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Epidemiology of perinatal mortality in rural Burkina Faso: A community-based prospective cohort study

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Dedication

This work is dedicated to:

My beloved mother
In recognition of all your sacrifices to make life better for me, your commitment to avoid me a perinatal death and your daily care for us. Thank you mom!

My late father
Your advice and your “upright conduct” are my source of inspiration and behaviour. Wherever you are, I am sure you rest in peace, as do the right people!

My son, Barké Yasser
Few days ago, I have missed for the third time your birthday when you were just celebrating your fourth anniversary. You are too young to understand the continuous moves of daddy, but I hope you will find them worthy when you will be able to read this thesis. I wish you a long and prosperous life and may you do better than your father as we say in Fulfuldé.

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To my supervisor, Professor Thorkild TYLLESKAR, CIH/UiB
I have been lucky enough to get to know you and even more lucky to have you as my supervisor. Your patience, availability, continuous support and guidance have been very important for me both in the implementation of the EBF trial in Burkina Faso, and especially in the writing of this thesis. While working with you, I have also learned and admired human qualities as your always good mood, your optimism and above all, this quality that French call “la force tranquille”. I know this is one of the steps in our goals, however I would like already to say thank you very much professor!

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Finally all of this would not have been possible without the love and support of my wife Aicha DIALLO, who committed herself to upbringing and caring for our son Barké Yasser while I was either in Banfora or in Bergen.

List of abbreviations and acronym

- ANC: Antenatal care
- BMI: Body mass index
- CFA : Communaute Financiere Africaine (African Financial Community) is the local currency for 14 francophone or lysophone countries in West and Central Africa. The conversion rate is fixed for Euro with 1 Euro=655.957 CFA.
- CI : Confidence intervalle
- CSPS : Centre de Sante et de Promotion Sociale. Correspond to a primary health care facility in Burkina Faso health care system.
- DHS : Demographic Health Survey
- DRC: Democratic Republic of Congo
- DSS : Demographic Surveillance Site
- EBF: Exclusive breastfeeding
- EU: european Union
- HIV: Human Immunodeficiency Virus
- INSD: Institut National de la Statistique et de la Demographie. This is the office for demographic survey and statistics in Burkina Faso
- IRB: Institutional Review Board
- MDG: Millennium Development Goals
- MoH: Ministry of Health
- PDA: Personal Digital Assistant; this is a handheld computer.
- PMTCT/HIV: Prevention of Mother –To- Child Transmission of HIV
- PNMR: Perinatal Mortality Rate
- PROMISE: Acronym for **PROM**oting **I**nfant health and nutrition: **S**afety and **E**fficacy of the promotion of exclusive breastfeeding. The PROMISE Consortium is coordinated by the University of Bergen (Norway)
- SD: Standard deviation
- SOWC: State Of the World Children (Annual report of the UNICEF)
- TBA: Traditional Birth Attendant
- UNAIDS: United Nations, HIV/AIDS Agency
- UNDP: United Nation Development Programme
- UNICEF: United Nations International Children's Emergency Fund
- VCT: Voluntary Counselling & Testing

- VPN: Virtual Private Network
- WHO: World Health Organization

Executive summary

Background:
Perinatal mortality is one of the major public health problems in Sub-Saharan Africa. It is estimated that over 6 millions infant deaths occur each year during the perinatal period either as stillbirths or early neonatal deaths. However, the accurate estimates on this burden are rare, especially in Africa where over 40% of all perinatal deaths take place. The lack of reliable data on PNMR in developing countries could be one of the reasons that make it invisible and therefore getting little attention from the funding agencies. We took the opportunity of the PROMISE-EBF trial, a randomized community-based study that aimed at assessing the effect of the promotion of exclusive breastfeeding by peer-counsellors on EBF rates and child morbidity at 12 weeks of age, to describe the magnitude of PNMR in Banfora health district, a rural area, South of Burkina Faso.

Study objectives:
To measure the PNMR in the EBF cohort in Banfora health district
To identify potential risk factors for perinatal death in this cohort

Methods:
We performed a secondary analysis on the datasets of the EBF study which was a cluster-randomized trial in 24 villages of Banfora with an intervention package consisting of one antenatal and 6 postnatal individual counselling sessions on EBF. Data of the two arms were considered as those of a single cohort and the PNMR, the stillbirth and the early neonatal mortality rates were estimated. In a multivariable logistic regression using baseline characteristics of the study participants as exposures and the perinatal death as outcome, we calculated crude and adjusted OR for perinatal death, stillbirth and early neonatal death. Covariates with an OR statistically significant ($p<0.05$) were considered as risk factors for PNMR.

Results:
900 pregnant women were sampled for data collection in the EBF trial. Five women were excluded later (wrong inclusions) and 20 women got multiple births (20 pairs of twins), and were excluded from further follow-up. 875 women with a single birth were followed up to day 7 postpartum and included in the final analysis. The PNMR, the stillbirth and the early neonatal mortality rates, were 73.1‰ [95% CI: 55.8-90.4], 56‰ [95% CI:40.7-71.2], and 18.1‰ [95% CI:9-27.2], respectively.
In the crude analysis, the young age of the mother (<20 years), the parity (nulliparous women), the season of birth (dry season), and the intervention appeared as the main risk factors for PNMR.
In a multivariable logistic regression adjusting for all variables that were found to be important in the occurrence of perinatal deaths, we found that the young age of the mother (OR=2.93 95% CI:1.54-5.57), a birth during the dry season (OR=1.85 95% CI: 1.19-2.87), and the intervention (OR=2.16 95% CI:1.20-3.89) were factors that increased significantly the risk of perinatal death. The intention of the mother to not EBF the future baby had a marginal effect on PNMR (OR=1.55 95% CI:0.97-2.49) but a statistically significant effect on the risk of stillbirth (OR=1.90 95% CI:1.04-3.47).

Conclusion:
Our study showed the burden of perinatal deaths in a rural area in Burkina with the highest PNMR ever reported in this country. The risk factors identified in this study have been reported in previous studies except the intention of the mother to EBF that need further investigations.

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- A post-term baby: A baby born after 42 weeks of gestation
- A preterm baby: A baby born before 37 weeks of gestation
- Early neonatal mortality rate: number of infant deaths occurring during the first week (0-6 days) of life divided by the number of live births for the same period.
- Low birth weight: A birth weight <2500g
- Neonatal mortality rate: number of infant deaths occurring during the first four weeks of life divided by the number of live births for the same period.
- Perinatal mortality rate: number of deaths occurring during the perinatal period (28 weeks of gestation up to 7 days after birth) divided by the total number of births that occurred in the same period.
- Sensitivity analysis: is the study of how the variation (uncertainty) in the output of a (mathematical) model can be apportioned, qualitatively or quantitatively, to different sources of variation in the input of a model.
- Skilled birth attendant: A person who has received a specific training on antenatal care and practice of delivery. Those are doctors, midwives, nurses, auxiliary-midwives in Burkina Faso.
- Stillbirth rate: number of foetal loss from the 28^{th} week of gestation (7 months) reported to the total number of pregnancies. If the foetal loss occurred before labour it is an antepartum stillbirth, and if it has occurred during the labour, this is an intrapartum stillbirth.

Introduction

Perinatal mortality is one of the major public health challenges in the developing world and especially in Sub-Saharan Africa (WHO(a) 2006). Perinatal mortality is the sum of all stillbirths and infant deaths occurring in the first week of life.
The global burden of perinatal mortality is estimated over 6 millions each year with 3 millions stillborn and 3.3 millions early neonatal deaths(WHO(a) 2007). Stillbirths account for over half of all perinatal deaths (WHO(a) 2006).
Neonatal deaths refer to infant deaths occurring within the first four weeks of life and were about to 3.7 millions in 2004 (WHO(a) 2007). It is estimated that 25-45% of the neonatal deaths occur just within the first 24h hours after birth (Lawn, Cousens et al. 2005) and almost three quarters of them during the first week of life (Lawn, Cousens et al. 2005).
Sub-Saharan Africa has the highest perinatal mortality rate estimated to be 56 per 1000 births in 2004, followed very closely by the Asian region with 47 per 1000 births (WHO(a) 2007). During the same year, the stillbirth rate and the early neonatal rate were estimated at 28 and 29 per 1000 births, respectively (WHO(a) 2007).
There is quite a spread in these figures within the African region, with the Central and West African regions having the highest perinatal mortality rates in the world, at 74 and 69 per 1000 births, respectively (WHO(a) 2007).

Some data suggest that with adequate care during childbirth, the intrapartum stillbirths estimated to count as much as one third of all stillbirths, could be reduced to less than 10% of all stillbirths (WHO(a) 2006).
While the exact causes of antepartum stillbirths remain unknown (WHO(a) 2006), there has been some data to show clearly that intrapartum stillbirths and early neonatal deaths are strongly dependent to the delivery conditions (Lawn, Cousens et al. 2004; Lawn, Cousens et al. 2005; WHO(a) 2006). The main risk factors identified for intrapartum stillbirth and early neonatal death are obstructed and prolonged labour, dystocia, malpresentation at delivery, infection associated to rupture of membranes > 24h, haemorrhages at delivery or in the postpartum period, inappropriate use of oxytocin during delivery and birth asphyxia (Kusiako, Ronsmans et al. 2000; Lawn, Cousens et al. 2004; Lawn, Cousens et al. 2005; WHO(a) 2006).
Recent studies from West Africa (Ogbolu 2007; Edmond, Quigley et al. 2008; Owolabi, Fatusi et al. 2008), and Central and Eastern Africa (Habib, Lie et al. 2008; Haggaz, Radi et al. 2008; Engmann, Matendo et al. 2009) have confirmed the previous knowledge on these risk factors and suggested that some socio-demographic factors including age, parity, education, socio-economic status and antenatal care of the mother may play a role in the occurrence of antepartum stillbirth.
It appears that the perinatal mortality burden is primary a reliable indicator of the availability, the accessibility and the quality of care for antenatal and childbirth services. It is also a good indicator of poverty as the most vulnerable women and babies are those living in the rural settings of Africa and Asia, and belonging to the poorest groups in these regions.

Because the perinatal mortality overlaps at least four goals (1, 3, 4, 5) of the Millennium development goals (United Nations 2008), it is important for the international community to seriously commit itself to defeat this “quiet killer” that takes

away each year about 6.3 millions lives. Indeed, perinatal death affects those who are yet to be born and those who are too young and too weak to cry their pain, and as such it is a big emotional issue.
However, perinatal mortality has also a more objective side, as several publications have raised the lack of data on this burden which makes it invisible. In two publications of the WHO (WHO(a) 2006; WHO(a) 2007) and in a series in The Lancet advocating for neonatal survival (Lawn, Cousens et al. 2004; Lawn, Cousens et al. 2005; Lawn, Cousens et al. 2006), the need for more precise and reliable estimates of the perinatal mortality throughout the developing countries and especially in the Sub-Saharan Africa has been demonstrated. It is obvious that one can only combat successfully a scourge which is identified and more effectively if we know where it occurs. Implementation of relevant and efficacious health programmes rely on data and it is crucial that the national health authorities in Sub-Saharan Africa make some efforts to provide these data.

Burkina Faso is one of the least developed countries in the world and belongs to those countries with scarce and unreliable health statistics (UNDP 2008; The World Bank 2009). The under-five child mortality rate was estimated to be at 191 per 1000 live births in 2007, with an infant mortality and a neonatal mortality rates 104 and 32 per 1000, respectively, (UNICEF 2009). Perinatal mortality data in this country are rare (see literature review section). The scarce estimates from DHS ranged from 32 to 50 per 1000 births (Burkina Faso 2000; Burkina Faso 2004).
We took the opportunity of the PROMISE-EBF study, an EU-funded multicentre cluster-randomized trial that aimed at measuring the effect of the promotion of exclusive breastfeeding by peer-counsellors from local communities on exclusive breastfeeding rates and child morbidity, to estimate the perinatal mortality in a rural area of Burkina Faso.
This study is a secondary analysis of the EBF-trial data with the objective to assess the magnitude of the perinatal deaths in rural Burkina Faso.

Study objectives

The overall goal of the main EBF trial was to investigate the effect of the promotion of exclusive breastfeeding by peers-counsellors on the exclusive breastfeeding rates at 12 weeks of child age and its impact on the prevalence of diarrhoea at 12 and 24 weeks of child age.

In this thesis, however, we will focus on the objectives of our secondary analysis that were:

General objective:

- To describe the epidemiology of perinatal deaths in the prospective community-based PROMISE/EBF cohort in rural Burkina Faso.

Specific objectives:

- To estimate the risk of perinatal death in this cohort as a proxi-indicator of the perinatal mortality rate in rural Burkina Faso.
- To describe the baseline characteristics of women who have experienced a perinatal death during the EBF study.
- To identify potential risks factors for perinatal deaths in this cohort.

Literature review & background information

A lot of studies have been conducted on perinatal mortality in different resource-limited countries with various objectives (Lawn, Cousens et al. 2005; WHO(a) 2006). The main limitations in these studies were, their small sample size, few were prospective cohort studies or community-based studies, and the use of non standardized tools for assigning causes of deaths (Rudan, Lawn et al. 2005). The most reliable data on cause of death come from hospital-based studies whereas in these area many pregnant women do not attend antenatal care services and a high proportion of deliveries are occurring outside health facilities, such as home (WHO(a) 2006; UNICEF 2009). Another source of data for perinatal mortality in sub-Saharan Africa regions is the Demographic and Health Surveys (DHS) that also have their methodological limitations (Lawn, Cousens et al. 2005; WHO(a) 2006) namely the reporting errors, the recall bias for issues related to previous infant mortality and the exclusion of some subgroups (women not alive on the day of interview). Furthermore, misclassification of stillbirths in many rural areas is another reason for unreliable estimates of the perinatal mortality in Africa.
This section will provide some information about the common definitions used in the assessment of perinatal mortality and summarizes the basic knowledge about the topic so far in Burkina Faso.

Definitions

Perinatal mortality is defined as the sum of foetal loss (from 28 weeks of gestation) and early neonatal deaths (by day 7 postpartum) reported for the total number of deliveries occurring during the same period. It is usually estimated over a period of one year and therefore is computed as a perinatal mortality rate. In fact to be statistically correct it is a perinatal mortality risk.
Perinatal mortality has two components:

- the ***stillbirth*** defined as any "foetal death prior to the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such separation the foetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord or definite movement of voluntary muscles" (WHO(b) 2007).
- the ***early neonatal death*** defined as any death of a live born baby "occurring during the first seven days of life (0-6 days), (WHO(b) 2007).

A ***live birth*** is defined as "the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached; each product of such a birth is considered live born", (WHO(b) 2007).
The perinatal period commences at 22 completed weeks of gestation and ends seven completed days after birth. However for international comparisons, the period from 28 weeks of gestation to 7 days is used (WHO(a) 2006; WHO(b) 2007).
The definition of the perinatal mortality and its methods of estimation are not consensual (Kramer, Liu et al. 2002; Kramer 2003; Engmann, Matendo et al. 2009). Indeed while the 28th week of gestation is the cut off for the Sub-Saharan Africa

countries and the WHO statistics, the developed countries with improved neonatal resuscitation equipment and neonatal care for preterm babies (incubators), have set this threshold at 22 weeks of gestation or often rely on a definition of a birth weight of 500 g and above.
It is a standard method to estimate the stillbirth rate per thousand births using as denominator the number of pregnant women in the cohort while the early neonatal death rate is estimated for thousand live births, meaning the denominator used is the total number of live births in the cohort.
Conventionally and because of their relative low frequency (Tartin JA 1999; WHO(a) 2006) and their high perinatal mortality risk (Canada 2003; Mahy. 2003), multiple births are not used in the denominator of perinatal mortality estimation in several studies.

It is also common in clinical practice to distinguish the fresh stillbirth (for which death has occurred within 12-24 hours of delivery without symptoms of skin disintegration) from the macerated stillbirth (for which death is beyond 12-24 hours prior delivery and with pulpy peeling skin).
From a public health perspective, there is also a usual approach to differentiate the antepartum stillbirths (where the intrauterine death occurs before onset of labour) from the intrapartum stillbirths (in which the intrauterine death occurs during labour) for etiological and interventional purposes.
No particular reason is identified for most antepartum stillbirths while the number of intrapartum stillbirths directly reflects the availability of health facilities and skilled birth attendants, the quality of care including emergency obstetric care and the effectiveness of the referral system in a country. Indeed it was shown that the proportion of intrapartum stillbirths is below 10% of all stillbirths in settings where women receive adequate care during childbirth (WHO(a) 2006).

The ***neonatal mortality rate*** is the number of deaths in the live born babies, occurring between birth and 28 completed days, in relation to the total number of live births during the same period.
The other important definitions to know while dealing with the topic of the perinatal mortality are listed below:

- ✓ The ***gestational age*** is the time measured from the first day of the woman's last menstrual cycle to date. It is expressed either in completed days or weeks.
- ✓ A pregnancy of “normal” gestation is approximately 40 weeks, with a range from 37 to 42 completed weeks
- ✓ Infants born before 37 completed weeks of gestation are considered pre-term.
- ✓ Infants born after 42 completed weeks of gestation are considered post-term.
- ✓ A neonate weighing less than 2500 g at birth is defined as a low birth weight.

The gestational maturity rating is measured by the Ballard scale or Dubowitz exam.

A ***traditional birth attendant*** (TBA) is a woman in any village who is assisting most of the village women during childbirth and who had got her skills either by self-learning or after a brief training (Engmann, Matendo et al. 2009).
In Burkina Faso, most of the TBAs have got formal literacy training and are officially recognized by the “health system” despite a notice from the Ministry of Health in

September 2006 (MoH, 2006) that immediately prohibited the TBAs from performing deliveries in their respective villages.
The health personnel providing antenatal and obstetric care in Burkina Faso's health system include doctors (practicing only in district hospitals), midwives, nurses and auxiliary-midwives (who are present both in district hospitals and in primary health care facilities in the local villages as well).

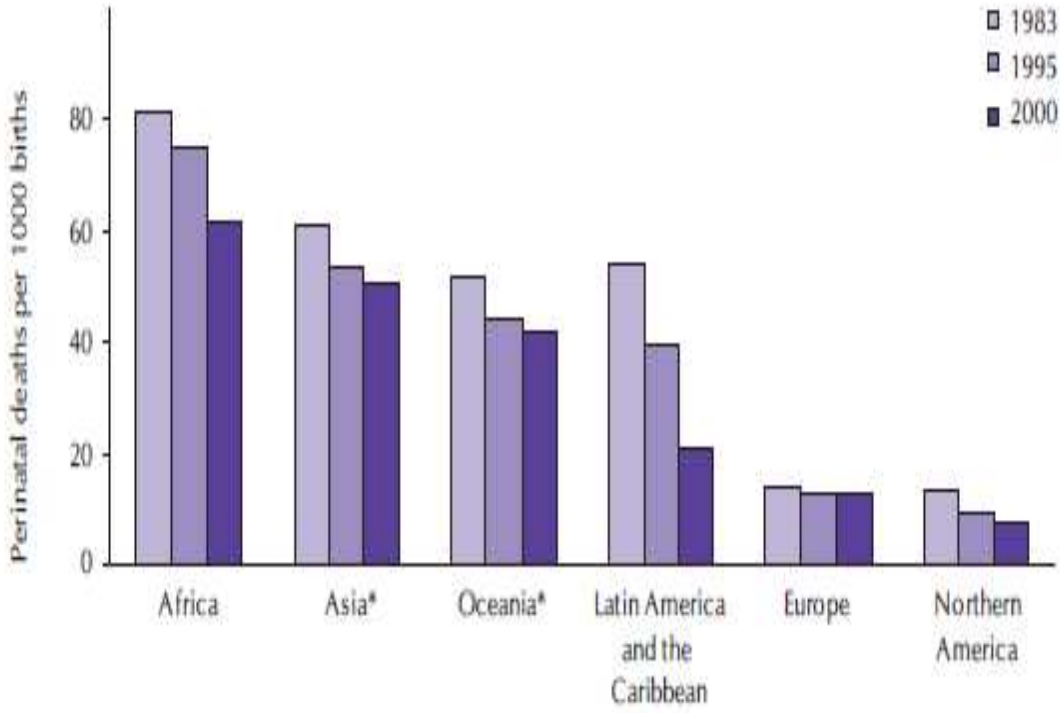
Global estimates of the perinatal mortality

The global estimates (WHO(a) 2006) suggest that over 7 millions perinatal deaths occur each year in the world. Almost 98% of them occur in developing countries and Sub-Saharan Africa has the highest perinatal mortality rate of 56 deaths per 1000 births (WHO(a) 2007). The West African region has one of the worse rates (table 1) in this continent with 69 deaths per 1000 births (WHO(a) 2006; WHO(a) 2007).

*Table 1: Global estimates of stillbirths, early neonatal, perinatal and neonatal mortality rates and numbers by level of development and geographical (United Nations) region and subregion, 2004 (**source: WHO, 2007**)*

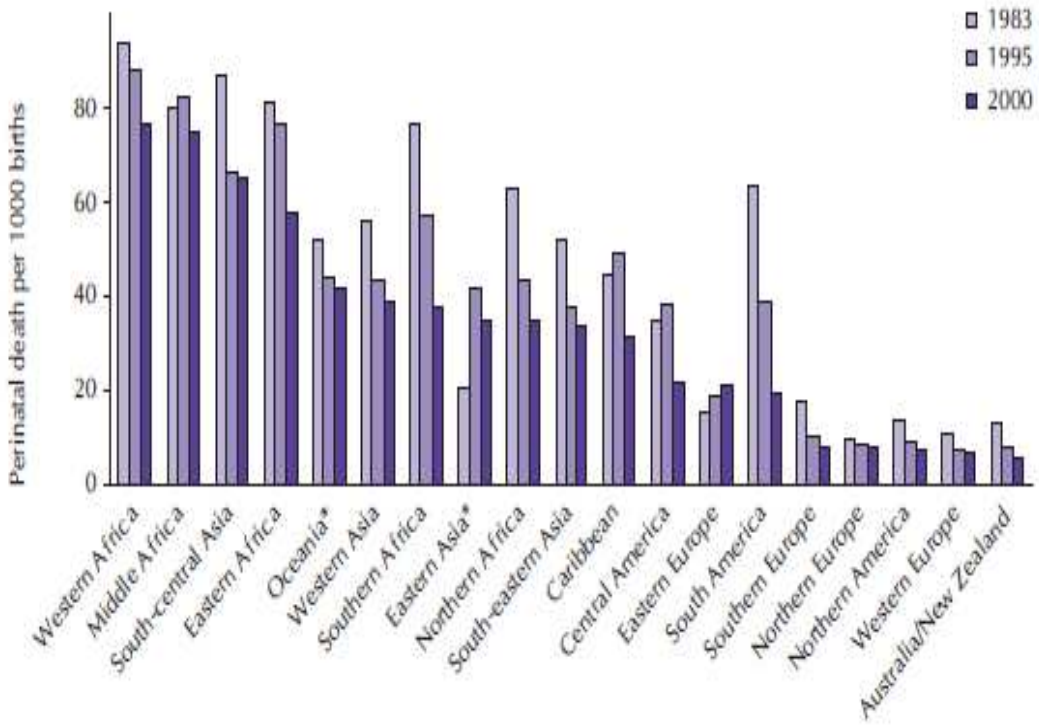
	Live births (1000s)	Perinatal mortality rate	Number of perinatal deaths (1000s)	Stillbirth rate	Number of stillbirths (1000s)	Early neonatal mortality rate	Number of early neonatal deaths (1000s)	Neonatal mortality rate	Number of neonatal deaths (1000s)
WORLD	**133 136**	**43**	**5 852**	**22**	**3 027**	**21**	**2 825**	**28**	**3 729**
More developed regions	13 291	7	95	4	51	3	44	4	56
Less developed regions	119 845	47	5 757	24	2 976	23	2 781	31	3 673
Least developed countries	27 823	60	1 718	31	878	30	841	41	1 130
AFRICA	**33 049**	**56**	**1 896**	**28**	**946**	**29**	**950**	**38**	**1 261**
Eastern Africa	11 388	48	560	21	239	28	321	37	421
Middle Africa	4 943	74	379	41	211	34	168	45	222
Northern Africa	4 746	31	150	16	76	16	74	21	100
Southern Africa	1 276	34	44	19	24	16	20	20	26
Western Africa	10 696	69	763	36	396	34	367	46	492
ASIA*	**74 794**	**47**	**3 630**	**25**	**1 923**	**23**	**1 707**	**30**	**2 254**
Eastern Asia*	18 307	30	563	17	310	14	254	18	327
South-central Asia	39 616	61	2 506	33	1 333	30	1 172	40	1 568
South-eastern Asia	11 458	30	346	15	177	15	169	19	213
Western Asia	5 413	39	215	19	103	21	112	27	145
EUROPE	**7 354**	**8**	**60**	**5**	**34**	**4**	**26**	**5**	**34**
Eastern Europe	2 916	11	32	6	16	5	15	7	20
Northern Europe	1 066	7	7	4	5	2	3	3	3
Southern Europe	1 490	6	9	3	5	3	4	4	6
Western Europe	1 882	6	12	4	7	2	4	3	5
LATIN AMERICA AND CARIBBEAN	**11 754**	**19**	**220**	**8**	**101**	**10**	**119**	**13**	**152**
Caribbean	767	29	23	16	12	14	10	18	14
Central America	3 316	19	63	9	31	9	31	13	42
South America	7 671	17	134	7	57	10	77	13	96
NORTHERN AMERICA	**4 464**	**7**	**29**	**3**	**14**	**3**	**15**	**4**	**19**
OCEANIA*	**249**	**42**	**11**	**23**	**6**	**19**	**5**	**26**	**7**
Australia/New Zealand	304	5	2	3	1	2	1	3	1
Melanesia	221	45	10	25	6	21	5	28	6
Micronesia	14	13	0.2	7	0.1	6	0.1	8	0.1
Polynesia	15	23	0.3	12	0.2	10	0.2	13	0.2

An analysis of regional and global trends of perinatal mortality (Lawn, Cousens et al. 2005; WHO(a) 2006) from 1983 to 2000 has shown a steady decline over time, with remarkable progress observed in Latin America and the Caribbean (figure 1). The declines have been less marked in Africa (figure 2) but some researchers argued that the previous estimates were less accurate and therefore one should be cautious in the interpretation of these trends (WHO(a) 2006).
The annual number of stillbirths is estimated to be over 3.3 millions and the risk of stillbirth is 14 times greater in developing than in developed countries (WHO(a) 2006). While the exact proportion of antepartum stillbirths is unknown, the studies (Lawn, Cousens et al. 2005; WHO(a) 2006) suggest that 24-37% of stillbirths occur during delivery, and are avoidable.
The other component of the perinatal mortality is the early neonatal deaths that are estimated to be around 3 millions each year (Lawn, Cousens et al. 2005; WHO(a) 2006), and occur almost all in low-income and middle-income countries. The early neonatal deaths represent three-quarters of the overall neonatal mortality that is estimated itself to be over 4 millions each year (Lawn, Cousens et al. 2005). The neonatal mortality is currently about 38% of the deaths in children younger than 5 years.



* Australia/New Zealand and Japan have been excluded from the regional estimates but are included in the total for developed countries.

*Figure 1: Perinatal mortality by region, 1983, 1995 and 2000 (**source: WHO, 2006**)*



* Australia/New Zealand and Japan have been excluded from the regional estimates but are included in the total for developed countries.

*Figure 2: Perinatal mortality by subregion, 1983, 1995 and 2000 (**source: WHO, 2006**)*

There is a huge variation of the perinatal mortality estimates throughout the time and the space, and even within a country. These variations are closely linked to the socio-economic factors, to the health care system, to the vital registration system and finally to some cultural factors.
The lack of functioning vital registration system in most of the developing countries combined with a weak health system make it difficult to capture the exact figures of perinatal mortality in many developing countries. In a review (WHO(a) 2006), the WHO has shown that out of the 192 countries whose datasets were used to compute the regional and global estimates of the perinatal mortality, only 53% reported data on stillbirths rate and 73% on early neonatal death rates.

The misclassification of the two components of the perinatal mortality is another challenge researchers are facing when trying to analyze the estimates for this outcome. Indeed in many of the Sub-Saharan Africa settings, there is little equipment for neonatal reanimation (Spector and Daga 2008) and where this equipment exists, the health personnel were not familiar to its use whenever needed (Cowles 2007; Spector and Daga 2008). As a consequence, a lot of early neonatal deaths are just classified as stillbirths either because the health worker did not check appropriately the vital status of the newborn (using the stethoscope) or because no attempt of resuscitation was performed. Another large source of this misclassification is the home deliveries that unfortunately represent over 50% of deliveries in rural areas of Africa (Lawn, Wilczynska-Ketende et al. 2006; WHO(a) 2006; UNICEF 2009) and

where mothers or their families very often report infant deaths that have occurred in the first hours after birth as stillbirths (Stanton, Lawn et al. 2006).
Finally, two other factors are cited also as potentially contributing to a poor knowledge of the perinatal burden:

- ✓ The administrative constraints linked to declaration of a live birth followed by early death in babies born in hospitals or when the parents report to the birth registration office and their incidental costs.
- ✓ Some cultural and emotional factors like mothers may feel less guilty if they declare having had a stillbirth rather than an early neonatal death.

Risk factors and determinants of perinatal death

Numerous efforts have been made especially by the WHO to describe the main risk factors of perinatal deaths in the world and mainly in the developing countries. The bulk of the available data come from the same sources as the estimates of the perinatal mortality (prospective hospital-based studies, DHS, and scarce case-control studies), and therefore carry the same limitations as stated above. Globally the risk factors and the determinants of the perinatal mortality are divided in three groups:

- ✓ Risk factors for antepartum stillbirths: these are poorly described and the exact causes remain unknown in most of the cases (WHO(a) 2006). However data suggest that maternal diseases during the pregnancy, maternal socio-demographic characteristics and pregnancy-related complications could play an important role. In a prospective community-based study in Malawi, McDermott et al. (McDermott, Steketee et al. 1996) found that reactive syphilis serology, history of perinatal death, nulliparity and the mother's height were important risk factors for antepartum stillbirths. In another multicentre study conducted in 6 West African countries, Chalumeau et al. (Chalumeau 2002) found that bleeding after the 7th month of pregnancy, hypertension and high multiparae were risk factors for antepartum stillbirth. In a more recent prospective study in central Africa, Engmann et al. (Engmann, Matendo et al. 2009) reported that absence of antenatal care, prematurity and low birth weight as important factors associated to occurrence of stillbirths.
- ✓ Risk factors and causes of intrapatum stillbirth: more data are available for this group and these mainly come from health facility-based studies. They include obstetric complications (obstructed labour, malpresentation, maternal hemorrhages, and misuse of drugs), maternal infections (including malaria) and congenital abnormalities. In a prospective study conducted in Ghana, Edmond et al. (Edmond, Quigley et al. 2008) found that the 59.3% of mothers who experienced a stillbirth had obstetric complications at delivery and that no reason was found in 31.5% of cases. Some cultural factors like female genital mutilation have been suggested in a WHO-study (Banks, Meirik et al. 2006).
- ✓ Risk factors and causes of early neonatal deaths: these are definitely the most well described (Lawn, Cousens et al. 2005; Lawn, Wilczynska-Ketende et al. 2006; WHO(a) 2006) and include three major factors: preterm birth, low-birth weight despite some controversies (Kramer, Liu et al. 2002; Lawn, Cousens et al. 2005; WHO(a) 2006) and maternal and newborn infections (tetanus, HIV, malaria, etc). Other factors involved are birth asphyxia, maternal health and nutritional status at the time of

conception. The gender of the newborn has been shown in some studies to be a potential determinant of early neonatal deaths and the theory of "natural resistance" of girls to neonatal deaths was developed (Ulizzi and Zonta 2002; Lawn, Cousens et al. 2005; WHO(a) 2006). However other authors claim that this biological difference is counteracted by the societies preferences for boys (Nielsen 1997).

In the Lancet series advocating for neonatal survival in 2005, Lawn et al. (Lawn, Cousens et al. 2005) have summarized in a table (table 2) the main risk factors for perinatal deaths from population-based studies.

Malaria and its induced anemia as well as HIV-infection are two constant factors that have been associated with poor pregnancy outcome in several studies in Sub-Saharan Africa (Steketee, Wirima et al. 1996; Brocklehurst and French 1998; Steketee, Nahlen et al. 2001; WHO 2005; Uneke 2008).

*Table 2: Adjusted OR for various risk factors for neonatal or perinatal death reported from population-based studies (**source: Lawn et al., 2005**).*

	Adjusted odds ratio*
Life-cycle factors	
Maternal age (years)	1·1–2·3
<18	1·3–2·0
>35	
Maternal size	
Height <150 cm	1·3–4·8
Prepregnancy weight <47 kg	1·1–2·4
Parity	
Primigravida	1·3–2·2
Parity >6	1·4–1·5
Poor obstetric history (previous perinatal death or instrumental delivery)	1·6–3·5
Antenatal factors	
Multiple pregnancy	2·0–6·8
Hypertensive disorders	
Pre-eclampsia	1·7–3·7
Eclampsia	2·9–13·7
Bleeding per vagina after 8th month	3·4–5·7
Maternal jaundice	2·0–7·9
Maternal anaemia (PCV <0·21)	1·9–4·2
Maternal anaemia (PCV <33%)	NS in 4 studies
Maternal malaria (blood test positive)	2·2–3·5†
Syphilis (perinatal death)	1·7–5·8
HIV (infant death)	7·2
Intrapartum factors	
Malpresentation	
Breech	6·4–14·7
Other	8·3–33·5
Obstructed labour/dystocia	6·7–84·9
Prolonged second stage	2·6–4·8
Maternal fever during labour (>38°C)	9·7–10·2
Rupture of membranes >24 h	1·8–6·7
Meconium staining of liquor	11·5

PCV=packed cell volume; NS=not significant. *Odds ratios included are from population-based studies adjusting for major confounders (parity and socioeconomic status) and significantly associated with intrapartum stillbirth or neonatal death or perinatal death unless given as NS in more than one study. †Risk for low birthweight not mortality.

Efficacious health interventions and health policy

The public health challenges posed by the perinatal mortality rates in Africa are numerous and complex. The crucial need for community-based data in rural regions to identify areas and social groups that urgently need the most specific and relevant health interventions is running against the pragmatic approach of acting in blind manner given the limited financial resources, infrastructure and equipment, and trained staff. Several authors have shown the similarity between the main causes of intrapartum stillbirths and those of early neonatal deaths (Lawn, Cousens et al. 2005; Lawn, Wilczynska-Ketende et al. 2006) and have been advocating for a concerted, harmonized, integrated and global policy targeting both perinatal and neonatal mortalities seen as two sides of the coin. There is also evidence that such a policy if implemented in a comprehensive approach would positively impact on maternal mortality.

The MDG-4 achievement in 2015 will depend mainly of the reduction of the neonatal mortality and more specifically on the reduction of the early neonatal deaths that represent 75% of neonatal deaths and an important component of the perinatal mortality. The global pragmatic strategies proposed so far include:

- ✓ The sustainability and scaling-up of community-based interventions that were shown to be feasible and accepted in resource-limited countries: antenatal care, prevention of malaria during pregnancy using the intermittent preventive treatment (IPT) with sulfadoxin-pyrimethamine and the impregnated-treated bed nets, supplementation of pregnant women with iron and micronutrients.
- ✓ Improve the accessibility, the coverage and the quality of the care in antenatal services including access to contraception for all women who need it, and access to the PMTCT of HIV in countries where HIV-prevalence is high.
- ✓ Improve the geographical and financial accessibility, the quality of care, the effectiveness of the referral system in health facilities, the availability of emergency obstetric care in childbirth services.
- ✓ The necessity to rely on simple and cheap health interventions such as immunizations of mothers and babies (tetanus, BCG), the early initiation of breastfeeding, the promotion of exclusive breastfeeding during the first 6 months, the health education of mothers and communities with a special focus on nutrition and transmissible diseases and hygiene.
- ✓ The training of more staff as well as the need of refreshment trainings for the existing staff is another important aspect of any policy that aimed at reducing perinatal mortality.
- ✓ Overall, the perinatal mortality is also the reflexion of social inequities and therefore any strategy targeting the burden of perinatal mortality need to address sincerely the gap between the richest and the poorest within a country and throughout the world. The need of maternal and child health programmes targeting the most vulnerable groups in rural settings has been reported in many studies (Lawn, Cousens et al. 2005; Lawn, Wilczynska-Ketende et al. 2006; WHO(a) 2006)
- ✓ Lastly but not the least, there is a need of an improved information for decision making on the perinatal mortality issue. This illustrates the need of more complete and reliable data on this outcome if we want to identify and address avoidable causes of stillbirths and neonatal deaths. As correctly

pointed out by Lawn et al. (Lawn, Cousens et al. 2005) “absence of consistent periodic estimates leads to invisibility, and invisibility contributes to inaction.”

Perinatal mortality in Burkina Faso (A literature review)

Data on the perinatal mortality rates in Burkina Faso are scarce. The main sources of data are rare hospital-based studies or from DHS. Another source of perinatal mortality rates is the annual national health statistics published by the Ministry of health (MoH/BF) but that encompasses the weakness of the health system that provides it, namely delay in publication, approximate figures, lack of standardization and complete lack of motivation of the health staff who often feel this task as an extra duty. The perinatal mortality rates range from 32.5 to 54 per 1000 depending of the year and the source of data (Chalumeau 2002; WHO(a) 2006). The stillbirth estimates varied from 16 to 50 per 1000 but were clearly unreliable, and few studies measured the early neonatal deaths for which the average estimation is 23 per thousand live births. The data of the last DHS (Burkina Faso 2000; Burkina Faso 2004) suggest a reduction in the child mortality in Burkina Faso in all the age groups as outline by the figure 3 but this needs to be confirmed by prospective community-based studies.

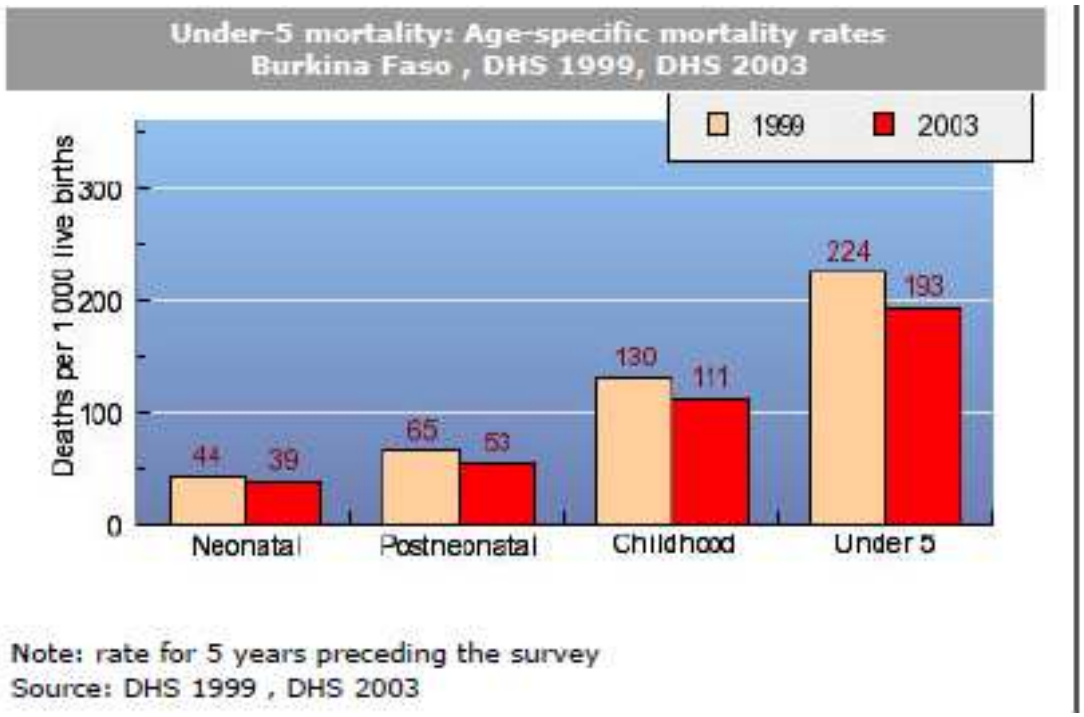


*Figure 3: Evolution of the mortality rates in Burkina between 1999 and 2003 (**source: WHO, 2006**)*

The table 3 below summaries the main findings of the literature review for perinatal mortality in Burkina Faso using Pubmed and WHO databases. The key words entered were: child mortality, neonatal mortality, stillbirth, perinatal mortality, poor

pregnancy outcomes, neonatal deaths, perinatal deaths, Burkina Faso. No limitation of date was set. We listed all available publications, read the summaries and downloaded full articles when accessible online. For non accessible articles, a request of printout was sent to the medical library of the University of Bergen (www.uib.no) to obtain the full articles. After reading the full articles, we summarized the findings that seemed to be of interest for the estimation and the risk factors of perinatal mortality in this country. We do acknowledge that given that the official language in Burkina Faso is French, it is possible that some scarce publications without summaries in English are unavailable in Pubmed. We are also aware that some data from hospital-based studies may only exist at the faculty of medicine in Ouagadougou where they have been used for medical degree theses. Such sources of data are not accessible online and have not been published in peer-reviewed journals.

Table 3: Literature review on perinatal mortality in Burkina Faso

First author	Study Year	Type of study	PNMR[a] (‰)	SBR[b] (‰)	ENMR[c] (‰)	NMR[d] (‰)	Year of publication	Comments
Armagnac C et al.	1969-1977	Repeated cross sectional studies (surveys)	-	50.0	-	-	1981	Study conducted in 9 villages in the region of Bobo-Dioulasso and Dedougou, mainly focused on fertility rates
Prazuck et al.	1989	Hospital-based case-control study	-	29.8	-	-	1993	This study was carried out in 3 maternity clinics of Bobo-Dioulasso, and focused on the risk factors for preterm delivery. No data is reported about early neonatal death
Burkina Faso, INSD	1998-1999	DHS	54.0	30.0	25.0	36.0	2000	2nd DHS in Burkina Faso
Chalumeau M.	1994-1996	Hospital-based study	32.5	20.9	-	-	2002	Performed in the university hospital of Ouagadougou as part of a multicentre study (MOMA)
Becher H et al.	1992-1999	Retrospective analysis of DSS data	-	-	-	-	2004	Study implemented in Nouna health district in 41 rural villages included. This study focused on risk factor of child mortality but no data on perinatal deaths is provided
Burkina Faso, INSD	2003	DHS	36.0	16.0	21.0	32.0	2004	3rd DHS in Burkina Faso
Hammer GP el al.	1999-2003	Retrospective analysis of DSS data	-	-	-	93.6	2006	Study conducted in Nouna health district where a DSS was implemented since 1992
Bank E et al.(WHO)	2001-2003	Prospective health facility-based study	50.0	41.7	7.9[e]	-	2006	This was a multicentre study carried out by the WHO in 6 countries including Burkina Faso and was focused on the impact of FGM on obstetric outcome. The exact figure of perinatal death for Burkina is not given.
Koueta F et al.	2002-2006	Retrospective hospital-based study	-	-	-	153.0	2007	Study carried out in the pediatric university hospital CDG in Ouagadougou. The study that focused on main neonatal morbidity and mortality did not specify the number of early neonatal deaths.
Fillipi V et al.	2004-2006	Prospective health facility-based cohort study	219.6	-	-	-	2007	This study targeted women with severe obstetric. complications so the PNMR is for a specific group

First author	Study Year	Type of study	PNMR[a] (‰)	SBR[b] (‰)	ENMR[c] (‰)	NMR[d] (‰)	Year of publication	Comments
Bell JS et al.	2001-2006	Community-based surveys	-	33	-	-	2008	Study conducted in 2 rural health districts in Ouargaye and Diapaga with a focus on maternal mortality.
Roberfroid et al.	2004-2006	RCT,Community-based study	31.7	20.6	10.3	14.6	2008	A RCT on maternal multiple micronutrient supplementation in Hounde health district, a rural area in Burkina Faso.
Becher H et al.	1998-2001	Retrospective analysis of DSS data	-	-	-	-	2009	Study carried out in Nouna health district. This study is a mathematical modeling of age and season effect on childhood mortality. No data on perinatal deaths.

[a] Perinatal mortality rate, [b] Stillbirth rate, [c] Early neonatal mortality rate, [d] Neonatal mortality rate [e] Computed only for the 2 first days of live

Description of the study site

Burkina Faso

Geography

Burkina Faso (literally means country of “Upright people”) is a francophone country located in the middle of West Africa. The country is land-locked surrounded by Cote d’Ivoire, Ghana, Benin and Togo in the South, by Mali in the north-west and by Niger in the North-eastern part as shown by figure 4. Burkina covers an area of 274 200 Km^2 with a Sudanese savannah climate in the South-western part and an almost desert-like climate in the Northern part (Sahel). Its current population is estimated at 14.1 millions (Burkina Faso 2009) predominantly rural (81%), with a higher proportion of females (52%). The country got its formal independence from France in 1960 but still has strong links with this country both in economic, political and cultural aspects. Today the country is organized into 13 administrative regions and 45 provinces.

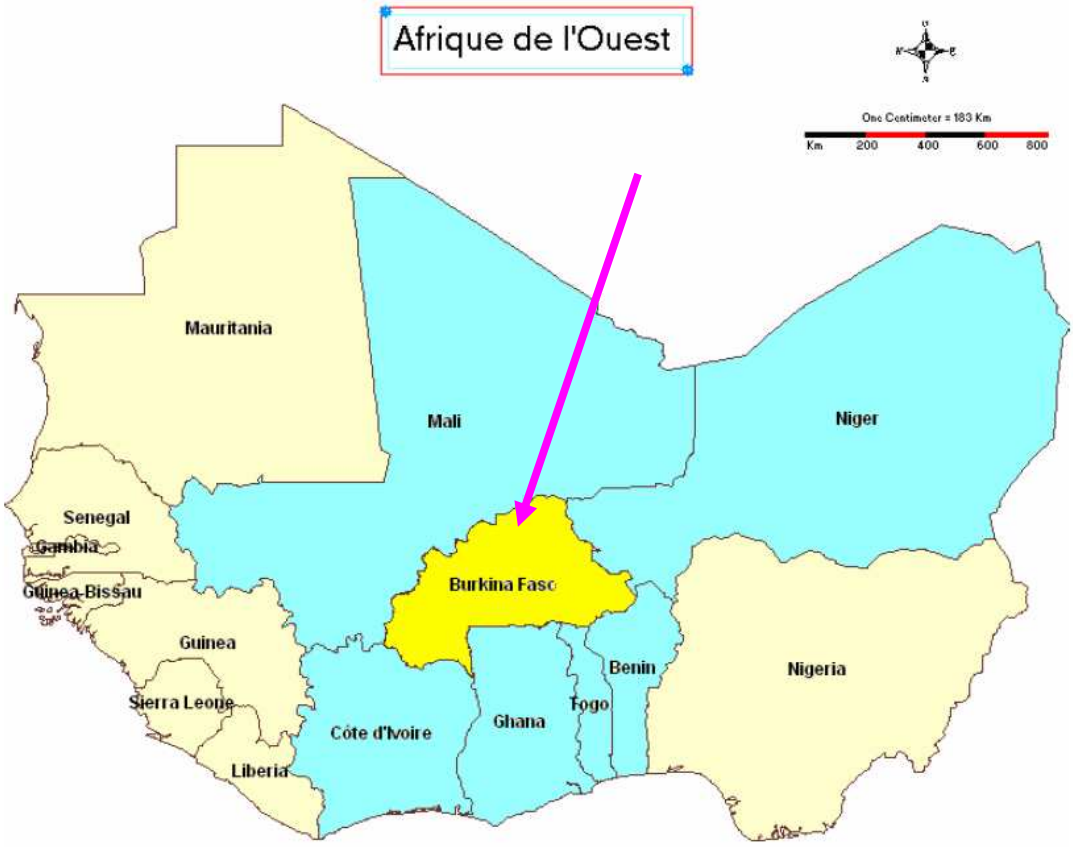


Figure 4: Geographic location of Burkina in West Africa (a mainland country)
(Source: INSD, 2009 Report)

Economics

Burkina Faso is one of the poorest countries in the world (UNDP 2008) and was ranked at 173/179 in 2008 with more than 46% of its population living below the international poverty line of 1.25 US per day (The World Bank 2009). The country does not have any substantial natural resources like oil, gold, diamonds, forest or sea. Small gold mines are scattered around the Central Eastern part and a

manganese deposit is yet to be exploited in the Northern part of Burkina. The main resources of the country come from agriculture and livestock that represent 45% and 16% of the gross domestic product (GDP), respectively. The gross national income (GNI) per capita was estimated at 430 US in 2007 (UNICEF 2009). The life expectancy at birth was at 52 years in 2007 (UNICEF 2009).

Demography and health

The population annual growth rate was estimated at 3 per 1000 in 2007 with a crude birth rate of 44 per 1000 for the same year. The crude death rate in Burkina was at 15 per 1000 in 2007 (UNICEF 2009) as outlined in table 4.
Illiteracy is a great problem in the country with a total adult literacy just at 29% and a net primary school attendance rate of 47% (UNICEF 2009).
From the health perspective, only 72% of the population have access to safe drinking water with a lower proportion in rural areas (66%).
In terms of health indicators Burkina has very high rates of morbidity with a crude morbidity rate at 5.8% (Burkina Faso(b) 2008) and a high crude mortality of 15 per 1000 (Burkina Faso 2009), similar to many other low-income countries.
Child mortality and morbidity are certainly among the worst in this region of Africa. Indeed the country stands at the sad rank of having the 7th highest under-five year mortality rate, estimated to be 191 per thousand live births in 2007 (UNICEF 2009). In the same period, the infant mortality rate was 104 per thousand live births, and a neonatal mortality rate of 32 per thousand live births (UNICEF 2009).
Despite timid progress in the trends of child health, the situation is still alarming.
The main causes of child deaths are malaria, pneumonia, meningitis and diarrhoea. Malnutrition is an underlying cause in more than 70% of the cases.
The country still continues to experience outbreaks of meningitis and measles almost every year and meningitis is responsible for 12% of the deaths among the under-five year olds.
The causes of morbidity are very similar with malaria representing the first reason (53%) for hospitalization in health facilities followed by acute respiratory infections (14%), meningitis (8%), diarrhoea (3%), malnutrition (2%) and other diseases like measles and HIV infection (Burkina Faso(a) 2008).
Among the under-five year olds, severe malaria is responsible for as many as 60% of the hospitalizations.
Despite large immunization coverage (99%) for most of the antigens, the infant mortality rate remains very high (104 per 1000 in 2007) raising a lot of questions about the reliability of this immunization coverage and the quality of the vaccines.

From the maternal health perspective, the situation is not brilliant with a maternal mortality ratio of over 484 per 100 000 live births (an adjusted rate at 700 in 2005), a low contraceptive use (17%) and a high home delivery rate (50%). The attendance of antenatal clinics seems acceptable with antenatal care coverage of 85% for one ANC visit (UNICEF 2009).
The broad reasons of maternal deaths include reduced access to health facilities, delay in reaching the health services, poverty and illiteracy, and lack of emergency obstetric care. The medical causes of maternal deaths are bleeding (haemorrhages), bacterial infections (sepsis), malarial anaemia, placental retention, and uterine rupture for higher multigravidae or long standing deliveries.

Malnutrition is another health challenge faced by Burkina Faso. The prevalence of low birth weight is at 16% with an exclusive breastfeeding rate of 19% at 3 months and 7% at 6 months (Burkina Faso 2004; UNICEF 2009). The prevalence of stunting among children under-five years was at 35% and that of wasted at 23% in 2007. The proportion of children from the same age group suffering from under-weight was at 32% for the same period and it was estimated that 73% of them got full supplementation of vitamin A (UNICEF 2009).

HIV infection has emerged in the late 1990s and has become a public health problem with an estimated prevalence of 7.1% in the general population in 1997. A strong involvement of the national health authorities has led to a substantial decrease of the HIV prevalence that was estimated at 1.6% in 2007 (UNICEF 2009) among the 15-49 years. The annual number of people living with HIV was roughly 130 000 in 2007, of which 10 000 were below 15 years (UNAIDS 2008).

Table 4: Summary of main health indicators of Burkina Faso from 1990 to 2007

Health indicators	**1990**	**2003**	**2007**
Crude death rate (/1000)	18	17	15
Under-5 year olds mortality rate (/1000)	206	197	191
Infant mortality rate (/1000)	112	103	104
Maternal mortality ratio (/100 000)	566	484	480
HIV-prevalence among 15-49 year olds (%)	7.1	2.7	1.6
Causes of hospitalisation among < 5 year olds (%)			
Malaria	38	63	60
Acute respiratory infections	20	10	13
Meningitis	16	6	9
Diarrhoea	20	4	4
Malnutrition	6	3	2

Sources: MoH/BF, INSD/2009, SOWC/2009

Organization of the health system and the health care

The health system is organized within the 13 administrative regions and 63 health districts with at the top of the system, the Ministry of Health and its central directorates. The health care follows closely the health system organisation in a three-level infrastructure. The university hospitals (two in Ouagadougou and one in Bobo-Dioulasso) are the most well equipped with experts in health care and clinical practice; at the intermediate level, there are 13 regional referral hospitals and the peripheral health facilities is formed both by the health districts (63) and primary health care facilities (1268). Large immunization programme has been operating in the country since 1970. Immunization was an intensive activity during the

“revolutionary power” between 1983 and 1987 with massive “alpha commando” campaigns involving the national army.
The country has also several vertical disease control programmes, established by the Ministry of Health in collaboration with partners like the WHO, European and American institutions, and regional African organs.
The most active of these programmes are the national HIV/AIDS control programme, the national malaria control programme, and the national tuberculosis control programme.
Burkina ratified the millennium development goals (MDG) convention in 2001.
The health policy is organized by the Ministry of Health and local communities are involved in some ways in the implementation of many health-related activities based on Alma-Ata and the Bamako initiative recommendations.

Centre MURAZ Research Institute

History of the Centre

Located in Bobo-Dioulasso, the second largest city in Burkina Faso, around 375 Km South of Ouagadougou, Centre MURAZ (figure 5) is the oldest and the largest national institute for health research in Burkina Faso. This Centre was initially created in 1939 by the French colonial authorities under the name of OCCGE (Coordinating organism against the hot endemics in French) to cover the entire West African region namely Cote-d’Ivoire, Benin, Togo, Senegal, Niger and Mali, and to serve as a research Unit against the so-called exotic diseases like trypanosomiasis (sleeping sickness), filariasis (onchocerciasis, dracunculosis) and malaria. The Centre remained a subregional Centre collaborating with similar francophone Units in Central Africa (Cameroon) and France up to 2000. It was finally handed over the national health authorities of Burkina Faso in 2001. The Centre was then renamed MURAZ (in memory of Colonel Gaston MURAZ, a French military doctor who worked at the institution in the 1940s).

Figure 5: Facade of one building inside the MURAZ campus

with old architectural style

Missions & organization

The Centre is now one of the technical advisory bodies of the Ministry of Health in Burkina with three main missions:

- ✓ Health research: conduct of epidemiological and basic research on diseases that are a national priority for Burkina Faso (malaria, HIV, tuberculosis, meningitis)
- ✓ Training of health personnel including medical doctors, pharmacists, biologists and laboratory technicians.
- ✓ Expertise in its areas of competence to be used wherever there is a need especially in Burkina Faso (health districts) and the West African sub-region.

The Centre is organized in four Departments of research and one infrastructure Department as shown in the figure 6.

Experience and partnership

The Centre MURAZ has an extensive experience both in basic and epidemiological researches with focus on national health priorities that are the control of malaria, meningitis and HIV/AIDS. However, expertise on other parasitic diseases (leishmaniasis, intestinal worms, schistosomiasis), microbial (tuberculosis) and viral infections (hepatitis B, yellow fever) is also available.

For malaria research, several clinical trials have been conducted by teams of MURAZ for the evaluation of malaria parasites resistance to drugs, assessment of the efficacy and safety of new drugs such as artemisinin-based combination therapy, monitoring of the parasite and resistance of its vectors.

In the field of HIV/AIDS, numerous randomized controlled trials on the prevention of mother to child transmission of HIV (PMTCT) were conducted early in 1997 by the Department of Epidemiology and most of the current national treatment strategies for HIV-infected people have been assessed and validated by teams from MURAZ before their implementation in routine care and scaling-up.

Maternal and child health is another area that has known successful research by MURAZ teams namely the evaluation of the current strategy for reducing maternal mortality in Burkina Faso, the assessment of the quality of care in peripheral maternities (caesarian section) in Burkina Faso as well as the measurement of infant mortality rate using verbal autopsy.

Moreover, the teams of MURAZ were involved in the diagnostic of a newly introduced bacterial strain, the Nesseria meningitis W135 that was responsible of a meningitis outbreak in 2002 in Burkina Faso. Centre MURAZ in collaboration with the WHO is monitoring the evolution of yellow fever in our region.

The teams of MURAZ are also very active in terms of publications with over 150 publications on Medline that are associated or conducted by Centre MURAZ.

Centre MURAZ has many and diversified partnerships throughout the world. Almost 90% of the Centre's funding is coming from external sponsors like the French Ministry of Cooperation but also from research grants awarded to researchers by funding agencies like EDCTP in Europe or NIH in USA. Furthermore and through the bilateral Cooperation, some countries amongst those Belgium, Netherlands, Denmark are providing substantial financial support to the Centre. Another non

negligible source of funding for Centre MURAZ is WHO-related agencies like the TDR program, and Unicef.
In addition, the institution keeps holding strong links with similar institutions in the region and is participating to multicentre studies with research teams from Senegal, Cote-d'Ivoire, Mali, Benin and Niger and the Centre is expected to become one the Centre for excellence in the economic organization of the West African states (ECOWAS) region.
The technical platform of the Centre is equipped with the most recent machines in malaria and HIV research (real time PCR, Dinabeads, flow cytometer, HMA, ELISA, HPLC, etc).
The research teams in Centre MURAZ are mixed and pluri-disciplinary with the young researchers working under the supervision of their experienced seniors colleagues. Many of the young researchers got their initial degree in the country and their postgraduate diploma in the West African region or in Europe or in USA.
Currently the Centre employs over 130 people of which 30 are researchers.

Perspectives for Centre MURAZ

The Centre is expected to increase its research capacities the next years by training many young researchers (Master and PhD) and strengthening its partnerships to attract more grants. There is a need to reinforce the capacities of the IT Unit in order to make the Centre more visible in the region. A new building including both offices, auditoriums and a modern conference room is on the way and should contribute significantly to the overall activities and to more visibility of the institute both at the national and international levels.

Role in the PROMISE/EBF study

Centre MURAZ was the Coordinating Centre for the EBF study in Burkina Faso and signed for this purpose a contract with the University of Bergen that was responsible for the overall conduct of this study in four African countries.
The local principal Investigator and the study Coordinator have both been working in this Centre since several years. A team of more than 7 people was built especially for this study which comprised personnel both from Centre MURAZ and also from other collaborative institutions in Bobo-Dioulasso and Banfora as well.
This experienced team has performed a huge amount of work mainly due to the need of adaptation to an English-driven consortium. It has assured the adaptation and translation of the research protocol and data collection tools, trained the data collectors and the peer-supporters, performed a regular supervision and monitoring of the intervention and the data collection, and finally assured the quality control, the cleaning and the analysis of the collected data.

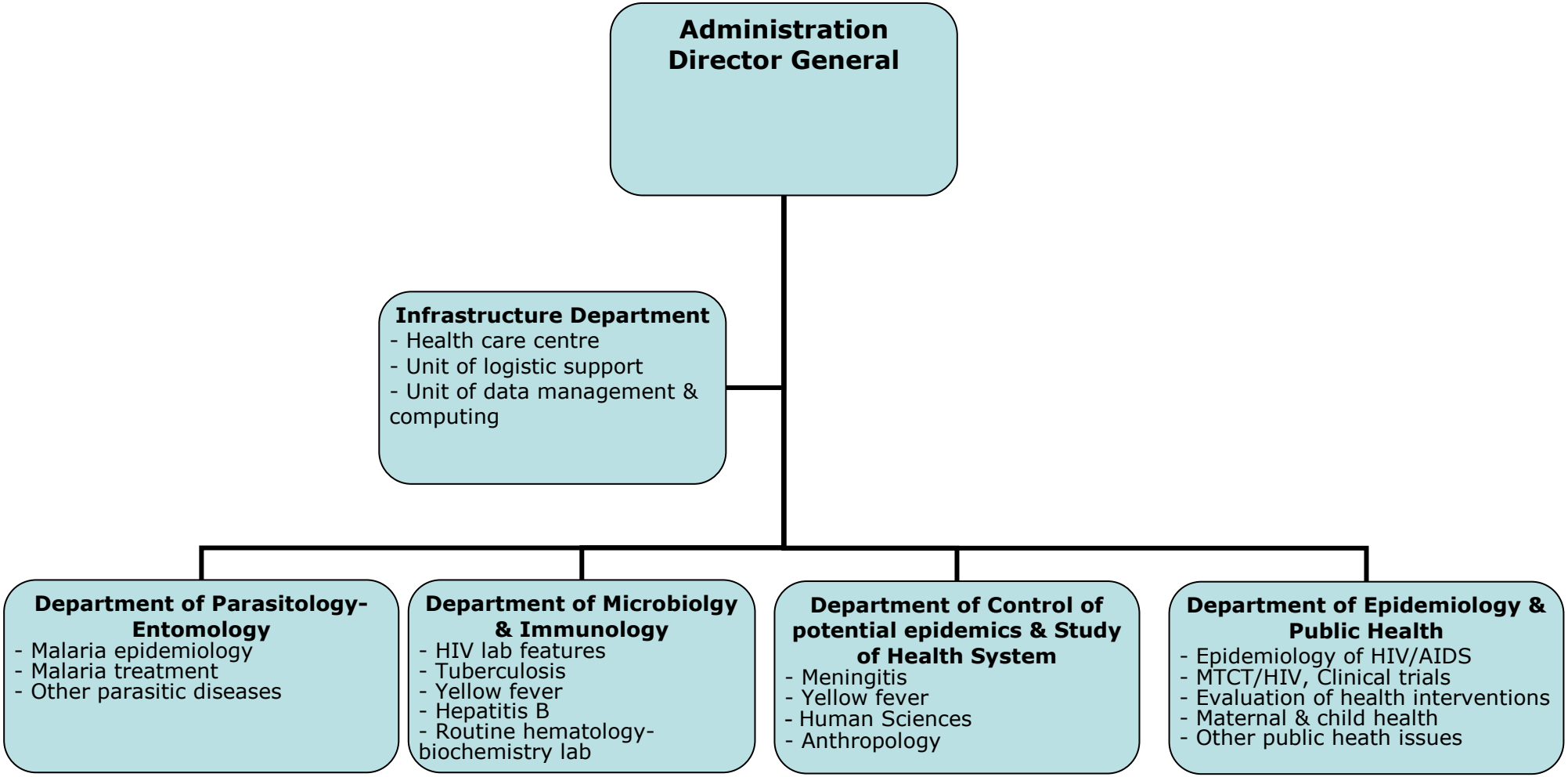


Figure 6: Organigram of Centre MURAZ in 2009 (Source: MoH/CM, technical document)

Banfora Health District

Banfora is the capital city of Cascades region (figure 7), one of the 13 administrative regions of Burkina Faso, situated 85 Km South of Bobo-Dioulasso. The region of Cascades is formed by 2 provinces (Comoé and Leraba). The study took place in the province of Comoé that comprises nine administrative departments. This area is the most watered of the country with an average annual rainfall of 1300 mm and deserves definitely its nick name of the "Farmer's city". The crops are the best in the country and over 80% of the region's economy stems from agriculture. Farmers grow cotton, maize, millet, rice, groundnuts, sesame, beans, cassava, potatoes, and sugar nuts. The culture of fruits is another large activity in this region especially the production of mangoes, oranges, bananas, as well as a lot of vegetables (tomatoes, salad, onion, aubergine, etc).
Animal husbandry and fishing are other sources of income in the region mainly in the department of Sideradougou where a large community of cattle keepers is settled since 1970.

Figure 7: Geographic situation of Banfora region in Burkina Faso

From the health perspective, Banfora houses the regional health directorate of the Cascades that comprises three health districts (Banfora, Sindou, and Mangodara) and one regional hospital (Banfora regional hospital that is the largest and the most well equipped).

The PROMISE/EBF study was implemented in the health district of Banfora that is also the largest one and covers the four administrative departments of Banfora.
This district covers a total area of 15000 km^2 and has a population of 385 000 (Burkina Faso(c) 2008). The district has 2 district hospitals (Niangoloko and Banfora) and 41 primary health care facilities called CSPS in French.
In terms of health statistics, Banfora health district is not very different from the rest of the country. Malaria is seasonal (during the rainy season from May to October) and remains the first cause of morbidity and mortality among the under-five year olds; it is followed by lower respiratory tract infections and diarrhoea. Surprisingly and despite excellent crops, the prevalence of child malnutrition is among the highest in the country (35% for stunting, 24% for wasting and 46% of underweighted) (Burkina Faso(a) 2008). The proportion of low birth weight was estimated at 12% in 2007.
This health district has experienced the annual meningitis outbreak the last three years. An outbreak of yellow fever has also been reported in 2006 because the region is bordering Cote-d'Ivoire, one of the main reservoirs of this disease transmission in the West African region.
The under five mortality and the infant mortality rates have been reported to be 211‰ and 113‰ in 2003 (Burkina Faso 2004).
The maternal mortality ratio has been estimated to be at 37 for 100 000 live births in 2007 (Burkina Faso(a) 2008) but was definitely underestimated. The attendance rate of antenatal clinics seems very good with a proportion of 99% of pregnant women having at least one ANC visit (Burkina Faso(a) 2008) but contrasts with the proportion of assisted delivered in health facilities that was only 47% during the same period. .
The HIV-prevalence is high in the City of Banfora presumably because of the intense commercial traffic near the Ivorian border and was estimated to be 2.4% in 2003 (Burkina Faso 2004).
The exclusive breastfeeding rates are among the lowest in the country both for cultural and economic reasons. Indeed previous statistics (Burkina Faso 2004), (Burkina Faso(b) 2008)) have shown EBF rates below 20% at three months. The proximity to Centre MURAZ in Bobo-Dioulasso, and the low EBF rates are among the reasons for selecting Banfora as the EBF study site in Burkina.

Selection and randomization of the study clusters

Prior to the implementation of the study, a research team from Centre MURAZ conducted a survey for the collection of topographic, demographic and health statistics data in the district of Banfora. Then provided a report containing the GPS coordinates, the physical accessibility of the area, the availability of health facilities, the meetings point of local communities (wells, markets, schools, mosques, churches, mills, etc) and health statistics from primary health facilities as well. Out of a total of 92 clusters that were initially visited and mapped, 38 were found to be eligible to the study using geographical, demographic and health statistics criteria. In a second step, our team based on the mapping of the 38 pre-selected clusters has created corridors to prevent potential contamination between clusters. Finally a list of 24 clusters was established and sent to the University of Bergen for randomization into the study two arms.
Based on the report provided by Centre MURAZ that contained detailed information and maps of the selected clusters, and using an excel sheet (Excel 2003), a list of pseudorandom number was generated and linked to each cluster. Thereafter, the

allocation to each arm was randomly done by ordering the random numbers and allocating the first twelve to the intervention arm and the last twelve to the control arm. The final list of randomized clusters was sent back to Burkina Faso. The figure 8 below gives a global overview of the selected 24 clusters for the EBF trial in Banfora health district.

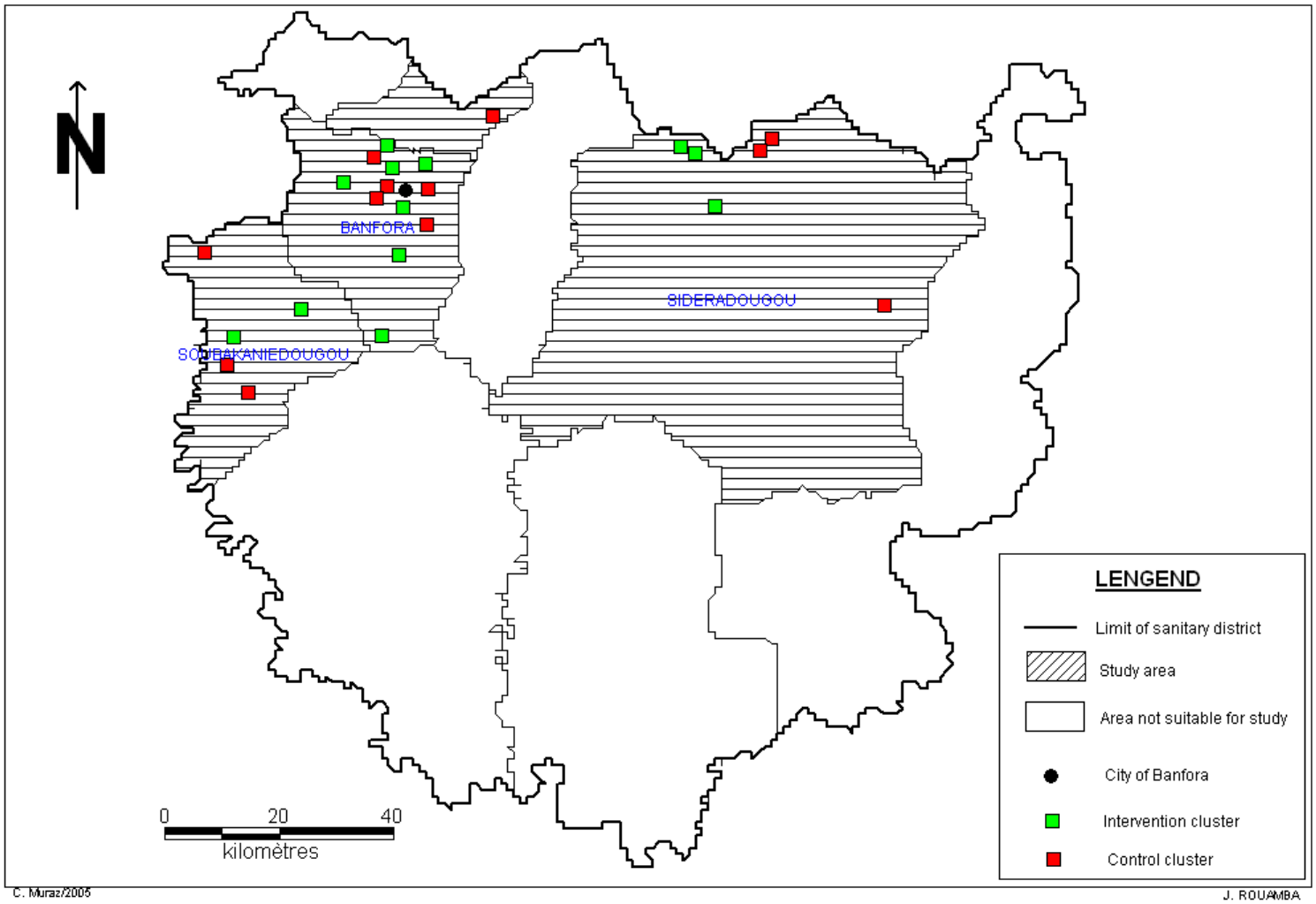


Figure 8: Overview of the 24 clusters of the EBF trial in Banfora, Burkina Faso

Study methods

Study design

The EBF trial was a community-based randomized trial implemented in 24 clusters (communities) in Burkina Faso. The primary unit of randomization was therefore the cluster defined here as a community with of population of about 500-1000 in the study area. The 24 selected clusters were randomized into two arms:

- the intervention arm: where we recruited and trained peer-counsellors for the promotion of exclusive breastfeeding. The delivery of a community-based service for the promotion of EBF through individual peer-counselling to each pregnant and lactating woman in the village was the intervention package.
- the control arm: the clusters randomized to this arm got the standard care in the Banfora health district. No community-based service about health was implemented. The study team recruited women called recruiters and their role was to assist the team in the recruitment of participants by identifying all the pregnant women or those who had recently given birth and reporting all relevant information to the team.
- the ratio of the intervention to control clusters was one to one, leading to selection of 12 control and 12 intervention clusters.

Study population

The 24 clusters selected for the EBF trial covered a total population of 35000 ranging from 1000 to 5000 inhabitants per cluster. The crude birth rate was 42.6‰ in this region. The child-bearing age group (15-49 years) was estimated to be 7700 (Burkina Faso(a) 2008). There were three main ethnic groups in the study area (Gouin, Karaboro, Dioula) and the common religion was Islam (>60%), followed by the African traditional religions. Heads of households were predominantly male subsistence farmers but women were actually the ones doing most of the farm work especially among the Gouin and Karaboro ethnic groups. Illiteracy was very high in the area and even higher among women (>80%).

Sampling & randomization procedures

As stated earlier, the main EBF trial aimed at measuring the effect of the promotion of EBF through peer-counsellors on EBF rates and diarrhoea. So the sample size of the study was computed based on these two outcomes with a baseline EBF rate at 20% and a prevalence of diarrhoea at 12%, respectively, at 12 weeks in the control group. The intervention was anticipated to double the baseline rate of the EBF (to 40%) and to reduce by one third (4%) the baseline prevalence of diarrhoea.

Of the two outcome measures the decrease in diarrhoea was seen as the most difficult to catch. Therefore it was the one used for final sample size calculations on the assumption that the diarrhoea prevalence will decrease from 12% to 8% in the intervention arm. With a 95% confidence (alpha error 0.05) and power of 80%, and an average number of 35 infants per randomised community, and a coefficient of variation between the communities of 0.3, we needed to randomise 48 communities in each arm – a total of 96 communities for the four African sites of the study. The table 5 below summarizes the full sample size calculations. This has resulted in the

selection of 24 clusters in each African site with approximatively 420 infants in each arm (35 * 12) in each country.

Table 5: Sample size estimation for the main EBF trial

		Increase in EBF from 20 to 40%	Decrease in diarrhoea
Proportion in the intervention group	P1	0.4	0.08
Proportion in the control group	P2	0.2	0.12
Percentage point for alfa error = 0.05	z1	1.96	1.96
Percentage point for beta error = 0.20	z2	1.28	1.28
Number of individuals in each community	n	35	35
coefficient of variation of proportions among communities in each group	k	0.4	0.3
Average of P1 and P2	P	0.3	0.1
Number of communities needed	C	12	48

This sample size will very accurately give us the increase in EBF rates and document the above decrease in diarrhoea morbidity.

From the assumptions used for this sample size calculation, we do anticipate that the current number of participants in the EBF trial would not be enough to catch any difference in terms of perinatal death rate between the two arms (since death is a more rare event than diarrhoea episodes) if the EBF intervention aimed at reducing this burden. However the sample of 840 women anticipated in this cohort could measure the perinatal mortality rate with an absolute precision of 1% based on previous estimates of the perinatal mortality rate in this country (Armagnac and Retel-Laurentin 1981; Burkina Faso 2000; Chalumeau 2002).

The selection of clusters and their randomization into two arms are already described in the study site section. It is important to remember that this has been a long process that required a lot of field work and collection of different types of information related to demographic, geographical accessibility, infrastructures/equipment and health statistics.

A simple random sampling (SRS) was performed at the time of participants' recruitment to select the participants who would undergo data collection and study follow-up. The aim of this sampling was to protect against any selection bias. Each month and for each cluster we had a complete list of all eligible women to be enrolled into the study. Then a community-meeting was scheduled with all the potential participants through community-leaders and community-workers recruited by the study (peer-counsellors and recruiters). On the agreed date and place, eligible women or their representatives were kindly invited to take actively part to the sampling procedure that was public under the supervision of the community-leader, the study team (data collector and supervisors) and independent community-members.

The rule was to include only 4 women per month and per cluster as the recruitment would last one year. To make the procedure more understandable to all eligible women, we relied on the method using sticks and a pot of sand. There were two

types of sticks: long ones and short ones. The selection of a long stick meant that the eligible participant will be enrolled for data collection if she agreed and if she met all the study inclusion criteria. The number of sticks was proportional to the number of women listed for a specific month in a specific cluster. All the sticks were planted in the pot of sand at the same height so that no one would know which ones were long or short. Eligible women or their representative were then asked to come forward in random order and pick one stick each. There were only four long sticks and the women who picked the long ones were selected for data collection. The sampling was performed without replacement meaning that women who had participated in the random sampling on a given month could not be sampled again the month after if they were not selected the first time. We did not include in the sampling list women who refused at the first contact any discussion about the study and their potential participation.
However because the EBF study was a cluster-randomized trial, all women in the intervention clusters received the intervention irrespective of their participation in the data collection.

Training of data collectors and community-workers (peer-counsellors and recruiters)

Seven data collectors were recruited by the study team in Centre MURAZ. All of them were from the study area and could speak fluently at least two of main local dialects in Banfora health districts. Another criterion for selection was their prior experience in working with rural communities. They got a one-week training workshop on the objectives and global methodology of the study and were extensively trained about each of the data collection tools (questionnaire, consent form, verbal autopsy form) to be used during the study. To improve the quality of the training and make sure the same wording would be used by all data collectors in field, we relied to an experienced translator who actively participated in the training and translated each question of each questionnaire in *dioula,* the main local language in the study area. After this phase of theory, data collectors went for one more week of training in the field with the objective of assessing each data collection tool and validating all the questionnaires. After this second phase, the best five data collectors were selected by the study team and the two remainders put on a waiting list.
Data collectors were living in the three administrative areas of Banfora health district and they lived in complete immersion in the communities throughout the entire study period.
In order for the study team to identify all the pregnant women in each cluster and to monitor the important study events like birth, death of the woman or her baby, we recruited some women in each cluster to participate actively in the data collection. These women were called “recruiters” and they were initially selected by their own communities based on their own criteria and the study team performed the final selection after a test that took part in the premises of the regional directorate of health in Banfora. The number of women recruited to work for our study was proportional to the population size of their village (based on last general population census in Burkina Faso) with an average of two recruiters per cluster. The initial plan was to distinguish the recruiters from the peer-counsellors in the intervention arm in order to keep the trial blinded. However due to resource constraints and to the practical difficulty of doing so, it was agreed that the peer-counsellors recruited by the

study team to implement the intervention package in each cluster of the intervention arm, also served as recruiters meaning they would have to identify all pregnant women in their village and provide the study team with all relevant information.
The intervention in the EBF trial consisted of 7 individual counselling sessions on exclusive breastfeeding, one in the antenatal period, and the other at week 1, 2, 4, 8, 16 and 20, respectively, after birth.
Both peer-counsellors and recruiters got a training workshop at different points in time and with different content. Indeed while the recruiters' workshop only focused on their role in data collection and lasted two days, the training of peer-counsellors took one week with the added intervention package that focused on promotion of exclusive breastfeeding. These two trainings were provided by different teams in different times in order for us to avoid any confusion of their roles. For the purpose of this thesis we will focus only on the role in the data collection of both recruiters (control arm) and peer-counsellors that were to:

i) Identify all pregnant women in the village by a weekly round of all households and approach them for an initial information about the study.
ii) send to the study team on a monthly-basis the names of all identified pregnant women.
iii) assist the team in communication with the local population to schedule a monthly meeting for the sampling of eligible participants.
iv) Make an appointment for the data collectors and assist them in identifying the house of the women who were sampled for data collection at the first contact only.
v) Inform any study participant of the data collector visit in case of missed visit and seek a new appointment if applicable.
vi) Provide the study team (data collectors) with relevant information about all women who have been enrolled into the study especially the outcome of all pregnancies (stillbirth, live births), the death of any mother or infant among the study participants or the migration of any mother out of their village.
vii) Note all this information in a written statement (at least the date of occurrence) and transfer it within 2 days to the study team throughout the local health facility of the village.
viii) It was clearly stated during the training that no recruiters (or peer-counsellors) should participate to the interview between the data collector and the study participant. This was one reason for choosing people from this region as data collectors, and also requiring them to be able to speak at least two of the main languages (*dioula* and *gouin/karaboro*) used by more than 90% of the population in this area.

These tasks were extensively discussed during the trainings of the recruiters/peer-counsellors and they were advised on the best ways to achieve what they were recruited for. All the trainers were speaking the main local dialect (*dioula*) so they made sure each recruiter had understood perfectly all her tasks, using the recruiter's mother tongue when needed. The second day of training was used to show to the recruiters how to fill the forms (simple data collection forms) namely which form (different colours) to used and when (new pregnant woman in yellow, birth in rose, death in green). The recommended format of the date (dd/mm/yyyy) was shown and they were instructed to always write the participant names in capital letters and especially to write carefully her study ID number (see below).
It is true that the overall educational level of our recruiters was low but the study team made sure during their selection that they knew at least how to write properly in

French or *dioula* names and dates, and they were strongly advised to collaborate closely with the health personnel of the local health facility that was informed on the study procedures.

Recruitment and inclusion of study participants

Once the eligible pregnant women were identified and listed by recruiters, and the monthly selection of study participants took place, the selected women were contacted by the data collectors through the recruiters for an initial recruitment visit.
The aim of this initial visit was to identify the house of the selected woman and to provide her with full information about the study objectives and methods. For this purpose a detailed information sheet written in French, translated into dioula first and then translated-back into French by two independent certified translators and validated by the IRB that approved the study in Burkina Faso (see approval form in annex) was used. The information were given in the dialect spoken by the woman and she was given a chance to ask all possible questions, and very often she had the time to discuss it with her husband as required by the culture in this region. An assessment of understanding of the administered information sheet was performed prior any consent approval. In most of cases, the data collector had to come the next day to obtain the approval (or not) of the woman. Once the woman agreed to study participation, the data collector had first to check carefully if she met all the study inclusion and exclusion criteria that were as followed:

Inclusion criteria:

1. Live in the selected cluster
2. Is pregnant ≥ 5 months
3. Has no plans to move outside the cluster within 1 year

Exclusion criteria:

1. Pregnant < 5 months, in which case the data collector will ask for permission to come back at a later point in time
2. Reduced ability to collaborate for psychological/mental reasons
3. Severely ill
4. Planning to replacement feed from start

Women fulfilling all the inclusion criteria and who agreed to participate were then asked to sign the written informed consent form (fingerprints or independent witness signature as required by the MURAZ's IRB), and the data collector could administer the recruitment questionnaire (see attached in appendix) to obtain baseline information of the study participant. The recruitment questionnaire contained four types of information:

- Demographic information like cluster name, age, ethnic group, parity, marital status, etc.
- Socio-economic status of the household including employment, income, possession of animals, household assets, and crops.
- Medical history of the mother: previous child deaths including perinatal or infant death, history of previous breast problems and experience of breastfeeding.

- Use of health services: antenatal visits, use of bednet, information about HIV/VCT.

After this initial interview, the woman was requested to inform the local recruiters of her village as soon as she gave birth irrespective of the pregnancy outcome (stillbirth, live birth).
After inclusion, each participant received a yellow card where her study ID number and names were written to help identifying her at each visit.
The recruitment period lasted exactly one year from 29th May 2006 to 29th May 2007.

Data collection and participants' follow-up

The recruitment interview was always performed in the woman's household as we needed the geographic coordinates of the household and the data collectors used a handheld computer (PDA) for the data collection. However at the beginning of the study and during the first two months of the study, we used both paper-based questionnaires and PDA. Indeed it was very important for our data collectors to familiarize themselves with the PDA and our team needed to assess under field conditions the validity, stability and user-friendliness of the PDA before we would drop the use of paper-based questionnaires.
Some troubles occurred with the PDAs mainly due to the hot climate and the instability of the Epihandy software. So we encouraged our data collectors to always have a ready-to-use paper-based questionnaire when they were going for an interview.
When using the paper-based questionnaire, the data collector had to tick the given answer while he moved in the questionnaire. He was instructed to always cross check each single questionnaire before leaving a study participant. He would then later enter all the information from the paper-questionnaire in the handheld using the electronic questionnaire of the PDA and its attached electronic pen to tick the answers.
In case of direct electronic data capture using the PDA, data collector would go through the same procedure as with the paper-based questionnaire.
The GPS coordinates were taken using an Etrex® GPS and an experienced health geographer trained our data collectors on its use.
Women enrolled in the main EBF trial got four more visits at week 3, 6, 12 and 24 after birth, respectively.
In order to collect data on perinatal mortality, we scheduled a visit within the first week after birth to record the pregnancy outcome and its date of occurrence. Women with stillbirths were scheduled to be interviewed for a verbal autopsy whenever possible within 6 months after their child loss. Women with neonatal deaths were administered a verbal autopsy form within the next 3 months. This difference of schedule was due to cultural considerations in the study area. Indeed it was seen as culturally inappropriate to come for data collection (asking questions) to a mother who recently had a stillbirth. This aspect has definitely impacted the completeness of our verbal autopsy forms. While we have managed to get detailed information on the circumstances of all infant deaths, we were only able to collect some few information items for stillbirths (outcome and the date of occurrence mainly).
A verbal autopsy form was designed based on the WHO standard verbal autopsy and covered the following topics:

- general information about the died infant (date of birth, gender, place of birth, age at death)

- description of the circumstances of death (disease, care seeking behaviour, treatment)
- potential causes of death (analyzed by paediatricians)
- feeding pattern before death (EBF, liquids, solids)
- immunization status at death

Criteria for study termination were: consent withdrawal, multiple births after inclusion, infant or maternal deaths and loss to follow-up.

Ethical considerations

The ethical clearance was sought from the institutional review board (IRB) of Centre MURAZ, Burkina Faso (see approval in appendix).
The consent sheet information was translated in *dioula* (the main local dialect in the study area) and then translated back into French by two independent certified translators as requested by the IRB's guidelines.
All data collectors spoke the local dialects and administered the consent form in local dialects as were the interviews.
The consent form insisted of the voluntary participation to the study and the possibility to withdraw from the study at any time if a woman wished so and without any type of prejudices.
Benefits from study participation were stated and were the possibility to receive individual peer-counselling on EBF for women from intervention clusters. Furthermore, all the mother-infants pairs enrolled in the study received free medications and care throughout the study period if they were sick and visited the local health facility. Indeed, Centre MURAZ signed a convention on this matter with the Banfora health district authorities and also made available commonly used medicines as antimalarials, antibiotics, rehydratation salts and small surgical material for treatment of breast abscesses. Mothers and infants with serious illness that could interfere with infant feeding were referred to Banfora regional hospital and the project paid all the related-fees from hospitalization to medication.
Many women did also appreciate that their child was regularly weighted by data collectors as many did not attend the regular well-baby clinics.
There was actually few risks linked to the EBF study participation but women were clearly told about the topics and time needed to answer to the data collector's questions and also the discomfort that may provide the frequent data collector visits. In order to facilitate this, we also sought for a household visit authorization that was signed by the head of each household involved in the data collection.

Data quality control and prevention of bias

We conducted weekly field supervisions during the first three months of data collection. The supervisions became monthly rounds from the fourth month up to the end of the study. Two experienced supervisors were recruited and trained for the need of this study. They spent more than 3 months working with the study coordinator on the study material (protocol and questionnaires) before the initiation of the data collection. They also actively took part to the training of the data collectors. They performed three types of supervisions:
- directs supervisions where supervisors were in field with the data collectors while these ones are conducting interviews. Supervisors were observing and listening to all

the questions and the answers of the mothers. They took notes and later discussed strengths and weaknesses noted with the data collectors.
- assessment supervisions: based on a random sample of participants (10-30%), supervisors went to the field and re-interviewed some mother-infants pairs already seen (or sometime to be seen during the same week by the data collectors). They then compared their data to those collected by the data collector before or later.
- data cross-checking: sitting in their offices, supervisors with the collaboration of the data manager picked a random sample of questionnaires (20-50%) already completed by a data collector and went through it entirely to check for consistency between answers, missing items, typing errors or invalid answers, etc. Thereafter, they produced a set of queries that were sent back to the field during the next supervisions and data collectors filled query forms and sent them back to the study team. All queries and their answers were kept in a separate binder that was used during the data cleaning procedure. In case of significant differences between the two questionnaires, that of the supervisor was used to validate the data on the condition that the time between the two interviews met the study procedures (±7 days).

Among the measures taken to reduce bias through the study methods we can list:

- The randomization of the clusters that was done by an independent researcher from the Centre for International Health in Bergen.
- The sampling frame for data collection prevented any selection bias from the community-workers recruited by the study team.
- We had a very reliable and updated log track form which the study team could use to monitor in real time what was happening on the ground and remind any data collector who had forgotten to visit a woman when the interview deadline was approaching. We also set up a phone VPN which allowed a permanent communication between the data collectors and their supervisors.

Data management

The data management centre in Centre MURAZ (Centre de Calcul) assured the overall management of the EBF trial data in Burkina Faso. Synchronization between handhelds and the central server was done on a weekly basis and a back-up system was available in three different hardrives. The data manager was actively involved in the data quality control and later in the exportation of datasets and the data cleaning process.

Data entry and cleaning

From the third month of participants' recruitment, we relied almost only on electronic data capture. Moreover, all the paper-questionnaires were always entered on the PDA within a maximum of 48 hours after the interview as stipulated in the data collection standard operating procedures (SOPs). So we had a complete electronic dataset on Epihandy software and this was one asset in using the PDA. One limitation of the early Epihandy version was the impossibility to edit the data and make the needed corrections in case of erroneous data entry. In order for us to deal with this, we created an excel sheet and reported all the queries and their answers in real time.

By the end of the study, Epihandy improved and we were finally able to start the data cleaning procedures based on the original datasets exported from this software to SPSS 15 using a syntax file. The entire data cleaning procedure was performed in Stata 10.1 (www.stata.com) after transferring the SPSS file (.sav) into a Stata (.dta) file using Stat transfer 8.2. In order to document all the data cleaning procedures, we used two types of do-files in Stata:

- The first called check.do aimed at identifying the errors, gaps, inconsistencies for each of 465 variables of the recruitment questionnaire, other follow-up questionnaires and the verbal autopsy forms as well.
- The second was named clean.do and aimed at editing all required changes after further checks on source documents from Centre MURAZ that included the log tracking forms, the copy books used daily in field by each data collector, the numerous field supervision reports, the paper-based or the electronic original questionnaires but also the forms filled by the recruiters and the peer-supporters. This job required more than 8 months of work and has been successfully conducted mainly due to the experience of the Centre MURAZ team in handling datasets. The cleaned datasets were cautiously named and locked definitively in the Central dataset server in Centre MURAZ.

Data analysis

The data analysis was performed on the cleaned datasets using Stata 10.1 (www.stata.com). We started by computing descriptive statistics (frequencies and means) of main variables at recruitment (age, parity, marital status, history of child death, etc) and follow-up (birth date, place, attendant), and drew a baseline table.
The comparisons between proportions were performed using a chi-squared test while continuous variables of different groups were compared using either the student test or the analysis of variance (ANOVA) when appropriate.

To determine the socioeconomic status of the study participants, we generated a new variable that was the sum of the assets owned by each household and the housing, allocating to each asset and the house its corresponding value in local currency (CFA) and also adjusting for depreciation. Ten items were included in the model: possession of car/truck, motorcycle/scooter, bicycle, mobile phone/telephone, chart, plough, type of house, roof, floor, and window. Based on this new variable, we divided the population into quartiles. Those in the lowest quartile were defined as “the most poor”; those in the two middle quartiles formed “the middle class” and those in the highest quartile were categorized as “the least poor”.

Because the main study was a cluster-randomized trial and therefore the intervention could be an important covariate in this study outcome (perinatal death), we also computed the baseline table per arm to ascertain if the randomization was successful. Following the study profile, we have described the baseline characteristics of the group of twins that was excluded from any further follow-up as stated in the study protocol.

We thereafter computed the overall risk of perinatal death in this prospective cohort by dividing the number of perinatal deaths by the total number of pregnant women enrolled in the study and who had a single delivery. This risk is reported per one

thousand deliveries as the standard definition of perinatal mortality includes both stillbirths and the early neonatal deaths. We also estimated the early neonatal death risk by dividing the number of early neonatal deaths by the total number of women who had a single live birth and reported it per thousand live births. Since the study recruitment lasted exactly one year, the corresponding perinatal death risk is worded as perinatal mortality rate.
In order to measure the association between perinatal death and many exposures, we have performed an univariable logistic regression analysis for binary outcomes and computed the 95% confidence intervals of the corresponding odds ratios. We looked at possible interactions and confounders and adjusted for clustering as the original data are from a cluster-randomized trial.

In a multivariable logistic regression using perinatal death as outcome, we constructed a model using both the variables that increased the odds of perinatal death in the univariable model ($p<0.10$), and other covariates which have been reported in previous literature or medial knowledge. We adjusted all analysis for clustering and intervention (Arm) to take into account the design of the main EBF trial. We therefore came up with three tables, one including all the perinatal deaths, one including only stillbirths and the last only including early neonatal deaths as outcomes, respectively. For each table, we have reported the crude odds ratios (OR) and their adjusted values, with corresponding 95% CI. All OR's estimates were considered to be statistically significant for a $p<0.05$ ($RR<1$ or $RR>1$).

We have also ran a sensitivity analysis assuming there have been some misclassifications among stillbirths. Because we did not find any recent and reliable data showing perinatal mortality rate in rural settings from Burkina Faso for women who did deliver in health facilities, we used the data from McDermott (McDermott, Steketee et al. 1996) in Malawi that seemed very close to our setting. We therefore computed the adjusted estimates of stillbirths and early neonatal deaths assuming that the same proportion of misclassifications of stillbirths had occurred in our cohort.

Results

Study profile

During one year (from 29th May 2006 to May 29th, 2007), 1162 pregnant women were identified of whom 21 refused any study participation (1.8%). 900 women were sampled for data collection in the 24 clusters of the EBF trial. Five women were later found to not meet all the inclusion criteria (one had a mental handicap, one was not pregnant and three had delivered more than 7 days before recruitment) and were excluded. Of the eight hundred ninety five (895) pregnant women included in the data collection, 20 had multiple births (all twins) and were excluded from further follow-up as stipulated by the study protocol (although we had their outcomes by day 7). The remaining eight hundred seventy five (875) mothers with single birth completed the 7-day follow-up. Figure 9 is showing the trial profile for the 7-day follow-up. No woman was lost to follow-up by day 7 post delivery.

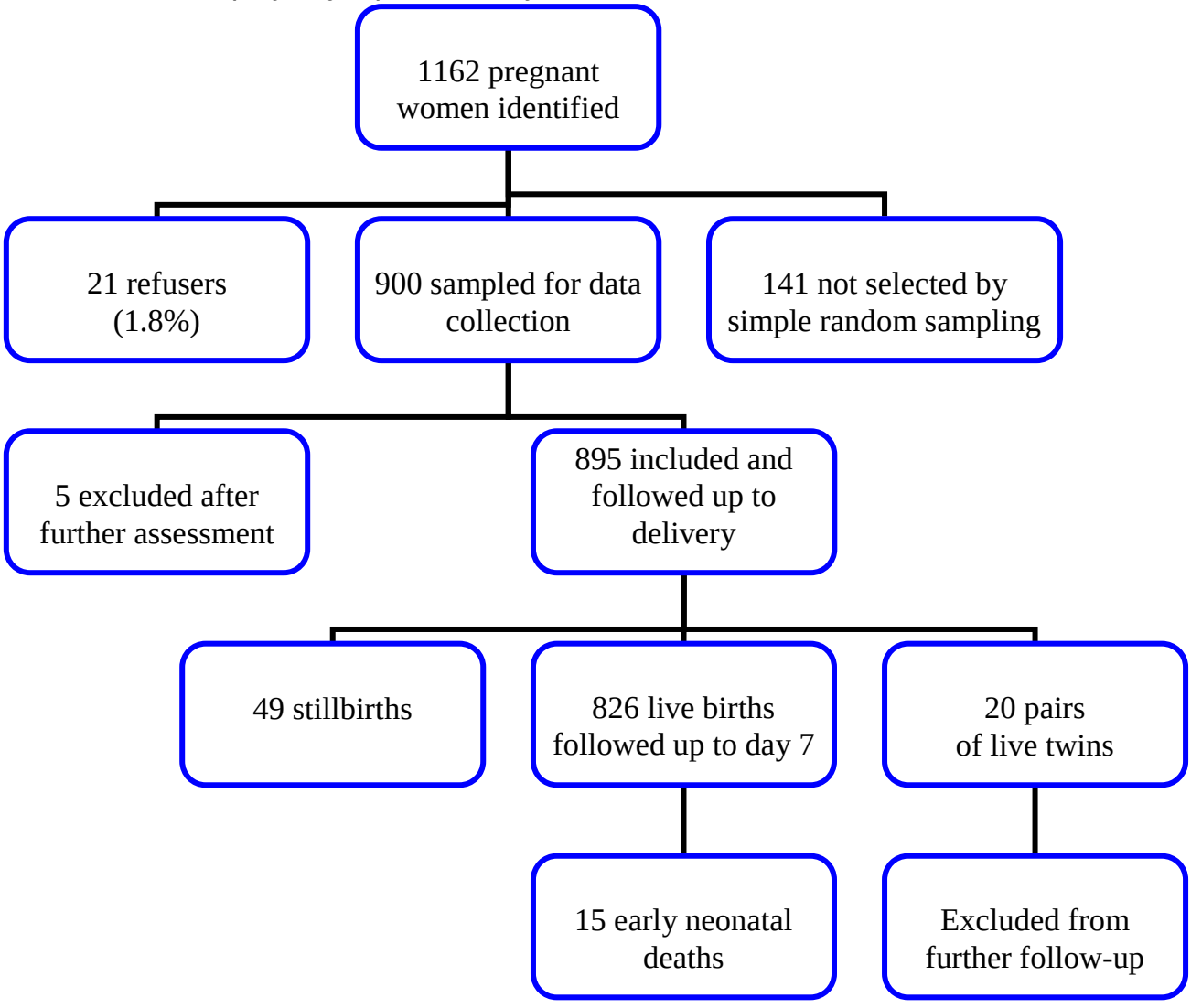


Figure 9: Study profile of the EBF trial in Banfora health district, Burkina Faso

One of the first things to do in a trial like this is to check whether randomization was successful. For most of the variables it seems there was an equal distribution between the intervention and control arm. However, for the variables history of breast problems, use of bednet during pregnancy, and the anticipated feeding plan by the mother, there were differences between the two study arms (table 6).

Table 6: Baseline socio-demographic characteristics of 875 mothers at inclusion per arm in the EBF trial in Burkina Faso

Characteristics	Control N=435 n (%)	Intervention N=440 n (%),
Area of residence		
- Rural	374 (86.0)	332 (75.4)
- Peri-urban	61 (14.0)	108 (24.6)
Age groups of mothers		
- <20	75 (17.3)	72 (16.4)
- 20-35	312 (71.7)	326 (74.0)
- >35	48 (11.0)	42 (9.6)
Parity		
- 0	73 (16.8)	79 (18.0)
- 1-5	294 (67.6)	299 (68.0)
- > 5	68 (15.6)	62 (14.0)
Educational level		
- None	349 (80.2)	355 (80.7)
- Literacy/primary/secondary school	86 (19.8)	85 (19.3)
Marital status		
- Not married	18 (4.1)	28 (6.3)
- Married	417 (95.9)	412 (93.7)
Socio-economic status based on household assets (in CFA)		
- Most poor (< 420 000)	146 (33.5)	159 (36.1)
- Middle (420 000- 730 000)	172 (39.5)	190 (43.2)
- Least poor (> 730 000)	117 (27.0)	91 (20.7)
Regular use of media (radio & TV)		
- No	361 (83.0)	351 (79.8)
- Everyday	74 (17.0)	89 (20.2)
History of breast problems		
- Yes	74 (17.0)	106 (24.0)
- No	361 (83.0)	334 (76.0)
History of previous child death		
- Yes	216 (49.7)	210 (47.7)
- No	219 (50.3)	230 (52.3)
History of previous perinatal death		
- Yes	47 (10.8)	39 (8.9)
- No	388 (89.2)	401 (91.1)
Use of bednet during pregnancy		
- Yes	143 (32.9)	190 (43.2)
- No	292 (67.1)	250 (56.8)
Antenatal visits		
- None	125 (28.7)	125 (28.4)
- 1-2	236 (54.3)	234 (53.2)
- > 2	74 (17.0)	81 (18.4)
Plan for feeding future baby		
- EBF anticipated	75 (17.2)	332 (75.4)
- No EBF	360 (82.8)	108 (24.6)

The pregnancy outcomes among the 875 women with single birth were 49 stillbirths and 15 early neonatal deaths. Moreover two mothers died in the postpartum period at day 3 and 7, respectively, but their babies were alive by day 7. The corresponding mortality rates for the different outcomes are shown in table 7. The stillbirths accounted for 76.5% of the total perinatal deaths and the ratio of stillbirths to early neonatal deaths was 3.26.

Table 7: Main pregnancy outcomes for 875 women with single delivery In a rural area of Burkina Faso

Pregnancy outcomes	Number	Mortality rate(‰)	95% CI of the mortality rate
Maternal deaths	2/875	2.3	[0.27-8.2]
Perinatal deaths	64/875	73.1	[55.8-90.4]
Stillbirths	49/875	56	[40.7-71.2]
Early neonatal deaths	15/826[a]	18.1	[9-27.2]

[a]: only live births (826) were used in the denominator

Baseline characteristics of the cohort

Multiple births were excluded from the EBF trial because of their anticipated relative low frequency and high risk of deaths in the peripartum period. Indeed in our cohort the frequency of multiple births was 2.2% (20/899) and the table 8 below gives an overview of the baseline characteristics of the 20 mothers of twins and the vital status of their babies by day 7.

Table 8: Baseline characteristics of mothers and babies vital status by day 7 in 20 pairs of twins in rural areas of Burkina Faso

Variables	Frequency N=20 n (%),
Age groups (years)	
- <20	1 (5)
- 20-35	18 (90)
- >35	1 (5)
Parity	
- primigravidae	1 (5)
- 1-5	17 (85)
- > 5	2 (10)
Socio-economic status (CFA)	
- most poor (< 420 000)	7 (35)
- average (420 000 -730 000)	12 (60)
- least poor (> 730 000)	1 (5)
Babies vital status by day 7	n=40
- stillbirth	0 (0)
- early neonatal death	8 (20)
- median age at death (days)	2

The analysis of the baseline characteristics of the 875 women with single births showed a rather young group (mean age of 26.2 years ± 6.6), predominantly rural (80.7%), with a high proportion of illiteracy (80.5%). The median gestational age at recruitment based on women's answers was 8 months. Only 365 women had their height taken and the mean height was of 161 ± 6.04 cm. The proportion of underweight (BMI< 18.5) was 7% in this group of women and only 4.4% were overweight (BMI >25). Data have also shown that this cohort was dominated by multigravidae with a median number of 2 children per woman, and breastfeeding was common with a median duration of 24 months for the last breastfed child. Interviews of women revealed that almost half of them (49.6%) had experienced at least one child death and 9.8% had experienced a perinatal death. However, this is the prevalence of perinatal deaths and does not provide a perinatal death rate.

The baseline characteristics of this cohort are summarized in table 9. Given the mean gestational age of women at inclusion, the median time from inclusion to birth was short (52 days with a range from 0 to 202). Most of the women had given birth at home (54.7%) with the assistance of family members, friends or a traditional birth attendant (TBA). The large majority of deliveries was vaginal deliveries, only 1% of the women got a caesarean section. Table 10 shows the main postpartum characteristics of the 826 women who had a single live birth. Given the high proportion of home deliveries, only 293 babies had their birth weight taken, and the mean birth weight (± SD) was of 2975 ± 524 g. The prevalence of low birth weight in this group was of 13.6% with a higher proportion among the primigravidae (33%).

The median age at death among the infants who experienced an early neonatal death was 3 days with three out of 15 (20%) who died the day of delivery.

The BCG immunization at birth was very low in this cohort with only 12% of infants receiving BCG and the first dose of oral polio (DPT-0) by day 7 of age.

Table 10 also describes the early feeding behaviour among the mothers with almost 70% of women who declared that they did exclusively breastfeed their babies during the first 72 hours.

Table 9: Baseline socio-demographic characteristics of 875 mothers at inclusion

Variables/Exposures	Number (%)
Area of residence	
- Rural	169 (19.3)
- Peri-urban	706 (80.7)
Age groups of mothers	
- <20	147 (16.8)
- 20-35	638 (72.9)
- >35	90 (10.3)
Parity	
- 0	152 (17.3)
- 1-5	593 (67.8)
- > 5	130 (14.9)
Educational level	
- None	704 (80.5)
- Literacy/primary school	116 (13.2)
- Secondary school	55 (6.3)
Marital status	
- Single	41 (4.7)
- Married	829 (95.0)
- Other	5 (0.3)
Socio-economic status based on household assets (in CFA)	
- Most poor (< 420 000)	305 (34.8)
- Middle (420 000- 730 000)	362 (41.4)
- Least poor (> 730 000)	208 (23.8)
Head of household	
- Man	851 (97.3)
- Woman	24 (2.7)
Regular use of media (radio & TV)	
- No	712 (81.4)
- Everyday	163 (18.6)
Ever breastfeed	
- Yes	718 (82.0)
- No	157 (18.0)
Had ever got breast problems	
- Yes	180 (20.6)
- No	695 (79.4)
History of previous child death	
- Yes	425 (49.6)
- No	450 (51.4)
History of previous perinatal death	
- Yes	86 (9.8)
- No	789 (90.2)
Use of bednet during pregnancy	
- Yes	333 (38.0)
- No	542 (62.0)
Antenatal visits	
- None	250 (28.6)
- 1-2	470 (53.7)
- > 2	155 (17.7)
Plan for feeding future baby	
- EBF anticipated	407 (46.5)
- No EBF	468 (53.5)

Table 10: Postpartum characteristics of 826 mothers and their singleton live babies

Variables/exposures	Number (%)
Season of birth	
- Dry season (November-April)	437 (53.0)
- Rainy season (May-October)	389 (47.0)
Place of birth	
- Home	452 (54.7)
- TBA	60 (7.3)
- Health facility	306 (37.0)
- Other (farm, market)	8 (1.0)
Assistance during delivery	
- None	68 (8.3)
- Family/friends	273 (33.0)
- TBA	176 (21.3)
- Health personnel	309 (37.4)
Had complicated labour/delivery (n=803)	
- Yes	17 (2.1)
- No	786 (97.9)
Gender of the newborn (n=813)	
- Girl	387 (47.6)
- Boy	426 (52.4)
Gave colostrum to baby (n=803)	
- Yes	708 (88.2)
- No	95 (11.8)
Discussed EBF at ANC visit	
- Yes	95 (11.5)
- No	731 (88.5)
Time to put baby on breast (n=803)	
- < 12 hours	421 (52.4)
- 12-24 hours	247 (30.8)
- > 24hours/did not receive breast	135 (16.8)
Did EBF during the first 72 hours (n=804)	
- Yes	562 (69.9)
- No	242 (30.1)

Description of the perinatal deaths

The study material for the 64 perinatal deaths is presented in the following tables 11 and 12.

Table 11: Features of 49 stillbirths in rural Burkina Faso

N°	Cluster	Maternal age(years)	Parity	Gestational age (weeks)	Previous child death	ANC visits	Month of occurrence
1	Noumousso	19	0	30	No	1	June
2	Zedougou	20	1	Unknown	No	3	July
3	Siniena	27	3	Unknown	Yes	4	June
4	Siniena	20	4	Unknown	Yes	3	June
5	Sikanadjo	38	9	Unknown	Yes	1	August
6	Noumousso	19	0	35	No	2	July
7	Karfiguela	25	2	Unknown	No	2	September
8	Nafona1	29	4	Unknown	Yes	0	October
9	Zedougou	32	2	Unknown	No	2	November
10	Zedougou	17	0	Unknown	No	3	October
11	Damana	18	0	Unknown	No	0	August
12	Nafona1	25	2	Unknown	Yes	1	November
13	Tiekouna	19	1	Unknown	No	1	September
14	Kotou	20	3	38	Yes	0	December
15	Siniena	19	0	Unknown	No	1	October
16	Tiempangora	19	3	Unknown	Yes	1	October
17	Lemouroudougou	22	1	Unknown	No	0	November
18	Niamirandougou	26	2	Unknown	Yes	1	September
19	Tiekouna	36	6	Unknown	Yes	0	December
20	Noumousso	20	1	35	No	1	December
21	Tiempangora	26	3	Unknown	Yes	0	December
22	Damana	20	2	Unknown	No	0	February
23	Kouere	24	1	35	Yes	2	November
24	Kotou	32	6	32	Yes	1	December
25	Kossara	20	2	Unknown	No	0	December
26	Siniena	19	0	Unknown	No	1	December
27	Degue-Degue	26	3	39	No	1	March
28	Tangora	29	4	Unknown	No	3	December
29	Zedougou	21	2	Unknown	No	0	December
30	Kirbina	26	4	Unknown	Yes	1	December
31	Kotou	18	0	35	No	0	January
32	Degue-Degue	18	1	37	No	0	March
33	Siniena	20	0	Unknown	No	2	April
34	Kouere	15	0	Unknown	No	0	May
35	Kotou	18	0	39	No	0	February
36	Damana	34	7	Unknown	Yes	2	March
37	Laferma	18	0	Unknown	No	2	February
38	Tiempangora	30	3	Unknown	No	0	March
39	Kirbina	20	1	Unknown	No	1	February
40	Zedougou	25	3	Unknown	No	2	March
41	Letiefesso	18	0	Unknown	No	2	February
42	Tangora	18	0	Unknown	No	3	March
43	Kirbina	28	1	Unknown	No	3	March
44	Gouin-Gouin	39	7	33	Yes	1	April

45	Letiefesso	23	1	Unknown	No	1	April
46	Noumousso	31	4	Unknown	Yes	0	April
47	Zedougou	20	0	Unknown	No	2	May
48	Noumousso	32	6	32	Yes	0	March
49	Gouindougouba	18	0	Unknown	No	2	April

Table 12: Characteristics of mothers and infants in 15 early neonatal deaths in rural Burkina Faso

N°	Cluster	Age mother	Parity	Previous child death	ANC visits	Place of delivery	Birth attendant	Age at death (d)	Place of death	Cause of death (verbal autopsy)
1	Niamirandougou	20	1	Yes	2	Health facility	Nurse	7	Home	Lbw[a]/preterm
2	Lemouroudougou	31	6	No	0	Home	Not specified	0	Home	Epistaxis
3	Siniena	32	8	Yes	4	Health facility	Nurse	3	CSPS[b]	Birth asphyxia
4	Gouindougouba	18	1	Yes	2	Health facility	Nurse	7	Home	Lbw/preterm
5	Lemouroudougou	17	0	No	1	Home	Not specified	6	Home	Unknown
6	Nafona1	22	3	Yes	0	Home	Not specified	0	Home	Unknown
7	Tiempangora	19	0	No	2	Home	Not specified	5	Home	Lbw/preterm
8	Karfiguela	33	4	Yes	1	Health facility	Nurse	3	Home	Unknown
9	Nafona1	33	6	Yes	0	Home	Not specified	3	Home	Sudden death
10	Siniena	21	1	No	1	Home	Not specified	7	Home	Infection
11	Sikanadjo	25	7	Yes	0	Home	Not specified	0	Home	Sudden death
12	Siniena	42	10	Yes	1	Health facility	Nurse	1	Home	Unknown
13	Gouin-Gouin	38	9	Yes	0	Home	Not specified	6	Home	Infection
14	Karfiguela	22	2	Yes	1	Home	Not specified	2	Home	Unknown
15	Kouere	19	1	No	1	Health facility	Nurse	1	Home	Lbw/preterm

[a] Lbw: Low birth weight

[b] CSPS: Primary health care facility in Burkina Faso

Distribution of the stillbirths

As mentioned above, there were a total of 49 stillbirths that occurred in 21 clusters (table 13). Three clusters did not record any stillbirths, Boborola, Lémouroudougou Cité and Tatana. Zedougou (12.2%), Noumousso (10.2%), Siniena (10.2%) and Kotou (8.1%) seem to be the clusters with the highest stillbirth rates and represent 40.7% of the total stillbirths.

There was no statistically significant difference in proportion of stillbirths between the peri-urban (5.33%) and the rural clusters (versus 5.67%, χ^2=0.03, p=0.86). When we looked at the distribution of stillbirths throughout the year, we found that most of the deaths did occur during the dry season with December and March being the two peak months (figure 10).

Table 13: Frequency of stillbirths in 24 clusters of Banfora health District, Burkina Faso

Cluster name	Number of deliveries	Frequency of stillbirths
Boborola	39	0
Damana	45	3
Degue-Degue	37	2
Gouindougouba	43	1
Gouin-Gouin	40	1
Karfiguela	27	1
Kirbina	31	3
Kossara	23	1
Kotou	36	4
Kouere	46	2
Laferma	31	1
Lémouroudougou Cite	16	0
Lémouroudougou village	28	1
Letiefesso	44	2
Nafona 1	30	2
Niamirandougou	38	1
Noumousso	31	5
Sikanadjo	19	1
Siniena	85	5
Tangora	41	2
Tatana	30	0
Tiekouna	30	2
Tiempangora	38	3
Zedougou	47	6
Total	**875**	**49**

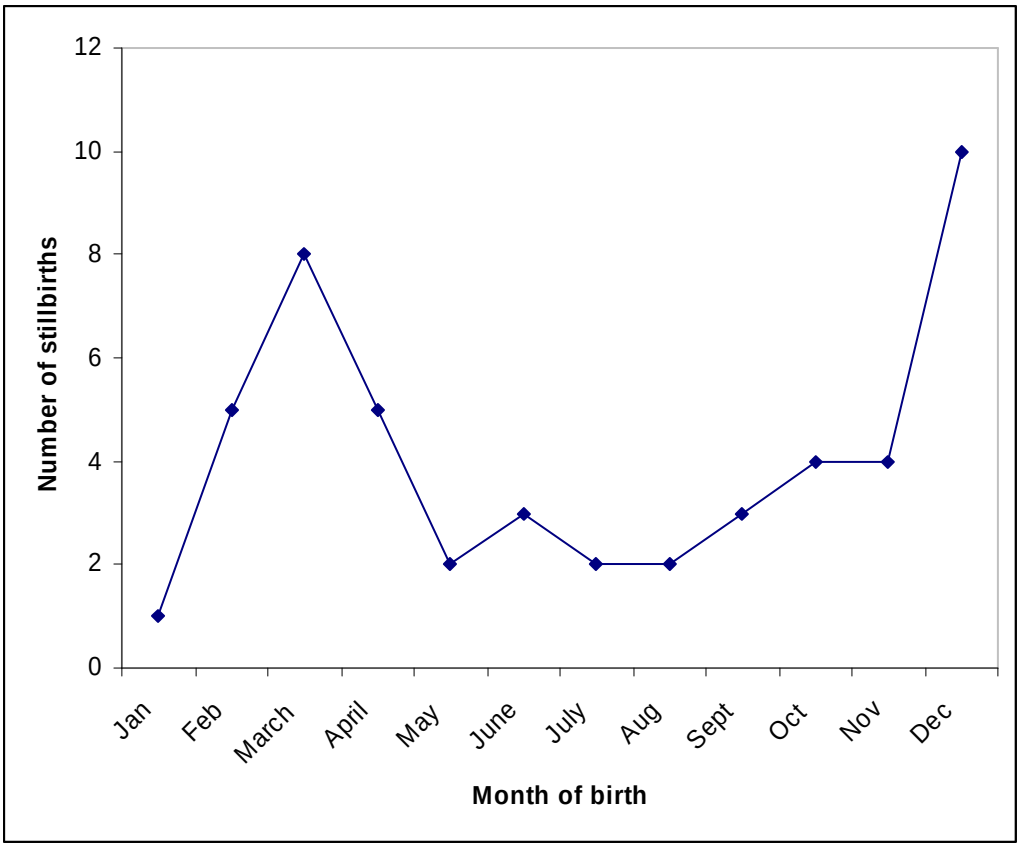


Figure 10: Monthly distribution of 49 stillbirths in Banfora health district, Burkina Faso

Analysis of the demographic indicators showed that women with stillbirths had a lower mean age (23.6 versus 26.4, p=0.01) compared to those without and a lower mean parity (2.14 versus 2.91, p=0.002) as illustrated by figure 11 and 12. The risk of stillbirth was statistically different with age groups with 10.88% for those <20 years, 4.7% among the 20-35 years and 3.33% for those >35 years, respectively (χ^2=9.6, p=0.008). The risk of stillbirth was also statistically different with the class of parity with 9.9% among the nulliparous, 4.72% in those with 1-5 previous deliveries and 4.6% for those with more than 5 deliveries (χ^2=6.3, p=0.04), respectively. However we did not find any statistically significant difference of the risk of stillbirth by marital status (p=0.31) including polygamy (p=0.57), socioeconomic status of the household (table 15, χ^2=0.01, p=0.99) or number of antenatal visits (table 16, χ^2=0.65, p=0.72). The analysis did not show any statistically significant difference of the risk of stillbirth by maternal education (table 14, χ^2=1.19, p=0.55), or regular use of media (χ^2=3.75, p=0.058). We did find that the proportion of stillbirths were statistically higher in the group of women who had more than two child deaths, irrespective of the age of death (8.75%) compared to those who had not experienced any child death (7.13%) or those who had had 1-2 child deaths (2.9%) as outlined in table 17 (χ^2=8.28 and p=0.01).

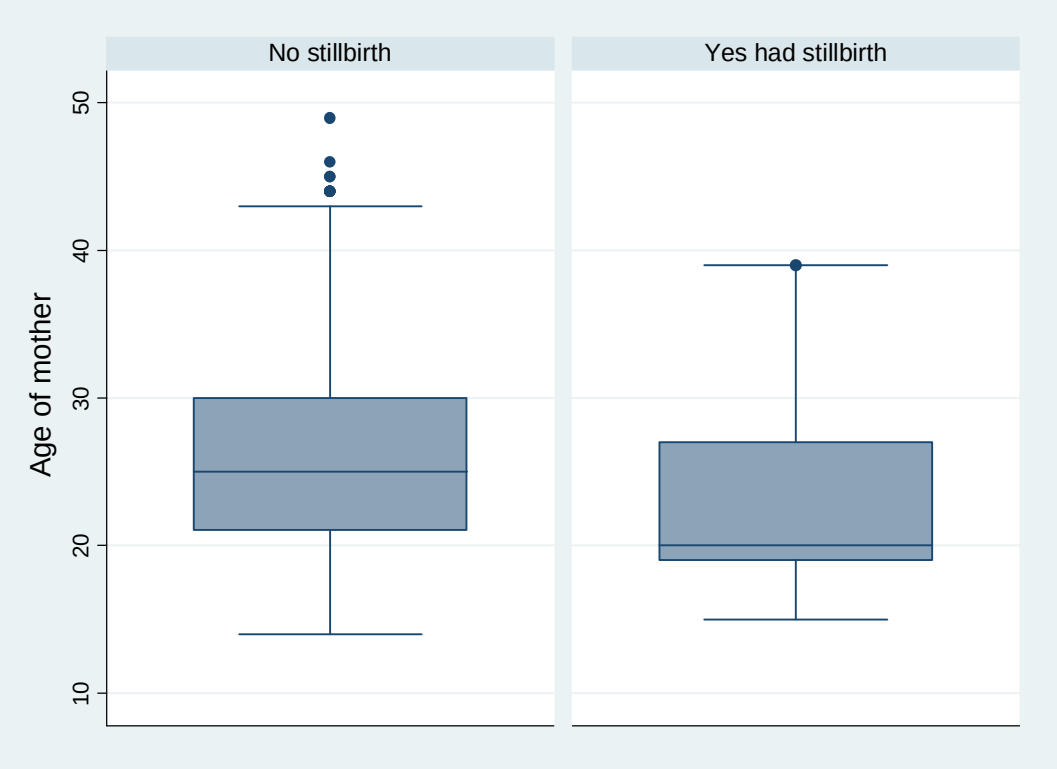


Figure 11: Age of mothers by pregnancy outcome

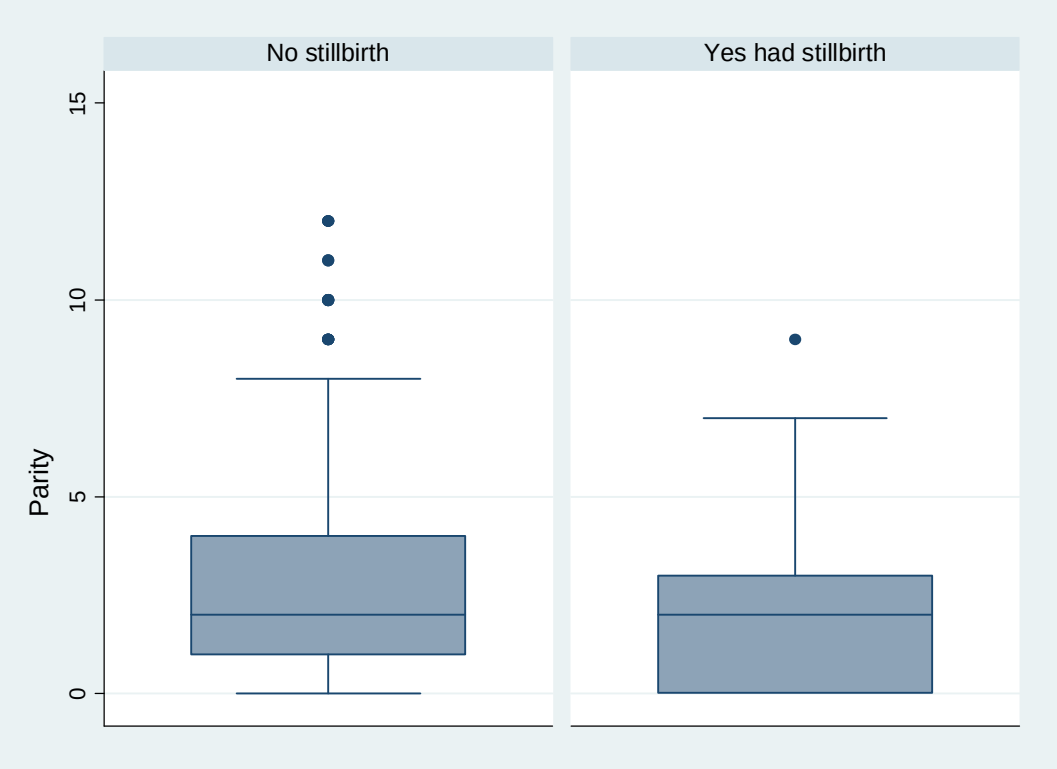


Figure 12: Parity of mothers by pregnancy outcome

Table 14: Distribution of stillbirths by mother's education and regular use of media in 875 women in Banfora health district, Burkina Faso

	Number of stillbirths (%)			
	Never attended	Primary school/Literacy	Secondary school	Total
No use of media	38/599 (6.34)	4/78 (5.12)	3/35 (8.57)	45/712 (6.32)
Use media everyday	4/105 (3.8)	0/38 (0)	0/20 (0)	4/163 (2.45)
Total	42/704 (5.97)	4/116 (3.45)	3/55 (5.45)	49/875 (5.6)

Table 15: Distribution of stillbirths by mother's socio-economic status and the size of household in 875 women in Banfora health district, Burkina Faso

	Number of stillbirths (%)			
Size of household	Poorest	Middle class	Least poor	Total
< 10	13/234 (5.55)	10/193 (5.18)	3/74 (4.05)	26/501 (5.19)
10-20	4/70 (5.71)	9/147 (6.12)	8/111 (7.20)	21/328 (6.4)
>20	0/1 (0)	1/22 (4.54)	1/23 (5.77)	2/46 (4.35)
Total	17/305 (5.57)	20/362 (5.52)	12/208 (5.77)	49/875 (5.6)

Table 16: Distribution of stillbirths by number of ANC visits and use of bednet in 875 women in Banfora health district, Burkina Faso

	Number of stillbirths (%)			
	0 ANC visit	1-2 ANC visits	> 2 ANC visits	Total
No bednet	10/148 (6.75)	17/286 (5.94)	5/108 (4.62)	32/542 (5.9)
Yes, sleep in bednet	6/102 (5.88)	9/184 (4.89)	2/47 (4.25)	17/333 (5.11)
Total	16/250 (6.4)	26/470 (5.53)	7/155 (4.52)	49/875 (5.6)

Table 17: Distribution of stillbirths by number of previous child deaths and history of breast problem during the last breastfed child in 875 women in Banfora health district, Burkina Faso

	Number of stillbirths (%)			
	No history of child death	1-2 previous child death	> 2 previous child deaths	Total
No breast problem	27/374 (7.22)	7/267 (2.62)	5/54 (9.25)	39/695 (5.61)
Yes had previous breast problem	5/75 (6.67)	3/79 (3.8)	2/26 (7.69)	10/180 (5.56)
Total	32/449 (7.13)	10/346 (2.9)	7/80 (8.75)	49/875 (5.6)

Distribution of early neonatal deaths

There were 826 single live births and 15 early neonatal deaths, a neonatal mortality rate of 18.1 per 1000 live births. These early neonatal deaths occurred in 11 clusters which were mainly in the rural settings (80.6%) and figure 13 shows their seasonal distribution. Data showed that 20% of the early neonatal deaths (3/15) occurred on the day of delivery and the proportion and age at death are illustrated by the figure 14. Nine out of the 15 babies who died within the first week were born at home (60%) and only 6 of them had a skilled birth attendant (nurse). Ten babies were boys and only one baby had a birth weight taken.

The risk of early neonatal death by maternal age was 3.05%, 1.48 % and 2.30%, for mothers <20 years, 20-35 years and >35 years, respectively. There was no statistically significant difference between the age groups (χ^2=1.62, p=0.34). This risk was however statistically different by parity and mothers whose parity was over 5, seemed to be at a greater risk (4.84%) compared to those with 1-5 previous deliveries (1.24%) or to primigravidae (1.46%) with χ^2= 7.5 and p=0.03.

Information collected from verbal autopsies revealed that 14 out of the 15 infants died at home (93%) and only three (20%) were seen in a health facility for care prior to the death. Table 18 summarizes other important baseline characteristics and early infant feeding pattern in the 15 early neonatal deaths in this cohort.

The probable causes of death analyzed from verbal autopsies are outlined in the table 11 above. They were unknown for one third of the children (5/15), low birth weight/preterm baby for 27% (4/15), and infection was the likely cause for 13% (2/15).

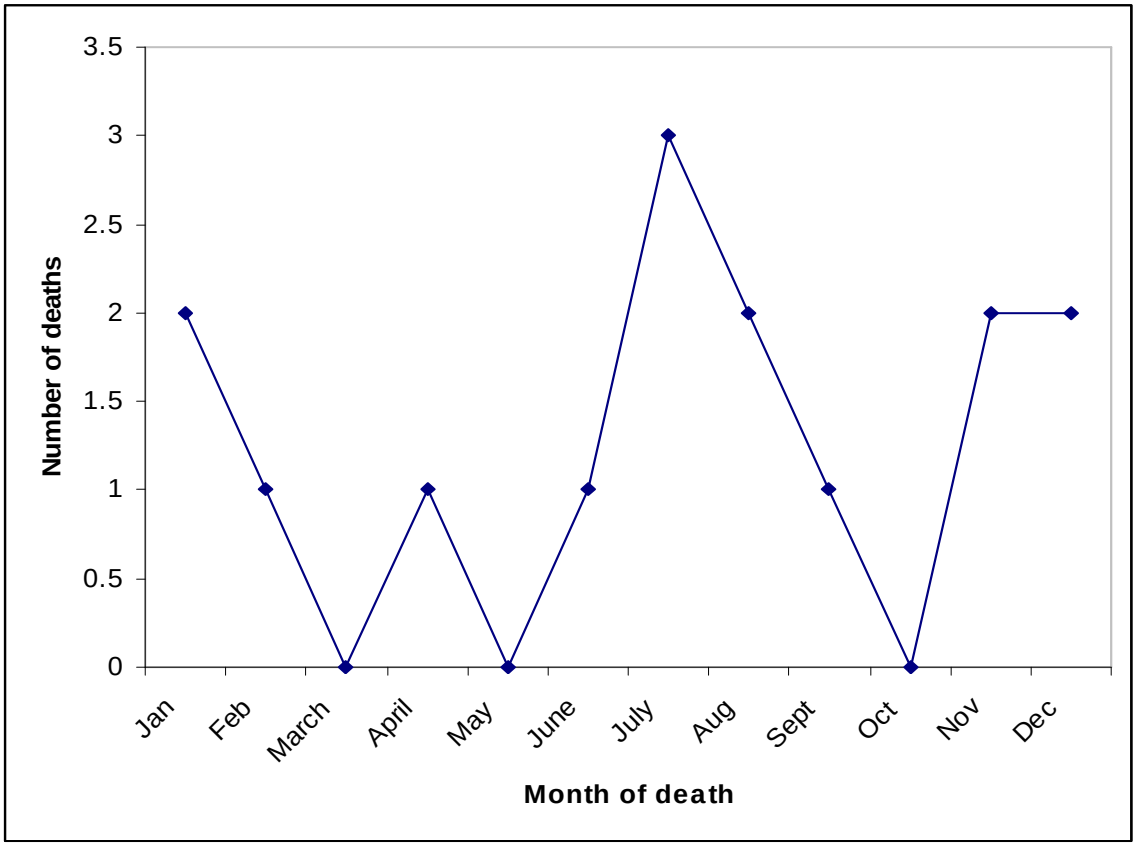


Figure 13: Monthly distribution of early neonatal deaths in rural Burkina Faso

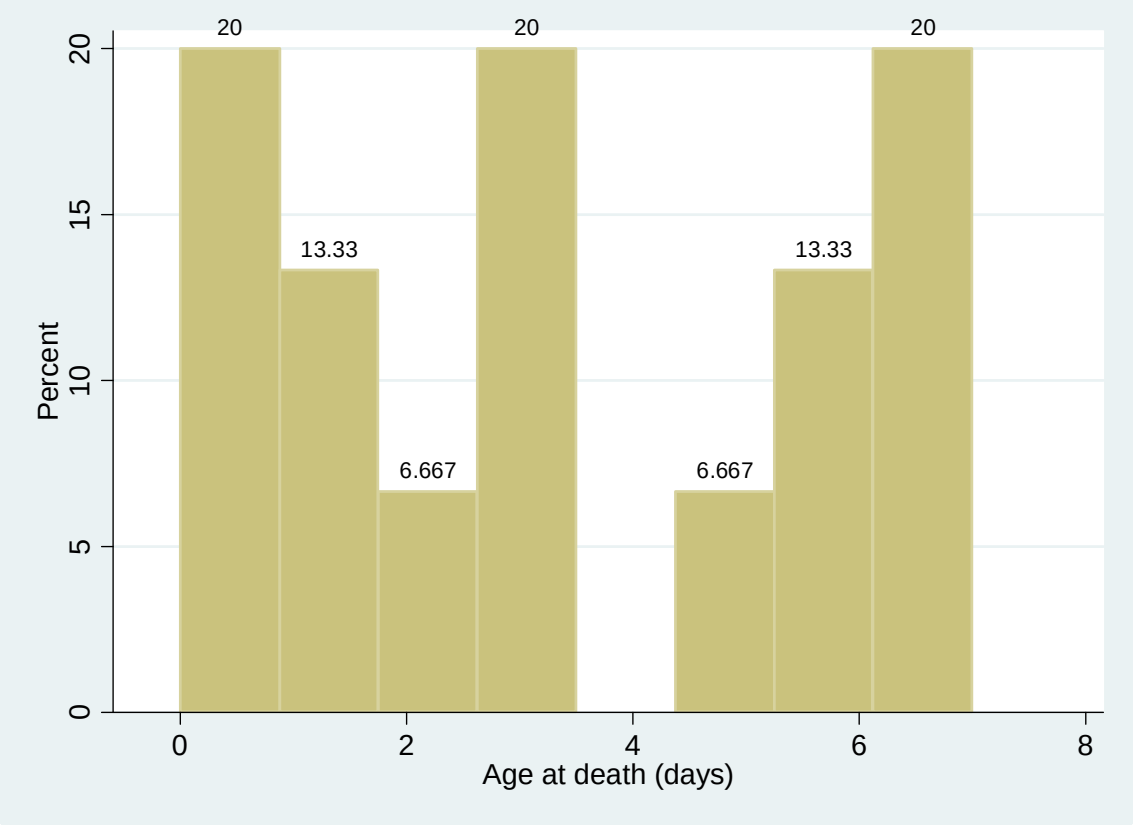


Figure 14: Distribution of 15 early neonatal deaths by age at death in Banfora health district, Burkina Faso

Table 18: Distribution of 15 early neonatal deaths by baseline and postpartum characteristics in Banfora health district, Burkina Faso

Exposures	Frequency of early neonatal deaths, n=15
Education of mothers	
- None	10/15 (67%)
- Got some education	5/15 (33%)
Regular use of media (radio, TV)	
- No	12/15 (80%)
- Yes everyday	3/15 (20%)
Socio-economic status of the household (CFA)	
- Poorest (< 420 000)	7/15 (47%)
- Middle (420 000-730 000)	5/15 (33%)
- Least poor (> 730 000)	3/15 (20%)
Polygamy	
- Yes	10/15 (67%)
- No	5/15 (33%)
Previous history of perinatal death	
- Yes	4/15 (27%)
- No	11/15 (73%)
Number of antenatal visit	
- 0	5/15 (33%)
- 1-2	9/15 (60%)
- > 2	1/15 (7%)
Had complicated delivery	
- Yes	0/15 (0%)
- No	15/15 (100%)
Gender of newborn	
- Girl	5/15 (33%)
- Boy	10/15 (67%)
Time to be put on breast	
- Did not receive breast	4/15 (27%)
- < 12h	6/15 (40%)
- 12-24h	3/15 (20%)
- > 24h	2/15 (13%)
Baby got colostrum at birth	
- Yes	11/15 (73%)
- No	4/15 (27%)
Baby was EBF before death	
- Yes	10/15 (67%)
- No	5/15 (33%)

Analysis of risk factors

Risk factors for perinatal deaths

In univariable regression analysis and while adjusting for clustering the following maternal factors increased the odds of perinatal death: age group (p=0.008), parity (p=0.03) and intervention (p=0.008). The only neonatal factor that independently increased the odds of perinatal death was the season of birth (p=0.001). There was a marginal effect (p=0.067) for the presence of toilets in the household.
We did not find any statistically significant association between perinatal death and any other socio-demographic factors such as marital status, polygamous household, history of child death, and source of drinking water as shown in table 19.

Table 19: Perinatal mortality by characteristics of the mother at recruitment in Banfora health district, Burkina Faso

Characteristics	PNMR per 1000 n=875	OR [95% CI]	p-value (Wald chi-squared)
Location of the cluster			
- Periurban	71.0	1.00	
- Rural	73.7	1.04 [0.56-1.91]	0.90
Marital status			
- Married	74.8	1.00	
- Not married	43.5	0.56 [0.18-1.74]	0.31
Size of the household			
- <10	69.9	1.00	
- 10-20	82.3	1.19 [0.68-2.07]	0.49
- > 20	43.5	0.60 [0.17-2.08]	
Polygamy			
- Yes	80.8	1.24 [0.74-2.06]	0.40
- No	66.1	1.00	
Source of drinking water			
- Safe	66.8	1.00	
- Unsafe	84.1	1.28 [0.78-2.10]	0.32
History of child death			
- Yes	63.4	0.75 [0.40-1.39]	0.36
- No	82.4	1.00	

We found an interaction between age group and parity of the mother, and parity was therefore excluded in the multivariable models.
Two models were computed in a multivariable logistic regression (table 20). In the reduced model (a), we adjusted for socioeconomic status, anticipated feeding mode of the future baby and clustering while keeping 3 of the 4 covariates that were independently associated to perinatal death. The OR for perinatal death increased for intervention (by 32%), for young mothers (by 6%) and for the mothers who were not intended to EBF their baby (52%). The OR for the covariate season of birth decreased (by -2%).
In the full model (b), we included all covariates present in model (a) and adjusted also for the following variables: presence of toilets in the household, education of the mother and her regular use of media (radio, TV), history of previous perinatal death, history of breast problem, number of antenatal care visit, use of bednet during pregnancy. The same 4 covariates as in model (a) appeared as risk factors for

perinatal death in this cohort with a marginal effect for the mother's intention to EBF (table 20).

Table 20: Risk factors for perinatal deaths in a multivariable analysis in 875 women in Banfora health district, Burkina Faso

Exposures	Perinatal deaths	Crude OR [95% CI]	Adjusted[a] OR [95% CI]	Adjusted[b] OR [95% CI]
Arm[c]				
- Control	24/435	1.00	1.00	1.00
- Intervention	40/440	1.71 [1.14-2.55]	2.26 [1.37-3.74]	2.16 [1.20-3.89]
Season of delivery				
- Rainy season (May-Oct)	23/453	1.00	1.00	1.00
- Dry season (Nov-April)	41/422	2.01 [1.31-3.07]	1.97 [1.32-2.94]	1.85 [1.19-2.87]
Age group				
- < 20	20/147	2.41 [1.33-4.38]	2.55 [1.40-64.65]	2.93 [1.54-5.57]
- 20-35	39/638	1.00	1.00	1.00
- > 35	5/90	0.90 [0.29-2.73]	0.91 [0.30-2.76]	0.88 [0.30-2.60]
Parity				
- 0	17/152	2 [1.17-3.42]		
- 1-5	35/593	1.00		
- > 5	12/130	1.62 [0.78-3.33]		
Education				
- None	52/704	1.00		1.00
- Yes some	12/171	0.94 [0.52-1.71]		0.85 [0.42-1.74]
Regular use of media (Radio, TV)				
- No	57/712	1.00		1.00
- Everyday	7/163	0.51 [0.22-1.19]		0.58 [0.24-1.39]
Presence of toilets in the household	25/439	1.00		1.00
- Yes	39/436	1.62 [0.97-2.73]		1.55 [0.91-2.66]
- No				
Socio-economic status (CFA)				
- Poorest (< 420 000)	24/305	1.15 [0.67-1.98]	1.12 [0.64-1.97]	1.01 [0.57-1.79]
- Middle (420 000-730 000)	25/362	1.00	1.00	1.00
- Least poor (> 730 000)	15/208	1.04 [0.49-2.23]	1.17 [0.58-3.36]	1.26 [0.64-2.46]
Ever got breast problems				
- Yes	16/180	1.31 [0.77-2.24]		1.31 [0.71-2.41]
- No	48/695	1.00		1.00
History of perinatal deaths				
- Yes	9/86	1.55 [0.79-3.06]		1.72 [0.81-3.66]
- No	55/789	1.00		1.00
Antenatal visits				
- None	21/250	1.24[0.65-2.34]		1.05 [0.50-2.21]
- 1 or more	43/625	1.00		1.00
Use of bednet during pregnancy				
- Yes	20/333	0.72 [0.37-1.40]		0.67 [0.35-1.30]
- No	44/542	1.00		1.00
Plan for feeding future baby				
- EBF anticipated	28/407	1.00	1.00	1.00
- No EBF planned	36/468	1.12 [0.70-1.79]	1.70 [1.04-2.78]	1.55 [0.97-2.49]

[a] Adjusted for Arm, age group, season of birth, socio-economic status, anticipated plan for feeding the baby, and for clustering. [b] Adjusted for all other variables in the table (except for parity) and for clustering. [c] To take into account the randomization of the EBF trial

To better understand the association between the intervention and the risk of perinatal death as outlined in table 20, we removed the study arm in the above multivariable regressions. The young age of the mother (OR=2.95, 95% CI: 1.55-5.62) and the birth during the dry season (OR=1.93, 95% CI: 1.24-2.99) remained risk factors for the perinatal death.
The intention to EBF was no longer statistically associated to the risk of perinatal death (OR=1.02 95% CI: 0.63-1.64). We did not find any interaction between the intervention and the intention to EBF, the use of bednet or the previous history of breast problem. Therefore we decided to keep the intervention in the multivariable regression as presented in table 20.

Risk factors for stillbirths

After having looked at the total perinatal deaths, now we considered only the stillbirths and ran the same analysis. In the crude analysis and while taking into account the cluster-design of the main study, intervention (p=0.03), birth during the dry season (p=0.002), young age of the mother (p=0.0007), and nulliparous women (0.02) were found to be the factors independently associated to stillbirth. The results of the multivariable logistic regression are shown in table 21.
In the reduced (model a) multivariable regression, the same pattern as for the total perinatal deaths was observed. Mothers younger than 20 years had the highest OR for stillbirth (OR=2.61) compared to those of 20-35 years. Women who had given birth during the dry season (Nov-April) also appeared to have a 129% increased risk of having a stillbirth compared to those who delivered during the rainy season. While the study intervention consisted only of one antenatal home visit for individual peer-counselling on EBF, the intervention appeared to increase the risk of stillbirth with an OR of 2.54 (p=0.001) compared to the control arm. In contrast, mothers who did not anticipate to EBF their baby after birth had a higher risk for stillbirth (OR=2.05, table 21). The socio-economic status had no effect on the risk of stillbirth.
In the full model of logistic regression (model b), we adjusted for all the variables included in table 21 (except parity of the mother). The same risk factors as for perinatal death were identified with the OR in the young mothers (<20 years) increasing by 10%. The inclusion of the other covariates (presence of toilets in the household, education of the mother and her regular use of media, history of previous perinatal death, history of breast problem, number of antenatal care visit, use of bednet during pregnancy) reduced slightly the OR for intervention (-4%), season of delivery (-4%), and the intention to EBF (-8%), but these factors remained statistically associated with the risk of stillbirth (table 21).
In the crude analysis as well as in the full regression model (model b), we did not find any statistically significant association between the education of the mother, the regular use of media, the number of antenatal care visits, the use of bednet, the previous history of perinatal death and the risk of stillbirth.
In the full regression model, mothers listening radio (or watching TV) everyday seemed having a lower OR for stillbirth but this was not statistically significant (OR=0.44, 95% CI:0.15-1.27). The same trend was observed for pregnant women who said they were sleeping regularly in bednets with an OR for stillbirth of 0.84 (95% CI: 0.47-1.48).

Table 21: Risk factors for stillbirths in 875 women in Banfora health district, Burkina Faso

Exposures	Stillbirths	Crude OR [95% CI]	Adjusted[a] OR [95% CI]	Adjusted[b] OR [95% CI]
Arm[c]				
- Control	18/435	1	1	1
- Intervention	31/440	1.75 [1.05-2.92]	2.54 [1.55-4.18]	2.45 [1.41-4.27]
Season of delivery				
- Rainy season (May-Oct)	16/453	1	1	1
- Dry season (Nov-April)	33/422	2.31 [1.36-3.93]	2.29 [1.35-3.89]	2.21 [1.25-3.89]
Age group				
- < 20	16/147	2.47 [1.48-4.11]	2.61 [1.56-4.37]	2.88 [1.60-5.19]
- 20-35	30/638	1	1	1
- > 35	3/90	0.69 [0.18-2.61]	0.71 [0.18-2.73]	0.72 [0.18-2.80]
Parity				
- 0	15/152	2.20 [1.21-4.01]		
- 1-5	28/593	1		
- > 5	6/130	0.97 [0.41-2.27]		
Education				
- None	42/704	1		1
- Yes some	7/171	0.67 [0.28-1.61]		0.59 [0.23-1.49]
Regular use of media (Radio, TV)				
- No	45/712	1		1
- Everyday	4/163	0.37 [0.13-1.06]		0.44 [0.15-1.27]
Presence of toilets in the household				
- Yes	20/439	1		1
- No	29/436	1.49 [0.77-2.87]		1.50 [0.79-2.85]
Socio-economic status (CFA)				
- Poorest (< 420 000)	17/305	1.00 [0.52-1.92]	0.97 [0.50-1.88]	0.85 [0.43-1.68]
- Middle (420 000-730 000)	20/362	1	1	1
- Least poor (> 730 000)	12/208	1.04 [0.45-2.40]	1.18 [0.55-2.56]	1.27 [0.60-2.68]
Ever got breast problems				
- Yes	10/180	0.98 [0.53-1.81]		0.97 [0.53-1.78]
- No	39/695	1		1
History of perinatal deaths				
- Yes	5/86	1.04 [0.40-2.70]		1.14 [0.37-3.53]
- No	44/789	1		1
Antenatal visits				
- None	16/250	1.22 [0.64-2.34]		1.02 [0.50-2.08]
- 1 or more	33/625	1		1
Use of bednet during pregnancy				
- Yes	17/333	0.85 [0.46-1.59]		0.84 [0.47-1.48]
- No	32/542	1		1
Plan for feeding future baby				
- EBF anticipated	20/407	1	1	1
- No EBF planned	29/468	1.27 [0.66-2.47]	2.05 [1.11-3.78]	1.90 [1.04-3.47]

[a] Adjusted for study arm, age group, season of birth, socio-economic status, anticipated plan for feeding the baby and for clustering. [b] Adjusted for all variables in the table (except parity) and for clustering. [c] To take into account the randomization of the EBF trial

Risk factors for early neonatal deaths

Despite the small number of early neonatal deaths in this cohort, the following variables: high parity (> 5), history of previous perinatal death and time to put the baby to the breast (>24h) were found to increase the odds of death by day 7 in the crude analysis (table 22). The results of a multivariable logistic regression adjusting only for the study arm, the history of perinatal death and for clustering showed that the history of perinatal death is a risk factor for early neonatal death (OR=3.59, p=0.028). The study intervention had no effect on the risk of early neonatal death.

Table 22: Risk factors for early neonatal deaths in 826[a] women in Banfora health district, Burkina Faso

Exposures	Early neonatal deaths	Crude OR [95% CI]	Adjusted[b] OR [95% CI]
Arm			
- Control	6/417	1	1
- Intervention	9/409	1.54 [0.56-4.18]	1.62 [0.61-4.31]
Age group			
- <20	4/131	2.09 [0.52-8.31]	
- 20-35	9/608	1	
- >35	2/87	1.56 [0.40-6.07]	
Parity			
- 0	2/137	1.18 [0.21-6.37]	
- 1-5	7/565	1	
- > 5	6/124	4.05 [1.43-11.45]	
Socio-economic status (CFA)			
- Poorest (< 420 000)	7/288	1.67 [0.68-4.14]	
- Middle (420 000-730 000)	5/342	1	
- Least poor (> 730 000)	3/196	1.04 [0.24-4.52]	
History of perinatal deaths			
- Yes	4/81	3.46 [1.07-11.23]	3.59 [1.14-11.24]
- No	11/745	1	1
Antenatal visits			
- None	5/234	1.27 [0.34-4.73]	
- 1 or more	10/592	1	
Birth attendant			
- Health personnel	6/309	1	
- Non health personnel	9/517	0.89 [0.36-2.17]	
Place of birth			
- Health facility	6/305	1	
- TBA/Home/others	9/521	0.87 [0.36-2.09]	
Baby got colostrum after birth (n=803)			
- Yes	11/708	1	
- No	4/95	2.78 [0.90-8.59]	
Time to put baby on breast (n=803)			
- <12h	6/421	1	
- 12-24h	3/247	0.85 [0.18-3.86]	
- >24h/did not breastfeed	6/135	3.21 [1.13-9.10]	
Gender of the newborn(n=813)			
- Girl	5/387	1	
- Boy	10/426	1.83 [0.64-5.22]	

[a] n <826 are reported into parenthesis for applicable variables. [b] Adjusted only for clustering, Arm and history of perinatal death.

Sensitivity analysis

We used the data from rural Malawi that were published by McDermott et al (McDermott, Steketee et al. 1996) to perform a sensitivity analysis and re-adjust our estimates of stillbirths and early neonatal deaths. In their study McDermott and al. found that stillbirths were overestimated by 12% in home deliveries as compared to health facility deliveries and also that death of neonates on the day of delivery was rather underestimated by 15%. We applied the same percentages to our sample and the results of adjusted estimates of stillbirths and early neonatal deaths are shown in table 23 below. The adjusted estimates suggest that misclassification of stillbirths would not change much both PNMR and early neonatal mortality rate in our study.

Table 23: Adjusted perinatal death estimates for possible misclassifications of stillbirths and early neonatal deaths in rural Burkina Faso.

Outcomes	Actual figures (‰)	Adjusted[a] estimates (‰)	p-values
Stillbirths	49/875 (56.0)	43/875 (49.1)	0.51
Early neonatal deaths	15/826 (18.1)	21/832 (25.2)	0.32
Perinatal deaths	64/875 (73.1)	64/875 (73.1)	-
Number of deaths at day 0	3/15 (200)	6/21 (286)	0.87

[a] Adjusted for misclassification errors of 12% for stillbirths and 15% for the day of birth in early neonatal deaths.

Discussion

Baseline characteristics of the cohort

The baseline characteristics of our cohort confirm the rural location of our study clusters. Indeed 81% of the study participants were living in remote rural settings, which are known for a high level of illiteracy (80.4% in our study), few nulliparous among the women (17.4%), low use of antenatal and childbirth services by pregnant women (home delivery was 54.7%). The descriptive statistics in our study about age, parity and use of health services are consistent with previous data from the area (Burkina Faso 2004; Burkina Faso(a) 2008) and also consistent with studies targeting similar populations in rural Burkina Faso (Filippi, Ganaba et al. 2007; Bell, Ouedraogo et al. 2008; Roberfroid, Huybregts et al. 2008).

The proportion of women with a previous child death irrespective of the child age was high in our cohort with 48.7% of women who reported a previous child death and is similar to the 46.7% (Roberfroid, Huybregts et al. 2008) found in a cohort study in rural Houndé (Burkina Faso). This finding illustrates the burden of child mortality in this country and especially in the rural settings. The reason of this high prevalence of history of child death may also be due to the median parity in our cohort (2 children per enrolled woman) which increases the probability of having one child death in this area. In the city of Bobo-Dioulasso, Prazuk et al. (Prazuck, Tall et al. 1993) reported a proportion of 19% of previous child deaths but the study population and location were definitely different from those of our study.

The proportion of women who reported a history of perinatal death (9.8%) was low compared to the 18.3% of “fetal loss” reported in the Houndé’s rural study (Roberfroid, Huybregts et al. 2008). However, one should remember that this figure gives an idea of the prevalence of the perinatal deaths among our participants rather than a perinatal mortality rate, as women responding did not experience the perinatal death during the same period of follow-up. The difference with the findings from Houndé may just come from how the question was phrased there, and if it did include fetal loss before 28 weeks of gestation (7 months).

Despite their exclusion from the EBF trial follow-up, our data on the group of twins showed a frequency of multiple births (2.2%) that was not different neither from previous results in Burkina Faso (Burkina Faso 2000; Chalumeau 2002; Becher, Muller et al. 2004; Roberfroid, Huybregts et al. 2008; Becher, Kauermann et al. 2009) nor from other African studies (Justesen and Kunst 2000; Engmann, Matendo et al. 2009). The perinatal death rate among the twins was high, 200‰, confirming the anticipation of the EBF-trial investigators and is in accordance with literature findings (Justesen and Kunst 2000; Becher, Muller et al. 2004; Becher, Kauermann et al. 2009; Engmann, Matendo et al. 2009).

The perinatal mortality rate

The perinatal mortality rate in this cohort was 73.1‰ (95% CI: 55.8-90.4) and seems to be the highest ever published in Burkina Faso. The two previous DHS in Burkina Faso (Burkina Faso 2000; Burkina Faso 2004) estimated the perinatal mortality rates

to 54 and 36 per 1000 births in 1999 and 2003, respectively. Furthermore, the scarce hospital-based (Chalumeau 2002; Chalumeau 2002; Banks, Meirik et al. 2006) and community-based studies (Bell, Ouedraogo et al. 2008; Roberfroid, Huybregts et al. 2008) conducted in Burkina have shown perinatal mortality rates ranging from 32.5 to 50‰, if we exclude the study on a specific group of women with obstetric complications that had found a perinatal mortality of 219.6‰ (Filippi, Ganaba et al. 2007).

The stillbirth rate found in our study (56‰, 95%CI: 40.7-71.2) is also unprecedently higher than the recent data published from Burkina Faso that ranged from 16 to 41.7‰ births (Chalumeau 2002; Burkina Faso 2004; Banks, Meirik et al. 2006; Bell, Ouedraogo et al. 2008; Roberfroid, Huybregts et al. 2008) and higher than the West African studies in the Gambia (Greenwood 1987), Ghana (Edmond, Quigley et al. 2008) and Nigeria (Owolabi, Fatusi et al. 2008).

Early neonatal mortality rate, the second component of perinatal mortality, was 18.1‰ in our study (95% CI:9-27.2) and was consistent with previous data from Burkina (Burkina Faso 2000; Burkina Faso 2004) but is slightly over the 10.3‰ reported by Roberfroid et al. in Houndé (Roberfroid, Huybregts et al. 2008).

In our view, three reasons may explain the high estimates of perinatal mortality rate in our study:
- The first reason is probably the design of this study. The EBF-trial was a prospective community-based study, which included the largest possible number of pregnant women that could be found in each cluster, and followed them up to 12 months after birth. Our “recruiters” were doing weekly households checking to identify all the new pregnant women in their village and we have good reasons to think that they have identified and reported most of them. In total 1162 pregnant women were identified in one year in the 24 clusters. The pregnant women selected for data collection and study follow-up (900) were randomly sampled from the total population of identified pregnant women, and the refusal rate was very low (1.8%). Therefore in such prospective cohort, community-based study with information collected on a daily basis from the community-members, we could expect to find a perinatal mortality rate higher than that of previous publications. Indeed DHS (Burkina Faso 2000; Burkina Faso 2004; Bell, Ouedraogo et al. 2008) used a questionnaire on recall of perinatal death in the five years preceding the surveys with a high risk for reporting errors and the studies from Houndé were either health-facility based (Filippi, Ganaba et al. 2007) or targeted only women coming for ANC in local health facilities (Roberfroid, Huybregts et al. 2008). The studies from Nouna DSS (Becher, Muller et al. 2004; Hammer, Some et al. 2006) could be expected to provide much more reliable estimates of perinatal mortality rate in rural Burkina Faso, but it seems that this DSS did not capture perinatal (no data reported) and neonatal mortality (instead estimated to 6% of all child deaths) in the available publications (Becher, Muller et al. 2004; Hammer, Some et al. 2006; Becher, Kauermann et al. 2009).
- The second reason that may explain this high PNMR is the rural location of our study site. It is known that rural settings in Burkina Faso have low availability of health infrastructures and limited access to health facilities (Burkina Faso 2004; Burkina Faso(a) 2008; Burkina Faso(b) 2008; Burkina Faso(c) 2008; UNICEF 2009). Where these health infrastructures exist, the poor quality of health care and the

presence of a non-motivated health staff have been two factors constantly associated with low attendance of health facilities and poor pregnancy outcomes (Darmstadt, Bhutta et al. 2005; Lawn, Cousens et al. 2005; WHO(a) 2007; Bell, Ouedraogo et al. 2008; Clark, Moro et al. 2009). In our study there was a discrepancy between the proportion of pregnant women who have had at least one ANC visit (71.4%) and those who delivered in a health facility (36.9%) raising a structural concern about the effectiveness and deliverability of the antenatal and childbirth services in rural Burkina Faso. Some cultural factors may play a role in this situation but a relevant assessment needs to be made.

- The third reason that may explicit the high stillbirth rate in this study is the potential misclassification of stillbirths. The first misclassification comes from the classification of miscarriage as stillbirth meaning that some foetal loss before 7 months of gestation could be classified as stillbirths. However, in our sample only 3 women stated that they were pregnant of less than 7 months and the checking of their ANC card showed an uterine height over 28 cm several weeks before their recruitment into the study. Furthermore, several publications from Burkina Faso confirmed pregnant women as having a late ANC visit with a median gestation of 6 months for the first ANC visit in rural settings (Burkina Faso(a) 2008; Burkina Faso(b) 2008; Burkina Faso 2009). If these 3 women were considered as being misclassified, this would not change much the estimate of PNMR in this study.

Another misclassification is that occurring when early neonatal deaths are reported as being stillbirths. In this study, stillbirths represented 76.6% of all perinatal deaths, much more than the 50-60% reported by other studies (McDermott, Steketee et al. 1996; Lawn, Cousens et al. 2005; WHO(a) 2007; Edmond, Quigley et al. 2008; Engmann, Matendo et al. 2009). Because of the high proportion of home deliveries in our cohort and the “limited” information collected (for cultural reasons) in the circumstances of foetal loss among the women who had experienced stillbirths, there is a chance that the stillbirth rate was overestimated in our study, some of them being actually early neonatal deaths. Nevertheless, some studies also have reported high proportions of stillbirths (Banks, Meirik et al. 2006; Habib, Dalveit et al. 2008; Habib, Lie et al. 2008). Misclassification is an important issue when calculating the perinatal mortality rate and has been reported in many studies in Sub-Saharan Africa (McDermott, Steketee et al. 1996; Edmond, Quigley et al. 2008; Spector and Daga 2008; Engmann, Matendo et al. 2009). Misclassification is a problem in health facility-based studies as well as in community-based studies because it may be due to a lack of equipment, insufficient training, economic or cultural reasons as initially stated in the literature review section. In a well documented study comparing misclassification for stillbirth and neonatal deaths in Malawi, McDermott et al. (McDermott, Steketee et al. 1996) have found a 12% difference between home deliveries and health facility deliveries. The misclassification in the Malawian study increased the stillbirth rate from 28.8‰ in health facility delivery to 51.6‰ in home delivery ($p<0.001$). However, the sensitivity analysis performed in our study using the same differential proportion as that reported by McDermott et al., did not make the difference statistically significant between the crude and corrected estimates of stillbirth and neonatal mortality rates (56 versus 49.1, and 18.1 versus 25.2, respectively, $p>0.30$). We therefore believe that, misclassification would have a limited impact on the stillbirth and neonatal mortality rates in our study.

If the perinatal mortality rate of 73.1 per 1000 births found in our study is the highest ever reported in a study in Burkina Faso, it is however important to note that this rate

falls in the range of estimates for the Sub-Saharan Africa region. In a recent study from Democratic Republic of Congo (DRC) in Central Africa, Engmann et al. (Engmann, Matendo et al. 2009) had found a perinatal mortality rate of 64 per 1000 births. Two studies (Greenwood 1987; McDermott, Steketee et al. 1996) reported perinatal mortality rates of 74.5‰ and 68.3‰ in the Gambia and Malawi, respectively. In its regional and global estimates for perinatal mortality rate in 2000 and 2004, the WHO's reports analyzing DHS and vital registrations of 170 countries, has estimated the PNMR to 62 and 56 per 1000 births, in 2000 and 2004, respectively, for the Sub-Saharan Africa. During the same period, the West and Central Africa were reported to have PNMR of 76‰ and 75‰ in 2000, and 69‰ and 74‰ in 2004.
We therefore believe that previous studies for methodological and location-related issues have underestimated the perinatal mortality rate in Burkina Faso, especially in the rural settings.

The overall reasons for a high perinatal mortality rate in rural Burkina are the same as those described in the causes of stillbirths and early neonatal deaths. The weakness of the health system could be summarized in low availability (ratio of 1 CSPS/9876 inhabitants in 2007, MoH/BF, 2008) and limited accessibility of health facilities (mean distance to CSPS was 10.7 Km in Banfora health district in 2007, MoH/BF accessible at URL http://www.insd.bf/), poor quality of the health care in antenatal and childbirth services partially due to under-staffed and non motivated health personnel and the unbelievable illiteracy over 80% among women (Bell, Ouedraogo et al. 2008; UNICEF 2009). Emergency obstetric care is officially stated to exist but our daily experience of 3 years in the Banfora health district and in other rural districts in the country has clearly shown that this is not effective always and everywhere. The country health system fact sheet published by the WHO in 2006 (www.who.int/whosis/en/), showed ratios for health workers of 0.06‰ for physicians, 0.13‰ for midwives, and 0.41‰ for nurses. It is obvious that these ratios did not fit the WHO' standards and were the worst in the AFRO region (WHO(b) 2006). The lack of motivation of the health personnel comes partly from their low salaries that are among the lowest in the world (Burkina Faso(b) 2008) and the absence of career promotion.

The risk factors for perinatal mortality

Four main factors were identified to increase significantly the risk of perinatal death in our cohort: the age of the mother, the season of birth, the intention to EBF the future baby, and the intervention (study arm).

The age of the mother

In our study, women younger than 20 years had an increased significant risk of perinatal death (OR=2.93, 95% CI: 1.54-5.57) compared to those 20-35 years old. This finding is consistent with several other studies (Greenwood 1987; Prazuck, Tall et al. 1993; McDermott, Steketee et al. 1996) and also with the medical knowledge (Lawn, Cousens et al. 2005; WHO(a) 2006). This group of young women was made of nulliparous women, another risk factor linked to the young age and present in our unadjusted analysis (OR=2, 95% CI: 1.17-3.42), and which also has been reported elsewhere (Greenwood 1987; Zeitlin, Combier et al. 1998; Chalumeau 2002; Engmann, Matendo et al. 2009). The first obvious reason for this over risk is that

young mothers have not given birth before and therefore carry a higher risk of obstructed labour. Obstructed labour often requires emergency obstetric care which is distant in this area. Another reason that could explain the vulnerability of this group could be the different infections. Several studies have shown that the burden of placental malaria on pregnancy outcomes is much larger on primigravidae (Steketee, Wirima et al. 1996; Uneke 2007). Other infectious causes responsible of high perinatal mortality in young mothers are syphilis (Armagnac and Retel-Laurentin 1981; Greenwood 1987; McDermott, Steketee et al. 1996) and HIV-infection (Verhoeff, Brabin et al. 1999; WHO 2005; Uneke 2007).
We also think that a cultural reason may explain at least in the context of Banfora the high perinatal deaths among the young mothers; indeed in a qualitative study carried out before the implementation of the EBF trial in this region (data not published), it was shown that the older women in the households were among the most influential family members when it comes to maternal and child health. Because of this power structure, it is possible that these young nulliparous mothers are those exposed to conventional harmful practices that may be associated with a poor pregnancy outcome. These harmful practices include traditional diets, administration of liquids to the newborn in the first 24h, rejection of colostrum.

The season of birth
In our study the dry season (November to April) was associated with an increased risk of perinatal death with an OR of 1.85 [95% CI: 1.19-2.87]. The season of birth has not been explored as a risk factor for perinatal deaths in Burkina. In a study on perinatal mortality in the Gambia, Greenwood et al. (Greenwood 1987) did not find a seasonal pattern for stillbirths but the authors found that neonatal deaths occurred with a peak during the rainy season. In a large Tanzanian study using a birth registry, Habib et al. (Habib, Lie et al. 2008) found a seasonal pattern similar to our study. The perinatal deaths were significantly higher during the dry season (OR=1.29, 95% CI: 1.04-1.59); however, it seems that in Tanzania, there is two rainy seasons, something that does no exist in Banfora. The only studies that reported a seasonal pattern in child mortality in Burkina were carried out in Nouna (Becher, Muller et al. 2004; Hammer, Some et al. 2006). However the authors who focused on a different study population (children from 1-60 months) found a seasonal pattern opposite to our findings, with a marked increase of infant deaths during the rainy season (OR=1.21, 95% CI:1.01-1.46 for infant mortality) and malaria was the most common cause of death. It is known that the causes of early neonatal deaths differ from those happening after the 4 first weeks of life (Lawn, Cousens et al. 2005; WHO(a) 2006; Edmond, Quigley et al. 2008). Congenital malaria is rare in our settings despite a relatively high prevalence of placental parasitemia (Cottrell, Mary et al. 2005; Sirima, Cotte et al. 2006; Gies, Coulibaly et al. 2009). We do not have a clear argument of the seasonal pattern of perinatal deaths observed in our study. However, we can think about the potential impact of the weather between November and January in Burkina (our “winter” with temperatures as low as 16℃) on the readiness for families with a woman already in labour to reach the local health facility especially in the night. We are also thinking that the seasonal pattern of perinatal mortality shown in our study does not exclude a potential role of malaria as one causal factor of perinatal deaths. Most of the women included in this study were multigravidae, a group shown to be less likely to experience the severe or complicated forms of malaria (cerebral malaria, severe anaemia, hypoglycaemia, haemorrhages) because the repeated exposures could provide a protective immunity against these forms but

do not prevent parasitemia (Gazin, Compaore et al. 1994; Fievet, Tami et al. 2002; Sirima, Cotte et al. 2006; Guitard, Cottrell et al. 2008). It is therefore possible that malarial infections during the rainy season had rather a chronic impact in the multigravidae inducing a delayed anaemia which impact on the pregnancy outcome is either moderate or occurring only several weeks later.

The intention of the mother to EBF (anticipated feeding mode of the baby to be born)
The reduced model (model a) of multivariable logistic regression using either perinatal death or stillbirth as outcome, showed an association between the intention to EBF the actual baby and the perinatal death risk. An OR of 1.7 [95% CI: 1.04-2.78] for perinatal death was computed in women who did not anticipate to EBF their baby to be born. It is true that this intention was already different between the two arms at recruitment (75.4% in the intervention arm versus 17.2% in the control arm), but the association remained statistically significant (p=0.02) even after adjusting for study arm. We think that this association may just be the combined effect of other behavioural factors such as the use of health services, the use of bednet and may be the education of the mother. Indeed in the full multivariable model (model b), the intention to not EBF had only a marginal effect (OR=1.55, 95%CI: 0.97-2.50) on the risk of perinatal death. However, if stillbirth is set as the main outcome, the association between the intention to EBF and the risk of stillbirth was statistically significant both in reduced (a) and full model (b) of multivariable regression. Mothers not planning to EBF had an OR for stillbirth of 2.05 (p=0.02) in model (a) and of 1.90 (p=0.037) in model (b). We did not find a study that has explored the intention to EBF as a risk factor for perinatal death. A study conducted in Ghana (Edmond, Kirkwood et al. 2007) has shown that delayed initiation of breastfeeding is associated with an increased neonatal mortality but early neonatal mortality was only 24% of all perinatal deaths in our study. We therefore felt the need for further studies on this association.

Study intervention (study arm)
Our findings showed a significantly increased risk of perinatal death in the intervention arm both in crude, reduced and full models of multivariable regressions. We could not see any consistent explanation of this association. The baseline table per arm (table 6) showed that 4 variables seemed unequally distributed: proportion of participants recruited in the peri-urban clusters (24.6% in the intervention arm versus 14% for the control), history of breast problems (24% in the intervention versus 17% in the control), use of bednet during pregnancy (43.2% in the intervention versus 32.9%), and the intention of the mother to EBF the future baby (75.4% to EBF in the intervention arm versus 17.2% in the control). Of these 4 variables, none was independently associated to the risk of perinatal death. Despite their inclusion in the full multivariable model, the intervention remained associated to perinatal death with a high odds (OR=2.16, p=0.01). A randomized control trial of multiple micronutrient supplementation in pregnant women conducted in rural Burkina Faso had similar results when analysing the trial effects on perinatal deaths (Roberfroid, Huybregts et al. 2008). The authors showed an OR of 2.08 (p=0.032) for perinatal death in the intervention group. After adjusting for the loss to follow-up, the OR for perinatal death was 1.78 for the intervention group and was really borderline (p=0.06). However in our study, we had no loss-to-follow-up by day 7 postpartum.
It is possible that this difference could come from an over-reporting in the intervention arm, where peer-supporters could be more motivated. However, the same data

collectors had worked in both arms, and the recruiters and the peer-counsellors were getting the same salary for working for the project. Furthermore, each mother reported by the recruiters in both arm to have had a perinatal death, was interviewed by the data collectors and all pregnant women included in the study were followed up to 12 months.
In the end, we think that there are two possibilities: spurious association or a randomization failure. This is supported by the fact that after removal of the study arm as covariate in the regression, both univariable and multivariable analysis showed the same findings except for the intention of the mother to EBF. There is no scientific reason to believe that an intervention aiming at the promotion of exclusive breastfeeding with only one antenatal individual counselling session would increase significantly perinatal mortality in Burkina Faso.

Other risk factors:
In our study, we failed to show any statistically significant association between perinatal death and marital status of the mother. Our findings differ from those of Gray et al. in Brazil (Gray, Ferraz et al. 1991), Zeitlin et al. in France (Zeitlin, Combier et al. 1998) and Engmann et al. in DRC (Engmann, Matendo et al. 2009) who showed that single mothers were more likely at risk of having a perinatal death than married or cohabitant mothers.
We did not also find any association between the socio-economic status of the household and the risk of perinatal death as did much larger studies (McDermott, Steketee et al. 1996; Habib, Lie et al. 2008) in Malawi and Tanzania. But a narrow gap between the least poor and the poorest in our study may explain this difference.
Neither did we find any association between the education of the mother or her regular use of media (radio or TV) and the risk of perinatal death. However, one should note that very few women in our cohort had any substantial education.
In two studies (Habib, Lie et al. 2008; Engmann, Matendo et al. 2009) in Tanzania and DRC, respectively, the authors found that mothers without education or those with a low education had a higher risk of perinatal death.
The number of ANC visits, the use of bednet during pregnancy, the history of perinatal death and that of breast problems of the mother were not associated with the occurrence of a perinatal death in our study. These results differ from those of Engmann et al. in DRC (Engmann, Matendo et al. 2009) and Owlabi et al. in Nigeria (Owolabi, Fatusi et al. 2008) who have shown that mothers with no ANC visit carried a higher risk of perinatal death than those with one or more prenatal care visit.
The differences observed with above mentioned studies may be due to the extremely small variations in our sample.

Risk factors for early neonatal death
The number of early neonatal deaths was too small in our cohort to allow a full model of multivariable logistic regression. However, in the univariable analysis, we found that 3 covariates were potential risk factors for early neonatal death: high multigravidae, mothers with previous history of perinatal death, and the time to put the newborn to the breast. Multigravidae women (parity > 5) had an OR of 3.97 (95% CI: 1.31-12.05) for early neonatal death when compared to those with 1-5 previous births.
Similarly, women with a previous history of perinatal death had an OR of 3.40 (95% CI: 1.05-10.96) for early neonatal death compared to those without. This association remained statistically significant in the reduced multivariable analysis adjusting for

intervention and clustering (OR=3.59, 95% CI: 1.14-11.24). These findings have already been shown in much larger studies in Sub-Saharan Africa (Greenwood 1987; Prazuck, Tall et al. 1993; McDermott, Steketee et al. 1996; Chalumeau 2002) and confirm that the same pattern prevail in rural Burkina Faso.
We also found an increased odds for early neonatal deaths in the group of women with delayed initiation of breastfeeding (> 24 h) when compared to those who started breastfeeding within 12 hours after birth (OR=3.21, 95%CI: 1.01-10.14). Similar results have been shown in Ghana (Edmond, Kirkwood et al. 2007). But given our small number of cases, we should be cautious in the interpretation of these results despite their consistency with prior knowledge.
Our study failed to show the place of birth (health facility versus non health facility) and the birth attendant (health staff versus non health staff) as risk factors for early neonatal death opposite to previous studies findings (McDermott, Steketee et al. 1996; Owolabi, Fatusi et al. 2008). We believe this is due to the insufficient power of our study to detect very small differences. Neither did we find any statistically significant association between the gender of the newborn and the risk of neonatal death, as reported by the literature (McDermott, Steketee et al. 1996; WHO(a) 2006; Engmann, Matendo et al. 2009).

Limitations and strengths of our study

We have performed a secondary analysis of the EBF trial data to look at the perinatal mortality rate and its potential risk factors in a rural area of Burkina Faso. The sample size in our trial (875 single births) was enough to measure the estimates of the perinatal mortality rate based on previous reports from Burkina (Burkina Faso 2000; Burkina Faso 2004; Roberfroid, Huybregts et al. 2008) that ranged from 32 to 50‰. However, this sample size was not enough to identify risk factors with small difference between the exposed and the non-exposed groups. Nevertheless, 3 of the 4 risk factors identified in our study have already been reported by previous studies in Africa. Another limitation of our study was the cultural difficulty to perform in-depth interviews of mothers who had experienced stillbirth using the verbal autopsy forms and to try to distinguish the antepartum from the intrapartum stillbirths, and possibly their causes. Apart from the site of delivery and the occurrence of complicated labour, we did not include other clinical factors that could be assessed as risk factors in our study.

Our study was prospective, community-based, in a rural area of Burkina Faso and involved community-workers who have been selected and accepted by their own communities. They have been monitoring on a daily basis the pregnant women enrolled in this prospective cohort. The data collectors were well-trained, spoke the local languages and had been themselves living in these communities throughout the study and the field supervisions had been regular and performed by an experienced team. The procedure of selection of pregnant women for data collection was random and we have good reasons to believe that our cohort is representative of the pregnant women in this area. This study is among the first to provide precise and reliable data on the perinatal mortality rate in rural Burkina Faso. The study has shown the burden of perinatal mortality in Banfora health district and it seems to be the highest ever reported in this country. The risk factors identified are consistent with the previous studies in this topic except the intention to EBF.

Once identified, risk factors need to be targeted by specific health policy and programmes. The use of childbirth services has appeared as one of the problem in this health district. The gap between the proportion of women with ANC visit and those delivering in health centres needs to be clarified by further studies including qualitative studies. Primigravidae need special attention and our findings may reflect the poor quality of the prenatal care and childbirth services that do not identify those at a higher risk during the pregnancy (hypertension, previous perinatal death, short stature) and labour (eclampsia, obstructed labour, etc).

The seasonal pattern of perinatal deaths identified in our study highlights the need to increase the geographic accessibility of health centres. Indeed December and January are the “winter” in this area, and few family members will manage to get a woman already in labour to a health facility 10 Km away by a weather of 16℃.

Finally, if the intention to EBF may be a risk factor for perinatal death as suggested by our findings, then health facilities could have more to play in the promotion of EBF during ANC visits and at birth by an early initiation of breastfeeding as recommended by the baby friendly hospital initiative that is no longer in practice in several health centres. Some of the interventions to improve maternal and child health should be delivered by the local communities themselves in order to give them a high chance of sustainability. Community-based health interventions are feasible, accepted and effective, once the first beneficiaries have themselves understood its importance as we seen it during the EBF trial.

Conclusion

A prospective, community-based study was conducted in 24 rural clusters in the Banfora health district, South of Burkina Faso. The study has shown:

- The highest perinatal mortality ever reported in Burkina Faso, with a PNMR of 73.1‰.
- Three main risk factors for perinatal death have been identified that are the young age of the mother, the season of birth, and the intention to EBF. The same factors were associated to the risk of stillbirth. Another fourth risk factor for perinatal death that was identified in our analysis was the study intervention (promotion of EBF) but we strongly believe this was either a spurious association or a randomization failure.
- The number of early neonatal deaths in our study was too small to make any strong statistical inference despite the identification of higher multigravidae (> 5) and the history of previous perinatal death as risk factors for early neonatal death in the crude analysis.

This study is among the rare to give a precise and reliable estimate of perinatal mortality rate in rural Burkina Faso.

The burden of perinatal mortality as measured in our study appeals for urgent and sustainable interventions to improve maternal and newborn health in rural areas of Burkina Faso.

Recommendations

Our study has highlighted the burden of perinatal death in rural Burkina Faso. This study has also identified risk factors and potential weaknesses of the health system that contribute to this major public health problem. We therefore would like to make some recommendations to the attention of the four main stakeholders of the health care system in our country:

- **For the attention of health researchers and Epidemiologists:**

- to provide further accurate data on the perinatal mortality rate in rural Burkina Faso as to make it a more visible public health issue.
- to explore by further studies (including qualitative studies) the gap between the use of ANC services and a lower use of childbirth services.
- to investigate further the seasonal pattern of perinatal deaths and the association between the intention to EBF and PNMR as found in our study.

- **For the attention of health policy makers and national health authorities of Burkina Faso:**

- to improve the national health statistics system in order to collect and provide much more precise estimates of the PNMR.
- to increase continuously the availability and the accessibility of health facilities but also the number of health staff.
- to improve the quality of care offered in prenatal care and childbirth services especially in rural settings.
- to increase the implementation at large scale of the community-based interventions that were shown to improve the child health and to reduce in a sustainable manner the perinatal and the neonatal mortality rates.
- to assess the feasibility of a national survey that could be included in the next DHS to capture the reasons of poor attendance of childbirth services and to identify the most important factors in terms of the quality of care from the users' perspective.
- to pursue the advocacy for more funding of maternal and child health programmes and have a more consistent and comprehensive health policy with integrated approaches of maternal and newborn health.

- **For the attention of the local communities:**

- to increase their attendance of antenatal and childbirth services wherever they are available and especially for the young nulliparous women.
- to actively participate in community-based interventions targeting maternal and newborn health and make sure they are sustained after the research phase.

- **For the attention of the international partners and donors for public health interventions:**

- to establish a more comprehensive strategy for maternal and child health; the vertical approaches used for so long need to be questioned and the higher funding of programmes targeting "spectacular public health issues" need to be reconsidered.
- to increase substantially the funds allocated to the maternal and newborn health programmes.

Appendix

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Data collection forms (recruitment form, D7 form, verbal autopsy forms)

FORM: Recruitment Interview - (ID: 135)

Q01, Page a (1), SECTION 0: Background

1. BACKGROUND INFORMATION

2. 1. Country/Site: - [01a01]

   1. [_] - [var] Burkina Faso
   2. [_] - [var] Uganda: Mbale Municipality
   3. [_] - [var] Uganda: Bungokho
   4. [_] - [var] Zambia: Site 1
   5. [_] - [var] Zambia: Site 2
   6. [_] - [var] SA Paarl
   7. [_] - [var] SA Rietveli
   8. [_] - [var] SA Umlazi

   (Select only 1 - ONE!)

3. 2. Interviewer - [01a02B]

   1. [_] - [DAJO] DAJO
   2. [_] - [COMA] COMA
   3. [_] - [SOSE] SOSE
   4. [_] - [TRDA] TRDA
   5. [_] - [TOED] TOED
   6. [_] - [8] Other, specify

   (Select only 1 - ONE!)

4. 3. Date: - [01a03]
   ___/____/_______

5. 4. Time: - [01a04]
   H:____M:____ S:____

6. 5. GPS coordinates (Optional) - [01a05]

   1. [_] - [01a05_1] Longitude _____ (Text)
   2. [_] - [01a05_2] Latitude _____ (Text)
   3. [_] - [01a05_3] Altitude _____ (Text)

7. CONSENT FOR SCREENING (Read out loud)
We come from the collaborative research project between Centre MURAZ Research Institute, the Regional health Directorate of Banfora, the Banfora health District and the Promise Study group.
   INFO: CONSENT FOR SCREENING (Read out loud)
We come from the Centre MURAZ Research Institute. We are conducting a study on Child Health. We wish to include you in this study. We will be visiting you regularly, asking some questions. Are you willing to participate?. (Full informed consent will be administered before).

8. This is study collaboration between four African countries which do research on safer child feeding and child health. We are conducting a study on child health.

9. We wonder if we could include you in the study, but before doing that we might ask you a few questions. Can we do that?

10. 6. Oral consent for screening given? - [01a06]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: If no, Rule EH : No ? Discontinuation from SI
Say thank you and ask for reason for non-participation; fill in separate form

11. 7. Another language spoken than the one chosen from the list? - [01a07]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: If no, skip to 10

12. 8. Which Language is the Interview translated into? - [01a08]
_____

13. 9. External Translator needed? - [01a09]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

14. 10. Sub-County/Division/Department (Do not read out) - [01a10B]

1. [_] - [4001] Banfora
2. [_] - [4002] Sidéradougou
3. [_] - [4003] Soubakaniendougou

(Select only 1 - ONE!)

15. 11. Parish/Ward (CLUSTER CODE in Burkina) (Do not read out) - [01a11B]

1. [_] - [4001] Boborola
2. [_] - [4002] Kossara
3. [_] - [4003] Damana
4. [_] - [4004] Deguè-Deguè
5. [_] - [4005] Gouindougouba
6. [_] - [4006] Karfiguéla
7. [_] - [4007] Kirbina
8. [_] - [4008] Kotou
9. [_] - [4009] Kouéré
10. [_] - [4010] Laferma
11. [_] - [4011] Lémouroudougou
12. [_] - [4012] Lémouroudougou Cité
13. [_] - [4013] Létiéfésso
14. [_] - [4014] Nafona 1
15. [_] - [4015] Niamirandougou

16.[_] - [4016] Sikanadjô
17.[_] - [4017] Siniéna
18.[_] - [4018] Tangora
19.[_] - [4019] Tatana
20.[_] - [4020] Tiékouna
21.[_] - [4021] Tiempangoura
22.[_] - [4022] Zédougou
23.[_] - [4023] Gouin-Gouin
24.[_] - [4024] Noumousso

(Select only 1 - ONE!)

Page b (2): Screening Questions ----------

1. INITIAL SCREENING QUESTIONS

2. 1. Do you have any intention to move from your village/cell within the next year? - [01b01]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

3. 2. Where will you move to? - [01b02]

1. [_] - [1] Within the cluster/village
2. [_] - [2] Outside the cluster/village

(Select only 1 - ONE!)
INFO: If alternative 2 chosen, Rule EH: Discontinuation from SI - Say thank you and fill in form ‘reason for non-participation

4. 3. I can see / have understood / have been told that you are pregnant now, can you please tell me how many months you have been pregnant? If obviously given birth; ask when.

- [01b03]

1. [_] - [1] Seven or more than seven months pregnant; specify months _____ (Number)
2. [_] - [2] Less than seven months
3. [_] - [3] Have given birth

(Select only 1 - ONE!)

5. 4. Do you have any intention to breastfeed the baby you are expecting/or if obviously given birth, ask :do you breastfeed your baby? (U/B)
- [01b04]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: RULE EH: No ? Discontinuation from SI - Say thank you and fill in form ‘reason for non-participation’

6. 5. All inclusion criteria fulfilled:

1. Lives in the selected cluster
2. Is pregnant
3. Has no plans to move outside the cluster within 1 year
4. Intends to breastfeed (U, BF, Z) - [01b05B]

1. [_] - [1] Yes
2. [_] - [2] No, specify _____ (Text)

(Select only 1 - ONE!)
INFO: Rule EH: No ? Discontinuation from SI

7. 6. No exclusion criteria fulfilled: 2.Reduced ability to collaborate for psychological/mental reasons 3.Severely ill 4.Having given birth and the baby is > 1 one week old
See help text - [01b06B]

1. [_] - [1] Yes
2. [_] - [2] No, specify _____ (Text)

(Select only 1 - ONE!)
INFO: If given birth and the child is < 1 week old, exclude if:
1. Multiple birth
2. Severe malformation
3. Death of baby or mother

8. 7. If less than 7 months pregnant: Ask for permission to come back later, and note approximate date of revisit: - [01b07]
___/____/_____

9. 8. In case she has given birth less than 1 week ago note Birth Date of baby. - [01b08]
___/____/_____

10. PAPER CONSENT FORM EXPLAINED AND ACCEPTED: USI given
If not, ask for reason for non participation and note it down on the form “Reason for non-participation"

11. 9. Participant Id no/ Unique Subject Identifier (USI)

- [01b09]
_____

12. 10. Reason for non-participation - [01b10]
_____
INFO: RULE: Do separate form: Reason for non-participation on paper, copi, fill in separately

Page c (3): SECTION I: Mother's Characteristics

1. MOTHER'S CHARACTERISTICS

2. 1. How old are you?
1b. What is your date of birth? - [01c01]
_____

3. 2. Have you ever attended school? - [01c02]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: RULE: SKIP: If no, skip to q.4

4. 3. What is your highest level of education? - [01c03B]

1. [_] - [1] CP1 (Primary)
2. [_] - [2] CP2 (Primary)
3. [_] - [3] CE1 (Primary)
4. [_] - [4] CE2 (Primary)
5. [_] - [5] CM1 (Primary)
6. [_] - [6] CM2 (Primary)/Certificate
7. [_] - [7] 6 (Senior)
8. [_] - [8] 5 (Senior)
9. [_] - [9] 4 (Senior)
10. [_] - [10] 3 (Senior) /BEPC
11. [_] - [11] 2 (Senior)
12. [_] - [12] 1 (Senior)
13. [_] - [13] Terminal (Senior)/BAC
14. [_] - [14] Certificate: 1 Year
15. [_] - [15] Certificate: 2 Years
16. [_] - [16] Degree/Bachelor/Licence
17. [_] - [89] Education higher than bachelor/Licence
18. [_] - [99] Other, specify; give completed years _____ (Text)

(Select only 1 - ONE!)
INFO: Give completed level

5. 4. Do you have any vocational training or have you had any apprenticeship?

- [01c04]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

6. 5. Can you read? - [01c05]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

7. 6. Can you write? - [01c06]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

8. 7. How often do you read a newspaper/ have them read for you (those who cannot read)? - [01c07]

1. [_] - [1] Never
2. [_] - [2] Less than once a week
3. [_] - [3] Atleast once a week
4. [_] - [4] A few times a week

5. [_] - [5] Almost everyday

(Select only 1 - ONE!)

9. 8. How often do you listen to the radio? - [01c08]

1. [_] - [1] Never
2. [_] - [2] Less than once a week
3. [_] - [3] Atleast once a week
4. [_] - [4] A few times a week
5. [_] - [5] Almost everyday

(Select only 1 - ONE!)

10. 9. How often do you watch television?

- [01c09]

1. [_] - [1] Never
2. [_] - [2] Less than once a week
3. [_] - [3] Atleast once a week
4. [_] - [4] A few times a week
5. [_] - [5] Almost everyday

(Select only 1 - ONE!)

11. 10. Are you single, married, co-habiting, widowed, divorced or separated now?

- [01c10]

1. [_] - [1] Single
2. [_] - [2] Married
3. [_] - [3] Co-habiting
4. [_] - [4] Widowed
5. [_] - [5] Divorced/Separated

(Select only 1 - ONE!)
INFO: RULE/SKIP: If not married (alt.2) skip to q.15

12. 11. How did you get married?

- [01c11]

1. [_] - [1] Religious
2. [_] - [2] Civil
3. [_] - [3] Traditional

(Select only 1 - ONE!)

13. 12. Does your husband have any other wives? - [01c12]

1. [_] - [1] Yes
2. [_] - [2] No
3. [_] - [3] Don't Know

(Select only 1 - ONE!)
INFO: RULE/SKIP: If no(alt. 2) or do not know (alt. 3), skip to q.15

14. 13. How many? - [01c13]

_____

15. 14. Do you share the same compound? - [01c14]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

16. 15. What is your tribe? - [01c15B]

1. [_] - [1] Dioula
2. [_] - [2] Karaboro
3. [_] - [3] Gouin
4. [_] - [4] Toussian
5. [_] - [5] Dogossé
6. [_] - [6] Sénoufo
7. [_] - [7] Other, specify _____ (Text)

(Select only 1 - ONE!)

17. 16. What is your religion? - [01c16]

1. [_] - [1] Protestantism/National church
2. [_] - [2] Catholic
3. [_] - [3] Islam
4. [_] - [4] Hinduism
5. [_] - [5] Budhhism
6. [_] - [6] Judaism
7. [_] - [7] Adventist
8. [_] - [8] Jehova's Witness/Mormones
9. [_] - [9] Traditional believer
10. [_] - [10] Other, specify _____ (Text)

(Select only 1 - ONE!)
INFO: Protestantism=
Any national church or free church sharing the basic theological concepts with Protestantism as Anglicans/ Lutherans/ Calvinists/ Baptists/ Methodists/ Pentecostals/
Newer free churches etc.
SDA: Seventh Day Adventists

Page d (4), SECTION II: Pregnancy History

1. PREGNANCY HISTORY

2. 1. How many children have you given birth to?
(Exclude the one who is the study baby, who she might have delivered less than 1 week ago) - [01d01]

1. [_] - [1] Given birth to one or more, specify number ____ (Number)
2. [_] - [2] Never given birth

(Select only 1 - ONE!)
INFO: ALT 2: See skip instruction SIII and SVII if alternative 2 ticked off

3. Now I will ask you questions about the child you expect:
INFO: RULE: To be disabled and activated if question : 01b03 alternative 3 is ticked off

PROBE: If she does not know

4. 2. Can you please tell me when your last menstrual period started? (See help text for probing) - [01d02]
_____

5. 3. Do you have any card from the ante natal clinic (ANC-card)? - [01d03]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: SKIP: If no, skip to S III

6. 4. May I please see it? - [01d04]

1. [_] - [1B] Yes
2. [_] - [2B] No

(Select only 1 - ONE!)

7. 4.1. Note last menstrual period given in the card: (date) - [01d04a1]
___/____/_______

8. 4.2/3. Note estimated duration of pregnancy at a given date: - [01d04a3]

1. [_] - [01d04a3_1B] Note duration in months (HU) _____ (Number)
2. [_] - [01d04a3_2B] Given date _____ (Text)

9. 4.4. Note estimated date of delivery - [01d04a4]
___/____/_______

Page e (5), SECTION III: Breastfeeding experience and intentions

1. BREASTFEEDING EXPERIENCE AND INTENTIONS

2. Now I am going to ask you questions about the child(ren) you had before the one you are expecting now (if she has already given birth; before the last one you gave birth to less than one week ago).

3. 1. Did you ever breastfeed any of your children? - [01e01]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: SKIP: If No, skip to q. 3

4. 2. For how many months did you breastfeed your lastborn child? - [01e02]

1. [_] - [1] Months _____ (Number)
2. [_] - [2] Still breastfeeding

(Select only 1 - ONE!)

INFO: Probe till you get duration in whole months as exsact as possible
(<1 mo = 0)

5. 3. How old was your last born child when you, for the first time, introduced water or any other water/juice like liquid? - [01e03]

1. [_] - [1] Days _____ (Number)
2. [_] - [2] Weeks _____ (Number)
3. [_] - [3] Months _____ (Number)

(Select only 1 - ONE!)
INFO: RULE:
Write answer in days or weeks or months.
Probe till you get it as exact as possible

6. 4. How old was the last born child when you, for the first time, introduced animal milk, porridge or any feeds? - [01e04]

1. [_] - [1] Days _____ (Number)
2. [_] - [2] Weeks _____ (Number)
3. [_] - [3] Months _____ (Number)

(Select only 1 - ONE!)
INFO: RULE: Write answer in days or weeks or months Probe till you get it as exact as possible

7. Now I will ask you questions about the child you expect:

8. 5. How do you plan to feed your baby in the first month after birth? - [01e05]

1. [_] - [1] Breast Milk only
2. [_] - [2] Formula feed only
3. [_] - [3] Only give other liquids like cow's milk/water
4. [_] - [4] Breast feed and give other liquids
5. [_] - [5] Breastfeed and give other semisolid/solid feeds
6. [_] - [6] Others, specify _____ (Text)

(Select only 1 - ONE!)
INFO: RULE: Tick off all that apply
RULE: Probe if alt. 1 only
PROBE:
Is that all?/Anything else

9. 6. Have you ever had any problems with your breasts? - [01e06]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: SKIP: If no, skip to section IV SES, EH page f q. 1

10. 7. What was the problem? - [01e07]

1. [_] - [01e07_1] Engorgement
2. [_] - [01e07_2] Cracked nipples

3. [_] - [01e07_3] Inverted/flat nipples
4. [_] - [01e07_4] Abscess
5. [_] - [01e07_5] Infection
6. [_] - [01e07_6] Operation
7. [_] - [01e07_7] Trauma
8. [_] - [01e07_8] Others, specify _____ (Text)

11. 8. When was that? - [01e08]

1. [_] - [1] Months Ago _____ (Number)
2. [_] - [2] Years Ago _____ (Number)

(Select only 1 - ONE!)
INFO: RULE:
Write answer in months or years ago. Probe till you get it as exact as possible (< 1 mo=0)

12. 9. What did you do about the problem? - [01e09]

1. [_] - [01e09_1] Nothing
2. [_] - [01e09_2] Local medicine
3. [_] - [01e09_3] Modern medicine, describe _____ (Text)
4. [_] - [01e09_4] Operation
5. [_] - [01e09_5] Others, specify _____ (Text)

Page f (6), SECTION IV: Socio-Economic Status

1. SOCIAL ECONOMIC STATUS

2. 1. How many people normally live in your household? - [01f01]
_____

3. 2. How many of these are adults over 18 years? - [01f02]

1. [_] - [1] Some, specify number _____ (Number)
2. [_] - [2] None

(Select only 1 - ONE!)
INFO: SKIP: If 0, skip to 4

4. 3. How many of these adults over 18 years are women and how many are men? - [01f03]

1. [_] - [01f03_1] Women _____ (Number)
2. [_] - [01f03_2] Men _____ (Number)

5. 4. How many are children between 5 and 18 years? - [01f04]

1. [_] - [1] Some, specify number _____ (Number)
2. [_] - [2] There is none

(Select only 1 - ONE!)
INFO: SKIP: If 0, skip to 6

6. 5. How many of these children between 5 and 18 are girls and how many are boys? - [01f05]

1. [_] - [01f05_1] Girls _____ (Number)
2. [_] - [01f05_2] Boys _____ (Number)

7. 6. How many are children less than five years old? - [01f06]

1. [_] - [1] Some, specify number _____ (Number)
2. [_] - [2] None

(Select only 1 - ONE!)

8. 7. How many of these children less than 5 years are girls and how many are boys? - [01f07]

1. [_] - [01f07_1] Girls _____ (Number)
2. [_] - [01f07_2] Boys _____ (Number)

Page g (7), Socio-Economic Status conti'd

1. SOCIAL ECONOMIC STATUS CONT'D

2. I am now going to ask you about what you have in your household. Please answer yes if you have it and no if you do not have it. Sometimes, I'll ask you to specify how many you have of a certain subject. I am interested in the items which work.

3. 8. How many of the following items do you have in your household? - [01g08]

1. [_] - [01g08_1] Chairs/Stools _____ (Number)
2. [_] - [01g08_2] Foam Matresses _____ (Number)
3. [_] - [01g08_3] Lanterns _____ (Number)
INFO: RULE: Write correct number for all alt.s

4. 9. Do you have electricity in the house you are living? - [01g09]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

5. 10. Do you have any of the following in your household? - [01g10]

1. [_] - [01g10_1] Cupboard
2. [_] - [01g10_2] Bicycle
3. [_] - [01g10_3] Radio
4. [_] - [01g10_4] TV
5. [_] - [01g10_5] Mobile Phone/Telephone
6. [_] - [01g10_6] Gas Heater/Electric heater
7. [_] - [01g10_7] Refrigerator

8. [_] - [01g10_8] Motorcycle/scooter
9. [_] - [01g10_9] Car/truck
10. [_] - [01g10_10B] Cart
11. [_] - [01g10_11B] Plough
INFO: Help: Read the alternatives from the list item by item

6. 11. What is the fuel used for cooking in your household? - [01g11]

1. [_] - [01g11_1] Wood
2. [_] - [01g11_2] Charcoal
3. [_] - [01g11_3] Paraffin/kerosene
4. [_] - [01g11_4] Gas
5. [_] - [01g11_5] Electricity
6. [_] - [01g11_6] Others, specify _____ (Text)

7. 12. What is the source of drinking water in your household? - [01g12]

1. [_] - [01g12_1] Pond, river or stream
2. [_] - [01g12_2] Unprotected natural spring
3. [_] - [01g12_3] Protected natural spring
4. [_] - [01g12_4] Rain water
5. [_] - [01g12_5] Open or unprotected well
6. [_] - [01g12_6] Covered well
7. [_] - [01g12_7] Borehole
8. [_] - [01g12_8] Public tap
9. [_] - [01g12_9] Piped into yard/plot
10. [_] - [01g12_10] Piped into dwelling
11. [_] - [01g12_11] Bottled water
12. [_] - [01g12_12] Others, specify _____ (Text)

8. 13. What do you do to the water before drinking it? - [01g13]

1. [_] - [1] Nothing
2. [_] - [2] Boil it
3. [_] - [3] Other, specify _____ (Text)

(Select only 1 - ONE!)
INFO: Help: Do not read out the list. Note spontaneous answer

9. 14. Do you own or rent the house you live in? - [01g14]

1. [_] - [1] Own
2. [_] - [2] Rent
3. [_] - [3] Other, specify _____ (Text)

(Select only 1 - ONE!)

Page h (8), Socio-Economic status cont'd

1. SOCIAL ECONOMIC STATUS CONT'D

2. 15. Does someone in your household own land? - [01h15]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

3. 16. Do you grow crops on any land? - [01h16]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: SKIP: If no, skip to q. 22

4. 17. Approximately how big is it? (acres #.#)
(See help text) - [01h17]
_____

INFO: Help: Ask for size in acres, if it is less than one write the correct 0.x

5. 18. What are you growing? - [01h18]

1. [_] - [01h18_1] Maize

2. [_] - [01h18_2] Rice
3. [_] - [01h18_3] Matooke
4. [_] - [01h18_4] Sorghum/Millet
5. [_] - [01h18_5] Fruits
6. [_] - [01h18_6] Legumes
7. [_] - [01h18_7] Root Vegetables
8. [_] - [01h18_8] Cotton
9. [_] - [01h18_9] Tea
10. [_] - [01h18_10] Coffee
11. [_] - [01h18_11] Tobacco
12. [_] - [01h18_12] Other, specify _____ (Text)

6. 19. How much do you harvest of these crops per year? (Sacks, See help text) - [01h19]

1. [_] - [01h19_1B] Maize sacks _____ (Text)
2. [_] - [01h19_2] Rice sacks _____ (Number)
3. [_] - [01h19_3] Matooke bunches _____ (Number)
4. [_] - [01h19_4B] Sorghum/millet sacks _____ (Text)
5. [_] - [01h19_5B] Fruit carts _____ (Number)
6. [_] - [01h19_6] Legume sacks _____ (Number)
7. [_] - [01h19_7] Root vegetable sacks _____ (Number)
8. [_] - [01h19_8B] Cotton tonne (1 tonne= 1000 kg) _____ (Number)
9. [_] - [01h19_9] Tea sacks _____ (Number)
10. [_] - [01h19_10] Coffee sacks _____ (Number)
11. [_] - [01h19_11] Tobacco sacks _____ (Number)
12. [_] - [01h19_12] Other, specify _____ (Text)

INFO: RULE: If the answer is difficult for the mother, train the DC to probe for season and multiply the crops with number of seasons. Year is more precise as number of seasons varies across countries and is item specific.

7. 20. How much are you usually selling of your crops per year? (Answer in sacks; See help text) - [01h20]

1. [_] - [01h20_1B] Sacks of Maize _____ (Text)
2. [_] - [01h20_2] Sacks of Rice _____ (Number)
3. [_] - [01h20_3] Bunches of Matoke _____ (Number)
4. [_] - [01h20_4B] Sacks of sorghum/millet sacks _____ (Text)
5. [_] - [01h20_5] Fruit carts _____ (Number)
6. [_] - [01h20_6] Sacks of legumes _____ (Number)
7. [_] - [01h20_7] Sacks of root vegetables _____ (Number)
8. [_] - [01h20_8B] Cotton tonne (1 tonne= 1000 kg) _____ (Number)
9. [_] - [01h20_9] Sacks of tea _____ (Number)
10. [_] - [01h20_10] Sacks of coffee _____ (Number)
11. [_] - [01h20_11] Sacks of tobacco _____ (Number)
12. [_] - [01h20_12] Other, specify _____ (Text)
13. [_] - [01h20_13] Do not sell

INFO: Uganda: A sack is approximately 100 kg, and we allow for 5 buckets in 1 sack. One bucket is therefore 0.2 sack.

8. 21. How much do you usually consume of your crops per season? - [01h21]

1. [_] - [01h21_1B] Sacks of maize _____ (Text)
2. [_] - [01h21_2] Sacks of rice _____ (Number)
3. [_] - [01h21_3] Bunches of matooke _____ (Number)
4. [_] - [01h21_4B] Sacks of sorghum/millet _____ (Text)
5. [_] - [01h21_5] Fruit carts _____ (Number)
6. [_] - [01h21_6] Sacks of legumes _____ (Number)
7. [_] - [01h21_7] Sacks of root vegetables _____ (Number)

8. [_] - [01h21_8B] Cotton tonne (1 tonne= 1000 kg) _____ (Number)
9. [_] - [01h21_9] Sacks of tea _____ (Number)
10.[_] - [01h21_10] Sacks of coffee _____ (Number)
11.[_] - [01h21_11] Sacks of tobacco _____ (Number)
12.[_] - [01h21_12] Other, specify _____ (Text)
INFO: Uganda: A sack is approximately 100 kg, and we allow for 5 buckets in 1 sack. One bucket is therefore 0.2 sack.

9. 22. Do you own domestic animals or birds? - [01h22]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: SKIP: If no, skip to SV; EH page i q. 1

10. 23. How many animals do you have of the following?

- [01h23]

1. [_] - [01h23_1] Cows, traditional cattle _____ (Number)
2. [_] - [01h23_2] Cows, diary cattle _____ (Number)
3. [_] - [01h23_3] Oxen/bulls _____ (Number)
4. [_] - [01h23_4] Pigs _____ (Number)
5. [_] - [01h23_5] Goats _____ (Number)
6. [_] - [01h23_6] Sheep _____ (Number)
7. [_] - [01h23_7] Horses/donkeys/mules _____ (Number)
8. [_] - [01h23_8] Other, specify: _____ (Text)

INFO: RULE: Write correct number for all alternatives
(0 ? n)
Only write animals in alternative 8 which has an income generating potential
If she does not know probe for the nearest number in groups of 5

11. 24. Approximately how much fowl do you have?
(see help text)
- [01h24]

1. [_] - [1] 0
2. [_] - [2] 1 - 4
3. [_] - [3] 5 - 9
4. [_] - [4] 10 - 19
5. [_] - [5] 20 - 29
6. [_] - [6] >= 30

(Select only 1 - ONE!)
INFO: RULE: Chicken, turkeys, hens/cocks, ducks, geese (Do not count doves here. Count ostriches as other animals q. 23)

12. 25. Do you have any of these animals or birds on your compound? - [01h25]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

13. 26. Which animals do you have on your compound? - [01h26]

1. [_] - [01h26_1] Cows, traditional cattle
2. [_] - [01h26_2] Cows, diary cattle
3. [_] - [01h26_3] Oxen/bulls
4. [_] - [01h26_4] Pigs
5. [_] - [01h26_5] Goats
6. [_] - [01h26_6] Sheep
7. [_] - [01h26_7] Horses/donkeys/mules
8. [_] - [01h26_8] Fowl
9. [_] - [01h26_9] Other, specify _____ (Text)

14. 27. Do you have any of these animals or birds in your house? - [01h27]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

15. 28. Which animals do you have in your house? - [01h28]

1. [_] - [01h28_1] Cows, traditional cattle
2. [_] - [01h28_2] cows, diary cattle
3. [_] - [01h28_3] Oxen/bulls
4. [_] - [01h28_4] Pigs
5. [_] - [01h28_5] Goats
6. [_] - [01h28_6] Sheep
7. [_] - [01h28_7] Horses/donkeys/mules
8. [_] - [01h28_8] Fowl
9. [_] - [01h28_9] Other, specify _____ (Text)

Page i (9), SECTION V: Activities/Employment

1. ACTIVITIES / EMPLOYMENT

2. 1. Who is the head of the household? - [01i01]

1. [_] - [1] A woman
2. [_] - [2] A man
3. [_] - [3] Not applicable, specify _____ (Text)

(Select only 1 - ONE!)

3. 2. Who is the main provider of income in the household? - [01i02]

1. [_] - [1] Father of baby in the womb
2. [_] - [2] Yourself
3. [_] - [3] Older male relative
4. [_] - [4] Older female relative
5. [_] - [5] Other household member living at home
6. [_] - [6] Not applicable
7. [_] - [7] Other, specify who _____ (Text)

(Select only 1 - ONE!)
INFO: RULE: Tick off her answers in the right category, do not read the list, but probe from it

SKIP: If alternative 2, skip q. 5 and 6

4. 3. Is the "main provider of income" currently employed? - [01i03]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

5. 4. What are the main sources of income ‘the main providers’ has? - [01i04]

1. [_] - [01i04_1] Regular employment
2. [_] - [01i04_2] Irregular employment
3. [_] - [01i04_3] Home employment
4. [_] - [01i04_4] Contribution from others
5. [_] - [01i04_5] Retirement pension/grant
6. [_] - [01i04_6] Other state grant, specify _____ (Text)
7. [_] - [01i04_7] Relief programme
8. [_] - [01i04_8] No response
9. [_] - [01i04_9] Don't know
10. [_] - [01i04_10] Other, specify _____ (Text)

INFO: (Alt 3 = Any income generating activity performed at home)

RULE:
Tick off her answers in the right category, do not read the list, but probe from it

Home employment
Animals
Farming
Small business
And others work at home

6. 5. Do you earn money for yourself? - [01i05]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

INFO: Not to be asked when she is the main provider q. 1 alt 2
SKIP: If no, skip to q. 7

7. 6. How do you earn money for yourself?

- [01i06]

1. [_] - [01i06_1] Regular employment
2. [_] - [01i06_2] Irregular employment
3. [_] - [01i06_3] Home employment
4. [_] - [01i06_4] No response
5. [_] - [01i06_5] Do not know
6. [_] - [01i06_6] Other, specify _____ (Text)

INFO: (Alt 3 = Any income generating activity performed at home)

RULE: Tick off all that apply

8. 7. Does your household have any other sources of income? - [01i07]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: SKIP: If no, skip to 9

9. 8. What kind of sources is that? - [01i08]

1. [_] - [01i08_1] Regular employment
2. [_] - [01i08_2] Irregular employment
3. [_] - [01i08_3] Home employmet
4. [_] - [01i08_4] Contribution from others
5. [_] - [01i08_5] Retirement grant/pension
6. [_] - [01i08_6] Other state grant, specify _____ (Text)
7. [_] - [01i08_7] Relief programme
8. [_] - [01i08_8] No response
9. [_] - [01i08_9] Do not know
10. [_] - [01i08_10] Other, specify _____ (Text)

10. 9. Do you work on land? - [01i09]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: SKIP: If no, skip to 11
ADRESSED TO THE MOTHER

11. 10. Is the land you work on your own land or rented land? - [01i10]

1. [_] - [1] Own land
2. [_] - [2] Rented Land
3. [_] - [3] Other, specify _____ (Text)

(Select only 1 - ONE!)
INFO: ADRESSED TO THE MOTHER
Your own land refers to the hh’s land.

12. 11. Do you work in a small or large business? - [01i11]

1. [_] - [1] Large
2. [_] - [2] Small
3. [_] - [3] Do not work in a business

(Select only 1 - ONE!)
INFO: SKIP: If alt. 3 ticked off, skip to 13
ADRESSED TO THE MOTHER

13. 12. Do you work in your own business, family business or someone else’s business?

- [01i12]

1. [_] - [01i12_1] Own business
2. [_] - [01i12_2] Family business
3. [_] - [01i12_3] Someone else's business
4. [_] - [01i12_4] Does not apply
5. [_] - [01i12_5] Other, specify _____ (Text)

INFO: ADRESSED TO THE MOTHER

14. 13. What is your monthly salary?
(adressed to the mother) - [01i13U]

1. [_] - [1] Burkina Faso: BFx _____ (Number)
2. [_] - [2] Uganda: UGx _____ (Number)
3. [_] - [3] Zambia: ZAx _____ (Number)
4. [_] - [4] South Africa: SAx _____ (Number)

(Select only 1 - ONE!)

15. 14. How much of your monthly earnings are you spending on yourself only? - [01i14]

1. [_] - [1] UGx _____ (Number)
2. [_] - [2] BFx _____ (Number)
3. [_] - [3] ZAx _____ (Number)
4. [_] - [4] SAx _____ (Number)

(Select only 1 - ONE!)
INFO: ADRESSED TO THE MOTHER

16. 15. Do you usually work throughout the year, or do you work seasonally, or only once in a while or does it not apply to you? - [01i15]

1. [_] - [1] Throughout the year
2. [_] - [2] Seasonally
3. [_] - [3] Once in a while
4. [_] - [4] Does not apply
5. [_] - [5] Other, specify _____ (Text)

(Select only 1 - ONE!)

17. 16. How much does your household spend a normal month on the following items?
- [01i16]

1. [_] - [01i16_1] Feeding _____ (Number)
2. [_] - [01i16_2] Housing _____ (Number)
3. [_] - [01i16_3] Schooling _____ (Number)
4. [_] - [01i16_4] Clothing _____ (Number)
5. [_] - [01i16_5] Water and drainage _____ (Number)
6. [_] - [01i16_6] Electricity _____ (Number)
7. [_] - [01i16_7] Rent of land _____ (Number)
8. [_] - [01i16_8] Modern medicine _____ (Number)
9. [_] - [01i16_9] Traditional medicine _____ (Number)
10. [_] - [01i16_10] Social activities _____ (Number)
11. [_] - [01i16_11] Other, specify _____ (Text)

INFO: Alt 1: Write the estimated amount from 0 and upward

Rule: Do not ask about electricity to hh without electricity

Probe for baptisms, weddings, funerals/burials and specify that under social, specify. Also ask for other expenses

Page j (10), SECTION VI: Questions on use of Clinical/Medical services

1. QUESTIONS ABOUT USE OF CLINICAL / MEDICAL SERVICES

2. 1. Have you attended any sessions at the antenatal care clinic (ANC)? - [01j01]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: SKIP: If no skip to q. 3

3. 2. How many times have you been there in this pregnancy? - [01j02]
_____

4. 3. Do you use a bed net for yourself? - [01j03]

1. [_] - [1] Yes
2. [_] - [2] No
3. [_] - [3] Sometimes

(Select only 1 - ONE!)

5. 4. Have you been informed about the HIV voluntary counselling and testing (VCT) service? - [01j04]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: SKIP: If no skip to q. 9

6. 5. Have you been counselled on HIV? - [01j05]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: SKIP: If no skip to q. 9

7. 6. Have you been tested for HIV? - [01j06]

1. [_] - [1] Yes
2. [_] - [2] No
3. [_] - [3] Don't Know

(Select only 1 - ONE!)

8. 7. Are you willing to tell me the result of your HIV-test? - [01j07]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: SKIP: If no skip to q. 9

9. 8. What was the result? - [01j08]

1. [_] - [1] Negative
2. [_] - [2] Positive
3. [_] - [3] Don't know

(Select only 1 - ONE!)

10. 9. If you were given the chance, are you willing to go for voluntary counselling and testing - [01j09]

1. [_] - [1] Yes
2. [_] - [2] No
3. [_] - [3B] Non response

(Select only 1 - ONE!)

Page k (11), SECTION VII: Previous child mortality

1. PREVIOUS CHILD MORTALITY

2. 1. Has any of your children who were born alive died? - [01k01]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: SKIP: If no, skip to SVIII; EH page l

3. 2. How many of your children have died? - [01k02]

1. [_] - [1] One child has died
2. [_] - [2] More than one child have died, specify number _____ (Number)

(Select only 1 - ONE!)
INFO: If alternative 1 given, disable q. 5

4. 3. May I ask how old your lastborn: (if more than 1 child death) child was when he/she died? - [01k03]

1. [_] - [01k03_1] Days _____ (Number)
2. [_] - [01k03_2] Weeks _____ (Number)
3. [_] - [01k03_3] Months _____ (Number)
4. [_] - [01k03_4] Years _____ (Number)

INFO: If she does not remember:
PROBE and fill in right cat below

Rule: Lastborn refers to the one “before the one she is carrying”/gave birth to = 1wk ago who might have died

5. 4. PROBE only if no answer in question 3:
PROBE: Was he/she less than one month, between one month and one year or between one year and 5 years:
 - [01k04]

1. [_] - [1] Less than one month
2. [_] - [2] Greater than/equal to one month and less than one year
3. [_] - [3] Greater than/equal to one year and less than five years
4. [_] - [4] Greater than/equal to five years

(Select only 1 - ONE!)
INFO: Disable this one if q. 3 answered

6. 5. IF more than 1 child deaths:
Note right age category according to PROBING above. See help text. - [01k05]

1. [_] - [01k05_1] Child 2 _____ (Number)
2. [_] - [01k05_2] Child 3 _____ (Number)
3. [_] - [01k05_3] Child 4 _____ (Number)
4. [_] - [01k05_4B] Equal or greater than 5 child deaths, Comment _____ (Text)

INFO: Age categories used:
1. [_] Less than one month
2. [_] Greater than or equal to one month and less than one year
3. [_] Greater than or equal to one year and less than five years
4. [_] Greater than or equal to five years

7. 6. What was the main sickness or reason which led to death for the child(ren) you have lost? - [01k06]

1. [_] - [01k06_1] Child 1 _____ (Text)
2. [_] - [01k06_2] Child 2 _____ (Text)
3. [_] - [01k06_3] Child 3 _____ (Text)
4. [_] - [01k06_4] Child 4 _____ (Text)
5. [_] - [01k06_5] Child 5 _____ (Text)
6. [_] - [01k06_6] More than 5, comment _____ (Text)

Page l (12), SECTION VIII: Mother's house and sorroundings

1. MOTHER'S HOUSE AND SORROUNDINGS

2. Thank you, now I am going to ask you some questions about your house and it’s surroundings.

3. 1. How many rooms do you have in your household which are used for sleeping? (If it's a single room, do not ask, capture that and go on) - [01l01]

_____

4. 2. Do you have a toilet/latrine? - [01l02U]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: SKIP: If no, skip to q. 5

5. 3. What type of latrine is it ? B - [01l03B]

1. [_] - [1] Nothing
2. [_] - [2] Open pit
3. [_] - [3] Pit latrine
4. [_] - [4] VIP latrine
5. [_] - [5] Flush toilette
6. [_] - [6] Other, specify _____ (Text)

(Select only 1 - ONE!)

6. 4. Do you share this/your toilet with any neighbouring households? - [01l04]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

7. 5. Where do you wash your hands? (If within reach/existing): May I please see it? - [01l05]

1. [_] - [1] Not within reach
2. [_] - [2] Insufficient water supply, no soap
3. [_] - [3] Sufficient water supply, no soap
4. [_] - [4] Sufficient water supply and soap

(Select only 1 - ONE!)
INFO: Tick off for the type of washing equipment or lack of washing equipment you see

Not within reach=she normally never wash hands because of the distance after a visit to the toilet

Page m (13), Observations

1. OBSERVATIONS

2. 6. Main material of the floor: - [01m6]

1. [_] - [1] Earth/Dung
2. [_] - [2] Cement
3. [_] - [3] Tiles
4. [_] - [4] Rudementary wooden
5. [_] - [5] Finished wooden
6. [_] - [6] Carpet/Vinyl
7. [_] - [7] Other, specify _____ (Text)

(Select only 1 - ONE!)
INFO: Tick off 1 alternative only

(Choose alternative which makes up > half of the floor)

3. 7. Main material of the roof:

- [01m07]

1. [_] - [1] Grass thatched
2. [_] - [2] Iron sheets
3. [_] - [3] Tiles
4. [_] - [4] Concrete
5. [_] - [5] Wood
6. [_] - [6] Other, specify _____ (Text)

(Select only 1 - ONE!)
INFO: Tick off 1 alternative only

(Choose alternative which makes up > half of the roof)

4. 8. Main material of the walls:

- [01m08]

1. [_] - [1] Mud and pole
2. [_] - [2] Wood
3. [_] - [3] Tin
4. [_] - [4] Bricks without mortar

5. [_] - [5] Burnt brick with mortar
6. [_] - [6] Plastered walls
7. [_] - [7] Other, specify

(Select only 1 - ONE!)
INFO: Tick off 1 alternative only

(Choose alternative which makes up > half of the walls)

5. 9. Status of toilet: - [01m09]

1. [_] - [1] Visible faeces
2. [_] - [2] No visible faeces

(Select only 1 - ONE!)
INFO: Tick off 1 alternative only

6. 10. Status of compound: - [01m10]

1. [_] - [1] Littered
2. [_] - [2] Not littered
3. [_] - [3] Animal faeces on the ground
4. [_] - [4] Human faeces on the ground

(Select only 1 - ONE!)
INFO: Tick off all that apply

7. 11. Main material of windows:

- [01m11]

1. [_] - [1] No material
2. [_] - [2] Wood
3. [_] - [3] Glass
4. [_] - [4] Other, specify _____ (Text)

(Select only 1 - ONE!)

8. 12. Main material of doors: - [01m12]

1. [_] - [1] No doors
2. [_] - [2] Only outer doors
3. [_] - [3] Outer and inner doors
4. [_] - [4] Other, specify _____ (Text)

(Select only 1 - ONE!)

9. 13.The data collector ticks off the type of house the mother lives in:
- [01m13]

1. [_] - [1] Shack
2. [_] - [2] Traditional hut
3. [_] - [3] Semi-permanent house
4. [_] - [4] Permanent house
5. [_] - [5] Other, specify

(Select only 1 - ONE!)
INFO: Tick off 1 alternative only

10. 14. Comments: (Optional) - [01m14]
_____

11. READ OUT LOUD: Thank you very much for your help! This is a great help for us!
Be free to thank/greet in local language to round off nicely!

FORM: Day 7 Interview/W3 - (ID: 136)

3 Week, Page a (1), SECTION 0: Introduction

1. INTRODUCTION

2. 1. Country/Site - [03a01]

1. [_] - [40] Burkina Faso
2. [_] - [51] Uganda: Mbale Municipality
3. [_] - [52] Uganda: Bungokho
4. [_] - [61] Zambia: Site 1
5. [_] - [62] Zambia: Site 2
6. [_] - [71] SA Paarl
7. [_] - [72] SA Rietveli
8. [_] - [73] SA Umlazi

(Select only 1 - ONE!)

3. 2. Interviewer - [03a02U]

1. [_] - [DONA] DAJO
2. [_] - [EVNA] COMA
3. [_] - [HEMU] SOSE
4. [_] - [MAKI] TRDA
5. [_] - [RANA] TOED
6. [_] - [8] Other, specify _____ (Text)

(Select only 1 - ONE!)

4. 3. Date: - [03a03]
___/____/_______

5. 4. Time: - [03a04]
H:____M:____ S:____

6. 5. GPS (Optional) - [03a05]

1. [_] - [03a05_1] Longitude _____ (Text)
2. [_] - [03a05_2] Latitude _____ (Text)
3. [_] - [03a05_3] Altitude _____ (Text)

7. 6. Participant Id no/ Unique Subject Identifier (USI)

- [03a06]
_____

INFO: 4 digit code starting at 1001 all sites; must be given from office before each visit

8. 7. The mother has moved after the recruitment interview - [03a07]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

9. 8. The mother has moved outside the cluster borders? - [03a08]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

10. 9. The mother has moved to another study cluster? - [03a09]

1. [_] - [1] Yes, specify where to _____ (Text)
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: If Yes, specify where

11. 10. Sub-County/Division/Department:
(Do not read out) - [03a10B]

1. [_] - [4001] Banfora
2. [_] - [4002] Sidéradougou
3. [_] - [4003] Soubakaniendougou

(Select only 1 - ONE!)

12. 11. Parish/Ward (CLUSTER CODE in Burkina)
(Do not read out) - [03a11B]

1. [_] - [4001] Boborola
2. [_] - [4002] Kossara
3. [_] - [4003] Damana
4. [_] - [4004] Deguè-Deguè
5. [_] - [4005] Gouindougouba
6. [_] - [4006] Karfiguéla
7. [_] - [4007] Kirbina
8. [_] - [4008] Kotou
9. [_] - [4009] Kouéré
10. [_] - [4010] Laferma
11. [_] - [4011] Lémouroudougou
12. [_] - [4012] Lémouroudougou Cité
13. [_] - [4013] Létiéfésso
14. [_] - [4014] Nafona 1
15. [_] - [4015] Niamirandougou
16. [_] - [4016] Sikanadjô
17. [_] - [4017] Siniéna
18. [_] - [4018] Tangora
19. [_] - [4019] Tatana
20. [_] - [4020] Tiékouna
21. [_] - [4021] Tiempangoura
22. [_] - [4022] Zédougou
23. [_] - [4023] Gouin-Gouin
24. [_] - [4024] Noumousso

(Select only 1 - ONE!)

Page b (2), Initial Screening questions about the mother - infant pair ---
---

1. INITIAL SCREENING QUESTIONS ABOUT THE INFANT- MOTHER PAIR

2. 1. She is the mother of the baby - [03b01]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

3. 2. It was a single birth - [03b02]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

4. 3. Severe malformation - [03b03]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

5. 4. The baby is dead - [03b04]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: ADMINISTER INFANT VERBAL AUTOPSY FORM
(SEPARATE DOCUMENT

6. 5. The mother is dead - [03b05]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: ADMINISTER MATERNAL VERBAL AUTOPSY FORM
(SEPARATE DOCUMENT

7. 6. The mother is away for other reasons - [03b06]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: ADMINISER MISSED VISIT/LOSS/TERMINATION FORM (SEPARATE DOCUMENT)

8. 7. Planned revisit - [03b07]
___/____/_______

Page c (3), SECTION I: Questions about the baby ----------
---

1. QUESTIONS ABOUT THE BABY

2. 1. What is your baby’s birth date? - [03c01]
_____

3. 2. Do you have a Child Health Card or any other health card or book for your baby? - [03c02U]

1. [_] - [Opt_1] Yes
2. [_] - [Opt_2] No

(Select only 1 - ONE!)

4. 3. May I please see it - [03c03]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

5. 4. Write down birth date written in the card: (Do not read out:) - [03c04]

___/____/_______

6. 5. Was the child weighed at birth? - [03c05]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

7. 6. What was the birth weight?

- [03c06]

1. [_] - [1] Mother's answer _____ (Number)
2. [_] - [2] Don't remember

(Select only 1 - ONE!)

8. 7. Birth weight written in the health card: (Do not read out:) - [03c07]

1. [_] - [1] Birth weight on the card _____ (Number)
2. [_] - [2] Weight not indicated on the card

(Select only 1 - ONE!)

9. 8. What is the name of your child - [name]

_____

10. 9. Is ${name}$ a girl or a boy? - [03c09]

1. [_] - [1] Girl
2. [_] - [2] Boy

(Select only 1 - ONE!)

11. 10. Where did the birth take place? - [03c10]

1. [_] - [1] At home
2. [_] - [2] Traditional birth attendant's place
3. [_] - [3] At the local maternity
4. [_] - [4] At the clinic
5. [_] - [5] At the hospital
6. [_] - [6] On the way to a health facility
7. [_] - [7] Other, specify _____ (Text)

(Select only 1 - ONE!)

12. 11. Who assited you? - [03c11]

1. [_] - [03c11_1] None
2. [_] - [03c11_2] Traditional birth attendant
3. [_] - [03c11_3] A Nurse/midwife
4. [_] - [03c11_4] Doctor/clinical officer
5. [_] - [03c11_5] Any other health personnel other than a nurse or doctor
6. [_] - [03c11_6] Friends/family
7. [_] - [03c11_7] Other, specify _____ (Text)

13. 12. What kind of birth did you have?
Was it normal, c-section (caesarean) a breech or something else?
- [03c12]

1. [_] - [1] Normal vaginal
2. [_] - [2] Caesarean section
3. [_] - [3] Breech
4. [_] - [4] Other, specify _____ (Text)

(Select only 1 - ONE!)

14. 13. Were there any problems during the birth? - [03c13]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

15. 14. What kind of problem was that? - [03c14]

1. [_] - [03c14_1] Needed technical assistance to get the baby out
2. [_] - [03c14_2] Had problems delivering the placenta
3. [_] - [03c14_3] Abnormal bleeding
4. [_] - [03c14_4] Needed abrupt caesarean section
5. [_] - [03c14_5] Other, specify _____ (Text)

16. 15. During your pregnancy, did you ever discuss with anyone at the antenatal clinic the best way for you to feed your baby? - [03c15]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

Page d (4), SECTION II: Initiation of Breast Feeding

1. INITIATION OF BREASTFEEDING

2. 1. Have you ever given breast milk to ${name}$? - [03d01]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

3. 2. When did you put the baby to the breast after birth? - [03d02]

1. [_] - [1] Within the first hour
2. [_] - [2] After the 1st hour up to 12 hours
3. [_] - [3] After 12 hours and up to 24 hours

4. [_] - [4] After 24 hours and up to 48hours (2nd day)
5. [_] - [5] After 48 hours and up to 72 hours (3rd day)
6. [_] - [6] After 72 hours (After the 3rd day)

(Select only 1 - ONE!)

4. 3. Did you give the first milk to the baby or did you express and discard it? - [03d03]

1. [_] - [1] Gave the first milk
2. [_] - [2] Expressed and discarded the first milk
3. [_] - [3] Borh gave and expressed it
4. [_] - [4] Other, specify _____ (Text)

(Select only 1 - ONE!)

5. 4. Within the first three days after birth, was ${name}$ given anything to drink other than breast milk? (Many mouthfuls) - [03d04]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

6. 5. Within the first days did the baby get anything to taste; a few drops of something or less than a mouthfull? - [03d05]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

7. 6. What was the child given to drink whitin the first 3 days after birht?[03d06]

1. [_] - [03d06_1] Water
2. [_] - [03d06_2] Water with sugar or glucose
3. [_] - [03d06_3] Water with salt
4. [_] - [03d06_4] Diluted cow's milk
5. [_] - [03d06_5] Undiluted cow's milk
6. [_] - [03d06_6] Infant formula
7. [_] - [03d06_7] Any other powdered milk
8. [_] - [03d06_8] Any porridge
9. [_] - [03d06_9] Any soup, specify _____ (Text)
10. [_] - [03d06_10] Any liquid as part of a ritual
11. [_] - [03d06_11] Alcohol
12. [_] - [03d06_12] Traditional medicine
13. [_] - [03d06_13] Non-prescribed medicine, specify_____ (Text)
14. [_] - [03d06_14] Prescribed medicine, specify _____ (Text)
15. [_] - [03d06_15] Honey
16. [_] - [03d06_16] Other, specify _____ (Text)

8. 7. What was the child given to taste? - [03d07]

1. [_] - [03d07_1] Water
2. [_] - [03d07_2] Water with sugar or glucose
3. [_] - [03d07_3] Water with salt
4. [_] - [03d07_4] Diluted cow's milk
5. [_] - [03d07_5] Undiluted cow's milk
6. [_] - [03d07_6] Infant formula
7. [_] - [03d07_7] Any other powdered milk

8. [_] - [03d07_8] Any porridge
9. [_] - [03d07_9] Any soup, specify _____ (Text)
10.[_] - [03d07_10] Any liquid as part of a ritual
11.[_] - [03d07_11] Alcohol
12.[_] - [03d07_12] Traditional medicine
13.[_] - [03d07_13] Non prescribed medicine, specify _____ (Text)
14.[_] - [03d07_14] Prescribed medicine, specify _____ (Text)
15.[_] - [03d07_15] Honey
16.[_] - [03d07_16] Other, specify _____ (Text)

Page e (5), SECTION III: Infant Feeding Recalls and questions on mother's health

1. INFANT FEEDING RECALLS AND QUESTIONS ON MOTHER'S HEALTH

2. 1. Do you still breastfeed ${name}$? - [03e01]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

3. 2. Did you ever breastfed your child? - [03e02]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

4. 3. For how long did you breastfeed your child? - [03e03]

1. [_] - [1] Weeks _____ (Number)
2. [_] - [2] Don't know

(Select only 1 - ONE!)

5. 4. What were your reasons for stopping to breastfeed/not breastfeed your child?

- [03e04]

1. [_] - [03e04_1] Work
2. [_] - [03e04_2] Education
3. [_] - [03e04_3] Illness, other than lactation problems
4. [_] - [03e04_4] Lactation problems
5. [_] - [03e04_5] Child not grow grow well
6. [_] - [03e04_6] Child crying a lot
7. [_] - [03e04_7] Not enough breast milk
8. [_] - [03e04_8] No answer
9. [_] - [03e04_9] Advice /pressure from others
10.[_] - [03e04_10] Other, specify _____ (Text)

6. 5. Have you ever had any problem with your breast since your child was born? - [03e05]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

7. 6. What did you have? - [03e06]

1. [_] - [03e06_1] Engorgement
2. [_] - [03e06_2] Cracked nipples
3. [_] - [03e06_3] Abcess
4. [_] - [03e06_4] Infection
5. [_] - [03e06_5] Operation
6. [_] - [03e06_6] Trauma
7. [_] - [03e06_7] Other, specify _____ (Text)

8. 7. How old was your baby when this occurred? (Report in full weeks) - [03e07]

_____

INFO: < 1 week = 0
Report in full week

9. I am now going to ask you questions about what you fed your baby from the time you woke up yesterday morning till you woke up this morning.

10. 8. From the time you woke up yesterday morning till you woke up this morning did you breastfeed your baby? - [03e08]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

11. 9. From the time you woke up yesterday morning till you went to bed last night, how many times did you breastfeed? - [03e09]

_____

12. 10. From time you went to bed last night till you woke up this morning, how many times did you breastfeed? - [03e10]

_____

13. 11. From the time you woke up yesterday morning till you woke up this morning:
Did you give any of the following items to the child? And if you did, will you please tell how many times you gave it? Did you give any:
- [03e11]

1. [_]Yes [_]No Water _____ (Number)
2. [_]Yes [_]No Water with sugar or glucose _____ (Number)
3. [_]Yes [_]No Fruit juice _____ (Number)
4. [_]Yes [_]No Herbs _____ (Number)
5. [_]Yes [_]No Tea without milk _____ (Number)
6. [_]Yes [_]No Tea with milk _____ (Number)
7. [_]Yes [_]No Rice water _____ (Number)
8. [_]Yes [_]No Diluted cow's milk _____ (Number)
9. [_]Yes [_]No Undiluted cow's milk _____ (Number)
10. [_]Yes [_]No Infant formula _____ (Number)
11. [_]Yes [_]No Other powdered milk _____ (Number)
12. [_]Yes [_]No Dairy product like yoghurt, cream, sour milk Number
13. [_]Yes [_]No Goat's milk _____ (Number)
14. [_]Yes [_]No Cereals, porridge, bread, fermented porridge Number
15. [_]Yes [_]No Fruits / vegetables _____ (Number)
16. [_]Yes [_]No Meat _____ (Number)
17. [_]Yes [_]No Fish _____ (Number)
18. [_]Yes [_]No Eggs _____ (Number)

19.[_]Yes [_]No Gripe water _____ (Number)
20.[_]Yes [_]No Non-prescribed medicine, specify_____ (Text)
21.[_]Yes [_]No Prescribed medicine, specify _____ (Text)
22.[_]Yes [_]No Alcohol like beer or brew _____ (Number)
23.[_]Yes [_]No Other, specify _____ (Text)

14. 12. Thinking one week back, have you breastfed your baby? - [03e12]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

15. 13. Now I am going to ask you if you ever have given the following to your baby and if you have done that, please tell us when you did that for the first time: - [03e13]

1. [_]Yes [_]No Water _____ (Number)
2. [_]Yes [_]No Water with sugar or glucose _____ (Number)
3. [_]Yes [_]No Fruit juice _____ (Number)
4. [_]Yes [_]No Herbs _____ (Number)
5. [_]Yes [_]No Tea without milk _____ (Number)
6. [_]Yes [_]No Tea with milk _____ (Number)
7. [_]Yes [_]No Rice water _____ (Number)
8. [_]Yes [_]No Diluted cow's milk _____ (Number)
9. [_]Yes [_]No Undiluted cow's milk _____ (Number)
10.[_]Yes [_]No Infant formula _____ (Number)
11.[_]Yes [_]No Other powdered milk _____ (Number)
12.[_]Yes [_]No Diary product like yoghurt, cream, sour cream Nber
13.[_]Yes [_]No Goat's milk _____ (Number)
14.[_]Yes [_]No Cereals, porridge, bread or fermented porridge Nber
15.[_]Yes [_]No Fruits/vegetables _____ (Number)
16.[_]Yes [_]No Meat _____ (Number)
17.[_]Yes [_]No Fish _____ (Number)
18.[_]Yes [_]No Eggs _____ (Number)
19.[_]Yes [_]No Gripe water _____ (Number)
20.[_]Yes [_]No Non-prescribed medicine, specify _____ (Text)
21.[_]Yes [_]No Prescribed medicine, specify _____ (Text)
22.[_]Yes [_]No Alcohol like beer or local brew ____ (Number)
23.[_]Yes [_]No Other, specify _____ (Text)

Page f (6), SECTION IV: Questions about leaving the child
1. QUESTIONS ABOUT LEAVING THE CHILD

2. 1. Have you ever left your child since childbirth so that someone else has fed the child? - [03f01U/B]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

3. 2. What did the one taking care of your child feed last time? - [03f02]

1. [_] - [03f02_1] Water-based liquids
2. [_] - [03f02_2] Milk-based liquids/semi-solid feeds
3. [_] - [03f02_3] Expressed breast milk from the mother
4. [_] - [03f02_4] Expressed breast milk from another woman
5. [_] - [03f02_5] Don't know
6. [_] - [03f02_6] Other, specify _____ (Text)

4. 3. How often did it happen the last week that you had someone else to feed the child? - [03f03]

_____

5. 4. How many times do you usually leave your baby per week? - [03f04]

_____

Page g (7), SECTION V: Bed Net, Vaccination and Micronutrients
1. Now I am going to ask you questions which are related to your baby’s health:

2. 1. Does ${name}$ sleep in your bed? - [03g01]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

3. 2. Is ${name}$ covered by a bednet at night? (Both a separate net for the baby and a shared net with the mother qualify for a "yes")

- [03g02]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

4. 3. Has ${name}$ got any vaccinations? (Mother's answer)
- [03g03]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: Probe for both injections and mouth drops

5. 4. Has ${name}$ got the BCG Vaccine? (Mother's answer)

- [03g04U/B]

1. [_] - [1] Yes
2. [_] - [2] No
3. [_] - [3] Don't Know

(Select only 1 - ONE!)
INFO: Given right upper arm (country specific)

6. 5. Has ${name}$ got the Polio Vaccine?, (The first one) (Mother's answer)
- [03g05U/B]

1. [_] - [1] Yes
2. [_] - [2] No
3. [_] - [3] Don't Know

(Select only 1 - ONE!)
INFO: Given as mouth drops

7. 6. Do not read out loudly: Ask again to look at the child's card: Note down vaccinations given which are stated in the child health card: - [03g06U/B]

1. [_]Yes [_]No BCG ____/____/_______ (day/month/year)
2. [_]Yes [_]No Polio 0 ____/____/_______ (day/month/year)

8. 7. Now I will ask some questions about yourself: Since you gave birth, have you taken any of these Vit A supplements? (Show the different types of Vit A commonly taken) - [03g07]

1. [_] - [1] Yes
2. [_] - [2] No
3. [_] - [3] Don't Know

(Select only 1 - ONE!)
INFO: Rule: DC show the different types of vitamin A capsules that commonly are used

9. 8. When you were pregnant did you take any of these Iron tablets? (Show the different types of Iron Tablets commonly taken by pregnant women) - [03g08]

1. [_] - [1] Yes, She has identified that she took one or several of the Iron tablets
2. [_] - [2] No, She confirmed that She didn't take any of the Iron tablets
3. [_] - [3] She is not sure whether she took any of the Iron tablets

(Select only 1 - ONE!)
INFO: Data collectors need to have a set of the most common iron tablets available so they can compare with those the woman show

10. 9. How many Iron Tablets did you take during the whole pregnancy? - [03g09]

1. [_] - [1] 1 - 10
2. [_] - [2] 11- 30
3. [_] - [3] More than 30
4. [_] - [4] Don't remember

(Select only 1 - ONE!)

11. 10. Did you take any other tablets containing iron during your pregnancy?, If so can you please show them to me. (Compare with the samples at hand)

- [03g10]

1. [_] - [1] No, did not take any other iron tablets
2. [_] - [2] Yes, and she showed tablets that contains iron
3. [_] - [3] Said yes and showed tablets with unclear content or without iron
4. [_] - [4] Said yes, but did not have any tablets to show

(Select only 1 - ONE!)

Page h (8), SECTION VI: Morbidity

1. DIARRHOEA 24-HOUR RECALL

2. 1. From yesterday morning till this morning, did ${name}$ have diarrhoea? - [03h01]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: Diarrhoea = loose or watery stools (1 to n times)

3. 2. Did ${name}$ pass any watery stools? - [03h02]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: Watery stools= stools with no formed matter whatsoever

4. 3. How many times did ${name}$ pass loose or watery stools? - [03h03]
_____

5. 4. Did any of the stools contain blood? - [03h04]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

6. 5. Were the stools of different consistency than before ${name}$ fell ill with diarrhoea? - [03h05]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

7. 6. Did the illness interfere with ${name}$’s ability to drink or eat? - [03h06]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

8. 7. Did you seek treatment for ${name}$? - [03h07]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

9. 8. Where did you go? - [03h08]

1. [_] - [03h08_1] Relatives and friends
2. [_] - [03h08_2] Traditional healer
3. [_] - [03h08_3] Drug shop/pharmacy
4. [_] - [03h08_4] Government or private clinic/community health centre including general practioner/surgery
5. [_] - [03h08_5] Emergency/outpatint departmet of a hospital
6. [_] - [03h08_6] Other, specify _____ (Text)

10. 9. Was the child admitted to a hospital? - [03h09]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

11. 10. Please give name of hospital? - [03h10B]

1. [_] - [1] Mbale main hospital _____ (Text)
2. [_] - [2] Bududa Hospital _____ (Text)
3. [_] - [3] Busiu
4. [_] - [4] Bushacori
5. [_] - [5] Other, specify _____ (Text)

(Select only 1 - ONE!)

12. 11. Was this the nearest health unit? - [03h11]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

13. 12. Why did you go there? - [03h12]

1. [_] - [03h12_1] Health services better than at the nearest health unit
2. [_] - [03h12_2] Transport was available
3. [_] - [03h12_3] The nearest health unit is more expensive than the one I went to
4. [_] - [03h12_4] I wanted to go to the biggest hospital I can afford
5. [_] - [03h12_5] I do not trust the people at the nearest health unit
6. [_] - [03h12_6] Other, specify _____ (Text)

Page i (9), SECTION VI Cont'd

1. DIARRHOEA 2-WEEK RECALL

2. 1. During the last two weeks that ended yesterday morning, did ${name}$ have diarrhoea? - [03i01]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: Diarrhoea = loose or watery stools (1 to n times

3. 2. Did ${name}$ pass any watery stools? - [03i02]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)
INFO: Watery stools= stools with no formed matter whatsoever

4. 3. The day ${name}$ had most loose or watery stools, how many times did ${name}$ pass loose or watery stools? - [03i03]

_____

5. 4. Did any of the stools contain blood? - [03i04]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

6. 5. Were the stools of different consistency than before ${name}$ fell ill with diarrhoea? - [03i05]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

7. 6. Did the illness interfere with ${name}$’s ability to drink or eat? - [03i06]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

8. 7. Did you seek treatment for ${name}$? - [03i07]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

9. 8. Where did you go? - [03i08]

1. [_] - [03i08_1] Relatives and friends
2. [_] - [03i08_2] Traditional healer
3. [_] - [03i08_3] Drugshop/ Pharmacy
4. [_] - [03i08_4] Government or private clinic/ surgery/community health centre including general practitioner
5. [_] - [03i08_5] The emergency/ outpatient department of a hospital
6. [_] - [03i08_6] Other, specify _____ (Text)

10. 9. Was the child admitted to a hospital? - [03i09]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

11. 10. Please give name of hospital? - [03i10B]

1. [_] - [1] Mbale Main hospital _____ (Text)
2. [_] - [2] Bududa Hospital _____ (Text)
3. [_] - [3] Busiu
4. [_] - [4] Bushacori
5. [_] - [5] Other, specify _____ (Text)

(Select only 1 - ONE!)

12. 11. Was this the nearest health unit? - [03i11]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

13. 12. Why did you go there? - [03i12]

1. [_] - [03i12_1] Health services better than at the nearest health unit
2. [_] - [03i12_2] Transport was available
3. [_] - [03i12_3] The nearest health unit is more expensive than the one I went to
4. [_] - [03i12_4] I wanted to go to the biggest hospital I can afford
5. [_] - [03i12_5] I do not trust the people at the nearest health unit
6. [_] - [03i12_6] Other, specify _____ (Text)

14. 13. ALT 1 if no diarrhoea yesterday: How many days did the diarrhoea last?
ALT 2 if diarrhoea yesterday: How many day has the diarrhoea lasted?
 - [03i13]

_____

15. 14. During this period of illness you have described, did you change the way you were feeding your child in any way? - [03i14]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

16. 15. In which way? - [03i15]

1. [_] - [03i15_1] Stopped breast feeding
2. [_] - [03i15_2] Stopped non-human milk
3. [_] - [03i15_3] Stopped other liquids
4. [_] - [03i15_4] Stopped solid foods
5. [_] - [03i15_5] Only breast fed at night
6. [_] - [03i15_6] Began giving other liquids
7. [_] - [03i15_7] Began giving solid foods
8. [_] - [03i15_8] Other, specify _____ (Text)

17. 16. During the period of illness did you feed your baby more often, more seldom than or just as often as before the illeness started? - [03i16]

1. [_] - [1] More often
2. [_] - [2] More seldom than before the illness started
3. [_] - [3] Did not change feeding frequency

(Select only 1 - ONE!)

Page j (10), SECTION VI Cont'd

1. PNEUMONIA 24-HOUR RECALL

2. 1. From yesterday morning till this morning, did ${name}$ have cough, fast breathing or difficult breathing? - [03j01]

1. [_]Yes [_]No Cough
2. [_]Yes [_]No Fast breathing
3. [_]Yes [_]No Difficult breathing

Difficult breathing

Difficult breathing

3. 2. Do not read out loud: The child had either cough, fast breathing or difficult breathing: - [03j02]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

4. 3. Did the illness interfere with ${name}$’s ability to drink or eat? - [03j03]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

5. 4. Was ${name}$ admitted to a hospital for the illness?

- [03j04]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

6. 5. Please give name of hospital? - [03j05B]

1. [_] - [1] Mbale Main hospital
2. [_] - [2] Bududa Hospital
3. [_] - [3] Busiu
4. [_] - [4] Bushacori
5. [_] - [5] Other, specify

(Select only 1 - ONE!)

7. 6. Was this the nearest health unit? - [03j06]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

8. 7. Why did you go there? - [03j07]

1. [_] - [03j07_1] Health services better than at the nearest health unit
2. [_] - [03j07_2] Transport was available
3. [_] - [03j07_3] The nearest health unit is more expensive than the one I went to
4. [_] - [03j07_4] I wanted to go to the biggest hospital I can afford
5. [_] - [03j07_5] I do not trust the people at the nearest health unit

6. [_] - [03j07_6] Other, specify _____ (Text)

Page k (11), SECTION VI Cont'd

1. PNEUMONIA 2-WEEK RECALL

2. 1. During the last two weeks that ended yesterday morning, did ${name}$ have cough, fast breathing or difficult breathing? - [03k01]

1. [_]Yes [_]No Cough
2. [_]Yes [_]No Fast breathing
3. [_]Yes [_]No Difficult breathing

3. 2. Do not read out loud: The child did have either cough, fast breathing or difficult breathing: - [03k02]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

4. 3. Did the illness interfere with ${name}$’s ability to drink or eat? - [03k03]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

5. 4. Was ${name}$ admitted to a hospital for the illness?

- [03k04]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

6. 5. Please give name of hospital? - [03k05B]

1. [_] - [1] Mbale Main hospital _____ (Text)
2. [_] - [2] Bududa Hospital _____ (Text)
3. [_] - [3] Busiu
4. [_] - [4] Bushacori
5. [_] - [5] Other, specify _____ (Text)

(Select only 1 - ONE!)

7. 6. Was this the nearest health unit? - [03k06]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

8. 7. Why did you go there? - [03k07]

1. [_] - [03k07_1] Health services better than at the nearest health unit
2. [_] - [03k07_2] Transport was available

3. [_] - [03k07_3] The nearest health unit is more expensive than the one I went to
4. [_] - [03k07_4] I wanted to go to the biggest hospital I can afford
5. [_] - [03k07_5] I do not trust the people at the nearest health unit
6. [_] - [03k07_6] Other, specify _____ (Text)

9. 8. During this period of illness you have described, did you change the way you were feeding your child in any way?

- [03k08]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

10. 9. In which way? - [03k09]

1. [_] - [03k09_1] Stopped breast feeding
2. [_] - [03k09_2] Stopped non-human milk
3. [_] - [03k09_3] Stopped other liquids
4. [_] - [03k09_4] Stopped solid foods
5. [_] - [03k09_5] Only breast feeding at night
6. [_] - [03k09_6] Began giving other liquids
7. [_] - [03k09_7] Began giving solid foods
8. [_] - [03k09_8] Other, specify

11. 10. During the period of illness did you feed your baby more often, more seldom than or just as often as before the illeness started? - [03k10]

1. [_] - [1] More often
2. [_] - [2] More seldom than before the illness started
3. [_] - [3] Did not change feeding frequency

(Select only 1 - ONE!)

Page l (12), SECTION VI [Hospitalisation]

1. HOSPITALISATION

2. 1. Since birth has ${name}$ ever been admitted to hospital? - [03l01]

1. [_] - [1] Yes
2. [_] - [2] No

(Select only 1 - ONE!)

3. 2. How many times has ${name}$ been admitted to hospital? - [03l02]
_____

4. 3. How old in weeks was your baby (each time) when he/she was in hospital? (Report in full weeks) - [03l03]

1. [_] - [03l03_1] 1st time, specify age _____ (Number)
2. [_] - [03l03_2] 2nd time, specify age _____ (Number)
3. [_] - [03l03_3] 3rd time, specify age _____ (Number)
4. [_] - [03l03_4] 4th time, specify age _____ (Number)
5. [_] - [03l03_5] 5th time, specify age _____ (Number)
6. [_] - [03l03_6] 6th time, specify age _____ (Number)

7. [_] - [03l03_7] 7th time, specify age _____ (Number)
8. [_] - [03l03_8] 8th time, specify age _____ (Number)
INFO: <1 week = 0,
Report in full weeks

5. 4. For how many days was ${name}$ (each time) in hospital? - [03l04]

1. [_] - [03l04_1] 1st time, specify days _____ (Number)
2. [_] - [03l04_2] 2nd time, specify days _____ (Number)
3. [_] - [03l04_3] 3rd time, specify days _____ (Number)
4. [_] - [03l04_4] 4th time, specify days _____ (Number)
5. [_] - [03l04_5] 5th time, specify days _____ (Number)
6. [_] - [03l04_6] 6th time, specify days _____ (Number)
7. [_] - [03l04_7] 7th time, specify days _____ (Number)
8. [_] - [03l04_8] 8th time, specify days _____ (Number)

6. 5. What was the reason ${name}$ was in the hospital each time:
(NB: USE CODING IN HELP TEXT!) - [03l05]

1. [_] - [03l05_1] 1st time, specify _____ (Text)
2. [_] - [03l05_2] 2nd time, specify _____ (Text)
3. [_] - [03l05_3] 3rd time, specify _____ (Text)
4. [_] - [03l05_4] 4th time, specify _____ (Text)
5. [_] - [03l05_5] 5th time, specify _____ (Text)
6. [_] - [03l05_6] 6th time, specify _____ (Text)
7. [_] - [03l05_7] 7th time, specify _____ (Text)
8. [_] - [03l05_8] 8th time, specify _____ (Text)
INFO: 1 = Diarrhoea
2 = Pneumonia/ “Cough and difficult breathing”
3 = Malaria
4 = Accident
5 = specify what

Page m (13), SECTION VII: Antropometry ----------

1. ANTHROPOMETRY

2. 1. Baby’s weight (kg (#.#)) - [03m01]
_____

3. 2. Baby’s length (cm (##.#)) - [03m02]
_____

4. 3. Any comments: (Optional) - [03m03]
_____

VERBAL AUTOPSY FORM (FOR STILLBIRTH):

I have understood/have been told that your baby has died. I am really sorry on your behalf. Will you please answer some questions about your child?(***obtain mother consent before anything!!)***

If multiple deaths (twins), Administer one autopsy form for each infant death

Section I
Date: /_____/_____/_____/ (dd/mm/yyyy)
Cluster: /_____/
Code DC: /_____/
Mother study ID: /_____/
Mother full names:
/_____

1. When did you loose your baby?:
   Date: /_____/_____/_____/ (dd/mm/yyyy)

   If exact date unknown, ask the month:
   Which month was it?: /_____/
   Was it at the beginning, the middle or the end of this month? (*Tick one*)
   Beginning: □
   Middle: □
   End: □
   Do not remember: □

2. How many months were you pregnant when you lost your baby?
   /_____/ months

3. Where did the birth take place? (*Tick one*)
   At home: □
   At the TBA place: □
   At the local health facility: □
   At the main hospital in Banfora: □
   Under transport toward the hospital: □
   Other (specify):_____

4. Where you feeling any baby's movements in your womb (stomach) before the start of labour? Yes□ No □ Don't remember □

5. If no when did you for the last time feel your baby's movements before the start of labour?
   The same day as labour/birth □
   The day before labour/birth □
   More than one day before the start of labour □
   Other
(specify):_____

6. Who assisted you at birth? (*Tick one or several options*)
   Nobody, I was alone: □
   Family members: □
   TBA: □
   Nurse/Midewife/Auxiliary midwife: □
   A doctor: □
   Other (specify):_____

7. What kind of delivery did you have?
   Normal vaginal: □
   Caesarean section: □
   Other (specify):_____

8. Did you experience any problem during the birth?
   Yes: □ No: □ Don't remember □
9. If yes, what type of problem was it?
   Needed assistance to get the baby out □
   Labour has lasted very long (> 8h) □
   Had placental retention □
   Had abnormal bleeding □
   Other
(specify):_____

10. Was it a single birth?
   Yes: □ No: □

11. Was the child a boy or a girl?
   Boy □ Girl □ Don't know □

12. Was the child weighed at birth?
   Yes□ N□ Don't know □

13. Did the baby cry at birth?
   Yes: □ No: □ Don't know □

14. Was the baby moving at birth?
   Yes: □ No: □ Don't know □

15. When was the child buried? (*Tick one option*)
   Immediately after birth (<4 hours) □
   The same day as birth (>4 hours and <24h) □
   The day after birth □
   Other (specify):_____

16. May I see your ANC health card or anything equivalent?
   Yes□ N□
If yes, please note the following information if available in the card, if not skip to section II:

16.1: Pregnancy outcome: abortion □ stillbirth □ live birth □
16.2 Date of occurrence: /____/_____/_____/ (dd/mm/yyyy)

16.3 Newborn gender: Boy□ Girl□

16.4 Birth weight written in the health card: /_____/ ####.## (g)

Section II

1. Did you have any illness in the last months preceding you baby death?
Yes: □ No: □ Don't remember □

1. How long approximately did the illness last before you child loss?
[_] Days, specify _____
[_] Weeks, specify _____
[_] Months, specify _____

2. Which illness was it? (*Tick one or more*)
Malaria □
Hypertension □
Fever □
Abdominal pain □
Not specified □

Allow for mother description of the disease and take note of the symptoms described and their sequence of occurrence:
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

3. Did you seek care for this illness?
Yes: □ No: □ Don't remember □

4. Where did you seek care?
Family/friends □
Traditional healer □
Local drugstore/street drug seller's □
Self administered infusion □
Local health facility □
Main hospital in Banfora □
Other (specify):_____

5. Which treatment did you receive (note mother's answer)

Infusion/herbs □

Modern medicine drugs □

Other

(specify):_____

6. If modern medicines, please ask either for medical prescription or empty packs and write down the names of medicines received:

_____
_____
_____
_____
_____
_____
_____
_____
_____

CLOSING THE INTERVIEW

Thank you so much for taking the time to speak with us today. Your comments are very valuable to us and will help us better understand the problems of child loss in your village.

Do you have any additional questions you would like to ask about the study we are conducting? *(Answer any questions the respondent asks as best as you are able.)*

Thank you again. We are very sorry for your loss and we sincerely appreciate your time.

INFANT VERBAL AUTOPSY (LIVE BIRTH):

I Questions about the baby

1.What is the exact birth date of your baby?
___/____/_____
(dd/mm/yyyy)
Do not know □

Probe if he/she does not know
Month: _____
Beginning □
Middle □
End □
Do not know □
Make rule in Epi-handy:
Beginning = 5th, Middle = 15th , End = 25th
Do not know = 15th

Birth date confirmed with written card, (CHC/RTHC) etc. Y□ N□

2. *If the baby is not there:* Is the baby still alive? Y□ N□
If the baby is there: Is this the baby? Y□ N□
Are you the mother of the baby? Y□ N□

If the baby is dead:
Administer verbal autopsy form

If the mother has also died please ask the informant at the household to answer your questions: Administer autopsy forms for the baby and the mother

Relationship to the child: _____

Relationship to the mother : _____

Use separate consent form: Consent given: Yes□ N□

I have understood/have been told that your baby has died. I am really sorry on your behalf. Will you please answer some questions about your child:

Section I

1. Was it a single birth? Y□ N□

In case of twins:
If both twins have died: Administer 2 autopsy forms.
If one twin has died: Continue with the autopsy for the one who has died.

2. What was the name of the child? ___<NAME>_____ *(Text)*

3. Was <NAME> a boy or a girl? Boy □ Girl □

4. Where and how did the birth take place?
1. [_] At home with no TBA, not assisted by friends or family
2. [_] At home with no TBA, assisted by friends or family
3. [_] Assisted by TBA at home/in her place
4. [_] At the local health unit/clinic
5. [_] At the main hospital
6. [_] Under transport
(*Train r.a. that this means in a vehicle on the way to the heath unit)*
7. [_] Other, specify _____

5. Was the child weighed at birth? Yes□ N□

If no q. 7, skip to q. 9
6. What was the birth weight _____(#,#) (*mother's report)*

7. May I see the child health card
(*or any equivalent)* Card seen: Y□ N□

Birth weight written at the health card, CHC etc _____

8. What kind of delivery did you have?
Was it normal, c-section (caesarean) a breech or something else?
1. [_] Normal
2. [_] Caesarean - section
3. [_] Breech
4. [_] Other, specify _____

Section II

1. Can you please tell me which date your baby died? ___/____/_____ Do not know □
(dd/mm/yyyy)
Only if q. 1 Do not know
2. Can you tell me the approximate age of your child when he/she died?
Days _____
Weeks _____
Months _____

2. Can you please tell me where the child died?
1. [_] At home
2. [_] At the traditional healer
3. [_] At the local health unit/clinic
4. [_] At the main hospital
6. [_] Under transport (*Train r.a. that this means in a vehicle on the way to the heath unit)*
7. [_] Other, specify _____

3. Do you have a death certificate?
If yes, ask permission to see the certificate and copy (writing down) the relevant information to answer questions

Age when died _____-

Date of death _____

Primary cause of death _____

Secondary cause of death _____

Long term medical problems _____

Was she on treatment, which _____

Do not ask repetitive questions, but fill in the answers from information already given:

MOTHER'S/CARETAKER'S DESCRIPTION OF CHILD'S ILLNESS

3. Please tell me about (Name of child)'s illness that led to death.
Interviewer: Allow the respondent to tell you about the illness in her/his own words. Do not prompt except for asking whether there is anything else after the respondent finishes or asking for clarification when needed (e.g., "What do you mean when you say…?"). Keep prompting until the respondent says there was nothing else. While recording, underline any unfamiliar terms. After the mother/caretaker stops talking, ask: Is there anything else?

Take a moment to tick all items mentioned spontaneously in the open history questionnaire (to be done by paediatrician later!).

A. Diarrhoea	P. Malformation
B. Cough	Q. Multiple birth
C. Fever	R. Very small at birth
D. Rash	S. Very thin
E. Injury	T. Born early
F. Coma	U. Pneumonia
G. Fit	V. Injury (specify) _____
H. Stiff neck	W. Malaria
I. Tetanus	X. Jaundice
J. Measles	Y. Other (specify _____)
K. Kwashiorkor	Z. Other (specify _____)
L. Marasmus	AA. Other (specify _____)
M. Difficult breathing	BB. Other (specify _____)
N. Rapid breathing	CC. Other (specify _____)
O. Complicated delivery	DD. Other (specify _____)

Section III:
Interviewer: Do not ask any questions that duplicate information already provided by the respondent. Also, do not read the listed answers unless the respondent needs clarification.

1. How long approximately did the illness last:
1. [_] Days, specify _____
2. [_] Weeks, specify _____
3. [_] Months, specify _____

2. During (Name)'s last illness, after how much time from the beginning of symptoms did you recognise that he/she was having a problem or illness? (*Do not read out the alternatives)*
1. [_] Immediately
2. [_] After hours
3. [_] After days, how many _____
4. [_] After months, how many _____
5. [_] Do not know
6. [_] No response

3. When the problem was recognised, was (Name) taken for treatment?
Yes□ N□ Don't know □

Only if yes q. 2:
3. How long after you recognized that there was a problem did you or your family take (Name) for treatment? *(Do not read out the alternatives)*
1. [_] Immediately
2. [_] After hours
3. [_] After days, how many _____
4. [_] After months, how many _____
5. [_] Do not know
6. [_] No response

Only if no q. 2:
4. Why was (Name) not taken for treatment?
(Check boxes: *Do not read out load the alternatives)*
1. [_] Had no money
2. [_] Health facility too far
3. [_] Transportation not easy
4. [_] Nobody could accompany
5. [_] Nobody could help with the home duties
6. [_] Family or friends advised not to go
7. [_] Home care is better
8. [_] Care and advises by traditional healer is better
9. [_] God's will
10. [_] Did not know where to go
11 [_] Died on the way to get medical treatment
12. [_] The child was too weak
13. [_] Other, specify _____

5. Where did (Name) receive treatment during the last illness?
(*Check boxes, do not read out load the alternatives)*

1. [_] Home
2. [_] Relatives/Friends
3. [_] Traditional Healer
4. [_] Spiritual/Religious leader
5. [_] Local Health Unit
6. [_] Private Clinic
7. [_] General Practitioner
8. [_] Public Hospital
9. [_] Other, specify _____

6. Do you know what kind of treatment your child got there? Please tell:

Tick off the appropriate alternatives, and probe from the list
1. [_] Rehydration
2. [_] Blood transfusion
3. [_] Intravenous medicine, specify _____
4. [_] Peroral medicine, specify _____
5. [_] Other, specify _____

7. How was (Name) treated at home?
1. [_] Rehydration
2. [_] Peroral medicine, specify _____
3. [_] Other, specify _____
4. [_] By bringing a health care provider to home
5. [_] By taking advice from a health care provider

Allow for spontaneous answer:

_____
_____
_____
_____
_____
_____
_____
_____
_____

Section IV:
Now I am going to ask you a few questions about how the baby was fed:

1. Had you ever given breast milk to <NAME>? Y□ N□

Make rule: If no q.1 skip to section IV q.12:
2. When did you put the baby to the breast after delivery?
    1. [_] Within the first two hours
    2. [_] Within the first 12 hours
    3. [_] Within the first 24 hours
    4. [_] Within the first 2 days
    5. [_] Within the first 3 days
    5. [_] After 3 days

3. Within the first three days after delivery, was <NAME> given anything to drink other than breast milk? Y□ N□
Probe: Not any liquid on the tongue?

Make rule: If no q.3 skip to q. 7
4. What was that?
    1. [_] Water
    2. [_] Water with sugar or glucose
    3. [_] Diluted cow's milk
    4. [_] Not diluted cow's milk
    5. [_] Infant formula
    6. [_] Any other powdered milk
    7. [_] Porridge of any kind

8. [_] Soup of any kind, what kind _____
9. [_] Other, specify _____
7. [_] Any liquid as part of a ritual, specify _____

7. Did you give the first milk to the baby or did you express and discard it?
   1. [_] Gave the first milk
   2. [_] Express and discard the first milk

Make rule: If q. 1 is yes skip to 7

8. Did you ever breastfed your child? Y□ N□

Make rule: If q. 2 is no skip to 5

9. For how long did you breastfeed your child?
   1. [_] Less than 1 week
   2. [_] Between 1 and 2 weeks
   3. [_] Between 2 and 3 weeks
   4. [_] Do not know

10. What was your main reason for stopping to breastfeed your child?

1. [_] Work
   2. [_] Education
   3. [_] Illness, other than lactation problems
   4. [_] Lactation problems
   5. [_] No answer
   6. [_] Other, specify _____

Make rule: If q. 2 is yes skip to q. 7

11. What was your main reason for not breastfeeding your child?

1. [_] Work
   2. [_] Education
   3. [_] Illness, other than lactation problems
   4. [_] Lactation problems
   5. [_] No answer
   6. [_] Other, specify _____

Make rule: Only if yes q. 4 or q.5 no 4, lactation problems

12. Have you ever had any infection, operation or trauma to your breasts? Y□ N□

If yes, she had:

1. [_] Infection
2. [_] Operation
3. [_] Trauma

Make rule: Only if yes q. 6

13. Did this happen while you were breastfeeding? Y□ N□

Make rule: Only if yes q. 7
14. How old was your baby when this occurred?
1. [_] First week
2. [_] Between 1 and 4 weeks
3. [_] Between 4 and 8 weeks
4. [_] After 8 weeks

15. Now I am going to ask you if you ever had given the following and if you did that, please tell us when you did that for the first time:

Have you ever given any of the following: First time:

1. [_] Water _____
2. [_] Any water with sugar or glucose _____
3. [_] Any fruit juice _____
4. [_] Any herbs in water _____
5. [_] Any tea without milk _____
6. [_] Any tea with milk _____
7. [_] Rice water _____
8. [_] Diluted cow's milk _____
9. [_] Not diluted cow's milk _____
10. [_] Infant formula _____
11. [_] Other powdered milk _____
12. [_] Any other dairy product like yoghurt, cheese or cream _____
13. [_] Goat's milk _____
14. [_] Cereals, porridge or bread _____
15. [_] Any fruits/vegetables _____
16. [_] Any meat _____
17. [_] Any fish _____
18. [_] Eggs _____
19. [_] Gripe water _____
20. [_] Any medicine, specify _____ _____
21. [_] Any alcohol like beer, brew _____
22. [_] Other, Specify _____ _____

V Questions about leaving the child

1. Did you leave your child so that someone else fed the child?
Y□ N□

2. What did they feed?
1. [_] Water based liquids
2. [_] Milk based liquids/semi-solid feeds
3. [_] Expressed breast milk
4. [_] Do not know
4. [_] Other, specify _____

VI Bed Net and vaccination

1. Did you use a bed net for your baby? □ Yes □ No

Vaccination status

2. Did <NAME> get any vaccinations? □ Yes □ No

Make rule: If no q. 2 skip to section VII:

3. Which vaccinations did your baby get?

Train the data collectors to look at the CHC or any other card and record the dates written or just "given" if that is the only thing written
BCG: _____
Polio O: _____
Polio 1: _____
DPT-HebB+Hib1: _____
Polio 2: _____
DPT-HebB+Hib2: _____
Polio3: _____
DPT-HebB+Hib3: _____
Measles: _____

CLOSING THE INTERVIEW

Thank you so much for taking the time to speak with us today. Your comments are very valuable to us and will help us better understand the problems faced by families with sick infants.

Do you have any additional questions you would like to ask about the study we are conducting? *(Answer any questions the respondent asks as best as you are able.)*

Thank you again. We are very sorry for your loss and we sincerely appreciate your time.

Informed consent forms

Page de signature
(Pour les femmes participant à l'étude Promise)

J'ai reçu les informations concernant l'étude PROMISE. Les informations reçues sont les suivantes :

- PROMISE est une étude pour apporter des informations sur la santé et la nutrition des bébés dans 24 villages de la région de Banfora.
- Pour rentrer dans l'étude je dois remplir certains critères et surtout je dois donner librement mon avis de participer ou pas à cette étude.
- Si je décide de participer à l'étude, je dois accepter indiquer mon domicile aux membres de l'équipe de recherche pour qu'ils puissent me voir, soit pour me donner des conseils, soit pour s'entretenir avec moi ou pour voir comment évaluent les choses (grossesse, accouchement, mouvements hors du village). A certaines visites ils pèseront et prendrons la taille de mon bébé. Ils me pèseront et prendront moi-même ma taille une fois.
- J'ai aussi été informée qu'on prélèvera 3-4 gouttes de sang chez mon enfant au 6ème mois pour voir s'il se porte bien et s'il a de bonnes vitamines dans le sang.
- Si j'ai mal aux seins ou si j'ai d'autres problèmes qui m'empêchent d'allaiter correctement je le signalerai à l'équipe PROMISE qui s'occupera de cela en me soignant gratuitement. De même si mon enfant a un problème de santé qui l'empêche d'allaiter, les gens de PROMISE vont m'aider en s'occupant de lui aussi. Je peux aussi m'adresser aux membres de l'équipe Promise pour leur exprimer mes préoccupations.
- Il est souhaitable que j'ai l'accord de mon mari (ou du père de l'enfant) pour les visites à domicile des gens de PROMISE.
- Si à un moment donné je ne veux plus faire partie de l'étude je peux me retirer en prenant soin de le dire aux gens de Promise. Cela n'affectera en rien la qualité des soins qu'on donnera à mon bébé et à moi-même dans les centres habituels de santé et je pourrai toujours demander des conseils aux gens de Promise.

Je soussignée (nom et prénom de la femme) :…….
Témoin Mr/Mme (Pour les cas d'illettrisme) ……..
Reconnais avoir reçu et compris toutes les informations ci-haut citées;
J'accepte librement et sans contrainte de faire partie de l'étude PROMISE.*

Lieu, date et signature de la femme

Date et signature du PI/Promise ou son Représentant

Lieu, date et signature du témoin

Autorisation de visites à domicile

(A remplir par le mari ou le père de l'enfant)

Je soussigné Mr…….résident au village de ……..et mari de Mme…….
Reconnaît avoir été contacté par les enquêteurs de Promise pour que je puisse les autoriser à visiter mon domicile et à s'entretenir périodiquement avec ma femme dans le cadre d'un travail qu'ils font sur la santé et l'alimentation des bébés.
Ils m'ont donné les informations suivantes :

- Ils travaillent pour le Centre Muraz qui est basé à Bobo pour avoir des informations sur la santé et l'alimentation des bébés. Ce travail se fait dans 24 villages de Banfora.
- Dans le cadre de ce travail ils vont causer avec ma femme pour lui expliquer dans les détails en quoi consiste leur travail ;
- Si ma femme est intéressée par leur étude elle pourra donner librement son avis de participation ;
- Si elle accepte alors ils vont s'entretenir avec elle pour lui poser des questions sur elle-même, sa grossesse et son entourage (niveau socio-économique).
- Si elle accepte, ils reviendront aussi la voir 4 fois après son accouchement ; A chaque fois qu'ils viendront la voir ils lui poseront des questions et pèseront son bébé ; ils la pèseront elle-même une fois ;
- Si ma femme ou mon enfant sont malades et que cela empêche l'enfant de téter, ils vont nous aider à les soigner.
- J'ai pu leur poser toutes les questions que je voulais et ils y ont répondu avec satisfaction ;

A présent que j'ai compris, je leur donne l'autorisation d'aller voir ma femme pour lui parler de leur travail ; elle est bien entendu libre d'y participer si cela l'intéresse et je m'engage à ne rien faire pour influencer son choix.

Fait à …….le ……..2006

Le mari (nom et prénom, signature) L'enquêteur (nom, prénom, signature)

NB : si le mari ne peut signer lui proposer d'apposer son empreinte digitale ; s'il hésite se contenter de son accord verbal ;

KUNNAFONIDISƐBƐ

(K'a ɲasin muso minw nindonnin lo Poromayisi ka lɔnniɲinibaara ra)

1. Anw ye jɔɔnw ye ?

N ne tɔgɔ……, n bi baara kɛ santiri Mirazi le fɛ, o min ye **ɲininikɛ baaradaba** ye, Burukina Faso kɛnɛya Minisiriso ra, n'a siginin be Bɔbɔ Julaso. N'aw jɛnna n'a ye, anw tun b'a fɛ ka baro kɛ n'aw ye, Poroze dɔ kunkan, min tɔgɔ ko Poromayisi, ni Santiri Mirazi bina min latigɛ musow yɔrɔ, aw ka mara la.

2. Poromayisi ye mun ye ?

Poromayisi ye ɲininikɛ Poroze ye min ka laɲini ye, ka sɛgɛsɛgɛli kɛ k'a filɛ, n'a y'a sɔrɔ ladilikɛlaw ka kɛta lɔyɔrɔ le ka bon siin dɔrɔn diko ra deen ma, a wolonin kalo kelen, ka taga se kalo wɔɔrɔ ma. Siin dɔrɔn dili kɔrɔ ko fɛɛn wɛɛrɛ te di deen ma baa sinji kɔ.

O kɔrɔ ko bagaw, furaburuw, furajiw, hali jii minta gwansan bɛɛ dili ye tana ye deen wolonin kalo wɔɔrɔ kɔnɔ. Nga, deen bi se ka sirow, furaw ni vitaminiw min, n'a banana.

Poromayisi ye ɲininikɛ Poroze ye min ɲininibaaraw_bi latigɛra yɔrɔ caaman na i n'a fɔ faragwɛjamana saba kɔnɔ n'o ye Nɔrivɛzi, Suwɛdi ni Faransi ye, ani Farafinjamana naani, n'o ye Uganda, Zanbi, Afirikidisidi, ani Burukina Faso.

3. Poromayisi bi fɛ ka mun kɛ ?

Poromayisi ka laɲini ye, sinji dɔrɔn dili yiriwali ye n'o fɛɛrɛw bina bɔ ladiliikɛlamusow ka baarakɛcogoya ra, sindimusow ma, dugu denninw na, farafinjamana naani nunu kɔnɔ. Lɔnniɲinibaara nin laban na, Poroze b'a fɛ k'a yira ko :

- Sinji dɔrɔn dilibaara yiriwali ladiliikɛlamusow fɛ, o ye baarakɛfɛɛrɛ ɲuman ye, min be dɔ fara sinji dɔrɔn dilibaara kan ;
- Sinji dɔrɔn dili yiriwali bi caaman bɔ kɔnɔboli ni fɔgɔfɔgɔbanaw sɔrɔli ra, o minw bi denmisɛnw faga, fantanjamanaw ra ;
- Sinji dɔrɔn dili bi deen mɔɔ diya .

4. Muna Poromayisi sigi ra ?

Denmisɛn miliɔn tan, minw sii ma saan duuru sɔrɔ, o bi sa saan o saan duniɲa kɔnɔ, sangofɛrɛ farafinna kɔnɔ, k'o sababu ke kɔnɔbolibananw, fɔgɔfɔgɔbananw, ɲɔnin, sumaya ani dumunidɛsɛbanaw ye,i n'a fɔ Burukina

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Faso denmisɛn 104 000 le bi sa saan kɔnɔn. Kamasɔrɔ, a yirala ko sinji dɔrɔn dili bi se ka denmisɛnsaya nɔgɔya 13% ra, saan kɔnɔ.

O b'a yira ko n'a tun be kɛra ten Burukina bɛɛ kɔnɔ, sinji dɔrɔn dili tun bina denmisɛn 13 520 ɲɔgɔnna kisi saan kɔnɔ. Kɛrɛnkɛrɛnninya ma, denmisɛn minw bi ta kalo fɔlɔ ra, ka se kalo 5 ma, n'o ma balo sinji ra, olu ka farati ka bon siɲa 5 ni 7 ɲɔgɔn, ka se fɔgɔfɔgɔbana walima kɔnɔbolibana fɛ, ka tɛmɛ tɔɔw kan, minw balora sinji dɔrɔn na.

Nin jatidaw yirali n'a ta bɛɛ, a bi kɔrɔsi ko sinji dɔrɔn dili hakɛ ka dɔgɔ kosɔbɛ farafinna kɔnɔ, kɛrɛnkɛrɛnninya ma, Burkina Faso. Poromayisi b'a laɲini k'o gwɛlɛya nin wili, ni siin dɔrɔn ka dili baara latigeli ye. A bi kɔn ka damina maradennin na, o kɔ, k'a jɛnsɛn jamana yɔrɔ bɛɛ ra.

5. An b'a miri ko Poromayisi baara bina latigɛ cogo di ?

Burukina Faso kɔnɔ, Banfora Erezɔn le sugandira k'a kɛ lɔnniɲinbaara nin latigɛyɔrɔ ye. Dugu 12 sindimusow le sugandira kunfɛ ten, ladilikɛmusow bina to ka taga bɔ u ye, wagati ni wagati, kalo 6 kɔnɔ. O ladilikɛmusonin fana bi sugandi dugu wɛɛrɛ kɔnɔ. Ale bina to ka ladiliw kɛ o ye, ani k'o dɛmɛ tuma bɛɛ, sang'o ka sɔn ka sinji dɔrɔn di, o ka denɲaninw ma kalo wɔɔrɔ ɲɔgɔnna kɔnɔ. Dugu 12 wɛɛrɛw bi sugandi, ladilikɛmusow tena ladili kɛ o dugu nunu kɔnɔ. Dugu nunu bɛɛ bina se ka taga o ka kɛnɛyakow ra dɔgɔdɔrɔsow ra, i n'a fɔ a tun bi kɛ cogo min, kakɔrɔ. O kɔrɔ ko, n'aw bi dugu kɔnɔ, min sugandi ra ladilikɛlamusow ka baara kanma, aw bina tɛmɛko 7 sɔrɔ, min labɛnna, aw yɛrɛ sago ra, ka fara, aw yɛrɛ ka furakɛlikɔrɔ kan, aw tun bi min sɔrɔ, a ka furakɛliyɔrɔ kɔrɔman na.

O lagwɛliw bina labɛn cogo min na, o filɛ :

Lagwɛliko kelen, ka kɔn aw jigiwagati ɲa, tile wolonfila min bi tugu aw ka jigili kɔ, loon kelen bi sugandi o ra. O kɔ, dɔ bi sugandi lɔgɔkun filanan, a naaninan, a seeginan, a tan ni seeginan n'a mugannan na.

Dugu 24 nunu ka musow bɛɛ bina Poroze ka baarakɛlaw ka lagwɛli sɔrɔ fana lɔgɔkun 3, 6, 12 ni 24 nan na, sango ka baro kɛ ni denbaw ye, o deenw ka kɛnɛya cogo kan, ani ka denɲaninw suma, anik'o gwiliya ta (k'o pese).

Kunnafonigwɛlɛn wɛɛrɛ min be yen k'a fɔ aw ye, o ye ko, kalo wɔɔrɔnan na, dɔgɔtɔrɔ dɔɔw bina tɛmɛ, k'aw ka deen joli fitinin ta, min caya ye kuyɛri dennin ɲa kelen ye, sango k'a filɛ, n'aw ka deen ka kɛnɛ walima ni vitaminiw b'a dɛsɛ.

6. Aw bina nafa jumanw le sɔrɔ, n'aw sɔnna k'aw *nindon* Poromayisi ka lɔniɲinibaara la ?

Min y'aw yɛrɛ ta ye, n'aw ye gwɛlɛya sɔrɔ aw siin fanfɛ, i n'a fɔ **s**indimi, min bi kɛ sababu ye deen te se ka siin min ka ɲa, an ben'a to, dɔgɔtɔrɔ dɔ k'aw filɛ, o ra, an be lɔ n'a furakow ye. Ni ɲiningaliw b'aw fɛ ka ɲasin sindi kan, aw bena se ka dɔgɔtɔrɔ ye, minw bena ladilikanw d'aw ma.
Min y'aw ka deen ta ye, k'a ninbɔ siin dɔrɔn dili ka nafa ra, deen ka kɛnɛya kan, jolita bina kɛ sababu ye deen ka furakɛ gwansan, n'a yɛra k'a man kɛnɛ i n'a fɔ jolidɛsɛbana. Min gwɛlɛya sɔrɔ aw siin fanfɛ, k'a sababu kɛ denɲanin ka dɛsɛ ka sinmin, lɔnniɲinibaarada bina nɔnɔmugu d'aw ma, yanni, o ka lɔ n'aw ka siinw koow ye.
Min ye dugumɔgɔw bɛɛ ye, aw ka **nindonni** lɔniɲinibaara nin na, o bina kɛ sababu ye ka siin dɔrɔn dili tɔnɔ yira, ka tila k'a jɛnsɛn jamana nin mara bɛɛ ra.

7. Denbaw k'o *nindon* lɔniɲinibaara nin na, farati jumanw b'o ra, ka ɲasin denmisɛnw ma ?

Denmisɛn min **niin donnin** bɛ jatimina nin na, farati foyi t'o ma, sabu, a te ɲini o fɛ, o ka fura ta, nga, o k'o baa sinji dɔrɔn le min, o min y'o ka dumuni ye. Ni gwɛlɛya sɔrɔla jolita seen fɛ kalo wɔɔrɔnan tuma na, Poroze bi lɔ n'o furaw musakaw bɛɛ ye.

8. Aw be se ka *nindon* lɔniɲinibaara nin na, cogo di ?

N'aw ba fɛ k'aw **nindon** lɔniɲinibaara nin na, a daan ye, aw n'a jɛnɲɔgɔn ka bɛn a ra, k'aw kaan di, k'aw bolonɔ bila sɛbɛ dɔ kan, an bina min labɛn a tɔgɔ ra. Lɔniɲinibaara **nindonnin** ye diyananko le ye. O b'a yira k'aw bi se k'aw

nindon a ra, n'a ka di, aw ye. A fana bi se ka ban walima k'a lalɔ, wagati o wagati k'aw diya, lɔnniɲininibaara nin tuma bɛɛ ra, basi foyi fana te sɔrɔ aw n'a den fɛ.

9. Yaala, a dagara, aw k'aw ka *nindonni* lalɔ lɔniɲininibaara nin na wa ?

N'aw ba fɛ k'aw **ninbɔ** lɔnniɲininibaara nin na, aw be se ka bɔ, wagati min k'aw diya. O te kɛ sababu ye, o ka ban ka lɔ n'aw ka kɛnɛyakow ye, walima ni deen taw ye, furakɛyɔrɔw la.

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10. Jɛnɲɔgɔnya juman le ka kan ka kɛ, an ni ɲɔgɔn cɛ ?

An bi kunnafoni minw ta, aw kan walima aw ka deen kan, o bi kɛ gundo ye, an ni ɲɔgɔn cɛ. Baarakɛlaw min sugandira lɔnniɲininibaara nin kanma, olu dɔrɔn le bi se k'aw ka kunnafoniw sɔrɔ,ani muso tɔɔw ta.
Fɛɛrɛw bɛɛ lajɛnni bena ta, sango, aw ka kunnafoniw kana bɔ lɔnniɲininibaarakɛlaw yɔrɔ, ka se kɛnɛmamɔgɔw ma.
Lɔnniɲininibaara ɲamɔgɔw sɔnna, baara nin ka latigɛ hɔrɔnyasira ni lananyasira kan. Ka bɛn ni lɔnniɲini sariyaw ye. N'a sɔrɔla ko lɔnniɲini baarakɛla dɔw m'o sariya siginin nunu labato, a bina ɲinni o fɛ, o k'o ninbɔ lɔnniɲininibaara nin na.

11. Jɔɔn le bi ni Poromayisi ɲamɔgɔya ye Burukina Faso ?

Santiri Mirazi min ye ɲininikɛbaarada ye kɛnɛya Minisiriso kɔnɔ, n'a siginin bɛ Bobo Julaso Burukina Faso kɔnɔ, o le bina lɔ ni Poroze nin ka latigɛli ye.
Santiri Mirazi be ni lɔnniyaba ye ɲininibaaraw la kɛnɛya kunkan. A bina janto, sango lɔnniɲininibaara nin ka latigɛ tigitigi dɔgɔtɔrɔsariyaw sira kan. Kɛnɛya ɲamɔgɔsoba min bi Banfora Erezɔn kunna, kunnafoni dira olu ma Poroze nin kan. O bina kɛ, an ka baarakɛɲɔgɔnw ye baara nin latigɛliko ra.

Ethical approval

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Regional komité for
medisinsk forskningsetikk
Vest-Norge (REK Vest)

Bergen, 08.09.05
Sak nr. 05/8197

Professor Torkild Tylleskär
Senter for internasjonal helse, UiB
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Ad prosjekt: PROMISE EBF: Fremming av spebarnshelse og ernæring i Afrika sør for Sahara: sikkerhet og effektivitet av fremming av fullamming i en tid med HIV (175.05)

Det vises til søknad om etisk vurdering for denne studien. REK Vest vurderte den i møte den 25.08.05.

Begrunnelsen for å fremme studien for denne etikkomiteen er at den inneholder intervensjon og startes etter 1. juli 2005, og derfor må registreres som en "clinical trial" for å kunne publiseres. En slik registrering krever at en må oppgi egen etisk review board, sies det. Komiteen har vurdert denne saken.
Komiteen mener dette er en god og viktig studie som kan gjennomføres i den form den foreligger. Setningen i informasjonen, punkt "Confidentiality" "There is no risk for lack of confindtiality". Dette bør skrives om slik at det går frem at opplysningene behandles konfidensielt.

Studien er da endelig klarert fra denne komité sin side.

Vennlig hilsen

Arnold Berstad
leder

Arne Salbu
sekretær

Ministère de la Santé

Secrétariat Général

Centre Muraz

Comité D'Ethique

Burkina Faso
Unité – Progrès - Justice

N/Réf. 013 – 2005/CE-CM

Rapport de la 2ème session des 25 et 26 mai 2005

Le mercredi 25 et jeudi 26 mai 2005 à partir de 15 H 30 mm, dans la salle de réunion de l'IRSS-Bobo, s'est tenue une session ordinaire du Comité d'Ethique Institutionnel du Centre Muraz. Deuxième de l'année 2005, elle avait pour ordre du jour, l'examen des projets de recherche.

Etaient présents :

- Professeur Jean Bosco OUEDRAOGO
- Madame Odette KY-ZERBO
- Docteur Rasmané BEOGO
- Madame Martine SOMDA
- Madame Odile Hato ZAMPA
- Madame Paré Léa TOE
- Docteur Germain TRAORE
- Docteur Abdoulaye TRAORE

Etait absent/excusé :

- Docteur Marie Claire HENRY

2. Examen de projet de recherche « Promotion de la santé et de la nutrition infantiles en Afrique subsaharienne : innocuité et efficacité de la promotion de l'allaitement maternel exclusion (AME) dans le contexte du VIH » présenté par Dr. Hama DIALLO

Recommandations et avis

Après avoir délibéré des différentes questions de discussion, le CEI a formulé les recommandations suivantes à prendre en compte dans la mise en œuvre de cet essai :

- Réduire et simplifier la fiche d'information ;
- Porter un rectificatif à la fiche de consentement éclairé, p 2. : « *j'accepte librement et sans contrainte* » est antinomique avec «*avec l'accord de mon partenaire ou époux* » ;
- Marquer sur la fiche de consentement éclairé que l'emprunte digitale pour les illettrés aura valeur de signature ;
- Proposer systématiquement le test VIH à toutes les femmes ;
- Transmettre au CEI/CM le contenu des messages qui seront délivrés aux femmes par les paires-conseillères, en même temps que les autres amendements.

Le Comité d'Ethique a donné un avis favorable pour l'exécution du projet sous réserve de la prise en compte des amendements ci-dessus mentionnés.

Fait à Bobo-Dioulasso le 28 mai 2005

Le Rapporteur

Dr. Abdoulaye TRAORE

Le Président

CENTRE M... R.M.Z. Président Comité d'Ethique Institutionnel

Pr. Jean-Bosco OUEDRAOGO