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

FULL/LONG TITLE OF THE STUDY

High-quality mental capacity assessments for hEalthcare decisions: improving Leadership, assessment Procedures, and service user Support

SHORT STUDY TITLE / ACRONYM

HELPS

PROTOCOL VERSION NUMBER AND DATE

Version 2.3 03Mar2024

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Version	Date	Author	Reason
V1.0 WP1	May 2023	Domenico Giacco	To originate the document
V1.1 WP1	September 2023	Emanuele Valenti	BSREC approved version
V2.0 WP1	October 2023	Emanuele Valenti	Integration of WP2 and WP3 in appendix
V2.1 WP1	December 2023	Emanuele Valenti	Change of software for recording interviews: from Teams to Audacity
V2.2 WP1-2-3	December 2023	Emanuele Valenti	Merging WP2 and WP3 with WP1

V.2.3 WP1-2-3	March 2024	Emanuele Valenti	Changes in the PPIs' section, added LEAP meeting costs and budget

SIGNATURE PAGE

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

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

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

For and on behalf of the Study Sponsor:

Signature: ..... Date: ...../...../.....

.....

Name (please print):

.....

.....

Position:

.....

.....

Chief Investigator:

Signature:

Date: 19/12/2023

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Professor Domenico Giacco

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Joint-sponsor(s)/co-sponsor(s)	N/A
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STUDY SUMMARY

Study Title	High-quality mental capacity assessments for hEalthcare decisions: improving Leadership, assessment Procedures, and service user Support (HELPS)
Internal ref. no. (or short title)	HELPS
Study Design	Qualitative interview study

Study Participants	Service managers working within Integrated Health Care Systems (ICS) in England and Regional Partnership Boards (RPB) in Wales
Planned Size of Sample (if applicable)	45 service managers
Follow up duration (if applicable)	N/A
Planned Study Period	July 2023-February 2024
Research Question/Aim(s)	What are the current service policies for MC assessments in England and Wales?

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN**
NIHR	£901,582.00

ROLE OF STUDY SPONSOR AND FUNDER

This study/project is funded by the National Institute for Health and Care Research (NIHR), Health and Social Care Delivery Research Programme (NIHR153264). The sponsor is the University of Warwick.

The Chief Investigator, protocol contributors and Programme Management Group have contributed to the study design and final decisions on the study design were not controlled by the sponsor or funder.

Any views expressed are those of the protocol developers and not necessarily those of the NIHR or the Department of Health and Social Care.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

The study has a **Programme Management Group** (PMG), whose members are mentioned on page 4. The PMG meets regularly during the project every month, and its members stay in

contact via online means of communication throughout. The PMG includes PPIE leads and makes decisions with regard to study design and programme management.

The PPIs' lead is Campbell. We are currently advertising for a National **Lived Experience Advisory Panel** (LEAP) for this project, for which we will appoint 8 people with experience of having been treated under the Mental Health Act (patients) or having supported someone treated under the Mental Health Act (carers). The LEAP will meet every 4-6 months and provide independent advice to the PMG and the Chief Investigator.

HELPS has a **Professional Advisory Group** including acute mental health, physical health practitioners, social care experts and independent Mental Capacity Act Advocates. The Professional Advisory Group will meet every six months and provide independent advice to the PMG and to the Chief Investigator.

HELPS has an **Independent Steering Committee Group,** including academics from different disciplines, i.e., mental health, law, ethics, and research methodology. The committee group will meet once a year and provide independent advice to the PMG and to the Chief Investigator.

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KEYWORDS: Capacity assessment; Mental Capacity Act; Health Economics Foundational Analysis, Participatory Action Research, Service Change Action

STUDY PROTOCOL

1. BACKGROUND

The HELPS project aims to improve the implementation of mental capacity (MC) assessments in England and Wales in acute and hospital care. In these settings urgent healthcare decisions are made and MC assessments are challenging due to limited time and competing pressures (*Lepping et al., 2015; Wilson, 2017*). To meet the standards recommended by the Code of Practice for the Mental Capacity Act (*MCA Code of Practice*), MC assessments need to be: criteria-focussed, evidence-based, person-centred and non-judgemental. People should be presumed to have capacity, be provided support to make their own decisions and be allowed to make unwise decisions if they demonstrate capacity.

Literature shows that 34% of service users in acute physical health care and 45% in acute psychiatric settings lack the capacity to participate and consent to healthcare decisions (*Luke et al., 2008*). People with acute mental health and physical health problems (*Luke et al., 2008; Jenkinson & Chamberlain, 2019*), and with learning disabilities (*King, 2021*) have been found to be at high risk of being exposed to unsatisfactory MC assessment practices. Failings were identified in assessment procedures, availability and quality of training and organisational arrangements within services (*Jayes et al., 2020; Ariyo et al., 2021*).

Lack of support and scarce information provision was reported by service users (*Wilson, 2017*). Identification and implementation of best practices and service improvements need to consider (*Jayes et al., 2020; Weick and Sutcliffe, 2003; Allen and Currie, 2011*): 1) the individual level, i.e. how professionals deliver assessments; 2) the training level, i.e. the availability, quality and benefits of training and supervision; 3) the organisational level, i.e. the leadership/management arrangements to monitor current practice, and enable best practices and interprofessional collaboration.

2. RATIONALE

MCA implementation in healthcare organisations presents issues at different levels: assessment procedures, training and organisational arrangements. Practices can be inconsistent with the MCA legal framework, professional training, assessment procedure and provision of support to service users are key issues for improvement.

Healthcare professionals may not have appropriate access to high-quality training in MC assessments (*Penn et al., 2021*) and this can lead to incorrect assessments (*Penn et al., 2021; Taylor, 2015*) and to problems in embedding MC assessments in their practice (*Dunlop & Sorinmade, 2014; Manthorpe et al., 2012*). Contextual challenges to MC assessments can be competing priorities and the pressure on clinicians to assess service users to reduce waiting times rapidly to. These challenges can be barriers to a thorough collection or provision of

information. Appropriate capacity assessments are central to preserving the human rights of service users to participate in care decisions when they can (*Wilson, 2017*) and to reduce risk to service users' safety and health when capacity is not present (*Healthcare Quality Improvement Partnership, 2018*). Lack of training and supervision can affect professional perceptions such that procedures are viewed as excessively complex, thereby contributing to professional stress (*Willner et al., 2011*), (*Cameron et al., 2022*), unsafe practices, and penalties for professionals and their employers for not following Care Quality Commission guidance (*CQC, The Mental Capacity Act, 2005*). Organisational barriers to best practices are seen as influential by professionals (*Ariyo et al., 2021*) but have not been investigated in detail. Solutions to overcome them are not currently available.

HELPS will address these needs by facilitating the identification and implementation of best practices and organisational learning within the NHS. This learning may also benefit integrated care partners such as social care and third-sector organisations when involved in urgent healthcare decisions. The capacity/commitment/culture (3Cs) will be the organising theoretical framework used by HELPS for identifying antecedents to organisational change, co-developing action plans for change and assessing their outputs (*Seibold & Gamble, 2015; Currie et al., 2020*). In the first work package of HELPS, we will focus on interviews with service managers to understand the overarching policy and practice management issues which may influence the practices of frontline workers and the experiences of service users and carers.

3. THEORETICAL FRAMEWORK

The framework of reference will be interpretivism-constructivism (*Mackenzie & Knipe, 2006*). This approach assumes that knowledge is social construction produced by the interaction between people participating in research implementation. The m research is co-constructed with people involved in the research process. In HELPS, the researchers will adopt a standpoint that they will have different perceptions of reality compared to participants and will check their interpretations with the participants during the interviews and workshops. Taking an interpretative/constructivist approach will allow us to construct the sampling frame by looking for a diversity of perspectives. We expect that different perspectives may come from different professional backgrounds of the service managers, but we will explore that reflexively with participants and the broad research team and change our sampling strategy if required. The interpretative-constructivist approach will be used intensively across the workshops. All the findings and inputs emerging from qualitative interviews will be discussed in the meetings of the Project Management Group (PMG), the Lived Experience Advisory Panel and the Professional Advisory Group so that the different lived experiences and professional perspectives can come to the fore, and we can take them into account.

4. RESEARCH QUESTIONS / AIMS

HELPS aims to improve the implementation of mental capacity (MC) assessments in England and Wales to meet the Code of Practice for the Mental Capacity Act standards
The project will a) help to understand organisational challenges in the implementation of MC assessments for urgent healthcare decisions, b) develop co-designed improvement actions and c) test and refine them. HELPS is based on a Participatory Action Research methodology carried out in three stages: 1) Interviews with 45 service managers in 15 'Integrated Care Systems' (England) and 'Regional Partnership Boards' (Wales) to explore current policies and practices; 2) In-depth evaluations with case note analysis, interviews and practice observations of MC assessment practices and experiences in four areas; 3) Co-design workshops with multiple stakeholders (service users, carers, professionals, managers) to develop changes to practices.

The work package one will explore service managers' views working within Integrated Health Care Systems (ICS) in England and Regional Partnership Boards (RPB) in Wales. In addition to organisational aspects and policies for capacity assessments, we will review and integrate the most updated evidence on cultural competence assessment toolkits and discuss these findings in our interviews.

The specific research question will be:

- What are the current service policies for MC assessments in England and Wales?

5. STUDY DESIGN/METHODS

5.1 WP1: Understanding service policies and practices (Month, M1-6)

Study design

Qualitative interview study.

Participant selection

We will interview service managers working within Integrated Health Care Systems (ICS) in England and Regional Partnership Boards (RPB) in Wales. We will purposively sample the areas for geographic location (North of England, Midlands, South of England, Wales) and ethnic composition. We will interview service managers working within Integrated Health Care Systems (ICS) in England and Regional Partnership Boards (RPB) in Wales. The managers will be NHS Band 7 or higher, or in equivalent positions in social care and third-sector organisations, i.e. positions involving management responsibilities. The participants will be purposively sampled to include medical, nursing and other allied professionals' backgrounds.

The degree of ethnic diversity on an area level will correlate with other variables of potential relevance, such as urbanicity, social deprivation and social fragmentation (*Gov.UK., 2020*). In addition to organisational aspects and policies for capacity assessments, we will review and integrate the most updated evidence on cultural competence assessment toolkits and discuss these findings in our interviews. We will attempt to interview three service managers (one for each of the HELPS service users' groups) per 15 ICS/RPB areas, one-third of all ICS/RPBs, i.e. 45 managers. When possible, we will interview service managers with different professional backgrounds (e.g. medical doctors, nurses, and social workers).

Taking an interpretivist/constructivist approach, we will construct the sampling frame looking for a diversity of perspectives. We expect that different perspectives may come from different professional backgrounds, but we will explore that reflexively with participants and the broad research team and change our sampling strategy if required.

Procedures

Participants will be reached through networks created during the ASSENT, the BABEL and other projects led by the applicants (*ASSENT project*; *RESPECT project*; *ARIADNE project*; *BABEL project*; *Singh et al., 2013; Heywood et al., 2019; Giacco, 2019; Giacco et al., 2018)* and through applicants' personal networks and/or email published on Trusts', local authorities' and/or relevant organisations' websites. The interviews will be carried out via phone or videoconferencing. We expect to use Microsoft Teams as it is currently approved by the University of Warwick and NHS Trusts for use and guarantees appropriate data security. Virtual or in-person visits to services may be agreed upon with managers. Local documents and tools will be accessed and included in the analyses.

Interviews

The interviews will be semi-structured and carried out by Giacco and an employed senior researcher. A topic guide was developed, and the senior researcher and Giacco will meet weekly to discuss and harmonise the interview style. Participants will provide information on Trusts' practices regarding a) guidance and tools for MC assessments; b) availability of training; c) training, assessment procedures, supervision and interprofessional collaboration; d) activities to increase cultural competence; e) areas and services which are representative of best practices and areas for improvement, to guide WP2 site selection; f) supervision; g) views on what improvements in services' culture might improve MC assessments; h) views on potential clinical and organisation gains and risk management benefits from improving MC assessments; i) What resource barriers restrict services from improving MCAs / what investment would best allow that improvement (finance, personnel, technology). The managers will also be asked to signpost researchers to local policy documents.

Analysis and outputs

Thematic analysis (*Vasileiou et al., 2018; Clarke et al., 2015; Fereday and Muir-Cochrane E., 2006)* will be used to summarise guidance materials and tools, training types and organisational barriers and facilitators in relation to the Capacity/Commitment/Culture theoretical framework. Data from interviews will be integrated with the analysis of local policy documents. An interim analysis after 30 interviews will be carried out to review the sampling frame. The procedure adopted for the interim and final analysis will be the following: a) data will be coded from two independent analysts (Giacco and senior researcher), and a codebook will be developed; b) The analysts will meet with Currie as an independent adjudicator in case of disagreements; c) codes will be grouped into themes; d) themes will be sent to participants with anonymised quotes for validation and/or comments as per our /constructivist paradigm; e) wider validation will be sought from the PMG (co-applicants) and by an independent professional advisory group (PAG) which will include representatives of medical, nursing, independent Mental Capacity Act advocates and social work frontline professionals. The themes and data emerging from the analysis will inform the decision on the geographical areas selected for WP2 case studies.

Ethics approved BSREC 143/22-23 University of Warwick

5.2 WP2: Assessing current clinical and organisational practices (M7-12)

Study design

Mixed method study including structured practice observations, case note analysis and semi-structured interviews. The WP will be led by Griffiths and Giacco, with the two employed senior researchers undertaking data collection and a senior research nurse who will support the recruitment. One of them, previously involved in WP1, will have knowledge of services (from managers' interviews). For the qualitative data, we will use thematic analysis to understand experiences in depth.

Procedures

Development of a structured rating tool for observation and case note analysis

The tool will be based on the criteria for the quality of mental capacity assessments described earlier and on a review of tools identified during WP1. A draft tool will be developed based on WP1 results, and we will offer guidance to the raters. Researchers undertaking the ratings will be trained in a series of half-day workshops. From previous studies (*Eli et al., 2021*), Griffiths has data from observation of decision-making for acutely ill patients in hospital settings. Extracts of this data will be anonymised to provide examples of what happens during these events. We will role-play these events and their observation to develop researcher skills in rating and negotiating their presence as observers. We have used this method in a previous study (*Griffiths et al., 2019*). We will pilot and refine the tool within an area not selected for the main study (30 observations and 30 case notes). We have used this approach in previous

studies involving observation (*Griffiths et al., 2019*) and evaluation of case notes (*Eli et al., 2021*). Pilot observation and pilot case-note analysis will follow the sampling, recruitment and data collection/extraction process described below for the main study of WP2. Two researchers will observe the same event and score independently to assess the inter-rater reliability of observed events. We have undertaken this successfully in a previous study (*Babalola et al., 2022*). The tool has been elaborated by reviewing relevant literature about the subject, (*Applebaum & Grisso, 1995*; *Scott, 2010; Kong, 2017*) and the MCA Code of Practice. Literature has been thematically analysed through NVivo 12 software, and coding informed the elaboration of the tool's items. Case notes will be scored independently. A structured case-note extraction tool has been developed to facilitate research nurses' case-note data extraction, protect patients' confidentiality, and collect relevant data. The extraction tool was also designed based on a literature review (*Scott, 2010*). Inter-rater reliability statistics, i.e., Cohen's kappa, will be calculated. In sample size determinations based on the Central Limit Theorem (*Kwak et al., 2017*), a sample size of 30 or greater is usually sufficient to ensure that the sample means approximate a normal distribution. Case notes will be assessed by applying a structured case note extraction tool developed by Appelbaum and Grisso and adapted to the MCA Code of Practice. Given the recruitment effort needed for this pilot, we will assess the results and consider if the data is robust enough to include with the main study results.

Participant selection

Field sites

Four ICS/RGP areas will be identified during WP1 by three sampling criteria: 1) being representative of organisational barriers and best practices as identified in WP1; 2) being in the North of England, Midlands, South of England, Wales; 3) representing a variety of experience of working with people from different ethnic groups, in a diverse degree of urbanicity and social deprivation.

Mental capacity assessments

MC assessments will be sampled for occurring with service users from the three HELPS groups, i.e., people with mental health conditions, physical health conditions and learning disabilities. We plan to observe a minimum of 10 assessments/ case note reporting per area (overall 40) to observe at least three assessments per group per site. Health provision will be acute services in the hospital and community care. These will be usually, but not necessarily, delivered by NHS Trusts (in some areas, they may be delivered by private providers or charities). Sampling will be consecutive within planned fieldwork sessions for observation and case note analysis. These sessions will be 3-4 hours long and spread throughout the week/weekend/24 hours.

Interviews
We will invite observed service users/carers and a professional involved in their MC for interviews. Depending on response rates, we may recruit further service users/carers via sequential sampling of case notes in use by clinical teams (e.g. clinical notes on a ward/admissions unit or within an acute community team or emergency department) during the timeframe (overall 5 weeks across WP2 and WP3) of the fieldwork in each area.

Recruitment

Field sites
Previous interviews will be an opportunity to select field sites according to their characteristics and accessibility (in all areas to be included, the relevant services will have electronic clinical information systems to support case note analysis). Field site characteristics will reflect the representativity of organisational barriers and best practices identified during the previous data collection. WP1 interviews will explore the interviewee's availability to be involved in further research activities. Information will be collected at each interview, and a database for recruitment will be implemented within the progress of WP1. At the start of the WP2, all participants available will be contacted by email, and a first visit to the field site will be agreed upon. The visit will be an opportunity to present the study to the team and explore how each site is organised and who can support the researcher in each site. When available, a research nurse will meet with the researcher to plan observations and case note analyses. Field site visits will be agreed upon with the research nurse or other NHS Trust available personnel.

Mental capacity assessment observations
The project researchers will spend 1-2 days with the clinical team in each field site to familiarise themselves with how the team works and how capacity assessments are undertaken, including for patients likely to have the capacity, those where there is doubt about their capacity and those where their previously documented lack of capacity needs to be reviewed. The researchers will then arrange a timetable of observation in each field setting to maximise the opportunity for observation of MC assessments.

Mental capacity assessment case notes
All field sites will have electronic health records. The research nurse will access case notes of the identified sample (see above) once consent has been secured from the patient/carer (see below).

Interviews
We will interview 17 participants per study area (overall 68 interviews). For each of the three HELPS groups, we expect to interview at least two users/carers, two frontline healthcare workers and a manager in each study area. All participants will have been involved in an

observed MC assessment or involved in an assessment in the last three months. Service providers will be interviewed as soon as possible after observed MC assessments (usually within 24 hours). As service users are acutely ill during the MC assessment, we will delay approaching them for an interview for at least 4 weeks. Our recruitment process will be refined with our PPI group. Service users may have regained the capacity to consent to research if previously lost. Otherwise, their carers will be approached for an interview. Professionals and managers will have medical, nursing, or social work professional backgrounds. Previous multisite qualitative studies identified 15 participants per area sufficient to reach data saturation (*Vasileiou et al., 2018*).

Patients/carers will be sent an invitation for an interview by their clinical team. The research nurse will support this process. The invitation will be sent to the patient if the clinical team expect the patient to have capacity or to the carer if the clinical team expect the patient not to have capacity. Three letters will be drafted, for the patient, the carer and one combined with informed consent for case note analysis (see below). Health professionals observed undertaking mental capacity assessments will be invited for interview by the researcher undertaking the observation. Managers will be approached for an interview by the research team. We aim to undertake these interviews after we have undertaken the initial analysis of data from all the other sources and across field sites so we can probe managers about issues arising. The interviewers will be trained to ensure no data is revealed during these interviews.

Informed consent

Ethics TBC

Observations

The researchers will be observing the practice of the healthcare workers undertaking the MC assessment. At the start of each observation period, consent for observation will be obtained from the healthcare workers being observed. Users/carers/ present during the observation will be asked for verbal assent for the researcher to remain during their engagement with the healthcare worker. If this is not given, the researcher leaves. This approach has been used successfully in previous research funded by the NIHR (*Griffiths et al., 2019; Eli et al., 2021*; *Babalola et al., 2022*). For field sites where the patients are likely to have Learning Disabilities, we will work with Learning Disabilities England experts to refine our approach to seeking verbal consent for the researcher to remain.

Interviews

The project will be explained to all interviewees, and informed consent will be obtained.

Mental capacity assessment case notes analysis
The provider organisation will send a letter to the patient, or for patients who lack capacity, the person recorded as their carer or their designated next of kin recorded by the provider organisation. This will inform them about the study. Information will include the study's purpose, the information that will be collected, and how it will be anonymised before secure transfer to the study team. The letter will include details of the ways in which the person can let the study team know that they do not want their medical records to be used in the study. This letter includes an invitation to interview (see above). Participants recruited to the interview study can opt out of the clinical notes' evaluation. Each information sheet and response form will have a unique study identification code. The study team will use it to inform the provider organisation if someone informs them that they do not wish to be included in the case note analysis. No personal identifiable information will be transmitted to the study team.

Data collection

Observation
The researcher will complete the assessment tool for each MC assessment and write field notes. Field notes will include the context and physical and verbal behaviours related to the MC assessment. Clarifying questions will be asked after interactions with users/carers are complete to avoid interrupting the interaction. Researchers will observe the daily work and meetings of relevant clinical teams. In addition to the MC assessment, they will note supervision arrangements, interprofessional collaboration and service culture. Researchers will expand field notes immediately after observation periods. Researchers will hear personal information about patients, but this will not be noted in field notes.

Case note analysis
The research nurse will identify the pages in the clinical record where the MC assessment is recorded. The nurse will copy the pages, add the study ID to the copy and redact al personal identifiers before securely sending to the study team.

Interviews
These will be semi-structured. We will explore the experience of MC assessment, perceptions of quality, enablers and barriers to optimal MC assessment, what could be improved and how. In the end, the topic guide for service providers will include questions to explore their socio-demographic characteristics, and those for patients/carers will collect information about their previous experiences with the services and MC assessment.

Data management

Data collected during the study will be handled and stored in accordance with GDPR, the 2018 Data Protection Act and WMS Standard Operating Procedures. Prior to participant consent to participation, all personal data will be held by the relevant care provider organisation. The care provider organisation will complete data collection spreadsheets (1. Patients/carers and 2 Providers/Managers). This will include details of patients/care providers where their MCA was observed, as needed, patients who had an MCA recorded in their clinical notes but not observed, and relevant filed-site managers. Each potential participant entered will be given a unique identifier code. This database will be used to send invitation letters to patients/carers by research nurses and to service providers/managers by the research team. Only aggregate, anonymous data about patients/carers will be provided to the Warwick co-ordinating research team. Participants who contact the research team and agree to take part in interviews will, with their agreement, have their name and contact details stored securely on the University server for the purposes of contacting them again to arrange an interview. Consent for observation and interview will be taken, and researchers will collect data from the co-ordinating study team. Consent forms will be stored at Warwick University in the Division of Health Sciences in a locked filing cabinet in a locked room with access limited to the study team.
Interviews will be recorded, transcribed verbatim and anonymised, with each participant being assigned a unique interview ID. Observation notes and transcripts will be stored in a separate electronic folder to the database of names and contact details of participants. Recordings of interviews will be collected on encrypted devices and then securely transferred on the same day to the secure university server. After transfer, the recording will be deleted from the recording device. Transfer to any transcription services will be done via a secure system, according to Warwick data transfer SOPs and a data sharing agreement. Any handwritten field notes will be kept in a locked filing cabinet in a locked room at the University. Field notes recorded electronically will be on an encrypted, password-protected laptop while the researcher is at the site and then uploaded to secure university servers the same day**.** Transcripts will be uploaded to NVivo or similar university-approved qualitative analysis software for data management together with any field notes. All transcripts and notes of conversations will be coded, 30% independently by a second researcher. Data analysis will be concurrent with data collection, and initial analysis will inform subsequent data collection.

Analysis and outputs

For practice observations and case notes, ratings of each item of the assessment tool will be collated and summarised. For the interviews, we will use thematic analysis for fieldnotes and interviews (*Fereday and Muir-Cochrane, 2006*) structured by service user group, practitioner, and team level. The thematic analysis will follow the usual stages of familiarising the data, coding, generating, reviewing, and defining and naming themes. The codebook will be discussed with LEAP and PAG members. Initial analysis will be sent to participants and to PMG, PAG and LEAP members for validation before the final stage of writing up. For the integration

of findings: Findings from interviews, practice observations and case notes analysis will be discussed with the PMG, PAG and LEAP and synthesised to draw out general lessons for organisations and a baseline for WP3 activities. For case note analysis, we will extract key indicators of quality of MCA recording and quantitise this qualitative data. For the HE analysis: During data analysis, we will identify the views of service users and clinicians regarding the benefits of high-quality MC assessments, which will be used to inform a logic model for health economics evaluation of practice improvements and organisational changes, codesigned during WP3. The outputs will be a) a tool for evaluating MC assessments, b) a tool for case note analysis, c) a list of training needs (practitioner and leadership), d) a report on potential organisational changes based on experiences from patients and clinicians and practice observations.

5.3 WP3: Co-designing and testing service change actions (M11-26)

Study design

Participatory action research will be carried out across four areas in the North of England, Midlands and South West and East. The first phase, with four workshops per site (site workshops phase), will develop localised actions. The second phase (cross-site workshops) will compare different actions and contexts and try to identify interventions which have a potential for generalisability. COREQ and STROBE guidelines will be followed in the mixed methods evaluation and in the reporting. The interpretivist-constructivist approach will be used intensively across the workshops. All the emerging themes and inputs will be verified at the end of each workshop and/or minuted and validated during the following workshop. Giacco will have the overall responsibility for the WP3 but will be supported by: a) Currie for the design of the workshop and the development of the change actions in relation to the 3Cs model; b) Griffiths, who will co-lead the mixed methods evaluation through case notes analysis, practice observations and interviews; c) Madan and Noufaily who will support and oversee the foundational health economics work and the quantitative analyses, respectively; d) Campbell who will support service user and carer involvement and its monitoring. All workshops will be mixed, including service users, carers and different types of professionals. To foster meaningful participation of service users and carers, we will offer one-to-one feedback meetings to service users and carers participants between workshops. This will help us capture any points they felt they could not make during workshops and develop strategies to increase their contribution during workshops if needed.

Site workshops

Four workshops per site (total: 16 workshops) will be held. Each workshop series will include 6-10 core participants with up to 5 additional one-off participants to discuss specific issues. WP1-2 data, including brief videos, and focused evidence summaries, will inform workshops. *First Planning-Action-Reflection-Evaluation (PARE) cycle:* Workshops (W)1-2 will brainstorm and identify immediate actions for service change and develop draft implementation plans. Actions are likely to be changes in policies for assessments, decision-making support tools and local guidance, availability of training or supervision for clinicians and specific small organisational rearrangements (e.g. minor changes in job plans, team meetings, structure of supervision sessions). We expect at least some of these changes will involve 'technical efficiency' and not require additional resourcing (see 'Health Economics component' paragraph). If treatment costs will be needed, arrangements for these will be included in implementation plans and identified within the relevant Trusts/organisations. Monitoring and evaluation strategies are likely to include the following, but details may change and be adapted to local situations and resources in PARE cycles: a. Audit of clinical records: We will provide an adapted and piloted version of our observation tool for case note analysis. We will identify whether change actions make MC assessments more likely to meet the MCA Code of Practice standards, in terms of general principles (criteria-focussed, evidence-based, person-centred and non-judgemental) and procedures (diagnostic and functional capacity assessment). Depending on actions, proxy variables for clinical gain, i.e. efficient use of services, crisis/relapse prevention or prompt treatment and organisational gains, i.e. reduction in complaints, fines and so on, will be considered. b. Peer observation: Interested WP2 participants will be asked to contribute to the discussion on sustainable methods of peer observation (among clinicians and/or with independent MCA advocates) and/or user/carer observation. We will offer a range of channels for participation, including mini interviews (telephone/email/text), and online or onsite focus groups. Researchers will conduct two additional site visits to contribute to observations and/or provide support and training. c. Key-informant interviews with front-line professionals and managers who regularly conduct MC assessments or are responsible for providing training and leadership (n=5x4 sites). These will explore the implementation of the first PARE cycle, challenges and how these have been/can be met; a summary of thematic analysis (*Fereday and Muir-Cochrane, 2006*) will feed into the second PARE cycle.

Second PARE cycle

W3 will refine actions or develop additional actions. These will be tested for three months in the relevant services (similar to the first PARE cycle). Stakeholders will also develop scenarios for longer-term improvements, which will be refined in W4 and national workshops.

Final site-level workshop

W4 will finalise immediate service changes and the implementation plans for longer-term or more radical service changes, e.g. requiring significant funding or organisational restructuring.

Health economics (HE) foundational analysis

The work described above will lead to a number of suggestions for improving MC assessments at the individual, developmental and organisational levels. Many of these may involve 'technical efficiency', i.e., managerial improvements that do not require additional resourcing. However, it is possible that some improvements would require resources. This might involve increased funding, but even if not, it might involve demands on people's time, which has an opportunity cost. While a formal economic evaluation is beyond the scope of this project, we will explore whether MCA assessment would benefit from additional resourcing. We will further explore qualitatively the scope of benefits that might result, which we expect to be wide-ranging and go beyond those commonly included in health economic analyses. Specifically, we will: a) embed questions within the WPs described above to elicit information about the perceived need for additional resourcing to deliver high-quality MCA assessments; b) identify and cost-specific examples of interventions with resource implications (if any), and c) explore via real and hypothetical examples potential process and outcome utilities from improved assessments to service users, staff, and the wider NHS. This might include clinical and organisational (e.g., reputational, staff wellbeing) impacts. The HE foundational analysis will highlight the resource implications of our recommendations, provide initial guidance on the value case for investment, assist stakeholders in formulating change actions and a 'business case' for them and highlight research and routine data required to strengthen this guidance strategy for HE. Outputs of HE work will be a) a qualitative assessment of how resource constraints restrict current MCA quality, b) the costing of specific enhancements developed during the action research cycles of WP3, c) a logic model for HE evaluation of practice improvements.

Cross-site workshops

A series of three cross-site workshops will include 15 participants, i.e., professionals, users and carers from WP3 workshops and national policymakers and PPI representatives in England and Wales. Common actions emerging across different sites and higher-level and longer-term management issues towards MCA implementation will be discussed. We expect that longer-term implementation issues will be around the effect of jurisdictional dynamics, the nature of knowledge to be mobilised to support assessments, and the antecedent cultural conditions that derive from managerial structures and processes (*Grove et al., 2022*; *Braun & Calnan, 2016*). Governance arrangements and processes will be discussed to identify resistance by professionals and managerial structures (*Horlick-Jones, 2005; Waring & Currie, 2009*). Based on our HE foundational analysis, we will highlight the resource implications of our recommendations, provide initial guidance on the value case for investment, and highlight research and routine data required to monitor the investment outcomes.

Analysis and outputs

Workshops will be audio-recorded and minuted initially and then fully transcribed. Critical decisions will be confirmed at the end of the workshop. Thematic analysis (*Fereday and Muir-Cochrane, 2006*) will identify emergent themes and actions to inform the following workshops. The emergent themes and actions will be refined and validated with participants in an iterative process. Depending on the actions co-designed by the workshop participants, quantitative before-after analyses will be designed with the support of the statistician and involve practice observations and/or case note analysis through the rating tool at different time points. The outputs will be a) at the site level, implementation and evaluation report for immediate actions; implementation plans for longer-term actions; b) at the national level, implementation plans for everyday immediate actions and consideration on their wider generalisability; and implementation plans for more significant systemic changes. Both, site-level and national reports, will include a general section and specific sections on the three HELPS service user groups.

Ethics TBC

5.4 WP4: PPI: implementation and evaluation (M1-30)

Procedures

The PPI lead will provide guidance and support to the research team to embed meaningful public involvement throughout the project. A Lived Experience Advisory Panel (LEAP) will be established. LEAP members recruitment will identify people with lived experience of having undergone MCA assessments in the previous five years and their informal carers. Opportunity to join the LEAP will be advertised through existing networks, including NIHR Applied Research Collaborations, Clinical Research Networks and applicants' networks). The LEAP will support the research team, meeting regularly to input into areas such as the recruitment of participants, interpretation of findings, dissemination plans, and overcoming barriers to research inclusion throughout the project. Support provided to LEAP members has been described in detail in the dedicated section.

Evaluation tools

Actions
Meetings of the LEAP will be minuted. Actions and plans for their implementation will be identified during the meetings.

Reflections

Public contributors will be asked to take reflective notes after each LEAP meeting and share them with the project team. Rapid content analyses will allow the identification of general themes. Theoretical frameworks for this analysis will be the same as for other WP and a constructivist approach will involve collaboration with and validation from LEAP members on the emerging themes.

Impact evaluation
The impact of each action on the project will be assessed using the GRIPP2 reporting checklist, a widely validated tool (*Staniszewska et al., 2017*).

Outputs

a) immediate actions impacting HELPS activities; b) a report detailing the evaluation of the PPI experience within this project c) LEAP members will help to develop user-friendly and easy-read summaries of the study findings, the study website and informative videos.

Multiple long-term conditions - study within a project (SWAP)

We will interview at least 15 service users with multiple long-term conditions (MLTC), i.e., who present with comorbidities between mental health disorders, physical health disorders and/or learning disabilities. Comorbidity is very frequent across the three service user groups considered. Hence, we expect we will be able to recruit and interview at least four participants within each of the WP2-3 sites. The interview will be analysed through thematic analysis (Clark et al., 2015; *Fereday and Muir-Cochrane, 2006*) and reported following the COREQ guidelines (*Tong et al., 2007*)

Ethics not required

6. STUDY SETTING

The HELPS project aims to improve the implementation of mental capacity (MC) assessments in England and Wales in acute and hospital care. In these settings, urgent healthcare decisions are made, and MC assessments are challenging due to limited time and competing pressures (*Lepping et al., 2015; Luke et al., 2008; Emmett et al., 2013; Willner et al., 2011; Jenkinson & Chamberlain, 2019; King, 2021; Wilson, 2017)*. The managers will be recruited in acute Trusts, mental health Trusts, local authorities and third sector or private organisations, when these organisations provide services to people from one of the target groups, i.e. people with acute physical health problems, acute mental health problems and/or learning disabilities. Non-participant observations and semi-structured interviews with users and providers will cover the North of England, the Midlands, the South of England, and Wales. Geographic areas will be characterized by different ethnic diversity and variation of professional experience for urbanicity

and social deprivation. Participants in the workshops will include service users, carers and different kinds of professionals involved in Mental Capacity Act decision-making. The catchment area for NHS services will cover England and Wales.

7. SAMPLE AND RECRUITMENT

Sample size

For WP1 we will interview service managers, frontline professionals, users and carers involved in Integrated Health Care Systems (ICS) in England and Regional Partnership Boards (RPB) in Wales. We will purposively sample the areas for geographic location (North of England, Midlands, South of England, Wales) and ethnic composition. The degree of ethnic diversity on an area level will correlate with other variables of potential relevance, such as urbanicity, social deprivation and social fragmentation (*Gov.UK., 2020)*. In addition to organisational aspects and policies for capacity assessments, we will review and integrate the most updated evidence on cultural competence assessment toolkits and discuss these findings in our interviews. We will attempt to interview three service managers (one for each of the HELPS service users' groups) per 15 ICS/RPB areas, one-third of all ICS/RPBs, i.e. 45 managers. When possible, we will interview service managers with different professional backgrounds (e.g. medical doctors, nurses, and social workers). Taking an interpretative/constructivist approach, we will construct the sampling frame, looking for a diversity of perspectives. We expect that different perspectives may come from different professional backgrounds, but we will explore that reflexively with participants and the broad research team and change our sampling strategy if required. For WP2, observations will include a minimum of 10 assessment/case note reports per area (overall 40), and we will observe at least three assessments per group per site. For the interviews, we will involve 17 participants per study area (overall 68 interviews). For WP3, we will include 6-10 core participants in 16 workshops, four per site, and each workshop may include up to 5 additional one-off participants. 15 participants will contribute to developing three cross-site workshops, including professionals, users and carers, national policymakers and PPI representatives in England and Wales.

Identification of participants

Participants will be reached through networks created during the ASSENT, the BABEL and other projects led by the applicants (*ASSENT project*; *RESPECT project*; *ARIADNE project*; *BABEL project*; *Singh et al., 2013; Heywood et al., 2019; Giacco, 2019; Giacco et al., 2018)* and through applicants' personal networks or Trusts', local authorities or relevant organisations' websites. The interviews will be carried out via phone or videoconferencing. We expect to use Microsoft Teams as it is currently approved by the University of Warwick and NHS Trusts for use and guarantees appropriate data security.

Recruitment

We will email healthcare managers to agree to an interview, which may include a virtual or in-person service visit if the managers are open to this. We will not be screening confidential data in service databases as managers' professional contacts are usually available on organisations' websites. Prior to conducting the interview, participants will be provided with an information sheet and consent form (which are attached to the IRAS application) and given the opportunity to ask any questions. After the project presentation, we will discuss the procedure related to obtaining informed consent. The final stage of the WP1 interview will explore participants' availability to be involved in the following research stages, and a visit to the site will be agreed upon to plan activities linked to the WP2 and WP3 implementation. A public campaign will reach PPIs and will be posted in the NIHR organisation "People in Research" and other similar organisations.

Consent

All managers who respond to the study information sent via email with interest will be invited to attend a face-to-face, phone or online before the WP1 interview. Researchers will go through the information sheets with potential participants and take the time to answer any questions or concerns raised. During the consent process, researchers will ensure that participants know their right to decline participation at any research stage. Before each interview, the interviewer will reformulate each consent item and double-check if the interviewee understands the information provided. When oral and written consent is obtained, the interviewer will formally start the interview. Participants will be asked to consent to the recorded interview by initiating, signing and dating an informed consent form before the interviews. Informed consent will be given via email through electronic signatures. A member of the research team will also sign completed consent forms. The participant will be sent a copy of the consent form, and the research team will retain the original. During the consent process, participants will be given the option to receive a copy of the findings from the study. This will be a lay summary of results developed with the assistance of the LEAP. Participants will also be asked if they agree to be contacted in the future for the opportunity to take part in other elements of the study. Before the observation, a research nurse will inform the patient and carer involved in the observation and will ask if they agree that the observer observes healthcare professional clinical work. Their assent will be required to start the observation, although that is previously agreed with professionals in the service. Observation will be focussed on how professionals assess mental capacity and data related to patients, and other clinical information which does not concern the assessment will not be recorded in the field notes.

Interview topic guides and procedures

The interviews are expected to last between 30 and 60 minutes. The interviews will be semi-structured, using questions outlined in Topic guides (attached to this application). Participants will be informed that they can withdraw all their data up until the end of 2024 (to allow analysis in late 2023) and that when the research is presented or published, their identity will not be disclosed. Interviews will be audio recorded using an encrypted digital recorder. After the data is analysed, all personal information on participants will be destroyed. The consent to participate in the interview and audio recording will be recorded in writing before the interview (see previous paragraph). Before turning the recorder on, the interviewer will verbally confirm the participant's consent to audio record the interview and stop the interview if this is not confirmed.

Withdrawal criteria

During the consent process, researchers will ensure that participants know their right to decline participation at any research stage and that withdrawing participation will not affect their treatment or rights. Participants who request to withdraw from their study participation will not be required to give a reason for declining or withdrawing their participation. If they also wish their data to be deleted, this will be possible before the end of December 2024. This is clarified in the PIS. If a participant wishes to withdraw from the study, researchers will record the withdrawal date and reason(s) for withdrawal (if provided). If a patient or carer involved in the observation asks for the observer to leave, observation will be immediately interrupted without asking for any reason, and the observer will abandon the observation space.

8. ETHICAL AND REGULATORY COMPLIANCE

Assessment and management of risk

Confidentiality
Information related to participants will be kept confidential and managed in accordance with the GDPR (2018), Data Protection Act (2018), NHS Caldecott Principles (UK), UK Policy Framework for Health and Social Care, and the conditions of Research Ethics Committee Approval, or corresponding legislation or approvals for a particular participating site.
To protect the identity of participants, study IDs will be created and assigned to each individual, and person-identifiable data will be stored separately in a locked filing cabinet at each participating Trust. An electronic file with restricted access (to the core HELPS research team only) will be maintained at the University of Warwick. A log will document any formal changes to the ID list.

Audio recordings

The interviews will be audio-recorded with participants' permission via Audacity software. Audio data generated via such software will be encrypted, securely stored, and shared. Any interview audio data recorded through Teams will be saved onto a restricted access folder within the University of Warwick, and interviews will be conducted on an encrypted laptop provided by the University of Warwick. These laptops are password-protected. Any interviews recorded through Teams will be transferred to Dictate2us, a transcription company that forms part of the University of Warwick's framework agreement for the Supply of Transcription Services. This supplier has been through the University's Information Security checks and has overarching Data Processing Agreements. Audio files generated through Audacity will be transferred to Dictate2us directly through their website, and the transcription will be sent back to the research team via email in the form of a Word document. The audio recordings will be destroyed immediately after transcription. The transcripts produced by Dictate2us will be saved into a restricted access folder within the University of Warwick.

Record retention and archiving:

In accordance with the UK Policy Framework for Health and Social Care Research and University of Warwick Research Data Management Policy, research data will be retained intact in an appropriate format and storage facility, for a period of at least 10 years from the date of any publication which is based upon it.

COVID-19, any return of social distancing directives:

The interviews may be conducted by researchers either online or over the phone in case of social distancing directive and/or if participants prefer that. If videoconferencing occurs, we will ensure that only audio recording is undertaken. However, if legal, safe and practical, interviews may be conducted face-to-face. Furthermore, the research team will check regularly what COVID-19 restrictions are in place in England, Scotland and Northern Ireland, and how this may impact face-to-face interviews. This involves checking the guidance and laws implemented by The UK Government. Attention will also be paid to localised restrictions. If a face-to-face interview were to be organised with a participant, the researchers will ensure they adhere to the law according to the advice provided by the Government. Examples of this include 1. Ensuring masks are worn by themselves and the participants 2. Social distancing measures are in place (minimum 2 metre distance). 3. The interview will be cancelled or reverted to online immediately if the researcher or participant are displaying symptoms of COVID-19 and therefore required to self-isolate.

Expected benefits from this research

The benefits for participants will be the opportunity of share their views and contribute to policy and practice development.

Research Ethics Committee (REC) review & reports

"The Principal Investigator will ensure that the study will be carried out in accordance with the ethical principles in the UK Policy Framework for Health and Social Care Research, with effect from November 2017 and its subsequent amendments as applicable and applicable legal and regulatory requirements".

As the University of Warwick will lead this study, before the study starts, it will require approval from the Health Research Authority (HRA) and by the University of Warwick Biomedical Science Research Ethics Committee (REC) Favourable Opinion for the study protocol, informed consent forms and other relevant documents, e.g. information sheets. We will not contact an NHS REC according to the guidelines offered in the IRAS form, that an NHS REC should not be contacted for studies focusing on staff.
Any substantial amendments requiring review by the REC will not be implemented until a favourable opinion has been granted.
The Principal Investigator will notify the REC, HRA and study sponsor of the end of the study, and will immediately notify the REC, HRA and study sponsor should the study end prematurely. This will include notification of the reasons for premature termination.

Indemnity

The study will have indemnity through a standard University of Warwick insurance scheme.

Amendments

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of the submission to the REC.

The amendment history will be tracked via version and date control of protocols.

9. PUBLIC AND PATIENT INVOLVEMENT

The PPI lead will provide guidance and support to the research team to embed meaningful public involvement throughout the project. A Lived Experience Advisory Panel (LEAP) will be established. LEAP members recruitment will identify people with lived experience of having undergone MCA assessments in the previous five years and their informal carers. Opportunity to join the LEAP will be advertised through existing networks, including NIHR Applied Research Collaborations, Clinical Research Networks and applicants' networks). Through previous engagement activity and projects (e.g. ARIADNE (*ARIADNE project*), OPAL (*OPAL project)*, BEAMS-ID (*BEAMS-ID project*), ASSENT (*ASSENT project*)), we have established links with third-sector organisations, mental health Trusts and independent carer/service user groups across the country. We will also place adverts in GP practices and seek to engage people involved in GP practices patient panels. We will engage with these groups in addition to established patient/service user groups linked to existing research networks. This will aid us in forming diverse patient/service user groups across several characteristics, including experience of involvement in research.

The LEAP will support the research team, meeting regularly to input into areas such as the recruitment of participants, interpretation of findings, dissemination plans, and overcoming barriers to research inclusion throughout the project. The dedicated section describes support provided to LEAP members in detail.

We will provide fees for one hour preparation and two-hour participation for eight people for each of seven LEAP meetings (hourly rate: £25). LEAP members will receive £515 for the participation in seven meetings (overall £3480 for eight LEAP members) and the elected LEAP chair will receive £315 in addition to this to support agenda preparation. LEAP members will receive £5 per meeting for internet/connection costs and out of pocket travel expenses for the two in-person LEAP meetings. Two LEAP meetings will be in person at Scarman and venue hire and subsistence costs will be £910.80. For two LEAP members with learning disabilities, specialised supporters appointed by Learning Disabilities England (LDE) will also attend all the LEAP meetings (£1840) and easy read and accessible materials (£4320) will be created for all the meetings by LDE. Three members of the LEAP, one for each patient group, will be involved in the preparation of videos (£1125 for 45 hours of work, to cover 15 hours of work of three people at £25/hour).

We will identify reasonable adjustments and supports needed for optimal participation in the LEAP. The general strategies will be: 1) augmenting communication and materials and ensuring our materials are shared in advance; 2) collaboratively choosing convenient times for meetings; 3) including supporters to help support meeting attendance and participation. Based on our experience (*Giacco D, Chevalier A, McNamee P, et al., 2023)*, the most helpful method for augmenting communication may be different for each LEAP member, e.g. phone calls/emails/regular posts for updates should all be considered and used depending on individual preferences. The researchers will be trained by Giacco and other clinical co-applicants to offer prompt debriefing during meetings. Giacco will be present or available during meetings to support debriefing and advise if the distressed person will require a higher level of support, informing and discussing this with local Principal Investigators.

For people with learning disabilities in particular, we have contacted Learning Disabilities England (LDE) to support our work. They will help us to recruit public contributors with learning disabilities by advertising the opportunity to be part of the project through their existing networks. Once recruited, we will assess the needs of public contributors and work with LDE to put in place the necessary support to best allow them to contribute to the LEAP. Within the application, we have budget adequately for Learning Disabilities England to assist us in providing this support to public contributors - £1,840 for LDE staff to attend each of the eight LEAP meetings, £4,320 for LDE to lead on the development of easy read and accessible materials for public contributors in advance to help ensure genuine participation from members to have additional needs. This was costed as part of the presented budget.

We will generally use easy-to-read text, appropriate fonts and succinct documents. We will use audio-visual tools to convey messages (e.g. videos summarising WP2 themes) as appropriate. We will develop study-specific materials for people with learning disabilities in collaboration with Learning Disabilities England (LDE). LDE have expertise in adapting information to improve accessibility for people with learning disabilities. These will be tailored to meet the needs of the people participating. In addition, we will consult with the newly produced ASSENT web-based guidance (whose development was led by Bunning), specifically the domain on ‘Reasonable Adjustments and Supports’. This considers language, media, context and relevance used for communication, and advises on practical strategies for optimal access. The Assent guidance can be accessed here Assent Guidance (marshallacm.co.uk)

Drawing on our experience with the ASSENT project (https://www.uea.ac.uk/groups-and-centres/assent), the meeting materials will be produced in a variety of accessible formats suited to the needs of the LEAP membership, e.g. narrated PowerPoint, graphically enhanced and simplified text.

10. DISSEMINATION POLICY

Dissemination policy

Dissemination activities will be influenced and supported by the Lived Experience Advisory Panel (LEAP). Throughout all phases of the research, we will disseminate information about the activities of the programme through different channels in order to reach a broader public audience. The LEAP will input in the design of e-learning modules for patients and carers. Three lived experience collaborators, one for each group, will be involved (15 hours each) in developing the script and reciting quotes as part of the two modules.

The outputs produced by the HELPS project will be several. Some of them will be at the site level (although they may be of interest to other similar sites), and others will be across sites and of relevance across England and Wales. 1) Site-level outputs will include a) immediate actions for service change and evaluation reports. b) implementation plans for longer-term actions. 2) Cross-site level outputs across England and Wales will include implementation plans for immediate actions which appear to be widely relevant and considerations on their wider generalisability; and implementation plans for more significant systemic generalisable changes. The site-level reports and the cross-site report for England and Wales will include a general section and specific sections on the three HELPS service user groups and on MC assessment with people with multiple long-term conditions. Audience-specific e-learning modules will be developed. Four modules will focus on managers in NHS, social care and integrated care/regional partnerships boards; four modules will focus on clinicians; two modules will be aimed at patients, carers and the interested public (these modules will also be published on the study website). All of them will have an introductory video.

Beneficiaries will be from different constituencies:

- Commissioners and service managers will be helped in planning improvements and monitoring the services they fund or manage.
- The public service users and carers will be clearer on what to expect in terms of optimal MC assessments and support for their decisions.
- Clinicians and managers will take advantage of both information materials and online interactions through the organised events to inform their practice and their engagement in challenging and changing ineffective organisational arrangements.

We will produce a bi-monthly newsletter which will be on the website. Links will be actively sent to LEAP and PAG members and study participants if they opt in to receive emails. All those who receive the newsletter will be in blind copy. Through the newsletter, participants will be updated towards the progress of the project and on the findings as they arise. Participants who

will not opt-in to be included in the newsletter will be able to access the website, and the details will be on the Participation Information Sheets for the different studies.

Authorship eligibility guidelines and any intended use of professional writers

Authorship will be determined by contribution to the study design, study management, data collection, data analysis and interpretation and writing up of the study. No professional writers will be used to write study reports.

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