Oral Health of Low Income Children:

Procedures for Atraumatic Restorative Treatment (PRAT)

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This project is dedicated to the children of Ecuador, Panama and Uruguay, without whose participation, no results would have been possible. We promise to utilize these findings to ensure that they and the millions of children in other countries have better oral health.

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Abbreviations

ART	Atraumatic Restorative Treatment
CEA	Cost-Effectiveness Analysis
DMFT	Decayed, Missing or Filled Teeth
IADB	Inter-American Development Bank
LAC	Latin American and Caribbean
MOH	Ministry of Health
PAHO	Pan American Health Organization
PRAT	Procedimientos de Restauración Atraumática y Tratamiento (or Procedures for Atraumatic Restorative Treatment)
USPHS	United States Public Health Service

Executive Summary

Throughout the LAC Region, the traditional treatment for dental caries disease remains the Amalgam-based approach, which can be costly and is not always widely available, especially for disadvantaged populations. As PAHO and its partners seek to expand the promotion of health and health services, with a special focus on increasing access to oral health services, the organization is exploring various alternative methods for treatment and prevention of dental caries. The Atraumatic Restorative Treatment (ART) technique, which has gained international praise for its treatment success in other parts of the world, is a "leading-edge" intervention that may have great potential for usage throughout the Region. However, there exists a knowledge gap for how this nontraditional intervention may be employed in the context of specific local settings and if the intervention would be a cost-effective technique for usage among low-income populations. This knowledge gap includes the question of if, and how, the use of non-traditional providers (hygienists, in this case) may help increase access to oral health services.

In accordance with the 1997 PAHO Directing Council Resolution regarding oral health in the Americas, Member States were urged to focus more resources on increasing access to oral health services for the neediest populations in their respective countries. PAHO supported these efforts by proposing to the IADB a cost-effectiveness analysis (CEA) of the ART technique versus the traditional Amalgam technique in the community setting in three LAC countries. In the late 1990s, PAHO sparked interest among the leadership of several LAC countries to conduct operational research on the application of the ART technique and how it compares in terms of efficiency and effectiveness with conventional, Amalgam-based treatments and/or the absence of treatment due to the lack of available funds. It was believed that a program that undertook to reveal this type of cost-efficiency data, that is, comparing the costs of a new health intervention with the costs of a traditional intervention, would yield information about the scenarios under which the implementation of the new health intervention would be considered feasible. Hence the birth of Project PRAT, a study whose main objective is to demonstrate the cost-effectiveness of the ART technique in a variety of settings in the Region in comparison with the cost-effectiveness of the Amalgam technique in the same settings.

In the current study, the basic techniques of economic assessment, namely those involved in cost-effectiveness analysis (CEA), were used for evaluation of the practice of the ART technique. The research aimed to introduce ART in government dental care facilities in Panama, Ecuador and Uruguay as a restorative treatment modality to treat carious lesions in both primary and permanent teeth, thus extending coverage of oral services to additional populations of children, including those currently without access to conventional Amalgam-based treatment.

In order to conduct the study, children in the three countries were examined to determine their eligibility for the study. Evaluators chose children with enamel caries and/or dentine lesions on the first permanent molars to participate. After being randomly assigned to one of the treatment groups (ART or Amalgam), children were then to be re-evaluated at 12-, 24- and 36-month intervals to track the success of the restoration and the development of any new caries. Later in the project, additional children were chosen to receive ART treatment by auxiliaries. Evaluation data, materials usage and time measurement were all recorded throughout the process to ensure that a cost-effectiveness ratio could be calculated, at the close of the project.

The findings from the PRAT study clearly demonstrate the cost-effectiveness of the ART technique in a variety of settings in the Region in comparison with the cost-effectiveness of the Amalgam technique in the same settings. Even if PRAT is provided at the lowest cost service modality, and even under a failure scenario, it produces acceptable outcomes. In Ecuador and Panama, the effectiveness of PRAT delivered by dentists when compared with dental auxiliaries was similar; in Uruguay, the results were even better. The costs of employing the PRAT approach for dental caries treatment, including retreatment, are roughly half the cost of amalgam without retreatment. PRAT as a best practice model provides a framework to implement oral health services on a large scale, and it can reduce the inequities for access to care services. The PRAT study has produced evidence to guide downstream investment to improve equity, efficiency and quality of life in the Americas.

1. Introduction

. . . There are profound oral health disparities across Regions, countries and within countries. These may relate to socioeconomic status, race or ethnicity, age, gender or general health status. Although common dental diseases are preventable, not all community members are informed of or are able to benefit from appropriate oral health-promoting measures. . . Reducing disparities requires far-reaching wide-ranging approaches that target populations at highest risk of specific oral diseases and involves improving access to existing care.

—Ottawa Charter for Health Promotion, World Health Organization, 1986[1]

The prevention and appropriate treatment of common oral diseases are part of the core component of primary health care, and low-income populations are particularly at risk due to a variety of factors, including a lack of access to dental care, high cost of dental services and a general lack of information about the vital role that oral health plays in the overall health and well-being of individuals. Bringing basic health services to all people in developing nations remains a key strategy of improving global health in an equitable way.

Dental caries, generally defined as a bacterial process that results in the gradual loss of minerals making up the tooth structures,[2] is one type of oral disease that is preventable, yet it still affects more than 80 percent of children at 12 years of age in the Region.[3] Tooth decay in developing countries affects all segments of the population, but the prevention and treatment of this condition remains more easily accessible to the middle and higher income groups. Thus, tooth decay and its negative effects impact the disadvantaged (low-income, poorly educated and/or geographically isolated) disproportionately, constituting a source of infection and impairing chances of education and employment.

In partnership with the Inter-American Development Bank (IDB), the Pan American Health Organization (PAHO) is working to reduce and prevent the prevalence of oral disease throughout the Latin American and Caribbean (LAC) Region, as well as to increase access to oral health services, particularly for under-served populations.[4] In its 1997 Resolution on Oral Health, PAHO's Directing Council urged Member States to "promote the establishment and strengthening of effective and sustainable national oral health services that are accessible to the neediest populations."[5] The implementation of the Atraumatic Restorative Treatment (ART) technique, which is an alternative, low-cost, restorative treatment that requires minimal technology and can be implemented by trained health personnel without a dental degree, is one strategy that can be used to reach disadvantaged populations that may have little or no access to dental services.[6] The current study is an investigation into the cost-effectiveness of the innovative ART technique in a variety of settings within the LAC Region.

ROLE OF ORAL HEALTH IN OVERALL HEALTH

Oral health has broad implications for an individual's overall health; it is essential for good general health and for overall well-being, and it is vital to quality of life.[7] According to the World Health Organization (WHO):

[Oral health] implies being free of chronic orofacial pain, oral and pharyngeal (throat) cancer, oral tissue lesions, birth defects such as cleft lip and

New treatments for cavities restoration made available by the development of new techniques and less costly procedures using less expensive materials provide the possibility to make appropriate dental treatment more easily available to lower income people.

palate, and other diseases and disorders that affect the oral, dental and craniofacial tissues, collectively known as the craniofacial complex.[8]

The strong correlation between oral and general health can be seen in a number of ways. Recent studies have demonstrated associations between oral infections and diabetes, heart disease, stroke and other health problems.[9] The mouth also provides protection against microbial infections and environmental threats. Deep dental carious lesions, for example, may permit harmful bacteria to enter the bloodstream and spread infection. Other health conditions, while not necessarily caused by poor oral health, may manifest themselves in the mouth. Additionally, there is a correlation between oral health and low birth weight; for instance, new research shows that pregnant women who have periodontal disease may be seven times more likely to have a baby that is born too early or too small.[10] Dental decay can also bring pain and discomfort; left untreated, decay spreads and introduces the opportunity for infection, which can negatively impact overall health. The onset of dental caries, if not treated, can also reduce quality of life and productivity by restricting work and school activities.[11]

THE SOCIOECONOMIC DIVIDE

Because costly technology and equipment have been an integral part of traditional oral health care, dental treatment historically has been expensive. In combination with infectious diseases, noncommunicable chronic diseases, such as dental caries, create a heavy burden for disadvantaged populations, who have less access to oral health services. Dental extraction is the only treatment effectively available to large proportions of the population because it is relatively inexpensive. This is particularly true for those of lower socioeconomic strata and in geographically isolated areas, who generally have little or no access to dental services. In this case, individuals may put off treatment for such long periods of time, allowing the problem to worsen, that their only alternative may be extraction.

The number of decayed, missing or filled teeth (DMFT) has long been used as a way to determine the oral health of individuals. Higher numbers indicate poorer oral health status. Given the correlation between income level and access to dental health services, a higher DMFT generally coincides with lower income individuals. On average, developing countries have higher DMFT scores than industrialized nations, where a greater percentage of the population has access to affordable dental care.

Advances in technology and knowledge have not always benefited developing countries to the fullest extent possible. In accordance with this fact, access to treatment has been restricted and the priorities assigned by institutions in charge have been limited by the availability of scarce funds. It has been estimated, for example, that only 10 percent of funding for global health research is allocated to health problems that affect 90 percent of the world's population.[12] Clear disparities in economic strength, political will, scientific resources and capabilities, and the ability to access global information networks have, in fact, widened the knowledge gap between rich and poor countries. New treatments for cavities restoration made available by the development of new techniques, such as ART, and less costly procedures using less expensive materials provide the possibility to make appropriate dental treatment more easily available to lower income people. This new paradigm will permit a more exact alignment between the perceived importance of the problem by the public and the accessibility to effective services.

STATUS OF ORAL HEALTH AND HEALTH SERVICES IN THE REGION

Comprehensive data on oral health in the LAC Region are scarce; however, there are some data that allow an overall evaluation of the current status and recent trends, especially in dental caries and needs for periodontal treatment. An overview of current

oral health data in the LAC region indicates that most member countries have a high prevalence of dental caries and periodontal disease.[13] These two conditions, though highly prevalent throughout the Region, are most severe among low-income, poorly educated subgroups.[14] Additionally, public dental services are poorly organized, underfinanced and understaffed, and quality care may only be accessible in urban areas and at high costs.[15] Another factor that complicates the picture of oral health in the LAC Region is the curative, rather than preventive, nature of dental care. That is, dental school curricula mostly emphasize curative interventions, and very little is offered on public health dentistry.[16] PAHO is playing a key role in a number of initiatives to adapt dental practice in the Region to the oral health needs of communities, and the present study is an example of PAHO's leadership in supporting innovative health interventions that target under-served populations.[17]

At the World Health Assembly in 1979, the World Health Organization (WHO) established a standard by which to measure progress in oral health. Countries established the following goal: by the year 2000, the global average for children at 12 years of age ($DMFT_{12}$) should not exceed 3 DMFT.[18] In 1980, according to the WHO Oral Health Data Bank, of the 107 countries for which oral health data was available, 51 percent had a $DMFT_{12}$ score of 3 or less. By the year 2000, of the 184 countries for which oral health data was available, 60 percent had $DMFT_{12}$ less than 3.[19] However, in most LAC countries that report dental statistics, the $DMFT_{12}$ score still exceeds the WHO objective; in fact, the mean $DMFT_{12}$ score in the Region is 3.6.[20] While countries had made significant progress toward this oral health goal in the 20-year span, addressing dental caries, especially among children, remains a challenge for a large number of developing countries. According to PAHO, dental caries continues to affect almost 90 percent of 5- to 17-year-olds in the LAC Region, and it remains the most common disease among children in the Region.[21] Table 1 demonstrates the most recent available data for $DMFT_{12}$ for selected countries in the Region. Overall, there is a wide range of caries prevalence in the Region.

In 1994, PAHO drafted a *Regional Oral Health Strategy for the 1990s*; the overall goal of the strategy was to ensure that PAHO and country resources were used as efficiently as possible so as to improve the oral health of the people of the Americas.[22] PAHO set out two main strategic objectives to guide the organization's activities:

1) To promote improvement of oral health conditions in the countries of the Americas, building on the momentum of health sector reform; and
2) To assist countries develop accessible, effective and sustainable oral health services.

The development and enhancement of fluoridation programs throughout the Region was a major strategic component of caries prevention. The strategy emphasizes caries prevention by ensuring that any fluoride deficiency in the population of the Region is compensated by the ingestion of fluoride either through the traditional means of water or salt. It was PAHO's intention, along with more than 38 member governments to aggressively pursue national programs of salt and water fluoridation for the majority of the member countries in the Region.[23] The regional strategy called for feasibility assessments, measurement of oral health status, development of fluoride surveillance systems, assessment of the salt industry's capacity to fluoridate salt, cost-benefit studies and follow-up evaluations.

When the fluoridation plan was developed, a regional framework was proposed that allows for recognition of individual country problems and for the development of targeted strategies to alleviate those weaknesses. PAHO began by working with countries to develop a plan for country classification, or typology.[24] A first approximation, based on available data and a framework, indicated that $DMFT_{12}$ was the most important factor in grouping countries along an oral health continuum. A second criterion, the presence or absence of a national salt fluoridation program, was also used in assessing a country's typology. Using these criteria, three stages of oral health development were defined:

Emerging:	$DMFT_{12}$ score greater than 5
Growth:	$DMFT_{12}$ score between 3 and 5
Consolidation:	$DMFT_{12}$ score lower than 3

Based on these criterion and the resulting classification of countries along the oral health development

Table 1 DMFT index and percentage reduction in children 12 years of age, selected countries of the Americas, 1980–2004.

Subregion/Country	Year (1980s)	DMFT	Year (1990–2000s)	DMFT	Reduction (%)	Annualized reduction (%)
North America						
Canada	1982	3.2	1990	1.8	43.8	6.94
United States	1986–1987	1.8	1988–1991	1.4	21.8	7.86
Mexico	1988	4.42	1997–1998	3.11	29.6	3.45
	1987	4.60	2001	2.50	45.7	6.55
Central America and Panama						
Guatemala	1987	8.1	2002	5.2		
Belize	1989	6.0	1999	0.60	89.5	20.18
El Salvador	1989	5.1	2000	1.4	74.5	11.69
Honduras	1987	7.7	1997	4.0	48.4	6.41
Nicarágua	1983	6.95	1997	2.78	(1983–1997)	6.34
	1988	5.9			60.0	
Costa Rica	1988	8.4	1992	4.9	(1988–1992) 42.2	12.82
			1999	2.5	(1988–1999) 72.5	10.61
Panama	1989	4.2	1997	3.64	13.3	1.77
Andean Area						
Venezuela	1987	3.67	1997	2.1	42.2	4.13
Colombia	1977–1980	4.8	1998	2.30	52.1	3.70
Ecuador	1988	5.0	1996	2.95	40.5	5.95
Peru	1988	4.8	1990	3.09	N/A	
Bolivia	1981	7.6	1995	4.61	39.3	3.51
Chile	1987	6.0	1992	4.70	(1987–1996) 47.8	6.98
			1996	4.10	(1992–1996) 12.8	3.36
			1996	3.4		
Southern Cone and Northeast						
Argentina	1987	3.4				
Uruguay	1983–1987	8.5	1992	4.2	(1992–1999) 40.6	7.18
		6.0	1999	2.5		
Paraguay	1983	5.9	1999	3.8	35.1	2.66
Brazil	1986	6.66	1996	3.1	(1986–1996) 54.0	7.4
Suriname			1992	2.7		
			2002	1.9		
Guyana	1983	2.7	1995	1.3	51.9	5.91

Source: Estupiñán-Day, S. "Promoting Oral Health: The Use of Salt Fluoridation to Prevent Dental Caries," Pan American Health Organization, Scientific and Technical Publication No. 615, Washington, D.C., PAHO, 2005.

continuum, PAHO developed a series of activities and provided technical cooperation to the countries aimed at moving from high levels of disease and lacking appropriate preventive policies toward achieving improved status indicators and policies.[25]

Complementing the fluoridation preventive approach with the application of simplified, restorative and cost-effective procedures would improve significantly the impact on the general population's dental health. This is especially important for school children ages 7 to 12, who are highly affected by the pain and trauma of tooth decay. The implementation of the ART technique, as investigated in this study, may provide such a cost-effective solution for reaching disadvantaged populations and improving a country's overall oral health picture.

PANAMA, ECUADOR AND URUGUAY SELECTED AS COUNTRIES WITH DIVERSE POPULATIONS

In order to accurately investigate the cost-effectiveness of the ART technique, it was necessary to conduct the

Table 2 Selected Indicators of PRAT Countries[27]

	Panama	Uruguay	Ecuador
Total Population (2004)	3,177,000	3,439,000	13,192,000
GNI per capita (2002 US$) (current value)	$4,020	$4,340	$1,490
Population below Int'l Poverty Line (1995–01)	7.2%	2.0%	17.7%
Annual Population Growth (2004)	1.8%	0.7%	1.4%
Nat'l Health Expenditures as % of GDP (2001) (public/private)	4.4% / 2.2%	4.7% / 5.6%	2.2% / 2.4%
Life Expectancy at Birth (2004) (male/female)	72.6 / 77.7	72.0 / 79.3	68.6 / 73.9
Number of Dentists per 10,000 Inhabitants (2001)	2.5	12.4	1.7

Source: PAHO, 2004.

study in several different countries with varying social, economic and cultural settings that manifest themselves in differences in rurality, institutional development and epidemiological profiles. By incorporating countries with diverse populations in the study, the investigators and Ministry of Health officials would be able to draw conclusions about the technique in a variety of settings.

By analyzing the country classification system for oral health born from the *PAHO Regional Oral Health Strategy for the 1990s*, PAHO began to seek out appropriate testing grounds for the ART clinical study in the late 1990s.[26] Recognizing the geographic, epidemiological and economic diversity in the countries of Panama, Uruguay and Ecuador, as well as the potential benefits of the ART technique for underserved populations in those countries, PAHO staff approached authorities in the three countries to invite them to participate in a clinical study that would test the cost-effectiveness of the ART technique in a community setting. Table 2 represents a basic profile of the three countries involved in the study.

Because these countries have a wide array of cultural, social, economic and epidemiological circumstances that are more or less representative of the diversity in the LAC Region, it is expected that the research conducted in these countries will provide useful data that will help countries in the Region to make more informed decisions about the cost-effectiveness of the ART technique in different settings.

BRIEF HISTORY OF THE ART TECHNIQUE

There have been a number of clinical research efforts directed to find a more simple and more environmentally neutral dental filler, and the ART technique has been studied and tested extensively in clinical trials as an alternative method of treating and preventing dental caries. Clinical trials conducted in Thailand (1991–1994) and Zimbabwe (1993–1995) have shown proportions of post-treatment problems no larger than those of restorations of composite resins, which are more expensive.[28] When using the ART technique for sealing permanent teeth for the prevention of cavities, studies show only about 3 percent have retention problems.[29] ART trials continue to be conducted elsewhere in the world, and the technique has received ample support as a valid alternative treatment from the WHO.

The Conventional Amalgam Treatment

Dental Amalgam, a compound of mercury and silver-based alloys, remains the most widely used material as a dental restorative. Amalgam restorations are durable and cost-effective, but they are 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.[30]

What is Atraumatic Restorative Treatment (ART)?

Atraumatic Restorative Treatment is a nontraditional method for treating and preventing dental caries. The technique 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 does not require electrically-driven equipment and is consistent

The reduction or elimination of pain is an important factor in successfully reaching and treating dental patients, especially children.

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, no anesthesia is required and pain often does not occur at all or can be kept to a minimum. Thus, fear of dental procedures is reduced. The reduction or elimination of pain is an important factor in successfully reaching and treating dental patients, especially children. 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 rural areas where no conventional oral health services are available.[31]

In addition to restorations, glass ionomer is used for sealing pits and fissures adjacent to the restoration and for sealing caries-prone surfaces of molars. Based on epidemiologic evidence, sealants are indicated for children and young adults. Their median retention rate summarized from dozens of studies is 83 percent in Year One, 69 percent in Year Three and 68 percent in Year Ten. More importantly, sealants are proven to stop progression of caries.[32]

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2. Project Description and Methodology

STUDY OBJECTIVES AND STUDY DESIGN SUMMARY

Throughout the LAC Region, the traditional treatment for dental caries disease remains the Amalgam-based approach, which can be costly and is not always widely available, especially for disadvantaged populations. As PAHO and its partners seek to expand the promotion of health and health services, with a special focus on increasing access to oral health services, the organization is exploring various alternative methods for treatment and prevention of dental caries. The ART technique, which has gained international praise for its treatment success in other parts of the world, is a "leading-edge" intervention that may have great potential for usage throughout the Region. However, there exists a knowledge gap for how this nontraditional intervention may be employed in the context of specific local settings and if the intervention would be a cost-effective technique for usage among low-income populations. This knowledge gap includes the question of if, and how, the use of nontraditional providers (hygienists, in this case) may help increase access to oral health services.

In accordance with the 1997 PAHO Directing Council Resolution regarding oral health in the Americas, Member States were urged to focus more resources on increasing access to oral health services for the neediest populations in their respective countries.[1] PAHO supported these efforts by proposing to the IDB a cost-effectiveness analysis (CEA) of the ART technique versus the traditional Amalgam technique in the community setting in three LAC countries. In the late 1990s, PAHO sparked interest among the leadership of several LAC countries to conduct operational research on the application of the ART technique and how it compares in terms of efficiency and effectiveness with conventional, Amalgam-based treatments and/or the absence of treatment due to the lack of available funds. It was believed that a program that undertook to reveal this type of cost-efficiency data, that is, comparing the costs of a new health intervention with the costs of a traditional intervention, would yield information about the scenarios under which the implementation of the new health intervention would be considered feasible. Therefore, the main objective of this study is to demonstrate the cost-effectiveness of the ART technique in a variety of settings in the Region in comparison with the cost-effectiveness of the Amalgam technique in the same settings.

In the current study, the basic techniques of economic assessment, namely those involved in cost-effectiveness analysis (CEA), were used for evaluation of the practice of the ART technique. The research aimed to introduce ART in government dental care facilities in Panama, Ecuador and Uruguay as a restorative treatment modality to treat carious lesions in both primary and permanent teeth, thus extending coverage of oral services to additional populations of

The main objective of this study is to demonstrate the cost-effectiveness of the ART technique in a variety of settings in the Region in comparison with the cost-effectiveness of the Amalgam technique in the same settings.

children, including those currently without access to conventional Amalgam-based treatment.

In order to conduct the study, children in the three countries were examined to determine their eligibility for the study. Evaluators initially chose 1,629 children with enamel caries and/or dentine lesions on the first permanent molars to participate. After being randomly assigned to one of the treatment groups (ART or Amalgam), children were then to be re-evaluated at 12-, 24- and 36-month intervals to track the success of the restoration and the development of any new caries. Later in the project, 830 more children were chosen to receive ART treatment by auxiliaries. Evaluation data, materials usage and time measurement were all recorded throughout the process to ensure that a cost-effectiveness ratio could be reached at the close of the project.

It is important to note that, given a significant amount of documented evidence on the ART clinical and epidemiological benefits, the participating countries were not seeking a trial of ART clinical effectiveness *per se* but, predominantly, an evaluation of the cost-effectiveness of the two approaches in the community setting. The utility of the study is to show scientifically the conditions and the specific settings in which the ART technique would have cost-effectiveness superiority over the traditional Amalgam technique. Based on the analysis of data resulting from this study, Ministers of Health and health planners throughout the LAC Region would then be able to make more informed, evidence-based decisions as to which technique would be a better investment of scarce resources.

As with any careful scientific study, the basic assumption that guided the current study design was that of impartiality. None of the options was viewed *a priori* as unconditionally superior to others. The ART technique was not viewed as a *replacement* for dental Amalgam, but rather that ART would successfully complement the Amalgam technique by addressing the issues of oral health status and treatment needs that conventional techniques fail to address.

OPERATIONAL PLAN

In order to create a sound environment for a useful and unbiased scientific study, PAHO PRAT staff gave particular attention to the following components: careful sample selection, training, execution of the clinical component, evaluation and data collection. This section discusses the details of the Project PRAT's operational plan and study methodology, and lays the foundation for the section that follows, which will provide a summary of the data collected.

The study is a complex longitudinal community trial in three countries, and required the participation of two types of dental personnel: dentists ("operators") and hygienists ("auxiliaries"). Within each country two to three regions were chosen and, within them, rural and urban communities. The study took place in the following communities:

PANAMA
Provinces: Coclé, Colón, Panamá
Cities: San Miguelito, Colón, Coclé, Buena Vista

URUGUAY
Provinces: Montevideo, Canelones, Salto
Cities: Montevideo, San Bautista, Salto, Tala

ECUADOR
Provinces: Guayas, Pichincha
Cities: Quito, Tumbajo/Yaruqui, Guayaquil, Duale

Children were sampled at the school level. The sampling unit in this study was the child and the sampling frame was the schools, but the study focus is the restorations performed on the first permanent molars within the child's mouth. The operational plan calls for a three-year study, which would evaluate treatment results and cost-effectiveness data. Due to a number of unforeseen delays, such as complexity in school cycles in the three countries and strikes within the Ministries of Health and Education, which will be elaborated later in this report, Year Three data for operators will not be available until the third quarter of 2006. The results from the intervention (i.e. Year Zero, Year One and Year Two for operators) are included in this study, and tentative recommendations are set forth in this report, according to those results. Likewise, because of the delay in beginning the auxiliary component of the PRAT project, only Year Zero and Year One data is available for auxiliaries.

Prior to any treatment or data collection, the PAHO PRAT staff needed to ensure that the study would meet legal and ethical requirements in each country. Whenever human subjects are used, it is necessary, both by PAHO standards and national law, to inform subjects of the risks and benefits of such a study and to acquire each subject's informed consent. Likewise, the PAHO PRAT staff was required to gain the approval of the project's research protocols and field activity by PAHO's Ethics Committee and by each country's Ministry of Health and Ethics Board or Committee. The overall process took nine months, and no field measurements could begin prior to the ethical approval.

Sample Selection

The PAHO PRAT team created a set of criteria to guide decisions regarding a subject's or tooth's inclusion and exclusion in the project.[2]

The inclusion criteria were as follows:

- Male and female school children, 7, 8, and 9 years of age in rural and urban schools designated for the project in each country.
- Presence of at least one lesion with one of the following characteristics: 1) initial enamel caries, and 2) teeth with dentinal lesions on a first permanent molar.[3]
- Parental consent.

The exclusion criteria were as follows:

- Lesions with very large or deep caries that are very close to the pulp.
- Lesions where caries have compromised the pulp (inflammation or infection of the pulp).
- Healthy teeth without an apparent risk of caries as well as overall good health.

To obtain the study sample, children were screened in each country as follows:

1. **Panama:** Approximately 850 children were examined and 593 chosen for the study. The Panama sample was later augmented to 648 and those children entered the study.
2. **Ecuador:** Approximately 1,500 children were examined and 789 were chosen for the study. Additional children were chosen so that the study began with 834 children.
3. **Uruguay:** A total of 600 children were examined and 212 were chosen for the study. The size of the sample of 212 participants could have been a limiting factor in the country analyses because of the small numbers, which would have made it more difficult to detect whether a difference in survival of the restorations was real or an artifact of chance. Consequently, this number was augmented by almost 200 children. A total of 405 children were randomized into treatment groups. The number of children actually treated in the intervention was 340.

Sample size augmentation was done to ensure that there would be enough children in the overall sample and in each of the three countries, in view of the risks of loss to follow-up (which was estimated to be 10 percent). Having a larger sample in Uruguay meant that it would be more plausible to make in-country comparisons if differences were found at the overall study level. Still, because of sample size limitations, it is not possible to study the three countries as though they are completely independent.

Weighting

Because the study is a complex design and the results will be used to make national estimates, it was necessary to weight the samples so that they were representative of the populations of at-risk children in each nation in order to generalize from the sample findings to the larger populations.

The ART samples were purposive/convenience samples of school children drawn from urban and rural districts in each country. They were not random samples. Records were not maintained for non-response and refusals; therefore it was not possible to weight the sample using standard procedures for non-response.

It is possible that the selection procedures used by the dental technicians or other factors influencing participation led to distortions in the sample. For example, there may be more older children in the sample, more males, or more children drawn from urban schools. The problem is that age, sex or loca-

tion could be correlated with outcomes, and results could reflect demographic sampling biases rather than treatment differences in survival of restorations. To reduce this possibility, the sample was weighted so that the children's demographic characteristics match the demographic characteristics of rural/urban children in each nation. In effect, the samples will appear as if they were large random samples with no biases. In addition, the variances in the results could appear to be higher than they actually are if the sample is not weighted to the population. Weighting helps prevent inflation of the variance estimate.

The 2002 population for each country was estimated using detailed census statistics for each country, and information was used from results of some oral health studies, although most of these did not apply to the age group in question. Response rates and prevalence of cavities were estimated based on the following evidence and logic:

1. The proportion who volunteer for treatment. It was assumed a higher proportion of children would appear for treatment in Ecuador and Panama than Uruguay. In the first round of sampling in Uruguay only 212 (35%) children out of 600 sampled showed up for treatment (and showed evidence of dental caries). The comparable proportion in Ecuador was 88 percent and the comparable proportion in Panama was 59 percent. Children in Uruguay could have greater access to private treatment. Thus, their parents saw less need to sign a release for free treatment in school and the children may have had fewer cavities.
2. Urban vs. Rural. Response rates should be higher among rural children since they have less access to treatment than urban children and their parents are less able to pay for treatment than those who live in urban areas.
3. Prevalence and Nationality. The assumption was that the overall prevalence of cavities would be lower in Uruguay than in Ecuador and Panama. Uruguay has a higher per capita income and education levels than the other countries. Children in Uruguay may get more private treatment than those in other countries.
4. Prevalence and Age. It was assumed the prevalence of children with cavities would increase with age.
5. Sex and Urban/Rural. Most of the respondents in Ecuador said there were no differences in the prevalence of cavities by sex or urban/rural residence. It was assumed the same was true for Panama.

Randomization

Because this is a multi-country study, the largest unit of measure within the ART and Amalgam study groups is the country. The children who are participating in this project were chosen from their schools. Within each country, the children were randomized into groups at the school level, by treatment, e.g., ART or Amalgam. The schools were identified in terms of their proximity to MOH dental services. One of the basic premises of the project was that the children be treated in groups, e.g., standard treatment in the MOH dental clinic or ART at the school, in order to test the transportability of ART.

A simple fixed allocation randomization scheme was originally proposed. Ultimately a permuted blocked design was used. The children were randomized by school. Each school had different numbers of children, some with fewer than 15 children. In order to ensure balanced treatment groups within the schools, children were randomized in blocks of 4 or 10 depending on the size of the school. Schools with 15 children or fewer and, whenever possible, within a reasonable distance from one another were collapsed. The randomization was accomplished using a computer-based (SAS) block randomization using random number seeds from a random digit table. The random numbers were chosen from the random number table using the second two numbers in each random number sequence and moving from left to right diagonally and skipping one line in between. If a random number was repeated, the next number was used. Assignment for all three countries was done in Washington, DC to ensure consistency. The children within each school were randomly assigned to the PRAT (study) or Amalgam (control) groups, stratified by age and gender. Each child had the same chance of being assigned to one of the two groups.

Training

All operators and auxiliaries that participated in the PRAT project were licensed practitioners and are employed in the public sector, with the exception of Uruguay, where the MOH does not employ dental hygienists. Some operators also maintained a private practice in addition to their public sector work.

Two types of training were conducted for both operators and auxiliaries: technique training and data collection training. Since ART is not routinely taught in dental schools it was necessary to train the operators in the ART approach. In the case of operators, the procedures of the Amalgam approach were also reviewed. Technique training sessions for operators were conducted by Drs. Christopher Holmgren and Jo Frencken, and took place as follows:

Panama—October 2001
Ecuador—January 2002
Uruguay—March 2002

Auxiliary training, which excluded training in the Amalgam approach, began much later in the project due to a number of delays that are discussed in detail later in this report. Technique training for auxiliaries was conducted by Dr. Oswaldo Ruiz, and took place as follows:

Panama—August 2002
Ecuador—February 2003
Uruguay—June 2004

The operators and auxiliaries in each country were also trained in the procedures necessary to carry out the study, covered primarily in the protocols for "Instructions for Completing Treatment and Materials Data Collection Form" and "Day-to-Day Activities for Study Coordinators and Operators." The project's economist/statistician consultant, Ann Goldman, MPH, of the George Washington University (GWU), conducted the data collection training for both operators and auxiliaries.

Treatment times were also a vital part of the PRAT study because salary is an important component in the economic evaluation of the ART and Amalgam approaches. As such, operators and auxiliaries were trained to record time spent performing the procedure. Treatment times were determined by two methods: time study and activity sampling. The method of time study is used to obtain a specific time for ART or Amalgam procedures in measurement of minutes, and key activities were coded with a two-digit identifying number and samplings were made at 15-minute intervals.

Restorations

For both the ART and Amalgam restorations, operators were to follow a very specific set of procedures delineated in Operator Protocols (#6 and #7). Each working team consisted of a dental operator and an assistant, or under Phase II, an auxiliary and an assistant, and interventions began only after each subject was evaluated, diagnosed and assigned to one of the treatment groups (ART or Amalgam).

The restoration interventions performed by operators began in late August 2002 in Panama, late October 2002 in Uruguay and November 2002 in Ecuador. Panama completed most of the interventions by December, but a small group of children were treated later. Most of these children had been excluded for age reasons by the operators and a decision was made to ask them to treat the children and collect the data for the study. The Uruguay team completed nearly half of the intervention by December 2002. Some children were treated in the Amalgam group in January and the rest were treated in March–April 2003. In Ecuador, the intervention began in the province of Guayas. Approximately half of the children were treated between November and December 2002 and the balance of the Guayas group was treated in May 2003. The Pichincha province operators did not begin work until late February 2003 and a series of national strikes and other events delayed the intervention so that it took the better part of nine months to complete. Auxiliary restoration measurements began in April 2003 in Panama, in September 2003 in Ecuador, and in December 2004 in Uruguay.

ART restorations took place at the schools, which provided a more informal and accessible setting for patients, while Amalgam restorations took place at MOH health clinics, which are more formal health services clinics. Because of this arrangement, ART restorations and evaluations were easier to complete because, once parents had signed the parental con-

sent form, operators could examine the child at his/her school. This was more difficult for the Amalgam treatment group, where children often did not come to the appointments set up for them at the clinic; treatment and evaluation for this study group required more time and effort, since children often had to travel to the clinic and a parent or caregiver might have to take time off from work to accompany the child to the clinic. Follow-up, then, became more difficult for the Amalgam treatment group.

Restoration Evaluation

The evaluation component of the PRAT study is vital to obtaining clear, accurate and reliable data. Because of variability in factors such as individual interpretations, past training, fluctuations in interest/energy levels, and differences in visual acuity, it was essential that participating evaluators be trained to make consistent clinical judgments. Therefore, the PRAT project required its restoration evaluators to be trained and calibrated according to strict standard criteria so that their assessments were reliable and comparable. Evaluators were to work in pairs during the evaluation exercise. From Ecuador, there were three evaluators, two from Panama, and two from Uruguay.

In November 2004, a week-long training workshop for evaluators was held in Panama prior to the start of the 1st year evaluations. Objectives for the evaluator training workshop included:

- Train evaluators in the use of both the ART criteria and the United States Public Health Service (USPHS) criteria for the evaluation of restorations and sealants.[4]
- Train evaluators in caries detection using criteria adapted from the manual *Oral Health Surveys: Basic Methods* (WHO, 4th Edition, 1997).[5]
- Train evaluators in the organization and management of the examinations, including re-examination for calibration purposes.
- Calibrate the evaluators to achieve an adequate level of reproducibility intra- and inter-evaluator.
- Train evaluators in the use of the evaluation forms of the ART project and their later management.

Because it is as important for the evaluator to be consistent in his/her evaluations (intra-evaluator reliability) as it is for there to be consistency among several evaluators (inter-evaluator reliability), the PRAT team set up exercises throughout the evaluation period to sharpen the evaluators' judgments. To reduce the tendency for evaluators to change the way they apply diagnostic criteria during the course of a long series of examinations, and to measure its extent, it was necessary for each evaluator to conduct duplicate examinations on about 10 percent of the sample from the main study. To the extent possible, the evaluator was not able to identify the subjects who were re-examined, nor did he/she know if the subject had been examined previously, since this knowledge may subconsciously influence the degree of attention and possibly cause the quality of the exercise to be biased. The recorder was therefore requested to arrange for the re-examination of 10 percent of the subjects during the course of the survey, which offered information on changes occurring during the survey period. At least 20 duplicate examinations in each age group at each period were performed so that a reasonable estimate of any changes could be made.

A carefully crafted protocol on annual evaluations set out the procedures and criteria for Project PRAT evaluations. Procedures include:

1. The evaluation will be performed in 12 months, 24 months, and 36 months, after the restorations have been placed.
2. All examinations except those using USPHS criteria will be undertaken using a metallic probe CPI (ball end of 0.5 mm.) The USPHS examinations will be conducted with a straight caries probe.
3. All molars will be examined, including those that did not receive treatment during the initial intervention.
4. Every surface to the molar should be evaluated.
5. All the subjects should brush their teeth without toothpaste immediately before the evaluation.
6. All restorations or sealants will be evaluated with both the ART and USPHS criteria.

7. The caries evaluation will be done with the criteria adapted from the manual *Oral Health Surveys: Basic Methods*.[6]
8. The original treatment data collection form will be used to score the status of restorations and sealants with ART criteria and for caries evaluations. A separate form will be used for USPHS criteria.
9. The criteria used in this evaluation are internationally accepted for this type of study.
10. After the evaluation, the operators should confirm the findings of the evaluation and make the recommendations dental treatment, on the basis of the criteria described in the operative protocols (ART and Amalgam).
11. At the end of each year's evaluation, a report will be presented with the most important findings.

Evaluations were to take place at 12, 24 and 36 months. Given the potential of logistical and other obstacles for evaluating all children exactly 12 months after treatment, the investigators agreed on a three-month window (between 11 and 13 months from the time of treatment) wherein evaluations could take place and still maintain possible variation because of elapsed time. Finally, to ensure the reliability of data over the course of the three-year study by reducing the tendency for evaluators to change the way they apply diagnostic criteria over time, it was necessary to conduct a series of inter-evaluator calibration exercises on an annual basis. At the end of the third year, an external international evaluator will conduct a final evaluation of the condition of restorations performed during the course of the project.

DATA COLLECTION

The data was collected through the use of several forms, designed to keep track of all interventions, evaluations, treatments and consumption of time and materials (costs) for the project. As children were examined by evaluators, the "Treatment and Materials Data Collection" form was completed so that operators could begin treatment. Operators and auxiliaries used the "Time Measurement" form to register the activity completed in 15-minute increments. A separate form was used to track the consumption of materials and the usage of instruments in treatments. The PAHO PRAT team, through the protocols, specific coding and in-depth training, instructed operators, auxiliaries, evaluators and country coordinators in the proper usage of the PRAT forms.

Each form required such information as the location, city, school, name and address of child, grade, age and gender. Children were given unique identifier numbers so that they could be clearly identified by the project; the ID numbers also infused more anonymity for the study subjects. At least one form was completed per tooth in the study; depending on whether more than one independent restoration was performed on the same tooth, there may have been more than one form per tooth. In this way, data could be collected about individual (independent) restorations.

Country coordinators received all forms and lists from the PAHO representative in each country, where they were stored after the initial interventions, or Time 0. Evaluators were charged to recheck all data entered on the forms before returning the completed forms to the country coordinators, who were responsible for delivering them to the PAHO representative. Forms were then scanned and saved to CD-rom before being mailed to PAHO headquarters in Washington. A copy of the CD and forms remained in country.

Data entry was carried out in country by a counterpart of each Ministry of Health. Country coordinators were required to retrieve the original forms from the PAHO representative (after scanning of forms and CD-rom) and the information was entered into an electronic file (Epi Info 6), which has an incorporated verification program. Finally, Epi Info 6 databases were delivered to PAHO Office of the Regional Health Advisor (at headquarters) and a copy remained in country. Ann Goldman, the project's economist/statistician consultant, oversaw the maintenance and organization of the data at this stage.

While the original databases were in Epi Info 6 format, these were exported later to SAS for analysis. Data cleaning processes varied by country according to delays in data entry or scanning of the treatment forms for verification. In the case of Uruguay, records were selected at random for print-

ing and checking against the scanned forms, since these were the first to be delivered. However, the scanned forms from Ecuador and Panama did not arrive until the summer of 2005. In the meantime, photocopies of the Panama treatment forms were used for verification but there were groups of forms that were not available. In addition, the error rate for the Panama treatment forms was very high, which resulted in significant delays in rectifying some of the errors in the database. Delays also occurred in some cases where forms lacked necessary information or they were illegible. When this occurred, forms and duplicates were returned to the countries to be corrected so that the data could be properly calibrated and cleaned.

It should be noted that there are two datasets for each country: one for the initial intervention, and the other for the evaluation process that produces the data to determine the effectiveness of the two approaches. The reason behind maintaining two datasets is that the original study was designed for using ART criteria only for the evaluation; however, a decision was later made to also use USPHS criteria to evaluate the restorations. The decision to use the USPHS code allows for wider comparability with the results of other studies utilizing the USPHS codes.

PHASE I AND PHASE II (AUXILIARY COMPONENT)

Under the original project document, it was proposed that the Amalgam treatment be provided exclusively by qualified dental personnel at a health facility or mobile dental clinic, and that the ART restorations be performed by "low qualified personnel" at the participating schools. The caveat to this operational plan was laid out in the foundation protocol of the project, which clearly stated:

> *Before allowing nurses in the PRAT project, political and cultural appropriateness of their involvement should be verified with the health administrators and parents of prospective patients.*[7]

The PAHO PRAT team recognized early on the difficulties and risks in trying to implement this facet of the project. In a risk analysis of the incorporation of auxiliaries, PAHO staff cautioned that "comparing dentists to auxiliaries . . . would be an unequal measurement, particularly in a study evaluating the cost-effectiveness of an approach in a new context."[8] Additionally, incorporation of the auxiliaries raised legal issues within the participating countries, as national laws regulate the function of auxiliaries and so exemptions would be required for their participation. Finally, cultural and political mindsets served as obstacles to including auxiliary personnel, as there was significant resistance in each country to allowing them to provide dental care.

Despite the ramifications of implementing the auxiliary component, the IDB and PAHO ultimately agreed that auxiliaries should be included in the study and PAHO staff entered into consultations with national oral health authorities to allow the auxiliary component to proceed. Resistance to the idea required a substantial level of lobbying the participating Ministries of Health, particularly in Uruguay, where the reaction of MOH staff to the implementation of the new component varied from neutral to extremely negative. Although PAHO PRAT staff was able to overcome initial resistance from each country's MOH officials, the consultation process created more serious delays for the project. As with other aspects of the project, changes in MOH officials complicated the project's progression; each time a new Minister or Chief Dental Officer was appointed, PAHO staff had to reinitiate the process of introducing the project and acquiring cooperation. This was most acute in Ecuador where over the life of the project a total of eight (8) Ministers of Health and Dental Chief Officers were changed.

For the project purposes therefore the implementation of the study using dentists became known as phase I, and with auxiliaries, phase II.

DEVELOPMENT OF PROTOCOLS

The development and refinement of research instruments and protocols is an integral part of ensuring a sound scientific study. In the case of the PRAT project, these protocols derived form and anchored to an initial master protocol, guided the details of the investigation, including data collection and measure-

ment, ethical concerns, health and safety issues, sample selection, and calibration of training and clinical operations. Following is a brief description of the study's operational protocols.

Protocol #1: Subject Selection Criteria

This protocol specifies the ages and condition of the children who may participate in the study.

Protocol #2: Selection Criteria for Teeth

This protocol provides specific criteria for tooth location and the type of caries eligible to be part of the study.

Protocol #3: Biosafety/Infection Control

This protocol specifies the infection control precautions, including acceptable methods of sterilization, and procedures that are to be observed during the clinical activities of the project.

Protocol #4: Ethics and Informed Consent

This protocol sets out the ethical procedures that are to be adhered to during the course of the project, and it also includes the letter of parental consent to allow the child to participate in the project.

Protocol #5: Emergency and Referral Treatment

This protocol delineates the procedures to be followed when urgent treatment or referral for treatment may be necessary.

Protocol #6: Operational Procedures for ART Restorations

This protocol describes in detail the procedures to be followed for performing ART restorations.

Protocol #7: Operational Procedures for Amalgam Restorations

This protocol describes in detail the procedures to be followed for performing Amalgam restorations. The particular protocol is not relevant to the auxiliaries, as they perform only ART restorations.

Protocol #8: Instructions for Completing the Treatment and Materials Data Collection Form

This protocol describes in detail the procedures to be followed when recording the clinical data on the Treatment and Materials Data Collection form.

Protocol #9: Day-to-Day Activities of Study Operators and Coordinators

This protocol sets out in detail all procedures that are necessary for the preparations for the clinical activity and data collection, and the control and storage of data collected.

Protocol #10: Time Measurement

This protocol delineates the procedures for time measurement and activity sampling in the study.

Protocol #11: Materials Consumption

This protocol explains how materials will be acquired and distributed throughout the course of the study. The protocol emphasizes that these materials are to be used exclusively for the PRAT project, and it provides a set of procedures for replacement of all materials as well as transportation of the materials for treatment sessions in the schools.

Protocol #12: Case Studies

This protocol offers case studies that emphasize the important points of ART restorations for the purposes of training.

Protocol #13: Operator and Patient Survey

This protocol requires operators to complete two questionnaires, one after 50 practices and one after 50 interventions, to determine the level of operator comfort and competence with the application of the techniques, as well as their perceptions of the ART technique versus the Amalgam technique. A section was included to determine the reaction of patients to each technique.

Protocol #14: Statistical Protocol

This protocol describes the background and full methodology for the study.

Protocol #15: Cost-Effectiveness Protocol

This protocol describes the method by which the project's Cost-Effectiveness Analysis will be performed.

Protocol #16: Evaluation Protocol

This protocol describes the methods for evaluating the study.

Based upon the PRAT project protocols for dental operators, a second set of protocols was revised for use of the auxiliary personnel, who would be trained in and execute only the ART intervention. Both sets of protocols in their entirety can be found in the appendix of this report.

Additionally, the PRAT project utilized a set of forms for data collection. These forms included the following, which can also be found in their entirety in the appendix of this report:

Form #1: Treatment and Materials Data Collection Form (Annex to Protocol #8)

Form #2: Time Measurement Form (Annex to Protocol #10)

Form #3: Materials/Instruments Consumption Form (Annex to Protocol #11)

Form #4: Urgent Treatment or Referral for Treatment Form (Annex to Protocol #5)

NOTES

1. Pan American Health Organization, *Supra*, note 4.

2. For more precise information about inclusion/exclusion criteria, please refer to the report's Appendix I, which contains the full protocol regarding criteria.

3. When the sample was augmented in Ecuador, there were some difficulties in finding children that met the study criterion of at least one lesion on one of the first permanent molars. A decision was made to include children with deep pits and fissures in the study.

4. See the "Project Protocols" section in the Appendix to this report for more discussion of both ART criteria and USPHS criteria.

5. World Health Organization. *Oral Health Surveys: Basic Methods*, 4th Edition. Geneva: WHO, 1997.

6. *Ibid*.

7. Pan American Health Organization. *Oral Health of Low Income Children: Procedures for Atraumatic Restorative Treatment (PRAT), Progress Report Number 2*. Washington, DC: PAHO, 2002, p. 13.

8. *Ibid*, p. 209.

3. Data Report Summary

UNIT OF ANALYSIS

The unit of analysis is the tooth. There are a small number of tables that identify the number of children. This alternative enumeration is for informational purposes only. All analyses of failure and cost-effectiveness are performed at the level of the individual tooth.

INCLUSION CRITERIA

While the protocol had specifically indicated that children should be between the ages of 7 and 9 at baseline, not all children were within this age range. Age data were assumed to be correct and a number of children (and all the children's teeth) were excluded because of being outside the age range. The other criterion that was applied in the analyses was to include only those cases that had a non-missing date of initial treatment.

STUDY GROUP

All teeth had non-missing data for the group of teeth that were assigned to be treated by a dentist—either a dentist using amalgam or a dentist using ART. There were occasional missing data on the group assignment for teeth in the group assigned to have ART performed by auxiliary personnel. However, since all the teeth in the auxiliary data files were treated by an auxiliary, the assumption was made that all these teeth were included in the auxiliary ART group. Thus, the auxiliary ART group was assigned to any tooth record with missing data for group assignment.

WEIGHTED DATA

Weights were provided. All weights for Ecuador and Uruguay were equal to exactly one. This surprising result was checked by examining the two components of the final weighting variable; both were 1 in all cases. The weights in Panama varied by sex, age, and urban/rural area. Weights were provided only for the teeth that were treated by dentists. To provide weights for the teeth treated by auxiliary personnel, the average of the weights that were specific to a sex-age combination, which varied between urban and rural areas, were applied to the teeth in the auxiliary data set. The average treated each weight equally. This was necessary because the schools in the auxiliary file were numbered differently from the schools in the dentist file. The data from Uruguay provided an urban/rural indicator for the teeth treated by auxiliaries, but in Uruguay all weights were exactly 1.

DESCRIPTIVE ANALYSES

The teeth were described in terms of age, sex, and urban/rural status. Each of these descriptions was done by country and by group within country.

OUTCOME ANALYSES

In order to provide meaningful outcome data, a tooth would have had to have been observed and evaluated

based on USPHS criteria at 12 months or 24 months or both. The number of teeth observed and evaluated at each point in time was documented. Some teeth were not observed. Others had missing data on evaluation. Some of the evaluation for the United States Public Health Service (USPHS) did not correspond to what was documented as the correct coding. However, decisions were made about how to treat each of these.

The primary outcome measure was failure based on the criteria of the (USPHS). These were coded separately at 12 and 24 months, although the two observations were not treated as completely independent. In particular, data on failure at 12 months should inform the data at 24 months. Specifically, if failure has occurred at 12 months this can be imputed forward, i.e. the tooth cannot "survive" at 24 months if it has failed at 12 months. This "forward imputation" will occur regardless of whether the data at 24 months were observed. This changed some 24 month data from survival to failure and changed other 24 month data from missing to failure.

Given the lack of perfect correspondence between survival at 24 months and survival at 12 months in the observed data, survival at 24 months was not imputed backward to the 12 month observation. Thus, although some teeth were observed to have survived at 24 months, we did not consider these teeth to have non-missing data at 12 months indicating survival. Conversely, it was impossible to determine when a tooth observed as "failed" at 24 months had failed, i.e. whether it had it failed before 12 months or between 12 and 24 months. Thus, observed 24 month data are really useful only if 12 month data were also observed.

Both cumulative and incident failure were characterized. Calculating cumulative failure, we used all data that were available. The denominator for incident failure at 24 months was only teeth for which survival at 12 months was actually observed and for which the 24 month data were also observed (regardless of failure or survival).

Other basic outcomes described were cooperation and pain during the filling procedure at baseline.

More complex analysis of the differential risk of failure was also conducted using regression analysis. Failure at 12 months was modeled comparing all three groups (dentist amalgam, dentist ART, and auxiliary ART). The analyses were conducted using a variety of specifications, and were done by country and controlling for country. The analyses were conducted without controlling for age, sex, and urban/rural and controlling for these demographic variables. Finally, clustering among teeth was allowed at both the level of the child and the level of the "operator."

In addition to the multiple specifications for regression analysis of failure at 12 months, logistic regressions were also run for incident failure at 24 months (i.e. using only those who were observed at 24 months and for whom survival at 12 months had actually been observed).

The data can also be structured to perform a discrete time survival analysis (modeling failure at either 12 or 24 months) in a manner suggested in the STATA manual. This type of analysis creates a second observation for any tooth for which the treatment is observed to have survived at 12 months. This second observation is missing if the tooth was not observed at 24 months. The second observation is then coded as a survival or failure as appropriate for teeth that are observed at 24 months. Both the 12 month and 24 month observations are included in the final analytic data set. A regression analysis similar to a Cox model in continuous survival then includes an indicator for each time period other than the first time period. In this case, the analysis includes only one additional time period. The analysis also includes an interaction term between the ART group and the second time period as the survival of the treatments appears to be quite different by group between the first and second period. This may be a function of the failure to observe a larger number of teeth that were treated by amalgam at 24 months, so that it is not clear whether the higher observed failure rate in the second period is a function of a true difference or of the fact that the teeth for which the treatment had survived were not observed.

INCREMENTAL COST-EFFECTIVENESS ANALYSIS

Final specifications for the cost-effectiveness analysis use the results from separate regressions by group to project the probability of failure if a given

treatment were applied to the entire population of teeth in each country. This is a fairly straightforward prediction of the probability of failure for one year when all three groups are being prepared. This is more complicated for the two year survival for the teeth treated by a dentist. The most interesting comparison is to project the expected number of years of survival of each tooth's treatment. This can be calculated as follows:

(1-Prob[12 Month Failure]) +
(1-Prob[12 Month Failure])(1-Prob[24 Month Failure|12 Month Survival])

The number of years of treatment survival is then a relevant outcome for comparing the treatments and making a cost-effectiveness assessment.

Cost-effectiveness analyses performed include:

- Two year cost-effectiveness of survival for teeth treated by dentists
- Two year costs including the cost of retreatment for teeth treated by dentists
- One year cost-effectiveness of survival for teeth treated by all providers
- One year costs including the cost of retreatment for teeth treated by all providers
- One year costs including the cost of retreatment for teeth treated by all providers in Panama and Uruguay assuming that all treatments take the same amount of time (i.e. there is a learning effect that will eventually make the performance of ART as efficient as treatment by amalgam)
- One year costs including the cost of retreatment with greater equipment costs assigned to the auxiliary personnel (for whom equipment costs were not included)

The cost-effectiveness analyses are limited by the exclusion of training and travel costs for ART. However, the key question is how much less costly the treatments requiring training and travel are. The lower costs provide some insight into how costly training and travel can be while still allowing the total costs to the health care system to be lower. No analyses were done including the family's costs of bringing a child to a dentist's office.

DEMOGRAPHICS

The general demographics and sample size characteristics of the subjects provide a solid background for understanding the results of the PRAT study.[1] This section details the demographics of those subjects by country, region, age, sex and study group.

Panama had a total of 572 subjects selected as suitable for the PRAT study, while Uruguay had a total of 322 and Ecuador had a total of 735 subjects, so the total sample size was 1,629 children. Figure 1, below, shows the distribution of subjects by country.

Table 3, below, demonstrates the differences in geographic location where subjects were treated. Children were categorized as living in urban or rural areas.

The data shows that the study is fairly heavily biased toward urban populations, as more than 60 percent of the study sample comes from urban areas. This bias may partially be explained by the fact that the schools chosen for the study were necessarily within a short distance from a national MOH dental clinic.

Older children tended to dominate the study, as shown by the figures below. While Panama's participants were closely split between the age groups of 7-, 8- and 9-year-olds, there were few 7-year-olds in the Uruguay and Ecuador populations. Figure 2, below, shows the ages of the children involved in the study, and Figure 3 shows the weighted percentages of children by age in the sample size as a whole.

FIGURE 1 Total Sample Size by Country

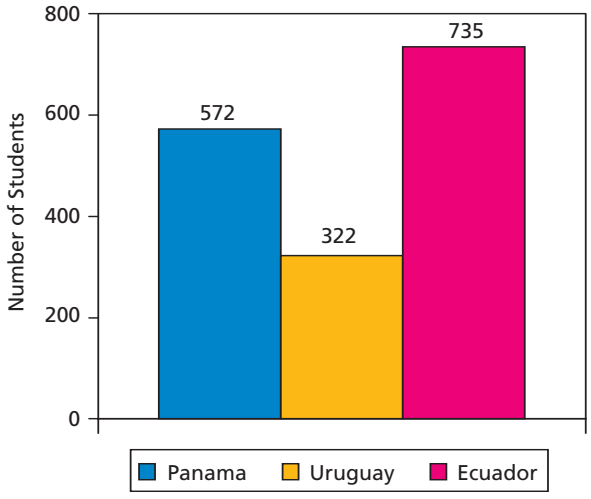
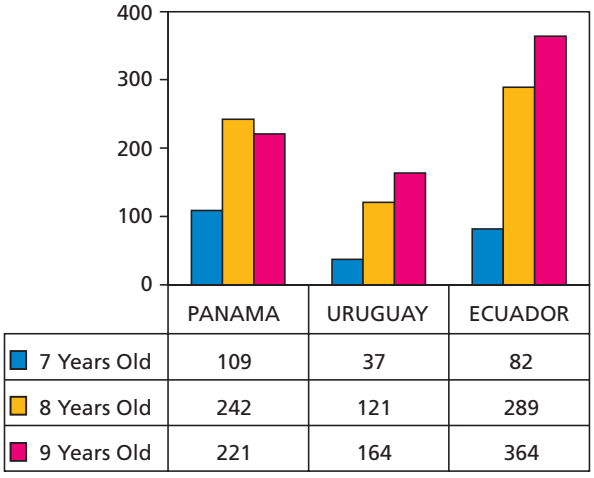


Table 3 Distribution of Children by Geographic Location (Urban/Rural) and by Country

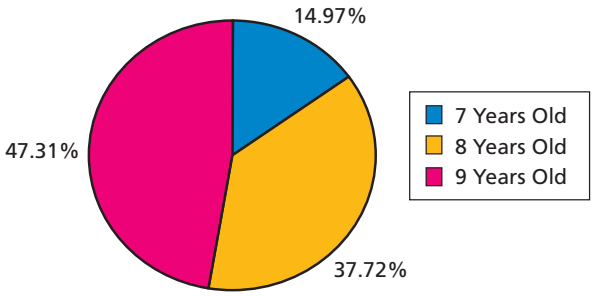
	Panama	Uruguay	Ecuador	All Countries
Geographic Location	*Frequency* (%)	*Frequency* (%)	*Frequency* (%)	*Frequency* (%)
Urban	302 (47.65)	140 (43.89)	560 (76.06)	1002 (62.77)
Rural	270 (52.35)	182 (56.11)	175 (23.94)	627 (37.23)

FIGURE 2 Distribution of Children by Age and by Country



	PANAMA	URUGUAY	ECUADOR
7 Years Old	109	37	82
8 Years Old	242	121	289
9 Years Old	221	164	364

FIGURE 3 Distribution of Children by Age—All Countries



The sample, both between and among countries, was fairly evenly split between the male and female population. There were slightly more females involved in the study (48.62 percent were males compared to 51.38 percent which were females). Table 4, below, shows the distribution of subjects by sex.

The number of children in the study in each treatment group and in the overall sample by country is described in Figure 4, below. The figure shows that the ART group included 303 children from Panama, 174 children from Uruguay and 391 children from Ecuador. Additionally, the Amalgam group included 269 children from Panama, 148 children from Uruguay and 344 children from Ecuador. Figures 5 and 6 show the composition of the Treatment Groups in terms of proportion of children from each country.

Overall, the study groups are quite similar by country, gender and geographic location. In Panama, for example, the proportion of children in both study groups is about 19 percent based upon the weighted proportions. In Uruguay, Amalgam and ART groups are between 25 and 26 percent, respectively, while in Ecuador they are 55 percent and 56 percent, respectively. Figures 4 and 5, above, reveal these trends.

Likewise, the male/female ratio between the two treatment groups was very similar to the ratio in the sample as a whole. Because, as previously noted, the sample includes slightly more females in the study than males, females represent a slightly larger proportion in each treatment group. Table 5, below, shows the distribution of subjects by sex and by treatment group.

Table 4 Distribution of Children by Sex and by Country

	Panama	Uruguay	Ecuador	All Countries
Sex	*Frequency* (%)	*Frequency* (%)	*Frequency* (%)	*Frequency* (%)
Male	278 (50.88)	157 (48.90)	351 (47.74)	786 (48.62)
Female	294 (49.12)	165 (51.10)	384 (52.76)	843 (51.38)

FIGURE 4 Distribution of Children by Treatment Group and by Country

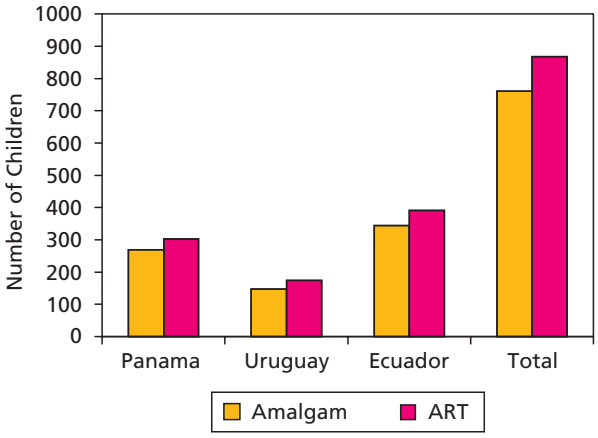


Table 5 Distribution of Children by Sex and by Treatment Group

	Amalgam	ART
Sex	*Frequency* (%)	*Frequency* (%)
Male	368 (49.16)	418 (48.15)
Female	393 (50.84)	450 (51.85)

Table 6 Distribution of Children by Geographic Location and by Treatment Group

	Amalgam	ART
Geographic Location	*Frequency* (%)	*Frequency* (%)
Urban	465 (62.29)	537 (63.19)
Rural	296 (37.71)	331 (36.81)

FIGURE 5 Distribution in Amalgam Treatment Group by Country

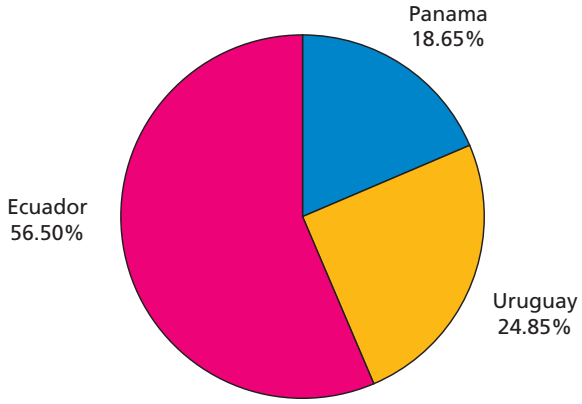
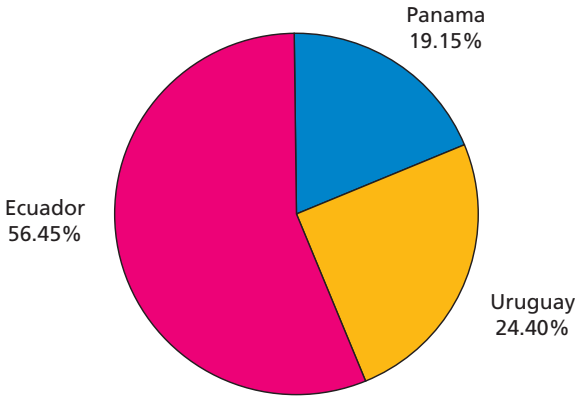


FIGURE 6 Distribution in ART Treatment Group by Country



As noted above, more urban children participated in the study than rural children. Table 6, below, shows the distribution of geographic location of children within the treatment groups.

The treatment groups differ significantly by age category, as shown in Figures 7 and 8. The category that seems to be most different is the groups of children age seven or less, which is the smallest group with 89 children in the Amalgam group and 139 in the ART group. The two other age categories are similar to one another in size. There are 312 8-year-old children in the Amalgam group and 350 8-year-olds in the ART group. For the 9-year-old category (which included a few 10-year-olds), there are 360 children in the Amalgam group and 389 in the ART group.

TREATMENT NEEDS AND CARIES

Table 7 summarizes the caries experience of the children by lesions diagnosed in the study. It shows that most of the caries identified on the first permanent molars were enamel caries, followed by dentine caries, both of which were the lesions targeted for the study. It should be noted that, in Ecuador, it was difficult to find children with carious lesions on the first permanent molars and so the criteria were widened to allow children with deep pits and fissures. Deep pits and fissures are considered a risk for future caries. This explains the high number of

FIGURE 7 and 8 Distribution of Children by Age and Treatment Groups

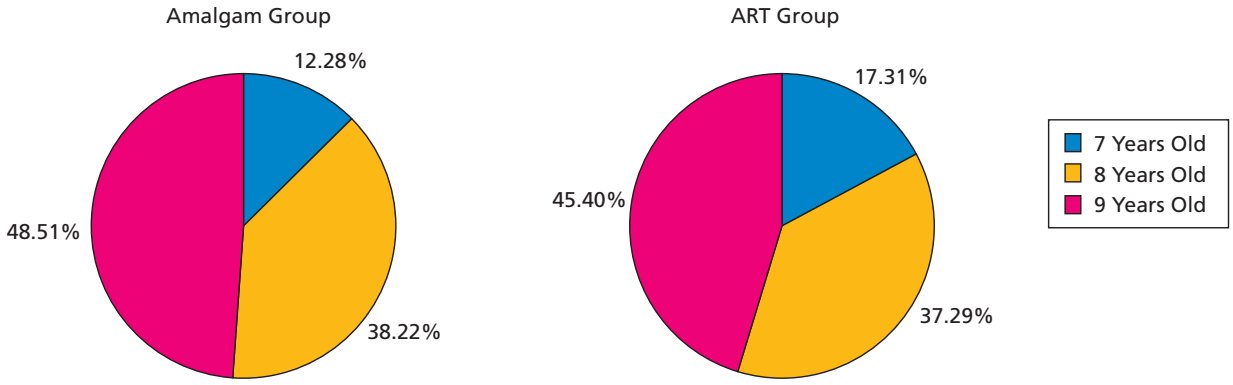


Table 7 Distribution of Caries Diagnostic Codes on Tooth Surfaces by Treatment Group at Initial Intervention (Time 0) (August 2002–October 2003) by Country

	Panama			Uruguay			Ecuador			All Countries		
Caries Dx Codes	Amal (%)	ART (%)	Total (%)	Amal (%)	ART (%)	Total (%)	Amal (%)	ART (%)	Total (%)	Amal (%)	ART (%)	Total (%)
No caries	17 (0.91)	67 (2.55)	84 (1.78)	9 (2.72)	23 (5.81)	32 (4.39)	22 (2.05)	327 (18.37)	349 (10.78)	48 (2.00)	417 (12.31)	465 (7.51)
Enamel caries	394 (68.85)	552 (81.62)	946 (75.58)	148 (69.39)	292 (88.95)	440 (79.94)	472 (63.05)	801 (68.37)	1273 (65.89)	1014 (65.70)	1645 (75.94)	2659 (71.18)
Dentine caries	250 (23.66)	150 (14.18)	400 (18.66)	69 (25.17)	25 (4.65)	94 (14.11)	318 (25.81)	180 (9.69)	498 (17.19)	637 (25.24)	355 (9.28)	992 (16.71)
Deep dentine caries	29 (5.68)	6 (1.64)	35 (3.55)	6 (2.72)	1 (0.58)	7 (1.57)	67 (7.33)	24 (2.30)	91 (4.64)	102 (5.89)	31 (1.75)	133 (3.68)
Possible pulp lesion	0 (0)	2 (0)	2 (0)	0 (0)	0 (0)	0 (0)	16 (1.76)	9 (1.02)	25 (1.36)	16 (0.99)	11 (0.58)	27 (0.77)
Missing data	3 (0.90)	4 (0)	7 (0.43)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.26)	1 (0.14)	3 (0.17)	5 (0.14)	8 (0.16)
TOTAL	693	781	1474	232	341	573	895	1342	2237	1820	2464	4284

sealants in the Ecuador group. Also, the table represents the number of diagnoses made on individual tooth surfaces; therefore, one tooth could have more than one diagnosis. **NOTE:** As noted before, all percentages are *weighted* percentages, while frequency numbers represent *unweighted* numbers unless otherwise noted.

NOTE

1. It is important to note that these demographic data *do not* represent an epidemiological baseline for the project. The examinations conducted were to qualify children for the study; no information was collected on children that did not qualify for the study.

4. Project Findings

Table 8 shows the number of teeth in the analytic data set by country and by group to which the teeth were assigned. The numbers are unweighted—and the weighting is largely irrelevant as the weights in two of three countries are all identical. The proportion of teeth in each of the groups is also shown. Finally, the number of teeth that were in the original data provided but were not included because of not meeting inclusion criteria is shown.

Table 9 illustrates the number of children in the analytic data set, a total of 2,298. Many children had more than one tooth in the data set. The children are more evenly distributed across the three countries. This reflects a difference in the average number of treated teeth per child in the three countries.

Table 10 shows the age distribution of the teeth in each country. The modal age is 9 in both Ecuador and Uruguay. The modal tooth is 8 years old in Panama. In all three countries, 7 year old teeth are the least represented. The median tooth is 8 years old in Ecuador and Panama but 9 years old in Uruguay.

Table 11 shows the distribution of the age of the teeth by group within country. Panama has the most similar distribution across the three groups.

Table 12 shows the distribution of the gender with the tooth as the unit of analysis. In Panama

Table 8 Number of Teeth in Analytic Data Set

		Dentist Amalgam	Dentist ART	Auxiliary ART	Total in Analytic Data Set	Excluded Because Age<7 or Age>9 or No Date of Baseline Treatment
Ecuador	(N)	888	1336	1261	3485	189
	(%)	25.5%	38.3%	36.2%	100%	
Panama	(N)	677	769	693	2139	101
	(%)	31.7%	36.0%	32.4%	100%	
Uruguay	(N)	232	341	576	1149	62
	(%)	20.2%	29.7%	50.1%	100%	

Table 9 Number of Children in Analytic Data Set

		Dentist Amalgam	Dentist ART	Auxiliary ART	Total in Analytic Data Set	Excluded Because Age<7 or Age>9 or No Date of Baseline Treatment
Ecuador	(N)	339	387	320	1046	44
	(%)	32.4%	37.0%	30.6%		
Panama	(N)	258	294	208	760	41
	(%)	33.9%	38.7%	27.4%		
Uruguay	(N)	147	172	173	492	27
	(%)	29.9%	35.0%	35.2%		

Table 10 Age of Teeth in Analytic Data Set by Country

		Age			
		7	8	9	Total in Analytic Sample
Ecuador	(N)	582	1382	1521	3485
	(%)	16.7%	39.7%	43.6%	
Panama	(N)	467	890	782	2139
	(%)	21.8%	41.6%	36.6%	
Uruguay	(N)	136	400	613	1149
	(%)	11.8%	34.8%	53.4%	

Table 11 Number of Teeth in Analytic Data Set by Age of Child and Group by Country

			Age			
			7	8	9	Total in Analytic Sample
Ecuador	*Dentist Amalgam*	(N)	64	337	487	888
		(%)	7.2%	38.0%	54.8%	
	Dentist Atraumatic Restorative Therapy	(N)	185	514	637	1336
		(%)	13.8%	38.5%	47.7%	
	Auxiliary Atraumatic Restorative Therapy	(N)	333	531	397	1261
		(%)	26.4%	42.1%	31.5%	
Panama	*Dentist Amalgam*	(N)	128	311	238	677
		(%)	18.9%	45.9%	35.2%	
	Dentist Atraumatic Restorative Therapy	(N)	160	321	288	769
		(%)	20.8%	41.7%	37.5%	
	Auxiliary Atraumatic Restorative Therapy	(N)	179	258	256	693
		(%)	25.8%	37.2%	36.9%	
Uruguay	*Dentist Amalgam*	(N)	14	86	132	232
		(%)	6.0%	37.1%	56.9%	
	Dentist Atraumatic Restorative Therapy	(N)	51	127	163	341
		(%)	15.0%	37.2%	47.8%	
	Auxiliary Atraumatic Restorative Therapy	(N)	71	187	318	576
		(%)	12.3%	32.5%	55.2%	

and Uruguay the teeth are nearly split evenly between boys and girls, whereas in Ecuador this is not the case.

Table 13 shows the distribution of gender by group and country. The results in this table reveal the fact that the most uneven distribution by gender is among the teeth treated by auxiliaries in Ecuador. The teeth are nearly evenly split between males and females in all groups in Panama.

Table 14 shows the distribution of urban and rural teeth by country. In Uruguay, the teeth are nearly evenly divided. In Panama approximately 60% of the teeth are urban, and in Ecuador nearly ¾ of the teeth in the analytic sample are from urban areas. Table 15 shows the distribution by group and by country. As noted earlier, for Ecuador and Panama it is impossible at present to show the distribution for the group treated by auxiliary personnel. In Ecuador the distribution for the two groups treated by dentists is very similar. The same can be said of the sample in Panama. In Uruguay the results show that a majority of the teeth treated by dentists are in rural areas while 56% of the teeth treated by auxiliary personnel are in urban areas.

Table 16 shows that the proportion of teeth for which there are follow-up data varies in important ways by the group to which the teeth are assigned, the country, and the time period. As coded, all teeth

Table 12 Number of Teeth in Analytic Data Set by Sex of Child and Country

		Male	Female	Total in Analytic Sample
Ecuador	(N)	1476	2009	3485
	(%)	42.4%	57.6%	
Panama	(N)	1073	1066	2139
	(%)	50.2%	49.8%	
Uruguay	(N)	589	560	1149
	(%)	51.3%	48.7%	

Table 13 Number of Teeth in Analytic Data Set by Sex of Child and Group by Country

			Sex		
			Male	Female	Total
Ecuador	*Dentist Amalgam*	(N)	437	451	888
		(%)	49.2%	50.8%	
	Dentist Atraumatic Restorative Therapy	(N)	610	726	1336
		(%)	45.7%	54.3%	
	Auxiliary Atraumatic Restorative Therapy	(N)	429	832	1261
		(%)	34.0%	66.0%	
Panama	*Dentist Amalgam*	(N)	330	347	677
		(%)	48.7%	51.3%	
	Dentist Atraumatic Restorative Therapy	(N)	396	373	769
		(%)	51.5%	48.5%	
	Auxiliary Atraumatic Restorative Therapy	(N)	347	346	693
		(%)	50.1%	49.9%	
Uruguay	*Dentist Amalgam*	(N)	106	126	232
		(%)	45.7%	54.3%	
	Dentist Atraumatic Restorative Therapy	(N)	163	178	341
		(%)	47.8%	52.2%	
	Auxiliary Atraumatic Restorative Therapy	(N)	320	256	576
		(%)	55.6%	44.4%	

Table 14 Number of Teeth in Analytic Data Set by Location by Country

		Urban	Rural	Total
Ecuador	(N)	1655	569	2224
	(%)	74.4%	25.6%	
Panama	(N)	870	576	1446
	(%)	60.2%	39.8%	
Uruguay	(N)	586	563	1149
	(%)	51.0%	49.0%	

have an indication of whether the treatment failed based on USPHS criteria, although this seems like it might be a coding error in the ENCH6 program rather than a true representation of what was observed. Presumably, unless an unobserved tooth is assumed to have a particular result or the ART criteria have an indefinite result, the number of teeth for which there are outcome data should be similar for the two sets of criteria. The number of teeth observed and evaluated at 24 months is somewhat smaller than the number observed and evaluated at 12 months. The number of forward imputations is actually small—the difference between the second and third columns.

Table 17 shows the cumulative failure rates at 12 and 24 months by country and by type of treatment. In Ecuador, the cumulative failure rate is approximately 5 percentage points higher when the tooth

Table 15 Number of Teeth in the Analytic Data Set by Location and Group by Country

			Urban/Rural		
			Urban	Rural	Total
Ecuador	*Dentist Amalgam*	(N)	637	251	888
		(%)	71.7%	28.3%	
	Dentist Atraumatic Restorative Therapy	(N)	1018	318	1336
		(%)	76.2%	23.8%	
	Auxiliary Atraumatic Restorative Therapy	(N)	RURAL/URBAN INDICATOR UNAVAILABLE		
		(%)			
Panama	*Dentist Amalgam*	(N)	401	276	677
		(%)	59.2%	40.8%	
	Dentist Atraumatic Restorative Therapy	(N)	469	300	769
		(%)	61.0%	39.0%	
	Auxiliary Atraumatic Restorative Therapy	(N)	RURAL/URBAN INDICATOR UNAVAILABLE		
		(%)			
Uruguay	*Dentist Amalgam*	(N)	101	131	232
		(%)	43.5%	56.5%	
	Dentist Atraumatic Restorative Therapy	(N)	162	179	341
		(%)	47.5%	52.5%	
	Auxiliary Atraumatic Restorative Therapy	(N)	323	253	576
		(%)	56.1%	43.9%	

Table 16 Observations with Follow-Up Data Available for USPHS Failure Criteria

			All	USPHS 12	USPHS 24	Cumulative USPHS 24*
Ecuador	*Dentist Amalgam*	(N)	888	755	609	624
		(%)		85.0%	68.6%	70.3%
	Dentist Atraumatic Restorative Therapy	(N)	1336	1206	984	1003
		(%)		90.3%	73.7%	75.1%
	Auxiliary Atraumatic Restorative Therapy	(N)	1261	1040		
		(%)		82.5%		
Panama	*Dentist Amalgam*	(N)	677	617	557	559
		(%)		91.1%	82.3%	82.6%
	Dentist Atraumatic Restorative Therapy	(N)	769	672	622	625
		(%)		87.4%	80.9%	81.3%
	Auxiliary Atraumatic Restorative Therapy	(N)	693	655		
		(%)		94.5%		
Uruguay	*Dentist Amalgam*	(N)	232	211	211	211
		(%)		90.9%	90.9%	90.9%
	Dentist Atraumatic Restorative Therapy	(N)	341	301	304	304
		(%)		88.3%	89.1%	89.1%
	Auxiliary Atraumatic Restorative Therapy	(N)	576	260		
		(%)		45.1%		

*This tells the number of teeth for which we could identify a 24 month cumulative outcome (failure or success).

Table 17 USPHS Cumulative Failure in Analytic Data Set with 12 Month Failure Imputed Forward

			12 Month USPHS	24 Month USPHS
Ecuador	*Dentist Amalgam*	(N)	43	70
		(%)	5.70%	11.22%
	Dentist Atraumatic Restorative Therapy	(N)	127	168
		(%)	10.53%	16.75%
	Auxiliary Atraumatic Restorative Therapy	(N)	165	
		(%)	15.87%	
Panama	*Dentist Amalgam*	(N)	6	8
		(%)	0.97%	1.43%
	Dentist Atraumatic Restorative Therapy	(N)	14	22
		(%)	2.08%	3.52%
	Auxiliary Atraumatic Restorative Therapy	(N)	101	
		(%)	15.42%	
Uruguay	*Dentist Amalgam*	(N)	12	15
		(%)	5.69%	7.11%
	Dentist Atraumatic Restorative Therapy	(N)	12	19
		(%)	3.99%	6.25%
	Auxiliary Atraumatic Restorative Therapy	(N)	15	
		(%)	5.77%	
Total	*Dentist Amalgam*		61	93
	Dentist Atraumatic Restorative Therapy		153	209
	Auxiliary Atraumatic Restorative Therapy		281	
Total Failures			495	302

was treated by a dentist using ART than when the tooth was treated by a dentist using amalgam. At twelve months, the failure rate for teeth treated by auxiliary personnel using ART was another 5 percentage points higher than for dentists using ART. In Panama, the cumulative failure rates were approximately double for dentists using ART compared with dentists using amalgam. Both rates were lower than the dentist using ART failure rate in Ecuador. In contrast, the failure rate for auxiliary personnel using ART was similar in Panama to the rate in Ecuador. In Uruguay, the failure rate for dentists using amalgam was higher than the failure rate for dentists using ART and similar to the rate for auxiliary personnel using ART at 12 months. The failure rate for dentists using ART remained lower than the failure rate for dentists using amalgam at 24 months.

Table 18 shows the four different USPHS failure criteria that were used and the number that were coded as a failure for each criterion. Some teeth failed in more than one criterion.

Table 19 shows incident rather than cumulative failure. The results in this table correspond to what would be expected based on differences over time reported in Table 18.

Tables 20 and 21 show the results of cooperation and pain measures. The distributions differ only marginally. In each country, the dental amalgam is least likely to have the best level of cooperation (level 0). In each country, the auxiliary using ART is

Table 18 USPHS Recode Failure Criteria at 12 and 24 Months

	12 Month				24 Month			
Level	Anatomical Form	Marginal Integrity	Sealant Retention	Recurrent Carries	Anatomical Form	Marginal Integrity	Sealant Retention	Recurrent Carries
A or 0	4906	4798	3901	5075	3066	3025	2410	3203
B	199	278	488	76	96	132	200	31
C	286	142	358	40	67	36	55	31
D		256			1	54		
H			750				602	1
N			1					
Z	23	6	13	15	18	5	7	9
Coded but not Alphabetical	100	48	16	7	33	33	11	11
Missing Data	1259	1245	1246	1560	3492	3488	3488	3489
Total Coded Alphabetical	5414	5480	5511	5206	3248	3252	3274	3275
Total	6773	6773	6773	6773	6773	6773	6773	6775
Failure	309	262	371	131	85	59	62	71

Table 19 Incident Failure (for 24 months only if not failed at 12 months) with USPHS Failure Recodes

		12 Month USPHS Criteria	24 Month USPHS Criteria
Ecuador	*Dentist Amalgam*	5.70%	4.81%
	Dentist Atraumatic Restorative Therapy	10.53%	4.68%
	Auxiliary Atraumatic Restorative Therapy	15.87%	
Panama	*Dentist Amalgam*	0.97%	0.38%
	Dentist Atraumatic Restorative Therapy	2.08%	1.21%
	Auxiliary Atraumatic Restorative Therapy	15.42%	
Uruguay	*Dentist Amalgam*	5.69%	1.51%
	Dentist Atraumatic Restorative Therapy	3.99%	2.42%
	Auxiliary Atraumatic Restorative Therapy	5.77%	

associated with the least pain. In Panama and Uruguay, the dentist using ART yields less pain than the dentist using amalgam.

Table 22 uses the failure data at 12 months to estimate the odds ratios of failures for teeth on which ART was performed by either dentists or auxiliaries compared with teeth on which dentists used amalgam. The dentist using ART has an odds ratio of 1.75 ($p<0.05$), even when controlling for country, age, and sex, weighting the data, and allowing for clustering by operator. This relationship is insensitive to the exclusion of variables other than the treatment group and to clustering at the level of the child rather than the operator. The odds ratio for auxiliary ART when controlling for other variables, weighting, and allowing for clustering by operator is 3.43 ($p<0.05$). While these odds ratios are consistent with a higher odds of failure for treatments other than the traditional dentist performing an amalgam treatment, given the generally low risk of failure, it is still possible that the alternatives will be cost-effective.

Table 23 shows the wide variation in odds ratios for different treatment groups when estimating relationships for the different countries. These are reflective of the basic failure rate data. Neither of the odds ratios is statistically significantly different from the one in Uruguay. The large odds ratios are

Table 20 Cooperation at Baseline by Group by Country

			0	1	2	Total
Ecuador	*Dentist Amalgam*	(N)	795	72	15	882
		(%)	90.1%	8.2%	1.7%	
	Dentist Atraumatic Restorative Therapy	(N)	1211	109	13	1333
		(%)	90.8%	8.2%	1.0%	
	Auxiliary Atraumatic Restorative Therapy	(N)	1189	59	13	1261
		(%)	94.3%	4.7%	1.0%	
Panama	*Dentist Amalgam*	(N)	542	85	28	655
		(%)	82.7%	13.0%	4.3%	
	Dentist Atraumatic Restorative Therapy	(N)	675	43	17	735
		(%)	91.8%	5.9%	2.3%	
	Auxiliary Atraumatic Restorative Therapy	(N)	595	84	7	686
		(%)	86.7%	12.2%	1.0%	
Uruguay	*Dentist Amalgam*	(N)	180	36	16	232
		(%)	77.6%	15.5%	6.9%	
	Dentist Atraumatic Restorative Therapy	(N)	278	40	22	340
		(%)	81.8%	11.8%	6.5%	
	Auxiliary Atraumatic Restorative Therapy	(N)	440	84	15	539
		(%)	81.6%	15.6%	2.8%	

Table 21 Pain at Baseline by Group by Country

			0	1	2	3	Total
Ecuador	*Dentist Amalgam*	(N)	690	145	27	20	882
		(%)	78.2%	16.4%	3.1%	2.3%	
	Dentist Atraumatic Restorative Therapy	(N)	1024	230	28	51	1333
		(%)	76.8%	17.3%	2.1%	3.8%	
	Auxiliary Atraumatic Restorative Therapy	(N)	1225	25	11	0	1261
		(%)	97.1%	2.0%	0.9%	0.0%	
Panama	*Dentist Amalgam*	(N)	513	138	8	11	670
		(%)	76.6%	20.6%	1.2%	1.6%	
	Dentist Atraumatic Restorative Therapy	(N)	668	75	6	11	760
		(%)	87.9%	9.9%	0.8%	1.4%	
	Auxiliary Atraumatic Restorative Therapy	(N)	660	18	4	1	683
		(%)	96.6%	2.6%	0.6%	0.1%	
Uruguay	*Dentist Amalgam*	(N)	180	40	9	3	232
		(%)	77.6%	17.2%	3.9%	1.3%	
	Dentist Atraumatic Restorative Therapy	(N)	308	28	3	1	340
		(%)	90.6%	8.2%	0.9%	0.3%	
	Auxiliary Atraumatic Restorative Therapy	(N)	538	27	1	1	567
		(%)	94.9%	4.8%	0.2%	0.2%	

reflective of the low odds of failure for dentists using amalgam.

Table 24 is necessary for the cost-effectiveness analysis. The table shows the predicted failure rates assuming that all teeth are treated similarly rather than being treated in the group assigned. The key finding is that the rates that were observed are nearly identical in all cases to the rates that were predicted, suggesting that controlling for age and sex does not make a large difference in the predicted

Table 22 Odds Ratios of Failures of Alternatives to Amalgam Treatment by a Dentist at 12 Months (N=5981)

	Group Only	Group and Country	Group, Country, and Age	Group, Country, Age, and Sex^	Group, Country, Age, and Sex Weighted Clustering by Operator
Dentist ART	1.88*	1.81*	1.80*	1.81*	1.75*
Auxiliary ART	4.19*	4.10*	4.07*	4.18*	3.43*

^ Results are insensitive to clustering by child with multiple teeth or by operator who treated multiple teeth
*p<0.05

Table 23 Odds Ratios of Failures of Alternatives to Amalgam Treatment by a Dentist at 12 Months (N=5981)

	Group, Country, and Sex Weighted Clustering by Operator	Group and Sex Weighted Clustering by Operator for Ecuador	Group and Sex Weighted Clustering by Operator for Panama	Group and Sex Weighted Clustering by Operator for Uruguay
N	5717	3001	1944	772
Dentist ART	1.75*	2.00*	2.29	0.69
Auxiliary ART	3.43*	3.39*	21.25*	1.01

* p<0.05

Table 24 Average Predicted 12 Month Failure By Country Assuming All Teeth Treated Same Way

			Observed Failure		
		Predicted Failure	Actual	95% CI LB	95% CI UB
Ecuador	*Dentist Amalgam*	5.6%	5.7%	4.2%	7.6%
	Dentist ART	10.5%	10.5%	8.9%	12.4%
	Auxiliary ART	16.3%	15.9%	13.7%	18.2%
Panama	*Dentist Amalgam*	0.9%	0.9%	0.4%	2.1%
	Dentist ART	1.9%	2.0%	1.1%	3.5%
	Auxiliary ART	15.7%	15.7%	12.7%	18.4%
Uruguay	*Dentist Amalgam*	5.7%	5.7%	3.0%	9.7%
	Dentist ART	4.0%	4.0%	2.1%	6.9%
	Auxiliary ART	5.8%	5.8%	3.3%	9.3%

rates of failure. The predicted rates of failure will be used in assessing the cost-effectiveness of alternative treatments.

Table 25 shows results similar to those in Table 24 but for incident failure in the second year.

Table 26 shows the average expected years of survival of treatment for the treatments performed by dentists along with the number of retreatments that would be necessary among teeth treated by auxiliary personnel using ART. A tooth treated by a dentist using amalgam in Ecuador would last approximately 0.1 years longer (over a two year period) than a tooth treated by a dentist using ART. 55 of every 1000 teeth treated by dentist using amalgam would need to be retreated at the end of the first year. Of these, assuming they received the same treatment and had the same failure rate, 3 would need an additional treatment at the end of the second year. 45 more teeth would need to be retreated at the end of the second year, although they survived the first year. Thus, with a dentist using amalgam, there would need to be 104 retreatments after treat-

Table 25 Average Predicted and Observed Incident 24-Month Failure By Country Assuming All Teeth Treated the Same

			Observed Failure		
		Predicted Failure	Actual	Unweighted 95% CI LB	Unweighted 95% CI UB
Ecuador	*Dentist Amalgam*	4.7%	4.8%	3.2%	6.9%
	Dentist ART	4.6%	4.7%	3.4%	6.3%
Panama	*Dentist Amalgam*	0.4%	0.4%	0.0%	1.4%
	Dentist ART	1.1%	1.1%	0.5%	2.5%
Uruguay	*Dentist Amalgam*	1.5%	1.5%	0.3%	4.3%
	Dentist ART	2.4%	2.4%	1.0%	4.9%

Table 26 Expected Years of Treatment Survival by Group by Country

				Per 1000 Children		
		Years of Treatment Survival	End of Year 1 Re-treatment	End of Year 2 Re-treatment of those Retreated at End of Year 1	End of Year 2 Re-treatment of Those only Treated at Baseline	Total Re-treatments
Ecuador	*Dentist Amalgam*	1.84	56	3	45	104
	Dentist ART	1.75	105	11	41	157
	Aux ART		163			
Panama	*Dentist Amalgam*	1.98	9	0	4	13
	Dentist ART	1.95	19	0	11	30
	Aux ART		157			
Uruguay	*Dentist Amalgam*	1.87	57	3	14	74
	Dentist ART	1.90	40	2	23	65
	Aux ART		58			

ing 1000 teeth initially. An auxiliary using ART on 1000 teeth in Ecuador would be associated with 163 retreatments after only one year.

Similar analyses were performed for Panama and Uruguay. The difference in survival over two years is very small in Panama. In Uruguay, the treatment of teeth by dentists using ART has a longer expected survival over two years than the treatment of teeth by dentists using amalgam.

Table 27 shows the results of the discrete time survival analysis. In all cases, the odds of failure in the second year are lower than the odds of failure in the first year. ART is associated with a greater odds of failure in Ecuador and Panama, although the difference is statistically significant only in Ecuador. The odds ratio for ART in the second year is not statistically significantly different from the odds ratio for ART in the first year in Panama and Uruguay. However, the odds ratio for ART is lower in the second year than in the first year in Ecuador. The results are consistent with the risk of failure in the second year in Ecuador being almost identical for the two treatments performed by dentists.

Table 28 shows the cost results using the data that were available. Supplies and equipment costs were reported for dentists in each country. Supplies and equipment costs were reported for auxiliary personnel in Ecuador. No equipment was reported for auxiliary performing ART in Ecuador. The wages for different types of personnel were supplied by PAHO, and average times required for each procedure are shown in Table 28b. The personnel cost per proce-

Table 27 Odds Ratios of Discrete Time Survival Model (Weighted and Clustered by Operator)

Variable	OR	p-value	Lower Bound 95% CI OR	Upper Bound 95% CI OR
Year 2	0.837	0.513	0.492	1.425
ART	1.949	0.001	1.299	2.924
Year 2 * ART	0.499	0.035	0.261	0.952
Year 2	0.503	0.099	0.222	1.139
ART	2.281	0.138	0.768	6.774
Year 2 * ART	1.123	0.861	0.307	4.107
Year 2	0.254	0.054	0.063	1.026
ART	0.689	0.642	0.143	3.319
Year 2 * ART	2.355	0.119	0.801	6.923

Table 28 Cost per Amalgam and ART Therapy Administered by Dentists

		N	Supplies	Equipment	Average Non-Personnel Cost Per Procedure	Personnel Cost Per Procedure	Total Cost Per Procedure
Ecuador	*Amalgam*	888	$1,470.56	$3,905.99	$6.05	$1.72	$7.77
	Dentist ART	1336	$2,372.88	$317.19	$2.01	$1.63	$3.64
	Aux ART	1261	$1,225.72	$0.00	$0.97	$0.51	$1.48
Panama	*Amalgam*	677	$3,611.55	$3,779.44	$10.92	$2.03	$12.95
	Dentist ART	769	$4,602.41	$298.58	$6.37	$2.63	$9.00
	Aux ART	693	$2,132.11	$0.00	$3.08	$0.40	$3.48
Uruguay	*Amalgam*	232	$1,411.98	$2,521.89	$16.96	$16.69	$33.64
	Dentist ART	341	$1,441.81	$117.87	$4.57	$14.80	$19.38
	Aux ART	576	$1,271.81	$0.00	$2.21	$1.16	$3.37

dure was based on the average time and the wages. The relative personnel and non-personnel costs were calculated for auxiliary-performed procedures in Ecuador. The costs of supplies for auxiliary personnel in Panama and Uruguay were obtained by assuming that the ratio of personnel and non-personnel costs in Panama and Uruguay were the same as in Ecuador. No equipment costs were assigned to any auxiliary performing the procedures. The cost of dentists performing amalgam was always higher than the cost of dentists performing ART. This is driven by non-personnel costs. The cost of dentists performing procedures in Uruguay was much higher than in the other two countries. The cost of auxiliaries performing ART was the lowest in all countries.

Table 28a shows how low the costs could be for the ART procedures in Panama and Uruguay if the times to perform these were as low as the time to perform amalgam. Intuitively, the time to perform ART should be no longer than the time to perform an amalgam treatment. This table basically demonstrates what the effect of learning to perform the ART procedure more efficiently might be.

Table 28b simply illustrates the different amounts of time for the different procedures calculated from data at the individual tooth level. In general, the average times are 10-15 minutes, although dentists in Panama were able to perform the amalgam procedure in less than 9 minutes, and auxiliary personnel in Panama and Uruguay required more than 15 minutes to perform ART.

There are six versions of Table 29 (a-f) showing the cost-effectiveness results. Table 29a shows the incremental cost-effectiveness of dentists perform-

Table 28a Cost per Procedure if All Times in Panama and Uruguay were at Minimum Observed Average

		N	Supplies	Equipment	Average Non-Personnel Cost Per Procedure	Personnel Cost Per Procedure	Total Cost Per Procedure
Panama	*Amalgam*	677	$3,611.55	$3,779.44	$10.92	$2.08	$13.00
9 min	*Dentist ART*	769	$4,602.41	$298.58	$6.37	$2.08	$8.46
	Aux ART	693	$2,132.11	$0.00	$3.08	$0.22	$3.29
Uruguay	*Amalgam*	232	$1,411.98	$2,521.89	$16.96	$14.87	$31.82
14 min	*Dentist ART*	341	$1,441.81	$117.87	$4.57	$14.87	$19.44
	Aux ART	576	$1,271.81	$0.00	$2.21	$0.73	$2.94

Table 28b Average (Unweighted) Times Taken for Procedures

		Mean Time
Ecuador	*Dentist Amalgam*	13.22
	Dentist ART	12.48
	Auxiliary ART	10.50
Panama	*Dentist Amalgam*	8.79
	Dentist ART	11.35
	Auxiliary ART	16.72
Uruguay	*Dentist Amalgam*	15.71
	Dentist ART	13.94
	Auxiliary ART	22.32

ing amalgam compared with dentists performing ART. Uruguay is different from the other two countries, because dentists performing amalgam treatment is dominated in this case. This is inferred because the amalgam treatment is more expensive and less effective than the ART treatment, when the measure of effect is the expected number of years of survival of the treatment over a two year period.

When modeling the treatment of 1000 teeth, it would cost an extra US$4000 to have dentists use amalgam rather than ART in Ecuador. This would result in an extra 93 years of treatment survival for the 1000 teeth over the two years. The end result is spending US$45 for each extra year of treatment survival. A similar calculation is shown for Panama. It is difficult for policy makers to interpret whether spending $45 to gain an additional year of treatment survival is a worthwhile expenditure. Table 29b facilitates the value comparison.

Table 29b includes a focus on retreatments (as shown earlier in Table 26). In this case, the effectiveness of amalgam in comparison with ART is the number of retreatments that are avoided. For Ecuador, this is 53 retreatments avoided. Calculating the dollars spent to avoid a retreatment in a way

TABLE 29a INCREMENTAL COST-EFFECTIVENESS OF DENTIST CARE OVER 2 YEARS (COHORT OF 1000 TEETH)

		Cost	Tooth-Years of Success	Incremental Cost	Incremental Tooth-Years of Success	Extra Dollars per Extra Year of Successful Treatment
Ecuador	*Dentist ART*	$3,644	1750			
	Dentist Amalgam	$7,775	1843	$4,131	93	$45
Panama	*Dentist ART*	$9,000	1950			
	Dentist Amalgam	$12,951	1978	$3,952	28	$141
Uruguay	*Dentist ART*	$19,378	1896			
	Dentist Amalgam	$33,643	1871	$14,266	–24	DOMINATED

TABLE 29b TWO YEAR COST-EFFECTIVENESS FOCUSING ON RE-TREATMENTS AVOIDED

		Cost	Re-treatments	Incremental Cost	Incremental Re-treatments Avoided	Extra Dollars per Re-treatment Avoided	Cost of Re-treatment (Assuming Same Cost per Treatment)	Total Cost Including Re-treatment
Ecuador	*Dentist ART*	$3,644	157				$572	$4,216
	Dentist Amalgam	$7,775	104	$4,131	53	$78	$809	$8,583
Panama	*Dentist ART*	$9,000	30				$270	$9,270
	Dentist Amalgam	$12,951	13	$3,952	17	$232	$168	$13,120
Uruguay	*Dentist ART*	$19,378	65				$1,260	$20,637
	Dentist Amalgam	$33,643	74	$14,266	–9	DOMINATED	$2,490	$36,133

similar to what was done to calculate the dollars spent to gain a year of treatment survival, the result is spending $78 to avoid a retreatment. Assuming that the tooth can be retreated in a way that is similar to the initial treatment, this would appear to be a costly way to avoid retreatment. The last two columns on the table illustrate that this is a correct conclusion. The last two columns show the costs of the retreatments (assuming that they are identical to the costs of initial treatment) and the total cost of the initial treatment plus retreatment over a two year period. In all three countries, the total costs of treatment and retreatment with a dentist using ART are lower than the total costs of a dentist using amalgam. The comparison does not include the cost of training the dentist to perform ART or to travel (if that were an option). The cost difference illustrates how much could be spent on training and travel for dentists while still having a less costly program than dentists using traditional treatment. A minimum of $3800 could be spent on training and travel (in Panama) while still having costs using ART be lower than costs using amalgam.

Table 29c uses the number of teeth experiencing one year survival as the outcome. This is essentially the same as the years of survival over a one year period. Again, dentists using amalgam in Uruguay is dominated by dentists using ART and by auxiliary using ART. In the other countries, the dentists using ART are somewhat more expensive than the auxiliary personnel using ART, while the dentists using amalgam are the most expensive. As is typical in cost-effectiveness results, the cost to achieve an extra surviving treatment increases when moving to more expensive alternatives within a country.

Table 29d again helps to illustrate whether the costs to achieve extra years of survival have value. In all three countries, the combined costs of initial treatment and retreatment (with the same treatment) are the lowest for the auxiliary using ART. Again, this does not consider the costs of training and travel. Further, it makes the assumption that the tooth will be no worse off after failure of the first treatment than it was with the original need for treatment.

Table 29e simply illustrates that if the ART procedure could be done as rapidly as the amalgam procedure, the cost savings associated with ART increase.

In Table 29f, the costs of equipment are added to the auxiliary ART (assuming that they need the same basic equipment that dentists would need). This closes the gap somewhat but does not lead to a conclusion that auxiliary performing ART is more expensive than dentists performing ART.

The analysis of the effect of three different options in Ecuador over an interval of one year of effectiveness uses a tree with a decision node indicating the choice (which provider/treatment in Ecuador) and then showing branches with the three choices: dentist amalgam, dentist ART, auxiliary ART. On each of these branches is a chance node (denoted by a circle) with two possibilities: Year 1 Success and Year 1 Failure. The probability of failure shown under each "Year 1 Failure" branch for each comes directly from our data. The "#" under each "Year 1 Success" branch indicates that it has the remainder of the probability, i.e. 1 – the probability of failure. The

TABLE 29c ONE YEAR COST-EFFECTIVENESS COMPARING ALL THREE OPTIONS OF PERSONNEL AND TREATMENT NOT INCLUDING FOLLOW-UP TREATMENT

		Cost	Teeth Experiencing One Year Survival	Incremental Cost	Incremental Tooth-Years of Success	Extra Dollars per Extra Year of Successful Treatment
Ecuador	*Auxiliary ART*	$1,482	841			
	Dentist ART	$3,644	895	$2,162	53	$41
	Dentist Amalgam	$7,775	943	$4,131	48	$85
Panama	*Auxiliary ART*	$3,481	843			
	Dentist ART	$9,000	981	$5,519	138	$40
	Dentist Amalgam	$12,951	991	$3,952	11	$368
Uruguay	*Auxiliary ART*	$3,370	942			
	Dentist ART	$19,378	960	$16,007	17	$924
	Dentist Amalgam	$33,643	942	$14,266	–17	DOMINATED

TABLE 29d ONE YEAR COST-EFFECTIVENESS FOCUSING ON TREATMENTS AVOIDED

		Cost	Teeth Requiring Re-treatments	Incremental Cost	Incremental Re-treatments Avoided	Extra Dollars per Re-treatment Avoided	Cost of Re-treatment (Assuming Same Cost per Treatment)	Total Cost Including Re-treatment
Ecuador	*Auxiliary ART*	$1,482	159				$235	$1,717
	Dentist ART	$3,644	105	$2,162	53	$41	$384	$4,027
	Dentist Amalgam	$7,775	57	$4,131	48	$85	$443	$8,217
Panama	*Auxiliary ART*	$3,481	157				$548	$4,028
	Dentist ART	$9,000	19	$5,519	138	$40	$174	$9,174
	Dentist Amalgam	$12,951	9	$3,952	11	$368	$112	$13,063
Uruguay	*Auxiliary ART*	$3,370	58				$195	$3,565
	Dentist ART	$19,378	40	$16,007	17	$924	$784	$20,162
	Dentist Amalgam	$33,643	58	$14,266	–17	DOMINATED	$1,944	$35,587

TABLE 29e SENSITIVITY ANALYSIS ONE YEAR COST-EFFECTIVENESS FOCUSING ON TREATMENTS AVOIDED AND ASSUMING SAME TIMES FOR PANAMA AND URUGUAY

		Cost	Teeth Requiring Re-treatments	Incremental Cost	Incremental Re-treatments Avoided	Extra Dollars per Re-treatment Avoided	Cost of Re-treatment (Assuming Same Cost per Treatment)	Total Cost Including Re-treatment
Panama	*Auxiliary ART*	$3,294	157				$518	$3,813
	Dentist ART	$8,457	19	$5,163	138	$37	$164	$8,621
	Dentist Amalgam	$13,001	9	$4,544	11	$423	$112	$13,113
Uruguay	*Auxiliary ART*	$2,937	58				$170	$3,107
	Dentist ART	$19,440	40	$16,503	17	$953	$787	$20,227
	Dentist Amalgam	$31,823	58	$12,383	–17	DOMINATED	$1,839	$33,662

TABLE 29f ADDING IN COST OF EQUIPMENT FOR AUXILIARY ART

		Cost	Teeth Requiring Re-treatments	Incremental Cost	Incremental Re-treatments Avoided	Extra Dollars per Re-treatment Avoided	Cost of Re-treatment (Assuming Same Cost per Treatment)	Total Cost Including Re-treatment
Ecuador	*Auxiliary ART*	$1,734	159				$275	$2,009
	Dentist ART	$3,644	105	$1,910	53	$36	$384	$4,027
	Dentist Amalgam	$7,775	57	$4,131	48	$85	$443	$8,217
Panama	*Auxiliary ART*	$3,939	157				$620	$4,558
	Dentist ART	$9,000	19	$5,061	138	$37	$174	$9,174
	Dentist Amalgam	$12,951	9	$3,952	11	$368	$112	$13,063
Uruguay	*Auxiliary ART*	$3,921	58				$227	$4,148
	Dentist ART	$19,378	40	$15,457	17	$893	$784	$20,162
	Dentist Amalgam	$33,643	58	$14,266	–17	DOMINATED	$1,944	$35,587

value at each end node represents how the outcome is counted: 0 for failure and 1 for success. The "rolled back" (or solved) version of this tree shows that the dentist amalgam branch would be chosen if the only criterion were the number or probability of success. The result shows the calculated probability of success and the "value" of each choice based on the expected outcome. The dentist amalgam has the highest expected value. This is not difficult to see when there is only one event.

The two year analysis has two chance nodes. The first is failure in Year 1. The second is failure in Year 2. Again, each probability comes from the data. The result of success in both years is counted as a value of "2" indicating the number of years of success. A success in Year 1 but failure in Year 2 is counted as "1" for one year of success. A failure in Year 1 counts as zero. The expected number of years of success (with a maximum of 2) is now determined by the probability of failure in each year. In Ecuador, the dentist amalgam has a higher number of expected years of success (1.84) compared with dentist ART (only 1.75 years of success). Thus, based only on the criterion of expected years of success, the dentist amalgam would be chosen.

CONCLUSIONS

While the odds of treatment failure are higher for an auxiliary using ART than for a dentist using amalgam in Ecuador and Panama, the cost savings that can be achieved are substantial. Even including the cost of equipment and factoring in a cost of retreating teeth for which the treatments fail, the total cost of having auxiliary personnel treat and retreat over a one year period is half the cost of having a dentist use ART and less than one-third the cost of having a dentist use amalgam. Thus, having auxiliary personnel use ART appears to be a good investment. It is important to note that this also encourages cooperation and seems to produce less pain.

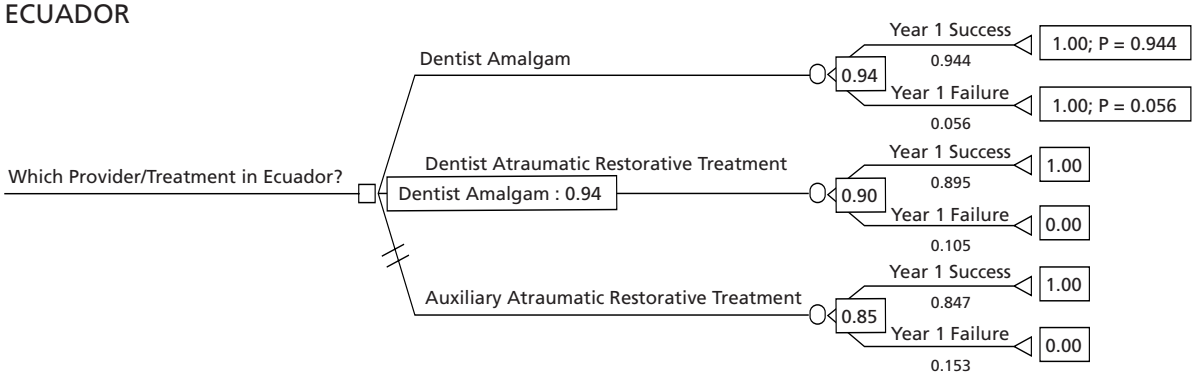
Several additional points of interpretation are useful. It is important to note that the costs reported do not include training and travel. However, the training and travel costs would have to double the costs of the entire program in order for the costs of having an auxiliary personnel perform ART exceed the costs of having a dentist perform ART. As a dentist would still be likely to perform ART in his or her office, the societal costs would likely still be larger as the parents of the children would have to bring the children to the dentist's office. This cost is not easily captured in the analysis but is important to note. Finally, the cost-effectiveness analysis focused on teeth that actually present for treatment. It is quite likely that fewer teeth would present at dentists' offices than could be checked and treated by auxiliary personnel in the community.

There are several limitations to the analysis. The biggest is the lack of data on the costs for auxiliary personnel in Panama and Uruguay. However, it is

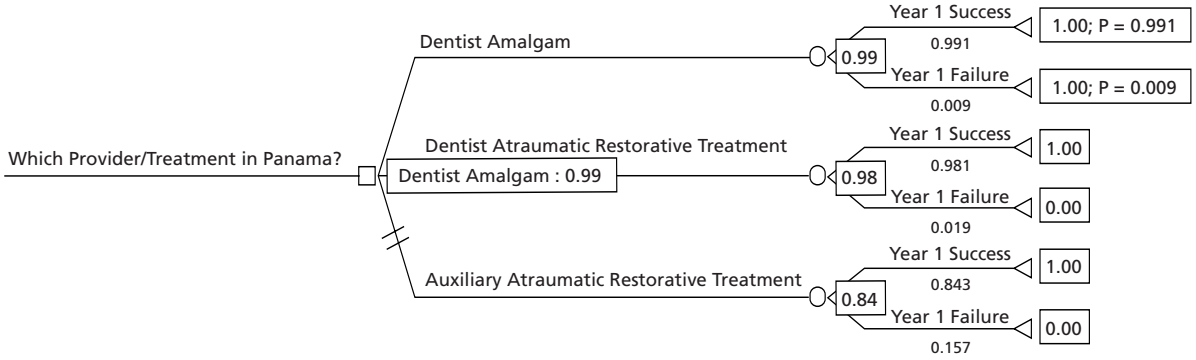
DECISION PROBABILITY TREES:

YEAR 1 RESULTS:

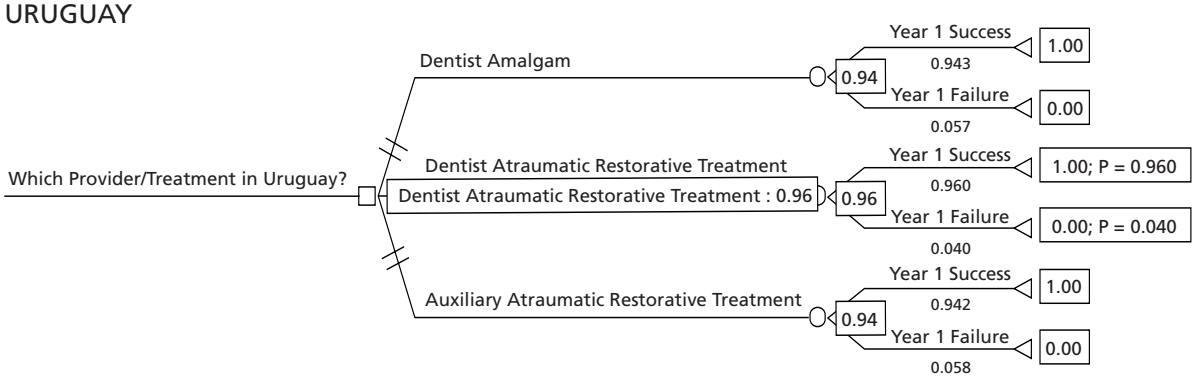
ECUADOR



PANAMA

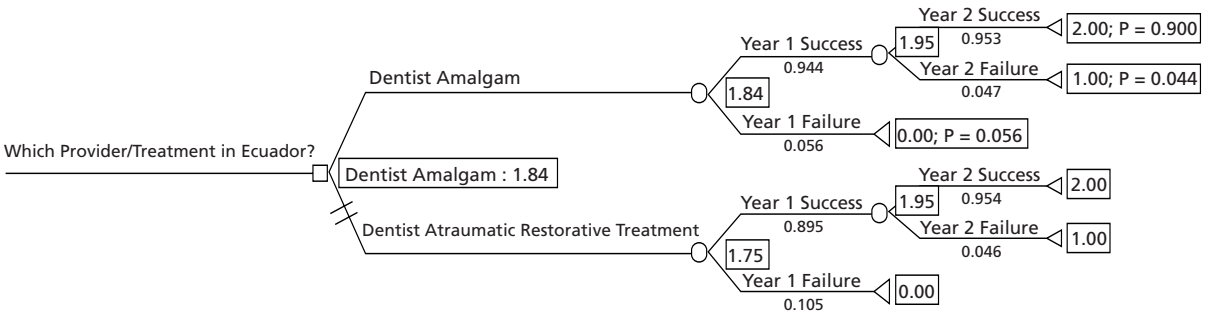


URUGUAY

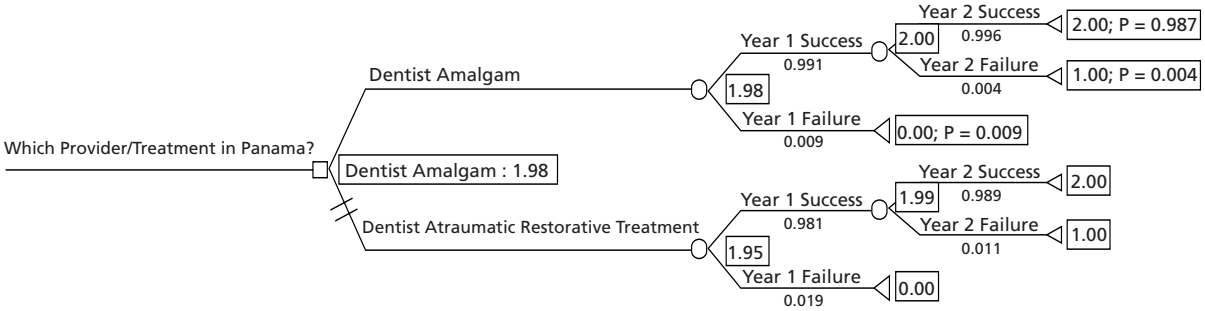


YEAR 2 RESULTS:

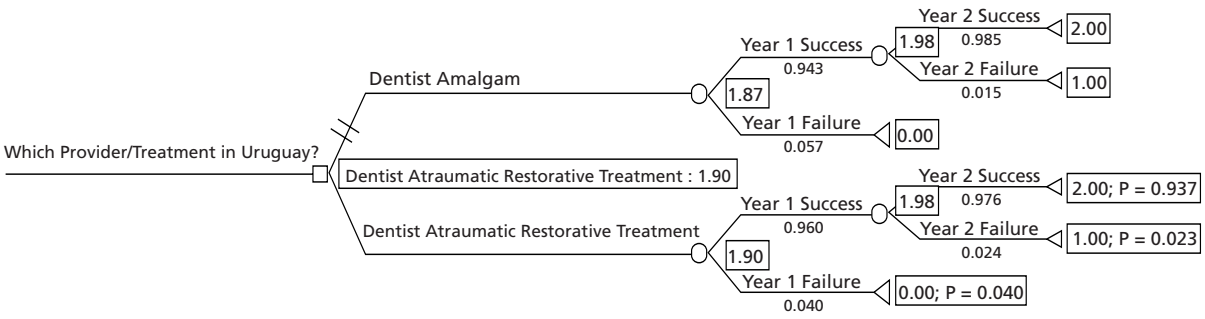
ECUADOR



PANAMA



URUGUAY



clear that the costs in these two countries would have to be much different from the costs in Ecuador for the total cost of having auxiliary personnel perform ART to exceed the costs of having dentists operate on the children. Another limitation is the exclusion of many office-based costs for the dentists. If these were included it would further separate the cost of having dentists treat the children from the cost of having auxiliary personnel treat the children. The final limitation is the non-use of the ART criteria for failure. While these are difficult, if not impossible, to apply to the amalgam treatments, using the ART-specific criteria to evaluate the success of the ART treatments would be useful for comparison with the more general USPHS criteria. The final limitation is having no knowledge of whether a tooth that needs to be retreated is in worse condition than when it first needed treatment. The assumption in the cost comparison analyses has always been that the teeth for which the treatment fails could simply be re-treated using the same treatment.

In closing, this research suggests that the auxiliary personnel performing ART will lead to treatment survival that is expected to be lower than dentists using amalgam or dentists using ART in most cases. In spite of the greater risk of failure, the rate is not unacceptable and the cost savings that can be obtained are larger. Governments and donors should consider how much training and travel would cost, enter this into their consideration, and make policy based on a willingness to trade off lower short-term costs (and presumably lower long-term costs) for a somewhat higher risk of failure and whatever additional deterioration of the tooth may occur.

5. Summary of External Project Evaluation[1]

In 2005 the PRAT team hired an experienced external project evaluation expert to determine the effectiveness and suitability of the project design and execution, and to comment on the suitability of the results obtained and their use in subsequent project scaling-up. The evaluation was based on comparison to a standard NIH study protocol judged to be current state of the art, and the study design was also reviewed by select biostatisticians and epidemiologists. In addition to a desk study with some interviews of key personnel, evaluation activities included an expert review panel and a more extensive literature review. A summary of the report follows here.

EVALUATION METHODOLOGY AND CONCEPTUAL FRAMEWORK

The evaluation methodology selected was based upon reference to a gold standard for clinical trials with interviews undertaken in support of documentation as it related to such a standard. The standard utilized was that of a clinical trial research protocol from the National Institutes of Health in the United States. Although overly rigorous, such a protocol is an appropriate measure of design and completeness for clinical research.

A complete and well-documented study protocol is one good indicator of success in the execution of any field study. All studies are different and all require creativity and adjustment in the process. A careful plan which emphasizes a theory-based approach will provide the standards which allow for the investigator(s) and the implementers to adjust and change during the course of the study without doing damage to the design or overall objectives. This is essentially what happened during the PRAT study and, as a result, the findings are valid and appropriate even though several operational changes took place during the study execution.

Study protocols generally include the following topics:

Introduction and background. The PRAT PAHO study provides a complete background of the theoretical objectives of the ART method and why a community trial is both appropriate and needed. As a potential major contributor to oral health among the less-served populations in the Americas, there is no question as to the potential utility of this trail and its value in providing further public health evidence for appropriate action.

Objectives (including research questions and hypotheses to be tested). The objective of this community trial has been stated from the initial documents as follows: ". . . the main objective of this study is to demonstrate the cost-effectiveness of the ART technique in a variety of settings in the Region in comparison with the cost-effectiveness of the Amalgam technique in the same settings." The original study protocols were developed with appropriate research questions and pre-determined methodology. An overly optimistic assessment of the ease of fulfilling needed local vetting and approvals, combined with inadequate intelligence regarding details such as academic years and the efficacy of local workers collecting data, delayed the actual study such that all of the data originally intended for collection during the three year period was not collected. Enough was collected, however, to assure sufficient power for the economic analysis.

Background (including the literature review and theoretical framework). The literature review and theoretical framework were particularly strong with respect to the already established public health benefits for the ART technique. Additionally, as part of this assessment we undertook a review of appropriate methods related to the economic analysis of similar health-related outcomes. This review supported the approach taken here and provided further validation to the study.

Methods (study design, subjects, procedures, measurement and analytic techniques). The methods originally programmed in the PRAT project documents followed acceptable standards from a clinical and field trial perspective. What follows however is a detailed review of the PRAT protocol as to compliance with the core and peripheral components of gold standard. In particular, some problems in the data collection and analysis resulted in less than optimal outcomes and some difficulties in organizing and developing the database for analysis. An initial effort to summarize results by the first year project statistical analyst resulted in some false starts and time wasted. The recruitment of a talented dental epidemiologist for data organization and management and an appropriately qualified economist and statistician resulted in efforts that were able to correct the majority of the issues that had emerged from the earlier problems with the field data collection and documentation. By changing the unit of analysis to the individual tooth as the appropriate denominator and carrying out subsequent analysis accordingly, the results are both robust and consistent.

Better documented data collection and, in particular, cost data would have most probably improved the precision of the results; however the numbers are large enough and the impact strong enough that the overall objective of the study was achieved. Project leadership should be complimented in having the insight to recognize and correct problems in the data management and methodological part of the project in time to provide appropriate resolution.

EVALUATION GUIDELINES AND RESULTS

The following guidelines were used to review each step of the original protocol and compare from interviews and observation the outcomes.

1. Items reviewed for the Evaluation	PRAT Protocol
(a) Reason for the study given	Yes
(b) Historical background and literature review	Yes
2. Study objectives	Yes
3. Survey methods	Yes
(a) Population to be studied	Yes(with modifications)
(b) Controls	Appropriate
(c) Design—cross sectional: longitudinal community trial	Yes
(d) Measurements of exposure (important in clinical trials)	Yes
1. Current	Yes
2. Historical	Yes
3. Measurements of response	Yes
4. Symptoms	Yes
Clinical	Yes
Laboratory	No
Psychological	No
Other variables	No
Definitions (both traditional and operational)	Yes

4. Agreements	Yes
(a) Management	Yes
(b) Unions	
(c) Ethical	Yes
5. Tools	Yes
(a) Check lists for field visits	Yes
(b) Questionnaires	Yes
(c) Data collection and summary forms	Yes
(d) Consent forms and Subject Information Sheets/Letters	Yes
6. Data analysis	Yes
(a) Statistical advice (pre and post study)	Yes[2]
(b) Computer support	Yes[3]
(c) Field data collections	Yes[4]
(d) Data management and storage archiving systems	Yes[5]
7. Target dates	Yes
(a) agreement of protocol (including ethical consideration)	No
(b) survey	Yes[6]
(c) Statistical analysis	Yes[7]
(d) Completion of report	Yes[8]
(e) Publication	No
8. Publication	No
(a) authors	No[9]
(b) media	No

CONCLUSIONS AND RECOMMENDATIONS

Undertaking a community clinical trial is a complex and difficult task requiring experience and resources. Commercial entities will often budget 3 to 500 million dollars to bring a new drug or process through all stages of a clinical trail and, ultimately, to the market. While this standard is well beyond most public sector activities, it does serve to provide a benchmark for this current study. Using this benchmark it is noteworthy that PAHO's vastly underfinanced study did as well as it did during the implementation phase.

The PRAT trial was a well-conceptualized and much needed effort. The level of support in retrospect was inadequate, resulting in a number of issues that were overcome by creative senior management. The end result provides convincing proof of the cost-effectiveness, and therefore the public health value, of the ART procedure under all circumstances applied by either fully qualified dentists or paraprofessionals. This type of study has tremendous potential public health benefits and should definitely be encouraged in the future. There are many appropriate and useful questions that this research did not answer relating to training costs, social acceptability and the best operational approach to ART interventions. Given the clear outcomes with respect to cost-effectiveness, however, it is likely that an investment in an ongoing operations and applied research capability would have significant payoffs for the future of dental health in the Americas. The relatively small investment in pursuing evidence-based approaches to policy and training changes in dental public health can have a major impact in improving the health of particularly the under-served elements of the population at risk. We therefore strongly support

this specific research effort as being a model of operations and applied research that has great potential impact on health outcomes. The idea was good, the research sound and the results conclusive. What is lacking is an appropriate dissemination and education strategy to assure that the results are implemented in an appropriate fashion that will have the greatest positive impact on the health of the people.

NOTES

1. William E. Bertrand, PhD, Project PRAT external evaluator. Dr. Bertrand is currently Director of the Payson Center for International Development and Technology Transfer and the Wisner Professor for Public Health at Tulane University. He was previously Senior Vice President of Institutional Research, Planning and Innovation and the Chair of the Department of International Health and Development at Tulane's School of Public Health and Tropical Medicine. His previous experience includes the design and implementation of the Kinshasha School of Public Health, and consultant to the Rockefeller Foundation team responsible for developing schools of public health in Uganda, Zimbabwe, Viet Nam, Ghana, and Senegal. His teaching and research interest include innovation and technology transfer impact, social epidemiology, monitoring and evaluation of service delivery systems, information technology use, management information systems, economic development and food security. He is a member of several technology and foundation advisory panels and boards.

2. As noted in the text, the statistical advice for the early stages of the project was lacking. The individual employed lacked the training and experience to carry out complex field trial and economic analysis. Most of the difficulties encountered in the final data analysis could be traced back to lack of preparation and documentation. When this individual was changed and other more appropriate experts employed, appropriate outcomes were realized. In the future it might be useful to establish minimal standards of training and experience as criteria for employment of consultants charged with such important work.

3. Computer support followed the same problems noted above. In the initial activity, the outside consultant was in charge of keeping, updating and analyzing the data set. Loss of control of the data by the implementing institution is not ever recommended. A well documented data collection and management protocol should have been developed which included documented and shared procedures for data storage, documentation, updating and the normal reliability and validity tests. The lack of consistency and professional management of this process by the initial consultant created difficulties for the final data analysis team. Again, in future efforts this needs to be addressed and carefully managed. At all times the data should be accessible and transparent to the Principal Investigator (PI).

4. Field data collection in three different Latin American countries with different levels of expertise and sophistication is a major challenge even under the best of circumstances and with unlimited funding. This study simply underestimated the level of effort required to exercise control at this most basic level. As a result, issues arose in the documentation and validation of the data. Some such problems are normal and expected; however many could have been avoided with more careful review and training/feedback at the field level. The quality and comparability of the data are most affected by field data collection. While it was possible through cross checks and review of the original questionnaires to rectify the majority of these issues, greater investment in the data collection stage would have improved the outcomes. In particular the loss of some cases due to the children not fitting within the age protocol requirements suggests that greater supervision and checking in the field would have been useful.

5. Data archiving and storage shared the same problems as the general computer support in that a consultant was charged with archiving and updating the database. Lack of appropriate documentation of the process and reliance on non-relational database software created an environment whereby some steps had to be recreated and some records were lost. The same principles apply to archiving and storage, i.e., that it should never be out of the control of the PI and that all stages and changes be fully documented.

6. Target date slippage created some of the greatest problems in data collection and survey application, and all of this was reflected in final analysis and completion of the final report. This was due to a host of issues including host country school schedules, recruitment of field staff and the normal slippage in dealing with three countries and public sector bureaucracies. While major investments in supervision may have served to improve this process given the light supervisory infrastructure, much of the slippage was inevitable. A greatly increased field execution staff managed by experienced research personnel would be a major improvement for any future activities. Of particular note was the target date slippage for data analysis resulting in direct issues for both the final report and evaluation. When the evaluator first came on board in September 2005, requests for basic documentation and data sets could not be met. This resulted in a complete review of progress to that point and a change in personnel. Earlier review of deliverables might have caught this problem at an earlier stage. While all of the issues caught have been resolved in a professional and scientifically correct fashion by project leadership, careful attention should be given to any future efforts involving community trials to assure more routine monitoring and reporting.

7. *Ibid.*

8. *Ibid.*

9. Publications became an issue among certain consultants. In general for projects funded by public funds and where Institutions have the responsibility for execution, the data becomes the property of the organization. Prior protocols established by the organization for authorship and use of the data apply. Although PAHO has standard protocols, the consultants demonstrated their lack of experience by asserting their rights of authorship. Because publication is such a benefit for academics, this is often a problem. In general, paid consultants lose their right to claim authorship precisely because they are paid for their efforts. A clear signed pre-contract agreement is the only appropriate step to assure that expectations are not raised and individuals understand completely their role and position in any future publications that result from the research. This would be a definite need for any future research.

6. Recommendations and Lessons Learned

The PRAT study has clearly demonstrated the cost-effectiveness of the ART technique in a variety of settings in the Region in comparison with the cost-effectiveness of the Amalgam technique in the same settings. Even if PRAT is provided at the lowest cost service modality, and even under a failure scenario, it produces acceptable outcomes. In Ecuador and Panama, the effectiveness of PRAT delivered by dentists when compared with dental auxiliaries was similar; in Uruguay, the results were even better. The costs of employing the PRAT approach for dental caries treatment, including retreatment, are roughly half the cost of amalgam without retreatment. PRAT as a best practice model provides a framework to implement oral health services on a large scale, and it can reduce the inequities for access to care services. The PRAT study has produced evidence to guide downstream investment to improve equity, efficiency and quality of life in the Americas.

Based on these findings, the PAHO PRAT team proposes the following recommendations.

A PRAT-based strategy for expanding coverage at reduced cost should become a cornerstone of policy at the regional and country levels.
It is believed that the implementation of the PRAT system in schools and on a community-wide basis, and integrated into the primary health care system will be an important and effective way to increase access of basic dental services to presently underserved sectors of the society.

Use of auxiliary personnel.
It is interesting that the data produced in this study demonstrated a higher cost-effectiveness of auxiliary personnel in some countries than traditionally trained dentists. The recommendation therefore to utilize more auxiliary personnel, suitably trained, using the PRAT system, and as part of an overall health team, suitably integrated, will ensure more access to basic oral health care services in regions of countries where none presently exist.

Dental public health programs.
The promotion of health for all and the implementation of the health-related MDGs must ensure the integration of dental public health programs into primary health care infrastructure and provision of services. The PRAT system offers the ideal way to do this. It is a cost-effective intervention and is able to be implemented in remote and isolated areas. A variety of health providers may also be trained in how to deliver it. This recommendation therefore calls for its full integration into the basket of health services being offered by the primary health care services in all countries in the region.

Ministries of Health should consider greater investment in oral health promotion/treatment, including the use of simple technologies such as PRAT, so as to improve the overall health and well-being of all citizens.
This study has been able to measure the costs in a variety of settings for the traditional amalgam system and the PRAT system. The large scale implementation of the PRAT system will, according to the data produced in this study, afford the best level of cost-effectiveness so as to provide basic oral health services nationally and especially in areas and communities not presently served. This in turn will improve overall health and the well-being of all citizens.