CLINICAL EVIDENCE & ACCESS STRATEGY

The Cost of Guessing

How Diagnostics Can Break the Cycle of Antibiotic Overuse

A case study in evidence generation, stakeholder alignment, value demonstration, and patient access.

Maren S. Fragala, PhD, CSCS

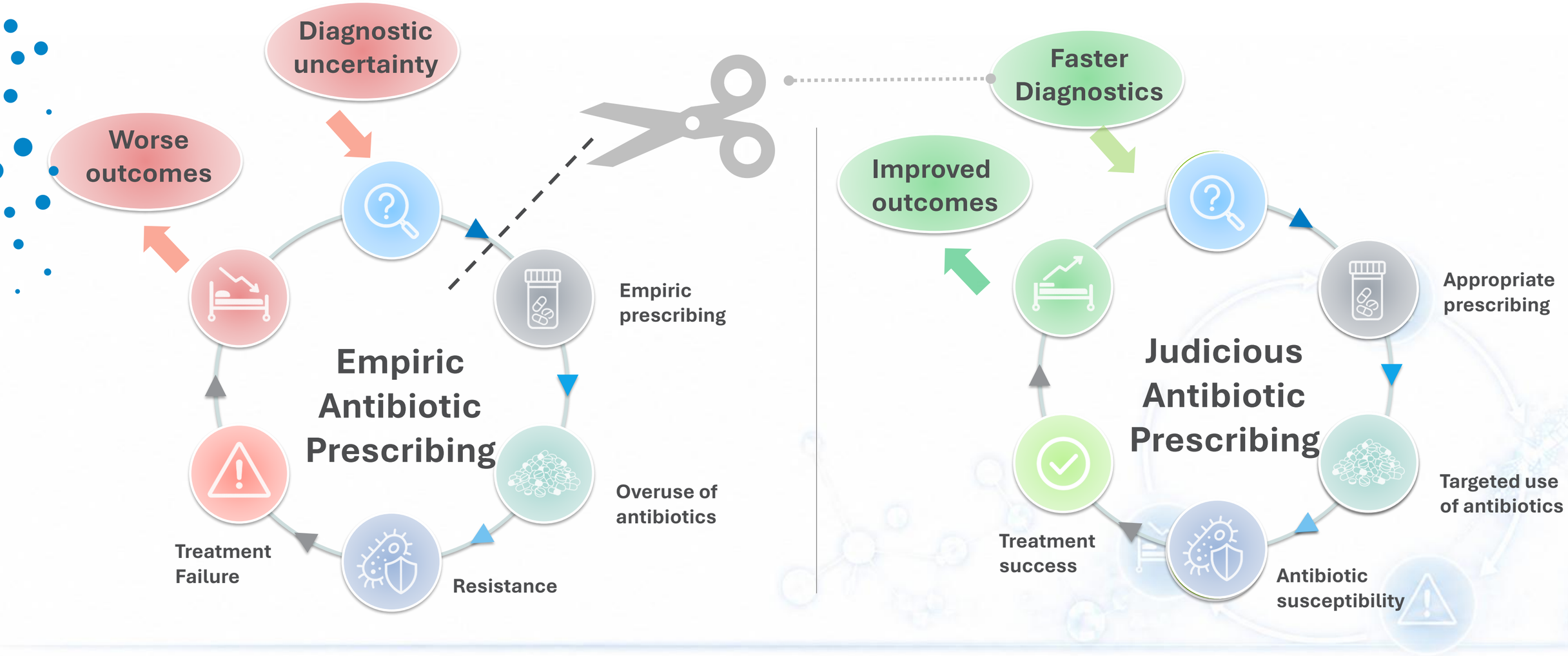
Applied Research Scientist & Evidence Strategy Leader



Image: Concept and direction by M.S. Fragala, 2026; visual created with OpenAI generative AI, 2026.

Diagnostics help break the cycle of inappropriate prescribing

Fast & accurate molecular diagnostics enable more timely, targeted, and appropriate therapy



Breaking the cycle requires aligning stakeholders

Multiple stakeholder alignment is required to enable access to testing

Patients
Faster answers • Accurate diagnosis • Affordable access

Providers
Actionable results • Clinical confidence

Payers & purchasers
Better outcomes • Demonstrated value

SHARED OUTCOMES PRIORITIES
- Appropriate treatment
- Improved patient outcomes
- Sustainable healthcare value

Regulators & policymakers
Accuracy • Equity • Public health

Test Developers
Relevant evidence • Scalable innovation

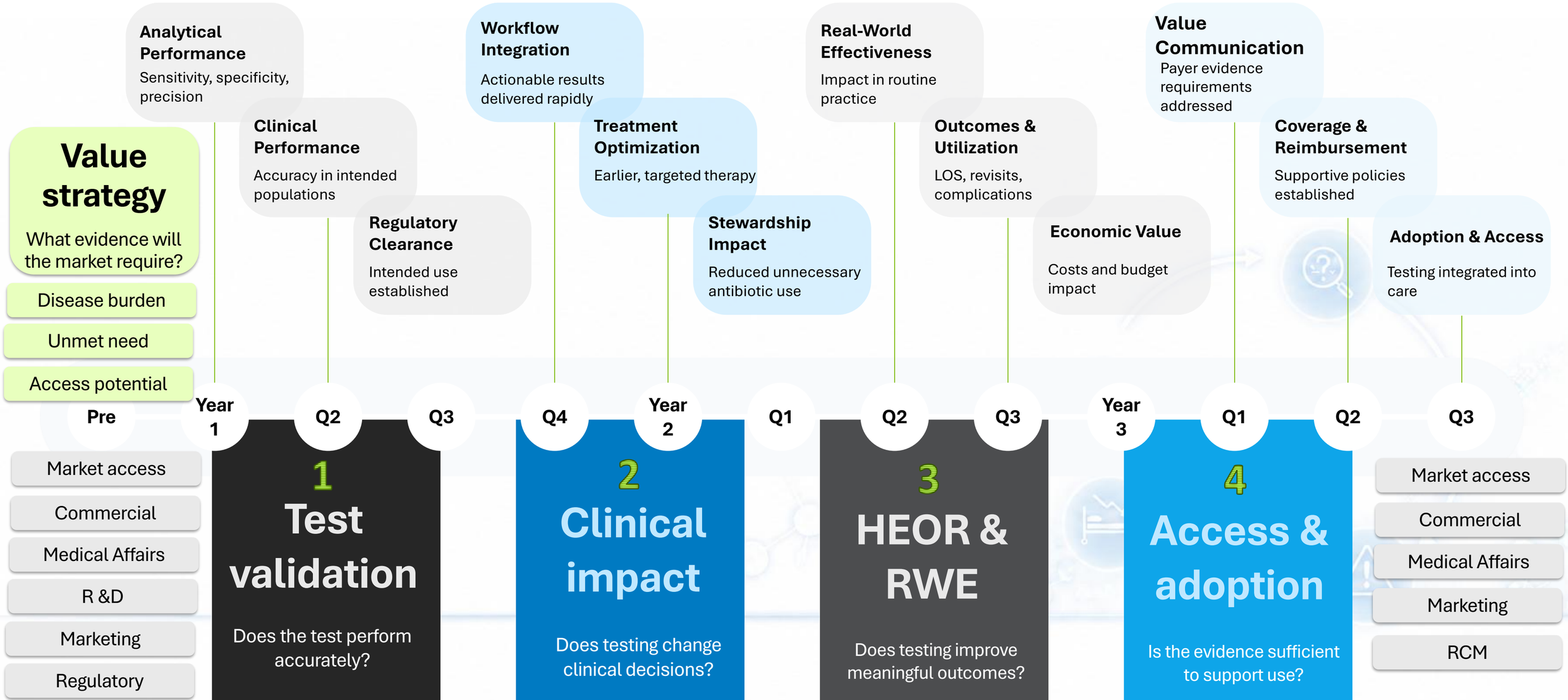
Health Systems
Safer care • Lower utilization



Image: Concept and direction by M.S. Fragala, 2006; visual created with OpenAI generative AI, 2026.

Breaking the cycle requires value & access

Integrated evidence strategy transforms diagnostic performance into access and adoption



Generating evidence of value

Translated stakeholder insights into a coordinated integrated evidence plan

Targeted literature review



Cataloged existing evidence across:

- Clinical
- Economic
- Utilization
- Prescribing behavior

Evidence landscape

Evidence gap analysis



Identify unmet requirements

- Evidence dependencies
- Recurring themes
- Highest-value gaps to address

Prioritized research pathway

Stakeholder Insight & Alignment



Validate and prioritize needs with external cross-functional leaders:

- Advisory boards
- Payer advisors
- Consultants

Stakeholder-aligned priorities

Evidence needs assessment



Defined evidence requirements

- Priority endpoints
- Target audiences
- Data sources
- Potential study concepts

Evidence requirements framework



EVIDENCE

Topic	Title	Journal and year	Key finding
Antibiotic prescribing	Is Pathogen Molecular Testing Reshaping Outpatient Antibiotic Prescribing?	*American Journal of Medical Quality, 2025*	Testing may reshape prescribing
Provider-reported outcomes	Pathogen Molecular Testing and Its Impact on Antibiotic Prescribing and Patient Outcomes: Results of a Provider Survey	*Journal of Urgent Care Medicine, in revision*	Testing improves prescribing and outcomes
Antibiotic stewardship	Resisting Inappropriate Antibiotics: How Judicious Use of Molecular Testing Helps Clinicians Prevent Overprescription	*Urgent Caring, 2026*	Testing reduces inappropriate prescribing
Ambulatory diagnostics	Harnessing the Power of Molecular Diagnostics in Ambulatory Care: Prospects and Pitfalls	*Journal of Molecular Diagnostics, in review*	Benefits and implementation challenges
Urgent care diagnostics	Role of Rapid Molecular Diagnostics for Lower Respiratory Tract Infections in Urgent Care	*Journal of Urgent Care Medicine, 2025*	Addresses lower-respiratory diagnostic gap
Clinical practice	Diagnostics and Decisions: Molecular Test Insights in Shared Decision-Making for Managing Respiratory Infections	*Journal of Participatory Medicine, 2025*	Test insights support shared decisions
Respiratory outcomes	Real-World Evaluation of Next-Day Molecular Respiratory Infectious Disease Testing on Healthcare Resource Utilization and Costs	*ClinicoEconomics and Outcomes Research, 2025*	Lower utilization and costs
Respiratory outcomes	Healthcare Resource Utilization and Costs Among Patients Receiving Diagnostic Tests for Respiratory Infections	*American Journal of Managed Care, 2025*	Testing affects utilization and costs
Respiratory outcomes	Molecular Testing for Respiratory Tract Infections May Have Favorable Impact on Real-World Healthcare Costs	*American Journal of Infectious Diseases, 2024*	Molecular testing may reduce costs
Women's health outcomes	Healthcare Utilization and Costs Following PCR Diagnostic Testing Among Patients With Vaginitis	*Journal of Comparative Effectiveness Research, 2024*	PCR testing reduces utilization and costs
Women's health outcomes	Molecular Testing for Women's Gynecologic Health: Real-World Impact on Health Care Costs	*Population Health Management, 2024*	Molecular testing lowers care costs
Women's health outcomes	Utilization of Syndromic Vaginitis Diagnostic Testing Reduces 6-Month Follow-Up Outpatient Service Healthcare Costs	*Healthcare, 2024**	Lower six-month outpatient costs

* Commercial Medical Policy

Translating Evidence | Utilization & costs

Molecular diagnostics for respiratory infections were associated with lower healthcare utilization and costs[1]



CLINICAL

Health Care Utilization and Cost of Diagnostic Testing for Respiratory Infections

Azia Evans, PhD; Riddhi Doshi, MBBS, PhD, MPH; Jason Yeaw, MPH; Katharine Coyle, BA; Steven E. Goldberg, MD, MBA; Elizabeth J. Wang, MS; Maren S. Fragala, PhD; and Jairus Reddy, PhD

ABSTRACT

OBJECTIVES: This study compared all-cause health care resource use (HCRU) and costs between patients with acute oropharyngeal infections and respiratory tract infections (RTIs) receiving targeted syndromic real-time polymerase chain reaction (RT-PCR) tests with next-day results vs matched patients receiving other/no diagnostic tests.

STUDY DESIGN: Propensity-matched, retrospective study.

METHODS: Two cohorts with *International Classification of Diseases, Tenth Revision, Clinical Modification* codes for diagnosis or symptom(s) of oropharyngeal infection or RTI (first diagnosis = index) on an outpatient claim were identified in the IQVIA PharMetrics Plus database (July 2020–October 2023). HCRU and costs were examined over 6 months post index across 5 subcohorts: patients receiving syndromic RT-PCR and 4 matched subcohorts (other PCR, point-of-care [POC] only, culture, or no test).

RESULTS: The mean (SD) costs for postindex total outpatient services [$2598 [$7564] vs $2770 [$8617]; *P* < .0001), physician office visit [$624 [$1150] vs $689 [$1082]; *P* = .0002), emergency department (ED) [$290 [$1145] vs $397 [$1430]; *P* = .0192), and other medical services ($1684 [$4799] vs $1883 [$7568]; *P* = .0001) were significantly lower for the oropharyngeal RT-PCR subcohort than the matched culture subcohort. The mean (SD) postindex costs for any outpatient medical services [$2796 [$11,453] vs $3221 [$7873]; *P* < .0001), physician office visits [$525 [$974] vs $703 [$2635]; *P* = .0057), ED visits [$253 [$1034] vs $355 [$1200]; *P* = .0011), and other medical services [$2018 [$10,986] vs $2163 [$6458]; *P* < .0001) were significantly lower for the RTI RT-PCR subcohort than the matched culture subcohort. Patients in both RT-PCR subcohorts had lower utilization of other medical services and any outpatient services compared with all matched comparator subcohorts.

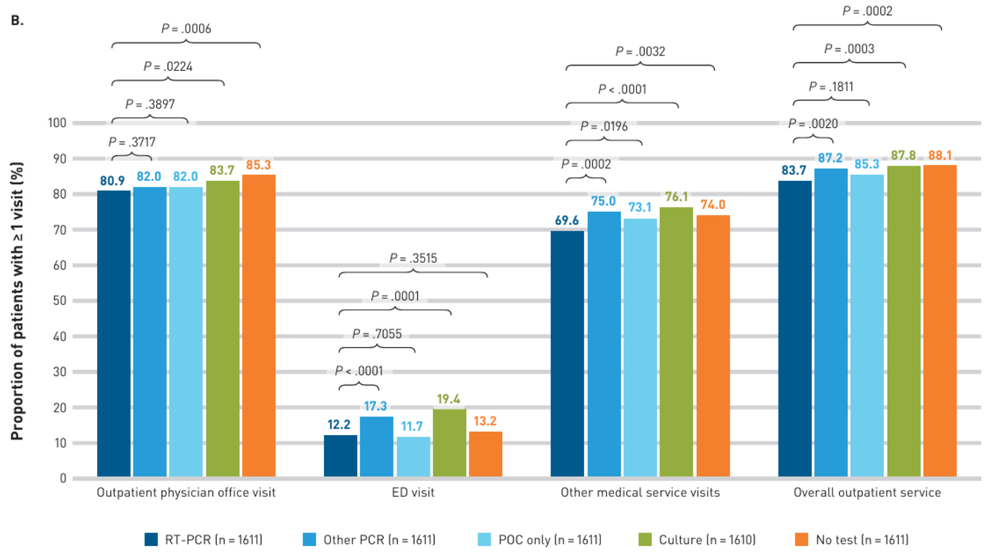
CONCLUSIONS: This propensity-matched study provides evidence on the economic impact of syndromic RT-PCR tests for respiratory infections, highlighting their advantages over traditional diagnostic methods.

Am J Manag Care. 2025;31(9):e249-e257. doi:10.37765/ajmc.2025.89789

Respiratory tract infections (RTIs) including acute oropharyngeal/respiratory infections are a serious health care concern in the US, with an age-standardized incidence of 339,703 per 100,000 people and accounting for 13.6 per 100,000 deaths (~2% of all deaths) in 2019.[1] Oropharyngeal infections and RTIs also result in substantial health care resource utilization (HCRU): almost one-fifth of all outpatient visits (194 visits per 1000 people)[2] and more than $1 billion in health care expenditures in the US.[3,4]

Oropharyngeal infections, such as pharyngitis, characterized by sore throat, sneezing, cough, and/or fever,[5,6] can be caused by both viral and bacterial etiologies. Streptococcal infections alone account for more than 5.2 million outpatient visits among people younger than 65 years.[6,7] Common causes of other RTIs include respiratory viral pathogens, known bacterial pathogens such as *Mycoplasma pneumoniae*, and frequent colonizers of the respiratory tract, including *Streptococcus pneumoniae* and *Haemophilus influenzae*.

Accurate and timely diagnosis of oropharyngeal infections and RTIs is challenging because the clinical signs and symptoms are not pathogen specific, thereby delaying the initiation of targeted treatment when indicated.[8] Traditional in-office diagnostic testing, including serological tests and rapid antigen detection point-of-care (POC) tests, lacks specificity and/or sensitivity, detects only a limited number of pathogens, and requires dedicated resources during the respiratory season. Culture-based techniques are time-consuming and often require technical expertise to interpret results, increasing the risk of misdiagnosis and adverse health outcomes.[8,9] Polymerase chain reaction (PCR)–based testing has emerged over the past decade as more accurate and sensitive at identifying complex and mixed bacterial compositions. Rapid molecular testing for viral conditions offers considerable advantages. It may reduce unnecessary antibiotic use, enhance antiviral prescribing, and minimize the need for additional ancillary testing.[8,10,11] Newer syndromic PCR tests provide fast results and a broader array of causative organisms/viruses based on patient presentation.[8,12] Despite the advantages over other tests, utilization of PCR tests in clinical practice remains low. Yet observational research has shown that, despite low overall utilization, antibiotic use is significantly lower



- Propensity-matched
- n= 1,611 per group
- IQVIA PharMetrics Plus claims database
- US commercially insured < 65 y

$425

Lower outpatient costs for patients who received RT-PCR

> Using syndrome-driven RT-PCR tests for patients with respiratory tract infections is associated with **lower HCRU** and **costs** through lower utilization of outpatient services."

Mean outpatient costs were $425 lower per patient for the RT-PCR group ($2,796+11,453) than the culture group ($3,221+7873): median $531 vs. $799)

1. Evans A, Doshi R, Yeaw J, Coyle K, Goldberg SE, Wang EJ, Fragala MS, Reddy J. Health care utilization and cost of diagnostic testing for respiratory infections. Am J Manag Care. 2025 Sep 1;31(9):e249-e257. doi: 10.37765/ajmc.2025.89789. PMID: 40966599. Link