

Key Considerations for Clinical Trial Design in Diagnostic Interventions



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Rawson TM, Moore LSP.

[Understanding how diagnostics influence antimicrobial decision-making is key to successful clinical trial design.](#)

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While rapid molecular diagnostics offer more accurate microbial diagnosis at the point of care, recent research¹ suggests this does not necessarily impact patient outcomes or antimicrobial stewardship metrics. When evaluating diagnostics as part of the infection management pathway, it is crucial to understand where in the decision-making pathway these interventions may have an impact and the benefits of nonculture-based diagnostics in settings with high rates of empiric antimicrobial prescribing.

Diagnostics and Decision-making

- There is a lack of large, well-designed clinical trials in this area
- Identifying at which stage in the decision-making process the intervention is likely to have an impact on metrics and outcomes is crucial in developing and assessing diagnostic methods
- Multiple factors should be considered for the effective utilization of new diagnostic tools
- Developing approaches for integrating diagnostics into the broader decision-making pathways may lead to successful adoption and impact

Molecular Diagnostics and Bacterial Infection

- Molecular diagnostics are more sensitive and rapid than traditional culture-based methods but the two approaches are complementary, with molecular tests providing organism identification and susceptibility testing determining the phenotype
- Optimal interpretation of results and decision-making can be achieved by integrating methods such as multiplex PCR (mPCR) with additional modes of decision support, such as procalcitonin (PCT)

Role of Procalcitonin

- PCT has a clear role in supporting decision-making around antimicrobial cessation
- PCT predicts negative outcomes and can guide treatment cessation or avoid prescribing for certain patients, leading to similar clinical outcomes
- Utilizing PCT to aid in early treatment cessation could lead to shorter hospital stays and lower medical expenses

In conclusion, when conducting clinical trials for diagnostics, it's important to ask relevant clinical questions about the intervention being evaluated and the trial design should take into account other factors involved in making decisions about the intervention.

¹ Fartoukh M. Respiratory multiplex PCR and procalcitonin to reduce antibiotic exposure in severe SARS-CoV-2 pneumonia: a multicenter randomised controlled trial. *Clin Microbiol Infect.* 2023;18. <https://doi.org/10.1016/j.cmi.2023.01.009>. S1198-743X(23)00031-9.



“The design of future trials needs to consider the appropriate time to perform a diagnostic, the decision node where information from this test will be applied, and what decision aspect it will influence,” explained the study authors.