Ten Steps to Successful Breastfeeding programme to promote early initiation and exclusive breastfeeding in DR Congo: a cluster-randomised controlled trial

Marcel Yotebieng, Miriam Labbok, Heidi M Soeters, Jean Lambert Chalachala, Bruno Lapika, Bineti S Vitta, Frieda Behets

Summary

Background Optimisation of breastfeeding practices could reduce high mortality rates in children younger than 5 years, but in DR Congo, despite near-universal breastfeeding initiation and nine of ten children still breastfeeding at 1 year of age, exclusivity remains a difficulty. We assessed the effect on breastfeeding outcomes of a short-cut implementation of a programme called the Ten Steps to Successful Breastfeeding, the key component of the Baby-Friendly Hospital Initiative (BFHI).

Methods We did a cluster-randomised controlled trial and randomly assigned health-care clinics in Kinshasa, DR Congo, to standard care (control group), BFHI steps 1–9 (steps 1–9 group), or BFHI steps 1–9 plus additional support during well-child visits (steps 1–10 group) with computer-generated random numbers used to assign matched pairs to study groups. Mothers at these clinics who had given birth to one healthy baby during enrolment, and who expressed their intentions of visiting a well-baby session at the same clinic, were eligible and received the treatment assigned to their clinic. Mother–infant pairs were excluded if the mothers intended to attend well-baby clinic visits at a different health facility, or to travel before the child was aged at least 6 months. Participants and independent interviewers were masked to group assignment (ie, they were recruited after randomisaion and training of the clinic staff and were not informed of the study scheme), but clinical staff were unmasked. BFHI steps 1–9 and 1–10 were given by health-care staff trained with the WHO/UNICEF BFHI course. The primary outcomes were breastfeeding initiation within 1 h of birth and exclusive breastfeeding at age 14 and 24 weeks, assessed at face-to-face interviews in the clinic. Analysis was by intention to treat. Prevalence ratios (PR) were adjusted for cluster effects and baseline characteristics. This trial is registered at ClinicalTrials.gov, number NCT01428232, and is closed to new participants.

Findings Between May 24, and Aug 25, 2012, we randomly assigned two eligible clinics to control, two to BFHI steps 1–9, and two to BFHI steps 1–10. We enrolled 975 eligible mother–infant pairs (304 in the control group, 363 in the steps 1–9 group, and 308 in the steps 1–10 group). 230 (76%) of infants in the control group, 263 (72%) in the steps 1–9 group, and 220 (71%) in the steps 1–10 group were breastfed within 1 h of birth; these results did not differ significantly between groups. Prevalence of exclusive breastfeeding at age 14 weeks was 89 (29%) in the control group, 237 (65%) in the steps 1–9 group (adjusted PR 2·20, 95% CI 1·73–2·77), and 129 (42%) in the steps 1–10 group (1·40, 1·13–1·74). At age 24 weeks, the prevalence of exclusive breastfeeding was 36 (12%) in the control group, 131 (36%) in the steps 1–9 group (3·50, 2·76–4·43), and 43 (14%) in the steps 1–10 group (1·31, 0·91–1·89).

Interpretation In the setting of health-care clinics in DR Congo with a high proportion of mothers initiating breastfeeding, implementation of basic training in BFHI steps 1–9 had no additional effect on initiation of breastfeeding but significantly increased exclusive breastfeeding at 6 months of age. Additional support based on the same training materials and locally available breastfeeding support materials, offered during well-child visits (ie, step 10) did not enhance this effect, and might have actually lessened it.

Funding Bill & Melinda Gates Foundation and the Carolina Global Breastfeeding Initiative at the University of North Carolina (OH, USA).

Lancet Glob Health 2015; 3: e546–55

Published Online August 3, 2015 http://dx.doi.org/10.1016/S2214-109X(15)00012-1

See Editorial page e501

See Comment page e506

Ohio State University, College of Public Health, Division of Epidemiology, Columbus, OH, USA (M Yotebieng MD); **Department of Epidemiology** (M Yotebieng, H M Soeters PhD), **School of Medicine** (F Behets PhD), **and Carolina Global Breastfeeding Institute, Department of Maternal and Child Health** (M Labbok MD), **University of North Carolina at Chapel Hill, Chapel Hill, NC, USA; School of Public Health** (M Yotebieng, J L Chalachala MD) **and the Department of Anthropology** (B Lapika PhD), **University of Kinshasa, Kinshasa, DR Congo; and University of California at Davis, Department of Nutrition, Davis, CA, USA** (B S Vitta PhD)

Correspondence to:
Dr Marcel Yotebieng, Division of Epidemiology, College of Public Health, Ohio State University, Columbus, OH 43210, USA
yotebieng.2@osu.edu

Introduction

Democratic Republic of the Congo (DR Congo) is one of 13 countries that has had no progress towards Millennium Development Goal (MDG) 4, a reduction of mortality in children younger than 5 years by two-thirds by the year 2015.[1] DR Congo has the third largest burden of child deaths worldwide,[2] and mortality in children younger than 5 years has remained high: from 180 deaths of every 1000 livebirths in the year 1990 to 170 of 1000 livebirths in 2010. Additionally, of 116 per 1000 babies born alive in 2010 who survived through the first 28 days and subsequently died before their fifth birthday, 20 died from diarrhoea and 23 from pneumonia; only malaria claimed more lives of children younger than 5 years.[2] By 6 months of age, more than 10% of infants in this country are already stunted in growth, and 15% are underweight or emaciated.[3]

Research in context

Evidence before this study

The rationale for our investigation was based on a 2007 Cochrane review of 44 trials in 14 countries and a review by the US Agency for Healthcare Research and Quality, which both showed that all forms of extra support had a positive effect on the duration of exclusive breastfeeding, and that the treatment effect was greater when the intervention was delivered by non-professionals (lay support). But whether those findings were applicable in Africa was unclear because no study of healthy mothers from this region was included in the reviews. The Cochrane review was updated in 2011, but only two of the 52 studies included in the update were from low-income countries and only one was from Africa. In a study called PROMISE, undertaken in Burkina Faso, Uganda, and South Africa, breastfeeding counselling by peer counsellors (lay support) had a substantial positive effect on the prevalence of exclusive breastfeeding. On Jan 24, 2015, we searched PubMed for English-language publications with the terms "randomized control trial", "breastfeeding", and "promotion", and identified results from four trials that were reported since the updated Cochrane review published in 2011. Again, only one of those trials was done in Africa (Nigeria), which showed that monthly group counselling by trained peer educators (lay support) combined with text and voice messages sent every week had a positive effect on timely initiation of breastfeeding and on exclusive breastfeeding at 6 months. Additionally, diarrhoea and infections of the respiratory tract have been the most frequently reported child-health outcomes related to breastfeeding peer counselling. Five studies from the updated Cochrane review have reported about diarrhoea and two about infections of the respiratory tract. In each investigation, the number of babies with reported diarrhoea or infections was reduced in the intervention groups.

Added value of this study

A short-cut implementation of the Ten Steps to Successful Breastfeeding by training health personnel with the WHO/UNICEF training course in Democratic Republic of the Congo (DR Congo) resulted in effects similar to those noted from interventions with lay workers in previous studies. This low-intensity, non-technical intervention, which is very suitable for rapid scale-up, raised the prevalence of exclusive breastfeeding and decreased the rate of diarrhoea at age 6 months in our context of high breastfeeding initiation, and high prevalence of mortality in children younger than 5 years in DR Congo. However, additional support during well-child visits did not increase these effects, and might actually have lessened them.

Implications of all the available evidence

Although the scalability and cost-effectiveness of this short-cut implementation warrant further investigation, efforts should be renewed to provide health-care personnel with the appropriate skills they need to support optimum breastfeeding, especially in countries with a high prevalence of child mortality.

The predominant role of diarrhoea, pneumonia, and malaria in mortality and poor growth during the post-neonatal period, suggest suboptimum infant feeding practices. Best breastfeeding practices, including immediate post-partum initiation of skin-to-skin contact and breastfeeding within 1 h of birth, exclusive breastfeeding for 6 months,[4] and continuation of breastfeeding up to 24 months and beyond in accordance with age-appropriate feeding, have great potential for reducing mortality in children younger than 5 years.[5–7] In DR Congo, despite near-universal initiation of breastfeeding and nine of ten children still breastfeeding at age 1 year, poor exclusivity of breastfeeding remains a problem. National surveys show that in 2010, only 69% of babies aged 0–1 month and 35% of those aged 2–3 months (about 10–14 weeks) were exclusively breastfed.[8]

Since 1990, global initiatives to improve breastfeeding practices have focused on maternity-level policies and practices known as the Ten Steps to Successful Breastfeeding (panel),[9] which are the basis for the Baby-Friendly Hospital Initiative (BFHI).[10] However, successful implementation of BFHI resulting in certification is a challenge, and many countries in sub-Saharan Africa have not been able to scale it up nationwide. In DR Congo, UNICEF led the main attempt to implement BFHI in the early 2000s as part of a national campaign to promote breastfeeding. Overall, only 25 health facilities in DR Congo, including 13 in the capital Kinshasa, of more than 6000 eligible health facilities were certified through this effort. The need for additional resources to organise the external assessment needed for certification and to set up and run community support groups (one approach to step 10 in the initiative) represent major barriers.

Whether a short-cut (without accreditation) implementation of the ten steps that can be more easily scaled up would be as effective in improving the proportion of infants that are exclusively breastfed through 6 months of age, in the context of high breastfeeding initiation, needs to be tested. In DR Congo, despite challenges in accessing health care, data from the 2007 Demographic and Health Survey[3] showed that 85% of pregnant women attended at least one antenatal visit in DR Congo, 70% of livebirths happened in a health-care facility (97% in Kinshasa); and 71%, 59%, and 45% of children received the first, second, and third doses, respectively, of the diphtheria, tetanus, and pertussis vaccine according to WHO's immunisation schedule[11] at age 6, 10, and 14 weeks during well-child clinic visits. These data suggest that, if empowered with more knowledge and skills, health-care staff in well-child clinics could counsel mothers to continue exclusive breastfeeding and to manage breastfeeding difficulties, which could thus

serve as an easy-to-implement alternative for step 10 of the BFHI.

The objectives of our study were therefore to compare against standard of care the effectiveness of implementation of steps 1–9 and steps 1–10 (additional breastfeeding support provided during well-child clinic visits), of the BFHI on initiation and exclusivity of breastfeeding in a health-care setting in DR Congo.

Methods

Study design and participants

We did a cluster-randomised controlled trial, with health-care facilities as the unit of randomisation, in Kinshasa, DR Congo. We selected six health facilities from a network of 44 that, at the time, were being supported by the University of North Carolina at Chapel Hill and Kinshasa School of Public Health partnership to implement activities to prevent mother-to-child transmission of HIV. To inform the selection, study staff (two medical doctors) visited all 44 facilities between October, and November, 2011, and collected information about factors that might affect the quality of care provided in each facility, including the type of management, location, number of deliveries, number and type of personnel, presence of a separate well-child clinic and a maternity clinic, and proportion of mothers who return for the 1 week post-partum visit. Health-care facilities were then stratified by location (urban or periurban) and type of management (government, confessional, or private for-profit). Government and private for-profit health facilities were excluded because they were almost all exclusively located in the urban area. Within each stratum, facilities were sorted by the number of deliveries and the proportion of mothers returning for the 1 week post-partum visit and matched across strata for the average workload (number of deliveries divided by number of personnel). Three pairs of facilities with relatively similar workloads, number of deliveries per month, and proportion of mothers returning for the 1 week visit were selected. This selection scheme was chosen to ensure, for example, that health-care facilities at the centre of the city, which might have lower patient volumes and more patients with a higher socioeconomic status than facilities in periurban areas, were included in the final sample while reducing the overall heterogeneity among the selected facilities.

All mothers who gave birth to one healthy child in one of the participating facilities between May 24, and Aug 25, 2012 and who intended to attend well-baby clinic visits in the same facility were eligible. Mother–infant pairs were excluded if they intended to attend well-baby clinic visits in a different health facility, or to travel before the child was aged at least 6 months. To recruit suitable participants, we approached eligible mothers in the post-partum wards of each participating clinic 1–2 days after delivery, and invited them to participate in our study. All participants provided written informed consent. The study was approved by the Institutional Review Board of the University of North Carolina at Chapel Hill and the Ethical Committee of the Kinshasa School of Public Health.

Panel: **Ten Steps to Successful Breastfeeding**

The Ten Steps to support successful breastfeeding serve as the basis for the Baby-Friendly Hospital Initiative. The steps are:

1. Having a written breastfeeding policy that is routinely communicated to all health-care staff
2. Training all health-care staff in skills necessary to implement this policy
3. Informing all pregnant women about the benefits and management of breastfeeding
4. Helping mothers to initiate breastfeeding within 30 min of birth
5. Showing mothers how to breastfeed and maintain lactation, even if they are separated from their infants
6. Giving newborn infants no food or drink other than breastmilk, unless medically indicated, and not accepting free or low-cost breastmilk substitutes, feeding bottles, or teats
7. Allowing mothers and infants to remain together 24 h per day
8. Encouraging breastfeeding on demand
9. Giving no artificial teats or pacifiers to breastfeeding infants
10. Fostering the establishment of breastfeeding support groups and referring mothers to them on discharge from a hospital or clinic

Additional material on the Baby-Friendly Hospital Initiative can be accessed on the UNICEF website.

For more on the **Baby-Friendly Hospital Initiative** see http://www.unicef.org/programme/breastfeeding/baby.htm

Randomisation and masking

The three pairs of facilities were ranked alphabetically and a computer was used to generate three random numbers. The randomisation was done by the study statisticians who had no involvement in enrolment or follow-up of participants. A priori, the pair with the highest number was assigned to the standard of care (control group), the second to the implementation of BFHI steps 1–9 alone (steps 1–9 group), and the last pair with the lowest number to the implementation of BFHI steps 1–9 plus additional support provided in well-child clinics (steps 1–10 group). We assigned the facilities rather than mother–infant pairs to minimise the potential for contamination between groups and to mimic the real-world implementation of the intervention.

Staff in participating clinics could not be masked to the interventions or to group assignments because of the nature of the interventions. However, independent interviewers and mothers were masked to group assignment, because they were recruited after randomisation and training of clinic staff, and were also not informed of the study scheme. The masking worked quite well for the mothers, but not so well for the interviewers.

For the **study protocol** see http://cph.osu.edu/sites/default/files/biopage/docs/DRC_Promotion_and_Support_of_Exclusive_Breastfeeding_6_Months_May_18_11.docx

Procedures

For implementation of steps 1–9 in clinics randomly assigned to the steps 1–9 and 1–10 groups, we trained health-care staff from antenatal and maternity care (ie, delivery rooms and post-partum wards) in the intervention facilities using the WHO/UNICEF course[12] (for more detail of training, see appendix). No organised breastfeeding support system, whether informal or formal, where mothers can be referred to get support when needed, is available in Kinshasa. Therefore Session 14 of the training on "Ongoing support for mothers" was limited only to "Describe how to prepare a mother for discharge". Session 15 on "Making your hospital baby-friendly" was not covered. For facilities in the steps 1–10 group, staff from well-child clinics also received the same training. Although the development of community groups where women could be referred for support after discharge from the postpartum ward was not fostered, the well-baby clinic and its trained staff was to serve as a clinic-based alternative. Additionally, for the steps 1–10 facilities, we distributed flyers containing locally developed materials with culturally appropriate messages addressing behaviours identified in a pretrial survey as the main contributors to suboptimum breastfeeding practices (such as giving the baby water in the first 6 months of life), in French (the official language of DR Congo) and Lingala (the main spoken language in Kinshasa) to mothers before discharge from the post-partum ward and during well-child clinic visits. We also provided additional material in French developed in part by the Linkages project[13–15] to staff in clinics randomly assigned to intervention groups (table 1). Implementation of steps 1–9 was assessed at the end of the study using the hospital self-appraisal questionnaire and each of the clinics randomised to intervention groups met at least 80% of the global criteria for each step. In facilities randomly assigned to standard of care, besides a briefing before randomisation, nothing else was provided. A detailed description of the standard of care in those facilities is reported elsewhere.[16]

We obtained outcome information through face-to-face interviews at enrolment (in the post-partum ward 2–3 days after birth), age 1 week (at the post-partum clinic visit), and age 6, 10, 14, 18, and 24 weeks (at well-child visits). In addition to sociodemographic characteristics of the mother–infant pair that we obtained at enrolment, we assessed infant feeding practices at each timepoint, and asked mothers whether their infant had had any diarrhoea, fever, or cough since the last interview. For mother–infant pairs who did not return for a visit, interviewers traced them and visited them at home, interviewing them within 2 weeks of the missed visit. We double-entered questionnaire data for assessment and regularly compared them, to correct for inconsistencies.

Outcomes

We assessed two coprimary outcomes: the proportion of mothers who initiated breastfeeding within 1 h of birth and the prevalence of exclusive breastfeeding at 14 and 24 weeks post partum. WHO definitions[17] and two timeframes (the past 24 h and past 7 days) were used for maternal recall of exclusive breastfeeding. We also assessed two secondary outcomes: the prevalence of infants with reported diarrhoea and the prevalence with reported respiratory illness (fever with cough) between 10 and 14 weeks and between 18 and 24 weeks post partum.

Statistical analysis

We calculated sample sizes for exclusive breastfeeding at age 14 and 24 weeks. We assumed a coefficient of

	Where or to whom intervention was delivered		
	Standard of care group	Steps 1–9 group	Steps 1–10 group
Training			
Staff were taken away from their clinic for 2 days' intensive (16 h) didactic training using the WHO/UNICEF BFHI course. During the month that followed the training, study personnel visited each clinic at least once a week to observe the trainees practise in real life conditions. At the end of each visit, a group and individual debriefing was held to provide both collective and individual feedback.	None	ANC clinic staff Delivery room staff Post-partum ward staff	ANC clinic staff Delivery room staff Post-partum ward staff Well-baby clinic staff
Documentation			
Materials in French developed in part by the Linkages project for clinic staff	None	ANC clinics Delivery room Post-partum ward	ANC clinics Delivery room Post-partum ward Well-baby clinic
Flyers containing culturally appropriate messages addressing behaviours identified in a pretrial survey as main contributors to sub-optimal breastfeeding practices, in French (official language) and Lingala (main spoken language in Kinshasa) to mothers	None	None	Postpartum ward Well-baby clinic
Community support			
Referral for any breastfeeding support after discharge from post-partum ward	None	None	None

BFHI=Baby-Friendly Hospital Initiative. ANC=antenatal care.

Table 1: **Interventions by study group**

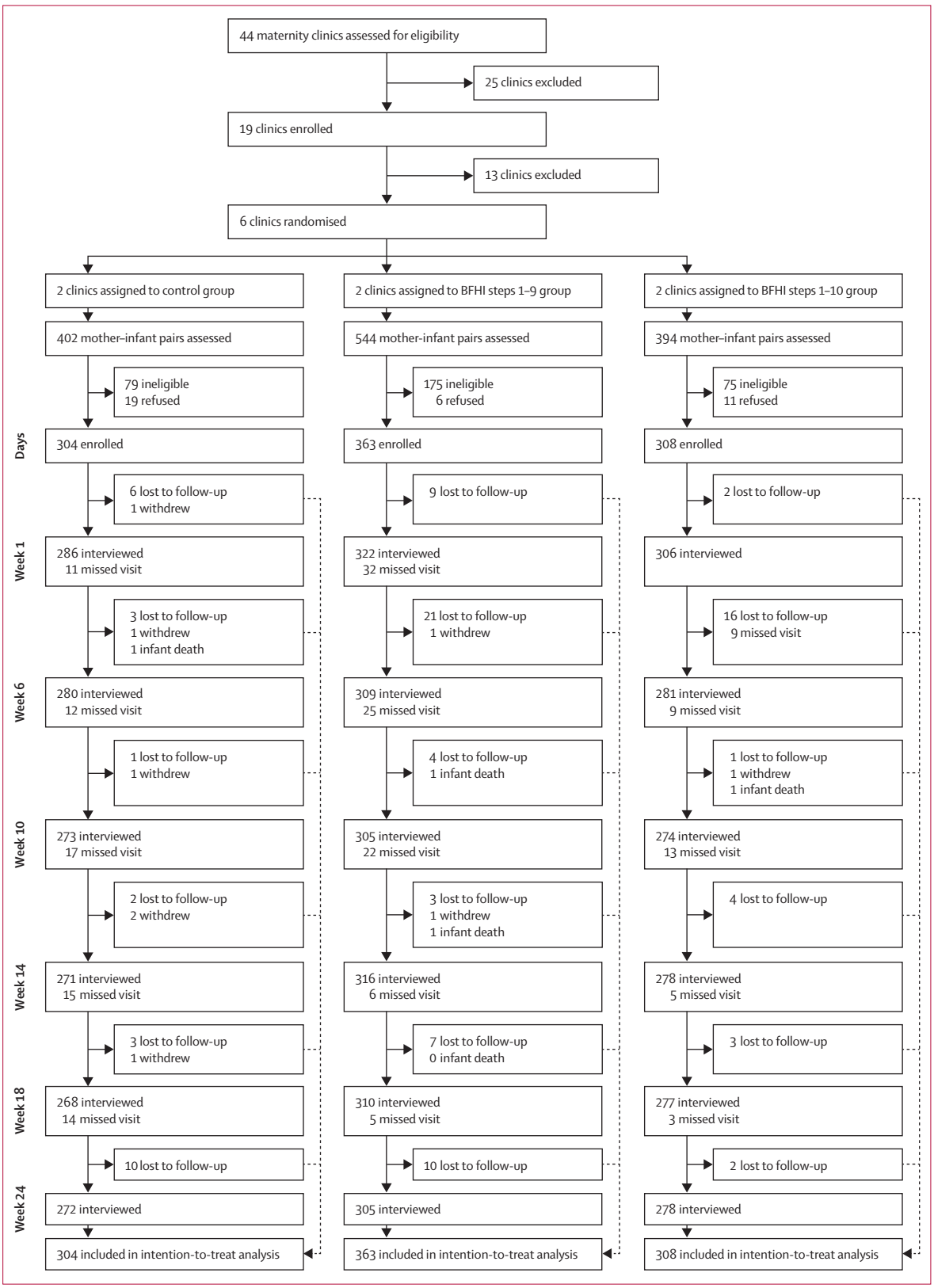

Figure: **Trial profile**
BFHI=Baby-Friendly Health Initiative.

	Overall (975 [100%])	Control (304 [31%])	BFHI steps 1–9 (363 [37%])	BFHI steps 1–10 (308 [32%])
Age (years)	27 (23–32)	28 (24–33)	26 (23–32)	26 (22–31)
Marital status				
Married/live-in boyfriend	847 (87%)	269 (88%)	322 (89%)	256 (83%)
Never married/separated/divorced	127 (13%)	35 (12%)	41 (11%)	51 (17%)
Education (years)	10 (8–12)	11 (8–12)	9 (7–12)	10 (8–12)
Owns the house where she lives?				
Yes	415 (43%)	146 (48%)	130 (36%)	139 (45%)
No	557 (57%)	158 (52%)	230 (63%)	169 (55%)
Electricity in house?*				
Yes	917 (94%)	279 (92%)	346 (95%)	292 (95%)
No	58 (6%)	25 (8%)	17 (5%)	16 (5%)
Water source*				
Piped yard or home	852 (87%)	246 (81%)	318 (87%)	288 (94%)
Borehole/tap/surface water	122 (13%)	58 (19%)	45 (13%)	19 (6%)
Type of toilet*				
Flush	418 (43%)	81 (27%)	179 (49%)	158 (51%)
Pit/open/none	557 (57%)	223 (73%)	184 (51%)	150 (49%)
Parity				
Primiparous women	238 (24%)	81 (27%)	78 (21%)	79 (26%)
Multiparous women	737 (76%)	223 (73%)	285 (79%)	229 (74%)
Previously had a child who died?				
Yes	191 (20%)	67 (22%)	78 (21%)	46 (15%)
No	784 (80%)	237 (78%)	285 (79%)	262 (85%)
Place of attendance of antenatal clinic visit				
Facility	888 (91%)	278 (91%)	329 (91%)	281 (91%)
Outside facility	80 (8%)	24 (8%)	29 (8%)	27 (9%)
No antenatal care	7 (<1%)	2 (<1%)	5 (1%)	0
Antenatal care visits				
<4	464 (48%)	91 (30%)	194 (53%)	179 (58%)
≥4	511 (52%)	213 (70%)	169 (47%)	129 (42%)

Data are mean (%) or median (IQR). *Type of toilet, electricity in the house, and water sources were highly correlated. Thus, of these three categories, only type of toilet was included in the adjusted models. Not all variables were available for each mother–infant pair.

Table 2: **Demographic characteristics of mothers at enrolment**

variation of 25% and a 15% prevalence of exclusive breastfeeding in the control group at 6 months, and calculated that a minimum of two clusters with 150 mother–infant pairs per group was needed to detect a minimum increase of 20% compared with standard of care with 90% power (appendix).

See Online for appendix

We did an intention-to-treat analysis that included all mother–infant pairs irrespective of whether or not they continued to visit the facility after enrolment and for which all missing information was set to non-event (not exclusive breastfeeding, not having diarrhoea or respiratory infection) whatever the reason for missing information (eg, death of the baby or mother, loss to follow-up, or missed visit); a complete-case analysis with data restricted to participants with available information; and a per-protocol analysis restricted to participants who attended the clinic for a particular visit (because to receive the intervention, the mother had to attend the clinic), thus excluding data from mothers who were interviewed at home.

We entered questionnaire data into the Epi Info program. All analyses were done with SAS 9.3 (SAS Institute, Cary, NC, USA). We used generalised estimating equations and log-binomial models to estimate the prevalence ratios (PR) and 95% CIs, comparing intervention groups with the control group while accounting for clustering. We adjusted final results for any maternal baseline characteristic that was imbalanced between groups.

This trial is registered at ClinicalTrials.gov, number NCT01428232.

Role of the funding source

The funders of the study had no role in 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 randomly assigned six eligible clinics to treatment groups (of 44 assessed); 975 mother–infant pairs (of 1340 assessed) were enrolled in the study and received treatment according to the clinic they were in (304 to control, 363 to steps 1–9, and 308 to steps 1–10). 855 pairs completed the 24-week interview (figure). Few imbalances in baseline characteristics were noted between the intervention and control groups. Mothers in the control group were slightly older and more likely to have attended at least four antenatal visits compared with mothers in the two intervention groups (table 2). Most participants in each group missed no more than one follow-up visit (figure 1). Except for week 1 post partum, when attendance was lower in the control group, attendance was consistently higher in the control group than in the intervention groups throughout the study. This difference was significant only at the week 6 visit when 77% (control), 63% (steps 1–9), and 70% (steps 1–10) of participants returned to their respective health facility for well-child services (appendix). Baseline characteristics did not differ between mother–infant pairs who attended follow-up visits and those who did not.

In the intention-to-treat analysis, the proportions of children breastfed within 1 h of birth in the intervention groups were not significantly different from those of the control group: 230 (76%) of infants in the control group, 263 (72%) who received steps 1–9, and 220 (71%) who received steps 1–10 (table 3). However, the prevalence of exclusive breastfeeding at age 14 weeks, calculated on the basis of 24 h recall, was more than twice as high in the steps 1–9 group than in the control group, and 1·5 times higher in the steps 1–10 group than in control (table 3). The prevalence of exclusive breastfeeding at age 24 weeks, calculated on the basis of 24 h recall, was about three times higher in group 1 than in the control group, but not significantly different from control in the steps

	Control	BFHI steps 1–9			BFHI steps 1–10		
	n/N (%)	n/N (%)	Crude prevalence ratio (95% CI)*	Adjusted prevalence ratio (95% CI)*†	n/N (%)	Crude prevalence ratio (95% CI)*	Adjusted prevalence ratio (95% CI)*†
Intention-to-treat analysis‡							
Initiation of breastfeeding within 1 h	230/304 (76%)	263/363 (72%)	0·99 (0·78–1·26)	1·01 (0·79–1·30)	220/308 (71%)	0·95 (0·71–1·28)	0·98 (0·73–1·32)
Exclusive breastfeeding at 14 weeks							
24 h recall	89/304 (29%)	237/363 (65%)	2·23 (1·79–2·75)	2·20 (1·73–2·77)	129/308 (42%)	1·46 (1·19–1·78)	1·40 (1·13–1·74)
7 day recall	78/304 (26%)	231/363 (64%)	2·45 (1·93–3·10)	2·46 (1·91–3·18)	126/308 (41%)	1·60 (1·28–2·01)	1·51 (1·14–1·99)
Exclusive breastfeeding at 24 weeks							
24 h recall	36/304 (12%)	131/363 (36%)	3·08 (2·39–3·97)	3·50 (2·76–4·43)	43/308 (14%)	1·17 (0·79–1·74)	1·31 (0·91–1·89)
7 day recall	35/304 (12%)	129/363 (36%)	3·14 (2·20–4·50)	3·65 (2·64–5·05)	42/308 (14%)	1·19 (0·79–1·79)	1·36 (0·95–1·95)
Complete-case analysis§							
Initiation of breastfeeding within 1 h	230/304 (76%)	263/363 (72%)	0·99 (0·78–1·26)	1·01 (0·79–1·30)	220/308 (71%)	0·95 (0·71–1·28)	0·98 (0·73–1·32)
Exclusive breastfeeding at 14 weeks							
24 h recall	89/256 (35%)	237/315 (75%)	2·14 (1·81–2·54)	2·12 (1·78–2·52)	129/276 (47%)	1·36 (1·12–1·65)	1·33 (1·07–1·64)
7 day recall	78/268 (29%)	231/312 (74%)	2·48 (1·95–3·17)	2·44 (1·87–3·20)	126/276 (46%)	1·55 (1·21–2·00)	1·51 (1·14–2·01)
Exclusive breastfeeding at 24 weeks							
24 h recall	36/255 (14%)	131/300 (44%)	3·01 (2·05–4·41)	3·13 (2·29–4·28)	43/276 (16%)	1·10 (0·68–1·79)	1·20 (0·71–1·89)
7 day recall	35/269 (13%)	129/304 (42%)	3·14 (1·94, 5·09)	3·35 (2·23, 5·02)	42/276 (15%)	1·15 (0·68, 1·93)	1·27 (0·79, 2·01)
Per-protocol analysis¶							
Initiation of breastfeeding within 1 h	230/304 (76%)	263/363 (72%)	0·99 (0·78–1·26)	1·01 (0·79–1·30)	220/308 (71%)	0·95 (0·71–1·28)	0·98 (0·73–1·32)
Exclusive breastfeeding at 14 weeks							
24 h recall	82/218 (38%)	207/272 (76%)	2·03 (1·82–2·25)	2·01 (1·84–2·20)	117/226 (52%)	1·38 (1·19–1·61)	1·36 (1·15–1·62)
7 day recall	72/228 (32%)	201/269 (75%)	2·38 (2·17–2·60)	2·35 (2·20–2·51)	114/226 (50%)	1·59 (1·41–1·79)	1·56 (1·39–1·76)
Exclusive breastfeeding at 24 weeks							
24 h recall	31/188 (16%)	113/219 (52%)	3·34 (2·98–3·74)	3·85 (3·14–4·72)	38/187 (20%)	1·22 (1·01–1·48)	1·41 (1·09–1·83)
7 day recall	31/199 (16%)	111/220 (50%)	3·61 (3·05–4·26)	4·16 (3·14–5·51)	37/186 (20%)	1·37 (1·13–1·66)	1·59 (1·19–2·12)

*For all 95% CIs, generalised estimating equations were used to account for clustering. †Adjusted for mother's age, maternal education, ownership of the house in which they live, type of toilet, having had a previous child who died, and the number of visits to an antenatal clinic made before delivery. ‡The main assumption especially for steps 1–10 was that mothers would return to the facility for their well-child visit. Therefore, for the intention-to-treat analysis, all missing outcomes were treated as a failure (ie, not exclusively breastfeeding). §For the complete-case analysis, only individuals with outcome data available were included. ¶For the per-protocol analysis, only participants who returned for the scheduled visit to a well-child clinic were included.

Table 3: **Primary outcomes**

1–10 group (table 3). 7 day recall raised the estimated PRs, but not substantially (table 3).

The prevalence of diarrhoea at age 14 weeks was similar between the control and steps 1–9 groups, but significantly higher than control in the steps 1–10 group. Prevalence increased between week 14 and week 24 in all groups, but was significantly lower than control in the steps 1–9 group and significantly higher than control in the steps 1–10 group (table 4). No significant differences between groups were noted in the prevalence of reported respiratory infections (fever with cough) at age 14 or 24 weeks (table 4).

In the complete-case analysis with only available information, similar results were obtained for each of the outcomes (table 4). As expected, restriction of the analysis to participants who attended the clinic visit in the per-protocol analysis resulted in stronger effects and the PRs for exclusive breastfeeding at 24 weeks in the steps 1–10 group versus control became significant (table 3). Additional results for each timepoint when the outcomes were assessed and the calculated intraclass correlation coefficients are in the appendix.

Discussion

Overall, our results show that provision of training in the Ten Steps to Successful Breastfeeding for health professionals is an effective strategy to enhance the practice of exclusive breastfeeding, even in settings with high breastfeeding initiation such as DR Congo. The intervention was also associated with a significantly reduced prevalence of diarrhoea in the infants by age 24 weeks. However, the combination of this intervention with training of staff at well-child clinics and provision of educational flyers (the steps 1–10 group) did not increase the effect in this setting and actually seemed to lessen the effect of the training, resulting in a smaller effect than the implementation of steps 1–9 alone.

Findings from a systematic review and meta-analysis[18] of breastfeeding support show that training health-care professionals with the WHO BFHI course raised the prevalence of exclusive breastfeeding compared with a control group. However, none of the studies in the meta-analysis included specific additional training for the clinic visits or were from the African region. Implementation of steps 1–9 in our investigation tripled the prevalence of

	Control	BFHI steps 1–9			BFHI steps 1–10		
	n/N (%)	n/N (%)	Crude prevalence ratio (95% CI)*	Adjusted prevalence ratio (95% CI)*†	n/N (%)	Crude prevalence ratio (95% CI)*	Adjusted prevalence ratio (95% CI)*†
Intention-to-treat analysis‡							
At age 14 weeks							
Diarrhoea since last visit	14/304 (5%)	18/363 (5%)	1·01 (0·59–1·70)	1·03 (0·63–1·67)	27/308 (9%)	1·72 (1·04–2·83)	1·57 (0·95–2·62)
Fever with cough	36/304 (12%)	20/363 (6%)	0·51 (0·19–1·36)	0·66 (0·31–1·40)	21/308 (7%)	0·60 (0·21–1·71)	0·72 (0·34–1·54)
At age 24 weeks							
Diarrhoea since last visit	45/304 (15%)	28/363 (8%)	0·52 (0·32–0·84)	0·50 (0·34–0·73)	56/308 (18%)	1·23 (0·88–1·71)	1·23 (1·03–1·46)
Fever with cough	70/304 (23%)	47/363 (13%)	0·60 (0·30–1·18)	0·84 (0·43–1·62)	67/308 (22%)	1·03 (0·66–1·59)	1·16 (0·71–1·88)
Complete-case analysis§							
At age 14 weeks							
Diarrhoea since last visit	14/271 (5%)	18/315 (6%)	1·02 (0·61–1·70)	1·05 (0·67–1·64)	27/277 (10%)	1·70 (1·09–2·64)	1·58(0·98–2·56)
Fever with cough	36/271 (13%)	20/315 (6%)	0·54 (0·20–1·41)	0·73 (0·34–1·54)	21/278 (8%)	0·60 (0·21–1·68)	0·73 (0·35–1·52)
At age 24 weeks							
Diarrhoea since last visit	45/271 (17%)	28/304 (9%)	0·54 (0·37–0·78)	0·53 (0·40–0·71)	56/278 (20%)	1·19 (0·96–1·48)	1·21 (1·12–1·30)
Fever with cough	70/272 (26%)	47/305 (15%)	0·62 (0·34–1·14)	0·62 (0·35–1·11)	67/278 (24%)	1·01 (0·68–1·50)	1·03 (0·67–1·59)
Per-protocol analysis¶							
At age 14 weeks							
Diarrhoea since last visit	7/231 (3%)	17/272 (6%)	1·99 (0·76–5·18)	2·16 (0·84–5·54)	18/227 (8%)	2·50 (0·93–6·70)	2·46 (0·89–6·74)
Fever with cough	27/231 (12%)	20/272 (7%)	0·68 (0·28–1·64)	0·88 (0·47–1·67)	17/228 (7%)	0·65 (0·24–1·80)	0·83 (0·45–1·56)
At age 24 weeks							
Diarrhoea since last visit	37/201 (18%)	24/220 (11%)	0·56 (0·43–0·73)	0·63 (0·50–0·79)	39/188 (21%)	1·12 (1·04–1·21)	1·17 (1·07–1·27)
Fever with cough	52/202 (26%)	45/220 (20%)	0·84 (0·45–1·58)	0·84 (0·43–1·62)	51/188 (27%)	1·11 (0·74–1·66)	1·16 (0·71–1·88)

*For all 95% CIs, generalised estimating equations were used to account for clustering. †Adjusted for mother's age, maternal education, ownership of the house in which they live, type of toilet, having had a previous child who died, and the number of visits made to an antenatal clinic before delivery. ‡The main assumption especially for steps 1–10 was that mothers would return to the facility for their well-child visit. Therefore, in the intention-to-treat analysis, all missing outcomes were treated as a failure (ie, not exclusively breastfeeding). §For the complete-case analysis, only individuals with outcome data available were included. ¶For the per-protocol analysis, only participants who returned for the scheduled visit to the well-child clinic were included.

Table 4: **Secondary outcomes**

exclusive breastfeeding at age 6 months (24 weeks) compared with the control group (36% *vs* 12%). A similar effect was shown in PROMISE,[19] a large community trial of promotion of exclusive breastfeeding in three sub-Saharan African countries, in which individual peer counselling resulted in a prevalence, based on 24 h recall at age 24 weeks, of 73% in the intervention group versus 22% in the control group (PR 3·33 [95% CI 1·74–6·38]) in Burkina Faso and 59% versus 15% (3·83 [2·97–4·95]) in Uganda. The consistency of the results between the two studies suggest that, in settings with high breastfeeding initiation, the provision of quality breastfeeding support to mothers in clinical settings might be as effective as the provision of community support through peer counselling.

Although the prevalence of exclusive breastfeeding in our study was similar in both intervention groups at 1 h after birth, by the age of 24 weeks, it had reduced by about 29 percentage points in the steps 1–10 group, compared with 7 percentage points in the steps 1–9 group, suggesting that the addition of educational flyers starting at maternity discharge and training staff in the ten steps for well-child clinic settings might have produced an effect opposite to what was postulated (ie, they discouraged continuation of breastfeeding rather than encouraging it). The motivation behind the distribution of flyers was to engage family members to support optimum breastfeeding and tackle the social customs that might encourage some suboptimum practices.[16] The lower prevalence of exclusive breastfeeding in the steps 1–10 group suggest that the materials used might not have provided the accurate or necessary messages for this setting, or that engagement of family members might have led to misunderstandings or incorrect advice that were not sufficiently countered by group counselling from nurses during well-child visits. This theory is at least partly evident because the PRs comparing the steps 1–10 and control groups at 6 months was larger and significant when the analysis was restricted to mother–infant pairs who attended well-child clinics. Good breastfeeding practices might also have been inappropriately changed by engaged family members in the steps 1–10 group. Similar antagonistic effects of combined interventions have been previously reported.[18] For instance, results of subanalyses in the meta-analysis[18] show that the combination of support from both lay people and professionals had a weaker effect than support provided by lay workers alone in this setting. However, in other settings, studies clearly show that support by a well trained professional during the post-partum weeks has a significantly more profound effect

on post-partum practices than support from a lay counsellor.[20] Furthermore, a study in Australia, where similarly most women initiate breastfeeding, showed that the practices, rather than the BFHI designation per se, were associated with improvements, as did a US study in several non-designated hospitals where a lower percentage initiated breastfeeding.[21,22]

Another possible explanation is that the WHO materials are designed to promote initiation of breastfeeding, rather than to address common difficulties with breastfeeding that occur in later weeks and months. If the clinic staff tried to use the interventions designed for newborn babies at these later ages, without the ability to address breastfeeding issues for mothers of older children, this might have led to inappropriate advice being offered by well meaning clinicians.

Our results show that receiving antenatal, labour, and delivery care, and immediate post-partum care from health professionals who had received the training was associated with a significant rise in optimum breastfeeding and associated with a significant reduction in diarrhoea at 24 weeks compared with standard of care. The PROBIT study,[23] done in Belarus with a similar ten-step approach, showed that infants from the intervention sites who were more likely to be exclusively breastfed at 3 months and 6 months, had a significant reduction in the risk of one or more infections of the gastrointestinal tract, but no significant reduction in infections of the respiratory tract, similar to our investigation. Moreover, a review published in 2010[24] identified five randomised trials in which prevalence or incidence of diarrhoea was reduced by promotion of exclusive breastfeeding.

The DR Congo context is important in understanding our results. In DR Congo, free formula milk is not provided through the national health-care system and breastfeeding is almost universally initiated.[8] In a pre-trial survey of the participating facilities,[16] we showed that water supplementation was a major contributor to the high rates of non-exclusive breastfeeding, a result of mothers not fully knowing either the quality of breastmilk or the recommended duration of exclusive breastfeeding. Hospital practices such as systematic provision of sugar water in the first hours after birth were also shown to contribute to low rates of exclusive breastfeeding and were a result of health-care professionals who did not have formal training in breastfeeding support.[16] The practice of supplementing breastfed infants with water in an environment where only 23% of the urban population has access to improved sanitation facilities and less than 50% to improved sources of drinking water could account for some of the increased risk of diarrhoea.[25]

Despite being a randomised trial, we could only afford to study a few health facilities; therefore, groups might not be fully similar. However, our adjustments for baseline characteristics did not change any of our results substantially, and any change mainly strengthened the unadjusted effect. Despite the use of independent interviewers, the facility-based approach could possibly have resulted in the self-report of socially desirable answers. A bias towards desirable answers and thereby an enhanced effect size cannot be ruled out. However, the large effects on reported exclusive breastfeeding are unlikely to be attributable to information bias alone.

Implementation of BFHI steps 1–9 by training health personnel with the WHO/UNICEF training course—a fairly low-intensity low-tech intervention which is very suitable for rapid scale-up in maternity settings—significantly raised the proportion of infants exclusively breastfeeding at age 6 months and decreased diarrhoea prevalence by half at this age. The large-scale implementation of steps 1–9 in similar settings could help to quickly reduce mortality in children younger than 5 years and increase the likelihood of meeting MDG 4.

Contributors

MY, FB, BL, and ML designed the study. MY and JLC obtained the data. MY and HMS analysed the data and wrote the report. HMS created the figures. MY, FB, BL, ML, and BSV interpreted the data.

Declaration of interests

We declare no competing interests.

Acknowledgments

This study was supported by a grant from the Bill & Melinda Gates Foundation to FHI 360, through the Alive and Thrive Small Grants Programme (University of California, Davis, CA, USA) via a subaward to the University of North Carolina (OH, USA; subagreement 09-000076-AT11-123-UNC-DRC). BL was supported by the Carolina Global Breastfeeding Institute Endowment at the University of North Carolina. Partial funding for Open Access was provided by the Ohio State University Open Access Fund. We thank the study mothers and infants for their participation and time; personnel of the participating clinics for their time and effort; Aimee Lulebo, Bienvenu Kawende, Dinah Kayembe, Landry Kiketa, Kathryn Salisbury, and Deidre Thompson for technical support; Clever Akili, Dyna Anambatu, Valerie Chalachala, Marie Dauly, Dydy Kayembe, Mamie Lulebo, Fanny Matadi, Myriam Mbonze, Espérance Mindia, Sarah Mushiya, Gisèle Mvumbi, Dodo Mwela, Jolly Ntirume, and Ros Samba for data collection and data entry contributions; University of North Carolina, Kinshasa School of Public Health, and the Alive and Thrive administrative teams for administrative support; and the Alive and Thrive technical advisory group for helpful advice.

References

1 UN Interagency Group for Child Mortality Estimation. Levels and trends in child mortality, 2011. New York: United Nations International Children's Emergency Fund, 2011.

2 Liu L, Johnson HL, Cousens S, et al. Global, regional, and national causes of child mortality: an updated systematic analysis for 2010 with time trends since 2000. *Lancet* 2012; **379:** 2151–61.

3 Ministère du Plan avec la collaboration du Ministère de la Santé Kinshasa RDdCaMIIC final report, 2007. Democratic Republic of the Congo: DHS, 2008 (in French).

4 WHO. Global strategy for infant and young child feeding: the optimal duration of exclusive breastfeeding. 2001. http://apps.who.int/gb/archive/pdf_files/WHA54/ea54id4.pdf (accessed Sept 1, 2010).

5 Bhutta ZA, Ahmed T, Black RE, et al. What works? Interventions for maternal and child undernutrition and survival. *Lancet* 2008; **371:** 417–40.

6 Jones G, Steketee RW, Black RE, Bhutta ZA, Morris SS. How many child deaths can we prevent this year? *Lancet* 2003; **362:** 65–71.

7 Edmond KM, Zandoh C, Quigley MA, Amenga-Etego S, Owusu-Agyei S, Kirkwood BR. Delayed breastfeeding initiation increases risk of neonatal mortality. *Pediatrics* 2006; **117:** e380–86.

8 Ministere du Plan, Institut National de la Statistique, UNICEF. Enquete par grappes a indicateurs multiples–RDC 2010: resultat preliminaires. 2010. http://www.childinfo.org/files/MICS_RDC_2010.pdf (accessed Jan 24, 2012 [in French]).

9 WHO/UNICEF. Protecting, promoting and supporting breast-feeding: the special role of maternity services–a joint WHO/UNICEF statement. Geneva: World Health Organization, 1989.

10 UNICEF. The baby-friendly hospital initiative. Jan 12, 2005. http://www.unicef.org/nutrition/index_24806.html (accessed July 20, 2012).

11 WHO. WHO recommendations for routine immunization–summary tables. 2010. http://www.who.int/immunization/policy/immunization_tables/en/index.html (accessed Oct 26, 2012).

12 WHO/UNICEF. Baby-friendly hospital initiative : revised, updated and expanded for integrated care. 2009. http://whqlibdoc.who.int/publications/2009/9789241594967_eng.pdf (accessed July 20, 2012).

13 Kroeger M. Facts for feeding: birth, initiation of breastfeeding, and the first seven days after birth. 2003. http://rehydrate.org/breastfeed/facts-birth-7days.htm (accessed March 19, 2012).

14 Kroeger M. Facts for feeding 1–4: recommended practices to improve infant nutrition during the first six months. 2004. http://rehydrate.org/breastfeed/facts-first-6months.htm (accessed March 19, 2012).

15 Kroeger M. Exclusive breastfeeding: the only water source young infants need–frequently asked questions. 2004. http://rehydrate.org/breastfeed/faq-exclusive-breastfeeding.htm (accessed March 19, 2012).

16 Yotebieng M, Chalachala JL, Labbok M, Behets F. Infant feeding practices and determinants of poor breastfeeding behavior in Kinshasa, Democratic Republic of Congo: a descriptive study. *Int Breastfeed J* 2013; **8:** 11.

17 WHO. Indicators for assessing infant and young child feeding practices. 2008. http://www.who.int/maternal_child_adolescent/documents/9789241596664/en/index.html (accessed July 17, 2012).

18 Renfrew MJ, McCormick FM, Wade A, Quinn B, Dowswell T. Support for healthy breastfeeding mothers with healthy term babies. *Cochrane Database Syst Rev* 2012; **16:** CD001141.

19 Tylleskär T, Jackson D, Meda N, et al. Exclusive breastfeeding promotion by peer counsellors in sub-Saharan Africa (PROMISE-EBF): a cluster-randomised trial. *Lancet* 2011; **378:** 420–27.

20 Bonuck K, Stuebe A, Barnett J, Labbok MH, Fletcher J, Bernstein PS. Effect of primary care intervention on breastfeeding duration and intensity. *Am J Public Health* 2014; **104** (suppl 1): S119–27.

21 Brodribb W, Kruske S, Miller YD. Baby-friendly hospital accreditation, in-hospital care practices, and breastfeeding. *Pediatrics* 2013; **131:** 685–92.

22 Taylor EC, Nickel NC, Labbok MH. Implementing the Ten Steps for Successful Breastfeeding in hospitals serving low-wealth patients. *Am J Public Health* 2012; **102:** 2262–68.

23 Kramer MS, Chalmers B, Hodnett ED, et al. Promotion of Breastfeeding Intervention Trial (PROBIT): a randomized trial in the Republic of Belarus. *JAMA* 2001; **285:** 413–20.

24 Chapman DJ, Morel K, Anderson AK, Damio G, Perez-Escamilla R. Breastfeeding peer counseling: from efficacy through scale-up. *J Hum Lact* 2010; **26:** 314–26.

25 WHO/UNICEF. Progress on sanitation and drinking water 2010 update. Geneva: World Health Organization, 2010.