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# Outpatient diagnostics, antimicrobial stewardship, and health equity

## Closing gaps in the fight against antimicrobial resistance

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**T**he spread of antimicrobial-resistant (AMR) infections poses a global public health threat, with over 1 million resistant infections diagnosed annually.<sup>1</sup> With more than 200 million antimicrobials prescribed in outpatient settings, including primary care clinics, urgent care centers, emergency departments (ED), and skilled nursing facilities, it is evident that these treatment settings facilitate the spread of AMR infections.<sup>2,3</sup> These are areas of unmet need as most antimicrobial stewardship (AMS) programs, designed to optimize unnecessary antimicrobial prescribing, have traditionally focused on addressing gaps in inpatient settings.<sup>4</sup> Given the lack of oversight in outpatient AMS, it is unsurprising that there have been growing reports of inequities in the diagnosis and management of AMR infections, specifically among marginalized populations.<sup>3,5,6</sup>

While identifying as part of a marginalized group is not a biological risk

factor for developing an AMR infection, marginalization is often accompanied by systems of oppression such as racism and classism.<sup>7</sup> These systems can lead to inequities in the social determinants

of health (SDoH), such as education, socioeconomic status (SES), and access to healthcare.<sup>8,9</sup> For example, individuals who identify as racially and ethnically marginalized (REM) are

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### LEARNING OBJECTIVES

Upon completion of this article, the reader will be able to:

1. Discuss how gaps in outpatient antimicrobial stewardship (AMS) have contributed to antimicrobial resistance and health inequities.
2. List and describe the various tests used in rapid detection of antimicrobial infections and the benefits of diagnostic advancements in the outpatient space.
3. Discuss potential gaps in the use of rapid diagnostics tests in outpatient settings.
4. Describe equitable strategies and solutions that can be integrated for successful AMS efforts in outpatient settings.



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underrepresented among college graduates.<sup>10</sup> This highlights potential barriers to health literacy and understanding of diagnosis severity and instructions for antimicrobial use.<sup>11</sup> Additionally, areas of low SES are more vulnerable to shortages in healthcare providers and associated resources.<sup>12</sup> Ultimately, limited access to care can lead to treatment delays or the absence of treatment for chronic and acute infectious illnesses.

Integrating diagnostics and appropriate stewardship principles has revolutionized inpatient AMS programs.<sup>4</sup> With the evolution of existing diagnostics and the emergence of innovative rapid diagnostics tests (RDTs), including rapid antigen tests (RADTs) and molecular diagnostics, there is an opportunity to optimize AMS in outpatient settings. Furthermore, point-of-care tests (POCTs), often defined as those RDTs not performed in a centralized laboratory and run with a Clinical Laboratory Improvement Amendments (CLIA) waiver or that are moderately complex, also have accelerated management capabilities the closer they get to the patient.<sup>13</sup> Ultimately, if integrated and utilized appropriately, RDTs may lead to a reduction in antimicrobial usage and further inequitable impacts of resistant infections across marginalized groups. Here, we provide an overview of the Centers for Disease Control and Prevention (CDC) guidance on outpatient AMS programs and insight into the microbiology laboratory's role in integrating RDTs into AMS procedures. We also provide insight into the use of RDTs in outpatient settings. Finally, we conclude with strategies for integrating these diagnostic modalities into outpatient AMS programs to narrow AMR-related health equity gaps by reducing inappropriate antimicrobial prescribing and use.

### Overview of the CDC outpatient antimicrobial stewardship framework

To address the estimated 30–50% of unnecessary prescriptions in the outpatient community, the CDC published ambulatory AMS guidance in 2016 with the following core elements: commitment, action for policy and practice, tracking and reporting, and education and expertise.<sup>14</sup> Despite The Joint Commission endorsing outpatient stewardship initiatives the following year, widespread adoption has been slow due to barriers such as variable governance and data structures, diverse models of care, lack of administrative commitment, and

disparities in resource allocations.<sup>15</sup> A survey of Vizient member hospitals, representing 20% of the country's ambulatory market, reported that only 7% had a fully functioning ambulatory AMS program compared to 88% of inpatient settings.<sup>16</sup> Analogous to inpatient clinical laboratories, RDTs (including RADTs and molecular diagnostic tests) can augment AMS efforts in the outpatient setting

85.6% and 95.4%, respectively, compared to throat culture.<sup>18</sup> While high specificity may support actionable results when positive, the moderate sensitivity raises questions about back-up throat cultures in children aged three and older, negating the quick turnaround time, or whether the cause of pharyngitis is secondary to a viral pathogen or non-infectious etiology.

	RADTs	Molecular RDTs
Advantages	<ul style="list-style-type: none"> <li>• High specificity</li> <li>• Low cost</li> <li>• Rapid TAT (5-24m)</li> <li>• Easy to perform</li> <li>• Minimal equipment required</li> </ul>	<ul style="list-style-type: none"> <li>• High sensitivity and specificity</li> <li>• Rapid TAT (15-90m)</li> <li>• Multiplex capability (Detects multiple pathogens simultaneously, often &gt;15)</li> <li>• Demonstrated AMS and clinical benefits in outpatient setting</li> <li>• Expanding specimen types (NPS, TS, ANS) for easier collection</li> <li>• Detects low organism load (early infection)</li> <li>• Reduces need for confirmatory culture in many cases</li> </ul>
Disadvantages	<ul style="list-style-type: none"> <li>• Low sensitivity</li> <li>• Variable sensitivity**</li> <li>• Culture follow-up for GAS in children &gt;3 years of age</li> <li>• Inability to rule out colonization (GAS RADT)</li> <li>• Single pathogen detection</li> <li>• Limited specimen types per test</li> <li>• False negatives can occur in early infection</li> </ul>	<ul style="list-style-type: none"> <li>• Inability to rule out non-viable organism, colonization</li> <li>• Higher cost</li> <li>• Requires specialized equipment and trained personnel</li> <li>• May detect clinically irrelevant organisms (overdiagnosis risk)</li> <li>• Limited availability in some settings</li> </ul>
<p>** Reduced (self-collection, children, low viral load); Increased (symptomatic, early in disease state).                      AMS: antimicrobial stewardship; ANS: anterior nares swab; GAS: group A Streptococcus; NPS: nasopharyngeal swab; RADT: rapid antigen detection test; TAT: turnaround time; TS: throat swab</p>		

Table 1. Comparison of RADTs and molecular RDTs.

and provide clinicians with timely and actionable information by differentiating commonly encountered pathogens implicated in the greatest driver of unnecessary outpatient antibiotic prescriptions: upper respiratory tract infections (URIs).

### Diagnostic advancements Rapid antigen diagnostic tests (RADTs)

RADTs are commonly used in point-of-care settings as they provide results within 5-30 minutes for frequent URI pathogens such as group A *Streptococcus* (GAS), influenza viruses, and SARS-CoV-2. These tests are inexpensive lateral flow immunoassays without specific storage constraints that produce a visible signal from migrating antigen-antibody complexes by capillarity.<sup>17</sup> More information on RADTs is available in Table 1.

Many guidelines recommend using RADTs for GAS, which demonstrate pooled sensitivities and specificities of

Similar to RDTs for bacterial pathogens, viral RADTs are also not without limitations. SARS-CoV-2 demonstrates pooled sensitivities and specificities of 71–82% and 99%, respectively; however, performance is dependent on several factors.<sup>19</sup> Rapid influenza diagnostic tests (RIDTs) also report variable performance with sensitivities and specificities of 61–69% and 98–99%, respectively; however, real-world practice often records sensitivities as low as 25–50%.<sup>20</sup> These poor sensitivities reduce diagnostic certainty, thereby limiting antibiotic prescriptive confidence resulting in antimicrobials “just in case” for negative tests and/or additional confirmatory PCR testing when clinical suspicion is high.

### Molecular diagnostic tests

To overcome some limitations of RADTs, molecular RDTs for GAS and respiratory viruses use either thermocycling or isothermal amplification, with PCR

being the most common thermocycling method. Newer RDTs employ isothermal techniques such as Nicking Enzyme Amplification Reaction, Loop-Mediated Isothermal Amplification, and Helicase-Dependent Amplification.<sup>18</sup> Pooled sensitivities and specificities are significantly higher at 97.5% and 95.1%, respectively, for GAS.<sup>21,22</sup> Sensitivities for viral analytes may be as high as 100% depending on the analyte and test.<sup>22</sup> Certain molecular RDTs can simultaneously detect viral and bacterial targets from nasopharyngeal, anterior nares, and throat swabs, providing integrated sample-to-answer systems that identify multiple pathogens within 15–90 minutes.<sup>23</sup>

### **Molecular tests in point-of-care settings**

Recent data suggest promising outcomes, particularly among marginalized patients, when newer POCT diagnostics are leveraged in the outpatient space. Meltzer and colleagues compared a multiplex respiratory POCT with a ~15-minute turnaround time to an observational control for the management of URIs in the ED.<sup>24</sup> Notably, REM patients were less likely to receive antibiotics with confirmed viral infections (6.5% versus 20.2%;  $p=0.009$ ) and median length of ED stay was shortened (4.3 hours versus 6.5 hours;  $p<0.001$ ). Moreover, providers noted increased diagnostic confidence, and patients reported higher satisfaction with result timeliness. Utilizing the same POCT, improved patient outcomes and reduced prescriptions were reproducible in additional outpatient cohorts.<sup>25,26</sup> Based on these recent studies, molecular RDTs offer significant opportunities for reducing unnecessary antibiotic use in the outpatient arena to combat AMR; however, notable barriers to increase community access and AMS integration need to be considered.

### **Current and anticipated gaps in the use of RDTs in outpatient settings**

The COVID-19 pandemic exposed barriers that can hinder the equitable use of RDTs to enhance outpatient AMS initiatives. By using deprivation indices like the social vulnerability index (SVI) and area deprivation index (ADI), which assess the effects of social, material, and economic disadvantages on health outcomes, researchers have obtained intriguing findings.<sup>27–29</sup> Several studies have shown disparities in the availability of RDTs, with high social vulnerability



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areas less likely to have access to test-to-treat locations; a situation likely to worsen due to shifting government funding priorities.<sup>30,31</sup>

The shortage of test-to-treat sites is a significant concern because socially vulnerable areas—often inhabited by marginalized groups—are expected to face increased burdens from vaccine-preventable illnesses in upcoming viral seasons. This is due to changes in the dissemination of reliable vaccine information and evolving vaccine recommendations, which could influence the future accessibility and affordability of immunizations. These health systems, frequently categorized as safety-net institutions, tend to be understaffed and underfunded.<sup>32</sup> Such errors could lead to delayed or missed treatment of viral infections, potentially fostering the development of infections caused by AMR bacteria.<sup>33</sup> Even more concerning, these limitations in diagnosis and management might erode trust in future clinician diagnoses and the perceived effectiveness of antimicrobial therapy prescribed in outpatient settings.<sup>33</sup>

Other operational concerns regarding the deployment of RDTs in outpatient settings were also raised during the pandemic.<sup>34</sup> These concerns include difficulty in complying with the manufacturers' specifications and storage requirements, staff training and competency validation, and regulatory compliance with laboratory accreditation and regulatory standards. These issues are likely to be more prevalent and harder to address in outpatient settings in vulnerable areas, where healthcare shortages and turnover are most pronounced.

Financial reimbursement for RDTs is also a point of contention, as batch testing is often cheaper.<sup>34</sup> There may be variability in the tests for which insurance programs are willing to provide coverage, which may affect the reliability of the results and the treatment prescribed based on the test output.

### **Strategies, solutions, and how to augment current successes in outpatient antimicrobial stewardship efforts**

Integrating RDTs into outpatient AMS programs can play a major role in addressing inequities in AMR infections.

Outpatient providers believe published local resistance patterns would incentivize ambulatory stewardship implementation

Nonetheless, this effort will not be without challenges. Therefore, in this section we provide evidence-based strategies for clinicians to consider as guidance for the equitable inclusion of RDTs in outpatient stewardship programs.

Notable resource-limited interventions include antibiotic commitment posters or screensavers, delayed prescribing prescription pads, and signed antibiotic commitment letters by office and clinic staff.<sup>35,36</sup> With increased sensitivity of molecular RDTs compared to

RADTs, one increasingly utilized strategy is pairing clinical prediction rules with patient assessment. One group embedded the Centor score into the electronic health record with pharyngitis testing to improve pre-test probability.<sup>37</sup>

While information technology plays a key role in AMS success, not every outpatient setting may have this resource. Risk assessment scoring tools could be available in posted guidance documents for pharyngitis, which would align with the recently updated Infectious Diseases Society of America (IDSA) GAS Pharyngitis guideline.<sup>38</sup> It is outside the scope of this article to list all supplemental strategies for outpatient stewardship programs, though additional resources can be found on the CDC's Outpatient Stewardship and the Agency for Healthcare Research and Quality (AHRQ) websites.

Another notable barrier to successful instrumentation deployment is lack of awareness of availability of testing and the valuable information and outcomes that can be harnessed from specific platforms for key stakeholders (e.g., providers, patients and care givers, insurers). Outpatient providers believe published local resistance patterns would incentivize ambulatory stewardship implementation.<sup>39</sup> Local epidemiology could come from state health departments, regional clinical microbiology laboratories, or de-identified reports directly from RDTs platforms. One such surveillance system is BioFire Syndromic Trends by bioMérieux who publishes respiratory pathogen and gastrointestinal trends publicly. This data provides near real-time information on circulating pathogens to guide management decisions.<sup>40</sup> Compared to the CDC's Respiratory Virus Hospitalization Surveillance Network (RESP-NET) detailing national trends for influenza, COVID-19, and RSV, Syndromic Trends includes results with additional viruses (e.g., adenovirus, seasonal coronaviruses, entero/rhino virus, parainfluenza, human metapneumovirus) from a comprehensive multiplex panel directly from U.S. clinical laboratories using this technology.

Patients and caregivers are also major determinants of antibiotic prescriptions in the community. While this is multifactorial, one potential driver is that the public is largely unaware of the risks associated with antibiotic use, especially those with marginalized identities.<sup>41</sup> Nearly 4 in 5 providers agree that stewardship efforts would be

ineffective unless paired with efforts to educate patients on resistance and the importance of de-prescribing antibiotics for viruses.<sup>39</sup>

In addition to clinic stewardship commitment pledges, providers can explain the value of broader multiplex panels that help detect yearly circulating respiratory viruses like rhinovirus and enterovirus. By providing targets beyond the traditional quadruplex (e.g., Influenza A/B, SARS-CoV-2, RSV), 44% more detections were identified in one study with a multiplex system, which allows for more comprehensive management and de-prescribing of antibiotics for viral infections.<sup>42</sup> Lastly, external market access stakeholders (e.g., government and regulatory agencies, payors) must be informed of the clinical value and patient benefit of IVD technology in the outpatient setting for updating coverage policies associated with test utilization.<sup>43</sup>

For addressing RDT accessibility concerns, the Prioritizing Equity in Antimicrobial Stewardship Efforts (EASE) framework, aligned with Joint Commission and CMS Health Equity principles may represent an effective strategy.<sup>44</sup> The framework, which includes five focus areas, states that reviewing institutional data should be the starting point when designing an intervention to create change. Following this guidance, investigators could identify an outpatient setting and a disease area to review data for. With the growing reports of *S. pneumoniae* inequities in the diagnosis of AMR *S. pneumoniae* infections, this may be an ideal starting point for clinicians and researchers.<sup>6</sup> Following the guidance provided in the EASE framework, researchers could begin with extracting data on *S. pneumoniae* infections treated in their affiliated outpatient settings. The investigators could further disaggregate the data by levels of deprivation (using the ADI or SVI), race/ethnicity, or insurance status to see whether differences in AMR *S. pneumoniae* infections exist. Investigators have used non-susceptibility to at least one of the 27 antimicrobials clinically used to treat pneumococcal infections as specified in the National Healthcare Safety Network (NHSN) Antimicrobial Use and Resistance (AUR) reporting module as an indicator for *S. pneumoniae* resistance, which other researchers can consider as their definition for an AMR

*S. pneumoniae* infection.<sup>45</sup> Based on these findings, investigators and clinicians can design an intervention to address uncovered inequities, with accessibility as a focus. The intervention should consider operational barriers, including staff workload and competency. Costs and insurance coverage should also be evaluated when deciding who should be tested, when tests should be used, and which RDTs should be prioritized for use. With these considerations, a possible intervention could involve deploying RDTs only for individuals at higher risk for AMR pneumococcal infections. This approach could ensure that patients at increased risk receive the right antimicrobials promptly, thereby reducing the development and propagation of resistant infections among high-risk groups.

## Conclusion

The evolution of diagnostics for infectious diseases has increased accuracy, reduced turnaround times, and broadened the spectra of detections with one test. RDTs boost diagnostic certainty, translating into improved antimicrobial use and clinical outcomes in the inpatient and outpatient settings alike. Health disparities present predictable barriers to ensuring access to RDTs in marginalized populations, though these challenges can be met. The spread of AMR is not constrained by geography or socioeconomic status.

Availability of outpatient RDTs for all communities ultimately align with the CDC's Ambulatory Stewardship guidance, strengthening antibiotic prescribing practices and protecting population health at large—reflecting the principle: “Whatever affects one directly, affects all indirectly.”<sup>46</sup>



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