

# Integrating family planning messages into immunization services: a cluster-randomized trial in Ghana and Zambia

Gwyneth Vance,<sup>1\*</sup> Barbara Janowitz,<sup>1</sup> Mario Chen,<sup>1</sup> Brooke Boyer,<sup>1</sup> Prisca Kasonde,<sup>1</sup> Gloria Asare,<sup>2</sup> Beatrice Kafulubiti<sup>3</sup> and John Stanback<sup>1</sup>

<sup>1</sup>FHI 360 - Program Sciences, Durham, NC, USA, <sup>2</sup>Ghana Health Service, Accra, Ghana and <sup>3</sup>Zambia Ministry of Health, Kabwe, Zambia

\*Corresponding author. Gwyneth Vance, 2224, E. HWY 54 Durham, NC 27713, USA. E-mail: gvance@fhi360.org

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<b>Accepted</b>	15 March 2013
<b>Objective</b>	To determine whether integrating family planning (FP) messages and referrals into facility-based, child immunization services increase contraceptive uptake in the 9- to 12-month post-partum period.
<b>Methods</b>	A cluster-randomized trial was used to test an intervention where vaccinators were trained to provide individualized FP messages and referrals to women presenting their child for immunization services. In each of 2 countries, Ghana and Zambia, 10 public sector health facilities were randomized to control or intervention groups. Shortly after the introduction of the intervention, exit interviews were conducted with women 9–12 months postpartum to assess contraceptive use and related factors before and after the introduction of the intervention. In total, there were 8892 participants (Control Group Ghana, 1634; Intervention Group Ghana, 1129; Control Group Zambia, 3751; Intervention Group Zambia, 2468). Intervention effects were evaluated using logistic mixed models that accounted for clustering in data. In addition, in-depth interviews were conducted with vaccinators, and a process assessment was completed mid-way through the implementation of the intervention.
<b>Results</b>	In both countries, there was no significant effect on non-condom FP method use (Zambia, $P=0.56$ and Ghana, $P=0.86$ ). Reported referrals to FP services did not improve nor did women's knowledge of factors related to return of fecundity. Some providers reported having made modifications to the intervention; they generally provided FP information in group talks and not individually as they had been trained to do.
<b>Conclusion</b>	Rigorous evidence of the success of integrated immunization services in resource poor settings remains weak.
<b>Keywords</b>	Family planning, immunization, integration, vaccinators, referrals

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## KEY MESSAGES

- There is much interest and promise in investing in integrated immunization services; however robust evidence in support of the effectiveness of integrated services is lacking.
- A rigorously designed study to evaluate the impact of integrating family planning messages and referrals into routine child immunization services was completed in Ghana and Zambia, but the anticipated impact on contraceptive uptake was not observed.
- The most likely reason for the lack of observed impact was due to incomplete implementation of the intervention.
- Evidence of the success of integrated immunization programs in low resource settings remains weak.

## Introduction

There is increasing enthusiasm surrounding the integration of underutilized health services into child immunization programs. Wallace *et al.* (2012) noted that ‘the number of reports (on integration into immunization programs) published during the past 5 years alone were similar to the number published during the previous 20 years’. However, in their updated review, the researchers also concluded that despite the increased discussion about integrated immunization services, there was still a dearth of robust literature on its impact. The limited evidence, however, has done little to dampen optimism. The Global Alliance for Vaccines and Immunization calls for the integration of ‘other critical health interventions with immunization’ (WHO 2011), and the United States Agency for International Development (USAID) recently added the integration of family planning (FP) services in the post-partum period, up to 12 months after delivery, into immunization programs as one of their recommended high impact practices (USAID 2011).

Immunization and FP integration is considered a promising practice due to the strategic importance of meeting the FP needs of women in the post-partum period and the opportunities for doing so through child immunization programs. Post-partum women have some of the highest levels of unmet need for FP (defined among non-pregnant women as not wanting a child for 2 or more years and not using an FP method). In a 27-country study, Ross and Winfrey (2001) found that 65% of post-partum women had an unmet need for FP. At the same time, there are serious adverse health outcomes associated with birth intervals that are too short, including early infant and maternal mortality (WHO 2005; Rutstein 2008) making pregnancies in the post-partum period high risk and post-partum women a high priority for FP programs.

One reason many post-partum women do not use contraception in spite of a widespread desire to not become pregnant is that they may not realize they are at risk of pregnancy. There is a period of post-partum infecundability after giving birth, and many post-partum women may erroneously rely on return of menses to signal return of fecundity (Salway and Nurani 1998; Borda and Winfrey 2010) not understanding that they could become pregnant before onset of menses (Chao 1987; Gray *et al.* 1987; Campbell and Gray 1998; Gray *et al.* 1990). Thus, post-partum women may be confused over their own susceptibility to pregnancy and need information on return to fecundity and the importance of using FP for spacing births after delivery.

While the use of FP services by post-partum women is low, the use of child immunization services is high (Dulli *et al.* 2010;

Cooper *et al.* 2012). The Expanded Program for Immunization makes over an estimated 100 million client contacts per year (WHO/UNICEF 2012), and at multiple time points within the post-partum period as immunization schedules typically call for at least five vaccinations in an infant’s first year. Given that pregnancies during the post-partum period hold the greatest risk for mothers and infants, and the first 12 months present the greatest opportunities in terms of the number of immunization contacts, integrating FP into immunization services has the potential to increase FP coverage among a key demographic group (JSI 2007; Clements *et al.* 2008).

A recent assessment of child immunization services as an entry point for post-partum FP services conducted in Madagascar found that both mothers and vaccinators were open to receiving and offering FP services, and the researchers concluded that there was an opportunity for the addition of FP services (Dulli *et al.* 2010). Nevertheless, there is limited evidence supporting the effectiveness of such an approach. Three recent reviews on integrated health services found only one study of reasonable quality examining the impact of integrating FP into immunization services (Briggs and Garner 2006; Wallace *et al.* 2009; Kuhlmann *et al.* 2010). The research was conducted in Togo in 1993 and tested an intervention where vaccinators were trained to give three simple birth spacing and FP messages to women presenting for services with their children. Subsequently, there was a 54% increase in the number of new FP clients (Huntington and Aplogan 1994). Although the results were positive, the study did not determine definitively whether the intervention led to higher contraceptive use among women exposed to the intervention, as the findings were based on FP service statistics pertaining to all FP clients and not just post-partum clients.

If such an intervention could be successful, however, a simple, low-cost means for improving contraceptive uptake in the post-partum period, which is replicable in many low- and middle-income countries will have been identified. Therefore, we conducted research to test the hypothesis that providing FP messages and referrals to post-partum women through facility-based child immunization services will increase FP use among post-partum women.

## Methods

### Study design and settings

The study was designed as a cluster-randomized controlled trial and was completed from 2009 to 2010 in Central Region, Ghana

and Central Province, Zambia. In each country, 10 public sector health facilities were purposefully selected to be as geographically as separate as possible to minimize contamination of facilities acting as controls from those exposed to the intervention. The only eligibility criteria were that facilities offer both FP and immunization services. The co-location of clinics ensured that women would have easy access to FP if they chose to act on messages and referrals received from vaccinators. We randomly assigned the selected facilities to either control or intervention groups using a randomization sequence generated by Excel 2003.

At selected facilities, women were approached for recruitment after receiving services for their child. Women were eligible if they were 9–12 months post-partum. This criterion was selected because it corresponds with the recommended timing of the measles vaccine (a convenient point to recruit participants) and because women no longer meet the criteria outlined by lactational amenorrhea method (LAM) and need to use an FP method if they want to prevent pregnancy.

**Intervention**

In facilities randomized to the intervention group, vaccinators were trained to screen women for pregnancy risk, deliver a birth spacing message and refer mothers interested in

preventing pregnancy to co-located FP services during their child’s immunization visit. They were given a job-aid to guide them through this process that was made available in English and the local language (Figure 1). Pregnancy risk screening was based on LAM criteria, which outlines biological insusceptibility to pregnancy if post-partum women are (1) fully or nearly fully breastfeeding, (2) have given birth less than 6 months prior and (3) have not had their menses since delivery (Kennedy and Visness 1992).

Vaccinators were to use the tool every time a mother brought her child for immunization; her exposure would depend on the number of visits she made, with a likely maximum of four exposures before we assessed FP use, as in both Zambia and Ghana, the recommended vaccination schedule calls for child immunizations at birth, 6, 10 and 14 weeks and 9–12 months. Despite the limited contact time between clients and vaccinators, screening, message delivery and referrals were to be individualized because a one-on-one interaction was thought to be the best means for determining and conveying an individual’s risk. The screening and message delivery process was designed to ensure it would take less than 30 seconds, similar to the Togo research.

To ensure proper implementation of the intervention plan, one-half day trainings were conducted at each intervention

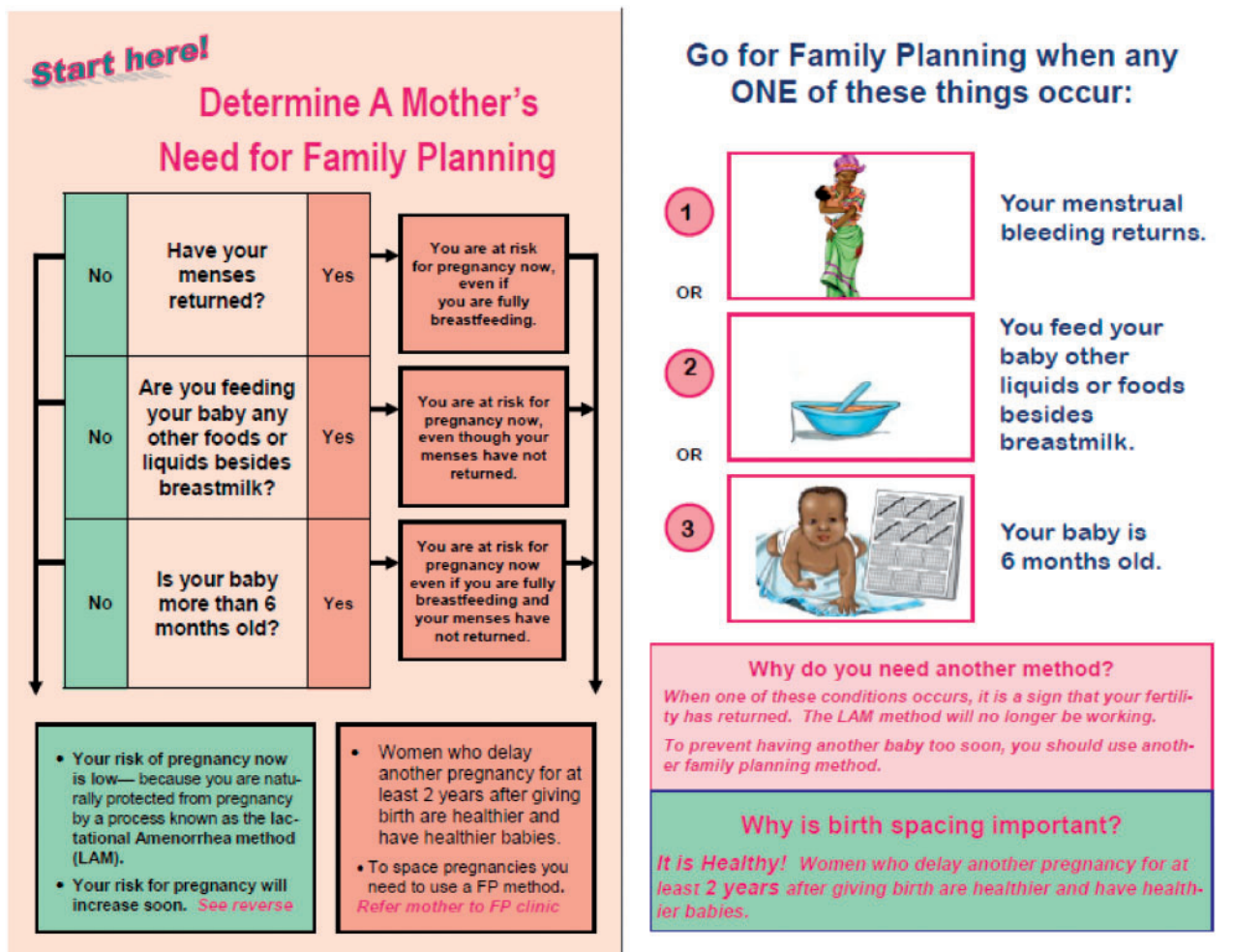


Figure 1 Job-aid (front and back, English version).

facility. Topics covered included the LAM method and the benefits of FP for the health of women and children. Vaccinators were also oriented to the job-aid and importance of clients receiving messages individually. Regional health directors or their deputies participated in trainings and made field visits after implementation to encourage use of the job-aids. Study staff also followed up regularly at facilities.

In addition, the FP providers in co-located clinics were trained to use a job-aid known as the 'pregnancy checklist' (Stanback *et al.* 1999). Previous research examining barriers to FP service provision (Stanback *et al.* 1997) has shown that providers often rely on the presence of menses to rule out the possibility of a pregnancy before providing an FP method. Because many post-partum women are amenorrhic, this could pose a challenge to FP uptake; however, following checklist criteria should allow most amenorrhic women to initiate FP, eliminating this potential barrier.

### Interim assessment

Shortly after the introduction of the intervention, exit interviews were conducted with 10–15 women from each intervention facility to assess whether vaccinators were delivering the intervention messages and referrals as planned. Based on the client reports, it appeared they were not, and vaccinators were re-trained in both countries.

### Data collection and outcomes

Participants were recruited and interviewed by research assistants (RAs) about contraceptive use and related factors at both baseline and 7 months after the introduction of the intervention. Although vaccinators and clients were not blinded to the intervention, RAs were not informed of a facility's intervention status. A 7-month intervention period allowed women to be exposed to the intervention at earlier vaccinations and, in response, adopt an FP method by the time of interview (9–12 months post-partum). Each round of data collection lasted approximately 3 months. However, there was a nurses' strike during baseline data collection in Zambia, causing a month-long hiatus in services and subsequently data collection. Data collection resumed the following month.

To guide the interviews, structured questionnaires were developed and translated into Bemba and Akan for use in Zambia and Ghana, respectively. Women were interviewed in English or the local language based on their preference. In the Zambia site, questionnaires were revised at post-test to capture more information about FP referrals. Data were double entered into EpiData and converted to Stata 10.0 and SAS 9.2 for analysis.

The primary outcome was reported use of a non-condom modern FP method among all participants, including pregnant women, because it was assumed pregnancy resulted from lack of method use. This outcome was selected for two reasons. First, condoms are used for HIV and pregnancy prevention; excluding condoms helps isolate the intended intervention effects, which was to increase use of contraception. Second, consistent condom use is highly effective at preventing pregnancy, but difficult to measure. Secondary outcomes were knowledge around LAM criteria and reported referrals by a vaccinator to FP services. Knowledge was assessed in two ways;

women were asked to spontaneously identify LAM criteria and to answer true/false questions related to LAM.

RAs also conducted 30 in-depth interviews with vaccinators to assess intervention implementation approximately 5 months after its introduction. Interviews were completed using a guide in English or the local language based on the participant's preference and were audio recorded and transcribed. Transcripts were coded and analyzed using NVivo 8 software. A codebook was created prior to interviewing; however, continual coding occurred as additional themes were identified. Coding and analysis were performed by one analyst; an independent analyst cross-checked coding.

### Statistical considerations

To calculate the needed sample size, a z-approximation for comparisons of change from baseline between the groups using a logistics model with adjustment for clustering effects was used (Presser *et al.* 2007). Based on estimates of the proportion of women currently using contraception during the post-partum period, FP use was not expected higher than 20% in both sites (Central Statistical Office (CSO), Central Board of Health (CBOH), and ORC Macro 2003; Ghana Statistical Service (GSS), Noguchi Memorial Institute for Medical Research (NMIMR), and ORC Macro 2004). A minimum sample of 140 women per facility gave at least 80% power to detect an increase of 12 percentage points in non-condom FP use when comparing intervention and control groups with a one-sided test at 5% significance level. These calculations accounted for clustering effects; assuming an intra-class correlation of 1% and a pre-post-test correlation no larger than 0.5%.

The intervention effects were assessed by comparing changes from baseline between the two study groups. We used a logistic mixed model to account for clustering at the facility level. A separate model was fitted for each country. No additional covariates were included in the model. The changes in the level of referrals and knowledge of the LAM criteria were examined descriptively.

## Results

Overall 8982 women participated in the client interviews, with variation in sample sizes between countries, time points and study groups (Figure 2). More women participated in Zambia than Ghana, and in both countries, more women were interviewed at baseline than post-test. Also, in both countries, more women were interviewed in the control compared with intervention groups. The latter was pronounced in the Zambia control group. However, a nurses' strike in 2009 appears to have affected the number of clients sampled at baseline because client monthly attendance at immunization clinics increased in July after the strike (data not shown).

Despite the variation in the numbers of women participating, the percentage of eligible women who participated varied little between the study groups and time points. The one exception, and with no apparent explanation, was a very high level of post-test participation in the control group in Ghana (Figure 1).

Participants in intervention and control groups were similar at baseline in the two countries (Table 1). In Zambia, however,

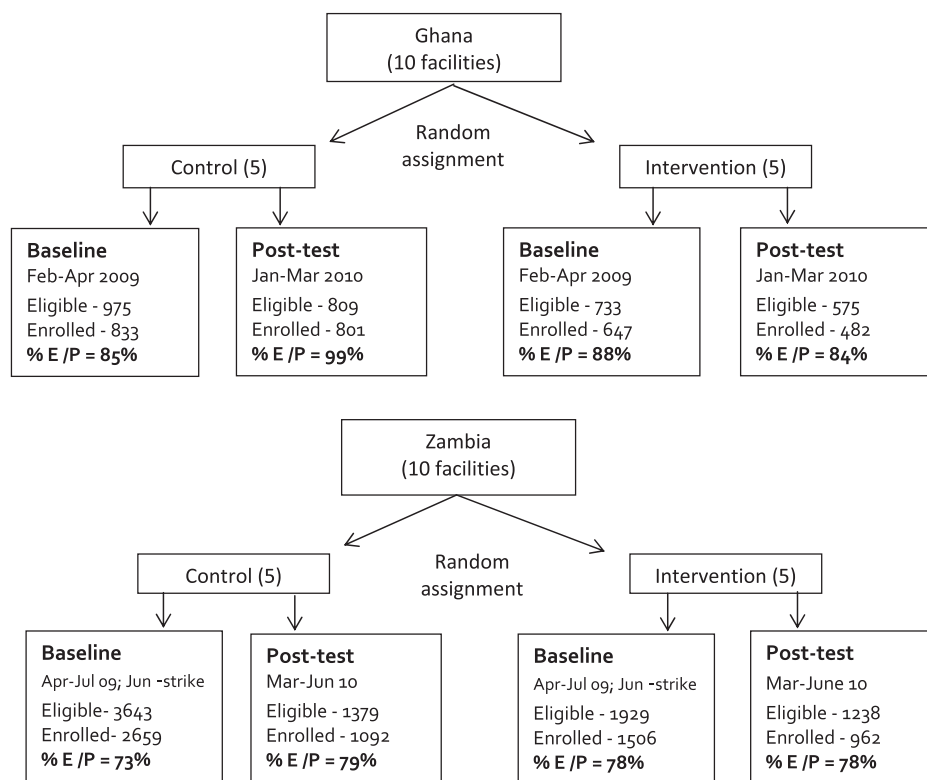


Figure 2 Study recruitment. % E/P=percent of eligible women who participated.

Table 1 Characteristics of women by study group at pre-test<sup>a</sup>

Characteristics	Ghana (pre-test)		Zambia (pre-test)	
	Control (n=833)	Intervention (n=647)	Control (n=2659)	Intervention (n=1506)
Mean age of child (months) <sup>b</sup>	10.0	10.2	10.3	10.2
Mean parity of mother	2.4	2.3	3.1	2.4
Mean age of mother (years)	28.3	27.5	26.0	24.9
Mothers who had sex since delivery (%)	75.6	75.5	85.0	81.7
Mothers whose menses returned (%) <sup>c</sup>	70.7 (n=802)	64.5 (n=600)	59.7 (n=2570)	61.1 (n=1463)
Mothers who are still breastfeeding (%) <sup>c</sup>	96.1 (n=802)	92.5 (n=601)	91.6 (n=2570)	92.4 (n=1463)

<sup>a</sup>Only changes of n > 5 for each category and study group are noted.

<sup>b</sup>Only mothers of children aged 9–12 months were eligible to participate in this study. The age of the child corresponds to the mother’s months post-partum. Age data were documented to the nearest whole month.

<sup>c</sup>Excludes pregnant women.

mothers in the control group had a higher parity than mothers in the intervention group. Characteristics of mothers in the post-test were similar to those in the baseline (data not shown).

No significant differences in changes from pre- to post-intervention in use of a non-condom, modern FP method were observed in the intervention group compared with the control in either country (Zambia, *P* = 0.56 and Ghana, *P* = 0.86; Table 2).

Based on the client report of receipt of a referral to FP from a vaccinator, referrals in the Ghana site increased in the control group compared with the intervention group. In Zambia, increases of reported referrals were observed in the intervention group compared with the control; but differences were not large (Table 3).

Table 2 Use of a non-condom modern family planning method

Country and method type	Control		Intervention		<i>P</i> *
	Pre-test	Post-test	Pre-test	Post-test	
Ghana					
<i>n</i>	833	801	646	482	0.86
Use of a non-condom modern method (%)	20.8	21.7	21.6	24.0	
Zambia					
<i>n</i>	2659	1092	1506	962	0.56
Use of a non-condom modern method (%)	31.7	35.8	41.3	49.4	

\**P* values obtained from the logistic mixed model fitted for each country.

Almost no women in Ghana or Zambia could name all three LAM criteria spontaneously at pre-test or at post-test (Table 4). Very few women could name two criteria, although at least 50% of women in every study group could name at least one of the criteria spontaneously. Of women naming one criterion, 'return of menses' was the most commonly identified; it was named by over 80% of these women (data not shown). Knowledge assessed by asking women to respond to specific questions about pregnancy risk before the onset of menses and while breastfeeding also showed no improvement (Table 4).

Eleven of 15 vaccinators in both intervention groups in Ghana and Zambia reported using the job-aid with all of their clients, and 9 out of 15 in each country felt they increased referrals made to FP services. In Zambia, 13 of 15 vaccinators reported providing information to clients in group settings as opposed to individually. The same was not noted in in-depth interviews in Ghana.

In the 'client post-test' questionnaires in Zambia, 32.7% of women in the intervention group reported receiving a referral. When the question was broadened to any FP discussion with a vaccinator, 85.6% indicated they had discussed FP with

a vaccinator. Among those reporting a referral or a discussion, only 12.1% in the intervention group received information or referrals individually; the rest received messages in a group.

## Discussion

It was hypothesized that the main barrier to FP use in the post-partum period was a misunderstanding of fecundity. The analysis did confirm that there is an over-reliance on menstruation as an indicator of fecundity. However, in response to the intervention, knowledge related to the three LAM criteria did not improve and neither did the percentage of women reporting referrals from vaccinators to FP. A major part of the theory behind the intervention design was never evaluated; it is still unclear whether a better understanding of fecundity could improve FP use among post-partum women.

It also remains unclear whether routine child immunization services are a suitable platform for the delivery of FP messages and services. The available process information, which included the interim assessment, in-depth interviews with vaccinators and the additional post-test data collected in Zambia, indicates incomplete implementation of the intervention. Although vaccinators reported using the job-aid and referring mothers to FP, it would appear that in Zambia, vaccinators generally delivered the messages in group settings and not individually. In Ghana, there is little evidence that the messages were consistently delivered to individuals or groups. Therefore, the intervention training and follow-up did not appear to change vaccinator behaviour as we intended, and subsequently the intervention was not implemented as planned.

This brings into question whether the intervention could have been implemented as designed. Providing individualized messages during child vaccinations may be too difficult in many developing country service delivery settings, which often do not

**Table 3** Client exposure to the intervention, receipt of referral and information about family planning services by study group

Referrals and information (%)	Control		Intervention	
	Pre-test	Post-test	Pre-test	Post-test
Ghana				
<i>n</i>	833	801	646	482
Ever received a referral to FP (%)	35.5	44.0	35.0	33.8
Zambia				
<i>n</i>	2658	1090	1505	962
Ever received a referral to FP (%)	31.8	25.9	26.3	32.7

**Table 4** Client knowledge of LAM criteria by study group<sup>a</sup>

Knowledge indicators (%)	Control		Intervention	
	Pre-test	Post-test	Pre-test	Post-test
Ghana				
<i>n</i>	827	793	638	470
Spontaneously identified all three LAM criteria (%)	0.7	0.4	0.3	0.4
Spontaneously identified two LAM criteria (%)	9.7	9.7	7.7	6.1
Spontaneously identified one LAM criteria (%)	60.2	68.1	69.9	64.3
Knows women can get pregnant before menses return (%)	61.5	59.6	58.8	56.4
Knows women can get pregnant while breastfeeding (%)	52.8	68.0	54.6	47.3
Zambia				
<i>n</i>	2566 <sup>b</sup>	1088	1423 <sup>b</sup>	961
Spontaneously identified all three LAM criteria (%)	0.1	0.7	0.0	0.3
Spontaneously identified two LAM criteria (%)	2.5	11.7	1.3	5.4
Spontaneously identified one LAM criteria (%)	70.8	53.0	65.5	46.0
Knows women can get pregnant before menses return (%)	52.7	46.0	51.9	56.9
Knows women can get pregnant while breastfeeding (%)	74.4	75.9	79.7	74.2

<sup>a</sup>Only changes of  $n > 5$  for each category and study group are noted.

<sup>b</sup>Cases where it was evident that a woman misunderstood the question by indicating a sign of pregnancy were excluded.

allow for more than a few minutes of one-on-one time between clients and vaccinators. This was understood when the intervention was designed, but this may have been a bigger limitation than anticipated.

Adding a staff member dedicated to FP would address this concern. If adding another provider is not realistic, it may be feasible to transfer other staff to the immunization service on days designated for child immunizations. Perhaps FP providers or community health workers could be assigned to work in immunization clinics to help generate demand for FP instead of vaccinators. However, inadequate staffing within many developing country health systems was one of the main reasons we did not increase or rearrange service delivery personnel. The FP integration activity we tested was added to the immunization services with minimal disruption; services were not re-organized to accommodate the new activity and no resources were added beyond the implementation costs, which included costs for training, job-aid printing and travel for supervision.

Assuming resources will continue to be a limiting factor for low- and middle-income country health systems, the main questions moving forward, and this research was not able to answer, relate to whether vaccinators can be more efficient, and if so, how they can be more efficient. Based on our experience working with immunization services, two possibilities seem plausible and may warrant further exploration.

First, it is conceivable that services could be organized differently to accommodate the addition of other interventions. The immunization services in many low-resource settings are similarly arranged; often occurring on 'immunization days' where activity is concentrated within a few hours on specific days of the week designated for child vaccination. If immunization activities were more evenly distributed throughout a given day or week, this might allow for more time for the delivery of other services.

Second, with greater health systems support around the implementation of the interventions, the changes in vaccinator behaviour we hoped to induce with our implementation plan might occur. A recent review of existing integrated programs classified integration across critical levels of the health system, which included stewardship and governance, financing, planning, service delivery, monitoring and evaluation systems and demand generation, and most integrated programs spanned more than one level (Atun *et al.* 2010). In contrast, our intervention sought only to achieve integration in the service delivery arena. Integration across other levels may be necessary to add new services the way we envisioned to create the vision, expectation and, perhaps most importantly, the accountability necessary for change. Vaccinators must understand new expectations and be supported and monitored in meeting them.

There are limitations of our research to consider. The selection of study sites within each country limits generalizability. Potential biases relate to differences in participation between study groups, which may account for the unexpected increase in reported referrals in the Ghana control group. In both countries, more women were sampled in the control groups than the intervention groups and at baseline compared with post-test. This likely resulted from variation in client load by

facility and the strike in Zambia. Finally, our data may be subject to reporting bias because it was based on self-report.

Despite recent enthusiasm about the potential benefits of integrated immunization services, rigorous evidence of its success in resource poor settings remains weak. To be successful, immunization services may need to be organized differently to allow for the addition of other interventions, and vaccinators may need greater support within the health system to perform new activities as designed.

## Ethical Clearance

The protocol was approved by the Protection of Human Subjects Committee, the Ghana Health Service Ethical Review Committee and ERES Converge in Zambia. Signed informed consent was obtained from all participants. The study was registered through ClinicalTrials.gov (ref NCT00949481).

## Funding

This work was supported by funding from the United States Agency for International Development (GPA-A-00-05-00022-00 and GPO-A-00-08-00001-00).

## Conflict of interest

None declared.

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