

COST-BENEFIT ANALYSIS OF THE INTRODUCTION OF ELISA FOR THE DIAGNOSIS OF ANIMAL TRYPANOSOMOSIS IN AFRICA

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Abstract

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Socio-economic data was requested by questionnaires from researchers in 15 different National Agricultural Research Systems (NARS). The results of the survey were analysed and used for a socio-economic cost-benefit analysis, comparing the costs of 'diagnosis, treatments and drug-resistance' in the two alternatives 'with' ELISA and the 'without' situation. The major assumptions of the cost-scheme used are: 1) an increase in the occurrence of drug-resistance if nothing changes in the current practice of drug-use; 2) large scale diagnosis in test & treatment practice, combined with the use of pour-on's, would lead to the abolishment of the current practice of administering prophylactic drugs. In order for this to be a feasible option, the development and subsequent promotion of ag-ELISA and pour-on's is recommended. The first alternative, with BCT, has a slightly better cost-benefit ratio (1 : 53) than the second alternative, with ag-ELISA (1 : 44). However, the latter is still considered the only feasible option because of the applicability of pen-side ELISA on local level and the low cost allowing for cost-price savings. The budgetary restrictions for the use of BCT and its labour-intensiveness explain the relatively small amount of diagnoses in current practice.

1. INTRODUCTION

A socio-economic cost-benefit analysis was conducted to evaluate the efforts made by 'the project', i.e. a succession of research programmes as co-ordinated by the Joint FAO/IAEA Division and financed by the Directorate General of International Co-operation (DGIS) of the Netherlands, concerning further development and validation of ELISA, and improving the capability of African NARS laboratories to conduct these tests.

The practice of drug usage without previous diagnostic testing was an important consideration in this study. It is of great importance to tackle this problem in order to prevent further development of drug-resistance. Therefore, in the cost-benefit analysis potential changes of testing and drug-use were considered. For these changes to be a viable scenario, alternatives to prophylactic drug-use should be promoted and adopted on a large scale. This is already one of the objectives of many research programmes. For the further development of pour-on's and also pen-side ELISA tests (i.e. in the form of a dip-stick), an additional budget of US\$ 5 million was put on the cost side of the cost-benefit analysis, together with the estimated total of local budgets of the NARS spent on trypanosomosis research. The savings in the costs of diagnoses, treatments and drug-resistance in the alternatives 'with' ELISA as compared to the 'without' situation, could be considered the 'benefit' arising from international research as co-ordinated by 'the project'.

2. MATERIALS AND METHODS

2.1. Questionnaires

A questionnaire was designed and dispatched to 15 researchers involved in the Co-ordinated Research Programme (CRP). Responses came from twelve out of fifteen countries. Some additional data were requested at a later stage from several Research Contract Holders (RCH's) and the project co-ordinator.

The questionnaires were analysed and the results are presented below. Subsequently, the data were used in the calculation of cost-schemes of the 'costs of diagnosis, treatments and drug-resistance' in the 'without' situation and in two 'with' alternatives, as described below.

2.2. Cost-benefit analyses

Only the costs of 'the project' could easily be summed up. The benefits are not as unambiguous, because the project beneficiaries are the NARS and indirectly the local veterinarians and livestock owners living in the tsetse infested areas of Africa.

The 'Socio-Economic' approach to Cost Benefit Analysis we used, is a refinement of the (National-) Economic approach which looks at a project from the viewpoint of a society as a whole, taking into account the interest of country's producers, consumers and the state [1, 2]. The socio-economic variant additionally considers that the utility of extra money is greater to someone with a low income than to someone with a high income. We expected the major *benefit* of 'the project' to be its contribution to changes in livestock-herd management and in the application of diagnoses and drugs by local farmers, hence augmenting their income, which justifies a socio-economic approach.

The 'costs of diagnosis, treatments and drug-resistance' were calculated for the 'without' situation, suggesting increasing occurrence of drug-resistance, and for two 'with' alternatives. Both 'with' alternatives suggest the use of antibody-detection ELISA (Ab-ELISA) at full scale in surveys and monitoring. For testing in 'test and treatment practice', in the first alternative the large-scale use of the buffy coat technique (BCT) was suggested, although the feasibility of this option was questioned, and in the second alternative the large-scale adoption of a pen-side antigen-detection ELISA (Ag-ELISA) was considered.

The time span we used was based on the confident anticipation that overall control techniques will be ready for implementation well within five years, and the assumption was made that within 10 (or 20) years the degree of political and civil stability will be sufficient to enable complete control [3]. We assumed that complete control would in place from year 11 onwards, and focused on the intermediate 10 years that demand critical attention, because of the current risk of drug-resistance. One of the major assumptions made under the 'with' alternatives is that enabling large scale diagnosis in test and treatment practice, combined with the large scale use of pour-on's, would lead to the abolishment of the current practice of administering prophylactic drugs. As the course of this process is as indefinite as the actual implementation of overall control after year 10, we have not bothered to make the levels of adoption of the different changes time dependent. Hence, the full benefit of the eventual 'with' alternatives, have been implemented from year 1. However, in the 'without' situation, we have followed a more conservative approach, the costs of increasing drug-resistance (mortality of cattle) are increasing to the assumed maximum of 25% in year 10.

The total 'costs of diagnoses, treatments and drug-resistance' of the two 'with' alternatives were compared. This can be seen as a cost-efficiency comparison between two alternatives to slow down the occurrence of drug-resistance in a time span presumed to be ten years, until complete control and eradication can be implemented. Furthermore, the *avoided losses* due to the 'with' alternatives were considered to be their *benefit*, and were compared with the cost of the research in the cost-benefit analysis.

3. RESULTS

3.1. Questionnaires

The data provided by the respondents on populations, regional herds, trypanosome infection rates and risk areas, was used as long as regional herds were specified and additional information on infection rates was provided. The data from three countries (Burkina-Faso, Cameroon and Kenya) was used to calculate the potential need for diagnosis in prevalence studies using models based on assumptions on future surveys and monitoring control and eradication operations in the 3 countries. The estimated average sample need 1.4% of the total susceptible cattle at risk, was used for all Africa, to obtain an estimated total need of 500.000 tests to access disease prevalence.

Information was gathered on local prices of trypanocidal drugs, on some aspects of the drug-use practice, such as the frequency of intervention by veterinarians, and on the signalled occurrence of drug resistance. On the basis of the RCH's estimates, the average prices for curative and prophylactic drugs were estimated for West & Central Africa and for East & Southern Africa. However, overall African average prices were later used in the cost-benefit analysis: respectively US\$ 1,15 (curative

drugs) and US\$ 1.95 (prophylactic drugs) per treatment. It was estimated that veterinary intervention was the case in 50% of drug-use practice and its cost at 20% of the cost of the drugs used.

On the basis of the data on the current tests-practised in some NARS laboratories, the average number of tests per laboratory was estimated at 7640 per month. This would mean that some 240.000 diagnoses would be practised if each tsetse-infected country presently had a similar veterinary laboratory. Furthermore, weighted averages of the country specific repartitions of diagnoses according to their purpose of use, suggested the following overall repartition: 46% of the test are used for prevalence studies, 26% in evaluation of control, 10% for decisions on how to treat and 9% for the evaluation of treatments.

The investigated price of the usual parasitological test protocol (with BCT) varies from US\$ 0.20 to 1.65. But it was clear that the true cost-price were not known to the respondents, and the prices they gave were the prices 'as charged'. They might reflect the costs of the supplies used, but do not include any remuneration for the overhead cost.

The answers on questions concerning the direct and indirect influence of 'the project' were all laudatory. Some of the most mentioned influences are: the creation of awareness of disease importance; capacity building through provision of appropriate equipment; capacity building through training and the organisation of international meetings; enabling prevalence studies and monitoring of control. We investigated the contributions by 'the project' to the NARS institutions of the RCH's. Those consisted of three parts: A yearly financial contribution of about US\$ 6000, equipment supplied and training. The RCH's perception of the training received was again laudatory. They were asked to estimate the replacement value of the skills they obtained and the skills they passed on to their personnel. With that, the total monetary replacement value of the training could be estimated at US\$ 1.152.500. With the data on the 'equipment supplied' and the 'percentage-use for other purposes' we computed that the total monetary value of the equipment provided, in its usefulness to the NARS laboratories was US\$ 471.054. The total financial contributions made in two succeeding project terms were some US\$ 550.000. The yearly RC-contributions were on average 31% of an institute budget spent on trypanosomosis research. The portion of the total institutes budget spent on trypanosomosis research ranged from 1 to 40%, and on average is only 2.5%.

The respondents' perception of the use of antibody- and antigen-ELISA's was investigated. At the time of the questionnaire (autumn 1998), Ag-ELISA had been used in a process of test-validation and was successfully used in Ghana, Kenya and Uganda for screening and monitoring trypanosomosis control. The work on evaluation of Ab-ELISA was in progress in most of the countries. Promising results had already been recorded which pointed at the tests usefulness in epidemiological screening and surveillance, and in proving the tsetse-free status of areas after initial eradication. The most important problems encountered during the distribution of ELISA-kits were all related to local conditions, such as transportation and taxes.

About the potential future use of ELISA's, all but two institutes stated as their objective to use ELISA's routinely for diagnostic purposes. On the question whether ELISA's could eventually be replacing the parasitological test protocol, 7 out of 12 respondents agreed that because of their poor specificity the ELISA's could never be sufficient on their own, but because of their higher sensitivity they would complete the parasitological test protocol. Only 3 respondents thought that high levels of specificity and sensitivity could eventually be achieved.

Most of the respondents stressed the high cost of serology and the restrictions to its use due to laboratory requirements and a certain level of technical expertise required. One third of the respondents mentioned the need to simplify the ELISA test and/or the usefulness of a pen-side test. Considering the adoptability of a future pen-side test, it was stressed that such a test should detect current infections in order to be adopted. Hence, it should be an antigen-ELISA test.

The proposed reasonable market prices for pen-side test in order for them to be adopted are remarkably concurring with the true costs of a diagnosis with ELISA, as proposed by IAEA (US\$ 0.33 - 0.70 for testing one sample twice). Based on the current practice the lowest prices were suggested in West-Africa: US\$ 0.10 - 0.15 (Burkina-Faso), US\$ 0.15 (Ivory Coast) and US\$ 0.20 (Ghana). Gambia, Kenya, Uganda and Zambia all suggested US\$ 0.50 to be a reasonable price, and Nigeria and Tanzania only stated an upper limit of about US\$ 1.

3.2. Cost-benefit analysis

Both the 'with' alternatives assumed the use of Ab-ELISA in surveys and monitoring. We computed that this need would be some 500.000 tests yearly in tsetse-infested Africa. The potential need of tests in 'test and treatment practice' would be much more important, we estimated it at 8.750.000 (BCT or Ag-ELISA) tests.

We used an estimate of 35 million trypanosomosis susceptible cattle in the tsetse-infested areas of Africa. The total number of treatments in tsetse areas is usually estimated at 30 or 35 million doses of trypanocidal drugs [4, 3]. We assumed that in the 'without' situation 15% of these doses are used for curative treatments of cattle pre-selected by farmers-own-judgement, hence 5.250.000 doses. We valued these at the average price of curative drugs: US\$ 1,15 (estimated from result of the questionnaire). Resulting in a total cost of some US\$ 6 million spent on curative treatments. Eighty five percent of the estimated 35 million doses remain for prophylactic treatments. Assuming the practice of administering prophylactic drugs twice during the rainy season implies that only 42.5% of the 35 million cattle under challenge are given prophylactic treatments (twice). Hence 29.750.000 doses of prophylactic drug, valued at the estimated average price of prophylactic drugs: US\$ 1,95 gives the total of US\$ 58 million spent on prophylactic drugs in the initial 'without' situation. We let the total cost of prophylactic treatments decrease every year inversely proportionate to the increase of drugs-resistance. We computed this with a one-year delay, considering that a logic reaction of farmers behaving rational to the perception that part of the prophylactic drugs they administered last year did not prevent their cattle from getting the disease.

The most rigorous assumption made in the 'without' situation is that drug-resistance will increase by 2.5% yearly to a maximum of 25% ten years from now. Due to this, the cost of mortality of infected cow treated with ineffective curative drugs will increase considerable. Valued at US\$ 100 per bovine, this cost increases from some US\$ 9 million in year 1 to almost US\$ 90 million in year 10. The indirect losses of the production of the lost cattle were not taken into account. In the 'with' alternatives the direct losses due to mortality do not occur, thus they are 'avoided losses' which are benefits.

Furthermore, it was estimated that if the overall infection rate is 10%, in the 'with' alternatives cattle owners would pre-select 15% of their herd to be tested for the decision on whether and how to treat. Later the 10% infected cattle would be tested again for evaluation of the treatment they received. Hence a total of 8.750.000 tests were needed, and they were valued at US\$ 1.0 (BCT) or US\$ 0.5 (Ag-ELISA) with an extra 20% of these prices reserved for the intervention by a veterinarian (even though with a pen-side test this might not be necessary). The total yearly cost of diagnosis in test and treatment practice in the two 'with' alternatives was respectively US\$ 10.500.000 and US\$ 5.250.000.

The total 'cost of diagnosis, treatments and drug-resistance' per year in the various scenarios were first discounted and subsequently summed-up. The sum-totals are given in Table 1. Furthermore two ratios are computed by dividing the total cost in the 'without'-change situation by the total cost in the various 'with'-ELISA alternatives. The first ratio expresses that if the practice suggested by the first alternative could be realised, the total actual costs and potential losses in the next ten years could be reduced with two thirds (1: 4,2). The second ratio expresses that if the second alternative could be realised, then only one ninth of these costs and losses would remain (1: 9,2).

The discounted totals in Table I can also be used to conduct a cost-effectiveness comparison of the two 'with' alternatives. The desired 'effect' would be: avoiding (or reducing) the risk of drug-resistance occurring in the presumed ten years until full control and eradication might be implemented. The cost-effectiveness ratio of 2.2 : 1 (or 197 / 90) confirms the simple fact that the second alternative, with the use of Ag-ELISA in test and treatment practice, is the cheapest option.

When the total cost from the 'with' alternatives, are deducted from the total cost in the 'without' situation, the figures that remain are 'avoided cost' or 'avoided losses', hence the benefit of the 'with' alternatives. The IAEA's contributions in the cost of 'this project' were known or calculated, the local budgets spent on trypanosomosis and ELISA research were estimated and added.

TABLE I. TOTAL COST OF DIAGNOSIS, TREATMENTS AND DRUG-RESISTANCE OVER A TEN YEAR PERIOD

		*Discount rate: 5%		(In US\$)	Ratio's
Without	Sum total (ten years)	\$	1.058.985.938		4,2 : 1
	Sum of discounted total* (ten years)	\$	834.878.935		
With alternative 1	Sum total (ten years)	\$	243.300.000		9,2 : 1
	Sum of discounted total* (ten years)	\$	197.263.301		
With alternative 2	Sum total (ten years)	\$	112.080.188		
	Sum of discounted total* (ten years)	\$	90.872.617		

In Table II the benefits from the first 'with' alternative are compared to the total expenditures for 'this project'. But it would not be right to compare the benefits arising from the alternative with ag-ELISA, only with the development cost made until today. Because the Ag-ELISA has not yet been successfully developed into a pen-side test. Therefore we budgeted an extra US\$ 5 million as the cost of development and promotion of Ag-ELISA (and pour-on's). Both resulting cost-benefit ratios: 1 : 53 and 1 : 44 are very promising. Even more because we started our calculations from very conservative assumptions.

TABLE II. COST-BENEFIT RATIOS

Comparing the 'gross benefit' of saved cost in the with antibody-detection ELISA alternatives to the direct-cost of the diagnosis research project:

Discount rate: 5%

Cost:			Ratio's
Total expenditures research project (rounded)	\$	12.000.000	1: 53
Total expenditures + extra research on Ag-ELISA	\$	17.000.000	
Benefit:			
WITH alternative 1 Sum of 'benefit' (ten years)	\$	815.685.938	1: 44
Sum of discounted 'benefit' (ten years)	\$	637.615.633	
WITH alternative 2			
Sum of 'benefit' (ten years)	\$	946.905.750	
Sum of discounted 'benefit' (ten years)	\$	744.006.317	

We also conducted a 'sensitivity analysis' varying the main magnitudes surrounded by uncertainty, in order to study their impact on the outcome of the cost-benefit analysis. The variables that have the greatest impact on the results are: the assumed increasing level of drugs-resistance occurring and the price of cattle. We used three different options for the maximum level of drug-resistance: 10%, 25% and 50%. The price for cattle that we used first was an incontrovertible low estimate of US\$ 100. We then increased it to US\$150. Using this higher yet still reasonable price for cattle, boosted the ratio of the total cost of the 'without' over the 'with' ELISA alternatives. And even if we used the smallest estimate of 10% for the maximum level of drug-resistance in year 10, the cost-benefit ratio's were still very promising: respectively 1 : 37 and 1 : 33.

4. DISCUSSION

In the absence of this project, the current malpractice in drug-use will continue without change. Local livestock owners will be faced with increasing mortality of cattle when drug-treatments become ineffective. Furthermore, the NARS laboratories would miss an important incentive if the project was not contributing to their research through financial assistance, training and the provision of equipment. Without ELISA, the monitoring of ongoing control programmes would demand a considerable amount of labour and be more expensive. The efficiency gained and the costs saved in control by the introduction of ELISA, will contribute to diminishing the losses in overall agriculture due to trypanosomiasis estimated at 4,5 billion annually [3]. However, one should avoid attributing too many (or too few) positive effects to a project. Hence, it is important to define the boundaries of the project. Therefore, we chose to limit the comparison to the more direct and quantifiable implications of changing diagnosis- and drug-use practice.

The cost-benefit considerations suggested that the costs made in the research and development of ELISA may be regarded as cost effective when compared to the potential *savings* in 'costs of diagnoses, treatments and drug-resistance'. Including the reduced costs of diagnoses and treatments of other domestic animals would strengthen the conclusions on the benefit of 'with'-ELISA alternatives as compared to the present situation.

The cost-benefit ratio computed for the first alternative, with ab-ELISA & BCT was very promising (1 : 53). Suggesting that, if it was possible to have BCT used on a large scale in test and treatment practice, it would be very worthwhile to promote. Unfortunately, this is not considered a feasible option. Considering the cost-benefit ratio (1 : 44) of the second alternative, with Ab-ELISA and Ag-ELISA, although being lower than that of the first 'hypothetical' alternative, it is still regarded as very promising. Therefore, the second alternative is recommended, i.e. the further development and promotion of Ag-ELISA, preferably in a dip-stick.

Furthermore, we considered two main aspects of changing diagnosis: the precision and the price. The precision of a test is not that important when just investigating the disease prevalence [5]. However, its sensitivity is important when the test is used in test and treatment situations. As large-scale use of BCT is not easily to realize, here lies a role for ag-ELISA. Due to institutional constraints the budgets of local laboratories are usually not so flexible, and form an economic constraint on the number of diagnoses performed. Because the true costs-price of ELISA is probably 1 to 5 times cheaper than BCT, the large-scale distribution of pen-side ag-ELISA could probably be achieved with maintaining the present level of local overhead-costs. And the cost-price advantage would be considerable due to the potential 8.750.000 tests demanded annually.

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