

The impact of a novel franchise clinic network on access to medicines and vaccinations in Kenya: a cross-sectional study

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ABSTRACT

Objectives: To study the impact of a new franchise health clinic model (The HealthStore Foundation's CFWSHops) on access to vaccinations and treatment for acute illnesses in a nationally representative sample of children in Kenya.

Design: The authors used multivariate linear and count regressions to examine associations between receipt of vaccinations or treatment and proximity to a franchise health clinic, adjusting for individual, household and clinic attributes as well as region fixed effects.

Setting: Demographic and Health Survey data from Kenya, 2008–2009.

Participants: 6079 Kenyan children younger than 5 years, of whom 2310 reported recent acute illness.

Main outcome measures: Outcomes for all children were number of polio doses received, number of DPT doses received, receipt of BCG vaccine, receipt of measles vaccine and number of total vaccinations received. Outcomes for acutely ill children were receipt of any medical treatment, treatment for fever, treatment for malaria and treatments specifically stocked by CFWSHops.

Results: Children living within 30 km of a CFWSHops received 0.129 ($p=0.017$) and 0.113 ($p=0.025$) more DPT and polio doses, respectively; and 0.285 more total vaccinations ($p=0.023$). Among acutely ill children, CFWSHops proximity was associated with significant increases in the probabilities of receiving any medical treatment (0.142; $p<0.001$), treatment for fever (0.117; $p=0.007$) and treatments specifically stocked by CFWSHops (0.064; $p=0.015$). Use of CFWSHops services was not significantly different for lower-income vis-a-vis higher-income households.

Conclusions: The franchise health clinic model could substantially increase access to essential vaccinations and treatments in low-income countries. Moreover, the model's benefits may accrue to lesser- and higher-income households alike.

ARTICLE SUMMARY

Article focus

- Can franchised health clinics improve access to essential medicines and vaccinations among children?
- Do the benefits of this social enterprise only accrue to individuals who are relatively less poor?

Key messages

- Our study is the first to demonstrate empirically that proximity to franchised health clinics is associated with increased take-up of vaccinations and treatment for acute illnesses.
- The positive relationship between proximity to CFWSHops and healthcare access is equally strong for high- and low-wealth households alike.
- The franchise clinic model has the potential to fill an important gap in health service delivery in low-income countries by delivering care in remote areas and exploiting returns to standardisation and economies of scale.

Strengths and limitations of this study

- Geocode data on franchise clinic location enable us to identify impacts on a large nationally representative sample of children in Kenya.
- The major limitation in this study is the endogenous placement of CFWSHops. In future studies, CFWSHops should be phased in at randomly chosen locations (from a suitable set of locations).

INTRODUCTION

The populations of many low-income countries still lack adequate access to essential medicines and preventive health technologies.¹ Where treatments are available, they are often prohibitively expensive.² The most

¹For example, one survey across 36 low-income countries found that the availability of low-cost essential medicines at public sector medicine outlets ranged from 30% to 54%.¹

²A WHO survey across 40 countries found that the cost of generic drugs was, on average, 2.5 times the international market price.²

salient barriers to achieving adequate access are: an inadequate supply of medicines^{1 3 4}; unreliable or non-existent distribution systems^{5 6}; a lack of public healthcare infrastructure and staff, especially in remote areas^{7 8}; large price mark-ups from private providers^{2 6}; and the pervasiveness of counterfeit drugs.^{9–11} New healthcare delivery models designed to overcome these barriers have the potential to generate large public health gains.

Given that households in low-income countries use the informal healthcare sector for the majority of acute illness episodes,¹² private sector delivery models have received considerable recent interest.^{13 14} In this paper, we focus on one novel idea in this class of delivery models: the application of the franchise business model to healthcare delivery, leveraging the benefits of standardisation across a network of identical outlets. Standardisation, in theory, allows each outlet to offer consistently high-quality (non-counterfeit) drugs and lowers costs by exploiting economies of scale within the franchise. The franchise clinic model plays an increasingly important role in many low-income countries, usually through via small-scale non-governmental organisations and particularly among reproductive health clinics.^{3 15 16} Yet, despite its potential effectiveness and increasing prevalence in low-income contexts, no study, to our knowledge, has examined the impact of the franchise clinic model in terms of enabling better access to disease treatment and prevention. In this paper, we examine the impact of the HealthStore Foundation's (HSF) network of franchise health clinics in Kenya on households' access to treatment for acute illnesses and basic vaccinations.

The HSF has, since its inception in 2000, created a network of 83 nearly identical child and family wellness clinics in Kenya under the brand name 'CFWShops'. The HSF creates a blueprint for local nurses to own and operate CFWShops, by providing business training, preparing a physical location, conducting regular inspections to ensure compliance to business plans and providing assistance in ordering inventory and running marketing programmes. The majority of CFWShop franchisees are nurses with at least 4 years of training and 10 years of field experience (the equivalent of a nurse practitioner in the USA). These nurses own the CFWShop outlet and also operate the clinic and interact with patients. Each CFWShop provides diagnostic services, treatment options and drug dispensing for common illnesses, including malaria, parasites, respiratory infections, diarrhoea and bacterial infections. CFWShops also offer rapid HIV testing, vaccinations, antenatal care, general health counselling and a range of retail hygiene products (soap, water purification products and bed nets, among others).

We sought to evaluate the impact of CFWShops on healthcare delivery in Kenya. We analysed nationally representative household survey data to determine whether living within a CFWShop catchment area affects healthcare-seeking behaviours and receipt of treatments and vaccinations for children. We also examine whether poor households are able to equally reap the benefits of

CFWShop proximity since the argument is often made that private sector healthcare delivery models exclude these households.

METHODS

Data and measures

We use data from two sources: the 2008–2009 Kenya Demographic and Health Survey (DHS) and CFWShop data provided by the HSF. The Kenya DHS is a nationally representative household survey that includes information on household demographics, child vaccination history and health services utilisation, including data on care for recent acute illness episodes. We also obtained (randomly skewed) global positioning system coordinates for the location of each survey cluster, which we used to match households to CFWShop catchment areas.

The HSF provided the date of opening for all the 83 CFWShops currently in operation in Kenya. Of these 83, 24 have closed. Unfortunately, we do not have data on the date of closure; therefore, we exclude all clinics that are no longer in operation. Of the 59 remaining clinics currently in operation, 44 clinics opened before 1 January 2009 (ie, before DHS survey enumeration occurred). We defined catchment areas by drawing a 30 km radius around each of these 44 CFWShops. We then superimposed global positioning system coordinates for each DHS cluster on this map to determine which clusters fell within the catchment areas and which were outside. Note that under this mapping procedure, 14 CFWShops did not qualify as the nearest shop to any DHS cluster. Thus, in our analyses, we are effectively using treatment and comparison areas defined by 30 CFWShops. **Figure 1** summarises the CFWShop sampling procedure.

The main independent variable used in analysis is a binary indicator that equals 1 if the household lives

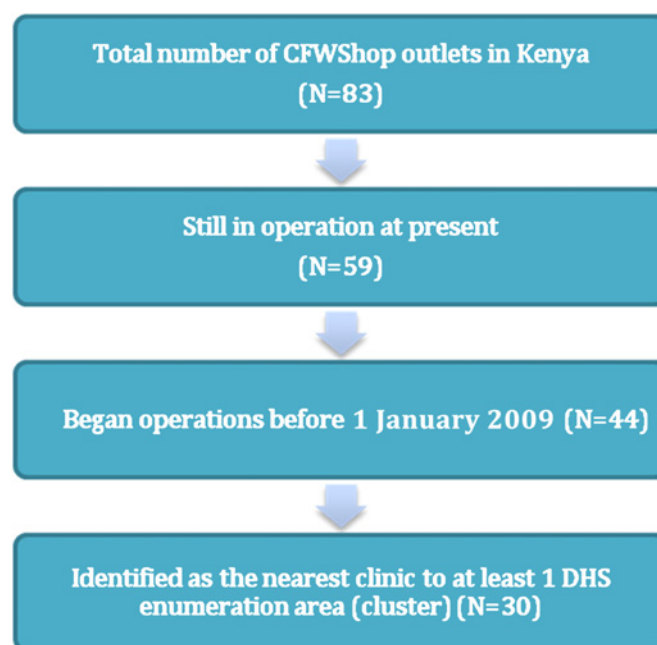


Figure 1 Sampling frame development. DHS, Demographic and Health Survey.

Table 1 DHS summary statistics by sample

| Variable | Whole sample | | | CFWShop sample | | | Comparison sample | | |
|---------------------------------------------------|--------------------------|---------|------------------------------|----------------|---------------------------------|-------|-------------------|---------|---------|
| | N | Mean | SD | N | Mean | SD | N | Mean | SD |
| Child age (0–4 years) | 5706 | 1.944 | 1.425 | 1619 | 1.929 | 1.408 | 4087 | 1.950 | 1.431 |
| Wealth index ^{1–5} | 6079 | 2.812 | 1.516 | 1751 | 3.556 | 1.420 | 4328 | 2.511 | 1.449 |
| Education index ^{1–5} | 6079 | 1.677 | 1.410 | 1751 | 2.310 | 1.411 | 4328 | 1.420 | 1.326 |
| Rural | 6079 | 0.759 | 0.428 | 1751 | 1.000 | 0.490 | 4328 | 0.823 | 0.382 |
| Child sex (1=male, 2=female) | 6079 | 1.484 | 0.500 | 1751 | 1.488 | 0.500 | 4328 | 1.483 | 0.500 |
| Sick | 6079 | 0.380 | 0.485 | 1751 | 0.488 | 0.488 | 4328 | 0.484 | 0.484 |
| Distance to nearest CFWShop (km) | 6079 | 148.209 | 254.600 | 1751 | 15.223 | 7.879 | 4328 | 202.010 | 284.563 |
| Vaccinations | | | | | | | | | |
| BCG | 5696 | 0.911 | 0.285 | 1618 | 0.943 | 0.234 | 4078 | 0.891 | 0.311 |
| Measles | 5680 | 0.698 | 0.459 | 1616 | 0.725 | 0.447 | 4064 | 0.678 | 0.467 |
| Total DPT | 5695 | 2.434 | 1.022 | 1617 | 2.573 | 0.897 | 4078 | 2.205 | 1.184 |
| Total polio | 5696 | 2.354 | 1.013 | 1617 | 2.461 | 0.912 | 4079 | 2.151 | 1.163 |
| Total vaccinations | 5657 | 6.398 | 2435 | 1612 | 6.702 | 2.142 | 4045 | 5.831 | 2.883 |
| Variable | Whole sample (N=2310) | | CFWShop sample (N=684) | | Comparison group (N=1626) | | | | |
| | Mean | SD | Mean | SD | Mean | SD | | | |
| Among the acutely ill | | | | | | | | | |
| Fever in past 2 weeks | 0.600 | 0.490 | 0.608 | 0.489 | 0.596 | 0.491 | | | |
| Cough in past 2 weeks | 1.300 | 0.954 | 1.294 | 0.956 | 1.303 | 0.953 | | | |
| Diarrhoea in past 2 weeks | 0.820 | 0.984 | 0.750 | 0.969 | 0.850 | 0.499 | | | |
| Received any treatment in past 2 weeks | 0.364 | 0.481 | 0.418 | 0.494 | 0.341 | 0.474 | | | |
| Received fever treatment in past 2 weeks | 0.293 | 0.455 | 0.354 | 0.478 | 0.268 | 0.443 | | | |
| Received malaria treatment in past 2 weeks | 0.148 | 0.356 | 0.183 | 0.387 | 0.134 | 0.341 | | | |
| Received CFWShop-stocked medicine in past 2 weeks | 0.058 | 0.235 | 0.069 | 0.253 | 0.054 | 0.226 | | | |

within a CFWShop catchment area, as defined above, and 0 otherwise. Twenty-nine per cent of observations fell within a CFWShop catchment area using the 30 km definition. We ran sensitivity tests in which catchment area radius varied from 10 to 50 km, at 5 km increments. We find qualitatively that the results do not change substantially; these results are available upon request.

We focus on the sample of children younger than 5 years, for whom vaccination histories, healthcare-seeking behaviours and treatments are recorded. The 2008–2009 Kenya DHS includes 6079 children aged 5 years or younger, of whom 2310 had self-reported symptoms of cough, fever and/or diarrhoea within 2 weeks prior to survey (the child's mother self-reports acute illness). Means and SDs of key variables used in analysis are reported in table 1.

The main outcomes used in this study pertain to vaccination histories and to the receipt of medical treatment for acute illness. We construct binary indicators for receipt of BCG and measles vaccines, and count variables for the number of total DPT vaccine doses (maximum 3), total polio vaccine doses (maximum 3) and total overall vaccinations received. These variables are constructed using data from the health card or, if health card data were missing, from the mother's self-report of vaccination history for her child. For treatment following an acute illness, we construct (separate) dummies for whether treatment was received for

fever, malaria and diarrhoea; a dummy for receipt of any treatment and a dummy for whether the child received a treatment that is stocked by CFWShops.

A number of explanatory variables, expected to be associated with health delivery outcomes, were chosen based on theory and related literature of similar topics.^{17–19} We included integer age fixed effects and a female dummy to ensure that health differences based on age and sex did not bias the estimated associations between CFWShop proximity and treatment or vaccination status. Mother's education level (five categorical dummies: no education, incomplete primary, complete primary, incomplete secondary, complete secondary and higher) and wealth index (derived from principal components analysis on DHS wealth indicator variables, stratified into quintiles) were used as measures of socioeconomic status, to ensure receipt of treatment results were not confounded by an ability to pay.ⁱⁱⁱ A full

ⁱⁱⁱDHS collects data on a range of household assets and utility services and then calculates an overall 'wealth index' using principal components analysis based on these variables. The DHS data include a variable that categorises each household into five quintiles of the wealth index distribution. Wealth index was used as an explanatory variable because national-level wealth indices have been shown to be the best predictor of maternal health services utilisation and a more reliable socioeconomic proxy than income or other quantitative socioeconomic status measure.²⁰

Table 2 Association between CFWSshop presence and receipt of vaccination

| Vaccinations | BCG | Measles | Total DPT | Total polio | Total vaccinations |
|-------------------------|-----------------|-----------------|-------------------|-------------------|--------------------|
| Regression type: | OLS | OLS | Negative binomial | Negative binomial | OLS |
| Variables | | | | | |
| CFWSshop (SE) | 0.0194 (0.0136) | 0.0233 (0.0180) | 0.0516* (0.0217) | 0.0467* (0.0208) | 0.285* (0.125) |
| p Value | 0.154 | 0.196 | 0.017 | 0.025 | 0.023 |
| N | 5690 | 5674 | 5689 | 5690 | 5651 |
| Dependent variable mean | 0.911 | 0.698 | 2.434 | 2.354 | 6.398 |

Robust SEs in parentheses (* $p < 0.05$). SEs are clustered at the household cluster level categorised by Demographic and Health Survey. All specifications include controls for age (as fixed effects) and gender of the child as well as wealth and education of the mother. Controls also include a dummy for whether the household is located in an urban area, a dummy variable for each district and region of the sample, the type of the nearest CFWSshop outlet (if within 30 km catchment area) and its age. OLS, ordinary least squares.

set of region dummies, as well as a rural/urban dummy, were used to control for spatial factors, such as the availability of health facilities and other unobserved time-invariant local factors that may influence the health of the local population. Given issues with recall of health history,²¹ a health card dummy variable (ie, a variable that equals 1 if the mother can produce the health card for the particular child at the time of interview) was included in all analyses to proxy for ability to recall correctly. Finally, two characteristics of the nearest CFWSshops were used: whether the CFWSshop was a shop or clinic, and the 'age' of the closest CFWSshop, a continuous variable based on date of outlet opening.

All regression analyses use clustered SEs, which allow for arbitrary correlation in the error terms within each DHS cluster, which was the primary sampling unit for the survey.

All analyses were performed using statistical software, V.11 (STATA).

RESULTS

Vaccinations

To determine the impact of CFWSshop proximity on the receipt of one-time vaccinations (BCG and measles), ordinary least squares regression was used.^{iv} To determine the impact of CFWSshop proximity on receipt of three-time vaccinations (polio and DPT), negative binomial regressions were used with the number (count) of vaccinations of each type received as the dependent variables. Finally, to determine the impact of CFWSshop proximity on total vaccinations received (out of eight recommended shots covered in the DHS survey), ordinary least squares regression was used.^v

^{iv}We chose to use linear probability models over binary-dependent variable models like probit and logit because linear probability models allow for easy interpretation of interaction effects, whereas the non-linear models do not. We have replicated the results using these non-linear models, and the magnitudes and significance of the coefficients are unchanged (results available upon request).

^vWhen number of total vaccinations is the dependent variable, we estimate OLS models rather than a count (negative binomial or Poisson) model because the range for the dependent variable is large enough to justify using OLS.

The results are reported in table 2. Children living within 30 km of a CFWSshop were not significantly more likely to receive the BCG vaccination or the measles vaccination. Proximity to a CFWSshop was associated an increase in the expected counts of DPT ($p = 0.017$) and polio ($p = 0.025$) vaccinations received.^{vi} Proximity to a CFWSshop was associated with receiving 0.285 more total vaccinations ($p = 0.023$) on average.

Treatment for acute illnesses

Next, we examined whether CFWSshop proximity was associated with greater access to treatment for acutely ill children. The results of these estimations are reported in table 3. Acutely ill children within 30 km of a CFWSshop were 14.2 percentage points more likely to receive some treatment for their illness ($p < 0.001$). This is a 39% increase above the dependent variable mean (0.364). Among children presenting with fever ($N = 1385$), when fever and malaria treatment were analysed separately, the coefficients were similar in sign and magnitude: 11.7 ($p = 0.007$) and 7.7 percentage points ($p = 0.061$), respectively. When we restrict attention to only those antimalarial treatments stocked by CFWSshops (artemisinin-based combination therapy and quinine), the estimated coefficient remains positive and significant (6.4 percentage points; $p < 0.05$). No statistically significant relationship was found between CFWSshop within 30 km and diarrhoea treatment received, but the coefficient is positive.

Impact of CFWSshops stratified by wealth index

We also examined whether poor households had less access to vaccinations and treatment for acute illnesses at CFWSshops. We ran interaction models, in which the coefficient of interest was on the interaction of CFWSshop proximity with a dummy for 'low-income' household, which is defined as households in wealth categories between 1 and 2, inclusive (non-poor households were those in wealth categories 3, 4 and 5).

^{vi}The coefficients on the catchment area dummy in the DPT and polio count regressions imply that CFWSshop proximity increases expected number of doses by approximately 0.187 and 0.162, respectively.

Table 3 Association between CFWSshop presence and receipt of treatment for acute illness

| Variables | Received any treatment | Received treatment for fever | Received treatment for malaria | Received CFW-stocked treatment | Received diarrhoea treatment |
|-------------------------|------------------------|------------------------------|--------------------------------|--------------------------------|------------------------------|
| CFWSshop (SE) | 0.142*** (0.0348) | 0.117*** (0.0434) | 0.0768* (0.0408) | 0.0642** (0.0263) | 0.0678 (0.0551) |
| p Value | <0.001 | 0.007 | 0.061 | 0.015 | 0.219 |
| N | 2310 | 1385 | 1385 | 1385 | 946 |
| Dependent variable mean | 0.364 | 0.406 | 0.225 | 0.0888 | 0.502 |

Robust SEs in parentheses (***p<0.01, **p<0.05, *p<0.1). SEs are clustered at the household cluster level categorised by Demographic and Health Survey. All specifications include controls for age (as fixed effects) and gender of the child as well as wealth and education of the mother. Controls also include a dummy for whether the household is located in an urban area, a dummy variable for each district and region of the sample, the type of the nearest CFWSshop outlet (if within 30 km catchment area) and its age.

The results are reported in tables 4 and 5. In table 4, we find that the coefficient estimate on the interaction of CFWSshop proximity with the 'low-income' household dummy is tightly bound around 0, while the main effect of CFWSshop proximity remains significantly positive. In table 5, we find that for all treatment receipt dummies except malaria treatment, the same pattern holds. The coefficient on the interaction between CFWSshop proximity and the 'low-income' dummy in the malaria treatment regression is, in fact, *positive* (0.135; p=0.064). Overall, these results find no support for the claim that access to medicines and vaccinations at franchise health clinics is differential across relatively higher- and lower-income households.

DISCUSSION

Principal findings

The franchise clinic model has the potential to fill an important gap in health service delivery in low-income countries by exploiting returns to standardisation and economies of scale. Similar models are increasingly prevalent in low-income countries, yet no study, to our knowledge, has examined the impact of franchise health clinics on access to medicines and preventive health technologies for target populations. We attempt to answer this question by combining nationally representative household survey data with data on HSF health clinics in Kenya. We find consistently positive and significant associations between proximity to CFWSshop and receipt of vaccinations and appropriate treatment

for illnesses, suggesting that the franchise clinic model may be a useful innovation in healthcare delivery where there is a dearth of access to essential medicines and preventive technologies. The magnitudes of the estimated coefficients are large.

Experts have warned that because profit maximisation is often a salient objective for private models of healthcare provision, these models may not be able to increase access—and ultimately improve public health outcomes—for the bottom of the income distribution. Instead, it is argued, private delivery models might engage in cream-skimming since market-based pricing would be affordable only to relatively non-poor households and would neglect the poorest populations.

We find—using empirical specifications that include interactions between CFWSshop proximity and relative wealth—that the benefits of CFWSshop proximity do not appear to accrue differentially to lower-income vis-a-vis higher-income households.

Strengths and limitations of the study

To our knowledge, this study is the first to empirically evaluate the impact of a new and potentially important healthcare delivery model—the franchise health clinic—on access to prevention and treatment for acute illness. Geocode data on franchise clinic location enables us to identify these impacts on a large nationally representative sample of children in Kenya.

This study has some limitations that should be addressed in future work. First, endogenous placement

Table 4 Heterogeneous effects of poverty—vaccinations

| Variables | BCG | Measles | Total DPT | Total polio | Total vaccination |
|-------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| CFWSshop (SE) | 0.0186 (0.0165) | 0.0302 (0.0197) | 0.0586** (0.0255) | 0.0598** (0.0239) | 0.338** (0.146) |
| Low income (SE) | 0.00263 (0.0218) | -0.0178 (0.0302) | -0.0236 (0.0330) | -0.0403 (0.0308) | -0.161 (0.185) |
| × CFWSshop | | | | | |
| Low income (SE) | -0.00158 (0.0109) | -0.0291* (0.0150) | -0.00324 (0.0181) | -0.00162 (0.0171) | -0.0510 (0.0977) |
| p Value | 0.904 | 0.556 | 0.475 | 0.191 | 0.385 |
| N | 5690 | 5674 | 5689 | 5690 | 5651 |
| Dependent variable mean | 0.911 | 0.698 | 2.434 | 2.354 | 6.398 |

Table 5 Heterogeneous effects of poverty—treatment

| Variables | Received any treatment | Received fever treatment | Received malaria treatment | Received CFW Shop-stocked treatment | Received diarrhoea treatment |
|-------------------------|------------------------|--------------------------|----------------------------|-------------------------------------|------------------------------|
| CFWShop (SE) | 0.115*** (0.0403) | 0.0852* (0.0497) | 0.0325 (0.0439) | 0.0709** (0.0329) | 0.110* (0.0596) |
| Low income (SE) | 0.0690 (0.0564) | 0.105 (0.0775) | 0.135** (0.0638) | −0.0154 (0.0453) | −0.109 (0.0882) |
| × CFWShop | | | | | |
| Low income (SE) | −0.0146 (0.0317) | 0.00165 (0.0462) | −0.0585 (0.0362) | −0.0198 (0.0241) | −0.0912* (0.0505) |
| p Value | 0.222 | 0.178 | 0.035 | 0.735 | 0.217 |
| N | 2310 | 1385 | 1385 | 1385 | 946 |
| Dependent variable mean | 0.364 | 0.406 | 0.225 | 0.0888 | 0.502 |

of CFWShops could bias the measurement of programme impact. Though we introduce a variety of key control variables to minimise this bias (including wealth index dummies, urban/rural dummies and, importantly, the full set of district fixed effects), some bias in the estimate may remain. CFWShops are placed based on a list of criteria on a 'Franchise Location Rating Form'. This form includes indicators such as population density, proximity to schools, proximity to other health facilities, disease load and household income. We attempt to control for proxies of each in our analysis to minimise any bias in CFWShop impact measurement. Despite these controls, the lack of randomisation of clinic placement remains a limitation in the study. Future work could include the design of a prospective study in which the spatial roll-out of CFWShops (or similar innovations) is randomised, and household surveys in treatment and control catchment areas are conducted to evaluate programme impact on access to prevention and care and on health outcomes. Second, the definition of CFWShop catchment area could be modified to take into account local topography, transportation infrastructure, population density and other factors that could influence access.

Conclusions and policy implications

A short list of illnesses—malaria, respiratory infections and diarrhoeal disease, among others—accounts for 70% of childhood deaths in developing countries. A shortage of existing public health infrastructure and human resources, particularly in remote areas, often prevents developing country governments from devoting the necessary attention to treating and preventing these diseases.

Since the results suggest that CFWShops are associated with increased access to prevention and care for children, future work should investigate what features of the delivery model might generate the most impact. CFWShops could potentially have success due to a variety of reasons: focus on remote regions, local ownership, standardisation, consistent quality assurance, brand equity and economies of scale. The results of a follow-up study that is able to isolate the separate impact of these various mechanisms would be useful in adapting the

franchise clinic model to maximally increase access to medications in low-income areas.

Overall, our results suggest that models similar to the one employed by the HSF could reap substantial returns in terms of increased access to prevention and care and improved public health outcomes, particularly for young children. Global health policymakers should continue to look towards innovative delivery models like the franchise health clinic model to improve cost-effectiveness and efficiency in treating the diseases that pose the greatest burden on children.

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Contributors Both authors (JB and AA) made substantial contributions to the conception, design, data acquisition and analysis of the study. Both authors contributed equally to the writing, revising and approval of the final version of the paper.

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Competing interests None.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cohort studies

| Section/Topic | Item # | Recommendation | Reported on page # |
|--------------------------|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Title and abstract | 1 | (a) Indicate the study's design with a commonly used term in the title or the abstract | 1 |
| | | (b) Provide in the abstract an informative and balanced summary of what was done and what was found | 2-3 |
| Introduction | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 4 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 4 |
| Methods | | | |
| Study design | 4 | Present key elements of study design early in the paper | 5 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 5 |
| Participants | 6 | (a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up | 5 |
| | | (b) For matched studies, give matching criteria and number of exposed and unexposed | |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | |
| Data sources/measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 5 |
| Bias | 9 | Describe any efforts to address potential sources of bias | 5-6 |
| Study size | 10 | Explain how the study size was arrived at | 5 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 5 |
| Statistical methods | 12 | (a) Describe all statistical methods, including those used to control for confounding | 5-6 |
| | | (b) Describe any methods used to examine subgroups and interactions | 5-6 |
| | | (c) Explain how missing data were addressed | |
| | | (d) If applicable, explain how loss to follow-up was addressed | |
| | | (e) Describe any sensitivity analyses | (Available on request) |

| | | | |
|--------------------------|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|
| Results | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 5 |
| | | (b) Give reasons for non-participation at each stage | 5 |
| | | (c) Consider use of a flow diagram | 9 |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 5-6 |
| | | (b) Indicate number of participants with missing data for each variable of interest | |
| | | (c) Summarise follow-up time (eg, average and total amount) | |
| Outcome data | 15* | Report numbers of outcome events or summary measures over time | 6-7 |
| Main results | 16 | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | 6-7 |
| | | (b) Report category boundaries when continuous variables were categorized | 6-7 |
| | | (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | |
| Discussion | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 7-8 |
| Limitations | | | |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 7-8 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 8 |
| Other information | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 2 |

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.