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The AIDS Ribbon is a Noose Around the Neck of Africa

Dedicated to the memory
of my friend and great Zulu warrior,
Professor Sam Mhlongo.

As of May 7, 2008, there were 440 clinical trials underway in South Africa. Ten were evaluating Atazanavir, Efavirenz, Tenofovir, and Acyclovir in combination with different toxic anti-retroviral drugs (known as HAART) in HIV-positive people (Department of Health, 2008). In 2005, the Dr. Rath Health Foundation Africa (a not-for-profit organization) contracted with my friend Professor Sam Mhlongo, Head of Family Practice at the Medical University of Southern Africa (MEDUNSA), to sponsor a clinical trial titled "Vitamins in HIV-positive patients". The clinical trial was a professionally designed double-blind, placebo-controlled, randomized study of the value of nutritional supplements in preventing and reversing the various diseases known as AIDS in Africa. I was asked to setup and run the analysis lab that would support the clinical trial. We spent almost two years trying to get the nutritional clinical trial approved.

President Thabo Mbeki's political enemies along with the AIDS mainstream prevented this trial from taking place. Professor du Plooy of MEDUNSA led the attack. Below is the formal complaint we sent the Department of Health regarding Professor du Plooy's opposition to our study.

Complaints against Professor du Plooy
By David Rasnick, PhD and Professor Sam Mhlongo, MD
Dec. 2005

1. We accuse Professor du Plooy, chairman of the ethics committed, of bias against the Dr. Rath Health Foundation, Dr. Rath personally, Professor Mhlongo and Dr. Rasnick. This bias is manifest in du Plooy's public statements and leaking information to the Democratic Alliance, Treatment Action Campaign, and Medicines Control Council.

2. We accuse du Plooy of systemically blocking the ethics committee approval of our micronutrient clinical trial at MEDUNSA.

3. Professor du Plooy's blocking of the micronutrient clinical trial has kept crucial information from the people of South African on the natural approach to health.

4. Professor du Plooy's blocking of the micronutrient clinical trial has cost the Dr. Rath Health Foundation considerable time and money that could have been devoted to helping the people of South Africa.

Professor du Plooy's ever-changing requirements for ethics committee approval are a moving target. The fact that he brings up bogus objections at the eleventh hour, after more than a year of review reflects a definite effort to delay indefinitely the start of our clinical trial.

Professor du Plooy is a member of the secret Medicines Control Council, which has experienced considerable pressure from the DA (opposition party of which du Plooy is a member), the Treatment Action Campaign, and the South African Medical Association to halt any and all investigations by the Dr. Rath Health Foundation into the health benefits of micronutrients in the context of AIDS in South Africa.

On October 13, 2005, Professor du Plooy justified his rejection of our proposed clinical trial in an interview with *Health-e*: "In this case, MCC approval has not been submitted to us yet. We normally look out for, in the protocol, whether it should get MCC approval or not. And this one should get MCC approval."

Professor du Plooy shared with the interviewer that the committee raised over 34 concerns with the protocol, implying major problems. Almost all of those 34 concerns were pointing out typographical errors. The substantive issues were: 1) better Tswana translation of patient information leaflet, and 2) proof of insurance for the study.

All of the ethics committee's "34 concerns" of May 5, 2005, were completely dealt with months before the Professor's interview with *Health-e* on Oct. 13. Specifically:

a. All typos were corrected as suggested.

b. The Tswana version was completely re-translated and checked by two independent readers fluent in Tswana. Both readers said that the Tswana translation was a fair and accurate representation of the corrected English version.

c. Also, we provided proof that we had purchased insurance coverage for the doctors and patients in the study.

Professor du Plooy's assertion that our proposed micronutrient clinical trial should have MCC approval is disingenuous, at best. There is no reason for MCC approval because our trial involves only micronutrients, not pharmaceutical drugs or medical devices. Micronutrients do not come under the purview of the MCC.

Further along in the same *Health-e* interview, Professor du Plooy confuses the nutritional programs in Khayelitsha with the proposed micronutrient clinical trial under review at MEDUNSA, saying: "It's an unethical trial." There is nothing unethical about the nutritional programs in Khayelitsha, which have nothing to do with the proposed MEDUNSA clinical trial.

The nutritional programs in Khayelitsha are organized and conducted under the auspices of SANCO. The Dr. Rath Health Foundation provides SANCO with micronutrients free-of-charge. The nutritional programs use licensed South African physicians to monitor the health of individuals and give the micronutrients to them at no charge. It is certainly well-within the law for licensed physicians to provide vitamins and other micronutrients to people.

The Annex 2 of Prof W J du Plooy is complete nonsense, clearly instigated by outside forces intent on killing our clinical trial. The formulations used in the trial are not for supplementing the diets of healthy people. They are test formulations proved in Europe and elsewhere and deemed necessary by the principal investigator for the study. This is standard practice in all clinical trials. The fact that du Plooy brings up this bogus objection at the eleventh hour, after more than a year of review, indicates a definite effort to delay indefinitely the start of our clinical trial.

At President Mbeki's instruction, Health Minister Manto met with us to discuss how best deal with Professor du Plooy's attacks on our proposed clinical trial. The Minister agreed to contact du Plooy directly and resolve the problem. Regrettably, this didn't happen.

The first week of January 2006, Sam and I went to talk with President Mbeki about this. Sam was allowed over one hour with the president. However Essop Pahad, Minister to the President, advised Mbeki not to see me. He told Mbeki it would be politically bad if it were leaked that the president had spoken with an employee of the Dr. Rath Health Foundation. The President told Sam he wished he could have met with me and that he privately supports the work of the Foundation but there can be no direct link with its activities.

Faced with the inability to get approval for our nutritional clinical trial, I left South Africa July 2006. Sadly, in October 2006, my friend Sam Mhlongo was killed in a traffic accident. The following is the story of what we were able to accomplish in spite of the mean-spirited and relentless opposition to our efforts.

To understand AIDS in Africa one needs only to understand the African context.

> *"I was in Malawi and met with a group of women living with HIV. As I always do when I meet people with HIV/AIDS and other community groups, I asked them what their highest priority was. Their answer was clear and unanimous: food. Not care, not drugs for treatment, not relief from stigma, but food."*
>
> Peter Piot, UNAIDS Executive Director (Piot, 2003)

Sam continually asks, Where do you find AIDS in Africa? In the affluent areas of Cape Town, Durban, and Johannesburg? or across the bay from Cape Town in Khayelitsha township? Or north of Pretoria in Soshanguve township? or the countless shantytowns without names where tens of millions of desperately poor black South Africans live?

In the 1950s, the United Nations and its agencies became involved in evaluating the extent of profound malnutrition worldwide. Since then, considerable resources have been directed towards improving the treatment of those suffering from this serious and complicated condition. Tragically, however, the fatality rate for severe malnutrition has remained unchanged over the past five decades (Schofield and Ashworth, 1996).

The growing gap between nutritional knowledge and practice in the developing world led Alan Berg of the World Bank in 1993 to accuse nutritionists and pediatricians of malpractice for failing to improve nutrition in the developing world despite considerable research advances in nutritional science (Berg, 1993).

> "Malnutrition is still staggering," he said, "and in some places, particularly sub-Saharan Africa, it is getting worse. We of the international nutrition community, I'm embarrassed to say, have made a disappointingly small dent in improving that condition."

The situation has gotten worse over the years because interest in malnutrition has largely been supplanted by AIDS. As a consequence, African diseases due to malnutrition are increasingly being listed as AIDS and consequently treated with toxic drugs.

Over a decade ago, international organizations had implemented nutritional interventions for reducing mortality from diarrhea, pneumonia and other common diseases of malnutrition caused by poverty (Mosley, 1993). Now, however, the growing practice of treating these diseases as AIDS has largely replaced and undermined those early efforts (Brewster et al., 1997). Indeed, Alex de Waal and Alan Whiteside have even gone so far as to hypothesize that AIDS is responsible for the present food crisis in southern Africa (de Waal and Whiteside, 2003). However, a more conventional and convincing explanation for the worsening malnutrition in southern Africa is the simple fact that many Africans lead desperate lives.

According to the Institute for Democracy in South Africa (Idasa), substantial proportions of all adults across 15 African countries face at least some shortages of basic necessities. Over one-half go without enough food to eat at least once a year, and almost one fifth go without "many times" or "always" (Institute for Democracy in South Africa (Idasa), 2004). Just under one-half go without enough clean water, and 40% have no toilets. A majority face shortages of needed medicines or medical treatment. Nearly half go without enough fuel to cook their food. According to the authors, underlying this deprivation is Africa's "unemployment crisis". Fully three out of four Africans go without cash income at least once, and over a third do so frequently.

Confusing malnutrition with AIDS has contributed to the 50% mortality rates in the hospital-care of severely malnourished children in the developing world (Nolan et al., 2001; Schofield and Ashworth, 1996). In sub-Saharan Africa, studies have shown that 25% of children with malnutrition have antibodies to HIV, although the patterns of malnutrition are indistinguishable from those who are HIV-negative (Ball, 1998). A study of two South African hospitals, for example, found that for 2000-2001, 50% of the deaths of severely malnourished children were due to doctor error and another 28% to nurse error (Ashworth et al., 2004). The authors of the study found that malnutrition was simply not a priority in the training of the doctors. AIDS so dominates the training and thinking at the largest teaching hospital in South Africa that diabetes and other common problems are being misdiagnosed as AIDS (Mhlongo, 2005). In mid 2006, Sam reported to Mbeki that 90% of seventh-year medical students across the country cannot diagnose 80% of the diseases and conditions South Africans suffer because of the over-emphasis on AIDS.

I agree with Andrew Tomkins who said in 2005,

> "Now that specific nutrition interventions have been shown to have beneficial effects, particularly multiple micronutrient interventions and infant feeding options, governments, development partners, including various UN agencies, and NGOs need to act" (Tomkins, 2005).

Physician-sponsored nutritional programs

There were signs early in 2005 that Mbeki's opponents would block our proposed full-scale nutritional clinical trial. As a backup, the Dr. Rath Health Foundation Africa implemented Physician-sponsored nutritional programs in several communities throughout South Africa but principally in Khayelitsha, a township near Cape Town.

Background
Micronutrients play a critical role in the proper functioning of the immune system. Therefore, it is not surprising that at the beginning of the AIDS epidemic, researchers began to notice micronutrient abnormalities in AIDS patients. Chronic diarrhea, anorexia, malabsorption, impaired nutrient storage, increased energy demands and altered metabolism were the primary contributors to these nutritional deficiencies (Tang et al., 2005).

Awareness of the importance of micronutritients in the maintenance of a healthy immune system has been increasing as demonstrated by studies of micronutrient supplementation among antiretroviral drug-naive populations. A series of trials conducted in Durban, South Africa examined the effects of vitamin A supplementation on the morbidity and mortality of so-called HIV-infected mothers and their offspring. Among all children, the supplemented group had a 30% lower overall morbidity (diarrhea, thrush, lower and upper respiratory tract infections, rash) than the placebo group (Coutsoudis et al., 1995). Between 1995 and 1997, over 1000 so-called HIV-infected pregnant women in Tanzania were enrolled into a double-blinded, placebo-controlled micronutrient supplementation trial that continued through lactation. Multivitamin supplementation, but not vitamin A, was significantly associated with improved birth outcomes and improvements in CD4 and CD8 cell counts among these women (Fawzi et al., 1998).

Other studies have shown that providing pregnant women with multivitamins resulted in higher birth weight (Fawzi et al., 2000), reduced mortality and progression of disease among children (Fawzi et al., 2002) and their mothers (Fawzi et al., 2004), and decreased risk of infant diarrhea (Fawzi et al., 2003). The disease-preventing and life-preserving effects of micronutrients have been demonstrated in adults as well (Jiamton et al., 2003).

Below is documented the extensive clinical benefits from a short-course of micronutrients (specific vitamins, amino acids, minerals and polyphenol extracts from green tea) administered by physicians to so-called HIV-positive residents of Khayelitsha who have never used antiretroviral drugs.

Enrollment of patients
The people of Khayelitsha display a spectrum of diseases associated with poverty and malnutrition that overlaps substantially with the Bangui definition of AIDS (World Health Organization, 1986). According to the Bangui definition, Africans with fever, diarrhea, persistent cough, weight-loss, and (since the mid 1990s) TB are suffering from AIDS.

Local officials of the South African National Civic Organization (SANCO) were responsible for enrolling the 100 patients for the Khayelitsha nutritional program. Beginning May 11, 2005, people were free to join the nutritional program if they satisfied the following criteria: be over the age of 13, not pregnant, test positive for antibodies to HIV, not be on antiretroviral drugs nor have a history of their use, have clinical diseases (i.e. CDC stages 2 or 3), likely to survive the two-months of observation as determined by the examining physician, be willing to comply with the vitamin regimen and dosage, and sign the waiver-informed consent form.

Upon enrolling, patients were interviewed and their health history assisted with the aid of a questionnaire. They were then examined by a licensed South African physician and treated for specific diseases such as diarrhea, TB, and other common ailments, with the appropriate standard therapies. Patients were hospitalized when necessary. The patients were given a four-week supply of pills containing micronutrients. The dosing was 5 pills three times a day. Patients returned every four weeks for another medical exam and to pick up a new supply of micronutrients and packages of food. The patients were interviewed about changes in their health. The period of formal clinical observation was eight weeks. After eight weeks, the patients were provided with the micronutrients free-of-charge for as long as they wanted.

Micronutrients
The combination of micronutrients consisted of: vitamins (ascorbic acid, Nicotinate, Pantothenate, Thiamine, Riboflavin, Pyridoxine, Cyanocobalamin, Folic Acid, Biotin, Beta-carotene, cholecalciferol, d-alpha-Tocopherol), minerals and trace elements (Magnesium, Calcium, Potassium, Phosphate, Zinc, Manganese, Copper, Selenium, Chromium, Molybdenum), amino acids (Taurine, L-Lysine, L-Proline, L-Arginine, L-Carnitine, L-Cysteine, N-Acetylcysteine), and other essential nutrients (Green Tea Leaf Extract, Bioflavonoids, Inositol, Coenzyme Q-10).

Clinical and Nutritional Assessment
Enrollees were scored from 0-4 (0 normal, 4 severe) for severity of numerous indicators of health. Among them were the typical AIDS-defining diseases for Africa (De Cock et al., 1991; Weniger et al., 1992; World Health Organization, 1986): fever, diarrhea, cough, weight-loss, TB, and opportunistic infections. Other physical symptoms were assessed: swollen glands, joint pain, numbness or tingling in the hands or feet, nausea or vomiting, headache, bloating, rash, irregular heart beat, pain in mouth (lips or gums), cracks in lips or mouth, sore tongue, wounds and sores that would not heal, gum bleeding, loose teeth, eyes burning or itching, eyes sensitive to light, blurred vision, dry or itchy skin, skin bruises, muscle cramps, cold hands or feet, sweating without work or exertion, unusual thirst, colds and flues. Indicators of general well-being were recordered: nervousness, irritation, anxiety, depression, insomnia, loss of appetite, fatigue, dizziness, memory loss.

Finally, enrollees were questioned as to the frequency with which they consumed specific items of food available in Khayelitsha: mielie pap, samp, white bread, brown bread, sweets, hot chips, rice, noodles, sweet potatoes, fish, chicken, red meat, pronutro/cereals, lemons, oranges, tomatoes, bananas, grapes, nuts, green peppers, salads, milk, and apples.

Analysis of Data
The results from the questionnaires and clinical findings were compiled and scored from 0 to 4, where 0 indicated no complaints or symptoms for each indication and 4 was severe. One-way analysis of variance was performed to generate the averages, standard deviations and significance values.

RESULTS

Of the 100 people who enrolled, 56 completed all three visits of the 8-week nutritional program sponsored by SANCO that began on May 11, 2005, in Khayelitsha. In addition to the usual reasons people fail to return for scheduled doctor appointments was the pressure and intimidation the Treatment Action Campaign (TAC) put on the enrollees personally to stop taking the micronutrients.

The observational phase of the nutritional program ended October 30, 2005. The results for the 56 enrollees showed that within 4-8 weeks of taking the micronutrients there was a significant reduction (58% overall) in 16 clinical symptoms and conditions (Figure 1). Panels a-f of Figure 2 show there were rapid and substantial reductions in the AIDS-defining symptoms (De Cock *et al.*, 1991; Weniger *et al.*, 1992; World Health Organization, 1986). Fevers declined 52%, diarrhoea 51%, coughs 39%, weight-loss 70%, TB 60%, and opportunistic infections 89%. There was dramatic healing of wounds and sores that had persisted for months prior to taking the micronutrients (Figure 2g) and skin rashes dramatically improved (Figure 2h). There was also a significant reduction in swollen glands (Figure 2i).

CONCLUSION

The broad-spectrum clinical benefits observed for a short-course of micronutrient supplementation given to the poor of Khayelitsha township argues powerfully for formal clinical trials to assess the extent and duration of these benefits. People with and without antibodies against HIV should be included to determine if there is a difference between the groups.

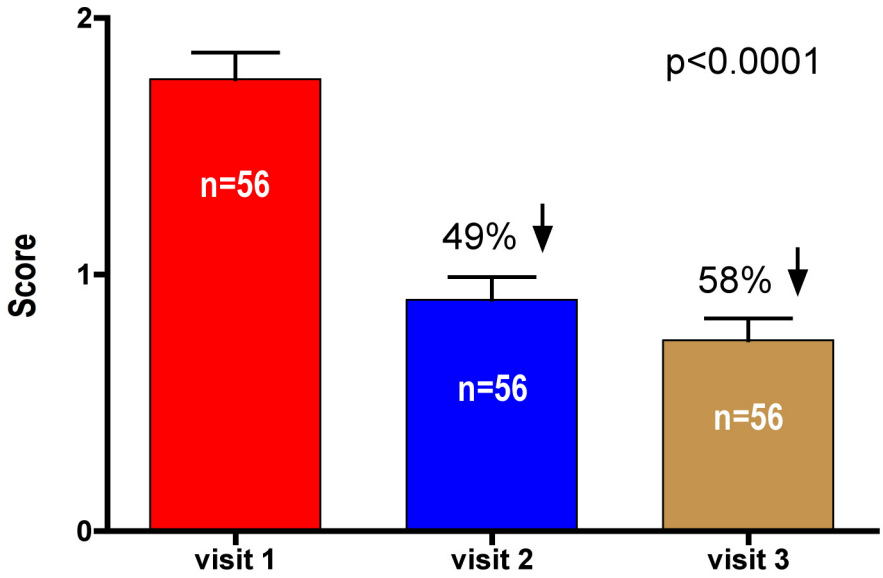
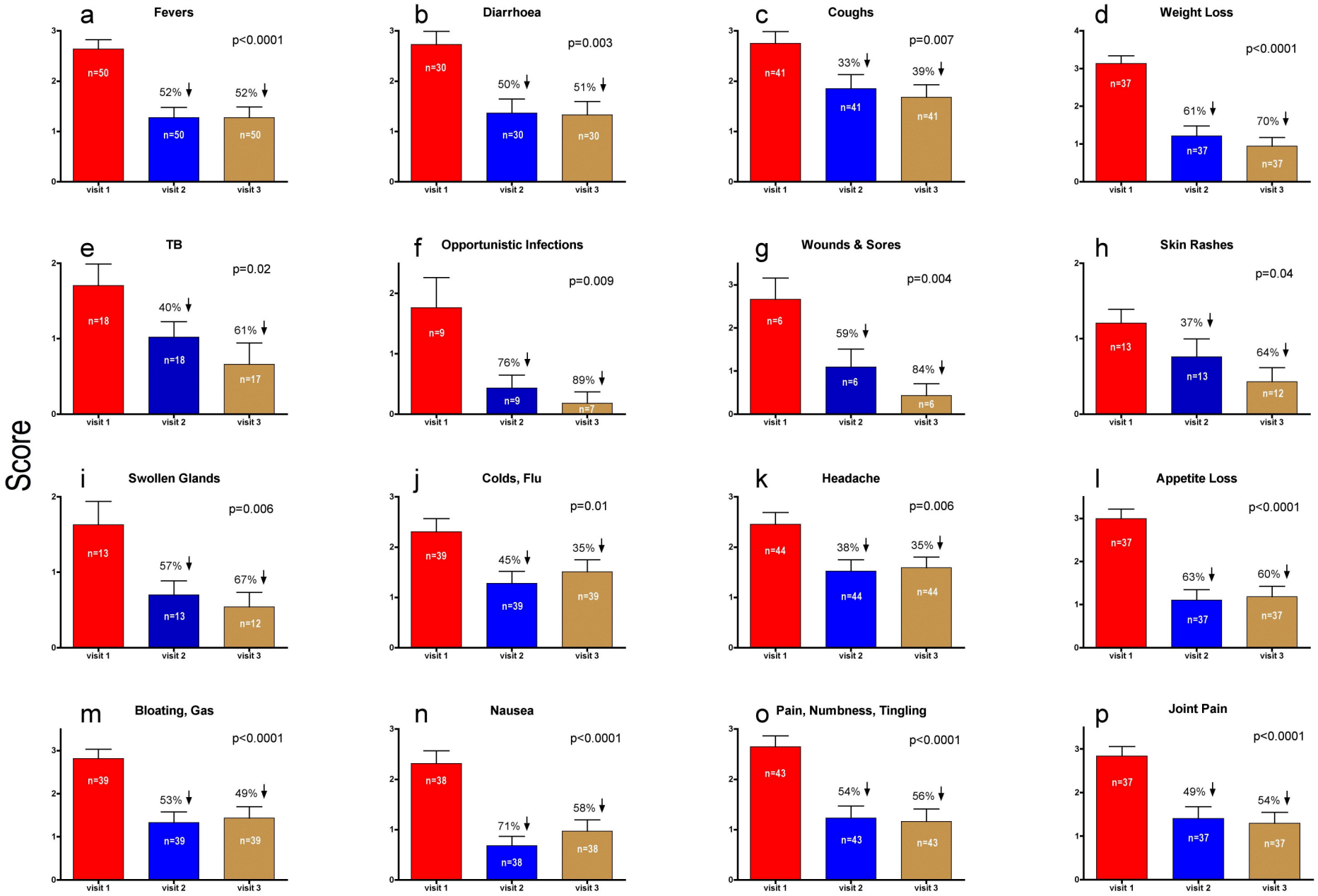


Fig. 1. Overall improvement of 16 clinical symptoms combined during an 8-week course of micronutrient supplementation.
Of the 100 people that enrolled in the micronutrient program, 56 completed all three visits. There was a 49% improvement after only 4 weeks on the micronutrients, that increased to nearly 60% at week 8.

Fig. 2. Improvements in Specific Clinical Symptoms.
(a-f) There were significant reductions in the AIDS-defining symptoms (Weniger *et al.*, 1992; World Health Organization, 1986) after only 4 weeks of taking micronutrient supplementation. Fevers declined 52%, diarrhoea 51%, coughs 39%, weight-loss 70%, TB 60%, and opportunistic infections 89%. (g) There was dramatic healing of wounds and sores that had persisted for months prior to taking the micronutrients. (h) Skin rashes dramatically improved. (i) There was also a significant reduction in swollen glands.


Score
a
Fevers
p<0.0001
n=50
52%
n=50
52%
n=50
visit 1
visit 2
visit 3
b
Diarrhoea
p=0.003
n=30
50%
n=30
51%
n=30
c
Coughs
p=0.007
n=41
33%
n=41
39%
n=41
d
Weight Loss
p<0.0001
n=37
61%
n=37
70%
n=37
e
TB
p=0.02
n=18
40%
n=18
61%
n=17
f
Opportunistic Infections
p=0.009
n=9
76%
n=9
89%
n=7
g
Wounds & Sores
p=0.004
n=6
59%
n=6
84%
n=6
h
Skin Rashes
p=0.04
n=13
37%
n=13
64%
n=12
i
Swollen Glands
p=0.006
n=13
57%
n=13
67%
n=12
j
Colds, Flu
p=0.01
n=39
45%
n=39
35%
n=39
k
Headache
p=0.006
n=44
38%
n=44
35%
n=44
l
Appetite Loss
p<0.0001
n=37
63%
n=37
60%
n=37
m
Bloating, Gas
p<0.0001
n=39
53%
n=39
49%
n=39
n
Nausea
p<0.0001
n=38
71%
n=38
58%
n=38
o
Pain, Numbness, Tingling
p<0.0001
n=43
54%
n=43
56%
n=43
p
Joint Pain
p<0.0001
n=37
49%
n=37
54%
n=37

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Posted: May 14, 2008
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