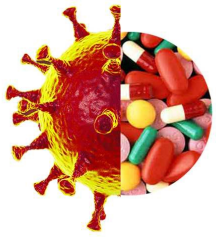
May 10, 2024

Protocol to Investigate Factors Impacting Antimicrobial Stewardship (AMS) Implementation Before and During COVID-19 in Two Acute Care Settings to Fight Antimicrobial Resistance



DOI
dx.doi.org/10.17504/protocols.io.yxmvmenj9g3p/v1

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OPEN ACCESS

DOI: dx.doi.org/10.17504/protocols.io.yxmvmenj9g3p/v1

Protocol Citation: Rasha Abdelsalam Elshenawy, Nkiruka Umaru, Zoe Aslanpour 2024. Protocol to Investigate Factors Impacting Antimicrobial Stewardship (AMS) Implementation Before and During COVID-19 in Two Acute Care Settings to Fight Antimicrobial Resistance. **protocols.io https://dx.doi.org/10.17504/protocols.io.yxmvmenj9g3p/v1**

Protocol status: Working
We use this protocol and it's working

Created: May 09, 2024

Last Modified: May 10, 2024

Protocol Integer ID: 99512

Keywords: Antimicrobial resistance, Antimicrobial stewardship, Public health, COVID-19 pandemic, Acute care setting, Antibiotics, Microbiology, Protocol

Abstract

This protocol aims to investigate factors affecting the implementation of antimicrobial stewardship (AMS) before and during the COVID-19 pandemic in two acute care settings. The research comprises three sequential studies: a systematic literature review to investigate AMS implementation in the previous two decades, a retrospective medical records review to evaluate AMS practices at two hospitals within one NHS Foundation Trust in the United Kingdom, and a prospective survey study to explore healthcare professionals' knowledge, attitudes, and perceptions (KAP) towards antibiotic prescribing, antimicrobial resistance and AMS.

The expected results include identifying AMS measures used before and during the pandemic based on Public Health England's "Start Smart – Then Focus" toolkit. This research will provide insights into healthcare professionals' KAP regarding antibiotic prescribing and AMS implementation, offering a comprehensive understanding of the pandemic's impact on AMS practices.

Attachments

PDF

Protocol V1.2- Inves...

1.6MB

Materials

List of Materials Required for the Protocol

1. **Summary and Abstract Section**
- Summary document
- Abstract document

2. Abbreviations Section
- List of abbreviations used in the protocol

3. Research Synopsis
- Research synopsis document

4. Study 1: Systematic Literature Review
- Literature search strategy document
- Inclusion and exclusion criteria document
- Data extraction and synthesis templates
- Classification of outcomes
- Quality assessment tool

5. Study 2: Retrospective Cross-sectional Medical Records Review Study
- Protocol for observational study
- Inclusion and exclusion criteria
- Access permissions to identifiable patient data
- Confidentiality Advisory Group (CAG) approval documents
- Anonymization guidelines
- Data collection templates
- Quality check guidelines for data extraction
- Sample size calculation tool
- Statistical analysis plan

6. Study 3: Prospective Cross-sectional Survey Study
- Online survey questionnaire template
- Inclusion and exclusion criteria
- Consent form
- Participant information sheet
- Confidentiality guidelines for participant data
- Data collection and analysis plan
- Sample size calculation tool

7. Timelines
- Detailed Gantt chart

- Research project flowchart

8. Ethical Considerations

- Good Clinical Practice guidelines
- Risk assessment framework
- Research Ethics Committees approval documents
- Validity and reliability assessment tools

9. Data Protection and Confidentiality of Study Data

- Data protection guidelines
- Confidentiality agreements

10. Regulatory Considerations

- Discontinuation/Withdrawal policy
- Study approval documents

11. Peer Review Section

- Peer review feedback

12. Finance Section

- Financial plan

13. Publication Policy

- Publication strategy document

14. Appendices Section

- Appendix 1: Research Development Training materials
- Appendix 2: Detailed Gantt Chart
- Appendix 3: Research project flowchart
- Appendix 4: AMS intervention strategies and related outcomes
- Appendix 5: PHE antibiotic prescribing behaviour in acute care settings
- Appendix 6: University of Hertfordshire conference poster presentation
- Appendix 7: Innovative strategies for AMS during COVID-19
- Appendix 8: Global pharmacists' contribution in AMS during COVID-19
- Appendix 9: European Congress of Clinical Microbiology presentation
- Appendix 10: NIHR Good Clinical Practice (GCP) certificate
- Appendix 11: Clinical research certificate
- Appendix 12: Royal Pharmaceutical Society membership certificate
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- Appendix 15: Data collection tool
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- Appendix 18: AMS during COVID-19 pandemic
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Introduction

1 The prevalence of antimicrobial resistance (AMR) has risen significantly over the last 40 years, and a few novel antimicrobials have developed [1]. AMR has increased the pressure on existing antibiotics and more significant challenges in treating patients. Inappropriate use of antimicrobials increases the risk of infection with resistant organisms and subsequent transmission to other patients. AMS is an essential element of the UK's five-year antimicrobial resistance strategy from PHE [2]. AMS is a set of actions that aims to promote the effective use of antimicrobials. Such stewardship initiatives aim to contribute significantly to the reduction and spread of AMR. Additionally, AMS intervention strategies seek to improve antimicrobial prescribing and decrease AMR (Appendix 4). The National Institute for Health and Care Excellence (NICE) produced AMS guidelines in 2017 and recommended its implementation in acute care settings [1]. Additionally, the PHE toolkit of AMS, Start Smart - then Focus provided an impressive outline of evidence-based AMS implementation within the secondary healthcare settings [2] (Figure 1).

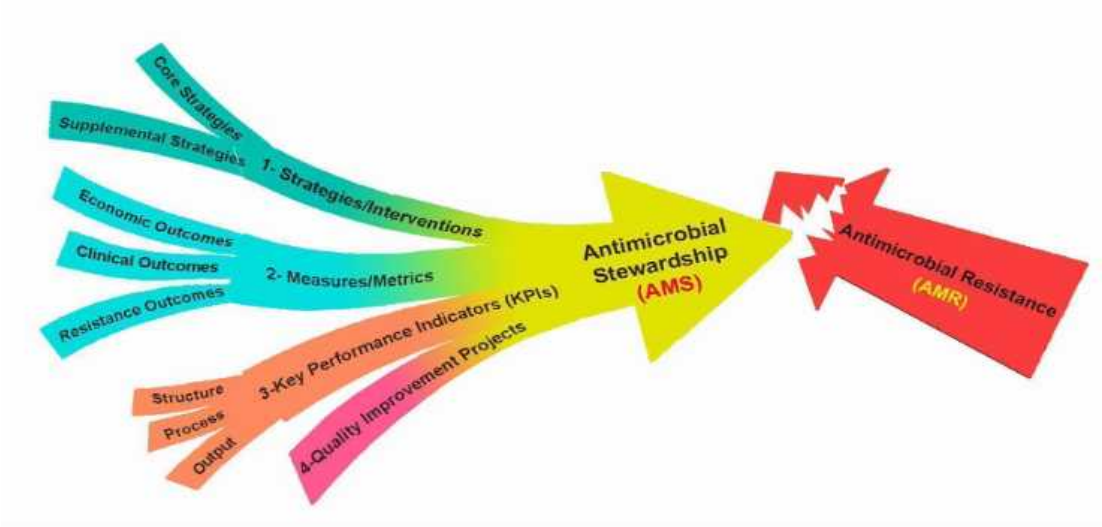

Figure 1. The bundle of AMS implementation

1.1 The COVID-19 pandemic has accelerated the threat of AMR. Inappropriate antibiotic prescribing has increased during the COVID pandemic. The World Health Organisation (WHO) discourages antibiotics for mild cases of COVID-19. WHO was concerned about the inappropriate use of antibiotics, particularly during this pandemic [3]. AMR was responsible for

700,000 annual deaths worldwide. In the shadow of COVID-19, antimicrobial resistance (ABR), one of the world's worsening pandemics, has been 'silenced'. Inappropriate antibiotic prescribing within the hospitals has increased as the number of severely unwell COVID-19 patients increased. Diagnostic uncertainty and concern about secondary bacterial infections may have contributed to this adverse change in antibiotic prescribing [4]. It is essential to learn from the COVID-19 pandemic and prepare for any upcoming emergencies or future pandemics. This study will focus
on AMS as a practical way to improve the safety and quality of patient care. It will contribute significantly to the reduction of AMR (figure 2).

Figure 2. COVID-19 Pandemic and Antimicrobial Resistance Silent Pandemic

Research project

2 This research project investigates AMS implementation before and during the COVID-19 pandemic. It includes three sequential studies (Figure 2).

Systematic literature review: The first study was undertaken on the published information available in scientific journals and reports to obtain evidence about antibiotic use and AMS intervention in acute care settings. It aimed to explore the practice of AMS in acute care settings before and during the COVID-19 pandemic, using a range of explicit strategies and measures, which showed promising outcomes in improving antibiotic prescribing and maintaining the rational use of antimicrobials, especially during COVID-19. Effective AMS

implementation is linked to the improved overall health of adult patients and positively influences reducing AMR. Nonetheless, further studies are required to investigate AMS intervention strategies and the factors affecting AMS implementation in the future.

Phase 1: Observational study of hospital retrospective data: It will review the medical records of patients with RTIs or pneumonia who were admitted to Bedfordshire Hospitals before and during the COVID-19 pandemic.

Phase 2: Online survey: It aims to understand their perceptions, attitudes, practices and identify the factors that affected AMS implementation among Healthcare Professionals (HCPs) before and during the COVID-19 pandemic.
Figure

Description of the research project

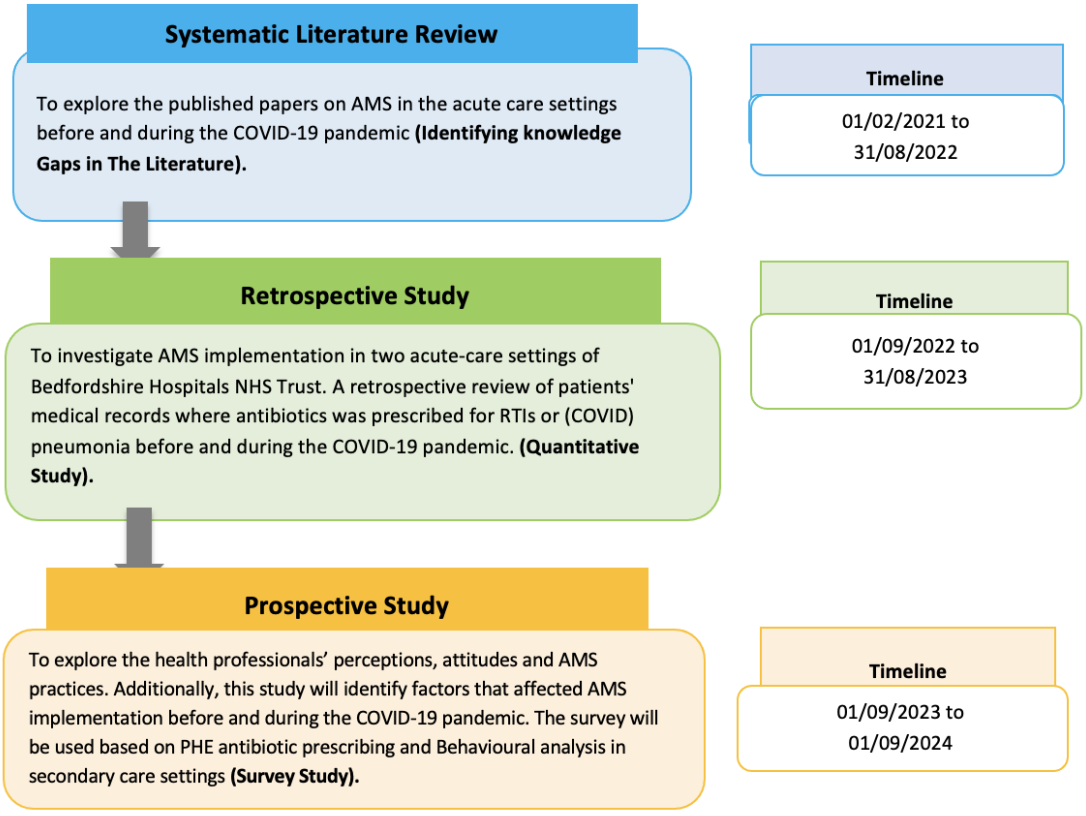

Figure 3. Description of the research project

Systematic literature review

3 **A Systematic Review of Antimicrobial Stewardship Intervention Before and during the COVID-19 Pandemic in Acute Care Settings**

Introduction:
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 [9]. COVID-19 challenged all aspects of healthcare, especially the appropriate antibiotic use. AMS is a set of actions to promote the effective use of antibiotics. PHE emphasised the need for AMS implementation in acute care settings to maintain the appropriate, effective, and safe use of antibiotics. It is essential to find out AMS strategies that could be used effectively in any crisis. This systematic review explored AMS implementation strategies in acute care settings before and during the COVID-19 pandemic.

Method: A systematic literature search on MEDLINE, Embase Classic, OVID, International Pharmaceutical Abstracts, Psychosocial Instruments, MIDIRS, PubMed, Scopus, Web of Science, CINAHL PLUS, OpenGrey and Google Scholar were undertaken. The inclusion criteria were: (i) research studies focusing on antibiotic use in acute care settings; (ii) AMS intervention; (iii) AMS implementation strategies during the COVID-19 pandemic; (iv) adult patients of any gender; and (v) studies reported in the English language (Table 1).

	A	B	C
		Inclusion criteria	**Exclusion criteria**
	Participants	Studies targeting the public/patients' use of antibiotics. HCPs responsible for prescribing, dispensing, or administering antibiotics (doctors, pharmacists and nurses)	Non-HCPs (patient family or community or nursing or long-term care patients)
	Intervention	Studies describe an intervention to improve antibiotic prescribing or AMS implementation strategies as iv- oral switch, and de-escalation, antibiotic review and discontinuation.	Studies that do not describe an AMS intervention.
	Comparison	Comparison with a control group/a group that carried out usual care without an AMS intervention.	
	Context	Interventions are carried out in adult inpatient settings in acute care settings.	Interventions are carried out in nursing homes, care homes or long-term healthcare facilities; community settings; pediatric setting/hospital; and

	A	B	C
			animals/ veterinary practice.
	Outcomes	Primary outcomes: reviewing the effectiveness of AMS intervention and strategies prior to the COVID-19 pandemic and during the pandemic.	
		Secondary outcomes: HCPs' knowledge, attitudes or behaviours related to antibiotic prescribing; rates of AMR; length of stay in hospitals; other measures, metrics, quality improvement, KPIs and COVID-19 pandemic impact on AMS intervention.	
	Study design	RCTs, non-randomized trials, CBA studies, interrupted time series designs, case-control studies and cohort studies, cross-sectional studies, qualitative studies	Systematic reviews, meta-analysis, single case studies, case reports, conference abstracts.

Table 1: Inclusion and exclusion criteria of the systematic literature review

Results: Sixteen articles met the inclusion criteria from an initial result of 8,763 identified article titles. A range of AMS interventions was identified based on AMS toolkit that was developed by PHE. Prior to the COVID-19 pandemic, the most reported AMS strategies in 67% of studies were prospective audit, feedback, and AMS Multidisciplinary Team (MDT). AMS education was also reported in 50% of studies. During the COVID-19 pandemic, AMS education and MDT were the most written strategies implemented in 25% of studies. These were followed by antibiotic review, streamlining/escalation and formulary restriction reported in 17% of studies. The antibiotic review was implemented equally before and during the COVID-19. This systematic review showed the global pharmacists' role in leading AMS implementation in acute care settings (Appendix 6). In addition, it showed some promising new innovative AMS implementation strategies, such as Procalcitonin (PCT) measurements, quality improvement initiatives and antibiotic dashboard that showed promising outcomes in AMS intervention during the COVID-19 pandemic.

Retrospective medical records review

4

(*Phase 1: Retrospective study at Two Hospitals of NHS Foundation Trust in the UK)*

4.1. Aim and Objectives:

This research investigates AMS implementation before and during the COVID-19 pandemic in two hospitals of NHS Foundation Trust in the UK.

4.2. Methodology:

This 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 undertaken at eight-time points, four before COVID-19 as baseline measures and four during the COVID-19 pandemic.

4.3. Inclusion criteria

1. Adult patients 25 years and older.
2. Adult Pregnant women and immunocompromised patients.
3. Patients admitted at the Trust.
4. Patient admitted in 2019 and 2020.
5. Patients who were prescribed antibiotics for RTIs or pneumonia.

4.4. Exclusion criteria:

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

4.5. Data collection:

As the seasonal variations affect antibiotic prescribing for RTIs or pneumonia. The highest incidence of pneumonia was noted in the winter season, followed by autumn, and spring. However, a low incidence of pneumonia was noted in the summer season [10]. As this study will compare the impact of the COVID-19 pandemic on AMS implementation before and during the COVID-19 pandemic. Randomised data will be collected from eight Interrupted time series (four before the COVID-19 pandemic and four during the pandemic) as shown below:

Four-time points before the COVID-19 pandemic

1. 1st week of March (Spring 2019)
2. 1st week of June (Summer 2019)
3. 1st week of September (Autumn 2019)
4. 1st week of December (Winter 2019)

Four-time points during the COVID-19 pandemic

1. 1st week of March (Spring 2020): The first wave of COVID.
2. 1st week of June (Summer 2020): First lockdown.
3. 1st week of September (Autumn 2020): The second wave of COVID.
4. 1st week of December (Winter 2020): Vaccination Rollout.

4.6. The Expected outcomes

Primary outcome:

- AMS implementation before and during the COVID-19 pandemic, such as Parenteral-to-Oral switch, antibiotic discontinuation, de-escalation, dose adjustment, and antibiotic review based on the local guidelines.

Secondary outcome:

- Measured the proportion of inappropriately prescribed antibiotics at admission, and after 48 to 72 hours.
- Laboratory and other diagnostic methods, such as chest X-ray (CXR), procalcitonin (PCT), C-reactive protein (CRP), Leukocytosis (WBC > 10,000/mm 3), and fever measured using the proportion of their use in patients infected with RTIs or pneumonia before and during the COVID-19 pandemic.

4.7. Sample size:

The sample size was determined based on the literature and the percentage of inappropriate antibiotic prescribing. According to PHE and the NICE guidelines, at least 20% of all antibiotics are inappropriately prescribed in the UK. The stats package Minitab was used for the sample size calculation. The PI obtained the figures on the total number of inpatient admissions in both hospitals mentioned above, to ensure the feasibility and accuracy of the calculated sample sizes. The Sample size was estimated according to the population size, the margin of error (ME) of 10%, and the confidence interval (CI) of 95 %. Then the sample size calculation was verified with the UH statistician. Data will be collected from 320 patient records prior to the COVID-19 pandemic and 320 patient records during the COVID-19 pandemic. Each time series will include the review of 80 medical records. The total sample size for this phase will be 640 patient records.

4.8. Method of analysis

The process of antibiotic use in the hospital consists of 5-stages, which are (1) prescribing, 2) transcribing and documenting 3) dispensing, 4) administering, and 5) monitoring. The appropriateness of antibiotic prescribing is measured based on the hospital **antimicrobial prescribing guidelines**. The rest of the antibiotic use process or antimicrobial stewardship will be measured based on **Public Health England Antimicrobial Stewardship Toolkit** and **NICE Antimicrobial Stewardship guidelines**.

Quantitative data: Statistical analysis will be performed. Descriptive statistics will be employed to ascertain the distribution of data. Inferential statistics employing parametric (if data is normally distributed) and non-parametric (if data is not normally distributed) tests to explain relationships within data will be performed. Means and standard deviations will be calculated for continuous variables, while percentages and proportions will be computed for categorical variables. Descriptive statistics for interval-level and ratio-level variables will be applied to report the results. Inappropriate antibiotic prescribing percentages prior to the COVID-19 pandemic will be compared with antibiotic use during the pandemic. Additionally, the ratio of AMS implementation strategies will be measured, including AMS strategies, such as IV-to-Oral switch, antibiotic discontinuation, de-escalation, dose adjustment, and antibiotic review based on the local guidelines measured. Further, measure antibiotic utilisation and

consumption before and during the COVID-19 pandemic. Laboratory and other diagnostic methods, such as chest X-ray
(CXR), procalcitonin (PCT), C-reactive protein (CRP), Leukocytosis (WBC > 10,000/mm 3), and fever in patients infected with RTIs or pneumonia before and during the COVID-19 pandemic among infected patients treated with antibiotics, will be analysed using the ANOVA test for multiple variables.

Prospective cross-Sectional survey study

5 Though the first phase of this research study will measure AMS implementation before and during the COVID-19 pandemic, there consequently remains a strong need to determine the antibiotic prescribing behaviours among HCPs. For this reason, this second phase is essential to explore the factors that affect AMS implementation before and during Covid.

5.1. Objectives:

In this phase, the survey will use closed and open-ended questions based on PHE antibiotic prescribing literature review and behavioural analysis [6]. The survey aims to explore the HCPs' perceptions, attitudes towards antibiotic prescribing and AMS implementation before and during the COVID-19 pandemic (Appendix 16).

5.2. Methodology:

This study will use a cross-sectional online survey based on PHE behaviour change and antibiotic prescribing in secondary care settings [6]. A mixed open and close-ended questionnaire survey will be conducted through a secured and UH trusted survey platform, Qualtrics XM. This survey aims to explore perceptions, attitudes, and AMS implementation among HCPs (doctors, nurses, and pharmacists) before and during the COVID-19 pandemic.

5.3. Inclusion criteria:

1. Health Care Professionals (doctors, nurses, and pharmacists).
2. Adults 25 years and older.
3. Registered with the relevant professional regulatory body; GMC, GPhC and NMC.
4. HCPs who were working before/during the COVID-19 pandemic at the Trustl and still working in one or two of these hospitals' sites.

5.4. Exclusion criteria:

1. HCPs (doctors, nurses, and pharmacists) who are not currently working at the NHS Trust.

5.5. Expected outcomes

Primary outcome:

- Antibiotic prescribing behaviour of HCPs will be explored using the range of knowledge, attitudes, and perceptions questions.

Secondary outcome:

- Factors affecting AMS implementation will be explored using the range of AMS implementation before and during the COVID-19 pandemic.

5.6. Sample Size:

To ensure the feasibility and accuracy of the calculated sample size, the PhD student/PI obtained the figures on the total number of employed registered pharmacists as 206, the total number of employed registered nurses as 2,140 and the total number of employed registered doctors as 5,636. Additionally, the PI obtained the total number of health professionals (headcount) which is 7,982. The sample size n and margin of error E are given by:

	A	B	C
	x	=	$Z(c/100)2r(100-r)$
	n	=	$N\,x/((N-1)E2 + x)$
	E	=	$\mathrm{Sqrt}[(N - n)x/n(N-1)]$

Where N is the population size, r is the fraction of responses that you are interested in, and $Z(c/100)$ is the critical value for the confidence level c. The sample size for the survey will be 240, with a margin of error is 5%, a confidence interval is 95%, and a response rate of 20%. All sample size calculations for both phases were verified by the University of Hertfordshire (UH) statistician support.

5.7. Method of analysis

An iterative data analysis process will be employed to identify and categorise ideas into key themes and their relationships. The quantitative data will be analysed using Qualitative Data Analysis Software (MAXQDA) to facilitate the categories process. The textual material will be analysed in terms of categories. Any disagreements will be resolved through discussion.

Conclusion

6 In this protocol, we have outlined a comprehensive plan to investigate antimicrobial stewardship (AMS) practices and antimicrobial resistance (AMR) challenges through a series of systematic studies. Our multi-phase research project aims to deliver impactful insights that align with the new UK Five-Year AMR Action Plan (2024-2029).

1. Study 1: Systematic Literature Review
By conducting a systematic literature review, we will consolidate existing evidence on AMS strategies and outcomes. This will provide a foundational understanding of global and national efforts in combating AMR, highlighting successful interventions and identifying research gaps.

2. Study 2: Retrospective Cross-sectional Review
The observational study aims to analyse hospital retrospective data to uncover trends and patterns in antibiotic use during the COVID-19 pandemic. This study will assess the effectiveness of AMS interventions and establish the impact of the pandemic on prescribing practices in secondary care settings.

3. Study 3: Prospective Survey Study
The online survey will gather insights from pharmacists about their knowledge, attitudes, and perceptions towards AMS and AMR. Understanding the perspectives of healthcare professionals is crucial for designing effective educational and behavioural interventions to improve AMS compliance.

Anticipated Outcomes

7

- **Improved Understanding of AMS Implementation**
  Our research will clarify current practices and challenges in AMS implementation, particularly during the COVID-19 pandemic, providing actionable recommendations for policymakers.

- **Contribution to National AMR Strategy**
  The findings will directly support the research priorities of the new UK AMR Action Plan, offering evidence-based guidance for improving stewardship practices.

- **Innovative Strategies for AMS**
  By identifying successful and innovative AMS strategies, our project will contribute to the global fight against AMR, emphasizing the role of pharmacists in stewardship programs.

Future Implications

8 This protocol serves as a strategic roadmap for researchers and healthcare professionals dedicated to tackling AMR. The evidence generated will not only reinforce existing knowledge but also illuminate new avenues for research and practice. Our work will be instrumental in informing future national and international AMS policies and ensuring the sustainability of antimicrobial effectiveness in healthcare.

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