

The Veron Community Scabies Education and Eradication Program

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Abstract

Skin infections by the ectoparasitic mite *Sarcoptes scabiei* are a preventable source of morbidity worldwide. While scabies affects all socioeconomic sectors, it is especially prominent in the developing world where crowding, poor hygiene, and limited access to basic health care are commonplace. Mass eradication efforts of this parasite have historically been hampered by delivery and compliance issues surrounding topical standards of care. There have been advances in eradication over the last decade due to the expanded use of oral Ivermectin for the treatment and prevention of ectoparasites such as scabies. Previous research focused on various treatment aspects of the disease, yet most identified the need for basic scabies health education to accompany future studies to improve program sustainability and the overall health literacy of target populations.

The Virginia College of Osteopathic Medicine sponsors a public health clinic in Veron, Dominican Republic that reports a high prevalence of scabies infections among its general patient population. The lack of any means of direct measurement, proper intervention, or control raises concerns that long-term infection may lead to multiple other secondary disease sequelae. The Veron Scabies Eradication and Education Program was designed to address this deficiency and build on previous studies related to this problem by using a novel treatment and education protocol.

The purpose of this research was to identify, treat, and prevent primary and secondary health problems due to long-term scabies infection in the community of Barrio Nuevo, Veron, Dominican Republic in order to provide long-term sustainable eradication through a researcher-designed health education program and medical service protocol. Participants continued typical daily life while interventions and education were monitored to detect change over a 9-month timeline using selected measurement intervals to test multiple scabies disease and knowledge objectives and related hypotheses.

Following this basic protocol, the following scabies markers were evaluated at baseline: subject demographics, scabies diagnosis and treatment history, baseline treatments and reported side effects, and scabies education pre-test results. The following scabies markers were also assessed at baseline and reassessed at 2 weeks, 1 month, 2 months, 8 months, and 9 months: risk and prevention behaviors, symptomatology, skin exam findings, and scabies education post-test results. There was a statistically significant post-intervention improvement in scabies markers when compared to pre-intervention values ($p < 0.05$).

This study demonstrated that a community scabies program involving large-scale treatment and education can provide rapid and long lasting improvements to the health of a highly endemic population. Community-wide scabies eradication is possible with the appropriate level of structure and support using low cost medication available to the health care system that serves Veron, Dominican Republic. Given the efficacy and safety profile of Ivermectin demonstrated in this study and substantiated by others, it is

recommended that the Dominican Republic Ministry of Health consider adopting Ivermectin as the standard of care for scabies treatments and enforce an existing formal ban on Lindane products. The protocol from this research should be considered for adoption to provide a sustainable, practical, self-sufficient model for improved health outcomes, health behaviors, and health literacy. Future studies should replicate this research to determine validation in other settings, cultures and situations, build on the findings by exploring additional variables related to environmental risk factors, and continue to develop interventions that promote health education and enhance clinical practices.

Dedication

I would like to dedicate this work to my parents, for always encouraging me to chase my talents, to live inside my heart, and to always seek the answers to the why's of this world. And to my dog Possum—my daily reminder that it is possible to love without condition. Finally, my respect and thanks to the good people of Veron, Dominican Republic—a beautiful illustration of the human endeavor.

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Chapter 1

Introduction

Scabies skin infections by the arthropod *Sarcoptes scabiei* var *hominis* have been reported for more than 2500 years. This obligate parasitic mite is responsible for an estimated 300 million annual cases worldwide, affects males and females of all socioeconomic stratas and ethnic groups, and is associated with poverty, crowding, hygiene, and war-centric pandemics (Burgess, 1994; Chosidow, 2000).

Primary scabies infections typically cause intensely pruritic and highly contagious skin infections that are little more than nuisance. But, long-term scabies infection acts as a gateway disease for secondary sequelae and complications such as polymicrobial colonization of skin lesions by Group A *Streptococcus*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*, poststreptococcal glomerulonephritis, rheumatic heart disease, impetigo, furunculosis, cellulitis, skin abscesses, and sepsis (Feldmeier, Singh, & Guerra, 2005; Potter, Earle, Mayon-White, Poon-King, Svartman, & Abidh, 1985; Verma, Chugh, & Bhatia, 1983; Whittle, Abdullahi, Fakunle, Parry, & Rajkovic, 1973).

Within the rural Dominican Republic community of Veron scabies prevalence reaches an estimated 20% of adults and 25% of children according to Veron public clinic personnel (Shafi, 2006). In fact, of 800 patient files evaluated at the clinic between September 2006 and May 2007, scabies was the 3rd most common diagnosis behind viral upper respiratory infections and intestinal parasites (Sutherland, 2007). Furthermore, in May 2006 the Barrio Nuevo neighborhood, consisting of roughly 10-15% of the Veron population, was treated for polio as part of a larger SESPAS vaccination campaign in the La Altagracia district. At that time Veron medical personnel also measured other disease prevalences, including scabies, which was calculated at 23% (Shafi, 2006).

The Veron community has many risk factors for long-term scabies infection: rampant poverty, overcrowding, poor hygiene practices, significant person-to-person contact, frequent bed and clothes sharing, and little separation of animals and humans. Despite the obvious need for large-scale intervention, there is currently no organized means of direct measurement, treatment, or education for the people of Veron.

Furthermore, the current standard of care for scabies infection in Veron is the repeated full-body application and removal of topical Lindane lotion, a highly toxic

medication that is banned for all uses in the Dominican Republic, as well as more than 80 other countries due to its neurotoxic effects on humans and its effects on the environment as an aquacide and herbicide (Boffa, Brough, & Ead, 1995; Davies, Dedhia, Mergade, Banquet, & Maibach, 1983). This drug is effective for the short-term control of the scabies mite, as well as head and pubic lice, but it confers no systemic immunity or prophylaxis and its efficacy hinges on proper use and patient compliance (Madan, Jaskiran, Gupta, & Gupta, 2001). Regardless of laws banning its use, Lindane remains the drug of choice in the Veron because there is little formal enforcement of its ban, it is inexpensive, and there is no alternative available to help remove it from the pharmacies in the area.

There is now compelling evidence that treating scabies with a one-time 200ug/kg dose of oral Ivermectin every 6 months is far superior to topical Lindane for many reasons: Ivermectin is also effective against scabies and pubic and head lice, as well as hookworm, ascariasis, trichuriasis, enterobiasis, hymenolepiasis, cutaneous larva migrans, filariasis, onchocerciasis, strongyloidiasis, and certain anopheline vectors, one dose confers 6 to 9 months of immunity and prophylaxis, its side effect profile is nonspecific and unremarkable, its ease of use and compliance, and over 60 million annual doses are currently being administered for other mass eradication campaigns worldwide, demonstrating its safety and efficacy (Buffet & Dupin, 2003; Chouela, Abeldano, & Pellerano, 1999; del Guidice, Chosidow, & Caumes, 2003; Elgart, 1999; Lawrence, Leafasia, & Sheridan, 2005; Walker & Johnstone, 2000). In fact, Ivermectin is now regarded as a first line choice when considering scabies control in endemic areas with significant polyparasitism, as is clearly the case in the Dominican Republic (Heukelbach, Winter, & Wilcke, 2004; Sutherland, 2007).

Previous mass scabies eradication campaigns using Ivermectin have clearly demonstrated a sustainable reduction in scabies signs, symptoms, and overall incidence (Buffet & Dupin, 2003; Chouela et al., 1999; del Guidice et al., 2003; Elgart, 1999; Lawrence et al., 2005; Walker & Johnstone, 2000). A similar theme in these studies and other scabies reviews is the call for improved scabies health education to allow study participants to become self sufficient in their ability to correctly recognize and react to a scabies infection (Buffet & Dupin, 2003; Chouela et al., 1999; del Guidice et al., 2003;

Elgart, 1999; Lawrence et al., 2005; Walker & Johnstone, 2000). Despite these recommendations, no studies to date have included an education component to compliment treatment efforts.

In an effort to answer this call, this thesis involves the creation and implementation of an innovative scabies treatment and education program that consists of community epidemiological monitoring, disease and prevention education, and mass treatment using oral Ivermectin. A title of Veron Scabies Education and Eradication Program (VSEEP) was created to communicate with the public and to provide a working title for the thesis.

It is believed that a scabies eradication program of this scale was the first attempted in the Dominican Republic, the greater Caribbean, as well as the first scabies program in the world to combine treatment and education in an attempt to improve community health and health behaviors (Walton & Holt, 2004).

1.1 Statement of problem

There is a high incidence of long-term scabies infection and infestation among the communities served by the public health clinic in Veron, DR without means of direct measurement, treatment, education, or control that may lead to multiple other secondary medical and environmental problems.

1.2 Purpose

The purpose of the Veron Scabies Education and Eradication Program was to identify, treat, and prevent primary and secondary health problems due to long-term scabies infection in the community of Veron, Dominican Republic in order to provide long-term sustainable eradication through a researcher-designed health education program and medical service protocol.

1.3 Research Objectives

1. Determine Barrio Nuevo demographics, including number of households, number of inhabitants, number of inhabitants per household, average duration of

- inhabitation, percentage of men and women, occupations, literacy rates, average years of school attendance, and average number of visits to the Veron clinic.
2. Determine the scabies-related medical history for the inhabitants of Barrio Nuevo, including previous diagnoses of scabies, previous scabies treatments, and locations of previous scabies diagnoses and treatments.
 3. Determine the pre and post-intervention prevalence of scabies-related prevention habits and risk factors, symptomatology, and skin exam findings for the inhabitants of Barrio Nuevo.
 4. Determine the pre and post-intervention levels of scabies education, as indicated by the results of a scabies knowledge test.
 5. Compare the levels of scabies disease and education prevalence and incidence data using the markers above in objective # 3 and 4 at baseline, 2 weeks, 1 month, 2 months, 8 months, and 9 months from program initiation.
 6. Evaluate the program for efficiency, effectiveness, and sustainability.

1.4 Research Hypotheses

- The pre-intervention sample mean is significantly greater than ($p < .05$) the post-intervention sample mean for scabies-related risk factors.
- The pre-intervention sample mean is significantly greater than ($p < .05$) the post-intervention sample mean for scabies-related symptomatology.
- The pre-intervention sample mean is significantly greater than ($p < .05$) the post-intervention sample mean for scabies-related physical exam findings.
- The pre-test sample mean for correctly answered questions is significantly less than ($p < .05$) the post-test sample mean for correctly answered questions.

1.5 Definition of Terms

Ivermectin: a broad-spectrum oral anti-parasite medication, sold under multiple trade names including Ivermectina, Mectizan, Revectina, and Stromectal.

Lindane: a topical lotion scabicide that is currently the drug of choice in the Dominican Republic despite a countrywide ban for all uses due to its neurotoxicity profile.

Permethrin: the standard of care topical scabicide commonly prepared in lotion and cream solutions, sold under multiple trade names including Acticin, Elimite, Nix, and Permethrina.

Polyparasitism: infection of a host by multiple parasite species, such as ectoparasites and gastrointestinal parasites.

Pruritis: itching of the skin as evidenced by excoriations and redness.

Scabies: a skin disease caused by the parasitic mite *Sarcoptes scabiei*. The disease is common throughout the developing world and is characterized by intense itching and possible secondary complications that include abscesses, heart disease, and renal failure.

Secretaría de Estado de Salud Pública y Asistencia Social: SESPAS, the Dominican Republic Ministry of Health.

1.6 Limitations of the Study

The study utilized a sample for the population of Barrio Nuevo—a typical neighborhood within the Veron area that housed approximately 1000 individuals during the time period of the research. This represents approximately 10-15% of the total Veron population, determined by door-to-door surveys and general census. Thus, the population parameters were limited by the time period and mobility within the community that changes due to the transient nature of the job seeking populous.

The neighborhood was chosen because it is representative of the living conditions throughout the entire Veron area, it has well-delineated borders that separate it from other neighborhoods in the area, and its inhabitants are a satisfactory cross-section of the citizens of Veron. Having a self contained subsection of Veron was important to contain

treatment and risk factors that would have much lower levels of control if randomly distributed across a large geographical area and population.

While this sampling strategy helped maintain external validity and generalizability to the larger Veron population, the study is limited by time and breadth of parameters measured. More specifically, the study is limited to a 9-month timeline to measure changes in scabies disease and education incidences. Furthermore, potential limitations to inter-rater reliability were controlled by the fact the researcher made observations, provided the treatment and education, and collected project data.

1.7 Significance of the Study

Based on a review of literature, this researcher-developed scabies eradication program was the first attempted in the Dominican Republic and the greater Caribbean, as well as the first scabies program in the world to combine treatment and education in an attempt to improve community health and health behaviors (Walker & Johnstone, 2000; Walton & Holt, 2004). Using a medication delivery methodology that is sustainable, cost-effective, and capable of stimulating system-wide treatment protocol changes in the Dominican Republic, this project has the potential to be an important contribution to the effort to eradicate a source of significant morbidity for both the people of Veron and the global community as a whole.

Chapter 2

Literature Review

2.1 Scabies Pathophysiology

Sarcoptes scabiei var *hominis*, as shown in Figure 2.1, is an obligate female parasitic mite that completes its entire life cycle on the human host. Other variants of the scabies mite can cause infection in other mammals such as dogs, cats, pigs, ferrets, and horses. Indeed, these variants can infest human skin as well, but typically only cause a transient dermatitis. The mite can sometimes be seen with the naked eye as it measures 0.3 to 0.4 mm long (Heukelbach & Feldmeier, 2004). As shown in Figure 2.2, the male mite fertilizes the female on human skin and then dies and it is the newly mated females that burrow into human skin, using proteolytic enzymes to dissolve the stratum corneum of the epidermis (Burgess, 1994). The female then deposits eggs in the burrows, which incubate and hatch after 3 to 8 days (Heukelbach & Feldmeier, 2004). About 90% of the hatched mites die, but those that survive go through various molting stages and reach maturity after a little more than 2 weeks (Burgess, 1994). The female adults, who never leave their burrows, die after 1-2 months (Heukelbach & Feldmeier, 2004). Anywhere from 3-50 mites live on the human host at any one time (Burgess, 1994).

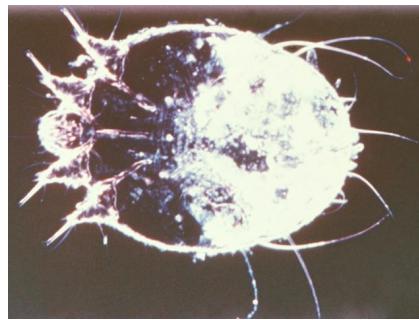


Figure 2.1 [photo courtesy of CDC]
Sarcoptes scabiei var *hominis*.

Considering mobility, scabies mites don't fly or jump, but crawl about 2.5 cm/minute (Heukelbach & Feldmeier, 2004). They are able to live on bedding, clothes, or other surfaces at room temperature for about 48 hours while remaining capable of infestation and burrowing. Below 20°C *S. scabiei* are immobile but viable (Heukelbach & Feldmeier, 2004). Because the mite is transmitted by direct skin-to-skin contact, it is considered a sexually transmitted disease (Burgess, 1994).

Once a host is acquired, a delayed-type IV hypersensitivity reaction to the mites, eggs, and scybala (packet of feces) occurs after about 4 weeks and with subsequent infections (Heukelbach & Feldmeier, 2004). The time required to induce immunity in primary infections probably accounts for the commonly observed latent period of 4 weeks in asymptomatic infections (Heukelbach & Feldmeier, 2004). In re-infection, the sensitized individual may develop a reaction rapidly, often within hours (Burgess, 1994). The resultant skin eruption, and its associated intense pruritis, is the hallmark of classic scabies, and is a result of a CD4 T cell-mediated immune response (Burgess, 1994).

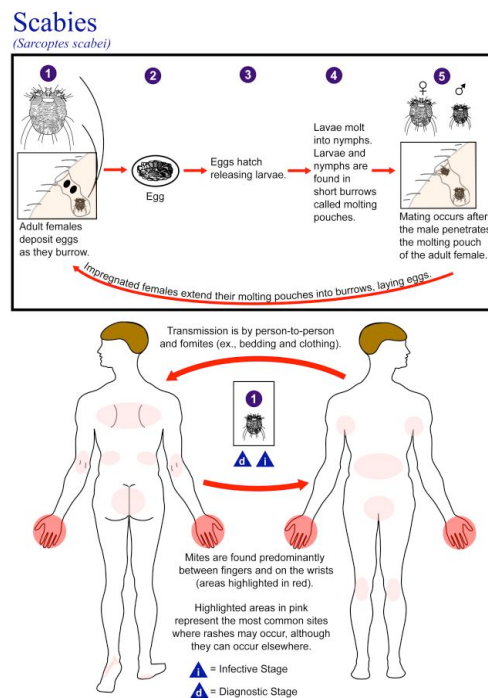


Figure 2.2 [public domain]
Life cycle and pathophysiology of *Sarcoptes scabiei*.

Norwegian, or crusted scabies is a distinct and highly contagious form of the infection typically seen in immunocompromised, elderly, or physically disabled and/or mentally impaired host where hundreds to millions of mites infest an individual (Burgess, 1994). Extensive, widespread, crusted lesions appear with thick, hyperkeratotic scales over the elbows, knees, palms, and soles (Burgess, 1994). Despite the extremely high serum immunoglobulin E (IgE) and immunoglobulin G (IgG) levels that commonly develop in these hosts, this CD8 T cell-mediated immune reaction does not seem to be protective (Burgess, 1994).

2.2 Scabies Epidemiology

Scabies prevalence reaches a reported 300 million cases annually (Walton & Holt, 2004). The disease is endemic to most tropical and subtropical regions, with extremely high rates (40 to 80%) reported in aboriginal Australia, Africa, South America, and most other developing nations (Walton & Holt, 2004). Epidemics also frequently occur in nursing homes, hospitals, long-term care facilities, and other institutions throughout the world (McCarthy, Kemp, & Currie, 2004). The parasite infects all ages, ethnic groups, socioeconomic levels, and sexes, but is most common in children (Fain, 1978; Green, 1989; Heukelbach & Feldmeier, 2004).

Research over the last 20 years details the factors perpetuating high prevalence in resource-poor regions and in vulnerable groups such as the homeless, young adults, and the elderly. As shown in Figure 2.3, these factors include: overcrowding and poor living conditions associated with poverty, increased temperatures and humidity producing a favorable climate for parasite breeding, health behaviors such as personal contact and sexual habits, restricted access to health care, treatment failures due to poor compliance, ineffective drug therapies, and decreased health education and literacy (Heukelbach, Walton, & Feldmeier, 2005).

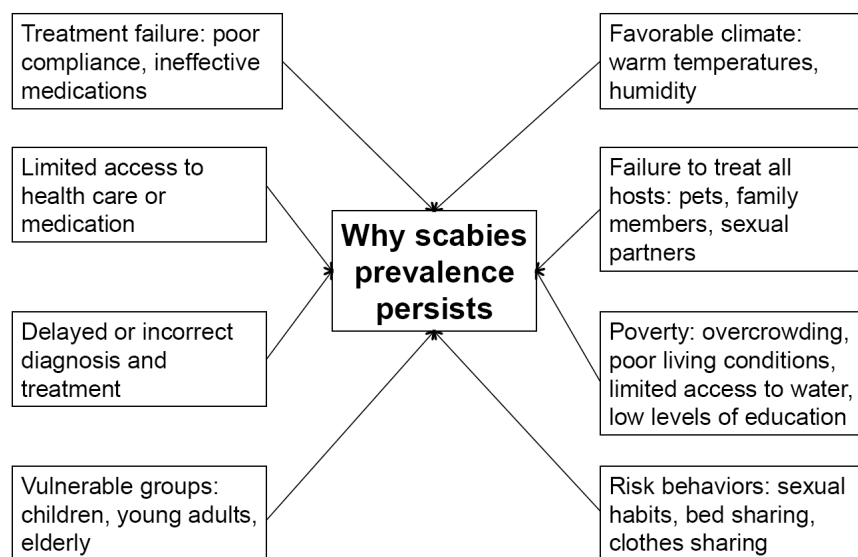


Figure 2.3
Contributing factors to high prevalence in resource-poor areas.

2.3 Scabies Signs and Symptoms

Primary scabies infections typically cause intense, persistent pruritis, especially at night or after a shower or bath. These symptoms are the direct result of a hypersensitivity reaction once the mite burrows into the epidermis, lays eggs, and produces scybala (Burgess, 1994). Signs and symptoms tend to crescendo progressively over 2 to 3 weeks before compelling the patient to seek medical attention (Burgess, 1994). This cycle typically causes sleep disturbance and discomfort, and can open the door for secondary disease sequelae in situations of long-term infection, as seen in impoverished populations where the scabies mite is highly endemic (Johnston & Sladden, 2005).

Secondary disease sequelae include: polymicrobial colonization of skin lesions by Group A *Streptococcus*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*, acute poststreptococcal glomerulonephritis, rheumatic heart disease, impetigo, furunculosis, cellulitis, skin abscesses, and sepsis (Feldmeier et al., 2005; Johnston & Sladden, 2005).

Aside from the clinical findings, research into the psychological consequences of the disease reveals significant stigmatization and ostracisation for individuals with longstanding scabies-induced lesions and scars (Heukelbach & Feldmeier, 2004; McCarthy et al., 2004). The cumulative potential consequences of long-term scabies infection are illustrated in Figure 2.4.

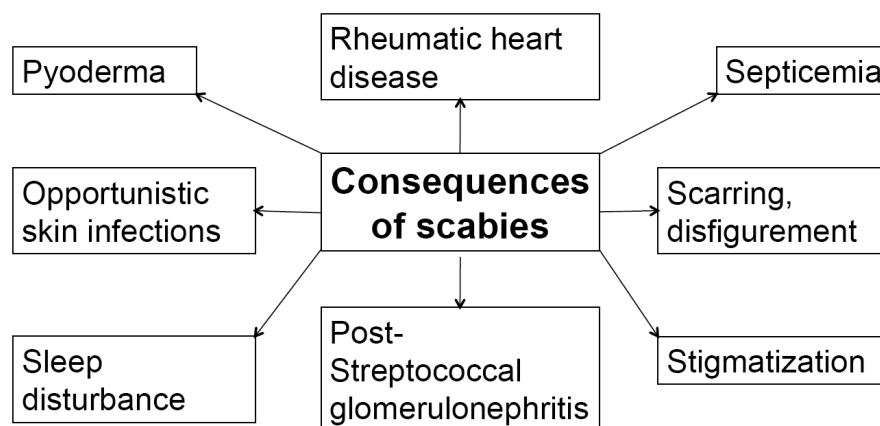


Figure 2.4
Consequences of short and long-term scabies infections.

The physical examination can be divided into primary and secondary dermatological lesions, as illustrated in Figure 2.5 (Karthikayan, 2005). Primary lesions

include general excoriations and S-shaped burrow lines in the superficial epidermis, which are pathognomonic for a scabies infection (Karthikayan, 2005). Burrows lines appear as thin (typically the width of a human hair), short (2-3 mm), gray/brown wavy channels on the skin, which may be visible to the naked eye as a small white dot (Karthikayan, 2005). Burrow lines are best detected in the web spaces of the fingers and feet, typically discovered once significant skin reactivity has already taken place (Karthikayan, 2005).

Secondary lesions commonly present as small, highly pruritic vesicles or papules that often appear at the end of a burrow (Johnston & Sladden, 2005). These lesions commonly appear in the flexor aspects of the wrists, antecubital fossa, axilla, peri-umbilical region, low back, and buttocks (Karthikayan, 2005). In women, the nipples and areola of the breasts are often affected (Karthikayan, 2005). In men, red papules or nodules on the penile glans, shaft, and scrotum are also pathognomonic for scabies (Karthikayan, 2005). Interestingly, the head and face is usually spared in adults, but less so in the young (Johnston & Sladden, 2005).



Figure 2.5 [photos courtesy of CDC]

Typical presenting areas of scabies lesions: pathognomonic skin burrows in the web spacing of the hands (top left) and wrists (top middle), close up of a burrow (top right), papules and vesicles found on a child's thigh (bottom left), scabbed lesions and oozing abscesses on the back and leg (bottom middle and right).

There are multiple documented variants of classic human scabies that differ in location, presentation, and severity. Nodular scabies may present as red nodules approximately 0.5 cm or larger, appearing exclusively on covered parts of the bodies,

such as the scrotum, penis, buttocks, groin, axillary folds, and upper back (Johnston & Sladden, 2005). Geriatric scabies demonstrates a propensity for the back, often appearing as excoriations (Johnston & Sladden, 2005). Norwegian, or crusted scabies presents with extensive crusting, psoriasiform-like lesions with thick, hyperkeratotic scales on the elbows, knees, palms, and soles, as shown in Figure 2.6 (Johnston & Sladden, 2005). Bullous lesions may be observed in immunocompromised patients (Johnston & Sladden, 2005). Canine or animal scabies (*Sarcoptes scabiei* var *canis*), which can cause temporary infections in a human host, does not exhibit the classic burrow. Instead, papules and vesicles are typically found mostly on the arms, chest, abdomen, and thighs (Johnston & Sladden, 2005). Because scabies is primarily a disease of the skin, its differential diagnosis includes most other dermatologic conditions and exposures, as listed in Appendix A.



Figure 2.6 [photo courtesy of CDC]
Norwegian or crusted scabies—a very severe form of the disease.

2.4 Scabies Treatment Overview

Treatment of scabies typically involves both medical intervention and health behavior changes to decrease risk of exposure. This includes treating all primary and secondary infections in the patient, as well as all household members and close personal contacts. Additionally, it is recommended that bedding, towels, and clothing be washed

in at least 60°C water and machine dried (Buffet & Dupin, 2003). If these items cannot be washed in hot water or machine dried, they should be washed with bleach. If these items are unable to be washed by any means they should be isolated from all human or material contacts for at least 3 days (Buffet & Dupin, 2003; Chambliss, 2000; Elgart, 1999; Karthikayan, 2005).

Considering medical interventions, scabies infections have historically been treated with topical lotions and creams, including benzyl benzoate, monosulfiram, malathion, lindane, crotamiton, permethrin, and sulfur (Walker & Johnstone, 2000). Each solution has varying degrees of efficacy, ranging from 48-98%, which is highly dependent on user compliance, proper application, and repeated dosing (Walker & Johnstone, 2000). These drawbacks, as well as their short duration of action leave little hope for their effective use in breaking the cycle of infection and infestation that is common in highly endemic areas, especially on a community level. The most common side effects with each topical medication include skin irritation, burning, and pruritis—collectively known as drug dermatitis (Walker & Johnstone, 2000). These side effects can further confound scabies treatment because they are often identical to the symptoms caused by the burrowing mite (Walker & Johnstone, 2000).

2.5 Permethrin Overview

According to Roos, Alam, Roos, Merk, and Bickers (2001), Permethrin 5% cream represents the current first line topical agent for classic scabies for its overall safety and efficacy. It has a chemical name of 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylic acid, (3-phenoxyphenyl) methyl ester, a molecular formula of $C_{21}H_{20}Cl_2O_3$, and a molecular weight of 391.29. This pyrethroid is active against lice, ticks, fleas, mites, and other arthropods by effectively disrupting nerve cell membrane sodium channel current and polarization, causing paralysis and death. Permethrin is rapidly metabolized by ester hydrolysis to inactive metabolites primarily excreted in the urine. Data from absorption studies with ^{14}C -labeled Permethrin indicate that 2% or less of the amount applied is systemically absorbed after a standard application of 5% lotion.

Multiple rat and mice carcinogenicity bioassays have been conducted using

Permethrin (Roos et al., 2001). Of the six evaluated for this review, no tumorigenicity was reported in rats, while species-specific increases in pulmonary adenomas were seen in each mouse study (Roos et al., 2001). Furthermore, one of these studies demonstrated an increased incidence of pulmonary alveolar-cell carcinomas and benign liver adenomas in female mice exposed to Permethrin concentrations of 5000 ppm (Roos et al., 2001). All mutagenicity assays using Permethrin were negative, showing no evidence of mutagenic potential in a battery of in vitro and in vivo genetic toxicity studies (Roos et al., 2001).

Reproduction studies have been performed in mice, rats, and rabbits using Permethrin dosage ranges from 200 to 400 mg/kg/day orally (Roos et al., 2001). None have revealed evidence of impaired fertility or harm to the fetus. Despite this information, no adequate or well-controlled studies have been conducted in pregnant women, resulting in a category B listing (Roos et al., 2001). Therefore, Permethrin is only indicated in pregnant or lactating women if clearly needed. Similarly, safety and efficacy in infants less than two months of age has not been established, thus Permethrin use should be reserved for children two months or older (Roos et al., 2001). No reported clinical studies have identified differences in responses between the elderly and younger patients (Roos et al., 2001).

Considering adverse events associated with Permethrin use, various clinical trials have reported mild and transient burning or stinging following proper lotion or cream application in about 10% of patients and was associated with the severity of infection (Roos et al., 2001). Pruritis was reported in 7% of patients, while erythema, numbness, tingling, and rash were reported in 2% or less of patients (Roos et al., 2001). Other adverse events that have been reported include: abdominal pain, diarrhea, nausea and/or vomiting, headache, fever, dizziness, and rare occurrences of seizures (Roos et al., 2001). None of these other events have been medically confirmed to be a direct result of Permethrin use (Roos et al., 2001).

Permethrin is administered for topical use in humans as a 5% solution in a lotion or cream medium. Proper application involves massaging the medication into the skin from the neck to the toes, avoiding the head, before bedtime. The medication should be washed off the skin in the morning or 8 to 14 hours later. One application, or about 30

grams in adults, is generally sufficient to achieve a clinical cure of scabies (Roos et al., 2001). Permethrin 5% currently lists for \$14.99/60g tube for a generic preparation in the United States (Karthikayan, 2005).

2.6 Lindane Overview

Lindane is the most commonly drug prescribed, purchased, and used in the Veron area for scabies infections. It is an ectoparasiticide and ovicidal gamma isomer of 1,2,3,4,5,6-hexachlorocyclohexane with the structural formula $C_6H_6Cl_6$ and molecular weight of 290.83 (Roos et al., 2001). Lindane is directly absorbed into parasites and ova to complete its parasiticide action (Roos et al., 2001). Topical applications on humans demonstrated an average serum half-life of 18 hours (Roos et al., 2001). Further pharmacodynamic studies show that Lindane 1% topical has a rapid distribution phase followed by a longer β -elimination phase, resulting in 10% systemic absorption from a typical application (Roos et al., 2001).

Multiple oral and topical Lindane studies using mice and rats demonstrate no clear increase in neoplasm incidence (Roos et al., 2001). Likewise, various tests using bacteria vectors do not indicate that Lindane is mutagenic (Roos et al., 2001). But, spermatogenesis studies in rats indicate that high levels of Lindane exposure (12 times the typical human dose) can significantly reduce spermatid formation (Roos et al., 2001).

Reproductive studies for Lindane using rats at day 6 of gestation through day 10 of lactation revealed reduced pup survival, increased number of stillborn pups, decreased pup weight, decreased weight gains during lactation, and decreased motor activity (Roos et al., 2001). Other animal studies suggest that increased neurologic developmental abnormalities may be observed in fetuses exposed to Lindane at levels similar to those needed to treat scabies (Boffa et al., 1995). This may be in part due to the increased susceptibility of the immature central nervous system of a fetus to drug exposure (Boffa et al., 1995). Indeed, there exists a case report of a stillborn infant following multiple maternal exposures to Lindane during pregnancy (Bhalla & Thami, 2004). Furthermore, Lindane is lipophilic and thus may accumulate in the placenta and breast milk (Bhalla & Thami, 2004). In light of these findings and because there are no known serious maternal or fetal health risks if scabies is not treated, Lindane has a category C listing and should

be avoided by pregnant or breastfeeding woman (Bhalla & Thami, 2004).

Regarding pediatric populations, animal data demonstrates increased risk of adverse events across species due to a higher surface to volume ratio and immaturity of organ systems such as skin and liver (Boffa et al., 1995). It is recommended that Lindane should be used with extreme caution in patients who weigh less than approximately 50 kg, especially infants (Boffa et al., 1995). To this end, it is advised that Permethrin be the first line medication in this susceptible population.

Lindane has a significant history of associated neurotoxic events, seizures, and deaths, especially when used for repeated or prolonged application due to significant bioaccumulation (Franz, Lehman, Franz, & Guin, 1996). But, these severe reactions have also been documented following a single application per appropriate directions (Bhalla, 2004). Furthermore, it is not known how soon after application of a single dose of Lindane lotion that a second dose can be safely applied (Bhalla, 2004). It is generally thought that infants, children, the elderly, and individuals with other skin conditions and those who weigh less than 50 kg may be at greater risk of serious neurotoxicity (Bhalla, 2004). Other at-risk populations that should generally avoid Lindane include patients with conditions that may increase the risk of seizure, such as HIV infection, history of head trauma or a prior seizure, CNS tumors, the presence of severe hepatic cirrhosis, excessive use of alcohol, abrupt withdrawal from alcohol or sedatives, as well as concomitant use of medications known to lower seizure threshold (Bhalla, 2004). Likewise, there are many drugs that can lower a seizure threshold, including: antipsychotics, antidepressants, theophylline, cyclosporine, mycophenolate mofetil, tacrolimus capsules, penicillins, imipenem, quinolone antibiotics, chloroquine sulfate, pyrimethamine, isoniazid, meperidine, radiographic contrast agents, centrally active anticholinesterases, and methocarbamol (Roos et al., 2001). Lindane should be avoided in patients taking these medications. Similar to other topicals, Lindane is also reported to cause contact dermatitis, as well as more serious adverse effects including alopecia, headache, pain, paresthesia, pruritis, and urticaria (Roos et al., 2001). Because of significant evidence of the risks described above, it is recommended that Lindane only be used in non-pregnant, non-breastfeeding adults who cannot tolerate other approved medications and have failed other scabies treatments (Roos et al., 2001). If prescribed,

proper application involves massaging a thin layer of Lindane 1% lotion into the skin from the neck to the toes, avoiding the head, before bedtime. The medication should be washed off the skin in the morning or no more than 12 hours later and repeat dosing should be avoided.

According to the Commission for Environmental Cooperation (2005), Lindane poses significant risks to human health and the environment due to its role as a potent herbicide and aquacide, it has been banned or limited for human and agricultural use in over 80 countries, including the Dominican Republic, as shown in Figure 2.7. Despite this ban, Lindane is the most commonly drug prescribed, purchased, and used in the Veron area for scabies infections. This contradiction occurs because there is no effective knowledge or enforcement of this ban at the clinic, pharmacy, or consumer level. Furthermore, its effectiveness has been called into question because of reports of widespread resistance in many endemic regions (Bhalla & Thami, 2004; Bigby, 2000; Boffa et al., 1995; Davies et al., 1983; Franz et al., 1996).

Banned	Egypt	Lithuania	Thailand	Canada	Philippines
Argentina	El Salvador	Mexico	Tonga	China	Samoa
Armenia	Finland	Mozambique	Turkey	Colombia	Senegal
Bangladesh	Gambia	Netherlands	Uruguay	Cuba	Spain
Barbados	Georgia	New Zealand	Vietnam	European	Sri Lanka
Belgium	Guatemala	Nicaragua	Yemen	Community	Sudan
Bulgaria	Honduras	Norway		Fiji	Switzerland
Burundi	Hong Kong	Paraguay	States Within	France	Trinidad/Tobago
Costa Rica	Hungary	Peru	U.S.	Germany	United Kingdom
Croatia	Jamaica	Poland	California*	Iceland	USA
Cyprus	Japan	Russia		Ireland	Venezuela
Czech	Kazakhstan	Singapore	Restricted	Israel	Yugoslavia
Republic	Korea, Dem. Rep	Slovakia	Algeria	Italy	
Denmark	Korea, Rep	South Africa	Australia	Madagascar	
Dominican	Lativa	St Lucia	Austria	Moldova	
Republic	Liechtenstein	Sweden	Belize	Morocco	
Ecuador		Taiwan	Brazil	Nigeria	

Figure 2.7
List of countries that ban or restrict the use of Lindane.

2.7 Ivermectin Overview

Current clinical and field research clearly points to oral Ivermectin as the best alternative to topical agents for the treatment of scabies (del Guidice et al., 2003). Ivermectin is an oral semisynthetic antihelmintic/antiparasitic agent developed from the fermentation products of *Streptomyces avermitilis* as a mixture of 90% 5-O-demethyl-22,23-dihydroavermectin A1a and 10% 5-O-demethyl-25-de(1-methylpropyl)-22,23-

dihydro-25-(1-methylethyl) avermectin A1a (del Guidice et al., 2003). This mixture has a chemical formula of C₄₈H₇₄O₁₄ and C₄₇H₇₂O₁₄ and molecular weights of 875.10 and 861.07, respectively (del Guidice et al., 2003). Various pharmacodynamics studies show that plasma concentrations are approximately proportional to the oral dose, with peak concentrations of 46.6 ($\pm$ 21.9) ng/ml for the major component and 30.6 ($\pm$ 15.6) ng/mL for the minor component, respectively, at approximately 4 hours after dosing (del Guidice et al., 2003). Following oral administration, the plasma half-life is 18 hours during which Ivermectin is metabolized in the liver (del Guidice et al., 2003). Almost all metabolites are excreted in the feces over 12 days while less than 1% is excreted in the urine (del Guidice et al., 2003).

As a member of the avermectin class, Ivermectin selectively binds with high affinity to glutamate-gated chloride ion channels in invertebrate nerve and muscle cells, leading to increased cell membrane permeability to chloride ions (del Guidice et al., 2003). This action causes prolonged hyperpolarization, resulting in paralysis and death (del Guidice et al., 2003). Furthermore, Ivermectin may also interact with lower affinity to ligand-gated chloride channels, as seen in the gamma-aminobutyric acid (GABA) neurotransmitter (del Guidice et al., 2003). This class of drugs demonstrates selective activity for non-mammalian glutamate and chloride channels and does not cross the blood-brain barrier, adding to its safety profile in humans (del Guidice et al., 2003).

Multiple eradication campaigns and clinical trials have demonstrated that Ivermectin covers a broad range of intestinal helminthes and ectoparasites, including: hookworm disease (*Ancylostoma duodenale*, *Ancylostoma braziliense*, *Necator americanus*), ascariasis (*Ascaris lumbricoides*), trichuriasis (*Trichuris trichiura*), strongyloidiasis (*Strongyloides stercoralis*), hymenolepiasis (*Hymenolepis nana*), filariae (*Wuchereria bancrofti*, *Brugia malayi*, *Onchocerca volvulus*, *Loa-loa*), *Sarcoptes scabiei*, *Pediculus humanus*, *Demodex follicularis*, and *Cheyletiella* spp (del Guidice et al., 2003; Heukelbach et al., 2004).

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of Ivermectin, but in vitro Ames microbial mutagenicity assays using *Salmonella typhimurium* strains with and without rat liver enzyme activation, Mouse Lymphoma Cell Line L5178Y cytotoxicity and mutagenicity assays, and an

unscheduled DNA synthesis assay in human fibroblasts each demonstrated that the drug is not genotoxic (del Guidice et al., 2003). Further studies have determined that Ivermectin has no adverse effects on the fertility in rats in studies at repeated doses of up to 3 times the maximum recommended human dose of 200 ug/kg (del Guidice et al., 2003).

Reproductive studies with Ivermectin have demonstrated teratogenicity in mice, rats, and rabbits when given in repeated doses of 0.2, 8.1, and 4.5 times the maximum recommended human dose (del Guidice et al., 2003). Because developmental effects were only found at or near doses that were maternotoxic to the pregnant female, Ivermectin does not appear to be selectively fetotoxic to the developing fetus (del Guidice et al., 2003). But, because there have never been adequate, well-controlled studies in pregnant women, Ivermectin is listed as a category C drug (del Guidice et al., 2003). Therefore, Ivermectin should not be used during pregnancy since its safety profile in pregnancy has not been established. Likewise, Ivermectin is excreted in human milk in low concentrations and breastfeeding women should delay treatment if possible to prevent risk to the newborn (del Guidice et al., 2003). Furthermore, safety and effectiveness in children weighing less than 15 kg has not been established, thus Ivermectin should be avoided in this population as well (del Guidice et al., 2003). Despite reports of its safe use in these populations, Ivermectin is currently only recommended in these populations if infection is extreme (del Guidice et al., 2003). Indeed, most studies exclude these populations from mass treatment protocols and divert them into a topical Permethrin 5% regimen (Bigby, 2000; Carapetis, Connors, Yarmirr, Krause, & Currie, 1997; del Guidice et al., 2003; Elgart, 1996; Heukelbach et al., 2004; Lawrence et al., 2005; Nnoruka & Agu, 2001; Roos et al., 2001).

Multiple clinical studies have been conducted on adverse events related to Ivermectin, demonstrating the following complaints in frequencies less than 2%: fatigue, abdominal pain, anorexia, constipation, diarrhea, nausea, vomiting, dizziness, somnolence, vertigo, tremor, pruritis, rash, and urticaria (del Guidice et al., 2003). In general, side effects related to Ivermectin use are considered minor, nonspecific, transient, and rare (Alexander, Bockarie, Kastens, Kazra, & Alpers, 1998; del Guidice et al., 2003).

The recommended dosage of Ivermectin for the treatment of classic scabies is 200 ug/kg once (del Guidice et al., 2003). A second dose may be administered 10 days later in severe cases, such as crusted or Norwegian scabies (del Guidice et al., 2003). Most mass distribution campaigns use a dosing interval of 6 months for prophylaxis, but for individual patients retreatment may be considered at intervals as short as 3 months (Bigby, 2000; Carapetis et al., 1997; del Guidice et al., 2003). Dosing tables based on both weight and height for the treatment of strongyloides and onchocerciasis have been successfully adapted to scabies treatment protocols to improve the efficiency of mass eradication campaigns, as shown in Figure 2.8 (del Guidice et al., 2003).

Weight (kg)	Height (cm)	Ivermectin dose (# 6mg tablets)
< 15	< 90	0
15-25	90-119	1
26-44	120-140	1.5
45-64	141-158	2
> 85	> 158	2.5

Figure 2.8
Weight-to-height Ivermectin dosing conversion chart used to create scabies treatment protocols.

2.8 Ivermectin and Global Eradication Efforts

Since its development and introduction by Merck Pharmaceuticals in 1981, this broad-spectrum antiparasitic drug has been used in one of the largest mass eradication programs in history aimed at onchocerciasis river blindness (Enk, 2006). The Onchocerciasis Control Program (OCP) was created in 1974 in an attempt to eliminate onchocerciasis as a public health problem throughout the 11-most endemic countries in Africa, as shown in Figure 2.9 (Enk, 2006). Its principal tool was vector control using aerial delivery of larvacides to rivers and streams to eliminate the fly larvae that acts as intermediate hosts (Enk, 2006). In 1986, Merck announced the Mectizan Donation Program—a medical compliment to the OCP where Ivermectin would be indefinitely supplied free of charge to endemic countries for mass distribution and treatment (Enk, 2006). This resulted in the OCP being hailed as one of the most successful partnerships in the history of development assistance and community health. This program virtually halted transmission of onchocerciasis throughout the 11-country program area, prevented over 600,000 cases of blindness by the conclusion of the program in 2002, spared 16

million children born since the program's inception from any risk of contracting onchocerciasis, and opened up an estimated 25 million hectares of arable land for resettlement and cultivation (Enk, 2006).

In 1995, the OCP was expanded to address the significant prevalence of onchocerciasis in the remainder of Sub-Saharan Africa, leading to the development of the African Program for Onchocerciasis Control (APOC) (Enk, 2006). This second program extended Ivermectin coverage to 19 other African countries with the goal of treating over 50 million people per year, as shown in Figure 2.9 (Enk, 2006). This expansion resulted in the development of a sustainable, community-directed Ivermectin delivery systems, thereby empowering grassroots communities to take responsibility and ownership for controlling the disease. In 1996, The Carter Center lead a coalition of partners dedicated to expanding this cause into Central and South America known as the Onchocerciasis Elimination Program of the Americas (OEPA), as shown in Figure 2.9 (Enk, 2006). Together, these programs were estimated to reach over 65 million people in 2007, administering over 50 million doses of Ivermectin with remarkable safety and efficacy (Enk, 2006).



Figure 2.9 [used with permission from World Health Organization]
Worldwide mass eradication campaigns for onchocerciasis.

The worldwide success of large-scale onchocerciasis eradication efforts using Ivermectin has been the basis for its application to other preventable parasitic diseases. In 1999, researchers began using Ivermectin for the mass control of scabies in a resource-poor community in Papua New Guinea (Bockarie, Alexander, Kazura, Bockarie, Griffin, & Alpers, 2000). While previous mass scabies control campaigns had been attempted in the past using various topical lotions and creams such as Permethrin, Lindane, and Benzoate, this was the first program to use, by comparison, a simpler, safer, compliance-

free, broader-spectrum, longer-lasting oral medication (Bockarie et al., 2000). Promising results from this study prompted other similar efforts in Nigeria, the Solomon Islands, Aboriginal Australia, and Brazil, each obtaining similar results (Alexander et al., 1998; Bigby, 2000; Bockarie et al., 2000; Buffet & Dupin, 2003; Chambliss, 2000; Chouela et al., 1999; del Guidice et al., 2003; Elgart, 1999; Heukelbach et al., 2004; Johnston & Sladden, 2005; Karthikayan, 2005; Leppard & Naburi, 2000; Madan et al., 2001; Nnoruka & Agu, 2001; Roos et al., 2001; Walker & Johnstone, 2000). Indeed, each of these studies demonstrated that oral Ivermectin is as effective as all the topical agents for the treatment of scabies, without any issue of application or compliance, very few side effects, or documented cases of resistance in humans. Furthermore, Lawrence et al. (2005) showed that mass treatments with Ivermectin also decrease secondary scabies disease sequelae, including: Group A Streptococcus skin colonization levels (as a marker for skin abscess formation) and hematuria levels (as a marker for post-Streptococcus glomerulonephritis kidney disease). Likewise, Heukelbach et al. (2004) demonstrated that, due its broad spectrum of coverage, oral Ivermectin is ideal for scabies mass eradication campaigns in communities that exhibit endemic or epidemic levels of co-infection with gastrointestinal parasites. This phenomenon, known as polyparasitism, is common throughout the developing world, including the Dominican Republic (Heukelbach et al., 2004; Sutherland, 2007). Collectively, these studies reported that one oral Ivermectin dose of 200µg/kg resulted in a sustained scabies reduction for 6 and 9 months when compared to baseline (Chouela et al., 1999; Elgart, 1996; Lawrence et al., 2005; Madan et al., 2001).

Each of these programs occurred in community settings that perpetuate scabies infection, each very similar to that of Veron. These community similarities include: overcrowding and poor living conditions associated with poverty, increased temperatures and humidity producing a favorable climate for parasite breeding, personal behaviors such as sleeping and sexual habits, restricted access to health care, treatment failures due to poor compliance, and ineffective drug therapies. Recognizing these preventable factors, the scientific community expanded Ivermectin research to include scabies outbreaks in institutional settings, such as hospitals, nursing homes, and prisons (Leppard & Naburi, 2000). Once again, these studies showed a rapid yet long-term statistically

significant reduction in scabies prevalence and incidence with no significant adverse events (Leppard & Naburi, 2000).

Indeed, throughout the literature there is a call for the increased use of oral Ivermectin for scabies eradication efforts due to its cost-effectiveness, reliable disease control, breadth of coverage, and safety profile. But, these recommendations always emphasize the need for improved community prevention and education programs in addition to medication use for better sustainability and long-term results (Bockarie et al., 2000; Carapetis et al., 1997; Chouela et al., 1999; Heukelbach et al., 2004; Lawrence et al., 2005; Nnoruka & Agu, 2001). In fact, researchers voice significant doubts that any scabies mass eradication effort can succeed in the long-term without placing equal emphasis on improving community health knowledge and education regarding scabies disease recognition, treatment, and prevention (Bockarie et al., 2000; Carapetis et al., 1997; Chouela et al., 1999; Heukelbach et al., 2004; Lawrence et al., 2005; Nnoruka & Agu, 2001).

2.9 Health Education Overview

Health education is an essential component to health promotion and disease prevention. Throughout both the developed and developing world, health education serves as the foundation for the public health system: from maternal and child health campaigns, to communicable disease prevention, to immunization promotion and delivery (Kickbusch, 2001). While all of these services hinge on the transmission of correct information, it is the understanding of relationships and novel applications within this process that have allowed great advancements in health promotion (Kickbusch, 2001). More than ever, the social and economic circumstances of the target population are a key determinant of how programs are developed and tailored to reach their goals (Kickbusch, 2001). This strategy comes as a result of many health education programs throughout the 1970's that were found to only achieve program goals among the most economically advantaged and educated within the community (Kickbusch, 2001). The 1980's saw significant increases in health promotion and education theories, such as the Theory of Planned Behavior and Social Learning Theory, which focused on health behavior within a social context and how people develop and maintain positive health behaviors

(Kickbusch, 2001). It was also during this time that school-based health education became a mainstay in the overall education system (Glanz, Rimer, & Lewis, 2002). What became obvious during this time was the complex relationship between knowledge, beliefs and perceived social norms as it related to health and health behaviors (Glanz et al., 2002). These observations, in turn, became the basis for the marriage of social marketing theory to health promotion as an effective strategy to influence social norms and behaviors on the population level (Andreasen, 1995). Indeed, Social Marketing Theory became an important tool for health education because it focused on how health information is communicated, especially in unique or at-risk populations (Andreasen, 1995).

But, despite these advancements and efforts related to health behavior change, the health status gap between differing socioeconomic groups remains wide (Kickbusch, 2001). What accounts for this? It is now known from recent epidemiological analyses of health and disease markers that health status is influenced by something more complex—an amalgam of individual characteristics and behavioral patterns significantly determined by the social, economic, and environmental circumstances of individuals and populations (Kickbusch, 2001). Researchers agree that making this observation is relatively easy, but acting on it appropriately is the challenge of health promotion (Kickbusch, 2001). This is the gap that needs to be bridged so that health promotion interventions and health modifications are connected. A key component of this bridge remains, more than ever before, health education and communication—collectively known as health literacy (Kickbusch, 2001).

2.10 Health Literacy

The term health literacy has been used for at least 30 years to describe the relationship between patient literacy levels and their ability to comply with a therapy regimen (Ad Hoc Committee on Health Literacy, 1999). Today, the term has significantly expanded to include basic or functional literacy, communicative or interactive literacy, and critical literacy (Nutbeam, 2000). Basic or functional literacy refers to the basic skills needed to read and write and perform necessary activities of daily living (Nutbeam, 2000). Communicative or interactive literacy refers to the more

advanced cognitive and social skills needed to extract, derive, and apply information to changing situations (Nutbeam, 2000). Critical literacy refers to the ability to critically analyze information to successfully control certain events and situations (Nutbeam, 2000). These definitions display a progression toward greater health autonomy, and are influenced by both individual cognitive ability and initiative and the communication contents and methods of the health intervention (Nutbeam, 2000).

It is the challenge of health promotion to provide a framework for this progression so that the social, economic, and environmental determinants of health are recognized in a way that individual and collective actions can lead to positive modifications (Nutbeam, 2000). In populations with inadequate fundamental literacy, the method of education is critical so that interaction, participation, and assimilation can occur (Nutbeam, 2000). Freire (1988) demonstrated this concept by creatively sidestepping reading and writing deficiencies in an attempt to elevate the critical health consciousness of functionally illiterate populations.

Nutbeam (2000) describes a health literacy model using the 3 definitions above that is based on 4 dimensions: the educational goal, the content of a particular activity, the expected outcome, and potential health worker actions. Level 1 involves developing functional health literacy of the individual using traditional health education to communicate facts and figures on health risks and how to navigate the health care system (Nutbeam, 2000). This level is typically focused on basic knowledge of risks and health services more than interaction, skills development, or promotion of autonomy (Nutbeam, 2000). Level 2 involves developing interactive health literacy so that the individual can act independently on health advice via improved motivation and self-confidence (Nutbeam, 2000). Level 3 involves developing critical health literacy on the population level so that individual action translates into improved social and political health changes (Nutbeam, 2000). This level represents personal autonomy and the ability to create positive health changes on the individual and population level by addressing the social, economic, and environmental determinants of health (Nutbeam, 2000). Overall, this model provides an effective framework by which health literacy campaigns can be built and implemented.

2.11 Dominican Republic Demographics

The following demographics information is direct quotes taken from the 2000 Pan American Health Organization survey and census of the Dominican Republic:

The Dominican Republic, as shown in Figure 2.10, occupies the eastern side and 74% of the territory of the island the Hispaniola, that it shares with Haiti, located between the Caribbean Sea the Atlantic Ocean. The country comprises 48,442 km², 30 provinces plus the National District.



Figure 2.10 [public domain]
Location of the Dominican Republic within the Caribbean.

Demography: The population of the Dominican Republic in 2000 was estimated at 8,396,164, with a population density of 173.3 inhabitants per km².

Economy: The economy was based on agriculture for decades, but mining began to gain importance (ferronickel, gold and silver) in the 1970s. There was also a fast development of free export industry zones and tourism. Through free trade agreements, a greater commercial integration to the Caribbean and Central America was achieved. The growth of GDP in 2000 was 6.8% (GDP per capita was US\$ 1,887 in 1999). In 1998, Hurricane Georges caused losses estimated at US\$ 2,024 million. In the period 1996-1999, social spending as a proportion of public expenditure averaged 39% (6 % of GDP), while public investment in social development (health, education and social welfare) represented 5% of GDP. In

1998, 25.8% of the population was below the poverty line (US\$ 60 per capita monthly). In 1999, 66.5% of the poor lived in cities. There is a great heterogeneity in poverty between regions of the country. In 1996, more than 75% of the poor households were located in two regions: Enriquillo and El Valle.

Education: In 1998, the literacy rate was 84.4% in adults over 15 years of age. Illiteracy is almost three times higher in rural than urban areas.

Mortality: The estimated crude mortality rate for 1995-2000 was 6 per 1,000; however, under-registration is believed to be as high as 42%. In 1998, 83.8% of deaths were physician-certified. In the same year, registered mortality by age was: 1-4 years, 2.4%; 5-14 years, 2.1%; 15-49 years, 23.8%; 50-64 years, 16.3%; and 65 and over, 43.9%.

Analysis by population group

Children (0-4 years): The estimated infant mortality rate was 40 per 1,000 live births (lb), 1995-2000. Under-registration of deaths in infants was estimated at 60% in 1998. In that year, conditions arising in the perinatal period accounted for 64.5% of infant deaths, communicable diseases 13%, and acute diarrheal diseases, 9.4%. Communicable diseases constituted the leading cause (40%) in the group 1-4 years of age, followed by external causes (24.6%). In 1999, the leading causes of morbidity in infants were acute respiratory infections (668.8 per 1,000 lb), acute diarrheal diseases (329.3 per 1,000 lb), and parasitoses (138.5 per 1,000 lb). The leading causes of morbidity in children 1-4 years were acute respiratory infections (221.2 per 1,000 population) and acute diarrheal diseases (69.4). According to the 1996 ENDESA survey, the prevalence of chronic malnutrition in children under 5 years was 10.7%. Age groups most affected by dengue in 1999 were infants (45.2 per 100,000 children) and children 1-4 years (28 per 100,000).

Schoolchildren (5-14 years): External causes and communicable diseases are the leading cause of death. The rate of dengue notified for 1999 in children from 5-9 years was 27.3 per 100,000 and in those of 10-14, of 18.4 per 100,000.

Adolescents (10-19 years): The estimated fertility rate in adolescents 15-19 years was of 87 per 1,000 in urban areas and 160 per 1,000 in rural areas.

Adults (15-59 years): In 1998, mortality among those 15-59 years of age was 14.4 per 1,000 and the most frequent causes of death were external causes (36.2%) and communicable diseases (20.7%), due mainly to an increase in mortality from AIDS and tuberculosis. In 1998, among those 50-64 years of age, diseases of the circulatory system were the leading cause of death (37.7%), and neoplasms (18.3%). The highest fertility rate occurred in the age group 20-24 years, with 199 births per 1,000 women. The total fertility rate was 2.3 births per woman. Contraceptives were used by 85% of women of childbearing age. In 1996, 98.5% of pregnant women had a prenatal visit, 98% being seen by a physician. The maternal mortality rate was 80 per 100,000 live births in 1999; the leading causes were toxemia, hemorrhage, and sepsis.

Elderly (60 years and over): The leading causes of death in 1998 were diseases of the circulatory system (52%) and neoplasms (15.7%). There is a network of homes for the elderly but the majority operates in precarious technical and financial conditions.

Family Health: In 1996, heads of households were women in 27% of homes. Eight percent of households were comprised of only one person. The majority of children under 15 (56%) lived with both parents, while 14% lived with neither parent.

Workers' Health: In 2000, there were 6,083 occupational injuries, the majority occurred in the manufacturing industry, primarily construction. Hospitalization was required for 77% of the injuries. There were 1,504 cases of occupational disease, heavy metal poisoning (14.8%), hypertension (14.7%) and low-back pain due to exertion (12.6%).

Population at the border: The country's greatest concentration of poverty is located along the entire area bordering Haiti. Some of the unmet basic needs are related to housing; overcrowding; wastewater and solid waste disposal, and access to potable water.

Analysis by type of health problem

Natural disasters: The country is exposed to hurricanes by its geographical location and to earthquakes by the proximity to a geological fault. The most

frequent natural disasters are floods. Hurricane Georges in 1998 had the most negative economic impact in recent years, when rains affected the entire population, causing 239 deaths and the destruction of 49,000 dwellings.

Vector-borne diseases: In 2000, there were 1,233 cases of malaria, with a slide positive index of positive of 0.21 and an annual parasite index of 14.7 per 100,000. There is endemic transmission of malaria in 36 municipalities of 6 provinces, linked to the cycles of crop production, and epidemic outbreaks linked to the construction industry. Dengue is endemic in the country; 3,462 probable cases were reported in 2000, 798 confirmed (23%), of which 58 corresponded to dengue hemorrhagic fever, with six deaths. Since July 2000, serotype 3 predominated. Indices of infestation by *Aedes aegypti* were high in urban areas (60%). Frequency of filariasis was low, but there was a control program including massive treatment of the population, once a year.

Vaccine-preventable diseases: In October 2000, an outbreak of poliomyelitis, caused by a poliovirus derived from the vaccinal virus Sabin type 1, was detected. Between July 2000 and June 2001, 104 cases of acute flaccid paralysis (3.4 per 100,000 children under 15) were detected, with 14 confirmed cases. National coverage with three doses of OPV in children under 1 year was nearly 80% in the last five years, but in Constanza, the municipalities where most cases were detected, the coverage had been between 20 and 30%. In 1997, a case of measles was confirmed. In December 1998, an outbreak in the east of the country lasted two years (14 cases confirmed in 1998, 274 in 1999 and 253 in 2000).

Vaccination coverage against measles in children under 1 year in 1997 and 2000 varied from 80 to 95%. Between 1997 and 2000, 145 cases of diphtheria were detected, with 36 deaths. Eighty-two cases and four deaths of whooping cough were recorded, 1997-2000. In 2000, 4 cases of neonatal tetanus were reported; 102 cases of non-neonatal tetanus were reported, 1997-2000. Vaccination against rubella had not been introduced into the Dominican Republic and in 2000, 346 cases of rubella were confirmed. There has been an annual incidence of *Haemophilus influenzae* type b (Hib) of 14 per 100,000 in children under 5 in the National District, 1998-1999; vaccination was started in 2001. The vaccination

coverage with third dose for hepatitis B in children under 1 year was 68% in 1999.

Intestinal infectious diseases: A 1999 survey showed that 65.5 % of schoolchildren were infested with *Blastomyces hominis* (27%), *Entamoeba coli* (26.7%) and *Giardia Lamblia* (17.7%), among others.

Communicable chronic diseases: Tuberculosis presented an incidence rate in the year 2000 of 62.4 per 100,000, with major variations among the provinces. The case rate with positive microscopic examination was 34.3 per 100,000 population. It was estimated that in 1999 only 60% of the cases were detected and that only 49.6% of them were cured. In 1999 the directly observed treatment (DOTS) was initiated. Leprosy has been reduced considerably and in 2000 the incidence was less than 3 cases per 100,000.

Zoonoses: Rabies is the most important zoonoses. 12 human cases were reported, 1990-1997, but none between 1998-2000. National coverage of canine vaccination has been very low; 1999 (27%) and 2000 (less than 5%). Cases and small outbreaks of leptospirosis were confirmed and infections were reported by toxoplasmosis in pregnant women in some areas of the country.

HIV/AIDS: The annual incidence of reported cases of HIV/AIDS declined from 6.4 to 3.9 per 100,000 (high underreporting is assumed), 1995-1998. In 1998, AIDS represented 3.7% of diagnosed mortality at the national level. The transmission was heterosexual in 80% of cases.

Sexually transmitted infections: According to surveys, estimated incidence of syphilis in women was 300 per 100,000; genital ulcers, (2,300); genital herpes, (900); and chlamydiosis, (620).

Nutritional and metabolic diseases: Low birth weight was recorded as 7.3%; a survey in 1996 found that 90% of children received breast-feeding at birth; acute malnutrition in children under 1 year attending health facilities was 0,75% in 1999, but deficit of height-for-age in schoolchildren was close to 20%. Micronutrient Surveys within children under 15 showed deficiencies: iron, 30%; iodine, 74%; vitamin A, 19%. Diabetes is a growing problem, representing 4.2% of deaths in 1998.

Diseases of the circulatory system: Prevalence of hypertension in adults was estimated at 24% nationwide. In 1998, the leading causes of mortality in the general population were: ischemic heart disease, 11.3 % (19.8 deaths per 100,000 population) and cerebrovascular diseases, 8.8%, (15.5 deaths per 100,000).

Malignant neoplasms: In 1998, malignant neoplasms represented 13.1% of registered deaths. Most frequent sites were prostate (1.9% of the total of deaths), other digestive organs, and peritoneum (1.8%), trachea, bronchia, and lungs (1.4%), stomach (0.9%), breast (0.8%), colon (0.6%), and cervix (0.5%).

Accidents and violence: Accidents and violence represented 19.5% of deaths in 1998. The mortality rate from accidents was 24.8 per 100,000; homicide, 8.2. Between 1986 and 1998 the suicide rate tripled, reaching 7.5 per 100,000 in 1998.

Emerging and reemerging diseases: In 1999, the mortality rate for meningococcal disease was of 2.3 per 100,000, with highest risk in those aged 9 years. Nearly 600 probable cases of bacterial meningitis were detected per year in the National district (50% confirmed).

Response of the health care system

National health policies and plans: As part of State modernization, 1996-2000, decentralization was a main orientation, as well as availability of services and drugs; actions were taken to face problems of coverage, organization, management and quality of services. A set of strategies based on primary care and democratization was addressed to improve equity with respect to access to services.

Health sector reform: In 1997, a framework was established for the management of health sector reform under six principles: universality, equity, comprehensiveness, solidarity, participation, and sustainability. In 1996-2000, a process of decentralization of the Ministry of Health and hospital management began; a new model of care was established, with emphasis on the first level care; standards of care were formulated; and health promotion strengthened. The Social Security Reform Law established the separation of financing, care delivery, and insurance, creating a compulsory basic universal health insurance plan. The General Health Law regulates the leadership role of the Ministry of Health.

Modernization of procurement, inventory, and distribution of drugs and medical supplies has been proposed to better meet the needs of providers.

The health system: The health system comprises two subsectors, the public subsector (insurance and provider institutions of nonprofit and for-profit services, governed by the General Health Law) and the private subsector (nonprofit and for-profit). The Ministry of Health provides leadership for the system and provides services to 75% of the population, most of whom are uninsured (care is free but with no guarantee of access or quality). The private sector provides services mostly to the upper-economic strata. Types of insurance include worker-employer prepayment schemes (such as the Social Security Dominican Institute), prepaid private health insurance, self-managed insurance and private providers.

Organization of regulatory actions: Standards of accreditation, regulations and good practices have been established for health facilities, laboratories and pharmaceutical companies, although regulatory processes are still needed to improve the quality of care, quality control and biosafety. The Bureau of Drugs and Pharmacies in the Ministry of Health is responsible for the evaluation, registry, and control of drugs. Between 1996-2000, the physical infrastructure of the health services network was improved and expanded, both in the public and private sectors with the introduction of new technologies. Strengthening of environmental action is carried out through primary environmental care. In the year 2000, the General Law on Environment and Natural Resources was promulgated.

Organization of public health services: Health promotion: In 2000, the General Law on Youth and the Law on Tobacco Use were enacted, and the Law of Traffic was amended to require seat belts. Between 1995-2001, the Bureau of Health Promotion and Education and the Department of Healthy Municipalities were created to initiate strategies on health promotion. The Secretariat for Health created the Comprehensive Adolescent Care Program, that in 2000 offered 37 specialized services and 5,000 organized adolescent "multipliers" who promote health in the community. Disease Prevention and Control: Maternal and child care are the most advanced Integrated Management of Childhood Illness and the

Expanded Program of Immunization; vector-borne diseases; zoonoses, tuberculosis, leprosy, and AIDS/STI. More than 100 community organizations participated to reduce maternal and child mortality. Health analysis and epidemiological surveillance: The General Bureau of Epidemiology has the normative responsibility for a decentralized surveillance system (a component for early warning and one prevention and control). At the central level, it includes units of surveillance, health situation analysis, and computer support. Potable water, sewerage, and management of solid waste: Potable water and sanitation are the responsibility of the National Potable Water and Sewerage Institute. Services in the communities are the responsibility of more than 20 associations of rural water supply systems. In 2000, 71.4% of the population had drinking water services. The coverage of excreta disposal systems was 89.5%, while coverage of sewerage services was only 20.1%. Air pollution prevention and control: Air pollution prevention and control is under the responsibility of the General Health Directorate and Environment of the Ministry of Health, with programs on education, prevention, and training in air quality.

Organization of individual health care services: The public subsector (administered by the Secretary of Health) is organized at four levels of management, central, regional, provincial and local. Health services are organized in three levels of care: primary care (1,099 ambulatory establishments; 474 are rural), secondary care (126 establishments with five basic specialties), and tertiary care (42 specialized hospitals). Furthermore, the Dominican Institute of Social Security and the Armed Forces have health care facilities of diverse complexity. During the period 1996-2000, mental health services were expanded. At least 10 hospitals incorporated beds for mental health patients, and 5 crisis intervention units, community centers and 1 daytime care hospital. Care of persons with disabilities is provided in more than 310 establishments, in public and private centers of health care. There are many clinical laboratories, some of them of great complexity, where quality has increased progressively. The state offers free oral health services, especially those of preventive character and those of low complexity and cost, with emphasis on maternal and child population.

Health inputs: The country has 51 hospital pharmacies, 1,937 community pharmacies, 740 popular drugstores, 100 national laboratories that produce drugs, and 682 warehouses for storage and distribution. In 2000, 70% of the products were imported.

Human resources: In 2000, the country had 15,679 physicians (19 per 10,000 population), 2,603 professional nurses (3 per 10,000), 12,749 auxiliaries or technical personnel of nursing (15 per 10,000), 7,000 dentists (8 per 10,000), and 3,346 trained pharmacists. There were several universities for health professionals, recognized by the National Board of Higher Education: 9 schools of medicine, 6 schools for training nurses and technicians, 7 for dentists, 4 for pharmacists. The number of nurses that graduates from the university (70 per year) is very low relative to country's needs. Fifty- three medical residency programs are carried out in 15 teaching hospitals with 20 specialties and six subspecialties. Four universities offered five public health-related programs and five had master's degree public health programs

Health research and technology: Most research has been carried out in the Maternal and Child Health Research Center. There are a growing number of institutions that offer access to technical literature through the Internet. There is a Virtual Health Library, but less than half of the eight libraries in the Hospital Library Network have access to Internet.

Expenditure and sectoral financing: In 1996, the total expenditure per capita in health was US\$ 111 (6.5 % of GDP) and as there were no significant structural changes between 1996 and 2000, it was assumed that the level remained stable over the period. The private sector finances the majority of health costs - 55% come directly from households, 75% of which have no insurance nor pre-payment mechanisms. The public sector allocates 64.5% of its budget to wages. The budgetary execution for the Secretary of Health in 1999 was 80%.

External technical and financial cooperation in health: International cooperation continues to be very active, where PAHO, UNICEF, UNDP, UNPF, FAO, and UNAIDS stand out. In regard to bilateral aid, USAID has committed US\$ 25 million for 2000-2004 and the European Union initiated a four-year

project of EU\$ 13.5 million, in 2000. Also, many nongovernmental organizations collaborate in local projects. The World Bank and the IDB finance two projects related to decentralized health management.

2.12 Veron Demographics

Veron can be described as a developing village on the eastern most tip of the Dominican Republic's La Altagracia province, as shown in Figure 2.11. It consists of roughly 8,000-10,000 inhabitants, most of which living well below the poverty line. The community is a product of coastal tourism developments that relocated previous fishing communities inland in exchange for housing and schools. The area is continually being developed, both by large tourism enterprises and local inhabitants. In this regard, Veron is sprawling and transitory, constantly under construction following a loose infrastructure and developmental plan. Most inhabitants of Veron work for the various construction or tourism entities in the area, as motorcycle or car taxis, or in local stores and food stands. All public utilities, including roads, water, sewage, and electricity, are in a constant state of repair to accommodate the area's rapid expansion and demand. The Veron public clinic supplies health care to the greater area and has begun collecting important health data on the area.

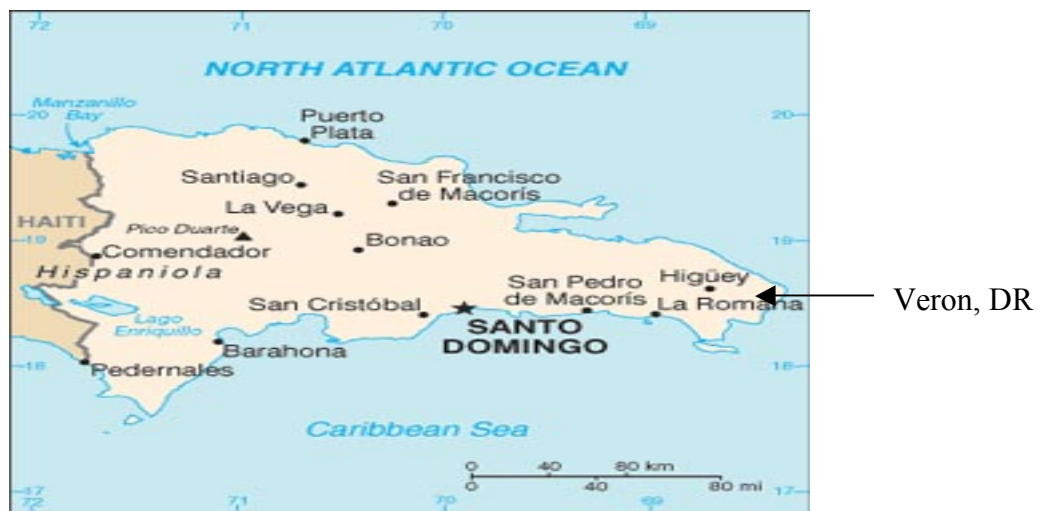


Figure 2.11 [public domain]
Map of the Dominican Republic with the location of Veron indicated with an arrow on the far-eastern tip of the island.

Sutherland (2007) conducted a survey of 800 Veron clinic patient files between September 2006 and May 2007. The report showed that 69% of patients were female, 39% male, 31% between 0-5 years of age, 14% between 26-30, and 12% between 21-25. Over 90% of patients neither drank alcohol nor smoked cigarettes. As shown in Figure 2.12, the most common diagnosis was viral upper respiratory illness (17%), followed by intestinal parasitosis (9%), scabies (6%), intrauterine pregnancy (5%), urinary tract infections (5%), gastritis (5%), *Streptococcus* pharyngitis (4%), *Tinea* fungal infections (3%), hypertension (2%), pelvic inflammatory disease (2%), low back pain (2%), other musculoskeletal pain (2%), trauma (2%), lacerations (1%), otitis media (1%), skin abscesses (1%), and the remaining 33% divided between 40 other diagnoses, each less than 1% of the total population surveyed.

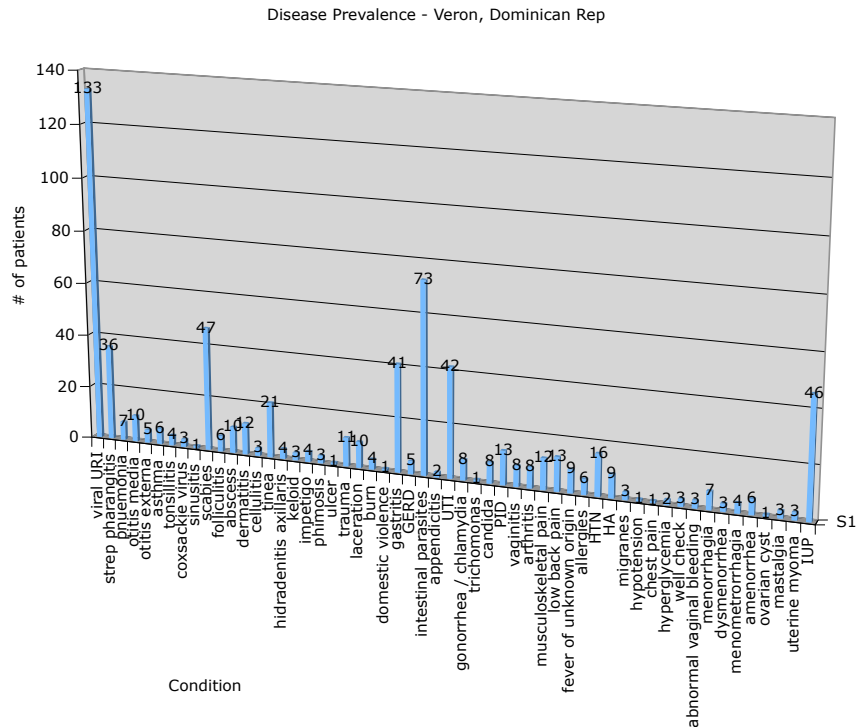


Figure 2.12 [chart courtesy of James Sutherland]
Disease prevalence survey of 800 Veron clinic patient files between September 2006 and May 2007.

Chapter 3

Methods

3.1 Rationale

The Veron Scabies Eradication and Education Program is a two-part program consisting of a medical treatment arm and a community education arm designed to effectively accomplish research objectives. Overall, the program was designed as an attempt to control highly endemic scabies in a practical, field setting by treating and educating an entire population at once, then following the population over time as they conduct their normal activities and habits. The underlying principle of this approach was to treat of as many as possible in the selected population to eliminate as many scabies parasites and potential hosts as possible. Likewise, households were provided the same scabies health education lesson as an ethical and medical standard of care for disease intervention. In keeping with this approach, pre-intervention scabies disease and education markers acted as the control by which systematic time interval measurements were compared.

3.2 Setting

The target population exists within Barrio Nuevo—a prototypical neighborhood located in the center of Veron, Dominican Republic. It is delineated by three main streets, each roughly 300m in length, which are connected by three cross streets, each roughly 100m in length (Figure 3.1). The neighborhood is surrounded by industrial developments or agricultural fields, making it somewhat isolated from other neighboring inhabitations. Most homes are strung together from scrap plywood and aluminum siding, with a few brick one-room homes and apartments at various locations in the neighborhood (Figure 3.1). These edifices typically have dirt floors, one light socket, and perhaps one electric outlet, and consist of one simple room with a curtain separating a bed (typically a twin or full mattress shared by 3 or more people) and the eating/cooking area. There are pit outhouses for every 6+ homes. A few neighborhood faucets supply cold, unfiltered water for bathing and cleaning purposes. Drinking and cooking water is purchased in plastic bags or bottles. Propane is the cooking fuel of choice, as most meals contain beans, rice, and perhaps fried meats and vegetables. The neighborhood roads

consist of dirt and rock that contain permanent craters full of stagnant water from the near-daily rain showers (Figure 3.1). Therefore, Barrio Nuevo is mostly traveled on foot, as vehicles must navigate the treacherous roads slowly and with caution. As illustrated in Figure 3.1, Barrio Nuevo is crowded, haphazard, and unsanitary.



Figure 3.1 [maps used with permission from Google]
location of Barrio Nuevo within Veron (top), one of two main streets in Barrio Nuevo (upper middle), trash disposal in Barrio Nuevo (lower left), typical cluster of homes in Barrio Nuevo (lower right).

3.3 Population

The target population was the neighborhood of Barrio Nuevo, which consisted of an estimated 300 households and 1000 inhabitants who represent a section of Veron and whose scabies exposures, risk factors, and responses to interventions are assumed to be generalizable to the greater Veron population. Based on selected risk factors there are apparent similarities to other areas of the developing world, as shown in Figure 3.2. These risk factors include: rampant poverty, overcrowding, poor hygiene practices, significant person-to-person contact, frequent bed and clothes sharing, little separation of animals and humans, limited access to health care, and decreased health literacy.



Figure 3.2

A typical scene in Barrio Nuevo, illustrating multiple environmental and health risk factors.

3.4 Sampling

The population residing within Barrio Nuevo was surveyed door to door and treated in an effort to create mass prophylaxis against the scabies mite. It was important to treat as much as possible a census of the population within Barrio Nuevo instead of via random selection because the goal was to protect all potential human hosts from ectoparasite infections in the target population.

3.5 Instrumentation

Quantitative data for the Veron Scabies Eradication and Education Program was collected using standardized medical diagnosis criteria for scabies, including: obvious excoriations from itching, burrow lines, pruritic vesicles, pruritic papules, healing or scabbed pruritic lesions, pruritic abscesses, obvious scars from past itching or lesions. Qualitative data was collected using researcher-subject oral interviews door to door, which was important because a significant portion of the Barrio Nuevo community members is illiterate.

All Ivermectin was acquired from Calox Laboratories in Santo Domingo, DR as 6mg tablets in sealed blister packs. All Permethrin was acquired from the SESPAS Dermatologic and Skin Surgery Institute in Higuay, DR as 5% lotion in 60 gram plastic bottles. All β -HCG urine pregnancy tests were acquired from BioMedica Laboratories in Santo Domingo, DR as individual urine dipsticks sealed in plastic pouches. Each of these products came from pharmaceutical companies that conduct in-house quality control and assurance testing per drug and medical device licensing and distribution law requirements. Deferring to these standards, no further product testing was conducted for the Veron Scabies Eradication and Education Program.

All scabies education instruments were developed by first evaluating multiple existing scabies information guides and pamphlets for general population and patient distribution from Medline, the World Health Organization, the American Academy of Dermatology, and other public health entities. While the Medline educational tool offered a succinct, interactive, visual-verbal scabies lesson, it was exclusively internet-based and not appropriate for a door-to-door field campaign. All other educational tools were mostly text-based with relatively limited pictures or pictographs. Because a large number of illiterate people live in Barrio Nuevo, these tools would also not be appropriate. In light of these observations, it was decided that an in-house lesson needed to be created to achieve educational goals.

The primary investigator developed an educational tool that revolved around a simple, interactive lesson on the basics of scabies disease, signs, symptoms, treatments, prevention strategies, and Veron clinic access and services. This was achieved using a combination of tools to supplement a visual-verbal based lesson, including: learner

handouts, pictures, pictographs, human models, and household items. The lesson plan was developed and honed using adapted methodologies from the Virginia Tech Department of Education Instructional Design curriculum. This approach yielded a set of objectives and test items and their accompanying learner and conditions requirements, as well as the learning domain the objective achieves (Appendix B). These items were used to develop a formal lesson discussed below to be delivered to each subject and to test scabies education hypotheses using standard pre-test/post-test methodology.

All printed educational materials were designed by the primary investigator using Microsoft Office software, submitted to a Veron clinic physician for revision and translation, and pilot tested on a series of clinic patients for feedback and further revision. The next draft was then used door-to-door for one day in Barrio Nuevo to test for content, portability, and efficiency. These results were applied to a final revision so that a final draft could be submitted for bulk printing and distribution.

All medical personnel involved in the study were trained by the primary investigator to use each instrument by the protocol described below to minimize threats to interval validity and maximize inter-rater reliability.

3.6 Scabies Education Protocol

The educational instrument was developed as described above and administered within each household so that subjects could learn and apply the lesson to their everyday environment. This approach also allowed medical educators to demonstrate certain concepts by using various household items and highlighting scabies lesions if discovered. The lesson consisted of an oral dialogue and visual teaching aids (Appendix C) that delivered the following basic scabies information to each participant in Barrio Nuevo:

1. Scabies is a common skin infection in Veron and Barrio Nuevo.
2. Scabies is caused by a parasite.
3. This parasitic burrows into the skin and causes intense itching, discomfort, and various skin lesions.
4. Scabies is easily spread to others via clothes, bedding, and personal contact.
5. If not treated, scabies can cause other health problems, including heart infections, kidney infections, and skin abscesses.

6. Scabies can be easily treated with the right medication, including Ivermectin pills and Permethrin 5% lotion.
7. The proper use of Permethrin 5% lotion is as follows: apply a thin layer to the entire body, excluding the head, before bedtime, wash off 8-12 hours later.
8. Proper medications will be given to you today and are also available at the Veron public clinic, as is most other medical services for you and your family. The clinic is located ½ mile past the gas station on the right when driving toward Punta Cana. It is open 9am to 5pm for general care and 24 hours for emergencies.
9. Three ways that scabies can be prevented include: increased bleach and hot water use for cleaning clothes and bedding, decreased clothes and bed sharing with others who have scabies, and decreased skin contact with animals and others who have scabies.
10. As stated before, scabies and other medical problems can always be cared for at the Veron public clinic. If you have further questions or need help, please visit the clinic.

Once this lesson was delivered to each household at baseline, post-tests were repeated at each measurement interval as a marker of post-intervention scabies knowledge and health literacy as the population carried on with normal life, interactions, and habits.

3.7 Scabies Treatment Protocol

Treatments were administered using the following indications: all males age 5 and older, taller than 90cm, and with no known allergies to Ivermectin were given 200µg/kg of oral Ivermectin dosed by height (Figure 3.3).

Height (cm)	Ivermectin dose (# 6mg tablets)
< 90	0
90-119	1
120-140	1.5
141-158	2
> 158	2.5

Figure 3.3: Dosing table for Ivermectin 6mg tablets based on subject height in cm.

All females age 5 or older, taller than 90cm, and with no known allergies to Ivermectin were given 200µg/kg of oral Ivermectin dosed by height if currently menstruating, able to show proof of using oral contraceptives (birth control pills) or injectable contraceptives (scheduled Depo Provera), or surgically sterile (hysterectomy or tubal ligation).

If the female subject was of childbearing age (still menstruating on a monthly basis), not currently menstruating, not able to show proof of using oral contraceptives (birth control pills) or injectable contraceptives (scheduled Depo Provera), and not surgically sterile (hysterectomy or tubal ligation) they were asked to undergo a rapid urine pregnancy test. If the test was negative they were given 200µg/kg of oral Ivermectin dosed by height.

If the subject was a female who was knowingly pregnant or lactating or who took the rapid pregnancy test that was positive, or a child shorter than 90 cm with no known allergies to Permethrin they were instructed on how to properly use Permethrin 5% lotion and given a 60gm bottle.

3.8 Protocol Overview

The Veron Scabies Eradication and Education Program population data was obtained via door-to-door visits within the Barrio Nuevo neighborhood to survey and treat every inhabitant, unless there was refusal or an absolute contraindication.

Subjects were first informed of the program and its intent, asked to sign a letter of patient confidentiality (Appendix D), and assigned a number identifier for tracking purposes. After consent was obtained, a medical professional collected information on subject demographics, scabies-related past medical and social history, scabies-related current medical history, and skin examination findings, as shown in Figure 3.4. The investigator then administered the scabies education pre-test, the scabies education lesson, the scabies education post-test, and concluded the interaction by giving the subject the appropriate scabies treatment. Each of these sections presented the following questions for data collection, translated into Spanish or Creole if necessary:

Subject Demographics:

1. Name?
2. Age?
3. Sex?
4. Occupation?
5. Length of time living in Barrio Nuevo?
6. Number of members living in household?
7. Number of completed years of school?
8. Number of times visited the Veron clinic?

Scabies-related Past Medical and Social History:

1. Have you been diagnosed with scabies in the past?
 - a. If yes, where and treated with what?
2. Were you treated for scabies in May 2007 (used in all subsequent surveys after program start in May 2007)?
 - a. If yes, did you have any significant side effects?
 - i. If yes, what symptoms?
3. Were you treated for scabies since May 2007 at the Veron clinic?
 - a. If yes, did you have any significant side effects?
 - ii. If yes, what symptoms?
4. Have other members of the household been diagnosed with scabies?
 - a. If yes, where and treated with what?
5. Is there hot running water in the house?
6. Is bleach used to clean bedding and clothing?
7. Is your bed shared with others?
8. Are your clothes shared with others?
9. Are there animals living in the house?

Scabies-related current medical history:

1. Are you currently experiencing significant itching?
 - a. If yes, is it worse at night or after a shower or bath?

2. Do you currently have lesions or eruptions on the skin associated with significant itching?
3. Are there members in your households with similar symptoms?
4. Have you ever been diagnosed with heart, kidney, or skin infections?

Skin Examination:

1. Obvious excoriations from pruritis?
2. Burrow lines?
3. Pruritic vesicles?
4. Pruritic papules?
5. Healing or scabbed pruritic lesions?
6. Pruritic abscesses?
7. Obvious scars from past itching or lesions?

Scabies Education Pre and Post-test:

1. Please identify the type of organism that classifies a scabies mite.
2. Please identify the primary location where scabies causes infection on the human body.
3. Please identify as many scabies infection signs and symptoms as possible.
4. Please identify how scabies is spread between people.
5. Please identify three organs that can become secondarily infected by scabies.
6. Please identify the scabies treatments available for Barrio Nuevo and their indications.
7. Please repeat the Permethrin 5% lotion application instructions that were just presented to you.
8. Please identify the location of the Veron public clinic and what services are available there for scabies care.
9. Please identify three ways that the spread of scabies can be prevented.
10. Please identify how and where you can receive further help regarding scabies or other medical needs.

Scabies Treatment:

1. Treated with Ivermectin tablets?
2. Treated with Permethrin 5% lotion?
3. Refused treatment?
 - a. If yes, for what reason?

After all subjects were evaluated in a household using this methodology, subjects were reminded of the next visit by medical educators, and an information pamphlet was administered for future reference (Appendix E). This protocol was followed until every household within Barrio Nuevo was visited and treated at baseline. Each household was revisited for data collection and follow up at 2 weeks, 1 month, 2 months, 8 months, and 9 months.



Figure 3.4
Medical educators completing program protocol in Barrio Nuevo.

3.9 Data Analyses

The Veron Scabies Eradication and Education Program data was coded, labeled, and translated into variables using Microsoft Excel computer software to create a project database. Data analysis occurred using both descriptive statistics to summarize the characteristics of the Barrio Nuevo community and inferential statistics to summarize the association of the intervention protocol based on the sample findings. All inferential statistical analysis occurred using Microsoft Excel and OpenEpi software to compare pre and post-intervention hypotheses at each interval. This was achieved using a one-tailed t-

test for means to either accept or reject the null and alternative hypotheses by 95% confidence intervals.

3.10 Program Evaluation

The Veron Scabies Eradication and Education Program was evaluated to determine if the program mission, goals, and objectives were met in an efficient, efficacious, and sustainable manner using the stepwise process of planning, data collection, data analysis, reporting, and application (McKenzie, Neiger, & Smeltzer, 2005). This evaluation was monitored by the Virginia Tech Department of Education faculty for Program and Product Evaluation.

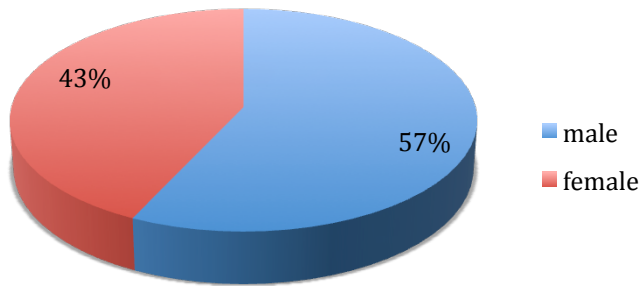
The Veron Scabies Eradication and Education Program evaluation results were analyzed for pertinent trends and characteristics and presented to all Veron Scabies Eradication and Education Program stakeholders, including: Virginia College of Osteopathic Medicine, Punta Cana Foundation, Secretaría de Estado de Salud Pública y Asistencia Social, and the Veron community. Evaluation results were then used for formal data management, processing, and developing articles for submission to peer-reviewed medical publications.

Chapter 4

Results

4.1 Subject Demographics

The initial target population evaluated in Barrio Nuevo consisted of 1057 subjects—604 males and 453 females with a mean age of 23.3 years (Figure 4.1). This target population was reassessed at 2 weeks, 1 month, 2 month, 8 month, and 9 month intervals using as many subjects from the initial population as could be located, yielding 1021 (96.6%), 1002 (94.8%), 954 (90.2%), 818 (77.4%), and 783 (74.1%) subjects respectively. Of these subjects, 33% were construction workers, 21% homemakers, 11% students, 9% taxi drivers or motorcycle couriers, 8% tourism employees, 6% storeowners, 3% retirees, 1% security guards, and 8% unemployed (Figure 4.1). Subjects inhabited Barrio Nuevo for an average of 9.3 months at initial assessment, with an average of 3.6 persons occupying each household. Members of each household averaged 4.1 years of school and 0.6 total visits to the Veron public clinic during their time living in Veron. Considering literacy rates in Barrio Nuevo, 32% of inhabitants 10 years or older reported an inability to read or write.



Barrio Nuevo at a Glance

- 604 males, 453 females
- Mean age=23.3 years
- Ave duration of inhabitation=9.3 months
- 294 dwellings
- Ave persons/household=3.6
- Ave years of school=4.1
- Ave visits to Veron clinic/person=0.6
- Percent unable to read or write=32%

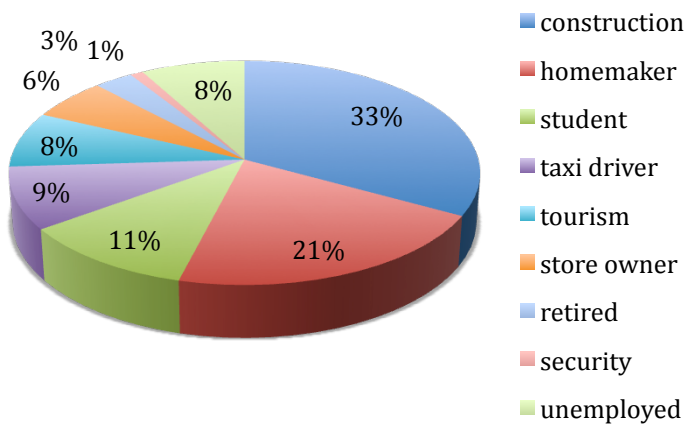


Figure 4.1: Barrio Nuevo demographics data collected at baseline from each household, n=1057.

4.2 Scabies Treatments and Reported Side Effects

Treatments at baseline consisted of 934 of 1057 individuals (88.4%) receiving oral Ivermectin, 98 of 1057 (9.3%) receiving topical Permethrin 5% lotion, and 21 of 1057 (2.0%) refusing any treatment (Figure 4.2). Of those subjects that refused, the most common reason was an insistence that the medication was not needed.

Beginning at 2 weeks, subjects were also evaluated for post-treatment side effects. Of the 934 oral Ivermectin users, 27 (3.0%) complained of abdominal discomfort, 13 (1.4%) complained of nausea, and 8 (0.9%) complained of diarrhea (Figure 4.2). Of the 91 topical Permethrin users, 7 (7.1%) complained of worsening pruritis (Figure 4.2). None of the subjects who complained of the above side effects sought further medical treatment. Furthermore, no subjects complained of any side effects, new or prolonged, after the 2-week interval.

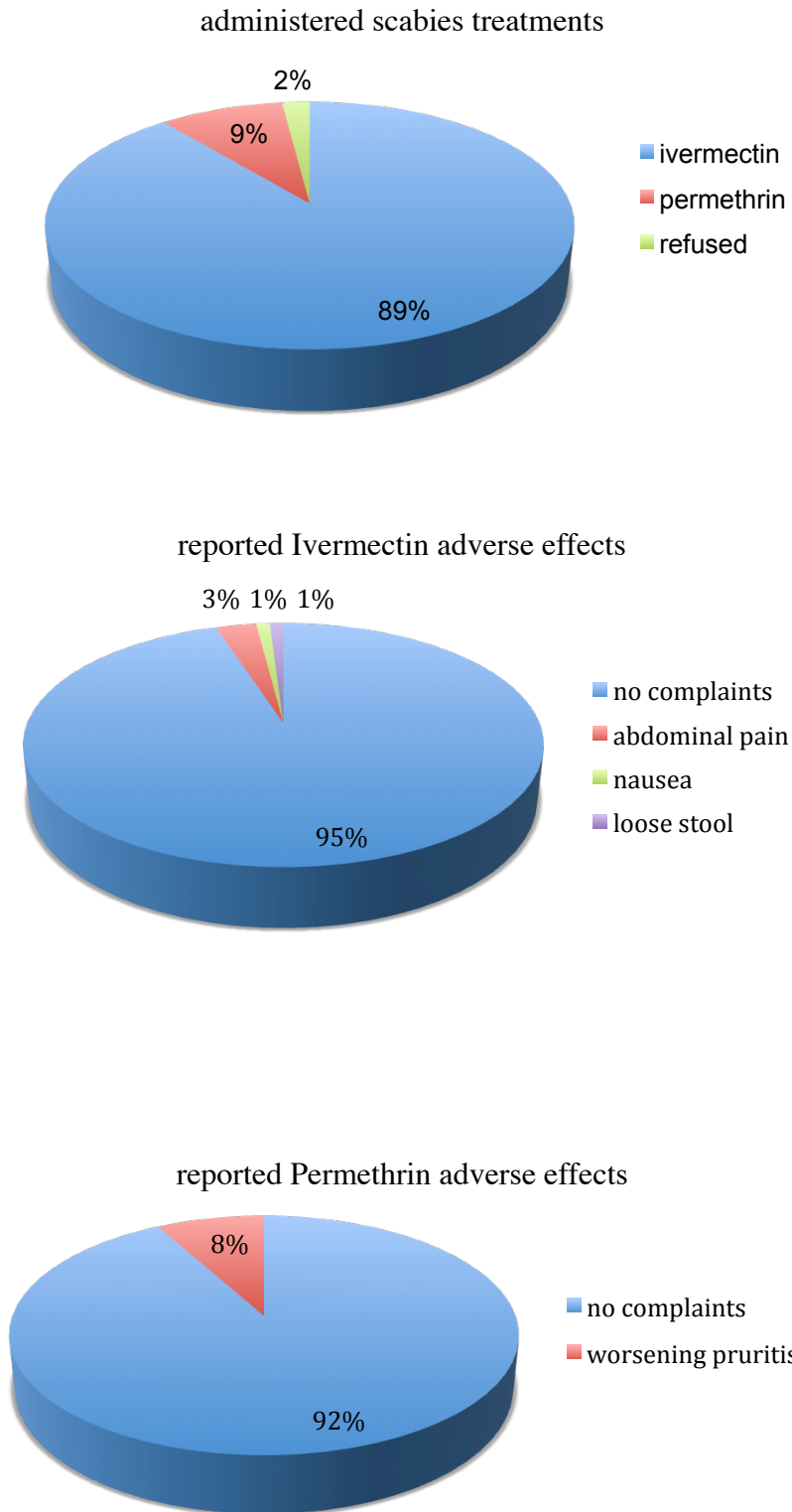


Figure 4.2: Scabies treatments administered to subjects in Barrio Nuevo at baseline and adverse effects per treatment reported at the 2-week measurement interval.

4.3 Scabies Medical History

Initial subjective scabies history revealed that 44.3% (468 of 1057) of subjects stated they had been diagnosed with scabies in the past during previous visits to healthcare providers, 32.6% (344 of 1057) possibly being infected but never diagnosed, and 24.1% (255 of 1057) never being infected (Figure 4.3). Of those stating previous scabies infection, 68.4% (320 of 468) never received treatment, 18.5% (87 of 468) received self-directed treatment at local pharmacies, and 13.1% (61 of 468) received physician-directed treatment at various public clinics in the area, including Veron, Otra Banda, La Romana, and La Altagracia (Figure 4.3). Of those who were treated in the past, 60.1% (89 of 148) received Lindane lotion, 12.8% (19 of 148) received Permethrin lotion, 9.5% (14 of 148) received hydrocortisone cream, 6.1% (9 of 148) received azole-based anti-fungal cream, 2.7% (4 of 148) received oral Ivermectin, 2.0% (3 of 148) received Metronidazole, and 6.8% (10 of 148) received an unknown treatment (Figure 4.3).

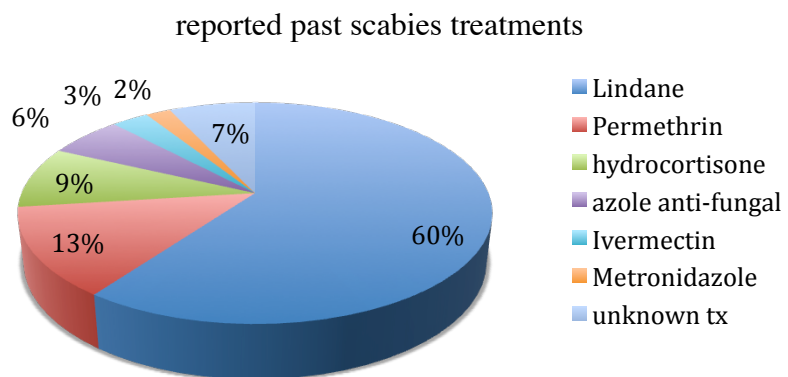
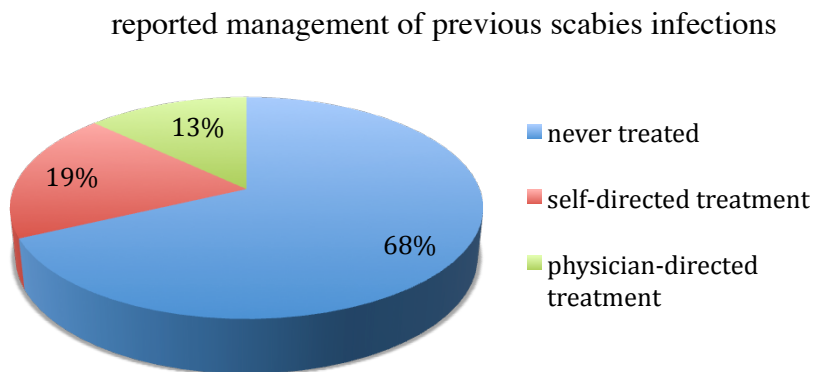
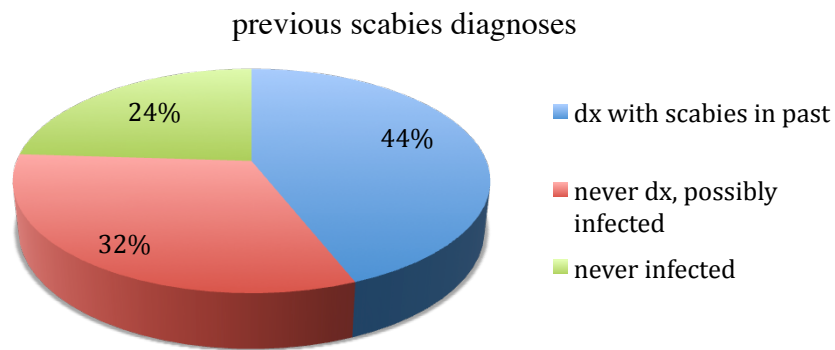


Figure 4.3: Percent of previous scabies diagnoses and treatments reported by Barrio Nuevo subjects.

4.4 Baseline Scabies Risks and Prevention Behaviors

Considering the risk factors that contribute to scabies spread, 0.0% of households possessed hot running water for bathing or laundry, 98.2% used bleach on clothes and bedding, 87.9% shared a bed, 14.4% shared clothing, and 34.3% had pets or livestock living in the home at baseline (Figure 4.4).

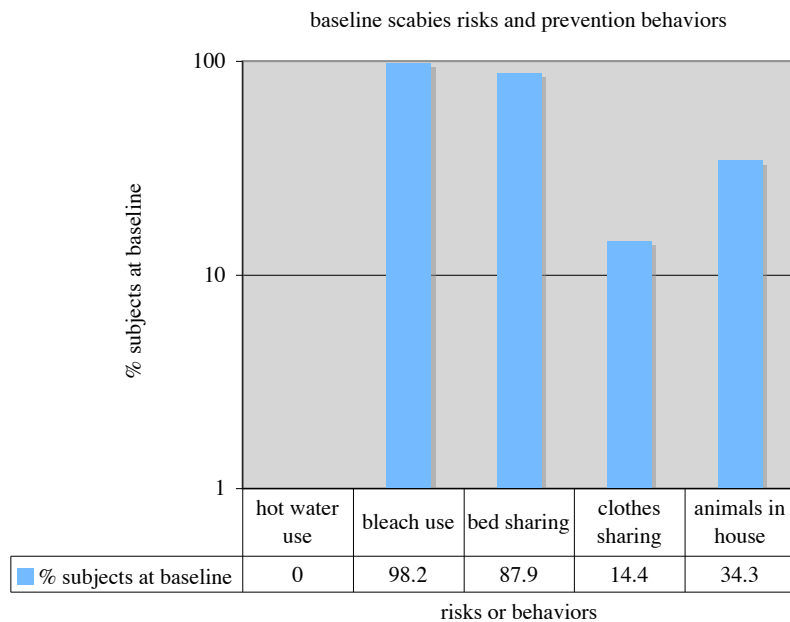


Figure 4.4: Baseline scabies spread risks and prevention habits reported as a percentage of Barrio Nuevo subjects.

4.5 Reported Hot Water Use for Cleaning Clothes and Bedding

While no households possess hot running water as a utility in Barrio Nuevo, subjects did begin reporting the act of boiling water to clean bedding and clothing at each interval—a statistically significant improvement from baseline ($p<0.05$). Reported use per interval was as follows: baseline, 0 of 1057 subjects (0.0%); 2 weeks, 23 of 1021 subjects (2.3%, 95% CI ± 0.91 , $p<0.001$); 1 month, 25 of 1002 subjects (2.5%, 95% CI ± 0.97 , $p<0.001$); 2 months, 19 of 954 subjects (2.0%, 95% CI ± 0.89 , $p<0.001$); 8 months, 4 of 818 subjects (0.5%, 95% CI ± 0.48 , $p<0.02$); 9 months, 5 of 783 subjects (0.6%, 95% CI ± 0.56 , $p<0.005$) (Figure 4.5).

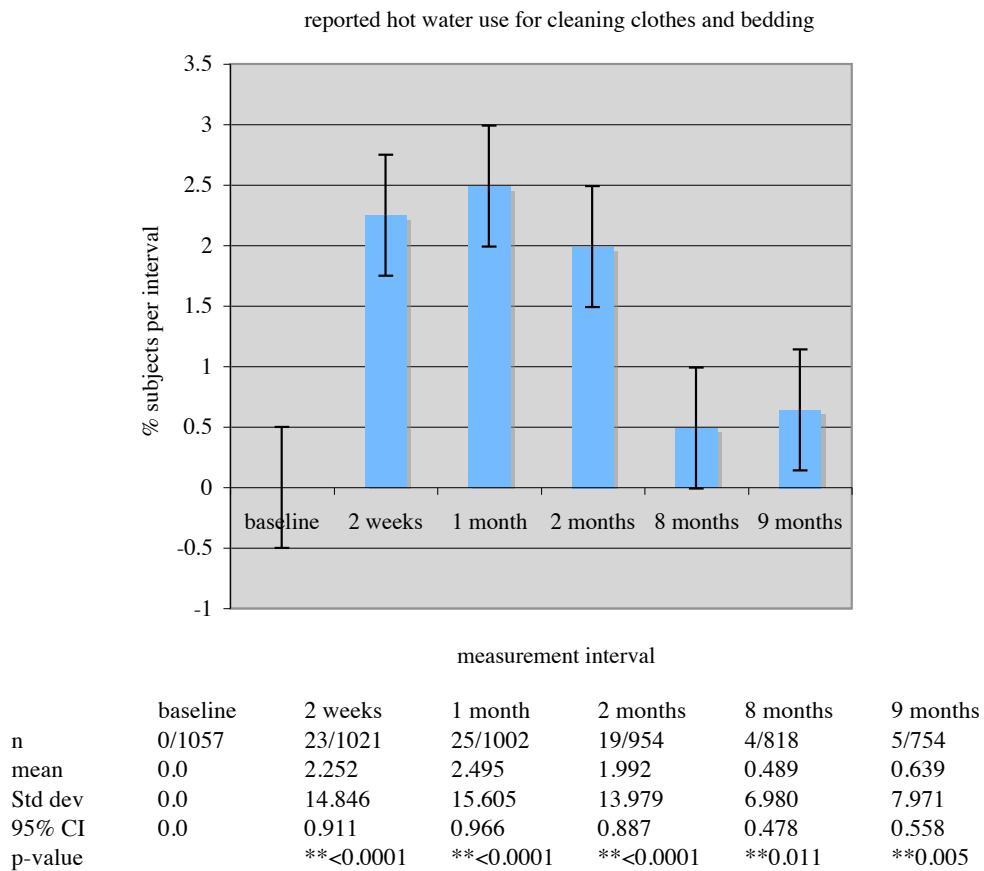


Figure 4.5: Percent of subjects who reported hot water use for cleaning clothes and bedding per measurement interval and corresponding statistical analysis (**statistically significant differences from baseline determined using $p<0.05$).

4.6 Reported Bleach Use for Cleaning Clothes and Bedding

Bleach use to clean clothes and bedding, already a standard practice in Barrio Nuevo, remained relatively constant at each interval compared to baseline. Indeed, no interval was statistically significant from baseline. Reported use per interval was as follows: baseline, 1038 of 1057 subjects (98.2%, 95% CI ± 0.80); 2 weeks, 1010 of 1021 subjects (98.9%, 95% CI ± 0.63 , $p=0.08$); 1 month, 982 of 1002 subjects (98.0%, 95% CI ± 0.87 , $p=0.37$); 2 months, 932 of 954 subjects (97.7%, 95% CI ± 0.95 , $p=0.21$); 8 months, 792 of 818 subjects (97.3%, 95% CI ± 1.1 , $p=0.10$); 9 months, 769 of 783 subjects (98.2%, 95% CI ± 0.93 , $p=0.49$) (Figure 4.6).

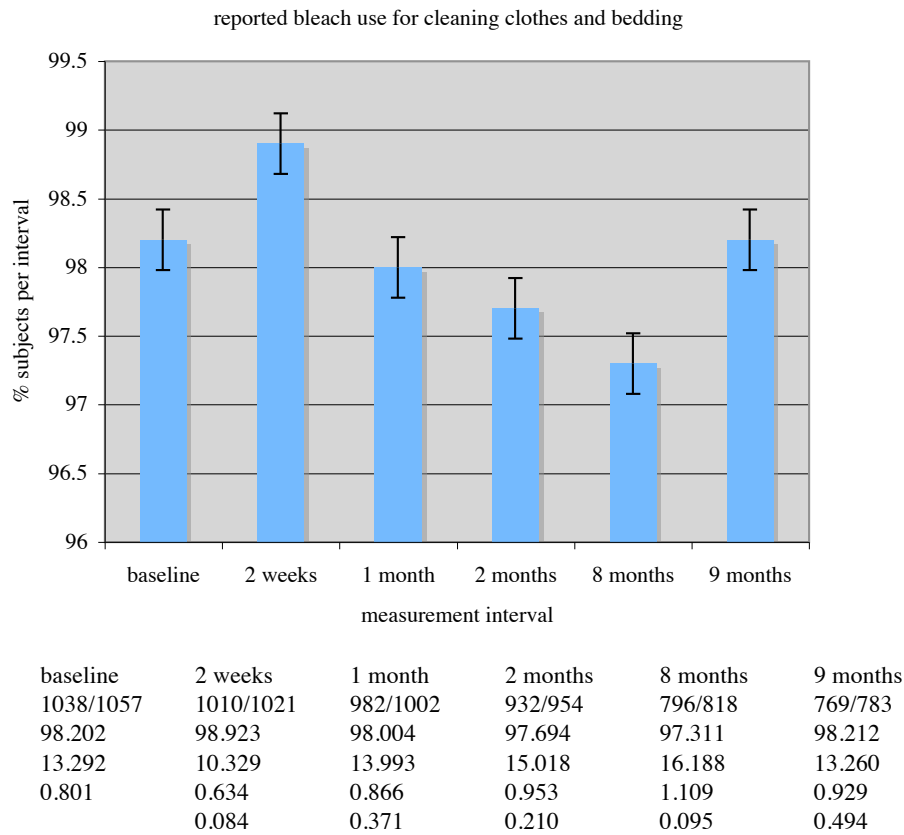


Figure 4.6: Percent of subjects who reported bleach use for cleaning clothes and bedding per measurement interval and corresponding statistical analysis (**statistically significant differences from baseline determined using $p<0.05$).

4.7 Reported Bed Sharing

Bed sharing displayed modest decreases, all of which were statistically significant ($p < 0.05$) until months 8 and 9, where they approached and surpassed baseline levels. Reported bed sharing per interval was as follows: baseline, 929 of 1057 subjects (87.9%, 95% CI ± 2.0); 2 weeks, 754 of 1021 subjects (73.8%, 95% CI ± 2.7 , $p < 0.001$); 1 month, 705 of 1002 subjects (70.4%, 95% CI ± 2.8 , $p < 0.001$); 2 months, 775 of 954 subjects (81.2%, 95% CI ± 2.5 , $p < 0.001$); 8 months, 703 of 818 subjects (85.9%, 95% CI ± 2.4 , $p = 0.11$); 9 months, 698 of 783 subjects (89.1%, 95% CI ± 2.2 , $p = 0.20$) (Figure 4.7).

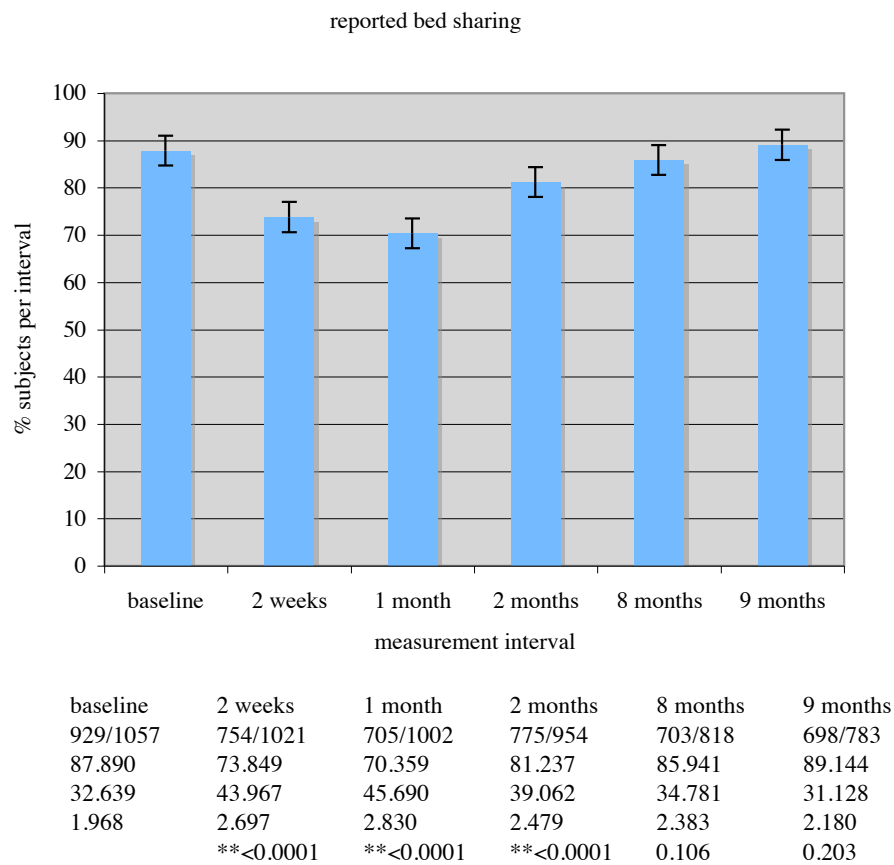


Figure 4.7: Percent of subjects who reported bed sharing per measurement interval and corresponding statistical analysis (**statistically significant differences from baseline determined using $p < 0.05$).

4.8 Reported Clothes Sharing

Clothes sharing showed significant decreases at 2 weeks and 1 month ($p < 0.001$), but began trending toward baseline by the 2-month interval. Reported clothes sharing per interval was as follows: baseline, 152 of 1057 subjects (14.4%, 95% CI ± 2.1); 2 weeks, 92 of 1021 subjects (9.0%, 95% CI ± 1.8 , $p < 0.001$); 1 month, 69 of 1002 subjects (6.9%, 95% CI ± 1.6 , $p < 0.001$); 2 months, 115 of 954 subjects (12.1%, 95% CI ± 2.1 , $p = 0.06$); 8 months, 106 of 818 subjects (13.0%, 95% CI ± 2.3 , $p = 0.19$); 9 months, 97 of 783 subjects (12.4%, 95% CI ± 2.3 , $p = 0.11$) (Figure 4.8).

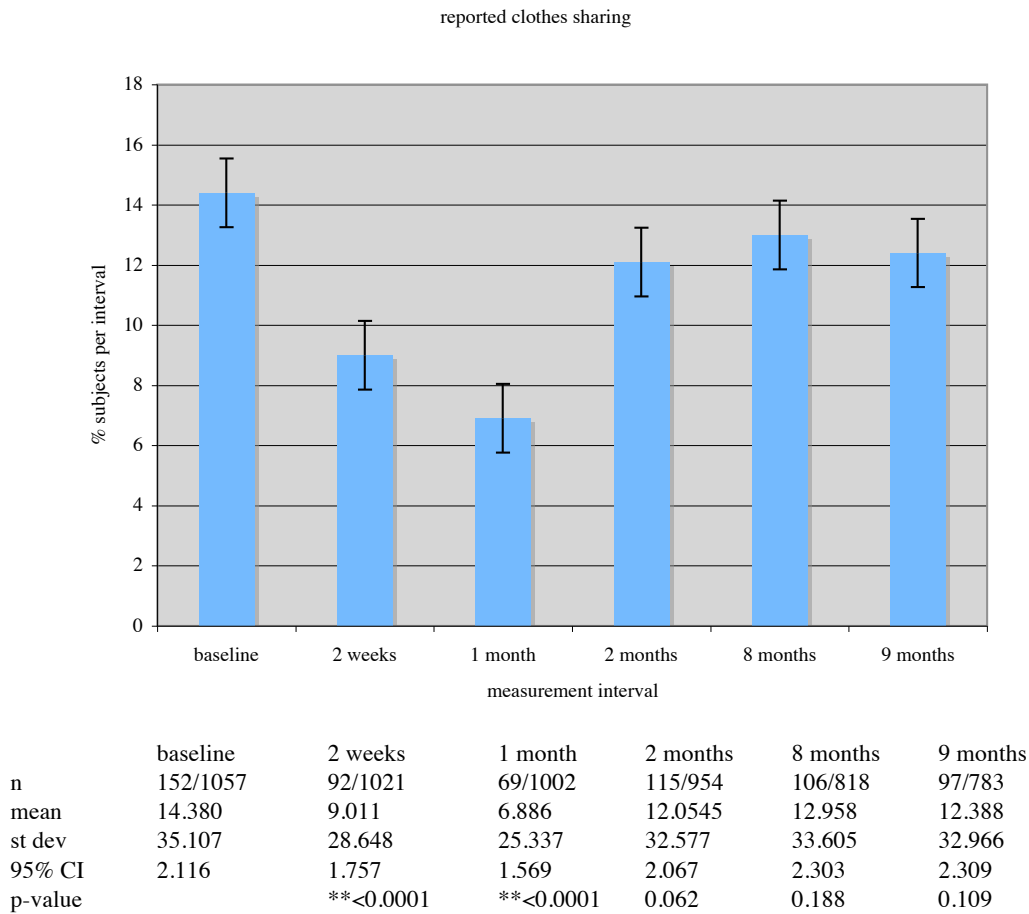


Figure 4.8: Percent of subjects who reported bed sharing per measurement interval and corresponding statistical analysis (**statistically significant differences from baseline determined using $p < 0.05$).

4.9 Reported Pets or Livestock Living in the Home

Pets or livestock living in the home decreased significantly at each interval ($p<0.01$) until 9 months when it re-approached baseline levels. Reported animals in the house per interval was as follows: baseline, 363 of 1057 subjects (34.2%, 95% CI ± 2.9); 2 weeks, 257 of 1021 subjects (25.2%, 95% CI ± 2.7 , $p<0.001$); 1 month, 244 of 1002 subjects (24.4%, 95% CI ± 2.7 , $p<0.001$); 2 months, 251 of 954 subjects (26.3%, 95% CI ± 2.8 , $p<0.001$); 8 months, 238 of 818 subjects (29.1%, 95% CI ± 3.1 , $p<0.01$); 9 months, 265 of 783 subjects (33.8%, 95% CI ± 3.3 , $p=0.41$) (Figure 4.9).

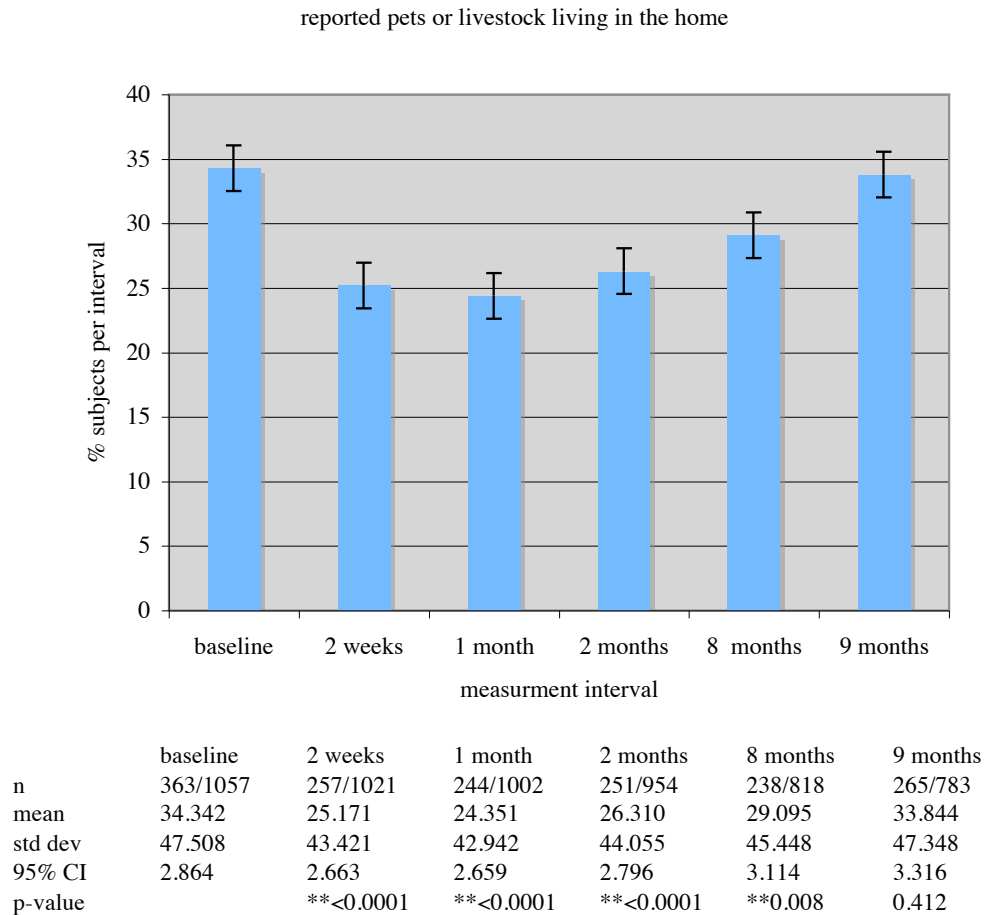


Figure 4.9: Percent of subjects who reported pets or livestock living in the home per measurement interval and corresponding statistical analysis (**statistically significant differences from baseline determined using $p<0.05$).

4.10 Scabies Symptomatology

When subjects were assessed for current scabies symptomatology at baseline, 37.4% complained of diffuse pruritis, of those 42.9% were worse after a shower or bath. Skin lesions or eruptions with associated itching were reported by 21.0% of subjects, 51.9% of which stated that at least one other household member had similar symptoms. Overall, 6.3% of subjects reported a diagnosed history of heart disease, kidney infections, or skin abscesses (Figure 4.10).

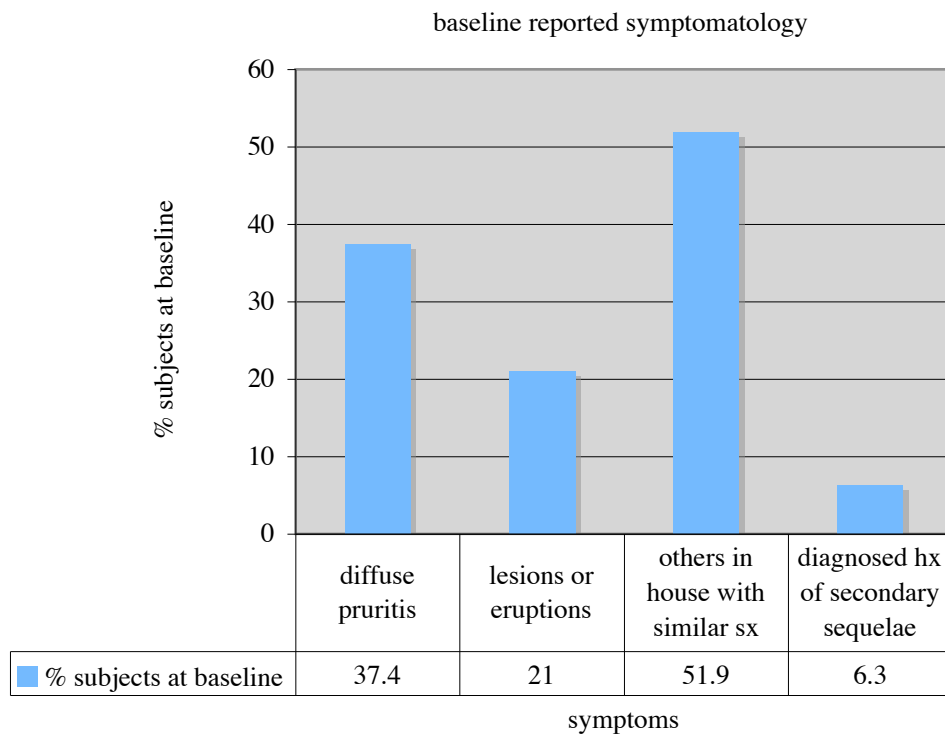


Figure 4.10: Scabies symptomatology at baseline reported as a percentage of Barrio Nuevo subjects

4.11 Reported Diffuse Pruritis

When subjects were reassessed for scabies symptomatology, the complaint of diffuse pruritis fell significantly below the initial level at each interval ($p < 0.001$). Reported pruritis per interval was as follows: baseline, 395 of 1057 subjects (37.4%, 95% CI ± 2.9); 2 weeks, 147 of 1021 subjects (14.4%, 95% CI ± 2.2 , $p < 0.001$); 1 month, 81 of 1002 subjects (8.1%, 95% CI ± 1.7 , $p < 0.001$); 2 months, 90 of 954 subjects (9.4%, 95% CI ± 1.9 , $p < 0.001$); 8 months, 102 of 818 subjects (12.5%, 95% CI ± 2.3 , $p < 0.001$); 9 months, 123 of 783 subjects (15.7%, 95% CI ± 2.6 , $p < 0.001$) (Figure 4.11).

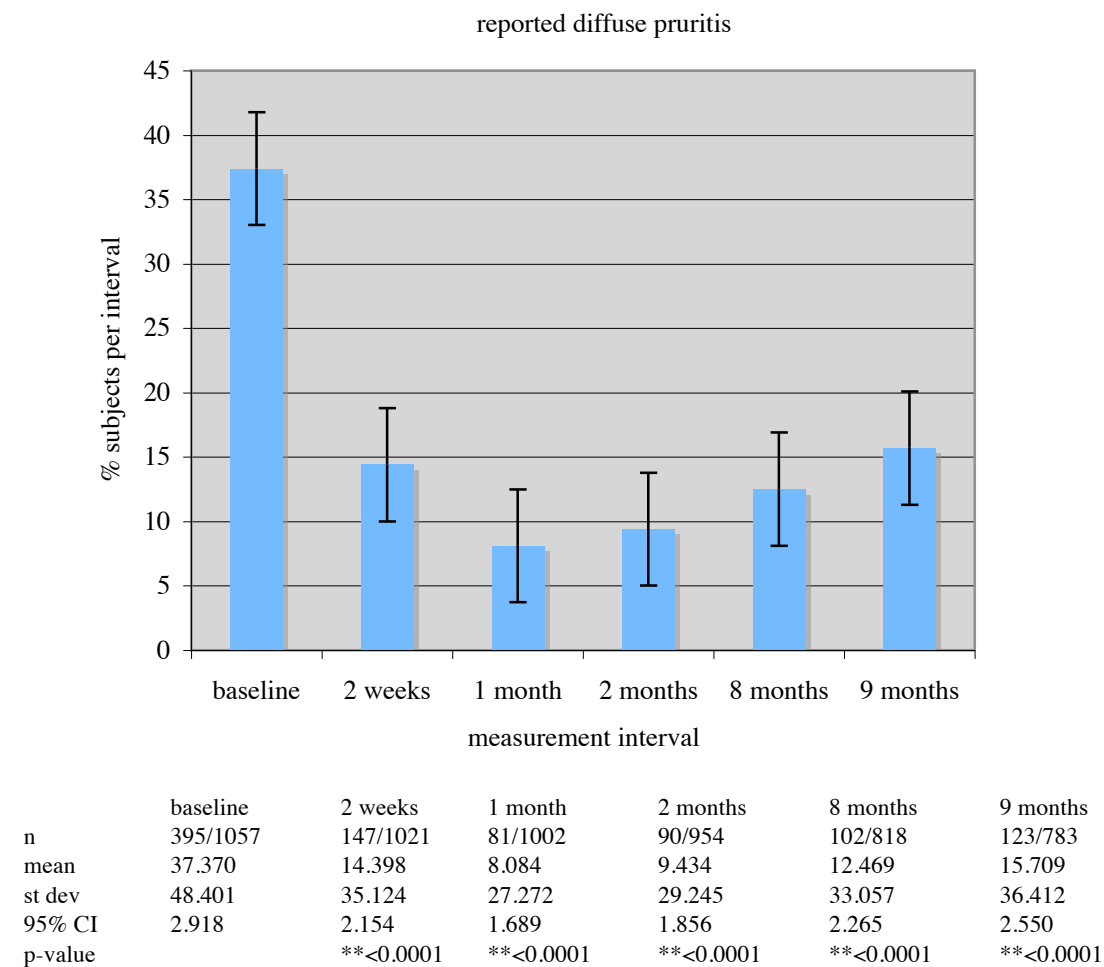


Figure 4.11: Percent of subjects who reported diffuse pruritis per measurement interval and corresponding statistical analysis (**statistically significant differences from baseline determined using $p < 0.05$).

4.12 Reported Pruritic Skin Lesions or Eruptions

The complaint of skin lesions or eruptions with associated itching also decreased significantly from baseline at each interval ($p < 0.05$), and was as follows: baseline, 222 of 1057 subjects (21.0%, 95% CI ± 2.5); 2 weeks, 76 of 1021 subjects (7.4%, 95% CI ± 1.6 , $p < 0.0001$); 1 month, 69 of 1002 subjects (6.9%, 95% CI ± 1.6 , $p < 0.0001$); 2 months, 131 of 954 subjects (13.7%, 95% CI ± 2.2 , $p < 0.0001$); 8 months, 117 of 818 subjects (14.3%, 95% CI ± 2.4 , $p < 0.0001$); 9 months, 133 of 783 subjects (17.0%, 95% CI ± 2.6 , $p < 0.02$) (Figure 4.12).

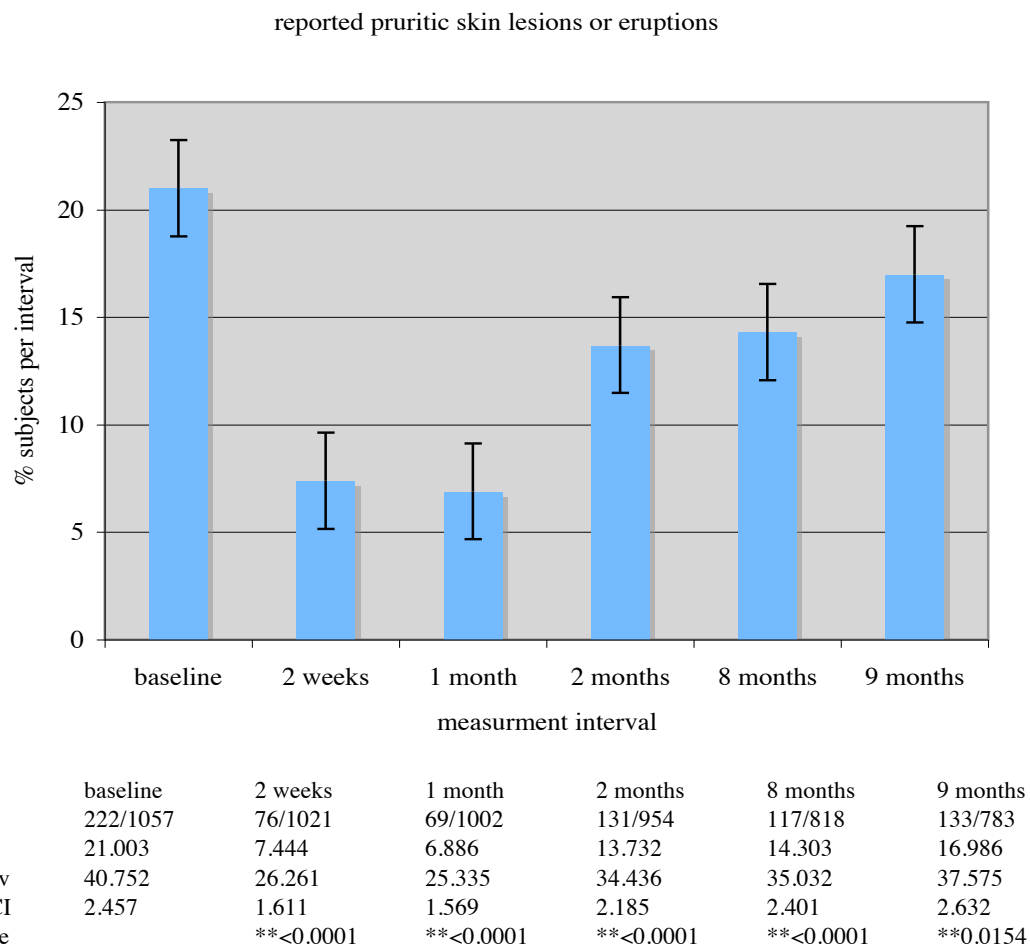


Figure 4.12: % of subjects who reported pruritic skin lesions or eruptions per measurement interval and corresponding statistical analysis (**statistically significant differences from baseline determined using $p < 0.05$).

4.13 Reported Others in House with Similar Symptoms

Likewise, the number of reports of family members with similar symptoms decreased significantly at each interval when compared to baseline ($p<0.001$). The results are as follows: baseline, 549 of 1057 subjects (51.9%, 95% CI ± 3.0); 2 weeks, 316 of 1021 subjects (31.0%, 95% CI ± 2.0 , $p<0.001$); 1 month, 122 of 1002 subjects (12.2%, 95% CI ± 2.0 , $p<0.001$); 2 months, 139 of 954 subjects (14.6%, 95% CI ± 2.2 , $p<0.001$); 8 months, 151 of 818 subjects (18.5%, 95% CI ± 2.7 , $p<0.001$); 9 months, 189 of 783 subjects (24.1%, 95% CI ± 3.0 , $p<0.001$) (Figure 4.13).

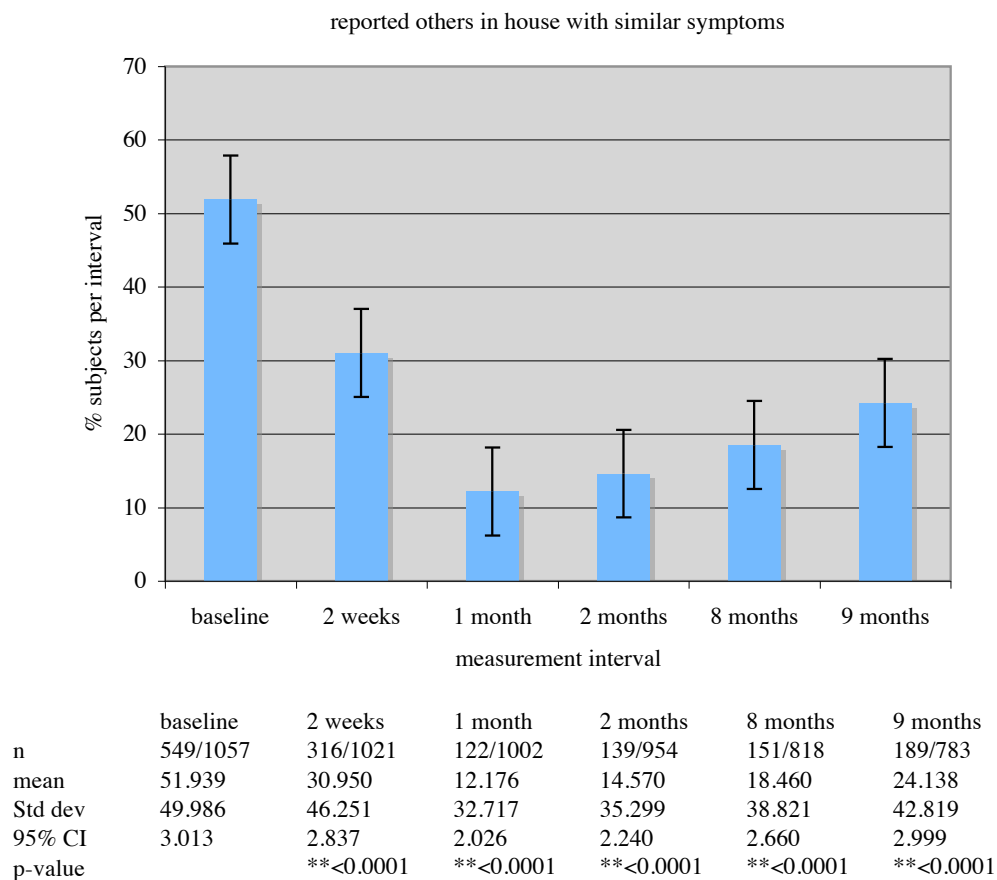


Figure 4.13: Percent of subjects who reported others living in their house with similar symptoms per measurement interval and corresponding statistical analysis (**statistically significant differences from baseline determined using $p<0.05$).

4.14 Scabies Skin Exam Findings

Upon initial physical exam, 27.0% of subjects displayed obvious skin excoriations, 18.2% displayed scabies burrow lines, 23.0% displayed pruritic vesicles, 20.9% displayed pruritic papules, 25.9% displayed healing or scabbed pruritic lesions, 6.0% displayed pruritic skin abscesses, and 26.2% displayed scars from previous lesions and itching (Figure 4.14, 4.15).

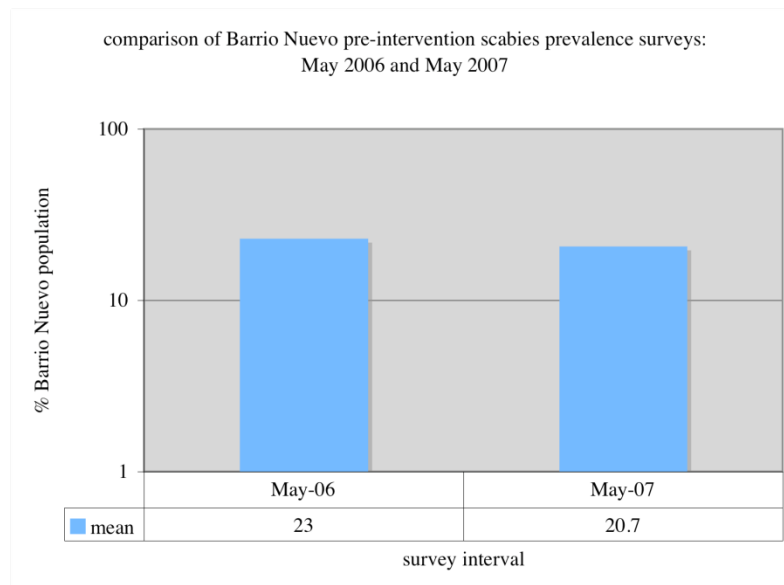
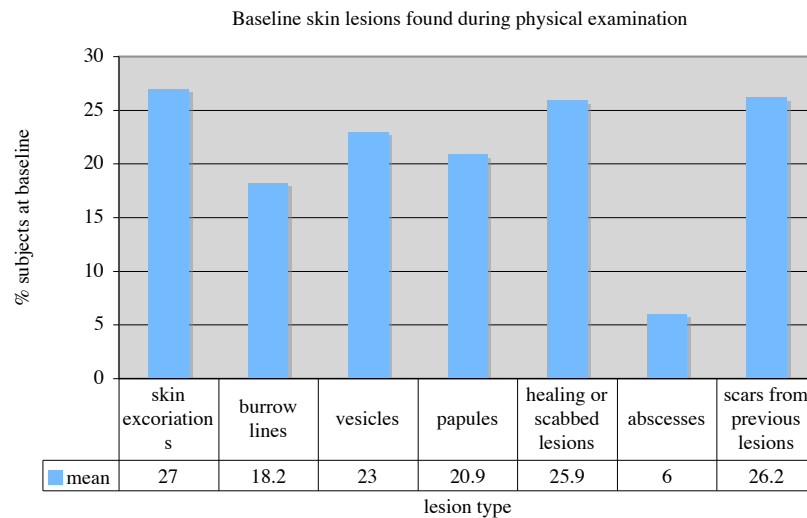


Figure 4.14; 4.15: Baseline skin lesions found during physical examination reported as a percentage of Barrio Nuevo subjects; comparison of two independent pre-intervention surveys of Barrio Nuevo scabies prevalence by Veron clinic medical personnel, May 2006 and May 2007.

4.15 Skin Excoriations

Skin excoriations measurements were significantly lower at each interval when compared to baseline ($p < 0.001$), and were recorded as follows: baseline, 285 of 1057 subjects (27.0%, 95% CI ± 2.7); 2 weeks, 63 of 1021 subjects (6.2%, 95% CI ± 1.5 , $p < 0.001$); 1 month, 51 of 1002 subjects (5.1%, 95% CI ± 1.4 , $p < 0.001$); 2 months, 123 of 954 subjects (12.9%, 95% CI ± 2.1 , $p < 0.001$); 8 months, 148 of 818 subjects (18.1%, 95% CI ± 2.6 , $p < 0.001$); 9 months, 146 of 783 subjects (18.6%, 95% CI ± 2.7 , $p < 0.001$) (Figure 4.16).

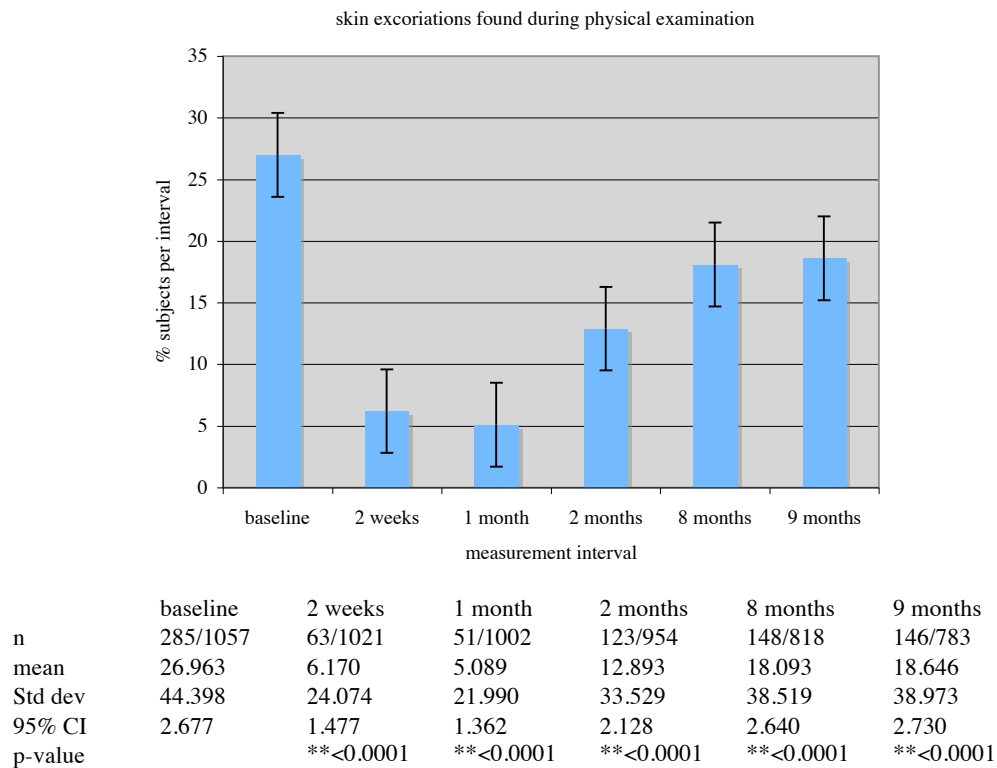


Figure 4.16: Percent of subjects found to have pruritis-associated skin excoriations during physical examination per measurement interval and corresponding statistical analysis (**statistically significant differences from baseline determined using $p < 0.05$).

4.16 Burrow Lines

Burrow lines similarly declined from baseline at each measurement interval ($p<0.001$): baseline, 192 of 1057 subjects (18.2%, 95% CI ± 2.3); 2 weeks, 39 of 1021 subjects (3.8%, 95% CI ± 1.2 , $p<0.001$); 1 month, 30 of 1002 subjects (3.0%, 95% CI ± 1.1 , $p<0.001$); 2 months, 76 of 954 subjects (7.9%, 95% CI ± 1.7 , $p<0.001$); 8 months, 71 of 818 subjects (8.7%, 95% CI ± 1.9 , $p<0.001$); 9 months, 83 of 783 subjects (10.6%, 95% CI ± 2.2 , $p<0.001$) (Figure 4.17).

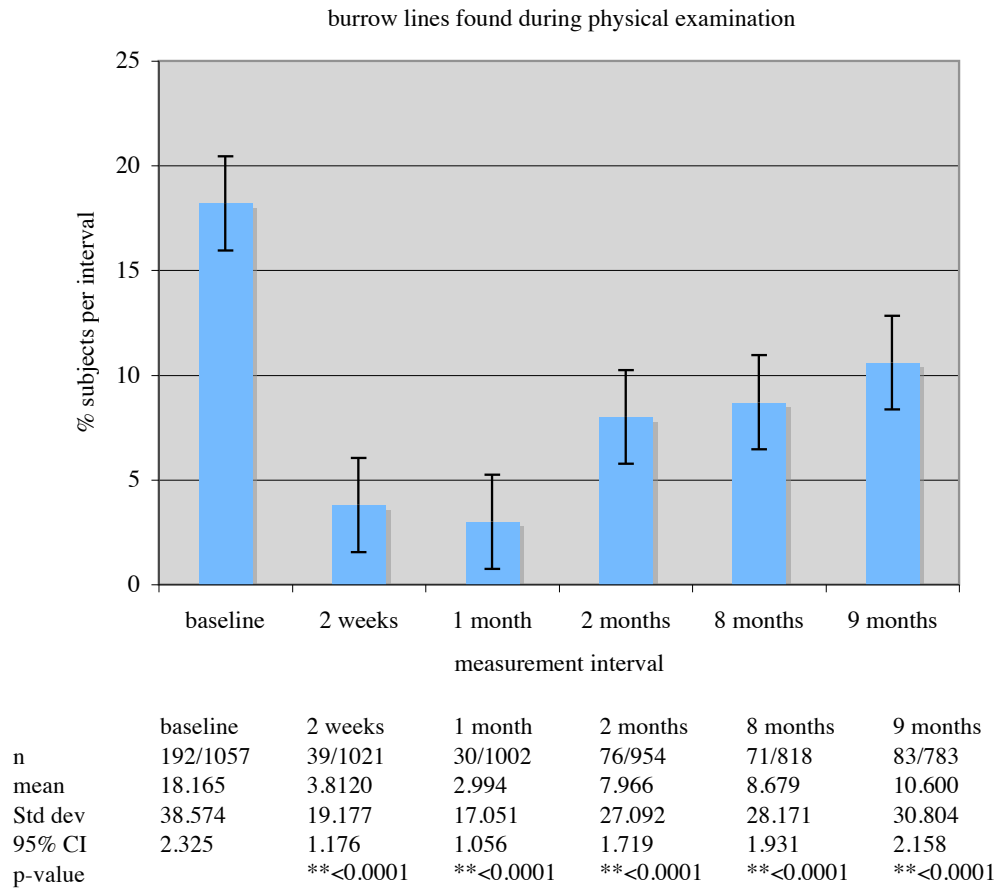


Figure 4.17: Percent of subjects found to have burrow lines during physical examination per measurement interval and corresponding statistical analysis (**statistically significant differences from baseline determined using $p<0.05$).

4.17 Skin Lesions: Pruritic Vesicles

There was also a significant reduction in all types of measured lesions, including vesicles, papules, healing or scabbed lesions, and skin abscesses ($p<0.05$) until the 9th month where abscesses re-approached baseline levels ($p=0.18$). Interval results for measured vesicles are as follows: baseline, 243 of 1057 subjects (23.0%, 95% CI ± 2.5); 2 weeks, 29 of 1021 subjects (2.8%, 95% CI ± 1.0 , $p<0.001$); 1 month, 23 of 1002 subjects (2.3%, 95% CI ± 0.9 , $p<0.001$); 2 months, 38 of 954 subjects (4.0%, 95% CI ± 1.2 , $p<0.001$); 8 months, 68 of 818 subjects (8.3%, 95% CI ± 1.9 , $p<0.001$); 9 months, 102 of 783 subjects (13.0%, 95% CI ± 2.4 , $p<0.001$) (Figure 4.18).

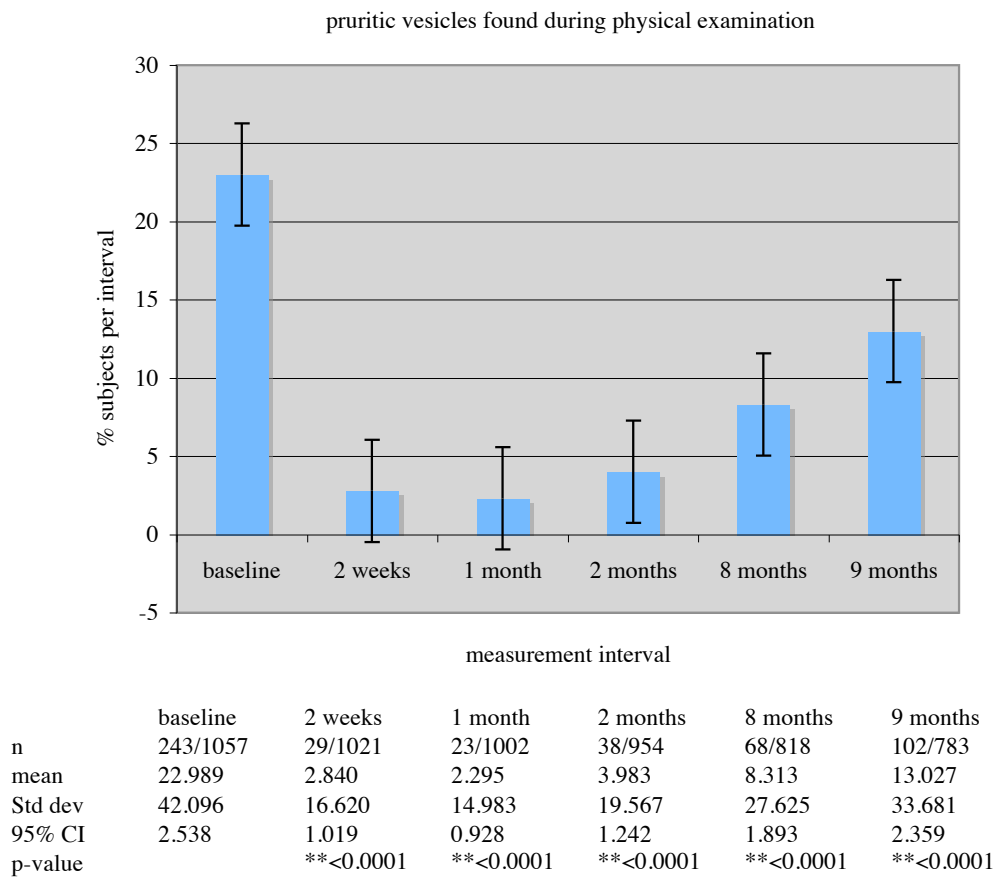


Figure 4.18: Percent of subjects found to have pruritic vesicles during physical examination per measurement interval and corresponding statistical analysis (**statistically significant differences from baseline determined using $p<0.05$).

4.18 Skin Lesions: Pruritic Papules

Interval results for measured papules are as follows: baseline, 221 of 1057 subjects (20.9%, 95% CI ± 2.5); 2 weeks, 38 of 1021 subjects (3.7%, 95% CI ± 1.1), $p < 0.001$; 1 month, 40 of 1002 subjects (4.0%, 95% CI ± 1.2 $p < 0.001$); 2 months, 57 of 954 subjects (6.0%, 95% CI ± 1.5 , $p < 0.001$); 8 months, 101 of 818 subjects (12.3%, 95% CI ± 2.3 , $p < 0.001$); 9 months, 123 of 783 subjects (15.7%, 95% CI ± 2.6 , $p < 0.003$) (Figure 4.19).

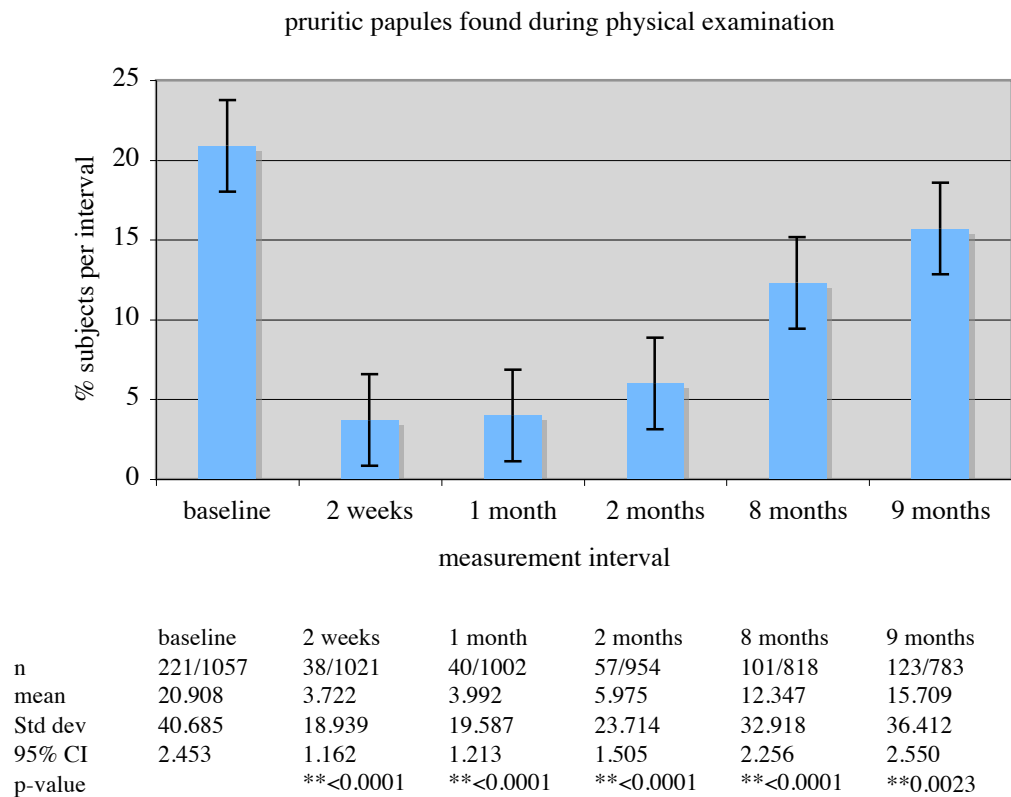


Figure 4.19: Percent of subjects found to have pruritic papules during physical examination per measurement interval and corresponding statistical analysis (**statistically significant differences from baseline determined using $p < 0.05$).

4.19 Skin Lesions: Healing or Scabbed Pruritic Lesions

Interval results for healing or scabbed lesions are as follows: baseline, 274 of 1057 subjects (25.9%, 95% CI ± 2.6); 2 weeks, 47 of 1021 subjects (4.6%, 95% CI ± 1.3), $p < 0.001$; 1 month, 61 of 1002 subjects (6.1%, 95% CI ± 1.5 $p < 0.001$); 2 months, 89 of 954 subjects (9.3%, 95% CI ± 1.8 , $p < 0.001$); 8 months, 102 of 818 subjects (12.5%, 95% CI ± 2.3 , $p < 0.001$); 9 months, 174 of 783 subjects (22.2%, 95% CI ± 2.9 , $p < 0.05$) (Figure 4.20).

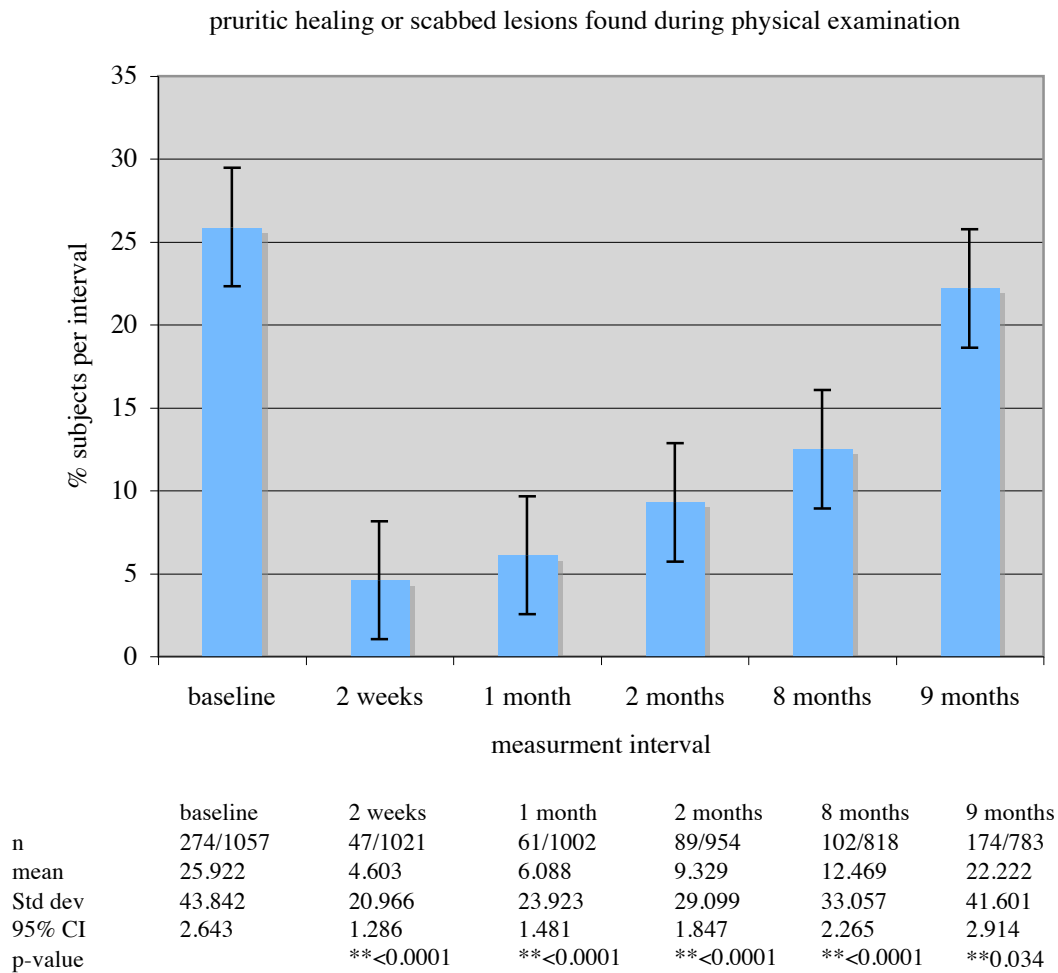


Figure 4.20: Percent of subjects found to have pruritic healing or scabbed lesions during physical examination per measurement interval and corresponding statistical analysis (**statistically significant differences from baseline determined using $p < 0.05$).

4.20 Skin Lesions: Abscesses

Interval results for measured skin abscesses are as follows: baseline, 63 of 1057 subjects (6.0%, 95% CI ± 1.4); 2 weeks, 9 of 1021 subjects (0.9%, 95% CI ± 0.6 , $p < 0.001$); 1 month, 8 of 1002 subjects (0.8%, 95% CI ± 0.6 , $p < 0.001$); 2 months, 19 of 954 subjects (2.0%, 95% CI ± 0.9 , $p < 0.001$); 8 months, 31 of 818 subjects (3.8%, 95% CI ± 1.3 , $p < 0.02$); 9 months, 39 of 783 subjects (5.0%, 95% CI ± 1.5 , $p = 0.18$) (Figure 4.21).

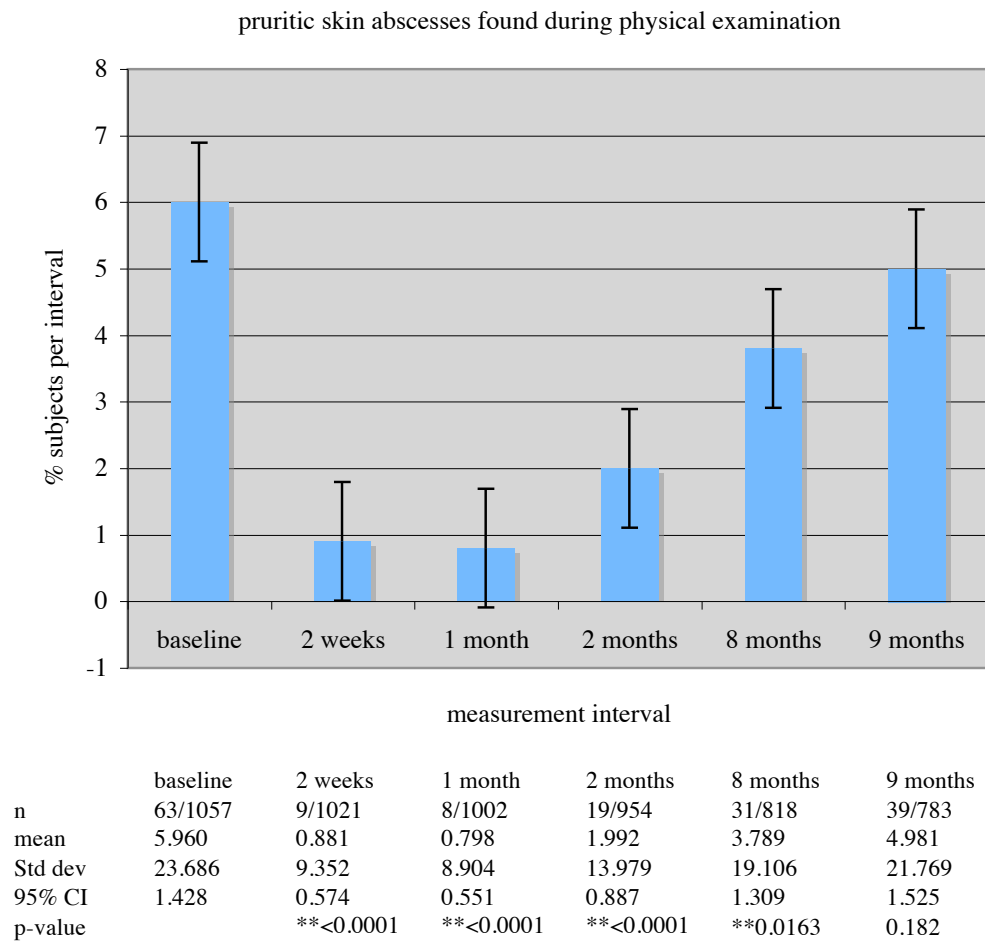


Figure 4.21: Percent of subjects found to have pruritic skin abscesses during physical examination per measurement interval and corresponding statistical analysis (**statistically significant differences from baseline determined using $p < 0.05$).

4.21 Skin Lesions: Scars from Previous Pruritic Lesions

Similarly, scars from previous lesions and itching significantly declined at each interval ($p < 0.003$) until the 9th month when they approximated baseline levels ($p = 0.19$). The results are as follows: baseline, 277 of 1057 subjects (26.2%, 95% CI ± 2.7); 2 weeks, 153 of 1021 subjects (15.0%, 95% CI ± 2.2 , $p < 0.001$); 1 month, 210 of 1002 subjects (20.9%, 95% CI ± 2.5 $p < 0.003$); 2 months, 114 of 954 subjects (11.9%, 95% CI ± 2.1 , $p < 0.001$); 8 months, 110 of 818 subjects (13.4%, 95% CI ± 2.3 , $p < 0.001$); 9 months, 191 of 783 subjects (24.4%, 95% CI ± 3.0 , $p = 0.19$) (Figure 4.22).

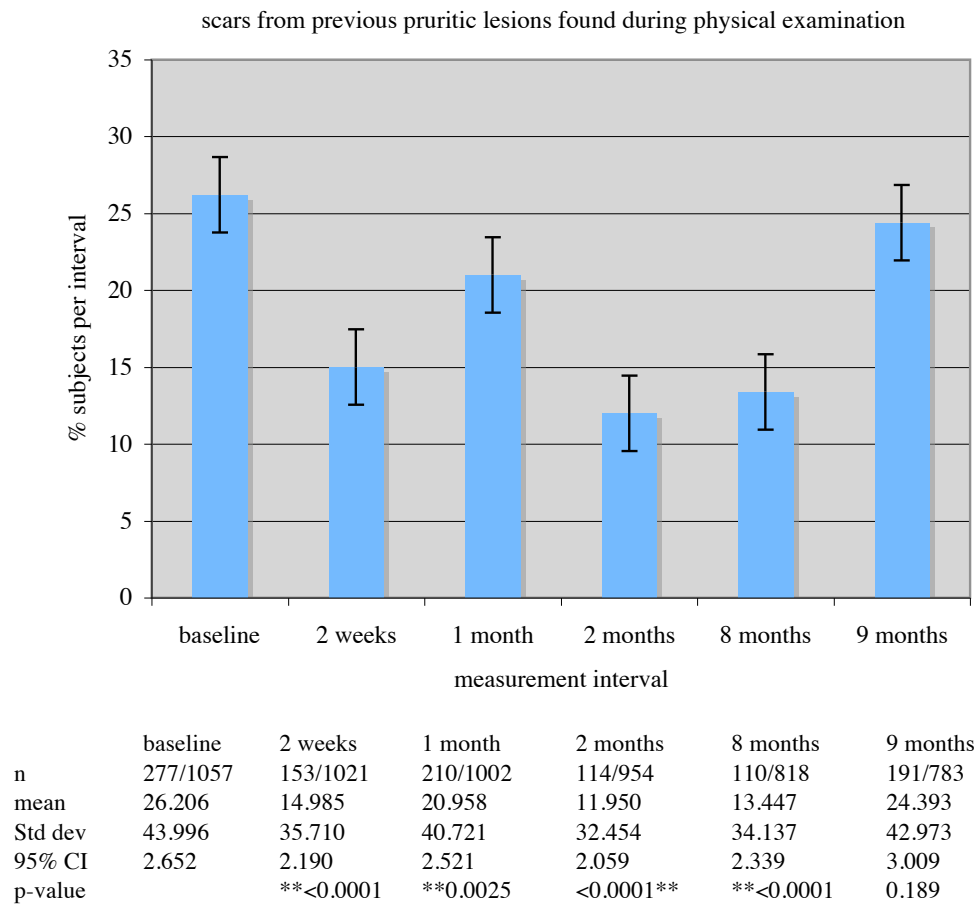


Figure 4.22: Percent of subjects found to have scars from previous pruritic lesions during physical examination per measurement interval and corresponding statistical analysis (**statistically significant differences from baseline determined using $p < 0.05$).

4.22 Scabies Education Pre-Test

The initial scabies education pre-test resulted in 12.1% of subjects correctly stating that scabies is caused by a parasite, 16.0% correctly stating that scabies primarily infects the skin, 8.9% correctly listing scabies signs and symptoms, 10.9% correctly stating that scabies is spread by human contact, 0.0% correctly stating that scabies causes secondary heart, kidney, and skin infections, 0.0% correctly listing the appropriate scabies treatment for Barrio Nuevo, 3.0% of subjects prescribed Permethrin 5% lotion correctly stating proper application instructions, 25.4% correctly stating Veron clinic location and services, 15.9% correctly stating how scabies can be prevented, and 25.9% correctly stating what to do if further medical help is needed (Figure 4.23).

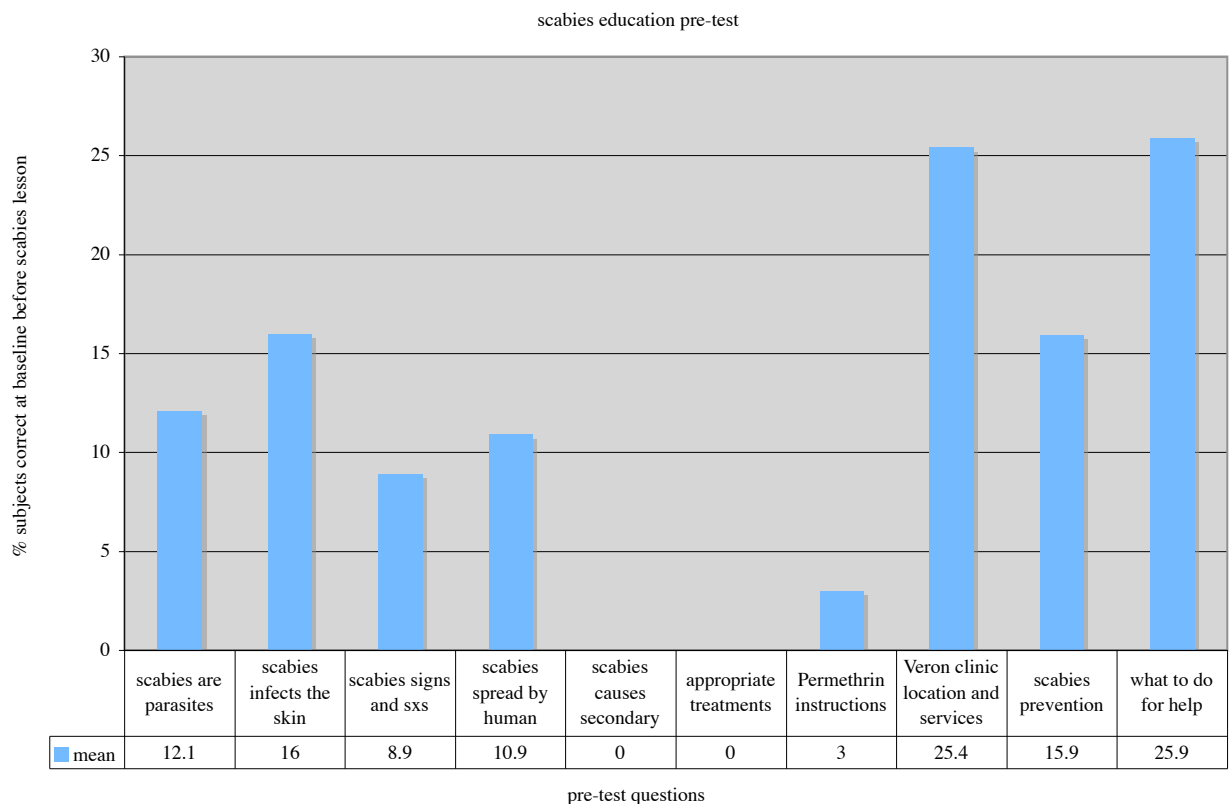


Figure 4.23: Correct answers to the scabies education pre-test given at baseline reported as a % of Barrio Nuevo subjects.

4.23 Scabies Education Post-Test

After the scabies educational lessons were completed, the scabies education post-test given at baseline and every successive measurement interval resulted in a statistically significant improvement in each lesson category when compared to the pre-test ($p < 0.05$). Despite all post-test intervals recording improved values when compared to the pre-test, there was an overall trend of knowledge decay over time that will be discussed.

4.24 Scabies Education Post-Test: Scabies are Parasites

The number of subjects correctly stating that scabies are parasites resulted in the following: pre-test, 127 of 1057 subjects (12.0%, 95% CI ± 2.0); post-test baseline, 761 of 1057 subjects (71.9%, 95% CI ± 2.8 , $p < 0.001$); 2 weeks, 553 of 1021 subjects (54.2%, 95% CI ± 3.1 , $p < 0.001$); 1 month, 611 of 1002 subjects (61.0%, 95% CI ± 3.1 , $p < 0.001$); 2 months, 303 of 954 subjects (31.8%, 95% CI ± 3.2 , $p < 0.001$); 8 months, 258 of 818 subjects (31.5%, 95% CI ± 3.3 , $p < 0.001$); 9 months, 205 of 783 subjects (26.2%, 95% CI ± 3.1 , $p < 0.001$) (Figure 4.24).

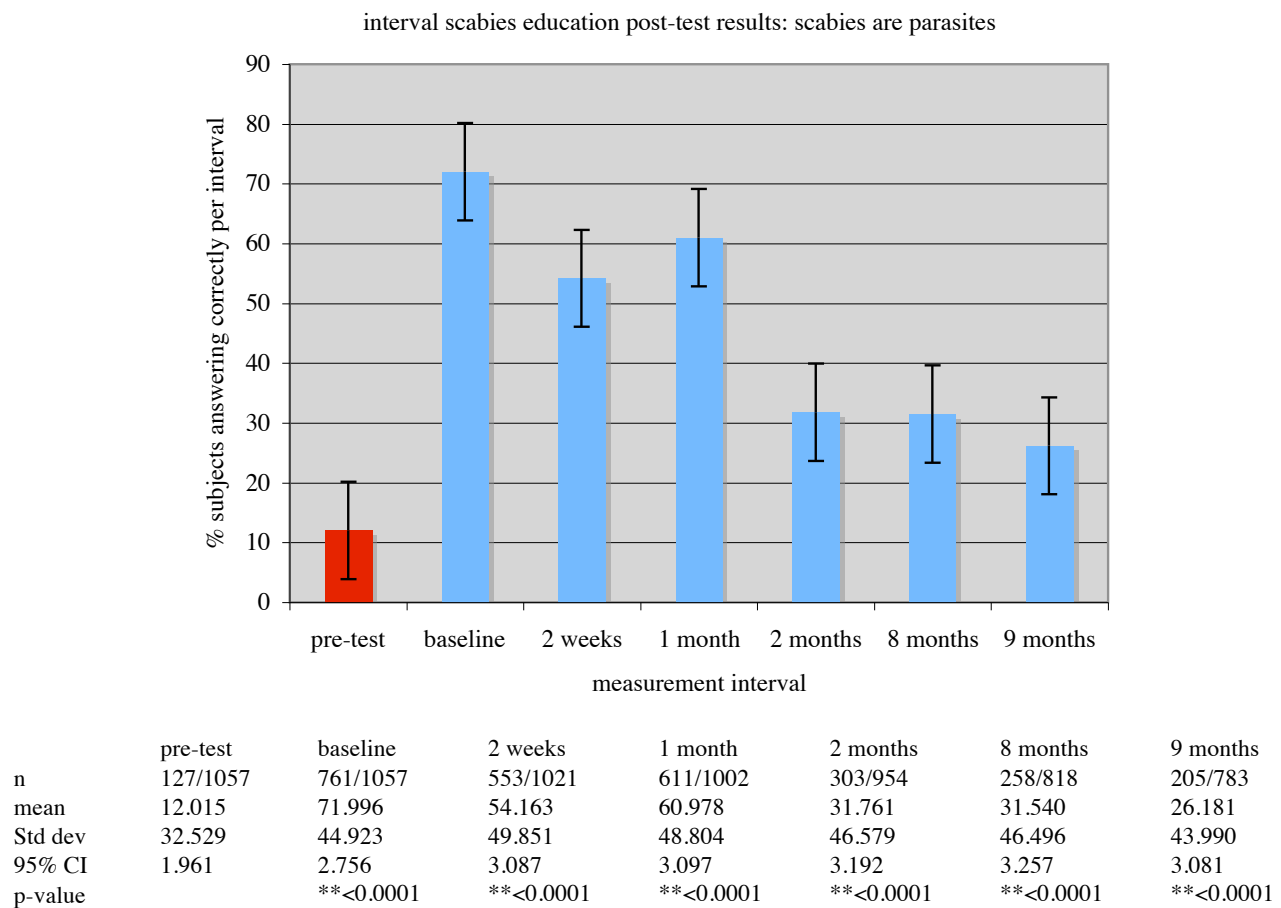


Figure 4.24: Results of scabies education pre-test and interval post-tests regarding the question, “what type of organism is scabies?” (**statistically significant differences from pre-test determined using $p < 0.05$).

4.25 Scabies Education Post-Test: Scabies Primarily Infects the Skin

The number of subjects correctly stating that scabies primarily infects the skin improved as follows: pre-test, 127 of 1057 subjects (12.0%, 95% CI ± 2.0); post-test baseline, 761 of 1057 subjects (71.9%, 95% CI ± 2.8 , $p < 0.001$); 2 weeks, 553 of 1021 subjects (54.2%, 95% CI ± 3.1 , $p < 0.001$); 1 month, 611 of 1002 subjects (61.0%, 95% CI ± 3.1 , $p < 0.001$); 2 months, 303 of 954 subjects (31.8%, 95% CI ± 3.2 , $p < 0.001$); 8 months, 258 of 818 subjects (31.5%, 95% CI ± 3.3 , $p < 0.001$); 9 months, 205 of 783 subjects (26.2%, 95% CI ± 3.1 , $p < 0.001$) (Figure 4.25).

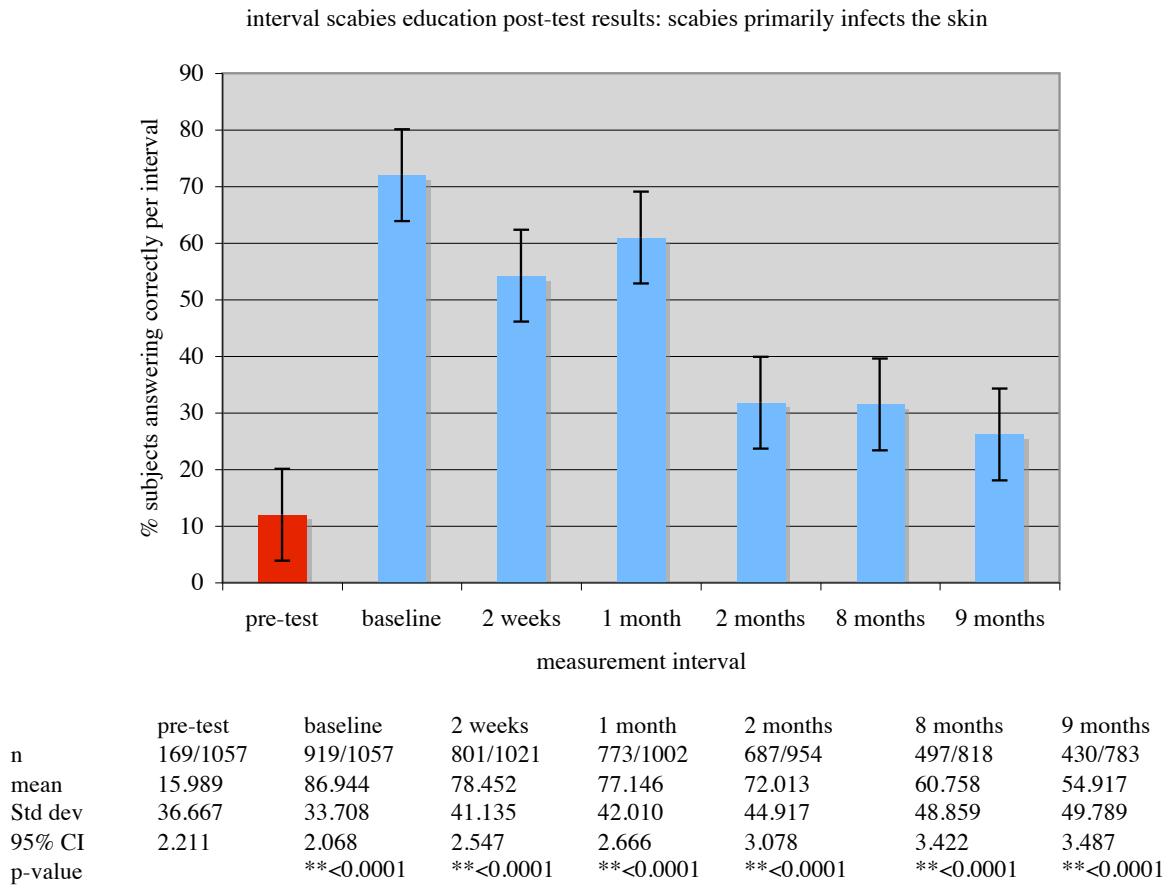
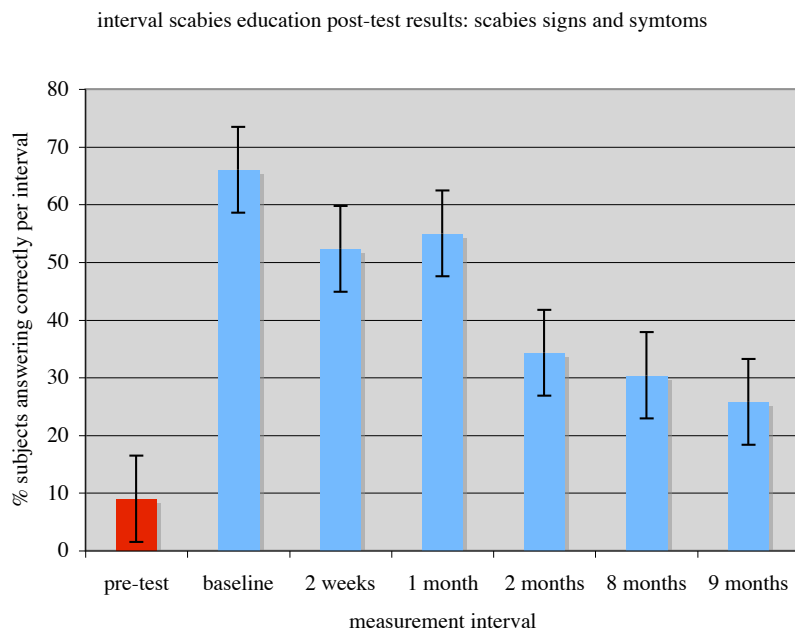


Figure 4.25: Results of scabies education pre-test and interval post-tests regarding the question, “what organ does scabies primarily infect?” (**statistically significant differences from pre-test determined using $p < 0.05$).

4.26 Scabies Education Post-Test: Scabies Signs and Symptoms

The number of subjects correctly listing scabies signs and symptoms improved as follows: pre-test, 95 of 1057 subjects (8.9%, 95% CI ± 1.7); post-test baseline, 697 of 1057 subjects (70.0%, 95% CI ± 2.9 , $p < 0.001$); 2 weeks, 534 of 1021 subjects (52.3%, 95% CI ± 3.1 , $p < 0.001$); 1 month, 551 of 1002 subjects (55.0%, 95% CI ± 3.1 , $p < 0.001$); 2 months, 327 of 954 subjects (34.3%, 95% CI ± 3.0 , $p < 0.001$); 8 months, 249 of 818 subjects (30.4%, 95% CI ± 3.2 , $p < 0.001$); 9 months, 202 of 783 subjects (25.8%, 95% CI ± 3.1 , $p < 0.001$) (Figure 4.26).



	pre-test	baseline	2 weeks	1 month	2 months	8 months	9 months
n	95/1057	697/1057	534/1021	551/1002	327/954	249/818	202/783
mean	8.988	65.941	52.302	54.990	34.277	30.440	25.798
Std dev	28.614	47.413	49.971	49.775	47.488	46.043	43.780
95% CI	1.725	2.908	3.094	3.159	3.254	3.225	3.067
p-value		**<0.0001	**<0.0001	**<0.0001	**<0.0001	**<0.0001	**<0.0001

Figure 4.26: Results of scabies education pre-test and interval post-tests regarding the question, “what are some scabies signs and symptoms?” (**statistically significant differences from pre-test determined using $p < 0.05$).

4.27 Scabies Education Post-Test: Scabies is Spread by Human Contact

The number of subjects correctly stating that scabies is spread by human contact improved as follows: pre-test, 116 of 1057 subjects (10.9%, 95% CI ± 1.9); post-test baseline, 940 of 1057 subjects (88.9%, 95% CI ± 1.9 , $p < 0.001$); 2 weeks, 827 of 1021 subjects (81.0%, 95% CI ± 2.4 , $p < 0.001$); 1 month, 771 of 1002 subjects (76.9%, 95% CI ± 2.6 , $p < 0.001$); 2 months, 562 of 954 subjects (58.8%, 95% CI ± 3.1 , $p < 0.001$); 8 months, 387 of 818 subjects (47.3%, 95% CI ± 3.4 , $p < 0.001$); 9 months, 312 of 783 subjects (39.8%, 95% CI ± 3.4 , $p < 0.001$) (Figure 4.27).

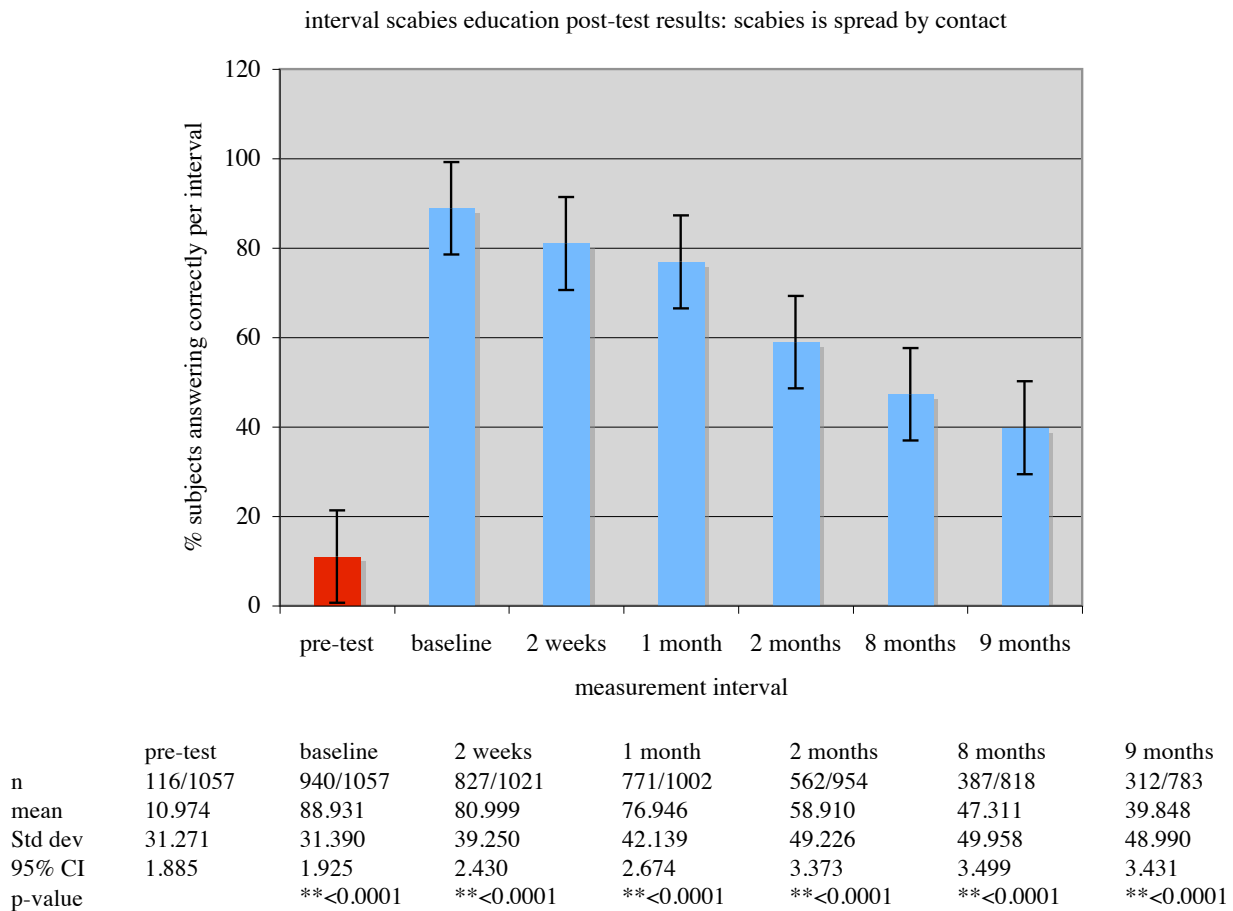


Figure 4.27: Results of scabies education pre-test and interval post-tests regarding the question, “how is scabies primarily spread?” (**statistically significant differences from pre-test determined using $p < 0.05$).

4.28 Scabies Education Post-Test: Scabies Causes Secondary Infections

The number of subjects correctly stating that scabies causes secondary heart, kidney, and skin infections improved as follows: pre-test, 0 of 1057 subjects (0.0%); post-test baseline, 564 of 1057 subjects (53.4%, 95% CI ± 3.0 , $p < 0.001$); 2 weeks, 436 of 1021 subjects (42.7%, 95% CI ± 3.0 , $p < 0.001$); 1 month, 356 of 1002 subjects (35.5%, 95% CI ± 2.9 , $p < 0.001$); 2 months, 297 of 954 subjects (31.1%, 95% CI ± 2.9 , $p < 0.001$); 8 months, 192 of 818 subjects (23.5%, 95% CI ± 2.9 , $p < 0.001$); 9 months, 140 of 783 subjects (17.9%, 95% CI ± 2.7 , $p < 0.001$) (Figure 4.28).

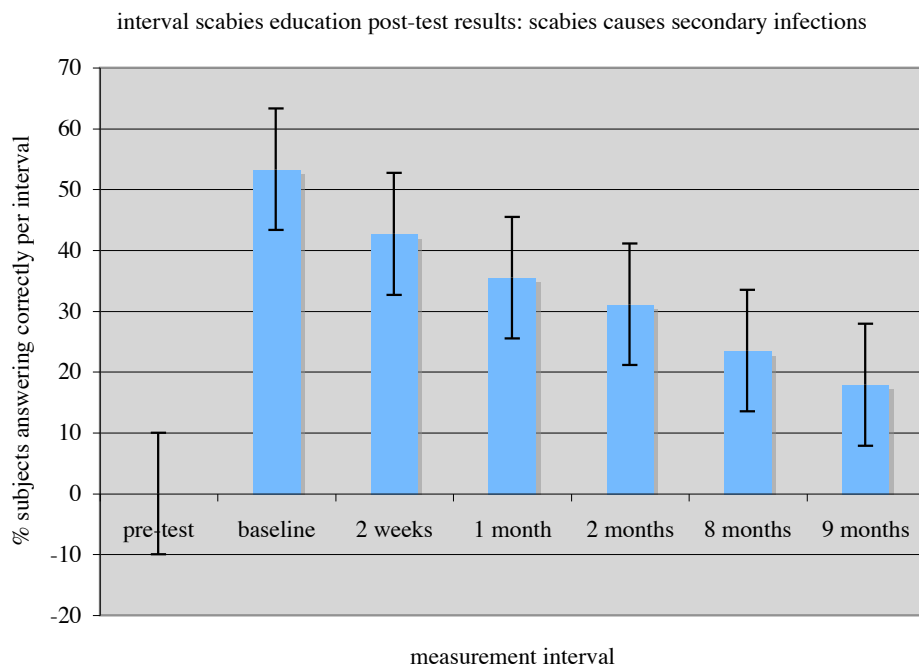
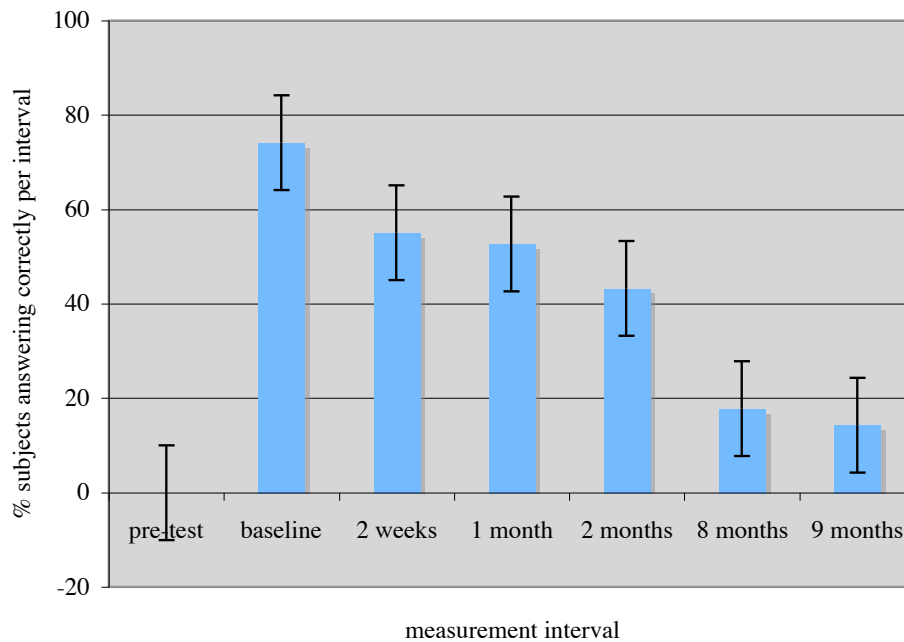


Figure 4.28: Results of scabies education pre-test and interval post-tests regarding the question, “what secondary infections can be caused by scabies?” (**statistically significant differences from pre-test determined using $p < 0.05$).

4.29 Scabies Education Post-Test: Appropriate Scabies Treatments

The number of subjects correctly listing the appropriate scabies treatment for Barrio Nuevo improved as follows: pre-test, 0 of 1057 subjects (0.0%); post-test baseline, 784 of 1057 subjects (74.2%, 95% CI ± 2.6 , $p < 0.001$); 2 weeks, 563 of 1021 subjects (55.1%, 95% CI ± 3.1 , $p < 0.001$); 1 month, 528 of 1002 subjects (52.7%, 95% CI ± 3.1 , $p < 0.001$); 2 months, 413 of 954 subjects (43.3%, 95% CI ± 3.1 , $p < 0.001$); 8 months, 146 of 818 subjects (17.8%, 95% CI ± 2.6 , $p < 0.001$); 9 months, 112 of 783 subjects (14.3%, 95% CI ± 2.5 , $p < 0.001$) (Figure 4.29).

interval scabies education post-test results: appropriate scabies treatments

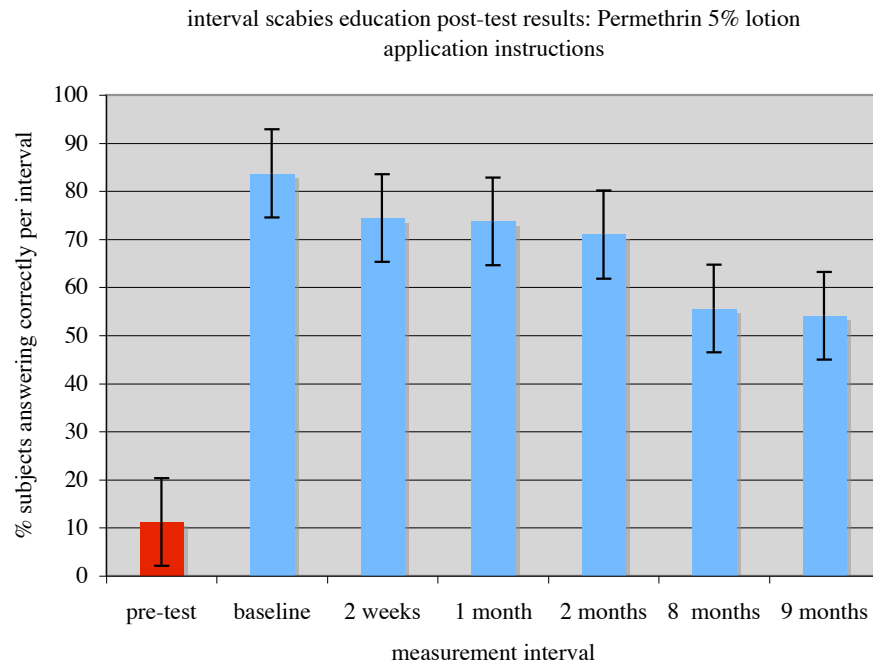


	pre-test	baseline	2 weeks	1 month	2 months	8 months	9 months
n	0/1057	784/1057	563/1021	528/1002	413/954	146/818	112/783
mean	0	74.172	55.142	52.695	43.291	17.848	14.304
Std dev	0	43.789	49.759	49.952	49.574	38.315	35.034
95% CI	0	2.686	3.081	3.170	3.397	2.684	2.454
p-value		**<0.0001	**<0.0001	**<0.0001	**<0.0001	**<0.0001	**<0.0001

Figure 4.29: Results of scabies education pre-test and interval post-tests regarding the question, “what are the appropriate scabies treatments for Barrio Nuevo?” (**statistically significant differences from pre-test determined using $p < 0.05$).

4.30 Scabies Education Post-Test: Proper Permethrin 5% Lotion Application

The number of subjects prescribed Permethrin 5% lotion correctly stating proper application instructions improved as follows: pre-test, 11 of 98 subjects (11.2%, 95% CI ± 6.3); post-test baseline, 82 of 98 subjects (83.7%, 95% CI ± 7.4 , $p < 0.001$); 2 weeks, 61 of 82 subjects (74.4%, 95% CI ± 9.5 , $p < 0.001$); 1 month, 56 of 76 subjects (73.7%, 95% CI ± 10.0 , $p < 0.001$); 2 months, 44 of 62 subjects (71.0%, 95% CI ± 11.4 , $p < 0.001$); 8 months, 25 of 45 subjects (55.6%, 95% CI ± 14.7 , $p < 0.001$); 9 months, 20 of 37 subjects (54.1%, 95% CI ± 16.3 , $p < 0.001$) (Figure 4.30).

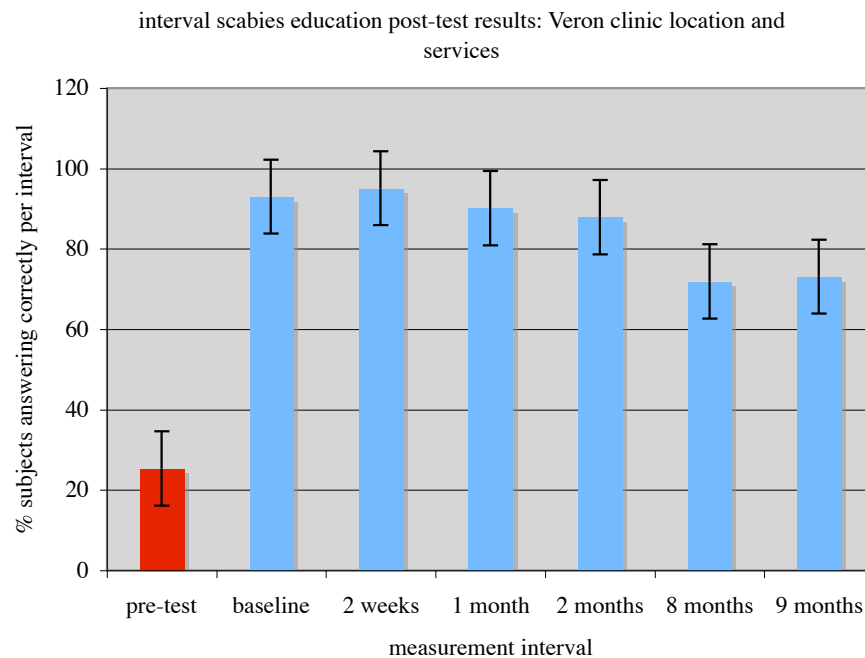


	pre-test	baseline	2 weeks	1 month	2 months	8 months	9 months
n	11/98	82/98	61/82	56/76	44/62	25/45	20/37
mean	11.224	83.673	74.390	73.684	70.968	55.556	54.054
Std dev	31.729	37.151	43.916	44.327	45.762	50.252	50.523
95% CI	6.282	7.355	9.505	9.966	11.391	14.682	16.279
p-value		**<0.0001	**<0.0001	**<0.0001	**<0.0001	**<0.0001	**<0.0001

Figure 4.30: Results of scabies education pre-test and interval post-tests regarding the question, “how is Permethrin 5% lotion correctly applied?” (**statistically significant differences from pre-test determined using $p < 0.05$).

4.31 Scabies Education Post-Test: Veron Clinic Location and Services

The number of subjects correctly stating Veron clinic location and services improved as follows: pre-test, 269 of 1057 subjects (25.4%, CI ± 2.6); post-test baseline, 983 of 1057 subjects (93.0%, 95% CI ± 1.5 , $p < 0.001$); 2 weeks, 971 of 1021 subjects (95.1%, 95% CI ± 1.3 , $p < 0.001$); 1 month, 903 of 1002 subjects (90.1%, 95% CI ± 1.8 , $p < 0.001$); 2 months, 818 of 954 subjects (87.9%, 95% CI ± 2.1 , $p < 0.001$); 8 months, 588 of 818 subjects (71.8%, 95% CI ± 3.1 , $p < 0.001$); 9 months, 572 of 783 subjects (73.1%, 95% CI ± 3.1 , $p < 0.001$) (Figure 4.31).



	pre-test	baseline	2 weeks	1 month	2 months	8 months	9 months
n	269/1057	983/1057	971/1021	903/1002	818/954	588/818	572/783
mean	25.449	92.999	95.103	90.120	87.945	71.883	73.052
Std dev	43.578	25.528	21.591	29.855	32.577	44.985	44.397
95% CI	2.627	1.566	1.337	1.894	2.232	3.151	3.110
p-value		**<0.0001	**<0.0001	**<0.0001	**<0.0001	**<0.0001	**<0.0001

Figure 4.31: Results of scabies education pre-test and interval post-tests regarding the question, “where is the Veron clinic located and what services does it provide?” (**statistically significant differences from pre-test determined using $p < 0.05$).

4.32 Scabies Education Post-Test: How Scabies can be Prevented

The number of subjects correctly stating how scabies can be prevented improved as follows: pre-test, 159 of 1057 subjects (15.0%, CI ± 2.2); post-test baseline, 850 of 1057 subjects (80.4%, 95% CI ± 2.4 , $p < 0.001$); 2 weeks, 778 of 1021 subjects (76.2%, 95% CI ± 2.4 , $p < 0.001$); 1 month, 728 of 1002 subjects (72.7%, 95% CI ± 2.8 , $p < 0.001$); 2 months, 669 of 954 subjects (70.1%, 95% CI ± 2.9 , $p < 0.001$); 8 months, 386 of 818 subjects (47.2%, 95% CI ± 3.4 , $p < 0.001$); 9 months, 281 of 783 subjects (35.9%, 95% CI ± 3.4 , $p < 0.001$) (Figure 4.32).

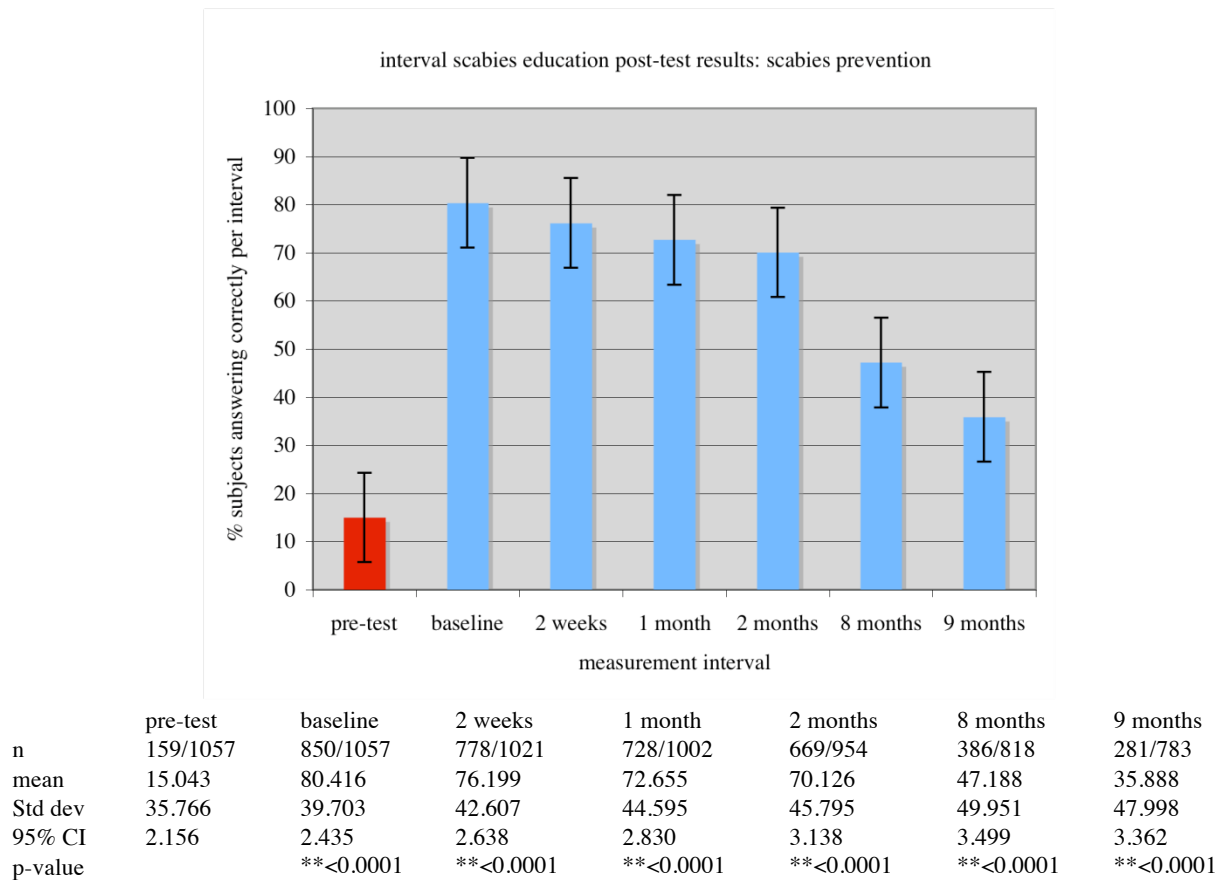


Figure 4.32: Results of scabies education pre-test and interval post-tests regarding the question, “what are 3 ways scabies can be prevented?” (**statistically significant differences from pre-test determined using $p < 0.05$).

4.33 Scabies Education Post-Test: What to do if Further Medical Help is Needed

The number of subjects correctly stating what to do if further medical help is needed improved as follows: pre-test, 274 of 1057 subjects (25.9%, CI ± 2.6); post-test baseline, 953 of 1057 subjects (90.2%, 95% CI ± 1.8 , $p < 0.001$); 2 weeks, 895 of 1021 subjects (87.7%, 95% CI ± 2.0 , $p < 0.001$); 1 month, 889 of 1002 subjects (88.7%, 95% CI ± 2.0 , $p < 0.001$); 2 months, 663 of 954 subjects (69.5%, 95% CI ± 2.9 , $p < 0.001$); 8 months, 486 of 818 subjects (59.4%, 95% CI ± 3.4 , $p < 0.001$); 9 months, 447 of 783 subjects (57.1%, 95% CI ± 3.5 , $p < 0.001$) (Figure 4.33).

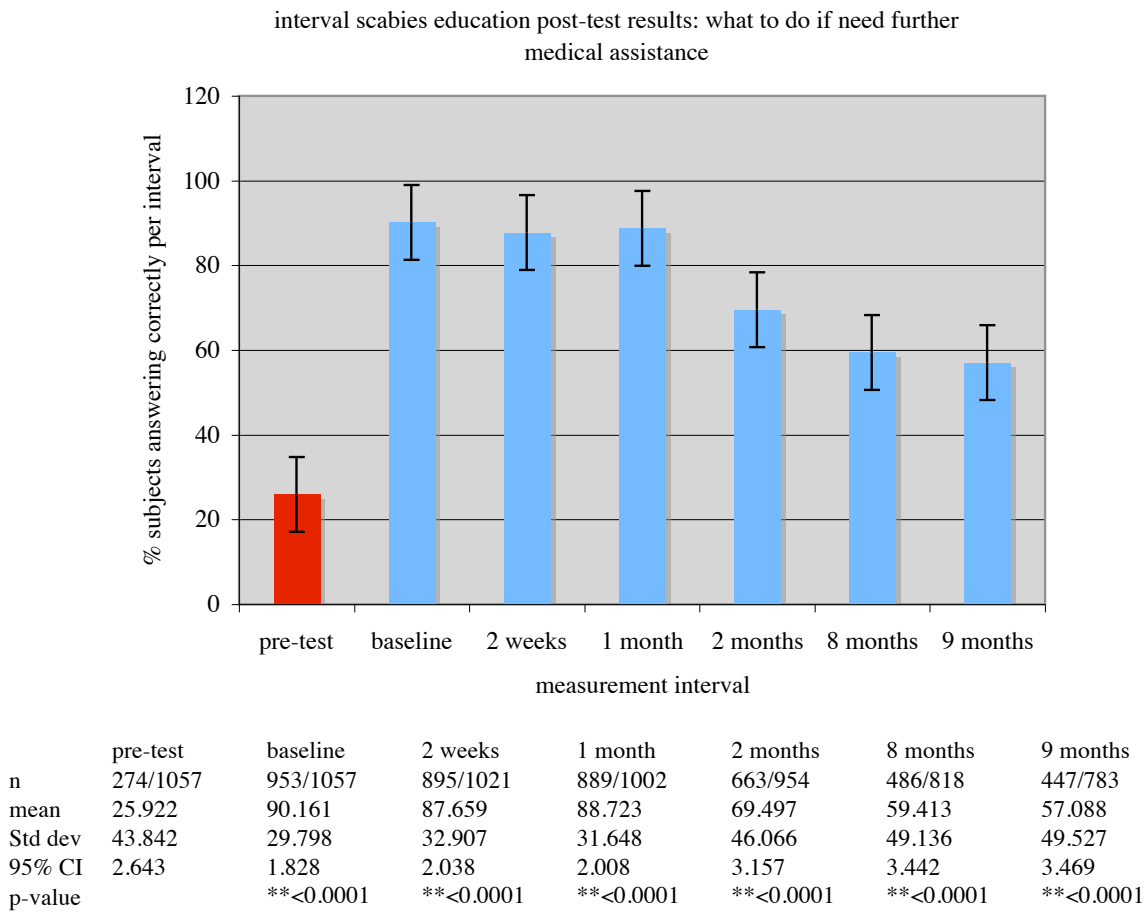


Figure 4.33: Results of scabies education pre-test and interval post-tests regarding the question, “what should you do if you need scabies or medical assistance?” (**statistically significant differences from pre-test determined using $p < 0.05$).

4.34 Discussion

4.35 Population Overview

Upon initial survey, it was obvious that Barrio Nuevo was inhabited by a young, hard-working, transient populace with limited opportunities for education, and thus health and functionally illiterate. The neighborhood was crowded but constantly moving as the daily comings and goings of those who labored outside the area crossed paths with those who spent their time tending to the chores within. The physical conditions alone lend much to perpetuating high levels of scabies infection. When these conditions couple with commonplace health behaviors that increase spread risks, it is no surprise that nearly a quarter of the target population suffers from scabies. This observation underscores the need to treat as many people as possible in an at-risk population to maximize the potential of breaking the infection-infectivity-spread chain that perpetuates endemic scabies.

To achieve this goal, it was obvious that all those able to take Ivermectin must be identified, considering the drug's proven long-term coverage compared to topicals such as Permethrin. This need was especially true in Barrio Nuevo's female population, which made up 57% of the total population. Whereas other scabies campaigns using Ivermectin allowed female subjects to tell investigators whether or not they may be pregnant, it was decided that a rapid β -HCG tests be used for this study for a more objective means of assigning treatment protocols. Moreover, because previous campaigns experienced problems with medication compliance, such as discarding or selling administered treatments, it was clear that direct observational therapy needed to be employed. This proved to be beneficial, especially in those subjects with questions, concerns, or apprehensions. When medications were administered, they were generally well tolerated. Side effects, if any, were reported as mild and transient, none lasting past the 1-month measurement interval.

4.36 Scabies-Related Medical History

When scabies-related medical history was obtained from Barrio Nuevo, it revealed that the disease was well recognized as a health problem in the community, even

prior to formal scabies education. Unfortunately, most of these prior cases went untreated, and if treated, they most often received a banned product (Lindane), incorrect (Metronidazole or an anti-fungal), or unknown. Only 16% of those treated in the past received an accepted medication for the treatment of scabies (13% Permethrin, 3% Ivermectin). When asked about these findings, many subjects incorrectly attributed their itching and skin changes to mosquito bites, and thus would not seek treatment. Many parents would allow lesions on their children to form abscesses before seeking care. When asked why, many stated a concern of stigmatization that may occur while waiting in line at the Veron clinic, whereas most stated no knowledge of care options.

4.37 Scabies Risk and Prevention Behaviors

Scabies risk and prevention behaviors were important considerations. Hot running water was not available in Barrio Nuevo as a utility, thus laundry was always done with cold water. But, it was easy to convince many infested households to heat water on their cooking stove to soak clothes and bedding for at least 10 minutes for the means of killing the mite. Bleach use was almost universal before and after program interventions, and therefore not a likely variable to create a significant impact on scabies incidence. Likewise, bed sharing was almost absolute, most likely out of necessity, as most homes consisted of one small room that lacked the space for a second bed. While it was possible for a statistically significant percentage of infested homes to find alternative sleeping arrangements for the first month, bed sharing soon returned near baseline. Clothes sharing followed a similar trend. Indeed, it was easier for subjects to find alternative clothing than beds, but a return to baseline was witnessed nonetheless. A similar trend also occurred for the existence of pets and livestock inside the home. When subjects were asked if they were able to find alternative sleeping arrangements, sets of clothing, or living spaces for their animals to avoid scabies exposure, most responded by saying it was difficult but possible, but many commented that because each member in their house was scabies-free they felt it was appropriate to resume these habits. This type of reasoning represents a logical application of scabies knowledge and an improvement of health literacy.

4.38 Scabies Symptomatology and Physical Exam Findings

Scabies symptomatology demonstrated a rapid decline in each category, followed by the study-wide gradual trending toward baseline. Indeed, through 9 months, there was a statistically significant decrease in reported pruritis, pruritic lesions or eruptions, and others in the home with similar symptoms. Interestingly, both reported pruritis and pruritic lesions or eruptions showed the greatest reduction by 1 month. This observation can be explained by the possibility of transient itching in the first 2 weeks as the skin reacted to dying mites or to the applied lotion, as seen with Permethrin-induced drug dermatitis. Reported secondary sequelae such as a diagnosed history of heart, kidney, or skin infections was recorded at baseline but not followed because many subjects confused low back pain with kidney infections and the like. This information was deemed of poor quality and thus it was decided that it was beyond the scope of this study, and probably impossible, to properly obtain this health information from subject medical records.

The scabies skin exam was used as a widely accepted, rapid, simple diagnostic test to objectively determine overall scabies prevalence and changes in scabies incidence pre and post-intervention. It was decided to evaluate multiple physical findings related to scabies infections (excoriations, burrow lines, vesicles, papules, etc) instead of a categorical scabies yes or no design to improve the diagnostic and evaluative power of the physical exam considering no skin scrapings or other specimens were taken. Because two independent Barrio Nuevo pre-intervention scabies prevalence surveys demonstrated similar results in May 2006 and May 2007 (23% and 20.7%, respectively), it is reasonable to conclude that the significant reduction in measured scabies symptomatology and physical findings was directly related to program interventions. Indeed, all recorded physical findings took a precipitous and significant fall from baseline within 2 weeks post-intervention. Again, a general trending toward baseline was observed by the 9th month. This trend resulted in no significant differences between baseline and 9-month levels of skin abscesses and scars from previous lesions. This observation can be explained by the fact that many different skin insults can cause skin abscesses and scars, and if the subject indicated that the wound was caused by another source (trauma, mosquito bite, etc) it was not counted in data recording.

4.39 Scabies Education

The scabies education arm began with a pre-test to determine overall pre-intervention scabies knowledge levels in Barrio Nuevo. As expected, the neighborhood as a whole knew very little about the details of the disease, despite 44% being diagnosed in the past and 32% never diagnosed but possibly infected. Considering these statistics, could a little scabies education go a long way? This was indeed the case, as there was a statistically significant improvement in each category of scabies knowledge when pre and post-tests were compared. To clarify, the baseline post-test was administered immediately after the scabies lesson, so it was expected to show a vast improvement over the pre-test. But how long would this improvement remain in the subject population? Interestingly, while all categories displayed a general decay in knowledge retainment over time, there were statistically significant differences between each category and baseline through 9 months. Knowledge of the Veron clinic location and services showed the least decay, as did proper Permethrin instructions and what to do if further help is needed, while the greatest decay occurred in the more detailed questions, such as the names of proper treatments and secondary disease sequelae. Because the Veron clinic is a commonly encountered physical location for the inhabitants of Barrio Nuevo, it is not surprising that a simple lesson on its exact location and services remained fresh in many subjects' minds. Similarly, because Permethrin instructions were followed by the physical application of the lotion to the subject's body, it is no wonder that the mental-motor memory of this process persisted in this population. Furthermore, the staying power of the scabies education in Barrio Nuevo may also be explained by the supplemental printed information pamphlet that was left in each home at the conclusion of the lesson for future reference.

4.40 Results Interpretations

Overall, 9 months tended to be the measurement interval where many categories were no longer statistically significant from baseline measurements. One probable explanation for this trend is the fact that Barrio Nuevo is not an isolated population where classic Hardy-Weinberg dynamics are possible. Indeed, few if any human communities are free from the effects of non-random mating, new mutations, selection, random genetic

drift, or gene flow. Surely, as time went on more migration in and out of the subject population occurred, as witnessed by the loss of subjects from the study pool. Thus, a smaller percentage of the overall Barrio Nuevo population was protected by Ivermectin as the study continued over time. This observation supports previous studies that stated Ivermectin's duration of effectiveness to range between 6 and 9 months. Furthermore, these observations support the need for repeat dosing of Ivermectin every 6 months to sustain the population-wise prophylactic effect of the drug and to prevent the loss of "herd immunity". Coupling this treatment schedule with the simple education lesson used in this study can provide a simple means to improve the overall scabies prevalence and health literacy of at-risk populations.

Chapter 5

Conclusions and Recommendations

Skin infections by the ectoparasitic mite *Sarcoptes scabiei* are a widespread, yet preventable source of morbidity worldwide. While scabies affects all socioeconomic sectors, it is especially prominent in the developing world where crowding, poor hygiene, and limited access to basic health care are commonplace. Mass eradication efforts of this parasite have historically been hampered by delivery and compliance issues surrounding topical standards of care. There have been important advances in these efforts over the last eight years due to the expanded use of oral Ivermectin for the treatment and prevention of ectoparasites such as scabies. Multiple eradication campaigns in various at-risk populations demonstrated rapid and long-lasting reductions in scabies prevalence and incidence levels. Each study focused on various aspects of the disease, yet all indicated the need for basic scabies health education to accompany future studies to improve program sustainability and the overall health literacy of target populations.

The Veron Scabies Eradication and Education Program was designed to answer this call using a novel treatment and education protocol. These two arms were evaluated at various measurement intervals and population means collected for several scabies disease and knowledge markers. These means were then used to test stated program hypotheses. Overall, participants continued typical daily life while interventions and education were monitored to detect change over a 9-month timeline using selected measurement intervals to provide scabies disease and knowledge markers in order to test researcher developed objectives and related hypotheses.

Following this basic protocol, the following scabies markers were evaluated at baseline: subject demographics, scabies diagnosis and treatment history, baseline treatments and reported side effects, and scabies education pre-test results. The following scabies markers were also assessed at baseline and reassessed at 2 weeks, 1 month, 2 months, 8 months, and 9 months: risk and prevention behaviors, symptomatology, skin exam findings, and scabies education post-test results.

Every assessment category except bleach use demonstrated a statistically significant post-intervention improvement when compared to pre-intervention values ($p < 0.05$), including: scabies risks and prevention behaviors (hot water use for cleaning

clothes and bedding, bed sharing, clothes sharing, and animals in the house), scabies symptomatology (diffuse pruritis, pruritic lesions or eruptions, and others in the house with similar symptoms), skin exam findings (skin excoriations, burrow lines, vesicles, papules, healing or scabbed lesions, abscesses, and scars from previous lesions), scabies education post-test items (scabies are parasites, scabies infects the skin, scabies signs and symptoms, scabies is spread by human contact, scabies causes secondary infections, appropriate scabies treatments, appropriate Permethrin instructions, Veron clinic location and services, scabies prevention behaviors, and what to do for further help). Because two independent pre-intervention scabies prevalence studies showed similar disease levels for Barrio Nuevo in May 2006 and May 2007, it is highly likely that the differences recorded in this study are associated with program treatment and education interventions.

5.1 Research Objectives

Demographics

1. Housing units in Barrio Nuevo typically contain dwellings of at least 3 people, most often consisting of a father working in construction and a stay-at-home mother. Mixed family/co-worker dwellings are very common as many inhabitants periodically pursue work or return to their families in other regions of the Dominican Republic or Haiti. The duration of occupancy averages less than 10 months, illustrating the transient, migratory nature of Barrio Nuevo and the greater Veron region. Conditions regarding housing occupancy quantity and flux result in close proximity of occupants and the constant introduction of potential disease vectors into the population, neither of which is favorable to scabies prevention and control.

2. The living conditions and related environmental factors in Barrio Nuevo typically consist of multiple single-room units built in a row from scrap aluminum or plywood on dirt floors. These structures house families or same sex groups of workers in close or overlapping proximity where the majority of households share clothes, beds, community latrines, and water sources. Additionally, there are no sources of hot running water and it

is common for livestock and pets to freely enter or live inside homes. Overall, the living conditions are crowded, unsanitary, and highly conducive to the spread of infectious diseases including scabies.

3. Adults typically have a fourth grade education or less and only basic literacy as most inhabitants have immigrated from Haiti or other regions of the Dominican Republic within the past 5 years. At the beginning of this study the majority of Barrio Nuevo inhabitants lacked the education or literacy levels, sufficient standards of housing, living conditions, or medical wellness and treatment resources to prevent and control scabies and other parasitic diseases.

Scabies-Related Medical History

1. The majority of inhabitants of Barrio Nuevo have suffered from scabies at least once in their life but never received treatment. Of those who did receive treatment, most purchased over the counter remedies at local pharmacies instead of seeking a consultation from a physician at the various clinics in the vicinity. Of these individuals, most received Lindane, a scabies medication banned for all uses in the Dominican Republic due to its toxicity profile. Only 11% of those evaluated reported receiving an approved scabies medication prior to program intervention, the remainder receiving various other medications, none of which are effective against scabies eradication. These results demonstrate that scabies is highly endemic to the Veron area without sufficient means of intervention or treatment.

Pre and Post-Intervention Prevalences

1. Hot water is not an available utility in Barrio Nuevo, yet a small but significant portion of the population began heating water to wash clothes and bedding after being educated on scabies eradication techniques. Bleach use for cleaning of clothes and bedding approached 100% both pre and post-intervention and thus is not considered an effective eradication tool. Both bed and clothes sharing are a necessity in Barrio Nuevo due to

limited financial resources and space in the home. A significant portion of the population decreased this behavior post-intervention after being educated on limiting scabies transmission. While this behavior began to return to baseline by the 8-month interval, the majority of households interviewed reported repeating this behavior either out of necessity or because no persons in the household were symptomatic, illustrating the synergy of a medically-prophylaxed population assimilating newly acquired health education into a high-risk setting. Pets or livestock are a common entity in Barrio Nuevo, many of which freely roam in and out of homes or are kept inside. A significant portion of the population limited this behavior throughout the majority of the study after being educated on the possibility of scabies spreading from animals to humans.

2. Nearly a third of the Barrio Nuevo population reported scabies symptomatology pre-intervention, including diffuse pruritis, pruritic lesions or eruptions. Of those over half reported others in their household with similar symptoms. Once the population was treated and educated reported symptomatology was decreased by more than half the pre-intervention levels and remained significantly lower than these levels throughout the study duration. Thus, the treatment and education protocol was an effective means to reduce scabies symptomatology in the Barrio Nuevo population. It is clear that a significant portion of the Barrio Nuevo population suffers from scabies symptoms and that the program interventions made a beneficial impact on associated sequelae.

3. Approximately a quarter of the Barrio Nuevo population has skin exam findings compatible with scabies pre-intervention, including skin excoriations, burrow lines, vesicles, papules, healing or scabbed lesions, abscesses, and scars from previous pruritic lesions. Once the population was treated and educated scabies-related skin findings precipitously decreased by significant levels within weeks of intervention and remained significantly lower than baseline levels throughout the majority of the study. Thus, the treatment and education protocol was an effective means to reduce scabies-related skin findings in the Barrio Nuevo population in both the short and long-term.

Pre and Post-Intervention Levels of Scabies Education

1. Less than a quarter of the Barrio Nuevo population was able to correctly answer pre-test questions regarding scabies knowledge, illustrating a general lack of understanding of the disease throughout the area. Post-test values revealed a tremendous improvement in scabies knowledge once the population was provided a simple, brief lesson on scabies disease, treatment, and prevention that remained significant throughout the duration of the study, improving the overall health literacy of the population.

Scabies Disease and Education Prevalence and Incidence Data Comparison

1. All interventions had the most significant impact within the first month of providing treatment and education. Over the 9-month period there was a general trend of return toward baseline, most markers remaining significantly improved throughout the study duration. This trend may represent the gradual loss of Ivermectin effectiveness, scabies education lessons forgotten, or dynamic changes in Barrio Nuevo population risk factors and disease vectors over time. The improvement or prevention of this trend of “decay” is a recommended topic of research for future studies.

Program Efficiency, Effectiveness, and Sustainability Evaluation

1. The Veron Scabies Education and Eradication Program was designed as a door-to-door campaign to collect important demographics and physical infrastructure data as it relates to scabies disease transmission and to treat and educate the entire Barrio Nuevo population. While the door-to-door campaign was effective in Barrio Nuevo and helped assure follow-up data collection, it was time and personnel intensive. Regarding sustainability, the program was designed with simplicity and affordability in mind. All education materials were designed in house and each 6-month dose of Ivermectin was calculated to average \$0.50US per person or roughly \$1US per person per year. Overall, the Veron Scabies Education and Eradication Program is highly effective and sustainable, but a modified delivery protocol will need to be designed in future implementations to

efficiently treat larger areas and populations.

5.2 Research Hypotheses

1. The pre-intervention sample mean is significantly greater than ($p < .05$) the post-intervention sample mean for scabies-related risk factors.

This hypothesis can be accepted for hot water use, bed sharing, and clothes sharing, but rejected for bleach use. Because bleach use was already an accepted practice in the population, there was no significant change pre versus post-intervention.

2. The pre-intervention sample mean is significantly greater than ($p < .05$) the post-intervention sample mean for scabies-related symptomatology.

This hypothesis can be accepted for all reported symptoms throughout the study duration, including diffuse pruritis, lesions or eruptions, and others in the house with similar symptoms.

3. The pre-intervention sample mean is significantly greater than ($p < .05$) the post-intervention sample mean for scabies-related physical exam findings.

This hypothesis can be accepted throughout the study duration for the following skin findings: skin excoriations, burrow lines, vesicles, papules, and healing or scabbed lesions. This hypothesis can be accepted for abscesses and scars from previous lesions through the 8-month interval.

4. The pre-test sample mean for correctly answered questions is significantly less than ($p < .05$) the post-test sample mean for correctly answered questions.

This hypothesis can be accepted throughout the study duration for the following tested topics: scabies as parasites, scabies infects the skin, scabies signs and symptoms,

scabies spreads by human contact, scabies causes secondary diseases, appropriate treatments, correct use of Permethrin, Veron clinic location and services, scabies prevention, and what to do is medical help is needed.

5.3 Recommendations

The findings from this program demonstrate that scabies prevalence can be significantly reduced and health literacy significantly improved in a large endemic population using oral Ivermectin and a simple health lesson on scabies disease, treatment, and prevention. Because all data collected over the 9 month program duration illustrated a trending return toward baseline levels after the 8 month interval it is first and foremost recommended that future programs adhere to repeat dosing and education every 6 months to preserve community-wide prophylaxis and prevention behaviors.

A formal program evaluation conducted in the weeks following program conclusion suggest several changes for future large-scale implementations. First, it is recommended that a central treatment and education location, such as the Veron clinic, be used in place of a door-to door-campaign. While the door-to-door campaign was effective in Barrio Nuevo and helped assure follow-up data collection, it was time and personnel intensive. A central point of delivery where subjects are treated and educated as a group every 6 months may be more appropriate for the larger Veron area where the population size surpasses 10,000 individuals. Furthermore, because Ivermectin is a broad-spectrum anti-parasitic drug effective on many gastrointestinal as well as ectoparasites, it is suggested that stool samples be collected from individuals treated for scabies with Ivermectin to detect and follow the drug's impact on polyparasitism in the greater Veron area. Lastly, a formal evaluation of Lindane usage, prescriptions, and purchases in the greater La Altagracia district is suggested so that SESPAS may recognize that the drug continues to be used despite a nationwide ban and clear evidence from this study that a safe, effective, inexpensive alternative exists and is readily available.

This study clearly demonstrated that a community scabies program involving large-scale treatment and education can provide rapid and long lasting improvements to

the health of a highly endemic population. Considering Ivermectin's impressive efficacy and safety profile demonstrated in this study and multiple others, it is now recommended that SESPAS consider making it the standard of care for scabies treatments and enforcing a formal ban on Lindane products.

Like all other mass eradication campaigns using Ivermectin, it was the objective of this program to provide a sustainable, practical, self-sufficient model for improved health outcomes, health behaviors, and health literacy. Indeed, this program has sufficiently demonstrated that community-wide scabies eradication is possible with the appropriate level of structure and support, without significant costs to the health care systems that serve the good people of Veron, Dominican Republic and beyond.

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Appendix

A. Common Scabies Differential Diagnosis (Johnston & Sladden, 2005):

- Insect bites
- Atopic dermatitis
- Contact dermatitis
- Psoriasis
- Fiberglass exposure
- Lichen planus
- Dermatitis herpetiformis
- Bullous pemphigoid
- Urticaria
- Chronic lymphocytic leukemia
- Necrotizing vasculitis
- B-cell lymphoma with monoclonal infiltrate

Norwegian or Crusted Scabies Differential Diagnosis (Johnston & Sladden, 2005):

- Eczema
- Psoriasis
- Ichthyosis
- Adverse drug reactions
- Seborrheic dermatitis
- Erythroderma
- Langerhans cell histiocytosis

B. Scabies education objectives, lesson, and test item development

Objective 1.0 – Given a lesson describing scabies from the medical educator, identify scabies as a parasite when asked what kind of organisms they are.

1. What will they need to do? The learners should be able to actively listen to a lesson and identify scabies as a parasite when asked what kind of organism they are.
2. What conditions will need to be provided? The learners will need to be given a lesson describing scabies from the medical educator.
3. Domain? *Verbal Information*. Learners will have to recite the fact that scabies mites are parasites when asked by a medical educator.
4. This objective will require a one-question oral examination test item asking learners to identify scabies organism type as parasites if correct.

Test Item 1.0 – Please identify the type of organism that classifies a scabies mite. (oral examination for learner, correct answer is “parasite”).

Objective 1.1 – Listen to a 5-minute lesson describing scabies infections given by the medical educator.

1. What will they need to do? The learners should be able to actively listen to a 5-minute lesson given by the medical educator
2. What conditions will need to be provided? The learners will need to be given a lesson describing scabies infections from the medical educator
3. Domain? *Psychomotor Skills*. Learners will have to complete a set of psychomotor steps that represent active listening.
4. This objective will require a checklist for the completion of the steps involved in active listening.

Test Item 1.1 – For the medical educator: monitor the learner during the 5-minute lesson for all behaviors that represent active listening (eye contact, head nodding, no distractions, not talking to others during lesson, not doing anything else during lesson, etc).

Objective 1.1.2 - Given a lesson describing scabies from the medical educator, identify scabies as a parasite that cause skin infections when asked where they cause primary infections in the human body.

1. What will they need to do? The learners should be able to actively listen to a lesson and identify scabies as a parasite that cause skin infections when asked where they cause primary infections in the human body.
2. What conditions will need to be provided? The learners will need to be given a lesson describing scabies from the medical educator.
3. Domain? *Verbal Information*. Learners will have to recite the fact that scabies are parasites that cause skin infections when asked by a medical educator.
4. This objective will require a one-question oral examination test item asking learners to identify scabies primary infection location on the human body as the skin if correct.

Test Item 1.1.2 – Please identify the primary infection location where scabies causes infection on the human body (oral examination for learner, correct answer “the skin”).

Objective 1.2 – Given a set of pictures of scabies mites, visually examine all pictures that are presented by the medical educator.

1. What will they need to do? The learners should be able to clearly see 4” x 6” photographs when held within appropriate range.
2. What conditions will need to be provided? The learners will need to be given a set of pictures of scabies mites.
3. Domain? *Psychomotor Skills*. Learners will have to complete a set of psychomotor steps that represent visual processing of pictures.
4. This objective will require a checklist for the completion of the steps involved in the visual examination of scabies mite pictures.

Test Item 1.2 – For the medical educator: monitor the learner during the 5-minute lesson for all behaviors that represent visual examination of scabies mite pictures (eye contact with each picture, scanning details of pictures, no distractions, holding pictures in hands to adjust distance to eyes, asking questions about pictures, making comments about pictures, etc).

Objective 2.0 – Given a lesson on scabies infection presented on a human body, correctly identify infection signs and symptoms.

1. What will they need to do? The learners should be able to listen to a lesson and identify scabies infection signs and symptoms when asked by a medical educator.
2. What conditions will need to be provided? The learners will need to be given a lesson describing scabies signs and symptoms from the medical educator.
3. Domain? *Verbal Information*. Learners will have to recite scabies infection signs and symptoms when asked by a medical educator.
4. This objective will require a one-question oral examination test item asking learners to identify as many scabies infection signs and symptoms as possible, such as: intense itching, worse at night, worse during or after a shower, inability to sleep, clusters of sores on body, sores all over body, especially around hands and feet, scratch marks on body, old scars on body, skin abscesses where sores get infected, and affecting multiple people in the house if correct.

Test Item 2.0 – Please identify as many scabies infection signs and symptoms as possible (oral examination for learner, correct answers include: intense itching, worse at night, worse during or after a shower, inability to sleep, clusters of sores on body, sores all over body, especially around hands and feet, scratch marks on body, old scars on body, skin abscesses where sores get infected, and affecting multiple people in the house).

Objective 2.1 – Visually examine each scabies lesion on yourself or another human body presented by the medical educator.

1. What will they need to do? The learners should be able to clearly see small skin lesions on their own body or on another human body presented by the medical educator.
2. What conditions will need to be provided? The learners will need to be prompted on where the scabies lesions are on their own body or on another human body by the medical educator.

3. Domain? *Psychomotor Skills*. Learners will have to complete a set of psychomotor steps that represent visual processing of scabies lesions on the skin.
4. This objective will require a checklist for the completion of the steps involved in the visual examination of scabies lesions on skin.

Test Item 2.1 – For the medical educator: direct the learner to either scabies lesions on their own skin or on another human body, monitor the learner for all behaviors that represent visual examination of scabies lesions on skin (eye contact with each lesion, scanning details of lesions, no distractions, moving themselves or the body to adjust distance to eyes, asking questions about lesions, making comments about lesions, etc).

Objective 2.2 – Given a set of pictures of scabies infections, visually examine all pictures that are presented by the medical educator.

1. What will they need to do? The learners should be able to clearly see 4” x 6” photographs when held within appropriate range.
2. What conditions will need to be provided? The learners will need to be given a set of pictures of scabies infections.
3. Domain? *Psychomotor Skills*. Learners will have to complete a set of psychomotor steps that represent visual processing of pictures.
4. This objective will require a checklist for the completion of the steps involved in the visual examination of scabies infection pictures.

Test Item 2.2 – For the medical educator: monitor the learner during the 5-minute lesson for all behaviors that represent visual examination of scabies infection pictures (eye contact with each picture, scanning details of pictures, no distractions, holding pictures in hands to adjust distance to eyes, asking questions about pictures, making comments about pictures, etc).

Objective 2.2.2 – Given a set of scabies pictures and a human body with scabies lesions, correctly match pictures of lesions with actual lesions found on the body.

1. What will they need to do? The learners should be able to clearly see 4” x 6” photographs and skin lesions on a human body when held within appropriate range.
2. What conditions will need to be provided? The learners will need to be given a set of pictures of scabies infections and a human subject with an active scabies infection.
3. Domain? *Psychomotor Skills, Intellectual Skills: Discrimination and Concrete Concept*. Learners will have to complete a set of psychomotor steps that represent visual processing of pictures, discriminate the difference between the lesions seen in the pictures and those seen on the human subject, and be able to match the two by their closest physical characteristics.
4. This objective will require a matching examination where learners will be asked to match the most similar scabies lesion pictures with those found on a human subject.

Test Item 2.2.2 – Please match as closely as possible what you see in the scabies lesion pictures with what you see on the skin of the human subject.

Objective 2.3 – When asked about scabies skin symptoms, correctly identify skin discomfort and itching and actively listen to a lesson regarding these symptoms by the medical educator.

1. What will they need to do? The learners should be able to actively listen and feel skin discomforts.
2. What conditions will need to be provided? The learners will need to be given a lesson on scabies skin symptoms.
3. Domain? *Verbal Information*. Learners will have to recite skin discomfort and itching as the main scabies skin symptoms when asked by a medical educator.
4. This objective will require a one-question oral examination test item asking learners to identify the main skin symptoms seen in a scabies infection, correctly answered as skin discomfort and itching.

Test Item 2.3 – Please identify the main skin symptoms seen in a scabies infection (oral examination for learner, correct answers approximate “skin discomfort and itching”).

Objective 3.0 – Given a lesson describing scabies spread and consequences from a medical educator, identify scabies as easily spread by human contact causing other medical problems when asked to recite lesson information.

1. What will they need to do? The learners should be able to actively listen to a lesson and identify scabies as easily spread by human contact causing other medical problems when asked by a medical educator.
2. What conditions will need to be provided? The learners will need to be given a lesson describing scabies spread and other scabies-related health problems from the medical educator.
3. Domain? *Verbal Information*. Learners will have to recite scabies as easily spread by human contact causing other medical problems when asked by the medical educator.
4. This objective will require a one-question oral examination test item asking learners to identify how scabies is spread between people and the consequences, correctly answered as human contact causing other medical problems.

Test Item 3.0 – Please identify how scabies are spread between people and the consequence of its spread to those who become infected (oral examination for learner, correct answer is “human contact, other medical problems”).

Objective 3.0.1 – Given a lesson describing scabies infection spread to other parts of the human body from the medical educator, identify three ways scabies infections can spread to other organs in the body.

1. What will they need to do? The learners should be able to actively listen to a lesson and identify three ways scabies infections can spread to other organs in the body.
2. What conditions will need to be provided? The learners will need to be given a lesson describing scabies spread to other parts of the body
3. Domain? *Verbal Information*. Learners will have to recite three ways scabies infections can spread to other organs in the body when asked by the medical educator.

4. This objective will require a one-question oral examination test item asking learners to identify three ways scabies infections can spread to other organs in the body.

Test Item 3.0.1 – Please identify three ways scabies infections can spread to other organs in the body (oral examination for learner, correct answers include “heart infections, kidney infections, and skin abscesses”).

Objective 3.1 – Listen to a 5-minute lesson describing scabies secondary disease risks and the need for household treatment given by the medical educator.

1. What will they need to do? The learners should be able to actively listen to a 5-minute lesson given by the medical educator
2. What conditions will need to be provided? The learners will need to be given a lesson describing scabies secondary disease risks and the need for household treatment from the medical educator
3. Domain? *Psychomotor Skills*. Learners will have to complete a set of psychomotor steps that represent active listening.
4. This objective will require a checklist for the completion of the steps involved in active listening.

Test Item 3.1 – For the medical educator: monitor the learner during the 5-minute lesson for all behaviors that represent active listening (eye contact, head nodding, no distractions, not talking to others during lesson, not doing anything else during lesson, etc).

Objective 3.2 – Given a set of pictures of diseased organs caused by secondary scabies infections, visually examine all pictures that are presented by the medical educator.

1. What will they need to do? The learners should be able to clearly see 4” x 6” photographs when held within appropriate range.
2. What conditions will need to be provided? The learners will need to be given a set of pictures of diseased organs caused by secondary scabies infections.
3. Domain? *Psychomotor Skills*. Learners will have to complete a set of psychomotor steps that represent visual processing of pictures.
4. This objective will require a checklist for the completion of the steps involved in the visual examination of pictures of diseased organs caused by secondary scabies infections.

Test Item 3.2 – For the medical educator: monitor the learner during the 5-minute lesson for all behaviors that represent visual examination of pictures of diseased organs caused by secondary scabies infections (eye contact with each picture, scanning details of pictures, no distractions, holding pictures in hands to adjust distance to eyes, asking questions about pictures, making comments about pictures, etc).

Objective 4.0 – Listen to a 5-minute lesson describing the use Permethrin 5% lotion and Ivermectin pills for scabies treatments given by the medical educator.

1. What will they need to do? The learners should be able to actively listen to a 5-minute lesson given by the medical educator.

2. What conditions will need to be provided? The learners will need to be given a lesson describing the use Permethrin 5% lotion and Ivermectin pills for scabies treatments given by the medical educator.
3. Domain? *Psychomotor Skills*. Learners will have to complete a set of psychomotor steps that represent active listening.
4. This objective will require a checklist for the completion of the steps involved in active listening.

Test Item 4.0– For the medical educator: monitor the learner during the 5-minute lesson for all behaviors that represent active listening (eye contact, head nodding, no distractions, not talking to others during lesson, not doing anything else during lesson, etc).

Objective 4.1 – Given a 5-minute lesson by a medical educator, identify Permethrin 5% lotion and Ivermectin pills as scabies treatments and their indications for Barrio Nuevo.

1. What will they need to do? The learners should be able to actively listen to a 5-minute lesson given by the medical educator and identify Permethrin 5% lotion and Ivermectin pills as scabies treatments and their indications for Barrio Nuevo.
2. What conditions will need to be provided? The learners will need to be given a lesson identifying Permethrin 5% lotion and Ivermectin pills as scabies treatments and their indications for Barrio Nuevo.
3. Domain? *Verbal Information*. Learners will have to recite Permethrin 5% lotion and Ivermectin pills as scabies treatments and their indications for Barrio Nuevo
4. This objective will require a two-question oral examination test item asking learners to identify Permethrin 5% lotion and Ivermectin pills as scabies treatments and their indications for Barrio Nuevo.

Test Item 4.1 – Please identify the scabies treatments available for Barrio Nuevo and their indications (oral examination for learner, correct answers include “Permethrin 5% lotion and Ivermectin pills” and approximates “pregnant or lactating women and children under 90cm receive Permethrin 5% lotion, all others can receive Ivermectin pills”).

Objective 4.2 – Given the indicated medication by the medical educator, take the medication in the presence of the medical educator during the lesson.

1. What will they need to do? The learners should be able to swallow pills or apply lotion.
2. What conditions will need to be provided? The learners will need to be given the indicated medication by the medical educator.
3. Domain? *Psychomotor Skills*. Learners will have to complete a set of psychomotor steps that ends in successfully taking the indicated medication.
4. This objective will require a checklist for the completion of the steps involved in swallowing an Ivermectin pill or applying Permethrin 5% lotion.

Test Item 4.2 – For the medical educator: observe the learner swallowing the correct Ivermectin dose or applying the first dose of Permethrin lotion, mark the checklist as successful or unsuccessful.

Objective 4.2.2 – Given verbal and written instructions on the proper use of Permethrin 5% lotion, actively listen to the medical educator for 5 minutes and correctly repeat these instructions to the instructor at the end of the lesson

1. What will they need to do? The learners should be able to actively listen to a 5-minute lesson given by the medical educator and verbally repeat simple instructions.
2. What conditions will need to be provided? The learners will need to be given a lesson on the proper use of Permethrin 5% lotion by the medical educator.
3. Domain? *Verbal Information*. Learners will have to recite Permethrin 5% lotion application instructions at the end of the lesson.
4. This objective will require a one-question oral examination test item asking learners to recite proper Permethrin 5% lotion application instructions.

Test Item 4.2.2 – Please repeat the Permethrin 5% lotion application instructions that were just presented to you (oral examination for the learner, the correct answer approximates “apply the lotion on the entire body, neck to toes, excluding the head, before bedtime, and rinse lotion off the following morning”).

Objective 4.3 – Given verbal and written directions to the Veron clinic and information regarding free scabies medication, education, and follow-up, correctly identify the Veron clinic location and services available.

1. What will they need to do? The learners should be able to actively listen to a 5-minute lesson given by the medical educator.
2. What conditions will need to be provided? The learners will need to be given verbal and written directions to the Veron clinic and information regarding free scabies medication, education, and follow-up.
3. Domain? *Verbal Information*. Learners will have to recite directions to the Veron clinic and information regarding free scabies medication, education, and follow-up.
4. This objective will require a two-question oral examination test item asking learners to recite directions to the Veron clinic and what scabies services are available there, correctly answered as towards Punta Cana, a half mile past the gas station on the right, and free scabies medication, education, and follow-up.

Test Item 4.3 – Please identify the location of the Veron public clinic and what services are available there for scabies care (oral examination, correct answers approximate “a half mile past the gas station on the right” and “free scabies medication, education, and follow-up”).

Objective 5.0 – Given verbal and written instructions on scabies prevention measures, actively listen to the medical educator for 5 minutes and correctly identify that scabies can be prevented by decreased human and animal contact, increased bleach and hot water use for cleaning, and decreased bed and clothes sharing.

1. What will they need to do? The learners should be able to actively listen to a 5-minute lesson given by the medical educator.
2. What conditions will need to be provided? The learners will need to be given verbal and written directions on scabies prevention measures.

3. Domain? *Verbal Information*. Learners will have to recite scabies prevention measures.
4. This objective will require a one-question oral examination test item asking learners to recite scabies prevention measures, correctly answered as decreased human and animal contact, increased bleach and hot water use for cleaning clothes and bedding, and decreased bed and clothes sharing.

Test Item 5.0 – Please identify three ways that the spread of scabies can be prevented (oral examination, correct answers approximate “decreased human and animal contact, increased bleach and hot water use for cleaning clothes and bedding, and decreased bed and clothes sharing”).

Objective 5.1 – Given verbal and written instructions on where bleach and detergent products are sold in Barrio Nuevo and how to properly use them, actively listen to the medical educator for 5 minutes and correctly identify where bleach and detergent products are sold in Barrio Nuevo and how to properly use them.

1. What will they need to do? The learners should be able to actively listen to a 5-minute lesson given by the medical educator.
2. What conditions will need to be provided? The learners will need to be given verbal and written directions where bleach and detergent products are sold in Barrio Nuevo and how to properly use them.
3. Domain? *Verbal Information*. Learners will have to recite directions where bleach and detergent products are sold in Barrio Nuevo and how to properly use them.
4. This objective will require a two-question oral examination test item asking learners to recite where bleach and detergent products are sold in Barrio Nuevo and how to properly use them, correctly answered as any of the various tiendas in the neighborhood and mixed with water and allowed to remain on the surface of the material being cleaned for at least 5 minutes before being rinsed off.

Test Item 5.1 – Please identify where bleach and detergent products are sold in Barrio Nuevo and how to properly use them (oral examination, correct answers approximate “any of the various tiendas in the neighborhood” and “mixed with water and allowed to remain on the surface of the material being cleaned for at least 5 minutes before being rinsed off”).

Objective 5.2 – Given verbal and written information scabies prevention, abstain from bed and clothes sharing or sexual relations with every person with a scabies infection.

1. What will they need to do? The learners should be able to abstain from bed and clothes sharing or sexual relations with every person with a scabies infection.
2. What conditions will need to be provided? The learners will need to be given verbal and written information regarding scabies prevention and the importance of abstaining from bed and clothes sharing or sexual relations with every person with a scabies infection.
3. Domain? *Attitude*. Learners must choose to abstain as a reflection newly acquired knowledge concerning scabies prevention.

4. This objective will require an oral survey of bed sharing, clothes sharing, and sexual habits with others who are known to have significant skin discomfort and itching before and after the scabies education program.

Test Item 5.2 – Do you currently share your bed, share your clothes, or have sexual relations with a person who is actively complaining of skin discomfort or itching? All answers are kept confidential and anonymous (oral examination to be administered before and after the scabies education program).

Terminal Objective - Given a personal scabies infection, access to medical treatment, water, cooking fuel, bleach, spare clothing, spare bedding, and alternative sleeping arrangements, identify scabies signs, symptoms, causes, and treatments, take an indicated treatment for cure and prevention administered by Veron clinic medical educators, affirm that each member of the household has also been treated, separate human and animal living quarters, heat water, wash bedding and clothes with hot water, detergent, and bleach, and abstain from sharing clothes, sleeping in the same bed, or sexual contact with others.

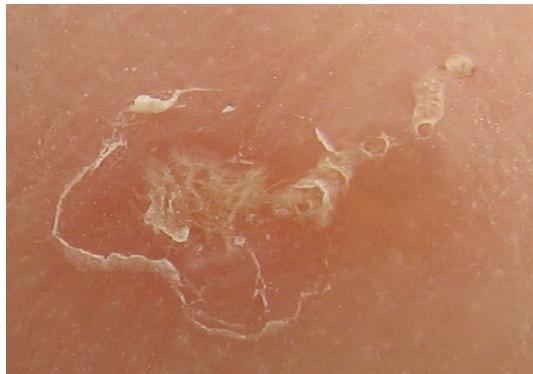
1. What will they need to do? The learners should be able to identify scabies signs, symptoms, causes, and treatments, take an indicated treatment for cure and prevention administered by Veron clinic medical educators, affirm that each member of the household has also been treated, separate human and animal living quarters, heat water, wash bedding and clothes with hot water, detergent, and bleach, and abstain from sharing clothes, sleeping in the same bed, or sexual contact with others.
2. What conditions will need to be provided? The learners will need to be assured access to medical treatment, water, cooking fuel, bleach, spare clothing, spare bedding, and alternative sleeping arrangements.
3. Domain? *Intellectual Skills: Higher-Order Rule*. Learners must be able to identify scabies signs, symptoms, causes, and treatments, take an indicated treatment for cure and prevention administered by Veron clinic medical educators, affirm that each member of the household has also been treated, separate human and animal living quarters, heat water, wash bedding and clothes with hot water, detergent, and bleach, and abstain from sharing clothes, sleeping in the same bed, or sexual contact with others.
4. This objective will require an observational study and survey of behavior that determines the following tasks as completed: able to identify scabies signs, symptoms, causes, and treatments, take an indicated treatment for cure and prevention administered by Veron clinic medical educators, affirm that each member of the household has also been treated, separate human and animal living quarters, heat water, wash bedding and clothes with hot water, detergent, and bleach, and abstain from sharing clothes, sleeping in the same bed, or sexual contact with others.

Test Item 5.3 – Medical educator: check off all behaviors witnessed during observational period: able to identify scabies signs, symptoms, causes, and treatments, take an indicated treatment for cure and prevention administered by Veron clinic medical educators, affirm that each member of the household has also been treated, separate human and animal living quarters, heat water, wash bedding and clothes with hot water, detergent, and

bleach, and abstain from sharing clothes, sleeping in the same bed, or sexual contact with others.

C. Scabies education lesson visual aid

Various Skin Presentations



D. Consent Forms

RESEARCH SUBJECT INFORMED CONSENT FORM

Prospective Research Subject: Read this consent form carefully and ask as many questions as you like before you decide whether you want to participate in this research study. You are free to ask questions at any time before, during, or after your participation in this research.

Project Information

Project Title: Veron Scabies Eradication and Education Program	Project Number:
Site IRB Number: VCOM062007	Faculty Advisor: Dean Sutphin, Phone: 540.231.6862
Principal Investigator: Jeremy Jason White	Organization: Virginia College of Osteopathic Medicine
Location: Blacksburg, VA	Phone: 540.250.6402
Other Investigators: Norberto Rojas	Organization: Secretaría de Estado de Salud Pública y Asistencia Social
Location: Veron, Dominican Republic	Phone: 809.917.6363

1. PURPOSE OF THIS RESEARCH STUDY

- You are being asked to participate in a research study designed to:
 1. determine the level of scabies infections and scabies knowledge in your community
 2. treat the community for scabies with medicine
 3. provide education on scabies and its prevention.

2. PROCEDURES

- You will be asked to:
 1. answer questions about your medical history
 2. undergo a brief skin exam
 3. possibly give a urine sample
 4. listen to a brief talk about scabies disease and prevention
 5. answer questions about scabies before and after the talk
 6. discontinue the use of Lindane
- If you have signs of scabies infection and you weigh less than 15kg or are pregnant or lactating, you will be given a tube of Permethrin 5% lotion and asked to:
 1. Apply the lotion to your entire body, excluding your head, before bedtime.
 2. Rinse off the lotion the following morning.
 3. Wash all bedding and clothes of affected people in your home with detergent, bleach, and hot water, if possible.
 4. Return to the Veron clinic 2 weeks after treatment for follow-up, sooner if problems arise.

- If you weigh more than 15kg and are not pregnant or lactating, you will be given one to three Ivermectin pills (depending on your weight or height) and asked to:
 1. Swallow the pills in the presence of the doctor.
 2. Wash all bedding and clothes of affected people in your home with detergent, bleach, and hot water, if possible.
- You are expected to participate in this study for 9 months, which includes:
 1. A treatment with Ivermectin or Permethrin if indicated
 2. Return to the Veron Clinic if scabies symptoms get worse or you have any complications from treatment.
 3. Repeat visits to your home to assess scabies disease and education levels in your neighborhood.
- Monitoring of scabies levels in the community via questions and skin exams will occur for 9 months after initial visit at 2 weeks, 1 month, 2 months, 8 months, and 9 months.

3. POSSIBLE RISKS OR DISCOMFORT

- Known or possible risks:
 - Ivermectin:
 - **PRECAUTIONS:** Before taking ivermectin, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. Tell your doctor your medical history, especially of: immune system problems (e.g., HIV), breathing problems (asthma), recent foreign travel (Loa-loa endemic areas). This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages. To minimize dizziness and lightheadedness, get up slowly when rising from a seated or lying position. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. This medication passes into breast milk. Consult your doctor before breast-feeding.
 - Permethrin 5% topical lotion
 - Side effects may include: itching, tingling, numbness, redness or irritation. Avoid if you have a known allergy to Permethrin.
- Any new information developed during the study that may affect your willingness to continue participation will be communicated to you

4. OWNERSHIP AND DOCUMENTATION OF SPECIMENS

- All documents and samples will be the property of SESPAS and VCOM and will remain confidential during and after the study until their disposal in the Veron clinic incinerator.

5. POSSIBLE BENEFITS

- If you currently have a scabies infection, you may reasonably expect a reduction or eliminations of your symptoms, reduced risk of secondary complications from scabies infection, and reduced ability to transmit the disease to others.
- If you currently do not have a scabies infection, you may reasonably expect a reduced ability to contract a scabies infection from others.

6. FINANCIAL CONSIDERATIONS

- There is no financial compensation for your participation in this research.
- There is no financial compensation for the investigators or the Virginia College of Osteopathic Medicine.
- Any scabies-related treatments and materials are provided to you free of charge.

7. AVAILABLE TREATMENT ALTERNATIVES

- A common scabies treatment alternative to Ivermectin and Permethrin is Lindane lotion, which is readily used in Veron and available in local pharmacies despite a ban for all use in the Dominican Republic due to its negative effects on the environment. This program upholds this ban and will not offer Lindane as an alternative medication, nor will prescriptions be written by Veron clinic physicians.

8. AVAILABLE MEDICAL TREATMENT FOR ADVERSE EXPERIENCES

- This study involves minimal risk. However, if you are injured as a direct result of taking part in this research study, emergency medical care will be provided by the Veron clinic medical staff or by transporting you to Higuay hospital.

- Neither the Veron clinic nor the Higuay hospital will be able to provide you with long-term medical treatment or financial compensation.

9. CONFIDENTIALITY

- All participants will be given random numerical identifiers for confidentiality and following purposes.
- No personal or health identifiers will be shared during or after the study.
- The results of the study, including laboratory or any other data, may be published for scientific purposes but will not give your name or include any identifiable references to you.
- However, any records or data obtained as a result of your participation in this study may be inspected by the sponsor, by any relevant governmental agency (SESPAS), by the VCOM Institutional Review Board, or by the persons conducting this study, (provided that such inspectors are legally obligated to protect any identifiable information from public disclosure, except where disclosure is otherwise required by law or a court of competent jurisdiction. These records will be kept private in so far as permitted by law.

10. TERMINATION OF RESEARCH STUDY

You are free to choose whether or not to participate in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate. You will be provided with any significant new findings developed during the course of this study that may relate to or influence your willingness to continue participation. In the event you decide to discontinue your participation in the study,

- These are the potential consequences that may result:
 - Increased susceptibility to scabies infections and scabies-related secondary diseases
- Please notify Norberto Rojas, Veron clinic physician of your decision so that your participation can be orderly terminated.

In addition, your participation in the study may be terminated by the investigator without your consent under the following circumstances:

- Significant adverse effects

It may be necessary for the sponsor of the study to terminate the study without prior notice to, or consent of, the participants under the following circumstances:

- Lack of resources
- Loss of funding
- **Any further questions you have about this study will be answered by the Principal Investigator Jeremy Jason White, and may be reached at 540.250.6402**
- **In case of a research-related emergency please call Norberto Rojas at 809.917.6363**

11. AUTHORIZATION

I have read and understand this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws.

Participant Name (Printed or Typed): _____

Date: _____

Participant Signature: _____

Date: _____

Principal Investigator Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

12. ASSENT FORM FOR MINORS

Veron Scabies Eradication and Education Program

Principal Investigator: Jeremy Jason White

My name is Jeremy White. I am trying to learn about infections caused by scabies mites because I want to improve the health and well being of the people in your community. If you would like, you can be in my study.

If you decide you want to be in my study, you will be asked some questions about your past and current health, possibly be asked to urinate in a plastic cup in private, have a brief visual skin exam, be given some medication to take, and be asked to repeat this procedure in six month.

If you currently have a scabies infection, you may benefit from this program by seeing a reduction or elimination of your symptoms, as well as a reduced ability to pass scabies on to others.

If you currently do not have a scabies infection, you may benefit from this program by having a reduced ability to catch scabies from others.

Other people will not know if you are in my study. I will protect your identity so that others outside of my study do not know about your private health information. When I tell other people about my research, I will not use your name, so no one can tell who I am talking about.

Your parents or guardian have to say it's OK for you to be in the study. After they decide, you get to choose if you want to do it too. If you don't want to be in the study, no one will be mad at you. If you want to be in the study now and change your mind later, that's OK. You can stop at any time.

My telephone number is 540.250.6402. You can call me if you have questions about the study or if you decide you don't want to be in the study any more.

I will give you a copy of this form in case you want to ask questions later.

Agreement

I have decided to be in the study even though I know that I don't have to do it. The project personnel have answered all my questions.

Signature of Study Participant

Date

Signature of Researcher

Date

13. PARENTAL CONSENT FORM FOR MINORS

Veron Scabies Eradication and Education Program

Principal Investigator: Jeremy Jason White

PARENT'S STATEMENT

I have read this consent form and have discussed with Jeremy White, Norberto Rojas, or their representatives the procedures described above. I have been given the opportunity to ask questions, which have been answered to my satisfaction. I understand that any questions that I might have will be answered verbally or, if I prefer, with a written statement.

I understand that I will be informed of any new findings developed during the course of this research study.

I understand that participation in this research study is voluntary. I understand that I/my child may refuse to participate in this study. I also understand that if, for any reason, I/my child wishes to discontinue participation in this study at any time, I/my child will be free to do so, and this will have no effect on his/her future care or treatment by his/her physicians or this hospital.

I understand that in the event my child becomes ill or is injured as a result of participating in this research study, medical care will be provided to him/her. However, such medical care will not be provided free of charge, even if the injury or illness is a direct result of this research study. I understand that no funds to provide financial compensation for research-related injury or illness are available.

If I have any questions concerning my child's rights as a research subject in this study, I may contact the Primary Investigator Jeremy Jason White at 540.250.6402.

I have been fully informed of the above-described study with its risks and benefits, and I hereby consent to the procedures set forth above. I have received a signed copy of this consent form.

I understand that as a participant in this study my child's identity and medical records and data relating to this research study will be kept confidential, except as required by law, and except for inspections by the U.S. Food and Drug Administration which regulates investigational drug studies, and the study sponsor.

Child's Assent (7 years and older)

Parent/Legal Guardian

Date

I have fully explained to _____ the nature and purpose of the above-
Parent/Legal Guardian/Participant
described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

Principal Investigator or Representative

Date

Witness

Programa de la Extirpación y Educación de Scabies en Veron: Información

E. Supplemental Information Pamphlet

¿Qué es la sarna/scabies?

- Una infección de la piel causada por el ácaro parasitarias

¿Cuáles son los signos y síntomas de la infestación de sarna?

- Intenso picor, especialmente en la noche
- Pimple-como irritaciones, madrigueras, cero marcas, y erupción en cualquier parte del cuerpo
- Lesiones causadas por arañazos que puede convertirse en infectados

¿Cómo llegué a la sarna?

- Contacto de la piel-a-piel con una persona infectada
- Compartir ropa, toallas, y ropa de cama con un persona infectada
- La infestación es fácilmente extendido a los miembros de la familia y parejas sexuales

¿Quién está en riesgo de infestación severa?

- Los niños, los ancianos y las personas con debilitado el sistema inmunológico

¿Mi mascota o animales propagación de la sarna?

- Posiblemente. Mascota y animal sarna es un parásito diferente que puede infectar a los humanos
- Es importante separar humana y animal cuartos partes viven si posible

¿Cómo se diagnostica la infestación de sarna?

- Un simple examen de la piel por un profesional de la salud

¿Puede ser tratada la sarna?

- Sí. Dos medicamentos están disponibles para su comunidad: una píldora llamada Ivermectina y una loción llamada Permethrina

¿Quién debe ser tratado por la sarna?

- Cualquier persona que es diagnosticada con sarna, así como todos los miembros del hogar para evitar que se repitan
- Consulte la siguiente tabla para guías de tratamiento

¿Qué puede suceder si no se tratan?

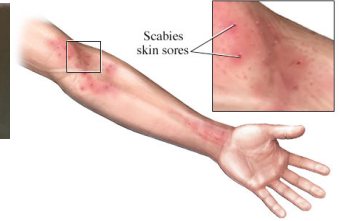
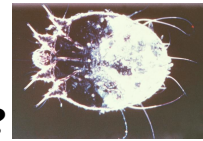
- Peor infecciones de la piel, abscesos, cicatrices, y enfermedades del corazón y riñones

¿Qué puedo hacer para ayudar a prevenir la sarna?

- Cualquier persona que se infecta debe buscar tratamiento inmediato
- Limpie ropa, toallas y sabanas con cloro y agua caliente
- Evitar la ropa de cama y de compartir con aquellos que están infectados

¿Dónde puedo ir si necesito más ayuda o consejo médico?

- La Clínica Pública de Veron



DIRECTRICES DE TRATAMIENTO

SI:

Embarazadas

Lactancia Materna

INFERIOR a 90cm

Uso Permethrina Loción no Ivermectina Pastillas



NO



OTRA:

Si NO embarazada, NO lactancia maternal, y ALTA de 90cm =

Uso Ivermectina Pastillas no Permethrina Loción



NO



F. Image Sources

Images from outside sources are credited below. All other images are by the author.

Figure 2.1 [public domain]
Scabies mite, photomicrograph. Center for Disease Control.
http://phil.cdc.gov/phil_images/20030514/15/PHIL_3810.tif (accessed February 1, 2008).
Works by the U. S. government are not eligible for U. S. copyright protection.

Figure 2.2 [public domain]
Life cycle and pathophysiology of *Sarcoptes scabiei*. Center for Disease Control.
http://phil.cdc.gov/phil_images/20030327/12/PHIL_3416.tif (accessed February 1, 2008).
Works by the U. S. government are not eligible for U. S. copyright protection.

Figure 2.5 [public domain]
Scabies hand burrows. Center for Disease Control.
<http://phil.cdc.gov/PHIL/Images/20031006/7d34b76a33e8484cb9fc2c95c16c875f/4800.tif> (accessed February 15, 2008). Works by the U. S. government are not eligible for U. S. copyright protection.

Figure 2.6 [public domain]
Norwegian or crusted scabies. Center for Disease Control.
<http://phil.cdc.gov/PHIL/Images/20031006/c23b9bf7fc8e453aab91da2ca009f841/4799.tif> (accessed February 15, 2008). Works by the U. S. government are not eligible for U. S. copyright protection.

Figure 2.9 [used with permission]
Worldwide mass eradication campaigns for onchocerciasis. World Health Organization.
http://www.who.int/blindness/partnerships/onchocerciasis_home/en/index.html (accessed February 20, 2008). WHO grants open permission for non-commercial, academic use of their materials.

Figure 2.10 [public domain]
Location of the Dominican Republic within the Caribbean. NASA.
http://rst.gsfc.nasa.gov/Sect6/Sect6_11.html (accessed April 22, 2008). Works by the U. S. government are not eligible for U. S. copyright protection.

Figure 2.11 [public domain]
Map of the Dominican Republic with the location of Veron. U.S. Department of State.
<http://www.state.gov/r/pa/ei/bgn/35639.htm> (accessed April 22, 2008). Works by the U. S. government are not eligible for U. S. copyright protection.

Figure 2.12 [used with permission]
Sutherland, James. Disease prevalence survey of 800 Veron clinic patient files between September 2006 and May 2007. Veron clinic patient file assessment, May 2007, La Altagracia district. Unpublished manuscript. Written permission for reprint granted by author.

Figure 3.1 [used with permission]

Location of Barrio Nuevo within Veron. Google Maps.

<http://maps.google.com/maps?tab=ml> (accessed April 22, 2008). Google Maps grants use of images for academic publications if their logo and copyright are displayed.

Appendix C [public domain]

Scabies hand burrows. Center for Disease Control.

<http://phil.cdc.gov/PHIL/Images/20031006/7d34b76a33e8484cb9fc2c95c16c875f/4800.tif> (accessed February 15, 2008). Works by the U. S. government are not eligible for U. S. copyright protection.

Appendix E [public domain]

Scabies mite, photomicrograph. Center for Disease Control.

http://phil.cdc.gov/phil_images/20030514/15/PHIL_3810.tif (accessed February 1, 2008). Works by the U. S. government are not eligible for U. S. copyright protection.

Bleach. Chilean Ministry of Health.

http://www.paritarios.cl/especial_cloro_domestico.htm (accessed December 30, 2007). No copyright restriction placed on images used for public health dissemination.

Health pictograms. U.S. Pharmacopeia.

<http://www.usp.org/audiences/consumers/pictograms/form.html> (accessed December 30, 2007). Use follows USP pictogram license agreement.