Effect of city-wide sanitation programme on reduction in rate of childhood diarrhoea in northeast Brazil: assessment by two cohort studies

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Summary

Background A city-wide sanitation intervention was started in Salvador, Brazil, in 1997 to improve sewerage coverage from 26% of households to 80%. Our aim was to investigate the epidemiological effect of this city-wide sanitation programme on diarrhoea morbidity in children less than 3 years of age.

Methods The investigation was composed of two longitudinal studies done in 1997–98 before the intervention (the sanitation programme) and in 2003–04 after the intervention had been completed. Each study consisted of a cohort of children (841 in the preintervention study and 1007 in the postintervention study; age 0–36 months at baseline) who were followed up for a maximum of 8 months. Children were sampled from 24 sentinel areas that were randomly chosen to represent the range of environmental conditions in the study site. At the start of each study an individual or household questionnaire was applied by trained fieldworkers; an environmental survey was done in each area before and after introduction of the sanitation programme to assess basic neighbourhood and household sanitation conditions. Daily diarrhoea data were obtained during home visits twice per week. The effect of the intervention was estimated by a hierarchical modelling approach fitting a sequence of multivariate regression models.

Findings Diarrhoea prevalence fell by 21% (95% CI 18–25%)—from 9·2 (9·0–9·5) days per child-year before the intervention to 7·3 (7·0–7·5) days per child-year afterwards. After adjustment for baseline sewerage coverage and potential confounding variables, we estimated an overall prevalence reduction of 22% (19–26%).

Interpretation Our results show that urban sanitation is a highly effective health measure that can no longer be ignored, and they provide a timely support for the launch of 2008 as the International Year of Sanitation.

Introduction

The importance of adequate water supply and sanitation in the prevention of diarrhoeal diseases and other infections, and of their contribution to poverty eradication, was recognised by the international community when coverage targets for both were included in the Millennium Development Goals (MDGs). Sanitation seems to be just as effective as a public health measure as is an adequate water supply; and the promotion of sanitation plus hygiene has emerged as one of the most cost-effective interventions against high-burden diseases in developing countries. Although the MDGs' target for water supply is likely to be met, the target for sanitation is unlikely to be achieved because the resources allocated to it are small. Meanwhile, diarrhoea and intestinal parasites continue to exact a heavy toll in developing countries. Part of the reason for this neglect of sanitation is the absence of rigorous evidence for its effectiveness in prevention of disease. In a meta-analysis, most studies were observational and therefore subject to serious confounding, and there are only a few intervention studies, but these have been done on a scale of one or a few small communities.

Large-scale sanitation programmes are complex interventions, and their epidemiological assessment is a challenge. Such interventions directly affect the transmission of several diseases in both the public and domestic domains. Sanitation programmes also have indirect effects that are mediated by ancillary components of the intervention and by changes in behaviour in response to it. Sanitation interventions take years to implement and generally cannot be randomised, and therefore can be subject to confounding. Several factors should be present for the intervention to be successful; at the very least, public investment in sewerage must be matched by individual households’ willingness to invest in a toilet and connect it to the network.

We know of no study of the health effects of a sanitation intervention done throughout a large city. Such a study is rendered more necessary by the failure of worldwide diarrhoea morbidity rates to decrease over past decades, despite the long-term tendency for water supply and, to some extent, sanitation coverage rates to improve. We therefore undertook an epidemiological study to quantify the effect of a sanitation programme implemented throughout the city of Salvador (population 2·5 million) on diarrhoea morbidity in very young children.

Methods

Study population We undertook two longitudinal studies, each consisting of a cohort of children aged 0–36 months at baseline. The
households investigated were randomly selected from 24 sentinel areas. These areas were selected from 111 small areas (each one consisted of one or more census tracts) by use of stratified random sampling to represent the poor unsewered part of the city, which, before introduction of the sanitation programme in 1997 (the intervention), represented about 75% of the population. Each sentinel area represented about 600 households. A sample of households with children aged 0–36 months was randomly selected from a census of each sentinel area and only one eligible child per household was randomly enrolled in the investigation.

Ethical approval was granted by the Research Ethics Committee, Instituto de Saúde Coletiva, Universidade Federal da Bahia, Salvador, Brazil. Written informed consent was obtained from the guardians of the children included in the study.

The preintervention study enrolled 944 children, beginning in December, 1997; the children were followed up for up to 15 months (until April, 1999). The postintervention study began in October, 2003, and enrolled 1127 children with a follow-up of up to 8 months (until May, 2004). Precipitation was very similar in the two study periods; average monthly rainfall was 137.6 mm in the first cohort compared with 138.1 mm in the second cohort. For the analysis, we selected children from these two studies with a minimum follow-up time of 90 days to increase the probability of recording at least one diarrhoea episode. For children of the preintervention cohort we considered only the first 8 months of the individual’s follow-up to achieve a similar distribution of follow-up time. The resulting final study population consisted of 841 children before the intervention (mean age at entry 20.1 [SD 9.6] months, median follow-up 243 [IQR 243–243] days) and 1007 children after the intervention (18.2 [9.8] months, 196 [173–213] days). Table 1 shows the other characteristics of the two study populations. Socioeconomic and environmental variables did not differ between children omitted from the study populations and those who were included in the analysis (data not shown).

### Intervention

Before the intervention, about 26% of households were linked to a safe sewer system, whereas the others used either sanitary alternatives (such as septic tanks) or insanitary methods (such as discharging their sewage into the street). In general, sewers served only the upper-socioeconomic and middle-socioeconomic areas that were situated in the oldest part of the city. The original objective of the sanitation project, known as Bahia Azul or Blue Bay, was the control of marine pollution, which was largely caused by the discharge of domestic waste water. The objective of the project was to increase the population with an adequate sewer system from 26% to 80%. About half the total budget of US$440 million, mainly financed by a loan from the Inter-American Development Bank, was earmarked for extending the sewerage network of Salvador; other investments were made in water supply improvements, solid waste management, and institutional capacity building, and in ten smaller towns in the state. The construction work was done by 140 different construction firms, of which the largest contract amounted to 20% of the total budget. In Salvador, construction included the laying of more than 2000 km of sewer pipes, building 86 pumping stations, and connection of more than 300000 households to the sewerage network during 8 years (from 1996 to 2004). In the first years of the project, the heavy engineering work (such as laying sewer pipes and building pumping stations) predominated, whereas most of the household connections were made in the later years of the project and almost none before the end of our first cohort study.

Sanitation projects in developing countries are generally linked to hygiene promotion campaigns, which raises the question of whether any effect on diarrhoea is attributable to the hardware or to the improved hygiene behaviour. In the Bahia Azul programme, $3 million, or roughly 1% of the total budget, was spent on a public education campaign that focused on promotion of sewerage connections and on conscientious use of the system, rather than on domestic hygiene promotion.

### Study design

The sampling and study design have been described elsewhere. Longitudinal prevalence of diarrhoea, which is not the same as a period prevalence, but is the number of days with diarrhoea divided by the number of days followed up, was used as the outcome measure to assess

| Characteristics | Before intervention (n=841) | After intervention (n=1007) |
|-----------------|-----------------------------|-----------------------------|
| Indoor toilet   | 677 (80.5%; 77.7–83.1%)     | 875 (86.9%; 84.6–88.9%)    |
| Adequate house excreta disposal* | 471 (56.0%; 52.6–59.4%) | 887 (88.1%; 85.9–90.0%) |
| No open sewage nearby† | 477 (56.7%; 53.3–60.1%) | 799 (79.3%; 76.7–81.8%) |
| Piped water in house | 735 (87.4%; 85.0–89.6%) | 885 (87.9%; 85.7–89.8%) |
| House with regular water supply§ | 341 (40.6%; 37.2–43.9%) | 493 (49.0%; 45.8–52.1%) |
| House with good refuse collection¶ | 603 (71.7%; 68.5–74.7%) | 911 (90.5%; 88.5–92.2%) |
| House served by paved road | 402 (47.8%; 44.4–51.2%) | 610 (60.6%; 57.5–63.6%) |
| Good hygienic behaviour|| 194 (23.1%; 20.3–26.1%)  |
| Satisfactory neighbourhood drainage system|| 299 (29.7%; 26.9–32.6%) |
| Indoor toilet   | 677 (80.5%; 77.7–83.1%)     | 875 (86.9%; 84.6–88.9%)    |
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Data are n (%; 95% CI)—exact binomial 95% CI. *Sewer or septic tank. †Within 30 m of house. ‡24 h water supply. §Daily or every other day collection. ¶Strina and colleagues. ||Contextual variables.

Table 1: Distribution of mediating variables that were assessed before (1997) and after (2003) the intervention in the 24 sentinel areas in Salvador, Brazil.
Articles

Figure 1: Conceptual model to investigate the effect of the Bahia Azul sanitation programme on childhood diarrhoea

the effect of the sanitation programme. Longitudinal prevalence of diarrhoea is shown to be more closely associated than incidence with long-term health effects such as weight gain and mortality.13,14 Diarrhoea data were obtained by 15 fieldworkers who made two home visits per week. During each visit, the fieldworker questioned the mother or child’s carer about the number and consistency of bowel movements, the occurrence of additional symptoms (such as fever, vomiting, and blood in faeces) over the preceding 3–4 days. A day with diarrhoea was defined as the occurrence of at least three liquid or loose stools starting when the child woke up in the morning.13,16

At the beginning of both cohort studies, individual and household questionnaires were applied by fieldworkers to assess potential confounding child and household variables. These included socioeconomic status, living and sanitation conditions of the household, and child-related variables (birthweight and breastfeeding). Anthropometric measurements of nutritional status were done at baseline, and height-for-age Z scores were calculated by use of the EPINUT programme (version 6.0). Missing data, although rare, were generated by imputation of the mean for quantitative variables and the mode for categorical ones. The fieldworkers were also trained to check a list of 23 forms of hygienic or unhygienic behaviour by the child or the child’s carer during two visits every week. On the basis of this information, a composite hygiene behaviour score was calculated for each child. Details of the hygiene behaviour observations are reported elsewhere.4

Contextual variables for the sentinel areas were identified on the basis of environmental surveys that were done in 199720 and 2004. These surveys used similar methodologies and their unit of sampling was the 100 m stretch of road running 50 m to either side of each sampled house. Some of the contextual variables were also used as potentially mediating variables in the present analysis.

Statistical analysis

A hierarchical modelling strategy based on a conceptual model (figure 1) was used to assess the effect of the Bahia Azul sanitation programme (the intervention). The model we implemented was hierarchical in two different ways. On the one hand, we used a hierarchical conceptual framework which assumed that the intervention mediates its effect on the outcome (diarrhoea prevalence) by changing the distribution of mediating variables such as neighbourhood infrastructure (increasing sewerage coverage and improvements in other environmental variables), household living conditions, and hygiene behaviour. On the other hand, we used a hierarchical multilevel modelling strategy that introduced a random effect to address potential clustering by sentinel areas. Furthermore, our model addressed potential confounding by variables that were assumed to be independent of the intervention such as age, sex, and socioeconomic status. Mixed-effects Poisson regression analysis was used to obtain multivariate prevalence ratios (before vs after intervention). Adjustment for child-specific, household-specific, and sentinel area-specific variables was done by including the variables as fixed effects in the model together with a gamma-distributed random effect to account for the clustering by sentinel areas.

The assessment was done in several steps. First, we obtained estimates of the overall effects of the intervention by calculating prevalence ratios, which were adjusted for variables that were assumed to be unrelated to the intervention (model A). Estimates of overall effects were also stratified by sentinel area. Meta-analysis techniques (ie, forest plots) were used to examine effect heterogeneity caused by area-specific variables (eg, baseline diarrhoea risk or sewerage coverage).20 Second, we implemented a hierarchical effect decomposition strategy to examine which variables mediated the effect of the intervention. Different models were used to fit the different blocks of variables. Model B, which included variables that we assumed to be directly related to the intervention (indoor toilet, excreta disposal, presence of open sewage nearby), sought to assess the effect mediated by the direct consequences of the main intervention. Model C included mediating variables and sought to measure ancillary changes in environmental infrastructure such as water supply, frequency of refuse collection, and drainage. We did not include intestinal parasites as mediating variables because a previous study in the same sentinel areas had shown parasites to have a negligible effect on diarrhoea risk. Model D included the hygiene behaviour score and
sought to estimate the effect that was not mediated by changes in hygiene behaviour. Finally, we fitted model E, which included the coverage of each area with the new sewer system.

For each model, we calculated the mediating proportion (MP), which is equal to

\[
\frac{(PR_{\text{adj}} - PR_{\text{unadj}})}{1 - PR_{\text{unadj}}} \times 100
\]

where PR_{unadj} and PR_{adj} are the crude and adjusted prevalence ratios, respectively—ie, the risk reduction accounted for by the variables in the model. Hierarchical effect decomposition was measured for the whole population and, to take account of the effect heterogeneity that we noted, stratified by baseline diarrhoea risk (ie, 12 areas with highest-baseline and 12 with lowest-baseline prevalence of diarrhoea were separately assessed). All statistical analyses were done by use of the statistical software package STATA (version 9.0).

Role of the funding source

The sponsors of the study had no role in study design, data collection, data analysis, data interpretation, decision to submit for publication, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Examination of the distribution of mediating variables before and after the intervention (table 1) showed a highly increased coverage with sewers and an improved neighbourhood environment, infrastructure (eg, no open sewage nearby and improved frequency of refuse collection), and household conditions (eg, excreta disposal) after introduction of the sanitation programme. Improvement in sewerage coverage was not uniform between high-risk and low-risk diarrhoea areas. The Bahia Azul programme improved the neighbourhood sewerage coverage from 0% in 1997 to more than 50% in 89% of the low-risk areas and 55% of the high-risk areas in 2004 (data not shown).

Stratified analysis by sentinel area showed that the effect of the intervention varied widely; unadjusted prevalence ratios ranged from 0.15 to 3.02. A forest plot with sentinel areas ordered by diarrhoea prevalence before the intervention in 1997 (figure 2) showed that the effect of the intervention increased (ie, prevalence ratio decreased) with diarrhoea prevalence at baseline. On the basis of this finding, we divided the sentinel areas into two equal groups (high-baseline and low-baseline risk) and the cutoff was 8 diarrhoea days per year. Only three of 12 areas with low prevalence before the intervention showed a significant reduction, whereas seven of 12 in the high-risk group did so.

Regression models A–E estimated the overall effect of the intervention in total and separately for high-

![Figure 2: Forest plot visualising the overall effect* of the intervention by sentinel area](image-url)
baseline-risk and low-baseline-risk sentinel areas (table 2). Overall, diarrhoea prevalence fell by 21% (95% CI 18–25%)—from 9·2 (9·0–9·5) days per child-year before the intervention to 7·3 (7·0–7·5) days per child-year afterwards. After adjustment for baseline sewerage coverage and potential confounding variables, we estimated a prevalence reduction of 22% (19–26%) (model A). Stratified analysis showed that the intervention was highly effective in high-risk areas where diarrhoea prevalence fell by 43% (46%–39%), whereas children in areas with low-baseline prevalence did not benefit from the intervention (prevalence ratio 1·20, 95% CI 1·11–1·29, data not shown).

Adjustment for changes in mediating variables from the conceptual model changed the prevalence ratios only slightly with models B, C, and D (table 2). Overall, sanitation-related variables explained 17%, other environmental variables 11%, and hygiene behaviour none at all of the risk reduction. By contrast, the risk reduction achieved (overall and in high-risk areas) could be completely explained by changes in sewerage coverage by use of model E.

Discussion

We have shown that, after adjustment for confounders, the implementation of the sanitation programme was accompanied by a reduction of 22% in the longitudinal prevalence of diarrhoea in the population of the city as a whole, and 43% in the areas where the baseline prevalence of diarrhoea was highest. Multivariate modelling of the reduction, both for the high-prevalence areas and for the city as a whole, showed that the reduction could be fully explained by the increase in coverage of each area with the programme’s sewer system. We used a large set of individual and ecological potential confounders and advanced statistical modelling to show the effect of improvements in basic sanitation on the population’s health on the scale of an entire city.

By contrast Sastry and Burgard,20 on the basis of data from the Demographic and Health Surveys, reported that diarrhoea prevalence did not diminish significantly in northeast Brazil from 1986–96, and that by 1996 “there was no statistically significant benefit associated with having a flush toilet”. In our investigation, a major sanitation intervention came between the two rounds of data collection, and diarrhoea data were obtained by frequent home visits rather than 2-week recall. Moreover, flush toilets are often installed in Brazil without any connection to a sanitary sewer; such toilets could benefit the domestic domain of the owner, but they also increase the faecal contamination of the public domain—the faecal domain of the owner. We also noted that an indoor toilet did not explain the reduction in diarrhoea (model B); however, the explanation for the reduction was that the neighbourhood coverage with the sewerage system reduced the faecal pollution of the public domain.

We cannot exclude the possibility that some of the heterogeneity in reductions in diarrhoea prevalence between sentinel areas with high-baseline and low-baseline prevalences results from regression to the mean, but a greater reduction was to be expected in the high-risk areas than the low-risk ones if their high initial prevalence was caused by worse faecal contamination, which is what was seen. Moreover, the significant reduction that was recorded for the city as a whole cannot be explained by this occurrence.

No major importance can be attached to the prevalence ratios of individual sentinel areas, even when the CIs (figure 2) do not include unity. Episodes of diarrhoea in only one neighbourhood are not statistically independent events, and to draw conclusions from the prevalence ratio of one sentinel area would be equivalent to a one-to-one comparison.21 In analysis of the dataset as a whole, we have allowed for clustering by area.

Admittedly, we did not study the same population of children before and after the intervention. Since age is a

| Model                      | PR, unadjusted | 95% CI | MPH | PR, unadjusted | 95% CI | MPH |
|---------------------------|----------------|--------|-----|----------------|--------|-----|
| PR, unadjusted            | 0·79           | 0·75–0·82 |     | 0·58           | 0·55–0·61 |     |
| Model A: PR adjusted for baseline sewerage coverage and potential confounders§ | 0·78 | 0·74–0·81 |     | 0·57 | 0·54–0·61 |     |
| Model B: PR adjusted for variables of model A and indoor toilet, open sewage nearby, and household excreta disposal | 0·81 | 0·78–0·85 | 16·7% | 0·57 | 0·55–0·62 | 0·0% |
| Model C: PR adjusted for variables of model A and water supply, refuse collection, paving of the road, and satisfactory drainage system | 0·80 | 0·76–0·84 | 10·8% | 0·59 | 0·56–0·63 | 4·4% |
| Model D: PR adjusted for variables of model A and hygiene behaviour | 0·76 | 0·72–0·79 | 0·0% | 0·57 | 0·54–0·61 | 0·2% |
| Model E: PR adjusted for variables of model A and coverage of Bahia Azul sewerage | 1·01 | 0·89–1·15 | 100·0% | 1·02 | 0·90–1·16 | 100·0% |

PR=prevalence ratio. MPH=mediating proportion. Results of the hierarchical effect decomposition are presented as crude and adjusted prevalence ratios. *24 areas, 1848 children, median baseline diarrhoea 4·5 days per child-year. †>8 diarrhoea days per child-year; 12 areas, 878 children, median baseline diarrhoea 6·0 days per child-year. §MP: risk reduction explained by changes in the mediating variables included in the model (MP=(PRunadj−PRadj)/(1−PRunadj)×100; PRunadj and PRadj are the crude and adjusted prevalence ratios, respectively). |Child’s mean age during the follow-up, birthweight <2·5 kg, exclusive breastfeeding till <6 months old, and height-for-age <−1 Z score, mother’s age at child’s birth <20 years, marital status (not married) and education (no schooling or ≤8th grade, or 5th to 8th grade, >8th grade, or higher education), housing type (shack) and floor (dirt floor), no independent kitchen.

Table 2: Prevalence ratios of diarrhoea (after vs before intervention) obtained by different regression models

Prevalence ratios of diarrhoea (after vs before intervention) obtained by different regression models.
major determinant of diarrhoea, there would have been little point in doing so. The two cohorts of children were similar, though not identical, but the differences between them, such as age, were treated as confounders in our models. We tested for interaction with calendar time by analysing the data for the two cohorts separately (data not shown) and noted that the same factors were associated with diarrhoea prevalence, with similar strength, in the two cohorts. This finding led us to consider a single model for both cohorts in our conceptual framework.

The mean duration of follow-up was slightly shorter for the second cohort, which does not explain the reduction in diarrhoea prevalence. Diarrhoea prevalence reported in longitudinal studies tends to decrease gradually with time as the novelty wears off and respondent fatigue sets in.22 Other things being equal, therefore, a short follow-up would usually be associated with a high prevalence, in which case the real effect of the sanitation programme would be even greater than our data suggest.

In our investigation, we were not in control of the intervention and the study was not randomised. Although conceptually possible, random allocation of the areas to the intervention might not be politically or ethically acceptable and also not feasible in the assessment of a complex intervention—ie, a sanitation programme in a large urban city.23 However, the study design went beyond a pair of longitudinal studies, because it followed a strategy designed to compare the degree of sanitation intervention in each of 24 sentinel areas with the associated change in diarrhoea prevalence. We used sentinel areas instead of a scattered sample to account for the neighbourhood effect or externalities23 of sanitation. The conceptual model was a preliminary effort to deal with the complexity of the intervention (figure 1). Two cohort studies were done to estimate, with great precision, the outcome—ie, longitudinal prevalence of diarrhoea.

A large range of individual and area-based variables that covered different aspects of urban life were systematically obtained before and after the intervention to account for the complexity of potential confounding and mediating variables in the context of a large urban centre. Variables that were independent of the intervention, but could bias the relation between the intervention and the outcomes, were deemed confounding. Variables that we expected to be chiefly related to the main intervention studied, but which could also be changed independently of it, were deemed mediating variables. Information based on questionnaires, structured observation, and environmental surveys27 that were done in accordance with a standard design and by the same staff in two different periods was used to define individual and contextual variables; this approach required substantial effort to overcome the absence of randomisation.

Household-based mediating variables partly explained the heterogeneity of the effect of the programme; sanitation-related variables explained 17%, other environmental variables 11%, and hygiene behaviour none at all. Rather, the key explanatory variable—coverage of each sentinel area with connections to the programme’s sewers—related to the neighbourhood as a whole. This finding provides support for our study design that was based on sentinel areas and on our use of ecological variables. More importantly, the implication is that diarrhoea transmission prevented by the programme was mainly in the public (as opposed to the domestic) domain, in which household risk factors are of little importance.9

The overall reduction in diarrhoea by 22%, and 43% in the high-baseline-risk areas, is comparable with the reductions of 36% and 32% (95% CI 13%–47%), respectively, seen in two previous reviews of the effect of sanitation.17 The overall reduction is remarkable because the intervention studies in those previous reviews were really efficacy trials done in a few communities, whereas our study can properly be called an assessment of effectiveness at a vastly greater scale. The reduction we reported is less than that seen on a smaller scale in Salvador 20 years ago.21

The effect of the city-wide sanitation programme is likely to have been more equitable than it might seem at first because the areas of high baseline risk are also the areas of the city with poorest sanitary conditions.27 Concerns had been voiced locally that the proportion of households requesting sewer connections was lower in the poorer areas of the city than in the richer areas. The Bahia State Government Audit Commission commented that a public education campaign “lacked the strength and continuity needed to have an effect on connection rates”.28 The campaign can also be presumed to have had little effect on hygiene behaviour. After controlling for socioeconomic confounders (model A), we identified no evidence that poverty had significantly blunted the effect of the programme on diarrhoea. Nevertheless, we believe that if improved coverage with sewer connections had been achieved in the high-risk areas, the programme would have resulted in a greater effect than we recorded. Our findings contradict those who claim that, “there appears to be little prospect of further reducing diarrhoea morbidity rates by investing further in sanitation”29 and provide a timely support for the launch of 2008 as the International Year of Sanitation. Sanitation contributes to many of the MDGs, but our results show that urban sanitation, as a highly effective health measure, can no longer be ignored.2

Unusually among preventive health interventions, sanitation is mainly paid for by the consumer. However, there are limits to what can be achieved by individual households alone, especially when what is mainly needed is not household toilets (in Salvador, 80% of households already have one), but sewers. Because sewerage is mainly external to houses and the fact that it prevents disease transmission in the public domain, public responsibility
is to ensure that sewerage is installed. At a typical cost per person of $160,$17 investment in sewerage is too large to be left to cash-strapped municipalities, and needs the involvement of international organisations, and central government and its agencies. The health sector is not generally an investor, but it nevertheless has a key part to play, through promotion, advocacy, and regulation, to ensure that toilets and sewers are properly built, used, and maintained, so that their full health benefits are realised by all.

Contributors
MLB, MGT, AMOA, and AS were involved in the study design. MLB, AS, MSP, RFR, SMAM, and DNS were involved in data collection. BG led the statistical analysis. MLB, SC, RFR, AS, CAT, MSP, SMAM, DNS, and LAS were involved in data analysis. All investigators contributed to data interpretation and writing the report. All investigators had access to all data in the study and held final responsibility for the decision to submit for publication.

Conflict of interest statement
We declare that we have no conflict of interest.

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