Full Study Title: Using the outcome prioritisation tool to elicit health outcome priorities of multi-morbid patients in a multi-age and multi-ethnic setting

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Confidentiality Statement

All information contained within this protocol is regarded as, and must be kept confidential.  No part of it may be disclosed by any Receiving Party to any Third Party, at any time, or in any form without the express written permission from the Chief Author/Investigator and / or Sponsor.

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TABLE OF CONTENTS

[1. AMENDMENT HISTORY 6](#_Toc33445180)

[2. SYNOPSIS 7](#_Toc33445181)

[3. ABBREVIATIONS 8](#_Toc33445182)

[4. BACKGROUND AND RATIONALE 9](#_Toc33445183)

[5. OBJECTIVES 10](#_Toc33445184)

[5.1 Primary Objectives 10](#_Toc33445185)

[6. STUDY DESIGN 11](#_Toc33445186)

[6.1 Summary of Study Design 11](#_Toc33445187)

[6.2 Questionnaire measures 11](#_Toc33445188)

[7. STUDY PARTICIPANTS 12](#_Toc33445189)

[7.1 Overall Description of Study Participants: 12](#_Toc33445190)

[7.2 Inclusion Criteria: 12](#_Toc33445191)

[7.3 Exclusion Criteria: 12](#_Toc33445192)

[8. STUDY PROCEDURES 13](#_Toc33445193)

[8.1 Informed Consent 13](#_Toc33445194)

[8.2 Screening and Eligibility Assessment 13](#_Toc33445195)

[8.3 Definition of End of Study 14](#_Toc33445196)

[8.4 Discontinuation/Withdrawal of Participants from Study Treatment 14](#_Toc33445197)

[8.5 Source Data 14](#_Toc33445198)

[9. SAFETY REPORTING 15](#_Toc33445200)

[10. STATISTICS 16](#_Toc33445201)

[10.1 Description of Statistical Methods 16](#_Toc33445202)

[10.2 The Number of Participants. 16](#_Toc33445203)

[10.3 The Level of Statistical Significance 16](#_Toc33445204)

[10.4 Criteria for the early termination of the study. 16](#_Toc33445205)

[10.5 Procedure for Accounting for Missing, Unused, and Spurious Data. 16](#_Toc33445206)

[10.6 Procedures for Reporting any Deviation(s) from the Original Statistical Plan 16](#_Toc33445207)

[10.7 Inclusion in Analysis 16](#_Toc33445208)

[11. DIRECT ACCESS TO SOURCE DATA/DOCUMENTS 17](#_Toc33445209)

[12. QUALITY CONTROL AND QUALITY ASSURANCE PROCEDURES 18](#_Toc33445210)

[13. CODES OF PRACTICE AND REGULATIONS 19](#_Toc33445211)

[13.1 Ethics 19](#_Toc33445212)

[13.2 Sponsor Standard Operating Procedures 19](#_Toc33445213)

[13.3 Declaration of Helsinki 19](#_Toc33445214)

[13.4 ICH Guidelines for Good Clinical Practice 19](#_Toc33445215)

[13.5 Approvals 19](#_Toc33445216)

[13.6 Participant Confidentiality 19](#_Toc33445217)

[14. DATA HANDLING AND RECORD KEEPING 20](#_Toc33445218)

[15. FINANCING AND INSURANCE 21](#_Toc33445219)

[16. PUBLICATION POLICY 22](#_Toc33445220)

[17. REFERENCES 23](#_Toc33445221)

# AMENDMENT HISTORY

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| **Amendment No.** | **Protocol Version No.** | **Date issued** | **Author(s) of changes** | **Details of Changes made** |
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# SYNOPSIS

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| --- | --- |
| **Study Title** | Using the outcome prioritisation tool to elicit health outcome priorities of multi-morbid patients in a multi-age and multi-ethnic setting |
| **Internal ref. no.** | 0763 |
|  |  |
| **Study Design** | Cross-sectional questionnaire  |
| **Study Participants** | Patients aged 45 or above and suffering from at least two or more long-term chronic health conditions.  |
| **Planned Sample Size** | 2000 |
| **Follow-up duration** | N/A |
| **Planned Study Period** | 24 months  |
| **Primary Objective** | To investigate the patient-reported relevance, ease of use and patient-perceived usefulness of the outcome prioritisation tool to ascertain the health outcome priorities of a multi-morbid population in a multi-age and multi-ethnic setting. |
| **Secondary Objectives** | To describe the health outcome priorities of patients by clusters of multi-morbidities and by age categories and different ethnic groups. |
| **Primary Endpoint** | N/A  |
| **Secondary Endpoints** | N/A |
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# ABBREVIATIONS

AE Adverse event

AR Adverse reaction

CI Chief Investigator

CRA Clinical Research Associate (Monitor)

CRF Case Report Form

CRO Contract Research Organisation

CT Clinical Trials

EC Ethics Committee (see REC)

GCP Good Clinical Practice

GP General Practitioner

OPT Outcome prioritisation tool

ICF Informed Consent Form

NHS National Health Service

NRES National Research Ethics Service

PI Principal Investigator

PIL/S Participant/ Patient Information Leaflet/Sheet

R&D NHS Trust R&D Department

REC Research Ethics Committee

SAE Serious Adverse Event

SAR Serious Adverse Reaction

SOP Standard Operating Procedure

SUSAR Suspected Unexpected Serious Adverse Reactions

SMF Study Master File

# BACKGROUND AND RATIONALE

Finding ways to improve the management of multimorbidity has been identified as a priority for health research [1]. It has been agreed that the delivery of patient-centred care, with the incorporation of patients’ priorities and preferences into decision-making, is key to the effective management of multi-morbidity [2], and the National Institute of Health and Care Excellence (NICE) highlights the inclusion of the patients’ priorities, values and goals, in their quality standards for the management of multimorbidity. Fried et al previously developed the outcome prioritisation tool, a simple tool to facilitate clinicians in ascertaining the health outcome priorities of their patients [3]. In this tool, patients are asked to rate between a scale of 0 to 100, how important four health outcomes are for them (maintaining independence, staying alive, reducing pain, reducing other symptoms), and therefore facilitates patients in prioritising the outcomes of their healthcare[3].

The feasibility of using the tool to elicit the priorities of multi-morbid patients aged over 65 [3, 4], and to facilitate medication review for multi-morbid patients aged over 65 [5, 6], has previously been investigated in the USA and the Netherlands. However, the outcome prioritisation tool has yet to be applied to a UK population, particularly a multi-ethnic population such as in the East Midlands. Moreover, little research has been done to investigate the health outcome priorities of multi-morbid patients under the age of 65, and the usability and relevance of the outcome prioritisation tool to elicit the priorities of multi-morbid patients under the age of 65 has not been investigated so far. Whilst a higher proportion of older adults (aged over 65) suffer from multi-morbidity [7], the prevalence of multi-morbidity in younger patients (aged under 65) is also high, and increasing [8]. Amongst those aged under 65, multi-morbidity is most prevalent in patients aged 45-64 [7].

The primary objective of this study is to investigate the patient-reported relevance, ease of use and patient-perceived usefulness of the outcome prioritisation tool to ascertain the health outcome priorities of multi-morbid patients in a multi-age and multi-ethnic setting. The secondary objectives of this study are to describe the health outcome priorities of patients by clusters of multi-morbidities and by age categories and different ethnic groups. The study population will be multi-morbid patients, defined as suffering two or more chronic conditions and aged 45 or above, in order to allow a comparison of prioritisation by age categories. We will also include a multi-ethnic population to determine if there are differences in prioritisation of people of different ethnicities. The benefits of this study are that its results can be used to determine whether the outcome prioritisation tool can be effectively used to ascertain the priorities of both middle-aged and older multi-morbid patients in primary care consultations in a UK setting. The results of this study will also make a novel contribution to existing literature on the health outcome priorities of a multi-ethnic multi-morbid population.

# OBJECTIVES

##

##  5.1 Primary Objectives

To investigate the patient-reported relevance, ease of use and patient-perceived usefulness of the outcome prioritisation tool to ascertain the health outcome priorities of multi-morbid patients in a multi-age and multi-ethnic setting.

5.2 Secondary objectives

To describe the health outcome priorities of patients by clusters of multi-morbidities and by age categories and different ethnic groups.

# STUDY DESIGN

## 6.1 Summary of Study Design

This is a cross-sectional study using a questionnaire for self-completion by patients aged 45 or above and suffering from at least two long-term conditions, in GP practice settings across the east midlands.

## 6.2 Questionnaire measures

The study questionnaire will measure participants’ basic demographic data including age, sex, ethnicity, and socio-demographic status (employment and education status). Participants’ history in terms of their long-term conditions and number of regular prescribed medications will also be measured. Participants’ health outcome priorities will be measured using the outcome prioritisation tool [3], and three Likert scale questions to be completed by participants after completing the outcome prioritisation tool will measure the relevance, ease of use and patient-perceived usefulness of the outcome prioritisation tool for multi morbid patients from a variety of age categories and ethnic backgrounds.

We conducted a patient and public involvement focus group with patients who fall under our study group to review the study documentation, including the participant information sheet and questionnaire booklet. The aim of this session was to obtain feedback regarding the readability and ease of understanding of these documents, and any suggestions for improvement. The feedback obtained from this session was used to amend the questionnaire to improve its readability and ease of understanding.

# STUDY PARTICIPANTS

## Overall Description of Study Participants:

The study participants will be patients suffering from at least two defined long-term physical or mental health conditions.

## Inclusion Criteria:

* Participants who are aged 45 or above and are suffering from at least two defined, long-term physical and/or mental health conditions, with no restriction by ethnicity or gender.
* Participants who are willing to participate in the study.

## Exclusion Criteria:

* Participants who are aged below 45 years of age.
* Participants not suffering from at least two long-term physical and/or mental health conditions.

# STUDY PROCEDURES

## 8.1 Informed Consent

Written versions of the participant information sheet will be presented to the participants detailing no less than: the exact nature of the study; the implications and constraints of the protocol; and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information, and the opportunity to question members of the practice team including the reception team, practice manager, nurses and GPs regarding participation in the study, or contact a member of the research team for further information.

We will not be collecting any identifiable data from participants and therefore the completed questionnaire booklets will be fully anonymised from the outset. We felt that introducing a formal written consent procedure would lead to the recording and collection of identifiable data (such as participants' name) which is otherwise not required for this study. Therefore, we have made the decision to not seek formal written consent, and instead assume implied consent from participants making the choice to complete the questionnaire booklets, after being presented with the participant information sheet.

## 8.2 Screening and Eligibility Assessment

Participating practices will receive information regarding the study background and particulars, including the eligibility criteria and information to be given to patients who are considering participating and also patients who are willing to participate in the study. This will include explaining that this is a research study, directing patients to read the participant information sheet for further information, explaining that participation is entirely voluntary and that patients can decline to participate or withdraw participation from the study at any time.

Potential participants will be identified by members of the direct care teams in the participating practices using practice records. Eligible patients will be sent a link to the participant information sheet and online questionnaire via text or e-mail, by the administration teams in the participating practices, with a brief message introducing the study, and an invitation to follow the link to read the participant information sheet for further information.

Once the social distancing measures put in place due to the COVID 19 pandemic are lifted, eligible patients will also be approached when they attend for their routine appointments. Eligible patients will be offered a PIS and questionnaire booklet by the reception team or another member of the practice team, and practice staff, such as the reception team, practice managers, GPs or nurses, will provide a brief introduction to the study to prospective participants. The practice staff will clarify with the patient if they have already been approached previously regarding this study, and if the patient had already been approached previously and had chosen not to participate in the study, they will not provide the patient with any further information regarding the study unless the patient wishes to receive this information. To ensure that participants completing an automated check-in for their appointment are also represented, posters outlining the inclusion criteria for the study will also be displayed at the participating practices, asking potential participants to review the PIS and questionnaire booklet and speak to a member of the practice staff or contact the study team for further information regarding the study if required.

Participants willing to complete the questionnaire online will be able to do so after confirming that they have read the participant information sheet. They will be able to submit their responses by clicking on the “submit” button after completing the questionnaire. The responses will be captured and stored onto a secure database through REDCap software. There will be no capture or storage of any personal or identifying information.

Participants willing to participate by completing the paper questionnaire booklet will have the option of completing the questionnaire either immediately before or after their appointment, and return it to a secure post-box in the reception area. This secure post-box will be regularly emptied by a member of the study team. If the participant is still completing the questionnaire when they are called in for their appointment, practice staff will have the discretionary option of assisting the patient in completing the questionnaire during the consultation, or asking the patient to defer completion of the questionnaire until after the consultation is completed. If participants wish to take the questionnaire home with them to complete, they will have the option of posting the completed questionnaire to the research team in a pre-paid and self-addressed envelope, or returning it to the reception team at their practice at another time. Participants can collect the pre-paid, self-addressed envelopes at their practice reception desk.

All completed questionnaires will be screened for eligibility prior to the data from the questionnaire being entered onto the study database, and data from questionnaires completed by ineligible participants will not be entered onto the study database. The questionnaires completed by ineligible participants will be shredded.

## 8.3 Definition of End of Study

Participant’s involvement in the study will cease when they return their completed questionnaire. The data collection will end when a minimum of 2000 questionnaire responses have been collected within the study period (24 months).The study will end when all questionnaire data has been analysed.

## 8.4 Discontinuation/Withdrawal of Participants from Study Treatment

 Participants may wish to decline participation in the questionnaire study and can do so with no effects on their future treatment. This may be by declining to take a questionnaire or deciding not to return a questionnaire that they did accept. In addition, the investigator may exclude a returned questionnaire from the study if the inclusion criteria are not met.

## 8.5 Source Data

Source documents will include completed questionnaires. There will be no case report forms.

# SAFETY REPORTING

##

Adverse events are not anticipated and will not be collected.

# STATISTICS

## 10.1 Description of Statistical Methods

The responses to the outcome prioritisation tool will be described by summary statistics and reporting of the highest ranked outcomes. The three responses to the Likert scale questions will also be combined and reported out of 100% as an overall mean (SD). Analyses will be carried out using the t-test to look for differences in health outcome priorities and categorical variables in the participants’ demographic information (such as ethnicity). Correlations will be sought between continuous variables in participants' demographic information (such as age) and health outcome priorities.

## 10.2 The Number of Participants.

In addition to the online questionnaires, we will print 4000 participant information sheet and questionnaire booklets and aim for a 50% response rate. Sample size will be driven by response rate and hence we have not set a formal sample size estimate. We will carry out retrospective review of power for any statistical comparisons made within data set

## 10.3 The Level of Statistical Significance

The level of statistical significance for all statistical tests will be 5%

## 10.4 Criteria for the early termination of the study.

None

## 10.5 Procedure for Accounting for Missing, Unused, and Spurious Data.

Any missing or spurious data will be excluded from the study. Rigorous measures will be taken to ensure that all of completed questionnaires are incorporated in the analytic process. However if any unused data is found, and the decision to include or exclude the data will be made after discussion with the lead researcher’s supervisor.

## 10.6 Procedures for Reporting any Deviation(s) from the Original Statistical Plan

Any deviations from the original statistical plan will be discussed with the lead researcher’s academic supervisor and will be made clear in the final report of the study and any other presentation of its results

## 10.7 Inclusion in Analysis

All eligible participants who have completed the tool and answered the survey questions after completing the tool.

# DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

All data will be stored securely in a study box at each recruitment location. Practice staff shall only have access to the study documents before the participants complete them. Once a participant has completed their questionnaire, these will be stored in a secure box to be collected by the study team. Receptionists/staff will be instructed to store the secure box in a locked office/cupboard outside of opening hours. Once a member of the study team collects the documents from each location, they will be securely transferred to the Leicester Diabetes Centre where they will be securely stored. The completed questionnaire booklets will not contain any identifiable data and will be anonymous from the outset.

# QUALITY CONTROL AND QUALITY ASSURANCE PROCEDURES

The study will be conducted in accordance with the current approved protocol, ICH GCP, r elevant regulations and standard operating procedures.

The University of Leicester operate a risk based audit programme to which this study will be subject.

# CODES OF PRACTICE AND REGULATIONS

## 13.1 Ethics

Maintaining confidentiality, maintaining information governance and respecting patient autonomy are the key ethical considerations in this study. Rigorous steps will be taken to ensure that confidentiality is maintained throughout the study and any published findings at a future date. All information gathered during the study will be handled in accordance with information governance policies of the University of Leicester and patient autonomy will be respected at all stages during the study.

## 13.2 Sponsor Standard Operating Procedures

All relevant Sponsor SOPs will be followed to ensure that this study complies with all relevant legislation and guidelines

## 13.3 Declaration of Helsinki

The Investigator will ensure that this study is conducted in full conformity with the current revision of the Declaration of Helsinki (last amended October 2000, with additional footnotes added 2002 and 2004).

## 13.4 ICH Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in full conformity with relevant regulations and with the ICH Guidelines for Good Clinical Practice (CPMP/ICH/135/95) July 1996.

## 13.5 Approvals

Once Sponsor authorisation has been confirmed, the protocol, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), Health Research Authority (HRA), and host institution(s) for written approval.

Once Sponsor authorisation has been confirmed, the Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

## 13.6 Participant Confidentiality

All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so.

# DATA HANDLING AND RECORD KEEPING

All study data will be entered on a password protected Excel spreadsheet and analysis carried out using STATA. No identifiable data will be collected in the questionnaire booklets and hence the data set generated from the completed questionnaire booklets will not contain any identifiable data. If a participant has contacted us to request the results of the study, we will use their name and address /email only to send them the results. In these instances, participants’ contact details will be stored in password protected folder with access only to members of the study team, on the ‘x-drive’ on University of Leicester networked computers. Participants’ personal data will be deleted as soon as the results have been distributed and will not be used for any other purpose.

All data will be stored on a restricted access secure server on a University of Leicester PC at the Leicester Diabetes Centre, with access limited to the study management team only. We will ensure security and restricted access to hard documents i.e. lockable environment.

# FINANCing and insurance

The only costs anticipated for the study are for the printing materials and charges for the questionnaires, travel expenses incurred by the researcher and archiving costs. The study will be funded by the NIHR Senior Investigators award at the Leicester Diabetes Centre.

There will be no staff costs for this study due to them already being employed within the Leicester Diabetes Centre.

No NHS Treatment costs or NHS support costs are anticipated.

Insurance for the study will be provided by the University of Leicester insurance policy.

# PUBLICATION POLICY

The open access publication policy outlined by the University of Leicester will be followed.

# REFERENCES

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