Tracking anti-microbial resistance across care settings in Liverpool (TRACS- Liverpool) - Part 1

Submission date 09/12/2021	Recruitment status No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 17/12/2021	Overall study status Completed	 Statistical analysis plan Results
Last Edited 30/03/2022	Condition category Infections and Infestations	 Individual participant data Record updated in last year

Plain English summary of protocol

Background and study aims

This mixed methods study is the first stage of a programme of research looking at how antimicrobial resistance is acquired and transmitted within care settings in Liverpool. Antimicrobial resistance (AMR) threatens the effectiveness of antibiotics that are widely used in modern medicine. Some resistant bacteria pose a particular threat, namely a group called Enterobacterales. These bacteria become resistant to antimicrobials when they acquire genes that enable the bacteria to produce enzymes that destroy antibiotics. People frequently carry these resistant bacteria without knowing. But in some cases they cause illness that can be life threatening or untreatable.

Although we understand how people can acquire these bacteria – either through direct exposure, such as swallowing them, or through exposure to antibiotics; it is less clear when and how these resistant bacteria are transmitted.

We know that people requiring frequent hospital admissions, or who live in long term care facilities are at particular risk of acquiring resistant bacteria.

We also know that rates of antimicrobial resistance are higher in the north-west than in the rest of the UK.

In order to be able to accurately plan and explore the problem of antimicrobial resistance locally we first need to understand it.

Who can participate?

Health professionals working in institutions that operate in Merseyside with knowledge and experience relevant to the research questions.

What does the study involve?

We will interview up to 50 key informants from local health and care organisations in order to gain a deeper understanding of how the hospital and care systems work locally. These participants will be identified by their key roles within health and care settings across Liverpool and will be invited to take part accordingly.

We will compare this information with specific datasets about antimicrobial resistant infection rates from selected local hospitals.

Combining these different sources of information will allow us to identify how and where potential transmission may be occurring. We can then accurately plan how to explore this further in the next stage of the research.

What are the possible benefits and risks of participating? None

Where is the study run from? Liverpool School of Tropical Medicine (UK)

When is the study starting and how long is it expected to run for? October 2021 to September 2022

Who is funding the study? UKRI Strength in Places Fund (UK) Unilever (UK)

Who is the main contact? Maria Moore, maria.moore@lstmed.ac.uk

Contact information

Type(s) Public

Contact name Ms Maria Moore

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Scientific

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number 309060

ClinicalTrials.gov number Nil known

Secondary identifying numbers Sponsor 21-089, IRAS 309060, CPMS 51757

Study information

Scientific Title

Tracking anti-microbial resistance across care settings in Liverpool (TRACS-Liverpool) Part 1: informing the design and development of an observational cohort study

Acronym

TRACS - Liverpool: Part 1

Study objectives

Rationale for the study:

1. To inform the development of survey questions for a future longitudinal cohort study.

2. To inform the development of the sampling and recruitment strategies for the longitudinal cohort study.

3. To estimate rates of ESBL-E/CPE acquisition and infection in two Liverpool acute hospitals to inform sample size calculations.

4. To scope and document relevant routine and secondary data sources on local ESBL-E/CPE transmission

5. To document key informants' perspectives on the acceptability of the Part 2 study and how to improve it.

6. To map facility infrastructure, describe patient journeys within and between care facilities, and suggest how these might affect ESBL-E/CPE acquisition and prevention.

7. To review and summarise infection control policies for ESBL and CPE and suggest how these might be linked to protection from or acquisition of ESBL/CPE

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16/02/2022, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ; +44(0)207 104 8143; gmsouthrec@hra.nhs.uk), ref:22/NW/0032

Study design

Observational cohort study

Primary study design Observational

Secondary study design Cohort study

Study setting(s) Other

Study type(s) Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Infection control

Interventions

Following enrolment participants will undertake a single semi-structured interview with the research team. This may be online or face-to-face. This will complete their involvement in the study.

Intervention Type

Other

Primary outcome measure

1.1. Estimate rates of ESBL-E/CPE acquisition and infection in two Liverpool acute hospitals, using readily available routine data sources at a single time point

Measured using interviews at a single time point:

2.1. Scope and document relevant routine and secondary data sources on local ESBL-E/CPE transmission.

2.2. Document key informants' perspectives on the acceptability of the Part 2 study and how to improve it.

2.3. Map facility infrastructure, describe patient journeys within and between care facilities, and suggest how these might affect ESBL-E/CPE acquisition and prevention.

2.4. Review and summarise infection control policies for ESBL and CPE and suggest how these might be linked to protection from or acquisition of ESBL/CPE

Secondary outcome measures

There are no secondary outcome measures

Overall study start date 01/10/2021

Completion date 30/09/2022

Eligibility

Key inclusion criteria

- 1. Male or female aged 18 years or above
- 2. Health professionals working in institutions that operate in Merseyside
- 3. Having knowledge and/or experience to share on the research questions
- 4. Able to facilitate access to relevant data required in the study

5. Willing and able to give informed consent for participation in the study

Participant type(s) Health professional

Age group

Adult

Lower age limit 18 Years

Sex Both

Target number of participants 45

Key exclusion criteria 1. Not willing or available to participate in the study

Date of first enrolment 01/02/2022

Date of final enrolment 30/04/2022

Locations

Countries of recruitment England

United Kingdom

Study participating centre Royal Liverpool Hospital

Liverpool University Hospitals Foundation NHS Trust Prescot Street Liverpool United Kingdom L7 8XP

Study participating centre NHS Liverpool CCG

2 Renshaw Street Liverpool United Kingdom L1 2SA

Sponsor information

Organisation Liverpool School of Tropical Medicine

Sponsor details

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Sponsor type University/education

Website http://www.lstmed.ac.uk/

ROR https://ror.org/03svjbs84

Funder(s)

Funder type Government **Funder Name** UK Research and Innovation

Alternative Name(s) UKRI

Funding Body Type Government organisation

Funding Body Subtype National government

Location United Kingdom

Funder Name Unilever

Alternative Name(s) Unilever Global, Unilever PLC, U

Funding Body Type Government organisation

Funding Body Subtype For-profit companies (industry)

Location United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journel. Dissemination of results amongst local stakeholders.

Intention to publish date 30/09/2023

Individual participant data (IPD) sharing plan Data sharing statement to be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No