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A trial to determine the feasibility of embedding an ePrescribing-based Antimicrobial Stewardship (ePAMS+) intervention into existing ePrescribing systems within a hospital setting

Submission date 10/03/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/03/2022	**Overall study status** Completed	
Last Edited 21/10/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Antibiotics fight infections caused by bacteria, but not all infections are caused by bacteria. When patients first come to the hospital, often it is too early to be sure of what is causing their illness so doctors may prescribe antibiotics 'just in case'. The more antibiotics a person takes the more likely they are to carry antibiotic-resistant bacteria in their body and to have antibiotic-resistant infections in the future. The ePAMS+ intervention is designed to manage antibiotic use within hospital settings by placing patients prescribed antibiotics on active review:

Under ePAMS+ the progress of a patient prescribed antibiotics will be reviewed in line with the national 'Start Smart - Then Focus' guidelines:
• Patients on review will have their antibiotics stopped if their doctors decide that their illness is not caused by bacteria
• When doctors have a patient's test results they can decide on how long they need antibiotics, and which ones they need
• Doctors may decide a patient will need to carry on with antibiotics because they are right for their illness

Who can participate?
No individual patients will be approached directly as part of this project. The national 'Start Smart – Then Focus' guidelines that all clinicians and hospitals should follow, underpins the ePAMS+ intervention. Although patient informed consent is not required or sought as part of this study, the implementation pack contains a resource (About Antibiotics – Information for Patients, Relatives and Carers) to help clinical staff explain antibiotic use and review to patients within participating clinical areas.

What does the study involve?
No individual patients will be approached directly as part of this project. This study will collect information on antibiotic use and prescribing behaviours in selected clinical areas at participating hospitals. Patients will be treated according to standard clinical care.

What are the possible benefits and risks of participating?
We do not anticipate that there will be any potential adverse effects or hazards associated with the research for any patients at participating hospitals or to staff using the intervention. There will be no direct benefit to patients or staff as a direct result of this study. However, the data will form part of the evidence base which will inform the care of other people who are prescribing antibiotics in the hospital setting.

Where is the study run from?
University of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
March 2022 to April 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Dr Christopher Weir, ePAMS.trials@ed.ac.uk

Study website
https://www.ed.ac.uk/usher/research/projects/epams

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
307085

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52225, RP-PG-0617-20009, IRAS 307085

Study information

Scientific Title
Complex ePrescribing-based Antimicrobial Stewardship intervention for Hospitals (ePAMS+) Feasibility Trial

Acronym
ePAMS+ Feasibility

Study objectives
To assess the efficacy of the feasibility of implementing ePAMS+ within the existing ePrescribing Cerner systems at two NHS hospitals in England

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/03/2022, London South East Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 2071048265; faye.slade@hra.nhs.uk), ref: 22/LO/0204

Study design
Interventional non-randomized trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
https://www.ed.ac.uk/usher/eprescribing-antimicrobial/the-programme

Health condition(s) or problem(s) studied
Management of antibiotic use within hospital settings.

Interventions
Current interventions as of 02/11/2022:
The ePAMS+ Feasibility trial to assess the feasibility of embedding the ePAMS+ intervention and extracting trial outcome measures using administrative data within selected hospital areas within two English NHS Trust organisations.

Sites
Two NHS Trust hospitals (Newcastle Teaching Hospitals NHS Foundation Trust and Royal Free London NHS Foundation Trust) have been selected to act as feasibility sites based on their use of Cerner e-Prescribing and Medication Administration (EPMA) systems.

ePAMS+ Intervention
The intervention has been developed to align with the national 'Start Smart — Then Focus' guidelines. It consists of the following tools embedded within the Cerner ePrescribing and Medicines Administration (EPMA) system:
• Antibiotic Order Plans to help prescribe antibiotics and set up review and revise processes
• Decision Aid to help communicate the original prescriber's level of certainty about the need for antibiotics (based on ARK intervention — add REF)
• Information pages within the EPMA to help team get most from ePrescribing tools when used
• Antibiotic Ward Task List to identify patients on antibiotics that may need review

Duration
ePAMS+ Feasibility trial will run until 31st December 2022, with data interpretation and analysis undertaken during the trial using regular data extracts. A checkpoint report for the funder will be submitted at the end of August 2022. If the ePAMS+ intervention is acceptable and feasible to implement, the main trial will be developed for implementation.

Research Participants
No individual patients will be approached directly as part of this project. The national 'Start Smart — Then Focus' guidelines that all clinicians and hospitals should follow, underpins the ePAMS+ intervention. Although patient informed consent is not required or sought as part of this study, the implementation pack contains a resource (Patient Information Leaflet) to help clinical staff explain antibiotic use and review to patients. Staff and patients within participating wards will be approached to participate in qualitative studies of acceptability and this is covered under the terms of an allied project (approved under IRAS ID: 259104).
Unconsented, de-identified data relating to antibiotic prescribing and treatment with antibiotics within the selected clinical areas will be extracted from electronic medical prescribing systems by IT teams at participating hospitals
• Data extracts will be processed at site by local IT teams to assign unique ePAMS+ IDs and to remove identifiers (i.e. date of birth, name, hospital numbers and NHS numbers.
• De-identified data extracts will be transferred via secure protocol to the Scottish Safe Haven maintained by Public Health Scotland
• Access to extracted and de-identified data will be granted by Public Health Scotland to named and trained members of the research team, with all outputs disclosure checked to ensure data confidentiality
• Data transfer agreements will be put in place between participating NHS Trusts, Public Health Scotland and the Sponsor institution

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Intervention Type
Behavioural

Primary outcome measure
1. Total antibiotic consumption measured as the number of defined daily doses (DDD), assessed overall and at site/ward level
2. Completeness of data extracted and whether standardised queries to capture data from Cerner systems are feasible/assessed via monthly data extracts
3. Assessment of the feasibility of measuring defined outcomes using extracted data

Secondary outcome measures
Mapping of critical decision points within Cerner systems to core principles of the intervention to develop fidelity index items, and determine how standardised queries to capture data from Cerner will enable coding of item response options (e.g. 'present', 'absent but should be present', 'not applicable') for automation of this coding structure for the cluster-randomised trial

The following outcomes will be assessed for feasibility (added 16/05/2022):
Length of hospital stay
Days of therapy (and intravenous therapy)
Diagnostics
Number of antibiotics prescribed
Number of antibiotic courses
Repeat courses for same indication
Number of courses for same indication
Switches
- of frequency
- of dose
- from intravenous to oral
- from oral to intravenous
- to alternative antimicrobial
- from narrow to broad spectrum
Discontinuation of therapy
Number of courses concordant with local guidelines for antibiotic choice/duration

Resistance rates
Susceptibility
Acquisition of multi-drug resistant organism
Healthcare-associated infection
Episodes of - Clostridium difficile infection (CDI)
- methicillin- resistant Staphylococcus aureus (MRSA)
- gram-negative bacilli (GNB)

Added 01/11/2022:
Site staff ePAMS+ training information will be captured on the Learning Management System to assess completion of training (i.e. professional discipline, date/time of module completion, time spent on learning and pre and post-test scores)

Overall study start date
10/03/2022

Completion date
30/04/2023

Eligibility

Key inclusion criteria
Medical records:
1. Adults >=16 years admitted to hospital as in-patients
2. Patients being treated with antibiotics (identified as Antibiotic Order Plans initiated and/or existing antibiotic use flagged within the electronic prescribing system)

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
14 wards/clinical areas - 1958 admissions

Total final enrolment
1768

Key exclusion criteria
Medical records:
1. Children <16 years

Date of first enrolment

01/06/2022

Date of final enrolment
30/11/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
The Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
TS1 4LP

Sponsor information

Organisation
University of Edinburgh

Sponsor details
Old College
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United Kingdom
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+44 1312429261
resgov@accord.scot

Sponsor type

University/education

Website
http://www.ed.ac.uk/home

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Added 09/08/2024:
Planned publication in a high-impact peer-reviewed journal (currently in the second round of peer review) and a synopsis report to the funder, adding the PubMed and DOI links to this registry record.

Intention to publish date

30/11/2024

Individual participant data (IPD) sharing plan

Current IPD sharing plan as of 21/10/2024:

The qualitative datasets generated and/or analysed during the current study are not publicly available to protect the anonymity of participants, but are available from co-author Kathrin Cresswell on reasonable request.

Previous IPD sharing plan as of 08/03/2024:

De-identified quantitative data for this trial are held within the Scottish National Safe Haven, having been obtained from routinely collected health data within the Cerner EPMA system. These data are not appropriate for public sharing, as consent was not sought from eligible admissions in this service-level evaluation of intervention feasibility.

Previous IPD sharing plan:

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		28/01/2023	30/01/2023	Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version 1.0	09/09/2022	11/03/2024	No	No
Results article		11/10/2024	17/10/2024	Yes	No