Effect of a multifaceted social franchising model on quality and coverage of maternal, newborn, and reproductive health-care services in Uttar Pradesh, India: a quasi-experimental study

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Summary

Background How to harness the private sector to improve population health in low-income and middle-income countries is heavily debated and one prominent strategy is social franchising. We aimed to evaluate whether the Matrika social franchising model—a multifaceted intervention that established a network of private providers and strengthened the skills of both public and private sector clinicians—could improve the quality and coverage of health services along the continuum of care for maternal, newborn, and reproductive health.

Methods We did a quasi-experimental study, which combined matching with difference-in-differences methods. We matched 60 intervention clusters (wards or villages) with a social franchisee to 120 comparison clusters in six districts of Uttar Pradesh, India. The intervention was implemented by two not-for-profit organisations from September, 2013, to May, 2016. We did two rounds (January, 2015, and May, 2016) of a household survey for women who had given birth up to 2 years previously. The primary outcome was the proportion of women who gave birth in a health-care facility. An additional 56 prespecified outcomes measured maternal health-care use, content of care, patient experience, and other dimensions of care. We organised conceptually similar outcomes into 14 families to create summary indices. We used multivariate difference-in-differences methods for the analyses and accounted for multiple inference.

Findings The introduction of Matrika was not significantly associated with the change in facility births (4 percentage points, 95% CI –1 to 9; p=0·100). Effects for any of the other individual outcomes or for any of the 14 summary indices were not significant. Evidence was weak for an increase of 0·13 SD (95% CI 0·00 to 0·27; p=0·053) in recommended delivery care practices.

Interpretation The Matrika social franchise model was not effective in improving the quality and coverage of maternal health services at the population level. Several key reasons identified for the absence of an effect potentially provide generalisable lessons for social franchising programmes elsewhere.

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Introduction

Over the past few decades, India's maternal mortality ratio has declined substantially from 437 deaths per 100 000 livebirths in 1992–93 to 167 deaths per 100 000 livebirths in 2011–13.[1,2] Despite these improvements, maternal health still requires urgent attention. India is the second largest contributor to the global burden of maternal deaths, accounting for 15% of all maternal deaths.[3] Maternal mortality remains high in Uttar Pradesh, India's most populous state, with the most recent estimate of maternal mortality at 285 deaths per 100 000 livebirths.[2] The Indian Government has had some success in increasing facility births.[4] However, concerns about quality of care and the capacity of the public sector to meet the increased demand for institutional deliveries need to be addressed.[5] Whether the private sector can be harnessed to improve health is at the forefront of ongoing debates in India and internationally.[6,7]

India's private health-care sector is extensive and diverse. It ranges from sophisticated tertiary hospitals, which provide medical care of an international standard, to unqualified rural health-care providers and alternative systems of medicine. Most registered doctors work in the private sector, which is often the first point of contact for a substantial proportion of the population.[8–10] Evidence on the most effective strategies to improve the quality of private sector services remains scarce.[7,11,12] Regulation of the private sector in India has proved challenging and alternative strategies that encourage private providers to raise standards are required.

One prominent strategy is social franchising, an organisational model that applies the principles of commercial franchising for socially beneficial ends. Social franchises

Research in context

Evidence before this study

We identified four systematic reviews that examined the effect of social franchise programmes in low-income and middle-income countries, the most recent of which was published in 2016. We updated the search in MEDLINE to March 15, 2017, with MeSH terms and keyword searches using the term "social franchising" and found one new study. Overall, the methodological rigour of studies was very poor, as indicated by the fact that no studies met the inclusion criteria in the Cochrane systematic literature review. The most recent review identified one randomised controlled trial and eight non-randomised controlled studies. Only two studies stand out for their methodological rigour. The first study examined a social franchising programme involving community health-care workers in Myanmar and showed that it increased treatment of childhood diarrhoea with oral rehydration solution containing zinc. The second study evaluated a social franchising programme for paediatric care in the state of Bihar (India) and found no measurable population effect on appropriate treatment for childhood diarrhoea or pneumonia. The remaining studies showed mixed results of the effect of social franchising on measures of use and quality of care. Social franchises have been documented in more than 40 countries, and in 2014, at least 90 social franchise programmes were in existence.

Added value of this study

To our knowledge, this study is one of very few rigorous studies examining the effect of a social franchising programme in health. We showed that the multifaceted social franchise programme did not increase facility births, or any other dimension of care, as measured by a large number of secondary outcomes across the continuum of care for maternal, newborn, and reproductive health. Reasons for why the intervention did not work provide potentially generalisable lessons for social franchising programmes elsewhere.

Implications of all the available evidence

Our results place a higher burden of proof on governments and donors looking to invest in social franchising for maternal health. The design of future social franchising programmes should take account of past failures.

are networks of private providers that pay a fee to operate under contract with a common agency under a single brand. In return, the franchiser markets the brand and supports the provider to adhere to quality standards through training, clinical protocols, drug-supply management, and new technologies such as telemedicine.[13] In 2014, franchises reached almost 30 million people in low-income and middle-income countries (LMICs), with most funding coming from international donors.[14] Although considerable resources are being channelled to social franchising in LMICs, evidence from rigorous studies on the effectiveness of clinical social franchising is scarce,[15–17] and this gap in knowledge urgently needs to be addressed.

In this study, we report results of an impact evaluation of the Matrika social franchise programme, implemented by World Health Partners (the franchiser) in partnership with Pathfinder International in India. We aimed to determine whether the social franchise model could improve the quality and coverage of health-care services along the continuum of care for maternal, newborn, and reproductive health.

Methods

Study design

The Matrika programme was a complex multifaceted intervention that sought to improve maternal health primarily by leveraging the private sector. The basic approach combined various activities to encourage more women to use services and raise the quality of antenatal care, obstetric care, and family planning services (panel). The core component of the programme was the Sky social franchise network of private providers, but it was also recognised that the capacity of, and linkages with, the public sector would need to be strengthened if the programme was to have an effect. The intervention was implemented in three districts (Kannuaj, Kanpur Nagar, and Kanpur Dehat) of the Indian state of Uttar Pradesh between September, 2013, and May, 2016. Our process to understand the theory of change for Matrika began with a meeting between the evaluation team and the implementing partners in December, 2013.[18] Over the course of implementation, we collected data on implementation and updated the theory of change to reflect adaptations (appendix).

The study was done in the three intervention districts and three neighbouring districts (Auraiya, Etawah, and Fatehpur), with a combined population of 13·7 million and facility births ranging from 51% to 62%.[19,20] The study districts were demographically similar to the rest of the state, according to the data from the Indian Census 2011 (appendix). The private market for maternal health care in the study area was largely made up of small, individually owned hospitals and clinics located in urban and periurban areas. Most facilities were owned by doctors formally qualified in allopathic medicine and, to a lesser extent, providers of ayurveda, yoga and naturopathy, unani, siddha, and homoeopathy (or AYUSH).

The study comprised a quasi-experimental impact evaluation, a process evaluation, and a costing and financial sustainability analysis. The study received ethics approval from the Indian Council of Medical Research (HMSC/2014/10/HSR), Public Healthcare Society in India (10/Nov/2013), and the London School of Hygiene & Tropical Medicine (London, UK; 8610). Women gave written informed consent to participate in

the study. The protocol for the evaluation was published before the completion of data collection.[21]

Procedures

We used difference-in-differences methods combined with matching to identify the effect of the social franchising intervention.[22] Such quasi-experimental (non-randomised) methods are increasingly used to evaluate population health interventions[23,24] and have been shown to replicate findings from randomised controlled trials.[25] Frequently, complex health system interventions such as social franchising cannot be randomised.[26] Moreover, findings are likely to be most relevant to policy makers when the intervention is implemented under real-world conditions without manipulation for the purposes of research.

The primary sampling unit was a cluster, defined as a ward (urban) or a village (rural) according to the Indian Census 2011. To estimate the population-level effects of the intervention, we did two rounds of a household survey to collect data on the outcomes of women in 180 clusters. The study involved the selection of three types of clusters: (1) intervention clusters with a Sky provider; (2) internal comparison clusters with no social franchisee in the three intervention districts; and (3) external comparison clusters in three neighbouring districts where the social franchise model was not operating (appendix).

We selected study clusters 1 year after the first social franchisee was contracted with the following procedures.[21] First, every Sky health provider was linked to its census area. 393 private providers were in the network at the time of selection, with membership reflecting decisions by the providers on whether to join and by the franchiser on which providers to target. The process of linking Sky providers to census areas led to the identification of 216 possible intervention clusters from which we selected 60 clusters at random. Second, we selected internal comparison clusters by matching without replacement the intervention clusters to 60 comparison areas within the same three districts.[27,28] We used census data on village characteristics for the matching.[21] To limit problems of contamination, we did not select comparison clusters adjacent to intervention areas. Finally, we did the same matching procedure to select 60 external comparison clusters from neighbouring districts.

Data came from two repeated cross-sectional household surveys administered to women who gave birth in the previous 24 months (round 1) or 18 months (round 2), including those individuals who had a stillbirth or whose child died since birth. The first round of data collection took place between January and February, 2015, and the second round between May and June, 2016. Eligible women were identified through a census of households, done 1 month before each round. Every member of the household was listed and then, for women aged 15–49 years, a series of questions probed whether she gave birth to a baby that was born alive, stillborn, or died before birth. Using the household census as the sampling frame and a computer random number generator, we randomly selected a maximum of 23 (round 1) and 30 (round 2) eligible women in each cluster for interview.

Panel: Matrika social franchise programme

The Matrika programme had three components: (1) establish the Sky social franchise network of private health-care providers and functional referral centres; (2) strengthen capacity of, and linkages between, rural private and public sector health-care providers to offer high-quality services; and (3) improve community awareness, demand, and linkages with maternal health services among rural populations.

Establish Sky social franchise

SkyCare providers made up the lowest level of the network. They were informal rural health-care providers, many of whom were medically unqualified and working from their home. The role of these providers was primarily to encourage women in the community to use services at higher levels in the network. The second level was SkyHealth centres. These were small clinics owned by individuals who typically had formal or alternative traditional medical qualifications. Their role was to provide antenatal care free of charge and channel clients towards appropriate facilities for delivery. Most SkyHealth centres were new providers of antenatal care. To be part of the network, they had to purchase a computer and other equipment, after which they could offer telemedicine consultations, connecting patients with doctors in a central medical facility. SkyHealth centres were also integrated into the public supply chain of iron and folic acid. At the highest level, social franchise clinics were private hospitals offering delivery and emergency obstetric care under a fee structure set by the franchiser. For all providers, the franchiser gave signage and marketed the Sky brand through various channels, such as wall paintings and radio spots.

Strengthen capacity and standardise quality of care

To improve and standardise quality of care, regular quality improvement (mentoring) visits and clinical training of 2–3 days were given to private providers in the network (not SkyCare) and public sector facilities in the same districts. Personnel at SkyHealth centres were trained to provide antenatal care, recognise and stabilise pregnancy complications, facilitate timely referrals, and provide post-partum contraception counselling. They were also trained in how to operate the telemedicine equipment. Training of higher-level social franchise providers and the public sector covered the same topics, in addition to emergency obstetric care. Non-pneumatic antishock garments were distributed to health-care providers and ambulances alongside training in how to use them.

Raise community awareness

Village-level information activities such as film shows, wall paintings, and billboards were used to increase the demand for maternal health services. Accredited Social Health Activists (ASHAs) also had 1 day of training on birth preparedness, recognition of danger signs during pregnancy, and appropriate sources of antenatal and delivery care, which they would encourage women to use.

Cost, scale, and outputs

The programme was implemented with a budget of US$3 250 000 over a 3-year period in three districts that together contained a population of 8·1 million people.

By the end of the programme, 365 SkyCare providers, 50 SkyHealth centres, and eight social franchise clinics were part of the network. Clinical training was given to 58 private providers and 188 public providers. 50 private facilities had 225 quality improvement visits and 88 public facilities had 235 visits. 2149 ASHAs had training and 221 non-pneumatic antishock garments were distributed.

See **Online** for appendix

Outcomes

The primary outcome was the proportion of women who gave birth in a health-care facility. To capture the full range of benefits and unintended consequences of the multifaceted intervention, we measured 56 additional outcomes. These outcomes covered the continuum of care from antenatal care through postnatal family planning and included indicators of health-care use, content of care, patient experience, patient knowledge, healthy behaviours, and financial strain. Many of the outcomes were standard and measured with established survey instruments that have been widely used in India and other LMICs.[1,19] Outcomes related to quality of care drew on evidence-based practices and research[29–32] measuring recommended delivery care practices, harmful or ineffective practices, frequently over-used practices, and respectful care. We prespecified all outcomes and there were no major deviations from the published protocol.[21] We removed two outcomes and modified one other. An outcome for multiple births detected at pregnancy was excluded because very few women in the sample had multiple births. An antenatal care content of care score outcome was excluded because it comprised indicators that were already included in the summary index for that family of outcomes. The family planning indicator differs from the outcome specified in the study protocol (modern contraceptive use at 3 months post partum), because it was not possible to calculate the indicator in the protocol with the available data (appendix). We also collected information on the characteristics of the mother and her household to control for potential confounding. Survey instruments were translated into Hindi and back-translated, and extensively piloted. Data were collected by trained enumerators with computer-assisted personal interviewing with automated checks to limit erroneous entries. Across the outcomes, the median percentage of women with missing data was 0% (range 0–14) and the mean was 1% (SD 2·5).

Statistical analysis

Our sample size was informed by an endline comparison of two groups (intervention *vs* comparison). With an observed institutional delivery of 50% at baseline[33] and an assumed coefficient of variation of 0·2, we estimated that a sample size of 60 intervention and 60 comparison clusters with 20 women in each cluster would provide 80% power to detect an 8 percentage point increase in the rate of institutional deliveries in the intervention group compared with the comparison at 5% level of significance; assuming a

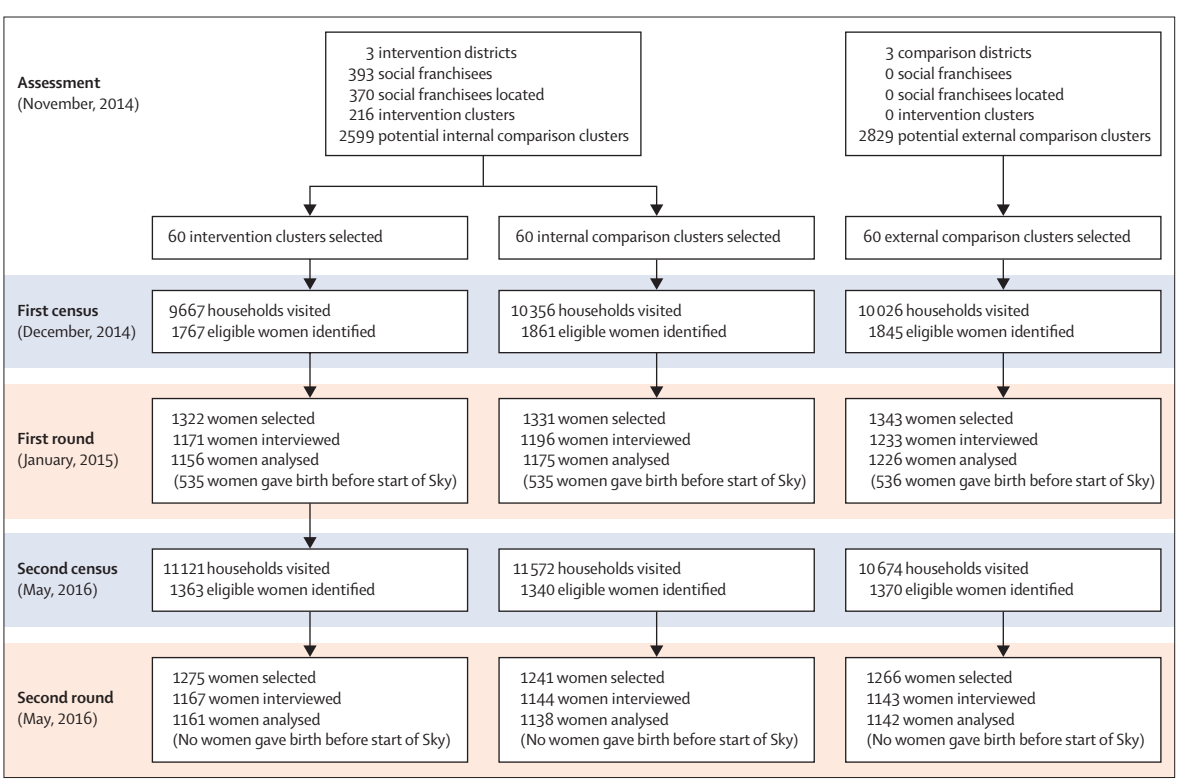

Figure 1: **Study profile**

Social franchisees located are those social franchises that could be matched to a census area. During the first round, 33 cases were dropped because the woman's date of delivery, which is essential for creating the exposure variable, was missing, and a further ten women were dropped because their reported date of delivery occurred before the start of 2013. During the second round, 11 cases were dropped because the woman's date of delivery was missing, and two women were dropped because their date of delivery was before 2015. The start of Sky was defined in each intervention cluster on the basis of administrative data from the franchiser on when the first Sky provider in the cluster received training. The same start date was used for the intervention clusters' matched control clusters.

coefficient of variation of 0·1 reduced the detectable difference to 6 percentage points. The coefficient of variation estimated ex-post was 0·18.

We tested whether the intervention had an effect using a difference-in-differences analysis, which compared changes in outcomes over time between intervention and comparison clusters.[22] The analysis exploited the longitudinal nature of the data generated by the recall period used in the two rounds of the household survey, and information on the precise timing of when the health-care provider became part of the social franchise network in each study cluster. The exposure variable was the introduction of social franchising, defined on the basis of the administrative data from the franchiser on when the social franchisee in the cluster first received training. To show descriptive data before and after the start of the intervention, we classified observations in the comparison clusters as before if the delivery occurred before the start of training in the matched intervention cluster.

The primary analysis compared intervention areas with the two sets of comparison areas (internal and external controls) pooled together. A secondary analysis addressed the possibility of contamination by comparing the intervention clusters with the external controls only (the comparison clusters in adjoining districts without social franchising). Both approaches allowed for flexible time trends with the use of a binary variable for each quarter year and allowed for differences between clusters through the inclusion of a binary variable for each cluster. We additionally controlled for characteristics of the woman, including poverty line status, urban residence, religion, ethnicity, maternal education, parity, multiple birth, and length of recall. In all analyses, we used individual data and clustered the standard errors at the cluster level.

The presence of multiple outcomes increases the probability of a chance finding of significance. We dealt with the problem of arbitrarily selecting or emphasising statistically significant treatment effects in the presence of multiple outcomes using two standard procedures.[34] First, we organised conceptually similar outcomes into 14 prespecified families (appendix). Within each family of outcomes, p values were adjusted for the family-wise error rate (FWER)—the probability of making at least one type-I error—with a free step-down resampling method.[35] We present unadjusted per-comparison p values alongside the FWER-adjusted p values. In general, focusing on the FWER-adjusted p values is appropriate because they account for the multiple tests that were done within each family. Per-comparison p values are appropriate if an individual outcome is of specific interest.[36] Second, we present standardised treatment effects by creating an index of multiple outcomes within each family, and testing for an effect on the *Z* score of each index.[37] This approach equally weighed each outcome in a family (appendix). We did all analyses in Stata 14.2.

	Intervention group (n=535)	Comparison group (n=1071)*	p value
Household has below poverty line card	..	..	0·094
No	461 (86%)	885 (83%)	..
Yes	74 (14%)	186 (17%)	..
Residence	..	..	0·820
Urban	38 (7%)	86 (8%)	..
Rural	497 (93%)	985 (92%)	..
Religion	..	..	0·183
Hindu	458 (86%)	970 (91%)	..
Other	77 (14%)	101 (9%)	..
Caste	..	..	0·795
General caste	98 (18%)	212 (20%)	..
Scheduled caste	163 (30%)	334 (31%)	..
Scheduled tribe	21 (4%)	29 (3%)	..
Other backward caste	253 (47%)	496 (46%)	..
Maternal education	..	..	0·434
None	155 (29%)	285 (27%)	..
Some primary	74 (14%)	164 (15%)	..
Some secondary	192 (36%)	415 (39%)	..
Secondary or above	114 (21%)	207 (19%)	..
Wealth quintile	..	..	0·454
First (poorest)	150 (28%)	270 (25%)	..
Second	123 (23%)	264 (25%)	..
Third	105 (20%)	215 (20%)	..
Fourth	82 (15%)	150 (14%)	..
Fifth (least poor)	75 (14%)	172 (16%)	..
Parity	..	..	0·619
First birth	144 (27%)	302 (28%)	..
Second birth	159 (30%)	306 (29%)	..
Third birth	92 (17%)	187 (17%)	..
Fourth birth	61 (11%)	129 (12%)	..
Fifth birth or more	79 (15%)	147 (14%)	..
Multiple birth	..	..	0·818
No	532 (99%)	1064 (99%)	..
Yes	3 (1%)	7 (1%)	..
Time since birth (quarter years)	5·9 (1·4)	5·8 (1·4)	0·296

Data are n (%) or mean (SD). Data are from a household survey of women aged 15–49 years who gave birth in the previous 2 years, including those women who had a stillbirth or whose child had died since childbirth. The baseline sample is comprised of women who gave birth before training of franchisee clinics started in the matched intervention cluster. *Internal and external comparison clusters pooled together.

Table 1: **Baseline characteristics of women who gave birth before the start of the intervention**

Role of the funding source

The funder of the study had no role in the study design, data collection, data analysis, data interpretation, 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

We enumerated a total of 30 049 households in round 1 and 33 367 households in round 2 in the 180 study clusters, which identified 5473 households (round 1) and 4073 households (round 2) with eligible women (figure 1). We randomly selected 3996 women (round 1) and 3782 women (round 2) for interview. Complete interviews were obtained from 3600 women (90%) in round 1 and 3454 women (91%) in round 2. In total, we included 6998 women in the analysis, of whom 1606 (23%) gave birth before (535 in the intervention clusters, 535 in the internal comparison clusters, and 536 in the external comparison clusters) and 5392 (77%) after the start of the intervention (1782 in the intervention clusters, 1778 in the internal comparison clusters, and 1832 in the external comparison clusters).

The characteristics of women in the intervention clusters were similar to those of women in the comparison clusters (table 1). Most outcomes were similar across study groups before the introduction of social franchising (tables 2–4). We were unable to reject the equality of means or proportions for 51 (89%) of 57 outcome measures at the 5% level (appendix).

Overall, 16% of women interviewed had a below poverty line card, 92% were living in rural areas, 89% were Hindu, and 27% had no education (table 1). At baseline, 73% of women gave birth in a health-care facility, 8% had a caesarean section, 36% had three or more antenatal care visits, and 38% received post-partum care within 48 h of birth (tables 2–4). Indicators on the content of antenatal care, recommended delivery care practices, and the content of newborn care show deficiencies in the provision of care.

Facility births increased from 71% to 74% in the intervention areas and remained the same over time at 71% in the comparison areas (figure 2). The difference-in-differences analysis estimated a non-significant effect of 4 percentage points (95% CI –1 to 9, p=0·100; table 3). The comparison and intervention clusters did not differ in any of the 14 antenatal care outcomes (table 2), in any of the 30 delivery care outcomes (table 3), or in any of the 13 post-partum and newborn outcomes (table 4). These findings hold, irrespective of whether we focus on our preferred FWER-adjusted p values or consider the unadjusted per-comparison p values that do not to account for multiple hypothesis testing.

For the family of outcomes, the difference-in-differences estimates showed a non-significant effect on recommended delivery care practices of 0·13 SDs (95% CI 0·00–0·27; p=0·053; figure 3). Furthermore, other family of outcomes did not differ, with many of the treatment effects close to zero in magnitude (figure 3).

We did a wide range of further analyses to test the robustness of our findings (appendix). First, we verified that trends in facility births were similar in the two groups before the introduction of the programme by testing for anticipatory effects. Second, we compared

	Before introduction of Matrika		After introduction of Matrika		Difference-in-differences effect (95% CI)	Per-comparison p value	FWER-adjusted p value
	Intervention group (n=535)	Comparison group (n=1071)	Intervention group (n=1782)	Comparison group (n=3610)			
Antenatal care use							
Received at least three antenatal care visits	189/535 (35%)	391/1071 (37%)	769/1781 (43%)	1538/3610 (43%)	3 (–3 to 10)	0·284	0·686
Received antenatal care visit in first trimester	265/535 (50%)	484/1071 (45%)	901/1781 (51%)	1870/3610 (52%)	–2 (–9 to 5)	0·659	0·885
Number of antenatal care consultations (visits)	2·3 (1·7)	2·3 (1·6)	2·4 (1·7)	2·4 (1·6)	0·07 (–0·14 to 0·28)	0·519	0·881
Received visit from ASHA	421/535 (79%)	784/1071 (73%)	1373/1781 (77%)	2762/3610 (77%)	1 (–4 to 6)	0·738	0·885
Antenatal content of care							
Fully immunised with tetanus toxoid	448/532 (84%)	871/1066 (82%)	1396/1754 (80%)	2917/3571 (82%)	–2 (–7 to 3)	0·404	0·952
Received iron supplementation	368/535 (69%)	710/1071 (66%)	1390/1781 (78%)	2612/3603 (72%)	5 (–1 to 11)	0·078	0·408
Iron supplementation for 100 days	59/534 (11%)	79/1070 (7%)	242/1777 (14%)	316/3597 (9%)	1 (–3 to 4)	0·726	0·987
Received test results for syphilis	47/535 (9%)	115/1071 (11%)	229/1781 (13%)	498/3610 (14%)	1 (–3 to 5)	0·569	0·985
Abdominal examination during antenatal care	246/535 (46%)	473/1071 (44%)	950/1781 (53%)	1822/3610 (50%)	1 (–5 to 8)	0·666	0·987
Received a drug for intestinal worms	36/535 (7%)	96/1071 (9%)	173/1781 (10%)	390/3610 (11%)	0 (–4 to 4)	0·920	0·987
Received a drug to prevent malaria	17/535 (3%)	60/1071 (6%)	96/1781 (5%)	235/3610 (7%)	0 (–2 to 3)	0·811	0·987
Antenatal knowledge and preparedness							
Knowledge of pregnancy complications (0 to 1)	0·2 (0·1)	0·2 (0·1)	0·2 (0·1)	0·2 (0·1)	0·003 (–0·01 to 0·02)	0·710	0·934
Knowledge of delivery complications (0 to 1)	0·2 (0·1)	0·2 (0·1)	0·2 (0·1)	0·2 (0·1)	0·002 (–0·01 to 0·01)	0·620	0·934
Birth preparedness index (0 to 1)	0·1 (0·2)	0·2 (0·2)	0·2 (0·2)	0·2 (0·2)	0·003 (–0·03 to 0·02)	0·824	0·934

Data are n/N (%), n, mean (SD), or as indicated. Data are from two surveys of women aged 15–49 years who gave birth in the previous 2 years (round 1) and 18 months (round 2), including those who had a stillbirth or whose child had died since childbirth. FWER=family-wise error rate. ASHA=Accredited Social Health Activist.

Table 2: **Estimated effect of the Matrika programme on antenatal care outcomes**

intervention clusters with the external comparisons only to allay concerns about contamination. Results for individual outcomes remained qualitatively the same. Aggregated results were also similar for all but one of the families of outcomes (appendix). The analysis showed a larger effect on recommended delivery care practices of 0·19 SDs (95% CI 0·05–0·33; p=0·008; appendix). Finally, we checked that findings were unaffected when we excluded controls for covariates, used an alternative definition for the start date of the intervention, and excluded from the analysis intervention clusters and their matched comparisons when survey teams could not locate the social franchisees.

Discussion

The study showed that the Matrika social franchise programme did not have a measurable effect on the proportion of women giving birth in a health-care facility, nor did it improve any other individual outcome. We measured a wide range of prespecified outcomes

	Before introduction of Matrika		After introduction of Matrika		Difference-in-differences effect (95% CI)	Per-comparison p value	FWER-adjusted p value
	Intervention group (n=535)	Comparison group (n=1071)	Intervention group (n=1782)	Comparison group (n=3610)			
Delivery care use							
Gave birth in a health-care facility	381/535 (71%)	790/1070 (74%)	1312/1779 (74%)	2681/3606 (74%)	4 (–1 to 9)	0·100	0·262
Gave birth with a doctor, nurse, or midwife present	490/535 (92%)	984/1070 (92%)	1577/1779 (89%)	3235/3606 (90%)	0 (–4 to 4)	0·869	0·984
Had a caesarean section	50/535 (9%)	76/1071 (7%)	172/1780 (10%)	287/3610 (8%)	0 (–3 to 4)	0·949	0·984
Recommended delivery care practices							
Delivery attendant used gloves	352/506 (70%)	681/1017 (67%)	1245/1713 (73%)	2351/3446 (68%)	3 (–2 to 8)	0·208	0·660
Delivery attendant washed hands with soap	372/445 (84%)	718/898 (80%)	1269/1526 (83%)	2490/3139 (79%)	0 (–5 to 6)	0·935	0·937
Woman had her blood pressure measured	189/535 (35%)	340/1071 (32%)	841/1780 (47%)	1585/3610 (44%)	4 (–2 to 9)	0·172	0·648
Mobility during labour	194/535 (36%)	372/1071 (35%)	720/1781 (40%)	1324/3610 (37%)	1 (–5 to 8)	0·723	0·926
Oral fluids during labour	194/535 (36%)	420/1071 (39%)	725/1781 (41%)	1435/3610 (40%)	3 (–3 to 10)	0·288	0·736
Heart rate of baby monitored	71/510 (14%)	79/1016 (8%)	317/1690 (19%)	434/3486 (12%)	2 (–3 to 6)	0·517	0·880
Use of anti-shock garment	6/535 (1%)	6/1071 (1%)	62/1780 (3%)	65/3610 (2%)	1 (0 to 3)	0·113	0·545
Harmful or ineffective delivery care practices							
Shaved pubic hair	100/535 (19%)	229/1071 (21%)	347/1780 (19%)	781/3610 (22%)	–1 (–7 to 4)	0·698	0·973
Enema given	86/535 (16%)	171/1071 (16%)	330/1780 (19%)	660/3610 (18%)	0 (–5 to 5)	0·952	0·980
Lithotomy position during labour	318/533 (60%)	615/1063 (58%)	925/1769 (52%)	1789/3593 (50%)	1 (–7 to 8)	0·864	0·980
Intravenous fluids during labour	76/535 (14%)	110/1071 (10%)	266/1780 (15%)	483/3610 (13%)	–2 (–6 to 2)	0·424	0·883
Delivery care practices frequently overused							
Urinary catheter	42/535 (8%)	61/1071 (6%)	161/1780 (9%)	242/3610 (7%)	1 (–2 to 4)	0·504	0·887
Pain control by epidural analgesia	58/535 (11%)	105/1071 (10%)	236/1761 (13%)	391/3559 (11%)	2 (–2 to 6)	0·431	0·887
Oxytocin augmentation	128/535 (24%)	216/1071 (20%)	454/1781 (25%)	836/3610 (23%)	–2 (–8 to 3)	0·434	0·887
Episiotomy	75/535 (14%)	138/1071 (13%)	238/1780 (13%)	443/3610 (12%)	–1 (–4 to 3)	0·781	0·887
Respectful care							
No support during labour	113/380 (30%)	225/787 (29%)	346/1312 (26%)	699/2672 (26%)	–1 (–10 to 8)	0·793	1·000
Medical procedure performed without consent	31/381 (8%)	56/790 (7%)	114/1312 (9%)	224/2681 (8%)	0 (–4 to 6)	0·854	1·000
Shouted at, scolded, or humiliated by health worker	21/381 (6%)	53/790 (7%)	85/1312 (6%)	195/2681 (7%)	0 (–3 to 4)	0·995	1·000
Slapped, pinched, or hit by health worker	7/381 (2%)	19/790 (2%)	30/1312 (2%)	70/2681 (3%)	1 (–1 to 3)	0·466	0·987
Gave birth without privacy	241/381 (63%)	513/790 (65%)	686/1312 (52%)	1508/2681 (56%)	–4 (–10 to 3)	0·246	0·887
Refused care for inability to pay	18/381 (5%)	39/790 (5%)	73/1312 (6%)	124/2681 (5%)	0 (–3 to 3)	0·851	1·000
Kept in facility for inability to pay	32/381 (8%)	65/790 (8%)	120/1312 (9%)	216/2681 (8%)	1 (–2 to 4)	0·620	0·997
Felt disrespected or abused during facility stay	9/381 (2%)	14/790 (2%)	35/1312 (3%)	66/2681 (2%)	0 (–2 to 2)	0·969	1·000
Financial consequences							
Out-of-pocket spending on delivery care (INR)	1865 (5002)	1910 (5997)	2478 (6792)	2092 (5920)	416 (–276 to 1109)	0·237	0·548
Borrowed money to pay for delivery care	78/535 (15%)	103/1071 (10%)	206/1780 (12%)	339/3609 (9%)	–2 (–6 to 2)	0·237	0·548
Household in debt to pay for delivery care	26/517 (5%)	35/1045 (3%)	84/1757 (5%)	170/3578 (5%)	–2 (–4 to 1)	0·191	0·539
Did not receive JSY cash	275/533 (52%)	523/1068 (49%)	975/1757 (55%)	1914/3578 (53%)	–2 (–9 to 4)	0·447	0·548

Data are n/N (%) or mean (SD). Data are from two rounds of a survey of women aged 15–49 years who gave birth in the previous 2 years (round 1) and 18 months (round 2), including those who had a stillbirth or whose child had died since childbirth. Indicators of respectful care were measured only for women who gave birth in a health-care facility. FWER=family-wise error rate. INR=Indian rupee. JSY=Janani Suraksha Yojana.

Table 3: **Estimated effect of the Matrika programme on delivery care outcomes**

	Before introduction of Matrika		After introduction of Matrika		Difference-in-differences effect (95% CI)	Per-comparison p value	FWER-adjusted p value
	Intervention group (n=535)	Comparison group (n=1071)	Intervention group (n=1782)	Comparison group (n=3610)			
Post-partum care							
Received post-partum care within 48 h	229/535 (43%)	383/1071 (36%)	797/1780 (45%)	1383/3610 (38%)	3 (–4 to 9)	0·449	0·460
Newborn received postnatal care within 48 h	184/531 (35%)	332/1070 (31%)	651/1758 (37%)	1136/3580 (32%)	3 (–3 to 10)	0·290	0·451
Newborn content of care							
Clean cord care	195/511 (38%)	424/1023 (41%)	693/1684 (41%)	1496/3425 (44%)	0 (–7 to 7)	0·949	0·993
Thermal care	98/506 (19%)	187/1017 (18%)	324/1698 (19%)	782/3433 (23%)	–3 (–8 to 3)	0·376	0·847
Baby weighed at birth	337/498 (68%)	617/990 (62%)	1171/1705 (69%)	2290/3455 (66%)	–2 (–8 to 3)	0·425	0·847
Baby registered and received certificate	139/515 (27%)	260/1038 (25%)	606/1709 (35%)	1062/3499 (30%)	0 (–5 to 6)	0·916	0·993
Neonatal health							
Neonatal mortality (per 1000)	15/721 (2%)	18/1474 (1%)	39/2074 (2%)	50/4243 (1%)	2·1 (–13 to 18)	0·784	0·843
One day mortality (per 1000)	11/721 (2%)	8/1474 (1%)	21/2074 (1%)	27/4243 (1%)	–3·4 (–17 to 10)	0·617	0·839
Birthweight (kg)	2·8 (0·5)	2·8 (0·5)	2·8 (0·5)	2·8 (0·5)	0·03 (–0·05 to 0·10)	0·495	0·839
Breastfeeding							
Immediate breastfeeding within 1 h of birth	300/531 (56%)	619/1070 (58%)	1025/1758 (58%)	2190/3580 (61%)	1 (–6 to 7)	0·845	0·870
Colostrum given to baby	387/530 (73%)	834/1070 (78%)	1277/1758 (73%)	2874/3580 (80%)	–3 (–9 to 3)	0·326	0·670
Exclusive breastfeeding for 3 days	355/531 (67%)	740/1070 (69%)	1198/1758 (68%)	2428/3580 (68%)	1 (–4 to 7)	0·610	0·870
Family planning							
Current modern contraceptive use	168/535 (31%)	277/1069 (26%)	284/1780 (16%)	534/3608 (15%)	–3 (–10 to 4)	0·332	0·332

Data are n (%) or mean (SD). Data are from two rounds of a survey of women aged 15–49 years who gave birth in the previous two years (round 1) and 18 months (round 2), including those who had a stillbirth or whose child had died since childbirth. Total values are higher for the neonatal mortality and 1 day mortality outcomes, because these indicators are calculated on the basis of all the women's previous deliveries, rather than their most recent delivery. FWER=family-wise error rate.

Table 4: **Estimated effect of the Matrika programme on post-partum and newborn outcomes**

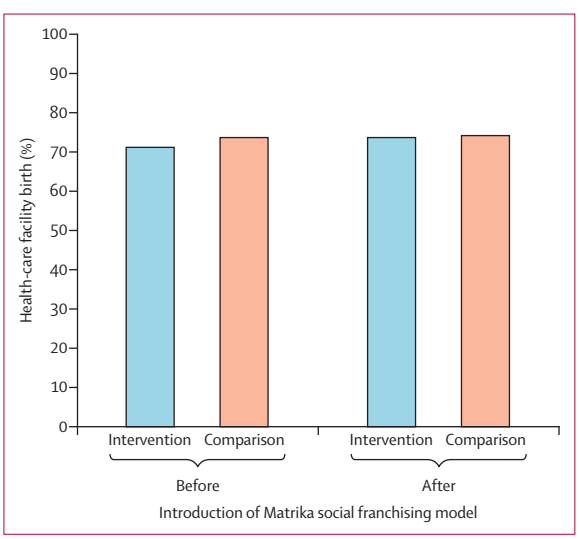

Figure 2: **Facility births in the intervention and comparison clusters**

along the continuum of care for maternal, newborn, and reproductive health, and found consistent results of no measurable effect. The only exception was weak evidence of an effect on recommended delivery care practices—which we regard as a proxy measure for the quality of normal delivery care. By selecting households in close proximity (within 1 km) to the social franchise providers in intervention clusters, the study design gave the programme its best chance of showing an effect.

Our study had several strengths, and some limitations. The evaluation was one of the few studies that has rigorously examined the population effects of social franchising. Although assignment of the intervention was not randomised, we used prospective matching to improve balance and a difference-in-differences research design that relies on weaker assumptions than most quasi-experimental methods. The findings were not sensitive to alternative definitions of treatment, start date, comparison area, or statistical models, giving us additional confidence in the results. With so many null findings, consideration of whether the study was sufficiently powered is important. The sample sizes we obtained exceeded estimates from the ex-ante sample size calculations, providing us with 95% CIs that were narrow enough to rule out moderate effects. The Matrika programme possibly had effects that were too small for the study to detect; however, effects of this magnitude are unlikely to have implications for public health.

The key limitations of the study concerned the outcomes. First, we were unable to use maternal mortality as our primary outcome because the sample size required would have been prohibitively large, and although we did measure neonatal mortality as one of the secondary outcomes, we were underpowered to interpret this result.

Instead we measured a wide range of upstream outcomes that could have indicated the potential of the intervention to improve health. Given the null findings, the intervention is extremely unlikely to have generated improvements in maternal health. Second, our measures of the content of delivery care were not ideal. Some provider practices during childbirth cannot be measured with a household survey and those practices that were measured might have had recall problems. With recognition of this limitation, we did 275 clinical observations of normal deliveries in public and private health-care facilities exposed to the intervention to assess the adequacy of the Matrika programme in improving clinical quality of normal delivery care.[38] Overall, we found that essential care at the time of birth, including active management of third stage of labour, was poor quality.[39] Although these findings do not address the casual effect of Matrika, they correlate well with the results we report here.

Our findings raise an obvious but important question. Why did the programme not improve population outcomes? The impact study reported here was accompanied by a process evaluation, which we intend to report in full elsewhere, in which we interviewed social franchise clients, health-care providers, and staff in the implementing organisations. Drawing on the process evaluation findings, we examined what aspects of the theory of change did not appear to work. The competitive nature of the market for antenatal care and delivery care meant that providers in the social franchise network achieved very low market share. For example, only 3% of women in intervention clusters used the franchise for antenatal care, with most relying primarily on government sources of care. Part of the challenge in obtaining market share might also have been that most SkyHealth providers offering antenatal care were male when there is a strong preference for female antenatal care providers in this setting. Branding and promotion of the social franchise were meant to attract women to services, but only 24% of women in intervention clusters were aware of the social franchise brand, and those who were aware of the brand did not recognise it as a signal of quality, suggesting that marketing activities were not effective.

SkyCare and community health-care workers (Accredited Social Health Activists or ASHAs) were expected to encourage women to attend antenatal care services, but this mechanism did not prove effective. There was no clear logic to why these actors would be effective in encouraging more women to use services when ASHAs in India have long been incentivised to play the same role under the government's Janani Suraksha Yojana programme. Moreover, SkyCare providers had little previous experience working in maternal health and did not see themselves as health educators. The Matrika model also relied on SkyHealth centres to refer women in need of delivery care to higher-level facilities in the network. In practice, this referral rarely happened because there were no strong incentives to do so. The telemedicine was intended to attract clients to use antenatal care as well as improve the content of such care. Women reported that telemedicine was a pull factor, but poor internet connectivity meant the telemedicine did not always work and was frustrating to use. Insofar as there was a small improvement in recommended delivery practices, this improvement was likely to be due to the clinical training and supervisory visits in the public sector. An established body of evidence has shown that training alongside supportive supervision can improve quality of care in LMIC settings.[40] We note that these activities could have been implemented without the need for a social franchise network.

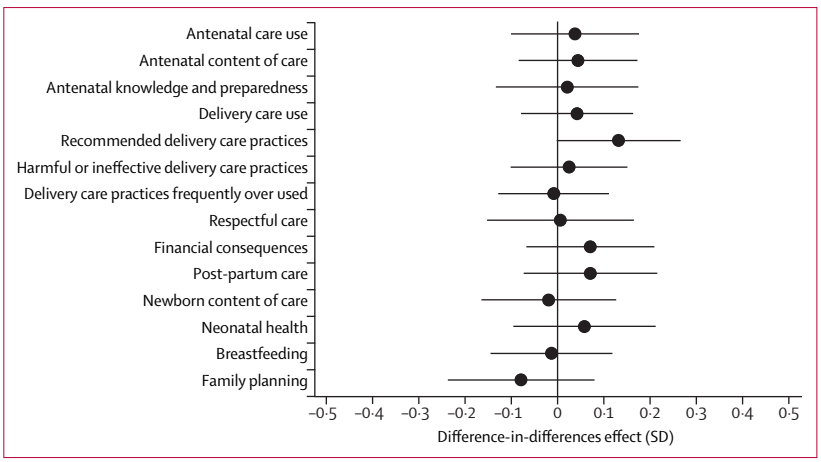

Figure 3: **Effect of the Matrika programme on summary measures of outcomes**
Data are from two rounds of a survey of women aged 15–49 years who gave birth in the previous 2 years (round 1) and 18 months (round 2), including those women who had a stillbirth or whose child had died since childbirth. This figure shows standardised treatment effects on indices generated from multiple outcomes within a family. We recoded individual outcomes when necessary so that higher values correspond to better outcomes. Treatment effects are presented in SD units of the comparison group. We did these analyses with all available data.

Our findings pertain to a specific model of social franchising and naturally we should be cautious in generalising beyond the study setting. For example, a different social franchising model in India focuses only on higher-level hospitals providing obstetric care.[14] However, some features of the Matrika programme are similar to other social franchise models and we can speculate what lessons might be learnt. First, it is important to distinguish between social franchises offering basic services such as family planning and franchises that seek to provide more complex health-care services such as obstetric care. Evidence on more complex health-care services is particularly scarce, but we note that our findings are similar to those findings from a study[41] of a comparable social franchising programme for paediatric care in the state of Bihar. Second, we question whether patients recognise the brand of a social franchise as a signal of quality,[42] particularly in contexts where the reputation of the doctor is what people care about. Third, the extent to which a social franchise network can have an effect depends on whether health-care providers in the network can establish or already have a reasonable market share. In markets that are already competitive, expanding market

share might prove to be a challenge.[41] Fourth, social franchises often rely on community health-care workers to carry out demand creation activities. In practice, this workforce might already be overburdened in their existing government role and are unlikely to prioritise activities for the social franchise programme.[43,44] Finally, in the standard model of a commercial franchise, businesses are partly incentivised to maintain standards through the threat of expulsion. This sanction can be harder to apply in the case of social franchising, raising the question of whether such programmes can in practice leverage such incentives. Programmes seeking to engage with the private sector might be better placed to affect changes in quality when they are linked to health financing initiatives that purchase services from private providers, giving them strong financial incentives to stay within the programme.

All these lessons point towards the importance of understanding market conditions, what patients value, and how improvements in quality can be encouraged, before the implementation of a social franchise programme. At the very least, our findings should place a higher burden of proof on policy makers and funders looking to invest in social franchising for maternal health.

Contributors

TP-J designed the impact evaluation, in consultation with ST, SP, VD, PK, CG, and KS. Data collection was overseen by PK, VD, KH, SP, ST, KS, VS, and TP-J. ST and TP-J did the analysis. TP-J wrote the first draft, which was reviewed by CG, with input from all authors.

Declaration of interests

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