Evaluation of the impact of water quality and hygiene interventions on the health status of children in the project area of Helvetas WARM-P Project in Nepal

Research legislation:	Ordinance on human research with the exception of Clinical trials (HRO) [1].
Type of Research Project:	Research project involving human subjects
Risk Categorisation:	Risk category A in accordance with HRO Art.7
Project Leader:	Regula Meierhofer Group Leader Swiss Federal Institute of Aquatic Science and Technology, Eawag Ueberlandstrasse 133 8600 Dübendorf +41 58 765 50 73 regula.meierhofer@eawag.ch
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PROTOCOL SIGNATURE FORM

Study Title	***Evaluation of the impact of water quality and hygiene interventions on the health status of children in the project area of Helvetas WARM-P Project in Nepal***

The project leader (main center) and the investigator (at the local center/site) have approved the protocol version ***[02 (dated 25.02.2018)]***, and confirm hereby to conduct the project according to the protocol, the Swiss legal requirements [1,2], the current version of the World Medical Association Declaration of Helsinki [3] and the principles of Good Clinical Practice.

Project leader (lead center/site)

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Date: 25.02.2018_____ Signature 

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Date: 25.02.2018_____ Signature: 

TABLE OF CONTENTS

GLOSSARY OF ABBREVATIONS

BASEC	*Business Administration System for Ethical Committees*
CRF	*Case report form*
FOPH	*Federal Office of Public Health*
HRA	*Human Research Act*
HRO	*Ordinance on Human*

1 BACKGROUND AND PROJECT RATIONALE

One of the important factors to cause serious health impacts among children is lack of access to clean water (Darvesh et al., 2017). Various types of pathogens can affect children in many different ways likewise the ones causing water-borne diseases such as cholera, diarrhea and intestinal parasitic infections (Bethony et al., 2006). There are various causes of fecal contamination of drinking water (Wright et al., 2004a). Even if the water at the source and at the point-of collection is safe, unhygienic conditions during transport and storage can lead to recontamination (Wright et al., 2004b). Dirty hands, storage containers used for water handling may contaminate water during collection, transportation and storage (Rufener et al., 2010). As a result, it has been estimated that 1.7 million children face death each year due to unsafe water and poor hygiene condition, where diarrhea is the primary cause of death in 9 out of 10 children whereas one third out of 1.7 million deaths occur in South East Asia (Khayet et al., 2003). Yet, to reduce these water-borne diseases, improving the water quality in the households and safe storage have shown to be effective (Fewtrell and Colford, 2004). Furthermore, there are different methods to reduce water-borne diseases (e.g. diarrhea, intestinal parasitic infections) morbidity and mortality and all of them may require behavioral change (Ashbolt, 2004; Bethony et al., 2006)

Moreover, adequate nutrition is also essential among children for ensuring healthy growth, proper organ formation and function, strong immune system, and neurological and cognitive development (De Onis et al., 2012). However, nutrition as a cross cutting theme, is closely interlinked with multifactorial determinants. The immediate causes of malnutrition in children is insufficient nutrient intake and food insecurity, while the underlying contributing factors include lack of access to safe water and sanitation, recurrent infectious diseases, lack of awareness on health and hygiene where the results indicated that both must be improved in conjugation to have an effect (Black et al., 2008). Therefore, it is of utmost importance to understand whether the contribution of water, sanitation and hygiene (WASH) interventions to minimize malnutrition (low BMI, inadequate dietary diversity, low hemoglobin (Hb) level) and decrease in incidence of infectious diseases such as intestinal parasitic infections among children.

Nepal faces a plethora of problems related to drinking water (Prüss-Ustün et al., 2014). In 2015, the WHO/UNICEF JMP reported that 92% of the Nepalese population had access to improved water, and hence, met the specific MDG target (WHO/UNICEF, 2015). However, about 71% of the water sources are contaminated with fecal coliforms. In addition, in 82 percent of households with access to an improved source, water is fecally contaminated. The proportion of households without improved drinking water using appropriate treatment methods is 14 percent (GON and UNICEF, 2015). According to the data from the Department of Health Service (DHS), Nepal, about 3500 children die each year due to water-borne diseases (Aryal et al., 2012). Intestinal parasitic infections and diarrheal diseases due to inadequate water and hygiene are the principal causes (Sah et al., 2013). Although, Nepal has abundant water resources, competing uses and often poor water resource management compromise quantity, quality and access (Dixit et al., 2012).

Similarly, malnutrition is the major underlying cause of child mortality within the country where 36% are stunted, 10% wasted and 27% are underweight. Anemia among the infants and children is high i.e. 53% (DHS, 2016). Complementary foods are not introduced in a timely fashion for all children and only one fourth of the age 6-23 months are fed appropriately based on recommended infant and young child feeding practices (DHS, 2016). Apart from taking insufficient intake of safe and quality food, the consumption of unbalanced food is also a problem, which together is responsible for the chronic nutritional problem in children.

As WASH and health, including nutritional status, are closely interlinked with multiple determinants, the objective of this study is to assess if improved water quality at the point of

consumption together with improved hygiene and sanitation conditions reduces the health burden (intestinal parasitic infections, anemia, malnutrition, nutritional deficiency) of children living in rural households in Nepal.

Previous collaboration activities with Helvetas in the WARM-P project area revealed significant changes in the hygiene and sanitation condition after a WASH education campaign. Nevertheless, a significant degree of water recontamination between the point of collection and the point of consumption was observed. The proposed study aims at assessing the impact of such an effective training strategy at household level, if the training is combined with an improved water quality intervention.

The impact study will be implemented in Western Nepal in collaboration with Helvetas International Cooperation in the context of their activities on Water Safety Planning in water supply schemes. The evaluation will assess the impact of two interventions aiming at increasing water quality at the point of consumption.

The study is an observational study. Children's caretakers in participating households, will participate twice in a quantitative interview. Health data will be collected from one or two children of participating households. Children's health will be analyzed on the basis of the following indicators: diarrhoea incidence (questionnaire), parasite infection (collection and analysis of stool samples), anthropometric measurements, clinical examination and finger prick tests. The examination of children will be conducted by qualified and trained health personnel. Only households will be involved in the study that have provided written informed consent.

The process of data collection will not cause any health risks to participating humans and therefore can be categorized into Risk category A in accordance with HRO Art.7.

Participating households will not receive any direct compensation for participating in the survey. However, participants will be informed about the outcomes of the study and the results of their personal examination. Those found infected with parasites will be treated in accordance with their infection at recommended doses following standard treatment schemes of WHO.

The study will contribute to understanding the effect of WASH interventions for achieving an improved health status of the targeted population. It will estimate the magnitude of the problems related to contaminated drinking water and critical hygiene in the study areas where the interventions will be carried out in comparison to control area. An evidence-based program for preventing WASH related diseases will be evaluated that can be replicated in other countries similar to Nepal. It is expected that insights gained from this study will improve future National programs and policies related to water supply, drinking water quality, hygiene and health in Nepal.

2 PROJECT OBJECTIVES AND DESIGN

2.1 Hypothesis and primary objective

Hypothesis

The main assumption is based on the idea that improved water management leading to safe water at the point of consumption either through system level chlorination or adequate household water treatment at the point of consumption and hygiene infrastructure such as hand washing infrastructure and improved sanitation will lead to a reduction of the water-borne diseases including intestinal parasitic infections.

Goal

The impact of a water quality intervention that comprises of system level water chlorination versus an intervention that comprises adequate household water treatment (including an effective filter and improved filter handling practice) as well as the impact of improved infrastructure for handwashing and sanitation together with hygiene education are evaluated.

2.2 Primary and secondary endpoints

Specific objectives
1) To analyze the impact of a water quality and hygiene intervention on:
- Water quality at the point of collection as well as at the point of consumption;
- Availability, condition and use of water, sanitation and hygiene infrastructure; and
- Knowledge, attitude and practice (KAP) of water management, sense of ownership, and hygiene.

2) To determine the burden of water-borne diseases (diarrhea and intestinal parasitic infections), malnutrition, nutritional deficiency and anemia among children within the households before and after the intervention.

2.3 Project design

Research design

A randomized controlled trial (RCT) will be conducted in a rural area, following a cross-sectional baseline assessment on situational factors, water quality at the point of collection and point of use, WASH infrastructure, knowledge, attitude and practice as well as health indicators using standardized tools. The follow-up assessment will be conducted 1 year after the intervention (if funding is available a second follow-up assessment 2 years after the intervention might be implemented). One to one matching with the intervention area will be done for the selection of the control area.

The study will comprise of the following intervention schemes

	Baseline scenario	Intervention	Nr of households
Area A	PWS	HHH + S-CHL	375
Area B	PWS	HHH + HWTS	375
Area C	PWS	HHH	375
Area D (Control)	PWS	-	375

PWS is an area with the availability of a piped water supply scheme, that has not yet received the WARM-P training intervention
HHH: household hygiene intervention in accordance with the WARM-P training, but not establishing access to products for household water treatment
HWTS providing access to high quality products for household water treatment and safe storage, including training on adequate product operation and maintenance
S-CHL providing scheme-level chlorination

Conceptual Framework of the Study

The framework of the study is based on the assumption that improved access to safe drinking water together with adequate hygiene and sanitation conditions will improve children's health by reducing diarrhea incidence as well as the incidence of intestinal parasitic infections and therewith improve children's nutritional status.
The framework illustrates that to have a sustainable effect on children's health status a combination of WASH infrastructure improvement and education interventions should be

implemented. The proposed study suggests to assess the improvement of water supply together with strategies to assure drinking water safety and the construction of handwashing stations and latrines. This infrastructural component will be complmented with behavior change interventions targeting drinking water treatment, handwashing and improved hygiene practices. Hence, we hypothesize that a combination of infrastructure and behavior related WASH interventions can influence children's health status. Children's health will further be influenced by the prevailing socio-demographic, socio-cultural, public policy and economic factors, and by the local food security situation.

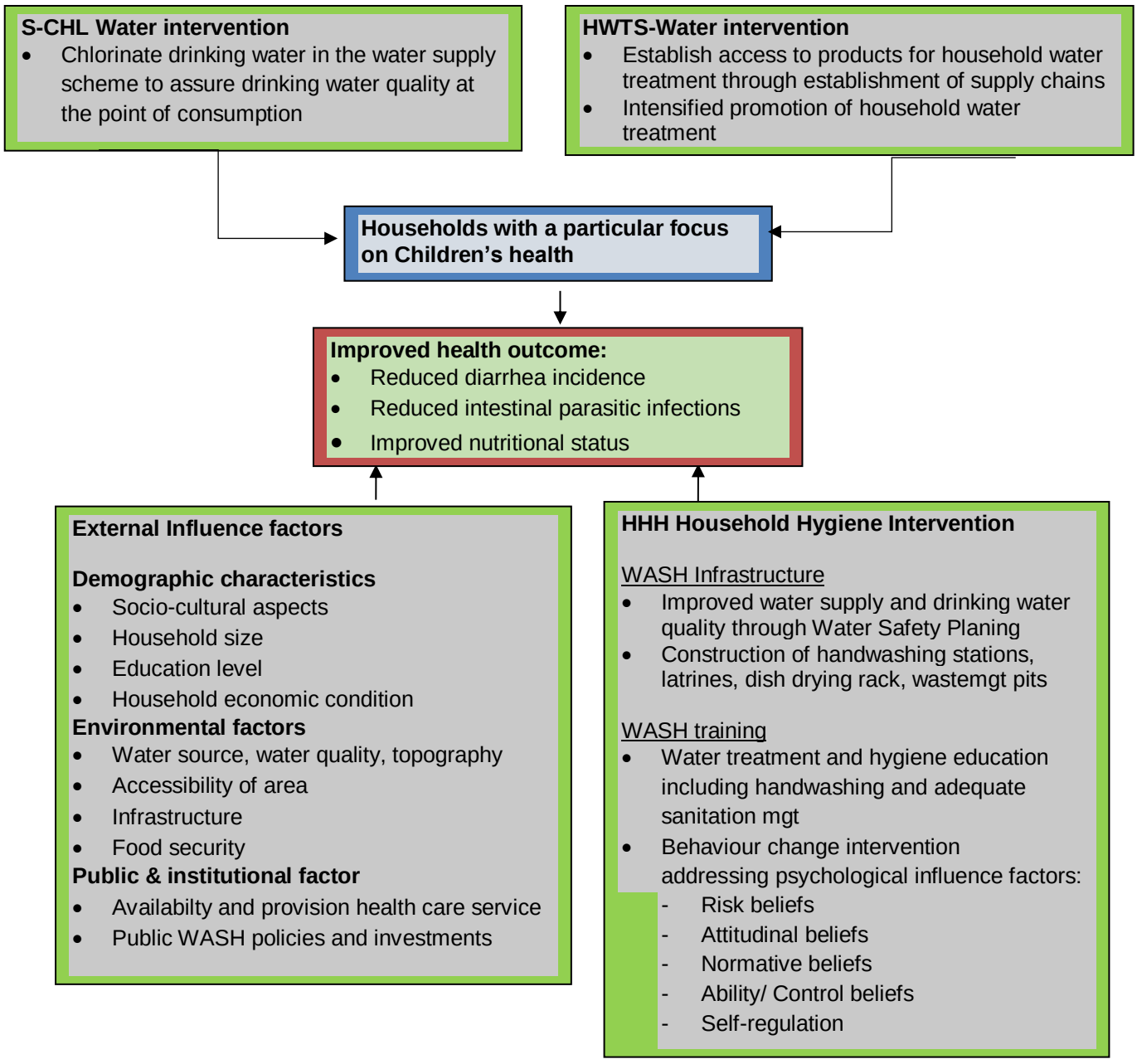

Figure 1: Conceptual Framework of the Study

Assessment indicators

The indicators collected at the household level at the baseline and after the intervention will focus on:

- Water quality at point of collection
- Water quality at the point of consumption,
- Water safety plan management
- Availability, condition and use of WASH infrastructure
- Knowledge, attitude and practice of improved water management and hygiene
- Psychological factors
- Health indicators such as diarrhea and intestinal parasitic infections, particularly the count of intestinal helminthic and protozoan eggs. With regard to children's nutritional status, the hemoglobin level will be measured for anemia detection; stunting, wasting, thinness, mid upper arm circumference will be measured. Clinical examination for detecting wasted appearance, dermatitis, pale conjunctiva, xeropthalmia, night blindness, loss of hair pigments etc. will be assessed.

Study area

The study will be conducted in Kalikot, Jajarkot, Dailekh, Surkhet and Achham Districts in Western Nepal.

Study Procedure

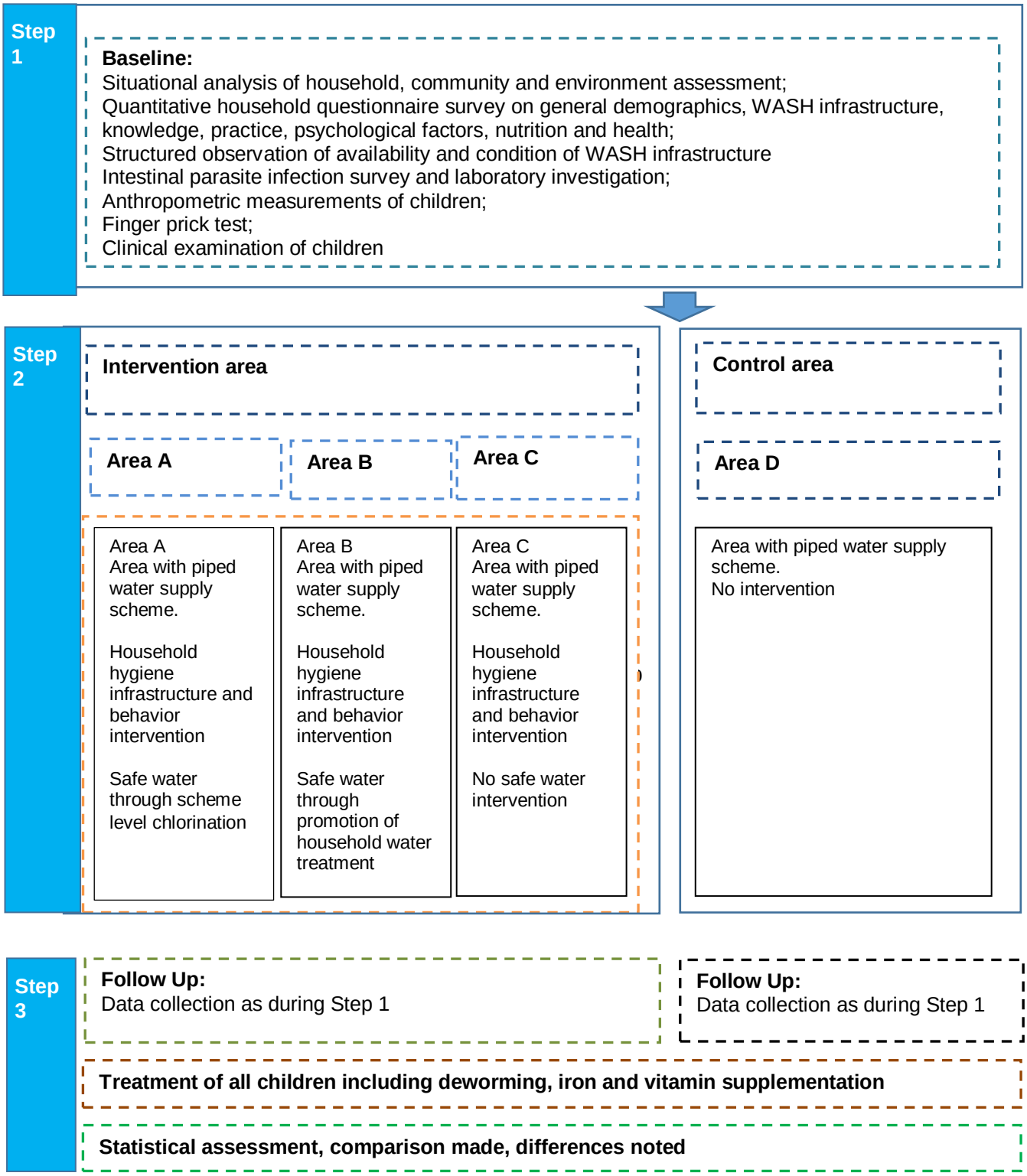

Fig 2: Research Plan

Intervention package

Baseline data collection will take place in the study areas, where households have access to a piped water supply scheme but have not yet received the comprehensive WARM-P WASH intervention.

Data will be collected from 1500 households (375 households per area). Only households providing informed consent will be involved in the study. Intervention activities will start after the completion of baseline data collection in May 2018.

Areas A, B and C will receive household hygiene (HHH), the WARM-P WASH training intervention that aims at improving uptake and use of the following WASH infrastructure elements at household level: the construction of hand-washing stations, dish drying racks, latrines and waste management pits. These infrastructure improvements will be coupled with behavior change training to strengthen improved WASH knowledge, and facilitate consistent practice. Hygiene trainings will be provided during adult literacy classes for caregivers, at schools and during door to door visits. Households complying with the intervention will be provided with a sticker at the door that indicates that the 5 indicators: safe water, better sanitation, personal hygiene, kitchen management and solid waste management have been reached.
The establishment of supply chains for water treatment products will not be part of HHH.

In addition to household level interventions, Area A, B and C will also focus on elements of water safety planning related to the respective water supply scheme, such as system upgrades and regular monitoring visits, while paying attention to the criteria below:

- Area A will equip the water supply schemes with a chlorination system so that chlorinated water is provided at the point of collection.
- Area B will focus on providing access to high quality products for household water treatment (for example high quality ceramic water filters) and safe storage, including training on adequate product operation and maintenance
- Area C will only receive HHH, without providing access to chlorinated water and without providing access to products for water treatment at the household level
- Area D will be the control areas and will not receive any intervention

The study will be implemented as a collaborative project between Eawag, the Swiss Federal Institute of Aquatic Science and Technology and the NGO, Helvetas Swiss Intercooperation Nepal, Eawag will be responsible for the study design, data collection, data analysis and reporting in accordance with the research design (Step 1 & Step 3). Helvetas Swiss Intercooperation will be responsible for the implementation of activities defined under Step 2.

3 PROJECT POPULATION AND STUDY PROCEDURES

3.1 Project population, inclusion and exclusion criteria

Data will be collected from 1500 households (375 households per area). Only households with at least one child in the age between 6 months to 10 years will be involved in the study. If a participating household has more than one child, the health of the youngest child will be examined as the vulnerability of young children for diarrhoeal infections is highest.

3.2 Recruitment, screening and informed consent procedure

Prior to data collection and intervention activities, the selected communities and their leaders will be informed about the goal, purpose and methodology of the study during community meetings. Households in the study site will be selected in accordance with randomized sampling procedures.

An interviewer team of two people will visit the selected households, inform the caregivers of children about the goal, purpose and methodology of the study and hand out the informed consent forms (in Nepali) and request written agreement. If a person is unable to read and write, the information is read out to them and consent will be provided by fingerprints. Households will also be given the contact information of Helvetas-Nepal in case they have any questions about the study. Data will only be collected from agreeing households.

Children displaying signs of defense against participating in the study or against one of the health measurements will not be involved in the study.

Participating households will not receive any direct compensation for participating in the survey.

However, all households in the project areas will benefit from the study by improved management of the drinking water supply, by receiving training on improved hygiene, sanitation and household water treatment and by receiving a facilitated access to products required for water treatment. In control areas, the information on water treatment and access to respective products will be provided after final collection.

Participants will also be informed about the outcomes of the study and the results of their personal examination. Those found infected with parasites will be treated in accordance with their infection at recommended doses following standard treatment schemes of WHO. If signs of infection or anaemia are visible in any of the older children in the participating households, also these older children will be provided with treatment.

3.3 Study procedures

Methods and approaches for objective 1: Water quality at the point of collection as well as at the point of consumption will be analyzed by field based methods using membrane filtration and the quantification of fecal indicators organisms such as E.coli and total coliforms. Water quality measurements will also include detection of free residual chlorine levels, turbidity, pH, conductivity, and nitrate.

Household information on WASH infrastructure, knowledge, attitude and practices will be gathered by a combination of qualitative (structured observations) and quantitative methods involving structured household interviews using tablets with digital questionnaires. Household survey questionnaires will include specific questions assessing KAP of WASH and health including household information, access to water, WASH know how, practice, attitude, self-efficacy, planning, behaviors, health status and risk awareness, social norms, perception of the water system, information on WASH promotion, market information, wealth index, and observation through interviewers.

Methods and approaches for objective 2: To determine the burden of water-borne diseases and the health impact of the interventions, the following indicators will be assessed by a combination of qualitative and quantitative methods:

- Diarrhea: baseline diarrhea incidence will be assessed by asking households about diarrhea prevalence during past 2 weeks prior to data collection. Households participating in the study will be requested to fill out a diary on diarrhea prevalence between baseline and of follow-up assessment.
- Intestinal parasitic infections: stool analysis will be done for determining the prevalence and type of intestinal parasites. Kato-Katz, formal-ether and wet mount methods will be used for soil-transmitted helminthes and intestinal protozoa respectively.

- Nutritional status: Anthropometric measurements for age will be used to account for normal growth and development of children. Children with z-scores for weight-for-height, weight-for-age, and height-for-age <2 standard deviations of the median of the WHO reference population will be considered wasted, underweight and stunted respectively.
- Nutritional deficiency: Physical examination and clinical observation including dermatosis, pale conjunctiva etc. will be conducted by a trained health care professional. (food security will be assessed through questions in the interview)
- Hemoglobin (Hb) level will be measured to determine anemia prevalence using Hemocue device.
- Data will be collected from local health centers to identify the recorded prevalence of intestinal parasitic infections, and the prevalence of severe diarrhea of the children in surveyed households.

Data collection tools and techniques

5 qualified interviewers with a minimum schooling qualification of intermediate level and with experience in conducting household surveys will be recruited for data collection. Each interviewer will be accompanied by a data collection assistant. It is assumed that an interviewer-team of 2 people will cover 6 households per day; 5 interviewer teams of 2 people therefore will collect data from 30 households per day (household interviews, collection of water samples, collection of stool samples and measurement of health indicators such as anthropometry, hemoglobin). Time required to conduct the interview, collect samples and measure health data shall not exceed 1.5 hours per household per survey. The period allocated to collect data for one panel (baseline/ final survey) is 3 months.

One lab assistant and one health assistant will supervise stool, blood collection and physical examination. The stools will be collected in labeled plastic cups and will be preserved. The samples will be processed for testing at the hospital. Parasitological examination of the feces will be conducted according to operating procedures defined by WHO. Random reprocessing of 5% of the stool samples will be performed for accuracy purpose. Presence of any parasitic infection will be defined by positive laboratory results for intestinal parasites. All the surveyed children with parasitic infections will be treated. Pre-testing of the data collection tools will be done and the instruments will be pilot tested in the area similar to the project area.

Timeline

	2018												2019												2020			
Activities	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4
Health Impact Study Nepal																												
Study preparation, development study tools																												
Baseline Data Collection																												
Intervention **Helvetas**																												
Data Collection																												
Data Analysis																												
Paper Preparation																												
Information Dissemination																												

Expected biases

We do not expect any biases

3.4 Withdrawal and discontinuation

In is expected that some household may drop-out during the course of the study either due to challenges with relocation of households or due to mobility. A slight oversampling will be done to compensate for the loss of households between baseline data collection and the second survey.

4 STATISTICS AND METHODOLOGY

4.1. Statistical analysis plan

Descriptive statistics will be calculated to describe the characteristics of the population and the status of WASH indicators. Frequencies and percentage will be computed for categorical variables while means and standard deviations will be calculated for continuous variables. Positive cases identified during health screening will allow estimating point prevalence. Pearson's chi squared and Fisher's exact test will be applied for finding the association with the prevalence of diarrhea, intestinal parasites (single, multiple), nutritional disorders and risk factors. Means will be compared by student's t test or ANOVA. Repeated measures multiple regressions will be used to find an association between binary or continuous outcomes and adjacent variables. Logistic regression analysis will be used to compare repeated binary health outcomes per child in multiple groups. Univariate association between two binary variables will be assessed through 2X2 tables. Categorical variables will be compared using design based chi-square analysis. In all analyses, a p- value (threshold of significance) <0.05 will be considered statistically significant.

Sample size and power calculations using G*Power 3.1 revealed a sample size of 350 households in each group to detect a small effect between 4 groups with a correlation of 0.1 among repeated measures with 80% power and a one-tailed alpha of 0.05 (Erdfelder *et al.* 1996). A sample size of 300 households will be required to detect a small to medium effect in Cohen's f2 at one-tailed alpha of 0.05 and a statistical power of 95% with multiple linear regression and 15 predictor variables (Faul et al., 2009).

We will sample 375 households per study area, which will have the advantage to better balance potential design effects. The same sampling plan will be used during the follow up study in both beneficiary and control areas. In addition, a drop-out rate of 7% is being considered.

4.2. Handling of missing data

Power calculations revealed a sample size of 300 households per areas. To compensate for eventual dropouts, 375 households will be sampled during the baseline data collection.

5 REGULATORY ASPECTS AND SAFETY

5.1 Local regulations / Declaration of Helsinki

This research project will be conducted in accordance with the protocol, the Declaration of Helsinki [3], the principles of Good Clinical Practice, the Human Research Act (HRA) and the Human Research Ordinance (HRO) [1] as well as other locally relevant regulations. The Project Leader acknowledges his responsibilities as both the Project Leader and the Sponsor.

5.2 Notification of safety and protective measures (HRO Art. 20)

The project leader is promptly notified (within 24 hours) if immediate safety and protective measures have to be taken during the conduct of the research project. The Ethics Committee will be notified via BASEC of these measures and of the circumstances necessitating them within 7 days.

5.3 Serious events (HRO Art. 21)

If a serious event occurs, the research project will be interrupted and the Ethics Committee notified on the circumstances via BASEC within 7 days according to HRO Art. 21[1].

5.5 Amendments

Substantial changes to the project set-up, the protocol and relevant project documents will be submitted to the Ethics Committee for approval according to HRO Art. 18 before implementation. Exceptions are measures that have to be taken immediately in order to protect the participants.

5.6 End of project

Upon project termination, the Ethics Committee is notified within 90 days. All data is anonymized upon termination of data analysis. Materials of water quality analysis and stool samples will be disinfected after analysis and disposed.

5.7 Insurance

Possible damages which are directly related to the study and are demonstrably the fault of Eawag, are covered by the liability insurance of Eawag (insurance policy 30/5.007.449) of the Baloise Insurance Ltd.

6 FURTHER ASPECTS

6.1 Overall ethical considerations

Children below the age of 5 are particularly vulnerable for diarrhoea related morbidity and mortality. The implementation of well-designed and effective programs to improve water supply, drinking water quality, hygiene and sanitation and establish the corresponding behavior effectively therefore is important to realize significant health gains.

Our study will evaluate the effectiveness of two different strategies aiming at providing participating households safe drinking water and it will assess the effectiveness of a WASH training program. Insights gained during the study will contribute to improving the quality and impact such interventions and therewith benefit future recipients of such programs.

The input required from participating caretakers and children is minimal - limited to time during the interview corresponding to less than 1 hour and to providing health data. The health measurements of children will not require more than 15 Minutes and will not expose children to any risks.

Participating household do not receive any financial benefit. However all households in the study area will benefit from the impact of the intervention with improved water supply and drinking water quality as well as improved hygiene. Also the control area will receive a water quality intervention after the completion of data collection. Households that participated in the study (in the intervention areas as well as in the control area) will be informed about the result of their examination and those found infected with parasites will be treated respective of their infection and at recommended doses following standard treatment schemes according to WHO. Similarly, adequate treatment and referral will be done for the nutritional deficiencies.

[1] A serious event is defined as any adverse event where it cannot be excluded, that the event is attributable to the sampling of biological material or the collection of health-related personal data, and which:
a. requires inpatient treatment not envisaged in the protocol or extends a current hospital stay;
b. results in permanent or significant incapacity or disability; or
c. is life-threatening or results in death.

The local authorities will be consulted about the aim and procedures of the study and their support will be solicited. All study participants will be given detailed information about the purpose of the study, the extent of their involvement and their right to be treated free of charge if found with any parasitic infection will be warranted. Informed and written consent will be obtained from all study participants. It will be pointed out that participation is voluntary and that the individuals may withdraw from the study at any time without further obligation.

6.2 Risk-Benefit Assessment

See above chapter 6.1.

6.3 Rationale for the inclusion of vulnerable participants

Children will be involved in the study because they are particularly sensitive to and affected by diarrhoea related morbidity and mortality. A study hypothesis therefore is, that particularly children below the age of 5 will experience the greatest health benefits from an intervention focusing on water safety and improved hygiene and health. Their health related indicators need to be assessed to confirm the hypothesis and evaluate the impact of the study on children's health. The collection of health data will not expose children to any risk.

Children's caretakers will be well informed about the purpose of the study and the methodology. Data will only be collected in households where children's caretakers have provided written informed consent. Participating children will be orally informed about the study and the purpose of the health measurements. They will be gently informed about the process of measurements before starting the examination.

7 QUALITY CONTROL AND DATA PROTECTION

7.1 Quality measures

All the enumerators will be trained on interviewing skills, questionnaire content, data quality and ethical conduct of human research. The co-principle investigator will assume the role of the supervisor during data collection in the field and will facilitate the field work during data collection and control quality of the data by auditing regularly. Interviewers and data collection assistants will contact the supervisor for any problem they faced during data collection and will keep the records of progress and problems/challenges faced during data collection process. Data quality will be ensured and will be cross checked regularly using a check file as well as for internal and external consistency. Laboratory investigation and anthropometric measurements will be revised after pre-test as per the need. Source data will be recorded digitally to avoid mistakes during manual data entry.

For quality assurance the questionnaire will be initially drafted in English, then translated into Nepali and back translation will be done to assure quality. The questionnaire will be pretested in a similar setting to identify required improvements, appropriateness, comprehensibility of questions and content validity.

Water quality analysis will include a random 10% double testing, each day, a negative control will be conducted by each team. The analysis of stool sample will involve a 5% random reprocessing of samples.

For quality assurance the Ethics Committee may visit the research sites. Direct access to the source data and all project related files and documents must be granted on such occasions.

7.2 Data recording and source data

Source data will be digitally recorded on tablets via ODK and will be electronically transferred for data analysis through SPSS or STATA. Source data comprises: data from household interviews and structured observations, results of water quality analysis, results of stool sample analysis, anthropometric measurements, results of finger prick test, results of clinical examination of children.

7.3 Confidentiality and coding

Project data will be handled with uttermost discretion and is only accessible to authorized personnel who require the data to fulfill their duties within the scope of the research project. On the CRFs and other project specific documents, participants are only identified by a unique participant number.

All personal data will be coded. Codes will be used for the labeling of water samples and stool samples and health data. Household's GPS data will be collected to identify households for the second panel of data collection. The participant identification list and GPS information will be stored by the principal investigator. Access to anonymized digital data will be restricted to researchers analyzing data by password protection. Back-ups of password protected files will be stored on external hard-drives.
Only anonymized data will be used for data analysis and to communicate study results.

Water quality & Stool samples will not identified by participant name but by a unique participant number. Samples will appropriately stored in a restricted area only accessible to authorized personnel. Samples and materials required for the analysis will be disinfected after the analysis and disposed.

7.4 Retention and destruction of study data and biological material

Study data will be archived for at least 10 years after study end. Water samples and stool samples will be disinfected and disposed directly after analysis.

8 FUNDING / PUBLICATION / DECLARATION OF INTEREST

There is no conflict of interest. The study will be funded by Eawag.

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