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FULL TITLE OF THE STUDY

Understanding inequalities in cancer diagnostic outcomes for people with Learning Disabilities

SHORT TITLE / ACRONYM

CancerLearn

PROTOCOL VERSION NUMBER AND DATE

v1.0, 01/03/2025

KEY CONTACTS

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This protocol has ethical approvals for work packages 2 and 3 as follows (work packages 1 and 4 do not require ethical approval):

RESEARCH REFERENCE NUMBERS

Clinical Practice Research Datalink	WP2: CPRD protocol 24_004304
IRAS Number	WP3: IRAS 334113 (under review, expected by end of June 2025)
Research Registry	researchregistry11137 https://www.researchregistry.com/browse-the-registry#home/
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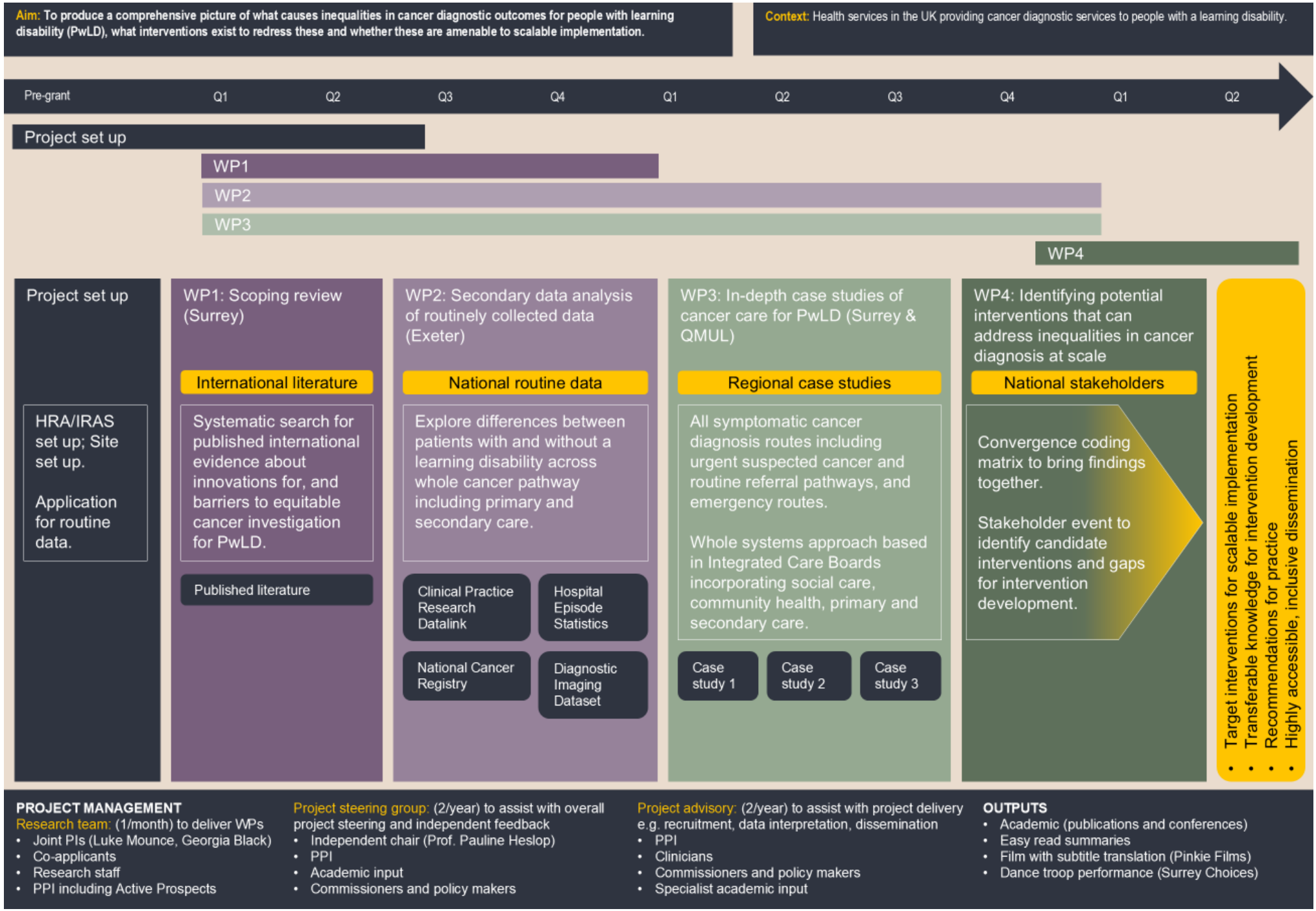
VERSION HISTORY

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
0	1.0	01/03/2025	N/A	N/A

STUDY FLOWCHART


Aim: To produce a comprehensive picture of what causes inequalities in cancer diagnostic outcomes for people with learning disability (PwLD), what interventions exist to redress these and whether these are amenable to scalable implementation.
Context: Health services in the UK providing cancer diagnostic services to people with a learning disability.
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Q1
Q2
Q3
Q4
Q1
Q2
Q3
Q4
Q1
Q2
Project set up
WP1
WP2
WP3
WP4
Project set up
HRA/IRAS set up; Site set up.
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Stakeholder event to identify candidate interventions and gaps for intervention development.
Target interventions for scalable implementation
Transferable knowledge for intervention development
Recommendations for practice
Highly accessible, inclusive dissemination
PROJECT MANAGEMENT
Research team: (1/month) to deliver WPs
Joint PIs (Luke Mounce, Georgia Black)
Co-applicants
Research staff
PPI including Active Prospects
Project steering group: (2/year) to assist with overall project steering and independent feedback
Independent chair (Prof. Pauline Heslop)
PPI
Academic input
Commissioners and policy makers
Project advisory: (2/year) to assist with project delivery e.g. recruitment, data interpretation, dissemination
PPI
Clinicians
Commissioners and policy makers
Specialist academic input
OUTPUTS
Academic (publications and conferences)
Easy read summaries
Film with subtitle translation (Pinkie Films)
Dance troop performance (Surrey Choices)

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SUMMARY OF THE RESEARCH

Scientific abstract

We will conduct the first study addressing inequalities in cancer diagnostic outcomes for people with learning disabilities (PwLD) across both primary- and secondary care, encompassing patients' living circumstances and support networks. Our goal is to identify existing scalable solutions as well as gaps in provision, underpinned by analyses that identify the main drivers of inequality for PwLD. The study has the potential to have a profound impact on cancer diagnostic outcomes for PwLD in England and other UK nations. We further anticipate that our findings will be applicable beyond cancer pathways to improve healthcare equality for PwLD more generally.

We propose four complementary work packages (WPs) following a mixed-methods design.

- **WP1**: A scoping review for published international evidence about interventions to support symptomatic cancer diagnostic pathways for PwLD.
- **WP2**: Quantitative analysis of large, linked routinely collected electronic health records from primary care, secondary care and the national cancer registry. This work will explore the interactions of PwLD with the healthcare system in the cancer diagnostic process, from presenting symptoms, investigations and referrals ordered, to diagnosis. It will highlight avoidable delays in stages of the process and cancer features that are currently unrecognised for PwLD.
- **WP3**: In-depth multi-site case studies to understand current practice and identify innovations to improve symptomatic cancer investigation for PwLD. We will gather data across the health and social care system, including interviews with patients, carers, support groups, and professional staff working across systems that contribute to cancer diagnosis (e.g. community link work, social care, primary care, diagnostic teams and integrated care boards).
- **WP4**: Cross work package data synthesis and triangulation, stakeholder engagement and dissemination. This WP will combine learning from the WPs 1-3 via a structured 'convergence coding matrix'[1] to identify innovations and extract their 'key ingredients', consider potential implementation and evaluation at scale, and highlight gaps in innovations for future research. It will include a dedicated stakeholder dissemination event.

Our dissemination strategy targets a wide range of stakeholders including; PwLD, support groups, Cancer Alliances, Integrated Care Systems, health and social care staff, and academics. We will work with people with lived experience to create a range of accessible outputs as well as clinically-relevant content. We will leverage national charity and healthcare networks to reach patients, NHS organisations, and social care providers. We aim to integrate our findings into healthcare practices and guidelines around improving healthcare for people with learning disabilities, maximising impact on patient outcomes and healthcare delivery.

Plain English Summary

Aim: To understand why there are delays in diagnosing cancer in people with learning disabilities and make recommendations for how this could be improved.

Background: People with learning disabilities are not diagnosed with cancer as quickly as people without learning disabilities. This means that by the time they are diagnosed their cancer is more advanced and harder to treat. We do not have a lot of information about what happens when people with learning disabilities have cancer-related symptoms, or what can support a timely diagnosis.

Design and methods: We have designed this research with experts by profession - academics and health care professionals specialising in cancer and/or learning disabilities - and experts by experience - people with learning disabilities, some who have experience of cancer diagnosis. Together, we have designed four linked work packages that will help us to understand why there are delays diagnosing cancer in people with learning disabilities and to identify interventions that support a timely diagnosis. We will:

1. Search all existing evidence of interventions that could support timely diagnosis of cancer for people with learning disabilities;

2. Analyse a large dataset drawing on patient's GP, hospital and cancer records (with people's names and personal details removed) to highlight where there are avoidable delays within the health system in the diagnosis of cancer for people with learning disabilities;

3. Observe and explore (through interviews) the experiences of people in three places in England to understand what prevents or helps a timely diagnosis of cancer for people with learning disabilities. We will observe and/or interview people with learning disabilities and those people who support them to find out if they have cancer, for example their family, carers, doctors and nurses, people from local healthcare and social care organisations and charity workers.

4. Feedback our results to key stakeholders (including people with learning disabilities) and work together to make recommendations for action to improve cancer diagnosis for people with learning disabilities across England.

Public and patient involvement: Our research team includes two patient representatives and an experienced co-production manager who supports people with learning disabilities to contribute to research. She will lead public and patient engagement and has already identified people with lived experience to advise our research. We will make provision to ensure activities are accessible to people with learning disabilities. They will continue to challenge and shape the work packages from design to dissemination, through regular engagement.

Dissemination: Our plans to share findings are strengthened by a member of our research team who has lived experience, a man with learning disabilities who has experience of cancer diagnosis. He has received a British Empire Medal for his influence and commitment to improving the lives of people with learning disabilities. Benefitting from his connections and passion, we will deliver a stakeholder event as well as creative and effective summaries of our findings in a range of accessible formats (film, easy read, audio) in addition to academic papers and conference presentations. In preparation for this, we have already developed relationships with national learning disability and cancer policymakers and networks, professional colleges, charities, and a medical education provider.

BACKGROUND AND RATIONALE

There are around 1.5 million people with learning disabilities (PwLD) in the UK, with an estimated 75% of such diagnoses missing from GP registers.[2,3] The term 'learning disabilities' covers varying degrees of intellectual impairment, and diverse support needs, but is defined by a lifelong reduced intellectual ability and difficulty with everyday activities.[4]

What is already known

PwLD experience health inequalities;[5–10] the patient-related reasons for this are multifactorial and intersectional, including severity of communication impairments, levels of regular contact with healthcare professionals, level of caregiver support, and other social determinants of health.[11–15] Healthcare systems also affect outcomes for PwLD, for reasons including lack of access, ableism and discrimination, poor staff attitudes, lack of awareness or recognition of LD needs, and diagnostic overshadowing.[16–19]

Research that is currently underway

We found substantial evidence that PwLD are experiencing avoidable, poor outcomes related to cancer. The LeDeR programme, funded by NHS England and NHS Improvement, reports annually on deaths of PwLD in England. The 2022 report, published in November 2023, found that cancer was the second most common cause of death and accounted for 15.7% of avoidable deaths.[20] Our own research has shown that PwLD have worse cancer diagnostic outcomes and disease outcomes than people without a learning disability (see below). Primary care is a crucial gateway for the ~40% of cancers diagnosed through an urgent suspected cancer referral,[21] and PwLD experience inequalities in primary care due to lack of healthcare provider training and knowledge/awareness, poor communication and unrecognised morbidity.[22] Ethnographic and survey studies have shown that access to healthcare for PwLD is often dependent on support from social care and advocates, which can lead to delays.[23,24] Carers have been

shown to have some knowledge regarding cancer, but are not clear on supporting symptomatic detection of cancer for PwLD.[25,26]

Research to date has mainly focussed on improving access to screening for PwLD rather than symptomatic detection, however, only 6.2% of cancers are detected through screening in the UK.[27] Some screening-specific interventions for PwLD have been developed e.g. screening liaison nurses, and accessible visits for patients to familiarise themselves with surroundings.[28,29] There is a gap in interventions designed to improve the speed and quality of symptomatic cancer pathways for PwLD.

Building on our existing research

The Spotting Cancer Among Comorbidities (SPOCC) Programme, led by Exeter, is a £1.8million NIHR Programme Grant for Applied Research (NIHR201070) exploring how patients' pre-existing conditions impact the cancer diagnostic process. Initial findings (publications pending), drawn from linked electronic medical records from approximately 288,000 cancer cases, reveal that PwLD had the worst cancer diagnostic outcomes, being; 42% more likely to be diagnosed with advanced stage, 2.6 times more likely to be diagnosed via an emergency presentation and 3.7 times more likely to die within 30 days of diagnosis. This is starkly in contrast to the overall finding that increasing morbidity conferred a benefit in diagnostic outcomes. SPOCC includes an intervention development component, though this will not focus on PwLD, as properly exploring how best to reduce inequalities for PwLD in the cancer diagnostic process needs specific additional resources and research skills including health psychology, implementation research and specialist clinical knowledge, and significant engagement with stakeholders relating to learning disability. This application has been designed to meet this need.

Additionally, we conducted pilot analyses for this application on a separate dataset exploring use of urgent suspected cancer referrals following presentation to primary care with 'alarm' symptoms.[30] PwLD were less than half as likely to be referred (odds ratio 0.430; 95% confidence interval 0.385 to 0.482, $p<0.001$). A thorough investigation is warranted and will be conducted in this project

This work also builds on findings from a recent scoping review by members of the applicant team about awareness of cancer risk-factors and symptoms among PwLD, their carers and healthcare practitioners.[31] The review found that awareness is very low among PwLD and their wider support network. Additionally, we found that paid carers and healthcare professionals were unsure of their role in facilitating cancer awareness, due to a lack of professional guidance and strategy in relation to cancer symptom awareness and risk-management for PwLD.

The clear indication from these findings is that more could be done to detect cancer early and use expedited referral pathways for patients with LD. The proposed study will allow us to make recommendations as to how this could be achieved, by identifying innovations that redress inequalities in the diagnostic pathway, and contextual factors required to implement these at scale.

Evidence explaining why this research is needed now

Improving cancer outcomes, and healthcare access and outcomes for PwLD is a key goal of the NHS Long Term Plan,[8] with ambitious targets of 75% uptake of annual health checks for PwLD and 75% of cancers diagnosed at stages I-II, and similar policies in the devolved nations.[32,33] PwLD are a priority group in NHS England's recent Core20PLUS5 approach to tackling healthcare inequalities.[34] The recent Health and Social Care Act 2022[35] also introduced new Learning Disability Improvement Standards following recommendations from the Learning Disability Mortality Review Programme, a landmark commissioned review to improve the standard and quality of care for PwLD.[7,36] Integrated Care Systems (ICSs) are now responsible for undertaking reviews of health and social care received by PwLD who have died.[10]

This study meets several targeted NIHR interests around primary care and LD, including: 23/77 National Learning Disability and Autism Programme Demand Signalling, as well as meeting James Lind Alliance priorities (23/20 NIHR James Lind Alliance Priority Setting Partnerships rolling call (PHR Programme)) for Patient Safety in Primary Care which highlights vulnerable patients as a top priority.

Research in this area is severely lacking, particularly with respect to evidence-based innovations that support symptomatic diagnosis of cancer through primary care or emergency presentations for PwLD.[18]

It is clear from the SPOCC Programme (see above) that there are profound inequalities in cancer diagnostic outcomes for PwLD.

Aims and research questions

Aim: To produce a comprehensive picture of what causes inequalities in cancer diagnostic outcomes for PwLD, what innovations exist to redress these in the symptomatic cancer pathway and whether these are amenable to scalable implementation.

Research questions (RQs):

RQ1: What are the main personal, social and organisational factors that contribute to inequalities in cancer diagnostic outcomes for PwLD?

RQ2: What is the current evidence for interventions to support symptomatic cancer diagnostic pathways for PwLD?

RQ3: Where in the diagnostic process are avoidable delays occurring for PwLD?

RQ4: What features of cancer do PwLD tend to present with and are they reliably acted on with referrals and investigations?

RQ5: How are symptomatic cancer diagnostic pathways and innovations for PwLD currently experienced by patients and carers, healthcare staff, social care, system leaders and charities?

RQ6: How does local context affect implementation of innovations to redress inequalities in cancer diagnostic outcomes for PwLD?

RQ7: What are the acceptable and feasible possibilities for tailoring existing innovations or designing new innovations to redress inequalities in symptomatic cancer diagnostic pathways for PwLD at scale?

RESEARCH PLAN

Four work packages (WPs) address our research questions. These have been co-designed in collaboration with a group of eight PwLD, organised by Active Prospects (a third sector organisation supporting PwLD) and two PPI co-applicants; one with lived experience of learning disability and one with lived experience of cancer. We will refer to this consultation as our ‘PPI work’ throughout the project plan.

Design and theoretical/conceptual framework

We will use a concurrent quasi mixed method multi-strand design for our study.[37] We will use a collaborative team approach in which quantitative and qualitative researchers contribute to the evolving research design and delivery, with defined milestones where the quantitative and qualitative WPs can be informed and enriched by interim discussion. Meta-integration will occur once the separate workstream packages have completed data collection and initial analysis.

Our project is underpinned by a principle of inclusion with respect to learning disability: we recognise that not all PwLD have a diagnosis, or have it recognised in their healthcare record. We also recognise that learning disability is highly heterogeneous. We are employing specific coding and recruitment procedures in our data collection as well as in our PPI group to enable inclusive representation as far as possible.

Our four WPs are informed by a **systems approach** to improving the diagnosis of cancer for PwLD, meaning that it includes all the interconnected components (e.g. health and social care professionals and organisations, technology, equipment, and workplace culture) that act together when a person is being investigated for cancer.[38] Improvement research designed from this viewpoint embraces the complexity and unpredictability of people’s healthcare encounters rather than trying to reduce predictable errors in one area.[38,39] We are also drawing on **Capabilities Theory** to understand how capabilities are realised or constrained by the current cancer diagnostic pathways and the barriers that PwLD face in accessing them. Capability is also related to accessibility, as a type of capability that includes both the ability to move and access valued opportunities. In cancer diagnostic pathways, accessibility depends on both opportunities to seek healthcare and the ability to overcome spatial barriers.[40]

These two theoretical approaches complement each other: Capabilities Theory emphasises the individual's agency and choice in pursuing their well-being and goals, whereas a systems approach recognises that people's behaviour can be driven by interdependent and interconnected environments (e.g. local services, availability of safe and accessible transport and so on). Our project encompasses both of these approaches by conducting research about individual experiences of care over time (shadowing), as well as exploring the multiple systems and entities that affect cancer diagnosis.

WP1 : Scoping review (co-leads Whitaker, Cox; RQ1 & RQ2)

Objective: to conduct a systematic scoping review of published international evidence about interventions with relevance to supporting equitable cancer diagnostic pathways for PwLD.

Aims and objectives:

This review aims to systematically scope innovations that could support symptomatic cancer diagnostic pathways for adults with learning disabilities in primary, secondary care, and community settings. We will focus on research which reports innovations that aim to improve symptomatic cancer diagnosis, as well as learning from research where cancer is relevant but not the main focus (e.g. innovations to support access to primary care or virtual health care for PwLD). Further, our PPI group highlighted the need to include research about support or caring roles in help-seeking, and to cover both primary and secondary care.

Methods and analysis

Protocol design

With the expansion of evidence-based healthcare as a field, and the accompanying increase in availability of primary research, novel methods of conducting reviews have occurred. The scoping review [46], sometimes referred to as a mapping or scoping study, is one such example of knowledge synthesis. According to the seminal framework developed by Arksey and O'Malley,[41] it is generally accepted that a scoping review addresses a broader topic than that of a systematic review, making it particularly suitable for advancing understanding in a relatively new or under-researched area.[42]. The aim of a scoping review is to rapidly map key concepts and detail the main sources and types of evidence available for a subject.[43] While research question/s, may be less defined, the review should be no less systematic in its approach to searching, extracting, and reporting data, with the process transparent, well-documented and replicable, thus increasing the reliability and validity of the findings.[41] As scoping reviews anticipate wide-ranging and diverse publication types on a given area, quality and risk of bias are not typically assessed. Rather, the available literature is compiled, indexed, and narratively synthesised to map the breadth of knowledge in the area. This scoping review will follow a six-stage methodological framework proposed by Arksey and O'Malley [41]: (1) identifying the research question; (2) searching for relevant studies; (3) selecting studies; (4) charting the data; (5) collating, summarising and reporting the results; and (6) consulting with stakeholders to inform or validate study findings. These stages are further clarified and enhanced by drawing from Levac et al.'s [44] recommendations, specifically in terms of balancing feasibility with breadth and comprehensiveness of the scoping process in stage two. The Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) [45] will guide the reporting of the review. Cumulatively, this scoping review guidance will ensure a rigorously conducted, transparent and trustworthy account of how research in this area has been conducted and a map of the available evidence for innovations to support equitable cancer diagnostic pathways for people with learning disabilities. To support transparency, this protocol will be registered on Protocols.io.

Stage 1: Identifying the research question

The review question was developed and categorised using the Population–Concept-Context (PCC) mnemonic recommended by the Joanna Briggs Institute (JBI) [46]:
What innovations have been developed that could support symptomatic cancer diagnostic pathways for adults with learning disabilities in primary, secondary care, and community settings?

The ‘population’ in this question is adults with learning disabilities. The ‘concept’ is innovations to support the symptomatic cancer diagnostic pathway, and the ‘context’ is broad in terms of primary or secondary care, or community, including internationally published studies since 2019.

Conducting a scoping review is often an iterative process, requiring reflexivity as familiarity with the literature progresses. As such, the research question, and sub-questions, below, are open to revisions and may be revisited and revised throughout the review:

- What innovations have been developed with the aim to improve symptomatic cancer diagnostic pathways for adults with learning disabilities?
- What innovations have been developed with the aim to improve access to healthcare for adults with learning disabilities, that may also improve symptomatic cancer diagnostic pathways?
- Where are innovations based (country/location)?
- Which cancer types do innovations support?
- What settings are innovations delivered in (primary care, secondary care, or the community)?
- Are the innovations focused on a particular subgroup of people with learning disabilities e.g. mild/moderate/severe and profound disability?
- What theory or frameworks underpin the innovations?
- Have people with learning disabilities been involved in the design of the innovations?
- What stage of development is reported: development/implementation/evaluation?
- What outcomes are proposed/employed to determine efficacy of the innovations?

Stage 2: identifying relevant studies

Databases

Scientific databases will be searched for peer-reviewed literature. The databases chosen for this review are Medline, CINAHL, PsycINFO, and Embase. Through Medline we will access peer reviewed publications in the field of medicine and life sciences. Similarly, Embase is a comprehensive biomedical database, with many records available across both, however Embase contains over 7,000,000 records which cannot be accessed via Medline.[47] PsycINFO is the largest index of psychological science, through which we will access more than 5,000,000 interdisciplinary bibliographic records across the spectrum of behavioural and social sciences.[48] CINAHL indexes the top nursing and allied health literature available, including nursing journals and publications from the National League for Nursing and the American Nurses Association.[49]

As this is an under-researched area, the search strategy will be developed to include broad terms and Medical Subject Headings (MeSH) to capture all literature. The keywords that will be used for building the search strategy are outlined in Table 1 below.

People with learning disabilities	"Intellectual Disability" (MH) OR "Developmental Disabilities"(MH) OR "Learning Disabilities"(MH) OR learning N5 disabil* (ti.ab) OR developmental N5 disabil* (ti.ab) OR Intellect* N5 impair* (ti.ab) OR Intellect* N5 disabil* (ti.ab)

Innovations	"Health Services Accessibility" (MH) OR "Quality Indicators, Health Care" (MH) OR "Quality Improvement" (MH) "Quality of Health Care" (MH) OR Access* (ti.ab) OR Equal* (ti.ab) OR Equit* (ti.ab) OR Inclusi* (ti.ab) OR Uptak* (ti.ab) OR Utilis* (ti.ab) OR Utiliz* (ti.ab) OR help-seeking (ti.ab) OR health seeking (ti.ab) OR patient-centred (ti.ab) OR patient centred* (ti.ab) OR or empower* (ti.ab) OR enable* (ti.ab) OR self-care (ti.ab) OR self care (ti.ab) OR facilitator (ti.ab) OR quality N2 health* (ti.ab) OR Quality improve* (ti.ab) OR Quality N5 indicator* (ti.ab)
Healthcare services	"Primary health care" (MH) OR "Secondary Care" (MH) OR "Community Health Services" (MH) OR "Health Services" (MH) "Health Services for Persons with Disabilities" (MH) OR “Cancer Care Facilities” (MH) OR “Oncology Service, Hospital” (MH) OR cancer (ti.ab) OR care (ti.ab) OR physical (ti.ab)
Combination	People with learning disabilities AND Innovations AND Healthcare services
Limiters	1) English language only 2) 1/1/2019 – current 3) Adult only 4) Human

Table 1: Search strategy health equity innovations for PwLD

Stage 3: study selection

Comprehensive searches of the 4 databases selected will be carried out by the lead researcher. Endnote reference management software will be used to extract search results. Initial papers will be screened, and duplicates removed. Web searching, forwards and backwards searching of reference lists will be carried out, with any additional publications added to the database. Results will be merged and exported to Rayyan software for collation, selection, and extraction. One researcher will screen all titles and abstracts according to the inclusion/exclusion criteria. Two other researchers will screen a proportion of titles and abstracts (20%) and be blinded to decisions of other researchers. Inter-rater agreement scores will be calculated and papers deemed not relevant removed. Full text for remaining papers will be sought and their contents matched to inclusion criteria, with final decisions for inclusion/exclusion made. Two reviewers will agree the final selection, with a third reviewer arbitrating any discrepancies. The selection process will be documented using a PRISMA flow chart.

Inclusion criteria

Empirical (qualitative, quantitative, mixed methods) articles will be identified and included if they meet the following criteria:

- Report the development, delivery or evaluation of innovations that that are specifically developed to ensure equitable access to healthcare and either directly or indirectly support symptomatic cancer diagnostic pathways for adults with learning disabilities, examples of which include:

    - Systems level innovations that support recognising and reporting of learning disability related needs
    - Systems level innovations that support access to healthcare for people with learning disabilities
    - Innovations to empower individuals with learning disabilities at an individual or community level to access healthcare
    - Innovations that adapt healthcare consultations to meet learning disability related needs
    - Innovations that aim to improve any of the six domains of healthcare for people with learning disabilities:
        - Patient safety
        - Effectiveness
        - Patient-centredness
        - Timeliness
        - Efficiency
        - Equity
- Report innovations with potential relevance to cancer investigations (though need not be part of the cancer pathway), we define innovation to include: novel products, interventions, services, processes, or methodologies.
- Peer-reviewed articles
- Articles published in the English language 2019 to present date (2025)

Exclusion criteria

Articles will be excluded if they meet the following criteria:

- Report innovations not specifically developed to support equitable access to healthcare for PwLD
- Report innovations exclusively focused on aspects of the healthcare pathway beyond diagnosis e.g., treatment or end of life care
- Do not report empirical research (e.g. editorials or reviews)
- Are published in languages other than English due to limited resources for translation
- Are published before 2019

Stage 4: charting the data

Data relating to the research questions will be extracted from all articles included in the scoping review, including quantitative data regarding effectiveness of interventions and participant quotes regarding acceptability (See Appendix 1 for full details). The data extracted will be summarised in a table developed and piloted by the research team. An example of the data extraction form is provided in Appendix 1. The team will follow an iterative process whereby the data charting will be reviewed, refined, and continually updated.[50] Disagreements will be resolved by discussion with the research team. Prisma flow chart will be updated and extended throughout the process to document any further exclusions.

Stage 5: synthesising and reporting results

The aim of the scoping review is to map and aggregate available evidence reporting the development, delivery, or evaluation of interventions to support symptomatic cancer diagnostic pathways for adults with learning disabilities, as opposed to critical analysis of the quality of individual studies. Data will be presented graphically in tabular form. Data extracted will be accompanied by a narrative report, relating the included articles to the research aims and questions.

Stage 6: consultation and patient and public involvement

A diverse patient and public involvement and engagement (PPIE) group has been established as part of a larger multistage research programme. Our partners have co-designed the PPIE strategy to ensure there is a robust and transparent process in place to capture and incorporate patient and public involvement throughout the research. For this scoping review, PPIE representatives (people with learning disabilities and/or their representatives) will share their concerns and priorities regarding primary/secondary healthcare access, early diagnosis, and experience of cancer care. Their involvement will inform and shape each stage of this review, which will be reported using the GRIPP2 checklist. PPIE

group members will be offered a variety of opportunities to suit their needs, this could include in-person engagement or providing input via email and/or virtual meetings.

WP2 : Secondary data analyses (co-leads Mounce, Abel; RQ3 & RQ4)

Objective: To develop and validate an expanded code list for Learning Disability. To explore PwLD's interactions with the health system in the cancer diagnostic process and highlight avoidable delays and inequalities.

This WP extends the secondary data analysis conducted in the SPOCC Programme, with improved capturing of learning disability (including subgroups), further data linkage, and detailed exploration of patients' journeys through the cancer diagnostic process. We are also including a cohort with cancer symptoms, whereas SPOCC included cancer cases only.

Data sources

We will use primary care data from the Clinical Practice Research Datalink (CPRD) Aurum dataset, which includes data from approximately 13% of the population of England, giving us a sample representative of different regions varying in socio-economic deprivation. Linkage will be obtained to Hospital Episode Statistics (HES) secondary care data, the Diagnostic Imaging Dataset (not included in SPOCC) and national cancer registry data. Learning Disability will be captured using SNOMED-CT codes (see above).

Patient population

We will obtain two cohorts: The "**Case Cohort**" will include PwLD aged 18 years or older, who were diagnosed with incident cancer between 2010 and the latest available registry data (likely to be 2020). The case cohort will be matched with two comparison groups, and one control group. For comparison group 1, patients with LD will be matched 1:5 to those without LD (but with cancer) on age at diagnosis, sex and cancer site. A second comparison group of PwLD without cancer will also be obtained, matched 1:5 on year of birth and sex. A final control group of patients without cancer or LD will be obtained, which will be matched 1:5 to the case cohort on year of birth and sex.

The "**Symptomatic Cohort**" will include all patients aged 18 years or older, presenting to a GP with a possible cancer feature between 2015 and 2019, with cancer registry follow-up to 2020 (or latest). These dates reflect the period by the current National Institute for Health and Care Excellence guidelines (NG12) [51]. All high risk (e.g. breast lump, haemoptysis, rectal bleeding, jaundice) and low risk (e.g. weight loss, fatigue, abdominal pain) cancer features for which referral to secondary care is recommended in NG12 guidelines [52], either urgent or routine, will be included.

Variables

Capturing Learning Disability in electronic health records health records

Conditions in electronic health records are identified by searching for medical codes relating to diagnoses - the contemporary coding system is called SNOMED-CT. The analyses from SPOCC used a list of learning disability SNOMED-CT codes from the Quality and Outcomes Framework (QOF) Business Rules. This list is not comprehensive, and many PwLD may not be captured. LM (Exeter), RK (Surrey) and NG (Surrey) have been collaborating on developing a broader code list, combining lists published in recent manuscripts and open repositories. When applied to the SPOCC dataset, this work in progress list increased the sample with LD by 86.8% over that found using QOF codes alone. We have budgeted time and resources to finalise and validate this larger list with input from clinicians and PPI stakeholders. These stakeholders will help define meaningful LD subgroups within the code list (e.g. by severity). This development process will not only benefit this WP but also future observational studies into LD, as we will make the code list freely available. There is potential for this new list to improve the proportion of PwLD captured on GP registers. Patients may have a coded record of LD but not be assigned to an LD register if entrance to that register is based on a narrow set of codes. Based on exploration of pilot data, we expect ample sample sizes of PwLD (see "Sample sizes" below).

Patient characteristics

Patient age at index date, gender, and smoking history will be extracted from CPRD. Age at index date is either age on the date of first presentation (symptomatic cohort) or age on the date of diagnosis (case cohort). Age will be categorised into 5-year age groups between 40 and 89 years and a 90 years and older group. A binary variable for smoking history will indicate whether patients had a record of ever having smoked. Ethnicity and patient level deprivation will be delivered by CPRD. National quintiles will be used to define the different levels of deprivation. Morbidity burden will be estimated using the Cambridge Multimorbidity Score (CMS) general outcome weighting. [53] The CMS makes use of medical and prescription codes recorded in CPRD for 37 (including cancer and LD) conditions and is weighted by primary care use, unplanned hospital admissions and mortality. For this study, we will not include cancer or LD as these are our core exposure variables. The score will be divided into tertiles for cases and controls with an estimated burden score higher than zero, resulting in four morbidity burden groups (none, low, medium, high burden).

Cancer site

Cancer diagnoses will be extracted from NCRAS. If several cancer diagnoses are recorded within the inclusion period, the earliest diagnosis date will be selected. Based on ICD-10 codes (C00-C97 and D05.1, but not C44), 25 common cancer sites will be identified, with remaining cancers assigned to an “other” category. For the case cohort, the date of patients’ first cancer record will be used as their index date.

Possible cancer features

Features listed in the NICE NG12 guidelines for urgent suspected cancer referral will be extracted from CPRD using pre-existing codelists. No codelists exist for presenting features for brain cancer (sub-acute loss of central neurological function), or remaining cancers classed as “other” as these are difficult to define. The date of a first presentation with a feature of possible cancer will be used as the index date for the symptomatic cohort.

Emergency route to diagnosis

The route to diagnosis will be extracted from NCRAS. Route to diagnosis information includes emergency presentation, among others. [54] Emergency presentation route to diagnosis includes emergency referral, transfer, admission, or attendance to or within secondary care. We will derive a binary indicator variable for emergency route to diagnosis from this variable. The indicator variable for whether or not a cancer was diagnosed as an emergency will be supplemented using HES Accident and Emergency data.

Intervals

The primary care interval will be defined as the number of days from a patient’s first presentation with a feature of possible cancer in primary care to their referral to see a specialist in secondary care. The diagnostic interval includes the number of days from when a patient presented to a GP with a feature of possible cancer to their diagnosis date. We will only include records of presentations with possible cancer features within one year of diagnosis, as features occurring more than a year before diagnosis are likely not due to cancer.

The secondary care appointment interval will be defined as the days between a referral and the first specialist appointment in secondary care relevant to the cancer site patients were diagnosed with. The secondary care diagnostic interval is the number of days from the first appointment with a specialist in secondary care relevant to the cancer site to the date of the cancer diagnosis. An existing codelist for whether a specialty could be relevant for a specific cancer type will be used.

Primary care referral and investigations

Primary care referral after presentation with a possible cancer feature will be taken from HES, and will include routine, two-week wait and urgent referral. Investigations ordered after a presentation with a possible cancer feature will also be extracted from HES. We will include records for colonoscopies, sigmoidoscopies, gastro-intestinal endoscopies, chest x-rays, abdominal ultrasounds and abdominal CT scans

Data analysis

All inferential models will cluster patients by general practice, either as a random effect (multilevel models) or using clustered standard errors.

Case Cohort

We will describe the interactions of PwLD with the health system through the cancer diagnostic process. Diagnostic timeliness will be examined using two approaches:

1) Methodology pioneered by GA, LM and BW [55] and used in multiple recent studies [56–58] will examine 'diagnostic windows'; i.e. the length of the interval in which cancers are potentially detectable and opportunities for earlier diagnosis. Patients with LD and a cancer diagnosis will be matched on age and gender to patients with LD, but without a record of a cancer diagnosis in NCRAS, and patients without LD or cancer. A mixed-effect negative binomial regression model with face-to-face and telephone consultation rates with a GP as dependent variable will compare patients with LD and a cancer diagnosis, and patients with LD, but without a cancer diagnosis to determine the timing of a significant increase in consultation rates which may be due to cancer. We will also run a mixed-effect negative binomial regression model for patients with LD and a cancer diagnosis, using patients without LD or cancer to control for baseline trend in consultation rates. Analyses will include the number of consultation days per month, a number of months before diagnosis variable (28-day aggregation), a grouping variable indicating cases or comparison group/controls, a relative time variable set at 0 for comparison group/ controls, and for cases a value created by subtracting an amount equal to the number of the period being tested from the month before diagnosis.

2) Accelerated failure time models will compare whether PwLD with a record of a cancer diagnosis in NCRAS experience longer waits between: presentation and referral, referral and specialist appointment, specialist appointment and diagnosis, and presentation and diagnosis compared to patients who were also diagnosed with cancer, but did not have a record of having LD in CPRD. By looking at these separate intervals, these models will further indicate at which step in the pathway delays are occurring. The accelerated failure time models will take into account age, gender, morbidity burden, deprivation, smoking history, ethnicity and year of diagnosis. The specifics of the models used will be guided by the data to decide the most appropriate technique. Generalised Linear Models with a log-link function and flexible parametric survival models being two examples of techniques we have used before. [59]

By looking at these separate intervals, these models will further indicate at which step in the pathway delays are occurring.

We will work back from diagnosis in those diagnosed via an emergency route to describe patients' interactions with primary and secondary care. We will examine whether PwLD presented with relevant symptoms in primary care, or attended investigations or consultations with relevant specialties in secondary care before their emergency presentation. We will study what type of possible cancer features these patients presented with, and whether the GP took any actions (investigations, referrals) related to these features. Multilevel logistic regression will be used to explore the association of patient characteristics (age, sex, ethnicity, smoking history, deprivation, whether presented in primary care, LD subgroup) with odds of an emergency presentation route to diagnosis. Further exploration of patients' interactions with the healthcare system based on emergent findings from WP3 will be made.

Survival

We will use parametric time-to-event models in the same way as described for the intervals analyses above, with the technique used being guided by the data. Follow-up time will be censored at the earliest of; end of registration, practice's last collection date or end of data coverage.

Symptomatic Cohort

We will descriptively explore the recorded cancer features, ordered investigations and referrals made for people with and without LD. We will use multilevel logistic regression to explore whether PwLD are less likely to receive their recommended diagnostic activity (referral, investigations) and how this differs by patient characteristics, including presenting feature, age, gender, ethnicity, deprivation and morbidity.

These analyses may indicate that certain features are less likely to be acted on for PwLD, suggesting possible avenues for intervention. The incidence of cancer in this group, and how it varies by patient characteristics, will be explored using multilevel logistic regression. Further exploration of patients' interactions with the healthcare system based on emergent findings from WP3 will be made. The team at Exeter have considerable experience of all the analyses to be undertaken and these data sources, and lead in such studies.[30,60–62]

Sample sizes

The SPOCC dataset contains all patients with CPRD records and an incident cancer between 2012-2018. 855/288,297 (0.3%) cases had LD captured by the QOF code list. Using our work in progress code list for LD, the SPOCC LD sample was increased by 86.8% to 1,597. Our pilot CPRD symptomatic cohort data, only covering two years of primary care observations and selected symptoms, contains 1,810,990 patients of whom 9,519 (0.5%) had LD using the QOF list. Our new cohorts will additionally have expanded date range coverage to increase our samples. Taking the most conservative baseline estimate of the proportion of people receiving a guideline-recommended referral after presentation with a cancer feature, i.e. 50%, at 90% power the sample size needed to detect a 5 percentage point change (i.e. to 45%) would be n=1,100 PwLD and n=22,000 without LD (prevalence of LD of 0.5%). We expect both far larger effect sizes than this, given our pilot data (see Background and Rationale), and to have ample sample sizes of PwLD in both cohorts. For the 'diagnostic window' analyses, a simulation approach demonstrated >90% power to detect a difference between inflection points in consultation rates at 9 and 6 months pre-diagnosis in those with and without learning disabilities respectively. Analyses by LD-subgroups will be performed, subject to identifying suitably large groups (dependent on definitions suggested by stakeholders).

WP3 : In-depth case studies of cancer care for PwLD (co-leads Cox, Black; RQ5 & RQ6)

Objective: to understand current practice and identify interventions to support PwLD with cancer diagnostic pathways with reference to contextual factors.

We will conduct a **multi-site case study** including observations and interviews.[63,64] Our case studies will encompass Integrated Care Boards (ICBs) including local health and social care provision, and relevant charity organisations, and all routes to a potential cancer diagnosis including emergency departments. ICBs are statutory NHS organisations responsible for planning healthcare to meet local population needs, including local service improvement based on reviews relating to deaths of PwLD. We have chosen ICBs as case study sites to capture both the breadth of organisations and totality of symptomatic routes to a potential cancer diagnosis in line with our systems approach (see Theoretical Framework).

We have selected three case study sites through preparatory collaborative work which have contrasting population demographics, geographical and organisational features.[64,65] The case study sites will form the basis of our patient and staff interview recruitment, and observations of clinical practice relating to cancer investigation for PwLD.

Focus on innovations

A key aim of this WP is to capture innovations within each case study site. We use the term "innovation" rather than "intervention" (as per WP1) specifically because an intervention denotes an action or strategy implemented to address a particular health issue, modify a behaviour, or improve health outcomes. By contrast, innovations that redress inequalities in healthcare outcomes for people with a learning disability may be developed with no particular aim or target outcome for improvement. This may include having a quiet waiting room in the radiology suite, for example, or making alternative communication tools available. Interventions that are specifically developed to improve care for people with a learning disability would be eligible for inclusion in our study. We define relevant innovations as follows:

- Innovations are defined as novel products, interventions, services, processes, or methodologies.
- Innovations included in our observations must specifically target PwLD
- These innovations must aim to ensure equitable access to healthcare with potential relevance to cancer investigations (though need not be part of the cancer pathway) for PwLD.

- Innovations must address barriers faced by individuals with learning disabilities in undergoing timely and appropriate cancer screenings or diagnostic procedures.

We will ask local collaborators to signpost local interventions that aim to improve access or quality of care for PwLD to include in our data collection. We will strategically target these interventions in our interviews and observations (see Figure 1). We take a plural approach to these innovations, which do not necessarily have to be limited to cancer care but would affect cancer pathway delivery e.g. interventions to improve access to primary care or diagnostics.

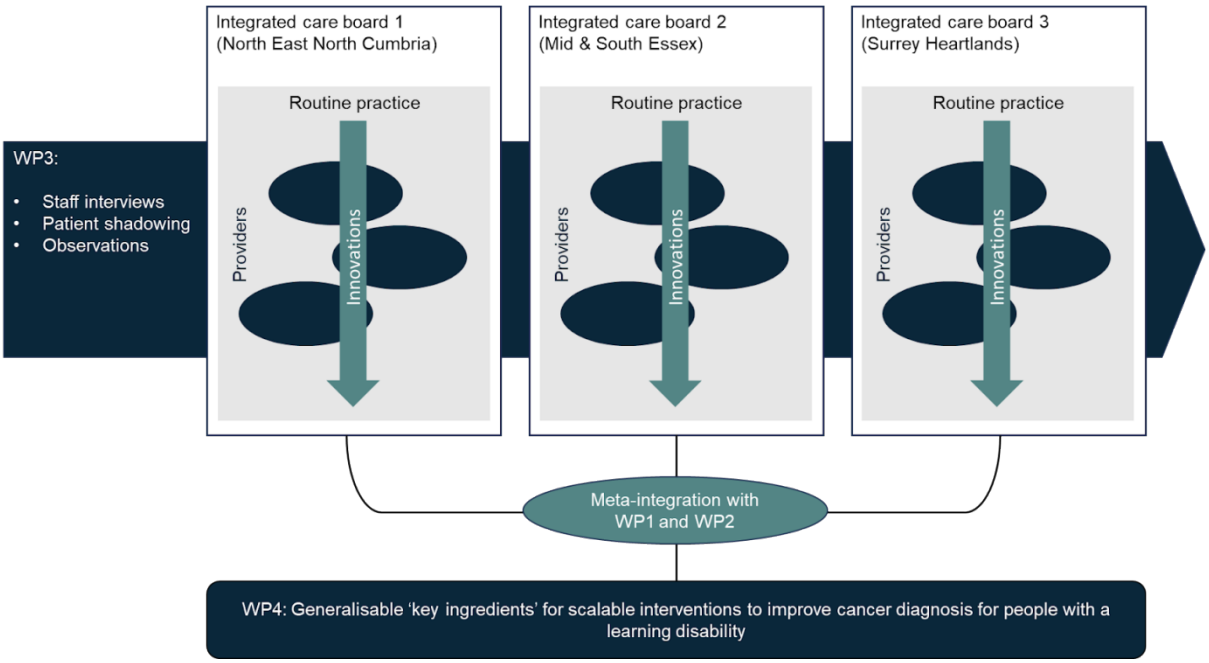


Figure 1. Case study design and data collection including integration with other WPs

Sampling

Our case study sites will include Surrey Heartlands ICB (population 1.1m), Mid and South Essex ICB (population 2.0m) and North East North Cumbria ICB (population 3.1m). These allow for demographic diversity in terms of deprivation, geographical features and population characteristics. Representatives for each site are included in the research team.

North East North Cumbria has been identified as a positive deviant case study site due to innovative cancer service improvement for PwLD.[66] For example, the region has a collaboratively-designed, reasonably adjusted care pathway for PwLD who require general anaesthetic for diagnostic imaging.[67]

Case study data collection process

Table 1 outlines the sequential process of collecting data in our case study sites. Below, each data source is discussed in turn, showing approximate recruitment numbers.

Table 1. Sequential data collection process for WP3

#	Activity	Approx N/site	Total N
1	Interviews with ICB key stakeholders (e.g. LeDeR coordinator) to identify innovations and key individuals	2	6
2	Interviews with local Learning Disability leadership figures e.g. advocacy or support work, patient involvement leads, and social or	6	18

	residential care provision		
3	Team meeting to decide on key innovations to follow at each case study site, balancing for impact on social care, primary and secondary care	3-5 meetings as needed	
4	Interview people associated with delivering innovations to understand nature of innovation and its delivery, aspirations, dependencies and resource use	6	18
5	Interview staff not associated with delivering or creating innovations (i.e. consultants, primary care professionals, radiology, care-coordinators, link workers, district nursing, specialist cancer nurses, administrators), to understand general experiences of working with PwLD	6	18
6	Observations in environments relating to innovation including document collection (2-4 observations)	~80-100hrs	
7	Interviews and follow up calls (shadowing) with patients and their families, formal and informal carers, advocates (up to 3 hours per patient)	7-10	20-30
8	Observations of care with shadowed patients (up to 5hrs per patient)	~40-60hrs	
9	Interviews with national and international experts to identify further interventions to support cancer investigation for PwLD, barriers, appreciative inquiry and targets for improvement.	n/a	5
	TOTAL interviews		Up to 95

Staff recruitment & interviews

Staff will be identified during case study observation work and through introduction by local collaborators. Staff interviews will use a semi-structured open-ended format based on questions covering:[68]

- Experiences of providing cancer-related care for PwLD
- Barriers experienced by staff in being able to provide high quality cancer care
- Experiences of inequitable care for PwLD e.g. delays, difficulty with referrals/investigations, poor communication practices
- Structural barriers for PwLD accessing cancer care (environmental, social, systems)
- Local reasonable adjustments made for PwLD (any services or interventions designed to improve care experience)

Patient recruitment

We will recruit PwLD, who are experiencing symptoms which could indicate cancer, and currently receiving investigations. We anticipate that some participants will need to be supported by people working with them (staff, family members, formal and informal carers; hereafter "*carers*") here to make the decision to participate. Our sample could include patients being investigated in primary care (e.g. through faecal immunochemical testing, chest X ray or blood tests), or secondary care, including urgent, routine or emergency pathways. All adult patients are eligible including those with Profound and Multiple, Moderate or Mild Learning Disability. Our PPI work highlighted that people might identify themselves as having a learning disability by using a sunflower lanyard, 'Just a Minute' card, by expressing it verbally, or by the fact that they have support staff with them. Our inclusion strategy incorporates ad hoc quota sampling for

diversity in symptoms experienced, age, gender, ethnicity, socioeconomic deprivation and severity of learning disability.

Patients can be recruited at any point during our case study data collection phase. Our PPI group highlighted that participants should be approached by someone known to them such as their GP or learning disability nurse. Our PPI group also advised that there should be a range of written, visual and spoken forms of information provision including an easy-read version, and consent procedures to meet a wide range of needs. Where patients do not have capacity to consent a consultee will be sought to advise on the potential participants wishes and feelings and whether they would decline to take part if they had capacity, in accordance with relevant legal frameworks and ethical principles (see Ethics section). We will use interpreting and translation to enable people to participate who do not speak English well.

Shadowing and interviews

Shadowing and interviewing will be conducted by experienced qualitative researchers with extensive experience in cancer diagnosis. Our shadowing approach will involve observing patients' subjective care experiences and the unfolding of care pathways over time within a network of health and social care settings, including primary care, blood test clinics, community diagnostic centres, and hospitals, as well as patients' residential settings where appropriate. Shadowing activities will be conducted in person, such as waiting for clinic appointments or tests, and through brief (repeated) telephone interviews to gather recent event information. This approach encompasses a wide range of patient care experiences such as expectations of care, practical considerations such as timetabling and transport, waiting and uncertainty around tests or results, access to and comprehension of information, and information transfer between different organisations. Researchers will make notes about expected 'next steps' and agree on a suitable time to re-contact the participant via telephone, text or email. Shadowing will end either when the participant requests it, or when their cancer investigations are complete.

With participants' consent, we will also extract each patient's GP referral form to see what was written about their learning disability. Our PPI work highlighted that shadowing would be acceptable as long as they had a support person with them, and could opt out of shadowing for specific procedures. The PPI group highlighted that we should capture the experience of waiting for tests or results, access to and understanding of information, and navigating reconsultation or rescheduled appointments. Specific needs highlighted included having support with them for tests, high anxiety about procedures, difficulty understanding information and potential need for sedation.

Shadowed patients/carers will participate in at least one semi-structured interview. We will offer a choice of tools to support communication, including Talking Mats, which is an Augmented and Alternative Communication tool (AAC),[69] which can enable and support self-expression, self-advocacy and relationship building, and facilitate effective communication for PwLD.[70] Open-ended biographical questions will cover their experience of symptom awareness, decision to seek help, presentation to primary care, re-consultation and referral following appropriate psychologically-informed models.[71] An accessible interview schedule will be co-designed with our PPI group using salient themes from a recent scoping review and other published literature.[31] This will be used to guide discussions with flexibility for unanticipated topics. Interviews will be digitally recorded and transcribed verbatim. Participants will be assigned a unique numerical ID to allow for their data to be anonymised.

Observations

The primary unit of our data collection is the integrated care board 'system', within which patient care for cancer investigation is planned and organised (as well as other health and social care needs). We recognise that there are policies and structures within this 'system' that are designed specifically for people with a recognised learning disability, but that our inquiry is not limited to these structures. This 'system' is conceptualised as comprising acute NHS hospital cancer diagnostic pathways around which other primary, community, rehabilitation and social care services are arranged. *Cancer investigation* is defined as recognition of symptoms (by either patients or their support teams), the decision to seek healthcare, the management and investigation of symptoms in both primary and secondary care, as well as the burdens or responsibilities of community-based health and social care to support this.

Our observations are designed to capture a range of activities characteristic of everyday practice relating either directly or indirectly to diagnostic pathways for cancer, including residential or social care provision,

patient-facing clinics, staff meetings, and administrative tasks. We will adopt an exploratory approach with the help of local collaborators in ICBs and healthcare Trusts to gain a comprehensive understanding of the environments relevant to our study. These collaborators will make formal introductions to organisations of interest; the research team will provide study information as well as offering meetings to arrange a period of observation. Our approach is designed to be flexible, with the possibility for unanticipated sites for data collection e.g. community support groups, local meetings and so on.

Observations will be conducted in-person or virtually, depending on the type of event, ethical issues, and advice from the team's case study collaborators. Data will be collected in the form of field notes, handwritten and electronically transcribed for storage and analysis by the researcher. Field notes will be unstructured and written in narrative form.

Key documents

Throughout the observation phase, our research team will collect pertinent documents such as policy documents, referral forms, business cases, and meeting minutes. This document collection will be a combination of responsive and proactive measures. Local staff members will provide some of the documents in response to our requests, while other documents will be obtained through targeted internet searches and requests for confidential document sharing. Our aim is to collect data to build a picture of local connected systems of health and social care, and how these affect cancer investigations. To understand how staff are introduced to and skilled to deliver these services, researchers will request communications and training materials (including introductory videos, information pamphlets and 'frequently asked questions', and posters).

Data analysis

Using NVivo software, interview transcripts, documents and observation notes will be analysed using thematic analysis to identify themes focussed on what increases or decreases patients' capability to access cancer investigations. Our PPI members will be involved in analysis and interpretation of data after initial coding supported by co-applicant Guest. We will employ analytic techniques that address:

- Longitudinal factors (patient shadowing to understand how patients' experiences of services evolve over time)
- Within case analysis (considering local and contextual factors that affect delivery of care for PwLD)
- Cross-case analysis (considering similarities and differences between our case studies to generate generalisable insights)

Based on our theoretical framework, we will identify key 'ingredients' in relation to innovations for PwLD in cancer pathways that support individuals to realise their capability, as well as their impact within different systems that affect the patient. For example, an intervention such as using sedation for blood testing may benefit PwLD and carers, but may increase pressure at a system level in terms of budget restraints. We will use the Capabilities Theory to identify any targets for improvement that increase (or reduce barriers to) capability for PwLD, and gaps in innovation. We will also identify targets for potential implementation at scale, and any necessary contextual conditions (e.g. specific professional groups, services or resources).

Further targets or lines of inquiry for data collection and analysis are expected to emerge from concurrent mixed methods research strategies such as monthly full team discussion (see Project Management), with defined milestones where the quantitative and qualitative WPs can be informed and enriched by interim discussion.

WP4 : Data synthesis and stakeholder feedback (Co-leads Watkin, Black, Mounce, Cox; RQ7)

Objective: this WP draws on WP1-3 to identify innovations and extract their 'key ingredients', consider potential implementation and evaluation at scale, and highlight gaps in innovations for future research.

Cross work package data synthesis

All researchers, co-applicants and advisory group members will meet regularly throughout the project to discuss emerging findings. Following the completion of WP2 and WP3, this group will convene at in-person meeting, during which quantitative and qualitative findings will be tabulated in a structured coding matrix.[1]

Meta-integration meeting to produce convergence coding matrix

This is a one-page document which summarises the main findings within data-driven categories. These are likely to include different parts of the pathway and wider system. Led by the principal investigators, meeting attendees will identify and discuss:

- Existing innovations and their components
- Factors contributing to inequalities in cancer diagnostic pathways for PwLD
- 'Key ingredients' or elements of these innovations making them effective
- Important local or contextual features contributing to the innovation
- Conflicts or discrepancies in the data
- Omissions or gaps in innovations relating to particular parts of the cancer pathway or specific barriers

The convergence coding matrix will take the form of a table which will be used to structure our stakeholder event and dissemination strategy.

Stakeholder event

We will discuss our findings at a stakeholder event with PwLD and carers, charity sector, national policy makers, clinicians, LeDeR directors, and social care representatives. The objective of the event is to use our research findings to agree on recommendations for scalable innovations, and discuss potential barriers or contextual factors to wider implementation. The presence of stakeholders in innovation roles such as Cancer Alliances, Integrated Care Boards and relevant NHS England programmes will increase opportunities for direct impact.

The event will be chaired by Scott Watkin and Georgia Black, led by the research team, with Helen Guest (PPI lead) facilitating inclusion for PwLD. Feedback from stakeholders will be incorporated into our report and future funding bids for new or existing implementation of innovations at scale, and evaluation work.

We will employ a number of techniques to facilitate inclusive, meaningful discussions that led to recommendations:

1. **Accessible communication**: we will use accessible language in all communications, providing materials in various formats (e.g., large print, audio, easy-to-read) and the use of visual aids and straightforward presentations.

2. **Pre-Event engagement**: we will conduct pre-event consultations with stakeholders, especially individuals with learning disabilities, to understand their needs and preferences. This will inform the planning process and ensure the event is tailored to be accessible and relevant.

3. **Inclusive environment**: we have identified a venue that is physically accessible and comfortable. We will consider sensory needs (e.g., quiet spaces, appropriate lighting) and provide accommodations such as sign language interpreters or support workers if needed.

4. **Facilitated discussions**: Watkin and Cox will train our research team members to act as skilled facilitators to guide discussions, ensuring that all voices are heard. Facilitators will be trained in inclusive practices and aware of the need to provide ample time for participants with learning disabilities to express their views.

5. **Interactive sessions**: we will use a mix of formats (e.g., small group discussions, and interactive activities) to cater to different communication styles and engagement levels. We will ensure that activities are accessible and provide support where necessary.

DISSEMINATION, OUTPUTS AND ANTICIPATED IMPACT

There are a number of key beneficiaries of our research who have been involved in the planning of the study, and we will continue to engage with them until the dissemination of findings. This includes PwLD, members of the public, and advocacy groups (North Cumbria Learning Disability Network, Active Prospects). We have also engaged with key dissemination channels including the Royal College of General Practitioners Special Interest Group in Learning Disabilities, NB Medical (the UK's leading provider of CPD for GPs and healthcare professionals), and the NHS England LeDeR programme team. We have engaged with Integrated Care Systems, particularly our host organisation NHS Cambridgeshire and Peterborough, but also the sites for our research (see below).

Our team includes leads for the Policy Research Unit for Cancer Awareness, Screening and Early Diagnosis (KW), close ties to the Cancer Research UK policy team (GA, KW, GBB), and membership of the Royal College of General Practitioners Special Interest Group in Learning Disabilities (KP, GBB, AC).

We have planned our dissemination according to these groups, which will be underpinned by an overall message matrix with primary findings, supporting messages or key statistics, behavioural/organisational factors and targets for improvement: Our PPI group will co-produce all dissemination materials.

What do you intend to produce from your research?

Table 2 outlines our intended outputs according to each beneficiary group, and the likely benefit of our research to them.

Table 2. Dissemination strategy

Group	Likely benefit of the research	Output
Patients and the public	• Increasing knowledge and health literacy about cancer pathways • Self-advocacy and empowerment • Resources to improve access to care	• Easy-read summaries to distribute via support groups • Video summary for inclusion on North East & Cumbria Learning Disability Network
Learning Disability support and advocacy groups	• Sharing advice • Empowering patients and carers	• Drama performance • Easy-read summaries to distribute via support groups
Primary care staff	• Local innovation/QI • Education • Potential for improved registration of learning disability	• NB Medical CPD training • Regular updates and dissemination of materials via RCGP special interest group • Public sharing of expanded, validated learning disability SNOMED-CT coding list
Cancer Alliances	• Regional QI • Pathway design	• Policy brief
Integrated Care Systems	• Recommendations for scalable innovation and improvement	• Dissemination of summary via LeDeR (Learning from lives and deaths) leads • Regular updates via advisory group attendance
NHS England	• Connecting to relevant programmes of work	• Policy brief • Regular communications through advisory

	• Potential policy influence	group membership
Academic audiences	• Methodological insight • Topic-specific interest and learning • Potential future collaboration	• Publications in peer-reviewed journals • Conference presentations • Social media feed

How will you inform and engage patients/service users, carers, NHS, social care organisations and the wider population about your work?

Our PPI members highlighted the importance of accessible, free resources as part of our outputs. They suggested that the best ways to disseminate information to patients, carers and the public was through direct contact and through local voluntary and advocacy groups. We will draw on the expertise and experience of our PPI group and co-applicant with lived experience (Watkin) to identify ways to share our video summary and easy-read materials that explain the results of the study, and ways in which people might access cancer investigations more easily.

Patient-facing materials will be developed in collaboration with our PPI team and co-applicants Frost and Watkin. These will include **easy-read summaries** of the key research messages which can be shared via email, social media and cascaded through our research team networks. We will also create a **video** which can be hosted on the North East & Cumbria Learning Disability Network **website**.

We have a number of channels through which we can disseminate our work to NHS organisations, including:

- Inclusion of our peer-reviewed publications and policy brief in the **LeDeR resource bank** (supported by collaborator Rachel Snow-Miller). This is an online repository for resources relating to healthcare for PwLD. This resource is managed and promoted by NHS England LeDeR programme.
- Presenting a **webinar** for Integrated Care Systems staff as part of the regular series hosted by the NHS England LeDeR programme.
- Inclusion in the LeDeR programme '**Action from Learning' report** which is published annually.

Through our integration into the Royal College of General Practitioners **Special Interest Group** in Learning Disabilities, we will be able to disseminate our policy brief and cascade our NB Medical training webinar to primary care practitioners and their colleagues.

We will cascade our policy brief to social care and voluntary organisations through **Integrated Care Board LeDeR and Research & Development networks**, supported by our ICS case study partners and host ICB (NHS Cambridgeshire and Peterborough). Through our advisory board's advice and network we will target appropriate health and social care conferences and meetings such as the Association of Directors of Adult Social Services (ADASS) forums.

How will your outputs enter our health and care system or society as a whole?

We have identified that our outputs will enter the health and care system through a number of mechanisms:

- Incorporation of our research evidence into national guidelines through the NHS England LeDeR programme and/or NHS Cancer Programme, and associated NHS England teams such as the Healthcare Inequalities Team (Snow-Miller is a collaborator; Black, Abel and Whitaker have existing relationships)
- Network dissemination of actionable insights through ICSs (host organisation will assist) and the RCGP Special Interest Group (Petersen, Cox and Black are members)
- Changes in practice due to training webinars (Black & Whitaker already have relationship with NB Medical and GatewayC)

What further funding or support will be required if this research is successful (e.g. From NIHR, other Government departments, charity or industry)?

This research is focussed on identifying key implementable solutions to aid the diagnosis of cancer in PwLD. Because our focus is on the examination of existing innovations being put into practice we do not envisage that the output of this work will be an innovation requiring a full-scale randomised control trial. Rather our focus is on scalable innovations, which may bear some cost for local NHS services. However, such cost will need to be reasonable such that delivery is possible.

What are the possible barriers for further research, development, adoption and implementation?

The main challenges with generating impact from this research are a) ensuring authentic engagement with PwLD (and their support networks) and b) being cognisant of constraints on an already pressurised healthcare system. To optimise impact, we are working closely with a wide array of stakeholders to address how to identify, adapt and evaluate innovations (defined as any service, policy or innovation that is intended to influence earlier cancer diagnosis for PwLD).

For example:

- *Acceptability* (how do PwLD react to the innovation?)
- *Demand* (estimated use of an innovation by PwLD)
- *Implementation* (extent and likelihood an implementation can be fully implemented as proposed in healthcare settings)
- *Practicality* (consideration of constraints, e.g. resources, time, commitment)
- *Adaptation* (e.g. changing contents/format for PwLD)
- *Integration* (system/organisational change)
- *Expansion* (applying innovations in a different population/setting)
- *Limited efficacy* (does the new idea/ innovation show promise?)

By embedding these principles across our work packages and subsequent outputs (e.g recommendations, education) we will anticipate and mitigate difficulties with generating impact.

What do you think the impact of your research will be and for whom?

The planned work will be unique in examining the journeys and experiences of PwLD through the cancer diagnosis process and will have international relevance. It is anticipated that this work will identify targets for innovation and examples of innovation which may be amenable to implementation at scale, to ultimately improve cancer diagnosis for PwLD, with findings highly likely to be applicable to a much broader health context. By undertaking the planned research we will understand the need for, and required facets of, any future innovations. Development, and evaluation of such innovations will form the basis of future funding applications to be made during the conduct of this award.

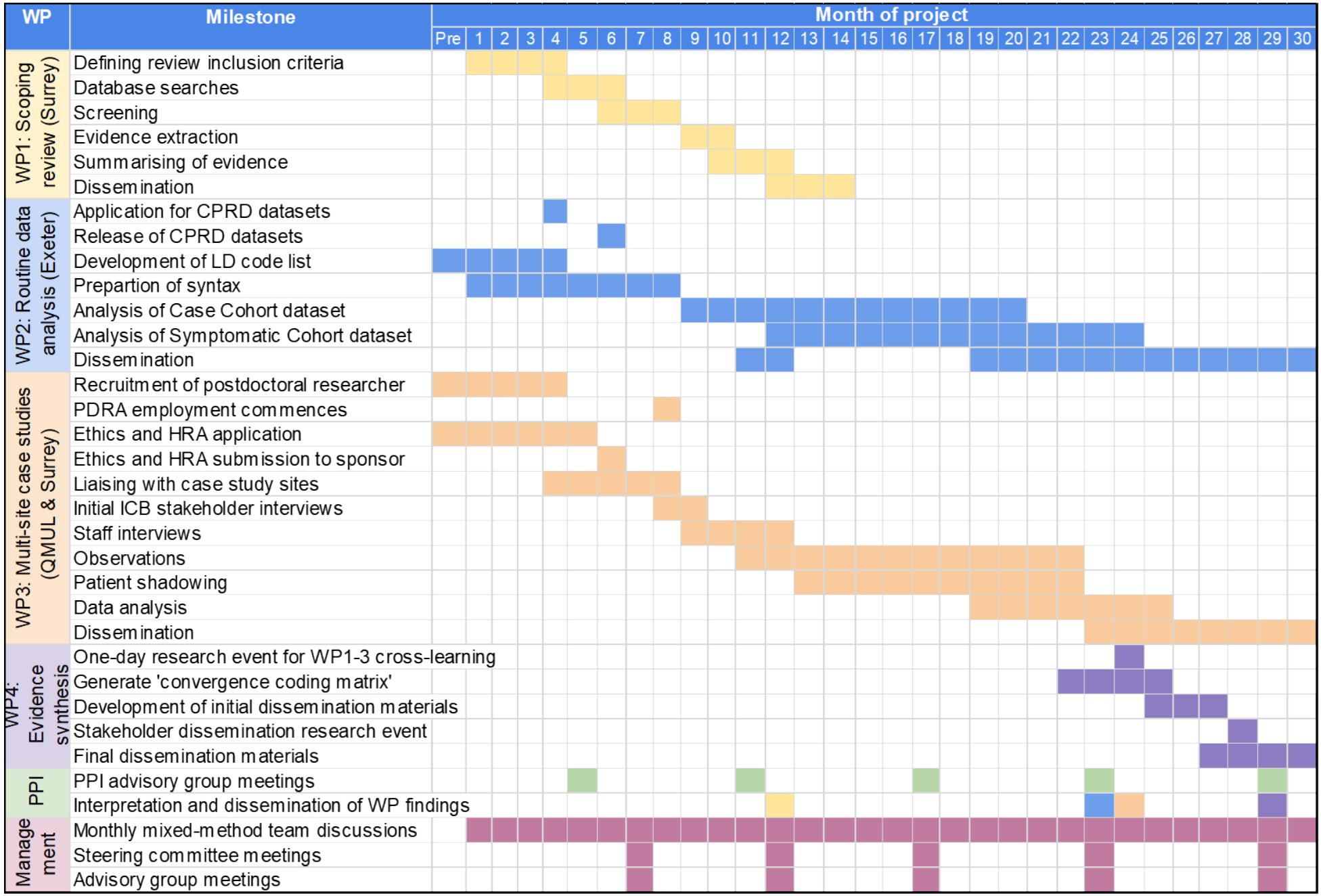
How will you share with study participants the progress and findings of your research?

Professional staff who have taken part in our study will indicate on their consent form whether they would like to be invited to our stakeholder event at the end of the study, and whether they would like to be sent dissemination materials. Representatives from each case study will attend our six monthly advisory meetings to be updated with study progress, understand key milestones and assist with overcoming barriers to research.

Patients and carers who take part will indicate their preferred method of communication e.g. post, email or telephone. The consent form will contain an item about whether they want to be sent information about the research findings. The study team will share easy-read summaries and other patient-facing outputs through these channels.

RESEARCH TIMETABLE

We set out key milestones for each Work Package, with their anticipated timings and duration, together with project management and PPI activities in the Gantt chart below.


WP
Milestone
Month of project
Pre 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
WP1: Scoping review (Surrey)
Defining review inclusion criteria
Database searches
Screening
Evidence extraction
Summarising of evidence
Dissemination
WP2: Routine data analysis (Exeter)
Application for CPRD datasets
Release of CPRD datasets
Development of LD code list
Prepartion of syntax
Analysis of Case Cohort dataset
Analysis of Symptomatic Cohort dataset
Dissemination
WP3: Multi-site case studies (QMUL & Surrey)
Recruitment of postdoctoral researcher
PDRA employment commences
Ethics and HRA application
Ethics and HRA submission to sponsor
Liaising with case study sites
Initial ICB stakeholder interviews
Staff interviews
Observations
Patient shadowing
Data analysis
Dissemination
WP4: Evidence synthesis
One-day research event for WP1-3 cross-learning
Generate 'convergence coding matrix'
Development of initial dissemination materials
Stakeholder dissemination research event
Final dissemination materials
PPI
PPI advisory group meetings
Interpretation and dissemination of WP findings
Management
Monthly mixed-method team discussions
Steering committee meetings
Advisory group meetings

PROJECT MANAGEMENT

The research will be led by Luke Mounce (LM) and Georgia Black (GBB), with substantial input from all workstream leads, co-investigators, PPI coordinator and members, and the research fellows in the team. GBB has substantial grant management experience with a total income of £7,463,002, including as Principal Investigator on five previous grants. GBB is an experienced researcher in primary and secondary care, delivering outputs on time and within budget. LM is PI on 2 grants and work package lead on a further 2 (9 grants totalling £2,958,413 funded since 2020). He has managed budgets, set milestones, completed annual and final reports and is highly regarded for his project management, earning promotion to Senior Research Fellow since the Stage 1 application. LM and GBB will meet weekly to discuss project running and assign leadership tasks. GA and LM already have an effective working relationship having worked together on numerous projects and co-lead a work package on the SPOCC programme. They will meet weekly, with GA mentoring LM in project management, budget handling and contracting, supplemented by informal contact as required. GA has completed mentorship training through the NIHR School for Primary Care research. LM will also be supported by NHS Cambridgeshire and Peterborough ICB, the contracting organisation, with whom Exeter have a longstanding (20 year), highly productive relationship.

Research team mixed-methods

The research team which includes all researchers at Exeter, QMUL and Surrey, and PPI representative Frost, will meet monthly (on average) to enable triangulation and mixed method dialogue. Most of these meetings will be virtual through Microsoft Teams, with notes and actions taken using automated software. Two of these meetings over the course of the project will be in person in line with specific milestones: (1) the interpretation of WP1 findings and WP3 set up; (2) interpretation of WP2 findings and WP4 convergence coding matrix development. Work package meetings will be held at QMUL, Exeter and Surrey including leads and research fellows. Secure file-sharing will take place using a secure OneDrive site hosted at the University of Exeter. Overall research governance and project management will be overseen by the University of Exeter. All data handling will comply with current Data Protection Policies.

We have appointed two forms of project governance to ensure the research is conducted to rigorous standards, to support our data collection and to ensure that our findings have rapid impact.

Advisory group to support data collection and dissemination

We have convened a group of advisors recognising both expertise in learning disability, service delivery and cancer diagnosis, as well as reflecting our systems approach to improvement. We have representation from front line NHS, Integrated Care Boards, NHS England, advocacy groups, academia and people with lived experience to maximise impact. Details are provided in the project/research expertise section.

Steering committee to provide independent feedback

We will convene a steering committee to provide overall supervision for the project on behalf of the project sponsor and project funder and to ensure that the project is conducted to rigorous standards. Meetings will be held twice a year for a 30-month project (i.e. five meetings in total) and precede advisory group meetings so that recommendations can be actioned. We have nominated Prof. Pauline Heslop (who has agreed) to chair the independent steering committee. Prof. Heslop is Professor of Intellectual Disabilities Studies and led the national Confidential Inquiry into premature deaths of people with learning disabilities. We will also appoint at least two PPI members and two independent academic members to the steering committee.

Both the advisory group and steering group will meet twice a year (five times in total), staggered so that the steering group feeds advice that can be acted on in the advisory group meetings. We anticipate these meetings will be held virtually on Microsoft Teams.

ETHICS

Procedures relating to WP3 will be reviewed by an NHS ethics committee. Data access for WP2 is already covered by existing ethics approvals; any project-specific approvals will be managed through the Electronic Research Applications Portal for CPRD. Trust approvals will also be required. This research is being conducted with people with experience and expertise in the inclusion of people with learning disabilities in

ethically sound research. There are five main ethical considerations relating to participation of people with learning disabilities in this study:

1. Information-giving/informed consent for people with learning disabilities and their family/informal carers

Through conversation with the person with learning disabilities and/or members of their support network, the professional identifying potential participants will adopt a collaborative approach to selecting the most appropriate time, setting (e.g. remotely or in person) and format (e.g. easy read, video, audio information) for sharing of study information to promote individual understanding. All study information will be produced in collaboration with experts by experience in the advisory group. In line with the Mental capacity Act (MCA, 2005), potential participants will be assumed to have capacity to make decisions for themselves unless proven otherwise. Guided by the MCA, the researcher seeking consent will consider whether the individual can understand the information relevant to the decision; retain the information; use or weigh the information; and communicate their decision (by any means). The researcher will seek the views of those involved in supporting the individual, to inform their consideration. In line with the UN Convention on the Rights of Persons with Disabilities (CRPD, 2022), the researcher will use a toolkit of resources in different formats to support potential participants to make a decision if they are able to do so. Potential participants who are unable to consent for themselves will not be excluded, a consultee will be sought to advise on the potential participants wishes and feelings and whether they would decline to take part if they had capacity, in accordance with relevant legal frameworks and ethical principles (guidance taken from CONSULT Project, www.capacityconsentresearch.com).

2. Support for participant autonomy

In line with project ASSENT guidance and the UN Convention on the Rights of Persons with Disabilities (article 12), this study will adopt a supportive approach to decision making. If a potential participant is considered to lack capacity to consent, a consultee will be asked about the potential participant's wishes and feelings, but the researcher will also seek positive assent from the participant themselves to support participant autonomy as much as possible.

3. Promoting inclusion and respecting those who decline participation or withdraw part way through

Whilst there are ethical implications to including people whose capacity to provide consent may be impaired there are also ethical implications arising from their exclusion (for example their needs and experiences are excluded from research and hence findings may not be appropriate to their needs), therefore our study has been designed to be inclusive of adults with impaired capacity to consent. It will be made clear in participant information that participation is voluntary and there will be no negative consequences from non-participation or withdrawal at any stage. Consent will be seen as a process rather than as an event, continued consent to participate will be checked at regular intervals during data collection.

4. Promoting benefit and minimising harm from participation

This study intends to provide knowledge that will improve the diagnosis of cancer for people with learning disabilities in the future, rather than directly benefiting participants. However, participation will not be invasive and the risk posed to participants is negligible. The applicants are mindful that the topic has the possibility of causing an emotional reaction. The research team has prior experience in undertaking sensitive interviews and will be mindful of the participants' needs and how they are responding. If participants feel sad, they can stop the interview at any time and will be signposted to the learning disability helpline hosted by Mencap (https://www.mencap.org.uk/contact/contact_mencap_direct) if additional support is required.

5. Safeguarding the rights and interests of participants and those they engage with as part of the project

The issue of confidentiality and exceptions to this will be made clear in participant information. If a participant discloses that they or another person is at risk of harm, the research team would respond in line with the University of Exeter Safeguarding Framework.[72]

Access to the routinely collected data to be analysed in WP2 is covered by existing ethical approvals, supplemented by study-specific applications for data release approvals through the CPRD's electronic research application portal (eRAP). The Exeter team are highly experienced in this and can complete the approval process before the project begins, allowing for our data release request to be processed immediately on study start.

RESEARCH EXPERTISE

This study is led by an experienced team with a wealth of completed collaborative research in early diagnosis of cancer and/or learning disability, with a focus on inequalities, access and service improvement.[55,68,73–76] We have expertise across healthcare and inequalities research including lived experience, cancer epidemiology, statistics, cancer pathway improvement, implementation science, psychology, clinical expertise, learning disability and public involvement. All research team members will draw on their particular expertise to contribute to research design, interpretation of findings and dissemination, including as co-authors to publications and reports.

Research team

Lead applicant **Mounce** (Exeter, 20%) will act as Chief Investigator for research and budget governance. He will hold responsibility for delivery of the overall research plan; lead data procurement and analysis for WP2; support WP4 and co-lead overall integration of the project findings. He will also manage co-applicant Wiering. Mounce has extensive experience in the use and analysis of routine data, and is Lead Statistician for the Electronic Risk of Cancer (ERICA) Trial (a cluster RCT in primary care).[77]
Co-lead applicant **Black** (QMUL, 15%) will act as Chief Investigator for stakeholder and research team management. She will co-lead WP3 and co-lead WP4. She will line manage the postdoctoral research fellow TBC2 (QMUL).
Cox (Surrey, 15%) is a Senior Lecturer in Health and Social Care in the School of Health Sciences with extensive experience of research with and about people with learning disabilities. She will co-lead WP1, WP3 and WP4.
Whitaker (Surrey, 5%) is a Professor of Psychology with a track record of research about inequalities in symptomatic diagnosis and help-seeking. She will co-lead WP1 and act as consultant for WP3 and line manage co-applicant Gil.
Abel (Exeter, 10%) is an Associate Professor of Statistics with extensive experience of leading projects using routine data to improve early diagnosis of cancer, including the SPOCC programme. He will co-lead WP2 and mentor co-PI Mounce in project management and have senior statistical oversight.
Kerrison (Surrey, 5%) is Senior Lecturer in Cancer Care with substantial experience in analysing routine datasets including cancer data and establishing strategies to compare outcomes for PwLD. He will provide consultancy to WP1 and WP2.
Wiering (Exeter, 100%) is a Research Fellow with a specialist interest in methodologies to identify patterns of consulting in primary care for different groups of patients before a diagnosis of cancer. She will be the responsible researcher for WP2 (100% FTE for 24 months).
Gil (Surrey, 80%) is a PhD student with experience of recruiting and interviewing PwLD, and review methodologies. She will be the responsible researcher for WP1.
Watkin (PPI) is an expert in research accessibility with widespread learning disability networks to support dissemination through his professional role as Head of Engagement at Seeability.
Frost (PPI) is a member of the public with personal experience of cancer, and caring for a person with a learning disability who has cancer.
Guest (Active Prospects) is PPI lead for the project. She is an engagement manager and has already made important contributions to the development of this application.
We will recruit two **postdoctoral research fellows** (TBC1; 80%, Surrey: TBC2; 100%, QMUL) to be principal researchers for WP3 and WP4.

Advisory group

Patient experience

Frost (see above) will attend advisory group meetings.

NHS England

Rachel Snow-Miller, Head LeDeR programme, will support data collection and assist with dissemination.

Integrated care boards

Philippa Brice and **Alexander Phillips**, NHS Cambridgeshire and Peterborough Integrated Care Board. This ICB is a specialist centre for primary and community care research and our contracting organisation. They will support research governance, project management and dissemination through local ICS, and regional and national fora.

Case study collaborators

Kathy Petersen, GP and learning disability lead, North East and North Cumbria ICS. She will provide insights on local services and innovations in NENC and advise the research team on clinical and primary care issues.
Julie Tucker, Facilitator for Patient and Public involvement, North East & Cumbria Learning Disability Network
Preeti Sud, Director of Strategy and Innovation, Mid and South Essex NHS Foundation Trust
Andrew Graham, LD Health Commissioner, Southend, Essex and Thurrock Local Authorities (Mid and South Essex Integrated Care Board)
Liz Williams, LD and Autism Commissioner, Surrey Heartlands ICS
Hollie Roberts, Acute Hospital Liaison for PwLD, East Surrey Hospital

Academic expertise

Genevieve Breau - Lecturer in Public Health, University of Greenwich and Secretary/Treasurer IASSIDD Health Issues Special Interest Research Group

Clinical expertise

James Green, Consultant Urological Surgeon and Network Director, Barts Health. Will advise on pathway improvement based on experience as National Clinical Lead for a Quality Improvement Programme.
Ruth Northway was the first Professor of Learning Disability Nursing with a research track record of improving access to healthcare for people with learning disabilities. She will advise on clinical matters and the inclusion of people with learning disabilities in the project.
Speech & language therapist/occupational therapist to be appointed

SUCCESS CRITERIA AND BARRIERS TO THE PROPOSED WORK

Success criteria	Mitigation/assurance measures
Meeting milestones as outlined in timeline	Regular meeting structure and experienced Co-PIs with mentorship
Evidence of engagement through project advisory group	Track record of engagement during bid development process with key advisory group members
Evidence of active PPI contribution throughout	Dedicated and experienced PPI coordinator

Engagement with key decision makers within the NHS (e.g. assessed by their attendance at workshops/ meetings or response to outputs from the grant)	Support and endorsement of the project by the NHS England LeDeR programme and project support from Cambridgeshire and Peterborough ICB and their networks
Production of recommendations for scalable innovations	Team expertise in quality improvement and strong PPI contribution to project
Delivery of stakeholder event with good attendance from people representing various stakeholder groups, and particularly with representation from those for whom the work is expected to impact	Detailed dissemination plan and representation of key stakeholder audiences within advisory group
Production of accessible outputs (e.g. easy reads, films) as well as traditional peer-reviewed publications/final report	Team track record in producing accessible outputs as well as academic papers and reports
Evidence of impact, for example, changes in policy or information provided to integrated care boards (e.g. commissioners) for the benefit of patients.	Agreement in principle to disseminate materials through national LeDeR resource bank and training webinars
Potential barriers	**Mitigation measures**
Ensuring diversity of patient/ carers (in PPI and research)	Budgeted plans for inclusive approach (e.g. costs for translation where needed, production of accessible invitation materials)
Optimising learning across a range of cancers/ health care experiences	Scoping review design to include evidence from a wide range of innovations indirectly linked to cancer diagnostic pathways
Managing ethical challenges	Recruitment and consent procedures co-created with PPI group, with ethical considerations section to reflect our understand of current laws and guidelines relating to PwLD and team track record of working to ethical standards with this participant group
Delays in accessing data (CPRD)	Formerly, obtaining data from CPRD with linked cancer registry data could take 12-18 months after an approved application for data release. This could put considerable pressure on project timelines. We had plans in place to mitigate this risk. As of April 2024, however, CPRD now has linked NHS Digital National Disease Registration Service (NDRS) datasets in-house and no-longer need third party involvement in the linkage. This has reduced data delivery timelines to just 1-3 months. We will apply for data release before the start of the project and anticipate no risk from delayed data release.

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