Cost-effectiveness of a weaning food safety and hygiene programme in rural Gambia

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Title/subtitle: **The cost-effectiveness of a weaning-food safety and hygiene programme in rural Gambia**

Short title: Cost-effectiveness of a weaning-food safety and hygiene programme

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Abstract (250 words)

Objective

The main objective of the economic evaluation was to determine the cost-effectiveness of a weaning food safety and hygiene programme in reducing rates of diarrhoea compared to the control in rural Gambia.

Methods

The public health intervention, using critical control points and motivational drivers, was evaluated in a cluster randomised controlled trial at 6- and 32-month follow-up. An economic evaluation was undertaken alongside the RCT with data collected prospectively from a societal perspective. Decision-analytical modelling was undertaken to explore cost-effectiveness over a longer time period (4 years).

Results

Direct out of pocket healthcare expenditure for households due to diarrhoea was large. The intervention significantly reduced reported childhood diarrhoeal episodes after six months (incident risk ratio =0.40, 95%CI 0.33, 0.49) and two years after the intervention (incident risk ratio = 0.68, 95%CI 0.46, 1.02). The within trial analysis found that the intervention led to total savings of 8064 dalasi six months after the intervention, and 4224 dalasi two years after the intervention. Based on the model results, if the intervention is successful in maintaining the reduction in the risk of diarrhea, the ICER is US$814 per DALY avoided over 4 years. According to the WHO CHOICE guideline, this is cost effective (below 3xGDP per capita).

Conclusions

This study suggests that there are substantial household costs associated with diarrhoeal episodes in children. The within trial analysis and model results suggest that the community-based approach to improving weaning food hygiene and safety is likely to be cost-effective compared to control.

Keywords

Cost-effectiveness, food safety, hygiene promotion

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Introduction

Diarrhoeal diseases represent a major public health issue in lower and middle income countries (LMICs) and their reduction is vital to achieving substantial Development Goals for health (1, 2). The improved health and nutrition of infants and children is often not prioritized in current discourses on food systems, but there is an urgent requirement to ensure that such systems better respond to their needs (3). Amongst children aged under five, diarrhoea is the second highest cause of mortality (4-6) and frequent diarrhoea is associated with damage to the gut, further malnutrition and stunting (7, 8). The weaning period, when a child starts eating solid food, but does not fully eat the family meal (between 6 and 24 months), is associated with particularly high rates of diarrhoea in LMICs (9, 10). Food-safety and food-hygiene interventions aimed at preventing the consumption of contaminated food and liquids are seen as important in reducing rates of diarrhoea in children, but there is limited evidence about their effectiveness in terms of impacts on child health outcomes (11, 12). In addition, there is very little economic evidence about sanitation and hygiene programmes in general (13) or on the cost-effectiveness of particular types of intervention (14-16) .

Following formative research in the Gambia, a weaning-food safety and hygiene programme was developed (17). This was a community-based behaviour change intervention, with effectiveness investigated via a cluster randomised controlled trial (RCT) involving thirty villages (clusters) in The Gambia (18). The trial focused on the effects of this complex intervention on the following outcomes: mothers' weaning-food safety and hygiene behaviour (primary outcome), boiling drinking water, microbiological contamination in weaning-food and drinking water, rates of diarrhoea, diarrhoea admission, and respiratory infection. The main objective of the economic evaluation was to determine the cost-effectiveness of the weaning food safety and hygiene programme in reducing rates of diarrhoea compared to the control. The purpose of the economic evaluation was to inform current policy in this area, as the success of any intervention in supporting healthy weaning needs to be balanced against the resources required to achieve this outcome, and additional costs must be assessed in terms of any additional benefits that can be attributed to them (19).

Methods

Study setting

The site for the study was The Gambia's Central River Region (CRR). CRR is Gambia's poorest region and has the highest rates of diarrhoea (20). This was a 1:1 parallel cluster-RCT, and the unit of randomisation was a whole village. The inclusion criteria for a cluster was the whole of an average sized (200–450 population (21)) "Primary Health Care (PHC) village" with a village health worker/volunteer (VHW) and a traditional birth attendant (TBA). Villages within 5km of previously selected villages for the pilot were excluded to prevent contamination.

The Intervention

Full details of the intervention are published elsewhere (22). In brief, we developed a low intensity, community-based behaviour change intervention for weaning-food safety and hygiene (17). The co-designed community-level intervention had previously been evaluated in Nepal (23, 24) and was adapted via formative research in the Gambia (17, 18). The main intervention was delivered over 25-days (4 community campaign intervention team visits on days 1, 2, 17, 25) with female volunteers (MaaSupervisors) encouraging the mothers in-between campaign visits (17). The campaign visits, home visits and community meetings included dancing, songs and drama, and communities were encouraged to continue the behaviours and disseminate them among new mothers, with no incentive or contact from outside of their community. Five months later, a reminder visit was undertaken to remind villagers about the key behaviours. Control villages received a 1-day health education campaign from a Public Health Officer on water use in domestic vegetable gardening, including a community meeting.

Resource use and cost definitions

An economic evaluation was conducted alongside the RCT, with decision-analytic modelling undertaken to analyse longer term costs and outcomes. The overall aim was to analyse cost-effectiveness from a societal perspective, which included costs and benefits for the agencies responsible for setting up and delivering the intervention and for the households in the intervention villages,

120 compared to the control. Costs associated with developing and delivering the intervention were
121 collected via trial reporting mechanisms. Costs to the household associated with episodes of childhood
122 diarrhoea were captured via a questionnaire which included healthcare resource use, impacts on
123 productivity and other costs. The questionnaire was delivered to participants in the trial during follow-
124 up at 6 months and 36 months. We also included potential costs for the participants associated with the
125 behaviour change promoted. As part of the intervention, households were encouraged to boil child's
126 drinking water and reheat stored food. We included these costs in the analysis based on market prices.
127
128 Data on effectiveness
129 Data on the prevalence of diarrhoea amongst children between 6 to 36 months old were collected at
130 baseline (before the intervention), 6 and 32 months after the 25 day intervention period. "Primary Health
131 Care (PHC) villages" (158) were grouped and randomized within 2 strata (north or south of the river
132 and by quartiles of the village population) into 15 control and 15 treated villages. The survey sampling
133 design was conducted in two stages. There were two strata, one with 86 villages (clusters) and another
134 with 72 villages. For each stratum, 15 villages were randomly chosen and within the villages 20
135 households were randomly chosen to conduct interviews and observations. The 15 villages from one of
136 the strata were treated with the intervention while the other was the control group (22).
137
138 Analysis of cost-effectiveness
139 We evaluated whether the intervention is cost-effective by extending from the framework proposed by
140 Borghi et al (2002). Trial data were used to estimate the impact of the intervention on the prevalence of
141 childhood diarrhoea[1] and the impact on healthcare resource use, productivity and wider household costs.
142 Using the estimates from the trial, a Markov model was used to analyse the longer term cost-
143 effectiveness of the intervention and this was compared with the WHO-CHOICE threshold (25, 26).
144

[1] Childhood diarrhoea prevalence is calculated as the number of children who has diarrhoea in the past 7 days at the time of interview divided by total number of children interviewed. The calculations also include sampling weights, where we weigh each observation according to the different probabilities of being chosen to be interviewed due to the sampling procedure.

Calculation of household savings per diarhoeal incident

We used Manjang et al. (2020) estimates of the treatment effect on childhood diarrhoea prevalence at household level (22). Manjang et al. (2020) estimated the treatment effect by using a mixed-effect Poisson model with a log-link, and adjusted for village-level stratification. The method allows for clustering within the level of randomisation (villages). We attached their point estimates of the effect of the treatment with the average cost of health treatment paid by households for one ill child to compute household savings per diarrhoeal incident.

Calculation of household and agency costs

Agency costs associated with delivering the intervention were collected prospectively using trial reporting processes. Costs associated with developing the intervention and training staff were assumed to be sunk costs which would not be borne by agencies and hence were excluded from the main analysis (see Appendix 2 for details of these costs). The costs included the resource use associated with delivering the intervention in a community setting. All costs were collected in Gambian Dalasi using trial processes. The costs were converted to US Dollars and inflated to 2017 prices (https://www.exchange-rates.org/Rate/USD/GMD/6-21-2014).

The intervention was comprised of several elements. The intervention involved travelling to villages and so transport costs were recorded and included. Technical equipment was necessary to deliver the intervention; this included a generator, a projector, a mobile printer, a tablet and a laptop. We assumed that this equipment could be re-used over a period of three years until they became outdated, and thus annuitised all these costs for three years (19). There were other re-usable resources used in the intervention (e.g. banners, fluorescent lights), again we assumed that these could be reused over a three-year period and annuitised costs accordingly. There were consumable resources associated with the intervention. This included soap, stationery and other items such as medals (given to participants).

Costs associated for participating in the intervention were calculated for households. We included the difference in means in expenditure for fuel between control and treatment groups, to take into account the impacts of the intervention on household fuel costs.

Decision-analytic modelling

A decision-anlaytic model was used to examine the longer-term costs and benefits of the intervention. The appropriate model structure for this study was a Markov model, due to the cyclical nature of diarrhoea infections (27). The model had four states, healthy, mild diarrhoea, severe diarrhoea and death; possible transitions between states are shown in Figure 1. Two diarrhoeal states were included (mild and severe), because the severe state is associated with a higher probability of death, a higher disability weight and increased healthcare costs (28). In addition to this, hygiene interventions are expected to reduce the probability of severe diarrhoea relatively more than mild diarrhoea (29). The model was simplified and substantially adapted from an existing published model for an intervention to rotavirus (28).

The cycle length for the model was established as one month and the time horizon was 4 years (from age 12 months-60 months), in order to represent the full weaning period. A Simpson correction is applied to DALYs but not to costs, since it is assumed that costs are incurred at the beginning of the period; this makes very little difference since the cycle length is very short. Within the model, the cohort all begins in the healthy state at age 12 months. Risk of developing diarrhoea declines in each cycle, reflecting higher incidence of diarrhoea at the beginning of the weaning period (20). Background mortality rate also declines over time as the cohort ages. Trial data were used to estimate the intervention effects on the relative risk of diarrhea and costs associated with the intervention. Table 1 shows the other parameters used to populate the model, along with the sources used. It was assumed that the risk of death from mild diarrhoea is the same as the background mortality. The transition probability from severe diarrhoea to

death is simply background mortality, which declines over time, plus a time-invariant risk of death from diarrhoeal disease. The risk of diarrhoea-related death given a severe diarrhoeal episode, and the annual reductions in risk of death and background mortality were all chosen to calibrate the model to ensure that overall mortality, incidence of diarrhoea and diarrhoea mortality matched the Gambian 2010 national health survey data (20). Diarrhoeal episodes confer some temporary immunity from further diarrhoeal infections; an individual in either of the diarrhoea states has a 10% lower chance than a healthy individual of having diarrhoea in the following period, after which risk returns to normal (30). Costs and DALYs were discounted by 3%, following WHO recommendations (26).

Sensitivity analysis

A probabilistic sensitivity analysis (PSA) was undertaken for the modelling element to examine the effects of the inherent uncertainty in the parameters (31). In a PSA all parameters are varied simultaneously, and multiple sets of values are sampled from defined probability distributions (32). This involved 1000 repeated random draws from the distributions to indicate how variation in the model parameters would affect the results and hence illustrate the decision uncertainty (33). Beta-distributions were used for binomial data and Gamma-distributions for costs (32).

Results

Intervention costs

The intervention required a range of resources for agencies (Table 2). This included vehicle hire, a driver and fuel to travel to each of the 15 villages for the four days of the intervention, equipment such as a generator, a projector, a laptop, mobile printer, a tablet, fluorescent torch

220 lights, medals, soap and stationery. The intervention required input from a range of personnel.
221 A Senior Public Health Officer (with an MPh in HIC) was responsible for the overall
222 implementation of the intervention, supported by Junior Public Health Officers. Traditional
223 Communicators were involved in delivering the culturally embedded drama and songs
224 (performing arts). One MaaSupervisor was appointed in each village and was given a small
225 amount of payment for this role. Combining the costs associated with wages and resources
226 used for 15 villages, the intervention cost approximately USD 1000 per village (Table 2).
227 There were also costs associated with the intervention for households. A significant difference
228 was identified in fuel expenditure between treatment and control groups. The households in the
229 treatment group spend 7.87 dalasi more than the households in the control group (see Table 3).
230 This translates to approximately 4.6 dalasi used per diarrhoeal incident in the sample at endline.
231 Soap costs were not included in the initial analysis as this was provided to participants as part
232 of the intervention.
233
234 *Costs associated with an episode of diarrhoea*
235 The findings from the survey demonstrated that both the direct cost and opportunity cost of a
236 child having an episode of diarrhoea were substantial. Panel A in Table 4 shows that
237 households sought help from various sources when a child had diarrhoea, with qualified health
238 practitioner being the most common. Direct out of pocket healthcare expenditure for
239 households was large (Panel B, Table 4) – in particular, medicine cost approximately 5% of
240 the Gambia's GDP per capita per month[2].
241 With only 76% of those surveyed reaching out for any help beyond friends and family (Panel
242 A, Table 4), it is important to calculate opportunity costs (time off work etc.). Panel C in Table

[2] GDP per capita for the Gambia in 2015 was USD 458.97 (World Bank, 2018). This is approximately 22948 dalasi. We divide that figure by 12 to approximate monthly income (1912).

4 reveals that 43 percent of households whose child had diarrhoea had gave up an amount of time or income from work. It is notable that for those households, the mean number of days lost was four working days.

Effectiveness of the intervention

The study found that the intervention significantly reduced reported childhood diarrhoeal episodes (defined as 3 watery stools in any day in the last 7 days as reported by mother) after six months (incident risk ratio =0.40, 95%CI 0.33, 0.49). This impact, albeit reduced in magnitude, persisted two years after the intervention (incident risk ratio = 0.68, 95%CI 0.46, 1.02) (22).

Cost-effectiveness of the intervention

Given the reduction in the prevalence of childhood diarrhoea in the intervention group, and the household costs associated with a child having an episode of diarrhoea, it was estimated that more than 47.26 dalasi was saved per diarrhoeal incident in a given one-week period in a treated village compared to a control village at six-month follow up and 24.76 dalasi at 36-month follow up (see Table 5). For the treatment group, it was estimated that 7571[3] dalasi (approximately equivalent to USD 151[4]) was saved six months after the intervention, and 3966 dalasi (approximately equivalent to USD 79) saved two years after the intervention.

In addition to the direct healthcare costs, a diarrhoeal episode meant that households also reduced income due to the need to care for the ill child by 3.08 dalasi per diarrhoeal incident at 6-month follow-up and 1.61 dalasi per diarrhoeal incident at the 36 month follow-up. Multiplying by the initial cases of diarrhoea in the treated villages at baseline, the opportunity

[3] Total savings from illness = Population illness in the treated villages at baseline x decrease of prevalence of illness x average cost. Approximately 160 households have a child who has experienced diarrhoea in the past 7 days at baseline (no. of households for treated villages times by average childhood diarrhoea prevalence at baseline)

[4] Used Dalasi-USD exchange rate: 0.02

cost saved for the intervention group is 493 dalasi six months after the intervention, and 258 dalasi two years after the intervention. The total cost incurred by a household due to a child having diarrhoea is the sum of direct cost (healthcare costs) and income lost. The intervention led to total savings of 8064 dalasi six months after the intervention, and 4224 dalasi two years after the intervention.

The Markov model was used to estimate the overall cost-effectiveness of the intervention from a societal perspective over a 4 year time horizon. Based on the model results, if the intervention is successful in maintaining the reduction in the risk of diarrhoea (to the level found two years after the intervention), the ICER is US$814 per DALY avoided, or US$30,786 per diarrhoeal death averted. According to the WHO CHOICE guideline, this is cost effective, since it is substantially below 3xGDP per capita (26).

The probabilistic sensitivity analysis conducted (Figure 2) indicates that taking into account statistical uncertainty, that both the cost difference and the effect difference is likely to be statistically significant as there are an appreciable number of points clustered around the point estimate. This is confirmed by the cost-effectiveness acceptability curve (Figure 3) which shows that almost 80% of replications would be considered cost-effective as they cost less than three times average per capita income per DALY averted.

Discussion

The study found that the community-based weaning-food safety and hygiene programme intervention is likely to be cost-saving for households over the shorter and longer term, and cost-effective from a societal perspective. Substantial savings for households were demonstrated, associated with the reduction in healthcare costs due to the reduction in the prevalence of diarrhoea. In addition, savings were identified due to the reduced need to take time off work to care for an infected child. From a societal perspective, the intervention was

found to be very cost-effective according to the WHO CHOICE guidelines, as it was substantially below 3xGDP per capita.

The strength of this study is that detailed and comprehensive data on costs and resource use were collected which can inform similar interventions in this area and enable comparisons with other research findings. This is the first study to use survey data from The Gambia to estimate the costs associated with a child having an episode of diarrhoea, in terms of both healthcare costs and wider costs for the family. In addition, a societal perspective was adopted to ensure that costs and consequences were captured comprehensively (in line with recommendations). In addition to trial data, a Markov model was used to estimate longer term impacts.

There are a number of limitations associated with the study. The first is the short time horizon adopted for the modelling component, which almost certainly under-estimates the cost-effectiveness of the intervention, since the deaths averted occur in young children, who potentially have many years left to live. In addition, improved food safety and hygiene are associated with other health benefits, such as reduced respiratory infections, which have not been taken into account in this study. The trial data at 6 months found a statistically reduced imbalance of respiratory infection in the intervention arm. Additionally, while the focus is on weaning food and therefore on children between 12 months and 5 years old, better adherence to food hygiene protocol is likely to have 'spillovers' to other members of the household, including older children and adults as mothers were found to have significantly improved their food safety and hygiene practices for preparation of all family's food. Again, this will result in the estimate of cost-effectiveness being an under-estimate of the true value (22). Other spill-over effects included improved self-efficacy on the part of the mothers and social cohesion and support amongst community members which are not accounted for here.

The simple model presented here does not accurately account for changes in diarrhoea risk resulting from accumulated immunity from previous infections (31); a much more complicated model structure would be required to take this fully into account (28).

The findings from this study contribute to wider evidence on the cost-effectiveness of interventions to improve food safety and hygiene. A recent study suggested that mass-media campaigns to promote healthy behaviours such as hygiene practices and taking ill children to a health facility was cost-effective. Similarly, an intervention to promote hygiene practices in Burkino Faso was found to be successful in reducing diarrhoeal disease incidence and cost-effective from a societal perspective. As there is very little economic evidence about sanitation and hygiene and none for household food safety and hygiene programmes (13), this study provides important information about the household costs associated with diarrhoeal episodes in children and the potential cost-effectiveness of a community-based approach to improving weaning food hygiene and safety.

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