

Low adherence to recommended infant feeding strategies among HIV-infected women:
results from the pilot phase of a randomized trial to prevent mother-to-child transmission in Botswana

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Funding for this study was provided by The Botswana-Harvard AIDS Institute Partnership
3,522 words

Abstract

Little is known about the ability of women to adhere to recommended feeding strategies to prevent mother-to-child HIV transmission (MTCT) from breast milk. We conducted a pilot study in rural Botswana to prevent MTCT from breast milk. Women were randomized to formula feed their infants or to breastfeed while providing prophylactic zidovudine. Women who chose to formula feed independently were also followed. Adherence to both feeding strategies was low. Among those with ≥ 3 postpartum visits, none of 31 women assigned to breastfeed did so exclusively. Eleven (32%) of 34 women in the formula arm reported breastfeeding in ≥ 1 visit, and evidence of breast milk on physical examination was present in 18 (53%) of 34 women in ≥ 2 visits beyond 1 month. Four (24%) of 17 women choosing formula reported breastfeeding, and breast milk was present in 9 (53%) of 17. We conclude that adherence to feeding strategies was difficult to achieve, whether assigned or chosen. Breast examination may be a useful adjunct to self-report, but needs to be validated and standardized. Low adherence to infant feeding strategies that differ from local norms will reduce their effectiveness in preventing MTCT.

Key words: HIV, AIDS, Breastfeeding, Infant formula, Botswana, Africa

Background

Mother-to-child transmission (MTCT) is the primary cause of pediatric HIV infection, accounting for most of the 800,000 infections among children that occur annually (UNAIDS, 2002). Although intrapartum MTCT can be reduced by more than 50% through short-course antiretroviral (ARV) medications given in the peripartum period (Connor et al., 1994; Shaffer et al., 1999; Guay et al., 1999; Lallemand et al., 2000), gains from such programs are eroded by ongoing postpartum MTCT through breastfeeding (De Cock et al., 2000; Dabis et al., 1999; Wiktor et al., 2000). In one multisite African study, a 63% reduction in MTCT by short-course ARVs compared to placebo at 6 weeks of age was reduced to only 33% at 18 months because of the effect of breastfeeding (Petra Study Team, 2002). The absolute risk of transmission through breastfeeding is approximately 12%-16% among chronically infected women and as high as 29% among recent seroconverters, and it also increases with the duration of breastfeeding (Dunn, Newell, Ades, and Peckham, 1992; Nduati et al., 2000; Coutsooudis et al., 2001).

Potential alternatives to breastfeeding that have been studied include providing replacement feeding (Nduati et al., 2000) (formula) where this strategy is safe and promoting exclusive breastfeeding with rapid weaning (Coutsooudis et al., 2001) where formula is not safe. Depending on the setting, each of these strategies has been recommended by WHO and other government and non-government agencies as a potential option for preventing MTCT among infants born to HIV-infected women in the developing world (UNAIDS, 2002; WHO, 2002; Heymann, 1990). The relative merits of formula feeding and exclusive breastfeeding have been extensively debated (Nduati et al., 2000; Coutsooudis et al., 2001; De Cock et al., 2000; Latham, Preble, 2002). Formula feeding is the accepted

standard for the developed world, and in a randomized trial in Nairobi, Kenya it was shown to increase 2-year HIV-free survival by 12% compared with breastfeeding (Nduati et al., 2000). However, its cost, acceptability, and safety in regions of the developing world lacking clean water remain significant obstacles to its universal endorsement. One study performed in Durban, South Africa suggested that exclusive breastfeeding had a similar MTCT rate as formula at 6 months (Coutsoudis et al., 2001), and this study, along with the well-documented benefits of breastfeeding for infant health, has been used to promote exclusive breastfeeding. Concern has been raised about the need to confirm the results of this study, and about the ability of women to adhere to this strategy.

In Botswana, the government recommends that HIV-infected mothers formula feed their infants, and free infant formula is provided to HIV-infected women in government health clinics. If breastfeeding is chosen, exclusive breastfeeding is recommended. However, formula feeding and exclusive breastfeeding are generally uncommon in Botswana, where breastfeeding with the early introduction of solid foods is traditional. Little is known about the ability of women in Botswana or elsewhere in Sub-Saharan Africa to adhere to either formula feeding or to exclusive breastfeeding. We therefore studied the ability of women to adhere to these two feeding strategies in a rural village in Botswana.

Methods

This study was performed in Molepolole, Botswana as part of the pilot phase of a randomized clinical trial comparing postpartum HIV transmission rates among infants receiving prophylactic zidovudine (ZDV) while exclusively breastfeeding, and infants receiving formula (Thior et al., 2002).

All women received ZDV from 34 weeks gestation through delivery, and all infants received prophylactic ZDV for 1 month, per the Botswana government protocol. Between April 2000 and March 2001, 75 women were randomized to either exclusively breastfeed their infants while providing daily prophylactic ZDV to uninfected infants for 6 months, or to formula feed their infants (while providing them with ZDV for 1 month). Infant formula was provided free of charge to women in the formula arm, and all women had access to a safe water supply from municipal standpipes in the village.

At presentation, a small group of women stated that they wished to formula feed their infants rather than join the randomized clinical trial, and therefore took part in the Botswana government MTCT program. These women were provided free formula, and were asked to consent to be followed in the clinic in the same manner as those participating in the clinical trial. These women served as an additional comparison group for the formula feeding arm, representing women who actively chose to formula feed their infants.

Demographic information was collected, and baseline CD4 count and viral load were performed, at the time of maternal entry into the study at 34 weeks gestation. Following delivery, women and their infants were seen at months 1-7 and at month 9. At each visit, women were counseled to exclusively follow their designated feeding strategy. Women in the breastfeeding arm were encouraged to begin weaning their infant to other liquids and solids beginning at five months. Exclusive breastfeeding was defined as the ingestion of breast milk only, with no other liquids or solids except supplemental vitamins or medicines. Exclusive formula feeding was defined as the absence of any breastfeeding.

A detailed infant feeding questionnaire was completed at each visit. Information about breast milk and formula ingestion, as well as other liquid and solid intake, was captured using this questionnaire. Maternal breast examinations were performed as part of the maternal physical examination at each visit, which also evaluated for the presence of mastitis and cracked nipples. During this pilot study, evidence of breast milk was assessed based upon the presence of at least a drop of expressible milk following three squeezes of the breast. For the primary analysis of the physical examination data, we excluded the 1-month visit to reduce the chances of identifying women who may still have been secreting milk following delivery as breastfeeding.

Informed consent was obtained from all women, and the study protocol was reviewed and approved by institutional review boards in Botswana and at the Harvard School of Public Health.

Data were analyzed using Epi-Info 6.02 computer software (CDC, Atlanta, GA) or SAS v6.12 (SAS Institute, 1989). Categorical data were compared by using the chi-square test or Fisher's exact test, and continuous variables were compared using ANOVA or the Wilcoxon Two Sample Test. Two-tailed p-values less than or equal to 0.05 were considered statistically significant.

Results

During the study period, 36 women were randomized to the breastfeeding arm, 39 women were randomized to the formula arm, and 75 infants (including one set of twins and excluding one stillborn) were delivered. There were 10 women (five in each arm) with fewer than three follow-up

visits attended, either because of loss to follow-up (seven) or infant mortality (three); these women were excluded from the analysis, leaving a total of 31 women in the breastfeeding arm and 34 women in the formula arm. Among these, 447 follow-up visits occurred from one to nine months postpartum, with an average of 6.7 visits per infant (range 0-8 visits). A maternal breast examination was performed at 402 (90%) of the visits. Characteristics of women in the two arms were similar; the median age in both groups was 25, women had a median of 2 children, most women were unmarried, and viral load and CD4 counts at baseline were similar (Table 1).

Among women in the breastfeeding arm, exclusive breastfeeding did not ever occur. Only four (13%) of 31 women reported breastfeeding their infants for all feedings in the first 5 months; when specifically prompted if water or other foods had ever been given to the infant during this period, all of the women answered affirmatively to at least one question. Thus, none of the 31 women exclusively breastfed their infants during the first 5 months postpartum. When the same analyses were performed for visits in the first 3 months postpartum, only five (16%) of 31 exclusively breastfed. Table 2 lists the liquids and foods other than breast milk that were commonly given to infants in the breastfeeding arm in the first 5 months of life.

Among women in the formula feeding arm, 11 (32%) of 34 reported any breastfeeding during the first 9 months. Of note, those women reporting breastfeeding often did so for the first time after several months of follow-up; the 3-month postpartum visit was the median visit (range 1 month to 9 months) for first report of breastfeeding. Evidence of breast milk on physical examination was also common. From 2 to 9 months postpartum, 18 (53%) of 34 women in the formula arm had evidence of breast milk on physical examination in at least two postpartum visits. Overall, breastfeeding was

reported at 12%, and breast milk was present on physical examination at 42%, of all visits among women in the formula arm from 1 to 9 months postpartum.

Before discharge from maternity, four women in the formula arm were witnessed to breastfeed; one was lost to follow-up, and the remaining three had evidence of breast milk at the 1-month visit. Of these, two reported never breastfeeding and did not have evidence of further breast milk, and one self-reported breastfeeding and continued to have evidence of breast milk on examination at subsequent visits.

Among women in the randomized pilot study, no associations were found between self-report of breastfeeding or evidence of breast milk on examination and socio-economic factors, age, or other demographic factors. Associations with measures of maternal health were mixed. Although no association was noted between evidence of breast milk and CD4 count, higher viral loads were significantly associated with having breast milk on fewer than two examinations from 2 to 9 months. The median viral load among women who had evidence of breast milk on fewer than two examinations was 94,763 copies and the median viral load among women with evidence of breast milk on at least two visits was 19,577 copies ($p = 0.004$).

An additional group of formula feeding women were also followed at the study site, and served as a second comparison group for the formula arm. These were women who chose not to participate in the randomized feeding trial because they expressed a preference to formula feed their infants and felt that they could safely do so through the government MTCT program. There were 17 women in this group with at least three follow-up visits, and these women differed from those who

agreed to join the study; they were older ($p < 0.05$), more likely to be married ($p < 0.05$), and had more children ($p < 0.05$). However, despite their choice to formula feed, their adherence was similar to those in the study. Four (24%) of 17 reported any breastfeeding from 1 to 9 months, and each of these reports first occurred from the 5 to 9 month visits. Breast milk was present in 9 (53%) of 17 on two or more visits from 2 to 9 months postpartum. Overall, breastfeeding was reported at 5% of all visits, and breast milk was present on physical exam at 33% of all visits, among these women from 2 to 9 months postpartum.

Figure 1 demonstrates the percentage of women reporting any breastfeeding from 1 to 9 months postpartum, by feeding group. Figure 2 demonstrates the percentage of all visits from 1 to 9 months postpartum that included breast examinations, by feeding group, where evidence of breast milk was found on examination. Among women assigned to breastfeed, evidence of breast milk was recorded at almost all visits until 6 months. Among women assigned to formula feed or choosing to formula feed, evidence of breast milk was more common in the early postpartum period than at later visits, but it remained common during the entire follow-up period.

Discussion

We studied the ability of HIV-infected women in a village in Botswana to exclusively adhere to either of two infant feeding strategies, and found that adherence was poor to both strategies. Low adherence to both exclusive breastfeeding and to formula feeding occurred despite the fact that these women were followed within the context of a controlled clinical trial. Women who agreed to be tested for HIV and then to participate in this trial were a select group, representing $< 20\%$ of all pregnant

women offered HIV testing during this pilot study. Furthermore, we believe that some of the women lost to follow-up in the postpartum period may have left the study because they were unsatisfied with their feeding strategy. Therefore, adherence within this clinical trial may overestimate actual adherence to these feeding strategies in the population.

The infant feeding methods recommended for HIV infected women within the trial and by the Botswana government are uncommon in Botswana, where the accepted norm is to breastfeed with the early introduction of solid foods, and where formula feeding is otherwise rare. Because HIV remains highly stigmatized in Botswana, women in our study may have chosen to avoid the potential disclosure of their status by feeding according to traditional practices. For women in the formula arm, this may have led to the initiation and continuation of breastfeeding to avoid the disclosure of their HIV status through the use of formula. For women in the breastfeeding arm, this may have meant adding other solids or liquids to their infant's diet in the presence of relatives or community members to avoid potential HIV disclosure. However, these early findings may underestimate adherence patterns over time. We observed an increase in voluntary counseling and testing (Stocking et al., 2002) and a probable reduction in the stigma of formula feeding over a two year period at our study site, as acceptance of the MTCT prevention program grew stronger in the community; thus, adherence to formula, and possibly to exclusive breastfeeding, is anticipated to have improved following this pilot phase of the MTCT prevention trial.

Our findings extend concerns raised by other published data regarding low adherence to exclusive feeding strategies in both studies and programs in Sub-Saharan Africa. In the study in Durban, South Africa, exclusive breastfeeding for at least 3 months was reported among 26% of

women who chose to breastfeed (Coutsoudis et al., 2001), as compared with 16% in our study at 3 months. In a cross-sectional survey among participants of the Botswana MTCT prevention program, only 20% of those women who were breastfeeding reported exclusive breastfeeding (Mompoti et al., 2002). However, in Nairobi, Nduati *et al* reported 62% exclusive breastfeeding at 3 months among women randomized to breastfeed (Nduati et al., 2000). This discrepancy may be accounted for by differences in local feeding practices, differences in the education provided to participants, or other differences in the studies (including the low overall participation rate of 25% in Nairobi, or the fact that ZDV prophylaxis was also offered to infants in our pilot study). Improved acceptance of exclusive breastfeeding practices following educational programs have been reported in Bangladesh (Haider, Ashworth, Kabir, and Huttly, 2000) but similar studies have not been reported in sub-Saharan Africa or among predominantly HIV-infected women.

Self-report of formula feeding in our trial supports the results of previous studies. Among those randomized to receive formula in Nairobi, Nduati *et al* found that 30% self-reported breastfeeding (Nduati et al., 2000). In the Botswana cross-sectional survey of MTCT participants, only 11% reported breastfeeding (Mompoti et al., 2002), which is lower than the 24% of formula feeding women who self-reported breastfeeding in our study; this may reflect the fact that our study was randomized, provided multiple opportunities to report breastfeeding over time, and occurred only in a rural setting. Evidence of breast milk on physical examination was not reported in previous studies. Because the acceptability of formula and the incentive to disclose non-adherence differ by location and between studies, it is difficult to estimate the extent to which breastfeeding might have been underreported in most settings.

Interestingly, several of the women either assigned to formula feed or choosing to formula feed who reported breastfeeding did so after 6 months postpartum, at a time when weaning was encouraged among the breastfeeding group. This finding likely represents women who became more comfortable reporting their actual feeding practices with time, and it raises concern that these women were not willing to wean early, or that they did not know to do so.

To our knowledge, this is the first study to use maternal breast examination to assess for the presence of breastfeeding. Breast examination appears to be sensitive in detecting breastfeeding when it occurs, as breast milk was detected at virtually all visits among women assigned to breastfeed. However, the specificity of the breast examination cannot be estimated from our study. To decrease the chance of incorrectly assuming breastfeeding in a woman who may still have been secreting milk following delivery without breastfeeding, our methodology was deliberately conservative, relying on evidence of milk expression on two occasions at or after the second month postpartum. Because the supply of breast milk depends on infant suckling by day 3 or 4 postpartum (Lawrence, 1998; Tay, Glasier, and McNeilly, 1992; Vorherr, 1974; Tucker, 1994), women who never initiated breastfeeding are thought to be unlikely to have evidence of milk on examination by this time point, although we cannot be sure that this was in fact the case. Women who do initiate breastfeeding for at least 3 to 4 days postpartum may have expressible breast milk for a number of weeks following its cessation (Lawrence, 1998; Wakerley, 1994). Thus, evidence of expressible milk at any follow-up visit from two to five months postpartum may be an indicator that breastfeeding occurred in the early postpartum period. We believe that the high number of examinations with breast milk at early visits, and the subsequent decline in prevalence of breast milk with each visit in the formula feeding mothers

(Figure 1), indicates some amount of early breastfeeding among this group, although residual postpartum milk secretion among non-breastfeeding mothers cannot be ruled out.

Following this pilot trial, to make our definition more accurately reflect feeding practices at the time of each visit, we changed it from “at least a drop” to “flow of more than a drop” of breast milk. We believe that the definition used in this pilot trial was sufficient to indicate *some* level of breastfeeding beyond the amount reported by women in the formula feeding arm, but it remains unclear the extent to which our findings represent actual breastfeeding or ongoing secretion among women who may never have breastfed. A validation sample of breast examinations among women known never to have breastfed would be useful to determine the predictive value of the breast examination to determine the presence of breastfeeding. Important questions that need to be addressed by such a study include the volume of expressible milk that is likely to indicate actual breastfeeding, and the anticipated time from either delivery or weaning until this volume is no longer expected upon examination. Other validation methods to determine the absence of breastfeeding using biochemical markers (such as serum prolactin levels or the sodium content of the expressed breast milk) may also have merit in the research setting.

Our study was limited by the fact that it was not specifically designed to test counseling strategies to promote exclusive adherence to each feeding method, and could not document the counseling that occurred at each visit. However, recommendations were presented uniformly at the initiation of the study, and variability among our counselors was likely typical of that found in most clinical settings. Determination of the presence of breast milk on physical examination may also have been non-uniform during the pilot phase, despite efforts to train all care providers in a standardized

examination technique. Data regarding the potential for manual expression of breast milk after delivery or weaning were not obtained, which may have influenced the results of the breast exam. Non-adherence to exclusive breastfeeding may have been influenced by perceptions among breastfeeding women that prophylactic ZDV given to their infant would prevent MTCT through breast milk, and that they could therefore safely practice mixed feeding. Finally, our study was limited by its small sample size. For example, the finding that women with higher viral loads (but not lower CD4 counts) were less likely to have evidence of breast milk than those with lower viral loads is difficult to interpret. Larger studies are needed to more fully evaluate any potential associations between disease status and the ability or choice to breastfeed.

In summary, we found low adherence to both exclusive breastfeeding and to formula feeding for the prevention of MTCT in a rural setting in Botswana. Breast examinations were used as an adjunct to self-report to determine the presence of breastfeeding, and if validated and standardized, could play a role in future research and in feeding program evaluations. Poor adherence to infant feeding strategies that differ from local norms must be considered when implementing infant feeding programs in the developing world. Randomized trials represent controlled settings where such strategies have the best chance of succeeding, and their failure in this setting bodes poorly for programmatic efforts to prevent the breastfeeding component of MTCT using these approaches, particularly in a village setting. Alternative strategies that allow women to feed their infants in the manner of their choosing, such as the use of prophylactic ARVs for infants or therapeutic ARVs for mothers, need to be evaluated.

Acknowledgments

The authors wish to thank Tlhongbotho Masoloko, Lillian Makori, Dipotso Arbi, Komotso Koloji, Tebatso Paul, Agnes Modise, Janet Moorad, Thaolakele Moyo, Molefhe Tiroyamodimo, Janet Grimes, Edward Garmey, Ria Madison, and Onalenna Ntogwa.

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Table 1. Characteristics of women participating in the pilot study who had three or more postpartum visits, by feeding strategy*

	Breastfeeding (N=31)	Formula feeding (N=34)
Median Age (range)	25 years (18-40)	25 years (18-44)
Median Number of Children (range)	2 (1-5)	2 (1-6)
Median Number of Persons Living in Home Compound	7 (2-13)	7 (2-15)
Married	19%	21%
Has Electricity in Home	6%	6%
Told Nobody of Her HIV Status	46%	54%
Median Baseline CD4 (range)	351 (95-730)	334 (133-1115)
Median Baseline Viral Load (range)	22161 (2009-296145)	46182 (2334- >750000)

* No significant differences were observed at the 0.05 level between feeding groups

Table 2. Liquids and foods given to infants in the breastfeeding arm, and percent of visits at which these were reported, from birth to 5 months.

Liquids / foods	% of visits reported
Water	72
Cereal / porridge	27
Juice	20
Fruits / vegetables	18
Cow's milk from the store	5
Cow's milk direct from the cow	5
Other animal milk	3

Figure 1. Percentage of women reporting any breastfeeding from 1 to 9 months postpartum, by feeding group

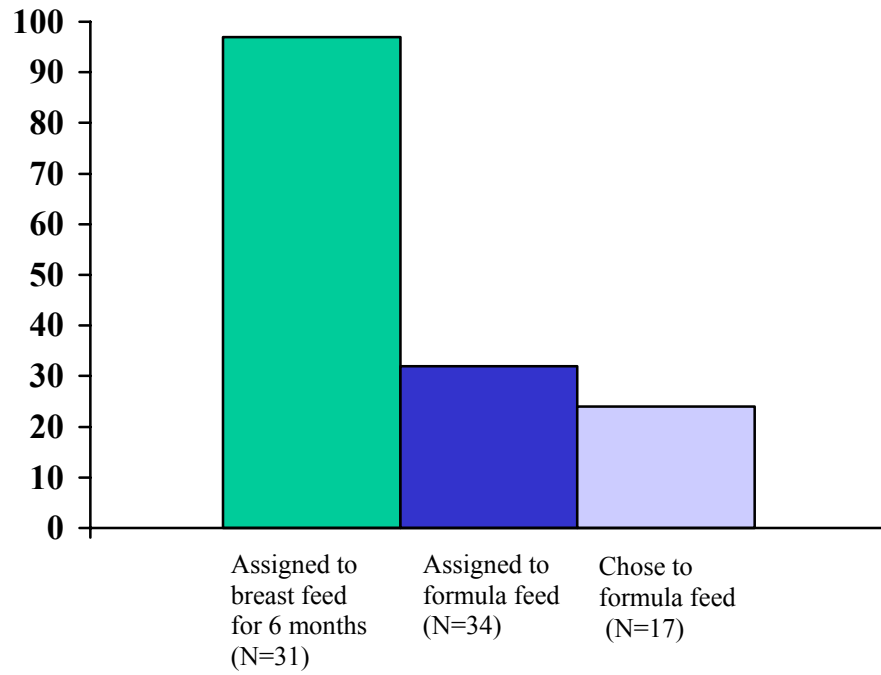
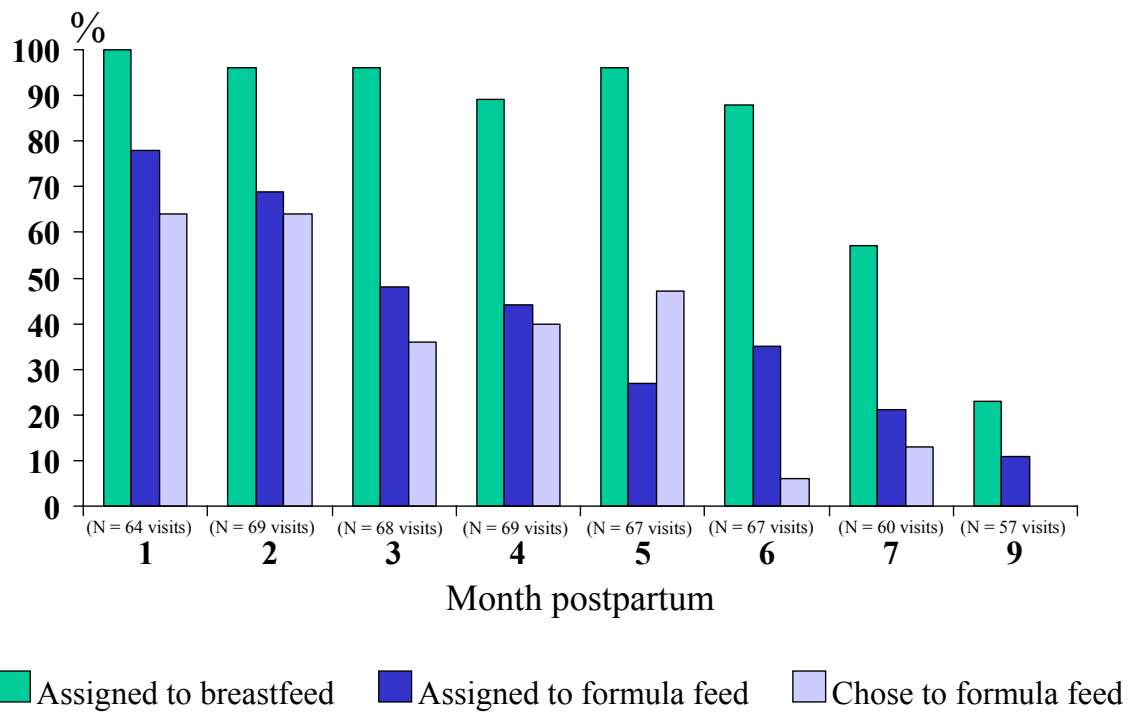


Figure 2. Percentage of visits from 1 to 9 months postpartum with evidence of breast milk on exam, by feeding group*



* Percentages reflect all visits for each month where a breast exam was performed

Figure Legend

Figure 1. Percentage of women reporting any breastfeeding from 1 to 9 months postpartum, by feeding group

Figure 2. Percentage of visits from 1 to 9 months postpartum with evidence of breast milk on exam, by feeding group*