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Perspective

Diagnostic stewardship in clinical microbiology: current status and perspectives in Korea

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Diagnostic stewardship aims to improve patient care quality by optimizing diagnostic test utilization, reducing unnecessary testing, and enhancing cost-effectiveness [1,2]. In Korea, diagnostic practices are in the early stages of developing a stewardship program. Although not exclusive to clinical microbiology, diagnostic stewardship programs (DSPs) has gained prominence owing to the global challenge of antimicrobial resistance, aligning with the expansion of antimicrobial stewardship programs (ASPs) [3]. This commentary examines the current status and perspectives of DSPs in clinical microbiology and highlights key strategies and future directions in Korea.

In Korea, ASPs have been actively developing with government support to combat antimicrobial resistance [4]. To implement ASPs, a DSP is required first. For example, the Korea Disease Control and Prevention Agency has been operating a national mandatory surveillance system for six multidrug-resistant organisms (MDROs) as critical priority pathogens of public health since 2010 [5]. This surveillance revealed that a continuous increase in carbapenem-resistant *Enterobacterales*, especially carbapenemase-producing *Enterobacterales* (CPE), threatened public health (Fig. 1). Building on these findings, resource allocation and strategic planning, such as ASPs, have been strengthened to address the increasing threats posed by MDROs.

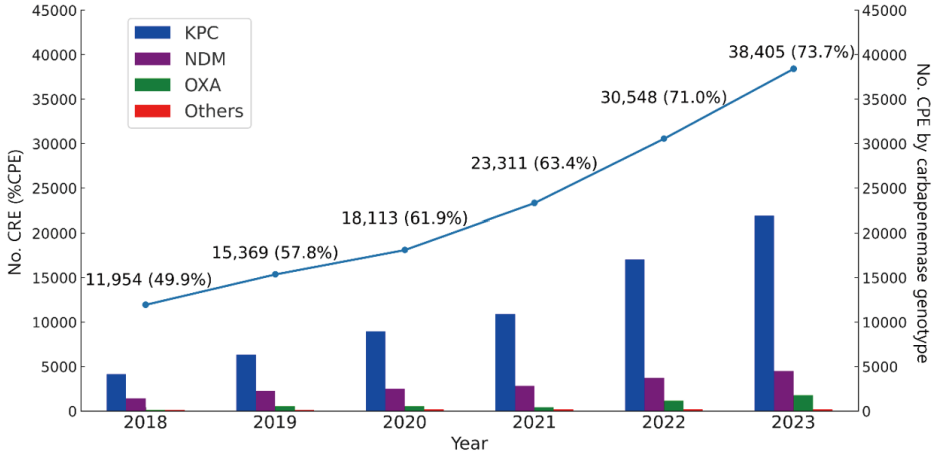

Fig. 1. National surveillance data of carbapenem-resistant *Enterobacterales* (CRE) in Korea from 2018 to 2023. The line represents the annual number of CRE cases with the percentage of carbapenemase-producing *Enterobacterales* (%CPE). The bars indicate the distribution of carbapenemase genotypes including KPC, NDM, OXA, and others among CPE isolates in each year.

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In clinical microbiology, diagnostic stewardship efforts have particularly focused on optimizing several key areas: First, the utilization of syndromic testing enabling the simultaneous detection of multiple pathogens from a single sample [6], Second, employment of sample-to-result rapid screening tests to quickly identify pathogens responsible for threatening outbreaks or serious morbidity and mortality, as well as carriers of MDROs to enhance infection control measures. The endemicity and frequent outbreaks of CPEs necessitate the active isolation of carriers via rapid preadmission screening in Korea [7]. Third, there is a strong emphasis on implementing rapid pathogen identification and antimicrobial susceptibility testing (AST) for positive blood cultures [8]. Currently, various molecular diagnostics and rapid phenotypic AST for bloodstream infections are available (Table 1). Therefore, DSPs are becoming increasingly crucial, as it enable clinicians to make informed decisions through timely reporting and alert systems issued by the laboratory (Fig. 2) [9].

Table 1. Rapid pathogen identification and antimicrobial susceptibility tests for application to positive blood cultures or direct blood samples that are currently available or expected to be available in Korea

Platform/kit (manufacturer)	Species-identification range	Antimicrobial-resistance determination
Molecular diagnostics		
cobas® ePlex BCID Panels (Roche Diagnostics)	BCID-GP: 20 GP with Pan-GN, Pan-*Candida* BCID-GN: 21 GN with Pan-GP, Pan-*Candida* BCID-FP: 15 fungal organisms	*mecA*, *mecC*, *vanA, vanB*, CTX-M, IMP, KPC, NDM, OXA-23/48, VIM
BioFire® FilmArray BCID2 (bioMérieux)	33 organism targets: 11 GP, 15 GN, 7 yeasts	*mecA/C*, MREJ, *vanA/B*, KPC, NDM, VIM, IMP, OXA-48-like, CTX-M, *mcr-1*
VERIGENE® BCID Panels (DiaSorin)	BC-GP: 13 GP genus/species BC-GN: 9 GN genus/species	BC-GP: *mecA*, *vanA*, *vanB* BC-GN: CTX-M, IMP, KPC, NDM, OXA, VIM
T2Candida® Panel (T2 Biosystems)[a]	5 *Candida* species directly from whole blood	None
MALDI Biotyper (Bruker)	Full range cover, ≥ 4,000 bacterial and fungal species - MBT Sepsityper (IVD), ≥425 microorganisms from positive blood cultures	Carbapenemase and cephalosporinase using MBT-STAR (IVD) Colistin resistance using MBT Lipid Xtract (RUO) Detection of bla_{KPC} and *cfiA* using MBT HT Subtyping (IVD)
Vitek MS (bioMérieux)	Full range cover, ≥ 1,000 bacterial and fungal species	None
Rapid phenotypic AST	Usually combined with direct species identification from positive blood cultures by MALDI-TOF	
dRAST (Quantamatrix Inc.)	GN and GP panel based on gram-stained microscopy of positive blood culture bottles	Phenotypic MICs based on microscopic imaging for 17–19 antimicrobials in 5–7 h
Accelerate PhenoTest BC kit (Accelerate Diagnostics, Inc.)	14 common bloodstream pathogens identified in 2 h	Phenotypic MICs based on microscopic imaging for 12–16 antimicrobials in 7 h
Blood culture-GN (PhAST)[b]	GN panel based on gram-stained microscopy of positive blood culture bottles	Phenotypic MICs based on microscopic imaging for 10 antimicrobials in 1 h
VITEK REVEAL (bioMérieux)	GN panel based on gram-stained microscopy of positive blood culture bottles	Phenotypic MICs based on sensing volatile organic metabolite produced by bacterial growth for 17–19 antimicrobials in 5 h
EUCAST RAST	8 common bloodstream pathogens	Disk diffusion in 4–8 h or 16–20 h
CLSI RAST	*Enterobacterales, Pseudomonas aeruginosa,* and *Acinetobacter* species	Disk diffusion in 8–10 h or 16–18 h

[a] Under process for IVD approval of Korea Ministry of Food and Drug Safety; [b] Under process for IVD approval of US Food and Drug Administration.
Abbreviations: MALDI, matrix-assisted laser desorption ionization; GP, gram-positive; GN, gram-negative; IVD, *in vitro* diagnostics; RUO, research use only; MS, mass spectrometry; AST, antimicrobial susceptibility testing; RAST, rapid antimicrobial susceptibility testing; MALDI-TOF, MALDI time-of-flight; MIC, minimum inhibitory concentration; EUCAST, European Committee in Antimicrobial Susceptibility Testing; CLSI, Clinical and Laboratory Standards Institute.

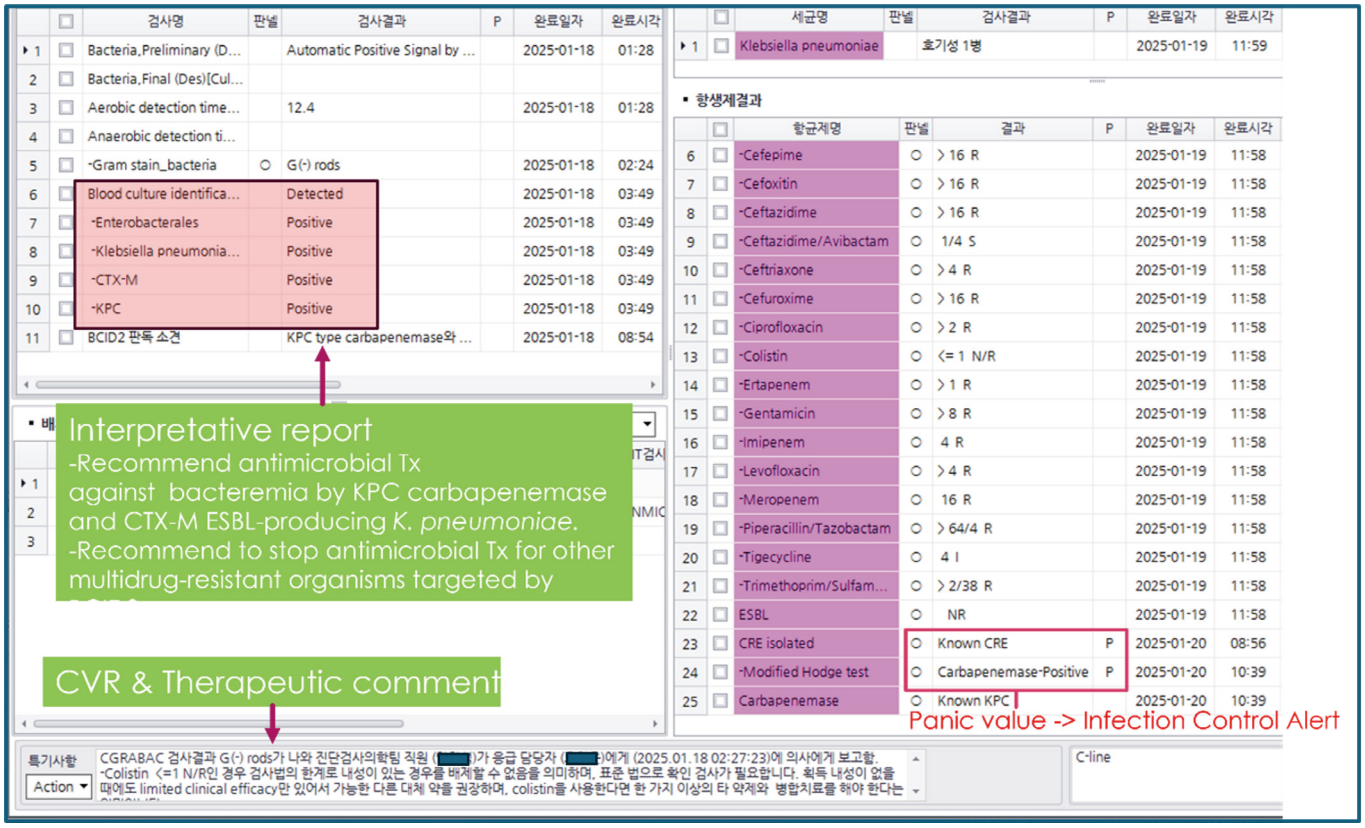

Fig. 2. Application of diagnostic stewardship to blood culture practice in a clinical microbiology laboratory. After BACTEC loading at 1-17 13:07, there were six moments of reports including a critical value report (CVR) and an infection control alert until the final report: (1) Positive signal at 1-18 01:28, (12.4 h from an aerobic bottle); (2) Gram stain results as gram-negative rods seen at 1-18 02:24; (3) Call to clinician at 1-18 02:27 recorded as a CVR, which initiates an automatic consult with infectious disease specialists for antimicrobial stewardship program, 3. KPC/CTX-M producing *Klebsiella pneumoniae* positive by BCID2 at 1-18 03:49; (4) Species identification and antimicrobial susceptibility test using colony at 1-19 11:59; (5) Phenotyping and genotyping of carbapenemase at 1-20 10:39; (6) A panic value for issuing an infection control alert.

Although advances in diagnostic technologies have resolved various issues associated with DSP, several challenges remain. The increasing availability of rapid and convenient molecular test kits can lead to their overuse, misuse, and potential underutilization [9]. For example, *Clostridioides difficile* infection (CDI) control and monitoring are process indicators of the national ASP actions in Korea [5]. Polymerase chain reaction (PCR)-based diagnosis contributes to overdiagnosis and subsequent overtreatment with antibiotics. Therefore, two-step methods, such as PCR followed by toxin enzyme immunoassay (EIA) or glutamate dehydrogenase EIA followed by toxin EIA and/or PCR for discordant results, are preferred for appropriate patient management, minimizing unnecessary antibiotic exposure, and mitigating the risks associated with CDI diagnosis and treatment [10]. Therefore, the significance of DSP throughout the entire testing process, spanning the pre-analytical, analytical, and post-analytical phases, is becoming increasingly apparent.

Looking ahead, collaborative efforts between clinical microbiologists and infectious disease specialists are expected to play a crucial role in improving patient care [9]. In severe infections, such as bacteremia, timely intervention by clinical microbiologists is critical to ensuring appropriate antimicrobial use and improving

overall patient outcomes. Thus, diagnostic stewardship in clinical microbiology involves a multifaceted approach, balancing technological advancements with judicious utilization and fostering interdisciplinary collaboration to optimize patient care and combat antimicrobial resistance.

Ethics statement

It is not a human population study; therefore, approval by the institutional review board or the obtainment of informed consent is not required.

Conflicts of interest

No potential conflicts of interest relevant to this article were reported.

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Data availability

None.

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