

Equipping Rural America for 21st Century COPD Care

Executive Summary

COPD patients in rural America face systemic barriers, limited access to pulmonologists, delayed diagnostics such as PFTs, and late interventions that increase the risk of hospitalization. The AGM100[®] provides a validated, non-invasive alternative that empowers primary care physicians to assess, stratify, and treat patients in real time. This paper outlines the current limitations of COPD care in rural settings and how realtime gas exchange assessment can bridge the diagnostic gap while supporting CMS-aligned goals in rural health equity, early intervention, and cost-effective care.

Overcoming Barrirs to COPD Care in Rural Settings

Chronic Obstructive Pulmonary Disease (COPD) disproportionately impacts rural communities, where patients experience higher rates of hospitalization and mortality than their urban counterparts. Limited access to pulmonologists and diagnostic infrastructure forces rural primary care providers to manage complex cardiorespiratory conditions with minimal support, often relying on subjective symptoms and limited tools. As a result, patients may wait weeks or months for a specialist diagnosis, delaying treatment and increasing the risk of exacerbations.

According to the Journal of the COPD Foundation, up to 60% of individuals with abnormal lung function are unaware they have obstructive lung disease.¹ This underdiagnosis is magnified in rural areas, where geographic isolation and constrained diagnostic resources hinder early detection and effective management at the point of care.

Key Takeaways

- Traditional pulmonary diagnostics are often unavailable or impractical in rural and resourcelimited settings, delaying critical care decisions.
- Traditional tools frequently underperform when clinical precision is most needed, particularly during care escalation.
- The AGM100[®] delivers real-time, non-invasive cardiopulmonary insights at the point of careeliminating delays from lab-based testing and enabling faster, more informed decisions.

COPD Resources Unavailable to Clinicians



Figure 1. Rural providers face major barriers to diagnosing COPD (adapted from Diaz del Valle F et al, COPD Foundation, 2021).

Why Traditional Tools Fall Short in Rural Settings

Access to timely, objective data is critical for accurate COPD diagnosis, yet rural providers often lack access to standard diagnostics. Arterial blood gases (ABGs), pulmonary function tests (PFTs), and imaging tools are typically unavailable or delayed.²



This diagnostic gap contributes to higher rates of missed or late-stage diagnoses, which lead to more severe exacerbations and increased hospital admissions. Studies confirm that COPD prevalence and mortality are nearly double in rural areas, driven in part by the absence of adequate diagnostic and management tools.³

Reframing Dignostics Expectations

While FEV1 / PFTs remain gold standards in COPD staging, their value diminishes when inaccessible. In rural communities, where wait times exceed weeks or a month and specialists are many hours away, primary care physicians need diagnostic tools that work in the real-world, not just the academic ideal.

A New Diagnostic Pathway: Bringing Gas Exchange to the Point of Care to Rural Medicine

A Point-of-care technologies offer a new model for rural COPD care. Devices like the MediPines AGM100[®] deliver real-time, non-invasive assessment of gas exchange, providing clinicians with essential data -

including oxygenation (PaO₂), carbon dioxide

elimination (EtCO₂), and Oxygen Deficit - directly at the bedside.



Figure 2: While appearing stable on the surface, this patient result shows severe hypoxemia, likely due to a problem with V/Q mismatch or diffusion limitation.

Revealing What Traditional Methods Miss in Gas

Exchange - COPD is a disease of impaired gas exchange. Physiological changes such as ventilation-perfusion (V/Q) mismatch, diffusion limitation, and CO₂ retention are not detectable with pulse oximetry or stethoscopes. In the absence of ABGs and PFTs, rural clinicians are left guessing, often responding only after symptoms become severe. The AGM100[®] fills this gap, revealing silent physiologic deterioration before clinical symptoms appear. By detecting gas exchange abnormalities early, providers can intervene sooner, reducing the risk of hospitalization.

A New Approach to Seeing What's Missed - By

providing real-time insight into gas exchange physiology, The AGM100[®] brings gas exchange assessment to the bedside, giving providers immediate insight into pulmonary function with no lab required. This enables rural providers to:

- Determine whether to initiate or adjust supplemental oxygen therapy
- Decide when to escalate care or refer to a specialist
- Track a patient's response to treatment in realtime

The comprehensive data generated by the AGM100[®] equips clinicians with objective, actionable insights. This helps guide decisions on supplemental oxygen use,

This technology instantly detects changes in pulmonary gas exchange in disease states such as COPD, pneumonia, influenza and Acute Respiratory Disease Syndrome (ARDS)...as a result premature mortality from respiratory disease can be prevented. Its intended use is for any patient aged 18+ suffering from respiratory distress.

W.H.O. Compendium of innovative health technologies for low-resource settings 2021

Clinicians can manage COPD with greater confidence and precision, minimizing unnecessary transfers to urban centers and allowing care to stay local.

Reducing Disparities, Improving Outcomes

By equipping rural clinics with advanced diagnostic insight, the AGM100[®] helps:

• Reduce preventable hospitalizations



- Enable proactive management of COPD and related conditions
- Support evidence-based care regardless of geographic location

In rural regions where logistical and financial barriers prevent patients from accessing specialty care, the AGM100[®] bridges the gap, bringing diagnostic precision to the frontlines.

Field Implementation: Bridging the Diagnostic Gap

Real-world use of the MediPines AGM100 has already demonstrated strong clinical utility in environments where access to advanced respiratory diagnostics is limited. Across a range of clinical settings, frontline healthcare providers have integrated the AGM100 into patient assessments to fill the diagnostic gap between basic pulse oximetry and complex lab-based testing.

- Outpatient Clinics: Providers have used the AGM100 to uncover gas exchange abnormalities in patients presenting with mild or nonspecific respiratory complaints, leading to earlier diagnosis and more tailored interventions.
- Critical Access Hospitals: Facilities with limited access to ABG testing report that the AGM100 has helped reduce unnecessary patient

transfers by providing actionable, real-time gas exchange data.

• Telemedicine-Enabled Practices: In hybrid care models, clinicians have used AGM100 data to remotely consult pulmonologists, enabling collaborative care without requiring patient relocation.

By integrating advanced diagnostics into everyday workflows, the AGM100[®] empowers frontline providers to close the rural care gap in COPD.

Evidence-Based Medicine

The MediPines AGM100[®] is supported by a growing body of clinical research demonstrating its diagnostic performance, operational simplicity, and patient impact across a spectrum of care environments. From rural clinics to advanced hospitals, clinicians are using the AGM100[®] to make faster, better-informed decisions, improving patient outcomes and streamlining the path to care.

- <u>Oxygen Deficit[™]: A Non-Invasive Indicator of</u> Pulmonary Gas Exchange Efficiency
- <u>Clinical Application of the AGM100[®] in</u> <u>Preoperative Risk Assessment</u>

For a full list of clinical publications and evidence, visit: <u>https://medipines.com/clinical-research</u>



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Supporting Healthcare Priorities with Real-World Evidence

The AGM100[®] addresses a critical clinical and operational gap by enabling timely, non-invasive assessment of cardiorespiratory function, directly supporting healthcare priorities in rural health equity, care quality, and cost reduction. The real-time output helps frontline clinicians make faster, more accurate decisions, reducing reliance on delayed lab diagnostics and minimizing preventable hospitalizations, inter-facility transfers, and unnecessary utilization.

MediPines is actively partnering with rural and community hospitals to collect real-world evidence (RWE) across key metrics, including:

- Avoided hospitalizations
- Reduce length of stay
- Reduced 30-day return visits
- Improved triage accuracy
- Better oxygen therapy targeting

These RWE collaborations not only support ongoing CMS and commercial reimbursement discussions, building on an initial APC structure already in place, but also advance the broader policy goal of expanding access to high-value, point-of-care innovation in underserved settings. Hospitals interested in joining current RWE efforts and contributing to future peer-reviewed publications and policy dialogue are encouraged to contact MediPines at <u>agm100@medipines.com</u>

References

Diaz del Valle F, Koff PB, Min SJ, et al. Challenges faced by rural primary care providers when caring for COPD patients in the western United States. Chronic Obstr Pulm Dis (Miami). 2021;8(3):336-349. doi:10.15326/jcopdf.2021.0215. Available here: <u>https://journal.copdfoundation.org/jcopdf/article/1558</u>

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The MediPines AGM100[®] is US FDA-cleared, Health Canada approved pulmonary gas exchange monitor that exclusively provides Oxygen Deficit, (AaDO2, aka. A-a gradient), as well as blood oxygen level (gPaO2), PETCO2, and other sensitive measurements of pulmonary gas exchange. The respiratory parameters are available from patient breathing gas sampling method typically lasting 2 minutes. Visit <u>www.medipines.com</u> for more information on <u>AGM100</u>.

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