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Safer infant feeding update

The risks of inadequate or unsafe replacement feeding

In 2001, WHO and UNICEF issued the following infant feeding guidance:

"When replacement feeding is acceptable, feasible, affordable, sustainable, and safe [the AFASS criteria] avoidance of all breastfeeding by HIV-infected mothers is recommended. Otherwise, exclusive breastfeeding is recommended during the first months of life. To minimise HIV transmission risk, breastfeeding should be discontinued as soon as feasible, *taking into account local circumstances, the individual woman's situation and the risks of replacement feeding (including infections other than HIV and malnutrition).*"

Recently, the risks of formula feeding have been in the news. For example, at the 2006 PEPFAR Implementer's meeting, there were several reports of malnutrition and high rates of morbidity and mortality among infants fed replacement foods in several different countries, even notably, Botswana, a middle income country, where infant formula is freely provided for a year and the water supply has been generally regarded as safe (see

<http://www.aidsmap.com/en/news/59415764-DC18-4383-AB43-04B312F8141A.asp>).

Together, these studies suggested that, at best, it is extremely difficult to meet the AFASS conditions in most resource-limited settings.

Diarrhoea outbreak associated with not breastfeeding in Botswana

More data on the diarrhoea outbreak in Botswana has recently been posted on the PEPFAR post-Implementer meeting site (http://www.blsmmeetings.net/implementhiv2006/TracyCreek_files/frame.htm).

To summarise, from November 2005 to February 2006, there were unusually heavy rains and flooding in Botswana; and by January 2006, there was an increase in infant diarrhoea and mortality. By February, the number of cases and deaths were overwhelming hospitals throughout the country. In fact, in the first quarter of 2006, in just twelve health districts, there were 22,500 cases of diarrhoea, with 470 deaths in children under five (compared to 9,166 cases and 21 deaths for the entire country in the first quarter of 2005).

The country had trouble blaming the outbreak on any one pathogen and proposed that it was caused by a gastroenteric virus. However, when it was clear that most of the cases appeared to be associated with bottle feeding, Botswana requested assistance from the US Centers for Disease Control (CDC). Dr. Tracey Creek of the CDC presented the results of the CDC's investigations at the PEPFAR meeting (Creek 2006a).

The CDC found widespread water contamination in four northern districts of the country. The public water supply, which has long been considered safe, was contaminated in 26 villages tested. But the water in Botswana comes from a variety of sources, and a number of strategies are used to treat the water. So it was perhaps not surprising that the CDC laboratories in Atlanta identified a variety of pathogens causing the outbreak, including

cryptosporidium, to enteropathogenic e. coli (classic bottle diarrhoea) and salmonella among others.

The CDC investigators identified a variety of risk factors (adjusted for SES, age, and mother's HIV status) that were associated with children with diarrhoea visiting the emergency room, such as caregivers not washing their hands (2.5 Adjusted Odd Ratio (AOR) (95% CI 1.1-5.0), standing water near home (AOR 2.6 (1.1-6.3), overflowing latrines (AOR 3.0 (1.1-8.6), storing drinking water (AOR 3.7 (1.5-9.1).

But far and away, the most significant risk factor was not breastfeeding (AOR 50 (95% CI 4.5-100).

The CDC conducted a closer evaluation of 154 children hospitalised for diarrhoea. The median age was 9 months; 93% were not breastfeeding; and more than half (51%) had had poor growth before illness.

However, it is not only women with HIV who wean their children early in Botswana — it has become increasingly common for women in Botswana to wean their children by six months of age. Among the hospitalised children, 65% of the mothers were known to be HIV-positive (94% had been tested), and only 18% of the infants were HIV-infected.

The illness was prolonged in many of the hospitalised patients, with 43% being discharged and then readmitted at least once. Many developed severe acute malnutrition though most had been growing poorly before diarrhoea. Twenty-one per cent (32/154) of these children died. Risk factors for death included not being breastfed (OR 8.5, p=0.04) and kwashiorkor (OR 2.6, p=0.03). HIV status (maternal or infant), socioeconomic status, water source, urban versus rural residence and pathogen were not associated with the risk of death.

Among the HIV-positive mothers, there did appear to be some problems with adequate and consistent formula supply. Although most were given the appropriate amount of formula at birth, only 51% received the amount of formula they should have received before their illness. "In many cases, mothers returned to clinics multiple times per month but still [were] not given adequate formula," according to Dr Creek.

The true extent of the mortality from this outbreak remains unknown, since many infants died outside of the health facilities. According to CDC estimates, it appears to be far beyond what was reported above, with 547 excess deaths in three districts alone. "One village we visited lost 30% of their formula-fed babies (and no other babies) during the outbreak," according to Dr Creek.

Mashi: higher early mortality among formula-fed infants and other observations

What makes these deaths all the more tragic is that they were foreshadowed by the high mortality observed in formula-fed infants in the Mashi study. This trial was conducted in Botswana between 2001-2003 and compared the efficacy and safety of six months of AZT plus exclusive breastfeeding versus one month of AZT plus formula feeding for the prevention of postnatal mother-to-child HIV transmission. The seven month results of this study have just been published in the August 16th issue of JAMA (Thior 2006a) while two year data from the study were presented in a poster in Toronto (Lockman 2006), along with a number of other poster presentations evaluating adherence and the immunological properties of the breastmilk in the study.

The trial involved 1200 HIV-positive pregnant women at four district hospitals, randomised to either exclusive breastfeeding or formula. All of the mothers and infants had received the standard

PMTCT regimen in Botswana at the time (AZT from 34 weeks gestation, and AZT and single dose nevirapine (sdNVP) during labour). Formula-fed infants received one month of AZT, while breastfed infants received six months of AZT.

The outcomes were evaluated in 1179 live born infants. As for HIV transmission, significantly more infants were HIV-positive in the breastfeeding arm, 54 out of 588 (9.2%) vs. 33 out of 591 formula fed infants (5.6%) (Lockman).

However, this trial is far from the definitive word on the effect of exclusive breastfeeding on HIV transmission because the majority of women randomised to exclusive breastfeeding did not practice it. In fact, adherence to exclusive breastfeeding was only 57% by month 1, and 18% by month 5, compared to adherence rates of 95% in the mothers randomised to formula feeding by month 1, and 91% by month 5 (Thior 2006b). Most of the mixed feeding in the breastfeeding arm involved giving the child other liquids, such as water and/or replacement formula, but even mixed feeding with liquids doubles the risk of transmission according to a South African study presented at Toronto (Coovadia 2006) (discussed in Safer Infant Feeding, Part Two).

But the more interesting finding is that once mortality is factored into the study's outcome (combined mortality and/or HIV infection), there is not much difference between the two trial arms — because early infant mortality was actually much higher in the formula fed arm.

The cumulative infant mortality at 7 months was significantly higher for the formula-fed group than for the breastfed group (9.3% vs 4.9%; $p = .003$). Although by month 24, this difference was no longer significant (likely because of progressive HIV-related mortality), in data out to July 28, 2004, more infants had still died in the formula fed arm, 61 compared to 50 of the breast fed infants.

Formula feeding was more commonly associated with grade 3/4 diarrhoea and grade 3/4 pneumonia (which were also the leading causes of death) (see table).

table 1: Rates of infant pneumonia, diarrhoea and death in FF vs. BF infants, by infant HIV status, 6 and 24 months of age

	All Infants			HIV-Infected Infants			HIV-Negative Infants		
	BF n=588	FF n=591	P value	BF n=54	FF n=33	P value	BF n=534	FF n=558	P value
Outcome by 6 months of age									
Pneu monia (% with ≥ 1 episode)	12.9%	16.2%	0.11	31.5%	48.5%	0.11	11.0%	14.3%	0.1
Grade 3 or 4 pneu monia	4.7%	7.8%	0.03	9.4%	32.5%	0.01	4.2%	6.3%	0.13
Diarrhoea (% with ≥ 1 episode)	33%	35%	0.41	38%	42%	0.73	32%	34%	0.39

Grade 3 or 4 diarrhoea	0.9%	3.8%	0.001	1.8%	9.9%	0.16	0.8%	3.4%	0.003
Wasting (%)	6.2%	4.0%	0.10	8.2%	22.7%	0.12	6.0%	3.2%	0.03
Death (%)	4.0%	8.4%	0.002	7.5%	33.3%	0.004	3.6%	6.9%	0.02
Outcome by 6 months of age									
Pneumonia (% with ≥ 1 episode)	27%	28%	0.69	70%	70%	0.95	22%	25%	0.25
Grade 3 or 4 pneumonia	8.0%	13.3%	0.01	21.5%	46.7%	0.02	6.7%	11.4%	0.03
Diarrhoea (% with ≥ 1 episode)	67%	66%	0.67	82%	75%	0.55	66%	66%	0.98
Grade 3 or 4 diarrhoea	6.2%	6.0%	0.91	16.4%	14.4%	0.86	4.9%	5.5%	0.66
Wasting (%)	5.2%	4.4%	0.64	3.1%	13.3%	0.24	5.4%	4.1%	0.42
Death (%)	8.7%	10.7%	0.26	29.5%	45.5%	0.14	6.7%	8.6%	0.23

Breastfed infants are probably protected from these illnesses by immunoglobulins and other immune factors in the mothers' breastmilk, even though breastfeeding was actually mixed and the mothers were HIV-positive. In fact, in a substudy of Mashi, no intrinsic breast milk deficiencies could be identified among HIV-infected breastfeeding mothers, whether their infants were either ill or well, and regardless of their CD4 cell count or viral load (Shapiro). In a multivariate analysis, the only factors that were associated with having a sick child was if the mother had already discontinued breastfeeding ($p=0.01$) or did not have a refrigerator ($p=0.02$).

Nor could any important differences be detected between the immunoglobulin content in the HIV-positive mother's breastmilk relative to that from a control group of HIV-uninfected women. Levels of most immunoglobulins were actually higher in HIV-positive women, although the relative proportion of IgA was lower.

Although the "functional quality of the immunoglobulins" is unknown, when taken together with the clinical data, these findings suggest that the breast milk of most of the breastfeeding mothers in Mashi conferred some protection against common pathogens. The protective effect against pneumonia may even persist beyond the six months of breastfeeding (see table).

Another critical observation in the presentation during Toronto was that the increased morbidity and mortality in the formula feeding arm was particularly pronounced when the infant was HIV-infected — which has important diagnostic and counselling implications (more on this in Safer Infant Feeding, Part 2).

Botswana PMTCT programme highly successful — except for the excess mortality

It is of critical importance that these observations have been made in Botswana, a middle-income country that has been the continent's flagship HIV control programme. Botswana's PMTCT programme has been going all out since 1999. As of early 2006, Botswana was identifying and providing free PMTCT services to a much higher percentage (~85%) of pregnant mothers with HIV than any other country.

The operational effectiveness of Botswana's PMTCT programme, at least in regards to preventing mother to child transmission of HIV, was clearly demonstrated by another study that Dr. Creek also presented at the 2006 PEPFAR Implementers meeting. In the study, dried blood spots were collected on a large cross-sectional sampling of HIV-exposed infants between the ages of 6 weeks to 17 months who visited government clinics around Francistown (in northern Botswana) for any reason.

The study found an HIV transmission rate of 7%. This stands in marked contrast to the transmission rate of 20.9% recently reported for the PMTCT programme in KwaZulu Natal South Africa (<http://www.aidsmap.com/en/news/74A5B372-0FAF-4EB1-8825-F84DDAB7D367.asp>). Although methods used in these two surveillance studies differ somewhat — in South Africa, all infants were first screened with antibody tests to identify ALL HIV-exposed infants, including those whose mothers were unaware of their own status (and who have a very high chance of passing the virus on). However, given that most women accessing mother-child services are routinely tested in Botswana, it isn't clear how much difference this would make in the outcomes. Furthermore, the infection rate in KwaZulu Natal can only be expected to increase with post-natal transmission.

For a breakdown of Botswana transmission rates by intervention offered see Table 2.

table 2: Percent of infants HIV-infected by PMTCT interventions received, DBS PCR pilot – Botswana 2005

Self-reported regimen received	N	% expected positive	N (%) actually positive
Nothing	15	35-40	33
Nothing to mother, AZT/NVP/formula to baby	24	12-20	12.4
AZT to mother (median 49 days)*	420	2-8	4.0
AZT and NVP to mother*	709	<1-5	3.7
AZT therapy to mother*	175	<1	0.6

Formula feeding has almost certainly played a key role in the low HIV transmission rates.

After a study in 2001/2 had concluded that Botswana met all the UNAIDS conditions for safe formula preparation (an uninterrupted formula supply for at least six months; access to safe drinking water, and the means to boil water for preparing formula and sterilising utensils, the country launched the free formula programme. Scaling up distribution of a year's worth of free formula to over one-third of

all the mothers of young infants in a country the size of Texas or France — and with less than a tenth of transportation infrastructure — was a Herculean effort.

Now, even if the delivery has at times been spotty, formula feeding among HIV-positive women is virtually universal in Botswana (~98% of infants in the HIV-transmission study were formula fed). The country has so strongly promoted formula feeding rather than breastfeeding— that even many HIV-negative women are using formula — or at least avoiding breastfeeding (which is rather problematic from a public health standpoint).

But the bottom line is, that despite the low HIV transmission data, in addition to the Mashi data and the CDC investigation, Botswana's own mortality data shows that something isn't working. While the introduction of ART has increased the lifespan of adults in the country, data show that infant mortality is still on the increase (see

http://www.path.org/files/Tanya_Doherty.pdf#search=%22infant%20feeding%20doherty%20%22path%22%22) warning – direct link to large pdf file).

Lessons from Mashi and the diarrhoea outbreak

Indeed, the CDC investigators concluded that the formula programme for HIV-positive women is expensive, complex, and that data from the Mashi study and outbreak indicate it is not saving lives. At this point, Botswana needs to consider whether alternative infant feeding strategies can achieve higher child survival.

Dr Creek believes that one of the first things that Botswana needs to do is promote breastfeeding in Botswana especially “as early weaning is common even among HIV-negative women.”

[However, some of the breastfeeding avoidance by HIV-negative women could be due to fears of contracting HIV while breastfeeding and then passing the infection onto her infant — an ever present danger for many women in high prevalence settings. Unfortunately, recent data may not prove at all reassuring to such mothers or those counselling them (more on this Safer Infant Feeding, Part 2)]

But among HIV-positive women, Botswana should do more to support *truly* exclusive breastfeeding among women who are at a lower risk of transmitting HIV (more on this Safer Infant Feeding, Part 2).

The government should also ensure that formula-fed infants have enough formula and safe water, more support (including training for mothers and healthcare staff in nutrition, hygiene and the management of diarrhoea) and close monitoring.

But if such a crisis can happen in Botswana, it is almost certain to occur in resource-constrained settings.

According to Dr Creek, the example of Botswana has important implications for other programmes. In general, “programmes offering formula should ensure clean water, uninterrupted supply of formula, growth monitoring, nutrition counselling,” and “health staff should be taught that formula fed infants are at risk, what to look for, and how to intervene,” she said.

Is AFASS to blame when replacement feeding leads to high mortality?

Dr Creek believes that the diarrhoea outbreak in Botswana reinforces use of WHO criteria for replacement feeding (acceptable, feasible, affordable, sustainable, and SAFE).

However, others, including the authors of one poster presentation at the World AIDS conference in Toronto, believe that reports such as Mashi and the diarrhoea outbreak provide evidence

“that the [AFASS] guidelines may actually increase risk to the mother/baby dyad as well as other infants in the community.” (Liles and Tompson 2006).

Liles and Tompson’s presentation involved a comprehensive literature review of sources cited as support for AFASS. It concluded that:

“The review of evidence on infant feeding in the context of HIV/AIDS does not show that the WHO policy will lead to improved survival or health outcomes in infants born to HIV positive mothers. It does suggest that current recommendations are likely to reduce mother-to-child transmission of HIV from breastfeeding. Policy based only on evidence of transmission rates relies on broad assumptions that a reduction in transmission will translate into improved survival. The evidence does not support that.”

Liles and Tompson point out that the terms “acceptable, feasible, affordable, sustainable, and safe” haven’t really been defined in any clinical study.

Studies have never determined what the optimal duration of breastfeeding in HIV-positive mothers really is or whether abrupt weaning (in order to avoid prolonged mixed feeding) truly translates into better outcomes. Finally, there have been no studies to assess the implementation or evaluation of guidelines based on AFASS.

Dr Tanya Doherty of Health Systems Trust and South Africa’s Medical Research Council said something quite similar during a PATH satellite session on breastfeeding.

“Defining ‘safe’ and ‘feasible’ etc, in practice is a challenge for health workers and counsellors,” she said. “The WHO/UNICEF guidelines are not being used effectively in operational settings to guide feeding choices.” Her team conducted research demonstrating that HIV-free infant survival could be improved if women choosing formula feeding as an option met specific criteria such as having piped water, fuel or HIV status disclosure (see tables 3 and 4). “Without these,” she concluded, “a choice to breastfeed would result in a better outcome.” (Doherty).

table 3: Defining appropriate choice

Score of appropriateness	N(%) women choosing to formula feed who had these criteria	Adjusted Hazard ratio 36 week HIV transmission/death (95% CI)
(A) Piped water in house or yard	152 (52.6)	0.51 (0.31-0.84)
(B) Piped water in house or yard plus fuel (electricity, gas or paraffin)	146 (50.5)	0.53 (0.32-0.88)
(C) Piped water in house or yard, fuel and disclosure of HIV status	94 (32.5)	0.32 (0.16-0.62)

table 4: Consequences of inappropriate choices

Appropriateness of feeding choice according to presence or absence of piped water, fuel and HIV disclosure (n=600)	Adjusted Hazard ratio 36 week HIV transmission/death	95%CI

Appropriate choice to formula feed (referent group) (n=94)	1	
Appropriate choice to breastfeed (n=216)	2.74	(1.48 – 5.05)
Inappropriate choice to formula feed (n=195)	3.45	(1.89 – 6.32)
Inappropriate choice to breastfeed (n=216)	2.72	(1.38 – 5.35)

“While there is an urgent need for evidence-based infant feeding guidelines,” wrote Liles and Tompson, “this policy seems to be fear-based rather than fact-based and has the potential to inadvertently set back critical gains already achieved in public health as a result of the protection and promotion of breastfeeding.”

To be fair, however, the fear of HIV transmission is, in and of itself, not unreasonable — it is only natural to want to avoid it. But the question is how to do this safely, and the safety of breastfeeding avoidance/formula feeding has first to be evaluated in each setting.

“Safety cannot be assumed,” said Dr Creek. “New programmes should verify that formula saves lives in their context *before* widespread implementation.”

The WHO policy states that HIV-positive mothers should be given information about both the risks and benefits of various infant feeding options based on *local assessments* and guidance in selecting the most suitable option for their situation. The problem is that few countries have such data available — and a number of settings may be encouraging mothers to formula feed based on overly optimistic assessments of whether they truly meet AFASS criteria.

Other reports on mortality associated with infant feeding practices

A handful of other reports at the recent World AIDS Conference in Toronto also addressed the issue.

For example, a prospective cohort study in over 1400 children from rural and urban South Africa reported a Kaplan-Meier cumulative 6 month mortality estimate of 10.1% among exclusively breastfed infants (94 deaths out of 1034 infants) vs. 15.1% amongst formula fed infants (8 out of 101 infants, all of whom died in the first three months of life) (Coovadia 2006). The risk of postnatal transmission by 6 months of age in exclusively breastfed infants who were negative at 4-8 weeks of age was 4.04%.

However, it is difficult to generalise about the safety of formula feeding in South Africa, given the widely variable access to water and refrigeration (Makin) (more in section on Counselling in Safer Infant Feeding, Part 2).

In rural Uganda, one small study of 85 HIV-exposed infants (followed for 11-15 months) found that a shorter duration of exclusive breastfeeding or total breastfeeding were both significantly associated with higher infant mortality (unadjusted hazard ratio 0.69 (0.53-0.91), p-value = 0.09; and an unadjusted hazard ratio of 0.71 (0.57-0.88), p-value 0.02, respectively) (Homsy 2006).

In a small study conducted in the Ife-Ijesa zone of southwestern Nigeria, thirty-eight (65.5%) and 20 (34.5%) of 58 HIV-positive mothers chose exclusive breastfeeding (EBF) and exclusive formula feeding (EFF) respectively (Adejuyigbe 2006). Over six months of follow-up, HIV-exposed infants whose mother chose formula feeding

were more frequently ill and admitted to the hospital ($p < 0.05$) and mortality was higher in this group of children. The primary causes of illness were diarrhoea, acute respiratory infection and sepsis.

But in the urban setting of Abidjan, Côte d'Ivoire, infant health and survival at eighteen months was similar whether infants were formula-fed or exclusively breastfed with early weaning (at around month four) according to the researchers of Ditrane Plus (Becquet 2006). It should be noted however, that the women who chose to formula feed were more likely to be highly educated and to have tap water in the house, which could be independent predictors of better infant survival. There also seemed to be a trend towards more deaths among the formula-fed HIV infected children by month 12 (survival probability of 0.56 vs. 0.73 in the breastfed) though the numbers were small. However, the mortality rate among HIV-infected children in Ditrane Plus was remarkably similar to what was observed in Mashi.

Finally, in the Breastfeeding Antiretroviral Nutrition (BAN) study in Lilongwe, Malawi, which is comparing outcomes of various interventions in 827 mother-infant pairs who are all breastfeeding (mothers all have over 200 CD4 cells), the investigators bemoaned 21 infant deaths in the study, which represent an infant mortality rate of 47.5/1,000. There is no formula feeding arm to compare this to, however, the usual infant mortality rate for Lilongwe (for HIV-exposed and unexposed infants) is 73/1,000 (Bramson). It is unlikely that formula feeding would be AFASS in the setting as the investigators stressed local problems such as "limited access to clean water, endemic food insecurity, little access to telephone or transport in emergencies, and severe understaffing in public hospitals."

End of Part One.

Part Two reviews recent data defining the risks of transmission, counselling issues and infant feeding alternatives

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about HATiP

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The newsletter is edited by Theo Smart (Cape Town) and Keith Alcorn, NAM's Senior Editor (London).

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