

## The health and economic impact of improved sanitation on the reduction of diarrheal disease of under-five children in Gurage zone, SNNPR state, Ethiopia

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본 글은 에티오피아 구라게 지역 식수위생사업에 대한 영향력 평가, 과정평가, 비용편익분석의 연구방법론입니다.

영향평가 사업에 대한 지식공유를 위해, 동 평가를 평가기획문서의 일부로서 에티오피아 정부의 윤리위원회에 제출하였던 제안서를 게재합니다.

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## 1. Introduction

### 1.1. Background Information

Lack of improved water and sanitation causes large disease burden in many developing countries. Diarrhoea is a major killer of under five children, accounting for 11% of child mortality in 2013(Liu et al. 2012). Soil-transmitted worm infections, trachoma, lymphatic filariasis and schistosomiasis are also highly related to poor sanitation(Emerson 2004). Sanitation coverage is still exceedingly below the target, whilst water coverage has considerably increased during the MDG campaign period(WHO/UNICEF 2005 WHO/UNICEF 2006 WHO/UNICEF 2010). If current trends in sanitation continue, the world's population without access to improved sanitation will be closer to 2.7 billion in 2015 furthermore, even though the world would meet the MDG target for both water supply and sanitation, 1.8 billion people would remain without access to improved sanitation in 2015 (WHO/UNICEF 2010). The populations without improved water and sanitation are generally the marginalized and vulnerable group. Of the 783 million people still using unimproved drinking-water sources, 83% (653 million) live in rural areas of the 2.5 billion people without improved sanitation facilities, 72% (1.8 billion) live in rural areas. Given this notable importance of scaling up of improved sanitation in many developing countries, further evidence should be collected to support a greater resource allocation to sanitation by donors and policy makers. The majority of previous studies exploring the effect of improved sanitation, however, were mainly based on observational studies. Furthermore, not many of the studies were designed to investigate the net effect of improved sanitation on diarrheal reduction of under-five children. In this program based proposal, we aim to describe the design of a cluster-randomized trial in Gurage, SNNPR state, Ethiopia, seeking evidence for the impact of improved sanitation on diarrhoea of under-5 children. Process evaluation will be undertaken to investigate the quality of the intervention in terms of delivery of activities and fidelity of Gott people

to the program. In addition, economic evidence is the key for acquiring more resources to the increase of water and sanitation. Cost-Benefit analysis will be conducted, and if proven to bring about large benefit to community in economic terms, this study will help justify increasing investment and expenditure in sanitation.

## 1.2. Problem Statement

### Significance of the study

One point eight million people were estimated to be killed by diarrheal disease per year(WHO 2005). Diarrhoea ranks as the third leading cause of both mortality and morbidity following respiratory infections and HIV/AIDS(WHO 2005). Four billion diarrheal cases occurred annually(Kosek et al. 2003). Children under-five years old take the largest share of the total burden of diarrhoea(Bartram et al. 2003). Among under-five children, diarrheal accounts for 11% of all deaths(Liu et al. 2012). Diarrheal diseases inhibit normal ingestion of foods and absorption of nutrients, and thus become an important cause of malnutrition, and eventually this leads to impaired physical growth and cognitive function(Guerrant et al. 1999; Petri et al. 2008), reduced resistance to infection(Baqui et al. 1993), and potentially long-term gastrointestinal disorders(Schneider et al. 1978). Diarrheal disease is also an enormous economic burden, resulting in significant costs, lost time at school, and other productive activities(Mulligan et al. 2005). This study will play a central role to accelerate diarrhoea-specific child mortality and morbidity reduction across the globe by demonstrating clear evidence of effectiveness of improved sanitation with rigorous methodology. By doing so, the result of this study will catalyze a variety of donors to make substantial investment on hygiene and sanitation improvements in developing countries.

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### 1.3. Rationale

Considering the remarkable burden of disease that is associated with contact with faeces, the paucity of rigorous studies investigating the effectiveness of sanitation interventions is striking. This lack of research on the health and economic impact of sanitation might have led to the severe lag in progress of sanitation coverage increase, resulting in off-track in the MDG sanitation target. Diarrhoea is one of the major killers of under-five children poor sanitation is recognized the main cause of diarrhoea. However, rigorous exploration on the health and economic effect of sanitation is scarce. The scarcity of the evidence of sanitation on the health outcomes may be retarding the implementation of sanitation project across the globe. This research will play a central role to accelerate increasing the coverage of improved sanitation, leading to substantial reduction of under-five child deaths globally. This study will provide further evidence to support investment in water supply and sanitation, and thus will help donors to justify adequate budget allocation for increasing water and sanitation coverage. This study will be a landmark for the coming post-MDG campaign period.

## 2. Program Description

### 2.1. Goal and Objectives of the Program

This sanitation and hygiene project, to be conducted in two Woredas in Gurage Zone, SNNPR, aims to reduce diarrhoea among children under-five years of age by improving household latrine and relevant hygiene practices. Promotion of proper latrine construction at individual household level, and constant use of these latrines by all household members are the primary objectives to be achieved as a result of activities planned. Since construction and use of latrines by household members cannot be fully achieved without necessary behavior

changes, hygiene promotion activities to tackle key issues with regards to diarrhoea including hand-washing using soap at critical times will be also carried out in target villages.

## 2.2. Context of the Program

In accordance with Ethiopian Government's guidelines on this issue, the primary approach for implementation of latrine improvement and hygiene promotion adopted for this program is Community-Led Total Sanitation and Hygiene, or CLTSH in short. Twenty four(24) Gotts in project area will be selected and intensively followed-up throughout the implementation period (approximately 12 months) for latrine improvement and hygiene promotion purpose. At the beginning of implementation period, one(1) villager from each Gott will be designated and trained as WaSH Promoter to carry out activities in his/her Gott. To ensure the coverage and quality construction of latrine in each Gott, and also long-term utilization of latrines to be built, combination of various approaches including technical advice for construction, collective awareness-raising, hygiene promotion on key WaSH aspects will be employed.

## 2.3. Activities

During the initial phase of implementation, WaSH Promoters in each Gott will be trained on key issues regarding latrine and hygiene. Once trained, these WaSH Promoters will be the leading agent to promote and follow-up on latrine improvement and hygiene-related behavior change in his/her Gott. More specifically, WaSH Promoters will be responsible for activities including household visit, community conversation, technical advice for latrine design, communication of key hygiene messages, promotion of better hygiene practices, organization of and participation in monthly review meeting with stakeholders, and so on. In line with Ethiopian Government's CLTSH Guideline, there will be no material subsidy

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provided for the construction of individual household latrines. Instead, most of the resources, both human and financial, of the project will be allocated for activities aimed at sanitation and hygiene behavior change of the community.

## 2.4. Stakeholders

Latrine improvement and hygiene promotion activities are primary responsibilities of health offices of Ethiopian Government structure. Therefore, health bureau, department, and offices at all government levels of Ethiopia are considered to be major stakeholders and partners of this project. These include Health Bureau of SNNP Regional State, Health Department of Gurage Zone, and Woreda Health Offices in project area(Enemor Ena Ener Woreda and Cheha Woreda). At the same time, all the water offices at all level of Ethiopian Government will also be stakeholders of great importance regarding water supply component of the project. Community representatives at both Kebele and Gott level are also important stakeholders for actual implementation of activities on the ground. Korea International Cooperation Agency(KOICA) will play a role as funding agency and partner for this project.

## 3. Literature Review

An estimated 2.6 billion people globally lack access to improved sanitation facilities, and especially the coverage of improved sanitation is just 50% in low income countries(WHO/UNICEF 2010). Furthermore, more than one billion people still defecate openly. Notably, more than 70% of people without improved sanitation are living in rural area. In 1977, the United Nations proclaimed Mar del Plata Declaration with the goal of providing safe water and sanitation for all by 1990 and it was renewed in 1990, extending the deadline to 1999. In 2002, sanitation target was added to the MDGs as the target 10 of Goal 7, reducing by half the portion of the population without access to basic sanitation. It is

expected that the world miss the MDG sanitation target by 13 percentage points and the number of people without basic sanitation will actually rise to 2.7 billion in 2015(WHO/UNICEF 2010). In sub-Saharan Africa, only 31% of people have access to improved sanitation and the number of people without improved sanitation is expected to rise by 91 million by 2015(UNDP 2007; WHO/UNICEF 2005).

The infectious agents associated with diarrheal disease are transmitted mainly through the faecal-oral route(Bayers et al. 2001). A wide variety of bacterial, viral, and protozoan pathogens excreted in the faeces of human and animals are known to cause diarrhoea. Among the most important of these are *Escherichia coli*, *Salmonella* spp., *Shigella* spp., *Campylobacter jejuni*, *Vibrio cholerae*, rotavirus, norovirus, *Giardia lamblia*, *Cryptosporidium* spp., and *Entamoeba histolytica*(Leclerc et al. 2002). These pathogens may be transmitted through the ingestion of contaminated food, water or other beverages, by person-to-person contact, and by direct or indirect contact with infected faeces(Leclerc et al. 2002).

Because of this variety of pathways, environmental interventions for the prevention of diarrheal disease typically include steps to improve the proper disposal of human faeces(sanitation), as well as improving water quality(Clasen et al. 2006), water quantity and access, and promoting hand washing and other hygiene practices(Curtis et al. 2003; Ejemot et al. 2008). There are other important risks to health associated with poor sanitation. These include schistosomiasis, soil-transmitted helminth infection(including ascariasis, trichuriasis, and hookworm infection), trachoma(Emerson et al. 2004), and tropical enteropathy. Tropical enteropathy, a subclinical disorder of the small intestine caused by faecal bacteria ingested in large quantities by young children living in conditions of poor sanitation and hygiene, may be a substantial cause of under-nutrition in young children that is entirely separate from diarrhoea (Humphery et al. 2009).

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However, there is a paucity of evidence of effectiveness of sanitation on diarrhoea, while the association between diarrhoea and contact with human faeces is well established. Much of the evidence of the effectiveness and mechanisms of improved sanitation to prevent diarrhoea derived from observational studies(Barreto et al. 2007; Genser et al. 2008; Green et al. 2009). The evidence is scarce based on rigorous experimental studies.

### Previous studies

Cochrane Review examined environmental sanitary interventions, executing strategic search and thus yielded 2028 titles and abstracts, of which only 13 met the review's inclusion criteria and all of them were published in journals(Clasen et al. 2010) and published the results as follows:

#### Main Results of Cochrane Review Group on the Effectiveness of Sanitation

Seven of the studies were published in Chinese(Hu 1988, Wei 1998; Xu 1990; Xu 1994; Yan 1986; Zhang 2000; Zhu 1997), five in English(Aziz 1990; Garrett 2008; Huttly 1990; McCabe 1957; Rubenstein 1965), and one in French (Messo 1997).

#### (1) Key Findings

Two of the 13 studies reported no protective effect from the intervention (Huttly 1990; Xu 1994). Huttly and colleagues suggested that the intervention may not have been effective in preventing diarrhoea in the particular setting due to problems in implementation of the sanitation intervention that led to low levels of coverage and to low utilization by children. Except for two studies(Garret 2008; Xu 1994), Confidence Interval was not provided. Only one trial(Messou 1997) reported on mortality as a study outcome, which involved a combination of improved latrines with source water improvement, an oral rehydration intervention and hygiene instruction. This trial was

designed to investigate the impact of the intervention on death using a before and after study design; only two intervention and two control villages were included; Confidence Interval was not calculated.

#### (2) Limitations of Previous Studies

Cochran review group could not provide a pooled estimate of effect from sanitation intervention because of substantial heterogeneity among interventions, settings, and methodologies, and the absence of reliable Confidence Intervals for most studies. Although most studies reported a protective effect, the review could not derive a reliable estimate of the size of the effect. Of the 13 studies examining the effect of sanitation, there was no trial executing randomization of the clusters with intervention. Most of the studies compared one or only a few intervention sites with a similar number of control groups. Furthermore, none of the studies assessed the effect of the sanitation intervention on intermediate outcomes, such as the quality of drinking water, microbial contamination of foods or presence of flies, which could suggest an objective impact of the intervention on common transmission pathways. Thus, there is no independent was to confirm that the intervention reduced exposure, much less disease. Only five studies consisted solely of improvement in excreta disposal and in eight other studies, the sanitation intervention was accompanied at least by improvement in drinking water supply.

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## 4. Objective of the study

### 4.1. General Objective

The purpose of this study is to assess the protective effect against diarrheal disease of improved sanitation solely and also by integrated water, sanitation and hygiene improvement in Gurage zone, SNNPR state, Ethiopia. Water pipe will be connected to 99 Gotts in Enemore Ena and Cheha Woreda and intervention for sanitation and hygiene improvement will be undertaken in 48 Gotts, of which

24 are under intervention and control arms respectively. This is the first study to investigate the effect against diarrhoea of improved sanitation adopting CLTS principle and approach with no financial or material support to households, using cluster randomized control trial.

## 4.2. Specific Objective

### (1) Impact Evaluation

This study is to conduct cluster randomized control trial comparing diarrheal incidence of Gotts (1) with and without improved sanitation (2) with and without integrated water, sanitation and hygiene improvement. (The control Gotts without improved latrine will also be intervened during the second phase for ethical clearance.)

The trial will have 84 percent power to detect a protective effect of 50 percent reduction of diarrheal incidence of improved sanitation at the 5 percent level of statistical significance during the ten months of community adoption of improved sanitation.

### (2) Process Evaluation

The objectives of this process evaluation are to provide information on the context of Gotts where the intervention will be implemented; document how the intervention will be delivered; assess exposure to the intervention among the people living in Gotts; explore associations between household exposure to community mobilization activities and construction of improved sanitation facilities.

### (3) Cost-Benefit Analysis

This study also aims to estimate community-level costs and benefits on a project basis of sanitation interventions and clean water supply by drilling borehole.

## 5. Methodology

### 5.1. Study Area and Period

The study area is Enemor Ena and Cheha Woreda, located in Gurage Zone, SNNPR state in Ethiopia. This study will be undertaken from December, 2014 throughout December, 2015.

### 5.2. Study Design

The cluster randomized trial takes Gott as the randomization unit since it is expected to be a cluster in which improved sanitation and hygiene will bring impact on diarrhoea transmission across households. All the interventions will be applied on Gott-wide basis. Since the purpose of the intervention is to reduce diarrhoea, Gott would be an appropriate dimension of transmission zone, where humans, vectors, and intermediate hosts are interacting and sharing a common pool of parasites.

We will use phase-in and factorial design. For improved sanitation and hygiene, project is to roll out only in intervention arm for the first phase and then the control arm will receive the intervention after the first phase trial completes. In addition, improved water will be supplied to the intervention arm for the second phase and the control will have access to improved water supply after the second phase trial completes.

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&lt;Table 1&gt; Assuring comparability between intervention and control group

Main outcome, covariate	Baseline Characteristics		Difference
	Intervention	Control	
Diarrhoea incidence	X1	X1'	Not significant
Coverage of improved latrine	X2	X2'	Not significant
Coverage of improved water	X3	X3'	Not significant
Mothers Education Level	X4	X4'	Not significant
Economic status	X5	X5'	Not significant
Hygiene related Knowledge, Attitude, Practice	X6	X6'	Not significant
Physical closeness to main road	X7	X7'	Not significant
Altitude	X8	X8'	Not significant

### 5.3. Source and Sample Population

Of the 240 Gotts, 99 Gotts will be selected for project implementation of clean water supply, and hygiene and sanitation improvement by the selection criteria on the basis of the degree of needs. The 99 Gotts will be stratified by altitude, water and sanitation coverage, accessibility to the main road, and socioeconomic status. 48 Gotts will be selected for trial arms by restricted stratified randomization process. Baseline survey will be conducted in these 48 Gotts, of which 24 Gotts will be randomly assigned to intervention and the other 24 to control in the cluster randomized control trial design. For increasing the comparability of the groups in each arms, we will stratify 48 Gotts into blocks having similar underlying, pre-intervention, risks of diarrhoea and then randomize within each block.

#### 5.4. Inclusion and Exclusion Criteria

Care will be taken to define the target population for the study.

Gott level eligibility criteria are (1) the lowest coverage of improved sanitation coverage, (2) the lowest coverage of improved water (3) no other WASH projects are to be expected to roll out from 2014 throughout 2015.

Households level eligibility are (1) having under five child (2) making informed consent on survey. We target the households with under-five children because the majority of morbidity and mortality associated with diarrhoea is occurred in this group and thus they are most likely to benefit from the interventions.

#### 5.5. Sample Size

Based on previous survey(BDS, World Vision survey), we estimate that the incidence density of diarrhoea in SNNPR was 40 % per child-months and assumed 50% will be reduced by our intervention on the basis of reflecting systematic reviews. Assuming a design effect with 2.14, an coefficient of variation with 0.5, and 20% loss to follow-up, 84% study power, incidence density(ID) 40(cases per 100 child\*months) in the absence of intervention and 50% reduction in incidence density of diarrhoea resulted in 48 clusters(48 Gotts) and 25 children per cluster, using the following formula(Hayes RJ & Bennett S 1999).

#### 5.6. Sampling Method

Two stage cluster sampling method will be employed for this study. Among the 99 project target Gotts for water pipe connection, sanitation and hygiene intervention, 48 Gotts will be selected as a primary sampling unit. Of the 48 Gotts residents, 1200 households will be sampled by employing proportional

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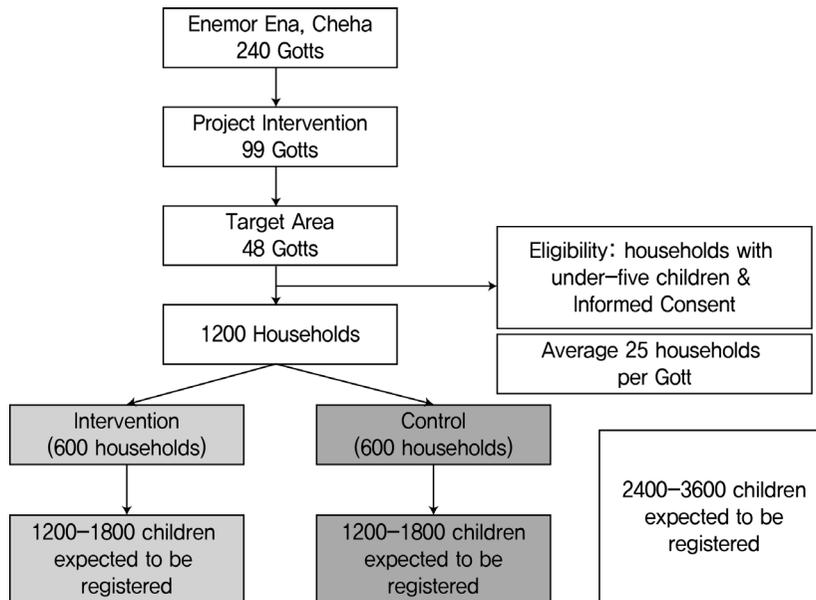
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probability sampling method(PPS). All the children under-five years will be registered for this study, endowed with identity number.

<Figure 0> Flow diagram of the study



## 5.7. Data Collection Method

### (1) Impact Evaluation

Enumerators for baseline survey will be recruited from the government officials, teachers or university students living in Gurage Zone. They will visit 48 Gotts for conducting interview mothers or caretakers of 1200 households. Questionnaires for Demographic characteristics, knowledge and behavior related to sanitation and hygiene, prevalence and incidence of water-borne disease will be administered during the household survey. In addition, direct observation will be conducted on sanitation conditions such as latrine and water storage facilities. Less than one hour will take for the baseline survey per each household. After

the intervention commences, enumerators will undertake household survey on monthly basis, during which period much simpler questionnaires for process and main outcome indicators will be collected such as adoption of improved pit latrine, practicing hand-washing at critical times, water treatment at point-of-use, and prevalence and incidence of diarrhoea, taking 10 to 20 minutes per each household. Enumerators will be recruited from the people living in nearby Gotts with educational background of more than senior high school and/or survey experience.

## (2) Process Evaluation

For process evaluation, we will undertake the systematic and continual documentation of key aspects of program performance that assesses whether the intervention will be operating as intended. Process evaluation data will be collected through review of key documentation, direct observations, and semi-structured interviews with Gott people and WASH promoters. M&E coordinators will be recruited for supervising data collection process. M&E coordinators will interview WASH promoters to obtain information on the community mobilization activities conducted in the Gotts and they will review documentation maintained by the WASH promoters. M&E coordinators will review WASH promoters daily diary and meeting notes recorded. They will visit each household to observe and record the status of sanitation facility. Quantitative surveys will be undertaken by independent data collectors, who will be recruited among Gotts people distinct from the survey target area. The same 1200 households will also be selected to administer the questionnaires for process evaluation, mainly for checking the level of awareness about community mobilization events undertaken by WASH promoters. Data will be combined at regular review meeting on monthly basis.

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Questionnaires will be translated into Amharic and retranslated into English for ensuring accuracy of translation.

### (3) Cost Benefit Analysis

#### (3.1) Investment cost

- (a) Investment costs will include planning and supervision, improved latrine and water facility construction, protection of water sources and technical education.
- (b) Recurrent costs will include operation and maintenance of facilities and replacement of parts, control of water supply, protection and monitoring of water quality, water treatment, and continuous hygiene education.

#### (3.2) Benefit

##### (a) Health Benefit

- (a. 1) Savings related to seeking less health care.

Health care savings will be estimated as a function of Gott people's treatment seeking rates, medical practices and unit costs of medical services. Medical practices include the types of Gott people's treatment for diarrhoea and the rate of in-patient admission or referral. In addition, patient and their care takers incur treatment-seeking costs such as travel costs.

- (a. 2) Savings related to produce times losses from diarrhoea.

Productivity losses will be estimated based on diarrhoea incidence, the number of days absent from productive activities, and the unit value of productive time. An economic value will be given instead to time based on the sick person's age.

- (a. 3) Savings related to reductions in premature mortality. Mortality will be valued using human capital approach to estimate the value of a premature death averted.

### (b) Time Benefit

The value for time savings due to closer access to water and sanitation facility and less waiting time for improved services will be calculated.

## 5.8. Data analysis

### (1) Impact Evaluation

The primary endpoint of this study is the incidence of diarrhoea per week(per month) in under-five children(cases / child\*week, cases / child\*month) and the incidence in all age group(cases / person\*week, cases / person\*month) is the secondary endpoint. Analysis will be done both on an Intention-to-Treat basis and Treated-on-Treatment basis. In other words, the incidence of diarrhoea will be compared between intervention and control Gotts, and also comparison will be conducted on the basis of actual sanitation uptake at Gotts and household level. Diarrheal incidence will be treated as a binary outcome using a log-binomial model(log link, binomial family) for the calculation of relative risk. Clustering at Gott level will be accounted for by generalized estimating equations(GEE). SAS 9.3 and STATA 13 will be used.

### (2) Process Evaluation

Level of awareness of main mobilization activities between intervention and control Gotts will be compared. Proportions of households participated in community mobilization activity will be calculated at Gott level. We will investigate association between the awareness of Gott people about community mobilization and the coverage of improved latrine using linear regression.

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### (3) Cost Benefit Analysis(Description of Main Benefits)

<Table 2> Description of Main Benefits

Benefit		Sanitation	Water
Main	Health	Averted cases of diarrhoeal disease	Averted cases of diarrhoeal disease
		Malnutrition-related disease	Malnutrition-related disease
		Health related quality of life impacts	Health related quality of life impacts
	Health economics	Cost related to diseases such as health care, productivity, mortality	Cost related to diseases such as health care, productivity, mortality
	Time value	Travel and waiting time averted	Travel and waiting time averted for collecting water
Others		-	

<Table 3> Variables of Main Benefit

Benefit by sector		Variable
Health	Health care costs of disease	Unit cost per treatment
		Visit or days per case
		Hospitalization rate
		Transport cost per visit
	Welfare gained due to days lost from work avoided	Days off work/episode
		Number of people of working age
		Opportunity cost of time
	Welfare gained due to school absenteeism avoided	Absent days/episodes
		Number of school age children(5-14)
	Welfare gained to parents due to less child illness	Days sick
		Number of young children(0-4)
		Opportunity cost of time
	Value of loss-of-life avoided	Discounted productive years lost(0-4)
		Discounted productive years lost(5-14)
		Discounted productive years lost(15+ years)
Opportunity cost per years of life lost		
Time	Direct	water collection time saved per household per

Benefit by sector		Variable
		day for better access
		Sanitation access time saved per person, moving from OD to private latrine
		Average household size
		Opportunity cost of time
	Indirect	time saved for travelling to hospital for children
		time saved for travelling to hospital for themselves

#### (4) Judgment matrix

We aim to increase the coverage of improved latrine at least up to 70 percent in all intervention Gots within one year. By doing so, we anticipate the incidence of diarrhoea of under-five children will be reduced by 50 percent.

#### 5.9. Data quality assurance

One M&E specialist and Two M&E coordinators will be recruited for supervising enumerators and assuring data quality.

- (1) All the questionnaires(Appendix) will be translated into local language, Amharic, and also they will be retranslated into English by other translator for checking appropriate translation.
- (2) Training enumerators will be conducted for one full day before baseline survey. For reducing bias between and within enumerators, administering questionnaires will be practiced during this training session. Several community people will be invited to participate in the mock survey and due payment will be made for his or her participation.

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For reducing bias between enumerators, some enumerators will conduct interview with the same person and the result will be compared and reviewed by enumerators and supervisors.

For reducing bias within enumerators, same enumerators will conduct interview more than two persons, and supervisors and all the other enumerators will observe him or her administering questionnaires and after the interview, they share the key finding found and correct some practices, if any, and reach a common understanding the definition of questionnaires in local language and appropriate interpretation of answers words by words.

(3) Pilot survey will be undertaken after training enumerators for half a day in one of the Gotts, where all the enumerators will observe administering questionnaires by some of the trainers. Supervisors will correct erroneous practices, if any, and train enumerators again after reviewing the survey result for another half a day.

#### (4) Post-enumeration Checks

We emphasize the great importance of having a system of routine supervision and regular checks to maintain the quality of work. We will check any ambiguities in the interpretation of responses to questions or misunderstandings of questionnaires. We will check any inconsistency of responses, and whether it is resulted from interviewer or respondent error. We will employ system design using replicate measures by the interviewer, co-worker and supervisor and routine review measures by the work team to provide and regular feedback. Quantitative and objective quality scores (for example, number of records completed without errors per day) and performance ratings for the work completed by the team will be kept and reviewed regularly. Reward will be employed on a team basis. The team's observation result will be independently

compared with Project Supervising Committee comprising government officials and community leaders of Gurage Zone.

### 5.10. Ethical Consideration

#### Scientific merit

The method of this research, cluster randomized control trial is most appropriate to the aims of our investigation. Results from previous studies are taken into account in this study design. The result from this study are most likely to provide appropriate answers to this study question exploring the extent of reduction of diarrhoea to which improved sanitation brings on.

#### Equitable selection of subject

To our comprehensive review, there was no harm resulted from improved sanitation. The target area of our intervention is the place where most vulnerable group is living. The intervention will not be restricted solely to the Gotts which participated in this study and also will be provided to the other Gotts in similar circumstances if it is found to be effective.

#### Informed Consent

We will obtain Informed Consent from household head or mother(or caretaker) from each household. Control Gotts will be selected randomization, which will be conducted in close collaboration with Woreda health officials, and Kebelle/Gotts leaders. By using baseline survey result, restricted strata will be established by ensuring comparability between intervention and control arms. Study Gotts will be randomly assigned to intervention or control arms by using coin toss, which will be conducted by community leaders during community leaders

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workshop/project launching ceremony. After the first phase of project implementation, comparable intervention will be rolled out also in control group. During the regular survey at household level, ORS will be provided for treating diarrhoea, for which further detailed action plan will be established in close consultation with Gurage zonal health office. A questionnaire will be administered to each mother or caretaker of enrolled household. Interviewer will read through Informed Consent Form word by word at every household for survey in local language because some household head(or caretaker) might be illiterate.

### Confidentiality

We will identify individuals on record forms by code number only, with the list linking names to the codes being kept separately in a secure place.

### Coercion

Coercion and deception will be strictly prohibited under any circumstances. We will make full and open explanations of all study procedures for all the interviewers and stakeholders.

### Anonymity of Gotts

We will keep the identity of the community anonymous particularly when discussing sensitive areas of behavior such as hygienic practices.

## 5.11. Dissemination of the Finding

The methodology for this study will be reviewed by prominent experts group and we will take steps for obtaining approval from the International Standard Randomized Control Trial(ISRCT) committee so that ISRCT number will be issued.

This study results will be disseminated across the world for sharing with scholars, experts, political leaders and working level officials of partners.

### 5.12. Limitation of the Study

The level of uptake and utilization is critically important because latrine can bring about clustered effect of sanitation on diarrheal reduction only when the coverage is over a certain percentage in a community. The success of this project depends on how many of households will construct and utilize improved latrine without any financial and material subsidy. If the coverage of improved latrine is not over 70 % in terms of uptake and utilization, we can hardly explore the genuine effect of improved latrine on community-wide diarrheal reduction.

## 6. Work Plan

The study to be conducted in the project area in Enemor Ena Ener Woreda and Cheha Woreda in Gurage Zone, SNNPR State, Ethiopia is expected to begin in January 2015. The total duration of the study will be approximately one year until March 2016, the end of the project period.

The proposal for Ethiopian Institutional Review Board is expected to be approved by November 2014. Project inception workshop with key stakeholders of the project will be also held in November 2014. The study and roll-out plan of the project are to be tightly aligned. Once the project activities based on CLTSH principle and approach starts in the intervention arm in January 2015, monthly cohort study both for intervention and control arm will be unfolded by collecting household data every month. Baseline survey will be independently conducted by external body apart from the study in December 2014, but will reflect the study design on the process in tight-knit cooperation between the

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survey consultant and the research team.

To ensure the quality and independence of the study, a separate team of Monitoring & Evaluation staff and enumerators will be formed and trained in December 2014 to work on monthly data collection, entry and management. Furthermore, a monitoring committee will be also organized consisting of key stakeholders of the project and periodical review meeting will be held to supervise the study process.

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