

# A study of multidrug resistant organisms in the adult intensive care unit at Addenbrooke's Hospital

<b>Submission date</b> 13/02/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 20/02/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/03/2020	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Healthcare-associated infections (HCAI) affect up to 10% of hospital patients, and are associated with an increased risk of death. Multidrug-resistant organisms (MDRO) are more common in hospitals. Patients in intensive care units (ICU) are particularly vulnerable to HCAI, and several outbreaks of infection with MDRO have been reported.

Current practices for screening for MDRO vary between countries, hospitals and units, reflecting a lack of information, and uncertainty about best practice. One strategy to reduce HCAI in ICUs would be to perform screening to look for MDRO in patients admitted to ICUs. This would enable earlier identification and treatment of MDRO and implementation of appropriate infection control measures to prevent their spread.

Whole-genome sequencing (WGS) is novel technology, which is more discriminatory than currently available typing methods. We are conducting a study to determine the rates of carriage, infection, and transmission of MDRO in the adult ICU at Addenbrooke's Hospital, using WGS. This study will facilitate translation of this technology from a research tool into day-to-day clinical practice. Information from this study will be used to inform infection control and public health policies and procedures.

### Who can participate?

All adult admitted to the John Farman Intensive Care Unit during the study period.

### What does the study involve?

All patients admitted to ICU during the study period will be screened for MDRO and clinical data on infections and antimicrobial use will be collected.

### What are the possible benefits and risks of participating?

No direct benefits for study participation. In terms of the risks of participation in the study,

these are negligible as the study is observational in nature and there are no study-specific interventions or treatments. All specimens will be collected by experienced nursing staff, in accordance with routine clinical practice.

Where is the study run from?  
Cambridge Biomedical Campus (UK)

When is the study starting and how long is it expected to run for?  
June 2016 to December 2016

Who is funding the study?  
1. Academy of Medical Sciences (UK)  
2. The Health Foundation (UK)  
3. National Institutes of Health Research Cambridge Biomedical Research Centre (UK)

Who is the main contact?  
Dr Estee Torok  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Integrated Research Application System (IRAS)**  
180415

**Protocol serial number**  
CUH R&D ref: A093680

## Study information

**Scientific Title**

Whole-genome sequencing to investigate colonisation and transmission of multidrug-resistant organisms in the adult intensive care unit at Addenbrooke's Hospital

## Acronym

ICU001

## Study objectives

What is the prevalence of the colonisation and is there evidence of transmission of multidrug-resistant organisms in the adult intensive care unit?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 21/04/2016, NHS Health Research Authority, East of England - Cambridge Central Research Ethics Committee (Royal Standard Place, Nottingham NG1 6FS, UK; +44 (0)207 104 8388; NRESCommittee.EastofEngland-CambridgeCentral@nhs.net), ref: 15/EE/0318

## Study design

Observational cohort study

## Primary study design

Observational

## Study type(s)

Screening

## Health condition(s) or problem(s) studied

Surveillance for multidrug-resistant organisms

## Interventions

All patients admitted to ICU during the study period will be screened for MDRO and clinical data on infections and antimicrobial use will be collected.

Participants will be screened for MDRO on admission to the John Farman Intensive Care Unit. All specimens will be assigned a unique anonymised identification number prior to transfer to the research laboratory the Department of Medicine for processing.

Participants will be screened for MDRO on discharge from ICU, and weekly during their ICU admission if the duration of admission is 7 days or longer.

## Intervention Type

Other

## Primary outcome(s)

Measured using patient records during the study period:

1. Number of patients colonised with multidrug-resistant organisms
2. Number of patients with clinical evidence of infection with multidrug-resistant organisms
3. Number of transmission events of multidrug-resistant organisms

## **Key secondary outcome(s)**

Measured using patient records during the study period:

1. Risk factors for colonisation / infection with multidrug-resistant organisms
2. Outcome of patients colonised / infected with multidrug-resistant organisms
3. Cost-consequences of whole-genome sequencing versus standard epidemiological investigation / typing for surveillance and investigation of suspected outbreaks and the management of confirmed outbreaks

## **Completion date**

30/06/2017

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18 years old or older
2. Male or female
3. Admitted to the John Farman Intensive Care Unit during the study period

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

Does not fulfil study inclusion criteria

### **Date of first enrolment**

20/06/2016

### **Date of final enrolment**

20/12/2016

## **Locations**

### **Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**Cambridge Biomedical Campus**  
Cambridge University Hospitals NHS Foundation Trust  
Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ

## Sponsor information

**Organisation**  
Cambridge University Hospitals NHS Foundation Trust

**ROR**  
<https://ror.org/04v54gj93>

**Organisation**  
University of Cambridge

**ROR**  
<https://ror.org/013meh722>

## Funder(s)

**Funder type**  
Research organisation

**Funder Name**  
Academy of Medical Sciences

**Alternative Name(s)**  
The Academy of Medical Sciences

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Universities (academic only)

**Location**  
United Kingdom

**Funder Name**

The Health Foundation

**Funder Name**

National Institutes of Health Research Cambridge Biomedical Research Centre

## Results and Publications

**Individual participant data (IPD) sharing plan**

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

**IPD sharing plan summary**

Other

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>	version v2.0		06/03/2020	No	No