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Continuing medical education: Methods of rapid diagnosis

Economic impact of rapid diagnostic methods in Clinical Microbiology: Price of the test or overall clinical impact☆

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ABSTRACT

The need to reduce the time it takes to establish a microbiological diagnosis and the emergence of new molecular microbiology and proteomic technologies has fuelled the development of rapid and point-of-care techniques, as well as the so-called point-of-care laboratories. These laboratories are responsible for conducting both techniques partially to response to the outsourcing of the conventional hospital laboratories. Their introduction has not always been accompanied with economic studies that address their cost-effectiveness, cost-benefit and cost-utility, but rather tend to be limited to the unit price of the test. The latter, influenced by the purchase procedure, does not usually have a regulated reference value in the same way that medicines do. The cost-effectiveness studies that have recently been conducted on mass spectrometry in the diagnosis of bacteraemia and the use of antimicrobials have had the greatest clinical impact and may act as a model for future economic studies on rapid and point-of-care tests.

Impacto económico de los métodos de diagnóstico rápido en Microbiología Clínica: precio de la prueba o impacto clínico global

Palabras clave:
Pruebas rápidas
Coste-efectividad
Impacto económico
Impacto clínico

RESUMEN

La necesidad de reducir el tiempo de diagnóstico microbiológico y la irrupción de nuevas tecnologías relacionadas con la microbiología molecular y la proteómica han favorecido el desarrollo de técnicas rápidas y de realización en el lugar de asistencia al paciente (*point-of-care*), así como de los denominados laboratorios *point-of-care*, espacios que concentran la realización de ambas técnicas como respuesta, en parte, a la externalización de los laboratorios convencionales de los hospitales. Su introducción no siempre se ha acompañado de evaluaciones económicas (estudios de coste-efectividad, coste-beneficio y coste-utilidad) y suelen limitarse al precio unitario de la prueba. Este último, influido por el procedimiento de compra, no suele tener un valor de referencia regulado, como en el caso de los medicamentos. Los análisis de coste-efectividad que mayor repercusión han tenido han sido los realizados recientemente con la espectrometría de masas en el diagnóstico de la bacteriemia y el uso de antimicrobianos y pueden servir como modelo de futuros estudios económicos de las pruebas rápidas y *point-of-care*.

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Introduction

As is the case for all of the activities involved in clinical patient management decisions, the diagnostic processes performed in Clinical Microbiology Departments and laboratories are continually evaluated in terms of their diagnostic efficacy and cost-effectiveness.[1] Rapid microbiological diagnostic tests are one of the areas that has been studied the most in this respect, not only because of the benefits of reducing technique duration in the diagnostic process and response time, but also in how they affect laboratory work organisation as well as patient management and clinical impact. These technique evaluations therefore usually include those performed where patients are treated (point-of-care tests). Although these tests were developed to be used outside the laboratory, they are often performed within a laboratory or in what are now termed point-of-care laboratories.[2,3] Self-diagnostic tests are usually excluded from this category, as their entry into the market has not been free of controversy. Although these tests are similar to point-of-care procedures, they are designed so that patients can perform them themselves. They may also be used by those interested in the diagnosis of an infectious agent, and they are available in pharmacies or even through web pages, although regulation of the latter is deficient.[4,5]

Rapid Microbiological diagnosis has been evaluated relatively often, above all in areas of knowledge where new technologies have become available. Its use has given rise to a high level of clinical impact.[6,7] Among other techniques, the use of mass spectrometry in the diagnosis of bacteraemia stands out, as do molecular techniques that target specific multiresistant pathogens such as methicillin-resistant *Staphylococcus aureus* or enterobacteriaceae that produce carbapenemases. There are also diagnostic panels that include different microorganisms associated with a single clinical entity, such as gastroenteritis, pneumonia, neurological infection or sepsis.[7–11] The majority of evaluations cover diagnostic performance in terms of sensitivity, specificity, positive and negative predictive power or pre-test probability Some evaluations cover cost analysis or budgetary impact and basically cover economic parameters (test price per unit multiplied by the volume of tests used). Complete economic evaluations of cost-effectiveness, cost-benefit or cost-utility are less common. Other rapid tests which are increasingly used in microbiology are lateral-flow immunochromatographic assays. These too have been analysed more often in terms of their diagnostic values, while the economic impact of their clinical use has been analysed less frequently.[3]

In this work we review the general concepts that are used in evaluating the economic impact of rapid diagnostic techniques in Clinical Microbiology, apart from the exclusive price of the test itself, which goes beyond the overall clinical impact and the benefit for the patient. Self-diagnostic systems are not included, given that this would require different considerations from rapid and point-of-care tests. Table 1 includes a glossary of terms to facilitate the reading of this paper.

Table 1
Glossary of terms habitually used in economic studies evaluating diagnostic tests.

Term	Meaning
Cost of the test	The total number of tests consumed multiplied by the unitary monetary value of the test.
Effectiveness	Effects arising from the use of tests, such as a shorter time to diagnosis, the suitability of targeted treatment. . .
Cost analysis	Economic study that compares the costs (in monetary units) of 2 different alternatives, but without comparing their results. This is not considered to be economic analysis.
Economic analysis	Economical study that compares the costs as well as the results (effectiveness) of 2 different alternatives.
Cost-effectiveness study	Economic evaluation that compares the costs of 2 different alternatives in terms of effectiveness, expressed in the units that are usually used in clinical practice (average hospitalisation time, mortality, deaths avoided, *etc.*)
Cost-benefit analysis	Economic evaluation that compares the costs of 2 different alternatives and their effectiveness, but also expressed in monetary units.
Cost-utility study	Evaluation which measures benefit in terms of quality-adjusted life-years [QALY]).
Cost minimisation study	Economic evaluation in which it is possible to assume that the results of the alternatives compared are the same, and therefore compare their costs.
Incremental costs-effectiveness ratio	Comparison of the economic costs and difference between interventions in comparison with the standard action or the intervention that has been proven to be the most effective.

Table 2
General characteristics of rapid tests and those which are performed at the point-of-care for microbiological diagnosis.

Characteristics	Rapid tests	Point-of-care tests
Location	Laboratory	At the "foot of the bed" or in a doctor's surgery/infirmary
Staff qualification	Medium-high	Low (or unnecessary)
Time taken to perform	2–7 h (<3 h)[a]	<1 h
Individual tests	Yes/no	Yes
Automated	Yes (in general)	No
Quality control	Yes	Yes/no
Connection to LCS	Yes	No

LCS: laboratory computer system.
[a] Optimum performance time.

Rapid tests, point-of-care tests and point-of-care laboratories

Table 2 shows the characteristics and general differences between rapid tests themselves undertaken in Clinical Microbiology laboratories and point-of-care tests performed where patients receive care, including doctors' or nurses offices and hospital units.

Rapid tests

Rapid diagnostic tests in Microbiology usually take place in the laboratory itself and usually take less time before the result is obtained than the duration of a typical working day lasting 7–8 h. Nevertheless, the majority of test results are available in 3–5 h. This difference of 2–3 h is essential so that the results reach the requester in the same working day and are immediately effective. In the case of discontinuous care a longer time would give rise to the risk of the requester not being efficiently informed of the results so that clinical decisions would be put off until the next day.

Unlike point-of-care tests, samples for rapid diagnosis have to be taken to a laboratory and generally prepared before processing. Specific training may be required for staff, and the technology tends to be more complex than the equipment used in point-of-care techniques. As rapid diagnostic tests are performed in a laboratory, they are included in quality management systems and their results are included in laboratory computer systems. The current tendency is for rapid diagnostic tests to be automated and used for specific clinical entities (such as a community-acquired respiratory infection, gastroenteritis or meningitis) rather than for a diagnostic problem associated with a single pathogen. Nevertheless,