GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Caerdydd a'r Fro
Cardiff and Vale University Health Board

NHS
Health Research Authority

Study Protocol

PROVISION

SHORT TITLE: Study to explore patient views of PROM data access and visualisation (PROVISION: PROm VISualisatION)

FULL TITLE: A qualitative study using focus groups to explore patient views on access to and visualisation of patient-level patient reported outcome measures (PROMs) in three exemplar clinical areas

Version 2.0 (23/03/23)

Canolfan Gwerth mewn Iechyd Cymru
Welsh Value in Health Centre

Cedar
Healthcare Technology Research Centre

Administrative details

Full title of the trial	A qualitative study using focus groups to explore patient views on access to and visualisation of patient-level patient reported outcome measures (PROMs) in three exemplar clinical areas
Short trial title / acronym	PROm VISualisION (PROVISION)
Protocol version number and date	Version 2.0 23/03/23
Chief investigator	Dr Laura Knight, Senior Researcher, Cedar, Cardiff & Vale University Health Board
Sponsor	Cardiff and Vale University Health Board
Sponsor reference	8427
Funders number	Internal funding from the Welsh Value in Health Centre
IRAS reference	319643
REC reference	22/WM/0280

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.

Chief Investigator:

Signature:
.....

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

Name: (please print):

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Contents

Abbreviations

CI	Chief Investigator
EQ-5D	EuroQol 5-dimension questionnaire
GDPR	General Data Protection Regulation
HF	Heart Failure
PAS	Post-arthroplasty surgery
PROM	Patient-Reported Outcome Measures
ViH	Value in Health

Key Study Contacts

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Funder(s)	Cedar (Cardiff & Vale UHB) will be funded to undertake all work on this study from an ongoing contract with the Wales Value in Health Centre.
Key Protocol Contributors	Dr Laura Knight (LK) Dr Judith White (JW) Dr Sally Lewis (SL) Dr Christina Lloydwin (CL) Dr Nia Jones (NJ) Michael Beddard (MB)

Study Summary

Study Title	A qualitative study using focus groups to explore patient views on the access and visualisation of patient-level patient reported outcome measures (PROMs)in three exemplar clinical areas
Research question	What are the perceptions and views of patients from 3 exemplar clinical areas about visualizing PROM data? Specifically: 1. What are the experiences of patients in relation to PROM collection and access to their own PROM? 2. What are the preferences of patients in relation to how they might access their PROM data? 3. What are the views of patients relating to how having access to their own PROM data may impact on their experience of their care? 4. What are the views of patients relating to how having access to their own PROM data may impact their condition and how they manage it? 5. What are the preferences of patients in relation to which PROM data should be displayed?
Study design	Pilot descriptive qualitative study using focus groups with patients from 3 exemplar clinical specialties.
Study participants	Patients under the care of clinical leads in 3 specialties, heart failure, epilepsy and planned hip arthroplasty. Purposive sampling in each group will be used to obtain maximum sample diversity.
Planned number of participants	Focus group (FG) participants – **two** for each of the medical conditions: • Focus group 1 (Heart failure): 4-8 (x2 FGs =8-16) • Focus group 2 (Epilepsy): 4-8 (x2 FGs =8-16) • Focus group 3 (Post hip arthroplasty surgery): 4-8 (x2 FGs =8-16) **Total number of participants: 24-48**
Planned study period	Recruitment will last up to 4 months after the study opens and the study will remain open for analysis 6 months after opening

Funding and Support in Kind

Funder(s)	Financial and non-financial support given
Welsh Value in Health Centre (WViHC)	Cedar Health Technology Research Centre (Cardiff & Vale UHB) receives funding from the WViHC to carry out research and evaluation functions.

Role of Study Sponsor and Funder

The Chief Investigator Dr Laura Knight (a representative of the study sponsor) is the first author of the protocol and has overall responsibility for its content. Subsequent iterations have been shared with collaborators for discussion and refinement of the content.

Cardiff and Vale University Health Board acts as Sponsor, fulfilling this role according to the principles of Good Clinical practice. This organisation assumes overall responsibility for the initiation and management of this study. The Sponsor has overall responsibility for the study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results, but delegates this to the CI.

Lay Summary

Patient-Reported Outcome Measures (PROMs) are standardised questionnaires that are completed by patients to gather their thoughts of their condition, wellbeing, or their perception of their health in relation to specific diseases or conditions. The collection of PROM data is widespread across the UK and is used by clinicians, government and in research. However, patients often complete PROM questionnaires but are not able to see or review the data once submitted, and so the use of individual PROM data by patients themselves is limited.

This study will use patient focus groups to gather their perspectives on what PROMs mean to them and how PROMs could be used to improve their own care. Patients will also be asked how they might like their data to be displayed for their own use and what method of viewing the PROM data they would prefer. This is a preliminary study which will invite patients who have received care in the NHS for heart failure, epilepsy and hip arthroplasty. The results of the study should establish the most effective ways of presenting patient PROM data so it is easily understood and meaningful to patients.

Study Flow Chart

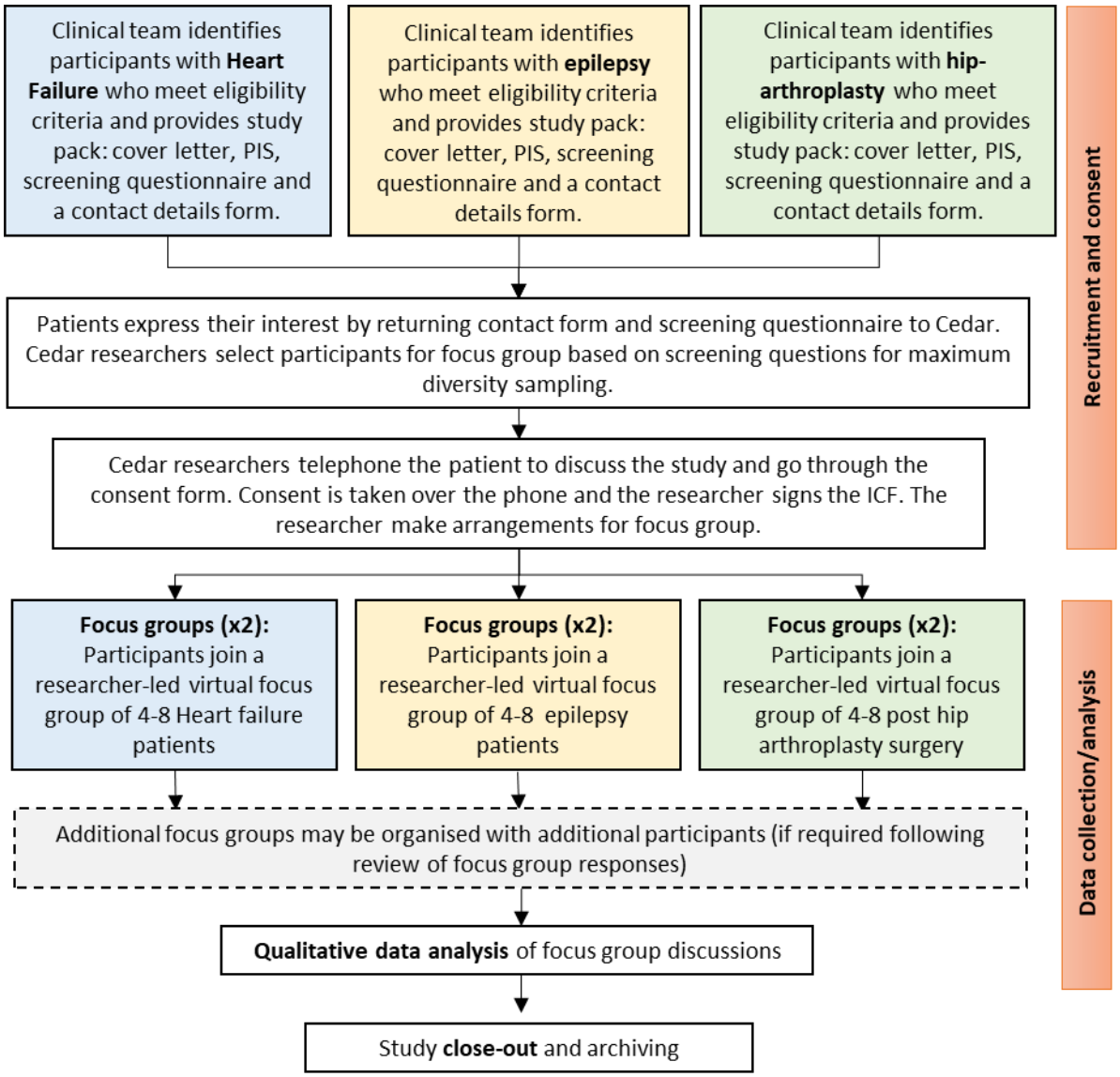

Figure 2. PROVISION study flow chart.

1. Background

1.1. Patient-reported outcome measures (PROMs)

Patient reported outcome measures (PROMs) are standardised, validated questionnaires that are completed by patients to measure their perceptions of their own functional status and wellbeing, or their perception of their health in relation to specific diseases or conditions (Dawson et al, 2010). Generic PROMs, such as EQ5D5L (Herdman et al, 2011) measure health concepts that are relevant to a wide range of patient groups, enabling aggregation and comparisons across varied conditions and settings. Condition-specific PROMs capture elements of health relevant to a particular patient group or condition.

Since 2009, the NHS in England has mandated the routine collection of PROMs from all NHS-funded patients undergoing planned hip or knee replacement, varicose vein surgery or groin hernia repair.

In Wales, a national electronic data collection platform for use in health boards has been implemented. In the UK, PROMs are one of the cornerstones of National Health Service reform for the transition towards a patient outcomes-orientated performance model (Gibbons et al, 2021).

PROMs are routinely collected in many areas of medicine in Wales, but are used primarily at the meso-level which aggregates data from within an organisation (clinic, hospital, treatment site) for clinical trials and registers, or to macro-level such as national audits using aggregated data to support policy makers to evaluate performance of providers. Historically, less emphasis has been placed on the use of PROM data at the micro-level where individual data are accessed by patients or their care team.

1.2. PROMs in direct patient care

PROM data can be used to promote patient-centred care and to facilitate patient and clinician understanding of how different treatments affect patient functioning and wellbeing over time, informing treatment decision making and, improving expectation management.

The use of PROMs in direct patient care has been well-studied, including in a recent Cochrane Review by Gibbons et al. (2021). The Cochrane review identified 116 randomised trials which assessed the effectiveness of PROMs feedback in improving processes or outcomes of care in a broad range of disciplines. The review found that feeding back patient questionnaire responses to healthcare workers and patients probably slightly improves quality of life and increases communication between patients and their doctors, but probably does not make a lot of difference to social functioning.

A recent systematic review has been conducted to report on patient and clinician experiences of using PROMs in clinical practice to inform the management of individual patients (Campbell et al., 2021). The review identified 52 articles and synthesised evidence indicated that both patients and clinicians reported many benefits of using PROMs in clinic.

These include five key benefits:

(1) promoting active patient involvement in their care by facilitating goal setting, and permitting discussion of sensitive topics;
(2) enhancing the focus of consultations by prioritizing care around patient needs;
(3) improving quality of care by enabling tailored, holistic care and prompting appropriate action;
(4) enabling standardized monitoring of outcomes over time to monitor PROM changes and track progress;
(5) enhancing the patient-clinician relationship by reassuring patients that clinicians care.

A number of limitations were also identified such as the capacity for PROMs to negatively shift the focus of consultations and reduce quality of care by inaccurately estimating symptoms and raising expectations for care that exceed clinicians' resources. In some studies, PROMs were reported to inhibit the patient-clinician relationship, lack clinically meaningful information and were not considered suitable for all patients.

1.3. PROM data visualisation

Data visualisation refers to a set of tools and approaches to explore, synthesise, display and communicate large amounts of data. Research suggests that the meaning of data is easier to understand when presented visually, and more effective than language or numbers alone (Szabo et al., 2019). For the information presented to be useful to patients and clinicians, it needs to be easily interpretable and meaningful, and not overburden the recipient with detail. Potential data visualisation approaches include:

- Numeric
- Graphical
- Pictorial
- Interactive

Pictographic presentation of data is generally well understood and accepted and has been advocated for risk communication (Gutacker et al, 2017). Snyder et al. (2019) conducted a stakeholder-driven, evidence-based, modified-Delphi process to develop recommendations for displaying PROM data in three different applications; one of which was individual patient data for monitoring/management. They found that when presenting individual patient PROM scores, there is value in using consistent representation and line graphs are the preferred approach. There should also be reference values for comparison populations if they are available. It was also important to show results that are possibly concerning in absolute terms, assuming the data to support a concerning range of results are available (Snyder et al., 2019).

In a study into longitudinal PROM data visualisation by patients, Stonbraker and colleagues found that participants preferred bar graphs that incorporated emojis which was also the easiest format for participants to interpret. Participants commented that there is not a 'one size fits all' format for visualizing longitudinal PROM data. These findings are consistent with much of the literature regarding preferred visualisations. Additional design considerations recommended by participants, consistent with the literature, are to use simple images that incorporate large fonts and bright meaningful colours (Stonbraker et al., 2020).

1.4. Programme of work

This project forms the first step in a programme of work by the Welsh Value in Health Centre to investigate the use of PROM visualisations in patient care. The outcomes of this project will be used to inform the development of a logic model for patient provided individual PROMs. Future work in this programme will explore the views of clinicians, health board leadership and technology experts followed by the developing and testing of prototype PROM visualisations.

2. Rationale

More emphasis is needed to facilitate patient access to their routinely collected PROM data, and their use in direct patient care. To do this, PROM data should be easily accessible and presented in a way which patients find useful such as using pictorial or graphical formats to track progress over time. This may be different to how clinicians and researchers wish to see PROM data. Patient-friendly visualisations may be developed for patients to use them in their home environment such as on a tablet/app or computer, without the help or guidance of a healthcare professional. Few studies

exist which aim to assess patient views in relation to whether and how they might wish to see their PROM data as part of their direct care. This pilot study aims to build on what we know about the value of PROMs as an aid to patient communication by exploring patient perspectives relating to how PROMs can be accessed and visualised. This is the first step to developing and implementing a patient-friendly model for visualisation of PROM data (which will be carried out in subsequent studies).

2.1. Clinical specialties of interest

Three exemplar clinical specialties have been selected to explore patient views across a diverse range of conditions. Hip arthroplasty, heart failure and epilepsy patients will be recruited from Cardiff and Vale University Health Board (CAVUHB).

2.1.1. Heart Failure (HF)

Heart failure occurs when the heart is unable to pump blood around the body properly. PROMs data is currently routinely collected from HF patients in Wales, therefore recruiting these patients has the added benefit of familiarity with PROMs. This patient group may also benefit from utilising their PROMs data to improve their symptom recognition and track symptom burden.

2.1.2. Epilepsy

Epilepsy is a common condition that affects the brain and causes seizures. As an overall patient group, those with epilepsy are younger than those with HF (Fiest et al., 2017; Taylor et al., 2019). Therefore, the inclusion of epilepsy patients is intended to widen the demographic characteristics recruited to this study.

2.1.3. Hip arthroplasty

It was considered that the experiences of patients undergoing episodic care may differ from those with chronic conditions in relation to their views on access to their PROMs data. The addition of this patient group will allow that questions to be explored and thus provide an overall sample that's more representative of patients overall.

3. Research objectives

The objective of this study is to use focus groups to explore the views of patients from 3 exemplar clinical areas regarding access to and visualising individual (patient-level) PROM data in direct patient care.

3.1. Research questions

1. What are the experiences of patients in relation to PROM collection and access to their own PROM?
2. What are the preferences of patients in relation to how they might access their PROM data?
3. What are the views of patients relating to how having access to their own PROM data may impact on their experience of their care?
4. What are the views of patients relating to how having access to their own PROM data may impact their condition and how they manage it?

5. What are the preferences of patients in relation to which PROM data should be displayed?

3.2. Operational objectives

We will:

1. Work with clinical leads to recruit a maximum variety sample of 4-8 patient participants from 3 clinical specialities each (HF, epilepsy, hip arthroplasty) aiming to represent a diversity of clinical, social, and personal demographics, and in health and IT literacy through the use of a screening questionnaire.
2. Cedar to carry out 2 remote focus groups with each clinical specialty to explore: patient understanding of PROMs and the data generated; patient views on how access to data may impact on their care and condition; initial patient preferences around how PROM data might be visualised.
3. The focus groups will be transcribed. This may involve the use of an external transcription company.
4. Transcripts will be analysed using thematic analysis.
5. If data saturation is not achieved during the focus groups and variation in responses is wide, the research team may conduct further focus groups to reach a wider cohort of patients in each of the 3 clinical specialties.
6. Compile findings report for publication in peer-reviewed journal. Also disseminate report for lay audience.
7. Use findings to plan next phase of research to develop and implement model for visualising PROM data in direct patient care.

4. Theoretical framework

This is predominantly a qualitative descriptive study for understanding the perspectives of patients as stakeholders on the visualisation of individual PROM data in direct patient care. Unlike traditional qualitative methodologies such as grounded theory (GT), which are built upon a particular, prescribed collection of steps, qualitative description is grounded in the general principles of naturalistic inquiry (Colorafi et al, 2016). The most frequently proposed rationale for the use of a descriptive approach is to provide straightforward descriptions of experiences and perceptions (Sandelowski, 2010), particularly in areas where little is known about the topic under investigation.

The study will touch upon aspects from the nonadoption, abandonment, scale-up, spread, and sustainability (NASSS) technology implementation framework (Greenhalgh et al, 2017), which will be addressed more thoroughly in the overall programme of work. The six domains within this framework are the health condition, the technology, the value proposition to patients, the adopter system (family physician and patient), the health care organization (including attention to implementation and adaptation), and the wider system (related political, regulatory, legal, professional, and sociocultural factors). We propose to use the framework prospectively and in real time to explore patients view on the usefulness of PROM data visualisation.

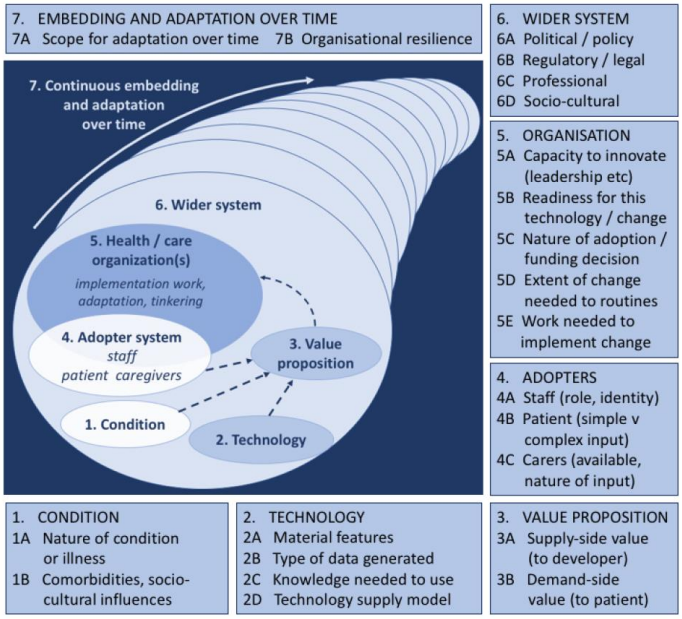

Figure 2: NASS technology implementation framework diagram

As this study is patient-focused, it will use the Capability, Opportunity and Motivation Model of Behaviour (COM-B model)(Michie et al., 2011), to develop topic guides and support analyses of patient views on whether access to their PROM data would support them in managing their health conditions. The COM-B model indicates that individuals require the capability, opportunity and motivation in order to successfully adopt and maintain new behaviours.

5. Study Design

This is a qualitative study which aims to elicit the views of patients on the visualisation of individual PROM data in direct patient care. Data will be collected through two rounds of focus groups (with the option for a third if required). Focus groups are an appropriate method of data collection to answer the study research questions seeking to explore views and perspectives of patients, where our analysis will aim to define key themes and points of consensus or divergence gathered through interaction. Patients will be presented with example data displays and ask to provide their views. Thematic analysis will be used to identify emergent recurring and/or salient themes in the focus group data. The themes will form the basis for recommendations to support the development of a model for visualising PROM data in direct patient care. Researchers will develop a list of key open-ended questions in a topic guide to be discussed in the first focus group, and where necessary, will include questions specific to each of the condition-specific PROM tools.

6. Data Collection and Analysis

6.1. Focus groups

Focus group discussion will be carried out by two researchers from Cedar (Cardiff & Vale UHB) who have experience in qualitative research. Each focus group is expected to last up to 90 minutes. They will be conducted via the NHS-approved secure Microsoft Teams platform, with the option to call in

using a telephone if participants are uncomfortable with videoconferencing software. The focus groups will be recorded on Microsoft Teams and also using voice recorders. The list of key open-ended questions (Appendix 1) will be used as a topic guide explore the patient's perceptions and their preferences on the use of their PROM data. The focus group discussions will be transcribed verbatim. Inductive thematic analysis will be carried out and preliminary coding structures will be developed for organizing the data thematically. NVivo (QSR International) will be used to help organise the data.

7. Study Setting

The study focus groups will be carried out remotely using Microsoft Teams. Patients under the care of three clinical specialties will be recruited to the study:

- **Heart Failure:** Zaheer Yousef (Cardiff and Vale University Health Board), Consultant Cardiologist
- **Epilepsy:** Khalid Hamandi (Cardiff and Vale University Health Board), Consultant Neurologist
- **Planned hip arthroplasty:** Phill Thomas (Cardiff and Vale University Health Board), Consultant Trauma and Orthopaedic Surgeon

NHS researchers from Cedar Health Technology Research Centre (Cardiff & Vale UHB) will carry out the focus groups, analyse the results, and report the findings.

8. Sample and Recruitment

8.1. Sampling

Purposive sampling will be used in this qualitative study to capture the breadth of experience of patients in three clinical specialties. In purposive sampling the aim is not to statistically 'reproduce' the characteristics of the total population, but rather to choose patients who may reveal important insights into the subject area. We will seek a maximum variation, sample of 8-16 patients from each of the 3 specialties (total of 24-48 patients within the whole study), with variety in factors such as clinical, social, and personal circumstances, and in health and IT literacy. We will achieve this by initially inviting all eligible patients to take part, and as cases accumulate we will actively seek out participants whose demographics are different to those already recruited.

8.2. Recruitment and consent

Delegated members of the care team from the 3 clinical specialties will identify potentially eligible participants using the inclusion criteria and provide them with information about the study. For each medical condition, two focus groups of between 4-8 patients will be created (24-48 participants in total in the study). Once identified as eligible, each potential participant will be given an invitation pack in person during a clinic visit to take home or by post. The invitation pack will contain the following:

i. cover letter from the clinical lead at that health board:
ii. patient information sheet;
iii. contact slip to express an interest in taking part;

iv. screening questionnaire (to enable researchers to select patients for inclusion in the focus group).

Patients will be asked to complete the contact slip and screening questionnaire and return these to Cedar (Cardiff & Vale UHB) using a stamped addressed envelope provided in the pack. On receipt of this information, a researcher at Cedar will then assess the screening questionnaires to identify those who can contribute to the maximum diversity sample (i.e. participants whose demographics are least similar to those already recruited). Once identified, a researcher will ring the patient and go through a consent form over the phone and initial and sign the consent form. Patients will be given the option to have a copy of the consent form sent to them if they wish. Taking consent over the phone offers a better option than simply asking the patient to sign the form in person at home because it allows a researcher to go through each point clearly and address any questions from the patient.

The researcher will then get the participants availability in order to arrange the focus groups. Those who have not been selected to take part in the focus groups, due to the sampling strategy, will be informed via, phone, email or post and their data destroyed. A member of the research team will be contactable by phone or email to respond to queries from patients.

Once numbers of between 4-8 for each clinical specialty is reached, focus groups will then be conducted using Microsoft Teams video call function and facilitated by 2 focus-group coordinators from Cedar (Cardiff & Vale UHB). Once the focus group begins, the names of coordinators and each participant will be visible on Microsoft teams, removing the need for name tags. Participants will also be given instructions to provide an “anon” name if they do not wish to share their name with the focus group. Researchers will also ask for verbal consent from all participants to record the meeting from the outset. The coordinators will familiarise themselves with the script, group dynamics, and equipment operation at the beginning of the focus group and introduce themselves. Verbal consent will be gained again to confirm that participants are happy to continue before the focus groups commence. Randomised self-introduction will be used for each of the participants. Confidentiality and ground rules will also be discussed. Investigators will collect sex, diagnosis of patients, age, ethnicity, and level of health and IT literacy ahead of the focus group.

8.3. Eligibility Criteria

8.3.1. Inclusion criteria

- Patients with a diagnosis of either Epilepsy, Heart failure, or patients who have undergone hip surgery (arthroplasty) within the last 12 months/years.
- Patients aged 18 years or over
- Patient lives in Wales
- Patient receives their healthcare in Wales

8.3.2. Exclusion criteria

- Patients unable to provide informed consent
- Patients on end of life care pathway

8.4. Size of sample

An estimated sample of 8-16 participants per clinical specialty will be recruited as a suitable size for a focus group study. Group sizes larger than 4-8 may become difficult to control virtually and can limit each person's opportunity to share insights and observations.

9. Ethical and Regulatory Considerations

The study will be conducted in compliance with the principles of the Declaration of Helsinki (2013) and the principles of Good Clinical Practice and in accordance with all applicable regulatory guidance, including but not limited to the Research Governance Framework for Health and Social Care (England).

This protocol and related documents (and any subsequent amendments) will be submitted for review to the relevant parties. Annual progress and safety reports and a final report at the conclusion of the study will be submitted to the REC within the timelines defined.

A project risk register will be established and maintained by Cedar researchers. Risks, issues and opportunities are regularly reviewed at internal project progress meetings. Monitoring and auditing of study conduct will be proportionate to the low-risk nature of this study, in accordance with local policies and procedures.

It will be made clear to participants during the informed consent process that if they disclose information of a serious, sensitive nature about themselves or others (for example, by referring to unsafe or illegal patient care practices), it will be reported to the PROVISION Chief Investigator and Cardiff and Vale University Health Board.

9.1. Regulatory Review & Compliance

Before the start of the study, approval will be sought from Health Care Research Wales (HCRW) and REC for the protocol, informed consent forms and other relevant documents. Amendments that require review by HCRW and REC will not be implemented until approval is granted.

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

A progress report will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended. It is the CI's responsibility to produce the annual reports as required. The CI will notify the REC of the end of the study. If the study is ended prematurely, the CI will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the CI will submit a final report with the results, including any publications/abstracts, to the REC.

9.2. Peer review

The protocol has undergone scientific review by a person independent of the study and with relevant experience. Furthermore, the protocol has been reviewed by C&V UHB as part of the Sponsor Assessment Meeting.

The study will be assessed for governance and legal compliance by HCRW. Once all checks are satisfied HCRW will issue HRA/HCRW approval. The study should not commence until local confirmation of capacity and capability is also received via email by the CI/ PI.

9.3. Patient & Public Involvement

Given the preliminary nature of this qualitative focus group study, we have not included a PPI representative as part of the trial management group.

10. Data protection and patient confidentiality

The study will take place in Cardiff and Vale UHB. Cardiff and Vale UHB will act to identify patients that appear to be eligible to take part in the study and post information packs to these patients. The patients will return consent forms, a contact form and a screening questionnaire to Cedar (Cardiff and Vale UHB) if they are interested in participating in the study.

All investigators and researchers must comply with the requirements of the General Data Protection Regulation EU (2016/679) with regards to the collection, storage, processing and disclosure of personal information. Study data will be stored and processed on secure NHS servers at Cardiff & Vale University Health Board; the data controller for this organisation is Cardiff and Vale University Health Board. Only authorised Cedar staff will be granted access to study data.

Data collected during the course of the study will be kept strictly confidential and accessed only by members of the study team. Recordings of the virtual Microsoft teams focus group will be saved on Cardiff & Vale UHB servers and will be kept confidential. Recordings and any participant personal details (name, address, contact details) will be stored at Cedar under the guidelines of the General Data Protection Regulation (GDPR), and used only for arranging the focus groups. Transcription may be carried out by an external company, in this case a company registered with the Information Commissioner's Office will be used and data will be processed in like with both the General Data Protection Regulation and the Data Protection act 2018. Cedar will request that the company destroy their copies of the transcripts following receipt. Transcripts will be stored on a password protected computer in Cardiff and Vale UHB for 5 years. Recordings will be deleted following transcription. Participants will be allocated an individual specific trial number which will be used to identify their data/responses in focus groups.

Participants' rights to access, change or move their information are limited, as the information needs to be managed in specific ways in order for the research to be reliable and accurate. If a participant withdraws from the study, the information about them that has already obtained will be retained, with the exception of their personal identifiable data.

Study data will be archived in accordance with the Cardiff & Vale UHB Archiving of Clinical Trial and Research Study Data Standard Operating Procedure. No personal identifiable data relating to patients will be retained beyond the end of the study.

10.1. Access to the final study dataset

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations. The full, final study dataset and focus group transcripts will only be accessible to Cedar staff (Cardiff & Vale UHB). The

full dataset is not expected to be made available for secondary research, due to small sample sizes within subgroups. In accordance with standard measures to prevent statistical disclosure, quantitative data relating to five or fewer individuals will be aggregated or redacted prior to publication. Similarly, full focus group transcripts will not be made available to external individuals or organisations due to the possibility of statistical disclosure from these qualitative data.

10.2. Archiving

The Trial Master File (TMF) containing essential documents will be archived at an approved storage facility for a minimum of 5 years after the end of the study. Trial data will not be destroyed without written permission from the sponsor who is responsible for ensuring trial data is archived appropriately.

11. Dissemination Policy

Ownership of the data arising from this study resides with the study team and their respective employers. On completion of the study, the study data will be analysed and tabulated, and a study report will be prepared. The study will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guideline. The study report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study. Summaries of results will also be made available to Investigators for dissemination within their clinical areas (where appropriate and according to their discretion). Study results will be published in a peer-reviewed scientific journal on an 'Open Access' basis so that they are freely available to anybody with internet access. Any publication would be in a journal that is peer reviewed and included in major evidence databases such as MEDLINE. The study report will follow the journal's authorship criteria and will acknowledge the contributions made by everyone related to the study.

The Welsh Value in Health Centre will be provided with regular updates and a final report on the study findings but will not have access to transcripts or any other identifiable data.

A lay language report of the study will be made publicly available on the Cedar website.

The study will benefit patients by helping them understand the purpose of PROMs, and how they can be used to improve their own care by enabling visualisation of the PROM data.

Researchers aim to present the findings at the National PROMs Annual UK Research Conference.

12. References

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