

Research Protocol

1. Project Title

Measuring what matters: Agreeing a standard list of outcomes to assess the benefits of integrated health and social care

2. Chief Investigator and Research Team

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3. Background and Rationale

Integrated care intends to join up silos of care across health and care systems, in particular to provide more effective patient-centred support for people with long-term complex health and care needs. In England, 42 Integrated Care Systems (ICSs) were introduced in 2022 to work more effectively on a population-based agenda to improve health and care outcomes. Although ICSs are undergoing changes (i.e. some ICSs are merging), the integration of care remains important to effectively support people. Professional and patient stakeholders believe that a key aim of integration is better outcomes and experiences for patients and service users (Crocker et al, 2020). However, there is no consensus on the indicators or metrics to use for assessing potential benefits of integration to patients and service users. ICS staff have highlighted the need for identifying appropriate measures and metrics, especially those that work across care pathways and address the success of integration (Lalani et al, 2023).

This research intends to address this gap by applying the methodology of developing a Core Outcome Set (COS) to assess outcomes for integrated care. A COS constitutes the minimum set of outcomes that should be assessed for a specific intervention (in this case integration of health and social services). COS were originally developed for clinical trials, to standardise outcome measures and to streamline comparisons between outcomes of different trials. A COS on integrated care would allow integrated care services, such as ICSs, to monitor outcomes and identify areas to target for quality improvements, and to combine data to evaluate quality more broadly across the NHS in England. A COS constitutes a list of outcomes that experts have agreed should be collected and reported, as a minimum, for a

specific area of health for a specific purpose. A COS defines *what* should be measured (which outcome domains) and *how* they should be measured (which measurement tools).

4. Research Aims and Objectives

The overall aim of this study is to develop a Core Outcome Set (COS) to assess the benefits of integrated care for people with long-term complex health and care needs and their families.

The objectives are:

- To achieve consensus on the types of outcomes ('what' outcomes) that should be assessed in integrated care
- To achieve consensus on the measures to use to assess each of the agreed outcomes

5. Study Design

COS studies take a standardized approach using literature reviewing to identify outcomes, and types of measures, and Delphi surveys to gain consensus. The design of the study is informed by the COS-STAD approach (Kirham et al, 2017) and COMET (Williamson et al, 2017). The surveys will be conducted online.

6. Study Setting, participants and recruitment

Setting:

England.

Participants

We will aim to recruit 120 participants for Delphi Survey 1 and we estimate that we will retain 70-80 participants for the final round of Delphi survey 2. To allow for attrition and considering the wide range of relevant stakeholders for this study, we aim to over recruit. There is no agreement on the number of participants needed for a Delphi survey, however Muchai Manyara et al (2024) suggest that a sample of 60-80 stakeholders provides a high level of replicability in multistakeholder Delphi surveys. Attrition is a recognized risk in Delphi studies and a wide range of attrition has been reported (between 31% and 55% (Gargon et al, 2019). A number of factors affect attrition such as higher number of items to vote on, item order, the number of rounds, length of time the rounds are open for (Gargon et al, 2019). To reduce attrition, we will limit the number of rounds to three. Additionally, we will follow suggestions by Hall et al (2018) where feasible e.g., developing a website with study information, co-producing plain language list of outcome domains, taking a personalised approach to emails, and sending short reports on progress.

Both professional and lay stakeholders will be invited to participate, with inclusion and exclusion criteria set out below. Professionals will include clinicians and frontline staff (health and social care), ICS staff, policymakers and their arms-length bodies, charities

representing relevant conditions or population groups, and researchers with an interest or expertise in outcome measurement, integrated care and/or relevant long-term health conditions. Lay stakeholders will include people with relevant long-term complex health and care needs (hereafter referred to as 'patients'), and their family members or friends who provide them with care and support (hereafter referred to as 'carers'). Relevant conditions and population groups were selected in consultation with PPIE advisors and include adults (18 years+) with long-term complex health and care needs due to a physical and/or mental health condition' or a carer (family/friends) of such an adult (18 years+).

We will aim for at least 30% of the participants to be lay participants. In terms of diversity, we will ensure representation of different types of health and social care professionals (e.g. their professional specialty or discipline, NHS and local authority staff, level of seniority, geographical location, sociodemographics) and lay participants (e.g. sociodemographic factors, condition-related factors, geographical location).

Professional participants

Inclusion criteria

- A professional role that is relevant to integrated care and/or outcome measurement such as clinicians and frontline staff (health and social care), ICS staff, policymakers and their arms-length bodies, charities representing relevant conditions or population groups, and researchers with an interest or expertise in outcome measurement, integrated care and/or relevant long-term health conditions.
- Aged 18 years or over
- Able to complete a survey in English online
- Exclusion criteria
 - Working outside of England

Lay participants

Inclusion criteria

- Adults with long-term complex health and care needs due to a physical and/or mental health condition' or a carer (family/friends) of such an adult
- 18 years or older
- Able to complete a survey in English online
- Living in England

Exclusion criteria

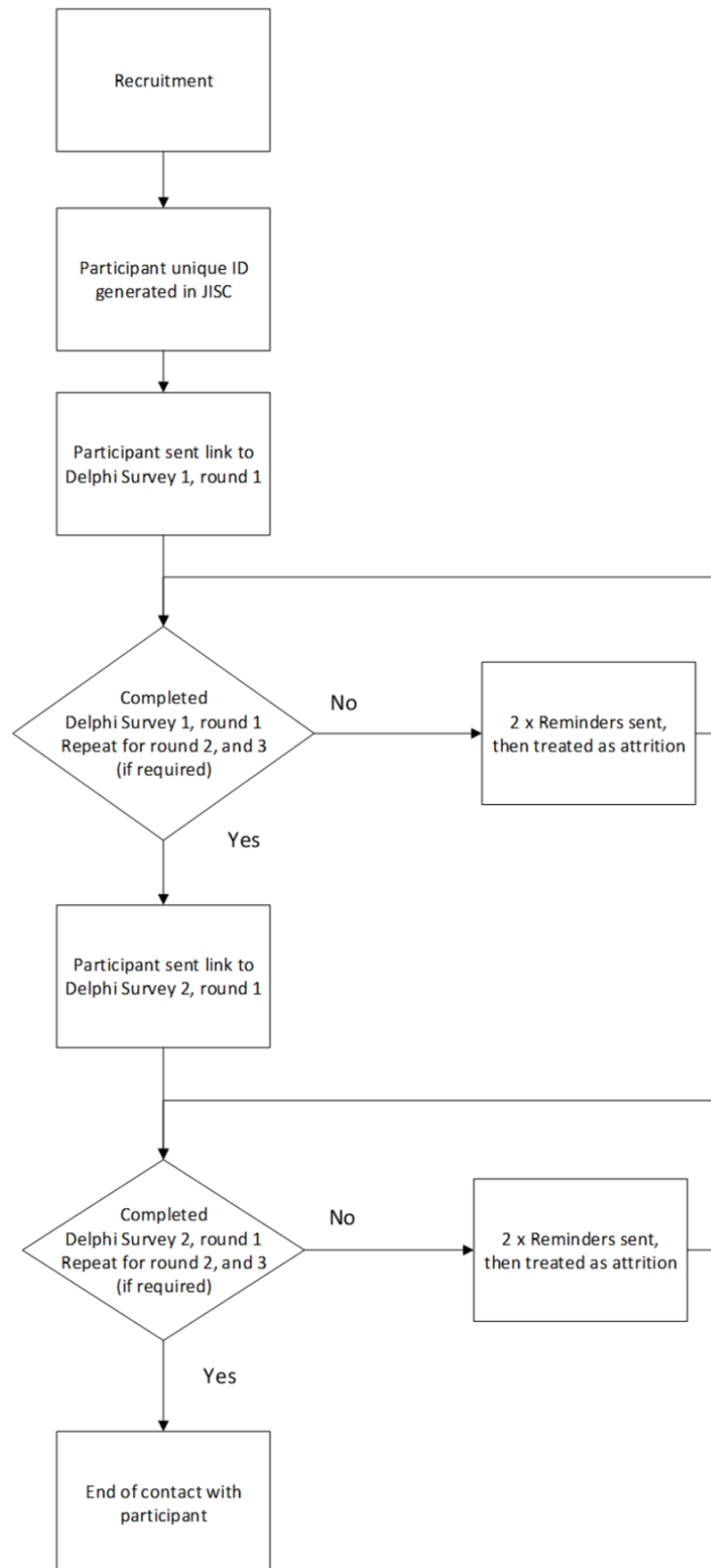
- People living outside of England
- People who lack capacity to consent

Professional participants will be recruited through existing contacts and networks, snowballing and publicly available information (e.g., ICSs, professional associations, voluntary sector organisations). Lay participants will be recruited through existing contacts (e.g. existing PPIE groups), snowballing and research networks such as NIHR Be Part of Research, Join Dementia Research and ENRICH, as well as care and support charities. Where possible for publicly available contact details or existing contacts, an email invitation, together with the relevant Participant Information Sheet (PIS), will be sent from the research team. Potential participants will be invited to register their interest with the research team. Once participants have registered interest and provided contact details (name and email address), the research team will ask participants to confirm eligibility to take part via email. Once confirmed a unique participant ID for each participant will be generated and participants will then be sent a link to the Delphi survey itself (which include an e-consent form to take part). Where direct invitation is not possible, a flyer/poster will be circulated by relevant networks, charities, and posted on social media platforms (such as X (formerly twitter)) owned by the research teams. The flyer/poster will include links to the study website and PIS (professional and lay) and invite participants to register their interest in taking part. Once eligibility has been confirmed via email participants will then be sent a link to the Delphi survey. Participants who register their interest to take part but are then deemed ineligible to take part will have their contact details securely deleted.

7. Data Collection

Data will be collected via two online Delphi surveys (administered via JISC surveys), the first in Jan-Feb 2026 and the second in Sept-Oct 2026. A Delphi survey is an iterative process of gathering opinions, summarising and sharing responses across multiple rounds with the aim of reaching consensus among those taking part. Our plans are informed by the COMET handbook (Williamson et al, 2017) and the COS-STAD approach (Kirkham et al, 2017). A flow chart (figure 1) is provided below to show how participants proceed through the study.

Figure 1: Flowchart of participants through the two Delphi Surveys



Delphi survey 1 aims to reach agreement on *which* outcome domains should be included in the COS. Delphi survey 2 aims to reach agreement on the measures to use i.e. *how* to measure the outcome domains identified in the first Delphi survey. Each Delphi survey will follow the same process and will consist of up to three rounds. We estimate that it will take no longer than one hour to complete the Delphi Survey 1 Round 1. Subsequent rounds are likely shorter as only items where consensus has not yet been reached will be rated. We will conduct no more than three rounds to minimize burden on participants and attrition.

At the start of the Delphi survey 1, participants will be asked to provide informed consent, to confirm their eligibility and that they agree to take part before they can proceed to the Delphi 1 survey. Delphi survey 1 will list outcome domains (determined through literature reviews and consultations with relevant stakeholders), together with brief descriptions of each domain (professional and lay descriptions will be provided). The survey will include a link to an optional short report on summarizing relevant literature. Participants will be asked to rate each domain on a 9-point scale for their relevance (scale from 1- 'not at all relevant' to 9- 'very relevant') to assessing integration for people with long-term complex health and care needs. Whilst a 9-point scale is more onerous than for example a 5 point scale, evidence shows that it is more highly discriminatory in gaining consensus (Remus et al, 2021). This means fewer domains are retained, which is desirable considering that a COS is a minimum outcome set. Delphi Survey 2 will focus on outcome measures. It will include a short (optional) report on the outcome measures under consideration. The review and selection of measures will be based on a review of the literature focusing on the psychometric or measurement properties of measures. A copy or link to measures that participants will be asked to rate will be made available.

- In **Round 1**, participants will be asked to rate the domains identified from the literature (Delphi Survey 1) OR the best measures to measure each domain (Delphi Survey 2). Additionally, Delphi Survey 1 will ask participants in open text boxes to comment on the domains (e.g. overlap or duplication) and to list additional (missing) domains for assessing outcomes of integrated health and social care. In Delphi Survey 2, open text options will ask participants to name other relevant measures if there is disagreement with the suggested measures.
- **Round 2** will present participants with the aggregated findings from the previous round (see below for analysis). Any domains or measures where consensus was achieved will be excluded. Participants will be asked to re-rate the domains or measures where consensus was not reached, and to rate any new domains or measures identified in Round 1.
- **Round 3**, will present aggregate group responses from rounds 1 and 2. Participants will be asked to re-rate domains or measures where consensus was not reached. Round 3 will only be conducted if full consensus was not achieved in Round 2.

Consensus Criteria

- Outcomes rated 7-9 by $\geq 70\%$ of participants will be considered to have reached consensus to include and will not be repeated in later rounds.
- Outcomes rated 1-3 by $\geq 70\%$ of participants and fewer than 15% score 7-9 will be considered to have reached consensus to exclude and will not be repeated in later rounds.
- Outcomes failing to reach consensus to exclude or include will be carried forward to Round 2.
- Outcomes that have not reached consensus for inclusion (rated 7-9 by $\geq 70\%$ of participants) by the end of Round 3 will be excluded.
- In Delphi survey 1, if any overlaps or duplication are highlighted in the free text boxes, only one domain (if both reach consensus for inclusion) or a merged domain will be taken forward. Any suggested domains (by at least 2 participants) that are considered new and relevant will be included in subsequent Delphi rounds.
- In Delphi survey 2, any new and relevant measures suggested by at least 2 participants will be included in subsequent rounds.

Following Delphi Survey 1, reviews will be conducted to identify the most relevant and psychometrically strongest measurement instruments for each of the agreed domains from Delphi survey 1. Publications included in the review on outcome domains are likely to provide some information on measurement instruments. This information will be supplemented with targeted searches on specific instruments for each of the domains that achieved consensus. Standard psychometric properties (e.g. validity, reliability) of the instruments will be evaluated, in addition to more practical feasibility issues (e.g. length or cost of instruments). Consideration will be given to instruments that have been used and/or validated in the context of integrated care and/or assessing outcomes across different types of relevant long-term complex health and care needs. The literature on relevant instruments will be concisely summarised to form the basis of Delphi survey 2. If multiple relevant and psychometrically strong measures are identified for a domain, multiple measures will be included in the Delphi survey 2; however, this will be kept to a maximum of 3 measures to reduce burden on participants. If no relevant or psychometrically strong measure is identified, this will be highlighted, and participants will be asked to make suggestions and/or to comment if such a measure needs to be developed. The process (rounds), consensus criteria and analytical steps will be the same as outlined above.

The domains and measures for which consensus was achieved will constitute the COS for ICSs. If for a domain, no measure was identified, recommendations will be made on how to address this gap.

8. Data Analysis

After each round, the survey data will be analysed to calculate the level of agreement with each item (domain or measures). Descriptive statistics will be used to calculate the level of

agreement; including sub-group analyses where relevant (e.g. to compare if consensus differs between professional and lay participants). Open text comments will be reviewed to identify new domains and/or additional outcome measures to consider. The findings will be summarised and presented as a short summary in the subsequent round, including which domains or measures consensus was achieved for. Consensus will be determined by the criteria set out above and only domains or measures where consensus has not yet been achieved or new domains or measures will be presented to participants in the next round.

9. Ethical Considerations

Ethical approval will be sought from the University of Kent School of Social Sciences Research Ethics Advisory Group (SSS REAG). Participant risks are minimal as data collected are participants' ratings of outcome domains or measures, rather than reporting on their own experiences of receiving health and social care services. Delphi surveys can be burdensome depending on how many items are presented and we aim to keep these to a minimum to keep the burden to participants as low as possible.

Participation is voluntary and participants can withdraw from the study at any time. If a participant fails to respond to a round after 2 reminders, we will no longer follow up with them and consider them withdrawn from the study.

10. Data protection

We will need to collect personal contact details (email addresses) to send participants the survey. Personal data and survey data will be kept separate. A personal unique ID code will be assigned to each participant to enable us to monitor responses/attrition and to link background (demographics, professional role and condition-related information) to subsequent responses. The unique ID code will be stored in a separate link file. Only anonymised survey data will be used in reports, and only aggregated data will be presented on demographics, professional background information, and condition-related factors.

We will offer participants the option to be named in the acknowledgments of any publications. Only consenting participants will be named. Our reports will present data in such a manner that it will not be possible to link participants named in the acknowledgments to their survey data (i.e. by only reporting aggregate data).

We will follow guidelines on secure storing of data on the University of Kent and Oxford secure servers. Contact details, consent forms and survey data will be stored in separate files. They will be password protected (each using their own password), encrypted, and will only be accessible to the research team. Any reports we share with participants will be sent individually or blind copied.

11. Patient and Public Involvement (PPI)

The study is supported throughout by three Patient and Public Involvement and Engagement (PPIE) advisors. The PPIE advisors have been/ will be involved in all stages of the study from conception to dissemination. To date, PPIE advisors have supported early scoping work to determine the focus of the COS (i.e. on adults (18 years+) with long-term conditions and complex health and care needs), the development of the protocol and participant facing documents, the literature reviews, and the development of the list of domains for Delphi Survey 1. Similarly, in the future, they will be involved in the analysis, the reviews to identify the most appropriate measure to assess each domain (for Delphi Survey 2), and the dissemination of findings.

12. Dissemination and Outputs

Outputs will include reports to the Department of Health and Social Care, academic articles, briefings for local stakeholders, (including webinars) and accessible summaries for lay audiences. The study website will be regularly updated with information about the study.

An end of project report will be offered to all participants

12. Timeline

Study Start Date: June 2026

Duration: 12 months

Milestones:

Delphi Survey 1 (Rounds 1-3): Jun-Jul 2026

Reviews on the measures for each agreed outcome domain: Jan 2026-Jul 2026

Development of Delphi Survey 2: Jul-August 2026

Delphi Survey 2 (Rounds 1-3): September-Oct 2026

Analysis and final Report Oct-Dec 2026

13. Funding

The study is funded by the NIHR Quality, Safety and Outcomes Policy Research Unit (NIHR QSO PRU) NIHR206117(03).

14. References

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