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FROM DETECTION TO DECISION: THE ROLE OF CLINICAL LABORATORIES IN COMBATING EMERGING INFECTIOUS DISEASES

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ABSTRACT

Background: Clinical laboratories support emerging infectious disease responses through pathogen identification and timely diagnostic information. **Objective:** To examine how laboratory testing contributes to diagnosis and clinical decisions using selected published evidence. **Methods:** A preliminary narrative synthesis examined three selected studies of clinical metagenomic sequencing and molecular point-of-care testing. Study-specific findings were summarized without statistical pooling; this was not a completed scoping review. **Results:** In a prospective study of 204 patients with suspected neurological infections, metagenomic sequencing identified 13 infections missed by clinical testing at the source hospital; seven of these diagnoses guided treatment. A separate seven-year evaluation of 4,828 cerebrospinal fluid samples found 697 positive samples (14.4%). In its clinically characterized subset, 48 of 220 infectious diagnoses (21.8%) were identified by sequencing alone. In a non-randomized COVID-19 study involving 499 point-of-care patients and 555 controls, median time to results was 1.7 versus 21.3 hours. **Conclusion:** Selected evidence indicates that advanced diagnostics can provide additional diagnoses and faster results, with treatment implications in some cases. These findings do not establish consistent improvements in patient outcomes or generalizability across emerging infections.

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INTRODUCTION

Emerging infectious diseases pose persistent challenges to healthcare systems because their recognition and control depend on identifying unfamiliar threats and translating incomplete information into timely action. These diseases encompass newly recognized infections, infections appearing in new populations or geographical settings, and established infections undergoing significant changes in incidence or epidemiology. A foundational global analysis demonstrated that infectious disease emergence was associated with socioeconomic, environmental, and ecological factors, highlighting the importance of surveillance capacity and its geographical distribution (Jones *et al*., 2008). These findings establish an enduring rationale for strengthening the laboratory systems through which emerging threats are recognized and investigated. Clinical laboratories occupy a central position between the presentation of an individual patient and the recognition of a wider infectious disease event. Their contribution extends across specimen assessment, pathogen detection, interpretation, and communication with clinical and public-health teams. At the population level, laboratory findings can inform the characterization and monitoring of infectious threats when connected with epidemiological information.

The World Health Organization's (WHO, 2022) global genomic surveillance strategy places diagnostics within an integrated system encompassing specimen collection, analysis, data sharing, and response. This perspective provides a basis for examining clinical laboratories as active contributors to infectious disease preparedness and decision-making. Advances in diagnostic technology have expanded the capacity to investigate infections with uncertain or unexpected causes. Metagenomic next-generation sequencing, for example, offers broad pathogen detection without requiring the initial selection of a single suspected organism. In a seven-year evaluation of clinical cerebrospinal fluid testing, Benoit *et al*. (2024) demonstrated the contribution of this approach to diagnosing difficult central nervous system infections, including infections not identified by other testing methods. Nevertheless, the study also identified important limitations involving turnaround time, access, and the interpretation of diagnostic performance. Although this evidence concerns a particular clinical setting, it illustrates both the potential and the practical constraints of incorporating advanced diagnostics into services relevant to emerging infectious threats. The transition from detection to decision therefore requires attention to the entire diagnostic pathway. In the study by Benoit *et al*. (2024), the interval

from specimen collection to the availability of results exceeded the laboratory processing interval, demonstrating the importance of delays outside analytical testing. The authors also acknowledged that clinical actionability and cost-benefit were not formally evaluated. These distinctions are essential when assessing laboratory contributions: additional pathogen detection, shorter processing time, documented changes in management, and improved patient outcomes represent different levels of evidence. An evaluation of laboratory value should examine how these levels are connected and identify where the evidence remains incomplete. Laboratory preparedness also depends on the conditions under which diagnostic services operate. WHO (2022) emphasizes the importance of workforce development, connectivity, and the use of genomic information within broader surveillance systems. Safe and sustainable service delivery further requires biosafety measures appropriate to the activities undertaken. The WHO (2020) *Laboratory biosafety manual* advocates an evidence-based approach in which risk assessment informs proportionate protective measures. Together, these considerations support an assessment of laboratory readiness that encompasses organizational capacity, communication, and safety alongside diagnostic capability. Against this background, the present scoping review aims to map evidence on the role of clinical laboratories in combating emerging infectious diseases, with particular emphasis on the translation of diagnostic findings into clinical and public-health decisions. It will examine diagnostic approaches, documented effects on management and response, and the barriers that influence the timely use of laboratory information. By organizing the evidence across the pathway from detection to action, the review seeks to identify priorities for laboratory practice, health-system preparedness, and future research.

METHODS

Study design: This study will adopt a scoping review design to map evidence on the contribution of clinical laboratories to the detection and management of emerging infectious diseases. Particular attention will be given to how diagnostic findings inform treatment, infection prevention and control, surveillance, and outbreak response. The review will follow JBI methodological guidance for scoping reviews (Peters *et al*., 2020), and reporting will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR; Tricco *et al*., 2018). A scoping approach is appropriate because the review will examine diverse diagnostic approaches, research designs, and healthcare settings rather than estimate a single intervention effect. A protocol specifying the review questions, eligibility criteria, search procedures, and synthesis methods will be developed before formal screening and deposited in an accessible repository. Any subsequent amendments will be documented and justified.

Review question and eligibility criteria: The review will address the following question: How do clinical laboratory services contribute to the translation of diagnostic findings into clinical and public-health decisions concerning emerging infectious diseases?. Eligibility criteria will be structured using the Population–Concept–Context framework. The population will include patients investigated for emerging or re-emerging infections and laboratory services supporting their diagnosis. The concept will encompass pathogen detection, interpretation and communication of results, and their relationship with subsequent decisions. The context will include hospitals, clinical diagnostic laboratories, and connected reference or public-health laboratory networks. Emerging infections will be operationally defined as newly recognized infections, infections increasing in incidence or geographical distribution, or re-emerging infections presenting new diagnostic or response challenges. Sources will be required to establish this relevance explicitly. Studies of established infections without a clear connection to emergence, preparedness, or outbreak response will be excluded. Eligible evidence will include diagnostic accuracy studies, clinical trials, observational studies, implementation evaluations, case series, and outbreak investigations. Official technical guidance and policy documents will also be considered but analyzed separately from empirical research. Laboratory studies limited to experimental assay development without clinical implementation or response relevance, editorials without supporting evidence, and conference abstracts lacking sufficient methodological information will be excluded. Review articles will support contextual understanding and reference searching but will not contribute duplicate primary findings to the evidence synthesis.

Information sources and search strategy: Searches will cover MEDLINE through PubMed, Embase, and Scopus from January 2015 to the final search date. This period is intended to capture contemporary diagnostic technologies and laboratory response systems. Database platforms, exact search dates, and any access-related changes will be reported in the completed manuscript. Relevant WHO publications and national public-health agency resources will be searched to identify supplementary technical and policy evidence. An initial search of PubMed will identify relevant terminology and indexing terms. The full strategy will combine controlled vocabulary and free-text terms relating to emerging infections, clinical laboratories, molecular diagnostics, point-of-care testing, and sequencing. Selected pathogen names will supplement general terminology to improve retrieval. Decision-related terms will not be mandatory because relevant studies may describe management changes without explicitly referring to decision-making. The strategy will be adapted to each database, and reference lists of included sources will be examined. No geographical restrictions will be applied. Inclusion will be limited to English-language publications because of available review resources, and the potential implications of this restriction will be acknowledged. Complete search strategies and records of supplementary searches will be provided as supporting material.

Selection of evidence: Retrieved records will be imported into reference-management software and deduplicated. Two reviewers will independently screen titles and abstracts, followed by full-text assessment of potentially eligible sources. The eligibility criteria will first be piloted on a sample of records to establish a shared interpretation. Disagreements will be resolved through discussion or consultation with a third reviewer. Reasons for exclusion at the full-text stage will be recorded. Multiple reports describing the same study will be linked to avoid double counting, while retaining complementary information. The selection process will be presented in a PRISMA flow diagram using the actual numbers identified, screened, excluded, and included.

Data charting: A standardized charting form will be developed and piloted before full extraction. One reviewer will extract the data, and a second reviewer will verify the entries against the original sources. Information will include publication details, country, study design, healthcare setting, population, pathogen or syndrome, diagnostic approach, comparator, and relevant outcomes. Diagnostic measures will include reported accuracy, diagnostic yield, and reference standards. Timing measures will distinguish laboratory processing time from specimen collection-to-result and result-to-action intervals. Decision-related information will include documented treatment changes, isolation or cohorting decisions, notification, and outbreak investigation. Costs, workforce requirements, access constraints, communication processes, and study limitations will also be recorded. Missing information will be marked as unreported.

Critical appraisal: Although critical appraisal is not required for every scoping review, it will be included to support cautious interpretation of evidence concerning clinical value. Two reviewers will independently assess empirical studies using JBI tools appropriate to each study design (JBI, n.d.). Appraisal findings will be reported at the item level and used to contextualize the synthesis; studies will not be excluded solely because of appraisal findings. Policy documents will be characterized by their issuing organization, purpose, and evidentiary basis and presented separately.

Data synthesis: Evidence will be summarized descriptively by publication year, geographical setting, study design, diagnostic approach, and decision domain. A structured qualitative synthesis will organize findings across detection, interpretation, communication, action, and documented outcomes. Additional themes will be developed where the extracted evidence identifies relevant barriers or enabling conditions. The synthesis will distinguish demonstrated management changes from anticipated benefits and separate diagnostic performance from patient or public-health outcomes. Findings from observational studies will be interpreted with attention to confounding and attribution. Statistical pooling is not planned because the review aims to map heterogeneous evidence. Tables and an evidence map will identify concentrations of research and gaps requiring further investigation.

Ethical considerations: The review will use published and publicly accessible information and will not involve participant recruitment or access to identifiable patient records. Institutional requirements concerning ethics review will be checked, and the applicable determination will be reported. Extracted data and search documentation will be made available as supplementary material, subject to copyright and licensing requirements.

RESULTS

Three published studies were examined: a prospective multicentre evaluation of metagenomic sequencing, a retrospective seven-year evaluation of the same clinical sequencing service, and a prospective, non-randomized controlled study of molecular point-of-care testing for COVID-19. Their characteristics are summarized in Table 1. The COVID-19 study directly addressed an emerging infectious disease response. The two neurological infection studies provided supporting evidence concerning broad pathogen detection and diagnostic actionability. Their populations were not restricted to emerging infections. In Wilson *et al*. (2019), 58 nervous system infections were diagnosed among 57 patients. Metagenomic sequencing identified 13 infections that clinical testing at the source hospitals had not identified, representing 22% of the diagnosed infections. Conventional investigations also identified infections missed by sequencing, demonstrating differences in diagnostic coverage. Benoit *et al*. (2024) reported positive sequencing results in 697 of 4,828 samples (14.4%). Within the clinically characterized subset, sequencing alone identified 48 of 220 infectious diagnoses (21.8%). Table 2 presents the principal quantitative findings.

Wilson *et al*. (2019) reported that eight of the 13 additional diagnoses had a likely clinical effect, including seven that guided treatment. This provided evidence of actionability in selected cases. Brendish *et al*. (2020) found that faster testing was associated with earlier arrival in definitive clinical areas and fewer bed moves. In-hospital and 30-day mortality were similar between groups. The non-randomized design and baseline differences limited attribution of management outcomes to testing alone. The studies measured different stages of the diagnostic pathway and were therefore summarized separately. Their sample sizes were not combined. The two sequencing evaluations concerned the same clinical service over potentially overlapping periods and should not be treated as wholly independent cohorts. Across these selected studies, evidence concerned additional diagnoses, treatment implications in some cases, and faster availability of results. Consistent improvements in patient outcomes, cost-effectiveness, and effectiveness across emerging infectious disease settings were not established. These observations describe the selected evidence and do not represent findings from a completed systematic search or scoping review.

DISCUSSION

The three selected studies illustrate how clinical laboratories can contribute to infectious disease management through additional pathogen identification and faster availability of diagnostic information. They also demonstrate the importance of distinguishing diagnostic performance from subsequent action and patient benefit. Wilson *et al*. (2019) examined additional diagnoses and their clinical implications, Benoit *et al*. (2024) evaluated the performance of a clinical sequencing service, and Brendish *et al*. (2020) investigated rapid testing during the COVID-19 response.

Table 1. Characteristics of the three selected studies

Study	Design and setting	Population or material evaluated	Diagnostic approach	Main focus
Wilson *et al*. (2019)	Prospective multicentre study at eight hospitals	204 paediatric and adult patients with suspected meningitis or encephalitis	Cerebrospinal fluid metagenomic next-generation sequencing alongside clinical testing	Additional diagnoses and clinical implications
Benoit *et al*. (2024)	Retrospective evaluation of a US clinical sequencing service	4,828 cerebrospinal fluid samples; clinical analysis included 1,164 samples from 1,053 patients	Clinical metagenomic next-generation sequencing	Diagnostic yield and performance
Brendish *et al*. (2020)	Prospective, non-randomized controlled study at a UK hospital	499 point-of-care patients and 555 contemporaneous controls	Molecular point-of-care testing compared with laboratory PCR	Time to results and hospital management

Sources: Wilson *et al*. (2019), Benoit *et al*. (2024), and Brendish *et al*. (2020).

Table 2. Principal diagnostic and timing findings

Study	Outcome	Reported finding
Wilson *et al*. (2019)	Infections identified by sequencing but not clinical testing at source hospitals	13 of 58 diagnosed infections (22%)
Wilson *et al*. (2019)	Treatment guidance among those additional diagnoses	7 of 13
Benoit *et al*. (2024)	Positive samples across the service evaluation	697 of 4,828 (14.4%)
Benoit *et al*. (2024)	Diagnoses identified by sequencing alone in the clinical subset	48 of 220 (21.8%)
Brendish *et al*. (2020)	Median time to results	1.7 hours with point-of-care testing versus 21.3 hours with laboratory PCR

Note. Sample positivity, additional diagnostic yield, and treatment guidance are distinct outcomes. The figures should not be interpreted as interchangeable measures of test accuracy.

Table 3. Decision-related evidence and interpretive limitations

Study	Documented contribution	Main limitation
Wilson *et al*. (2019)	Additional diagnoses with treatment implications in some patients	Selected neurological infection population; findings do not establish benefit across all infectious syndromes
Benoit *et al*. (2024)	Additional pathogen identification in diagnostically challenging cases	Clinical actionability and cost-benefit were not formally evaluated; diagnostic workups varied
Brendish *et al*. (2020)	Faster results associated with changes in patient placement and movement	Non-randomized allocation and baseline differences allowed residual confounding

Sources: Wilson *et al*. (2019), Benoit *et al*. (2024), and Brendish *et al*. (2020).

Together, these studies provide examples of the detection-to-decision pathway, although their different populations, designs, and outcomes limit direct comparison. Metagenomic sequencing offered additional diagnostic information in patients with challenging neurological infections. Wilson *et al*. (2019) identified 13 infections that clinical testing at the source hospitals had not detected, with seven of these diagnoses guiding treatment. This finding establishes a connection between additional detection and clinical action in selected cases. However, conventional investigations also identified infections missed by sequencing. The evidence therefore supports consideration of sequencing within a complementary diagnostic strategy, with its contribution assessed against the clinical question and the limitations of alternative methods. It does not establish that broader testing will consistently improve outcomes across infectious disease settings. The seven-year evaluation by Benoit *et al*. (2024) extends this diagnostic perspective by describing experience with a clinical sequencing service. The identification of 48 of 220 infectious diagnoses by sequencing alone in the clinically characterized subset indicates that the method contributed information unavailable from other investigations in those cases. Nevertheless, additional diagnostic yield should be interpreted separately from clinical effectiveness. The study did not formally evaluate clinical actionability or cost-benefit, and diagnostic workups varied between patients. Its findings therefore support the diagnostic contribution of sequencing while leaving uncertainty about its optimal timing, economic value, and effect on patient outcomes. The COVID-19 study provides a more direct example of laboratory information influencing hospital operations during an emerging infectious disease event. Brendish *et al*. (2020) reported a median time to results of 1.7 hours with molecular point-of-care testing compared with 21.3 hours with laboratory PCR. Faster testing was associated with earlier placement in definitive clinical areas and fewer bed moves. These findings suggest that diagnostic timeliness can have operational value when results are connected to established patient-management pathways. However, the non-randomized design and baseline differences leave the possibility of residual confounding. Similar mortality between groups also means that the reported operational advantages should not be presented as evidence of a survival benefit.

An implication of these findings is that laboratory services should be evaluated across the complete pathway from test selection to documented action. A result may provide new information without changing management, while a faster result may support earlier decisions without producing a measurable improvement in patient outcomes. Future evaluations could distinguish these stages by recording specimen collection-to-result time, result-to-action time, treatment changes, infection-control decisions, and relevant outcomes. This approach would help clarify where laboratory interventions contribute benefit and where other features of service delivery influence their effect. Several limitations constrain this synthesis. The three studies were selected for illustrative relevance rather than identified through a completed systematic search. Consequently, they cannot establish the overall balance or completeness of evidence. Two studies concerned neurological infections and were not restricted to emerging pathogens, limiting their direct applicability to outbreak preparedness. They also evaluated the same sequencing service over potentially overlapping periods, so their findings should not be treated as wholly independent. Differences in diagnostic comparators, patient selection, and outcome definitions further prevent meaningful pooling. The evidence supports a cautious conclusion: advanced laboratory approaches can generate additional diagnoses and faster results, with documented consequences for treatment or patient management in some settings. Establishing their broader contribution to emerging infectious disease control requires prospective evaluations across diverse settings, with explicit measurement of clinical action, costs, accessibility, and patient or public-health outcomes.

CONCLUSION

This preliminary narrative synthesis of three selected studies illustrates how clinical laboratories can support infectious disease management through additional pathogen detection and faster diagnostic results. Metagenomic sequencing identified infections missed by other investigations and informed treatment in some patients, while molecular point-of-care testing during COVID-19 was associated with shorter time to results and improved patient placement. These findings support evaluating laboratory services across the pathway from detection to documented action. However, the limited selection of studies, differences in design and population, and potential overlap between sequencing cohorts restrict broader conclusions. Consistent improvements in patient outcomes and cost-effectiveness were not established, and evidence from neurological infections cannot be generalized directly to all emerging infectious diseases. Further prospective research should assess how diagnostic information influences treatment, infection control, and public-health response across diverse healthcare settings.

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