Frequently Asked Questions

The CompreHensive geriAtRician-led MEdication Review (CHARMER) study is a UK National Institute for Health and Care Research (NIHR)-funded programme grant that has developed a behaviour change intervention to support geriatricians and pharmacists to proactively deprescribe inappropriate medicines with older adults in hospital.

In this definitive randomised controlled trial, using a step wedge design, we will be testing the CHARMER intervention in hospitals across England over a 21-month period.

Trial design

What is the trial design for the CHARMER trial?

- The CHARMER trial uses a stepped wedge design.
- All 24 hospitals will start at the same time (1 December 2023) and begin with baseline patient data collection.
- Hospitals will be grouped into four 'steps', with five hospitals per 'step'. Hospitals in the earlier steps will implement the intervention earlier than hospitals in later steps.
- Four additional hospitals will remain in baseline throughout the trial and will only be invited to implement the intervention if a site allocated to steps 1 to 4 is unable to continue to participate. These four baseline hospitals will receive the CHARMER intervention materials at the end of the trial period, but they will not receive project manager funding.

When will we know which 'step' our hospital is in?

- We will randomise sites once Capacity & Capability has been completed and we will confirm the step then.
- This means that you will have time to plan the staff resources you need for the two enhanced data collection periods and will have a clear timeline for when the project manager needs to start for the implementation phase.

Will we take part in the pilot phase of the trial?

Yes, all sites will take part from month 1 of the trial. The pilot phase is the first three months of the trial and is for us to confirm that patient turnover in the included ward(s) is as anticipated.

CHARMER intervention

What do we have to do in preparation for implementing the CHARMER intervention?

- You will need to identify a 0.2 FTE per week project manager (funded at Band 7, but not limited to band 7 roles) to support intervention implementation for 12 weeks, and two weeks post-intervention implementation.
- Each hospital can decide who is the most appropriate staff member to undertake this role based on the role descriptor.
- This person could for example be from R&D, the study ward, the transformation, clinical improvement, or quality improvement teams. If you are unable to identify a suitable project manager, then the Principal Investigator could take on this role if they have capacity.
- A manual and other materials to support implementation of the CHARMER intervention will be provided to the project manager by the CHARMER team.

What support will we receive to implement the CHARMER intervention?

- All CHARMER intervention materials (e.g., workshop materials) will be provided to hospitals by the CHARMER team the month prior to implementation.
- There will also be a user-friendly implementation manual to support the project manager and principal investigator with implementation.
- In addition, the Eastern Academic Health Science Network (EAHSN) will be actively supporting all project managers to implement the intervention.

What happens during the three-month intervention implementation period?

- These three months will allow you time to plan and then implement the five components of the CHARMER intervention.
- The project manager will work with the Principal Investigator to oversee the implementation of the intervention and hospitals have flexibility in how the project manager works during the implementation period to suit their hospital and requirements.

Does CHARMER change our clinical decision-making?

No, there are no changes to clinical decision-making. The intervention is a behavioural intervention designed to lead geriatricians and pharmacists to do more of what they are already doing using their clinical judgement.

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How much time is involved for geriatricians and pharmacists who take part in the study?

- The intervention and trial are designed to be low intensity.
- Geriatricians and pharmacists will each need to take part in a one-hour workshop during the three-month implementation phase.
- During the intervention phase, geriatricians and pharmacists will meet once a week to discuss any proactive deprescribing opportunities. They can choose how this happens – either at a set time or *ad hoc* and the meeting can be a brief as a few minutes.

Do all geriatricians and pharmacists working on the study ward(s) need to participate?

- Ideally, we want all patients on the ward to interact with the geriatricians and pharmacists who received the CHARMER intervention.
- However, if a geriatrician or pharmacist does not want to participate in the trial, we would ask you to identify a way to only include data from patients under the care of the geriatrician(s) who received the intervention.

Can the Principal Investigator also receive the intervention?

Yes. The Principal Investigator (geriatrician or pharmacist) can also receive the intervention.

We are already undertaking a deprescribing/medicines optimisation study at our hospital, can we still be a site for the CHARMER trial?

Yes. We will ask all sites to complete a short survey at the start of the trial; one of the questions is whether any medicines optimisation studies are being undertaken or have been undertaken in the past two years.

Patient enrolment, recruitment, and data

How many accruals can a site receive for CHARMER?

- We estimate that each hospital will generate approximately 1000 accruals.
- The accruals include those patients who are enrolled (but not approached for consent) during the non-enhanced data collection periods, those patients who are recruited during the two enhanced data collection months, and clinical staff who are participating in CHARMER.
- While an individual patient may be admitted to the intervention ward(s) on multiple occasions, their enrolment/recruitment into the trial is **only** in relation to their first admission during the trial period. The enrolment log has been designed to identify patients who have already been enrolled in the trial for ease of exclusion.

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Which patients are eligible to be enrolled in CHARMER?

All patients that are admitted to the study ward(s) during the CHARMER trial period are eligible to be enrolled and this is separate to recruitment. **The exceptions are:**

- Patients who are under the care of a consultant other than a geriatrician (e.g., if the ward(s) have some patients under the care of a cardiologist, those patients would not be eligible as the CHARMER intervention is received by geriatricians and pharmacists),
- Patients who choose to opt out of their data being used for research, or
- If a patient or consultee refuses consent/assent for all research activities during the two enhanced data collection periods (patients or consultees that decline questionnaire completion can still participate on the basis of access to routine data alone).

What happens if a patient is enrolled and then leaves the study ward to go to another ward?

Patients who transfer from the study ward to another ward during the trial period are still able to participate. Duration of their stay on the study ward and overall hospital stay is tracked in the CHARMER trial enrolment log.

How many patients do we need to recruit during the two enhanced data collection periods?

There are two enhanced data collection months – one during baseline and one after the intervention implementation. All eligible patients on the study wards during these two enhanced data collection months should be approached for consent/assent. Sixty patients per enhanced data collection period should be recruited (total of 120 patients) if possible. There is no upper or lower limit to the number of patients that can be approached or recruited.

Can we have more than one study ward?

- Yes, as we are looking for each hospital to enrol around 1000 patients, it is often more feasible to include more than one ward. The study wards need to be inpatient wards and the patients under the care of a geriatrician.
- If a study ward has patients under the care of different specialty consultants, we only want you to enrol patients under the care of the geriatrician(s) participating in the CHARMER trial.

Does it have to be a CRN nurse that collects data on enrolled patients?

No, this activity can be completed by any CRN staff member the team deems appropriate. The SoECAT has this research activity costed at 3 minutes per patient. This activity can also be shared amongst several people as long as they are detailed in the delegation log and have read the training documents.

Can patients who do not have capacity take part in the enhanced data collection period?

Yes. For patients who do not have capacity to consent, we ask that a personal consultee is contacted (e.g., friend or family member) or for nursing home residents only, a nursing home staff member can be contacted if a personal consultee has not been identified. The consultee will be asked to:

- provide assent on behalf of their friend/relative or resident.
- agree to their friend's/relative's or resident's health care data being used for the trial, and
- complete questionnaires about their friend's/relative's or resident's health and, if appropriate, their experience of having a medication review and medicines stopped.

For patients who do not have capacity to consent, can enhanced data collection still go ahead where there is no personal or professional consultee available?

Yes. Health Research Authority (HRA) approval including Confidentiality Advisory Group (CAG) and Ethics approval has been given for routine data collection for patients who are unable to give consent and for whom there is no consultee available. Including these patients is important to ensure that the results are generalisable to the whole ward population.

What happens if a patient is discharged or transferred to a different ward before being approached to give consent? Can enhanced data collection still go head?

It is best practice that all eligible patients are approached for consent. However, it is anticipated that it may not be possible to approach all patients admitted to the study ward prior to their discharge or transfer to another ward. In this instance, Health Research Authority (HRA) approval including Confidentiality Advisory Group (CAG) and Ethics approval has been given for enhanced data collection for patients who are unable to give consent due to:

- only being admitted to the study ward for a short period during which it is not possible for all patients to be approached,
- was off the ward at times when research staff were available to approach the patient to give consent.

Recruitment rates for questionnaire completion, and reasons for non-consent will be monitored using the enrolment log.

What patient data are collected during the non-enhanced data collection periods?

During the non-enhanced data collection periods, you will collect a minimum dataset for all patients in the Excel Enrolment Log we provide you. The minimum dataset includes:

- Patient name

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- NHS number & hospital number
- Patient home postcode
- Age
- Gender
- Ethnicity
- Date of ward and hospital admission
- Date of ward and hospital discharge
- Date of death during hospital admission (if applicable)

This data can be collected using the Patient Administration System (PAS) and copied into the Excel sheet or can be completed manually. Every month you will need to send the CHARMER team a copy of a worksheet in the Enrolment Log so your accruals can be awarded on time; more detail on how to do this will be provided. We have received approval from the Confidentiality Advisory Group (CAG) to receive pseudonymised routinely collected patient data without seeking consent from patients. The only time when pseudonymised patient data would not be included is when a patient has opted out of their data being used in research.

How will we know if a patient has opted out of their data being used in research?

This can be checked in the patient record or the list of patients on the study wards can be sent to NHS England to confirm whether they have opted out via MESH – more details for this can be found here: National Data Opt-Out.

What patient data are collected during the two one-month periods of enhanced data collection?

In addition to the minimum dataset, you will collect the following during the enhanced data collection periods:

- Number of regularly prescribed medicines on leaving the study ward
- Number of prescribed medicines for “when required” use on leaving the study ward
- Number of prescribed medicines that are stopped
- Number of prescribed medicines with dosage reduced
- Number of stopped medicines that are re-started
- Length of hospital stay for index admission
- These data will be collected by two FTE CRN staff members for two one-month periods six months apart and can be collected by running a query within your electronic prescribing systems for the study ward(s). During the enhanced data collection period, you will also approach all patients on the study ward(s) for consent to take part in questionnaires and interviews if applicable.