This protocol has regard for the HRA guidance and order of content

FULL/LONG TITLE OF THE STUDY
Before, during and after gender identity specialist services: improving the integration of care for trans adults

SHORT STUDY TITLE / ACRONYM

Integrating care for trans adults (ICTA)

PROTOCOL VERSION NUMBER AND DATE

Version 2.0 June 30 2020.

RESEARCH REFERENCE NUMBERS

IRAS Number:	262467
SPONSORS Number:	661833
FUNDERS Number:	**17/51/08**

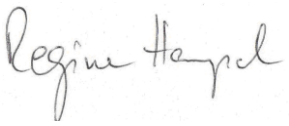
SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: 

Date:

June 30 2020.

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Name (please print):

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Position:

Associate Dean (Research Excellence), Faculty of Wellbeing, Education and Language Studies

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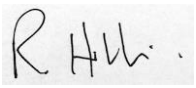
Chief Investigator:

Signature: 

Date:

June 30 2020.

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LIST of CONTENTS

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Sponsor	Prof Regine Hampel, Associate Dean (Research Excellence), Faculty of Wellbeing Education and Language Studies, the Open University
Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	Sue Pargeter Research Manager The NIHR Health Services and Delivery Research Programme National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre University of Southampton Alpha House, Enterprise Road Southampton SO16 7NS Email: sue.pargeter@nihr.ac.uk Tel: 02380597599
Key Protocol Contributors	N/A
Committees	N/A

STUDY SUMMARY

Study Title	Before, during and after gender identity specialist services: improving the integration of care for trans adults
Internal ref. no. (or short title)	Integrating care for trans adults
Study Design	There are two main elements to the research design: • A national screening survey followed by qualitative interviews of experiences of accessing services with a structured national sample of trans people • Six organisational case studies of attempts to improve the integration of care from multiple services relevant to trans adults. These will gather evaluative data from interviews with both service provider staff and service users Outputs will consist of reports and educational materials which capture lessons learned about how to improve integration between NHS and voluntary sector services used

	by trans adults for desired gender affirmatory treatment as well as their wider health and wellbeing needs.
Study Participants	Trans adults who use health and wellbeing services, and staff who work in services aiming to meet the needs of trans adults.
Planned Size of Sample (if applicable)	A total of 180 service users A total of 75 service provider staff
Follow up duration (if applicable)	N/a
Planned Study Period	March 2019 to Aug 2021
Research Question/Aim(s)	Aims: 1. To analyse empirically the current realities and derive conceptually-informed future possibilities as to how various NHS services and third sector organisations can work together effectively to address the needs of trans adults at different stages of their lives. 2. To disseminate this analysis and its implications for wider learning, improving the effectiveness of specialist and non-specialist services in meeting the needs of trans adults. Research Questions: 1. What is the range of models recently used in the UK for providing integrated care for meeting the specific health and wellbeing needs of trans people? 2. In the different integrated service models, how effective are the different aspects of services and their interaction in meeting the needs of people at different stages of their gender transition and at different ages? 3. Which factors make services more or less accessible and acceptable to the variety of trans adults who need them? 4. What lessons emerge as to how models for providing integrated care can be successfully implemented and further improved in meeting the needs of trans people within limited resources and continuing constraints resulting from the COVID-19 pandemic?

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
Sue Pargeter Research Manager The NIHR Health Services and Delivery Research Programme National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre University of Southampton Alpha House, Enterprise Road Southampton SO16 7NS Email: sue.pargeter@nihr.ac.uk Tel: 02380597599	£722,896.80

ROLE OF STUDY SPONSOR AND FUNDER

The Open University is the sponsor of the study. This protocol was developed during the process of applying for funding under and NIHR Health Service Delivery and Organisation call for research on Gender Identity Services. The Open University leads a wider project team including Northamptonshire Healthcare Partnership Trust, Leeds and York Partnership Foundation Trust, the LGBT Foundation and Yorkshire MESMAC. The OU team consulted with this project team in developing the protocol and application for funding, responding to comments and suggestions from the NIHR board and peer reviewers during the application and contracting processes. The sponsor will control final decisions on study design, conduct, data analysis and interpretation, manuscript writing and dissemination, subject to further peer review arranged by NIHR. NIHR will however control sign off of the final report on the research, once the OU team has responded to peer review of an initial draft.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

The conduct of the study is governed by the following groups.

The independent study steering group (SSG) monitors and supports the progress of this research against the plans set out in this protocol, representing the funder. The steering group will need to agree any proposals from the sponsor and research team to deviate significantly from the protocol. Members of the SSG are independent of the sponsor and other organisations involved in the research team, and include a number of Patient and Public Involvement (PPI) representatives as well as academic peers and an NHS clinician working in the field.

The PPI group consists of members of the adult trans population or people closely involved with trans service users. Its members are independent of the sponsor and research team, apart from its chair,

the PPI lead, who is a member of the Project Management Group (see below). The PPI group has an advisory role, commenting on all research plans and instruments, and ethics applications including proposed recruitment processes and consent materials. It will also have early sight of findings and be asked to comment on interpretations of data made by the research team. It will further play a key role in promoting the outputs of the research and raising awareness of and encouraging attendance at the national workshop to be held in the second year of the project.

The Advisory Panel provides further consultative input on the progress of the research, including a number of relevant professional perspectives, and is independent of the research team and sponsor. It includes NHS stakeholders who will be able to comment on the relevance and utility of project plans and outputs in terms of influencing practices in NHS settings, particular primary care and general practice. There are also representatives from two leading national third sector organisations that advocate for the rights of trans people and undertake educational work with NHS and other organisations. There is a further representative from the British Association for Counselling and Psychotherapy. This panel will critique and advise on dissemination of project outputs, including educational materials for service users and professionals.

The Project Management Group consists of the complete research team and meets quarterly to review progress and refine plans.

Its membership is:

Prof Richard Holti – OU/Chief Investigator(chair)
Dr Peter Keogh – OU/Co-investigator
Dr Naomi Moller – OU/ Co-investigator
Dr Paul Walley – OU/ Co-investigator
Dr Eli Joubert – Leeds and York Partnership NHS Foundation Trust, Co-investigator
Dr Bryan Timmins, Northampton Healthcare NHS Foundation Trust, Co-investigator
PPI Lead (to be appointed)
Jamie Fletcher – Researcher, Yorkshire MESMAC/ Co-investigator
Ellen Hill, Yorkshire MESMAC
Michael Petch – Researcher, LGBT Foundation
Emma Meehan, LGBT Foundation
Dr Ben Vincent - OU Research Fellow
Evelyn Callahan – OU Research Fellow
Sam Hope – PPI Lead

PROTOCOL CONTRIBUTORS

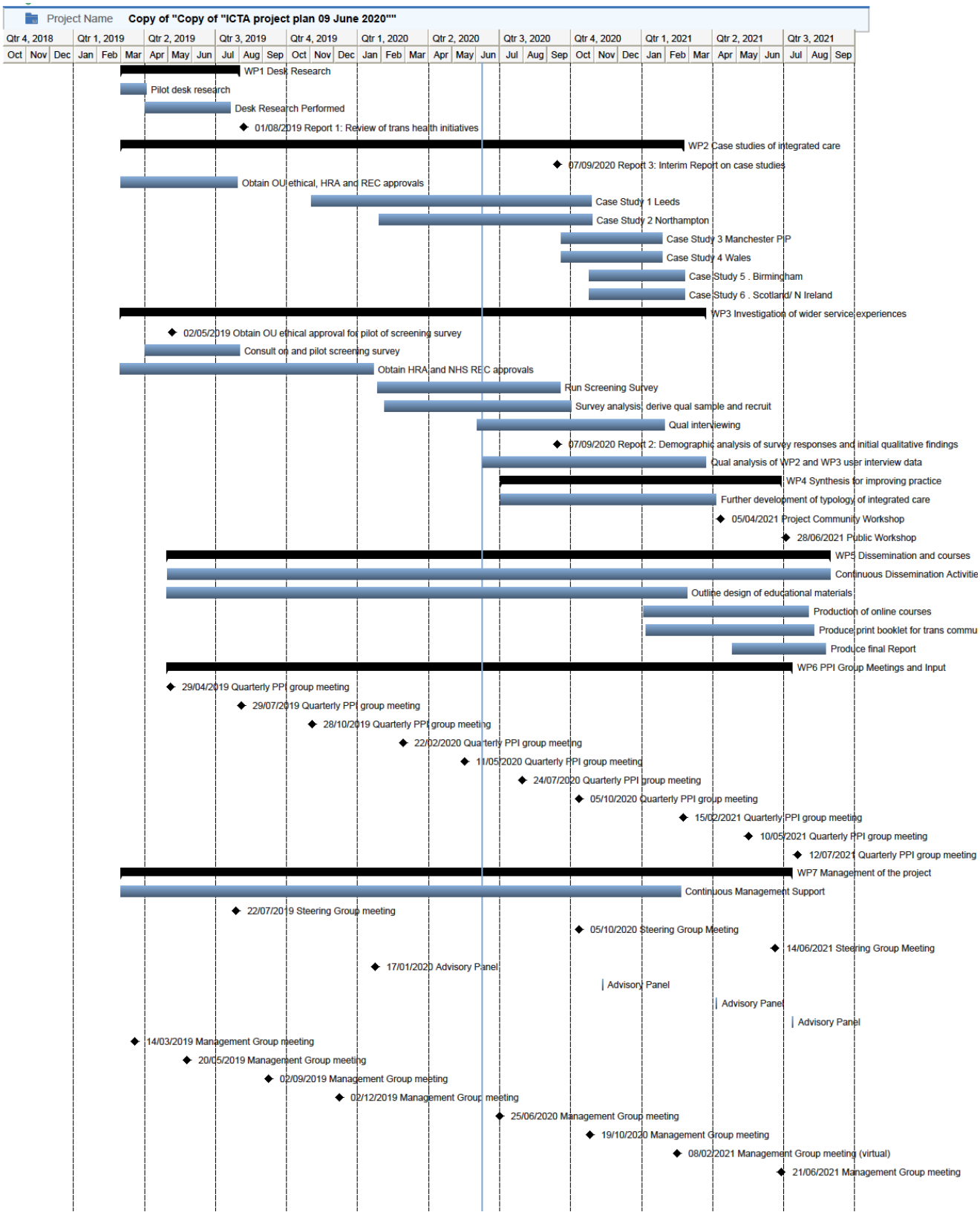
This protocol was developed during the process of applying for funding from NIHR. All members of the project team were involved reviewing drafts and in responding to feedback from NIHR reviewers, and we also ensured that the perspectives of a variety of trans people were represented. Drafts of this protocol were shared with a PPI lead during the proposal stage, who commented extensively, and this input has been incorporated. The conceptualisation and detail of the research plan were developed through dialogue with our third sector partners, who work closely with different parts of the adult trans community and also employ trans staff. Four members of the project team are trans.

KEY WORDS: Trans health care, gender identity services, integrated care

STUDY FLOW CHART

The Gantt chart on the following page shows the flow of project activities over a 30 month period from March 1st 2019. The project was originally scheduled to conclude after 24 months, but has been tentatively replanned to last an additional six months, following a period of being paused during the COVID-19- lockdown, beginning in mid- March 2020.

STUDY FLOW CHART



STUDY PROTOCOL

Before, during and after gender identity specialist services: improving the integration of care for trans adults

1 BACKGROUND

This research concerns developing effective models for the health services needed to support trans adults before, during and after they are seen by NHS-commissioned specialist gender identity services. Throughout this protocol we use the term trans to refer to the diverse group of people who identify with a gender or gender expression that differs from their birth-assigned gender.

Trans people over 17 who wish to make a medical transition are likely to seek care at one of the UK's ten Gender Identity Clinics (GIC), also known as Gender Identity Services (GIS). Their transition related care is also likely to involve other NHS services, including those of their GPs and practice nurse, other primary care services including pharmacies or dentistry, and may involve sexual and reproductive health services, mental health services, including those for common mental health conditions (Increasing Access to Psychological Therapies – IAPT), as well as a variety of medical and surgical specialisms. In addition, a range of third sector organisations provide support and advocacy for trans people, including the facilitation of peer support.

The need for co-ordinated care across services and specialisms and over time was recognised by the Select Committee Report on Transgender Equalities (House of Commons (HoC) 2016), which concluded that 'The NHS is letting down trans people' (HoC 2016:3). There is evidence of overly complex referral pathways and lack of joint working between generalist and specialist services (HoC 2016). The Medical Director for Specialist Services in NHS England has raised concerns explicit about long waiting times for GICs, as well as systemic failings in the care that trans people receive, including a pervasive lack of cultural awareness amongst NHS staff (Palmer 2017). This introduces a broader point about the health care needs of the trans population, whether these needs are directly concerned with a medical or transition or not. Throughout their lives, trans people may experience particular issues in receiving appropriate and well-integrated care concerning their general health and wellbeing (LGBT Foundation 2017).

There are local examples of innovation in providing better integrated services for trans adults, for instance the LGBT Foundation Pride in Practice primary care accreditation scheme in Greater Manchester and the support offered by Yorkshire MESMAC in collaboration with Leeds GIC for people on the GIC waiting list. There are also a variety of trans led organisations that promote health and wellbeing amongst trans adults facilitating access to NHS services. These include cliniQ in London and Navigate Brighton. However as yet there is little or no rigorous research on what is effective in terms of an integrated approach to health services for trans people, or how trans-specific care can be improved. A further challenge is to maximise the impact of the learning from such research throughout the NHS.

The adult trans population has significant and distinctive health and wellbeing needs, which the NHS currently struggles to meet. Whilst estimates of the UK trans population lack reliable data and remain speculative, a figure above 300,000 seems likely (GIRES, 2011). Waiting lists for the GICs in England totalled over 2,300 in 2015, with a total clinic population at that point of 6,000. Waiting times for first

appointments at that point varied between 9 and 64 weeks (Analysis Intelligence & Resource Unit, 2015).

Whilst NHS England is acting to improve the capacity and capability of the GICs (Palmer, 2017), a complementary challenge is to improve the whole system of care that trans people experience. There are strong arguments that specialist NHS services are in general most effective when collaborating closely with primary care, other non-specialist NHS and voluntary sector services (Robertson, Sonola, Honeyman, Brooke & Kothari, 2014; Future Hospital Commission, 2013). For a trans person, NHS primary care and third sector organisations may provide initial support and referral to a GIC. Such services may then provide further care or support during the extended period that most people wait to be seen by a GIC. Trans people may also experience a range of other primary or acute physical or mental health services as they are assessed and prepared for gender-affirming physical treatment by a GIC, and indeed whilst they are receiving it (NHS England (NHSE), 2015). Following discharge from the GIC they will then receive further care from their GP – for example a permanent hormone replacement therapy (HRT) prescription. They will then use other NHS services as well as possibly social care to support them in living well as they age.

Problems of co-operation between some GPs and GICs are illustrated by guidance on the websites of some GICs that people who find their GP unwilling to refer them or to prescribe hormones should consider changing their GP. Current NHS England proposals under consultation include locating responsibility for hormone prescribing and administration within specialist services. These may resolve some issues but exacerbate others, particularly for people who do not live near one of the GICs.

More generally, trans people may experience social isolation and stigmatisation and often encounter difficulties in accessing primary care and other branches of healthcare, facing particular barriers to receiving sympathetic and effective treatment (LGBT Foundation 2017). These challenges may become accentuated as people enter later life and develop greater need for a range of health and social care services. Although there are very few studies that document the health care experiences and needs of the variety of groups making up the trans spectrum in later life, research on the later-life health and social care needs of the wider population underlines the need for the coordination of services, spanning physical and mental health, as well as social care and social support (Ham & Curry, 2011). Trans people and those close to them may also have distinctive needs in decision-making during end-of-life care, which are often not well met by mainstream NHS services (Almack et al 2015).

Mental health and wellbeing services are also highly relevant to many trans people. A recent review of evidence suggests that the trans population carries a higher than average prevalence of common mental health conditions as well as suicidality (Millet et al 2017). Yet other studies indicate that the experience of receiving mainstream psychological therapies can be a difficult, unsatisfactory and even a fearful one for many trans people (Applegarth and Nuttall, 2016; McCann & Sharek 2014; McNeil et al., 2012). Although there is little existing large-scale research on the subjective wellbeing specifically of trans people, research on the wider LGBT community indicates lower levels of wellbeing than the wider UK population, on average (ONS 2017). One USA study specifically of trans people suggests that there may be significant differences in psychological wellbeing between different identity groups within this population, with some groups, particularly trans women, experiencing lower than average levels (Warren et al 2016).

On the positive side, there are collaborations with third sector organisations to make NHS primary care more supportive of trans people (LGBT Foundation 2015). The psychological therapies literature in the UK and USA includes models for meeting the needs of trans clients more effectively (Hendricks & Testa 2012, Austin & Craig 2015). Further, the main UK institutions responsible for professional standards in psychological therapies and primary care have recently updated a joint Memorandum of Understanding that takes a strong stance against 'conversion therapy', including that which targets gender identity, as well as sexuality (RCGP 2017).

Research is therefore needed to support the development of more integrated provision sensitive to the varied needs present within the heterogeneous trans population. This research is a response to the lack of rigorous evidence about the nature of effective integrated care for trans people as they seek help and support over time. Following the widespread impact of the COVID-19 lockdown on health services, and the likely continuing restrictions on face to face interactions, travel and services, the research will also explore how lessons about effective integration of care can best be implemented in the context of managing a continuing pandemic. The needs of trans people for better integrated care are likely to become even more pressing.

2 RATIONALE

This research brings together a unique collaboration of health services researchers, research psychologists and specialists in sexuality, gender and health with specialist clinical providers and third sector organisations. The research employs innovative and collaborative methodologies to learn from current initiatives to improve the integration of care. It provides a multi-perspective and mixed methods evaluation of current initiatives and draws out the wider implications for improving the integration of care.

3 THEORETICAL FRAMEWORK

The research is grounded within an epistemological framework of critical realism (Fleetwood, 2014). We are seeking to understand in depth the experiences and sense-making of service staff and service users, and how these are both shaped by and influence social structures and conditions people move within.

We build on three areas of wider health policy and organisational studies literature to enable critical evaluation and learning from attempts to improve the integration of care for trans adults.

Service integration

A first area concerns the concept of integrated care, which has received considerable attention in recent years. The concept has many different definitions referring to a wide variety of initiatives in designing and delivering health and social care services (Kodnor, 2009; Shaw et al., 2011). However, most commentators agree on some core driving principles, which together reflect the different perspectives of policy makers, commissioners service managers, clinicians and service users or patients. In any particular initiative to provide integrated care the following concerns are reflected to a greater or lesser extent (Lloyd and Wait, 2006):

- Service users requiring several distinct branches of medical or social care benefit from experiencing seamless or 'person-centred' care, rather than a fragmented experience of

separate attendances at different services, each one delivered apparently without a full understanding of what others are doing or the implications for the person.
- Clinicians and other service professionals often want to improve their inter-disciplinary coordination around cases, improving outcomes and preventing errors
- Managers want to improve the efficiency of services, removing redundancy or duplication, for example in the form of similar clinical or administrative work being carried out with the same person in two or more different places
- Commissioners or policy makers aspire to align the incentives of different services focussing on the needs of the same group of people, provide a more holistic system of care, and improve clarity as to who is accountable for achieving health outcomes.

What these principles mean in practice, and the processes, methods and tools suitable for achieving them, depend greatly on context, (Kodnor 2009: Goodwin, 2016). Reviewing existing research on integrated care and its relevance to UK contexts, Shaw et al (2011) identify five different *arenas* of integration, each with their attendant methods. These build on other similar classifications, such as that of Kodnor (2009). The five are: *systemic or policy-level development* of rules, frameworks and incentives; *normative interventions*, developing common goals and values amongst different staff groups; *organisational arrangements*, which give structures or contractual forms by which different providers can work together; *clinical practices*, including the protocols, roles and education needed to bring different aspects of care into a closer relationship; and *administrative processes*, such as the information systems and budgeting arrangements needed to achieve co-ordinated working (Shaw et al 2011). Any instance of integration may focus on one or several of these different arenas.

Yet further categories have been identified as useful in terms of characterising the options for customising aspirations for integrated care in particular contexts. Leutz (1999) sets out three different *levels or degrees* of integration: informal ad hoc linkages between distinct provider teams; more structured and sustained coordination between providers; and full integration of teams within a unified new organisational entity. Kodnor (2009) characterises the scope or breadth of integration in terms of (a) horizontal integration between similar services e.g. in primary care, to provide a more unified user experience and (b) vertical integration where different kinds of services e.g. hospitals, mental health services and primary care work together more closely. Shaw et al. (2011) point out that an integration initiative may involve both aspects of integration.

The research explores the relevance of each of these arenas and degrees of integration for understanding current initiatives for improving the health services experience of trans people, and the implications for strengthening them.

Person-centred care

Second, there are strong connections between integrated care and innovations in the field of 'person centred' approaches to healthcare and user involvement in the shaping and delivery of care (Coulter, 2011). A large body of evidence indicates that improved patient satisfaction and clinical outcomes are in general strongly related to integration in the sense of a person-centred approach to healthcare (National Voices 2014). Clear and full communication of clinical options to service users or patients, their involvement in decisions about their care, and continuity in the clinical and support personnel working with them all have positive effects. A related body of work elaborates the social, clinical and resource effectiveness of other modes of user involvement in care, in the sense of users being involved, either as individuals or collectively, in the design and delivery of the services they need (Greenhalgh, Humphrey & Woodard, 2011). Ideas of user-led approaches to service design are of

particular relevance to understanding innovations in health services for trans people, given the role of third sector organisations in advocating for and involving members of trans communities in shaping services. In particular the fostering of peer support groups and networks can itself be seen as a form of service integration. We will draw on the literature on person-centred care and user involvement in developing our typology of integrated services for trans people in Work Package 1, described below.

The research will draw on existing work to understand and measure outcomes of attempts to achieve service integration in terms of service user experience. Singer et al. (2011) make the case that attempts at service integration need to be subjected to the test of what they achieve for users, so that they are not simply meeting the needs of providers. These authors, in the company of Kodnor (2009) and Goodwin (2016) point out that the measurement of user experience must be relevant to the particular scope and kind of integration being attempted. In a comprehensive review of instruments for measuring integrated care Bautista et al. (2016) however identify two categories of standardised and validated instruments with potential for application to a wide range of integrated care contexts. These concern measurement of experiences of continuity of care and of patient- centred care. Haggerty et al. (2011) for example build on previous work to develop a promising generic measure of continuity of care in relation to patients encounters with several clinicians, including the degree to which the patient experiences themself as a care partner. We are building on such existing instruments in crafting data gathering tools – interview schedules and survey questionnaires - to assess the outcomes of integrated care initiatives for service users, whilst ensuring that our measures are relevant to the aims and scope of what is being attempted.

Dynamics of service innovation

Third, the research draws on traditions in organisational research that examine the practical difficulties and underlying dynamics typical of attempts to build integrated services. Our previous NIHR-funded research has shown that it is not sufficient for commissioners merely to understand what integrated care might look like. Achieving it in practice can be fraught with challenge and involves 'institutional work', often of a highly political nature, in breaking with established systems, professional and organisational boundaries, crafting and embedding new practices (Storey et al., 2018). We will examine these processes in depth and produce guidance for NHS commissioners, provider clinical leads and managers on what is involved in actually implementing improved and integrated models of care for trans people. Researchers of organisational innovation have long recognised that the emergence of new models of organising needs to be understood in context and as a process. The instigation and implementation of organisational innovations is a complex process, involving a range of actors and perspectives on what is to be achieved (Pettigrew 1985). The outcomes achieved depend as much on the process of change adopted as on the organisational templates being applied. In healthcare, there is evidence that leadership that engages staff and users participatively in change leads to better clinical outcomes (West et al., 2015).

Other literature illuminates the kinds of dynamics that need to be negotiated in such processes of change. Hudson (2007) contrasts two possible patterns of the dynamics of inter-professional working in care; a 'pessimistic' or defensive model where professions avoid real engagement with each other, and an 'optimistic' model where common values and a shared commitment to improving care over-ride restrictive views of professional practice and identity. Woodhouse and Pengelly (1991) shed additional light on the unconscious dynamics that can drive the pessimistic model. Different professions develop structures and routines for their work – such as the location, length and precise agenda for

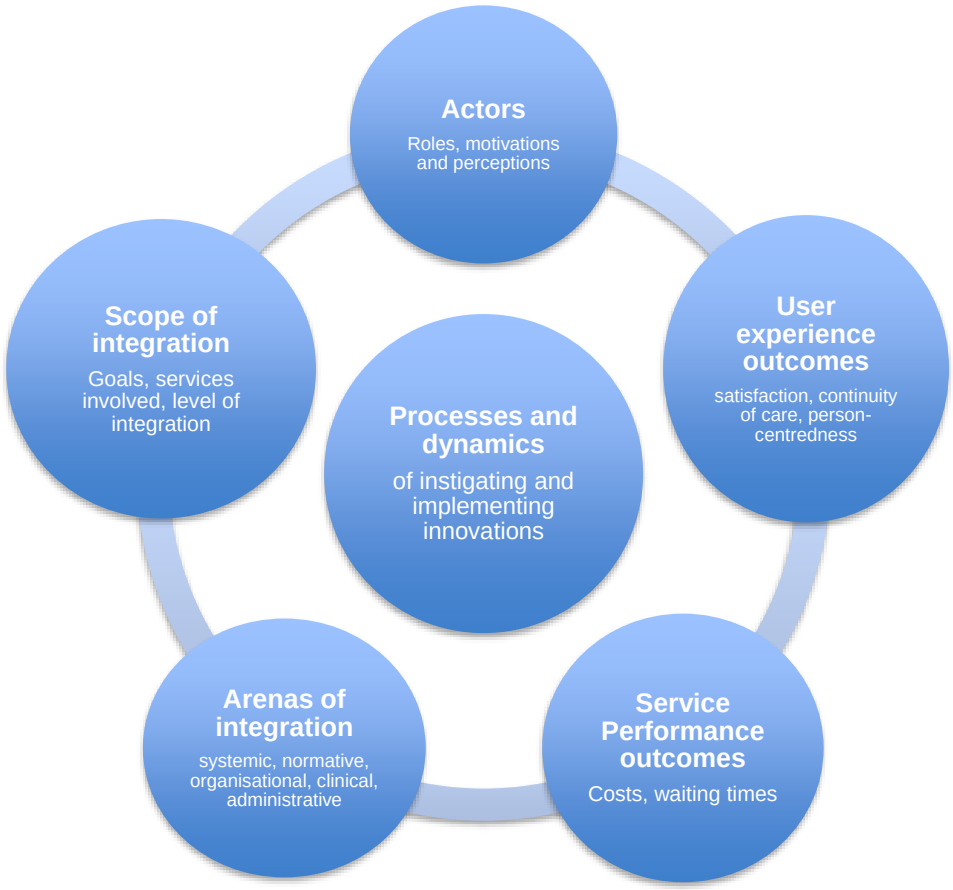
interactions with their client - which impose some order on potentially overwhelming issues and provide psychological containment and comfort for the care giver as well as for the client. Attempts to collaborate can threaten these socially organised defences against anxiety, heightening stress and undermining willingness to collaborate further. These are likely to be exacerbated when working with a client group subject to social stigma.

Our research draws out how those seeking to create integrated models of service provision for trans people can address the concerns that trigger the pessimistic model, and encourage open inquiry about what works in the spirit of the optimistic model.

Figure 1 summarises the conceptual framework that guides our data gathering and analysis. We examine in each of our six case studies (see Work Package 2) how a variety of actors, including NHS commissioners, managers, clinicians and support staff have worked with service users and voluntary sector representatives to instigate and implement innovative arrangements. We are investigating the development of the goals, scope and degrees of the integration (e.g. ad hoc, co-ordinated, unified) being attempted, the range of arenas involved (e.g. systemic, normative, organisational, clinical, administrative, user-led), and the outcomes in terms of user experience and service performance.

We also draw on theories of the dynamics of innovation (summarised above) to examine the impact of approaches used to implement these innovations, and the barriers or difficulties encountered.

Figure 1: Concepts for understanding the shaping of integrated care for trans adults



4 RESEARCH QUESTION/AIM(S)

4.1 Objectives

The **aims** of this collaborative research are:

A1. To analyse empirically the current realities and derive conceptually-informed future possibilities as to how various NHS services and third sector organisations can work together effectively to address the needs of trans adults at different stages of their lives.

A2. To disseminate this analysis and its implications for wider learning, improving the effectiveness of specialist and non-specialist services in meeting the needs of trans adults.

The overall **objective** is to *produce guidance material and on-line educational materials for trans people who use services, commissioners and staff in specialist and generalist services, so that they can better understand and shape cost-efficient and integrated provision*

The **research questions** (RQs) are:

RQ1. What is the range of models recently used in the UK for providing integrated care for meeting the specific health and wellbeing needs of trans people?

Output: an initial conceptually-informed typology of the options for service design, based on current good practices.

RQ2. In the different integrated service models, how effective are the different aspects of services and their interaction in meeting the needs of people at different stages of their gender transition and at different ages?

Output: an analysis of evidence about 'what good looks like' in integrated services for trans people, in terms of making services accessible and meeting service user needs in a cost-efficient way. This will be useful to a range of service providers, commissioners and also to service users.

RQ3. Which factors make services more or less accessible and acceptable to the variety of trans adults who need them?

Output: An analysis of empirical evidence as to what makes trans people likely to use services that are relevant to their needs and which factors in the way that services are promoted and delivered make people less likely to access or use them effectively.

RQ4. What lessons emerge as to how models for providing integrated care can be successfully implemented and further improved in meeting the needs of trans people, within limited resources and continuing constraints resulting from the COVID-19 pandemic?

Output: a distillation of lessons for designing, implementing and improving more integrated care for trans adults, including a revised conceptual typology of integrated service options indicating options for future exploration as well as those currently in existence; to be used by service providers, commissioners, as well as service users and their advocates as they consider viable models for gender identity services in the context of the profound impacts of the COVID-19 pandemic on the NHS.

4.2 Outcome

The research will deepen understanding for NHS commissioners and service providers for trans people, for integrated care and the options available for supporting trans patients in various stages of the heterogeneous process of considering and making a transition, and then living well afterwards. The research will look both at the provider service costs and the experience and satisfaction of users of different models for co-ordinating relevant aspects of care. It has the potential to improve the experience and wellbeing of service users, to improve how specialist and non-specialist services work together, and to improve the working lives of NHS staff providing these services, contributing to workforce wellbeing, development and retention.

The project will develop high quality guidance and online educational materials for disseminating the learning and engaging with service users, professionals and commissioners to bring about more effective models and practices in care.

5 STUDY DESIGN and METHODS of DATA COLLECTION and DATA ANALYIS[1]

(Note. This section includes the following information specified in the HRA guidance on protocols for qualitative research: the settings in which research data will be obtained as the approach to sampling and recruiting participants)

The overall research design is of a multi-component and mixed method study of initiatives to improve health care for trans people, leading to the identification of areas for improvement and the production of educational materials as a mechanism for achieving improvement. The research philosophy involves the coproduction of knowledge (Verschuere, Brandsen & Pestoff, 2012). It combines analytical rigour with a high level of engagement with service staff and users in the generation of data, analysis and understandings of where and how improvement can occur.

The research will take place over two years, consisting of five overlapping and tightly interconnected component work packages (WPs):

- WP 1 Desk research on current arrangements across the UK (Months 1 to 5). This addresses RQ1. We will review current initiatives to improve the care of trans people, develop an initial typology of integrated services, informed by theories of integrated care, and map the range of policy initiatives and practical examples in existence. This will provide a basis for identifying the case studies in WP2.

- WP 2 Six case studies of promising models of integrated care (Months 2 to 24). This addresses RQ2 and also contributes to answering RQ4. We will gather rich qualitative data as well as relevant quantitative data, from staff and service to users to examine the processes implementing integrated care initiatives, the challenges encountered, and the outcomes in terms of the experiences of users, other aspects of service performance, including waiting times and cost

[1] As well as covering study design, data collection and analysis, this section also includes the following information specified in the HRA guidance on protocols for qualitative research: the settings in which research data will be obtained; and the approach to sampling and recruiting participants. It also outlines the main elements of approach to data management.

- WP 3 A wider investigation of factors associated with service use and non-use. (Months 2-24). This addresses RQ3. An initial screening survey will be used to construct purposively a diverse sample of 90 participants for qualitative interviews. Interviews will explore the experiences of this sample of trans people, including those who have had positive experiences, those who have not been able to access services, and those who have not found the services they have accessed to be acceptable.

- WP 4 Synthesis of findings and implications for improving practice (Months 17 to 29). This addresses RQ4. We will develop an analysis of the nature of effective integrated care, drawing together findings from the case studies, the survey and purposive sample about what makes services effective and accessible, as well as inaccessible or unacceptable. We will refine the typology of integrated care arrangements from WP1, using theories of integrated care to indicate where enhanced integration might be attempted in future. We will also draw out the lessons about the challenges of implementing integrated care and ways of meeting these. This analysis will be tested out and refined in workshops with service staff and service users.

- WP 5 Outputs and dissemination (Months 3 to 30. This includes the production of booklets for users and professionals, as well as high quality online educational materials to meet the overall objective of helping service users and service providers better understand and shape cost-effective and integrated provision for trans and non-binary people.

WPs 1 to 4 are now described in detail. WP 5 is described in Section 7, Outputs and Dissemination Policy.

WP 1 Desk research on current arrangements (Months 1 to 5)

This consists of internet-based research on policy and reporting documents relevant to health services for trans adults. The purpose is to identify the range of integration arrangements in services for trans adults currently being used or planned.

We will examine NHS England policies for health services for trans adults, including the commissioning specifications for and reports on specialist services. We will also examine the policies, plans, specifications and reports on other services relevant to the care of trans peopled produced by all the regional Sustainability and Transformation Partnerships (STPs) in England, by a sample (provisionally 20, representing a 10% sample) of Clinical Commissioning Groups (CCGs) and the local authority public health departments associated with them, as well as the policies plans and service reports produced by UK third sector organisations that support LGBT populations (approximately 20). In addition, we will review similar documents produced by the Welsh, Scottish and Northern Irish Health Boards. CCGs will be selected to constitute a structured sample representing areas with different socio-economic conditions, as well as areas that differ in how close they are to existing GICs.

This allows us to build up a picture based on the information available of the current state and future planning of health services for trans adults before, during and after people are seen by specialist services, and in particular the nature of attempts to improve integration of care. This review of integration initiatives will for example take account of: primary care collaborations with GICs; third sector collaborations with GICs and/or primary care; other user-led third sector initiatives that seek to fill gaps in available care for trans adults; coordinated working between mental health services and GICs; and new patterns of referral, such as healthcare navigators or open access mental health

wellbeing clinics or centres, which allow people to access some services without going through their GP.

We are using a structured approach to selecting and analysing documents using thematic qualitative analysis, based on Qualitative Document Analysis (QDA), developed in political science research for the systematic, impartial and replicable analysis of policy documents (Altheide, 1996). Thematic qualitative data analysis will also be used in WP 2 and WP 3, adapted to different kinds of qualitative data and context. In this WP, the main features are:

1. The inclusion criteria for documents is (a) they are published within the last five years and refer to the health needs of trans or non-binary adults and/or how well these are currently being met; (b) they contain policies or plans concerning the nature of services needed to meet these health needs; (c) they report on arrangements or initiatives to provide care or improve care for trans adults.
2. Relevant documents are being collected through searching with appropriate keywords the websites of organisations in the categories listed above. In the case of the sample of CCGs/public health departments, we will also contact relevant programme directors, for example in mental health or sexual health, for them to recommend relevant documents. We may use a similar strategy with other bodies if documents prove difficult to access from their websites. We already have an agreement with Oxfordshire CCG to support us in piloting a document search.
3. We draw on conceptualisations of the options for integrated service provision to develop an initial typology of integration initiatives relevant to trans people. Documents in scope will be loaded into NVivo qualitative analysis software and coded according to analytical themes derived from the typology concerning (a) formulations of health needs for various groups within the trans population and (b) conceptions of how to improve the integration of services to meet these needs. Codes will be verified through independent coding by two members of the research team with inconsistencies resolved.
4. The thematic coding provides the basis for an analysis of areas of trans health need that are being addressed, which parts of the typology of the typology of integrated care arrangements are already populated, or being worked on in practice, and where there appear to be gaps in the way services are currently being integrated which might pose opportunities for future innovation.

The output is a report summarising the range of current initiatives to improve health services for trans adults, locating them within an initial typology of service integration arrangements and proposing particular promising types of integration which should be the focus of case studies in WP 2.

WP 2 Case studies of promising models of integrated care (Months 3 to 24)

Six case studies of service integration will be selected as promising models for learning from. These cases will be selected purposively as instances of where NHS and/or third sector organisations have developed potentially cost-efficient and innovative local approaches to supporting people within the trans population. These case studies will address a range of different groups within this diverse population. Case studies will be selected to cover different regions of the UK, different contexts in terms of geographical proximity to a GIC, as well as different aspects of the typology of arrangements developed in WP1.

We are selecting cases on the basis that (a) they represent an espoused intent to address the problems of fragmented care for trans people evidenced in our proposal (b) they represent a range of the categories of integrated care mechanisms emerging from the desk research in WP1. The purpose of the in-depth case study research is to assess what they are actually achieving for users, including the degree of integration or continuity of care actually experienced. We anticipate that as in most attempts to integrate or improve health services, there will in practice be both achievements and

difficulties. The role of the cases is to advance knowledge about what works in attempts to integrate. We assume that across the cases, we will be able to document and explain some achievements, for example in the cost-efficient integration of GIC care with primary care, whilst also revealing areas where integration is working less well and needs to be improved.

Six cases will allow us to study a range of different mixes of services, and each case to be interpreted within a wider context so that unique features or circumstances can be understood as such.

Five such organisational case studies have now been identified:

- The collaboration between Leeds GIC run by LYPFT and Yorkshire MESMAC to support trans people waiting to be seen by the GIC;
- The 'Pride in Practice' accreditation scheme for GP practices in Greater Manchester developed by LGBT Foundation, which aims to improve primary care support for trans people, as well as other LGBT groups;
- Arrangements being put in place by the NHFT Daventry GIC to improve coordination between the care they offer and that provided by service users' local NHS primary care;
- Clinic trans, a sexual health service based in Birmingham for trans service users, run by Umbrella sexual health (hosted by Birmingham University Hospitals NHSFT) in collaboration with Birmingham LGBT;
- The Local Gender Teams in Wales, practitioner teams for each Local Health Board which are responsible for the initial stages of GIC-directed healthcare, and liaise between the Cardiff GIC and local GPs.

A further case study is being negotiated within Northern Ireland, in order to better represent the four nations of the UK and capture a wider range of trans experiences. The Brackenburn Clinic in Belfast has reportedly not seen a new patient since January 2018, leaving trans service users without access to a specialist gender service. The case will be arranged in collaboration with TransgenderNI, and focus on trans experiences of healthcare management in this context and mechanisms of community support. It will also gather from those involved in health care delivery who have also engaged with the needs of trans adults, whilst working in services such as primary care or sexual health. This case study will draw out lessons of wider relevance in particular concerning the nature of effective community support for trans service users, and ways that non-specialist NHS services can adapt to the needs of trans adults.

Data from service providers

In each organisational case study, researchers will gather quantitative and qualitative data relevant to understanding different perspectives on the phenomenon – an attempt to provide integrated care for trans people – in its context (Yin 2003). Researchers will examine policy and operational documents concerning the instigation and implementation of these innovative service arrangements.

OU researchers will then carry out semi-structured interviews with the staff (clinicians, support workers, managers and commissioners, up to 15 per case study) involved, either face to face or remotely by telephone or video conference. In the COVID-19 context we anticipate that the vast majority, if not all, interviews will be conducted remotely.

Potential interviewees will be identified in collaboration with local service managers and/or lead clinicians who have agreed that their organisation should be the focus of case study. The inclusion criteria are that the staff have been involved in either or both of instigating and implementing the attempt to provide more integrated care.

Potential interviewees will then be contacted by email by the research team, with an invitation to take part in an interview and an information sheet on the research. Staff will have the opportunity to accept or decline the invitation to be interviewed. Those who accept the invitation will have the opportunity to ask questions of the researcher interviewing them before being asked to sign a form indicating their informed consent to be interviewed and provide data for the research.

Together, the documentary analysis and interview data will allow researchers to explore how the system of care has been conceptualised, planned for and implemented in practice, as well as the challenges encountered.

Data from service users

Researchers will also draw on three sources of data on the experiences of service users:

Existing quantitative and qualitative data collected by provider organisations on service user satisfaction and experience (e.g. service user feedback surveys, Friends and Family Test results of NHS providers).

A case-specific survey open to all users of the integration initiative, administered in both online and pen and paper modes. The survey questionnaire used here will be essentially the same as that developed for the wider screening survey of trans experiences in WP 3, asking respondents for demographic data, which combinations of services they have used and their satisfaction with them. We anticipate contacting at least 300 users per case, with a targeted return of at least 30 per case, with 60 as a working target. This case specific survey will not be relevant for the Northern Ireland case, however, since there is no identified provider. In this case, the national screening survey will be used to identify service users based in Northern Ireland. In the other five cases, the survey will require the permission of the service providers.

In all cases, we will promote the survey through materials in waiting rooms, where appropriate online mailing to clinic cohorts and periodic researcher presence in clinics to promote the survey or administer the survey in interview form in the clinic itself. Members of the research team have experience in administering multi-mode surveys in clinical contexts. For example, for a recent survey of HIV patients, we used a time-sampling approach to locate researchers in clinic waiting rooms to recruit and/or administer the survey as appropriate and to ensure supplies of promotional materials and print surveys are available (Weatherburn et al, 2013). We will also use snowballing techniques (Browne, 2005) to ensure the survey reaches individuals who are reluctant to engage with research. The survey will run for at least two months within each case to maximise uptake. We will adapt our combination of recruitment methods to the circumstances of each case.

Researchers will carry out further qualitative interviews with ten to 15 users per case, targeted at understanding in more depth which aspects of care or support – physical, psychological, social, and administrative – users have found more or less helpful, using semi-structured face to face and telephone interviews to ensure that users from different identity groups, with a range of ages, social backgrounds and histories are included. Where relevant, the views of people close to service users will also be gathered. These interviews will be carried out by members of the OU team, sometimes working as a pair with one of the two named researchers from our third sector partners. The latter will bring additional sensitivity to the experiences and contexts of participants, and lead the questioning on some topics. The third sector researchers will work as researchers under the supervision of their OU colleagues, and pairs of interviewers will undertake joint training before undertaking any interview

Service users will be recruited for these interviews through their participation in the case-specific survey. A unique identifier will be generated for each paper survey form distributed and each survey response commenced online. On completing the survey, the respondent will be asked if they are willing to take part in a qualitative interview. Those willing will be asked to supply contact information which will be collected separately (either a tear-off self-seal page to be returned under separate cover, or a new online survey) and held separately to the main survey dataset. This allows us to contact individuals for interviews without linking to their survey responses.

In each case study, the proposed detailed method for recruiting users and purposive structuring of the sample for interview will be discussed in advance with the PPI group and service providers involved. The aim will be to be ensure that the sample as far as possible represents a range of different identity groups, ages, social backgrounds and histories.

Participants will be sent an information sheet in advance of their interview, and have the opportunity to put questions to the researcher(s) conducting the interview. Before commencing the interview, participants and researchers will sign a form indicating the participant's informed consent to the interview and the use of the resulting data for the purposes of this research project. As part of this process, researchers will assess the capacity of potential participants to give informed consent.

In the context of COVID-19 restrictions, we anticipate that the majority of interviews will be conducted by secure video conference, with audio-only recording that is not cloud-based. The respondent must be sure that they can participate under conditions offering sufficient privacy. It may be possible to conduct some interviews face-to-face. Such interviews will take place at a location convenient to and comfortable to the respondent –at their home, at a service agency, a clinic or a hired venue –under conditions of complete privacy in a quiet, closed room. Each participant taking part will be given a shopping or cash voucher as a 'thank-you' for their time.

The format for interviews will combine semi-structured questioning about experiences with some use of visual methods, in particular the use of a timeline to describe people's experiences of healthcare over a number of years (Harper, 2002).

Data collection, handling and analysis

Interviews with both staff and service users will be audio-recorded, fully transcribed, and then anonymised before analysis. Interview audio files will be immediately transferred from password-protected digital recording devices to a secure server and then transferred securely for full transcription. Transcripts will then be anonimised and original recordings destroyed.

Transcripts and service documents will be uploaded onto NVivo qualitative data analysis software and a full thematic analysis (Braun and Clark, 2006; Bryman and Bell (2011) undertaken. This moves through the development of initial codes to identify elements of data relevant to the research questions, to development of themes which allow the coded data to be utilised as evidence for explanatory analysis. There are generally several iterations. Coding will be both theory-derived, from the research framework in Figure 1, and inductive. (Miles and Huberman, 1994). Two members of the research team will carry out all coding independently, with differences discussed and resolved through clarification of the coding scheme.

This thematic analysis of qualitative data will be compared with quantitative analysis of the case-specific user survey data. The latter will be carried out with SPSS software and consist of descriptive statistics of demographic characteristics, services accessed and attitudinal variables (using Likert

scales) used to measure satisfaction with services. A particular feature of the development of themes in analysing the case study data will be examining the relationship between the data from staff and the data from service users, both from the qualitative interviews and from the case-specific user survey. Different groups of staff and users are likely to have distinct perspectives on the outcomes of services, and what is important in their integration (Dyas, Apekey, Tilling, Middleton & Siriwardena, 2010). Examining these perspectives in a process of triangulation (Bryman & Bell, 2011) will reveal causal mechanisms in the shaping of integrated services and what they deliver for users.

Within each case study researchers will also build up a picture of the typical service user journeys involved. They will analyse provider data available on waiting times as well as on the costs associated with each pathway. Costs will be assessed initially using reference costs for episodes of care (NHS Improvement, 2017a), where this cost data exists, to highlight the expected costs of each model of care. This will be compared with individual site calculations drawn from patient-level information and costing systems (PLICS) (NHS Improvement 2017b) to establish the relative efficiency of the site's provision of care.

The qualitative analysis of patient experiences and process mapping will also highlight where errors or rework may occur, through factors such as increased instances of handover of care or lack of integration. These instances of unplanned extra work will also be factored into the cost analysis. Any cost impact on the patient or service user, for example in making unnecessary trips or taking time off work to attend clinics, will also be considered, to highlight if the service is passing costs on to users. We are aware of the NHS costing transformation programme and will adapt our methodology if changes to the costing systems at study sites allow further in-depth comparison between cases.

We will also take account of third sector service costs, considering how the third sector provision of some element of the care package reduces demand for services within the NHS, either by direct substitution or through better self-care. The costs of third sector involvement can be tracked by identification of commissioning costs or grants provided by the NHS to deliver specific components of the care packages. The relative costs of NHS or third sector care can be compared by studying reference costs and third sector contracting costs.

Within each case, an analysis of outcomes in the sense of user experiences and other aspects of service performance, including costs, will be related to the thematic analysis of the factors shaping the course of the integrated care initiative, and the features of integration involved, as per the research framework in Figure 1.

A provisional analysis of each case study will be shared and refined in a workshop with members of staff and users from the services involved, in the spirit of coproduction of knowledge (Filipe et al 2017). The outputs will be a report on each case study, analysing achievements for users and service providers, and areas for improvement, to be disseminated for learning within the professional and user communities involved. These 'within case' reports will then provide a basis for the further cross-case analysis during WP 4.

In each case we will analyse multiple perspectives on the benefits (and disbenefits) for service users, and other achievements of services, such as operational efficiencies (e.g. numbers seen, waiting times, cancellations, DNAs, adverse incidents), drawing on the views of clinicians, managers, commissioners, and service users. We will also gather data on provider costs, and where relevant, costs to users, such as time off work and travel. We will then facilitate debate within each case study

community as to how outcomes and experiences for users, providers, and the associated costs, can be improved.

We do not assume that it will be possible to adopt a unified measure of effectiveness across the cases, rather that we can apply a similar approach to identifying benefits and costs and then debating how to improve them. Our analysis in each case will also explore the relationship between the effectiveness of individual services and the overall effectiveness of the ensemble of services. We envisage that different attempts at integration across the cases may have different and distinctive combinations of goals associated with them, so different detailed measures of benefits and costs will be relevant. The commonality in the approach to each case will however be that we will bring to light the range of benefits sought, analyse valid evidence as to whether they are being achieved and the issues being encountered, and examine the scope for improving the relationship between benefits and costs. This approach will be replicable to other circumstances.

WP 3 A wider investigation of factors associated with service use and non-use (Months 2-24)

This WP will explore the service experiences of a larger sample of trans people across the UK, in order to establish the factors that make services more or less accessible and acceptable for them. It is likely that the sample of users recruited across the six case studies in WP 2 may display some homogeneity in terms of the types and intensity of recent service use and their satisfaction with services. It is important therefore to enrich this sample by recruiting those with more diverse experience of services use.

The purpose of WP 3 is to gather information on service need and use as well as the barriers and facilitators to accessing services from a diverse sample recruited across the UK. Recruiting this sample will enable us to:

(a) explore any variation in service needs, service use, and service satisfaction across the regions of the UK.
(b) examine the experiences of particular groups:
    i. those not currently engaging with GI services (for whatever reason).
    ii. specific sub-populations where social or demographic factors may influence need for and acceptability of GI and other services (for example BAME groups, older adults, migrants, or those with lower educational qualifications).
(c) identify further examples of good practice in the provision of integrated care for trans people, beyond those emerging from the case studies in WP 2.

The trans population as a whole is hard to survey in a representative way. There have been no previous surveys of the UK adult trans population, and people in this population often simply do not wish to be detected (GIRES, 2015). An open survey of the trans population runs the risk of only including a small percentage of the total and therefore incorporating sampling bias. Our approach here is therefore to focus our effort on obtaining a carefully structured sample of 90 qualitative interviews, representing significant aspects of the diversity of the wider trans population. This is a large sample for a qualitative survey and will allow us to explore the range of experiences within the trans community in some depth. The purposive sampling approach means that we cannot claim that our sample represents the entire UK trans population in any strict sense. We will however be explicit about the particular criteria we use to structure the sample, and will develop an in-depth understanding of the factors shaping the experiences of the particular groups studied. The sample size of 90 has been selected to match that of the number of service users who will be interviewed across the case

studies in WP 2. We estimate that a total of 180 qualitative interviews with users is the maximum number we can carry out and analyse within the resources we are asking for.

We will use a screening questionnaire to collate basic demographic and service use information on a still larger sample of trans people in different regions - at least 500 people. The screening questionnaire will invite participants to indicate willingness to take part in a further qualitative interview. We will use these responses to construct the purposive sample of 90 people.

The screening questionnaire

The screening process consists of a multi-mode administration of a screening questionnaire in order to determine the demographic characteristics of participants, and basic information on their health service use, including how far they have used a specialist GIC or GIDS. It builds on existing knowledge about the best ways to identify and describe trans people (GenIUSS, 2014). The survey responses will provide a pool of possible interviewees sufficiently large to permit our purposive sample of 90 interviewees to represent the breadth and diversity of the trans population (Wilmot, 2005).

This larger pool of screening survey respondents affords several advantages. It mitigates pitfalls associated with 'first come first served' quota sampling which has the potential to over-sample those 'with the loudest voices' or the strongest motivation to engage (for example a particularly bad – or good – experience of a service). It also allows much greater flexibility and control in constructing a sample that is capable of segmentation in a range of ways for sub-sample analysis. Thus, our purposive sample of 90 participants might be segmented to yield six demographically diverse regional sub-samples (each consisting of 15 people) whilst simultaneously yielding 3 or 4 demographically specific sub-samples gathered from across the regions (for example a sample of 20 people from BAME groups, a sample of 20 older people, etc.).

It has been argued that a successful screening process of a hidden or hard-to-reach population is necessarily interactive (Sifaneck & Neaigus, 2001). Thus there will be a dynamic relationship between the screening and interviewing stages. If we find that particular sub-populations are underrepresented in the screening survey, we will make additional efforts to recruit them. We will review and refine the interview sample progressively over a number of months, agreeing with our Advisory Panel and PPI Group which are the most important groups to cover in successive rounds of interviewing, refining the design of the purposive sample in the light of recruitment achieved and data collected.

To minimise burden for respondents in the screening survey, completing it should take no more than 15 minutes. The survey consists predominantly of category selection responses for independent variables and Likert scales for measures of satisfaction. Our outline list of items is:

- Demographic and transition-related information
    - Demographics (including age, ethnicity, location, sexual orientation, employment status, educational attainment etc.);
    - Gender (including assigned gender at birth and current gender identity expression);
- Experiences of Gender Identity Specalist Services
    - *Knowledge* of services (including knowledge of location and access)
    - *Use* of services, including which elements (NHS and private; past, current, or anticipated/future use).
    - *Satisfaction* with services used.
    - Perceived or experienced *barriers* to service use.

- Non-specialist clinical services and support services (including primary and community care services, private vs. NHS servces, acute care services, domiciliary care, mental health services, community/voluntary sector support, facilitated peer support, social care etc.)
    - *Use* of services, including which elements (past, current, or anticipated/future use).
    - *Satisfaction* with services used.
    - Perceived or experienced *barriers* to service use.

To develop our survey instruments, we have conducted a search of previous survey items used with this population as well as items developed specifically to measure satisfaction with and outcomes of integrated care. For example, although not validated, the Patient Satisfaction Questionnaire for Individuals with Gender Dysphoria (PSQ-GD) has been used successfully in several studies both in the UK and US and includes 19 satisfaction questions using 5-point Likert scales followed by open questions allowing respondents to expand on positive or negative experiences of attending services (Davies et al, 2013). Other items used in surveys of the trans population measure experience of non-specialist services and satisfaction with a range of specialist services. Moreover, we have identified items which examine experiences of or satisfaction with mental health and other non-specialist services developed for use specifically with trans populations and used in surveys both in the UK and Canada (McNeil et al, 2012; Ellis et al, 2015). We have selected items based on both the relevance of their content to the objective of the screening survey and their psychometric properties.

We have conducted a small-scale pilot of the screening survey, recruiting participants through the PPI Group. This pilot has speeded the process of finalising the screening survey and obtaining ethical and governance approval through HRA.

In the main screening survey, we are using multi-mode data collection to maximise response. We include internal checks during data preparation to identify duplicate responses across modes. Multi-mode surveys which include an online option are highly effective with sexual and gender minority populations who are geographically scattered, stigmatised or partially hidden and otherwise demographically diverse (Prah *et al.,* 2016) On-line research has also been shown to be an effective way to access specifically the trans population (Miner et al., 2012).
Our provisional selection of modes is:

- An online survey accessed directly through links on social media, community and clinic/patient websites and promoted through printed materials (cards, fliers, posters) placed in community, relevant commercial and clinic settings. The online survey will be enabled for completion using PC, tablet or mobile phone. Our third sector partners and the PPI group will advise on websites and Facebook pages accessed by different sections of the trans community.
- A pen and paper version of the same survey available in a self-sealing, self-addressed booklet form which can be completed and returned to the research team via freepost. Survey booklets and materials promoting the survey will be available in community, relevant commercial and clinical settings.
- Both the online and paper surveys will also be administered by researchers in interview form either face to face or by phone/Skype, in order to enable those with literacy, language or vision issues to take part.

The survey has already run for five months to allow maximum exposure. We may choose to run the survey for up to nine months, promoting it to particular groups who we feel important to have represented in our qualitative sample.

We will promote and administer the screening survey in both community *and* clinical settings, in the seven GIC clinics in England as well as in the two GICs in Scotland, the GIC in Northern Ireland and

the GIC planned in South Wales. The inclusion of clinic recruitment is essential to minimise sampling bias associated with community-based survey samples. We will use our extensive existing links with clinics (and the links we will develop as part of WP2 activities) to enable survey administration in clinics. We will use the same approaches as in WP2 to promote the survey within all GIC clinics, including snowballing techniques, to ensure the screening survey reaches individuals who may not be connected with clinical or community networks and targeted recruitment approaches will be used to reach out to groups who may be less likely to respond (for example, older people, BAME people etc.).

We will analyse the responses to the screening survey using descriptive statistics to show the distributions of: demographic characteristics e.g. location, age, current expression of gender identity, gender assigned at birth; histories of use of specialist GIS services and other health services; and levels of satisfaction with services. We will then discuss in depth with the PPI Group and wider research team how to structure the sample to be invited for the 90 qualitative interviews. We will generate and discuss questions and hypotheses around service use and acceptability that will indicate options for segmenting our sample, most likely by demographic or transition-related factors and/or by type of service used. This will allow us to examine in more depth key groups and services (for example, older, post-transition people's use of primary care services, self-medication, alternative therapies, speech and language therapy).

We recognise that language must not be a barrier to the participation of asylum seekers, particularly for those who seek asylum because of their victimisation as trans. We will work with the PPI Group and our third sector partners to seek participation by this group in our survey and interview sample and provide interpreters if needed. We anticipate that numbers will however be low and that we will be able to supply interpretation within the resources budgeted.

In addition to the purposive structuring of the sample of 90, we will also explore the descriptive statistics on the data generated through the screening survey. They are likely to offer additional context for and complement the qualitative data analysis from the interviews (Maxwell, 2010).

In-depth qualitative interviews with the purposively-selected sample

The purpose of this stage is to gain in-depth insights into the factors that increase or decrease the accessibility and acceptability of services to different sub-groups of trans people and how these factors affect individual's experiences, perceptions, and understandings. The insights gained here will enable us to make recommendations as to how to remove barriers to people accessing services in a timely and co-ordinated way, as well as recommendations about possible future service integration and introducing more tailored services for currently under-served groups.

As in WP 2, our qualitative sample will be recruited from screening survey participants using the technique of a unique identifier attached to each response. Once we have defined the composition of our purposive sample, a dataset will be derived which will include all survey cases which meet a set of sampling inclusion criteria (for example, people over 60 who have never accessed a GIC) and who are willing to be contacted again. Unique identifiers will be used to retrieve the contact details of all individual within this group who will then be contacted for interview. This approach allows us to target individuals within groups without ever having to directly link contact and survey responses on an individual case level.

Interviews, including obtaining informed consent, data handling and analysis will be conducted as described in WP 2. We will in fact combine our case-study-recruited and screening survey- recruited

qualitative samples (each of 90 people) to explore and contrast the experience of particular groups across both samples. For example, we could compare the experiences of older people who have accessed clinical services with those who have not or those who have accessed NHS services compared to those who accessed clinical services privately.

The output of this process is probably best understood as a series of smaller scale 'studies' each based on a particular segmentation of the overall sample. For example, we might carry out analyses to yield the following reports:

Regional: An analysis of how service need and experience varies by region of the UK.

Socio-demographic groups: In-depth explorations of the needs and experiences of key sub-groups – to be decided in consultation with the PPI and Advisory Groups, e.g. BAME people, people transitioning later in life, migrants, other socially disadvantaged groups.

'Patient groups' In-depth explorations of needs and experiences of key 'patient groups' defined by their self-identified need for a specific (clinical/or non-clinical) service, and decided in consultation with the PPI and Advisory Groups , e.g. those receiving /not receiving surgery, those receiving /not receiving psychological services, those receiving /not receiving speech and language therapies.

As in WP 2, we will focus on service models yielding positive experiences of care and outcomes as well as those yielding negative experiences.

In analysing the data from this qualitative sample and comparing with data from the service users interviewed across the case studies in WP 2, we will use the Framework approach to thematic analysis, which is an enhanced version of the procedure described under WP 2. Framework analysis enables an interdisciplinary team with different proficiencies in qualitative analysis to jointly engage in the analysis of a dataset under the guidance of an experienced analyst (Gale et al, 2013). Moreover, it allows lay people or non-researchers direct access to and participation in the analytic process. Framework involves a process where case data is summarised and charted according to pre-set criteria. This allows the presentation and comprehension of large amounts of data by a group of analysts who then generate a thematic coding frame. Coding is generally done by a sub-group of the research team and inter-rater reliability is constantly checked. Analysis and interpretation can therefore also be a collective activity which limits researcher bias and generates a consensual approach.

WP 4 Synthesis of findings and implications for improving practice (Months 17 to 29)

The purpose of this work package will be to identify how the models of service integration studied can be improved and built upon to meet the varied needs of the trans community more effectively. Data from WP 2 and WP 3 will be used both to develop and refine the typology of integrated service arrangements developed in WP 1. WP 4 will seek to clarify what has been learned about the benefits to users of particular forms of service integration, as well their costs to providers. It will also seek to develop conclusions as to how existing forms of integration can be improved or diffused more widely, in the context of a healthcare landscape profoundly affected by the current pandemic and associated restrictions on travel and face to face contact. This work package will also explore why it might be useful in the future to mount initiatives addressing relatively unpopulated categories in the initial typology of integration produced in WP1. Learning about both existing forms of integration and those theoretically possible will therefore be produced, and related to the constraints and possibilities of service delivery in post-COVID healthcare.

A process of structured and participative interpretation will be used to achieve this. This will consist of two stages of activity.

1. We will first convene a structured workshop for the project research community, including the Project Management Group, the Advisory Group, the PPI Group and all of the research partners. Provisionally, this will take place in month 25, based on discussion papers indicating the findings from each of WP 1,2 and 3. This workshop will also review outline designs for the edu cational materials to be developed in WP 5. Given the likelihood of continuing restrictions due to the pandemic, this is likely to an online workshop, possibly with two or more sessions held on successive days.
2. The outputs from this will then form the basis for further testing out of working hypotheses concerning effective forms of integrated services in a national workshop, which will be open to all interested NHS and third sector providers, as well as commissioners and members of the public. It will take place in month 28 and beforehand will be promoted widely within the trans community and relevant NHS services throughout the UK. Again, given the likelihood of continuing restrictions due to the pandemic, this is likely to an online workshop, possibly with two or more sessions held on successive days.
3. Provisional findings and recommendations from our research will be offered in an engaging form, with questions for facilitated debate within carefully designed small group and plenary sessions. Participants will also be asked to comment on the proposed design of the educational materials from WP5, on the basis of being shown some prototype materials. This event will be designed using the principles and techniques of 'whole system' dialogue and development (Bunker and Alban 1996). Such events have been strongly advocated and used with success for healthcare service redesign (Pratt, Gordon & Plamping, 2005).

The output will be guidance for NHS commissioners, service providers and service users on the range of models for providing effective care for trans people at various stages of transitioning and at different life stages, the typical issues encountered and options, supported by evidence, for improving these models in the future. This guidance will need to take account of the prevailing pandemic-related developments affecting service delivery within both the NHS and the third sector.

6 ETHICAL AND REGULATORY CONSIDERATIONS

6.1 Assessment and management of risk

Since the study does not involve any clinical intervention the benefits and risks to participants stem from their involvement in providing data on the effectiveness of current services. On the positive side, participants may benefit from having the opportunity to describe their experiences of using or providing services, and so being able to make sense of and process these with a receptive listener. Some participants may find the research encounters, by talking to a relative stranger, therapeutic or useful for reflexive professional practice (Dempsey *et al* 2016). They may feel affirmed from recalling what has been good about their experiences of receiving or providing care. They may also welcome the opportunity to contribute their ideas on how care and its integration can be improved.

On the negative side, the key risks identified are:

i. **Ensuring confidentiality.** User participants may fear that what they tell researchers, either through completing the screening survey or during the course of interviews, may in some way be passed to service providers and negatively impact their future care. Staff participants in interviews may fear that their critical views on services may be passed to senior colleagues and damage their standing as members of staff.

Validity - *how well your evidence addresses the relevc*

standard

Authenticity – *how well your evidence showcases your*

Currency –*how recent and timely your evidence is*

Sufficiency –*whether your evidence is sufficiently deta*

ii. **Demonstrating appropriate respect and protecting wellbeing**. During qualitative interviews, being asked to describe aspects of care or its integration which have not been satisfactory may be uncomfortable or distressing for participants, particularly for people who have encountered lack of respect or stigma in many settings within society.

The key elements of the risk management plan in response are:

i. Measures to ensure confidentiality of data

All information received by researchers will be treated as confidential, unless there are safeguarding or whistleblowing concerns (see item (ii) below)

Responses to the screening survey will be separated from any identifying personal data items, as already described, using a unique identifier for each response. When a participant is contacted for a subsequent qualitative interview, researchers will have no access to any survey data items from that participant.

Qualitative interviews will be transcribed and fully anonymised, and stored securely on password-protected OU servers, under the same unique identifier for each participant. A key document linking names of participants to unique identifiers will be stored securely and separately from the anonymised data and destroyed once analysis has been completed. Only the named members of the OU research team will have access to the key document.

If researchers use direct quotations in any project reports or publications, these quotations will be not be attributed to an identified individual without the written permission of that individual. Researchers will also ensure that the content of the material quoted cannot be used to identify the speaker, for example by referring to their particular context or role.

Following the end of the project, survey and interview data will be archived in fully anonymised form.

Participant information sheets and consent forms for both the screening survey and qualitative interviews will explain these measures to protect confidentiality.

ii. Measures to uphold respect for participants, protect their wellbeing and the wellbeing of others concerned

The researchers are all experienced with these kinds of interviews. They are all undergoing further project-specific training so that they adhere to a common set of practices to protect participant wellbeing, including signposting participants to supportive services as necessary, as well as acting appropriately should participants disclose intentions either to harm themselves or others.

Training covers interviewing when the topic is emotionally sensitive or difficult, including indicators of risk of harm to self or others, such as reports of feeling currently very depressed, hopeless or angry. It also covers sensitivity to the importance in questioning and conversation of using terminology that demonstrates respect for and understanding of the experiences of trans people (Vincent 2018). Such sensitivity to nuances of language is vital given a history of research that has referred to trans people in ways that pathologise or stigmatise them (Adams *et al* 2017). Participant information sheets and consent forms for both service staff and service

users make it clear that interview participants are able to stop the interview at any time and the researchers are able to shorten the length of an interview should someone become distressed, tired or otherwise burdened by talking.

Training further includes how to engage in safeguarding procedures. In these procedures, the first preference will always be to make a referral for support with the consent of the participant, but researchers will also do so without the consent of the participant if they judge it is in the interests of a participant who refuses to cooperate or leaves the interview without further discussion. Researchers will also break confidentiality if they judge appropriate following a disclosure of an intention to harm others or a disclosure that malpractice has occurred. In each case study site, there will be a designated safeguarding contact who will be informed immediately of such issues, in accordance with local safeguarding or whistleblowing (disclosures in the public interest) policies.

Where interview participants are not linked to particular case studies divulge evidence of malpractice or intentions to harm others, researchers will seek immediate advice from a designated clinical safeguarding lead for the project, and/or, as appropriate, report their concerns to any relevant care provider identifiable and/or the local police force.

Participant information sheets and consent forms will make it clear that interviewee confidentiality may only be broken under such circumstances.

6.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of piloting of the screening survey, a favourable opinion on the pilot survey and associated information sheets will be sought from the Open University Human Research Ethics Committee. Before the start of data collection on the final version of the screening survey and the case studies, a favourable ethical opinion and governance approval for the research protocol as whole, including information sheets and informed consent forms, will be sought from an NHS Research Ethics Committee, through the Health Research Authority.

All correspondence with the REC will be retained, and the Chief Investigator will produce annual progress reports to the REC as required. The Chief Investigator will notify the REC of the end of the study. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Before any site can enrol service users into the study, the Chief Investigator will ensure that appropriate approvals from participating NHS and non NHS organisations are in place.

Amendments

If the research team decides that an amendment needs to be made to the protocol, the Chief Investigator will follow HRA guidance and decide whether the proposed amendment is substantial or non-substantial. If the amendment is substantial, the Chief Investigator will submit a valid notice of amendment to the REC for consideration. Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.

Amendments will also be notified to the HRA and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Each amended version of the protocol will have a version number and date.

6.3 Peer review

The protocol was peer reviewed within the Open University at two different stages during the process of applying for funding from NIHR. The application to NIHR for funding was also subject to peer review.

6.4 Patient & Public Involvement (PPI)

A PPI lead, Sam Hope, is responsible for recruiting and coordinating the work of a PPI Group with seven other members. The PPI lead is involved in the research for two days a month throughout the project, including attending all project management meetings and chairing all meetings of the PPI group, of which there are four per year. The PPI group comments on all research plans and instruments, and ethics applications including participant recruitment processes and consent materials before they are used. It will also have early sight of findings and be asked to comment on interpretations of data made by the group of researchers. It will further play a key role in promoting the outputs of the research and raising awareness of and encouraging attendance at the national workshop in month 28. The PPI lead will play a significant role in designing and delivering this workshop. The PPI group will be paid travel and subsistence as well as fees at the recommendation INVOLVE rates for attending meetings. It will also be supported by training and facilitation at its first meeting, for which we have allocated a budget.

The PPI Group has a generative rather than merely responsive role. The first meeting of the PPI group involved the entire project team, to review the project objectives and plan, capturing the priorities and concerns of the PPI Group. This workshop also developed more detailed plans for how to involve the PPI Group meaningfully through its quarterly meetings and on a continuing basis between meetings. This will include early involvement in the conceptualisation of the online educational materials, as well as critical review of prototypes. PPI Group members are welcome to attend all project management group meetings, with meeting minutes and papers available to them, and take part in dissemination activities. The PPI lead also represents the project at trans community events and conferences.

The PPI Group needs to represent the diversity of the trans community in terms of current expression of gender identity, time since any medical transition, intersecting health issues, as well as ethnic, cultural and socio-economic diversity. We have worked with the PPI lead to achieve this, using multiple formal and informal networks in recruiting the group. We however recognise that it will not be possible for any PPI group to include direct representatives of all identity groups within the range of trans communities.

6.5 Protocol compliance

Research team members are required to report any breaches of this protocol to the Chief Investigator. We recognise that accidental breaches can happen, any breaches reported will be discussed at the next Project Management Group meeting and measures agreed to prevent recurrence. Both the breaches and preventative measures will be documented, and reviewed at subsequent meetings.

6.6 Data protection and participant confidentiality

Research data will be collected, processed and stored in full compliance with the requirements of the General Data Protection Regulation (GDPR) of the European Parliament (2018). All research team members must comply with GDPR requirements with regards to the collection, storage, processing and disclosure of personal information and will uphold GDPR core principles. As already described, personal data will be collected and stored only for the purposes of organizing interviews, and subsequently destroyed.

Participant information sheets cover:

- the purpose of the research
- What data will be gathered
- Benefits and risks of taking part
- How data will be stored during the project
- Who will have access to it
- How qualitative and quantitative data be anonymised
- Plans for data preservation and sharing
- Contact details for the researcher, institution and funder.

These sheets will describe the detailed processes for handling data and protecting confidentiality of participants, as a basis for prospective participants to give freely their informed consent for each of the ways that their data will be processed and used. Information sheets also make it clear that participants have the right to withdraw their participation from the study and how this can be done. Participants have the right to erasure (to have their data removed) but it is also made clear that this cannot be done once the data has been anonymised.

Consent forms will be signed both by participants and by a member of the research team. They will be stored securely within a locked cupboard on the Open University campus, accessible only to the Chief Investigator and Study Coordinator.

Only the five members of the OU Research Team will have access to the project data set during the duration of the project's funding, as needed for data analysis, quality control and audit. Dr Ben Vincent, the study coordinator, will act as data custodian.

Following completion of the project, fully anonymised data will be added shared with an accessible data repository and openly shared with the research community. Any other project data will be destroyed. No other data will be shared with the funder.

6.7 Indemnity

The Open University is covered by insurance for all that it is deemed legally liable for.

LGBT Foundation is covered by insurance for that is deemed legally liable for.

Yorkshire MESMAC has insurance in place for Public Liability and all insurance that it is deemed legally liable for.

7 OUTPUTS and DISSEMINATION POLICY

7.1 Outputs

The plan for WP 5 describes the outputs to be produced over the course of the research.

WP 5 Dissemination and the development of learning materials (Months 6 to 30)

A series of public reports on the project will explain how the research aims have been addressed and the findings in relation to them. The reports will be as follows:

- Interim report 1 (month 6): An overview of UK policy, commissioning and provider initiatives in healthcare to support trans adults
- Interim report 2 (month 19): Progress with a qualitative investigation of the service experiences of trans people
- Interim report 3 (month 25): Initial findings from case studies of arrangements for improving the integration of healthcare for adult trans people.
- Final report (month 30): Before, During and After Specialist Gender Identity Services: Improving the Integration of Care for Trans Adults.

These reports will be targeted at NHS commissioners, managers, clinicians and professionals, third sector organisations that work with trans communities and service users. The final report will contain guidelines for commissioners, general practitioners, other primary care providers, and mental health services as to how they can respond to the needs of trans people, and the range of other services and pathways that may be involved. It will also summarise effective practices within specialist services for improving user experiences through improved liaison with primary care and other services. Case studies will be reported in a way that conforms with case study reporting guidelines developed for research within the NHS (Rodgers et al, 2014). The reports will provide the basis for articles published in leading academic journals relevant to the range of disciplines involved in the research.

We will also produce two print booklets summarising our findings and recommendations. One will be targeted at the trans community of service users. The second will be targeted at NHS and third sector practitioners. The reports and booklets will be promoted through relevant professional bodies, such as the Royal College of General Practitioners, the Royal College of Psychiatrists, the British Psychological Society, the Royal College of Speech and Language Therapists and the World Professional Association for Transgender Health, as well as NHS forums concerned with service design, such as NHS Clinical Commissioners. They will also be promoted by our third sector partners at events and within online forums for trans and wider LGBT communities.

A further key mechanism for translating the research findings into practical action will be a set of educational materials. The collaboration will produce the following, and make them available free of charge on the OU's OpenLearn platform:

- A short (1 to 2 hours) course for the general public who want to understand the range of health services available for trans people and how to improve them.
- A one-hour standalone on-line professional development session for therapists and mental health professionals, giving an overview of good practices in services for trans people. This will also serve as an introduction to two further six-hour sessions for those who wish to improve their understanding and skills in addressing the needs of trans people, in the context of integrated care. This will be endorsed by the British Association for Counselling and Psychotherapy (BACP) as a partner to this proposal. This will include a stand-alone one-hour session for practitioners who want an initial level of education. Provisionally, one six-hour session will look at services and approaches likely to be relevant to trans people in earlier adulthood, and the second at services and approaches likely to be needed in later life.
- A one-hour standalone on-line professional development session for CCG commissioners, GPs and other primary care clinicians, and health navigators, giving an overview of good practices in services for trans people. This will also serve as an introduction to two further six-hour on-line sessions, which will explain the options for integrated care for trans people, and help clinicians explore how they can adapt their practice and collaborate to achieve greater coordination of care. Again, the two six-hour sessions will provisionally focus on needs and services characteristic of earlier and later adulthood.

All learning materials will involve video case studies and interactive learning activities, which invite to engage with knowledge generated from research and critically assess its relevance to their own professional concerns and practice. This will provide an immersive and engaging learning experience. Learners will be able to study at a time and pace of their choosing. These materials will be developed with input from our PPI Group throughout, from initial concept to review of rough cuts and prototypes. The materials will be trialled with groups of users and clinicians and NHS managers during the course of the project. We will seek to establish or contribute to online communities of practice within various clinical groups concerned with trans people, on the basis that change in clinical practice and service design are most effectively achieved within such groups, rather than expecting individual clinicians to act on the basis of information input alone (Gabbay & May, 2004).

Impact and contribution

We anticipate that our outputs will influence commissioners, managers and clinicians working with trans people, in both specialist and generalist services, to make improvements in the way that care is provided and coordinated for trans adults. This will occur both through the formal commissioning process and through individual clinicians studying our online materials and deciding how to change their practice. Commissioners and providers will be able to draw on a richer understanding of integrated care options in seeking to reduce the current waiting lists for GICs, and responding to the challenges of delivering services in the wake of the pandemic. There may for example be a need to explore the possibilities of considerably greater use of video conferencing for interactions between clinicians and service users. There are potential longer-term impacts on the wellbeing of the population of trans adults currently engaged with GICs, and those who may be encouraged to seek care from better integrated services.

Our research will contribute significantly to the body of practical scholarship in healthcare. We will develop a new typology of integrated service arrangements, involving NHS and third sector providers, relevant to trans adults. In terms of integration models already in existence, we will produce grounded knowledge as to how and why aspirations for providing integrated care may succeed or falter in practice, and what can be done to optimise benefits to patients within the resources available. We will also identify relatively untried types of integration that are worthy of future attention. This analysis of

the current realities and future possibilities of integrated care will shed light on what it means to work effectively with stigmatised user groups, and may be of wider relevance.

7.2 Dissemination policy

The final report on the study will be published by NIHR, following peer review and any required amendments.

All research participants who ask to be informed about the final report will be notified of its publication.

The fully-anonymised dataset from the study will be archived on password-protected OU servers.

Any of the co-investigators and other research team members will have the right to draw on the data set for publication, subject to the agreement of the chief investigator. All publications will acknowledge the financial support of NIHR.

7.3 Authorship eligibility guidelines

The final report of the project will be jointly authored by the entire research team. Manuscripts submitted for publication based on the work of the project will have individual authors listed based on contribution, or in alphabetical order if contributions are equal. Authorship of manuscripts submitted for publication and any other articles

8 REFERENCES

Adams, N., Pearce, R., Veale, Radix, J.R., Castro, D., Sarkar, A., and Thom K.C. (2017) Guidance and Ethical Considerations for Undertaking Transgender Health Research and Institutional Review Boards Adjudicating this Research, Transgender Health Volume 2.1, DOI: 10.1089/trgh.2017.0012 https://doi.org/10.1089/trgh.2017.0012

Almack, K., Yip, A., Seymour, J., Sargeant, A., Patterson, A. and Makita, M. (2015) The Last Outing: exploring end of life experiences and care needs in the lives of older LGBT people: A Final Report. Nottingham: University of Nottingham

Altheide, D. (1996) 'Process of Document Analysis', in D. Altheide, Qualitative Media Analysis, Thousand Oaks: SAGE Publications: 23–43

Analysis Intelligence & Resource Unit (2015) *Operational Research Report Following Visits and Analysis of Gender Identity Clinics in England*, NHS England: London

Applegarth, G., & Nuttall, J. (2016). The lived experience of transgender people of talking therapies. *International Journal of Transgenderism*, *17*(2), 66-72.

Austin, A., & Craig, S. L. (2015). Transgender affirmative cognitive behavioral therapy: Clinical considerations and applications. Professional Psychology: Research and Practice, 46(1), 21-29. **http://dx.doi.org/10.1037/a0038642**

Braun, V. and Clarke, V. (2006) Using thematic analysis in psychology. Qualitative Research in Psychology, 3 (2). pp. 77-101. ISSN

1478-0887 Available from: http://eprints.uwe.ac.uk/11735

Bunker,B & Alban, BT (1996) Large Group Interventions: Engaging the Whole System for Rapid Change, Jossey-Bass : San Francisco

Coulter, Angela (2011) Engaging Patients in Healthcare, Open University Press: Maidenhead

Dempsey, L., Dowling, M., Larkin, P., & Murphy, K. (2016). Sensitive interviewing in qualitative research. *Research in nursing & health, 39*(6), 480-490.

Dyas, J. V., Apekey, T. A., Tilling, M., Ørner, R., Middleton, H., & Siriwardena, A. N. (2010). Patients' and clinicians' experiences of consultations in primary care for sleep problems and insomnia: a focus group study. *The British Journal of General Practice*, *60*(574), e180–e200.

Eisenhardt K, Graebner M. (2007) Theory building from cases: Opportunities and challenges. Academy of Management Journal 2007;50(1):25-32.83.

Fleetwood, S. (2014) Bhaskar and critical realism. In: Adler, P., Du Gay, P., Morgan, G. and Reed, M., eds. (2014) *Oxford Handbook of Sociology, Social Theory and Organisation Studies: Contemporary Currents.* Oxford: Oxford University Press, pp. 182-219.

Filipe, A Renedo, A and Marston,C (2017) The co-production of what? Knowledge, values, and social relations in health care, PLOS Biology May 3, 201 https://doi.org/10.1371/journal.pbio.2001403

Future Hospital Commission (2013). 'Future hospital: caring for medical patients.' A report from the Future Hospital Commission to the Royal College of Physicians, September 2013. Available at: www.rcplondon.ac.uk/projects/future-hospital-commission (accessed on 06 Feb 2018).

Gabbay, J., & le May, A. (2004). Evidence based guidelines or collectively constructed "mindlines?" Ethnographic study of knowledge management in primary care. *BMJ : British Medical Journal*, *329*(7473), 1013.

Gale N, Heath G, Cameron E, Rashid S, Redwood S. (2013) Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med Res Methodol. 2013; 13: 117.

GIRES (2011) The Number of Gender Variant People in the UK - Update 2011 http://www.gires.org.uk/wp-content/uploads/2014/10/Prevalence2011.pdf

GIRES (2015) Monitory Gender Nonconformity – A Quick Guide

http://www.gires.org.uk/wp-content/uploads/2014/09/Monitoring-Gender-Nonconformity.pdf

Guillemin, M., & Drew, S. (2010). Questions of process in participant-generated visual methodologies. *Visual studies*, *25*(2), 175-188.

Greenhalgh, T. Humphrey, C., & Woodard, F., (2011) User Involvement in Healthcare, Blackwell: Chichester

Harper, D. (2002). Talking about pictures: A case for photo elicitation. *Visual studies*, *17*(1), 13-26.

Hendricks, M. L., & Testa, R. J. (2012). A conceptual framework for clinical work with transgender and gender nonconforming clients: An adaptation of the Minority Stress Model. *Professional Psychology: Research and Practice*, *43*, 460–467. doi:10.1037/a0029597

House of Commons (2016) Report of the Women and Equalities Committee on Transgender Equality, HMSO, London

Hudson, B. (2007). Pessimism and optimism in inter-professional working: The Sedgefield Integrated Team. *Journal of Interprofessional Care,* 21, 3-15.

LGBT Foundation (2017) Transforming Outcomes, A review of the needs and assets of the trans community, LGBT Foundation, Manchester

LGBT Foundation (2015) Salford Pride in Practice Project: End of Project Evaluation April 2015, LGBT Foundation, Manchester

Lloyd & Wait 2006

McCann E, Sharek D. (2014) Survey of lesbian, gay, bisexual, and transgender people's experiences of mental health services in Ireland. Int J Ment Health Nurs. 2014 Apr;23(2):118-27.

Meyer I & Wilson P (2009) Sampling lesbian, gay and bisexual populations. Journal of Counselling Psychology. 56 (1) 23-31

Miles, M and Huberman, A (1994) Qualitative Data Analysis: An Expanded Sourcebook, 2nd Edition, Sage, Thousand Oaks CA

Millet, N., Longworth, J., & Arcelus, J. (2017). Prevalence of anxiety symptoms and disorders in the transgender population: A systematic review of the literature. *International Journal of Transgenderism*, *18*(1), 27-38.

National Voices (2014) Prioritising person-centred care: Enhancing experience, Summarising evidence from systematic reviews https://www.nationalvoices.org.uk/sites/default/files/public/publications/enhancing_experience.pdf

NHS Improvement (2017a) Reference costs 2016/17: highlights, analysis and introduction to the data

https://improvement.nhs.uk/resources/reference-costs/

NHS Improvement (2017b) PLICS cost collection guidance

https://improvement.nhs.uk/uploads/documents/2016-17_acute_cost_collection_guidance_-_March_update_ed2_2_final.pdf

Palmer, James (2017) We are meeting concerns on gender services, blog at https://www.england.nhs.uk/blog/we-are-meeting-concerns-on-gender-services/ accessed 06 Feb 2018

Prah,P Hickson,F Bonell,C McDaid,LM Johnson,AM Wayal,S Clifton,S Sonnenberg,P Nardone,A Erens, B Copas,AJ Riddell,J Weatherburn,P & Mercer,CH (2016) Men who have sex with men in Great Britain: comparing methods and estimates from probability and convenience sample surveys. Sexually Transmitted Infections, 92:455-463 .

RCGP (2017) http://www.rcgp.org.uk/news/2017/january/uk-organisations-unite-against-conversion-therapy.aspx

Robertson, R., Sonola, L., Honeyman, M., Brooke B., & Kothari, S (2014) Specialists in out-of-hospital settings, The Kings Fund: London

Rodgers M, Thomas S, Harden M, Parker G, Street A, Eastwood A. (2016) Developing a methodological framework for organisational case studies: a rapid review and consensus development process. Health Serv Deliv Res 2016;4(1)

Shaw, S Rosen, R and Rumbold,B (2011) *What is integrated care? An overview of integrated care in the NHS*. Nuffield Trust, London

Storey, J Holti, R Hartley,J Marshall, M & Matharu,T (2018) *Mobilizing Clinical Leadership in and around Clinical Commissioning Groups: A mixed methods study*, Final Report on an NIHR research project, HMSO, London

Verschuere B, Brandsen T, & Pestoff V. (2012) Co-production: The State of the Art in Research and the Future Agenda. VOLUNTAS: International Journal of Voluntary and Nonprofit Organizations. 23: 1083–1101.

Vincent, B (2018): Studying trans: recommendations for ethical recruitment and collaboration with transgender participants in academic research, Psychology & Sexuality, DOI: 10.1080/19419899.2018.1434558 https://doi.org/10.1080/19419899.2018.1434558

Warren, J. C., Smalley, K. B., & Barefoot, K. N. (2016). Psychological well-being among transgender and genderqueer individuals. *International Journal of Transgenderism*, *17*(3-4), 114-123.

West, M., Armit, K., Loewenthal, L., Eckert, R., West, T., & Lee, A. (2011) *Leadership and Leadership Development in Health Care: The Evidence Base*, Faculty of Medical Leadership and Management https://www.fmlm.ac.uk/resources/leadership-and-leadership-development-in-health-care-the-evidence-base

White Hughto J M. and Reisner, S L (2016) A Systematic Review of the Effects of Hormone Therapy on Psychological Functioning and Quality of Life in Transgender Individuals, Transgend Health. 2016 January ; 1(1): 21–31. doi:10.1089/trgh.2015.0008

Woodhouse, D and Pengelly, P (1991) Anxiety and the Dynamics of Collaboration, Aberdeen University Press, Aberdeen

Yin, R (2003) Case Study Research: Design and Methods, 3rd Edition Sage, Thousand Oak

11. APPENDICIES

11.1 Appendix 1- Required documentation

The following documents will be required before initiating the screening survey and the case studies:

CVs of the research team

Participant information sheet (screening survey for users)

Participant information sheet and consent form (user interviews)

Participant information sheet and consent form (staff interviews)

11.2 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	2.0	30 June 2020	Richard Holti Ben Vincent	Research questions modified to take account of pandemic context of services for recommendations for improving integration Focus of case studies modified to take account of views of staff and service users on the future of services in a pandemic context Research methods modified to be based on remote interviewing rather than face to face, to assure safety of researchers and research participants, under the pandemic.

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.