International Initiative for Impact Evaluation

Water and Sanitation Interventions to Combat Childhood Diarrhoea in developing countries

3ie Synthetic Reviews 1 – SR 001
Protocol
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1. Background

One billion people worldwide lack access to clean water, and 2.5 billion do without adequate sanitation (United Nations, 2008). Interventions to effect improvements in water, sanitation and hygiene (WSH) are therefore an important focus of efforts to improve quality of life in developing countries. By improving access to clean water and sanitation facilities and promoting better water-use, sanitation and hygiene practices, WSH interventions contribute towards better health outcomes, higher incomes, improved educational attainment and gender equality. All of these are important objectives for the international community, and reflected in the Millennium Development Goals.

WSH interventions are diverse, ranging from interventions to improve access to water through household and community provision, quality of water through provision of treatment and storage facilities at the source or point-of-use, sanitation facilities through public and community latrines to promote safe disposal of waste, and behaviour change communication to promote safe hygiene practices through education and outreach. Frequently, multiple interventions are promoted simultaneously.

WSH interventions improve health outcomes directly where they reduce the risk of contracting disease, such as diarrhoea, dysentery and cholera, by providing barriers to pathogens carried from faeces into the body via fingers, flies, food and unclean water (Figure 1). This in turn reduces the risk of malnutrition and mortality.[1] The health impact has second-round effects, for example, on household income, through reduced health expenditures and increased production and productivity of labour; on children's educational attainment, through better facilities, fewer sick days and household financial resources being freed-up to spend on education; and on gender equity, for example, where water provision reduces time spent, typically by women and girls, collecting water for the household.

There is a large and growing literature examining the effects of WSH interventions on outcomes in developing countries, utilising a range of study methodologies. Most of this literature focuses on direct health outcomes, in particular childhood diarrhoea risk (IEG, 2008). In recent years, a number of reviews have been conducted to examine the results of these studies systematically, using literature review, meta-analysis and/or meta-evaluation. In most cases, after assessing the internal validity of each study design, which determines whether it is possible to attribute the differences observed in an outcome measure to an intervention, reviews pool 'valid' estimates using meta-analytic techniques with the objective of making 'externally valid' generalisations on the relative effectiveness of different interventions. The following paragraphs summarise the main results of the major reviews conducted thus far.

Esrey *et al.* survey 144 studies and calculate median percentage reductions in diarrhoea morbidity across studies of 33 percent for hygiene interventions, 27 percent for water quantity interventions, 22 percent for sanitation interventions and 17 percent for water quality interventions. They conclude that "safe excreta disposal and proper use of water for personal and domestic hygiene appear to be more important than drinking water quality in achieving broad health impacts" (1991: 31).

[1] The World Health Organisation estimates that diarrhoea accounts for 15 percent of deaths of under-5s in developing countries per year (WHO/UNICEF, 2000).

Fewtrell and Colford (F&C, 2004, also published as Fewtrell *et al.*, 2005) conduct meta-analysis of 60 studies, finding that hygiene education and water quality interventions reduce diarrhoea risk on average by about 40 percent each, while sanitation provision and water supply reduce risk by only around 20 percent each. The difference in findings with respect to water quality improvements between the two reviews is due to the former being based on studies examining water quality treatment at source, while the latter includes many studies of water quality improvements at point-of-use. Since there are multiple ways in which clean water may be contaminated between source and point-of-use, most recent interventions have focused on household water treatment and safe storage, with beneficial results.[2]

A meta-analysis of 33 studies conducted by Clasen *et al.* (2007) also supports the finding that water treatment at point-of-use, particularly flocculation or disinfection, is more effective in reducing diarrhoea risk than water source improvements. Arnold and Colford (2007) review 10 studies examining household chlorination, finding a pooled effect estimate of 29 percent reduction in diarrhoea risk among children. But they also note concerns relating to sustainability of the interventions given the reduced effectiveness in longer-term trials. Schmidt and Cairncross (2009) report on the possible bias induced in non-blinded trials of point-of-use water treatment technologies, finding zero effect significance in five studies which did use blinding, three of which were conducted in developing country settings. They conclude that "widespread promotion of household water treatment is premature given the available evidence" (p. 986).

Three other meta-analyses examine the impact of hand-washing on diarrhoea risk. Curtis and Cairncross (2003) analyse 17 studies finding a reduced risk of 50 percent. Aiello *et al.* (2006) find reduced risk of gastrointestinal illness 34 percent across 12 studies conducted in developing countries. Ejemot *et al.* (2008) find a reduced risk of one-third across five randomised controlled trials (RCTs) in developing countries.

Drawing on these and more recent impact evaluations, the World Bank's Independent Evaluation Group (IEG, 2008: 17) concludes that there is "overwhelming evidence that hand washing, sanitation, and household and point-of-use water treatment improve health outcomes... However, there do not appear to be health gains for water treatment at the source. Furthermore, the health impact of combined methods has not been found to be stronger than any single approaches."

Systematic review aims to combine similar studies of sufficient quality (internal validity) with the aim of generating credible, generalisable (externally valid) results. Its origins lie in the medical literature, though it is increasingly being applied to the social sciences, under the auspices of organisations such as the Campbell Collaboration (C2), and more recently in the developing country context, advocated by organisations such as the International Initiative for Impact Evaluation (3ie). Problems with internal validity of WSH intervention designs have been well-documented previously (Blum and Feacham, 1983). Determining the external validity of studies – that is, relating to the context and the behavioural mechanisms underlying the intervention – is particularly

[2] One issue not addressed by these studies is that of sustainability of water quantity and quality interventions. The benefit of water supply interventions over quality improvements is that they frequently require limited behavioural change on the part of the beneficiaries, aside from collecting water from the 'safe' source. In contrast, water quality interventions that require treatment and safe storage at point-of-use require significant and sustained behavioural change from beneficiaries in the household.

problematic in the field of socio-economic interventions, and vital to the credibility of any conclusions made from meta-analysis. In the case of WSH interventions, studies vary in type of intervention, how they are conducted and by whom, social, political, cultural and legal backgrounds, characteristics of target groups, not to mention measures of outcome variable, base-line situations and study designs, all of which will reasonably impact on 'effect' estimates.

This review will take the existing systematic reviews of WSH interventions to reduce diarrhoeal risk as its starting point, notably F&C (2004). However, our survey of previous reviews has identified some methodological weaknesses associated with combining effect estimates, which may invalidate pooled estimates of effect size. For example:

- The outcome variable varies across studies: to take some examples, Alam *et al.* (1989), Semenza *et al.* (1998) and Stanton *et al.* (1988) measure diarrhoea incidence, defined as three or more loose stool samples in 24-hour period; Azurin and Alvero (1974) and Colwell *et al.* (2003) measure incidence of cholera defined as those testing positive for cholera vibrosis.
- The computation method varies, with most estimates taken from studies reporting effect estimates using difference between treatment and control over time and at least one estimate coming from using single difference within treatment group over time (Alam *et al.*, 1989).
- Estimates are sometimes pooled from different estimation procedures, e.g. risk ratios, rate (or 'incidence density') ratios, prevalence ratios and odds ratios, which is likely to bias pooled effect sizes, and from different study designs (randomised controlled trials, quasi-experimental and case-control studies), which affect standard errors and therefore confidence intervals of the estimates obtained.
- Use of low quality studies, such as case-control design, or studies in which comparability of treatment and control groups is questionable.

Finally, the systematic reviews surveyed focus on estimating net benefits of interventions, but often stop short of evaluating in detail why such interventions have been effective or not, and, moreover, do not assess adequately cost-effectiveness and sustainability. These are of overriding importance to programme planners.

Which factors determine whether a WSH intervention will be effective in improving outcomes and why? To answer these questions one has to examine the behavioural mechanisms through which the intervention works and the context in which it is based (Figure 2). A recent systematic review (van der Knapp *et al.*, 2006) aims to answer the 'why' question by combining C2 systematic review with the context-mechanism-outcome model of Realist Evaluation promoted by Pawson (2006). They argue that the effectiveness of a programme depends on the combined action of the behavioural mechanisms underlying it and the context in which it takes place. Behavioural mechanisms operate through the values, beliefs and past experiences of individuals in the social system. Thus, factors such as interpersonal networks and individual agency are important in the adoption and rejection of an intervention. The action of mechanisms depends in part on the context in which they are used. Behavioural change is achieved via the entire system of social relationships (the context) and, therefore, an intervention geared towards the achievement of behavioural change must be aligned with the context in which it is used.

The importance of taking into account the context and behavioural mechanisms in programme design is highlighted in an example from an intervention to supply clean drinking water through public spigots in villages in Egypt (Rogers, 1995). Despite provision of piped water and government media campaigns warning people of the risks from drinking canal water, the level of use of spigots was low. Surveys and interviews conducted subsequently found that users complained of a chemical taste of the chlorinated water and reported rumours that the government's family planning programme had added chemicals to decrease population growth. Moreover, villagers had a vessel for water collecting which they perceived as purifying the water. Socially, the women preferred gathering water from the canal banks where they also washed their clothes and dishes; and because of long queues and low water pressure there were reports of fighting in the queues. Ultimately, the piped water was perceived as unreliable. It was also highlighted that village religious leaders could have played a role in promoting pure drinking water, but this strategy was not pursued by government change agents.

2. Objectives

The objective is to provide a systematic review of the effectiveness of interventions in Water, Sanitation and Hygiene in promoting better health outcomes in developing countries as measured by the incidence of diarrhoea among children. The study will update the existing systematic reviews and meta-analyses in WSH (Curtis and Cairncross, 2003, Fewtrell and Colford, 2004, Clasen *et al.*, 2007, Ejemot *et al.*, 2008, and IEG, 2008), drawing on new evidence and rectifying any methodological shortcomings. It will attempt to answer why interventions are effective or not, by drawing out evidence on the behavioural mechanisms at work and the underlying context, and attempt to synthesise information on the cost-effectiveness and sustainability of interventions.

3. Study team

Hugh Waddington (literature search, literature review, study coding, data analysis) is an independent consultant with previous experience in impact evaluation in health and nutrition at the Independent Evaluation Group of the World Bank, which included meta-analysis of child mortality and nutrition outcomes (see Charmarbagwala *et al.*, 2004).

Birte Snilstveit (literature search, literature review and study coding) is an independent consultant with an MA in Political Economy of Development, training in research methods and an interest in social analysis of poverty and development.

Dr Howard White (technical advisor) is the Executive Director of 3ie, previously at the Independent Evaluation Group of the World Bank and Fellow of the Institute of Development Studies, University of Sussex. He is a proponent of theory-based impact evaluation design and has led a number of impact evaluations in the areas of education, health, rural development and rural electrification. He also has experience of meta-evaluation and meta-analysis (e.g. IEG, 2008; Charmarbagwala *et al.*, 2004).

Dr Lorna Fewtrell (technical advisor) led the previous systematic review of WSH interventions on diarrhoea morbidity (F&C, 2004) and is Senior Research Fellow of the Institute of Geography and Earth Sciences at Aberystwyth University.

4. Methods

Selection criteria

Studies selected will assess the effectiveness of WSH interventions on risk of diarrhoeal illness using experimental design, including randomisation at individual level (e.g. Quick *et al.*, 1999) and community level (e.g. Haggerty *et al.*, 1994), and non-randomised trials with baselines and concurrent control groups (e.g. Alam *et al.*, 1989). Studies will also be included that use quasi-experimental design, including those which use household surveys and methods such as propensity-score matching to construct the control group (e.g. Jalan and Ravallion, 2003). Regression-based studies based on household surveys will be selected where they use multivariate techniques with adequate control for confounding variables[3] and statistical methods such as instrumental variables to correct for endogeneity of programme placement. Excluded studies are those which do not control for endogeneity of programme placement or self-selection into the programme.

Articles will be selected that:

- report specific water, sanitation and/or hygiene intervention(s);
- are conducted in developing (low- or middle-income countries);
- use an infant or child as the unit of observation;
- estimate impact on diarrhoea morbidity, measured under endemic (i.e. non-outbreak) conditions.

Search methods for identification of studies

Following F&C (2004), relevant studies will be identified by searching databases pairing the following terms:

- 'sanitation', 'water quality', 'water quantity' or 'hygiene' against 'diarrhoea' or 'diarrhea'.
- 'sanitation', 'drinking-water', or 'hygiene' against 'intervention' or 'evaluation'.

These search terms will be used to search the following databases: PubMed, Embase, LILACs, Web of Science (including Science Citation Index Expanded; Social Sciences Citation Index; Conference Proceedings Citation Index- Science), JOLIS, BLDS and the Cochrane Library. IDEAS, which covers unpublished economics papers and Google Scholar, which has the advantage of covering all disciplines and unpublished material, will also be searched, using the same search terms as above. As it is anticipated this will generate a high number of results, we will limit our review to the first 1,000 results for each combination of search terms. The searches in the databases included in the Fewtrell and Colford review (Pubmed, Embase, LILACs and the Cochrane Library) will be limited to papers published since 2003, while the searches of Web of Science databases, JOLIS, BLDS and Google Scholar will be limited to papers published since 1998. The Conference Proceedings Citation Index- Science goes back to 1990 and no time limitations will be used when searching this database.

A count will be made of all unique papers identified in the initial search. The titles and abstracts resulting from the searches will be reviewed and the references to potentially relevant studies will be downloaded into the bibliographical

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[3] Confounding variables are those which are correlated with exposure to environmental pathogen levels and, independent of exposure, are risk factors for the outcome. For non-RCTs, confounding is dealt with by matching groups based on confounding variables or by controlling for confounders in multivariate analysis. Examples of confounding variables for WSH interventions are general water and sanitation conditions in the locality, socio-economic status, income and education levels of household.

management software Refworks. We will then obtain full text copies of these studies in order to determine if they meet the inclusion criteria. Bibliographic back-referencing will be undertaken to identify any further relevant papers and a hand-search will be conducted of journals and relevant book shelves of the University of Birmingham library.

The following organisations working in the field will also be contacted or their websites searched for relevant studies: African Development Bank, Asian Development Bank, Australian Aid Agency, Canadian International Development Agency, Danish Development Agency, Department for International Development, European Commission, GTZ, Inter-American Development Bank, Japan International Cooperation Agency, Japan Bank for International Cooperation, Pan American Health Organization, Swedish development agency, US Agency for International Development, the World Bank (Office of Evaluation and Development), World Health Organization, organisations of the United Nations (UNICEF, UNEP, UNDP, UN-HABITAT, UNRISD), Christian Aid, IRC International Water and Sanitation Centre, International Rescue Committee, Oxfam, Red Cross, WaterAid, African Medical and Research Control, Centers for Disease Control and Prevention, Fresh Water Action Network, and International Water Management Institute. Finally, we will personally contact key researchers in the field in order to seek recent unpublished trials.

Data collection and coding

Experimental study design involves comparing the outcomes of those in a treatment group subject to an intervention to those in an otherwise identical control group, not receiving treatment. For dichotomous outcomes, such as incidence of diarrhoeal disease, this involves comparing the risk of having the event (or odds) between the two groups. The relative risk or risk ratio (RR) of diarrhoea is the risk of diarrhoea in the treatment group divided by the risk in the control group, which is calculated by dividing the incidence of diarrhoea in the treatment group by the incidence of diarrhoea in the control group. The odds ratio (OR) is the odds in the treatment group divided by that in control group. An RR or OR of less than one indicates that diarrhoea is less likely in the treatment than control groups. An RR or OR of greater than one indicates diarrhoea is more likely in treatment than control groups. An RR or OR equal to one indicates no difference between either group. RR and OR calculations produce similar results for the same data where the risk of the event is low; however, OR will always be further from the point of no effect (OR=1, RR=1) than RR. This may be a source of bias in calculating average effects in meta-analysis, and will be accounted for as a potential source of heterogeneity when conducting the meta-analysis.[4] Note that in addition to risk ratios and odds ratios, studies report rate ratios, point prevalence ratios and longitudinal prevalence ratios; impact heterogeneity will be explored by ratio type.

Outcome data will be collected from each reference selected for review on computation procedure of outcome variable and estimated effect and 95 percent confidence interval. To allow for impact heterogeneity, multiple effect estimates will be collected where reported for each intervention type per study, though only one effect estimate will be used in each aggregation across studies. Wherever possible, data will be drawn out to calculate RR and confidence interval. Where studies report adjusted and unadjusted measures, the most adjusted estimate will be included in the analysis. In all cases the RR (OR) will be expressed such

[4] A number of previous meta-analyses have treated RR and OR as equivalent (e.g. F&C, 2004, Curtis and Cairncross, 2003).

that RR<1 (OR<1) means the intervention has reduced the frequency of diarrhoea in the treatment group in comparison to the control group.

The review will stratify WSH into groups of related interventions:

- *Hygiene interventions*: including hygiene and health education and the encouragement of specific behaviours, such as hand-washing.
- *Sanitation interventions*: providing means of excreta disposal, usually latrines, either public or household.
- *Water supply interventions*: including provision of a new or improved water supply and/or improved distribution, such as the installation of a hand pump or household connection, either at the public or household level.
- *Water quality interventions*: water treatment for the removal of microbial contaminants and/or clean storage, either at the source or at the household level.
- *Multiple interventions*: were those which introduced water, sanitation and hygiene elements to the study population.

It should be noted that there remains substantial variation in the types of interventions within each of the five strata. For example, water quality interventions include physical treatments such as boiling, UV exposure and filtration, and chemical treatments such as chlorination, ion exchange and treatment with acid or base. Similarly, hygiene interventions include promoting hand-washing with soap and not allowing animals in the household. Water supply improvements are implemented either at community and household level. Where sufficient studies exist on a particular type of intervention, further stratification will be made for sub-categories. This will facilitate calculations of cost-effectiveness, where these can be made.

Studies will be classified as good and poor quality, building on the method outlined in F&C (2004). Poor quality studies are those with inadequate or inadequately described control groups, no clear measurement or control for confounding variables, no specific definition of diarrhoea or the particular diarrhoeal health outcome used, or a health indicator recall period of more than two weeks. For studies reporting diarrhoea and dysentery rates, where possible, combined measures will be made, since not all studies differentiate between the two types. Control adequacy will also be defined according to collection of baseline data or not, and whether baseline diarrhoea outcomes are, or are not, significantly different (since this affects whether single difference estimates measure the 'true' effect); this means that ex-post analyses with no baseline data will all be coded as of low quality.

The following data, where available, will be extracted from each study (see Annex A):

- General: Author, publication date, publication type, funding agency.
- Intervention design: intervention type, methods and period.
- Study design: design type, description of treatment and control group selection, recall period, data collection method and frequency, sample size.
- Context: country, location, participant age band, baseline water and sanitation provision, baseline incidence of diarrhoea, confounding variables.
- Output: measurement of output, e.g. environmental pathogen-load, functioning of intervention or behaviour change among beneficiaries.
- Outcome: definition and outcome metric, treatment and control means before and after intervention; effect estimate, confidence interval, p -value, other outcomes reported.

- Other: unit-cost data; explained behavioural mechanisms; moderators used; sustainability of intervention and outcomes.

Where available evidence concerning resource use, unit costs of intervention or cost-effectiveness is available, this information will be collected. In order to make comparisons across interventions, cost data will need to be standardised to a single currency and price year. Finally, articles will be searched for evidence or speculation on why the interventions have been effective, or not (see below), and whether issues of sustainability have been considered.

Baseline water and sanitation facilities will be categorised according to likely risk of faecal-oral pathogen intake (Table 1). Very high risk baseline conditions are those with basic water and basic sanitation, or improved water and basic sanitation, while high risk conditions are identified as those with basic water and improved sanitation and improved water and improved sanitation (Prüss *et al.*, 2002). Where baseline data on pre-intervention water and sanitation provision are not available for extraction, the study will follow F&C (2004) in applying the water and sanitation provision of the majority of the population according to WHO/UNICEF (2000) in each relevant country and location as a baseline scenario.

The review will be conducted using C2 standards as explicated. However, the discussion will also attempt to focus on explaining why different interventions work, which involves examining the behavioural mechanisms at work and the context in which interventions are conducted. This will be done by collecting detailed information on how the intervention was conducted and by whom; whether beliefs, values or experiences of treatment group and information on economic, social, administrative or legal factors are relevant in explaining effectiveness and ought to be taken in account; and the effect of moderator variables,[5] which would indicate whether an intervention is more effective among certain groups. These factors will be appropriately coded.

Statistical analysis
The study will conduct meta-analysis using STATA software (STATA Corporation, College Station, TX, USA) random and fixed effects meta-analysis command. The pooled meta-analysis estimates and 95% confidence intervals will be presented for each category and sub-category of study, together with forest plots. Tests for homogeneity and publication bias will be carried out using this software.

Where appropriate, meta-regression will be performed to account for heterogeneity among study results arising from differences in study design and quality, effects of location and pre-intervention baseline scenario, and characteristics of the population being treated such as education and socioeconomic status.

5. Timeframe

Registration of title with C2: December 2008
C2 review of protocol: January 2008.
Searches for studies: December week 1 -January week 2.
Assessment of relevance of studies: January weeks 1-4.
Extraction of data: January week 2 - February week 2.
Statistical analysis: February weeks 3-4.

[5] A moderator (or interaction) variable modifies the way in which the intervention affects the outcome at different values; examples for studies reviewed here include age of child and education or income level of carers.

Preparation of draft report: March.
Presentation of draft report at Cairo Impact Evaluation Conference and C2 Colloquium Oslo: April-May.
Revision of draft report: May.

6. Statement concerning conflict of interest

There is no conflict of interest arising from researcher interest or financial sources.

7. References

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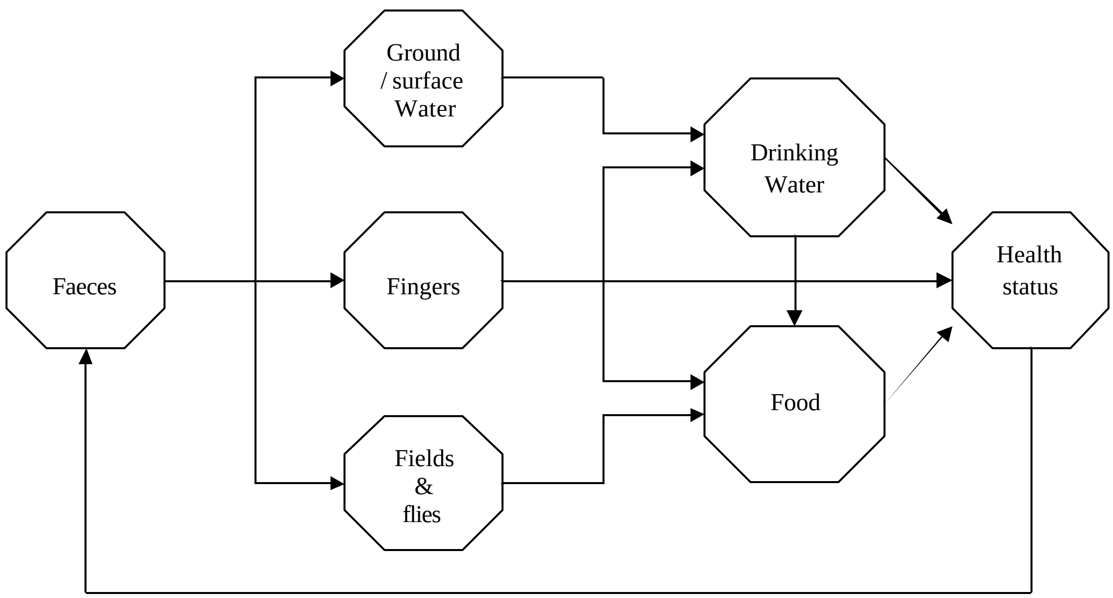
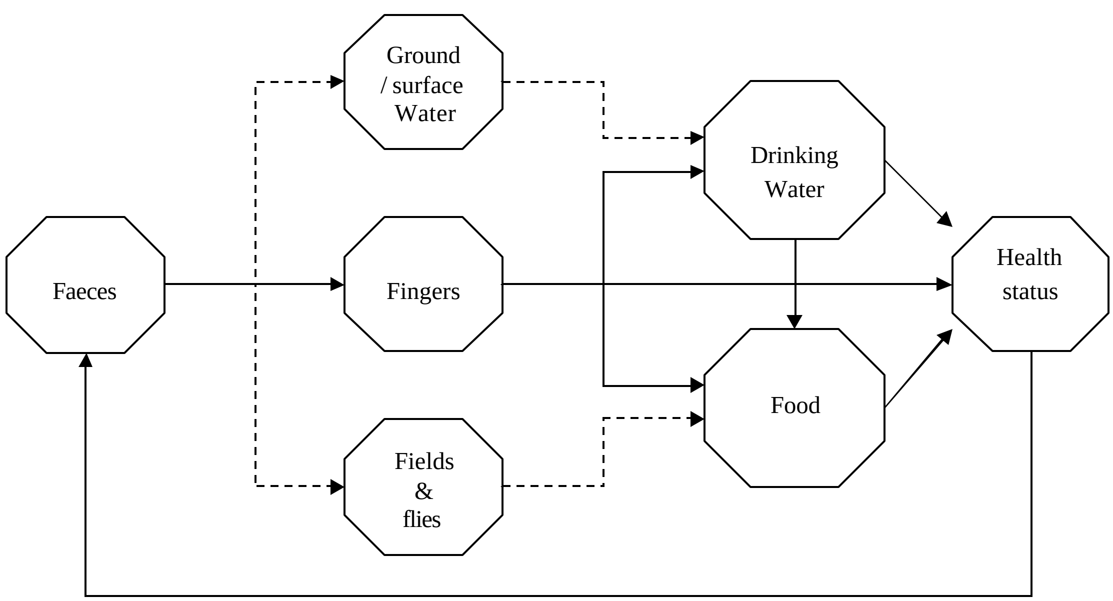
8. Figures and tables

Figure 1: Water treatment, sanitation and hygiene barriers to disease transmission

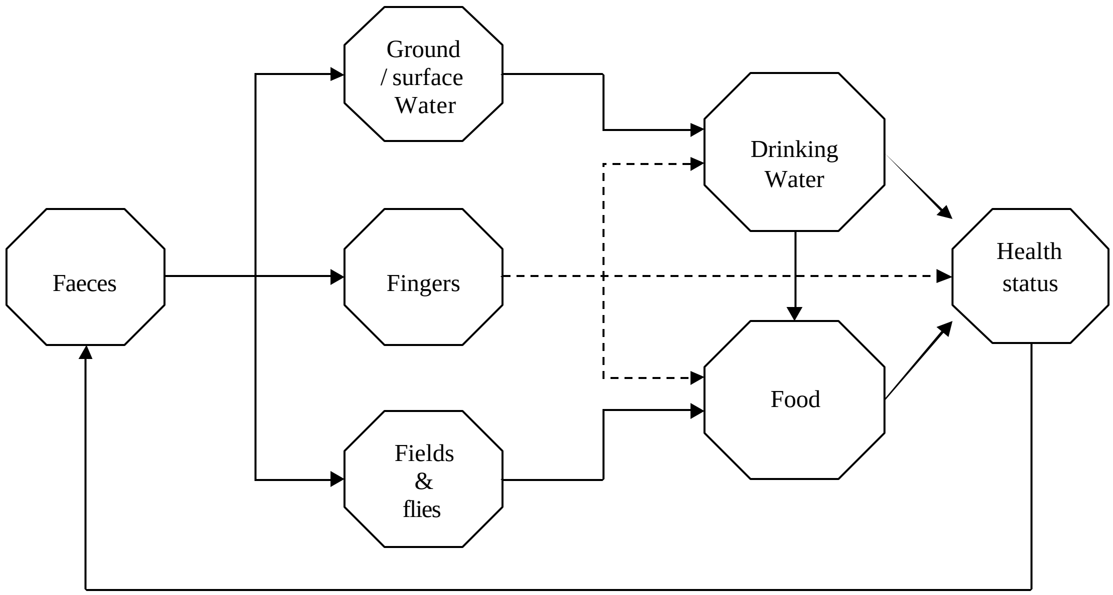
(a) Faecal-Oral contamination model: arrows represent transmission routes for pathogens



(b) Sanitation barriers to transmission



(c) Hygiene barriers to transmission



(d) Water treatment (at source or point-of-use, POU) as a barrier to transmission

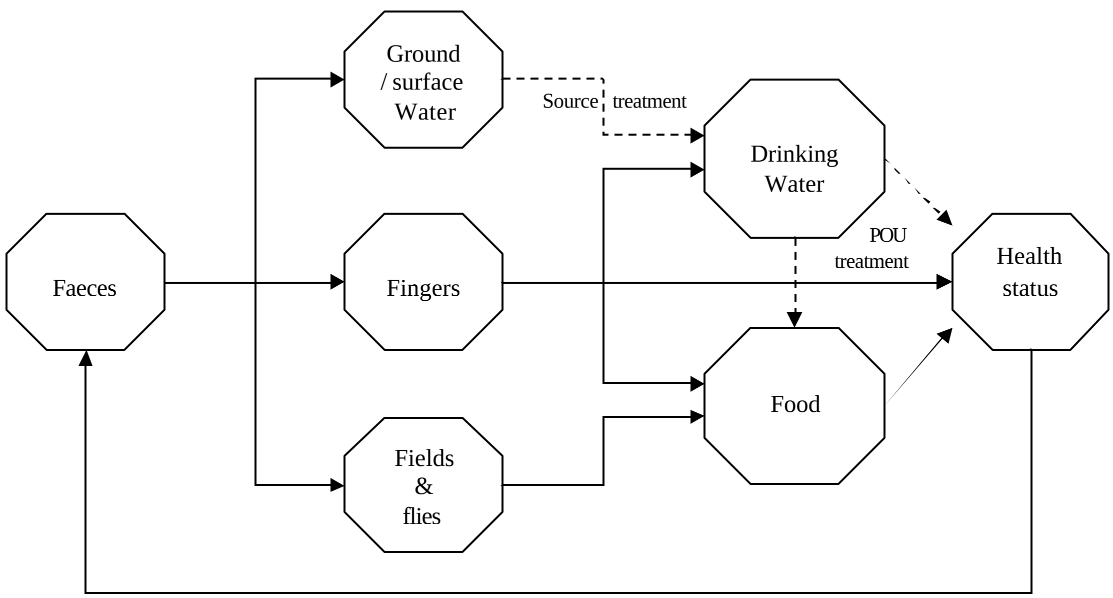


Figure 2: Effects of intervention on outcomes are mediated by context and behavioural mechanisms

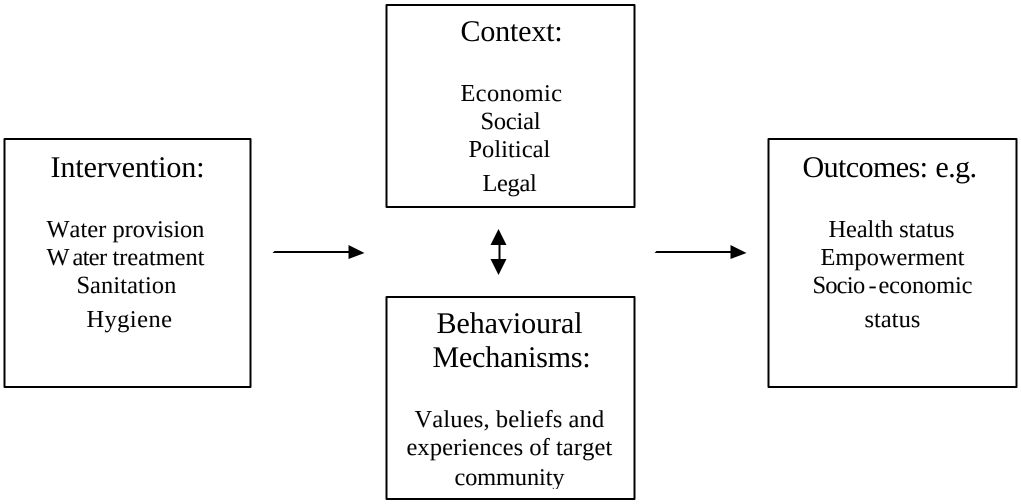


Table 1: Definition of basic and improved water and sanitation facilities

	Water	***Sanitation***
Basic	Unprotected well Unprotected spring Vendor-provided water Bottled water Tanker-truck provided water Rivers, canals, ditches	No facilities Service or bucket latrines (where excreta are manually removed) Public latrines Latrine with an open pit
Improved	Household connection Public standpipe Borehole Protected dug well Protected spring Rainwater collection	Connection to a public sewer Connection to a septic system Pour-flush latrine Simple pit latrine Ventilated improved latrine

Source: WHO/UNICEF (2000).