

AN ABSTRACT OF THE THESIS OF

Fernando Ortega for the degree of Doctor of Philosophy in Public Health
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Chunhuei Chi

A Cost-Effectiveness Analysis of a targeted intervention for community control of Ascariasis was carried out in three rural communities near Quito, Ecuador. Targeted treatment with Paico (*Chenopodium ambrosioides*) and Albendazole (ABZ) was applied to children aged 5 to 15 years attending primary local schools in Aglla, Checa and Iguinaro. Prevalence and intensity of ascariasis and prevalence of other intestinal parasitic diseases were determined immediately before and after one month of the intervention to assess the effectiveness of treatment regimes. A written informed consent and a parasitic survey were applied before the screening test of stool samples. All registered students were assigned at random to three different treatment regimes: Andean-traditional (Paico), modern-Western (ABZ) and control group (doing nothing). Treatment was provided within the schools with the assistance of the school teachers. Significant differences in prevalence before and after treatment were recorded for both types of treatment. Information on social and cultural patterns of the three communities, as well as information on resource use was also collected for cost analysis. Logit logistic regression analysis was used for categorical data interpretation. The final model included three **predictive variables related to environmental and social conditions present in the**

villages. Reduction in the prevalence of parasitism approached statistical significance in both treatments. Paico demonstrate to be four times more effective than control (doing nothing) group, while ABZ was two times more effective than Paico. The results were expressed in terms of the cost per child treated. The results showed Paico to be more cost-effective than the other two procedures.

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A Cost Effectiveness Analysis
of Anthelmintic Intervention for Community Control of Ascariasis:
Traditional vs. Pharmaceutical Therapy

by

Fernando Ortega

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I understand that my thesis will become part of the permanent collection of Oregon State University libraries. My signature below authorizes release of my thesis to any reader upon request.

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Fernando Ortega, Author

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Dedication

This thesis is dedicated to all those women and men concerned about parasites, since the beginning of the times. Is dedicated to those who experimented the symptoms of parasitism and died without affordable treatment. Is dedicated to the memory of those shamans, medicine-men, “curanderos” from different cultures, who used their own traditional medicine to cure their patients against parasites. Is dedicated to pharmaceutical research for improving the effectiveness of current treatments. Is especially dedicated to those surviving with less than a dollar a day, with no sewage, potable water or food, ...to those without money to buy the treatment in the pharmacy.

A Cost Effectiveness Analysis of Anthelmintic Intervention for Community Control of Ascariasis: Traditional vs. Pharmaceutical Therapy

1. INTRODUCTION

Intestinal parasitic diseases, especially soil and water-transmitted helminthiasis and protozoan infections, are highly prevalent in developing countries. Soil and water contamination, economic, social and cultural conditions; as well as health, educational and nutritional circumstances are factors related to the persistence of endemic parasitism (Amahmid et al., 1999; Rahman, 1998; Hagel et al., 1999).

Ascariasis is one of the most prevalent human parasitic diseases in the world. Eastern and Western hemispheres are affected by this pandemic helminthiasis caused by *Ascaris lumbricoides*. Tropical and semi-tropical regions are most affected. The disease is characterized by an early pulmonary phase related to larval migration and a later, prolonged intestinal phase.

In 1988, an International Task Force for Disease Eradication (ITFDE) was formed to evaluate the potential eradication of candidate diseases, to identify specific surmountable barriers, and to promote eradication efforts. Four years later,

after evaluating the potential eradicability of Taeniasis, Cholera, Chagas, Schistosomiasis, Ascariasis and Hookworm disease, the ITFDE found that Ascariasis is not actually eradicable, but it could be better controlled by chemotherapy and hygienic interventions, especially among school-aged children (Arata et al., 1992).

Considering the analysis of almost a million and a half fecal examinations in a population of 1.13 billion people, recent studies found that ascaris is the most prevalent of intestinal helminths in China (Hotez et al., 1999).

Intestinal parasitism in Latin America is one of the major public health problems claimed by health authorities. A review of the prevalence of Ascariasis in twenty-three Latin American countries (1975 - 1987) showed that an average of 25.5% of the examined samples were positive for *Ascaris lumbricoides* (cf. Crompton 1989:225). In this region, Ascariasis is not equally distributed; it varies from 61.8% in Argentina and 60.7% in Ecuador, to only 0.9% in Cuba. Different research techniques, non-standardized sampling, and doubtful representativeness of samples in each country are reasons to make comparisons inapplicable. However, the data clearly shows that Ascariasis is highly prevalent.

The attributed cause of endemic parasitism in the Andean region of Latin America is the use of raw sewage for fertilizing potatoes and vegetable plantations.

The same cause was attributed to the 1948 epidemic of Ascariasis in Darmstadt, Germany (Krey, W. and Baumhogger, W., in: Crompton 1989:369-371). In Jerusalem, the elimination of the use of raw sewage for the fertilization of fields producing vegetables reduced the prevalence of Ascariasis from 35% in 1947 to 1% in 1960 (Shuval et al. 1984).

In addition to soil and water forms of contamination, fecal-oral (hand) and air (dust) ways of transmission have to be taken into account. They are part of other social and cultural factors (poverty, environmental pollution, poor hygienic habits, lack of safe systems of sanitation and sewage disposal) that increase the risk of Ascariasis.

According to the World Health Organization, WHO, innovative preventive and control strategies are required to assist government, community and individual efforts to cope with the endemicity of intestinal parasitic diseases. It is also required to demonstrate social and cultural competency and active participation of community members in developing and implementing health care programs (WHO: 1987).

In many countries the government has a central role in promoting healthy behavior among the population as well as controlling and preventing parasitic infections. The active participation of the members of the community is also

important to improve their health conditions. Health care services are assumed to be accessible to the population; however, the lack of physical infrastructure, the distance to health facilities and different languages or cultural backgrounds limit people's willingness and ability to seek western medical care.

Facing these conditions, many communities in developing countries have generated appropriate local alternatives. Their logical response to health problems is the use of their own local resources in traditional medicine. Shamans, healers, medicinal plants, other remedies and procedures are currently used.

People from many cultures have made use of a wide variety of simple to complex preparations of medicinal plants to treat diseases. There are many examples of the traditional use of plants, such as those relative to *Digitalis purpurea* due to its favorable effects in heart dynamic contraction, *Erythroxylum coca* due to its anesthetic effects, etc. Parasites have also been treated with plants such as *Chenopodium ambrosioides* for helminthiasis, and *Cinchona officinalis* (Quinine) that has been used against fevers (e.g., malaria).

Chronic intestinal infections, including Ascariasis, need re-evaluation, bearing in mind the shifting of emphasis from curative to preventive medicine. Active participation of health workers and community involvement is required. The prevention and control of Ascariasis fit in well within the principles of Primary

Health Care, (PHC) which is considered an important approach to providing health care services to the world population. Since the declaration of Alma-Ata (WHO 1978), many countries have adopted PHC strategy, with goals including: universal coverage and care according to need; favorable impact on mortality and morbidity; government, community and individual affordability; social and cultural adjustability; and active participation of community members in developing and implementing the health care system.

Most publications focus on the high prevalence of parasitism in the world population. However, little effort has been made to evaluate the health and economic costs of intestinal parasitic diseases in rural populations (cf. Camillo-Coura 1989:223). Humidity, temperature, altitude, presence of wild or domestic animals, local practices of personal and household hygiene, feces disposal, the quality and accessibility of the water supply, and community attitudes and practices in coping with parasitism are inadequately known.

A comprehensive study of a disease like Ascariasis requires a multidisciplinary approach. In this opportunity; social, medical and ecological sciences joint efforts to find an explanation to causes and consequences of this persistent parasitic challenge. The contribution from the anthropological disciplines such as; physical anthropology, ethnobotany, linguistics and cultural anthropology is combined with the recent input of ethnomedicine and medical anthropology.

From the medical perspective the sciences involved in this study are biology, chemistry, pharmacology, parasitology, and internal medicine. Ecology, economy and statistics also made their important contribution.

1. 1. Problem statement

Over the past twenty-five years, Ecuador has experienced critical conditions as a result of political, ecological and economical calamities. The outcome has had high morbidity and mortality rates and the deterioration of living standards, especially affecting rural areas. In order to implement a local program of prevention and control of parasites, the Ecuadorian health authorities have requested a study to provide the medical community with information regarding prevalence, location, costs and other factors related to intestinal fecal-oral induced parasitism.

The prevalence and intensity of parasitism have not been established in rural areas near Quito, nor has clinical research concerning traditional and pharmaceutical treatment of Ascariasis in Ecuador ever been conducted. The authorities urge obtaining information about new possibilities of treatment of Ascariasis by traditional or modern methods compatible with PHC principles, in an effort to reduce costs.

The justifications for the control of Ascariasis are many. In 1985, Davis stated that where prevalence and/or intensities are very high or where there is clear evidence of associated morbidity, it is perfectly feasible to implement a chemotherapeutic strategy for control (cf. Davis 1985: 239-240).

Davis also affirms that the modern anthelmintic drugs are highly effective, and that their toxicity is many orders of magnitude less than the compounds used even as recently as the 1950s and 1960s, and that population acceptance is good (cf. Crompton, D.W.T. et al 1985:240).

Traditional remedies have been effective for treating many ailments in different cultures. Ascariasis in Andean communities is treated with medicinal plants as reported in the literature (Naranjo 1997, White 1986, Ortega 1983 and 1997).

Traditional and modern chemotherapeutics claim effectiveness of their treatments. However, isolated chemotherapeutic efforts to control these infections have experienced temporary success; re-infection soon brings parasitism back to the initial levels. Treatment costs are also a very important factor to be taken into account when a public health program is established.

1. 2. Purpose of the study

The purpose of this study was to determine which is the most cost-effective treatment for Ascariasis, comparing the effectiveness of Andean-traditional and modern-Western methods, in school-age children of rural communities near Quito, Ecuador.

1. 3. Goals

To compare the effectiveness of Andean-traditional versus modern-Western treatments of children (5 to 15 years) infected with *Ascaris lumbricoides*. The accomplishment of this goal will provide the health authorities with information required, to establish measures necessary to promote community health.

To establish the cost-effectiveness of Andean-traditional and modern-Western treatments of children (5 to 15 years) infected with *Ascaris lumbricoides*. This will enhance the understanding of the therapy of Ascariasis by adding to the existing body of knowledge and research the confirmation or rejection of therapeutic methods in common use by physicians and by community members at the most affordable cost.

1. 4. Objectives

- To estimate the prevalence and risk factors of Ascariasis among school-age children in three rural communities near Quito, Ecuador.
- To provide mass targeted treatment with Andean-traditional and modern-Western products to school-age (5-15 years) children in the communities of the study.
- To evaluate the effectiveness of Andean-traditional vs. modern-Western treatment of Ascariasis.
- To evaluate the Cost - Effectiveness of both treatments:
 - To estimate the costs of Andean-traditional treatment
 - To estimate the costs of modern-Western treatment
 - To compare the differences in cost and effectiveness
- To evaluate the two types of treatment within the cultural and ecological context of Ecuadorian Andean rural communities.

1. 5. Research questions

Based on the research objectives, this study proposes the following research questions:

- What is the prevalence of Ascariasis in school-age children of three rural Andean communities near Quito, Ecuador?

- What are the risk factors of Ascariasis affecting school-age children of three rural Andean communities near Quito, Ecuador?
- What is the effectiveness of Andean-traditional remedies based on *Chenopodium ambrosioides* preparations used in the communities as a local resource to cure Ascariasis?
- What is the effectiveness of albendazole (anthelmintic product from modern-Western medical system) to cure Ascariasis?
- What is the cost of curing a patient with *Chenopodium ambrosioides*?
- What is the cost of curing a patient with albendazole?
- What is the most cost-effective method of treating Ascariasis in the study population?
- With regard to this research, are there any recommendations that can help health authorities of this geographic area to plan and implement treatment measures to control Ascariasis?

1. 6. Hypothesis

Among the above research questions, the effectiveness of the Andean-traditional versus the modern-Western treatments of Ascariasis will be examined in the form of hypothesis testing. The operationalization of the hypothesis testing will be presented in Chapter # 3.

1. 7. Significance of study

This study provides a unique opportunity for transcultural interaction. Ecuador is characterized by great biodiversity. Demographic diversity has created a very interactive relationship between many different ethnic groups. Cultural diversity is favoring the exchange of cultural values such as those related to the prevention or treatment of human ailments. Different groups have different procedures and approaches to solving the same health problems.

To know the magnitude of Ascariasis infection in communities is valuable information not only for physicians, but also for healers and other members of the community who are concerned with the control and future prevention of such disease. The community people are open to new initiatives that will let them reach optimal conditions of health. The communities are highly motivated to participate in their own health improvement, and physicians need accurate information to establish alternative plans of therapeutic action.

For the majority of western medicine practitioners the use of medicinal plants means lack of scientific knowledge. Local concepts of disease etiology, classifications, diagnosis and treatment procedures are difficult to understand because they are different to those of the dominant medical system. Opening a scientific space for exchanging knowledge and practices applied to common

problems will be an important contribution with mutual benefits for both systems, but especially to the patients.

The emphasis of this research is to identify which treatment for Ascariasis is most cost-effective. Besides the importance of an economical evaluation in monetary terms, it is also valuable to recognize and support traditional concepts of local knowledge and actions developed through centuries of ethno-botanical praxis. Traditional medicine has played a significant role in the discovery and further development of Western-scientific medicine. It is time for western scientists to recognize that traditional methods of healing were created based on constant experimentation, valued by their users as effective ways to decrease or to cope with ailments, culturally adjusted and economically affordable. It is important to recognize that modern-Western methods also based on experimentation have increased the effectiveness of curing, but not necessarily at affordable costs.

In addition this study is important in demonstrating how a clinical trial and methods for the economical evaluation of health care could be applied to traditional medicine, which is still rare in literature. Thus, a clinical trial and cost-effectiveness analysis are proposed to compare the effectiveness and costs of pharmaceutical and traditional treatments of Ascariasis in rural communities of Ecuador.

According to WHO, innovative preventive and control strategies to cope with parasitic infections must be identified. This study is a response to that demand. It demonstrates cultural and social sensitivity and competency through active participation of the community members in program design and implementation.

1. 8. Limitations

Several constraints were considered before and during the implementation of this study: insufficient budget, following-up experimental and control cases, side or adverse effects of drugs, tight field work schedules, and further feasibility.

-Financial: Due to economic constraints, the budget for this research was insufficient to buy all required doses of pharmaceutical products. The use of chemotherapy was limited to available products donated by two different non government organizations, NGOs¹. This meant that the decision to use albendazole as the anthelmintic drug of choice was taken based on the availability of this product in both sponsoring institutions. The Laboratories of the Universidad San Francisco de Quito collaborated by reducing the prices of direct and concentrated coproscopic tests.

¹The Western-modern treatments for this study were provided by Rotary Club (Club Rotario del Valle Interocéanico) and by Plan International (former Foster Parents). Both organization provided Albendazole and Tinidazole. The first was used to treat helminths, and the latter to treat protozoan.

-Follow-up: As in most prospective studies, difficulties in following-up experimental groups were also a constraint to obtaining accurate information along with the project implementation. Community and family participation helped to cope with this risk, as well as the principal researcher providing extra time to supervision during fieldwork implementation.

-Adverse effects: reports of side or adverse effects of local preparations (Andean region) of *Chenopodium ambrosioides* have never been published. For the pharmaceutical product used in this experiment, the most common of patient complaints were transitory abdominal pain, nausea, and vomiting. The patients and their relatives in this study were informed about these possible side-effects. No medical attention was required during the days of the administration of such treatments with regard to adverse reactions.

-Time constraint: due to academic schedules, field activities occurred mostly on weekends. Activities included mapping, conducting a demographic census, and interviewing the parents of the students in distant dispersed communities. School-age children were treated on week-days under a different schedule requiring the principal researcher to dedicate full-time efforts during a period of two months.

-The results of this study are relevant to the communities where the research was conducted. The results could also be compared to other studies using the same methodology. This study contributes to the expansion of the body of current knowledge about Ascariasis in rural Andean areas. It provides information not only related to the prevalence of Ascariasis, but also about the quality of information in this study such as: sample size, population structure, how subjects were chosen for the study and other elements. In this way this study contributes to a better understanding of current parasitism in Ecuador and Latin America.

1. 9. Definition of terms:

Several terms used in this study may need clarification. The following list will clarify an understanding of these concepts:

Ascaris lumbricoides: refers to the human roundworm. Ascariasis is used to denote infection with ***Ascaris lumbricoides***. The term *Ascaris* will be used as synonym of ***Ascaris lumbricoides***.

Efficacy refers to the capability of a particular substance to produce an expected outcome or desired effect under optimal conditions. The efficacy of Albendazole, for example, is its capability to kill helminths by affecting the tubulin polymerization, which results in the loss of cytoplasmic microtubules. In other

words, under controlled optimal conditions such as the laboratory environment, ABZ kills larval and adult forms of the parasite.

Effectiveness refers to a drug's capability for killing the parasite out of the experimental assay, that is, whether it works in the real world instead of in a control laboratory. For better understanding of drug effectiveness two questions must be asked: Is this an operative drug? Does this drug work for treating patients? In real life there are other variables to be taken into account. These variables are related to accessibility, affordability, presentation, taste, doses, adverse effects, and the patient's satisfaction.

Efficiency implies that given proven effectiveness the drug achieves the outcome at a minimal cost. Efficiency adds to the last two definitions, productivity and economy. This means satisfactory results for less money. This concept of efficiency is derived from the concept of "technical efficiency" in economics.

Traditional medicine. One of the most generally accepted definitions for traditional medicine was made by a group of experts from the African Region (AFRO) that met in Brazzaville in 1976. Traditional medicine is: "the sum total of all the knowledge and practices, whether explicable or not, used in diagnosis, prevention and elimination of physical, mental or social imbalance, relying exclusively on practical experience and observation handed down from generation

to generation verbally or in written. Traditional medicine might also be considered as a solid amalgamation of dynamic medical know-how and ancestral experience” (AFRO: 1976).

This definition establishes the cultural framework and provides theoretical and practical elements of health systems. It is also complemented by the description of the role of the traditional use of vegetable, animal and mineral substances and certain other methods based on the social, cultural and religious background (Ortega: 1993).

Traditional medicine has been called: ethnomedicine, folk medicine, primitive medicine. It has been categorized with other different types of medical procedures around the world as: alternative medicine, natural medicine or unconventional medicine (Foster: 1972).

Chenopodium ambrosioides: a perennial herb usually found in temperate zones of both hemispheres. This plant was classified as *Chenopodium ambrosioides* Sp. Pl. (1753) 219 by Linnaeus as part of the family Chenopodiaceae.

Intervention and control groups: There are two experimental or intervention groups. One received the Andean-traditional treatment based on ***Paico*** (*the popular Quechua name for Chenopodium ambrosioides*), while the other

received **Abz** (the abbreviation for Albendazole), the modern-Western treatment. There is one control group, which received no treatment.

Cure: In this research an individual is considered cured when three weeks after treatment their stool test changes from positive to negative. This is the outcome measurement for the effectiveness evaluation of both treatments. For cost-effectiveness the outcome measurement will be cost-per-case cured.

2. REVIEW OF LITERATURE

2.1. *The Worm: Ascaris lumbricoides*

Ascaris lumbricoides is only one of the 134 species of helminth claimed to infect the human alimentary tract. The first scientific descriptions of *A. lumbricoides* are attributed to Tyson in 1683. Linnaeus provided the present name in 1758, and Yamaguti has recognized 15 additional species labeled as parasites of mammals (Cf. Crompton 1989:10).

Ascariasis is an endemic problem in Ecuador. Certain geographical regions are more affected than others. The prevalence rates stay stable due to the reproductive potential of the parasites and easy re-infection in highly contaminated environments. Tropical forest areas are affected with prevalence above 60% (Tenorio: 1999), while the communities located in rural highlands of the Andean valleys are infected with prevalence above 40% (Cruz: 1993).

In endemic areas the prevalence of Ascariasis reaches a maximum level between the ages of 4 and 14 years and then persists or declines at adult ages. The infection has a slight difference in sex distribution; women are more affected where household transmission is common. It is also frequently aggregated in families due to their specific hygienic habits (Pawlowsky: 1990).

The life cycle of *A. lumbricoides* starts, as in many other species, when the sexually mature male and female worms copulate in the small intestine of the human host. The fertilized eggs develop to the ineffective second-stage larvae. Production and release of eggs occur at human body temperature. Embrionation depends on temperature in the human intestine, oxygen, shade, moisture and warmth during the extra human developmental phase of *A. lumbricoides*' life cycle.

The adult *Ascaris lumbricoides* are large (15 to 40 cm in length) cylindrical worms with blunt ends. The population of adult worms increases by adding the individuals that survive the process of hatching, larval migration and growth and maturation, while losses are due to death of adult worms (Cf. Crompton, 1989:18).

There are two morphological forms of eggs of *A. lumbricoides*: fertilized and unfertilized eggs. Fertilized eggs are spherical or ovoidal in shape (50-70x40-50 μm). The shell that covers the egg has four different layers. The outer layer is a deposit of sticky mucopolysaccharidae that provides adhesiveness to many surfaces in the human environment (Kagei, 1983). The inner layer is responsible for the survival of the parasite. The selective permeability of the layer increases in response to an increase in ambient temperature; this explains why desiccation or dryness is a great hazard to eggs. The external morphology of a fertile egg shows a mammillated albuminous coat. The unfertilized eggs are more elliptic in shape than

the spherical fertilized eggs, measuring 60-100x40-60 μm . Both types of eggs appear brown due to the presence of a tanning protein that provides additional protection (Wharton, 1980). The mammillated covering of the infertile eggs is attenuated or missing in many cases.

The life span of a fertile female adult is 6 to 18 months, during which she will release an average of 200,000 eggs daily. The eggs are soil-transmitted, and they can be found in as many sites as people touch. For example, clothes, hands, door handles, insects, furniture, dust, fruits and vegetables or paper money, can be infected. The eggs of *A. lumbricoides* grow vigorously in poor communities where water is also contaminated and safe systems of sanitation and sewage disposal are not available. They require a period of soil incubation before they become infective, which under optimal conditions of warmth, shade and moisture, occurs in 2 to 3 weeks. The eggs then may remain viable for up to six years in temperate climates and may survive freezing.

When invasive eggs are ingested, the larvae are liberated in the small intestine. It migrates through the wall, is carried by the bloodstream and reaches the liver via the portal vessels or the lymphatic system. The larvae then migrate to the lung. After about ten days in the capillaries and alveoli, the larva passes in turn up the bronchioles, bronchi, trachea and epiglottis, is swallowed, and returns to the jejunum. There the larvae grow and develop organs. They develop into mature

adult worms within two to three months of ingestion. Adult males are thinner than females and can be recognized by the prominent curvature of the posterior end where the copulatory spiracles are located.

2. 2. *The Host: Human being*

2.2.1. Epidemiology

Ascaris lumbricoides, also called round worm², is distributed world-wide. It contaminates rural and urban areas, from sea level to high altitudes where human life is present. A quarter of the world's population is affected. Crompton reported that a total of 153 countries out of 218 countries considered for *Ascaris* prevalence have confirmed the presence of *A. lumbricoides*. The other 65 countries did not have accessible information when the research was performed in 1989. This does not mean, however, that Ascariasis is absent from those areas.

Ascariasis prevalence is low in infants before their weaning period, but increases rapidly thereafter until adult age, when it reaches a plateau that will remain stable. Several reports confirm that prevalence by age is not significantly different from children to adults (Martin et al., 1983; Elkins et al., 1986), but others mention the contrary (Richard-Lenoble et al., 1982 and McCullough 1974). The same applies to prevalence by gender. Most publications indicate higher prevalence

²*Ascaris lumbricoides* in Latin America has other popular names such as: cuicas, bichos, lombrices, parasitos or gusanos, all meaning worms.

among women (McCullough, 1974; Cross et al., 1975; Arfaa and Ghadirian, 1977; Shield et al., 1980, Cabrera and Valeza, 1980; Harinasuta and Charoenlarp, 1980). Ascariasis is more prevalent in rural rather than urban areas of Africa, but different in other regions such as Peru and Morocco. In Malaysia, there is no significant difference ($p < 0.05$) between urban and rural schoolchildren prevalence (Rahman: 1998).

Although the distribution of Ascariasis includes cosmopolitan areas, the most affected countries are those located in tropical and semi-tropical regions. There is an important correlation between Ascariasis and Infant Mortality Rate, IMR. Ascariasis occurs in 92.5% of countries with an IMR above 100 deaths/1000 live births, in 91.2% of countries with an IMR between 64 and a 100, in 85.7% of countries with an IMR between 25 and 50, and in 80% of 35 countries with an IMR of less than 25, UNICEF (1985).

Ascariasis is a soil-water-hand-air-transmitted gastrointestinal parasitism of human beings. Considering the last characterization of *Ascaris* from human and pig hosts by nuclear ribosomal DNA sequences, the host for *Ascaris lumbricoides* definitely is human. "All *Ascaris* samples from humans had six (1.3%) nucleotide differences in the first internal transcribed spacer compared with those from pigs" (Zhu: 1999).

Several studies have revealed that raw sewage is used for farming purposes around the world. Recent field trials confirmed that irrigation of crops by raw waste water leads to contamination. However, cultures irrigating with fresh or treated waste water were free from contamination. Collected crops in irrigated fields were potatoes, coriander, carrots, radish, mint and others. *Giardia* cysts and *Ascaris* eggs were detected at different levels of contamination (Amahmid: 1999).

Infection follows the ingestion of the embrionated eggs contained in the hands after contact with contaminated soil, contaminated food, feces or water. Less commonly, in dry, windy climates, the eggs may become airborne.

In epidemic areas, the infection is maintained primarily by small children who defecate carelessly in the area of the home. In tropical areas of the developing world where the lack of sanitary facilities exposes populations to the greatest risk, the prevalence of infection may be as high as 80 to 90 percent. Children are almost universally infected in these areas. The infection occurs in family clusters (cf. Harrison 1987:817).

2.2.2. Clinical and pathological aspects of Ascariasis

Fever, dyspnea, cough, wheeze, eosinophilic leucocytosis, and pulmonary infiltrates may occur during the passage of the larvae through the lung. The severity of the symptoms is apparently related to both intensity of infection and the degree

of sensitization resulting from previous exposures. Adult worms may produce no symptoms. They may be detected accidentally when vomited or passed in the stool.

Abdominal pain and malabsorption of fat, protein, carbohydrate, and vitamins may be a consequence from heavier infections. Until 1985, the intestinal pathology attributed to *A. lumbricoides* has been related to mucosal abnormalities that include crypt elongation, villous deformation and cellular infiltration of the lamina propria. In children the effects are also related to nutritional imbalance due to steatorrhea, impaired nitrogen retention and depressed xylose absorption (cf. Stephenson 1980). In malnourished children this may produce growth retardation. In recent studies conducted in tropical regions of Venezuela, there is an evident association between helminthic infection and anthropometric indicators of nutritional status. "The proportions of children at or below the 10th percentile for height/age and weight/age were demonstrated significantly higher in those presenting helminthiasis than in those uninfected" (Hagel: 1999). These study also confirmed that children at risk of malnutrition are more susceptible to parasitic infections, even after a prolonged parasite-free period.

Volvulus, intussusception, or intestinal obstruction in the ileocecal area may be occasionally seen due to a parasite bolus. Children are most likely to have these complications because of their anatomically smaller intestines and larger worm loads. The diagnosis is usually made by finding fertilized eggs in the feces. The

fertilized eggs are usually numerous, characteristic, and not easily confused with those of other helminths (cf. Harrison 1987:817).

2.2.3. Role of immune system

The immune system responds vigorously to the migrating larvae stages. The response seems to be more allergic than protective. The common findings in these cases are respiratory problems and transient urticaria. There are also laboratory findings: increased IgE and mast cell degranulation (Coles .1985:167-184).

In immune hosts the entry of new larvae to the lungs may provoke edema, emphysema and the rapid mobilization of inflammatory cells, such as eosinophils, which can result in destruction of larvae. Similar reactions can be expected at the liver and other infected organs. Protective humoral immunity has been described with a correlation between high levels of antibody and low *Ascaris* burdens in man (Leikina and Guseinov, 1954; Leikina, Hefter and Zorikhina, 1957).

Immunosuppression of antibodies to diphtheria, typhoid and paratyphoid in children and adults has been described by Suslov (1962) and Levinas (1964).

Commonly accepted strategies to control Ascariasis based on chemotherapy are massive treatments of the population. Treatment of the whole population every three months has been suggested in areas where prevalence is high; however treatment strategy has to be adjusted to local conditions and resources. Selective

mass treatment given to those most heavily infected is a demonstrated effective strategy.

The ethnomedical approach to the popular conception of Ascariasis detected the use of a common phrase to refer the presence of this disease: *Estas con ciucas!!!*, meaning: You have worms!!!. This quichua expression, widely use in Andean Ecuador is the confirmation of a popular diagnosis made by adding the following symptoms and signs: abdominal pain, drooling, diarrhea episodes, pale skin, and preference for sweet food or candies. The confirmation of this diagnosis is sometimes achieved when adult worms are passed spontaneously in the feces.

Medical Anthropology provides several examples in which anthropological theory enables the researcher, the health worker, and/or the decision maker to obtain a sense of commitment to learn from the local people to adopt treatment to their needs. Local health knowledge and practices exist as social adaptive responses to particular health problems. The process of curing is a process of continuous experimentation. Trial and error learning is as old as mankind. It is an error to judge former procedures of prevention or cure as insignificant events. It is important to take into account to contexts of each health system. Modern medicine has demonstrated great success, as well as limitations.

2. 3. *The Cure: Remedy vs. medicines*

2.3.1. The remedy: **Paico** (*Chenopodium ambrosioides*)

People throughout the Americas have used medicinal plants for deparasiting. The herbal pharmacopoeia includes *Chenopodium*, a perennial herb usually found in temperate zones of both hemispheres. This plant was classified as *Chenopodium ambrosioides* Sp. Pl. (1753) 219 by Linnaeus as part of the family Chenopodiaceae. The genus has been well investigated. The chemical components isolated from *Chenopodium ambrosioides* are multiple but those with identified anthelmintic, vermifuge or nematicide effect are: Ascaridole, Geraniol, Limonene, Safrole and Vanillic-acid (Duke 1992A). Other chemical-related components are triterpene saponines, flavonoides, betacyanins and essential oils.

Ascaridole's chemical name is: 1-Isopropyl-4-methyl-2,3-dioxabicyclo[2.2.2]oct-5-ene. The molecular formula is: C(10)H(16)O(2). It is the active principle of chenopodium oil. It is an unstable liquid which is liable to explode when heated or treated with organic acids.

Chenopodium ambrosioides seeds were discovered in stools of the prehistoric population that lived in Humboldt Cave near Lovelock, Nevada, USA. From about 2,000 B.C. to sometime later than A.D. 1,000 (Heizer: 1975, p. 14., Dunn: 1978, p. 109). Nowadays, many ethnic groups in Latin America still use this plant considered to be purgative and vermifugal (cf. Ortega, 1983). In Mexico and

Central America, *Chenopodium ambrosioides* is known as Epazote or Apazote (Foster: 1978, 2). Its name changes with every ethnic group. The Siona of Ecuador call it as wasi-iko, which means worm remedy; the Kofan use paiko-nume-mba-se-he-pa, and the Quechua and Quichua of the Andes in Peru, Bolivia and Ecuador know this plants by the name of Paico. In Argentina it is known as “Te jesuita” probably because this group (the Jesuits) obtained the knowledge from aboriginal tribes and used it frequently (cf. von Reis and Lipp, 1982:55).

Other names of *Chenopodium ambrosioides* are: Mexican tea, Jesuit tea, Spanish tea, ambrosia, stickweed, wormseed, or Jerusalem Oak goosefoot, and stinking weed. The seeds are used as a very active vermifuge and for orthodox treatment of roundworms (*Ascaris*), for which the plant is considered one of the best expellants (Harris 1972:194).

For the Tikunas of the Amazon jungle, adults take one cup of *Ch. ambrosioides* before eating in the morning for three successive days while children use only half-doses. The leaves are used as decoction or as juice. Schultes and Raffauf reported that a decoction of leaves and roots of this plant has contraceptive and abortive effects (Schultes and Raffauf, 1990:127).

The distillation of the whole plant provides an oil known as *Chenopodium* oil, given as a single dose for adults at the rate of 1 cc. per dose. “In home

medicine, a teaspoonful of the seeds may be mixed with honey, to be given twice in one day and followed with a good laxative” (cf. Coon, 1963:103).

Chemical studies of essential oils extracted from the whole plant of *Ch. ambrosioides* have detected that a variable concentration of its main vermifuge component is a terpene compound known as Ascaridol. Concentrations may vary from 36 to 86% depending on the geographic location of plants collected (Tetenyi 1970:128).

The biological activities and chemical components of *Chenopodium ambrosioides* have been listed by Duke (1992). Anthelmintic, nematocide and vermifuge attributes are given to *Ch. ambrosioides*. The concentration of Ascaridole in the leaf of a plant ranges from 185 to 18,000 ppm. There are three more chemical components with nematocide functions found in Paico plant: Geraniol 100 micrograms/ml., Safrole 1 mg/ml. and Limonene 100 microgm/ml. A fifth component is Vanillic acid with attributed anthelmintic, ascaricide and laxative characteristics (Duke: 1992a). Curiously, antimitotic activity may also exist in this plant because of the presence of Ferulic-acid.

The extract of this plant (Chenopodium oil) as a drug is efficient, but it is also very toxic. Smillie reported 22 deaths out of over a million people treated in Brazil with this drug before 1944.

Four persons to whom he administered the drug died with convulsions.

“Faust believes that oil of *Chenopodium* should never be employed in the treatment of Ascariasis alone, but that it may be employed in conjunction with the treatment of an accompanying hookworm infection in the following way...” (cf. Strong 1944:1229).

Chenopodium oil is also known as: Aetheroleum Chenopodii; Esencia de Quenopodio Vemifuga; Oil of American Wormseed; or Wurmsamenol. It is obtained by distillation with steam from the fresh flowering and fruiting plants, excluding roots, of *Chenopodium ambrosioides*. Chenopodium oil was formerly used as an anthelmintic for the expulsion of roundworms. It is toxic and has caused numerous fatalities (Micromedex: 1999).

Although the toxic effects of this substance are known, current use of it has been reported by Hersch-Martinez in 1996. He makes reference to two plants of the family of the Chenopodiaceae currently traded in regional trading companies in Mexico. The two vermifuges mentioned are: *Chenopodium foetidum* (Epazote de zorrillo) and *Teloxys ambrosioides* (Epazote de comer or epazote morado). In both cases, leaves and stems are used against intestinal parasites, and particularly for worms (Hersch-Martinez 1996: 110).

2.3.2. The medicine: Albendazole (ABZ)

Piperazine, Pirantel pamoate and Mebendazole have been used for removing adult worms from human intestines; however, during the last decade other products have been researched and are now available for treatment of intestinal helminthes in humans (cf. Harrison 1987:817).

Albendazole (ABZ) is one in a class of benzimidazoles used to control helminth infection. Chemically it is Methyl 5-(propylthio)-2-benzimidazolecarbamate. It is practically insoluble in water and is poorly absorbed in the gastrointestinal tract due to its low aqueous solubility. The metabolism, residue levels and plasma pharmacokinetic profiles resulting from a single dose of ABZ were well documented (Glanzer et al.: 1988; Gyurik et al.: 1981).

Albendazole has been shown to be an effective anthelmintic for a variety of intestinal animal and human nematodes, cestodes and trematodes. Its spectrum of activity includes hydatid cyst, neurocysticercosis, and it is broader than that of other agents. It is effective against *Strongyloides estercoralis*, *Taenia species*, *Ancylostoma duodenale*, *Necator americanus*, *Trichuris trichuria* and *Ascaris lumbricoides* (Micromedex Inc. Healthcare Series Vol.102, 1999).

Compared to other anthelmintics, albendazole is the only drug active against all stages of the helminth life cycle (ova, larvae, and adult worms) (Tech Info Zentel (R), 1990).

The systemic anthelmintic activity has been attributed to the primary metabolite, albendazole sulfoxide. The parent compound is short-lived with the major metabolites being generated by a combination of oxidative and hydrolytic process. Albendazole 2-aminosulfone, another major metabolite, has been designated as the marker metabolite. This metabolite is 70% bound to plasma protein and is widely distributed throughout the body (PDR: 2000).

The mechanism of action of ABZ is its binding of the tubulin (subunit of protein in the microtubules) and thereby inhibiting polymerization, which results in the degeneration of cytoplasmic microtubules in intestinal and tegmental cells of the parasites. Cholinesterase secretion and glucose up take are impaired, glycogen is depleted and secretory substances are accumulated intracellularly (Gilman et al, 1990). This product has antimitotic activity in helminth eggs, which provide some reproductive control following the treatment.

Albendazole is generally indicated as a single oral dose of 400 milligrams for adults or children above 2 years when treated against Ascariasis. Doses will vary, depending upon which parasitic infection is being treated. A dose of

approximately 10mg/kg of Albendazole has been indicated to treat pediatric patients with hydatid cyst. Albendazol should be taken with food (PDR: 2000).

2. 4. Economic evaluation of alternative treatments

Economic evaluation in health care has been conducted by individuals or multidisciplinary groups by applying a range of methods such as: cost analysis, cost-benefit analysis, cost utility analysis and cost-effectiveness analysis. Each method has played a relevant role in decision making in health care (cf. Drummond 1987, Gold 1996, Cox 1997).

Cost Effectiveness Analysis, CEA, is a full economic evaluation method in which costs are related to a single common effect that may differ in magnitude between alternative programs. CEA are designed to assess the comparative impacts of expenditures on different health interventions. In comparing these alternatives we would calculate cost per unit of effect, as well as the cost-effectiveness ratio, which is the difference in the two alternative costs divided by the difference in their effectiveness.

CEA is important because resources are scarcer than the needs for which they can be used. CEA furnish information that can be used to choose the least costly method for controlling a particular disease by comparing therapeutic resources of a community. CEA can also provide important information about how

health care resources might be allocated in the most effective and efficient manner (cf. Gold 1996). Finally, CEA would give decision makers to understand the relative efficiencies of different health interventions.

3. RESEARCH DESIGN AND METHODOLOGY

3. 1. Study design

The choice of a study design depends on the amount of information that is already known about a particular health issue. When relatively little is known, as is the case of Ascariasis in Ecuador, then the study has to start establishing first what is the natural history of the disease. In addition, it is important to know what is the rate of prevalence of the disease of interest among the population.

A second aspect of importance for designing a study is the nature of the procedures intended to apply. To evaluate the effects of different types of treatment, which is one of the objectives of this study, it was required to observe the individuals at least two times during the study.

Other factors that influence the selection of the model are: a) The directionality of exposure. The research started with individuals who already have the disease of interest, exposing them to different types of treatments, then in order to follow the evolution of the events, the directionality of exposure obligate to perform a prospective study based on a recent baseline data collection. b) The timing of data collection was also important. Short periods of time were mandatory between exposure to treatment and cure (three to four weeks average between the

screening test and the second test) or outcome measurement. c) The unit of observation for this design is the individual, however, a group analysis was also perceived important.

Two considerations contributed to choice the study design: the interest of maintaining the control of the exposure to the treatments, and the random assignment of study subjects to one of the experimental groups or to the control group. In this case, we refer to a process in which chance determines the likelihood of subjects' assignment to treatment. As the researcher required control of exposure and random assignment, therefore the study design was experimental to test the efficacy of different therapies. To evaluate the cost-effectiveness of both treatment regimes the most appropriate design was also the experimental study. In this particular case, the design corresponds to a pre-test post-test prospective experiment with two intervention groups and one control group. The inclusion of a no treatment control group brings to evidence how common external factors of daily experiences in the community continue affecting the part of the population that is not taking any medication.

The study follows the treatment after diagnosis method of clinical trials. A sequence of events was implemented to develop this design (See appendix A). In order to establish the diagnosis, three steps were taken: a) a written consent form was sent to all parents of children registered in school. It was collected with the

corresponding signature. b) a parasitic survey form was applied and collected in school, and c) a first laboratory test of stools (screening test) was performed (See appendixes B, C, D, E, F, and G).

Then, the effectiveness of each treatment was evaluated. Finally, the cost-effectiveness of each treatment was calculated and compared complying with the following method of analysis (See Section # 3.5.).

3. 2. Population and Study Subjects

3.2.1. Population

This study was conducted in three Andean communities near Quito, the capital city of Ecuador. The estimated population living in these three communities is 4,000 inhabitants. These communities are characteristically homogeneous with similar ethnic backgrounds (Quichua Andean Group), ecology (rural location, temperate weather), altitude (8,800 - 10,000 feet above sea level), traditions, occupations and impoverished socio-economic conditions.

Rural location refers not only to the geographical location of the communities (50 kilometers far from Quito or 90 minutes distant by bus), but also to the conditions of public services prevalent in this area, that is: contaminated drinking-water, lack of sewage and sanitary disposal of feces, use of untreated-

surface water (Aglla and Iguiñaro), domestic animals at home, lack of health facilities or absence of medical personnel.

Residents' cultural background is the same; however, the process of trans-culturation has increased during the last three decades due to Quito's vicinity and expansion. As a consequence of this process, only Spanish is spoken in the communities, most of male workers have a job in the city (factories, plantations or construction industries), and women's labor is not only dedicated to agricultural and home activities but is changing to flowers production (women employment has recently increased in flowers industry).

Although there are many social changes in many Ecuadorian communities certain values persist. Mothers are the first source of diagnosis and treatment of household members' illnesses, including the endemic helminthic and protozoan intestinal infections. Mothers of these communities have often complained that their children have parasites.

3.2.2. Study subjects

The total population of the Checa parish is 5,295 inhabitants, distributed into seven different neighborhoods, one central and principal town and six rural locations. This study was applied in Central Checa (2,600) and Aglla (620). The other rural sub-sectors were not part of the study. Among this population there were approximately 620 children between 5 and 15 years in Central Checa and 150

in Aglla. Iguinaro is a sub sector of El Quinche parish, and has a total population of 780 inhabitants of which 220 are children between 5 and 15 years.

Not all these children attend local schools and not all the students registered in local schools come from the same community. The candidates to participate as study subjects were all those children registered in local schools for academic year 1,999 - 2,000.

**Table 3. 1. Study Population:
Steps followed to establish the study population.**

Community	Total population in the area.	Children between 5 and 15 years	%	Children registered in local schools *	%	Number of children with screening test	%	Cases included in the study	%
Checa	2600	620	24	596	96	568	95	528	93
Aglla	620	150	24	240	160	202	84	144	71
Iguinaro	780	220	28	85	39	85	100	82	96
Totals	4000	990	25	921	93	845	92	754	89

* The school of Aglla has a high registration rate. It registers not only local students but also children from other communities. This explains why there is a 160% of children registered in Aglla. In Iguinaro occurs the contrary. All percentage calculations used the counts of previous columns.

The number of cases included as valid cases in this study corresponds to 89% of those children that sent a sample for the screening test. There are 11% of cases excluded because the stool sample boxes were empty, or because some data was absent in their parasitic surveys.

A randomized control trial is the most powerful tool for assessing the effectiveness of medications, this particular research used random assignment of

subjects to both study treatments. This study did not require a blinding process because the coproscopic tests were performed in the laboratories of the university. The technician only received white plastic boxes with a number in the coverlid for identification of cases. This procedure allowed the assessment of outcomes (parasitic test results) avoiding any evident relationship between technician and community or individuals). This procedure minimizes observer bias and also reduces confounding due to known and unknown variables.

All those students who presented written informed consent and had the screening test were randomly assigned to one of three different groups for treatment: One third was control group, other third was Paico group and the last third was assigned to ABZ treatment. All individuals participating to this research were required to furnish proper informed consent to participate.

The first experimental group called “Paico group” used preparations based on *Chenopodium ambrosioides*, following the community patterns of medication. The procedure for Paico preparation is as follows: plants were collected in the backyards of several houses in the communities, washed in potable water, and rinsed. All stems and big branches were removed. Only leaves, flowers and small-green branches were used. The jar of an Osterizer three speeds blender was filled with rinsed Paico leaves (150 gm.) and a cup of potable water was added (240ml.). The content was blended at mid-speed for one minute. The liquified leaves were

strained and the green suspension received the name of “Zumode Paico”. The children assigned to this group were administered 30ml. of Paico suspension before lunch break at school, as indicated by the mothers in the community.

The second experimental group called “Albendazole group” received the pharmaceutical treatment albendazole, as indicated by the international pharmacopoeia. Aglla children received a tablet of 400 mg. of Albendazole, while Checa and Iguiñaro children received two tablets of 200 mg. of Albendazole after meal during the lunch breakfast in school.

The third group called “control group” was tested first at the beginning of a three week period for testing all students in this research. The control group did not receive any medication (during those three weeks) until the second test was performed.

After three weeks of intervention all participating students had a second stool test to confirm the effectiveness of each treatment. The non-existence of eggs in the stools of those students treated with both types of treatment led the researcher to consider those students cured.

3. 3. Data Collection

3.3.1. Collecting data

Field work data collection started after a series of meetings were held in each community to inform the primary school staff and the community leaders about the project objectives, procedures and limitations. Required logistics were discussed and commitment of the community and teachers was requested. The same schedule of implementation was established in each community with the agreement of community authorities.

As children entered school the field work began in the first week of classes with a conference addressed to the parents of the students explaining the objectives of this project and requesting their collaboration and input.

Three weeks were dedicated to stools testing. Simultaneously, a parasitic survey began. Very strict coordination was established with the Directors of each school. The students' mid-morning snack time was used to administer their treatments. The strategy was to establish three different groups of treatment as explained in next section. Each teacher in the school also helped recording any symptoms detected or referred by their students.

The method for detection of Ascariasis consists of a microscopic stool examination to detect the presence and the amount of eggs of *Ascaris lumbricoides*

per microscopic field. Microscopic screening of *Ascaris lumbricoides* and other parasites was performed. Consecutive direct fecal smears were examined before confirming absence of parasites in any individual tested. This is known as the most cost effective method to implement in a community-based survey. Concentration of feces and counting of eggs were also implemented and the most important technique used (See appendix F).

The parasitic survey form included a section dedicated to sanitary living conditions, such as: quality and accessibility to water supply, sewage or latrines, domestic animals, and local practices of personal hygiene. This form also included questions related to cost analysis such as: income, wage, time to prepare drugs, fuel, types of costs of each treatment, and the level of satisfaction manifested by each patient after treatment, and cost per case cured, which is the outcome measure.

3.3.2. Gathering information

A sequence of research techniques was implemented to evaluate the effectiveness of Andean-traditional versus modern-Western treatments of Ascariasis (first objective of the study). Anthropological Rapid Assessment Procedures were applied to collect information about the most relevant characteristics of the communities involved in this study. The most important techniques used are: conversation, observation, photography, videotaping, laboratory testing of stools samples and interview.

The main complaints associated with signs and symptoms of Ascariasis were collected in a short parasitic survey applied to all children registered in school. The information to establish the prevalence of Ascariasis as well as other parasitic diseases was provided by laboratory testing of feces of all primary school children. A single laboratory technician performed the first microscopic test of stools reducing the potential observer bias that could be introduced by several technicians. A very important criterion for including children in this study was their participation in a first general screening of parasites and a signed written informed consent.

To avoid contamination, this study considered very important to maintain the control group in the same original conditions since the beginning of the research. Any treatment activities to be conducted with the other two groups were held until obtaining the results of the first test in all school registered children (three weeks). This permitted the researcher to be sure of not introducing any bias in the results of the control group as it was also selected from the same community.

Traditional-Andean and modern-Western treatments were both orally administered. The main interest of this research did not focus on the concentration of chemical ingredients of the traditional remedy. The study did not pretend to obtain any specific concentration or dilution of this plant other than the form the

community is accustomed to utilizing. Pharmaceutical treatment followed the normal prescription of Albendazole.

Monitoring for adverse reactions followed the administration of both treatments. Modern and traditional treatments were initiated at the same time and evaluated for effectiveness at three week and three months intervals. Effectiveness was measured by a second set of coproscopic tests, which was assumed to be negative after treatment or the same for control group. The expected outcome of both treatments was the proportion of children that resulted cured. In other words, the calculation of that proportion is obtained by dividing the number of children cured by using the traditional treatment by the total number of children receiving treatment that traditional treatment. The same calculation applies to pharmacological treatment.

3.3.3. Data cleaning

All collected data had to follow the same cleaning process. The parasitic survey data as well as the results of the first and second tests for parasites were typed into an Excel worksheet. Later, every variable was defined while data were entered in SPSS file for statistical analysis. Only one person typed the data in order to maintain consistency in data cleaning. Outliers were checked as well as non-corresponding answers or lack of response.

3. 4. Hypothesis

The null hypothesis (H_0) is that the effectiveness of pharmaceutical and traditional treatments of Ascariasis is the same ($H_0 = \pi_{ph} - \pi_t = 0$); while the alternative hypothesis (H_a) is that pharmaceutical and traditional treatments have different effectiveness ($H_a = \pi_{ph} \neq \pi_t$).

3. 5. Method of Analysis

3.5.1. Data analysis.

Experimental design enables the testing of a hypothesis by reaching valid conclusions about the causal relationships between independent (type of treatment) and dependent variable (persistency of Ascariasis or cure). The experimental design selected (control group design with random allocation), allows differentiation between the influence of the treatment and the influence of extraneous variables on the dependent variable. To achieve the highest degree of internal validity the experiment was conducted in the school, then extraneous variables like hour of administration, amount administered, method of preparing the remedy, and substance used to drink the pharmaceutical product were strictly controlled. The external validity was protected by random assignment of intervention subjects with positive microscopic test for *Ascaris lumbricoides*.

The analysis of the data follows the steps of the experimental design (pre-test/treatment/post-test) model, which includes two different treatment groups and a non-treatment group for control.

The data analysis is determined by the way the variables are used in the data set. Most of the variables of this study are **nominal variables** (Stevens: 1951). This means that each observation belongs to one of several distinct categories. This categories represented by numbers are not necessarily numerical. Sex for example uses the codes 0 for male and 1 for female categories. There are few ratio variables, but no ordinal or interval variables.

Certain variables are used to measure outcomes, cured or not cured cases, or to explain factors related to the presence of a particular outcome. E.g. Ascariasis: age, hands cleanliness, consumption of raw-contaminated water. As the data set is large each variable had to follow the same procedures of cleanliness and preparation for analysis.

The steps followed to prepare the data were: a) Data entry: assigning attributes to data, entering data and screening out of range values. b) Data management: combining data sets previously prepared in Excel worksheets for each community, transforming some basic data in more complex variables, such as the

cure and not cured after treatments, and checking results, and c) Creating a list of codes, as follows:

Table 3. 2. a. General characteristics of the children.

	Variable	Definition	Scale	Variable type	Codes
1	Id	numeric code	Nominal		
2	Age	in years	Ratio	ind.	# years
3	Sex	Gender	Nominal	ind. binomial	0=male 1=female
4	Weight	Kilograms	Ratio	ind.	# of kilograms
5	Height	Centimeters	Ratio	ind.	# of centimeters

Ind. = independent Ind. Binomial = independent and binomial

Table 3. 2. b. Variables related to community, water source and child's hygiene.

	Variable	Definition	Scale	Variable type	Codes
6	Community	Community name	Nominal	ind. 3 categ	1 to 3
87	Contami	Contaminated	Nominal	ind. Binomial	0=no, 1=yes
8	Treated	Treated water	Nominal	ind. Binomial	0=no, 1=yes
9	Rain	Collected water	Nominal	ind. Binomial	0=no, 1=yes
10	Boiling	Boiled water	Nominal	ind. Binomial	0=no, 1=yes
11	Hands	hands cleanliness	Nominal	ind. Binomial	0=clean, 1=dirty
12	Nails	Fingernails clean	Nominal	ind. Binomial	0=clean, 1=dirty

Table 3. 2 (Continued)**Table 3. 2. c. Variables related to parent's characteristics.**

	Variable	Definition	Scale	Variable type	Codes
13	Fact	father activity	nominal	ind.	0=no father 1 agriculture 2 construction 3 employee 4 artisans 5 flowers 9 no answer 10 commerce
14	Mact	mother activity	nominal	ind.	0=no mother 1 agriculture 2 flowers 3 employee 5 household 9 no answer
15	Finc	father income	interval	ind.	Amount in 1000 sucres
16	Minc	mother income	interval	ind.	Amount in 1000 sucres
17	Faminc	Family income	interval	ind	Amount in 1000 sucres
18	Feduc	education years	interval	ind.	0 to 13 years
19	Meduc	education years	interval	ind.	0 to 13 years

Table 3. 2. d. Variables related to the presence of animals at home.

	Variable	Definition	Scale	Var. type	Codes
20	Dog	Living in the house	nominal	ind. binomial	0=no, 1=yes
21	Cat	Living in the house	nominal	ind. binomial	0=no, 1=yes
22	Pig	Living by the house	nominal	ind. binomial	0=no, 1=yes
23	Cow	Living by the house	nominal	ind. binomial	0=no, 1=yes
24	Sheep	Living by the house	nominal	ind. binomial	0=no, 1=yes
25	Chicken	Living by the house	nominal	ind. binomial	0=no, 1=yes
26	guinea pig	in the house	nominal	ind. binomial	0=no, 1=yes

Table 3. 2 (Continued)**Table 3. 2. e. Variables related to the presence of symptoms.**

	Variable	Definition	Scale	Variable type	Codes
27	Abpain	abdominal pain	nominal	ind. binomial	0=no, 1=yes
28	Abdilat	abdominal dilation	nominal	ind. binomial	0=no, 1=yes
29	Nausea	Nausea	nominal	ind. binomial	0=no, 1=yes
30	Vomit	vomiting	nominal	ind. binomial	0=no, 1=yes
31	Diarrea	Diarrhea	nominal	ind. binomial	0=no, 1=yes
32	Drool	Drooling	nominal	ind. binomial	0=no, 1=yes
33	Dizzy	dizziness	nominal	ind. binomial	0=no, 1=yes
34	Itchy	anal itching	nominal	ind. binomial	0=no, 1=yes
35	Worms	has passed worms recently	nominal	ind. binomial	0=no, 1=yes
36	Headache	headache	nominal	ind. binomial	0=no, 1=yes
37	Other	Other symptoms	nominal	ind. binomial	0=no, 1=yes
38	No sympto	not symptoms	Nominal	ind. binomial	0=no, 1=yes

Table 3. 2. f. Variables related to the presence of parasite eggs or cysts in stools.

	Variable	Definition	Scale	Var. type	Codes
39	Gia1	Giardia cysts (1)	Nominal	ind. binomial	0=no, 1=yes
40	Ame1	Ameba cysts (1)	Nominal	ind. binomial	0=no, 1=yes
41	Asc1	Ascaris eggs (1)	Nominal	ind. binomial	0=no, 1=yes
42	Ten1	Tenia eggs (1)	Nominal	ind. binomial	0=no, 1=yes
43	Trico1	Trichuria eggs (1)	Nominal	ind. binomial	0=no, 1=yes
44	Oxiur1	Enterobius egg(1)	Nominal	ind. binomial	0=no, 1=yes
45	Protoz1	other protozoan 1	Nominal	ind. binomial	0=no, 1=yes
46	Noparas1	no parasite 1st test	Nominal	ind. binomial	0=no, 1=yes
47	Eggs1	counted eggs (1)	Ratio	ind.	# of eggs
48	Gia2	Giardia 2nd test	Nominal	ind. binomial	0=no, 1=yes
49	Ame2	Ameba 2nd test	Nominal	ind. binomial	0=no, 1=yes
50	Asc2	Ascaris 2nd test	Nominal	ind. binomial	0=no, 1=yes
51	Ten2	Tenia 2nd test	Nominal	ind. binomial	0=no, 1=yes
52	Trico2	Trichuria 2 nd test	Nominal	ind. binomial	0=no, 1=yes
53	Ox2	Enterobius 2nd t.	Nominal	ind. binomial	0=no, 1=yes
54	Other2	other protozoan 2	Nominal	ind. binomial	0=no, 1=yes
55	No paras2	no parasite 2 test	Nominal	ind. binomial	0=no, 1=yes
56	Eggs2	eggs counted 2	Ratio	ind.	number of eggs

3.5.2. Descriptive measures for nominal data analysis.

Taking into account the nature of most of these variables, the appropriate statistical measures to describe nominal data are: a) for graphics: bar graphs or pie charts, b) for measurement of the center of the distribution: the mode, and c) for variability of the distribution: binomial and multinomial variances.

The binomial variance for the variable sex which only have two possible outcomes is calculated as follows:

$$p = \frac{p(1-p)}{N}$$

where p is the proportion of male (code 0), $(1-p)$ is the proportion of female (code 1), and N is the number of subjects analyzed.

3.5.3. Multivariate analysis

The decision of what multivariate analysis is appropriate also depends on the type of variables, dependent versus independent and nominal versus ratio. Some dependent variables considered in this study are: Ascariasis prevalence, cured versus not cured cases, most cost-effective versus less cost-effective treatment. The rest of the variables are considered independent variables.

The following table provides a general guide for what analysis should be considered:

Table 3. 3. Suggested data analysis under Steven's classification of variables.

	Independent variables			
	Nominal		Ratio	
Dependent variables	1 variable	> 1 variable	1 variable	> 1 variable
One Nominal Variable	* X ² Test * Fisher's exact test	* Log-linear model * Logistic regression	* Discriminant function * Logistic regression * Univariate statistics (e.g. two-sample t Test)	* Discriminant function * Logistic regression
More than one Nominal Variable	* Log-linear model	* Log-linear model	* Discriminant function	* Discriminant function
One Ratio Variable	* t-Test * Analysis of variance * Survival analysis	* Analysis of variance * Multiple classification analysis * Survival analysis	* Linear regression * Correlation * Survival analysis	* Multiple regression * Survival analysis
More than one Ratio Variable	* Multivariate Analysis of variance * Analysis of variance on principal components * Hotelling's T ² * Profile analysis	* Multivariate Analysis of variance * Analysis of variance on principal components	* Canonical correlation	* Canonical correlation * Path analysis * Structural models

(Afifi and Clark: 1996)

In order to avoid any imbalance among the groups a covariate adjustment will be used in this analysis to minimize the effect of the differences. This will also reduce the variance in the test statistic. As the response variable is discrete (Ascariasis or not Ascariasis) then the analysis used Chi-square test for 2x2 tables to compare group differences. Logit logistic regression analysis in SPSS provides all this calculations.

3.5.4. Prevalence and risk factors of Ascariasis data analysis design

The principal purpose of this part of the analysis is to establish a model to explain or describe the influence of the explanatory variables on the response variable. Independent variables such as: household water source, history of drinking untreated water, active participation in agricultural labor, and fingernails and hands hygiene are assumed to influence the prevalence of Ascariasis. Most of these variables are discrete variables and the unit of analysis is the individual, who is classified as affected by Ascariasis or not. All these conditions suggest the use of logistic regression analysis. This type of analysis is also suitable for continuous variables.

Assumptions to use logit model:

- a) The model assumes that $\ln(\text{odds})$ is linearly related to the independent variables. This is checked using goodness-of-fit measures. It may require transformations of the data to achieve this.
- b) Limit the number of variables because computations are time consuming
- c) Logistic regression should not be used to evaluate risk factors in longitudinal studies in which the studies are of different durations.

d) The coefficient for a variable in a logistic regression equation depends on the other variables included in the model. The coefficients for the same variable, when included with different sets of variables could be quite different.

e) If a matched analysis is performed, any variable used for matching cannot also be used as an independent variable

f) There are circumstances where the maximum likelihood method of estimating coefficients will not produce estimates.

g) It is assumed that the logarithm of the odds of belonging to one population is a linear function of the variables used for classification. The result is that the probability of belonging to the population is a multiple logistic function.

In this research the dependent variable or first outcome studied is the presence or absence of Ascariasis (dichotomous yes-no variable). In multiple logistic regression analysis the outcome variable is the probability or odds of this dichotomous outcome. The odds of having a disease are the chances of having it divided by the chances of not having it. The odds can thus vary from 0 if there is no chance of having it, up through 1 if there is a 50-50 chance of having it, up to infinity if it is certain that the disease is present. Logistic regression does not use the odds itself as the dependent variable, but rather the log, that is, the natural logarithm of the odds.

The model is: Multinomial Logit and the design equation is:

$$\text{ASC ln(odds)} = \alpha + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \dots + \beta_n X_n$$

For example:

$$\text{ASC ln(odds)} = \text{Constant} + \text{CONTAMINATED WATER} + \text{COMMUNITY} + \text{FINGERNAILS}$$

α and β have to be calculated to best-fit the data. Log odds changes when a particular variable X changes and is multiplied by its β coefficient.

As most variables are nominal we use logistic regression, the logit model is used. When the relationship of two discrete variables is analyzed, Chi-square two-variable test (contingency analysis) is employed, using 0.05 level of significance. t-Test is used for ratio continuous variables.

3.5.5. Analysis for evaluating the effectiveness of treatment outcomes.-

The term *Effectiveness* refers to the extent to which a specific treatment produces its intended effect when employed in a real world setting. *Efficacy* refers to the potential effect of the treatment under optimal conditions (laboratory for example). Therefore, effectiveness analysis considers the results of all subjects according to their originally assigned treatment groups, irrespective of failures in compliance, discontinuation, or other reasons for withdrawal. Efficacy analysis

includes only participants who completed the clinical trial protocol and received their intended treatment (Gerstman: 1998).

3.5.6. Cost-Effectiveness Analysis

The clinical experiment was complemented evaluating the cost-effectiveness of both treatments. Local estimation of cost was obtained by applying Rapid Assessment techniques. Direct observation and interview were used in more than 30 households in all communities. A guide was especially designed for data collection. It included the following components:

Direct costs:

- Cost of pharmaceutical drugs when bought dose by dose.
- Overhead costs: water, electricity, gas, pots and equipment for remedy preparation, as well as time used searching the plants or buying the medicine.

Indirect costs:

This includes not only monetary value of the use of the time of the patient's mother in other economically productive activities, but also the monetary value of other uses of resources and other values of time. Fear, inconvenience, and discomfort caused by a medical treatment were also taken in mind for the analysis.

Definition of particular terms: charge and payment:

Charge: is the amount the hospital, medical doctor MD, pharmacy attempts to recover for a good or service. E.g.: Charge by manufacturer per dose.

Payment: is the amount actually paid by the individual for a good or service. E.g.: Price of a tablet of aspirine.

Once prevalence of Ascariasis was determined and effectiveness of treatment was assessed, this study determined the costs of these treatments.

Cost effectiveness analysis begins with comparing the effectiveness of alternative courses of action. A treatment could be considered cost-effective if it matches at least one of the following recommended criteria: 1) Less costly and at least as effective; 2) more effective and more costly, with the added benefit worth the added cost; 3) less effective and less costly, with the added benefit of the alternative not worth the added cost; and 4) cost saving with an equal or better outcome (Doubilet, Weinstein, and McNeil, 1986). In this research, the criterion we select is the lowest cost per outcome.

The model is:

Paico treatment	Albendazole treatment	Control
$\frac{\sum \text{Costs}_p}{\text{Outcome}_p}$	$\frac{\sum \text{Costs}_{ABZ}}{\text{Outcome}_{ABZ}}$	$\frac{\sum \text{Costs}_c}{\text{Outcome}_c}$

Where Σ Costs represent the addition of different costs:

C O S T S			
D I R E C T		I N D I R E C T	
Tangible	Intangible	Tangible	Intangible
Medical care costs, out of pocket, materials.	Side effects of treatment.	Patient or relatives time lost from study or work.	Survey and census costs, donations.

Outcome measurement:

As cost effectiveness analysis requires the adoption of a particular perspective to proceed with the analysis, this research adopts a family-school perspective in preparation to establish a program of control of Ascariasis in community settings with active participation of an educated children-parents-teachers force.

Cost-effectiveness analysis compares the outcome of decision options (alternative treatments) in terms of their monetary cost per unit of effectiveness. Then, with the adopted perspective, we consider which costs should be included in the analysis and what economic outcomes are considered benefits. The cost will then be expressed as cost per unit of the outcome measured (patient cured). In this way we will compare the two options in relation to net cost per unit of outcome (cf. Petitte 1994:32). The cost of one decision option in relation to the other is computed by subtraction, and the net cost per unit of net outcome is computed by division.

Cost effectiveness is measured as a ratio of cost to effectiveness, and can be calculated as an average ratio or as an incremental ratio. The first is estimated by dividing the cost of the intervention by a measure of effectiveness without regard to other alternatives. The second is an estimate of the cost per unit of effectiveness of the cost of using one treatment in preference to another. Thus, incremental cost effectiveness = difference in cost / difference in effectiveness, where difference in cost = cost of intervention - cost of alternative, and difference in effectiveness = effectiveness of intervention - effectiveness of alternative (Petitte 1994:171).

4. RESULTS OF ANALYSIS AND DISCUSSION

4.1. *Summary statistics*

The summary statistics of the results of this study are presented by groups of independent variables as they were grouped in Chapter 3. The first group of variables included one nominal (gender) and three ratio variables (age, weight and height). Mean and standard deviation are presented for ratio variables, mode for nominal. Section 4.1 of this analysis will comment only average data. If special attention is required in certain cases, a more detailed analysis will be done.

Table 4. 1.
Age, gender, weight, and height.

Variable	N	Min	Max*	Mean	SD
Age in years	754	5	15	9.17	2.33
Gender	754	0	1	.52 (Mode 1)	.5
Weight in kg.	754	14	52	25.42	6.83
Height in cm.	754	96	161	123.17	12.08

*Gender variable has two codes: 0 represent male cases and 1 represents female cases.

Considering mean and standard deviation as the most appropriate descriptive measures for age, the study population has 68% of children between 6 and 12 years of age with a skew to the right (.224) due to children who have repeated courses or enter school a little later.

Gender is evenly distributed with mode 1, meaning that 51.9% are girls. This information is important because in other rural areas of Ecuador there is a

predominant male registration to school. This particular characteristic confirms the process of acculturation of this geographical area. At least for the last two generations, it was observed there is a significant consistency of the process of educating men and women equally in primary school. In table 4. 6. parent's education is detailed. The percentages of fathers and mothers with primary education are very similar to those of children.

Weight and height need a deeper analysis. It will be required to establish first a child's nutritional condition combining age, weight and height. Then, after comparing to a standard measurement, a new variable (nutritional status) could be created for logit analysis.

Table 4. 2.
Study population distributed by community.

Variable	Category	Count	Percent
Community			
	Aglla	144	19.1
	Checa	528	70.0
	Iguiñaro	82	10.9
	Total	754	100

The distribution of the population of this study follows the natural distribution of the general population in this geographical area. Checa, characterized as the center of the parish, also has the biggest group of population, while Aglla and Iguiñaro are only small neighboring communities. The distribution of cases per community also has a relationship with the educational facilities

installed in each location, and with the level of preference of the parents to register their children in a particular institution. This applies mostly to Iguinaro and Aglla..

Table 4. 3.
Water source by type and use.

	Category	Count	Percent
Contaminated water			
	Not used	498	66
	Used	256	34
	Total	754	100
Treated water			
	Not used	256	34
	Used	498	66
	Total	754	100
Boiling water			
	Not used	436	57.8
	Used	318	42.2
	Total	754	100

Something important to remark in table 4.3. is the complementary relationship between contaminated and treated water. Each family answered one or the other option. They both are mutually exclusive. Boiling water can be seen as a hygienic practice observed in just 42.2% of families. If the majority of the population is concerned about the quality of the water, only a few of them boil the water for more than 10 minutes. Health authorities enforce the practice of boiling water in Andean communities. Due to altitude (2:800 meters above sea level) and barometric pressure (520 Hg ml.), the boiling temperature of water is approximately 82-Celsius degrees. A good and recommended process of purifying water is to boil it for at least 20 minutes.

Table 4. 4.
Hygienic habits: hands and fingernails cleanliness among the children.

Variables	Category	Count	Percent
Hands cleanliness			
	Clean	303	40.2
	Dirty	451	59.8
	Total	754	100
Fingernails cleanliness			
	Clean	212	28.1
	Dirty	542	71.9
	Total	754	100

Fieldwork information collected by Rapid Assessment Procedures matches with quantitative information collected by survey. Only 21.4% of household responses to survey mentioned the use of open canal water. Aglla inhabitants do not have other water system, than contaminated open canal water. In Iguiñaro the population complaints about the quality of the piped water they receive, “it is piped but not treated.” Some of them also use open canal water.

Most of the households in Checa are connected to a piped system that works in good conditions. However, for certain periods of the year they complaint about the color and taste of the water. Then, 21.4% of contaminated water corresponds mostly to Aglla people (19.1%) and a few (2.3%) to the other two communities. To avoid any subjective interpretation of the collected data, this study also performed a series of microbiological tests of the water conditions in all communities. Water testing reports (Appendix G) confirm and describe the type and degree of water contamination.

If water is known to be contaminated, it could be assumed that certain hygienic measures have been implemented by the community to avoid its use. Nevertheless, 42.2% of the responses present a different reality. A high percentage of the population does not boil the water regularly. Improved hygienic habits cannot be assumed as a community response to the lack of potable water. To confirm this, a physical examination of the hand palms and fingernails cleanliness was carried out to all school children. Sixty percent of children had dirty hands, and 72% dirty fingernails. These two variables showed high frequency, then they may not be considered variables; contrary to that they must be called “constants”.

The description of frequencies allows the researcher to decide which variables are more likely to be included in a predicting model for statistical analysis. From tables 4.2., 4.3., and 4.4. all independent variables are included for further analysis.

Table 4. 5.
Parent’s economic activity.

Father’s activity		
Variable	Frequency	Percent
Father activity		
No father	67	8.9
Agriculture	203	26.9
Construction	112	14.9
Employee	81	10.7
Artisan	66	8.7
Flowers plantation	209	27.7
Commerce	16	2.1
Total	754	100

Table 4. 5 (Continued)

Mother's activity		
No mother	8	1.1
Agriculture	77	10.2
Employee	32	7.5
Flowers plantation	236	31.3
Domestic affairs	377	50
Total	754	100

The influence of environmental and solar conditions in a temperate climate has provided the best opportunity for flower industries to install their facilities in the territory of the communities of this study. They are located very close to the equator line, where the perpendicularity and bright solar illumination influence positively the flowers production.

The presence of these industries has captured an important percentage of labor force from male and female population. Almost a third of parents are engaged in flower plantations. Only 50% of mothers continue in domestic affairs; the other 50% are working.

This variable could be assumed as having an effect in hygienic conditions of small children and in hygienic education and care of all members of the household.

Table 4. 6.
Parent's level of education.

Years of education	Father		Mother	
	Frequency	Percent	Frequency	Percent
0	77	10.2	84	11.1
1	17	2.3	18	2.4
2	25	3.3	35	4.6
3	85	11.3	98	13
4	47	6.2	54	7.2
5	38	5	28	3.7
6	345	45.8	333	44.5
7	13	1.7	11	1.5
8	14	1.9	16	2.1
9	28	3.7	31	4.1
10	10	1.3	15	2
11	2	.3	4	.5
12	44	5.8	24	3.2
13	9	1.2	3	.4
Total	754	100	754	100

The level of education of fathers and mothers is very similar when primary education figures are compared. There is an evident difference between genders in secondary or higher education, fathers 7% compared to mothers 3.6%.

Table 4. 7.
Parent's income in 1000 sucres per month.

Variable	Father		Mother	
Monthly income (in 1000 sucres)	Frequency	Percent	Frequency	Percent
0 (0)	72	9.5	324	43
From 1 to 499 (1)	132	8	113	15
From 500 to 999 (2)	478	63.4	250	33.1
From 1000 to 1499 (3)	116	15.4	61	8.1
From 1500 to 1999 (4)	23	3	6	.8
From 2000 up (5)	5	.7	0	0
Total	754	100	754	100

Ecuadorian local currency until 1999 was Sucre. Exchange rate = 25.000 sucres per U.S. dollar.
Since February 2000 the local currency is the American Dollar.

Eighty percent of fathers earn less than 40 dollars a month. Ninety-one percent of mothers earn the same amount. Most of the families are 5 members. This variable could have a predictable value from a statistical point of view. However, this economic data needs social interpretation. How can this population survive with 0.26 dollars a day per capita?

Table 4. 8.
Family income by community.

	Aglla		Checa		Iguñaro	
Code	Count	Percent	Count	Percent	Count	Percent
0	3	2.1%	8	1.5%	3	3.7%
1	22	15.3%	20	3.8%	11	13.4%
2	78	54.2%	187	35.4%	40	48.8%
3	35	24.3%	140	26.5%	20	24.4%
4	4	2.8%	121	22.9%	6	7.3%
5	2	1.4%	52	9.8%	2	2.4%

Income codes: 0=0, 1= 2-499, 2=500-999, 3=1000-1499, 4=1500-1999, 5=2000 or more

There is a clear contrast between Checa and the other two communities when comparing family income. 71.6% in Aglla and 65.9% of the families in Iguñaro earn less than 40 dollars a month, while only 40.7% earn the same amount in Checa.

Economic differences among communities can play an important role because family income is just one of the differences. Public services such as: piped water, house-by-house garbage collection, public transportation in town, auxiliary nurse and pharmacy services, make Checa's living standard superior when compared to the other two neighborhoods.

Table 4. 9.
Most frequent domestic animals at/by the household.

Variable	Category	Frequency	Percent
Dog			
	None	251	33.3
	Yes	503	66.7
	Total	754	100
Cat			
	None	529	70.2
	Yes	225	29.8
	Total	754	100
Pig			
	None	486	64.5
	Yes	268	35.5
	Total	754	100
Chicken			
	None	470	62.3
	Yes	284	37.7
	Total	754	100
Guinea pig			
	None	511	67.8
	Yes	243	32.2
	Total	754	100

It has been clearly established that the physical similar shape of animal worms, such as: *Ascaris suum* in pigs and *Toxocara canis* in dogs, does not mean necessarily a cross parasitism between animals and humans. ***However, the presence of animals in a household with poor hygienic conditions could increase the exposure of children to eggs of Ascaris lumbricoides.*** The presence of dogs (66.7%), pigs (35.5%), and chickens (37.7%) could play an important role as vectors or carriers of disease. These variables will be included for logit analysis.

The rest of animals, such as cow, sheep or parrots are assumed as less predictive variables due to their lower presence.

Table 4. 10.
Most frequently mentioned symptoms potentially related to Ascariasis.

Variable	Category	Frequency	Percent
Abdominal pain			
	None	248	32.9
	Yes	506	67.1
	Total	754	100
Headache			
	None	452	59.9
	Yes	302	40.1
	Total	754	100
Diarrhea			
	None	492	65.3
	Yes	262	34.7
	Total	754	100
Drooling			
	None	501	64.4
	Yes	253	33.6
	Total	754	100

Abdominal pain (67.1%) and diarrhea (34.7%) are two symptoms closely related to Ascariasis in the medical literature. Drooling more than medically associated to Ascariasis is a popular symptom use in Andean communities to complain about parasites. Headache has a high percentage (40.1%) and could be indirectly related to multiple parasitism if anemia and malnutrition also affect the child.

Table 4. 11.
Less frequently mentioned symptoms potentially related to Ascariasis.

Variable	Category	Frequency	Percent
No symptoms			
	None	709	94
	Yes	45	6
	Total	754	100
Abdominal dilation			
	None	678	89.9
	Yes	76	10.1
	Total	754	100
Passed worms			
	None	661	87.7
	Yes	93	12.3
	Total	754	100
Anal Itching			
	None	623	82.6
	Yes	131	17.4
	Total	754	100
Nausea			
	None	621	82.4
	Yes	133	17.6
	Total	754	100
Other symptoms			
	None	601	79.7
	Yes	153	20.3
	Total	754	100
Dizziness			
	None	585	77.6
	Yes	169	22.4
	Total	754	100

The symptoms grouped in this table probably are less predictive for Ascariasis, but on the contrary they should recall the attention of health authorities due to high levels of complaining.

Table 4. 12.
More frequent parasites found in the screening test.

Variable	Category	Frequency	Percent
Other protozoan			
	None	115	15.7
	Yes	619	84.3
	Total	734	100
Ameba			
	None	473	64.4
	Yes	261	35.6
	total	734	100
Giardia			
	none	585	78.7
	Yes	149	20.3
	Total	734	100
Ascaris			
	None	632	86.1
	Yes	102	13.9
	Total	734	100

The prevalence of Ascariasis found in the literature affirmed that Ecuador had 60.7% Ascariasis by the end of the decade of the 70's. The reference did not mention population size, main groups affected or location. The prevalence of Ascariasis in that study was considered useful to establish a comparison among 23 Latin American countries (Crompton, 1978). Official figures, if they exist, are difficult to be obtained from Ecuadorian health authorities. Several local studies have shown different prevalence for varied groups of population. Tenorio mentioned 45% for communities living in the confluence of Coca and Napo, rivers in the rain forest of the Amazon jungle of Ecuador (Tenorio, 1999), while Cruz found a prevalence of 36 % in the northern Andes of Ecuador (Cruz, 1985). Our study conducted at the end of the twentieth century in high altitude, rural Andean

communities, closed related to the capital city found 13.9% of Ascariasis among children in school age.

The prevalence of protozoan diseases has a higher prevalence than any of the helminthic parasitism. Very few children (5.6%) were free of parasites in this study.

Table 4. 13.
Less frequent parasites found in the screening test.

Variable	Category	Frequency	Percent
No parasites			
	None	693	94.4
	Yes	41	5.6
	Total	734	100
Tenia			
	None	709	96.6
	Yes	25	3.4
	Total	734	100
Trichuris			
	None	709	96.6
	Yes	25	3.4
	Total	734	100
Test 1 not performed			
	None	734	97.3
	Yes	20	2.7
	Total	754	100

** The total of 754 was reduced to only 734 valid cases. There were 20 missing values.*

If these two helminthes are not very frequent does not mean they are not important. In this communities water transmitted protozoan are prevalent but water-soil-hands transmitted parasitism is also present.

Table 4. 14.
Children's distribution into Treatment and Control Groups.

Variable	Frequency	Percent
Controls		
	132	17.5
Paico		
	327	43.4
Albendazole		
	292	38.7
Total	754	100

Table 4. 15.
More frequent parasites found in the second or post-treatment test.

Variable	Category	Frequency	Percent
Other protozoan			
	None	209	30.3
	Yes	480	69.7
	Total *	689	100
Ameba			
	None	509	73.9
	Yes	180	26.1
	total	689	100
Giardia			
	none	630	91.4
	Yes	59	8.6
	Total	689	100
Ascaris			
	None	625	90.7
	Yes	64	9.3
	Total	734	100

*A total of 65 cases were excluded from analysis because of missing values. The total of cases that were analyzed is 689, not 754.

After the selective treatment of school age children, that was the only activity implemented in these communities; no other actions that could modify their hygienic habits, water supply or style of living were introduced. The second stools test was conducted after three to four weeks from treatment. The prevalence of each

parasite was reduced but not abolished. The next section will provide a better approach to the potential reasons for these results. To optimize the analysis, the following variables were selected for further analysis: age, gender; contaminated water, treated water, boiled water, hands and fingernails cleanliness, father and mother activity, father and mother education, family monthly income; dog, cat, pig and guinea pig; abdominal pain, diarrhea, no symptoms, drooling and headache; ameba, giardia, other protozoan, trichuris, and no parasites.

The other variables are not excluded from further analysis. They could be included depending on the needs of the analysis.

4.2. *Groups comparison: use of X^2 and t test*

The main interest of this section is to determine whether there is some association between two variables: the dependent or response variable, Ascariasis, and the selected independent variables from the precedent section. The purpose is to find those factors that can fit well in a statistical model to predict ascariasis.

Most of the variables in this study are categorical. Most answers classify the cases into one or few categories. The most appropriate test to work with frequencies or qualitative data is chi-square test. For practical purposes of this study chi-square test is applied to determine independence between two variables, it is also important to determine whether the distribution of a particular characteristic is similar for various communities (homogeneity), and certainly in this study chi-square analysis is used as in most health studies to analyze two-by-two tables in which there are two groups and two possible responses. With such data, it is possible to compute a Chi-square statistic directly, avoiding the need to compute expected frequencies.

In the first table all chi-square estimated values, degrees of freedom and asymptotic significance are showed. All independent variables are studied looking for association with the results of the first coproscopic test, which also establishes the prevalence of Ascariasis and other parasitism.

Table 4. 16.
Chi-square test for association between Ascariasis and selected explanatory variables.

Variable	Value	Df	p-value
Gender	1.848	1	.174
Contaminated water	4.594	1	.032
Treated water	4.594	1	.032
Boiling water	3.403	1	.065
Hands cleanliness	3.367	1	.067
Fingernails cleanliness	.078	1	.780
Father's activity	15.284	6	.018
Mother's activity	5.962	4	.202
Father's education	13.419	13	.416
Mother's education	10.623	13	.642
Dog	.118	1	.732
Pig	.080	1	.777
Cat	4.518	1	.034
Guinea pig	6.034	1	.014
Abdominal pain	5.703	1	.017
Dizziness	.316	1	.574
Drooling	2.264	1	.132
Diarrhea	4.472	1	.034
Anal itching	.816	1	.366
Passed worms	1.291	1	.250
Headache	.024	1	.876
Giardia	5.334	1	.021
Ameba	.531	1	.466
Trichuris	38.344	1	.000
Other protozoan	5.542	1	.019

The resulting Chi-square values of several variables fall well into the critical region; therefore we reject the hypothesis of independence between Ascariasis and these factors. This suggests that there is an association between Ascariasis and: contaminated water, father activity, cat, guinea pig, abdominal pain, diarrhea, giardia, other protozoan, and trichuris among the children of the three communities.

The variables which in Table 4. 16. fall in the critical region are selected to be included in the regression model.

Table 4. 17.
Variables associated with Ascariasis. Chi-square Test.

Variable	Ascaris in Test 1			p-value
	Category	Yes	None	
Trichuris trichuria test 1	yes	11	14	.000
	none	621	88	
Flowers	Flowers	42	159	.001
	Other	80	473	
Community	Aglla	26	118	.004
	Checa	57	451	
	Iguñaro	19	63	
Guineapg	Yes	44	195	.014
	none	58	437	
Contaminated water	yes	45	210	.032
	none	57	422	
Boiling water	yes	34	272	.065
	none	68	360	
Hands cleanliness	Dirty	383	249	.067
	Clean	52	50	
Gender	Male	55	295	.174
	Female	47	337	

For ratio or interval variables a t-test for the difference of means was applied. In table 4. 18. there are only two variables with characteristics to be included in the logit regression: years of mother's education and the count of *Ascaris* eggs in the screening test. The association between mother's years of

education and Ascariasis seems to be weak. The estimated value suggests a weak participation of this variable in predicting Ascariasis $t\text{-test} = 2.035$ $p\text{-value} = .042$.

The former variable is only part of the laboratory testing techniques. The first technique applied to all stool samples was a simple mount of feces in a slide with physiologic solution in one side and iodine stain in the other. These results confirm the validity of this simple or direct technique. Counting eggs of *Ascaris* was the second technique implemented. It establishes the intensity of this particular parasitism.

Table 4. 18.
t-Test for Equality of Means.

Variables	T	p-value	Mean Difference	Std. Error Difference	95% Conf. Interval	
					Lower	Upper
Age in yrs	.023	.982	5.80E-03	.25	-.49	.50
Weight kg	.483	.630	.35	.73	-1.09	1.80
Height cm	.788	.431	1.02	1.30	-1.53	3.57
Father's income	.661	.509	24.33	36.80	-47.92	96.59
Mother's income	-.129	.897	-5.52	42.63	-89.22	78.18
Family income	.309	.757	18.82	60.91	-100.76	138.39
Father's years of education	.879	.380	.28	.32	-.35	.92
Father's activity	-2.820	.005	-.95	.34	-1.61	-.29
Mother's years of education	2.035	.042	.62	.30	2.18E-02	1.21
Count of ascaris eggs	-18.996	.000	-22.77	1.20	-25.12	-20.42

As mentioned at the beginning of this section it is often important to determine whether the distribution of a particular characteristic is similar for

various communities. Here, the groups in comparison are the communities. They are compared by variables related to environmental conditions prevailing in the households, like hands cleanliness, presence of domestic animals at home (cat), diarrhea as one of the most common symptoms related not only to ascariasis but to other parasites, and trichuris which is the other helminth present in the results of the first coproscopic test. This is a section goes one step further preparing the data to fit in a predictive model.

Table 4. 19.
Cross tabulation between Ascariasis and hands cleanliness by community.

Community			Hands cleanliness		Total
			Clean	Dirty	
Aglla	Ascaris lumbricoides test 1	none	61	57	118
		Yes	19	7	26
	Total		80	64	144
Checa	Ascaris lumbricoides test 1	None	156	295	451
		Yes	18	39	57
	Total		174	334	508
Iguñaro	Ascaris lumbricoides test 1	None	32	31	63
		Yes	13	6	19
	Total		45	37	82

Chi-Square Tests: Aglla p-value=.047; Checa p-value=.652; Iguñaro p-value=.176

Chi-square test for Aglla is the only estimate, which is statistical significant, meaning that there is an association between the parasitism under study and the lack of hands cleanliness among the children in the school.

Table 4. 20.

Cross-tabulation between Ascariasis and presence of a cat in the house by community.

Community			Cat in the house		Total
			None	Yes	
Aglla	Ascaris lumbricoides test 1	None	87	31	118
		Yes	19	7	26
	Total		106	38	144
Checa	Ascaris lumbricoides test 1	None	330	121	451
		Yes	34	23	57
	Total		364	144	508
Iguñaro	Ascaris lumbricoides test 1	None	33	30	63
		Yes	9	10	19
	Total		42	40	82

Chi-Square Tests: Aglla p-value=.946; Checa p-value=.033; Iguñaro p-value=.702

The association between Ascariasis and the presence of animals in the household was tested using cat as one of the potential vectors for disease transmission. The estimate statistic for Checa is significant.

Table 4. 21.

Cross-tabulation between Ascariasis and diarrhea by community.

Community			Diarrhea		Total
			None	Yes	
Aglla	Ascaris lumbricoides test 1	None	69	49	118
		Yes	18	8	26
	Total		87	57	144
Checa	Ascaris lumbricoides test 1	None	298	153	451
		Yes	46	11	57
	Total		344	164	508
Iguñaro	Ascaris lumbricoides test 1	None	36	27	63
		Yes	12	7	19
	Total		48	34	82

Chi-Square Tests: Aglla p-value=.558; Checa p-value=.026; Iguñaro p-value=.641

Abdominal pain and diarrhea are the most frequent symptoms among the investigated children. Here the association between Ascariasis and diarrhea is significant in Checa.

Table 4. 22.

Association between Ascariasis and Trichuriasis by community.

Community			Trichuris trichuria test 1		Total
			None	Yes	
Aglla	Ascaris lumbricoides test 1	None	114	4	118
		Yes	25	1	26
	Total		139	5	144
Checa	Ascaris lumbricoides test 1	None	446	5	451
		Yes	44	13	57
	Total		490	18	508
Iguiñaro	Ascaris lumbricoides test 1	None	61	2	63
		Yes	19		19
	Total		80	2	82

Chi-Square Tests: Aglla p-value=.908; Checa p-value=.000; Iguiñaro p-value=.432

Trichuriasis is associated to Ascariasis in Checa. The estimate is high as well as highly significant.

4.3. Risk factors of Ascariasis:

Regression Analysis

Logistic analysis is used whenever an individual is to be classified into one of two different responses, e.g. children affected or not affected by Ascariasis, cases cured by Paico or not cured by Paico. Logistic analysis is also used to predict the presence or absence of a characteristic or outcome based on values of a set of

explanatory variables. It is similar to linear regression models, but is suited to models where the dependent variable is dichotomous, and is applicable for any combination of discrete and continuous explanatory variables. In this section, the highlighted variables from tables 4. 16. and 4. 18., as well as new variables created or transformed from original variables are included for regression analysis.

As discussed previously in chapter III, the most appropriate way of studying the type of variables of this research is using Logistic Regression, in which the behaviors of the response variables are thought to be explained by the independent variables. The response variable is always categorical, while explanatory variables can be either categorical or continuous.

Logistic regression coefficients can be used to estimate odds for each of the independent variables in the model. The logarithm of the odds of the response variables (instead of the cell count in the loglinear model) is expressed as a linear combination of parameters. The model used is appropriated to cases where there is only one response variable with two categories. The data from this Clinical Trial report two types of results from laboratory coproscopic tests: cases affected or not affected by Ascariasis.

Computerized programs that include logistic analysis can calculated the following statistics: total cases, selected cases, valid cases. For each categorical

variable there is a table with the parameter coding. For each step the variables are entered or removed, and information related to iteration history; -2 log-likelihood, goodness of fit, Hosmer-Lemeshow goodness-of-fit statistic, model chi-square, improvement chi-square, classification table, correlations between variables, observed groups and predicted probabilities chart, and residual chi-square, can be requested.

For each variable in the equation the following statistics are automatically calculated: coefficient (β), standard error of B, Wald statistic, R, estimated odds ratio ($\exp(\beta)$), confidence interval for $\exp(\beta)$, log-likelihood if term removed from model. In this study the binary logistic regression analysis model used block entry of variables, and forward LR stepwise methods.

In order to establish the predictive model in this study the variables used were those variables that presented significant differences when Chi-square and t-Tests were applied, as well as those variables which frequency suggested their inclusion. After a process of fitting the model by including or excluding variables, the model that explains the relationship between variables and predicts Ascariasis in the three communities is presented in table 4. 23:

Table 4. 23.**Logistic Regression:****Variables in the Equation: TRICO1, GUINEAPG, HANDS, BOILING, CONTAMI, FAMINC, FLOWERS, SEX, AGE.**

	β	<i>p</i> -value	Exp(β)
TRICO1 (0-1)	1.125	.000	3.08
GUINEAPG (0-1)	.246	.031	1.28
HANDS (0-1)	-.223	.054	----
BOILING (0-1)	-.225	.059	----
CONTAMI (0-1)	.25	.030	1.28
FAMINC	.000	.585	----
FLOWERS (0-1)	.38	.002	1.46
SEX (0-1)	-.1627	.150	----
AGE	.019	.683	----
Constant or intercept	.2949	.615	----

a Variable(s) entered on step 1: TRICO1, GUINEAPG, HANDS, BOILING, CONTAMI, FAMINC, FLOWERS, SEX, AGE.

Table 4.23. presents the final model obtained through the logistic regression analysis after the inclusion of six controlling explanatory variables (hands cleanliness, boiling water practices and the presence of co-parasitism due to *Trichuris trichuria*, sex, family income, and age). The option is the proposed model, with *p*-value .000. The contribution of dirty hands and boiling water practices to the main independent variables (guinea pig, contaminated water and father activity in flowers); is only marginal from the statistical point of view. The variable Trico 1 confirms the association of co-parasitism and is useful as controlling variable.

The exponent β for each variable included in this model represent the odds of that variable. The variable flowers represent the fathers working in flower plantations. The estimated β value for this variable is .38. The exponent (β) is the

exponent of that estimated which is equivalent to 1.46, then the odds of a child having Ascariasis when his father works in a flowers plantation is: 1.46 times higher than the odds with a father working in other type of activity.

The same procedure is applicable to the other two variables:

CONTAMI $\exp(\beta) = 1.28$, then the odds of having Ascariasis if contaminated water is consumed are: 1.28 times higher than the odds not consuming contaminated water, and

GUINEAPG $\exp(\beta) = 1.28$ the odds of having Ascariasis if there are guinea pigs at home is: 1.28 times higher than the odds without guinea pigs at home.

4. 4. Analysis of risk factors

In order to answer the first research question of this study: **What is the prevalence of Ascariasis in school age children?** The prevalence of Ascariasis is defined as the number of children with a stool test in which results were positive for *Ascaris lumbricoides*, divided by the total number of children who were tested for the first time in the three communities of the study in 1999.

To avoid common problems calculating the prevalence the denominator was established with all school children from the three communities (Aglla, Checa and Iguiñaro) who have supplied the informed written consent format signed, the parasitic survey answered, and have provided a stool sample to the laboratory. The numerator was established with all those children who tested positive for *Ascaris lumbricoides* as a result of the screening procedures in 1999.

Not only Ascariasis was detected as prevalent in these communities. Actually, Amebiasis (35.6%), Giardiasis (20.3%), and other protozoan diseases (84.3%) were also diagnosed during the screening.

To determine what was the general prevalence of Ascariasis in this study, we divided the number of cases identified as positive (102) by the total number of tests performed (734 valid cases) in 1999. The result is the prevalence average for the three communities: 13.89% (95% CI= 11.39% to 16.39%). In each community there are different values for local prevalence.

It is important to evaluate the prevalence of Ascariasis by comparing the number of positive tests to the number of children in each community. Here we compare by gender in table # 4.24. and by age in table # 4.25.

Table 4. 24.
Prevalence of ascariasis by community and gender.

	GENDER								
	MALE			FEMALE			TOTAL		
	Total	Ascaris	%	Total	Ascaris	%	Total	Ascaris	%
Aglla	68	15	22.05	76	11	14.47	144	26	18.05
Checa	259	30	11.58	269	26	9.66	528	56	10.61
Iguñaro	36	9	25	46	10	21.73	82	19	23.17
Total	363	54	14.87	391	47	12.02	754	101	13.39

Chi-Square Tests: Aglla p-value .237; Checa p-value .339; Iguñaro p-value .728

The prevalence of Ascariasis in Checa (10.61%) is duplicated by the prevalence in Aglla (18.05%) and Iguñaro (23.17%). The difference in average prevalence within gender (male 14.87% and female 12.02%) in the three communities is not statistically significant. (Chi-square is 1.39, while the upper 5% chi-square value for 1 degree of freedom is 3.84).

Table 4. 25.
Prevalence of Ascariasis by community and age in years.

	Aglla			Checa			Iguñaro			Total		
Age	(-)	(+)	%	(-)	(+)	%	(-)	(+)	%	(-)	(+)	%
Total	118	26	22	451	57	12.63	63	19	30.1	734	102	13.9
5	12	2	16.6	11	1	9	2			25	3	12
6	16	2	12.5	64	7	10.9	6	2	33.3	86	11	13
7	15	4	26.6	72	9	12.5	15	3	20	96	16	17
8	17	5	29.4	76	6	7.9	13	4	30.7	105	15	14
9	16	2	12.5	73	4	5.5	5	1	20	89	7	8
10	22	5	22.7	83	13	15.7	12	4	33.3	112	22	20
11	19	3	15.8	57	2	3.5	9	4	44.4	83	9	11
12	13			63	12	19	7	1	14.3	83	13	16
13	7	1	14.3	17	1	5.9	7			31	2	6
14	3	1	33.3	7	1	14.3	5			14	2	14
15	4	1	25	5	1	20	1			20	2	20

(-) Negative result in screening; (+) Positive cases of ascariasis.

Chi-Square Tests: Aglla p-value .545; Checa p-value .165; Iguñaro .306

a 13 cells (59.1%) have expected count less than 5. The minimum expected count is .54.

b 5 cells (22.7%) have expected count less than 5. The minimum expected count is .56.

c 16 cells (72.7%) have expected count less than 5. The minimum expected count is .23.

When the differences in the prevalence of Ascariasis are compared in each community, the null hypothesis cannot be rejected. The minimum expected count of cells in the chi-square test went above the limit of 20% while using age groups by year. Recoding or regrouping the data does not improve the analysis. The differences are not statistically significant; that is, the differences in our samples are not greatly enough to rule out chance, as the explanation of differences.

Table 4. 26.

**Prevalence of Ascariasis in children by father's activity
(Flowers plantation and other activities by community).**

Community	Activity	Count	Ascariasis	Prevalence
Aglla	Other activities	119	15	12.6%
	Flowers	25	11	44%
Checa	Other activities	351	32	9.1%
	Flowers	157	25	15.9%
Iguñaro	Other activities	63	13	20.6%
	Flowers	19	6	31.6%

Chi-Square Tests: Aglla p-value .00; Checa p-value .02; Iguñaro .32

d 1 cells (25.0%) have expected count less than 5. The minimum expected count is 4.40.

Considering that working in a flower plantation is only one of the activities of the fathers in the region we compared this activity to other activities for those cases with and without Ascariasis by community. The difference is statistically significant for two communities as is shown when Chi-Square test is applied; children of fathers working in flowers have higher prevalence rates.

As it was observed in the first section of this chapter, 50% of mothers work at home while the other 50% works in different occupations in the community or

far from home. If the activity of the father is a variable associated with the presence of Ascariasis, the logical assumption is to also believe that the variable mother's activity could be associated with Ascariasis, because the mother takes care of children, animals, land, and maintains the control in the household; however, the differences between types of maternal occupation are statistically significant only in one community, Checa.

Table 4. 27.
Prevalence of Ascariasis in school age children by maternal activity and community.

Community	Mother's activity	Ascaris Count	Yes	Total
Aglla	Other	121	21	17.4%
	Flowers	23	5	21.7%
Checa	Other	325	30	9.2%
	Flowers	183	27	14.8%
Iguinaro	Other	61	12	19.7%
	Flowers	21	7	33.3%

Chi-Square Tests: Aglla p-value .62; Checa p-value .06; Iguinaro p-value .20

a Computed only for a 2x2 table

b 1 cells (25.0%) have expected count less than 5. The minimum expected count is 4.15.

c 0 cells (.0%) have expected count less than 5. The minimum expected count is 20.53.

d 1 cells (25.0%) have expected count less than 5. The minimum expected count is 4.87.

Here is a comparison of the correlation values established between Ascariasis and the variables: fathers working in flowers, Pearson's correlation .12 p-value = .00; mothers working in flowers, Pearson's correlation .06 p-value .08, and both fathers and mothers working in flowers, Pearson's correlation .41, p-value = .000. Correlation is significant at the 0.01 level (2-tailed).

The correlation when father and mother are both working in flower plantations is very high and statistically significant. These results suggest that some factor related to parental employment in flower production raises the probability of a child having Ascariasis. Further work is needed to determine whether the maternal absence from home, or the nature of the activities in their place of work, or children behavior while both parents are working is different than when they are home. Rapid assessment procedures could be useful to develop a systematic observation of family behaviors related to personal hygienic habits, food and water consumption and other risk factors involved with Ascariasis.

4.5. *Evaluation of effectiveness of treatments*

The second and the third research questions are answered in this section.

What is the effectiveness of Paico (*Chenopodium ambrosioides*) to cure Ascariasis?, and

What is the effectiveness of ABZ (Albendazole) to cure Ascariasis?

To answer these two research questions, first, we define what is effectiveness in the study and then the calculations are done. Effectiveness of treatment is defined as the reduction of prevalence of Ascariasis among those cases that were found positive in the first stool test, which became negative in the second test after the correspondent treatment.

To evaluate the effectiveness there are two basic assumptions: first, there must be little or no difference among the prevalence of control cases before (test 1) and after (test 2), because there was no intervention; and second there must exist differences among the prevalence in the other two groups of treatment (Paico and ABZ), not only before and after the implementation of the corresponding treatment, but also when each treatment is compared to the effects of the control (non-treatment) group.

To calculate the effectiveness the number of positive cases found in the second test or test 2 are divided by the number of cases treated with the three different methods. To calculate the effectiveness of each procedure: control group (non-treatment), Paico treatment and ABZ treatment we compare the results from first and second tests in next table.

Table 4. 28.
Comparison of results from Test 1 and Test 2 by type of treatment

Test 1	Treatment	Test 2			
		(+) Count	(+) %	(-) Count	(-) %
Ascaris (+) 101	Control 31	27	87.09	4	12.9
	Paico 34	18	52.94	16	47.06
	ABZ 36	2	5.56	34	94.44
	Total 101	47	46.53	54	53.46
Ascaris (-) 565	Control 87	1	.01	86	98.85
	Paico 268	16	5.97	252	94.03
	ABZ 210	0	0	210	100
	Total 565	17	3	548	97

The effectiveness of each treatment is presented in Table 4.28. To calculate the effectiveness we have divided the number of negative results in Test 2 (count column) by the corresponding number of cases assigned at random for that group of treatment (treatment column). E.g., to calculate the effectiveness of control group or “doing nothing” type of treatment, we divided the negative result of tests 2 (4) by the number of total cases assigned to control group (31). The result of such division ($4/31=0.1289$) is a proportion which represent the 12.9% of cases which do not continue with Ascariasis.

Paico treatment has effectiveness equivalent to 47.06%, and albendazole, ABZ presents an effectiveness of 94.44%. Pharmaceutical literature reports the effectiveness of ABZ above 90% as is also proved in this study. ABZ folds by two the effectiveness of Paico, and Paico folds by four the effectiveness of control group (non-treatment).

To compare the effect of treatments the model used is as follows:

	Treatment 1	Control
Success rate	A	B
Not success rate	C	D

Where the difference in success rate is computed as: $A - B$

The relative effectiveness as: A / B , and

The Odds ratio or cross-product ratio as: $A \times D / B \times C$

These calculations are:

	Paico treatment	Control
Success rate	47.1%	12.5%
Not success rate	52.9%	87.5%

Results: Difference in success rate: $47.1 - 12.5 = 34.6$
 Relative effectiveness: $47.1 / 12.5 = 3.77$, and
 Odds ratio: $47.1 \times 87.5 / 12.5 \times 52.9 = 6.23$

	Albendazole treatment	Control
Success rate	94.4%	12.5%
Not success rate	5.6%	87.5%

Results: Difference in success rate: $94.4 - 12.5 = 81.9$
 Relative effectiveness: $94.4 / 12.5 = 7.55$, and
 Odds ratio: $94.4 \times 87.5 / 12.5 \times 5.6 = 118$

	Albendazole treatment	Paico treatment
Success rate	94.4%	47.1%
Not success rate	5.6%	52.9%

Results: Difference in success rate: $94.4 - 47.1 = 47.3$
 Relative effectiveness: $94.4 / 47.1 = 2.00$, and
 Odds ratio: $94.4 \times 52.9 / 47.1 \times 5.6 = 18.93$

Paico and Albendazole treatments are beneficial when compared to no treatment (control). When Albendazole is compared to Paico, it is also beneficial. Relative effectiveness and Odds ratio are bigger than one for all computed operations.

It is important to underline that when the second test was applied among those cases whose first test was negative a total of 17 new cases was discovered. Most of these new cases (16) correspond to Paico treatment. To explain this finding three possible answers are suggested: a) there was a problem of precision in the diagnosis technique during the screening test; b) the female parasite adopted a particular behavior by chance; and c) the traditional treatment motivated certain reaction in new or undetected adult female parasites which started laying eggs after treatment. The ease way to solve the problem is to blame the sensibility and specificity of the screening test.

In this study the sequence of tests -- two direct mounts, one on saline solution and the other on iodine solution, plus two concentration saline and iodine slides-- constituted four opportunities to find eggs of *Ascaris* during the test 1 or screening test. The laboratory accuracy for testing stools samples has never been challenged as it was done in this research. The possibility of lack of precision in testing exists, but after testing four slides the probability of error must be very small.

The second option is a particular behavior of the parasite. If it is assumed that the screening test was correct and specific, and 3% of the negative cases in the first test became positive in the second test (the 17 new cases), the possibility is that the parasites did not lay eggs before the first test because they were biologically unable to start laying eggs (immaturity).

The third option is that Paico treatment motivated a change in immature parasites stimulating the expulsion of eggs. To explain this, 5.9% of new cases probably were induced by one of the treatments (Paico), will require further investigation. The absence of new cases in the treatment group ABZ is explained by the mode of action of Albendazole, which is able to kill eggs, larvae and adult parasites.

4. 6. *Cost/effectiveness analysis*

When the economic conditions do not allow a patient or his relatives to spend money buying a pharmaceutical product, a common practice in many developing countries is reducing expenses. This practice of cost saving solves the ethical dilemma of allocating scarce resources not only in the family level but also in the community and in the government institutions.

To judge if a particular procedure is worthwhile or not to address a difficult condition, like the presence of a disease, is subject to variations in the perspective and value structure of the individual making such decisions. In a practical sense we could question whether or not buying ABZ for a certain amount of money is “worth” treating Ascariasis?

The judging turns complicated when the person making the decision does not know which is the most appropriate modern-Western treatment. As we mentioned in chapter two, there are several types of treatment for Ascariasis (Piperazine, Pirantel pamoate, Mebendazole), which are currently sold in rural pharmacies. This condition creates uncertainty about the efficacy of the pharmaceutical product and allows other factors to complicate the decision, including the best advice (guess) of the pharmacy attendant (not necessary a certified pharmacist), the marketing of a variety of pharmaceutical industries, the charge per doses, the possibility of buying a medicine without medical prescription, and also the presentation of the product (tablets, suspension or powder).

In many cases, the last decision is to return to the use of traditional remedies as part of the ethnomedical background of each individual, but in the majority of cases the decision has been to do nothing.

To decide which alternative is appropriate requires the calculation of costs and benefits. If a treatment provides a benefit at an acceptable cost it is appropriate to call it “Cost-Effective” (Doubilet, Weinstein, and McNeil, 1986).

During the last decade the participation of the community members in making their own health decisions has been supported by national and international health policies. Self-sustainability has been reinforced in many health care programs; however, the community needs to make informed decisions. The perspective or point of view for the analysis of cost-effectiveness in this study is the perspective of the family. The aim of this study is to provide the community members with alternative ways to solve their self-detected health problems.

This section of the analysis tries to determine which costs must be included and what economic outcomes are considered benefits, in order to answer the fourth and fifth research questions:

What is the cost of curing a patient with *Chenopodium ambrosioides*?, and

What is the cost of curing a patient with Albendazole?

The rationale to estimate costs from the family point of view starts by the basic assumption that in the majority of cases it is the mother who provides health care to the members of the household. As part of the current community patterns

all mothers used to take care of food preparation, childcare, care of the animals and culture of the land. These activities (so-called domestic affairs) are not economically rewarded; however, mothers are active and their time has a value. There are 50% of other mothers who work far from the household. These mothers receive a monetary income. Any time expended in other activities could be considered a reduction of productivity and as consequence a reduction of income.

Then, direct and indirect costs should be calculated with regard to the mother's dedication; however, doing so is valuing or making a value judgment that can induce bias. To avoid it, the calculations use average values for mother time-dedication.

The elements to estimate the costs by type of treatment are presented in Table 4. 29. In order to prepare the remedy, the cost of using some kitchen appliances was estimated, assuming that the price of a brand new blender in Ecuador was approximately 50 dollars. The equivalent in local currency is divided by a minimum of 5 years (period of use of a blender in normal conditions); then, the result is divided by 365 days a year; then, by 24 hours, and finally by 60 minutes per hour. The total time of blending Paico is just one minute. The cost is 0.5 cents of sucre. If there is no blender at home, then the preparation could be made using a manual grinder or a stone grinder that will reduce the cost five times.

The cost of all plastic devices such as a strainer, jar and a glass, was estimated using current market prices in sucres. The calculation assumes that this equipment will last no more than two years, and that the time of use for the preparation is 8 minutes. The cost of using those plastic devices for 8 minutes is 1.52 sucres.

The time spent by the mother in collecting and preparing Paico, as well as her time buying ABZ, were measured with a chronometer during the field work. Different timing was put into calculations for different communities. The distribution of houses in Checa is dispersed in a bigger territory if compared to the other two communities. This made searching for Paico plants in Checa to take a little more time. For ABZ purchase, there was no need of a bus service in Checa.

Paico is a wild weed found in the backyard of most of the households in the region. It is not cultivated, it is collected from nature. Paico leaves are saved for culinary and medical purposes. Paico has no monetary value in the communities, but if it is not found in the backyard due to the dry season (July, August and September) then, the mother would need to buy it in the next open market. The charge for a bunch of fresh Paico in October 1999 was approximately 200 sucres per dose.

During the implementation of this study the water used for treatment was bottled water, which cost 9,000 sucres for a bottle of 2 liters. The amount of water used per child was 50 ml. The cost of bottled water per child was 225 sucres. If boiled water is used the cost per 50 ml. minimizes to 1.62 sucres. Calculations are made only with boiled water, because that is the element to be used in any further program of control of Ascariasis. The market charge for a cylinder of gas is \$35,000 that lasts 30 days when is used for three hours of cooking. The, $35,000 / 30$ days / 3 hours / 60 minutes = 6.48 sucres per minute. To boil 4 liters of water during 20 minutes the cost will be: $6.48 \times 20 = 129.63$. As the amount of boiled water that is needed for one single dose of Paico is only 50 ml. Then, $\$129.63 \times 50$ ml. / 4,000 ml.= \$1.62

To estimate the cost of mothers' time dedicated to preparing the remedy or buying the medicine, the average income for mothers in domestic affairs and for mothers in other activities was calculated as is shown in table 4.29.

Table 4. 29.
Average income of mothers in thousands of sucres by type of activity

Mother's activity	Mean	N	Std. Deviation
Other occupations	694.16	377	295.14
Domestic affairs	61.27	377	174.81
Total	377.72	754	398.78

Anova: F = 1283.37; p-value .000

The cheapest cost for treating a child in Aglla, Checa or Iguñaro depends on the availability of Paico at home, the time it takes the mother preparing the remedy, and the possibility of boiling water. The average cost is \$4.67. These calculations took into account the average income of the mothers because it is their time invested in this activity, which is equivalent to the time they did not spend doing other activities during the same period of time. When Albendazole is the treatment of choice, the cost is \$4,521.16. (See next page, Table 4. 30.)

Table 4. 30.
Elements for cost estimations when treating Ascariasis

Costs	Paico Treatment	ABZ Treatment
Direct costs		
Equipment for preparing and delivering the treatments	Blender \$.48 Plastics \$ 1.52 (strainer, jar, glass) Subtotal \$ 2.00	Glass \$ 0.50 Subtotal \$ 0.50
Mother's labor	Average time spent preparing Paico suspension: Activity Minutes Collecting the plants 12 Washing 3 Soaking/cutting 3 Blending/grinding 1 Straining .5 Serving .5 Total 20	Average time spent buying Albendazole: Activity Minutes Walking to the road 15 Waiting for the bus 15 Time in the bus 10 Buying the product 15 Waiting bus to return 15 Time to return in bus 10 Walking back home 15 Total 95
Transportation	Paico growths in the community	Round-trip bus fare \$1,600.00
Materials	Paico no commercial charge	ABZ charge \$2,914.00
Overhead and induced costs		
Gas for boiling water	\$1.62	\$1.62
Indirect Costs*	Maternal Lost Wages Average income \$377.72/120 hours of monthly labor / 60 minutes = \$0.053 *Maternal Lost Wages 20 minutes x .053 = \$1.05 *Inconvenience (strong taste)	Maternal Lost Wages Average income \$377.72 / 120 hours of monthly labor / 60 minutes = \$0.053 *Maternal Lost Wages 95 min x .053 = \$ 5.04 *Difficulty to swallow tablets
Direct + Indirect costs =	\$4.67	\$4,521.16

All calculations use local currency, which exchange rate is 25.000 sucres per dollar.

From a pure financial perspective the column cost in Table 4. 39., presents Paico as the treatment with the lower cost per case treated.

Table 4. 31.
Cost/Effectiveness calculation

COSTS	EFFECTIVENESS	COST-EFFECTIVENESS BLANKET TREATMENT*	COST-EFFECTIVENESS FOCUS TREATMENT**
PAICO Single dose \$4.67 Four doses cost, (one year treatment) \$18.68 Total cost/case/year \$ 18.68	The Effectiveness of treating with Paico is 0.47 or: 47 children cure per 100 cases	Cost per treatment x 100/ Average prevalence x Net cure (Paico cure – Control cure) = $18.68 \times 100 / 15.2 \times (.471 - .129) = 359.34$ Blanket treatment cost with Paico = \$359.34 US\$0.01	(Laboratory costs x 100) + (cost per treatment with Paico x average prevalence) / % Positive cases treated x Net cure = $(25,000 \times 100) + (18.68 \times 15.2) / 15.2 \times (.471 - .129) = 480,971.83$ Focus treatment with Paico = \$480,971.83
ABZ Single dose \$4,521.16 Four doses cost (one year treatment) \$18,084.64 Total cost/case/year 18,084.64	The Effectiveness of treating with ABZ is 0.94 or: 94 children cure per 100 cases	Cost per treatment x total cases treated / Net cure (ABZ cure – Control cure) = $18,084 \times 100 / 15.2 \times (.944 - .129) = 146,699.98$ Blanket treatment cost with ABZ = \$146,699.98 US\$5.87	(Laboratory costs x 100) + (cost per treatment with ABZ x average prevalence) / % Positive cases treated x Net cure = $(25,000 \times 100) + (18,084.64 \times 15.2) / (15.2 \times 81.1) = 225,101.95$ Focus treatment with ABZ = \$225,101.95

All calculations are expressed in sucres. Exchange rate is 25,000 sucres per dollar.

* Blanket treatment = All cases assigned at random to different types of treatment received the treatment before the results of the screening test were known. For this calculation it is assumed not to include the cost of laboratory. **Focus treatment = In this study and for the calculation of this Cost-Effectiveness Analysis focus treatment refers to those cases with a positive screening test for Ascariasis. As screening test was performed, the calculation takes into account the cost of direct smear as the only technique applied to each stool sample.

Treating a child with Paico instead than with ABZ could generate a false image of saving financial resources in 4,516.49 sucres per single dose or 18,065.96 sucres if the treatment is provided during a year. It is very important to consider that Paico and Albendazole have different effectiveness (second column in Table 4.

31.), and that the net effectiveness (Paico effectiveness or ABZ effectiveness – no treatment effectiveness) and the number of cases treated in each alternative must be included in the calculations.

The cost of doing a blanket treatment (treatment without stool test) to 100 children with Paico for a year period is 1,868 sucres. This value is divided by the result of multiplying the average prevalence by the net cure, which is 5.1984. This calculation gives a cost of blanket treatment of 359.34 sucres. The blanket treatment with Albendazole applied to 100 children and for the same period has a cost of 146,699.98 sucres. *Evidently, Paico is much more cost-effective if the treatment is provided without paying attention to the cost of testing the stools.*

The cost-effectiveness of a focused treatment shows that Albendazole becomes more cost-effective due to its high effectiveness. However, the costs are also higher due to the tests. The cost of a coproscopic test done by direct mount technique in a rural laboratory (which is the prevailing practice) is approximately 10,000 sucres average. The cost of transportation of the sample plus the cost of the transportation of the results of the test have to be added (\$1,600 x 2 times). If a concentration test is required, (which is very rare in rural areas) these calculations have to be duplicated in laboratory costs.

Cost effectiveness is measured as a ratio of cost to effectiveness, and can be calculated as an average ratio or as an incremental cost ratio (ICR). The first is estimated by dividing the cost of the intervention by a measure of effectiveness without regard to other alternatives. The second is an estimate of the cost per unit of effectiveness of the cost of using one treatment in preference to another. Thus, incremental cost effectiveness = difference in cost / difference in effectiveness, where difference in cost = cost of intervention - cost of alternative, and difference in effectiveness = effectiveness of intervention - effectiveness of alternative (Petitte 1994:171). $ICR = (18,084.64 - 18.68) / (.9444 - .4706) = 18,065.96 / .4738 = \$38,129.92$

This means that treating the children with Albendazole in a blanket treatment increments the cost of treating them with Paico by \$38,129.92. *The adopted perspective of this study was the family perspective. If any parent has to decide which treatment must be used, the recommendation depends on the availability of financial resources. From a practical point of view, nobody repeats four times a year a coproscopic exam; then, the blanket treatment could be recommended. As Paico is considered not only a medicine for parasites, but also a condiment that is included in several culinary preparations, this traditional practice should be recommended.*

5. CONCLUSIONS

5. 1. *Multidisciplinary approach*

Human beings are constituted by biological, psychological and cultural essentials, which receive the influence of social and physical environments. To understand why a particular disease could become a persistent affliction for humans, it is required a multidisciplinary approach where biomedical, socio-cultural, psychological and ecological perspectives help to find an explanation of the endemicity of such an ailment. That is the case of Ascariasis among the population under study.

Biomedical sciences help to explain the relationship between host and parasite in terms of subsistence. The parasite needs the host to survive, not any host but a specific one. Along the natural evolution of its biology the parasite *Ascaris lumbricoides* has developed these mechanisms to survive: enormous numbers of eggs laid by a very fecund female, extremely protective egg shells, adhesiveness, resistance to dryness and to acid environments, specific host, chyme and intestinal debris feeding source.

The parasite has a specific strategy to multiply and survive which is related to the effective ways it found to reach its host. If environmental conditions of

humidity and shade are optimal, the soil-transmission pattern in addition to the host's behavioral practices resulted in the most expanded intestinal helminthic food borne-hand borne parasitism. However, there are other factors which can be considered as barriers to the expansion of Ascariasis, such as: heavy losses of eggs in the environment, few fertilized eggs have the chance to develop into invasive eggs, dryness, cold, acid gastric environment, immunological system, sewage and latrines.

Socio-cultural factors related to the transmission, suffering and treating of this "ailment" include not only behavioral practices and local sanitary conditions prevalent in the population, but also cultural concepts of the meaning of parasitism, different cross-cultural etiological reasons for having parasites, taxonomy of parasites, suffering roles and symptoms related to worms, illness, and "appropriate" ways of treatment.

Some hygienic concepts and practices among the members of a social group could be the main reason for a common and constant exposure to parasites, in this particular case to *Ascaris lumbricoides* invasive eggs, for example: dirty hands and fingernails, drinking contaminated water, agricultural activities which involve the use of water or solid wastes for soil fertilization, and sharing the household with domestic animals such as: dogs, cats, guinea pigs and chicken.

Among socio-cultural factors, the lack of economic resources must be considered as an important risk factor for the appearance and maintenance of disease. Low salaries are commonly related to poor housing conditions, undernourishment, crowding, unemployment, and lack of basic services like: electricity, telephone, potable water and sewage system. Anthropological techniques, such as: those integrating Rapid Assessment Procedures, were important in detecting defecating practices, the irrigation of crops by raw waste water leading contamination of soil and food, as well as the particular needs of each community.

From the psychological perspective having parasites could involve suffering from parasites. Suffering a disease deals with illness behavior or the way in which symptoms are perceived, evaluated and acted upon by a person who recognized some uncomfortable feelings or changes of his /her regular function. These changes or malfunctions are symptoms or signs related not only to a particular case of Ascariasis, but also shared by other parasitic infections. In this study we found an association of Ascariasis with abdominal pain and diarrhea, however, the interpretation of these symptoms and signs are culturally regulated by specific patterns of behavior. Cultural patterns define an action to remove the cause of that illness. That action could also be influenced by environmental or economical conditions. As it was already mentioned in chapter IV, “doing nothing” is a

common response when a parasitic disease shows up with mild symptoms combined with a lack of family economic resources.

Having all these factors in mind and with the results of this study the first question to ask is: which are the main conclusions of this research? And the second question is: what are the recommendations to plan and/or implement a program of control against Ascariasis? Answering these two questions is also answering the last research question of this study.

Ascaris is the happiest actor in this drama. It is also proud of its success. Environmental conditions such as dryness, separated houses in the communities, cold mountain weather, perpendicular sun rays over 12 hours a day, blue skies, acid stomachs, and immunological host systems could not impede its presence in the scene.

Traveling around the invasive eggs explored many ways to reach their intestinal goals. In these communities, they found good conditions to survive. First, the eggs were deposited in the land by the house. Some of them stayed in the vegetation. Part of that vegetation (vegetables) was consumed at home. Other vegetation was given (as food) to the guinea pigs. Other eggs used a faster vehicle to go back. The furred skin of the dog, the cat or the guinea pig help them to that purpose. The children are the best hosts and they also like caressing their pets, not

washing their hands, not cutting their fingernails, and they really like when their both parents have to work far from home. When the eggs became larvae they enjoy empty stomachs and the weak immune systems of their new hosts.

A number of environmental and biocultural influences on the predisposition to Ascariasis have been demonstrated. The ecological conditions in the three communities are very similar: latitude, altitude, temperature, humidity, rainy and dry seasons, land slope, and agricultural production. However, there are other ecological related conditions that could explain certain differences in the results. For example: Checa has a piped water system that works in good conditions most part of the year, while Aglla and Iguiñaro only have raw water conducted to the communities by long, open canals. Most of Checa homes are connected to a sewage system, but there is no sewage in Aglla and Iguiñaro. These two characteristics stress the rural conditions of these two communities.

Some social and cultural factors are also very similar in all three communities: the educational level among parents, the proportion of students attending school, the religious believes, a carbohydrate diet, the types of occupation, low salary rates, domestic animals sharing the same space with their owners at home. On the contrary, there are also certain social differences between communities. The only pharmacy of the parish is located in Checa, as well as

telephone service, bus service and a health center. The religious and political authorities of the parish are also centralized in Checa.

A combination of these factors permitted to fit a statistical predictive model which includes father's occupation (flowers plantation), contaminated water and presence of guinea pig at home as the main variables with statistical significance to predict ascariasis. The odds of developing ascariasis when these three conditions are together are at least 1.5 times higher than if they are not (See page 69).

Ascariasis is the most prevalent intestinal helminthic infection in the communities of this study. Its average prevalence (13.9%) has a different distribution between the communities. It is more prevalent in Iguinero (23.17%) and Aglla (18.05%) than in Checa (10.61%). Chi-Square Tests: value 11.017 with 2 degrees of freedom and p-value .004.

There are other important factors that are appropriate to underline although they were not included in the statistical model, because of their constant presence. That is the case of personal and domestic poor hygienic conditions such as: dirty hands (59.8%), dirty fingernails (71.9%), lack of boiling water habits (57.8%), and pets at home (dog 66%).

From the medical point of view, there are three symptoms that are not a cause of Ascariasis but are a consequence: abdominal pain, headache, and diarrhea. The three can be added to the statistical predictive model maintaining high beta values, chi-square test estimates and significant p-values. Abdominal pain is the most frequent complaint (67%), headache second (40%), and diarrhea third (34.7%). If abdominal pain and diarrhea are added to the model, the odds of having abdominal pain as an associated symptom with ascariasis are 5 times higher than not having abdominal pain, and 5.95 times higher the odds of having diarrhea than not having such symptom.

The lack of health facilities in Aglla and Iguiñaro, the scarce personnel in Checa health care center, the absence of a program of control of parasites and the lack of economical resources among the population to treat their children against parasites force many parents to adopt a “do nothing” attitude (76%). Less than 12% of children reported to have been treated using traditional medicine (medicinal plants) six months before the implementation of this study. Another 12% reported the use of pharmaceutical products such as: Piperazine, Mebendazole or Albendazole.

Endemic Ascariasis has been characterized as closely related to economic and social developmental processes in other projects as well as in this study, therefore its control is a sensitive economically, socially and politically.

The measurement of the morbidity caused by Ascariasis was assumed to be important to inform the health authorities and to plan control activities with the direct participation of the community members. The perspective adopted by this study tries to respond the mutual necessity of information in the community and in the health system. A second assumption is that a community that is better informed about the magnitude of the health problem will contribute with practical actions to control several factors involved in the process. 'A community informed about the effectiveness of its own traditional remedies can potentially reinforce its cultural health patterns to improve its health conditions. On the contrary, if the effectiveness of a new alternative is better, the community could adopt a different and more effective procedure of control.

With these assumptions in mind, this study has established the particular effectiveness of using Paico as one of the more expanded traditional remedies used for more than 4000 years in the territory of the Americas. Paico net effectiveness (34.2%) was compared to ABZ net effectiveness (81.1%). Paico treatment was found four times as effective than “doing nothing” attitude. When costs were measured and cost-effectiveness was evaluated, a blanket treatment with Paico appeared more cost effective than the other two alternatives.

The costs and effects of different targeted chemotherapies have been evaluated. Chemotherapy is just one of the short-term useful procedures to control an endemic parasitism. Chemotherapy means treating, curing. Curing means the presence of the disease and its consequences. Curing also means a failure in the medical system. Curing could be interpreted as lack of interest in preventing. To implement preventive measures it is very important to have in mind the mechanisms used by the parasite to success.

If the natural history of Ascariasis is reviewed, there are several strategies to increase the obstacles and prevent *Ascaris* successful reproduction. Those strategic barriers deal with: improving the hygienic and safe disposal of feces, increasing personal hygienic habits (hands washing, fingernails care), increasing environmental hygienic measures (waste disposal), changing patterns in the use of safe water, providing domestic animals their own space in a hygienic environment, improving nutritional conditions of the population by reinforcing diet and diet supplementation with vitamin A and iron.

The contribution of Medical Anthropology to understanding the relationship between host, environment, and parasite stresses the importance of human behavior in the presence, persistence and cure of infectious diseases such as Ascariasis.

5.2. Limitations of this study

The first limitation already commented in first chapter is that the results of this study are relevant to the communities where the research was conducted. The results could also be compared to other studies using the same methodology. This study contributes to the expansion of the body of current knowledge about Ascariasis in rural Andean areas. It provides information not only related to the prevalence of Ascariasis, but also about: sample size, population structure, how subjects were chosen for the study and other elements. In this way this study contributes to a better understanding of current parasitism in Ecuador and Latin America.

The data corresponds to school age children and must be use to compare the prevalence of the same age group (5 to 15 years).

Cultural prevailing patterns can make difficult to estimate morbidity and mortality. E.g.: Diarrhea episodes are considered “normal” because there is no need to home sick leave or hospitalization.

The results of this study are only relevant to the use of Albendazole and Paico, other pharmaceutical products or traditional remedies may be different.

Paico doses were prepared in accordance with local patterns used by community mothers. Concentrated doses of Paico, such as: the use of *Chenopodium* oil, could be harmful.

5.3. Recommendations for further research:

Rapid Assessment Procedures RAP, are anthropological techniques recommended to describe health risk behaviors and practices among different groups of the population, such as: personal and domestic hygiene, patterns of use of water by age groups, domestic animals care by age, gender or activity (pre-school children, school children and adults), fingernails trimming, parents activity and the division of domestic roles among family members.

In order to complement the information related to epidemiological distribution of Ascariasis among different age groups it is important to determine the prevalence in preschool age children and among adult population, as well as the incidence or re-infection of those cases already treated.

The analysis of all nutritional data already collected in the schools of this study is relevant to evaluate the nutritional status of those children with and without Ascariasis. Nutritional indicators must be compared in a yearly base to estimate the

changes introduced by potable water supply and health promotion and education programs.

Ecuadorian ethnomedicine is rich in procedures and healing elements. It is mandatory to continue studying local manifestations of health and disease prevention from medical, anthropological, pharmaceutical, ecological and economical perspectives. In this particular disease, Ascariasis, it is recommended to evaluate the use of other remedies of the traditional medicine assumed to have effective results treating intestinal worms, such as: the dry seeds of “Zapallo” *Cucurbita pepo*, or “Zambo” *Cucurbita sp.*

A next step in the investigation of Paico is to evaluate the use of *Chenopodium ambrosioides* as a common ingredient in the diet of the family or as condiment in traditional cuisine.

5.4. Policy implications:

School teachers are the ideal and motivated personnel to implement and evaluate the effects of targeted programs of treatment of parasites. The implementation of targeted blanket treatments addressed to the school population should include Paico with a periodicity of two months. This therapy should be complemented by a selective ABZ treatment of those cases highly infected. This

strategy could be promoted among the communities located in the Andean territory, where the prevalence is similar to the communities of this study.

Different national and international organizations should be interested in applying targeted Paico treatment against intestinal worms in school age children. Their program budget, currently spent buying costly pharmaceutical products could be better employed expanding the range of the intervention to serve a larger population.

The participation of multiple institutions in the development, implementation and evaluation of population oriented programs should be promoted. The economical and technical contribution of each institution could favor mutual benefits with a reduced investment. The efforts of the community, the university and the local organization should overlap in one common purpose, the benefit of the population. The only requirement is the establishment of a common vision and the personal decision to commit serious efforts to accomplish what is co-decided.

In Ecuador, the Ministry of Public Health implements Nation-wide a program of control of helminthiasis based on Albendazole. That program is part of the institutional policy for treating infectious parasitic diseases. The program is implemented in an intramural basis, and is delivered upon demand of regular

patients that receive medical attention in public health centers. The communities of this region require a different approach. The recommendation for the health authorities of this Health Area is to start a program of control of parasitic diseases in coordination with community authorities, school directors, NGO's agencies and national and international universities.

The program should be applied in communities served by the Health Area, where the educational system has school units. The method and techniques used by this study should be observed. A few sentinel schools must be assigned for control.

The active participation of parents and school teachers should be considered as a potential strategy in improving sanitary and hygienic conditions within the school and within the community. Targeted Traditional and/or Modern chemotherapy is positively received by the members of the family whose children receive free and culturally adapted treatment for parasites.

The adoption of hygienic habits have positive side effects not only by controlling parasitic diseases, but also reducing diarrhea episodes, skin infections, zoonotic diseases, and vector born diseases. Targeted chemotherapy must be the opportunity for health promotion.

Encouraged hygienic habits are: hands washing, fingernails trimming, use of latrine, clean water consumption and maintenance, cleanliness of the house and courtyard, outdoor pets, food washing and preserving.

Contributions of this study

- * This is the first clinical trial applied to the use of traditional medicine in Ecuador.
- * It is the first study that implements Cost-Effectiveness Analysis to compare traditional and modern chemotherapies of parasitic infection in Ecuador.
- * It is the first study of prevalence of Ascariasis and other parasitism in the rural areas surrounding Quito.
- * This study has contributed to confirm the high effectiveness of ABZ for *Ascaris* treatment.
- * This study has established for the first time the effectiveness of a single dose of Paico (*Chenopodium ambrosioides*) to treat Ascariasis.

*This study has integrated different actors interested in improving living conditions and health status of children in school age, as well as to cope with parasitism: local schools (teachers, parents and children), non-governmental organizations and university students.

*This study took into account the advice of local mothers in each community to prepare Paico, following the prevailing practices in rural geographical areas surrounding Quito.

* Opening a scientific space for exchanging knowledge and practices applied by traditional and modern health care systems to the solution of common problems, is an important contribution of this study. The benefits of this multidisciplinary approach are important not only for both systems, but especially to the patients.

* A successful intervention requires the commitment of the population. A conscious and motivated community can easily work for its own development. External agents such as: university students, non-governmental organizations, municipal governments are temporary elements that may contribute with financial, material or technological support and advise, but the key for success is in the people who want to satisfy its needs, and work together.

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APPENDICES

Appendix A Research events sequence

Activity	Day
First contact with community and school leaders	1
Information meetings with children parents in school	8
Collection of signed written informed consent forms	8-15
Parasitic survey	8-15
Random assignment to three groups: Paico, ABZ and Control	10
Ascariasis screening - test 1	15-36
Treatment of both groups: Paico and ABZ	43
Second test for Control group	43-47
Second test for Paico and ABZ groups	65-85
Treatment of Control group	90

Appendix B Informed Consent Document

English version

A Title of the Study

Cost-effectiveness analysis of the anthelmintic intervention for community control of Ascariasis: traditional remedy vs. pharmaceutical treatment

B Director of the Study

Dr. Fernando Ortega

C Purpose of the Study

The purpose of this study is to determine the most cost effective treatment against Ascariasis, comparing traditional and pharmaceutical methods, in school age children in rural communities near Quito.

D Procedure

As father, mother, or guardian (legal representative), I understand that my daughter/son (child under my legal care) can participate voluntarily in this study. In this study, the following may occur:

1. His/her participation to the pre-study screening will involve no costs. I will not be responsible for paying for the coproscopic examinations that they will conduct to determine which members of the community have intestinal parasites. If the coproscopic parasitic examination is positive, that is if my child has parasites, he or she will be selected to receive treatment, without cost and in benefit of his/her personal health.

2. If my child has been selected to receive treatment, I understand that he/she must follow the following steps.

2.1. He will not change his diet or his habits during the days of the study.

2.2. He/she will not take another medication or remedy that is not provided by this study.

2.3. He/she will use the medicine or the treatment in the amount indicated.

2.4. I will notify the researchers about any symptoms that my child has both before and after the treatment.

2.5. I will deliver one or more fecal sample of my child (or the child of which I am guardian) to Dr. Ortega 21 days after treatment to be sure that the treatment that my child took did get rid of the parasites.

3. I am aware the only potential risks that my child could feel as a subject in this research could be some intestinal discomfort (abdominal cramps, nausea, vomiting, diarrhea) mild headache, dizziness or insomnia as potential side effects of pharmaceutical treatment as reported in other medical studies: WHO 1995 and PDR 1999.

4. The benefits of his/her participation to this study are:

Completely free coproscopic tests,

Completely free treatment for all parasites founded,

Potential improvement of his/her health conditions due to treatment provided during this study,

The personal benefits he/she will receive will be also community benefits in the long run, because the risk of re-parasitism will be reduced among the population of my community,

The results of this study will be used by the health authorities of this area to conduct similar treatments in other communities of the region, as well as in other schools of my country.

E Confidential information

Any information that I have provided or that has been obtained from my child's stools samples will be kept strictly confidential. A numeric code will be used to identify the samples, analysis outputs as well as all oral or written information that we could provide the researcher. The only persons with access to the information will be the investigators. The name of my child or represented cannot be used in any list of data or publication.

F Voluntary participation statement

The participation of my child or represented to this study is completely voluntary. By his/her own decision he/she can withdraw the study the moment he/she or myself will decide to withdraw without any kind of penalty. I understand that if he/she retires from the study before it is completed, he/she will not receive the result of stools tests, or the treatments offered if he/she would continue in the study until its end.

G Questions

I understand that any questions I could have with regard to this study I can directly address in person, by phone or mail to Dr. Fernando Ortega, Director of the Department of Community Health and Development at Universidad San Francisco de Quito. Ave. Jardines del Este y Vía Interocéánica. Cumbaya. Phone: 895.723 Ext. 210.

My signature below confirms that I have read and that I understand the procedures described in this document. I give my informed and voluntary consent therefore my child or represented can participate to this study. I understand that I will receive a signed copy of this consent form.

Father/Mother signature _____

Representative signature _____

Study Director signature _____

Date _____/_____/_____

Child's name _____

Appendix C Documento de Consentimiento Informado

A.- Título del Estudio:

Análisis de costo efectividad de la intervención antihelmíntica para el control comunitario de la Ascariasis: remedio tradicional vs. tratamiento farmacéutico.

B.- Director del Estudio:

Dr. Fernando Ortega.

C.- Propósito del estudio:

El propósito de este estudio es determinar el costo-efectividad del tratamiento contra la ascariasis, comparando la efectividad de los métodos tradicional y farmacéutico, en niños de edad escolar de comunidades rurales cercanas a Quito.

D.- Procedimientos:

En calidad de padre, madre o representante legalmente autorizado, comprendo que mi hijo/hija o representado/a, participa voluntariamente en este estudio, en el mismo que puede ocurrir lo siguiente:

1. Participará sin costo alguno en el análisis coproparasitario inicial que se realizará para conocer qué personas de la comunidad tienen parásitos intestinales. Si el examen coproparasitario resulta positivo, es decir si tiene parásitos, será seleccionado/a para recibir tratamiento antiparasitario, sin costo y en beneficio de su salud personal.

2. Si ya ha sido seleccionado para recibir el tratamiento propuesto en este estudio, entiendo que deberá realizar los siguientes pasos:

- 2.1. No modificará ni la dieta ni sus hábitos durante los días que dure el estudio,
- 2.2. No tomará otra medicación o remedio casero que no sea el tratamiento indicado en el estudio,
- 2.3. Recibirá la medicación o el remedio del estudio en la cantidad que sea recomendada,
- 2.4. Informará e informará de ser necesario sobre cualquier síntoma que tuviera antes y después del tratamiento,
- 2.5. Entregaré una nueva muestra de heces de mi hijo/hija o representado/a al Dr. Fernando Ortega después de 21 días del tratamiento para estar seguros que el tratamiento que recibió le quitó los parásitos.

3. Estoy consciente que como efecto del tratamiento que recibirá, existe la posibilidad o riesgo potencial de sentir alguna molestia gastro-intestinal (anorexia, calambres abdominales, náusea, vómito, diarrea) o dolor de cabeza leve, mareo, somnolencia, insomnio o ronchitas como ha sido reportado en otros estudios médicos.

4. Los beneficios que recibirá participando en este estudio son los siguientes:

- 4.1. Recibirá en forma gratuita los resultados del examen coproparasitario de su muestra de heces,
- 4.2. Recibirá en forma gratuita el tratamiento inicial para los parásitos que se le encuentre,
- 4.3. La mejora potencial de su condición de salud gracias al tratamiento antiparasitario recibido,
- 4.4. Los beneficios que personalmente recibirá serán también beneficios para mi comunidad a largo plazo, porque disminuirá el riesgo de reparasitación de los pobladores de mi comunidad,

4.5. Los resultados de este estudio serán utilizados por las unidades del área de salud para realizar tratamientos semejantes en otras comunidades de la región, así como las escuelas del país contarán con un procedimiento que beneficie a una población escolar mayor.

E.- Información Confidencial

Cualquier información que haya sido obtenida de mí o de las muestras de heces de mi hijo/hija o representado será mantenida en forma estrictamente confidencial. Un código numérico será utilizado para identificar las muestras, los resultados del análisis y la información oral o escrita que podamos dar al estudio. Las únicas personas que tendrán acceso a esta información serán los investigadores y no se utilizará el nombre de mi hijo, hija o representado en ninguna lista de datos o publicación que se pudiera realizar.

F.- Participación Voluntaria

La participación de mi hijo/hija o representado en este estudio es completamente voluntaria. Puede por su propia voluntad retirarse del estudio el momento que decida o decidamos sin ser objeto de ningún tipo de castigo. Comprendo que si se retira del estudio antes de que sea completado, no recibirá ni los resultados de los exámenes realizados, ni el/los tratamientos que hubiera recibido si continuaba en el estudio hasta su terminación.

G.- Preguntas

Se que cualquier pregunta que yo tenga respecto de este estudio puedo dirigirla personalmente, por teléfono o por correo al Dr. Fernando Ortega, Director del Departamento de Desarrollo y Salud Comunitaria. Universidad San Francisco de Quito. Ave. Jardines del Este y Vía Interoceánica. Cumbaya. Teléfono: 895.723 Extensión 210.

Mi firma indica que he leído y he comprendido los procedimientos descritos en este documento. Doy mi consentimiento voluntario e informado para que mi hijo/hija o representado pueda participar en este estudio. Entiendo que recibiré una copia firmada de este consentimiento.

Firma del padre/madre

Nombre del Niño o Niña

Firma del representante legalmente autorizado

Fecha

Firma del Director del Estudio

Appendix D Parasitic Survey

English version

Student's name	Community	Date of Birth
Father's activity	Mother's activity	
Father's monthly income	Mother's monthly income	
Father's educational level?	Mother's educational level?	

Symptoms

A	Abdominal pain	B	Dilated abdomen
C	Nausea	D	Vomiting
E	Drooling	F	Dizziness
G	Anal itching	H	Has recently passed worms
I	Diarrhea	J	Headache
K	other symptoms		

Has your child received any treatment against parasites?

When was the last treatment he/she has received?

Date:

What kind of medicine he/she received?

Was she/he cured?

How much did you pay for that treatment?

Did you use any home remedies against parasites?

What kind of water do you consume at home: channel water, potable water, raining water

Do you boil the water?

Which animals do you have at home? Dog, cat, pork, cow, chicken, guinea pig, sheep, other

Appendix D (Continued)

Spanish version: ENCUESTA PARASITARIA

Nombre del /la estudiante:

Barrio o comunidad:

Fecha de nacimiento:

En que trabaja el padre:

En que trabaja la madre:

Ingreso **mensual** del padre:

Ingreso **mensual** de la madre:

Hasta que grado estudió el padre?

Hasta que grado estudió la madre?

SINTOMAS QUE PRESENTA EL NIÑO O LA NIÑA:

Por favor encierre en un círculo los síntomas que presenta su hijo o hija:

A. Dolor de barriga

B. Barriga inchada

C. Nausea

D. Vómito

E: Babea la almohada por las noches

F: Mareos

G: Comezón en el ano
últimamente?

H: Le han salido BICHOS

I: Diarrea

J: Dolor de cabeza

K: otros síntomas

Ha recibido algún tratamiento para los bichos?

Cuando fue el último tratamiento que recibió?

Fecha:

Qué tipo de medicina le dieron?

Qué cantidad diaria le dió?

Le produjo alguna reacción ese tratamiento?

Cuanto le costó ese tratamiento?
bichos?

Que remedios caseros le ha dado para los

Que tipo de agua consumen en casa:

Agua de acequia

potable

de lluvia

Hace hervir el agua?

Cuales de estos animales hay en casa: perro, gato, chancho, vaca, cuy, oveja, otros.

Appendix F Laboratory techniques used in this study

Simple smear.-

The saline wet mount was used for the initial microscopic examination of stools. It was good in demonstrating worm eggs, and protozoan cysts and trophozoites. This technique was complemented with the iodine wet mount which stained glycogen and the nuclei of cysts. To apply this technique a drop of saline solution was placed on the left side of the slide and a drop of iodine solution was placed on the right side. A small portion of the specimen was mixed with the saline solution with an applicator. The same was done with the iodine solution. After a systematic examination of both mounts any present parasites were reported in the corresponding format. X-10 and X-40 objectives were used to examine all specimens.

In addition to direct wet mounts, supplementary concentration technique was used to recover eggs, larvae and cysts. The wet mount direct examination of feces was mandatory as the initial phase of microscopic examination of all samples. As the number of organisms in the stool specimens could be low and the examination may not detect parasites in all cases, we proceeded to use the concentration technique as described below.

Concentration technique.-

The concentration technique we used is the formalin-ether method. All types of worm eggs, larvae and protozoan cysts were recovered by this method.

The concentration procedure followed these steps:

1. One gram of feces was stir in 10 ml. of 10% formalin producing a slightly cloudy suspension.
2. The suspension was filtered through a gauze filter and placed into a centrifuge tube (7 ml).
3. The filtered suspension was added 3 ml of ether, mixed for one minute and centrifuged for one minute.
4. The supernatant debris was pour away and a drop of the sediment was transfer to a slide for examination.
5. The mount of concentrated material was examined in the same way as direct wet mounts: the saline mount was examined systematically, looking for eggs, larvae or cysts. Then the iodine mount was checked to see more details. Only ascaris eggs were counted per mount.

In this study the Cellophane thick smear or modified Kato-Katz method was not use because of the availability of equipment and an experimented laboratory installed in the University Medical Center. The specimens were collected every day and immediately transferred to the laboratory in numbers that could be processed during the next three hours. Following the WHO Experts Committee recommendations, concentration techniques are better suited to research studies than to diagnosis in communities, however taking into account the improved sensibility and specificity of this laboratory techniques, and the feasible use of a closed modern laboratory, the decision was to apply a combination of direct smear with saline and iodine solution plus a formalin-ether concentration technique.

Appendix G Water quality reports



Laboratorios BioQuality
Universidad San Francisco de Quito

I.- INFORME DE ANALISIS MICROBIOLOGICOS

Análisis Solicitado por: Dr. Fernando Ortega
Fecha de Recepción de la Muestra: 10/dic/99
Fecha de inicio del análisis: 10/dic/99
Análisis No: 86-99

I. DATOS DE LA MUESTRA:

Muestra: Agua (grifo de cocina) Water (kitchen faucet)
Procedencia: Comunidad Checa. Familia Naranjo
Apariencia: Incolora, transparente

II. RESULTADOS:

<u>Análisis</u>	<u>Especificación*</u>	<u>Resultado</u>	
Aerobios totales	Máx. 30 colonias/mL	10 UFC/mL	
Coliformes/100 mL	Ausencia	Ausencia	(Negative)
<i>E. coli</i>/100 mL	Ausencia	Ausencia	(Negative)

* Según Norma INEN 1108 y Codex Stan 151-1985

Datos adicionales:

UFC: Unidades formadoras de colonias

III. OBSERVACIONES:

El muestreo se realizó el mismo día e inmediatamente se transportó la muestra al laboratorio.

2.- INFORME DE ANALISIS MICROBIOLOGICOS

Análisis Solicitado por: Dr. Fernando Ortega
Fecha de Recepción de la Muestra: 24/feb/97
Fecha de inicio del análisis: 24/feb/97
Análisis No: 8-97

I. DATOS DE LA MUESTRA:

Muestra: Agua (Muestra No. 5)
Procedencia: Aglla - Escuela
Apariencia: Turbia.

II. RESULTADOS:

<u>Análisis</u>	<u>Especificación*</u>	<u>Resultado</u>
Aerobios totales	Máx. 30 colonias/mL	1400 UFC/mL
Coliformes/100 mL	Ausencia	Presencia (Positive)
<i>E. coli</i> /100 mL	Ausencia	Presencia (Positive)

III. OBSERVACIONES:

El muestreo se realizó aproximadamente 24 h antes del análisis.

3.- INFORME DE ANALISIS MICROBIOLOGICOS

Análisis Solicitado por: Dr. Fernando Ortega
Fecha de Recepción de la Muestra: 24/feb/97
Fecha de inicio del análisis: 24/feb/97
Análisis No: 7-97

I. DATOS DE LA MUESTRA:

Muestra: Agua (Muestra No. 4)
Procedencia: Aglla - Tanque
Apariencia: Turbia

II. RESULTADOS:

<u>Análisis</u>	<u>Especificación*</u>	<u>Resultado</u>
Aerobios totales	Máx. 30 colonias/mL	1000 UFC/mL
Coliformes/100 mL	Ausencia	Presencia (Positive)
<i>E. coli</i> /100 mL	Ausencia	Presencia (Positive)

III. OBSERVACIONES:

El muestreo se realizó aproximadamente 24 h antes del análisis.

4.- INFORME DE ANALISIS MICROBIOLOGICOS

Análisis Solicitado por: Dr. Fernando Ortega
Fecha de Recepción de la Muestra: 24/feb/97
Fecha de inicio del análisis: 24/feb/97
Análisis No: 5-97

I. DATOS DE LA MUESTRA:

Muestra: Agua (Muestra No. 2)
Procedencia: Aglla - Bajo hacienda (SAMPLE FROM THE FARM)
Apariencia: Ligeramente turbia. Tierra sedimentada en el fondo del frasco.

II. RESULTADOS:

<u>Análisis</u>	<u>Especificación*</u>	<u>Resultado</u>	
Aerobios totales	Máx. 30 colonias/mL	4000 UFC/mL	
Coliformes/100 mL	Ausencia	Presencia	(Positive)
<i>E. coli</i> /100 mL	Ausencia	Presencia	(Positive)

III. OBSERVACIONES:

El muestreo se realizó aproximadamente 24 h antes del análisis.

5.- INFORME DE ANALISIS MICROBIOLOGICOS

Análisis Solicitado por: Dr. Fernando Ortega
Fecha de Recepción de la Muestra: 14/feb/98
Fecha de inicio del análisis: 14/feb/98
Análisis No: 2-98 **Analizado por:** Juan M. Chávez

I. DATOS DE LA MUESTRA:

Muestra: Agua
Procedencia: Iguinaro - Tanque azul
Apariencia: Incolora, transparente

II. RESULTADOS:

<u>Análisis</u>	<u>Especificación*</u>	<u>Resultado</u>	
Aerobios totales	Máx. 30 colonias/mL	300 UFC/mL	
Coliformes/100 mL	Ausencia	Presencia	(Positive)
<i>E. coli</i> /100 mL	Ausencia	Presencia	(Positive)