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Economic evaluation of point-of-care diagnostic technologies for infectious diseases

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Abstract

We review the growing number of economic evaluations of individual point-of-care (POC) tests for diagnosis of infectious diseases in resource-limited settings that use either cohort studies or mathematical models. We focus on studies that evaluate POC diagnostic tests for the control of human immunodeficiency virus (HIV) and malaria, tools that are central to the WHO prevention guidelines for infectious diseases in developing countries. Although rapid diagnostic tests for HIV and malaria seem to be cost-effective in these standard analyses, these do not take into account the reduction in patients' waiting time and the number of clinic visits required to receive results, or future benefits from the reduction in antimalarial drug pressure. Those additional cost reductions would be considerably greater with POC rapid tests, and the cost-effectiveness of POC tests would therefore be improved. Findings from cost-effectiveness analyses suggest that, despite the relatively small additional cost incurred, decision-makers should strongly consider using POC tests throughout or during parts of HIV and malaria epidemics, where this is feasible in terms of local human resources and logistical conditions.

Keywords: Cost-effectiveness, HIV/AIDS, malaria, point-of-care testing, review

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Introduction

Recent figures from the WHO [1] suggest that 33 million individuals are living with HIV infection worldwide, more than two-thirds in developing countries with limited resources. The scale-up of antiretroviral therapy (ART) in low-income and middle-income countries has been unprecedented, with more than 4 million people estimated to have had access to ART at the end of 2008 [1]. Despite the global effort to control the AIDS pandemic, human immunodeficiency virus (HIV) infection continues to spread relatively unabated in many parts of the world. The transmission rate for HIV-infected individuals unaware of their infection is up to 3.5-fold higher than that for those who are aware [2]. Identifying those who are acutely HIV-infected is a first priority in order to reduce transmission rates through the use of both behavioural interventions and effective treatment programmes. Expansion of HIV testing is therefore urgently required, and mechanisms must be developed to ensure that HIV diagnosis occurs early on in the course of disease, at affordable costs, especially for people living in resource-limited countries.

The same holds true for malaria. Its diagnosis has traditionally relied on the clinical presentation of disease symptoms and microscopic examination of Giemsa-stained blood films [3]. Diagnosis based on symptoms alone is unreliable, because the symptoms of malaria are non-specific, overlapping with those of other febrile diseases [4]. Studies in Africa have shown that between 50% and 99% of those clinically diagnosed with malaria and then prescribed antimalarial drugs have illnesses attributable to some other cause, depending on endemicity in the clinical setting [5,6]. This results in overdiagnosis of malaria and overprescription of antimalarial drugs, as well as underdiagnosis and inappropriate treatment of non-malarial febrile illnesses [7,8]. In addition, antimalarial drug pressure ultimately contributes to the development and spread of drug resistance [9]. Most victims of malaria still die because the disease is not diagnosed in time by health workers [10].

It appears that existing diagnosis technologies are poorly adapted for use in resource-limited settings. "Current technologies are very expensive and require delicate instruments, cold chain, and stable electricity, which are not available in areas where the majority of the patients reside" [11]. In addition, when testing is carried out in centralized laboratories, turn-around times are of the order of several months for specimens sent from rural areas in developing countries [12,13].

How can high-quality test results be provided in the most cost-effective way? One solution is the use of point-of-care (POC) tests. These are diagnostic tests performed close to the patient. They require less laboratory infrastructure, are potentially cheaper, and can be designed to be easy to use and interpret [14–16]. These advantages can help reduce the workload for laboratories and streamline care in settings where large numbers of patients are treated daily. In addition to improving the standard of care, a test that can be performed while the patient is at the clinic means that fewer patients are lost to follow-up and the burden on patients is reduced [11]. Because the procedures are very simple (the need for equipment such as centrifuges and electricity being eliminated), involve a limited number of steps, and do not require high precision, they can be used outside traditional laboratory settings by staff with no formal laboratory training.

In the face of economic constraints, it is critically important to evaluate how best to utilize available resources [17,18]. Cost-effectiveness analysis is a well-established methodology for understanding, prioritizing and optimizing healthcare services. By comparing testing alternatives in terms of their relative advantages and costs, cost-effectiveness analysis can serve as one key element to inform decision-makers, in order to define public health policy [19].

In this article, we review the growing number of economic evaluations of individual POC tests for diagnosis of infectious diseases in resource-limited settings that use either cohort studies or mathematical models. We focus on studies that evaluate POC diagnostic tests for the control of HIV and malaria, tools that are central to the WHO prevention guidelines for infectious diseases in developing countries.

Review of Recent Studies on the Cost-effectiveness of ART

We used the Medline database to conduct a literature search of articles published between 2006 and 2010. We then reviewed citation and reference lists to identify additional studies. Table 1 provides a summary of the results and describes the methodological features of each analysis that evaluates the cost-effectiveness of POC diagnostic tests for HIV disease and malaria.

Cost-effectiveness of Rapid POC Diagnostic Tests for the Control of HIV

In 1992, the Global Programme on AIDS and the WHO first recommended the use of testing strategies based on combinations of screening tests (including simple, rapid tests) for blood screening, surveillance, and diagnosis, instead of the enzyme immunoassay and western blot techniques previously used [20]. Although these recommendations were revised as the range of antibody tests expanded, they were still intended for serum or plasma testing. Instead, recently developed rapid tests detect HIV antibodies in whole blood specimens, making it possible to evaluate the performance and the cost-effectiveness of POC HIV testing in settings with limited laboratory facilities and where the demand for voluntary counselling testing is likely to increase.

For several reasons, the expanded use of POC rapid HIV testing promises to play an important role in HIV prevention, both in developed and in developing countries. First, access to immediate HIV test results could improve the application of prophylactic regimens to reduce vertical transmission when used intrapartum or postpartum [21–23]. In line with this objective, Menzies *et al.* [24] studied the cost-effectiveness of initiating diagnosis with a rapid HIV test to screen out HIV-uninfected infants. The comparator that they used was the current diagnosis-testing algorithm DNA-PCR. The study population comprised HIV-exposed children <18 months of age attending two postnatal screening programmes in Uganda between 2005 and 2006. The authors used a decision-analytical model to compare the DNA-PCR and rapid HIV test approaches, and found that the former identified 94.3% (91.8–94.7%) of HIV-infected infants, as compared with 87.8% (79.4–90.5%) for the latter. Moreover, the total cost of the POC testing programme was about 40% less than that of DNA-PCR ($59 vs. $38 per infant aged 6–9 months). The rapid POC test is therefore more cost-effective than the comparator, as the incremental cost per HIV-infected infant correctly diagnosed using the latter ranges from $559 (95% CI $261–$2702) with low compliance to $7165 (95% CI: $3322–20 127) with perfect compliance.

Second, as several studies indicate that persons who are aware of their HIV infection more frequently adopt behaviours to reduce the likelihood of transmission [25–27], the use of rapid tests as a tool for prevention strategies promoting the need for awareness of one's own and one's partner's