

# A study to determine which bacteria and viruses are detected in patients who develop pneumonia while in hospital

<b>Submission date</b> 09/02/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 04/05/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/06/2022	<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

Hospital-Acquired Pneumonia (HAP) is a common and serious lung infection that occurs in all hospitals and on all wards. It particularly affects elderly patients. A new test called is available to help doctors decide which treatment to use for a patient with HAP. The test is called the BIOFIRE® FILMARRAY® PNEUMONIA PANEL - FAPP for short. The FAPP is approved for use in the EU and USA (CE marked and FDA approved). It detects the bacteria and viruses that cause HAP and genes that indicate resistance to certain antibiotics.

HAPOSS is a preliminary study aimed at describing how often different casues of HAP the FAPP would be detected if it were it were to be used in an NHS hospital.

### Who can participate?

Adult patients (18 years or older) whose doctor wants to treat them for HAP.

### What does the study involve?

HAPOSS involves using the FAPP to test a patient's sputum sample.

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

There are no direct benefits to patients who participate in HAPOSS however the results obtained will benefit future patients with HAP.

There are no risks associated with participation in HAPOSS.

FAPP can be used outside of a laboratory and requires only brief training and no prior laboratory experience. Results take 75 minutes, which is much quicker than standard microbiological tests.

### Where is the study run from?

The study is run by a team who work at the University of Liverpool and the Liverpool University Hospitals NHS Foundation Trust (UK).

### When is the study starting and how long is it expected to run for?

September 2018 to August 2022

Who is funding the study?  
University of Liverpool (UK)

Who is the main contact?  
Dr Dan Wootton, [dwootton@liverpool.ac.uk](mailto:dwootton@liverpool.ac.uk)

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Dan Wootton

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## Additional identifiers

**Integrated Research Application System (IRAS)**  
268957

**Central Portfolio Management System (CPMS)**  
44564

**Protocol serial number**  
UoL001494

## Study information

**Scientific Title**  
Hospital Acquired Pneumonia Study of Sputum

**Acronym**  
HAPOSS

**Study objectives**  
The aim of HAPOSS is to describe the pattern of pathogen detections made by the bioFire Film Array Pneumonia Panel when used to sample a representative cohort of patients treated for non-ventilator acquired Hospital Acquired Pneumonia.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 05/03/2020, East of England - Cambridge Central Research Ethics Committee (Royal Standard Place, Nottingham, NG1 6FS, UK; +44 2071048270; CambridgeCentral.rec@hra.nhs.uk), ref: 20/EE/0004

**Study design**

Observational cohort study

**Primary study design**

Observational

**Study type(s)**

Diagnostic

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

Non ventilator acquired hospital acquired pneumonia

**Interventions**

The population of interest are patients who are about to be treated for non-ventilator acquired hospital acquired pneumonia (HAP).

At the discretion of the treating clinical team, sputum samples, obtained as part of standard clinical practice, are sub-sampled and tested using the bioFire FilmArray Pneumonia Panel.

The remaining sputum is sent for standard microbiological investigations which are reported in the usual way.

Results of the bioFire FilmArray Pneumonia Panel test are not revealed to the clinical team but are stored and analysed retrospectively.

Analysis will be descriptive and the results will be summary statistics such as frequency counts and proportions of individual pathogens detected, multiple pathogen detections and resistance genes detected.

The interpretation will be performed in the light of local and national treatment guidelines.

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

bioFire FilmArray Pneumonia Panel

**Primary outcome(s)**

Pneumonia pathogens are detected at baseline using the bioFire® FilmArray® Pneumonia Panel Plus

**Key secondary outcome(s)**

There are no secondary outcome measures

**Completion date**

01/08/2022

## Eligibility

**Key inclusion criteria**

Adults of 16 years or older who are treated as HAP within the two recruiting hospitals

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Intention is to palliate rather than cure
2. Non-English speaking
3. Patients from whom a sputum sample cannot be obtained within 6 hours of the administration

**Date of first enrolment**

01/08/2021

**Date of final enrolment**

01/08/2021

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Liverpool University Hospitals NHS Foundation Trust**

Royal Liverpool University Hospital

Prescot Street

Liverpool

United Kingdom

L7 8XP

# Sponsor information

## Organisation

University of Liverpool

## ROR

<https://ror.org/04xs57h96>

# Funder(s)

## Funder type

University/education

## Funder Name

University of Liverpool

## Alternative Name(s)

The University of Liverpool, , Universidad de Liverpool, UoL

## Funding Body Type

Government organisation

## Funding Body Subtype

Universities (academic only)

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version 2	13/02/2020	15/02/2022	No	Yes
<a href="#">Protocol file</a>	version 5	10/02/2020	15/02/2022	No	No

