are key to understanding the impact of PPI on research outcomes.

The remaining section of this review attempts to understand more specifically what is known and not known about the impact of PPI in healthcare and research on process and outcomes (review question two). After exploring the next body of evidence, how the author's thinking has been advanced about the two distinct areas is knowledge is considered in the form of a conclusion.

Body of evidence 2: 'The impact of PPI healthcare research on process and outcomes'

Introduction

The remaining body of literature discussed in this review focuses on the impact of PPI on healthcare research in process and outcomes (i.e. review question two). The articles were primarily aimed at researchers, policy makers and scholars. They were mainly UK-based, whilst some were international (see table 4 for details). These articles offered descriptions of impact of involvement on research processes.

Eight literature or systematic reviews (Oliver et al. 2004; Nilsen et al. 2006; Daykin et al. 2007; Staley 2009; Boote et al. 2010; Mockford et al. 2011; Brett et al. 2014a; and Brett et al. 2014b) on the topic of impact of PPI were found and used in this review to demonstrate growing thematic knowledge since 2004. Very little was found on the impact of PPI specifically on research outcomes (Wilson et al. 2015). This is evidence that the literature has at least considered the impact of PPI on: healthcare (Daykin et al. 2007; Mockford et al. 2011); researchers, patients and public (Brett et al. 2014b); and the research process (Staley 2009). Only one isolated example from healthcare research evaluation observed that no evidence was available towards understanding impact of PPI on research outcomes (Wilson et al. 2015). The literature also demonstrated a gap in the quality of reporting of PPI (Staniszewska et al. 2017).

The impact of PPI on healthcare

To understand the impact of PPI on *healthcare*, a systematic review by Daykin et al. (2007) set out to evaluate the Patient Advisory Liaison Service (PALS). Daykin et al. (2007) assessed n=8 PALS groups across England. Whist acknowledging their work did not focus on outcomes, they argued that their review offers a comprehensive account of wider PPI literature. Four themes were present in the work: the impact of organisational culture; leadership and change management; the impact of PPI; and the need for robust

research on impact. Daykin et al. articulated that an organisational culture in support of PPI initiatives was a key component for successful PPI outcomes, stressing the need for shared understandings between staff and patients. Daykin et al. identified a range of 'outcomes':

> The studies report a diverse range of outcomes, from enhanced subjective experiences to discrete initiatives at the collective level, including a mental health charter (Hodge, 2005), a counselling service targeting black and minority ethnic communities (Crowley et al. 2002) and the establishment of a flagship health centre (Kashefi and Mort, 2004).
>
> (Daykin et al. 2007 p57)

Daykin et al. (2007) go further and state that whilst there was a tendency to report on positive outcomes of PPI initiatives, there was less discussion of negative outcomes, even though most authors reviewed reported barriers to the development of PPI. Daykin et al. (2007 p57) also identified that: '*One of the difficulties in assessing this evidence is that there is often a time lag reported between an intervention and the outcomes.*' This echoes the point made by Rivera et al. (2017) and is discussed later in the review of Wilson et al. (2015) later.

Similarly, a systematic review by Mockford et al. (2011), focused on healthcare rather than research that had PPI, identified n=42 papers which showed that PPI had a range of impacts. Their work described that there was little evidence of economic analysis of the costs of PPI and found reporting limitations of the evidence base due to poor quality reporting on impact. In their review, only a few studies defined what was meant by PPI but with little theoretical or conceptual insights. Mockford et al. (2011) identified a gap in robust measurement of impact, and that descriptions lacked detailed evidence. Only n=15 reported impacts of PPI on outcomes. Mockford et al. (2011) themed these impacts into seven areas: 1) the design of new healthcare buildings; 2) the location and access to services; 3) the provision of additional services; 4) re-organisation of existing services; 5) improved changes of organisations in acute trusts; 6) improved dialogue between health professionals and patients; and 7) improved dialogue between patients and managers. Interestingly, all seven themes are important markers of significant change and yet they all are very different.

In summary, when discussing the impact of PPI on healthcare services, Daykin et al. (2007) and Mockford et al. (2011) highlight a range of improvements. However, capturing the audit trails of these improvements are notably absent in their discussions.

The impact of PPI on research processes

There were many examples of impact at all stages of the research process where members of the public and patients had been involved. The patient and the public have been involved in: setting the health research agenda (Entwistle et al. 2008); initiating research projects (Terry et al. 2007); deciding what research to fund (Lindenmeyer et al. 2007); determining the focus of a research study (Mosavel et al. 2005); and choosing the methods and tools used in the research (Barnard et al. 2005). In a Health Technology Assessment (HTA) review by Oliver et al. (2004), they identified n=286 documents that mentioned 'consumer' involvement helping to identify areas for research. Oliver et al. (2004) also addressed barriers to involvement which included negative attitudes and poor working relationship; difficulties in communication and time constraints. They argued that these aspects could be reversed with leadership and outreach to the community.

Other research studies have reported on the positive impact of PPI in research studies on recruitment (Viswanathan et al. 2004); data collection (Pandya 2007); analysis (Best et al. 2017); and writing up and disseminating (Pandya 2007). A Cochrane review by Nilsen et al. (2006) on n=6 randomised controlled trials, reported that one of the main outcomes from PPI on the research processes leads to more readable and understandable research materials.

PPI in the research process had also resulted in improving the research process itself and had led to positive outcomes (and negative, discussed below) whilst conducting the research. For example, Langston et al. (2005) conducted a randomised controlled trial on patients with Paget's disease. Patients in this trial joined the peer-review process, and attended the trial steering committee, provided advice to study participants and promoted the work of the trial. There are other examples too, in the work of Rhodes et al. (2002) which worked with people in setting up a diabetes service for patient and public advisory

groups. Byas et al. (2002) conducted a study on mental health in young service users, who acted as co-researchers; Walmsley (2004) similarly reported involving people with learning disabilities in their research. Other researchers have reported impacts such as research quality improving governance and ethical acceptability of studies (Marsden and Bradburn 2004). Boote et al. (2010) reviewed n=7 case examples of PPI in primary research design and reported that group meetings were the most common method of engagement. Contributions made by the public were largely in the areas of review of consent procedures and patient information sheets, outcome suggestions, and recommendations on participant recruitment.

Brett et al. (2014a) identified n=66 studies which reported on PPI and its impact on health and social care research. Again, positive impacts on the process of PPI were reported, including: enhanced quality and appropriateness of the research focus and questions; development of accessible research information; better recruitment in studies; public-member-focused interpretation of results; and better dissemination. But the authors concluded that the evidence base behind the impact of PPI still remained weak and needed significant enhancement. It is fair to summarise thus far that the impact of PPI on the research process is well documented but understanding of its impact on outcomes is insubstantial.

Staley's (2009) review which also focused on the impact of PPI in research found that n=89 studies offered information regarding impact. Most of the evidence on impact was based on the views of researchers and members of the public who had worked together on research projects. Her review reported that there was inconsistency regarding how impact was described in journal entries. This inconsistency was because there were no guidelines about reporting PPI impact until 2017 (Staniszewska et al 2017). Whilst there is not a consistent approach to defining and assessing impact, the benefits of doing so, and added time and costs reported, were similar across the studies. Staley (2009. p5) identified that there were impacts reported '*… on the research (at all stages and levels), on the members of the public who were involved, on the researchers, on participants, on community organisations and the wider community'*. Staley also found that people involved had 'influenced whether the results of research have been used to bring about

change'. This latter point was precisely what the current study was designed to further understandings about. Staley (2009) added in her report:

> the individuals involved in research have on occasion formed new relationships with key policy makers and local agencies. They have then been able to use their new skills and confidence to continue to affect community action and change
>
> (Staley 2009, p83).

It seems that Staley was referring to an important part of the jigsaw for this current study, suggesting that for PPI to impact on research outcomes the people involved had strong agency and leadership traits which helped maintain the implementation agenda after the research.

The impact of PPI on people involved in the research process

A systematic review (Brett et al. 2014b) using n=65 studies reported impacts on the patient and public feeling valued and gaining confidence and life skills. Researchers reported that such involvement led to greater understanding and insight into their research area, gaining respect and a good rapport with the community. The communities reported becoming more aware and knowledgeable about their condition. Other studies found that through PPI, people acquire new skills (Donà 2006); have more confidence (Rhodes et al. 2002); have better supported networks (Faulkner 2004); gain a sense of enjoyment (Barker and Weller 2003); and ultimately could gain sufficient experience from the studies to result in employment (Allen et al. 2006).

But impacts can also be negative and there was a reluctance among researchers to admit this (Staley 2009). A few cases have been documented during PPI in research which led to emotional difficulties with immigrant women (Meyer et al. 2003), work overload (Clark et al. 2004) and unwanted media exposure about socially taboo areas, such as teenage pregnancy (Pertrie et al. 2006). Brett et al. (2014b) identified that a lack of preparation and training led to some feeling unable to contribute to the research and became too overburdened with the work involved. Similarly, researchers reported

difficulties in incorporating the public in meaningful ways due to lack of money and time. Possibly the most difficult lasting negative experience of impact could be feelings of anger and frustration at being powerless to make changes (Rowe 2006). The work of Pandya-Wood et al. (2017) found that PPI in research design work was sometimes unintentionally carried out in an unethical manner (i.e. before studies are funded and formal ethical processes begin).

Impact of PPI on research outcomes

The literature review revealed a major gap in information about the evidence base concerning the impact of PPI on research outcomes. Wilson et al. (2015) applied realist evaluation (which focuses on context, mechanism and outcomes and was developed by Pawson and Tilley 1997) to PPI's evaluation and found that across n=6 topic areas using a scoping exercise, online survey and case studies, researchers reported no evidence of any immediate outcomes of PPI: *'Among the eight that were completed, we found no evidence of any immediate outcomes of PPI for the research findings …'* (Wilson et al. 2015, p110). The RAPPORT study was designed specifically to meet the gap in knowledge about impact of PPI process and outcomes. So, the conclusion was important as it showed that *'no evidence of immediate outcomes'* was reported. They used Normalisation Process Theory (NPT) (May and Finch 2009) which uses four mechanisms to help identify how interventions are embedded and 'normalized' within routine care. These mechanisms of NPT are: coherence; cognitive participation, collective action and reflexive monitoring (May and Finch 2009). Whilst NPT offers a helpful possible framework for the evaluation of PPI, it has also been used extensively in the evaluation of health care interventions and therefore its efficacy is becoming increasingly well established (McEvoy et al. 2014, May et al. 2011).

When reviewing the limitations of their study, Wilson et al. (2015) identified, as Daykin et al. (2007) also did, that a longer time period was needed to understand and see the outcomes related to PPI in research: *'Outcomes of PPI on research findings and impact on services and clinical practice requires a longer-term follow-up study'* (Wilson et al. 2015 p.171).The study by Wilson et al. was the only work to have tried to address what this current research is focused on, and yet its inconclusive evidence points to a further

reason for why the current study is necessary. An earlier paper by Mathie et al. (2014) on the RAPPORT study found that even though PPI processes were well described in grant applications, there was a lack of monitoring on how PPI operates as the study develops, providing a glaring difference of what happens during study planning and conducting, i.e. research governance is lacking when a study is running.

Poor quality reporting in the field is well established as a possible reason for the lack of literature on the impact of PPI on research outcomes. Furthermore, currently there is no consistent language to identify what is meant by impact of PPI on research processes or outcomes (Brett et al. 2010; Mockford et al. 2011; Staley 2009).

Poor quality reporting on PPI

Several authors have commented that reporting and assessment of PPI by researchers was poor (e.g. Brett et al. 2010). Mockford et al. (2011. p28) argued:

> *There is, surprisingly, a dearth in research about the impact of PPI on services …and how services have changed (the outcomes), because of it [or] the extent of changes, or how much it costs….*

Staniszewska et al. (2011) point out that the difficulty in assessing the impact of PPI outcomes is due to poor methods of reporting how impact was understood as a marker of change.

However, the non-appearance in the literature about changes observed, costs and other issues does not equate to no impact: '*…the absence of evidence does not indicate an absence of impact, rather it indicates inadequate reporting with a lack of valid and reliable tools to capture the impact of public involvement'* (Mockford et al. 2012 p396). In some situations, the impact may easily be noticeable, while in most cases impact of PPI is much more elusive (Popay et al. 2014). However, Staniszewska et al. (2011) raised that descriptions of impact by their nature were insufficient because:

> The main ways in which PPI impact is represented is through short descriptions. No standard formats exist for describing or capturing these impacts, and so they tend to vary in content, structure, and presentation.
>
> (Staniszewska et al. 2011 p396)

Mockford et al. (2011) argued for a need for tools to help form an evidence base for the impact of PPI in research outcomes, with clear concepts, economic guidelines, and guidelines for reporting. The Guidelines for Reporting Involvement of Patient and Public (GRIPP) (Staniszewska et al. 2011) were subsequently devised from systematic reviews. In response to the above anomalies, there was a sense of urgency for common definitions, for tools and theoretical models:

> While there are some helpful definitions of involvement, the conceptualization or theorization of PPI has generally been poor. There have been some attempts to develop conceptual or theoretical frameworks, but there is no overall conceptual model of PPI impact that captures the essence of the concept and has been empirically tested.
>
> (Staniszewska et al. 2011 p394)

Staniszewska et al. (2011 p389) made a further point and explained that identifying the necessary components to create the much-needed tools was important: '…[to] *enable a greater understanding of what works, for whom and in what circumstances.'* They argued that context might concern conditions for PPI to make an impact such as support, training and resources. In relation to circumstances, they argued for the need to have insights into the PPI process, such as the methods used to undertake the PPI. The authors highlight that PPI is a complex process that has many different angles of assessment connected to it: *'the importance of context and process suggests that PPI should be viewed as a complex intervention that requires multi-layered reporting.'* (Staniszewska et al. 2011 p394).

Staniszewska et al. (2017) devised an international checklist with consensus on what researchers should be reporting about on PPI processes (and to some extent, outcomes). The checklist came in two forms, a short format (SF) and a long format (LF) outlining guidelines eliciting comment on the impact of PPI. Not intentionally perhaps, the LF

offered pointers to the implementation process. It is worth reminding the reader that usually reporting or publishing occurs retrospectively, as does assessing impact. But perhaps one distinctive aspect of PPI is that it could help bring a unique focus to implementation work because it could concern prospective and retrospective thoughts, as patients and the public remain patients and the public, before and after research studies end. Thus GRIPP 2 can help in planning PPI and reporting PPI (Chapter 4 and Chapter 9 demonstrate this).

Gaps and important knowledge identified

The two bodies of literature relating to impact of research, and the impact of PPI on healthcare and research, have both discussed the importance of context, mechanism and outcomes. In the impact of research literature, writers have not fully acknowledged the growing work in the field of PPI. Similarly, in the impact of PPI on healthcare research on process and outcomes, scholars, until recently, have regarded dominant impact structures such as the REF to be something that does not warrant comment regarding the impact of PPI on research work. These points will now be expanded and considered in relation to the current study.

Summary and gaps: 'The impact of research'

Exploring collectively the broader literature on impact of research particularly, 'research context', 'application of new knowledge', 'research evaluation tracing tools' and implementation science, has helped to confirm that PPI as an agenda for health research implementation is largely absent. This might partly explain why the impact of PPI on research outcomes appears to be an underdeveloped area of knowledge. Thus, the implications for the current study from the impact of research literature demonstrated six gaps:

1. When considering the impact of PPI on research, timeliness must be taken into account because population needs evolve and doing the right thing at the right time appears to make a difference (Bensing et al. 2003).

2. There has been a lack of effort on creating consistent language, how engagement efforts with patients and the public could help usability of new knowledge. There was also no explicit mention of PPI in the application of new knowledge.
3. The tabulated framework of Rivera et al. (2017) helped to identify that knowledge on impact frameworks available does not include the impact of PPI. And although there was mention of 'end users', this was not at involvement level, it was at an engagement level.
4. The CFIR provided by Damschroder et al. (2009) has the potential to help establish how the impact of PPI outcomes could be better understood by offering attention to adapting the intervention, considering alignment between inner and outer settings, using the insights of people and then making the change. Application of the work by Damschroder et al. (2009) is unique because it inherently considers the ideas of complex interventions which can help PPI in implementation work.
5. Broader factors pointing to PPI being a complex intervention also related the three challenges that the impact of research literature has identified. I.e. the importance of context equates to a favourable PPI climate; the need for clarity about how research will be applied will equate aligning appropriate PPI processes; and what impact tools to use may equate to how PPI can be evaluated.
6. Guidelines and frameworks such as those of Rivera (2017), Damschroder et al. (2009) and Staniszewska et al. (2017) could be useful not just retrospectively but perhaps also during the research process planning as '*...[guidelines and frameworks] can help to understand the conditions or features which support intervention effectiveness, its implementation and ideally, how to achieve sustained practice change'* (Brocklehurst et al. 2017. p333). Thus, following implementation guidelines during research conduct offers the research context up-to-date knowledge, and offers the application of the research timely information. Therefore, impact can be assessed and traced more easily as the impacts emerge over time and yet the perspectives remain fresh. Though in the real world, funding does run out and so too can people's motivations.

Summary and gaps: 'The impact of PPI in healthcare research on process and outcomes'

On the impact of PPI, studies report a diverse range of outcomes including, 1. the design of new healthcare buildings; 2. the location and access to services; 3. the provision of additional services; 4. re-organisation of existing services; 5. improved changes of organisations in acute trusts; 6. improved dialogue between health professionals and patients; and 7. improved dialogue between patients and managers (Mockford et al. 2011), There were also specific improvements in mental health services and improvements for BME communities. (Daykin et al. 2007).

The impact of PPI on research processes was better documented than outcomes (Staley 2009) but understandings about the impact of PPI on outcomes was underdeveloped. Staley (2009) argued that patients and the public who had strong agency and managers with strong leadership were in a firmer position to affect community action and change. Thus, here it seems that Staley is implying that implementation and impact may be achievable with individual agency and good leadership. The impact of PPI on people involved in the research process was documented by Brett et al 2010 but the impact of PPI on research outcomes was a major gap. Wilson et al. (2015) applied realist evaluation and NPT and found no evidence of impact. Others revealed that reporting and assessment of PPI was poor (e.g. Brett et al. 2010; Mockford et al. (2011). Robust evidence of impact is needed for a variety of reasons concerning process and outcomes:

1. PPI in research-process related reasoning might encourage researchers to commit to the process of PPI (Staley et al. 2014). It would help to ensure that research is carried out with integrity (Snape et al. 2014a). Thus, overall would improve research quality (Morrow et al. 2010; Wright et al. 2011) and reduce negative ethical implications for patients and public, and for the research process itself (Pandya-Wood et al. 2017). Moreover, PPI in the research process would help to justify resources allocated to PPI (Staniszewska 2011).
2. In relation to impact of PPI on research outcomes, understanding the impact of PPI on services and policy will help to strengthen the link between research and practice (Brett et al. 2011; Mockford et al. 2011).

3. Staniszewska et al.'s. (2017) framework of GRIPP 2 will be piloted and over the next few years and providing researchers use it, poor-quality about the impact of PPI reporting could become a diminishing problem.
4. PPI context, PPI mechanisms and PPI outcomes need to be considered in understanding the impact of PPI on research outcomes, echoing ideas of realist evaluation (Pawson and Tilley 1997)
5. Implementation theory such as NPT has been used to understand how to embed PPI into routine healthcare, thus suggesting that implementation science as a field of academic knowledge may offer new ideas for the current study, the CFIR has never been used.

What this tells us is that there is a vague and not explicit link between the two distinct bodies of literature. The concept of PPI is not on the 'radar' of research impact literature but literature on impact of PPI on research are starting to form links in the way of a concept analysis which takes us from what research impact means to what impact of PPI means (Hughs and Duffy 2018).

Methodological limitations

In this critical narrative review there are methodological aspects which require acknowledgment. The terminology used to specify the people who use or are meant to be served by healthcare was broad. The meaning of the term 'impact' was also broad and was rarely addressed in the PPI literature.

The articles were grouped to help understand whether they were concerned with empirical or theory-based writing. The literature presented here came from a mix of qualitative, quantitative and mixed methods approaches used by others to study the impact of PPI and impact of research, thus generalisability in the qualitative studies is not possible to determine as samples were often small.

The reporting of PPI, as Staniszewska et al. (2017) note, has been poor and this has no doubt affected the content of the critical narrative review, especially that which concerns

the impact of PPI. In the current review it was found that PPI in research is multi-layered and cuts across a diverse number health conditions and different disciplines. This means that what may seem to work as a plausible explanation for one study, may not work in another. Hence a further reason why the need for understanding context, mechanism and outcomes (principles of realist evaluation) has been a popular choice for some (Wilson et al. 2015).

Mason (2002 p154) argues that no research or story can be ontologically neutral (ontology is a point which is explored in the next chapter). The main focus of this review was to generate an understanding about the impact of PPI on research outcomes. The data in articles presented varied from primary and secondary sources, meaning that these sources have already been interpreted once before, by others who compiled and presented its arguments, thus taking these as evidence requires a degree of caution. To help gain an overview of knowledge it was helpful to use several literature reviews compiled by others since many of the key messages about the area under investigation were already summarised. They also offered the research enquiry details about insights into how to approach fieldwork for the current study (which is in the next chapter).

Conclusion

This critical narrative review has identified many studies, from a range of health disciplines, which address the 1. The impact of research and 2. The impact of PPI on healthcare research on process and outcomes. Various themes have emerged for consideration for the current study which have been summarised.

The appraised literature problematised the impact of PPI in that more time and money was needed to enhance it. Better training, leadership and communication processes are also needed to help embrace its value. Collectively, the impact of PPI in the *processes of research* is understood better than impact of PPI on the *outcomes of research and healthcare.* This finding mirrors the previous chapter: achieving outcomes at implementation stage is an enduring challenge for PPI. The above impacts are diverse and rich in information about how they affect, mostly positively, healthcare services, the research process itself, the topic of interest being researched, and the people involved.

However, most of the impacts found did not focus upon the issue this study is concerned with, which is the impact of PPI on research outcomes. This is an important point because it implies that PPI evaluation needs to take account of stages of PPI evaluation, as reporting is poor. Perhaps efforts need to be placed on planning evaluations of PPI at certain points of time in order to understand smaller steps of achievement after a study has ended with PPI. Methodological limitations describe some of the challenges identified in using the literature particularly around using systematic reviews. In the next chapter, the methodological decisions made for the current research study are set out.

Chapter Four: Research Design and Methodology

Introduction

The aim of this study was to advance knowledge about how to evaluate the impact of PPI on cancer research outcomes. This social science inductive inquiry used a combination of interpretivist and pragmatic approaches, resulting in qualitative, mixed methods design (using interviews and a Delphi survey with patients and the public, healthcare researchers and stakeholders). At key stages of the research, the study utilised the principles of involvement with 'end users'.

This chapter explains decisions that were made to ensure that the methodology was congruent with the research aims and objectives. It begins with a discussion about research strategy concerning understandings of empiricism, epistemology and ontology because through these understandings of the researcher's world view, methodological decisions were made. The 'involvement section' follows because involvement was threaded throughout the research design and involvement often resulted in methodological decisions. As involvement with end users was a large part of this study, it needed to be presented separately because those encounters were carried out before or after a key stage of research (e.g. data collection) therefore the involvement section demonstrates precisely what its aim was, how the involvement happened and what it resulted in before the researcher describes 'her side of the story'. After this, an overarching design is presented, followed by detailed information about the approaches used in both phase 1 and phase 2. The chapter then reviews quality assurance and ethics.

'Participant' and 'panellist' distinction

Throughout this thesis in relation to the current research the author will be using the terms 'participants' to mean (only) interview participants (phase 1), and 'panellists' to mean those taking part in the Delphi (phase 2).

Methodological stance and theoretical orientations

Personal values inform the methodology chosen by a researcher (Crotty 2003). Under this section the epistemological, ontological and involvement influences on the researcher are outlined.

Fundamentally, there are two main and opposing epistemological positions, positivism and interpretivism. A positivist position implies that one reality exists, and that the researcher will discover this reality (Robson 2002). The positivist position offers measurements of human opinion, suiting numeric answers, working out physical theories or hypotheses (Bryman 2012). Positivists see the researched world as independent of the researcher. On the other hand, interpretivists believe that the social world is understood differently from the natural world, i.e. we are born into a gendered, cultured and politicised world in which all experiences have meanings to each individual which are unique to them. Interpretivism offers room for difference and disputes, valuing varied perceptions and opinions (Dyson and Brown 2006). Initially, because this thesis' aim was exploratory, an interpretivist epistemological position was adopted. 'Perceptions of impact' implied richer understandings based on people's experiences, accounts and reasons behind their thoughts. However, early involvement work, clearly identified that something useful and tangible should come from the current study to help shorten the gap of understandings about impact of PPI on research outcomes and impact of research. Thus, the current research also needed to be pragmatic. Pragmatism in this research study:

> "… accepts, philosophically, that there are singular and multiple realities that are open to empirical inquiry and orients itself toward solving practical problems in the ''real world"
>
> (Feilzer 2010, p8)

Linked to the idea of epistemology is the question about social ontology, which refers to the nature of social entities:

> Whether social entities can and should be considered objective entities that have a reality external to social actors, or whether they can or should be considered social constructions built up from the perceptions and actions of social actors.
>
> (Bryman 2012, p32)

There are two main competing concepts for ontological grounding: objectivism and constructivism. Objectivism implies that people in the world are recipients to rules and regulations beyond reach or influence and tasks are carried out to maintain procedures. Facts and values are inseparable (Robson 2002). In contrast constructivists believe that meanings are constantly being revised to build a body of knowledge (*ibid*). Constructivism associates well with interpreting social phenomena. The current researcher's social ontology aligned to the constructivist view because new meaning unfolds every day about aspects affecting the current research question, and together these opinions and theories build knowledge. The current study also aligned to the idea of inductive enquiry, rather than deductive enquiry. Inductive enquiries explore how the data generated relate to theory, allowing researchers to generalise interpretations from data followed by deduction (Bryman 2012). Whereas a deductive inquiry is when a researcher begins with a theoretical position and tries to gather and analyse data according to the theory (Brett Davis 2007).

The use of qualitative data collection, then analysis, followed by further data collection was necessary to help the pragmatic angle. Traditionally, this has not been compatible for some researchers (Denzin and Lincoln 1998, p8). However, increasingly there is a growing view that mixing methods offer tangible benefits to social research because one of two datasets could serve as an explanation towards the other (Bryman 2012). By employing two approaches to data collection, data integrity and credibility could be enhanced because findings would help to build further understandings (Max Burgman 2008).

Thus, data refinement would offer pragmatic understandings that were needed for the richness of the data collected (Cresswell 2003). However, to use two methods – both of which were mainly qualitative – required careful consideration. There is an emerging field of thought that combining qualitative with more qualitative data can be classed as mixed method research (Morse 2009). The qualitative findings could offer context to the external validity or broader variables uncovered through the counted data (Creswell et al.

2008). In turn these aspects would help to generate understanding towards a diversity of views across the groups (Bryman 2012).

And there is room in qualitative work for counting. Autonomous counting in qualitative research is used when, for example, ranking may help demonstrate the significance and importance of a particular (set of) issue(s) (Hannah and Lautsch 2011). Now that the epistemological and ontological position has been established, a description is offered about involvement informing the study.

End user Involvement

This section outlines why and how end user involvement was carried out. There are two entwined aspects that require explanation as they impacted upon the thinking behind this study. Firstly, the researcher's own reflexivity on the topic being studied and secondly, critical consideration of the involvement of others and their impact on this study. Mindful of this, it was decided that an involvement reporting tool would be used called GRIPP 2 (Staniszewska et al. 2017) as described in the previous chapter.

This tool was designed to help researchers to report on the involvement aspects carried out in their studies. Table 6 (below) demonstrates the application of GRIPP 2 to this present study. A deeper reflection on end user involvement is offered in chapter nine.

Table 6 - GRIPP 2 adapted to report end user involvement in the current study

Title (Staniszewska et al. 2017p3)	Application to this study
A) Provide a clear description of methods by which patients and the public were involved;	Consultative level of involvement was maintained throughout the study (Hanley 2005). Consultation is when people are asked for their views about the study and then these views inform the researcher's decision making in the study. Several PPI consultation meetings occurred whenever the researcher felt there was a strong purpose or need for clarity in the research (see below in sections G, H and I). In summary, workshops had between 5-17 attendees. Sometimes the focus was just patient and public input, other times the focus was researcher or stakeholder input. The input depended on who the focus of the study was on at a given time and on the availability of people and the researcher's availability to 'piggy back' onto existing events that were being planned by her affiliated universities. Where possible an email was sent out in the form of a summary of the research and the reason for PPI input to whoever was planning the event to allow for a PPI workshop. The reason for sending out a summary was so that people who chose to be involved were briefed beforehand. At the end of the workshops the researcher would summarise what had arisen from discussions and ask for clarity, followed by explaining to those present how the content or people's input might be used in the study. On reflection choosing consultation as a method of involvement had pros and cons. Consultation was useful as it provided flexibility to this PhD. As this is a PhD study, no funds were provided to run PPI workshops. Consultation was sometimes difficult to manage because ideally people involved would have liked to have known how their input changed the research but in reality, this did not happen unless people explicitly asked. People rarely did ask – which sometimes made the involvement in this work feel slightly publicly isolated and disconnected from what they had raised. It was also difficult for the researcher to keep up with emailing everyone who was present.
B) Provide a description of patients, carers, and	The 'researched' in the current research spanned the experiences of patients and public, applied healthcare researchers, healthcare policy staff and clinical staff. Thus, the involvement in this study reflected the above range of people (See details below in D).

Title (Staniszewska et al. 2017p3)	Application to this study
the public involved with the PPI [patient and public involvement] activity in the study;	On reflection it is important to note that the patients and the public involved in this study were sometimes experienced individuals who were on occasion highly verbal about the training that they had been exposed to in their PPI roles. At shorter workshops (45 mins) it felt as if the focus of the current research needed a longer time for them to digest the content and frustratingly just as content became useful the workshops were almost over. Over the course of the study sometime the same groups of people came to workshops and their knowledge on the topic had evolved or grown partly because the researcher was able to articulate better on the topic and partly because they had been exposed to more impact of PPI related information through their own networks. Researchers were often the hardest group to help understand the focus of the study because they were not attuned to PPI in research all the time or sometimes they felt that PPI was about participants in the study. This confusion often diverted valuable time allocated for discussion on the topic, away from it. Not surprisingly the theoretical discussions which were held in 2017 were most fruitful amongst academic researchers.
C) Report on how PPI is used at different stages of the study	The principles behind the researcher's deliberative design aligned with reflection and critical feedback on methodological decision making, and to help with conceptual clarity, both at the following stages of the current work: - study aims development; - research design – both phases; - piloting questions for fieldwork – both phases; - analysis – both phases; and - discussion planning.
D) Report the level or nature of PPI used at various stages of the study.	Involvement took shape in the form of mostly planned face-to-face meetings, workshops, telephone calls, Skype calls and email exchanges. Impromptu involvement also influenced this work and a research diary that was kept recording details of these occurrences.

Title (Staniszewska et al. 2017p3)	Application to this study
E) Report the methods used to qualitatively explore the impact of PPI in the study;	Regular supervision discussions, an audit trail, a reflective diary and a poster on this very topic were used, applying Lincoln and Guba (1985) (see Appendix 1). This helped the researcher conceptualise what impact meant for the current work. Below in section G, H and I a summary reflects how useful each encounter of planned and unplanned involvement was, documenting direction and change for the current work.
F) Report the methods used to quantitatively measure or assess the impact of PPI;	This study used mixed methods sequential design. But input from end users was in dialogical ways, see below in section G, H and I, but from a numeric assessment in summary: 12 consultations occurred (on average, twice yearly) over the course of the research process with over 110 people spanning a range of academic and patient and public involvement backgrounds.
G) Report the rigour of the method used to capture or measure the impact of PPI; H) the results of PPI in the study, including both positive and negative outcomes; I)the positive and negative impacts	G), H) and I) are combined below in 1-13 'influential meetings' which describe the rigour and impact of the involvement encounter and whether it was positive or negative. **1)December 2008 - organic discussion prior to the study starting - favourable context** Observations on the front line and a discussion at a national Research Design Service (RDS) meeting presented the challenges of understanding the impact of PPI on research outcomes. The idea of studying the impact of PPI on research outcomes was discussed as a potential useful piece of work to help current debates on why researchers should engage with patients and the public in applied health research studies. **The PhD was registered in April 2009 and initial literature reviews started in 2010.** **2)April 2011 - relevance of question/aims via a workshop** A workshop held with academics at the Health Policy Research Unit (HPRU) at De Montfort University (which is a cluster of professionals interested in academic research concerning the topic of this work).

Title (Staniszewska et al. 2017p3)	Application to this study
that PPI has had on the research, the individuals involved (including patients and researchers), and wider impacts;	**Outcomes and impact from the workshop** - Brainstorming led to the aims and objectives of this study. -The research needed to develop tangible and pragmatic outcomes from it. -The importance of having PPI in the study itself was unveiled by the workshop attendees. -It became apparent that the 'end users' of this research were not just patients and the public but also the researchers and academics interested in this work. -The importance of focusing on one topic area was raised at this workshop and as a result, the disease of cancer was selected over other topics of health (autism, substance abuse and HIV were the researcher's background before the current role in the NIHR RDS). -The workshop resulted in early peer review of the proposed design of the study. **3)November 2011 - ethical clarity was needed for phase 1 via two face-to-face meetings** During the ethics approval process from De Montfort University, clarification was needed about whether NHS ethics approval was needed for this study; an ethics committee member and a Research and Development office manager were approached for a discussion. **Outcomes and impact from the two meetings** They confirmed that NHS ethics approval was not necessary for this study as people involved as participants would be offering their expertise of research and not concerning their cancer. They raised that recruitment for participants was to be carried out via publicly searchable and approachable means. After this, ethical approval was successfully attained (before the researcher began maternity leave for 13 months). **4)June 2013 - data collection tool (patient and public sensitive)**

Title (Staniszewska et al. 2017p3)	Application to this study
	The questions developed needed to be piloted to ensure that there was flow and that they were serving their purpose. Two members of the public offered opportunity for piloting the work. Both were in remission. Piloting took place face to face. **Outcomes from the pilot interviews with patients** Certain questions were omitted from the interview guide as a result of the pilot. For example, it was felt that a probing question about involvement in prior cancer research studies should be reworded. Because of this suggestion, the question was altered on the interview guide. **5)June 2013 - data collection tool (researcher appropriate)** Two pilot interviews with academics from the Faculty of Health and Life Sciences at De Montfort University were carried out to ensure that the questions were researcher appropriate **Outcomes from pilot interviews with researchers** Feedback indicated some of the questions were too long and wordy, which helped the researcher to adjust the interview guide for the current research. **6)August 2013 - data collection tool (stakeholder appropriate)** Two pilot interviews with healthcare professionals from the University of Leicester were held (to ensure that the questions during interview were applicable for the stakeholders. **Outcomes from pilot interviews with stakeholders** For consistency, impact of research needed to be explained within the interview itself. The interview guide was adapted to include this point. They said some questions were not suitable for stakeholders and should be phrased differently e.g. original question was 'can you describe the study you were involved in' changed to 'how were you connected to the … study'?

Title (Staniszewska et al. 2017p3)	Application to this study
	7)May 2014 – data analysis focus workshop with researchers A seminar at the HPRU was held to present the researcher's analysis of the interview data. The key themes were presented. Workshop attendees were also asked for suggestions for the focus of the Delphi 'stimulus paper'. **Outcomes of the data analysis workshop with researchers** At this seminar, a discussion took place about how the data were very varied and broad. The main reasons for the variations were because of the various types of studies that the different groups (patients researchers and stakeholders) has focused to speak about during interviews, their real-life examples of studies ranged from clinical trials to qualitative interviewing in the community (palliative care).It was suggested that common themes running across the three groups needed to be focused on rather than other aspects from the data. **8)May 2014, data analysis focus workshop with stakeholders** A seminar at the University of Leicester SAPPIRE group was held on data analysis focusing on common themes across the three groups. Workshop attendees were asked specifically about Delphi 'stimulus paper'. Feedback was offered from the previous workshop too. **Outcomes from the data analysis workshop held with stakeholders** An important point raised here was also concerning the vastness of the data and that the researcher should try and simplify the data (there were seven themes) these needed to be the focus. Attendees posed the question of why refinement was necessary if the work was interpretivist, to which the researcher's response was that something applicable needed to come from this study to help further the field. Workshop attendees agreed that the study needed to be pragmatically focused. **9)June 2014 data analysis focus workshop with patients and the public** At the Research Engaging with Patients and Public (REPP) forum a summary of findings was presented in a lay format. **Outcomes from the workshop held with patients and the public**

Title (Staniszewska et al. 2017p3)	Application to this study
	Small group discussions were arranged. Those present (45 patients and public) had concerns that the findings were too 'broad and quite academic'. Hence, the issues relating to PPI in research processes were in their words a *'red herring'* for this research and some if it needed to be carefully sifted out of the analysis, so that the stimulus paper issues related to the outcomes rather than processes. Public members at the workshop also said it was 'very hard to think about impact of PPI without a definition'. Attendees were asked to comment on what they would like to find out through the Delphi if they were conducting the research. The main messages were that impact of PPI needed defining, and that process issues were already known about, so the Delphi needed to be *'very outcomes focused'.* These three workshops (points 7,8,9 in this section) impacted on this work considerably because it helped the researcher gain clarity that the focus of the Delphi needed to be on the seven factors identified from the data (PPI processes, Dissemination, Power and leadership, Resources and the political context, Networks, Information and Communication technology and Wanting to make a difference). The Delphi needed a starting point about what impact of PPI on research outcomes meant for the current study. The stimulus paper developed reflected these aspects. **10)August 2014 - October 2014 Phase 2 Delphi study planning, checking and piloting over six weeks** Questions for phase two needed planning, checking and piloting within the intensive six weeks. A carer agreed to pilot all three rounds of questions. **Outcomes from planning, checking and piloting Delphi study** Rounds one, two and three questions were all piloted with a carer. Wording was adjusted on all three rounds some questions were made more 'lay-friendly'. After data collection was complete, results were recorded in a journal and a discussion workshop was needed to gain theoretical and conceptual clarity. (A second maternity break followed after data was collected for phase 2. in September 2015, for 14-months

Title (Staniszewska et al. 2017p3)	Application to this study
	11)May 2017 - Theoretical clarity workshop A workshop was held with HPRU members on theoretical clarity and the focus of the Discussion from this study. **Outcomes of theoretical clarity workshop** It was suggested that the researcher needed to focus on the pragmatic use of theories **12)May 2017 - Theoretical clarity workshop** A final workshop was held with the SAPHIRRE group on the theoretical clarity and the focus of the Discussion chapter. **Outcomes of theoretical clarity workshop** Workshop attendees raised that the researcher needed to be mindful that the work needed to have a pragmatic focus These conceptual workshops later led the researcher to the work of Damschroder et al (2009).
J) The influence of any contextual factors that enabled or hindered the process or impact of PPI;	There were various influential factors, concerning the context of this research which enabled and hindered the process of the study and the impact of the planned involvement for this study. Between 2009-2012, MRC and NIHR funded five studies on the impact of PPI on research. As a result, momentum on the topic started to gain pace. Thus, the context began to shift, and the impact of PPI began to feature regularly in national conferences and meetings. This in turn initiated several conversations between the researcher and others (e.g. one prominent conversation in February 2011 was with a rheumatologist researcher who challenged the researcher by asking 'how are you researching the impact of PPI without involving people?' This conversation contributed towards the idea of having focused discussions at the HPRU seminar with end users about how this current study might involve people and who the end users were.

Title (Staniszewska et al. 2017p3)	Application to this study
	In November 2016, upon returning from a second maternity leave, several new publications had been published on the topic being researched. As all the national funded studies had finished, this suggested that the field was gaining sophisticated momentum from scholars.
K) The influence of any process factors, that enabled or hindered the impact of PPI;	Involvement in this work has often felt reactive. The goodwill of people who have been involved has been partly because of the researcher's professional work in the field. In hindsight this work could have explored whether two or three consistent people could help plan the involvement as did Robinson (2012) in her work on Asperger's syndrome and Thompson (2009) in her work on PPI in the cancer research setting. Despite this observation and the length of time taken to conduct this work, meaningful involvement at the highest standard has been achieved due to the researcher's own values and interest in the topic. Thus, the impact of the approach of involvement used in this work has been successful as people involved offered a diverse critical and constructive sounding board. More on reflections about end user involvement is offered in chapter nine.
L) Any conceptual or theoretical development in PPI that have emerged; testing of theoretical models;	The work of Damschroder et al. (2009) has been applied to the study discussion to help consider PPI at an implementation level.
M) Aspects of instrument development and testing (e.g. validity, reliability, feasibility, acceptability, responsiveness,	The following models were used: The work of Lincoln and Guba (1985) was used for reliability and validity understandings - see section on Research rigour in this chapter. The five domains that Damschroder et al. (2009) identified have been used to understand interpretability of how data from the current study which is about advancing knowledge about the impact of PPI, can be considered via the domains of adapting the intervention, the inner and outer settings, offering thought to the types of people involved in making change happen (their individual agency) and actually carrying out the change. The use of GRIPP 2 itself (Staniszewska et al. 2017) has been adapted and used retrospectively to help respond to the gap in specially designed tools for recording PPI work. In

Title (Staniszewska et al. 2017p3)	Application to this study
interpretability, appropriateness, precision)	this work, in the absence of other tools GRIPP2 LF and SF has been adapted and used as a tool to record how involvement in this study has resulted into change (impact) and this table demonstrates that, with flexibility and adaptation, a methodology can reflect the GRIPP 2.

Adapted from 'Guidelines for Reporting Involvement of Patients and Public 2' Long Format (GRIPP 2 LF) (Staniszewska et al. 2017)

As table 6 demonstrates, the involvement of potential 'end users' had an impact on the current study's research design from a pragmatic point of view, to help methodological decision making, and to aid conceptual clarity. Involvement occurred during: study aims development; research design for both phases; piloting questions for fieldwork in both phases; analysis in both phases; and discussion planning. Involvement encounters occurred mostly in face-to-face and sometimes remotely (over email and telephone). Overall, 12 key influences of involvement occurred over the course of the study (on average, twice yearly) and over 110 people were involved at a consultative level (Hanley 2005). The context for the study was favourable because numerous studies were funded nationally on the topic at the time (implying momentum of new knowledge was gaining pace). The following scholars' work was applied and influenced the conceptual clarity of involvement for the researcher. Lincoln and Guba (1985) Damschroder et al. (2009) and Staniszewska et al. (2017). Table 6 demonstrates that deliberation was woven through the work. However, whilst theories are important to help demonstrate what had influenced the researcher, it is worth remembering, they are only after all hopes and aspirations and not strict guidelines (Platt 1986).

Overarching study design

This work adopted an exploratory sequential design for data collection (Creswell et al. 2008). Data were collected in two phases, through interviews and a Delphi survey. Phase 1 took place between June 2013-February 2014 with a total of n=23 participants who took part in qualitative interviews. Interviews were chosen to form rich accounts of understandings about perceptions of impact of PPI on research outcomes. Patients, researchers and stakeholders took part and provided information about research studies which had finished. Themes identified from the interviews were fed into a unique paper which was called the 'stimulus paper' in this study. Prior to the interviews, literature reviews were carried out (and parts of these were published in book chapters: Pandya-Wood and Robinson 2014, Rivas and Pandya-Wood 2014 and Pandya-Wood et al. 2018).

Phase 2 of the research was carried out in the form of a three-round modified Delphi survey (interview data themes formed the preliminary work for the Delphi) with experts from the field. The Delphi survey's purpose was to offer a sophisticated yet practical

understanding of the complex social issues that the interviewees had identified from their accounts of understandings and perceptions concerning the impact of PPI on research outcomes. This phase was carried out between September 2014 and December 2014 with n=35 panellists (those working in leading charities and large non-government organisations, policy-makers, academics, independent consultants, government department leads, and 'expert patients'/patient champions). Figure 3 demonstrates the data collection process.

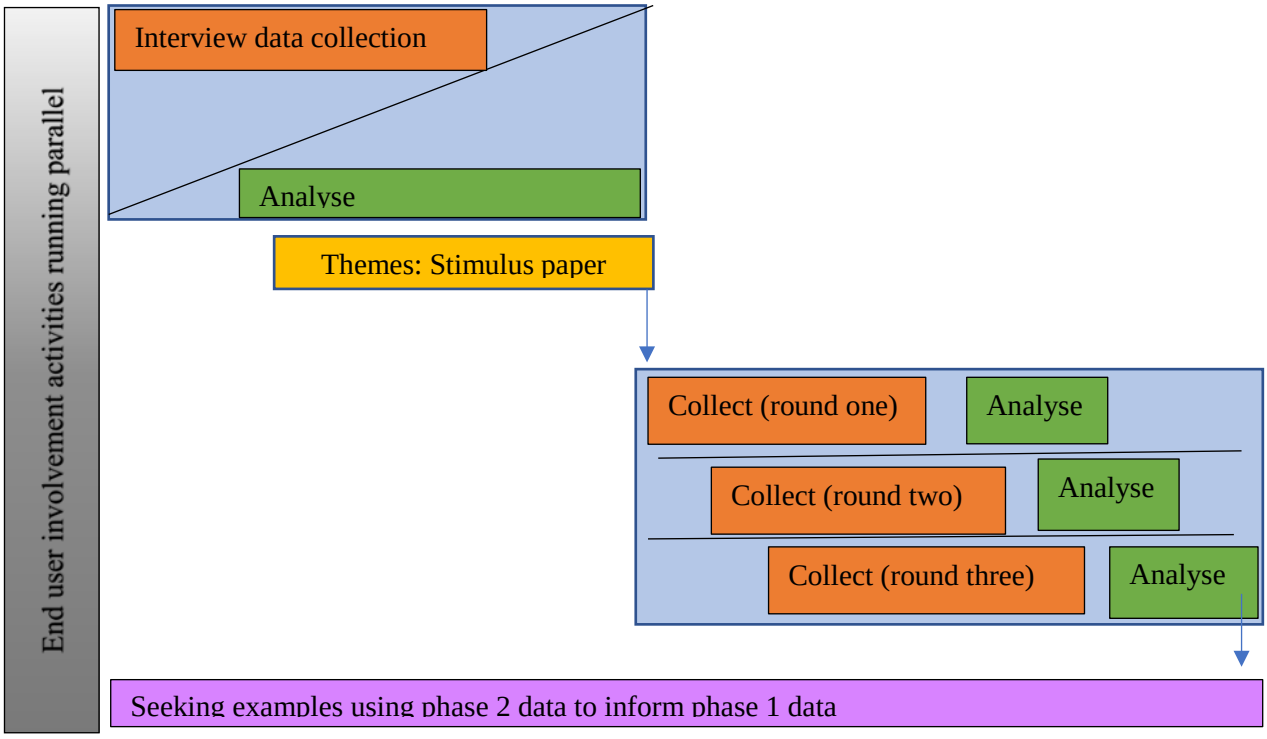

Figure 3 Data collection process

Phase 1 - Qualitative interviews

The interview is a well-used research method chosen usually by qualitative researchers. They are essentially a conversation with a focus, bringing in rich and thick descriptions about the phenomenon being researched. Interviews are useful because they can be structured in their style, semi-structured or totally unstructured, offering varying degrees of information (Britton 2006). Ives and Damery (2014) argue that the real strength of an interview is the flexibility of the research encounter to be both proactive to obtain the data, and also reactive to the data obtained, probing more questions. They allow for views

to unfold by asking the participants to consider using their own thoughts, perceptions and feelings driven by their own experiences.

The aim of this qualitative research was to understand the experiences of others, inviting them to describe their own perspectives. Semi-structured interviews, through probing, also enable follow-up questions for further clarification and detail. They can allow a space and opportunity to talk, rather than being constrained by pre-identified categories of response, using people's own vocabulary about what they find significant and important to them (Brett Davies 2007). Interviews were therefore planned to be conducted face to face, rather than remotely.

Limitations of interviews

The author was mindful of interviewing being a skill that required practice and constant reflection. Roulston (2010) found that four problems were encountered by novice researchers, summarised as: 1) difficulty in dealing with unexpected participant behaviours; 2) managing the researcher's own prejudice and beliefs; 3) difficulty in constructing and delivering questions; and 4) difficulty handling sensitive topics. By carefully planning and piloting (described in table 6) each of these problems were overcome.

But there are further challenges to interviews because they were always retrospective accounts (Taylor 2005) and past events can be misremembered, implying inaccurate data might be collected. To mitigate this, participants with recent experience were sought. With interviews there are subtle power dynamics between the researcher and the participant (Robson 2002). The issue of power may be connected to participants feeling intimidated by researchers, and power dynamics could well be present between a researcher and elite interviewees (Littig 2009). In this work, interviews were planned with professors, senior investigators and those holding significant public office, titles or in receipt of national recognition. Therefore, being confident in interviewing was deemed important for the current researcher right from the outset. Similarly, the interview pilot phase needed to ensure that research questions were accessible to reduce any intimidation.

Preparing an interview guide

An interview guide was developed by the researcher so that a list of appropriate and focused questions could be asked about people's experiences and knowledge about the impact of PPI on research outcomes. When preparing the interview guide, the main issue kept in mind was: *'just what is it that is puzzling me?'* (Lofland and Lofland 1995 p78) because this raised a sense of inquisitiveness in helping to ask the necessary questions needed from each group (patients, researchers and stakeholders). From reading the literature on the topic of impact of PPI on research outcomes, the researcher was aware of where knowledge was limited. The planned involvement channels of this work also helped with potential questions. National meetings, such as INVOLVE conferences, helped the researcher consider frontline issues that patients, researchers and stakeholders were struggling with in relation to impact on outcomes. At the time when data collection was being planned, five national studies had been funded on – the impact of PPI. These studies became public knowledge on the funders' websites. Efforts were made to ensure the current study remained uniquely focused on the impact of PPI on research *outcomes.* Finally, discussions with colleagues were also considered when generating questions.

The interview guide questions were designed in a way that was suitable for any of the three groups being interviewed. Topics for questions followed a logical and chronological structure. The interviews opened with two familiarisation questions: 1) information about the study and 2) what the motivations were for involvement in the study. Then it was necessary to ask, 3) how patients and public were supported for their roles in the research (mindful that this would also generate research process issues – but necessary, as it added more context). The interview then proceeded to ask questions about the outcomes from the study, including 4) key messages disseminated, 5) what had happened since the study had finished and lastly, 6) how participants understood impact. A copy of the interview guide is set out in Appendix 2. Within the current study, the interview schedule (appendix 2), was not used verbatim but as a topic guide.

Pilot interviews

Once developed, the interview questions and interview process needed to be piloted with individuals from each of the three groups; two people from each group were involved.

The pilot phase was invaluable for many reasons: the six pilot interviews helped the researcher to gain confidence; ensure that the questions followed a logical flow; adjust wording of certain questions; and monitor the smooth running of time. The length of time for an interview ranged from 45 minutes to two hours although adjusting the interview guide and the pilots helped to ensure that questions could be completed in one hour. Minor changes were made to suit each of the three groups and cues for questioning certain groups. Data from pilots was not used in the analysis.

Sampling framework

Data should continually be collected until data saturation has been reached, i.e. when information generated becomes repetitive and nothing new is being raised (Ives and Damery 2014). In the current research, participants were identified using purposive, non-probability sampling (Tansey 2007). In this study, finding a range of views and perceptions about the understandings of the impact of PPI on research outcomes was the primary concern. Using academic and professional networks, three groups were recruited: patients and the public, researchers and stakeholders.

To help the current study retain its unique focus, the following inclusion and exclusion criteria were applied:

- Researchers and patients interviewed were required to be able to discuss a cancer research study from the last five years[2] which had patient and public involvement in the research design and conduct.
- Preference was given to finding participants from the East Midlands. Focusing on one regional geographical boundary enabled convenience and snowball sampling approaches to be used by the researcher (Denscombe 2014).
- Participants needed to be over the age of 18 and able to speak in English. Excluding non-English-speakers was a limitation for this research but was necessary because there were no funds available for translation services. This limitation was magnified given that Leicester, from where most participants were recruited, is a diverse and multicultural city where over 130 languages and dialects

[2] According to the Research for Patient Benefit funding stream it is possible to demonstrate patient benefit between 3-5 years of a study finishing.

are spoken (Census 2011). Sheldon and Parker's (1992) work on race and ethnicity highlighted problems associated with health research and its limitations for not integrating aspects of race and ethnicity into health research strategies that include all groups.

Recruitment, consent and arranging interviews

All potential participants were identified through the researcher's professional networks as Regional Lead and Senior Advisor for Patient and Public Involvement for the Research Design Service, East Midlands. Emails were sent with a poster to people (Appendix 3) the researcher was aware of and those who fitted the sampling framework. In addition, a professional virtual network was contacted via an email advertising this research. The professional virtual network cuts across health and social care sectors. It celebrates a broad membership list, where members can select which subgroups they want to join for targeted information to be sent to them. Interest areas, to list a few, range from: 'PPI', 'Cancer', 'Better care without delay' and 'Service improvement'. See Table 7 for targeted recruitment for each group.

Table 7 - Targeted recruitment (Phase 1)

Patients	Researchers	Stakeholders
NIHR Cancer Research Network Cancer Support groups in the East Midlands PPI forums at Leicester, Nottingham, Derby, Lincoln and Northampton CHAIN Network 3 Twitter tweets resulted in 7 retweets Snowballing (word of mouth) Public Face Newsletter (East Midlands wide)	Existing contacts CHAIN (Contact, Help, Advice and Information Network) DMU staff newsletter	Existing contacts CHAIN INVOLVE

If potential participants put themselves forward and if they fitted the criteria, an information sheet (Appendix 4) and consent form (Appendix 5) were provided. Some people requested a telephone conversation, others took part in an email conversation, to find out more about the research. This initial contact was a valuable opportunity to allow

people to ask any questions about the research, and to arrange potential interview dates, times and venues.

Interview sample and data collection process

Interviews were carried out with n=23 participants. Details of their demographics and background information are set out in Table 8 and Appendix 6 demonstrates how this information was collected.

Table 8 - Participant demographics and key information (Phase 1)

Category	Patients	Researchers	Stakeholders
Sex	F (n=4) and M (n=2).	F (n=3) and M (n=5).	F (n=4) and M (n=5).
Age range	60 – 65 across group.	40 – 60 across the group.	22 – 60 across the group.
Ethnicity	All White British (n=6).	All White British (n=8).	All White British (n=9).
Religion	All Christian (n=6).	Christian (n=5), and No religion (n=3).	Christian (n=4), No religion (n=3), and left bank (n=2).
Experience	Breast Cancer (n=3), Oesophageal Cancer (n=1), Non-Hodgkin's Lymphoma (n=1), and Stomach Cancer (n=1).	Clinical geneticist (doctor) (n=1), and Clinical and Academic Professor (n=7).	Broad and varied ranging from junior policy staff in charities, to professors and directors of research centres and a hospice. Two had been awarded an OBE. Some had PhD and Professor in their title.
Locations	Northamptonshire (n=1), Nottinghamshire (n=1), Leicestershire (n=1), Lincolnshire (n=2), and Derbyshire (n=1).	Nottinghamshire (n=3) and Leicestershire (n=5).	Nottinghamshire (n=4), Leicestershire (n=3), and East Midlands in general (n=2).
Type of cancer study involving PPI	Randomised Control Trials (RCTs) (n=2), Community research (n=1), Surveys (n=1), Service improvement/ redesigning a service (n=1), and Improving cancer experience (n=1).	Randomised Control Trials (RCTs) (n=4), Palliative care (n=1), Cancer health provision inequalities (n=1), and Community care (n=2).	Community research (n=2), Palliative care (n=2), Participatory Action Research (n=1), and Improving cancer experience (n=9).
Funder	Research for Patient Benefit (n=2), Cancer Research UK (n=2), and unknown (n=2).	Marie Curie (n=1), Macmillan (n=1), European Union and Sanofi (pharmaceutical company) (n=1), Economic and Social Research Council (n=1), Research for Patient Benefit (n=3), and unknown (n=1).	Health Technology Assessment (n=1), Service Delivery Organisation (now Health Services and Delivery Research) (n=1), Cancer Research UK (n=2), Marie Curie (n=1), Macmillan (n=1), Collaborative Leadership for Applied Health Research Care (n=1),

Category	Patients	Researchers	Stakeholders
			Breast Cancer UK (n=1), and Prostate UK (n=1).

Interviews with patients took place in their own homes and were generally 'social' and relaxed in style, typically lasting 90-120 minutes. Interviews with researchers took place in hospital settings and university offices and lasted just under an hour - these interviews were the shortest. Interviews with stakeholders took part in university offices, hospital offices and hospital cafes all over the East Midlands, for a duration of 90 minutes. After all of the interviews were completed, each participant was informed about the potential next stages of this work. Later, a handwritten card was posted to each participant to express gratitude for their time.

Data analysis

This section demonstrates how two overarching themes with seven subthemes were identified using Braun and Clarke's (2006) model of analysis. The first theme was the *'Impact of PPI in research processes'* (two subthemes under this were *'PPI processes'* and *'Wanting to make a difference'*). The second overarching theme was '*Impact of PPI on research outcomes'*. Under the latter theme, the main focus of the PhD, the subthemes generated were: *Networks*; *Leadership and power*; *Resources and the political context*; *Dissemination*; and *Information and Communication Technology*.

All the interviews were recorded and transcribed verbatim. Braun and Clarke's (2006) six stages of data analysis was applied to this process. The process entails: data familiarisation, generation of initial codes, searching for themes, reviewing themes, defining and naming themes, and producing a report. The stages are now described:

1) *Data familiarisation*

This stage for Braun and Clarke (2006 p2) involves *'the researcher immersing themselves in their dataset by reading and re-reading each and every data item (and listening to any audio data at least once), to learn the content of the dataset 'inside out''*. Once all the data were transcribed, the audio recordings were heard, and corrections were made to the

Microsoft Word files. Once the transcripts were ready for analysis, these files were grouped according to the participants (patients researchers and stakeholders). These files were all printed and also uploaded onto NVivo.

2) Generation of initial codes

For Braun and Clarke (2006) this phase concerned coding data to help generate initial codes. The idea behind coding is to find interesting data which relate to meaningful information. At the very least a code can signify surface level information but at a deeper level a code might have hidden meanings such as assumptions that participants may have. Using NVivo, familiar and recurring issues raised were coded (Robson 2002 p274). See Appendix 7 for coding frameworks for phase 1. n=122 codes were identified and applied in this stage. For example, three codes were: *'Rewards and incentives'*, *'Stretched resources' and 'Involving charities'*

3) Searching for themes

For Braun and Clarke (2006 p2) the analysis here *'shifts to a wider focus. A theme identifies a meaning patterned across the dataset, which is important for illuminating the research question'*. Despite efforts to minimise data content on the impact of patient and public involvement on research processes, more than half of the overall data appeared to be on this topic (see Figure 4 - process codes map). Briefly, this large theme was useful because it grounded the data they provided during interview. At any opportunity participants eloquently spoke about their experiences of PPI processes (and in the case of researchers how they were (mostly) pro-involvement), they discussed from how opportunities about research were advertised to how what the work had led to since. Patients spoke of what it felt like to be a patient, what skills researchers were looking for, what skills they brought to the research process and the sorts of things that motivated them to get involved. Stakeholders described the unique value of research which had involved patients and the public, suggesting that the respective research study's they were describing were 'better quality because of PPI elements'. It was decided that this information was key to understanding the outcomes of research.

After PPI processes were grouped as a theme in their own right providing background information to help consider ‘contextual issues’, they were placed to one side to revisit later. Once all the remaining codes were themed, 15 ‘parent codes’ were identified as relating to impact (see Figure 5) and 20 codes identified as relating to barriers and/or facilitators of impact (see Figure 6). (To see full breakdown of these codes, along with their tiers of information, ‘parent’, ‘child’ and ‘grandchild’ codes that were also identified in NVivo, please see Appendix 7).

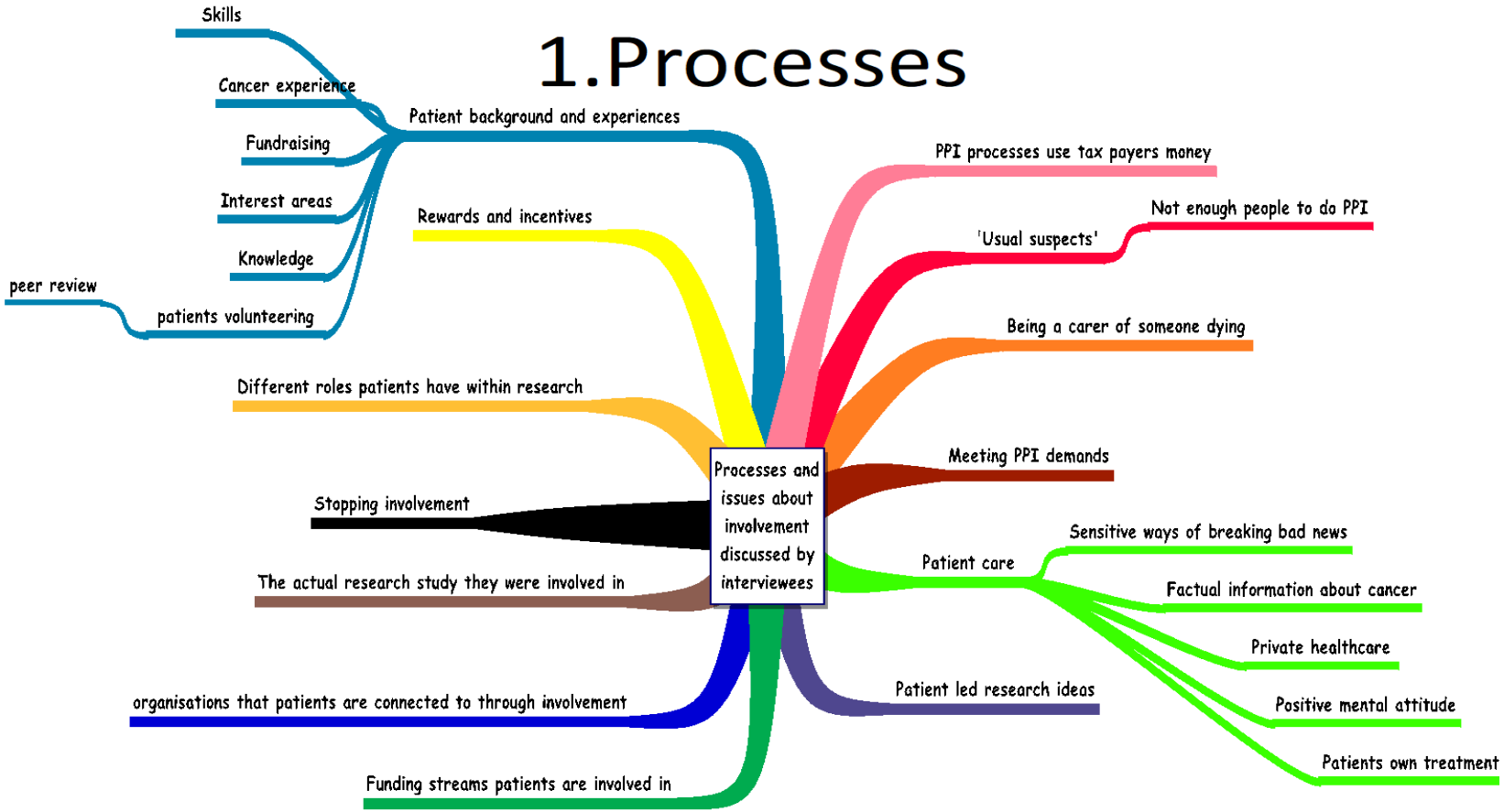

Figure 4 - PPI processes discussed during interviews (map)

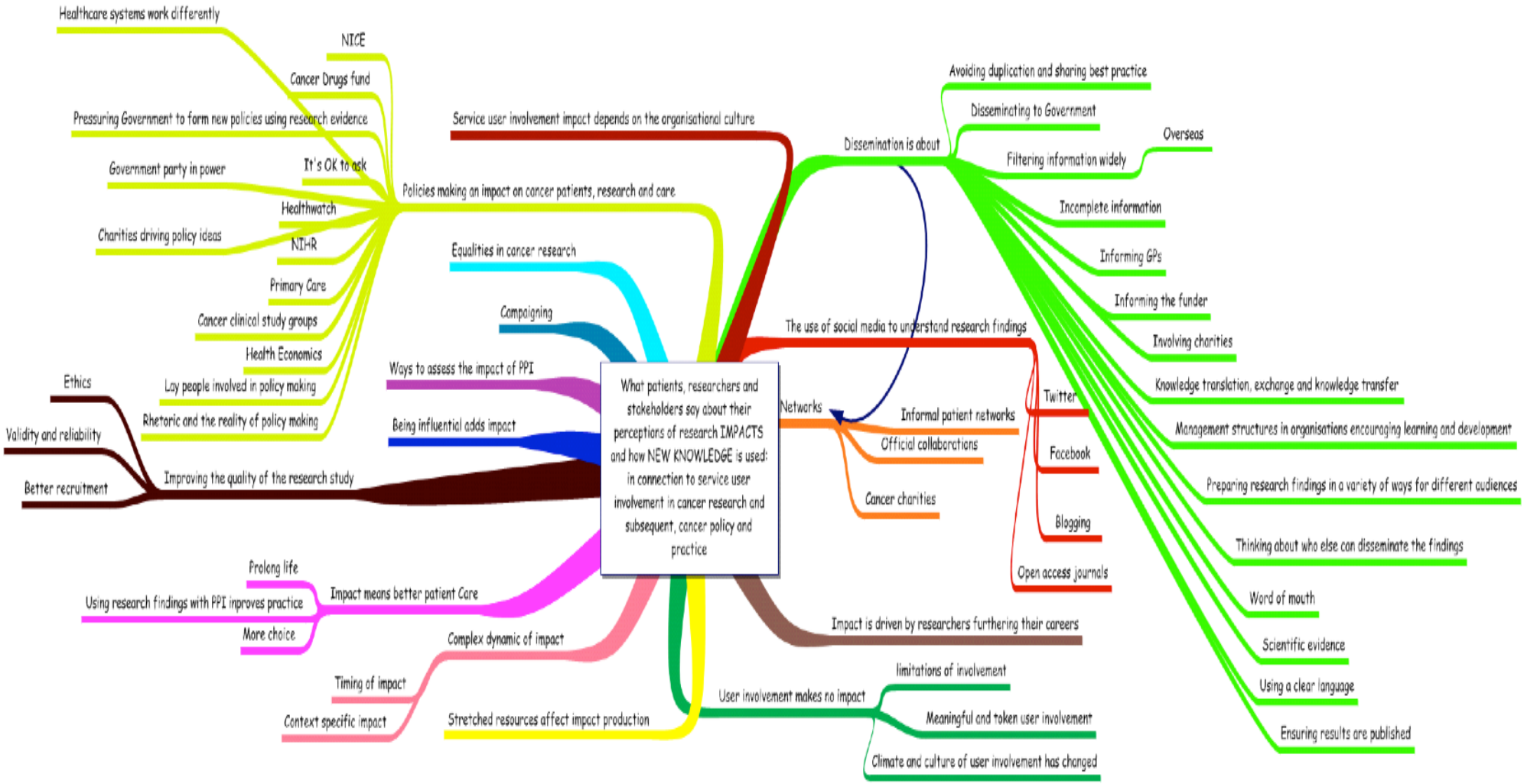

Figure 5 - Perceptions of impact of PPI mentioned during interviews (map)

Involvement within the current study helped at this stage as the codes identified were grouped using the knowledge of workshop attendees.

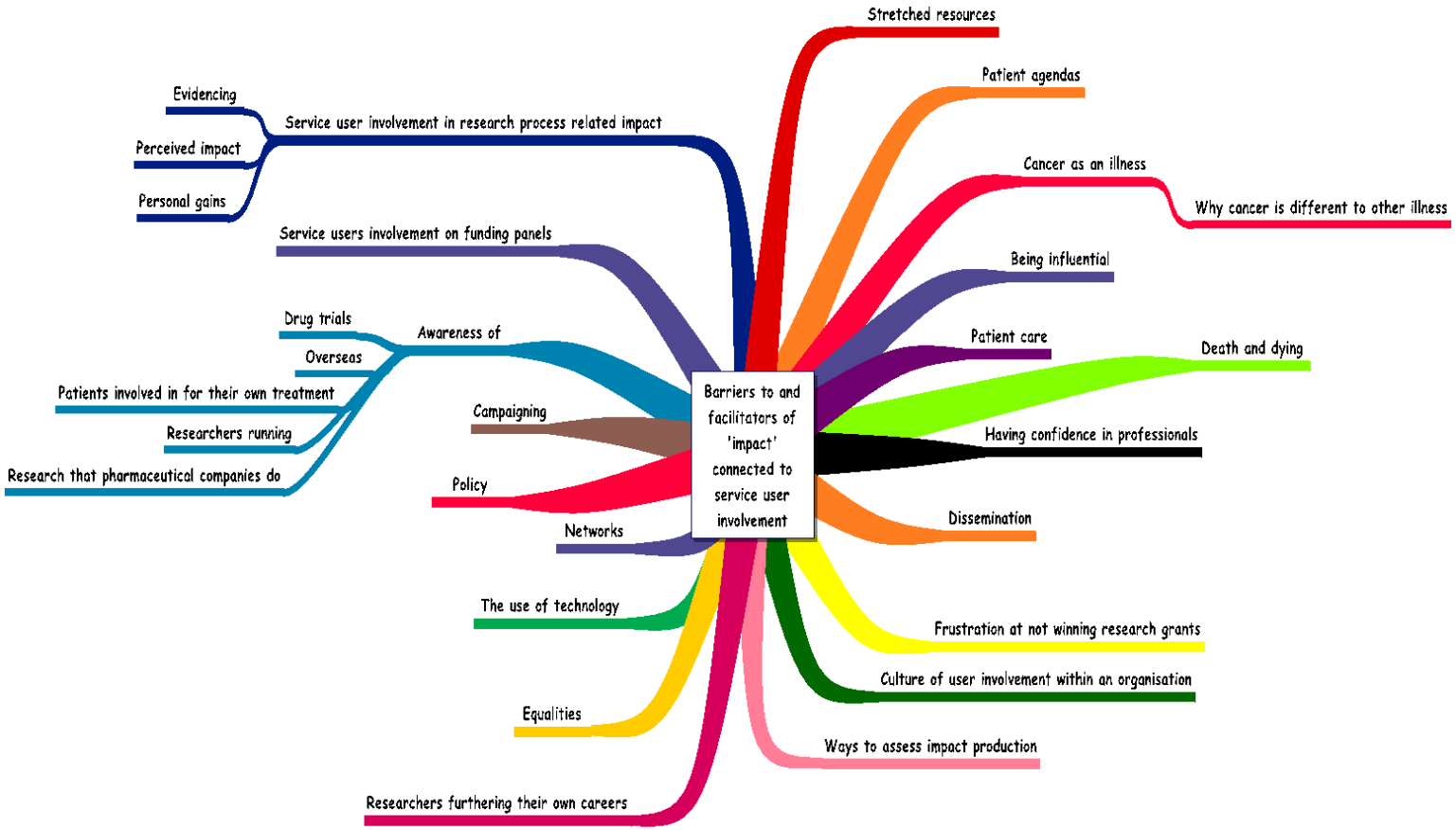

Figure 6 - Barriers and facilitators of impact of PPI (map)

4) Reviewing themes

Braun and Clarke (2006) argue that in order to review the themes, there are two levels: checking that the themes work in relation to the coded data and; checking that they work across the entire dataset. The researcher will check to see that the theme is distinct, coherent and has distinct boundaries. To ensure that the analysis so far was an accurate reflection of the emerging themes, a sample of transcripts were sent to the researcher's supervisors to help ensure consistency. This acted as a quality check of the researcher's analysis technique. Themes identified by the supervisors helped to clarify that some themes overlapped, e.g. 'networks' and 'dissemination'.

5) Defining and naming themes

This was an important stage for the analysis. Braun and Clarke (2006) state that the researcher will produce detailed and complex definitions of each theme which capture the uniqueness of the theme and how it relates to others, clearly addressing how the data reflect the research questions. To ensure this process was carried out carefully, three 'making sense of the data' workshops were held with 'end users'. They were asked to help broadly categorise the data. They were not shown the coding framework generated on Nvivo, they were only shown the Inspiron generated maps (Figures 4, 5 and 6).

This process along with the researcher's own demonstrated that there were seven overarching themes: 'PPI process'; 'Wanting to make a difference'; 'Networks'; 'Leadership and power', 'Resources and the political context'; 'Dissemination'; and 'Information and communication technology'.

6) Producing a report (to serve as a 'Stimulus paper')

This stage of the Braun and Clarke (2006) model concerns using clear language to describe the themes. A short description was written by the researcher about each of these themes to help identify the area of focus for the next stage of the study. The content developed was used towards the 'Stimulus paper' (see Appendix 8) for the Delphi in phase 2.

The seven major themes here form the basis of the first data chapter (chapter five).

Phase 2 - Delphi survey

This phase used the Delphi survey to help data refinement and enhancement. The broad themes generated during the interviews needed data refinement to understand how the findings reflected the real lives of policy makers, politicians and other experts. This section sets out why the Delphi technique method was selected and what the process entailed. Crucial to the success of the Delphi technique was the use of a 'stimulus paper'.

Stimulus paper

The literature on Delphi surveys provides no definition of a stimulus paper, but the use of 'stimulus text' in interviews is well documented. Silverman and Brull (1993) suggest a stimulus text offers context, more than just a question or a sentence making a proposition. A stimulus text is a description about an *'outline or story of an event or action, seen or experienced from a viewpoint, uttered by an identifiable or unidentifiable narrator'* (Silverman and Brull, 1993, p91–92). The description of the stimulus offering context fits with this research, as the data that were generated in phase 1 provided initial contextual information about the impact of PPI on research outcomes. For Törrönon (2002), a stimulus text presents important analysis of what has been studied and found:

> The stimulus text …are expected to articulate the phenomenon under examination to make it perceptible in such a way that the…[those]… interpreting the stimulus text, are 'empowered' to express their social experience and cultural knowledge of the issue under question:
>
> (Törrönon 2002p345)

Adapting Törrönon (2002) line of thinking in this work meant that the 'stimulus text' needed to be succinct and articulate, summarising the data themes from phase 1, with the Delphi questions. In determining how long the paper should be, the researcher followed guidance on developing executive summaries, which suggested that many writers produce a summary under three pages (Custom Writing and Research website 2013). The paper needed to be short enough to be read by busy professionals but long enough to be a stand-alone document. The final stimulus paper was two pages long and addressed the seven major themes (also known in the data chapters as Factors of PPI): 'PPI process';

‘Wanting to make a difference’; ‘Networks’; ‘Leadership and power’, ‘Resources and the political context’; ‘Dissemination’; and ‘Information and communication technology’.

The Modified Delphi technique

The Delphi technique is a consensus building method that collects data sequentially through two or more rounds of questionnaires (Campbell et al. 2004). The modification means that prior data was collected (Custer et al. 1999) through phase 1 in this study.

Panellists are often experts in their field (Snyder-Halpern et al. 2000). Panellists either develop statements or are given the statements by a researcher(s) (Martino 1983) which in the current study took the the form of a two-page stimulus paper.

The questions in a Delphi survey are completed anonymously as panellists do not meet face-to-face (Hasson et al. 2000). As part of the process, each questionnaire response is fed back to the panel in a controlled way by the researcher (ibid). The panel will usually be dispersed geographically (Snyder-Halpern et al. 2000). Thus, the Delphi technique was superior because it had four key features: anonymity, iteration, controlled feedback, and statistical aggregation (consensus forming/voting) (Rowe and Wright 1999).

The Delphi survey is designed to *‘obtain the most reliable consensus of opinion of a group of experts…by a series of intensive questionnaires interspersed with controlled opinion feedback’* (Dalkey and Helmer 1963 p458). The Delphi technique allows for panellists to interact with each other in a controlled way, i.e. the researcher pooling their combined knowledge into the controlled feedback (Rowe and Wright 1999), without physically coming together i.e. not allowing dominant members of a group to taint the views of others (Bolger and Wright 2011). The technique reduces chances of powerful professionals with seniority manipulating others (Jairath and Weinstien 1994). Thus, people taking part would not feel obliged to conform to fellow participants (Murphy et al. 1998). In the field of impact of PPI on research, the Delphi survey has been used successfully by Boote et al. (2006) on the principles and indicators of successful PPI in

research. The study found that a common understanding was reached across all stakeholders on manifestations of positive service user involvement in research.

Phase 2 of the research was concerned with confirming the importance of the themes identified in phase 1, enhancing their credibility and offering external validity using a diversity of views. Therefore, a modified Delphi was useful for the current study as the themes provided panellists the context required for their particular opinions (Snyder-Halpern et al. 2000). There are a number of strengths identified in using this approach.

The Delphi provides a means of interaction between experts who cannot physically come together but whose participation may increase the credibility of the information gathered Linstone and Turoff (1975). From a financial point of view the Delphi was inexpensively facilitated. Another strength of the Delphi was that all communication was carried out via email and using the Blind Carbon Copying (BCC) rule which meant anonymity was achieved. This anonymity aspect proved useful if something important but controversial was raised by a panellist. Including controversial responses in the controlled feedback was important.

Snyder-Halpern et al. (2000) found that email responses, compared to posted responses were more legible, eased data entry and enhanced communication. Another advantageous feature of the Delphi survey was iteration. Between each questionnaire, controlled feedback was offered, through which the researcher presented a summary of the range of opinions in a numeric way highlighting voting patterns of themes, helping the group see where there was emerging importance, consensus and disagreement, allowing panellists an opportunity to reconsider their views.

Consensus and voting

The Borda count is often described as a consensus-based voting system rather than a majoritarian one. The Borda count is named after the French mathematician and political scientist Jean-Charles de Borda, who devised the system in 1770 (Emerson 2013). The Borda count allocates points corresponding to the number of options ranked lower. Once all votes have been counted the option with the most points becomes the winner and the

order of preference for the remaining issues being voted on is also achieved e.g. 1st, 2nd, 3rd etc. This method was used for the consensus-building-aspect of the study (Lakhanpaul et al. 2014). The method was useful for the current research because it determined which of the seven (which later became nine) themes were deemed most to least important. Figure 7 illustrates an example of the Microsoft Excel spreadsheet used for counting and developing graphs to share in the controlled feedback between rounds.

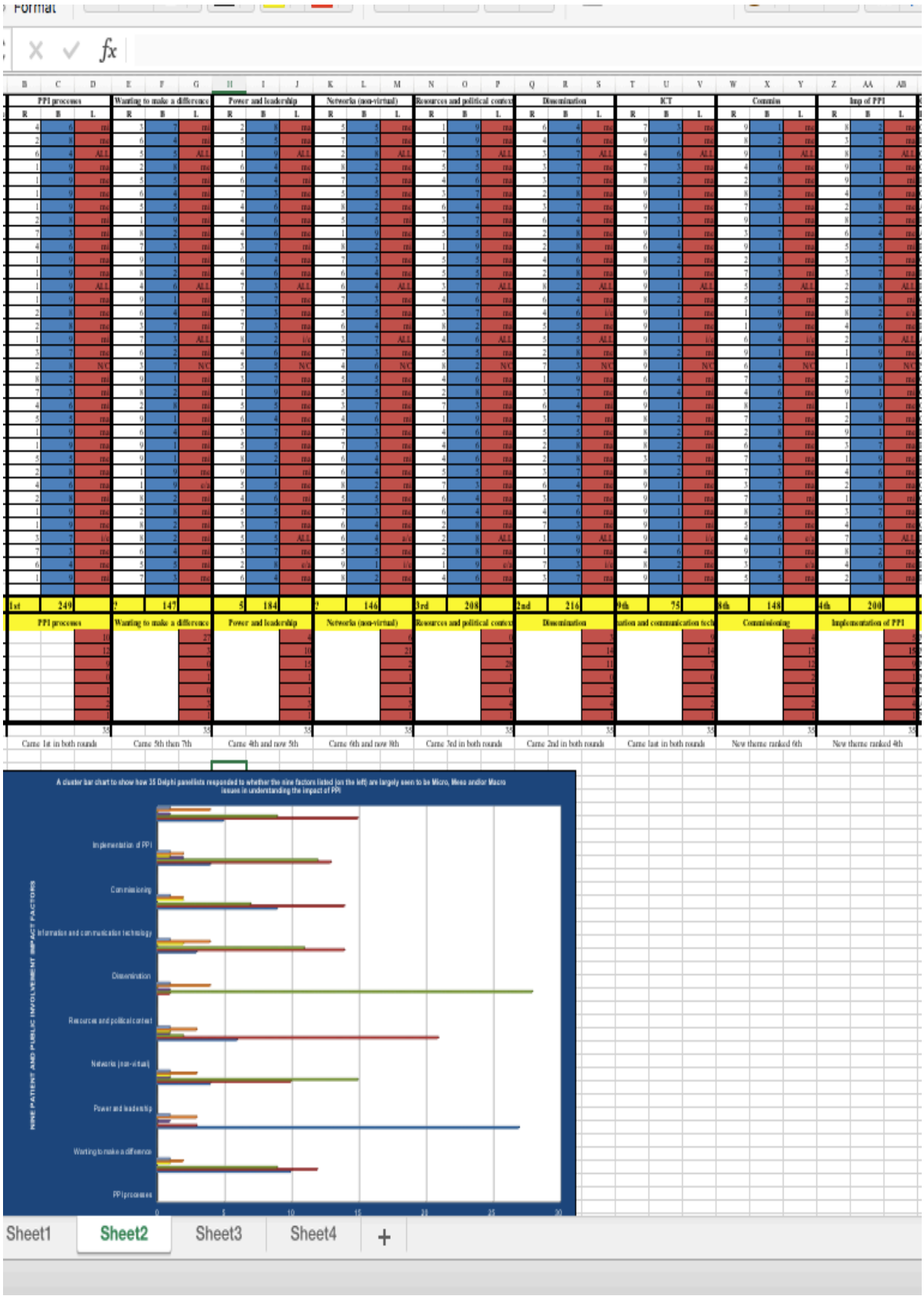

Figure 7 - Borda Count (Delphi Round 1 - Example)

Limitations of the modified Delphi technique

There are limitations to using the Delphi technique as the survey is reliant upon the use of 'expert' knowledge. The term 'expert' has been critiqued (Green et al. 1999) because it suggests that the involvement of a 'layperson' may be unacceptable for a study (Meyrick 2003, p10). On the contrary, in the Delphi survey by Boote et al. (2006) the research teams involved 'lay' as well as 'expert' people to make the study reflective of its focus, demonstrating PPI, and arguably this may well have contributed to the study's success. Gutierrez (1989) argues that participants in a Delphi survey should be a group of knowledgeable people, not necessarily 'experts'. Panellists should be those who can provide relevant input to the process, potentially have the highest authority possible, and be committed to and interested in the research aims.

Another known problem with Delphi surveys is participant attrition as rounds progress (Mayaka and King 2002). To reduce attrition rates in the current study, participants were reminded of the commitment needed for the study and the time window for the Delphi was kept short (six weeks) in order to retain panellists. Analysis for each round was undertaken in just one week (there were three rounds). According to Hasson et al. (2000) rates of attrition also depended on how much preparation the current researcher did beforehand. Therefore, when a potential panellist offered to take part in the Delphi, a visual Delphi process diagram was also sent to every panellist so that they could understand the dates they were needed and the process to which they were signing up to, showing when each round opened and closed.

Delphi surveys can become very intense, especially between rounds (Pandya 2005). The researcher was mindful that people recruited into the Delphi were busy professionals. A word limit for each question was not set so that panellists could, if they wanted, provide examples to help further contextualise their response. It was also decided that busy professionals were unlikely to read controlled feedback which was longer than two sides of A4 paper (applying the same principle as for the stimulus paper length). There were three rounds to this work but there could have been more (Keeney et al. 2006), or fewer rounds (Hasson 2000). After the panellists had read the stimulus paper this work needed to establish: 1) how relevant the themes were to panellists in terms of order of importance,

and why; 2) whether anything new should warranted a theme of its own, and why; and 3) how impact of PPI on research outcomes could be better understood. Therefore, it was anticipated that three rounds would suffice for the current study.

Sampling framework Delphi

Keeney et al. (2006) argue that a researcher conducting the Delphi must decide on the inclusion and exclusion criteria before the study commences, such as the gender, professional experience, educational background and employment background of the panellists. As argued already, to reduce Delphi limitations professional and non-professional (lay) people were considered as useful for this study. Panellists would have a broad range of skills and knowledge spanning a range of groups covering policy, practice, academia, patient experience to list a few. A theoretically informed set of inclusion and exclusion criteria was devised.

Participants could take part in the study from anywhere in England. They needed access to the internet during the data collection phase of six weeks. They needed to be able to read and write English and they were selected on the basis of their particular specialist expertise for this study from one of six groups:

1. Working in leading health charities and large non-government organisations because, according to Tritter et al. (2003), the voluntary sector plays an increasingly large role in the funding, provision and delivery of services and nowhere is this more apparent than in cancer care.
2. Policy-makers, because they provide insight and understanding regarding the broader set of economic, administrative, managerial, or policy-related factors that may influence the implementation of cancer care (Cotterell et al. 2011) at a political level.
3. Academics, as they have insight into why evidence-based healthcare has featured as a policy concern in many healthcare systems over the last decade, driven by a growing recognition that healthcare delivery does not always reflect what is known to be best practice. Studies suggest that up to 30-40% of patients do not receive care which complies with current scientific evidence (Schuster and McGlynn 1998; Grol 2001).

4. Independent consultancies dealing with PPI and service improvement because these types of organisations provide additional business-driven insights into why involvement is important.
5. Government department leads and politicians, who help build further knowledge on how legislation is being used/not being used to support the case for PPI in policy and practice in health and social care (Hughes et al. 2009).
6. 'Expert patients'/patient champions, to help further understand their knowledge of services affecting them and the extent to which they can challenge professionals' assumptions toward those with chronic illness (Wilson 2001).

Sample size and recruitment Delphi

According to Reid (1988) there are variations in sample sizes for Delphi surveys depending on the type of research being planned. Sample sizes can range anywhere from 10 to 1,500 people (Reyens and Hehn 2000). Murphy et al. (1998) suggest that larger samples are likely to provide more reliable datasets when research questions have a limited range of answers. This work relied on some qualitative responses and therefore too many participants would have become too complicated to manage for one researcher. Any fewer than 20 participants would have been likely to lead to incomplete understandings of this complex research area. Recruiting at least six people from each of the six backgrounds seemed manageable and realistic.

To recruit the Delphi participants, purposive and convenience sampling strategies were applied (Proctor and Allen 2006). The researcher approached known academics, cancer charities, consultancies and policy networks. An poster (see Appendix 9) inviting people to participate were sent. The study was also advertised via INVOLVE's advisory group meeting. Individual letters were sent to local Members of Parliament, Department of Health leads and to members of European Parliament. For a full list of participants please see the virtual panel composition in Table 9. Basic demographics and roles of participants were collected before the Delphi survey commenced (see Appendix 6) to help identify their ethnicity, age, religion and professional/social background (also presented in Table 9). Any interested people who came forward were telephoned first to check that they met the criteria for selection, were available when the Delphi survey was planned and that

potential participants understood that they needed to be committed to the entire six-weeks process. If they met the criteria, they were then emailed an Information sheet (see Appendix 10), a Delphi process diagram with dates (Appendix 11) and a Consent form (Appendix 12). This initial contact was also an important opportunity for potential panellists to ask questions.

Table 9 - Participant demographics and key information (Phase 2)

Category	Patients and carers	Academic and clinical researchers	Policy and commissioning work	Stakeholders/ Healthcare professionals and PPI work
Sex	F [n=5] M [n=2].	F [n=5] M [n=3].	F [n=10] M [n=7].	F [n=5] M [n=2].
Age Range	55 -70 [n=7] across group.	40-65[n=8] across group.	35-60 [n=17] across group.	40-65 [n=7] across group.
Sexual preference	Heterosexual [n=6] and Gay[n=1].	Heterosexual [n=8].	Heterosexual [n=17].	Heterosexual [n=7].
Ethnicity	White British [n=7].	White British [n=6], Asian British [n=1], and Black British [n=1].	White British [n=15], Asian British [n=1], and White and Black African [n=1].	White British [n=6], Asian British [n=1].
Religion	Christian [n=4], No region [n=2], and Atheist [n=1].	Christian [n=4], Hindu[n=1], and No religion [n=3].	Christian [n=8], Sikh [n=1], and No religion [n=9].	Christian [n=4], Spiritual [n=1], Sikh [n=1], and No religion [n=1].
Disability	No disability [n=6], Physical and mobility impairment [n=1].	No disability [n=6], Long term illness or health condition [n=1], and Learning disability[n=1].	No disability [n=16], Learning disability [n=1].	No disability [n=7].
Experience	Cancer [n=5], Carer [n=2].	Professor status [n=5], Independent researcher (Dr) [n=2], and Unknown [n=1].	Commissioning [n=3], Government [n=7], and Cancer policy work [n=7].	PPI work [n=5], Communication [n=1], and Quality [n=1].
Locations	Northeast [n=1], London [n=1], South Central [n=1], Southeast [n=2], Southwest [n=1], East of England [n=1], and of these, [n=7] covered all of England.	Northeast [n=1], Northwest [n=1], Yorkshire and Humber[n=1], East Midlands [n=1], West Midlands[n=2], London[n=2], and of these [n=3] covered all of England.	Yorkshire and Humber[n=1], East Midlands [n=5], West Midlands[n=1], Southeast[n=3], Southwest[n=2], No region just national [n=5] and of these [n=15] covered all of England.	East Midlands [3], London[n=2], South Central[n=1], Southeast [n=1] and of these [n=4] covered all of England.

Recruitment was relatively straightforward, and the researcher was satisfied with the broad range of expertise people brought with them. The Delphi survey was carried out via email, apart from when the MPs were involved, where two physical meetings were

scheduled to answer the Delphi questions. During the Delphi period, for the major political parties, it was conference season – hence them requesting an interview rather than email. This adjustment to the planned data collection (a face-to-face-meeting rather than electronic email response) was necessary as the MPs were too busy to take part in some of the rounds and reading the controlled feedback. To mitigate dropout the researcher offered verbal controlled feedback and asked the questions directly. This may have impacted on the data collection as others on the Delphi (although each participant had direct access to the researcher's telephone number to call if they had any questions) did not have the opportunity to discuss their answers.

In addition to the steps set out in the process (Figure 8, below), the researcher mitigated against attrition by sending email reminders midway through a round, and text reminders for those who had not submitted on the final day of each round. As a result of this thorough strategy of retention, of the 39 people recruited only four people dropped out (a Member of the European Parliament, a representative from an independent political party focused on health, one patient and one academic). The analysis process between rounds was intense and took on average 80 hours, making the whole process very demanding. Supervisory input was essential to help the researcher remain focused.

Delphi analysis and controlled feedback

Each Delphi round was analysed in real time. The system of analysis was similar to phase 1, using the approach to thematic analysis set out by Braun and Clarke (2006). As most of the data produced were not too long in content, at the end of each round the key points made by participants about emergent themes were noted. Qualitative data generated were often descriptive and NVivo was used to manage data. Turoff and Hiltz's (1996 p71) technique was used to ensure that clarity, issues of bias, missing information, patterns, hidden disagreements and issues to focus the answers upon should were considered throughout. They outline the following:

1) The data analysed and offered in the feedback needed to present a range of views and considerations;
2) That hidden disagreements and judgemental biases needed to be exposed to further clarification;

3) To detect and clarify any missing information or cases of ambiguity in interpretation by different participants;
4) To analyse complex situations only by analysis procedures (e.g. such as using Braun and Clarke 2006);
5) To detect patterns of information and of sub group positions (e.g. whether patients took a certain stance in their ranking preference); and
6) To detect critical items that need to be focused upon in the subsequent rounds (e.g. raising further questions about the themes or about impact of PPI on research outcomes).

The first and second points were clarified through round two of questions but point three was clarified by email with participants as soon as responses started to come in, particularly if responses seemed ambiguous to the researcher. Points four and five used Braun and Clarke's (2006) thematic analysis process to understand patterns (see coding framework for phase 2, Appendix 13).

Once responses were received to each set of questions within the specified deadline, a list of answers was drawn up to keep in mind that the best opinion may have become 'watered down' (Sackman 1975) or that the survey might generate 'bland statements' (Rennie 1981). Researcher awareness of these criticisms reinforced the notion that analysis was important in Delphi surveys as it needed rigorous attention to detail concerning each participant's opinion for each answer. Where possible, quotations were offered in the controlled feedback so that the original tone was retained, and any important messages were not misrepresented.

During the Delphi analysis, the supervisory input was key as it offered support in reading a sample of opinions and confirmed or queried the researcher's decisions. The supervisors were helpful in raising any concerns about any points that the current researcher may have missed and offered critical suggestions any new questions that the researcher felt needed to be explored in the new rounds of questioning to help the refinement process. Involvement from an independent academic and a carer helped too in this stage.

Round one

In round one the Delphi panellists were asked to read the stimulus paper and then to answer the questions posed in the email (see Appendix 14 for a summary of the questions that were generated for each round based on issues raised from previous rounds). Panellists were asked to reflect on the findings, then drawing on their own work background and specialist topic knowledge they were asked to rank the themes in order of importance, and to add any new themes they felt were missing.

Controlled feedback - round one

In the second round, controlled feedback was offered on the ranking exercise consensus thus far, demonstrating the 'order of importance' generated, along with a description of the two 'new themes' they had identified ('*PPI in commissioning*' and '*PPI in implementation*'). Panellists had also raised that importance was hard to rank without appreciating the micro, meso and macro levels that the themes were situated within. Finally, round one had raised that there was not a definition for the impact of PPI.

Round two

For round two, panellists were asked to rank the nine themes this time, along with their understanding of whether the themes were micro, meso or macro level factors. They were also asked to provide in their words a definition of impact of patient and public involvement.

Controlled feedback – round two

In the controlled feedback, data were pooled together, and the knowledge generated was shared, helping the next round (Reyens and Hahn 2000). Items for which there was a lack of agreement among participants were also included. A synthesised definition (impact of PPI) was developed by the researcher, capturing the panellists' combined efforts and this definition was shared in the controlled feedback.

Data synthesis can be conducted for different purposes (Mays and Pope 2008). For the current study it served the purpose of formulating a definition of the concept of impact of PPI. The data that was used to form the definition came from an open-ended question

asked to the panel: to provide in their own words, a definition of impact of PPI. Based on the 35 answers received a list of typologies were devised using the help of NVivo software. Characteristics of the impact of PPI were drawn up mapping focal issues demonstrated in Appendix 13.

Panellists were asked to indicate to what extent the proposed definition captured their responses from round two. The ranking exercise was also summarised to demonstrate how the themes sat at the sociological positioning of micro, meso and macro levels. Panellists were asked to comment on whether the findings would apply to other disease areas. Panellists commented on future use and applicability of the findings, along with further research questions the work may have raised for them.

Round three

By this point the two controlled feedback summaries had raised vital points, channelling the discussion towards impact of PPI on research outcomes, in light of the views of the group as a whole (Reyens and Hahn 2000). Consensus was reached on the order of importance for the nine themes. Participants also commented on the transferability of the findings and future research on the topic.

Final controlled feedback – round three

When the Delphi process was complete, participants were informed of the convergence and divergence of opinions that had occurred during the course of the study (see Delphi findings, chapter six). Figure 8 summarises the entire Delphi study.

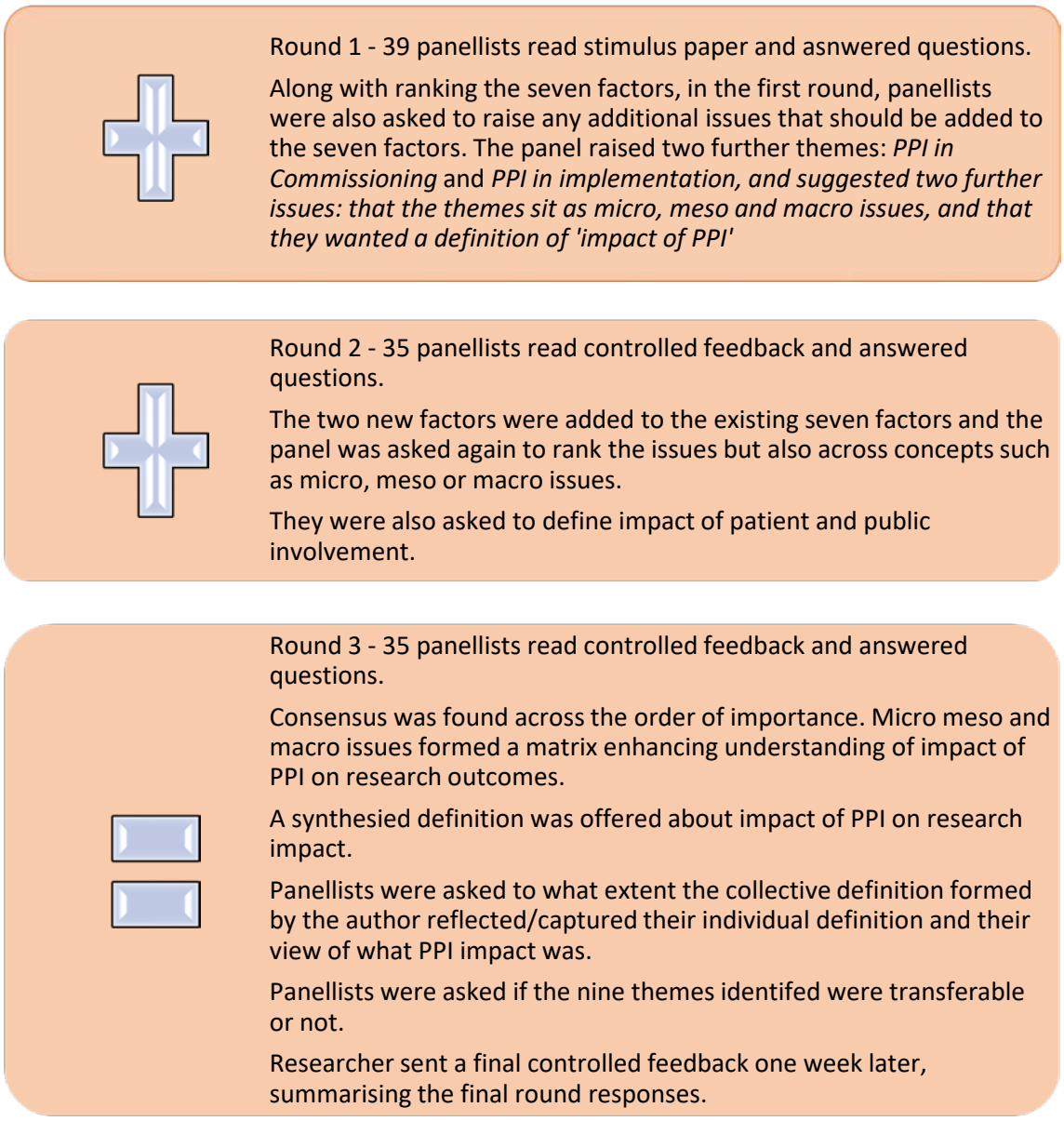

Figure 8 - Illustration of the Delphi process

Outcomes of the Delphi survey

In this research, the use of the Delphi survey was successful because it refined and developed the seven themes to become nine themes. It was reassuring that the two areas that panellists felt should be themes in their own right were originally within two other themes.

The Delphi also helped to rank order of importance and furthered understanding about whether the themes were situated at micro, meso or macro level. The information about

micro, meso and macro level influences raised was highly useful for considerations of how the (themes) findings could be presented under implementation frameworks such as Damschroder et al. (2009).

Forming a definition of the impact of PPI was not part of the plan for the Delphi, but by 'going with the flow' of what panellists were raising in the first round, the opportunity was exploited. With some quick thinking, panellists were asked to define impact themselves, and a definition was also achieved through data synthesis.

Once the Delphi survey was complete, a thank you card was sent to all participants. Two senior people contacted the researcher afterwards to say that they felt the research had been conducted very well and efficiently and that the text reminders acted as a personal touch, as did the thank you card.

The data gained from phase 2 forms the basis of chapter six. After the Delphi data collection was complete, further analysis was carried out and the next section explains this process.

Seeking examples of PPI on research outcomes – A method adopted for chapter seven

Exclusion criteria

This analysis part was concerned primarily, to seek understandings of impact of PPI on research outcomes by applying the nine major themes identified. A further analysis was necessary to understand what impact of PPI on research outcomes actually meant. Thirteen of the 23 interviews demonstrated impacts of PPI on research process but not on research outcomes. Of these 13 interviews it was noted that:

- Interviewees were speculating, guessing or hoping the research would have an impact, rather than offering concrete examples.
    - On two circumstances interviewees were describing the impact of PPI on research outcomes from the drug industry and not a government funded national peer reviewed piece of research.

- On five occasions the interviewees were discussing community engagement, but this was a more training and development-based impact rather than research-based impact.
- In one case, impact was purely academic knowledge generation, were the person interviewed was attempting to advance the field for PPI.
- Finally, on five occasions, it was too early to judge the impact of a study.

This seeking examples section formed the basis of six examples which chapter seven discusses concerning evaluation.

Ethics processes followed

Whilst conducting this research, ethically conscious working standards were adhered to at all times. Ethical approval for phases 1 and 2 was conferred by the Faculty of Health and Life Sciences Research Ethics Committee (FREC) at De Montfort University (see letters from the FREC in Appendix 15). Additionally, The Wellcome Trust (WT) *Good Research Practice Guide* (2007) was adopted for use in this study.

The WT guide discusses researchers needing to be '*honest in respect of their own actions in research…*' in relation to this point, the posters (Appendix 3 and 9) information sheets (Appendix 4 and 10) and consent forms (Appendix 5 and 12) were all developed with full transparency. Regarding 'Openness' the WT guide stated: '*the Trust expects the researchers …to be as open as possible in discussing their work with other scientists and with the public in order to help foster an informed public climate'*. This study developed a climate of openness by involving people in the work to offer an opportunity to discuss the direction of the study. Also, a paper was developed about ethical practice of PPI (outside of this study see Appendix 16) which the researcher led. (Pandya-Wood et al. 2017).

In relation to 'guidance from professional bodies' the WT: '*expects researchers to observe the standards of research practice set out in guidelines published by scientific and learned societies…*' thus for the current study this was understood as following the

researcher's own institutional code of ethical practice (DMU's own ethical standards) i.e. using the FREC as the anchor process. For 'leadership and cooperation' the WT stated that: *all members of a research team are encouraged to develop their skills and in which the open exchange of ideas is fostered'*. Where possible, when research groups were requiring research students, the researcher would offer seminars, e.g. one such talk was about the Delphi technique. The WT guide requires *'supervisors to supervise all stages of the research process'* and regular supervisions took place between the researcher and her supervisors. For 'training' WT stated that: '*researchers should undertake appropriate training'*. All training courses offered by the doctorate college at DMU were attended including using NVivo to help with analysis and coding. For 'primary data/samples' it stated that *'Researchers should keep clear and accurate records of the procedures followed'*. This study kept clear audit trails that monitored carefully when research direction changed. In relation to 'ethical practice in Research involving human participants' WT stated: '*Researchers should ensure the confidentiality of personal information relating to the participants in research, and that the research fulfils any legal requirements such as those of the Data Protection Act 1998'*. Research data was kept safe by using a password protected PC, using a lockable filling cabinet and ensuring that all participants information was given an alias name (see table 10, p119). Lastly the WT discusses 'publication practice'. Although papers from the current study are yet to be published, papers are underway (see chapter ten).

Confidentiality

Conducting research using the focus of the cancer disease, and within the East Midlands region, requires a brief discussion of how researching participants in one geographical location led to ethical issues identified by Goodwin (2006). There were occasions when confidentiality issues arose. For example, when interviewing patients, three of the patients knew that the researcher had already interviewed two others. They each discussed with the researcher that they knew that the researcher had spoken to the other participants, one of whom made disparaging comments about another participant's reasons for participating in the current study. The researcher was careful not to delve into a conversation about who had been involved and reminded each of them to respect confidentiality. Pseudonyms were used by the researcher in the findings chapter (see table

10 for a list of participants and panellists and their alias names). In similar fashion, there was a time when a certain oncologist researcher participant also spoke of her colleague (a researcher) who had already been interviewed. She spoke about how he was ‘anti PPI in research’ and that he was the ‘devil’s advocate of PPI’, again implying that she knew the researcher had already interviewed this particular oncologist (suggesting the researchers had had a conversation about the current research study). Another clinical researcher referred to a young patient of his (who he did not name but the current researcher knew personally). Perhaps if the current research (phase 1) had been conducted nationally, then participants would not have so easily known about each other’s input. Also, if the researcher had chosen to explore more than one disease area then these instances might not have happened.

During analysis, the researcher was mindful that at times people’s names and sensitive material were being disclosed. To ensure confidentiality and anonymity all transcribers were asked to complete a confidentially agreement.

During phase 2, a very close family friend of the author had just died from ovarian cancer and a close colleague had lost his mother to cancer. The researcher’s own emotional awareness was an unidentified issue but became apparent during the data collection stage when the issue of how distressing the disease of cancer is and its effect on people’s lives.

Table 10 - Study participants (n=62)

Patients (n=13)	Stakeholders/ Healthcare Professionals and PPI work (n=14)	Academic and Clinical Researchers (n=16)	Policy and Commissioning work (n=19)
(IP1) Sarah Breast cancer **(IP2) Jane** Breast cancer **(IP3) Helen** Lymphatic cancer **(IP4) Paula** Breast cancer **(IP5) Gary** Non-Hodgkin's Lymphoma **(IP6) Ben** Stomach cancer **(DEP1) Reese** Expert patient **(DEP2) Della** Expert patient **(DEP3) Louise** Carer **(DEP4) Olivia** Expert patient **(DEP5) Grace** Expert patient **(DEP6) George** Carer **(DEP7) Daisy** Expert patient	**(IS1) Dennis** Implementation science lead **(1S5) Jenna** Trials coordinator **(IS8) Patsy** Hospice senior staff **(IS7) Michael** Academic department lead **(IS3) Steven** Hybrid role (national PPI policy work) **(IS4) Barry** PPI lead **(IS6) Hannah** National PPI policy role **(DPPIL1) Alice** PPI lead **(DPPIL2) William** PPI lead **(DPPIL3) Dean** PPI lead **(DPPIL4) Patricia** PPI lead **(DPPIL5) Kim** PPI lead **(DPPIL6) Marian** PPI lead **(DPPIL7) Pam** PPI lead	**(IR1) Priscilla** Oncologist professor **(IR2) Joanne** Social science professor **(IR3) Janine** Palliative care professor **(IR4) Philip** Oncologist professor **(IR5) Robert** General practitioner professor **(IR6) David** Geneticist doctor **(IR7) James** Oncologist professor **(IR8) Gerald** Social science professor **(DAC1) Mark** Academic doctor **(DAC2) Ajay** Clinical professor **(DAC3) Rebecca** Clinical academic **(DAC4) Kylie** Clinical academic **(DAC5) Carolyn** Academic doctor **(DAC6) Ranjit** Healthcare commissioner and doctor **(DACTT7) Jean** Academic doctor **(DAC8) Matilda** Clinical academic	**(IS7) Katy** National cancer policy staff **(IS2) Nick** Cancer charity **(DONHS1) Anna** Senior NHS policy **(DONHS2) Caroline** Senior NHS communications **(DONHS3) Denise** Senior NHS communications **(DONHS4) Janice** Senior cancer nurse with policy **(DOCom5) Felicity** Research commissioner **(DOCom6) Hersha** Commissioner of health education **(DPCh1) Holly** National cancer charity policy **(DPCh2) Hallie** National cancer charity policy **(DPCh3) Marina** National cancer charity policy **(DPCh4) Luke** National cancer charity policy **(DPCh5) Stan** National cancer charity policy role **(DPCh6) Bob** National patient champion body **(DPG7) Stuart** Member of Parliament **(DPG8) Keely** Member of Parliament **(DPQG9) Shane** Senior Department of Health and Social Care official **(DPQG10) Jonny** Senior member of national research ethics service **(DPTT11) Mat** Policy thinktank of health research

(Key: Pink = Interviewees and Blue = Delphi panellists)

Research rigour

Reliability and validity are terms generally associated with measurement whilst this research was interpretivist with a pragmatic focus. By employing mixed methods, the credibility of the findings was enhanced because they furthered the internal and external research rigour process (Le Compte and Goetz 1982). The two datasets helped to serve

as an explanation for each other. The qualitative findings provided sufficient accounts of rich and thick descriptions, helping to firmly establish the context of the themes for the Delphi survey. Similarly, themes were confirmed as valuable in the importance order ranking exercise. Context was offered to the themes when Delphi panellists were asked to rank the themes and each panellist confirmed the themes' validity, linked to personal experience and understanding of the topic. This meant it was highly likely that the qualitative data collected did reflect the diversity of panellists' views. Therefore, the two methods used complemented internal and external validity.

To further assess research rigour, Lincoln and Guba (1985) list four areas: *credibility*, *transferability*, *dependability* and *confirmability*. These will now be discussed individually and were previously presented as a poster at the national INVOLVE conference (see Appendix 1).

Credibility

Credibility concerns having confidence in the 'truth' of the findings. There are several aspects that have helped the credibility of the current study. Firstly, the section on involvement, outlines the influence that end users have had on this research and a chapter on reflections about this is also offered (Chapter nine).

Through mixing methods, the two phases of the research design helped to contribute towards the validity of the knowledge created and increased understanding about the types of knowledge that people had about impact of PPI on research outcomes. Phase 2 refined the findings about impact using consensus-building methods. This double layering of data collection acted as a quality measure for internal validity (Morse et al. 2011). The interviews were carried out across three groups of people, drawing on a variety of viewpoints and experiences. Furthermore, in the Delphi survey elicited a range of views from central government through to patients, resulting in consensus of the themes generated. A further assertion of credibility is via the list of publications generated outside of this study but show the researcher's awareness about the topic being studied (Walker and Pandya-Wood 2014; Pandya-Wood and Robinson 2014; Rivas and Pandya-Wood

2014; Pandya-Wood et al. 2017; Pandya-Wood et al 2018). Finally, the thesis largely reflects the broader literature base.

Transferability

The concept of transferability implies that the findings have applicability in other contexts and settings. Lincoln and Guba (1985) have suggested that qualitative researchers should be encouraged to produce 'thick description' which provides a strong foundation to make a judgement about transferability of the findings. Thick descriptions were produced during the interviews. These descriptions became the themes studied in the Delphi survey. Furthermore, during the Delphi survey, panellists ranked the information, suggesting that the data themes reflected a sense of reality for the panellists. Not one panellist questioned the content of the themes' descriptions which were provided. Also, panellists were asked a direct question about the applicability of the current research in other contexts of health and disease (i.e. how transferable the findings were). Their responses demonstrated that, largely, data from this work were transferable beyond the disease of cancer, for studying the impact of PPI on research outcomes.

Dependability

Dependability concerns the findings being consistent and reproducible. Lincoln and Guba (1985) suggest that an audit trail be kept by researchers as an aid memoir. During the current research notes on involvement meetings, fieldwork pilots, supervision meetings, discussions with colleagues and all versions of data collection tools and analytical procedures were kept. This criterion demonstrates transparency and that the decisions made about the research are justifiable.

Confirmability

Confirmability is about the degree of neutrality, which concerns being mindful of the researcher's own identity. Throughout the thesis, where possible, the researcher's own values and experiences are outlined to show awareness of confirmability. Working for the National Institute for Health Research, Research Design Service East Midlands (NIHR RDS EM) has placed the researcher in a unique position to conduct this doctoral study. Other approaches that have helped with confirmability include having regular involvement meetings in this work. Involvement has occurred in various stages, as

already outlined in this chapter. The researcher argues that involvement enables better research and achieves the confirmability feature of Lincoln and Guba's (1985) model.

Summary

This chapter focused on the research process, describing how data collection was planned and executed. It also outlined in detail the involvement process and described how the two datasets were analysed. Over the next three chapters, the research data are presented: Chapter Five presents interview data about the seven factors (major themes) presented in phase 1. Chapter Six concern presentation of the Delphi study and Chapter Seven presents analysis of both phases of data collected together – which attempts to deepen understanding about evaluation of PPI.

End user involvement influencing this stage

November 2011 – To confirm ethical processes to adopt in the study. Involvement in the form of **consultation,** n=2 separate email and telephone meetings took place with people from ethics and research development backgrounds on whether NHS ethical approval was needed for phase 1. It was clarified that NHS ethical approval was not necessary for the current study as patient participants would be found outside of the NHS system, via publicly searchable means and the patients would be participating in a voluntary capacity.

June 2013 – Development of data collection tools. Involvement in the form of **collaboration** took place with n=2 patients individually in a face to face meeting in Leicester. To ensure that the data collection tool developed (interview topic guide) was patient sensitive, the two meetings helped to ensure that there was flow to the questions and some questions were changed in light of suggestions these patients made.

June 2013 – Development of data collection tools. Involvement in the form of **collaboration** with n=2 academics individually in a face to face meeting in Leicester. Feedback from these academics showed that some of the questions were too long and that some questions should be shortened. As a result, the interview topic guide was adjusted.

June 2013 – Development of data collection tools. Involvement in the form of **collaboration** with n=2 stakeholders individually in the form of face to face meetings in Leicester. Feedback offered by these stakeholders suggested that an impact explanation should be offered during interviews to help with consistency of meaning. As a result, the interview guide included a statement on impact which was used as a guide to explain what impact meant (appendix 2).

It is important to note that during the process of engaging and involving end users, dilemmas about how much end user input to utilise was becoming a question for the researcher because the PhD requires independent critical thought and inviting input meant that the knowledge and expertise of others was shaping the study. This point is discussed in the Chapter nine.

Chapter Five: Factors that contribute to the impact of PPI on research outcomes

Introduction

As the literature review identified, there was a significant shortage of evidence in understanding the impact of PPI on research outcomes. The views and opinions of participants on these aspects was therefore critical to capture across the two phases of data collection. Prior to the Delphi study with experts (which is discussed in the next chapter), the researcher conducted 23 in-depth interviews with: patients who have been involved in cancer research; researchers who won national peer reviewed cancer research funding which required them to involve patients in the study; and stakeholders who have used or considered applying cancer research findings. The studies discussed in the interviews were required to have been completed in the last five years[3] at the time of conducting interviews. These interview findings are presented in this chapter.

This is the first of three chapters that present findings from the study. In order to locate this first chapter in context, an overview of how the entire data is presented is offered here to assist the reader.

During data analysis of interviews it became apparent that participants unproblematically described the impact of PPI on research outcomes as being achieved through the PPI in research processes. It was clear that untangling the beliefs that participants had about the impact of PPI on research outcomes was much harder to achieve because impact on outcomes, they each felt, were linked to the processes of PPI. Therefore, the current chapter's purpose is to set out the key ***factors of PPI*** identified by interview participants as contributing to and shaping the impact of PPI on research outcomes, either by strengthening or by hindering the impact of PPI. These are called 'factors of PPI' throughout the data chapters.

[3] Some research funders believe that research impact can be demonstrated between three and five years after a research study has been completed.

However, at the end of this chapter it is argued that as data presented as factors of PPI were so diverse and varied, refinement was necessary. Thus, the Delphi survey's role was to refine and where possible enhance understanding about these contributory factors of PPI. Thus, chapter six's purpose is to complete the identification of contributory factors shaping the impact of PPI on research outcomes, and to rank these in order of perceived importance, by setting out the refinement process undertaken through the Delphi study.

Thus, chapter seven presents an analysis of six examples of the impact of PPI on research outcomes extracted from the interviews. The examples enable us to examine which of the nine contributory factors of PPI can be seen to have shaped the reported impact, and to highlight challenges about how such impact might be evaluated. It is important to note that chapter seven was based on re-examination of the combined data. The three findings chapters can be summed up as shown in the Table 11.

Table 11 - How three data chapters are organised

	Chapter five	Chapter six	Chapter seven
Which data and what is the title of the chapter	Interview data Factors which contribute to impact of PPI on research outcomes	Delphi data Refinement of factors which contribute to impact of PPI on research outcomes	Integrated use of Delphi and interviews Examples of PPI on research outcomes and challenges for evaluation
Purpose	Purpose is to set out the key factors identified by interview participants as contributing to and shaping the impact of PPI on research outcomes, either by strengthening the impact of PPI or by hindering it. These are called 'contributory PPI factors'.	Purpose is to complete the identification of contributory factors shaping the impact of PPI on research outcomes, and to rank these in order of perceived importance, by setting out the refinement process undertaken through the Delphi study.	Purpose is to set out six examples of the impact of PPI on research outcome identified by interview participants and to examine, in each example, which of the nine contributory factors can be seen to have shaped this impact. To highlight challenges in evaluating the impact of PPI on research outcomes?
Content covered in the chapters	Factors identified as shaping the impact of PPI on research outcomes 1. Wanting to make a difference 2. PPI in research processes 3. Information and Communication Technology (ICT) 4. Networks 5. Dissemination 6. The significance of power and leadership 7. Resources and the political context	1. Ranking the seven factors plus 'PPI in commissioning' and 'PPI in implementation'). 2. Situating the factors of PPI as micro, meso and macro levels 3. A definition of the impact of PPI	1. Examples against analysis of the nine factors of PPI specifically exploring: a) what PPI activity brought about the impact within the example b) why participants felt that factors of PPI influenced the ability to have this impact; and; c) how PPI on research process and outcomes are conceptualised for evaluation

Introducing the contributory factors of PPI

This current chapter uses data from the interviews. Interviews were carried out with patients, researchers and stakeholders who were in a position of speaking in hindsight about completed cancer research studies which had PPI in the process of the study. During thematic analysis of the transcripts there appeared to be seven complex factors of PPI. These factors were embedded in interviewees' discussions of particular projects. These factors of PPI were the major themes identified in the 'making sense of data workshops' by end users of this study. These factors of PPI are labelled as: 1. 'Wanting to make a difference'; 2. 'PPI in research processes'; 3. 'Information and Communication

Technology (ICT)'; 4. 'Networks'; 5. 'Dissemination'; 6. 'The significance of power and leadership'; and 7. 'Resources and the political context'. The reason these factors of PPI are central is because they acted as a foundation of understanding the impact of PPI on research outcomes. All interviewees perceived these factors as acting as barriers and facilitators.

Factor 1. Wanting to make a difference

Wanting to make a difference concerned people's motivations for PPI. Participants spoke about: hope for change, the idea of democracy, having equality and better services, the pragmatic knowledge that patients and the public brought to research and accountability.

Hope for change

All six patient participants stated their individual experiences for PPI in research began with the significant and life-changing event of their own cancer diagnosis. It was after they became well (in remission) that they were able to consider helping future cancer research. For Jane, her cancer led her to devote the rest of her life to cancer research: *'I mark my experience as what led me into becoming involved…'* (Jane, cancer patient, IP2). Helen, talked about how there was *'hope in trials'* (Helen, cancer patient, IP3) implying cure as the central reason for why she decided to get involved in research. For Ben though, he wanted to transform his bad experience into something positive. Ben used words like 'our' and 'we' indicating that he had identified with other patients previously, about their collective poor experiences of cancer diagnoses and prognoses:

> …being told the diagnosis, being told the prognosis, and based on our experience we felt that …our experiences, …Without going deeper into it, …the way I was told, and the way it was initially handled, was quite poor.
>
> (Ben, cancer patient, IP6)

For Helen and Jane, becoming involved in cancer research concerned offering insights about how a new drug trial could be set up, implying technical insights. But for Ben, he appeared to have knowledge about how negative experiences of oncology could be avoided, so what Ben was offering was a different type of championing role from that of Helen and Jane.

Democracy

Sarah responded independently to a national newspaper advert inviting the public to join a research study. Sarah demonstrated democratic principles for her reason of wanting to make a difference, implying intrinsic values relating to citizen duties, accountability and moral consciousness in her PPI role. This opening part of the interview summarises these points:

> One day I was reading the newspaper and I noticed an advert which said 'are you interested in cancer research?' …so I applied…. when I was working I couldn't but now it's time to because research is paid for by public money and I have a duty to offer my views. Do you know, hand on heart, I feel strange at meetings when they offer us tea and biscuits, let alone a payment for our time.
>
> (Sarah, cancer patient, IP1)

Sarah's involvement was driven by helping cancer research through her practical insights, led by her own cancer experience to improve things for others. These examples demonstrated that patient motivations concerned wanting to make a difference by helping researchers to improve cancer treatment, improving standards of care, improving the oncology consultation experience and ensuring democratic rights.

Equality and better services

Unlike other researchers, Joanne (a research professor) was strongly motivated by working towards equality for LGBT communities in cancer services. One particular aspect which made Joanne passionately motivated to conduct PPI in research was that when women were going through a breast cancer diagnosis process there would be a review of their medical history and during this time, their family and sexual orientation would be likely to be captured on file. Joanne's work was driven by particularly negative accounts of oncology experiences from lesbian women. For example, one woman told her that she had to disclose her sexuality over and over again:

> if you're a lesbian wanting to be treated holistically for cancer and you have to come out to 79 people, it is exhausting…. So, it's bringing those experiences closer to you, …One lady said she was asked, hello Mrs Smith where's your husband today? You know that kind of thing is what these women experience.

(Joanne, academic, IR2)

Joanne maintains links with her PPI group to keep herself grounded. These regular conversations with women, she argues, is what helps lead to subtle directional research changes, as they offer up to date and real understandings about what LGBT women are going through. She articulated: *'I don't know why anyone would do research without embracing PPI principles'* and that her job will not be over until she witnessed equality in the health service.

Pragmatic knowledge

Researcher motivations were often driven by the practical insights that PPI offered to the research process. For example, Philip (research professor) stated that cancer trials often under-recruited and for this reason he could see, from past experiences, that there was great value that PPI contributed to making research run more effectively. In the trial he spoke about during interview, the PPI group had practical patient insights and suggestions:

> They would say things like, drop that blood test that would save an extra trip to the hospital. As an oncologist those are the things that we might miss but are valuable to patients …these insights make or break research.

(Philip, oncology professor, IR4)

In one study Robert (research professor), stated the funder expected PPI, which prompted him and his team to ask a cancer charity to join the team. Robert said that the funding panel had been impressed with his application because the charity became a co-applicant and that when the study was actually taking place they asked helpful questions during the entire process, offering a 'reality check' to the research:

> … They pulled us in the right direction …Saying, for example, if we do an interview, what do you ask; if you get a result, what do you interpret; if we put some questions in a questionnaire, well – those don't make sense,…

(Robert, GP and professor, IR5)

Generally, across the researchers it seemed that intentions for PPI in their respective studies was channelled by experiences from previous work and that patients had helped research and the winning of research funding.

But not all interviewees who were researchers were as positive and embracing of PPI. James for example, had an alternative understanding and his belief was that PPI offered little to the research process, attributing the phenomenon itself to 'political correctness'. Similarly, he felt that patient knowledge was limited and not helpful to research:

> Patients don't make a huge contribution, it's just political correctness all this patient involvement…. Even our lay summary was put together by our academic secretary. …I have sat for 15 years on research committees that have got public involvement and frankly [they]don't contribute much. I think you're kidding yourself if you think they do…
>
> (James, oncology professor, IR7)

The interview with James was insightful. He was open about how he felt PPI added little to medical research. James said in his interview that the research grant for had requested links with wider cancer charities and expected that a 'lay summary', which James said he called a 'non-specialist summary', not a lay summary or a plain English summary.

Other than James, most researchers spoke of PPI being something of positive value but there were examples of 'tokenism' and 'self-selection', identified by Priscilla:

> Priscilla: I am PI for 20 studies at the moment ….one or two of them might have a bit [of PPI], but these are drug trial studies. So, I have got a study at the moment where ….we have got …on the application form for the grant …a nominated patient but actually in practice they are not really.
>
> RP-W: are you saying that their involvement is tokenistic?
>
> Priscilla: Yes, but then you could argue actually does it warrant more input? …The only thing that patients can do really is have a look at the protocol and decide whether [it's]reasonable. …they are a self-selected group because they volunteer to do this. So, they may well say oh absolutely its ok to have two extra endoscopies because they are motivated and they are committed. Whereas Mr Smith in the street may well think very, differently.
>
> (Priscilla, oncology professor, IR1)

Priscilla was referring to an important point about representation, that PPI is not representative. Another interesting point was made by Patsy (hospice senior staff), who said that patients are seen on a daily basis in clinics and yet the problem with PPI is that the focus is on the one person who comes forward in the PPI capacity, not the very many other patients who have been seen. She said PPI placed too much emphasis on those one-off encounters which are not representative:

> I suppose the other thing that happens in people's minds is that you know how many thousands of patients I have seen in my career compared to the person that comes largely with their own experience, which may be just them, it might be their family, it may be they come from a group of other patients that they are kind of representing. But it's unrepresentative, [and] always quite personal isn't it?
>
> (Patsy, hospice senior staff, IS8)

Accountability

Overall, stakeholders, generally felt that PPI addressed in cancer research, strategic and accountability issues. Steven (who was once a cancer patient and now working in cancer policy work thus had a hybrid role), offered insights about a strategic review of cancer research funding, questioning policy-makers about future funding and previous spending on cancer. His motivations for PPI focused on ensuring that cancer research spending was carefully considered across all cancers, not just some:

> So me and others amongst us… Through our input we found out where the cancer spending was going, Breast and leukaemia spending was huge but pancreatic and lung cancers had nothing, so … the facts and figures were being exposed and we could start to challenge them [the funders].
>
> (Steven, hybrid role, IS3)

Jenna's view (trials manager, IS5) also reflected that patients have a strategic role in cancer research work. Jenna recollected that over the last 25 years there had been a steadily growing view that PPI could help cancer research planning. Her experience of engaging with patients in trials reflected that patients not only comment on plain English summaries and patient information sheets, but PPI also helps with prioritising what should be funded in the first place.

For Barry, a PPI lead, researchers move on to new pieces of work, but patients carry on being patients. They are changed by their experience of cancer and are therefore in a unique position to see outcomes through:

> When the researchers finish a piece of research they go on to another piece of research. But the people involved in that project might not, they…have a personal involvement in wanting to see it happen…so they will be able to see, well we've suggested this and five years later these guidelines are out and that has had implications from the research.
>
> (Barry, PPI lead, IS4)

Factor 2. PPI in research processes

Participants described the PPI in the research processes that they had been involved in either setting up or had experienced. Under this factor, PPI in commissioning, PPI in research design, managing individual agendas during PPI work, PPI in the research conduct and appropriate and meaningful PPI are discussed.

PPI in commissioning

More than half of the interviewees had commented that PPI in commissioning had added significant value to research. But participants struggled to give examples. Research planning with the people it affects was believed as vital in transforming services and improve outcomes of cancer care as Paula explained:

> I had a telephone interview to hone in about my diagnosis with a commissioner.... I was also able to give them information that I've suffered late effects, which is common with my type of cancer and treatment.
>
> (Paula, cancer patient, IP4)

Research commissioning panels were able to question the research team if they had doubts about PPI. Priscilla spoke about how she was asked by the funding panel to make significant PPI related changes to her application:

> We had to change our plans, so it started off with four [patients on the steering committee], when we got our grant they suggested we increased it to a minimum of six, which we did.
>
> (Priscilla, oncology professor, IR2)

Another issue discussed at a commissioning level was how public members could become public co-applicants on research grants. To help the funders have confidence that the study was capable of recruiting despite having ethical issues:

> I am a co-applicant for a study [of which Paula explained ethical implications] … So, in a way it could be a little bit controversial in terms of recruitment. And that's really where, … us as advocates […] can help. And [the Principal Investigator] has engaged me as a member of [charity] to be a co-applicant.
>
> (Paula, cancer patient, IP4)

Clearly these examples demonstrate that commissioners wanted to see how research calls were being carefully planned, that researchers were considering different ways to involve people and that if the commissioning research panel were unsatisfied they could ask for more PPI.

PPI in research design

Just as commissioning processes were perceived as being important in research impact generation, proactive PPI in research design was perceived to lead to more focused and relevant research, which in turn was seen as being more likely to achieve impact later. However, finding suitable people to involve first was often seen to be problematic. More than half of the interviewees spoke of how they found it difficult to involve people, from finding suitable people to struggling to support their training and payment.

Patient Sarah talked about how her skills and knowledge increased over time, however initially she confesses to knowing very little about PPI in research. Sarah said as time went by, she felt she was able to make useful suggestions. She also expressed that being involved in research is not for everyone and requires a level of basic skills and confidence to do the role:

> What I found is that I knew nothing about anything when I started, but gradually […] you start to make sensible comments, […]it's obviously not everyone's cup

> of tea to do this [PPI in research], you've got to be able, … have some sort ability to read, write and speak up and more than anything else not be intimidated by 30 professors in the room!
>
> (Sarah, cancer patient, IP1)

Sarah, by describing the essential skills of reading and writing, highlights that those who struggled to read and write were at a disadvantage immediately. Sarah's continuity of being involved in research led her to having confidence towards PPI.

But continuity appeared to serve other purposes. Phillip (a research professor) believed that if a certain group of patients are involved at earlier phases of trials then the same group should follow the work through because they are knowledgeable about that particular piece of work:

> I think the same users need to be involved in follow-up trials. So, for phase 1, phase 2 etc., the same users could be involved, with sequential studies etc., as they will be better equipped to advise and guide for the second and third [phases]and so on…This helps with continuity and it helps with buy-in too.
>
> (Philip, oncology professor, IR4)

However, there was tension in the data about PPI in research benefitting from patients who have been involved for a long time versus those who felt PPI needed fresh perspectives. Four participants felt that using the same group of people meant that people became too acclimatised to research systems and moved away from their original experience of cancer which led them to becoming involved in the first place. This point was raised by patients particularly. Here is an example from patient Jane:

> What you really want is… new people because we've got too many old ones. We need to manage some of the old ones off, who are now a long way away from when they first had cancer or had experience of cancer as a carer.
>
> (Jane, cancer patient, IP2)

Another patient, Helen, raised that there simply are not enough people to get involved in research. She said that there are lots of trials currently running and they all expect PPI,

but the task of finding people is difficult because there are not enough sufficiently trained numbers of people willing to help:

> The trouble is, PPI is embedded …there's hundreds of these research trials and if you haven't got enough[trained] people to actually be involved in them, then it's actually quite difficult for researchers to find people.
>
> (Helen, cancer patient, IP3)

Seven participants raised a connected problem, one of retention. In cancer research, PPI might not survive the length of the research study, or patients may withdraw their involvement due to deterioration of their health. Ben explained how he witnessed this:

> … the last couple of meetings I went to, there were only three of us, …one person wasn't too well… another had decided that they would like to go and do a bit of travelling… because, they felt that their cancer was progressive …so it did slightly dwindle but I wanted to see it through.
>
> (Gary, cancer patient, IP5)

Janine said one way in cancer research to fulfil PPI aspects was by involving carers or those better. This was particularly important in palliative care, as carers' perspectives were perceived as a useful secondary insight into patients' lives as well as those who were not palliative patients:

> The difficulty in cancer research is people don't live long enough …That's why we asked relatives and carers and people who have [been] cured from their cancer but not people who are on active treatment or those who have got secondary disease.
>
> (Janine, palliative care professor, IR3)

Managing individual agendas during PPI

The effect patients feeling intimidated was acknowledged by researcher professor Janine:

> …some people haven't a clue on what professionals around them are doing. They dare not say anything and feel very uncomfortable about having all these medics about.

(Janine, palliative care professor, IR3)

Janine's view raised an important question about how this negative effect of confidence resulted in managing patient agendas. Several interviewees spoke about the issue of individual patient agendas being difficult to manage. This was especially the case when patients became too dominant about their own cancer experience:

> The trouble is A finding someone, and B finding someone who hasn't got an axe to grind, you see …there's a patient representative, …he brings up his diagnosis in every possible meeting….
>
> (Janine, palliative care professor, IR3)

But it seemed that patients' needs changed over time. Priscilla explained that agendas of patients are in transition during their cancer experience and this can affect their 'state of mind' relating to PPI:

> … in that awful time when you have just been told, your brain doesn't work. … her head wasn't in a place where she could have made any real decisions. However, now a few years down the road it's very different, …she wants to lead all the decision making but at that stage she just couldn't
>
> (Priscilla, oncology professor, IR2)

Priscilla's point reminds us that patients' feelings evolve as research progresses, and whilst sometimes people might not be at their best during one phase of their cancer research PPI experience, as their health and prognoses change their input will change too. The challenge therefore may be that gaining the best input from people is highly dependable on their situation at the time.

PPI in research conduct

In each interview, the broad issue about difficulties of conducting PPI were discussed. Conducting PPI work involved training issues, supporting and ensuring that people where paid for their time doing PPI. Four patients received training for their PPI role. Most researchers and stakeholders also had opinions about training. Patients linked up to larger organisations described the sorts of training they had been offered.

> I've got a really good mentor… if my comments are not relevant he'll explain why and if they are, he'll encourage me to put them forward.
>
> (Paula, cancer patient, IP4)

Helen, talked about her experience of a cancer biology study day that she was sent on through a charity that she was involved in, which helped her understand why cancers generally were not detected sooner. She also explained how gaining access to this training resolved her inner anger of being diagnosed late. This helped her to move her own bitterness towards cancer to one side, enabling her to focus on the PPI role:

> I was angry that they hadn't picked it up. And it wasn't till shortly afterwards I went on this biology [training]that I realised how minute the pinprick is of the cancer cell and when it gets to a certain size that's when it has to get its own blood supply and that's when they can pick it up. …And then that clarified a lot in my mind.
>
> (Helen, cancer patient, IP3)

But training could be highly specialised and involved significant travel. Patient Paula recounted how she was awarded a scholarship to go to California to learn about breast cancer and patient advocacy work.

> Luckily, I got a scholarship to go to California, a breast cancer science course …they provide a training course for breast cancer advocates …I was sponsored.
>
> (Paula, cancer patient, IP4)

However, for some patients not connected to larger patient groups, reimbursements were all that they were offered, and one patient refused payment.

> They offered us money … and most of us said no …keep the money. We just want to do it for the good of other people that are coming behind us.
>
> (Gary, cancer patient, IP5)

Joanne simply gave 'a bouquet of flowers' to each of her PPI because there were not any funds to pay for honoraria from the grant; these flowers were bought from her own money. Most researchers spoke of comprehensive payment systems that they had worked

out ahead of the study starting. For example, Katy described a payment system, she listed the amounts that the group members could expect from attendance for PPI work:

> …if it's half a day …we pay them around £50. If they are doing …maybe 5 or 6 hours meeting and they are having to prepare and read lots of papers and maybe do a presentation, we have a rate of £150.
>
> (Katy, national cancer policy staff, IS7)

It is clear to see that training was sometimes offered to PPI but also as an acknowledgement through the form of a 'thank you'. But there was no consistency across the examples of how and, indeed, how much patients were being paid.

Appropriate and meaningful PPI

19 interviewees commented on the different roles for PPI from reviewing patient information sheets, plain English summaries, to helping with data collection. Examples were offered about how PPI had led the research studies to be more 'appropriate and meaningful'. Research-related issues were raised to improve or change the research process/ focus. The next set of quotations display this.

Gerald articulated that if someone has experienced cancer then they may find it hard to separate out their individual issues and experiences from what is being researched and therefore they should not be collecting or analysing data as this could lead to data bias:

> I think people who maybe have had cancer are very changed by their experience and therefore may have very strong views about what should or shouldn't be done. Which may make it very difficult for them to be impartial in how they collect or interpret data….
>
> (Gerald, social science professor, IR8)

Many interviewees (half of whom were stakeholders and researchers) felt that patients can help with recruitment. But Gary (patient) made the following observation:

> There's nothing like someone who's done the study [i.e. participated] saying to someone else it was really important, very straightforward, I'm glad I did it. So that helps recruitment, as an advocate for the study I suppose. In a way the researchers can't twist people's arms like that (laughs) can they?

(Gary, cancer patient, IP5)

Echoing Gary's opinion was Steven's (hybrid role) who discussed that whilst patients may not be developing cancer research trials, they do impact on the way trials are thought out. He offered the example of targeted access to a new trial:

> So, one of the areas they hadn't thought of in the trial was raised by the PPI person on their steering committee, they said 'oh no, I think this is a really important question for people with breast cancer….' And they opened that trial locally because of that. So, whilst we don't develop the trials… I think people do have more of an impact on things that you wouldn't necessarily think of.

(Steven, hybrid role, IS3)

Helen discussed how she was able to influence a trial management committee to change the upper age limit because she had turned 60 that year and aside from the cancer, she was fit. Helen had wondered why the trial had a cut-off age of 60:

> I'd turned sixty. And, course, a lot of the cut-off dates for a trial is sixty. My question was; well, hang on a minute! A healthy sixty-year-old is probably a lot healthier than somebody who's been abusing their body in their forties. So why is there a cut-off date at sixty? Surely it should be up to how the individual patient is, and not just a blind cut-off date. That made 'em sit up and think.

(Helen, cancer patient, IP3)

There was a sense generally that patients can help with ethical issues in research and Priscilla explains how this happened for her study.

> We were wanting to try and get patients to sign up to take part in the study before they had been seen in oncology. So, at a time when they were really vulnerable. Were really struggling ethically to decide how we could actually encourage [and] invite them to attend without upsetting them further. The patient group were very helpful in logistics, in the end the patient group wrote the letter of invitation, not us. So, they basically wrote the letter to say we are a group of patients we have been here, this work is being done that we are helping with, we would very much like to invite you to participate. If you would like to take this further, then one of our researchers will be in touch.

(Priscilla, oncology professor, IR1).

Factor 3. Information and Communication Technology (ICT)

We live in a technological world and this was conveyed in many ways during interviews. Patients, researchers and stakeholders all talked about various ways that technology is being used and applied in everyday PPI in research work and this factor of PPI reflects using ICT. The use of smartphones for emails about PPI, google groups also known as virtual platforms, social media and blogs as well as sharing information on video streaming channels were all discussed.

Smartphone use for emails about PPI

Four patients discussed the use of their smartphones for PPI work. Paula throughout the day checked her smartphone for new public involvement requests/tasks, implying both that checking her emails was a big part of her day and also that requests from researchers were routinely coming in:

> … I'm dealing with requests on my smartphone, I'm always, having cheeky looks at my smartphone most of the day because I'm getting stuff in from… the trial I mentioned I am co applicant for, most of the day.

(Paula, cancer patient, IP4)

Virtual platforms for PPI

Three patients explained how they were part of a virtual platform where patients could comment on studies that researchers were planning:

> …. there's a Google group… and people will comment on this group and so they [researchers] can collect together comments and get comments from quite a number of patients.

(Sarah, cancer patient, IP1)

Smartphone applications being developed by PPI work in research processes

Barry a stakeholder in a PPI role described a smartphone application that a PPI group had developed to help a research study, demonstrating impact on the research process because Barry recollected that researchers had adopted the ideas generated by the PPI group. The study has not yet been completed but shows how PPI work can help with technological ideas:

…the medics [researchers] have real-time reporting now, …the smartphone app is a quick way of doing it. They took the proposal to the PPI group that I chair, and the PPI group, in half an hour had generated some possible applications and uses of this thing that the researchers hadn't contemplated; and the researchers wrote back to the panel to say, here are four things that we hadn't thought of, that you did, and we're now going to work on them.

(Barry, PPI lead, IS4)

Social media and blogging

15 participants emphasised the use of social media to help generate interest about a study and a subsequent campaign from the study. The ease of using social media such as Twitter, Facebook, blogging and crowdsourcing was raised as a way of further reaching people about new research and improvement initiatives:

It's a lot easier now with things like social media, Twitter, Blogging, …crowdsourcing, that kind of stuff. People are interested in what's been done and how it's changed services…

(Katy, national cancer policy staff, IS7)

Katy then went on to explain the reach of a campaign generated through cancer research with PPI:

… there is an evaluation report published about the reach of that campaign and the difference it's made [and] how many clinicians it's reached, and the patients and the public were involved. So, we had the TV and radio interviews …thousands of people Twittering [sic] and you name it.

(Katy, national cancer policy staff, IS7)

But for researchers like Robert, they expressed concerns about not knowing who was using the findings that were produced. He expressed that social media can help with dissemination, but that it was difficult to know how far findings can travel or how they might be used:

…. I suppose it's like people who tweet and then people who retweet tweets, you do something but you don't know how far it is going to go and who's going to end up with it.

(Robert, GP and professor, IR5)

Three participants had a blog. Steven, who had a hybrid patient and professional role, described how his blog, which he wrote in his dual capacity of patient and a professional, impacted positively on research work: He felt he was able to assert and challenge policy through this medium:

> There is something about the way we are strategically linked virtually, the way we have got our networks, the way we are beginning to alter policy. The way we have stopped just being the quiet voice within…, [by using online platforms] we are challenging, we are assertive, we are known. … my blog's an example, where we are actually speaking out and becoming leaders.
>
> (Steven, hybrid role, IS3)

Steven discussed blogging but at the heart of what he was saying was about leadership, a point which will be revisited in the factor of *'power and leadership'* (below). Steven then said that social media and new technology offered a way to share what PPI has achieved for research:

> I think we can use social media and new technology, we can use them to actually say here is some of the discussion around this [the impact a study has made].
>
> (Steven, hybrid role, IS3)

The use of YouTube and hyperlinks

The traditional use of YouTube is to allow users to upload, view, rate, share, add to favourites, report and comment on video clips. But it seemed that YouTube was being used for PPI work. In the interviews with David and Katy, they offered examples of impact of PPI on research outcomes and described the use of YouTube to help with cancer genetics research work:

> I am delighted that we have got the first YouTube channel in the world for clinical genetics, that's just under 10,000 views and it's been viewed in 12 countries.
>
> (David, geneticist doctor, IR6)

Katy discussed that they asked their PPI group to comment on YouTube clips that researchers had developed:

[….] if you look on their website they have got a seven-minute clip and we sent that out to all our lay networks to say have a look at this, what do you think, does it help?

(Katy, national cancer policy staff, IS7)

Almost all researchers and stakeholders validated how easy it was to inexpensively send information about a study using their email and sending documents presented in Portable Document Format (PDF) and hyperlinks to the other side of the world, at the click of a button, to help generate impact:

Having a PDF or a hyperlink …these days it's so easy [and inexpensive] you can zing it over to New Zealand or Australia,

(Nick, cancer charity, IS2)

Factor 4. Networks

This factor of PPI was about the importance of networks, and the richness of different perspectives that come from working collaboratively, building and forming partnerships. Patients all described networks they were connected to. Stakeholders and researchers described how professional networks impacted on them and their work.

Patient networks

All patients identified how their own networks helped them with their PPI roles. Paula was involved in a number of other PPI research related activities, these other roles helped her more generally in PPI work:

If the patients are already members of charities, they are not just coming in blind to one area. They normally, …like me, are involved in other areas so understand wider issues of PPI.

(Paula, cancer patient, IP4)

Steven, was actively involved in other work which researched long-term effects of life after cancer. Steven shared how he and other patients like him are connected to a stream of influential patient networks. Steven explained that he was invited to the House of Lords

at Question Time to discuss the networks he represented and what they wanted to be the focus of research:

> I have just been invited again to the House of Lords at Question Time… one of my questions was about improving the research for long-term survivors of cancer, like me.
>
> (Steven, hybrid role, IS3)

But Steven believed that this visit to the House of Lords was not the only place where he was able to make impact; he also had his own networks to share research and make impact. He believed collaborative working amongst patient networks could potentially demonstrate 'reachability' of his networks

> We have got our own networks of people. And they then influence other people because they are all sitting as members of Breast Cancer Campaign, Ovarian Cancer Trust etc. So, if you did a Venn diagram, …mapping all the circles of the patient's community you will see…we find our own ways of making change happen.
>
> (Steven, hybrid role, IS3)

No example of change was provided by Steven despite the point made. However, Jane also talked about how she was involved in patient networks via a charity that she was involved in. She discussed how the charity offered her 'clout' when approaching political figures. Jane had contacted local MP's to gain political backing for the charity she was part of to help improve cancer patient care in a rural part of the country:

> So, we [Jane and the charity she was part of] are contacting our local MPs, we are talking to MPs who are interested in this topic [improving cancer patient care]'.
>
> (Jane, cancer patient, IP2)

Several patients mentioned that charities helped to keep the cancer patient voice alive. One unique charity, which is a network of cancer patient survivors the charity develops links between cancer researchers and patients, by training patients to become confident advocates in cancer research.

I came across a charity [and] decided to become a full member of this national group, which specialise in training advocates to be effective voices in research, and that's right at the cutting edge of research. It's mainly, looking at proposals, research questions and protocols prior to going on to funding for study. So, it's actually helping with funding and fundamentally that's what a lot of [members in this charity] are doing.

(Paula, cancer patient, IP4)

Stakeholder networks

Stakeholders spoke of a UK-wide partnership between government, charity and industry which promotes co-operation in cancer research, where partners can achieve greater progress by working together. Jenna spoke of how this cancer network is highly dedicated in the role of co-ordinating cancer research:

… for cancer …we haven't just got the research networks with the clinicians doing the work and the research staff helping them run it, we've got these national groups and these regional groups, …and the national clinical studies groups. I think we are in a better place than any other disease area... So, [this network] would call that like a whole systems approach. …they are trying to make sure that the key people nationally are in a group, they're developing the right studies…where there's gaps, and they then making sure that they go out there and are being implemented after. …But I think we are unusual in cancer because we have got that whole structure behind it.

(Jenna, trials coordinator, IS5)

Katy described the same partnership as Jenna but in more detail (note the excerpt is long but necessary to illustrate cancer networks in the UK):

…we partner very closely with the [network]. NCRI is a partnership of all the key funders for cancer research in this country, so people like Cancer Research UK, Macmillan etc., etc., the key charities. You have got all the key government bodies …key pharmaceutical industry [and] they all work together and put money into a pot and agree on funding and prioritising for research in this country. ….We have got patients going into that, directly advising that group, …And a few years ago, when [the network] was redoing its strategy for …[patients] said well actually it's great that people are looking for a cure for cancer, …but actually cancer is a much more long-term condition now, people are living with this day to day, month to month. We would like to see more research on the effects of living with cancer, not just… physically but psychologically, on our economic situations, being able to work etc. And their voice was taken into account, it informed the strategy.

(Katy, national cancer policy staff, IS7)

Researcher networks

It seemed that networks were significant and each researcher spoke about how they worked in collaboration with others. Some regarded networks as relationships, signalling respect and perhaps unspoken support for the work, based on trust and working together:

> I've got some pretty good relationships in the palliative care field, in the end of life care strategy field. I will make sure that I take this work to quite a lot of different forums.
>
> (Janine, palliative care professor, IR3)

Although Janine is discussing dissemination plans, it is included here as it reflects the essence of networks. She then went on to explain that when knowledge is shared it should not be uncritically accepted because: '*in a relationship you work it out because lots of other things need to happen too'*. Researcher Philip said that he was involved with a charity and through this role he had a significant group of people whom he could connect with to encourage them to lobby government.

Factor 5. Dissemination

In this factor dissemination is explained. Participants believed that before research studies made an impact at implementation stage, several dissemination aspects needed to be carefully considered. They discussed the limits of academic dissemination, the importance of disseminating information more widely, the importance of PPI in the dissemination process and that dissemination cannot carry on for ever.

Limits of academic dissemination

Every researcher discussed the effects of open access journals, writing journal papers and speaking at conferences, but some more interesting issues were also raised which were felt to affect the impact of PPI on research outcomes. Effective dissemination was about getting the findings of research to the people who can make use of them, to maximise the benefit of the research without delay. Most patients, researchers and stakeholders commented on the limits of academic dissemination, acknowledging that academic dissemination practices often have only reached a few people. For example, posters, Patsy said, were not 'proper' dissemination:

… Quite frankly the number of people that look at a poster is very, small, that's not proper dissemination.

(Patsy, hospice senior staff, IS8)

Another point about the limits to academic research dissemination was made by a head of an academic department, who said that journal papers quite possibly only reach a relatively small number of people:

If you're publishing in a journal it is quite possible that only two hundred people will ever read that research paper.

(Robert, GP and professor, IR5)

Disseminating information more widely

There was a consistent message across the interview findings that information needed to be produced in a variety of ways, for a series of audiences:

…part of dissemination is trying to get it put into practice, so …it means producing [information]in different ways for different audiences.

(Nick, cancer charity, IS2)

Nick offered an example, saying that he emailed the information, he presented a poster at a conference, he shipped out hard copied of the reports and he tweeted about the report using a link. He then made a point about dissemination being an on-going process:

My dissemination tactics have been emailing it to people, going to conferences, presenting posters, leaving copies on tables. […emails and tweeting] as well.

(Nick, cancer charity, IS2)

Patients and the public in the dissemination process

PPI in the dissemination process itself was believed to make an impact on research outcomes. It was believed if patients and the public were involved in dissemination delivery itself, they can convey the message in a captivating way.:

…I think it's very emotive… listening to a patient's story is very powerful. And what we are looking at is something that might require doctors to change their practice and that's a really hard ask. But actually, if you have got a patient who is telling you the results of this study which show it makes a difference rather than me I think that's very, compelling.

(Priscilla, oncology professor, IR1)

Helen discussed that if patients have been involved in the study, then the person disseminating must raise that in the content:

If you're involving patients …you've got to be telling policy makers and all-important bodies, telling them and others 'look, you've got to take this seriously, patients were involved in this'.

(Helen, cancer patient, IP3)

Patient Paula said that: *'If the patients are involved they can disseminate…. Widely'*. Patients Ben and Gary's view chimed with Paula's, even though Ben spoke less of his connections to charities. He said for the study he was involved in, he felt charities would find it valuable to hear about what the next stages of the work might entail: '*what mustn't be forgotten is dissemination to patient groups. You know, to charities etc. about this work [his input in the study]'*. Steven asserted that patients are usually connected to other patients, so for that reason they are likely to reach other patients quickly:

We can no longer just sit around a table …that's insufficient. It's a two-way process, when we get involved it is incumbent on us to tell others. So, I spend a lot of my time [talking to] patient groups, patients' communities, self-help groups, to talk to them about research. …Because the more we spread the word out into those communities the better it is.

(Steven, hybrid role, IS3)

Dissemination cannot carry on forever

Four researchers said during their interviews about the reality of the situation that researchers are faced with. It is a researcher's imperative to apply for more research grants to keep them in a job:

I don't think it is anything sinister in what the academics are doing in relation to dissemination, …they can't do everything. They've got to draw a line in the

research and when it stops paying their salary and …staff they have an imperative to get more funding so that they don't all become unemployed.

(Robert, GP and professor, IR5)

Factor 6. The significance of power and leadership

Having the leadership in research of someone with a position of power and influence was brought up by 10 participants. Leadership sometimes meant commitment and influence and organisational support for PPI, for others it was management in research willing to support the PPI. It also meant influential figures, such as MPs, celebrities, champions and experts, supporting and even leading the PPI work. Ultimately, there was a belief that if the institution hosting the research grant was 'PPI active' then the impact of PPI on research outcomes would be far greater.

Having patient influence

Paula described in her interview how one particular patient was very inspiring for her to learn from at the charity she was part of. Paula spoke about how this one woman was routinely approached by oncology researchers, with the mind-set of asking her to lobby for their work. Researchers would use her name to other researchers and healthcare professionals saying: *'something must happen about this, because [name] has told them!'* Paula went on to explain that this woman was very formidable in a positive way because of her family links to a particular Baroness in the House of Lords:

… [A] Baroness …who campaigns [for a cancer research charity] and is … in a very good position in healthcare …is a formidable person [many people follow her work and values of PPI] … and a lot of researchers, clinicians, oncologists across the UK know [her]. You just need to say her name, you don't need to say her surname and they are with you on the PPI.

(Paula, cancer patient, IP4)

Having celebrity influence

The significance of power and leadership also included influences from celebrities, according to four participants. Reference was made to Jade Goody, Peirce Brosnan's wife, Kylie Minogue and Angelina Jolie, who was found to have a gene that caused cancer. Ms Jolie, chose to have preventative surgery. Around the time of the media

attention this celebrity generated, English hospital referral rates hit record numbers. David said that his work became busier after the story of the actor reached the news, rather than his own efforts of PPI. He suggested therefore that celebrity backing for particular cancer research had influence on research uptake and understandings amongst the general public:

> We know that since Angelina Jolie mentioned …she'd had preventative surgery it's doubled our referrals rates and, in some cases, trebled in different parts of the country.
>
> (David, geneticist doctor, IR6)

Having Government support

Having the backing from powerful people was helpful in manoeuvring campaigns according to Katy, who described a campaign that has been successful in generating research impact. The campaign was created through her work. Katy explained how she has managed to reach Whitehall.

> …The message 'It's Ok to Ask' was a direct result of the [survey], patients helped to get questions in, those questions came up with the finding that most people want to be asked and expect to be asked about [cancer] research.
>
> (Katy, national cancer policy staff, IS7)

Katy described the leaders present and their backing of this particular campaign:

> all the key political groups - the All Parliamentary Group on Cancer… the Secretary of State for Health …politicians, the decision makers - people like the cancer tsar… all coming together…
>
> (Katy, national cancer policy staff, IS7)

Katy said that when they were presenting the findings to the government about the patient driven questions, they had an opportunity to ask a direct question to the then, Health Secretary, Jeremy Hunt:

> …we talked about the patient-driven work …and its impact and we asked if he could reassure us that the government would take seriously about supporting patient services …for the future to help drive service change. … being a typical politician he didn't give a direct answer, but he did say, he thought [our survey] was a very positive piece of work and he would like to see that kind of work

carried forward. …So that was good that we had the opportunity to talk to someone at the top …

(Katy, national cancer policy staff, IS7)

Katy's example demonstrates that cancer research and cancer patient experience work, if created through established channels, generates political interest at the highest level.

Organisational power and leadership

Strong organisational leadership was also seen to have an inextricable link with impact. An interesting aspect of 'power' was organisational support for PPI; it was believed that if the institution conducting cancer research was active in PPI work then the impact from that research would be far greater:

So… in an environment where staff are routinely part of a PPI in research culture and environment, where there is an expectation that research takes place …there seems to be a statistical link with better outcomes for patients.

(Michael, academic department lead, IS7)

Organisational PPI respect

One researcher, Janine, described her highly respected and reputable charity organisation, based in a university hospital setting. Janine's research centre had firm support for PPI in their palliative care research work. Janine explained that the organisation that she was part of had a strong PPI ethos and in her opinion the university was keen to keep a strong relationship with patients at the heart of their work:

…so, we are part [a charity] and we sit inside the brand-new school [within the university] So, this is a philanthropically funded research and education department, …we've got a range of funded research …without exception every single one of our studies has got a degree of user involvement [PPI]. We have a regular meeting planned …three times a year and, in that way, we can keep a continuing relationship… with [PPI] and we can also plan engagement …about studies that are ongoing or new studies that we want to develop. But then there's also particular studies which might have an advisory group where we invite particular research partners to join that advisory group and so that study will decide its own schedule of meetings. And there might also be some individual consultation that goes on. So, we tend not to be hard and fast about this is the way we're going to do it, it's on needs must basis. And we have had studies… which have been at the participatory end of the spectrum where we've actually

worked …closely with maybe five or six patient research partners and they've been an integral part of the research team,.

(Janine, palliative care professor, IR3)

Although the above quotation from Janine overlaps with 'PPI processes', it is shared here to demonstrate the value of having an organisation with strong PPI in leadership.

It seemed that other researchers such as Robert were striving for this ethos that Janine was describing. Robert, who was once the Head of Department but since is semi-retired, came to work for an ongoing project he was principal investigator for. He raised the issue that the department still needed to work more closely with patients to form a partnership between the department and the community, but the department had not been able to achieve this as yet. Robert made the comparison that colleagues from other teams, such as cardiovascular research, had already developed a strong relationship with cardiovascular patients:

I think as a department …we've probably got a way to go. I have tried suggest …that we have to have some sort of patient partners…the community, …that we could talk to about various things. … but you know, that didn't really get taken up. … it'd be really nice to have a group of people with whom we interacted. Yet you know, …other Departments [cardiovascular]… they've already got, …patients who they talk to … but we don't.

(Robert, GP and professor, IR5)

James, who felt generally uneasy about PPI practice in research anyway, was not too concerned that his hospital seemed to lack leadership regarding PPI. James showed the researcher, during his interview, how the hospital's monthly briefing report raised nothing about PPI:

…what's he [the chief executive of the hospital] fussed about? Nursing staff review. …this venue from GemaSim[4] risk, are we hitting targets …on …waiting times for cancer treatment, …Local Supervising Authority …Emergency care performance, are we hitting the four-hour deadline, adopt discharges, financial

[4] GemaSim is a computer-based, 'non-technical skills' training- and assessment tool. A laptop-based simulator, GemaSim is designed to demonstrate, and to give experience of the 'real human factor'. It allows for the experience, observation, analysis, modification and consolidation of authentic behavioural patterns.

performance of the various divisions, clinical management group dates, executive team portfolios, listening in action, update from IT – that's this month's briefing. Can you find anything in there about patient involvement? No!

(James, oncologist professor, IR7)

Similar to hospitals, it seemed that some universities were developing the wrong kind of leadership. REF complicated the impact of PPI because it was driven by academic outputs rather than actual change:

Public involvement impact is not helped by the REF…There's impact in academic [work] which is all about getting in the journals that are read most, …So that's impact number one.

(Michael, academic department lead, IS7)

Michael called this the 'REF bastardisation of impact', implying a muddle and conflation of real values about what impact of research should be rather than what it currently is. Similarly, Robert said that despite having a strong desire to make efforts to inform the patients and the public, researchers are bound by what they can and cannot do. Once a study has finished, if the institution the researcher works in does not value efforts to engage the public then that will act as a strong barrier. He implied that academia continues to value papers in high impact journals, rather than supporting a culture where researchers hold community events:

…often the outcomes of research are papers and presentations because that's what's valued by the employers/universities and therefore that's how people respond… you know, you don't get promoted because you held a patient dissemination event, but you might get promoted because you've written a paper in the BMJ [British Medical Journal]. So where do your efforts go?

(Robert, GP and professor IR5)

Michael raised a similar point:

I don't like to reduce people to being sort of rational self-interested homo economicus-es [sic], but the incentive structures …are not designed to try to break down the walls to the ivory towers. They are designed to maintain the institution …and make the academics speak to other academics…

(Michael academic department lead IS7)

Patsy said impact of research is what is countable:

> …in order to keep their jobs, they've got to comply with what's asked of them, which is quantifiable, measurable things about how many papers you produce, what money's come in and how many times you've been cited. because you can only measure the measurable

(Patsy, hospice senior staff, IS8).

It seemed that impact from health research was being forced uneasily into neat audit trails. Undoubtedly, the REF criteria for impact offers the dominant benchmark for researchers in academia.

There were examples in the data to demonstrate the existence of an aloof culture of academia, and that often researchers' salaries and careers depended on creating audit trails, rather than demonstrating meaningful and active engagement. These issues were believed to add to the complexities regarding how the impact of PPI could be evaluated.

Barry, a PPI lead, discussed how easily a lack of leadership can lead to 'mission drift'. Even with the best intentions initially, when people move on to new roles a loss of direction is unavoidable for the organisation:

> there's a kind of natural tidal flow of values, passion and commitment around a particular organisation.. [they start with] clarity of vision, there's a distinct purpose, everybody knows …what they're trying to do and there's an alignment of what that organisation is about to that single purpose; and then stuff happens…quickly and sometimes it happens slowly …things leak; values get buried, passion ebbs away, the pioneering innovative leader hands over the job to somebody else who doesn't quite get it. There's an ebbing away of clarity, of focus, there's a mission drift, there's the loss of purpose and direction. …I …take this organic view of organisations which is …as real as seasons following one another.

(Barry, PPI lead, IS4)

Barry explained how easy it is for organisational values to dissipate regarding PPI. According to Barry, if all research is conducted in an environment with strong PPI leadership then the work is more likely to have a positive start. But weakening of

leadership will inevitably affect the impact of PPI on research and therefore, impact as a whole.

Connected to leadership and power were organisational issues which were believed to affect impact. For example, Janine articulated the importance of organisations being led by senior researchers who can help with facilitating and minimising bureaucracies. These include enabling payment for PPI, using plain language when engaging patients, and training students and staff so that PPI can flourish over time:

> I think it's very unfortunate that universities make us jump through so many hoops in order to get the money to people [who get involved in research], [because of] hugely bureaucratic and difficult rules. …I've learnt also that you've got to teach other people to engage with users. …some of the PhD students just go in there and they talk to them in either a patronising language or they talk to them in terms that they're simply not going to understand. And of course, there's a balance to be reached, …these are mature people who've lived a life and they've probably had a different life to the one that we've had….
>
> (Janine, palliative care professor, IR3)

Factor 7. Resources and the political context

Resources and the political context concerned the range of contextual factors which, despite having good PPI in the study, might affect or diminish the successful production of impact. It included policy making challenges, priorities changing, the effects of restructuring from NHS budget cuts, short staffing, the impact of wider socio-political factors and uncertainty of the new knowledge gained from research.

Policy making challenges

The uptake of research findings, with or without PPI, was not straightforward or linear. For example, Robert described that when new information is found and analysed in the scheme of existing knowledge available it becomes problematic and harder to see how information will be used in practical ways. He recalled an example from NICE:

> I was involved in the cancer referral guidelines that were produced at NICE in 2005, and they're up for being updated …And there's actually quite a bit of new work on the cancer referral guidelines… but even then, you can produce your

recommendations and there's evidence but what do people do with it and how do they use it in practical ways is …not clear.

(Robert, GP and professor, IR5)

Patients agreed. Helen articulated that in drug trials the decision will always come down to NICE and the costs associated with the drug being adopted widely.

…It's NICE guidance who say …"Yes, we'll accept that drug and give it out to NHS patients," or "No we won't, it's too expensive," …I know some of our trials …it's got right to the …end and then NICE have said – "on your bike, we're not using that." …you know- and some of the consultants, they're absolutely gutted because they've spent years on it…. Long term the drug has got to be cost effective to the NHS.

(Helen, cancer patient, IP2)

However, David felt that sometimes decisions made by policy makers were wrong and based on short term solutions of cost saving rather than long term costs. He gave the example of his research saying that, in screening, the implications of making savings by far outweigh the cost of treating cancers and ongoing cancer screening.

So, if you have got a person who is 30, who we prove has not got a very high risk of breast cancer, they won't need 30 more years of high level screening, then if it costs £1000 a year to screen them, …that's saved £30,000. Chemotherapy …drugs can become extremely expensive. [Also]…there are huge social and economic costs of losing people in their thirties, forties and fifties and leaving young families behind. So, for me it's about trying to reduce the burden of cancer on families. Which is quite straightforward if you have someone at high risk of bowel cancer and you remove their bowel they are not going to get it… But there isn't a formal assessment of either the financial or the medical aspect…

(David, geneticist doctor, IR6)

Apparently though, grant committees do have evaluation processes where expectations and resources are weighed up side by side and the job for the policy maker is providing best value. James stated that the role is not an easy one when policy makers have to make decisions:

For a policy maker, …they have a dreadful job …trying to manage expectation against resources and by in large what they want is the best value for their resource, and that's why we have huge research evaluation committees to evaluate grants. They're trying to evaluate demands against resource.

(James, oncology professor, IR7)

Robert also tried to sympathise with the role of the policy maker, saying that policy makers are not being illogical. They are considering pros and cons of change:

to make something generalizable …it might be expensive, …time consuming, …but then other factors may have changed ….before your findings come out. …the fact that it is difficult is because it is difficult. It's not because some people are being stupid or irrational.

(Robert, GP and professor, IR5)

Priorities change

Changing political priorities, especially in connection to PPI, had negative effects because people had invested their time, energy and emotions. Dennis, Robert, Priscilla and Joanne all shared this feeling but also accepted that environmental circumstances change when there is a change in government:

When this …study ended which involved patients through the process, …Not in the design of the project I have to say but in the conduct. …There were no clear dissemination plans set by the funders, …they had funded the project, they'd set the title so they wanted this piece of work, but it wasn't something that we suggested. …We did it and then they did next to nothing with it at the end. …I was left in the position of suggesting to their communications manager how it might be disseminated, they seemed to have no ideas of their own and very little interest and as a result the questionnaire that we designed which was never fully used in the NHS… So, an awful lot of effort went in to produce something that was never really used.

RP-W: And how much was that funded for?

Err in an excess of £300,000

RP-W: What a waste,

Yeah, yeah it is. …sometimes the piece of research you are doing is important but by the time you have produced the findings ….the games moved on.

(Dennis, implementation science lead, IS1)

Sometimes research required further funding to understand the implementation process, as in Priscilla's case, but follow up funding has not been secured:

> We've been writing grant after grant after grant for this work but it has not got through, we just have to accept. …it's just very very difficult work to fund in this current climate.
>
> (Priscilla, oncology professor, IR1)

The effects of restructuring from NHS budget cuts

When governments change, restructuring and reorganising takes place and a direct effect of this on ongoing research ventures was seen to be highly problematic. In Joanne's case, a senior person was made redundant and this had a knock-on effect on her research endeavours:

> I want [my research on LBGT work] to have a direct impact on people's lives and on practice and that is so difficult to achieve this goal because there are so many external circumstances as a researcher you don't have control over. …the coalition won the election, austerity measures kicked in as a result of that [name removed] lost her job and there was a whole redesign and restructuring of services. So, there are some barriers to understanding what the impact has been…We might have had a follow up piece of work and you would know how my research was applied.
>
> (Joanne, social science professor, IR3)

The effects of funding cuts were a critical aspect of understanding impact of PPI on research outcomes. Dennis explained that, when it came to implementation in the health services, the outcomes were highly sensitive to finances, with profound effects:

> You know there was another project that we were involved with which showed some promise in terms of changing service delivery but then it was up to the Trust to review that and decide whether or not they wanted to reorganise their service accordingly. That project finished a couple of years ago and …they've not made a decision yet. …Business cases often have to be made.
>
> RPW: What for?
>
> … if it involves more money …Part of the problem has been that they've all undergone massive reorganisation.…PCTs …abolished, …and Clinical Commissioning Groups start up. …community health services moved from PCT

to the mental health trust, so they had a massive increase in their function. So, they had to cope with a lot of new services as well. … hospitals …affected I think by the funding squeeze … the increase in A&E - attendance which is draining …ever-increasing parts of their budget. And they're finding it very difficult to manage. …the NHS …is under very severe financial pressure and it's very difficult for them to maintain a clear and sustained focus on getting to grips with research evidence and getting it into practice. …people are changing jobs rapidly and yes, they may say getting evidence into practice is very important, …but it's not a quick process …we're in a time of great uncertainty and reorganisation and we don't have the time to focus on that [research findings] at the moment.

(Dennis, implementation science lead, IS1)

Dennis described financial pressure, clinical chaos, staff shortages and lack of focus. Together all of these issues have implications for the uptake of research evidence. Dennis ended by saying that the political importance given to a piece of research evidence changes when governments change:

So, you might think job done and then you have a change of Secretary of State …So those sort of things, even with good PPI, you can't foresee…

(Dennis, implementation science lead, IS1)

Short staffing

Gary believed that short staffing affected the ability to make use of new knowledge derived from PPI, especially when medical and nursing staff were being pulled in different directions:

… there are numbers of conferences about PPI, … lots of meetings and lots of people, trying to keep up to date with the latest information. But when you have one nurse look after 12 patients …The poor girl, man, or doctor, are probably up to their eyeballs with today's battles, with not having time to find out about tomorrow's weapons. I don't know how you fix it.

(Gary, cancer patient, IP5)

The impact of wider socio-political factors

Michael pointed out that expecting PPI to have an impact on practice is asking for too much, because the socio-political aspects will influence research more than anything else, and perhaps evaluation needs to consider these 'other aspects' rather than the PPI:

all those people who are looking for impacts on practice from PPI are probably being… unfair…, aside from whether or not it has the impact there's the socio-political imperative …why not have some people looking at it from a different perspective. Overseeing what is being done in the name of, …public funds and how they are being spent …different perspectives, different experiences…

(Michael, academic department lead, IS7)

Uncertainty of the new knowledge gained from research

Participants recognised that other factors play a part in research knowledge use and uptake. The gradual nature of evidence use was something that eleven participants interviewed raised. They described that thorough knowledge-gathering took place over time and taking account of other research was very important: Janine: '*How does your research with PPI fit into that rich tapestry of the community of concern?'*.

But resistance to change is also important; if the fit is wrong, insufficient knowledge should never be applied as we were reminded by Michael:

…well they might be the wrong findings, it might require resources that we don't currently have, or they have got to fit into systems that we already have …and there are all sorts of stakeholders that are going to be resistant to change. I might not believe you, I might think that is all very well but that you have missed this really important point. You know there are figures about, about there being a seventeen-year lag between generation of findings and putting them into practice, I think it is much worse than that. I think that most evidence never finds its way into practice, and thank God because a lot of it shouldn't ever find its way into practice, and even when it does, you probably wouldn't recognise it from when the research was originally done.

(Michael, academic department lead, IS7)

Michael then said when a research study is being conducted, an interface is useful between those who are likely to use the knowledge and those who are researching it as the work will have more up to date questions and answers, as well as reveal the pressures of adopting change.

a better process would be a more integrated knowledge translation process. an interface between, while the research is taking place, or before the research is even initiated, …those who might use the knowledge and those who might inform it. And I use "inform" advisedly because there is all sorts of knowledge that we are pulling into this research process… If this research venture,

> …involves end users then you are more likely to get the right questions, …more likely to understand the clinical context in which that evidence has got to fit, …more likely to understand the human resource pressure and the financial pressures on the organisation.
>
> (Michael, academic department lead, IS7)

Summary of the seven factors of PPI

This chapter has revealed seven factors contributing to the impact of PPI on research outcomes. 1. 'Wanting to make a difference' reflected ideas around hope for change, democracy, equality and better services, pragmatic knowledge and accountability. 2. In 'PPI in research processes' further areas were identified. These were PPI in commissioning, PPI in research design, and PPI in research conduct. 3. 'Information and Communication Technology (ICT)' highlighted the digital nature of PPI in the form of smartphone use for emails about PPI, virtual platforms for PPI, smartphone applications being developed by PPI work in research processes, social media and blogging, the use of YouTube to generate the impact of PPI on research outcomes, and the ease of sharing evidence online. 4. 'Networks' comprised vast structures of formal and informal collaborations. Patient networks, stakeholder networks and researcher networks were described. 5. 'Dissemination' explored the limits of academic dissemination, disseminating information widely, the involvement of patients and the public in the dissemination process, and that dissemination cannot carry on forever. 6. The significance of 'power and leadership' including the importance of having patient, celebrity and government influence was discussed by interviewees. Organisational power and leadership was also discussed here, how leaders and powerful people can help organisations reduce bureaucracy concerning PPI processes. 7. Finally, 'resources and the political context' which concerned policy making challenges, priorities changing, the effects of restructuring from NHS budget cuts, short staffing, the impact of wider socio-political factors and uncertainty of the new knowledge gained from research.

Each of the factors of PPI described in this chapter demonstrate that PPI outcomes are entwined with motivations, circumstances and context and thus outcomes are difficult to determine without paying close attention to the PPI processes themselves. In the next findings chapter, this study's Delphi process is described, which refines these findings to

complete the identification of contributory factors shaping the impact of PPI on research outcomes.

End user involvement influencing this stage

May 2014 – Developing themes from the data. Involvement in the form of **collaboration** with n=10 researchers at a workshop at De Montfort University. Key themes from the interviews were presented, and workshop attendees were asked for suggestions for the focus of the Delphi stimulus paper. The workshop helped the researcher to see that that data were broad because of the different types of studies discussed (from randomised clinical trials to community-based social science research) and that the backgrounds of interviewees ranged from lay to professional. It was at this workshop that attendees suggested that common themes needed to be the focus of the Delphi study.

May 2014 – Developing themes from the data. Involvement in the form of **collaboration** with n=9 stakeholders at a workshop at the University of Leicester. Slides used for the previous De Montfort University workshop and feedback from its attendees was presented at this workshop. An important point raised at this workshop was that seven themes were present, and these seven themes should be the focus of the Delphi process.

June 2014 – Developing themes from the data. Involvement in the form of **collaboration** with n=45 patients and the public at a workshop which was tagged on to an existing PPI event in the East Midlands. At this event data from the study as well as feedback from the previous two workshops were offered. Those in attendance raised that the data were too focused on research processes and to help this current study the stimulus paper needed to be focused on outcomes. The patients and members of the public suggested that some process related content should be placed to one side as it acted as a 'red herring'. They also said that importance of themes is tricky to rank if a common definition is not agreed first. This was a general comment and observation they made which later influenced round two of the Delphi by asking panellists to offer their own definitions of the impact of PPI.

These three workshops impacted considerably on this phase of work because it was decided here that the Delphi needed to focus on the seven factors identified which were: PPI processes, dissemination, power and leadership, resources and the political context, networks, wanting to make a difference, and information and communication technology.

The running of these workshops was made possible because of existing PPI events already paid for by the NIHR and the university I was funded by. Without these opportunities the end user involvement would have been compromised or not possible. See chapter nine for details about the limitations and reflections

Chapter Six: Refinement of factors which contribute to impact of PPI on research outcomes – a modified Delphi Study

Introduction

The purpose of the Delphi study was to enhance and refine the understanding of the seven factors of PPI discussed in the interviews, by presenting an expert panel with these. The factors were: *'PPI in the research processes'; 'Wanting to make a difference'; 'Power and leadership'; 'Networks', 'Resources and the political context'; 'PPI in dissemination';* and *'Information and communication technology'*. These were identified, through the interviews, as contributory factors shaping the impact of PPI on research outcomes.

This chapter will set out how, through the Delphi survey, the seven factors expanded to include a further two factors: *'PPI in commissioning' and 'PPI in implementation'*. It presents the order of importance of these factors, as ranked by the Delphi panellists who drew on their professional and personal expertise. The chapter highlights how Delphi panellists situated these nine factors of PPI at micro, meso and macro levels, which could potentially help the study to understand how each PPI factor could be better understood (i.e. whether it was more about PPI processes or PPI outcomes) for evaluation purposes. Panellists in the Delphi found it difficult to consider the meaning of impact of PPI but a common definition was formed via consensus.

A total of three rounds were undertaken during the Delphi study, and each is summarised in this chapter. The panel began with an active group of n=39 panellists. By the third round only four panellists had left the study. The combined response rate at the end of Round 3 was 89%. The panel's composition is outlined in table 9 in chapter four.

Each round's questions, responses, analysis and controlled feedbacks are summarised in this chapter (using tables, graphs, figures, quotations and typologies). Information is presented in chronology of occurrence and excepts from the 'controlled feedback reports' have been used to present the data in this chapter.

Delphi round 1

Panellists were asked to read the stimulus paper (discussed in chapter four) an extract of which, covering the summary of the seven factors, is produced in table 12 (the full paper appears in Appendix 8):

Table 12 - Description of seven factors of PPI

Factors	Description
'PPI in the research processes'	As a foundation for the production of impact the need for effective PPI during the planning and conduct of the research study. Challenges related to involving patients and the public were described as: where and how to find people to involve; individual patient agendas; patient-led research ideas; patients feeling inspired about research; patients feeling experienced enough to get involved in research; and PPI being assessed by funding panels. Participants suggested that the point of PPI in the research process was to help 'iron out' the non- medical assumptions of what patients want or need. Successful involvement was perceived to lead to more focused and relevant research, which in turn was seen as being more likely to achieve impact.
'Wanting to make a difference'	How personal motivations and a desire to contribute to change or improvement facilitated the production of impact. Patient stories included a desire to give something back to society, in order that others wouldn't go through the same (negative) experiences, or would not be faced with losing a loved one. There was a desire to achieve complete equality in cancer care. Some participants felt that the use of public money to fund research implied a moral obligation to make improvements. Some researchers described this motivation to make a difference in terms of career aspirations
'Power and leadership'	The idea that support or input from particularly influential individuals or organisations could enhance the likelihood of achieving impact, increasing the power of the patient voice. Participants discussed what having influential people added to research, celebrities, MPs, national policy figures and influential patients. An aspect of power was about organisational PPI support, it was believed that if an organisation was PPI active then the impact of PPI would be far greater.
'Networks'(non-virtual)	The use of networks to share information. Physical meetings were seen as a place where people shared new research findings and discussed its importance within current healthcare systems. Patients talked about the networks they are connected to via charities, patient user groups and the social circles that their

	involvement roles linked them to. Stakeholders and researchers talked about how professional networks impacted on them and their work, making contact with the right people, chance encounters, networking at meetings etc
'Resources and the political context'	A range of contextual factors, which (despite having good PPI in the study) might affect or diminish the successful production of impact. These included a lack of funding or stretched resources affecting staffing, equipment, training, ability to purchase certain drugs, and choice of implementation of interventions. It included wider policy which effectively 'moved the agenda on' leaving the research apparently no longer relevant
'PPI in dissemination'	To whom, where, how, what, when and why research findings are disseminated. Participants felt that the link between dissemination and impact was fundamental. Dissemination plans should involve patients in developing the strategy: Messages were seen as needing to be targeted and made easier to understand. Participants also discussed how generating impact was about the timeliness of research and doing "the right research at the right time for impact generation
'Information and communication technology'	Of the use of technology to aid impact generation, for example the use of smartphones and computers to search for and share information by sending important new research knowledge far and wide. It was also about blogging and using social media to keep informed at the "zing of a button". Some participants suggested that their PPI work required them to be confident and regular users of Twitter and Facebook. Blogging was perceived as a way of helping people stay connected

After reading the text, panellists were asked the following:

1. How important is the factor for generating impact from research which has included PPI (please use your professional/personal experience as appropriate)? Rank the factors please.
2. Please explain why you ranked them in the order you did.
3. Please explain if you felt anything was missing.

Delphi round 1 responses

The Borda count ranking method (see chapter four) was used to determine the order of importance of the factors that shape the impact of PPI on research outcomes based on the first round's responses. Table 13 presents the results in round 1, followed by a consideration of panellist responses.

Table 13 - Ranking order of factors of PPI - Delphi Round 1

PPI factors	Borda count ranking value N=39 (panellists) x 7 (factors) = 273 (273 being the highest possible score)	Round 1 Factors ranked at positioning
'PPI in the research processes'	205	1st 75.9%
'PPI in dissemination'	175	2nd 64.1%
'Resources and the political context'	173	3rd 63.37%
'Power and leadership'	167	4th 61.17%
'Wanting to make a difference'	142	5th 52.1%
'Networks'	141	6th 51.65%
'ICT'	88	7th 32.23%

1 – 'PPI in the research processes' came first in the ranking with 75.9% of panellists believing this to be the most influential factor to generate PPI impact. Many panellists said that PPI in the research process adds quality to the research and this is followed through to the outcomes of the research. A panellist who gave this factor a high ranking said:

> Consumers are able to represent and promote the voice of patients to the NHS and its partners such as the NCRI [National Cancer Research Institute] and DH [Department of Health] etc. NICE have acknowledged that two agents for sarcoma … were unlikely to have been approved for NHS use without involvement from lay members of the Sarcoma Clinical Studies Group.
>
> (Reese, cancer patient, DEP1)

Whereas a panellist who gave this factor a low ranking expressed the following reasons:

> Good PPI is important and can ensure the research is appropriate in its methods, relevant to patients. …However, even though I think PPI is desirable and can maximise the impact of research, there are examples [where] it is not critical.

(Holly, national cancer charity, policy role, DPCH1)

PPI leads and patients gave this factor a high ranking whereas none of the charities ranked it above second place.

2 – 'PPI in dissemination' came second, scoring 64.1%. Many panellists felt that dissemination was important in a general sense but were not always able to offer concrete examples:

> …patients are passionate about disseminating especially if they have somehow been involved.

(Janice, senior cancer nurse, policy role, DONHS4)

But generally, it was understood that patients were seen to make a better impact during dissemination:

> Hearing it from the horse's mouth has greater impact.

(Carolyn, academic, independent PPI consultant, DAC5)

However, one of the few examples offered demonstrated *how* dissemination is important in generating impact of PPI:

> I led an SDO [Services Delivery Organisation] funded study which was entirely co-produced with older people, and we had a hugely successful and well attended final dissemination event. I believe that this was, in no small part, down to the co-research methodology which people were curious/interested to hear more about, as much as the findings. What was incredibly striking at this event (and others we held) was the power of research findings being shared by 'everyday' people and service users, not just 'stuffy' researchers like me. …We wrote up this project as an impact case study for the REF [Research Excellence Framework] and I do think that the various examples of impact we could point to were largely because of the co-research approach.

(Jean, academic researcher at a thinktank, DACTT7)

Lastly, the quotation below captures the essence of 'active' dissemination, i.e. giving a message about something that will help to pinpoint where and how professionals might improve services:

> I think the inevitable aim of all research should be translation into service. So it's anything that helps translation into service or to improving services rather.... So really for me dissemination is anything that can do that.
>
> (Hersha, commissioner of health education in HE, DOCom6)

3 – 'Resources and the political context' was ranked third at 63.37% by the panel. Panellists tended to base their ranking on concrete examples and beliefs that generally, not just exclusively to PPI, NHS budget restrictions shape the outcomes of any research study. Many said that without resources none of the other issues listed mean anything. One panellist said that the allocation of resources in relation to access to treatment in the cancer field is literally about life and death:

> I am a lay member at [region] Cancer Drug Fund[5] ... It is sad to see the numbers of individual patients coming through to the panel (anonymously of course from their consultants) who are at a crucial stage in their cancer disease and cannot get treatment to extend their lives. All because of cost, and having to choose who does and who does not, through applying certain criteria, to get the drug
>
> (Olivia, cancer patient, DEP4)

Those that ranked it last gave reasons that echoed this MPs response:

> You can throw resources into something and it might still not change and you can be short of resources and can achieve change. Everyone thinks throwing money into something makes change: actually it depends on the conditions around the resources. E.g. in the NHS there was a huge increase of money put in in the last decade and it achieved very little, because there wasn't the leadership, there wasn't the engagement, there wasn't the dissemination to make a difference
>
> (Stuart, MP, DPG7)

[5] Now redundant, the Cancer Drugs Fund was for cancer drugs that were not routinely available on the NHS. This may have included drugs that had not been approved for funding, were yet to be approved for funding or were not approved for a specific type of cancer.

4 – 'Power and leadership' was ranked fourth (61.17%).

> …the All Party Parliamentary Group on Cancer produce reports relating to patient experience of the NHS on a yearly basis and they have the infrastructure behind them, political support and the Britain Against Cancer conference to disseminate the results of their research very effectively

(Luke, national cancer charity, policy role, DPCh4)

Yet, a panellist representing a patient champion body reported having:

> witnessed projects fail because someone of influence was not involved.

(Bob, national patient champion body, DPCham6)

An academic who ranked it last said that 'power and leadership':

> is an outcome of the other factors.

(Kylie, academic doctor, DAC4)

This factor was given a high ranking by an MP and two panellists from governmental organisations.

5 – 'Wanting to make a difference' This factor divided the panel. 52.1% of panellist who ranked it higher conveyed a similar message to this one:

> Whilst patients and the public should be actively involved throughout the whole process of a research study, this [motivation] becomes very important when wanting to generate impact and sharing this impact in the most suitable way.

(Kim, PPI lead, DPPIL5)

Others who ranked it lower said that:

> While it may be useful, I am not sure whether the fact that involved individuals wanted to make a difference would ultimately affect impact of a study, at least not in any direct way.

(Mark, academic professor, DAC1)

And:

Although having someone's motivation is a nice thing, it doesn't actually make a huge difference.

(Ajay, clinical professor, DAC2)

6 – 'Networks' This factor also divided the panel and just over half (51.65%) ranked it sixth. Those that ranked 'Networks' high, said:

Cancer networks in England are highly respected.

(Marina, national cancer charity policy role, DPCh3)

And:

networks help in channelling the findings of a study as they are seen as 'opportunities' for sharing.

(Felicity, research commissioner, DOCom6)

Networks help to identify the:

next steps and changes that may be needed as a result of the research.

(Stan, national cancer charity policy role, DPCh5)

A panellist who ranked it last said that:

networks are important for getting patients during clinical trials but not as influential when it comes to implementing findings of research.

(Anna, senior nurse, DONHS1)

In the few concrete examples that were offered, panellists discussed successful collaborations they were aware of:

charities such as Sarcoma UK run a "voices" project encouraging patients and carers to be heard in the NHS. Leukaemia & Lymphoma Research has a

Prioritisation of Patient Need Programme which includes a key activity to listen to and engage patients.

(George, carer of a cancer patient, DEP6)

7 – 'Information and Communication Technology' (ICT) came last in the ranking (32.23%). This was the only factor that was ranked consistently low across all groups. Some said that 'ICT' acted as a barrier. Yet in some situations panellists praised the use of 'ICT', for example in paediatric research:

[a] young people's group will often explain [to researchers] how the use of technology was important as a way of generating impact rather than meetings…

(Alice, PPI lead, DPPIL1)

New factors to consider for Round 2

As well as commenting on these seven issues above, panellists raised new issues for consideration in the next rounds. These were: *'PPI in commissioning research'*, *'PPI in implementation'*, *'the lack of definitions of impact of PPI'* and *'working out the level of problem'***.** A brief description of these new factors was offered to the panel in the controlled feedback when round two started:

1. 'PPI in commissioning'

This factor, panellists suggested was about by whom and why the research is funded.

I would have thought prioritisation of research or determining what research should receive funding in the first place is an important factor.

(Dean, PPI lead, DPPIL3)

And:

Who has commissioned the research, as potentially this will determine the power of implementation.

(Felicity, research commissioner, DOCom6)

2. 'PPI in implementation'

This factor concerns how the evidence from PPI informed research actually translates into practice and policy in the real world:

> Dissemination is not enough, implementation is missing. You have the challenge of the second translational gap.
>
> (Matilda, clinical academic, DAC8)

And 'PPI in implementation' was is about the detailed understanding, insights and intelligence that PPI brings to implementation. One MP said:

> The detail is what's missing. Change management [in the health service] usually fails because people haven't checked out all of the details. Being straightforward about what is realistic [and likely] to work. Most change management that doesn't work that I know about is concerned with having a big vision and then not working out the finer details about how you get from this side of the river to that side – you can't do change management from 50,000ft – it's not possible, you have to be in there working with the people to work it out, understanding how and what situations they face.
>
> (Stuart, MP, DPG7)

3. The lack of definition of 'impact of PPI'

Several panellists raised the problem of there being a lack of commonly understood definitions of impact of PPI. It was felt by the panel that this made it difficult scrutinise because it was contextual and sometimes process-driven.

> A definition of impact of PPI is missing.
>
> (Ranjit, healthcare commissioner, DAC6)

And another panellist stated:

> How are we all talking about the same thing? You need a definition about measuring success or impact.
>
> (Rebecca, clinical academic DAC3)

4. Working out the level of problem

A few panellists said that they found difficulty in ranking the issues. They were: *'quite confusing'* (Denise, Senior NHS communications, DONNHS3). Another panellist said:

> I appeared to be ranking against two factors: the significance of the factor on helping create impact at the 'project level' or micro level v's the macro level impact.
>
> (Dean, PPI lead, DPPIL3)

Another panellist felt that the factors were:

> …all meshed together, they need unpicking because they are evolving and a multi-faceted challenge to understanding the impact of PPI.
>
> (Della, cancer patient, DEP2)

Delphi round 2

In Delphi round 1, the panellists identified two new factors which they felt needed to be added to the ranking: *'PPI in commissioning'* and *'implementation'* Of note, these two factors were included for ranking in round two. Round two was therefore guided by four questions:

1. To re-rank the nine factors (the seven original factors together with two new factors: *'PPI in commissioning'; and 'PPI in implementation').*
2. To indicate if they felt the factors reflected micro, meso or macro level issues
3. To explain any thoughts about 1 - in relation to the impact of PPI on research outcomes (this would ensure phase 1 data was similar to what Delphi panellists were raising about the two areas)
4. Define the 'impact of PPI'.

35 Panellists ranked the seven original factors along with PPI in *'PPI in commissioning'* and *'PPI in implementation'* and were asked to explain their choices. Panellists were then also asked to indicate whether they believed the factors were largely *micro, meso* or *macro* issues. All panellists were then asked to offer a *PPI impact definition*. The following short description was developed for micro, meso and macro levels:

- Micro issues – small-scale interactions on individual projects, such as conversations, between individuals, or group dynamics that influence something.
- Meso issues – (the middle of micro and macro) which includes the consideration of organisations and communities. For example, hospitals, care settings and health education settings which may be the structures that influence something.
- Macro level – these are large-scale social processes, such as social change, political movements, patterns and trends that are influential.

Round 2 responses

Ranking of the nine factors showed the order of importance. In addition, the factors were also ranked on whether they were perceived as micro, meso or macro factors. Table 14, below, presents the results from the counting exercise in round two[6], followed by the consideration of panellists' responses.

Table 14 - Ranking order of factors of PPI - Delphi round 2

Factors of PPI	Borda count ranking value N=35 (panelists) x9 (factors) = 315 (315 being the highest possible score)	Round 1 (based on 39 panelists)	Round 2 (based on 35 panelists)
'PPI in research processes'	249	1st 75.9%	1st 79.05%
'PPI in dissemination'	216	2nd 64.1%	2nd 68.57%
'Resources and political context'	208	3rd 63.37%	3rd 66.3%
'PPI in implementation'	200	Was not a factor in its own right	4th 63.49%
'Power and leadership'	184	4th 61.17%	5th 58.41%
'PPI in commissioning'	148	Was not a factor in its own right	6th 46.98%
'Wanting to make a difference'	147	5th 52.1%	7th 46.67%
'Networks'	146	6th 51.65%	8th 46.35%
'Information and communication technology'	72	7th 32.23%	9th 22.86%

[6] 4 panellists chose not to vote but still wished to be part of the exercise

Analysis of Table 14 shows that, interestingly, even with the two new factors *('PPI in commissioning'* and *'PPI in implementation'*), the green on the table shows that positioning for *'PPI in the research processes'* (1st), *'PPI in dissemination'* (2nd), *'Resources and the political context'* (3rd), and *'ICT'* remained in the same ordering from the first round, implying strong consensus on the three most influential factors and the least influential factor. These four factors scored consistently 1st, 2nd, and 3rd and last. The yellow boxes show how the two new factors relate to the rest of the factors, thus, suggesting that implementation was considered more influential by expert panellists than perhaps the uncontrollable elements around a research study such as the significance of *'Power and leadership'*. The pink boxes show where a factor had a strong competitor with a one-point difference in the Borda count value between *'PPI in commissioning'*, *'Wanting to make a difference'* and *'Networks'*.

The most interesting finding from the ranking exercise is found in the blue boxes with a Borda count value of 200 or more (just under 2/3 of the panel), suggesting that to turn research into action there is a direct level of understanding about impact being associated with dissemination and implementation processes on PPI. After *'PPI in the research processes'* (designing and conducting a study) when research studies end, the dissemination and implementation plans are controllable (providing there are resources in place) and thus is directly concerned with the impact of PPI on research outcomes.

Implementation came fourth in the ranking (63.49%), perhaps because of reasons in this statement:

> "I thought of placing this item into 2nd spot. I felt that evidential proof in its <u>entire format</u> (the success of clinical outcomes in a research study) would influence commissioners in terms of funding either a continuance or variation of similar studies in the future (if both health and economic benefits are shown). However, as we are talking about evidential proof of **PPI informed** research translating into practice, I felt 4th place was appropriate…."
>
> (William, PPI lead, DPPIL2)

Whereas, another panellist who ranked implementation high said:

…there is a lot of PPI research in cancer that has focused on patient experience, and national patient experience surveys are run in most areas of the UK to inform politicians on what is or isn't working in the health service for patients and to inform incremental changes. This has an impact on practice…particularly relating to the national cancer plans

(Hallie, national cancer charity policy role, DPCh2)

A panellist who ranked implementation lowest said that:

'PPI in implementation' is misleading as if you do your PPI well involving both end users and potential implementers of your research as the key stakeholders, the implementation will follow.

(Pam, PPI lead, DPPIL7)

Several panellists said that they saw this factor being key work for the thirteen funded Collaborations for Leadership in Applied Health Research in Care (CLAHRC). This factor concerned how the evidence from research translates into policy and practice in the real world. From a PPI point of view, public involvement in the implementation processes was about the detailed understanding, insights and intelligence that such involvement brings to implementation. There was an example in the data of how patients had contributed to NICE approval of drugs of sarcoma to be offered on the NHS.

Consumers are able to represent and promote the voice of patients to the NHS and its partners such as the NCRI [National Cancer Research Institute] and DH [Department of Health] etc. NICE have acknowledged that two agents for sarcoma … were unlikely to have been approved for NHS use without involvement from lay members of the Sarcoma Clinical Studies Group.

(George, carer of cancer patient, DEP6)

A nurse also believed that implementation required people inside the NHS to be ready to get involved in change:

In order to make change happen you need to be part of it. You can't expect people to change if you are not willing to demonstrate and lead that change…. You need to be prepared to get your hands dirty.

(Janice, senior nurse with a policy role, DONHS4)

'PPI in commissioning' came sixth in the ranking (46.89%). A panellist who ranked this lowest said:

> Having commissioned research with PPI, from my experience PPI in commissioning seems a bit of a tackle … in reality on the ground it simply doesn't happen… meaningfully.
>
> (Ranjit, healthcare commissioner, DAC6)

An academic who ranked 'PPI in commissioning' higher said:

> there is a big difference between a researcher-led and a commissioned call from an independent research funder; there is also a difference between calls issued by research funders and calls issued by policy/service delivery organisations (e.g. Department of Health or an NHS provider organisation, versus NIHR or a research council). Calls issued by policy / service delivery organisations might, on the face of it, have more potential for direct impact, but this cannot be guaranteed as sometimes research will have been commissioned for appearances rather than for substantive role in developing policy and services.
>
> (Mark, academic doctor, DAC1)

Five panellists raised that whilst PPI at commissioning level is fundamental, details about funding decisions are missing:

> …more explicit and detailed information [is needed on] how the funders assess the PPI elements…what [application] passes and what fails.
>
> (Dean, PPI lead, DPPIL3)

Some patient panellists said that they were familiar with priority setting partnerships to help deal with this concept in a better way:

> The James Lind Alliance[7] goes some way towards this and offers a useful model.
>
> (Louise, carer of cancer patient, DEP3)

[7] James Lind Alliance is a research priority setting partnership between patients and researchers.

There was a split in opinions about the extent to which public or stakeholder involvement at the commissioning stage generated impact later, illustrated when one research commissioner argued that:

> Public involvement in commissioning is a powerful driver for pushing implementation but this by no means guarantees it…
>
> (Hersha, commissioner of health education in HE, DOCom6)

A patient also felt that involvement at the commissioning stage was not influential (especially outside of National Institute of Health Research (NIHR) funding programmes):

> If commissioning means all forms of funding committees then in theory it is important. However, the reality is that most UK cancer research trials are funded by CTAAC [Clinical Trials Awards and Advisory Committee], with Pharma a closing second place. Most other cancer research in the UK is by charities or by government, and although there may be PPI presence there is no significant PPI impact on those bodies/organisations at that level of decision-making. NIHR programmes are the exception, but even here, where there are PPI reps on committees and a requirement to show PPI in the application, there are no judgements about the effectiveness (or even appropriateness) of the PPI in the research. PPI in commissioning ought to be more important and more significant than it is. Moreover, CTAAC and HTA/RfPB committees decide what is fundable, not what gets funded, another reason why PPI in commissioning is not as influential as people believe.
>
> (Reece, cancer patient, DEP1)

There were no observable patterns in which groups on the panel (clinicians, charities, patients etc.) ranked which of the two factors high or low. The nine factors were also not intended to be exhaustive and there was a strong sense across the two rounds so far that some factors overlapped and were closely connected. The two rounds also demonstrated a need to explore the nine factors in isolation.

Micro, Meso and Macro question responses

In Delphi round 2, panellists felt that the ranked factors were very broad and by categorising them as *Micro, Meso or Macro* issues would help. As a result, it became a question concerning the *scale* of the challenge in enhancing our knowledge about how

the factors are understood better. Some panellists found it difficult to answer this question. The cluster bar chart below captures how the panellists perceived the factors to be situated as *micro*, *meso* and or *macro* levels (figure 9). An interesting but perhaps unsurprising finding here was how *'Wanting to make a difference'* (longest red line), *'Networks'* (longest yellow line) and *'Resources and the political context'* (longest green line) were strongly associated at *'micro'*, *'meso' or 'macro'* levels. Yet *'PPI in the research processes'* and *'PPI in commissioning'* divided the panel.

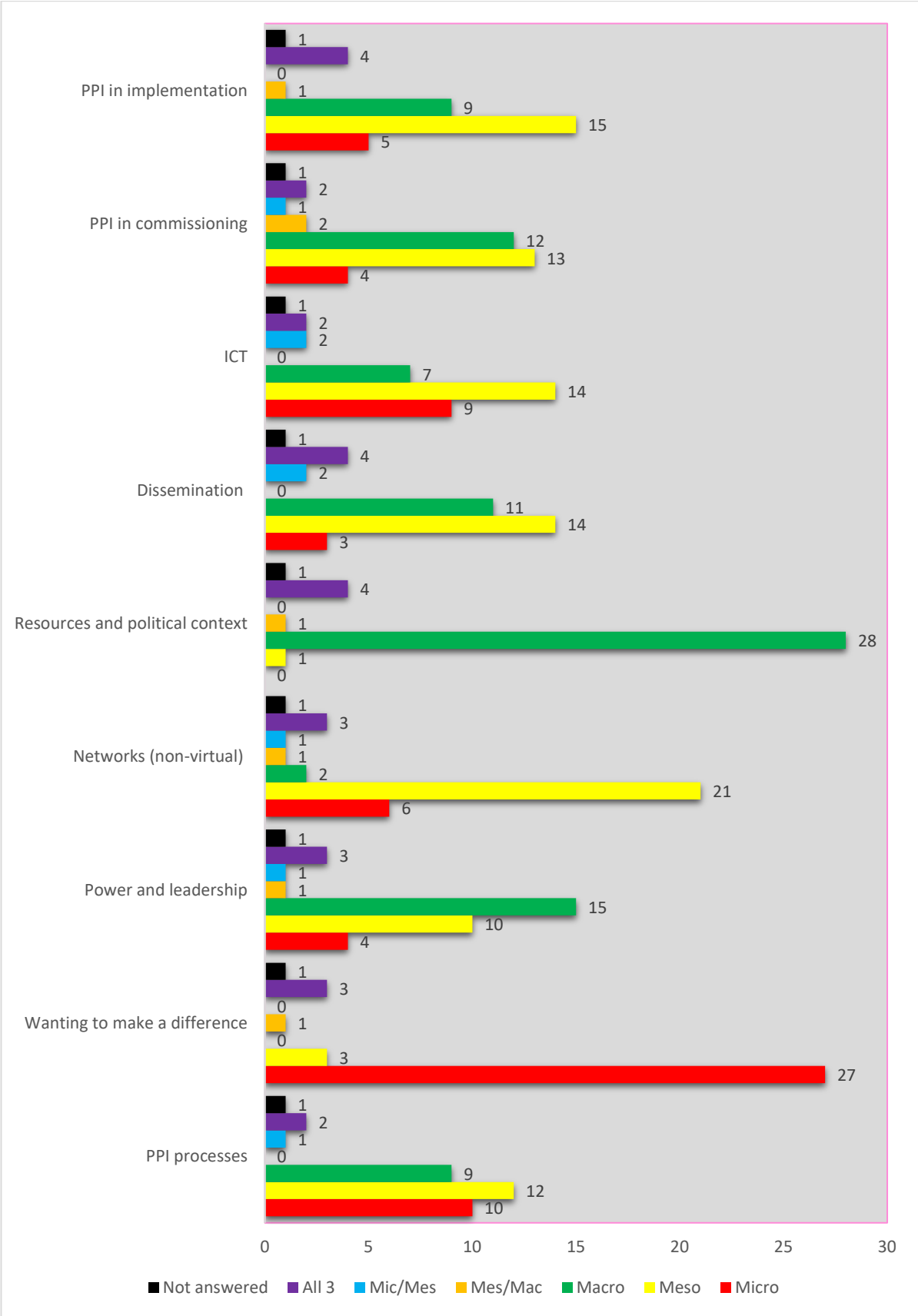

Figure 9 - Micro, meso and macro ranking of factors of PPI - Delphi round 2

Definitions of PPI impact

Panellists were asked to give a definition of PPI impact and every definition was coded using Braun and Clarke's (2008) procedures. Some panel members gave extensive definitions, whereas others gave shorter answers to this question and not in the form of a definition. Some panellists gave academic/critical definitions, while others offered clinical research process focused definitions. Most panellists said in their response that this question was challenging to answer because one definition cannot encompass all PPI impacts a study might have. A synthesis of these definitions and statements were formed (see figure 10, below). Nine examples from the data are offered here, to demonstrate the variety of views.

Example one presents three key words concerning impact (policy, theory and practice) which were frequently mentioned in related discussions about the topic by panellists in their definition text:

> patient and public involvement impact is the specific impact on practice, theory or policy that arises from a research project, which would likely not have arisen had PPI not been included.
>
> (Mark, academic doctor, DAC1)

Example two offered another type of impact, concerning 'patient outcomes or experience':

> patient and public involvement impact is about how far evidence-based recommendations from PPI research have been implemented and directly improved patient outcomes or experience.
>
> (Holly, national cancer charity policy staff, DPCh1)

Example three used words such as 'likelihood', 'drivers' and 'barriers' suggesting subtle and nuanced issues, with competing interacting components:

> Does involving patients and the public in the research increase the likelihood of research being implemented? Or What are the drivers and barriers to research being implemented and does involving patients and the public in research have any effect on them?

(Jonny, senior member of national research ethics)

Example four was more of a list of useful questions to consider when thinking about the effect of impact on the research process. It used the words ‘multiple layers’ and the ‘entire research journey’. It was felt important that the synthesised definition should reflect those elements:

> Defining PPI Impact is multi-layered. This is dependent upon which part of the clinical research process you are referencing. For example: Did PPI reps work with researchers in determining which ‘unanswered’ research question was prioritised? Did the study design benefit from meaningful PPI? Did the study documentation benefit from meaningful PPI lay assessment? Did the dissemination of the study findings involve PPI reps in any way? And ultimately, was the PPI impact a fundamental factor in the: Success of the funding application Helped to sustain participants in a study(ies) Translation of research into clinical practice. If you can answer ‘yes’ to all of the above, then each in their own right (and this is far from an exhaustive list), defines ‘PPI impacts’. Maybe what you need is a universal term that covers ALL of the elements in the research cycle that benefits from PPI impact e.g. ‘Clinical research will benefit across the board when meaningful PPI interventions are embraced and enabled at any point of the clinical research cycle journey as appropriate. Commitment to such approaches is likely to demonstrate positive PPI impacts in your research.

(William, PPI lead, DPPIL2):

Example five captured the difficulty associated with assessing the impact of PPI: at least four panellists expressed a similar view that any single definition could not capture all types of impact. Importantly, whilst the following statement identifies the complexity of assessing impact, none of the panellists said that PPI made no impact.

> It is impossible to come up with one size fits all ‘metric’ to measure/ assess impact therefore it is pretty unlikely that we will come up with a similar one size fits all definition of what should be defined and measured as PPI impact in the first place.

(Dean, PPI lead, DPPIL3):

Example six raised another aspect that came up in other panellists’ definitions, the word ‘meaningful’. It was felt important that the synthesised definition should reflect this word:

> I have liked and adopted the term 'meaningful PPI' in my own work but if I was asked what does 'meaningful PPI' look like I would probably have to say it depends on all the things that we all know well now that have been highlighted in the various impact reviews etc., including placing importance on context etc., asking 'what works for whom, when why and how?' but perhaps in a more qualitative way. […] this may give us an idea of what meaningful PPI may look like to different people in different situations and for different types of study.
>
> (Kim, PPI lead, DPPIL5):

Example seven referred to the socio-political terms 'micro, meso and macro factors'. Although the words are not in lay usage, they were deemed important to reflect the essence of what these terms mean in the definition:

> [the definition should include] … micro, meso and macro factors and the role they will play in that possible impact. It is important that we capture the impact of the PPI but also to recognise the other factors involved.
>
> (Felicity, research commissioner, DOCom5):

Example eight concerned ensuring that PPI is observable and transparent. The aspect of pellucidity concerned being able to see clear examples of how far PPI has shaped the research, and the extent to which involvement will continue to shape future work:

> It is about being able to slice through the research at any point in its cycle and be able to clearly identify how it has been shaped by patients and the public up to that point and be clear about the future role they will be playing.
>
> (Shane, senior DHSC official, DPQG10)

The last example, nine, was unique because it acknowledged that context is rich and varied. New research findings are only useful to people and environments that are receptive to change. The definition identified that the impact of PPI in research can be greater if end users are involved earlier. It accepted that impact depended on a blend of internal and external research study factors:

> PPI impact is the extent to which what research does and what practice is looking for aligned. Research findings make a difference in situations where the context (and those who are decision-makers within it) are receptive to change, are research literate, want to challenge themselves to do things differently, have the freedom and support to do things differently. In addition to these factors, where research includes PPI, impact may be greater where the 'end user' of the research

(be that policymakers, professionals, health system leaders etc.) really values what matters to patients, their carers and families and wants to improve services to better meet their needs and expectations. So, it's a blend of factors internal to a study and factors external to it (which are features of the wider contextual and decision-making environment) which are important.

(Jean, academic doctor at a thinktank DACTT7):

Drawing on these, a collective definition was formed via a process of data synthesis. This resulted in the statement set out in figure 10:

Patient and Public Involvement (PPI)[8] impact is something that is not only controlled by people and processes but also through the structures that we are part of and live in. PPI impact can be made transparent by understanding four aspects: of which the first three are: 1) taking account of whether the research was consultative, collaborative or PPI controlled[9]; 2) knowing the motivations for involvement, which vary and can be a mixture of experience, values and task focused; and 3) noting the subtle or significant changes as they happen to the direction of something because of PPI. This change of direction can ripple in many ways on the surface or behind the scenes in some or all tasks on the research cycle[10]. PPI impact is not linear, but something that is contextually multi-layered, relational and developmental. It might be qualitative (seen/experienced) and or quantitative (countable/measurable). The changes might lead to something positive (or negative). PPI impact is resource-sensitive, enveloped by the immediate surrounding and the socio-economic climate. As a result, 4) is about working collectively to understand where and when to look at the relevance and focus that the meaningful PPI helped to create: sometimes PPI impact is complex to pin down, not because it isn't there, but because it translates in a combination of ways over time into the 'real world' on patients and public, the professionals, the given research, the health systems (policy and or practice) and society.

Figure 10 - Combined definition of impact of PPI -Delphi round 2

[8] *"INVOLVE defines public involvement in research as research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them."*
[9] Hanley et al. (2004) Involving the Public in NHS, *Public Health and Social Care Research: Briefing notes for researchers. Eastleigh: INVOLVE Support Unit.*
[10] *Research Cycle: identifying and prioritising, commissioning, designing and managing, undertaking disseminating, implementing and evaluating impact.*

The statement from figure 10 went into the controlled feedback to start Delphi round three. Other issues that were raised in Delphi round two, which needed further clarity in the final round, concerned the usability and transferability of the current study.:

An observation – given the focus of this study is on PPI in cancer research and usability, cancer is somewhat missing from the context of these questions.

(Rebecca, clinical academic, DAC3)

The panel was selected for their expert knowledge of cancer research, PPI and implementation science experience, cancer policy knowledge and cancer experience. Therefore, whilst the word cancer was not in the questions, it formed the lens through which this research was conducted. For the author this observation alluded to a discussion on transferability, which in turn was connected also to the validity and reliability of the data (across the two project phases). The observation also linked to how the findings from this research might be used by others in other fields of health and illness and knowledge generation on impact of PPI. Therefore, these aspects were considered for the final round.

Delphi round 3

In round three, the following questions were put to the panel:

1. To what extent does the combined definition of the impact of PPI definition reflect your definition/statement? Panellists were asked to keep in mind the nine factors when they answered and to indicate their agreement on four point scale of completely/mostly/slightly/not at all.

2. What might be the next steps for this work?

3. Which of the nine factors are unique to the disease of cancer? Can and should they be transferable to other areas of health and disease research with PPI?

By the third round, the seven factors were refined to nine factors. The panelists had helped to situate these factors at micro, meso and macro levels. Panellists had already had offered their understandings about the definition/statement of the ‘impact of PPI’ and these had

been synthsised to form a combined definition. This was presented to panellists as controlled feedback to prepare for round three. Figure 11 shows that: seven panellists completely agreed with the definition; 19 mostly agreed; seven slightly agreed; one said it sat somewhere between mostly/slightly and one panellist found it did not capture their submitted definition at all.

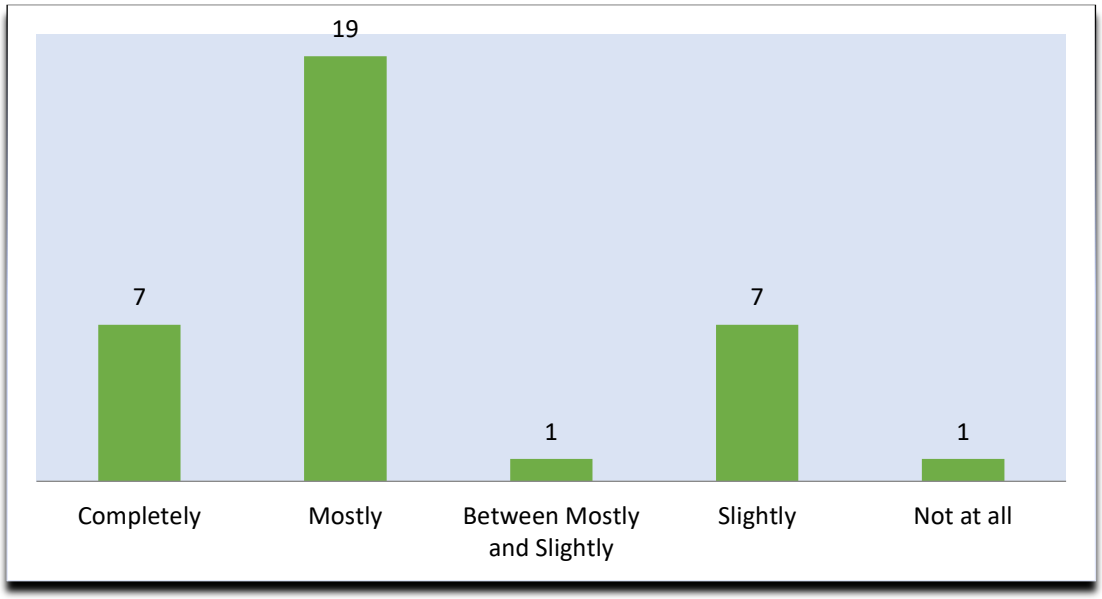

Figure 11 - Extent to which panellists accepted the combined definition of impact of PPI - Delphi round 3

Table 15 (over) summarises an overview of the panel responses to the combined definition, presenting the responses as ‘endorsements’ or ‘critiques’ of the statement.

Table 15 - Responses to the combined definition of impact of PPI - Delphi round 3

Endorsements	Critiques
• A great discussion starter about PPI impact. • Captures the steps to record/assess and measure PPI impact. • Broad and hard to disagree with. How can anyone argue with it? • Articulates that PPI interventions translate over time in a combination of ways into systems. • Non-linearity and its complexities described well. • PPI impact *is* an evolving state. It is both a perception and evidence. • The definition captures that PPI is not just a tick box exercise. • Once we understand how to assess it, we will understand the factors that influence it. • It encompasses everything possible. • Pleased that the word 'meaningful' appears in it. • Very detailed and far reaching. • Impact is qualitative and quantitative. • It captures different motivations for PPI.	• Too long. • Too academic and not lay enough – it could be in plain English. • Not a definition. • Not straightforward enough. • Limited to just research rather than involvement activity. • Not clear whether it is about PPI impact or PPI impact on research. • The bit about consultation, collaboration and user controlled is unhelpful as this could all be happening in one meeting. • PPI Impact is a lot more straightforward than its influencing factors. • The bit about change being positive (and negative) is unclear because the presence of impact is the presence of change. • Too 'process driven' rather than 'principles' • Covers how rather than what it is.

One panellist did not respond, stating that:

> This question has confused me considerably because I thought that the stimulus paper set out quite clearly what the focus of the research is and defined this term as follows: "..what difference PPI makes to the research outcomes and how it affects implementation of research findings into policy and practice (hereafter referred to as the 'impact of PPI')". So, I was confused by the statement in the paper for this round saying that some of the other participants found the lack of a clear definition made it difficult to talk about the issue because for me it was clearly defined in the stimulus paper. (Jonny, senior member of national research ethics panel DPQG10)

A PPI lead, who said the definition only slightly aligned with his, made this point:

…[Who's the measurement for]… One definition probably is not adequate …My attempt to answer this question previously made reference …[to]…PPI as a complex social intervention. Several of these 'bandwagony' studies are reporting now or will shortly do so at the forthcoming [name removed] conference. Perhaps we need a fresh approach looking at what PPI impact is not (rather than what it is)? I was pleased (but not surprised) to see that the phrase 'meaningful' appears there but ask again, meaningful to whom, when and how? It feels sometimes as though 'meaningful' is simply a pseudo technical word to give weight or credence to PPI work but in actuality it is fairly meaningless. How do we measure 'meaningful'? lastly, …[why do we not assess the impact of others]…e.g. stats; Health Economics, in quite the same way as we continually do for PPI.

(Dean, PPI lead PPIL3)

And:

It is difficult for me to see how this definition can be applied to the real world. (Daisy, cancer patient, DEP7)

And:

Very complex, not clear.

(Bob, national patient body champion, DPCham6)

And:

The definition I gave was about commissioning in research this is much broader.

(Hersha, commissioner of health education in HE, DOCom6)

The panellist who said that she somewhat agreed with the definition raised the following point:

Pawson and colleagues 2005 helps to consider factors that shape and influence impact drawing attention to subtle contextual conditions that influence impact. (Jean, academic doctor at a thinktank, DACTT7)

Initially, arriving at such a definition was not the purpose of the Delphi study. However, the lack of working definition was identified in round 1 responses and the opportunistic

moment of exploring this further through the panel was exploited. N=26 responses suggest that the definition developed mostly (n=19) or completely (n=7) captured the responses, thus suggesting strong support for the formed definition. By drawing attention to the more negative comments the researcher is demonstrating that the presented definition does require further work.

Panellists were then asked if they felt the nine factors were considered unique to the context of cancer. Their responses were presented in Table 16.

Table 16 - Views on transferability of factors of PPI beyond the cancer disease - Delphi round 3

Factors facilitating PPI's influence in enhancing research impact	Are they unique to the cancer context?
'PPI in the research processes'	Yes – 0, No – 35, Maybe – 0
'PPI in dissemination'	Yes – 0, No – 35, Maybe – 0
'Resources and the political context'	Yes – 0, No – 29, Maybe – 6
'PPI in implementation'	Yes – 0, No – 31, Maybe – 4
'Power and leadership'	Yes – 1, No – 31, Maybe – 3
'PPI in commissioning'	Yes – 0, No – 31, Maybe – 4
'Wanting to make a difference'	Yes – 0, No – 33, Maybe – 2
'Networks'	Yes – 2, No – 30, Maybe – 3
'Information and Communication Technology'	Yes – 1, No – 32, Maybe – 2

Overall most panellists felt that all nine factors are largely transferable to other research contexts and areas of priority. However, there was some ambivalence around some of the factors: a small number of panellists felt that cancer research is an example of applied health research which has unique characteristics that differentiate it from other disease areas. This was often linked in the comments to cancer being positioned as a leading priority disease and to its related embeddedness is national research systems and infrastructure. For example, with regard to *'Resources and the political context'* it was felt that cancer is particularly well placed to benefit from government funding and that cancer research charities attract large sums of money from public donations.

Funding issues were also seen as important in terms of commissioning research with PPI since it invariably follows national priorities. The particular success that cancer charities

have in advocating the patient voice was also highlighted as important for *'PPI in implementation'* of findings. The existence of the National Cancer Patient Experience Survey (conducted across England annually) was felt to be a unique feature of the well-developed leadership in this research field. The well-established *'Networks'*, and the use of *'ICT'* in cancer research, were both felt to be more advanced than in other areas of disease research.

The last question posed to the panel was about what the next stages of this work might look like and table 17 summarises the suggestions that were made on future possibilities.

Table 17 - Future possibilities - Delphi round 3

- Fine tuning the language used to describe the nine factors, through dialogue and (physical rather than virtual) discussion to see if the factor ranking-order changes.
- A Delphi study explicitly about PPI impact definition forming.
- Applying the nine factors to some real exemplars in the context of cancer research.
- More work on how to assess/measure PPI impact.
- Understanding the boundaries and crossover of boundaries of factors existing at *micro meso* and *macro* levels.
- Understanding the significant obstacles/problems for PPI in research impact.
- Developing a PPI impact framework based on this work.
- Understanding whether the factors apply to other long-term chronic conditions.
- Breaking down the PPI work into different types of research (health services, health policy, clinical trial design, and genomic/genetic research) to see the varying degrees of impact.
- Sharing that the nine factors affecting PPI impact are an original contribution to knowledge.
- To develop practical guidance for researchers about the nine factors.
- Explore the nine factors (as far as possible) against studies that haven't had PPI to see if those studies make impact.
- Explore the most obviously existing factors at *micro*, *meso* and *macro* levels to see what priority action can be taken to influence it.
- Developing a toolkit/training programme for managers, commissioners and researchers about the nine factors that influence PPI impact.
- Groups that should know about this work are INVOLVE, National Institute for Health Research (NIHR), Breaking Boundaries Review (Department of Health), the National Institute for Health and Care Excellence (NICE) and Clinical Commissioning Groups (CCGs). This work can give them some clues on how to influence healthcare.
- All major cancer charities need should be briefed on this work.

- Publish findings and then invite a debate: it is clear this work has interested the panel and has relevance to the health service.
- Use normalisation process theory to help shape thinking.
- Present the nine factors at conferences

The information presented in this chapter provides a verbatim account of what was presented in the controlled feedback to panellists. The only aspect which was not explained in the controlled feedback was how the synthesised definition was created, due to word count limits set for the controlled feedback.

Summary

This chapter has shown how data collection in this study has revealed nine factors contributing to the impact of PPI on research outcomes and how these factors are ranked in order of importance. The Delphi also demonstrated that the PPI factors were considered to operate at micro meso and macro levels. For example, *'Wanting to make a difference'* was dependant on micro level negotiations. Thus, the impact of people *'Wanting to make a difference'* needed to factor in how people perceived what had changed since the study ended. The Delphi has demonstrated that the impact of PPI on research outcomes can be a mixture of direct and indirect, or seen or experienced impact. Impact was definitely not perceived as linear and was seen as being highly resource-sensitive with resources coming in at 3rd place. Panellists felt that impact was translating in a combination of ways over time. The definition which was developed also reflected the factors which had emerged, i.e. motivation, values, processes for PPI, resources, and how change can be subtle.

What the Delphi findings have demonstrated is how each of the nine factors were understood in terms of importance. *'PPI in the research processes'* were clearly important in understanding the impact of PPI on research outcomes, which could explain why phase 1 data had a lot of information about this point and why interview participants struggled to disentangle the two areas *('PPI in the research processes'* from *'PPI in commissioning'*).

The Delphi data show is that *'Wanting to make a difference'*, *'PPI in commissioning'*, *'PPI in the research process'*, *'Networks'*, *'Resources and the political context'*, *'Power and leadership'*, and *'ICT'* were all factors of PPI which were concerned with *indirect* impact of PPI on research outcomes. *'PPI in dissemination'*, and *'Implementation'* can be seen as *direct* impacts of PPI.

Just under two thirds of the panel rankings demonstrated a high value for these factors which were not concerning *'PPI in research process'* or wider contextual issues that were indirect. For dissemination, Carolyn, Jean and Hersha explained that patients and the public are able to articulate in a unique way what needs to happen in terms of action. For implementation similarly, Matilda, Stuart, Hallie and George all offered insights into this factor of PPI by saying that for cancer services in the UK, PPI in the implementation process is at an advantageous position.

'Resources and political context' and *'PPI in research processes'* are already understood in terms of impact of PPI affecting the research design in Brett et al. (2010), and Staley (2015), but *'PPI in dissemination'* and *'PPI in implementation'* were deemed as meso issues implying control and influence was achievable directly.

Whilst there may be an unclear boundary here between direct and indirect impact of PPI on research outcomes, it is clear from this Delphi data that the later stages of research which include the use of PPI helps the generation of impact of PPI on research outcomes, according to the experts on the panel. The next chapter presents an analysis of the nine factors of PPI, by presenting examples of PPI on research outcomes extracted from the interviews by applying new knowledge gained from the Delphi study.

August – October 2014 – Checking accessibility of language used in Delphi rounds. Involvement in the form of **collaboration**. Each Delphi round needed planning and executing carefully to help this process. Over the intensive six weeks process a carer of a patient with cancer agreed to pilot each round to help ensure that the questions were lay friendly and accessible. This was done over the telephone and by email. The wording on the questions was adjusted on all three rounds after receiving helpful feedback via this process.

Chapter Seven: Examples of PPI on research outcomes and challenges for evaluation

Introduction

After the Delphi was complete, the transcripts from the interviews were re-read against the nine factors of PPI, and evaluation aspects for PPI impact were considered. The purpose of this chapter is to set out six examples of the impact of PPI on research outcomes and to examine them in relation to the role of each of the nine factors of PPI identified through the interviews and the Delphi process as contributing to the impact of PPI on research outcomes. The chapter will consider which factors appear to recur as contributory factors of PPI and whether any of the nine factors identified through the interviews and Delphi process were absent from these examples. The second purpose of this chapter is to demonstrate what the participants felt about the evaluation of PPI and its impact, whether there was a linearity (or not) from when research ended, and impact started. In doing so, the chapter offers insights into how these contributory factors of PPI might be evaluated.

This chapter sets out the six examples of PPI on research outcomes. An analysis of these examples is offered, considering the presence of the nine factors of PPI and the stage at which the research study was described to be in: pre-implementation, partial implementation, during-implementation and post-implementation. It will also consider how the factors of PPI may be regarded as 'direct' or 'indirect' for impact building. Finally, the chapter considers further excerpts from the interviews to illustrate what the evaluation of PPI impact needs to consider.

The chapter concludes with a summary of key findings.

Six examples

Six examples of PPI on research outcomes were found in the data. Each of these examples arose from completed studies and time had passed from when the respective studies had ended. Interviewees were able to retrospectively form judgements about the PPI work that was undertaken for their respective studies. The studies were as follows:

1. Oncology consultation aid – although developed it has never been adopted.
2. Cancer patient experience survey – results have led to many areas of improvement in cancer services.
3. Palliative cancer care – A new connected study has started as a result of this.
4. Prostate cancer care – A questionnaire has never been adopted but the recommendation of more workforce in prostate care has led to an increase in workforce.
5. Cancer genetics testing – Referral rates for genetic testing have increased in BME groups. New studies are being planned.
6. LGBT cancer services – Some policy recommendations have been adopted. New studies are being planned.

Each of the examples is now explored in detail, followed by a summative analysis.

Table 18 - Example one: Oncology consultation aid

Example one: Oncology consultation aid developed but not been adopted.
interviews with: Ben (cancer patient) and Priscilla (oncologist professor)

Study context: From 2009 until 2012, almost £250k worth of funding was awarded to help develop a consultation aid to an 'acceptable format', to be later used by oncologists across the NHS and patients newly diagnosed with cancer. The consultation aid came in the form of a questionnaire to help doctors and patients to discuss diagnoses and prognoses in the first meetings. The consultation aid's aim was to reduce the mismatched agendas between patients and oncologists. The patient would fill out the questionnaire at home before the first meeting with the doctor and discuss with their families what they needed to ask during the initial consultation meeting. The filled-out questionnaire would be sent back to the doctors, giving the doctors a chance to consider what the patient knows about the growth (i.e. whether it is cancerous or not). This initial understanding would also ease the doctor's job about potentially having to give patients bad news about the cancer and move on to more pressing things such as treatment pathways for the newly diagnosed patient. The consultation tool had shown positive effects, as it has been trialed locally. The team now needed to 'scale-up' the project, so that patients, nationally, could benefit from its use. The research aim was to develop the aid to an 'acceptable format', but the next level was always going to be an intervention study to validate its use more widely. Since completing the study, the team had failed to obtain further funding. The 'climate' meant obtaining funding was challenging, and applications kept getting rejected.

Type of outcome achieved: The problem identified by patient Ben about the way his cancer diagnosis miscommunication was handled was taken seriously by oncologist Priscilla and as a result a research study was funded to develop a consultation aid for using in oncology work. However, since the aid had been developed in an acceptable format, further funding for an intervention study has not been found, which was the whole point of the consultation aid developed in the first place.

The reported role of PPI in shaping the outcome of the research: The research team was asked by the commissioners to have six members instead of four members which the team did. A PPI group was established comprising of six patients, post-cancer treatment. Some members of the PPI group helped design the study including Ben, others joined after the funding was obtained. The group expressed the sensitivity that oncologists needed during the initial time of someone's cancer diagnosis. Patients were reminded what the doctors needed to know about the patient's treatment plans. They co-produced the aid. PPI helped recruit participants locally to trial out the work. Patients in the PPI group were reimbursed for out of pocket expenses and no training was provided. When the study finished patients were involved in dissemination plans. They produced information about the study for cancer patient groups. The next stage of this work requires a pilot study of its use but subsequent funding has not been found. Since the study has finished, patients have written letters of support to funders endorsing its use, but so far, the team of

researchers and patients have not been unsuccessful in securing funding for a follow up intervention study.

Table 19 - Example two: Cancer patient experience survey

Example two: Cancer patient experience survey - findings implemented to improve services
Interviews with: Steven (hybrid role) and Katy (national cancer policy staff)

Study context: The Department of Health annually funds a Cancer Patient Experience Survey for England. The survey reaches 70,000 cancer patients in England and has a high response rate. One cancer network works with private researchers on the development of the survey. This network has national partners from cancer research funders and together they develop a five-year strategic plan for cancer research in England. The network is renowned in cancer research. All of the major cancer charities and the cancer tsar support its work. PPI is woven through the infrastructure of the network and within the member organisations. When studies are funded by the charities which are part of the network, PPI is expected in the application and patients are involved in scrutinising bids. This network covered 22 distinct cancer study areas. There were 32 cancer research sites, and all of these were performance managed by this network. The survey results were used in many ways. For example, patients with network staff had developed a presentation of six slides which were sent to the different sites about their results. The last slide was left blank so that each site could respond when they were asked what they would do differently to improve cancer research services by the following year. The blank slide was filled out by each hospital and sent back to the network (from all 32 sites). The information provided fed into the annual reporting of the network, suggesting immediate impact about how the survey results may lead to specific changes. Other outcomes from the survey included a campaign about cancer research clinical trials. Furthermore, the survey led to more and newer questions to be included in future surveys suggested by patients, e.g. life after cancer and employment. Broader links the network had with particular study areas e.g. a sarcoma research group, helped to feed into NICE guidelines about sarcoma treatments. Finally, government and parliamentary attention was achieved. The network's PPI group was invited to the All Party Parliamentary Group on Cancer and to Question Time at the House of Lords. Results of the survey were also fed back to the Chief Medical Officer. A direct question was asked to Jeremy Hunt to continue supporting the work of the network.

Type of outcome achieved: Implementing national cancer survey results for improved patient experience of cancer, e.g. improved cancer care across hospitals, amended NICE guidelines, a new campaign and policy attention.

The reported role of PPI in shaping the outcome of the research: The network had PPI woven into their work. Each clinical study area had an established PPI group which offered input into the design of the survey. Each PPI group was well resourced. Survey results were analysed with the help of PPI members of the groups and a suggestion was made by a patient to develop a campaign about it being ok for patients to ask about cancer clinical trials to their doctors. PPI members were bloggers,

tweeters and avid users of social networks. A specific PPI group for the survey lobbied Government for the 2011 survey to introduce cancer research trial questions in the following year's survey. All of the PPI members were offered out of pocket and honoraria payments and appropriate training. The team had established systems for paying members of the public who help in this way.

Table 20 - Example three: Palliative cancer care

Example three: Palliative cancer care – further research studies started
Interviews with: Patsy (senior hospice staff) and Janine (Palliative care professor)

Study context: This study was awarded nearly £300k in 2009 (with two other countries) looking at palliative care practices of different healthcare professionals. The study was qualitative and involved understanding the perspectives of those involved (a physician, a nurse, and the bereaved relatives after somebody had died). The research team was based in a large academic institution with a charity part funding its work. The researchers were renowned in this field. Palliative care is a controversial area and policy on palliative care frequently divides public opinion. After the research study was complete it struck the research team that decision-making processes about palliative cancer care were only discussed as a medical matter. In England, it was the community nurses primarily, not the (doctors) who had responsibility of patients who lived out in the community and were dying. Thus, prescriptions were written up in advance of difficult symptoms that patients may experience when they were dying, and it was these community nurses who contacted the doctors to move onto decisions to change the drugs [to help palliatively]. So, after disseminating the results widely with the help of patients and cancer networks, to further this work, a grant was awarded for two further related issues. This work was presented by the researcher at a conference, where a local hospice practitioner was present. When the researcher was presenting the data from the study, the PPI in the study was also described. As a result of this work, one team of hospice staff has had meetings with their consultants and registrars about what the findings mean for their hospice practice. They have looked at the evidence via different mediums about this work (journals, social and mass media).

Type of outcome achieved: Policy attention has been achieved and has led to further debate and more research on palliative care. Practitioners are yet to be convinced.

The reported role of PPI in shaping the outcome of the research:
Various ethical and methodological aspects of the study had been helped by a pre-study PPI group of 16 bereaved older people. The group were sensitised to the area of death and dying in cancer and helped researchers to find suitable ways to overcome ethical and methodological problems around recruitment. The group met regularly and were offered training, expenses and honoraria payments. They helped to develop and write research the studies protocols. The team had established systems for paying members of the public who help in this way.

Table 21 - Example four: Prostate cancer care

Example four: Prostate cancer care – more workforce funded
Interviews with: Dennis (implementation science lead) and Robert (GP and professor)

Study context: In 2009 a prostate study was funded for around £300k. The study had a pre-arranged research brief, with research aims set to meet an identified gap in prostate cancer service provision. The aim was to develop a quality of life questionnaire and understand the role of community cancer nurses. Since the study ended more community nurses have been funded in response to a recommendation made by the researchers but government priority had shifted about the use of the quality of life questionnaire and as a result the questionnaire had not been adopted. The researchers who secured the funding would not have chosen the development of the questionnaire themselves, had it have not been in the funding brief. The team of researchers were new to PPI. They asked a large national charity to be a co-applicant on the work and this element helped considerably to make the funders have confidence that the research would meet its aim. The project outcomes have been mixed. Whilst positive change has been witnessed since the study finished, resulting in more community nurses as recommended by the research, a negative outcome from this work has resulted in the non-adoption of the quality of life questionnaire which was part of the initial commissioning brief set by the funder. There are no plans for follow up work.

Type of outcome achieved: Better prostate cancer care in the community through the increase in resources.

The reported role of PPI in shaping the outcome of the research:
The funders expected PPI in the study and were impressed with the PPI planned for the study. A new PPI group was developed and four patients/public members were involved in the research. One of the reasons the research team were awarded the funding was because of the novel aspect of a charity co-applicant having links to wider patient groups. No training was provided for the PPI in the study. Although out of pocket expenses had been offered to patients and the public involved, no honoraria payments were offered to patients and the public as PPI was relatively new for the institution that the researchers were based in. When the study finished PPI were involved in the dissemination work. Information was also cascaded about the study to various cancer networks via the charity involved.

Table 22 - Example five: Cancer genetics work

Example five: Cancer genetics work - increased referral rates
Interview with: David (cancer genetics doctor)

Study context: A small grant had been obtained by David in 2009 for under £30K and some further funds from a charity were also obtained. Both of these grants expected PPI in the design of the study. The work aimed to address three problems with the help of patients and the public to increase referral rates from BME communities. At the time the study was running, several high-profile celebrities had undergone preventative surgery to reduce their chances of breast and ovarian cancers. David's referral rates from BME communities have risen. The researcher believes that he and his team were doing the right research at the right time.

The study had three aims, to increase referral rates within BME communities presenting for cancer genetics testing, as those presenting for testing were often white, middle class and highly educated. The researchers wanted to target those who were traditionally harder to reach. Secondly those who were coming in for testing were often presenting themselves too late, when most people in their family had already died from cancer and so there were no bio markers for testing which made it difficult to understand why the cancer had occurred in the family. The third reason for this study was that when people were referred to cancer genetics testing, researchers wanted to address if there was anything which could have been improved for the patient e.g. access to other services: physiotherapy, dietetics, psychotherapy and support groups.

Type of outcome achieved: Increased referral rates in BME communities. The work led to a 'medical supermarket' idea where all the patients had access to 25 facets of holistic care. A chance celebrity story had helped the referral rates increase.

The reported role of PPI in shaping the outcome of the research:
Although no consistent group of patients and the public were part of the study, the work involved various streams of engagement including working with different patients which the researcher argued was better than using the same group as they could have a wider reach to different communities. The researchers have involved different communities in writing to local newspapers; running community events; local radio call in shows; piggybacking off community events directed at BME communities; and working closely with various high-profile cancer charities and susceptibility support groups who raise awareness of hereditary genes of cancer. BME community members have been involved in developing a YouTube video about hereditary cancers and how to raise awareness.

Table 23 - Example six: LGBT cancer services and policy change

Example six: LGBT cancer services and policy change
Interview with: Joanne (academic professor)

Study context: The researcher had won a grant for around £15k to translate findings about a previous piece of work on the experiences of LGTB women undergoing routine assessment for diagnoses of cancer in the NHS. The researcher has a strong relationship with the LGBT community. This researcher felt that LGBT women had an unjust experience of cancer care due to their sexuality. Joanne was aiming to challenge the homophobic attitudes of clinicians treating LGBT women. Whilst translation was taking place, momentum started to change in direction, as a result of the coalition government coming into power. There had been a reduction in how much support the researcher was able to achieve from government about this work. Although some policy attention had been achieved. The researcher says that one person who was senior in a charity and who had a strong relationship with someone who worked in government was able to influence government decisions about the researcher's work. However, that person had since left, leaving certain areas of the researcher's work underdeveloped.

The type of outcomes achieved: Health services professionals were better informed about health inequalities in the treatment of women with cancer from LGBT backgrounds. The researcher had written policy for the DHSC, describing how to support LGBT groups during cancer service provision, but more work remains to be done.

The reported role of PPI in shaping the outcome of the research:
An active and regular PPI group had been involved from the start of this researcher's career. This same group had been involved in the subsequent work carried out by her. There had been keen support from national charities and the LGBT community. No funding for PPI input was available to the researcher. No training was offered to the PPI group for their input. Joanne used her own funds to pay people their out of pocket expenses. As a thank you to the woman who helped the research, she bought them flowers. They continue to be involved.

Figure 12 - Analysis of the nine factors across the six examples

D = Perception that the factor **directly** affects impact of PPI on research outcomes
I = Perception that the factor **indirectly** affects impact of PPI on research outcomes
✓= Perception of the factor's presence in the example
X = Perception of the factor not being present in the example

Colour code
Red: Pre-implementation (i.e. PPI were part of the study's commissioning, research and dissemination process. No further work has happened in relation to that study since it finished, and the PPI group has dissolved)
Purple: Partial pre-implementation (some recommendations from the research have been taken up. The study has ended and no further implementation work is planned. PPI group has dissolved)
Blue: During implementation (i.e. the researchers with PPI are planning the next stage of the work)
Green: Post implementation (i.e. the researchers with PPI are actively working on the next phase of the work)

Case	PPI in the research processes (I)	PPI in dissemination (D)	Resources and the political context (I)	PPI in implementation (D)	Power and leadership (I)	PPI in commissioning (I)	Wanting to make a difference (I)	Networks (I)	ICT (I)
1	✓	✓	X	N/A	X	✓	✓	X	N/A
2	✓	✓	✓	✓	✓	✓	✓	✓	✓
3	✓	✓	✓	✓	✓	✓	✓	✓	✓
4	✓	✓	X	N/A	X	✓	✓	X	N/A
5	✓	✓	✓	✓	✓	✓	✓	✓	✓
6	✓	✓	X	✓	X	✓	✓	✓	X

Analysis of examples

Participants had backgrounds in running/being involved in/utilising the results of: randomised controlled trials (RCTs), social science research, community research on palliative care, emancipatory research with LGBT groups and on training for healthcare practitioners. Therefore, the outcomes of each of these studies and the driving forces behind each of them varied immensely. Figure 12 demonstrates that the six examples have some common ground, which might explain some of the nine factors of PPI found from the current research. Each of the examples described had: *'PPI in commissioning'* of the research; '*PPI in the research processes'* in the studies; they each had *'PPI in the dissemination'*; as well as people involved who were *'Wanting to make a difference'*. At a closer look at the table, the red (study 1) and purple (study 4) had questionnaire development as part of the research focus and due to changes in government, the uptake of these questionnaires did not materialise. Similarly, both red and purple did not have pre-existing PPI groups, which suggest that the researchers were not so experienced in PPI or that resources for PPI were not available before the funding. Data show that the red and purple studies hardly referred to *'Networks'* nor the use of *'ICT'*. Whilst the cancer genetics study (blue) appeared to have data representing each of the factors of PPI, the implementation process was helped by the celebrity story. This highlights that timing and serendipity can affect impact of PPI.

But timing can hinder outcomes too. The LGBT cancer study was a good example of how *'Resources and the political context'* as well as *'Power and leadership'* can have an unfavourable effect on the ability of PPI to have an impact on research outcomes. The researcher from this study described how austerity was affecting the impact of her work. She and her PPI group had ideas for follow up research, but the work was struggling due to people in power not being available to listen to, and act upon, her findings on how people from LGBT communities could experience better care. However, she had achieved some policy change and the grant that she was describing during her interview was a knowledge translation grant to help pay for translation aspects of the bigger study.

The examples in green on the table are examples of studies that are flourishing. These two studies had pre-existing PPI groups with PPI payment systems, demonstrating that organisationally, the studies were situated in departments within universities with strong PPI values and experience. Both studies had the resources in place to support training for PPI. There was support of established cancer networks, the backing of political groups, strong leadership and strategic steer in how they operated and generally these seemed the most organised in relation to PPI from all the other examples presented.

Overall, two aspects can be determined from reviewing these six examples that help illuminate understanding of the impact of PPI on research outcomes. The first is that the impact of PPI on research outcomes can be a fluid phenomenon, underpinned by various interacting components. Most examples (green and blue studies) had more work to do and because of this, the impact of PPI needed to be understood as ongoing. One study was 'stuck' in pre-implementation phase (red study). After the prostate study, more community nurses were funded but the quality of life questionnaire was not adopted in the NHS. The ones in blue were during implementation and some were post implementation (green studies). The second aspect is that all six of these studies were enveloped by various motivational, contextual and circumstantial factors. These factors acted as favourable or unfavorable conditions for developing direct or indirect impact of PPI on research outcomes.

'Wanting to make a difference' was *indirectly* connected to the impact of PPI on research outcomes as change does not automatically take place after a study ends despite peoples' motivation to want to see change. *'PPI in the research processes'* was *indirect* as although PPI ensured appropriate and meaningful design and delivery, the messages from the research still needed translating and policy makers still needed convincing. *'Resources and the political context'* was also *indirect* as researchers and PPI could not control the political climate. The conditions for change include the need for leadership and commitment. Similarly, having the help or influence of important people, whilst it offers favourable conditions which later might affect implementation, this was not *directly* connected to the impact of PPI. Using information and communication technology ('*ICT*') to enhance PPI outcomes was useful through social networks such as

twitter and blogging but this would not create change itself, so was also *indirect. 'Networks'* were *indirect* because whilst they were important they could not guarantee change, but they could create mass support for the findings to be adopted. Finally, whilst *'PPI in commissioning'* provides a strong foundation that the research is needed, commissioned research does not always have a role in policy making, thus is also *indirect*. Therefore, seven of the nine factors are *indirect,* creating either favourable or unfavourable conditions for impact of PPI on research outcomes.

Conversely, *'PPI in dissemination'* was likely to achieve *direct* impact because people would have an active role in informing policy makers and decision makers. And *'PPI in implementation'* was also likely to achieve *direct* impact as patients and the public were involved in the delivery of making change. It is important to note that there is an unclear boundary here because if PPI is not carried out well, or if the other factors of support are missing, then *'PPI in dissemination'* and *'PPI in implementation'* would also potentially fail.

Use of the terms 'direct' and 'indirect factors' suggests they were tightly bound and specific. In reality the factors contributing to research impact are more fluid, sometimes absent and of greater or lesser strength when present. The direct and indirect factors found in this study may not apply to all contexts in the same way on each occasion. For example, in co-produced research patients and the public are working much more closely with researchers and therefore it may become much easier to unpick together, through observations and discussions, how impact was achieved because at a micro level, negotiations are being carried out constantly.

What re-examining the data has demonstrated was that *'PPI in the research processes'* and outcomes are linked, but not in a linear way. Interview data found that the relationship between process and outcomes was unclear and highly complex to track. Some data from revisiting the interview codes was identified and has been presented next to highlight the interaction between PPI in research processes and outcomes.

The relationship between PPI in research process and outcomes

Twenty participants from the 23 interviewed described that PPI in research processes helped to achieve impact of PPI on research outcomes. For example, Janine explained that change is achieved by working together during dissemination events and with the help of networks. She felt that the impact of PPI on research outcomes is not something that metrics could solve. For her, communities, networks and other research work going on around the topic being researched, are all influences on each other and their dissemination paths:

> …PPI impact …it's absolutely non-linear and sometimes [trying to] reduce it to a set of metrics is fatally flawed. …in the end it's about communities of activity or …practice and I think it's probably better to try to give an account of how your work is situated in a wider set of activities going on. To understand that, it is networks and collaborations that drive the ability to do research and the ability to disseminate research and that research has to happen at lots of different levels.
>
> (Janine, palliative care professor, IR3)

Janine went on to say that once research findings were out we should not postulate that the findings are usable in their current form just because patients and public were involved in the study. Janine concluded her point by stating there is no linearity between research process and outcomes but it was more like 'ripples of effects'.

> So there's no linearity, it's more like dipping a toe in the water and then some sort of chain reaction occurs.
>
> (Janine, palliative care professor, IR3)

In similar fashion, Michael's view was that the impact of PPI outside of academia was complex to see, judge and trail:

> the impact that they [PPI] have outside the academic field is always going to be …defused, indirect .[and…] mediated through all sorts of other things very difficult to see, trace and audit …its ideas and ideas don't belong to any one person.
>
> (Michael, academic department lead, IS7)

Michael then went on to describe why there was not a perceived linear relationship between 'PPI in the research processes' and outcomes, on account of a number of other factors:

> I think that there is unlikely to be a linear relationship because there is a lot of confounding variables. …Carefully thought through [PPI] is likely to improve the quality of the research, potentially the validity of the research…. Will it lead to more or better impact? I just think there are so many extraneous variables, there are so many confounders and control variants that you could never tell for sure.
>
> (Michael, academic department lead, IS7)

Helen did not discuss non-linearity in the same way the others did. She felt that the relationship between process and outcomes of PPI was about asking the right questions and then pursuing something until the end. In her mind, PPI influenced many aspects important for research and those suggestions remained in the researchers' minds when they move on to newer research studies:

> if they [researchers] haven't done [PPI] before, then some of them find actually it makes a huge difference to them [indirectly] and generates things they hadn't thought of, they then put those suggestions forward in all their research in the future and… that influences other types of research and topics.
>
> (Helen, cancer patient, IP3)

Helen went on to say that PPI influences dissemination processes in an automatic way. Patients and the public have a personal reason of wanting to see something happen as a result of the work. She explained that PPI widens the thinking on who the work should go to, and how it might be important for those people the work gets disseminated to. She referred to having the perseverance to seeing change through:

> …if you've got good PPI throughout the project, then they [PPI] help to get it into practice. Because the PPI people on board understand the practical aspects affecting the new knowledge. PPI people have already made their connections mentally before disseminating/ they have already thought about who this work will influence. Because again, we're on the ground, so able to see, we've suggested this and five years later these guidelines are out and that has had implications from the research. We make sure something is spoken about, its talked until we are satisfied.

(Helen, cancer patient, IP3)

Robert made an interesting point about the appropriateness of PPI and its connection to the link between process and outcomes of PPI. He believed that PPI only works if patient experience is at the centre of the research study. Thus, implying that PPI is not for every study but for only those with patient focused outcomes:

> PPI works well when you are actually interested in what the experience of patients are or the outcomes for patients are. Where the interventions are possibly available for patients then that's probably very appropriate. [those studies]would produce more relevant output. More rounded findings.

(Robert, GP and professor, IR5)

Robert explained that as every study had such different outcomes the relationship of *'PPI in the research processes'* was influenced by these potential outcomes. In RCT research, there was a tendency for clear messages, whereas in other studies it becomes much harder to equate that the research led to the change not attributable to other factors:

> Robert: …It will always be 'this research in the context of other things going on led to that'. Ultimately, …if the finding is easy to distinguish, …something quite straightforward. So – just – drug X is fantastically better. You know, it's a really crisp simple message. Where it becomes a complex whole system change, as a process for research is where… you are connecting up the dots about patient care/patient experience - it is rather more challenging.

(Robert, GP and professor, IR5)

Hannah, who worked in PPI policy role, said that there was difficulty with tracing the impact of PPI because of the everyday possibilities that facilitate impact:

> …actually the impact might be small, and it might snowball, and it might not, one person might say, the impact might just be in a conversation, …say, and that might trigger off a thought process, that, has a huge impact, but you would never capture that. So a lot of impact, isn't always possible to capture it [or]track it because it might have been invisible, it might have been a relationship that two people had, it might have been a specific group of people within a specific context that built something and to actually separate that from everything else is going to be really hard.

(Hannah, national PPI policy role, IS6)

Hannah then went on to say that the problem with demonstrating impact of PPI was that when *'PPI in the research processes'* were in place, with strong people in the roles, attributing impact can be difficult:

> I think the trouble with all of this is most of the evidence is saying, that …it's an opinion. …The trouble is, that once you've got really good public involvement …it's integral to the whole process, determining what their influence was on the research and on the design can be very difficult to pull out…
>
> (Hannah, national PPI policy role, IS6)

Patsy was the only participant who suggested that too much emphasis is placed on PPI and actually, clinical encounters should also be weighed up with PPI encounters. Patsy eloquently explained that she sees patients every day and for her PPI must add value to the study, otherwise the PPI interaction is no different to her everyday encounters:

> …what comes out at the end is added value to the study. … does it really make a difference? … clinical researchers are with patients all the time! So,… they are interacting to a lesser or greater extent every day. So that level of service user involvement [PPI] may be going on all the time. So, does having an additional separate entity like a PPI group really add anything to my conversations with patients in clinic on a daily basis?
>
> (Patsy, hospice senior staff, IS8)

Patsy said that she could see value in PPI when it came to researching and reaching the 'hard to reach' communities because without them researching could not be possible:

> … for me it [PPI] is about reaching hard to reach people both in language terms but also willingness to talk in this subject area. Then it's going to be vital to have people who can open those doors…
>
> (Patsy, hospice senior staff, IS8)

She finished the point she was making by saying that she was involved in a piece of research looking at non-invasive ventilation. The study idea did not come from patients, but the PPI has been vital in eliminating research barriers for her:

> So, I'm involved in a piece of research to look at the withdrawal of non-invasive ventilation …sometimes I think biomedical intellectual curiosity is a really important driver as well. It may not have been a patient who had planted that idea in my head, but you know …they've [the PPI group] offered to be a catalyst in this work and have removed some hurdles.
>
> (Patsy, hospice senior staff, IS8)

For David, the relationship between PPI in research processes and research outcomes was an on-going one. For him, because patients were already part of other groups and charities, there would be a feedback cycle, where patients informed other patients which are then sent back to the researcher via the PPI. Thus, the process and outcomes of PPI was not linear but cyclical:

> The other interesting idea is that if you have patients that take part in research who are involved in support groups it's possible in the longer run that as and when new developments occur that you might be able to get a feedback loop going.
>
> (David, geneticist doctor, IR6)

It was becoming clearer that participants felt that demonstrating the impact of PPI on research outcomes was complex. Ultimately, what the data shows next is that it was only possible to evaluate something which had clearly, at a much earlier stage (perhaps before a study commences), identified very specific outcomes which are evaluable for certain stages of the programme of research. Thus, outcomes may be a mix of: research process related outcomes (e.g. winning funding, gaining ethical approval and recruitment aspects); outcomes important to patients and public (e.g. improved experience of care or comfort); and outcomes important for follow up work (e.g. uptake of research recommendations, more funding, policy change etc.). Thus, evaluation for PPI needed to consider these smaller steps first to help evaluate it more precisely. The next part of this chapter attempts to capture some of these points by describing participants' thoughts about evaluation of PPI and timing.

Timing evaluation of PPI

When evaluating the impact of PPI, it is important to acknowledge that PPI is not static. It was very much a 'fluid' phenomenon. Thus, evaluation of PPI needed to acknowledge

timeliness of certain outcomes, a point raised by eight participants. Evaluation of PPI could take place pre-implementation, partial-implementation, during-implementation and post-implementation. It seemed, during analysis of the current study, that the impact of PPI on research outcomes was an amassing of knowledge about a body of information being researched, and how patients and the public could influence the growing knowledge at different stages. Therefore, Helen and Robert said that questions important to patients today will typically take a few years to develop into specific health research questions, then a few more years to fund and carry out the research, therefore impact from the work will take time.

> You have to remember that for an awful lot of research it takes three or four years of writing something, getting the questions right, then getting funding takes a couple of years, then five years to run it.... so impact will take time.
>
> (Helen, cancer patient, IP3)

Robert's perception, which conflated impact of research with the impact of PPI stated that evidence formulation takes too much time. Often by the time the course of the study has finished, and safety checks have been carried out, the impact of the research may have faded:

> …people understand there has to be certain checks and balances and that takes time. But equally there are sometimes when it's just far too long and the impact is going to be diminished.
>
> (Robert, GP and professor, IR5)

Helen and Robert's excerpts link to the *'Resources and the political context'* because as one researcher raised in chapter five, research priorities often change, and this affects the overall direction of impact. However, the data suggest that evaluation strategies for PPI in the way proposed at PPI at pre-implementation, partial implementation, during implementation and post implementation, could work.

Pre-implementation stage evaluation of impact of PPI

On three occasions researchers and stakeholders said that before funding is obtained for a study, 'at pre-funding stage' the impact of PPI could be assessed via a table of 'you said

- we did', which would also indicate how PPI work influenced the overall application. In another example, Katy discussed some work she had been doing within her organisation to identify the impact of her research work. The entire portfolio of work carried out required involvement from patients and the public affected by cancer. Katy discussed that an audit trail was kept which captured the impact of early discussions concerning the prioritising of research questions that were developed by patients:

> I've just been doing some case studies, …looking at, small examples of the impact of PPI on the design of the research, and, some of that links into identifying the topics, because it might be that the researcher then uses the topics that have been identified by service users, patients, carers, … explores an audit trail of what difference those processes are making, and patients are involved in those processes all along the chain. So yes, there is definitely documentary evidence about how we have improved or changed our performance and patients and carers are directly involved in all of those decision-making processes.
>
> (Katy, national cancer policy staff, IS7)

Similarly, three researchers suggested that the impact of PPI could be assessed through looking at how well trials recruited patients, and then scaling the figures against the previous years, in a trial without PPI:

> … you could easily look at getting stakeholders involved to try and increase recruitment. And actually, benchmark that against previous years' accruals and see if that makes a difference.
>
> (Priscilla, oncology professor, IR1).

David had a similar view concerning the recruitment stage of trials, but he proposed a study where PPI would 'step in' mid-way through studies which were not recruiting so well. The PPI would be the intervention and this may lead to some thought-provoking information about PPI and its impact:

> We know what our recruitment figures are, we have to produce them …And what would be interesting to see would be to look at a group of studies, …where we think actually they are probably not recruiting to their potential, they plan to run over five years, and we can then do some sort of intervention with using patient involvement and then just look at numbers at the end of that. That would be a really straightforward thing to do, and you might learn some really helpful strategies there.

(David, geneticist doctor, IR6)

Along similar lines, patient information sheets were mentioned. Janine commented that two information sheets for a trial could be compared, one developed by patients and the public, and the other developed by the professionals. It could be possible to see which of the information sheets recruited better:

> You could [have two information sheets the same, and] set two groups, one for the original information sheet and the other with a PPI group and then see how the sheet gets modified and after that which sheet recruits better. You could look at two studies, one with and one without PPI and see which trial is more acceptable to patients.

(Janine, palliative care professor, IR3)

Katy stated that impact of PPI was most notable on recruitment and also whether a study wins the funding or not:

> There are two different measures: recruitment uptake and getting funding. Both of those measures are greatly increased through involving people.

(Katy, national cancer policy staff, IS7)

But for Patsy, she believed that impact of PPI was more possible to demonstrate via an RCT as the outcomes would be clearer:

> …impact on the quality of the research and…degree to which that research influences ….audiences are the two obvious ones. How can you evidence …measure …evaluate it? It is obviously difficult. I think it's more difficult in some research fields than others. I think certain kinds of clinical research …it's probably much more obvious. I don't think it would be easy but it's more possible than it would be with certain kinds of research….

(Patsy, hospice senior staff, IS8)

These ideas suggest that there are ways to evaluate PPI at the pre-implementation stage. The prostate cancer and the oncology consultation tool examples demonstrate that these types of strategies could work because both studies had ended and no further work was planned.

Partial, During or Post implementation stage of evaluating impact of PPI

Other than keeping an audit trail, which four researchers mentioned, another researcher suggested that developing a focus on very specific issues concerned with PPI impact would be more appropriate to help evaluate it. For example, Dennis spoke of CLAHRC funded studies as an example when he was explaining his idea. At the time of interview, CLAHRC had 25 projects on their database, all of which had some degree of PPI:

> …[focusing]…on one particular area as a group across [the name of UK region] …would it then give us a bit more focus. Yes we want everyone involved all the way through the process but rather than trying to do that in 25 projects and getting dissipated, if we particularly focused on one particular aspect of PP that could actually then help target …[data collected]…
>
> (Dennis, implementation science lead, IS1)

Dennis was offering insights into precise areas for evaluable outcomes. He then suggested that other CLAHRC units across the country could focus on other aspects. He said that trying to understand the entirety of impact of PPI on all of these projects would lose focus of purpose on evaluating impact of PPI. However, if a researcher focused on a few areas such as 'dissemination' or 'mutual relationships', then a richer understanding of impact on those particular aspects could be generated for each project:

> So for me the two big things that we have really gone after, one would be setting direction and my main second hope is the dissemination. I suppose the third one is about a mutual relationship of asking and improving what we are developing all the time in a monitoring and advisory process.
>
> (Dennis, implementation science lead, IS1)

Often when participants described evaluating impact they suggested that the process was uncontainable with too many variables, but Dennis' understanding (above) illustrates that those who evaluate impact must think carefully about particular evaluable aspects of PPI.

Two researchers believed that the impact of PPI could be something that could potentially be better understood by applying a 'realist evaluation':

> Qualitatively, it's a bit more feasible especially if you're doing …theory-based evaluation or realist evaluation or something like that.

(Robert, GP and professor, IR5)

Other than Dennis and Robert's pointers, no other suggestions about how impact of PPI could be evaluated for outcomes, were offered.

Summary

From re-examining the data, the six examples of PPI on research outcomes were found. It became clearer that understanding the impact of PPI was affected by: 1) the nine factors of PPI; 2) whether these were direct or indirect; and 3) the time/stage the study was at.

The second half of this chapter has presented data which complements the six examples because the perceptions about the relationship between process and outcomes of PPI were shared. There was strong feeling amongst participants that the relationship was not linear, that outcomes needed to be precise and evaluable, and that somehow that evaluation needed to take consideration of the broader, context, mechanisms and outcomes. There were also some examples offered that might encourage new approaches to assessing and evaluating the impact of PPI on research outcomes.

The final point to acknowledge, which perhaps is not clearly embedded in the six examples or quotations, is that the very essence of evaluation relies on having pre-set outcomes, yet often as data in chapter five showed, sometimes PPI is carried out tokenistically and without a strong purpose. Thus, evaluating something without clear purpose becomes difficult. For example, Robert argued that: *'…it much harder to evaluate things that are less well defined such as PPI and its impact as they are more diffuse than those things that are kind of containable'*. The definition of the impact of PPI which was developed during the Delphi study also reflected this point. Similarly, Patsy said that perhaps the important deciding factor about the impact of PPI was teasing out understandings of how the newly generated research adds value across the rest of the body of available knowledge. Patsy: *'The question is: what is their [PPI] impact in the existing body of knowledge concerning the research?'* These pointers suggest that the impact of PPI is complex and tricky to trace/audit. Without favourable values, context

and processes the impact of PPI would be less achievable. In the discussion chapter these points will be explored in depth.

End user involvement influencing this stage

May 2017 – To help discover the original contribution to this work. Two theoretical clarity workshops took place after data collection was complete. Involvement in the form of **consultation** occurred at De Montfort University (n=9 researchers and stakeholders) and at the University of Leicester (n=15 researchers and stakeholders). At these workshops data were presented using interpretations and conceptualisations derived from critical theory. Feedback from participants suggested that critical theory failed to offer a pragmatic solution and that an alternative model may be more suitable. This influenced the researcher to focus subsequently on using the CFIR model (Damschroder et al. 2009).

The running of these workshops was made possible due to the research networks at the two institutions and the good will and interest of existing contacts to help in the capacity of end users. See chapter nine for more details on the limitations of this approach.

Chapter Eight: Discussion

Introduction

The aim of this study was to advance knowledge about the impact of PPI on research outcomes. It did so through two phases of work. In the first phase, qualitative interviews were used to generate new data on the perceptions of the impact of PPI on research outcomes amongst patients, researchers and stakeholders. In the second phase, a Delphi study was used to refine interview data to produce a common understanding of the impact of PPI on research outcomes.

This chapter presents the original contribution to knowledge in the thesis by:

- arguing first, that PPI can be considered as a complex intervention (Craig et al. 2008);
- secondly, that as a complex intervention, the impact of PPI on research outcomes can therefore be evaluated using the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al. 2009) by demonstrating evaluable PPI outcomes;
- thirdly, using the CFIR, particularly the domain of 'Process of implementation', helps to draw out new theoretical insights about the evaluation of impact of PPI on research outcomes by enhancing understandings about PPI implementation and evaluation theory relating to complex interventions such as PPI.

The chapter is organised in two parts. The first part considers how the impact of PPI on research outcomes can be considered for evaluation in terms of a complex intervention evaluation. It draws on the components of complex interventions as set out by Craig et al. (2008) and uses data from the study to illustrate these components. In the second part, it is argued that PPI is evaluable using the five domains and 36 constructs of the CFIR (Damschroder et al. 2009). This part of the chapter is organised theoretically using the domains of the CFIR (Damschroder et al. 2009) to structure the discussion. As the main aim of the current study was to address how the impact of PPI on research outcomes might be understood, the domain of the 'process of implementation' is key, although the

other four domains are also relevant to understanding PPI being a complex intervention because they help to consider process, mechanisms and outcomes (Staley et al. 2014).

The CFIR was selected due to its flexibility of applicability towards approaching PPI in research evaluation and implementation, something which has not yet been achieved in the literature. Thus, in the absence of other evaluation tools available for understanding specifically the impact of PPI on research outcomes (not just processes), the effects of context and mechanisms on outcomes is considered within the CFIR, to help gain a more sophisticated understanding of the impact of PPI on research outcomes. At the end of each domain of the CFIR, a summary table is presented to demonstrate evaluable outcomes of PPI.

Whilst the CFIR was not designed for PPI evaluation purposes it goes further than most other tools for evaluating PPI because it offers a common and transferable framework. The justification therefore for using the CFIR is that it offers tractability for evaluating complex interventions, i.e. when several aspects need considering together. Also, when using the CFIR to evaluate PPI, a chronology is inherently present which allows flexibility for evaluation to suit pre-implementation, partial implementation, during-implementation, and post-implementation focused PPI evaluations; the chronology point will be discussed throughout this chapter. This point also links to Craig et al.'s. (2008) component four about complex interventions having varied outcomes, and component five about there being flexibility in how the intervention evaluation can suit particular situations.

At the very end of the chapter a conclusion is offered about how this discussion makes an original contribution to knowledge to the evidence base of PPI evaluation and implementation theory.

Part 1. PPI as a complex intervention

Complex interventions offer a way of thinking about inherent aspects and features to consider when developing, evaluating and implementing health and social care (Craig et

al. 2008). The boundary between a complex and a simple intervention is not clear but according to Craig et al. (2008) a complex intervention has five aspects that set it apart from a simple intervention:

1) the intervention will have a number of interacting components within it;
2) the intervention which is complex would normally experience difficulty in eliciting the behaviours required by those delivering or receiving the intervention;
3) in a complex intervention there will be a number of groups or organisations targeted by the intervention;
4) there will be a number of varied outcomes;
5) a complex intervention will offer flexibility in shaping the intervention to suit particular situations.

As outlined in chapter 3, the evaluation of PPI in research has been suggested as having the characteristics of a complex intervention, (Farrell 2004). This point has also been made by others in the field of PPI, e.g. in operational PPI research (Pearson et al. 2013), PPI in systematic reviews (Harris et al. 2015) and PPI with hard-to-reach groups (Morgan et al. 2016). However, to date, authors who have suggested that PPI could be thought of as a complex intervention have focused on PPI in research processes. In this thesis, the aim was to consider evaluating the impact of PPI on research outcomes. It could be argued that if we think about PPI as a complex intervention, the components set out by Craig et al. (2008) would also therefore apply to attempts to understand the impact of PPI in research and translational work (the outcomes). This means that in considering PPI as a complex intervention we must consider PPI in research processes and on outcomes in conjunction because they interact.

It must be acknowledged that there are alternative views about whether PPI can be considered a complex intervention. Some scholars argue for example, that PPI is not a complex intervention and rather, that PPI is itself an integral part of the research process which helps ensure that the research is patient centred. This argument forms the normative

argument for PPI (Elderman and Barron 2016) or as what Snape et al. (2014) refer to as the intrinsic values of PPI (discussed in the introduction).

The normative argument for PPI considers PPI to be part of the research process, the same way that statisticians are needed to calculate the statistics, or clinicians and others on the research team are needed for other aspects integral to the research process. Elderman and Barron (2016) argue that PPI in research helps to ensure that the voice of the researched is taken on board and therefore considering PPI in research to be a complex intervention, loses PPI's purpose and the values that underpin it.

One study which supports Elderman and Barron's view explored major system change in stroke care (Mc Kevitt et al. 2018). The authors argued that PPI in research in the NHS required direct invitation from researchers for lay people to be involved in activities that were already planned. They suggested that this type of 'invited involvement' was different from patient movements which concerned social justice and emancipation, and which usually arose from outside of such structures. These different purposes of PPI therefore invite different approaches to evaluation as McKevitt et al (2018).

The central point here is that PPI serves different purposes in different research projects. The findings from the present study which evaluated other studies' PPI demonstrate how PPI can be considered a complex intervention because they show that a variety of contextual aspects affect the impact of PPI in research for example: funding supporting PPI in a research project; the attitudes of people conducting the PPI (researchers and patients) and their commitment levels to PPI; the individual and organisational values placed on PPI and; the systems in place to support PPI.

Thus, whilst studies by Pearson et al. (2013), Harris et al. (2015) and Morgan (2016) might help us to understand the specific processes of PPI as a complex intervention, none of these studies specifically explore the implications of how we might measure the impact of that intervention (PPI) in research outcomes**.** There is a particular gap when evaluating how PPI shapes outcomes using the components of a complex intervention set by Craig et al. (2008). Most importantly these authors do not explain that when a study has ended, *how* that study might go on to be evaluated at the implementation and translational phases

of the work. They simply, and rightfully, argue that PPI context, PPI mechanisms (PPI processes) and PPI outcomes need considering together and point to realist evaluation ideas about what works for whom and when (Pawson and Tilley 1997). The focus on process centres on the level of involvement - consultation, collaboration and user control or stage of research cycle (Brett et al. (2010). For PPI context - it is usually described as the nature of the research project as aims and design (Staley et al. 2012). 'PPI outcomes' according to Staley et al. (2012) refer to the outcomes the involvement made to the project itself, not specifically the translational and implementation phases (i.e. the focus of the current study). Hence what the current study proposes is an intervention evaluation approach to understanding the impact of PPI on research outcomes.

Table 24 shows how might we understand the impact of PPI on research outcomes as a complex intervention by applying the five components of Craig et al. (2008). Throughout, the author draws on examples from the data to illustrate how each component relates specifically to the evaluation of the impact of PPI on research outcomes.

Table 24 - The impact of PPI as a complex intervention

Complex intervention characteristic set by Craig et al. (2008)	PPI as a complex intervention (with an added emphasis on the impact of PPI on research outcomes)
1. a number of interacting components	Brett et al. 2010 argue the **architecture for PPI** as a complex intervention has three interacting components, these are context, mechanism and outcomes. **PPI Context -** would concern national strategies for PPI and resource allocation. Example 2, the National Cancer Experience Survey showed that the government in power supported the work. This would be a favourable context. In contrast, in Example 6, the LGBT Cancer study, government support for Joanne's work had eroded as a result of government changes, thus, the context acted unfavourably towards PPI on research outcomes. The factors of PPI found in chapter five, *'Resources and the political context'* and *'Significance of power and leadership'*, demonstrate the PPI context affecting the PPI outcomes.

	PPI Mechanisms - these might be the locally available resources for PPI and the values of people engaging in PPI. Example 2, the Cancer Survey, demonstrated that having trained PPI in the design of the cancer survey was important. PPI mechanisms are different for every research project using PPI. Chapter five demonstrated a range of mechanisms including: *'PPI in commissioning'*, *'PPI processes'* and *'PPI in dissemination'*. It is reminded here to the reader that mechanisms are generally process issues and that the relationship here is that data also demonstrated that good PPI processes were highly influential for the impact of PPI on research outcomes. **PPI outcomes** varied from project to project in the data from the current study. PPI outcomes ranged from securing further funding for follow up work with PPI, policy attention with PPI help, policy change with PPI help and a new campaign designed by patients (example two). Thus, the interacting components here found from data in the current study are: PPI context **(**factors of PPI **'Resources and the political context'** and '**Significance of Power and Leadership')** + PPI mechanisms **('PPI in commissioning'** and **'PPI processes')** = PPI outcomes **('PPI in dissemination'** and **'PPI in implementation')** which might be those listed above for PPI outcomes.
2. difficulty eliciting required behaviours	This could include the **problem points for PPI on research outcomes,** resulting in a combination of problems from different stakeholders. In example 4, the Prostate Cancer study, Dennis and Robert said that a quality of life questionnaire for men with prostate cancer was not adopted in the NHS after it was developed through the research study with PPI. The difficulty of eliciting behaviours can therefore mean that policy makers and/or senior leaders may not accept a new intervention, despite good PPI. Secondly, mandatory expectations about PPI from funders in studies may lead researchers to carry out PPI purely to secure funds, rather than meaningfully, thus potentially asking the wrong question in the study with PPI leading to unusable findings. The third difficulty may be that patients and the public might have had their own agendas. A fourth, may be to convince those who hold budgets to allocate resources for

	PPI and the fifth may be not knowing how to do PPI in research well. Finally, there are effects of bureaucracy on PPI on research outcomes. The factors of PPI '**Wanting to make a difference'**, '**Resources and the political context'** and '**Significance of power and leadership'** particularly relate to this component of complex interventions.
3. a number of groups or organisations targeted by the intervention	This applies to **how we capture the various views of the different people and organisations affected by PPI and how these affect the overall outcomes of PPI**. Targeted groups are the patients and the public (people like Ben and Steven), researchers (Joanne and Janine), charities (Katy and Patsy), higher education systems (Robert), scientists, INVOLVE/NIHR, funded research schemes and research council PPI leads. The PPI factor of **'Networks'** particularly relates to this point.
4. a number of varied outcomes	This component is about **how we can measure that the PPI on research outcomes has worked**. For the current study this component of the complex intervention is central for the current study and the focus of the question. Four stages of evaluation were found in chapter seven. These stages were **pre-implementation** (i.e. PPI were part of the study's commissioning and research processes. But after the study no further work has happened in relation to that study since it finished, and the PPI group has dissolved). **Partial-implementation** (concerned were some recommendations from the research had been taken up during dissemination. The study had ended and no further implementation work was planned. The PPI group has dissolved). **During implementation** (was when the researchers with PPI were planning the next stage of the work). The last was **Post implementation** (i.e. the researchers with PPI were actively working on the next phase of the work). Aside from those listed above, outcomes may also be general or specific aspects such as the increased use of PPI in research nationally and how these may be counted, capturing the increased knowledge about PPI and what it can add, amongst stakeholders. It may be about the increased numbers of funders implementing PPI in their schemes or how much funding is annually offered for PPI in

	research. It could also mean how clearly PPI is reported in journals using tools such as GRIPP 2 (Staniszewska et al. 2017). Or how it is assessed in PPI in research dissemination work - e.g. who was present at an event and how the dissemination event has broadened somebody's thinking about PPI and the usability of the findings presented. As Patsy said that when she heard Janine's case at a conference she held a meeting at her hospice about the potential of using the findings from Janine's research. In the data the **six examples** demonstrate the reported role of PPI in shaping the outcome of the research – evaluation of outcomes of PPI can therefore consider all of these reported roles of PPI securing the impact.
5. flexibility in shaping the intervention to suit particular situations	Together the four points above demonstrate that PPI is a complex intervention because there is **flexibility and scope** on *what* aspects to evaluate and *when* if we consider the pre, partial, during and post implementation stages. This allows the evaluator some options on what to include and what not to whilst being mindful of the impact of context and mechanisms on outcomes. In chapter seven, Robert made an interesting point about the appropriateness of PPI and its connection to the link between process and outcomes of PPI. He believed that PPI only works well if patient experience is at the centre of the research study. Similarly, others felt that an RCT would help to establish the impact of PPI on research outcomes. Others raised that when evaluating the impact of PPI, it is important to acknowledge that PPI is not static and therefore is timing sensitive. Thus, the flexibility and scope for evaluating the impact of PPI on research outcomes is highly sensitive to both context and mechanism.

Based on the defining characteristics of a complex intervention offered by Craig et al. (2008) it can be argued by referring to table 24, that PPI in research is a complex intervention and therefore can be evaluated as such. To understand the impact of PPI on research outcomes, in the context of recognising it as complex intervention, requires us to utilise a framework that considers all interacting components. For this, we turn now to implementation science and specifically to the work of Damschroder et al. (2009).

Part 2. The Consolidated Framework for Implementation Research

The Consolidated Framework for Implementation Research (CFIR) developed by Damschroder et al. (2009) reviewed 19 implementation theories and amalgamated them into one meta framework. They found five domains which reflected all of the 19 theories these were:

6. Intervention characteristics – which are the core components of an intervention;
7. Inner setting which recognise that people on the ground will be affected by the issue, therefore policies must be ready for change;
8. Outer setting which are the contextual aspects e.g. politico-social issues with need to be aligned to the inner setting;
9. Characteristics of individuals involved in making the change e.g. must include all 'end users' including patients, public and stakeholders; and
10. Process by which implementation is accomplished needs careful planning and executing.

(Damschroder et al. 2009)

A domain may be defined as: *'a pragmatic structure for approaching complex, interacting, multi-level, and transient states of constructs in the real world'* (p1). The five domains identified under CFIR are: Intervention characteristics; outer setting; inner setting; characteristics of the individuals involved; and the process of implementation. The constructs within the domains interact in rich and complex ways to influence implementation effectiveness. Damschroder et al. (2009) selected constructs based on:

> 'conceptual or evidential support in the literature for influencing implementation, high consistency in definitions, alignment with our own experience, and potential for operationalisation as measures.'
>
> (p3)

Table 25, below, identifies the constructs and domains within the framework. The rest of this section draws on the entire dataset from the current study and the literature to demonstrate how the domains and constructs relate to understanding the impact of PPI on research outcomes and its evaluation. Exploring each domain and construct in turn

will demonstrate how it can advance PPI implementation and evaluation theory. In each case, the domain is first defined and explained and then the focus is given to the specific case of PPI impact on research outcomes; which is the focus of this thesis. Based on Craig et al. (2008) the outcomes of PPI being a complex intervention are a mixture of contextual and mechanistic aspects, linking to outcomes. Therefore, various outcomes of PPI on research can be generated by considering the different values (characteristics of the intervention and individuals involved), different processes (inner setting and processes of implementation) from the different people (e.g. patients, leaders, researchers, stakeholders, policy makers) and the variable outcomes that range from securing further funding for follow up work with PPI, achieving policy attention with the PPI help, policy change with PPI help or even a new campaign designed by patients.

In evaluation terms, what the description above implies is that whilst the CFIR can be used to evaluate PPI more generally, this thesis is only concerned with the outcomes of PPI, which is an important point. The constructs may interact in rich ways with each other. The characteristics of an individual's domain (i.e. a domain which could be described as a domain about values and norms people have) will be influenced by the outer setting domain (i.e. a domain about socio political and economic context at the time of the study). This may mean, for example, that patients and researchers may hold strong values about PPI but that does not guarantee impact on outcomes if the overall political culture of a country does not value or fund resources to support PPI efforts in research. So, the CFIR can help to consider these aspects of PPI on research outcomes within one interacting model.

Damschroder et al. (2009) list 36 constructs and it is argued in this discussion that each of these constructs can offer insights into the evaluation of the impact of PPI on research outcomes. However, the domain of significant interest in this study is the 'Process of Implementation' (the fifth domain in the model) as this is where evaluation theory in relation to the impact of PPI on research outcomes can enhance new knowledge. To show how each domain advances thinking about evaluation of impact of PPI on research outcomes, a summary box is provided after the discussion of each domain.

Table 25 – The five CFIR domains and their respective constructs identified by Damschroder et al. 2009.

Five Domains descriptions				
1.Intervention characteristics Adaptation is key, without this there will be a poor fit, resisted by individuals who will be affected by the intervention. The core components are the indispensable elements which make the intervention unique.	**2.Outer setting** Economic and political context within which the organisation resides.	**3.Inner setting** These are the structural, political and cultural contexts through which the implementation process will proceed. The line between inner and outer setting is not always clear. The interface is dynamic and sometimes precarious. Readiness for implementation = RFI Implementation climate = IC	**4.Characteristics of individuals** Individuals have agency, can make choices and can wield power on others with predictable and unpredictable consequences. Individuals are carriers of cultural, organisational, professional, and individual mind-sets, norms interests and affiliations.	**5.Process of implementation** This is the active change process aimed to achieve individual and organisational level use of the intervention. Individuals may actively promote the implementation process and may come from inner or Outer setting. Engaging = E
The constructs below each domain				
1. Adaptability 2. Complexity 3. Evidence strength and quality 4. Trialability 5. Cost 6. Intervention source 7. Design and quality packaging 8. Relative advantage	1. Patient needs and resources 2. Cosmopolitanism 3. Peer pressure 4. External policies and incentives	1. Structural characteristics 2. Networks and communications 3. (RFI)- access to knowledge/information 4. (RFI)- Available resources 5. (RFI)-Leadership 6. (IC)- Tension for change 7. (IC)- Compatibility of fit 8. (IC)- Relative priority 9. (IC)- Incentives and rewards 10. (IC)- Goals and feedback 11. (IC)- Learning climate 12. Culture	1. Knowledge and beliefs about the intervention 2. Self-efficacy 3. Individual stage of change 4. Individual identification with organisation 5. Other personal attributes	1. Planning 2. Executing 3. E- Opinion leaders 4. E- Formally appointed internal implementation leaders 5. E- Champions 6. E-External change agents 7. Reflecting and evaluating

Domain 1: Intervention characteristics of impact of PPI on research outcomes

Damschroder et al. (2009) identified Intervention characteristics as '*the characteristics of the intervention being implemented into a particular organisation* (p.3). For understanding the impact of PPI on research outcomes this might include the goal to reduce the research and practice gap (Savory 2010) or enabling 'bench to bedside' alignment (Callard et al. 2011) for an organisation. The eight constructs of intervention characteristics will now be argued to show fit for PPI impact on research outcomes.

Damschroder et al. (2009) suggest an intervention characteristic must have *Adaptability* to suit the setting:

> The intervention is often complex and multi-faceted, with many interacting components. Interventions can be conceptualized as having 'core components' (the essential and indispensable elements of the intervention) and an 'adaptable periphery'.
>
> (Damschroder et al. 2009, p5).

The intervention characteristic in this work concerns the evaluation of PPI impact on research outcomes. Data from the current study in chapter seven show that PPI outcomes can be adaptable to any study trying to understand the translational phase. In the current study these phases were found to be evaluable at:

- **Pre-implementation** (i.e. Example 1: Oncology Consultation Tool) where PPI was part of the study's commissioning, research and dissemination processes, but after the study, no further work had happened and the PPI group had dissolved.
- **Partial-implementation** (i.e. Example 4: Prostate Cancer study) where some recommendations from the research had been taken up but others had not. The study had ended, and no further implementation work was planned. The PPI group had dissolved.
- **During implementation** (Example 5: Cancer Genetics and Example 6: the LBGT Cancer study) was when the researchers with PPI were planning the next stage of the work.

- **Post implementation** (impact Example 2: Cancer Survey and Example 3: Palliative Care) where researchers with PPI were actively working on the next phase of the work.

The adaptability aspect of the intervention characteristic links back to the introduction to this study which detailed the intrinsic values associated with PPI. Snape et al. (2014a) found consensus that these intrinsic values included consideration of: what research is undertaken, and how it is used; that different types of knowledge are important, and that members of the public have a unique knowledge (Snape et al. 2014). These values were significant for the current study, because participants explained that the values had adaptability across research planning and the application of PPI views to research, and that PPI knowledge was a vital ingredient in successful implementation.

The literature showed that involvement took place across a spectrum of consultative, collaborative and user-controlled involvement (Fleming and Hudson 2009). The literature also demonstrated that there was a growing field of spectra (Hanley et al. 2005), frameworks (Shippee et al. 2013) and models (Forbat et al. 2009) to help understand characteristics of PPI in research. Thus, the adaptability element suggested by Damschroder et al. (2009) is observable in PPI as a complex intervention. Data from the interviews and the Delphi reflected this point well as each study cited by participants was different and demonstrated stark contrasts in how they had adapted the principles of PPI to suit their work. The six examples (chapter seven) further demonstrate that outcomes can be highly subjective.

However, the diversity and adaptability of PPI, added to its *'complexity'*, affecting its evaluation. Damschroder et al. (2009) articulated that intervention characteristics needed to address the *'perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement'* (p6). This point links to the evidence base of PPI. Participants in the current study provided details about PPI processes, for example, the number of meetings, number of patients and the public involved in a study, the payments offered, training for PPI, managing patient agendas and other process factors. The literature

pointed out that PPI characteristics have highly subjective ways in which the evidence base is understood. Damschroder et al.'s (2009) construct of *'evidence strength and quality'* was defined as: *'stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes'* (p6). This point is important because it also links to the evidence base of PPI. In the literature, the impact of PPI on research outcomes was sensitive to barriers and facilitators. PPI was documented in a variety of ways in healthcare research to have positive outcomes on different stages of the research, for example: winning funding for the research, designing a study, recruitment in a study, and selecting outcomes of a study (Domecq et al. 2014). But collectively, the literature showed that the impact of PPI on the *processes of research* was understood better than impact of PPI on the *outcomes of research.* Poor quality reporting was a possible reason for the lack of literature on the topic of the impact of PPI on research outcomes (Staniszewska et al. 2011).

Furthermore, there was no consistent language to identify what was meant by the impact of PPI on research processes or outcomes (Brett et al. 2010; Mockford et al. 2011; Staley 2009). Data from the Delphi study showed that the concept formation of impact of PPI in language is achievable by synthesis and trialability. But *'trialability'* for Damschroder et al. (2009) concerned the *'trialability and usability testing (with staff and patients) [which] promotes successful adaptation of the intervention'* (p6). And yet this point is sensitive to the *'cost'* of PPI. The costs to trial PPI as an intervention at research design stage or pre-implementation stage, for example, has to be set against the funding for PPI, an issue raised by participants in this study. Damschroder et al. (2009) highlight a number of costs including those of: *'the intervention and costs associated with implementing that intervention, including investment, supply, and opportunity costs'* (p7).

Snape et al. (2014b) found consensus in their work on impact barriers and drivers that are central components to implementation work with PPI, arguing that PPI work required research team cohesion and most importantly here, suitable resources (i.e. funds). Data from the current study reflected this point too: impact was noticeable in example 3: Palliative Care and example 2: Cancer Survey where researchers had an

existing PPI group and this group kept the research-related understandings at an implementable level i.e. the messages that the field of palliative care needed to know. Similarly, in example 2, Katy asked trusts to consider how they could deal with addressing local anomalies.

Damschroder et al. (2009, p6) describe '*Intervention source'* as whether the '*intervention is internally or externally developed… as a good idea […] solution to problem'* (p6). In chapter two, it was highlighted that PPI in healthcare was rationalised in two ways: democratic in that it is an attempt to legitimise services, and technocratic which related to attempts to improve services. Neoliberal governments have placed value on PPI as a solution to the perceived democratic deficit (Florin and Dixon 2004).

For the '*Design quality and packaging'*, PPI has been presented as potentially achieving better research outcomes. Damschroder et al. (2009) suggest when packaging an intervention, there needs to be *'perceived excellence in how the intervention is bundled, presented, and assembled'* (p7). Much of the literature on PPI suggested it was fashionable to conduct research with PPI, with scholars adopting, en masse, the INVOLVE definition of *'Doing research 'with' or 'by people', not 'to' 'about' or 'for them''* (INVOLVE 2018). Similarly, the *'Going the Extra Mile'* (GEM 2015) review had packaged PPI in research to have a new vision, mission and set of goals for the next ten years specifically to address research-related PPI complexities (NIHR 2015). Thus, PPI is positioned as being innately good and packaged as resulting in better research outcomes.

However, the problem of this uniformity in how PPI is sold to researchers is that it can mask what good/bad PPI looks like. Poor PPI can lead to poorer outcomes of PPI. Data reflected this point. In James' interview, he said that too much value was placed on PPI itself, which made him doubtful of its real effectiveness. These points from the literature and data relate to the *'relative advantage'* of having PPI in a study. Relative advantage concerns: *'stakeholders perception of the advantage of implementing the intervention versus an alternative solution'* (p6), for example, a study without PPI. The literature reviewed in this thesis identified that, in healthcare, the choice of

method and the approach used needed to be aligned to the particular aims of specific health initiatives (Anderson et al. 2002). Without this link (of the method to the approach), the initiative would fail at being meaningful and relevant to the needs of patients and the public, which would potentially later affect outcomes. Thus, funders making PPI mandatory supposedly helped alignment of method to health initiative, making researchers believe that PPI is a good idea to resolve the problem (whatever the research intervention) (Harrison and Mort 1998).

Relative advantage is an important construct for PPI on research outcomes because as Abelson et al. (2003) argued, the trend of PPI in research governance suggested that policymakers wanted a more sceptical and critical public, and PPI provided a way of self-governing. PPI in research initiatives speaks to sceptical publics, as in the case of example 1, the Oncology Consultation Tool, where patient Ben wanted to challenge medical professionals for his poor experience at the start of his cancer treatment.

Thus, considering PPI as a complex intervention, the characteristics of the intervention allow us to think of PPI in research outcomes to be a combination of foundational aspects for assessment. The outcomes may be assessed as summarised in table 26.

Table 26 - Evaluable characteristics of intervention characteristics

Intervention characteristics	Evaluable outcomes
Adaptability	1)Pre, partial, during or post implementation 2)Values 3)Spectrum of involvement
Complexity	Number of: a) pre /partial/during and post implementation meetings, b) with patients/public involved c) whether payments were offered to patients and public d) whether training was offered on for e.g. what dissemination and implementation processes are and why they are important for PPI on research outcomes.
Evidence strength and quality	Use of consistent language, winning further funding, co-authoring a paper
Trialability	Evaluation concept testing
Cost	Resources made available for PPI on research outcomes
Intervention source	What was its purpose of PPI? has it achieved its purpose?

Design quality and packaging	Does the PPI work reflect national/local policy ideas and recommendations? How?
Relative advantage	What is the alternative solution to implementation if PPI was not part of it? What is the distinctive advantage of PPI?

Domain 2: Outer setting of impact of PPI on research outcomes

The outer setting concerns the political and cultural context within which organisations are situated. Changes in the outer setting can influence changes in the inner setting, and the boundary between the outer and the inner setting is often not clear cut. However, the domain was defined as follows:

> Generally, the outer setting includes the economic, political, and social context within which an organization resides, and the inner setting includes features of structural, political, and cultural contexts through which the implementation process will proceed [22]. However, the line between inner and outer setting is not always clear and the interface is dynamic and sometimes precarious. The specific factors considered 'in' or 'out' will depend on the context of the implementation effort.
>
> (Damschroder et al. 2009 p7)

Two impact examples help us to make sense of the outer setting. Example 1: The Oncology Consultation Tool and Example 4: The Prostate Cancer study, both demonstrated that the questionnaires developed within one hospital (inner setting) were not taken up outside of the setting (the outer setting). The implementation efforts made in these examples were not entirely successful. The constructs will help to unpack why this was so.

There were four constructs to the outer setting. For the construct of *'patient needs and resources'* Damschroder et al. (2009) argued these concern: *'the extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization'* (p7). The literature on research impact context demonstrated that generally there seemed to be a failure to connect how PPI interventions affected the context of research. This resulted in a mismatched alignment from 'bench to bedside' (Callard et al. 2011). Furthermore, if a dialogue between researchers and patients was not kept alive concerning what was needed from research findings, implementation efforts could fail (Morris et al. 2011). In the data,

researchers and patients discussed efforts they had made to engage with commissioners, and participants discussed how they used their networks to ensure that research reflected what patients wanted. This point linked to Damschroder et al.'s (2009) construct of *cosmopolitanism*:

> the degree to which an organization is networked with other external organizations. …Social capital is one term used to describe the quality and the extent of those relationships and includes …shared vision and information sharing. …[including] external bridging between people or groups outside the organization
>
> (Damschroder et al. 2009 p7)

The literature demonstrated that NIHR-funded organisations were supported by recommendations made in the GEM report. One such piece of work was the documentation of values, principles and standards for PPI, which were co-produced with the public and other partners (GEM 2015). GEM outlined six principles covering: *respect, support, transparency, responsiveness, diversity* and *accountability*, and six standards which comprised: *inclusive opportunities, working together, support and learning, communications, impact* and *governance* (NIHR 2017). These standards of working will potentially offer leverage to articulate common goals of PPI in research outcomes (e.g. to achieve the working together principle). The point of cosmopolitanism links highly to two of the other constructs under this domain of Outer setting, *'Peer pressure'* and *'External policies and incentives'*. Discussing peer pressure, Damschroder et al. (2009) explained the construct as follows:

> 'peers' can refer to any outside entity with which the organization feels some degree of affinity or competition at some level within their organization
>
> (p7)

And external policies and incentives as:

> External policies and incentives concern the 'broad constructs that encompass external strategies to spread interventions, including policy and regulations …external mandates, recommendations and guidelines…'
>
> (p7)

Both of these constructs within the literature concern long-term investment, leadership and co-ordination, which were recommended in the GEM report. The outer setting echoes the general concerns about leadership found in wider research impact and implementation literature (e.g. Kuruvilla et al. 2006) as well as in the PPI literature (e.g. Jinks et al. 2016). The building of trust between researchers, patients and the public, and staff in PPI leadership roles requires investment. Learning about what approaches in PPI work best, in different healthcare research settings, requires detailed understandings about the complex interplay of involvement dynamics, here the blurring of the boundary between inner and outer setting. PPI interventions concern: clarity of purpose, defined roles and relationships, organised support and a strongly funded infrastructure, which are all components believed to create the spaces for strong and supported PPI in research endeavours (Jinks et al. 2016). The data on networks (researcher, stakeholder and patient) links here because without strong networks, relationships will struggle to materialise.

In the data, relationship building was a key component for which resources and political backing for PPI work were vital. Janine's study, Example 3: Palliative Cancer Care demonstrated this point well. She described how PPI in research work relied on strong relationships and these built up a rich tapestry of information. The impact of PPI on research outcomes needed these strong networks to share information generated from PPI-informed research. The data across the six examples reflected that at a commissioning level and research process level active efforts were being made by researchers to suitably meet the needs of those involved. However, this point was highly sensitive to funding for PPI. If an organisation was not awarded any PPI funds, then the efforts they made for PPI were vulnerable. Joanne, the researcher in LGBT work (Example: 6), explained in her interview how she used her own money to pay for flowers to thank PPI members. Impact in her work had stalled because the government context was chaotic and hindered her research plans. The more established PPI groups performed much better, such as in the PPI group working on the Example 2: Cancer Survey conducted by a cancer network and Example 3: Palliative Care, where trained and well-resourced PPI groups were part of the organisational infrastructure. Of note, these examples demonstrated better PPI-related outcomes than the others set out in chapter seven.

The outer setting for shaping the impact of PPI on research outcomes therefore concerns patient needs and resources, cosmopolitanism, peer pressure and external policies as investments for PPI, and these are all channelled as a form of PPI leadership and strategic direction. Without resources, political backing, and power and leadership, PPI efforts are sensitive to failure and tokenism.

Table 27 - Evaluable characteristics of outer settings

Outer setting	Evaluable outcomes
Patient needs and resources	Understanding how dialogue kelp alive pre, partial, during and post implementation. Listing the ways that patients could request needs and resources
Cosmopolitanism	Listing networks that have been involved and how the national standards for PPI have been assessed across the networks?
Peer pressure	How are other well performing research groups researching similar areas achieving their implementation plans for PPI? Can learning be achieved?
External policies and incentives	What PPI guidelines, and recommendations are in place for PPI on research outcomes and implementation?

Domain 3: Inner setting of impact of PPI on research outcomes

The domain of inner setting concerns the internal issues faced by organisations during implementation. Damschroder et al. (2009) argued that a there is a complexity in describing how the constructs identified under the inner setting are related. They found that there was very little systematic research addressing how the constructs related to each other or which of the constructs was most important. Damschroder et al. (2009) argued that the inner setting *'Contribute[d] to the complexity inherent in describing the many constructs related to the inner setting.'*(p7) and that in particular it:

> may be composed of tightly or loosely coupled entities […] tangible and intangible manifestation of structural characteristics, networks and communications, culture, climate, and readiness all interrelate and influence implementation.

(Damschroder et al. 2009 p5).

Example 6: LGBT Cancer study demonstrated strong networks internally but struggled as the outer setting, via the resources and political context, was not fully responsive to Joanne's policy recommendations. This was despite the evidence of adequate PPI processes being in place.

The domain of inner setting for Damschroder et al. (2009) has 12 constructs. The *'structural characteristics'* construct, Damschroder et al. (2009) demarcate as: *'the social architecture, age, maturity, and size of an organization. … The number of units or departments represents diversity of knowledge in an organization [show importance]'* (p7). In this context, it could concern the organisation needing to adopt the ethos of PPI. But to do this it would also require leadership and the other constructs in favour of the implementation effort. In Example 3: Palliative Care study, Janine commented on the location the study was situated within (a palliative care research wing, within a university hospital). This positioning of her research centre, she argued, provided her study with a strong culture embracing the values and ethos of PPI. This example demonstrated flourishing impact of PPI on research outcomes because further funding and policy attention to her research findings were achieved, and there was presence of an *'implementation climate'* for PPI. Damschroder et al. (2009) identifies the implementation climate as:

> the absorptive capacity for change, shared receptivity of involved individuals to an intervention…, and the extent to which use of that intervention will be 'rewarded, supported, and expected within their organization.
>
> (p8)

All of Janine's research studies had PPI within them and many of her studies were follow on studies – this work was mature and reinforced over time, as were her relationships with the people involved. Therefore, PPI relies on networks and collaborations, a central theme in the current study. The *'networks and communication'* of PPI concerned relationships and positioning of how powerful interventions such as PPI could be. Damschroder et al. (2009) outline that:

> the nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization. Research on organisational change has moved beyond reductionist measures of organizational structures and increasingly embraces the complex role that

networks and communications have on implementation of change interventions

(Damschroder et al. 2009, p8)

The data demonstrated the cancer network was at the centre of the success of the Cancer Survey (Example 2). They had the infrastructure and commitment to help lead findings into the implementation phase. The PPI factor of *'ICT'* also links to this domain's construct as ICT provided a visible profile outside of the groups about how PPI outcomes were to be used.

But for PPI work to flourish, access to *information and knowledge* about PPI was necessary. For Damschroder et al. (2009, p9) this point offers the inner setting *'ease of access to digestible information and knowledge about the intervention'*. In the data to reflect this point, the issue of training was mentioned in almost every dataset. Connected to this was '*available resources'* to help achieve good PPI. According to Damschroder et al. (2009, p9) available resources include: *'the level of resources dedicated for implementation and ongoing operations including money, training, education, physical space, and time'*. Not having this kind of support can lead to negative effects, as Barry mentioned in his interview when he described how easily values for PPI can ebb away if strong leadership was lacking. *'Leadership'* for PPI values was important: '*commitment, involvement, and accountability of leaders and managers…[…]with the implementation'* (p9). Government leadership (in support for the findings) was not observable in the Example 1: Oncology Consultation Tool, Example 4: Prostate Cancer study or Example 6: LGBT Cancer Study, even though these studies had PPI in the commissioning and research processes.

Damschroder et al. (2009) observed '*tension for change'* as: *'the degree to which stakeholders perceived the current situation as intolerable or needing change'* (p8). Katy and Steven independently spoke of Example 2: Cancer Survey and how its results were challenging for underperforming healthcare trusts. There was also evidence of *'compatibility'* of PPI plans between partners. Compatibility for Damschroder et al. (2009) was expressed as:

> The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.
>
> (Damschroder et al. 2009, p8)

Again, in the data this point was reflected in Example 2: The Cancer Survey, explaining how underperforming organisations would tackle the results of the survey.

The compatibility element links to the *'relative priority'* of PPI within an organisation. The term relative priority for Damschroder et al. (2009) concerns how: *'individuals' shared perception of the importance of the implementation [in this case the implementation of the PPI] within the organization'* (p8). But these shared understandings need organisational *'incentives and rewards'*, i.e. rewarding good quality PPI. Damschroder et al. (2009, p8) refers to 'rewards and incentives' as: *'extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary, as well as less tangible incentives such as increased stature or respect'*. In the data, cancer networks were praised for their quality work and co-ordinated efforts towards achieving good services and progress for patients.

'Goals and feedback' for Damschroder et al. (2009) concern *'the degree to which goals are clearly communicated, acted upon, and fed back to staff…'*(p9), which links back to the *'learning climate'* about harnessing openness about concerns about PPI. A learning climate for Damschroder et al. (2009) proposes to be a climate where:

> leaders express their own fallibility and need for team members' assistance and input; team members feel … essential, valued, and knowledgeable partners in the change process; individuals feel psychologically safe to try new methods; [with]time and space for reflective thinking and evaluation.
>
> (Damschroder et al. 2009p9)

There was a presence of a learning climate in impact examples 2, 3, 5, 6 but not in examples 1 and 4. Interestingly these two latter examples were the only studies which were not showing signs of PPI in implementation (these studies fell under pre-implementation and partial implementation stages). In the literature, there were

examples offered by Brett et al. (2014b) reporting positive impacts of PPI on the patients and public, who felt valued and gained confidence and life skills. They reported that researchers found that involvement led to greater understandings and insights into their research area, gaining respect and a good rapport with the community. However, building links with the community also takes time and commitment. Thus, outcomes here may be whether an existing PPI group is in place for scrutinising the implementation efforts. Learning climate links to *culture*, and there was a belief that PPI interventions were not always embraced in academia, an 'ivory tower' culture that promoted writing journal papers over organising community talks and events. This would suggest the need for cultural change to enable the impact of PPI on research outcomes. Damschroder et al. (2009) propose that culture in the inner setting concerns *'norms, values, and basic assumptions of a given organization'(p8).*

On several occasions the point was made that incentive structures in academia are designed unfavourably away from PPI and that the REF is designed to maintain the ivory towers culture. For academics**,** research impact for REF was defined as *'any identifiable benefit to, or positive influence on, the economy, society, public policy or services, health, the environment, quality of life, or academia'* (HEFCE 2014p. 26). But evaluating this type of impact is complicated. Rivera et al. (2017) found five tiers of impact across short- medium- and long-term time periods, although they do not explicitly state how many years each tier could take. The first tier proposed by Rivera et al. (2017) was primary-research-related impact, which the authors argued were immediate research outcomes such as journal papers. Their second category focused on influencing policy; the third tier involved health systems impact; the fourth tier was health-related and societal impact; and the fifth tier was broader economic impact. Based on these categories offered by Rivera et al. (2017), third-tier impact was observable in Example 2: Cancer Survey and second-tier impact for Example 3: Palliative Care.

The twelve constructs of the inner setting offer ideas about what can and might be suitable for evaluating the impact of PPI on research outcomes. Special attention needs to focus on PPI in leadership work, the use of ICT in PPI work (presenting the

outward-facing PPI via social networks and online platforms) and how various different PPI-focused networks (used by patients, researchers, charities and stakeholder) enable inner setting to be more effective.

Table 28 - Evaluable characteristics of inner settings

Inner setting	Evaluable outcomes
Structural characteristics	Age of organisation? PPI in research history? (for example, is there an active PPI group?) Staffing levels?
Networks and communication	Which networks are working with the setting where translational work (pre, partial, during and post)/ implementation work has happened? What are the goals of the organisation around outcomes of PPI being met and how are these communicated with staff and those involved in the process.
(RFI) - Access to information and knowledge	Those who will be part of translational work, how are they being trained and how easily is training, or knowledge needed made available? Who will they go to if they need support?
(RFI) - Available resources	
(RFI)- Leadership	How are leaders, managers and seniors committed to the work, what is their long, medium and short term commitment and understandings about the implementation/translational work plans
(IC)- Tension for change	How tolerable is the current situation? What will happen if the desired PPI outcome does not materialise?
(IC)- Compatibility	What are the pros and cons of the PPI outcome and how easily can actions be taken on to help the PPI outcome take shape.
(IC)- Relative priority	Does everyone involved understand why the outcome is so necessary?
Incentives and rewards	How will success and good practice about the intervention be praised to help keep motivations alive about moving towards the PPI outcomes (the intervention)
(IC)- Goals/feedback	To what extent have goals been achieved about the implementation and how is this feedback to help the implementation plans internally?
(IC)- Learning climate	How are people able to express their self-doubts and how supported do they feel afterwards?
Culture	Are PPI involved in developing the intervention with the organisation, subconsciously does the organisation attempting the intervention with PPI, value community input or does the research organisation value publications and academic impact?

Domain 4: Characteristics of individuals of impact of PPI on research outcomes

As the title suggests, this domain focuses on the people involved in carrying out an intervention. Damschroder et al. (2009) describe this domain thus:

> Individuals have agency; they make choices and can wield power and influence on others with predictable or unpredictable consequences for implementation. Individuals are carriers of cultural, organizational, professional, and individual mindsets, norms, interests, and affiliations. Greenhalgh et al. [2004] . describe the significant role of individuals: 'People are not passive recipients of innovations. Rather...they seek innovations, experiment…, evaluate…, find (or fail to find) meaning…, develop feelings (positive or negative) …, challenge…, worry…, complain…, 'work around'…, gain experience…, modify… to fit particular tasks, and try to improve or redesign them–often through dialogue with other users.
>
> (Damschroder et al. 2009, p5)

In the six examples a strong cross cutting PPI factor was *'Wanting to make a difference'*. Damschroder et al. (2009) stated that there was little research focusing on the interplay between individuals involved in research and the organisation that they are part of. With patients and the public being the nucleus of what PPI concerns, this domain of the CFIR is highly influential, because here the characteristics of those involved will fuse between the patients and the public, researchers carrying out the PPI intervention, and other stakeholders affected by the research.

There were five constructs offered under this domain, the first was *'knowledge and beliefs about the intervention'*. For Damschroder et al. (2009) this point relates to:

> individuals' attitudes toward and value placed on the intervention, as well as familiarity with facts, truths, and principles related to the intervention. Skill in using the intervention is a primarily cognitive function how-to knowledge and knowledge of underlying principles or rationale for adopting the intervention.
>
> (Damschroder et al. 2009, p9)

In the introduction to the study PPI was contextualised as a global policy imperative set by the World Health Organisation (WHO). Clinical breakdowns in the UK suggested that PPI could be a way of delivering safer care and a method of improving health services' accountability, moving from paternalism towards patient empowerment (Ocloo and Fulop 2012). The UK government embraced the following principle from the NHS constitution: 'The patient will be at the heart of everything the NHS does' (Department of Health 2009). Arguably the link here to research outcomes is made logically, that health research will ultimately translate into the NHS, if done well. Thus, the knowledge and beliefs about the intervention require conveying eloquently and in a tailored way by those involved. In Example 3, Palliative Care study, Janine spoke of how she went to a conference to disseminate her research. In the audience was Patsy who worked in a hospice. Patsy was not convinced of Janine's research. Although she praised the findings, her hospice was not heightened to change their practice.

Damschroder et al. (2009, p9) state that *'self-efficacy'* involves *'individual belief in their own capabilities to execute courses of action to achieve implementation goals'* and linked to this is an *'individual stage of change'*. These are the *'characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention'* (p9). The data found that the sentiment behind PPI in research concerned hope for change, the idea of democracy, equality, pragmatic insights into disease, and accountability.

It is important to consider here the professional researchers who are part of the implementation process (professionally and in the PPI roles) because in the literature it was found that involvement opportunities were often undermined or controlled by the powerful (Beresford and Campbell 1994) and as a result involvement could end up being tokenistic or manipulative to advance professional interests (Milewa et al. 1999). Martin (2008b) argued that because involvement initiatives were not representative, involvement was contingent on micro-level negotiations. Here the problem of legitimacy of knowledge arguments could be formed because involvement relies on self-selection as those that come forward for PPI roles are often from middle-class cross-sections of society (Church et al. 2002). In the data there was striking

information about this point. Several patients spoke of how there were not enough patients and public for the growing demands of PPI work, and one patient was working out a strategy for removing those who had been involved for too many years.

Furthermore, in this study, the entire patient group was white, nine of the 13 patients were women and all of the patients were over the age of 60. The researchers spoke during their interviews of how they found it hard to engage BME groups in cancer research for PPI activity (the point was raised in four separate interviews with researchers). What this suggests is that there is a huge barrier for BME groups to engage in PPI in research endeavours and that more work is needed to understand this anomaly. Dawson et al.'s (2017) review found that despite the widespread promotion and inclusion of PPI in the last ten years, involvement is limited in scope as to who is involved, with PPI activity not mirroring the diversity of the population. Perhaps the point of BME groups not engaging in PPI activity is rooted in some of the *'other personal attributes'* mentioned by Damschroder et al. (2009), who argue that the characteristics of those involved need to include traits such as *'tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity [and] innovativeness' (p10).* People in BME communities, like others, may well have all of these traits, but the bigger issue for PPI work involving people with cancer might concern the stigma associated with the disease in BME communities (Elkan et al. 2007).

Finally, the broad construct of 'individual identification with organization' concerns:

> how individuals perceive the organization and their relationship and degree of commitment to that organization. These attributes may affect the willingness of staff to fully engage in implementation efforts or use the intervention.
>
> (Damschroder et al. 2009, p10)

Within the literature there was a strong case demonstrating a neoliberal agenda in healthcare. This point is relevant because the literature on healthcare demonstrated that rapid reshuffles of PPI structures were interpreted as an indication that something unclear was steering involvement initiatives. The changes also destabilised people's understandings of what government was trying to do, by diverting attention away from

universal healthcare and its collectivist origins. The GEM report (2015) however, has shown how the agenda for PPI in research is strong and has a clear sense of direction. Thus, the effect on the ground for those conducting research, those engaging in PPI work and importantly those involved in developing PPI on research outcomes feeds off this strong steer and helps to generate a common starting point for everyone involved. The only data which reflected this was the work of Example 2: Cancer Survey. Steven described how he was invited through his network to attend an All Party Parliamentary Group on Cancer to discuss what the survey had generated. He discussed how satisfied he felt about the work and also of the network organisation which he belonged to.

The effect of the domain of individuals involved, for understanding the impact of PPI on research outcomes, is complex. The meshing of values, pragmatic knowledge, the case of representation, the problem of stigma and clarity of involvement efforts all fall within this domain.

Table 29 - Evaluable characteristics of the individuals involved

Characteristics of individuals involved	Evaluable outcomes
Knowledge and beliefs about the intervention	What are the intrinsic values of PPI on research outcomes? Who is selling the intervention and who is listening? How did the dissemination event broaden somebody's thinking about PPI and the usability of the findings presented?
Self-efficacy	Who is involved? What is their background on PPI on research outcomes? how representative do they feel to meet the outcome? How confident are they that they are the right person for the role to reach the PPI outcome?
Individual stage of change	What training is needed for the individual to make the PPI outcomes flourish? How enthusiastic are they about the outcome?
Individual identification with organisation	How willing are people to represent the organisation? What effort are they actively putting in to achieve the outcome of PPI?

Other personal attributes	How tolerant/competent/innovative are people towards change?

Domain 5: Process of implementation

As mentioned above, the main aim of the current study was to consider how the impact of PPI on research outcomes might be better understood. Thus, the domain of the *Process of Implementation* is highly relevant. For Damschroder et al. (2009) it concerned four ingredients, planning, engaging, executing, and reflecting and evaluating. The latter point being significant for the current study as it concerns recognising the impact of PPI on research outcomes. They argued that:

> Successful implementation usually requires an active change process aimed to achieve individual and organizational level use of the intervention as designed. Individuals may actively promote the implementation process and may come from the inner or outer setting … The implementation process may be an interrelated series of sub-processes that do not necessarily occur sequentially. There are often related processes progressing simultaneously at multiple levels within the organization [Pettigrew et al. 2001]. These sub-processes may be formally planned or spontaneous; conscious or subconscious; linear or nonlinear, but ideally are all aimed in the same general direction: effective implementation.
>
> (Damschoder et al. 2009 p5)

Damschroder et al. (2009) state that for the *'planning'* construct it is concerned with:

> the degree to which a scheme or method of behaviour and tasks for implementing an intervention are developed in advance and the quality of those schemes or methods. … The plan can be formal or informal but should consider all salient contextual factors–both modifiable and non-modifiable.
>
> (Damschroder et al. 2009, p10)

Planning links to the factors of PPI concerning *'PPI in dissemination'* and *'PPI in implementation'* found in the data. These two factors were the only two themes which appeared to have a direct impact on research outcomes. They were both linked by the participants to tailoring messages and all people affected needing to work together. Linked to this construct was *'executing'*, which for Damschroder et al. (2009, p10) signalled *'carrying out or accomplishing the implementation according to plan'*. Existing research also suggest that this is a challenge in PPI. In the literature, Graham

et al. (2006) found at least 29 terms that refer to acting on findings; this presented a challenge for researchers and policy makers in applying new knowledge and how the terms differed slightly in meaning. For example, knowledge transfer represented the process of moving research-based knowledge or ideas from one area to another, supporting a culture of evidence-based decision making in healthcare (LoBiondo-Wood and Haber 2005), suggesting that knowledge can be 'rolled out'. But the knowledge-base for healthcare is diverse; from health management, health policy makers, through to clinicians, patients and the public, and the nature of these 'agents' is fragmented across healthcare (Walker 2007). There were reasons offered about why knowledge transfer presented difficulties. Including, knowledge being 'sticky' or difficult to share beyond the immediate setting (Szulanski 1996; 2000). The knowledge may also lead to problems associated with 'absorptive capacity' when trying to transfer it to healthcare staff (Cohen and Levinthal 1990), implying the new knowledge may not suit the staff or the setting in which it is being offered.

The data reflected these points in places. The six impact examples in chapter seven demonstrated what change had taken place as a result of the PPI in the research study. It was striking that (in the PPI factor of '*dissemination*') participants described the limits of academic dissemination in all of these studies (i.e. 'planning' versus 'actual executing'). They stated that journal papers made very little impact but preparing information widely for a variety of people and using the help of patients and the public in the dissemination process did make an impact.

This point was also made by Delphi panellists. Clarity between dissemination and implementation was achieved via these examples, which show that dissemination was seen to be about reporting and planning what to do next, whilst the implementation factor of PPI concerned action and actual change – research *outcomes*. In chapter five, Janine (a researcher) spoke about how her Palliative Care study (Example 3) work was making good progress with major policy attention, yet Patsy (a stakeholder working in a hospice) argued that, for her, it was one study and that was not enough to change practice in her hospice. Thus, the idea of knowledge transfer is sensitive to wider research in the field: only when there was evidence of alignment (in this case, the alignment of highly sensitive issues to their practice), would Patsy's hospice adopt

Janine's findings. Whilst these examples demonstrate that PPI was part of the study it also demonstrates that PPI had little influence over practice change because ultimately knowledge needs to be assessed against other salient issues.

Damschroder et al. (2009) state that *'engaging'* concerned:

> Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modelling, training, and other similar activities. Engaging members of teams tasked with implementing an intervention (or to be 'first users') is an often overlooked part of implementation… It is vital that early members are carefully and thoughtfully selected or allowed to rise naturally.
>
> (Damschroder et al. 2009 p11)

They identified four types of leaders to engage: *opinion leaders*, *formally appointed leaders*, *champions* and *external change agents*. Opinion leaders for Damschroder et al. (2009, p11) are: *'formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention … experts and peers'*. The formally appointed leaders are: *'Individuals from within the organization who have been appointed with responsibility for implementing an intervention'* (p11). Engaging champions concerns:

> Individuals who dedicate themselves to supporting, marketing, and driving through an [implementation]…A defining characteristic of champions is their willingness to risk informal status and reputation because they believe so strongly in the intervention
>
> (Damschroder et al. 2009 p11).

Lastly, external change agents are: people from outside the organisation *'who formally influence or facilitate intervention decisions in a desirable direction'* (p11).

Not surprisingly, collectively there was a feeling across the participants that the *'significance of power and leadership'*, or input from particularly influential individuals, could enhance the likelihood of achieving research impact. The data confirmed that leaders were thought to be a variety of different types of individuals ranging from expert cancer patient ambassadors, to cancer charity patrons, as well as celebrities living with cancer. The more conventional 'top-down' leaders readily

associated with healthcare change were also discussed, such as: cancer 'tsars', government health officials, cancer policy-makers, cancer researchers and NHS cancer service managers. However, the former group (expert cancer patient ambassadors, cancer charity patrons and celebrities living with cancer) can be identified as 'new leaders' in implementation, a term borrowed and adapted from Kelleher's work on 'new social movements' (2001).

It seemed that several patient participants aspired to and took steps to become these new leaders; they discussed how they regularly checked their smartphones for requests to join new research trials as co-applicants. They had technology *savoir-faire*. Some even wrote their own personal blogs about their input in health research. Some were avid Tweeters using the social network Twitter and had a large group of followers (people who had chosen to read their Tweets). In some examples, they had enlisted mass media support. They had highly visible profiles in PPI work, often supporting several studies at one time, and had enthusiasm and support to influence decision-making. One patient described how he had successfully influenced decisions as he was invited on more than one occasion to speak at the All Party Parliamentary Group on Cancer.

New leaders have emerged from outside of the traditional forms of management and leadership found in the public sector. These opinion-formers showed strong personalities after their cancer treatment had finished. Perceptions of patients and policy makers suggested that powerful and high-profile personalities like expert cancer patients/carers had a role in policy making but it is difficult to draw any concluding ideas about PPI activities that are appropriate and effective for policy development (Conklin et al. 2012).

The construct of '*reflection and evaluation'* for Damschroder et al. (2009) was about being on top of:

> quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.
>
> (Damschroder et al. 2009 p11).

A major gap in information about the evidence base concerning the impact of PPI on research outcomes was identified about reflection more specifically by Wilson et al. (2015). Furthermore, Wilson et al. (2015) and Daykin et al. (2007) identified that a longer time period was needed to understand and assess the impact related to PPI on research outcomes.

In relation to the evaluation point by Damchroder et al. (2009), one distinctive aspect of PPI as a complex intervention is that it could help bring a unique focus to implementation work, as patients and the public remain patients and the public, even when researchers move on to new ventures, thus the current author proposes evaluation for PPI to be carried out at different stages. Brocklehurst et al. (2017) argued that:

> ...[guidelines and frameworks] can help to understand the conditions or features which support intervention effectiveness, its implementation and ideally, how to achieve sustained practice change

(Brocklehurst et al. 2017, p333).

This could mean that by following implementation guidelines during research conduct (pre-implementation stage) there are opportunities for up-to-date knowledge and the iterative application of information about knowledge translation, exchange and transfer. Therefore, impact can be assessed and traced more easily as the impacts emerge over time and the perspectives remain fresh. In the current study, data demonstrated that the impact of PPI on research outcomes is assessable in at least four stages.

Following Rivera et al. (2017) who suggest that impact of research in general can be assessed in the short, medium and longer term, the impact of PPI could also be mapped against a similar time line. ‘Pre-implementation’ could be a suitable first point to assess the impact of PPI on research outcomes i.e. studies which are presenting similar outcomes to Example 1: Oncology Consultation Tool study where a PPI group has dissolved and the study has ended. Further evaluation of PPI on research outcomes could be formed when partial implementation is observed, e.g. when some

recommendations of a study have been taken up but other recommendations have not i.e. the Example 4: Prostate Cancer study. Then more evaluation can be carried out when new implementation work is being achieved i.e. the Example 5: Cancer Genetics study and Example 6: LGBT Cancer study both of these groups had an active group of patients supporting the implementation work – this would fall under the 'during implementation stage'. Finally, to consider the contribution post-implementation, longitudinal work could allow PPI to be assessed as impacts emerge over time (Rivera et al. 2017). This was the stage Example 2: Cancer Survey and Example 3: Palliative Care was at and these studies had with their PPI groups moved into a new phase of work.

There are obvious aspects attached to CFIR model of evaluation proposed that need careful consideration, such as who would conduct the evaluations, who would fund the evaluation, and for how long the evaluations on PPI would continue. However, currently, with the duty and ambivalence placed on PPI, the idea of the evaluation of PPI and its outcomes as a complex intervention requires resources, commitment and time. The domain of Process of Implementation is therefore highly important for the study of PPI (as a complex intervention) for achieving understandings about the impact of PPI on research outcomes.

Table 30 - Evaluable characteristics of process

Process	Evaluable outcomes
Planning	How messages have been tailored for implementing PPI on research outcomes Knowing the timing for evaluation How needs have been met How goal have been achieved
Executing	Should executors of change be direct/indirect
(E)- Opinion leaders	Blogging, tweeting about the intervention, How many tweets/retweets have occurred.

(E)- Formally appointed leaders	What is the style of leader, the method of leading and sharing success.
(E)- Champions	What authority/credibility do they have?
(E)- External change agents	What risks they are willing to take/have they taken for the intervention? Balancing a space for working in and yet being physically close enough to the implementation process
Reflections and evaluations	Is the evaluation pre, partial, during or post implementation evaluation. Where on Rivera et al. (2017) table do the outcomes sit? Goal progress

Conclusion

The discussion in this chapter offered an original contribution to knowledge in three ways: 1) demonstrating that PPI can be considered as a complex intervention (Craig et al. 2008); 2) therefore, as a complex intervention, PPI can be evaluated using the CFIR (Damschroder et al. 2009) and showing evaluable PPI outcomes; and 3), by focusing specifically on the domain of process of implementation, we can develop improved understandings about the impact of PPI on research outcomes. In turn, this allows the advancement of PPI and implementation theory in new directions; specifically, in terms of impact of PPI on research outcomes.

Using mixed methods data about perceptions of impact of PPI on research outcomes, the thesis shows in principle, how PPI can be evaluated using the CFIR model. Given the aim of this PhD was to consider PPI on research outcomes specifically, the discussion here draws attention to PPI on research outcomes which can be obtainable/observable via the domains of intervention characteristics (outcomes listed in table 26); outer setting (outcomes listed in table 27); inner setting (outcomes listed in table 28); characteristics of individuals involved (outcomes listed in table 29); and process (outcomes listed in table 30). The third original contribution concerns the fifth domain of process of implementation. This study has found that to evaluate the impact of PPI on research outcomes, evaluators need to be sensitised to chronology because the very nature of research is ongoing, thus context will change and may become favourable or unfavourable towards implementation efforts, and the outcomes of PPI are changeable because they respond to context. The essence of PPI on research outcomes concerns this domain more than the other domains because currently there

are no tools for specifically assessing the impact of PPI on research outcomes and this domain of the CFIR draws attention to how context, mechanism and outcomes interact.

The CFIR offers insights into PPI-related expectations and outcomes for those who are carrying out the intervention and evaluation and of those affected, such as end users involved and patients and the public. Thus, the CFIR provides a comprehensive taxonomy of influences which might affect how complex interventions such as PPI might be assessed for evaluation.

The caveat to PPI being a complex intervention and applying the CFIR is that PPI aims and objectives must be explicitly and specifically defined from the outset. This is raised here as a caveat because it is acknowledged that PPI is sometimes carried out for its own sake rather than as an intervention with intended outcomes. Thus, point four about what outcomes the evaluation is assessing raised by Craig et al. (2009) will need careful thought if adopting PPI as a complex intervention.

Although PPI as a complex intervention suggests a macro-level identity, at a closer level of scrutiny, the analysis demonstrates highly sensitive micro-level cohesion, and meso-level logistics. The macro factors at a deeper level concern: the values placed on PPI by government and funders; how PPI is sold as the answer; the relative advantage placed on PPI; how adaptable the PPI plans are to suit and trial PPI work; having the funds to pay for it in the first place; and managing it in a cohesive way.

At an outcomes level, the ability to assess the impact of PPI becomes complex because sometimes the intervention is not defined, and assessment becomes weak. Damschroder et al.'s (2009) constructs of adaptability, complexity and trialability helps PPI to be recognised as a complex intervention and complements Craig et al.'s (2009) definition of complex interventions. The participants did not mention complex interventions explicitly but judging by how they have described PPI and its tricky strategies, mixed values, influential components, needs and problems, they do all imply the hallmarks of a complex intervention. These points lead (or not) to impact

(the outcomes). Undoubtedly logic tells us that the CFIR suits complex intervention evaluation ideas because PPI is confounded by context process-and outcomes-related-aspects.

The outer setting for PPI as a complex intervention in research can be summarised as external issues which are outside of the control of implementers. Patient needs and resources, cosmopolitanism, peer pressure and external policies are investments for PPI. These investments are channelled in the form of PPI leadership and strategic direction holding onto PPI's values as an anchor for its investment efforts. Without resources and political backing, and power and leadership, PPI efforts are sensitive to failure and tokenism.

The twelve constructs of the inner setting for PPI as a complex intervention in research offered reflections of individuals involved and the mixing of values and pragmatic knowledge, the issue of representation, the problem of stigma and clarity of involvement efforts all affect this domain.

Lastly, the domain of process of implementation is highly important for the current study of PPI as a complex intervention for achieving research impact. When research ends and implementation begins, resource allocation is a sensitive topic. The consideration of impact of PPI on research outcomes could send a beacon of confidence to all involved in the process, because the public and patients have been engaged/involved in the design of implementation plans. Boutin et al. (2017) argues that a number one priority for culture change requires stakeholder organisations to effectively communicate change messages, whether positive or negative. This includes whether the issues of change concern addressing a waste of resources or endorsing a message, a particular new policy or a research study offering investment. There are no doubt many professed benefits associated with the assessment of research impact more generally, including: (1) assessing the quality of the research and its subsequent benefits to society; (2) informing and influencing optimal policy and funding allocation; (3) demonstrating accountability, and the value of research in terms of efficiency and effectiveness to the government, stakeholders, and society;

and (4) maximising impact through better understanding the concept of, and pathways to, impact (Rivera et al. 2017).

However, this research was specifically about the contribution that patients and the public made to research impact. The lack of clarity in this area has given rise to a poorly monitored and complex fields of activity, leading to unclear expectations from research funders, policy makers, host organisations, researchers, health activists and volunteers (Madden and Speed 2017). This poses a threat to the impact of PPI on research outcomes because if the field is not carefully monitored, PPI efforts will fail. In this study, Damschroder et al's (2009) framework was used retrospectively. There are some limitations to using the CFIR retrospectively and two criticisms are offered here.

First, it has been suggested that the CFIR model does not help researchers decide or prioritise which aspects of an interventions to evaluate (Williams 2011). Instead, the model suggests that equal importance is placed on all domains and constructs, leaving the researcher to approach the CFIR in a 'pic 'n' mix style', which Williams suggests is therefore a limitation of CFIR.

The second, related criticism concerns questions of transparency and the justifications used for adopting specific CFIR constructs and domains. In a review looking at the ways in which the model has been used, it was found that researchers had used a variety of constructs for evaluation (Kirk et al. 2015). Furthermore, they found that these researchers often offered little description of methods or logic for selecting particular CFIR constructs or domains. Thus, the reasoning behind use of specific domains and constructs is sometimes lacking and needs to be made explicit (Kirk et al. 2015).

This should not necessarily be seen as an inherent flaw of the model itself, however, and Damschroder et al. (2009) recommend and invite discretion in the selection of domains and that researchers using the model should explicitly report the decision and rationale for selecting domains and constructs. This suggests that the omission of reporting noted by Williams (2011) sits with individual researchers applying the CIFR and not within the CFIR model itself.

In the current study it has been made clear that for PPI in research, the CFIR domain of 'process of implementation' is highly important to help with evaluating the impact of PPI on research outcomes and hence to be prioritised.

We now know, through accounts and perceptions of the participants from this study, to what extent PPI made a difference to research outcomes, which was initially a gap in knowledge (Mockford et al. 2011). We also now know, through the participants' accounts, the extent and types of factors which have affected the implementation of research findings into policy and practice, which the literature review had also highlighted as absent (Staniszewska, 2011). Furthermore, we now understand at an implementation level, what and why difficulties are present for PPI evaluation. This study was designed to address these knowledge gaps and to some extent has now revealed new information about how to evaluate the contribution of PPI to research outcomes. The final two chapters offer a conclusion, starting with a reflective account of PPI in this present PhD study.

End user involvement influencing this stage

September 2018 raising awareness of the current study and its findings. After submitting the PhD and before the viva, involvement in the form of **consultation and engagement** with an existing Leicester, Leicestershire and Rutland PPI group of older people at the University of Leicester occurred, 10 patients and the public were present.

The overall idea of using Damschroder et al. (2009) was presented to the group, and a general discussion about the domains and constructs was offered. The group were invited to constructively critique the model for evaluation purposes. They were enthused by the idea of how helpful the CFIR was and agreed that the model works as a way to evaluate PPI generally. They discussed other ideas for disseminating this research study including a public lecture on the topic and academic publications.

Chapter Nine: Reflections on end user involvement in this PhD

This chapter reflects on the end user involvement in this PhD study. As a reminder, in the critical narrative review (chapter three), the Guidelines for Reporting Involvement of Patients and the Public 2 (GRIPP2) (Staniszewska et al. 2017) was described as a way forward for helping to achieve better quality in the reporting of PPI in studies. GRIPP2 was developed to help researchers to report on how PPI worked, in what context, for whom and why and is itself based on some very recent understandings that have emerged in published research. Whilst the majority of this present study was completed prior to the publication of GRIPP2, deploying it as an assessment tool following the research does provide a helpful way to evaluate how involvement has shaped the present study.

In the critical reflection section of their paper, Staniszewska et al. (2017) invite researchers to: '*Comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience'* (p.4). Taking this steer, the author has decided to use this present chapter to explore some of her own questions in relation to PhD involvement in this study:

1. **What** is role of 'PPI' in a PhD?
2. **Who** are the people involved in a PhD study and can a mix of lay and professional knowledge work?
3. **Where -** how did I find the people to take part in this PhD study?
4. **Managing -** how is PPI in a PhD managed when there are resource implications?
5. **When -** the frequency of PPI encounters in a PhD study and the implications of time.
6. **How** was my experience unique?

The chapter is organised around these questions, outlining the issues faced, resolutions taken and offering suggestions for how PPI might further be improved.

Before commencing this process of reflection, it is worth restating how involvement has shaped this research and the nature of the impact of PPI on this study. Table 6 in chapter four demonstrates that the involvement of end users has had an impact on the current study in a number of ways, notably through the research design, methodological decision making and to aid conceptual clarity. Involvement occurred during key phases including: study aims development; research design for both phases; piloting questions for fieldwork in both phases; analysis in both phases; and discussion planning. Involvement encounters occurred mostly in the form of face-to-face meetings and sometimes remotely (over email and telephone). Overall, 13 involvement events occurred over the course of the study (on average, twice yearly). All involvement was at a consultative level (Hanley 2005).

What is the role of 'PPI' in a PhD?

By its very nature a PhD requires researchers to work independently (Dunleavy 2003). Yet PPI in research is about working with people (INVOLVE 2012). From an epistemological point, this can result in a difficult balance between the process of independent thinking whilst working with end users. Linked to this were questions about who the genuine end users were i.e. patients and the public using services and those working in organisation (Tarpey 2013) and how they could shape this work without compromising the need for independent doctoral research. As Dunleavy (2003) reminds us:

> 'Independent critical power' is almost as vague a criterion as 'originality'… presumably the idea here is that the thesis author shows … some significant theoretical or thematical argument …from a perspective of her own.
>
> (Dunleavy 2003, p23)

Liabo et al. (2018) argue that PPI has inherent power imbalances and that to begin to solve these requires patient partners to be made more than mere data providers. Instead, '*patient partners are included at all stages of the research'* (p1). In this study, this presented particular challenges because originality required independence, yet involvement required levels of co-dependence. There is no guidance about how to resolve this, so the idea of what constitutes 'meaningful and relevant' involvement was considered here (Wright et al. 2010). Thus, information that was provided about this PhD at involvement events needed be concise with a focus about the purpose. It

was explained at the beginning that in this study '*PPI is not like involvement in funded research studies because it is a PhD research study and today help is needed to understand your thoughts on…*'. This approach worked mostly for the current study. But there were times when influential thoughts became difficult to disentangle because many ideas were discussed at involvement workshops and how some of these ideas could shape the thesis. For example, when data collection phase 1 was completed, three 'making sense of the data' workshops were run. The sole purpose was to offer an opportunity for people to comment on the early development of codes formed (see Appendix 7 and pg. 97-99) and these workshops helped me to analyse and interpret what the data meant. However, when the data were presented to end users (researchers and academics), it became quickly apparent that the data were too broad, which would not help in evaluating of impact of PPI.

Having been immersed in data until that point, some questions triggered a discussion amongst academic end users which later led to ideas about regarding PPI as a complex intervention (Craig et al 2008), but at the time, complex interventions were not considered in the discussion explicitly. On reflection these workshops helped with conceptual mapping. The idea of balancing 'independent thought' and PPI in PhDs requires some attention, as the number of PhD studies featuring involvement continues to grow (e.g. Thompson 2009 and Robinson 2015). In the case of both Thompson and Robinson's studies, the same group of people remained throughout as part of the involvement process, so input was described as tense at times, and perhaps even harder to balance than for the current study. In the current study, as end users were potential patients, researchers and stakeholders, there needed to be balance of perspectives, thus it was less of a difficult issue to manage, but for PhDs with considerably more involvement, this may become a more complex challenge. However, mixing lay and professional views brought its own challenges, discussed next.

Who are the 'PPI' in a PhD study and can a mix of lay and professional knowledge work?

An end user can be someone who is likely to make use of the study results. These are people who are often most affected by the research, including patients and healthcare professionals (Farrington 2016). Therefore, for the current study the people most

likely to be affected ranged from academics to patients and the public. But the problem with the former group at an involvement level meant there was danger that 'involvement' could be misunderstood as a 'research seminar' where academics would attend the workshop with a set of expectations different to my own. Despite explaining in emails that the workshop was about addressing the involvement element to the PhD, there would be conversations with colleagues about what they had thought the workshop was about and what it was actually about. Therefore, it was sometimes difficult to explain to colleagues with mutual interest on the topic that their input was at an involvement consultation level inviting deliberation on whatever was planned. Consultation concerns asking people for their views and using these views to inform your own decision making (INVOLVE 2012). This differs from a traditional research seminar and reconceptualises the role of an academic as an 'end-user'.

Similarly, patients and members of the public where also confused when they would hear that academic researchers were part of the involvement process for this work because it was sometimes questioned how professionals could offer an 'end user' view about a topic which broadly affected PPI, because in their minds involvement was about patients and the public contributing and not 'professionals'. Here the arguments of lay verses scientific knowledge arise (Popay et al. 2003) and feature within the PhD study – another point not recorded anywhere in the literature. More work is needed to establish the challenges relating to this point.

Where did I find 'PPI' for this PhD study?

As no guidance is available on where to find suitable end users for a PhD study, the following initiatives were taken. Before involvement was planned with patients and the public, the opportunity to input this work was made possible by a patient forum the researcher had set up for her professional work as PPI adviser. Thus, patients and the public were already interested in the impact of PPI and this research. Some were affected by cancer research themselves, they were all geographically close in proximity, willing to help, interested in the study and available to offer comments at a given time (Dörnyei 2007). In research terms this approach matches convenience sampling ideas (Taub et al. 2014). Over the course of the study over 70 patients and members of the public have been part of involvement processes but for resource and

time constraints, most participants have come from one region - the East Midlands. Thus, a criticism of this approach may concern how representative these people are (or not) (Martin 2008b) and their involvement is therefore highly likely to generate localised understandings (Veronesi and Keasey 2015). Despite this, localised knowledge can be beneficial. INVOLVE itself recognises the importance of local level work: *'INVOLVE takes forward its work by: working with others at a national and local [level]…'* (NIHR 2016). For the current study this suggests that even highly localised involvement is useful and important because it offers some perspectives beyond the researcher's.

Similarly, 'end users' were also academics who were also found locally, via university research networks across the two local universities (DMU and University of Leicester). Over the course of the study around 45 academic researchers have attended workshops (in addition to those who featured as researcher interviewees in the current study). Many end users were already known professionally to the researcher and therefore professional contacts offering an 'end user' perspective may have been as a result of people feeling obliged to help by attending out of goodwill and collegiate support rather than them being genuine 'end users' of cancer research. But academic discussions did extend the scope of the study through insightful contributions, e.g. especially how the REF impact definition was of primary concern for those working in academia. Therefore, these types of contributions were valuable despite localised input for a study which potentially has national relevance.

Managing PPI in a PhD when there are resource implications?

Managing a PPI process in this PhD concerned thinking creatively with the resources available. Involvement in this work was carried out without a tight budget. This meant that university rooms were hired for free and involvement sessions often ran during lunchtime when workshops were taking place within the university setting.

Where possible 'piggy-backing' on existing PPI events was carried out (Parker and Tritter 2006). For example, the patient and public *'making sense of data workshop'* was a final afternoon session at a pre-existing PPI event that the researcher had co-convened. As the workshop was not part of the official event, in the event email

correspondence sent out to people who had said they were attending, it was explained that a workshop was taking place after the event and people could leave after the session before the workshop. But most people stayed and because the event covered their expenses, the workshop was made possible. No refreshments were provided at any time of the involvement during the PhD. The lack of resources argument is well grounded in the PPI literature (Florin and Dixon 2004). Based on this experience it would be recommended that higher education institutions consider setting up resources for PhD students to cover the costs of PPI. PPI is increasingly being taught in HE degrees at graduate and post-graduate levels (Fundamentals of Research Module handbook (UOL) 2018) with a central message that research must have PPI, yet the lack of resources to support PPI work is commonplace.

When – the frequency of PPI encounters in a PhD study and the implications of time?

Without the PPI in this study – the study would have been submitted earlier. The implications of the time that PPI takes, must not be taken lightly. Time pressures faced by researchers is a well-known barrier for PPI (Florin and Dixon 2004; Pandya-Wood et al. 2017). It is important to note that the length of time taken to complete the current study has been eight and a half years. Having taken two maternity breaks (2012 and in 2015, 27 months in total) contributed to a feeling that inviting input from end users was a burden on me as a researcher (RDS PPI handbook 2014). This was especially the case after the second period of leave.

However, having committed to the process, PPI needed to be carried out. I would argue that research institutions need to fully consider how the PPI in the research agenda links within the Athena Swan charter. Athena Swan is an equality challenge that UK universities are embracing (Athena Swan 2018). If research is increasingly expected to have PPI, then women researchers will have extra challenges. A genuine problem I experienced was managing this research with PPI and balancing career breaks to have children. The institution I am part of was accommodating towards this, but PPI does exacerbate the time pressures already placed on women having career breaks and conducting research. Supervision notes from November 2016, March 2017 and June 2017 discuss involvement and maternity breaks and the added implications of time.

How was my experience unique - a symbiotic relationship?

An important issue which was raised in GRIPP 2 concerned the 'context' of the study (Staniszewska et al 2017). When the study started in 2009, very little was known about the impact of PPI. But particularly after the phase 2 data were collected, PPI in research was becoming well-grounded in the literature. New publications were more frequent and funded national studies about PPI and impact were starting to publish. All of these aspects were exacerbating the pressures of a part-time nature of the PhD. But the involvement workshops needed to happen and required careful planning in personal PhD time. However, on a positive note as more PPI related publications were coming out, interest in this study was also growing. At the last two involvement workshops entitled '*the discussion – seeing the wood from the trees'*, 24 people attended, which suggested increasing interest.

End-user involvement in research helped to heighten researcher awareness and organise the 'messy data' in a useful way. Certain aspects could only be dealt with at the right times (after 'end user' involvement had taken place). For example, there were times when I wanted to make my own research judgements but having committed to end-user involvement and its values, certain tasks could only be dealt with after a discussion with people who were likely to use the work.

Therefore, I argue that being a PhD student researcher studying PPI and working as a research practitioner advocating for PPI in research studies, combines to make a unique experience. It was clear that there was a symbiosis of the two roles relying on each other. i.e. PPI with patients and the public being made possible at workshops, as a result of my role as PPI lead, and the role of PPI lead allowing me to ask the question in the PhD which mattered to those on the ground conducting studies. This is a highly privileged and unique position for a PhD study.

Summary

In this chapter I have described a reflective account of how PPI has affected the research process and how PPI problems in this study have been and could be further addressed, so that future PhD researchers can consider how PPI can feature in their own PhDs and how HE can support this. By answering some pertinent questions, I

have reflected on my unique experience. Firstly, a reflection is offered about independent study of a PhD on PPI which required a level of co-dependence. Guidance is lacking and is needed to help future PhD students on how to achieve a balance of independent thinking but also to consider what is meaningful and relevant in a PhD about 'PPI'. I also argue that in a PhD a mix of lay and professional knowledge from PPI is helpful as it offered insights about different end users views. It is clear that scientific and lay knowledge differences may arise as a result. I argue that highly localised 'PPI' for this PhD study was suitable despite its national relevance. I also reflected on how to manage PPI in a PhD when there are no resources. By thinking creatively, I was able to overcome challenges about expenses which meant that patients and the public were not left out of pocket. A part time PhD on PPI studied by women who take career breaks demonstrates that universities need to carefully consider how PPI efforts are encouraged within their institution's Athena Swan equality challenge. Finally, I argue that my experience was unique because of practicing and studying PPI simultaneously. In the next chapter, a conclusion of the study is offered.

Chapter Ten: Conclusion

Introduction

This concluding chapter will consider how the current study has achieved its aim of advancing knowledge about how to evaluate the impact of PPI on cancer research outcomes. It will also consider ways that the study can be used and applied to build further knowledge. The aims of the study are re-stated, followed by a summary of how these aims have been met. A discussion is offered about key findings and their implications for future research and governance. The limitations of the study are considered concerning the location, methods and the lack of BME participants. The future directions of publications and further research recommendations from this work are mapped out. Lastly, an autobiographical account is presented considering how this present doctoral experience has shaped the identity of the author, as an independent researcher and as a person.

How the aims and objectives have been met

Knowledge about how to evaluate the impact of PPI has been gaining momentum across healthcare (Mockford et al. 2011). However, whilst some progress has been made to understand the impact of PPI on research processes (Staley 2009), little work has considered the effects of PPI on shaping the outcomes (Staniszewska et al. 2011). Some authors suggest that PPI has the traits of a complex intervention because PPI has various contexts, mechanisms and outcomes which require simultaneous evaluation (Brett et al 2014a). But at a research outcomes level, there are insufficient understandings about longer-term effects of PPI on research outcomes (Wilson et al. 2015). This study set out to explore these gaps. Specifically, this exploratory and inductive social science research study aimed to advance knowledge about how to evaluate the impact of PPI on cancer research outcomes. The objectives were:

1. To explore perceptions of and experiences relating to the impact of PPI on research outcomes amongst patients, researchers and stakeholders involved in cancer research

2. To identify factors which affect the implementation of PPI informed research findings in policy and practice

3. To enhance and refine understandings of factors that shape the impact of PPI

4. To enhance knowledge and understanding about the link between implementation theory and how evaluation of impact of PPI on research outcomes might be achieved.

Data from 23 interviews and a Delphi survey identified common factors which acted as barriers or facilitators towards PPI having an impact on research outcomes: 1. 'Wanting to make a difference'; 2. 'PPI in research processes'; 3. 'Information and Communication Technology (ICT)'; 4. 'Networks'; 5. 'Dissemination'; 6. 'The significance of power and leadership'; and 7. 'Resources and the political context'; 8. 'PPI in commissioning'; and 9. 'PPI in implementation'. The data demonstrated that PPI context and PPI processes were vital components towards achieving PPI outcomes.

Following the interviews and Delphi, the identification of these contributory 'factors of PPI' were further analysed which resulted in six examples of PPI. These six examples offered insights into how such impact can be evaluated at different stages across different research studies. Across the six examples a journey was observable for stages of when evaluation of PPI may be possible. This helped to consider the evaluation of impact of PPI in four distinct ways, these were: pre-implementation, partial-implementation, during-implementation and post-implementation-evaluation. Thus, the adoption of a mixed method, sequential design, contributed significantly towards the staged evaluation of PPI because the factors of PPI were combined from interviews and the Delphi survey, suggesting that mixed methods were necessary to gain a stronger insight into what can be evaluable about PPI on research outcomes. The six examples from Phase 1 only became notable once data from Phase 2 were found to feedback into Phase 1 analysis.

To offer an original contribution to knowledge, this study has argued first that PPI can be considered as a complex intervention (Craig et al. 2008). Secondly, that as a complex intervention, the impact of PPI on research outcomes can be evaluated using the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al. 2009). Thirdly, using the CFIR, particularly the domain of 'Process of implementation', helps to draw out new theoretical insights about the evaluation of

impact of PPI on research outcomes by enhancing understandings about PPI implementation and evaluation theory.

Implications of the current study on future researchers

PPI has been characterised as a complex intervention (Brett et al. 2014, Wilson et al. 2015) This thesis has extended this idea to consider how we might evaluate the impact of PPI on research outcomes by applying it to the characteristics of complex interventions set out by Craig et al (2008). In this respect, evaluating PPI outcomes then allows for external issues (such as the funding made available for PPI) to be taken into account. However, in order to evaluate complex interventions, a framework is required that will take account of the many different interacting components. Whilst conceptual tools such as Normalisation Process Theory (NPT) have been suggested for its evaluation (Wilson et al. 2015), no previous study has used the CFIR as a tool for evaluating PPI.

The CFIR (Damschroder et al. 2009) is appropriate for the task of evaluation as it provides a taxonomy of evaluable phenomena which can be applied to PPI. The flexibility of CFIR is expanding and the CFIR is being adopted to study implementation science across healthcare more generally (Kirk et al. 2015). But its use as a tool for evaluation is still relatively new. Whilst the CFIR was not designed for evaluation, more recently, the utility of CFIR for rapid evaluation has been adopted (Keith et al. 2017) as well as for studying barriers and facilitators for collaborative work in care (Wood et al 2017). These two studies lend insights which further suggests its extended suitability for posing original ideas for PPI evaluation.

The evaluation of PPI using CFIR has flexibility and the component of flexibility is inherently present in the ideas of PPI being a complex intervention (Craig et al. 2008). Flexibility could concern exploring each domain and construct in turn, or it may involve using just a single domain, to help develop highly specialised knowledge about PPI. It may involve using a combination of pertinent constructs, depending on the PPI evaluation study focus. But according to the current study the CFIR will only be applicable if ideas of a complex intervention are applied first. This is because complex interventions, such as PPI, are a mixture of contextual and mechanistic

aspects that link to outcomes. Therefore, various outcomes of PPI can be generated by considering how the different domains influence each other.

In evaluation terms, whilst the CFIR can be used to evaluate PPI more generally, this thesis was only concerned with the outcomes of PPI. Despite this, constructs in the CFIR interact in rich ways and this means that PPI processes can also be evaluated within this model. For example, the 'characteristics of individuals involved' domain (i.e. a domain which could be described about values and norms people have) will be influenced by the 'outer setting' domain (i.e. a domain about socio political and economic context). Thus, whilst patients and researchers may hold strong values about PPI during a study, the impact of PPI is not guaranteed if the political culture of a country does not value or fund further resources to support PPI efforts. Thus, whilst outcomes of PPI might be limited, an understanding can still be formed about why the impact of PPI was favourable or poor. The CFIR can help to consider these aspects of PPI evaluation within one interacting framework.

Within the CFIR, the 'process of implementation' domain relates to the active change process where individuals interested in PPI may actively promote the implementation of PPI knowledge through planning and engaging with opinion leaders, change agents and champions of PPI to execute implementation outcomes. During this process, they would continually reflect and evaluate at different stages of the study. This is where evaluation theory in relation to the impact of PPI on research outcomes can enhance new knowledge by considering stages of evaluation and what might be achievable e.g. winning new funding because PPI was invested in even after an initial study might have ended.

In sum, if future researchers regard PPI as a complex intervention, then they will be able to evaluate PPI using the CFIR (Damschroder et al. 2009). But by focusing particularly on the domain of 'process of implementation', we can develop improved understandings about the impact of PPI on research outcomes specifically. In turn, this allows the advancement of PPI and implementation theory to take new directions; specifically, in terms of the impact of PPI on research outcomes.

Future researchers will need to fully consider before evaluation, what stages the studies needing evaluation are at, e.g. what previous work has already been carried out in line of the study being evaluated. If an entirely new area with PPI is being studied, researchers could plan when evaluation should occur before a study starts, as this will offer insights into the points of time where outcomes may be observable – this approach can help prospective planning too (Moore et al. 2015).

Future researchers also need to consider that staged evaluation of PPI in the way proposed here will have a further cost (Pizzo et al. 2014) and time implication already known (Ocloo and Matthews 2016). This study found four stages where evaluation could occur and in the real-world evaluation of PPI at different stages may not always be achievable because studies end, and researchers move on to new studies. Similarly, PPI groups might dissipate or for long period of time, there may not be any involvement (Evans et al. 2014) after a study.

But if cost and time are not an issue and if a PPI group is still active, then the evaluation process proposed in stages may help to distinguish the smaller achievements at suitable set points of evaluation. Researchers may be able to see, for example, that if a PPI group remains active even after the study ends, new outcomes of PPI may become observable, such as: developing a new research grant for further research; obtaining further funding; achieving policy attention; and ultimately seeing actual change. As Mc Kenna (2015) argues there is a reciprocal relationship between research impact and PPI, and increasingly with dominant systems such as REF, the impact of PPI on research outcomes needs to be made more visible.

Generally, PPI evaluations occur once at the end of an intervention study due to restraints on funding and time (e.g. Pizzo et al 2014), but PPI as an intervention needs to be understood as a unique intervention which requires commitment of multiple stages of evaluations, despite it adding further complexity to the intervention evaluation (Petticrew et al. 2015). As Petticrew et al. state, pragmatic solutions such as the one proposed in this study are worthy of full consideration in the absence of other suitable tools, especially given the overwhelming emphasis placed on the need for PPI in research (Madden and Speed 2017).

Future directions – facing forward

During the course of this study, PPI in health research has seen significant and sometimes serendipitous change. This section draws together some of the key future challenges and opportunities for PPI in health research by considering recent political and economic shifts, particularly in the context of neoliberalism, the integration of health and social care, financial austerity in the UK and Brexit.

PPI, both in the delivery of services and in research, takes shape within an NHS which continues to embody collectivist principles, but which is increasingly shaped by neoliberal notions of market competition, individualism and reduced government accountability (Baggott 2011). Neoliberalism, therefore, continues to be an important component in understanding PPI and its impact, because it shapes the social and political context within which PPI operates. As chapter two illustrated, the perceived 'democratic deficit' was one primary driver for an increase in PPI initiatives, with the accompanying argument that too many healthcare decisions were made in the absence of input from patients and the public. As a result, social movements and state structures, designed to help people become more engaged in shaping healthcare were catalysed (de Frietas 2017). However, as that chapter demonstrated, PPI was also seen as a way of legitimising a number of policy reforms that reflected neoliberal principles – the patient as a 'consumer' being a case in point.

Throughout recent history, UK governments have embodied varying degrees of faith in the power of localism to fulfil democratic engagement in healthcare. In neoliberal terms, this ostensible shift from central state to local decision making has been underpinned by a belief that individuals want freedom from the so-called 'nanny state' and the reduction in state interference in individual lives. However, these moves invite criticism from a number of perspectives, notably the absence of genuine power to affect change. For example, critics have pointed out that neoliberalism transfers the responsibility for entrenched and enduring social and health problems to individuals and away from the state (Kemshall and Wood 2007). Genuine democratic involvement is reduced, in favour of more narrow technocratic ideals, with the

government inviting people to provide insights into their health needs in order to shape services, without being able to shape strategy or priorities. This poses enduring questions about the purpose and impact of PPI more generally. Are patients and the public genuinely empowered to challenge health services, health inequalities and health priorities? Or are they merely 'accountable' agents, increasingly responsible for their own 'good' health behaviour and tackling social problems, without the corresponding power to do so (Feiler 2018)?

These questions hold resonance for PPI in research. It raises questions about whether people involved in research are really helping to challenge health services and health inequalities or are they simply justifying pre-defined health priorities (Bissell et al. 2018; Maguire and Britten 2017). The currently fashionable agenda relating to co-production in research allows patients and the public to understand that there are power sharing opportunities in shaping healthcare research, but without evaluating PPI in research it is difficult to know what impact this has.

Another development that warrants future attention is the increasing integration of social care and health at local and national government level. Health researchers are now likely to expand on their domain of study to embrace social care, and PPI will potentially therefore also become increasingly prominent in social care research. The joining of health and social care may change their relative status (perhaps by increasing the relative status of social care) and will allow for greater PPI opportunities. Mental health, social work and youth and community care are already becoming more pronounced in NIHR research. The new Department of Health and Social Care means that healthcare professionals and researchers may consider patient views in a more integrated way, for example delivering and evaluating social work interventions in primary care settings (McGregor et al. 2018).

These reforms also fit the recent government promises to increase NHS budgets in times of austerity, with its focus on health and social care. The government has set out a 10-year plan to improve services within the NHS with an increasing focus on technological innovation and preventative medicine (NHS England 2019). Ham and Murray (2018) argue that the focus of NHS reform should be kept on improving

population health in a measurable way and to reduce health inequalities through better stakeholder and public involvement. The issue of representation once again becomes important here. If the 10-year plan is to incorporate better public and stakeholder involvement, then the question of who is involved needs to be at the centre stage. As discussed in the early part of this thesis, PPI policies, especially in terms of holding healthcare to account, have been prone to almost constant upheaval and flux. One challenge for government in ensuring PPI representation might to embrace and enhance existing structures (such as Healthwatch) rather than destabilise them, unless there is a case for replacing them with something stronger and more representative. These debates also apply to PPI in research. As we have seen throughout the thesis, there has been a gradual shift towards the inclusion of the public and patients within established peer reviewed health research funding awards. As research priorities shift towards better understanding and evaluating preventative approaches and integrative healthcare, models for PPI will need to keep apace.

Of most importance in the current context is the looming challenge of Brexit. At the time of writing, the UK heads towards exit from the European Union with questionable clarity about our future relationship with the bloc. The challenges for healthcare, healthcare research and the role of PPI are bound up in this uncertainty, and it makes predictions of the future direction all the more difficult.

It is perhaps easy, in these macro debates, to lose sight of the importance of the voice of patients and the public. Yet, as has been argued throughout this thesis, these voices might be instrumental in helping to democratise and improve healthcare and healthcare research. Therefore, understanding how PPI in healthcare research works, and why it matters, remain central questions. These are the questions that have shaped this thesis and have guided its contribution to future research that seeks to evaluate the impact of PPI on outcomes.

Limitations of the study

Methodological limitations

Purposive sampling had advantages for phase 1 and the researcher's work within a Research Design Service offered a unique position from which to conduct this work.

All interviews were carried out regionally in phase 1. The researcher's professional knowledge and networks helped to find suitable national participants for phase 2 by targeting recruitment information. Thus, potentially suitable participants outside of these networks may not have engaged in study materials. To widen reach, the study materials were circulated by INVOLVE and CHAIN networks to achieve national publicity.

Links within the research field meant that some of those with whom there was contact with through work became participants, and their participation sometimes resulted into snowballing (Noy 2008). This was particularly the case with stakeholders. It needs to be acknowledged therefore that there may have been the potential for the obligation on people to participate (Feeley 2002). However, an environment was created which tried to ensure that participants felt comfortable with withdrawing from the study. In the Delphi survey a panellist who was expert patient did indeed leave the study after round 1. In an email correspondence outside of the Delphi process, he felt that the current study was not about cancer as he had thought initially and the focus around impact was too abstract for him. This was despite the attempts to ensure that the study information sheet was clear about the aims and focus. His experiences of cancer research were linked to very specific understandings about cancer trials and finding a cure. This example illustrates that patients did feel able to withdraw from the study.

There was one qualitative researcher in the Delphi survey who raised that they had found the process of the Delphi useful and successful, but interaction not fulfilling enough. This panellist would have preferred face-to-face consensus-forming. This point demonstrates that at least one person did feel able to voice criticism during data collection, putting aside the current researcher's relationship to them. In this situation, it was explained why the Delphi was selected, grounding the answer in the Delphi's cost effectiveness suitability and strengths, i.e. panellists being anonymous and not feeling pressured to answer in a particular way.

Diversity-related limitations

The researcher is a black woman with an Indian heritage. During the recruitment stage, active efforts were made to find participants from BME backgrounds to help understand if there were any different experiences amongst the participants based on their ethnicity (Dawson et al. 2018). No participants came forward from this group. One reason for the lack of BME patient and public participants might be because cancer can be stigmatised in BME communities (Jones et al. 2015) and because of this stigma they may participate less in PPI roles. In phase 1, all six patient participants came from a white background, and in phase 2, once again, all seven expert patient panellists identified as white, thus the sample does not reflect the various different subgroups of populations living in the UK.

Geographical limitations

Phase 1 of the study was designed to be East Midlands focused but phase 2, the Delphi survey, was national with a diverse mix amongst the 10 regions represented in the sample. Whilst the findings therefore present a valuable and valid account, the work was limited to England. Those working in the field of PPI evaluation elsewhere will find inevitable differences in the 'outer settings' of Damschroder et al.'s (2009) framework.

Despite these limitations to the work, the findings from this study have implications for further work. This next section explains some of these next steps.

Next steps and recommendations for future research

Dissemination is planned as follows:

Develop five journal papers: 1) an original contribution paper, advancing the field, which will apply the thinking of complex interventions and the CFIR (Damschroder et al 2009) and particularly how domain five process of implementation helps to focus understanding about the impact of PPI on research outcomes; 2) an epistemological paper on the tensions associated with conducting this study with end user involvement 3) a paper on PPI in research policy and GEM's critique and implications for addressing impact; 4) a methodological paper on the Delphi approach addressing

specifically the use of stimulus material; and 5) A paper on the synthesised definition of impact formed from the Delphi.

The findings from this study will be presented in print and oral form at local meetings and conferences to patients and researchers: local and regional organisations such as Collaborative Leadership of Applied Health Research and Care (CLAHRC and soon to be ARCs) and cancer charities. National audiences such as the NIHR impact working group, INVOLVE, funders, The GEM Review panel (at the Department of Health and Social Care), the National Institute for Health and Care Excellence (NICE) and Clinical Commissioning Groups (CCGs). International conferences will be targeted to generate international perspectives on the evaluation of PPI.

Recommendations for further research

Four new ideas for further research have been considered:

- Forming a definition of the impact of PPI for usability in the field was beyond the scope of the current study and therefore did not allow a determination of the applicability of the Delphi synthesised definition of impact (chapter six). However, there is potential for further study to develop a shorter definition of impact of PPI combined with the recent work of Hughs and Duffy (2018) in order to gain consensus on the concept of the impact of PPI.
- Exploring new methods for developing a PPI impact framework by breaking down the different types of PPI roles, in different studies for example health services, health policy, clinical trial design, genomic/genetic research and community work. Thus, some practical guidance/toolkit for researchers about the nine PPI factors could also be developed considering the complex intervention of PPI (Craig et al 2008).
- Evaluating the impact of REF requirements and its connections to PPI. This would be a multi-site mixed method study of universities assessing how university researchers negotiate PPI work (Caress 2013). Using understandings generated from the current study, it would apply the CFIR to help understand tensions researchers face in academia around PPI and how the REF guides what university researchers do, data from the current study has found that ivory tower culture may hinder the impact of PPI.

- This study has focused evaluation ideas using the CFIR and complex interventions specifically on the impact of PPI on research outcomes, but a study could be carried out across the entire PPI journey – in the form of longitudinal work. This study would be wholly concerned with context, mechanism and outcomes of PPI, using the CFIR along with insights from NPT (Wilson et al. 2015; Wilson et al 2018).
- More work could explicitly examine the role of PPI in a PhD study. Here the arguments of lay verses scientific knowledge can be formed applying Popay et al. (2003) about how a PhD study requiring independent thought and health research applying PPI principles can be better understood.

Autobiographical critical reflection

A reflexive researcher is one who considers how their own influences (such as their age, race, gender, ability, social class, professional status and distance) affects research work (Mays and Pope 2008). Whilst carrying out this study, wherever possible, disclosure of race, gender and professional status has been made to participants so that participants can see why there is interest from the researcher about the topic. Serrant-Green (2002) argues that all researchers fall somewhere between complete insiders and complete outsiders, occupying different spaces which affect the research process and research outcomes. Thus, conducting this doctoral research study shows that research is a 'messy' process which sometimes blurred intellectual, personal, social and at times emotional boundaries.

There are many acknowledged skills acquired over the last eight and a half years. From reading some of the best works available in the field of PPI in research and impact, it has been made possible to grasp what experts are raising and how to consider these arguments in different ways and across disciplines. Other skills cultivated have been in writing and publishing resulting in being able to critically examine and communicate knowledge and awareness of PPI (see Appendix 16 for a list if outputs influenced through this PhD). The skills of communicating publicly, and how to have frequent, and private contact with a range of groups from patients through to high-profile politicians, have been developed through this study. These experiences have enhanced fieldwork confidence skills, but also away from the field have taught

how to confidently commit pen to paper and write the thesis, despite being diagnosed with dyslexia (very early on in the PhD journey).

Lastly, whilst undertaking this research study some invaluable life skills have been gained, not least in how to overcome self-doubt and become emotionally resilient when coping with shifts in research directions. That self-discipline has been necessary to survive the endurance of a PhD journey whilst balancing the role of parenting to a young family as well as holding down a demanding job. These skills go beyond academia because, ultimately, they teach the meaning of patience and keeping the drive and determination as a focus to complete something that is worthy and important to me.

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Appendices

Appendix 1 - Lincoln and Guba Poster

Title: **A reflexive account of the *trustworthiness* and *authenticity* of data using Lincoln and Guba's (1985) work in a PhD research study: *Understanding the impact of public involvement in cancer research:* Pandya-Wood R (2014).**

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PhD Background: Mixed methods, two phased doctoral research study. Phase 1 explored perceptions about research impact and research knowledge use with those who have had experience of public involvement in research. Phase 2 enhanced and refined the perceptions about the impact of public involvement on research outcomes.
Methodology: qualitative using n= 23 interviews (phase 1) and an expert Delphi Panel n= 35 (phase 2).

The aim: this poster shares the application of **Lincoln and Guba's (1985)** criteria for judging or evaluating reliability and validity of research processes. Concepts of *trustworthiness* and *authenticity* were considered in a reflexive analysis of the stages of the PhD carried out to date. **Particular consideration is given to the use of this model for evaluating public involvement in research.**

Trustworthiness Criteria

1. **Credibility** – Confidence in the 'truth' of the findings. Through mixing methods: it is anticipated that the use of more than one source of data has acted as a quality measure. Findings will also be analysed against a body of similar work discussed in the literature review which will help to ensure this work has created trustworthy data.

2. **Transferability** – That the findings have applicability in other contexts and settings. Lincoln and Guba (1985) suggest qualitative research produces 'thick description' which provides a strong foundation to make a judgement about transferability of the findings. Nearly 32 hours of interview data. Field notes from the in depth interviews were kept. Interviews were coded and transcribed. Delphi participants were also asked a direct question about the how the current research could be used in other contexts of health and disease by furthering knowledge about public involvement impact.

3. **Dependability** – Concerns that the findings are consistent and could be repeated. An audit trail was kept notes on: stakeholder involvement meetings or fieldwork pilots, supervision meetings and discussions and all versions of data collection tools and analytical procedures. A reflective diary has helped to understand possible influences. This criterion demonstrates transparency and that the decisions made about the research can be justifiable.

4. **Confirmability** – This is about the degree of neutrality which concerns being mindful of the researcher's identity. Working for the National Institute for Health Research, Research Design Service East Midlands (NIHR RDS EM) as the Public Involvement in Research Lead has placed the researcher in unique position to conduct this PhD . Other issues that have helped with confirmability have been through having regular stakeholder involvement meetings in this work. Involvement has occurred in the *Designing the sampling strategy, Piloting the questions to ask and Formulating a focus for the Delphi technique*. The researcher argues that stakeholder involvement enables better research and achieves the confirmability feature of Lincoln and Guba's (1985) model.

Authenticity Criteria

1. **Fairness** – Does the research concern different viewpoints – This work has used a wide variety of viewpoints to collect data and to shape the study, including: cancer researchers, cancer patients, academics and policy makers (who are working as MPs or staff in cancer charities and government organisations).

2. **Catalytic authenticity** – This step concerns change ideas. The research has already fed into the *Breaking Boundaries* review being led by the government to understand the next 10 years for the direction of public involvement work and key themes from this work have been shared with members of that review. The findings generated will also be published to help generate debate.

3. **Ontological authenticity** – Does the research help members of the public to arrive at a better social milieu? The researcher also plans to arrange a debate about the final outcomes to further understand the issues the research has identified.

4. **Educative authenticity** - concerns aiding knowledge generation of what issues are being experienced by the people affected by the research. Several stakeholder involvement events and meetings have helped to direct this work and to focus the key themes that this research addresses.

5. **Tactical authenticity** – This concerns whether the research empowered stakeholders to take action. Several cancer patient participants have explicitly asked the researcher to publish this work and have also been helpful in formulating a dissemination strategy. Some Delphi panellists have asked if they can share this work on their websites to raise awareness of the emerging findings.

Conclusion: Whilst this work is still underway, an emerging reflexive appraisal suggests Lincoln and Guba's (1985) criteria help demonstrate *trustworthiness* and *authenticity* as a useful methodological model for research which includes and is about public involvement in research. This poster identifies the complex issues that concern validity and reliability. The *trustworthiness* criteria have been useful indicators to highlight how transparency and reflexivity can be achieved when conducting research concerning public involvement in research. The *authenticity* criteria in particular as applied here illustrate how the application of Lincoln and Guba's (1985) work compliments the ethos and value of public involvement research. From a theoretical perspective, the poster demonstrates that Lincoln and Guba's (1985) model is applicable to research concerning public involvement in research and more specifically, research concerning impact of public involvement.

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Appendix 2 - Interview Guide

The impact that cancer service user involvement has on cancer research and its usability

Pre Interview sheet completed? ☐ Information sheet read? ☐ Requested a copy of findings? ☐ Instructions about how to answer questions given? ☐ Explain that the questions are the same for each group? ☐ Any questions asked? ☐	Questionnaire code (no of int/data from an R,S or P/ DATE

Topic guide and examples of questions to ask	**Key words**
Context – The research and you 1. (ALL) What was the finished cancer research study you had in mind for this interview? 2. (R and P) Can you briefly talk me through your role in it? 3. (R and P) What did you hope this research would achieve? 4. (R and P mostly) Can you tell me a little bit about… ✓ The aim of user involvement *(offered in the study?)* ✓ Training *(offered in the study?)* ✓ Reimbursement and reward *(offered in the study?)* ✓ Organisational culture *(of where the study took place?)* ✓ Aspects of user involvement that worked aspects that didn't work (*in the study?)* ✓ How often was there contact between users and researchers? *(in the study?)* ✓ Do you have previous experience of user involvement, do you think it made any difference? *(in the study?)* 5. (ALL) Overall what **value** is there in having service user involvement in cancer research? 6. (ALL) How do you think service user involvement made a difference to the overall projects impact/ Do you think health research that has service user involvement makes a greater impact on health services	**Context of user involvement and study** **Impact of user involvement**

7. (ALL) A study by (Barber et al 2011) has shown that it is possible to evaluate the impact of user involvement in research when • identifying topics to be researched, • prioritizing topics to be researched, • disseminating research, • evaluating involvement impact on members of the public who got involved and • evaluating impact on members of the research team who were involved. Do you think there are other aspects of user involvement that can be evaluated or evidenced for impact? If so what could they be and how might you record it? 8. (ALL) Academic papers suggest that user involvement leads to more focused and relevant research which subsequently is more likely to lead to services that patients want to see being delivered, in your opinion do you think this happens?	
Dissemination 9. (ALL) What does dissemination mean to you? 10. (ALL) Whose role is it to disseminate and use research? 11. (Stakeholders – how did you hear about the study findings?) (R and P – How did you disseminate the finding of the study (from earlier) when it finished? ✓ Who was involved? ✓ Where have you disseminated it? ✓ Were any service users involved? What did they do?	**Dissemination**
Evidence base and impact (ALL) 12. What does **using research evidence** mean to you? 13. What are the most important **impacts** of research to you? 14. What might be the most important research impact for the other two groups I am interviewing?	**Evidence base and impact**

15. Can you explain how the research you talked about earlier has been used to: ✓ Influence cancer policy in the UK ✓ Cancer care and service planning in the UK ✓ Change practice ✓ Help build a case for evidencing or changing something (in the UK or wider)? 16. Determining the impact of health research is not a straightforward task. Policy and service development is not a linear process, and decisions are rarely taken on the basis of research evidence alone. This makes it difficult to pin down the role that an individual piece of research has played. The timing of evaluation also presents challenges. Too soon after the research ends may mean that any impact has yet to fully develop. Too late, and the impact may no longer be traceable as people involved have moved on. How do you think service users and carers can help with this?	
Knowledge Translation (ALL) 17. In your opinion, how might cancer research findings be better used? (applied to different organisations, share best practice, advance new clinical discoveries) 18. Knowledge Translation is a term often used when research has finished and when new knowledge generated from the research might get used. The idea of using 'new' knowledge to shape 'healthcare systems' is complex; where different professions/organisations and people come together. As you can imagine it is a complicated thing to do and sometimes research messages can get confused, poorly communication or even lost, how might this be fixed?	**Knowledge Translation**
Closing questions (ALL) 19. As the focus of this PhD is service user involvement in cancer research, to the best of your knowledge do you think things work differently in other fields of research as far as impact of user involvement goes? (Is the issue of impact different in other fields of research?) 20. Is there anything else you think would be useful for me to know which we haven't already discussed today?	**Closing questions**

Version 7. 1/7/2013

Appendix 3 - Poster Phase 1

"Please help!

My PhD IS LOOKING AT THE IMPACT service user involvement HAS ON cancer research AND its usability

1. Are you living in the **East Midlands**?
2. Were you successful in winning or getting involved in a cancer **research grant** (applied health, rather than laboratory research)
3. Was the research funding **nationally awarded**?
4. Was the research completed in the **last five years**?

If you answered **yes** to all of the above and identify yourself as one of the **three groups** below…

- **ex cancer patient** (who got involved in the research, offering a patient's view as a 'user' or 'PPI' (patient and public involvement)
- **academic/clinical cancer researcher**
- or a **cancer research stakeholder?**

I would like hear from you. Could you volunteer **an hour** of your time for an interview towards my PhD research? If yes then for more information call **07838 134 202**, or email me on: rpandya@dmu.ac.uk **Thank you"**

Raksha Pandya-Wood

Appendix 4 - Information Sheet Phase 1

Successfully shaping our world

Information sheet about this PhD Research

Understanding the impact that service user involvement has on cancer research and its usability

This information sheet is for phase one of this research and is designed for **service users, researchers** and **stakeholders.** Please read it to help you decide if you would like to take part in the work – which will be one hour of your time.

The research team
The student researcher is Raksha Pandya-Wood, who is also a part time member of staff at De Montfort University. Raksha works as the lead for patient and public involvement in research for the Research Design Service for the East Midlands. Raksha's supervisors are Jennie Fleming who is a Reader in Participatory Research and Dr Nicky Hudson who is a Senior Research Fellow. Both supervisors are based at De Montfort University within the Faculty of Health and life Sciences.

What is this research about?
In the last five years a lot of emphasis has been given to service user involvement in health research and its impact. This study is the first of its kind in attempting find out how service user influenced research findings are used to inform practice and policy in the field of cancer research.

There are two phases in this research and you are being invited to participate in phase one. Phase one involves conducting 18 interviews with six different service users, six different researchers and different six stakeholders. Just to clarify, it is just one interview per person.

The interviews with the different people will help to develop an understanding about what meanings are connected to the word 'impact' in relation to service user influenced research. Ultimately how this impact might be demonstrated in policies and practice. Phase two (which isn't what you are part of) but for your information purposes will be using a research approach called a "Delphi Technique".

Delphi Technique is a research method that involves asking questions to experts, usually by email or post. People in this process will be key opinion formers, people working in the NHS, or perhaps national government run organisations and health think tanks. Using the Delphi approach is normally helpful in this type of research where knowledge on a topic is limited. The information generated from the interviews will have been pooled together, analysed and themed. Before starting the Delphi, the themes will be presented in a document. All the people involved in the Delphi will be asked to further refine and consider expanding on the topic.

It is anticipated that by combining interviews and the Delphi technique, data will help develop an understanding about the impact that cancer service user involvement has on cancer research

Why is cancer the chosen focus of the study?
Cancer research is an NHS priority and lots of people are already actively involved in cancer research, therefore it has been chosen as a focus for the study. However the research is not about cancer, but about understanding how involving service users in research, influences the overall impact of the cancer research.

Why have I been asked to take part?
You have been asked to take part because you have indicated that you have experience of conducting, or using applied health research, and that you belong to one of the three groups below:

1. You have been a service user involved in cancer research
   (for example you helped with one or more of the following: to identify and prioritise, design, develop the proposal, conduct, analyse, disseminate implement evaluate and monitor the research study on the basis of your experience as a user of cancer health services);
2. You have conducted applied cancer research with service users and they were involved in one or more of the following: identifying and prioritising the topic, designing, developing the proposal, conducting the research, analysing the findings, disseminating, implementing and evaluating and monitoring your research);
3. You have used service user influenced cancer research findings in your work (for example you might have lobbied for a new treatment to be made widely available and used cancer research evidence to make your case heard or you may have used the evidence to develop some new guidelines on cancer patient care).

How recent does my experience need to be?
You must have been involved in or have used findings from a study that was completed within the last five years.

How will the interview be carried out?
The interviews will be carried out by the researcher Raksha Pandya-Wood on a one to one basis. It will last about 60 minutes and can be done face-to-face or over the telephone. Interviews will be audio-recorded and can be carried out at a time of your choosing, either at De Montfort University or an alternative venue. It is hoped that the interviews will be carried out between the months of June 2013 - Dec 2013.

What will happen to the recorded interviews?
They will be typed up word-for-word. The electronic recordings and typed up files will be kept on a password-protected PC. Printed transcripts will be kept in a locked filing cabinet. All transcripts will be anonymised and any information that could identify you (e.g. place names, doctors' names etc) will be deleted. The anonymised typed up files from the study will be stored for five years beyond the completion of the PhD, in compliance with De Montfort University's Data Storage and Retention Policy.

What will happen to my personal details and will my taking part be kept private?
In accordance with the UK Data Protection Act 1998, your personal details will be kept in a locked filing cabinet, away from the recordings and the typed up files. All data files and documents will be password protected. Your involvement in the study will be kept confidential.

Will I be contacted again once the interview is finished?
It is unlikely, but you may be contacted after the interview for two reasons; 1) Clarity may be needed on a certain point that you made when the data is being analysed, 2) Once the study has finished, you may have indicated that you would like to know the outcomes of the study and therefore the researcher will contact you about this at the end of the study.

How will my data be used?
Once all 18 interviews are completed the data will be analysed to give a better understanding of people's experiences and perceptions of service user influenced research and its impact. When the study is being written up in the thesis and for publication, quotes from your interview may be included. Again, all quotes will all be anonymised.

What will happen at the end of the project?
There will be a summary of the findings from the study available at the end and you can receive a copy of this if you wish.

Do I have to take part?
No, taking part is totally your choice. You are also free to withdraw at any time without giving a reason. If you decide to take part and then change your mind, please inform Raksha as soon as possible, so that someone else can be offered an interview instead.

What happens if I have a problem with the project?
If you have a concern about any aspect of this research you should speak to the supervisors whose details are at the end of this information sheet.

Who is conducting and paying for the research?
The study forms part of Raksha Pandya-Wood's doctoral (PhD) research, which De Montfort University is funding.

Who has reviewed the study?
The study has been reviewed by the Research Ethics Committee at De Montfort University who have given their approval for its conduct.

If you have any questions about this research please contact Raksha Pandya-Wood by mobile on: 07838 134 202 or by email: rpandya@dmu.ac.uk

If you have any concerns about this study, please contact the supervisors:

Jennie Fleming
Faculty of Health and Life Sciences
De Montfort University
Leicester LE1 9BH
E-mail: jfleming@dmu.ac.uk

Dr Nicky Hudson
Faculty of Health and Life Sciences
De Montfort University
Leicester LE1 9BH
E-mail: nhudson@dmu.ac.uk

You will be given a copy of this information sheet and a copy of the signed consent form to keep.

Thank you for reading this information.

Appendix 5 - Consent Phase 1

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Successfully shaping our world

Understanding the impact that cancer service user involvement has on cancer research and its usability

Phase One - Consent Form

	Please initial the box if you agree. Put an X if you disagree:
I confirm that I have read and understood the information sheet that was given to me about the above study. I have had the chance to think about the study, ask questions and have had them answered to my satisfaction by Raksha Pandya-Wood (the researcher).	☐
I understand that taking part in an interview is completely voluntary and that I am free to withdraw or end the interview at any time.	☐
I understand that my name and any other details that could potentially identify me will be removed from my interview transcript.	☐
I understand that quotes from my interview may be published and that I will not be identifiable from them.	☐
I agree for the Raksha Pandya-Wood to keep my name and contact details so I can be informed about the study findings at the very end.	☐
By agreeing to take part in this study, I agree to: a) take part in a recorded interview face to face or over the phone	☐
b) anonymous quotations from my interview being used in publications where appropriate.	☐

If you are happy that all your questions have been answered and you agree to take part in the study, please put your name, signature and date in the spaces below.

Name of participant_____ Date_____

Participant signature_____

Please keep one copy of this consent sheet safe and pass the other one to Raksha Pandya-Wood.

Thank you for offering to take part.

Raksha Pandya-Wood
Faculty of Health & Life Sciences, The Gateway, Leicester, LE1 9BH
Email: rpandya@dmu.ac.uk

Version 2. 11-May-2013

Appendix 6 - Demographics

I would like to ask you to answer the following questions. This is so I can understand the groups of people who took part in this research project and so I can report on the composition of participants. You do not need to provide your name. Completing this form is voluntary, and you can still take part in the research project if you do not complete this form.

In which region of England do you live in?

[_] Northeast
[_] Northwest
[_] Yorkshire and Humber
[_] East Midlands
[_] West Midlands
[_] East of England
[_] London
[_] South Central
[_] Southeast
[_] Southwest

What is your job title?

Does your job cover all of England or certain regions?

[_] All of England
[_] Certain regions

What is your age group?

[_] under 25
[_] 25-34
[_] 35-44
[_] 45-54
[_] 55-64
[_] 65 or older
[_] Prefer not to say

Do you consider yourself to be disabled? The Equality Act 2010 states a person has a disability if they have a physical or mental impairment that has a substantial and long-term adverse effect (likely to last 12 months or more) on their ability to perform normal day-to-day activities (e.g. eating, washing, walking and going shopping). Please select all that apply.

[_] No disability
[_] Specific learning difficulty or disability (e.g. dyslexia)
[_] General learning disability (cognitive)
[_] Social/communication impairment (such as Asperger's syndrome or other autistic spectrum disorder)
[_] Long term illness or health condition
[_] Mental health condition
[_] Sensory impairment – Deaf or serious hearing impairment
[_] Sensory impairment – blind or serious visual impairment
[_] Physical or mobility impairment
[_] Other disability

What best describes your ethnic group?

[_] Arab
[_] Asian / Asian British Indian
[_] Asian / Asian British Pakistani
[_] Asian / Asian British Bangladeshi
[_] Any other Asian background
[_] Black or Black British African
[_] Black or Black British Caribbean
[_] Any other Black / African / Caribbean background
[_] Chinese
[_] Gypsy or Traveller
[_] White
[_] White and Asian
[_] White and Black African
[_] White and Black Caribbean
[_] White and Asian
[_] Other Mixed Background
[_] Any Other Ethnic Origin
[_] Not known
[_] Prefer not to say

Is your gender identity different to the sex you were assumed or thought to be at birth? (For example: you were assigned or thought to be male sex at birth, and now live in a female gender identity, or you were assigned or thought to be female sex at birth, and now live in a male gender identity.)

[_] No (I have the same gender identity as assumed at birth)
[_] Yes (I have a different gender identity to the one assumed at birth)
[_] Other
[_] Prefer not to say

What best describes you religion or belief?

[_] No religion
[_] Buddhist
[_] Christian (including Church of England, Catholic, Protestant and all other Christian denominations)
[_] Hindu
[_] Jewish
[_] Muslim
[_] Sikh
[_] Spiritual
[_] Any other religion – please specify
[_] Prefer not to say

What is your sex?

[_] Female
[_] Male
[_] Other

[_] Prefer not to say

What best describes your sexual orientation?

[_] Bi-sexual
[_] Gay
[_] Lesbian
[_] Heterosexual
[_] Other
[_] Prefer not to say

Would you like to hear about this study's findings when it is finished?
[_] Yes
[_] No

Thank you for completing this form. **PLEASE SEND TO:** rpandya@dmu.ac.uk

7/2/2014
Version 2

Appendix 7 - Coding Framework Phase 1

Parent code	Child codes	Grandchild codes (if any)
PATIENT CARE IMPACTS	Patient choice expansion	
	Prolong survival	
	Using research evidence - improves practice	
	Improve quality of life	
	direct example of impact on patient care because of a trial	
	Better palliative care	
	Breaking bad news	
	Wanting factual information about cancer	
	Positive mental attitude	
	Having confidence in professionals	
	Cancer as an illness	
	Unique ideas for demystifying PPIR	
	Why cancer is different to other illness	
FEATURES OF IMPACT	Timing of impact	
	PPI makes no impact	
	Ways to assess impact of PPI	
	Climate and culture of PPI has changed	
	Examples of context specific real impact	
	Limitations of involvement	
	Meaningful V Tokenism	
	PPI leads to better dissemination and that affects overall impact	
	What impact is and isn't	
	Process impact	Evidencing PPIR impact
		Perceived impact during PPIR
		Personal gains
POLICY IMPACTS	Policy rhetoric and reality	
	NICE	
	Health economics	

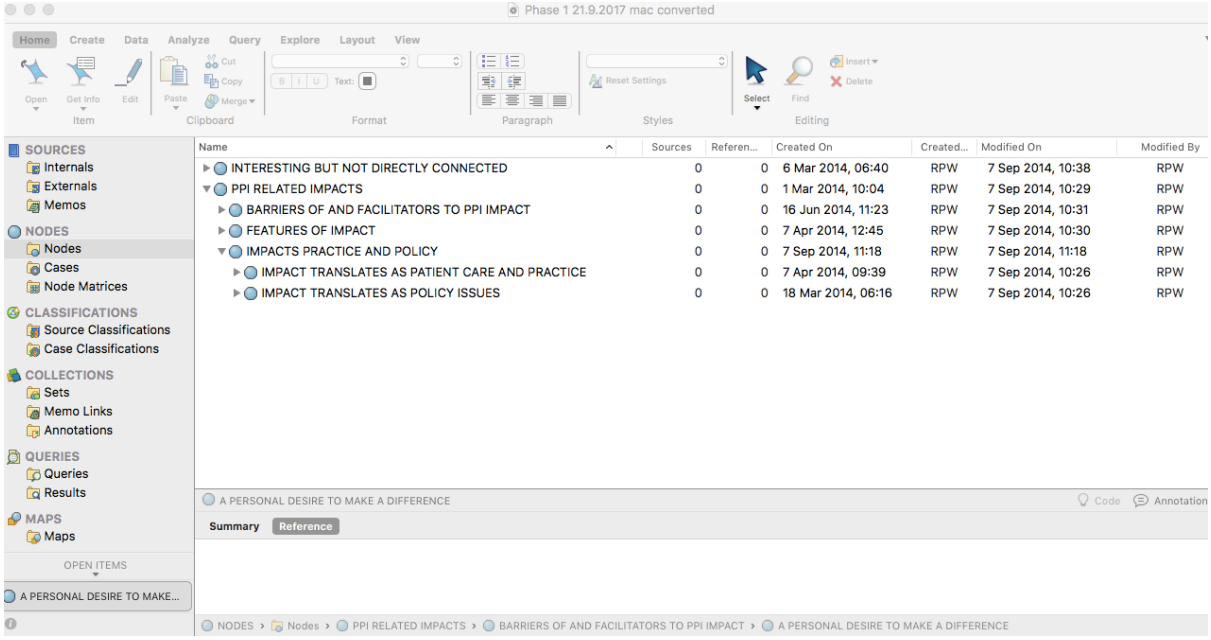
	Process impact	Evidencing PPIR impact
		Perceived impact during PPIR
		Personal gains
POLICY IMPACTS	Policy rhetoric and reality	
	NICE	
	Health economics	

	Department of Health	
	Government party	
	Cancer Policies	
	Cancer Drugs Fund	
	Lay people involved in policy making	
	Healthcare systems work differently	
	HealthWatch	
	Pressuring government to form a new policy using evidence	
	NIHR CLAHRC AHSN CRN RDS	
	Innovation health and wealth	
	It's ok to ask	
	Primary Care	
	Charities driving policy ideas	
DISSEMINATION RELATED IMPACTS	Involving charities	
	Overseas	
	Whose role to disseminate	
	Who should know about research	
	Incomplete information	
	Filtering information and sharing widely	
	Management structures encouraging LD	
	Word of mouth	
	Avoiding duplication sharing good practice	
	Scientific evidence	
	Informing the funder	
	Results not being published	

	Word of mouth	
	Avoiding duplication sharing good practice	
	Scientific evidence	
	Informing the funder	
	Results not being published	
	Using a clear language to communicate	
	Disseminating to government	
	Knowledge translation	
	Preparing the findings in a variety of ways	
	Wasted findings - not used	
	informing GPs	
	Service users disseminating	
IMPROVING RESEARCH IMPACT	Ethics	
	Improved quality and validity of research	
	Quality of the research question	
	Adding qualitative elements to quantitative research	
	PPI and qualitative research	
	Improved recruitment	
NETWORKS PARTNERSHIPS AND COLLABORATIONS	Cancer charities	
	Network impact	
	Universities	
	NIHR Infrastructure	
	Trusts	
	GPs	
	Industries and pharmacies	
	Patient groups	
TECHNOLOGY	Electronic journals	
	Searching	
	Virtual membership	
	Email	

	Smart phones	
	TV Radio Newspapers	
	You Tube	
	Social Media, Facebook, twitter, blogging	
BARRIERS OF AND FACILITATORS TO PPI IMPACT	Usual suspects starting PPI work	
	Patient Led Research Ideas	
	Suitability to the work	
	Organisational culture	
	Death and dying	
	Patient agendas	
	Using tax payers money for research	
	Frustration at not winning research grants	
	Stretched resources	
	Equalities in cancer research	
	Being influential renown	
	Feeling inspired	
	Impact of teaching hospitals	
	Campaign	
	Researchers furthering their careers	
	PPI on funding panels	
	Stakeholder role	
	Not enough people to do PPI	
	Researcher Role	PPI culture in the organisation
		Difficulties with PPIR
		Missed opportunities
PPIR WORK PROCESSES	Travelling and meetings	
	Volunteering	
	Peer reviewer	
	Organisations people are associated with	
	Skills people bring to PPI work	

	Organisations people are associated with	
	Skills people bring to PPI work	
	Being a carer	
	Meeting PPI demands	
	Stopping involvement	
	Metaphors used in description	
	Patient names	
	People helping to fundraise for cancer research	
	Funding streams patients are involved in	
	Cancer experience	
	Private healthcare	
	Patient interests	
	Patients involved in trials for their care	
NON PPI RELATED IMFORMATION - DRUG TRIALS MENTIONED	Researchers running	
	Overseas	
	Awareness	
	Pharmacuetical companies	



Appendix 8 - Stimulus Paper

Factors that shape the impact of patient and public involvement in research outcomes: a Delphi study

Introduction

You have agreed to participate in a doctoral research study: *Understanding the impact of patient and public involvement*[1] *(PPI) in cancer research.* The aim of the study is to advance knowledge about how research which has involved patients and members of the public is used to inform practice and/or policy development. The purpose of this paper is to stimulate responses from *you,* the Delphi panel, in relation to a brief summary of the findings from Phase 1 of the study. The paper begins by offering some background to the research and how it is being conducted. It then focuses on some of the key findings from the data collected so far. A major theme: 'factors which shape the impact of PPI in research outcomes' is presented below, responses to which are invited during this Delphi.

Background

In the UK and internationally in the last decade, interest in the benefits of patient and public involvement (PPI) in health and social care research has been growing. At the same time there has been increasing demand for researchers to articulate and demonstrate the value of PPI to national funding bodies.
While there is now evidence about the benefits of patient and public involvement in the *process* of research, we still do not know is specifically what difference PPI makes to the research outcomes and how it affects implementation of research findings into policy and practice (hereafter referred to as the 'impact of PPI'). There is a dearth of published high-quality research assessing the impact of PPI, possible reasons being that evaluation is too difficult and that PPI is thought to be of inherent value and therefore needing no further justification (Snape et al. 2014). However, there remains a need to assess its effectiveness, both positive and negative (Staley 2009), as well as the related ethical issues (Marsden and Bradburn 2004) and economic implications (Staniszewska et al. 2011). At an implementation level, difficulties exist for clinicians, patients and managers in terms of how research findings can be transferred into policy and/or practice (Forbat et al. 2009). This PhD project was designed in order to contribute to the knowledge gap that currently exists surrounding the implementation of research findings which included PPI.

Research Method and Design

The study sits within the field of social sciences/health sciences; it uses a mixed methods design (interviews and Delphi technique) and employs a participatory approach, involving key stakeholders throughout.
In Phase 1, interviews were used to explore perceptions about the impact of PPI in relation to cancer services and policies. Twenty-three participants with experience of cancer services/research were interviewed, including cancer service users (patients), cancer researchers (clinical and academic) and cancer stakeholders (PPI/implementation roles). The findings from Phase 1 have been analysed and used to inform the content of this paper. In Phase 2, (current phase) a Delphi study is used to refine the findings generated from Phase 1 in order to **explore ways to enhance the impact of PPI in the outcomes of health-related research**.

Summary of Findings

Phase 1 interviewees discussed a range of factors that were perceived to shape the way implementation of research findings might be achieved. A summary of the factors that emerged are now set out.

A. *Successful PPI processes as a foundation for the production of impact*

This theme is about the need for effective PPI during the planning and conduct of the research study. Challenges related to involving patients and the public were described as: where and how to find people to involve; individual patient agendas; patient-led research ideas; patients feeling inspired about research; patients feeling experienced enough to get involved in research; and PPI being assessed by funding panels. Participants suggested that the point of PPI in the research process was to help 'iron out' the non-medical assumptions of what patients want or need. Successful involvement was perceived to lead to more focused and relevant research, which in turn was seen as being more likely to achieve impact. *"To understand the impact of PPI outcomes, you cannot ignore the processes of PPI…"*

[1] Involvement in this work uses the INVOLVE definition of public involvement in research as research being carried out **'with'** or **'by'** members of the public rather than **'to'**, **'about'** or **'for'** them. This includes, for example, working with research funders to prioritise research, offering advice as members of a project steering group, commenting on and developing research materials, undertaking interviews with research participants.

B. Wanting to make a difference

This theme was about how personal motivations and a desire to contribute to change or improvement facilitated the production of impact. Patient stories included a desire to give something back to society, in order that others wouldn't go through the same (negative) experiences, or would not be faced with losing a loved one. There was a desire to achieve complete equality in cancer care. Some participants felt that the use of public money to fund research implied a moral obligation to make improvements. Some researchers described this motivation to make a difference in terms of career aspirations.

C. The significance of power and leadership

This theme represented the idea that support or input from particularly influential individuals or organisations could enhance the likelihood of achieving impact, increasing the power of the 'patient voice'. Participants talked about what *"having the sway of someone influential: perhaps a celebrity, MP or a national policy figure"* can potentially lead to. This theme was also about the power that one patient or several in patient groups may have when campaigning and advocating messages. An interesting aspect of 'power' was organisational PPI support - it was believed that if the institution was 'PPI active' then the impact of PPI outcomes would be far greater.

D. Networks (non-virtual)

This was about the use of networks to share information. Physical meetings were seen as a place where people shared new research findings and discussed its importance within current healthcare systems. Patients talked about the networks they are connected to via charities, patient user groups and the social circles that their involvement roles linked them to. Stakeholders and researchers talked about how professional networks impacted on them and their work, making contact with the right people, chance encounters, networking at meetings etc.

E. Resources and the political context

This was about a range of contextual factors, which (despite having good PPI in the study) might affect or diminish the successful production of impact. These included a lack of funding or stretched resources affecting staffing, equipment, training, ability to purchase certain drugs, and choice of implementation of interventions. It included wider policy which effectively 'moved the agenda on' leaving the research apparently no longer relevant *"Shortly after we had finished the research …£250k something study – which paid for the design of [the tool], we were told [the tool] was no longer needed for the health service!"*

F. Dissemination

This was about to whom, where, how, what, when and why research findings are disseminated. Participants felt that the link between dissemination and impact was fundamental. Dissemination plans should involve patients in developing the strategy: Messages were seen as needing to be targeted and made easier to understand. Participants also discussed how generating impact was about the timeliness of research and doing *"the right research at the right time for impact generation – the mass media coverage only follows the flavour of the month"*.

G. Information and communication technology

This theme included discussion of the use of technology to aid impact generation, for example the use of smartphones and computers to search for and share information by sending important new research knowledge far and wide. It was also about blogging and using social media to keep informed at the *"zing of a button"*. Some participants suggested that their PPI work required them to be confident and regular users of Twitter™ and Facebook™. Blogging was perceived as a way of helping people stay connected "*…there is something about using technology… keeping me…. strategically linked to the outside* [world]".

References

Forbat, L., Hubbard, G., & Kearney, N. (2009). Patient and public involvement: models and muddles. *Journal of clinical nursing, 18*(18), 2547-2554.

Marsden, J., & Bradburn, J. (2004). Patient and clinician collaboration in the design of a national randomized breast cancer trial. *Health Expectations*, *7*(1), 6-17.

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

Snape, D., Kirkham, J., Preston, J., Popay, J. Britten, N., Collins, … Jacoby, A. (2014).Exploring areas of consensus and conflict around values underpinning public involvement in health and social care research: a modified Delphi study. *British Medical Journal Open*, 4: e004217. doi: 10.1136/bmjopen-2013-00421

Staniszewska, S., Brett J, Mockford C, et al. The GRIPP checklist: strengthening the quality of patient and public involvement reporting in research. *Int J Technol Assess Health Care* 2011;27:391

Appendix 9 - Poster Phase 2

"Please help!

My PhD IS LOOKING AT THE IMPACT service user involvement HAS ON cancer research AND its usability

1. Can your **job make an impact** on policy and practice at a national level?
2. Do you live and work in **England**?
3. Are you **interested in cancer care, research and practice?**

If you answered **yes** to all of the above and identify yourself as a key informant from one of the **six groups below then please consider taking part in a Delphi Survey:**

- 'Expert cancer patients' or 'cancer patient champions'
- Leading cancer charity directors/policy staff
- Think-tank policy makers - cancer care and services
- Academics in cancer research
- Consultant independent service user involvement companies
- MPs and civil servants – health

I would like to understand your views on how far and to what extent service user involvement makes a difference. If you are interested, then please call: 07838 134 202, or email me on: rpandya@dmu.ac.uk

Thank you"

Delphi research starts on the **15th September 2014** and finishes on the **17th October 2014**

Raksha Pandya-Wood

Appendix 10 - Information Sheet Phase 2

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Successfully shaping our world

Information Sheet

Title: Understanding the impact that service user involvement has on cancer research and its usability: Phase two

You have been invited to take part in a Delphi survey. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish to. Ask if there is anything that is not clear or if you would like more information. Do take time to decide whether you wish to take part or not. Thank you for reading this.

What the study is about?

In the last five years a lot of emphasis has been given to service user involvement in health research and its impact. Cancer research, which is what this research concerns, is an NHS priority. This research is not about cancer per se, it is about understanding how involving service users in cancer research influences the overall research and its usability in order to inform cancer policy and practice in England.

Phase one is now complete, which was a series of interviews carried out across the East Midlands with patients, clinicians and stakeholders: the patients became involved in national peer reviewed cancer research; the clinicians won national peer reviewed research funding competitions, which had service users involved in the research design/study conduct; and the stakeholders made use of cancer research findings and implemented them.

Now this work is in its second phase, which is concerned with refining the issues that came out of the interviews. In brief the second phase will consider how the phase one findings are understood by people like you, who make use of research to inform policy and practice in cancer healthcare within England.

What does this study involve?

This research would like your help to understand the policy making process and how the impact of service user involvement in research is understood by you and others who work or are involved in shaping cancer health care settings. The research method employed is a Delphi survey. There are many styles of doing a Delphi survey but in this situation:

- the Delphi survey is a series of nine emailed questions,
- over three rounds spread out over six weeks.
- The 'three-part' survey will be emailed out to you and 24 others using blind carbon copying (BCC) so you and the others recruited won't know who the other participants are.
- Each survey will ask you to answer three questions. From each of the questions, a detailed answer will be needed from you. A short answer will not be helpful, as this

You will be given a copy of this information sheet and a copy of the signed consent form to keep.

Information sheet 26/6/2014, version 2

type of research is known as 'qualitative research' and the opinions and experiences of participants are very important.

- Each round will take you about 30 minutes to complete. It is hoped that you can offer as much detail as possible, giving examples if possible to each answer, referring to your area of knowledge and expertise.
- Each round will allow participants to have a full working week (Monday – Friday) to answer three questions.
- I will need time to collate all the responses and feedback what all the participants said. Rounds will be two weeks apart.

The time frame you will be needed for this research is Monday 15th September 2014, until Friday 17th October 2014. Access to the internet is essential during the time of this research. It is anticipated that each participant will be a key informant; sometimes in the research text books, participants in a Delphi survey are called 'experts'.

Why have I been chosen?
This phase of the research requires participants to already be in positions with a certain amount of knowledge. It is anticipated that four people from each of the following backgrounds will come forward to take part:

- 'Expert cancer patients' or 'cancer patient champions'
- Leading cancer charity directors/policy staff
- Think-tank policy makers - cancer care and services
- Academics in cancer research
- Consultant independent service user involvement companies
- MPs and civil servants – health

You have been chosen as you might be working in one of the six categories. Your work might span a national role/regional role with national recognition, for example, working as a Senior Policy worker in the Department of Health or a senior policy role at a national cancer charity. If you are unsure whether you might fit the criteria, please just ask me.

What is a Delphi survey?
The Delphi method is a structured communication procedure which is systematic level of interaction. The interaction relies on a panel of participants also known as experts helping to decide a way forward. The experts answer questionnaires in three rounds. After each round, an anonymous summary is provided to each participant by the researcher. The summary sent at the end of each round is a way of offering some feedback in a controlled way. The feedback will be in response to what participants raised collectively. Normally, it would highlight the main points raised and ask a further set of questions for further thoughts. Thus, experts are encouraged to revise their earlier answers in light of the replies of other members of their panel. It is believed that during this process the range of the answers will decrease and the group will converge towards a mutually agreed way forward".

How much of my time will be required?
All contact will happen via email. The process from start to finish will be within a six- week window and will require a time commitment of three hours in total. The first round will take

the longest, as a short paper will be circulated highlighting the themes that emerged from phase one.

Round 1) Monday 15th until Friday 19th September 2014 (five working days)
After the paper has been read, three questions will be asked to the participants. They will have a week to reply. After all the responses have arrived, a week later, a summary paper will be devised by the researcher about what the participants said.

Round 2) Monday 29th September – Friday 3rd October 2014 (five working days)
The summary paper and a further three questions will be sent to all the participants. Once again, participants will have a week to read and respond to the questions. All answers will be collated and developed into a further summary paper and fed back to all the participants.

Round 3) Monday 13th October – 17th October 2014 (five working days)
For the last time the summary paper together with three questions will be sent to the participants. Participants will have a week to read and answer the questions. All answers will for the final time be summarised with a clearer understanding of what the unified set of answers/themes might look like.

Once the research is finished what will happen to the data?
Data will be saved on a Microsoft Word™ file and kept on a password-protected PC. Printed data will be kept in a locked filing cabinet. All files will be anonymised and any information that could identify you (e.g. place names, doctors' names etc.) will be deleted. The anonymised files from the study will be stored for five years beyond the completion of the PhD, in compliance with De Montfort University's Data Storage and Retention Policy.

What will happen to my personal details and will my taking part be kept private?
In accordance with the UK Data Protection Act 1998, your personal details will be kept in a locked filing cabinet stored in a locked room. All data files and documents will be password protected. Your participation in the study will be kept confidential.

Will I be contacted again once the Delphi method is finished?
You may be contacted afterwards for two reasons: 1) Clarity may be needed on a certain points that you made when the data is being analysed; 2) Once the study has finished, you may have indicated that you would like to know the outcomes of the study and therefore I will contact you about this at the end of the study.

How will my data be used?
As each of the three rounds is being completed, the data will be analysed to give a better understanding of what each panelist is saying about service user influenced research and its impact. When the study is being written up in the thesis and for publication, quotes from your answers may be included. Again, all quotes will all be anonymised.

What will happen at the end of the project?
There will be a summary of the findings from the study available at the end and you can receive a copy of this.

You will be given a copy of this information sheet and a copy of the signed consent form to keep.

Information sheet 26/6/2014, version 2

Do I have to take part?
No, taking part is totally your choice. You are also free to withdraw at any time without giving a reason. If you decide to take part and then change your mind, it would be helpful if you could inform me as soon as possible. This may enable someone else to be invited.

What if something goes wrong? / Who can I complain to?
If you have a concern about any aspect of this research you should speak to the supervisors whose details are at the end of this information sheet.

Who is conducting and paying for the research?
The study forms part of Raksha Pandya-Wood's doctoral (PhD) research, which De Montfort University is funding.

Who has reviewed the study?
The study has been reviewed by the Research Ethics Committee at De Montfort University who have given their approval for its conduct.

Further information
If you have any questions about this research please contact Raksha Pandya-Wood by mobile on: 07838 134 202 or by email: rpandya@dmu.ac.uk

If you have any concerns about this study, please contact the supervisors:

First Supervisor
Dr Kathryn Jones
Senior Research Fellow
E-mail: kljones@dmu.ac.uk
Department of Politics and Public Policy
Faculty of Business and Law
3.45 Hugh Aston Building
De Montfort University
The Gateway
Leicester
LE1 9BH
T: 0116 207 8749

Second Supervisor
Dr Nicky Hudson
Senior Research Fellow
E-mail: nhudson@dmu.ac.uk
School of Applied Social Sciences
Faculty of Health and Life Sciences
Room 0.30 Hawthorn Building
De Montfort University
The Gateway
Leicester
LE1 9BH
T: 0116 207 8766

You will be given a copy of this information sheet and a copy of the signed consent form to keep.

Information sheet 26/6/2014, version 2

Appendix 11 - Delphi Process Phase 2

Open the Delphi survey - a six-week process from start to finish

Delphi Round

Start Date: Monday 15th September 2014
Participants will be asked to read the stimulus paper about key themes that have emerged from data in phase one. There will be three questions about the paper. Participants will be asked to send their

Delphi Round

Start Date: Monday 29th September 2014
Round 1 will be summarised and controlled feedback will be offered on issues raised by the participants. A further three questions will be sent. Participants will be asked to send their comments by **Friday 3rd October**

Delphi Round 3

Start Date: Monday 13th October 2014
Round 2 will be summarised and participants will be offered further controlled feedback. The final three questions will be sent. Participants will be asked to send their comments by **Friday 17th October 2014.**

Collate last set of comments offer a summary by the 27th October 2014 on the range of convergence/divergence of opinions and close Delphi.

Appendix 12 - Consent Phase 2

Consent form

Title of research: Understanding the impact that cancer service user involvement has on cancer research and its usability, Phase Two

Name of researcher: Raksha Pandya-Wood

Please initial the box if you agree

I confirm that I have read and understood the information sheet 26/6/2014, version 2 that was given to me about the above study. I have had the chance to think about the study, ask questions and have had them answered to my satisfaction by Raksha Pandya-Wood (the researcher). ☐

I understand that taking part in a Delphi panel via email is completely voluntary and that I am free to withdraw or end my participation at any time. ☐

I agree that non identifiable quotes may be published in articles or used in conference presentations. ☐

I understand that data collected during the study may be looked at by a supervisor from De Montfort University. I give permission for the supervisor to have access to my data. ☐

I agree for Raksha Pandya-Wood to keep my name and contact details so I can be informed about the study findings at the very end. ☐

I agree to take part in this study. ☐

Name of participant_____ Date_____

Participant signature_____

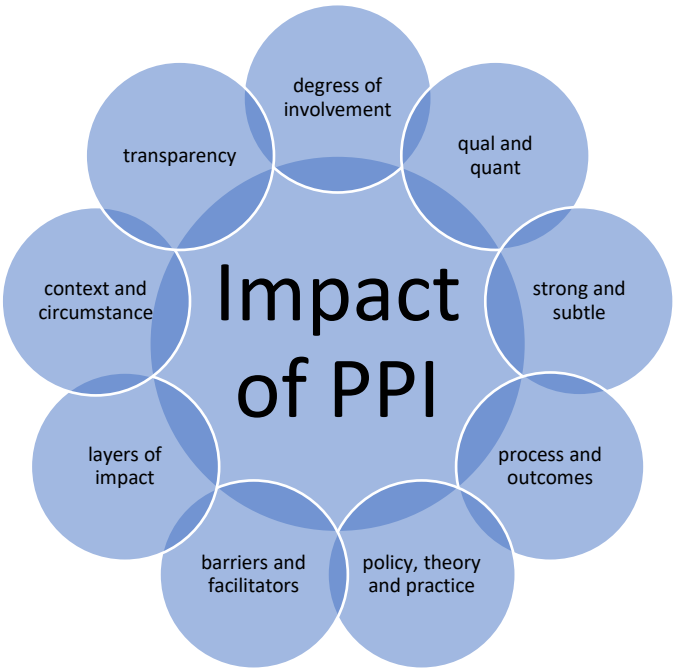
Please keep one copy of this consent sheet safe and pass the other one to Raksha Pandya-Wood.

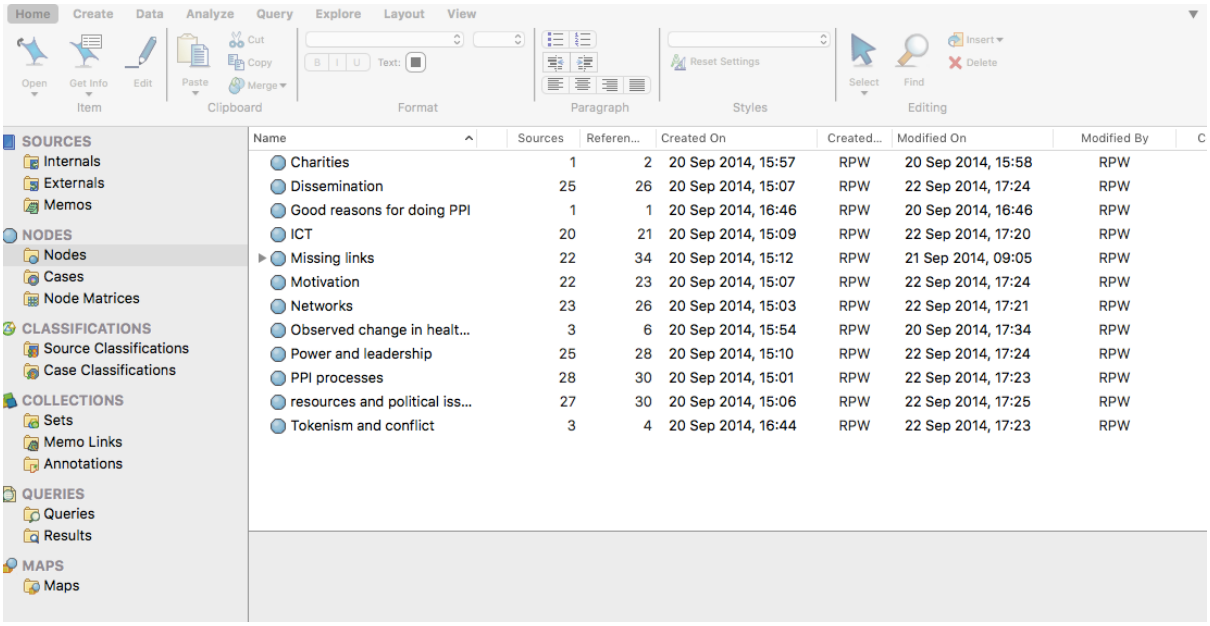
Thank you for offering to take part.

Raksha Pandya-Wood
De Montfort University Faculty of Health & Life Sciences, Hawthorn 0.14a The Gateway, Leicester, LE1 9BH
Email: rpandya@dmu.ac.uk

Version 2. June 2014

Appendix 13 - Coding Frameworks Phase 2





Name	Sources	Referen...	Created On	Created...	Modified On	Modified By
Charities	1	2	20 Sep 2014, 15:57	RPW	20 Sep 2014, 15:58	RPW
Dissemination	25	26	20 Sep 2014, 15:07	RPW	22 Sep 2014, 17:24	RPW
Good reasons for doing PPI	1	1	20 Sep 2014, 16:46	RPW	20 Sep 2014, 16:46	RPW
ICT	20	21	20 Sep 2014, 15:09	RPW	22 Sep 2014, 17:20	RPW
Missing links	22	34	20 Sep 2014, 15:12	RPW	21 Sep 2014, 09:05	RPW
Motivation	22	23	20 Sep 2014, 15:07	RPW	22 Sep 2014, 17:24	RPW
Networks	23	26	20 Sep 2014, 15:03	RPW	22 Sep 2014, 17:21	RPW
Observed change in healt...	3	6	20 Sep 2014, 15:54	RPW	20 Sep 2014, 17:34	RPW
Power and leadership	25	28	20 Sep 2014, 15:10	RPW	22 Sep 2014, 17:24	RPW
PPI processes	28	30	20 Sep 2014, 15:01	RPW	22 Sep 2014, 17:23	RPW
resources and political iss...	27	30	20 Sep 2014, 15:06	RPW	22 Sep 2014, 17:25	RPW
Tokenism and conflict	3	4	20 Sep 2014, 16:44	RPW	22 Sep 2014, 17:23	RPW

Appendix 14 - Delphi Questions Rounds 1-3 - Phase 2

Delphi Round 1
Monday 15th – Friday 19th September

Question 1.

Based on the stimulus paper that you have just read, please rank the seven factors in order of importance **('1' being most and '7' being least important, using each number only once).**
Your ranking should be guided by how important you feel each factor is for generating impact from research that has included PPI. You should also base your answers on your own professional/personal experience as appropriate. Place your ranking in the boxes provided.

Successful PPI processes as a foundation for the production of impact ☐

Wanting to make a difference ☐

The significance of power and leadership ☐

Networks (non-virtual) ☐

Resources and the political context ☐

Dissemination ☐

Information and communication technology ☐

Question 2.

Using the expandable box below, please explain the reasoning for your ranking, why the issues are ranked in the order they appear? (Particularly, offering thought to any significant issues or challenges associated with the factor) applying your professional/personal expertise to the answer.

Question 3.

Using the expandable box below, please explain, did you sense that there was anything missing in the findings presented that you would have expected to see?

Delphi Round 2
Monday 29th September – Friday 3rd October

You are asked to revise your earlier ranking in light of two new themes as well as categorising your answers according to whether they reflect:

Micro issues – small-scale interactions on individual projects, such as conversations, between individuals, or group dynamics that influence something.
Meso issues – (the middle of micro and macro) which includes the consideration of organisations and communities. For example hospitals, care settings and health education settings which may be the structures that influence something.
Macro level – These are large-scale social processes, such as social change, political movements, patterns and trends that are influential.

Question 1 a.
From what you have just read, please rank the nine factors (seven factors brought forward from the first round and two new ones**) ranking them in order of importance **('1' being most and '9' being least important, using each number only once).**
As previously, your ranking should be guided by how important you feel each factor is for generating impact from research that has included PPI. You should also base your answers on your own professional/ personal experience as appropriate. **Place your ranking in the left-hand row of boxes provided.**

Successful PPI processes as a foundation for the production of impact (this came 1st in the previous round)		
Wanting to make a difference (this came 5th in the previous round)		
The significance of power and leadership (this came 4th in the previous round)		
Networks (non-virtual, includes collaborative working) (this came 6th in the previous round)		
Resources and the political context (this came 3rd in the previous round)		
Dissemination (this came 2nd in the previous round)		
Information and Communication Technology (this came 7th in the previous round)		
***Commissioning of research (new theme)*		
***PPI in implementation (new theme)*		

Question 1 b.
Based the above ranking, please indicate in the **right-hand row of boxes** which factors you would categorise as a 'micro', 'meso' or 'macro' level factors: by placing a **'MI'** for micro, a **'ME'** for meso and a **'MA'** for macro in the box.

Question 2.
Using the expandable box below please make any other comments concerning your thoughts about new items 'H' - *Commissioning of research* and 'I' - *PPI in implementation* in support of your ranking.

.

Question 3.
You now have the opportunity to consider the issue of defining 'PPI impact'. Please give me your definition of this in the box below.

Delphi Round 3
Monday 13th October – Friday 17th October 2014

To what extent does the PPI impact definition capture/include your submitted definition and or your view of what PPI impact is (keeping in mind the 9 factors and their levels of complexity)

Completely [ ]
Mostly [ ]
Slightly [ ]
Not at all [ ]

Any other comments about this:

Which of the nine factors are unique to the topic of cancer and can and should they be transferable to other areas of health/illness research with PPI?

Factors that shape the impact of PPI in research outcomes	***Unique to cancer research with PPI? Yes/No/Maybe***	***Transferability beyond cancer*** *Please explain:*
Successful PPI processes		
Dissemination		
Resources and the political context		
PPI in implementation		
The significance of power and leadership		
PPI in commissioning research		
Wanting to make a difference		
Networks		
Information and Communication Technology		

There are three emerging findings from this Delphi study: A) the nine complex and interrelated factors that shape the impact of PPI in research outcomes; B) the factors exist at *micro, meso and macro level(s)*; and C) a collective definition of *PPI impact. I would like your views about what the next steps for this work might look like. Please explain your answer in the box below, thinking about people/groups and organisations that might benefit from knowing about these findings, any recommendations you have, any unanswered questions this work raises for you etc.*

Appendix 15 - Ethics Approval

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DE MONTFORT UNIVERSITY
LEICESTER

HLS FREC Ref: 933

28th May 2012

Raksha Pandya-Wood
PhD Candidate
Faculty of Health & Life Sciences

Dear Raksha,

Re: Ethics application – Understanding the impact of impact of service user influenced research: Phase one (ref: 933)

I am writing regarding your application for ethical approval for a research project titled to the above project. This project has been reviewed in accordance with the Operational Procedures for De Montfort University Faculty of Health and Life Sciences Research Ethics Committee. These procedures are available from the Faculty Research and Commercial Office upon your request.

I am pleased to inform you that ethical approval has been granted by Chair's Action for your application. This will be reported at the next Faculty Research Committee, which is being held on 14th June 2012.

Should there be any amendments to the research methods or persons involved with this project you must notify the Chair of the Faculty Research Ethics Committee immediately in writing. Serious or adverse events related to the conduct of the study need to be reported immediately to your Supervisor and the Chair of this Committee.

The Faculty Research Ethics Committee should be notified by e-mail to HLSFRO@dmu.ac.uk when your research project has been completed.

Yours sincerely,

Dr Richard Davies
Deputy Chair
Faculty of Health and Life Sciences
Research Ethics Committee

Faculty of Health and Life Sciences, The Gateway, Leicester LE1 9BH.
Tel: (0116) 255 1551 / **Fax:** (0116) 257 7135

DE MONTFORT UNIVERSITY
LEICESTER

HLS FREC Ref: 1328

29th May 2014

Raksha Pandya-Wood
PhD Candidate

Dear Raksha,

Re: Ethics application – Exploring the impact of service user involvement in cancer research and its usability. (Ref: 1328)

I am writing regarding your application for ethical approval for a research project titled to the above project. This project has been reviewed in accordance with the Operational Procedures for De Montfort University Faculty of Health and Life Sciences Research Ethics Committee. These procedures are available from the Faculty Research and Commercial Office upon your request.

I am pleased to inform you that ethical approval has been granted by
Chair's Action for your application. This will be reported at the next Faculty Research Committee, which is being held on 19th June 2014.

Should there be any amendments to the research methods or persons involved with this project you must notify the Chair of the Faculty Research Ethics Committee immediately in writing. Serious or adverse events related to the conduct of the study need to be reported immediately to your Supervisor and the Chair of this Committee.

The Faculty Research Ethics Committee should be notified by e-mail to hlsfro@dmu.ac.uk when your research project has been completed.

Yours sincerely,

M. Grootveld.

Professor Martin Grootveld
Chair
Faculty Research Ethics Committee
Faculty of Health & Life Sciences
De Montfort University

Email: hlsfro@dmu.ac.uk
Web: http://www.dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/health-and-life-sciences-ethics-procedures.aspx

Research & Commercial Development Office, Faculty of Health and Life Sciences
1.25 Edith Murphy House, The Gateway, Leicester LE1 9BH. **T:** (0116) 257 7765 **E:** hlsrcogeneralenquiries@dmu.ac.uk

Appendix 16 - Summary of research outputs generated

Outputs influenced by this PhD study

Two peer-reviewed papers

1. **Pandya-Wood R,** Barron D and Elliot J (2017) A framework for public involvement at the design stage of NHS health and social care research: time to develop ethically conscious standards. *Research Involvement and Engagement*, *3*(1), p.6.
2. Walker DM, and **Pandya-Wood R** (2013) Can research development bursaries for patient and public involvement have a positive impact on grant applications? A UK-based, small-scale service evaluation, *Health Expectations.*

Three book chapters

3 **Pandya-Wood R,** Elliot J and Barron D, (2018) Service user and lay involvement in healthcare in Ayers S, Baum A, McManus C, Newman S, Wallston K, Weinman J and West R eds *Cambridge handbook of psychology, health and medicine*. Cambridge University Press

4 **Pandya-Wood R** and Robinson A (2014) 'Patient and Public Involvement in Your Research' in Walker D.M. (Ed.) *An Introduction to Health Services Research*, London, Sage

5 Rivas C and **Pandya-Wood R** (2014) Dissemination in Walker D.M. (Ed.) *An Introduction to Health Services Research*, London, Sage.

Three conference papers

6 **Pandya-Wood R**, Blackburn S, Day R, Ingram C, Hapeshi J, Khan S, Muir D, Baird W (2017), Being a lay co-applicant on national peer reviewed research funding grants, *Research Involvement and Engagement,* 3(Suppl 1):O8 Abstracts from the NIHR INVOLVE conference London, UK. 28 November 2017

7 Horobin A, Ewart C, Higton F, Vanhegan S, **Pandya-Wood R**, Stewart J, Wragg A, Wray P, Widdowson K (2017), The East Midlands Sharebank – a cross-institutional model for sustainable learning and development for public involvement in research, *Research Involvement and Engagement,* 3(Suppl 1):O20 Abstracts from the NIHR INVOLVE conference London, UK. 28 November 2017

Two conference posters

8 **Pandya-Wood R** (2014) A reflective account of the trustworthiness and authenticity of data using Lincoln and Guba's (1985) work in a PhD research study: Understanding the impact of public involvement in cancer research, INVOLVE conference, Nottingham, UK.

9 Smith G, Eglinton L, De Cort L and **Pandya-Wood R**, (2014) Lay reviewing scientific research: untangling three perspectives, INVOLVE Conference, Nottingham, UK.

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