COMPARATIVE ECONOMIC EVALUATION OF AN ATRAUMATIC RESTORATION TREATMENT PROGRAM: STUDY DESIGN AND PROTOCOL FOR SELECTED LATIN AMERICAN COUNTRIES

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EXECUTIVE SUMMARY

The report presents the concept, technical design, protocol, and preliminary inputs for the cost-effectiveness analysis (CEA) of atraumatic restorative treatment (ART), the key dental health approach under the PRAT Project. PRAT (from the Spanish acronym for *Práctica de Restauración Atraumática*) will be managed by Pan American Health Organization (PAHO) and funded by the Inter-American Development Bank (IDB) funds. The project is conceived as a financial and management vehicle for pilot implementation of ART in Ecuador, Panama and Uruguay.

CEA will be conducted alongside ART-related clinical activities and will be based on *a longitudinal community field trial involving an ART intervention sample and a non-ART control sample*. Given a significant amount of documented evidence on the ART clinical and epidemiological benefits, the upcoming study will not be a trial of ART clinical effectiveness *per se* but, predominantly, an evaluation of ART cost effectiveness relative to a conventional alternative. Amalgam-based treatments will play the role of such alternative. The study will produce a comparative cost-effectiveness rating of ART reflecting the correctness of its application in terms of compliance by caregivers of a specific country with the ART planning, organizational and clinical requirements. If ART does not withstand the evaluation, it will mean that cost-effectiveness must have critically eroded due to non-compliance. If it yields results superior to a conventional alternative, this will lead to the conclusion that ART delivered on the expectations because its application was adequate.

According to the proposed study design, CEA will aim to solve one or both of the following two dilemmas. Dilemma 1: "The implementation of ART versus continuing with traditional services at their historical level of accessibility, i.e. changing nothing". Dilemma 2: "The implementation of ART versus provision of amalgam-based restorations increased up to the level of need". Solution of the first dilemma from the standpoint of cost-effectiveness would probably lead to the conclusion that ART is a good clinical option. However, it will not allow to make an unambiguous judgment as to whether ART constitutes the best use of limited community resources for provision of dental care in a more equitable way. Testing of the second dilemma, therefore, is indispensable for the equity-driven agenda of the PRAT Project. In order to consider amalgam restorations as a competitive alternative to ART, it must be assumed that amalgam is made available at the same (need-based) level of supply as ART is intended to be, i.e. as if amalgam were brought to currently under-served communities. Baseline study on the CEA sample will include estimation of the currently existing supply gap and to what extent it can be filled by dental clinics and practices on the basis of their office operation. The demand for outreach services will be identified. To add this component, the one-time cost of procuring or renting mobile units will have to be factored in. Staffing and operating such units will add to recurrent costs of conventional dental care. In summary, the ART alternative will be compared not to the currently available amalgam-

based treatments but to the amalgam-based treatments made available on a larger scale and in a more equitable way.

Concurrent with the definition of the study as a controlled community trial, the CEA sample will consist of two sub-samples: intervention group (also termed experimental, or trial group) and control group. Children in the intervention group will undergo annual dental examinations and will receive ART procedures based on need, largely, determined by the number of decayed teeth at the point of examination. Children in control group also will be taken through annual examinations and would get amalgam-based treatment financed to the extent possible through locally available third-party sources. Should a financing gap result from the inability of local sources to cover the entire cost of amalgam restorations, PRAT will cover that gap. The ability of PRAT to absorb the cost of conventional dental care for the control group will be carefully verified in order to keep the project budget within the pre-approved limits.

Both the control and the trial samples will be comprised of a similar number of children and will be drawn from the same community populations in order to control for the background variables of dental health status, such as age, income, education, place of residence. Mean DMFT score must also be close in both groups at the start of the project. The sample size will be determined in two ways: (1) on the basis of PRAT pre-assessed budget; (2) by means of statistical sampling. Eventually, the outputs from both approaches would be reconciled in order to make the sample both accurate and affordable.

The ART procedures provided for intervention group, and conventional treatments provided for control group will be costed at production or charge-based costs and calculated by in-country experts. The report offers an elaborate algorithm of cost identification, measurement, valuation, and adjustment for differential timing (discounting).

Besides producing the 'main' cost-effectiveness (C/E) ratio for each alternative that would derive from a core set of measurements and assumptions, CEA is designed to generate a range of supplementary scores, each one being a product of alternatively set values of input variables in the cost-effectiveness equation. Such multi-scenario simulations (known as sensitivity analysis in CEA terminology) will allow to assess how modification of patient age structure, reduction or growth of restoration survival rates, shift from international to domestic procurement and pricing system, change of discount rate and statistical confidence level would affect C/E ratios. The best, the worst and the break-even scenarios will be determined for ART. A break-even scenario will produce 'threshold' parameters of ART application at which an ART program would turn from looser into winner or the opposite way, dependent on how its comparative status was defined according to the 'main' C/E ratio.

Based on the above, the proposed CEA will make a significant contribution to *country-specific* knowledge in the following areas: the ART potential of abating progression of dental caries; clinical domains in which ART is superior, inferior and complementary to

conventional alternatives; the optimal design and targeting of ART programs by age and socioeconomic groups, and scale of implementation; clinical and operational setup required to maximize clinical outcomes while containing costs of ART services; the ability of the current health financing system to bring conventional treatment to previously under-served communities and populations on a sustainable basis.

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LIST OF ACRONYMS

ART	Atraumatic restorative treatment
CBA	Cost-benefit analysis
C/E ratio	Cost-effectiveness ratio
CEA	Cost-effectiveness analysis
D	Decayed teeth, a component of DMFT score (see DMFT)
DMFT	Decayed, missing, and filled teeth
F	Filled teeth, a component of DMFT score (see DMFT)
IDB	The Interamerican Development Bank
M	Missing teeth, a component of DMFT score (see DMFT)
PAHO	Pan American Health Organization
PRAT	Práctica de restauración atraumática, the title of the project under evaluation
QALY	Quality-adjusted life years
WHO	The World Health Organization

INTRODUCTION

Bringing basic health services to all people in the developing nations remains the key strategy of improving global health in an equitable way. Prevention and appropriate treatment of common oral diseases make part of the core component of primary care and as such are included in the package of basic health services in a variety of its definitions. The consensus statement released by the participants of the WHO Consultation in Geneva in March 1997 asserts that "dental caries (tooth decay) is a common oral disease and its prevention is in accord with the main mission of WHO" [*WHO, 1997: xi*].

The advancement of primary health care, including basic dental services, towards universal availability has been and continues to be impeded by lack of operational knowledge. There is a gap between, on the one hand, state-of-the-art medicine and, on the other hand, insufficient understanding of how potentially effective interventions and techniques should be applied in particular country settings, targeted to specific populations, supported with community and health infrastructure. "Much still needs to be learned about [basic health care] application under local conditions, and during its operation, control and evaluation questions will arise which will require research. These may be related to such issues as the organization of primary health care within communities and of supporting services; the mobilization of community support and participation; the best ways of applying (existing and appropriate) technology; the planning for and training of community health workers, their supervision, their remuneration and their career structure; and methods of financing primary health care" [*WHO, 1978: 3-4*].

This or similarly outlined agenda of operations research may be used as a blueprint for validation of each new health intervention believed to be advantageous over a conventional alternative. A successful operations research results in a set of rules of how the innovative option should be optimally applied in order to reveal its potential benefits. This new knowledge should, then, be enhanced with economic assessment. The costs of and health gains from the new program (in its optimally customized version) should be quantified and compared with the costs and effects associated with the older alternative. Based on such comparative assessment the decision would be taken as to the feasibility and scope of implementation of the new health intervention.

In the current study design, the basic techniques of economic assessment, namely those involved in cost-effectiveness analysis, are proposed for evaluation of the practice of atraumatic restorative treatment (ART). The research is aimed at strengthening the PRAT Project proposal to IDB that seeks to introduce ART in government dental care facilities of Ecuador, Panama and Uruguay as a restorative treatment modality to treat carious lesions in both primary and permanent teeth, thus, extending coverage of oral health services to additional children's populations, including those currently without access to conventional amalgam-based treatment [*IDB, 1998: 8-9*].

The basic assumption that guided this study design was that of impartiality. None of the options should be viewed *a priori* as unconditionally superior to others. It is likely that ART will not be able to replace dental amalgam but will successfully complement it by addressing the issues of oral health status and treatment needs that the conventional approach failed to address. The application of ART, therefore, would have to be reasonably selective to fill the cavities in the existing public oral health activities while, at the same time, avoiding areas of overlap in which it would not necessarily be clinically competitive with the traditional treatments. ART *adequate profiling* is, thus, the final purpose of this research design. By profiling we understand the identification of optimal targets and scope of ART application, as well as of critical execution requirements that must be met in order to prevent the method's potential advantages from erosion.

Review of published reports on previous ART demonstrations has allowed to refine the initial statement of purpose. It has led to the conclusion that a new study would hardly be able to revert the extensive documented evidence on ART as a feasible technique, provided that it is correctly targeted and properly implemented. The implicit purpose of this study design, therefore, would be to set out evaluation guidelines to monitor compliance of the project activities with ART basic resource requirements and application protocols; and to see whether the peculiarities of selected countries may lead to a critical loss of effectiveness, thus, turning a potentially attractive method into its opposite. In summary, the analysis is not so much about shedding light on the strengths and weaknesses of the ART as such. It is, primarily, about evaluating and controlling the quality and effectiveness of the ART strategy and practice in specific settings of the proposed pilot countries.

The subject of the current report is focused on the study design but is not limited to it. Besides a conceptual framework and a protocol of the cost-effectiveness analysis (CEA) the report feeds information into selected steps of the proposed CEA algorithm and shares solutions pertinent to the CEA agenda if such were found available from the past experience or could be sought out on a preliminary basis by the designers of this study. The material, thus, presents both the study protocol and, selectively, the input information and solutions required by that protocol. The information should be viewed as tentative and subject to verification since it is drawn from the authors' creative thinking and international experiences not necessarily applicable to the targeted Latin American countries. It is hoped, nevertheless, that in many cases the proposed approaches would be found valid and would save time and resources on CEA activities.

Following introductory description of the CEA concepts, definitions, and basic elements (Chapter 1), the report consecutively focuses on each of the components of the CEA technical algorithm in its adaptation to ART and the proposed PRAT project in three Latin American countries (Chapter 2). In conclusion the report offers a summary of activities, input data, and outputs from CEA. It also highlights selected trial management activities, staffing requirements, and estimated level of effort by key CEA team members. Selected data reporting forms and data processing worksheets for the study are displayed in the report's tables and Annex 3.

1. CONCEPTUAL DESIGN OF COST-EFFECTIVENESS ANALYSIS

1.1 The Basics of Economic Evaluation

The success of dental services as well as of any other clinical intervention, program and strategy critically depends on the quality of planning and decision-making. Adequate tools must be available so that "needs can be identified and priorities established for what should be promoted, to whom, how and under what conditions" [*Frazier et al., 1983*]. Such tools are embodied in a variety of methods of economic evaluation.

Economic evaluation relates effectiveness of a health care program (and underlying clinical intervention) to its cost. The notion of effectiveness is based on sustainable clinical and socioeconomic outcomes (benefits) expected from program implementation. The notion of cost involves the concept of opportunity cost, i.e., outcomes achievable under an alternative program which have been (would be) forgone by committing resources to a preferred program. The economic evaluation, thus, seeks to justify an innovative program by comparing it with a conventional alternative. The presence of more than one alternative in the subject of the study and the consideration of both costs and benefits of each alternative are the two key features of *full economic evaluation*. The latter is superior in its explanatory power to partial economic evaluation in which the research is restricted to a single course of action and/or costs and benefits are not examined together.

The relationship between an "incumbent" and a new program is not always that of uncompromising rivalry. They may be complementary, e.g., addressing various stages of disease or providing better solutions for particular cohorts of population. The issue of complementarity is addressed from a perspective of economic evaluation "by recognizing that there are numerous combinations of the main treatment options, each [combination] constituting an 'alternative'" [*Drummond, 1980: 23*]. Once such "composite" alternatives are identified, the economic evaluation gets back into its methodological mainstream, i.e., the comparison of costs and benefits between alternatives. ART and dental amalgam, presumably, are mutually complementing techniques and may form a number of composite strategies dependent on how each method is targeted and implemented.

1.2 The Preference for Cost-Effectiveness Analysis

Full economic evaluation relies on a variety of techniques, such as cost-minimization analysis, cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis. The differences between the techniques lie in the identification and measurement of outcomes as identified below:

- *Cost-minimization analysis* is the recommendable choice when the alternatives yield identical or almost identical outcomes. The evaluation is, then, essentially a search of the least-cost alternative.

- *Cost-effectiveness analysis* considers costs related to a single, common effect which may differ in magnitude between the alternatives. The results may be stated either in terms of cost per unit of effect, or effects per unit of cost.

- Cost-benefit analysis and cost-utility analysis are used when it is not possible to reduce relevant outcomes to a single effect common to both alternatives, or when the consequences of alternatives differ significantly. *Cost-benefit analysis* measures both the costs and outcomes of alternatives in monetary terms. The results are stated either as a ratio of monetary costs to monetary benefits or as a sum representing the net benefit (loss) of one alternative over another. *Cost-utility analysis* employs the value of improvement of health status as a measure of the value of program effects. The results are expressed in terms of the cost per healthy day or cost per quality adjusted life year.

The reviewed classification is drawn from [*Drummond et al., 1987: 9-14*], a compendium of *academic* insights into economic evaluation in the health sector. A layman's choice of the study techniques is simpler and leaves little room for the aforementioned fine distinctions among the programs according to the nature of their outcomes. In particular, cost-minimization analysis is not a widespread option since analysts would usually feel uncomfortable about committing themselves to the restrictive condition that the outcomes must be identical. Also, cost-minimization analysis is viewed by some researchers as "the cost-minimization form of CEA" and is not considered as a separate option [*Donaldson et al., 1996: 268*]. Cost-utility analysis is an adequate approach for health strategies and interventions with strong demographic and socioeconomic impact. There should be enough ambition among the analysts to equate a program outcome to change in life expectancy or to quality- or disability-adjusted years of life saved. In practice, if the intervention is not already rated in the World Bank QALY charts, it would not be a viable idea to go into independent assessment of QALY dividends of a particular program unless there are enough resources to bear this vast front of activities.

Thus, the customary range of economic evaluation options is reduced to cost-effectiveness analysis (CEA) and cost-benefit analysis (CBA). The main practical difference between the two is in the scope of "monetization" of outcomes. CEA is satisfied with non-monetary outcome measurements while CBA is keen to measure both costs and effects in monetary terms. An in-kind outcome estimation is possible, usually, as long as the program has a single or clearly dominant outcome. If multiple consequences must be taken into account, those should be summed up, and money is the conventional currency to make them commensurable (as long as relevant outcomes are not readily transferable into QALY terms). Therefore, programs sharing a single effect may be evaluated using CEA. Programs involving various effects would be analyzed on the basis of CBA.

Quite often, the final choice of an economic evaluation technique is not possible at the research design stage, since the number and nature of consequences of each alternative are yet to be identified. The initial research protocol may be tentatively geared to the CEA algorithm assuming that it would be possible to reduce the outcomes to a single or most relevant effect. An approximate 20-30% of resources should be requested and reserved in extension of the CEA basic budget in order to accommodate the need for additional research if the evaluation deviates towards CBA somewhere along the way.

Considering ART and dental amalgam as the alternatives to be evaluated, the choice of the analysis technique, presumably, will depend on the perception of outcomes. If it is agreed that both programs pursue the same and single goal of abating caries, CEA will be quite appropriate. The outcome would, then, be expressed in the cost per avoided unit of increment in D or DM score. If, however, the decision is taken that ART secondary benefits, such as treatment pain reduction and a potential for higher population coverage, are important enough not to be excluded from quantification, CEA may be modified to evolve into CBA.

Additional effects, however, may be included in the evaluation in such a way that CBA will still not be necessary, yet new elements would have to be added to the originally designed CEA protocol. Such add-on components may include an ART consumer survey to assess how many people with fear of pain and, for that reason, previously unused access to conventional restorative treatments are determined to bring their other children for ART treatment once one child in the family discovered its relatively unobtrusive character. Additional population coverage may be transformed into additional avoided increments in D(M) score, thus, making the pain reduction effect commensurable with the main health benefit from ART implementation. The ART potential of reaching out to rural and other disadvantaged communities, likewise, would be estimated from the standpoint of additional population coverage and D(M) avoidance. This outcome, too, will be captured in kind, allowing the study to stay within the CEA boundaries.

Consequently, the CEA deserves preference not just as a good mid-point technique open to further refinements and evolution towards other tools, as may be required by additional information on outcomes, but also as a method that may absorb more than one outcome as long as all identified outcomes can be captured in the same non-monetary measurements.

Since the basic convention of this study was to provide as much input information for the ART economic evaluation as possible, the choice of research technique had to be made to enable comparability between documented findings from past evaluations and the format and methodology of the upcoming assessment. From this standpoint, too, the initial selection points at CEA and CBA as the most widely used options. "Cost-minimization analysis in relation to fissure sealant programs has not been extensively addressed in the literature... Cost-effectiveness and cost-benefit analysis have been widely used in relation to fissure sealant programs. While cost-utility analysis has recently begun to appear in other areas of dental health services research, no studies in relation to fissure

sealants have been reported to date" [*Lewis, 1993: 80*]. This observation is equally applicable to ART restorations.

A limited review of the literature on economic evaluation of dental care programs suggests the incorrect use of terms in labeling analyses with the trend towards excessive utilization of the term "CBA" as a misnomer for single-outcome CEA.[1] Therefore, while choosing between CEA and CBA, it will stand to reason to start with CEA as, probably, the technique that promises the widest body of empirical evidence from the past research.

In summary, the preference for CEA over other tools of economic evaluation is justified from at least three points of view: (1) as the mid-point technique from which it is the easiest to adapt the initially designed research protocol in order to access other options, if required by newly collected information on program outcomes; (2) as a self-sufficient technique that in many cases can quantify multiple effects in the same in-kind terms, thus, producing a cumulative quasi-*single effect* as the methodological premise of CEA; (3) as the technique with the highest amount of documented evidence from previous research that can facilitate a new study.

1.3 A Review of CEA Concepts, Terms and Stages

This section displays CEA concepts and outlines main steps in the CEA process. Preliminary design decisions pertinent to the evaluation of dental care alternatives are proposed to illustrate the CEA basic concepts and algorithm. In the next chapter such design decisions will be refined and developed in operational terms. Chart 1 allows to visualize the narrative and may be used as a graphics guide to the CEA research protocol. The numbering of paragraphs in the subsequent text of this section is coordinated with the numbers on Chart 1.

1) The CEA enters the decision-making process when a need and a new opportunity for meeting that need form a potentially viable match, worth further consideration. The PRAT Project Proposal contains the following unambiguous statement of the key need: "The Region of Americas has a high burden of dental caries requiring wide-spread prevention programs and treatment alternatives to address current unmet needs" [*IDB, 1998: 8*]. One potentially suitable alternative is ART.

2) The key issues of the study would be as follows: (1) to ascertain the ART potential in containing the progression of dental caries, (2) to identify areas in which ART is superior, inferior and/or complementary to conventional alternatives, (3) to specify how ART

[1] For example, in [*Hannerz, 1995: 40-41*] differences in caries incidence (an *in-kind* outcome measure) between the two groups of children were studied longitudinally in order to account for the benefit of delegation of routine examinations and certain treatments from the dentist to auxiliary personnel. This standard CEA is erroneously termed CBA.

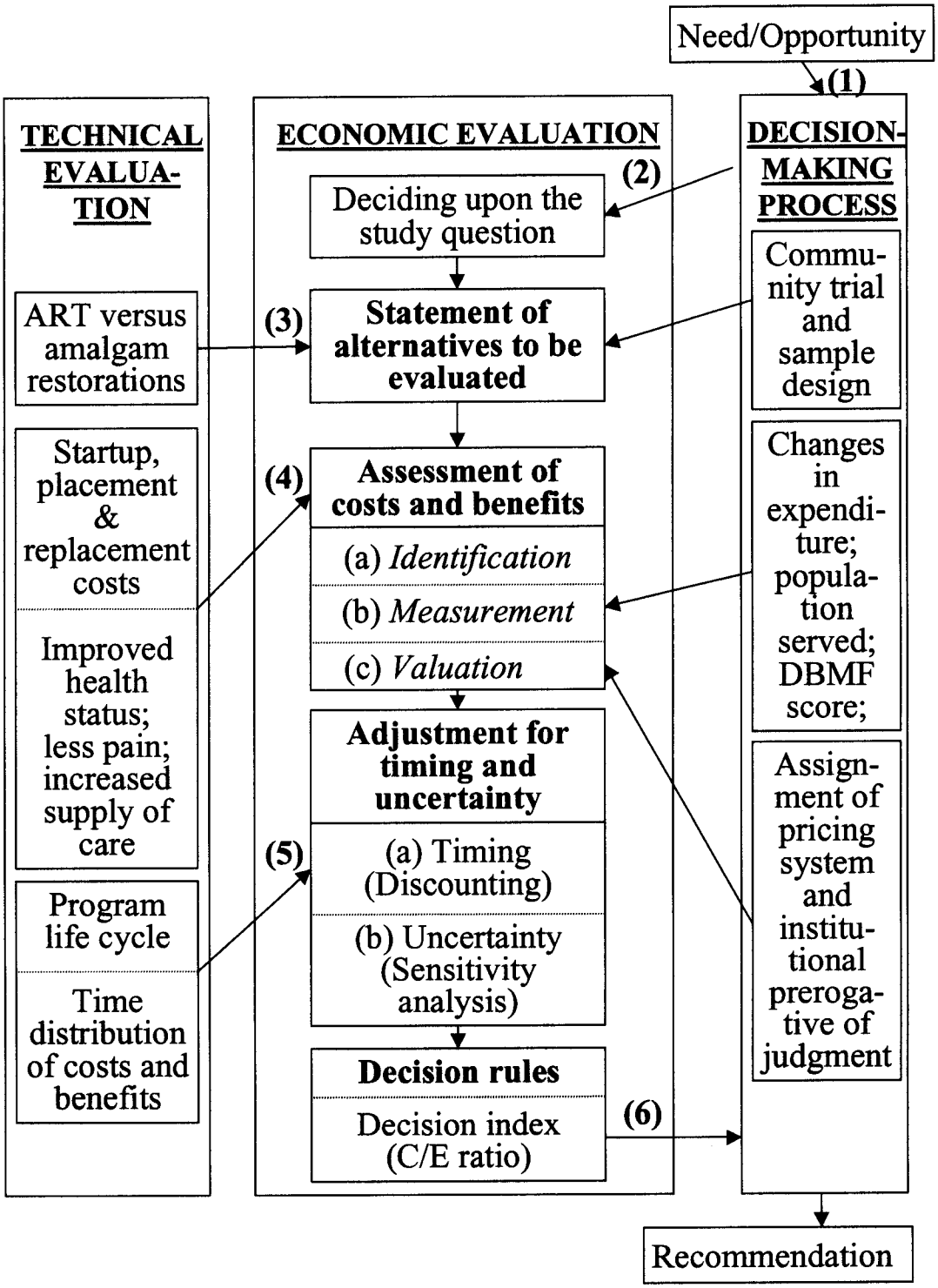

Chart 1. Stages and Selected Technical Inputs in Cost-Effectiveness Analysis: the Case of Caries Prevention and Treatment Alternatives

should be profiled by target population and scope of implementation, (4) to define the clinical and operational setup required to enable full realization of the ART potential.

3) The outlined agenda leads to the statement of alternatives: atraumatic treatment based on glass ionomer material versus amalgam-based restorative treatment.

4) Cost-effectiveness analysis is a formal process for organizing information so that the costs of alternatives and their relative effectiveness in meeting a given objective can be compared systematically [*Reynolds, 1985: 7*]. Comparative assessment of costs and benefits of the alternatives lies, therefore, at the heart of the CEA method. This process consists of three distinct stages: enumeration, quantification and valuation of the relevant costs and benefits.

4a) Enumerating is just compiling a list of costs and benefits regardless of whether those can be subsequently quantified in uniform in-kind terms as required by CEA basic methodology. The key unmeasurable costs and benefits should be viewed as relevant for final policy recommendations even though they may not be integrated into the final cost-effectiveness score. Presented alongside such score, the unmeasured would be considered in conjunction with the measured to assure selection of the best alternative.

Benefits: The *ART* approach based on the use of glass ionomer materials is praised by its proponents for its positive effect on dental health; has adequate longevity on appropriately selected tooth surfaces and population groups; is less obtrusive (i.e., glass ionomers are biochemically compatible with oral tissues; less or no tooth tissue is required to be removed during cavity preparations, therefore, less pain caused); has positive prevention effects (e.g., through fluoride release from sealant materials); can be furnished in mobile settings and, therefore, offered to rural and other disadvantaged populations whose primary alternative in the mainstream of dental care is extraction on demand [*Reich, 1997: 12-13; Phantumvanit et al., 1996: 141*]. *Dental Amalgam* is deemed invincible from the standpoint of the wide indications for use, ease of handling and goods physical properties [*WHO, 1997: xi*]. Its longevity is good and generally higher than for alternative materials. The benefits of both alternatives are in part offset by the pitfalls and risks associated with their application.

Costs: The detailed structure of costs will be considered in the respective part of the study protocol. Here it will suffice to note that both dental care strategies involve three types of costs: (a) the one-time costs, e.g., fixed investment and personnel training; (b) the costs of initial placement of restorations; and (c) the costs of replacement as the function of the durability (longevity) of the initially placed fillings.

4b) Measuring intends to estimate the size of costs and benefits of each alternative and the amount of gains or losses from switching between the alternatives or complementing one alternative with another. The costs and benefits would be compared in this study between the researched options from the standpoint of their impact on resource use (savings under a preferred alternative), output (better accessibility of a preferred alternative), and health status (containment of caries). Consequently, the expenditure, population served, and DMFT score or its components would be the three axes to form a three-dimensional measurement structure for this study. The amount and accuracy of the

measurement work will depend on the community trial and sample design: how many patients will be covered during the project, where care will be provided, how patients will be selected by geographic area, age group and other relevant characteristics. Some of the design decisions would stem from the realistically assessed project budget. In other words, a practical approach to sampling would consist of reconciling statistical sampling requirements with the maximum number of subjects in the sample that can be afforded under a predetermined project budget.

4c) Valuating involves assigning weights to specific costs and benefits, particularly (but not only), to the unmeasured and non-commensurable ones. Selection of a pricing system for cost measurements is another valuation issue. In many cases it is taken for granted that market prices provide the supreme judgment on costs. Sometimes, however, adjustments in market (actual acquisition) prices may well be in order if it is found out that those are distorted by monopolistic effects, taxes, subsidies, or just price volatility due to low turnover of goods and services relevant for the study. The latter is the likely case whenever it comes to procurement of materials for innovative treatment for which no established procurement infrastructure may exist in a developing country. To avoid inconsistencies, some of the inputs may be priced at the international competitive level, assuming that the national procurement system, once it matures, will rely on the global markets. International market pricing, since it is backed up with price information better than domestic procurement may be, is instrumental in overcoming the information gap and saving time and effort on CEA data gathering activities. Also, international market prices improve cross-national comparability of results in the context of CEA involving more than one country. If international procurement prices are subsidized by donor institutions they may, nevertheless, be preferred for CEA costing if it is believed that donors will maintain supplies on preferential terms throughout the life of the project. It should be ascertained, however, whether such preferences put the conventional alternative at a significant disadvantage cost-wise. Its costs should, then, be adjusted to assure comparability.

There is an important rationale for preferring domestic procurement prices over international competitive prices. It is to ascertain the cost of sustainable practice of ART in the aftermath of the PRAT Project. If international support with purchasing is discontinued there will be no alternative to conventional channels, inefficient as they may be. Relating increase in costs should be factored in cost-effectiveness (C/E) ratio in order to provide a realistic assessment of ART sustainability in a specific country.

Another valuation aspect is the selection of the institutional source of judgment. In the current study, policy-makers' views will prevail for two reasons. First, health system leaders, realistically speaking, are the most informed judges, even of the good of the patient. Second, there may be not enough resources in the study budget to access families for the assessment of their views on the comparative benefits of ART and amalgam treatments. In summary, explicit value judgements are inherent in CEA concept, design and protocol and should be accepted as legitimate. It is the researchers' responsibility, however, to highlight possible institutional biases and to advise the decision-makers on the alternative judgments potentially worth consideration.

5) Two refinements should be carried out to secure the accuracy of CEA results. These are: the allowance for the differential timing of costs and benefits; and the allowance for risk and uncertainty in costs and benefits.

5a) The commonly used technique of adjustment for differential timing is *discounting.* Discounting is based on the acceptance of an obvious fact that benefits and costs of a treatment are distributed unevenly over the life of the program and may behave in a rather uncoordinated way. Usually, time elapses until benefits are returned on the initial investment. This is particularly the case with interventions that require substantial startup expenses and are focused on prevention. For example, the proposed PRAT project involves a large-scale training of health personnel. It will take a number of years for the associated one-time costs to pay off. Regardless of the peculiarities of a specific project, the general trend is that spending comes in advance of returns. Waiting for returns is tantamount to increased costs since resources already spent are not available for any alternative beneficial use. Such thinking is based on *a positive rate of time preference*, i.e., the earlier the returns happen, the more attractive they are and, by the same token, the more distant in time the returns are, relative to investment, the less valuable they are. To account for this kind of time differential, both costs and benefits must be projected on the same point on the time scale, or *discounted to their present values*. Discounting in the current CEA will involve one of the following two procedures: (1) Future benefits should be devalued proportionately to the time gap between investment and returns. (2) Current investment should be appreciated proportionately to the same time gap at the established *discounting rate*, i.e., projected annual rate of return from readily available alternative investments, forgone because of the investment in the program.

The time factor in discounting is geared to the life cycle of the program. This is the main technical reason (let alone planning and management considerations) why the length of the program must be carefully determined as part of CEA. The program life should be sufficient for all treatment alternatives to generate meaningful clinical results and for the expenditure cycle to come full circle. A viable recommendation would be to synchronize the project life cycle with the useful life of fixed assets and with the longevity of treatment effects.

5b) The uncertainty adjustment is necessary to account for unpredictability of clinical and economic outcomes of the program. ART is new to the Latin American countries selected under the PRAT Project. We do not know how steep the learning curve will be among newly trained caregivers, how well the community will support the effort, how correctly population and dental surfaces will be selected for ART, and the clinical protocols observed, finally, whether enough time will be given for the project to get up to speed in terms of achieving an optimal scope of activities and sustainable quality of services. Economic estimates are prone to uncertainties, too. Latin American economies remain under inflationary pressure with significant variation of inflation rates from year to year. If alternatives are unequally affected by inflation (e.g., because ART is backed up with international procurement, thus, being in part insulated from domestic price volatility, while conventional treatment programs, being linked to domestic input prices, have larger

exposure to inflation), the price factor alone may distort the CEA outcomes to the extent that would affect the choice of the best alternative.

Sensitivity analysis addresses the uncertainty issue by producing multiple estimates, each one based on a differing set of input values. Such approach excuses the researchers from the obligation to condense the CEA results into a single 'expected' outcome. The main objective here is to identify a *break-even scenario* under which the sliding of variables from 'favorable' to 'unfavorable' values reaches the point at which the aggregate value of a specific, potentially preferred alternative critically erodes and the alternative looses its edge over the 'competitors'.

Multi-variant simulations under sensitivity analysis usually require projection of variable values outside the range of the empirically tested. To ensure accuracy of such projections, it is important that extrapolations rely on meaningful baseline values recorded during the experimental part of CEA. The core set of scenarios should be based on empirical rather than on speculative evidence. To illustrate the point, it is technically possible to project the restoration survival rates for many years to come using an appropriate actuarial function. The purpose of the experimental trial is to calculate the survival rates on a representative longitudinal patient sample for the first several years (as many as the project life permits) so as to provide a solid base line for projections.

6) The concluding stage in the CEA process is the calculation of a decision index based on which the final recommendation of the most cost-effective alternative will be submitted to policy-makers. In CEA, where outcomes are not 'monetized', the integral ratings compare alternatives by cost per unit of outcome (improvement in a desirable effect or combination of effects). Such ratings are based on the cost effectiveness ratio (*C/E Ratio*) which comes in the following most general form:

$$C/E = \frac{\Delta cost}{\Delta outcome} = \frac{\Delta present\ cost}{\Delta outcome} + \frac{\Delta future\ cost}{\Delta outcome} \qquad (1)$$

The *present* discounted cost and outcome would be measured annually and cumulatively over the life of the project and would relate to spending and health gains directly linked to the targeted condition (i.e. prevention and treatment of caries).

The *future* cost and outcome component of C/E ratio may be an important issue if intervention under evaluation incurs secondary medical conditions, thus, inducing an additional prospective demand for and cost of treatment of those conditions. Likewise, if a given intervention reduces risks of other diseases, the C/E ratio, in theory, should indicate future savings, along with the present cost/outcome effect.

Change in 'secondary' demand for and cost of medical care, i.e., the demand and cost associated with other diseases but deriving from the evaluated intervention, has been taken into account in a number of CEAs. However, the literature and practice remain ambivalent regarding the extent to which theoretical concerns about future costs and

outcomes should be translated into empirical valuations. A landmark article on the subject argues that "the difficulty of assessing multiple changes in expenditures resulting from a particular medical intervention argues for including the *minimum* number of adjustments [in expenditures]" [*Meltzer, 1997: 45*]. The Panel on Cost-Effectivenes in Health and Medicine, in its recommendations on CEA methodology to the U.S. Public Health Service, left the inclusion of the future cost/benefit factor to the discretion of the analysts and, at the same time, urged them to report a sensitivity analysis if the effect of future costs is likely to be important in the particular alternatives considered [*Weinstein, 1997: 127*].

In the current study design, the 'future' component will not have a role for the following two reasons: (1) There are no consistently reported up-river/down-stream outcomes of ART and dental amalgam that produce long-term impact on the demand for other health care services. This circumstance renders irrelevant consideration of future costs and benefits related to 'secondary' health care problems. (2) Dental caries, generally speaking, has no significant bearing on disability or mortality. There would be no change, therefore, in non-health future costs and benefits in association with dental care alternatives, such as lifetime income loss or gain and additional cost of living because of lengthier life.

Returning to notation 1, the lowest *present* cost per unit of *present* outcome will be the key reason for recommending an intervention as the preferred alternative. "Present" refers to costs and outcomes observable within the time span of the project with the option for reasonable extrapolation of those observations beyond the life of PRAT. Proposed decision rule is consistent with the CEA basic principle suggesting that the greatest amount of good can be derived from a given budget by allocating funds to those activities which generate the greatest beneficial outcome per unit of expenditure or require the lowest expenditure per unit of beneficial outcome.

2. CEA TECHNICAL DESIGN AND PROTOCOL

The structure of this chapter reflects a multifaceted goal and format of the current report. As was stated in the Introduction, the report is not limited to the research protocol in its formal definition but offers pieces of evidence, assumptions, and other input information in execution of the protocol. These inputs are considered tentative and are open for verification, refinement, and revision in the course of the proposed study. In many cases, however, they will provide important shortcuts for the study activities, thus, saving time and effort to the PRAT project.

Consistent with the above, the description of each protocol step will include several or all of the following:

- Rationale,
- Suggested approach,
- Methods,
- Activities, required data, worksheets.

2.1 Statement of Problem, Need and Opportunity

Prior to designing a CEA, there should be a clear indication that the proposed innovative intervention is viewed as potentially instrumental in responding to the need for resolving a serious problem. A problem/need/opportunity statement, thus, is the starting point of the study design.

The following statement reflects the views of the PRAT Project proponents and would be shared by health policy strategists of the participating countries:

"Dental caries is the most common disease among Latin American and Caribbean (LAC) children. It affects approximately 90% of the 5- to 7-year-olds. The World Health Organization has established as objective for the year 2000 a mean DMF-T_{12} of 3.0 or lower. In 16 out of 23 LAC countries which reported dental health statistics in the past 10 years, the DMF-T_{12} score is higher. Of particular concern is the large share of untreated decayed teeth. The D component of the DMF-T_{12} total exceeds 50% in all LAC countries as compared with 20-27% in the United States. Resources for delivery of oral health care services are limited, and curative care is restricted to those with the ability to pay or those with access to social insurance schemes. It is, however, the socially disadvantaged populations (low-income, poorly educated, and geographically isolated) who, on the one hand, suffer from more prevalent and severe dental caries, on the other hand, are confined to the most insufficient and inappropriate care [*IDB, 1998: 3,5,6*]. In view of a significant socioeconomic mismatch between demand for and supply of dental services, the adverse situation with dental health is unlikely to improve with traditional treatment regimens of limited affordability under public dental health coverage. Therefore, there is an important

need for clinically effective and cost efficient restorative treatments that could reach out to the currently disenfranchised populations.

An innovative approach that brings safe and effective care for dental decay to communities without the need for expensive dental equipment is *atraumatic restorative treatment* (ART). Under this approach dental decay is removed solely with hand instruments and the cavity is filled with an adhesive, tooth colored material which releases fluoride. This material is also used to seal caries prone tooth surfaces. Thus ART is considered a combined preventive and restorative procedure to control dental decay. This means that restorative care is no longer restricted to the dental clinic setting but can be delivered virtually anywhere. Even where traditional restorative care is available, this approach brings care closer to all" [*WHO, 1998: 2*].

The above proposed statement should be reviewed and with necessary revisions cosigned by the PRAT Project leader and the national, regional and community health coordinators of each country pilot site. Alternatively, it can be signed by all PRAT Project participants as a document based on international consensus. The statement may be entitled "Memorandum of Understanding" or "Memorandum of Commitment". The first two paragraphs may be customized for a specific country to reflect the dissatisfactory dental health status of its population and the scope of inequality in access to conventional restorative services. Another paragraph should be added of the following tentative contents:

"Cognizant of the clinical and social potential of ART, the signatories of this Memorandum commit their political support and administrative resources to the activities planned under PRAT project in {*community/region names*} aiming to strengthen organizational infrastructure, professional skills and public support for the practice of ART, to pilot-test this treatment method, evaluate its interim outcomes and longer-term potential, and prepare conditions for its sustainable application on the national scale".

A sample Memorandum of Commitment preceded by the Letter to a Signatory are attached in *Annex 1*. One month may be needed for formal communications between the PRAT Project Coordinator team and signatories in specific countries. During this time period, appropriate customization and revision of the document will be carried out. A formal signing ceremony is advisable. It can be arranged at the regional level with the national health ministers of the participating nations and the PRAT Project leader putting their signatures in conclusion of the signing process and to officially kick off the project. Alternatively, the ceremony can be held in each country, with a more comprehensive attendance by the in-country participants.

2.2 Statement of Alternatives and Cost-Effectiveness Measures

2.2.1 Basic Approach

The basic approach to this CEA stems from the assumption that glass ionomer will be used, primarily, for restorations but also for sealants and will be compared with a conventional alternative. It is broadly agreed that amalgam-based treatment would represent such alternative. By distinguishing amalgam the study designers decide that other traditional dental interventions have to be ignored. Understandably, if the number of alternatives to be evaluated increases beyond two, the PRAT evaluation component may overwhelm the project budget and divert ground resources from the project's clinical main stream. Yet, an *a priori* restriction on the study design ("amalgam and nothing but amalgam") indicates loss of objectivity and may distort findings and policy recommendations stemming from CEA.

This section proposes the logic of reconciliation of the existing resource limits on the study design, on the one hand, and objectivity concerns, on the other.

There is a strong case for dental amalgam as a plenipotentiary representative of conventional dental treatments. It remains the most frequently used material for restoring decayed teeth. Out of 200 million dental restorations performed in the United States in 1990, 96 million were dental amalgam procedures [*Jacobson, 1997: 208*]. With over a century-long experience with amalgam, reinforced along the way with significant improvements in the technology, amalgam will remain a viable option for dozens of millions of patients around the world.

Yet, there are also composite materials, gold foil, gold alloy, metal-ceramic crowns and, perhaps, other alternatives. Importantly from the standpoint of the PRAT target population, *pediatric* dentists in the United States are relying more on composites than amalgam to treat their patients [*Jacobson, 1997: 208*]. Patient choice in Scandinavia steers dental practice away from amalgam and towards resin composites as restorative materials [*Widström, 1997: 202*]. In many countries there is a marked overall decline in the use of amalgam.

What should a health economist in charge of the CEA design make out of the technologic diversity and rapid change in dental practice? -- Evidently, the choice of the material stems from the tooth status, size of lesion, type of surface, affordability and, increasingly, safety concerns regarding amalgam. The interplay of all listed factors emphasizes the complementarity of alternative methods: decayed, missing and filled teeth require different treatments and materials. It is impossible to rely exclusively on any one technique in managing dental health at the community level. Similarly, it is impossible to disentangle contribution of particular techniques to the overall change of DMFT scores, unless multiple experimental clinical studies are conducted in parallel, each one focused on a particular method and material.

Even two actively managed samples (e.g., one for ART and another one for amalgam) is quite a challenging option for this study, since the philosophy of the PRAT Project is that of implementation of the ART method, not its testing. Massive empirical evidence behind ART speaks for itself and can hardly be challenged with an additional trial. CEA comes forward to evaluate not the strength of ART but the correctness of its application in terms of compliance among caregivers of a specific country with the ART planning, organizational and clinical requirements. The basic assumption is that if ART does not withstand the evaluation, it will mean that the quality of ART care might have been compromised. If it yields results superior to conventional alternatives, this means the ART delivered on the expectations because its application was adequate.

With the aforementioned considerations in mind, the designers and sponsors of PRAT decided, nevertheless, to invest in provision of conventional treatments as well, to ensure maximum accuracy of comparative evaluation of ART and amalgam-based strategies of containing caries.

2.2.2 Dilemma 1: Implementation of ART Versus No Change

The CEA will be conducted according to one of the two or both approaches described as Dilemma 1 and Dilemma 2 in the current section of the Report.

If geared to the first dilemma, the CEA will not resort to a dual sample-based experimental clinical trial involving an actively managed 'ART intervention sample' and an actively managed 'amalgam intervention sample'. Instead, it will be conducted alongside ART implementation and will be based on *a longitudinal community field trial involving an ART intervention sample and a non-ART control sample*. Both samples will be comprised of a similar number of children with the baseline sample mean characteristics as close as possible in order to control for background factors affecting dental health status, such as age, income, education, place of residence. Mean DMFT score must also be close in both groups at the start of the project.

The ART sample will be considered as intervention sample and will be managed in an active mode:

(1) D or DM score will be measured at the beginning of the project and annually as the proxy of ART outcome.
(2) Children will be treated with glass ionomer restorations and sealants where appropriate, in the course of the PRAT Project. Treatment will include placement of primary restorations and sealants and replacement of defective (lost) restorations and sealants identified through annual dental examinations.
(3) Same children may be treated with amalgam and other materials outside the PRAT Project. Such conventional treatments will be recorded under PRAT-sponsored annual examinations. If conventional treatments are medically needed but not

provided, they will be recorded all the same as unmet need, i.e., by the number of decayed teeth requiring restorations with materials other than glass ionomer.

(4) Total cost associated with ART will be accounted annually.

(5) Integral D (DM) increments will be determined in annual and cumulative terms for the life of the PRAT project. Along with aggregate measurements, increments will be tracked for sub-samples, i.e., grouped by year of age (separately for 7-year-olds, 8-year-olds, etc.), and by quartile of baseline D (DM) score.

(6) Reported DM increments will be adjusted *upward* to allow for the increments that did not occur because of conventional treatments provided to the intervention group on teeth not medically indicated for ART or bypassed by ART for any other reason. Thus adjusted D (DM) increments will be adjusted once again, this time *downward* to allow for the increments that occurred because conventional treatments were not provided on teeth not medically indicated for ART. The resulting D (DM) increments will be attributable exclusively to ART.

The non-ART sample, as was initially proposed, should have been managed in a passive mode in the sense that no treatment would have been provided to this group under PRAT[2]. Later, at the request of IDB, it was decided that amalgam-based treatments would be provided to the control group with the costs covered in part by the locally available third-party sources, and in part by PRAT. In any case, the control group will entail the following activities:

(1) D (DM) score will be measured at the beginning of the project and annually.

(2) Conventional treatments of decayed teeth outside PRAT will be recorded.

(3) Unit cost of key conventional services (on decayed teeth) will be estimated by PRAT experts at production cost or charge price.

(4) Annual and cumulative conventional treatment costs will be accounted by multiplying unit costs of each conventional treatment by the number of treatments provided.

(5) DM increments will be accounted annually and cumulatively.

Based on the aforementioned activities the following incremental cost-effectiveness ratio will be calculated:

$$\frac{(C_1 - C_2)}{E_2 - E_1} = \frac{\Delta C}{\Delta E} \qquad (2)$$

where,

C_1 is the total cost associated with ART procedures in the intervention group;
C_2 is the total cost of conventional treatments provided to the control group;

[2] To mitigate the sentiment of unfairness among families of children included in the control sample and not receiving treatment, unlike their schoolmates in the intervention group, the PRAT Project coordinators may want to consider providing such children with a dental hygiene consultation and a dental self-care kit (with a moderate stock of renewable supplies) every time they attend annual dental examination. Also, PRAT personnel should refer children in the control group to a local provider for conventional restoration treatment.

E_2 is D (DM) increment in control group;
E_1 is ART-related D (DM) increment in intervention group, such that

$$E_1 = E_{Rec.} + E_{Conv.prov.} - E_{Conv.not\ prov.} \qquad (3)$$

where,

E_{Rec} is the resulting D (DM) increment in intervention group;
$E_{Conv.prov.}$ is a D (DM) increment that could have occurred, had conventional treatments not been provided to ART intervention group;
$E_{Conv.not\ prov}$ is a D (DM) increment that would not have occurred had conventional treatments been provided to intervention group as the most appropriate treatment option.

The incremental cost-effectiveness ratio in notation (2) measures the additional costs of the ART program per unit of additional effect incurred by the program. The ratio expresses a cost of ART per D (DM) averted. The dilemma evaluated by this ratio should be formulated as **"The implementation of ART versus continuing with traditional methods at their historical level of accessibility".** "The implementation of ART versus changing nothing" – is another interpretation of such dilemma. The expected result by the end of the trial would be a higher cost and a lower D (DM) increment for intervention group than for control group. The CEA, thus, would indicate that the cost of ART is justified by an observable positive outcome.

2.2.3 Dilemma 2: Implementation of ART Versus Increasing Supply of Conventional Treatments

Evaluation of Dilemma 1 would lead to the conclusion that ART is a good clinical option. However, it will not allow to make an unambiguous judgment as to whether ART constitutes the best use of limited community resources. Such judgment will require estimation of an incremental cost-effectiveness ratio for the conventional treatment and its comparison with similar ratio for ART. Verbally the dilemma will be: **"The implementation of ART versus expansion of conventional restorations (presumably, amalgam-based) to the level of need".** The following notation gives algebraic interpretation of this alternative:

$$\frac{C_1}{\sum_{a_0}^{a_0+t}(E_0 - E_1)^{t_0+t}} \vee \frac{C_2}{\sum_{a_0}^{a_0+t}(E_0 - E_2)^{t_0+t}} \qquad (3)$$

where,

C_1 - the cost of ART in intervention group;
C_2 - the cost of conventional treatment if provided at the level of need in control

group;

E_0^t - baseline D (DM) scores measured for all ages involved in PRAT at the beginning of the project;

a_0 - age at the beginning of reporting period;

t_0 - year of project at the beginning of reporting period;

t - year of project at the end of reporting period;

E_1 - D (DM) score measured in intervention (ART) group for ages a_0 to a_0+t at the end of reporting period;

E_2 - D (DM) score measured in control (conventional) group for age a_0+t at the end of reporting period.

The denominator in the left and right sides of notation (3) presents for each reporting period a sum of age-specific increments in DM scores. All such increments are determined for a time period selected within the time line of the project and chosen as the reporting period. This can be the first year ($t_0=0$, $t=1$); the first two years ($t_0=0$, $t=2$), the second year ($t_0=1$, $t=2$), the second and third years ($t_0=1$, $t=3$), etc. The main line of reporting will be annual and for the entire life of the project. Each age group includes children that reached respective age by the end of the reporting period. The increment is measured between D (DM) score of the respective age prior to the project and D (DM) score of the same age achieved by the end of the reporting period as a result of PRAT activities (E_1) in the intervention group and in the event of expanding conventional treatments to the level of need identified in control group (E_2).

Sample management plan will be the same as for the evaluation of Dilemma 1, except that item 4 in the case of control group will entail multiplication of unit costs per number of procedures determined by currently unmet demand. Unit costs will be geared to unmet demand too, which will probably make them higher than for office-based treatments. Reaching out to currently under-served communities would entail renting mobile units and additional time to be spent in travel. If patients commute to stationary dental offices to receive amalgam restorations, the transportation cost and opportunity cost of time in travel will have to be factored in the cost estimation.

Prior to providing additional explanations on Dilemma 2, let us outline the logic of and propose a decision on the age limits of the study sample. It is assumed that children will be the target population of the PRAT Project. ART will be provided at schools. Consequently, school age should be viewed as broadly defined age range. Age 12 is an important benchmark in dental health statistics. The alternatives under evaluation should be able to reveal their potential if applied to patients moving towards that age. Also, for the sake of sample stability (i.e. to minimize the sample shrinkage) during the evaluation period, the sample should be geared to the school age when compulsory school attendance is observed more or less strictly. In summary, the secondary school age bracket of 7 to 12 years should be considered as a viable age interval for the intervention and study sub-samples.

Chart 2 serves as a guide for more specific definition of the age pool to be targeted with ART. At the beginning of PRAT there are 6 age groups in the pool: 7, 8, 9, 10, 11 and 12 year-olds. 12 year-olds finish school before the project starts or before it gets to the first interim annual evaluation. 11 year-olds will drop out at the end of the 1st year of the project and 10 year-olds after the second year of the project. The sample may include ages from 7 to 11 years old. It will experience attrition due to the exiting of 10 and 11 year-olds. To keep the sample steady, which is highly recommendable, it should involve ages from 7 to 9 years as of the beginning of PRAT. All these age cohorts can be kept in the sample throughout the designated project life of 3 years. Such age composition of the sample corresponds to the area within the diamond on Chart 2. It should be emphasized that D (DM) scoring will also involve ages 10 to 12.

If the proposed age design of the sample is accepted, D (DM) integral increments will be calculated as follows:

Beginning of PRAT:

At the beginning of PRAT baseline D (DM) scores (E_0) will be recorded for ages 7 to 12.

First year:

1) At the end of the first year D (DM) scores will be recorded in all three age groups involved in the project. At the beginning of PRAT those children were 7 to 9 year-olds. During the first year they grew up to the age of 8 to 10 years. For intervention (ART) sample the newly recorded D (DM) scores may be denoted as: E_1^8, E_1^9, E_1^{10}. For control (conventional) sample those will be: E_2^8, E_2^9, E_2^{10}.

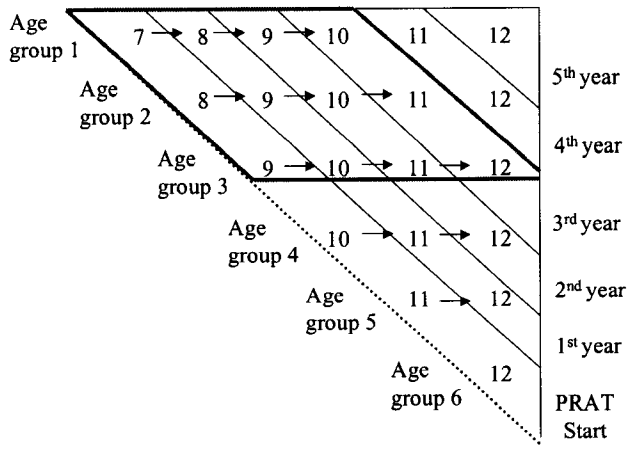

Chart 2.
PRAT Project Time Line and Age Structure of the Sample

2) Age-specific 'expected' D (DM) increments will be calculated as:

$$E_0^8 - E_0^7 = \Delta_0^1;$$
$$E_0^9 - E_0^8 = \Delta_0^2;$$
$$E_0^{10} - E_0^9 = \Delta_0^3;$$

3) Integral 'expected' D (DM) increment will be calculated as the total of age-specific increments:

$$E_0^1 = \Delta_0^1 + \Delta_0^1 + \Delta_0^3$$

4) Age-specific actual D (DM) increments will be calculated for intervention group as:

$$E_1^8 - E_0^7 = \Delta_1^1;$$
$$E_1^9 - E_0^8 = \Delta_1^2;$$
$$E_1^{10} - E_0^9 = \Delta_1^3;$$

For control group the notation, respectively, is:

$$E_2^8 - E_0^7 = \Delta_2^1;$$
$$E_2^9 - E_0^8 = \Delta_2^2;$$
$$E_2^{10} - E_0^9 = \Delta_2^3;$$

5) Integral actual D (DM) increment for intervention group will be calculated as the total of age-specific actual increments:

$$E_1^1 = \Delta_1^1 + \Delta_1^2 + \Delta_1^3.$$

For control group, respectively:

$$E_2^1 = \Delta_2^1 + \Delta_2^2 + \Delta_2^3.$$

6) By deducting expected D (DM) increment (based on baseline values) from actual D (DM) increments, we produce D (DM) avoided, which is a relevant measure of effect from ART (in intervention group) and from conventional treatments (in control group). Hence:

$$E_0^1 - E_1^1 = \Delta E_1^1$$
$$E_0^1 - E_2^1 = \Delta E_2^1$$

7) These values will be compared, then, with the costs associated with ART and conventional treatments to produce two incremental cost-effectiveness ratios (see notation (3). Their comparison will answer the question which program was more effective during the first year of PRAT.

Following the above described algorithm, D (DM) increments and C/E ratios may be calculated for any other year, sub-period and entire period of the PRAT Project. Furthermore, baseline and actual D (DM) scores and increments may be extrapolated by using an appropriate actuarial function, thus, opening way to the calculation of projected D (DM) increments. If those projections can be matched with projected costs of ART and conventional treatments, the cost-effectiveness of both alternatives would be estimated outside the PRAT life span, in a perspective of 5 to 10 years. Survival rates of ART restorations would be one of the key factors affecting ART annualized costs in a mid-term and long-range perspective.

2.3 Description of Alternatives and Expected Benefits

Three treatment techniques are described in this section. *Glass ionomer restorations* and *glass ionomer sealants* relate to ART and form the innovative alternative in the current CEA context. *Amalgam restorations* constitute the conventional alternative. The current step of the research protocol requires that the following narrative be reviewed, expanded, revised, or otherwise refined by the PRAT leaders and country coordinators in order to reflect a consensus-based understanding of treatment objectives and expected benefits.

ART restorative treatment consists of removing carious tooth structures with hand instruments only and restoring the prepared cavity with an adhesive filling material such as a glass ionomer. ART requires no electrically driven equipment and is consistent with the modern concept of restorative care of minimal intervention. Because the purpose of ART is to remove only demineralized and insensitive outer carious dentine, pain often does not occur at all or can be kept to a minimum. Thus, fear of dental procedures is reduced. The advantageous properties of glass ionomer, including fluoride release, which has a caries preventive effect, chemical bonding to tooth structure and biocompatibility with oral tissues make it a potentially suitable restorative material. ART techniques may serve as the basis for oral health care programs for use in outreach situations, i.e., in the rural areas where no conventional oral health services are available. [*Frencken et al., 1998 (1): 3; Frencken et al., 1998 (2): 119-120; IDB, 1998: 8; Phantumvanit et al., 1996: 141*]

Besides restorations the glass ionomer is used for sealing pits and fissures adjacent to the restoration and for sealing caries-prone surfaces of other teeth. Based on epidemiologic evidence, sealants are indicated for children and young adults. Their median retention rate summarized from two dozens of studies is 83% in one year, 69% in 3 year, and 68% in 10 year. More importantly, sealants do stop progression of caries. [*Weintraub, 1989: 317,320*]

Dental amalgam, a compound of mercury and silver-based alloys, remains the most widely used as a dental restorative material. Amalgam restorations are durable and cost-effective. They are, however, not tooth-colored. While much research has been devoted to the development of dental restorative materials, there is currently no direct filling material that has the wide indications for use, ease of handling and good physical properties of dental amalgam. [*WHO, 1997: xi*]

Comparative economic evaluation of both alternatives is based on such key factors as their ability to control caries progression, unit cost per restoration, longevity of restorations and sealants, and accessibility for patients with high risk of caries. The ART effectiveness in controlling caries progression, even though found visible in limited studies, is still subject to study [*Frencken J., 1998 (1): 7*]. Median longevity estimated from a variety of published studies is considered 8-12 years for amalgam and 5 years for glass ionomer. [*Jacobson, 1997: 215*] A predominant opinion is that ART is less expensive than amalgam since it is less labor-intensive and has no critical dependence on costly environment of a specialized dental office. If supply of amalgam-based treatments

is to be increased up to the level of demand from disadvantaged populations, their cost would grow by the cost of mobile units, thus, making conventional care even more expensive. At the same time, there is a warning from the advocates of amalgam, alleging that "The restorative materials currently available as alternatives to dental amalgam significantly increase the cost of dental care" [*WHO, 1997: xi*]. Overall, the utilization of amalgam is declining in many countries on concerns of safety and as new technologies, particularly, those based on composite materials, become available.

Apparently, *comparative* evidence on amalgam and its ART alternatives is limited and not without ambiguity. Each country would have to verify this evidence on the basis of its own evaluations, customized for the national setup in service delivery and dental health policy agenda.

2.4 Identification of Costs

The costs of PRAT Project, on the one hand, and activities related to conventional treatments, on the other, will depend on the following three factors:

- one-time costs;
- recurrent costs per treatment;
- clinical volume, i.e., planned number of treatments.

These are costs in their crude estimation. They will be subject to refinement through discounting dependent on how project-wide costs will be distributed over time. Discounting will be reviewed as the next step of the CEA protocol.

Costs of all types must be calculated on an annual basis. Annual costs and volume of clinical and other activities may be accounted by school year, given that activities are likely to be stalled during summer vacations. Annual reporting for evaluation purposes should be carried out 1-3 months ahead of the PRAT internal reporting, such that PRAT team could include in its report findings from the latest evaluation.

2.4.1 One-Time Costs

One-time costs reflect the initial investment and other non-recurrent costs of the program. Such costs gravitate towards the beginning of the project but are not necessarily limited to its first year. Almost always, however, these costs bear heavily on the initial year of a new program. If one-time costs are factored in the annual cost-benefit ratios, they are likely to render the project ineffective at the initial stage of its implementation. Following years, by contrast, would feature dramatic improvement in project performance. Alternatively, start-up costs may be included only in project-wide C/E estimation, thus, being spread across all years of project implementation. The underlying assumption here is that one-time costs are not loaded onto recurrent costs and are not charged to unit costs of dental services provided by the program.

In the PRAT context, the following expenditures would be classified into one-time costs of the project's first year:

Demonstration:

- Procurement of equipment and furniture.

Training:

- National workshops on PRAT to train the trainers;
- Workshops on PRAT management for in-country dentists;
- Design and startup of economic evaluation studies;
- Training and calibration of examiners;

Information Support and Evaluation:

- Data management and analysis in their part relating to the setup of computer equipment, design, testing and installation of databases, and other predominantly one-time activities.

Dissemination:

- Preparation, reproduction and distribution of educational materials.

Listed items would account for estimated 25-30 percent of the annual budget. In subsequent years the share of one-time costs would decline to 15%.

2.4.2 Recurrent Costs: Materials, Labor, Overhead

Recurrent costs cover operating and maintenance cost of the program activities. Unlike one-time costs, recurrent costs are charged to dental services and, therefore, can be transformed into unit costs per restoration or sealant. Recurrent costs are comprised of direct and overhead costs. Direct costs include: (1) direct tools, (2) direct materials and supplies; (3) direct labor.

Direct costs may be calculated top-down and bottom-up. Top-down approach in the upcoming CEA study may be carried out simply by subtracting one-time costs from the PRAT proposed budget. Whatever is not classified as "one-time" will be "recurrent". Unit costs, then, would depend on the number of provided ART and needed amalgam-based procedures which in turn will derive from the number of subjects in the intervention and control samples. Such number should be large enough to create economies of scale and bring the unit costs down to a realistic level.

Table 1. Essential List of ART Tools and Materials Coordinated with the Clinical Protocol for Glass Ionomer Restoration (a Prototype for Discussion)

Clinical Protocol	Tools	Materials and Supplies
1. Isolate the tooth to be treated.	Mouth mirror	
2. Remove plaque from the tooth surface with a wet cotton wool pellet.		Cotton rolls and cotton wool pellets
3. If necessary, make the entrance of the cavity wider with a dental hatchet.	Hatchet (10-6-12)	
4. Remove the outer carious dentine with excavators starting at the enamel-dentine junction and then further centrally.	Spoon excavators: small and medium	
5. Break off unsupported thin enamel with the hatchet. Make sure that the enamel does not contain any carious spots.	Hatchet	
6. Clean the cavity with wet and dry cotton wool pellets.		Cotton wool pellets
7. Clean the occlusal surface. All pits and fissures should be clear of plaque and debris.		
8. If the glass ionomer liquid is used as a dentine conditioner, apply one drop of liquid on a slab or pad.	Glass slabs	
9. Dip a moist cotton wool pellet in the conditioner and clean both the cavity and the adjacent pits and fissures for 10 to 15 seconds.		Dentine conditioner, cotton wool pellets
10. Wash the cavity and fissures immediately at least twice with cotton wool pellets dipped in water.		Cotton wool pellets
11. Dry the surfaces with dry cotton wool pellets.		Cotton wool pellets
12. Mix glass ionomer according to manufacturer's instructions.		Glass ionomer restorative material
13. Insert mixture in small amounts into cavity and adjacent fissures, using the blunt blade of the applier/carver. Use the round surface of a medium excavator to push the mixture into deeper parts of the cavity and under any overhang.	Carver/applier (Ash 6 special), medium excavator	
14. Rub some petroleum jelly on gloved index finger.		Gloves, petroleum jelly
15. Place the index finger on the restorative material, press and remove the finger sideways after a few seconds.		
16. Remove visible excess of glass ionomer with a medium or large excavator.	Medium or large excavator	
17. Wait till the material feels hard whilst keeping the tooth dry.		
18. Check the bite using articulation paper and adjust height of the restoration with the applier/carver.	Carver/applier	Articulation paper
19. Apply new layer of petroleum jelly or varnish.		Petroleum jelly/varnish
20. Ask the patient not to eat for at least 1 hour.		

CEA, however, should be used as an opportunity to conduct a more accurate and, therefore, tedious job of calculating direct costs bottom-up, i.e., aggregating the itemized costs of production inputs and activities into an integral cost of ART restoration or sealant. Itemization of cost items, thus, becomes the initial step of direct costing.

Tools, Materials and Supplies

Enumeration of costs stems from the work flow chart or operations list. An ART restoration clinical protocol [*Frencken et al., 1998 (1): 3*] displayed in the left column of Table 1 serves as an operations list and a guide for the development of the list of hand tools and materials presented in the right column of the same table. This step of the study protocol requires careful evaluation of the clinical protocol of the ART approach and verification of the list of inputs required by that protocol.

Some other tools (explorer and a pair of tweezer) and materials (wedges and plastic strip) are claimed to be necessary although were not mentioned in the above clinical protocol.

Labor

Direct labor costs depend on the following factors: (1) occupational add skill category and number of caregivers; (2) time required for treatment; (3) occupational level of evaluator (assuming it is not the same person as operator); (4) time required per person for annual examination.

Operators

In the community projects analogous to PRAT there was an important experience of employing mid-level dental personnel: senior and junior dental therapists in Zimbabwe (1994-97) and dental nurses in Thailand (1989-92). In the Zimbabwe study, there was no statistically significant difference observed in the survival percentage of ART restorations between dentists, senior and junior dental therapists. However, further analysis comparing one of the dentists and one of the junior dental therapists revealed a statistically significant difference for ART restorations ($P = 0.02$). It indicated that the senior, more experienced dentist performed significantly better than the junior, less experienced dental therapist [*Frencken et al., 1998 (1): 6*]. In the Thailand study, the researchers concluded that the survival of ART restorations was not at all affected by a provider type. Results were similar for the dentist and dental nurses [*Phantumvanit et al., 1996*].

Interpretation of the above findings by a non-clinician suggests caution. If quality is a top priority, ART restorations should be performed by dentists. A viable approach would be to entrust 50 percent of restorations to doctors and 50 percent to dental nurses. Such mix would secure acceptably high average quality and at the same time would generate empirical evidence on comparative performance of dentists versus mid-level dental professionals. Before allowing nurses in the PRAT Project, political and cultural

appropriateness of their involvement in a restorative treatment should be verified with the health administrators and parents of prospective patients.

As regards glass ionomer sealants, there is enough reason to conclude that those can be placed by mid-level medical and trained community personnel. Trained schoolteachers could be a "low-end" alternative under what we consider as a somewhat relaxed approach. There are studies asserting that no difference was found "in the effectiveness of sealants placed by a dentist or by a trained schoolteacher in preventing dental caries." [*Songpaisan et al., 1995: 28*]

An indisputable advantage of ART techniques is that they allow to save on chairside assistance, regardless of what the professional level of operator is.

Treatment Time

The following mean characteristics could be used as a benchmark for planning the PRAT budget and sample size, and assessing labor cost: 19.8 min per restoration (15.7 ÷ 24.4 min by operator) and 10.7 min. per sealant (9.2 ÷ 15.1 min by operator). [*Frencken et al., 1998 (1): 6*]

Evaluators and Examination Time

Examiners, optimally, should be independent from operators. They can be mid-level dental professionals taken through training and, most importantly, calibration. Examination time can be estimated from international practice or measured during workshops planned for examiners during the first year of PRAT.

Overhead Cost

Overhead cost includes all indirect operating costs. These costs range from supervisor's salaries and salaries of personnel shared by the whole project, to space and utilities. The following line items on the PRAT proposed budget may be classified into overhead expenses:

- Project manager,
- In-country personnel responsible for demonstration and evaluation of ART,
- Regional project coordinator(s),
- Consultant's travel,
- Data management and analysis,
- Recurrent dissemination activities, i.e., newsletters, reports, etc.

Presumably, general and administrative support would be built in the rates of key management personnel included in the above displayed list. This has to be verified, however. There is little doubt that such support will be available in the expatriate segment of the project. At the same time, it may be unavailable in the field unless separately funded.

There is a question regarding space and utilities. If ART procedures and examinations are carried out in school buildings, PRAT may not be charged for space rent, heat, water or electricity. These costs may be omitted, therefore, as non-existent at the experimental stage of ART implementation. If the project leaders want to consider the costs of *sustainable* delivery of dental care in the aftermath of PRAT, respective costs should be factored in, even though they may be reimbursed from the school budgets.

The approach to cost identification proposed in this section was discussed and detailed in its application to ART activities. It should be clear, nevertheless, that the same algorithm is applicable to the amalgam-based treatment alternative.

The following issues should be reiterated in the context of cost identification for conventional dental care. In order to include amalgam restorations in CEA as a competitive alternative to ART, it must be assumed that amalgam is available at the same (need-based) level of supply as ART. Amalgam, therefore, should be brought to currently under-served local communities. Baseline study on the CEA sample will include estimation of the currently existing supply gap and to what extent it will be filled by dental clinics and practices on the basis of their office operation. The outreach component will also be identified. To add this component, the one-time cost of procuring and equipping mobile units will have to be factored in. Staffing and operating such units will add to recurrent costs of conventional dental care. The opportunity cost of time lost to travel and travel expenses will be estimated in order to account for the cost to patient of *office-based* amalgam restorations.

Other than that, costing of amalgam treatments can be geared to actual production costs and calculated by in-country experts. As an alternative to production costs, charge-based costs may be estimated. Those would reflect diverse rate schedules in various health financing components of the national dental care system. If conventional care is expected from more than one component (e.g., both private and health insurance) charge-based costs may require adjustment for cross-sectional compatibility. Eventually, costs of amalgam-based care would be increased by a weighted average margin reflecting the actual mix of not-for-profit and for-profit activities in conventional dental care.

2.5 Sampling

Costs will critically depend on the number of treatments to be provided on the basis of ART and amalgam, and identified as unmet need if conventional care fails to reach the entire the community. This, in turn, will depend on the population to be served (sample size) and the number of procedures per capita (per sample subject). The sample size will be defined in one of the following two ways: (1) On the basis of PRAT pre-assessed budget; (2) By means of statistical sampling. Eventually, the output from both approaches would be reconciled to make the sample accurate yet affordable.

2.5.1 Sampling Based on Predetermined Budget

It may well be that the PRAT budget will be predetermined prior to the estimation of the sample size: some 'benchmark budget' would be spoken of and pre-approved, and no additional funding should be expected. Within this budget as many children should be provided with care as possible. The patient pool should be maximized in order to produce the highest socioeconomic impact possible and to keep unit costs (per capita, per ART procedure) on a reasonably low level. The latter is important for the correct estimation of the ART cost-effectiveness potential. It will be a pity if a complex CEA results in an inferior cost-effectiveness ratio for ART simply because of PRAT internal inefficiency: heavy sunk costs did not pay off due to insufficient clinical volume.

In this situation, the number of served children (N) will be directly proportionate to the PRAT budget (B) and inverse to the estimated cost per child included in the PRAT sample. Per capita expenditure will depend on the projected baseline dental health status score D_0, restoration survival and sealant retention rates (S), and cost per treatment (C):

$$N = f(B,\ 1/D_0,\ S,\ 1/C) \qquad (4)$$

Function (4) may be transformed in the following equation:

$$N = \frac{B}{CP} \qquad (5)$$

where P is the total per capita number of placements.

P consists of initial placements and replacements. The total number of placements grows in time according to the following schedule:

Table 2. Accumulation of Dental Placements by Year of Project

(t_0) Initial placements	(t_1) Replacements in one year	(t_2) Replacements in two years	(t_3) Replacements in three years
D_0 +	$D_0(1-S_1)$ +	$D_0(S_1-S_2)$ +	$D_0(S_2-S_3)$ +
		$D_0(1-S_1)(1-S_1)$ +	$D_0(1-S_1)^2(S_1-S_2)$ +
			$D_0(S_1-S_2)(1-S_1)$.

This formula-schedule was consistently applied in the estimation of per capita number of ART restorations (see lines 1 – 12 of Table 3). Possible sources of inaccuracy are as follows: (1) Not all decayed teeth may be indicated for ART restorations; (2) Survival rates differ considerably across various studies. The rates entered in Table 3 (e.g., 67% in three years), apparently, is a low-extreme estimation. In the Zimbabwean study it amounts to 85% [*Frencken et al., 1998 (2): 149*]. (3) Not all failures would be replaced with new ART restorations. (4) Of critical importance is the baseline D score. It is likely to be lower for ages 7 to 9 (on which PRAT, supposedly, will be targeted) than for age 12

entered into calculations in Table 3. All four considerations would drive the per capita number of placements somewhat lower.

The number of sealants was estimated differently than the number of restorations, since it is not quite clear at this point how the need for sealants is linked to the D component of baseline DMFT score. The need-based number of sealants was determined according to the number of initially placed sealants in percent of initially placed restorations (25%) borrowed for our estimation from the Zimbabwe 1994-97 study report. The need for replacement of sealants was ignored since the retention rate for the first three years is very high: 96.3% [*Frencken et al., 1998 (1): 5*]. The thus determined 'nominal' number of needed sealants was transformed into restoration cost equivalence terms by relating the

Table 3. Estimation of Need for ART Procedures Per Sample Subject

Line #	Indicators	Uruguay	Ecuador	Panama	Data Source
1	DMFT-12	4.10	2.94	3.61	IDB, 1998: 5 (Table 1)
2	%D	60.98	83.05	72.02	IDB, 1998: 6 (Table 2); for Panama = arithmetic mean of Uruguay and Ecuador
3	D score	2.50	2.44	2.60	
4	Cumulative survival rates for one-surface ART restorations (children <13 years old) CI = 95%				Phantumvanit, 1996:142 (the Thailand study)
5	In 1 year ((S_1)	0.92	0.92	0.92	
6	In 2 year (S_2)	0.80	0.80	0.80	
7	In 3 years (S_3)	0.67	0.67	0.67	
8	Initial placements (D_0)	2.50	2.44	2.60	=D score
9	Replacements in 1 year	0.20	0.20	0.21	See the t_1 column of Table 2
10	Replacements in 2 years	0.32	0.31	0.33	See the t_2 column of Table 2
11	Replacements in 3 years	0.35	0.34	0.36	See the t_3 column of Table 2
12	***TOTAL RESTORATIONS***	***3.37***	***3.29***	***3.50***	=sum (lines 9 to 12)
13	Number of sealants in % of restorations	25%	25%	25%	Frencken et al., 1998 (1): 5 (the Zimbabwe study)
14	Time per restoration, min.	19.8	19.8	19.8	Frencken et al., 1998 (1): 6 (the Zimbabwe study)
15	Time per sealant, min.	10.7	10.7	10.7	Frencken et al., 1998 (1): 6 (the Zimbabwe study)
16	Time-adjusted cost of a sealant in % of a restoration	54.0%	54.0%	54.0%	=line 16 / line 15
17	***TOTAL SEALANTS (in restoration cost equvalent terms)***	***0.45***	***0.44***	***0.47***	=line 13 x line 14 x line 17
18	**GRAND TOTAL (restorations & sealants)**	**3.82**	**3.73**	**3.97**	=line 13 + line 18

the time used per sealant to the time per restoration. These operations are reflected in lines 13 to 17 of Table 3. Finally, the grand total of per capita restorations and cost-adjusted sealants was calculated in line 18 of Table 3.

The proposed assessment needs to be scrutinized by the CEA team for validity of input information and clinical assumptions.

Chart 2 provides a summary and additional insights into the estimation of sample size based on predetermined project budget. It is important to keep in mind that the study sample will consist of two sub-samples: intervention group and control group. Children in the intervention group will undergo annual dental examinations and will receive ART procedures based on need, largely, determined by the number of decayed teeth at the

point of examination. Children in control group will not get treatment but will be taken

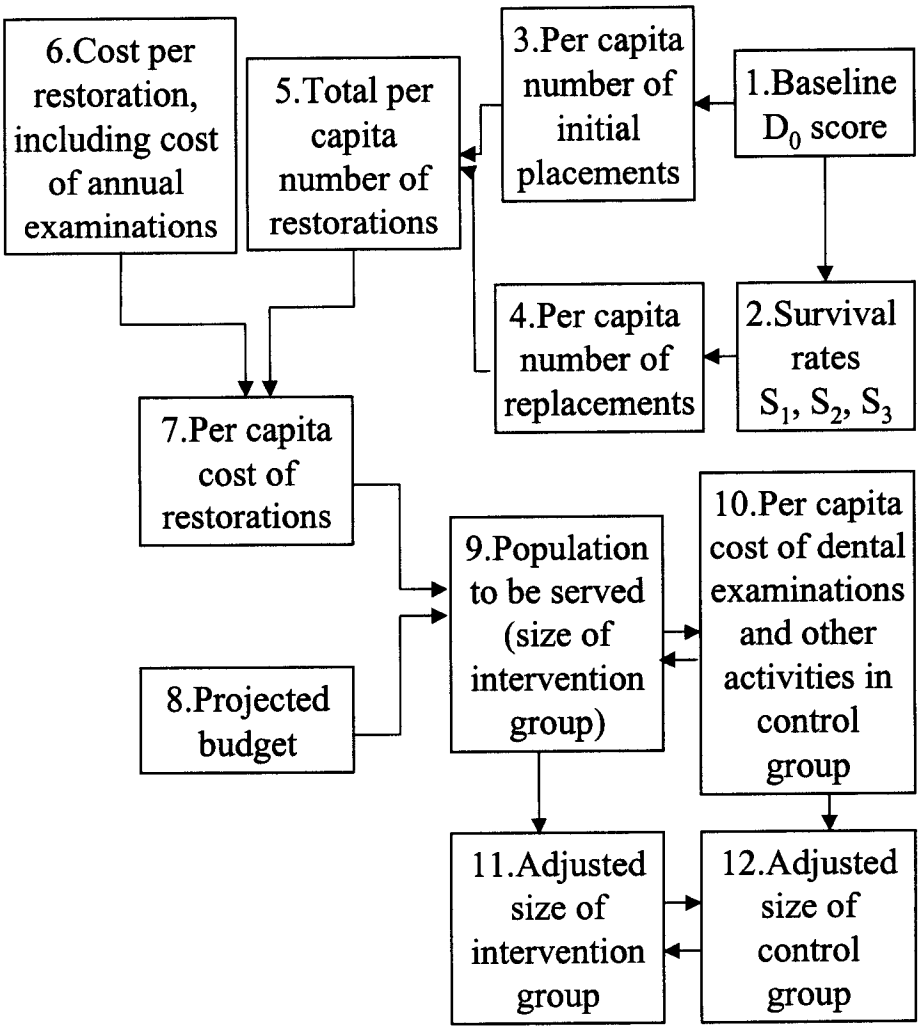

Chart 3. Estimation of Sample Size Based on PRAT Projected Budget

through annual examinations and may receive a general dental consultation, a referral for conventional treatment outside PRAT, and a dental hygiene kit as a small reward for their cooperation with the PRAT Project. These activities in the control group must be provided with resources. The size of the control group must be as close as possible to the size of the intervention group, as was mentioned earlier. Based on these considerations, the per capita cost of four annual dental examinations and related activities should be

estimated. As the next step, the total cost of activities in the control group should be estimated by multiplying the per capita cost by the initially estimated size of intervention group (box 9 on Chart 3). This will ensure that both groups are equal in size and provided with resources. If the thus estimated total amount of resources exceeds the PRAT projected budget, both samples should be scaled down. A number of iterations may be needed in the calculation process to reconcile the budget constraint, required activities and the condition of equal size of both subsamples. These iterations are depicted with two-way arrows linking boxes 11 and 12 on Chart 3.

2.5.2 Sampling Based on Statistical Methods

Statistical sampling techniques are usually explained under a separate heading of the CEA research protocol. Sampling is important for the basic correctness of the study design, to ensure that the sample is representative enough to reflect epidemiological profile of the whole studied population, correctly measures clinical outcomes of dental care, and properly targets population with ART activities. From the purely economic point of view, sampling defines the scope and, therefore, the cost of project activities. Since CEA, after all, is a method of economic evaluation, it justifies the inclusion of this issue in the section on cost estimation.

The sampling methods and, eventually, the sample size will depend on the objectives of sampling, particularly on how to enable accurate measurements of demand and clinical effectiveness.

Demand Considerations

The primary concern in designing a sample is to assure that the sample captures the prevalence of dental caries in the local population at the beginning of the project. The *sample* mean D component of DMFT should approximate the *population* mean. If this is achieved the sample will serve as a good instrument for measuring demand for dental restorations and will enable an accurate sample-based projection of the clinical volume and costs associated with conventional and innovative alternatives, as well as potential savings that may derive from the most efficient treatment option.

The statistical problem, then, should be formulated in the following manner:

To estimate the prevalence of dental caries among children of 7 to 9 age in the pilot rural communities. How many children should be included in the sample so that the prevalence could be estimated to $\pm\varepsilon\%$ of the true value with $100(1-\alpha)\%$ confidence, if it is known that the true rate is unlikely to exceed $P\%$?

Input variables and values are as follows:

Anticipated population proportion: $P = 50\%$

In Ecuador 22.4% of children were found with DMF score = 0, while in Uruguay 14.7% [*IDB: 1998: 6*]. Since D component accounts for up to ¾ of the DMFT aggregate, the percentage of children without decayed teeth may be higher by 1.5-1.7 times. It would be all the more higher for children of 7 to 9 years-old relative to the aforementioned numbers for 12 year-olds. The lower the P value is, the larger the sample size has to become in order to capture a disease with relatively low incidence. It makes sense, therefore, to start with a reasonably conservative (low) P value. Should the sample size prove to be unaffordable, the P value should be increased. If the initially estimated sample is smaller than the project budget allows to cover, P value should be reduced. Another approach is to conduct a preliminary sampling (with n>=30) in order to obtain an estimate of local population proportion with caries.

Confidence level: $100(1-\alpha)\% = 95\%$

This level of confidence guarantees that the output has enough statistical significance.

Relative precision: $\varepsilon = 10\%$

With 95% probability the estimate will fall within 8 percentage point of its true value, which for the expected prevalence rate of 40% will indicate 10% relative precision: $\varepsilon P = 10\% \times 40\% = 36\% \pm 4\%$

Calculation is conducted according to the following formula:

$$n = z^2_{1-\alpha/2}(1-P)/\varepsilon^2 P \qquad (6)$$

The resulting sample size is 384 subjects. This number needs to be doubled to create both intervention and control groups. If it is impractical, with respect to time and money, to manage such a large sample, the investigators can lower their requirements of confidence. At 90% instead of 95% the required sample size would be reduced to 271. Most likely, however, the reduction of the sample size will be justified by a higher than 50% estimate of caries prevalence.

The proposed sample size applies to one country. With three countries in the plan, the number of subjects may be tripled, or defined proportionately to children's population in each pilot country, or calculated independently for each country by feeding variable values in equation (6) reflective of a specific country setting. The latter is the recommendable approach. It will make country-specific sample size dependent on the epidemiological situation which, after all, is the key factor of demand for dental care. The reference Table 2-1 of Annex 2 provides sample size based on the above discussed input values. Using that table the CEA team will be able to swiftly adjust the sample size to each country's baseline conditions.

The proposed sample size for a single country (384 x 2 = 768 persons) exceeds that in the Thailandese study (277 persons) and in the Zimbabwean demonstration (618 students) [*Phantumvanit et al., 1996: 141; Frencken et al., 1998 (1): 5*]. Since no parameters are reported for those samples, the observed differences cannot be analyzed.

The proposed sample size will be sufficient for comparing both alternatives according to the cost of covering with alternative treatments of two equal-size populations with similar socioeconomic profile and accurately assessed baseline risk of caries. The cost-effectiveness differential will be stipulated by the difference in unit costs (including program-wide recurrent costs associated with each alternative) and by the different longevity of restorations.

Clinical Effectiveness

From the outset of the research design process it was determined that PRAT would not be a trial of ART clinical effectiveness but, predominantly, a trial of ART cost effectiveness relative to a conventional alternative. There is a certain temptation, however, to test the sample for its future ability to ascertain accuracy of caries progression rates. It would be desirable to have such potential for accuracy built in the sample, in case it occurs to the PRAT leaders to measure both alternatives by their clinical outcomes alone, i.e. regardless of cost considerations.

It may be assumed that the failure rate of amalgam restorations and the probability of complications developing over three years of PRAT life are low, given that the longevity of amalgam is assessed at 8 to 12 years [*WHO, 1997: 215*]. Therefore, the proportion of patients treated with amalgam restorations and developing caries over 3 years may be estimated at a realistically low 0.5%. The failure rates for ART restorations would be higher, given that predicted longevity of ionomer is 5 year [*WHO, 1997: 215*], and 3-year survival rates for one-surface ART restorations on secondary school students are assessed in the range of 67% to 85% [*Phantumvanit et al., 1996: 142; Frencken et al., 1998 (2): 119*]. Out of 33 failures examined in Zimbabwe only 7 had caries. This equals 20% of the 15% failure rate. Consequently, the caries prevalence in teeth with failed ART restorations may be tentatively assessed at 3.0% - 3.2% in 3 years from placement. In both cases the researchers would have to deal with small proportions and a small difference. The smaller the predicted difference between the sub-samples is, the larger each sub-sample has to be in order to account for such difference.

Statistical definition of the problem consists in finding out how large should the sample size be in each of the two groups of patients if an investigator wishes to detect with a probability of 80% whether the prevalence of caries under the second approach (ART) is higher than under the first one (amalgam) or vice versa, at the 95% level of confidence.

Input variables and values are as follows:

Test difference in caries incidence rates $P_1 - P_2 = 0\%$

Anticipated caries incidence rates	$P_1 = 0.5\%; P_2 = 3.0\%$
Level of significance	$100\alpha\% = 5\%$
Power of the test	$100(1-\beta)\% = 80\%$
Alternative hypothesis: either	$P_1 - P_2 > 0$ *or* $P_1 - P_2 < 0$ *(for one-sided test)*

Calculation is carried out according to the formula for a one-sided test for small proportions:

$$n = (z_{1-\alpha} + z_{1-\beta})^2 / [0.00061(arcsin\sqrt{P_2} - arcsin\sqrt{P_1})^2] \qquad (7)$$

For $P_1 = 0.005$ and $P_2 = 0.03$, a sample of 290 would be needed in each group. This is comfortably below 384 subjects estimated under the first, demand-driven sampling test, although of the same order of numbers. Table 2-2 of Annex 2 should be used as a reference table to find out how large two sub-samples should be to capture a relatively minor difference in caries prevalence between intervention and control groups. It also should be used to estimate how much 'resolution' can be achieved in measuring the difference between two sub-samples of a given size. For example, if instead of the expected prevalence rate differential of 0.5% and 3.0% we expect a larger differential of 0.25% and 3%, the sufficient sub-sample size declines to about 190 subjects.

Throughout the sampling exercise it is assumed that the samples are random and that intervention and control groups are drawn from the same population. The question whether and to what extent a community trial can ensure full randomization would have to be addressed during the field stage of the project. Should a strong 'design effect' be identified, the experimental area would have to be selected differently or the sample would have to be enlarged.

2.6 Measurement and Valuation of Costs

Cost measurement involves selection of a pricing system and structure. PRAT is conceived as a multi-national project with expatriate and domestic resources to be jointly used in every country site. If costs are to be measured by or referenced to PRAT expenditure, two options may be considered:

(1) To estimate costs by their nominal value, i.e., without any adjustment for price differential among international and domestic markets, various systems of procurement, or diverse pricing methods (whereby some contracts would be geared to costs, others would be issued on a cost-plus basis). This approach to costing will most likely be applied anyway to the PRAT internal cost accounting. It will enable calculation of cost-effectiveness ratio of ART activities over 3 years of PRAT Project in nominal purchasing prices used under PRAT procurement. Two main drawbacks are expected in this case: (a)

It will be difficult to compare the pricing system under PRAT with that of conventional dental practice in the pilot countries. This will affect the comparability of alternative-specific 'monetized' outputs from CEA. (b) Estimated C/E ratios may not be instrumental for longer-term planning of ART sustainable application. Indeed, ART may be found to be a viable option as long as it is backed up with PRAT procurement and resource management capacity. After the project expires, practice of ART would have to be transferred on domestic administration, procurement, and pricing of respective Latin American Countries. It may loose its efficiency edge because of less competitive prices and higher transaction costs on the local markets. Eventually, the efficiency benefits of the ART approach would fade out, and the findings from PRAT-related CEA would have to be reconsidered in favor of the conventional alternative.

(2) To ascertain whether ART can remain a sustainable option in the aftermath of PRAT, the cost of ART restorations and other recurrent activities should be simulated in domestic prices, even though during PRAT international competitive prices may be prevalent. Under this approach most of the cost finding work would have to be done in coordination with local dentist offices and public health authorities, to recreate a plausible combination of not-for-profit and for-profit activities in the future ART practice and to identify whether procurement is more efficient in the private or in the public sector. Recommendations for improving purchasing management might become an important outcome of the cost valuation exercise. If ART is to remain in dental public health domain, charges would not include profit margin, thus, making ART prices lower for the payor than amalgam-based treatments that would have to be purchased for currently under-served patients from private practice. This would increase the competitiveness of ART relative to conventional, commercially available options.

Having said that, we stated an important assumption that underlies this whole study design: CEA will consider cost-effectiveness of both alternatives from the standpoint of the government as the health and social policy center and, prospectively, the main payor for ART dental services. Economic evaluation may produce different results if institutional viewpoint is shifted towards consumer or provider of services. The focus on the public good as seen through the prism of government policy should not preclude the PRAT research team from conducting a consumer survey by the end of PRAT demonstration. Lower pain and better accessibility postulated among the benefits of ART remain important gains expected from the ART alternative. They may be evaluated in qualitative and/or numeric terms through a questionnaire that would compare the household historical and new experiences along two lines:

(1) Accessibility: to evaluate the consumer attitudes toward not having had caries prevention and treatment in the past, on the one hand, and having gained access to ART restorations and sealants recently, on the other. More concretely, it should be found out how many children in the intervention group did not have regular contacts with dental care. Broadly formulated multiple-option questions should be as follows: Indicate the number of encounters and type of treatment received by your children in the past year, 2 years, 3, years? How far and to what type of facility would you travel with a specified regularity for pediatric dental treatment?

(2) Pain: (a) If conventional treatments were available, how would you compare from a conversation with your child the amount of pain and psychological strain associated with amalgam and ART restorations? How can you describe your child's behavior and emotional status in the aftermath of amalgam-based and ART treatments (In tears, stressed, relaxed, smiling, etc.)? (b) How many more children do you have? (c) What would be your preferred choice of a treatment technique for your children, considering your newly acquired experience with ART?

The answers to these questions may help estimate the consumer impact of the new alternative and an additional demand for ART expected from relatively non-obtrusive nature and higher accessibility of this method. If additional demand is identified, economies of scale may be anticipated and adjustment in unit and national costs of an ART program would be made. Overall, the C/E ratio would improve on the cost side, thus, adding to the sustainability of ART.

Finally, proper cost measurement and valuation may require adjustment for inflation. The inflationary effect should be considered offset as long as both alternatives are equally exposed to price instability. If this assumption is found valid for a specific country, cost measurement in current prices will be acceptable. If not, price deflation is in order. The existence of deflators specifically for the health care sector is unlikely. Consumer price index (CPI), usually, is a standard indicator in the national income and product accounting and should be used as a proxy of price growth in any one particular sector.

In a single-digit inflation setting, adjustment for inflation can be made retrospectively, i.e., in line with inflation rate observed in the past year. If inflationary pressures are considerable, *projected* inflation rate (CPI) may serve as the basis for next-year cost adjustment. The Ministry of Finance (MoF) usually sets out the guidelines for deflation and recommends those for valuation of projects in the public sector. The deflation work as part of PRAT-related CEA should be coordinated with those guidelines or, in their absence, discussed with the MoF experts on budget planning.

2.7 Discounting

A brief overview of the rationale for and principles of discounting was provided in the "Review of Concepts, Terms and Stages of CEA" chapter of this report. This section elaborates on the concept of discounting, offers concrete techniques, and recommends key values to be entered in the net present value formula.

An evaluation of future costs and cost savings of a project is made more meaningful if all future money value amounts are converted to a current money value equivalent. Decision makers could then compare investment options, taking into account both the magnitude and the timing of costs and cost savings for each alternative.

The method consists of multiplying the value of costs occurring in future years by a weighting factor, so that they can be compared as if they all occurred at the same point in time.

Consider ***C*** as the amount of funds that has to be obligated for PRAT today but would not be spent until the project's ***T***-th year. This amount may be invested for ***T*** years and would return at a certain interest rate before time comes for it to be spent on PRAT. The expected investment growth allows to allocate today less than would be needed in ***T*** years. A smaller amount ***A*** will grow to the required amount ***C*** thank to the expected investment return characterized by a conservatively assessed annual interest rate ***R***. The problem of finding ***A*** is solved as follows:

$$A = C / (1+R)^T \qquad (8)$$

A is termed the 'net present value' of ***C***, giving name to the entire discounting technique.

If the interest rate is positive, ***A*** will be smaller than ***C*** because ***C*** is divided by a factor greater than one. Discounted costs, thus, become 'lighter' on a comparable scale as the projects moves from one year to another. The truism holds true that expenses deferred are less 'expensive'.

R is termed discount rate. The greater it is the higher the preference would be for future expenses versus today's expenses. ***R*** should be a safely guaranteed interest rate. It is often equated to the return rate of a public borrowing instrument of superior rating. In most cases, the discount rate is recommended or set forth as mandatory by policy decision of the government of a particular country. For example, in the UK the Treasury held the rate of 10% between 1969 and 1978 and reduced it thereafter to 7% [*Drummond, 1980: 122*]. The Office of Management and Budget of the U.S. Congress requires all cost-benefit computations for annual one-time and recurrent costs/savings be discounted to present value using a 10% factor [*USDVA, 1998: 15*]. Discount rates for the PRAT pilot countries should be recommended in conformity with the discounting guidelines from international development banks and national governments. They would also depend on financial investment alternatives existing in the pilot LAC countries. Listed three types of information should be reviewed in the consecutive order, implying that the first one is ranked higher for importance than the others.

In principle, discounting would be unnecessary if:

1. The rate of time preference were equal to zero: for example, alternative investment is totally unattractive (which does not seem so unrealistic given, for example, macroeconomic experience of Japan in the 90s);
2. All the effects brought about by the health treatments under appraisal occurred over a period so short that the relative timing of costs and outcomes did not matter; or
3. One project completely 'dominated' the other, i.e. the net benefits being greater in each and every year.

2.8 Sensitivity Analysis

As was briefly discussed in the previous chapter, many of the assumptions used in the primary CEA are subject to a degree of uncertainty. Sensitivity analysis allows to assess how cost-effectiveness ratios of both alternatives may be affected by modifying key values of the C/E variables. The following four sets of inputs may be recommended for the sensitivity simulations as part of this CEA:

- Shifting the assumptions on the dental health outcomes due to alternatively defined age coverage, survival rates, and assessment of outcomes of cases lost to follow-up;
    - Testing C/E ratios at the lower and upper boundaries of the established confidence interval (= 95%) for program effectiveness (survival rates);
        - Shifting cost estimations, i.e., assuming different input prices under alternative systems of procurement.
            - Shifting discount rate.

Testing most of the listed inputs seems to be a straightforward statistical exercise. More detail should be provided on the handling of dropout cases. Loss to follow-up due to shrinkage of the sample over the course of the project may be addressed in three ways:

1. Ignore the dropouts and limit calculation of mean survival rates to cases followed during the entire period of observation. The estimated survival rate for the entire life of the PRAT project will be computed in this case by dividing the number of intact teeth followed throughout 3 years by the total number of teeth minus lost cases. This is the most conservative methodology.

2. Assume that each individual withdrawal achieved the same annual DMFT score (or any of its components) in years subsequent to withdrawal as their average annual increment incurred up to the year of withdrawal. Average of previous measurements would, thus, be carried forward. This assumption is considered the upper scale of program effectiveness based on intention-to-treat, in contrast to the most conservative estimate provided under the first option [*Morgan et al., 1998: 21,22*].

3. Assume that the probability of survival is similar for lost cases and cases with complete follow-up information. Under this option we would apply to the drop-outs the *sample average* increment of a D(MFT) score in the year of withdrawal. Under the previous option, *individual past average* record of the dropouts themselves was used for extrapolation.

It is not necessarily clear how survival rates would compare under the three approaches. The third one is recommended for this study, given the availability of a simple methodological framework for its application and its relative precision.

The methodology is known as the life table method. It allows to estimate yearly and cumulative survival rates taking into account cases lost to follow-up. The input and output information relates to treated teeth, not to treated patients. The calculation algorithm is presented in Table 4 based on the numbers borrowed from the Zimbabwean study [*Frencken et al., 1998 (1): 121*] and, in part, guestimated for the sake of illustration. The following description of the table's columns is adapted from [*Thylstrup, 1975: 121-122*]:

Column 1: Time intervals between examinations (treatments): x to $x + k$, where k is the number of months. The intervals of observation are not restricted to being of equal size.

Column 2: Teeth intact at beginning of interval (l_x). The first row in this column indicates the sample-wide total number of teeth in need of treatment. The values decrease over time because of failed and otherwise withdrawn teeth (columns 3 to 5). Next-year entries in column 2 are obtained according to the formula:

$$l_{x+k} = l_x - (d_x + u_x).$$

Column 3: Failures during interval (d_x). This column gives the number of observed failures.

Column 4: Lost cases during interval (u_x). This column indicates the number of teeth for which the status was unknown at the close of the study. The length of observation for each tooth lost to follow-up is the time elapsed from the date of treatment to the date last seen to be intact.

Column 5: Effective number of teeth exposed to failure (l_x'). It is assumed that: (1) the teeth lost to follow-up during an interval were exposed to the risk of failure for an average of one-half of the interval; (2) the failure rate did not change within the intervals; (3) withdrawals were equally distributed over time within the interval. In order to satisfy the second condition, the starting interval may be shorter, e.g., 3 months, since the rapid failure rate immediately after treatment is not identical to the rate for the rest of the first year. The formula to calculate the number of teeth effectively exposed to risk of failure is as follows:

$$l_x' = l_x - (u_x/2)$$

Column 6: The proportion of failures during interval (q_x). The formula used for deriving the probability of failure during an interval is:

$$q_x = d_x / l_x'$$

Column 7: Proportion surviving the interval (p_x). The survival rate or probability of surviving the interval p_x is the complement to q_x, i.e. $p_x = 1 - q_x$.

Column 8: Cumulative proportion surviving from treatment to end of interval (P_x). P_x is computed by cumulatively multiplying the survival rates from each preceding interval:

$$P_x = p_1 * p_2 * \ldots * p_x$$

Column 9: Standard error of survival rate $\sigma_{(Px)}$. To calculate it by the life table method with unequal time intervals, the following formula is applied:

$$\sigma_{(Px)} = P_x \sqrt{\sum_{x=1}^{k} \frac{q_x}{l'_x - d_x}} .$$

The standard error is used to establish confidence limits:

$$P_x \pm z_{\alpha/2} \sigma_{(Px)}.$$

For the 95% confidence interval ($\alpha = 0.05$), $z = 1.96$. Consequently, with 95% probability the 'true' value of cumulative survival rate will fall in the range of mean survival rate ± 1.96 standard error.

Table 4. Life Table Algorithm. Calculation of Yearly and Cumulative Survival Rates with Consideration of Cases Lost to Follow-up. Input Numbers from the Zimbabwean Study of 1993-97 [Frencken et al, 1998 (1):121]

Time Span in Months	Teeth Intact at Beginning of Interval	Failures during Interval	Cases Withdrawn from Sample	Effective Numbers Exposed to Risk of Failure	Failure Rate During Interval	Survival Rate for Interval	Cumulative Survival Rate	Standard Error	Lower Limit Survival Rate at 95% Confid.	Upper Limit Survival Rate at 95% Confid.
x to $x+k$	**l_x**	**d_x**	**u_x**	**l'_x**	**q_x**	**p_x**	**P_x**	**S.e.(P_x).**	**Px – 1.96 S.e.**	**Px + 1.96 S.e.**
0-3	307	7	30	292.0	0.0240	0.9760	0.9760	0.0259	0.9252	1.0000
3-12	270	5	28	256.0	0.0195	0.9805	0.9570	0.0254	0.9071	1.0000
12-24	237	7	21	226.5	0.0309	0.9691	0.9274	0.0246	0.8791	0.9757
24-36	209	14	31	193.5	0.0724	0.9276	0.8603	0.0229	0.8155	0.9051

Adapted from [*Thylstrup, 1975: 7*]

The second set of scenarios for the sensitivity analysis will consist of estimating C/E ratio of ART for the lower and upper boundaries of the established 95% confidence interval.

The third set of scenarios will be based on different assumptions regarding pricing and, therefore, costs. The assumptions will be shaped up by the study of procurement and charge structure in the dental care sector of pilot countries.

The fourth set of scenarios will be formed by varying the discount rate. The lower and upper bounds of the range to be tested and the step of increment of the discount rate from one scenario to another will be decided upon, based on the rate's initially selected value and other considerations that may materialize in the course of empirical work.

Sensitivity analysis will go through many dozens of iterations, each one formed by a combination of input values provided by four sets of input scenarios. Probabilistic techniques, e.g., Monte Carlo simulations may be needed to generate best, worst and break-even scenario, the latter featuring the C/E ratio for the ART approach at the same or almost the same level as the C/E ratio for amalgam-based treatments. The clinical, organizational and resource parameters of the 'break-even' scenario will be highlighted as thresholds to be observed when planning the targets, scale and resources for ART activities in a specific country.

2.9 Final Recommendations

The recommendation of a better alternative will be based on the cost-effectiveness measures proposed in Subsections 2.2.2 and 2.2.3. Measurements set out in Subsection 2.2.3 for CEA of the second dilemma (implementation of ART versus expansion of conventional restorations to the level of need) will allow to identify the alternative which ensures unit minimization of D or DM increment among children of targeted age groups at the lowest cost, provided that both ART and amalgam-based treatments are supplied to currently under-served populations at the level of need. To satisfy the second condition, the assumption will have to be made that conventional treatment activities are stepped up and made available to distant and poor communities. The upward or downward effect of increased supply of conventional dental care will be evaluated in the cost-estimation part of CEA.

Based on the measurements proposed in Subsection 2.2.2 for the first dilemma (implementation of ART versus no change), there may be a strong recommendation in favor of an alternative that is more successful in containing caries, even regardless of comparative costs. Such recommendation would be appropriate if the baseline caries level and progression rate are found alarmingly high, such that additional supply of dental care would be recognized as a critical need that responds to the priorities of the national dental public health policy of the pilot countries.

IN LIEU OF CONCLUSION: SUMMARY OF ACTIVITIES, DATA REQUIREMENTS, OUTPUTS, STAFFING AND LEVEL OF EFFORT

This concluding section of the report summarizes proposed CEA design and protocol by distilling from Chapter 2 activities, input data requirements and outputs associated with each stage of the research and evaluation process (see Table 5). Estimated staffing requirements and level of effort are displayed in Table 6.

The table format of this section is aimed to present the CEA protocol as an outline for the CEA action plan, thus, making it easier to integrate the proposed economic evaluation into the mainstream of PRAT activities.

Table 5. Protocol of CEA Activities, Input Data Requirements, and Expected Outputs

***Technical Objectives* and Activities**	**Data Requirements and *Sources of Information***	**Outputs**
1. *State dental health and related problems, the need for their solution, and the capacity of ART in meeting that need:* 1.1 Review and revise draft statement presented in Annex 1 and discussed in Section 2.1 of this report with the PAHO Oral Health Program experts and national public oral health policy-makers of the pilot countries. 1.2 Prepare final version of the Memorandum of Commitment to the PRAT Project and cosign it at bilateral or multilateral ceremonies indicating an official commencement of PRAT.	1/1. National epidemiological statistics: DMFT scores for children, including D and M components: *PAHO Oral Health Program, National Ministries of Health, National Dental Associations.* 1/2. Statistics and/or survey-based and anecdotal evidence of inequality of access to dental care by income groups, e.g., variation in provision of dentists, yearly number of visits per capita; date of last visit (relative to the reporting date); commuting time to the nearest dental provider, coverage by dental insurance schemes: *National MoH, Central Statistical Office, Regional Health Authorities, Dental Association.*	1-1. Memorandum of Commitment signed by the PRAT leaders, international sponsors of and participants in the project. 1-2. Optionally: a policy document (White Paper) with an alarmist assessment of the current situation and a statement of determination to improve population's dental health.
2. *State alternatives for cost-effectiveness evaluation:* 2.1 Organize half-day proceedings of 1-2 focus groups to be formed of PRAT leaders, country coordinators, dental professionals, and community representatives in order to provide	2/1. Elaboration of dilemmas will be based on the materials provided by focus groups in response to the following questions: 2/1/1. What is your basic conventional strategy of containing and preventing caries? 2/1/2. What are the prospects for improving access of poor and	2-1. Opinions of the focus group members will be transformed into a set of consensus-based statements, including definition of

in-depth responses to the questions presumably answered in general terms during preparation of the Memorandum of Commitment (for questions, see column to the right). 2.2 Based on the findings from focus groups, review and revise if necessary, proposed Dilemmas 1 and 2 (see Subsections 2.2.2 and 2.2.3 of the Report): "Implementation of ART versus no change" and "Implementation of ART versus expansion of amalgam-based treatment to the level of need". 2.3 Accept or reject Dilemma 2 as the principal, and Dilemma 1 as the secondary (supplementary) subject of CEA. Propose an alternative definition of the key dilemma(s) if necessary.	geographically isolated communities to conventional treatments? – E.g., Strengthening third-party financing schemes? Creating non-financial incentives for dental offices for developing outreach care? 2/1/3. If prospects are not clear, should reliance on conventional approach continue, or a new alternative should be considered for implementation? Can ART be viewed as such alternative? 2/1/4. What are the fair, meaningful and affordable terms of weighing ART against amalgam-based treatments, the latter presumably, being the main conventional approach?	dilemma(s) proposed for evaluation by means of CEA.
3. *Select pilot sites (provinces, communities, localities) for the PRAT Project:* 3.1 Evaluate sites recommended by the Ministries of Health and/or PRAT country coordinators from the following standpoints: 3.1.1 Compliance of their socioeconomic characteristics with the requirements stemming from CEA goals and concepts, e.g., low income, limited geographic mobility, steady school attendance, low health insurance coverage, insufficient supply of conventional dental care. 3.1.2 Compliance of the local population profile with PRAT demographic targeting and minimum sampling requirements. 3.1.3 Availability of schools or other community-based facilities and personnel for delivery of	3/1. Statistical profile of regions and communities relative to the national average, by the following indicators: 3/1/1. Population size; 3/1/2. Mean household income; 3/1/3. Poverty rate; 3/1/4. Extreme poverty rate; 3/1/5. Unemployment rate; 3/1/6. Labor force status (incl. Prevalence of the self- and informally employed); 3/1/7. Assessed % health insurance coverage; 3/1/8. Dental health status (DMFT, D and M scores: population-wide median and at age 12); 3/1/9. Supply of dentists and dental care professionals; 3/1/10. Spacial accessibility of dental practices (mean distance and commute time);	3-1. A summary report with: 3-1-1. The baseline demographic, socioeconomic, and dental health status profile of the pilot sites; 3-1-2. Evaluation of their community resources available for contribution to PRAT clinical and evaluation activities.

ART. 3.1.4 Preparedness of local health authorities and conventional dental care providers for collaboration with PRAT on cost estimation and other aspects of CEA, relating to conventional treatments. 3.2 Should the overall compliance of the initially proposed sites be found insufficient, work with the national health authorities to identify more adequate sites.	3/1/11. Utilization of dental services (number of visits per year); 3/1/12. Number of children in age group 7-9 years; 3/1/13. Of that number, school students; 3/1/14. Number of children per class (school) in ages 7 to 12; 3/1/15. Percent school attendance at ages 7-12; 3/1/16. Annual dropout rates from grades accommodating children of age 7 to 12 years.	
4. *Describe selected clinical interventions from the standpoint of their strengths/weaknesses and expected benefits:* 4.1 Review published reports. 4.2 Hold discussions with the national health policy-makers, administrators and dental practitioners. 4.3 Analyze information and prepare a brief on organizational, clinical and socioeconomic profiling of ART strategy and amalgam-based dental care, should the latter have to be stepped-up to cover currently under-served populations. 4.4 Separate the identified features into those to be quantified under CEA, those quantifiable but not to be necessarily included in C/E ratios, those to be considered in qualitative terms only.	4/1. Documented international evidence and newly identified local perceptions relating to: 4/1/1. Broadly-defined contribution of ART and amalgam-based treatment to containment of caries; 4/1/2. Relative costs; 4/1/3. Optimal targeting by age groups; 4/1/4. Optimal targeting by type of teeth and dental surface; 4/1/5. Optimal, customary, and acceptable choice of practice settings; 4/1/6. Optimal and acceptable choice of operator; 4/1/7. Outreach mobility; 4/1/8. Support from existing health financing mechanisms; 4/1/9. Amount of pain; 4/1/10.Provider and environmental safety; 4/1/11. Other considerations.	4-1. A summary of benefits to be evaluated by means of CEA.
5. *Present the basic concept and design of CEA:* 5.1 Review the proposed definition of CEA (Section 2.2) as	5/1. Chapter 1 and Section 2.2 of this Report. The key feature of the proposed study design is that C/E ratio for the intervention group will be based on the	5-1. A verbal agreement of what the study should be and

a longitudinal community field trial involving an actively managed ART *intervention* sample and a conventional treatment *control* sample. 5.2 Review a CEA basic algorithm proposed in general methodological form in Chapter 1. 5.3 Review cost-effectiveness (C/E) measures proposed for both alternatives. 5.4 Review proposed age limits to be targeted by ART. 5.5 Revise, accept or replace the proposed concept and design of the study.	costs and outcomes of actually delivered ART procedures, while C/E ratio for the control group will be based on: (1) estimated need for dental restorations, (2) estimated costs of amalgam-based treatments had they been supplied at the level of need, and (3) the outcomes of those treatments based on international or country-specific evidence on amalgam longevity. 5/2. Optional: Additional documented evidence on CEA best practices and reports of similar studies conducted in the past.	what activities it will entail. 5-2. A methodological summary of the study design as the guidelines for CEA technical design, planning and management.
6. *Quantify outcomes:* 6.1 Collaborate with the clinical coordinators of PRAT to ensure that dentition status and treatment needs are properly recorded in both intervention and control groups at the beginning of the project and at yearly intervals. 6.2 Accept from the PRAT clinical experts the measure of clinical outcome of restorations. Current report is based on the assumption that D and M components of DMFT score are of primary importance. 6.3 Develop a concise instrument for a consumer survey to be addressed to parents of treated children at the end of PRAT. The purpose is to evaluate patient satisfaction with ART as a less painful and more accessible alternative to conventional dental care.	6/1. For calculation of DMFT score and its components: 'ART Clinical Evaluation Form' [*IDB, 1998: 21*] or 'Dentition Status and Treatment Need form' [*WHO, 1997 (2): 28*]. 6/2. For methodology of dental health scoring for the purposes of this study: Discussion with the PRAT clinical team and in-country dental care experts and practitioners. 6/3. For patient survey design: respondent's personal data fields from the 'PRAT Clinical Evaluation Form' and key questions proposed in Section 2.6 of this report.	6-1. Concrete methodological decisions leading to accurate and consistent over project life measurements of clinical outcomes of both alternatives. 6-2. A questionnaire for patient survey to be conducted at the end of PRAT.
7. *Determine sample size:* 7.1 Conduct preliminary estimation of the minimally required sample size by means of statistical sampling: Discuss	7/1. For demand-driven sampling: Baseline D score for children's population at the regional level of the pilot country and/or any other statistics of dental health that can help project the caries-prone population	7-1. Sample size for intervention and control groups. Statistical parameters of the

techniques proposed in Section 2.5.2 of this report for correct measurement of demand for and clinical outcome of care in both intervention and control groups. Reconcile sampling requirements identified under the two techniques. 7.2 Reconcile the initially estimated sample size with what is affordable under a realistically pre-assessed PRAT budget.	proportion. The higher proportion is expected, the smaller sample will suffice to measure it correctly. 7/2. For outcome-driven sampling: Projected difference between caries prevalence in intervention and control samples as a result of ART and conventional treatment activities. The higher difference is expected the smaller sample will be enough to capture it with satisfactory precision. 7/3. For reconciliation of the sample size with budget constraints: one-time and unit costs per ART treatment and pre-assessed PRAT budget (to be determined under the *Cost Estimation* section of this table)	samples (projected or pre-assessed population proportion with caries, confidence level, etc.)
8. *Estimate costs:* 8.1 Decide on whether costs will be estimated at the level of production costs or based on provider charges. The latter would imply inclusion of net revenue in the costs of conventional care furnished by for-profit providers. 8.2 Identify cost items and estimate unit and program costs involved in provision of ART procedures in PRAT procurement prices and in prices projected in the aftermath of PRAT when domestic procurement practice and sources take over. 8.3 Identify cost items and estimate unit and program costs involved in provision of amalgam-based treatments. 8.4 Adjust costs of conventional dental care for prospectively increased provision of services to currently under-served communities. 8.5 Consider adjustment of costs for inflation if ART and amalgam alternatives are found to have different exposure to price hikes.	8/1. For ART cost estimation: 8/1/1. ART clinical protocol: the one proposed in Table 1 in Subsection 2.4.2 of this report, or its revised or an alternative version. 8/1/2. One-time costs of the PRAT project: outlined in Subsection 2.4.2 and subject to discussion in each country-specific setting. 8/1/3. National procurement rules, procedures, practices, and pricing, based on findings from discussions *with MoH, import regulatory and custom control agencies, major importers, dental professional associations, and dental practitioners*. 8/1/4. Recurrent costs of ART activities: 8/1/4/1. Tools, materials and supplies: a list coordinated with ART clinical protocol is proposed in Table 1 (Subsection 2.4.2) and is subject to validation and pricing. 8/1/4/2. Labor: calculation technique is proposed on the basis of caregiver category and treatment time reported under previous studies (Subsection 2.4.2). Subject to validation and pricing. 8/1/4/3. Overhead: space rent, utilities, clerical and other ancillary personnel are to be priced on the basis of various assumptions as to which part of these costs will be charged to dental services and	8-1. Unit and aggregate cost flow tables.

	which part will continue to be funded through educational and community budgets (see Subsection 2.4.2). 8/2. For cost estimation of conventional treatments: 8/2/1. Clinical protocol of amalgam placements reflecting common dental practice in each pilot site. 8/2/2. Costs accounted for the same cost elements as for ART. 8/2/3. Costs adjusted for differential charge structure in various segments of care delivery system. 8/2/4. Travel costs of patients receiving office-based amalgam treatments. 8/2/5. Income lost to travel by patients seeking office-based amalgam treatments. 8/3. For deflation of costs of both alternatives: 8/3/1. Consumer price index or alternatively proposed proxy of price change in the dental health sector: based on discussions with *the Ministry of Finance.*	
9. *Discount costs:* 9.1 Discuss the need for discounting in each country-specific setting. 9.2 Review distribution of costs by year of PRAT, as set out in the PRAT budget proposal. Make revisions as necessary. 9.3 Determine the discount rate based on international and national guidelines. 9.4 In the absence of applicable rules, set out guidelines reflecting economic and investment opportunities andd macroeconomic stability in the pilot countries. 9.5 Discount yearly costs to their net present value using technique described in Section 2.7 of this report.	9/1. Discounting rules applied by international development banks and other donor institutions to the LAC project budget estimations: to be identified in discussions with the *WB, IDB, and WHO.* 9/2. Nationally practiced discounting rules: to be discussed with the *Ministries of Finance and/or the Ministries of Planning and Economy* of the pilot countries. 9/3. Major instruments of public borrowing and their interest rates. Indicators of macroeconomic stability and attractiveness of investment.	9-1. Core discount rate and its variation range to be tested in sensitivity analysis. 9-2. Yearly expenses associated with ART and conventional care, discounted to their net present value.

10. Calculate C/E ratios and rank evaluated alternatives by their cost effectiveness: 10.1 For intervention and control groups at large. 10.2 By age cohort. 10.3 By quartile of baseline D (DM) score.	10/1. Per capita costs (unit costs multiplied by number of provided ART procedures and needed amalgam-based procedures) and mean D (DM) increments for the entire sample and sub-samples based on age and dental health status.	10-1. Preliminary recommendation of a preferred alternative.
11. *Conduct sensitivity analysis:* 11.1 Test C/E ratios for sensitivity for alternative estimations of dental health outcomes, including those of dropout cases. 11.2 Determine C/E ratios at the lower and upper boundaries of the established confidence interval (95% confidence level recommended). 11.3 Test C/E ratios under alternatively priced inputs (e.g., due to variable mix of procurement sources). 11.4 Test C/E ratios under alternatively defined discount rates. 11.5 Discuss whether other parameters in the cost-effectiveness model should be considered for sensitivity analysis. 11.6 Conduct multi-variant simulations, each based on a combination of values from items 11.1 to 11.4. 11.7 Select a break-even scenario, i.e., a combination of C/E variable values that yields a C/E ratio for ART equivalent to that for conventional treatments.	11/1. Variation range to be tested in sensitivity simulations: 11/1/1. Yearly and cumulative survival rates for ART and amalgam-based restorations. 11/1/2. Yearly dropout rates as a reflection of sample shrinkage. 11/1/3. Price differentials on production inputs due to change in procurement sources, type of dental operator, time per procedure, work schedules, etc. 11/1/4. Alternatively defined discount rates.	11-1. C/E ratios of ART under the best- and worst-case scenarios. 11-2. Threshold parameters, i.e. those of the break-even scenario. 11-3. Final recommendations as to the C/E potential and applicability of ART, and the minimum-efficiency requirements regarding the scope of its application, costs, and clinical outcomes. 11-4. Recommended design of a sustainable national ART program to be introduced in the aftermath of PRAT.

Projected CEA activities would require estimated staffing and level of effort as shown in Table 6.

Proposed level of effort is based on the following contributions expected from each team member:

Table 6. Estimated Staffing and Level of Effort of the CEA Team, in Person-Months Per Country

Staffing	Project Start	1st year	2nd year	3rd year (Project End)	TOTAL
1. Economist/Statistician – expatriate	2.0	0.5	0.5	2.0	5.0
2. CEA country coordinator – in-country	1.2	0.8	0.8	1.2	4.0
3-5. Field personnel – 3 persons – in-country	3	1.5	1.5	3	9.0
6. Report production/dissemination specialist – at PRAT HQ	0.5	0.25	0.25	0.5	1.5

Economist/statistician:

1) Key policy and methodological discussions at the PRAT headquarters and in the pilot countries;
2) Transfer of experience to and setting operational guidelines for in-country personnel:
   - Pilot site evaluation (including one site visit per country);
   - Preparation and moderation of focus groups (one per country);
3) Design of statistical reporting forms;
4) Design of consumer survey instrument;
5) Data processing;
6) Preparation of reports;
7) Presentation of key policy recommendations based on the PRAT outcomes.

CEA Country Coordinator:

1) General responsibility for timely production of country inputs to CEA;
2) Main responsibility for pilot site evaluation;
3) Moderation of most focus groups and regular methodological discussions at the national and regional levels;
4) Supervision and training of field personnel on data collection and entry;
5) Monitoring of quality of reported and estimated data;
6) Briefing national and regional policy-makers on CEA interim and final results.

Field Personnel:

1) Information gathering from domestic statistical sources and discussions with dental health authorities and practitioners on costs and benefits of evaluated alternatives;

2) Collection and validation (testing for consistency and accuracy) of yearly information on changes in the health status of children in intervention and control groups;
3) Pre-testing of consumer survey instrument; field survey work;
4) Entering information in computer data files.

Report Production/Dissemination Specialist:

1) Report editing, printing and publishing, and distribution according to a PRAT mailing list.

The above estimations are based on the assumption that CEA activities will rely on general administrative support from the PRAT main budget.

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ANNEXES

Annex 1. Draft Memorandum of Commitment and Cover Letter to the Signatories

Dear Signatory of the *Memorandum of Commitment*:

Please, review the enclosed final version of the Memorandum and express support for its contents by signing on the line with your name.

It is our understanding that you had an opportunity to review and propose changes to this document which must have led to consensus-based revisions of its text.

Please, be advised that your signature means the consent of your institution to participate in the PRAT Project activities throughout the term of the pilot experiment in your country, region and community. The authority of your name and of the institution that you represent will serve as an encouragement for professionals, communities, and patients alike, and as an assurance to the international sponsors of the project that their good will and investment will result in desirable outcomes.

Thank you for your perseverance in promoting dental health in the Latin American and Caribbean world.

_____ _____

(PRAT Project Coordinator) *(Date)*

Memorandum of Commitment to the PRAT Project Sponsored by IDB

_____ _____

(Place of signing) *(Date of signing)*

The signatories of this Document express their deep concern regarding dissatisfactory dental health conditions in the Latin American and Caribbean countries {*or a particular country*} and on behalf of the institutions that they represent pledge their support for the IDB-sponsored PRAT Project whose noble goal is to promote the atraumatic restorative treatment (ART) of dental caries, a technique and a public health strategy that gives hope of improved quality of and more equitable access to key dental services for currently disadvantaged populations.

The following consensus-based statement explains the signatories' motivation for facilitating the PRAT Project activities:

Dental caries is the most common disease among Latin American and Caribbean (LAC) children. It affects approximately 90% of the 5- to 7-year-olds. The World Health Organization has established as objective for the year 2000 a mean DMF-T_{12} of 3.0 or lower. In 16 out of 23 LAC countries which reported dental health statistics in the past 10 years, the DMF-T_{12} score is higher. Of particular concern is the large share of untreated decayed teeth. The D component of the DMF-T_{12} total exceeds 50% in all LAC countries as compared with 20-27% in the United States. Resources for delivery of oral health care services are limited, and curative care is restricted to those with the ability to pay or those with access to social insurance schemes. It is, however, the socially marginalized populations (low-income, poorly educated, and geographically isolated) who, on the one hand, suffer from more prevalent and severe dental caries, on the other hand, are confined to the most insufficient and inappropriate care. In view of a significant socioeconomic mismatch between demand for and supply of dental services, the adverse situation with dental health is unlikely to improve with traditional treatment regimens of limited affordability under public dental health coverage. Therefore, there is an important need for clinically effective and cost efficient restorative treatments that could reach out to the currently disenfranchised populations.

An innovative approach that brings safe and effective care for dental decay to communities without the need for expensive dental equipment is ART. With this approach dental decay is removed solely with hand instruments and the cavity is filled with an adhesive, tooth colored material which releases fluoride. This material is also used

to seal caries prone tooth surfaces. Thus ART is considered a combined preventive and restorative procedure to control dental decay. This means that restorative care is no longer restricted to the dental clinic setting but can be delivered virtually anywhere. Even where traditional restorative care is available, this approach brings care closer to all.

Cognizant of the clinical and social potential of ART, the signatories of this Memorandum commit their political support and administrative resources to the activities planned under the PRAT project in {*community/region/country names*} aiming to create organizational infrastructure, professional skills and public support for the practice of ART, pilot-test this treatment method, evaluate its interim outcomes and longer-term potential, and prepare conditions for its sustainable application on the national scale.

(PRAT Project Coordinator)	*(The National Health Minister)*
(Regionsal Health Administrator)	*(Pilot Site Director/ Community Health Director)*

Annex 2. Sampling Reference Tables

Annex 3. Selected Table Formats for CEA Input and Output Data