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Full title: Building an evidence base for the use of ADvice and GuidancE Referrals at the primary-secondary care interface – a multistage mixed-methods study

Short title / acronym: BADGER

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Funder	NIHR: Health and Social Care Delivery Research
Funding reference number	NIHR 158681
Project registration	ISRCTN awaited(Qualitative components WP 1b & 3) CPRD Protocol# 24_004022 (CPRD study 1, WP 1a)
IRAS ID	333799 (Qualitative components WP 1b & 3). 24/NE/0110 13/06/24
Version Number and Date	2.0 18/06/2024

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List of Abbreviations

AE	Adverse Event
A&G	Advice and Guidance
CI	Chief Investigator
CPRD	Clinical Practice Research Datalink
CRN	Clinical Research Network
CQC	Care Quality Commission
DMC	Data Monitoring Committee
DPIA	Data Protection Impact Assessment
EHR	Electronic Health Records
eRAP	Electronic Research Applications Protocol
GCP	Good Clinical Practice
GP	General Practitioner
HCP	Health Care Professional
HRA	Health Research Authority
HSCR	Health and Social Care Research
IRAS	Integrated Research Application System
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Numbers
NICE	The National Institute for Health and Care Excellence
NP	Advanced/Nurse Practitioner
PA	Physicians Associate
PCC	Primary Care Clinician
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
PPIE	Patient and Public Involvement and Engagement
RDG	Research Data Governance
REC	Research Ethics Committee
SCS	Secondary Care Specialists
SMG	Study Management Group
SMS	Short Messaging Service
SOP	Standard Operating Procedure
WP	Work Package

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RESEARCH SUMMARY

Study Title	Building an evidence base for the use of ADvice and GuidancE Referrals at the primary-secondary care interface – a multistage mixed-methods study
Short Title / Acronym	BADGER
Study Aim	The overarching aim of the proposed study is to measure the impact of Advice & Guidance (A&G) on patients, primary care clinicians, secondary care specialists, and the healthcare system in terms of quality of care, satisfaction with the process and service utilisation to understand how it works for whom, where, and why. Specific objectives are to: 1. Describe the use of A&G across the NHS 2. Measure the association between A&G and quality and use of healthcare 3. Explore the A&G pathway from perspectives of patients, primary care clinicians (PCCs), secondary care specialists (SCCs), and commissioners 4. Develop resources to support the best use of A&G, reduce compound pressures and address health inequalities.
Study Design	A multi-stage mixed-methods study adopting four work packages (WPs) to address the objectives: <u>WP1: Mixed-methods to develop methodology for WP2</u> 1a. Map the use of A&G over time using a nationally representative UK electronic health records database (the Clinical Practice Research Datalink (CPRD)) 1b. Describe current use of A&G from primary care perspectives using qualitative interviews with PCCs <u>WP2: Quantitative analysis of routinely collected electronic healthcare records</u> 2a. Describe outcomes of tracer conditions following A&G compared to initial direct (non two-week wait) referral pathways 2b. Describe healthcare utilisation and patient burden (for example, further consultations, referrals or prescribing in primary care, unplanned admissions, outpatient appointments) comparing A&G and direct referral pathways. <u>WP3: Qualitative interviews with clinicians, commissioners, and patients</u> 3. Evaluate the experiences of A&G and related needs from the perspectives of the patient, clinician and commissioner. <u>WP4: Developing outputs from WP1-3 findings</u> 4.Co-design and produce resources for patients, primary care, specialist services and commissioners to enable most effective use of A&G services <u>Study Within A Project (SWAP)</u>

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	A SWAP will run across WP2, WP3 and WP4. The objectives of the SWAP are: SWAPa. To describe how the process of A&G accounts for multiple long term conditions (MLTCs) SWAPb. To measure the impact of MTLCs on the outcomes of referral decisions
Committees	Study Management Group (SMG) Study Steering Committee (SSC) Data Monitoring Committee (DMC)
Recruiting Countries (WP1b&3)	England
Participants (WP1b&3)	Patients will be invited if they are 18 years of age or older, have an episode of Advice and & Guidance (A&G) recorded in their general practice medical record in the past 3 months, and have capacity to consent to an interview. Primary care clinicians and secondary care specialists will have experience of requesting and providing A&G respectively. Specialists and commissioners must be currently working in the NHS or familiar with A&G use at Trust / local System level.
Planned Sample Size (WP1b&3)	Approximately 30 patients, 20 primary care clinicians, 20 secondary care specialists and five healthcare commissioners will be interviewed.
Number of participating sites (WP1b&3)	Patients will be recruited from approximately 35 general practices from the West Midland and North West Coast Clinical Research Networks. Primary care clinicians will be from these same practices or recruited through professional networks including social media. Secondary care specialists will be recruited from a small number of trusts, or professional networks including social media. Commissioners will be recruited through professional networks.
Planned Research Period	01/06/2024 – 31/05/2026 = 24 months
Funder	NIHR This study is funded by the NIHR HSDR Programme (NIHR158681). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

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1 INTRODUCTION

1.1 BACKGROUND

1.1.1 Summary of the research

Whilst the use of Advice and Guidance (A&G) has been identified as a crucial part of managing NHS waiting lists, there is little evidence to understand its effectiveness in reducing compound pressures whilst maintaining a high standard of care. This multistage mixed-methods study will use large, anonymised patient data sets to explore use, benefits, and potential harms of using A&G in comparison with direct referral pathways. Parallel qualitative research will explore the use, experience, and perspectives of A&G from patients, clinicians, and commissioners, integrating findings from the quantitative research. We will provide the evidence required, an understanding of how A&G is working for whom, where, and why, to support primary care and specialist services to effectively work together to reduce compound pressures across the system, whilst promoting high quality care. The outputs of this research may serve to: a. reassure A&G users of its benefits and or b. provide recommendations to improve use to safeguard quality of care in a pressured healthcare environment.

For the purposes of this application 'Primary Care Clinician' (PCC) will be used to describe the General Practitioner (GP), Advanced/Nurse Practitioner (NP), Physician Associate (PA) or other clinician based in primary care, initiating the A&G request. 'Secondary Care Specialist' (SCS) will be used to describe the Consultant or other non-medical Clinician providing the A&G.

1.1.2 Background and rationale

"Referral is a key part of the GP role"[1] and describes a process that has a direct consequence on patients' experience of care as well as the inevitable subsequent costs to the health care system. Referrals from primary care to secondary care may be made for reasons including: to establish a diagnosis and/or initiate specialist management; for a specialist test or investigation not available in primary care; and/or for advice or reassurance. Referral usually involves a transfer of clinical responsibility and can be a complex area of decision making, balancing the PCC roles as both patient advocate as well as NHS gatekeeper. The (pre-Covid) Royal College of General Practitioners' (RCGP) guidance on making quality patient referrals acknowledges that at a time of rising demand driven by demographic changes and strain on resources, this is an increasingly challenging task, with potential consequences for the GP-patient relationship and the GP's ability to make high-quality referrals.[2]

The General Medical Council (GMC) Good Medical Practice (GMP) mandates doctors to ensure a good standard of practice and care and to refer a patient to another practitioner, when this serves the patients' needs. This transfer of care means sharing relevant information with colleagues when a referral takes place and being satisfied that the person providing care has the appropriate qualifications, skills and experience to provide safe care.[3] The Kings Fund GP Inquiry Paper describes a high-quality referral as including three key elements: "*necessity, patients are referred as and when necessary, without avoidable delay; destination, patients are referred to the most appropriate place first time; process, the referral process is conducted well*."[1] This process includes referral letters containing necessary information in an accessible format, patients being involved in the decision-making process, all parties sharing an understanding of the purpose and expectation of the referral, and appropriate investigations being performed prior to a referral.

PCCs have several referral options when they make a shared decision with a patient to seek care from another clinician or service. Emergency referrals with the likely need for hospital admission or very urgent investigations are organised through the local healthcare systems (for example, to an Accident and Emergency Department or specialty admission unit). Patients presenting with

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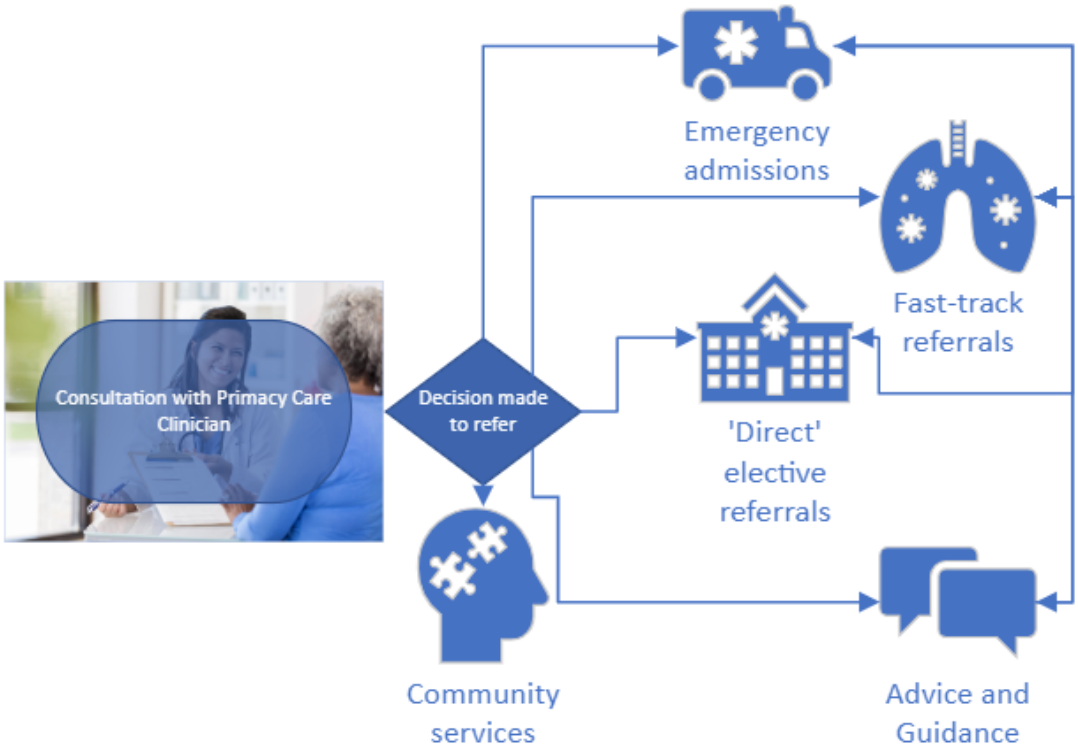
symptoms in-keeping with a potential cancer diagnosis would be referred on a ‘two-week wait’ or ‘fast-track’ suspected cancer pathway. Referrals for elective (non-emergency, non-cancer) specialist care are usually made through Choose & Book (via the electronic Referral System (e-RS), where the options include ‘Advice & Guidance’ or ‘Refer/Advice.’ An A&G query is inputted in free text and can be monitored through the system until a response is received. Refer/advice allows the user to make a ‘direct referral’ to a particular speciality. The referral can be designated as ‘urgent’ or ‘routine.’ It is these two elective options that will be the focus of the study. The roadmap diagram below demonstrates how these options to refer work and interact:



A&G is a two-way dialogue that enables primary care to seek specialist input into a patient’s care through formal recorded means. A&G is a non-face-to-face process delivered synchronously (voice call) or asynchronously (electronic communication). A&G has been identified to transform the way referrals are managed by enabling patients’ care to be managed in the most appropriate setting with specialist advice, avoiding unnecessary outpatient activity and waiting list additions.[4]

On 29/08/23 a PubMed Central search was conducted using the terms ((("primary care"[Abstract] OR "general practice"[Abstract]))) AND ((((((“advice and guidance"[Abstract])) OR "advice & guidance"[Abstract]) OR "A&G"[Abstract])) OR "electronic referral"[Abstract]) from database inception until the present. 37 items were identified, three of which were relevant to the use of A&G at the primary-secondary care interface. Three publications explored the use of A&G at the primary specialist care interface. One study detailed the evaluation of an A&G service set in a neurology department and identified barriers and facilitators of service delivery including liaising with primary care and agreeing on appropriate patients for whom A&G is suitable.[5] A further study reported outcomes of the use of A&G to inform clinical decision making around COVID vaccination, which was shown to be efficient and effective.[6] The third presented an audit of 2244 A&G requests made to a surgical department over 13 months. Outcomes were: deferral to outpatient clinic (61%), investigation required (18%), advice provided (10%), different speciality referral (8%).[7] Further searches were conducted on Google Scholar, professional websites and primary care media outlets.

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Case studies published by NHS Digital describing the use of A&G have found challenges to effective working including work-flow planning, the quality of clinical information contained in the two-way dialogue, and risk management of missing information.[8] A 2021 survey of primary care staff (n=390), and interviews of primary care staff and commissioners (n=34) commissioned by NHSE and conducted by the North of England Commissioning Support Unit (NCES) identified five themes relating to uptake, outputs, barriers and opportunities: keeping the process simple, maintaining A&G as part of a range of options to access specialist care, time and resource challenges for primary care, the need to build collaboration and the need to measure system outcomes. A quantitative analysis reported variation in A&G activity across specialties and a recommendation to consider this in future healthcare planning was made. Analysis of future patient outcomes was limited by the inability to follow patients through electronic systems.[9]

The Patient Association undertook work to explore the patient's voice. Unable to engage GP practices, patients were recruited through their own newsletter and stakeholder activities. Patients (n=8) with self-reported experience of A&G primarily reported a lack of shared decision-making and partnership working and a lack of effective communication during the referral process. Improvements suggested included establishing dialogue between patients, GPs, and specialists.[10]

A survey of Royal College of General Practitioners clinical advisors in 2022 showed that 91.7% of GPs use A&G, with 83% finding it useful. However, concerns were identified and escalated to the CQC and NHSE. Whilst secondary care waiting lists increased following the pandemic, the number of referrals to secondary care that were rejected also increased. This rejection does not end the need for patient care and more patients and carers were felt to be being 'held' in the community, increasing the pressure on, and creating a backlog, in primary care.[11] The RCGP reported that A&G is being used by some providers to manage waiting lists (as a tool to convert referrals to A&G or using A&G to decline referrals) to the detriment of patients and primary care.

A further survey of 366 GPs, published in Pulse Magazine in early 2023, reported that 68% felt A&G was blocking necessary referrals. 78% felt that A&G was increasing their workload, 60% felt that A&G was requiring them to work beyond their competence, and 68% reported that patients were complaining because their wish to see a specialist had been diverted.[12] SCSs report the challenges of providing useful advice based upon limited A&G referral information, such as being asked to interpret results of investigations in the absence of relevant clinical history and/or findings and patients report being unfamiliar with referrals process and disenfranchised from A&G pathways.

Literature demonstrates that A&G can be efficient and effective in particular settings, that key aspects for service development include an understanding of suitable cases, collaborative working across the health system, consideration of resource implications, and that existing A&G services may still yield high outpatient appointments with relatively few requests ending with expedited patient journeys (e.g., investigation requests and direct advice). The evidence to date has set the scene for effective use of A&G but flagged how use varies across specialties.

It is not known how A&G impacts upon longer term outcomes for patients and the health service (for example the impact on time to diagnosis of significant disease, mortality rates, healthcare utilisation). Furthermore, there is no evidence to support whether A&G is implemented equitably. There has been little focus on its use for those living in under-served communities, nor how we can develop patient involvement in their own referral journey. This study seeks to address this knowledge gap through a mixed-methods approach with an emphasis on working with under-served communities.

1.2 RATIONALE FOR RESEARCH PROJECT

This research is needed to tackle the compound pressures that have led to 7.3 million people waiting for consultant-led elective care. Waits for 3.3 million people are over 18 weeks and 360,000 are waiting for over one year.[13] These waits impact health and wellbeing and increase the pressure

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across the health and social care system.[14] The National Elective Care Recovery and Transformation Programme[4] seeks to eliminate waits of longer than a year for elective care by March 2025. One of the key components identified to support delivery is the mobilisation of A&G services.

Efficient and timely communication using A&G has great potential to reduce compound pressures by shortening patient journeys through the system, enabling prompt appropriate management of conditions requiring specialist advice, and reducing the burden on primary care that is exacerbated by long waits for specialist opinions. The Transformation Programme[4] has identified A&G as reducing the need for people to travel for hours to a hospital appointment lasting a few minutes saving time, cost, and stress by doing things differently as well as having a positive environmental impact. This in turn supports the Government aim to Deliver a Net Zero National Health Service[15] and can also address health inequalities as access to specialist advice is delivered locally by primary care teams through effective joint working across services.

The COVID pandemic accelerated use of the A&G process, which has been in use since 2012. There were approximately 135,000 A&G referrals sent through e-RS in February 2023.[8] However, there are misgivings amongst those who use A&G, with GPs expressing concerns over increasing workload, the potential for A&G to 'block' necessary referrals, and a requirement for practitioners to work beyond their competence.[12] Preliminary stakeholder conversations described challenges that specialists experience in providing useful advice based upon limited A&G referral information, for example being asked to interpret results of investigations in the absence of relevant clinical history and examination findings. Our public involvement work highlighted an unfamiliarity with the option and use of A&G pathways and a sense of disenfranchisement around the referrals process.

The landscape of the primary-secondary care interface is ever changing. Access to patient records is currently being rolled out and patients are increasingly aware of the dialogues that take place in their medical record.[16] Our PPIE group have made it clear that A&G is a process of which many members of the public were not aware, in some cases until seen in their online record. There is a clear desire from PPIE for clear communication to patients about, and involvement of patients in, their referral processes. Furthermore, recent reports (September 2023) outline that referrals from primary care to secondary care may cease for non-urgent conditions, with A&G becoming the sole pathway to seek specialist opinions from primary care.[17]

The widespread use of A&G, now with its imminent potential roll-out as the sole pathway to access the specialist advice that is critical for patient health and well-being, and the continued developments around patient access to medical records, means that the BADGER study is highly relevant to today's complex and pressured NHS. Understanding the risk and benefits associated with A&G and how it is navigated by all stakeholders will enable policy makers, commissioners, clinicians and patients to be certain that is it safe and effective. Our study outputs will facilitate best use of A&G, maximising activity across the primary-secondary care interface to realise the great potential to address compound pressures whilst simultaneously improving health inequalities and sustainable healthcare.

1.3 THEORETICAL FRAMEWORK

This study is underpinned by the pragmatist research paradigm. Accordingly, the study is problem centred and "real-world practice oriented" in asking "what works?" in relation to A&G to bring about change in quality care. We take a pluralist approach to answer research questions that require quantitative and qualitative lines of enquiry. Our mixed-methods evaluation has a sequential design with 4 work packages (WPs). WP1 is mixed-methods and will include a descriptive quantitative study using electronic healthcare records (EHR), specifically CPRD, and qualitative study using semi-structured in-depth PCC interviews to describe the use and experience of A&G, to identify tracer conditions[18] and create a focus for WP2. WP2 will involve retrospective cohort studies, repeated for

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several tracer conditions. We will describe patient characteristics within the type of referral, with type of referral defined as A&G only; direct referral only; A&G and direct referral; no A&G and no direct referral. We will then observe the linked EHR to identify impact on quality and healthcare utilisation of A&G. WP3 runs in parallel to WP1 and WP2 and includes in-depth qualitative interviews with patients, SCSs, PCC and commissioners to understand their perspectives on the use of A&G. Interpretive description methodology[19] will use clinical knowledge and the perceptions and experiences of participants to develop findings which can be applied to clinical practice, healthcare commissioning and policy development.

Reflexive thematic analysis[20] will be used as the specific analytic strategy to identify these findings. Reflexive thematic analysis will be used allowing for familiarisation, coding, and generating and reviewing themes. Themes and subthemes will be generated iteratively by researchers independently according to commonality across the dataset, significance, and relevance to the research questions. Generated themes will be discussed with the PPIE group and stakeholders for their reflection.

WP4 uses results of WP1, WP2 and WP3 to co-design recommendations, as described below, to support best use of A&G in reducing compound pressures, whilst providing high quality care, and addressing any identified health inequalities.

Interpretive description is a methodology well established for use with qualitative research in healthcare settings[19] and has been widely used to investigate patient experiences and perceptions of illness, healthcare and healthcare environments. It is a conceptual label which acknowledges the clinical positioning of members of the research team and the applied focus of the study as it investigates practical aspects of real-world phenomena, with a consideration of how those findings can be later used to shape further investigation and within practice. Interpretive description methodology will be engaged as the overall strategy throughout this study, complementing our analytic strategy, reflexive thematic analysis.[20]

2 RESEARCH OBJECTIVES

2.1 OBJECTIVES

2.1.1 Aim

The overarching aim of this study is to measure the impact of Advice and Guidance on patients, primary care clinicians, secondary care specialists, and the healthcare system in terms of quality of care, satisfaction with the process and service utilisation to understand how it works for whom, where, and why.

2.1.2 Objectives

Specific objectives by Work Package are to:

<u>WP1: Mixed-methods to develop methodology for WP2</u>

1a. Map the use of A&G over time using a nationally representative UK electronic health records database (the Clinical Practice Research Datalink (CPRD))

1b. Describe current use of A&G from primary care perspectives using qualitative interviews with Primary Care Clinicians

<u>WP2: Quantitative analysis of routinely collected electronic healthcare records</u>

2a. Describe outcomes of tracer conditions following A&G compared to initial direct (non two-week wait)* referral pathways

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2b. Describe healthcare utilisation and patient burden (for example, further consultations, referrals or prescribing in primary care, unplanned admissions, outpatient appointments) comparing A&G and direct referral pathways.

**non 2 week wait means referrals that are not on fast-track suspected cancer pathways that are used for patients with suspected cancer*

WP3: Qualitative interviews with clinicians, commissioners, and patients

3. Evaluate the experiences of A&G and related needs from the perspectives of the patient, clinician and commissioner.

WP4: Developing outputs from WP1-3 findings

4.Co-design and produce resources for patients, primary care, specialist services and commissioners to enable most effective use of A&G services

Study Within A Project (SWAP)

A SWAP will run across WP2, WP3 and WP4. The objectives of the SWAP are:

SWAPa. To describe how the process of A&G accounts for multiple long-term conditions (MLTCs)

SWAPb. To measure the impact of MTLCs on the outcomes of referral decisions

3 STUDY DESIGN

This is a mixed-methods study comprised of 4 work packages, which address the above objectives. The study will span 24 months. A schematic of the design is included as an appendix to this document. We will describe work to be conducted in each WP in the sections below, however this is an iterative study and some details will not be determined until earlier WP's have been reported.

3.1 RESEARCH SETTING

For qualitative WPs (1b & 3) we will work with the CRN West Midlands and North West Coast to recruit patients and PCC from approximately 35 general practices and SCSs from a range secondary care trusts. The sites must be actively engaging in the A&G process. The same types of activity will be taking place at each site in terms of identifying and recruiting patients and clinicians. Participants will be interviewed once over the course of the study.

Quantitative WPs (1a, 2a &2b) will be conducted within the Clinical Practice Research Datalink (CPRD).

4 WORK PACKAGE 1A (QUANTITATIVE)

This section of the protocol relates to CPRD Protocol ID: 24_004022, approved by the Research Data Governance Secretariat on 11/06/2024.

Study Title: Trends over time in the use of Advice and Guidance and variation by sociodemographics and type of health condition: repeated cross-sectional and cohort study

4.1 OBJECTIVES, SPECIFIC AIMS & RATIONALE

The objective of this sub-study is to determine the extent of variation in use of Advice and Guidance (A&G) in primary care. The specific aims are to determine:

1) if use of A&G has increased over time in comparison to direct referrals

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2) variation in use of A&G by socio-demographic characteristics

3) which specialties and health conditions have higher rates of A&G

4) the percentage of A&G which end up with a direct referral.

This study is the first part of a programme of work which has the overall aim to understand whether A&G reduces waiting times and access to specialist care as planned, without making the quality of patient care worse. This initial study will examine changes in use of A&G over time and how it varies by sociodemographic characteristics and specialty.

4.2 STUDY DETAILS

4.2.1 Study type

Descriptive and exploratory / hypothesis generating

4.2.2 Study design

Repeated cross-sectional and cohort

4.2.3 Feasibility counts

A feasibility count between 2015 and 2023 indicates approximately 1.7million A&G requests for 975,000 individuals.

4.2.4 Outcomes to be measured

Advice and Guidance requests

Direct referrals to specialties

4.2.5 Sample size considerations

The feasibility count of 975,000 individuals gives an estimated mean of 108,000 per annum over the nine years of the study. Assuming an annual denominator population of 14 million (and hence prevalence of A&G of approximately 800/100,000), then per annum 95% confidence limits for the prevalence of A&G will be ± 5/100,000. For assessing percentage of A&Gs which result in a referral, assuming an estimate of 50%, then per annum 95% confidence limits will be ±0.3% overall and ±3% for a lowest covariate (e.g.. ethnicity group) category prevalence of 1%.

4.2.6 Planned use of linked data and benefit to patients in England

Patient level Index of Multiple Deprivation (IMD) data will be used in order to assess extent of variation and potential inequality in use of A&G by deprivation. If Patient level IMD is missing, we will include a ‘not recorded’ category.

Use of the CPRD Aurum Ethnicity Record has shown to yield representative distributions across ethnic categories compared to national data on the UK population and a smaller proportion classified as ‘other’.[21] Use of the CPRD ethnicity records will:

1) allow us to access an immediate source of ethnicity with clear and consistent allocation of an ethnicity category that has already been derived for each individual,

2) reduce extent of missing data on ethnicity,

3) use ethnic groupings returned from an externally developed and validated algorithm,

4) allow consistency and hence greater comparability with other studies using CPRD,

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5) allow finer definitions of ethnicity (within Asian, black, mixed/multiple, white, other groups), hence more opportunity to detect inequalities across ethnic groups, rather than just comparing white versus non-white.

CCG pseudonym is requested to explore extent of variation in A&G use across healthcare localities in order to identify potential inequities in practice.

The use of linked data will be beneficial to patients in England by determining whether the use of A&G versus usual referral varies by key socio-demographic factors, e.g. patient-level deprivation, or locality, e.g. by CCG pseudonym, only available through linkage.

The outputs of this research may serve as reassurance to A&G users of its benefits to support primary care and specialist services work together effectively and safeguard quality of care for patients in a pressured healthcare environment. We may, however, identify inequity in practice that will be fed back into the wider programme of research to develop evidence-to-practice recommendations.

4.2.7 Definition of the study population

All individuals in the CPRD Aurum database, regardless of age, with an A&G or referral recorded between 01/01/2015 to date of the most recent Aurum build (currently March 2024). For determination of incident A&G, they must have 24 months prior registration in CPRD Aurum or be aged 2 years or under. There is no comparison or control group.

4.2.8 Exposures, outcomes and covariates

1) Advice & Guidance

We will determine coded A&G events and, where possible, the specialty linked to the A&G. When a Choose and Book referral is made through e-RS (by selecting either the satellite button for “advice and guidance” which equates to an A&G request or the “Refer/Advice” satellite button which equates to the standard or direct referral to secondary care), the referral must be saved before the activity can be completed and exited back to the clinical software system. To save the activity, a code must be entered to then move back into another part of the healthcare record. For A&G requests, the coded term is “Advice and guidance requested.” We will also include in our codelist the code “Advice and guidance received” which we will use to indicate A&G if the patient does not have an “Advice and guidance requested” code within the same study time period. We will map A&G to specialty (e.g. rheumatology, neurology) and type of health condition (e.g. musculoskeletal, cardiovascular). Given A&G coded events may not routinely have the specialty recorded we will use information from direct referrals (sampled from 3 specified years - 2015, 2019, 2023 - within our study period) as the basis for mapping to specialty. We will first determine morbidity/symptom codes recorded on the date of all direct referrals (defined below) with a named specialty, or in the prior 2 weeks. We will determine which Read or SNOMED CT codes are most frequently recorded with referral to each specialty and use these to map (impute) specialties in those with an A&G event based on matching these codes to Read/SNOMED CT morbidity or symptom codes recorded on the date of A&G or in the prior 2 weeks. Where the specialty is still unknown after this mapping exercise, we will review all codes in the 2 weeks prior to or on date of A&G request and agree on specialty (guided by Read code chapter) by consensus or define as unknown if no consensus. Type of health condition will be based on specialty or morbidity/symptom code at date of A&G event.

2) Direct referral

To derive the comparative prevalence and incidence of elective referrals, direct routine referrals will be determined using codes with a term indicating a referral and defined by consensus of study team to indicate a routine referral to a specialty (i.e. not fast track or referral with an intention to admit / emergency referral). To ascertain A&G events which result in a direct referral, we will determine

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referrals within 122 days (4 months) after date of an A&G request. These will be defined as i) a direct referral code defined as above and by ii) linking events in the Referrals table to the Observation table and determining duration of time between the linked observation event and the A&G request date. We will also determine referrals within 122 days (4 months) before an A&G request to see how often A&G requests follow a referral request. As a sensitivity analysis we will repeat for 365 days (12 months) either side of the A&G request date. Code lists for A&G have been derived and used in our CPRD feasibility study (FS_002830). The draft code list for direct referral has also been developed. These code lists are included in the appendix.

Covariates:

1) Age at date of A&G request (categorised)

2) Sex

3) Geographical region

4) CCG pseudonym

5) Ethnicity group

6) Deprivation (based on IMD quintiles)

4.3 DATA / STATISTICAL ANALYSIS

We will determine the annual total number of A&G and total number of routine direct referrals from 2015 to 2023. Annual prevalence will then be defined as the total number of patients with i) an A&G and ii) a routine referral code recorded within each calendar year, divided by the total registered population at the start of each calendar year and expressed per 100,000 persons. Annual incidence will be defined (as in our previous incidence studies) as the total number of patients with i) A&G and ii) routine referral codes recorded within each calendar year who have no recorded A&G or routine referral codes in the previous 24 months, divided by the total registered population with at least 24 months registration at the start of each calendar year, and expressed per 100,000 persons. We will determine prevalence and incidence overall, and stratified by age and sex.

Patterns of A&G use (number, prevalence, incidence) will also be described across specialties and type of health condition, and by neighbourhood deprivation, ethnicity, CCG, and geographical region to assess if any change over time in consultation incidence and prevalence varies by these characteristics. We will produce caterpillar plots to show variation by geographical region and CCG. We will repeat for quarterly incidence and prevalence of A&G (up to date of most recent CPRD Aurum build). We will use joinpoint regression analysis and segmented regression on the annual and quarterly prevalence and incidence to determine impact of the COVID pandemic [2020/2021] and changes in policy on A&G.

Within those with A&G we will derive the percentage with a recorded referral in the 122 days (4 months) i) before and ii) after A&G record and compare these over time, and by the covariates (excluding those with less than four months of follow-up), descriptively and by using binary logistic regression. We will repeat for the sensitivity analysis of 12 months. We will descriptively compare trends in incidence and prevalence of A&G and routine direct referrals with publicly available data on trends on e-referrals from https://digital.nhs.uk/dashboards/ers-open-data which currently covers the period October 2019 to March 2024.

4.3.1 Plan for addressing confounding

This is a descriptive/exploratory and hypothesis generating study. We will acknowledge in dissemination unmeasured factors like symptom or disease severity may confound associations between the covariates and A&G and in referral following an A&G.

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4.3.2 Plans for addressing missing data

We will assume that if no code for A&G or referral is entered, it did not occur. It is possible the quality of recording has improved in recent years and will discuss this as a limitation in dissemination, but we do not expect bias in recording by the covariates. Not everyone will have an ethnicity recorded, and we will use a “Not recorded” category.

4.3.3 Limitations of the study design

As above, it is possible recording of A&G and referral has improved over time.

As an observational study, there is the potential for unmeasured confounding factors to affect the findings. It will not be possible to conclude any causal relationship between variations in locality or socio-demographic characteristics for A&G versus usual referrals due to our study being both exploratory and descriptive. Misclassification of cases, exposures, and covariates is possible but expected to occur at random and so not introduce a significant degree of bias.

There may be other locality-dependent portals available for primary care clinicians to access specialist input without requiring a formal referral, such as teledermatology services and applications such as Consultant Connect, which facilitate telephone contact with the consultant/specialist and may not be coded by the GP. The consequence of this is that there may be missed episodes of A&G, but we believe this to be the minority of cases or at the more urgent end of the spectrum of clinical presentations rather than our focus on elective care.

5 WORK PACKAGE 2 a&b (QUANTITATIVE)

This section of the protocol relates to Work Package 2 a&b and will be designed iteratively as findings from WP 1b and our work with our PPIE and stakeholders emerge. Permissions will be sought from the RDG Secretariat via the electronic Research Application Portal.

Study Title: Determining outcomes of the use of Advice and Guidance: a cohort study

5.1 OBJECTIVES, SPECIFIC AIMS & RATIONALE

The aim of this sub-study is to determine outcomes of the use Advice and Guidance (A&G) in primary care. Specific objectives are to:

2a. Describe outcomes of tracer conditions following A&G compared to initial direct (non two-week wait)* referral pathways

2b. Describe healthcare utilisation and patient burden (for example, further consultations, referrals or prescribing in primary care, unplanned admissions, outpatient appointments) comparing A&G and direct referral pathways.

**non 2 week wait means referrals that are not on fast-track suspected cancer pathways that are used for patients with suspected cancer*

5.2 STUDY DETAILS

5.2.1 Study type

Descriptive and exploratory / hypothesis generating

5.2.2 Study design

Retrospective cohort

5.2.3 Feasibility counts

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A feasibility count between 2015 and 2023 indicates approximately 1.7million A&G requests for 975,000 individuals.

5.2.4 Outcomes to be measured

For WP2a, the outcome for those with an A&G and/or direct referral recorded will be the time to diagnosis from the first recorded A&G or direct referral to index diagnosis date.

For WP2b, outcomes will be guided by our PPIE and Stakeholder groups as well as emerging results from interviews with PCC's. They are likely to include in the 12 months following referral:

i. Number of consultations recorded in primary care;
ii. Number of prescriptions recorded in primary care;
iii. Number of referrals recorded in primary care;
iv. AE attendance recorded in HES AE
v. Number of additional outpatient appointment recorded in HES outpatients
vi. Overnight unplanned hospital admission recorded in HES APC (admitted patient care);
vii. Mortality recorded in ONS.

5.2.5 Sample size considerations

Taking multiple sclerosis as the example condition, we expect around 11,000 people to have a new diagnosis between 2015 and 2022 in CPRD (based on reported national incidence of 7,000 per year,[24] CPRD covering 20% of UK population and study period of 8 years). Based on the feasibility study in SLE, if 5% received A&G then we could detect a hazard ratio of 1.15 or more with 90% power at a 5% significance level. We expect other conditions to be more prevalent.

5.2.6 Planned use of linked data and benefit to patients in England

In addition to patient level Index of Multiple Deprivation (IMD) data and the CPRD Aurum Ethnicity Record as previously described, we will use Hospital Episode Statistics (HES; NHS Digital, 2022) data to access hospital admission data. The Office for National Statistics (ONS) death registration data will provide mortality records. Linkages are necessary to identify patient outcomes and healthcare utilisation.

5.2.7 Definition of the study population

All individuals in the CPRD Aurum database, regardless of age, with a first recorded index tracer condition between 01/01/2015 to 31/12/2022 and 24 months prior registration in CPRD Aurum. We will compare outcomes for patients with a recent history of A&G to those with direct referral, stratified by tracer condition. A&G and direct referrals will be obtained from primary care records in the 24 months prior to index (first diagnosis) date. Patients with both A&G and direct referral will be classified based on whichever happened first. We will include age at index date, gender, neighbourhood deprivation, geographical region, and ethnicity, as common covariates for all analyses as well as covariates (e.g. multiple long term conditions) specific to each tracer condition. There is no comparison or control group.

The tracer conditions will be informed from the work in WP1, including interviews with PCCs, and the experiences and advice of our PPIE and Stakeholder groups.

5.2.8 Exposures, outcomes and covariates

1) Advice & Guidance

Please see 4.2.8

2) Direct referral

Please see 4.2.8

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3) Tracer conditions

Relevant codes for tracer conditions will be derived from existing code lists (e.g. those already held at Keele and / or using open access lists such as those held by OpenCodelists) or developed and validated through consensus of EHR researchers and clinical academics within the study team and the EHR Research Group at Keele University, a group led by co-applicants KJ and KM. This research group has set procedures for developing code lists. Codes for covariates and outcomes will be derived in a similar process.

5.3 DATA / STATISTICAL ANALYSIS

For WP2a, the outcome for those with an A&G and/or direct referral recorded will be the time to diagnosis from the first recorded A&G or direct referral to index diagnosis date. We will calculate median (interquartile range) days to diagnosis from first recorded A&G or direct referral code and incidence rates per 1,000 person years and present with 95% confidence intervals. We will use flexible parametric survival analysis to compare A&G and direct referral on time to diagnosis. Flexible parametric survival analyses are preferred to Cox proportional hazards regression as they allow easier modelling of time-dependent effects and the ability to determine absolute risks of outcome.[25] 'Exposure' will be the initial method of referral (A&G, direct referral) prior to index date. Hazard ratios will be presented as unadjusted and adjusted for covariates with 95% confidence intervals (CI).

For WP 2b, individuals with each index condition will be categorised as i) A&G only, ii) direct referral only, iii) A&G and direct referral, iv) no recorded A&G or direct referral in the 24 months before diagnosis:

- negative binomial or zero-inflated negative binomial regression will be used to estimate incidence rate ratios for the number of consultations, referrals and prescriptions in primary care, and number of outpatient appointments,
- robust Poisson regression will be used to compare A&E and unplanned admission in secondary care;
- flexible parametric survival analysis will estimate hazard ratios for mortality.

Rates or ratios will be presented as unadjusted and adjusted for covariates with 95% CI.

As part of the Study Within A Project (SWAP) (see Section 8), the impact of multimorbidity and frailty on decision to use A&G and its outcomes will be considered by including multimorbidity and frailty (defined by Charlson comorbidity index/number of prescriptions and electronic frailty index) as predictors and moderators of A&G outcome in the models.

5.3.1 Plan for addressing confounding

This is a descriptive/exploratory and hypothesis generating study. We will acknowledge in dissemination unmeasured factors like symptom or disease severity may confound associations between the covariates and A&G and in referral following an A&G.

5.3.2 Plans for addressing missing data

We will assume that if no code for A&G or referral is entered, it did not occur. It is possible the quality of recording has improved in recent years and will discuss this as a limitation in dissemination, but we do not expect bias in recording by the covariates. Not everyone will have an ethnicity recorded, and we will use a "Not recorded" category.

5.3.3 Limitations of the study design

As above, it is possible recording of A&G and referral has improved over time.

As an observational study, there is the potential for unmeasured confounding factors to affect the findings. It will not be possible to conclude any causal relationship between variations in locality or

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socio-demographic characteristics for A&G versus usual referrals due to our study being both exploratory and descriptive. Misclassification of cases, exposures, and covariates is possible but expected to occur at random and so not introduce a significant degree of bias.

There may be other locality-dependent portals available for primary care clinicians to access specialist input without requiring a formal referral, such as teledermatology services and applications such as Consultant Connect, which facilitate telephone contact with the consultant/specialist and may not be coded by the GP. The consequence of this is that there may be missed episodes of A&G, but we believe this to be the minority of cases or at the more urgent end of the spectrum of clinical presentations rather than our focus on elective care.

6 WORK PACKAGES 1B AND 3 (QUALITATIVE)

This section of the protocol is covered by IRAS 333799 and was reviewed by the North East-Tyne & Wear Research Ethics Committee on 22/05/24. Approvals were given on 13/06/24 (24/NE/0110).

6.1 STUDY POPULATION

6.1.1 Number of participants

Semi-structured interviews will be conducted with approximately 30 patients, 20 PCCs, 20 SCSs and 5 commissioners. We will recruit patients and PCCs from approximately 35 general practices and SCSs from approximately 5 to 10 trusts. Commissioners will be recruited through professional networks. Recruitment of PCCs (WP1) will be open for approximately 6 months, and recruitment for patients, SCSs and commissioners (WP3) will be open for approximately 8 months.

6.1.2 Inclusion criteria

Patients: Adult patients (18 years or over) registered at a participating practice with an episode of A&G recorded in their electronic health record in the last 3 months, and have capacity to consent to an interview.

PCCs: participants will be eligible if they currently work in the NHS and are users of A&G.

SCSs: participants will be eligible if they currently work in the NHS and are users of A&G.

Commissioners: participants will be eligible if they currently work in the NHS and are familiar with its use at Trust / local System level.

6.1.3 Exclusion criteria

Patients: participants will be excluded if they do not have capacity to consent for themselves, or are unable to meaningfully communicate about their experiences in an interview. If English is not their first language, translation services will be used so as not to exclude due to language barriers.

PCCs, SCSs, Commissioners: participants will be excluded if they have no experience of using or knowledge of A&G.

6.1.4 Sampling

We will work with our CRNs to ensure diversity within our general practice sites (including practice size, rural/city location, staff makeup, patient population demographics) including practices who have a large CORE20 (the most deprived 20% of that national population) cohort. When declaring interest in the study, patient baseline characteristics will be collected including age, gender, ethnicity, and neighbourhood deprivation (postcode) and used to sample those invited to interview to ensure maximum variation in terms of empirical and demographic diversity. Results from WP1 may also be used to guide sampling of patients referred to key specialities. We will purposively sample PCCs by age, gender, job role, time in practice, and self-reported level of A&G use. We will sample SCSs and

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commissioners by clinical specialty, age, gender, job role, and time in service as a specialist (clinicians) and Trust demographics (commissioners). In all cases, maximum variation sampling will be applied using the REP-EQUITY toolkit, developed by Retzer et al (2023), to support the process of sampling, with the aim of capturing a representative and equitable sample. [22]

Data saturation is incompatible with the reflexive thematic analysis approach (Braun and Clarke),[23] We will use the construct of information power (as advocated by Braun and Clarke) to reflect on the information richness of our dataset and how it aligns with our aims and study requirements. We outline an approximate sample size and this will be monitored across the study to ensure a broad and diverse sample of experiences of A&G within each group of patients, PCCs, SCSs and commissioners, to provide a detailed understanding of how A&G is used within the NHS.

6.2 PARTICIPANT / SAMPLE SELECTION, RECRUITMENT AND ENROLMENT

6.2.1 Identifying participants / sample

Patient participants will be identified by participating GP practices, supported by the WM and NW Coast CRNs teams, via searches using routinely collected primary care data, from general practices in the West Midlands and North West Coast areas. Searches will identify instances where an A&G episode has been recorded in the past 3 month period. Text messages will be sent out via the GP practice system to those whose record indicates an episode of A&G in the past 3 months. For those who don't have a recorded mobile phone number, a paper invitation will be posted. The searches, texts and posted invitations will all be carried out by the GP practice staff, the CRN staff will not have access to patient records. Translation links will be available. PCCs will have postcards with links to the study website they can hand to patients if a decision is made to use A&G within a consultation setting. Posters (paper and electronic) will be created for practices to display in their waiting areas, on their websites and social media, and through patient participation group media (e.g. newsletters), providing information about the study so that prospective patients are aware of the study and its legitimacy before they receive their invitation. Contact details will be included on the documents for patients to get in touch with the research team if they have any queries. SCSs will be recruited through their Trust communications (including work email, staff intranet, social media). If we are unable to recruit sufficient PCCs from participating practices or SCSs from participating trusts, then we will recruit from professional networks including social media. Commissioners will be recruited through professional networks including social media.

Identifiable personal information will be collected and securely stored with consent, at the time a patient or clinician expresses interest in the study. This information is required to support purposive sampling.

Personal data or records will not need to be shared with the research team before participant consent has been obtained as it will be the participants who will choose to contact the research team and provide this information themselves.

Participants will be reimbursed for their time in line with existing payment frameworks.

6.2.2 Approaching Potential Participants

A multi-modal approach to recruitment will be used. PCCs will have postcards with links to the study website they can hand to patients if a decision is made to use A&G within a consultation setting and they feel that the patient meets the study inclusion criteria to the study e.g. able to provide informed consent. Text messages will be sent out via the GP practice system to those whose record flags an episode of A&G. For those who don't have a recorded mobile phone number, a paper invitation will be posted. Translation links will be available. Posters (paper and electronic) will be created for practices to display in their waiting areas, on their websites and social media, and through patient participation group media (e.g. newsletters), providing information about the study so that

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prospective patients are aware of the study and its legitimacy before they receive their invitation. Contact details will be included on the documents for patients to get in touch with the research team if they have any queries. Practice advertisements will also help to allay concerns about the validity of text messages received about the study. Those who have declined consent for their medical record to be used for research will not be sent a text message or letter but will still be able to take part in the study if they reach out to the study team through other methods of referral.

For PCCs, the CRN will contact the recruiting practice and pass on the study invitation to clinicians, so that we can make attempts to interview (separately) PCCs and patients from the same episode of A&G to gain different perspectives of the same process, though this may be challenging. If we are unable to recruit 20 PCCs through the CRNs, we will recruit through professional networks.

SCSs will be recruited with support from the CRNs in the first instance, with the CRN sharing the study invitation. If we do not reach approximately 20 SCSs through the CRN, we will recruit through professional networks. Healthcare commissioner participants will be recruited through professional networks.

As described for patients, participants will be provided with participant information sheets, informed consent will be taken, and interviews will take place remotely over video software such as MS Teams.

Prospective participants with an interest in the study will be invited to complete screening questions and return their answers to the research team. By completing and returning the form, the prospective participant will be consenting to the research team accessing their personal data (as provided on the reply slip/screening questions) and using their contact details to get back in touch with them.

6.2.3 Consenting participants

6.2.3.1. Informed Consent Process

Informed consent must be obtained prior to the participant undergoing any activities that are specifically for the purposes of the research project. The interviewing researcher is responsible for ensuring informed consent is obtained before any protocol specific procedures are carried out. The decision of a participant to participate in research is voluntary and should be based on a clear understanding of what is involved.

Participants will receive adequate verbal and written information; appropriate Participant Information and Informed Consent Forms will be provided. The verbal explanation to the participant will be performed by the investigator or qualified delegated person and must cover all the elements specified in the Participant Information Sheet and Consent Form.

The participant will be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information. The participant will be given sufficient time to consider the information provided. It should be emphasised that the participant may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled.

We will not ask practices to send a text message to patients who have declined to receive text messages. Prospective participants with an interest in the study will be invited to complete screening questions and return their answers to the research team. By completing and returning the form, the prospective participant will be consenting to the research team accessing their personal data (as provided on the reply slip/screening questions) and using their contact details to get back in touch with them.

Participants will be given the opportunity to ask the research team for support with the information sheet e.g. provide a translation or explain any medical terms, and ask any questions before they decide if they want to take part. Participants will be able to complete the consent form at home/location of their choice before taking part in the interview and will return the completed consent form to the researcher. If the participant has not returned a signed consent form by the start of the

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interview, the interviewer will tell the participant about the study and go through the consent form with them and ask for verbal consent before the interview begins. Location of the interview/consent taking will be arranged with the participant.

Participants must have capacity to consent to interview and we will not recruit minors or vulnerable groups unable to consent and / or be interviewed. Capacity will be judged by the interviewing researcher.

We do not foresee any limitations in the interviewing researcher taking informed consent. We do not foresee any obvious risk as a result of participating in this research. However, there is the potential that discussing their experience of A&G could prove distressing for some people. If a participant indicates they are feeling distressed, or exhibits behaviours indicating distress, e.g. crying or appearing tearful, or incoherent speech, the interview will be paused with participants being given the option of whether they wish to continue the interview after a break, rearranging the interview or terminating the interview. All participants will be given the option of withdrawing from the study up to one week after the interview, and if they do then their data will be deleted.

To minimize the risk of distress, interviews will take place either remotely or in a safe and secure environment where privacy and confidentiality can be ensured. Participants will have the option of being interviewed with a significant other if preferred. Interviews will be paced according to the interviewees, who are free to withdraw at any time.

There is also a potential risk that patients seek clinical advice from the interviewer. It will be made clear that interviewers are not medical professionals and are therefore unable to provide clinical advice, participants will be advised to seek support from their own clinical teams if necessary.

If concerns are raised in the interview relating to professional practice, we would encourage the participant to follow their internal processes for raising concerns. In the case of patients raising concerns, this would be following the GP surgery's complaints procedure. Any concerns will be discussed within the research team and escalated if appropriate to the senior GP Partner or Medical Director of the secondary care Trust.

Research participants may find that they enjoy the opportunity to discuss the use of A&G. Taking part in this study will not directly help the research participants but may have wider benefits for other patients whose care involves A&G and healthcare professionals using A&G through the dissemination of our comprehensive understanding of how A&G works, and how to make use of the system in a safe, effective and efficient manner to reduce compound pressures on the NHS.

Written material will be available in written and electronic format and will be co-produced with our PPIE group and in consideration of accessibility guidelines.

Participants will be invited to ask questions throughout the consent and interview process.

Once the participant has made contact with the study team to participate in the study, they will be given the time that they need to decide whether or not to take part, and arrange an interview time. If, at any point in this process, they cease to maintain contact with the study team (e.g. not replying to emails), the research team will phone the participant or send one follow up email (depending on their preferred form of communication) approximately one week after their latest point of contact to confirm that they are still interested in participating in the study. If the prospective participant doesn't respond to that communication, they will receive no further contact from the study team unless they initiate communication again. Participants who do not turn up to an arranged interview will receive one follow up email or phone call to confirm whether or not they still want to take part. If they do not respond, they will receive no further contact from the study team unless they initiate communication again.

For in-person consent, the investigator (or delegated member of the research team) and the participant will sign and date the Informed Consent Form(s) to confirm that consent has been

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obtained. The participant will receive a copy of this document if they wish and a copy filed in the Investigator Site File (ISF). It will not be necessary to store a copy in the participant's healthcare records. In the case of remote interviews, electronic consent will be taken. The participant will receive a copy of the document if they wish.

6.2.3.2. Loss of Capacity following informed consent

Participants will only be asked to attend one interview with the research team, this is anticipated to last approximately one hour. There is a low risk that participants will lose capacity to consent to participate in this time period.

In the unlikely incident that the participant appears unable to continue to consent to participate during the interview, the researcher will contact emergency services as appropriate. The participant will be withdrawn from the study and any data collected to that point will not be included in the study.

6.2.3.3. Withdrawal of Research Participants

Participants will be free to withdraw from the research at any time without giving reasons and without affecting their care. However, participants will be made aware (via the information sheet and consent form) that should they withdraw more than one week after the interview, then the data collected to date may not be erased in accordance with the University's Research Privacy Notice and information given in the Participant Information Sheet and may still be used in the final analysis. If the participant withdraws up to one week following the interview, then all collected data will be deleted.

Participants may also be withdrawn at the discretion of the investigator, if it is considered to be in their best interests. The participants will be made aware that withdrawal will not affect their future care.

Withdrawn participants will be replaced by another from the same participant group.

6.3 DATA COLLECTION

6.3.1 Data collection

Participants will be offered the option of being interviewed remotely or face-to-face. Face-to-face interviews will take place either at Keele University or in the participant's home or quiet public space (with appropriate policies in place). It is anticipated, from research experience, that patient interviews are likely to take place in participants' homes or on MS Teams. Patients will have the option of being interviewed with a significant other if preferred.

Semi-structured interviews will be conducted using topic guides co-developed by and in agreement with our PPIE group and collaborating stakeholders. Topic guides will explore patient interviewees' experiences and perceptions of the use of A&G during and after the consultation process, and aspects of an 'ideal' interaction between patients and health care professionals in relation to the use of A&G. Clinician participants will be interviewed around their own experiences and perceptions of the A&G process. Topic guides will be used flexibly to allow interviewers to explore any unexpected findings and enable comparison between accounts during analysis.

Interviews will be digitally recorded with consent. Audio-recordings of interviews will be transcribed and anonymised before analysis. A reflexive thematic analysis approach will be taken to obtain a rich and contextualised understanding of the strengths and weaknesses of the use of A&G in patient care at the primary secondary care interface.

Interviews are likely to last between 30 and 90 minutes and will be single events. There will be no follow-up/longitudinal interviews. Participants will be free to pause or stop their interview at any point

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without any expectation to continue. It will be made clear that interviewers are not able to provide clinical advice and will advise participants to seek support from their own clinical teams if necessary.

An inductive, reflexive thematic analysis will be carried out on the data following the principles outlined by Braun & Clarke.[20] The data will be analysed within the participant groups, and as a complete dataset to holistically explore the experiences and interactions of the participants, and to identify any patterns and consistencies across the accounts.

6.3.2 Data analysis

The interviews will be audio/video recorded on a Dictaphone or via MS Teams and saved onto the private Teams channel, as set out in the Data Protection Impact Assessment (DPIA) for the study. These data will be transcribed by a professional transcription company who are acting under a Service Level Agreement (SLA) with the University. Audio files will be uploaded to the company via their secure portal and they will return transcripts via email to the qualitative researcher in the form of an encrypted password protected file. On receipt, the qualitative researcher will upload the file to the private Teams channel. This file will be anonymised by the qualitative researcher as soon as possible afterwards. The audio/video recordings will be deleted at the end of the study. This will allow for audit during the study and review during the project.

Participants will be pseudonymised and will be allocated a participant code for use during the study. A document which matches these participant codes to identifying features e.g. demographics will be kept separately to the transcripts and consent forms. Personal data (demographic and contact details) and research data will be stored securely and separately on a private Teams group, as set out in the DPIA for the study. All research staff work to robust data security procedures and have explicit duties of confidentiality, equivalent to the duty placed on NHS staff, written into their employment contracts. This being in line with the UK General Data Protection Regulation (GDPR, 2018), the Keele Quality Management System (QMS) and the UK Policy Framework for Health and Social Care Research. During and after completion of data collection, all research data will be kept strictly confidential and will be anonymised before analysis.

Only the research team will have access to the participants' personal data during the study. Members of staff from the sponsor and/or regulatory bodies may also require access to study participant's data in order to carry out audits. All these staff work to robust data security procedures and have explicit duties of confidentiality. Information about who will access participant's personal data will be detailed in the participant information sheet (PIS) and participants will be asked to confirm whether they have read and understood the PIS by signing the consent form.

NVivo will be used to systematically code transcripts and identify concepts inductively. Transcripts will be coded by at least two members of the team, who will bring perspectives from different disciplines. Themes and subthemes will be generated iteratively by both researchers independently according to commonality across the dataset, significance, and relevance to the research questions. Developing themes will be discussed with our PPIE groups and clinical stakeholders for further reflection and to aid interpretation of findings.

All information collected during the course of the study will be kept strictly confidential. Research data (anonymous transcripts of the interviews and demographics - age, ethnicity, gender) will be held securely and managed electronically in the Keele University teams folder which has been set up for use for this project, only the research team will have continued access to the data. All research data will be securely stored for 10 years after completion of the study; after this time all data will be destroyed.

6.4 DATA MANAGEMENT

Data management will be carried out in accordance with Keele University Health and Social Care Research (HSCR) Standard Operating Procedures (SOPs). The research data will be stored on Keele University storage servers within the UK and protected by industry standard security tools. All

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confidentiality arrangements adhere to relevant data protection regulations and guidelines (Data Protection Act 2018, UK General Data Protection Regulation (UK GDPR), Caldicott, General Medical Council (GMC)) and the Chief Investigator and the Data Custodian have responsibility for the use, security and management of all data generated by the study.

All information collected during the course of the research will be kept strictly confidential. Information will be held securely on paper and managed electronically by Keele University, in compliance with data protection regulations:

- Appropriate storage, restricted access and disposal arrangements for participant personal and health-related details
- Personal data can only be linked to research data by individuals with appropriate permissions.
- Consent from participants for access to their healthcare records by responsible individuals from the research staff or from regulatory authorities, where it is relevant to research participation.
- Consent from participants for the anonymous data collected for the research to be used to evaluate safety and develop new research.

6.4.1 Personal data

The following personal data will be collected as part of the research:

- Participant name
- Participant group: patient, primary care clinician, secondary care specialist, commissioner
    - Healthcare professionals will be asked for their work title / role
- Age
- Ethnicity
- Postcode (for patient participants only)
- Contact details: telephone number and/or email address
- Patients who request an in-person interview will be asked to choose a location for the interview. If they choose to be interviewed at their home, their address will be collected. This will not be collected as standard from participants.

Personal data will be stored by the research team on a secure university network drive, with access limited to the research team. The exception to this would be in the case of any safeguarding concerns, or if distress requiring additional support is identified or divulged. Further information is contained in the DPIA.

Personal data will be deleted once we are confident that we don't need to make contact with participants again (which will either be before the end of the study, or at the end of the study if the participant would like to receive communication about the study findings).

All Investigators and research site staff involved with this study must comply with the requirements of the appropriate data protection legislation (including the General Data Protection Regulation and Data Protection Act) regarding the collection, storage, processing and disclosure of personal information.

Published results will not contain any personal data and be of a form where individuals are not identified, and re-identification is not likely to take place.

6.4.2 Data information flow

Electronic transfer by magnetic or optical media, email or computer networks:

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Audio/video recordings of the interviews will be electronically transferred to the transcription company either via a secure portal or password-encrypted by email. The Transcription Company has a contract with the sponsor ensuring confidentiality.

Use of personal addresses, postcodes, faxes, emails or telephone numbers:

Practice staff will use patient names and addresses to send the study packs to prospective participants via post. Participants will provide the study team with their contact details (phone number or email), and, in the case of patient participants, postcode and personal address (if needed for arranging an interview) which will be stored electronically as specified in the DPIA and any paper containing this information will be destroyed.

Use of audio/visual recording devices:

The interviews will be audio-recorded (and also video-recorded where Teams is used to host the interview) and the recordings will be transferred to a secure university network drive as possible after the interview has taken place. Consent will be gained from participants to audio (and video) record the interviews.

Storage of personal data:

Manual files: Physical signed copies of the consent forms will be scanned and uploaded to the university secure storage system. Once the file has been uploaded, the physical copy of the consent form will destroyed securely. Personal data will be stored once we are confident that we don't need to make contact with participants again (which will either be before the end of the study, or at the end of the study if the participant would like to receive communication about the study findings).

University computers

Personal data (demographic and contact details) and research data will be stored securely and separately on a private Teams group, as set out in the DPIA for the study.

Publication of direct quotations from respondents:

Direct quotations from respondents will be used but will be anonymised during transcription and care will be taken during reporting not to publish quotations that allow identification of participants. This is made clear in the relevant information sheets and consent forms.

6.4.3 Transfer of data

Data collected or generated by this research project (including personal data) will not be transferred to any external individuals or organisations outside of the Sponsoring organisation, apart from for the purposes of transcription.

6.4.4 Data breaches

Any data breaches will be reported to Keele University’s Data Protection Officer (DPO) who will onward report to the relevant authority according to the appropriate timelines if required. If these data breaches also meet the definition of a protocol non-compliance or a potential serious breach, they will also be reported as such.

6.4.5 Access to the final study dataset

Only necessary members of the research team (AFN, RH, VW, CB, CJ) will have access to the participants' personal data during the study. Members of staff from the sponsor and/or regulatory bodies may also require access to study participant's data in order to carry out audits. All these staff work to robust data security procedures and have explicit duties of confidentiality. Information about who will access participant's personal data will be detailed in the participant information sheet (PIS)

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and participants will be asked to confirm whether they have read and understood the PIS by signing the consent form.

6.4.6 Archiving

At the end of the research, data will be securely archived in line with the Sponsor's procedures for 10 years after end of study declaration and until the Sponsor authorises destruction. Archiving will be carried out in accordance with Keele University SOPs.

6.5 OVERSIGHT ARRANGEMENTS

6.5.1 Research oversight Groups / committees (where applicable)

A Study Management Group (SMG) will be responsible for the recruitment set-up, ongoing management and monitoring, promotion of the study, and for the interpretation of the results. The SMG will meet on a monthly basis, with sub-groups (e.g. the qualitative and quantitative teams) meeting more frequently, as determined by the phase of the study.

An independent Study Steering Committee and a Data Monitoring Committee will be established and provide independent oversight of the research project. These committees will meet initially at the start of the research and subsequently at regular intervals as agreed by the SSC/DMC.

6.5.2 Inspection of records

Investigators and institutions involved in this research project will permit related monitoring and audits on behalf of the Sponsor, REC, and regulatory inspection(s). In the event of audit or monitoring, the Investigator agrees to allow the representatives of the Sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation.

6.5.3 Study monitoring and audit

The study will be managed in accordance with Keele University SOPs. The study Chief Investigator (CI) is responsible for the conduct of the study and will convene a Study Management Group (SMG) comprising key stakeholders involved in the A&G process (patient, GPs, Consultant Rheumatologist, healthcare commissioner) who will work alongside individuals with methodological expertise in epidemiology, statistics, data management and qualitative methodologies. All team members will work collaboratively to develop results, key findings and outputs in conjunction with our Stakeholder group and our PPIE support groups.

Regular meeting of the SMG will take place throughout the study. It will oversee the protocol completion, obtaining regulatory approval and site set-up and software development. They will be responsible for the delivery of the study, data collection and the ongoing management. The group will monitor recruitment procedures, review against timelines and complete regulatory reporting requirements. In addition, they will also oversee the analyses and the interpretation of the results. The group will also ensure there is sufficient staffing support available for the study.

Study monitoring will be carried out in accordance with a risk proportionate Study Monitoring and Data Management Plan and Keele University SOPs which lay out the procedures for monitoring the data collection, protocol compliance and data management procedures.

In accordance with their standard operating procedures, the Sponsor may conduct audit(s) of the study. Should audit be required, details will be captured in an audit plan. Audit of Investigator sites, study management activities and study collaborative units, facilities and 3rd parties may be performed.

6.6 ETHICAL AND REGULATORY CONSIDERATIONS

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Health Research Authority (HRA) approvals will be applied for and obtained before the study commences. HRA Approval is the process for the NHS in England that brings together the assessment of governance and legal compliance, with independent Research Ethics Committee opinion provided through the UK Department of Health's Research Ethics Service.

6.6.1 ETHICAL CONDUCT

Before the start of the study, a favourable opinion will be sought from an appropriate Research Ethics Committee (REC) for the study protocol, informed consent forms and other relevant documents e.g. advertisements.

Substantial amendments that require review by the REC will not be implemented until the REC grants a favourable ethical opinion for the amendment (note that amendments may also need to be reviewed by NHS R&D departments before they can be implemented in practice at sites).

All correspondence with the REC will be retained in the Study Master File.

The Chief Investigator will notify the Sponsor and REC of the end of the study.

The Chief Investigator (or their delegate) will submit an annual progress report to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.

If the study is ended prematurely, the Chief Investigator will notify the Sponsor and 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.

6.6.2 Peer review

The Detailed Research Plan, upon which this protocol is based in its entirety, has been reviewed by the NIHR Health Services Delivery Research programme panel, and the West Midlands Research Design Service.

6.6.3 Regulatory Compliance

The study will be conducted in accordance with the principles of Good Clinical Practice (GCP) in research studies and the UK Policy Framework for Health and Social Care Research. Keele University has a quality management system in place containing standard operating procedures which will be adhered to in the conduct of the research.

6.7 STUDY CONDUCT RESPONSIBILITIES

6.7.1 Protocol amendments

Any changes in research activity or approved documents, except those necessary to remove an apparent, immediate hazard to the participant in the case of an urgent safety measure, must be reviewed and approved by the Chief Investigator.

Amendments will be submitted to the Sponsor in accordance with their processes for review and authorisation before being submitted in writing to the appropriate REC and HRA (as applicable) for approval prior to implementation.

6.7.2 Management of protocol non-compliance

The research will be conducted in compliance with this protocol and GCP guidelines. Deviations from study protocols and GCP occur commonly in health and social care research. The majority of these instances are technical non-compliances that do not result in harm to the participants and do not

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compromise data integrity, or significantly affect the scientific value of the reported results of the research.

Prospective protocol deviations, i.e. protocol waivers, will not be approved by the Sponsor and therefore will not be implemented, except where necessary to eliminate an immediate hazard to a participant or participants as an Urgent Safety Measure (USM).

Protocol non-compliance (deviations, violations) must be reported to the Chief Investigator at c.burton@keele.ac.uk and will be recorded and monitored by the research team and escalated to the Sponsor in accordance with their requirements.

Deviations and violations are non-compliance events discovered after the event has occurred.

6.7.3 Serious breach requirements

A serious breach is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the study; or

(b) the scientific value of the study.

If a potential serious breach is identified by the Chief investigator, a Principal Investigator or a member of the research team or participating site, the Sponsor (research.governance@keele.ac.uk) must be notified within 24 hours. In collaboration with the CI, the Sponsor will assess the impact of the breach on the scientific value of the study, to determine whether the incident constitutes a serious breach and report to research ethics committees as necessary.

6.7.4 Study record retention

All study documentation will be kept for 10 years from the protocol defined end of research point. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the Sponsor.

6.7.5 End of research

The end of this research project is defined as 12 months after the last participant interview.

The end of the research will be reported to the REC and Sponsor within 90 days, or 15 days if the study is terminated prematurely. The Chief Investigator (or their delegate) will inform participants of the premature study closure and ensure that the appropriate follow up is arranged for all participants involved. The end of study notification will be reported to the Sponsor via email to research.governance@keele.ac.uk.

A Final Summary Report of the study will be provided to the REC within 1 year of the end of the research.

6.7.6 Insurance and indemnity

The Sponsor is responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and research staff.

The following arrangements are in place to fulfil the Sponsor's responsibilities:

- The Protocol has been designed by the Chief Investigator and researchers employed by the Sponsor and collaborators. The University has insurance in place for negligent harm caused by poor protocol design by the Chief Investigator and researchers employed by the University.
- Sites participating in the study will be liable for clinical negligence and other negligent harm to individuals taking part in the study and covered by the duty of care owed to them by the

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sites concerned. The Sponsor requires individual sites participating in the study to arrange for their own insurance or indemnity in respect of these liabilities.

- Sites which are part of the United Kingdom's National Health Service will have the benefit of NHS Indemnity. Agreements between the Sponsor and participating NHS organisations detailing study conduct and the responsibilities to be honoured by each party will be fully executed before the study can start at the any participating site.

7 WORK PACKAGE 4

Work Package 4 encompasses the co-design of outputs generated from the findings of WP 1-3. Given WP 4 is focused on dissemination and accelerating impact, as opposed to generating new research, ethical permissions will not be required, however our interactions will be carried out ethically.

7.1 AIMS & OBJECTIVES

The aim of this WP is to co-design recommendations and resources, as described in Section 10.1.2, to support best use of A&G in reducing compound pressures, whilst providing high quality care, and addressing any identified health inequalities.

The objective of WP4 will bring together research findings from WP1, WP2 and WP3 in conjunction with our Stakeholder group and our study PPIE groups.

7.2 APPROACH

WP4 will involve a series of community conversations with groups within seldom heard communities, which will take place over the life course of the study. We will take our research findings out to these community groups and work together with our media producers to co-develop outputs that are widely accessible to patients, clinicians, commissioners and policy makers.

8 STUDY WITHIN A PROJECT (SWAP) – MULTIPLE LONG-TERM CONDTIONS

This SWAP will be carried out within existing approvals and will not require additional permissions.

8.1 AIMS, OBJECTIVES & RATIONALE

Multiple long-term conditions (MLTCs) refers to the co-existence of two or more chronic conditions (mental or physical) and is often used synonymously with the term ‘multi-morbidity.’ MLTCs are associated with poorer quality of life and higher mortality when compared to the general population. The number of people with MLTCs is increasing, with more than one in four adults in England living with two or more conditions. The National Institute for Health and Care Excellence suggests that as the complexity and impact of MLTCs increase with time, so does the need for management strategies that take MLTCs into account, which includes decisions to refer for specialist advice from secondary care. Our Study Within a Project (SWAP) will seek to address the following:

SWAPa. Describe how the process of A&G accounts for MLTCs

SWAPb. Measure the impact of MLTCs on the outcomes of referral decisions

8.2 APPROACH

The SWAP objectives will be answered through WP1b, WP2, and WP3 using EHR data and qualitative data. The presence of MLTC will be used as a covariate in analyses for WP2. As such, the SNOMED codes reflecting MLTC will be derived from previous / current work being undertaken by the Keele EHR group. We will include mental health and learning disabilities as part of this data

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as requested by our PPIE group. Our planned interviews with patients, PCC, SCS, and commissioners will include an item in the topic guide that explores the impact of the presence of MLTC on the decision to refer through particular pathways, including specifically mental health and learning disabilities. Topics that may arise during the interviews include how MLTCs influence decisions to make a direct referral rather than using A&G, how the presence of MLTC impact upon the A&G provided by SCSs, and how patients feel about the use of A&G for patients with complex MLTC.

For the quantitative work, data will be applied for in the same application as WP2 as part of the same data cut. For the qualitative work, an item in the topic guide will cover MLTCs, with evolution of the specific aspects according to emerging findings. Outputs and dissemination will be integral to those described for the main study above. Where possible, we will start to publish outputs specifically relating to MLTCs towards the end of WP2 and WP3 to enable guidance relating to MLTC more generally to include the BADGER study findings.

9 PATIENT AND PUBLIC INVOLVEMENT

9.1 INVOLVEMENT TO DATE

Patient and Public Involvement (PPIE) has been integral to the development of this study. First, a PPIE meeting ahead of application was held. This meeting allowed public contributors to share their thoughts about A&G generally and advise the team about topics from a patient perspective that would need to be taken into account in the evaluation. The group were unfamiliar with the process and felt that patients lacked input into the pathway. Concerns were raised about clinical decisions being made by specialists based only on what their GP had written, without full access to their practice record. This highlighted the need for research into the quality and safety of the process.

Second, our team includes a PPIE co-applicant. JH has attended meetings with the research team ahead of application submission and provided input into discussion related to all study design issues. His insights into the concerns about patients being detached and even removed from the process, have been invaluable.

Third, we held two PPIE meetings between stage 1 and stage 2 applications. The first meeting was with our local Keele PPIE group. This meeting focused on the CPRD part of the study. The second meeting was a regional meeting with 16 members of the NIHR ARC West Midlands Patient Advisory Committee with a focus on dissemination plans and inclusivity.

In each meeting we discussed recent experiences of the referral processes in the NHS and considered how recent changes in the way patients can access their health care data may impact on experiences across the healthcare system.

Additional considerations that have been raised by our PPIE groups included: whether A&G can be used in the mental health sector and whether mental health conditions and learning disabilities can and should be considered during the use of A&G. PPIE members voiced concern about the process of A&G, questioning if it was worked into clinician's job plans or completed on an unfunded ad hoc basis and furthermore, how an increase in requests at scale might impact on capacity and other clinical activities and responsibilities. Members enquired if safeguards were in place to ensure queries were answered in secondary care and picked back up by clinicians in primary care. This will be considered in our qualitative and stakeholder work. In addition to SLE and MND, further potential targets for tracer conditions were suggested, including women's health conditions (endometriosis) that would network well with charities working to raise awareness.

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Recommendations for patient facing outputs were also suggested including materials for Patient Participation Groups newsletters, waiting room slide shows, text message templates with links to further information / videos. It was highlighted that all materials should be culturally appropriate and easily accessible.

We have had two further meetings with the BADGER group to support development of the patient-participant study information sheet, postcard, and topic guide. Incorporated changes included colour scheme, language used and imagery in the information guide.

9.2 ACTIVE INVOLVEMENT IN THE STUDY

We will continue working closely with our PPIE group and wider public contributors, to ensure our focus remains on enhancing patient benefit within the pressured healthcare system. We believe benefit from this research is more likely if the relevance of the work is optimised, and also if lesser heard voices can input throughout to make sure findings are meaningful across different community groups.

The dedicated PPIE group will continue to advise on all aspects of the study including key findings and dissemination through regular meetings across the study period. Upon request from the Keele PPIE group, we will be sending regular written updates about study progress.

Our lay co-applicant will join our SMG meetings to contribute to the running of the study, interpretation of results and dissemination of the work at a detailed level. PPIE work will be guided by the principles set out in the UK Standards for Public Involvement. We will ensure that everyone understands what is expected and that public contributors have been able to help define their own roles. All contributors are offered support from our User Support Worker and offered payment in line with NIHR guidelines.

We will work with the Keele Impact Accelerator Unit (specifically with our Race Equality Ambassador, and our PPIE User Support Worker) who are building relationships with local under-served communities. We will embed the NIHR RDS Equality, Diversity and Inclusion Toolkit[26] best practice recommendations into all stages. Community conversations with these groups will take place throughout the course of the study and be an integral part of our dissemination and implementation work package.

The named lead for PPIE is AFN who has substantial experience of working with PPIE groups to develop and disseminate research in innovative and creative ways. AFN will be supported by RH who is also experienced in supporting PPI members' contribution throughout the research cycle.

We will continue working closely with our PPIE group and wider public contributors, to ensure our focus remains on enhancing patient benefit within the pressured healthcare system.

10 REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

10.1 DISSEMINATION PLAN

10.1.1 Overview

Ownership of the data arising from this research project resides with the research team. A Final Summary Report of the study will be provided to the REC within 1 year of the end of the study.

The full study report will be accessible on the study website hosted by Keele University. Participating individuals will not have right to publish study data outside of the Research Team. The Research

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Team will publish in accordance with the NIHR research and publications guidance. A full account of the research project will be published in the NIHR Journals Library. The NIHR will be acknowledged within publications, who will not be required to review the publication. The HSDR Programme will notified of outputs via REALMS. Publications will be published in accordance to the NIHR Open Access publication policy and under the Creative Commons attribution licence (CCBY).

We have identified key partners and influencers and will invite them to be part of the BADGER Stakeholder group. We will continue to focus on our engagement plan during each of our Stakeholder meetings, asking the same question (who needs to know about the results of BADGER, and how will they find out?) until we are satisfied that we have an extensive engagement strategy to carry us through BADGER and beyond. Our selected partners will help to formulate our outputs to ensure that they are grounded in the current NHS landscape and support dissemination of our message to their audiences.

Running alongside our Stakeholder Group, we will have our Keele PPIE group (also called our Public Advisory Group), and our community groups with whom we will work with in collaboration with the Keele IAU (referred to as Community Conversations). We plan to have quarterly meetings with our Keele PPIE group throughout BADGER to ensure that our work remains relevant to patients throughout. We intend to work with our community groups through the Keele IAU from the beginning of BADGER and hope that early engagement will support effective partnership working and the development of further community links through which we can share our findings as BADGER progresses.

We will notify participants of the outcome of the study, through making publications available on our website and through our co-produced outputs, to be determined by our engagement work (for examples, newsletters, social media outputs). These will be produced over the course of the study period and finalised after publication of the Final Study Report.

The only data shared outside of the research team as part of the BADGER project will be anonymised quotes from interviews published in research outputs. Participants will be informed about this prior to participation and will give consent to this before the interview.

10.1.2 Planned outputs

Sharing our understanding how A&G works for who, where, and why, and our resulting resources will be delivered throughout the project. Essential components of our outputs include highlighting ‘quick wins’ to enable rapid uptake to ease compound pressures, focus on health inequalities, fostering sustainable healthcare and adoption of future IT innovations. Outputs will enable optimization of the established A&G system, delivering practical, real-world solutions to primary care, specialist services and overarching Integrate Care Boards, patients and policy makers in how to make use of the system in a safe, effective, and efficient manner to reduce compound pressures on the NHS. By WP, our outputs are as described:

WP1:

The first output will be a guide for patients that describes the referral process across the primary-secondary care interface, including an explanation of the A&G pathway. This will be co-produced in conjunction with our PPIE (including community groups) and Stakeholder groups from the beginning of the study with the aim of releasing this by the end of month 3. We plan to use the processes involved in developing the guide to engage our community groups at a beginning of the project so that we can work together across the whole study to co-produce outputs along the way, rather than at the end of the project. We will use the resulting guide as a basis for our interviews both in the study information pack and as a prompt during our interviews with patients. The referral guide will be produced in several languages, and we will also produce adapted versions of study documents, for example audio recordings of the documents or ‘easy-read’ versions made with simple language and

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pictorial representations, to increase accessibility for people who may otherwise struggle to engage with the study documents. These guides will be made available for practices to use on their websites, social media, waiting room notice boards and patient participation group newsletters.

By month 12, we intend to release a report detailing the mapping exercise, based on WP1a. The information contained in this report will support ongoing ICB work around A&G whilst our practical guidance is awaited. The report will be shared through social media, our links with policy makers, the Department of Health and Social Care (DHSC), and commissioners alongside traditional means of publication.

WP2 and WP3:

Associations between A&G and quality and use of healthcare will be shared through peer-reviewed journals, conferences, and communication with policy makers and commissioners.

WP4:

Resource development will be delivered in three parts:

i) A&G toolkit for ICBs to disseminate and use across their primary-secondary care interface. This may include resources such as templates that can be used to capture and frame information pertinent to the A&G request and response and make recommendations of how best to involve patients in these conversations about them. We will also produce materials for practices that they can use on their websites, social media, waiting room notice boards and patient participation group newsletters. We will also write a series of text templates that can be adapted and used to link to our materials and update patients with the progress of their episode of A&G. Our resources for clinicians and commissioners will be developed in conjunction with our Stakeholder group.

ii) resources for patients to use. This may include written and multi-media materials explaining what A&G is, how it is being used in their healthcare journey and what they might expect as an outcome. All of our resources for patients will be co-produced with our PPIE groups and through our community conversations. We will also be working with our media producers (Keele media students who we have successfully collaborated with on an NIHR-funded study to produce a suite of health resources for children, young people and their families).

iii) a Policy Brief. Using guidance produced by the NIHR Policy Research Unit (PRU) (“Research engagement with policy makers: a practical guide to writing policy briefs”) we will produce an evidence-focussed Policy Brief that can be used to drive our recommendations through on a national level.

10.2 AUTHORSHIP

Authorship will be available to those who fulfil the International Committee of Medical Journal Editors (ICMJE) criteria. No-one who fulfils the ICMJE criteria should be excluded from authorship credit and, of equal importance, no-one who fails to fulfil the four criteria should receive authorship credit. This includes academic staff and students as well as research managers, administrative, informatics, IT and nursing staff, and patient/public representatives where they fulfil all four criteria above. However, individuals have the right to choose not to be an author on a particular paper.

Staff heavily involved in the practicalities of study operationalisation and delivery, including dedicated research co-ordinators, will be considered for co-authorship of protocol papers on the condition they can contribute to critical revision of drafts, approve the final version, and be accountable for the content.

There is no intention to use professional writers.

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12 APPENDIX 1 AMENDMENT HISTORY

Amendment No.	Protocol Version	Protocol Version Date	Brief details of changes

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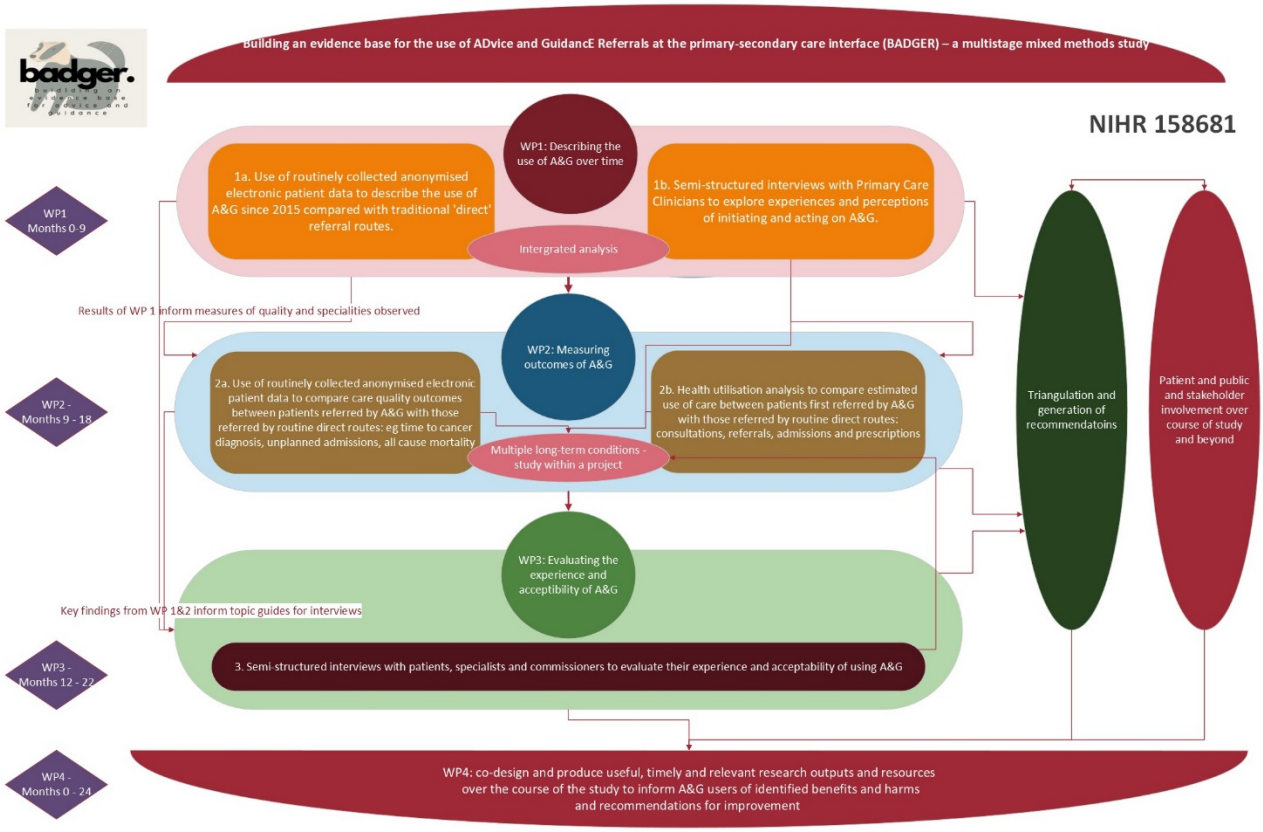
13 APPENDIX 2: STUDY SCHEMATIC



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