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Antibiotic prescribing in an English secondary care setting before and during the COVID-19 pandemic

Submission date
18/05/2022

Recruitment status
No longer recruiting

Registration date
23/05/2022

Overall study status
Completed

Last Edited
07/12/2023

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
Antimicrobial resistance (AMR) is a global crisis that requires urgent attention and action. More than 1.2 million people died worldwide in 2019 from infections caused by bacteria resistant to antibiotics, according to the last most extensive study on the issue to date. This is more than the annual death toll from malaria or Aids. The COVID-19 pandemic challenges all aspects of healthcare, especially the management of serious acute bacterial infections and effective delivery of antimicrobial stewardship. The World Health Organization (WHO) have declared AMR one of the biggest threats to global health and one of the biggest health challenges.
Antimicrobial stewardship (AMS) is a set of actions to promote the effective use of antimicrobials. Public Health England AMS and NICE AMS guidelines urge the AMS implementation in the acute care settings to maintain the appropriate use of antibiotics and maintain the safety and quality of patient care.
The proposed study will investigate the factors affecting antimicrobial stewardship (AMS) implementation before and during the COVID-19 pandemic.

Who can participate?
Patients aged 18 years or older admitted at Bedfordshire Hospitals NHS Trust from 2019 to 2020, and healthcare professionals who worked during the OCVID-19 pandemic.

What does the study involve?
This research project consists of two different phases:
Phase one: In this earlier phase, the retrospective quantitative review will be conducted; it aims to review the medical records of patients prescribed antibiotics for respiratory tract infections (RTIs) or pneumonia before and during the COVID-19 pandemic.
Phase two: In this later study, an online survey explores doctors, pharmacists and nurses' prescribing behaviour, perceptions, attitudes, AMS practices and factors affecting the AMS intervention during the COVID-19 pandemic.

What are the possible benefits and risks of participating?
For the benefits, there is no direct benefit to you. But, your participation will help the study

team, and a wider audience better understands the factors affecting AMS implementation in both hospitals during the COVID-19 pandemic. It is anticipated that the overall results of this study will inform the development of policies and actions to support effective AMS in any future emergencies or future pandemics as appropriate.
Regarding the risks:
Phase 1: The NHS Confidentiality Agreement Group (CAG) will provisionally support, with satisfactory responses, the confidential patient information collection and anonymisation throughout this phase. Access to patients' identifiable data will be restricted only to the PhD student/Principal Investigator (PI) under the complete supervision of the collaborators from the direct care team at Bedfordshire Hospitals NHS Trust (Luton & Dunstable Hospital and Bedford Hospitals). Data will be saved as password-protected documents on the hospital sites. The PhD student/PI will anonymise the extracted data and store it on the University of Hertfordshire secured network storage system, which requires a double security check for analysis. All identifiable data will be anonymised before leaving the research hospital sites.
Phase 2: All survey responses will be anonymised entirely; there are no anticipated disadvantages to your participation other than the time required. You can ask for further information or raise concerns directly to the study team (contact information provided further on).

Where is the study run from?
Bedfordshire NHS Foundation Trust (Luton and Dunstable Hospital and Bedford Hospital) (UK)

When is the study starting and how long is it expected to run for?
November 2020 to November 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Rasha Abdelsalam Elshenawy, r.a.elshenawy@herts.ac.uk, dra21sha@gmail.com

Study website
https://stewardshipcovid.wordpress.com/

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
314805

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 314805

Study information

Scientific Title
An investigation into antimicrobial stewardship implementation prior to and during the COVID-19 pandemic in a secondary care setting in England

Study objectives
Current study hypothesis as of 06/12/2023:
This study aims to investigate the factors affecting antimicrobial stewardship in patients with Respiratory Tract Infections (RTIs), including pneumonia and COVID-19 pandemic at on English NHS Foundation Trust prior to and during the COVID-19 pandemic.

Previous study hypothesis:
This study aims to investigate the factors affecting antimicrobial stewardship in patients with Respiratory Tract Infections (RTIs) or pneumonia at two acute care settings before and during the COVID-19 pandemic

Ethics approval required

Ethics approval required

Ethics approval(s)
1. Approved 19/10/2022, East Midlands - Leicester South Research Ethics Committee (Equinox House, City link, Nottingham, NG2 4LA, United Kingdom; +44 (0)207 104 8115; Leicestersouth.rec@hra.nhs.uk), ref: 22/EM/0161

2. Approved 21/03/2022, Confidentiality Agreement Group (CAG) (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44(0)207 104 8100; cag@hra.nhs.uk), ref: 22/CAG/0039

Study design
Phase 1: Retrospective medical records study of hospital retrospective Data from Bedfordshire Hospitals NHS Trust (Luton and Dunstable Hospital and Bedford Hospital), from December 2021 to May 2023.
Phase 2: Prospective Cross-sectional survey questionnaire study, for the healthcare professionals (doctors, pharmacists and nurses) at Bedfordshire Hospitals NHS Trust, from June 2023 to November 2023.

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Investigating the antibiotic use in patients with (COVID) pneumonia

Interventions
Current interventions as of 06/12/2023:
Phase 1: The first phase will include reviewing medical records of patients prescribed antibiotics for RTIs or pneumonia before and during the COVID-19 pandemic. Data collection will be through eight-time points (Four before COVID-19 as baseline measures, and four during the COVID-19 - wave 1, wave two and post wave 2).

Four-time points before the COVID-19 pandemic
1. 1st week of January (Winter 2019): higher pneumonia or RTIs.
2. 1st week of April (Spring 2019): midway of pneumonia or RTIs.
3. 1st week of July (Summer 2019): low pneumonia or RTIs.
4. 1st week of October (Winter 2019): midway of pneumonia or RTIs.

Four-time points during the COVID-19 pandemic
1. 1st week of January (Winter 2020): the first wave of COVID.

2. 1st week of April (Spring 2020): the first lockdown.
3. 1st week of July (Summer 2020): the second wave of COVID.
4. 1st week of October (Autumn 2020): the implementation of the vaccination programme.

Phase 2: This phase will use a cross-sectional online survey based on Public Health England (PHE) Behaviour change and antibiotic prescribing in secondary care settings (Literature review and behavioural analysis). It aims to explore the knowledge, attitudes, and perceptions towards antibiotic prescribing and antimicrobial stewardship practices during the COVID-19 pandemic. A mixed open and close-ended questionnaire survey will be conducted through a secured and trusted survey platform (Qualtrics XM)

The aim is to explore perceptions, attitudes, and AMS practices among healthcare professionals (doctors, nurses, and pharmacists) during the COVID-19 pandemic.

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Intervention Type
Mixed

Primary outcome measure
Current primary outcome measure as of 06/12/2023:
Phase 1:
The prevalence of antibiotic prescribing before and during the pandemic, additionally, identify the Antibiotic stewardship (AMS) measured using the proportion of inappropriately prescribed antibiotics at admission, 48 and 72 hours before and during the COVID-19 pandemic.

Phase 2:
Overall knowledge, attitudes and perceptions towards antibiotic prescribing during the

pandemic, additionally, the impact of the COVID-19 pandemic on the AMS activities during the pandemic.

Previous primary outcome measure:
Phase 1:
Antibiotic stewardship (AMS) measured using the proportion of inappropriately prescribed antibiotics at admission, 48 and 72 hours before and during the COVID-19 pandemic.

Phase 2:
Antibiotic prescribing behaviour of healthcare professionals measured using the range of knowledge, attitudes, and perceptions during the COVID-19 pandemic.

Secondary outcome measures
Phase 1:
1.1. AMS strategies, such as IV-to-Oral switch, antibiotic discontinuation, de-escalation, dose adjustment, and antibiotic review based on the local guidelines measured using the proportion of strategies implemented before and during the COVID-19 pandemic.
1.2. Laboratory and diagnostic methods, such as chest x-rays, procalcitonin test, CRP, WBCs, and fever, measured using the proportion of their use in patients infected with RTIs or pneumonia before and during the COVID-19 pandemic.

Phase 2:
Factors affecting the AMS implementation measured using the range of AMS practices during the COVID-19 pandemic.

Overall study start date
01/11/2020

Completion date
01/11/2023

Eligibility

Key inclusion criteria
Phase 1
1. Adult patients 18 years and older.
2. Adult Pregnant women and immunocompromised patients.
3. Patients admitted at Bedfordshire Hospitals NHS Trust.
4. Patient admitted in critical care areas between 2019 and 2020.
5. Patients who were prescribed antibiotics for RTIs or pneumonia.

Phase 2
1. Healthcare professionals (doctors, nurses, and pharmacists).
2. Adults 18 years and older.
3. Registered with the relevant professional regulatory body; GMC, GPhC and NMC.
4. HCPs who worked during the COVID-19 pandemic and still working at the hospital.

Participant type(s)
Mixed

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Phase 1: 640 patient records in the retrospective study| Phase 2: 240 healthcare professionals in prospective study

Key exclusion criteria
Phase 1:
1. Patients who were not prescribed antibiotics.
2. Children and patients admitted for less than 48-72 hours.

Phase 2:
1. Doctors who worked before during the COVID-19 pandemic but not currently working at the Bedfordshire Hospitals NHS Trust.
2. Pharmacists who worked before during the COVID-19 pandemic but not currently working at the Bedfordshire Hospitals NHS Trust.
3. Nurses who worked before during the COVID-19 pandemic but not currently working at the Bedfordshire Hospitals NHS Trust.

Date of first enrolment
01/12/2022

Date of final enrolment
30/05/2023

Locations

Countries of recruitment
England

Study participating centre
Bedfordshire Hospitals NHS Foundation Trust
Lewsey Road
Luton
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Sponsor information

Organisation
University of Hertfordshire

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Sponsor type
University/education

Website
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ROR
https://ror.org/0267vjk41

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
01/12/2023

Individual participant data (IPD) sharing plan
Raw data will be stored on the secured network storage system of the University of Hertfordshire (UH).
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Stored in non-publicly available repository, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan			16/03/2023	No	No
Dataset			04/12/2023	No	No
Dataset			04/12/2023	No	No
Interim results article	Retrospective study		04/12/2023	Yes	No
Other publications	Systematic review	10/02/2023	04/12/2023	Yes	No
Other unpublished results		01/11/2023	04/12/2023	No	No
Protocol file	version 2	01/09/2022	04/12/2023	No	No
Participant information sheet	version 2.0	14/06/2023	06/12/2023	No	Yes