TRIC - MAN

Trainee Research Intensive Care network project:
A national audit Measuring ANtimicrobial prescribing and resistance in Critical Care Units in the United Kingdom (TRIC-MAN)

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Project Overview

Title of study	Trainee Research Intensive Care network project: A national audit measuring antimicrobial prescribing and resistance in Critical Care Units in the United Kingdom (TRIC-MAN)
Design	Prospective, multi-centre audit
Study objectives	1) Evaluate adherence to United Kingdom Health Security Agency (UKHSA) 'Start Smart Then Focus' and National Institute for Health and Care Excellence (NICE) guidance for initiation of antimicrobial therapy, review of prescriptions and review of microbiological results in critically ill patients in the UK 2) Explore antimicrobial stewardship and infection prevention and control (IPC) practices in UK critical care units
Target population	All patients ≥18 years of age admitted on/to a participating critical care unit during the study period
Interventions	None
Study duration	Twenty-four hours (with fourteen-day follow-up)

Background

For patients with sepsis, the Surviving Sepsis Campaign guidelines state that "early administration of appropriate antimicrobials is one of the most effective interventions to reduce mortality" (1). The use of antibiotics with insufficient antimicrobial coverage is associated with worse outcomes (2, 3). This is against a backdrop of increasing antimicrobial resistance (AMR), a global threat to public health, responsible for over a million excess deaths worldwide (4).

It Is generally accepted that antimicrobial stewardship (AMS) reduces AMR, including in critically ill patients (5, 6). In 2023, the United Kingdom Health Security Agency (UKHSA) published an updated antimicrobial stewardship toolkit titled 'Start Smart Then Focus' (SSTF) (7). Key components of this guidance are prescribing antimicrobials according to local or national guidance and then reviewing and revising antimicrobial prescriptions at 48-72 hours in light of clinical and microbiological data. This approach is also supported by National Institute for Health and Care Excellence (NICE) guidance (8). At the 48–72-hour timepoint, prescriptions can be: 1) ceased if there is no evidence of infection; 2) amended, either broadened or narrowed, to ensure effective and proportionate treatment; 3) extended, with a future review or stop date; 4) switched to oral therapy; or 5) referred for out-patient treatment.
It is over twenty years since the last national survey of antibiotic use specifically in Intensive Care Units (ICUs) in the UK (9). In this survey, 11% of patients had admission prescriptions changed due to antibiotic resistance and 13% of patients had multiple resistance. Given that around 70% of critically ill patients are treated with antibiotics (10) and per-capita antibiotic use is highest in intensive care units in secondary care (3), it is essential to regularly evaluate the use of these drugs.

There is high prevalence of antimicrobial resistance in ICUs across Europe (11) and the rest of the world (12-14). However, comparatively little is known about the prevalence of AMR in ICUs in the UK. For example, resistance data for UK ICUs is not routinely reported by English surveillance programme for antimicrobial utilisation and resistance (ESPAUR) (3); the European Centre for Disease Prevention and Control (15); the WHO CAESAR Network (16); or Infection in Critical Care Quality Improvement Programme (17).

This national audit will assess how often antibiotics are used in critically ill patients per UKHSA and NICE guidance and further examine how many prescriptions are required to be amended due to confirmed resistance in a cultured isolate. As part of the audit, we will examine the resistance profiles of priority bacterial pathogens as defined by ESPAUR (3) and WHO (18) to evaluate how they influence prescription practices. Finally, we will examine unit-level stewardship and infection prevention and control (IPC) practices across the UK.

Aims:

1) Evaluate adherence to UKHSA and NICE guidance for initiation of antimicrobial therapy, review of prescriptions and review of microbiological results in critically ill patients in the UK
2) Explore antimicrobial stewardship and IPC practices in UK critical care units

Methodology

TRIC-MAN will comprise of two components:

- An audit of antimicrobial prescribing and certain microbiological results in critically ill patients across the UK
- A cross-sectional unit-level survey to examine the antimicrobial stewardship and IPC practices in critical care units across the UK

The methodology has been informed by well-established point-prevalence survey methodology in conjunction with representatives from ESPAUR (19).

Study setting

All adult critical care units in the UK offering level 2 and/or level 3 care will be invited to participate in the study. A full definition is provided in Appendix 1.

Inclusion Criteria

All patients ≥18 years of age admitted on/to a participating critical care unit on the chosen study day.

Exclusion Criteria

Nil

Data for certain antimicrobials will not be collected, which is outlined in the next section.

Data collection

Study sites will choose a single calendar day during a two-week national period (31st March-28th April) to start data collection.

All eligible patients admitted on/to the critical care unit on the specified day (Day 0 – 0000 to 2359) will be screened for antimicrobial therapy, including those temporarily off the unit, for example, in theatre.

If the patient is not receiving an antimicrobial on this day, then only basic non-identifiable demographics will be collected.

If a patient does receive antimicrobial therapy on Day 0, further data will be collected including immunosuppression, colonisation with AMR resistant organisms and antimicrobial treatment(s), as well as outcome at Day 14.

If a patient has started antimicrobial therapy on one of the three calendar days prior to Day 0 or Day 0 itself, they will be included in the prospective audit cohort. Data will be collected for all ongoing antimicrobial choices (between Day -3 and up to Day 14), review of therapy and certain microbiological results up until Day 14.

If the antimicrobial therapy was started prior to three calendar days ago, data on antimicrobial use will be limited to the reason for prescription of that regimen only and no microbiological data will be collected. This is to ensure accuracy and ease of data collection for clinicians.

Data collection will cease if the patient is discharged/transferred from critical care, antimicrobials are stopped for 48 hours or at 1200 on Day 14. If antimicrobials have been stopped for a given indication and a patient develops a separate infection at a new anatomical site, data will not re-commence for this second episode, even if within 48 hours of stopping the initial regimen.

Figure 1 outlines example scenarios for data collection.

Data regarding antimicrobials used: for selective decontamination of the digestive tract (SDD); for gut motility; for superficial candidiasis; for hepatic encephalopathy; for tuberculosis, HIV or hepatitis; or topical treatments will not be collected. Antimicrobials prescribed for prophylaxis peri-operatively (except those only used in the theatre department) or after cardiac arrest or trauma will be included, but no other prophylactic antimicrobials will be included in data collection (for example, in immunosuppressed patients or those with chronic lung disease).

Microbiological data will only be collected for specific samples: normally sterile sites (blood cultures, line tips, intra-operative tissue samples, abdominal fluid, pleural fluid, cerebrospinal fluid, bone, synovial fluid and bone marrow); urine; bronchoalveolar lavage (directed or non-directed); and screening swabs for AMR organisms from admission to critical care. Specific resistance patterns will be collected for certain organisms outlined in Table 1 below, as part of the audit of how prescribing is influenced by culture results.

Further definitions for data collection are provided in Appendix 1. Any queries related to data collection will be rapidly answered by email by the co-ordinating team.

A single, cross-sectional unit-level survey to examine the antimicrobial stewardship and IPC practices will also be completed once for each participating unit.

Data collection will be performed by intensive care or infectious disease/microbiology staff under supervision of a consultant. The involvement of the critical care or AMR-specialist pharmacist will be encouraged.

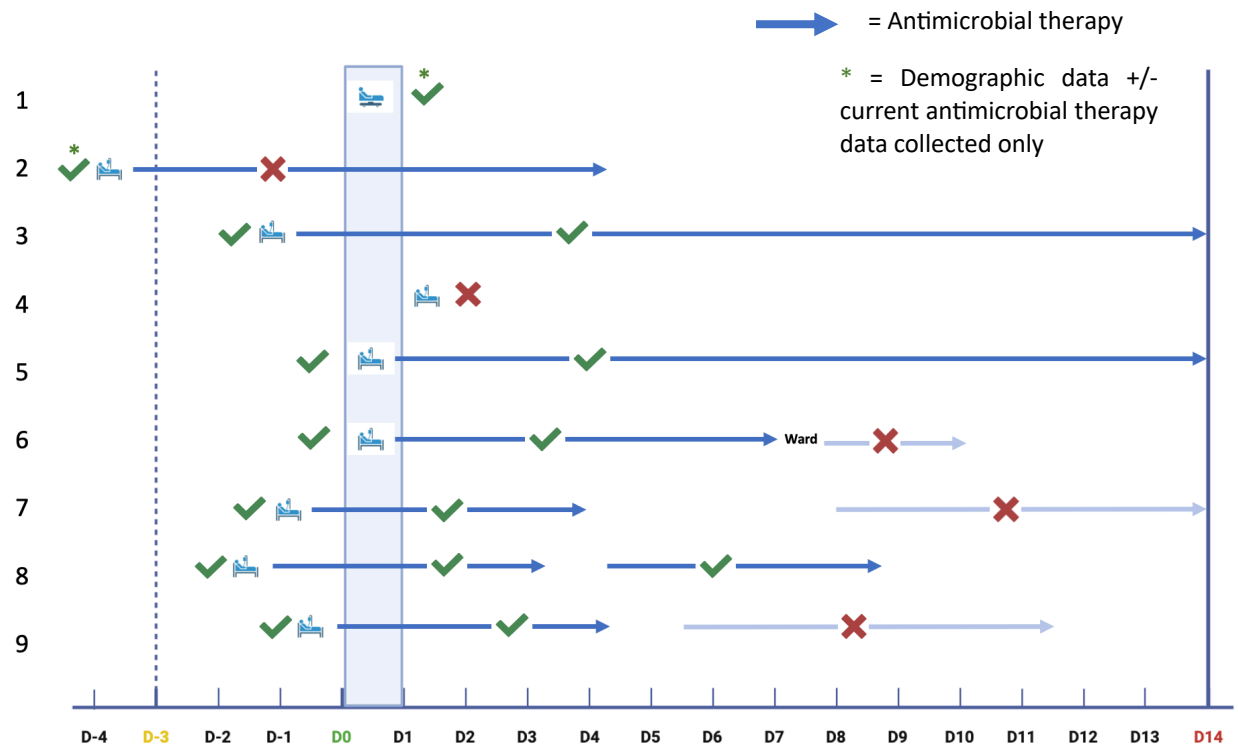

Figure 1. Example scenarios for data collection.

(1) Patient is **not** prescribed any antimicrobial therapy on Day 0. Only basic demographic details are collected and then data collection finishes, even if starts on antimicrobials later in the admission.

(2) Patient is on antimicrobial therapy on Day 0 for **>3 calendar days** (**for a given indication**, even if regimen changed more recently), even if therapy stopped on Day 0. Demographic details are collected, as well as limited data about current prescription but **no follow-up** invasive isolate or antimicrobial data are collected.

(3) Patient is on antimicrobial therapy on Day 0 for **≤3 calendar days** and therefore included in prospective cohort, including if therapy stopped on Day 0. Data for **all** eligible antimicrobials and microbiological data is collected. If antimicrobials remain ongoing then data collection is stopped at 1200 on Day 14.

(4) Patient is not admitted until after Day 0 and is not included.

(5) Patient is admitted to critical care on new antimicrobial therapy during Day 0 and is included for the duration of antimicrobial therapy (stopped at 1200 on Day 14 if applicable).

(6) Patient is started on antimicrobials on Day 0 and then discharged from Intensive Care on Day 7, when data collection ceases (even if antimicrobial therapy continued on a ward).

(7) Patient is on antimicrobials on Day 0 so data are collected. On Day 4, antimicrobials are ceased for over 48 hours so no further data are collected after this day.

(8) Patient is on antimicrobials on Day 0, which are stopped for 36 hours on Day 3 before restarting for the same indication after patient deteriorates. Data are collected for entire course.

(9) Patient is on antimicrobials on Day 0 and ceased on Day 4. On Day 5, antimicrobials are started for a different indication. Data are collected for the first infection but are not collected for this second infection.

Data will be collected on electronic case-report forms on using a secure, password-protected data entry web portal, 'Research Electronic Data Capture' (REDCap, www.project-redcap.org), hosted by the Liverpool School of Tropical Medicine.

Consent and safety

Individual patient consent is not required as this is an audit to examine the adherence to the national AMS toolkit published by UKHSA (7) and NICE guidelines (8) and no patient identifiable data will be collected. All data collectors will be members of the care team and no alterations to routine practice will be made.
There are no anticipated patient risks with the collection of data and staff entering data will be asked to confirm that each microbiological isolate entered has been noted by the treating clinicians to ensure safety. Site staff will highlight any key safety issues or concerns, such as resistant pathogens not covered by current therapy, to the treating clinician.

Each site will be required to gain permission to conduct the audit with their local audit department before being provided with login details for the database and entering data.

Standards/guidelines being evaluated

"Start smart then focus: antimicrobial stewardship toolkit for inpatient care settings" – UKHSA, September 2023 (7).

- "Comply with local antimicrobial prescribing guidance informed by local resistance patterns or national guidance"
- "Avoid indiscriminate use of broad-spectrum antimicrobials – to preserve the effectiveness of these agents, reduce collateral damage to the patient's microbiota and reduce the risk of opportunistic infection (such as *Clostridioides difficile*)"
- "Include treatment duration where possible or specify a review date – to avoid unnecessarily prolonged treatment"
- "Review and revise the clinical diagnosis and the continuing need for antimicrobials at 48 to 72 hours and document a clear plan of action from the antimicrobial review outcomes"
- "Amend antimicrobials – ideally to a narrower spectrum agent – or broader if required – to ensure that treatment is effective and proportionate"

"Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use" – NICE, August 2015 (8).

- "Consider…monitoring and evaluating antimicrobial prescribing and how this relates to local resistance patterns"
- "Consider prioritising the monitoring of antimicrobial resistance, to support antimicrobial stewardship across all care settings"
- "When prescribing any antimicrobial, undertake a clinical assessment and document the clinical diagnosis…in the patient's record"

- “For patients in hospital who have suspected infections, take microbiological samples before prescribing an antimicrobial and review the prescription when the results are available”
- “Use an intravenous antimicrobial from the agreed local formulary and in line with local (where available) or national guidelines for a patient who needs an empirical intravenous antimicrobial for a suspected infection but has no confirmed diagnosis”
- “Consider reviewing intravenous antimicrobial prescriptions at 48–72 hours in all health and care settings”

Key audit criteria

In how many prescriptions is the reason for antimicrobial therapy documented (either on a prescription chart or in the medical notes)?
Target 100%

How many empiric antimicrobial prescriptions are started as per local/national guidelines or specialist guidance, unless documented reason for deviation (for example, allergy or colonisation with resistant organism)?
Target 100%

How often is antimicrobial therapy reviewed within 72 hours?
Target 100%
Note: A change in antimicrobial prescription within 72 hours will be classed as a review even without a corresponding entry in the medical notes as previously agreed in a Delphi consensus on antibiotic prescribing audits (20).

Other priority questions

How frequently is empiric antimicrobial therapy amended based on antimicrobial resistance to the prescribed antimicrobial?

In those on antimicrobials for 3 days or fewer, what is the prevalence of antimicrobial resistance in priority pathogens (Table 1) in blood-stream/sterile-site infections in critically ill patients in the UK as defined by ESPAUR (3) and WHO (18) and do these lead to changes in antimicrobial prescriptions?

Pathogens	Key Antimicrobial resistance
Enterobacteriaceae: Escherichia coli, Klebsiella spp., Enterobacter spp., Proteus spp., Citrobacter spp., Serratia spp., Morganella spp.	Ciprofloxacin, Gentamicin, 3rd generation Cephalosporin, Carbapenems, Piperacillin-Tazobactam, Co-amoxiclav, Amikacin
Pseudomonas aeruginosa	Ciprofloxacin, Gentamicin, Ceftazidime, Carbapenems, Piperacillin-Tazobactam
Acinetobacter baumannii	Gentamicin, Ciprofloxacin, Piperacillin-Tazobactam, Carbapenems
Staphylococcus aureus	Oxacillin (i.e., MRSA), Vancomycin, Teicoplanin, Linezolid, Tigecycline, Macrolides, Tetracyclines, Clindamycin
Streptococcus pneumoniae	Penicillins, Macrolides, Tetracyclines
Enterococcus faecalis	Vancomycin, Teicoplanin, Linezolid, Daptomycin, Ampicillin/Penicillin
Enterococcus faecium	Vancomycin, Teicoplanin, Linezolid, Daptomycin
Candida (albicans vs non-albicans)	Fluconazole, Amphotericin B, Echinocandin

Table 1. Priority pathogens cultured at normally sterile-sites to be evaluated for resistance profiles against key antimicrobials. Normally sterile sites include: blood cultures, line tips, intra-operative tissue samples, abdominal fluid, pleural fluid, cerebrospinal fluid, bone, synovial fluid and bone marrow.

Dissemination plan

Study findings will be disseminated at the conclusion of data collection and analysis through peer-reviewed academic publications, social media, and through conference papers and presentations.

Authorship plan

Members of the TRIC-MAN steering group will be named authors on future publications. Site-specific staff will be named as collaborators.

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Appendix 1- Definitions

A “critical care unit” is defined as a location in a hospital where prolonged Level 2 or Level 3 organ support can be provided. Units would be typically be staffed by intensive care specialists and submit data to the Case Mix Programme or the Scottish Intensive Care Society Audit Group. Units that, for example, provide time-limited organ-support post-operatively or peripheral vasopressors, respiratory non-invasive ventilation units or similar would not be included.

Patients defined as “receiving antimicrobial therapy” at the time of study if there is an active prescription for at least one antimicrobial between 0000-2359 on Day 0 of the audit. This includes once daily antimicrobials (e.g. gentamicin) if given within the past 24 hours and antimicrobials that are given less frequently than once per day e.g. for renal dysfunction but remain ongoing. Antimicrobials include antibiotics, anti-virals, anti-fungals and anti-parasitics.
Excluded antimicrobials are those for: selective decontamination of the digestive tract (SDD); for gut motility; for superficial candidiasis; for hepatic encephalopathy; for tuberculosis, HIV or hepatitis; and topical treatments. Antimicrobials prescribed for prophylaxis peri-operatively (except those only used in the theatre department) or after cardiac arrest or trauma will be included, but no other prophylactic antimicrobials will be included in data collection (for example, in immunosuppressed patients or those with chronic lung disease).

Antimicrobial and microbiological data will be collected for a “single-episode of infection”, up until fourteen days from the audit date. If patients are treated for multiple infections concurrently (e.g., a blood-stream infection and *Clostridioides difficile*), data will be collected for both infections. Data collection will end if a patient has been off antimicrobials for 48 hours or if a patient develops a new infection at a separate anatomical site that the clinical team judge to be unrelated. If a micro-organism is a common contaminant, the treating clinicians will be asked to judge if this is pathogenic or a contaminant.

An “antimicrobial review” is defined as either an entry in the medical notes referencing antimicrobial choice/course length or a change in prescription within 72 hours. A change is defined as a new antimicrobial prescription or a discontinuation of part of combination therapy within this time-frame.
“Narrowing” of antimicrobial therapy is defined as a change in regimen where the initial therapy is likely, or known due to culture results, to have provided adequate coverage for treatment but extended microbiological coverage is unnecessary. “Broadening” of antimicrobial therapy is defined as a change in regimen where the initial therapy did not provide adequate therapy due to resistance, or a regimen is changed to provide wider empirical cover.

“Hospital-acquired infections” are those evident at least 48 hours after hospitalisation.

“ICU-acquired infections” are defined as those occurring at least 48 hours following admission to the ICU.

Other “Health-care associated-infection” refers to infections in a patient who meets any of the following criteria: 1. Received intravenous therapy at home; received wound care or specialized nursing care through a health care agency, family, or friends in the 30 days prior to hospital admission patients whose only home therapy was oxygen use were not included), 2) Attended a hospital or hemodialysis clinic or received intravenous chemotherapy in the 30 days prior to hospital admission, 3) Had been admitted to an acute care hospital for 2 or more days in the 90 days prior to hospital admission, 4) Resided in a nursing home or a long-term care facility.(10)

Type of admission:
Surgical - defined as having surgery in the week preceding ICU admission. Elective surgery is defined as surgery scheduled > 24 hours in advance and emergency surgery as that scheduled within 24 hours of operation. Trauma is defined as an ICU admission directly related to, or as a complication of, a traumatic event in the 30 days preceding ICU admission.(10)

Appendix 2 – Exemplar Clinical Governance Form

Title: Trainee Research Intensive Care network project: A national audit Measuring ANtimicrobial prescribing and resistance in Critical Care Units in the United Kingdom (TRIC-MAN)		**Advisory notes**
Division:	Critical Care and Anaesthetics	*Your local site division or department may have a different name*
Specialty:	Intensive Care Medicine	
Departmental Audit/Clinical Governance lead:	[Consultant in Intensive Care Medicine]	*This will be the consultant within your unit who has overall role for audit/clinical governance*
Audit/Project Supervisor:	[Consultant in Intensive Care Medicine]	*In most hospitals, this will require a named consultant to sponsor the project*
Project lead:	[Your Name]	
Other project team members:		*Insert names of other collaborators for data collection*
Type of project:	☐ Local ☐ National ☐ NICE ☐ Quality standard	*Select national or equivalent*
Site:	[Trust/hospital name]	*Insert your hospital name or if your trust has intensive care units across multiple sites, list them all*
Proposed start date:	31/03/2025	
Proposed completion date:	28/04/2025	

National Patient Data Opt-Out/Information Governance		
Are you using anonymous data (non-identifiable patient data)?	Yes	*TRIC-MAN **does not** request nor hold data which is identifiable or likely to be identifiable.*
Do you have the patient's consent to use their data?	No	*As an audit, this is not required*
Does this audit have CAG approval under Section 251? *(National Audits only)*	No	
Do you intend to present the audit findings outside the Trust?	Yes	*You **must** inform your local information governance team this project will have data collected centrally.*

Further common aspects of audit/QI/service evaluation registration forms:

Standards/Guidelines being reviewed/audited:

"Start smart then focus: antimicrobial stewardship toolkit for inpatient care settings"
UKHSA, September 2023
https://www.gov.uk/government/publications/antimicrobial-stewardship-start-smart-then-focus/start-smart-then-focus-antimicrobial-stewardship-toolkit-for-inpatient-care-settings

Standards:

- "Comply with local antimicrobial prescribing guidance informed by local resistance patterns or national guidance"
- "Avoid indiscriminate use of broad-spectrum antimicrobials – to preserve the effectiveness of these agents, reduce collateral damage to the patient's microbiota and reduce the risk of opportunistic infection (such as *Clostridioides difficile*)"
- "Include treatment duration where possible or specify a review date – to avoid unnecessarily prolonged treatment"
- "Review and revise the clinical diagnosis and the continuing need for antimicrobials at 48 to 72 hours and document a clear plan of action from the antimicrobial review outcomes"
- "Amend antimicrobials – ideally to a narrower spectrum agent – or broader if required – to ensure that treatment is effective and proportionate"

"Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use"
NICE, August 2015
https://www.nice.org.uk/guidance/ng15

Standards:

- "Consider…monitoring and evaluating antimicrobial prescribing and how this relates to local resistance patterns"
- "Consider prioritising the monitoring of antimicrobial resistance, to support antimicrobial stewardship across all care settings"
- "When prescribing any antimicrobial, undertake a clinical assessment and document the clinical diagnosis…in the patient's record"
- "For patients in hospital who have suspected infections, take microbiological samples before prescribing an antimicrobial and review the prescription when the results are available"
- "Use an intravenous antimicrobial from the agreed local formulary and in line with local (where available) or national guidelines for a patient who needs an empirical intravenous antimicrobial for a suspected infection but has no confirmed diagnosis"
- "Consider reviewing intravenous antimicrobial prescriptions at 48–72 hours in all health and care settings"

Audit Criteria

Audit Criteria (What should be happening, e.g. Prescriptions should be clearly signed and dated)	**Acceptable audit target** (% of cases where this should happen)
In how many prescriptions is the reason for antimicrobial therapy documented (either on a prescription chart or in the medical notes)?	100%
How many empiric antimicrobial prescriptions are started as per local/national guidelines or specialist guidance, unless documented reason for deviation (for example, allergy or colonisation with resistant organism)?	100%
How often is antimicrobial therapy reviewed within 72 hours?	100%

Methodology

Refer to Methodology section in the protocol