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Auditing tools for antimicrobial prescribing in solid organ transplant recipients: the why, the how and an assessment of current options

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Proposed tweet (200 characters):
Standardized auditing tool tailored for #antimicrobial Rx in #SOT patients is an unmet need. We compared 3: NAPS, Global-PPS & NHSN AU/R. Each has varying capabilities, limitations & #EHR integration.

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Key words: antimicrobial use, auditing tool, benchmarking, appropriateness, indication, antimicrobial resistance
Running title: Antimicrobial auditing tools for SOT patients

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Abstract (250 words)

Background: Antimicrobial stewardship (AMS) aims to optimize antimicrobial use. Auditing and reporting of antimicrobial prescribing are essential. Auditing tools for solid organ transplant (SOT) patients should tailor to their needs.

Methods: We reviewed published data describing auditing tools in the general and solid organ transplant population.

Results: We focused on three internationally or nationally available auditing tools. The National Antimicrobial Prescribing Survey (NAPS) is web-based tool to report antimicrobial consumption and assess appropriateness using standardized definitions based on consensus guidelines, therefore NAPS is applicable to SOT patients if guidelines are available. In the absence of guidelines, adjudication is based on AMS principles . An automated dashboard, analyses by indication or antimicrobial, and benchmarking reports are available. An antifungal survey is an upcoming feature pertinent to SOT patients. The National Healthcare Safety Network Antimicrobial Use/Resistance module was developed by the Centers for Disease Control and Prevention for hospitals to upload monthly data, which are standardized for benchmarking. It does not assess appropriateness or address SOT wards. The Global-Point Prevalence Survey from bioMérieux collects data on antimicrobial regimen, indication and microorganisms by resistance type. Variables unique to SOT patients include morbidities and devices, however, assessment of appropriateness is limited to guideline adherence. Benchmarking requires pre-arrangement. Advances in electronic health record systems and clinical decision support tools can improve the efficiency of the auditing process.

Conclusion: Each AMS auditing tool has unique features for SOT patients. Capturing immunosuppression, source control, organ dysfunction, donor-derived infection, serology and colonization status will enhance their applicability.

Introduction

As a patient safety initiative grounded in quality improvement, antimicrobial stewardship (AMS) is defined as a coordinated set of interventions to improve and measure the appropriate use of antimicrobials by promoting the selection of the optimal antimicrobial regimen including dosing, duration of therapy, and route of administration.[1] Multidrug-resistant organisms (MDRO) pose significant threats to solid organ transplant (SOT) patients, impacting colonization status and infection pre- and post-transplant, as well as adverse events associated with antimicrobial antreatment.[2,3] Despite the availability of new antimicrobials targeting MDRO, especially against gram-negative rods, clinicians are urged to be judicious in prescribing these agents to preserve their effectiveness.[4,5] Under the auspices of quality improvement and patient safety, the goal of antimicrobial stewardship programs is to promote responsible use of antimicrobials in SOT patients.[6,7] To accomplish that goal, prospective audit and feedback is one of the "Core Elements of Antibiotic Stewardship" recommended by the US Centers for Diseases Prevention and Control, the Centers for Medicare Medicaid, the Joint Commission, and the Agency for Healthcare Research and Quality, the UK's National Health Services, Accreditation Canada and Health Standards Organization for antimicrobial stewardship programs, among many countries and jurisdictions.[8-11] However, data comparing auditing tools and their suitability to address the unique and complex needs of SOT patients are limited. This review aims to describe the role of auditing, the current landscape of auditing tools, and examine their potential use for antimicrobial stewardship in SOT patients.

What is the Role of a Standardized Antimicrobial Auditing Tool in Solid Organ Transplant Patients?

The goal of auditing is to assess the patterns of antimicrobial use, encompassing the quantity and quality of prescribing against a "gold standard" or best practice, which may be local, regional, national or published syndrome-based guidance.[12-14] In the absence of an accepted standard—a challenge more prevalent in SOT patients than the general population due to scarcity of data[15]—adjudication of the antimicrobial regimen may be deferred to the guiding principles of antimicrobial

stewardship based on patient factors, the most likely causative pathogens, local epidemiology, and the pharmacological characteristics of the antimicrobial.[1] Unique to SOT patients, the auditing process ought to accommodate additional pertinent factors such as type of transplant, organ function, source control attainment and the net state of immunosuppression.[16,17]

The rationale for standardizing the auditing tool is to ensure the instrument is valid with pertinent variables easily identified and collected, while applying a consistent adjudication framework to evaluate the quality and quantity of antimicrobial prescribing.[18] Subsequently, the survey reports are used for internal and external benchmarking. Therefore, a standardized auditing tool plays several roles in an antimicrobial stewardship program. First, it is an instrument for prospective audit-and-feedback conducted at point of care by the AMS team.[13] The primary aim is to generate dialogues with SOT prescribers, such as but not limited to the so-called "handshake stewardship."[2,10,13,19,20] The discussion may involve validating the prescriber's antimicrobial plan, or recommending an alternative regimen based on patient factors, antimicrobial factors, microbiology, best practices and supporting evidence.[8,10] Although currently there is no general consensus on the preferred format to conduct audit and feedback with SOT clinicians, a standardized auditing tool will improve the efficiency of the AMS team in its day-to-day work at the patient level.[2,20]

Second, at the transplant program or unit level, the AMS team can use a standardized auditing tool to conduct point-prevalence studies (PPS), either at a singular time point to gain insight into the prescribing behaviors of a particular clinical area (e.g. a specific organ transplant), or serially at pre-specified intervals to monitor changes following implementation of AMS interventions. The AMS team can review the longitudinal data to better understand the potential impact of their interventions on prescribing behavior, and identify gaps in knowledge.[18,21] Therefore, serial auditing with a standardized tool fulfills the requirement to demonstrate the AMS program's accountability

to the institution,[8] while simultaneously sets targets and identifies new opportunities to optimize antimicrobial use. Extrapolating from experience in benchmarking at the facility level,[22] SOT-specific PPS has the potential to be used in internal and external benchmarking antimicrobial prescribing among transplant programs of similar resource allocation and patient population.

Third, at the individual prescriber level, a valid, standardized auditing tool can generate prescriber-specific report on process measures such as adherence to guidelines.[8,14,23] In this context, the auditing process and the ensuing report is in itself a behavioral change intervention that motivates practice change through self-reflection.[24,25] Additionally, it is an opportunity to raise awareness about best practices.[8,26] However, data supporting the role of prescriber-specific feedback as an AMS intervention in SOT population are limited.

What Constitutes the Ideal Auditing Tool for Antimicrobial Use in Solid Organ Transplant Patients?

An ideal standardized auditing tool needs to fulfill several criteria: 1) able to capture valid data elements that are well defined and convenient to identify; 2) has an intuitive user-interface for data entry; 3) applies an *a priori* adjudication framework that incorporates applicable local consensus guidelines, yet maintains flexibility to accommodate clinical scenarios where guidelines do not exist or are not applicable.[27-32] 4) Crucially, retrieval of data for reporting the quality and quantity of antimicrobial prescribing should be efficient, timely, and transportable.[22,30,33] 5) To encourage widespread use in hospitals in both resource-rich and resource-limited jurisdictions, cost of the auditing tool should be sufficiently low. For an auditing tool specific to SOT patients, however, accommodation for data collection and adjudication framework are required to reflect diagnostic ambiguity, degree of immunosuppressive therapy, organ dysfunction, serological and colonization status, iatrogenic exposure to antibiotic-resistant nosocomial pathogens including donor-derived infections, as well as technical difficulties with source control attainment.[16,17] As for benchmarking,

although there are common characteristics shared among SOT patients, there is significant heterogeneity between organ recipients (e.g., liver vs. lung), which influences the approach to infection management.[17] While clinical guidelines for SOT patients exist,[34] they do not and are not expected to address all common infections, and facility-specific guidelines tailored to local context may be resource-intensive to develop. These factors culminate to the need for a standardized auditing tool that is both specific and flexible for the complexity of SOT patients.

How Do Current Antimicrobial Stewardship Auditing Tools Compare in Their Abilities to Meet The Needs of Transplant Programs?

Although there is no standardized auditing tool created solely for adjudicating antimicrobial prescribing in SOT patients, there is increasing recognition of an unmet need.[2] This review will focus on three auditing tools that have the potential to accommodate the unique needs of immunocompromised patients (Table 1).

Australia's National Centre for Antimicrobial Stewardship developed the National Antimicrobial Prescribing Survey (NAPS).[28,35] NAPS is a web-based tool (printable forms available) to adjudicate antimicrobial regimens, with standardized definitions of appropriateness centered around consensus guidelines, and in the absence of guidelines, the principles of antimicrobial stewardship are applied.[30,35] Variables included in the auditing tool are standardized, validated and frequently updated to meet the needs of end-users.[30] In addition to access to the raw data, a distinctive feature of NAPS is its dashboard and benchmarking report which is automated and offers a real-time, at-a-glance summary of the pertinent metrics on the quantity and quality of antimicrobial prescribing.[30] Quality parameters are categorized into appropriate prescribing, which is further sub-categorized into optimal or adequate use; and inappropriate prescribing which is sub-categorized into suboptimal or inadequate use.[30] Thus, NAPS is an instrument to assess, report and monitor

antimicrobial use, as well as a behavioral change intervention to optimize prescribing practices. Beyond Australia, it has been piloted in Canada, Malaysia, Bhutan, New Zealand, Fiji, Timor-Leste, and the UK. Specific to immunocompromised patients, although NAPS can be used to assess adherence to febrile neutropenia guidelines in hematology-oncology, stem cell transplant and solid tumor patients[29], details of cancer therapy are not captured. Currently, there are no features to accommodate the unique needs of SOT patients such as details of immunosuppression. Nevertheless, NAPS is applicable to SOT patients if facility-specific consensus guidelines dedicated to SOT patients are available.[30] Importantly, NAPS captures all antimicrobial classes (antibiotics, antifungals, and antivirals) with each antimicrobial regimen linked to a detailed, coded indications list. The antimicrobial stewardship team is therefore afforded a high degree of flexibility to explore prescribing practices addressing specific antimicrobial class, antimicrobial, indication (infectious syndrome), ward, prescriber and prescriber group (specialist consultation). Furthermore, using the Delphi method, NCAS has established a set of core metrics to comprehensively evaluate the quantity and quality of antifungal prescribing [36] A detailed antifungal stewardship audit has been incorporated into the hospital NAPS, which is expected to be released soon.[37] Both initiatives are relevant to SOT patients given their vulnerability to invasive fungal diseases.[16] NAPS offers an *a priori* adjudication framework based on consensus guidelines, and has potential flexibility to accommodate clinical syndromes where guidelines are not available or applicable to SOT patients.

The US Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Antimicrobial Use (AU) and Antimicrobial Resistance (AR) module was developed for hospitals to track, analyze and report antimicrobial consumption and resistance data electronically for internal and national benchmarking.[31,38] Hospitals submit monthly antimicrobial use data, and one of the output from the module is the Standardized Antimicrobial Administration Ratio

(SAAR).[31,33] The SAAR is a risk-adjusted benchmarking measure developed by the CDC to inform stewardship efforts through comparison with peer facilities of similar characteristics, and are available for review.[31] Longitudinal data are used to inform and assess AMS interventions.[39] As of 2021, more than 2,100 acute care hospitals across the US have submitted at least one month of data.[40] There are specific technical requirements in the format of Health Level 7 Clinical Document Architecture, as manual entry is not an option due to the volume of data to be uploaded.[38] The SAAR reports are categorized by ward type and antimicrobial classes. Currently, the SAAR is benchmarked to baseline year 2017 (2018 for neonatal data). Specific to immunocompromised patients, reports addressing the general hematology-oncology ward are available, but not for solid organ transplantation.[39] Appropriateness of antimicrobial use is assessed through a separate checklist to be completed periodically to evaluate AMS program effectiveness and adherence to clinical practice guidelines for certain common infectious syndromes, such as community-acquired pneumonia and urinary tract infections. Currently, there is no special accommodation to address infectious syndromes in SOT patients.[41]

The Global Point Prevalence Survey (Global-PPS), made available by bioMérieux, involves an international network of hospitals grouped by the United Nations region to measure antimicrobial prescribing and resistance with a standardized surveillance method.[42,43] Data are collected manually using printable forms or a web-based data entry tool.[44] There are three survey periods for data collection within the calendar year and at the end of 2018, Global-PPS has been used in over 700 hospitals in more than 70 countries worldwide.[43] The Global-PPS auditing tool collects detailed data on patient demographics, antimicrobial regimen, indication by diagnostic codes, and intention (prophylaxis, empirical, or targeted therapy). Similar to the NHSN AU and AR module, microorganisms by resistance type is categorized and reported. Specific to immunocompromised patients, reporting from the hematology-oncology ward and SOT ward are available for peer facility

or regional benchmarking, with permission.[42,44,45] Accommodation for the unique concerns among SOT patients are made through a selection of "underlying morbidities" and "inserted devices", which are optional data variables to address healthcare-associated infections.[44] Global-PPS data provide granular details on antimicrobial consumption and resistance. Quality of prescribing are limited to whether the regimen is compliant with guideline, without more refined quality measures.[45] Hospital-specific data and report are available for download.[44]

What are the implications of electronic health record systems?

Large-scale electronic health record systems (EHR) from vendors such as EpicSystems (Verona, Wisconsin), Cerner Corporation (North Kansas City, Missouri), and Meditech (Westwood, Massachusetts) have become increasingly common among hospital systems in well-resourced regions.[46] In the US, following the Health Information Technology for Economic and Clinical Health (HITECH) Act, adoption of EHR was financially incentivized by the Centers for Medicare and Medicaid Services.[46-48] Most EHR systems offer built-in modules to facilitate the workflow for AMS interventions, and reporting of pertinent quality improvement metrics such as antimicrobial consumption and nosocomial *C. difficile* infection rates.[46-52] These advanced EHR systems provide clinical decision support tools, such as syndrome-specific order sets, best practice advisories, and recommended dosing, to guide the prescriber at point-of-care. They can streamline the information gathering process, thereby improving the efficiency in adjudicating appropriateness of use by syndrome or by antimicrobial, irrespective of which auditing tool is used. Alternatives to advanced EHR systems are "add-on" clinical decision support software that interface with or support an existing EHR system to facilitate the workflow of antimicrobial stewardship interventions.[46,53] One software, Spectrum Mobile Health™ (Firstline Clinical, Vancouver, BC, Canada), was paired with NAPS to audit and benchmark appropriateness of antimicrobial use at two tertiary academic

hospitals in Canada.[54] Although the study was not aimed at SOT patients specifically, it demonstrated the potential synergy between add-on software and auditing tools.

What are the limitations of currently available auditing tools?

A common gap among the three auditing tools is that they do not assess situations of under-treatment where an antimicrobial is indicated but is not prescribed,[55] since only antimicrobials that are active on the day of the survey are included. Furthermore, auditing tools tailored to assessing antimicrobial prescribing in outpatient SOT care are lacking. The context of antimicrobial prescribing for outpatient differs from that for inpatient, as pertinent microbiology or laboratory results may not be readily available, and follow-up assessment to antimicrobial therapy may be indirect or delayed. The three tools described above are primarily designed to assess inpatient prescribing and consumption of antimicrobials. Although much AMS efforts are directed at hospitalized SOT patients, antimicrobials are frequently prescribed in the SOT ambulatory clinics or by primary care providers.[2] Therefore, auditing outpatient prescribing practices is an "untapped territory" for AMS in SOT.[2] Lastly, there are auditing tools created specifically for a geographical region or hospital network to meet local needs. Therefore, they are context-specific for internal benchmarking to standardize care. However, they are not necessarily accessible, validated or applicable outside the particular institution or hospital system, which limits their external validity and the opportunity for external benchmarking. It is beyond the scope of this review to examine their suitability for external benchmarking in the wider SOT patient population.

Conclusion

With the ongoing global COVID-19 pandemic, rising antimicrobial use and resistance have been reported as a result of bacterial coinfections or secondary infections, creating additional pressure for antimicrobial stewardship.[56] Although the full impact of the pandemic on SOT patients remains to be

elucidated, coupled with an ever increasing number of patients undergoing organ transplant, challenges in AMS for SOT patients persist, and may continue to grow.[57,58] A standardized auditing tool to assess antimicrobial use that accommodates the unique complexities of SOT patients is an unmet need that requires attention.

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Table 1. Comparison of NAPS, NHSN and Global-PPS on their ability to meet the needs of SOT patients

Parameters	NAPS	NHSN AU/R Module	Global-PPS
Survey type	Point-prevalence of active antimicrobials prescriptions	Monthly data upload of antimicrobial usage	Point-prevalence of active antimicrobials prescriptions
Data input format	Web-based or printable form for manual input	Web-based only	Web-based or printable form for manual input
Technical requirements	Internet access	Internet access Health Level 7 Clinical Documentation Architecture for data upload	Internet access

Adjudication framework	Consensus or locally endorsed guidelines. Principles of antimicrobial stewardship are applied in the absence of guidelines.	Does not assess appropriateness of use.	Consensus guidelines.
Data output	Hospital's own data on prescribing, indication and appropriateness. Automated dashboard reports on the quantity and quality of prescribing. Microbiology result is captured but not as discrete variable. Links antimicrobial regimen to a coded list of indication, ward prescriber, prescriber group. Analyses can be made to address prescribing practice by antimicrobial class, antimicrobial, indication, and prescriber.	Hospital's own data on quantity of prescribing and antimicrobial resistance. AU/R module does not include assessment of quality of prescribing by indication. Automated reports on antimicrobial use and resistance. A separate assessment tool for appropriateness of antibiotic use in common infectious syndromes based on guideline adherence is available. Not tailored for SOT patients.	Hospital's own data on quantity of prescribing, antimicrobial resistance and indication. Feedback report available on quantity of antimicrobial use, resistance and indication. Quality parameter limited to guideline adherence.
Benchmarking	Available and included for internal and external benchmarking	Available and included for internal and external benchmarking using SAAR.	Pre-arranged with Global-PPS leader
Accommodation	Not tailored specifically	Not tailored specifically for	Addresses unique

for SOT patients	for SOT patients unless local guidelines for SOT patients are available. Future surveys include antifungal stewardship, which is relevant to SOT patients. Reports can be run at the ward level if there is a dedicated SOT ward.	SOT patients.	needs of SOT patients under categories of morbidities and devices. Reports specific for transplant wards available.
Antimicrobial needed but not prescribed	Not addressed	Not addressed	Not addressed
Proprietary vs. open-access	Proprietary to Royal Melbourne Hospital (Melbourne Health)	Proprietary to the CDC. External information technology support may be required for data upload.	Proprietary to bioMérieux

NAPS: National Antimicrobial Prescribing Survey; NHSN AUR module: National Healthcare Safety Network Antimicrobial Use/Resistance Module; Global-PPS: Global Point Prevalence Survey and Resistance.