Ethical and public health considerations on breastfeeding in the context of HIV

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Investment

Love

Legacy
Breastfeeding recognised as the single most important intervention to prevent child deaths

Child survival II

How many child deaths can we prevent this year?

Gareth Jones, Richard W Steketee, Robert E Black, Zulfiqar A Bhutta, Saul S Morris, and the Bellagio Child Survival II Group*

This is the second of five papers in the child survival series. The first focused on continuing mortality (over 10 million each year) from preventable causes: diarrhoea, pneumonia, measles, malnutrition, and a small group of causes leading to neonatal death. We reviewed evidence for interventions feasible for delivery at high coverage in low-income settings, and classify these as level 1 (sufficient evidence of effect), level 2 (limited evidence), or level 3 (inadequate evidence). Our results show that level 1 intervention is available for preventing or treating each main cause of death among children under 5 years, apart from birth asphyxia, for which a level 2 intervention is available. There is also evidence for several other interventions. However, global coverage for most interventions is below 50%, if level 1 were universally available, 63% of child deaths could be prevented. These findings show that the inaction to achieve the millennium development goal of reducing child mortality by two-thirds by 2015 are not being delivered to the mothers and children who need them.
ORIGINAL ARTICLES

Slim Disease: a New Disease in Uganda and its Association with HTLV-III Infection
D. Serwadda, MB, R. D. Mugerwa, MB, N. K. Sewankambo, MB.
A. I. Wegaba, MB, J. W. Carswell, FRCS, G. B. Kirva, MB, A. C. Bayley, FRCS.
R. G. Downing, PhD, R. S. Tedder, MRCPath, S. A. Clayden, BSc.
Prof R. A. Weiss, PhD, A. G. Dalgleish, FRCP

Unrelated Individuals Matched for MHC-extended Haplotypes and HLAs Identical Siblings Show Comparable Responses in Mixed Lymphocyte Culture
Z. L. Aweh, PhD, Prof C. A. Alper, MD, E. Eynon, BS, S. M. Allocco, BS,
R. Stein, Prof E. J. Yunis, MD

First Trimester Diagnosis of Hypophosphatasia with a Monoclonal Antibody to the Liver/Bone/Kidney Isoenzyme of Alkaline Phosphatase
K. C. Warren, MRCPG, Christina McKenzie, SCM, C. H. Rodeck, MRCPG,
Gonzalo Moscoso, MD, Prof D. J. Brock, PhD, Lilias Barron, BSc

Are Varicose Veins and Coronary Artery Bypass Surgery Compatible?
Robert MacFarlane, MB, R. J. Godwin, FRCS, A. P. Barbas, FRCS

Malignant Melanoma in Scotland 1979–1983
Prof R. M. MacKie, FRCPATH, J. F. Smyth, FRCP, D. S. Soutar, FRCS,
Prof K. C. Calman, FRCP, A. C. H. Watson, FRCS, J. A. A. Hunter, FRCP,
K. M. McLaren, MRCPath, J. B. MacGillivray, FRCPATH, J. L. McPhie, MRCPath,
R. Rankin, MRCPath, A. W. Hutchison, MRCPath, I. W. Kemp, FFPSM

Case for Concluding that Heat-treated, Licensed Anti-haemophilic Factor is Free from HTLV-III
Dr J. C. Petricciani and others

Isolation of AIDS Virus from Cell-free Breast Milk of Three Healthy Virus Carriers
Dr L. Thirty and others

Cancer among Workers Exposed to Strong Static Magnetic Fields
Dr Lars Barregard and others

Regional Physiological Functions Depicted by Sequences of Rapid Magnetic Resonance Images
Dr Dieter Matthai and others

Asylums in an Age of Community Psychiatry
Prof Sydney Brandon;
Mrs Gwyneth Hemmings, BSc;
Dr C. R. Tomsen

The Prison Medical Service
Mr Tony Smythe

Evaluation of “Unorthodox” Clinical Practice
Dr Ian Chaillmer

Medical Coordination during Disasters
Dr Alan Gibson

Breastfeeding and Adoption
Dr A. M. Meeke

Examination Nerves and the Medical
Relieved

Unaware

Scared
If prevention of mother-to-child transmission of HIV were the only priority then ...

- Give all HIV-infected mothers antiretroviral drugs, and,
- Stop all breastfeeding
Geographical distribution of HIV burden

- 67% of people living with HIV are in sub-Saharan Africa
- 50% of people living with HIV are women (60% in sub-Saharan Africa)
- 19 of 20 countries with highest PMTCT burden are in sub-Saharan Africa

Source: UNAIDS 2008
Changes in World Poverty 1981-2001
73.7 million more people in SSA in poverty since 1987

Chen and Ravallion 2004
In sub-Saharan Africa more than 1.1 billion people worldwide do not have access to clean water,
2.6 billion do not have adequate sanitation and diarrhoea due to a lack of clean water kills five times more children than HIV/AIDS.
the “..roots of the crisis in water can be traced to poverty, inequality, and unequal power relationships, as well as flawed water management policies ...”.

UNDP. Human Development Report. 2006
Preventing HIV .... while protecting child survival
WHO recommendations on HIV and infant feeding

2000

• When replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-infected mothers is recommended
• Otherwise, exclusive breastfeeding is recommended during the first months of life

2006

• The most appropriate infant feeding option for an HIV-infected mother should continue to depend on her individual circumstances, including her health status and the local situation, but should take greater consideration of the health services available and the counselling and support she is likely to receive.
• Exclusive breastfeeding is recommended for HIV-infected women for the first 6 months of life unless replacement feeding is acceptable, feasible, affordable, sustainable and safe for them and their infants before that time

HIV-infected women should be given ‘specific guidance in selecting the option most likely to be suitable for their situation’ i.e. promote informed and free choice of infant feeding methods for HIV-infected mothers

Assumes accuracy of information and that women can enforce their ‘choice’
Does a recommendation endorsing breastfeeding to an HIV-infected mother in Africa, represent duplicity in ethical standards?
Breastfeeding is not just nutrition
An Ermelo man who allegedly whipped a woman to death with a sjambok was arrested on Tuesday, Mpumalanga police said yesterday. The 33-year-old man allegedly whipped Ellen Nkosi to death at about midnight on Monday. Police said he shouted at her for not breastfeeding her baby to make it stop crying, and then whipped her” – Sapa
The first four years are crucial in the growth of your child’s teeth, bone structure and mouth tissue, so be sure you are only using teats and dummies that encourage correct orthodontic development.

Nuk’s innovative orthodontic teat designs make this range of bottles and dummies the right choice.

**Your next best choice**

A recent survey amongst orthodontists, shows that Nuk is the next best thing to mom’s breast.

Nuk was recommended over any other feeding range by 82 percent of orthodontists. Its closest competitor was only recommended by 6 percent of orthodontists.

Nuk silicone and latex teats are durable and specially designed to imitate the shape of a nipple during breastfeeding.

And Nuk dummies and bottles come in a range of fun designs babies love. It’s encouraging to know that most paediatricians use or have used Nuk products for their own children and recommend Nuk to their patients.

When making a choice that will affect you and your child, invest in the best.

Nuk teats and dummies promote good dental health and are the natural choice of professionals and parents alike, because you both want the best for baby.

Put your money where baby’s mouth is
"After years of being hated by advocates of breast-feeding, Nestlé and the rest of the baby food industry must have wept with delight at articles in the *Wall Street Journal* last December (2000).

The *Wall Street Journal* …… painted the baby food manufacturers as heroes poised to save African children from certain death."

"HIV – will it be the death of breastfeeding?"
WHO recommendations: 2000 and 2006

• Reflected the evidence available at that time, namely the significant influence of context on what may be best for the infant and therefore the need for individualised counselling
  – 'nondirective counseling—used in situations where the risks and benefits are highly uncertain and idiosyncratic'

• But ... *evidence-based guidelines are not necessarily the driver of practices*
Feeding at some PMTCT sites in South Africa

The quality of infant feeding counselling translated into HIV free survival of infants

Woldenbeset. IAS 2009
Knowledge of nurses and counsellors about the risk of HIV transmission through breastfeeding

**Qu:** If 100 HIV-infected mother breastfeed their children up to 2 yrs, how many children will be infected? *(mother and child do not receive any ARVs)*

334 nurses/ counsellors interviewed in 4 countries

**Chopra and Rollins, Arch. Dis. Child. 2008**
Preparation of mothers to stop breastfeeding

✔ Counsellors gave limited practical advice to guide mothers to successfully stop breastfeed early and rapidly

“I usually tell them, if it is cold, rainy or sunny, the day you have chosen to stop breastfeeding, it is THE day when you stop breastfeeding once and for all.”
(PMTCT counsellor, 23 years)

“We just tell them that when the baby is crying you have to try by all means to give formula or just anything to him/her.”
(PMTCT counsellor, 22 years)
Should/can counselling be offered on an individual basis?

Are counsellors able to differentiate the circumstances of individual women and provide appropriate ‘specific guidance’?

How to communicate the concept of competing risks to women who are disadvantaged by poor education, and subject to gender inequality?
Guidelines on
HIV and infant feeding
2010

Principles and recommendations for infant feeding in the context of HIV and a summary of evidence
Revised WHO Recommendations on the use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants (2010)

- The 2010 recommendations ... provide two alternative options for women who breastfeed and are not on ART:
  - A) daily NVP for infants from birth until the end of the breastfeeding period.
  or
  - B) continued regimen of triple ARV therapy to the mother until the end of the breastfeeding period.
National (or sub-national) health authorities should decide whether health services will principally counsel and support mothers known to be HIV-infected to:

- breastfeed and receive ARV interventions, **or**
- avoid all breastfeeding,

as the strategy that will most likely give infants the greatest chance of HIV-free survival.

This decision should be based on international recommendations and consideration of the socio-economic and cultural contexts of the populations served by Maternal and Child Health services, the availability and quality of health services, the local epidemiology including HIV prevalence among pregnant women and main causes of infant and child mortality and maternal and child under-nutrition.
High quality evidence that ...

- ARV interventions to infants or mothers significantly reduce HIV transmission through breastfeeding
  - No evidence of diminished protection over time

- No evidence of significant drug-related adverse events
  - No increased adverse events with prolonged ARV intervention.
  - NVP adverse events occur within first few weeks and do not accumulate with longer exposure
  - Dose of NVP given to infants as prophylaxis is less than that routinely given as ART for infected infants

- Significant increased morbidity and mortality with not breastfeeding or stopping breastfeeding early
2009 WHO Guideline meeting

- Is a public health 'blanket' approach justifiable?
  - Is there an ethical conflict between a public health approach and the principle of individual human rights (a mother's right to choose the infant feeding practice)

  - Do no harm (Non-maleficence / primum non nocere)
  - Do good (Beneficence)
  - Respect people’s right to choose / autonomy
  - Be fair
Convention on the Rights of the Child

• Article 3: “In all actions concerning children … the best interests of the child shall be a primary consideration.”

• Article 6: “… every child has the inherent right to life … survival and development ….”
Public Health Population Focus

- The U.S. Institute of Medicine defines public health (approaches) as “what we as a society do collectively to assure the conditions in which people can be healthy”
- A key characteristic of public health is a focus on population-level concerns
- In this sense, public health is different from clinical practice, which focuses on the interests of an individual patient
- Question: how can the concept of individual rights fit into public health population focus?
Why Is a Focus on Individual Rights Important for Public Health Activities?

- Focusing on individual rights enhances the efficacy of public health activities
  - Example: non-discrimination
- A focus on rights also reminds public health practitioners of their reciprocal obligations
  - Example: duties to health care workers
- Human rights principles are not barriers to essential public health activities, but they establish boundaries and parameters
The Siracusa Principles

Limitations on human rights must be
- in accordance with the law
- based on a legitimate objective
- strictly necessary in a democratic society
- the least restrictive and intrusive means available
- not arbitrary, unreasonable, or discriminatory
Informed consent is a basic principle of medical ethics. It is not itself a human right, but it is grounded in the human right to bodily integrity. Yet, the nature of the consent process can vary depending on the circumstances, and in some cases the requirement for consent can be waived entirely. Decisions about how the consent process should be structured reflect both individual and community-based concerns.
A continuum of options

Confidence in intervention
• Balance of risks between options not clear (equipoise)
• Effective interventions supported by high quality evidence and cost-benefit
• Danger to others if intervention not adhered to

'Counselling' approach
• Non-directive counseling (e.g., genetic testing; medical research)
• Disclosure of all options combined with professional recommendation (e.g., most major medical treatment)
• Disclosure of single option as standard, with notification of right to refuse (e.g., HIV testing)
• Disclosure of single option as standard; right to refuse may be recognized, but patients are not notified of this right (e.g., TB treatment)
• Nonconsensual interventions (e.g., psychotropic medications to stabilize dangerous patients)
• The effectiveness of ARVs to reduce HIV transmission transforms the landscape in which decision can/should be made;

• In conjunction with the known benefits of breastfeeding to reduce mortality from other causes, an approach that strongly recommends a single option as the standard of care can be justified:
  – Information about options should be made available but services would principally support one approach.

• **Consider:** "What does the 'reasonable patient' want to hear?"
  – If there is a medical consensus in favour of a particular option, the reasonable patient would prefer a recommendation.
Mma bana study

2 randomised arms and one observational
Mothers not eligible for ART received either:
- lopinavir/ritonavir and combivir } for 6m
- abacavir/AZT/3TC } while BF
Mothers eligible for ART – outcomes observed

1248 pregnant women referred to study sites. After counselling about study interventions, 110 (8.8%) declined enrolment as preferred to give formula feeds.
Debates continue ...

Within a country such as South Africa where there is great heterogeneity among the population and quality of health services, is a 'blanket' approach justified?

Do HIV-infected mothers really need to stop breastfeeding, especially if they are on lifelong ART?
2010 WHO Principles on HIV and infant feeding

1. Balancing HIV prevention with protection from other causes of child mortality;
2. Integrating HIV interventions into maternal and child health services;
3. Setting national recommendations for infant feeding in the context of HIV;
4. When antiretroviral drugs are not (immediately) available;
5. Informing mothers known to be HIV-infected about infant feeding alternatives;
6. Providing services to specifically support mothers to appropriately feed their infants;
7. Avoiding harm to infant feeding practices in the general population;
8. Advising mothers who are HIV uninfected or whose HIV status is unknown;
9. Investing in improvements in infant feeding practices in the context of HIV.
2010 WHO Recommendations on HIV and infant feeding

1. Ensuring mothers receive the care they need;
2. Which breastfeeding practices and for how long;
3. When mothers decide to stop breastfeeding;
4. What to feed infants when mothers stop breastfeeding;
5. Conditions needed to safely formula feed;
6. Heat-treated, expressed breast milk;
7. (Feeding) When the infant is HIV-infected.
How would a breastfeeding/ARV approach relate to the national policy on IYCF?

• Simplified messages.
  – All infants can now gain the protection and benefits of breastfeeding
  – If mothers have HIV-infection, then clinics will provide ARV interventions (ART or prophylaxis) that significantly reduce the risk of transmission
  – Mothers who are HIV-infected should breastfeed for 12 m while HIV uninfected mothers should breastfeed for 24m
How would a decision to support BF and ARVs translate into approaches in clinics and hospitals – initial messages / support provided?
Key principle 4.
Informing mothers known to be HIV-infected about infant feeding alternatives

Pregnant women and mothers known to be HIV-infected should be informed of the infant feeding strategy recommended by the national or sub-national authority to improve HIV-free survival of HIV-exposed infants and the health of HIV-infected mothers, and informed that there are alternatives that mothers might wish to adopt;

- This principle is included to affirm that individual rights should not be forfeited in the course of public health approaches.
Key principle 5. Providing services to specifically support mothers to appropriately feed their infants

Skilled counselling and support in appropriate infant feeding practices and ARV interventions to promote HIV-free survival of infants should be available to all pregnant women and mothers;

- Recommending a single option within a national health framework does not remove the need for skilled counselling and support to be available to pregnant women and mothers.
- The nature and content of counselling and support that are required will be specified in implementation guides and training courses.
Mothers known to be HIV-infected (and whose infants are HIV uninfected or of unknown HIV status) should exclusively breastfeed their infants for the first 6 months of life, introducing appropriate complementary foods thereafter, and continue breastfeeding for the first 12 months of life.

Breastfeeding should then only stop once a nutritionally adequate and safe diet without breast milk can be provided.

When HIV-infected mothers decide to stop breastfeeding (at any time) they should do so gradually within one month.

- 12 months represents the duration for most HIV-infected mothers that capitalizes on the maximum benefit of breastfeeding in terms of survival (excluding any consideration of HIV transmission). In the presence of ARV intervention to reduce risk of transmission, this combination may give best balance of protection vs. risk.

... in settings where national authorities decide to promote and support BF and ARVs to improve HIV FS in exposed infants ...