Challenges With The Evolving Diagnostic Landscape For MBL-Producing Gram-Negative Infections: Insights From Healthcare Professionals

David Grolman[1], Andy Townsend[2], Gregory Stone[3], Shweta Kamat[4]

[1]Pfizer Inc, Sydney, Australia; [2]Pfizer Inc, Tadworth, UK; [3]Pfizer Inc, Groton, Connecticut, USA; [4]Pfizer Ltd., Mumbai, India

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Background

- Metallo-β-lactamase (MBL)-producing Gram-negative infections are an escalating global health concern, particularly in regions with variable access to diagnostic infrastructure
- Rapid Diagnostics Tests (RDTs) offer the potential to accelerate detection and guide early, targeted treatment, yet their adoption remains inconsistent
- Of the countries in this analysis, MBL prevalence is highest in India and Brazil, with rising rates in China and Saudi Arabia
- The emergence of double-carbapenemase infections further complicates treatment selection and reduces the utility of single-target diagnostics

Methods

- Diagnostic readiness and test availability across Brazil (BR), China (CH), India (IND), Mexico (MX), Saudi Arabia (SA), and Taiwan (TW) was assessed between November 2024 and January 2025
- 42 qualitative interviews with infectious disease experts, microbiologists, intensive care unit (ICU) physicians, and laboratory directors were conducted to explore diagnostic workflows, technology use, and systemic barriers to access and adoption in both public and private healthcare settings

Results

- Differences in diagnostic access and challenges to adoption were reported (Table 1)
- Advanced tools like MALDI-TOF and syndromic panels are largely confined to tertiary hospitals (Table 2)
- While lateral-flow assays and syndromic panels are valued for their speed and comprehensiveness, their use is limited by high costs and inadequate reimbursement (Figure1, Table 3)
- Infrastructure gaps, restricted laboratory hours, and lack of reimbursement for tests further hinder equitable access to rapid diagnostics (Table 1)
- Country-specific strategies are needed to optimise rapid diagnostic testing for bacterial infections (Figure 2)

Table 1. Comparison of Country Specific Diagnostic Workflow and Barriers for Adoption

Country	Diagnostic Workflow	Systemic Barriers for Adoption
	Culture-based ID/AST, MALDI-TOF (if available), LFTs and syndromic panels for critical/private cases	Cost limits advanced diagnostics, limited lab hours, infrastructure disparities, access depends on ability to pay, protocols updated only if cost-effective
	Tertiary hospitals use MALDI-TOF and automated AST, LFTs/molecular for high-risk, lower tiers refer out to central laboratories	High cost, lack of standardised pricing, infrastructure gaps, limited access to advanced diagnostics
	Syndromic panels for urgent/affording cases, MS for ID, VITEK-2 for AST, LFTs emerging	Cost, ability to pay, limited access in lower tiers, limited skilled staff
	Tier 3/private: MALDI-TOF, VITEK-2, syndromic/PCR for severe; others: culture-based	Cost, infrastructure, slow adoption of advanced diagnostics, limited awareness, lack of pharma support
	Tertiary: MALDI-TOF, syndromic, PCR; smaller: culture-based, refer out to central laboratories	Cost, limited access in smaller hospitals, reliance on central labs, access depends on insurance or ability to pay
	Large: MALDI-TOF, automated AST, syndromic for research/urgent; small: manual ID/AST	Cost, limited insurance coverage, few approvals, slow adoption, lack of manufacturer interest, out-of-pocket payment

Source: Country Specific Interviews, Nov 2024 to Jan 2025

Table 2. Heavy reliance on automated ID/AST across the leading centres in RoW countries in the study; MALDI-TOF also available, but even more restricted

Country	Simple CBP	Aut. ID/AST	MALDI-TOF
	Cost-effective option to identify MoR	Reserved for priority cases	Limited access
	Used in a few tertiary hospitals	Widely available – 'gold-standard'	Widely available tertiary hosp.
	Considered out-dated	Widely available in tier 1 (and some tier 2) hospitals	Leading centres only
	Considered low cost with a simple protocol	Widely available in leading Tier 3 hospitals	Limited adoption due to infrastructure constraints
	Option in cost-constrained settings	Available in tertiary and other leading centres	Available in tertiary centres only
	Traditional methods (mCIM/eCIM) preferred	Most hospitals have VITEK-2, some Phoenix, rare Microscan	Widely used in Taiwan hospitals

Source: RoW Interviews, Nov 2024 to Jan 2025

Established | Supported | Not Used

Table 3. Diagnostic Approach - Relative Cost Perception Per Test

	Brazil	China*	India	Mexico	Saudi Arabia	Taiwan**
MALDI-TOF						
LFTs						N/A
Fast Phenotyping	N/A	N/A	N/A	N/A	N/A	N/A
Molecular Diagnostics						N/A
Syndromic						
Automated ID/AST						

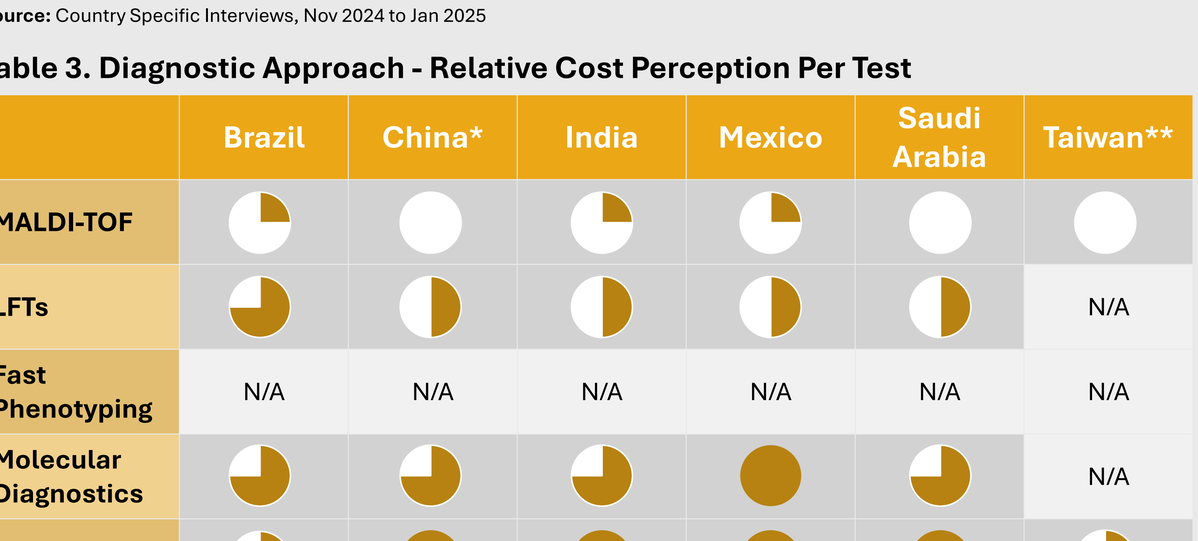
Source: RoW Interviews, Nov 2024 to Jan 2025

Very High | High | Medium | Low | Very Low

*Relative costs were provided unprompted for two different types of NGS (tNGS and mNGS); both considered expensive but cost-effective due to broad targets, speed, and sample flexibility

**NGS costs two-to-three times more than syndromic tests; may be used for complex cases

Figure 1. LFT use remains at a low-level across the sample countries; genotypic Dx has a stronger position in IND, CH and KSA, but under-used in BR, MX and TW



Source: RoW Interviews, Nov 2024 to Jan 2025

China | India | Brazil | Mexico | Saudi Arabia | Taiwan

Figure 2: Creating the conditions to enabling earlier identification remains key to address the healthcare challenges posed by MBL-producing Gram-negative infections.
Themes to consider as country-specific strategies are developed.

Expanding access to LFTs
Encouraging rapid, cost-effective diagnostics as the backbone for MoR detection

Supporting the development of 24-hour laboratory services
Enabling around-the-clock diagnostics to expedite treatment decisions

Scaling syndromic test adoption
Supporting the use of comprehensive diagnostic panels for critical cases

Promoting on-site blood culturing
Reducing time-to-result by decentralising culturing capabilities

Enhancing simpler PCR platform use
Utilising PCR as a cornerstone for identifying MBL-producing pathogens

Addressing logistical and IT challenges
Facilitating seamless workflows for faster reporting and decision-making

Standardising guidelines for diagnostic protocols
Bridging the gap in diagnostic uniformity across regions

Expanding workforce training
Bridging the diagnostic skill gap through education and support

Advocating for diagnostic reimbursement policies
Ensuring affordability of advanced diagnostics by generating evidence of cost effectiveness

Integrating fast phenotypic testing
Supporting rapid phenotyping to inform same-shift clinical decisions

Conclusion

To fully leverage the benefits of RDTs, cross-sectoral collaboration is essential. Strategic investments in diagnostic infrastructure, workflow optimisation, policy advocacy for pricing and reimbursement, and a focus on education and awareness will be critical to ensure access to RDTs that can unlock timely, appropriate treatment of MBL-producing infections.

AST, antimicrobial susceptibility testing; Aut., automated; BR, Brazil; CBP, carbapenemase-based phenotypic test; CH, China; Dx, diagnostics; eCIM, EDTA-modified carbapenem inactivation method; ICU, intensive care units; ID, identification; IND, India; KSA, Kingdom of Saudi Arabia; LFT, lateral flow test; MALDI-TOF, matrix-assisted laser desorption/ionisation–time of flight; MBL, metallo-β-lactamase; mCIM, modified carbapenem inactivation method; mNGS, metagenomic next-generation sequencing; MoR, molecular resistance; MX, Mexico; NGS, next-generation sequencing; PCR, polymerase chain reaction; RDT, rapid diagnostic test; RoW, rest of world; tNGS, targeted next-generation sequencing; TW, Taiwan.

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