Health Impact Assessment of Solar Disinfection (SODIS) of Drinking Water in Three African Countries

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A dissertation submitted to the Royal College of Surgeons in Ireland for the degree of Doctor of Philosophy

September, 2010

RCSI

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CANDIDATE THESIS DECLARATION

I declare that this thesis, which I submit to RCSI for examination in consideration of the award of a higher degree Doctor of Philosophy, is my own personal effort. Where any of the content presented is the result of input or data from a related collaborative research programme this is duly acknowledged in the text such that it is possible to ascertain how much of the work is my own. I have not already obtained a degree in RCSI or elsewhere on the basis of this work. Furthermore, I took reasonable care to ensure that the work is original, and, to the best of my knowledge, does not breach copyright law, and has not been taken from other sources except where such work has been cited and acknowledged within the text.

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ACKNOWLEDGEMENTS

Sincere thanks are expressed to:

Dr Kevin McGuigan who supervised this project. I am indebted to him for taking me on as a PhD candidate, for constructive and positive criticism and wise council at critical times during this project.

Prof. Conroy for statistical analyses and help to understand the concepts.

The Council of Scientific and Industrial Research (CSIR), South Africa for most generous financial support.

Barnard Steyn, my son, for continuous support and reminding me to "get it done".

Dr. Kevin Murray for invaluable help and support throughout this study.

The European Commission who funded the project under the Sixth Framework Programme, FP6-2004-INCO-DEV-3, grant agreement no. 013650

Wouter le Roux for assistance in the laboratory and dealing with many of the day-to-day responsibilities at work to create time for me to focus on writing this thesis.

GLOSSARY

Anthropometry: The study of human measurements. In this research the following measurements were taken: Child height (or baby length) (cm) and weight (kg).

Barcode: A unique barcode (with associated number) used to identify individual children, households and sample bottles. Each could be automatically scanned (or manually inserted) onto the handheld computers either during monitoring visits (for households and children) or in the laboratory (for sample bottles). All barcodes have the syntax: ANNNNN where A=country ID and N=digit from 0 to 9, e.g. K00005 for a Kenyan barcode.

Blinding: Procedures that prevent study participants, caregivers, or outcome assessors from knowing who received an intervention and which intervention was received.

Bloody diarrhoea: This is a clinical diagnosis that refers to any loose or watery stool that contains visible red blood or mucus. This does not include episodes where streaks of blood is observed on the surface of the stool, when blood is detected by microscopic examination or biochemical tests or in which stools are black owing to the presence of digested blood .

Borehole: A hole drilled into the ground for the purposes of extracting groundwater.

Canal: An artificial waterway usually constructed for irrigation of crops. It is usually lined with either plastic or concrete to prevent the water seeping away.

Carer: The single person in the household primarily responsible for (a) caring for the children and (b) filling in the diarrhoeal diary every day.

Control group: The group of households not allocated a SODIS bottle. The results of the test group are compared against this group to determine the effectiveness of solar disinfection.

Country computer: The main computer (a laptop) used in each country for SODIS-related work.

Database, Master country: The database in each country containing the data captured in the pre-survey and measured in each subsequent three-monthly (monitoring) visit.

Diarrhoea: Three or more loose stools in one day.

Diarrhoeal diary: A paper form used to keep a record of the number of loose stools and the presence of blood or mucus produced by the children selected for the study (in both test and control groups).

Dysentery day: A single day in which one or more stools (whether regarded by the carer as ‘normal’ or loose) contain either blood or mucus. Dysentery can be associated with *Shigella* bacterial species.

Dysentery episode: When one or more consecutive dysentery days occur followed by three consecutive days on which neither dysentery nor non-dysentery diarrhoea occurs.

E. coli: The bacterium *Escherichia coli*. It is used in this study to indicate the degree of microbial contamination of the storage water and water in the SODIS bottle.

Field worker: Person responsible for (a) helping the supervisor during the pre-survey and monitoring visits and (b) collecting completed diaries from households on a monthly basis.

GPS (Global Positioning System): Used to refer to the Garmin etrex device that is used in this study to (a) mark the waypoints of households and (b) locate these houses on subsequent field visits.

Handheld computer: Small computers used in the field or laboratory to capture responses to questionnaires (including automatic scanning of barcodes). For example, individual questionnaires include:

- Household details (address, head, etc.);
- Child details (name, date of birth, etc.);
- Participation confirmation (during monitoring visits);
- Anthropometry measurements during monitoring visits);
- Storage samples (during monitoring visits);
- SODIS bottle samples (during monitoring visits);
- *E. coli* measurements in the water samples etc.

Health impact assessment: A combination of procedures, methods and tools by which a policy, programme or project may be judged as to its potential effects on the health of a population, and the distribution of those effects within the population

Incident rate ratio: Ratio of the incidence rate in test group to the incidence rate in the control group.

Intention to treat: Is a standard term in the analysis of controlled trials. It refers to the use of all participants, regardless of their compliance, in the analysis. It is the preferred primary analysis method, as recommended by the CONSORT guidelines. Everyone who begins the treatment is considered to be part of the trial, whether they finish it or not.

Meta-analysis: A statistical analysis of the combined results of several studies of acceptable methodological quality that address a set of related research hypotheses, normally by identification of a common measure of, for instance, the size, of a health effect (for example, diarrhoea in children), for which a weighted average could, for example, be the output.

Monitoring visit: A visit to all households four times at three-monthly intervals (*i.e.* over one year) during which:

- Continued participation of the household is confirmed;

- Anthropometry measurements of the children are taken;
- Storage water samples are taken; and
- SODIS bottle water samples are taken (if the household is in the test group).

Non-dysentery diarrhoea day: A single day in which there are three or more loose stools and none contain blood or mucus.

Non-dysentery diarrhoea episode: When one or more consecutive non-dysentery days occur followed by three consecutive days on which neither dysentery nor non-dysentery diarrhoea occurs.

Odds ratio: The ratio of the odds of exposure among the test group to the odds of exposure among the control group.

Placebo: A health or medical effect manifested solely on the power of suggestion.

Pre-survey: A period at the start of the study involving identification of participating households and the completion of the pre-survey questionnaires (including allocation of unique barcodes to households and each individual child) which capture important information about the household (names, address, GPS waypoint and name, protocols relating to water use and hygiene).

***Non-dysentery diarrhoea*:** Diarrhoeal episodes during which loose watery stools without blood or mucus is produced.

Protected water source: A source of drinking water that is physically protected from potential sources of contamination (especially faecal). This may be achieved by restricting access to the source (especially to animals) by a fence of other enclosure. It also includes dug wells lined with bricks or concrete.

SODIS Bottle: The 2-litre transparent plastic soft-drink bottle that is filled to 5 cm from the top with water, shaken well and placed in the sun, for example on the roof, for at least 6 hours to disinfect the water. This study tests how effective this process is.

Spring: A location where groundwater comes out of the ground onto the surface.

Standpipe: A vertical small diameter pipe with a tap at the upper end.

Storage water: The water stored in the household and used for domestic purposes, particularly drinking.

Supervisor: Person primarily responsible for (a) completing the pre-survey questionnaires on the handheld computers, and (b) completing the other questionnaires at each of the subsequent four (three-monthly) visits to the households, and (c) downloading the captured responses to the questionnaires on a daily basis to the country computer.

Test group: The group of households allocated a SODIS bottle. Also referred to as the test group.

Unprotected water source: A source of drinking water that is not physically protected (*e.g.* by a fence or other enclosure, or concrete lining in the case of a borehole) from potential source of faecal contamination (*e.g.* by animals).

Well: A hole dug into the ground for the purpose of extracting water.

UV dose: The total received light intensity over a specific time period (kJm^2)

UV: Ultraviolet light, that portion of the electromagnetic spectrum (propagated in waves) that lies between X-rays and visible light (~10nm to ~400nm wavelength).

ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
CDC	Centers for Disease Control
CFU	Cell Forming Unit
CSIR	Council for Scientific and Industrial Research
DALY	Disability-Adjusted Life-Year
DEHA	di(2- ethylhexyl)adipate
DEHP	di(2-ethylhexyl)phthalate
DNA	Deoxyribonucleic acid
EU	European Union
GBD	Global Burden of Disease
GC/MS	Chromatography/Mass Spectrometry
GPS	Global Positioning System
HIV	Human Immunodeficiency Virus
HWT	Home Water Treatment
ICROSS	International Community for the Relief of Starvation and Suffering
IEG	Independent Evaluation Group
IRR	Incident Rate Ratio
IWSD	Institute of Water and Sanitation Development
MDG	Millennium Development Goals
MPN	Most Probable Number
NGO	Non-Governmental Organisation
NTU	Nephelometric Turbidity Unit
PET	Polyethylene Terephthalate
PVC	Polyvinyl Chloride
RNA	Ribonucleic acid
SODIS	Solar Disinfection
ROS	Reactive Oxygen Species
UN	United Nations
UNICEF	United Nations Children’s Fund
USAID	United States Agency for International Development
UV	Ultra Violet
USEPA	United States Environmental Protection Agency
WHO	World Health Organization
YLD	Years of Life Lived with Disability

YLL	Years of Life Lost

PREFACE

The European Union (EU) under the Specific Programme, Integrating and Strengthening the European Research Area, Call Title: Specific Targeted Projects for African, Caribbean, Pacific Partner Countries, Call Identifier: FP6-2004-INCO-DEV-3, funded the project titled: Solar Disinfection of Drinking Water in Developing Countries or in Emergency Situation (SODISWATER), grant agreement number 013650. The project started in October 2006 and ended in March 2010.

The aim of SODISWATER was to demonstrate that Solar Disinfection (SODIS) of drinking water is an appropriate, effective and acceptable intervention against waterborne disease for vulnerable communities in developing countries without reliable access to safe water.

The scientific objectives for the overall project were to initialise in depth research in each of the following topics:

1. Health impact assessment studies in three African countries.
2. Microbiological studies to determine the response of the most important untested waterborne pathogens to solar disinfection.
3. Enhancement techniques designed to improve the efficiency of inactivation (e.g. continuous flow systems, compound parabolic reactors).
4. Socio-psychological studies concerned with successful diffusions and behavioural change strategies for sustainable adoption of solar disinfection.

This thesis describes the rationale, methods and findings of the first scientific objective “Health impact assessments in three African countries.” The author was responsible for the overall coordination of the three African studies based on the protocol of the health impact assessments she developed during the proposal development phase. The health impact assessments were undertaken in South Africa by the Council for Scientific and Industrial Research (CSIR), and two non-governmental organisations (NGOs), the Institute for Water and Sanitation Development (IWSD) in Zimbabwe and the International Community for the Relief of Starvation and Suffering (ICROSS) in Kenya.

The study design of the health impact assessments were undertaken by a multidisciplinary research team consisting of a software developer, a statistician and the author who is a trained microbiologist.

Standardisation of the procedures for the multi-country health impact assessments was made possible by the development of two manuals: 1) *SODISWATER Field Manual* (**Appendix A**) and 2) *Diarrhoeal Diaries Data Entry Manual* (**Appendix B**). The author provided the basis appropriate for inclusion of all relevant aspects for the development of the manuals and contributed to the design and contents of these manuals. The development of the manuals was undertaken in collaboration with a software developer who was also responsible for the development of the database and accompanying software used for managing and verifying the captured data. The software developer also assisted with programming the handheld computers that were used for capturing field data.

Field workers and field coordinators from South Africa as well as the field coordinators from Kenya and Zimbabwe attended a five day course developed and presented by the author. The course content was based on the procedures described in the manuals. To familiarise the attendees with the use of the electronic equipment, anthropometry equipment, water analysis method and interpretation of the results, practical sessions were conducted at the CSIR. The attendees were trained in the use of handheld computers, downloading information onto the database, use of the dedicated project computers and how to correct mistakes in the data when possible. A small pilot study, undertaken in the study area, provided the opportunity to apply the knowledge gained under real field conditions. The attendees were encouraged to use the manuals as guidance during execution of all procedures necessary to conduct the health impact assessments in the respective countries. Ethical issues were highlighted and advice given on how to approach and address potential study participants respectfully.

The author was responsible for the initial questionnaire development. These were refined in collaboration with the project teams from Kenya and Zimbabwe. The author also acquired the equipment and consumables for the respective studies

The author personally co-ordinated the South African trial and was closely involved in all the activities, including overseeing the field workers, data collection, data capturing, data correction and initial analysis. The study teams and study areas in Kenya and Zimbabwe were visited in person by the author when specific problems had to be resolved. General problems experienced by field co-ordinators in Kenya and Zimbabwe were resolved by using electronic mail and the telephone.

Basic statistical analyses were performed by the author. However the bulk of the sub-group analyses were performed by a fully trained statistician. The author endeavoured to understand the basis of sub-analyses and the interpretation thereof.

The author compiled the entire thesis.

EXECUTIVE SUMMARY

Solar disinfection (SODIS) refers to disinfection of water in transparent plastic bottles using sunlight. The effect of SODIS on diarrhoea in children was determined in South Africa (January, 2007 to December 2008), Kenya (July 2007 to March 2009) and Zimbabwe (June 2009 to November 2009). Based on information of census data and accessibility, peri-urban and rural areas with different socio-economic levels and water sources were selected as study areas.

Households without in-house piped water and at least one child aged 6 months to 5 years were included in a sample frame of households consisting of addresses and geographical coordinates. Households were randomly allocated to control and SODIS groups using a table of random numbers. Written informed consent was obtained from participants.

The health outcome was dysentery and non-dysentery diarrhoea. The control children drank water from in-house storage containers and the test group drank SODIS water. Dysentery and non-dysentery diarrhoea were recorded using pictorial diaries. Anthropometric measurements were recorded for both control and test group. *Escherichia coli* levels in SODIS and storage water were measured to determine the microbial quality of the water.

The household was the unit of randomisation. However, statistical analyses were based on a child-based measure of effect size, namely, the rate of dysentery per child per year determined using robust variance estimation procedures that allow adjustment of the calculation to allow for the clustering of children within households.

In South Africa the effect of SODIS and high participant motivation (>=75%, based on the extent of diary completion) showed a significantly lower incidence of dysentery than controls (IRR, 0.36, 95% CI 0.16 to 0.81, P=0.014). There was no significant reduction in risk at lower levels of motivation. Incident rate ratios (IRR) for standpipes were lower than for other sources (0.38, 95% CI 0.12 to 1.2, P=0.091), however not statistically significant.

In Kenya the IRR ratios for all health endpoints were statistically significant: dysentery: IRR 0.56 (CI 0.40 to 0.79); dysentery episodes: IRR 0.55 (CI 0.42 to 0.73); non-

dysentery days: IRR 0.70 (CI 0.59 to 0.84); non-dysentery episodes: IRR 0.73 (CI 0.63 to 0.84).

There was no evidence that SODIS was associated with the risk of dysentery in Zimbabwe.

Weight and height of South African children was not affected by SODIS. Median height-for-age and weight-for-age were significantly increased over a 1-year period over the group as a whole in Kenya (1.3 cm, 95% CI 0.54 to 2.2 cm, P=0.001 and 0.4 kg 95% CI 0.16 to 0.64 kg, P<0.001).

E. coli levels in SODIS water and storage water were not significantly reduced by SODIS.

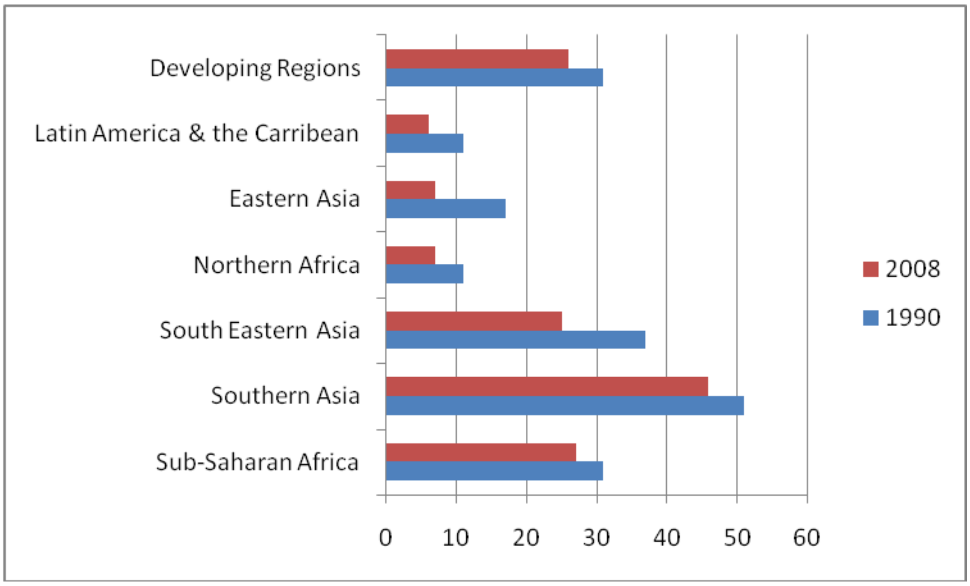
In essence, given the variety of political cultural difficulties faced in all three countries, and the associated lack of data quality and quantity in some instances, SODIS was effective in respect of reducing diarrhoea.

CHAPTER 1: BACKGROUND

1.1 INTRODUCTION

Access to affordable, safe and sufficient quantities of water is fundamental to health and dignity of all humans. However, in 2006 an estimated 1.1 billion people still had no access to safe water and 2.6 billion lacked access to basic sanitation (UNICEF, 2010). An estimated 94% of the diarrhoeal burden of disease is attributable to the environment, and associated with risk factors such as unsafe drinking water, lack of sanitation and poor hygiene (Prüss-Üstün and Corvalán, 2006). Water contaminated with waterborne pathogens has a direct and profound negative effect on human health and consequently livelihoods, in the developed and developing world. The immediate adverse health effects of ingesting enteric waterborne pathogens mostly manifest in the form of diarrhoea. Globally diarrhoea ranks as the second largest cause of morbidity (UNICEF/WHO, 2009). One in five deaths in children is caused by diarrhoea bringing the number to a staggering 1.5 million children each year (UNICEF/WHO, 2009). Young children are impacted the most and for those infected with the human immunodeficiency virus (HIV) who have developed acquired immunodeficiency syndrome (AIDS), diarrhoea can be prolonged and severe and can ultimately cause death (USAID/BASIC, 2007).

Under-nutrition, measured by growth standards (WHO, 2006a), is an important underlying cause of child morbidity and it is closely related to diarrhoea. Lactose intolerance (Nyeko et al., 2010) and a much higher prevalence and severity of diarrhoea (5 to 7 times higher prevalence and 3 to 4 times greater in severity) and high susceptibility to other illnesses characterises the health status of malnourished children (Memon et al., 2007). Compared to the World Health Organization (WHO) growth standards (WHO, 2006a), children who are underweight in the under five age group declined from 29% to 18% for the period 1990 to 2005 but in spite of the decline 186 million children in this age group are still affected by stunted growth. Children are not just under weight because of lack of food but also the lack of quality food. Southern Asia and sub-Saharan Africa are the two regions with the highest number of under nourished children less than five year old (UN, 2010).



(Data adapted from the United Nations Millennium Development Goals Report, 2010)

Figure 1.1: Percentage of children who were under weight in 2008 and 1990

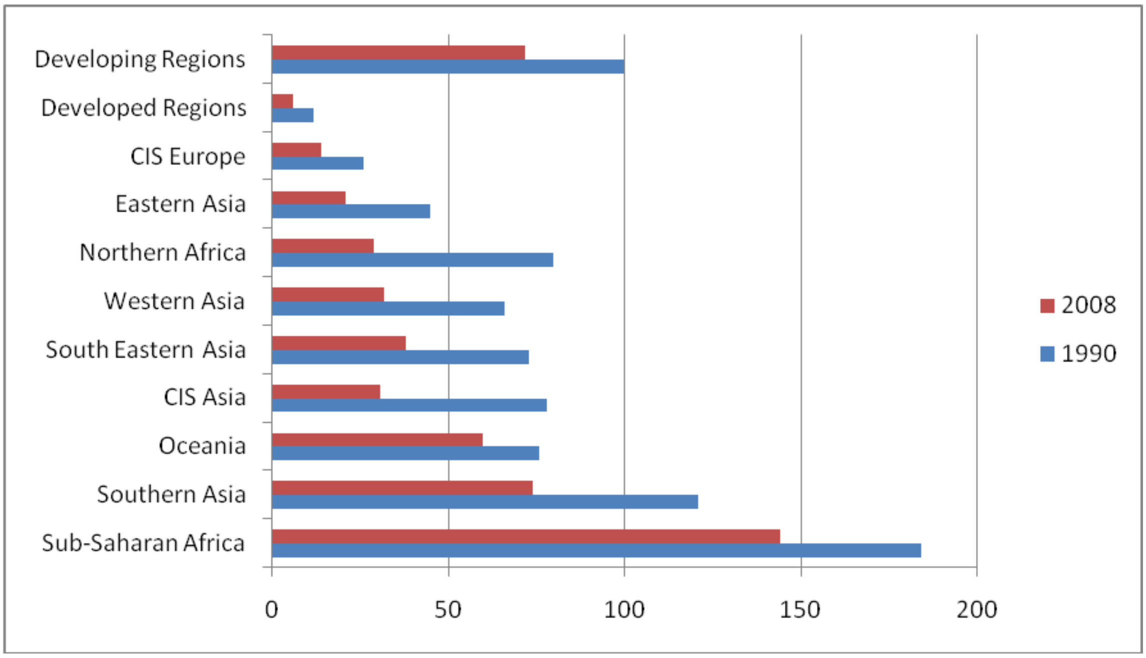
Appropriate health planning and decision making require detailed assessments of the leading causes of disease and injury burden in populations and should incorporate both the causes of death and the main causes of illness. To satisfy these requirements the first Global Burden of Disease Study (GBD), commissioned by the WHO was undertaken by Murray and Lopez (1997). This study generated the first comprehensive and consistent set of estimates of mortality and morbidity, split by age, gender and geographical region. Moreover it also introduced a new unit of measurement - the disability-adjusted life-year (DALY).

The disability-adjusted life-year (DALY) quantifies and compares the health of populations using a summary measure of both mortality (the years of life lost, YLL), and disability (years of life lived with disability, YLD), weighted by the severity of the disability. The burden of disease is a metric of the gap between the current health of a population and the ideal situation where the total population lives into old age in full health. One DALY consists of one year of healthy life lost by either death or illness or disability (Mathers et al., 2007; Murray and Lopez, 1996).

The DALY has become a recognised metric not just for global studies but also for studies investigating regional health and national burden of disease (Mathers et al., 2007; Bradshaw et al., 2000; Mathers et al., 2000). It has also found application in the realm of cost-benefit analysis and cost-effective analysis. The outcomes of health expenditure have traditionally been measured using cost-benefit analysis based on the infrastructure for water provision and excreta removal. A more holistic measurement would be one that includes the social benefits affected through the provision of the infrastructure, termed the cost-effectiveness. The latter allows reporting the results in terms of cost-effectiveness analyses of environmental health intervention benefits in terms of DALYs averted for each dollar invested (Clasen 2008a). This is an important development underpinning decision maker's choices for future health interventions.

Based on the DALY the disease burden from unsafe water, sanitation and hygiene was estimated at the global level, taking into account various disease outcomes, principally diarrhoeal diseases (Murray and Lopez, 1996). The global burden of disease attributed to water sanitation and hygiene accounts for approximately 82 196 000 disability-adjusted-life-years.

Although diarrhoea is preventable and treatable, globally it ranks third after respiratory diseases and HIV/AIDS as leading cause of death among children under five years of age. Increasing the availability of clean water, and improving sanitation and hygiene can prevent an estimated 94% of cases of diarrhoea and subsequently save the lives of many children (WHO, 2007). Substantial progress towards Millennium Development Goal (MDG) no. 4, reducing under-five child deaths by two thirds by 2015, has been made since 1990. Some of the world's poorest countries showed the most striking progress. Bangladesh, Bolivia, Eritrea, Lao People's Democratic Republic, Malawi, Mongolia and Nepal all reduced mortality rates by 4.5% (UN, 2010). Sub-Saharan Africa still has the highest rate for child mortality where one in seven children died before their fifth birthday. The rate at which the current decline (22%) has been achieved is insufficient to meet the MDG target (UN, 2010). The current death rate per 1000 births from 1990 to 2008 is presented (**Figure 1.2**).



(Data adapted from the United Nations Millennium Development Goals Report, 2010)

Figure 1.2: Comparison of under-five mortality rate per 1000 live births for 1990 and 2008.

Cutler and Miller, (2005) investigated the importance of nutrition, hygiene education and clean water technologies relative to the health gains derived from them at the end of the 19th Century and the beginning of the 20th Century in America. The authors showed that about 50% of the reduction in mortality noted for this period could be explained by the provision of filtered or chlorinated water (Cutler and Miller, 2005). Hence in many cities and densely populated areas central, large scale solutions for supply and water treatment are favoured

In many developing countries, however, failures of these systems, caused by an inability to provide sufficient water around the clock at a constant water pressure, volume and quality are common problems that contribute to the provision of water of uncertain microbial quality. Interruptions and pressure loss have been associated with a high risk of diarrhoeal disease (Nygård et al., 2007). Under these circumstances households, communities and governments are forced to adopt alternative water sources that might hold serious health risks under certain circumstances (Kyessi, 2005: Zerah, 2000). The importance of reliable water provision was demonstrated by Hunter et al. (2009) using models constructed on the waterborne pathogens rotavirus, *Cryptosporidium* and enterotoxigenic *E. coli.* The study outcome indicated that annual health benefits from improved supplies will almost be totally lost when people revert to untreated water for just a few days.

In developing countries and rural areas where populations are dispersed over large areas and in densely populated slums and unplanned semi-urban areas, costs associated with the provision of piped water make it an unattainable option for many. Moreover, most governments do not have the financial means to provide the infrastructure or maintain it. A recent survey of the status of improved systems in the northern areas of South Africa revealed poorly constructed boreholes, boreholes with insufficient water to provide everyone in the community with water, delays in maintenance caused by disputes about payments for diesel and pump maintenance and damage to taps and standpipes (Rietveld et al., 2008). In response to these kinds of problems and failure of government support, some African countries and communities have embarked on a 'self help' trend to provide drinking water where the government systems had failed. Civil societies including political party organisations, private individuals, youth and women groups, and the donor community now combine efforts to provide water to people living in such areas (Kyessi, 2005).

International organisations, donors, non-governmental organisations (NGOs) and governments are addressing the problem by providing improved water sources and options for sanitation. Nearly $5.5 billion were, for example, invested by the World Bank in improving water supply sources and quality through interventions such as well digging and sanitation programs in rural Africa during 1978 to 2003 (Iyer et al., 2006). An improved source includes a source of water and/or improved distribution point, such as piped water, protected boreholes or standpipes, provided either as a central public water source or household (point-of-use) source (**Table 1.2**). Improvement does not necessarily mean that the water is safe. It, however, meets minimum criteria for accessibility and measures are taken to protect the water source from contamination.

A huge gap between private water connections and alternative options for water provision, for example standpipes, reselling water from private connections, water tankers, or carts, exists in sub-Saharan Africa. One of the main reasons for the disparity is the tremendous rate of urbanisation taking place in sub-Saharan Africa (Keener et al., 2010) where standpipes represent the main source of water for unconnected households. Utilities often subsidise the costs of standpipes by expanding household connections. Countries, with on average 71% and 48% standpipe coverage, for example, are associated with high and medium to low private connection rates, respectively. In countries where the household connection rates are low, an average of 32% of the unconnected population relies on standpipes (Keener et al., 2010.

An analysis of water prices by service provider goes from 1.3 times the utility price for small piped networks to 10 to 20 times the utility price for mobile distributors (Keener et al., 2010). **Table 1.1** shows a comparison of costs for household connections, standpipes and water vendors for 23 African countries. Household connections were on average less costly than standpipes and water vendors much more costly than the private connections or standpipes.

Table 1.1: Prices for water by household connection, standpipe and water vendor

Country	Household connection US$/3 m^3	Standpipe US$/3 m^3	Water vendor US$/3 m^3
Benin	0.41	1.91	No data
Burkino Faso	0.90	0.48	1.67
Ethiopia	0.19	0.87	No data
Mozambique	0.96	0.98	No data
Niger	0.52	0.48	1.79
Nigeria	0.17	No data	5.71
Rwanda	0.44	1.79	No data
Senegal	0.37	1.53	2.29
South Africa	0.05	No data	No data
DRC	0.05	1.02	No data
Ghana	0.52	5.51	6.89
Kenya	0.18	1.73	3.47
Lesotho	0.40	2.58	No data
Malawi	0.12	1.16	No data
Namibia	01.45	No data	No data
Sudan	0.37	1.15	3.00
Zambia	0.56	1.67	3.00
Cape Verde	2.67	9.44	11.38
Chad	0.22	No data	No data
Cote d' Ivoire	0.04	0.93	3.35
Madagascar	0.11	1.24	2.33
Tanzania	0.39	0.87	2.56
Uganda	0.25	1.40	4.50
Average price	**0.49**	**1.93**	**4.00**
Median price	**0.37**	**1.24**	**3.00**

Data obtained and adapted from Keener et al., 2010.

Sanitation ('hardware') improvements provide improved options for excreta disposal through latrines or connection to a public sewer. Removal or isolation of excreta lessens the probability of contamination of human environments and creates fewer opportunities for human exposure to excreta (Fewtrell and Colford, 2004; Curtis et al., 2000). In a study in Uganda Lule et al, (2005) for instance observed fewer days and episodes with diarrhoea in households with a latrine. **Table 1.2** lists the types of water and sanitation facilities classified as basic and improved in WHO/UNICEF (2000).

Table 1.2: Examples of basic and improved water sources and sanitation facilities.

	Water	Sanitation
Basic	Unprotected well Unprotected spring Vendor provided water Bottled water Tanker or truck provided water Rivers, canals, ditches	No facilities Service or bucket latrines with manual removal of excreta Public latrines Latrines with an open pit
Improved	Household connection Public standpipe Borehole Protected dug well Protected spring Rain water collection	Connection to public sewer Connection to septic system Pour-flush latrine Simple pit latrine Ventilated improved latrine

WHO/UNICEF (2002)

Maintenance of these types of interventions has historically been a major problem. The World Development Report, 2004 (World Bank 2003) estimated that more than a third of rural water infrastructure in South Asia are dysfunctional. In Western Kenya almost 50 percent of borehole wells dug in the 1980s had fallen into disrepair (Miguel and Gugerty, 2005).

Low-cost technologies applied at the household level as opposed to centralised systems or improved sources offer an alternative means of addressing the need of adequate access to safe water and sanitation. A large variety of technologies have been developed and many have been tested and shown to be effective for the production of safe drinking water at the household level. Technologies that have been well researched are discussed here in terms of costs of use. Solar disinfection is probably the only almost zero-cost technology that exists. It is an effective way to inactivate contaminating micro-organisms but the technology is dependent on sunny weather and therefore alternative disinfection methods need to be practised in combination with solar disinfection, for example rain water harvesting. This ensures a constant supply of safe water during periods that the sun is obscured by cloudy weather. Costs practicing solar disinfection consist of replacing the plastic bottles the water is disinfected in and comes to approximately US$ 0.40 (Meierhofer et al., 2009). Dilute hypochlorite solution is another very effective low cost technology. Approximate costs for chlorination have been estimated at US$1.60 to US$8 for initial cost of hardware (per capita; per household) and US$0.60 to $3.00 for annual operating cost per capita per household (Sobsey, 2002). Hunter (2008), in a comparison of the effectiveness of different types of home water treatment technologies for their inactivation of waterborne organisms has shown ceramic filters to be the most effective. Costs for commercially available ceramic filters, however, are very high (approximately US$60; one replacement ceramic candle costs US$6). Less expensive ceramic filters are manufactured in local factories and widely used in some countries at about US$10 per filter (Brown and Sobsey, 2010). These filters are not as effective as the commercially manufactured filters and quality measures need to be adhered to during the manufacturing process to produce high quality filters (Lantagne et al., 2010). Boiling is a very effective disinfection process but potentially costly and environmentally unsustainable. Costs range from US$7.99 to US$8.34 per household per year in India (Clasen 2009) and US$3.24 (to collect fuel) to US$20.16 (to purchase fuel) in Vietnam (Clasen, 2008). Sand filtration is a low cost technology widely used in the form of simple sand filters and the BioSand filter. The latter costs approximately US$100 for training and installation. This type of filter is very durable but not always very effective in the removal of contaminating microorganisms in the water (Sobsey et al., 2008). Additional technologies, used at a smaller scale are, for example, flocculation and coagulation, iodine and silver solutions.

1.2 WATER AND DISEASE-CAUSING ORGANISMS

A list of the better known enteric pathogens that are mostly waterborne is given in **Table 1.3**. The table gives an indication of the variety of organisms that can cause diarrhoea and some other related infections.

The burden of disease in developing countries is inextricably connected to the presence of water in the environment and the absence of water of sufficient quantity and quality in the home. Knowledge of the transmission routes and the fate of pathogens in the water and the environment underpin decisions for appropriate feasible decision making and provision of appropriate technology for prevention of disease.

Table 1.3: Known pathogens of which waterborne transmission has been established or waterborne transmission is probable

Group, Family or Genus	Species, subgroup or type	Reservoirs and sources
Bacteria		
Campylobacter	*C. jejuni*	Human and animal faeces
	C. coli	Human and animal faeces
Escherichia	*Enteroheamorrhagic* (EHEC)	Human faeces
	Enterotoxigenic (ETEC)	Human faeces
	Enteropathogenic (EPEC)	Human faeces
	Enteroinvasive (EIEC)	Human faeces
	Enteroaggregative (EAEC)	Human faeces
Helicobacter	*H. pylori*	Human faeces
Legionella	*L. pneumophila*	Hot water systems
Leptospira		Animal and human urine
Mycobacterium	*M. tuberculosis*	Water distribution systems, hot water systems, soil
	M. avium	Water distribution systems
	M. intracellulare	Water distribution systems
Pseudomonas	*P aeruginosa*	Water
Salmonella	*S. typhi*	Human faeces
	S. paratyhi	Human faeces
	S. enterica	Human faeces
Shigella	*S. sonnei*	Human faeces
	S. dysenteriae	Human faeces
	S. flexneri	Human faeces
Vibrio	*V. cholerae*	Human faeces and zooplankton
	V. parahaemolyticus	Human faeces and zooplankton
	V.fluvialis	Human faeces and zooplankton
Yersinia	*Y. enterocolitica*	Water
Viruses		
Picornaviridae	Polio	Food water fomites human contacts
	Entero	Human faeces
	Coxsackie	Human faeces
	Hepatitus A and E	Human faeces
	Echo	Human faeces
Adenoviridae	Adeno	Human faeces

Group, Family or Genus	Species, subgroup or type	Reservoirs and sources
Caliciviridae	Noroviruses, and small round-structured viruses	
	Caliciviruses	Human faeces
	Astroviruses	Human faeces
Reoviridae	Rotavirus	Human faeces
	Protozoa	
Acanthamoeba	*A. castellani*	Human faeces
Balantidium	*B. coli*	Human and animal faeces
Cryptosporidium	*C. parvum*	Water, human and animal faeces
	C. hominis	Water, human and animal faeces
Isospora	*I. beli*	Human faeces
Entamoeba	*E. histolytica*	Water animal and human faeces
Giardia	*G intestinales*	Water, human and animal faeces
	G. lamblia	Human faeces
Naegleria	*N. fowleri*	Warm water
Microsporidia	*Encephalitozoon intestinalis, Enterocytozoon bieneusi*	Human faeces
	Nematoda	
Helminth	*A. lumbricoides*	Eggs in human faeces, waste water
	Fungi	
Fusarium	*Fusarium solani*	Human faeces, waste water
	Yeast	
Candida	*Candida albicans*	Urine and human faeces

Information adapted from a combination of lists that were identified as potential waterborne pathogens by either the Guidelines for Drinking-water Quality, Vol. 1 3rd edition, World Health Organization, 2006, Ashbolt, 2004 or the USEPA Drinking Water Contaminant Candidate List.

Transmission routes of diseases relating to water have been classified into four classes (Bradley et al., 1977):

- Waterborne: Diseases that are transmitted by consuming contaminated water, including bacteria, viruses and parasites such as cholera, typhoid and cryptosporidiosis.
- Water-washed: Diseases caused by insufficient water quantities for personal and domestic hygiene. Spread, other than through water, for example, contaminated food is included in this category.

- Water-based: Diseases that are caused by pathogens that require aquatic organisms as hosts during part of their life cycle. Transmission is through repeated contact, for example washing clothes, unsafe use of wastewater for example using excreta and grey water in agriculture (WHO, 2006a) or ingestion of contaminated water.
- Water-related: Diseases spread by insects or vectors. These insects are those that breed in or near water, like malaria and onchocerciasis.

Endemic diarrhoeal diseases are often those that belong to the categories water-washed rather than waterborne. Feachem (1977) and Cairncross (1996) therefore proposed that the 'waterborne diseases' category be replaced with one for 'faecal-oral diseases'.

The lack of water quantity, quality, access to water, availability of sanitation and appropriate hygiene behaviour and other factors, for example nutritional status, all contribute to a complex environment that could lead to adverse exposure and subsequent disease causality. The implication is that enteric organisms follow a range of infection pathways within this system (Ezzati et al., 2005; Curtis et al., 2000), and therefore provision of sanitation, adequate water supply and adequate hygiene should be considered in addition to clean water to bring about the desired reduction in disease. Although the organisms are all potentially waterborne some of the infectious enteric organisms can be transmitted by contaminated food and soil and person-to person contact and by contact with infected faeces, for instance. Given that the organisms are associated with diarrhoeal disease, chiefly transmitted through the faecal-oral route, and therefore ingestion, options to minimise this route of infection are a natural and important choice of action.

The scientific bases for drinking clean water to reduce infectious diseases and to enhance the health of humans are well established (Cutler and Miller, 2005: Clasen et al., 2007; Zwane and Kremer, 2007). The World Health Organization has estimated that 94% of all diarrhoea cases could be prevented with the provision of clean drinking water and improved sanitation and hygiene (WHO, 2007). Consequently much focus, over the last decades, has been on interventions aimed at providing drinking water of good microbial quality to humans and providing knowledge of the basic principles of hygiene. Many interventions addressed infrastructure related to water and sanitation provision while many others addressed technologies applicable for water disinfection at the household level.

1.3 HOME WATER TREATMENTS

Many people have no choice other than to resort to drinking contaminated water from wells, natural springs, rivers or ponds. This situation is created when there is no access to treated water or when water provision systems are interrupted or not functioning properly or has completely stopped functioning. Being dependent on water from piped systems some distance away from the household, and improved and untreated sources, for example boreholes, wells and springs or rivers, encourages people to collect large volumes of water and to store the water in containers in their homes for convenience and easy access. Storing water creates many opportunities for microbial contamination resulting in post-collection contamination in households (Levy et al., 2008; Gundry et al., 2004; Momba and Notshe, 2003; Wright et al., 2004). Post-collection contamination by unwanted microorganisms takes place during transport, and during unsafe storage and handling practices. These include using unhygienic ways to dispense water from the container (Trevett et al., 2005), washing the containers with sand to get rid of algae, and inadequately protecting the water from flies and animals by leaving containers open or not sufficiently covered (Nath et al., 2006). Considerable health risks are associated with drinking re-contaminated water.

A meta-analysis of the results of 57 studies, measuring bacterial counts for source and storage water, concluded that, in general, bacteriologic quality of drinking water significantly declines after collection (Wright et al., 2004). In a study by VanDerslice and Briscoe (1995), both improvement (for 16% of the households) and initial decline of water quality between source and point-of-use were observed. However, no effort was made to determine how the microbial quality of the water would change over a longer storage time in any of these studies. Levy et al. (2008) conducted a study in a rural setting aimed at determining how the microbial quality of storage water would change over a long storage time and how the changes observed would relate to the original quality of the source water. The study also investigated water use practices and how these impacted on water quality and subsequently change levels of contamination over time (Levy et al., 2008). Water was collected from the same source at the same time as the household members filled their water containers. A sample of this source water was also stored in a control container. Both the control container and the container used by the household were sampled and analysed over a period of five days. The authors observed a significantly higher level of indicator organisms in the source water than the in-house storage water and the control containers. This natural initial decrease in levels of indicators in the storage containers was observed for a period of three days. On the third day, however, re-contamination by unhygienic household practices, in approximately half the households, became evident.

Thus the fundamental principle for home water treatment (HWT) is the improvement of the microbiological quality of drinking water at the point-of-use. The aim is to reduce the chances of ingesting waterborne infectious microorganisms that can cause enteric disease. Apart from providing better microbial quality drinking water, HWT has some other advantages. It is, for example, not always dependent on a specific supply source and therefore is not affected by water interruptions. Most HWT devices can easily be transported from one place to another, external contamination can easily be minimised and water of a better microbial water quality can be made available in a very short time.

Home water treatment has become an attractive alternative intervention for the provision of safe drinking water. Treatment at household level has the potential to effectively inactivate or remove waterborne pathogens from drinking water (Sobsey et al., 2003). The effectiveness of these treatment methods to reduce the morbidity and mortality associated with diarrhoea in poor communities and developing countries has been confirmed under laboratory conditions and during field trials. A large and growing body of scientific information on the possible health gains of HWT is available. A range of intervention types and combinations of interventions have been tested and shown to be successful for the provision of water of a better microbial quality and reduction of diarrhoea. These include, amongst others, boiling (Rosa et al., 2010), solar disinfection (Hindiyeh and Ali, 2010; Rose et al., 2006; Conroy et al., 2001; Conroy, 1996), ultra violet light (Brownell et al., 2008) disinfection and safer storage (Quick et al., 2002; Roberts et al., 2001; Quick et al., 1999; Quick et al., 1996; Mintz et al.,1995) flocculation and chlorination (Crump et al., 2004a; Rangel et al., 2003), chlorination (Arnold and Colford 2007), combinations of water sanitation and hygiene (Nana et al., 2003), ceramic and sand filtration (Stauber et al., 2009; Brown and Sobsey, 2006; Clasen and Boisson, 2006; Clasen et al., 2006a; Clasen et al., 2004).
The interventions can be classified into three broad categories:

1) Physical removal of pathogens (e.g. filtration, adsorption, or sedimentation).
2) Chemical disinfection methods that inactivate or kill pathogens, most commonly with chlorine.
3) Disinfection by heat (e.g. boiling or pasteurisation) and ultraviolet (UV) radiation, either using the sun (solar disinfection) or UV lamps.

The most important technologies are briefly discussed.

1.3.1 Filtration

Filtration removes microbial organisms by size exclusion. Filtration can consist of using a simple cloth, ceramic filters or sand filters. The effectiveness is dependent on the variation in filter medium and pore sizes of the filters. Ceramic filters are considered as one of the most effective methods for the removal of microorganisms from drinking water (Clasen et al., 2007).

One of the most basic methods for filtration is using the Indian sari cloth. In 1996 Huq et al. showed that the use of sari cloth can successfully remove particles and copepods carrying cholera bacteria from pond water. This filtration method is still in use and significantly reduces the incidence of cholera in Bangladesh (Huq et al., 2010).

Figure 1.3: Commercially available ceramic water filter.

Ceramic filters of high quality, as shown in **Figure 1.3**, are commercially available. These filters have guaranteed filtration ratings, are impregnated with silver and contain activated carbon. Ceramic filters have been shown to effectively reduce diarrhoea in young children by 80% (du Preez et al., 2008) and between 70% and 83% for people of all ages (Clasen et al., 2005, Clasen et al., 2004). However, currently costs for such filters are too high for general use in poor communities. The Potters for Peace movement has been manufacturing cheaper clay filters that are used in Cambodia and Bolivia and a number of other countries. Lantagne, (2010) confirmed that the provision of good quality clay ceramic filters to poor communities is a highly successful means for managing water quality in households. The effectiveness of these clay filters is highly dependent on the quality control procedures followed during the manufacturing process (Hagan et al., 2009). Their effectiveness for the removal of microbial pathogens has been proven in field trials in, for example, Cambodia where a 46% reduction in diarrhoeal disease, and a 95.1% average (and up to 99.99%) reduction of *E. coli* in drinking water was recorded (Brown and Sobsey, 2010; Brown and Sobsey 2006). Virus removal of 90-99% and a 90% reduction in *E. coli* was shown in the study of Brown and Sobsey (2010).

Figure 1.4: The bio-sand and ceramic pot filter

The bio-sand filter (**Figure 1.4**) is a household version of the slow sand filter developed to address costs of the provision of safe water, the issue of bigger volumes of safe water and sustainability at household and community level. The bio-sand filter is smaller than the traditional sand filters and water does not need to flow through it all the time. It consists of a built structure that produces a sizable volume of drinking water (20-30 L). When water is added to the bio-sand filter a biofilm (which takes about 30 days to develop) forms on top of the layer of sand. This layer biologically removes potentially pathogenic organism and is called the "*schmutzdecke*". Controlled field trials have shown that the bio-sand filter improves the water quality and reduces diarrhoea incidence. A six months intervention undertaken in households using the bio-sand filter significantly improved drinking water quality and reduced diarrhoeal disease indicating a significant protective effect of the bio-sand filter against waterborne diarrhoeal disease (Stauber et al., 2009; Tiwari et al., 2009; Stauber et al., 2006). It has been suggested that the bio-sand filter has a higher potential to become widely and sustainably used because it can potentially provide a large volume of water, is a passive system and requires very low maintenance. The removal of bacteria by the bio-sand filter, however, does not comply fully to levels set for the Water Quality Guidelines for Drinking Water of the WHO (Sobsey et al., 2008). With continued use, flow rate of the water decreases, leading to imposed application of excessive flow. When high or excessive flow is imposed purification may become inadequate (Tellen et al., 2010; Anders and Chrysikopoulos, 2006).

1.3.2 Chemical disinfection

The disinfection processes most commonly applied during interventions at household levels are chlorination and a combination of chlorination and flocculation. Chlorination has been used successfully to disinfect water effectively and at low cost when compared to other disinfection methods, since 1948 (Baker, 1948). Chlorination has also been shown to be effective in the reduction of diarrhoea (McLaughlin et al., 2009; Crump et al., 2004a; Quick et al., 1996). The pooled effect estimate across the 10 studies obtained for a meta-analysis of interventions indicated that point-of-use treatment of drinking water with chlorine reduces diarrhoea in children by 29% (relative risk, 0.71; 0.58 to 0.87) (Arnold and Colford, 2007). There was no evidence of publication bias based on the Begg test ($Z=-0.63$, $P=0.53$), and sensitivity analysis indicated that no single study had a disproportionate impact on the summary effect estimate (Arnold and Colford, 2007).

Water purification tablets, for example AQUATABS®, conveniently contain chlorine and a flocculant in one tablet which makes them easy to use. Manufacturers of these types of tablets have put much effort into reducing the taste of chlorine in the water because this is one of the reasons people do not use chlorination widely and sustainably.

The intended health gains by disinfection procedures are often compromised by post-collection and post-disinfection contamination as a result of inappropriate storing methods in a household. In response, the Center for Disease Control and Prevention (CDC) and the Pan American Health Organization developed a narrow-mouthed container referred to as the “CDC” container which is used in conjunction with sodium hypochlorite (household bleach) and flocculent and a program of behavioural change (Centers for Disease Control, 2005; Reller et al., 2003). In field trials, this approach has reduced diarrhoea by 44% in Bolivia (Quick et al., 1999), 85% in Uzbekistan (Semenza et al., 1998), and 48% in Zambia (Quick et al., 2002).

1.3.3 Disinfection by heat

Boiling is a widely used and an effective means for disinfecting drinking water (Rosa et al., 2010; Clasen et al., 2008). Rosa and Clasen, (2010) extracted data from 76 home water treatment surveys and found that 598 million people in low- and medium-income countries use boiling as method of making their drinking water safe. Boiling effectively inactivates all classes of microbes (bacteria, bacterial spores, viruses, fungi, protozoan parasites and helminths). The turbidity or dissolved constituents in the water do not adversely affect the boiling process. To prevent unnecessary contamination from external sources it is recommended to store the water in the container it was boiled. It is, however, a method high in cost in terms of the use of energy and the environment and subsequently sustainability.

Pasteurisation refers to thermal disinfection of liquids, for example milk and water. Disinfection takes place at a much lower temperature than boiling. The inactivation effect is dependent on the time the fluid is kept at temperature. Typical procedure for pasteurisation is heating to 75 ºC for ten minutes (Burch and Thomas, 1998). Solar pasteurisation has also been applied successfully (Jamil et al., 2009).

1.3.4 Ultraviolet radiation using lamps

Ultraviolet (UV) light is electromagnetic radiation with a wavelength shorter than that of visible light, but longer than X-rays, in the range 10 nm to 400 nm. Common names and ranges of the electromagnetic spectrum of ultraviolet light are given in **Table 1.4**. Practical application of UV disinfection relies on the germicidal ability of UVC and UVB when commercially available low- and medium pressure arc lamps are used for disinfection of water.

Table 1.4: Names and ranges of the electromagnetic spectrum of ultraviolet light

Name	Abbreviation	Wavelength range in nanometers
Ultraviolet A, long wave or black light	UVA	400-315
Near	NUV	400-300
Ultraviolet B, or medium wave	UVB	315-280
Middle	MUV	300-200
Ultraviolet C, short wave or germicidal	UVC	280-100
Far	FUV	200-122
Vacuum	VUV	200-100
Low	LUV	100-88
Super	SUV	150-10
Extreme	EUV	121-10

Data were obtained from the ISO standard on determining solar irradiances (ISO-DIS-21348)

Commercial UV lamps have been shown to inactivate contaminating waterborne organisms effectively (Hayes et al., 2006; Marshall et al., 2003, Linden et al., 2002).

These lamps are used in smaller treatment plants but the difficulties with up-scaling have prevented widespread use for bulk water disinfection. Some of the shortcomings are:

- UV disinfection systems require a reliable source of electricity to operate sensors, valves, command and control electronics, and lamps.
- UV lamp output will decline over time due to lamp aging.
- The dose delivery to the microbes in the water will vary depending on whether the microbes are present as individual cells or whether they are associated with other particulate matter.
- The inactivation of microbes within particles will depend on the particle size, structure, and composition.
- The presence of UV absorbing materials (iron and humic acids) within the particulates will shield microbes from UV.
- Larger particles will be more difficult to disinfect than smaller particles.

One of the primary concerns in drinking water disinfection is the protozoan parasite *Cryptospordium parvum.* This parasite is very resistant to conventional disinfection chemicals such as chlorine (Craik et al., 2001; Sobsey 1989) and can cause infection by the ingestion of as few as 10 cysts. However, it is susceptible to UV light from low pressure UV lamps, making it an attractive additional disinfection method for the treatment of drinking water (Shin et al., 2001; Clancy et al., 2000).

1.3.5 Solar disinfection (SODIS)

The fundamental principles of solar disinfection were first discussed in 1877 by Downes and Blunt (1877). Controlled irradiation experiments were performed using *E. coli* and radiation of 265 nm and 350 to 490 nm, by Alexander Hollaender in 1943. Remarkably accurate information that is still valid today was recorded for these experiments. Hollaender exposed *E. coli* cells to 265 nm and showed a linear log inactivation curve while cells exposed to 350 to 490 nm showed little inactivation for the first 40 minutes of exposure. This finding is representative of the ‘shoulder’ phenomenon (described below) that is still valid for current research. He also noted growth inhibition of exposed cells in broth and concluded that wavelengths below 300 nm directly damage “various structures of the cell” and that the effect of irradiation increases as temperature increases. In 1980 Acra and his colleagues from the American University of Beirut set out to lay the foundations for the further development of solar irradiation of water and oral rehydration solutions (Acra et al., 1980; Acra et al., 1989).

1.3.5.1 Optical inactivation mechanisms

The mechanisms for inactivation of microorganisms in water by sunlight are both optical and thermal. Approximately 70% of the inactivation process is contributed by optical processes (Acra et al., 1980). Sunlight reaching the surface of the earth consists mostly of UVA (~320-400 nm), UVB (~290-300 nm), visible (400-700 nm) and infra-red (>700 nm) (**Figure 1.5**).

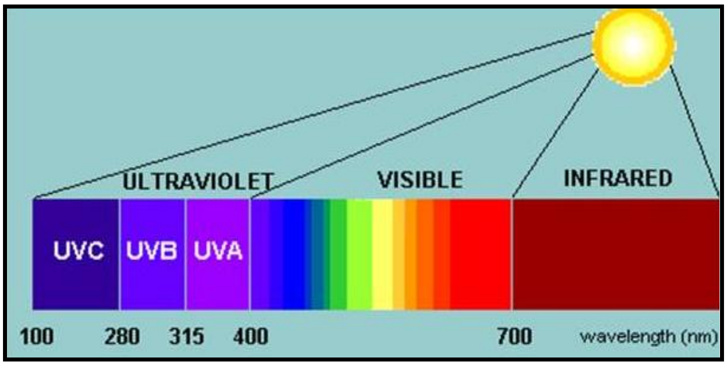


Figure 1.5: Illustration of the spectrum of sunlight energy from ultraviolet to infrared.

The microbial inactivation process of UV light is attributed to the photochemical damage of the nucleic acids of microorganisms during exposure. UV radiation is absorbed by nucleotides, the building blocks of cellular ribonucleic acid (RNA) and deoxyribonucleic acid (DNA), in a wavelength dependent manner with peaks near 200 and 260 nm (Von Sonntag and Schuchmann, 1992). UVA and UVB irradiation halts the fission process of cells by the formation of cyclobutane pyrimidine dimers (Fernández Zeňoff et al., 2006). Absorbed UV promotes the formation of bonds between adjacent nucleotides, creating double molecules or dimers. While the formation of thymine-thymine dimers are the most common, cytosine-cytosine, cytosine-thymine, and uracil dimerization also occur.

UVA irradiation causes indirect damage to lipids, proteins and the DNA through photosensitisers and reactive oxygen species (ROS) that damage outer cell membranes and cause subsequent leakage resulting in dysfunctional cell processes followed by death (Berney et al., 2006). Photosensitisers consist of humic acids in water and flavins and porphyrins in the microbial cell (Curtis et al., 1992). When photosensitisers absorb UVA photons they enter an excited state during which they react with molecular oxygen to form ROS such as hydroxyl radicals, superoxide, and hydrogen peroxide (Reed et al., 2000). These reactions enhance the inactivation by increasing the rate 4 to 8 times for faecal bacteria in oxygenated water compared to deoxygenated water (Reed, 1997a). Factors that affect these processes are the turbidity of the water and clumping of bacterial cells. The turbidity can have both beneficial and detrimental effects. When the turbidity is very high (more than 200 nephelometric turbidity units (NTU), 99% of the incident radiation is absorbed within the first centimetre of the optical path (Joyce et al., 1996). At such turbidities the opacity associated with the water will change the optical absorption characteristics, which in turn affect the thermal inertia of the sample. This affect is brought about as a result of the higher emmisivities of the darker surfaces than lighter surfaces and the turbid agent (dust, algae, etc.) that will usually have a lower specific heat capacity than the water itself. Consequently the temperature dynamics of highly turbid water samples can be faster than those of clearer samples which enhance the thermal inactivation processes (Joyce et al., 1996).

1.3.5.2 Thermal inactivation mechanisms

Although only approximately 30% of the inactivating processes can be attributed to thermal processes, their contribution can be significant especially at temperatures above 45 ºC when optical and thermal processes are strongly synergistic (McGuigan et al., 1998). These synergistic processes were demonstrated by Berney et al. (2006) at temperatures higher than 45 ºC under simulated sunlight conditions using *E. coli* K-12. It has been shown that a much weaker UV dose was sufficient for inactivation of *E. coli*, enteroviruses and bacteriophages at temperatures above 50 ºC (Wegelin et al., 1994). When water is exposed to sunlight its temperature is raised by the infrared radiation of the sun. The temperature increase is dependent on the size of the water container and weather conditions. Temperatures above 50 ºC can be reached under optimal weather conditions in small volumes in polyethylene terephthalate (PET) bottles or plastic bags to effectively inactivate bacteria under field conditions (McGuigan et al., 1998). Viruses studied so far, namely bovine rotavirus, encephalomyocarditis virus, bacteriophage f2 and polio virus, (Wegelin et al., 1994), are particularly sensitive to the optical inactivation mechanisms that result from solar exposure, possibly because viruses are unable to repair optically induced damage to their DNA or RNA. Even hardy parasitic cysts for example *Giardia* and *Entamoeba hystolitica* (54 ºC) and eggs of *Schistosoma* and *Taenia* (55 ºC and 57 ºC, respectively) can be inactivated (Sommer et al., 1997) under situations where synergistic processes are active.

1.3.5.3 Overall inactivation model

The inactivation curve obtained of a bacterial population exposed to sunlight produces a shoulder followed by an exponential decrease. In some instances a tailing-off effect is evident. The shoulder is observed because initial processes causing damage to multiple targets, for example membranes and enzymes, have to be established before any form of die-off is initiated (Reed, 2004). Importantly, a UV dose that surpasses the rate of repair has to be applied. When the UV dose threshold is reached inactivation is initialised and the exponential phase follows, usually in a single exponential decay pattern. High solar intensity can result in a double exponential decay pattern as a result of the presence of a light sensitive population that is inactivated first, followed by inactivation of the more resistant population (Reed, 2004; Dejung et al., 2007).

1.3.5.4 Solar disinfection of waterborne microorganisms

One of the important beneficial applications of the microbial inactivation properties of sun light is solar disinfection of drinking water. The procedure consists of filling transparent plastic soft-drink bottles with the water that needs decontamination and placing the bottles in the sun for at least 6 hours. SODIS is an easy, minimum cost method. This disinfection method can potentially inactivate waterborne infectious pathogens responsible for enteric infections, reduce the associated diarrhoea incidence and provide drinking water to people who do not have access to safe water.

The major enteric microorganisms associated with diarrhoea are *Vibrio cholerae, Shigella* spp., *Campylobacter jejuni*, enterotoxigenic and enteropathogenic *E. coli*, *Aeromonas* spp., *Clostridium difficile*, *Cryptosporidium parvum, Giardia lamblia, Entamoeba histolytica,* rotavirus and Hepatitis A and E. The inactivation kinetics of these organisms has been established using SODIS under laboratory and field conditions (**Table 1.5**). The results indicated effective inactivation under different weather conditions, turbidities and temperatures. Very promising is the fact that the inactivation process seems complete and that no regrowth or recovery of membrane functions have been found using *E. coli* cells (Berney et al., 2006a; Oates et al., 2003; Reed, 1997; Joyce et al., 1996; Wegelin et al., 1994). Some further work conducted towards this issue by Bosshard et al. (2009) corroborated these findings for two of the common waterborne pathogens during an investigation into the inactivation mechanism, survival and repair after irradiation using *Salmonella typhimurium* and *Shigella flexneri.* The efficiency of UVA disinfection for the permanent inactivation of bacteria recorded in the laboratory, where temperature, turbidity and the chemical composition of water can be controlled has undoubtedly been confirmed. In the field, where environmental factors and their influences cannot be controlled, the desired level of disinfection may not always be obtainable. In addition, human behaviour plays an important role that can easily compromise the desired outcome for SODIS.

Table 1.5: Organisms for which inactivation by SODIS has been recorded.

Pathogen	Solar simulation	References
Bacteria	*Enterococcus* sp *Pseudomonas aeruginosa* *Salmonella typhi* *Salmonella typhimurium* *Shigella dysenteriae* Type 1 *Shigella flexneri* *Vibrio cholerae* *E. coli* O157 H7	Joyce et al.,1996; Kehoe, 2001 Lonnen et al., 2005 Smith et al., 2000 Kehoe et al., 2004 Kehoe et al., 2004 Wegelin et al., 1994 Kehoe et al., 2004; Lonnen et al 2005 Ubomba-Jaswa et al.,2008
Protozoan parasites	*Acanthamoeba polyphaga trophozoites* *Cryptosporidium parvum* oocysts *Giardia muris* cysts	Haeselgrave et al., 2006 McGuigan et al., 2006; Mendez-Hermida et al., 2005, 2007 McGuigan et al., 2006.z-
Viruses	Polio virus	Haeselgrave et al., 2006
Fungi	*Candida albicans* *Fusarium solani*	Kehoe et al., 2004 Lonnen et al., 2005
	Natural sunlight	
Bacteria	*Campylobacter jejuni* *Escherichia coli* *Pseudomonas aeruginosa* *Shigella dysenteriae* Type 1 *Vibrio cholerae* *Yersinia enterocolitica*	Boyle et al., 2008 Acra et al., 1984 Acra et al., 1984 Acra et al., 1984 Conroy et al., 2001 Boyle et al., 2008
Viruses	Bacteriophage F2 Encephalomyocarditis virus Rotavirus	Wegelin et al., 1994 Wegelin et al., 1994 Wegelin et al., 1994
Fungi	*Fusarium solani*	Sichel et al., 2007

1.3.5.5 Dysentery or shigellosis

Of particular importance for the health impact assessments undertaken during this study was the incidence of dysentery or bloody diarrhoea in children. *Shigella* infections are often, but not exclusively associated with bloody diarrhoea (Wang et al., 2005) or dysentery (WHO, 2005). Bloody diarrhoea is a clinical diagnosis that refers to any loose or watery stool that contains visible red blood or mucus. This does not include episodes where streaks of blood is observed on the surface of the stool, when blood is detected by microscopic examination or biochemical tests or in which stools are black owing to the presence of digested blood. Dysentery has the same definition (WHO, 2005).

Monitoring dysentery in this study was aimed at obtaining information about bacterial enteric infections which could specifically be associated with microbiologically poor source water resulting in shigellosis and severe diarrhoea with blood and mucus in the stool as was found by Gundry et al. (2009). Dysentery is also strongly associated with the rates of growth of children (Alam et al., 2000), an aspect specifically addressed in this study by inclusion of anthropometric measurements of the participating children. The anthropometric measurements represent a health metric that cannot be influenced by bias. This is an important factor in light of the doubt cast on the true health gains reported for various HWT interventions. Findings of several meta-analyses of the results of many HWT interventions were ascribed to unacceptable levels of responder and observer bias, reporting bias (selective reporting bias) and recall bias (Schmidt and Cairncross, 2009; Aiello et al., 2008; Ejemot et al., 2008; Arnold and Colford, 2007; Clasen et al., 2007; Clasen et al., 2006b; Fewtrell et al., 2005; Fewtrell and Colford 2004; Curtis and Cairncross, 2003). Thus, an objective measurement that is indirectly related to the expected health effect of an intervention could provide the necessary confirmation of the true effect of a health intervention.

Shigellosis or dysentery is endemic throughout the world where it is held responsible for some 120 million cases annually, the overwhelming majority of which occur in developing countries and involve children less than five years of age (Nyogi, 2005). Dysentery is caused by organisms belonging to the genus *Shigella*. *Shigella* organisms are Gram-negative, facultative intracellular pathogens (Nyogi, 2005; Lewis, 1997). They were recognized as the etiologic agents of bacillary dysentery or shigellosis in the 1890s (Shiga 1898). These organisms are members of the family *Enterobacteriaceae* and the tribe *Escherichia.* Four species are recognised: *Shigella dysenteriae, Shigella flexneri, Shigella boydii*, and *Shigella sonnei*, also known as groups A, B, C, and D, respectively. They are non-motile and non-encapsulated. Group A has 13 serotypes, group B has 6 serotypes, group C has 18 serotypes, and group D has 1 serotype. *S. dysenteriae* serotype 1 causes deadly epidemics, *S. boydii* is restricted to the Indian subcontinent, and *S. flexneri* and *S. sonnei* are prevalent in developing and developed countries, respectively. *S. Flexneri* is responsible for the worldwide endemic form of bacillary dysentery. They are spread by contaminated water and food and through person-to-person contact (Nyogi, 2005).

The infectivity dose is extremely low. As few as 10 *S. dysenteriae* bacilli can cause clinical disease, whereas 100 to 200 bacilli are needed for *S. sonnei or S. flexneri* infection (Rowe and Gross, 1984; DuPont, 1990). The characteristic virulence trait is encoded on a large (220 kb) plasmid responsible for synthesis of polypeptides that cause cytotoxicity. *Shigella* organisms that lose the virulence plasmid are no longer pathogenic. Importantly, *Escherichia coli* (*E. coli* O157:H7) also harbour this plasmid and behave clinically like *Shigella* bacteria (Venkatesan et al., 1989).

Worldwide, the incidence of shigellosis is estimated to be 164.7 million cases per year, of which 163.2 million were in developing countries, where 1.1 million deaths occurred. About 60% of all episodes and 61% of all deaths attributable to shigellosis involved children younger than 5 years. The incidence in developing countries may be 20 times greater than that in developed countries. Although the relative importance of various serotypes is not known, an estimated 30% of these infections are caused by *S. dysenteriae* (Kotloff et al., 1999; WHO, 2010).

Case-fatality rates for *S. dysenteriae* infections may approach 30%. Patients with malnutrition are at increased risk of having complications. *Shigella* infection in malnourished children often causes a vicious cycle of further impaired nutrition, recurrent infection, and further growth retardation. *S. dysenteriae* infection is associated with substantial morbidity and mortality rates in the developing world.

- The overall mortality rate in developed countries is less than 1%.
- In the Far East and Middle East, the mortality rates for *S. dysenteriae* infections may be as high as 20 to 25%.

Studies on the Asian continent showed that incidence of *Shigella* diarrhoea are more ubiquitous in Asian impoverished populations than previously thought (von Seidlein et al., 2006; Wang et al., 2005) and that the incidence is substantially underestimated in children and older people in impoverished communities (Chompook et al., 2005).

1.3.5.6 Application at household level

SODIS at household level entails filling transparent plastic bottles, usually PET bottles, with contaminated water, shaking the closed bottle to dissolve some of the oxygen in the space above the water level in the bottle and leaving the bottles in full sunlight for six hours. The effect of SODIS is dependent on the availability of sufficient sunlight. The solar radiation intensity required of 2500 Wh/m^2 for total inactivation of microbes can easily be achieved within six hours of solar exposure on a sunny or partially cloudy day in countries between latitude 35 °North and 35 °South. During days of partial rainfall, cloudy weather or fog, the bottles may have to be exposed for 2 consecutive days to disinfect the water. During days of continuous rainfall, boiled water or stored SODIS water should be consumed (Meierhofer and Landlot, 2009). SODIS requires relatively clear water with a turbidity of less than 30 NTU to be effective (Wegelin et al. 1994). A simple test is available to check if water is clear enough for the application of SODIS:

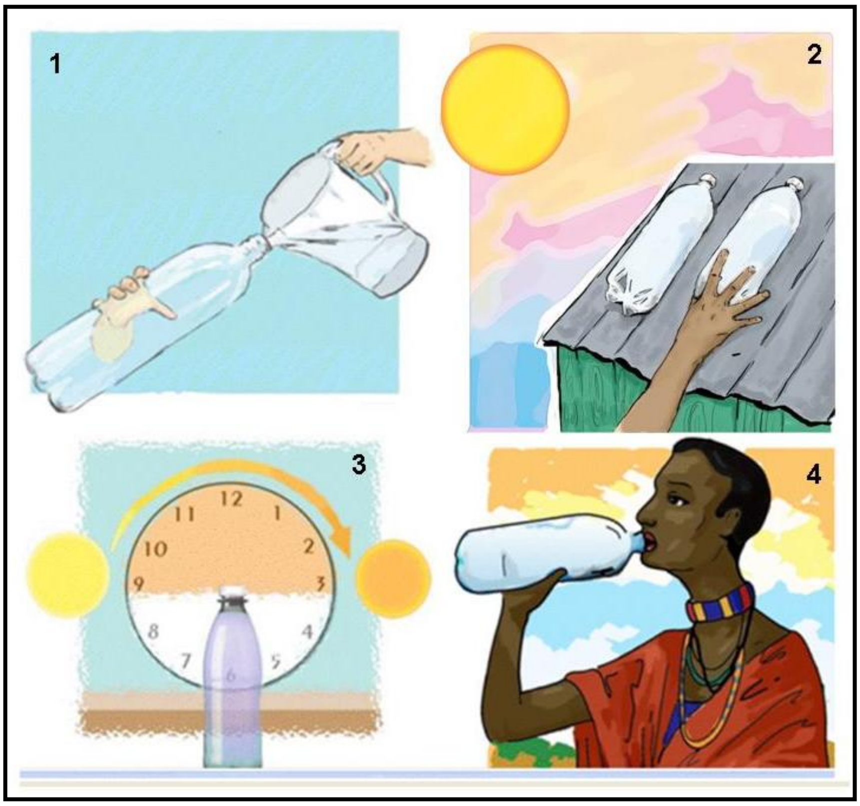


Figure 1.6: A diagrammatic representation of the four easy steps to produce SODIS disinfected water.

Place the open bottle upright onto the headline of a newspaper. Look through the mouth of the bottle and through the water in the bottle at the headline on the newspaper. If it is possible to read the headline the water is clear enough for SODIS. Options for reducing the turbidity are to:

- Allow particles to settle by letting the bottles stand for a while; or
- Filter the water through a folded cloth.

The water should be consumed within 48 hours after disinfection. The process to disinfect water in bottles using sunlight is illustrated in **Figure 1.6.**

1.3.5.7 Polyethylene terephthalate (PET) bottles

Transparent two litre plastic bottles are recommended for solar disinfection of drinking water at household level. PET plastic bottles are preferred because they are almost unbreakable, light weight, do not transfer any taste to the water and are chemically stable. An important advantage of using PET bottles for solar disinfection is the high transmittance of UVA possible through PET plastic (Wegelin et al., 2001; McGuigan et al., 1998). These bottles are widely used and distributed as beverage containers which also make them easily obtainable in many countries.

Plastic bottles are either manufactured from polyethylene terephthalate (PET) or polyvinyl chloride (PVC). Both contain additives to increase their stability, to protect the bottles and their content from oxidation and UV radiation. PET plastic contains fewer additives when compared to PVC. The production of PVC requires the manufacture of raw chemicals, including chlorine, ethylene dichloride and a vinyl chloride monomer that is considered mutagenic (Benfenati et al., 1991). PET is produced by the polymerization of the petroleum monomers terephthalic acid and ethylene glycol by antimony-, or germanium-based catalysts (Ceretti et al., 2010).

Public health concerns with regard the leaching of harmful chemicals into bottled water and other beverages have initiated ongoing research, mostly undertaken by the food industry. Migration of potentially mutagenic or carcinogenic compounds into the water in PET bottles has been evaluated under light and dark conditions, different temperatures, after short and long exposure times using toxicity tests, short term mutagenicity tests (*Tradescantia* and *Allium cepa* micronucleus tests, the Comet assay on human leukocytes and the AMES *Salmonella* test), and chemical analysis using gas-chromatography/mass spectrometry (GC/MS) (Ceretti et al., 2010; Keresztes et al., 2009; Westerhoff et al., 2008; Biscardi et al., 2003; De Fusco et al., 1990).

To determine the extent of compounds migrating from PET bottles used under normal conditions for SODIS Wegelin et al. (2001) exposed bottles in Switzerland and Malaysia for 15, 31, 63 and 128 days under dark and sun light conditions. For those compounds that were identified no difference in chemical composition of the water exposed to sunlight and the water kept in the dark was observed. Carbonyls, for example acetaldehyde and formaldehyde, were detected in bottles exposed for a longer time but at concentrations well within the limits set by Swiss legislation in place at the time the study was conducted.

Plasticisers used during manufacturing, that potentially could adversely affect the health of humans, have been identified during thermal degradation of PET bottles. They include di(2-ethylhexyl)phthalate (DEHP), di(2- ethylhexyl)adipate (DEHA), phatalic acid, dimethyl terephthalate, disobutyl and dibutyl phthalate (Montuori et al., 2008). An investigation undertaken by the Swiss Federal Laboratories for Material; testing and Research in 2003 determined the concentrations of DEHA and DEHP in bottles used under SODIS conditions and non-SODIS conditions (Schmid et al., 2008). Both plasticisers were present in the water (DEHA at 0.046 µg/l, DEHP at 0.71 µg/l) but these concentrations were below the limits of the WHO Guidelines for Drinking Water Quality (2004) which were set at 80 µg/l and 8 µg/l for DEHA and DEHP, respectively.

A recent study (Ubomba-Jaswa et al., 2010) investigating the possible risks of genotoxic compounds being released into the water under normal SODIS conditions, using the AMES fluctuation test, found that no harmful compounds were released. Importantly this study was conducted over a period of six months during which the same PET bottles were emptied and refilled daily.

The general indication is that PET bottles used under normal SODIS conditions hold no health risk to the users. However caution is necessary when PET bottles are stored under extreme conditions, notably high temperatures.

1.4 IMPACT AND SCALING UP OF HOME WATER TREATMENTS

The findings of a very large number of research studies undertaken to prove the effectiveness of HWT interventions currently make an impressive case for wider implementation or scaling up. Scaling up is a higher rate of spatial and temporal provision of appropriate and effective interventions, to target needy populations with simultaneous insurance of sustainable maintenance and use for achieving quality health benefits. Many definitions describe "scaling up" (DFID, 2000, Curtis et al., 2003; Pokhrel, 2006) in terms of "coverage", an epidemiological term which measures the extent to which services extend to the need for those services. Clasen (2009) stresses the importance of both, that is, that coverage (ensuring the intervention reaches the population) and uptake (promoting use) are necessary for success.

A large body of information has been amassed through studies measuring the change in health of populations attributed to improved water supply, sanitation and hygiene interventions. A range of interventions and analysis methods are used mostly focussed on direct health outcomes, in particular childhood risk of diarrhoea (IEG, 2008). Correspondingly, there are many reports based on systematic reviews and meta-analyses based on the outcomes of these intervention studies. (Esrey et al., 1991; Curtis and Cairncross, 2003; Fewtrell et al., 2005; Fewtrell and Colford 2004; Clasen et al., 2006b; Clasen et al., 2007; Aiello et al., 2008; Arnold and Colford, 2007; Ejemot et al., 2008; IEG, 2008; Schmidt and Cairncross, 2009; Waddington et al., 2009; Cairncross et al, 2010). The objectives of the systematic reviews and meta-analyses were to determine the exact health impact of interventions, across studies, to enable broader generalisations to be made about their relative effectiveness and whether or not current evidence is enough to support scaling up of the intervention. The outcomes of the analyses are summarised in the following paragraphs.

The health contribution of the improvements in water quality was considered of less importance than water quantity and sanitation two decades ago (Esrey et al., 1985; Esrey et al., 1986). The median reduction in diarrhoea from interventions to improve water quality was 16% (9 studies), compared to 22% (10) for sanitation, 25% (17) for water quantity and 37% (8) for water quality and availability. An update of these reviews was undertaken by Esrey et al. (1991). Drawing on three systematic reviews the authors surveyed 144 studies and calculated the median percentage of effects of diarrhoea morbidity across the studies for hygiene interventions, water supply interventions, sanitation interventions and water quality interventions. The relative calculated reduction was 33% for hygiene interventions, 27% for water supply interventions, 22% for sanitation interventions and 17% for water quality interventions. The authors concluded that excreta disposal and adequate water for personal and domestic hygiene were of bigger importance than clean drinking water to achieve "broad health impacts".

A wide range of interventions including hygiene, sanitation, water supply, water quality (which included point-of-use interventions) and combinations of interventions (water, sanitation and hygiene) from 38 studies were analysed for their relative impact on risk of diarrhoea (Fewtrell et al., 2005). Hand washing was found to reduce the risk by 44% while hygiene education reduced the risk by 28%. Improving the microbial safety of water at the point-of-use seemed to be very effective in reducing diarrhoeal disease (relative risk 0.61, 95% CI, 0.46 to 0.81). Similar to observations reported by Esrey (1991) and colleagues the effect of multiple interventions were found not to be additive. Importantly the study highlighted the issue of sustainability of studies. The authors highlighted the importance of evaluating the sustained use of interventions and making this an explicit part of future study designs. Revisiting the study sites at regular intervals and measuring the sustainability, as well as the positive and negative impact factors, should be included as part of future interventions. It was also noted that current findings are not generalisable to all age groups because the focus of the majority of the studies analysed was on children. Evidence of substantial heterogeneity among studies was also noted.

A meta-analysis of 33 studies focussing specifically on water quality and its health gains was conducted by Clasen et al. (2007). The outcome supported the findings of the study of Fewtrell and colleagues (2005), namely, interventions to improve water quality reduce diarrhoea but interventions at the household level were more effective than those at the source. Substantial heterogeneity was observed and the authors suggested that blinded studies are conducted over a longer periods and that they demonstrate affordability (Clasen et al., 2007; Clasen et al., 2006b).

The information generated on the health gains associated with washing hands was also evaluated. Results for three meta-analyses reported reduced diarrhoeal incidence of 50% (Curtis and Cairncross, 2003, 17 studies), 34% (Aiello et al., 2008, 34 studies) and 30% (Ejemot, 2008, five randomised control studies), respectively.

Arnold and Colford (2007) reviewed and performed a systematic analysis of 21 studies that measured impacts of diarrhoea on children in relation to the impact of chlorine disinfection of drinking water at point-of-use. The risk of childhood diarrhoea was reduced (pooled relative risk 0.71, 0.58 to 0.87) as well as the risk from *E. coli* contamination of stored water (pooled relative risk 0.20, 0.13 to 0.30). The authors noted that studies were generally conducted over short periods and suggested that longer studies are necessary to assess acceptability and sustainability in full.

The World Bank's Independent Evaluation Group (IEG, 2008) concluded that there is "overwhelming evidence that hand washing, sanitation, and point-of-use water treatment improve health outcomes". However, there do not appear to be health gains for water treatment at the source. Furthermore, the health impact of a combination of more than one intervention method per study has not been found to be stronger than any single approach.

A systematic review of the effectiveness of interventions in water, sanitation and hygiene (WSH) in promoting better health outcomes in developing countries, as measured by the incidence of diarrhoea among children, has been conducted by Waddington et al. (2009). The study updates the existing studies of Esrey et al., 1991; Curtis and Cairncross, 2003; Fewtrell and Colford, 2004; Clasen et al., 2007; Ejemot et al., 2008; and IEG, 2008, summarised in the first paragraphs of this section. The Waddington study rectifies specific methodological shortcomings observed in previous analyses. These include combining effect estimates which may reduce validity of pooled estimates of effect size. For example, estimates are reported from different estimation procedures including risk ratios, rate (incidence density) ratios, prevalence ratios and odds ratios, and others (Waddington et al., 2009). Previous systematic reviews have also omitted detail about:

- Why interventions are effective or not; and
- Whether or not the intervention was sustainable.

The results obtained were generally consistent with previous reviews. Water quality interventions are significantly more effective than interventions to improve water supply. While water supply interventions appear ineffective – averaging an insignificant impact on diarrhoea morbidity compared to controls – water quality interventions on average effect a 42% relative reduction in child diarrhoea morbidity (95% confidence interval 0.50 to 0.67). Reporting bias and publication bias and heterogeneity between intervention results were again highlighted.

Schmidt and Cairncross (2009) reviewed aspects pertaining to acceptability, scalability, adverse effects and non-health benefits in context of the effect of HWT on diarrhoea. The objective was to determine how much evidence is necessary for scaling up. The authors concluded:

- That scaling up is premature.
- High quality studies are needed to prove that HWT indeed reduces diarrhoea and to estimate the size of the effect. Future studies should either be blinded or include as the primary outcome measure an objective outcome such as mortality, weight gain, or growth.
- Conflict of interest may add to biased results in cases where industry is involved. Improving water access and sanitation remain the top priorities in the water, hygiene and sanitation sector.

Critical questions put by the authors are:

- How much of the currently cited disease reduction of HWT is due to bias, including the placebo effect and courtesy bias?
- What is the effect of HWT on nutritional status (weight gain and growth)?
- At which populations should HWT be targeted?

A natural outflow from the above analyses that focussed on the results obtained across different types of interventions was to compare the different types of interventions using meta-regression (Hunter, 2009). The lack of blinding and heterogeneity seen in the previous studies were specifically addressed (Hunter, 2009). The following variables were shown to be main predictors of effectiveness of an intervention: Study duration, whether or not the study was blinded and being conducted in an emergency setting

(Hunter, 2009). Compared to the effectiveness of the ceramic filter all other interventions were much less effective with SODIS the least effective.

In a recent re-evaluation of three systematic reviews (Cairncross et al., 2010), diarrhoea risk reductions were 48% for hand washing with soap, 17% for improved water quality and 36% for excreta disposal. The considerable reduction in risk for hand washing with soap was found consistent across various study designs. However, it should be noted that hand washing with soap is dependent on the availability of water.

The authors again highlighted reporting bias associated with non-blinded studies, particularly for interventions addressing water quality. It seems to be a significant problem associated with the reported reductions of diarrhoea incidence. A valid argument that is biologically plausible is made in regard to the infectious dose and volume of water the subject needs to ingest - only a large volume of water will contain enough infectious organisms to cause an infection. The anomaly that the reduction in diarrhoea seems independent of the quality of the ambient water before it is treated was also highlighted and so was the fact that most of the trials have been funded by water treatment chemical manufacturers, and that bias, because of their vested interest, may have been encouraged.

The general conclusion was that conclusive evidence of the effect on diarrhoea for improvements in water hygiene and sanitation is not currently available. Despite existing uncertainties and doubts around interventions, they, however, do have some substantial effect on morbidity and mortality from diarrhoea (Cairncross et al., 2010).

Recurrent themes seem to be the lack of blinded trails, the true effect on diarrhoea of water quality interventions and the heterogeneity among outcomes of HWT interventions. Responding to these apparent inconsistencies and project design shortcomings, Clasen (2009) highlighted the difficulties of blinding an intervention study. For both technical and ethical reasons blinding of HWT interventions is often not possible. Authors of blinded studies have themselves admitted shortcomings in such studies and therefore the superficial comparison between blinded and open studies can be misleading.

The evidence for the health impact of microbiological quality of water is compelling when compared to no impact observed for sufficient water quantity and access (Cutler and Miller, 2005). A substantial protective effect is still possible even when adjusting for the inflated effect of 25%, attributed to the absence of blinding, as suggested by Wood et al. (2008).

Two studies (Mahfouz et al., 1995; Quick et al., 1999) are cited that contradict the suggestion of Schmidt and Cairncross (2009) with regard to intervention trials not being objective. They argued that high levels of heterogeneity are consistent for HWT interventions and that there are valid underlying effects that cannot be ascribed to bias (Clasen, 2009). Current HWT interventions are subject to a very wide variety of issues such as different exposure pathways, different types of interventions, different study methodologies, different study communities etc. Thus any given trial, whether blinded or open, is unlikely to yield an estimate of effect that is fully generalisable (Clasen, 2009).

The overriding message is that with the exception of a few studies the interventions evaluated by these authors all improved the health of children to some degree even though some results may have suffered from reporting bias, recall bias and lack of randomisation. Poor acceptance and poor sustained use of interventions is at the root cause of many of the problems highlighted by the authors and many of the interventions cited in this document. Human behaviour, which drives the success or failure, acceptance and use of an innovation or intervention, should not be underestimated when evaluating the outcome of such studies. Efforts should therefore be specifically directed at human behaviour and understanding its influence on intervention outcomes.

1.5 HEALTH IMPACT ASSESSMENTS

Many of the studies referred to in previous sections of this document involved health impact assessments. This section discusses those directly related to solar disinfection.

Health Impact Assessment (HIA) is defined by different agencies in different ways, but there is a general consensus around a broad definition, published in 1999 as the ‘Gothenburg Consensus Paper’ by the WHO Regional Office for Europe (WHO ECHP, 1999). That definition is: “a combination of procedures or methods by which a policy, program or project may be judged as to the effects it may have on the health of a population.” HIA may thus include assessment of high level policy programs as well as individual developments and projects. Health impact assessment can also be defined as a process that systematically identifies and examines, in a balanced way, both the potential positive and negative health impacts of an activity. Health impact assessments vary in depth and complexity. In the context of the studies summarised in previous and following sections, 'health impact assessment' refers to smaller scale randomised controlled and open project study designs testing a variety of interventions. The aim of the interventions is to improve the quantity and quality of drinking water or sanitation and hygiene, and to prove that a positive change in the health of people, practicing the interventions, can be realised.

The following sections will focus on the use of SODIS as an intervention to improve the quality of water for household consumption and the consequent reduction in diarrhoea incidence in those ingesting SODIS water.

At the outset of this study reported herein, published information on HIAs determining the effectiveness of SODIS as an intervention in the field consisted of only three reports (Conroy et al., 1996; Conroy et al., 1999; Rose et al., 2006). Two of these trials were undertaken in a rural area of Kenya and one in India. In Kenya children between 5 and 16 years were provided with plastic bottles and instructed how to use them. The test group put their filled bottles in the sun while the control group kept their bottles in their homes (Conroy et al., 1996). This amounted to a certain degree of blinding of the study. After adjustment for age, solar treatment of drinking water was associated with a reduction in all diarrhoea episodes (odds ratio 0.66; 95% CI, 0.50 to 87) and in episodes of severe diarrhoea (0.65; 95% CI; 0.50 to 0.86). In an extension of the previous trial, 349 Maasai children younger than 6 years old were randomised by alternate household to drink water either left in plastic bottles exposed to sunlight on the roof of the house or kept indoors (control) (Conroy et al., 1999; McGuigan, 1999). The results showed that in a two week period prevalence of diarrhoea was 48.8% in the test group compared with 58.1% in the control group. Important observations were the continuous use of SODIS after the completion of the study. During a cholera outbreak in the same Maasai community only three out of 155 children less than six years who drank solar disinfected water contracted the disease. Amongst those children (144) who did not drink solar disinfected water 20 contracted the disease (Conroy et al., 2001). Noteworthy is the general poor quality of the water both in terms of indicator bacteria (*E. coli* counts were $20x10^5$ CFU/mℓ) and turbidity that ranged between 5 to 2000 NTU (Joyce et al., 1996). *E. coli* levels of 10^3 CFU/mℓ and turbidities in excess of 200 NTU were reported for the study undertaken in 1999 (Conroy et al., 1999).

Rose et al. (2006) conducted a randomised controlled study in India. Participating children (under 5 years old) were given twelve one-litre polyethylene terephthalate bottles which had one vertical half painted black. Diarrhoea was recorded when there was passage of three or more loose or watery stools in a 24 hour period. An important issue addressed in the study was compliance and acceptance. Compliance was measured by observing the water bottles being put in the sun and was recorded as the percentage of visits during which the water bottles were found in the correct position. A questionnaire and focus group studies indicated that SODIS was acceptable in terms of cost and ease of use. The volume of water and taste were two factors highlighted as unsatisfactory in a few households. A six month follow up with weekly visits showed a 50% reduction in diarrhoea in children despite consumption of other sources of drinking water by 85% of the children. Compliance was good, with 78% of the families recording compliance on 75% of the visits (Rose et al., 2006).

A more recent cluster randomized control trial in 22 rural communities in Bolivia was reported by (Mäusezahl et al., 2009). It included 376 test children with 349 serving as controls. Mean compliance with SODIS was 32.1%. The reported incidence rate of diarrhoea illness in children in the test group was 3.6 compared to 4.3 episodes per year at risk in the control group. The relative rate of diarrhoea adjusted for intra-cluster correlation was 0.81 (95% confidence interval 0.59 to 1.12). Based on these findings the authors concluded that there was little evidence of substantial reduction in diarrhoea or compliance and that an important requirement, prior to global initiation of SODIS, would be "better evidence of how the well-established laboratory efficacy of this home-based water treatment method translates into field effectiveness before global promotion of SODIS" (Mäusezahl et al., 2009).

A recent randomised control study of 2 911 households in Cameroon (Graf et al., 2010) again confirmed the reduction in diarrhoea SODIS can have on children under five years of age. Diarrhoea prevalence amounted to 34.3% among children prior to the study. After the intervention, it remained stable in the control group (31.8%) but decreased to 22.8% in the test group. Households adhering fully to the SODIS intervention exhibited diarrhoea prevalence of 18.3%.

A small blinded, population based interventional prospective SODIS study was conducted in Sikkim, India (Rai et al., 2010) for a period of 8 weeks. Sixty under five year old children were randomised to SODIS and 71 to control (non-SODIS). The blinding process was not totally clear from the description of the process but SODIS bottles were coded. Percentage diarrhoea prevalence of 7.7% for SODIS users and 75.8% for non-users (χ^2 = 10.69, df=1; P=0.05) were recorded after four weeks. After eight weeks the percentage prevalence was 7.6% and 31.4% in SODIS users and non-SODIS users, respectively (χ^2 = 1125, df=1; P=0.05).

1.6 SODISWATER PROJECT

1.6.1 Overall objectives

In 2005 funds became available from the European Union (EU) under the Specific Programme: Integrating & Strengthening the European Research Area, Call Title: Specific Targeted Research Projects (STREP) for African, Caribbean, Pacific (ACP) Partner Countries, Call Identifier: FP6-2004-INCO-DEV-3 for the study titled: Solar Disinfection of Drinking Water for use in Developing Countries or in Emergency Situations.

The overall objective of the study was to demonstrate that Solar Disinfection (SODIS) of drinking water is an appropriate, effective and acceptable intervention against waterborne disease for vulnerable communities in developing countries without reliable access to safe water.

The strategic objectives of SODISWATER were:

- To demonstrate that Solar Disinfection (SODIS) of drinking water is an appropriate, effective and acceptable intervention against waterborne disease for vulnerable communities in developing countries without reliable access to safe water.
- To evaluate and test different diffusion and behavioural change strategies in areas with different social and cultural conditions for sustainable adoption of solar water disinfection.
- To disseminate these research outcomes throughout the international aid and emergency relief communities so that SODIS is adopted as one of a range of standard water quality interventions (e.g. filtration, chlorination, desalination, etc.) for use in the immediate aftermath of natural (Tsunami, flood, earthquake, hurricane/typhoon) or man-made disasters (war-zone, famine, refugee camp).
- To develop a spectrum of appropriate SODIS enhancement technological innovations that can be matched to varying socio-economic conditions. Such technological innovations would include UV dosimetric indicators of disinfection, photocatalytic inactivation and continuous flow compound parabolic collector arrays for small community distribution systems.

1.6.2 Objectives of this study

The focus of the work described in this thesis pertains to the first strategic objective of the overall EU study: *To demonstrate that Solar Disinfection (SODIS) of drinking water is an appropriate, effective and acceptable intervention against waterborne disease for vulnerable communities in developing countries without reliable access to safe water.*

The effectiveness of SODIS would be determined primarily by health impact assessments in South Africa, Kenya and Zimbabwe. The HIAs would also establish to some extent how 'acceptable' SODIS is in the selected areas of the respective countries.

Specific objectives for the health impact assessments were:

1. Assessment of the change in health reasonably attributed to the provision of solar disinfected drinking water at the point-of-use in three African countries;
2. Assessment of the relationship between solar disinfected drinking water and selected health indicators (including morbidity due to non-bloody diarrhoea and dysentery, weight loss, mortality, growth rates);
3. Demonstration of the effectiveness of SODIS at household level; and
4. Demonstration of the degree of acceptance of SODIS as a disinfection method.

CHAPTER 2: STUDY DESIGN

2.1 INTRODUCTION

To address the above-mentioned overall objective, this study specifically focussed on dysentery and non-dysentery diarrhoea in children between 6 months and 5 years of age in the three African countries, South Africa, Zimbabwe and Kenya. Anthropometric measurements were also recorded to determine general growth of the children over a period of one year.

2.2 STUDY SCHEDULE

Figure 2.1 depicts the schedule for the field studies conducted over a one year period and the follow up procedures during which SODIS was extended to include the control group. Chapter references refer to the Field Manual (see Section 2.3.7).

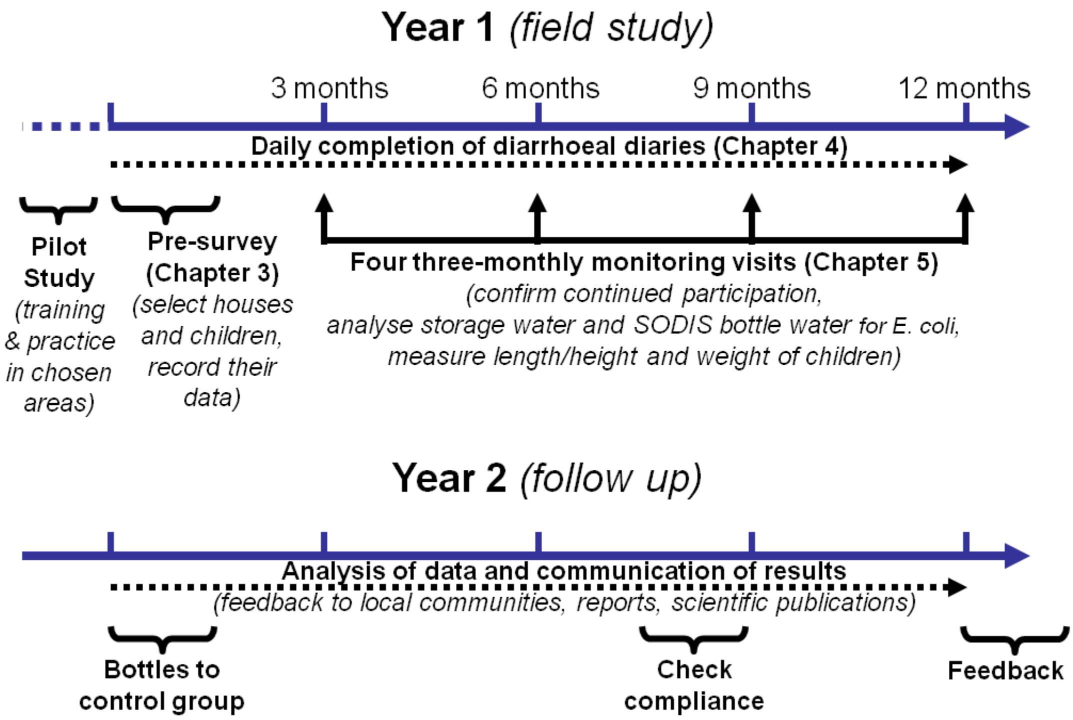


Figure 2.1: Schematic overview of field study schedule.

2.3 PHASE 1: INITIALISATION

2.3.1 Choice of study areas

At the outset of the health impact assessments criticism levelled at the size (number of participants), the duration, and the lack of blinding of drinking water quality interventions were common. The research team was thus encouraged to include a large number of participants and to follow them for a period of one year.

Census data and local knowledge were accessed to determine the diarrhoea morbidity and mortality in children less than 5 years and the level of water access in the surrounding areas of Pretoria in South Africa, Harare, Zimbabwe and Nakuru, Kenya. The areas chosen had different socio-economic development levels, cultures and utilised different types of drinking water sources. They were also within reasonable distance from the cities and easily accessible for field workers. Both rural and peri-urban communities were included. It was not possible to blind the studies. Detailed descriptions of each area are given in the results sections (Chapters 3, 4, and 5).

2.3.2 Liaison with authorities

Key role players in the relevant administrative and decision making structures of each country were identified. Community leaders and the communities themselves were involved in the choice of study areas. Introductory meetings and information sessions were convened. They had the following objectives:

- **Provision of an overview of the project:** This entailed presenting to the community the objectives of the overall project and the field study in particular. Sufficient detail was given so that the community understood the underlying principles of the study and what it aimed to achieve.

- **Facilitation of discussion on the study design:** When the objectives were understood the study design was discussed. This helped the team assess its feasibility in each area. Local community members were employed on the project whenever possible.

- **Determination and allocation of roles and responsibilities:** This helped create a clear understanding of what the community involvement would entail. Local community leaders were involved and helped with project coordination at the community level. This included identification of specific community members to assist the project team, community liaison, and facilitating cooperation. Appropriate community members were then formally recruited.

Formal permission was obtained from the appropriate authorities at all levels in each country before the study commenced. Local and district leaders were also kept informed of the progress of the study for the duration of the study.

2.3.3 Questionnaires

The following questionnaires were developed to help capture data and information directly relevant to the objectives of the study. The questionnaires are available in the SODISWATER Field Manual Section 2.2.6.

- **Pre-Survey phase**
    - **Household**. Data on individual households, including hygiene and water use practices.
    - **Children**. Personal data on individual children (one or more per household).

- **Main survey phase**
    - **Participation**. Confirming ongoing participation or recording reasons for leaving the study.
    - **Storage Water**. Storage water sample bottle barcode, etc.
    - **Anthropometry**. Child height and weight.
    - **SODIS Bottle**. SODIS bottle sample bottle barcode, etc.
    - **Child Death**. Date and cause of death (if known).
    - **Lab Quanti-Tray Fill**. Used in laboratory to record sample bottle barcodes and associated Quanti-Tray barcodes.
    - **Lab Quanti-Tray Wells**. Used in laboratory to record Quanti-Tray barcodes and associated numbers of positive wells.

These questionnaires were loaded onto Symbol Pocket PC handheld computers using the Pendragon proprietary software. These handheld computers were used in the field to capture all the necessary data (**Figure 2.2**).

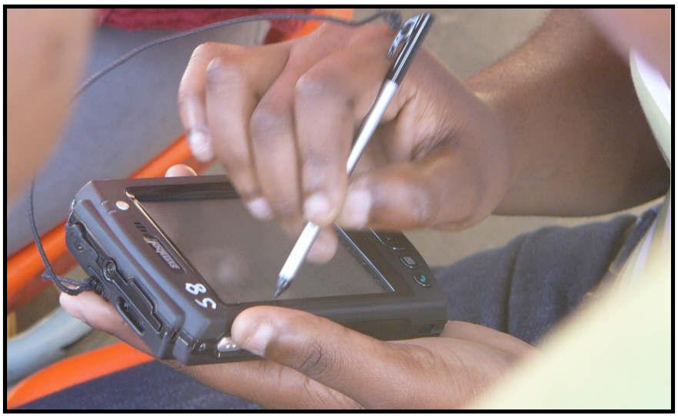


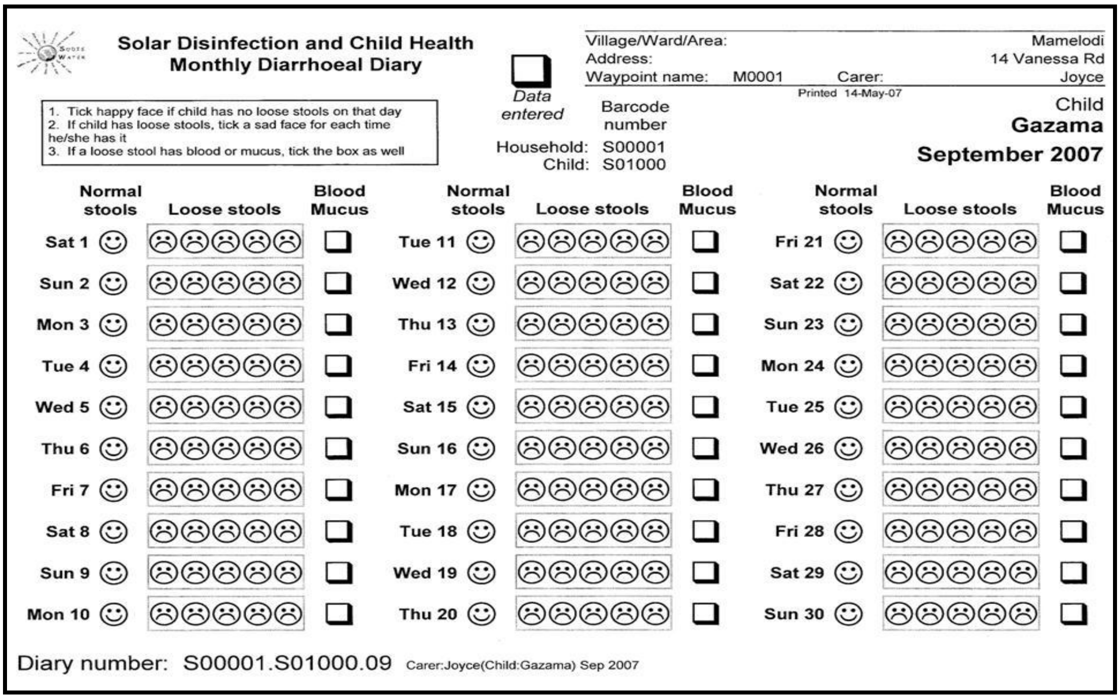
Figure 2.2: Symbol Pocket PC handheld computer used to capture field data.

2.3.4 Diarrhoeal "smiley" diary development

A paper-based method based on that of Wright et al. (2006) was developed for recording (a) the number of loose stools produced daily by the participating children and (b) whether or not those stools contained blood or mucus. It involved the use of a printed page with simple happy (smiley) faces (☺) representing normal stools and sad faces for loose stools (☹). A special box is marked if blood or mucus is present. The diary does not require people to be literate (**Figure 2.3).** The definitions for diarrhoea and bloody diarrhoea used are those of Baqui et al. 1991.

Each page was personalised with each child's name and their carer and covered one calendar month. It also conveniently showed household details, the child's name, a unique diary number (comprised of the household barcode, child barcode and 2 digit relative month code). Twelve such pages were produced for each child, one per month for twelve months. This was done using the SODIS Country Master Database described below (Section 2.3.6).

The carer or parent of each child was trained to daily record whether or not any of the children had diarrhoea or not. Fieldworkers ensured that the carers understood the definitions of both non-bloody- and bloody diarrhoea clearly. Carers were asked to mark a smiley face every time a child passes a normal stool and an unhappy face when a child passes a loose stool. When a child passes stool with blood or mucus the square on the diary was marked.


Solar Disinfection and Child Health
Monthly Diarrhoeal Diary

Village/Ward/Area: Mamelodi
Address: 14 Vanessa Rd
Waypoint name: M0001 Carer: Joyce
Printed 14-May-07

1. Tick happy face if child has no loose stools on that day
2. If child has loose stools, tick a sad face for each time he/she has it
3. If a loose stool has blood or mucus, tick the box as well

Data entered

Barcode number
Household: S00001
Child: S01000

Child
Gazama
September 2007

	Normal stools	Loose stools	Blood Mucus		Normal stools	Loose stools	Blood Mucus		Normal stools	Loose stools	Blood Mucus
Sat 1				Tue 11				Fri 21			
Sun 2				Wed 12				Sat 22			
Mon 3				Thu 13				Sun 23			
Tue 4				Fri 14				Mon 24			
Wed 5				Sat 15				Tue 25			
Thu 6				Sun 16				Wed 26			
Fri 7				Mon 17				Thu 27			
Sat 8				Tue 18				Fri 28			
Sun 9				Wed 19				Sat 29			
Mon 10				Thu 20				Sun 30			

Diary number: S00001.S01000.09 Carer:Joyce(Child:Gazama) Sep 2007

Figure 2.3: Example of a monthly diarrhoeal diary.

2.3.5 Ethical review

Ethical review, a prerequisite in all three countries, was obtained from The Royal College of Surgeons in Ireland and the respective organisations in each country:

1. South Africa: Faculty of Health Sciences Ethical Committee, University of Pretoria, South Africa;
2. Zimbabwe: Medical Research Council of Zimbabwe; and
3. Kenya: KEMRI (Kenya Medical Research Institute).

2.3.6 Database development

The following two Access databases were developed for use in this study.

- **SODIS Country Master Database**. A copy of this database was used in each participating country to store the data downloaded from the Pocket PC handheld computers used to collect the field and laboratory data. The database consisted of:
  - **Tables**. A table existed for each of the above-mentioned questionnaires. Other tables were also created to facilitate various other database operations.
  - **Queries**. The primary purpose of these queries was to check the integrity of downloaded data as soon as possible after capture. This

allowed the problems detected to be fixed, if possible, as soon as possible while the conditions of their collection were fresh in people's minds. The queries specifically facilitated the detection of incorrect, inconsistent or missing data. For the two Pre-Survey tables they detected invalid barcodes in 3 circumstances, duplicate and unmatched barcodes each in 2 circumstances, households with no children, children of invalid age, etc. For the main survey (monitoring) tables the queries also detected invalid and duplicate barcodes each in 10 possible circumstances and unmatched barcodes in 14 different circumstances.

  - **Forms**. 16 forms were developed to act as user-friendly interface 'windows'.
  - **Report**. Two reports were developed. The first allowed printing of 'house detail' pages kept in ring-bound files that provided basic location information and names of carers and children for field workers. The second allowed printing of personalised monthly diarrhoeal diaries for each child in the study, distributed manually to each household.

- **Diarrhoeal Diaries Individual Database**. This database was designed to allow multiple copies of it to be used in each country by different individuals to capture data from the monthly paper 'smiley diaries'. These individual databases were then combined into a single database for each country at the end of the study. The database consisted of:
  - **Tables**. The main table is the one containing the actual diarrhoeal diary data for each child. Other tables were also created to facilitate various other database operations.
  - **Queries**. Most queries were created to check data integrity such as invalid diary numbers, diary numbers with ambiguous barcodes, duplicate diary numbers, checking for the same child occurring in different households, checking for missing diaries, and checking for daily data problems like days with nothing marked by the carer.
  - **Forms**. Seven forms were developed to act as user-friendly interface 'windows', allowing, for example, inserting new data and viewing and editing of existing data, etc.

2.3.7 Development of manuals

In an endeavour to obtain data from the different countries that could be compared, standard procedures were devised that would be implemented in as much the same way as possible in the three countries. To facilitate this, two manuals were developed that defined these standard procedures before any field work started.

1. **SODISWATER Field Manual**. This was used by project team members involved in the practical field work and the subsequent data capture from handheld computers onto laptop computers. It contains the following:
    a. Glossary;
    b. Confidentiality of personal data;
    c. Using the equipment (laptops, handheld computers, GPS, anthropometry, *E. coli* Quanti-Trays, etc.);
    d. Pre-survey (choosing the area and households, barcodes, SODIS bottles, the daily routine, household protocols, and database management);
    e. Diarrhoeal diaries (printing, distribution, use, monthly collection, data entry, and data integration);
    f. Monitoring visits (the daily routine, and database management).

2. **SODISWATER Diarrhoeal Diaries Data Entry Manual**. This was used by project team members or other persons specifically recruited to capture the diarrhoeal data from the paper 'smiley diaries' into the specially-designed Diarrhoeal Diaries Individual Databases.
    a. Glossary;
    b. Creating individual databases;
    c. Entering new diaries;
    d. Editing existing diaries;
    e. Viewing existing diaries;
    f. Viewing/editing the main table; and
    g. Checking for problems.

These two manuals are available as separate documents in **Appendix A** and **B**

2.4 PHASE 2: PILOT STUDY

Community workers living in the respective study areas were selected and trained as field work supervisors. They were trained to do household interviews, capture data using handheld computers, take water samples and do anthropometric measurements (**Figure 2.4**). They were also given in depth training about the SODIS process and completion and verifying diarrhoeal diaries. The number of field workers per country ranged between 8 and 10. In addition graduated coordinators were employed to oversee the field work. In South Africa two supervisors completed an ethical training course “Good clinical practice” at the University of Pretoria prior to initialisation of the study. Field supervisors and graduated field coordinators from each country also attended a training course in South Africa. The course covered the following:

- The overall structure of the field study (summarised in Section 2.1 above);
- The practical use of:
  - Barcodes;
  - The Garmin etrex GPS;
  - The handheld computers, including downloading of data; and
  - The Colilert method for measuring *E. coli* levels.
- Database management;
- Printing, distribution, use, and collection of the diarrhoeal diaries;
- Diarrhoeal diary data capture into the database (Section 2.3.6);
- The Pre-Survey; and
- The main survey (monitoring visits).

Figure 2.4: Attentive fieldworkers during the pilot study training course.

The SODISWATER Field Manual and the SODISWATER Diarrhoeal Diaries Data Entry Manual were used as course material during the practical sessions (Section 2.3.7). Potential problems were highlighted and procedures for avoiding and solving them were discussed.

Immediately after this training a pilot study, aimed at in-the-field familiarisation and testing of all procedures, was conducted in South Africa in a limited number of households. After assessment of the outcomes, recommendations for changes to the proposed procedures were considered and implemented prior to full implementation of the main study. These changes were captured in updated manuals.

The participating countries subsequently carried out their own pilot studies in their own countries to test and assess procedures under their respective local conditions.

2.5 PHASE 3: PRE-SURVEY

Once the study areas had been identified and the associated permissions obtained, individual households and children were identified. The criteria for selecting the households were:

1. Storage of drinking water in the house was essential.
2. A drinking water tap in the house or garden was not permitted.
3. At least one child (but not more than 5) between 6 months and 5 years old had to reside in the house. A child could only be included if their 5th birthday was AFTER the day on which the visit to that household occurred.

Sample size was estimated based on comparison of two Poisson event rates in the presence of significant clustering. Since neither the underlying rates of dysentery nor the strength of clustering effects within households were known, we carried out a series of calculations based on rates of 1 to 10 days of dysentery per year and on different degrees of clustering effects. The projected sample of 1,000 children was chosen as offering a 90% power to detect a 10% reduction in risk where the underlying rate was 5 episodes per child per year and clustering effects were strong (rho = 0.2). The sample provided more than 90% power to detect a 20% reduction in incidence for all rates of 2 episodes per child per year or greater.

An information sheet explaining the aim of the study, what was expected from the household, the study period and the kind of questions a household would be asked to answer, was read to participants or read by the participants themselves. Written consent was then obtained from the head of each household. These documents were translated from English (see **Appendix C**) to the local languages in Kenya and Zimbabwe. These were re-translated back into English to ensure the original intent of the questions was clear.

2.5.1 Randomisation

South Africa

The greater study area for the South African trial is situated in the Tshwane Municipality, Gauteng Province. Four peri-urban sub-districts, Soshanguwe, Legonyane, Fafung and Kwarriekraal were selected based on the availability of children five years and younger and the types of sources used for drinking water. The villages residing in each of the sub-districts that were included in the initial sample frame of households were the following:

Sub-district Soshanguwe: Stinkwater, Newstand and RDP (900 households).
Sub-district Legonyane: Wendam Lesung, Leogeng, Reserve, Legaeng, Vaalboschloot, Waterval, Rooiwal and Newstand (428 households).
Sub-district Fafung: Roman, Droogpan, Lehwiriling, Mmotong, Sephai and Newstand. (650 households).
Sub-district Kwarriekraal: Newstand, Kwarriekraal (250 households).

Eligible households (no tap in the yard or house and children in the house between 6 months and 5 years old) were chosen from 19 villages. Field workers located the eligible households on foot and recorded their addresses. A waypoint name, linked to the Global Positioning System (GPS) coordinates of the household, was allocated to each household. The addresses and coordinates constituted the sample frame of households. For each household a random number between zero and one was generated. If the random number was less than 0.5 the household was allocated to the test group. Otherwise it was allocated to the control group. Field workers were unaware of how the numbers were allocated. Six hundred and forty nine households were included at completion of the randomisation process.

Kenya

The six sub-districts and villages selected for household selection in the Kenyan trial are situated in and in the surrounding areas of Nakuru (**Table 2.1**). The location of eligible households was undertaken by fieldworkers, and randomisation was done according to the method described for South Africa. Seven hundred and ninety eight houses were included for follow-up.

Table 2.1: Sub-districts and communities included in the selection of the initial sample frame of households in Kenya

Bondeni	Kaptembwo	Lanet	Mogotio	Salgaa	Wanyororo
Bondeni	Baba Kang'ethe	Free Area	Athinai	Belbur	Heshima Complex
Flamingo	Baringo Street	Home Centre	Athinai Primary	Jua Farm	Jehovah Witness Church
Kaloleni	Embenezer	Kiratina	Lomolo Primary	Ndoreni	Kagoto
Kimuthi	Githima	Makao	Lomolo Staff 1&2	Rongai	Kakias
Kivumbini 1	Heshima	Mrogi		Salgaa Village	Sokoni
Kivumbini 2&4	Mombassa	Nairobi Area			Stage One
Lakeview	Nakuru West	Upendo			
Manyani	1. Nyatoto				
Pangani	Nyondarwa				
Ziwani	Paramount				
	Pembe				
	Shainning Star				
	Stima Line				
	Tumaini				
	Virginia				

Zimbabwe

The trial in Zimbabwe was undertaken in a peri-urban area known as Hatcliffe, approximately 10 km from the capital city, Harare. Eligible households in Extension 1, 2, 3 and 4 of Hatcliffe were selected based on the methods described for the randomisation of households in South Africa. A total of 1 100 households were included in initial selection. However, as a result of political interference and the provision of chlorine tablets to halt the spread of cholera in the community the original set of households and their allocation to test and control could not be retained to completion of the study.

2.5.2 SODIS training

After randomising households into the test and control groups the control group was asked to continue drinking water from the storage containers in the house. Each child in the test group were given two two-litre PET bottles and carers or parents were requested to provide the children only with SODIS water for drinking and also to mix milk formula or fruit juice concentrates with SODIS water. Clear instructions pertaining to SODIS as well as demonstrations were given in the home language of the carer of the participating children of each household. These included correct procedure for filling the bottles, prior treatment of very cloudy water, shaking the bottles to dissolve oxygen trapped between the water level and lid and choosing an appropriate spot for exposure of the bottles so that the maximum amount of sunlight could be utilised for disinfection. Basic information on the SODIS disinfection process, what to do on cloudy and rainy days were also given. Participants were instructed to drink the water within 48 hours after disinfection.

Once consent had been given, the two pre-survey questionnaires (household and children) were completed on the handheld computers

A household sheet that contained the address, GPS coordinates child name, child barcode, house barcode, date and parent or carer’s name were generated for each household. A folder, for each of the sub-districts, was created which contained all the household sheets of all the households. These folders were used to access GPS coordinates of households and to verify the monitoring visit number as well as the names of children during the monitoring visits and unannounced visits. The household sheets were also used during collecting and giving out diarrhoeal diaries. Changes in addresses and other general information were also captured on the household sheets. Diarrhoeal diary sheets were also printed and distributed to the households. The concepts of diarrhoea and bloody diarrhoea were explained and carers were carefully instructed on how to complete a diary and requested to fill in the diary every day for the one year’s duration of the field study. These instructions were repeatedly reinforced during monitoring (every three months) and other visits (at least monthly and some unannounced visits) to the households. Field coordinators joined the field supervisors on the monitoring visits and during collection of the diaries.

2.6 PHASE 4: 12-MONTH MAIN SURVEY

The main survey comprised two main activities.

First, daily records of loose stools and whether or not they contained blood or mucus were kept by the carers using the printed diarrhoeal diaries. These were collected by field staff at regular intervals. When diary sheets were detected that had been incorrectly completed, fieldworkers repeated the appropriate instructions. The capture of these data from the printed sheets into the Diarrhoeal Diaries Individual Databases (Section 2.3.6) also occurred continually throughout the main survey.

Secondly, monitoring visits to all households took place four times at three-monthly intervals over the one-year survey period. The first monitoring visit occurred three months after the pre-survey. This allowed some time for health-related effects to manifest.

Figure 2.5: Transporting typical small water storage containers used in the households.

At each household, participation was confirmed or child deaths or reasons for leaving the study recorded. If participation was confirmed children were weighed and their heights or lengths measured. Samples of the water stored in the test and control households and the solar-disinfected water (test households only) were collected. For each activity handheld questionnaires were completed that recorded the necessary data (e.g. anthropometric) and information (e.g. sample bottle barcodes, etc.). If necessary, ongoing guidance was provided by the field workers in appropriate use of the SODIS bottles.

Cases of severe diarrhoea detected in children were managed by referring them to local clinics or district hospitals where treatment was free. Oral rehydration salts were provided to mildly sick children.

Upon return to the laboratory each day, water samples were analysed and the data on the handheld computers were downloaded into the SODIS Country Master Database

(Section 2.3.6) on laptops and the handheld batteries charged in readiness for the next day.

The procedures in the field and laboratory were guided by the details in the relevant manuals (Section 2.3.7).

2.6.1 Analytical methods

2.6.1.1 Water quality

Water samples were transported on ice to the laboratory where they were analysed for the bacterium *E. coli* using the Colilert® method (Covert et al., 1989). This method is based on the Defined Substrate Methodology (DST) for simultaneous detection of coliforms and *E. coli* with no need for confirmation. DST utilises two indicator substrates, *o*-nitro-phenyl-β-D-galactopyranoside (ONPG) and 4-methylumbelliferyl-β-D-glucuronide (MUG), which are combined to simultaneously detect total coliforms and *E. coli.* Total coliforms produce the enzyme β-galactosidase that hydrolyses ONPG and thereby releases *o*-nitrophenol that produces a yellow colour. *E. coli* produces the enzyme β-glucoronidase that hydrolyses MUG to form a fluorescent compound (Olsen et al., 1991).

The method uses a Quanti-Trays® sealer (**Figure 2.6**) to seal Quanti-Trays (**Figure 2.7**) that contain 51 small wells in which *E. coli* colonies grow if present. The fluorescent compound is visualised using an ultra violet lamp. The levels (Most Probable Number (MPN), counts/100 mℓ) of *E. coli* in the original sample were obtained from a table using the number of positive wells in the Quanti-Tray after 18 hours incubation at 37 ºC. The maximum count that can be obtained using the 51-well Quanti-Tray is 200.5/100 mℓ. and minimum is <1/100 mℓ.

Water from the storage containers and SODIS bottles were collected every three months in commercially available 100 mℓ sample bottles containing sodium thiosulphate to neutralise any residual chlorine in the water.

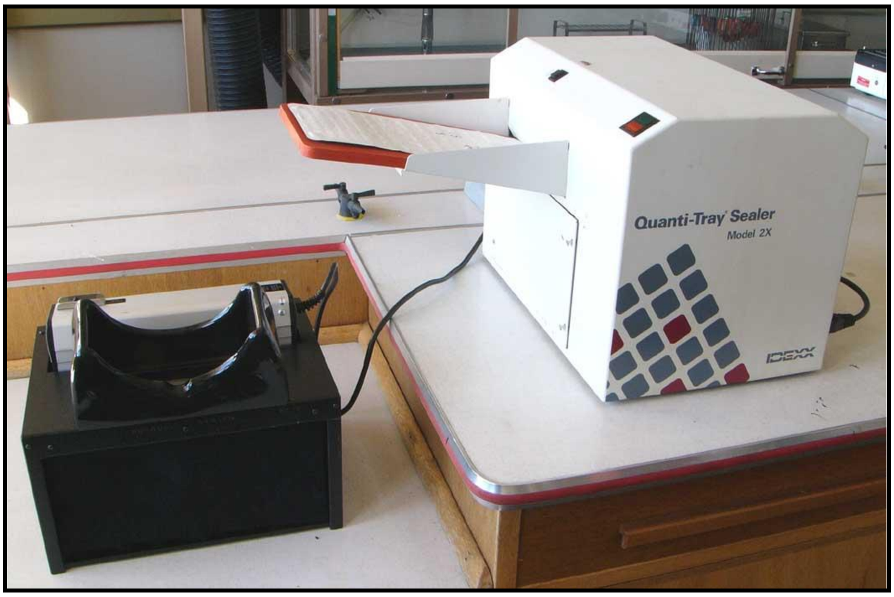


Figure 2.6: Colilert Quanti-Tray sealer and UV light.

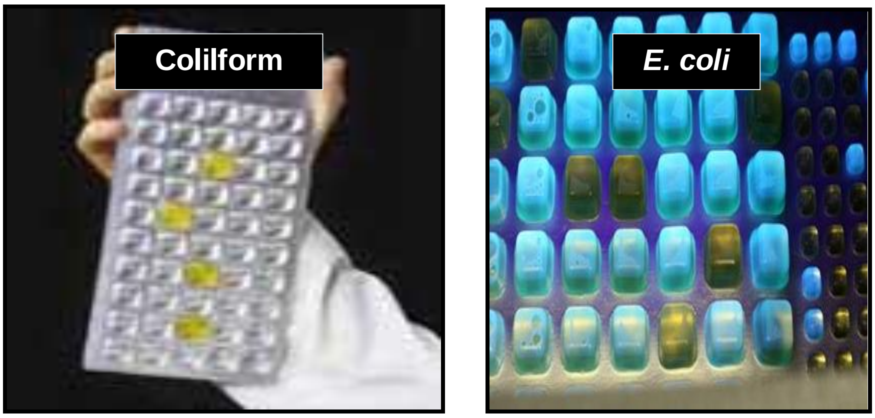


Figure 2.7: The Quanti-Tray used in the Colilert method to measure *E. coli levels*.

2.6.1.2 Anthropometry

Anthropometry is the study of human measurements. The recumbent height of children less than 24 months old was measured on a Raven Rollametre 100 (0.01 cm precision) consisting of a small foam or plastic mattress with a headpiece and a foot-board. Two observers were employed, with one person holding the head in place and exerting a gentle upward traction on the mastoid processes while pressing the headpiece firmly against the crown of the head. The second person was responsible for the correct position of the knees and feet of the subject. The height of the children older than 24 months was measured using a stature metre.

Body weight was measured on minimally clad subjects on digital battery-operated calibrated weighing scales. Uncooperative babies were weighed in the arms of the mother or adult family member whose weight was subtracted later. Personnel taking the measurements were not standardised. The following measurements were taken at each of four monitoring visits that took place over a period of one year: Child height (or baby length) (cm) and weight (kg) **(Figure 2.8)**.

Figure 2.8: Anthropometry measurements: Weight, height and length.

Anthropometric measurements are traditionally standardised against internationally accepted cut-off points of nutritional status. Nutritional indicators are usually calculated using the Z score (Z score = (measured value–median reference value)/(standard deviation of reference) relative to the reference population, namely the American population (WHO, 1986). The WHO developed a more representative set of child growth standards (i.e. length/height-for-age, weight-for-age, weight-for-length, weight-for-height and body mass index (BMI)-for-age, based on measurements of children from birth to 71 months old from Brazil, Ghana, India, Norway, Oman and USA (WHO, 2006a).

Anthropometric measurements provide a metric that is not directly related to disease. This has important implications for water quality HWT interventions when the ongoing debate about the true benefits of water quality and quantity is taken into consideration (Schmidt and Cairncross, 2009). Several meta-analyses conducted in recent years showed highly variable results for health outcomes of various types of interventions Esrey et al., 1991; Curtis and Cairncross, 2003; Fewtrell et al., 2005 Fewtrell and Colford 2004; Clasen et al., 2006b; Clasen et al., 2007; Aiello et al., 2008; Arnold and Colford, 2007; Ejemot et al., 2008; IEG, 2008; Schmidt and Cairncross, 2009; Waddington et al., 2009; Cairncross et al, 2010).. It has been suggested that the true values may be inflated as a result of reporting bias, recall bias, and the fact that studies have not been blinded (blinding implies that neither the investigators nor the target individuals or population in an intervention study has knowledge about who is randomised to the intervention and who is randomised to the control group).

Anthropometric measurements provide information on a health benefit that cannot easily be influenced by bias or non-blinding of an intervention and is therefore considered a sounder metric than diarrhoea reduction.

2.7 PHASE 5: POST-SURVEY COMPLIANCE

Upon completion of the year-long study, all control households were offered training in the use of the SODIS bottles. If they indicated a willingness to adopt SODIS, they were given SODIS bottles and the necessary instructions. The degree of compliance of SODIS in all the households using the bottles was evaluated after six months. In South Africa a questionnaire (**Table 3.17**) interview, conducted at 92 households that used SODIS during the main study, determined some of the perceptions in the community with regard to using SODIS.

2.8 PHASE 6: DATA ANALYSIS

The data collected from the main surveys in each country was submitted to the database developer at the end of each survey. The databases were cleaned of problematic data, collated and prepared for analysis by statisticians. These analyses aimed to determine whether or not correlations exist between the use of SODIS and its effectiveness in reducing either dysentery or non-dysentery diarrhoea in young children. The effects of a variety of factors, such as water quality, sanitation, hygiene behaviour etc., were also examined.

Stata/SE, release 11 was used for the analysis of repeated observations of dysentery and non-dysentery diarrhoea in children in families controlling for clustering within households. Poisson and binomial regression (with and without adjusting for more than one child per household), were used for initial analysis of the observed data for dysentery and non-dysentery diarrhoea. Water quality data recorded for the test (SODIS) and control groups were compared using the chi-square test. A paired t-test based on the observed data, was used to compare changes in weight and height between female and male children and the overall observed change in these parameters over the trial period. In addition an analysis of covariance (ANCOVA), with and without controlling for the age of the children, was used for the analysis of the anthropometric measurements. Techniques for sub-group analysis for dysentery and non-dysentery data and the anthropometric data are described in detail in the respective result sections (Chapters 3 and 4).

The randomisation unit was the household for this trial, however, for the data analysis an effect size based on the child was necessary, in this case the rate of dysentery per child per year. The reason was the impracticality of randomising children within households to SODIS (test) or control. Standard statistical procedures assume that participants are randomly sampled and that variation between participants represents the 'natural' variability of the study outcome (dysentery in this case), but because households with more than one child were included in the trial the natural disease variability would have been underestimated because of the clustering within such households. The solution was to either calculate a household-based measure of effect size (which is not plausible for dysentery) or to calculate the effect size with an adjustment for the clustering effect. The latter was made possible by methods developed by Huber (1967) and White (1980) for robust variance estimation. Robust variance estimation allows a child-based measure of effect size with adjustment of the calculation to allow for the clustering of children within households. Thus, the unit of randomisation must be the basis for the variance calculation but the effect sizes can be calculated for different units with appropriate statistical correction.

2.9 PHASE 7: FEEDBACK

Feedback to local participating communities has occurred. Selected final project documents have been provided to appropriate community leaders in Kenya and Zimbabwe. Participants were informed of the main outcome of the studies at community meetings in the three countries. The poster produced in South Africa is shown in **Appendix D**. The poster was distributed to the clinics in the study area.

CHAPTER 3: RESULTS - SOUTH AFRICA

3.1 INTRODUCTION

The health impact assessment in South Africa was initiated in 2008. The start and end dates used to distinguish between data in the SODIS Master Country Database collected during the four monitoring visits were as follows:

1. 2008/02/12 to 2008/05/13
2. 2008/05/14 to 2008/09/01
3. 2008/09/02 to 2008/11/04
4. 2008/11/05 to 2008/12/31

The analysis that follows investigated various relationships between source water types, water quality, gender and age in terms of the dysentery and non-dysentery days that were recorded. The relationship between the anthropometric measurements and dysentery was also investigated.

3.2 DATABASE CLEANUP

Notwithstanding many data integrity checks in the design of the handheld computer questionnaires, the master country database and the diarrhoeal diary database, it is inevitable in studies of this nature that invalid, inconsistent and incomplete data still occur. Although the data were checked regularly for invalid, duplicate and unmatched barcodes and where possible corrected some data were lost as a result of incorrect information recorded on the handheld computers.

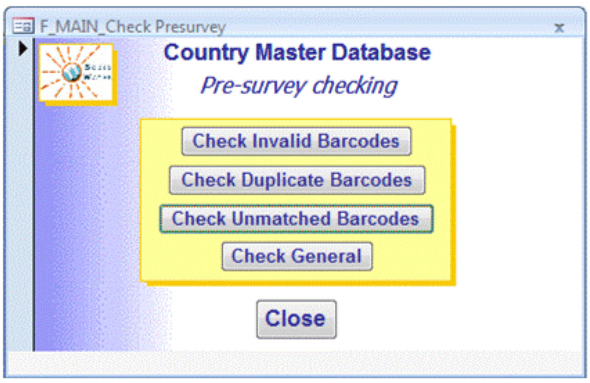


Figure 3.1: Example of one of the many database screens allowing checking of data integrity.

Upon completion of the field work and laboratory work, these were dealt with in the following ways. Under no circumstances were fixes introduced unless the correctness of the fix was certain.

- Invalid barcodes were either corrected or associated records deleted (if an appropriate fix was uncertain).
- In some cases invalid dates (referring to 2004) were detected, inevitably caused by the date on the handheld computer not being correctly set on the day it was used in the field. These were either fixed or left unchanged when this could not have any adverse effect.
- Records in tables in the Access database with duplicate barcodes were fixed as follows: If the records were identical, then one was deleted. If they were not identical, they were usually both deleted since it could generally not be established which one was the correct one. The exception was the diarrhoeal diary data because original diaries could be examined to establish which one was correct. It was important to fix records with duplicate barcodes because these cause inconsistencies during data extraction.
- It was not possible to rectify problems caused by unmatched barcodes. (An unmatched barcode is one that exists in one table and should appear in another table but does not.) Not fixing these problems does not cause inconsistencies during data extraction. They only result in missing data points.
- Minor problems like the question "May a sample be taken?" being answered in the negative when a sample was actually taken were fixed by changing the answer to positive.

3.3 NUMBERS OF DATA TYPES

Table 3.1 shows a summary of the numbers of various data types obtained during the field study and presented for statistical analysis.

Table 3.1: South African field study summary of numbers of data types.

Data type	Number
Children in control group (without SODIS bottle)	386
Children in test group (using SODIS bottle)	438
Male children	402
Female children	421
Total children	824
Households	649
Households using standpipes	323
Households using protected boreholes	231
Households using unprotected boreholes	82
Households using protected springs	10
Households using protected dug wells	1
Households using other water sources	1
Households for which water source not established	1
Children with some diarrhoeal diary data	728
Non-dysentery diarrhoea days	2 692
Non-dysentery diarrhoea episodes	1 043
Dysentery days	1 379
Dysentery episodes	307
Storage water *E. coli* measurements (Monitoring visit 1)	425
(Monitoring visit 2)	394
(Monitoring visit 3)	436
(Monitoring visit 4)	418
SODIS water *E. coli* measurements (Monitoring visit 1)	191
(Monitoring visit 2)	171
(Monitoring visit 3)	191
(Monitoring visit 4)	182
Children with some anthropometry data (Monitoring visit 1)	541
(Monitoring visit 2)	548
(Monitoring visit 3)	513
(Monitoring visit 4)	389

3.4 CHARACTERISTICS OF THE STUDY AREA

This trial was conducted in four peri-urban sub-districts, Soshanguwe, Legonyane, Fafung and Kwarriekraal, in the Tshwane Municipality of the Gauteng Province, South

Africa (**Figure 3.2**). The sites were selected based on their reliance upon better quality water for drinking water than undertaken by previous studies (Conroy et al., 1996; Conroy et al 1999) and practice of storing water in the home. Gauteng has a population of approximately 10.5 million people of whom roughly one million are aged under five (STATSA, 2007). Access to piped water, either in the house or outside the yard is available to 97.7% of the inhabitants (STATSA, 2007a). The majority of the people live in 2 to 5-roomed houses, mostly constructed of brick with corrugated iron roofs.

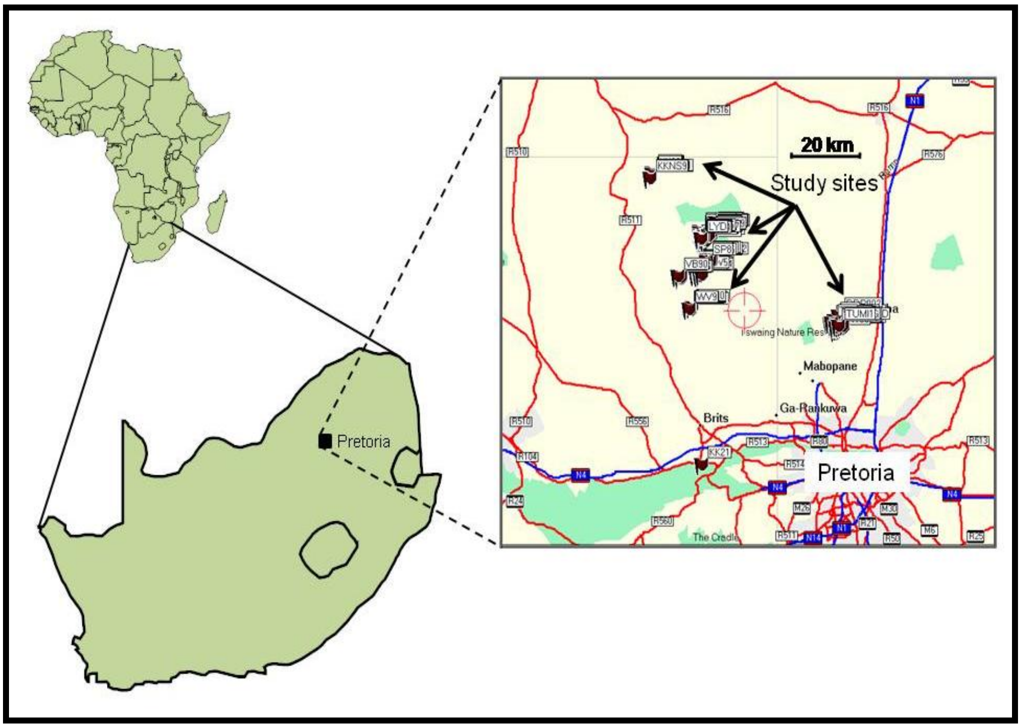


Figure 3.2: The position of the South African study areas in the Gauteng Province, South Africa.

The areas are provided mostly by standpipes situated between a 100 to 500 distance away from the houses. The Soshanguwe area received, amongst other sources, chlorinated standpipe water. Many of the Soshanguwe households also had boreholes in their yards. During interruptions in the water supply, households had recourse to water from their own borehole or, that of their neighbour's. These boreholes are at ground level with the borehole opening fortified with a cement edge. The water table in the Soshanguwe area is very high which caused an increase in turbidity (turbidity was not measured but visually observed) during the summer rainfall period. Contamination from external sources included plastic- and tin scooping buckets, fastened to pieces of string or wire, used for scooping water from the boreholes. The buckets were rinsed with the first scoop of water from the borehole but seldom washed with soap and water. Some study participants were aware of hygiene factors and practiced hand washing, when possible, but seldom understood the connection between hygienic behaviour and health in terms of infectious organisms

Figure 3.3: Typical brick houses with corrugated iron roofs common in the area

The Legonyane, Fafung and Kwarriekraal sub-districts are provided with groundwater pumped to 10 000 litre holding tanks from where it flows to standpipes. This water was not treated but was of good microbial quality. Some residents also had their own boreholes.

In comparison to other African countries the inhabitants of these areas have a relatively high standard of living. The average salary is $200 per month. Most families have their own house and often rent out back rooms to paying customers. There are several large shopping centres in the area and satellite educational institutions for tertiary learning.

Figure 3.4: Typical South African protected borehole with small bucket used as a scoop.

However, the unemployment rate is high 25.8% (STATSA, 2009). Few women have permanent employment. Opportunities for work in the area are limited and women find it particularly difficult to find employment. Women are responsible for doing the chores at home which included drawing water from the standpipes. Some income is generated by managing small shops and day-care centres for pre-schoolers. There are a number of schools that provide some employment and a few larger businesses such as garages (selling petrol etc. and servicing vehicles) and cafes selling food. Many men are taxi drivers. Commuting to and from Pretoria and Johannesburg, the two main cities of Gauteng Province, is common because relatively well-paid jobs are available in these cities. However, the long distances commuted (two to four hours per day), require leaving very early in the morning and arriving back home very late. As a result children are often left to fend for themselves or left with siblings or grandparents.

The diarrhoea incidence in under five year olds was 120 per 1000 children in the Soshanguwe district and 380 per 1000 children in the remaining three sub-districts in 2005/6 (Baron et al., 2006). Gauteng has a high incidence (29.9% in 2008) of HIV and AIDS, undermining the traditional social support system of the extended family (NDoH, 2008). The high number of teenage pregnancies is an important factor contributing to irresponsible parenting. Government grants for these teenagers that are intended as child support are sometimes squandered on alcohol or on needs of the other household members. This lack of social cohesion in the study area may have contributed to poor engagement in the study and hence the degree of compliance to SODIS protocols.

3.5 PARTICIPANTS

Sample size was estimated on the basis of comparison of two Poisson event rates in the presence of significant clustering. Since neither the underlying rates of dysentery nor the strength of clustering effects within households were known in advance, we carried out a series of calculations based on rates of 1 to10 days of dysentery per year and on different degrees of clustering effects. The projected sample of 1000 children was chosen as offering a 90% power to detect a 10% reduction in risk where the underlying rate was 5 episodes per child per year and clustering effects were strong (rho=0.2). The sample provided more than 90% power to detect a 20% reduction in incidence for all rates of 2 episodes per child per year or greater.

Eligible households were chosen based on the criteria given in Section 2.5. Randomisation was achieved as described in Section 2.5.1. Written informed consent was obtained from the household head or child carer after details of the study, and what would be expected from each household during the trial, was explained. This was achieved by giving each household head or carer a printed version of the basic procedures and an opportunity to read it themselves as well as a verbal explanation. Children participating in the study with severe diarrhoea were referred to local clinics or district hospitals where treatment is free. Oral rehydration salts were provided to children with persistent diarrhoea.

3.6 SAMPLING AND SURVEILLANCE

The household selection started in July 2007 and was finalised by the end of August 2007. Four graduate field-coordinators completed a course in research ethics prior to the study. Eight field workers were recruited from the local community where they resided. They were thoroughly trained in SODIS, ethical conduct, procedures of the study and were well aware of the objectives of the study. They visited households every two weeks to assist with problems people experienced, distribute and collect diarrhoeal diaries and to encourage households to do SODIS. Water sample collection and anthropometric measurements were done under the supervision of the field coordinators. The field coordinators also joined the field workers on many occasions and for unannounced visits to the areas to assist the field workers and familiarise themselves with the problems and progress of the field study.

Baseline household information with regard to basic hygiene, sanitation, and water use practices was also collected. To ensure a well established SODIS-related health effect the monitoring visits started three months after completion of the household selection and ended in December 2008. The parents and carers were given verbal and written information on the disease concept and a simple explanation of the solar disinfection process and its effect on the microbial quality of their drinking water. Two 2 litre PET bottles were provided for each child in the test group. During training to do SODIS carers were instructed to fill one bottle each day and place it in unobscured sunlight for a minimum of six hours for use the following day. Consequently children always had access to water disinfected the previous day. Participants were instructed to never keep water in the bottles for longer than 48 hours which minimized exposure to possible bacterial regrowth in the water. Children were advised to drink directly from the bottle, if possible, to minimize recontamination of the solar disinfected water. Children in the control group were not provided with SODIS bottles and instead were instructed to continue drinking water stored in storage containers in the house.

The main survey took place over a 1 year period during which diarrheal incidence was recorded daily for both control and test children using the daily diarrhoea diary that was completed by the carer for each child and collected by field workers on a monthly basis. Field data were captured using hand-held computers and scanable barcodes to link records. The data were downloaded into a database and checked for completeness and consistency before analysis. Water from the storage containers and SODIS bottles were collected every three months in commercially available sterile 100 mℓ sampling bottles containing sodium thiosulphate to neutralise any chlorine residuals in the water. Samples were transported on ice and analysed on the same day in the laboratory using the Colilert-18 Quantitray method (Section 2.6.1).

To have some measure of compliance to the protocol by the SODIS participants they were asked (i) whether they have put out their bottles the day before (using SODIS) and (ii) whether it was possible to collect a water sample from the SODIS bottle that was in use.

3.7 BASELINE DATA

Baseline data for the sub-districts, Soshanguwe, Legonyane, Fafung and Kwarriekraal and aggregate data for the test and control groups are shown in (**Table 3.2** and **Table 3.3**). All households used in-house storage containers of which the majority were wide mouthed (594, 91.5%). The number of participating households dependent on standpipes was 323. Eighty-three households used unprotected boreholes and 232 protected boreholes. The remaining sources consisted of 10 protected springs and one dug well. Toilet access ranged from 72.6% to 93.3% between the four sub-districts. These were often shared with up to 18 people including household members, back yard tenants, and neighbours. The level of hygiene practices relating to hand washing was very high (**Table 3.3**). Hand-washing practices and access to a toilet did not differ between intervention and control groups (χ^2 test, all P=>0.065). There was a significant difference between the test and control groups in terms of access to a flush toilet rather than a pit latrine, with more of those in the intervention group having access to flush toilets (χ^2 test, P=<0.001). There was no difference in the distribution of water sources between the groups (χ^2 test, P=0.345).

Table 3.2: Numbers and percentages of drinking water sources, used in the different sub-districts and the aggregate for the test and control group.

	Soshan-guwe	Legonyane	Fafung	Kwarrie-kraal	Total	Test	Control
Type of water source							
Standpipe	200 57.9%	93 46.3%	19 26.0%	11 36.7%	323 49.8%	177 52.2%	146 47.1%
Borehole unprotected	42 12.2%	22 10.9%	11 15.1%	8 26.7%	83 12.8%	42 12.4%	41 13.2%
Borehole protected	103 30.0%	78 38.8%	40 54.8%	11 36.7%	232 35.7%	113 33.3%	119 38.4%
Spring protected	0 0.0%	7 3.5%	3 4.1%	0 0.0%	10 1.5%	7 2.1%	3 0.2%
Dug well protected	0 0.0%	1 0.5%	0 0.0%	0 0.0%	1 0.2%	0 0.0%	1 0.1%

Table 3.3: Numbers and percentages of baseline data for each sub-district and for the aggregate test and control group.

	Soshan guwe	Legonyane	Fafung	Kwarrie -kraal	Total	Test	Control
Hands washed							
Before preparing food	343 99.0%	196 97,5%	72 98.6%	30 100%	640 98.6%	333 98,2%	307 99.0%
Before eating	341 98.8%	195 97.0%	73 100%	30 100%	639 98.5%	333 98.2%	306 98.7%
After toilet	343 99.4%	196 97.5%	73 100.0%	30 100.0%	642 98.9%	335 98.8%	307 99.0%
After changing nappy	341 98.8%	191 95.0%	72 98.6%	30 100.0%	634 97.7%	332 97.9%	302 97.4%
Sanitation							
Toilet access	283 82.0%	146 72.6%	63 86.38%	28 93.3%	520 80.1%	267 78.8%	253 81.6%
Use the bush	38 11.0%	5 2.5%	11 15.1%	0 0.0%	54 8.4%	28 8.3%	26 8.4%
Toilet type							
Pit latrine	277 80.5%	194 96.5%	71 97.3%	30 100.0%	572 88.3%	274 80.8%	298 96.4%
Flush	65 18.9%	2 1.0%	0 0.0%	0 0.0%	67 10.4%	62 18.3%	5 1.6%
VIP**	1 0.3%	1 0.05%	0 0.0%	0 0.0%	2 0.3%	1 0.3%	1 0.3%
Other	1 0.3%	4 2.0%	2 2.7%	0 0.0%	7 1.1%	2 0.6%	5 1.6%

*Ventilated improved pit latrine

3.8 ASSESSMENT OF HEALTH OUTCOMES

The following sections contain an assessment of the health outcomes based on the data recorded during the study. Data summaries are presented as well as preliminary and sub-group statistical analyses.

3.8.1 Analysis Approach

The South African data were analysed in respect of two concepts of compliance or adherence to the SODIS protocol. The first concept is referred to as **motivation**.

Motivation was based on the percentage completion of diarrhoeal diaries as a proxy. The second concept, referred to as **compliance** in the text, was based on the answer to the question “Did you put out your bottle yesterday?”

Summary diarrhoea data recorded for the test and control groups are shown in Section 3.8.2.

Preliminary statistical analyses are presented in Section 3.8.3.

Sub-group analyses based on dysentery days and the degree of **motivation and compliance** are presented in Section 3.8.4.

In the remaining sections water quality and anthropometry data are analysed and discussed.

3.8.2 Data summary

The South African trial had 824 children and 649 households enrolled at the start of the first of four monitoring visits. The number of children using SODIS (test group) was 438 and those drinking the normal storage water (control group) in their homes were 386.

An overall summary of the records for the different diarrhoeal endpoints measured during the trial are shown in **Table 3.4**. Generally a greater number of dysentery- and non-dysentery days and episodes were recorded for the control households than the test households.

Table 3.4: Dysentery- and non-dysentery days and episodes recorded for the duration of the study in South Africa

	Dysentery days	Non-dysentery days	Dysentery episodes	Non-dysentery episodes
Total data points	1379	2692	307	1043
Intervention	512	1281	150	498
Control	853	1411	157	545

The number of children that suffered from dysentery and non dysentery diarrhoea is summarised in (**Table 3.5**). The data indicated that a greater number of individuals suffered from diarrhoea in the control group, as one would have expected, with the exception of dysentery days.

Table 3.5: Numbers of actual children that suffered from dysentery or non-dysentery diarrhoea in South Africa

	Dysentery days	Non-dysentery days	Dysentery episodes	Non-dysentery episodes
Test (383 Children)	92	134	11	18
Control (344 children)	64	159	63	138

(**Table 3.6 and 3.7**) summarise dysentery- and non dysentery days and episodes associated with the different water sources and the respective number of users per source for the test and control groups, respectively.

Table 3.6: Dysentery and non-dysentery days and episodes associated with each water source type for the test group

Source & no. of users	Borehole unprotected (47)	Borehole protected (120)	Standpipe (207)	Spring protected (8)
Dysentery days				
Number	81	310	121	0
Mean	1.7	2.6	0.6	0.0
Non- dysentery days				
Number	233	638	406	4
Mean	5.0	0.6	0.3	0.5
Dysentery episodes				
Number	23	73	54	0.0
Mean	0.5	0.6	0.3	0.0
Non-dysentery episodes				
Number	58	239	197	4
Mean	1.2	2.0	1.0	0.5

Table 3.7: Dysentery and non-dysentery days and episodes associated with each water source type for the control group

Source & no. of users	Borehole unprotected (41)	Borehole protected (128)	Standpipe (163)	Spring protected (2)	Dug well Protected (1)
Dysentery days					
Number	117	537	182	17	0
Mean	2.9	4.2	1.1	8.5	0.0
Non-dysentery days					
Number	97	699	577	13	25
Mean	2.4	5.5	3.5	6.5	25.0
Dysentery episodes					
Number	14	105	37	1	0
Mean	0.3	0.8	0.2	0.5	0.0
Non-dysentery episodes					
Number	55	261	216	5	8
Mean	1.2	2.0	1.3	2.5	8.0

3.8.3 Preliminary statistical analysis

The South African data for dysentery- non-dysentery days and episodes were analysed using various statistical models with and without taking account of clustering in households. The following models were used:

1) Poisson regression without adjusting for clustering of children in households.
2) Poisson regression where only one child from each household is included in the analysis.
3) Poisson regression when adjusting for clustering of children in households.
4) Negative binomial without adjusting for clustering of children in households.
5) Negative binomial when only one child from each household is included in the analysis.
6) Negative binomial when adjusting for clustering of children in households.

The results obtained are presented in (**Table 3.8**). Incident rate ratios using Poisson regression, first unadjusted for clustering and secondly adjusted by including a randomly chosen child from each household and thirdly adjusted for all the children in each household showed that children in the test group had approximately twice the risk of having any one of the four diarrhoea outcomes. This was statistically significant for the unadjusted and adjusted analysis that included one child per household. However, adjusting for all the children, the incident rate ratios were not statistically significant with the exception of dysentery days.

The analyses assumed that the incidence of dysentery follows a Poisson distribution, however, a goodness-of-fit chi square analysis confirmed that the data did not conform to a Poisson distribution. The negative binomial distribution can be used as an alternative to the Poisson distribution. It is especially useful for discrete data over an unbounded positive range whose sample variance exceeds the sample mean. In such cases, the observations are overdispersed with respect to a Poisson distribution, for which the mean is equal to the variance.

Using negative binomial regression (**Table 3.8**) the analyses showed that incident rate ratios for the unadjusted data, data adjusted by including one child from each household and finally adjusted for all the children were not statistically significant. Based on this analysis one concludes that SODIS did not reduce dysentery and non-dysentery diarrhoea. It was not clear whether or not the failure of SODIS to significantly reduce diarrhoea in the children could be attributed to low motivation to adhere to the protocol or incorrect use of SODIS which would be reflected, to some degree, in the quality of the water (*E. coli* levels). Further analyses based on subgroups and their level of motivation to do SODIS, and *E. coli* levels in the drinking water were therefore undertaken.

Table 3.8: Incident rate ratios for dysentery- and non-dysentery days and episodes obtained using various statistical analyses methods for the intervention and control groups

Parameter *	Analysis	IRR	P value	95% CI
Dys days	Poisson Unadjusted	1.98	<0.001	(1.78 ; 2.21)
Non-dys days		1.31	<0.001	(1.22 , 1.42)
Dys epis		1.24	0.059	(0.99 ; 1.55)
Non-dys epis		1.30	<0.001	(1.15 ; 1.47)
Dys days	Poisson adjusted for one child in a households	2.12	<0.001	(1.87 ; 2.40)
Non-dys days		1.28	<0.001	(1.17 ; 1.39)
Dys epis		1.39	0.015	(1.06 ; 1.80)
Non-dys epis		1.26	0.001	(1.09 ; 1.44)
Dys days	Poisson adjusted	1.98	0.016	(1.14 ; 3.47)
Non-dys days		1.31	0.194	(0.87 ; 1.98)
Dys epis		1.24	0.395	(0.75 ; 2.05)
Non-dys epis		1.30	0.111	(0.94 ; 1.80)
Dys days	Negative binomial unadjusted	1.36	0.317	(0.74 ; 2.50)
Non-dys days		1.19	0.333	(0.84 ; 1.70)
Dys epis		1.15	0.509	(0.75 ; 1.77)
Non-dys epis		1.31	0.054	(0.99 ; 1.74)
Dys days	Negative binomial adjusted for one child in a household	1.37	0.374	(0.68 ; 2.77)
Non-dys days		1.20	0.382	(0.80 ; 1.80)
Dys epis		1.24	0.379	(0.77 ; 2.02)
Non-dys epis		1.27	0.144	(0.92 ; 1.75)
Dys days	Negative binomial adjusted	1.36	0.382	(0.68 ; 2.73)
Non-dys days		1.19	0.446	(0.76 ; 1.87)
Dys epis		1.15	0.573	(0.69 ; 1.91)
Non-dys epis		1.32	0.076	(0.10 ; 1.79)

*Dys days = Dysentery days; Non-dys days = non-dysentery days; dys epis = dysentery episodes; non-dys epis = non-dysentery episodes.

3.8.4 Sub-group analyses-Dysentery

The initial analysis confirmed that incidence rates of dysentery were over-dispersed, making a Poisson regression inappropriate. Generalised negative binomial regression was used to calculate the effect of SODIS as incidence rate ratios (IRR). This also allows for variation in disease rates between individuals who have the same risk factor (some households had more than one child participating in the study) and allows this variation to be modelled as a function of predictor variables (such as age, diarrhoea, water source type, compliance, etc.).

3.8.4.1 SODIS and incidence of dysentery

A total of 121 children were lost to follow-up during the study. Reasons given for loss to follow-up included the following: (i) seven children died; no cause of death for any was available; (ii) nine children were in households that moved out of the study area; and (iii) caregivers of the remaining 105 children lost interest and chose not to continue participation.

Data were available on 383 children controls in 297 households. The median number of days for which diarrheal data had been recorded was 182 (25^{th} percentile 122, 75^{th} percentile 274). Control and intervention groups did not differ in the average quantity of data (P=0.415, least-squares regression, adjusted for clustering within households). The annual incidence of dysentery in the control group was 4.9 days (95% CI 4.6 to 5.3) and 2.5 days (95% CI 2.3 to 2.7) in the intervention group.

Stata's robust variance estimation routines for clustered data, implemented in the statistical survey procedures were applied for the sub-group analyses. It was used to adjust for the effects of the multistage sample design. Data were stratified on sub-district (four levels) with the primary sample unit identified as village (19 units) and the second-stage sample unit of household. Extra-Poisson variation in incidence of dysentery was significantly associated with the proportion of 360 days of completed diarrhoea diaries and was also significantly greater in one of the four districts, Kwarriekraal. Incidence rate ratios were lower in households drinking water from a standpipe than from any other source (IRR 0.38, 95% CI 0.12 to 1.2, P=0.091) and lower in those drinking solar disinfected water (IRR 0.64, 95% CI 0.39 to 1.0, P=0.071), though both effects were of borderline statistical significance.

3.8.4.2 Relationship between motivation and dysentery

The level of motivation of households to do SODIS was measured by calculating the proportion of 360 days on which diarrhoea diaries had been recorded. This measure allowed calculation of motivation for both intervention and control households. In addition it could be determined whether associations between motivation and the effect of SODIS in the intervention households were attributable to socio-demographic correlates of motivation by testing for a similar relationship between motivation and disease rates in the control households. Motivation was initially examined by dividing participants into those who completed diarrheal diaries for less than 25%, 25% to 50%, 50% to 75%, and 75% to100% of the trial days. However, analysis revealed no differences between the first three groups in the effect of SODIS. Accordingly, motivation was classified as low (less than 75% of diarrhoeal diary information completed) and high (75% or more complete). A summary of the dysentery incidence rates as a function of the motivation categories are given in **Table 3.9.**

Table 3.9: South African dysentery incidence rates (based on 360 days) as a function of motivation.

Characteristic	Motivation level			
	< 25%	**25%–50%**	**50%–75%**	**75%-100%**
	Control group			
No. of children	61	72	113	83
No. of households	46	58	96	62
Dysentery incidence rate	11.7	1.8	2.7	7.4
Mean no. of days with diarrhoeal data	47.2	133.2	203.2	313.6
	Test group			
No. of children	61	70	152	96
No. of households	51	53	125	64
Dysentery incidence rate	8.8	4.2	2.0	2.4
Mean no. of days with diarrhoeal data	55.1	128.7	209.4	310.7

Overall, 25.3% of participants kept diarrheal diaries for 75% or more of the days of the trial, with no difference between controls and intervention groups (each 25.3%). A further 37.4% kept diaries for 50% to 75% of the days, 20.1% for 25% to 50% of the days, and 17.2% for fewer than 25% of the days. Overall, those who had the poorest level of data recording had the highest annual incidences of dysentery with rates of 12.9 days per year in those not on standpipe water sources and 4.8 in those on standpipe sources. Those in the intermediate categories, 25% to 50% and 50% to 75%, had significantly lower incidence rate ratios: 0.32 (P=0.038) and 0.35 (P=0.042), respectively. Those recording 75% or more days had an incidence rate ratio of 0.47 (P=0.132) compared with the lowest group. Adjusted for these effects, those in the SODIS group with the highest level of motivation (75% or more of data recorded) had a significantly lower incidence of dysentery (incidence rate ratio 0.36, 95% CI 0.16 to 0.81, P=0.014). Examination of the other motivation categories revealed no significant effect of SODIS at lower levels of motivation

Compared with control, participants showing motivation to complete 75% of the diarrhoeal diaries achieved a reduction of 64% in dysentery which was statistically significant. However, there was no significant reduction in risk at lower levels of compliance.

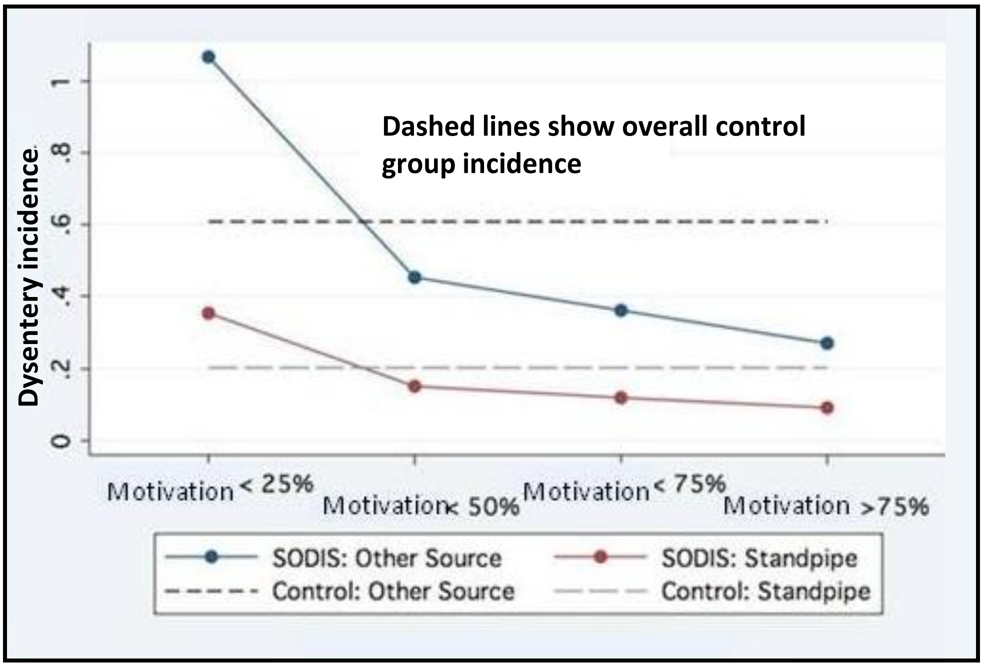


Figure 3.5: South African adjusted 30-day dysentery rates for control and tests households in relation to different categories of motivation

Figure 3.5 shows the 30-day incidence of dysentery in relation to motivation. The health benefit provided to those children drinking standpipe water is clearly illustrated by the lower incidence of dysentery in those on SODIS who used standpipe water as source compared to those on SODIS who used any of the other water sources. In respect of the levels of motivation an indication of how a progressively increased level of motivation resulted in a progressively decreasing incidence of dysentery.

3.8.4.3 Non-dysentery diarrhoea

The variation in risk of non-dysentery diarrhoea was investigated. Solar disinfection was not significantly associated with risk overall (P=0.419) nor was having water taken water from a standpipe (P=0.109). There was no significant effect of motivation on risk (P=0.150), nor was there evidence that those with 75% or more motivation for data recording had a reduced risk compared with controls (P=0.415).

3.8.4.4 Correlates of motivation

Examining additional factors associated with motivation showed that, among the controls, there was no relationship between the level of motivation and storage water quality. In the SODIS group, interval regression showed 0.8 log_{10} units higher levels of *E. coli* in storage water of the high-motivation group compared with the mean counts of those with less than 75% compliance with data recording (P=<0.001). Likewise, there was no relationship between access to a flush toilet and high motivation in the control group (P=0.639), but in the SODIS group, the highly motivated were less likely to have access to a flush toilet (odds ratio 0.1, P=0.002). Finally, we examined the difference between storage water quality and water quality measured in the SODIS bottles. We classified effective solar disinfection as a reduction of 1 log_{10} unit in bacterial concentration or better. In the 200 follow-up, water quality analyses in which bacteria were detected in the storage water the quality of water in the SODIS bottle was improved in 20% of low motivation households and 34% of high motivation households. Overall, the highly motivated were more likely to achieve this than the other households in the SODIS group (odds ratio 2.2, P=0.034 adjusted for clustering by household).

3.8.4.5 Relationship between compliance and dysentery

Figure 3.6 represents the number of dysentery and non-dysentery days in relation to compliance measured by asking the question "Did you put your bottle out yesterday? Overall compliance was defined as the percentage of monitoring visits in which they said they had or had not put their bottle out yesterday.

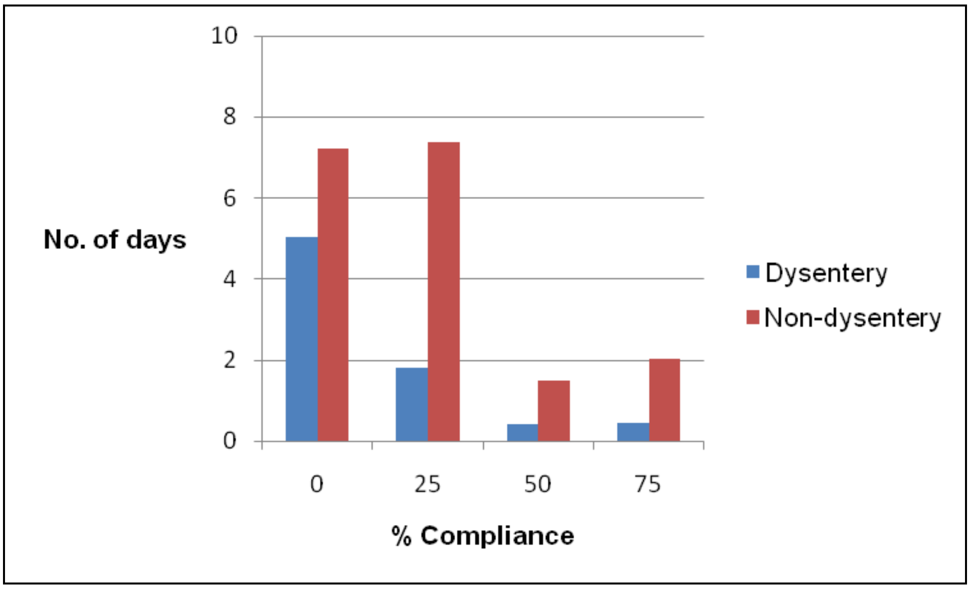


Figure 3.6: Number of days of dysentery and non-dysentery in relation to compliance

The question pertaining to compliance: "Did you put your bottle out yesterday?" were posed to the participants only four times. It should be noted that only those data points where four responses, whether it was ”Yes” or “No,” were included in the graph. A hundred percent compliance was assumed when participants answered “Yes” four times, 75% when they answered “Yes” three times, 50% when they answered “Yes” two times and 25% percent when they answered “Yes” twice. Zero (0%) compliance was recorded when participants answered “No” four times. Based on this selection process, only 178 children had compliance data for all four visits. No child had 100% compliance. The level of diarrhoea was plotted as the average number of dysentery days or non-dysentery days per child. The number of children was 26, 38, 66 and 48 for compliance levels 0, 25, 50 and 75%, respectively.

It appears that the higher the compliance (50 and 75%) the lower dysentery and non-dysentery diarrhoea days were recorded and *vice versa*. Caution is necessary when interpreting the findings as very few data points were available for analysis.

3.8.5 Water quality

3.8.5.1 Compliance to WHO standards

Overall 62.4% of the samples from the study households met World Health Organization guidelines for zero thermotolerant coliforms per 100 mℓ and a further 21.8% had levels under 10 per 100 mℓ. Interval regression using $\log_{10}$-transformed values revealed no significant difference in geometric mean values between the test and control groups (P=0.176).

3.8.5.2 E. coli levels in relation to the trial period

This section uses observed *E. coli* levels recorded for both the SODIS bottles and storage containers of households in the test group to investigate changes in the levels of the bacteria in relation to the duration of the follow-up. One would expect a progressive decrease in levels in the SODIS water as the trial progressed when participants practiced SODIS correctly and consistently.

The Colilert® method (Section 2.6.1.1) used to analyse the water samples has some shortcomings that result in consequences for interpretation of the data and the representation thereof: The maximum count that can be obtained using the 51-well Quanti-Tray is >200.5/100 mℓ and the minimum is <1/100 mℓ. The recorded numbers cannot be used in an analysis or representation without making certain assumptions about what the real counts may have been. In **Figure 3.7** for example, zero was assumed each time <1/100 mℓ was recorded and 200.5 each time the maximum count of >200.5/100 mℓ was recorded. To illustrate the effect of this assumption or any other, an arbitrary number (1000 instead of 200.5/100 mℓ) was also included in **Figure 3.7**.

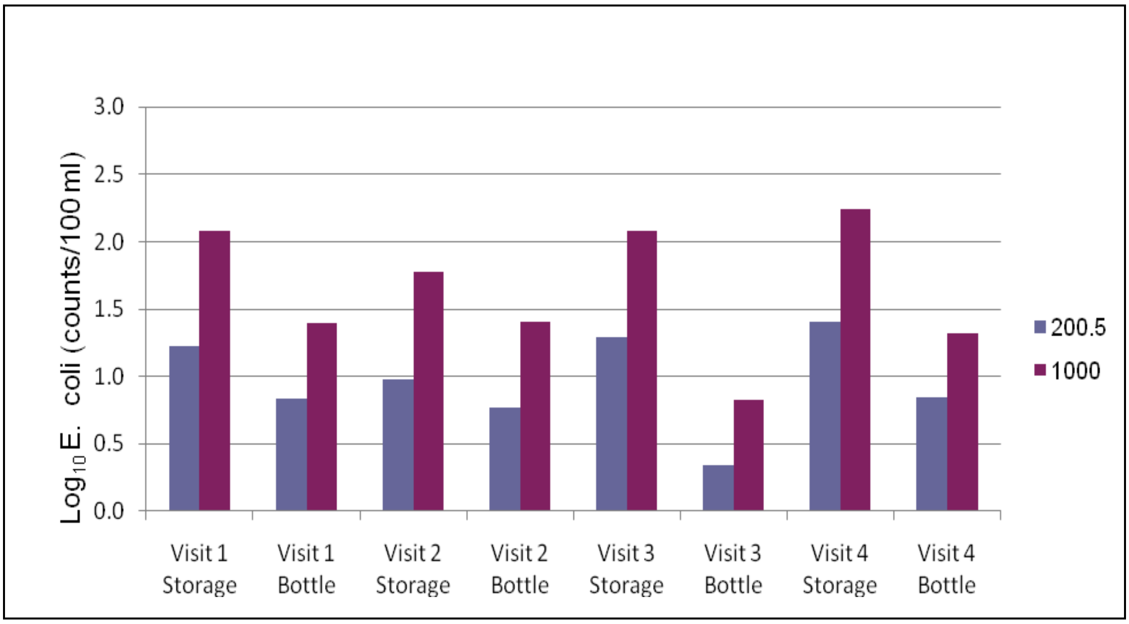


Figure 3.7: *E. coli* levels obtained for storage and bottled water is displayed for each monitoring visit using 200.5 and 1000 as maximum counts

To represent the change in the observed *E. coli* levels over the four monitoring visits the observed counts recorded for the storage water and the SODIS bottles, assuming <1 as zero and >200.5 as 200.5 as maximum are shown in **Figure 3.8**. Log $_{10}$ counts for each monitoring visit showed that the bottle water levels of *E. coli* gradually decreased during the first three visits but increased to approximately the same levels recorded for monitoring visit one during the last visit. The *E. coli* levels in the storage water also showed a decrease for the first two visits but began to increase from visit three to four to even higher levels than at the beginning of the trial.

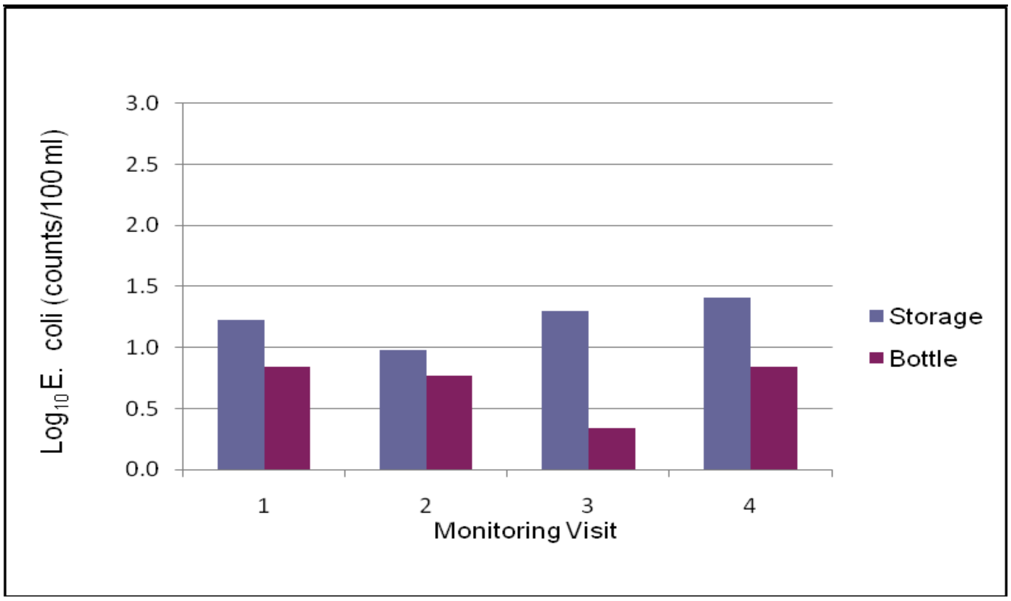


Figure 3.8: Log $_{10}$ *E. coli* counts for storage and SODIS water per monitoring visit assuming zero and 200.5 as minimum and maximum counts.

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Levels in the storage water was generally higher than those observed for the SODIS bottle water.

3.8.5.3 Water quality and compliance

In this section 'compliance' refers to the response of the participants to the question "Did you put out your bottle yesterday?"

E. coli data were transformed to a log scale and analysed using interval regression. This allows values of zero to be analysed as representing <1 cell forming unit (CFU) and values above the upper threshold of the system (>200.5) to be analysed as representing a value greater than the threshold. The advantage of this method is that it allows the presence of values which are interval-censored (not known precisely, but known to lie in a defined interval). In these cases, the intervals are defined by the minimum and maximum detectable concentrations.

The relationship between *E. coli* concentrations and duration of follow-up was modelled using fractional polynomial regression. This allows the calculation of the least complex curve to fit the observed data by permitting a statistical test of the model improvement brought about by the addition of an additional polynomial term.

(**Figure 3.9**) is shows *E. coli* levels in stored drinking water for test control households over a period of 40 weeks (for which data were available). The values are predicted for a fractional polynomial interval regression, and are displayed as points rather than lines to illustrate the gaps between monitoring visits. The reason for the latter was an unforeseen delay between monitoring visits.

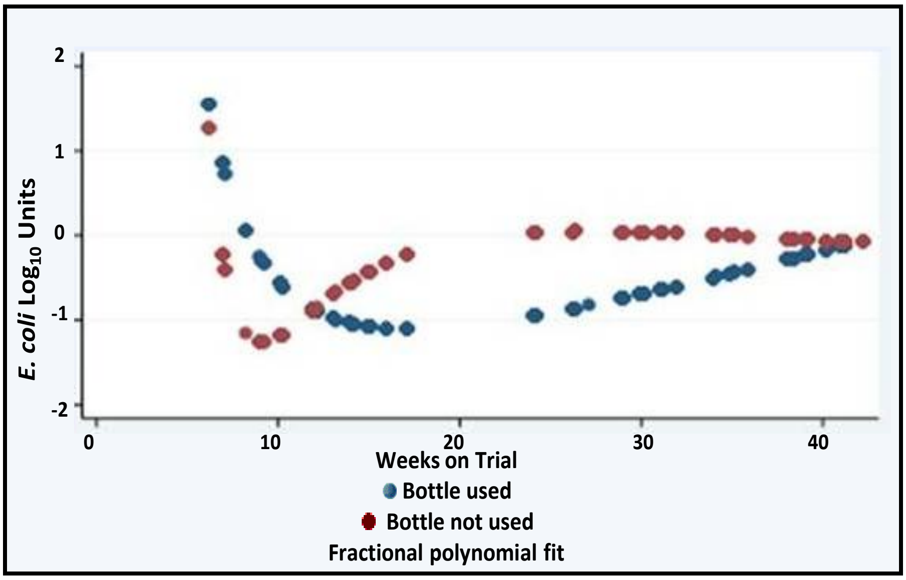

Figure 3.9: The graph shows *E. coli* concentrations in stored drinking water in cases and controls

Initially, contamination levels in the storage water of both the test and control groups declined. However, by week 10, levels of contamination in the control group had begun to rise. This rise was also seen in the test (SODIS) group, but it occurred gradually. Nevertheless, by the 40^{th} week of the trial there was essentially no difference between the *E. coli* levels of the two groups.

At the first follow-up visit (median time since start of study: 10 weeks), *E. coli* levels were not significantly different between test and control (P=0.366). However, at second monitoring visit (median time since start of study: 17 weeks), *E. coli* levels in stored water in test households was on average 0.35 $\log_{10}$ units lower than in controls (P=0.040). At the third monitoring visit (median time since start of study: 34 weeks) the mean difference was similar (0.39 log units, P<0.001). However, at the fourth visit (median time since start of study: 41 weeks), there was no significant difference (P=0.982).

Carers' response to the question "Did you put your bottles out yesterday" and the associated degree of contamination with *E. coli* for those who did (compliers) and those that did not (non-compliers) are represented in **Figure 3.10**. A similar time trend already evident in the **Figure 3.9** was observed. Levels of *E. coli* decreased sharply in the first half of the study, but rose in the second. Over the whole study period, the average difference between compliers and non-compliers was 0.5 $\log_{10}$ units

(P=0.026), adjusted for weeks since the start of study. As can be seen, however, this adjustment can only be partial, since there are no data on compliers after week 36.

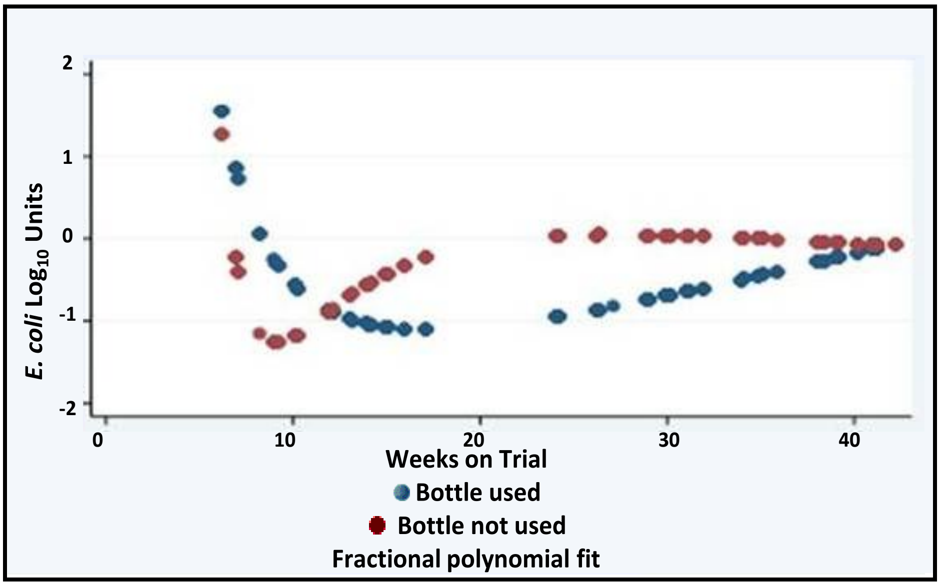

Figure 3.10: The average difference in *E. coli* levels in SODIS bottles between compliers (bottle used) and non-compliers (bottle not used) to the SODIS protocol in South Africa.

The compliance levels on an ongoing basis in the test group were also examined. It was assessed on the basis of the answer to the question "Did you put out a SODIS bottle yesterday?"

Figure 3.11 shows the relationship between compliance and duration of study. In order to show the density of the field work visits, which were unequally spaced through the follow up period, these have been graphed above and below the line (which shows the logistic fit), separated into those who did (top) and did not (bottom) report that they had put out a SODIS bottle. Each data point has been jittered (a small amount of random noise added to the value) so that points will not overplot. As can be seen, reported compliance is initially high, but has dropped sharply by the beginning of the second round of field work visits after week 20. However, by week 40, reported compliance was less than 30%. This decrease compliance could indicate a general decrease in acceptance of the SODIS protocol as the year-long field study progressed.

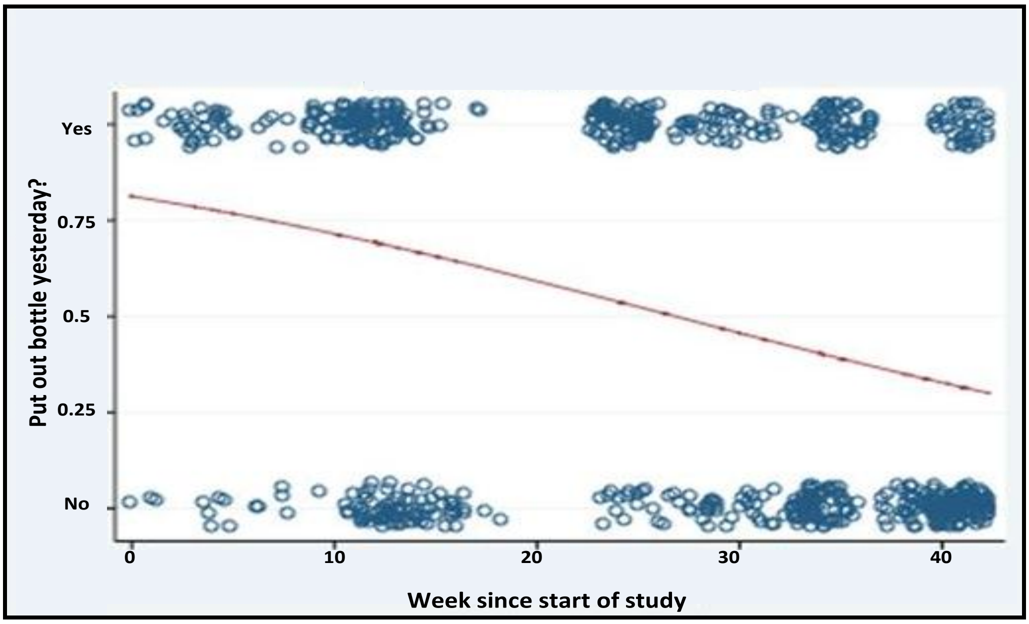

Figure 3.11: The relationship between compliance and duration of the South African study: The points show individual households, and the line shows the logistic fit.

3.8.5.4 E. coli levels

A large proportion of the households in the Soshanguwe area had access to chlorinated water from standpipes. In contrast the remainder of the sub-districts, Legonyane, Fafung and Kwarriekraal had access to untreated borehole water from standpipes. To determine the possible difference in water quality between the Soshanguwe area and the other areas a comparison of the overall geometric mean of the microbial water quality measured for the test and control households in the respective areas are shown in **Table 3.10**. The difference between the geometric means calculated for the *E. coli* counts were not significant. (P=0.838).

Table 3.10: Comparison of the geometric mean *E. coli* count for the overall test and control groups.

	Geometric mean	N	95% CI
Control	2.63	258	(2.29 ; 3.01)
Test	2.58	288	(2.24 ; 95)
			P=0.838

There was no statistical significant difference between the geometric means for *E. coli* counts of the control and test group in Soshanguwe. There also was no statistical significant difference between the geometric means for *E. coli* counts for the control group and test group for the combined results of Legonyane, Fafung and Kwarriekraal, P values were 0.480 and 0.476 respectively (**Table 3.11**). However, a comparison between the control group results of Soshanguwe and the combined results of the control groups of Legonyane, Fafung and Kwarriekraal were statistical significantly different (P=0.003). Comparing the results obtained for the test group for Soshanguwe and the test groups combined for Legonyane Fafung and Kwarriekraal showed a statistically significant difference (P=0.035)(**Table 3.11**).

Table 3.11: Differences in *E. coli* geometric means obtained for control and test groups for Soshanguwe and Legonyane, Fafung and Kwarriekraal combined

Area	**Control**			**Test**			
	GM*	**N**	**95% CI**	**GM***	**N**	**95% CI**	**P-Value**
Soshanguwe	2.07	132	(1.72 ; 2.50)	2.28	167	(1.89 ; 2.74)	0.480
Legonyane. Fafung. Kwarriekraal	3.37	126	(2.79 ; 4.08)	3.05	121	(2.50 ; 3.73)	0.476
Difference	-1.30 P=0.003			-0.77 P=0.035			

* Geometric mean

E. coli numbers in storage water and SODIS bottle water were enumerated every three months during this one year study in each of the sub-districts, Soshanguwe, Legonyane, Fafung and Kwarriekraal. A comparison of the geometric means obtained for each sub-district for each of the monitoring visits for both the test and control groups are shown in **Table 3.12**. The differences in geometric means for the respective visits and sub-districts were not significant with the exception of two observations made for Legonyane and Kwarriekraal during visit two. The confidence intervals for Kwarriekraal however are unacceptably large (**Table 3.12**).

Table 3.12: *E .coli* geometric means for storage and SODIS water for Soshanguwe, Legonyane, Fafung and Kwarriekraal observed at each monitoring visit.

Sub-district	Visit	GM*	N	CI, 95%	GM*	N	CI, 95%	P
		Control			Tests			
Soshanguwe	1	2.82	21	(1.07 ; 1.55)	1.69	148	(1.36 ; 2.10)	0.061
	2	2.11	28	(1.13 ; 1.50)	1.10	109	(1.04 ; 1.17)	0.035
	3	2.32	25	(2.49 ; 4.63)	3.08	141	(2.26 ; 4.18)	0.653
	4	1.50	26	(2.57 ; 5.55)	3.23	132	(2.35 ; 4.43)	0.534
Legonyane	1	4.31	60	(2.77 ; 6.69)	5.02	48	(2.89 ; 8.70)	0.665
	2	5.57	62	(3.53 ; 8.81)	3.06	56	(1.94 ; 4.82)	0.065
	3	4.08	73	(2.67 ; 6.24)	2.68	51	(1.74 ; 4.11)	0.164
	4	3.86	64	(2.43 ; 6.15)	3.83	51	(2.31 ; 6.35)	0.978
Fafung	1	2.82	21	(1.30 ; 6.11)	2.32	23	(1.23 ; 4.39)	0.692
	2	2.11	28	(1.18-3.78)	2.07	37	(1.29 ; 3.30)	0.953
	3	2.32	25	(1.28 ; 4.18)	1.89	30	(1.14 ; 3.14)	0.597
	4	1.50	26	(0.96 ; 2.34)	1.95	32	(1.12 ; 3.38)	0.455
Kwarriekraal	1	3.99	9	(1.23-12.96)	5.05	8	(0.92 ; 27.88)	0.793
	2	1.71	9	(0.75-3.86)	6.58	12	(1.94 ; 22.34)	0.056
	3	1.24	10	(0.76-2.03)	2.53	11	(0.83 ; 7.74)	0.215
	4	5.03	7	(0.67-37.81)	15.99	12	(4.63 ; 55.19)	0.270

*=Geometric mean

3.9 ANTHROPOMETRY

3.9.1 Data summary

Table 3.13 and **Table 3.14** show the observed mean height and weight of female and male children for each of the monitoring visits for the test and control groups, respectively.

Table 3.13: Height and weight for each monitoring visit for males and females of the test group

Test group							
Visit	1	1	2	2	3	3	4
Height/weight	Height	Weight	Height	Weight	Height	Weight	Height
Sex:	Male						
Mean:	91.6	13.5	92.7	14.2	94.0	14.4	95.2
Std Dev:	10.4	3.0	10.2	2.9	10.1	3.2	9.9
N:	140	140	136	136	128	128	90
Sex:	Female						
Mean:	91.0	13.3	92.9	14.0	94.6	14.3	95.6
Std Dev:	12.0	3.2	10.7	3.2	10.9	3.4	11.2
N:	149	149	161	161	142	142	114

Table 3.14: Height and weight for each monitoring visit for males and females of the control group

Control group							
Visit:	1	1	2	2	3	3	4
Height/weight	Height	Weight	Height	Weight	Height	Weight	Height
Sex:	Male						
Mean:	89.1	13.0	91.0	13.7	91.2	13.5	92.8
Std Dev:	11.7	4.0	10.9	3.1	10.9	3.2	11.0
N:	124	124	117	117	115	115	80
Sex:	Female						
Mean:	90.2	13.1	91.4	13.8	92.2	13.8	94.0
Std Dev:	11.7	3.1	11.0	3.2	10.9	3.1	10.6
N:	128	128	133	133	127	127	105

3.9.2 Preliminary analyses

Overall change in the observed length and weight of the children drinking SODIS water were compared with those children drinking storage water. The difference between the mean height of the control and test children and the difference between the mean weight of the test and control children was not significant (**Table 3.15**).

Table 3.15: Overall mean change in weight and height of test and control children

SODIS		Mean	P-Value.
Yes	Height change, cm	4.08	0.579
No		3.75	
Yes	Weight change, kg	1.0	0.355
No		1.09	

3.9.3 Sub-group analyses

Anthropometric measurements are traditionally standardised against internationally accepted cut-off points of nutritional status. Nutritional indicators are usually calculated using the Z score (Section 2.6.1.2). In view of the lack of suitable growth norms for African children, the data generated during this trial were used to construct norms for height-for-age, weight-for-age and height-for-weight. This was done by fitting a fractional polynomial curve to the data, adjusting the number of polynomial terms until no improvement in fit could be obtained by adding a further term. The fractional polynomial procedure was used to fit a curve corresponding to the tenth centile of each index (height-for-age, weight-for-age and height-for-weight). The tenth centile was chosen because the effects of SODIS were expected to be more pronounced for the extreme of the distribution, the smaller and shorter children. The endpoints were defined as falling below the 10th centile for each index – height-for-age, weight-for-age and height-for-weight. The odds ratio associated with use of SODIS in relation to each endpoint, height-for-age, weight-for-age and height-for-weight, were calculated. The odds ratios associated with the use of SODIS are shown in **Table 3.16**.

There was significant variation in the prevalence of underweight children between monitoring visits, probably due to selective participant attrition. Adjusting for this, there was no material change in the odds ratios associated with solar disinfection. There was also no significant relationship between water source characteristics and anthropometry indices.

Table 3.16: South African odds ratios and adjusted odds ratios for weight-for-age, height-for-age and weight-for-height of children.

Endpoint	Odds Ratio	Adjusted odds ratio*
Weight-for-age	1.1 (0.71 ; 1.8)	1.1 (0.71 ; 1.8)
Height-for-age	0.96 (0.62 ; 1.5)	0.95 (0.60 ; 1.5)
Weight-for-height	0.97 (0.65 ; 1.4)	0.97 (0.66 ; 1.4)

*Adjusted for visit number

The effect of solar disinfection on the three anthropometry indices adding the level of motivation to fill in diarrhoeal diaries was examined. There was no significant variation in the indices between the motivation categories (<25%, 25% to 50%, 50% to 75% and 75% to 100%). The effect of SODIS at each monitoring visit was examined separately. Again, there was no significant effect observable at any of the four follow-up visits.

3.10 HEALTH RISK FACTORS

In order to put the above results relating to health indicators in perspective, the risk of dysentery diarrhoea associated with various risk factors was examined.

3.10.1 Water source

There were 287 households of the 564 whose water came from standpipes (51%). These accounted for 370 of the 718 children in the study group (52%).

There was a substantially lower risk of dysentery in those children drinking standpipe water, with an incidence rate ratio of 0.36 (P=0.049). There was no evidence that any other water source type was associated significantly with risk of dysentery.

There was also no evidence of an interaction effect between water source type and the effect of SODIS (t = –0.12, P=0.908).

3.10.2 Water drawing method

Water storage containers used in the households consisted of narrow mouthed 25 L and wide-mouth 50 to 100 litre containers. Usually water is poured into cups from narrow mouthed containers and scooped from wide-mouthed containers. Only 48 households (8.5%) poured water from their containers while the remainder used a scoop to draw water.

The risk of dysentery was substantially increased by the use of a scoop, with an incidence rate ratio of 39.3, $P<0.001$. There were too few households to examine the possible interaction with the effect of SODIS with any degree of confidence.

3.10.3 Hand washing

There were high levels of reported hygiene: 556 householders reported washing their hands before preparing food (98.6%), 554 (98.2%) before eating, 557 (98.8%) after using the toilet and 553 (98.0%) after changing a nappy. There was insufficient variation in hand washing behaviour to analyse the effect on dysentery.

3.10.4 Toilet facilities

The majority of the households have access to a pit toilet in their yard. There were 447 households (79%) with access to a toilet, of which 62 households (11%) had access to flush toilets. There was no evidence that access to a toilet reduced dysentery risk (incidence rate ratio 1.1, $P=0.716$). However, compared with those without access to a toilet, those with access to a flush toilet had a significantly lower rate of dysentery, with an incidence rate ratio of 0.03 ($P=0.001$). However, it is likely that this association is at least partly the product of other household characteristics associated with access to a flush toilet.

3.11 ACCEPTANCE OF SODIS

Very few control households showed a willingness to adopt SODIS at the end of the main field study. Assessment of post study compliance was determined by interviewing 92 households who used SODIS bottles during the main study. The questionnaires were administered by the previously trained field workers with supervision of the field coordinators. A summary of the questions asked and the percentage responses received from the participants are shown in (**Table 3.17**).

Table 3.17: Summary of the main questions and percentage responses relating to SODIS use in South Africa.

Question	Reply (%)
How safe do you think your current drinking water is?	
Very safe	50.6
Safe	27.2
Quite safe	2.3
Not safe	20.6
How safe do you think SODIS water is?	
Very safe	56.7
Safe	40.4
Quite safe	3.3
Not safe	0
How important is it that your drinking water does not make you sick?	
Very important	55.4
Important	40.6
Quite important	2.3
Not very important	2.3
Not important	0.0
How important is it to treat your drinking water?	
Very important	34.1
Not so important	34.7
A bit important	4.4
Not at all important	27.2
Do you see your current drinking water sources as trustworthy?	
Very trustworthy	25
Trustworthy	75
How time-consuming is SODIS?	
Very time-consuming	40.2
Time-consuming	25.0
Somewhat time-consuming	3.5
A little bit time-consuming	1.1
Not time-consuming	30.4
How much effort is it to prepare SODIS water?	
A lot of effort	10.9
Quite an effort	8.9
It is no effort	80.8
Can you treat enough water with SODIS?	
More than enough	44.4
Enough	50.4
Not enough	4.3
Far too little	1.1
Does drinking SODIS water prevent diseases?	
I agree	98.0
How do you feel about SODIS?	

Question	Reply (%)
Very positive	72.9
A little positive	24.0
Neither positive nor negative	2.2
Negative	1.1
Very negative	0.0
How do you think about others who do SODIS?	
Very positive	66.3
Positive	23.9
A little positive	2.2
Neither positive nor negative	0.0
A bit negative	1.1
Negative	0.0
Very negative	6.0
How do other people think about you when you do SODIS?	
Very positive	14.1
A bit positive	51.1
Neither positive nor negative	1.1
A bit negative	1.1
Negative	26.1
Very negative	6.5
Do you think it is good or bad to do SODIS?	
Very good	65.1
Good	33.7

The results of the questionnaire confirmed that 50.6% of the inhabitants considered there water sources as very safe and 27.2 as safe. A fifth (20.6%) thought their current supply was unsafe. Almost everyone indicated that SODIS is a safe source of water. Treating their water source was considered not very important which confirms that the water sources were perceived of good quality. Only 34.1% thought that it was important to treat their current water supply and 34.7% did not consider it as very necessary while 27.2% thought it unnecessary. However when asked if they think their current water was trustworthy everyone interviewed responded positively. Although SODIS was considered as a method of little effort 40.2% thought it was very time consuming and 25% thought time consuming. Noteworthy is the fact that 94.8% of the respondents thought that 4 litres of solar disinfected water was an adequate volume. This may be explained by the fact that solar disinfected water was only used for the children under five years of age and that an adequate volume of water was available from other sources (e.g. standpipes and boreholes) for the rest of the family.

The general attitude towards SODIS seemed positive. When respondents were asked how they feel about SODIS 72.9% were very positive. Interviewees also indicated that they did not perceive other SODIS users in the community as odd. However, the responses to the question “How do other people think about you when you do SODIS?” were less convincing (**Table 3.17**).

Responses to the questions pertaining to why others did not use SODIS and why the compliance was so low indicated that participants rated ignorance in the rest of the community about SODIS as the main reason. This was confirmed by responses such as: “They think it will make their children sick”, “SODIS cannot disinfect water”, “people not using SODIS think we are crazy to use it” and “it is a waste of time.”

3.12 SUMMARY OF OBSERVATIONS AND CONCLUSIONS

SODIS EFFECTIVENESS

- **Dysentery**: Based on the levels of motivation of participants to fill in the diarrhoeal diaries, a significant reduction in risk of dysentery was observed in approximately 25% of the households. Equivalently, when motivation was low no significant reduction in risk occurred. The health benefit provided by good quality standpipe water was reflected in the lower levels of dysentery recorded for both test and control children whom had access to standpipe water as their source.
- **Non-dysentery diarrhoea**: Using SODIS bottles did not affect the overall risk of non-dysentery diarrhoea nor did the degree of compliance to the SODIS protocol affect this risk. In particular, even good compliance did not affect the risk.
- **Storage water quality**: On average, the difference in storage water quality, based on *E. coli* levels, between test and control group was not significant in the first and last (fourth) monitoring visit. However, they were significantly different for the third monitoring visits.
- **Disinfection**: Based on compliance (whether or not participants said they had put the SODIS bottle out in the sun the previous day), the average difference in *E.* coli levels in the SODIS bottles between those that did not and did was about 0.5 $\log_{10}$ units. This indicates a general disinfection effectiveness of the SODIS protocol.
- **Anthropometry indices**:
    - The use of SODIS did not significantly affect the odds ratio weight-for-age, height-for-age and weight-for-height of children.
    - The use of SODIS did not significantly affect the mean anthropometry indices (height and weight) of participating children, compared with those in the control group.

- There was no significant variation in the anthropometry indices as the degree of motivation increased.
- There was also no significant relationship between water source characteristics and anthropometry indices.

HEALTH RISK FACTORS

- **Water source**: There was a substantially lower risk of dysentery in those children drinking standpipe water. There was no evidence that any other water source type was associated significantly with risk of dysentery. There was also no evidence of an interaction effect between water source type and the effect of SODIS.
- **Water drawing method**: The risk of dysentery was substantially increased by the use of a scoop to draw water from the storage container compared to pouring from the container.
- **Hand washing**: High reported levels of hygiene and insufficient variation in the data precluded an analysis of the effect of hand washing on risk of dysentery.
- **Toilet facilities**: There was no evidence that access to a toilet reduced dysentery risk. However, compared with those without access to a toilet, those with access to a flush toilet had a significantly lower rate of dysentery.

ACCEPTANCE OF SODIS

- **During study**: Compliance, based on the answer to the question "Did you put out a SODIS bottle yesterday?", decreased from above 75% at the start of the study to less than 30% at week 40. This indicates a general decreasing acceptance of the use of SODIS.
- **Post-study**: Very few control households showed a willingness to adopt SODIS at the end of the main field study. One of the main reasons may be that many perceived their water to be of adequate quality.

CHAPTER 4: RESULTS - KENYA

4.1 INTRODUCTION

The health impact assessment in Kenya was initiated in 2008. The start and end dates used to distinguish between data in the SODIS Master Country Database collected during the three monitoring visits were as follows:

1. 2008/07/22 to 2008/10/07
2. 2008/10/08 to 2009/01/06
3. 2009/01/07 to 2009/03/14

The analysis that follows investigated various relationships between source water types, water quality, gender and age in terms of the dysentery and non-dysentery diarrhoea days that were recorded.

4.2 DATABASE CLEANUP

The databases were cleaned by team members in Kenya and sent to the database developer for preparation for statistical analysis. No invalid barcodes were detected in either the diary or main databases. No duplicate barcodes were detected in the main database. However, when the three individual diarrhoeal diary databases were merged into one, a few duplicate barcodes were detected. These were fixed in the same way as the South African data.

The checks for unmatched barcodes only indicated missing data, not inconsistent data. Therefore, no changes were made to the database on the basis of unmatched barcodes.

4.3 NUMBERS OF DATA TYPES

Table 4.1 shows a summary of the numbers of various data types obtained during the field study and presented for statistical analysis. It should be noted that numbers actually used in the analyses described in the following sub-sections may be less than those in the table.

Table 4.1: Kenyan field study summary of numbers of data types.

Data type	Number
Children in control group (without SODIS bottle)	554
Children in test group (using SODIS bottle)	579
Male children	568
Female children	565
Total children	1 133
Households	798
Households using standpipes	440
Households using protected boreholes	64
Households using unprotected boreholes	73
Households using protected springs	1
Households using protected dug wells	2
Households using unprotected dug wells	3
Households using rivers	163
Households using canals	1
Households using other water sources	51
Children with some diarrhoeal diary data	1 089
Non-dysentery diarrhoea days	8 085
Non-dysentery diarrhoea episodes	3 829
Dysentery days	2 850
Dysentery episodes	1 128
Storage water *E. coli* measurements (Monitoring visit 1)	471
(Monitoring visit 2)	447
(Monitoring visit 3)	441
(Monitoring visit 4)	0
SODIS water *E. coli* measurements (Monitoring visit 1)	262
(Monitoring visit 2)	232
(Monitoring visit 3)	232
(Monitoring visit 4)	0
Children with some anthropometry data (Monitoring visit 1)	656
(Monitoring visit 2)	653
(Monitoring visit 3)	632
(Monitoring visit 4)	0

4.4 CHARACTERISTICS OF THE STUDY AREA

The study was undertaken in and in the vicinity of the town of Nakuru, the third largest city in Kenya, north of the capital city Nairobi (**Figure 4.1**).

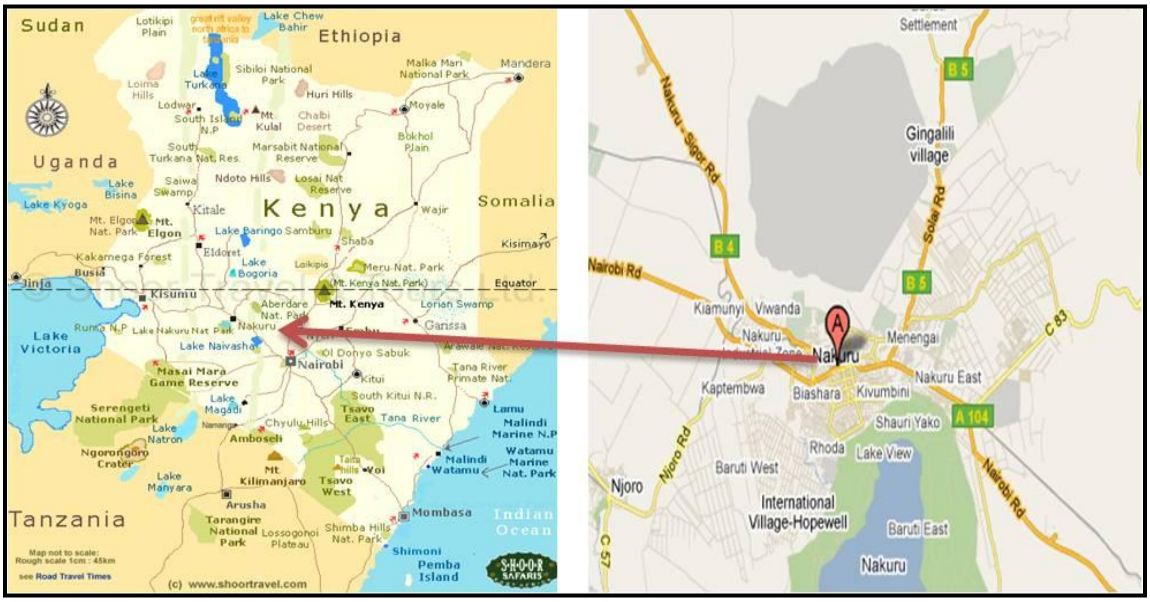

Figure 4.1: A map of Kenya showing where Nakuru is situated.

The geographic coordinates of Nakuru is 0º 17.1′ South and 36º 4.0′ East, putting the area well within the *moderately favourable* region for practising SODIS (Accra et al., 1984). The area included both peri-urban communities and rural communities using protected and unprotected drinking water sources. The population of Nakuru and surrounding rural areas is approximately 315 863 people (CIA World Factbook, 2007), some extremely poor, resides in the following sub-districts: Bondeni, Kaptembwa, Lanet, Mogotio, Salgaa and Wanyororo. The population consists of many different tribes and cultures. An average income for a person living in this area was approximately $5.00 per day (Personal communication, ICROSS, 2010). Forty two percent of the total Kenyan population is between 0 to 14 years of age, 55.2% is 15 to 64 and 2.6% is older than 56. A high risk for waterborne, food borne and malaria exists. The percentage of adults in 2003 that were infected with HIV/AIDS was 6.7% (CIA World Factbook 2007). The under five mortality rate was 128 per 1000 children.

Water in the town of Nakuru is provided by Nakuru Water Sanitation Services Company Limited. Interruptions of the water supply are common forcing residents to access other water sources. In contrast to South Africa water in Kenya is a commodity paid for by the users. Payment is determined according to the volume used. Those without the means to pay, illegally access water from main supply pipes, at times. The main procedure for disinfection of water sources other than tap water is boiling.

Medical services available to the communities are not free as is the case in South Africa (Personal communication, ICROSS, 2010).

Figure 4.2: Typical Kenyan urban and rural households

Housing in the peri-urban area consisted of buildings of 15 to 20 single rooms. Occupants each rented one room often shared with up to 5 people. Drinking water access per building typically consisted of one standpipe. The tap was padlocked to prevent unauthorised use of the water. Inhabitants usually had access to four to six pit toilets situated within the building site.

Houses in the rural areas consisted of typical round mud houses and some brick buildings with corrugated iron roofs. A variety of water sources was used including springs, protected and unprotected boreholes, unprotected dug-wells, standpipes, river water and canal water. Sanitation facilities consisted of mostly pit latrines, some very rudimentary and a few flush toilets.

4.5 PARTICIPANTS

Sample size was estimated as described in Section 3.5. Eligible households were chosen as described in Section 2.5. Randomisation was achieved as described in Section 2.5.1.

Participants were recruited by the field workers trained in aspects of community work and data collection during field studies. The team consisted of a principal coordinator, a coordinator, an accountant, a graduate intern, six data collectors and six assistant data collectors. They resided in the communities and were familiar with the area and many of the households. Households were visited regularly, every two weeks when possible. Field workers distributed diarrhoeal diaries and collected them monthly. During these visits problems with completion of the diarrhoeal diaries were addressed and people were reminded to do SODIS. Water collection and measuring children were undertaken under the super vision of the coordinators.

4.6 SAMPLING AND SURVEILLANCE

The household selection was started in July 2007 and was completed by August 2007. The procedures for sampling and surveillance are described in Section 3.6.

4.7 BASELINE DATA

The urban locations were supplied almost exclusively by standpipes provided by the Nakuru Water Sanitation Services Company. A total of 220 test and 220 control households had access to standpipes. Seventy three households used unprotected boreholes and 64 protected boreholes. In the rural locations, water sources were more variable (**Table 4.2**). Only Salgaa was partly supplied by standpipes (54 of 97 households). River water was used by 163 households. The remainder of the sources were a canal, protected and unprotected springs. In **Table 4.2** the water sources of the peri-urban areas, Bondeni, Kaptembwa, Lanet, and the rural areas Mogotio, Salgaa and Wanyororo have been combined. The differences in types of water sources (combining the spring, dug well, dug well unprotected and the canal and other) used by the test and control groups were not statistically significant (χ^2 square test. χ^2=4.3945, df=4, P=0.3552). Political unrest in the beginning of 2008 forced some of the participating households to abandon their homes resulting in the use of other available water sources of which no record exists. The water drawing method was evenly distributed with 195 households pouring into a cup and 227 households using scoops.

Table 4.2: Water source types and, water drawing methods for the peri-urban areas (Bondeni, Kaptembwa, Lanet) and rural areas (Mogotio, Salgaa, Wanyororo) combined, the aggregate and test and control

Water source	Peri-urban	Rural	Total	Test	Control
Standpipe	386 87.7%	54 12.3%	440 55.1%	220 50.0%	220 50.0%
Borehole unprotected	1 1.4%	72 98.6%	73 9.1%	43 58.9%	30 41.1%
Borehole protected	27 42.2%	37 57.8%	64 8.0%	38 59.4%	26 40.6%
Spring protected	0 0.0%	1 100.0%	1 0.1%	1 100.0%	0 0.0%
Dug well unprotected	0 0.0%	3 100.0%	3 0.4%	1 33.3%	2 66.7%
Dug well protected	0 0.0%	2 100.0%	2 0.3%	1 50.0%	1 50.0%
River	0 0.0%	163 100.0%	163 20.4%	87 53.4%	76 46.6%
Canal	0 0.0%	1 100.0%	1 0.1%	1 100.0%	0 0.0%
Other	3 5.9%	48 94.1%	51 6.4%	30 58.8%	21 41.2%
Total	417 52.3%	381 47.7%	798 100.0%	422 52.9%	376 47.1%
Container type					
Pour into a cup	229 64.1%	128 35.9%	357 44.7%	195 54.6%	162 45.4%
Scoop	188 42.6%	253 57.4%	441 55.3%	227 51.5%	214 48.5%
Total	417 52.3%	381 47.7%	798 100.0%	422 52.9%	376 47.1%

Table 4.3: Numbers and percentages of baseline hygiene practices for the peri-urban areas, toilet access and toilet type (Bondeni, Kaptembwa, Lanet) and rural areas (Mogotio, Salgaa, Wanyororo) combined, the aggregate and test and control

	Peri-urban	Rural	Total	Test	Control
Hands washed					
Before preparing food	385 51.5%	363 48.5%	748 93.7%	391 52.3%	357 47.7%
Before eating	415 52.3%	378 47.7%	793 99.4%	420 53.0%	373 47.0%
After toilet	405 52.3%	370 47.7%	775 97.1%	406 52.4%	369 47.6%
After changing nappy	316 51.2%	301 48.8%	617 77.3%	318 51.5%	299 48.5%
Sanitation					
Access to toilet	409 55.5%	328 44.5%	737 92.4%	387 52.5%	350 47.5%
Toilet type					
Pit latrine	346 50.9%	334 49.1%	680 89.8%	350 51.5%	330 48.5%
Flush	44 86.3%	7 13.7%	51 6.7%	33 64.7%	18 35.3%
Other	26 100.0%	0 0.0%	26 3.4%	11 42.3%	15 57.7%

The characteristics of the households with regard to basic hygienic practices and access to sanitation and the type of water storage containers are shown in **Table 4.3.** There was no statistically significant difference between the test and control group for hand washing at critical times for example preparing food, before eating, after changing a baby's nappies and after being to the toilet.

4.8 ASSESSMENT OF HEALTH OUTCOMES

Summaries of the data recorded in the Kenyan health impact assessment and statistical analyses of the data are presented in this section.

4.8.1 Analysis approach

Stata/SE, release 11 was used for statistical analyses.

The unit of randomisation was the household but the analysis of variance was based on the children (see Section 2.8).

Compliance in Section 4.8.4.2 refers to compliance based on the answer to the question “Did you put out your bottle yesterday”.

Section 4.8.2 contains summaries of the diarrhoea data for test and control groups.

Preliminary statistical analysis is shown in Section 4.8.3. The same approach (Section 3.8.1) followed for the South African data was followed for the Kenyan data. For the subgroup analysis the concept of measuring motivation to complete diarrhoeal diaries as a proxy for compliance was not used. The reasons are a much higher rate of adhering to the SODIS protocol than was observed in the South African trial and the amount of diarrhoea diary data generated in the Kenya trial was heavily dependent on the social upheavals as well as on compliance.

4.8.2 Data summary

The total numbers of households at the start of the monitoring visits were 798 and the total number of children 1 133. Male children counted 568 and females 565. The test group that used SODIS water consisted of 579 and the control group of 554 children.

Summaries of the data collected for the different diarrhoeal endpoints are shown in **Table 4.4.**

Table 4.4: Dysentery- and non-dysentery days and episodes recorded for the duration of the Kenyan study

	Dysentery days	Non-dysentery days	Dysentery episodes	Non-dysentery episodes
Total data points	2850	8085	1128	3829
Intervention	1144	3433	438	1614
Control	1706	4652	690	2215

These were recorded over a period of 21 months. The number of children that actually suffered from diarrhoea illness is shown in **Table 4.5**.

Table 4.5: Numbers of the actual children that suffered from dysentery or non-dysentery diarrhoea in Kenya

	Dysentery days	Non-dysentery days	Dysentery episodes	Non-dysentery episodes
Test (579 children)	192	380	189	378
Control(554 children)	238	388	238	387

The numbers and means of the recorded dysentery and non-dysentery days and episodes associated with each water source type are shown in **Table 4.6** and **Table 4.6**.

Table 4.6: Dysentery and non-dysentery days and episodes associated with each water source type for the intervention group

Source & no. of users	Borehole un-protected (53)	Borehole protected (55)	Stand-pipe (287)	Dug well protected (2)	River (316)	Canal (1)	Other (44)
Dysentery days							
Number	57	182	542	0	316	0	47
Mean	1.1	3.3	1.9	0.5	2.9	0.0	1.1
Non- dysentery days							
Number	274	478	1875	11	591	7	197
Mean	5.2	8.7	6.5	5.5	5.4	7.0	4.5
Dysentery episodes							
Number	25	63	223	0	110	0	17
Mean	0.5	1.1	0.8	0.0	11.0	0.0	0.4
Non-dysentery episodes							
Number	121	196	875	6	318	4	94
Mean	2.3	3.6	3.0	3.0	2.9	4.0	2.1

Table 4.7: Dysentery and non-dysentery days and episodes associated with each water source type for the control group

Source & no. of users	Borehole unprotected (42)	Borehole protected (34)	Stand-pipe (322)	Dug well protected (2)	Dug well unprotected (4)	Other (26)
Dysentery days						
Number	77	68	945	19	6	90
Mean	1.8	2.0	2.9	9.5	1.5	3.5
Non- dysentery days						
Number	235	224	3209	7	3	137
Mean	5.6	6.6	10,0	3.5	0.8	5.3
Dysentery episodes						
Number	34	27	386	8	4	42
Mean	0.8	0.8	1.2	4.0	1.0	1.6
Non-dysentery episodes						
Number	115	100	1507	3	3	77
Mean	2.7	2.9	4.7	1.5	0.8	3.0

4.8.3 Preliminary statistical analysis

The Kenyan data for dysentery- non-dysentery days and episodes were analysed using the approach described in Section 3.8.3.

Regardless of the method and whether data were adjusted for clustering the findings presented in **Table 4.8** confirm that all diarrhoea endpoints were reduced significantly.

Table 4.8: Incident rate ratios for dysentery- and non-dysentery days and episodes obtained using various statistical analyses methods based on the intervention and control groups

Parameter *	Analysis	IRR	P value	95% CI
Dys-days	Poisson Unadjusted	1.60	>0.001	(1.48 ; 1.72)
Non-dys days		1.44	>0.001	(1.38 ; 1.54)
Dys epis		1.68	>0.001	(1.48 ; 1.89)
Non-dys epis		1.46	<0.001	(1.37 ; 1.56)
Dys-days	Poisson adjusted for one child in a households	1.69	>0.001	(1.55 ; 1.85)
Non-dys days		1.46	>0.001	(1.38 ; 1.54)
Dys epis		1.72	>0.001	(1.49 ; 1.98)
Non-dys epis		1.48	<0.001	(1.37 ; 1.60)
Dys-days	Poisson adjusted	1.60	0.004	(1.56 ; 2.20)
Non-dys days		1.44	<0.001	(1.18 ; 1.76)
Dys epis		1.68	0.001	(1.25 ; 2.25)
Non-dys epis		1.46	<0.001	(1.23 ; 1.76)
Dys-days	Negative binomial unadjusted	1.57	0.003	(1.17 ; 2.11)
Non-dys days		1.34	0.001	(1.13 ; 1.59)
Dys epis		1.65	<0.001	(1.29 ; 2.11)
Non-dys epis		1.35	<0.001	(1.18 ; 1.54)
Dys-days	Negative binomial adjusted for one child in a household	1.72	0.002	(1.21 ; 2.44)
Non-dys days		1.37	0.002	(1.12 ; 1.67)
Dys epis		1.73	<0.001	(1.29 ; 2.31)
Non-dys epis		1.40	<0.001	(1.19 ; 1.65)
Dys-days	Negative binomial adjusted	1.57	>0.016	(1.09 ; 2.27)
Non-dys days		1.34	0.017	(1.05 ; 1.71)
Dys epis		1.65	0.002	(1.20 ; 2.27)
Non-dys epis		1.35	0.002	(1.11 ; 1.63)

*Dys days = Dysentery days; Non-dys days = non-dysentery days; dys epis = dysentery episodes; non-dys epis = non-dysentery episodes.

4.8.4 Sub-group analyses-Dysentery

Generalised negative binomial regression was used, adjusted for the effects of the multistage sample design, with children sampled within houses, and stratified by village (6 units).

Twelve of the participating children died during the study period. The cause of death was not determined. Post election violence caused displacement of households in

February 2008 resulting in a loss of 444 children directly after the upheaval. Many households returned to their homes once the violence ended and at the end of the study only 32 children were completely lost to follow-up.

4.8.4.1 Diarrhoea incidence

There were 765 households, with 404 (53%) randomised to the control group. The total number of children randomised was 1 089, with 555 (51%) randomised to solar disinfection. There was no difference in age or sex distribution between test and control groups. Median follow-up (determined by the number of monitoring visits) was 14 months; 25% of participants had 9 months or less, 75% had 17 months or less and 21% had 17 or 18 months. **Table 4.9** shows the rates of dysentery and non-dysentery diarrhoea.

Table 4.9: Kenyan unadjusted annual rates of dysentery and non-dysentery diarrhoea.

	Dysentery		Non-dysentery diarrhoea	
Group	**Days**	**Episodes**	**Days**	**Episodes**
Control	5.20	2.02	10.89	4.75
Test (SODIS)	3.34	1.31	8.07	3.65

Table 4.9 shows incidence rate ratios for each endpoint with estimates adjusted for water source (standpipe versus other water source), study area (entered as 5 dummy variables) and child age in whole years (4 dummy variables). Dispersion was parameterised by study area (5 dummy variables).

Table 4.10: Kenyan incidence rate ratios for dysentery and non-dysentery days and episodes with estimates adjusted for water source, study area and child age.

Endpoint	Incidence rate ratio	95% CI	P-value
Dysentery days	0.56	(0.40 ; 0.79)	<0.001
Dysentery episodes	0.55	(0.42 ; 0.73)	<0.001
Non-dysentery days	0.70	(0.59 ; 0.84)	<0.001
Non-dysentery episodes	0.73	(0.63 ; 0.84)	<0.001

All diarrhoea endpoints were significantly reduced by use of solar disinfection, with reductions of roughly 45% in the incidence of dysentery and approximately 30% in the incidence of non-dysentery diarrhoea (**Table 4.10**).

4.8.4.2 Relationship between compliance and dysentery

Figure 4.3 represents the number of dysentery and non-dysentery days in relation to compliance. Overall compliance was defined as the percentage of monitoring visits in which responses were recorded to the question “Did you put your bottle out yesterday?” (See Section 3.8.1)

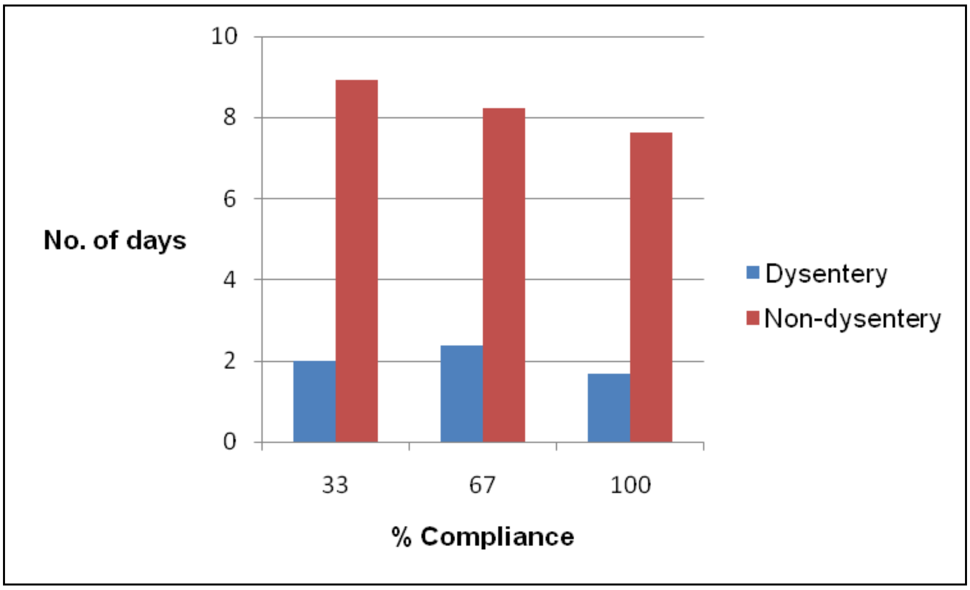

Figure 4.3: The number of dysentery and non-dysentery days in relation to compliance

The question was posed to the participants only three times. It should be noted that only those data points where three responses, whether it was ”yes” or “no,” were included in the graph. A hundred percent compliance was assumed when participants answered “yes” three times, 67% when they answered “yes” twice and 33% when they answered “yes” once. There were no records with three “no” responses. Based on this selection process, 281 children had compliance data for the three visits

.

The level of diarrhoea was plotted as the average number of dysentery days or non-dysentery days per child. The number of children was 14, 119, and 148 for compliance levels 33, 67 and 100%, respectively.

It appears that when compliance was high lower dysentery and non-dysentery diarrhoea days occurred and *vice versa*.

4.8.5 Water quality

4.8.5.1 Compliance to WHO standards

E. coli counts were recorded for 726 SODIS water sample samples. Sixty eight percent of these samples were in compliance with the World Health Organization's guidelines for zero thermotolerant coliforms per 100 mℓ. The percentage samples with <10 counts per 100 mℓ was 76%.

4.8.5.2 E coli levels in relation to the trial period

The change in the observed *E. coli* counts in relation to the trail follow-up period is represented in **Figure 4.4.** A decrease in *E. coli* is shown between visit one and two. At visit three levels started to increase. The shortcomings of the analyses methods and its influence on representing the data graphically are described in Section 3.8.5.2.

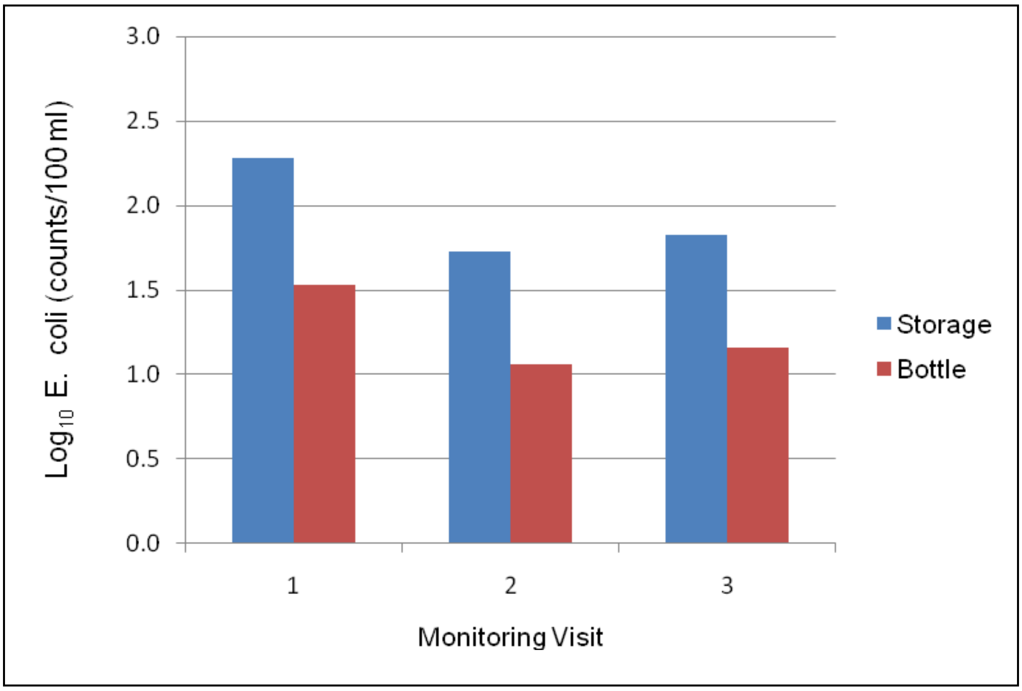

Figure 4.4: Log $_{10}$ *E. coli* counts for storage and SODIS water per monitoring visit assuming zero and 200.5 as minimum and maximum counts.

E. coli levels in storage water and SODIS water in test households were converted to a log scale and analysed as described in Section 3.8.5.3. Three monitoring visits (**Table 4.11)** were undertaken. **Table 4.12** shows the *E. coli* levels at each monitoring visit. At visit one and three the difference between the storage and SODIS water was not significantly different (P=0.686 and P=0.617), respectively. However, at visit two a significant difference was observed (P<0.001).

Table 4.11: Kenyan monitoring visit durations.

Visit	Households	Started at week	Median time	Ended at week
1	471	24	28	34
2	447	34	35	40
3	441	47	48	55

Table 4.12: Kenyan *E. coli* levels (log_{10} units) at each monitoring visit.

Visit	Group	Mean level	CI 95%	P-Value
1	Control	0.91	(0.69 ; 1.14)	0.686
	SODIS	0.94	(0.74 ;1.14)	
2	Control	1.08	(0.88 ; 1.28)	0.001
	SODIS	0.69	(0.51 ; 0.86)	
3	Control	0.54	(0.31 ; 0.77)	0.617
	SODIS	0.54	(0.33 ; 0.75)	

4.8.5.3 Water quality and compliance

Similar to the approach used for the South African data (Section 3.8.1), compliance in the SODIS group was based on the answer to the question "Did you put out your bottle yesterday?" Reported compliance was 85% at visit 1, 79% at visit 2 and 86% at visit 3. Associated *E. coli* levels in SODIS bottles of households who had and had not put a bottle out the previous day were examined (**Table 4.13**).

Table 4.13: Kenyan *E. coli* levels in SODIS bottles based on compliance.

Visit	Bottle out previous day?	Mean (log_{10})	CI 95%	P-Value
1	No	-0.43	(-1.16 ; 0.30	0.535
	Yes	-0.67	(-0.98 ; 0.37	
2	No	-1.60	(-2.23 ; 0.97	0.094
	Yes	-1.03	(-1.37 ; 69	
3	No	-0.53	(-1.14 ; 0.09	0.217
	Yes	-0.94	(-1.28 ; 0.59	

Compliance, assessed by whether the household had put out a SODIS bottle the previous day, was associated with a lower *E. coli* levels at visit two, apparently indicating SODIS effectiveness when participants complied with this aspect of the

SODIS protocol. However, this difference had disappeared at visit three. It was noted by field workers that participants were very reluctant to admit that they had not put the SODIS bottle out, and consequently this may be a poor indicator of compliance.

4.9 ANTHROPOMETRY

4.9.1 Data summary

Table 4.14 and **Table 4.15** show the mean height and weight of female and male children observed at each of the monitoring visits for the test and control groups, respectively.

Table 4.14: Height and weight for each monitoring visit for males and females of the test group

Test group						
Visit:	1	1	2	2	3	3
	Height	Weight	Height	Weight	Height	Weight
Sex:	Male					
Mean:	92.8	13.7	94.8	14.1	96.7	14.6
Std Dev:	11.7	3.2	11.1	3.0	10.9	3.0
N:	131	131	132	132	129	129
Sex:	Female					
Mean:	92.9	13.4	94.3	13.8	95.7	14.0
Std Dev:	10.6	2.8	10.8	2.8	10.4	2.8
N:	118	118	117	117	115	115

Table 4.15: Height and weight for each monitoring visit for males and females of the control group

Control group						
Visit:	1	1	2	2	3	3
	Height	Weight	Height	Weight	Height	Weight
Sex:	Male					
Mean:	93.0	13.7	94.9	14.2	96.6	14.6
Std Dev:	10.4	2.6	10.3	2.8	10.0	2.8
N:	109	109	109	109	102	102
Sex:	Female					
Mean:	92.4	13.4	94.1	13.9	95.5	14.4
Std Dev:	11.3	3.0	11.3	3.1	11.2	3.2
N:	117	117	120	120	116	116

4.9.2 Preliminary assessment

Based on the overall observed data the difference (0.29 cm) for the mean height of the children on SODIS compared to children not on SODIS was statistically significant (P=0.02). The difference (0.03 kg) observed between the children on SODIS and children not on SODIS was not significant (P=0.39) (**Table 4.16**)

Table 4.16: Overall mean height and weight for the test and control group

SODIS		Mean	P-value
No	Height change	3.02	0.02
Yes		3.31	
No	Weight change	0.85	0.39
Yes		0.88	

A paired t-test was used to test if there was a significant increase in height between the first visit and last visit based on the observed data for test and control groups and gender. In the test group, both the males and females had a significant increase in height. In the control group, both males and females also had a significant increase in height **(Table 4.17**). To test if this increase in height differed between the different groups, an analysis of variance was carried out. This test showed no significant difference in the increase in height between the test and control groups, or between genders.

Table 4.17: Mean difference in height and weight between male and female children

Mean difference in height in cm						
Gender	Test group			Control group		
		P-Value	CI 95%		P-Value	CI 95%
Male	3.52	<0.001	(3.17 ; 3.90)	3.16	<0.001	(2.77 ; 3.54)
Female	3.27	<0.001	(2.92 ; 3.61)	2.93	<0.001	(2.55 ; 3.32)
Mean difference in weight in kg						
Male	0.97	<0.001	(0.79 ; 1.15)	0.81	<0.001	(0.64 ; 0.99)
Female	076	<0.001	(0.58 ; 0.94)	0.92	<0.001	(0.77 ; 1.07)

The same analysis approach was followed for the weight of the children. The results showed that for both the test and control groups, both the males and females had a significant increase in weight. The analysis of variance showed no significant difference in the increase in weight between the test and control groups, or between genders (P=0.98).

The analyses approach subsequently used for the Kenyan anthropometry data is described in Section 0. The differences (based on the observed anthropometric measurements) for the mean height and weight, between the test and control children, were not statistically significant with or without adjustment for clustering of children households (P=0.116; P=0.650) (**Table 4.18**).

Table 4.18: Comparison of the effect of SODIS and storage water in respect of change in weight and height

Anthropometry parameter	Analysis	Intervention	Mean (95%; CI)	P-Value
Height change	ANCOVA (Unadjusted for clustering)	SODIS	3.27 (3.07 ; 3.47)	0.074
		Storage	2.99 (2.78 ; 3.19)	
	ANCOVA (Adjusted for one child per household)	SODIS	3.25 (3.03 ; 3.48)	0.133
		Storage	2.99 (2.74 ; 3.22)	
	ANCOVA (Adjusted for clustering)	SODIS	3.27 (3.05 ; 3.48)	0.116
		Storage	2.99 (2.74 ; 3.23)	
Weight change	ANCOVA (Unadjusted for clustering)	SODIS	0.85 (0.76 ; 0.95)	0.711
		Storage	0.83 (0.73 ; 0.92	
	ANCOVA (Adjusted for one child per household)	SODIS	0.88 (0.78 ; 0.98)	0.527
		Storage	0.83 (0.72 ; 0.94)	
	ANCOVA (Adjusted for clustering)	SODIS	0.86 (0.78 ; 0.93)	0.650
		Storage	0.83 (0.76 ; 0.91)	

4.9.3 Sub-group analysis

The recorded data were used to construct norms for height-for-age, weight-for-age and height-for-weight (Section. 3.9.3). The height-for-age and weight-for-age were examined by modelling the effects of age on each parameter as a two-term fractional polynomial, having verified that no significant improvement in fit was obtained by modelling age as three parameters. The effect of SODIS was modelled by converting the length of time in days on SODIS to a fraction of a year, allowing calculation of the effect of 365 days or a year on SODIS for each child. This allowed the inclusion of growth related to getting older as well as the length of time on SODIS. The median height of children was used instead of the average to exclude the effect of extreme measurements that have been recorded. Median height-for-age was significantly increased in those on SODIS, corresponding to an average of 1.3 cm over a 1-year period over the group as a whole (95% CI 0.54 to 2.2 cm, P=0.001). Median weight-for-age was similarly higher in those on SODIS, corresponding to a 0.4 kg difference in weight after a year on SODIS (95% CI 0.16 to 0.64 Kg, P<0.001). We examined the effects of SODIS on the extremes of the tenth centile of weight-for-age and height-for-age to see if the effects were more pronounced for the extreme of the distribution (smaller and thinner children), but found similar differences to those reported for the median (data not shown).

4.10 HEALTH RISK FACTORS

4.10.1 Water source

There were 419 households of the 765 whose water came from standpipes (55%). These accounted for 609 of the 1 089 children in the study group (56%). However, there was no evidence that children drinking from standpipe water sources had a lower rate of dysentery (incidence rate ratio 0.81, P=0.247). In view of the disruption to water supplies and the necessity for some households to move to escape the outbreaks of violence, it is perhaps not surprising that a single measure of water source is not associated with risk.

4.10.2 Water drawing method

A total of 423 households (45%) used a scoop to draw water, while the remainder used a cup. The risk of dysentery was, however, unrelated to the use of a scoop (IRR 0.97, P=0.882).

4.10.3 Hand washing

There were high levels of reported hygiene: 718 householders reported washing their hands before preparing food (93.8%), 761 (99.5%) before eating, 744 (97.2%) after using the toilet and 591 (77.2%) after changing a nappy. There was therefore insufficient variation in hand washing behaviour to analyse the effect on dysentery except washing after changing a nappy. This item was not associated with risk of dysentery (IRR 1.3, P=0.167).

4.10.4 Toilet facilities

There were 737 households (92.5%) with access to a toilet, of which 51 households (7.6%) had access to flush toilets. There was no evidence that access to a toilet reduced dysentery risk (incidence rate ratio 1.1, P=0.723) and there appeared to be no advantage to having access to a flush toilet in particular (IRR 1.0, P=0.920).

The number of people sharing the toilet ranged up to 200. A quarter of households used toilets shared with 8 people or fewer, of whom 5% were sole users. Half of households used toilets shared by 15 people or fewer and three quarters used toilets shared by 30 people or fewer. Risk of dysentery rose by 15% for each one quartile increase in the number of people using the toilet (P=0.041).

Figure 4.5: A Kenyan rural communal toilet.

4.11 ACCEPTANCE OF SODIS

Due to the financial and political problems outlined above, it was not possible to accurately assess the degree of acceptance of SODIS. However, observations by the fieldworkers confirmed satisfactory adherence to the SODIS protocol for most of the study period.

4.12 SUMMARY OF OBSERVATIONS AND CONCLUSIONS

SODIS EFFECTIVENESS

- **Dysentery**: A significant (roughly 45%) reduction in days with dysentery and dysentery episodes results when using the SODIS bottles.
- **Non-dysentery diarrhoea**: A significant (roughly 30%) reduction in days with non-dysentery diarrhoea and non-dysentery diarrhoea episodes results when using the SODIS bottles.
- **Storage water quality**: On average, the difference in storage water quality, based on *E. coli* levels between test and control group was not significant in the first and third monitoring visit. However, during the second visit the levels were lower in the test households.
- **Disinfection**: Based on whether or not participants said they had put the SODIS bottle out in the sun the previous day, there was weak evidence of

SODIS disinfection effectiveness when participants complied with this aspect of the SODIS protocol in the second monitoring visit.

- **Anthropometry indices**: The use of SODIS had a significant effect on weight-for-age, height-for-age of children.

HEALTH RISK FACTORS

- **Water source**: There was no evidence of a lower risk of dysentery in those children drinking standpipe water. However, this may be as a result of disruption to water supplies and the need for some households to move to escape the outbreaks of violence.
- **Water drawing method**: Either a scoop or a cup was used. The risk of dysentery was not related to the use of a scoop.
- **Hand washing**: There were generally high reported levels of hygiene (and therefore insufficient variation in the data for analysis) except for washing after changing a nappy. However, this was not associated with a risk of dysentery.
- **Toilet facilities**: There was no evidence that access to a toilet reduced dysentery risk and there appeared to be no advantage to having access to a flush toilet in particular. However, the risk of dysentery rose with increasing numbers of people sharing a toilet.

4.13 FACTORS THAT HAMPERED THE STUDY OUTCOMES

4.13.1 Political unrest

In March 2009 political elections caused eruptions of violence all over Kenya. The study area was one of the areas hardest hit. Many of the participating household members fled the area or were displaced and some were killed. Field workers could not enter the areas during this period. This lack of contact with field workers caused uncertainty amongst the participants about the continuation of the study. As a result some participants left the study. Almost 444 children no longer participated in the study.

4.13.2 Financial constraints

Delays in payment of funds to ICROSS meant that salaries could not be paid and staff had to be laid off at the end of March 2009. As a result the fourth monitoring visit could not be carried out. Data are therefore only available for the first three monitoring visits.

The planned post-SODIS compliance phase could also not be undertaken.

CHAPTER 5: RESULTS - ZIMBABWE

5.1 INTRODUCTION

The health impact assessment in Zimbabwe was initiated in 2008. As a result of political unrest the field work had to be abandoned. The field work was re-initialised in 2009. The start and end dates used to distinguish between data in the SODIS Master Country Database collected during the four monitoring visits were as follows:

1. 2009/03/01 to 2009/06/30
2. 2009/07/01 to 2009/09/30
3. 2009/10/01 to 2009/11/30

Data obtained from the field study lacked consistency and accuracy. Consequently only a limited analysis was warranted.

5.1.1 Enhancing the study outcome

Several factors that threatened to jeopardise the study outcome was investigated and addressed in March 2009 and a concerted effort was made to consolidate the household participation and data collection. In order to enhance data collection during the last nine months of the study 10 SODIS field assistants were employed in Hatcliffe to monitor the participants (control and intervention groups) frequently, to assist with filling in the diaries correctly and to motivate and educate the intervention group about the accurate use of SODIS.

In total 521 households were visited on a regular basis during the month of June and each field assistant was responsible for an average of about 60 households. The 10 SODIS field assistants (3 men, 7 women) in Hatcliffe visited their households successfully up to five times each in these 4 weeks. However, most of the participants (children and their care-givers) were only found once or twice at their home due to several reasons among them, visiting family members, currently in rural areas and attending funerals. It was reported that fourteen of the participants had relocated within Hatcliffe.

It was observed that 77% of the participants filled in their diaries correctly. Nonetheless, 23% of the child care-givers did not tick the diaries properly (e.g. the diary was blank, ticked in advance or did not give the true reflection of the child's condition) or were separated from the child and therefore not able to observe the child's stool condition. Data from the field indicated that the control and intervention group in the database did not fully overlap with the actual identified control and intervention groups on the ground. The data from the field assistants showed that 315 of the visited households thought they belonged to the control group whereas 190 thought they belonged to the intervention group. From these 190 households only 120 households were registered as intervention participants in the database. Furthermore only 96 intervention households on the ground were doing SODIS (have bottles in the sun or stored) at the time. In total 175 bottles exposed to the sun were observed during the first visits and 163 during the second visits.

Regarding the few households visited during the month June (mostly only once or twice) the captured data could not reveal the routine of applying SODIS within the participating households. Compliance to the protocol was generally poor.

In response to the cholera outbreak in August 2008 several NGO's distributed Aquatabs (water purifying tablets) to the residents in Hatcliffe to treat their water at the household level. A big share of the control group as well as of the intervention group used Aquatabs to treat their drinking water. This also caused serious doubt about the true health impact of SODIS.

The slow adoption of the method has been explained as linked to the socio-political environment. However the strong belief of fearing to be poisoned when you leave bottles outside when not around is still an issue and people are not willing to leave the bottles outside unattended.

5.2 DATABASE CLEANUP

The databases were cleaned by team members in Zimbabwe and sent to the database developer for preparation for statistical analysis. No invalid, duplicate, or unmatched barcodes were detected. However, there was evidence that the laboratory data may not have been captured using the handheld computers, as the protocol required. This raises some concerns about the integrity of these laboratory data.

5.3 NUMBERS OF DATA TYPES

Table 5.1 shows a summary of the numbers of various data types obtained during the field study and presented for analysis.

Table 5.1: Zimbabwean field study summary of numbers of data types.

Data type	Number
Children in control group (without SODIS bottle)	547
Children in test group (using SODIS bottle)	292
Male children	437
Female children	402
Total children	839
Households	648
Households using protected boreholes	21
Households using unprotected boreholes	43
Households using protected dug wells	45
Households using unprotected dug wells	539
Children with some diarrhoeal diary data	670
Non-dysentery diarrhoea days	1 249
Non-dysentery diarrhoea episodes	494
Dysentery days	382
Dysentery episodes	127
Storage water *E. coli* measurements (Monitoring visit 1)	387
(Monitoring visit 2)	339
(Monitoring visit 3)	318
(Monitoring visit 4)	0
SODIS water *E. coli* measurements (Monitoring visit 1)	70
(Monitoring visit 2)	38
(Monitoring visit 3)	54
(Monitoring visit 4)	0
Children with some anthropometry data (Monitoring visit 1)	480
(Monitoring visit 2)	0
(Monitoring visit 3)	0
(Monitoring visit 4)	0

5.4 CHARACTERISTICS OF THE STUDY AREA

The selected study area was a peri-urban informal settlement called Hatcliffe about 10 km from the capital Harare. It has a population of about 8 149 people living in about 2 197 households. Sanitation, at 52% coverage, consisted of pit latrines. Using the street and bush as latrines was common in the area. Access to improved water sources in the country was 82% in 2008 (UNSTATS, 2010). The Hatcliffe community had access to unprotected wells, boreholes and standpipes. Water availability at the standpipes was very erratic during the study period and during 2008 the standpipes did not received any water (Personal communication, IWSD, 2010). Very few people had formal employment. Subsistence farming and selling vegetables or other commodities from informal shops were the main means of income generation. Many households are simply constructed from four poles covered with thick plastic sheets. Humanitarian organisations were very active in the area during the study period. The age structure of the population is as follows:

- 0 to 14 years, 37.2%
- 15 to 64 years, 59.3%
- 65 years and over, 3.5%

The under five mortality rate in Zimbabwe was 96 per 1000 children in 2008 UNSTATS, 2010) and the HIV/AIDS rate was 24.6% in 2001 (CIA, World Factbook, 2007). The risk for enteric infectious diseases, malaria and schistosomiasis in the country are high (CIA, World Factbook, 2007).

Figure 5.1: Typical households and a latrine in Hatcliffe, Harare.

5.5 BASELINE DATA

The baseline information gathered in Hatcliffe is shown in **Table 5.2** and **Table 5.3.** Included are the types of water sources people had access to in the area, basic hygiene practises such as hand washing at certain critical times and the availability and type of toilet.

Table 5.2: Water source types for Hatcliffe Extensions 1, 2, 3 and 4 and household water drawing methods

	Ext 1	Ext 2	Ext 3	Ext 4	Total	Test	Control
Water source							
Borehole unprotected	2 4.7%	2 4.7%	0 0.0%	39 90.7%	43 6.6%	11 25.6%	32 74.4%
Borehole protected	0 0.0%	0 0.0%	0 0.0%	21 100.0%	21 3.2%	3 14.3%	18 85.7%
Dug well unprotected	119 22.1%	203 37.7%	178 33.0%	39 7.2%	539 83.2%	191 35.4%	348 64.6%
Dug well protected	12 26.7%	8 17.8%	18 40.0%	7 15.6%	45 6.9%	12 26.7%	33 73.3%
Container Type							
Pour into a cup	68 14.6%	151 32.3%	148 31.7%	100 21.4%	467 72.1%	162 34.7%	305 65.3%
Scoop	65 35.9%	62 34.3%	48 26.5%	6 3.3%	181 27.9%	55 30.4%	126 69.6%

Access to water consisted mostly of unprotected dug wells in Hatcliffe. Of the total of 539 household 191 in the test group and 348 in the control group used dug wells. The remaining sources consisted of unprotected boreholes 39 out of 43, and 21 protected boreholes. There was no statistically significant difference between the types of source waters used by the test and control groups (χ^2= 7.626, df=5, P=0.178).

The water drawing method consisted mainly of pouring into a cup (72.1%) and scooping (27.9%). This is an indication that containers with narrow mouths were used in most of the households **Table 5.2.**

Table 5.3: Baseline data for Hatcliffe Extension 1, 2, 3, and 4 and the aggregate test and control groups

	Ext 1	Ext 2	Ext 3	Ext 4	Total	Test	Control
Washing hands							
Before preparing food	128 20.7%	203 32.9%	190 30.8%	96 15.6%	617 95.2%	206 33.4%	411 66.6%
Before eating	133 20.6%	212 32.9%	194 30.1%	106 16.4%	645 99.5%	216 33.5%	429 66.5%
After toilet	131 20.5%	211 33.0%	193 30.2%	104 16.3%	639 98.6%	215 33.6%	424 66.4%
After changing nappy	121 20.9%	202 34.9%	170 29.4%	85 14.7%	578 89.2%	180 31.1%	398 68.9%
Sanitation							
Access	133 21.3%	206 33.0%	181 29.0%	105 16.8%	625 96.5%	212 33.9%	413 66.1%
Toilet type							
Pit latrine	132 20.7%	211 33.0%	190 29.7%	106 16.6%	639 99.2%	213 33.3%	426 66.7%
VIP	0 0.0%	0 0.0%	2 100.0%	0 0.0%	2 0.3%	1 50.0%	1 50.0%
Other	1 33.3%	1 33.3%	1 33.3%	0 0.0%	3 0.5%	2 66.7%	1 33.3%

Statistically significant differences (**Table 5.3)** were not observed between the test and control group for any of the baseline factors with the exception of washing hands after changing a baby's nappy (χ^2=12.262, df=1, P=<0.0001)

5.6 ASSESSMENT OF HEALTH OUTCOMES

There were 839 children recruited. However, diarrhoea diary data are only available on 670 (80%) and anthropometry on 480 (57%). Diarrhoea and anthropometry data are available from 418 (50%).

There were 28 children in Hatcliffe Ext 4 who were the only participants drinking from a protected borehole, of whom 6 were randomised to SODIS. There was no dysentery recorded in this group. These children have been excluded from the analysis.

There were 228 children randomised to SODIS (35.5%) and 414 (64.5%) to control. Randomisation to SODIS varied significantly by village, with as few as 20% or as many as 45% of children randomised (P=<0.0001, Chi squared test).

5.6.1 Dysentery

Incidence of dysentery was modelled using generalised negative binomial regression. Compliance with protocol was measured, as above, using the proportion of diary days filled in. The rate of dysentery was lower in those with higher compliance, whether SODIS or control. There was no evidence, however, that SODIS itself was associated with risk of dysentery. In univariate analysis, the incidence rate ratio was 1.4 (95% CI 0.71 to 2.7, P=0.337). Adjusting for compliance with protocol changed this little: IRR=1.5, 95% CI 0.79 to 2.8, P=0.215.

5.7 SUMMARY OF OBSERVATIONS AND CONCLUSIONS

Only a limited analysis was possible because of the lack of data integrity.

SODIS EFFECTIVENESS

- **Dysentery**: There was no evidence that use of SODIS was associated with risk of dysentery.

5.8 FACTORS THAT HAMPERED THE STUDY OUTCOMES

5.8.1 Political unrest

The study was initiated in September 2007 at the height of the political unrest. A number of conditions set by politicians of the ruling party at the time hampered household selection and prevented participation in an open and free manner. Overall progress was slow and delays were common throughout 2007 and at the beginning of 2008. The situation worsened when all NGOs were banned from doing any work in the area by the Ministry of Labour in May 2008. Water sampling was also affected by political campaigns and the elections for Provincial elections. During the ban contact could not be maintained with the participants. Consequently the participants lost interest in the study to such a degree that when work could be resumed after the ban was lifted in August 2008, the process of household selection and randomisation to test and control groups had to be repeated.

Further delays in the execution of the study could also be attributed to organisational changes at the Institute for Water and Sanitation Development (IWSD). By the end of December 2008 the senior field supervisor of the SODISWATER project in Zimbabwe immigrated to South Africa. When the replacement field supervisor was appointed, the Zimbabwean team was provided with a schedule aimed at restoring the control and test group households and execution of the monitoring visits.

5.8.2 Cholera outbreak

At the time of the field study endemic cholera had broken out in Zimbabwe and thousands of people were ill or dying. UNICEF initiated an aggressive campaign of distributing chlorine tablets (Aquatabs) to all the inhabitants in affected areas, including Hatcliff. Additional boreholes were drilled and the water from the boreholes was chlorinated. NGOs also provided households with chlorine solutions, bars of soap and food. Shelters were constructed where hygiene information and Aquatabs were freely available.

Notwithstanding the inevitable effects of these important practices on the water quality, a decision was made to continue with the SODIS study.

5.8.3 Cultural factors

Field workers were unsuccessful in obtaining water samples and diarrhoea information on many occasions. Some of the participants were unavailable because they were tending their farms during the rainy season some distance away from Hatcliff.

On the other hand, the application of SODIS sometimes changed local behaviour. For example, many participants feared poisoning and would not leave their SODIS bottles unattended.

5.8.4 Financial constraints

Delays in the payment of funds from the European Commission at the end of 2008 hampered the execution of the study. The uncontrolled inflation rate also had a serious detrimental effect on exchange rates. This required complex practices to manage funds during the study period.

CHAPTER 6: DISCUSSION AND CONCLUSIONS

6.1 GENERAL OBSERVATIONS

The overall objective of the study related primarily to the effectiveness of using solar disinfection in respect of microbial quality of water and associated reduction of waterborne related diarrhoea. The study used the incidence of two forms of diarrhoea in children between 6 months and 5 years old as indicators of effectiveness. The two forms of diarrhoea were dysentery (or bloody diarrhoea) and non-dysentery (non-bloody) diarrhoea. Anthropometric measurements, specifically weight and height, as health indicators, were also recorded. As secondary objectives, the study also intended to create a better understanding of the role of certain risk factors related to diarrhoea and the degree to which the SODIS method was accepted by the target communities.

In order to ensure statistically useful data, large numbers of children, 800 to 1000, per country, were initially enrolled for participation. Study areas with different characteristics were selected to achieve representative data for geographically different areas and populations of different socio-economic status. This created significant logistical challenges. It also determined to some extent the location of the field study sites.

The main field studies occurred over a period of one year and aimed at minimising the exaggerated positive effects associated with short term trials highlighted in other water quality intervention studies (Arnold and Colford, 2007, Clasen et al., 2007; Clasen et al., 2006b). It therefore covered the whole hydrological cycle, which ensured possible seasonal differences caused, for example, by different rainfall patterns. Possible seasonal effects were however not explicitly examined.

The three countries chosen for the field studies, namely South Africa, Kenya and Zimbabwe, had both similarities and differences. The South African study sites consisted only of peri-urban areas. These areas have a relatively high socio-economic status. People have adequate access to free water which is stored in containers in the households. The water provided is of reasonably good quality and diarrhoea incidence in the area was not very high. In Kenya the socio-economic status in the peri-urban areas and rural areas included in the trial was much lower than in South Africa. People paid for water provided at standpipes in the peri-urban areas while a number of water sources, including untreated water sources, were available to people in the rural areas. People in Hatcliffe, Zimbabwe, lived under circumstances of abject poverty and sub-standard housing conditions. Standpipes in Hatcliffe were dry for the entire study period and access to water consisted mainly of unprotected sources. However, the differences mentioned were ultimately not the most important deciding factors. The outcomes of the field studies in each country were much more fundamentally determined by events outside the control of the project teams. These included the serious political unrest and financial problems that beset both Kenya and Zimbabwe. Zimbabwe also suffered a severe cholera outbreak during the trial period.

6.2 STUDY DESIGN

The logistics of undertaking three randomised controlled SODIS interventions in three countries within the same study period is complex. Correct utilisation at an acceptable standard of the same procedures in the three countries was based on a sound study design captured in manuals describing each procedure explicitly and training of field co-ordinators and field workers. Handheld computers for data collection and a specially designed database improved data capture and safe storage. The randomised controlled trials allowed for selection bias control and permitted adjusting for probable confounding between control and intervention groups and in-house study site clustering (Esrey and Habicht, 1986) but could not rule out bias completely.

6.3 SODIS AND MOTIVATION

South Africa

In the South African trial the degree to which carers adhered to completion of daily diarrhoeal diaries, required from both the intervention and control groups for the duration of the trial, was used as a proxy for motivation for participation. This measure allowed calculation of motivation for both intervention and control households and it could also be used to determine both the incidence of diarrhoea and the level of motivation in the community. The possible effect of associations between motivation and the effect of SODIS in the intervention versus the control households, as a result of socio-demographic correlates of motivation, could thus be examined. Our data showed that only a quarter of the households complied with this measure for 75% of 360 days of the trial. Incidence rates were lower in those drinking solar disinfected water (Incidence rate ratio 0.64, 95% CI 0.39 to 1.0, P=0.071) but not statistically significant. Compared with control, participants with higher motivation in the SODIS group (75% or more data recorded) achieved a significant reduction in dysentery (Incidence rate ratio

0.36, 95% CI 0.16 to 0.81, P=0.014). The variation in risk of non-dysentery diarrhoea showed that solar disinfection was not significantly associated with risk of non-dysentery diarrhoea nor was having water taken from a standpipe. There was no significant effect of motivation on risk of non-dysentery diarrhoea, nor was there evidence that those with 75% or more motivation with diarrhoeal data recording had a reduced risk compared with controls. Overall no significant difference in the microbial quality of the drinking water was observed between SODIS and storage water. We classified effective solar disinfection as a reduction of 1 $\log_{10}$ unit in bacterial levels or better. Water in the SODIS bottles was improved in 20% of low motivation households and 34% of high motivation households. Overall, the highly motivated households were more likely to achieve this than the other households in the SODIS group (Odds ratio 2.2, P=0.034 adjusted for clustering by household).

The decision to use motivation to fill in the diarrhoeal diaries as a proxy for adherence to the SODIS protocol came in the wake of significant doubt that was cast upon the effectiveness of solar disinfection by the publication of a large trial in Bolivia (Maüsezahl et al., 2009). Despite an intensive health promotion intervention in 11 communities, compliance with SODIS was very low (32%), and the SODIS group did not show a statistically significant reduction in incidence of diarrhoea. The reason for the failure of the trial was unclear as it could either have been a failure of SODIS to reduce risk, or a failure of the intervention to generate sufficient compliance with SODIS to achieve a reduction in risk as pointed out by Bhutta (2009). Compliance was measured using “four different subjective and objective indicators” (Maüsezahl et al., 2009). The authors state that “Judgement criteria for this main compliance indicator study included observing regular SODIS practice and bottles exposed to sun or ready to drink in the kitchen and being offered SODIS-treated water upon request.” It is, therefore, unclear as to what their stated compliance rate of 32% could have been attributed to. However, it is notable that their compliance indicator was not correlated with risk of diarrhoea, suggesting that either (a) it was too imprecise a measure of compliance to show a graded association or (b) that even the most compliant households failed to comply sufficiently to show any effect on disease. However, the finding highlights the importance of understanding the role of participant motivation in the effectiveness of SODIS.

Previous reports have attempted to measure compliance with SODIS as a determinant of effectiveness by noting, for example, if SODIS bottles are in place in the sunlight when a field worker makes an unannounced visit (Rose et al., 2006) as well as self-reporting by carers and being offered a drink of SODIS water on request (Maüsezahl et al., 2009). However, this suffers from a number of drawbacks. The first, and most serious, drawback is that these measures cannot distinguish between the effects of a generally higher level of health consciousness and of health-promoting behaviour in the compliant households and the effects of SODIS in particular. It may be that households who are more likely to use the SODIS bottles also differ in other factors associated with risk of diarrheal disease, including hygiene behaviour, social status, and environmental characteristics. The second problem is that it is seldom possible to make an unannounced visit to an entire community. On occasion we have observed bottles appearing on roofs where no bottles were evident moments earlier when field workers are spotted in the village. Field worker observation on a small number of such visits may be a poor proxy for measuring actual compliance over the much longer periods of time involved in SODIS trials. Finally, as a measure of the motivational level of a community, it provides little information on whether SODIS would be an effective intervention, since it can only be assessed after the implementation of SODIS.

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The advantages of using motivation are that both intervention and control households can be included in the calculation. This is important, as households with poor compliance with SODIS may differ in baseline risk of disease from those with good compliance due to differences in socio-demographic, environmental, and health behavioural factors. Consequently, any attempt to examine the effects of compliance must adjust for these differences. Examination of the South African data showed that baseline risk of dysentery was higher in the poorly motivated households, regardless of whether they were randomized to SODIS or control groups.

Opting for 'motivation' as a proxy measure for compliance, allowed assessment of the effects of participation motivation for the first time. Given the poor outcomes of using self reporting and observer data to determine compliance this proxy measure seems a more realistic and plausible one.

Findings for the South African study were similar to that of Maüsezahl and colleagues: where low levels of motivation were achieved, solar disinfection of drinking water could not deliver a worthwhile reduction in risk of dysentery in children. When higher levels were achieved, (75% compliance or better for this trial), a reduction in dysentery in the children has been demonstrated.

Kenya

Using the completion of diarrhoeal diaries as a proxy for compliance to SODIS was not feasible for analysis of the Kenyan data because the amount of diary data recorded was dependent on both compliance and the socio-political upheavals evident during the main study. Incidence rate ratios for dysentery and non-dysentery diarrhoea, adjusted for water sources, study areas and child age in whole years, showed statistically significant reductions for days on which dysentery occurred (dysentery days, 44%; dysentery episodes, 46%; non-dysentery diarrhoea days, 30%; and non-dysentery diarrhoea episodes, 27%). Importantly evidence of the health gains of SODIS, other than diarrhoea illness, was obtained. Anthropometric measurements taken during the trial were statistically significantly different for the height-for-age and weight-for-age of children drinking SODIS water when compared with children in the control group. This finding is highly significant in light of the current debate about the true effect and relative health benefits of improved water quality and water quantity interventions that have been questioned by several authors, for example Schmidt and Cairncross, 2008, Clasen 2009, Hunter, 2009 and Arnold and Colford, 2007.

Zimbabwe

In Zimbabwe, there was no evidence that SODIS was associated with the risk of dysentery. However, this is not necessarily a negative conclusion in respect of SODIS effectiveness because of the lack of data integrity. It may only be a negative conclusion in respect of the ability to conduct studies of this kind.

6.4 OTHER SODIS TRIALS

At the outset of the trials conducted in South Africa, Kenya and Zimbabwe, information in the published literature was available on only three other randomised SODIS trials. Two trails undertaken in Kenya (Conroy et al., 1996; Conroy et al., 1999) were conducted in an area where people had access to water with high microbial contamination levels and high turbidity. The supervision of a Maasai elder resulted in very high levels of adherence to the protocol. Test households were instructed to leave their bottles in the sun while control households kept their bottles in-house. This affected a degree of blinding but at the same time probably provided safe storage resulting in an underestimation of the reduction in diarrhoea recorded (Clasen et al., 2007). The reduction in diarrhoea reported over a 12 week period was 9.3% for all diarrhoea and 24% in the incidence of severe diarrhoea in two-week diarrhoea prevalence in 5 to 16 year olds (Conroy et al., 1996). During a year-long extension of the trial with 349 children younger than six years a 16% reduction was reported (Conroy et al., 1999). The third trial was conducted in India by Rose et al. (2006). Diarrhoea in children 6 to 59 months old was reduced by more than 40%. Diarrhoea data were obtained from carers during weekly visits.

Recently a cluster-randomised controlled trial in 22 communities in children younger than five years in Bolivia reported a reduction in diarrhoea in both the control and intervention arms but, in spite of extensive SODIS promotion campaigns, the finding was not statistically significant. A rate ratio of 0.81 was shown for the incidence rate of diarrhoea episodes among children assigned to SODIS compared to controls. Based on the broad CI achieved (RR=0.81, 95%, CI 0.59 to 1.12) the authors concluded that reduction of diarrhoea in this setting was not substantive (Mäusezahl et al., 2009). They expressed their concern with further global promotion of SODIS until such time clearer and convincing evidence of the health gains of SODIS becomes available.

None of these trials differentiated between dysentery and non-dysentery diarrhoea. With the exception of the study by Mäusezahl and colleagues the studies were conducted over periods of a maximum of six months. Recording of diarrhoea was based on recall by carers and determining the actual water quality seemed not to be of high priority in any of these studies.

6.5 DIARRHOEA AND DYSENTERY

The study design described in this thesis allowed daily recording of dysentery as well as non-dysentery diarrhoea using diarrhoeal diaries. Monitoring dysentery in this study was aimed at obtaining information about the possible presence of enteric pathogens representing a major health problem in developing countries where sanitation and water provision is poor, which has a low infectious dose and is commonly spread through the faecal-oral route of infection. Importantly, an intervention based on high quality ceramic filters in Zimbabwe and South Africa showed that dysentery was associated with the faecal contamination of source water quality while non-dysentery diarrhoea was not associated with water quality at the source (Gundry et al., 2009). Dysentery is also strongly associated with the rates of growth of children (Alam et al., 2000), an aspect specifically addressed in this study by inclusion of anthropometric measurements of the participating children.

The majority of the published interventions that had diarrhoea as an outcome focussed on recording non-dysentery diarrhoea only. Recording methods and the recall time for diarrhoea incidence varied from study to study. Weekly incidence (Rose et al., 2006, Clasen et al 2004; Quick et al, 2002; Reller et al., 2003), two weekly (Conroy et al 1996) or monthly (Boisson et al 2010) are periods commonly seen in published work. Our study and that of Gundry et al. (2009) used daily diarrhoea diaries able to record both dysentery diarrhoea and non-dysentery diarrhoea. Mäusezahl et al. (2009) used a daily morbidity diary that recorded non-dysentery diarrhoea, fever and coughing. The ease with which diarrhoeal diaries can be adapted to differentiate between different types of diarrhoea and, for example, record additional information such as the volume of water ingested, weather conditions and other illnesses for a specific length of time, make them an invaluable tool in intervention studies. Diaries have the added advantage of providing daily records but the danger of participant reporting bias and recall bias cannot be avoided as the information capturing relies heavily on the integrity and level of engagement of the persons completing the forms. Recall bias occurs when carers lack the discipline to complete the forms daily and instead quickly complete the forms, based on information from memory, when the field workers enter the village. In this study similar behaviour was also noticed for SODIS bottles that were filled and left outside the moment field workers started their village rounds.

6.6 BIAS

The health contribution of the improvements in water quality was considered of less importance than water quantity and sanitation two decades ago (Esrey et al., 1985; Esrey et al., 1986; Esrey et al., 1991). These findings spurred the development and testing of numerous locally adapted water interventions and low-cost technologies to provide safe drinking water in developing countries. Meta-analyses of the performance of these technologies confirmed that improving water quality is effective in reducing diarrhoea and interventions to improve drinking water at the point-of-use are more effective than those at the source (Fewtrell et al., 2005, Clasen et al., 2006b). In light of the urgency to save people lives and to improve the health of people by provision of safe water, created by the Millennium Development Goals (UNSTATS, 2010), the logical next step was large scale and worldwide implementation of water quality interventions at the household level. Questions, however, were raised about the acceptability, sustainability, true health effects and the size of the effects achieved by these technologies (Schmidt and Cairncross, 2009; Waddington et al., 2009; Hunter, 2009).

The important shortcomings that were highlighted included heterogeneity among trials, lack of blinding, short trial time periods and methodological quality of randomised trials. In reality so many factors are at play in any intervention, for example, geographical position, socio-economic status of the target community, the type of intervention, and human behaviour, that it indeed becomes a complex system difficult to control. Most intervention studies suffer to some extent from one or more of these factors (Clasen, 2009). Blinding and inclusion of an objective primary outcome measure for example mortality, weight gain, or growth have been suggestions towards more reliable outcomes (Schmidt and Cairncross, 2009). Blinding cannot guarantee total protection against bias but it can contribute towards diminishing responder and observer bias. Publication bias and statistical direction of trial results cannot easily be controlled.

Only four published blinded home-based water quality trails are currently available (Boisson et al., 2010; Jain et al., 2010; Austen, 1993; et al., 2005; Kirchoff et al., 1985). None showed any significant effect on diarrhoeal disease. Contradictory to these findings most un-blinded HWT studies have reported substantial reductions in diarrhoea (Rose et al., 2006; du Preez et al., 2008; Clasen et al., 2004; Reller et al., 2003; Mafouz et al., 1995). Naturally this discrepancy cast doubt on the true effect of HWT interventions.

Our intervention studies were not blinded and neither were any of the SODIS trials undertaken to date. However, Conroy et al. (1996) afforded their trial in Kenya a manner of blinding by asking participants in the control group to keep their SODIS bottles indoors. Reasons for not blinding our study are obvious and the substantial effort that will be necessary to attempt to blind a SODIS intervention study will have to be considered carefully.

6.7 ANTHROPOMETRY

Additional options, apart from blinding to obtain true effect sizes are objective primary outcome measures, for example, mortality, weight gain, or growth. Schmidt and Cairncross (2009) investigated the existing evidence for the effectiveness of HWT in order to determine whether or not a solid case exists for promoting widespread adoption of HWT in poor settings. Although much evidence exists on how improving the water quality at the point-of-use dramatically improves water quality and subsequently reduces diarrhoea as much as 40% at household levels (Arnold et al., 2007; Clasen et al., 2006; Fewtrell et al., 2005; Sobsey et al., 2002; Kirchhoff et al., 1985), Schmidt and Cairncross (2009) concluded that the true effect size, for specifically home water treatment interventions are strongly biased. HWT affords very few non-health benefits, for example savings in time and costs, when compared to access to water and sanitation. The non-health benefits of implementing the latter interventions outweigh the benefits of HWT even when the disease reduction effected by water access or sanitation is small. Moreover, blinded studies (See Section 6.6 above) were unable to show evidence of a reduction in diarrhoea. Schmidt and

Cairncross therefore suggested that HWT intervention studies should either be blinded or include, as the primary outcome measure, an objective outcome such as mortality, weight gain, or growth. These types of measurements cannot easily be influenced by bias and therefore have the ability to show whether the effect size of HWT can truly be attributed to the intervention or not.

Our studies included measuring the height and weight of children and the length of babies. It must be noted that the measurements were undertaken by field workers with very little training in anthropometry and were recorded only four times over the year long trial. Instead of using the standard cut-off points of nutritional status usually calculated using the Z score relative to the reference population (WHO, 2006a), the recorded data were used to construct norms for height-for-age, weight-for-age and height-for-weight. Based on the developed norms and the median values for height and weight statistically significant differences were observed for the two measurements in children in Kenya. Although the change in height was only 1.3 cm and the weight 0.4 kg the importance of these findings in respect of the effectiveness of SODIS as a HWT cannot be denied.

6.8 WATER QUALITY AND HEALTH EFFECTS

Under controlled laboratory circumstances SODIS is a highly effective disinfection method for inactivating enteric pathogens and the subsequent provision of safe drinking water. Transferring this efficiency to the field seems difficult.

Although a reduction in *E. coli* counts were recorded during this study a clear relationship between the water quality and reduced non-dysentery and dysentery diarrhoea observed was not obviously evident. Intent to treat analysis showed a statistically significant difference in Kenya for *E. coli* counts. In South Africa only a small difference in water quality was observed between SODIS bottle water and storage water. We argued that carers that completed diarrhoeal diaries regularly would also be more motivated or compliant to do SODIS. We therefore, examined the relation of the water quality to compliance. The carers' response to the question "Did you put your bottles in the sun yesterday?" and the degree of *E. coli* contamination for those who did (compliers) and those that did not (non-compliers), showed a 0.5 $\log_{10}$ units (P=0.026) difference between compliers and non-compliers. In Kenya, compliance, assessed by whether the household had put out a SODIS bottle the previous day, was associated with a significant lower *E. coli* levels only for the second of three analyses rounds undertaken.

Several explanations for contradictory findings concerning general or non-dysentery diarrhoea have been addressed in the systematic review of health outcomes related to household water (Gundry et al., 2004). Like most published work in this regard thermotolerant coliforms (faecal coliforms and *E. coli*) had been used to determine the microbial water quality of water. These organisms have been the traditional indicators of a possible recent water contamination event by faeces. The presence of thermotolerant coliforms may, however, not be a good proxy measure for pathogens. Thermotolerant organisms in water show no correlation with the presence of enteric pathogens such as rota- and astro viruses, protozoan parasites and bacterial pathogens, for example, *Campylobacter* species, thus accounting for the apparent absence of a relationship between diarrhoea and thermotolerant organisms. Reporting bias by study participants and fieldworkers and changed hygiene behaviour, as a result of heightened awareness, could also explain contradictory findings. Two studies were designed to compare the effects of hygiene education on its own with hygiene education and water treatment (Wilson and Neveu, 1995; Luby et al., 1998). These studies suggested that whilst additional water treatment interventions undoubtedly improve water quality more than hygiene education alone, there may only be a slight reduction in diarrhoea associated with water treatment and education compared with hygiene education alone. However, the solar disinfection study of Conroy et al. (2001) showed that only those children who drank disinfected water were at lower risk of cholera. Household members in this study, that may have been influenced to change their hygiene behaviour, did not drink the SODIS water and showed no reduced risk to cholera. Other faecal-oral pathways, for example, contaminated food and hands, may contribute to a greater degree to diarrhoea illness than is expected. Black et al. (1982) related contaminated food with morbidity but not with bacterial counts in stored water, for instance.

Although re-contamination of the SODIS water was not examined in this study a possible source of re-contamination may have been unwashed drinking cups. Children enrolled in the three country study were advised to drink directly from the bottle which constitutes safe storage, but the younger children were still too weak and small to lift filled two-litre bottles to drink from them. They drank from cups and baby bottles. Clear instructions were given with regard to the cleanliness of these containers, why they become contaminated and how disinfected water is re-contaminated but control over this type of external contamination is nominal. Rufener et al. (2010) investigated critical points of re-contamination of SODIS water and found that *E. coli* counts from drinking cups were significantly higher than that of the SODIS water, negating the intended health benefits. The effect of recontamination could very possibly have contributed to diarrhoea incidence in this study.

Published SODIS intervention studies have assumed inactivation of waterborne bacteria by SODIS and therefore did not determine the quality at all during the intervention (Conroy et al., 1996) or only at baseline (Mäusezahl et al., 2009) or for a minimum number of water samples (Rose et al., 2006). Water quality measurements in the intervention study of Hobbins (2004) showed a notably high reduction in *E. coli* counts of 90%. Published data on chlorination (Quick et al., 2002) filtration (Clasen et al, 2004; Stauber et al., 2009) and boiling water (Rosa et al., 2010) in contrast have documented the quality of the water in detail.

The blinded studies showed efficient water quality improvement but insufficient diarrhoea reduction. Kirschoff et al. (1985) in a small blinded chlorination intervention recorded a considerable reduction in *E. coli* (90%) in the treated water but observed almost no decrease in the diarrhoea episodes in the participants. Jain et al. (2010) reported a similar observation for chlorination and so did Boisson et al. (2010) who conducted a one year double-blinded study in the Congo. A 99.8% reduction in thermotolerant coliforms were obtained in intervention households using the Lifestraw Family filter (Boisson et al 2010) but the effect was not translated to a reduction in diarrhoea in the intervention group.

In the light of the current debate and evidence gathered recently with regard to the effect of blinding on interventions, these obvious differences in outcome between the above-mentioned studies indeed seem to indicate that the SODIS water studies may have over-estimated the health outcome. An approximate 25% overestimation has been assigned to the absence of blinding and objective outcomes collectively (Wood et al. 2008). Adjusting the pooled effect from the HWT trials' current outcome for diarrhoeal reduction a protective effect of more than 30% indicated that in spite of much current doubt, HWT interventions do achieve a reasonable degree of health gains (Clasen, 2009). Within this context our studies, therefore, achieved a reduction in diarrhoea in spite of possible methodological shortcomings.

6.8.1 Stand pipes

Noteworthy is our findings in respect of standpipes. The water quality of stand pipes in South Africa was of a better microbial quality than any of the other water sources available to the participants during the trial. The effect of the better quality water, though not statistically significant, was subsequently reflected in a lower incidence rate in dysentery in children drinking tap water. This finding provides some evidence for the health benefit associated with access to an improved source.

6.9 INCREASING PARTICIPANT DISINTEREST

SODIS is an intervention that, to a large degree, depends on behavioural change in individuals and communities, specifically relating to acceptance and compliance. The latter is difficult to sustain, which in turn adversely affects the desired health outcome. The SODIS trials undertaken in the three countries in this study introduced SODIS by visiting individual households, a practice continued on regular bases throughout the study period. Nevertheless, the success rate for acceptance and adherence to the protocol was low in South Africa although considerably better in Kenya. Political upheaval in Zimbabwe completely undermined all efforts to initiate and sustain the study appropriately.

Examining possible causes for disinterest in the application of the method highlighted barriers often communicated by SODIS study participants, for example, the time it takes to fill the bottles, inadequate volume of disinfected water, shortage of PET bottles and disbelief that the sun actually disinfects water. A similar phenomenon has been observed in other intervention trials where high initial acceptance and compliance were observed just to gradually diminish as the studies progressed. The study period seems directly related to this phenomenon. Studies undertaken for shorter periods of time had higher acceptance and compliance than studies that were sustained for a year and longer. After one year only 32% of participants were compliant in the study of Mäusezahl et al. (2009) in their one-year study. Only 20% compliance was recorded for the study of Hobbins, (2004) which was also sustained for one year. In the six-month study of Rose et al. (2006) 75% compliance was reported. Interestingly in the study of Conroy et al. (1999), 50% of the households were still using SODIS a year after completion of the study.

Meierhofer and Landlot (2009) emphasised the importance of availability of bottles and that a single information event is not conducive to full engagement and sustained use. Educational level, social pressure related to acceptance of SODIS in the broader community and positive promoters further enhance the uptake of SODIS. In spite of rigorous adherence to these study design features, the drop-out rate recorded over a number of studies initiated worldwide since 2000 ranged from 20 to 80%.

Myriad factors can be mentioned that potentially influence the outcomes of intervention studies. It starts with the selection of the study site. It is important to take into account the degree to which a community perceives the need for clean water and the depth of understanding of the connection between their health status and poor water quality. Adopting an intervention such as SODIS to prevent some future diarrhoea event that may or may not happen holds very little incentive and consequently contributes to the slow rate of adoption and gradual disinterest over time (Heri et al., 2008; Rogers, 1959). Behavioural studies addressing aspects of persuasion (Kraemer and Mosler, 2009) and interpersonal strategies such as engaging promoters and opinion leaders (Tamas et al, 2009) have been shown to enhance acceptability of SODIS.

6.10 UNFORESEEN EVENTS

However well planned an intervention might be external factors not controllable by the field workers, promoters, coordinators or study design can arise unexpectedly. Both the Kenyan and Zimbabwean studies were seriously affected by political unrest and cultural practices. In addition, in Zimbabwe a cholera outbreak, concomitant with aggressive campaigns for use of a chlorine tablets to disinfect water, jeopardised the validity of the data.

6.11 STATISTICAL ANALYSIS: RATIONALE AND LIMITATIONS

The statistical analysis of the data is made complex by a number of features of the design and the actual data. Some of the difficulties experienced during this study is highlighted in the following sections.

6.11.1 Sampling issues

Recruitment of more than one child per household generated clustering within the data, since children within the same household shared environmental factors that may have affected health to a greater extent than children from different households within the same village. The effects of clustering causes under-estimation of the variability of measurements, and thus invalidate both the calculation of confidence intervals and statistical tests of significance, since both of these rely on estimates of the variability in the underlying population (the standard error). One solution is to analyse only aggregate data – in this case, to analyse village-level data. However, this would cause a loss of valuable information about the effect of the intervention on the individual child, which would greatly reduce the external validity of the trial.

The alternative is to apply a correction to the estimation of variance in the data which takes account of the clustering caused by the design. The method used was proposed independently by Huber (1967) and White (1980), whose contributions were synthesised by Binder (Binder 1983) and are implemented in Stata's-svy-routines. Huber-White estimators have a number of distinct advantages over alternative approaches such as multilevel modelling in situations in which the clustering variables are not of intrinsic interest (there is no purpose, for example, in examining interactions between solar disinfection and village). The first, and most important, is that the variables which drive the clustering need not be identified and measured. Secondly, the method keeps the false positive error rate to less than or equal to the specified level (normally 5%) but minimises the false negative error rate to approach the error rate which would have arisen from non-clustered data. The only requirement for the approach is that the primary sample unit be identified. This is the sample unit within which subsequent sample units are clustered.

In the data analysis for this study, the approach was stratification by district and to set the primary sample unit to village within district. The stratification afforded a cluster sampling design carried out independently in four districts.

6.11.2 Data issues

The second statistical issue that had to be dealt with arose from the nature of the data. While Poisson regression is a valuable tool in the analysis of rate data where rates are small, allowing presentation of effect sizes as incidence rate ratios, the Poisson distribution has only a single parameter which determines both its mean and its shape. In the diarrhoea data, attempts to fit a Poisson distribution revealed that the data had considerably more variation than predicted by a Poisson distribution. Specifically, more variability occurred among children with the same set of background factors than was expected under a Poisson distribution. This extra-Poisson variability is a feature of real-life data, and has prompted a number of proposed solutions, including the use of robust variance estimation methods such as the Huber-White method. However, a more general method exists – generalised negative binomial regression – which allows not simply correction for over-dispersion but to model the over-dispersion as a product of predictor variables. This refinement allows the analysis to reduce the total unexplained variation in the data, thus increasing the power of statistical tests of significance for treatment effects.

In the case of the South African data, a number of models were fitted before goodness of fit statistics showed a reasonable model fit. As might be expected, the variability in diarrhoea data was a function of the number of days of data recorded. Participants who were poorly motivated tended to return diaries which had obviously been completed all at once rather than day by day, with series of smiley faces indicating absence of diarrhoea, while well-motivated participants were more likely to return diaries that showed evidence of being completed day by day (different pens/pencils used, differences in size or orientation of tick marks). Other factors could have caused overdispersion, and we examined demographic data for possible candidates. The only variable which was associated with an indicator variable was the Kwarriekraal district.

The use of the generalised negative binomial regression model in conjunction with robust standard error estimation allowed a solution to the two most problematic features of the data: the clustered design and the over-dispersed data.

6.11.3 Analysis of *E. coli*

Analysis of *E coli* data presents some difficulties too. Not all water samples give an *E coli* count. Some samples will be above the maximum CFU count that is readable by the Colilert method, and some samples will yield no CFUs. Frequently, values in excess of the maximum readable concentration are treated as if they were equal to the maximum, causing under-estimation of mean values and of differences between groups where one group contains more excess values than the other. In converting CFUs to log units for analysis, the problem arises that zero has no definable logarithm. The solution adopted is often to add a small value to zero, such as 0.1 or 0.01. This is, however, arbitrary, and different means will result from different decisions.

The approach adopted here uses interval regression, a generalisation of Tobit regression. Interval regression allows values of the dependent variable to be censored within a defined interval. So, values above the maximum readable value are defined as falling in the interval between the maximum readable value and plus infinity, while readings of zero are treated as concentrations of less than one. This approach relies on the assumption that the distribution of CFU levels in the samples which gave above-maximum or zero readings follows the same distribution as the samples in the observable range – an assumption which, in the case of water quality data is reasonable. The use of interval regression allows for the accurate estimation of means and mean differences.

6.11.4 Limitations

While the study was powered to detect a difference in incidence rates, there are not sufficient data to examine one important question in the literature: the effect of time since the start of the trial on the effects of solar disinfection. In addition, the effect of time since the start of the study is confounded with participant motivation: the participants from whom there is long-term data are the better motivated participants (since the poorly motivated dropped out). Thus, an effect of time since randomisation cannot be separated from the effect of motivation.

While it would have been invaluable to have a valid and reliable measure of compliance, this was not possible without making frequent unannounced visits to the study site. Furthermore, the experience of field staff was that as soon as they arrived in a village, bottles would appear on roofs, making it unlikely that even this method would produce a valid compliance measure. The analysis had to be conducted using a factor which is termed 'motivation' – the proportion of diarrhoea diary days recorded – and which is possibly the best available surrogate measure of compliance with SODIS for this study.

6.12 CONCLUDING REMARKS

SODIS is a low cost simple point-of-use method proven to inactivate enteric pathogens in drinking water and subsequently reduce diarrhoea in humans. The randomised controlled SODIS health impact studies undertaken, in different settings during this project, confirmed its ability to protect against diarrhoea in children younger than 5 years of age. Importantly, the effectiveness of SODIS could be confirmed by the inclusion of an objective anthropometric metric, weight and height of children. This is an important finding in light of the ongoing debate with regard the lack of blinding of HWT interventions and questions raised with regard the true effect and effect size of intervention outcomes. The lack of significant effects found in only a few available blinded studies resulted in attributing the outcomes of un-blinded HWT point-of-use interventions to courtesy- reporting- or recall bias and the placebo effect.

For obvious reasons blinding was not considered as an option in our study design and similarly to most HWT interventions our study suffered from it to a certain degree in spite of randomisation. Dysentery and non dysentery diarrhoea data, for instance, were dependent on self reporting and courtesy bias was evident in at least the South African intervention. Future studies need to take cognisance of the importance of blinding and include it as a measure in their study design if possible, or at least have an objective counter metric, for example, morbidity or anthropometry.

The reduced levels of diarrhoea recorded in our study could not clearly be related to the quality of the water measured by the presence of *E. coli* as an indicator organism. The levels of diarrhoeal causing viruses and protozoan parasites, known to make a sizable contribution to the diarrhoeal burden in children were not determined for either the storage or SODIS bottle water. The possible additional diarrhoeal burden from these organisms therefore was unknown. Bearing in mind that SODIS has been shown to successfully inactivate such organisms it is possible that the reduction in diarrhoea reported in our studies could be in part be ascribed to the inactivation of such organisms. This is an important oversight that urgently needs addressing, not just for SODIS applications in the field but also for most HWT trials. Correlation of corresponding DNA patterns of pathogens isolated from the water and those isolated from diarrhoeal stool samples could provide further confirmation of the relationship between water contamination and waterborne disease. To enhance current understanding of why SODIS reduces diarrhoea without any seemingly sizable reduction in indicator organisms it is essential that research on the inactivation characteristics of SODIS of waterborne pathogens, especially viruses and parasites and some of the emerging bacterial organisms for example *Campylobacter* are investigated under situations typical of rural households. This will provide fundamental information currently lacking and may provide a better basis for future study designs.

Acceptance and adhering to the SODIS and other types of intervention methodology are closely related to the success or failure of an intervention. SODIS requires a substantial behaviour change before general acceptance becomes reality. The lack of immediate visible health effects hardly justify the effort and time spent on filling bottles and putting them out in the sun every day. Knowledge at the microbiological level, that is making the effect of SODIS visible to target communities will go a long way to enhanced acceptability and hopefully sustainability. Community meetings prior to the execution of intervention trials could provide opportunities for enhancement of knowledge of participants at this level. The 'seeing is believing' effect may prove invaluable for acceptability, compliance and sustainability.

Safe water intervention is aimed at minimising exposure to enteric pathogens in drinking water and to maintain exposure to such organisms to the minimum. This is inherently dependent on whether or not each of the following components of the causal pathway is in place and is maintained adequately (de Wilde et al., 2008):

- Drinking water is the main route of exposure to waterborne pathogens;
- The intervention provides adequate amounts of water;
- The population drink the safe water consistently and reliably;
- Water is protected from microbial contamination until it is ingested.

Intervention study designs should be based on these principles and adequate control measures should be in place and applied throughout the study to identify deviations that could affect the outcome of the study and to correct deviations early in the study.

Human behaviour is probably the most important deciding factor and almost the most difficult to deal with when it comes to the acceptance, compliance and sustainability of small and large scale interventions. Assessing the population dynamics including community capacity, community knowledge base, community preferences and household preferences of convenience, socio-economic status, the causal path of water contamination, water sanitation and hygiene levels, will provide an in depth understanding of the needs and how best to channel these in favour of an intervention.

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APPENDIX A

SODISWATER Field Manual

APPENDIX B

SODISWATER Diarrhoeal Diaries Entry Manual

APPENDIX C

Information leaflet and consent form

INFORMATION LEAFLET AND CONSENT FORM

Title of the research study: Solar Disinfection of Drinking Water for use in Developing Countries or in Emergency Situations

Title: SODISWATER
INCO-DEV: International cooperation with developing countries.
Contract Number:

Introduction:
We are researchers of the_____ (Name of institution)
We are doing this research as part of a bigger study funded by the European Union.

Name of Researcher/s: ____________________________________
Contact numbers: ____

Purpose of the study:
To investigate how well sunlight can purify water for drinking purposes. This will be done by observing whether children younger than five years that drink such water are healthier than those who do not. Health will be measured by how often they have diarrhoea.

How your household was selected
Your house is one of 400 houses selected with the help of your community leaders. Each house that was selected was given a number like this 1, 2, 3, 4, 5……400. All these numbers were mixed. The first 200 hundred that were picked are the households that will be asked to put their drinking water in the sun. The remaining 200 hundred will be asked to give their children ordinary drinking water the way they usually do.

Taking part: what it involves
If you (the carer/ parent) agree to participate, the following things will happen:

- You will have to answer some questions about how you live, and the water you drink.
- You will be asked to note, every day, when your young child/children or children you take care of have diarrhoea.
- Your children or the children you take care of which are part of the study will be asked to drink water purified by sunlight.
- The water you normally use for drinking in your house will be tested for the presence of bacteria that cause diarrhoea.
- The water purified by sunlight at your house will be tested for the presence of bacteria that cause diarrhoea.
- Your children or the children in your care will be weighed and their height measured.
- Taking part in the study cannot harm you or the children in any way.
- The study will take one year to complete. During this year we will visit your house every two weeks to collect information on diarrhoea. Information on the quality of the water will be collected every two months. The children's height and weight will also be recorded every two months.

Confidentiality:

- All information gathered during this study will be confidential and used only for research purposes.
- It will not be shared with anyone else.
- It will be stored in a way that protects your identity.
- Results from the study will be reported as group data and will not identify you in any way.
- Your identity and those of the children will be kept confidential at all times.

Questions:
If there is anything that you are not clear about, please feel free to ask one of us or contact us at the

contact numbers provided.
M du Preez 012 841 3950 Wouter le Roux 012 841 2189

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CONSENT TO PARTICIPATE IN SODISWATER RESEARCH STUDY
Title of research study:

Solar Disinfection of Drinking Water for use in Developing Countries or in Emergency Situations

Short Title: SODISWATER

I have been provided with an information sheet about this study. The information on the sheet has been explained to me. I understand what is involved in the study, and I agree to take part. I understand that I am free to withdraw from the study at any time.

Signature of Householder: ___________________ Date: ____________

Name: ________________

Signature of Researcher: ___________________ Date: ____________

Name: ________________

Signature of Witness: ___________________ Date: ____________

Name: ________________

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APPENDIX D

South African Community Feedback Poster

SODISWATER

Cleaning water with sunshine to make children healthy

The Aim

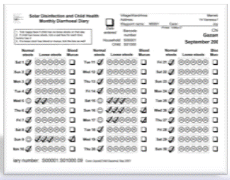

Bottles disinfecting in the sun …

… and 6 hours later safe to drink.

This poster reports on the South African part of a research project funded by the European Commission that also took place in Kenya and Zimbabwe.

The aim of the study was to determine whether drinking water disinfected in a bottle by the sun improved the health of young children. The number of times the children had **dysentery** (bloody diarrhoea) or **non-bloody diarrhoea** was used to indicate their health. A person has diarrhoea when they produce three loose stools in one day.

The Field Study



The study included 649 households with children between 6 months and 5 years old. 348 children were given SODIS bottles to put in the sun and drink from (these were the 'test group'). Another 438 children drank their usual water (these were the 'control group').

Using a handheld computer to capture the data

Child carers were asked to fill in a paper 'diarrhoeal diary' which recorded their children's stools every day, including whether or not it contained blood (which indicates dysentery).

Measuring weight, height and length

Analysing for *E. coli* in the laboratory

All children were visited four times over a period of one year (i.e. every three months). Their **weights and heights** (or **lengths** in very young children) were measured and samples of the household **storage water** and **SODIS bottle water** were collected. Data were captured on small handheld computers and downloaded onto the main database each day. The water samples were analysed in a laboratory for the bacterium *E. coli* which can cause dysentery and non-bloody diarrhoea.

The Results

The health of those children who drank SODIS water was compared with the health of those children who did not.

In South Africa it was found that when people used the SODIS method properly it reduced the number of times the children had dysentery. Those that did not use it properly did not have this health benefit. It may be that the South African participants thought their water was already of good quality and therefore did not feel that the SODIS method was necessary.

In South Africa it was found that the risk of dysentery in the children was less when:

1. Drinking water from standpipes (compared with those drinking water from other sources);
2. Water was poured from storage container (compared to using a scoop); and
3. There was access to a flush toilet (compared with those who did not have access to a toilet).

This information, however, has nothing to do with drinking SODIS water. It simply tells us about the normal dysentery risks when SODIS water is not used.

Helpful fieldworkers

In Kenya where the water was generally of worse quality and the people were much poorer, the SODIS method was shown to be very effective. It significantly reduced the number of times the children had dysentery and non-bloody diarrhoea.

Unfortunately, the **weight, height and length data** were not of good enough quality to establish whether or not they were affected by drinking the SODIS water.

Happy children

APPENDIX E

Peer reviewed publication