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Feasibility of Implementing an Early Intervention Program in an Urban Low-Income Setting to Improve Neurodevelopmental Outcome in Survivors Following Birth Asphyxia

Faisabilité de mise en œuvre d'un Programme d'Intervention Précoce dans les milieux urbains à faibles revenus afin d'améliorer le résultat neurodéveloppemental chez les enfants survivant à une asphyxie à la naissance

Viabilidad de la aplicación de un Programa de Intervención Precoz en un entorno urbano de bajos ingresos para mejorar el neurodesarrollo en los supervivientes luego de un cuadro de asfixia perinatal

Elwyn Chomba, Waldemar A Carlo, Elizabeth M. McClure, Fred Basini, Linda L.Wright, Evans Mpabalwani, Musaku Mwenechanya, Lineo Thahane and Jan L. Wallander

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Feasibility of Implementing an Early Intervention Program in an Urban Low-Income Setting to Improve Neurodevelopmental Outcome in Survivors Following Birth Asphyxia

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Abstract. Birth asphyxia is a leading cause of neonatal mortality, accounting for 23% of neonatal deaths. An early intervention program (EIP) could improve neuro-developmental outcomes in survivors of birth asphyxia, but its feasibility in low-income countries has not been tested. In this pilot study in Zambia, eighty live-born infants ≥ 1500 g of weight who had birth asphyxia and received resuscitation with bag and mask were enrolled for a study of standard care or EIP. Mothers/babies pairs were randomized into control (standard care) and intervention (EIP) groups and were followed up at home on a bi-weekly basis from 8 weeks to 8 months of age. Forty two mothers/babies (52.5%) completed the study at 8 months. Reasons for not completing the study were: 19 (50.1%) were lost to follow up, 16 (42.1%) withdrew, and 3 (7.8%) died. Follow-up to 8 months of age was not feasible for the majority in a large urban city with a low income population. Thus, interventions for children who have suffered birth asphyxia that require additional health care visits may not be currently feasible in the setting tested. There is a need to conduct further EIP studies to determine ways to improve follow up rates of children surviving birth asphyxia. Integrating early intervention programs with other successful health programs, such as the existing immunization programs, may improve follow up rates.

Keywords. Birth asphyxia, neurodevelopment, early intervention program, neonatal mortality, low income, poverty, global health, children.

1 Introduction

Ninety-eight percent of the 3.7 million neonatal deaths per year occur in developing countries; the majority of these deaths occur during the first week of life (Lawn *et al.* 2009). Globally, the major direct causes of neonatal death are preterm birth (28%), severe infections (26%), and birth asphyxia (23%) (Lawn *et al.* 2005) (Figure 1).

Mortality and morbidity from birth asphyxia disproportionately affect infants in low and low-middle income countries, particularly those from the lowest socioeconomic groups (Lawn 2009). It is estimated that an equal or larger proportion of survivors suffer brain damage resulting in mental retardation and cerebral palsy. In a multicenter prospective study in eight countries in eastern, central, and southern Africa, the primary cause of neonatal mortality was identified as birth asphyxia (Kinoti 1993). Thus birth asphyxia has a large impact, especially in low resource countries.

Although little work has been done on neuro-developmental outcomes of babies surviving birth asphyxia in developing countries (Halloran 2009), Ramey and colleagues in the 'Abecedarian Project' demonstrated that intensive early intervention could enhance the development of many high-risk babies (Ramey 1992). Their EIP resulted in an IQ of 105 compared to the control average of 85 at three years.

In most developed countries, infants who are at risk for developmental delay (genetic factors, prematurity, congenital infections, and birth asphyxia) are routinely followed up. Appropriate early intervention programs are instituted to allow the child to develop to maximum potential. However, this is uncommon in low resources countries. Only a few studies have evaluated the feasibility and efficacy of EIP in

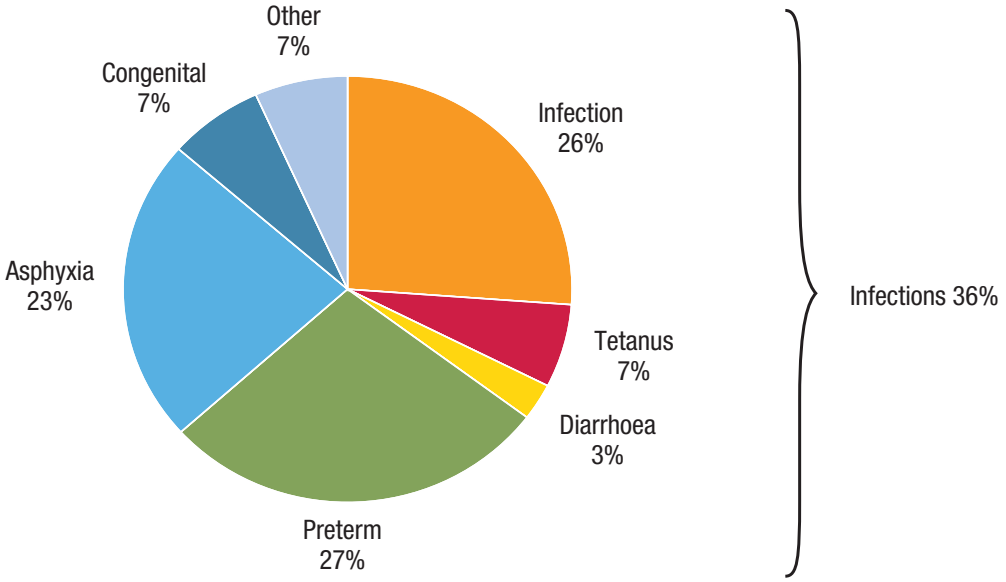

Figure 1. The estimated distribution of the direct causes of 4 million neonatal deaths for the year 2000 based on vital registration data for 45 countries and modeled estimates for 147 countries.

these settings. In a study by Badr *et al.* (2006), developmental outcomes in response to EIP were evaluated at 2 months, 6 months, and 8 months on infants with brain injury using the Bayley Scale of Infant Development (BSID). There were minimal positive effects on Mental Development Index (MDI) and Physical Development Index (PDI) of infants in the EIP group when compared to the control group. The attrition rate was 31% (Badr *et al.* 2006). In the randomized trial by Zhang *et al.* (2007), infants in the intervention group received early intervention guidance and follow up after discharge from Neonatal Intensive Care Unit (NICU) in China. The developmental outcome was evaluated based on MDI and PDI at 1 year. The MDI and PDI scores of the group with high compliance were markedly higher than in the less compliant group. This study showed that early intervention can improve the neurodevelopmental outcome of preterm infants at 1 year of age. Thus, there are some encouraging findings from studies of high risk infants in low resource countries that their development can be enhanced through early intervention.

However, the effects of an EIP on early child development for infants with birth asphyxia in low resource countries have not been evaluated sufficiently to determine if these interventions would be effective. We are aware of only one such study. A small single centre randomized controlled trial in mainland China (Bao *et al.* 1997) evaluated the effects of EIP in 64 infants with birth asphyxia who were randomized to EIP (n=34) or conventional care (n=30), At 18-24 months of age, using a modified BSID, MDI was 105 +/- 15 in the early intervention group vs 91 +/- 11 in the conventional care group ($p<0.0001$) and 100 +/- 13 in the normal term infants who received conventional care. PDI did not differ significantly between the groups.

Our study was conducted to identify infants at risk for neuro-developmental disorders and to evaluate the feasibility of implementing an innovative trial of home-based, parent-delivered early developmental stimulation intervention in Lusaka, Zambia (Figure 2). The intention was to inform a larger trial evaluating the efficacy of EIP in low resources countries that could follow.

Total population	**12,935,000**
Gross national income per capita ($)	**970**
GDP/capita($)	**1280**
Infant (under 12 months) mortality rate	**92**
Child (under 5 years) mortality rate	**148**
Total expenditure on health per capita (Intl $, 2009)	**68**
Total expenditure on health as % of GDP (2009)	**4.8**

2 Methods

Lusaka is the capital and largest city of Zambia. It has a population of about 1.7 million (ZHDS 2007). It is a commercial centre as well as the centre of government and dominates the country's urban system accounting for 32 percent of the total urban population in the country. About 70 percent of Lusaka's population lives in poor, unplanned settlements comprising 20 percent of the city's residential land. Urban poverty is reflected by the fact that informal settlements are expanding faster than the rest of the city. All of these mushrooming informal settlements are similar in that they lack adequate shelter, essential infrastructure as well as inadequate access to water and sanitation facilities. Thus, the situation in the unplanned urban settlements makes its residents vulnerable to epidemics. The housing, health, and environmental conditions in the growing informal settlements of city consequently are extremely poor. Road accessibility is

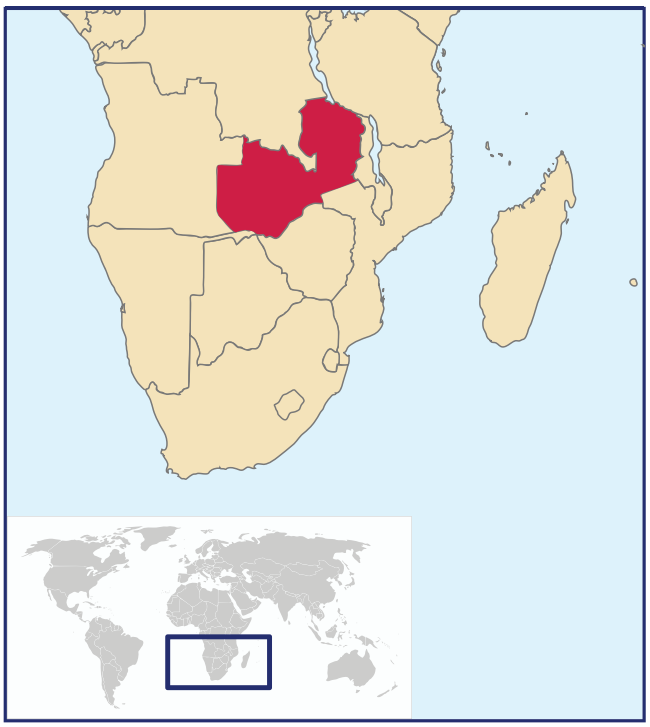

Figure 2. Socioeconomic characteristics of Zambia (source: www.raise-a-smile.org)

almost impossible during the rainy reason which starts from November to March as most of the roads are washed away.

Eighty live born infants weighing ≥ 1500 g were recruited from delivery centers in Lusaka. The babies had birth asphyxia defined by the inability to initiate or sustain breathing at birth (WHO definition) (WHO 1997) and needed resuscitation with bag and mask. Mothers/babies pairs were randomized into control (n=40) and intervention group (n=40).

Starting at 8 weeks, college-trained physiotherapists and nurse health counselors gave parents in both groups WHO health messages (Appendix 1) at home on a bi-weekly basis up to 8 months of age. Messages emphasized exclusive breastfeeding, infant feeding, immunizations, etc. The intervention group parents were trained in engaging their babies in stimulating developmentally appropriate activities, following the Partners for Learning Curriculum (Sparling & Lewis 1984). This is a home-based parent provided model which allows the intervention to occur in the family context for a child aged 0-3 years. A home-based, parent-implemented EDI model was chosen because the home is the foremost natural environment for learning to occur for a child aged 0-3 years, and the parent (or the equivalent) is one of the limited numbers of caring persons with whom the infant or toddler is attached (Ramey & Ramey, 1998). This approach supports the parent in the role as the first teacher of the child and provides opportunities for strengthening the parent-child bond. This model is also especially well suited for low-resource settings because it requires relatively little infrastructure and resources to implement, compared to alternative models, such as center-based interventions.

Partners for Learning has several components that are transmitted via a trainer who visits parents in the children's homes. During each visit, lasting about 45 minutes, the trainer presents playful interactive learning activities, which are depicted on cards. Each activity targets a developmentally appropriate competence. Cycles of use allow the parent to implement several activities for a while, but then move on to new activities as the child masters each competence. This progression is guided by the trainer, who selects activities to match and enhance the child's developmental competences. *Partners for Learning* covers a full spectrum of 23 developmental skill areas, organized into the four areas: (1) cognitive and fine motor, (2) social and self-help, (3) gross motor, and (4) language skills. The trainer encourages the parent to apply the targeted activities until the next home visit by integrating them into daily life with the child. The activities can thus enrich care routines such as diapering, feeding, dressing and special one-to-one times. By applying these activities and observing how the child changes and acquires these competences, general principles gradually emerge that enable the parent to gain a deeper understanding of early child development. With this understanding, the parent can appreciate her own important contribution to the child's development, thereby gaining enhanced efficacy in the parenting role and becoming empowered as an important agent in the child's life.

Six health workers (3 physiotherapists and 3 nurses) were trained by two senior child development experts for a period of one week. This included lectures and practical sessions both at the institution and in the community (Figure 3).

The assessment was matched to the developmental period with an upper limit of 2 weeks. The sessions in the control group lasted for 45 minutes and 75 minutes in the intervention group

Stringent methods were put in place to trace babies. Researchers would look for mothers who changed location by interviewing neighbors and looking up these mothers at their new addresses. When found, mothers were encouraged to continue to receive the parent trainer during scheduled home visits. To compare compliance with EIP to another health intervention, we obtained the rates of attendance at immunization clinics of babies born during the same time as the study population.

3 Data Management

Data were entered locally and transmitted electronically to the data coordinating center (RTI International, Research Triangle Park, NC, USA) where edits and data analyses were performed.

4 Human Subjects Protection

This study was approved by the University of Zambia's Research Ethics Committee and the University of Alabama at Birmingham's Institutional Review Board.

5 Results

A total of 99 mother/babies pairs were screened, with birth weight > 1500g. One baby (1.0%) had notable severe mental/

Figure 3. Health workers being trained by child development experts.(source: WHO 2011)

physical impairments. All lived within the study area in rented accommodations (Table 1).

Consent was obtained from the participants and 80 were enrolled into the study. Mother's mean age was 23.7, median 22.0 with a standard deviation of 5.6. All the mothers were African, and 67 (83.8%) were married and 13 (16.3%) were single. The mean for years completed at school was 8.8, median 9.0, standard deviation of 3.0 (Table 3).

Most of the mothers had an average of 2 children (Table 4). Multiple births (twins) occurred in 7 (8.8%) of the mothers, and 98.8% of the mothers attended antenatal care. The mean gestation age at delivery was 36.8, median 36.0 with a standard deviation of 2.6. The mean age at first visit was 4.6 weeks, median 4.0, standard deviation of 2.1 (Table 5).

Completion in this study was defined as infants followed up at bi-weekly intervals by the research assistants and assessed at 4 months and 8 months of age. Of the 80 enrolled, 42 infants (52.5%) completed the study at 8 months (22 from intervention, and 20 from the control groups). Of the 38 (47.5%) who did not complete the study, reasons were as follows: 19 (50%) were lost to follow up, 16 (42.1%) withdrew, and 3 (7.8%) died (Table 2). The mean length for the EIP visits was 38.7 minutes; median was 40.8 with a standard deviation of 17.6 (Table 6).

6 Discussion

Our study aim was to assess the feasibility of implementing EIP in an urban, poorly resourced setting. In the study, 52.5% of the enrolled infants completed the study to 8 months; 22 from the intervention group and 20 from the control group. This study used the Partners for Learning curriculum which is a home-based parent provided model that allows the intervention to occur in the home, a natural environment for learning to occur for a child aged 0-3 years. One advantage of this model is that it relies on tools/materials normally found in the home. It was envisaged that by training eight health workers in administering the Partners in Learning Curriculum, these would become Trainer of Trainers in conducting EIP. This model could then be used not only for infants surviving from

Table 1. Screening information

	Total
Total number screened (N)	99
Speaks English - n/N (%)	57/95 (60)*
Baby > 1500 g at Birth - n/N (%)	98/99 (99)
Severe mental/physical impairment - n/N (%)	1/99 (1)
Lives in study area - n/N (%)	98/99 (99)
Consent obtained - n/N (%)	80/99 (80)

*4 missing

Table 2. Study completion information

	Number	**%/mean + std**
Total number enrolled	80	100%
Completed study	42	52.5%
Did not complete study	34	42.5%
(Reasons for not completing the study)		
Loss to Follow up	14	41.2%
Withdrew	16	47.1%
Died	3	8.8%
Other	1	2.9%

Table 3. Demographic information

	Statistic	Total
Total number enrolled	N	80
Mother's age	N	78
	Mean	23.7
	Median	22.0
	Std Dev	5.6
	Min – Max	15 - 38
Mother's race	N	80
African - n/N (%)	n (%)	80/80 (100)
Marital Status	N	80
Married	n/N (%)	67/80 (84)
Single	n/N(%)	13 (16)
Years of School Completed	N	79
	Mean	8.8
	Median	9.0
	Std Dev	3.0
	Min – Max	0 – 15

Table 4. Pregnancy History

	Statistic	Total
Total number enrolled	N	80
Gravida	N	80
	Mean	1.9
	Median	1.0
	Std Dev	1.6
	Min – Max	1 - 7
Parity	N	73
	Mean	2.0
	Median	1.0
	Std Dev	1.7
	Min – Max	1 - 7
Number of children (excluding this one)	n	35
	Mean	1.8
	Median	1.0
	Std Dev	1.6
	Min – Max	0 - 5
Pregnancies lost at or before birth - n/N (%)	n	6/80 (8)
Number of preterm babies that died at or bebefore birth	n	4
	Mean	0.8
	Median	1.0
	Std Dev	0.5
	Min – Max	0 - 1
Number of term babies that died at or before birth	n	5
	Mean	1.4
	Median	1.0
	Std Dev	1.5
	Min – Max	0 - 3

birth asphyxia but in other high risk infants such as those with very low birth weight.

Developmental assessments of babies who survive birth asphyxia also serves as an audit for those performing resuscitation, as an increase in mental handicap following birth asphyxia would warrant a review of skills of birth attendants. Strategies such as WHO Essential Newborn Care have been or are being rolled out to reduce neonatal deaths from birth asphyxia in developing countries. However there is some concern that the survivors may end up with minor to major developmental problems. It is therefore important that well designed control follow-up studies of babies at risk be conducted to assess neuro-developmental outcomes of these interventions (Wallander *et al.* 2010).

However, in our study there was a high loss to follow-up in comparison with the relatively high compliance for immunization visits, which have a similar schedule (Appendix 2). The immunization coverage for measles was 84% (WHO 2006). One difference that may account for the better compliance rate is that immunization has been a long and pro-active campaign in educating parents on the need to have infants immunized. It also requires parents to take their children to a specified location. The immunizations are done at the health centres where families can also access treatment for their babies. EIP in contrast is a novel concept in this culture. The message conveying the rationale and benefits of EIP would need careful development to match well this cultural context.

In order to improve follow up for implementation of an EIP in families living in urban slums there needs to be a careful evaluation of resources (human and financial) required for an effective program. In our study, follow-up of these children in their homes on a bi-weekly basis was expensive both in time and human resources for the health workers. In most developing countries such as Zambia, there is a shortage of healthcare workers, who are needed to

Table 5. Current pregnancy information

	Statistic	**Total**
Total number enrolled	n	80
Current pregnancy is multiple births - n/N (%)	n	7/80 (9)
Number of fetuses - n/N (%)	n	7
2	n (%)	7/7 (100)
Mother had prenatal care for current - n/N (%) (%)pregnancy	n	79/80 (99)
Number of prenatal visits	n	59
	Mean	4.2
	Median	4.0
	Std Dev	1.8
	Min – Max	1 - 10
GA at first prenatal visit (weeks)	n	8
	Mean	14.3
	Median	16.0
	Std Dev	5.7
	Min – Max	2 - 20
GA at delivery (weeks)	n	79
	Mean	36.8
	Median	36.0
	Std Dev	2.6
	Min – Max	26 - 44
Age of child at visit (weeks)	n	79
	Mean	4.6
	Median	4.0
	Std Dev	2.1
	Min – Max	2 - 10

Table 6. Study visit/assessment information

Variable	**Statistic**	Total
Total number enrolled	N	80
Total number of visits	N	512
Number of visits per participant	N	511
1-2	n/N(%)	125(24.5)
3-5	n/N(%)	154 (30.1)
6-8	n/N(%)	110 (21.5)
9-11	n/N(%)	76 (14.9)
12-14	n/N(%)	38 (7.4)
> 14	n/N(%)	8 (1.6)
Age of participant (months)	(N)	512
	Mean	4.2
	Median	4.0
	Std Dev	2.0
	Min-Max	1-8
Visit location	N	508
Home	n/N(%)	210 (41.3)
Clinic	n/N(%)	298 (58.7)
Visit type	N	506
EIP	n/N(%)	419 (82.8)
ASQ assessment	n/N(%)	18 (3.6)
EIP & ASQ assessment	n/N(%)	6 (1.2)
Control	n/N(%)	63 (12.5)
Age ASQ assessment completed (months)	N	21
4	n/N(%)	16 (76.2)
8	n/N(%)	5 (23.8)
Length of EIP visits (minutes)	N	405
	Mean	38.7
	Median	40.0
	Std Dev	17.6
	Min-Max	1-330
Rating of mother's use of activities	N	182
1	n/N (%)	4 (2.2)
2	n/N(%)	9 (4.9)
3	n/N(%)	32 (17.6)
4	n/N(%)	53 (29.1)
5	n/N(%)	84 (46.2)

attend to the high disease burden. Most of the health workers therefore deal with life threatening illnesses at the health facilities. Diverting health workers to long-term prevention programs may not be preferable under these conditions. Community based interventions using trained *non-professional* individuals and creation of mother support groups may improve not only the survival of children (through health care messages given at home) (WHO 2006), but also may improve the neuro-developmental outcomes. In a study by Bang *et al*. (Bang 1999) village health workers trained in neonatal care made home visits and managed birth asphyxia, premature birth or low birth weight, hypothermia, and breast-feeding problems. This package of

home-based care included the management of neonates with septicemia, meningitis, and pneumonia. Neonatal and infant mortality was reduced by nearly 50% among the malnourished, illiterate, rural study population.

The parent trainer sessions in the intervention group in our study lasted about 45 minutes per session on a bi-weekly basis, raising questions to sustainability and success in implementation. This may be too much to expect from mothers given the various demands they face. Among the majority of rural and low-income urban dwellers, women perform all domestic tasks, while many also farm and trade. They are also responsible for the care of other children (most participants had more than one child at home), the sick and the elderly, in addition to performing essential social functions within their communities. This poses a challenge for improving neurodevelopmental outcomes through home-based programs where women are overburdened by multiple family chores (Manuh 1998). It is envisaged that exploring new ways of implementing EIP such as the use of trained community based workers and shortening the parent training session may result in a higher compliance rate.

Studies in developed countries and a few in developing countries have shown that EIP can improve a child's development (Bennett *et al*. 1991, Wasik *et al*. 1990, Brooks-Gunn *et al*. 1994, McCarton *et al*. 1997, Reynolds 1994, Bonnie 2008). Follow-up evaluations as long as 18 years have shown significant positive effects for those who received EIP during the first two years of life on measures of intelligence, reading comprehension, mental health, and self-esteem (Walker *et al.* 2005). Empirical data are now available from a small-scale single center trial that suggests that low-cost home-based parent-provided early interventions can improve developmental outcomes in infants with asphyxia also in developing countries (Bao *et al*. 1997). However, its suitability to the varying conditions among low resources countries must be evaluated.

To be successful as the immunization programs, interventions to implement neuro-developmental programs for children who have suffered birth asphyxia need further development, taking the social conditions of each setting into consideration.

7 Conclusion

In this study we achieved a follow up rate of 52% at 8 months. There is need to conduct further EIP studies to determine ways to improve follow up rates of children surviving birth asphyxia. Integrating early intervention programs with the existing immunization programs may improve follow up rates in the first year of life. It is also important to consider that community based trained interventionists become the core group to spearhead EIP as this would be cost-effective and sustainable due to the shortage of health workers.

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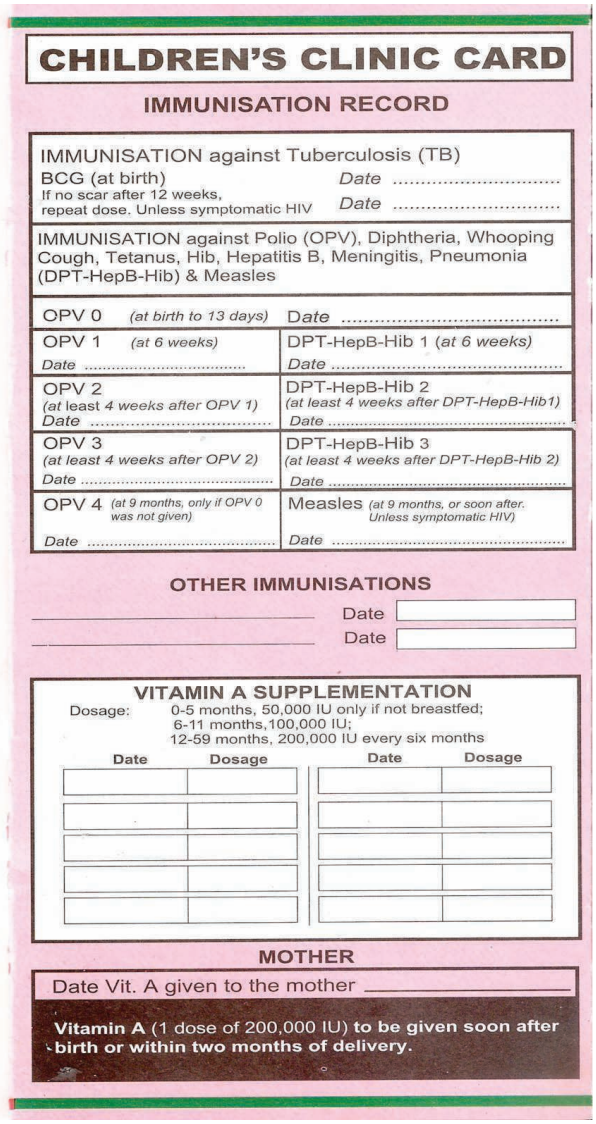
Appendix 1. IMCI messages for home visitor's health counselling

VISIT NO.	MESSAGE NO.	MESSAGE CONTENT
1	4	Exclusive BF for 6/12
2	12 13	Washing Hands
3	14 15	Immunization of children When to immunize children
4	5	When to take the young child below 2/12 to the H/W
5 6	25 16	Recognizing when sick children need treatment outside home and care from appropriate health personnel Use of bed nets to prevent malaria
7	26	Follow advice given by the health worker on giving medicines
8	27	Take the child back to the H/C after specified number of days for follow up
9	6	Introduction of complementary foods @6/12 of age
10	7	Infant Feeding 6/12 months
11	10	Feeding iron rich foods and iron supplements
12	11	Feeding Vitamin A rich foods and Vitamin A
13	18	Care of a child with fever where malaria is common
14	19	Providing interactive and exciting environment for children
15	20	Providing opportunities for play to children
16	15	Immunization repeated
17	21	Feeding fluids to sick children
18	2	Continuing feeding food to sick children

2 visits in a month
At every visit, counselor will assess child's health and home situation to decide on a topic to discuss

Appendix 2



CHILDREN'S CLINIC CARD

IMMUNISATION RECORD

IMMUNISATION against Tuberculosis (TB)

BCG (at birth) *Date* .....

If no scar after 12 weeks, repeat dose. Unless symptomatic HIV *Date* .....

IMMUNISATION against Polio (OPV), Diphtheria, Whooping Cough, Tetanus, Hib, Hepatitis B, Meningitis, Pneumonia (DPT-HepB-Hib) & Measles

OPV 0 *(at birth to 13 days)* *Date*	
OPV 1 *(at 6 weeks)* *Date*	DPT-HepB-Hib 1 *(at 6 weeks)* *Date* .....
OPV 2 *(at least 4 weeks after OPV 1)* *Date*	DPT-HepB-Hib 2 *(at least 4 weeks after DPT-HepB-Hib1)* *Date* .....
OPV 3 *(at least 4 weeks after OPV 2)* *Date*	DPT-HepB-Hib 3 *(at least 4 weeks after DPT-HepB-Hib 2)* *Date* .....
OPV 4 *(at 9 months, only if OPV 0 was not given)* *Date*	Measles *(at 9 months, or soon after. Unless symptomatic HIV)* *Date* .....

OTHER IMMUNISATIONS

_____ Date

_____ Date

VITAMIN A SUPPLEMENTATION

Dosage: 0-5 months, 50,000 IU only if not breastfed;
6-11 months,100,000 IU;
12-59 months, 200,000 IU every six months

Date	Dosage	Date	Dosage

MOTHER

Date Vit. A given to the mother _____

Vitamin A (1 dose of 200,000 IU) **to be given soon after birth or within two months of delivery.**