

ETHICAL REVIEW COMMITTEE, ICDDR,B.

228

Principal Investigators: Claquin, Horton. Trainee Investigator (if any) _____

Application No. 80-041(P) Supporting Agency (if Non-ICDDR,B) _____

Title of Study Limited Study: cost effectiveness study of hospital and ambulance services at Matlab treatment center. Project status:
 New Study
 Continuation with change
 No change (do not fill out rest of form)

Circle the appropriate answer to each of the following (If Not Applicable write NA).

- 1. Source of Population:
 - (a) Ill subjects Yes No
 - (b) Non-ill subjects Yes No
 - (c) Minors or persons under guardianship Yes No
- 2. Does the study involve:
 - (a) Physical risks to the subjects Yes No
 - (b) Social Risks Yes No
 - (c) Psychological risks to subjects Yes No
 - (d) Discomfort to subjects Yes No
 - (e) Invasion of privacy Yes No
 - (f) Disclosure of information damaging to subject or others Yes No
- 3. Does the study involve:
 - (a) Use of records, (hospital, medical, death, birth or other) Yes No
 - (b) Use of fetal tissue or abortus Yes No
 - (c) Use of organs or body fluids Yes No
- 4. Are subjects clearly informed about:
 - (a) Nature and purposes of study Yes No NA
 - (b) Procedures to be followed including alternatives used Yes No NA
 - (c) Physical risks Yes No NA
 - (d) Sensitive questions Yes No NA
 - (e) Benefits to be derived Yes No NA
 - (f) Right to refuse to participate or to withdraw from study Yes No NA
 - (g) Confidential handling of data Yes No NA
 - (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure Yes No NA

- 5. Will signed consent form be required:
 - (a) From subjects Yes No
 - (b) From parent or guardian (if subjects are minors) Yes No
 - 6. Will precautions be taken to protect anonymity of subjects Yes No
 - 7. Check documents being submitted herewith to Committee:
 - ___ Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).
 - Protocol (Required)
 - Abstract Summary (Required)
 - ___ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)
 - ___ Informed consent form for subjects
 - ___ Informed consent form for parent or guardian
 - Procedure for maintaining confidentiality
 - ___ Questionnaire or interview schedule *
- * If the final instrument is not completed prior to review, the following information should be included in the abstract summary:
- 1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
 - 2. Examples of the type of specific questions to be asked in the sensitive areas.
 - 3. An indication as to when the questionnaire will be presented to the Cttee. for review.

We agree to obtain approval of the Ethical Review Committee for any changes involving the rights and welfare of subjects before making such change.

Due Horton
Principal Investigator

Trainee

80-041(p)

Rec'd.

25/11/80

SECTION I - RESEARCH PROTOCOL

- 1. Title: Limited Study: cost effectiveness study of hospital and of ambulance services at Matlab treatment centre
- 2. Principal Investigators: P. Claquin, S. Horton
- 3. Starting date: October 1980
- 4. Completion date: January 1981
- 5. Total direct cost: US \$ 3,000.00
- 6. Scientific Programme Head:

This protocol has been approved by the Community Services Research Working Group.

*Signature of Scientific Programme Head: A. J. Souza

Date: 10.11.80

*This signature implies that the Scientific Program Head takes responsibility for the planning execution and budget for this particular protocol.

7. Abstract Summary:

There have been two earlier studies of cost-effectiveness of hospital treatment of diarrhoea at Matlab, five and ten years ago (1, 2). The present study aims to update earlier studies and provide more breakdowns of costs by type of service.

Effectiveness of services will be assessed by the following criteria: estimated mortality averted, numbers of users, revealed preferences of users i.e. changes in utilization patterns as service availability changed, and user characteristics. The implications of changing utilization patterns for cost will be examined. Characteristics such as age, sex and SES of users of different services will be compared to measure effectiveness.

The protocol involves no additional data collection. Procedures to ensure confidentiality were implemented at the time of original data collection.

8. Reviews:

- (a) Ethical Review Committee: _____
- (b) Research Review Committee: _____
- (c) Director: _____
- (d) BMRC: _____

ABSTRACT SUMMARY - PARTICULAR ITEMS

1. Not applicable.
2. Not risks.
3. Not applicable.
4. See next page.
5. No additional informed consent required.
6. Not applicable.
7. No benefits to individual. Benefits to society in general from better understanding of cost-effectiveness of use of scarce resources, and of service user characteristics. Information may aid allocation of resources and design of services.
8. Study uses cost data from financial, time use and supply records. Study also uses hospital, and census records including 1974 SES tape.

CONFIDENTIALITY STATEMENT

The study involves use of collected data only. Consent was obtained at the time of original data collection. Data on users is on tape or written sheets. It is necessary to code census numbers of individuals to link user characteristics and service use records. Staff with access to the identifying information are trained and aware of its confidential nature. Data will be published only in aggregate. No follow-up is required.

Access to data: P. Claquin, S. Zimicki, S. Horton, personnel in data management.

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objective: The study aims to provide information on resource allocation for different services. It is intended to update previous cost estimates for the hospital, provide cost estimates for new services, and provide more detail by type of service. The OT field trial data is not within the purview of this study. It is intended to compare service effectiveness by four criteria. The objective is to assist resource allocation and service design.
2. Background: Cost benefit and cost effectiveness studies are widely used in resource allocation studies and for planning purposes: they are appropriate for use also in health areas, since there exists the problem of scarce resources and competing needs.

Cost benefit studies have been occasionally used in the health area (eg. 3). However, because it is difficult to assign a monetary value to human life and suffering, cost effectiveness studies are preferred (eg. 4). Here service cost is compared to effectiveness of achieving a particular outcome. Different outcomes may be used, such as deaths averted, morbidity averted, change in nutrition status. It is proposed here to use four criteria utilizing available information, namely, deaths averted, numbers of users, number of users switching between services as services changed, and user characteristics.

The cost of hospital operation have been studied twice previously at Matlab (1, 2). Since then, costs and types of services have changed considerably. It is proposed to use distance to hospital and speed boats as one important variable in determining use patterns. The changes in use when one ambulance station was withdrawn and replaced by a local treatment centre (Sataki) will also provide information on changing use patterns. Cost effectiveness of ambulance operation as against treatment subcentres can be examined.

3. Rationale: Cost, and alternative services provided have changed sufficiently to warrant a re-examination of the cost effectiveness of the hospital. Ambulance operation is sufficiently costly to merit examination, especially as data on an alternative service, a treatment centre, is now available.

The data can assist service design. Work on user characteristics can complement existing work on differential need for services as measured by differentials in mortality, nutrition status etc. for the same groups of people. Thus one can examine which services reach which sections of the target population.

B. SPECIFIC AIMS

1. To calculate costs of hospital operation, ambulance operation for July 1979 to June 1980. To calculate costs of a local treatment centre since its inception in November 1979. To provide break-downs by categories such as costs of workers, supervisors, maintenance, supplies, equipment, transport and administration.
2. To calculate effectiveness of services, using:
 - a) estimated deaths averted
 - b) numbers of users
 - c) user preferences, as revealed by numbers switching to alternative services as these became available
 - d) user characteristics of different services
3. Hence study cost-effectiveness of the three services -- Sataki, ambulance services, and the hospital.

C. METHODS OF PROCEDURE

1. Costs: Cost data will be obtained from financial records, and checked against time use sheets for workers and equipment, and against supply records for materials.

Methodological issues include:

- a) Allocation of joint costs for workers and equipment with multi-purpose use. For workers it is proposed to allocate costs according to proportion of time spent in different activities. For supervisor, it is proposed to use time input allocation of workers under supervision. For equipment either numbers of users or duration of use may be used. For transport allocation of driver and equipment use time, and of gasoline, will be used. Allocation of administrative inputs may be difficult and somewhat subjective. For administrative staff, and supervision in Dacca, the cost included will be salary multiplied by estimated fraction of time spent on the hospital. The fraction will be obtained from the individual concerned.
- b) Average and marginal, long and short run costs will be presented. This enables fair comparison of capital and labour intensive services.
- c) Where appropriate, equipment costs will be amortized using straight line depreciation and expected lifetime. Where appropriate discount rates are required, a rate appropriate to long run government development projects will be used.

- d) Estimates will be presented in Taka for 1979-80 financial year. Equipment costs will be at 1979-80 replacement cost. If appropriate, shadow prices for foreign exchange may be employed.
- e) Methodology will follow standard economic practices for cost effectiveness (5) and methodology suggested for application in health area (6, 7).

2. Effectiveness

- a) Deaths averted. Sampled hospital records for July 1979 to June 1980 will be used. The first 150 cases for each month will be drawn as sample. These may later be compared to previous years to control for yearly disease variability. Both written records, and those coded onto oral therapy hospital tape, may be used. Use of OT hospital records will ensure that the OT field trial study has precedence in reporting results or agreement on this point will be reached with the relevant investigators. Mode of transport used will be obtained from admission records, and also from speed boat log books. Admission records for Sataki subcentre will be used.

Deaths averted will use Chen's (8) methodology, of estimating numbers of patients with a given dehydration status, and assuming that a given fraction of these would have died in absence of treatment. This can be corrected for multiple causes of death as in Chen (8). One would use age and sex specific rates separately.

- b) Number of users. The same records can be used to calculate number of users, and number within particular age, sex, distance and dehydration status categories.
- c) User preferences. It is standard economic practice to assume that switch in use of services reflects a benefit to the user. Thus numbers switching between services will be analysed, for switches from hospital to local treatment centre, and ambulance to local treatment centre. This can be compared also to cost savings. The characteristics of persons switching use are obtained by comparing previous speed boat users, to users continuing after Sataki began, to new users of Sataki. Around 15 villages were found with a significant decrease in use of Matlab, and a level of use of Sataki judged to be appreciable.

- d) User characteristics. More detailed analysis will be done on user response, including effect of SES, sex, family size, order of child in family. This will require matching files of 1974 census data. This interest here is to consider the issue of adequate targeting of services, and to speculate as to reasons behind use of a particular service (such as personal costs, educational attainment, "acceptor-nonacceptor" households). This part of the analysis is most speculative and possibly only preliminary results will be obtained, and hypotheses for later testing. Results can be compared with similar studies in Bangladesh, on characteristics of users of other medical services (10, 11, 12). This exercise is of interest for policy purposes. Certain services are used more heavily by certain groups. A fee paying treatment centre such as Sataki may be used more by the more affluent, than a free ambulance service. This is necessary to consider in policy decisions as to which service to provide.

D. SIGNIFICANCE

There has been no cost effectiveness study on recent years' data, nor one at the level of detail suggested. In the light of changes in services and levels of costs, such a study may aid resource allocation and service design. Nor have user characteristics of different services been compared, which could aid service design.

Such a study may be of interest both to the ICDDR,B for assessment and planning purposes for diarrhoea disease treatment. It may be of interest methodologically to the ICDDR,B as a tool for analysis and planning for other services. It may be of interest to other countries or places considering implementation of diarrhoea treatment.

E. FACILITIES REQUIRED

1. Office space: no additional needs
2. Laboratory space: none
3. Hospital resources: none
4. Animal resources: none
5. Logistic support: no additional needs
6. Equipment: none
7. Personnel: keypunching and computer facilities
8. Supplies: stationery, computer cards, tapes

F. COLLABORATIVE ARRANGEMENTS - None

SECTION III - BUDGET

A. Detailed Budget

1. Personnel services

<u>Position</u>	<u>% Effort</u>	<u>No. Days</u>	<u>Annual Salary</u>	<u>Project Taka</u>	<u>Requirement Dollars</u>
1 Visiting research associate	75	60	\$ 1,800	-	1,500
1 Data entry personnel	50	60	27,105	2,259	-
1 Data processing assistant	50	60	27,105	2,259	-
1 Coding assistant	50	60	22,529	1,878	-
1 Programmer	50	60	48,776	4,065	-
1 Computer operator	50	30	48,776	2,033	-
			Sub-total	12,494	1,500

2. Supplies and materials

Stationery				1,500	-
Computer punch cards, tapes, diskettes					100
			Sub-total	1,500	100

3. Equipment - None

4. Patient hospitalization - None

5. Outpatient care - None

6. ICDDR,B transport - None

7. Travel and transportation of persons - None

8. Transportation things - None

9. Rent, communications and utilities - None

10. Printing and reproduction

15 copies protocol	X			750	
50 copies final report.	X				

11. Other contractual services

Computer charges				6,000	
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12. Construction, renovation, alterations - None

13. Miscellaneous

Other				256	
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B. Budget Summary

FY 1980

<u>Category</u>	<u>Taka</u>	<u>Dollar</u>
1. Personnel	12,494	1,500
2. Supplies	1,500	100
3. Equipment	-	-
4. Hospitalization	-	-
5. Outpatients	-	-
6 ICDDR,B transport	-	-
7. Travel, persons	-	-
8. Transportation, things	-	-
9. Rent/communications	-	-
10. Printing/reproduction	750	-
11. Contractual services	6,000	-
12. Construction	-	--
13. Miscellaneous	256	-
Total.	<u>21,000</u>	<u>1,600</u>

Total (in US \$) 3,000

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