Impact and determinants of community-level SODIS-interventions: Experience from a community-randomised trial on solar water disinfection

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It is a matter of common knowledge that the acknowledgements section is one of the most read sections in a thesis. Thus, I thought it should include some main findings and conclusions:

- To implement this community-randomised trial (BoliviaWET), 38 intercontinental flights were necessary. This makes 478’040 air miles and a mileage of 26’890 litre Kerosene!
- Working 3 years with more than 26 rural communities of the Totora district makes you the top-selling godfather of approx. 1500 children.
- Coffee consumption during the course of obtaining a PhD is exorbitant. It is associated with an unexpectedly high financial investment (on average 2 cups/day is about 1825 sFr!)
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- Deciding to conduct a PhD, travelling to the other end of the world and live in rural communities in Bolivia for 3 years, conducting a community-randomised controlled trial in a crisis-ridden area, and finally writing a thesis is not possible without a social network, which leads me to the people and institutions I would like to acknowledge in this thesis.

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SUMMARY

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Unsafe drinking water, insufficient sanitation and hygiene behaviour and indoor air pollution are some of the most important environmental risks, which are harmful to health. They cause diarrhoea, pneumonia and sepsis, and are with 65% the leading cause of death in children under 5 years of age. Diarrhoeal disease due to unsafe water and lack of basic sanitation and hygiene claims every year the lives of more than 1.8 million people; 90% are children under 5. Lack of safe water perpetuates the cycle whereby poor populations become further disadvantaged and poverty entrenched.

With the Millennium Development Goals (MDG), 192 United Nations member states pledged to halve the proportion of people without sustainable access to safe drinking water and basic sanitation by 2015. The current strategies attempt to set realistic targets, develop achievable plans, and allocate adequate funding and resources to bring safe drinking water to the populations in need. Although the number of people without access to improved drinking water has dropped below one billion in 2005, WHO reports insufficient improvements in some countries and whole regions like sub-Sahara Africa.

The nowadays best known solution to solve the problems of safe drinking water provision, the instalment of communal water supply infrastructures, is costly and very complex. In addition, the direct handling of drinking water during transportation and at home can lead to contamination with pathogens. Hence, the WHO found an international network to promote household water treatment and safe storage suggesting that potentially billions of people could benefit from effective point-of-use household water treatment and safe storage systems (POU-HWT). Home-based solar water disinfection (SODIS) represents one of those POU-HWT systems that could potentially contribute to reach the MDG drinking water target.

The SODIS-method consists of exposing water-filled, transparent PET bottles to sunlight for at least 6 hours. The evidence base of the health effectiveness of SODIS from population-based scientific evaluations is limited and experiences from large-scale roll outs of SODIS interventions are equally scarce. The community-randomised trial described in this thesis investigates the health effectiveness and the factors that lead to the uptake of the intervention.

The main goal of this thesis was to assess the effectiveness of a Latin American community-level SODIS dissemination programme in reducing child diarrhoea and the determination of factors related to the adoption of SODIS among the population. A community-randomised controlled trial was thus, conducted in 22 community-clusters situated in the district of Totora (Province of Carrasco, Cochabamba Department) in Bolivia from 2004 to 2006. SODIS was implemented in the intervention communities by a local NGO (Project Concern International) during 15 months. The promotion of SODIS consisted of interactive, repeated, and standardised events hold on community and household level. The SODIS campaign involved district- and community stakeholders. In order to comprehensively describe both, application and uptake, and the health effect of SODIS, we established a health surveillance system with community-based staff measuring compliance with SODIS as well as the occurrence of diarrhoea in children under 5 and the general population. Since no standards to classify households according to their SODIS-use exist, we employed different indicators for use, which were measured by evaluators independent from the implementing NGO. Further surveys assessed relevant risk factors for child diarrhoea and identified household determinants as well as SODIS promotion and -campaign factors, which were associated with the SODIS adoption.

Despite the extensive SODIS promotion campaign a possible health impact in this typical rural Bolivian setting was too low to be assessed by this study. The intention-to-treat analysis of the 1-year health monitoring of 725 children <5 (425 households) detected no significant difference in diarrhoea morbidity between the intervention and the control communities. This finding is neither in line with the results of former trials assessing the health impact of SODIS, nor with the results of trials testing a variety of different other POU-HWT technologies. This inconclusive finding might be explained by the moderate compliance or the fact that most of the endemic diarrhoeal disease is not exclusively transmitted through the consumption of contaminated drinking water only, but rather transmitted from person to person by hands, food and other fomites due to poor hygiene practices. In fact, we registered faecal contamination in about 60% of the yards of participating households. Those risk factors could potentially have disguised the health effect of SODIS. In addition, the observed quantity of treated water provided by SODIS did not meet the requirements for consumption (hydration and food preparation) and basic hygiene and resulted in people using and consuming both, SODIS-treated and untreated water. Supposable a more ‘holistic’ approach including community water improvements, sanitation and hygiene may produce better health outcomes than SODIS as a POU-HWT alone.

During the project and before the cessation of the SODIS promotional activities we measured an overall compliance with the intervention of 32% at any given day during the study. The identification of SODIS-user by community-based staff relied on daily observations of the correct application, placing bottles in plain sunlight, or having bottles ready to drink in-house, and/or getting drinking water from a SODIS-bottle when asking household members for it. In contrast, around 80% of households reported using SODIS regularly after the first phase and again at the end of the implementation. The SODIS-implementing NGO observed an average SODIS-usage rate of 75%. The remarkable discrepancies of compliance with SODIS registered in our study when assessed by different staff raise questions of how to interpret the compliance rates of other published SODIS-effectiveness studies. The occurrence of bias due to self-reporting and courtesy of villagers resulting potentially in an over-estimation of SODIS-use could be prevented in future SODIS evaluations if assessed by independent agencies.

The continuous monitoring by our community-based staff of adoption, application, rejection and discontinuation of the SODIS intervention allowed the identification of household determinants and SODIS-campaign factors leading to adoption or rejection of the method among different SODIS-user groups. These evaluations are essential for a better understanding of the mechanisms involved in the acceptance of the method and may help targeting future SODIS implementations for household use. The analysis revealed that frequent SODIS-use is associated (i) with the presence of adolescent children at home, who may act as important vectors for the diffusion of SODIS among their families by being eager adopters of new ideas; (ii) with the need for caring for a child with an adverse nutritional status, which may increase the awareness of the household members on health issues; and (iii) with a more frequent exposure to the campaign, which indicates that pre-existing motivation of disinfecting drinking water is a positive predictor for the adoption of SODIS. When discussing factors limiting the uptake or the sustained use of the SODIS method, many adopters mentioned its laborious application and the limited amount of disinfected water provided by the method. In general, SODIS was described as an interim solution until the authorities bedight all communities with an own house-connection to the community water system.

In order to achieve a sustained health impact of public health significance by introducing POU-HWT, it is essential to assure its acceptance and long-term use. However, difficulties maintaining high post-implementation usage levels after cessation of intensive promotion, as in field trials and marketing campaigns, are widely reported from POU-HWT technologies. SODIS interventions need to achieve long-term health effects if a roll-out and scaling up of SODIS is considered. Thus the home-based SODIS application needs to be integrated into the daily routine as a regular habit independently of continued implementation efforts. To achieve this, sophisticated persuasive product marketing strategies need to be applied in order to establish the use of SODIS as a confirmed everyday habit. Considering the moderate success of widespread and promising POU-HWT systems especially when focusing on sustainability an exigency for innovative and locally developed concepts continues to exist. Stimulated by the moderate uptake of SODIS in our study and participants requesting more tangible benefits from our interventions we developed a technical solution which is socially accepted rather due to immediate convenience gains than to future health improvements. The concept unifies two technical solutions (a water purification device and an improved stove) to provide both, safe water and improved indoor air. In a pilot study the water disinfection stove (WADIS) indicates high efficacy in improving water quality and reducing indoor air pollution. The combined technical WADIS-device appears to be a promising solution for reducing common environmentally mediated diseases on a longer term. It is highly appreciated for its convenience by the users. Therefore, such a combined ‘pure-water/clean-air device’ as part of a well designed product marketing strategy may provide better health impact and sustained us than a single intervention.

In summary, this thesis demonstrates that the SODIS-method promoted in a typical rural Bolivian setting was not effective in reducing diarrhoeal disease in children under 5 years, despite a comprehensive SODIS-dissemination of a local non-governmental organisation. Unless the overall adoption and acceptance of POU-HWT methods, especially across broad levels of the population most in need will be considerably increased, the public health benefit and contribution toward achieving the MDGs will be modest. This research suggests that additional work is needed to better understand how the well-established laboratory efficacy of this POU-HWT method translates into field effectiveness under various cultural settings and intervention intensities. It is therefore, premature to widely promote SODIS without further evaluations of its health effect.

SINOPSIS

Agua no segura, deficientes o inexistentes condiciones sanitarias, hábitos higienicos insuficientes y aire contaminado en el interior de las viviendas son algunos de los factores ambientales más importantes que perjudican la salud. Enfermedades causadas por estos factores, como diarrea, pulmonía y sepsis son responsables del 65% de todos los casos de muerte entre recién nacidos y niños menores de cinco años. Cada año 1,8 millones de personas mueren a causa de la falta de acceso a agua potable, inexistentes facilidades sanitarias para la disposición segura de heces fecales y escasas condiciones higienicas. 90% de los cuales son niños menores de cinco años. La falta de acceso a agua potable pepetúa el ciclo por lo cual poblaciones pobres se vuelven mas desventajadas y la pobreza may estrechante

Con los objetivos del desarrollo del milenio (MDG), 192 miembros de las Naciones Unidas se comprometieron a, en el 2015 reducir por la mitad la proporcion de personas sin acceso sostenible a agua potable y sanidad basica. Las strategias actualmente usadas tienden a estableces metas realisticas, desarrollar planes alcanzables y asignar adecuadamente fondos y recursos para llevar agua potable a las poblaciones que en necesidad. A pesar de que el número de personas sin accesso a agua potable ha sido reducido a menos de un billon, en el 2005 la OMS informa de mejoramientos insuficientes en algunos paises y regiones como el Africa subsahariana.

Por el momento la mejor, pero mas constosa y compleja solución para al problema de proveimiento de agua segura es la instalacion de infrastructuras communales para distribución de agua. Adicionalmente, el manipuleo directo de agua potable al traspoortar el agua a las viviedas puede causar contamiación con patogenos. Por lo tanto, la OMC fundó una red intenacional para promover el tratamiento y almacenaje seguro de agua sugiriendo que potencialmente billones de personas podrian beneficiarse de este efectivo sistema de tratamiento y almacenamiento de agua de punto de uso (POU-HWT). El método casero de desinfección solar de agua (SODIS) es uno de esos sistemas de punto de uso que podría contribuir a alcanzar el objetivo de desarrollo del milenio con respecto a el agua potable.

El método SODIS consiste en exponer, botellas transparentes de plástico (PET), llenas de agua al sol durante por lo menos 6 horas. La evidencia en base al efecto de

SODIS en la salud de poblaciones es limitado. De la misma forma experiencias emergentes de grandes implementaciones de SODIS son escasas. El ensayo randomizado comunitario descrito en esta tesis investiga la efectividad en la salud y los factores que conducen a la adopción asic como una posible diseminación a mayor escala de la intervención.

La meta principal de esta tesis fue determinar la efectividad de la diseminacion del programa SODIS a nivel comunitario en America Latina a partir de la reducción de diarrea infantil, asi como la determinar los factores relacionados con la adopción del metodo SODIS en la población. De esta manera del 2004 al 2006 un ensayo comunitario alleatoreamente controlado fue conducido en 22 comunidades (clusters) en el distrito de Totora (Provincia Carrasco, Departamento de Cochabamba) en Bolivia. Durante 15 meses SODIS fue implementado en las comunidades de intervencion por una ONG local (Project Concern International). La promoción de SODIS consistio en eventos interactivos, repetidos y estandarizados que fueron conducidos a nivel comunitario y domiciliario. La campaña SODIS involucro actores distritales y comunitarios. Con el fin de describir comprensivamante ambos, la aplicacion y adopción asi como el effecto de SODIS en la salud establecimos un sistema de monitoreo de salud con personal con base en las comunidades, los mismos que median la conformidad con SODIS asi como la precencia de diarrea en niños menores de 5 y de la población en general. Debido a que no existen estandards, utilizamos diferentes factores de uso para clasificar los hogares de acuerdo al uso de SODIS, los mismos que fueron medidos por evaludores independientes a la ONG a cargo de la implementación. Consultas adicionales determinaron los factores de riesgo de diarrea infantil e identificaron determinantes caceras asi como factores de la campaña de SODIS que podrían ser asociados con la adopción de SODIS.

Pese a una campaña de promoción extensa un possible impacto en la salud en estas comunidades típicas de Bolivia fue muy bajo para ser determinado en este estudio. Los análisis por intencion de tratar de los resultados de un año de monitoreo de salud de 725 niños <25 (425 viviendas) detecto una diferencia no significante de la morbididad de enfermedades diarreicas entre las comunidades de intervencion y de control. Estos resultados no van en linea con resultados de estudios previos que determina el impacto en la salud de SODIS asi como tampoco con los resultados de de estudios examinando una variedad tecnologias POU-HWT. Estos resultados no concluyentes pueden ser explicados por la moderada aplicación del metodo o al hecho de que en su mayoría las enfermedades diarreicas endemicas no son exclusivamente transmitidas por medio de consumo de agua contaminada, sino tambien de persona a persona por la manos, la comida y otras formas de contagio debio a prácticas higienicas insuficientes. De hecho, registramos contaminación fecan en approximadamente 60% de los patios de las viviendas particpantes. Estos factores de riesgo podrian haber disminuido el effecto curativo de SODIS. Adicionalmente, observamos que la cantidad de agua tratada con SODIS no satisfacia los requerimientos de consumo (hidratación y preparación de comida) e higiene basica resultando en el consumo de ambos, agua SODIS asi como agua contaminada. Probablemente un enprendimeinto mas «holistico» incluyendo mejoramiento de agua domiciliario y de practicas de higiene habría producido mejores resultados que SODIS como unico POU-HWT.

Durante el proyecto y antes de cesar las actividades promocionales de SODIS la adopción general medida en un día cualquiera del estudio fue de 32%. La identificacion del usuario SODIS por medio del personal en las comunidades fue determinado en base a observaciones de la aplicacion correcta, la colocación de botellas al sol, o la posibilidad de ofrecer agua SODIS en el hogar durante la visita del personal del estudio. En contraste, al rededor de un 80% de viviendas reportó el uso regular de SODIS despues de la primera face y nuevamente al final de la implementación. La ONG a cargo de la implementación de SODIS observo un promedio de uso de SODIS de 75%. Esta discrepancia excepcional en nuestro estudio entre la adopción de SODIS registrada por diferente tipos de personal plantea la pregunta de como interpretar la adopción reportadas en previos estudios acerca de la efectividad de SODIS. La presencia de errores systemáticos debido al auto-reporte y la cortesía de los comunarios resulta probablemente en una sobre estimación del uso de SODIS, esto podría ser prevenido en futuras evaluaciones de SODIS al ser determinada por agencias independientes.

El monitoreo continuo de la adopción, aplicación, rechazo y uso descontinuado de SODIS por medio del personal en las comunidades, permitio la identificación de determinantes domiciliarias y de factores de la campaña SODIS que conduzen a la adopción o rechazo del método entre los diferentes grupos de usuarios SODIS. Estas evaluaciones son esenciales para un mejor entendimiento de los mecanismos involucrados en la aceptación del método y podrían ayudar a planificar futuras implementaciones de SODIS para el uso cacero. Los análisis revelaron que la frecuencia de uso de SODIS esta asociado con (i) la presencia de adolesentes en la familia, quienes podrían actuar como vectores importantes de difusión de SODIS entre los miembros de la familia por la ardua disponibilidad de adoptar nuevas ideas; (ii) la necesidad de cuidar a un niño de estado nutricional precario podría incrementar el conocimiento conciente de asuntos relacionados con salud entre los miembros de la vivienda; (iii) una exposición más frecuente a las campañas, la cual indica la motivación pre-existente para desinfectar agua para el consumo es una prediccion positiva para la adopción de SODIS. Al discutir factores que limitan la adopción o el uso sostenible del método SODOS, muchos usuarios mencionan la laboriosa aplicación y la cantidad limitada de agua desinfectada que el método provee. En general, SODIS ha sido descrito como una solución provisional hasta que las autoridades provean a todas las comunidades con una conección propia al sistema de agua potable comunitario.

Para poder alcanzar un impacto saludable sostenible significativo en salud publica por medio de la introducción de POU-HWT, es esencial asegurar su aceptación y uso a largo plazo. Sin embargo, dificultades en mantener altos niveles de uso después del término de la campaña, en esayos de campo asi como en campañas de marqueting de tecnologías POH-HWT han sido frecuentemente reportadas. Antes de considerar una diseminación o lanzamiento de SODIS, es necesario asegurar que los efectos saludables alcanzados por las intervenciones de SODIS sean de largo plazo. Asi la aplicación de SODIS en las viviendas necesita ser integrada a a rutina diaria como un hábito regular independientemente de los esfuerzos por continuar la implementación. Para alcanzar esto, estragias convincentes sofisticadas de marketing deben ser aplicadas, para que el uso de SODIS sea confirmado como un habito diario. Considerando el éxito moderado y poco prometedor de diseminación de sistemas POU-HWT, todavía continua existiendo, una exigencia de conceptos desarrollados localmente con especial enfoque especialmente en sostebilidad. Motivados mayormente por la adopción moderada de SODIS en nuestro estudio y por el requerimiento de los participantes de obtener un beneficio más palpable de nuestas intervenciones de uso sostenible, desarrollamos una solución técnica, la misma que fue rapidamente socialmente aceptada debido a efectos de conveniencia inmediata y no necesariamente a un posible mejoramiento de la salud en el futuro. El concepto unifica dos soluciones récnivas (un dispositivo depurificación de agua y una estufa mejorada) para proveer ambos, agua segura y mejor aire dentro de las viviendas. En un estudo piloto la estufa de desinfeción de agua (WADIS) indica alta eficacia al mejorar la calidad de qgua y al reducir la contaminacion del aire interior. El dispositivo tecnicamente combinado WADIS parece ser una solución prometedora para reducir a largo plazo enfermedades ambientales comunes. Es altamente apreciado por los usuarios debido a su conveniente uso. Por esta razón, un dispositivo de purificación de agua y de aire combinado como parte de una estrategia de marketing bien diseñada podría proveer un mejor y mas sostenible impacto a la salud que una intervención simple.

En resumen, esta tesis demuestra que el método SODIS promovido en un contexto rural típico en Bolivia no redujo efectivamente la enfermedades diarreicas en niños menores de 5 años, a pesar de la diseminación conprensiva de SODIS por medio de una organización no guvernamental local. A menos que la adopción y aceptación de métodos POU-HWT, especialmente atravez de amplios niceles de populaciones necesitadas, sean considerablemente incrementados, el beneficio de salud pública y la contribución para alcanzar los objerivos del milenio MDG seran modestos. Esta investigación sugiere que trabajo adicional es requerido para entender mejor como traducir la eficacio de los médotos POU-HWT bien establecido en el laboratorio en efecividad en el campo bajo contextos culturales variados e intensas intervenciones. Es por eso que una amplia diseminación de SODIS sin evaluaciones adicionales del impacto a la salud sería prematura.

ZUSAMMENFASSUNG

Unsauberes Trinkwasser, mangelhafte oder fehlende sanitäre Einrichtungen, unzureichende hygienische Bedingungen und Luftverschmutzung in Wohnräumen gehören zu den wichtigsten gesundheitsschädlichen Umweltfaktoren. Daraus resultierende Krankheiten, wie Durchfallerkrankungen, Lungenentzündungen und Sepsis, sind für 65% aller Todesfälle bei Neugeborenen und Kindern unter fünf Jahren verantwortlich. Jedes Jahr sterben aufgrund ungenügender Versorgung mit sauberem Trinkwasser, fehlender sanitärer Einrichtungen zur Fäkalienentsorgung und dürftiger Hygiene 1,8 Millionen Menschen. Davon sind mit 90% grösstenteils Kinder unter fünf Jahren betroffen. Aufgrund der wechselseitigen Beziehungen von beeinträchtigter Gesundheit und Armut, entsteht durch unsauberes Trinkwasser häufig ein Teufelskreis in den mehrheitlich armen Regionen dieser Welt.

Mit der Formulierung der Millenniumsziele zur Entwicklung und Armutsbekämpfung (MDG) im Jahre 2000, verpflichteten sich 192 Mitgliedstaaten der Vereinten Nationen unter anderem, den Anteil der Menschen ohne Zugang zu unbelastetem Trinkwasser und sanitären Infrastrukturen bis 2015 zu halbieren. Gegenwärtig werden Strategien ausgearbeitet und finanzielle Mittel bereitgestellt um diese Ziele zu verwirklichen. Das Hauptaugenmerk wird dabei auf die Formulierung realistischer Ziele und die Planung von weitreichenden und nachhaltigen Projekten gerichtet, die den am meisten Bedürftigen den Zugang zu sauberem Trinkwasser ermöglichen. Wie die Weltgesundheitsorganisation (WHO) vor kurzem berichtete, betrug die Anzahl der Menschen ohne Zugang zu sauberem Trinkwasser im Jahre 2005 erstmals weniger als eine Milliarde. Trotz dieser ermutigenden Meldung, konnte eine positive Entwicklung in den ärmsten und am stärksten betroffenen Regionen und Ländern dieser Welt, wie zum Beispiel in weiten Teilen Afrikas südlich der Sahara, nicht festgestellt werden.

Eine Möglichkeit um das Trinkwasserproblem zu lösen, besteht in der Errichtung von kommunalen Trinkwasserversorgungen. Jedoch ist dieser Ansatz zum einen sehr kostspielig und aufwändig, zum anderen kann das Wasser während dem Transport und bei der Handhabung im Haus mit Krankheitserregern kontaminiert werden. Infolgedessen hat die WHO ein internationales Netzwerk ins Leben gerufen, welches einfache im Haushalt angewandte Wasserdesinfektions- und Aufbewahrungsmethoden (HWD) weltweit etablieren soll. Davon würden Milliarden von Menschen auf einfache und effiziente Weise profitieren. Eine in diesem Zusammenhang häufig als vielversprechend erwähnte Methode, ist die solare Wasserdesinfektion (SODIS).

Bei der SODIS-Methode werden transparente, wassergefüllte PET-Flaschen für mindestens 6 Stunden der desinfizierenden Wirkung von UV-A Licht aus der Sonnenstrahlung ausgesetzt. Dabei werden – eine ausreichende Strahlungsintensität vorausgesetzt – verbreitete Krankheitserreger weitgehend abgetötet. Leider konnte die Wirksamkeit dieser Methode, die Gesundheit der betroffenen Bevölkerung merklich zu verbessern, bisher nicht zuverlässig nachgewiesen werden. Auch fehlen objektive Dokumentationen grossangelegter SODIS Kampagnen.

In der vorliegenden Dissertation werden die Ergebnisse einer randomisierten und kontrollierten Studie beschrieben, welche die Wirksamkeit von SODIS im ländlichen Bolivien eruiert. Auch wurden Faktoren identifiziert, welche die Akzeptanz dieser Methode beeinflussen. Diese Resultate geben Aufschluss über das Potential von grossangelegten SODIS Kampagnen. Die Studie wurde zwischen 2004 und 2006 in 22 Dörfern, des Totora Distrikts (in der Provinz Carrasco, Cochabamba, Bolivien) durchgeführt. Während 15 Monaten wurde die SODIS-Trinkwasseraufbereitung als neue Methode von der lokalen Nicht-Regierungsorganisation (NRO) Project Concern International, in 11 zufällig ausgewählten Dörfern eingeführt und verbreitet. Die SODIS Kampagne, die auf Dorfschaftsebene und in Haushalten durchgeführt wurde, beinhaltete standardisierte, interaktive und repetitive Aktivitäten mit dem Ziel, die Leute zu motivieren, die neue HWD-Methode regelmässig anzuwenden. Dabei wurden wichtige lokale Regierungsvertreter und Akteure der Bauernvereinigung, des Gesundheits- und Schulsystems und der Dorfgemeinschaften mit in die Aktivitäten einbezogen. Um die Auswirkungen auf die Gesundheit der Dorfbewohner und im speziellen auf Kinder unter fünf Jahren zu erfassen, wurde ein Gesundheits-Monitoring System in jedem Dorf aufgebaut. Parallel zum Gesundheits-Monitoring wurde wöchentlich, anhand von mehreren Indikatoren, die regelmässige Anwendung der SODIS Methode erfasst. Zudem wurden anhand von mehreren Erhebungen allgemeine Risikofaktoren für Durchfallerkrankungen, Haushaltscharakteristika, sowie SODIS-Promotionsfaktoren, welche mit der Benutzung von SODIS assoziiert werden können, erfasst.

Die Resultate der Studie konnten – trotz einer aufwändigen SODIS-Werbe- und Schulungskampagne in einem typisch Bolivianischen, ländlichen Siedlungsgebiet – keinen statistisch abgesicherten Gesundheitseffekt belegen. Eine „intention-to-treat“ Analyse, der während eines Jahres gesammelten Gesundheitsdaten von 725 Kindern unter fünf Jahren aus 425 Haushalten, zeigte einen nicht-signifikanten Unterschied in der relativen Durchfallhäufigkeit zwischen den Dörfern der SODIS-Interventions- und Kontrollgruppe (0.81; 95% CI 0.59 - 1.12). Diese Ergebnisse sind weder konsistent mit den Resultaten von zuvor durchgeführten SODIS-Studien, noch mit den Resultaten von Evaluationen zur Wirksamkeit anderer HWD-Methoden. Eine Ursache könnte darin bestehen, dass die meisten Durchfallerkrankungen nicht ausschliesslich durch unsauberes Trinkwasser übertragen werden. Alternative Übertragungswege können bei den relevanten Krankheitserregern eine wichtige Rolle spielen. Unter ungenügenden hygienischen Bedingungen erfolgt eine Infektion mehrheitlich durch Kontakt mit kontaminierten Oberflächen, von einer Person zur anderen, oder über kontaminiertes Essen. Wir registrierten in der Tat, dass ungefähr 60% der unmittelbaren Umgebung der Häuser mit Fäkalien verunreinigt waren. Diese zusätzlichen Risikofaktoren, könnten einem potentiell positiven Effekt von SODIS entgegengewirkt haben. Desweiteren muss bemerkt werden, dass die Menge an Wasser, die mit SODIS desinfiziert wurde, nicht den minimalen Bedarf an sauberem Wasser für den täglichen Gebrauch (Konsum, Nahrungszubereitung, Körperhygiene, etc.) decken konnte. Dies führte dazu, dass die Leute zusätzlich zum behandelten auch unsauberes Trinkwasser konsumierten. Eventuell hätte ein ganzheitlicher Ansatz, welcher auch die Verbesserung von kommunalen Wasserssystemen, sanitären Einrichtungen und Beratung zur verbesserter Hygiene mit beinhaltet, eine signifikante Gesundheitsverbesserung erzielt.

Über die gesamte Studiendauer, die von einer aktiven SODIS-Kampagne begleitet war, wurde eine korrekte Anwendung der Methode bei 32% der wöchentlichen Hausbesuche festgestellt. Das in den Dörfern angesiedelte Studienpersonal klassifizierte die beobachteten Hausehalte hinsichtlich ihres SODIS-Verhaltens. Dabei waren die folgenden Kriterien massgeblich, (i) ob die Plastikflaschen korrekt der Sonnenstrahlung exponiert wurden (ii) oder ob sich trinkbereite Flaschen mit desinfiziertem Wasser im Haus befanden und (iii) ob die Studienteilnehmer dem Interviewer SODIS-Wasser anbieten konnten, wenn diese danach gefragt haben. Bei einer direkten Befragung der Bewohner zu ihrem Verhalten zu Beginn und am Ende der Studie, gaben etwa 80% an, SODIS regelmässig anzuwenden. Die internen Beobachtungen der NRO ergaben eine durchschnittliche SODIS-Anwendung von 65-75%. Der markante Unterschied zwischen der vom NRO-Personal erhobenen Anwendungshäufigkeit und jener, die von unserem (unabhängigen) Personal vor Ort erfasst wurde, wirft die Frage auf, ob die Resultate in der bisherigen Literatur, die mehrheitlich auf selbst berichtetem Verhalten oder auf Einschätzungen der implementierenden Organisation basieren, nicht als zu optimistisch zu beurteilen sind. Werden Personen von der NRO direkt befragt, ob sie die Instruktionen zur Anwendung von SODIS befolgen, so muss mit einer Verzerrung der Ergebnisse, aufgrund falsch positiver Aussagen gerechnet werden. Dies könnte in zukünftigen SODIS-Studien vermindert werden, indem die Daten von unabhängigen Institutionen erhoben werden.

Das kontinuierliche Monitoring der korrekten Verwendung der SODIS Methode durch in den Dörfern stationiertem Personal, ermöglichte die Identifikation von beeinflussenden Faktoren seitens der Dorfbewohner und der Promotionskampagne, welche zur regelmässigen Anwendung, oder zur Ablehnung der SODIS-Methode führten. Die daraus gewonnen Erkenntnisse sind für das tiefere Verständnis der Akzeptanz von Trinkwasserinterventionen von besonderer Bedeutung. Auch können die Erkenntnisse dazu beitragen, bei künftigen SODIS-Kampagnen das Zielpublikum im Vorfeld zu identifizieren bei denen eine hohe Akzeptanz erwartet wird und, wenn nötig, die Implementierungsstrategie entsprechend der lokalen Bedingungen anzupassen. Die Resultate dieser Studie ergaben, (i) dass Heranwachsende, mit ihrer Offenheit gegenüber Neuem, als wichtiger Vektor für die Verbreitung von SODIS in der Gesellschaft fungieren können, (ii) dass Familien mit unterernährten Kindern eher bereit sind SODIS zu benützen, und (iii) dass eine häufigere Teilnahme an den Aktivitäten der SODIS-Kampagne zu einer häufigeren SODIS-Anwendung führen kann. Wurden die Dorfbewohner zu den Gründen befragt, welche gegen eine Anwendung der Methode sprechen, so wurde diese häufig als zu kompliziert und aufwändig beschrieben. Zusätzlich wurde die geringe Menge sauberen Wassers, die mit der Methode erzielt werden kann, bemängelt. Die meisten StudienteilnehmerInnen sahen SODIS als eine Zwischenlösung, bis zur Einrichtung einer permanenten kommunalen Wasserversorgung durch die Regierung oder private Institutionen.

Soll mit der Einführung von einer HWD-Methode eine merkliche Verbesserung der Gesundheit erreicht werden, so müssen die Akzeptanz und die regelmässige Anwendung der Methode über einen längeren Zeitraum gewährleistet sein. Allerdings wird gerade die begrenzte Nachhaltigkeit der Kampagnen nach deren Ende häufig kritisiert. Man muss davon ausgehen, dass SODIS im Zusammenhang der mangelnden Nachhaltigkeit keine Ausnahme darstellt, auch wenn bis jetzt keine verlässliche Informationen zur Verfügung stehen, die dies bestätigen würde. Eine Grundvoraussetzung für die erfolgreiche längerfristige Nutzung von SODIS besteht darin, dass die Methode ein Bestandteil der alltäglichen Routine wird. Dazu müssten ausgeklügelte Marketingstrategien angewendet werden. In Anbetracht der mässigen Erfolge, die bis anhin mit der Einführung von verfügbaren HWD-

Methoden über eine längere Zeit erzielt werden konnten, dürfen die Bemühungen, nach neuen innovativen technischen Lösungen zu suchen, nicht eingestellt werden. Inspiriert durch die oben erwähnten Einschränkungen der SODIS- und anderer HWD-Methoden, ist im Rahmen dieser Dissertation ein neues technisches Konzept entwickelt worden. Dieses wurde von den Versuchspersonen rasch aufgrund der mit diesem Konzept verbundenen Annehmlichkeiten und nur in zweiter Linie wegen der gesundheitlichen Vorzüge angenommen. Das innovative Konzept vereint zwei technische Komponenten in einem Kochherd, welcher gleichzeitig Wasser desinfiziert und der Raumluftverschmutzung entgegenwirkt. Der sogenannte "Wasser-Desinfektions-Ofen" (engl. water disinfection stove; WADIS) besitzt ein erhebliches Potential, um die Wasser- und Luftqualität mit einfachen und lokal verfügbaren Mitteln zu verbessern.

Die vorliegende Dissertation beschreibt die Wirksamkeit der allgemein als vielversprechend geltenden SODIS-Methode, die Gesundheit von Kindern unter fünf Jahren in einer realitätsnahen Studienumgebung zu verbessern. Die Ergebnisse deuten darauf hin, dass die Methode unter den Studienbedingungen, nicht eindeutig als wirksam bezeichnet werden kann. Vor allem solange die Akzeptanz der SODIS-Methode nicht verbessert und deren Anwendung nicht über eine längeren Zeitraum aufrechterhalten werden kann, ist ein überzeugender Beitrag zum Erreichen der MDG, als gering einzuschätzen. In Anbetracht dieser Erkenntnisse bedarf es weiterer Studien, wie die unter Laborbedingungen eindeutig nachgewiesene Wirksamkeit und Effizienz der SODIS-Methode nun auch als Gesundheitsverbesserung in der Bevölkerung erzielt werden kann. Solange dieses Wissen nicht vorliegt, ist es verfrüht, SODIS im grösseren Rahmen zur globalen Durchfallbekämpfung zu verbreiten.

"Hygiene, sanitation, and water for all still remain among the grand challenges for public health in the 21st century. The endeavours and achievements so far were a necessary, but far from sufficient, step along the way towards completing John Snow's unfinished agenda."

(Val Curtis & Sandy Cairncross, 2003)

PART I

Introduction to BoliviaWET: Background, objectives and methodological overview of the SODIS evaluation trial

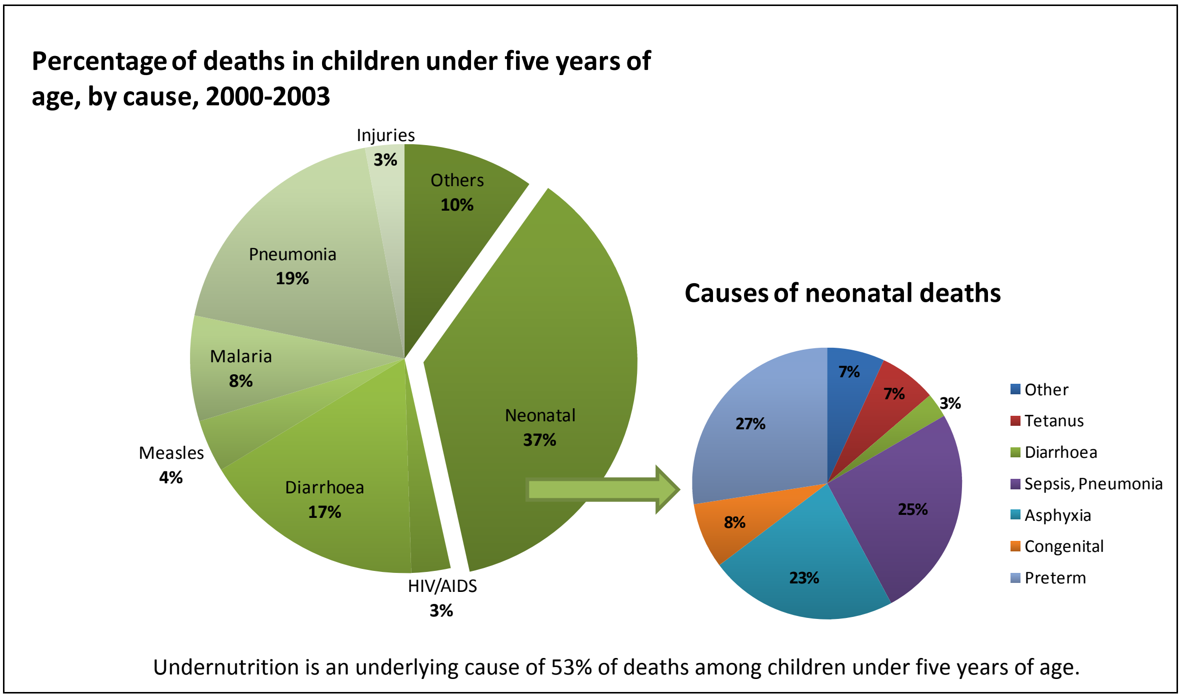
CHAPTER I:

Introduction

1. BACKGROUND

The environment consists of a variety of natural and built factors that may affect human health. Safe living environments and populations´ cognition of potential environmental risks are effective preventive measures reducing injuries, infectious diseases and death caused by adverse environmental health factors. Individuals can make certain choices that affect their lifestyle and health, but changing lifestyle to prevent exposures to health risks depends on the knowledge that certain environmental factors could affect health. This knowledge depends on effective health education provided by private or public authorities. However, protection from unsafe environments or the cognition and knowledge, how to prevent the exposure to health risks are often inexistent, especially in poor living settings, which are predominant in developing countries. Simple technologies and methods exist which can improve the living environment and have therefore the potential to prevent injuries, diseases and death and their underlying causes. Nevertheless, successful promotion and diffusion of preventive measures and knowledge how to reduce those environmental risks is complex and challenging.

Figure 1. Pneumonia and diarrhoea is a major child killer. Adapted from *Fuel for life: Household energy and health (WHO, 2006)*



There are hundreds of environmental risks that are harmful to health; and there are important implications for better understanding the disease burden they cause across the world. In this thesis we focus on few of the most important environmental health determinants, namely unsafe drinking water, insufficient sanitation, indoor air pollution and hygiene behaviour. Related adverse environmental risks can cause diarrhoea, pneumonia and sepsis, and are with 65% the major killer of neonatal and children under 5 (WHO, 2006) (Figure 1).

This thesis deals with the complexity and the results of implementing, monitoring and evaluating a household-based water and hygiene intervention in a rural setting of Bolivia. In the first section we provide a description of the contextual background of this study with an overview on the burden of water-, and excreta related diseases, the variety of water and hygiene interventions existing in this context, and the global achievements to reduce this disease burden. In the second, third and fourth sections we report on the effectiveness of the solar water disinfection method called SODIS, determinants for its adoption and use and present an alternative combined technology to disinfect water and improve indoor air quality simultaneously. In the last section we summarise and discuss the results of the previous sections by putting them in perspective to the United Nations' millennium development goals.

1.1. Water related and excreta-related diseases

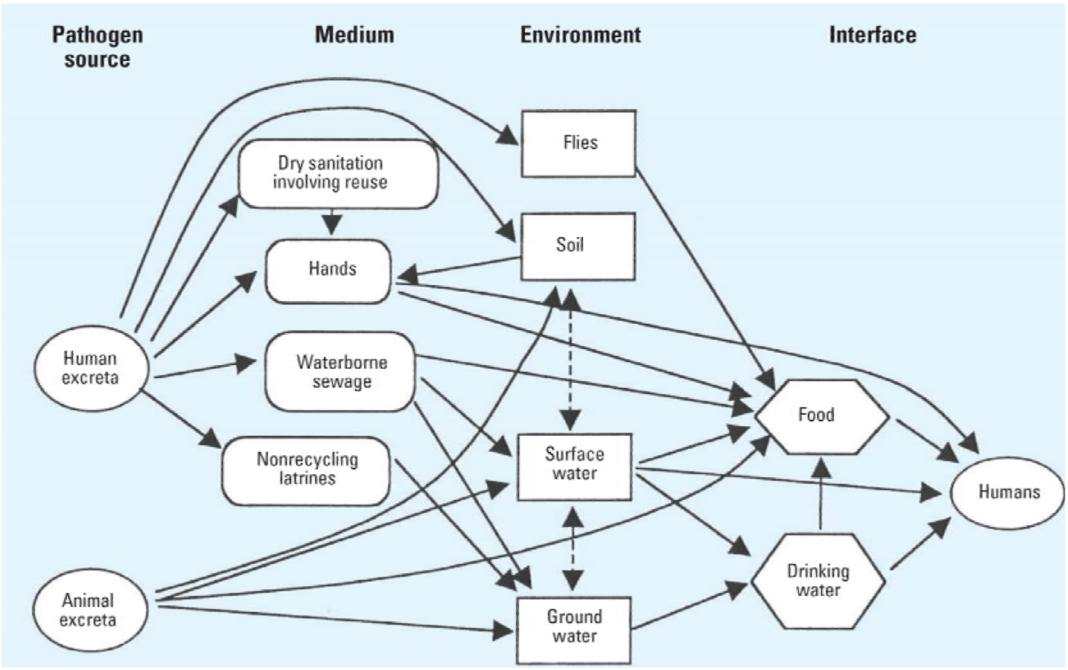
Safe drinking water, sanitation and good personal hygiene are fundamental to health, survival, growth and development. It is estimated that unsafe water and a lack of basic sanitation and hygiene every year claim the lives of more than 1.8 million people every year from diarrhoea; 90% are children under five years old. This amounts to 18% of all under-five deaths and means that more than 5,000 children are dying every day as a result of diarrhoeal diseases (WHO, 2005). Many millions children have their development disrupted and their health undermined by diarrhoeal or water-related diseases. In all, more than 1 billion people do not have access to drinking water from improved sources, while 2.6 billion are without basic sanitation – yet these foundations for healthy living are taken for granted by the majority of people on the planet (UNICEF, 2006b; WHO, 2004).

Undernutrition, which is associated with more than half of all under-five deaths (UNICEF, 2006a) is closely linked to diarrhoea. Infectious diseases and diarrhoea in particular, are the main determinants of wasting and stunting of growth in children in developing countries (Checkley et al. 2004).

Along with diarrhoeal disease, pneumonia takes more than 2 million of young children's lives every year (WHO, 2005), and recent studies suggest that hand washing with soap may help reduce the incidence of childhood pneumonia, as well as diarrhoea, in the developing world (Curtis and Cairncross, 2003; Luby et al. 2005).

There are a number of diseases related to unsafe water, poor sanitation and insufficient hygiene, whereas the disease causing pathogens are transmitted on the faecal-oral route. The faecal-oral route comprises a number of interrelated transmission pathways, which are enmeshed in our everyday habits (Figure 2).

Figure 2. Transmission pathways of faecal-oral disease (Pruss et al. 2002).



'Unsafe water, sanitation and hygiene' is considered to be the most important global risk factor for diarrhoeal illnesses and is among the three top risk factors of all illnesses in developing countries (Pruss et al. 2002). Eliminating the risk of diarrhoeal diseases through unsafe water, sanitation and hygiene could relieve developing countries of 4-5% of their entire disease burden (WHO, 2002).

Water as a single risk factor can affect faecal-oral disease transmission in two ways. One is through water-borne transmission, in which faecal contaminated water transmits the pathogen directly to the new host. Contaminated drinking water may expose large numbers of people simultaneously to infection and can cause dramatic epidemics. The second way is through water-washed transmission, caused by poor personal hygiene due to insufficient quantities of water for washing. Where water is scarce, it is very difficult to maintain clean hands, clean food, and the clean household environment is essential to control many of the other routes of faecal-oral transmission (Barry and Hughes, 2008). The various categories of water-related diseases, transmitted through water-borne, water-washed, water-based intermediate host, and water-related insect vectors, including diarrhoeal diseases, skin and eye infections, and the neglected tropical diseases are listed in table 1 (White et al. 1972).

Table 1. Bradley classification of water-related diseases (Barry and Hughes 2008), adapted from (White et al. 1972)

Mode of Transmission	Description	Examples
Waterborne	The pathogen is in water that is ingested or inhaled	Cholera Hepatitis A and E Noroviruses Typhoid fever Giardia Legionella
Water-washed	Person-to-person trans-mission occurs because of a lack of water for hand washing	Shigella dysentery Trachoma Scabies Acute respiratory infections
Water-based intermediate host	Transmission occurs by means of an aquatic intermediate host, such as a snail or copepod	Schistosomiasis Guinea worm
Water-breeding insect vector	Transmission occurs by means of insects that breed in water or bite near water	Dengue Malaria Trypanosomiasis

A similar classification exists for excreta-related diseases (Feachem et al. 1983) but are often used interchangeably for water-related diseases, such as the faecal-oral transmission route:

- faecal-oral,
- soil-transmitted helminths; include roundworm, whipworm and hookworm, which infections are transmitted when eggs are passed in human faeces,
- food-based tapeworms; tapeworms live in animal hosts and humans are infected when eating animal meat that is not sufficiently cooked, and,

- excreta-related insect vectors; includes mosquitoes, flies and cockroaches.

Kosek et al reviewed from the literature that child mortality from diarrhoeal diseases fell by more than 40% over the last four decades, whereas child morbidity from diarrhoeal diseases remained constant. Nevertheless, diarrhoeal diseases still account for about 21% of all child deaths (Kosek et al. 2003). Steady morbidity rates show that preventive measures could not keep pace with population growth, migration and impoverishment. However, the observed decrease in mortality during the last four decades seems to point towards a substantial improvement in access to and use of health care (Kosek et al. 2003). The following preventive measures and modern case management approaches may explain the decline in diarrhoea mortality:

- advising mothers to increase fluids and continue feeding during future episodes
- continuing breastfeeding and complementary foods during diarrhoea and increasing intake afterward
- counselling mothers to begin suitable home-prepared rehydration fluids immediately on the onset of diarrhoea
- treating mild to moderate dehydration early with oral rehydration solution (ORS), reserving intravenous electrolytes for severe dehydration

1.1.1. Diarrhoeal diseases

In the following part diarrhoeal disease is described in detail, since the here described study deals with the assessment of the effectiveness of one specific intervention preventing water-, and excreta related diseases, using diarrhoea as the outcome measure.

- *Defining diarrhoea*

The normal intestinal tract regulates the absorption and secretion of electrolytes and water to meet the body's physiological needs. More than 98% of the 10 litres per day of fluid entering the adult intestines are reabsorbed in the lower intestinal tract (Keusch 2001). The remaining water in the stool, is primarily related to the indigestible fibre content, and determines the consistency of normal faeces from dry, hard pellets to mushy, bulky stools, varying from person to person, day to day, and stool to stool (Keusch et al. 2006). This variation complicates the definition of diarrhoea. The frequent passage of formed stool is not diarrhoea (Black and Lanata, 2002). Although young breastfeed children tend to have five or more bowel movements per day, mothers know when the bowel movement pattern changes and their children are suffering by diarrhoea (Ronsmans et al. 1988).

The World Health Organization defines diarrhoea as follows: *'Diarrhoea is the passage of 3 or more loose or liquid stools per day, or more frequently than is normal for the individual'*. Nevertheless, Baqui and colleagues reviewed the diarrhoeal disease literature and revealed that the definition of diarrhoeal episodes varies considerable (Baqui et al. 1991). Hence, the choice of one definition of diarrhoea and episodes may lead to misclassification, may affect the estimates of the disease burden in communities, and impairs comparability of the findings from different studies. The definition of a diarrhoeal episode: '*three or more loose stools or any number of loose stools containing blood in a 24–hour period'* and separated by at least three diarrhoea symptom-free days seems to be the optimum to define a new episode (Baqui et al. 1991).

1.2. Preventive strategies to reduce the burden of diarrhoeal diseases

The Millennium Development target 7.3 calls "to halve the proportion of the population without sustainable access to safe drinking water and sustainable sanitation by 2015." WHO estimates that 94% of diarrhoea cases are preventable through modifications to the environment, including interventions to increase the availability of clean water, and to improve sanitation and hygiene (Prüss-Üstün and Corvalán, 2006). If the target 7.3 were met, health-related costs avoided would reach $7.3 billion per year, and the annual global value of adult working days gained as a result of less illness is estimated to be $750 million (Bartram J, Lancet 2005).

A 2005 systematic review of 46 studies (out of 2120) about water, sanitation, or hygiene interventions examining only the specific measure of diarrhoea morbidity as the health outcome concluded that most interventions significantly reduced the risks of diarrhoeal illnesses (Fewtrell et al. 2005). The overall degree of interventions' impact on diarrhoea (relative risk estimates) ranged between 0.63 and 0.75. Improving water supply reduced diarrhoea episodes by 25%, improving sanitation by 32%, and hand-washing by 45%. These results agree with those from previous reviews (Esrey et al. 1985; Esrey et al. 1991; Esrey and Habicht, 1986), but underscore that household water treatment and safe storage were found to be more effective (diarrhoea reduction: 39%) than previously thought. On the other hand, multiple interventions (consisting of combined water, sanitation, and hygiene measures) were not more effective than interventions with a single focus (Fewtrell et al. 2005).

A more recent (2006) Cochrane review of randomised and quasi-randomised controlled trials of interventions to improve the microbial quality of drinking water confirmed the key role of point-of-use (POU) water interventions in reducing diarrhoea episodes, reporting a reduction in diarrhoeal disease morbidity by roughly half, on average, with some studies resulting in disease reductions of 70% or more (Clasen et al. 2006; Clasen et al. 2007b). Both, Clasen and Fewtrell conclude that there is no cumulative effect enhancing effectiveness in combining interventions. The significant heterogeneity among these two reviews and the trials suggests that the level of effectiveness may depend on a variety of conditions that research to date cannot fully explain (Clasen et al. 2007a).

The most recent systematic literature reviews and analysis of specific interventions to reduce water-related diseases was published by Arnold and Colford, Aiello, and Ejemont. Arnold and Colford conducted a systematic review of studies that measured the effect of POU chlorine drinking water treatment. The intervention seems to significantly reduce the risk of child diarrhoea by 29% and reduces the risk of stored water contamination with *E.coli* by 80% (Arnold and Colford, 2007). The review from Aiello quantified the effect of hand-hygiene interventions and revealed that improvements in hand hygiene resulted in a 31% reduction of gastrointestinal illnesses and a 21% reduction in respiratory illnesses (Aiello et al. 2008). These findings are almost identical with the results from the Cochrane review of Ejemont (Ejemot et al. 2008) and in line with the results of the review from Curtis and Cairncross reporting that the risk of diarrhoea in children under the age of five could be reduced by almost one half through just improving hand-washing behaviour (Curtis and Cairncross, 2003). The expectation that at least two of the major disease burdens can be reduced considerably through hand hygiene, underlines the importance of ensuring basic hygiene services and access to safe water in under-served populations.

More traditional child health interventions - including breastfeeding, immunisation against diarrhoeal diseases, oral rehydration therapy (ORT), and micronutrient supplementation - have been shown to be both, effective and cost-effective in treating and preventing diarrhoea in a series of randomised trials (Hill et al. 2004).

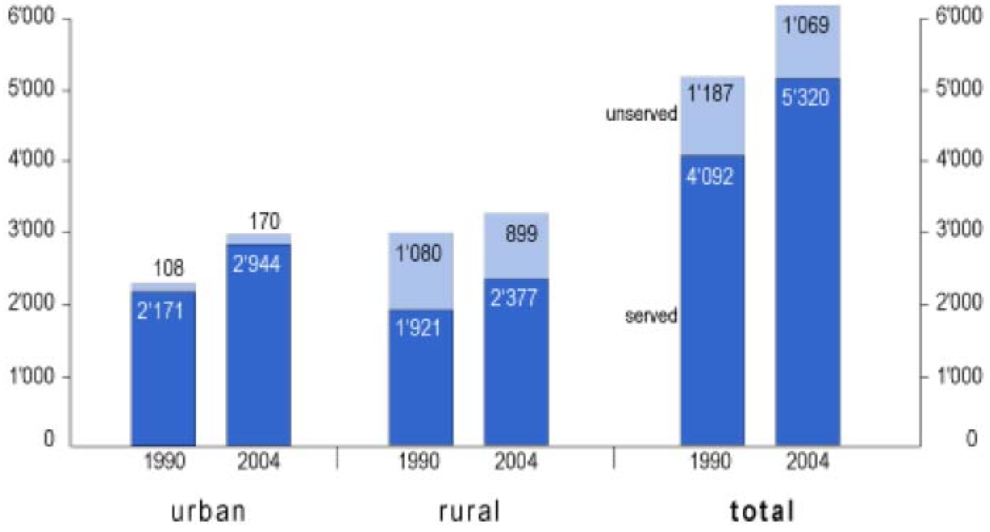
In conclusion, point-of-use household treatment and safe storage (POU-HWTS), handwashing, improved sanitation, improvement of access to and quality of water and fly control can block major transmission pathways associated with contracting diarrhoea in developing countries.

1.3. Improving access to safe water

The Millennium Development Goal (MDG) 7 stipulates as a third target that by 2015 the proportion of people without sustainable access to safe drinking water should be halved (United Nations General Assembly, 2000). However, advances toward achieving MDG 7 also positively impacts on other MDGs. Progress towards target 7.3 could contribute significantly to the reduction of child mortality (goal 4), improvement of maternal health (goal 5) and quality of life of slum populations (target 7.4). Additionally it may contribute to gender equality and empowers women (goal 3), and is linked to school enrolment and attendance, especially of girls (goal 2). Meeting the target would contribute to reducing poverty and hunger (goal 1) through use of water supply in agriculture, saving productive time in accessing closer water sources and sanitation facilities. Importantly, improved water supply and sanitation promotes economic equity since the disadvantaged tend to be the poorer and more vulnerable population segments (Hutton and Bartram, 2008). The most urgent issues relating to MDG 7 are the development of new strategies for scaling up the provision of and access to basic services, assuring their sustainability, safety and environmental compatibility.

The WHO/UNICEF Joint Monitoring Programme for Water Supply and Sanitation (JMP) provides statistics about the coverage of water supply and sanitation since 1990 at national, regional and global level and analyses trends towards the achievements of the MDGs (2015) (http://www.wssinfo.org/en/welcome.html). The last WHO/UNICEF JMP report showed that the number of people without improved drinking water has dropped below one billion, which means that more than half of the global population now benefits from piped water reaching their homes. The report also shows that the proportion of population using unimproved water supplies is decreasing (Figure 3). Nonetheless, some regions, such as sub-Saharan Africa are struggling to stay on track (WHO/UNICEF (JMP), 2008).

Figure 3. Water supply coverage in 1990 and 2004 (Global level) (WHO/UNICEF (JMP) 2008)



Population (in millions) served and not served with improved drinking water (total access)

WHO and UNICEF defined new indicators of *improved* water supply for the JMP. In general, improved water supplies should provide water of better quality and with greater convenience than traditional unimproved supplies (Table 2).

Table 2. Definitions of indicators for improved and unimproved water sources (WHO/UNICEF (JMP) 2000)

Improved drinking water sources	Unimproved drinking water sources
Household connection	Unprotected well
Public standpipe	Unprotected spring
Borehole	Rivers or ponds
Protected dug well	Vendor-provided water
Protected spring	Bottled water*
Rainwater collection	Tanker truck water

* Bottled water is not considered improved due to limitations in the potential quantity, not quality, of the water

However, simply providing improved access to water even where the water provided is of good quality appears to have little effect on health. In contrast, moving the same tap from the public site more proximal to the home, e.g. to the yard may produce a substantial reduction in diarrhoea morbidity because most endemic diarrhoeal diseases are transmitted by water-washed rather than waterborne routes (Cairncross and Valdmanis, 2006).

Another important aspect of improved water interventions is how its quality is perceived by its users. The perception of satisfactory water supplies various between individuals from different social classes, different cultures and countries. In rural Africa for example, a hand pump 500 meters from the household could be perceived as meeting the demands for adequate access to clean water in sufficient quantities. In contrast, most residents in urban Latin America may not consider themselves adequately served by an improved water supply unless a house connection is provided. Water supply is not a single, well-defined intervention, such as immunisation, but can be provided at various levels of service with varying benefits and differing costs (Cairncross and Valdmanis, 2006).

The MDGs, emphasise the safety of the services provided. The last JMP report does not identify the water quality component and the proportion of the population using safe drinking water can be assumed lower than the percentage using improved water sources (WHO/UNICEF, 2004). More people than reported using improved water sources consume contaminated water on a daily basis; and in addition to contamination occurring at the water source, inaccurate water handling in the home leads to secondary contamination of drinking water that places consumers at risk of waterborne diarrhoeal disease.

POU-HWTS were proclaimed as decentralised – and therefore promising – options for populations that cannot be reached by water systems in the near future, or continue drinking contaminated water after access to improved water supplies is provided (Mintz et al. 2001).

In conclusion, current strategies for providing people with access to improved water supply remains a matter of course to sustainably improve quality of life of people without this basic infrastructure. However, construction costs of water supplies are high in remote areas of low population density and with little perspective for economic growth (e.g. rural areas) and may therefore not be the best choice in the near future. A POU-HWT system that allows the disinfection of the water at the place where it is consumed may provide a low-cost, easy, and flexible interim solution for increasing drinking water quality and reducing waterborne diarrhoeal disease in the population in need.

1.4. Point-of-use household water treatment

The history of point-of-use drinking water treatment is dating back to 4000 years BC. A document written in Greek and Sanskrit describes the boiling and filtering of water, primarily to make it smell and taste better, although reducing visible particles and turbidity was also a goal (Barry and Hughes, 2008). 400 years BC Hippocrates invented the clothbag filter (or Hippocratic sleeve) and was among the first to believe that water filtering is healthful for the human body. It was then John Snow who proved after the famous cholera outbreak in 1854 in London that sand filtration and chlorination effectively prevents the spread of cholera. Now, 150 years later of acceptance of the health impact of unsafe drinking water, 884 million people still lack access to safe water, and 2,5 billion lack access to adequate sanitation (WHO/UNICEF (JMP), 2008).

To date a number of methods have been developed to improve water quality and to protect the microbiological integrity of water prior to consumption. These methods can be grouped into four main categories:

- Physical removal of pathogens (e.g. filtration, adsorption, or sedimentation).
- Chemical treatment to deactivate pathogens, most commonly with chlorine.
- Disinfection by heat (e.g. boiling or pasteurisation) and ultraviolet (UV) radiation, either using the sun (solar disinfection) or artificial UV sources.
- Combined approaches (e.g. filtration or flocculation combined with disinfection).

The quality of water can also be enhanced by protecting it from recontamination (e.g. residual disinfection, piped distribution, or safe storage). Systematic literature reviews and meta-analysis of health interventions to reduce diarrhoeal diseases found some evidence that POU-HWTS have the potential to improve health of people without safe drinking water supply (Aiello et al. 2008; Arnold and Colford, Jr., 2007; Clasen et al. 2006; Curtis and Cairncross, 2003; Ejemot et al. 2008; Fewtrell et al. 2005). However, Gundry et al. who reviewed the literature investigating the relationship of water quality at point-of-use and diarrhoea, trials of HWTS interventions has shown that diarrhoea had no clear association with point-of-use water quality (Gundry et al. 2004). A clear relationship with contaminated water was only found in case of cholera. Nevertheless, interventions did significantly reduce diarrhoeal incidence. Unfortunately, this review relies mainly on observational studies, contains only a limited number of studies, and fails to follow the guidelines for systematic reviews recommended by the Cochrane Collaboration and its Infectious Diseases Review Group (Clasen and Cairncross, 2004).

The reviews from Esrey and colleagues (Esrey et al. 1985; Esrey et al. 1991; Esrey and Habicht, 1986), ubiquitously cited in scientific journals and practical guides, led to the current dominant paradigm respecting water supply and sanitation interventions. The paradigm defines a simple and understandable priority to environmental health interventions for preventing diarrhoeal disease that greater attention should be given to sanitation and proper use of water for personal and domestic hygiene rather than to drinking-water quality. The recent systematic literature reviews and meta-analysis, however, called the validity of the dominant paradigm into question. The paradigm, which may not be wrong, should, however, be refined on the potential health impact of POU-HWTS interventions.

The promising findings from the most recent reviews on POU-HWT lead to the formation of the WHO-sponsored International Network for the Promotion of Safe Household Water Treatment and Storage. The network consists of a global collaboration of UN and bilateral agencies, NGO’s, research institutions and organisations and companies from the private sector committed to promote POU-HWT methods (http://www.who.int/household_water/network/).

WHO reviewed POU-HWT methods, with the objective of identifying the most promising methods (Sobsey, 2002). Criteria for the selection included: (a) high effectiveness in improving and maintaining microbial water quality; (b) significantly reduce water-borne infectious disease; (c) simple and accessible to the target population; (d) cost-effective for the beneficiary and provider; (e) socio-culturally acceptable, sustainable and with potential for large scale promotion. The following water treatment systems appeared to be the most widespread and promising:

- Boiling
- Solar disinfection by the combined action of heat and UV radiation
- Solar disinfection by heat alone ("solar cooking")
- UV disinfection with lamps
- Chlorination plus storage in an appropriate vessel
- Combined systems of chemical coagulation-filtration and chlorine disinfection.

Based on the above mentioned criteria, WHO earmarked solar water disinfection (UV and heat) and chlorination, including safe storage, as the most promising and effective household water treatment and storage systems to protect people from drinking contaminated water and diarrhoeal diseases (Sobsey, 2002).

Sobsey and colleagues recently published a review of those POU-HWT technologies, for which performance, efficacy and sustained use have been documented by microbiological efficacy and diarrhoeal impact studies (Sobsey et al. 2008). The critically reviewed technologies were chlorination with safe storage, combined coagulant-chlorine disinfection systems, solar disinfection (SODIS), ceramic filter and biosand filter. The publication revealed that except for boiling, none has so far achieved sustained, large-scale use. Surprisingly, ceramic and biosand household water filters were identified as the most effective according to the evaluation criteria applied. The two technologies also showed the greatest potential to become widely used and are sustainable for improving household water quality to reduce waterborne disease and death (Sobsey et al. 2008). The available evidence suggests that SODIS and chlorination do not achieve sustainable, long-term, continuous use by populations once the intervention studies end (Sobsey et al. 2008).

Nevertheless, SODIS remains appealing as one of the simplest technologies to apply without costs by using sunlight (UV-light and temperature) to disinfect water in freely available polyethylene terephthalate (PET) bottles. To date, efficacy of the method has been well documented (see below). However, effectiveness (actual result observed in “real life” situations) has not been evaluated so far.

The research presented in this thesis focused on SODIS; on i) estimating the effectiveness of SODIS in reducing the burden of diarrhoeal disease in a rural, Andean area in Bolivia; and ii) determining household and campaign factors determining the adoption and use of SODIS.

1.5. Solar Water Disinfection – SODIS

1.5.1. Technical aspects and efficacy of SODIS

SODIS is a simple technique essentially consisting of a disposable translucent plastic bottle (PET) of 1-2 litres volume in which pathogen-containing water is purified by the combining pathogen-inactivating effects of solar radiation of UV-A and light of wavelengths of 320-450nm (Acra et al. 1980; McGuigan et al. 1998; Wegelin et al. 1994). It is a point-of-use water treatment method that avoids secondary water contamination that commonly occurs through storage (Mintz et al. 2001).

Acra and colleagues from the American University of Beirut detected that coliform and other enteric bacteria (*Salmonella typhi*, *-enteritis*, *-paratyphi B* as well as

E.coli) were deactivated through exposure of plastic containers to sunlight (Acra et al. 1984; Acra et al. 1980). These promising findings motivated several research groups to assess the efficacy of the method on additional pathogenic organisms. Solar treatment not only reduces and inactivates *Vibrio cholerae* (McKenzie et al. 1992; Solarte et al. 1997), *Shigella dysenteriae* (Kehoe et al. 2004), *Salmonella typhimurium* (Smith et al. 2000), but also viruses (Dejung et al. 2007; Wegelin et al. 1994). Field experiments in Bolivia found an inactivation rate for *Giardia lamblia* and *Cryptosporidium parvum* ranging from 34% to 68%, depending mainly on the climatic region – efficacy was highest at high altitudes. These experiments confirmed previous laboratory simulations that *Cryptosporidium parvuum* was more resistant to sunlight than *Giardia lamblia*, and might not be easily destroyed by the SODIS process (Almanza, 2003; Oates et al. 2003; Zerbini, 2000). Current field research is examining the effect of sunlight on *Entamoeba histolytica* cysts in different regions of Bolivia.

More recently a study examined pH, turbidity and faecal contamination of drinking water from storage containers from 40 households in Nepal and tested the efficacy of SODIS in improving the water quality. The highly contaminated water was effectively treated at household level, although SODIS was only routinely adopted by 10% of participating households (Rainey and Harding, 2005).

For detailed information on the history of SODIS, it is referred to the Dissertation of Michael Hobbins (Hobbins, 2004).

1.5.2. Health impact of SODIS

The easy application of SODIS suggested promoting SODIS for emergency situations. However, the reduction of water contamination through sunlight exposure seemed to vary according to local conditions, such as altitude and intensity of ultraviolet light (McKenzie et al. 1992). After further evidence of the efficacy of the process "under the weak Irish sun" was provided (Joyce et al. 1992), Joyce and colleagues performed first experiments in Kenya under sub-optimal conditions (Joyce et al. 1996). Here, findings indicated that sunlight exposure of turbid water (~200NTU) effectively reduced indicator bacteria, if the water temperature was more than 55°C (Joyce et al. 1996). These studies led to two SODIS intervention trials and a post-cholera outbreak evaluation conducted by Conroy and colleagues among children in a secluded Maasai community in Kenya between 1994 and 1998 (Conroy et al. 1999; Conroy et al. 2001; Conroy et al. 1996).

In their first randomised controlled trial they reported a statistically significant 10% reduction in the incidence of diarrhoea and a 24% reduction of severe diarrhoea in the intervention group (Conroy et al. 1996). A subsequent and larger one-year study among Maasai children <5 years showed a similar reduction of 9.3% of diarrhoea (Conroy et al. 1999). With the occurrence of a cholera outbreak in their study area in 1997/98 the group was able to demonstrate the efficacy of solar water disinfection for cholera prevention in children below the age of 6 years but not in adolescents or adults (Conroy et al. 2001).

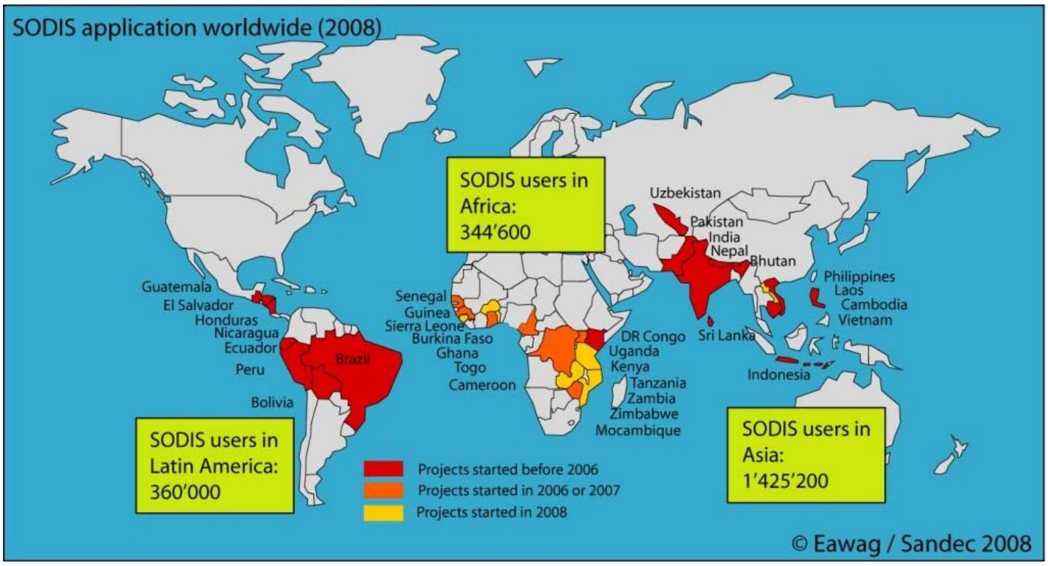
A study in an urban slum in Vellore, Tamil Nadu, registered a significant reduction of diarrhoea incidence (RR=0.64: CI 20.48 to 0.86) and a risk reduction of 40% in 100 children randomly selected for the SODIS intervention and compared with age and sex-matched controls (Rose et al. 2006).

In Conroys' and Roses' trials demonstrating the efficacy of SODIS in reducing diarrhoea in children under 5, steps were taken to ensure high compliance by household level re-enforcement (Conroy et al. 1999; Conroy et al. 1996; Rose et al. 2006). Thus, in order to demonstrate external validity, - a drawback of all previous randomised trials testing SODIS - randomised trials assessing the effectiveness of SODIS in reducing diarrhoeal diseases under real life conditions are required.

1.5.3. Diffusion of SODIS

SODIS as a simple and cheap technology is a promising strategy to provide safe drinking water at household level, and thus, to reduce diarrhoeal disease. Hence it is advocated and disseminated worldwide. The main driver for its dissemination is the Swiss Federal Institute of Aquatic Science and Technology (EAWAG), through the Department of Water and Sanitation in Developing Countries (SANDEC). It coordinates SODIS promotion projects in 37 countries (Figure 4).

Figure 4. Countries from Latin America, Africa and Asia where SODIS is implemented



Currently they report more than 2 million people are using SODIS (www.sodis.ch). Despite of its obvious advantages and considerable promotional activities, this innovation has had a limited uptake considering 25 years of dissemination. The aim of several studies was therefore to identify and understand factors affecting the diffusion of SODIS. A field study from Nicaragua, where 81 families in 2 communities were interviewed regarding their SODIS use, or non-use, respectively, reported that intention to use and actual use are related to a positive attitude toward the new technology (Altherr et al. 2008). More recent studies from Bolivia, applying the theory of the diffusion of innovations from Rogers (Rogers, 2003), revealed from 644 interviewed households exposed to previous SODIS campaigns that several factors, like good taste of treated water, cost savings, compatibility of the method with daily tasks, habits and household chores, perceived reduction in diarrhoea episodes, and participation at campaign events were positively related with SODIS use (Heri and Mosler, 2008). The second study investigated the influence patterns between groups predicting SODIS adoption (Moser and Mosler, 2008). Again, applying the diffusion of innovations model from Rogers Moser and Mosler analysed adoption dynamics and demonstrated that early adoption was predicted by increased involvement in the topic of drinking water, adoption in the middle of the diffusion process by recognition of majority of supported the technology and late adoption was characterized by recognition that the majority had SODIS already adopted (Moser and Mosler, 2008). The identified factors and determinants for SODIS adoption and use described in these studies do not seem to confirm that typical diffusion processes are taking place if SODIS is introduced to population under resource constraints.

So far, many different implementation strategies have been applied in different cultural settings by non-governmental organisations and by governmental ministries, including community mobilisation and school based interventions, as well as through household visits and specific motivational techniques. Nevertheless, the lack of reports on lessons learnt, and the lack of using standardised indicators for evaluating the success of SODIS implementations does not allow concluding on ideal implementation strategies.

1.6. Conclusion

This literature review about strategies to reduce the diarrhoeal disease burden due to unsafe drinking water highlights the potential and necessity of POU-HWT to reduce the risk of waterborne diseases in societies, where provision of safe water supplies at household level is difficult.

To reach the MDGs, the search for an effective and sustainable POU-HWT is ongoing. SODIS, with its simple and inexpensive application, promises to be one of the ideal candidates of a HWT method to reduce the risk of waterborne diarrhoeal disease at point-of-use. Indeed, global efforts are underway promoting SODIS as an environmentally sustainable, low-cost solution for household drinking water treatment and safe storage in 37 countries in Latin America, Africa and Asia (www.rcsi.ie/sodis). Despite this widespread promotion and the well documented efficacy of SODIS in disinfecting contaminated drinking water, conclusive evidence for the implementation and health effectiveness of the method is limited. The only three reported SODIS randomised controlled trials to date implemented the intervention at household level in highly controlled settings, that ensured very high compliance (Conroy et al. 1999; Conroy et al. 1996; Rose et al. 2006). Hence there is an urgent need for an extensive community-randomised intervention trial to assess its effectiveness – also because SODIS is typically rolled out through community rather than household level promotion.

Nonetheless, the effectiveness of SODIS in sustainably reducing diarrhoeal disease in areas of high risk of waterborne gastrointestinal illness depends largely on the adoption and regular use of the intervention and, thus, on behavioural change (Stanton and Clemens, 1987). Findings obtained from careful monitoring of implementation programmes can be used to develop successful strategies to disseminate new interventions

(Curtis et al. 1995). However, standardised success indicators needs to be established to disentangle the factors which lead to successful uptake and use of a POU-HWT intervention and to relate compliance to public health outcomes. There is a lack of, and hence a need for robust success indicators (or a combination thereof) that are applicable to specific contexts and contents to measure real changes in household water treatment behaviour.

If SODIS turns out to be an optimal choice for treating household water at point-of-use, it still provides only one measure to control one single main burden of disease (diarrhoea) that is largely preventable at household level. Indoor air pollution is the cause for the second most important disease burden (LARI) preventable at household level. Hence combining two interventions – an effective household drinking water treatment method and improved cooking stoves – in one technical solution could result in notable positive convenience and health benefits. Consequently, further research needs to be done to develop new, innovative, and attractive technologies reducing several disease burdens at once.

This background provides the rational for the research presented in this thesis: i) to estimate the effectiveness of SODIS in reducing the burden of diarrhoeal disease; ii) to identify household determinants and campaign factors influencing the adoption and regular use of SODIS, iii) and to present an alternative technology to disinfect water and improve indoor air quality at the same time.

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CHAPTER II:

Goals & Objectives

1. GOALS AND OBJECTIVES

The overall goal of this thesis was to assess the health impact of the solar water disinfection (SODIS) from a population-based evaluation and gain insight into the dynamics and determinants of the adoption process of SODIS at household and community level to inform potential future scaling up of SODIS.

1.1. General Objective

To achieve this goal the general objective of this thesis was to assess the effectiveness and determinants of an ongoing community-level intervention of home-based solar water disinfection method in rural Bolivia.

1.2. Specific Objectives

- To evaluate the effectiveness of home-based solar water disinfection (SODIS) in reducing diarrhoeal disease in children less than 5 years of age in rural Bolivian communities applying a community-randomised trial design.
- To develop and implement a morbidity surveillance system to assess the daily occurrence of child diarrhoea in rural communities of the Totora district, Bolivia.
- To develop and implement a SODIS implementation strategy for continuous evaluation and improvement of the implementation.
- To identify household determinants and SODIS campaign factors predicting SODIS adoption to develop future implementation strategies.
- To develop and apply SODIS-use indicators for measuring compliance with the water treatment method.
- To develop and pilot-test the water disinfection stove (WADIS) as an alternative for SODIS to improve household drinking water and indoor air quality

CHAPTER III:

The implementation of BoliviaWET: A methodological overview of the SODIS evaluation trial

3. BACKGROUND

The effectiveness of SODIS when applied to communities has not been rigorously evaluated so far. The limited information available on effectiveness of SODIS from three prior trials does not provide sound and generalisable conclusions on the health effects of SODIS under real world conditions (Conroy et al. 1999; Conroy et al. 1996; Rose et al. 2006). The Conroy trials were all conducted in the same single community where tight cultural norms force participants to adhere exclusively to the treatment (SODIS intervention). Thus, the results from these closely controlled trials reflect ideal 'experimental' conditions, and ignore potential inconsistencies in human behaviour (such as use of multiple sources of drinking water) and shortcomings that are expected in large scale programs and everyday life.

For the present study we employed several measures to assure a high internal and external validity. We chose a community-randomised trial design rather than a household- or individual randomised trial design primarily because SODIS is typically disseminated through community rather than household promotion. Differing from the above mentioned evaluations the SODIS intervention of this study was embedded in an ongoing SODIS dissemination programme in Bolivia. To assess the primary outcome measure (diarrhoea incidence) we set up a community-based health surveillance system monitoring daily occurrences of diarrhoea in the study subjects. Further, in assuring high quality data we employed data collection tools that were pretested for precision and accuracy. Those tools were applied by field workers which were extensively and continuously trained in specific data collection procedures. We devoted the biggest attention to the data collection and management processes.

On this note, this chapter documents the BoliviaWET (Bolivia Water Evaluation Trial) overall methodology and its innovative approaches that made the acquisition of high quality data in this community-cluster randomised trial possible.

3.1. Objective of the community-cluster randomised SODIS intervention trial

The primary goal of the BoliviaWET (Bolivia Water Evaluation Trial) was to assess the effectiveness of a comprehensive solar water disinfection (SODIS) promotion campaign to improve the health in rural Bolivian communities.

4. OVERVIEW OF THE DESIGN

The primary aim of the project was to evaluate the effectiveness of SODIS to reduce diarrhoea among children less than 5 years of age in rural Bolivian communities. To achieve this objective we conducted a pair-matched, cluster-randomised controlled trial (cRCT) following equal numbers of children in each of 22 community-clusters. Specific surveys assured the achievement of the specific objectives. The cRCT was divided into different phases, which are summarised below.

1. *District and community selection:* The eligibility of the Totora district was assessed by using national demographic and socio-economic statistics (national census; INE 2001). Additional eligibility criteria were rurality, population having limited access to safe drinking water, distance to collaborators operational premises, and availability of a functioning health system. 24 community-clusters from the selected Totora district were assessed for enrolment into the trial (selection criteria see Figure 5).
2. *Enrolment:* In each eligible community that gave consent to participate, households with children <5 years of age were identified by a screening survey. All households containing at least one child <5 and consenting to participate were enrolled.
3. *Baseline survey:* Health status of study subjects was monitored and demographic, socio-economic, and health risk factors were assessed during a 6-week baseline survey.
4. *Pair-matching:* The community-clusters were pair-matched on the incidence rate of baseline diarrhoea.
5. *Randomisation:* Within each pair of clusters, one cluster was randomly selected for the “treatment” arm and the counterpart for the “control” arm.

6. *Intervention:* The SODIS intervention was introduced to all households of each intervention community during a period of 15 months (3 months before the start of the diarrhoea follow-up survey and 12 months alongside the follow-up survey).
7. *Follow-up survey:* Enrolled children (all <5 years old at enrolment), were followed and monitored for the occurrence of diarrhoeal diseases over a period of 12 months. Data on diarrhoeal illness were obtained from weekly morbidity diaries kept by caregivers and through weekly home visits by project staff. Caregivers of participating children were interviewed not only at baseline but repeatedly during the trial with regard to current water management, behaviour and exposures of their children to environmental health factors.
8. *Post follow-up SODIS promotion:* For ethical reasons SODIS was implemented in control communities after follow-up survey has ended.

4.1. Study site

The study was conducted in the Totora district located in the province of Carrasco, one of the 16 provinces in the department of Cochabamba. Totora city is the capital of this region (approx. 1600 habitants). Community settlements are widely dispersed (in a radius of 30 km around the city of Totora) and found at altitudes between 1700 and 3400 metres. The number of inhabitants of the area is around 15600 (from which 2650 are children under 5 years of age) in 2900 households, with a number of inhabitants per household ranging between 2.4 and 9.8. The incidence of diarrhoea in children <5 years of age is estimated from different national studies at 4-5 episodes/child/year. (Prado and O'Ryan, 1994; Quick et al. 1996; Quick et al. 1999). Despite the small area covered by this district, each village has specific agroecological conditions (e.g. altitudes range from 1700 to 3400 metres). Market access varies, as well as their pattern of settlement (concentrated versus dispersed) and type of organization. The majority are subsistence farmers with small parcels of land who grow a variety of crops – main crops are potatoes, wheat and maize – for their own consumption and for marketing. They keep some livestock (chicken, goats, sheep and sometimes cows). The income is usually supplemented by seasonal migratory labour. During a few months of the year they work as building labourers in the Totora town and area, as agricultural labourers and men often work in the coca plantation in the tropical areas of the district. Some households receive an additional income from a broad range of ancillary activities, or provide intra-community supply services like natural healers or communal politicians.

The communities are situated in an area that is unsuitable for well sinking but offers good conditions for gravity water supplies. However, rural water supply coverage is low: 68% of households consume water from a source which is considered as unsafe (Daigl et al. 2008; *Manuscript* II)

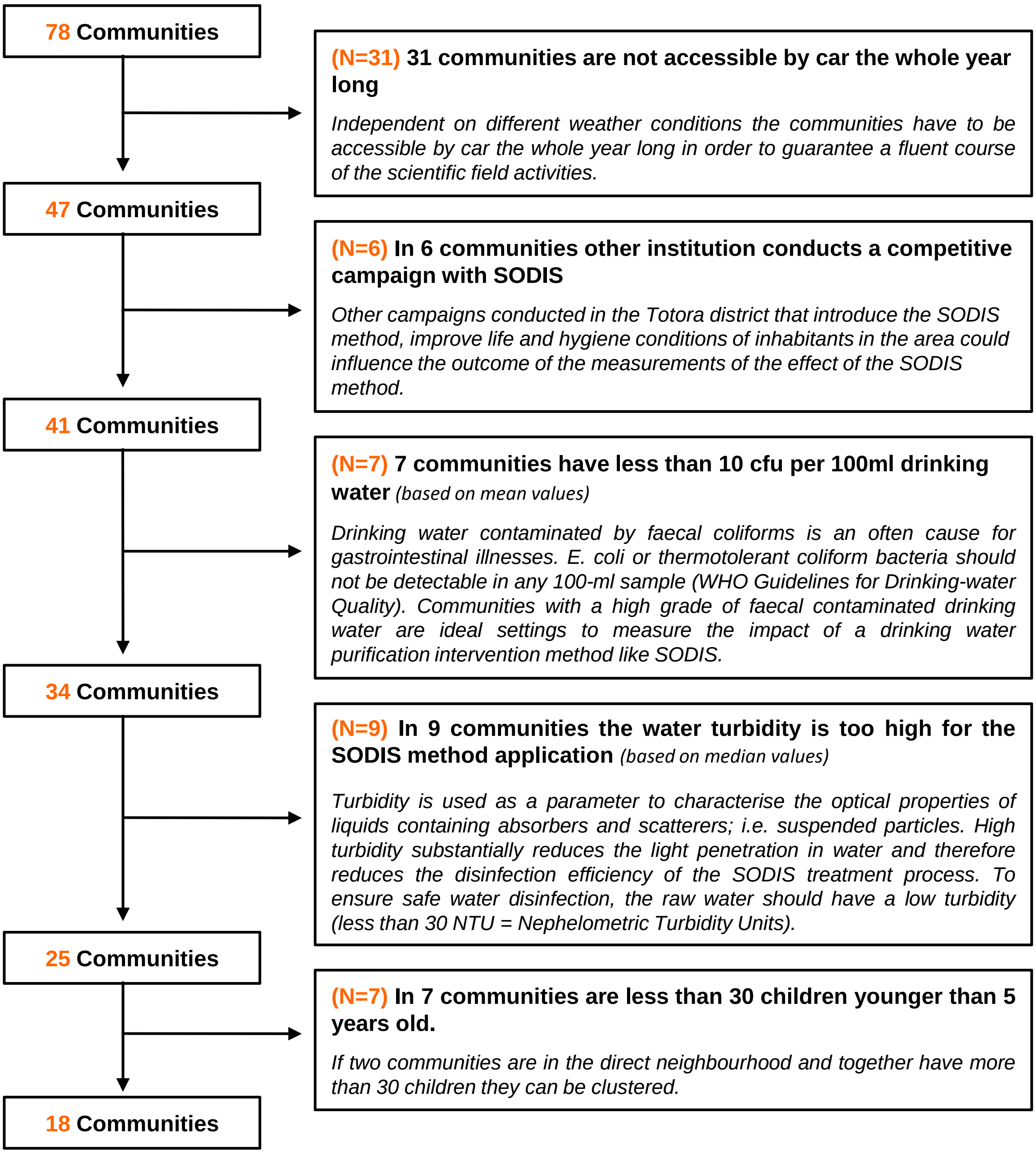
4.2. Community-cluster selection

A total of 79 communities from the rural Bolivian highlands of the Totora district were identified for the study. The communities were selected based on the following eligibility criteria:

- *All-year accessibility:* Communities had to be accessible by car the whole year long independent on different weather conditions in order to guarantee continuity during data collection.
- *No other health-related intervention programmes during the study:* Communities anticipated no health-related interventions other than those of the Latin American SODIS programme (as documented in the village water and sanitation development plans and discussed with the municipality or other NGOs), since competitive campaigns might act as potential confounders.
- *Evidence for faecal contamination of household stored drinking water*: Communities with a median of more than 10 faecal coliforms/100 ml household stored drinking. Communities with a high level of faecal contaminated drinking water comprise ideal settings to measure the impact of a drinking water purification intervention method like SODIS.
- *Acceptable levels of water turbidity so that the SODIS method represents a valid mean of disinfection and safe storage of drinking water:* To ensure safe disinfection, communities must comprise drinking water with less or equal a median of 30 Nephelometric Turbidity Units (NTU).
- *At least 30 children <5 years of age per village:* The necessary sample size for study children per community cluster was 30 to detect a meaningful health impact of the intervention.

In 2004 a survey was carried out in the Totora district to select communities based on the above mentioned eligibility criteria. 18 communities matched the criteria and were eligible for selection (see Figure 5). In order to reach the necessary number of 22 community-clusters the selection criteria for the water contamination was adjusted from the median number of 3 CFU/100ml to 10 CFU/100ml water resulting in 24 eligible communities. In addition two pairs of neighbouring communities with less than 30 children were merged in order to have 22 community-clusters with at least 30 children each.

Figure 5. Community-cluster selection flow-chart: 22 community-clusters out of 78 communities of the Totora district selected for the SODIS community-cluster randomised trial, Bolivia.



4.3. Enrolment

4.3.1. Community enrolment

After the selection of communities, authorities were contacted and asked to organise a community meeting in order to introduce the BoliviaWET study to all community members. The study director (AC) and a representative of the Totora municipality jointly presented the principal aims and phases of the study. Each collaborator of the project was introduced and its role elucidated. Subsequently the community voted whether to participate or not. If the community decided to participate three identical consent forms were signed by the community head, study director and the representative of the municipality witnessing the consent. One copy remained with the community archives, one was handed over to the municipality and one to the study director. All selected communities (24) gave consent to participate.

Involving communities in scientific studies implies to formalise collaboration by embedding scientific requirements to local systems, cultures, and rules. Obtaining community consent depends on the acceptance of staff representing the institution and institutions' mandate. Collaboration with central authorities, in particular, and district- and community leaders, prior to approaching study participants substantially facilitates successful project implementation.

4.3.2. Informed consent and study participant enrolment

After the community leaders gave consent to participate in the BoliviaWET study a demographical survey was carried out in the 22 community-clusters to identify eligible households with children less than 5 years of age and permanently living in the community. Field staff visited each household to provide detailed information about the study. Research procedures were explained to parents of potential study participants on an information sheet written in simple language and illustrated by using a booklet with drawings that was comprehensible by the potential participant. Subsequently, informed consent was requested from all eligible parents willing to participate or – in case that parents are permanently absent – the closest caregiver. The consent form contained all information about the design of the study, activities involved when participating and potential risks and benefits. For illiterate candidates the main study activities were explained by using the illustrated booklet showing the research procedures. Before asking for consent to participate candidates were asked standardised questions about key study procedures in order to verify if they understood the given information. Afterwards, the consent was read to them and they were asked to provide permission verbally in front of two witnesses. Signatures of both parents and all adult household members living permanently in the household were required. If the consent form was not completed during the first visit field staff arranged for follow-up meetings until household accepted or refused to participate. The informed consent was supplemented by an enrolment questionnaire. A sub-sample of 220 children (10 per community) was randomly selected to participate in a stool specimen- and household stored drinking water sampling survey. Results of the enrolment and participants' flow diagram are presented in *Manuscript I.*

4.4. Primary outcome

Primary outcome was incidence rate of diarrhoea among children, defined as number of diarrhoea episodes per child and year at risk obtained from daily assessment of individual diarrhoea occurrence. We applied the WHO definition for a diarrhoea episode of three or more watery bowel movements or at least 1 mucous/bloody stool within 24 hours with a 3-days symptom-free period between two episodes. Diarrhoea was reported by closest caregiver using the vernacular term K'echalera which corresponds to the WHO definition of diarrhoea as has been previously established (Hobbins 2004). The primary outcome is described in *Manuscript I* in further detail.

4.5. Secondary outcome measure

4.5.1. Diarrhoea prevalence and severe diarrhoea

For a complementary analysis we calculated the percentage of person-days with diarrhoea calculated as the sum of the number of days each child suffered from diarrhoea divided by the total number of days of observation. In addition we used a longitudinal prevalence measure because of its close relation to severity, growth faltering and mortality (Morris et al. 1996). Severe diarrhoea was defined as suffering from diarrhoea on more than 10% of the observed days to compare results with those of others (Luby et al. 2006). An episode of diarrhoea was labelled 'dysentery' if signs of mucus or blood in the stool were recorded at any time. Results are presented in *Manuscript I*.

4.5.2. Gastrointestinal infection status

Stool samples from a random sample of 220 children were collected and analysed to elucidate three issues of particular interest in the current setting: i) the prevalence of asymptomatic bacterial, viral and parasitic infections in rural Bolivian children, ii) the proportion of diarrhoea attributable to infection in the different treatment arms, and iii) the pathogen-specific attributable risk for diarrhoea. (NB. the stool sampling and analysis were part of the field work but findings of this component are not part of this thesis).

4.6. Covariates

4.6.1. Socio-demographic and environmental characteristics

To characterise the study population and to describe the effects of randomisation and comparability of the control and intervention arm we collected information on socio-demographic and environmental factors such as age, sex, household size, socio-economic status, and water and sanitation conditions.

4.6.2. Exposure to risk factors

To be able to describe and assess possible transmission pathways data were collected on different pathways that account for transmission occurring within the household, between households, and at community-level. Within the household and in communal settings such as schools, play areas, and bathing sites we assessed environmental and behavioural factors for the person-to-person transmission. Environmental-to-person transmission was assessed measuring the exposure to faecally contaminated home environments, food stuff, and water. Information about hygiene- and general behaviour and poor sanitation was collected to describe person-to-environmental pathways that account for transmission of pathogens to the environment.

4.6.3. Drinking water quality

Systematic monitoring of water quality of water sources and of household water ready-to-drink was conducted in order to describe the potential risk of waterborne diarrhoeal illness. Indicators such as total coliforms, faecal coliforms, including *Escherichia coli*, bacteriophages and protozoan parasites (*Cryptosporidium parvuum* and *Giardia lamblia*) were used to assess the microbiological water contamination. Bacteriophages (F-RNA-coliphages) were used as indicators for viral contamination and faecal Streptococci (*Streptococcus faecalis*) was used to assess the source of contamination (human or animal). Given the frequent identification of *G. lamblia* in indigenous children (Cancrini et al. 1988, Quick et al. 1999) we tested one main water source per community qualitatively for the presence of *G. lamblia* and *C. parvum.*

4.6.4. Compliance with the SODIS intervention

A valid assessment of the compliance with the SODIS intervention requires complete monitoring of SODIS-use over the entire study period. This information is needed to relate study subjects' health to the level of SODIS-use.

There are several challenges associated with measuring SODIS compliance. The limited amounts of water that can be treated with the SODIS method may result in people using and possibly consuming both SODIS-treated and untreated water (Altherr et al. 2008; Rose et al. 2006). A limitation of assessing compliance with SODIS is the lack of a reliable SODIS-use indicator. Therefore we identified and applied a broad definition of households' SODIS use, combining a number of indicators that capture signs of use as well as behavioural aspect use. Aspects of assessing SODIS compliance are further discussed in *Manuscript II*, *III* and in the *Part V* of this thesis.

4.6.5. Economics related to health costs and SODIS programme costs

The overall aim of collecting this information was to estimate the unit cost for averting one episode of diarrhoea by SODIS. In addition we collected information to describe net savings for a household per episode of diarrhoea averted. We collected data on following parameters: a.) direct costs for medication, care services, or transportation, b.) indirect costs of caregiver-time lost from work due to caring for the sick child, c.) time lost for transportation and d.) time lost for a visit (waiting and treatment). Assessed programme costs include the following costs: a.) for community building/training for the use of SODIS, b.) for actual costs of the SODIS bottles, and c.) their distribution. (NB. Data collection related to the SODIS cost-effectiveness analysis (CEA) was part of the field work but the CEA is not part of this thesis.).

4.7. Sample size

Sample size was calculated according to methods outlined by Hayes and Bennett (Hayes and Bennett 1999) assuming an incidence rate in the control communities of 5 episodes/child/year, and accounting for clustering, the number of episodes, and the expected effect.

We assumed a coefficient of between-cluster variability of similar studies, between 0.1–0.25 (as cited by Hayes and Bennett, 1999) and a minimum of 10 child-years of observation per cluster. We calculated that 9 pairs of clusters were required to detect a difference of at least 33% in the incidence rate between the control and intervention arms (significant public health impact and comparable to achievements of other well designed national diarrhoeal disease control programmes in developing countries (Huttly et al. 1997; Stanton et al. 1987)) with 80% power, k= 0.20 and an alpha level of 0.05. Anticipating a drop-out of at least one cluster per arm and a loss of follow-up of individuals, the final sample size was adjusted to 11 pairs of clusters with 30 children per cluster.

5. RANDOMISATION

We matched community-clusters on the pre-intervention cluster diarrhoea rates given the small number of clusters (Murray 1998). The intervention was then assigned randomly to one community within each of the 11 consecutive pairs. This was done in a public event because key political stakeholders were worried about possible backlash, public outcry, or drop-off in group participation that would result from providing some members with a new benefit while others got "nothing". It was agreed that a public drawing event was necessary to increase perceived fairness among the participating district- and municipal authorities. Three authorities, - the district head (Alcalde), a representative of the Ministries of Health and Education, and the deputy of the farmers union (Central Campesina)-, each drew one of two balls (with community codes inscribed that were randomly assigned beforehand) representing paired communities from a concealed box. It was agreed that the first draw assigned the community to the intervention arm. The group allocation was immediately recorded in a protocol by an independent witness. Subsequently, the witness disclosed the sequence, informed the community members and the authorities present in the town hall and all drawers signed the protocol. Copies of the protocol were handed over to each community head, the municipality, the SODIS implementing NGO, and to the study director.

Randomisation is an essential and complex scientific concept that needs to be well understood by all stakeholders involved. In order to have communities accept a decision to receive an intervention, i.e. SODIS, or not requires the continued support by local authorities and community leaders in particular also to assure subsequent adherence to the group allocation over a prolonged period of the study. Hence, explaining and involving local authorities in the randomisation activity may be a key element to complete a scientific evaluation of this kind.

6. INTERVENTION

6.1. The device: Solar Water Disinfection (SODIS)

Solar water disinfection (SODIS) provides a simple and efficient drinking water treatment option. It represents one of the most promising home-based water disinfection methods, due to its low cost and reliance on abundant and natural energy. SODIS is essentially consisting of a disposable translucent plastic bottle of 1-2 litres volume in which water is treated. It is a point-of-use water treatment method that avoids secondary water contamination that commonly occurs through storage (Mintz et al. 2001). Disinfection is achieved by the combination of solar radiation and solar heating (McGuigan et al. 1998, Wegelin et al. 1994). The synergistic effect of UV-A and temperature eliminates 99.9% (3-log-reduction) of the viral and bacterial contamination in the water.

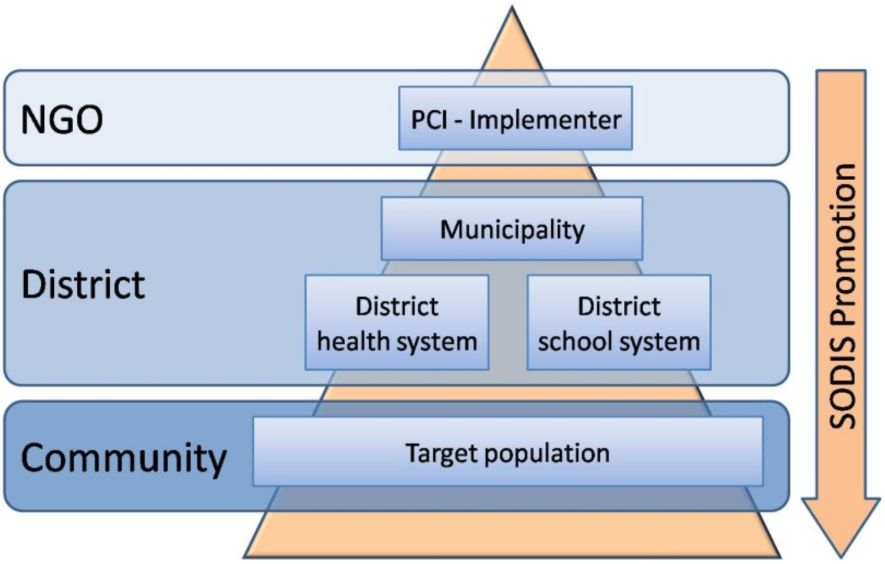
6.2. Implementer

The study site selection was a decisive criterion for choosing the SODIS implementer. Project Concern International (PCI) is a NGO operating in the Totora district and had already vast experience implementing SODIS. PCI is a US-co-funded NGO and since more than 26 years conducting community development programmes (http://www.pci-bolivia.org). The current community development called "salud integral" consists of an activity profile including maternal child health, disease preventions, water and sanitation, basic education and agricultural production. PCI is intending to scale up its activities in the field of water, sanitation and hygiene education and has thus, teamed up with the SODIS Foundation to jointly disseminate the method in different districts within Bolivia. These circumstances made PCI the ideal study collaborator for the SODIS implementation.

6.3. SODIS Implementation strategy

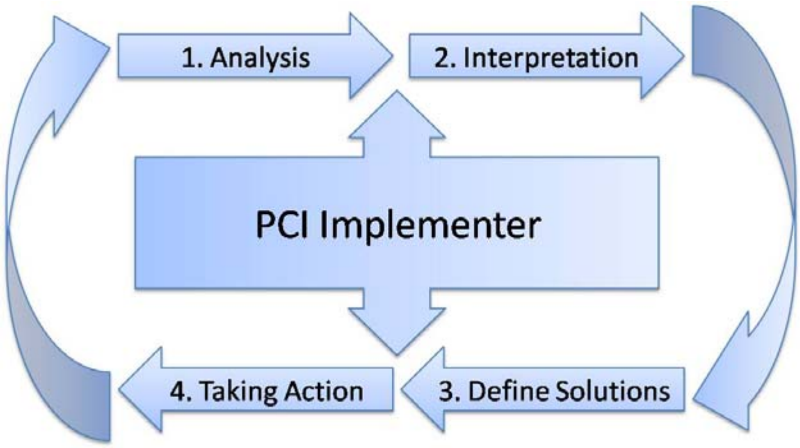
The SODIS method was implemented in the intervention communities in the Totora district by PCI during an intensive three month phase before starting the diarrhoea follow-up and alongside the follow-up for other 12 month. The standardised and repeated interactive promotion of SODIS in the district of Totora based on an active participative implementation approach involving main district and community stakeholders. District stakeholders from the farmers' union and the official local government, health and school system representatives and, formal and informal community leaders were involved in promoting SODIS. This approach facilitated the complex individual behaviour change of adopting SODIS as a new water management pattern. The method was promoted by PCI staff, leaders and advocates, health personnel and teachers, through focus group venues, community- and school events, community training workshops and home visits. Figure 6 shows the implementation process at the different district levels with the involvement of different stakeholders and its interactions to each other.

Figure 6. Hierarchical stakeholder model of the SODIS implementation.



The primary aim was to achieve a significant proportion of beneficiaries using SODIS to disinfect their drinking water. The methodology based on a participatory approach to facilitate the adoption of new ways of thinking and thus, to adopt new patterns of behaviour. The campaign had the two main objectives: i) to create a demand for safe drinking water, and ii) to establish a sustainable application of SODIS as a water disinfection method at household level. The approach relied basically on strengthening local knowledge and initiatives in understanding the relation of health and the living environment, including water. The main elements of community participation were defined and explained at the beginning of the activities (initial analysis, training, logistical assistance, follow-up and evaluation). Following this procedure the beneficiaries passed an informed decision making process, and set priorities and assumed responsibilities from the very beginning of the project. The following diagram shows the awareness and solution finding process for environmental health problems (Figure 7).

Figure 7. The community analysed and interpreted their reality, identified its resources, took decisions and assumed responsibilities, initiated actions and executed proposed solutions, evaluated their performance, celebrated their achievements and systematised its experience to move forward. PCI implementer facilitated this process.



6.3.1. Phases of the SODIS implementation:

- *Analysis:* The community analysis its living environment with a focus on health risks related to water and sanitation (facilitated by the implementer).
- *Reflexion and interpretation:* The reflexion and interpretation of the results of the analysis enabled the contextualization of identified problems.
- *Solution:* Once the problems have been identified the community participative planned in a structured manner action for change and developed appropriate measures for improvement of their living environment.
- *Taking Action:* The community determined its participation in the process of action taking and assumed the responsibilities of the actions in the execution.

Moving through these phases the community assumed responsibility in the development of activities, learned to evaluate the progress and to celebrate the success, which finally provided the basis for a sustainable development of the implementation.

6.3.2. SODIS Implementation at district level

- *Involvement of district authorities:* The active involvement of official district authorities from the municipal governance, health and education system in the planning and implementation of the SODIS method facilitated the overall acceptance of the project. The collaboration between the municipal entities and the implementer was formally concluded. The municipality contributed in-kind by subsidizing catering, transportation and provision of premises for events and workshops on district level. Support from the authorities was guaranteed for the formalisation of the cooperation between communities and the implementer and if conflicts arouse. The officials were informed though quarterly progress reports by the PCI directorate..

- *Involvement and training of health personnel:* In general participating communities were located in remote areas and homes were far-scattered. The decentralized local health system offers basic health provision at health facilities in these remote areas. The facilities are staffed by nurses or physicians, which were trained by PCI staff in supervisory skills, correct application and promotion of SODIS, correct water management (transport, storage and handling of drinking water) and control of, issues, topics, knowledge about water related diseases. Health personnel supported and attended motivational events in the village and coordinated together with PCI staff the implementation and monitoring of success at families homes.
- *Involvement and training of school personnel:* The educational units, which are uniformly distributed in the area according to the child population in the communities, and its teachers, were considered strategic key players in the dissemination and promotion of the SODIS method. The teachers were jointly trained with local healthcare workers to establish mutual stimulation for the rational to disseminate the SODIS method. In schools SODIS was introduced and the relation between health and consumption of safe water engrossed. In addition children were encouraged to enhance their social skills, develop leadership and to critical analyse their environment and to creatively and independently search for possibilities to improve it. Acquired knowledge was infiltrated/brought, transpired by the pupils to their families where the message of safe water and sanitation use was enhanced.

6.3.3. SODIS implementation at community level:

- *Community-level events:* At community level participative motivational and educational events were hold two-monthly during the pre- and follow-up phase. During these events, to which all village members have been invited, people were trained and motivated to practice SODIS at their homes every day. The village members were informed about environmental health issues related to water and sanitation. In addition drinking water related topics like water management and supply at community level were discussed. The framework of these village events enabled also the formalisation of agreements between the implementers and the village members, which specified deadlines for compliance and modalities to be used. These agreements signed by village leaders and witnessed by local district authorities were used as a natural monitoring system. At the end of each community-level meeting PCI distributed PET bottles if required. In addition, PCI organised events in order to increase motivation and involvement of families to adopt and apply SODIS through development of mini projects for the benefit of the general community. The so-called mini-projects which were indirectly related to safe water and sanitation are detailed described in section 6.4.2.).

- *Involvement and training of community leaders and community health workers (CHW):* Community leaders and CHW represent important key persons within the communities. Voluntary CHWs - nationwide established primary health care programme supported by the ministry of health - act as opinion leaders and are the ideal vector for knowledge transfer into the community. CHW link the community and the modern health system. Acting as counsellors they respond to health needs of the community and interact with the district health personnel. Voluntary CHW are members of the community and therefore perfectly integrated and in ease contact with all community members. They were trained by PCI staff in health issues related to contaminated drinking water, drinking water management (type and maintenance of water sources, handling of drinking water at home, like transport and storage), and instructed in the correct application of SODIS. In addition they were trained in promoting the use of the method and the monitoring of compliance.

6.3.4. SODIS implementation at household level

Experienced health promoters from PCI introduced the SODIS method to household members of the intervention communities at their homes on a two-weekly base. The overall aim of their implementation activities at household level was to motivate the people to disinfect to disinfect their drinking water before consumption and to change or improve hygiene behaviour towards a daily routine in a less contaminated environment. Their task was to train and motivate people in the correct application of the SODIS method and to empower people in the achievement of changing their hygiene behaviour. The strategies used were based on motivational home visits and included participatory hygiene and sanitation transformation methodologies and motivational interviewing (Narayan, 1993; Narayan, 1995; Srinivasan, 1990).

6.4. Components of the SODIS implementation

The SODIS implementation in the Totora district consisted of different events and activities with a big diversity as regards content and with different purposes hold on the district, community and household level. Participants were introduced to and taught in the different fields through participative interactions during district and community events. The contents of the SODIS promotion events and activities are described below and are based on the two basic objectives of the campaign mentioned in section 4.3.

6.4.1. Creating the demand for the SODIS method

To facilitate the community creating a true demand for safe drinking water and coming to the conclusion that consumption of safe drinking water improves health and living condition, community members were lead through an identification process. The relation of the living environment, the universe of water and its relation to health was issued during participative activities and events. Following the different thematic components of the events are described below.

- *Hydrologic cycle:* Dealing with the subject of the hydrologic cycle enables people to learn where their drinking water comes from, how their water and its sources are related to the overall water balance and to estimate and value the existence and amount of water they are provided with.
- *Social value of water:* The aim of this topic was to show that water has its own value and importance.
- *Household water management:* The purpose and quantity of water use at home was analysed in detail. The aim was to emphasize on the importance of having access to safe water.
- *Water and human contamination cycle:* This topic helped people to understand that some of the most common diseases are environmental and water related. Faecal contamination of the environment with pathogens and the possible ways of infection through exposure to the contaminated environment in particular alleviated people to understand the importance of blocking those contamination pathways.
- *Cause and prevention of water related gastrointestinal diseases:* In this session people were introduced to possible blocking mechanisms for the different

contamination pathways. Special emphasize was given on water treatment methodologies and in particular on SODIS.

- *Participative planning:* The community planned the implementation activities once SODIS was defined as the method to be implemented in order to prevent water related diarrhoea in children and all family members. The programming was facilitated by PCI staff. The output of this event was the overall plan of the implementation for this community with defined roles for key players like community leaders, CHW, and PCI staff. In order to guarantee a standardised intervention in all communities PCI subtly guided the programming process.

6.4.2. Establishing sustainable SODIS use

Sustainability of a health intervention at household level is the most important indicator for a successful intervention. Thus, reaching sustainable SODIS application at household level should be the overall goal of each SODIS intervention.

It was important that the decisions how to improve the living environement were taken according to the demand determined, and that decisions were taken by the beneficiaries themselves. The role of the project team (PCI) was to guide, facilitate and encourage the local decision making. The independency from external stimulus to integrate and achieve sustainable use of a new method is essential for achieving long-lasting sustainability. If these conditions and processes are not fulfilled the sustainability of the intervention fully depends on external inputs and stimulations. Unfortunately, the effect of applying SODIS rarely translates into perceivable health benefits. To overcome some of these hurdles for sustainability, PCI implemented small-scale motivational projects being conducive to community mobilisation and enabling further activities to promote the SODIS methodology.

- *Motivational events:* The main objective of these community events was to increase motivation and involvement of families of the communities to adopt and apply SODIS through development of mini projects for the benefit of the general community. The contents of the projects were selected based on an analysis process identifying predominant needs which were if possible SODIS-, but not necessarily directly health related. Infrastructural and socio-economic deficits within the community which were plausibly to be dealt with by small scale projects were identified and selected by the community. On the basis of these activities three projects were elaborated and executed in all communities. The projects were assessed as very successful according to high mobilisation of minorities and active participation. One project introduced simple filtering techniques at household level to reduce turbidity of drinking water as a prerequisite for an appropriate SODIS application. In another project the community received a small credit and women-clubs (autonomously organised women clubs) of the communities were guided to introduce and establish a micro trading system with local NGOs and institutions for basic comestible goods and plastic bottles for the SODIS application. The contribution of the community was to find a women-club which provided the basic social structure to implement the micro trading system. The third project entailed making a small kitchen garden for vegetables, fruits and plants which are not common but very coveted. The taking care of these treasured plants is a rooted notion in this farmer culture and was used as a metaphor for the care for children's health.

6.5. Standardisation

Standardisation in implementing the SODIS intervention in a community cluster randomised intervention trial is important to prevent the introduction of bias and spurious causality. The SODIS method was promoted in all communities in the same way and intensity. Besides some minor exceptions the same activities were carried out in each of the intervention communities at community-cluster level.

7. DATA COLLECTION

Epidemiological research presumes that the data collected are precise and unbiased. Whereas this assumption presumes that the data collection approach complies with highest quality standards and that no measurement errors occurs. Sophisticated and well designed studies might fail, if data collection approach does not feature the desired quality. Biases are often introduced in epidemiological studies, where e.g. the manifestations of interest are directly inquired from human study participants through interviews or direct observations. Insufficiently trained interviewing staff and inadequate designed data collection instruments lead to loss in data quality. Often insufficient resources are allocated to the training of staff, and the pre-testing of data collection instruments.

Recognising that the data collection process in a community-cluster randomised intervention trial requires special attention, the following part describes the processes and measures in the BoliviaWET study applied to guarantee high quality data.

7.1. Field staff

Field staff tasked with field data collection and data processing, were selected with care.

7.1.1. Staff recruitment and selection:

The different positions were advertised in local newspapers, broadcasted by local radio stations and posted at the hospital and municipality boards in Totora city. The profile for the staff wanted included proficiency in the native language Quechua, a basic school degree, and the willingness to work and live in a rural community for several months. About one third of the total number of applications was refused. The remaining candidates were invited to participate in a 10min structured interview and a written and oral Quechua examination. After the second selection, 10 candidates more than required (45 candidates) were invited to participate for an one-week training. Candidates participating in the training week were introduced to the defined tasks and responsibilities for all positions (Morbidity Monitoring Staff, Field Supervisors, etc).

The training was not remunerated; BoliviaWET covered transportation, board and lodging costs. In order to evaluate performance, candidates completed individual or in-group “tasks” after each training module. Team building and recreational activities such as games, sport events or in-group workshops helped assessing the social competences of the different candidates. Finally, 33 persons were selected at the end of the training; four field supervisors, 24 community-based monitoring staff, one data entry supervisor, and four data entry clerks.

Inclusion of people who belonged to or were affiliated with any political or evangelising party was avoided due to the constant political conflicts in the study area.

7.1.2. Training of the field staff

It is always a challenge to develop training that combines community mobilisation and empowerment with research. The training of the study team was an educational empowering process. Participants in partnership with each other and with those able to assist them, identified their strength, limitations and needs, mobilised resources, and assumed the responsibility to plan, manage, and conduct the individual and collective data collection activities.

The training was a continuous process that began with the team recruitment and ended with the study. The main focus was to develop a “bottom-up” approach for the data collection. Regular feedback sessions at the end of training modules helped to improve further training sessions and confirmed that the overall education strategy was well accepted.

Three weeks before a new data collection activity started, new tools were introduced, pre-tested and adjusted with the study team. As a part of the training, the study team was involved in the operational planning and development of the data collection activity.

Half-day feedback sessions were held every week throughout the duration of the project. During the feedback sessions the team was informed on their performance, and of forthcoming activities. Field worker were encouraged to report on difficulties encountered when performing their activities and to provide solutions, or suggestions for modifications.

7.1.3. Training modules

Training modules consisted of different parts that were followed in order to prepare and sensitise the study team for carrying out interviews and epidemiological observations, data checks and records and general approaches for community motivation. The team was equipped with the technical knowledge and skills required to collect qualitative and quantitative socio-cultural data.

- *Introduction to the BoliviaWET study:* Each member of the study team was extensively introduced to the study. Everyone received a clear and simple written summary of the study including background, objectives and the contributions this research was expected to provide to the overall understanding of SODIS. Visual methods to introduce the project to the study team as power point presentations and video projections were employed. In addition, each staff member received an overview of overall planning of the study (project structure plan), a description of all collaborators and partners involved and their responsibilities and roles. BoliviaWET aimed to apply a personnel management approach built on a horizontal organisation structure and role allocation.

- *Training in research ethics:* Since the research involved human participants all members of the study team were trained in ethical research principles. The training was based on the Research Ethics Training Curriculum of FHI (Family Health International; http://www.fhi.org /training/en/RETC/). The course referred to the text of the 45CFR46 ('Public Welfare and the Protection of Human Subjects of the U.S. Code of Federal Regulations', 'The 1993 International Ethical Guidelines for Biomedical Research Involving Human Subjects', 'Operational Guidelines for Ethics Committees That Review Biomedical Research', 'The Belmont Report', and 'The World Medical Association Declaration of Helsinki'). Staffs' knowledge was then evaluated by the FIH written test and consequently each staff member received the certificate of completion of the test from FHI.
- *Training in interviewing, observation and documentation techniques:* Staff was introduced and trained in observation and interviewing techniques using approaches and methods for assessing water and sanitation related hygiene practices described in the book of Almedom (Almedom et al. 1997). An interview is a two-way dialogue which calls for a high level of interaction. Interviewers where taught to pay attention to their own value system and to be prepared to rethink pre-conceptions, be self-critical, self-aware and to learn from mistakes in order to enhance personal development. Interviewers were sensitised to self-critical awareness in order to be alert of personal biases and to be open for other persons' realities. They were advised and encouraged not to disrespect other peoples' opinion or habits as the interview would affect its validity. Being able to establish rapport was one of the most emphasised skills staff was advised to develop. Creating rapport means that the interviewer should make study participants feel comfortable talking individually or openly in a group situation. While it is the responsibility of the interviewer to guide the discussion, they had to avoid offering opinions and substantive comments. Morbidity monitoring staff (MMS) had to be prepared to live and to become an active member of the community where they had to collect the data. They had to describe how communities in the Totora district are structured and organised.

7.2. Morbidity surveillance system

Field workers were trained in general approaches to community mobilisation and were based and socially integrated in communities in order to optimally facilitate acquisition of high quality data. Community-based MMS were responsible for visiting every participating household weekly and to monitor health status of household members and to inconspicuously observe household environment and water management, including compliance with SODIS.

During the weekly household visits MMS distributed and recollected from caregivers a 7-day-morbidity diary. The purpose of the morbidity diary was to record daily occurrences of diarrhoea, fever, ARI, eye irritations in study subjects and household members (Appendix A). MMS checked information on diaries and observation protocols at their homes in the communities. If they found incomplete or inconsistent information on the forms they revisited the household on the next morning. At the end of the week each MMS returned to the research office and participated at the feedback and training sessions conducted each Saturday morning.

In addition, MMS participated in the monthly community meetings to inform community members on the progress of the project and on the results of the source water analysis. Community members welcomed and fostered the active participation of the MMS in community activities such as community fairs, harvesting and other convivial community gatherings. Those activities tremendously increased MMSs' rapport in the community and hence increased the reliability of information collected from study participants. MMS was randomly rotated between communities every three months to equally distribute any potential residual interviewer bias among all communities.

7.3. Supervision of the field staff

Supervisors' main responsibility was to supervise the data collection by the MMS. Additionally, supervisors were in charge of collecting stool and water samples. Ideally supervisors visited each MMS two times a week. Visits were unannounced. Supervisors coded the forms at the homes of the MMS and provided an immediate feedback on the data collection performance of the MMS. The collected forms were brought back to the research office and information and coding was checked. If some inconsistencies were found, the forms were handed back to the supervisor who then did a follow-up on registered inconsistencies. Once the forms were approved by the coder, forms were handed over to the data management unit.

Supervisors revisited 5.7% of the households each week and reviewed the history of diarrhoea among household members. Any discrepancies between supervisors and MMS' records were clarified during a joint revisit to the home.

7.4. Measuring SODIS compliance

SODIS use and compliance with intervention was assessed by two different institutions; first, by NGO-implementer's field staff responsible for the SODIS dissemination recording during home visits number of bottles exposed to sunlight, bottles ready to drink in kitchen/home and those available (empty/filled) to make SODIS. And secondly, by the MMS who as part of the community society observed in a casual but nonetheless standardised direct way compliance by recording for each home the number of exposed bottles to sunlight, SODIS-bottles ready to drink and visible in the living space. In addition they observed actual drinking of SODIS water during weekly household visits (observational protocol can be found in Appendix B). At beginning and end of follow-up community-based staff assessed caregivers' knowledge of and attitudes toward the SODIS intervention. Self-reported SODIS-use was assessed two months after starting and at the end of the intervention campaign (after 15 months).

7.5. Stool sampling and analysis

Prevalence of asymptomatic and symptomatic infection was obtained through the microbiologic testing of the random sample of 220 children at baseline and at the end of the follow-up survey. In addition we collected stool samples from the 220 children at the time of their first episode during the follow-up survey.

Testing of the stool specimen was done at the *Laboratorio de Investigacion de medicina* (LABIMED), University of San Simon (UMSS)/Medical Faculty. The day before the survey, each caregiver was issued with a stool collection kit including three small container tubes and was instructed to collect stool from their children. They were instructed through field staff, if possible to catch around 40mL of the stool directly in the provided plastic, wide-mouth blank container or to extract material from the top of the fresh stool that was not in contact with anything else. From this specimen, field staff extracted stool of 1-3mL, that was filled in a plastic tube with 5mL of sodium acetateacetic acid-formalin (SAF). For the investigation of intestinal parasites; a swab-tube with Cary-Blair transport medium (Copan, Brescia, Italy) was used and filled by field staff. In addition the field worker recorded details on child's health status, use of antibiotics or other drugs. Before being transferred to the research office, each specimen was examined macroscopically for consistency, colour, and presence of digestive rests, with special emphasis on liquid specimens and on blood and/or mucus visible by eye. The specimen was stored in cooler boxes at 4°C and transported to the local research office where refrigeration was possible. From there they were transferred to the central laboratory at LABIMED in Cochabamba within 48 hours. Participants were notified by the study team about the test results and treatment initiated upon consultation with the medical centre. A comprehensive array of tests was performed at LABIMED. Detailed description of stool sampling and analysis is described in the Appendix C.

7.6. Water sampling and analysis

Water quality was assessed during six surveys: once during baseline and five times during the follow-up surveys at community- and at household-level. The survey at baseline consisted of water sampling from the main water sources frequented for drinking water collection (up to five) in each community and from households where stool specimens were collected (10 households per community). During each follow-up survey water quality was routinely monitored from the main sources in each community and in one sentinel household in each community. The sentinel household ranked median reported diarrhoeal morbidity as established at baseline. Water samples from the 220 households selected for the baseline assessment were collected once again at the time of a symptomatic case of diarrhoea in the household and during the last survey at the end of the follow-up. Detailed description of water sampling and analysis is described in the Appendix D.

8. ETHICS

Since the SODIS implementation is part of a national SODIS promotion campaign and all communities, independently if control or intervention communities, are involved, every household had access to the SODIS technology by the end of the study. Each community was informed about the date of the forthcoming implementation of the SODIS intervention, i.e. communities in the control arm of the trial knew and had agreed upon their "delayed-intervention" status. However, resentful demoralization due to differential treatment of intervention and control communities necessitated compensatory actions. The community government as well as the community representatives gave their consent for the whole project. Children were enrolled in the study following written informed consent of both of their parents. Withdrawal from the trial was possible at any time without any consequences for the child, family and household. All information obtained from the questionnaires was treated as strictly confidential and was not passed to any other person or institution outside of the designated research team. All children identified during any survey suffering from a severe form of diarrhoea (fever and/or signs of dehydration present) was referred to the nearest health facility or transported to the hospital. Health service delivery to the study participant was provided primarily through the regular health care system. The health care system seconded a medical practitioner to the study team in order to facilitate immediate ad hoc treatment if necessary. Treatment was provided free of charge through the office of the District Medical Officer (DMO). In addition, as services of local health posts were often interrupted due to delayed or inadequate supply of drugs the project made budgetary provisions to support the local health posts in the project area to ensure these services to the study participants.

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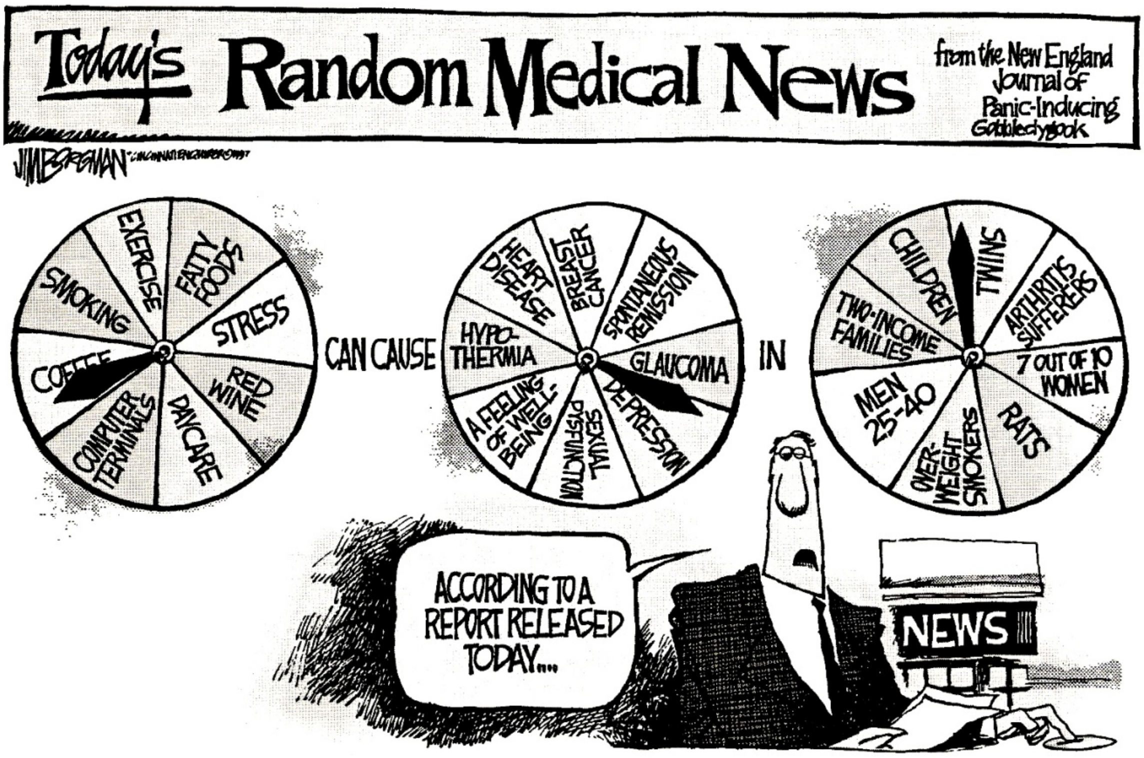

PART II

SODIS effectiveness

Cartoon by Jim Borgman, first published by the Cincinnati Inquirer and King Features Syndicate, 27 April 1997; Forum section: 1 and reprinted in the New York Times, 27 April 1997, E4.

Manuscript I

Solar Drinking Water Disinfection (SODIS) to Reduce Childhood Diarrhoea in Rural Bolivia: A Cluster-Randomized, Controlled Trial

Solar Drinking Water Disinfection (SODIS) to Reduce Childhood Diarrhoea in Rural Bolivia: A Cluster-Randomized, Controlled Trial

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Abstract

Background: Solar drinking water disinfection (SODIS) is a low-cost, point-of-use water purification method that has been disseminated globally. Laboratory studies suggest that SODIS is highly efficacious in inactivating waterborne pathogens. Previous field studies provided limited evidence for its effectiveness in reducing diarrhoea.

Methods and Findings: We conducted a cluster-randomized controlled trial in 22 rural communities in Bolivia to evaluate the effect of SODIS in reducing diarrhoea among children under the age of 5 y. A local nongovernmental organisation conducted a standardised interactive SODIS-promotion campaign in 11 communities targeting households, communities, and primary schools. Mothers completed a daily child health diary for 1 y. Within the intervention arm 225 households (376 children) were trained to expose water-filled polyethyleneteraphtalate bottles to sunlight. Eleven communities (200 households, 349 children) served as a control. We recorded 166,971 person-days of observation during the trial representing 79.9% and 78.9% of the total possible person-days of child observation in intervention and control arms, respectively. Mean compliance with SODIS was 32.1%. The reported incidence rate of gastrointestinal illness in children in the intervention arm was 3.6 compared to 4.3 episodes/year at risk in the control arm. The relative rate of diarrhoea adjusted for intracluster correlation was 0.81 (95% confidence interval 0.59–1.12). The median length of diarrhoea was 3 d in both groups.

Conclusions: Despite an extensive SODIS promotion campaign we found only moderate compliance with the intervention and no strong evidence for a substantive reduction in diarrhoea among children. These results suggest that there is a need for better evidence of how the well-established laboratory efficacy of this home-based water treatment method translates into field effectiveness under various cultural settings and intervention intensities. Further global promotion of SODIS for general use should be undertaken with care until such evidence is available.

Trial Registration: http://www.ClinicalTrials.gov NCT00731497

Please see later in the article for the Editors' Summary.

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Abbreviations: CI, confidence interval; GLMM, generalized linear mixed model; ICC, intracluster correlation coefficient; IQR, interquartile range; IR, incidence rate; NGO, nongovernmental organisation; OR, odds ratio; RR, relative rate; SODIS, Solar drinking water disinfection.

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Introduction

Globally, 1.8 million people die every year from diarrhoeal diseases the vast majority of whom are children under the age of 5 y living in developing countries [1]. Unsafe water, sanitation, and hygiene are considered to be the most important global risk factors for diarrhoeal illnesses [2].

Recent systematic reviews concluded that interventions to improve the microbial quality of drinking water in households are effective at reducing diarrhoea, which is a principal source of morbidity and mortality among young children in developing countries [3–5]. One widely promoted water disinfection method with encouraging evidence of efficacy in laboratory settings is solar drinking water disinfection (SODIS) [6]. Global efforts are underway to promote SODIS as a simple, environmentally sustainable, low-cost solution for household drinking water treatment and safe storage (www.who.int/household_water, www.sodisafricanet.org). SODIS is currently promoted in more than 30 countries worldwide (www.sodis.ch) and in at least seven Latin American countries through the SODIS Foundation including in Bolivia.

Despite this widespread promotion, evidence of the effectiveness of SODIS from field studies is limited. The three reported SODIS trials to date implemented the intervention at the household level, two of them in highly controlled settings that ensured very high compliance [7–9]. The highest reduction in incidence (36%) was recorded in a trial carried out among 200 children in an urban slum in Vellore, India [9].

Because SODIS is a behavioural intervention designed to reduce infectious diarrhoea, disease transmission and its interruption likely have community level dynamics [10]. In addition, because SODIS is typically rolled out in practice through community rather than household level promotion, there is an urgent need for effectiveness data from such settings. We conducted a community-randomized intervention trial to evaluate the effectiveness of SODIS in decreasing diarrhoea in children <5 y in rural communities in Bolivia.

Methods

Ethics Statement

The study was approved by the three human subjects review boards of the University of Basel, Switzerland, the University of California, Berkeley, and the University of San Simon, Cochabamba, Bolivia. The Cochabamba and Totora municipal authorities also approved the study and informed consent was obtained from community leaders and male and female household heads prior to implementation of the study. Informed consent was obtained before randomisation to the treatment arms (Figure 1). Mildly ill children from households participating in the study were provided with and instructed to use oral rehydration salts, or they were referred by field staff to the local health system where clinical services were provided free of charge. The project provided transport and treatment costs for those patients. All project staff completed training on research ethics (www.fhi.org/training/sp/Retc/). Project staff comprised all project personnel of all project partners. Field staff comprised all personnel working in our laboratories and at our Totora field station including data enumerators and data- and project-management staff, supervisors, and community-based field workers living in the study communities. The trial protocol (Text S1) and the CONSORT statement checklist (Text S2) are available online as supporting information.

Site and Population

Our trial, the Bolivia Water Evaluation Trial (BoliviaWET), was conducted in an ethnically homogeneous Quechua setting in rural Totora District, Cochabamba Department, Bolivia. Our study was part of a comprehensive SODIS roll-out programme in collaboration with Project Concern International, a nongovernmental organisation (NGO). Most of the local residents are farmers, typically living in small compounds of three buildings with mud floors, with five or more persons sleeping in the same room. Our own surveys showed that 15% of homes have a latrine or other sanitary facilities and that most residents defecate in the nearby environment.

Drinking water is typically stored in 10-l plastic buckets or open jerry cans of 5–20 l in the household. Baseline assessments of the drinking water quality in the home indicated a median contamination of thermotolerant coliforms (TTC) of 32 TTC/100 ml (interquartile range (IQR) = 3–344; $n = 223$). Samples of at least one water source per community were tested for *Giardia lamblia* and *Cryptosporidium parvum*. The two parasites were detected in 18/24 and 11/23 water samples, respectively.

Parasites were detected by using immunomagnetic separation and PCR techniques [11]. Piped water, when available, is not chlorinated.

Design

Twenty-seven of 78 communities in the study area fulfilled the selection criteria (geographically accessible all year round; at least 30 children <5 y; reliance on contaminated drinking water sources). Two communities were excluded because of other ongoing health and hygiene campaigns, and three communities withdrew participation before baseline activities because of a change in political leadership. Community health workers undertook a census and identified households with at least one child <5 y. All children <5 y were enrolled in the participating villages.

We pair-matched communities on the incidence of child diarrhoea as measured in an 8-wk baseline survey [12]. The intervention was then assigned randomly to one community within each of the 11 consecutive pairs. This assignment was done during a public event because key political stakeholders were worried about possible backlash, public outcry, or a drop-off in group participation, which would result from providing some members with a new benefit while others got "nothing." It was agreed that a public drawing event was necessary to increase perceived fairness among the participating district and municipal authorities. Three authorities, the district head (Alcalde), representatives of the Ministries of Health and Education, and the deputy of the farmers union (Central Campesina), each drew one of two balls (with community codes inscribed that were randomly assigned beforehand) representing paired communities from a concealed box. It was agreed that the first draw assigned the community to the intervention arm. The group allocation was immediately recorded in a protocol by an independent witness. Subsequently, the witness disclosed the sequence, informed the community members and the authorities present in the town hall, and all drawers signed the protocol.

We explicitly chose community-level randomization because important components of the intervention (i.e., community efforts to encourage adoption of the SODIS-method) would occur at the community level. Randomization below the community level would not reflect the reality of scale-up programme implementation, and we would not have captured the potential community-level reinforcement of the behaviour change. Furthermore, community-level randomization is considered ethically optimal, because participants expect to equally benefit from interventions within their community [13–15]. Additionally, we believed cross-contamination (of the intervention) between the intervention and control communities was minimised by vast geographical dispersion of the communities. Control communities knew from the beginning of the study that they would receive the intervention as part of the NGO's development plans after study completion. It was not possible for the NGO to carry out the intervention in all the communities at the same time, thus making randomization feasible and acceptable to the three ethical review boards overseeing the study.

Sample size was calculated according to methods outlined by Hayes and Bennett [16], assuming an incidence rate (IR) in the control villages of five episodes/child/year [17], and accounting for clustering, the number of episodes, and the expected effect. We assumed a coefficient of between-cluster variation (k) of similar studies, between 0.1–0.25 (as cited by Hayes and Bennett) and a minimum of 10 child-years of observation per cluster [16]. We calculated that nine pairs of clusters were required to detect a difference of at least 33% in the IR between the control and intervention arms with 80% power, $k = 0.20$ and an alpha level of 0.05. Anticipating a drop-out of at least one cluster per arm and a loss of follow-up of individuals, the final sample size was adjusted to 11 pairs with 30 children per community cluster. We powered the study to detect a 33% reduction in diarrhoea incidence after reviewing the evidence base for point-of-use water treatment at the time of the study's inception in 2002 [18].

Implementation of the Intervention

The SODIS intervention was designed according to the published guidelines for national SODIS dissemination (http://www.sodis.ch/files/TrainingManual_sm.pdf). Promotion activities were targeted at primary caregivers and all household members (biweekly), whole communities (monthly), and primary schools (three times) by the NGO as part of its regional community development programme. Eleven communities (262 households and 441 children) were randomized to the intervention; 11 communities (222 households, 378 children) served as a control group (Figure 1). The implementation scheme and detailed description of the intervention in the intervention arm (and the control arms after study end) are described in Figure S1. For a period of 15 mo an intensive, standardised, and repeated interactive promotion of the SODIS method was implemented in the intervention communities beginning 3 mo before the start of follow-up.

Within the intervention arm, participating households were supplied regularly with clean, recycled polyethyleneteraphtalate (PET) bottles. The households were taught through demonstrations, role plays, video, and other approaches to expose the water-filled bottles for at least 6 h to the sun. NGO staff emphasized the importance and benefits of drinking only treated water (especially for children), explained the germ–disease concept, and promoted hygiene measures such as safe drinking water storage and hand washing as they relate to the understanding of drinking water and the faecal–oral route of transmission of pathogens (Figure S1). During household visits the NGO staff encouraged all household members to apply the method, answered questions, and assisted mothers and primary caregivers to integrate the water treatment into daily life. The same intervention (in terms of contents and messages) was supplied to the communities in the control arm by the NGO-staff at the end of the study (Figure S1).

Outcome

The primary outcome was the IR of diarrhoea among children <5 y, defined as number of diarrhoea episodes per child per year obtained from daily assessment of individual diarrhoea occurrence. We applied the WHO definition for diarrhoea of three or more watery bowel movements or at least one mucoid/bloody stool within 24 h [19,20]. We defined a new episode of diarrhoea as the occurrence of diarrhoea after a period of 3 d symptom-free [20–22]. An episode of diarrhoea was labelled "dysentery" if signs of blood or mucus in the stool were recorded at any time. We also calculated the longitudinal prevalence (number of days a child suffered diarrhoea divided by the number of days of observation) because of its closer relation to severity, growth faltering, and mortality than diarrhoea incidence [19,23]. Severe diarrhoea was defined as the occurrence of diarrhoea on more than 10% of the observed days [24].

Data Collection and Field Staff

The primary outcome was measured by community-based field workers who were recruited nearby and who lived one per community during data collection periods. The field workers were extensively trained in interviewing and epidemiological observation techniques, data checking, recording, and in general approaches to community motivation. Community-based field workers were randomly rotated between communities every 3 mo. Child morbidity was reported by the closest caregiver using the vernacular term "K'echalera," which had been established previously to correspond to the WHO definition of diarrhoea [25]. Mothers or closest caretakers kept a 7-d morbidity diary recording daily any occurrence of diarrhoea, fever, cough, and eye irritations in study participants [25]. Community-based field workers visited households weekly to collect the health diaries, and supervisors revisited an average 7% of homes. Discrepancies between supervisors and community-based field workers' records were clarified during a joint home revisit. Child exposure risks were also assessed by community-based staff interviewing mothers once during baseline and twice during the 1-y follow-up.

Compliance with the SODIS method was measured using four different subjective and objective indicators. Three of the indicators were assessed by field staff independent from the implementing NGO: (i) the number of SODIS-bottles exposed to sunlight and, (ii) the number of bottles ready-to-drink in the living space, and (iii) the personal judgment about families' user-status was provided by community-based field workers living among the families in the intervention arm. 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. The fourth SODIS-use indicator was based on self-reporting and caregivers' knowledge of and attitudes toward the intervention that was assessed at the beginning (i.e., 3 mo after start of the intervention) and at the end of the 12-mo follow-up period.

Statistical Analysis

An intention-to-treat analysis was applied comparing the IR of diarrhoea between children <5 y in intervention and control communities. Diarrhoea prevalence (PR) and severe diarrhoea (SD) were additionally analysed. Generalized linear mixed models (GLMM) were fitted to allow for the hierarchical structure of the study design (pair-matched clusters). In contrast to our original trial protocol we selected the GLMM approach rather than generalized estimating equations (GEE) because recent publications indicated that the latter method requires a larger number of clusters to produce consistent estimates [26].

The crude (unadjusted) model included only the design factors and the intervention effect [12,27]. Further models included potential confounders (selected a priori: child's age, sex, child hand-washing behaviour, and water treatment at baseline). Following an evaluation of the best fit, the GLMM included the

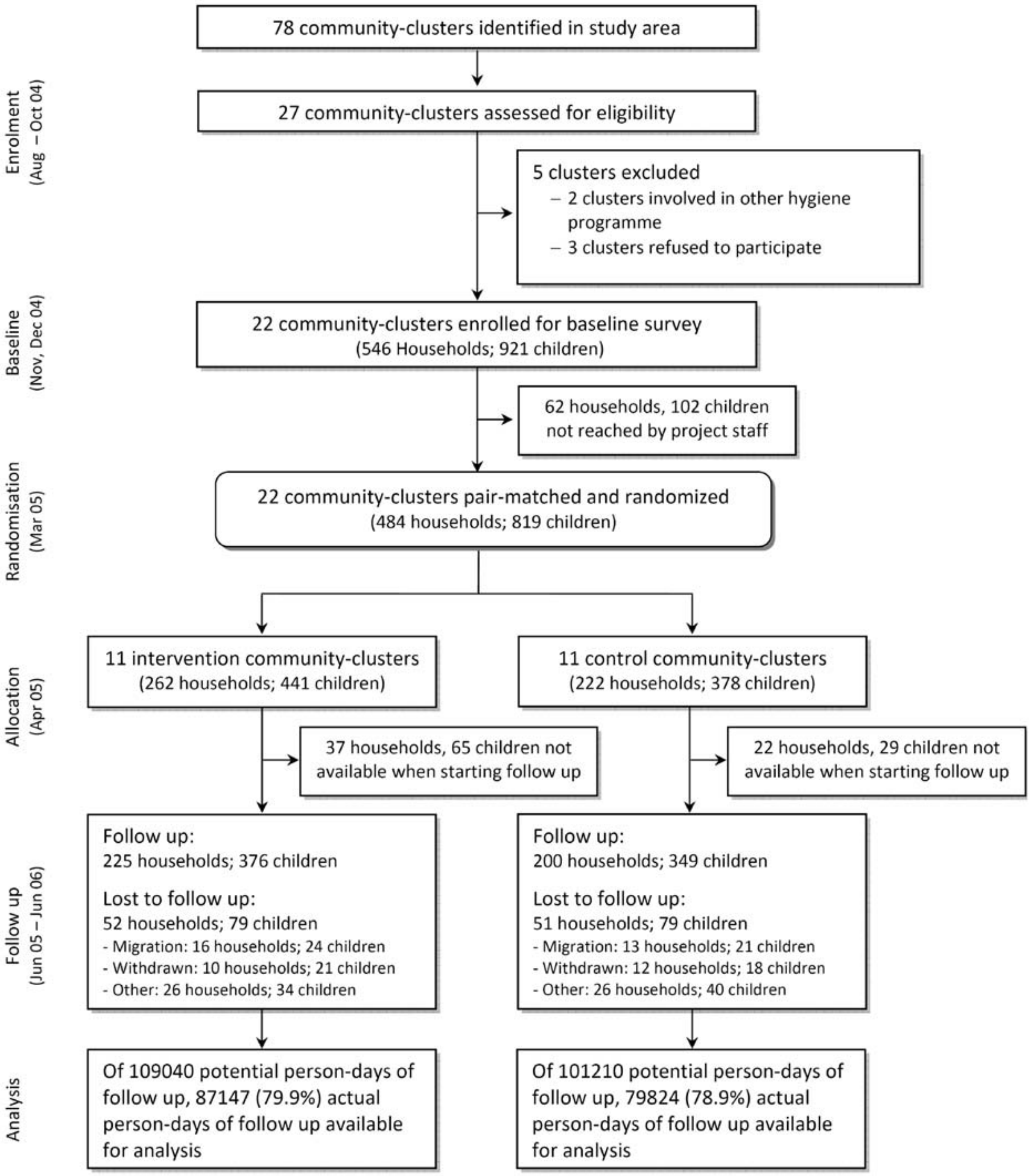

Figure 1. Community-randomized trial flow diagram on point-of-use SODIS in Totora District, Bolivia.
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log link function for negative binomial data (IR) and logit for binomial data (PR and SD). Denoting the link function of the outcome Y by $g(E(Y))$, the crude and adjusted models were: $g(E(Y_{ijk})) = \mu+B_i+\tau_j+\xi_{ij}$, and $g(E(Y_{ijk})) = \mu+B_i+\tau_j+\xi_{ij}+x'b$ where Y_{ijk} denotes the observed outcome value for the kth individual from a community allocated to the jth intervention, in the ith pair, μ is the general mean, B_i is the random effect of the ith pair $\approx\mathcal{N}(0, \sigma^2_p)$, τ_j is the fixed effect of the SODIS intervention, and ξ_{ij} is the random effect of the interaction of the ith pair with the jth intervention applied to the community $\approx\mathcal{N}(0, \sigma^2_{pt})$ (signifying the within-pair cluster variance and used as error term for τ_j), x is the vector of potential confounding factors, and b the vector of the corresponding regression coefficients.

The intracluster correlation coefficient (ICC) and the coefficient of between-cluster variation (k) were calculated after data collection to validate the degree of clustering and our assumptions for the sample size. ICC and k were estimated from the unscaled variance of the IR's GLMM. To estimate the uncertainty of ICC and k, we obtained the 95% credible region (Bayesian equivalent of 95% confidence interval [CI]) through an analogous Bayesian hierarchical regression [28]. Noninformative priors were used. The statistical analyses were performed using SAS software v9.1

(PROC GLIMMIX, SAS Institute Inc.) and WinBUGS v1.4 (Imperial College and MRC).

Results

Participant Flow and Recruitment

Among the 1,187 households in the 22 communities there were 546 that met the inclusion criteria (Figure 1). The median number of participating households with children <5 y per community was 22. Because of political unrest and national election campaigns in 2005 a period of 6 mo passed between the baseline and the start of follow-up. Subsequently, 62 households (102 children) were no longer traceable before randomisation, and 59 households (37 intervention, 22 control) were lost before data collection had started. The loss to follow-up was balanced in intervention and control arms. Data were obtained from 376 children (225 households) in the intervention and 349 children (200 households) in the control arm, thus reaching our originally planned sample size.

Follow-up started in June 2005 and ended in June 2006. During the 51 wk of the study, information on the occurrence of diarrhoea was collected for 166,971 person-days representing 79.9% and 78.9% of the total possible person-days of child observation in intervention and control arms. We excluded from the potential observation time the experience of 94 children who dropped out before the start of follow-up. National festivities, holidays, and political unrest over the entire year amounted to further 9 wk during which outcome surveillance needed to be suspended. The main reasons for incomplete data collection were migration (28%) and withdrawal (67%). Supervisors reevaluated the outcome during 984 unannounced random home visits, and discrepancies between community-based field workers' and supervisors' records were found for five (0.5%) of all visits.

Baseline Characteristics

At baseline the households in the different study arms were well balanced on multiple other factors suggesting successful randomisation (Table 1). The main types of water sources for household chores and drinking were similar in both arms as was the distance to the source (median distance 50 m and 30 m in the control and intervention arms, respectively). Storing water for longer than 2 d was more common among the intervention (26.8%) than the control arm (13.9%). Nearly 30% of all households reported treating water regularly before drinking. Boiling was the most common water treatment before the trial (20.2% in both arms).

Intervention and Attendance

The NGO conducted 210 community events and 4,385 motivational household visits in intervention communities; 3,060 visits occurred in the households with children <5 y followed up and analysed for the study, and 1,325 household visits took place in homes that were not taking part in the study. Study households attended a median of nine community events (IQR = 5–12) and were visited by the SODIS-programme team a median 11 times at home (IQR = 7–18). To ensure a sufficient number of PET bottles, the NGO provided as many SODIS-bottles as required by participants (mean 955 bottles/community).

Diarrhoeal Illness in the Control and Intervention Arm

Children in the SODIS-intervention arm reported a total of 808 episodes or a mean of 3.6 per child per year-at-risk (Table 2). In the control arm there were 887 episodes and an annual mean of 4.3 per child per year. In both arms median length of episodes was 3 d. The unadjusted relative rate (RR) estimate (0.81, 95% CI 0.59–1.12) suggested no statistically significant difference in the number of diarrhoea episodes between the SODIS and control arms of the study (Table 3). In an analysis of the longitudinal prevalence of diarrhoea we found no significant treatment effect (odds ratio [OR] = 0.92, 95% CI 0.66–1.29). Furthermore, no strong evidence was detected for the reduction of odds of severe diarrhoea cases (OR = 0.91, 95% CI 0.51–1.63) and dysentery (OR = 0.80, 95% CI 0.55–1.17).

A multivariable model adjusting for age, sex, baseline-existing water treatment practises, and child hand washing was consistent in its estimate of effect (RR = 0.74, 95% CI 0.50–1.11). We repeated the analysis by including confounding covariates in the order of occurrence of the variables in Table 3 to confirm that the conclusions were not sensitive to the choice of covariates. None of the models yielded significant results for the effect of SODIS (all p-values>0.1) or resulted in meaningful changes in estimates of ORs. Figure 2 shows the relationship between study time and diarrhoea in the control and intervention arm. We found no statistically significant effect of the interaction of time and intervention in a time-dependent model.

The ICC was estimated as 0.0009 with a 95% posterior credible region between (0.0001, 0.0025); k was estimated to be 0.27 with a 95% confidence region of (0.11, 0.46).

Compliance

Community-based field workers who were living in the communities throughout the study observed a mean SODIS-user rate of 32.1% in the intervention arm (minimum 13.5%, maximum 46.8%, based on their personal judgement) (Figure 3). The mean proportion of households with SODIS-bottles exposed to the sun was 5 percentage points higher than the assessment by community-based field workers. In contrast, almost 80% of the households reported using SODIS at the beginning and end of the follow-up. About 14% of the households used the method more than two-thirds (>66%) of the weeks during observation, and 43% of the households applied SODIS in more than 33% of the observed weeks (Table 4).

Diarrhoeal Illness by Compliance

No positive effect of compliance (proportion of weeks of observed SODIS use) on the IRs in the intervention arm was observed. The incidence did not decline with the increase of weeks using SODIS (Figure 4). Seasonal variation in compliance was observed. The proportion of SODIS-practising households was consistently below average during weeks 4–16 (January 2005–April 2006), which corresponded to the labour intensive cultivating period from November to May.

The median proportion of sunny days with more than 6 h of sunshine was 70.2% and 67.2% in intervention and control communities, respectively, consistent with the technical and climatic conditions necessary for the proper functioning of the ultraviolet SODIS purification process [29] during the study (Table 4).

Discussion

We conducted a community-randomized trial within the operations of an ongoing national SODIS-dissemination programme, which provided an intensive training and repeated reinforcement of the SODIS intervention throughout the study period. In this context of a "natural experiment" we found a RR of 0.81 for the IR of diarrhoea episodes among children assigned to SODIS compared to controls. However, the CI was broad and included unity (RR = 0.81, 95% CI 0.59–1.12) and, therefore, we conclude that there is no strong evidence for a substantive

Table 1. Baseline community and household characteristics of a community-randomized trial of SODIS.

Category	Description	*n* Children or Households	Control 11 Clusters	*n* Children or Households	Intervention 11 Clusters
Demography	Community size: *n* of households [mean (SD)]	—	50 (20)	—	58 (20)
	Household size: *n* of household members [mean (SD)]	N = 222	6.2 (2.1)	N = 262	6.3 (2.6)
	n of children <5 y per household [mean (SD)]	—	1.8 (0.7)	—	1.7 (0.8)
	n of children <5 y per community [mean (SD)]	—	35.3 (6.6)	—	41.4 (9.9)
	Female household head [*n* (%)]	—	20 (9.0)	—	14 (5.4)
	Closest child caregiver (female)	—	223 (99.5)	—	266 (99.6)
	Age of closest child caregiver (y) [mean (SD)]	—	31(9)	—	30 (10)
	n of children <1 y	—	65 (4.7)	—	67 (4.1)
	n of children <5 y	—	369 (26.6)	—	426 (25.9)
Education	Household chief: reported years of education [mean (SD)]	N = 167	4.1 (2.6)	N = 178	4.2 (2.4)
	Closest child caregiver: reported years of education [mean SD)]	N = 179	2.5 (1.9)	N = 198	2.7 (1.8)
Socio-economic	Main occupation of the household chief as farmer	N = 208	180 (86.5)	N = 228	207 (90.8)
variables	Ownership of truck, car, or motorbike	—	12 (5.8)		14 (6.2)
	Ownership of radio	—	129 (86.1)		194 (85.1)
	Ownership of bicycle	—	109 (52.4)		121 (53.1)
	Ownership of television	—	24 (11.5)		15 (6.6)
	n of rooms in the house [mean (SD)]	—	2.9 (1.4)		2.8 (1.2)
Water management	Spring as source of drinking water	N = 208	100 (48.1)	N = 228	136 (59.6)
and consumption	Tap as source of drinking water	—	108 (51.9)	—	129 (56.6)
	River as source of drinking water	—	46 (22.1)	—	29 (12.7)
	Rain as source of drinking water	—	31 (14.9)	—	71 (31.1)
	Dug well as source of drinking water	—	31 (14.9)	—	37 (16.2)
	Distance to water source (m) [median (Q1, Q3)]	—	50 (7.5, 100)	—	30 (6, 150)
	Container for water collection: plastic bucket	—	189 (90.9)	—	205 (89.9)
	Container for water collection: jerry can	—	165 (79.3)	—	156 (68.4)
	Container for water collection: bottles	—	32 (15.4)	—	36 (15.8)
	Container for water collection: jar/pitcher	—	13 (6.3)	—	20 (8.8)
	Container for water collection: barrel	—	10 (4.8)	—	25 (10.9)
	Child's consumption of untreated water (glasses/day) [mean (SD)]	M = 318	1.2 (1.2)	M = 359	1.2 (1.4)
	Treat water before drinking	N = 208	59 (28.4)	N = 228	67 (29.4)
	Store water for >2 d	—	29 (13.9)	—	61 (26.8)
	Water storage container: jerry can	—	23 (11.1)	—	49 (21.5)
	Water storage container: plastic bucket	—	17 (8.2)	—	37 (16.2)
	Water turbidity in water storage container >30 NTU	—	13 (11.2)	—	24 (18.8)
Sanitation	Reported *n* of interviewee's hand washing per day [mean (SD)]	N = 177	3.8 (1.7)	N = 200	4.1 (1.8)
	Reported *n* of child hand washing per day [mean (SD)]	M = 348	2.5 (1.2)	M = 376	2.6 (1.4)
	Child washes hands: before eating	—	228 (65.5)	—	270 (71.8)
	Child washes hands: when hands are dirty	—	62 (17.8)	—	56 (14.9)
	Child washes hands: other occasions	—	58 (16.7)	—	50 (13.3)
	Latrine present	N = 208	27 (13.0)	N = 228	38 (16.7)
	Use of latrine by the interviewee (day or night)	—	15 (7.2)	—	20 (8.8)
	Feces visible in yard	N = 202	121 (59.9)	N = 219	124 (56.6)

Data shows numbers and percentages unless otherwise specified. Baseline data from December 2004.
Abbreviations: 30NTU, threshold for efficacious pathogen-inactivation of the SODIS method; M, number of children; N, number of households; NTU, nephelometric units; SD, standard deviation.
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reduction in diarrhoea among children in this setting. Subsequently, we discuss the primary outcome in the context of other study findings, and explain why we hypothesize that the true effect—if there is any—might be smaller.

First, the estimate for the longitudinal prevalence of diarrhoea was substantially smaller (OR = 0.92, 95% CI 0.66–1.29) than the estimate for incidence and there is some evidence that prevalence is a better predictor in terms of mortality and weight gain than

Table 2. Diarrhoea episodes, length of illness, and days ill with diarrhoea.

Health Condition	Class or Parameter	*n*	Control	*n*	Intervention
Diarrhoea illness overview		**Children**		**Children**	
Days under observation	Median (Q1, Q3)	349	263 (213, 274)	376	263 (222, 273)
Days at risk	Median (Q1, Q3)	349	246 (192, 265)	376	247 (202, 265)
n Episodes	Median (Q1, Q3)	349	1 (0, 3)	376	1 (0, 3)
n Dysentery episodes	Median (Q1, Q3)	349	1 (0, 2)	376	1 (0, 2)
Days spent ill	Median (Q1, Q3)	349	4 (0, 11)	376	4 (0, 12)
Episode length (d)	Median (Q1, Q3)	349	3 (1, 5)	376	3 (2, 5)
Days under observation	Total		79,829		87,140
Days at risk	Total		75,077		82,682
n Episodes	Total		887		808
n Dysentery episodes	Total		460		431
Days spent ill	Total		3,111		3,038
Diarrhoea incidence	**Age class**	**Children**	**IR**	**Children**	**IR**
n Episodes/(child×year at risk)	<1	16	7.8	15	11.1
	1–2	67	7.1	70	5.5
	2–3	67	4.3	82	3.8
	3–4	77	3.2	75	2.8
	4–5	71	3.4	80	2.1
	5–6	50	2.7	53	2.5
	Total[a]	349	4.3	376	3.6
Diarrhoea prevalence	**Age class**	**Children**	**Mean (SD)**	**Children**	**Mean (SD)**
n Days ill/(child×year)	<1	16	27.4 (28.3)	15	42.3 (40.7)
	1–2	67	31.4 (42.2)	70	23.0 (26.1)
	2–3	67	19.0 (47.5)	82	16.4 (28.4)
	3–4	77	11.7 (24.5)	75	7.3 (9.7)
	4–5	71	9.5 (15.1)	80	6.2 (12.4)
	5–6	50	6.9 (11.8)	53	7.7 (10.4)
	Total[a]	349	16.5 (32.8)	376	13.5 (22.4)
Diarrhoea illness	**Days spent ill**	**Children**	**Percent**	**Children**	**Percent**
	0 d	97	27.8	126	33.5
	1–2 d	50	14.3	42	11.2
	3–7 d	91	26.1	80	21.3
	8–14 d	49	14.0	59	15.7
	15–21 d	27	7.7	33	8.8
	22–40 d	18	5.2	21	5.6
	>40 d	17	4.9	15	4.0
	Total	349	100	376	100
Diarrhoea illness duration	**Episode duration**	**Episodes**	**Percent**	**Episodes**	**Percent**
	1 day	250	28.2	191	23.6
	2–3 d	303	34.2	292	36.1
	4–7 d	258	29.1	250	30.9
	8–13 d	54	6.1	59	7.3
	>13 d	22	2.5	16	1.9
	Total	887	100	808	100
Prevalence of other symptoms (d/[child×year])		**Children**	**Mean (SD)**	**Children**	**Mean (SD)**
Vomit		349	5.5 (13.2)	376	4.0 (8.9)
Fever		349	21.0 (33.0)	376	15.1 (19.8)
Cough		349	41.9 (48.3)	376	30.9 (39.4)
Eyes irritation		349	12.8 (29.8)	376	8.3 (19.5)

[a]Includes one child per treatment arm with unknown age. SD, standard deviation.
doi:10.1371/journal.pmed.1000125.t002

Table 3. Effect of SODIS on diarrhoea episodes, longitudinal prevalence, severe diarrhoea, and dysentery episodes.

Outcome	Model	*n* Children	Parameter	RR/OR	95% CI	*p*-Value
***n* Episodes (RR)**	Unadjusted	725	Intervention	0.81	(0.59–1.12)	0.19
	Adjusted	644	Intervention	0.74	(0.50–1.11)	0.14
			Age	0.75	(0.70–0.81)	<0.001
			Sex	1.03	(0.84–1.26)	0.80
			Water treatment	1.05	(0.81–1.36)	0.69
			Hand washing	0.93	(0.85–1.02)	0.13
Prevalence (OR)	Unadjusted	725	Intervention	0.92	(0.66–1.29)	0.62
	Adjusted	644	Intervention	0.91	(0.64– 1.30)	0.60
			Age	0.67	(0.61–0.73)	<0.001
			Sex	1.05	(0.84–1.31)	0.68
			Water treatment	1.00	(0.76–1.33)	0.97
			Hand washing	0.94	(0.84–1.04)	0.23
Severe diarrhoea (OR)	Unadjusted	643	Intervention	0.91	(0.51–1.63)	0.75
	Adjusted	589	Intervention	1.02	(0.52–2.01)	0.95
			Age	0.52	(0.40–0.67)	<0.001
			Sex	1.12	(0.63–2.01)	0.69
			Water treatment	1.59	(0.81–3.12)	0.18
			Hand washing	0.94	(0.75–1.19)	0.62
Dysentery (OR)	Unadjusted	725	Intervention	0.80	(0.55–1.17)	0.23
	Adjusted	644	Intervention	0.75	(0.47–1.18)	0.20
			Age	0.73	(0.67–0.80)	<0.001
			Sex	1.00	(0.80–1.26)	0.97
			Water treatment	1.15	(0.87–1.53)	0.33
			Hand washing	0.91	(0.82–1.01)	0.06

Number of episodes, *n* of episodes per days at risk; prevalence, *n* of days ill per days under observation; severe diarrhoea, diarrhoea during >10% of all days (only children with more than 100 d of observation are included); unadjusted, general linear mixed models, only design factors and treatment are included; adjusted, effects of treatment and covariates; sex: 0, female; 1, male; water treatment: water treatment at baseline, 0, no treatment; 1, treatment (chlorination or boiling or SODIS); hand washing, reported number of child's hand washing per day at baseline.
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incidence [23]. The absence of a time-intervention interaction in our time-dependent analysis suggested no increased health benefits with the ongoing intervention. Furthermore, within the intervention arm, there was no evidence that increased compliance was associated with a lower incidence of diarrhoea (Figure 4). However, we interpret this post hoc subgroup analysis cautiously because compliant SODIS users might differ in important ways from noncompliant users. A compliant SODIS user might be more accurately keeping morbidity diaries, whereas less compliant families may tend to underreport diarrhoeal illness. Or, households with a high burden of morbidity might be more likely to be compliant with the intervention. Both of these scenarios could lead to an underestimation of the effectiveness of SODIS.

Further, analysing the laboratory results from 197 randomly selected stool specimens also did not provide convincing evidence for an intervention effect: the proportion of *C. parvum* was lower in the intervention children (5/94 versus 2/103), but other pathogens were found at similar proportions in intervention and control children (*G. lamblia*, 39/94 versus 40/103; *Salmonella* sp., 2/94 versus 3/104; *Shigella* sp., 3/94 versus 3/104). In further exploring the occurrence of other illness symptoms we found the prevalence of eye irritations and cough to be lower in the intervention group compared to the control group. This difference could be the result of the hygiene component in the intervention that increased hygiene awareness among the treatment communities. An alternative explanation is that the lack of blinding led to biased (increased) health outcome reporting in the intervention group.

Due to the nature of the intervention neither participants nor personnel were blinded to treatment assignment. Ideally, blinding to the intervention allocation should apply to the NGO staff administering the SODIS intervention and our enumerators assessing outcomes [30]. Although the former could not be blinded in our study (for obvious reasons), the latter would inevitably be able to identify the intervention status of the cluster through the visible display of bottles to sunlight in the village or directly at the study home during home visits. These problems are consistent with nearly all household water treatment interventions [5] and other public health cluster randomized trials [31,32]. Schmidt and Cairncross [33] recently argued that reporting bias may have been the dominant problem in unblinded studies included in a meta-analysis reporting a pooled estimate of a 49% reduction of diarrhoea in trials investigating the effects of drinking water quality interventions [5]. However, their review of only four available blinded trials showing no effect demonstrates weak support for contrast. In addition, all of the blinded trials exhibited analytical shortcomings or had very broad CIs suggesting very low power. In the absence of blinding—unavoidable in many behavioural change interventions or household water treatment studies—we believe that data collection independent from the implementation is a crucial factor. Future reviews should include reporting on such additional quality parameters.

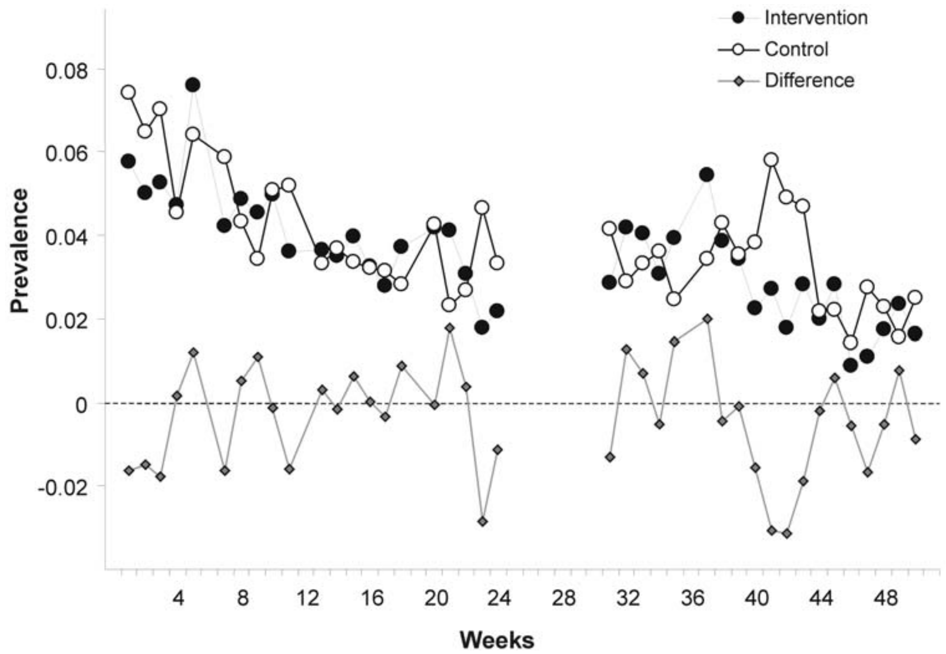

Figure 2. Weekly prevalence of child diarrheal illness. Weekly points are derived from daily prevalence data of each participating child.
doi:10.1371/journal.pmed.1000125.g002

In our study the lack of blinding may have reduced motivation in the control communities. However, the number of households lost during follow-up and the number of days under observation were almost identical in both arms. Additionally, the control communities knew that they would receive the intervention after study end. Finally, a reduction of diarrhoea frequency of 20% might be insufficient to be well perceived, i.e., have a noticeable impact in a population with a high burden of child diarrhoea and will, thus, not result in a sustainable behavioural change. Faecal contamination in about 60% of the yards indicates a highly contaminated environment with presumably a large potential for transmission pathways other than consuming contaminated water. This simultaneous exposure to a multiplicity of transmission pathways may explain why we found no significant diarrhoea reduction due to SODIS.

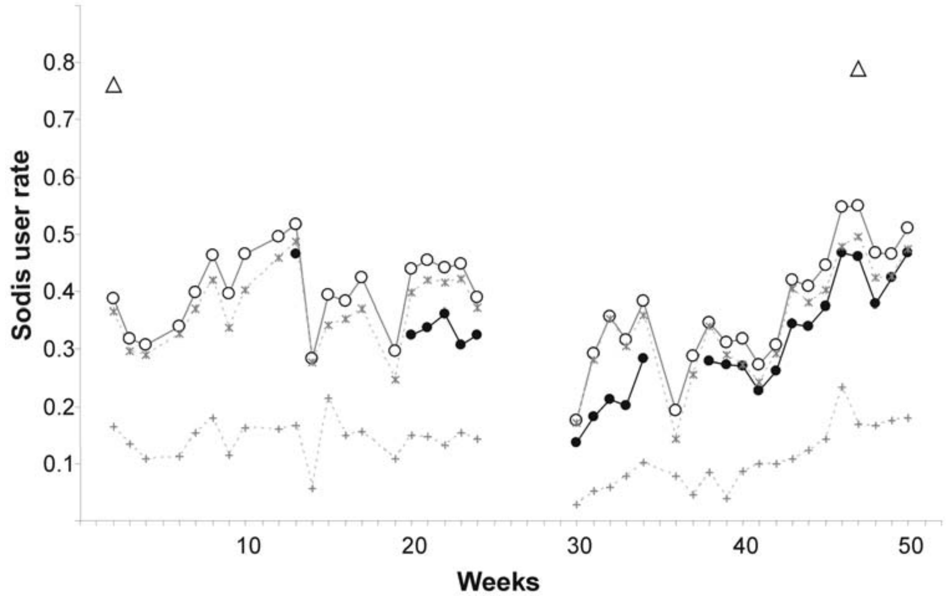

Figure 3. Weekly observed proportion of households using SODIS as point-of-use drinking water purification method. Open triangles, self-reported SODIS use at the beginning (after 3 mo of initial SODIS promotion) and at the end of follow-up; filled dots, SODIS use observed by project staff living in the community (see Methods for definition); open circles, SODIS bottles observed on the roof and/or in the kitchen; stars, SODIS-bottles on the roof; crosses, SODIS-bottles in the kitchen.
doi:10.1371/journal.pmed.1000125.g003

Table 4. Climatic conditions and SODIS use of a cluster-randomized trial involving 22 rural communities of Totora District, Bolivia.

Category	Description	Control (n = 11 Clusters)	Intervention (n = 11 Clusters)
Climate	Percentage of sunny days (>6 h sunshine) [median of clusters (min, max)]	70 (57, 78)	67 (44, 77)
	Average duration of sunshine [median of clusters (min, max)]	7.0 (6.3, 8.0)	7.1 (4.5, 8.3)
SODIS-use	**Observed level of SODIS use[a]**	**Percentage of households**	**Percentage of households**
	0.66–1	0%	14%
	0.33–0.66	0.5%	29%
	0–0.33	99.5%	57%

[a]Proportion of weeks in which SODIS was used, as estimated by community-based project staff at the end of study. Households with <10 wk of observation are excluded.
doi:10.1371/journal.pmed.1000125.t004

On the other hand, our result of a 19% reduction in diarrhoeal episodes appears to be roughly consistent with results of the two other SODIS trials both from Maasai cultural settings conducted by Conroy and colleagues among children <6 y and 5–16 y of age. They report a 16% reduction (in <6 y olds, 2-wk prevalence of 48.8% in intervention, and 58.1% in control group) [8] and a 10.3% reduction in the 2-wk diarrhoea prevalence (in 5–16 y olds) [7]. However, these randomized controlled trials were undertaken in a socio-cultural setting assuring a 100% compliance (as stated by the authors) in water treatment behaviour through social control by Maasai elders who promoted the method [7,8]. In the results presented in these studies adjusted models with post hoc selected covariates were presented (i.e., no unadjusted models were provided). These trials were carried out in conditions of heavily contaminated drinking water and very high diarrhoea rates—important considerations when attempting to generalize these results. The only other—quasi-randomized—trial to estimate the effect of solar water disinfection was carried out in the urban slum in Vellore and resulted in a remarkable reduction of diarrhoea among children <5 y (IR ratio, 0.64; 95% CI 0.48–0.86) despite 86% of SODIS users also drinking untreated water [9].

To our knowledge this is the first community-randomized trial and the largest study so far to assess the effectiveness of the SODIS

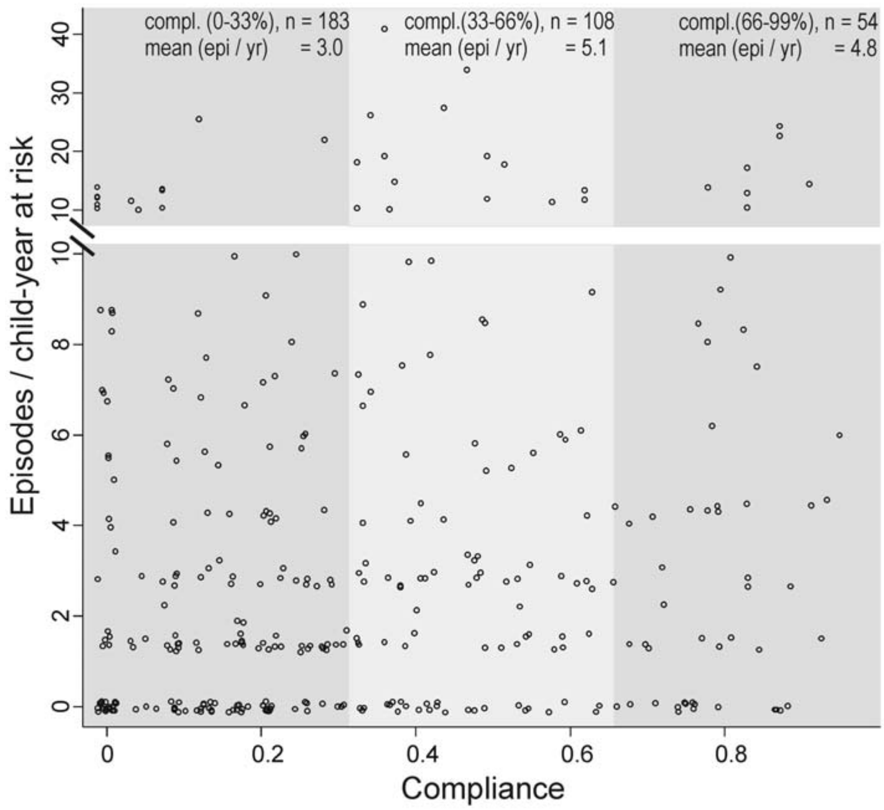

Figure 4. Compliance of using SODIS and child diarrhoea in rural Bolivia. Compliance of SODIS use is estimated as the proportion of weeks a family has been classified as a SODIS user by community-based project staff. Dots, number of episodes per child-year at risk. Small random noise was added to the dots to avoid over plotting. Only children with at least 110 d under observation are included.
doi:10.1371/journal.pmed.1000125.g004

method under typical social and environmental conditions in a general rural population setting where children drink untreated water.

Our study was sufficiently powered to detect a 33% reduction in the effectiveness of the SODIS intervention, and we accounted for clustered design in our analysis. On the basis of a post hoc sample size calculations using the model-based estimate for the between-cluster variability ($k = 0.27$), we would have needed a study 2.5 times larger for a 20% difference to be significant.

The implementing NGO, which had global experience in disseminating SODIS, adapted a campaign to the local and cultural needs and also involved the public health and educational system in the roll-out. This comprehensive SODIS campaign resulted in a mean SODIS usage of 32% on any given study day. In using the SODIS-use indicator on the basis of the personal judgement of community-based staff, we intended to measure actual use in combining objective, visible signs of use (e.g., bottles exposed to sunlight) with proxies more responsive to actual treatment behaviour (e.g., SODIS water can be offered to drink upon request). We consider this a restrictive, more conservative definition of SODIS use compared to that in other studies, which recorded reported use [9] or the number of bottles exposed to sunlight [34]. Both are indicators that can easily and reliably be measured, but which are prone to over-reporting due to low specificity for actual use. Further studies will need to validate different compliance indicators and formally assess the dimension of reporting bias.

It is possible that respondents would like to please field staff and over-report use out of courtesy. Also, observing exposed bottles on the roof may overestimate use (Figure 3), because some households were noted anecdotally to have placed bottles on the roof to avoid discussions with the SODIS-implementing NGO staff. Figure 3 is indicative of this phenomenon, as reported use at the beginning and reported use and satisfaction with the method at the end of the study reached the 80% mark—a usage figure consistent with other studies relying on reported compliance [9] and evaluation reports from grey literature. We conclude that self-reported SODIS use may overestimate compliance and a combination of reported and objectively measurable indicators provides more accurate SODIS-compliance data.

There are limitations to our study. As in other studies [24,35], we observed a decline in the reporting of child diarrhoea during the observational period in both arms (Figure 2). If true, seasonal variation of diarrhoea could be one possible cause; increased awareness leading to more attention to basic hygiene and hence to illness reduction may be another reason. Alternatively, the pattern could be due to survey fatigue.

Despite a comprehensive and intensive intervention promotion campaign, we detected no strong evidence for a significant reduction in the IR of diarrhoea in children <5 y in families using SODIS in our trial in a typical setting in rural Bolivia. We believe that clearer understandings of the discrepancy between laboratory and field results (obtained under typical environmental and cultural conditions), the role of compliance in effectiveness, and a direct comparison of SODIS to alternate drinking water treatment methods are needed before further global promotion of SODIS.

Supporting Information

Alternative Language Abstract S1 Spanish translation of the abstract by MC.
Found at: doi:10.1371/journal.pmed.1000125.s001 (0.03 MB DOC)

Figure S1 SODIS promotion and implementation scheme (based on Perera et al. [36]).
Found at: doi:10.1371/journal.pmed.1000125.s002 (2.14 MB PDF)

Text S1 Trial protocol.
Found at: doi:10.1371/journal.pmed.1000125.s003 (0.52 MB PDF)

Text S2 CONSORT statement checklist.
Found at: doi:10.1371/journal.pmed.1000125.s004 (0.10 MB PDF)

Acknowledgments

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Author Contributions

ICMJE criteria for authorship read and met: DM AC GDP FAT MI MEZ MC JH MDC BA TAS JMC. Agree with the manuscript's results and conclusions: DM AC GDP FAT MI MEZ MC JH MDC BA TAS JMC. Designed the experiments/the study: DM TAS JMC. Analyzed the data: DM AC GDP JH MDC BA JMC. Collected data/did experiments for the study: AC MC MI. Enrolled patients: AC MC. Wrote the first draft of the paper: DM AC JH. Contributed to the writing of the paper: DM AC GDP MC JH MDC BA TAS JMC. Responsible on site for the overall study coordination and supervision: AC. Contributed to the laboratory studies specifically the microbiological monitoring of water quality: MI. Conducted analysis of stool specimen: MEZ. Responsible for the coordination and supervision of the field activities and field data collection team: MC. Administrative and technical support: JH. Advised on data analysis: TAS.

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Editors' Summary

Background. Thirsty? Well, turn on the tap and have a drink of refreshing, clean, safe water. Unfortunately, more than one billion people around the world don't have this option. Instead of the endless supply of safe drinking water that people living in affluent, developed countries take for granted, more than a third of people living in developing countries only have contaminated water from rivers, lakes, or wells to drink. Because of limited access to safe drinking water, poor sanitation, and poor personal hygiene, 1.8 million people (mainly children under 5 years old) die every year from diarrheal diseases. This death toll could be greatly reduced by lowering the numbers of disease-causing microbes in household drinking water. One promising simple, low-cost, point-of-use water purification method is solar drinking water disinfection (SODIS). In SODIS, recycled transparent plastic drinks bottles containing contaminated water are exposed to full sunlight for 6 hours. During this exposure, ultraviolet radiation from the sun, together with an increase in temperature, inactivates the disease-causing organisms in the water.

Why Was This Study Done? SODIS has been promoted as an effective method to purify household water since 1999, and about 2 million people now use the approach (www.SODIS.ch). However, although SODIS works well under laboratory conditions, very few studies have investigated its ability to reduce the number of cases of diarrhea occurring in a population over a specific time period (the incidence of diarrhea) in the real world. Before any more resources are used to promote SODIS—its effective implementation requires intensive and on-going education—it is important to be sure that SODIS really does reduce the burden of diarrhea in communities in the developing world. In this study, therefore, the researchers undertake a cluster-randomized controlled trial (a study in which groups of people are randomly assigned to receive an intervention or to act as controls) in 22 rural communities in Bolivia to evaluate the ability of SODIS to reduce diarrhea in children under 5 years old.

What Did the Researchers Do and Find? For their trial, the researchers enrolled 22 rural Bolivian communities that included at least 30 children under 5 years old and that relied on drinking water resources that were contaminated with disease-causing organisms. They randomly assigned 11 communities (225 households, 376 children) to receive the intervention—a standardized, interactive SODIS promotion campaign conducted by Project Concern International (a nongovernmental organization)—and 11 communities (200 households, 349 children) to act as controls. Households in the intervention arm were trained to expose water-filled plastic bottles for at least 6 hours to sunlight using demonstrations, role play, and videos. Mothers in both arms of the trial completed a daily child health diary for a year. Almost 80% of the households self-reported using SODIS at the beginning and end of the study. However, community-based field workers estimated that only 32.1% of households on average used SODIS. Data collected in the child health diaries, which were completed on more than three-quarters of days in both arms of the trial, indicated that the children in the intervention arm had 3.6 episodes of diarrhea per year whereas the children in the control arm had 4.3 episodes of diarrhea per year. The difference in episode numbers was not statistically significant, however. That is, the small difference in the incidence of diarrhea between the arms of the trial may have occurred by chance and may not be related to the intervention.

What Do These Findings Mean? These findings indicate that, despite an intensive campaign to promote SODIS, less than a third of households in the trial routinely treated their water in the recommended manner. Moreover, these findings fail to provide strong evidence of a marked reduction of the incidence of diarrhea among children following implementation of SODIS although some aspects of the study design may have resulted in the efficacy of SODIS being underestimated. Thus, until additional studies of the effectiveness of SODIS in various real world settings have been completed, it may be unwise to extend the global promotion of SODIS for general use any further.

Additional Information. Please access these Web sites via the online version of this summary at http://dx.doi.org/10.1371/journal.pmed.1000125

- The *PLoS Medicine* editors wrote an editorial arguing that water should be a human right
- The World Health Organization provides information about household water treatment and safe storage and about the importance of water, sanitation, and hygiene for health (in several languages)
- The SODIS Reference Center provides detailed information about solar water disinfection (in several languages)
- The SODIS Foundation in Bolivia provides practical information for the roll-out of solar water disinfection in Latin America (in Spanish and English)
- Project Concern International provides information about its campaign to promote SODIS in Bolivia (in Spanish)
- The Water Supply and Sanitation Collaborative Council (WSSCC) is a global multi-stakeholder partnership organization with a goal of advocating to achieve sustainable water supply and sanitation for all people

"Failures to change the behaviour do not necessarily indicate poor willpower or insufficient understanding of health issues but instead the power of situations to trigger past responses."

(David T. Neal, Wendy Wood & Jeffrey M. Quinn, 2006)

PART III

SODIS adoption & use

MANUSCRIPT II

Adoption of home-based solar water disinfection (SODIS) in rural Bolivian homes

Adoption of home-based solar water disinfection (SODIS) in rural Bolivian homes

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Working paper

ABSTRACT

After an initial campaign to promote SODIS in twelve rural Bolivian communities, repeated weekly behavioural data were collected over six months from 241 households. We report the adoption rates of SODIS and evaluate the factors leading to adoption or rejection.

Following the implementation campaign SODIS users' rates were between 31-52% in the study villages. Household members who walk long distances to collect water were less likely to use SODIS (OR=0.77, 95%CI=0.60;0.98, for a 10-times increase in distance). Households using an unsafe water source at baseline were less likely to adopt SODIS compared to households using a safe water source (OR=0.53, 95%CI=0.42;0.97). Adoption of SODIS increased significantly for each additional child aged 10-14 living in the household (OR=1.23, 95%CI=1.04;1.45).

Households using potentially contaminated water and with limited access to water – i.e. those who would most need to treat water – were less likely to adopt SODIS. This indicates that high risk groups in this setting may be more difficult to reach with this household method to treat water and store it safely. Involvement of adolescents in dissemination campaign may help inducing behavioural change, the young should be considered when planning dissemination programmes.

INTRODUCTION

Gastrointestinal diseases are the second leading cause of disease and the fourth leading cause of death in the world, responsible for four billion of cases and three millions of deaths annually. Of these deaths, 1.6 million are estimated to be related to unsafe water, sanitation and hygiene (Murray and Lopez 1997a, 1997b; WHO 2005a). The World Health Organisation estimates that household water treatment and safe storage (WTSS) may reduce the burden of diarrhoeal disease by 35-39% (WHO 2005b). According to a recent UNICEF report to monitor progress for children towards the MDGs advances to provide drinking water to the needy were made (Unicef 2006) but the goal of achieving access to 'safe drinking water for all ' is far from being reached. Even where access to drinking water is available, achieving high water quality is an equally important goal (Fewtrell et al. 2005). Water treatment and safe storage therefore represent valuable means by which to assure good drinking water quality and reduce the burden of waterborne disease, particularly gastroenteritis in developing countries (Mintz et al. 1995; Clasen and Mintz, 2004; Clasen and Cairncross, 2004; Mintz et al. 2001).

Solar Water Disinfection (SODIS) is a simple, environmentally sustainable, low-cost solution for drinking water treatment and safe storage at household level (Sommer et al. 1997; Oates et al. 2003). Drinking water from potentially contaminated community water sources is filled into transparent polyethylene terephthalate (PET) bottles and exposed to full sunlight for at least six hours. During exposure the synergistic effect of UV-radiation and increased temperature inactivates pathogenic micro-organisms causing water-borne diseases. The SODIS method has been repeatedly demonstrated to be efficacious in laboratory and field studies (Sommer et al. 1997; Acra et al. 1990; Wegelin et al. 1994; Lonne et al. 2005; Robins, 2000; McGuigan et al. 1998; Reed et al. 2000). Nonetheless, the effectiveness of SODIS in achieving better health outcomes in areas of high water-borne transmission of gastrointestinal illness depends largely on the adoption of an effective intervention and, thus, on behavioural change (Stanton and Clemens, 1987.). Findings obtained from careful monitoring of development programmes (e.g. the SODIS dissemination in Latin America) can be used to develop successful dissemination mechanisms (Curtis et al. 1995). This study aims to identify the factors that influence the adoption of SODIS after a promotional campaign in rural Bolivian communities.

METHODS

We used data from the intervention arm of BoliviaWET (Water Evaluation Trial), a two-arm community-randomised study designed to investigate the effectiveness of SODIS for reducing the burden of childhood diarrhoea (Mäusezahl et al. 2009). Twenty-two communities were included in the trial and randomised to receive either a campaign to promote point-of-use drinking water disinfection or to continue with current water treatment practices. All the households enrolled until the end of 2005 were included in the analysis.

The study population near Totora, Bolivia, represents the Cochabamba valley rural setting with altitudes ranging from 2000-3400 m.a.s.l. Households with children under 5 years of age living permanently in the area were randomly selected from each community and enrolled if they gave informed consent. Ten percent of the eligible households did not consent to participate or were lost to follow-up. We analyzed the factors associated with adoption of SODIS in the 12 intervention communities after the promotional campaign was started.

The SODIS implementation consisted of an intensive district-, and community-based dissemination of the SODIS method through training of stakeholders from the farmers' union, the local government, health and school system, formal and informal community leaders. Programme activities included focus group venues, community meetings, school events, village training workshops based on participatory hygiene and sanitation transformation methodology, individual two-weekly household visits, and activities in conjunction with municipal health campaigns.

The outcome of interest was the rate of adoption of SODIS observed in the households at any of the weekly visits. Adoption by a household was defined as observation by an interviewer of the presence of either SODIS bottles exposed to the sun or the SODIS bottles ready to drink and stored inside the house. The interviewers were not involved in any SODIS promotion and implementation activities.

For the purpose of summarizing the pattern of adoption over the period of observation, the households participating in the study were grouped in four categories defined *a priori* according to the number of times they were observed to adopt

SODIS: “non-adopters” if they were never observed to use SODIS, “reluctant users” if SODIS-use was observed in less than 33% of all visits, “occasional adopters” if SODIS-use was observed 33-66% of the time, and “enthusiastic users” if SODIS-use was observed more than 66% of all visits. Descriptive summary statistics were produced for the four SODIS adopters’ groups.

A local non-governmental organization performed the SODIS community-based promotion activities starting at different time points in the different communities. The structure of the dataset was therefore treated as hierarchical, with repeated measurements nested within a household, and households nested within communities. A three-level logistic regression model with random community- and household effects was chosen (Appendix E). The estimation used the unbiased procedure RIGLS (Goldstein, 2003) and Penalized Quasi-Likelihood with 2nd order Taylor approximation to linearise the relationship between the response and the explanatory variables. The effect of the baseline covariates was explored by incorporating fixed parameters in the model. Fixed effects were tested by the Wald statistics. An analysis of residuals was performed on the final subject-specific model to check the assumptions and the need to model complex variation.

Information available from a baseline survey included a set of 30 potential determinants. These are described in table 3 and included households’ characteristics, socio-demographic and home environmental data, water management, drinking water quality, and health related information. Univariable and multivariable analyses were performed. The final multivariable model was selected with a stepwise forward procedure: p-values smaller than 0.05 were used to select the variables to be retained for the final model. Factors that reduced the size of the sample by half due to missing values were not considered in the final model.

Data processing and descriptive statistics were performed in SAS (SAS 2006). The MLwiN software (MLwiN 2006) was used for the GLMM analyses.

The study was approved by the Cochabamba and Totora municipal authorities and informed consent was obtained from community leaders, male and female household heads prior to implementation. The BoliviaWET study was approved by the three human subjects review boards overseeing the study, the

University of Basel, Switzerland, the University of California, Berkeley and the University of San Simon, Cochabamba, Bolivia.

Table 3. Description of potential determinants for the adoption of solar water purification of drinking water

Potential Determinant	Description
Water management	
Use of unsafe drinking water sources	An household was classified as using unsafe water sources if the interviewee declared using either water from a river, a spring, a water dike, or an irrigation channel; whereas it was classified as not using unsafe water sources only if it declared not to use any of these sources.
Walking distance to the main water source	Estimated in meters by the interviewer.
Use of SODIS previous to the campaign	As declared by the interviewee.
Use of other methods of water disinfection and safe storage	Boiling, chlorination or filtering and safe water storage (i.e. storage container cleaned before use and covered, container for water collection was closed for transport and in case of long time storage, the container was covered).
Faecal contamination of drinking water	Thermotolerant coliform counts.
Water turbidity	Nephelometric turbidity units (NTU).
Socioeconomic factors	
Years of maternal schooling	Years of formal education of mother.
Years of household's chief schooling	Years of formal education of household chief.
Monthly household income	Reported income converted to US$ (1US= 8 Bolivianos).
Possession of a radio	Reported.
Possession of a television	"
Possession of a bicycle	"
Possession of a motor vehicle	Reported ownership of a motorcycle, car or lorry.
Mother is a farmer	Reported.
Mother is a vendor	"
Household's chief is a farmer	"
Household's chief is a driver or a vendor	"
Cleanliness of mother	Cloths and hands were found to be clean (interviewer assessment based on training).
Demography	
Household size	From enrolment records.
Number of children under 5	"
Number of children aged 5-9	"
Number of children aged 10-14	"
Number of members aged >=15	"
Housing factors	
Availability of a bathroom or latrine	Reported.
Number of rooms	Reported.
Household environment	Cleanliness of yard assessed by composite indicator created from absence of garbage, faeces or flies
Kitchen tidiness	Based on a composite indicator created from observed absence of faeces, animals or flies in the kitchen and the presence of soap.
Availability of electricity	Reported access to electricity.
Children health status	
Wasting in children under 5	A family was identified as having wasted children if at least one child was falling below -2 standard deviations for weight-for-height.
Stunting in children under 5	A family was identified as having stunted children if at least one child was falling below -2 standard deviations for height-for-age.

RESULTS

Two hundred forty one households were monitored for a period of 23 weeks from July to December 2005 (median: 19 visits, IQR: 17-20, range: 1-21). Data on the adoption of SODIS could be obtained during 3’959 (71%) of 5‘543 potential household-weeks of observations.

Table 4. Distribution of potential determinants of SODIS adoption at baseline, data are no. (%) unless otherwise specified.

	total			SODIS user groups: non-adopters			reluctant			occasional			enthusiast		
	n			n			n			n			n		
Drinking water source															
River	206	25	(12)	23	4	(17)	67	12	(18)	71	6	(8)	45	3	(7)
Spring	206	120	(58)	23	13	(57)	67	45	(67)	71	45	(63)	45	17	(38)
Dike/small dam	205	18	(9)	23	4	(17)	67	6	(9)	70	4	(6)	45	4	(9)
Irrigation channel	205	25	(12)	23	4	(17)	67	14	(21)	70	5	(7)	45	2	(4)
Unsafe water source	206	140	(68)	23	16	(67)	67	55	(82)	70	47	(66)	45	22	(49)
Collected rain water	205	59	(29)	23	6	(26)	67	27	(40)	70	16	(23)	45	10	(22)
Dug well	205	35	(17)	23	5	(22)	67	11	(16)	70	15	(21)	45	4	(9)
Tap	206	120	(58)	23	12	(52)	67	27	(40)	71	50	(70)	45	31	(69)
Walking distance to water source															
Distance in m: median (Q_1;Q_3)	206	25 (5;150)		23	100 (5;240)		67	60(15;200)		71	10 (5;100)		45	6 (5;50)	
Drinking water treatment and storage previous to the campaign															
Use of SODIS	205	7	(3)	23	0	(0)	66	2	(3)	71	2	(3)	45	3	(7)
Boil	205	38	(19)	23	6	(26)	66	13	(20)	71	10	(14)	45	9	(20)
Use chlorine	205	2	(1)	23	0	(0)	66	1	(2)	71	1	(1)	45	0	(0)
Filter	205	19	(9)	23	3	(13)	66	6	(9)	71	4	(6)	45	6	(13)
Use of other methods of water disinfection and safe storage	201	8	(4)	23	0	(0)	66	2	(3)	69	4	(6)	43	2	(5)
Drinking water quality															
Thermotolerant coliforms count (cfu/100mL)															
>1	107	99	(93)	13	13	(100)	37	33	(89)	37	37	(100)	20	16	(80)
>100	107	42	(39)	13	6	(46)	37	16	(43)	37	15	(41)	20	5	(25)
median (Q_1;Q_3)	107	45 (7;360)		13	57 (30;255)		37	46 (7;660)		37	32 (10;293)		20	23 (2;184)	
Turbidity (Nephelometric Turbidity Units)															
> 30	106	24	(23)	12	3	(25)	37	12	(32)	37	4	(11)	20	5	(25)
median (Q_1;Q_3)	106	5 (5;20)		12	8 (5;110)		37	9 (5;40)		37	5 (5;10)		20	5 (5;30)	
pH: mean (SD)	106	6.9	(0.4)	12	6.9	(0.3)	37	6.9	(0.4)	37	6.8	(0.4)	20	6.9	(0.4)

Table 4 (cont.): Distribution of potential determinants of SODIS adoption at baseline, data are no. (%) unless otherwise specified.

	total		non-user		reluctant		occasional		enthusiast	
			SODIS users groups							
	n		n		n		n		n	
Socioeconomic factors										
Maternal schooling: median (Q_1;Q_3)	165	3 (2;4)	20	4 (2;4)	54	3 (1;4)	56	3 (2;4)	35	3 (2;4)
Paternal/chief schooling: median(Q_1;Q_3)	167	4 (3;5)	17	4 (3;5)	59	4 (3;5)	55	4 (3;5)	36	4 (3;5)
Monthly income in US$: median($Q_1$;$Q_3$)	124	17(1;38)	15	10(0;25)	43	13(3;38)	43	25(9;38)	23	15(0;38)
Monthly household income >30 US$	124	38 (31)	15	3 (20)	43	12 (28)	43	17 (40)	23	6 (26)
Possesses a radio	206	172 (84)	23	21 (91)	67	57 (85)	71	61 (86)	45	33 (73)
Possesses a television	206	15 (7)	23	3 (13)	67	6 (9)	71	4 (6)	45	2 (4)
Possesses a bicycle	206	111 (54)	23	13 (57)	67	39 (58)	71	35 (49)	45	24 (53)
Possesses a motor vehicle	206	15 (7)	23	3 (13)	67	1 (1)	71	7 (10)	45	4 (9)
Mother's occupation: farmer	168	56 (33)	20	8 (40)	56	12 (21)	56	26 (46)	36	10 (28)
Mother's occupation: vendor	152	3 (2)	19	0 (0)	53	0 (0)	47	2 (4)	33	1 (3)
Chief's occupation: farmer	205	188 (92)	23	19 (83)	66	63 (95)	71	66 (93)	45	40 (89)
Chief's occupation: driver or vendor	148	7 (5)	19	0 (0)	49	3 (6)	46	2 (4)	34	2 (6)
Hands and cloth of mother are clean	202	67 (33)	23	8 (35)	66	21 (31)	69	25 (36)	44	13 (30)
Demography										
Household size: median (Q_1;Q_3)	237	6 (4;8)	27	5 (4;7)	81	6 (4;8)	79	6 (4;8)	50	6 (5;7)
Children under 5: median (Q_1;Q_3)	219	2 (1;2)	24	1 (1;2)	78	2 (1;2)	75	2 (1;2)	42	1 (1;2)
Children aged 5-9: median (Q_1;Q_3)	219	1 (0;2)	24	1 (0;2)	78	1 (0;2)	75	1 (0;2)	42	1 (0;2)
Children aged 10-14: median (Q_1;Q_3)	219	0 (0;1)	24	0 (0;0)	78	0 (0;1)	75	0 (0;2)	42	1 (0;2)
Members aged >= 15: median (Q_1;Q_3)	219	2 (2;3)	24	2 (2;3)	78	2 (2;3)	75	2 (2;3)	42	2 (2;3)
Housing										
Availability of a bathroom/latrine	206	34 (17)	23	1 (4)	67	11 (16)	71	4 (6)	45	18 (40)
Number of rooms: median (Q_1;Q_3)	206	3 (2;4)	23	2 (2;4)	67	3 (2;3)	71	3 (2;3)	45	3 (2;4)
Clean household environment	201	41 (20)	23	7 (30)	65	13 (20)	70	12 (17)	43	9 (21)
Tidy kitchen	179	21 (12)	21	4 (19)	59	4 (7)	58	9 (16)	41	4 (10)
Availability of electricity	206	39 (19)	23	5 (22)	67	19 (28)	71	9 (13)	45	6 (13)
Health status of children under 5										
Wasting in children under 5	74	7 (9)	6	0 (0)	22	1 (5)	28	4 (14)	18	2 (11)
Stunting in children under 5	86	62 (72)	7	4 (57)	24	17 (71)	36	25 (69)	19	16 (84)

According to the categorization described previously we observed 29 (12%) non-adopters, 81 (34%) reluctant , 79 (33%) occasional, and 52 (21%) enthusiastic households, respectively. The overall SODIS user rates varied between 31 and 52% during the study period.

Baseline characteristics

The distribution of baseline factors at the household level according to the four SODIS users groups is shown in Table 4. Rural water supply coverage was low: 68% of the households declared consuming water from a source which was considered as unsafe. The use of household water treatment in combination with safe storage before the campaign was rare: 3% of the interviewees reported using SODIS before the campaign was started and 4% reported using other methods of water disinfection and safe storage. The microbiological testing of the water stored in the homes revealed faecal contamination ranging from 0 cfu/100mL to too-numerous-to-count (median: 45 cfu/100mL, IQR range: 7-360 cfu/100mL). Most of the samples (93%) exceeded the WHO's threshold of 0 thermotolerant coliforms/100mL, and in 39% of the cases the contamination exceeded 100 cfu/100mL. For 23% of the samples the turbidity levels were above 30 NTU, the threshold above which the efficacy of SODIS is compromised (EAWAG 2005). Less than one fifth of the homes had sanitation coverage or access to electricity.

Univariable analysis

Single baseline covariates were added to the basic model (Appendix E: equation 1). After adjusting for time effects and accommodating for random effects both at household and community levels, the single additional covariate regressions with the GLMM (Table 5) revealed that household members who have to walk longer distances to collect water are less likely to adopt SODIS (OR=0.73, 95%CI=0.58,0.91, for a 10-times increase in distance). Moreover, households using an unsafe water source at baseline were less likely to adopt SODIS compared to households using a safe water source (OR=0.65, 95%CI=0.44-0.95). Further, adoption of SODIS increased significantly with the number of children aged 10-14 living in the household (OR=1.18, 95%CI=1.01-1.39, for one additional child). There was some evidence that households with stunted children were more likely to adopt SODIS (OR=1.60, 95%CI=0.99-2.60).

Table 5. Associations between SODIS adoption and explanatory variables after adjusting for the effect of time and accommodating for community and household effects.

Potential explanatory variables	n	OR	95% CI	p
Drinking water habits				
Use of unsafe drinking water sources	206	0.65	0.44;0.95	0.026
Distance to the main water source (x10)	206	0.73	0.58;0.91	0.006
Use of SODIS previous to the campaign	205	1.32	0.53;3.24	0.552
Use of other water treatment and safe storage methods (not SODIS)	201	1.08	0.48;2.45	0.855
Faecal water contamination (thermotolerant coliforms count)	107	1.00	1.00;1.00	0.581
Water turbidity (NTU)	106	1.00	1.00;1.00	0.606
Socioeconomic factors				
Years of maternal schooling	165	1.03	0.92;1.15	0.584
Years of paternal schooling	167	1.02	0.95;1.09	0.658
Monthly household income (US$)	124	1.00	1.00;1.00	0.798
Possession of a radio	206	0.80	0.53;1.23	0.312
Possession of a television	206	1.01	0.51;1.99	0.976
Possession of a bicycle	206	0.93	0.66;1.32	0.701
Possession of a motor vehicle	206	1.34	0.71;2.51	0.363
Mother is a farmer	168	1.19	0.78;1.81	0.429
Mother is a vendor	152	1.09	0.26;4.54	0.902
Household's chief is a farmer	205	0.89	0.49;1.64	0.712
Household's chief is a driver or vendor	148	1.15	0.52;2.57	0.732
Cleanliness of mother	202	0.88	0.63;1.24	0.469
Demography				
Household size	237	1.06	1.00;1.12	0.658
Number of children under 5	219	1.08	0.88;1.32	0.483
Number of children aged 5-9	219	1.09	0.94;1.26	0.262
Number of children aged 10-14	219	1.18	1.01;1.39	0.040
Number of members aged >= 15	219	1.04	0.93;1.18	0.485
Housing factors				
Availability of a bathroom or latrine	206	1.43	0.85;2.42	0.175
Number of rooms	206	1.07	0.93;1.23	0.368
Clean household environment	201	0.99	0.66;1.48	0.952
Tidy kitchen	179	1.08	0.62;1.89	0.775
Availability of electricity	206	0.85	0.55;1.33	0.484
Children health status				
Wasting in children under 5	74	1.29	0.55;3.05	0.558
Stunting in children under 5	86	1.60	0.99;2.60	0.057

Multivariable analysis

The results of the final multivariable model including the effects of time, community, and the baseline determinants for adopting SODIS are presented in Table 6. Three factors were found to determine attitude towards SODIS: walking distance to the water source (p=0.033), use of an unsafe water source (p=0.035), and number of children aged 10-14 living in the household (p=0.019). The adjusted effect of each variable is reported in Table 6. There was no evidence of an effect of time in the final model (p=0.227).

The presence of stunted children might explain some of the observed effect on SODIS adoption but was not included in the final model since regression including this factor would have reduced the subgroup to less than half of the population under study (100 households).

Table 6. Results of the final model (fitted on a subgroup of 193 households)

Explanatory variables	OR	95% CI	P
Walking distance to the water source (10x)	0.77	0.60;0.98	0.033
Use of unsafe drinking water sources (yes/no)	0.63	0.42;0.97	0.035
Each additional child aged 10-14	1.22	1.03;1.45	0.019
Each additional week since start of survey	1.04	0.98;1.10	0.227

DISCUSSION

We investigated the determinants of successful adoption of SODIS as a point-of-use drinking water treatment in the intervention arm of a water intervention effectiveness trial in Bolivia. Three factors were found associated with the adoption of SODIS: walking long distance to - and, safety of the water source, and an increased number of children aged 10-14 living in the household.

Households located further from the water source and that relied on unsafe water sources were less likely to adopt SODIS. This phenomenon of high risk groups not participating in healthy behaviours is fairly common in the field of health intervention and leads to significant impact on effectiveness and cost-effectiveness of health programmes (Glasgow et al. 1999). No detailed information was available on participation of the households in the implementation activities. We may speculate that high-risk households were less likely to be reached by the campaign or that they were less prepared for behavioural change. This would imply that additional efforts, more focused on high-risk groups, would be required to improve dissemination programmes.

A greater number of children aged 10-14 in a household was associated with increased adoption of SODIS. Children of this age group may act as an important vector of diffusion of innovations such as SODIS among their families by being eager adopters of new ideas brought into the communities from the outside (e.g. through NGO campaigns). Consistent with this hypothesis is the fact that competing priorities of daily household chores have been found to be a barrier to drinking water management and the use of SODIS in particular (Rainey and Harding 2005). Having more adolescent children in the house may provide the needed workforce for this kind of activities and may free up the time to treat water.

There was some evidence that presence of stunted children in the household is associated with the adoption of SODIS. Stunting may increase the awareness of the household members on health issues. Interestingly, we found a large percentage of households with stunted children (72%) contrasting with 36% in children less than 5 reported by a 1998-national survey in rural area (Morales et al. 2005). The common definition for stunting may not hold in these Bolivian settings. Previous studies argued that small heights might reflect genetic adaptation to high-altitude hypoxia among Andean populations (Miller 1993). However, recent studies found that the growth in height, and weight of well-fed children under 5 years is reasonably similar along different countries and ethnic groups (Mei and Grummer-Strawn 2007) and that genetic factors seem to play a minor role in this age-class. Morales et al. (2005) argue for specific cultural factors inherent to child raring in Quechua culture as a specific predictor for stunting without substantiating the claim.

This study did not find an association between adoption of SODIS and other factors like SODIS-use preceding the intervention, presence of a latrine, and the years of education. The proportion of SODIS users prior to the intervention was probably too small to produce significant differences. The effects of sanitation measures like the presence of a latrine were probably captured by the community level random effects in the GLMM models. Some of the communities had indeed been provided with latrines through the activities of an earlier sanitation programme. Education was not found to be associated with the adoption of SODIS, but the study population was relatively homogenous in their education level so we likely did not have enough variability to assess the association.

This study did not find any association between socioeconomic variable and SODIS adoption. It is questionable whether the socioeconomic determinants measured at baseline do assess well the socioeconomic reality. Merely a half of the households provided information on monthly income. Households that did not provide this information might belong to a special socioeconomic group. Other factors like the possession of a radio and of a bicycle were easy to assess but do probably not capture differences in the socioeconomic levels of the population. Possession of television and motor vehicle were rare and might only help in identifying classes of the population which belong to a particularly wealthy group of people. There might be other variables not assessed in this study that might better capture differences in the socioeconomic level of households.

SODIS adoption

Beyond the variability in the adoption of SODIS over time among the communities the initial campaign in 12 rural Bolivian communities generated high proportions of SODIS adopters after only three months of implementation (31-52% versus 3% previous to the campaign). Although the design of this study does not enable us to assess the causal effect of the intervention campaign on SODIS adoption, we observed a marked increase in users' rates. The observed percentages were much higher than those found in a study on SODIS acceptability in Nepal (Rainey and Harding 2005.) These high proportions could possibly be due to the fact that the intervention was performed as an extensive community-based campaign rather than on individual training and combined different synergistic activities such as school based education, parent education, and community workshops. Health education programmes are usually perceived to have a stronger impact when interventions work together rather than as stand alone interventions (Cairncross et al. 1996; Lantz et al. 2000). An analysis of the resources involved in this campaign compared to those of less successful campaigns would be of interest (e.g. cost-effectiveness analysis).

Limitations

The data used for this study were from the intervention arm of the BoliviaWET trial and included the results of the initial phase of the SODIS dissemination campaign. To measure sustainable behavioural change as a result of the SODIS implementation would require post-intervention evaluation long after the end of the campaign.

Information about the psychosocial determinants such as health beliefs (Curtis et al. 1995) and participation of households' individuals to the campaign activities was not available for that time period. The ineffectiveness of the campaign observed in some groups of households might be explained by such factors. A study in Nicaragua found that a positive attitude towards SODIS can predict whether a household is to adopt it, and that the choice of the promoters can therefore play a very important role in the success of a campaign (Altherr et al. 2006).

Approximately 30% of the weekly records on SODIS adoption were missing. Incomplete data is a typical problem in epidemiological cohort studies with repeated measurements. One third of the missing information on SODIS-use was caused by political unrest resulting in two weeks without any data collection. This may lead to uncertainty about time of adoption of SODIS and time effects. Information about most of the determinants investigated was complete.

A high percentage of households was found to have problems with turbidity levels too high for SODIS to be efficacious (i.e. >30NTUs). SODIS should therefore be proposed as one of several alternatives to water treatment and safe water storage to approach to water quality problems.

The definition of SODIS adopters using the criteria of the observation of SODIS bottles exposed to sunlight (e.g. on the roof) or present in the kitchen should allow comparison of the results with those of similar studies. However, this definition may have led to a slight overestimation of the user rate in this study: our measurement criteria is a proxy for the regular consumption of SODIS water.

CONCLUSIONS

The objective of this study was to investigate the factors that influenced the level of adoption of the SODIS method of household water treatment in 12 intervention communities in a rural Andean region of Bolivia. Three factors appeared in multivariable analysis to be significant: the walking distance to the drinking water source, its safety and the number of children in the age group 10-14. These findings may be of help for the many governments and non-governmental organizations which are scheduled to begin SODIS campaigns in the near future (35).

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MANUSCRIPT III

Factors associated with compliance among users of solar water disinfection in rural Bolivia

Factors associated with compliance among users of solar water disinfection in rural Bolivia

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ABSTRACT

Background: Diarrhoea is the second leading cause of childhood mortality, with an estimated 1.3 million deaths per year. Promotion of Solar Water Disinfection (SODIS) has been suggested as a strategy for reducing the global burden of diarrhoea by improving the microbiological quality of drinking water. Despite increasing support for the large-scale dissemination of SODIS, there are few reports describing the effectiveness of its implementation. It is, therefore, important to identify and understand the mechanisms that lead to adoption and regular use of SODIS.

Methods: We investigated the behaviours associated with SODIS adoption among households assigned to receive SODIS promotion during a cluster-randomized trial in rural Bolivia. Distinct groups of SODIS-users were identified on the basis of six compliance indicators using principal components and cluster analysis. The probability of adopting SODIS as a function of campaign exposure and household characteristics was evaluated using ordinal logistic regression models.

Results: Standardised, community-level SODIS-implementation in a rural Bolivian setting was associated with a median SODIS use of 32% (IQR: 17-50). Households that were more likely to use SODIS were those that participated more frequently in SODIS promotional events (OR=1.07, 95%CI: 1.01-1.13), included women (OR=1.18, 95%CI: 1.07-1.30), owned latrines (OR=3.38, 95%CI: 1.07-10.70), and had severely wasted children living in the home (OR=2.17, 95%CI: 1.34-3.49).

Conclusions: Most of the observed household characteristics showed limited potential to predict compliance with a comprehensive, year-long SODIS-promotion campaign; this finding reflects the complexity of behaviour change in the context of household water treatment. However, our findings also suggest that the motivation to adopt new water treatment habits and to acquire new knowledge about drinking water treatment is associated with prior engagements in sanitary hygiene and with the experience of contemporary family health concerns. Household-level factors like the ownership of a latrine, a large proportion of females and the presence of a malnourished child living in a home are easily assessable indicators that SODIS-programme managers could use to identify early adopters in SODIS promotion campaigns.

BACKGROUND

Systematic reviews of water, sanitation, and hygiene interventions in developing countries suggest that improved drinking water or hand hygiene interventions could prevent between 20% and 35% of the global 3.5 billion diarrhoea episodes per year [1-5]. The evidence to date led the World Health Organisation (WHO) to conclude that household water treatment (HWT) is the most cost-effective approach to reach the United Nations millennium development target 7c of halving the number of persons with no access to safe water (WHO report 2002).

However, the majority of evidence has been collected in controlled intervention trials that document efficacy of HWT by improving water quality and reducing diarrhoeal disease in developing countries [6]. These tightly controlled experiments typically last fewer than six months and include both subsidized (or free) materials and high levels of behaviour reinforcement [7]. Evidence for effectiveness on a larger scale and sustained use are rarely addressed by HWT studies [4,8], but such evidence is necessary to guide global efforts to scale up HWT [9,10].

Solar water disinfection (SODIS) is one of the simplest and cheapest technologies for household water disinfection. The method relies on disposable translucent plastic bottles of 1-2 litres in which pathogen-containing water is purified by the combined pathogen-inactivating effects of solar radiation and heating [11,12]. Laboratory experiments proved its efficacy in improving the quality of water [12-14]. The method is widely disseminated in developing countries to improve health in settings where safe drinking water is not available. Despite this widespread promotion, only a few field studies assessed its health impact and evidence on acceptance, regular use, and scalability of the method is scarce and inconclusive [9,10,15-18]. Recent studies demonstrate that SODIS promotion is unlikely to reduce diarrhoea in children below 5 years of age if there are low adoption rates and limited long-term use by the target population [6,15,19,20]. It is therefore, important to identify and understand the mechanisms that attenuate the health impacts of SODIS despite its high efficacy for improving water quality under ideal conditions [12,21].

One challenge of assessing the effectiveness of SODIS implementation is the lack of a reliable, unbiased and accepted indicator to measure SODIS-use. Compliance with the SODIS-intervention (e.g. consumption of the SODIS-treated water) is an important indicator of success of the implementation strategy. To our knowledge, none of the SODIS studies that measured its effectiveness to improve water quality for preventing diarrhoea assessed determinants of compliance directly. To date, the most common end-points used to assess SODIS-use rely on self-reported use or the direct observation of water-filled plastic bottles exposed to sunlight [16,18,22-25]. Indicators are often assessed once, usually at the end of the intervention, and the reliability of these indicators is unknown. Self-reported use in the context of an interview is known to produce inflated results due to reporting bias [26-29]. Togouet et al. use five measures of self-reported use, direct observation and interviewer opinion to create a 0-5 score to classify 'non-users,' 'irregular users,' and 'regular users' [18]. However, this approach to user classification uses a score that weights all components equally, and forces the investigator to subjectively choose cut points in that score. There is a need for objective methods to classify households into distinct SODIS user groups.

In this article we present a detailed analysis of SODIS compliance among recipients of a SODIS-intervention who participated in a community-randomised, controlled SODIS trial (cRCT) in rural Bolivia (BoliviaWET). The trial detected no statistically significant reduction in diarrhoea in children under age 5 with an overall SODIS compliance of 32% based on community-health worker assessment [15], a measure that was more conservative than indicators applied in studies with high SODIS-usage rates [16-18]. Here, we use weekly data collected over 12 months from the SODIS compliance monitoring and the SODIS promotion campaign of BoliviaWET to objectively classify households into distinct SODIS-use groups using principal components and cluster analysis. We then use the classified groups to describe the household determinants and campaign implementation factors that are associated with the adoption and utilisation of SODIS in our setting.

METHODS

Twenty-two communities from the Totora district, Cochabamba department, Bolivia were included in the cRCT and randomised to receive the SODIS as a HWT. Data of 216 of 225 households enrolled in the 11 intervention communities of the cRCT were included in this analysis. We excluded 9 households from the analysis that were monitored for fewer than 6 weeks over the 12 month follow-up period.

Study site: The Totora district covers an area of 2000 km2. Community settlements are widely dispersed at altitudes between 1700 and 3400 m. The majority of the ethnically homogeneous Quechua population are subsistence farmers that grow potatoes, wheat and maize. Households keep livestock for their own consumption and for sale. Families typically live in small compounds of three buildings with mud floors, with several persons sleeping in the same room. Only 18% of the homes have a latrine. Most residents defecate in the nearby environment. Unprotected springs are the predominant drinking water sources.

SODIS campaign: The campaign had two main objectives: i) to create demand for safe drinking water, and ii) to establish a sustainable application of SODIS as a drinking water disinfection method at household level. A non-governmental organisation, Project Concern International (PCI), implemented the campaign. PCI was well known in the study communities from prior work, and at the time of the intervention had experience promoting SODIS in rural Bolivia. PCI introduced SODIS during an intensive 15-month period that started 3 months before the 12-month epidemiologic field trial and continued for three months after the trial in the communities of the control arm.

The implementation in intervention communities was standardised at the community and household levels. The campaign introduced SODIS along with water and sanitation hygiene messages to study communities through participative interactions during district events, community events and personal home visits. District-level stakeholders (farmers' union, local government officials, health and school system representatives) as well as formal and informal community leaders were involved in promoting SODIS. In the field, PCI staff and local community advocates (health personnel and teachers) promoted SODIS through focus groups, community- and school events, community training workshops and monthly home visits. Community events were held at least monthly. All community members were invited to these events where they were trained and motivated to practice SODIS daily in their homes.

Experienced health promoters from PCI conducted motivational home visits to empower participants to disinfect their drinking water before consumption and to adopt or improve hygiene habits to create a less contaminated home environment. The motivational home visit strategy was based on participatory hygiene and sanitation transformation methodologies and motivational interviewing [30-32].

SODIS-use assessment: Data regarding SODIS-use were collected by community-based field workers who were integrated into the community and were not involved in any

SODIS promotion or implementation activities. The field staff was extensively trained in interviewing and epidemiological observation techniques, data recording, and participatory community motivation approaches. Field staff recorded SODIS-use indicators during weekly home visits with a structured, inconspicuous, observational protocol. In addition, field staff recorded self-reported SODIS-use three months after the beginning and at the end of the intervention campaign (after 15 months).

PCI measured study participants' degree of exposure to the SODIS implementation campaign by registering the individual attendance during SODIS promotional events.

In order to arrive at an outcome that describes meaningful types of users, we selected a priori four complementary survey indicators that measure multiple dimensions of potential SODIS-use (Table 7). In addition, we supplemented our SODIS-use indicators with two monitoring indicators (Table 7) to identify households that contributed limited information to the classification process due to infrequent observation. We used all six indicators to classify households into adoption groups (more below) to reduce the potential for reporting bias and misclassification error in SODIS-use behaviour.

Table 7. Indicators for SODIS-use

Indicator	Rational and Interpretation
SODIS-use indicators	
1. *"Bottles sun-exposed"* Proportion of weeks during which SODIS bottles were observed to be exposed to sunlight (as observed by community-based staff)	Indicator for the intention to disinfect water using SODIS. Indirect indicator to measure actual use.
2. *"Bottles ready-to-drink"* Proportion of weeks during which SODIS bottles were ready-to-drink (as observed by community-based staff)	Households regularly disinfecting water with SODIS usually have bottles of SODIS-treated water ready-to-drink available in-house. Considered to be a more reliable indicator for actual use than "bottles exposed to sunlight"
3. *"Classified user"* Proportion of weeks during which a family was classified as SODIS-user (judgement of community-based staff after observing the family for at least 4 weeks).	Considered the most reliable indicator for actual use. Staff living in the community bases their judgement on daily observations of correct application, placing bottles in plain sunlight and/or getting drinking water from a SODIS-bottle when asked for.
4. *"Behavioural change"* Regression coefficient of a logistic regression of the occurrence of bottles exposed to the sunlight (yes/no in a given week) *versus* time.	Indicates behavioural change over time. Coefficient reflects an increase (high values), decrease (low values) or constancy of exposing bottles to sun throughout monitoring time. Note: a coefficient of B=0 indicates constant SODIS-use at high or low

levels

Monitoring indicators	
5. *"Time in Study - Bottles sun-exposed"* Total number of weeks during which *"Bottles exposed to sunlight"* was recorded	Discriminates and identifies households with few weeks observed.
6. *"Time in Study - Classified user"* Total number of weeks during which *"Classified user"* was recorded	Discriminates and identifies households with few weeks observed to classify as SODIS-user.

Statistical analysis: To identify patterns of SODIS-use, we explored the multivariate distribution of study households in terms of the six quantitative SODIS-use indicators (Table 7) using principal component analysis [33]. Identification of meaningful SODIS-user groups was done by Ward's grouping algorithm using R-squared distances as the metric of similarity between households. The Ward's method proved to generate the best qualitative classification among several clustering algorithms tested. Five differentiated groups were identified by this approach (Figure 5). To confirm the patterns of SODIS-use we further examined the distribution of the study households in the data defined by the factorial axes of a principal component analysis based on the SODIS-use indicators [33].

SODIS implementation measures and community- and household level characteristics were tested for univariate differences between groups with the Fisher's exact test for binary data and the Kruskal-Wallis test for non-normally distributed quantitative data. Characteristics with (i) two-sided p-values smaller than 0.1, (ii) less than 25% of missing values (to avoid data sparseness problems), and (iii) no collinearity with other covariates were included in a multivariable, ordinal logistic model. The previously identified SODIS-user groups were used as the categorical-ordinal outcome variable ranging from "non-adopters" to "emerging-adopters". Robust standard errors were calculated to account for community level clustering. All analyses were performed in STATA 10 (StataCorp. 2007) and in SAS (SAS Institute Inc., Cary, NC, USA).

Ethics: Ethical approval for this study was granted within the framework of the registered BoliviaWET cRCT (ClinicalTrials.gov Identifier: NCT00731497) [15]. In addition, measures taken to meet ethical standards, including the processes to obtain necessary clearances and staff training, are described in the same publication.

RESULTS

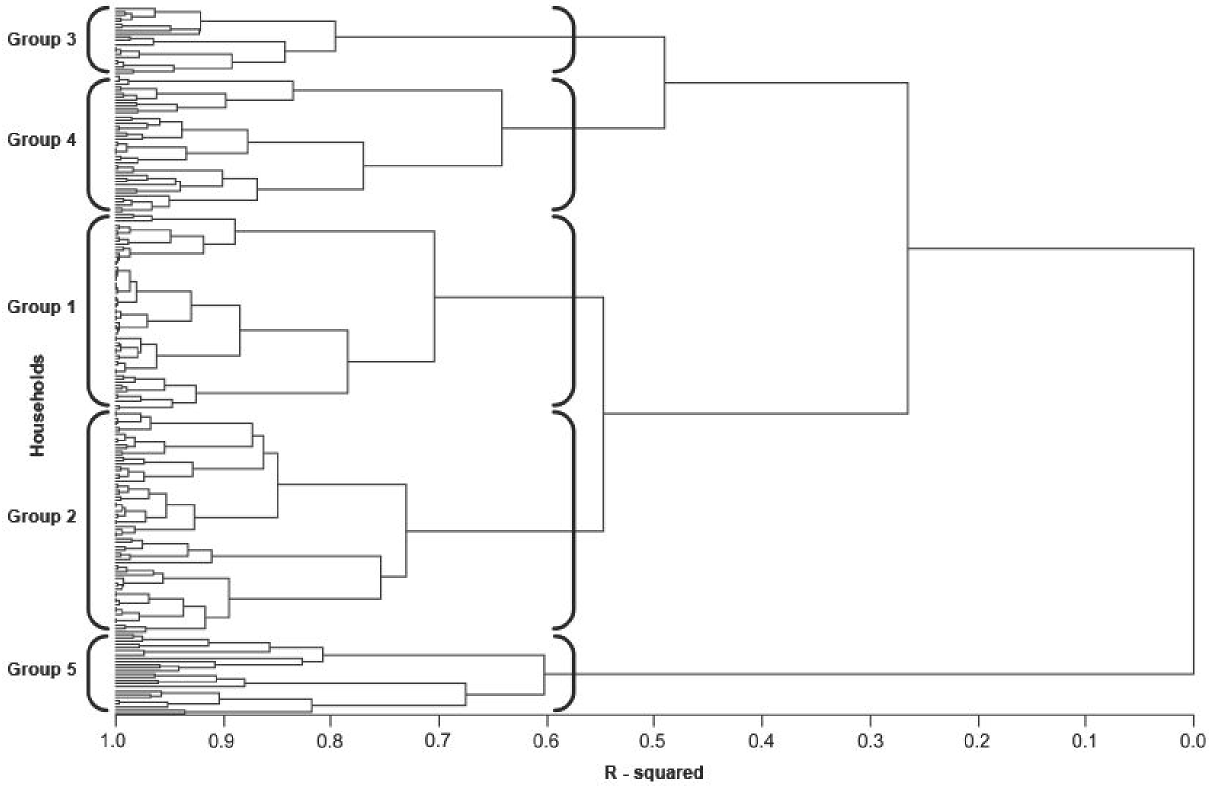
Intervention activities and compliance: The field-based monitoring staff assessed household intervention compliance weekly for a period of 42 weeks from June 2005 to June 2006 (median: 39 visits, IQR: 34-40).

At the community level, PCI conducted a total of 210 group events, which consisted of 108 community- (median 8 /community, IQR: 7-12), 77 women- (median 7 /community, IQR: 3-10), and 25 school-events (median 3 /community, IQR: 1.5-3). During the study PCI conducted 2886 motivational household visits (median 12 /household, IQR: 8-18).

The level of SODIS-use varied depending on the indicator used and the source of information. The community-based staff observed an overall median of 33% (IQR: 17-50) of households with SODIS bottles exposed to sunlight during weekly visits. The SODIS-implementing PCI staff registered during monthly household visits a median proportion of 75% (IQR: 60-85) of households with SODIS bottles exposed to the sun. After three months of intensive implementation, PCI staff recorded 77% of household respondents reporting regular SODIS-use, and 88% at the end of the study.

SODIS-user group classification: Figure 5 summarizes the results of the cluster analysis, which identified five distinct SODIS-use groups based on household-level use indicators. Group 5 (25 households) differed from the other groups with respect to the time under observation (indicators 4 and 5): its time under observation (median 20 weeks, IQR: 16-23) was considered too short to obtain a valid estimate of SODIS-use and led to high variability in all of the indicators. Based on the limited information in group 5, we decided to exclude it from further analysis. Groups 3 and 4 comprised households with the highest SODIS-usage rates; group 3 with an initially high uptake and declining SODIS-use over time, group 4 with an emerging adoption pattern. Based on this group separation, we used characteristics of households in the groups to describe them in meaningful, qualitative terms: Group 1 = 'non-adopters', Group 2 = 'minimal-adopters', Group 3 = 'declining-adopters' and group 4 = 'emerging-adopters' (see also Appendix F).

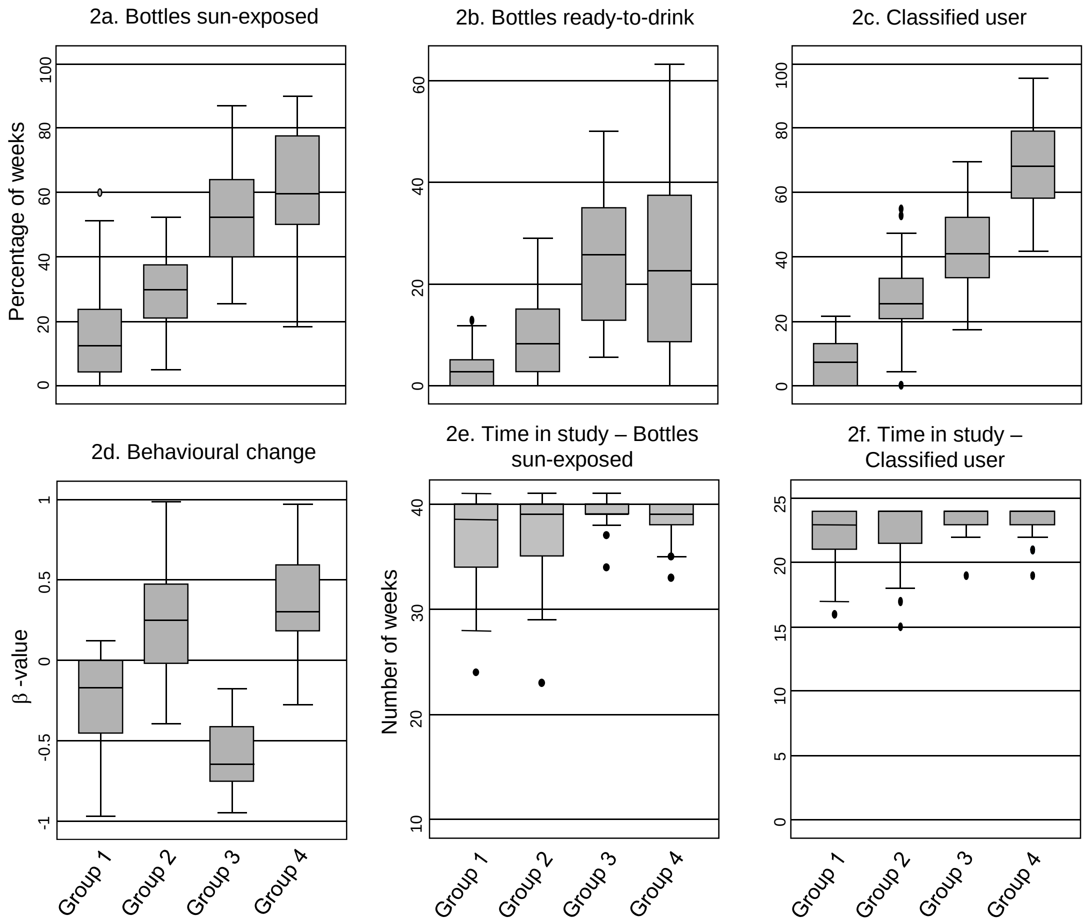
Figure 5. Cluster analysis dendogram



Legend: Horizontal axis denotes the linkage distance (R-square distance) between households according to their SODIS-use indicators listed in Table 7.

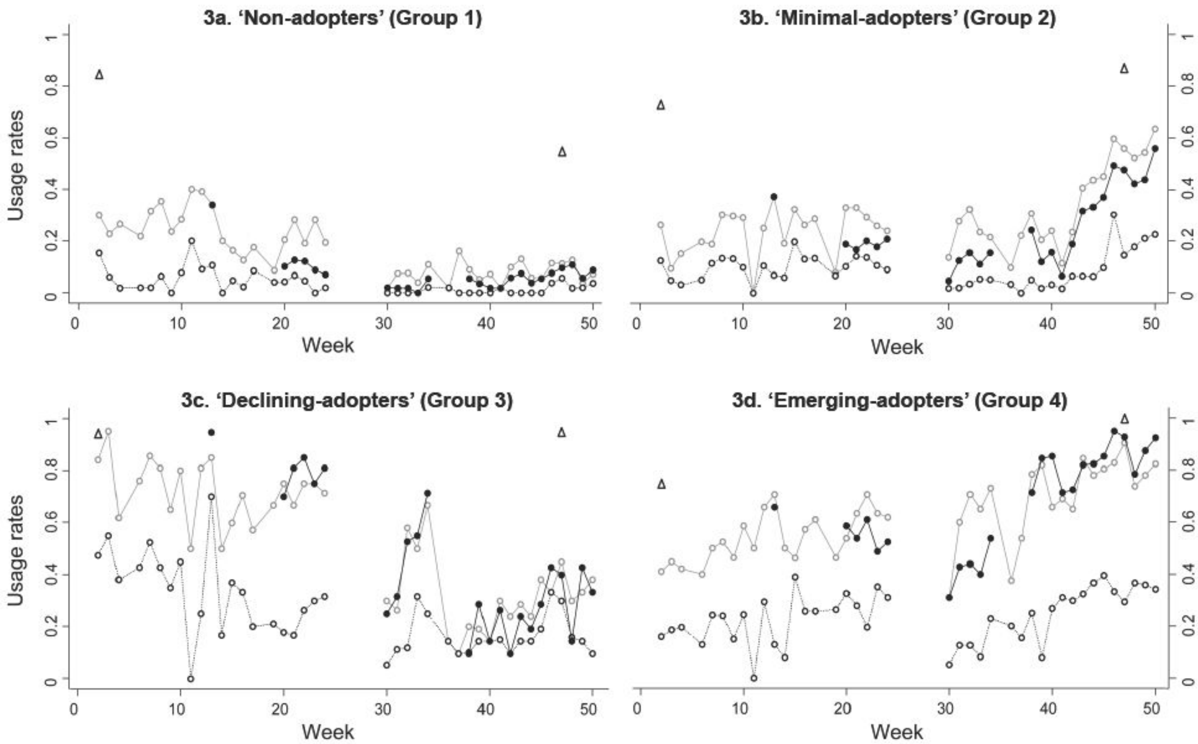
Figure 6 shows the difference between groups in four different SODIS-use indicators (self-reported and observed use) and two monitoring indicators (Table 7), and Figure 7 shows different SODIS-usage rates over time using the same indicators for the four user groups.

Figure 6. Box-plots of four SODIS-user groups differing in six SODIS-use indicators (see table 7)



The group of 'non-adopters' consisted of households with little interest in adopting and using SODIS (median proportion of weeks with bottles exposed to sun were observed: 0.13; IQR: 0.04-0.24) (Fig. 6: 2a and 3a). 'Minimal-adopters' used SODIS more frequently: median proportion: 0.3 (IQR: 0.21-0.38) (Fig. 6: 2a and fig. 7: 3b) of the weeks observed. The 'declining- and emerging adopters' constituted the households with the highest SODIS-usage rates (median: 0.53 and 0.60; IQR: 0.40-0.64 and 0.50-0.78) (Fig. 6: 2a and fig. 7: 3c and 3d). 'Declining-adopters' used SODIS more often at the beginning of the follow-up (Indicator 4 "Behavioral change" in Table 7, logistic regression coefficient bottles exposed to sun vs. time) median: -0.65; IQR: -0.75-0.38 (Fig. 6: 2d and fig 7: 3c). 'Emerging-adopters' used SODIS more often toward the end of the follow-up with a median of 0.30; IQR: 0.20-0.60 (Fig. 6: 2d and fig. 7: 3d).

Figure 7. Weekly observed proportion of households using SODIS in five SODIS-user groups



Legend: Open triangles: self-reported SODIS-use at the beginning (after 3 month of initial SODIS promotion) and at the end of follow-up; filled dots: SODIS-use observed by project staff living in the community (see table 7 for definition); open grey circles: SODIS bottles observed on the roof; open black circles: SODIS bottles observed ready to drink.

Factors influencing SODIS adoption: Table 8 includes the characteristics of the four different SODIS user groups. Some household characteristics differed significantly at a 95%-confidence level between SODIS-use groups. 'Emerging-adopters' consisted of more females compared to the other groups. 'Decreasing-adopters' were more likely to own bicycles. Households from both 'emerging-' and 'decreasing- adopter' groups were more likely to own a latrine (56% and 26%) than 'non- and minimal- adopters' households (both 8%). Further, they were more likely to have severely wasted children (two times substandard weight-for-height = 65% and 66%, respectively) than 'non-adopters' (17%) and 'minimal-adopters' (25%). Groups with the highest SODIS-usage rates lived in close proximity to their water source: the median distance was 5m ('declining-adopters') and 10m ('emerging-adopters'); in contrast, 'non-adopters' lived the furthest distance away from their water source with a median of 100m, followed by the 'minimal-adopters' (30m).

Table 8 - Distribution of potential household determinants of SODIS-use

	Total n=216			Groups based on SODIS-use behaviour: Group 1 ('non-adopters') n=60			Group 2 ('minimal-adopters') n=68			Group 3 ('declining-adopters') n=21			Group 4 ('emerging-adopters') n=42			p-values*
Demography																
Number of household members	216	6.0	(5;9)	60	6.0	(5;8.5)	68	6.0	(4;9)	21	6.0	(5;7)	42	7.0	(5;9)	0.24
Age of household members	216	15.8	(13;18.1)	60	15.5	(13.7;17.6)	68	15.9	(13.3;18.7)	21	15.9	(13;17.8)	42	16.0	(12.1;18.4)	0.88
Number of females	216	3.0	(2;4)	60	3.0	(2;4)	68	3.0	(2;5)	21	3.0	(2;4)	42	4.0	(3;6)	**0.04**
Pregnant women at start of campaign	216	0.0	(0;0)	60	0.0	(0;0)	68	0.0	(0;0)	21	0.0	(0;0)	42	0.0	(0;0)	**0.09**
Children aged < 5	216	1.0	(1;2)	60	1.0	(1;2)	68	2.0	(1;2)	21	1.0	(1;2)	42	2.0	(1;2)	**0.06**
Children aged 5-9	216	1.0	(0;2)	60	2.0	(0;2)	68	1.0	(0;2)	21	1.0	(0;2)	42	1.0	(1;2)	0.60
Children aged 10-14	216	0.0	(0;1)	60	0.0	(0;2)	68	0.0	(0;1)	21	0.0	(0;1)	42	0.0	(0;2)	0.80
Members aged 15-19	216	0.0	(0;1)	60	0.0	(0;1)	68	1.0	(0;1)	21	0.0	(0;1)	42	0.0	(0;1)	0.95
Members aged > = 20	216	2.0	(2;2)	60	2.0	(2;2)	68	2.0	(2;2.5)	21	2.0	(2;2)	42	2.0	(2;2)	0.17
Caregivers' age	208	28.0	(23;36)	58	28.8	(23;35)	67	29.0	(23;37)	19	30.0	(22;36)	41	28.0	(23;40)	0.87
Socioeconomic characteristics																
Years of household heads' schooling	155	4.0	(3;5)	43	4.0	(2;5)	52	4.0	(3;5)	14	4.0	(3;5)	28	4.0	(2.5;5)	0.38
Monthly household income in US$	120	16.9	(0;37.5)	35	12.5	(0;25)	37	12.5	(0;31.3)	7	25.0	(12.5;37.5)	24	31.3	(0;47.5)	0.25
Bicycle: n (%)	192	107	(55.7)	49	25	(51)	65	40	(61.5)	18	14.0	(77.8)	39	17.0	(43.6)	**0.07**
Radio: n (%)	192	158	(82.3)	49	41	(83.7)	65	55	(84.6)	18	13	(72.2)	39	30	(76.9)	0.53
Gas cooker: n (%)	181	32	(17.7)	53	9	(17)	66	16	(24.2)	20	3	(15)	42	4	(9.5)	0.28
Number of rooms	192	3.0	(2;4)	49	2.0	(2;3)	65	3.0	(2;4)	18	3.0	(2;3)	39	3.0	(2;4)	0.29
Latrine: n (%)	192	34	(17.7)	49	4	(8.2)	65	5	(7.7)	18	10	(55.6)	39	10	(25.6)	**>0.001**
Electricity: n (%)	192	36	(18.8)	49	11	(22.5)	65	16	(24.6)	18	1	(5.6)	39	3	(7.7)	**0.06**
Solar panel: n (%)	130	30	(23)	29	9	(31)	50	8	(16)	12	3	(25)	25	5	(20)	0.44
Tiled roof: n (%)	181	57	(31.5)	53	19	(35.9)	66	18	(27.3)	20	8	(40)	42	12	(28.6)	0.60
Environmental housing factors																
Use of improved water source: n (%)**	192	149	(77.6)	49	36	(73.5)	65	53	(81.5)	18	15	(83.3)	39	29	(74.4)	0.69
Use of unimproved water source: n (%)***	192	133	(69.3)	49	37	(75.5)	65	48	(73.9)	18	10	(55.6)	39	24	(61.5)	0.23
Distance to water source in metres.	192	22.5	(5;50)	49	100.0	(10;200)	65	30.0	(7;100)	18	5.0	(4;30)	39	10.0	(5;200)	**0.03**
Turbidity of source water (NTU)	101	5.0	(5;20)	30	5.0	(5;40)	34	5.0	(5;20)	7	5.0	(5;40)	19	5.0	(5;15)	0.79
Faecal contamination of housing environment: n (%)	185	106	(57.3)	50	31	(62)	62	34	(54.8)	16	9	(56.3)	36	16	(44.4)	0.46
Animals present in the kitchen: n (%)	168	45	(26.8)	42	15	(35.7)	57	13	(22.8)	15	3	(20)	33	6	(18.2)	0.32
Soap, detergent present in the kitchen: n (%)	166	29	(17.5)	41	6	(14.6)	56	12	(21.4)	15	3	(20)	33	4	(12.1)	0.68
Household members health status																
Households with at least one stunted child < 5: n (%)	167	62	(37.1)	43	12	(27.9)	53	19	(35.9)	17	8	(47.1)	35	16	(45.7)	0.33
Households with at least one wasted child < 5: n (%)	167	85	(50.9)	43	17	(39.5)	53	25	(47.2)	17	11	(64.7)	35	23	(65.7)	**0.08**
Diarrhoea incidence in children < 5 before start of intervention	216	3.0	(0;7)	60	3.0	(0;5)	68	3.0	(1;7)	21	6.0	(1;12)	42	3.0	(0;6)	0.22
Diarrhoea prevalence (%) in children < 5 before start of intervention	216	7.0	(1;14)	60	5.0	(0;12)	68	8.0	(2;14)	21	7.0	(2;32)	42	6.0	(0;17)	0.26
Cough prevalence (%) in children < 5 before start of	216	8.0	(0;20)	60	5.0	(0;17)	68	8.0	(2;21)	21	1.0	(0;17)	42	10.0	(0;24)	0.72

intervention																
Fever prevalence (%) in children < 5 before start of intervention	216	7.0	(2;15)	60	6.0	(0;16)	68	5.0	(1;11)	21	6.0	(2;19)	42	7.0	(2;22)	0.58
Hand-washing behaviour																
Hand-washing per day of children > 5 and adults	169	4.0	(3;5)	44	4.0	(3;5)	57	3.0	(3;5)	15	3.0	(3;5)	33	4.0	(3;5)	0.27
Hand-washing per day of children < 5	192	2.6	(2;3)	49	2.5	(2;3)	65	2.5	(2;3)	18	3.0	(2;3)	39	2.7	(2;3)	0.96
Household water management																
Safe storage: n (%)	155	19	(12.3)	34	4	(11.8)	57	5	(8.8)	14	5	(37.5)	30	2	(6.7)	**0.06**
Water disinfection: n (%)	192	42	(21.9)	49	12	(4.5)	65	13	(20)	18	5	(27.8)	39	9	(23.1)	0.86
Household water consumption [l / household day]	189	40	(20;50)	58	35	(20;50)	67	40	(20;60)	21	50	(20;60)	41	30	(20;60)	0.81
Satisfied with quality of drinking water: n (%)	201	190	(94.5)	54	51	(94.4)	64	59	(92.2)	19	19	(94.7)	40	39	(97.5)	0.76

Legend: Baseline data are median (Q1; Q3), otherwise specified. *: Kruskal-Wallis and Fisher's exact test for comparing group 1, 2, 3, and 4; **: Improved water source: piped water into dwelling, plot or yard; tubewell/borehole; protected spring; rainwater collection. ***: Unimproved water source: unprotected dug well or spring; bowser-truck; surface water (river, dam, pond, irrigation channels).

Table 9 summarizes household exposure to the SODIS campaign through active participation at community-level events and through passive exposure to motivational activities during household visits. Since the implementation was standardised at community- and household levels there is no difference between the four SODIS-user groups regarding campaign features such as 'Number of events taken place per community', 'Average number of participants per event and community', and 'Number of household visits per household'. However, groups differed significantly regarding active participation at those events. 'Non-adopters' participated on average at half of the events offered, whereas 'declining and emerging adopters' participated at 78% and 71% of the events. The level of participation at school events was similar across groups, since participation was mandatory for school children in all schools in the study site.

Since SODIS implementation indicators were correlated with each other, only one indicator ('Total number of events visited by at least one household member') was included in the multivariable model because it encapsulates the others. Estimates from the ordinal logistic model indicate that 'Total number of events visited by at least one household member' was positively associated with frequent SODIS use group membership (Table 10). For each additional event visited the odds of being in the next higher category of adoption was 1.07 (95% CI: 1.01-1.13). The multivariable model showed that higher adoption groups were more likely to own a latrine (OR: 3.38; 95% CI: 1.07-10.70) and to have at least one wasted child living in the household (OR: 2.17; 95% CI: 1.34-3.49). Furthermore, more females living in a household was positively associated with increased SODIS adoption (OR: 1.18; 95% CI: 1.07-1.30).

**Table 9 - ** SODIS campaign at household and community level

				Groups based on SODIS-use behaviour												
	Total			**Group 1 ('non-adopters')**			**Group 2 ('minimal-adopters')**			**Group 3 ('declining-adopters')**			**Group 4 ('emerging-adopters')**			**p-values ***
	n=216			n=60			n=68			n=21			n=42			
Household exposure to SODIS campaign																
Different events visited by at least one household member (n)	213	10.0	(6;13)	58	7.5	(6;12)	68	10.0	(6;12)	21	13.0	(9;17)	42	12.0	(7;14)	**0.002**
Events visited by at least one household member (n)	213	11.0	(6;15)	58	8.5	(6;14)	68	11.0	(6;15)	21	16.0	(11;22)	42	14.0	(10;18)	**0.004**
Proportion of possible events per community visited (%)	213	62.0	(39;83)	58	50.0	(32;80)	68	62.0	(44;81)	21	78.0	(57;100)	42	71.0	(48;94)	**0.017**
Events visited by most active household member (n)	213	6.0	(4;8)	58	5.0	(3;8)	68	5.5	(4;8)	21	9.0	(6;11)	42	6.0	(4;9)	**0.002**
Community events visited by at least one household member (n)	213	5.0	(3;7)	58	5.0	(3;7)	68	5.0	(3;9)	21	5.0	(3;6)	42	7.0	(5;9)	**0.019**
Women events visited by at least one household member (n)	213	2.0	(1;4)	58	2.0	(1;3)	68	2.0	(1;4)	21	7.0	(2;8)	42	3.0	(1;4)	**0.003**
School events visited by at least one household member (n)	213	0.0	(0;2)	58	0.0	(0;2)	68	0.0	(0;2)	21	0.0	(0;3)	42	0.0	(0;3)	0.515
Household visits by promoting NGO (n)	213	12.0	(8;18)	57	10.0	(6;19)	68	13.0	(9;18)	21	16.0	(12;21)	42	12.5	(9;18)	0.224
SODIS campaign at community level																
Events taken place per community (n)	216	18.0	(16;21)	60	19.0	(15.5;21)	68	18.0	(16.5;21)	21	21.0	(17;23)	42	17.5	(16;21)	**0.037**
Average number of participants per event per community	216	29.6	(23.2;40.4)	60	29.4	(20.1;40.4)	68	30.1	(24.0;48.8)	21	27.1	(27.1;30.1)	42	30.1	(27.1;40.4)	**0.071**
Average duration of events per community (hrs)	216	3.3	(2.9;3.8)	60	3.1	(2.8;3.6)	68	3.2	(2.8;3.7)	21	3.8	(3.4;3.8)	42	3.4	(3.1;3.8)	**0.018**

Legend: Data are median (Q1;Q3), otherwise specified. *: Kruskal-Wallis and Fisher's exact test for comparing group 1,2,3, and 4.

Table 10. Results of the multivariable ordinal logistic regression model

Predictor	Univariable model (n=189) (SODIS implementation factor only)		
	OR	**95% CI***	**P value**
Total no. of events visited by at least one household member	1.07	1.01-1.13	**0.02**
	Multivariable model (n = 146)		
	OR	**95% CI***	**P value**
Total no. of events visited by at least one household member	1.04	0.98-1.11	0.15
Nr of females per household	1.18	1.07-1.30	**0.001**
Household with pregnant women at start of campaign	1.33	0.67-2.64	0.41
Bicycle owenrship	0.75	0.35-1.64	0.48
Latrine	3.38	1.07-10.70	**0.04**
Distance (meters) to water source (log of)	0.94	0.73-1.22	0.65
Households with at least one wasted child under 5	2.17	1.34-3.49	**0.001**

* calculated from robust standard errors adjusted for community cluster

DISCUSSION

We characterised in a cluster analysis four distinct SODIS user groups after a 15-month comprehensive SODIS-dissemination campaign among the participants of a community-randomised, controlled SODIS-evaluation trial in rural Bolivia. Household characteristics that were most strongly associated with the adoption of the SODIS household water treatment method include the intensity of exposure to the SODIS campaign, the number of females per household, latrine ownership, and having severely wasted children living in the home. These three household characteristics that were strongly associated with SODIS-use may help to target SODIS promotion efforts to the population that would more easily adopt SODIS and would, thus, increase the impact of such efforts. The systematic identification of delivery strategies to improve compliance in HWT campaigns is important because improved compliance has consistently been associated with larger reductions in child diarrhoea across numerous HWT efficacy trials [2,3,5].

Our findings suggest that the motivation to adopt new water treatment habits and to acquire new knowledge about drinking water treatment is associated with prior health-related engagements, e.g. in latrine construction, and by with the experience of family health concerns such as living with an acutely malnourished child. In addition, higher SODIS-use was associated with the frequency of exposure to SODIS promotion of anyone of the household members. It is likely that eager adopters of new ideas and technological inventions such as SODIS are more interested in participating at the related promotional events.

Our findings are consistent with previous studies: In a similar setting in Bolivia, Moser and Mosler [25] found existing knowledge about the need to treat drinking water predicted early SODIS adoption. Applying the theory of the diffusion of innovations from Rogers et al. [34] in a SODIS diffusion programme in rural Bolivia they found that participation at SODIS-campaign events correlated positively with SODIS-use [24]. Further, a field study from Nicaragua reported that intention to use and actual use were related to a positive attitude toward the new technology [35]. These coherent findings on the motivating factors for SODIS adoption underscore the importance of determining a target population's characteristics and its attitude towards new technology prior to promoting SODIS.

The indicators we employed in our analysis to measure households' weekly SODIS-use were based on inconspicuous structured observations conducted by our community-based staff who were not involved in any SODIS-promotion activity. In combining objective indicators that measured visible signs of use (e.g. bottles exposed to sun) with proxies more responsive to the direction and magnitude of the change of treatment behaviour (e.g. weekly observation of correct application of SODIS), we increased the quality of measurement and reduced the potential for reporting bias and misclassification error [26-28]. Our independent evaluation of SODIS-use generated much lower adoption rates than estimates from the implementing organization, PCI (32% versus 75%). This underscores the potential for bias in situations when implementers evaluate their own work. Such courtesy bias and over-reporting of compliance with the intervention is well known from water, sanitation and hygiene intervention studies [7,26,36-42]. The discrepancy between the levels of SODIS compliance assessed through different indicators in our study raises questions about the consistency of compliance rates reported in prior studies in peer-reviewed and grey literature. Our results highlight the importance of choosing independent staff and a valid and responsive indicator to assess use and to draw conclusions about the implementation effectiveness of HWT intervention programmes.

Despite an intensive 15-month promotion campaign carried out by a highly qualified implementing organization, we observed 32% overall compliance with the solar water disinfection method during our 12 months of follow-up [15]. Our findings suggest that SODIS promotion would benefit from re-assessing the core marketing messages and approaches to reach the critical 50% fraction of early and willing SODIS adopters in the population [25].

Our analysis identified some characteristics associated with frequent use. However, it is the characteristics of willing but occasional user groups (our 'minimal adopters') to whom new marketing and promotion strategies should be targeted [43]. Based on the characteristics that we measured, it was difficult to differentiate the 'minimal adopters' from 'non-adopters' (Table 8). In this population, the 'non-adopter' and 'minimal-adopter' groups included the most marginalized households by observable characteristics: they were poorer, lived further from water sources, rarely owned a latrine, had more frequently faecally contaminated home environments, and had more animals roaming their kitchen area; yet, unexpectedly, they were less likely to have wasted children in their families (Table 8).

Criteria to plan for the successful roll-out and targeting of water and sanitation programmes based on demand-responsive approaches have often been suggested [44]. In the Bolivian context, SODIS-programme planning may benefit from assessing easy measurable household-level factors like the latrine ownership, a large proportion of females and the presence of a malnourished child to identify population subgroups that can be targeted for rapid uptake of the SODIS HWT method. Those insights supported by our data are consistent with recommendations for a successful roll-out of water and sanitation programmes deriving from previous studies [45-47].

There are limitations to this study. The participating communities were not homogenous regarding pre-existing water supplies and sanitation infrastructures, previous exposure to sanitation and hygiene campaigns, as well as political support to participate in the study. Further, the ordinal logistic regression assumes that the categories follow an intrinsic order. This order is evident for 'non- and minimal adopters' but is less obvious in the case of 'declining- and emerging-adopters'. We felt the ordinal grouping was justified because from the programme-implementation viewpoint the sustained users (the 'emerging adopters' in this analysis) are the most valuable group for sustained impact [34]. To ensure that our findings were not sensitive to the modelling approach, we repeated the analysis using multinomial regression, which does not impose an order to the categorical outcome. Analogous to our presented results, the multinomial regression identified latrine ownership and presence of severely wasted children as the most important predictors of SODIS-use categories (results available from the authors). Finally, data on the SODIS-use indicator 'Households rated as SODIS-user by implementation-independent field worker', was incomplete because (i) the indicator was implemented after an intensive 3-month pilot phase, and (ii) it required the randomly-rotated field staff (every three months) to familiarize themselves with each local community for a period of four weeks before they could report the indicator [15]. While we believe this measure reduced systematic reporting bias and enhanced the reliability of SODIS-use measurement, it reduced the total observation time available for analysis.

CONCLUSIONS

Analyses of implementation effectiveness and the dynamics of SODIS-uptake from large- scale SODIS dissemination programmes are rarely published. Our findings suggest that households that have more women, own a latrine, have malnourished (wasted) children and are close to their water source are more likely to adopt SODIS during an intensive promotion campaign. Households that did not adopt SODIS tended to be poorer, further from water sources and having less hygienic home environments. This finding suggests how implementers could identify populations most likely initially to begin SODIS use and to sustain its use over time.

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AUTHORS' CONTRIBUTIONS

AC and DM conceived the idea and developed the design for the study. AC wrote the original draft manuscript, and incorporated revisions from each of the co-authors. GDP and JH contributed to the conception and design of the manuscript and conducted the statistical analysis. AC and MC coordinated and supervised data acquisition. DM, JH, GDP, and BFA wrote parts of the paper and together with, MC, JMC, and SI contributed to the conception of the manuscript and provided revisions. All authors read and approved the final manuscript.

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"Accepting the lack of good evidence may be preferable to deciding on the basis of misleading evidence"

(Wolf-Peter Schmidt and Sandy Cairncross, 2009)

PART IV

Improving water quality & reducing indoor air pollution at once

MANUSCRIPT IV

Safe drinking water and clean air: An experimental study evaluating the concept of combining household water treatment and indoor air improvement using the Water Disinfection Stove(WADIS)

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SHORT COMMUNICATION

Safe drinking water and clean air: An experimental study evaluating the concept of combining household water treatment and indoor air improvement using the Water Disinfection Stove (WADIS)

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Abstract

Indoor air pollution and unsafe water remain two of the most important environmental risk factors for the global burden of infectious diseases. Improved stoves and household water treatment (HWT) methods represent two of the most effective interventions to fight respiratory and diarrhoeal illnesses at household level. Since new improved stoves are highly accepted and HWT methods have their drawbacks regarding sustained use, combining the two interventions in one technical solution could result in notable positive convenience and health benefits.

A WAter DIsinfection Stove (WADIS) based on a *Lorena*-stove design with a simple flow-through boiling water-treatment system was developed and tested by a pilot experimental study in rural Bolivia. The results of a post-implementation evaluation of two WADIS and 27 *Lorena*-stoves indicate high social acceptance rather due to convenience gains of the stove than to perceived health improvements. The high efficacy of the WADIS-water treatment system, with a reduction of microbiological contamination load in the treated water from 87600 thermotolerant coliform colony forming units per 100 mL (CFU/100 mL) to zero is indicative.

The WADIS concept unifies two interventions addressing two important global burdens of disease. WADIS' simple design, relying on locally available materials and low manufacturing costs (approx. 6 US) indicates potential for spontaneous diffusion and scaling up.

Keywords: Improved stove; Indoor air pollution; Household water treatment; Water disinfection; Hygiene; Sustainability

Introduction

Indoor air-pollution and unsafe water are considered to be amongst the most important global risk factors for lower respiratory infections and diarrhoeal illnesses (Prüss-Üstün et al., 2008). Burning coal and biomass fuels for use in unvented stoves is the domestic energy source for almost 3 billion people, and the resulting smoke contributes significantly to the global illness and disease burden, accounting for about 1.5 million of the 59 million deaths annually, mainly among children under 5 years of age and women (WHO, 2005; Ezzati and Kammen, 2002; Bruce et al., 2000; Smith et al., 2000). Unsafe water, inadequate sanitation and hygiene are among the three top health risk factors in developing

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countries accounting for 4.0% of all deaths and 5.7% of the total disease burden (in disability-adjusted life years) occurring worldwide (Prüss et al., 2002).

Combining the two interventions at the household level – household water treatment (HWT) and vented stoves to improve indoor air quality (IAQ) – offers the potential to make considerable contributions toward the achievement of Millennium Development Goals[1] (Gordon and Rehfuess, 2007). Implementations of improved stoves proved to be highly effective in removing smoke by means of chimneys, while evidence for improvement of health is inconclusive (Smith et al., 2004).

The two systematic reviews of Fewtrell et al. (2005) and Clasen et al. (2007) found that in controlled field trials HWT methods reduce the diarrhoeal burden by 20–35%. Despite these promising findings, only one study provides information on the sustainability of health improvements through HWT intervention after the immediate intervention period (Conroy et al., 1999), and behaviour-based methods may be difficult to sustain in non-trial conditions (Luby et al., 2008).

Simple, affordable HWT options such as disinfection with household bleach (sodium hypochlorite), ceramic filtration and solar disinfection have their advantages and disadvantages, and may be appropriate in different settings, but all depend on the effort and willingness of users to integrate the new technology into their daily life. Motivating such a behaviour change, which often adds work to the daily routine, can be complex when users do not perceive obvious health benefits that accrue from disinfecting water (Mäusezahl et al., 2008). Given such inherent barriers for adoption of HWT methods that are based on behaviour change, there is room for innovative water treatment technologies that do not create additional burdens for users. Tangible and immediate benefits will motivate their use.

The WAter DIsinfection Stove (WADIS) design provides a technical solution that (i) combines two effective interventions by simultaneously improving drinking water quality and reducing indoor air-pollution, and (ii) integrates seamlessly into a typical daily routine without requiring additional time-consuming steps. The WADIS stove, a simple-to-build ventilated cooking stove, purifies drinking water by a flow-through boiling water-treatment system when the stove is in use. A similar combined stove from Bangladesh, the *chulli* clay stove, with a simple water flow-through system pasteurising surface water to prevent the consumption of arsenic tube-well water, has shown high acceptance and efficacy in improving drinking water quality (Islam and Johnston, 2006). However, a recent evaluation of its acceptance and effectiveness two years after implementation revealed that the *chulli* stove was not competitive with the tube-well water due to poor durability, inconvenience, high cost and post-treatment contamination (Gupta et al., 2008). In contrast to the *chulli* stove, which is designed for outdoor cooking and disinfecting microbiological contaminated surface water, the WADIS with an inbuilt chimney is designed for indoor use. Hence, we think that the WADIS, installed in a different setting does not share the limitations of the chulli stove described by Gupta et al. (2008).

In this article we report preliminary results from a pilot experimental study to assess socio-cultural acceptability and evaluate the efficacy of a WADIS stove design in rural Bolivia. The study was carried out in the context of a community-randomised controlled intervention trial to measure the health effects of solar water disinfection (SODIS) in the same rural Bolivian setting (Mäusezahl et al., 2008).

Methods

Structure and concept of the WADIS

The WADIS device is based on the *Lorena* adobe-stove design originally developed as a simple-to-build vented cooking stove for use in Central America by a group of volunteers in Guatemala (www.aprovecho.org). *Lorena*-design based stoves, which are widely used in Central and South America have shown to significantly reduce air particle concentrations and are highly adaptable to local needs and available materials (Household Energy and Health Project, 2006; Masera et al., 2005). The fully enclosed *Lorena*-based stove consists of rammed earth construction, features one combustion chamber with three pot holes and chimney ventilation (see Fig. 1).

For the WADIS a *Lorena*-stove was fitted with a locally available galvanised iron water conduit pipe of 2 cm internal diameter and 3 m length. It was coiled in three helix structures with different diameters of 25–18 cm around the three pot holes of the *Lorena*-stove. The coiled conduit pipe was directly exposed to the hottest zones in the combustion chambers creating a flow-through boiling water-treatment system (Fig. 1). A 20-litre plastic bucket served as a raw water reservoir. A commercially available hosepipe was used for connecting the raw water bucket to the flow-through boiling water-treatment system. The outlet of the conduit pipe of the water treatment system was equipped with a commercially available water tap that allows regulating the water flow-through speed. Manufacturing and material (conduit pipe, horse pipe, water tap, and plastic bucket) costs for the WADIS stove were approx. 6 US dollars.

[1]Millennium Development Goals: 1 (eradicate poverty), 4 (reduce child mortality), 5 (improve maternal health) and 7 (environmental sustainability).

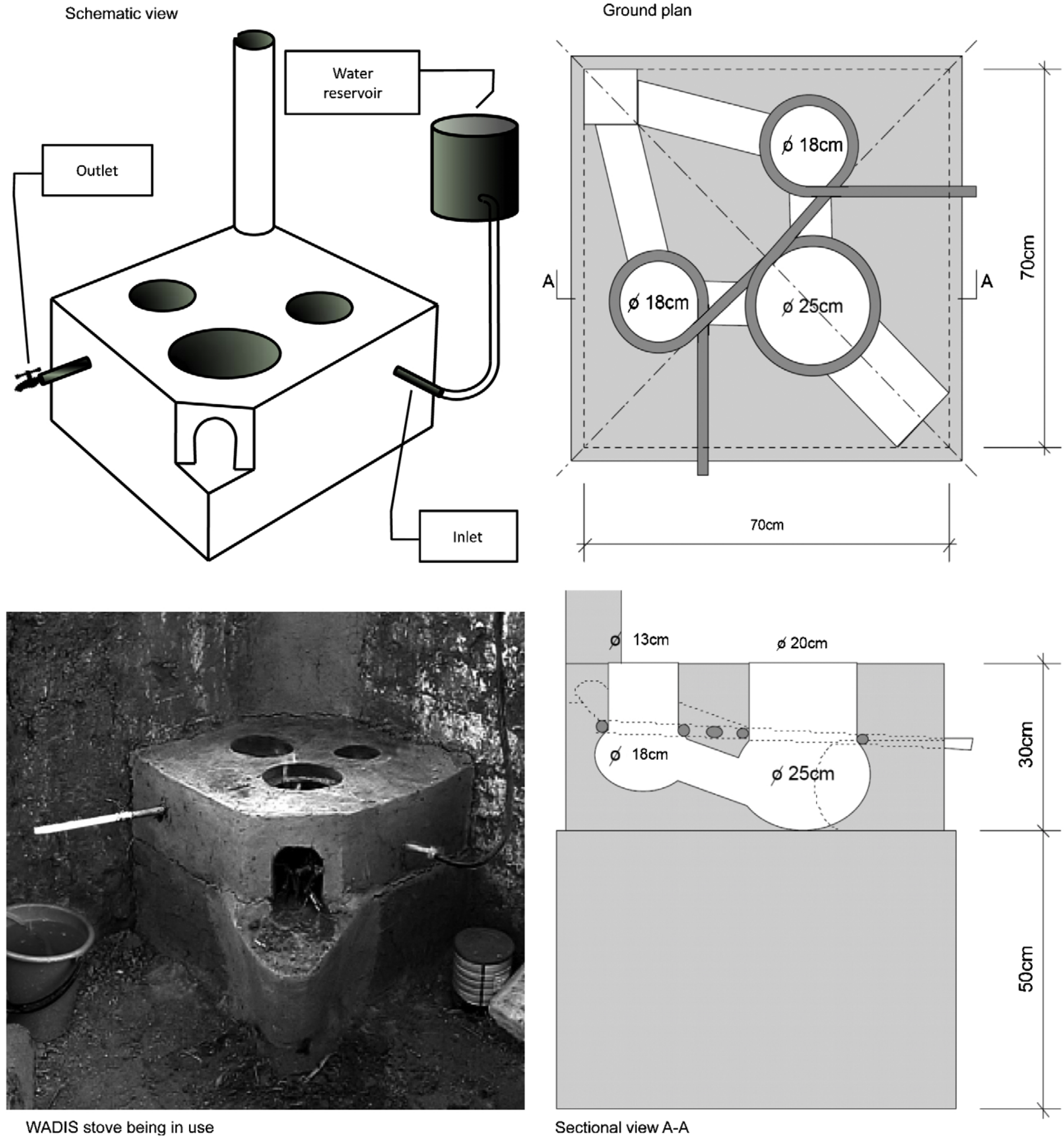

Fig. 1. Schematic diagrams of the Water Disinfection Stove (WADIS).

Ascertaining socio-cultural acceptability

To assess the socio-cultural acceptability of the WADIS-stove two households from a rural community closest situated to the field base were asked to volunteer for testing the stove in their homes. The two households were selected because they were typical households of the rural population that are subsistence farmers, with low income and 4 years of formal education. Both had children >5 years, and relied on unsafe drinking water sources. The owners of the two experimental WADIS-stoves provided detailed information on their experience and impact on their daily lives using the new WADIS technology.

To enhance the view of the two WADIS owners, the perception of further 27 *Lorena*-stove owners were assessed as the *Lorena*-stove is the closest proxy for the WADIS. The *Lorena*-stoves were implemented 6 months previous to this study in two communities in the Totora district, by a local NGO development programme. Information on the *Lorena*-stove, its usage and handling, cooking performance, fuel consumption, reduction of indoor smoke, and perceived effect on health compared to previous cooking stoves in use, was obtained from 27 interviews. The structured questionnaire with non-leading questions was applied by trained, local field staff from the randomised controlled SODIS trial (Mäusezahl et al., 2008).

Ascertaining efficacy

To assess the efficacy of the WADIS to improve drinking water quality, one of the two WADIS implemented in two households in a community in the Totora district was used. The efficacy assessment was done by comparing microbiologically contaminated water samples before and after treatment by the WADIS. In total four tests were done from an initial water sample of 20 litres from a nearby microbiologically contaminated community drinking water source. The degree of faecal contamination of the 20-litre sample was analysed (sample A). The contaminated water was led to flow from an elevated plastic bucket through the cold conduit pipe in the WADIS in order to assess baseline disinfecting effects other than heat (sample B). The two subsequent tests (samples C and D) were done with altering flow-through rates (1 and 2 litres per minute) after the WADIS was heated as usual for cooking. Tests were conducted after waiting additional 30 min to allow WADIS to reach operating temperature. All water samples (B, C and D) were collected after passing the conduit pipe in 1-litre sterile sampling containers and microbiologically analysed at the national referral laboratory (Centro de Aguas y Saneamiento Ambiental (CASA)). Efficacy of the boiling flow-through water-treatment system to inactivate pathogens was assessed by measuring the number of colony forming units/100 mL (CFU/100 mL) for thermotolerant coliforms and the most probable number/100 mL (MPN/100 mL) for total coliforms and *E. coli* in the 1-litre water sample before and after treatment. The 1-litre samples were processed in the laboratory using standard membrane filtration techniques (Franson and Clesceri, 1998) for thermotolerant coliforms, and Colilert®-18 dehydrated media (IDEEX, Westbrook Maine, USA) for the identification of total coliforms and *E. coli* bacteria.

The potential efficacy of the WADIS to reduce indoor smoke was assessed qualitatively by interviewing the 27 owners of the improved *Lorena*-stoves (used as a surrogate vented stove for WADIS) to determine whether they perceived a notable indoor smoke reduction since the installation of the improved stove.

Results

Socio-cultural acceptability

Detailed information provided by the two WADIS owners revealed that in addition to valuing the indoor smoke reduction, they especially valued the provision of hot/warm water in a larger quantity than before and specifically for having this commodity available for many hours during the day. The provision of running, hot water in the home lead to previously unanticipated benefits including: preparing baths for small children, laundry with warm water, and connecting sprinklers for showers (Box 1). The WADIS owners did not comment on limitations or concerns regarding the new stove.

Of the 27 households owning the *Lorena*-stove (used as a surrogate stove for WADIS) 26 reported to be satisfied with the general cooking performance of the stove. Among the 27 *Lorena*-stove owners 23 (85.3%) reported that the new stove produced less indoor smoke, and 19 (73%) stated that reduced smoke was the most important reason why they were satisfied with the new stove. Comparing the frequencies of illnesses before and after installment of an improved stove, 60.9% of the *Lorena*-users perceived reductions in cough, 30.4% reported reductions in eye irritation, and 21.7% reported suffering less of headaches. Seven (26.9%)

Box 1. Selected statements from Beneficiaries indicating the potential of the new WADIS:

- *''Now I have masses of warm water for the laundry, which is great!'' (23 year old woman, Totora)*
- *''My daughter wants to have her face washed every morning before going to school because the warm water makes her beautiful, she says.'' (31 year old woman, Totora)*
- *''I have connected a shower to the tap from the stove and everyone in the family wants to take a shower with warm water.'' (32 year old man, Totora)*
- *''Since I can use this hot water it is much easier to clean the dishes because the fat is now better soluble'' (31 year old woman, Totora).*

Table 1. Results of water analysis of faecally contaminated drinking water before and after treatment by the WADIS-stove.

Water sample	Flow-through rate (L/min)	Thermotolerant coliforms (CFU/100 mL)	Total coliforms (MPN/100 mL)	*E. coli* (MPN/100 mL)
A	–	87600	>2419.2	221.1
B	1	84300	–	–
C	1	0	0	0
D	2	0	0	0

A = initial contaminated water sample; B = control water sample after flow-through cold stove; C and D = water samples after treatment by flow through hot stove with different flow through rates; CFU = Colony Forming Units; MPN = Most Probable Number.

users reported that the new stove required less fuel compared to their prior stove; the remaining users reported no change in their fuel use. Besides cooking the *Lorena*-stove is also used to boil water (25/27 or 92.6%). Provision of hot/warm water for personal hygiene (68%), washing the dishes (6%) and provision of safe drinking water (48%) were the main reasons mentioned for wanting to boil water.

Efficacy tests

The WADIS-stove improved drinking water quality of two tested 1-litre water samples (samples C and D) from an initial contamination load of thermotolerant coliforms of 87,600–0 CFU/100 mL (Table 1). The complete elimination of thermotolerant coliforms in the contaminated drinking water by the flow-through boiling water-treatment system of the WADIS was confirmed in our tests of total coliforms and *E. coli* concentrations. Both indicators for faecal contamination were reduced to zero. Doubling of flow-through speed from 1 to 2 litres per minute did not influence efficacy of any measurement.

Discussion

This study provides preliminary results from testing a simple combined smoke-free cooking and water purification device (WADIS) based on the *Lorena*-stove. The microbiological analyses of water before and after treatment by the WADIS revealed that the simple technical supplement of the stove – a coiled iron pipe in the burning chamber – was highly efficacious in disinfecting faecally contaminated drinking water. Detailed information provided by the two WADIS owners confirmed that the main purpose of the combined interventions, namely the reduction of smoke and the provision of large quantities of hot/warm safe water were perceived as the main benefits of the technology. When prompted, owners of Lorena stoves, which were used as a surrogate-vented stove for the WADIS declared that illness symptoms related to indoor air pollution such as eye irritations, cough and headache decreased notably after using the new stoves. WADIS owners strongly valued the large quantity of hot/warm water generated by the stove and immediately incorporated their warm water use to previously unthought-of domains of household and personal hygiene such as dish washing, laundry, showering or baby bathing. Our findings from a small number of efficacy tests and interviews suggest that the users in rural Bolivia perceive immediate benefits from the combined stove/water treatment WADIS system and have little trouble integrating its use into their daily routine. These findings indicate potentially large benefits from combining improved stoves with a household water treatment concept represented by the WADIS.

For a household solution to have a positive public health impact an intervention needs to be scalable, i.e. easy to implement and people should desire it. The WADIS stove brings the basic prerequisites for being scalable and desirable by providing desired hot/warm water in large quantity for various household chores and by reducing spurious indoor smoke. The simple design, which relies on locally available materials and enables owners to maintain the stoves themselves, is additionally conducive for the scalability and self-driven diffusion of the technology. Manufacturing costs for a simple *Lorena*-based WADIS stove are approx. 6 US dollars. The production and sale of WADIS accessories, such as taps, showers and safe storage containers which are also widely available and affordable, can offer income-generating opportunities for local entrepreneurs. Recent progress in the social marketing of sodium hypochlorite for household-based water disinfection (Banerjee et al., 2007) and the commercial production and sale of various types of improved stoves (e.g. the 'Rocket stove' in Uganda (Habermehl, 2007), the ceramic *Jiko* in Kenya/Sudan (Ezzati et al., 2000)) provide some evidence of the demand for similar products even at full cost recovery.

The main limitations of this study are that only two experimental WADIS stoves could be built with the funds available and the low number of samples tested for assessing the efficacy. The short duration of follow up and the low number of WADIS built did not allow observing health effects on indoor air quality and water and hygiene related infectious diseases. The perceived benefits reported by the users of newly installed *Lorena*-stoves must be interpreted with care due to the lack of a comparison group (e.g. with a traditional stove). This applies particularly to the perceived smoke reduction since this was one of the main selling points of the *Lorena*-stove. In addition it should be mentioned that the views on WADIS of the two households testing the stove, might not be generalizable to the overall local population because they had established a close relationship with the study team.

In order to warrant the scalability and sustainability of the WADIS concept, it needs to be further developed and extensively evaluated in terms of choice of material for water heating coils, long-term durability and maintenance, functionality, safety and instruction for use. Mandatory for further tests is the development of preventive measures; for example against superheating and powerful discharge of hot vapour during the flow-through process in the water treatment system of the WADIS, which could potentially lead to injuries in adults and children standing close to the outlet of the WADIS conduit pipe. This issue could easily be addressed by simply preventing starting water flow into the empty coil of a pre-heated stove and using child and pressure-proof taps.

To reach the MDG and considering the moderate success of existing HWT methods especially when focusing on the provision of long-term solutions and sustainability in reducing the global burden of diarrhoeal disease an exigency for innovative, locally developed concepts continues to exist. The conceptual idea of integrating a simple flow-through boiling water treatment system in existing, effective and desirable improved stoves that reduce indoor air pollution and fuel consumption is a promising strategy for reducing common environmentally mediated diseases. The WADIS concept unifies two interventions addressing two important global burdens of disease at once (respiratory infections and waterborne gastrointestinal illness) and could contribute to the endeavours to help reach the MDGs.

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“Habits keep us doing what we have always done, despite our best intentions to act otherwise.”

(David T. Neal, Wendy Wood & Jeffrey M. Quinn, 2006)

PART IV

Discussion & Conclusion

CHAPTER IV:

Discussion

This section comprises summaries and discussions of the most important findings of this research. Following a critical review of the study methodology, we discuss how the specific findings of the individual manuscripts contribute to a better understanding of the effectiveness of the point-of-use solar water disinfection. At the end of this section we are putting our conclusions into an overall perspective.

10. EFFECTIVENESS OF SODIS

The primary goal of this research was to evaluate the effectiveness of the point-of-use household water treatment method SODIS in decreasing diarrhoea in children <5. For this purpose, a community-randomised intervention trial was conducted in rural communities from the Totora district in Bolivia. For this trial the SODIS intervention campaign was embedded in a national SODIS dissemination programme of a local NGO. The intervention approach increases the generalisability of the trial results making them applicable to other settings, where SODIS is typically implemented by local NGO's. Consequently, the results of this trial will help public health planners when choosing a POU-HWT method for providing safe drinking water to households that lack safe water supply.

Despite an extensive SODIS promotion campaign a possible health impact in this specific, but typical, setting in rural Bolivia was too low to be assessed by this study. The intention-to-treat analysis detected a non-significant diarrhoea reduction of 19% in the SODIS intervention group. Project staff observed throughout the study a mean SODIS-usage rate of 32% in the intervention. Possible reasons for the non-significant health impact of SODIS in our setting are briefly discussed in *Manuscript I*. Overall, these results are neither in line with the findings of former trials assessing the health impact of SODIS (Conroy et al. 1999; Conroy et al. 1996; Rose et al. 2006) nor with the results of trials testing a variety of different other POU-HWT technologies, summarised in the meta-analysis of Fewtrell et al. (Fewtrell et al. 2005) and Clasen et al. (Clasen et al. 2006).

10.1. Current evidence of the SODIS health effectiveness: Internal and external validity

Internal validity refers to the extent to which differences identified between randomised groups are a result of the intervention being tested. It thus depends on good design, implementation, analysis of the trial, and data collection with minimal bias (Altman et al. 2001; Delgado-Rodriguez and Llorca, 2004; Eldridge et al. 2008). External validity refers to the extent to which study results can be applied to other populations, individuals, or settings (Altman et al. 2001; Eldridge et al. 2008).

To our knowledge only three studies have been conducted for aiming to assess the effectiveness of SODIS so far (Conroy et al. 1999; Conroy et al. 1996; Rose et al. 2006). Conroy and colleagues tested SODIS during 12-weeks in secluded Maasai communities of very high child diarrhoea rates and highly contaminated drinking water sources. The health impact was reported as a 16%-reduction in <6 year old children and a 9%-reduction in diarrhoea prevalence (two-weekly) in 6-16 year olds. According to the authors, a 100% compliance with SODIS was assured through social control by Maasai elders. The same Maasai elders were responsible for the SODIS promotion and for the health data collection. A reasonably higher significant reduction in diarrhoea incidence (36%) was found in the study by Rose and colleagues. This 6-months study involved 200 children (100 assigned to receive the intervention) in an urban slum in Vellore, India. Compliance with SODIS was high, with 78% of households complying with the SODIS-use indicator on >75% of the visits.

Despite the high SODIS compliance reported by the three trials, it is important to discuss some methodological issues, which may have affected the internal and external validity of these studies. In the Conroy and Rose trials, SODIS was implemented at household level in highly controlled settings and participants were insistently encouraged to use SODIS ensuring very high compliance. The SODIS intervention should be implemented on community level, because SODIS is a behavioural intervention designed to reduce infectious diarrhoea with disease transmission and prevention being rather likely of having community level dynamics (Eisenberg et al. 2007). The assured high compliance with SODIS devaluates the external validity of these results and therefore impedes the judgement of its effectiveness under real life conditions. The fact that Conroy and colleagues did present only the results from adjusted models with *post-hoc* selected covariates influences the interpretation of the internal validity of the study. Furthermore, the approach chosen to blind participants by either exposing SODIS bottles to the sun or keeping the bottles in-house certainly reduces bias, but might contravene with ethical guidelines. Creating a mixed message in the control arm which is first made to believe that keeping water in the bottles in-house is an adequate form of water treatment to subsequently learn (after study end) of the superiority of UV-radiation exposure of SODIS-bottles might not be ethical. In addition, we have to assume that reporting bias was intensified by employing Maasai elders who simultaneously promoted SODIS and collected data on the main outcome, probably leading to a biased estimate of the effectiveness of the intervention.

For our study we employed several measures to assure a high internal and external validity. We chose a community-randomised trial rather than a household- or individual randomised trial design primarily because SODIS is typically disseminated through community rather than household promotion. In addition to the randomised allocation of the SODIS intervention on community level, we pair-matched communities on the baseline diarrhoea rates (pre-intervention) reducing the variance of our effect estimate and removing potential confounding effect of any imbalanced morbidity. We monitored child health on a weekly basis during an entire year (12 subsequent months) representing another design factor increasing the internal validity of our trial results. The one-year follow-up of participants accounts for seasonal effects on our outcome measure. Additionally it allows a better assessment of SODIS adoption rates, acceptability, and to some extent estimating the sustainability of the intervention.

Child diarrhoea as the outcome measure was assessed through self-reporting of diarrhoea by the children's caregivers and hence entailed the potential of reporting bias affecting our results (Baqui et al. 1991; Morris et al. 1994). One of the most effective strategies to reduce this kind of bias is blinding of those receiving and those administering the intervention (Altman et al. 2004; Schulz and Grimes, 2002). The term blinding refers to keeping trial participants, investigators (those collecting outcome data) unaware of the assigned intervention, so that they will not be influenced by that knowledge (Schulz and Grimes, 2002). However, in our study blinding of either those receiving or those administering SODIS and assessing the outcomes was not possible due to the nature of the intervention and ethical reasons. The intervention status of the cluster receiving SODIS was inevitably identifiable by the visible display of bottles to sunlight. Although double blinding (blinding investigators and participants) indicates a strong design and is a cornerstone of internal validity, trials that are not double blinded cannot automatically be deemed inferior (Schulz and Grimes, 2002). We aimed at controlling the differential assessment of outcomes (information bias), which could have occurred through non-blinding of outcome assessors and participants, by optimising the acquisition of data. We employed local field staff fluent in Quechua (local language), and provided them with a one month extensive training in interviewing and epidemiological observation techniques, and in general approaches to community motivation. Additionally, field staff was based in the communities, where they were socially well accepted and integrated. This allowed them to gather reliable health and hygiene behaviour data inconspicuously. Field staff was not involved in any SODIS promotion or other implementation activity. Furthermore, field staff was randomly rotated between communities every three months in order to reduce any interviewer bias.

10.1.1. Critical aspects of the outcome assessment affecting internal validity

The use of continuous diarrhoea surveillance is problematic. Underreporting occurs if recall period is longer than 2 or 3 days (Alam et al. 1989; Boerma et al. 1991; Ramakrishnan et al. 1999) and frequent disease surveillance may affect the reporting behaviour of the study participants (e.g. Hawthorne effect)(Schmidt et al. 2007). In our study, we used a 7-day-health diary recording the daily occurrence of diarrhoea. The diary was kept by the caregiver of the study child. Similar to other studies (Genser et al. 2006; Quick et al. 2002; Semenza et al. 1998), we detected a decline in reported diarrhea episodes over time, which was unlikely to be caused by seasonal variation (*Manuscript I*). The detected decline indicates that motivation to report diarrhoea may have decreased during the course of our study. In some occasions, caregivers anecdotally reported that the daily diarrhoea assessment was time-consuming. A possible way to reduce the influence of surveillance on participants' behaviour and minimizing recall error affecting the internal validity of trials is to intermittently sample diarrhoeal morbidity data as suggested by Schmidt and colleagues (Schmidt et al. 2007).

Another possible factor affecting the internal validity of our study is that caregivers of our study subjects who were not blinded to the intervention may have been aware of the possible diarrhoea reducing effect of SODIS. Hence, caregivers duteously applying SODIS might have been sensitised to health issues and hence, may have observed more carefully their children's defecation thus, tending to occasionally misclassifying some defecation of their children as diarrhoea. This could have led to a difference in diarrhoea reporting in the intervention and control arm.

We employed several data quality control mechanisms such as intensively supervising field staff, double data entry, and employing an independent coding process of the data (see methodology chapter and *Manuscript I* and *III*) in order to reduce the effects of possible reporting and observer bias introduced by the above mentioned primary outcome assessment approach.

10.1.2. Generalisability of findings: External validity

One of the overarching goals of our trial was to estimate SODIS effectiveness by generating results out of a setting that resembles closely current worldwide SODIS dissemination activities and hence achieving a high external validity. Therefore the SODIS intervention of this study was embedded in an ongoing SODIS dissemination programme conducted by one of the most active NGOs (Project Concern International) in promoting SODIS in Bolivia. Previous to the study, all SODIS implementation activities were piloted in communities in the neighbouring district of the study site (Pocona district). The SODIS intervention included implementation activities at all levels of the rural society (e.g. district-, community-, and household level) and involved relevant stakeholders, such as governmental district and community entities (e.g. municipality, health and education system, farmers association, community heads) and individual opinion leaders in each community. The SODIS intervention was implemented in a standardised manner which means that each promotional activity was conducted in the same way in each of the communities and households of the intervention arm. The standardised manner of the SODIS implementation, being embedded in an ongoing SODIS dissemination programme allows drawing conclusions on the effect of the intervention and generalising its results to similar settings and cultures.

In comparison with previous studies describing the SODIS effectiveness, we may conclude that our cluster-randomised trial, which measures effectiveness rather than efficacy (Donner and Klar, 2000), features important methodological components increasing the internal and external validity of our findings. The validity of the results of this study will contribute to the current knowledge base on the effectiveness of SODIS. This will yield in additional, valuable evidence influencing the decision-making on HWT campaigns at local and national levels.

10.2. Critical interpretation of the SODIS health impact

10.2.1. Domestic water quantity and health

In 2003 WHO provided some guidance on the quantity of domestic water that is required to promote good health (Howard and Bartram, 2003). For many years there has been an extensive debate about the importance of adequate water quantity for human health (Cairncross, 1990; Churchill, 1987; Esrey et al. 1985; Esrey et al. 1991; Kolsky, 1993; Thompson et al. 2001). Several studies suggest that the quantity used for hygiene, rather than water quality improvements, determines the health benefit (Cairncross, 2003). To meet the requirements for consumption (hydration and food preparation) and basic hygiene, a minimum of 7.5 litres per capita per day are usually required (Howard and Bartram, 2003). Table g in Appendix G summarises the requirements for water service levels to promote health.

Households participating in our study, which did apply SODIS, exposed on average 1.9 bottles of 1-1.5 litres to the sun, resulting in an overall treated water quantity of 2-3 litres per household per day. This amount of disinfected water seems to be too low to cover the basic requirements for consumption for one household including 6.25 members on average. In fact, the limited amounts of treated water resulted in people using and consuming both, SODIS-treated and untreated water. The amount of disinfected water was certainly not enough to be used for basic personal hygiene purposes. The above mentioned aspects militate against a possible health impact of SODIS and might be a possible reason for the none-significant reduction of diarrhoea detected in our study setting (*Manuscript I*).

In conclusion, we may agree with Cairncross and Valdmanis and Howard and Bartram claiming that the provision of a sufficient quantity and basic level of access to safe drinking water should still have priority for the water and health sectors (Cairncross and Valdmanis, 2006; Howard and Bartram, 2003).

10.2.2. Aspects of transmission pathways of faecal-oral disease

Most endemic diarrhoeal disease has multiple transmission pathways (Cairncross and Feachem, 1991; White et al. 1972). However, it is generally accepted that most diarrhoea infection is not waterborne, but transmitted from person to person via hands, food and other fomites because of poor hygiene practices (Curtis et al. 2000; Vanderslice and Briscoe, 1993). This raises the question of the relevance of water-borne transmission of diarrhoeal pathogens, in relation to other transmission routes by which these pathogens are spread.

In our study we registered faecal contamination in about 60% of the yards of our participating households. This indicates a highly contaminated environment and simultaneous exposure to a multiplicity of transmission pathways in addition to contaminated water. Study participants in our study washed their hands 1.4 times a day on average and 72% reported to be used to wash their hands before eating. Seeing that the majority of children do not wash hands much more than once a day, we assume that our study children were still heavily exposed to other diarrhoea risk factors than contaminated drinking water. In addition, children <1 suffering on average 9.5 diarrhoea episodes a year were mostly breastfeed (see *Manuscript I*) and were therefore not prone to waterborne diarrhoea, but were exposed to the contaminated environment by crawling on faecal contaminated floors.

Our inconclusive findings on diarrhoea reduction raise the question, if the manifold transmission pathways other than consuming water recorded in the living environment could have interfered with the effect of the SODIS intervention. We have to consider that either the application of SODIS was not efficacious in disinfecting the contaminated water in our setting, or that the source of infection was not primarily drinking water. On the one hand, we may disprove that SODIS was not efficacious in disinfecting drinking water, firstly because of the intensive training of participants in applying SODIS and the regular reinforcement visits at the households by the NGOs staff, and secondly because the disinfection efficacy of SODIS is proven (Acra et al. 1989; Kehoe et al. 2004; McKenzie et al. 1992; Wegelin et al. 1994). On the other hand, we might assume that the primary source of infection was not water, since Gundry and colleagues were able to show in a systematic review that no clear relationship with microbiological quality of point-of-use water and diarrhoea was found (Gundry et al. 2004). However, several meta-analysis of intervention studies improving point-of-use water quality showed, that the interventions did significantly reduce diarrhoeal disease (Arnold and Colford, Jr., 2007; Clasen et al. 2006; Fewtrell et al. 2005). The discrepancy of Gundry’s findings and the findings of the reviews on HWT effectiveness could be explained by several factors. Most interventions included in some form hygiene educational activities or at least raised the awareness of the importance of hygienic behaviour which could have influenced the positive effect of the water treatment interventions. The hygiene components of those interventions may have contributed more to the reduction of diarrhoea than the improved quality of drinking water itself. In addition, many of the studies reviewed by Fewtrell et al., Clasen et al., and Arnold and Colford were not blinded and study participants and field workers were aware that water treatment was intended to reduce diarrhoea and modified their responses to conform to the aim of the project. Furthermore, the reported effect estimates of the POU-HWT intervention studies, which have been considered in the above mentioned meta-analysis and which employed subjective outcome measures, might therefore be severely prone to responder and observer bias (Arnold and Colford, Jr., 2007; Clasen et al. 2006; Fewtrell et al. 2005; Wood et al. 2008).

In conclusion we may claim that although SODIS was correctly applied by our study subjects the intervention did not sufficiently intervene with the general transmission pathway of diarrhoea causing pathogens resulting in inconclusive findings on diarrhoea reduction. Without other environmental improvements the benefits of POU-HWT might be negligible. A more 'holistic' approach including community water improvements, sanitation and hygiene may produce better health outcomes than POU-HWT alone (Eisenberg et al. 2007). There is a need to evaluate such combined interventions employing objective outcome measures reducing potential systematic bias

11. COMPLIANCE WITH SODIS: FACTORS FOR ADOPTION AND USE

11.1. Measuring compliance with SODIS

Compliance with SODIS (i.e. consumption of the treated water) is an important factor in assessing potential impact of the intervention. There is a scarcity of general information on compliance with SODIS, and POU-HWT systems in general in the literature. None of the studies so far assessing effectiveness of interventions to improve water quality for preventing diarrhoea has assessed compliance directly (Clasen et al. 2006). Accurate monitoring of compliance and its mechanisms were scarcely dealt with in technical and interventional efficacy and effectiveness studies so far. This drawback complicates the interpretation of effect estimates of POU-HWT evaluations.

The SODIS implementation in our trial was a continuous process. Adoption, application and rejection of the SODIS intervention were continuously monitored through community-based staff. This allowed reporting associations between morbidity and compliance within the intervention arm (*Manuscript I*). Furthermore, we evaluated household determinants and SODIS campaign factors leading to adoption or rejection of the method (*Manuscript II & III*). However, measuring compliance is difficult since no gold standard indicator to assess actual use of SODIS exists. For that reason we applied different SODIS-use indicators throughout the course of the trial which revealed different usage rates. The most conservative indicator[1] employed by the community-based staff revealed a mean SODIS-usage rate of approximately 30%. Community-based staff´s judgement relied on daily observations of correct application, placing bottles in plain sunlight and/or getting drinking water from a SODIS-bottle when asked for. Regular SODIS use reported by household respondents was an additional indicator considered in a survey at the beginning and the end of the follow-up phase. This resulted in a self-reported user rate of 77% and 80% respectively. The remarkable discrepancy of compliance with SODIS assessed in our study when applying different SODIS-use indicators, raise questions of how to interpret compliance rates of published and un-published studies on the effectiveness of SODIS, but also in other studies evaluating POU-HWT methods.

The levels of compliance with SODIS differed depending on whether trial staff, staff of the implementer or independent staff assessed use. SODIS-use was monitored by the implementing NGO applying structured observations in addition to the compliance assessments conducted by the community-based field worker. SODIS promoters of the NGO, which monitored compliance with SODIS on a monthly basis and during their motivational household visits, reported an average SODIS-usage rate of 65 – 75% (table 10). In contrast, the assessments of the community-based staff (using the same indicators) revealed that SODIS was used only during 26 - 33% of the weeks when households were observed (see table 10). The striking difference suggests that households may have wished to demonstrate to the implementer their understanding and acceptance of the new water disinfection instructions. This courtesy bias causing an over-estimation of SODIS-use was anecdotally confirmed by community-based staff observing households placing bottles on the roof right before the visits of the NGO-staff.

The complexity of compliance measurements highlights the importance of choosing independent staff and a valid and responsive indicator to assess use and to draw conclusions on implementation effectiveness of health intervention programmes.

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1 Proportion of weeks during which a family was classified as SODIS-user by community-based staff after observing the family for at least 4 weeks.

Table 10. Compliance with SODIS

Compliance measured by implementation independent staff	Households (n=216)		
Weeks under observation	216	39	(34;40)
Percentage of weeks bottles observed exposed to sun	216	33	(17;50)
Percentage of weeks bottles observed ready to drink	216	8	(2.6;18)
Weeks under observation for SODIS use classification	216	23	(21;24)
Percentage of weeks classified as SODIS user by MMS	216	26	(8.7;50)
Compliance measured by implementer			
Weeks under observation	213	11	(7;18)
Percentage of weeks bottles observed exposed to sun	208	75	(60;85)
Percentage of weeks bottles observed ready to drink	213	65	(50;79)
Percentage of weeks SODIS-purified water consumption was observed	213	86	(71;94)

Legend: data are median (Q1;Q3)

11.2. Acceptance of SODIS

In order to assess the overall acceptance of the new water treatment method and intentions to use the method in the future we conducted a household survey at the end of the study. Respondents from 186 of 225 households from the intervention arm, which were willing to participate in this survey, were interviewed by the community-based field staff on convenience, water taste, and cost of SODIS.

Table 11 shows the opinions of SODIS-users regarding SODIS. Group 1 has the lowest SODIS-usage rate, group 3/4 the highest (see *Manuscript III*). Except one variable, the SODIS-user groups established based on six SODIS-use indicators (see table 7, *Manuscript III*) did not differ between each other. All respondents defined themselves as SODIS users and the answers given were mostly in favour of the new methodology. Regular SODIS-use was reported by 80% of the 186 respondents. They also reported having consumed SODIS water during a mean of 4.5 days in the previous week. The over-reporting of SODIS-use resulting from these assessments could be explained by either the respondents being overly happy with the new water disinfection method or respondents wanted to please the interviewer. We evaluated self-reported SODIS-use by asking the interviewers to observe the application of SODIS. A median of 1.8 bottles exposed to sun and a median of 1.4 bottles ready-to-drink were observed at the time of the interview. When asking the participants about the number of SODIS bottles having ready-to-drink, they reported a median of 3.6 bottles which approximately concurred with the observed number of exposed and ready-to-drink bottles. If asked for the reason why some people might not apply SODIS, 20% of the respondents mentioned laziness, 12% difficulty to understand the method, 30% disinterest, and 15% overall disinterest in topics related to their health. Interestingly 11% of the respondents mentioned the lack of continued monitoring and control of the NGO as a reason for not applying SODIS.

Table 11. Acceptance and use of SODIS in 3 different SODIS-user groups

SODIS-use patterns and opinions	Total n=186			Groups based on SODIS-use behaviour: Group 1 n=60			Group 2 n=68			Group 3/4 n=63			*p-values
Reported duration of SODIS use (month): median (Q1;Q3)	151	12	(8;12)	31	12	(6;12)	59	12	(8;12)	61	12	(10;12)	0.383
Motivation to use SODIS													
Convinced to use by implementing NGO	152	106	(69.7)	31	24	(77.4)	59	3	(59.3)	62	47	(75.8)	0.094
Desire to disinfect water	152	38	(25)	31	6	(19.4)	59	18	(30.5)	62	14	(22.6)	0.480
Easy to apply	152	12	(7.9)	31	0	(0)	59	7	(11.7)	62	5	(8)	0.114
Good taste	152	5	(3.3)	31	1	(3.2)	59	3	(5.1)	62	1	(1.6)	0.630
Intention to use SODIS in future	150	148	(98.7)	30	29	(96.7)	59	59	(100)	61	60	(98.4)	0.678
Children applying SODIS	186	54	(29)	55	17	(30.9)	68	22	(32.4)	63	15	(23.8)	0.526
Adults applying SODIS	186	118	(63.4)	55	16	(29)	68	50	(73.5)	63	52	(82.5)	**0.000**
Readiness to pay for 1 bottle	149	94	(63.1)	30	18	(60)	59	36	(61)	60	40	(66.7)	0.777
SODIS usage implies additional costs	151	9	(6)	31	3	(9.7)	58	2	(3.5)	62	4	(6.5)	0.495
SODIS usage saves money	150	143	(95.3)	31	30	(96.8)	59	56	(95)	60	57	(95)	1.000
Lasting of PET bottles for SODIS use (weeks): median	152	3	(1;4.3)	31	4	(1;4.3)	59	3	(1;4.3)	62	2	(2;4.3)	0.710
Increase of soap use since starting using SODIS	144	77	(53.5)	26	16	(61.5)	58	28	(48.3)	60	33	(55)	0.506
Increase of water consumption since starting using SODIS	149	86	(57.7)	29	20	(69)	58	32	(55.2)	62	34	(54.8)	0.396

Legend: n = number of households; Data are no (%), otherwise specified; Test-statistics: Kruskal-Wallis (ordinal) and Fisher's exact (categorical)

We conducted focus group discussions to further explore the reasons for the acceptance of SODIS. Results showed, that households that adopted SODIS and were more prone to integrate SODIS into their daily lives beforehand reported to be happy with the new method. However, when discussing limiting or less attractive factors of the method, many participants mentioned its laborious application and the limited amount of disinfected water available at the end. In general, the method was described as an interim solution until the authorities bedight all communities with an own house connection to the community water system. A recent review of POU-HWT methods confirms that the required time and effort to treat sufficient water quantities with SODIS for all daily household uses may contribute to declining usage rates and consumption of both treated and untreated water, undermining their overall effectiveness (Sobsey et al. 2008).

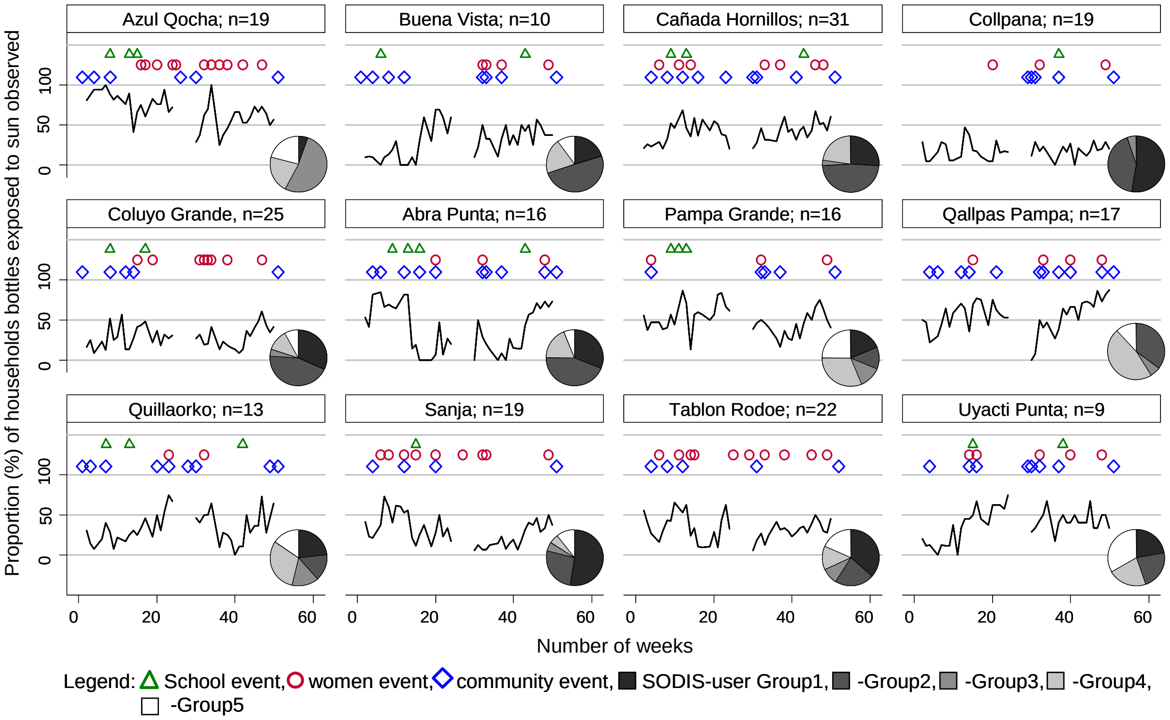
Overall, the SODIS method was well accepted and most of beneficiaries were mostly in favour of the new methodology. However, acceptance and regular application of use was not assessed as congruent. This might underpin the indication that SODIS, as simple its application seems to be, is a complex POU-HWT method not rendering the benefits it is supposed to.

11.3. Adoption of SODIS

Household and campaign factors that were associated with SODIS-use (*Manuscript II* and *III*) were determined. Comparing groups' characteristics in respect to their SODIS-use behaviour allowed identifying relevant factors that help understanding the acceptance of the method and targeting future SODIS implementations at households predestined to adopt the method. The evaluations revealed that households with long walking distances to water sources, relying on safe water sources, having an increased number of children aged between 10-14 years living in the household, intensively exposed to the intervention campaign, having severely wasted children, and owning latrines were using SODIS more frequently.

For the subgroup analyses of the above evaluations (*Manuscript II & III*) households were grouped regarding their SODIS-use and independently of the community they belonged to. Therefore, heterogeneous community level factors were probably equally distributed in these groups. If not, these factors were captured by the statistical models accounting for 'community-effects'. Although the design of this study did enable us to assess causal effects of interventional community events on SODIS adoption and use, we observed no marked increase or decrease in user rates over time due to certain activities. None of the specific events conducted on community level showed a significant impact on SODIS use in the 11 communities (see figure 16). Nevertheless, SODIS-user rates differed remarkably between communities and over time and should be further discussed here: Some of the intervention communities were not homogenous regarding pre-existing water supply and sanitation infrastructure, previous exposure to sanitation and hygiene campaigns, as well as political support to participate in the study. One community, Azul Qocha, showed a relatively high SODIS-use over time (see figure 16). This particular community was exposed during many years to previous sanitation and hygiene programmes. The community was well organised, featuring an accepted community leader and many committed women engaged in the SODIS promotion. In comparison, the community Sanja, which showed a moderate SODIS-usage rate, endured political conflicts during the study period resulting in several changes of community leaders.

Figure 16. SODIS-use and SODIS promotion events on community level over time. Pie-charts depict community composition as regards SODIS-user groups (see *Manuscript III*).



We also found an association between SODIS-use and presence of a latrine in the home, which indicates that previous exposure to sanitation and hygiene campaigns played a role in adopting SODIS. Previously published post-intervention studies from comparable settings revealed that an increased involvement in the issue of safe water were positively related with SODIS adoption (Altherr et al. 2008; Heri and Mosler, 2008; Moser and Mosler, 2008). All these findings indicated that community and household characteristics, such as political support to participate in the study, pre-existing health knowledge, motivation and knowledge of disinfecting drinking water acquired through previous exposure to water, sanitation and hygiene programmes is associated with adoption and use of SODIS. This underscores the importance of careful programme planning, determining populations' characteristics, and their attitude towards the new POU-HWT system.

12. Sustainability of POU-HWT Systems

In order to achieve health impact by introducing POU-HWT, it is essential to assure its sustainability. Broadly, sustainability is the ability to maintain a certain process or state. In connection with POU-HWT, the application of the newly introduced HWT method needs to be maintained over a long period, until better solutions for providing safe drinking water is available. It needs to become a part of the daily routine of the user. The sustainability of a POU-HWT intervention is determined besides behavioural and attitudinal factors, by the technologies' attractiveness, ease of application, durability, and the complexity of its maintenance over a long term. Sustainability of POU-HWT interventions can be assessed by monitoring the application of the method over a prolonged period of time and after cessation of active promotion.

Although a variety of POU-HWT technologies have been tested, and disseminated, not all have an evidence base of sustained use (Clasen et al. 2006; Clasen 2008; Fewtrell et al. 2005; Schmidt and Cairncross, 2009). Most studies documenting effectiveness for POU-HWT reducing diarrhoeal disease have typically lasted only months and do not address critical aspects of sustainability. Sustained use of SODIS has only been evaluated over study durations and continued use has been variable and often low (Sobsey et al. 2008). Sustainability of SODIS appears to be governed primarily by convenience and attitudinal factors that need further study to address barriers to long-term use (Hobbins 2004; Sobsey et al. 2008). Rainey and Harding found in a SODIS acceptability study, that unimproved taste, smell, and appearance of treated water, and the time and effort required to treat water are important determinants of acceptability (Rainey and Harding, 2005). The only study indicating that SODIS was used a few months after ending a formal trial of SODIS describes the usefulness of SODIS to control and prevent a cholera outbreak (Conroy et al. 2001). The study examined the protection offered by SODIS against cholera. It was conducted in an area of Kenya in which a formal trial of SODIS had finished and one month after a cholera epidemic occurred. Unfortunately no information is available if the application of SODIS was maintained after the cholera outbreak and after the study team had left the area.

Difficulties maintaining high post-implementation use levels after cessation of intensive surveillance and education efforts, as in field trials and marketing campaigns, are reported from other POU-HWT technologies. Flocculant-disinfection of water has been shown to be effective with a 39% diarrhoea reduction in Guatemala (Chiller et al. 2006). Six months after the study end only 5% of the households were still using the methodology even after efficacy was demonstrated within the communities and an aggressive and sophisticated marketing approach was applied (Luby et al. 2008). Another independent evaluation of the longest running national POU water programme that subsidised and marketed chlorine in Zambia showed, that within one year of the highest sales of chlorine, only 13% of households had residual chlorine in their drinking water at unannounced visits (Olembo et al. 2004).

Some researchers claim that POU-HWT is most effective in reducing the burden of diarrhoeal disease by providing safe water and safe storage in poor areas, in the absence of other environmental improvements, in particular sanitation (Clasen et al. 2006). However, priorities of the poorest populations are often not congruent with health priorities outlined by health planners. This makes it difficult to convince the beneficiary to sustainably apply the POU-HWT method. Poor populations favour projects increasing agricultural productivity, improving education, enabling access to markets, and reducing asset inequalities (Slaymaker et al. 2007). Thus, linking projects from those sectors with projects providing HWT methods, water supply and/or sanitation could contribute to a sustained improvement of health, economic growth and poverty reduction at once.

Considering the moderate success of widespread and promising POU-HWT systems especially when focusing on the provision of long-term sustainable solutions in reducing the global burden of diarrhoeal disease an exigency for innovative and locally developed concepts, - ideally covering several of the abovementioned needs at once -, continues to exist. One such example of an innovative concept is based on the idea of integrating a simple flow-through boiling water treatment system in existing, effective and desirable improved stoves that reduce indoor air pollution and fuel consumption *(*Water Disinfection Stove (WADIS), Christen et al. 2009; cf *Manuscript IV)*. The evaluation revealed high efficacy in improving the water quality and high social acceptance rather due to convenience gains of the stove than to perceived health improvements. It seemed that achieving the population health benefit of the intervention (reduction of diarrhoeal and respiratory disease) was itself not a motivation for families to apply the method. This suggests that motivating people to regularly use POU-HWT methods like SODIS will need to depend on more than only recognising a reduction in diarrhoea (Luby et al. 2008).

By making use of the heat emitted during cooking to disinfect water, almost every type of improved stove could be equipped with a similar water treatment device used and tested in the WADIS. Since big implementation campaigns of improved stoves are globally underway it would be intuitive to develop such simple water treatment supplements for the selected stoves and improve water quality and reduce indoor air pollution at once. The concept could be a promising strategy for reducing common environmentally mediated diseases and to overcome the shortfalls of single POU-HWTs regarding sustained application.

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CHAPTER V:

Conclusion

14. CONCLUSION

The world is on track to meet the millennium development goals' drinking water target (7.3). Current trends suggest that more than 90% of the global population will use improved drinking water sources by 2015 (WHO and UNICEF, 2008). Despite these advancements, there is still a need for improved drinking water supply in developing countries. Many of the areas of these countries with the poorest populations and with the highest disease risk appear unlikely to have access to piped drinking water in the near future. Several effective technical solutions to purify drinking water at household level are available today, at low price and ready for large scale dissemination to populations in need. However, many barriers for scale up of such point-of-use household water treatment solutions (POU-HWT) exist, ranging from complex management and maintenance and still too high costs to change complex behaviours and attitudes. Even if those barriers appear to be minor, contemporary implementation strategies, primarily subsidised development or government initiatives, have failed to scale up usage beyond a limited or project-based application (Clasen, 2008).

The implementation and health effectiveness of Solar Water Disinfection (SODIS) claimed one of the most promising home-based water treatment systems was evaluated and described in this thesis in order to inform on potential future scaling up of the SODIS method. Even under close-to-ideal conditions for prolonged SODIS implementation campaigns in the Bolivian highland setting the present evaluation using a randomised controlled trial did not show SODIS as an effective method in reducing diarrhoeal disease in children <5 years. Too many competing environmental risks for infectious diseases may have disguised the health effects of SODIS. In addition, the small quantity of treated water provided by SODIS was insufficient to prevent the consumption of contaminated drinking water and does not seem to meet the required quantity for human health. Supposable a more 'holistic' approach including community water improvements, sanitation and hygiene may produce better health outcomes than a SODIS intervention alone.

The present findings which also suggest that the wide promotion of SODIS is premature raise the question, if previous effectiveness evaluations generated too optimistic and biased results in terms of health impact. In fact Schmidt and Cairncross provide supporting evidences for this concern in their recent publication reviewing the evidence of the effectiveness of POU-HWT methods (Schmidt and Cairncross, 2009). They raise doubts whether the claims of health benefits published so far are true, and whether POU-HWT is scalable among poor populations. The current evidence on effectiveness does not exclude that the observed diarrhoea reductions are largely or entirely due to bias (Schmidt and Cairncross, 2009). They conclude that only observational studies and blinded RCTs with regard to effectiveness, long-term acceptability and identifying suitable target populations will provide additional scientific evidence on how established efficacy translates into effectiveness under various cultural settings and interventions (Schmidt and Cairncross, 2009). The effective dissemination of SODIS and of POU-HWT systems in general, depends not only on indentifying suitable target populations, but especially on promotional factors and the practicability, long-term attractiveness, and commercial viability of the method itself. Elaborative campaigns involving private and public stakeholders and sophisticated persuasive product advertisements must be conducted to increase adoption and constant application rates of POU-HWT methods. Since the overall goal is to convince the beneficiaries to re-arrange their habits and use a given water treatment method, it is indispensible to design effective interventions involving not only engineering and epidemiology disciplines, but also anthropology and consumer research. The pursuit of commercial viability presents a promising strategy by which to promote POU-HWTs' adoption and sustained use. Employing commercial approaches to transform the daily application of a POU-HWT method into a welcomed habit is essential to making POU-HWT technologies commercially viable (Harris, 2005; Curtis et al. 2007). However, convincing people to incorporate a new water treatment habit and introducing a new health intervention product to the competitive market could be very hard (Harris, 2005). Most recent developments of health promotion attempting to induce changes in hygiene behaviour have resorted back on common knowledge in the area of psychology and habit formation. Curtis and colleagues for example developed new public-health approaches employing evolutionary psychology, marketing and public-private partnerships (Curtis et al. 2007), which could be adapted and used to diffuse POU-HWT systems.

Unless the overall adoption and acceptance of POU-HWT methods, especially across broad populations will be considerably increased, the public health benefit and contribution to meeting the millennium development goals will be modest. Thus, much work is needed to better understand and incorporate into improved practice the role of education, behaviour change, individual and group perceptions, attitudes of the aesthetic qualities of water, and the social-cultural drivers that influence household water treatment choices and practices of individuals, households, and communities (Sobsey et al. 2008).

Finally, but maybe most important, we need to know if POU-HWT methods have the potential for a sustained adoption as only continuous use could remarkably reduce the waterborne diarrhoeal disease burden.

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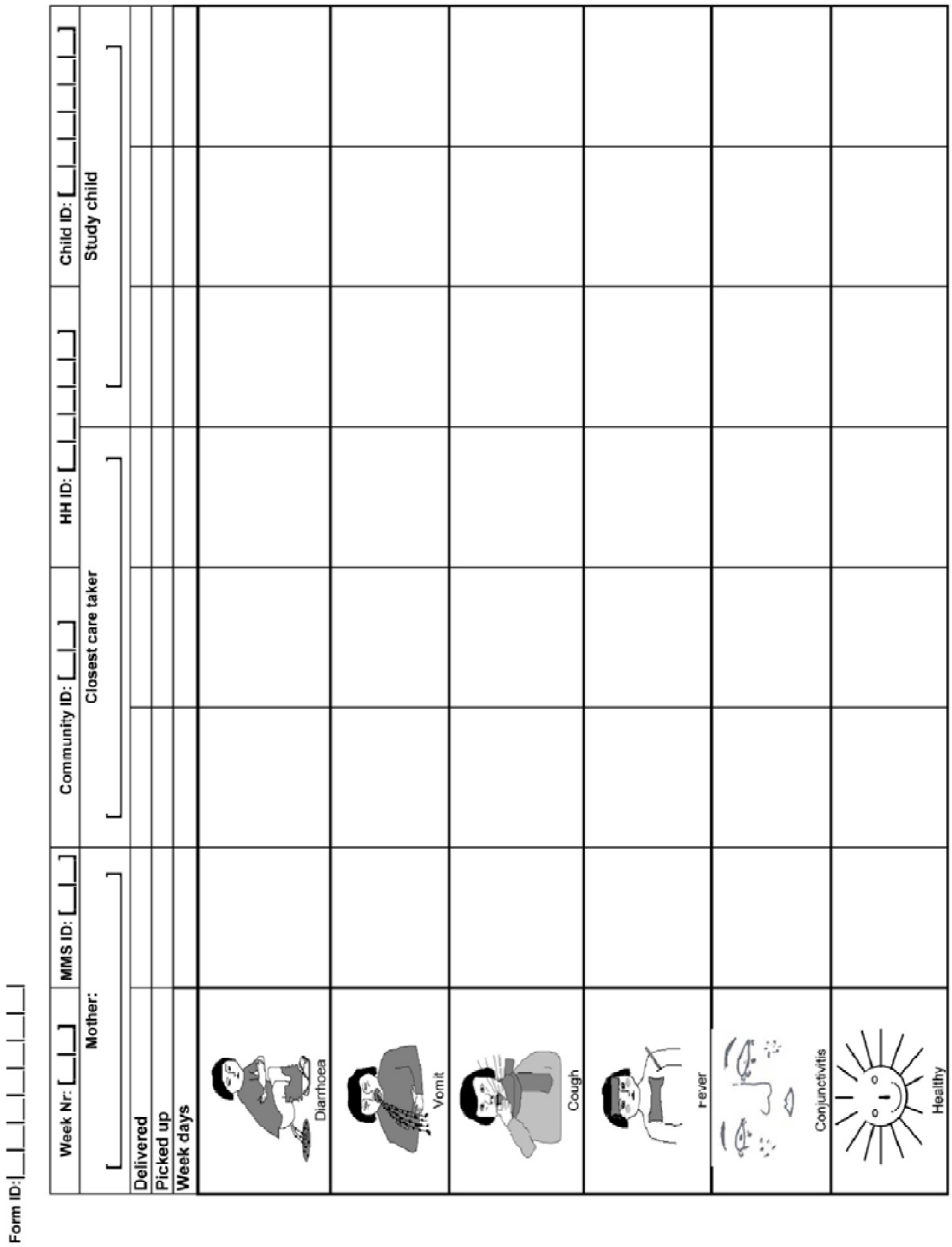
APPENDICES

Appendix A: Health monitoring tools

Health diary. Each week the field worker hands the diary over to the mother or closest caregiver of the study child. To each column week days are assigned by the field worker according to the day of the visit. The mother or closest caregiver of the study child puts stickers in the cells for each day the child showed the symptoms depicted in the left column.



Form ID: |__|__|__|__|__|__|

Week Nr: [__|__]	MMS ID: [__|__]	Community ID: [__|__]		HH ID: [__|__|__|__|__]		Child ID: [__|__|__|__|__|__]	
Mother: [ ]		Closest care taker [ ]				Study child [ ]	
Delivered							
Picked up							
Week days							
Diarrhoea							
Vomit							
Cough							
Fever							
Conjunctivitis							
Healthy							

Health diary collection tool: Each week the field worker hands over a new diary to the mother or the closest caregiver of the study child and at the same time collects the diary from the previous week. The field worker copies the information from the diary to the collection tool and thus conducts the first quality check of the information on the diary. For each day where the mother or closest caregiver has put a sticker on the diary the field worker poses the according questions listed on the collection tool.

BoliviaWET

Swiss Tropical Institute
Institut Tropical Suisse
Schweizerisches Tropeninstitut

Form ID.: [__|__|__|__|__|__|__]

Check MMS:	☐
Check FS:	☐
Coding:	☐
1. Data Entry:	☐
2. Data Entry:	☐

Collection tool for health diary

Page: 1
Created on: 06/06/2005

Week Nr: [__|__]	MMS ID: [__|__]	Community ID: [__|__]	HH ID: [__|__|__|__|__]	Child ID: [__|__|__|__|__|__|__]

Mother	Closest caretaker	Study child
Name:	Name:	Name:
Last name:	Last name:	Last name:

Delivered (diary):							
Picked up (diary):							
Week days:							
Sticker = 1 / No Sticker = 0	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
1.Do you remember how many times (child) relieved himself during this day? (33) DK	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
2. How did stool look like? (1)Water/ (2)Api/ (3)Arope/ (4)Milk rice/ (5)Smashed potatos/ (6)Sausage/ (7)Other/ (33)DK	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
2.1 If Other, please describe it?							
3. Did stool contain blood? (1)Yes/ (0)No/ (3)DK	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
4. Did stool contain mucus? (1)Yes/ (0)No/ (3)DK	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
5. Did child take any medicine to cure the diarrhoea? (1)Yes/ (0)No/ (3)DK	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
5.1 If Yes, what did [child] take?							
6. What do you think caused the K'echalera? (1)Fear/ (2)Sun/ (3)Water/ (4)Food/ (5)Cold / (6)Heat/ (7)Pacha Mama/ (8)Other/ (33)DK	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
6.1 If Other, what was the reason for the K'echalera?							
Sticker = 1 / No Sticker = 0	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
7. What do you think caused the vomit? (1)Fear/ (2)Sun/ (3)Water/ (4)Food/ (5)Cold / (6)Heat/ (7)Pacha Mama/ (8)Other/ (33)DK	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
7.1 If Other, what was the reason for the Vomit?							
Week days:							
Sticker = 1 / No Sticker = 0	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
8. What do you think caused the cough? (1)Fear/ (2)Sun/ (3)Water/ (4)Food/ (5)Cold / (6)Heat/ (7)Pacha Mama/ (8)Other/ (33)DK	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
8.1 If Other, what was the reason for the cough?							
Sticker = 1 / No Sticker = 0	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
9. What do you think caused the fiever? (1)Fear/ (2)Sun/ (3)Water/ (4)Food/ (5)Cold / (6)Heat/ (7)Pacha Mama/ (8)Other/ (33)DK	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
9.1 If Other, what was the reason for the fever?							
Sticker = 1 / No Sticker = 0	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
10. What do you think caused the Conjunctivits? (1)Fear/ (2)Sun/ (3)Water/ (4)Food/ (5)Cold / (6)Heat/ (7)Pacha Mama/ (8)Wind/ (9)Other/ (33)DK	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
10.1 If Other, what was the reason for the conjunctivits?							
Sticker = 1 / No Sticker = 0	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

Comments:

Appendix B: Weekly SODIS-use observational protocol

Weekly SODIS-use observational protocol (page 1): This form was filled by the community-based field worker after collecting the health diary from the participating household in the intervention arm.

BoliviaWET
SODIS Water Evaluation Trial

Swiss Tropical Institute
Institut Tropical Suisse
Schweizerisches Tropeninstitut

Form ID.: [__|__|__|__|__|__|__|__]

Check MMS: ☐
Check FS: ☐
Coding: ☐
1. Data entry: ☐
2. Data entry: ☐

Page 1 of 2

SODIS Use: *Weekly observations of SODIS Use*

Created on….
Filename…

Week number: [__|__]	MMS ID: [__|__]	Community ID: [__|__]	HHID: [__|__|__|__|__|__]
Name of the HH Chief: (Name/Prename)			

When visiting the household and when walking around in the village try to observe how people practice SODIS. Do it inconspicuously. Do not judge the observed habit. Describe it as objectively as possible.

Please be again reminded that this information is treated strictly confidential and never seconded to third persons by any member of the study. If you have comments or any questions contact your supervisor.

1. Date of observation: _____/_____/2005 — 1. [__|__] [__|__] 05

2. Time of observation: ___:___ — 2. [__|__]

3. SODIS use:

3. Does the family practice SODIS at all?
(1) Yes ☐ (➔4) (0) No ☐ (➔3.1) (9) NA ☐ *(End of the questionnaire)* — 3. [__]

3.1 *If NO*: Do you know why the family does not use SODIS? — 3.1
(1) They are too lazy ☐ (2) They do not have bottles ☐ [__][__]
(3) They do not believe in the method ☐ (4) They have too much work ☐ [__][__]
(5) They are boiling the water ☐ (6) They do not know how to do it ☐ [__][__]
(7) They say it has bad taste ☐ (8) They are not interested in ☐ [__][__]
(9) They do not have time ☐ (10) They say it is too complicated ☐ [__][__]
(11) There is no sun ☐ (12) They do not trust PCI ☐ [__][__]
(33) DK ☐ (13) Other ☐: ______________________ [__][__]

4. *If seen SODIS bottles exposed to the sun*: Observe the bottles and tick the corresponding options: — 4.
(1) Bottles are clean and filled with clear water ☐ [__]
(2) Bottles are clean and filled with turbid water ☐ [__]
(3) Bottles are dirty and/or scratched and fillded with clear water ☐ [__]
(4) Bottles are dirty and/or scratched and fillded with turbid water ☐ [__]
(9) NA ☐ *(e.g.there are not bottles)* [__]
(5) Other: ______________________ [__]

5. How many days per week does the family practice SODIS?
________ days (9) NA ☐ (3) DK ☐ — 5. [__] ←

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Weekly SODIS-use observational protocol (page 2):

2. *HHID: [__|__|__|__|__|__]* *Week number: [__|__]*

6. Does the family drink SODIS? (1) Yes ☐ (0) No ☐ (3) DK ☐ (9) NA ☐ — 6. [__]

7. What for does family use SODIS?

(1) Consumption (drinking) ☐ (2) Cleaning of dishes ☐
(3) For personal hygiene ☐ (4) Do not use it ☐
(5) To tranquilize/impress PCI ☐ (9) NA ☐
(6) Other ____________________

7. [__][__] [__][__] [__][__] [__][__]

8. Who in the family usually practices SODIS?

(1) Father ☐ (2) Mother ☐
(3) Children ☐ (4) All family members ☐
(33) DK ☐ (9) NA ☐
(5) Other ____________________

8. [__][__] [__][__] [__][__] [__][__]

9. Who in the family drinks SODIS?

(1) Father ☐ (2) Mother ☐
(3) Children ☐ (4) All family members ☐
(5) Nobody ☐ (9) NA ☐
(33) DK ☐ (6) Other ____________________

9. [__][__] [__][__] [__][__] [__][__]

10. Do you personnally consider this family as a SODIS User?
(<u>SODIS User:</u> Family, which states that they practice SODIS every day, have bottles exposed to the sun or ready to drink in the house and are able to offer you SODIS water when asked for during the weekly visit)
(1) Yes ☐ (0) No ☐(→10.1) (9) NA ☐ — 10. [__]

10.1 If NO: Why not?
(1) NO: Family does almost never practice SODIS ☐ — 10.1 [__]
(2) NO: Family states that they drink SODIS but never exposes bottles to the sun ☐ — [__]
(3) NO: Family states that they drink SODIS but NEVER drink it and only practices SODIS to fullfill PCIs' requirements ☐ — [__]
(4) NO: Family states that they drink SODIS but ONLY practices and drink SODIS during PCIs visit
(5) NO: Family state that they drink SODIS but only practice SODIS in order to have warm water for other purposes than drinking ☐ — [__]
(6) NO: Family state that they drink SODIS regularly but practice SODIS only 1-2 days per week ☐ — [__]
(9) NA ☐ — [__]
(10) NO: Other reason: ____________________ — [__]

Please feel free to write down your personal opinion about the way the family is using SODIS:

____

____

____

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Appendix C: Methodology of stool specimen analysis

Parasitological analysis

Occurrence of intestinal parasites was investigated on all samples. The SAF-conserved faecal samples were processed using a modification of the Ritchie formal-ether concentration method (Knight, 1976), and independently two times examined by two experienced laboratory technicians under a light microscope. Presence or absence of the following intestinal protozoa and helminths' eggs or larvae was recorded separately: *Blastocystis hominis, Entamoeba coli, Entamoeba hist/dispar, Iodamoeba bütschlii, Ascaris lumbricoides* (roundworm), *Hymenolepis nana* (dwarf tapeworm), larvae of *Strongyloides stercoralis* and *Trichuris trichiura* (whipworm). In addition monoclonal antibody-based enzyme linked immunosorbent assays (ELISA) were used to detect *Cryptosporidium parvuum* and *Giardia duodenalis* antigens (R-Biopharm, Darmstadt, Germany) and 3 adhesin (TechLab, Blacksburg, VA, USA) according to manufacturers' instruction.

Bacteriological analysis

All faecal samples were inoculated on Salmonella/Shigella (SS) agar, MacConkey (MC) agar and Sorbitol MacConkey agar (in case of samples with blood) (BD, Franklin Lakes, NJ, USA) and incubated at 35±2°C for 24 hrs. Morphologically different colonies (lactose-positive and lactose-negative colonies) were isolated from MC plates and SS plates and further identified by classical biochemical test (lactose, saccharose, glucose, gas, H2S, citrate, urease, lysine, ornithine, motility, indole, malonate, methyl red, Voges Proskauer). If the identification failed, an oxidase test was further performed. The colonies on MC plates were cultured in addition for 24h at room temperature in order to enable isolation of *Yersinia enterocolitica*. *Escherichia coli* colonies were isolated from MC plates and conserved in nutritive agar with 0.3% yeast extract supplement to be tested by Polymerase Chain Reaction (PCR) 24,25 to differentiate pathogenic enteric *E.coli* strains (EPEC, ETEC and EIEC). For the identification of *Salmonella spp.* a little aliquot of native sample was added to the swab sample and enriched in a tube with 10mL tetrathionate broth (TT) (BD, Franklin Lakes, NJ, USA) with 0.1% brilliant green (Fisher Scientific, Hampton, NH, USA) and iodine solution; incubated at 35±2°C for 6-8 hrs and inoculated onto brilliant green agar (BG), Hektoen enteric agar (He) and xylose lysine deoxycholate media (XLD) (BD, Franklin Lakes, NJ, USA); *Salmonella spp*. was identified with biochemical tests; if negative, the TT tube was incubated again at 35±2°C for 72-96h and the inoculation process described above was repeated. Tests for the following pathogenic enteric bacteria were performed: *Escherichia coli*, *Hafnia alvei*, *Pseudomonas*, *Proteus spp.*, Serratia (indicator of malnutrition), *Salmonella spp.*, *Shigella spp.* and *Yersinia enterocolitica*.

Virological analysis

All stool specimens from diarrhoea symptomatic cases were tested for the presence of *Rotavirus*, *Adenovirus*, *Norovirus* and *Astrovirus*. Test material was stored at –20°C immediately after arrival at the laboratory until testing with antigen based enzyme linked immunosorbent assays (ELISA) was performed. Tests were done according to manufacturer's instructions (R-Biopharm, Darmstadt, Germany).

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Appendix D: Methodology of water sampling and analysis

Detailed description of the water analysis

All water analyses were performed by staff from the Centro de Aguas y Saneamiento Ambiental (CASA) at the technical faculty of the University San Simon (UMSS). The water was sampled by the supervisors.

Water was sampled in 500mL plastic bottles, stored in cooler boxes at 4°C and transported to the local research office where refrigeration was possible. From there samples were transferred to the central laboratory at CASA in Cochabamba within 24 hours. Information on the condition of the source, on provenience of water stored in the household, water treatment and storage were gathered during sampling.

Community chiefs were notified by the study team about the test results of source water and household heads about the results of the household water analysis.

Bacteriological analysis

Faecal coliform tests were performed with portable equipment only during baseline. During follow-up survey all water samples were sent within 24h to the CASA laboratories.

Thermotolerant coliforms include the genus Escherichia, Klebsiella, Enterobacter and Citrobacter. The concentration of thermotolerant coliforms in water is often direct related with the concentration of E.coli (World Health Organization 2004). Analyses were performed on 10 and 100mL samples according to the membrane filtration technique as described by the American Public Health Association (Franson and Clesceri 1998). Two samples of 10 and 100mL were vacuum-passed through a sterile 5µm Supor membrane filter (Pall, East Hills, NY, USA) and incubated on a selective M-FC agar medium (Merck, Whitehouse Station, NJ, USA) at 44±0.5°C for 24-28 hrs in a Oxfam-DelAgua portable incubator (Robens Centres, University of Surrey, Gilford, Surrey, United Kingdom). Blue colony forming units of thermotolerant coliforms are counted (Lloyd and Helmer 1991), (and multiplied by 10 in the case of the 10mL sample) averaged and recorded as colony forming units (cfu) per 100mL. If a number of blue colonies grew from a volume of 10mL that was too numerous to count, a value of 7000 cfu per 100mL was artificially assigned.

Total coliform bacteria include organisms that can survive and grow in water. They are not accurate indicators to quantify faecal contamination of water. However they serve as an indicator of water treatment effectiveness and to assess functioning of water distribution systems (World Health Organization 2004). *E.coli* is considered to be the most reliable indicator for faecal contamination. 100mL samples from the main community water sources were tested for total coliforms and *E.coli* with the Colilert method. According to manufacturer's instructions 100mL sample volumes were added to Colilert®-18 dehydrated media (IDEEX, Westbrook Maine, USA) in sterile, transparent and non-fluorescing vessels. Samples were then shaken by hand to dissolve the media. The contents of the vessels were poured into sterile Quanti-Tray®/2000 (IDEXX, Westbrook Maine, USA) with the wells for enumeration of bacteria, and heat sealed. Quanti-Trays were incubated at 35±0.5°C for 18 hrs. After incubation, the yellow wells were counted and number of coliforms was calculated using a Most Probable Number (MPN) table. Then the fluorescing wells (366nm) were counted, and number of E.coli cells was calculated using the MPN table. Results were expressed in MPN per 100mL.

Main source water was tested for faecal streptococci. The detection and enumeration was performed with the membrane filtration technique as described by the American Public Health Association (Franson and Clesceri 1998). Two samples of 10 and 100mL were vacuum-passed through a sterile 5µm Supor membrane filter (Pall, East Hills, NY, USA) and incubated on a selective KF streptococci agar (Oxoid, Basingstoke, Hampshire, U.K.) at 37±0.5ºC for 24-48 hrs. The number of red colonies was counted (and multiplied by 10 in the case of the 10mL sample) averaged and recorded as colony forming units (cfu) per 100mL. If a number of red colonies grew from a volume of 100mL that was too numerous to count, the average of the 10mL sample was used.

Parasitological analysis

OOcysts are very persistent in water and extremely resistant to disinfectants commonly used in drinking-water treatment. These characteristics, coupled with the low numbers of oocysts required for an infection (DuPont et al. 1995; Okhuysen et al. 1998; Rendtorff 1954), place these organisms among the most critical pathogens in the production of safe drinking water from surface water.

Water was filtered and sampled from one main water source of each community to test qualitatively for the presence of cysts of *Giardia lamblia* and oocysts of *Cryptosporidium parvuum*. The Merifluor, Meridian kit was used to test for cysts of *G. lamblia* and oocysts of Cryptosporidium. Therefore, 500-1000L samples were filtered through a sterile 1µm polycarbonate filter (Cuno, Meriden, CT, USA). The filter was transported at 4-10°C to the CASA laboratories. The oocysts were separated by means of immunomagnetic separation (IMS); stained on well slides with fluorescently labelled monoclonal antibodies (Meridian, Cincinnati, OH, USA) and 4',6-diamidino-2-phenylindole (DAPI). The stained sample was examined using fluorescence and differential interference contrast (DIC) microscopy. Qualitative analysis was performed by scanning each slide for objects that meet size, shape, and fluorescence characteristics of Cryptosporidium oocysts or Giardia cysts. Potential oocysts or cysts were confirmed through DAPI staining characteristics and DIC microscopy.

Virological analysis

F-RNA Coliphages are viruses that use *E. coli* as host for replication. Coliphages replicate typically in the gastrointestinal tract of humans and warm-blooded animals, and are therefore indicators of faecal contamination. In addition, their presence indicates the potential presence of enteric viruses. All community water sources were tested for F-RNA Coliphages by applying a modification of the direct plaque assay as described by the American Public Health Association (Franson and Clesceri 1998). 20mL samples were mixed in aliquots of 5mL with a Tryptic(ase) soy agar (TSA) (Difco Laboratories, Deroit, MC, USA) containing the host *Escherichia coli* C (ATCC 15597) and plated on four 10-cm-diameter petri dishes. The plates were incubated at 35±0.5ºC for 8-10hrs. The number of plaques developed by lysing of the infected coliform bacteria was counted after incubation. The results were recorded as plaque forming unit (pfu) per 100mL by summing the plaques counts from the four plates and multiplying by 5.

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Appendix E: A three-level logistic regression model with random community- and household effects

The logistic regression model considers three important features of the data structure: i.) Dependent binary outcome; ii.) Time-dependent outcome (a linear trend on the log odds scale was hypothesised) and iii.) A three-level hierarchical structure with repeated measurements nested within a household and households nested within communities.

Given that π_{ijk} is the probability that household j in the community k adopts SODIS during the week i of survey; two models were fitted: a basic model (1) and a model including the covariates (2):

$$\log\left(\frac{\pi_{ijk}}{1-\pi_{ijk}}\right) = (\beta_1 + v1_k + u1_{jk}) + (\beta_2 + v2_k + u2_{jk})t_{ijk} \quad (1)$$

$$\log\left(\frac{\pi_{ijk}}{1-\pi_{ijk}}\right) = \eta_{ijk} = (\beta_1 + v1_k + u1_{jk}) + \underline{x}_{jk}^T \underline{\alpha} + (\beta_2 + v2_k + u2_{jk})t_{ijk} \quad (2)$$

where t_{ijk} is the time of observation expressed in weeks; v_k are the level-3 random effects (community effects); u_{jk} are the level-2 random effects (household effects); $\underline{x}_{jk}$ is the vector of baseline determinants; $\underline{\alpha}$ is the vector of regression coefficients for the time-independent covariates; β_1 is the log odds of SODIS adopters at time 0 for a household with level-2 and level-3 random effects equal to zero; and β_2 is the log odds ratio for the change in time over one unit of time.

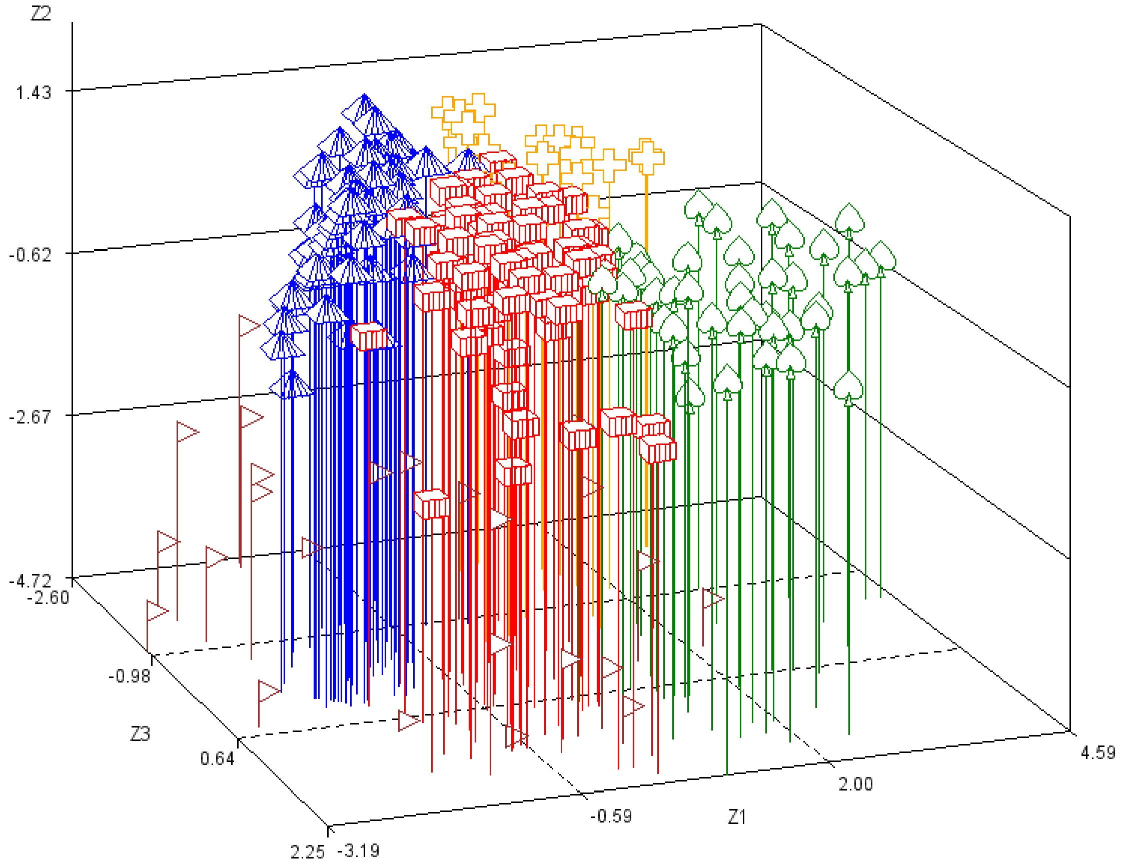
The assumptions underlying model (1.) are that: i.) both the link function and the linear predictor are correctly specified, ii.) the variance is a known function of the observed proportions, i.e. $Var(Y_{ijk}) = \pi_{ijk}(1-\pi_{ijk})$ and iii.) the random effects at different levels are uncorrelated and normally distributed with mean 0 and constant variance-covariance matrices $\Omega_u = \begin{bmatrix} \sigma_{u1}^2 & \\ \sigma_{u1,u2} & \sigma_{u2}^2 \end{bmatrix}$ and $\Omega_v = \begin{bmatrix} \sigma_{v1}^2 & \\ \sigma_{v1,v2} & \sigma_{v2}^2 \end{bmatrix}$.

Community (v_k) and household (u_{jk}) random effects were assumed to follow bivariate normal distributions with means zero and variance-covariance matrices $\Omega_v = \begin{bmatrix} 2.408 & \\ -0.130 & 0.009 \end{bmatrix}$ and $\Omega_u = \begin{bmatrix} 1.536 & \\ -0.063 & 0.005 \end{bmatrix}$.

Graphical inspection of the residuals' graphs revealed that there was no need to model complex variation and that the assumptions underlying the model were reasonably met.

Appendix F: Principal component analysis of SODIS user groups

Figure f. 3D scatter plot view of SODIS user groups of the first three principal components



Appendix G: Domestic water quantity and health

Table g indicates the likely quantity of water that will be collected at different levels of service. The estimated quantities of water at each level may reduce where water supplies are intermittent and the risks of ingress of contaminated water into domestic water supplies will increase. Where optimal access is achieved, but the supply is intermittent, a further risk to health may result from the compromised functioning of waterborne sanitation systems (Howard and Bartram et al. 2003) [1]

Table g. Summary of requirement for water service level to promote health (Howard and Bartram et al. 2003)

Service level	Access measure	Needs met	Level of health concern
No access (quantity collected often below 5L/c/d)	More than 1000m or 30 minutes total collection time	Consumption – cannot be assured Hygiene – not possible (unless practised at source)	Very high
Basis access (average quantity unlikely to exceed 20L/c/d)	Between 100 and 1000m or 5 to 30 minutes total collection time	Consumption – should be assured Hygiene – handwashing and basic food hygiene possible; laundry/ bathing difficult to assure unless carried out at source	High
Intermediate access (average quantity about 50L/c/d)	Water delivered through one tap onplot (or within 100m or 5 minutes total collection time	Consumption – assured Hygiene – all basic personal and food hygiene assured; laundry and bathing should also be assured	Low
Optimal access (average quantity 100L/c/d)	Water supplied through multiple taps continuously	Consumption – all needs met Hygiene – all needs should be met	Very low

[1] Howard,G. and J.Bartram. *Domestic Water Quantity, Service Level and Health*. 2003. Geneva, Switzerland, World Health Organization.

Appendix H: SODIS promotion and implementation scheme (based on Perera et al. 2007[1])

Graphic depicting the SODIS promotion and implementation of the SODIS cluster-randomized controlled trial described in this thesis.

Time	11 control community-clusters (222 households)			11 intervention community-clusters (262 households)	
	Community level	Household level	District level*	Community level	Household level
6 weeks baseline (Nov - March 05)	Baseline, pair-matching of control and intervention communities based on the diarrhoea incidence in children <5 years old, random assignment of the SODIS intervention to one of the community pairs§				
3 months before starting one-year follow-up (April - June 05)			A	A B	
Follow-up: 1-6 months (June - Dec 05)		G		A B D	G E F
Follow-up: 7-12 months (Jan - June 06)		G		A B D	G E F
Intervention: 3 months (July - Sept 06)	A B D	E			

* Municipality, health - and school system

§ The standard field operations of the implementing NGO (following published guidelines) were adjusted to the needs of our trial in three aspects: i.) the NGO accommodated the outcome of the randomisation to their regional SODIS implementation plans, ii.) the frequency of household visits was increased to bi-weekly instead of monthly to accommodate likely irregular attendance at community events of remotely situated households, iii.) NGO staff was trained in documenting and record-keeping of their own field activities and attendance and main reactions of their audience.

[1] Perera, R., Heneghan, C., Yudkin, P. **Graphical method for depicting randomised trials of complex interventions.** 2007. BMJ 334: 127–129.

Symbol	Promotion activity	Content, topic number
A	Introduction to and consolidation of SODIS and related water, sanitation, hygiene, and health issues	1; 2; 3; 4; 5
B	Community event (monthly)	1; 4; 5; 6
C	School event (two monthly)	1; 8
D	Motivational micro-project	7
E	Two weekly household visits	Address day-to-day problems with SODIS-application and management. No specific hygiene messages.
F	Weekly SODIS monitoring	Observational; by community-based staff (independent from the SODIS-implementing NGO)
G	Health monitoring	Health diary kept by mothers; collected by community-based staff (independent from the SODIS-implementing NGO)
Topic No	**Content**	
1	SODIS and water disinfection at household level: Understanding i.) the use of SODIS in areas with microbiolologically contaminated drinking water, ii.) the synergistic effect of UV-A light and heat in pathogen-inactivation, iii.) application of the SODIS method at home. The importance of safe water consumption for family health. Alternative household water treatment methods like boiling and chlorination were mentioned and not explained in detail.	
2	Sources of and value of water: Conveying the importance of water for life: for humans, animals and plants. Application of metaphors (e.g. growing of plants and raising children). Sources for drinking water (rain, surface, underground). Basic needs and volumes of water intake for human consumption and the consequences of dehydration.	
3	Waterborne and faecal-oral contamination: sources of contamination, drinking waterborne contamination and infection pathways, protection of water sources for good health, barriers for faecal-oral infection route and the potential role of SODIS as a barrier to transmission	
4	Safe water storage and transport: cleaning drinking and storage vessels and protection/covering of storage containers and the advantage of SODIS combining safe storage, transport and cover.	
5	Diarrhoea-pathogen relationship: sequels of diarrhoea, handwashing in relation to personal-, food- and drinking water handling incl. Cleaning SODIS bottles	
6	Videos: Animated SODIS promotion cartoon (www.sodis.ch). Showing popular movies to attract people to the community events	
7	Mini-projects in support of SODIS-application: i.) small garden (gardening and watering plants is like caring for a child), ii.) small trade (buying and selling food stuff for financing SODIS-women events), iii.) water system maintenance: cleaning existing gravity water systems, iv.) community-soccer tournament	
7	School events: Training pupils to use the SODIS manuals and SODIS comic books; perform participative role plays, and viewing SODIS videos (www.sodis.ch) to understand the role of SODIS in intervening in the diarrhoea-pathogen relationships, reducing waterborne contamination, and enhancing personal hygiene.	

CURRICULUM VITAE

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Date of birth	20. May 1975
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Education

2009	PhD in Epidemiology at the University of Basle on solar drinking water disinfection
2003	Master of Science in Biology
2002-2003	Master thesis in epidemiology at the Swiss Tropical Institute Topic: i) First assessment of the possible relevance of Norovirus mixed-infections in Switzerland. ii) Evaluation of a commercial ELISA Kit for the detection of Norovirus antigens in human stool specimens. iii) In-house validation of a Norovirus detection method in human stool specimens
1996-2003	Study in Biology at the University of Basle, Switzerland
1999-2000	Field course of animal ecology at the University of Helsinki, Finland
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Additional professional experience

2003-2006	Project management of a cluster randomised controlled trial in rural Bolivia. Funding agency: NIH

Publications

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