ASSESSING THE ECONOMIC IMPACT OF A RAPID ON-SITE MALARIA DIAGNOSTIC TEST

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Abstract. A set of three models has been developed for assessing the econimic impact of existing and new malaria diagnostic technology, specifically microscopy of blood slides and rapid on-site diagnostic tests (RDT). The models allow for phased introduction of the new technology in targeted areas. The derived computer software program facilitates evaluation of costs to the supplier, to the consumer and aggregate costs, with comparison among the three models to give relative costs of progressive transition from blood slides to RDT technology. The models and the related software program can assist planners in the health sector in determining costs of current programs and assessing the potential economic impact of introducing rapid on-site diagnosis. Details of the models and the operational software program are available on request.

INTRODUCTION

There are many challenges in malaria control, particularly in relation to economic costs and outcomes of differing strategies (Indaratna and Kidson, 1995). Considerable effort has been devoted to quantifying the analysis of costs of components of the control program in various countries (Kaewsonthi, 1989; Mills, 1991).

The majority of cases of malaria worldwide are treated on the basis of clinical diagnosis or self diagnosis, contributing to irrational drug use. Microscopy is the time-honored method of laboratory confirmation of malaria, including species identification but it is not immediately accessible in all appropriate sites in any endemic nation. So, excellent technology as it is in well trained hands, microscopy in practice is available on a more limited scale than is desirable for individual case management and disease control.

The introduction of a simple, rapid, on-site diagnostic test (RDT) for malaria that would provide definitive case identification at township or village level could substantially improve malaria case management by reducing waiting times, reducing presumptive treatment, increasing definitive radical treatment, reducing morbidity and mortality, eventually reducing local transmission and possibly slowing the development of drug resistance in the long term.

In this context the RDT 'ParaSight' (Becton Dickinson, MD, USA) is one promising such test as judged by sensitivity, specificity and stability (Shiff *et al*, 1993; Beadle *et al*, 1994; Premiji *et al*, 1994). A recent large scale field trial in Thailand using polymerase chain reaction (PCR) as gold standard showed that sensitivity and specificity are at least equal to the *best* microscopy (unpublished data). Although at present it permits recognition only of *Plasmodium falciparum*, with eventual addition of a *P. vivax* component (presently under development) in a single dipstick, this technology should greatly improve the ability of malaria control programs to cover malaria case detection and management, particularly at selected target sites at the primary health care level.

Changing the technology of case detection from blood slides to RDT will affect the costs of malaria control and the economic impact of the disease on the population concerned. This change will also lead to significant modifications in the system of control in each country, since realizing the benefits from introduction of RDT depends upon diagnosis and radical treatment being made available at primary health care level.

A decision by a Ministry of Health (MOH) of any country to introduce RDT in a malaria control service, as an alternative to microscopic examination of blood slides will therefore depend on critical evaluation of three factors:

1. Change in total costs incurred by the suppliers (malaria control units) and consumers (positive cases and non-positive patients) on changing from blood film to RDT for diagnosis or from clinical

diagnosis to RDT, rather than simply on the costs of test kits alone.

2. Changes in outcomes over an extended period of time, from earlier case detection and correct treatment, notably a potential decrease in the proportion of severe cases requiring hospital treatment, a reduction in morbidity and mortality, a reduction in the pool of infection and a reduction in patients wrongly treated for malaria instead of other diseases.

3. Operational and monitoring changes which may be required with use of the new technology and dispensing radical antimalarial drugs at health center level.

To assist health authorities in an evaluation of the first of these three factors, the costs arising and savings occurring upon introducing RDT, thre mathematical cost/outcome models have been prepared, together with a guidance document on the use of the software. Using existing data in each country, data from simple surveys and some assumptions for a given study area (local, provincial or national), the models facilitate assessment of:

1. The total and average costs incurred by supplier (MOH), consumers (positive cases and non-positive patients) and in aggregate, using current blood slide technology.

2. The change in toal and average costs incurred by supplier, consumer, and in aggregate on progressively introducing RDT into the control program for a variety of user selected conditions.

3. Training cost requirements on initial introduction of RDT into the control system.

The models are deliberately geared to *P. falciparum* and *P. vivax* diagnosis in the same test system; costing of current control programs can be carried out immediately, however, regardless of the stage of RDT development/availability, *so that the software has immediate global applicability to existing strategies.*

MODELS

To facilitate costing and analysis, on progressively introducing RDT, formal services under the control of the MOH in any given study area are classified into four groups: service unit without microscopes (i = 1) *eg* health centers, volunteers, or others; service centers with microscopes (i = 2) *eg* health centers, special malaria clinics; hospital outpatient services (i = 3); hospital inpatient services for positive cases (i = 4).

Hospitals may well use RDT for routine diagnosis as soon as kits are available; however analysis of the change in hospital outpatient and inpatient unit costs for the diagnosis and treatment of patients suspected of having malaria and of positive cases due to introducing RDT is not a primary concern in these models. Hospital costs are included so that supplier and aggregate costs reflect any *change in demand* for hospital care which may be expected to arise due to earlier case detection at i = 1 and i = 2.

Model 1: Determines costs incurred by supplier, consumer and in aggregate when current technology (microscopy of blood slides) are used at each of the four types of services.

Model 2: Determines costs incurred by supplier, consumer and in aggregate when RDT is used at service i = 1, microscopy of blood slides at service i = 2. It is assumed that no change occurs to unit costs for hospital outpatients and inpatients.

Model 3: Determines costs incurred by supplier, consumer and in aggregate when RDT is used at services i = 1 and i = 2. It is assumed that no change occurs to unit costs for hospital outpatients and inpatients.

This stepwise introduction of introducing RDT, which is a likely scenario in practice, allows for three analyses:

1. A three stage comparison of costs using microscopy of blood slides, or RDT, at service i = 1 and/or i = 2, assuming that demand for services and patient behavior are static at the time of comparison:

(a) at service i = 1 comparing models 1 and 2

(b) at service i = 2 comparing models 2 and 3

(c) at services i = 1 + 2 comparing models 1 and 3

2. Comparative static exploration of "what if" scenarios assuming changes in assumptions such as demand, patient behavior and component costs.

3. Exploration of "what if" scenarios under dynamic conditions assuming dynamic changes in demand for services, patient behavior and component costs.

In constructing the models it has been necessary to strike a compromise between three factors which affect confidence in the output : the inclusion of all variables which could affect costs; the feasibility of data collection for each variable; the accuracy of assumptions which may have to be made. The selected list of component costs incurred by each party (supplier, positive cases, non-positive patients) when considering each type of service in each of the three models are presented in Table 1. The models have also been designed to accommodate differences in supplier practices and patient behavior in each country under study.

In many countries data may not be available for

Table 1

Cost components incurred by parties in each model.

Cost components	Model 1 Service i =				Model 2 Service i =				Model 3 Service i =			
	1	2	3	4	1	2	3	4	1	2	3	4
Supplier (i = 1, 2, 3, 4)												
Taking blood slides	+	+				+						
Blood slide delivery	+											
Blood slide examination	+	+										
Presumptive treatment drugs	+											
Drug delivery to positive cases	+											
Radical drug treatment for positive cases	+	+			+	+			+	+		
Drugs for false positives	+	+			+	+			+	+		
Regular training of blood slide takers	+											
Regular training of microscopists (proportion)	+	+				+						
Supervision	+	+			+	+			+	+		
Administration	+	+			+	+			+	+		
RD test/examination					+				+	+		
Regular training of RD testers					+				+	+		
Diagnosis and treatment of malaria outpatients at hospitals			+	+			+	+			+	+
Diagnosis and treatment of malaria inpatients at hospitals			+	+			+	+			+	+
Positive cases (i = 1, 2, 3, 4)												
Using non formal services prior to attending service i	+	+	+	+	+	+	+	+	+	+	+	+
Using private medical services prior to attending service i	+	+	+	+	+	+	+	+	+	+	+	+
Diagnosis and treatment in using hospital outpatient services	+	+	+	+	+	+	+	+	+	+	+	+
Diagnosis and treatment in using hospital inpatient services	+	+	+	+	+	+	+	+	+	+	+	+
Morbidity time waiting for the results of diagnosis	+	+	+	+	+	+	+	+	+	+	+	+
Mobidity time prior to formal diagnosis at service i	+	+	+	+	+	+	+	+	+	+	+	+
Morbidity time as a result of false negative diagnosis	+	+	+	+	+	+	+	+	+	+	+	+
Malaria induced mortality	+	+	+	+	+	+	+	+	+	+	+	+
Non positive patients (i = 1, 2)												
Using non formal services prior to attending service i	+	+			+	+			+	+		
Using private medical services prior to attending service i	+	+			+	+			+	+		
Costs incurred in using service i	+	+			+	+			+	+		
Morbidity time costs prior to formal diagnosis at service i	+	+			+	+			+	+		
False positive diagnosis at service i	+	+			+	+			+	+		

some of the variables. Where this occurs, users are faced with three alternatives:

(a) undertake small scale (rough) surveys to obtain approximations;

(b) gather expert opinion;

(c) make guestimates.

While ideally one may not wish to use expert opinion or guestimates, in the absence of data and in the interests of time there are no alternatives. The significance of any guestimate can be determined by altering the magnitude of particular variables in "whai if" scenarios.

SPREAD SHEETS

Each model has been entered in an *Excel* spread sheet with data input and output sections. The latter show for each service i:

1. Cost components incurred by the supply organization, positive cases and non-positive patients.

2. Total and average costs (costs per positive case and costs per person examined) incurred by the supply organization.

3. Total and average costs (per positive case) incurred by positive cases at service i = 1 and i = 2.

4. Total and average costs (per person examined) incurred by non-positive patients at each service i.

5. Total and average costs (per positive case) incurred by the supply organization and positive case at each service i.

6. Aggregate and average aggregate costs (per positive case and per person examined) incurred by the supply organization, positive cases and non-positive patients at service i = 1 and i = 2.

7. Total costs (drugs and morbidity time) due to false diagnosis.

8. Total costs of initial training in the use of RDT at each service i.

Much of the output information from the spread sheet files for each of the three models is automatically transferred to a summary spread sheet file. The summary includes total and average costs for supplier, positive cases, non-positive patients and in aggregate. In addition, the summary includes the percentage of the total costs from each service and the total and average costs for each model compared as a ratio: Model 2/Model 1 (comparing the costs incurred on changing from microscopic blood slide examination to RDT at service i = 1; Model 3/Model 2 (comparing the costs incurred on changing from blood slide to RDT at service i = 2 and Model 3/Model 1 (comparing costs incurred on using RDT at service i = 1 + 2 with costs incurred on using blood slide technology at service i = 1 + 2). Component costs at each service *only* appear in the output from each model alone. All four files are linked.

A fundamental assumption made in the models is that on the introduction of RDT excess personnel (if any) can be redeployed in other work for the MOH, so there is no waste labor. Consideration therefore has to be given to any change in labor (persons and person months) which may be required on introducing RDT at service i = 1,2. Users have to decide what is an appropriate basis in their circumstances, for determining approximations for these variables, although guidance is given for this process. For the user's convenience the output from computation of the approximations are shown, against the relevant item in the spread sheets for models 2 and 3.

ANALYSIS OF OUTPUT INFORMATION

In assessing the economic implications of introducing RDT, a MOH should be *initially* concerned with comparing for the three models the aggregate costs, the costs incurred by the supplier, and the change in aggregate costs relative to the change in supplier costs.

Aggregate costs

Decision makers may question the relevance of aggregate costs, arguing that their only economic concern is what, if any, will be the change in supplier costs on introducing RDT. One may be sympathetic to this view because budgets are constrained. However, this perspective completely ignores the very purpose of control programs, namely, to reduce morbidity and mortality, and to achieve the maximum reduction in the social and economic impact of the disease on the population with the resources available. If the maximum re-

duction in the social and economic impact of malaria is the goal, then the effect of changing technology should be measured in those terms.

When decision makers question the magnitude and validity of all the aggregate cost components, two alternatives can be considered:

(i) Aggregate costs excluding those due to malaria induced mortality: While economists may argue that it is essential to include costs of malaria induced mortality the very high figures can be challenged on two grounds:

(a) the malaria mortality rate is ill defined, seldom known accurately and often will be no more than a guess.

(b) the per capita GDP value used to compute the costs of productive life years lost is likely to be much higher than the income of those who die from malaria since they are often in receipt of low or no income.

(ii) Aggregate costs excluding the costs of malaria mortality and the costs incurred by non-positive patients: While the latter is the cost incurred by patients because they believe they may be infected with malaria, decision makers may prefer only to consider costs incurred by the supplier and positive cases. However, inclusion of the costs of non-positive patients is more realistic since these patients impose a cost on malaria-related services, including presumptive drugs where these are in use.

Costs incurred by supplier

To allow a direct comparison of supplier costs on the progressive introduction of RDT, the number of patients seeking diagnosis and slide positive rate (SPR) at service i = 1, 2 should, in the first instance, be kept constant in all three models. In practice changes in the numbers of patients seeking services, in SPR, in distribution among services i = 1, 2, 3, 4 and in the costs incurred by positive cases and by non-positive patients can be expected to change. Possible implications of such changes should be determined where all concepts of aggregate costs are rejected and a decision is to be based upon costs incurred by supplier alone.

Three "what if" scenarios should also be considered in addition to the costs incurred by supplier under the initial condition of static "consumer" behavior:

1. What will be the economic effects if, on the introduction of RDT at service i = 1 (for the current practice) a significant proportion of cases switch from service i = 2 to i = 1?

2. What will be the economic effects if, on the introduction of RDT, demand for malaria outpatient and inpatient hospital services are reduced?

3. What will be the economic effects if, because RDT is quick, easy and is undertaken locally, there is an increase in the number of patients seeking diagnosis and the number of malaria cases detected increases, giving a truer indication of incidence?

COMMENT

This outline of models for economic assessment of the effects of introducing RDT into malaria control programs is designed to provide an overview of a practical computer-based program for deriving objective estimates of costs. The analysis begins, however, with a quantitative assessment of current practice using clinical diagnosis and microscopy, so that it offers a package for evaluation of malaria case management in classical control programs, as well as for comparative evaluation of two diagnostic technologies. This, we hope, may be of interest to control program managers whether or not they are presently contemplating the introduction of RDT.

The introduction of RDT into public sector malaria control programs requires situation-specific analysis and forecasting of costs and outcomes. Large areas within a country, or smaller areas within one or more provinces may require evaluation independently, given the wide variation in malaria endemicity that occurs. Endemic border areas between adjacent nations where substantial population movement and limited medical services make malaria case detection and management difficult may be attractive as target areas for potential RDT introduction. Health centers without local microscope services may be another target group, so to reduce the inefficient transport of blood slides to distant malaria clinics. Such target groups can be considered independently using these models, without the need to plan for program-wide use of RDT. At the same time the implications of nationwide introduction of the technology can just as well be evaluated.

While the program is geared to public sector services, it is important to consider the effect of patient diagnosis and treatment in the private sector. In many malaria endemic countries a substantial proportion of suspected malaria patients is cared for by the private sector. Private cases are not generally included in the national public disease reporting system and private sector costs are not incorporated into the total cost estimates of malaria disease burden. Private sector diagnosis is frequently by clinical criteria alone, without laboratory confirmation, although is some instances public sector laboratory facilities may be used by the private sector for confirmation. Potentially RDT can provide accurate on-site diagnosis for this group of patients, with resultant immediate radical drug treatment, so that in both public and private sectors the quality of service can be improved by the technology change. Thus potentially the impact on both sectors needs to be evaluated. This can be done using the models *separately* for private sector analysis, with minor modifications.

It may also be possible to use the diagnostic simplicity and immediacy of RDT to develop ways of encouraging the private sector to report positive cases to the national programs, so to permit more accurate determination of the true disease incidence and the true cost it represents to each nation.

Availability of the program

It is intended to make the analytical program available to appropriate investigators under signed agreement that it will not be used for commercial purposes. Interested parties should write to:

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