STUDY PROTOCOL

Integrating the delivery of health and development interventions: Assessing the impact on child survival in sub-Saharan Africa

The Millennium Villages Project
The Earth Institute, Columbia University
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ACT  | Artemisinin Combination Therapy
AIDS | Acquired Immunodeficiency Syndrome
CHW  | Community Health Worker
DHS  | Demographic and Health Surveillance
EmOC | Emergency Obstetric Care
EPI  | Expanded Program on Immunization
GPS  | Global Positioning System
HH   | Household
HIV  | Human Immunodeficiency Virus
IMCI | Integrated Management of Childhood Illness
IRB  | Institutional Review Board
ITN  | Insecticide Treated Nets
LLITN| Long-lasting Insecticide Treated Nets
LSMS | Living Standards Measurement Survey
MDG  | Millennium Development Goal
mHealth | Mobile Health
MNCH | Maternal-newborn-child health

MVIS | Millennium Village Information System
MVP  | Millennium Villages Project
NGO  | Non-governmental Organization
OECD | Organization of Economic Cooperation and Development
ORT/S| Oral Rehydration Therapy/Solution
PMTCT| Prevention of mother-to-child transmission
RCT  | Randomized Controlled Trial
RDT  | Rapid Diagnostic Test for malaria
SBA  | Skilled Birth Attendant
STD  | Sexually Transmitted Disease
TB   | Tuberculosis
TREND| Transparent Reporting of Evaluations with Non-randomized Designs
UN   | United Nations
UNICEF| United National Children’s Fund
UNDP | United Nations Development Program
VSAS | Verbal and Social Autopsy System
WHO  | World Health Organization
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Integrating the delivery of health and development interventions:
Assessing the impact on child survival in sub-Saharan Africa

I. Summary

Despite the priority placed on reducing child mortality within the Millennium Development Goal framework, an estimated 8.8 million child deaths take place each year. Mortality rates are highest in sub-Saharan Africa, where one in six children die before their fifth birthday. Over two-thirds of these deaths are entirely avoidable through the delivery of simple, effective and low-cost interventions. Weak health systems, an overemphasis on facility-based service delivery, and access barriers including cost, transport, and communication are critical obstacles to achieving universal coverage with essential health interventions. Equally important has been insufficient progress in addressing wider social and economic vulnerabilities outlined in the MDG framework such as poverty and hunger, low levels of education, and gender-based inequalities which are the foundation for sustainable gains in child survival.

The Millennium Villages Project (MVP) involves the coordinated delivery of a package of scientifically-proven health and development interventions with the aim of accelerating progress towards MDG targets. Villages are drawn from ‘hunger hot-spots’ across diverse agro-ecological zones, reflecting a range of challenges to income, food production, disease ecology, infrastructure and health system development. The project operates across 80 villages and 14 clusters in 10 sub-Saharan African countries covering an estimated 500 000 people.

One critical aim of project is to improve child survival (MDG 4). In order to do this, MVP is implementing a model delivery system for introducing high-impact interventions at the village level. In the health sector, it emphasizes integrated delivery of free minimum package of maternal-newborn-child health services, with goal of achieving universal coverage through inputs to referral hospitals and primary care clinics, alongside providing direct support to households through a cadre of paid-professional community health workers. As addressing broader social and economic vulnerabilities are critical for child survival, MVP coordinates inputs from multiple sectors including agriculture, business development, education and infrastructure. Inputs are cost-limited, with a modest annual ceiling of $110 per person per capita across all sectors ($40 for health) sustained over a 5-10 year period. Finally, the model is a locally-driven partnership between communities, local governments, external stakeholders and the project itself.

This protocol presents a framework and methodology for evaluating the effects of the MVP model on child survival. While specific interventions contained within the package have proven efficacy, assessing their impact, the feasibility of delivery, and their cost are imperative given the pressing challenges to child survival in much of the region. First, a pair-matched community intervention trial employing a cluster-level analysis will assess the impact of the MVP model on child mortality over a 5 year period. Second, a portfolio of implementation science will examine feasibility by documenting the specific components of the intervention package; their timing and sequence; key contextual barriers and facilitators to implementation; and potential synergies achieved from the integrated multi-sectoral approach. Finally, an economic costing study will assess the total cost of the interventions, as well as the relative contribution of project partners towards the $110 per capita annual cost ceiling. Taken together, this assessment will test the hypothesis that rapid gains in child survival in sub-Saharan Africa are achievable through a broad based MDG approach, generating lessons for replicability, scale-up and transfer to other contexts.
II. Background

Child mortality in sub-Saharan Africa

At the Millennium Summit in September 2000 the largest gathering of world leaders in history adopted the UN Millennium Declaration, committing their nations to a new global partnership to reduce extreme poverty and to address a series of time-bound health and development targets. Among these Millennium Development Goals (MDG) is a commitment to reduce child mortality by two-thirds between 1990 and 2015 (1). Despite this, each year nearly nine million children die before their fifth birthday, largely from preventable causes (2). More than one third die in the first month of life, usually at home, and without access to the essential health services and basic commodities that could save lives (3).

Important progress has been made in reducing child mortality in a number of settings. Since 1990, more than 60 countries have reduced their under-five mortality rate by 50 per cent – suggesting dramatic improvements can be rapidly attained (2). However, progress in sub-Saharan Africa has been slow. At present, child mortality rates are 26 times higher than industrialized countries, with one in six children dying before the age of five (2, 4). The region as a whole has experienced only a 12% decline since 1990 (5), with the absolute numbers of child deaths actually rising (6). No country is on track to achieve the goal of a two-thirds reduction in child mortality by 2015 (MDG 4). In ten countries, under-5 mortality rates have actually increased since 1990, while in another 19 progress has been so slow that at the current pace of change MDG targets will be missed by more than 35 years (2, 7).

Causes of child mortality

In this protocol, the term child mortality refers to deaths taking place between birth and five years, measured as the under 5 mortality rate. The under 5 mortality rate measures the probability (expressed as a rate per 1,000 live births) of a child born in a specified year dying before reaching the age of five, subject to current age-specific mortality rates (8). The immediate causes of child deaths are relatively few. Pneumonia (19%) and diarrhea (17%) are common in all settings (9, 10), while malaria (8%) and AIDS (3%) contribute substantially in endemic areas (2, 11, 12). Poor nutrition contributes to over half of child deaths (11, 12). Approximately 40% of under 5 deaths take place among newborns and occur during the first month of life – with nearly half in the first 24 hours (2, 13). Major preventable causes of neonatal mortality include severe infections, birth asphyxia, complications of prematurity, and neonatal tetanus (2, 11-14). Within sub-Saharan Africa, there has been no measurable fall in neonatal mortality in the past decade (13).

More broadly, child mortality is also a consequence of the wider social and economic vulnerabilities faced by poor households and poor communities. Deficiencies in food, education, and income are compounded by limited access to adequate housing, water and sanitation, transport and communication services (2, 12, 13, 15-19). Taken together, these ‘poverty traps’ act both to increase exposure and reduce resistance to disease and avoidable death (19-21).

Interventions to reduce child mortality
Global experience suggests that over two thirds of child deaths are entirely preventable (2, 22). A number of recent reviews assess the evidence and potential impact of simple and low-cost interventions to reduce child mortality (2, 12, 13, 22-24). Two interventions alone — oral rehydration therapy (ORT) and breastfeeding, were each estimated to prevent over 10% of deaths (22). Six additional interventions could each prevent a further 5% of child deaths. These include long lasting insecticide treated bednets (LLITNs) and artemesinin-based combination therapy (ACT) for the treatment of malaria, antibiotics for neonatal sepsis and pneumonia, complementary feeding and zinc supplementation (22). Most promising interventions can be delivered at the household level, with limited need for external support.

In relation to neonatal deaths, nearly three quarters can be prevented through basic antenatal care; a skilled birth attendant to ensure clean delivery and access to obstetric care; immediate breastfeeding; keeping newborns warm and dry; neonatal resuscitation; special care of low-birth weight infants; and treatment of infections (24). Thus, progress towards reducing child mortality is less about new vaccines, drugs, or technology and more about putting proven interventions into practice (2, 22).

**Challenges and structural obstacles**

Numerous challenges have been highlighted that hamper progress towards child survival in sub-Saharan Africa. First, weak and deeply under-financed health systems have been unable to introduce and sustain the delivery of critical interventions (25). Within poor countries, further distortions have been created by disproportionate resources flowing to specialized curative care; an overemphasis on service delivery through fragmented vertical disease-specific programs, and; unregulated commercialization of health care (26). Second, factors such user-fees, distance, and transport create significant access barriers. It is estimated that over a 100 million people fall into poverty each year due to out-of-pocket health expenses (27). Finally, sustainable gains in child survival are unlikely to be achieved in the absence of progress towards wider MDG targets for economic well-being, education, gender and the environment. These issues have been the focus of a recent WHO commission (28) and are echoed within the MDG framework, where the interdependence of the MDGs and their synergistic effects on health have been repeatedly emphasized (2, 29, 30).

**Strategies to improve in child survival**

Global experience over the past two decades has put forth a number of advances that, if implemented, carry the potential to rapidly accelerate gains in child survival.

1) **Integrated models**: As highlighted above, there is substantial evidence documenting the positive effects of a host of health and nutrition interventions on child survival (12, 23, 25, 31). Delivering these components together as a single package has the potential to greatly enhance coverage. A 2008 UNICEF report on child survival suggests "packaging a range of evidence-based, cost-effective interventions has the potential to be among the most effective methods to accelerate improvements in maternal, newborn and child health (MNCH) (2)."

While integration has intuitive appeal as a potentially efficient and cost-effective strategy, establishing systems to support their effective delivery are equally important (2). Recent post-mortems of the Integrated Management of Childhood Illness (IMCI) – a global initiative that took place in 100 countries over the past decade, suggest that
integrating services at the facility-level alone contributed only modestly to gains in child survival (32, 33). Rather, their experience highlighted the need to design and test novel mechanisms to strengthen the continuum of care between clinics, referral hospitals and vulnerable households, while simultaneously working with communities to stimulate demand for care. Emerging evidence suggests Community Health Workers (CHW) might be one potential strategy to extend the reach of proven interventions (23, 34, 35).

Despite the urgency of getting life-saving services to those that need them most, there are major shortcomings in the design and testing of scalable delivery systems to improve child survival. A recent Cochrane review of primary care systems noted few evaluations of integrated service delivery models, and not a single rigorous study of an intervention designed to stimulate community demand for services (36). These findings echo a recent assessment of child survival funding priorities, which notes while 97% of grants were allocated for the design and testing of new technologies only 3% support interventions to improve the delivery of essential services (37).

2) Universal coverage: Coverage is defined as ‘the proportion of people in a population who need a service and receive it’ (4). While there are a number of potential strategies for improving coverage with maternal-newborn-child health (MNCH) services, a critical first step involves removing financial barriers at the point of service. Recent studies suggest simply eliminating user fees can save about 233 000 child deaths a year in 20 sub-Saharan African countries (38).

Countdown 2015 is an international effort to track coverage with MNCH interventions in 68 priority countries where 98% of maternal and child deaths take place (39). Their 2008 report suggests significant progress has been made in improving coverage with interventions that can be delivered through single contacts or campaigns such as vitamin A or immunizations, in addition to interventions for high-profile diseases such as HIV. However, interventions that required ongoing engagement with well-functioning health systems, such as treatment for pneumonia, diarrhea, malaria, or malnutrition consistently performed poorly. In addition, progress in areas where behavioral and social changes were required has been insufficient, including early initiation of breastfeeding, proper complementary feeding, and contraceptive use (39, 40). Developing innovative strategies to address and monitor progress towards these ‘coverage-gaps’ are urgently required if rapid progress in reducing child deaths is to be achieved.

3) Addressing wider MDG targets: There is broad recognition that improving child survival will require efforts that extend beyond health services and health systems. Deaths from diarrhea, pneumonia and malnutrition are clearly linked to lack of access to basic water and sanitation facilities, indoor air pollution, overcrowding, poor housing quality and poverty (12, 16-19, 41). Child health is also directly related to the health and well-being of mothers, which must be supported through access to antenatal care, safe-delivery and family planning services, alongside wider support for female education and gender empowerment (2, 16, 23). Addressing multiple entry points simultaneously has the potential to create synergies over and above gains derived from single sector efforts. A recent cluster randomized trial documented encouraging evidence of synergies between health and economic interventions, suggesting multi-sector approaches can generate a wider range of benefits than single-sectors acting alone (42). While these findings may seem intuitive, the design and testing of complex
interventions that address wider MDG targets with the aim of improving child health remain at an early stage of development. Further innovation and operational research is urgently required.

**Summary**

While persistent challenges to child survival remain in much of sub-Saharan Africa, most child deaths can and must be prevented. We suggest that progress toward MDG 4 is less about innovative new technologies and more about developing real-world systems to more effectively deliver interventions that have been proven to work. Entry points include: integrating the delivery of a package of essential maternal-child health services; working to achieve universal coverage by providing free basic care, reducing access barriers, expanding coverage at the household level; stimulating community demand for services; and simultaneously intervening to address wider MDG targets in poverty reduction, gender equity, education and the environmental - which together provide a solid foundation for child health.

**III. Intervention Overview - Millennium Villages Project, the MDGs and Child Mortality**

The Millennium Villages Project (MVP) is a partnership between the Earth Institute at Columbia University, the NGO Millennium Promise, and the United Nations Development Program (UNDP). MVP involves the coordinated delivery of proven health and development interventions with the aim of accelerating progress towards MDG targets (43). Critical among the project’s priorities are efforts to reduce child mortality. 80 villages from 14 clusters in 10 sub-Saharan African countries have been selected as Millennium Villages, with total population coverage of approximately 500,000 people (Figure 1). Clusters have been drawn from a diversity of agro-ecological and economic zones, each designated 'hunger hot spots' with rates of childhood undernutrition of at least 20% (Table 1).

Figure 1: Agroecological Map of Millennium Village Sites
The basic MVP strategy involves integrated rural investment in five key areas: primary health, education, agriculture, infrastructure, and business development. The model is a delivery system for a comprehensive package of MDG-related interventions, characterized by the following key components:

- Integrated delivery of proven MNCH interventions with the goal of achieving universal coverage
- A coordinated multi-sectoral approach that simultaneously works to address wider MDG targets
- Cost-limited inputs, with a ceiling of $110 per capita overall, and $40 in the health sector
- A locally-driven implementation partnership between the project, government and local communities

**Integrated delivery of MNCH interventions:** In many MVP sites, health services have either been unavailable for large population groups, or such services were so grossly inadequate or fragmented that basic health-care infrastructure needed to be built or rebuilt, often from the ground up. The project works closely with national government to improve universal coverage with comprehensive primary services, making the most out of innovative tools and diagnostics, and facilitating a continuum of care by referral hospitals and primary care clinics directly to vulnerable households (44). In order to minimize access barriers, free basic health care at the point of service is made available in intervention villages. Extensive experience in numerous MVP sites, as well as published evidence, suggests that even modest co-payments can restrict access to care among the poorest half of the population (26, 38, 45). The aim is to facilitate adequate governance, financing, health workforce, infrastructure, supply chain and information management within health systems to reduce inequalities and foster high quality primary health care services for the long term (26, 45).
Within this context, an evidence-based package of essential MNCH interventions has been introduced at all sites (22, 23). Intervention components are in line with national and WHO guidelines and are implemented in an integrated fashion to optimize coverage (4) (Appendix 1).

A minimum human resource and infrastructure core supports service delivery at multiple levels (Figure 2):

- **Hospital**: In order to improve the availability, quality and accessibility of emergency care (particularly Emergency Obstetric Care, EmOC), the MVP works with district hospitals located outside the MVP clusters to ensure they are adequately staffed and equipped, and that basic transport and communication are available in all sites – including adequate roads, a simple ambulance service, and mobile phone coverage with a toll free emergency telephone number. One secondary hospital provides service to approximately 30,000 people. The facility is staffed by doctors, nurses/midwives, laboratory technicians, and a pharmacist, and equipped with comprehensive EmOC, a referral laboratory, and has the ability to initiate TB treatment and antiretroviral therapy.

- **Clinic**: One primary clinic for approximately 5,000 people is introduced in the MVP sites. These clinics are staffed by a minimum of 2 nurses, 1 mid-wife, 1 data clerk, 1 CHW Manager, 1 lab tech, and 2 ancillary staff. It is resourced with basic drugs, 24 hour delivery facilities, a basic laboratory, and communication and transport systems to facilitate referrals.

Figure 2: Health Sector Delivery Model
Community: The MVP employs trained professional community health workers (CHWs) at all sites – at a ratio of 1 CHW per 100-150 households. All CHWs have mobile phones and are linked to the local clinic. CHWs are an important link between the health sector and the community (2), and there is substantial evidence suggesting they can be effective vehicles for reducing maternal-child mortality and improving health outcomes (23, 34, 35). A randomized trial in the Gambia demonstrated a 61% reduction in neonatal mortality after traditional birth attendants were trained (46). Other more recent cluster randomized trials (31, 47-49) and controlled trials (50-52) have also documented pronounced benefits of CHW programs on reducing neonatal, perinatal and maternal mortality.

In the MVP context, CHWs are salaried high-school graduates from the local community who are trained in a minimum set of core competencies (Table 2). By taking health care from the clinics directly to the households, we hope to demonstrate improvements in disease prevention as well as in the early detection, treatment and referral of sick individuals.

<table>
<thead>
<tr>
<th>Table 2: Key competencies: MVP Community Health Worker (CHW) Program</th>
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<tr>
<td><strong>Total Catchment:</strong> 100-150 households</td>
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<tr>
<td><strong>Frequency of HH visits:</strong> minimum once per quarter (more frequently if required), monthly for pregnant women</td>
</tr>
<tr>
<td><strong>Target demographics:</strong> pregnant mothers, newborns, under 5s, adults</td>
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<tr>
<td><strong>Conditions for diagnosis and treatment:</strong> diarrhea (ORS and Zinc), simple malaria (using RDTs and ACT)</td>
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<tr>
<td><strong>Recognize and refer:</strong> eye and skin infections, malnutrition, worms and parasites, lower respiratory infection (incl TB) and sexually transmitted diseases (incl HIV).</td>
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**Maternal health:**
- Recognize pre-natal danger signs and know when to refer
- Refer for at least 4 prenatal visits during pregnancy
- Specialized referrals for HIV/AIDS infected pregnant women
- Counsel about folic acid, iron, tetanus toxoid, IPT for malaria and deworming
- Safe-delivery planning (recommend to give birth in the clinic when possible)
- Counsel about birth spacing, family planning, breast feeding and STDs

**Newborn health:**
- Post natal check within 3 days of delivery
- Counsel re: exclusive breast feeding practice
- Recognize postpartum danger signs in mother and refer to clinic/hospital
- Ensure immunizations are up to date
- Check that growth and weight have been monitored
- Counsel mother about how to feed newborn with a focus on breastfeeding techniques and problem-solving

**Child health:**
- Recognize danger signs and refer to clinic/hospital (including fever, diarrhea, malnutrition, LRI, malaria and pneumonia)
- Ensure immunizations are up to date
- Check that growth and weight have been monitored
- Check for appropriate growth and weight
- Counsel caretaker about proper nutrition for child, and complementary feeding

**Reporting and Management**
- Numbers of household visits
- Update roster of household members
- Births and deaths, with referral of deaths for verbal autopsy
2) **Multi-sector approach:** As acknowledged in WHO’s recent global report on primary health care, achieving sustainable improvements in child survival requires moving beyond health sector approaches, and working to address broader social and economic realities in high-risk communities (26). In response to this, the MVP model coordinates inputs from multiple sectors to address several MDG’s simultaneously, creating an important opportunity to generate synergies in achieving health outcomes (43). As 80% of the economic base in sub-Saharan Africa is in **agriculture**, critical components of the MVP model include the subsidized provision of improved seeds and fertilizers to support high-yielding crop varieties alongside training on best agronomic practices to reduce hunger and generate crop surpluses. Further inputs to enhance **business development** include diversifying farm enterprise toward high-value products, linking producer groups to markets, and supporting business enterprise development through access to microfinance and microenterprise services. Interventions in **education** support universal primary school enrolment; improving the quality of schools through ensuring adequate buildings, teachers and materials; introducing school meal programs which have been shown to enhance student attendance; and basic health interventions in schools including as twice yearly de-worming campaigns. Finally, these efforts are combined with investments in **basic infrastructure** to improve access to safe drinking water and sanitation facilities; the upgrading of local roads; and partnerships to expand mobile phone coverage, electricity (grid, solar), and internet access in all sites.

3) **Cost-limited inputs:** The range and selection of MVP interventions is based on the premise the rapid gains are achievable for a modest cost. Inputs are valued at a ceiling of $110 per capita per year for all sectors, sustained over a 5-10 year period. This a figure that is derived from a needs assessment conducted by the WHO Commission on Macroeconomics and Health, and reflects a scalable amount based on existing commitments for development assistance by Organization for Economic Cooperation and Development (OECD) member countries (53, 54). Of this figure, $50 comes from the project (MVP), $30 from national government, $20 from partner organizations including other NGOs and external donors, and $10 is from the local community and reflects primarily in-kind labor and commodity inputs. Within the health sector, components are implemented at an annual budget of $40 per person per capita for all inputs.

4) **Locally-driven partnership:** Past efforts at integrated rural development have not fully succeeded due in part to lack of stakeholder participation in project decision-making processes (55) (56). The MVP delivery model strives to follow a community-based approach founded on the principles of participation, social and gender inclusion, local ownership, and capacity building for local leadership of processes. There is broad recognition that such principles form the basis of delivery approaches that take into account lessons learned from previous integrated rural development programs.

In the MVs, delivery approaches are context specific based on local government and decentralization systems for service delivery, opportunities for partnerships, and community participation in the design and management of activities. Priorities are set via a community level planning process that is in line with national and local processes for participatory local development planning.

An **MVP Coordination Office** exists at each of the sites. These are led by a local PhDs, and staffed by representatives from the various sectors who are employed by the project. This office establishes relationships with local government, facilitates partnerships with external stakeholders, manages project contributions, and
oversees project implementation. The Coordination Office works on a daily basis with the communities in the project area via operational field teams composed of such staff as health and/or community facilitators, who work at the village level. Sector specific and/or cross-sector feedback meetings are held at minimum on a quarterly basis. Participation in these feedback meetings include project specific groups and reconstituted or existing sector groups at village level. Regular feedback meetings are organized either by MVP or by local institutions responsible for the activities, including the local government.

A rapid baseline assessment is conducted prior to initiating activities on the ground. Based on the results of this assessment, MVP Coordination office works together with communities and local governments to set priorities for intervention delivery in relation to the timing and sequence of various inputs. Previous empirical evidence suggests that community monitoring schemes can reduce child mortality independent of other interventions. The MVP has therefore been designed maximize the role and contribution of communities in the design and implementation of interventions (57, 58).

Summary

In summary, the MVP is an attempt to bring together the basic elements of a delivery system for a range of health and multi-sector inputs to accelerate progress towards the MDG targets and improve child survival. We feel these gains can be made in the short term both by eliminating structural barriers to the effective, universal delivery of proven health sector interventions, while simultaneously addressing known socioeconomic determinants of child mortality.

The intensity and practical village-level scale of the project, combined with the diversity of rural contexts, provide a unique opportunity for better understanding the inputs, systems and partnerships required for rapid progress in health and human development. Lessons learned from the project carry substantial potential to inform policy and programs to address child survival and its relationship to the MDG targets in sub-Saharan Africa and elsewhere.

The remainder of this protocol describes a methodology for examining its impact on child survival and related outcomes, assessing the feasibility of the integrated delivery system, and for measuring its cost relative to per capita spending limits that govern project inputs.

IV. Project Evaluation

A diverse range of methods will be employed to evaluate the MVP model. First, while the specific interventions contained within the MVP package have scientifically proven efficacy, assessing the impact of the delivery system is imperative given the pressing challenges to child survival in much of sub-Saharan Africa. Second, a portfolio of implementation science will generate new insights regarding project feasibility by documenting the content of interventions, their timing and sequence, and key barriers and facilitators to their introduction - providing lessons for replicability, scale-up and transfer to other contexts. Finally, an economic cost study will assess the costs of the interventions of the within the various sectors and the contribution of project partners relative to the $110 per capita cost ceiling of the project.

Aim
To evaluate the effects of the Millennium Villages Project on child survival in sub-Saharan Africa

**Study objectives**

1. To assess the impact of the MVP delivery model on child mortality
2. To explore the implementation and delivery of the MVP approach
3. To document the cost of all health and non-health related inputs to the project

**Study hypotheses**

- That after 5 years of operation, villages exposed to the MVP model will have a 50% lower rate of under-5 mortality and parallel gains in MDG-related secondary outcomes when compared to similar villages not receiving the intervention package;

- That the coordinated delivery a multi-sector package of health and development interventions implemented through a broad-based local partnership is feasible in a diversity of sub-Saharan African contexts, and;

- The intervention package can be delivered at a scalable cost of $40 per person per year in the health sector and $110 per person per year in total.

**V. Conceptual Framework**

*Figure 3* depicts a conceptual framework that guides both the delivery of the intervention and its evaluation. The MVP seeks to influence child mortality through combining proven health interventions with inputs that address wider social determinants of health and MDG-related targets.

**The outer circle:** reflects the key sectors within which MVP interventions are taking place – health, education, agriculture/business development, and infrastructure.

**The second circle:** represents the domains in which sector-based approaches have the potential to influence child survival.

- **Individual level:** Health sector interventions directly support neonatal and child health. As the health of the child and mother are closely linked, additional maternal interventions include antenatal and postnatal care, safe delivery, and addressing wider reproductive and sexual health needs of women including contraception and birth spacing.

- **Household level:** Interventions in education, agriculture and business development have the potential to improve household well-being through enhancing and diversifying incomes, livelihood strategies, food security and diet and nutritional diversity. In addition, efforts to increase school enrolment, attendance, and participation in school health programs such as de-worming and school meals have the potential to indirectly influencing the health of under-5s.

- **Community level:** Finally, the project is working across sectors to foster infrastructure improvements for healthier communities. This includes working with government and the private...
sector to introduce basic services such as the provision of protected water sources; sanitation facilities such as ventilated-improved pit latrines at homes, schools and market places; low energy cook stoves to reduce the time required to obtain fuel-wood and levels of indoor air pollution; alongside partnerships with government and external stakeholders to improve roads and transport, cell phone coverage and electrification.

The third circle: outlines the package of interventions being introduced across the relevant sectors. While not exhaustive, the list represents core components of the MVP package. It is also important to note that the implementation of specific components is likely to differ between sites based on the local context and epidemiology of disease, specific entry points for economic and business opportunities, the scope of pre-existing services, and perceived needs of local communities.

The inner circles: represent the six conditions that account for approximately 90% of child deaths in sub-Saharan Africa.

Figure 3: Conceptual framework linking the MVP interventions to child mortality
VI. Study Methodology

1) To assess the impact of the MVP delivery model on child mortality

**Evaluation Design:** A pair-matched community intervention trial

**Community selection and matching**

**Millennium Villages:** The choice of MVP sites was purposive and non-random. Criteria for country participation included that the gross national products of the countries were less than $300 per capita; that countries were reasonably well governed; that the government was committed to reaching the MDG targets; that the government was working with UNDP’s MDG technical support team on MDG-based national poverty reduction strategy plans; that the Head of State and national government invited and supports presence of MVP and is interested in using lessons from MVP to improve national MDG based strategy; and that the government was committed to partner in investments for the MVP including the secondment of extension workers (in agriculture, health etc), extending the electrical grid, repairing and maintaining roads, facilitating IT investments, and so forth.

At the local level, intervention sites represent 80 villages in 14 clusters across 10 countries. A village is a community of approximately 5,000 people that generally reside within the same administrative unit (subunit). Clusters are groups of ‘villages’ that are generally contiguous and located in the same agro-ecological zone and farming system. Villages within a cluster are contiguous and located in the same agro-ecological zone and farming system. MV clusters range from one to 11 villages and average approximately 35,000 people. Clusters were chosen to represent a diversity of agro-ecological zones that together represent the farming systems used by 90% of the agricultural population and 93% of the agricultural land area of sub-Saharan Africa. In most cases the cluster selection was ‘needs-based’ - where villages within each agro-ecological zone were identified as ‘hunger hot-spots’ as designated by the UN Millennium Hunger Task Force, with at least 20% of children under the age of five being malnourished (53) (59). Final selection was needs-based and made together by government and the project, with the MV cluster chosen from a range of potential candidate clusters deemed project-eligible.

It is also important to note that given the multi-sector nature of the MVP inputs, and the need to generate local economies of scale within sectors such as education, transport, communication, and health systems development, it was not feasible to implement in a phased manner and employ a ‘stepped-wedge design’ for project evaluation.

**Timing of the assessments:** Assessment rounds take place at baseline, prior to community exposure to any interventions, with follow-up assessments after 3 and 5 years intervention exposure. Assessment rounds were conducted pre-harvest to maximize recording of socio-economic and nutritional vulnerabilities, and where feasible during the malaria season. The timing of these assessments are intended to capture the respective phases of project evolution as articulated in the UN Millennium Project. The first phase of the MVP model involves a series of ‘quick wins’ where we hypothesize rapid health gains may be achievable through interventions such as malaria control and nutritional benefits resulting from seed and fertilizer for increasing staple crop production. In the second phase of years 4 to 5, we hypothesize that initial gains may deepen through realizing the benefits of longer-term ‘systems level interventions’ – such as improving the quality of the health and education systems, completing major infrastructure projects, and shifting from staple crop production towards high value crops, more diverse and nutritious crops,
improving access to markets and capital, and agro-processing activities. A third phase involving sustainability, realizing economies of scale and transitioning are anticipated for years 5-10 of the project and are beyond the scope of this protocol.

**Comparison villages:** Comparison villages are being introduced in 10 MVP sites during year 3 assessments. Comparison villages were not initially included in the evaluation design as the project started with just two sites – one each in Kenya and Ethiopia. During the project’s initial two years, substantial interest from national governments led to rapid expansion in the number of participating countries and village clusters. This expansion has afforded us the opportunity to conduct a more rigorous assessment using a matched pair design with cluster level analysis to assess the size and consistency of changes in child mortality and other MDG indicators in response to exposure to the MVP. We have opted to evaluate impacts in just 10 of the most recently introduced MV sites so that comparison villages selection takes place as close in time as possible their baseline assessment.

The choice of candidate villages for comparison was at random, and informed by both scientific and operational issues. Scientifically, a detailed matching process is undertaken to adequately characterize village attributes. DHS data are not sufficiently disaggregated to the degree of granularity such that potential local variations in levels child mortality between MV and comparison candidates are not known in advance. The matching process therefore involves collecting data on village-level parameters with the potential to influence child mortality and related MDG outcomes including: agro-ecological zone, accessibility (distance to tar roads and markets), principal livelihood strategies, crop types, levels of electrification, numbers of clinics and schools, and the presence of other development projects in the area. A full inventory of village matching criteria is detailed in Appendix 2. This inventory is collected both for the intervention and comparison villages and updated in parallel with each round of surveys. Operationally, comparison villages had to be logistically accessible to evaluation field teams, yet far enough away from the intervention site that ‘spillover’ from the MVP would be unlikely. The same field teams will conduct assessments in both intervention and comparison sites to ensure a standardize approach to the evaluation, as well as to minimize and evenly distribute potential bias.

Using these matching criteria, up to three comparison village candidates are assessed for potential inclusion in the study. Given the range of matching criteria being assessed, and the need for comparison villages to be contiguous and within the same agro-ecological zone and farming system as the intervention site, finding three potential matches was felt to be maximum logistically feasible. Among three comparison village candidates, one will be selected at random for inclusion.

It is recognized that the absence of pure baseline data from comparison villages is a limitation. Nonetheless, their inclusion at this stage will allow for a more detailed assessment of causality and attribution, and enhance the overall scientific rigor of the project. The presence of external interventions in comparison sites will be monitored throughout the evaluation to better understand the nature of secular changes taking place during the project period. Finally, we recognize that despite this detailed matching process, village-level ‘unobserved effects’ do have the potential to bias the uptake and adequacy of the intervention and the overall study results.

*Recruitment and sampling*
Household selection: Within each MVP village, a detailed household mapping was conducted prior to the initiation of interventions. This process included a household and population census, Global Positioning System (GPS) readings, and the generation of a household wealth score. Following this process, proportional sampling was used to randomly select 300 geographic and wealth-stratified households to undergo detailed periodic assessments.

Consenting households are followed longitudinally over three assessment rounds. In the event of refusals or household attrition, a replacement household from similar baseline wealth strata is chosen at random to maintain the sample size. Household selection within comparison villages mirrors the methods described for MVP sites.

Individual selection: Within each participating household, individuals are recruited for study inclusion based on the results of preliminary demographic assessment. Household members are defined as those who have lived in the household for at least 3 of the past 12 months, and who ‘normally eat from the same pot.’ The only exceptions are for persons who are the main provider for the household; infants who are less than 3 months old, and; newlyweds who have been living together for less than 3 months – all of whom are included in the sampling frame if age eligible.

Within each household, specific demographic groups are sampled with the following survey instruments:

- **Household Survey:** is administered to all household heads (and/or other knowledgeable household member where relevant) and collects information on household demography, education, employment, malaria bed net usage, land ownership and use, agricultural and non-agricultural sources of income, assets, expenditure, consumption and access to basic services including water and sanitation, and energy, transport and communication.

- **Adult Survey:** is administered to all adults aged 15-49 years old and examines health-related MDGs, nutrition and food security, alongside common causes of child mortality including diarrhea, pneumonia and malaria, and health seeking behavior.

- **Biological testing:** tests for malaria (thick and thin smears) and anemia using a Hemocue point-of-care device (Hemocue Inc, Lake Forest, California, USA) is conducted among all under-5s.

- **Anthropometric data:** weight, height and mid-upper arm circumference will be assessed among all under 5s using standard protocols (60).

<table>
<thead>
<tr>
<th>Table 3: Individual sampling</th>
<th>300 MVP Intervention households</th>
<th>300 Comparison households</th>
</tr>
</thead>
<tbody>
<tr>
<td>Household surveys</td>
<td>300 Household Heads</td>
<td>300 Household Heads</td>
</tr>
<tr>
<td>Adult surveys</td>
<td>All 15-49 year old adults</td>
<td>All 15-49 year old adults</td>
</tr>
<tr>
<td>Blood for anemia and malaria</td>
<td>300 under 5s</td>
<td>300 under 5s</td>
</tr>
<tr>
<td>Anthropometric monitoring</td>
<td>All under 5s</td>
<td>All under 5s</td>
</tr>
</tbody>
</table>

**Follow-up:** A complete census of all households in the cluster will be conducted in the month leading up to each assessment round. A sample of 300 households will be drawn from first from the baseline cohort, with replacement of households from the appropriate geographic and wealth strata in cases of household loss to follow-up in the event of out-migration or household dissolution. Anticipated losses are 5 to 10% of households per year. Household replacement has been adopted to maximize statistical power to measure changes in child mortality.
Within each household, all adult residents aged 15-49 years are followed. Adults within this age group are highly mobile, thus we anticipate substantial in and out-migration to take place over the course of the study period.

**Primary and secondary outcomes**

Survey tools have been developed to assess the delivery and uptake of specific interventions as well as to progress towards MDG targets. Definitions for most indicators come from standard UN MDG guidelines (8) and where these indicators are not appropriate at the village scale due to small sample sizes (maternal mortality, adolescent fertility, TB incidence) or measurement challenges (new HIV infections), proxy indicators have been developed. Where possible, survey questions have been drawn directly from international demographic, health and socioeconomic assessment tools for program monitoring and evaluation and policy decision making including the MEASURE Demographic and Health Surveys (DHS), UNICEF’s Multiple Indicator Clusters Surveys (MICS) and World Bank Living Standards Measurement Study survey to facilitate comparability. All study outcomes, indicators and data sources are listed in Table 3. All survey instruments are included in appendix 3.

**Primary outcome**: For the main impact assessment outlined in this protocol, the primary study outcome is child mortality expressed as the **under 5 mortality rate (U5MR)**, which is defined as the probability of a child born in a specified year dying before reaching the age of five subject to current age-specific mortality rates (expressed as a rate per 1,000 live births) (8). The average U5MR for MVP countries is 167 per 1000 live births. Baseline U5MR derived from national and sub-national data sets are presented in Table 3 below.

**Measurement**: Estimates of deaths and the age of death are derived from a standard Birth History Table as per DHS methodology (61). Birth History Tables ask women to list all live births (single and multiple) in chronological order for their entire lifetime, noting the date of birth and age at death.

**Calculation**: This is calculated based on the standard DHS formula which employs a synthetic cohort life table approach in which mortality probabilities for small age segments based on real cohort mortality experience are combined into the more common age segments. This approach allows full use of the most recent data and is also specific for time periods. The following age segments 0, 1–2, 3–5, 6–11, 12–23, 24–35, 36–47, 48–59 months (completed ages) are used for the calculation of the individual probabilities of dying (62).

**Numerator**: Number of deaths to live-born children during specified age range and specified time period.  
**Denominator**: Number of surviving children at beginning of specified age range during the specified time period.

The mortality rate calculation is as follows:

1. Calculate the component survival probability by subtracting the component death probability from 1.
3. Subtract the product from 1 and multiply by 1,000

The U5MR will be calculated for five-year period preceding the date of the survey. See Appendix 4 for additional detail on the approach.
Assessing U5MR in comparison villages: The Birth History methodology examines all of the births and deaths for a woman’s reproductive life in the time leading up to the survey. U5MR can be calculated for any time period – recognizing that reporting bias may be an issue for deaths that took place more remotely. For comparison villages, therefore, even in the absence of collecting baseline data at the onset of the intervention, U5MR can be assessed for the period leading up to commencement of the MVP in the matched-pair intervention site.

Generating comparable baselines: Fielding the birth history table is prone to enumeration errors and recall bias particularly when assessing neonatal deaths which are often under-reported. There are obvious concerns that generating comparable baseline data for U5MR may be biased if baselines are constructed from data collected at two different time points ie. at the start of the program in the intervention sites and at year 3 for the comparison sites. To address this potentially serious issue, we have chosen to calculate baseline U5MR for the five years leading up to the start of the program for intervention and comparison sites in an identical way, using data collected during year 3 surveys by the same enumeration teams.

Final assessment: The follow-up assessment of child mortality will be generated from year 5 surveys, which will provide estimates of U5MR for the five year period between the start of the intervention and the final assessment.

### Table 4: Baseline Under-five mortality rates

<table>
<thead>
<tr>
<th>Country</th>
<th>Rate per 1000 livebirths</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANG</td>
<td>120</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>100</td>
</tr>
<tr>
<td>Ghana</td>
<td>125</td>
</tr>
<tr>
<td>Kenya</td>
<td>150</td>
</tr>
<tr>
<td>Malawi</td>
<td>120</td>
</tr>
<tr>
<td>Mali</td>
<td>140</td>
</tr>
<tr>
<td>Morocco</td>
<td>160</td>
</tr>
<tr>
<td>Niger</td>
<td>180</td>
</tr>
<tr>
<td>Rwanda</td>
<td>200</td>
</tr>
<tr>
<td>Senegal</td>
<td>150</td>
</tr>
<tr>
<td>Tanzania</td>
<td>100</td>
</tr>
<tr>
<td>Uganda</td>
<td>120</td>
</tr>
</tbody>
</table>

Source: Sub-national DHS datasets

### Secondary outcomes: A series of secondary outcomes will assess the delivery and uptake of interventions as well as more proximal determinants of child mortality as outlined in the Conceptual Framework. Most secondary outcomes map directly to MDG targets. Standard definitions and measurements for each outcome will be applied in line with the UN MDG Indicator Guidelines as noted above (8).

### Table 5: Study outcomes

<table>
<thead>
<tr>
<th>Domain – neonatal and health</th>
<th>MDG target</th>
<th>Outcome</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health</td>
<td>4</td>
<td>*Child Mortality (Primary Outcome)</td>
<td>* † Under 5 Mortality rate</td>
</tr>
</tbody>
</table>

Source: Adult survey, Section C, Q518
<table>
<thead>
<tr>
<th>child</th>
<th>Health</th>
<th>1</th>
<th>Nutrition</th>
<th>Proportion of under 5s who are: Nutritional monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Stunted (low height for age Z-score)</td>
<td>Anthropometric monitoring</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wasted (low weight for height Z-score)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Underweight (low weight for age Z-score)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Duration of breastfeeding</td>
<td>Adult Female survey Section D, Q 553</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Age at introduction of complementary feeding</td>
<td>Adult Female survey Section D, Q 554</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Individual - child</th>
<th>Health</th>
<th>4</th>
<th>Prevalence of diarrhea</th>
<th>Proportion of under 5’s with diarrhea in past 2 weeks</th>
<th>Adult female survey Section E, Q 557</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Management of diarrhea</td>
<td>Proportion of under 5’s with diarrhea in past 2 weeks who receive ORS</td>
<td>Adult female survey Section E, Q 557,561-2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute respiratory infection</td>
<td>Proportion under 1s immunized against measles</td>
<td>Adult female survey Section G, Q 557</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Management of respiratory infection</td>
<td>Proportion of under 5s treated for pneumonia</td>
<td>Adult female survey Section F, Q 566-577</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Malaria prevalence</td>
<td>Prevalence of malaria among under 5s</td>
<td>Malaria smears</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Malaria treatment</td>
<td>Proportion of under 5s with a fever in the past 2 weeks who receive appropriate anti-malarial treatment</td>
<td>Adult female survey Section F, Q 566-57-7</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Use of ITNs for malaria</td>
<td>Proportion under 5s sleeping under LLINs</td>
<td>Household survey Section F, Q184-Q188</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Access to PMTCT services</td>
<td>Proportion of pregnant women who received an HIV test</td>
<td>Adult female survey Section D, Q 553</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Individual - neonatal</th>
<th>Health</th>
<th>4</th>
<th>Access to newborn care</th>
<th>Proportion of newborns receiving a post-natal check in the first week of life</th>
<th>Adult female survey, Section D, Q 549</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Individual - maternal</th>
<th>Health</th>
<th>5</th>
<th>Antenatal care coverage</th>
<th>Proportion of women who receive at least 4 ANC visits</th>
<th>Adult female Survey Section D (Q526)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Institutional delivery</td>
<td>Proportion of births attended by skilled health personnel</td>
<td>Adult female survey Section D, Q 542</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Household</th>
<th>Education</th>
<th>2</th>
<th>School quality</th>
<th>Survival rate to last grade of primary education</th>
<th>Household survey Section P, Q136 &amp; Q139-40</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Household</th>
<th>Income</th>
<th>1</th>
<th>Poverty</th>
<th>Asset based wealth index</th>
<th>Household survey Sections P, Q701-794</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Food security</td>
<td>Proportion of households reporting not enough food for 1 of past 12 months</td>
<td>Household survey Section K, Q251</td>
</tr>
<tr>
<td>Community</td>
<td>Infrastructure</td>
<td>7</td>
<td>Environmental Health</td>
<td>Proportion of the population using an improved drinking water source</td>
<td>Household survey Section T, Q370</td>
</tr>
</tbody>
</table>

24
Quantitative data collection and management

Interviews will be conducted in the local language by experienced enumerators. Specialized field teams will be employed to enumerate the Household and Adult survey tools respectively. Prior to each survey round, ten days of training will be conducted in the survey tools and Institutional Review Board (IRB) requirements. These trainings will be conducted by MVP site teams supervised directly by a monitoring and evaluation team specialist from New York.

Surveys and biological specimens will be collected from individuals after an informed consent process. All questionnaires will be checked for quality three times post-enumeration and sent back to the field as needed. Random household re-visits will be undertaken by field supervisors on 10% of households to ensure quality control.

Contemporaneous data entry will take place using a purpose built data entry template developed in CS-Pro (US Census Bureau, Washington, USA) containing a series of pre-programmed range, skip, and logic checks to minimize errors in data capture. Double data entry will be undertaken for key indicators to reduce errors in data capture. Data cleaning will be conducted concurrent to data entry, using CS-Pro’s batch edit functionality that allows an additional series of data checks to be performed.

Basic tabulation of MDG indicators will take place using CS-Pro, with data exported to Stata (v.10 Statacorp, Texas USA) employed for more complex analyses, such as income or child mortality, as required.

Sample size estimates

To assess the effects of exposure to MVP, we will survey 10 village pairs in 9 study countries (including 2 sites from diverse agro-ecological zones of Nigeria). Power calculations are based on the ability of the intervention to achieve a 40% difference in the U5MR for MVP sites relative to comparison villages for the 5 year period leading up to the survey.

The most recent sub-national rural data for U5MR from all MV countries were used to generate sample size estimates. For the power analysis, we assume that the U5MR in communities lacking interventions remains at 16.7% (average U5MR of 167/1000), and that the coefficient of variation within communities in the presence of the intervention is 0.33, which was derived from the variation in baseline rates of child mortality drawing from existing national or sub-national data sources where available (see Table 3 above).

Figure 4 plots the relationship between the minimum post-intervention U5MR difference, alongside the number of required observations in each of 10 village pairs where the coefficient of variation (k) is fixed at 0.33. To detect a difference at an 80% power and 5% significance level, approximately 200 births are required to detect a difference in Under 5 Mortality Rates of approximately 40% - or a ratio of U5MRs of 0.60. We have included a sensitivity analysis
in the Figure below where differences in Under 5 Mortality Rates of 43% to 37% can be achieved for 9 to 11 paired clusters respectively – or a ratio of U5MRs of 0.57-0.63.

With current fertility rates averaging 0.2 per woman-year across the MVP sites, 300 women in each intervention and comparison village will give birth to approximately 300 children over the 5 year observation preceding the assessment.

**Figure 4:** Sample size plot for the numbers of births per cluster required to observe changes in the U5MR ratios between paired intervention-comparison village clusters

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**Data analysis**

To assess the effects of the MVP intervention on primary and secondary outcomes, a pair-matched cluster-level analysis will be employed in two stages (63, 64). The first stage will generate unadjusted results and will follow these steps:

- The U5MR and, for secondary outcomes, the proportion of individuals experiencing an outcome will be calculated for each indicator by village.
- The geometric mean of this figure will be calculated for Intervention and Comparison villages separately.
A ratio of intervention and comparison villages will be calculated based on the U5MR, point estimate, or period prevalence depending on the indicator. An unpaired t-test will be used to compare the logarithms of these ratios and generate a statistical test of significance for the comparison between intervention and comparison clusters. A non-parametric test will be conducted to assess the robustness of the results. 95% Confidence intervals will be calculated for all primary and secondary outcomes on the basis of the cluster level variance.

The second stage of the analytic process will generate adjusted ratios for each of the outcome measures, using the following steps:

- An individual level regression model will be fitted in which the dependent variable is the measure of interest, and independent variables include terms to distinguish the matched-village-pairs and a series of factors thought to be possible confounders (age, sex etc). For variables where no data on baseline status exist, rural sub-national data will be imputed.
- This regression model will be used to calculate the expected (E) number of individuals experiencing the outcome in each village.
- For each village the ratio of the observed (O) to expected (E) number of individuals experiencing the outcome will be calculated (O/E).
- The geometric mean of this O/E value will be calculated to generate a point estimate of the adjusted risk / period prevalence ratio.
- An unpaired t-test will be used to compare the logarithms of this O/E ratio between intervention and control groups, and appropriate 95% confidence intervals will be constructed. A nonparametric test will be conducted to assess the robustness of the result. An unpaired test will be used to maximize the degrees of freedom given the relatively small number of clusters in this study (65).

In addition to the two-stage cluster-level analysis, a multi-level modelling framework will be used to more fully explore the contribution of village and household level characteristics, as well as the intensity or ‘dose’ of intervention, in helping to explain the observed effects.

**Stopping rules and interim analyses for quantitative survey data**

As this is not an assessment of unproven interventions, and as most interventions are delivered at the village rather than individual level, there are no stopping rules for the study.

Interim analyses post year 3 collection will be conducted to assess changes from baseline at MVP sites, as well as to compare levels of primary and secondary outcomes between matched intervention and comparison villages.

2) To explore the implementation and delivery of the MVP approach : Implementation Science
Understanding the process of implementation is particularly relevant to the MVP. While the individual components of the package are of proven value, the systems necessary to support their integrated delivery in a diversity of settings are poorly understood. To address this, a portfolio of implementation science (or process evaluation) will be conducted alongside the project. The overall aim of the process evaluation will be to assess the feasibility of the approach, and examine how the process of implementation affects project outcomes (66-69). Such assessments are increasingly recommended for evaluations of complex interventions (70, 71), including randomized trials and where interventions are introduced at the level of populations or clusters (63, 72, 73). Implementation science can also help to distinguish between interventions that are inherently faulty (failure of intervention concept or theory) and those that were simply badly delivered (implementation failure) (67).

Methodology

While specific methods employed in process evaluations are by nature contextual, a set of best-practice guidelines are emerging to guide implementation science assessments. These include disaggregating the evaluation design in line with multiple levels of the system including levels of interventions and project stakeholders (69, 74); incorporating the respective stages of a program’s development into the evaluation design (67); addressing questions about: 1) outcomes and 2) the mechanisms through which links between interventions and outcomes may be observed (68, 71, 74); and finally, documenting the underlying context in which the intervention is implemented to enhance external validity (73, 75).

The methods employed in the MVP process evaluation will incorporate aspects of these best-practice guidelines. A mixed methods approach will combine quantitative performance monitoring data with more exploratory qualitative techniques. A case-study approach will be adopted in order to allow for a thorough examination of the underlying context in which interventions are implemented. This is particularly advisable given a program with multi-site trials where the “same” intervention may be implemented and received in different ways, and thus expected to respond differently given the economic, political, organizational and environmental context (76).

Given the importance in complex interventions of examining process at the respective stages of a project’s implementation, each intervention will be examined in terms of its performance given various levels of project implementation, namely (1) Design, planning and targeting; (2) Organizational structure and personnel, (3) Budgeting and Finance; (4) Logistics and procurement; (5) Monitoring and Support; (6) Transitioning and Sustainability and (7) Sequencing and Synergies. Given that performance indicators for a particular intervention are likely to vary given different stakeholders the methodology will be structured to target three levels of stakeholders, namely (1) Project Staff; (2) Community and (3) External Agents (government and donors).

Steps will be taken to address the need to more explicitly link process evaluations to quantitative outcomes data. Emerging qualitative data will be used to develop quantitative evaluation components, the content of which can then be integrated with outcomes data in the analysis stage. Quantitative outcomes data will also be used as a reference point in conducting key interviews and participatory evaluations, where the perceived efficiency and impact of an intervention is contrasted with actual measured outcomes.
Finally, while the major focus of this dimension of the evaluation will be on the Millennium Village interventions, we will also use this opportunity to explore and document relevant contextual changes that may have taken place in the comparison village sites over the project period.

Given these broad guiding principles, the methods employed for this process evaluation will be as follows:

**Critical document review**

Field research in each site will be preceded by a critical document review. First we will examine planning documents, including original project proposals and concept notes, as well as MVP operational handbooks. The purpose of this is to define the “MVP model delivery system” as it was originally conceived of at project inception. Detail on the core interventions planned for each sector and their anticipated timing will be gathered. Second, we will review quarterly and annual reports from each site to compile an inventory of interventions undertaken since project interception, documenting the timing and sequence of their introduction. Finally, we will synthesize a summary of activities and outputs for each sector based on quarterly performance indicators that are reported regularly by sector heads at each site.

**Key informant interviews**

**Senior New York and MDG Center staff:** Key informant interviews will be conducted with individuals from the (i) New York staff at the Earth Institute, Millennium Promise and United Nations Development Program, and (ii) with the Directors of the MDG center offices in Nairobi, Kenya and Bamako, Mali. These interviews will focus on overarching issues regarding the organizational and operational structure of the MV model; intersections with donors, national governments, community and other stakeholders; and insights regarding barriers and facilitators to implementation both globally as well as at the specific case-study sites.

**Site teams:** Key informant interviews will also be conducted with sector heads at the respective field sites. The purpose of these interviews will be to document the process of implementation on the ground, areas where positive or negative effects were observed, alongside key barriers and facilitators to implementation.

Each interview will have two components. First, informants will be presented with the schematic of the MVP model of planned implementation that was prepared during the critical document review, and the interim list of interventions undertaken. Using these two schematics as reference points, open-ended questions will lead the informant through a discussion of the structure, content and rationale behind the proposed core model interventions and the rationale behind the prioritizing and sequencing of core interventions. The interview will also seek to verify the full inventory of interventions undertaken within each site; document the timing and sequence; describe how the model was adapted to the local context; identify how implementation differed from original program planning; highlight barriers and facilitators to implementation given the seven phases of project implementation; and draw up a summary list of key interventions that worked well, interventions that didn't work well, and why.

Second, the potential effects of interventions on MDG outcomes will be explored, combining qualitative probes with a quantitative ranking exercise. The informant will be presented with the list of outcomes indicators for each sector, and
asked to highlight outcomes they think will show exceptional (positive and negative) changes in the study site. For each highlighted outcome, the informant will be asked to give an estimate of the percentage change in outcomes over time - bearing in mind that informants are as yet “blinded” to the quantitative mid-term impact data outcomes. These rankings will then be discussed with reference to the interventions undertaken in the site, and used to develop with the informant interim (or hypothesized) impact pathways between key case-study interventions and MDG outcomes. These hypothesized causal pathways, along with the results of the “blinded” intervention rankings, will later be incorporated as an evaluation tool during the participatory assessments conducted with site teams (below).

**External Stakeholders:** Within each site, a few key informant interviews will be conducted with representatives from local government, non-government institutions, and bilateral and multilateral agencies (e.g. UNDP, the UN Children’s Fund – UNICEF, WFP, the International Livestock Research Institute, USAID, etc.). The objective of the interviews will be to gain external perspectives on the process of external stakeholder involvement during planning and design of MVP project; critically review the effectiveness of current MVP structures to integrate and feedback with external agents; document the successes and failures of key case-study interventions in sequencing with external projects.

**Participatory assessments**

**Site teams:** The purpose of these assessments is to highlight ‘key interventions’ within the MVP package, document lessons learned and examine potential cross-sectoral synergies. These assessments will comprise of a series of Focus Group Discussions (FGDs) with key members of the site teams including Sector Heads, Community Facilitators, Team Leaders and Science Coordinators. During participatory assessments, informants will be made aware of mid-term outcomes data. A facilitated discussion will examine the contrasts and similarities between the “blinded” rankings of key interventions, versus actual impacts. For specific interventions that have been linked via hypothesized impact pathways to MDG outcomes in earlier interview rounds, a pathway analyses will be facilitated with the group, with a view to discussing the facilitators and barriers between outcomes and interventions at each level of project implementation. Interventions characterized by large discrepancies (or synergies) between perceived efficiency (from earlier interviews) and actual outcomes will be flagged for detailed profiling. Subsequent FGDs and follow up interviews will focus more exclusively on profiling these key targeted interventions.

**Community:** Community feedback meetings are central to the Community Development initiatives of the MVP and take place in all of the MV project sites. They are comprised of sessions with community groups who meet regularly to discuss the progress of MVP interventions within their respective communities. Equally imperative to the objectives of the community feedback meetings is to explain the impact of the MVP on communities towards achieving the MDGs. Discussions will be facilitated by using the results of the mid-term surveys. The process evaluation will overlap with ongoing and concurrent efforts by the MVP Community Facilitators to deliver the results of the mid-term surveys to the community and solicit their responses. The process evaluation team will observe and document community responses to this feedback process, in order to assist in understanding participation, uptake and ownership of the interventions and MVP model in relation to local development priorities.

In addition to the community feedback meetings, a series of FGDs with purposively selected community members in order to solicit their understanding of the objectives of the MVP; attitudes, opinions and expectations related to implementation; perspectives on the successes and challenges and; perceptions related to the barriers and
facilitators that are associated with the MVP. Two FGDs (divided by gender) will be conducted in each site and will be comprised of 8-10 randomly selected adult men and women. To enrich the quality of data from the community, separate interviews will take place with 1-2 Community Leaders at each site. The methodology and field guides will draw on findings from the community feedback meetings to enhance and deepen our understanding of community participation in the MV process.

Data management and analysis: The content of qualitative interviews will be translated as necessary and transcribed. Analysis of qualitative data will involve thematic content analysis as well as critical appraisal where appropriate. Our approach to analysis will employ a system of coding and memoing [64], facilitated by the use of qualitative analysis software (NVivo 8, QSR International, Cambridge USA). Topics and issues emerging from the data will be identified through familiarization with transcripts or documents. Pertinent excerpts that illustrate emerging themes will be coded and memos will be written to summarize and synthesize key themes. These will be organized around the seven levels of project implementation, by stakeholder and by sector. Key themes from the qualitative data will also be contrasted with quantitative performance, which will be generated through a purpose-built web-based data capture tool termed the Millennium Village Information System (MVIS). The MVIS allows for the entry and interpretation of raw data relative to important denominators and targets, with a view to examining changes in the delivery and uptake of interventions over time.

From these data we will generate a detailed description of MV model, both as planned and as implemented at the respective case-study sites; a description of the process of implementation alongside barriers and facilitators; an overview of cross-sectoral synergies both anticipated and unanticipated, and finally a series of lessons learned to assist in replication and scale-up.

3) To document the cost of all health and non-health related inputs to the project: Economic Evaluation

An underlying hypothesis of the MVP is that an annual per capita investment of $110 is required to achieve the MDGs across all project clusters (77). Essential to this hypothesis is the assumption that the costs of project inputs will be shared by four categories of contributors: 1) national and local governments; 2) external donor organizations such as NGOs; 3) the communities themselves, and; 4) core project partners (UNDP, Columbia University, Millennium Promise). Understanding the nature, source, and cost of these inputs is critical to evaluating the success of the project in relation to the $110 per capita annual project target, in addition to assessing the sustainability and scalability of project interventions (78). Because the nature and intensity of inputs is likely to differ substantially between sites due to factor such as community needs, the local disease profile and the nature of the local economic base, developing a uniform system for tracking input costs is a necessary component of the project evaluation.

Methods

We will conduct a cost-consequence analysis to document 1) the prices of all project inputs for each sector, disaggregated by year and contributing partner type; and 2) the resulting multiplicity of intervention outcomes. This meso-level approach provides the most appropriate means of analysis for an integrated, multi-stakeholder, multi-center project such as the MVP, where the availability and quality of economic data will vary considerably, and where the evaluation requires a relatively coarse level of granularity (79, 80).
A full economic costing approach will be introduced as a strategy for monitoring project inputs in line with established methods of social and health policy interventions (81-85). The aim of the assessment is to document the absolute and relative contribution of project partners to all cluster-level activities within the Millennium Villages that contribute towards achieving the MDGs. This assessment will account for all inputs, both priced and non-priced, and will include a system for imputing the cost of non-priced inputs according to established practice (69, 86).

The consequences or effects of the intervention on primary and secondary outcomes will be assessed through sampling and analysis methods that have been described in detail in objective (1) above.

Finally, we will also be conducting a limited costing study in comparison villages primarily through valuing government and external stakeholder contributions which have been itemized in the Village Matching Checklist (appendix 2). We anticipate this will generate an important metric for assessing the ‘dose’ of the intervention to better understand observed differences between intervention and comparison villages.

**Data collection**

Data collection will occur at each of the study clusters and will be facilitated by the collection of budget and expenditure records and the conducting of key informant interviews within the following partner categories: government, external donor, community, and MV core. These records and interviews will serve to document the value of all contributions made by each project partner within each sector for each of the project years. The table below lists the four possible partner types, the main elements of their contributions to project interventions, the sources of data for these contributions, and the primary assumptions we will make when collecting and analyzing data.

**Cost imputation**

For contributions made in kind, all prices will be documented using the standard cost imputation method recommended for multi-center interventions (86-88). While the specific elements of project interventions will differ across clusters, valuing the cost of each intervention’s inputs will provide us with a satisfactory means of conducting a cross-cluster analysis (69). This will involve establishing local unit costs for each in-kind contribution (e.g. daily wage rate in the case of labor contributions). We will then use these unit costs along with qualitative data collected during key informant interviews to calculate a total cost for each contribution (e.g. daily wage rate x number of laborers x number of days worked)(86, 88). While the specific elements of project interventions will differ across clusters, valuing the cost of each intervention’s inputs will provide us with a satisfactory means of conducting a cross-cluster analysis (69).

**Table 6: Partner, contribution and source of data for economic costing study**

<table>
<thead>
<tr>
<th>Partner Type</th>
<th>Main contributions to interventions</th>
<th>Sources of data</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government</td>
<td>1. Infrastructure building</td>
<td>1. Government budget and planning records</td>
<td>1. When MV boundaries do not conform to administrative boundaries, governmental expenditures will be pro-rated using population numbers from the MVs.</td>
</tr>
<tr>
<td></td>
<td>2. Salaries for teachers in MV schools</td>
<td>2. Key informant interviews at government or ministerial offices</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Salaries for doctors in MV clinics</td>
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<td></td>
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<tr>
<td></td>
<td>4. Salaries for other extension workers</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>5. Medical supplies</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>6. Agricultural subsidy schemes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>External</td>
<td>1. Expertise</td>
<td>1. Budgets and expenditure records</td>
<td>1. For non-government concurrent programs operating</td>
</tr>
</tbody>
</table>
### Donors

|   | 2. Infrastructure building  
|   | 3. Materials, e.g. bed nets, piping  
|   | from external partners  
|   | 2. Key informant interviews at donor and site team offices  
|   | in the MV clusters (such as an NGO led HIV program), financial records will be sought, with the cost of services pro-rated to the proportion of clients benefiting from the service who originated in the cluster.  

### Community

|   | 1. Labor inputs for buildings – schools and clinics  
|   | 2. Labor inputs for school meals  
|   | 3. Material inputs for buildings  
|   | 4. Seed contributions  
|   | 1. Key informant interviews and MV reports  
|   | 2. Market wage rates for non-skilled labor  
|   | 3. Market prices for seeds and produce and other materials  
|   | 1. Values of in-kind contributions (materials, land, lodging, crops, and labor) with a clear market value will be imputed using basic cost imputation techniques.  
|   | 2. The value of in-kind contributions without a clear market value, such as land donations, will be estimated based on interviews with community leaders and cluster team members.  

### MV Core

|   | 1. Effort  
|   | 2. Infrastructure building  
|   | 1. MV expenditure records at site  
|   | 2. Interviews with MV site sector leaders and science coordinators  
|   | 3. Discounted value of MV infrastructure  
|   | 4. UNDP expenditure records  

### Data Analysis

Once the data has been collected and all costs have been imputed, we will undertake an analysis of yearly contribution data from each of the partner types to project interventions. For the purposes of both cross-cluster comparison and comparison to MV budget targets, all expenditure amounts will be converted to US dollars using average annual exchange rates for each year. We will then add the intervention expenditures for each year, sector, and partner type to obtain the total disaggregated expenditures per cluster. We will divide these total expenditures by the total cluster population to obtain each partner type’s per capita expenditures for the cluster for each year. A final step will be to conduct scenario analyses in which we consider the effect of different assumptions on our results. The scenarios we will analyze include the following:

- Annualizing/not annualizing the cost of infrastructure and capital expenditures
- Including/excluding the estimated value of infrastructure and capital depreciation as an annual maintenance cost borne by the national government
- Including/excluding health center user fees as a community contribution
- Counting land donations to public works as a community contribution
- Counting land donations to public works as a government contribution

All assumptions will be recorded in line with established procedures, allowing for a clear interpretation of the study’s results (89).

### VII. Strengths and limitations

The evaluation design employed in this community-based intervention has a number of strengths. A prospective design has been employed to minimize recall bias. The random selection of wealth-stratified households will generate a representative sample of village-level exposure to interventions and changes in MDG outcomes. Survey
tools utilize previously validated best-practice standards in economics, agriculture, infrastructure and health to generate a comprehensive picture of change over time in multiple sectors. The assessment also examines effects both on a distal primary outcome (child mortality) as well as more proximal secondary outcomes or pathway variables – which will allow inferences to be made regarding variable intervention and uptake, as well as some assessment as to mechanism of action (90).

Village-level matching and cluster-level analysis has been introduced to assist in assessing causality and attribution – whether observed changes were due to the MVP interventions or rather were a response to wider social forces unrelated to the intervention (65, 91). This dimension of the work is critically important given the 5 year study horizon and the rapid pace of positive and negative secular change currently underway in sub-Saharan Africa – where factors such as political instability, food and oil prices, drought and climate variability, and global economic recession have serious potential to influence MDG-related outcomes. External validity of the approach will be enhanced by assessing the consistency of effects across 10 diverse sites in nine sub-Saharan African countries.

A parallel portfolio of implementation science and economic research has the potential to generate important insights into differences in the content of the MVP package between sites, key contextual barriers and facilitators to effective delivery, and potential mechanisms of action – all important for replication, scale-up and transfer to other contexts (92, 93).

Finally, the overall project evaluation will adhere to Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) guidelines (94). This includes employing a clear theory-driven conceptual framework to guide intervention design, delivery and evaluation; the description of the settings and state of service delivery in both intervention and comparison communities; documentation of the intervention package at each site; monitoring and reporting on exposure and uptake of interventions; and adherence to presenting data on the full-range of pre-defined study outcomes using a pre-specified analysis plan.

There are also a number of potential limitations that are important to underscore. These include:

- **The non-random selection of intervention communities has the potential to introduce bias.** Non-random selection has the potential to introduce program placement bias – a common challenge in the assessment of complex interventions (95). In the MVP context, purposive selection was undertaken to ensure a diversity of agro-ecological zones and range of operational settings that characterize the sub-Saharan African context. Communities were often among the most disadvantaged - with high levels of baseline mortality and nutrition deficiencies felt to be desirable characteristics in the initial site selection(43). Issues of feasibility, political buy-in, community ownership and ethics also featured prominently in village selection for participation in large scale development programs such as MVP. Finally, as the efficacy of various components of the MVP package have already been demonstrated, our goal is to assess the adequacy of the MVP model in a diversity of settings, while generating the best possible evidence of plausible and consistent relationships between intervention exposure and a range of pre-specified primary and secondary outcomes (90, 96).

- **Both the intervention recipients and evaluation team are un-blinded to the intervention.** This has the potential to introduce interviewer or reporting bias and has been cited as a common challenge to community intervention trials (91, 97). The use of standardized training of study personnel with clear standard operating
procedures for field and data management systems is intended to minimize errors in survey enumeration, data capture, cleaning and analysis. Attempts to reduce response bias include using of objective outcomes as key primary and secondary outcomes including mortality, parasitemia rates and anthropometric measurements. In addition, during the informed consent procedure, it is made clear to respondents that participation in the evaluation has no bearing on the delivery of interventions at the household level.

- **Household attrition and individuals lost to follow-up.** It is likely that those who leave a community may differ from those that do not. Random household replacement from baseline wealth strata has been used to minimize the effect on statistical power. Comparisons of those lost to follow-up and those retained will be undertaken.

- **There are no systems in place to monitor a number of important MDG outcomes that may influence child health.** These include HIV infection levels, TB incidence or malaria death rates. In addition, given the evaluation design, sample sizes are insufficient to detect cluster-level changes in other important indicators such as maternal mortality or adolescent fertility.

- **Child mortality rates are themselves susceptible to recall bias.** The longer back in history one measures, the greater the potential for error. In addition, non-surviving births are thought to be more frequently omitted than surviving births(61). While this would cause mortality decline to be masked or underestimated, provided these errors are randomly distributed between intervention and comparison communities, we feel that the overall effect of these errors on final risk ratios will be limited.

- **Limited ability to make clear statements regarding baseline equivalence.** This is a consequence of including comparison villages within the mid-term/year 3 assessments. This limitation can be redressed for some indicators through the inclusion of historical questioning. In the case of the primary study outcome, an under-5 mortality rate can be constructed for the period leading up to ‘baseline’ for women from comparison communities. As part of the assessment of comparison communities, the introduction of new interventions by government or external actors is assessed within matching criteria. For many indicators, in the absence of new interventions it would be unlikely that substantive year on year changes would be witnessed, such as malaria prevalence, institutional delivery rates or child nutrition. However, for indicators that are highly sensitive to external forces, such as the effects of drought on agricultural production and income, definitive adjustment for baseline status in the final analysis will be limited.

- **A ten-by-ten cluster-level analysis is somewhat limited in its ability to detect statistical differences with certainty(91).** While we feel confident that data used to generate precision estimates coupled with the fertility rates from the sites are sufficiently conservative to allow a difference to be detected, a loss of one or several cluster-pairs for technical, ethical or logistical reasons has the potential to create serious challenges to the analysis.

- **Definitive statements regarding mechanism of action will be difficult to make.** Despite assessing a series of proximal and distal indicators, and concurrent portfolio of implementation science, the complexity of the intervention and uniqueness of project settings will likely lead to a diversity of implementation experiences (98, 99). We anticipate the application of a mixed-method approach will assist in generating lessons on how to deliver a package of essential maternal-child health services. We also hope that the multi-sectoral approach of the MVP will provide afford unique insights regarding potential synergies, carrying important implications for future research.
VIII. Project Sustainability

In the context of MVP, sustainability means that at the end of the project, sites should be able to continue their economic progress without a loss of momentum, a drop in living standards, or a decline in social services.

While the proposed evaluation is for the first five year project period, the full duration of MVP extends for ten years. The first five years of project activity emphasizes getting basic interventions up and running, documentation and measurement, and refinement and adaptation of the model as necessary. Years six though ten will involve a process of transitioning from current levels of project support to a model where a greater portion of resources supporting critical initiatives are derived from government and other stakeholders. This will take place in the context of wider scale up of the model and lessons learned within existing countries and new countries as highlighted above.

Sustainability is a pre-requisite for all project activities in the health sector. To support this goal, all inputs and interventions are in-line with government and WHO policies. The MVP works closely with government from project inception to ensure the construction or refurbishment of facilities and allocation of key staff are in line with government planning, and that government is committed to a ‘transitioning process’ – where a greater levels of support for staff salaries and the maintenance of infrastructure are received from government over the 5-10 year project horizon. A similar process is undertaken in the education and infrastructure sectors.

In agriculture and business development, the most important step towards MV sustainability will be the conversion of agriculture from subsistence to cash crops, with all of the attendant commercialization of village life that will accompany agricultural transformation (e.g. the active use of micro-saving and micro-credits, and the development of SMEs in non-agricultural sectors). This commercialization will not only obviate the need for the infusion of additional resources into the villages, but will also provide the economic motor for further development. These efforts towards sustainability will be supported by the completion of infrastructure investments (e.g. expansion of the road and power grid), and; scaling up of national and local social services, especially in health and education. Within this approach, it is anticipated that transformations across the various sectors, when combined with household level improvements in health, social, and economic outcomes, will generate long-term resilience and durability in rural communities.

IX. Project time line

<table>
<thead>
<tr>
<th>Site</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline Assessment</td>
<td>Year 3 Assessment</td>
<td>Year 5 Assessment</td>
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<td></td>
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<tr>
<td></td>
<td>Baseline reporting (x)</td>
<td>Year 3 analysis and reporting (x)</td>
<td>Final analysis and report (x)</td>
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<tr>
<td>Ghana</td>
<td>x</td>
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<td>x</td>
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<td>Kenya, Dertu</td>
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<td>Malawi</td>
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<tr>
<td>Mali</td>
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</tr>
</tbody>
</table>
X. Reporting and Dissemination

Provisional reports will be generated immediately after data collection and analysis for local project stakeholders to inform intervention targeting and delivery. Formal reports to the MDG centres (Bamako, Nairobi) and MVP head office in New York with clean data sets and MDG indicators will be available within 6 months of survey completion. Local feedback to communities will take place by Community Coordinators based on each site team.

Wider national and international dissemination will take place through reports to government and donors, conference presentations and publication in peer-review journals. A full mid-term assessment from most MVP sites will be prepared for dissemination at a United Nations Special Session on the Millennium Development Goals which will take place in New York in September 2010.

XI. Ethical Issues

A number of important ethical issues have been addressed for the purposes of the study protocol:

- **IRB approval:** All survey modules, questions and procedures employed as part of this assessment have undergone prior review and approval at Columbia University’s Institutional Review Board (Protocol number AAAA8202) as well as approval by all host country IRBs.

- **Community-level Informed consent:** Village leadership will be consulted prior to conducting assessments in all communities.

- **Individual-level informed consent:** Informed consent will be obtained from all participating subjects. In the event of illiteracy witnessed verbal consent will be obtained prior to questionnaire administration. However, for all biological specimen collection (anemia and malaria) a signature or other form of written consent or ‘mark’ will be obtained.

- **Minors:** As per the MVP protocol, adults will consent on behalf of survey respondents under 18 years old. Adults will give signed consent for blood specimens taken among under 5s.

- **Non-coerced:** Explicit mention is made on the informed consents that assessments are not linked to any particular intervention being made available to individuals or households at the time of survey or in the future.

- **Confidentiality:** Confidentiality will be ensured through a number of mechanisms as per the existing quality assurance and data storage plans including: all source documents will be kept in locked cabinets at the sites; all data sent from the sites will be encrypted when transferred or stored; data will only be stored on
limited access password protected computers; all database managers and investigators will have undergone IRB-approved training; all data will be anonymized prior to dissemination.

- **Referral of the seriously ill:** All under 5s with fever, who are malnourished (by MUAC or child health cards) or who have moderate to severe anemia (Hemoglobin<110g/l) will be immediately referred to the nearest health centre for assessment.

XII. Appendices

Appendix 1: MVP Health Sector Interventions
Appendix 2: Village Matching Forms
Appendix 3: Survey tools: Demography, Household, Adult
Appendix 4: Under 5 Mortality Rate calculation – detailed methods
XIII. REFERENCES


