Can Mass Media Reduce Child Mortality?

A Cluster Randomised Trial
in Burkina Faso

Statistical Analysis Plan

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Contents

1   Introduction

This document details the proposed strategy for analysing and reporting of results from the Wellcome Trust and Planet Wheeler funded trial "Can mass media reduce child mortality?" conducted in Burkina Faso.

The analysis strategy set out here focuses on the analyses to evaluate the effectiveness of a mass media in changing family behaviours and in reducing child mortality. The campaign is being implemented by Development Media International (DMI). The London School of Hygiene and Tropical Medicine (LSHTM), together with local partner Centre Muraz, is responsible for evaluating the effectiveness of the campaign. This document does not cover analyses of cost and cost-effectiveness. Analyses of a more exploratory nature will not be bound by this strategy.

2   Background Information

2.1   Aim of the Trial

The principal aim of the study is to provide evidence that comprehensive, multi-message media campaigns can lead to behaviour change on a sufficiently large scale to result in a detectable reduction in under-five child mortality.

2.2   Objectives of the trial

1. To implement a comprehensive media campaign using local community radio stations which reaches a high proportion of carers and families with young children aged less than 5 years. The campaign will deliver messages to promote simple household behaviours (e.g. breastfeeding) and recognition of when care-seeking and treatment is necessary.

2. To evaluate the "reach" of the campaign, the extent to which the campaign has resulted in behaviour change, and the effectiveness of the campaign in reducing child mortality.

2.3   Trial design

2.3.1   Selection of clusters and randomisation

The trial is being implemented in 14 rural clusters across Burkina Faso. Each cluster comprises the rural population (resident in villages with less than 5,000 population) living around (and at least 5km from) a town with a local community radio station. Seven of the clusters were randomly allocated to receive the intervention using pair-matched randomisation based on geography and radio penetration rate assessed prior the trial in March 2011 (Figure 1).

For each cluster a set of villages was identified for inclusion in the evaluation using data from the last national census of the Institut Nationale de la Statistique et de la Démographie (INSD, 2006). Villages with fewer than 5,000 inhabitants, located at least 5km from the radio station and with good radio signal strength were listed and those nearest the centre of the cluster (with the strongest radio signals) were selected. The study is designed to detect a 20% reduction in all-cause, post-neonatal under-five child mortality during the last year of the intervention. Based on sample size and power calculations, villages with a combined population of 40,000 were included in each cluster.

Figure 1   Map of Burkina Faso showing the fourteen trial clusters
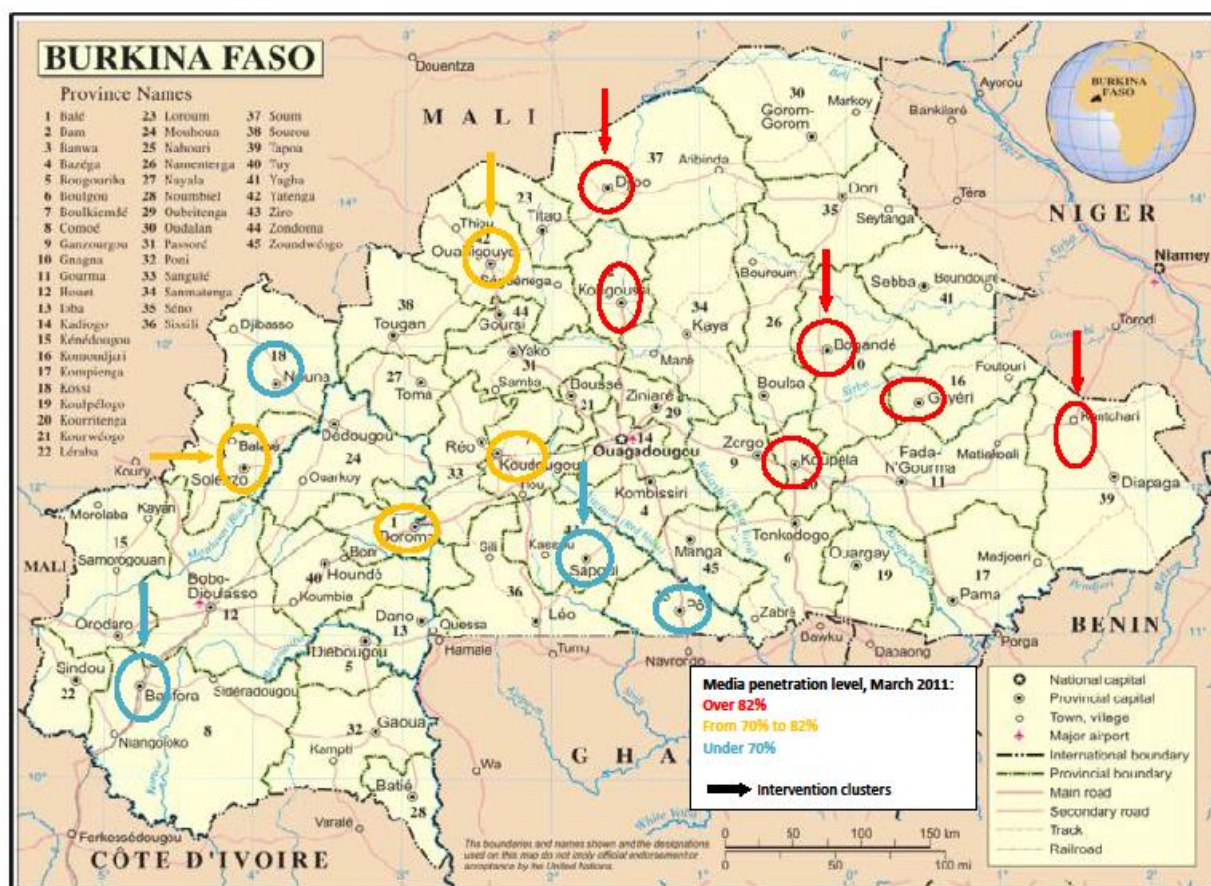
2.3.2   Data collection through household surveys

To address objective 2 (to evaluate the effectiveness of the campaign in changing behaviours and reducing child mortality) a cluster randomised trial design was adopted. Primary and secondary outcomes prior to implementation of the intervention have been or will be measured and compared with the same outcomes measured at the end of the trial, following a period of intervention.

Household surveys are being conducted in all clusters at three key time points: at baseline, at midline and endline. The baseline survey took place before the intervention started, from mid-December 2011 to February 2012. The midline survey was conducted in November 2013, 20 months after the launch of the campaign. The endline survey will be undertaken during and after the last months of the intervention (Figure 2).

Figure 2   Timeline of the trial
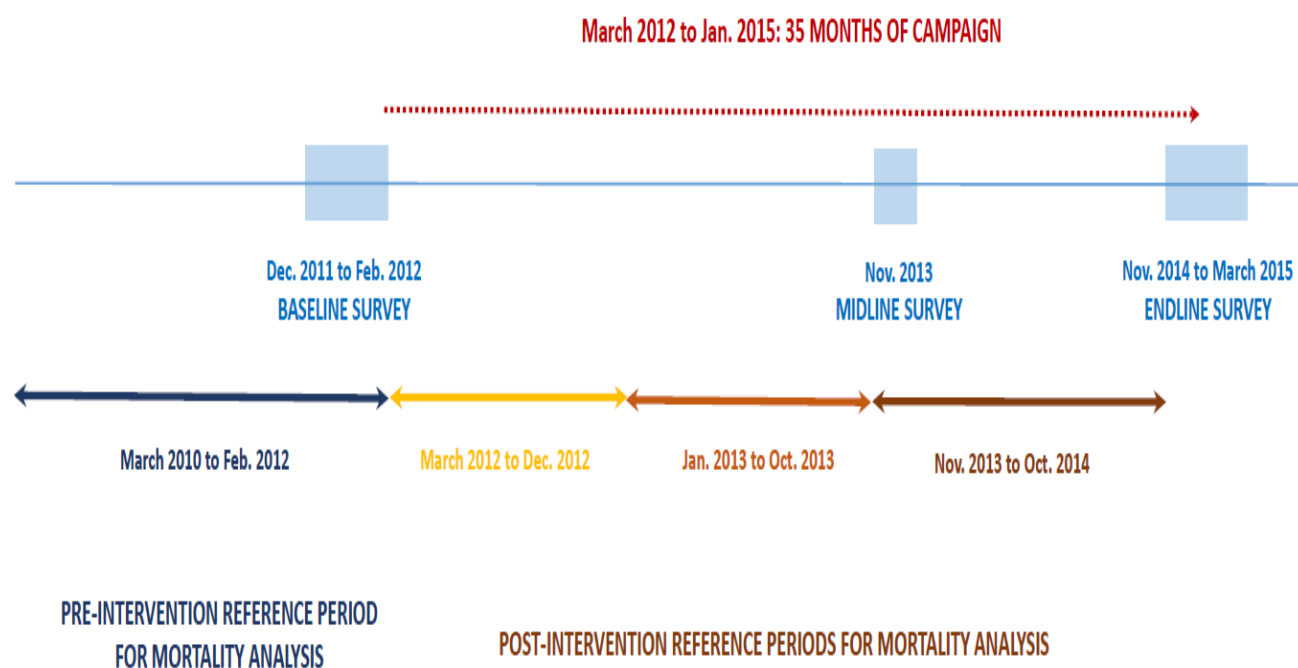
At baseline and endline, in each surveyed village, a census of all compounds and households within each compound is performed with GPS co-ordinates of the compound recorded. After a short interview with the household head to collect socioeconomic data and information on radio ownership, all women aged from 15 to 49 years old are interviewed on their pregnancy history.

At baseline, due to cost constraints, half of the population in each cluster (20,000 inhabitants) was randomly selected for inclusion in the survey. Pregnancy history data collection was truncated from January 2005 to the date of the interview. At endline, a full pregnancy history will be recorded to allow re-estimation of pre-intervention child mortality risks in all villages included in the trial.

In addition to pregnancy history data collection, at baseline, midline and endline, a random sample of 5,000 mothers with at least one under-five child living with them, are interviewed about their basic demographic characteristics, knowledge and behaviours of relevance to child health as well as their radio listenership. Questions regarding maternal and newborn health, i.e. antenatal care (ANC) and delivery, refer to the woman's last pregnancy of more

than 6 months duration. Questions regarding health care seeking for childhood illness, bed net use, nutrition and sanitation apply to her youngest child less than five years old. Illnesses (fever, cough, fast or difficult breathing, diarrhoea, dysentery) are recorded using a recall period of two weeks preceding the interview. Pneumonia is defined according to the Integrated Management of Childhood Illness (ICMI) algorithm as a case of fast or difficult breathing associated or not with a cough. Diarrhoea is defined as reported by the mother and dysentery as diarrhoea with presence of blood in the stools.

2.3.3 Data collection from health facilities

Routine health facility data from the Direction Générale des Etudes et des Statistiques Sanitaires (DGESS) of the Ministry of Health of Burkina Faso will be used to complement data on reported service dependent behaviours (e.g. ANC, health facility delivery, child growth monitoring and health care seeking for childhood illnesses).

In each cluster, all primary health facilities located in villages included in the trial will be included in the study. For each of these facilities, monthly data are being collected for the year 2011, before the implementation of the campaign, and the years 2012 to 2014, while the campaign is being broadcast.

2.4 Definition of Primary and Secondary Outcomes

2.4.1 Primary outcome

All-cause, post-neonatal under-five child mortality risk is the primary outcome of the trial. It is calculated using the number of deaths at ages 1 to 59 months as the numerator with the number of surviving children at age 1 month and above being used to calculate the denominator.

For each pregnancy reported the following information is recorded: duration of the pregnancy in months, the date of delivery, the vital status of the newborn at birth, and for all live births, the survival status of the child at the date of the interview, as well as, when the child is deceased, his/her age at death.

Missing months of births will be randomly imputed according to the DHS method. The method relies on the construction of logical ranges for each date, which are refined in three steps resulting in successively narrower ranges. In a fourth step, dates of birth are randomly imputed within the final constrained logical range.

Pierre Martel's Kaplan Meier survival analysis program, which implements the DHS synthetic cohort life table approach, will be used to compute post-neonatal under-five child mortality with 95% confidence interval accounting for between-cluster variation.

2.4.2 Secondary outcome

The secondary outcome of the trial is the all cause under-five child mortality risk, defined as the number of deaths at ages 0 to 59 months over the number of live births. All cause

under-five child mortality risk will be computed using the same approach to that described for the primary outcome (section 2.4.1).

2.4.3 Intermediate outcomes

Intermediate outcomes along the hypothesized pathway between the intervention and child survival include the coverage of the intervention, knowledge and family behaviours.

2.4.3.1 Coverage of the intervention

Two measures of the coverage of the intervention will be used:

> (i) The proportion of women who reported recognizing spots
> (ii) The proportion of women reporting recognizing the long format program

Both will be measured from interviews with mothers of children less than 5 years old at midline and endline.

2.4.3.2 Key family behaviours

Key family behaviours are measured using two different sources of data:

1. Interviews with mothers of a child less than 5 years old will provide estimates of the prevalence of key behaviours, as reported, at baseline, midline and endline as listed below:

    - Attendance at four or more ANC during the last pregnancy of more than 6 months duration
    - Savings during the last pregnancy of more than 6 months duration
    - Health facility delivery for the last pregnancy of more than 6 months duration
    - First bath delayed for 24 hours or more after birth for the last live birth
    - Breastfeeding initiation within 1 hour of birth for the last live birth
    - Exclusive breastfeeding in children under 6 months old
        - Since birth
        - On the day prior to interview
    - Complementary feeding in children aged 6 to 11 months
    - Age appropriate feeding in children aged 0-11 months on the day prior to interview
    - Attendance at child growth monitoring clinics among children aged 0-23 months
    - Health care seeking in a health facility or with a Community Health Worker for childhood illness: fever, fast or difficult breathing, diarrhoea
    - Treatment of fever with a recommended antimalarial
    - Treatment of fast or difficult breathing with an antibiotic
    - Diarrhoea treatment: ORS/increase in fluids, and similar or increased quantity of food

- Promptness of treatment (within 24 hours): antibiotic in case of fast or difficult breathing, recommended antimalarial in case of fever and ORS in case of diarrhoea
- Bed net use in under-five children and during pregnancy
- Household latrine ownership
- Safe disposal of youngest child's stools
- Hand washing with soap

2. Routine health facility data will provide estimates of the absolute number of women and under-five children attending health centres from 2011 (pre-intervention period) to 2012-2014 (intervention period) for:

- ANC
- Facility delivery
- Child growth monitoring
- Consultation with a health care provider for an episode of illness

2.4.3.3   Knowledge

Knowledge is measured along with family behaviours at the baseline, midline and endline surveys, through interviews with mothers of children less than 5 years old. Areas of knowledge to be measured are listed below:

- ANC and bed net use during pregnancy to prevent malaria
- Early breastfeeding after birth
- Exclusive breastfeeding until the age of 6 months old
- Danger signs in sick children
- Health care seeking in case of fast/difficult breathing
- Health care seeking in case of diarrhoea

2.5   Eligibility/inclusion criteria

All women aged 15 to 49 years, resident and present in the surveyed villages and providing written informed consent will be interviewed about their pregnancy history data at baseline and endline.

A random sample of 5000 women aged from 15 to 49 years old, who are mothers of a child less than five years old, will be interviewed about knowledge and behaviours at each of the baseline, midline and endline surveys.

3   Analysis of baseline comparability of the two arms

Baseline characteristics (demographic characteristics, socioeconomic status and behaviours) recorded during the baseline survey and pre-intervention mortality estimated from the endline survey will be presented by trial arm and overall.

No statistical tests will be performed to compare the intervention and control arms since the null hypothesis (that observed differences arose by chance) is known to be true when allocation is randomised.

4   Evaluation of the effectiveness of the campaign

All analyses will be performed on cluster-level summary measures and the primary analyses will be performed on an intent-to-treat basis. The analyses will be performed ignoring the matching procedure, as recommended by Diehr et al. (1995) for trials with fewer than 10 clusters per arm.

The choice of analyses based on cluster-level summaries is based on the recommendation of Hayes and Moulton (2009, pages 223-224). These authors recommend that with fewer than about 15 clusters per arm cluster-level analyses are preferable to methods based on individual which then seek to account for the cluster randomization, such as Generalised Estimating Equations (GEE) and random effects models. While GEE and random effects models have good asymptotic properties, they may not be robust when the number of clusters is small. The GEE approach tends to result in inflated type I errors in such situations (Bellamy et al., 2000; Austin, 2010), while the distributional assumptions of random effects models are difficult to verify without a large number of clusters (Bellamy et al, 2000, Ukoumunne and Thompson, 2001). The use of cluster-level summaries along with the t-test is therefore recommended, based on the remarkable robustness of the t-test to departures from the underlying assumptions (Donner and Klar, 1994).

"A common objection to cluster-level analysis is that information is wasted when the data are reduced to a set of summary measures. Investigators note that, in a trial with 10 clusters per arm, but following many thousands of individuals, the final analysis is based on two columns of 10 numbers. This objection, however, is not valid. The power of the study and the precision of the effect estimates will depend on the observed variability in the outcome between clusters. The observed between-cluster variance will be reduced if a large number of individuals is studied in each cluster." (Hayes and Moulton, 2009, page 163).

4.1   Effect of the intervention on post-neonatal under five child mortality

4.1.1   Pre and post-intervention reference periods

For the pre-intervention period, mortality over the two years March 2010 to February 2012 will be estimated (Figure 2). Using a 2-year reference period for the pre-intervention period mortality estimates will provide more precise estimates of the cluster specific pre-intervention mortality rates than using a 1-year reference period.

The post-intervention period will be split in three periods: From March 2012 to December 2012 (the first ten months of campaigning), January 2013 to October 2013 (next ten months) and November 2013 to October 2014 (the twelve months preceding the start of the endline survey) (Figure 2).

4.1.2 Primary analysis

The primary analysis of post neonatal under-five child mortality reduction at endline will be a cluster-level intention to treat analysis adjusted for pre-intervention mortality levels.

Adjusting for pre-intervention mortality levels aims to control for imbalance between arms in the pre-intervention mortality risks as well as improve the precision of the estimated risk ratio by "explaining", at least in part, between-cluster variation in post-intervention mortality (Hayes and Moulton, 2009, page 226).

The full pregnancy history data collected at the endline survey will be used to calculate both pre and post-intervention mortality estimates for each cluster. For each cluster and for each of the pre- and three post-intervention reference periods (see 4.1.1), a cluster-level summary of mortality will be computed as described in section 2.4.1.

These cluster-level estimates will then be log transformed prior to analysis. Two analyses of these data will be performed. First, the log(mortality risk) in the year before the start of the endline survey (after 30+ months of intervention) will be regressed on the log(mortality risk) during the pre-intervention reference period together with a variable representing the intervention. The risk ratio for the effect of the intervention in the last year of implementation (together with a 95% c.i.) will be obtained by exponentiating the coefficient for the variable representing the intervention in the regression and its 95% c.i.. Second, the log(mortality risk) during all three post-intervention periods will be regressed on the log(mortality risk) during the pre-intervention period plus variables representing the intervention, the post-intervention period (coded as 1, 2 or 3 and treated as a "continuous" variable) and the interaction between intervention status of the cluster (intervention/control) and the post-intervention period. Cluster-specific random effects will be added to this model to account for the expected correlation in post-intervention mortality risks estimated for each period in the same cluster. A test of the null hypothesis of no interaction versus the alternative that there is an interaction will be performed to look for evidence that the effect of the intervention on mortality increases over time.

Given that the endline survey is designed to cover similar population sizes in each cluster, no weighting will be used for the analysis of mortality, i.e. all clusters will be given equal weight in the analysis.

The mortality risks during the pre and each of the post-intervention periods in each arm with their 95% confidence intervals and the risk ratio together with a 95% confidence interval and a p-value for the test of the null hypothesis of no intervention effect will be presented as in Dummy Table 1.

A scatter plot showing, for each cluster, mortality in the last year post-intervention (Y-axis) versus mortality in the pre-intervention period (X-axis), together with the line of equality, will also be presented.

4.1.3   Secondary analyses

4.1.3.1   Adjustment for confounder score

A secondary analysis similar to that described in Section 4.1.2 will be performed adjusting for the confounder score described below.

At baseline a substantial imbalance was noted in mortality risk in intervention and control clusters. Mean post-neonatal under-five mortality risk was estimated at 113 per 1000 live births in the intervention arm versus 84 in the control arm, a risk difference of 29 deaths per 1000 live births and a risk ratio between of about 1.30.

Three factors which might be expected to predict mortality - distance to the capital (as a proxy for general level of investment and development), distance to a health facility (as a measure of access to care) and health facility delivery prevalence (as a measure of propensity to use services) – were found to be particularly imbalanced between arms at baseline (Table 1).

Table 1   Baseline imbalances

	Intervention arm	Control arm
Median distance to a health facility (km)*	6.3	2.5
Mean distance to the capital (km)	232	158
Baseline health facility delivery prevalence (%)	56	82

* For those villages surveyed at baseline

A Principal Component Analysis on cluster-level summaries of these three variables was performed to create a "confounder score" based on the first principal component. After controlling for this confounder score, the adjusted mortality risk difference between arms at baseline was 4.1/1000 (95% ci -33.5, 41.8) and the adjusted risk ratio was 1.05 (95% ci 0.73, 1.50).

4.1.3.2   Dose-response analysis

A further secondary analysis will look for evidence that the effect of the intervention is modified by radio ownership. Radio ownership is strongly correlated with radio listenership (Table 2) but is subject to less measurement error and seasonal variation. The interview with the household head regarding socioeconomic status will record radio ownership data for all women interviewed about their birth history at endline. Three categories of radio ownership will be defined: no radio in the compound (and in the household), radio in the compound (but not in the household), radio in the household.

Table 2   Cross tabulation of radio listenership in the past week and radio ownership (midline survey results)

Radio ownership	Number of women	% reporting listening in last week
No radio in compound	1476	14.4%
Radio in compound but not in household	1155	60.0%
Radio in household	2544	78.0%

For each cluster, cluster-level mortality risks during the pre and last year post-intervention reference periods will be computed by radio ownership group.

These cluster-level estimates will then be log transformed and a dose-response analysis will be performed similar to that for time period (Section 4.1.2).

4.1.3.3   "Per-protocol" analysis

At the midline survey "contamination" was detected in Gayeri, one of the control clusters. Among 375 women interviewed in Gayeri cluster, one third reported listening to Djaowampo radio station, a partner station of the campaign in the Bogande intervention cluster. Most of these women were living in villages located to the North and North West of Gayeri, towards Bogande. In villages located 90km or more from Bogande very few or no women reported listening to Radio Djaowampo. No contamination was detected at midline in any of the other control clusters. A "per-protocol analysis" will be conducted excluding villages in Gayeri cluster within 90km of Bogande.

Both unadjusted and confounder score adjusted dose response (4.1.3.2) and per-protocol (4.1.3.3) analyses will be performed.

4.2   Effect of the intervention on under five child mortality

The effect of the intervention on under-five child mortality (0 to 59 months) will be analysed using a similar approach to that described for the primary outcome (section 4.1).

4.3   Effect on reported knowledge and behaviours

4.3.1   Primary analysis

As for the analysis of mortality reduction at endline (section 4.1), the primary analysis of knowledge and behaviour change will be an intention-to-treat analysis performed on cluster level summaries.

Knowledge/behaviours will be analysed in terms of the absolute change in the knowledge item/behaviour (% point change) (either at midline or endline) from baseline. Interviews with mothers of under-five children will provide estimates of the prevalence of key knowledge items and behaviours (section 2.4.2) at baseline, midline and endline surveys. For each cluster, the cluster-level prevalence of key knowledge items/behaviours will be

computed at each survey. The cluster-level change in prevalence from the baseline to the follow-up surveys will then be computed and a Difference-in-Difference (DiD) analysis will be performed adjusted for baseline behaviour prevalence to control for the phenomenon of regression to the mean (Hayes and Moulton, 2009, page 227). I.e. the cluster-level differences between surveys will be regressed on the cluster-level baseline prevalence and the intervention status of the cluster (intervention/control).

The coefficient of the intervention variable will provide an estimate of the extent to which the average change across intervention clusters differs from the average change across control clusters.

For knowledge and behaviours assessed in all interviewed women similar sample sizes will be available in all clusters and therefore unweighted analyses will be performed. By contrast, some behaviours only apply to a sub-sample of women and their children (e.g. health care seeking and treatment among sick children). Though the effective sample size in each cluster may vary for these behaviours, in the absence of accurate estimates of ρ, the intraclass correlation coefficient (ICC), weighted analyses may be less efficient than unweighted analyses (Hayes and Moulton, 2009, page 179). Braun et al. (2001), using simulations, found that unweighted analysis tend to be more efficient as the ICC increases above about 0.05. Therefore, all clusters will be given equal weight for all behaviours in the analysis.

Since the campaign began in March 2012, analyses of maternal and newborn health related behaviours will be restricted to pregnancies ending after June 2012.

From baseline to midline, the change in all behaviours listed in section 2.4.2 will be analysed using this approach. From midline, messages on 5 behaviours – Delay of the first bath after birth, attendance at child growth monitoring clinics, complementary feeding, latrine ownership and safe disposal of children' stools - were no longer broadcast. Therefore, the analysis of change from baseline to endline will not include these behaviours.

The prevalence of key behaviours in each arm at baseline, midline and endline surveys together with their 95% confidence intervals will be presented, along with the "crude" DiD (based on individual data) and results from cluster level analysis: estimated DiD, 95% confidence interval and a p-value for the test of the null hypothesis of no intervention effect (Dummy Table 2). In addition an analysis to test for a trend in the intervention effect over time will be performed in the same way as for the mortality outcomes, but based on 2 rather than thre post intervention periods (midline and endline).

4.3.2   Secondary analyses

4.3.2.1   Adjustment for confounder score

The confounder score described in the secondary analysis of mortality reduction (section 4.1.3.1) will be used to adjust the analysis of change described above (section 4.3.1) for imbalance at baseline between arms for all behaviours.

4.3.2.2 Dose-response analysis

Radio ownership

As for the secondary analysis of mortality reduction (section 4.1.3.2), a further secondary analysis will be performed to look for evidence of effect modification by radio ownership group.

Broadcasting intensity

An analysis will be performed to examine the association between broadcasting intensity and behaviour change. For a reduced list of behaviours which are likely to be independent of each other (see below), broadcasting intensity will be calculated based on the number of weeks of spots broadcast from March 2012 to the survey (either midline or endline).

DiDs, both unadjusted and confounder score adjusted, will then plotted against the broadcasting intensity. Correlation and regression coefficients will be estimated:
- Attendance at four or more ANC and health facility delivery for the last pregnancy of more than 6 months duration
- Savings during the last pregnancy of more than 6 months duration
- First bath delayed for 24 hours or more after birth for the last live birth
- Breastfeeding initiation within one hour after birth for the last live birth
- Age appropriate feeding in children aged 0-11 months on the day prior to interview
- Appropriate care seeking for childhood illness[1]
- Bed net use in under-five children
- Hand washing with soap

4.3.2.3 Per-protocol analysis

A "per-protocol analysis" will be conducted excluding villages in Gayeri cluster within 90km of Bogande.

Both unadjusted and confounder score adjusted dose response (4.3.2.2) and per-protocol (4.3.2.3) analyses will be performed.

4.4 Change in the attendance at key health services

Summaries of routine health facility data will be presented by arm. Time trends in the absolute number of attendances at health facilities will be plotted by year, from 2011 to 2014, for each arm.

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[1] Defined as care seeking in a facility for with a CHW for a child with fever or fast or difficult breathing and use of ORS or increased fluids and similar or more foods for children with diarrhoea

For each cluster, a ratio of the absolute number of attendances in 2014 over the absolute number in 2011 will be calculated and evidence for an effect of the intervention will be sought by testing the null hypothesis of no difference between arms using a t test.

4.5   Other analyses suggested by the ISAC

We are currently investigating through simulations other analyses suggested by the ISAC.

4.5.1   Village-level instrumental variable analyses

We have performed simulations of mortality outcome to investigate the use of an instrumental variables approach applied to village level data approach to estimate the casual effect of listening to the partner radio station, with the randomized treatment assignment as the instrument. Based on 1000 simulations of a scenario with no treatment effect and using the ivregress command in Stata we obtained the following:

1. Using robust standard errors to account for within-cluster correlation resulted in an inflated type 1 error rate (P<0.05 in 9.3% of simulations)
2. Using a standard cluster bootstrap approach to account for within-cluster correlation resulted in an inflated type 1 error rate (P<0.05 in 10.3% of simulations).
3. Using a Wild cluster bootstrap approach to account for within-cluster correlation. Simulations still running.

4.5.2   Village-level random effects analyses

We are currently performing simulations to assess whether analyses based on village-level summaries with cluster-level random effects and bootstrapping to account for within-cluster correlations. Simulations still running.

5   References

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Hayes RJ, Moulton LH. Cluster Randomised Trials. Chapman and Hall, Boca Raton, 2009.

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6 Annexe: Numbers of villages per cluster and children per village

Cluster	Total number of sampled villages	Birth history data				Behaviours data				
		Villages surveyed at baseline*		Mean number of u5 children at risk per village	Number of villages with 0 death	Villages surveyed at baseline		Mean number of interviews per village at baseline	Villages surveyed at midline	
		n	%			n	%		n	%
banfora	22	13	59	303	0	13	59	28	8	36
bogande	25	13	52	467	0	13	52	28	9	36
djibo	33	18	55	194	0	18	55	20	9	27
kantchari	22	12	55	336	0	12	55	30	9	41
ouahigouya	44	24	55	196	2	24	55	15	7	16
sapouy	40	19	48	226	0	19	48	17	9	23
solenzo	17	9	53	622	0	9	53	39	8	47
intervention arm	**203**	**108**	**53**	**335**	**2**	**108**	**53**	**23**	**59**	**29**
boromo	22	11	50	478	0	10	45	40	6	27
gayeri	25	14	56	278	0	14	56	26	8	32
kongoussi	51	22	43	204	2	20	39	18	9	18
koudougou	19	9	47	268	0	8	42	40	6	32
nouna	47	26	55	227	0	26	55	15	9	19
po	40	18	45	166	2	18	45	20	8	20
pouytenga	36	19	53	255	3	18	50	20	8	22
control arm	**240**	**119**	**50**	**268**	**7**	**114**	**48**	**22**	**54**	**23**

* at baseline, half of the total number of villages were randomly selected

** at midline, 9 clusters of 20 women were randomly selected per cluster among villages surveyed at baseline using a PPS sampling

7   Dummy Tables

Table 1: Effect of the campaign on primary and secondary (mortality) outcomes

	Reference period*	Control arm			Intervention arm			Cluster-level analysis	
		# deaths	risk	95% CI	# deaths	risk	95% CI	RR**	95% CI
Post-neonatal under-five mortality	Pre-intervention							-	- -
	Post-intervention 1								
	Post-intervention 2								
	Post-intervention 3								
					P-value post-intervention period 3 =				
					P-value for time trend in intervention effect =				
Under-five mortality	Pre-intervention							-	- -
	Post-intervention 1								
	Post-intervention 2								
	Post-intervention 3								
					P-value post-intervention period 3 =				
					P-value for time trend in intervention effect =				

* Reference periods: Pre-intervention: March 2010 to February 2012; Post-intervention 1: March to December 2012; 2: January to October 2013; 3: November 2013 to October 2014.

** Risk ratio adjusted for baseline mortality, but <u>not</u> for confounder score. Risk ratios and P-values adjusted for the confounder score will also be presented in a similar way.

Table 2: Effect of the campaign on reported knowledge and behaviours

	Survey	Control arm			Intervention arm			Crude DiD	Cluster level analysis		
		n	%	95% CI	n	%	95% CI		DiD*	95%CI	p
Behaviour 1	BS								-	- -	-
	MD										
	ES										
								P-value at endline =			
								P-value for time trend in intervention effect =			
Behaviour 2	BS								-	- -	-
	MD										
	ES										
								P-value at endline =			
								P-value for time trend in intervention effect =			

BS: Baseline, MD: Midline, ES: Endline surveys

* DiD adjusted for prevalence of behaviour at baseline, but _not_ for confounder score. DiDs and P-values adjusted for the confounder score will also be presented in a similar way.