### "Start Smart" Empiric Antibiotic Prescribing Clinical Audit Tool

**Date:** / /  
**Prescriber/team/unit:** ___________________  
**Audit number:** _______

<table>
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<tr>
<th>Patient</th>
<th>Chart number</th>
<th>Indication documented in chart</th>
<th>Antibiotic choice in line with local guidelines</th>
<th>Antibiotic choice documented in chart</th>
<th>Cultures taken before starting antibiotics</th>
<th>Treatment duration, or review date, documented</th>
<th>Antibiotic given within 4 hours (or within 1 hour if sepsis)</th>
<th>Notes</th>
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</tbody>
</table>

**Audit score** /10 /10 /10 /10 /10 /10

**Observations:**

**Ideas for change:**

**Next steps:**
Instructions for completing audit tool

The audit tool is based on assessing ten patients prescribed empiric antibiotics for each audit cycle. This can be done prospectively (e.g. the first ten patients prescribed antibiotics on a unit/ward, or by my team, this week), or retrospectively (e.g. a random selection of patients prescribed antibiotics on a unit/ward, or by my team, over the previous week). At a minimum data should be collected on documentation of indication and compliance with local guidelines. However, it is helpful to complete at least one audit cycle that includes all of the components (to identify potential areas for improvement).

- **Date**: Record the date the audit is completed
- **Prescriber/team/unit**: Indicate to whom or where this audit is being applied
- **Audit number**: The audit tool is designed to facilitate rapid repeat audit cycles. Sequential number of audits facilitates assessing trends over time
- **Patient**: Each patient represents one observation in the audit, and are numbered sequentially (1-10)
- **Chart number**: It is not essential to record the chart number for each included patient. However, this may be helpful to ensure the same patient is not included more than once in the audit, or for collection of additional data at a later date
- **Indication documented in chart**: State if the indication for starting antibiotic therapy is clearly documented in the patient’s medical record. The indication should be for a known, or suspected, bacterial infection
- **Antibiotic choice in line with local guidelines**: Indicate if the choice of empiric antibiotic(s) is in line with local hospital prescribing guidelines. If the indication for antibiotic therapy is not covered in the local guidelines, indicate “not applicable” (NA)
- **Antibiotic choice documented in chart**: Indicate if the name of the antibiotic(s) has been clearly documented in the patient’s medical record
- **Cultures taken before starting antibiotics**: Indicate if appropriate cultures were taken before starting antibiotics (e.g. blood culture, in the case of suspected bacteraemia or sepsis; urine culture; in the case of suspected urinary tract infection)
- **Treatment duration/review date**: Indicate if the planned duration of therapy, or a plan to review aspects of the initial antibiotic regimen (e.g. choice of agent, route of administration, duration of therapy) at or by a specified time (e.g. within 24-48 hours), is documented in the patient’s medical record
- **Antibiotic given within 4 hours (or within 1 hour if sepsis)**: Indicate if the first dose of antibiotic(s) was given within four hours of prescribing, in the case of uncomplicated infections. For patients diagnosed with sepsis, or with neutropenic infection, indicate if first dose given within one hour (circle “4” or “1”, depending on which of the above categories apply to the patient in question)
- **Notes**: Include any notes, relating to the patient care episode being audited, that will help with the interpretation of the audit results
- **Audit score**: Calculate a score (out of a maximum of 10) for each element of the audit tool
Start Smart, then Focus: Clinical Practice Audit Guidance

1: Introduction and rational
Antibiotics are one of the most important medical advances of the past 100 years, allowing us to cure infections that would have frequently been fatal in the past, and also to treat many of the opportunistic infections that arise as a consequence of modern medical practice. However, in order to be effective they need to be used appropriately. Furthermore, this vital medical resource is under increasing threat from the rise in antibiotic resistance.

Antibiotics can be life-saving, but only if used appropriately. Getting the choice of antibiotic right, particularly for severe infections, is critical. A landmark study in 1999 showed that inappropriate antibiotic choice for infections in an ICU setting was associated with a two and a half-fold increase in infection-related mortality. ¹

Likewise, getting the timing right is equally important in ensuring effective antibiotic therapy. A 2006 study showed that, for patients with septic shock, each hour of delay in administering antibiotics after the onset of hypotension was associated with a 7.6% increase in mortality, and that only 50% of patients received their first dose of antibiotics within 6 hours of the onset of hypotension. ²

Thorough and systematic clinical assessment, early involvement of infection experts, and following local antibiotic policies can all help to ensure effective antibiotic choices.

Antibiotics are a very frequent cause of adverse drug reactions, along with other adverse events such as drug interactions and secondary infections.³⁵ Antibiotic-associated adverse events can result in long term morbidity, such as ototoxicity with aminoglycosides, and some can be fatal, such as severe *Clostridium difficile* infection.

Rising levels of antibiotic resistance represent the greatest threat to the ongoing effectiveness of antibiotics. Inappropriate use of broad spectrum antibiotics, in particular, is strongly associated with the selection or acquisition of antibiotic-resistant bacteria, such as Extended-Spectrum Beta-Lactamase (ESBL)-producing Gram-negative bacteria⁶,⁷ and MRSA⁸,⁹, in hospitalised patients. Broad spectrum antibiotics, such as cephalosporins, quinolones and clindamycin, are also the agents most frequently associated with *Clostridium difficile* infection.¹⁰,¹¹

Infections caused by drug-resistant bacteria result in increased morbidity and mortality for hospitalised patient. Nowhere is this better illustrated than with the rise in resistance among gram-negative bacteria, such as *E. coli*, *Klebsiella* and *Pseudomonas*. Infections caused by some strains of multiple drug-resistant *Klebsiella*
are associated with a close to 70% ICU mortality, while infections caused by multiple drug-resistant *Pseudomonas* have been associated with an almost 10-fold increase in mortality.\textsuperscript{12,13}

Unless we can curb the emergence and spread of antibiotic resistance, we face a potential return to levels of infection-related mortality not seen since the pre-antibiotic era. In such circumstances our ability to deliver many areas of modern medicine would be severely limited. Care bundles, which are a collection of high-impact evidence-based interventions, have been shown to be an effective way to ensure the effective and consistent delivery of high quality medical care. The RCPI Hospital Antibiotic Stewardship Working Group has developed a care bundle to define the key element required for safe and effective antibiotic prescribing in hospital settings. The care bundle has been adapted, with permission, from a care bundle developed by the UK Department of Health, and has been endorsed by RCPI and RCSI.

Applying the care bundle to all empiric antibiotic prescribing will ensure patients are given the best chance of having their infections effectively treated, while minimising the risk of adverse events and antimicrobial resistance. The care bundle is divided into two sections: Firstly, “Start Smart”, which outlines the decisions and actions that should be taken when considering whether or not to start antibiotics and “Then Focus”, which outlines the requirement for daily review of antibiotic therapy:
"Start Smart...."

When patients present to hospital with infection, or develop infection during a hospital stay, the exact cause of their infection is generally not known at the time of presentation or onset of symptoms. Thus, initial antibiotic therapy (if required) is usually empiric (rather than directed at a specific, known, bacterial pathogen). A combination of clinical acumen, review of available laboratory and radiological data, knowledge of local infection epidemiology, and local prescribing guidelines, is required to maximise the chances that the initial choice of antibiotic therapy will be effective against the most likely causative pathogen(s), while minimising the risk of harm relating to antibiotic therapy.
When considering whether or not to prescribe antibiotics and, if so, what antibiotic to choose, prescribers should:
1. Only prescribe antibiotics where there is a clear indication and, if so, in accordance with local guidelines
2. Ensure appropriate cultures are taken, which can guide effective antibiotic therapy
3. Document treatment decisions, to ensure the most effective antibiotic regimen has been chosen and
4. Ensure that antibiotics are started as soon as possible, particularly for patients with life-threatening infections

“...then Focus”
As the clinical picture evolves, and results of laboratory and radiological investigations become available, it is important to review the ongoing need for, and choice of, antibiotics. Thus clinicians should try to focus antibiotic therapy after 24 to 48 hours. This is referred to as the “Antimicrobial Prescribing Decision” and comprises five options:

1. Stop antibiotics, whenever possible, to avoid unnecessary adverse events and selection of antibiotic resistance
2. If the patient is receiving intravenous antibiotics, consider changing to an oral option (assuming the patient’s condition can be effectively treated with an oral antibiotic, and the patient is suitable for oral therapy)
3. If antibiotic therapy is still required, consider changing to narrower spectrum antibiotics where possible, or broader spectrum if needed, as indicated by clinical features and laboratory test results
4. Continue the current antibiotics, but review again after a further 24 hours
5. If the patient requires prolonged intravenous antibiotics, consider providing this as an outpatient

Hospital clinicians are at the front line in the battle against antibiotic resistance and need to ensure patients get the best possible chance of having their infections cured, while minimising their risk of adverse events. Applying the principles of “Start Smart, Then Focus” to prescribing practice can ensure antibiotics are used effectively, while protecting this vital medical resource for the future.

Clinical Audit for Empiric Antibiotic Prescribing (“Start Smart”)
The clinical audit tool for empiric antibiotic prescribing is based on the “Start Smart” component of the national antibiotic prescribing care bundle. The audit tool can be used to assess your personal prescribing practice, that of your team, or a wider group of prescribers. The tool is designed to be easy to use and facilitates rapid clinical audit cycles.

The audit components are chosen to ensure the effectiveness and safety of antibiotic prescribing. The rationale for including specific components is as follows:
• **Indication documented in chart:** This is included to aid clinical decision making and communication. Documentation of the indication for treatment can help to ensure effective clinical decisions are made. For example, a vague “catch-all” indication for treatment (such as “sepsis”, without documenting the likely source of sepsis) may lead to inappropriate choice of empiric antibiotic therapy, whereas a more specific indication (such as “pneumonia with sepsis”) is likely to guide more specific and effective therapeutic choices. Documentation of indication is also important for communication, both within and between teams in hospital.

• **Antibiotic choice in line with local guidelines:** Local antibiotic prescribing guidelines are generally derived from the best available national and international evidence-based guidance, and tailored to account for local epidemiology (e.g. specific patient cohorts or geographical variation in bacterial pathogens). Getting the initial choice of antibiotic right is critical, particularly in the setting of sepsis. Prescribing according to evidence-based guidelines has been shown to improve outcome in the treatment of infection.

• **Antibiotic choice documented in chart:** As with documentation of indication, documentation of the choice of antibiotic(s) also helps to ensure effective clinical decision making, and improved communication. Documenting the specific choice of antibiotic can also help to ensure the prescriber is alerted to potential drug allergies, interactions or other prescribing-related risks.

• **Cultures taken before starting antibiotics:** Isolation of a bacterial pathogen from appropriate clinical specimens ensures that antibiotic therapy can be effectively tailored to that specific infection, allowing antibiotic therapy to be narrowed or broadened as required.

• **Treatment duration/review date:** In situations where the optimal duration of therapy is clear at the time of initial prescribing of antibiotic, it is important to document the planned duration of therapy to ensure antibiotic therapy is not unnecessarily prolonged, and to ensure effective communication of treatment decisions. Likewise, the initial, empiric, antibiotic choice may have been appropriate to the clinical and laboratory findings at the time of prescribing. However, antibiotic therapy frequently needs to be revised, in light of the patient’s clinical course and additional laboratory or radiological findings. Therefore, either the planned duration of therapy, or planned review date, should be clearly documented.

• **Antibiotic given within 4 hours (or within 1 hour if sepsis):** The first dose of antibiotic therapy needs to be given within a reasonable time after prescription, in order to effectively treat infection. For most, uncomplicated, infections a four hour time window is sufficient. However, sepsis (or suspected systemic bacterial infection in the setting of neutropenia) is a time-dependant medical emergency and a delay in giving the first dose of antibiotics of more than one hour is associated with poorer outcome.

**Suggested approaches for using the audit tool**

The following are suggested approaches for using the audit tool, which may be modified or adapted to local requirements:

1. **Identify a target patient population to be included in the audit**
   The audit tool can be applied to a wide range of clinical situations where empiric antibiotics are prescribed. In general, however, it is best to apply the tool to relatively common indications for antibiotic therapy, to ensure ease of data collection and data analysis. Possible target populations might include:
- Patients admitted via an Emergency Department (ED) or Medical Assessment Unit (MAU) with a community-acquired infection requiring antibiotic therapy
- Patients admitted with a specific infection, such as community-acquired pneumonia
- Patients prescribed antibiotics while an inpatient on a specific ward or unit (e.g. ICU, care of the elderly ward, etc.)
- Patients prescribed antibiotics by a specific admitting team

2: Identify a way of finding patients to be included in the audit
Various data sources may be used to identify patients who have been prescribed antibiotics and are suitable for inclusion in a clinical audit. If you are auditing your own, personal, prescribing then you can simply enter data prospectively on the audit tool each time you prescribe antibiotics. Likewise, if you are auditing antibiotic prescribing by your clinical team, you can provide each team member with a copy of the audit tool and ask them to enter data prospectively. Otherwise, a variety of data sources can be used to identify patients for inclusion in the clinical audit, such as:

- ED or MAU admission books
- Ward/unit day books
- Survey of nursing staff during ward rounds (nurse managers will often know which patients are currently receiving antibiotics)
- Clinical pharmacy records
- Electronic patient management systems

3: Decide on an audit time frame
The audit tool is designed to facilitate rapid cycle audits, so audits should be done using a short time frame, typically one week (i.e. audit the first ten patients in the target population prescribed antibiotics this week). If the audit is based on a specific admitting team, it may be easier to audit periods when that team is on-call for acute admissions.

4: Decide on a data analysis and improvement plan
Once data have been collected on ten patients, examine the audit scores to identify which component, or components, of antibiotic prescribing should be targeted for improvement. Ideally, this should be done as part of a group or team discussion, as team members will often identify potential ideas for improvement as a group that may not be apparent when only examined as an individual. Use the space provided on the audit tool to record possible ideas for improvement and plan how these will be trialled. Possible ideas for improvement, in relation to antibiotic prescribing, might include:

- Standardised method for recording treatment decisions in the clinical notes
• Use of pre-printed stickers in the clinical notes or drug prescription record (“kardex”) to guide documentation of treatment decisions and choice of antibiotic therapy
• Provision of summary cards to prescribers/team members with most common antibiotic indications (based on local guidelines)
• Printed reminders or guideline summaries placed at point of prescribing (e.g. at staff base on ward)
• Providing incentives for prescribers/team members who achieve the highest audit scores
• Inclusion of reminders on copies of formularies (local formulary, BNF etc)
• Discussion of “antibiotic cases” at team meetings
• Feedback and discussion of data at grand rounds or case conferences
• Provision of summary of “Start Smart, then Focus” care bundle to prescribers/team members

5: Re-audit, to evaluate ideas for improvement
Once an idea for improvement has been put in place, repeat the audit as soon as possible to see if this has led to improvement. Ideally, a series of quick, repeated audits should be carried out to assess a range of improvement ideas and ensure improvement has been sustained.
Notes on Completion of RCPI Clinical Audit Record for CPD

The following are suggestions for completion of selected fields in the RCPI ePortfolio for recording clinical audit, based on auditing antibiotic prescribing:

- **Type of Audit:** select “Activity against appropriate standards/guidelines/best national/international practice”
- **Domain Reflected:** select 1. Patient Safety & Quality of Patient Care
- **Background:** this can be based on the background section of this document, e.g.: “Antibiotics are one of the most important medical advances of the past 100 years, allowing us to cure infections that would have frequently been fatal in the past, and also to treat many of the opportunistic infections that arise as a consequence of modern medical practice. However, in order to be effective they need to be used appropriately. Furthermore, this vital medical resource is under increasing threat from the rise in antibiotic resistance. I/We therefore undertook an audit to assess the appropriateness of empiric antibiotic prescribing at [HOSPITAL/WARD/SERVICE], based on the RCPI/RCSI “Start Smart, then Focus” antibiotic care bundle.
- **Aims of the audit:** Where possible, include a measurable outcome and target date for improvement in antibiotic prescribing (e.g. to ensure 90% of empiric antibiotic prescribing in [HOSPITAL/WARD/SERVICE] has a documented indication and is in line with local antibiotic prescribing guidelines by [DATE])
- **Standards:**
  - Strategy for the Control of Antimicrobial Resistance in Ireland (SARI) Guidelines for Antimicrobial Stewardship in Hospitals in Ireland, SARI, 2009
  - RCPI/RCSI Start Smart, then Focus Empiric Antibiotic Prescribing Care Bundle, RCPI/RCSI, 2012
- **Methodology:** Copy and paste from the section 7 (Suggested Approached for Using the Audit Tool) above, as required
- **Results:** List scores from completed audit tool (Appendix 1), or from repeated audits over time. If repeated audits completed, consider presenting results in tabular or graphical (run chart, bar graph) format. List any ideas for improvement that were tested, either from the suggested list (section 7.4 above) or locally-developed improvement ideas.
- **Conclusions:** Brief statement of baseline findings or improvement, such as: “Sequential auditing, and implementation of improvement ideas, led to a significant improvement in the quality of empiric antibiotic prescribing”
- **Recommendations and action plan:** Summarise any recommendations or plan for future activities. These might include:
  - Promoting safe and effective antibiotic prescribing for new staff
  - Spreading improvement ideas to other teams/wards/units
  - Applying improvement ideas to other areas of prescribing practice
  - Presentation of results within your organisation, or at national/international meetings
  - Publication of results
  - Future audits and improvement plans relating to other aspects of the “Start Smart, then Focus” care bundle, or to other aspects of antibiotic prescribing listed in Appendix 2
• **Re-audit**: Provide details of plans to re-audit and feedback of results