

The scientific evaluation of a cash transfer pilot project to support orphans and vulnerable children (OVC) in Manicaland, Zimbabwe

Background

Orphan prevalence is increasing in many sub-Saharan African countries due to increases in adult mortality resulting from high HIV prevalence¹. Further children are made vulnerable by increased morbidity amongst parents and other caregivers². Studies from sub-Saharan Africa, including many from Zimbabwe, indicate that orphans and vulnerable children (OVC) are at risk of a variety of adverse health, education and other social outcomes (e.g. increased risk of mortality³⁻⁶, morbidity⁷⁻¹⁰, malnutrition⁸⁻²², adverse sexual health outcomes and/or HIV infection²³⁻²⁹, reduced school enrolment and/or attendance^{14, 23, 30-38} and psychosocial distress^{28, 39-44}).

Interventions are required, therefore, that target the specific characteristics that lead to increased health and educational risks amongst OVC. One such intervention is cash transfer programmes, where cash is given to families caring for OVC. In some cases, the beneficiary families must comply with certain conditions relating to child health, education and general social welfare. There are other types of intervention that provide benefits for vulnerable children. However, cash transfer programmes do offer some particular advantages. They are relatively cheap to deliver (particularly in the case of unconditional cash transfers); they can benefit households/beneficiaries with a wide range of different capacities (e.g. less educated beneficiaries, those who are not capable of working); in logistical terms they are quite simple programmes, especially unconditional cash transfers, and can therefore be scaled up quickly even in regions with low administrative and technical capacities (e.g. in areas affected by HIV/AIDS); and they are flexible – they allow beneficiaries to tailor their spending to their specific needs (e.g. compared with food vouchers).

Lagarde et al.^{48, 49} conducted a review of conditional cash transfers (CCT) and their effects on health outcomes in low- and middle-income countries. Randomised controlled trials, controlled before-and-after studies, interrupted time-series analyses and multi cross-sectional studies were

included in the review and two authors independently reviewed the retrieved publications. Five studies were found that reported child health outcomes, all from middle-income countries of Latin America (Mexico, Brazil, Honduras, Colombia and Nicaragua). These programmes targeted disadvantaged communities and usually the poorest households within those communities. The cash transfers were generally conditional upon uptake of preventive health services and school enrolment/attendance. All the studies showed the transfers having positive effects on care-seeking behaviour and many of these effects were statistically significant. Positive effects were also found for immunization coverage, nutritional outcomes and occurrence of childhood illnesses, although fewer of these effects were statistically significant, with the most consistent evidence for positive effects being found for child health outcomes reported by a guardian rather than measured directly. In Brazil, a negative effect on weight-for-age of children under 7 years was found. This is thought to be due to a misunderstanding of the eligibility criteria – beneficiaries may have thought that at least one malnourished child was necessary for inclusion in the programme. The main limitation of the reviewed studies is that many sub-group analyses were presented, sometimes based on small age ranges and socio-economic stratification, which may have given rise to spurious significant results. Furthermore, the raw data were not always presented, only effect sizes, which limits interpretation of the results.

Since this review, several peer-reviewed articles on the effects of conditional cash transfers on child health in middle-income countries have been published, some of which have shown similar results to those mentioned above^{50, 51}. Further analyses of data from the conditional cash transfer study in Mexico show statistically significant positive effects of the transfers on child motor development, cognitive development, language development and child behaviour^{52, 53}. Another study found that the positive effects of the Mexican programme on stunting, maternally reported child behaviour and language development persisted after 10 years of follow-up⁵⁴. A study of CCTs in Malawi – a low-income country - that conditioned on school attendance and specifically targeted young women aged 13-22 years (particularly those that had already dropped out of school), found significant reductions in risky sexual behaviour, early marriage and pregnancy⁵⁵.

Adato and Bassett^{56, 57} published a review of cash transfers in the context of HIV and AIDS. They looked at conditional and unconditional (CT) cash transfers and at a wider range of

outcomes (poverty reduction, education, health and food consumption/nutrition) than Lagarde et al., although many of the outcomes focused on children. They also considered a wider range of sources; in particular, they searched extensively amongst the “grey” literature and contacted the authors/organizations that commissioned the studies. They looked at data and reports from a total of 20 different cash transfer programmes – 10 involving conditional cash transfers and 10 involving unconditional cash transfers. The interventions vary widely from unconditioned pensions for the elderly in South Africa to the conditional cash transfer programmes from Latin America described previously. Any study that reported quantitative evaluation data was included in the review, which means that rigorous evaluation designs were not always employed. Although quantitative data are reported, this review makes substantial use of qualitative findings, only reports positive effects, and does not provide sample sizes or confidence intervals.

The review found positive effects of CT programmes reported in several studies from sub-Saharan Africa, including improved nutritional status of children (Malawi, South Africa and Zambia), reduced reports of illness among children (Malawi and Zambia) and increased school enrolment and attendance (Ethiopia, South Africa, Zambia and Malawi). The review also found positive effects of CCT programmes on school enrolment and attendance from studies in Latin America, the Caribbean, Asia and Europe (Mexico, Nicaragua, Brazil, Honduras, Colombia, Ecuador, Bangladesh, Pakistan, Turkey, Cambodia and Jamaica). However, the studies evaluating CT programmes and, in sub-Saharan Africa, both CCT and CT programmes, have been less rigorous than those studies evaluating CCTs in middle-income countries – e.g. small scale studies often lacking control groups and/or baseline data and with publications not having been submitted for peer review.

The use of conditions in cash transfer programmes is controversial. Conditional cash transfer programmes are more complex and require greater logistical and administrative costs than unconditional cash transfer programmes. If conditions were not imposed, more households could be reached with the same budget or households could be given a larger sum of money. In particular, it has been argued that poor and vulnerable households will spend money to improve child wellbeing without the need for conditions. It may also be particularly problematic to enforce conditions relating to use of services in low income settings, where coverage of services

may not be complete. Conditional cash transfer programmes may tend to punish the most vulnerable households (e.g those affected by HIV/AIDS), who are also the households that are the most likely to struggle to meet conditions.

Adato and Bassett⁵⁶ also reviewed two small studies, from middle-income countries, comparing the effects of unconditional and conditional cash transfers. A study from Mexico⁵⁸ compared children that had accidentally failed to receive forms for monitoring school attendance with children that received the forms. This group was further divided into those who listed school attendance as a condition during the evaluation survey and those who did not. They found that children in those households that received the forms were significantly more likely to be enrolled in school than those that did not receive the forms and/or were unaware of the conditions. A similar study was conducted using data from Ecuador⁵⁹. In this programme, conditions were not enforced but programme officials and media campaigns stressed the importance of school enrolment and many households believed that there were conditions attached to the transfers. Data from the evaluation survey showed that the proportion enrolled was higher amongst children from households that believed conditions were attached.

Evidence from rigorous studies of CCTs in middle-income countries suggests that these interventions can have significant positive effects on education and child health outcomes. The quality of evidence regarding the positive effects of CT programmes is more limited. Furthermore, there is a need for large, rigorous studies of CT and CCT programmes in low income, high HIV prevalence settings, especially given the growing interest in cash transfer programmes within the international development community and the increasing number of governments and organisations considering implementing these programmes. In particular, it remains unclear whether the enforcement of conditions would be ethical, feasible or effective amongst vulnerable households in low income settings. The study proposed in this protocol is designed to help fill this gap in the evidence base.

Principal investigators

Constance Nyamukapa, Laura Robertson, Phyllis Mushati, Shungu Munyati, Simon Gregson

Main centres

Biomedical Research & Training Institute (BRTI), Zimbabwe; Imperial College London.

Contact details

Laura Robertson

Department of Infectious Disease Epidemiology

Imperial College London

St Mary's Campus

Norfolk Place

London W2 1PG.

Telephone: 020 7594 3288

Email: l.robertson06@imperial.ac.uk

Aim

The aim of the Manicaland Cash Transfer Trial is to measure the health, education and social effects of cash transfers (unconditional and conditional) on children living in vulnerable households in eastern Zimbabwe.

The primary objectives of the trial are as follows:

1. To determine whether cash transfers can increase the percentage of vulnerable children aged 0-4 years with a birth certificate;
2. To determine whether cash transfers can increase the percentage of vulnerable children aged 0-4 years with up-to-date vaccinations; and
3. To determine whether cash transfers can increase the percentage of vulnerable children aged 6-12 years attending primary school at least 80% of days per month.

Design

Since cash transfers are provided at the community-level and it would be logistically challenging and socially disruptive to provide transfers to randomly selected individuals within communities, we will employ a cluster randomised controlled trial design. The Biomedical Research and Training Institute (BRTI) and Imperial College London have been conducting a cohort study investigating HIV and sexual behaviour in 12 study sites in Manicaland province, eastern Zimbabwe – a predominantly rural area – since 1998. The sites represent four socio-economic strata – subsistence farming areas, roadside trading settlements, large-scale agricultural estates (tea estates and forestry estates) and small towns. Due to funding limitations, only ten of these sites will be involved in the Manicaland Cash Transfer Trial.

In cluster-randomised trials, the number of randomisation units is relatively small. This means that randomisation may not always ensure comparability across the intervention groups - i.e.

intervention and control groups may differ, with respect to important confounding variables, by chance. Matching on factors that are correlated with the outcome(s) of interest, prior to randomisation, can help to ensure comparability and thereby increase the power and precision of the trial. The study sites in Manicaland comprise four types of socio-economic strata – small towns, agricultural estates (tea and forestry estates), roadside trading settlements and subsistence farming areas. These sites will be split into three homogenous areas providing a total of 30 clusters that will form ten matched triplets. One site from each matched triplet will then be randomly assigned to one of the three study arms – the conditional cash transfer arm (CCT); the unconditional cash transfer arm (CT); and the control arm. It is hoped that socio-economic strata will be highly correlated with the primary endpoints.

Data on the primary endpoints will be collected using a rapid, baseline census of all households in the study clusters. A trained research assistant will administer a questionnaire (in the local language - *Shona*) to the most senior, available member of each household. Local guides will ask representatives from all households to convene at central meeting points (census zones) within reasonable walking distance of the respondents' homes, on specific days. Each zone will be visited on at least two days, separated by approximately a week, to ensure the enumeration of all households - i.e. to reduce the number of missed households. The household members will be provided with bars of soap as a gesture of good will for taking the time to complete the survey. The census and data verification will take approximately 5 months to complete. The cash transfer programmes will commence, in the intervention arms, shortly after completion of the baseline census. A similar follow-up census will be conducted two years after the initiation of the intervention.

Inclusion and exclusion criteria

Important causes of household vulnerability were identified using analyses of national data from Zimbabwe (Zimbabwe National OVC Baseline Survey 2004/05⁶⁰), regional data from Manicaland (Manicaland HIV/STD Prevention Study 2003/05⁶¹) and focus groups conducted with community members and various other stakeholders during a feasibility study conducted in

2007⁶². These data and other practical considerations informed the development of selection criteria for eligible households.

A household will be defined as individuals that live within the same homestead and eat from the same pot. A household will be defined as vulnerable and thereby eligible for inclusion in the programme if there are children aged under 18 years resident in the household and it is not in the least poor quintile of households at baseline (defined below) and the household satisfies one or more of the following conditions:

- Household is in the poorest quintile of households at baseline (defined below);
- Household contains one or more orphans at baseline;
- The household head is under 18 years of age at baseline;
- Household contains a chronically ill member;
- Household contains a disabled member.

Households already receiving cash transfers for OVC will not be eligible for inclusion in the pilot programme but we believe that the number of such households will be very small.

Data will be collected, during the baseline census, on household assets (fixed and movable), age of household head, disability and chronic illness among household members, and the orphan status of children resident in the household. We will also enquire about any financial support the household receives and the source of this support. The household asset data will be used to create a wealth index for each household using a simple summed score of asset ownership and the poorest 20% of households will then be identified based on this index. The summed score index has been developed and validated using data collected in Manicaland and has produced similar results when tested against wealth indices based on more complex methods (e.g. multidimensional scaling analysis)⁶³.

The cash transfer intervention will be delivered by a local NGO called Diocese of Mutare Community Care Programme (DOMCCP). Following the baseline census, BRTI will generate lists of all households in the study clusters, along with their status with respect to the various

eligibility criteria. These lists will be passed to DOMCCP who will then undertake a community-based targeting process. Small groups of community leaders, including village chiefs, village heads, councillors and other representatives nominated by the community during sensitization meetings (where the project and its aims will be explained to the local communities) will meet and perform a wealth ranking procedure. The groups, led by DOMCCP, will be asked to define characteristics of households that are “poorest”, “poor”, “average”, “less poor” and “least poor”. Using these characteristics as a guide, the groups will then rank the households on BRTI’s household lists by assigning each household to one of the categories listed above. Equal numbers of households will be assigned to each category and thus the poorest 20% will be identified.

Larger community meetings will also be held to go through the other data on the checklists and to verify its accuracy. The members of each of these groups will be familiar with the households in their area. Thus the community-based targeting will act to validate the baseline census information and to ensure complete enumeration of vulnerable households in the study clusters. In order to ensure that the most vulnerable households are targeted and to reduce potential for corruption, households must be identified as eligible in the BRTI census and in the community-based targeting exercise in order to qualify for inclusion in the CT programme. BRTI, DOMCCP and committees of local stakeholders will produce the final list of eligible beneficiaries in each cluster. During the trial, households that do not qualify at baseline but whose conditions later change such that they become eligible to participate in the pilot project will not be able to enrol. Households that relocate outside of the project areas during the follow-up period will no longer be eligible to be enrolled in the programme. Enrolled households will be monitored by DOMCCP and information about children entering or leaving the households will be collected. Thus, the amount of money payable to a household will change if the number of children in the household varies over the study period and if it no longer contains any children, the household will be removed from the programme (i.e. it will no longer receive transfers).

We will be carrying out extensive community sensitization activities alongside the community targeting process. Large public meetings will be held to explain the aims of the trial, the reasons for our methodology and also the plans for the targeting. The representatives that will be

involved in the community-based targeting will be selected at these meetings. We hope that this transparent approach will avoid possible conflicts arising.

Intervention

Eligible households, in the intervention clusters, will be approached by DOMCCP and enrolled into the Cash Transfer Programme. The details of the intervention, and the responsibilities of the beneficiary households, will be explained, in detail, during the enrolment process. A household representative (who will take responsibility for collecting the cash transfers) and a deputy representative will be nominated from within each household during the enrolment process and identification cards will be issued. DOMCCP will encourage households to appoint women, preferably primary caregivers, as representatives, although any household member can be a representative.

Each eligible household in the intervention clusters will receive payments, every two months, of US\$18 plus US\$4 per child in the house up to a maximum of 3 children - i.e. transfers will vary from \$22 to \$30. The transfers will be in US dollars as this has been identified as the most convenient currency for the beneficiaries. Cash will be taken to pay points, within a reasonable walking distance of the beneficiaries' homes, on a designated day every 2 months for disbursement to the beneficiaries. A timetable of cash disbursement days in each cluster will be prepared and distributed amongst beneficiary households and, prior to each disbursement, a network of local workers and volunteers will circulate information in the communities regarding the time and location of the next distribution. It will not be necessary to be literate to acquire information about the dates and locations of the cash distributions. The household representative will bring their identification card to the pay point, on the specified day, to sign for and collect the cash. Those unable to sign their signature when collecting the cash can use fingerprints. These disbursements will be witnessed by DOMCCP and their team of local volunteers, who will be extremely familiar with the local households in the area. If the household representatives are not available, another household member that is known within the community may attend instead. In this instance, payments must be authorised by two DOMCCP representatives. Any uncollected transfers will be made available to the household during the next disbursement. If the

money remains uncollected for a second time, without any explanations, then it will be forfeited. DOMCCP staff and their local volunteers will follow up on households that have missed payments. At the pay-points, household representatives will also be asked to report newborn children/deaths and in/out-migration of children so that the amount of their transfer can be adjusted appropriately.

Households in the CCT arm will be monitored for compliance with the following conditions:

- An application for a birth certificate must be made for all children under 18 years in the household who do not already have a birth certificate, including all newborn children within 3 months of birth.
- All children under 5 years in the household must be up-to-date with vaccinations.
- All children under 5 years must attend a growth monitoring clinic twice per year.
- All children 6-17 years in the household must have attended school at least 90% of days in the last month.
- At least one adult from each household must have attended at least 2 of the 3 most recent parenting skills classes.

Compliance check meetings will be held every 2 months, 2 weeks prior to the next cash disbursement. One member of each household – not necessarily the household representative, although this will be encouraged – will be required to attend these meetings. Compliance cards will be given to households in the CCT sites during the enrolment process. These will be signed by service providers when beneficiary households access services. The stamped/signed cards will then be brought to the compliance check meetings to be checked by DOMCCP and their team of volunteers. If a household fails to attend a compliance check meeting then they will forfeit their next transfer. Such households will be followed-up to ensure that they are able to attend future meetings. Some households will be exempt from certain conditions (e.g. if they have no school-age children) and this will be established during enrolment. Other initial reasons for households defaulting on conditions will also be discussed during enrolment and these will be addressed if possible (e.g. if a disabled child requires a wheelchair to attend school then this should be provided by the project). We believe that such instances will be rare. If a household gives a

reasonable reason for failing to meet conditions at a compliance check meeting (e.g. a child is too sick to attend school), the two weeks prior to cash disbursement will be used to verify this reason.

Information on the compliance of households is also available from records kept by service providers, although collecting this information for all households would be administratively intensive. To validate the compliance cards, spot checks will be performed on a random sample of household beneficiaries, from a sample of CCT sites, following each compliance check – i.e. the information on a sample of compliance cards will be checked against service provider records. The possibility of spot checks will be discussed with the households during enrolment. If a household is found to be non-compliant during a spot check, they will be flagged as a defaulter and will enter the standard defaulter pathway (see below). If a household loses their compliance card, they will be issued with a new one and their previous compliance history will be checked with the relevant service providers prior to disbursement of the cash.

There will be a 6-month grace period at the start of the programme where conditions will be monitored but there will be no repercussions for non-compliance. After this period, if a household does not comply with conditions at the next check meeting, they will be offered advice and support by DOMCCP. If the household fails to comply at the next check meeting, it will be assigned to a community volunteer, who will help the household to manage their budget and comply with conditions. It is hoped that the use of these volunteers will be a rare occurrence. Small tokens of appreciation (e.g. food hampers) will be offered to the volunteers. If after 4 months (2 compliance checks) of receiving help from a volunteer, a household is still not meeting its conditions, the amount of their cash transfer will be reduced by 10%. If the household is compliant during both of these checks, then the volunteer will no longer be needed and will be removed. Following the reduction in the cash benefit, if the household remains non-compliant at the next compliance check (i.e. 2 months later), the volunteer will assume control of some or all of the cash to ensure that it is spent for the benefit of the children. The extent to which the volunteer will control the spending of the payments will vary according to the needs of the household and will be reviewed regularly by the Community Cash Transfer Committee, which will be made up of representatives from DOMCCP and other local stakeholders (e.g.

school representatives, child protection workers etc). A standardised evaluation tool will be used to monitor households that are assisted by a volunteer to assess whether this service is still required.

A standard agricultural package (e.g. seed and fertiliser) will be distributed in all sites including the control sites as a gesture of goodwill to all those participating in the study. Parenting skills classes (see below) will also be made available in all sites including the control sites.

Randomisation process

This will be done following completion of the rapid baseline census. The random allocation of clusters to the arms of the trial will be done at a public gathering using a simple, easily understood random process (e.g. drawing labelled balls out of an opaque bag). The aims of the research and the need for randomization will be explained thoroughly to the communities prior to the randomization procedure. This level of transparency should reduce conflict resulting from the trial and its intervention within the study communities.

Allocation concealment and blinding

Since randomization will be performed at the community level after baseline data collection has been completed, baseline data collection will be collected under perfect allocation concealment. Due to the nature of the intervention, it will not be possible to blind study participants during the follow-up census. Since the research assistants are familiar with the communities they are working in, it will not be possible to conceal from them which communities are receiving transfers. Statisticians will perform the primary analyses blind.

Primary and secondary endpoints

Data will be collected, during the baseline and follow-up censuses, on the following co-primary endpoints (please see Rapid Baseline Census Questionnaire):

1. Proportion of children under 5 years in vulnerable households that have a birth certificate;
2. Proportion of children under 5 years in vulnerable households that have up-to-date vaccinations; and
3. Proportion of children aged 6-12 years that attended primary school 80% of days in the last month.

Verification of birth registration and vaccination status will be possible to some extent by checking birth certificates and child health cards (issued by health clinics). Local guides will tell the households that they should bring these to the census check points when they come to be interviewed. Attempts will be made to verify a sample of responses with service provider records (i.e. registers at schools, clinics and birth registration offices). The primary endpoint data will also be validated using information collected during the routine spot-checks of household compliance in CCT clusters and similar spot-checks carried out in CT and control clusters. During compliance monitoring in the CCT clusters, information regarding household compliance with conditions will be recorded by DOMCCP. These data will be compared with the census data.

At follow-up, extra questions will be added to the census questionnaire to capture information on secondary outcomes. This data will include the following:

- a. Illness in the last two weeks amongst children aged 0-4 years and 5-17 years.
- b. Attendance at a growth monitoring clinic in the last 6 months for children aged 0-4 years.
- c. Consumption of protein in the last week amongst children AGE
- d. Number of meals eaten the previous day in the household
- e. Having a pair of shoes amongst children aged 5-17 years.

- f. Hours per week spent working (not at school) amongst children 6-17 years
- g. Repeated grades at school amongst children aged 6-17 years
- h. O-level passes amongst 15-17 year olds
- i. Grade 7 passes amongst children AGE
- j. Member of household attended parenting skills class

There will also be data collected on the way in which the cash transfers have been spent by the households, awareness of and ability to meet conditions, level of satisfaction with the CT programme and information about other sources of funding/support to the household.

Detailed accounts will be kept by DOMCCP and their partners as they are delivering the CT and CCT interventions. They will also be undertaking their own monitoring and evaluation process, which will include entering data relating to the enrolment process, cash distribution, compliance monitoring and any spot checks into a database, which should provide information on a variety of process indicators e.g. the percentage of households eligible to receive cash that actually collect their cash at each dispersion, the percentage of eligible households who were properly enrolled in the programme and levels of compliance with the conditions of children and households, over time, in the CCT arm of the trial. This data should provide real time information about any problems with the implementation of the programme, which in turn should allow solutions for these problems to be implemented as the programme is progressing.

There is a parallel study being conducted by BRTI in the Cash Transfer Trial study sites during the study period – the Manicaland Child Cohort Study (MCCS). Funding has been secured for two rounds of the survey and the first round of data collection will begin in October 2010. Children aged 2-14 years (and caregivers) from one sixth of households in the CT trial sites and adolescents aged 15-17 years from two thirds of households in the trial sites will be enumerated in the MCCS and approximately 50% of these households will be enrolled in the CT programme – in CT, CCT or control communities. The main purpose of this study is to investigate risk factors for HIV prevalence and incidence in children aged 2-14 years and ethical approval has been sought for this study separately from the Imperial College Research Ethics Committee (reference number ICREC_9_3_13) and the Medical Research Council of Zimbabwe research

ethics committee (MRCZ/A//681). Since it will take approximately two years to complete each round of the MCCS survey, households will have been enrolled in the CT programme for varying periods of time when they complete the MCCS questionnaires. Thus the data collected will also be used to assess the effects of the Cash Transfer Programme on various aspects of child wellbeing including a wider range of health, nutrition and education outcomes, psychosocial wellbeing and HIV risk (including sexual behaviour data) – please see attached Child Questionnaire. It will be possible to compare children in intervention and control communities over time and to examine the different effects of long and short-term enrolment in the CT programme.

Negative effects reporting and quantification

The local network of community workers and volunteers delivering the cash transfer programme will be familiar with the majority of the beneficiaries and will have regular contact with many of them. Thus this network should be able to monitor for any negative effects. In particular, in the CCT arm of the trial, community workers and/or volunteers will follow-up with households that are not meeting their conditions and will offer these households help and support to overcome any challenges they are facing (see pg 11-13 for more information about this).

As part of our ongoing monitoring and evaluation activities we will be checking official records of service providers; monitoring the number of eligible households collecting their cash; and carrying out qualitative work with service providers, beneficiaries, those delivering the intervention and other community members. Hopefully these sources will provide information about problems that might occur within the programme and will help us to develop procedures to fix the problems and to avoid any similar issues should the intervention be rolled out on a larger scale. Our follow-up survey will also collect data on the beneficiaries' satisfaction with the cash transfer programmes. The Cash Transfer Committee, which comprises representatives of DOMCCP and various local stakeholders, will meet regularly (at least every two months or more frequently if necessary) to discuss the progress of the cash transfer programmes. These meetings will provide an opportunity for discussion of issues relating to negative effects of the cash

transfer programmes and an opportunity for finding solutions to these problems as the programmes are progressing.

At the cash distribution pay points there will be a programme representative available to answer questions and concerns from beneficiaries or other community members. These will either be addressed on the spot or fed back to the Cash Transfer Committee to discuss at their next meeting. Beneficiaries or community members may also make complaints directly to any member of this committee at any time. If a beneficiary or community member is not satisfied with the decision made by the committee regarding their complaint, they can request an appeal. Appeals will be considered and decided upon by a sub-group of the Cash Transfer Secretariat, which comprises representatives of DOMCCP, BRTI and Catholic Relief Services (CRS) – an international NGO that coordinates the work of various local partners, including DOMCCP, in Zimbabwe.

Finally, there are Child Protection Committees that comprise workers and volunteers with expertise in dealing with child protection issues and that meet regularly in Manicaland. If there are harmful effects of the programme within a household (e.g. conflict/domestic violence) or another type of problem is encountered during the programme (e.g. abuse or neglect), these problems can be referred to the committees.

Sample size and power calculations

Power calculations⁶⁴ were performed for all three primary outcomes. Baseline estimates for these outcomes and the intra-cluster correlation coefficients⁶⁵ were calculated using national data (oversampled for rural and socioeconomically disadvantaged urban areas) from the Zimbabwe Baseline OVC Survey⁶⁰. Data on the number of children in the area, the average number of children in a given age range per household, the number of eligible households in the area and the size of the clusters (maximum estimates of the sizes of the clusters will be used to be conservative) were estimated using data from the third round of the Manicaland HIV/STD Prevention Study (2003/2005)⁶¹. A previous community randomised trial conducted in the area

had a follow-up rate of 55% amongst adults aged 15-54 years in the intervention arm and 56% in the control arm over three years⁶⁶. The majority of losses were due to migration/dissolution of households, although some losses were due to the death of participants. In this trial we will be targeting children, a more stable population, and our follow-up period will be two years. We assume a follow-up rate of 75%.

Assuming 80% power and a two sided 0.05 significance, Table 1 shows the power calculations for each of the three co-primary outcomes⁶⁴. The “target prevalence” is based on the minimum improvement from the baseline prevalence that we would be powered to demonstrate, for each indicator, given the available sample size. These were presented to various stakeholders with experience of researching and delivering social welfare interventions in Zimbabwe (UNICEF, CRS, BRTI) and were concluded to represent feasible targets. The sample size is based on a two-armed trial with an extra arm added to allow for the second intervention arm. This means the trial will be powered to compare either intervention arm with the control arm. The power to compare the CT and CCT arms will depend on the size of the difference in effect across these two arms of the trial. If the effects are similar, then power to detect differences will be reduced. However, detailed information on the logistics and costs of each intervention will be collected by DOMCCP and the ease, sustainability and cost-effectiveness of CT and CCT will be compared.

All children aged 0-4 years (for the first two outcomes) and aged 6-12 years (for the third outcome) in households deemed eligible at baseline will be enumerated in the baseline and follow-up censuses and will be included in the analyses. Newborns and in-migrants, not present at baseline, will be included in outcome indicator estimates at follow-up. Children who will age out of a given outcomes’ age range after two years will be included in the baseline prevalence estimates but not in the follow-up estimates. Similarly, children who will age into a given outcomes’ age range after two years will be included in the follow-up estimates of prevalence but not in the baseline estimates. When we calculated the minimum demonstrable effect of the interventions, we assumed that closed cohorts of children aged 0-2 years and 6-10 years, respectively, would be included in the final analysis (reduced by 25% to account for losses to follow-up). This may have produced an under-estimate of the available sample size since

newborns, in-migrants and those aging into and out of the indicator age ranges will also be included in the follow-up estimates of the primary endpoints.

Our study is structured with children nested within households nested within clusters. A small number of households (see Table 2) may have more than one child within the age range for one of the outcome indicators. In this event, one child per household will be sampled at random for inclusion in the final analysis. This has been taken into consideration in the estimates of the number of children per cluster and the average number of children per eligible household presented in Table 1.

The effects of matching according to socio-economic strata were ignored in the power calculations presented in Table 1. To ensure that our design has enough matched triplets to have sufficient power to detect the treatment effects in Table 1, we calculated the number of matched triplets required using Donner and Klar's formula for a matched study comparing proportions⁶⁴. Data on baseline and target prevalence are from Table 1. The average cluster size – reduced by 25% to account for attrition – was used in this calculation as this provides a more conservative estimate of the required number of triplets than the maximum cluster size used previously. The results are summarized in Figure 1. The co-efficient of variation is a measure of the between-cluster variation in the outcome variable⁶⁷. In an unmatched study, a reasonable estimate for the co-efficient of variation would be around 0.25⁶⁷. If matching is successful (i.e. the matching factors are correlated with the study outcomes and thereby reduce between-cluster variation in the outcome variables within each matched triplet) the coefficient of variation should be reduced and the power of the trial increased.

Our matched triplets have been constructed by dividing the existing study sites in Manicaland into three homogenous clusters. As stated previously, each study site is located in one of four possible socio-economic strata – subsistence farming areas, roadside trading settlements, large scale agricultural estates and small towns. Thus, our triplets will be matched on socio-economic strata. An analysis of data collected in a household census in Manicaland between 2003 and 2005 showed that socioeconomic strata was strongly associated with availability of a birth certificate amongst children aged 0-4 years ($p < 0.0001$; $N = 4693$). Using data from a previous

child cohort study in Manicaland, which oversampled orphans, it was found that socio-economic strata was significantly associated with school attendance ($p=0.031$; $N=435$) amongst children aged 6-12 years, but not with being up-to-date with all vaccinations ($p=0.270$; $N=61$) amongst children aged 0-4 years, although the sample size used for this latter statistical test was small (only 7 children were not fully vaccinated) and large variation across the socioeconomic strata was observed with respect to child vaccination status. This suggests that the matching factor (socio-economic strata) is associated with the study endpoints and therefore that the COV for the trial endpoints will be reduced below 0.25 (the value for an unmatched study)⁶⁷. Thus figure 1 indicates that thirty matched triplets are likely to be sufficient to detect the minimum effect sizes for each primary endpoint, assuming 80% power and 95% confidence.

Table 1: Sample size and effect size calculations for the Manicaland Cash Transfer Trial

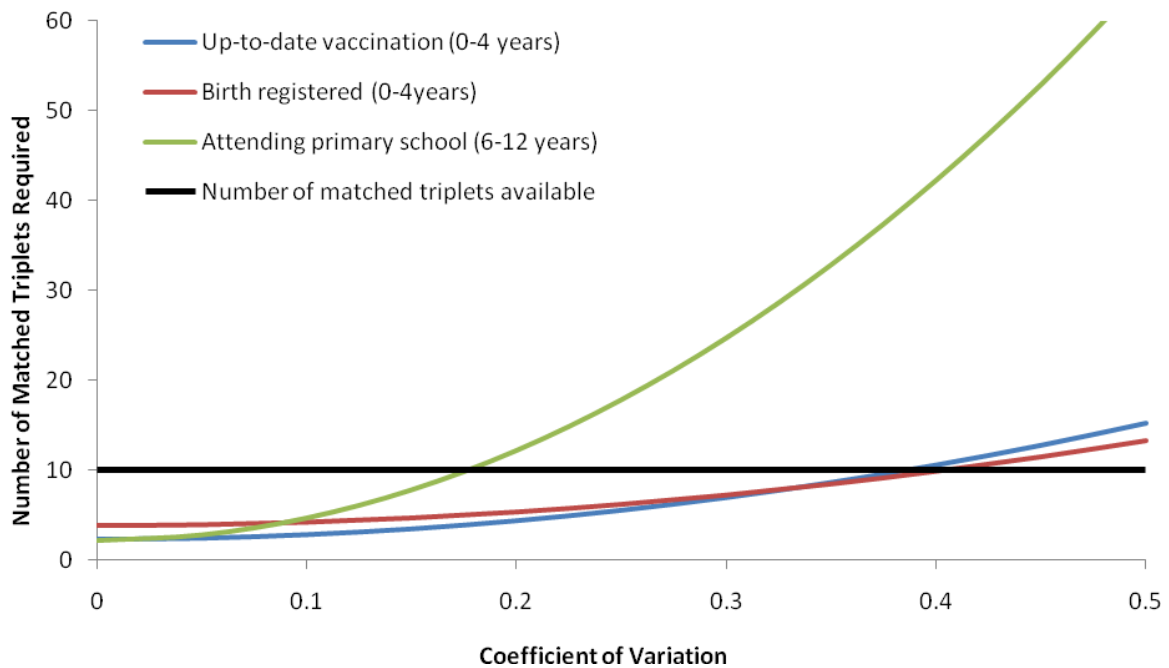
Endpoint	Baseline Prevalence	"Target" Prevalence	Estimated Number Per Cluster	Estimated ICC	Attrition Rate	Sample Size (n)	Average Number of Children per Eligible Household	Number of Households Required	Number of Households Available
Up-to-date vaccinations (0-4 years)	51%	81%	27	0.201	0.75	884	0.25	3527	3829
Vitamin A supplementation last 6 months (0-4 years)	35%	59%	27	0.105	0.75	947	0.25	3779	3829
Stunted* (0-4 years)	31%	15%	27	0.052	0.75	940	0.25	3750	3829
Underweight* (0-4 years)	21%	7%	27	0.052	0.75	894	0.25	3569	3829
Wasted* (0-4 years)	1%	0.1%	27	0.032	0.75	5796	0.25	23129	3829
Diarrhoea in last 2 weeks (0-4 years)	19%	5%	27	0.053	0.75	805	0.25	3211	3829
ARI in last 2 weeks (0-4 years)	7%	1%	27	0.014	0.75	861	0.25	3435	3829
Birth registered (0-4years)	35%	60%	27	0.107	0.75	917	0.25	3660	3829
Attending primary school* (6-12 years)	69%	87%	68	0.077	0.75	1965	0.58	3391	3829
Attending secondary school* (13-17 years)	56%	76%	53	0.084	0.75	1722	0.46	3712	3829
Has own pair of shoes (5-17 years)	40%	63%	97	0.105	0.75	2991	0.85	3511	3829

*Member attended school at any time in the current school year and was not absent for more than 2 consecutive weeks; †more than 2 standard deviations below the standard reference population [26] with respect to height-for-age z-score (stunting), weight-for-age z-score (underweight) & weight-for-height z-score (wasting); primary endpoints are shaded in grey.

Table 2: Percentage of eligible households with more than one resident child

Number of children in household	Children aged 0-4 years		Children 6-12 years		Children 13-17 years	
	Percentage	Cumulative Percentage	Percentage	Cumulative Percentage	Percentage	Cumulative Percentage
0	57.13	57.13	30.53	30.53	35.47	35.47
1	33.44	90.57	35.55	66.07	42.15	77.61
2	8.30	98.87	23.48	89.55	17.94	95.55
3	0.89	99.76	7.77	97.33	3.52	99.07
4	0.20	99.96	2.19	99.51	0.69	99.76
5	0.04	100.00	0.32	99.84	0.20	99.96
6			0.12	99.96	-	-
7			0.04	100.00	-	-
8					0.04	100.00

Figure 1: Effects of varying the coefficient of variation on the number of matched triplets required to adequately power the Manicaland Cash Transfer Trial



Statistical analysis plan

The primary analysis will be by intention to treat⁶⁴. A flow-diagram of households and children (by age) across the census rounds will be created indicating those followed-up, those lost to follow-up (with a breakdown of deaths, out-migrants and others where available), newborns, in-migrants and children aging out of and into the indicator age ranges. Socio-demographic characteristics and outcome indicators for the 3 arms will be compared at baseline to assess the success of the randomization. At each census round, when more than one child within an indicators' age range is present in a household, one of the children will be selected at random for inclusion in the analysis. For each primary endpoint, a linear regression model will be produced with cluster level prevalence of the indicator at follow-up as the dependent variable. The intervention group will be the independent variable and matched triplet, baseline prevalence of the indicator, and the cluster proportions/mean of any variables un-balanced at baseline will be added as covariates. For some of the secondary indicators – e.g. number of meals eaten in the household in the previous day – we will compare cluster means rather than the cluster proportions in the linear regression model.

We will check that the assumptions for linear regression are not violated by our data before conducting each analysis. If, for example, the cluster proportions are not normally distributed, we will perform a suitable data transformation before conducting the analysis. For non-sensitive, socio-demographic indicators, the numbers of missing values in the Manicaland study are typically very low (usually less than 3%), therefore those missing data will be ignored in the calculations of cluster level proportions/means. Numbers of missing values will be indicated in the final report.

As stated previously, data on other secondary indicators will also be collected in the Manicaland Child Cohort Study (MCCS) from a sample of households participating in the trial. The primary aim of this study is to estimate HIV prevalence and incidence amongst children in Manicaland and to investigate possible modes of transmission. Data will be collected on a variety of other variables including nutritional indicators, growth monitoring attendance and psychosocial distress and analyses of these data will allow further investigation of the effects of the cash

transfer programme. These analyses will not be presented in the initial publication of the primary trial results and plans for these analyses have not yet been finalised. **Ethics committee approval**

Full approval was granted from the Imperial College Research Ethics Committee (Reference number: ICREC_9_3_10), the Biomedical Research and Training Institute's Institutional Review Board (AP81/09) and the Medical Research Council of Zimbabwe (MRCZ/A/1518).

Informed consent form and information sheet

For the baseline and follow-up census questionnaires, each respondent will be given a consent form, which will provide information about the trial. They will be invited, by a research assistant, to join the study and will be requested to sign the consent form. The respondent will be informed that the information they provide will be kept strictly confidential and, during the follow-up census, they will be told that any answers they provide will not affect their right to be enrolled in the cash transfer programme, if they are eligible, or affect the amount of their transfers (if they are in the conditional cash transfer arm of the trial). The research assistants will read out the information sheets to any participant that is unable to read and understand the information sheets. At the start of all interviews, the research assistants will explain the study and answer any questions. All information sheets and consent forms have been prepared according to MRCZ guidelines and will be translated into *Shona* (the local language). Please see attached informed consent form.

Children living in child-headed households are particularly vulnerable and, in such cases, there is likely to be no adult available to complete the census questionnaire. If a child respondent is aged 15 years or over, then the same procedure as outlined above will apply and the research assistant will take extra care to explain the study carefully to the child. If a child is under 15 years, then consent will be sought from a responsible adult associated with the household (in practice, there is often an adult, usually a relative, who lives nearby and helps with the running of the household). Consent will also be sought from the child household head. A child-friendly consent form/information sheet will be used when appropriate (i.e. for children 12 years or younger) –

please see attached form. Research assistants will be trained to thoroughly explain the study and its aims to children and young adolescents.

Interim analyses and stopping rules

Official interim analyses of the primary outcomes with stopping rules are not planned. However, analyses of data from routine M&E (progress data, outcome data and financial information), the baseline and follow-up rapid censuses, and qualitative research will be reported in annual progress reports. Analyses of data from these various sources, together with information from DOMCCP from the field and from the complaints process, should allow any problems with the programme delivery and/or evaluation to be identified and addressed.

Independent data monitoring committee

There will not be an official data monitoring committee. However, there is a transparent stakeholder structure with several different organizations and individuals involved in monitoring data and other information generated during the delivery and evaluation of the programme.

Indemnities

We have negligent and non-negligent harm insurance through our sponsor – Imperial College London. Zurich Municipal Policy Number NHE01CA100013.

Publication plan

Once data collection is complete for the follow-up census, the final analysis will be published in a detailed implementation and impact report. Reports will be made available to government, donors and other partners and stakeholders. The results will also be disseminated within the local study communities, published in peer-reviewed scientific journals, and presented to the scientific and development community at conferences and other events. The interim analyses will also be published in annual progress reports which will be circulated amongst various stakeholders.

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World Bank

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Finishing date

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Reporting date

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