A Strategic Approach for Re-positioning Family Planning within Comprehensive Community-based Health Services: the Connect Project, Tanzania

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Abstract

The *Connect Project* in Tanzania a strategy for scaling-up a field trial to become a national program. It operationalizes and evaluates the current national primary healthcare policy by trialling the impact of a community-health worker program aimed at reducing child mortality. It commenced in 2011 as a randomized controlled trial with features to study the effects of implementation on health systems strength. Currently, *Connect* scientists are expanding the breadth of the project to address two problems: (a) the inadequate availability of reproductive health services to study populations, (b) the tendency of research to produce nonreplicable service delivery capabilities. *Connect* is solving this through the strategic introduction of DMPA injectable contraception into its service system. This is a process of organizational change that requires working in phases guided by evidence. What is feasible for re-orienting health and village systems for community-based services is learned through pilot and scaled-up in a case study assessing service coverage, quality, utilization, method continuity and organization normalization of new service capabilities. The design of *Connect* permits a scale up of the innovation into a trial of fertility and MDG 5 impact. Details of each phase, and the feasibility for the national scale-up, are reviewed and discussed.

Background

African family planning program policy is often motivated by a widely held, but seldom assessed, hypothesis that improving access to services reduces unmet need by improving acceptability, reducing costs, and expanding the climate of reproductive choice. A corollary proposition holds that broadening the contraceptive options available at convenient locations, improves contraceptive acceptability, advances adoption, and diminishes discontinuation for reasons unrelated to personal reproductive volition (i.e. Jain 1989). In 2009, these propositions were globalized by a United Nations decision to modify "Millennium Development Goal 5" – the aim to reduce maternal mortality by 75 percent over the 1990 to 2015 period – by adding to MDG5 the proposition that "Reproductive Health for All" should be achieved by 2015. This paper presents the design of a study set in rural Tanzania that tests the proposition that "reproductive health for all" can be achieved if family planning is re-positioned within comprehensive community-based health services and if expanding contraceptive choice accelerates the attainment of this goal.

Evidence from the last decade indicates that significant strides have been made towards MDG 5 targets, but that reaching them by 2015 is improbable (Lozano *et al.* 2011). Recently, fervor to addressing this problem has increased due to the mounting consensus that fertility reduction is associated with corresponding declines in maternal deaths (Ross & Blanc 2011; Ahmed *et al.* 2012; Jain 2011). This proposition is particularly compelling in countries, such as Tanzania, where fertility remains pre-transitional, unmet need for contraception is pervasive, and maternal risk over the life-span is high (Tanzania DHS 2010). International research has consistently shown that effective family planning interventions that increased the breadth and depth of access to effective contraceptives explain the onset, pace, and extent of fertility decline where demographic transitions have occurred (UNFPA 2012). However, in several sub-Saharan countries, the onset of reproductive change has lagged behind other regions of the world where demand for family planning is equivalently pervasive. Overall progress toward achieving universal access to family planning, in turn, has stalled, contributing to slowed fertility transitions, high rates of unintended pregnancy and stagnant levels of maternal mortality (Shah & Say 2007).

Throughout sub-Saharan Africa programs to address this challenge have focused on community-based distribution of family planning (CBD). Much of the evidence behind the proliferation of these programs comes from other countries and the findings from this research in Africa have been mixed. For example, studies have indicated that CBD decreases unmet need for family planning (e.g. Luck *et al.* 1996) and others have shown that it actually

has an increasing effect (e.g. Debpuur *et al.* 2002). Whereas there is evidence to support that CBD increases contraceptive adoption (Goldberg *et al.* 1989; Dube *et al*. 1998), there is little proof it has fertility effects (Phillips *et al.* 1999). Only one evaluation of CBD has proven to reduce fertility (Binka *et al.* 2001), but its plausibility design precluded the rigorous assessment of the impact of doorstep access on unmet need and fertility. Studies concerning the effects of increasing contraceptive choice have typically employed method acceptance and continuation (i.e. Jain 1989) and contraceptive prevalence (Thomas & Maluccio 1996) as analytical endpoints. Particularly relevant explorations have studied the effects of program effort to maximize method access for clients' patterns of use (Ross *et al.* 2002), but little exists in the literature indicating the actual fertility effects of the intervention. Thus, it holds that testing the impact of community-based strategies for achieving MDG5, mainly vis-à-vis their fertility effects, should constitute a foremost priority for current global health research.
Likewise, little is known about how to operationalize the "reproductive health for all" agenda. Even successful pilot programs rarely take into account the effects of contextual factors, implementation variation, and organizational behavior that denote how health systems perform (Partners for Health Reform*plus* 2004). Program evaluations are frequently hypothesis driven and seek evidence of impact, but give little attention to how and why the benefits achieved during a pilot actually occur and how they can be expanded (Simmons *et al.* 2007). Decisions based on impact findings alone often beget unanticipated challenges and costs which render scale-up unfeasible (Shortell *et al.* 1998).

Process-oriented approaches for evaluating health programs hold much promise but require methodological development for practical use (Barnes *et al.* 2003; Mason & Barnes 2007). Likewise, the need for system-wide success of reproductive health interventions in developing countries provides an opportunity for applying and refining these approaches (i.e. Van Belle *et al.* 2010). Nevertheless, this, at best, would offer plausible explanations of program results, but not probabilistic statements of what a program could attain at scale (Pawson & Tilley 1997). How to balance the need for evidence that family planning programs accelerate achievement of MDG 5 in sub-Saharan Africa with the demand for particularistic findings on how they work now constitutes a fundamental priority for attaining universal access to reproductive health.

The Connect Project: Introducing Community Health Agents to Accelerate Achievement of MDG 4 and 5 in Tanzania

In 2007, the Ministry of Health and Social Welfare (MOHSW) of Tanzania launched the Primary Health Services Development Plan (Mpango wa Maendeleo ya Afya ya Msingi – MMAM). The MMAM policy emphasizes the need for 'complex interventions' at community-, clinical- and health system-levels to expand the range, reach, and quality of access to maternal, newborn and child health (MNCH) interventions, including family planning (Tanzania Ministry of Health and Social Welfare 2007). Yet, the MMAM leaves no blueprint carrying out systemic reforms. To date there remains little evidence that shows which MNCH interventions work best in which settings, how districts can sustain them beyond pilot periods and implement them at scale.

This evidence gap is particularly prominent for family planning. Tanzania has yet to enter the global fertility transition. The rate of national population growth is ranked 7th in the world at 2.9 percent (UNFPA 2010) and reduction in population growth has stagnated (UNDP 2009). Decreasing total fertility is key to development in Tanzania and satisfying demand for family planning would avert a significant number of maternal and child deaths, bringing the country closer to achieving MDGs 4 and 5 (USAID 2009; Kanté *et al.* 2012). The highest levels of fertility and unmet need for family planning occur in rural areas where most Tanzanian women live. Rural mainland women have a total fertility rate of 6.1 births and the use of modern family planning methods remains low at 25 percent in rural areas (DHS 2010). Unmet need for family planning remains high, at 27 percent for rural women in 2009 (DHS 2010). For decades, projects have responded to this problem through community-based distribution (CBD) initiatives, but all initiatives to date have failed to produce large scale progress owing to a range of constraints: limited range of methods available, frequency of stock-outs, reliance on unpaid, inadequately trained and supported volunteers, the absence of comprehensive family planning as an integral component of the national primary health care program. As a consequence, there is no evidence that CBD has an impact on fertility (Mbunda 2010).

In response to the MMAM evidence gap the Ifakara Health Institute (IHI) with technical assistance from the Mailman School of Public Health at Columbia University (MSPH), designed an intervention, known as the *Connect Project*, which sought to operationalize the community-based piece of the MMAM vision by way of a paid community health worker program based in three rural districts of the country. Launched in 2010 with goal of providing evidence on both the impact and process which will guide the national roll out of the current policy, *Connect* is a randomized controlled trial that tests the childhood mortality and fertility impact of a new cadre – Community Health Agents (CHA) – using an

existing continuous demographic surveillance system in study areas as the core resource for assessing impact. The CHA service delivery package integrates general health promotion, education and referral for facility care, family planning counseling, distribution of oral contraceptives and condoms, safe motherhood promotion, essential newborn care, IMCI and case management of childhood illness.

Connect has completed two years of operation. It has recruited CHA, trained them for nine months in community-based primary health care, posted CHA to 50 villages, developed supervisory systems and community governance mechanisms, launched information and monitoring operations, and implemented logistics support systems. Presently, it is in the field as a community-based primary health care and family planning operation and will complete four years of observation of population exposure to services over the2011 to 2015 period. Though *Connect* is currently focused on accelerating gains against newborn and under-five mortality, it has monitoring capabilities and statistical power to evaluate impact vis-à-vis the key contributors to MDG5 such as contraceptive prevalence and unmet need for family planning, as well as fertility.

Objectives and Research Questions

In 2012, after reviewing the evidence of extensive unmet need for family planning in study areas, the project decided to structure within the trial an introduction of injectable Depot Medroxy Progesterone Acetate (DMPA) contraceptives – the most popular method in Tanzania (Tanzania DHS 2010). With this addition to the service regimen, *Connect* will test the proposition that increasing the mix of family planning methods available in communities can accelerate attainment of MDG 5. The counterfactual design will gauge the extent of impact of conveniently available, community accessible oral and injectable contraceptives and condoms relative to services confined to fixed points of dispensary and health center based care. An integrated program of implementation research will pursue actionable evidence for re-positioning family planning in Tanzania within the MMAM vision for health systems development.

The present paper develops a framework for exploring the pathway from the processes of expanding contraceptive choice and accessibility, to achieving impact at scale and systemic reform in Tanzania. This systematic program of 'learning by doing' addresses methodologies to enhance the study of health effects and the organizational changes that emerge from piloting community-based a reproductive health programs, scaling it up within the *Connect* experiment, in addition to demonstration sites throughout the country. Specifically, the paper

illustrates the role of research for informing population policymaking and program implementation:

1. What factors facilitate or hinder the success of programs to improve reproductive health outcomes?
2. What assessment features reflect the overall effectiveness of such programs?
3. What is the population impact of such programs at scale?
4. What is the potential for sustainable scaling up of such programs and what are the characteristics and processes that can lead to their sustainability?

Review of Literature

There is extensive evidence from neighboring countries as well as Asian programs that community-based distribution of DMPA is safe and effective (Malarcher *et al.* 2010), and that reproductive changes improves maternal and child health (Cleland *et al.* 2006). The WHO promotes CBD of DMPA injectable family planning globally (WHO 2009). While frameworks have been advanced for introducing new contraceptives into service systems (WHO 2002; Simmons *et al.* 1997), evidence of their impact is limited (Phillips *et al.* 1999) and little is known about how to translate innovation into the routine workings of health system organizations (Fajans *et al.* 2006). Research on knowledge translation indicates the relevance of management practice and organizational context (Van Belle *et al.* 2010; Grimshaw *et al.* 2004; Rubenstein & Pugh 2006). How health systems create and sustain an absorptive capacity for new knowledge and achieve a receptive organizational context for normalizing and scaling up evidence based practices is now a research priority (Greenhalgh *et al.* 2004; Fixsen *et al.* 2005).

Also influential are the structure and strategy of the implementing organization (Stetler *et al.* 2007). Theory-driven, realistic evaluations challenge assumptions that what is proven to work can work at scale and provide an understanding of what is being implemented, why and how it works within the culture and context where adopted (Chen 1989). By testing the premise of logic models (Fulbright-Anderson *et al.* 1998; Barnes *et al.* 2003; Mason & Barnes 2003) that indicate what works, in which conditions, and for whom, they contribute to the identification of underlying generative mechanisms of interventions, (Ogrinc & Batalden 2009) the influence of context upon the outcomes, (Koenig 2009) and the feasibility of approaches towards sustainably scaling up interventions in non-research settings.

Understanding how interventions work and why is vital for the adopters and managers of innovative practices, although policymaking is frequently guided by different concerns.

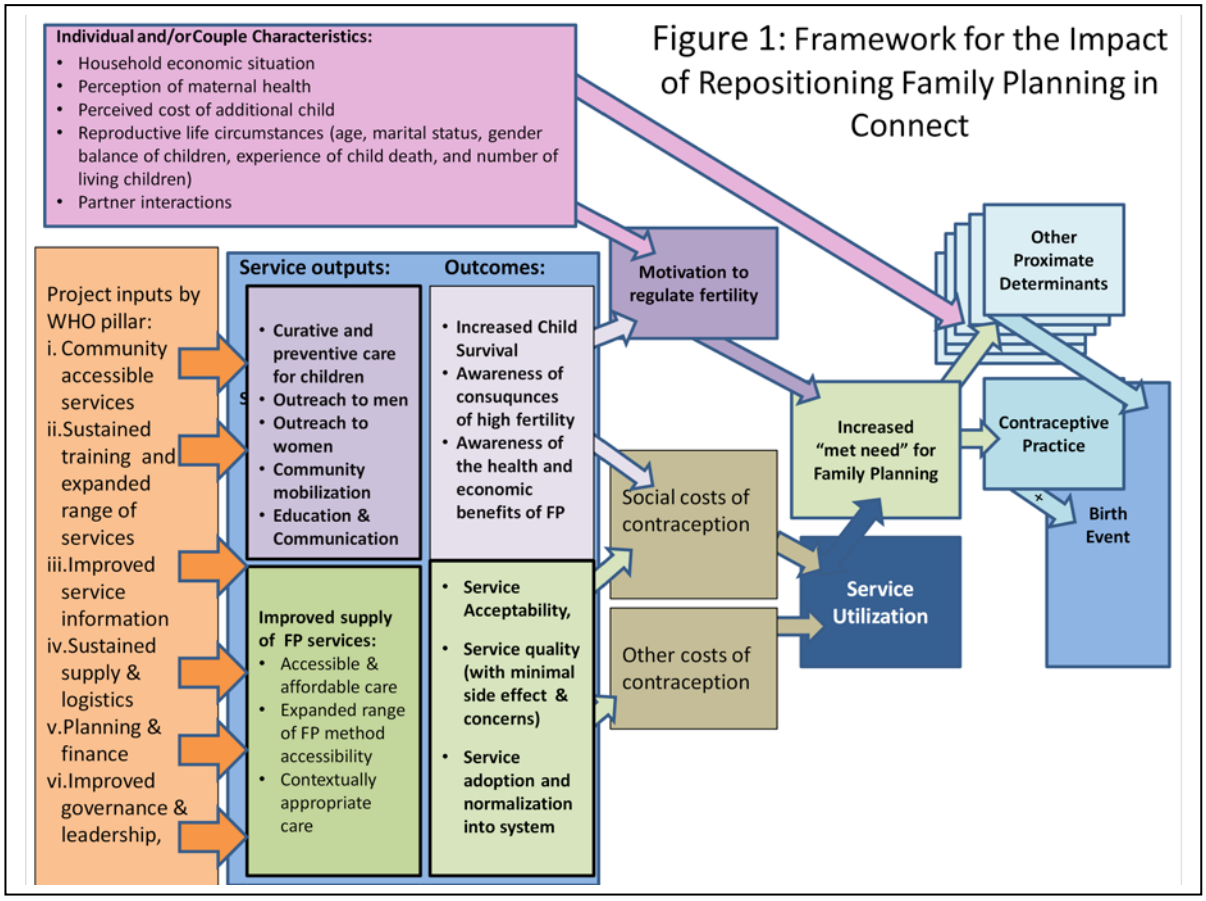
CBD research should test the notion that this approach affects preferences and unmet need by improving the climate for spacing and possibly introducing ideational change about limiting (i.e. Koenig *et al.* 1987). Efforts to accelerate adoption must demonstrate the ability to improve acceptability of contraception, and offset its perceived social costs (Bawah *et al.* 1999). The quality and effectiveness of such programs is often assessed by measuring contraceptive continuity and method failure (Hossain & Phillips 1996). Impact, will then be achieved by improving spacing, or to lesser extents delaying and limiting, as consequences of enhanced adoption and continuation, which, in turn, reduces fertility and begets improved health effects for women and children over the life course (Cleland *et al.* 2012).

Theoretical Framework

To demonstrate that MDG 5 can actually be achieved in adverse settings of sub-Saharan Africa, programs must address the need for evidence of impact and constructively portray how impact is achieved through implementation in context. Pilots of innovative practices in reproductive health, it follows, should take the form of policy experiments (Rondinelli 1993). Although few guiding examples exist, they remain necessary for underpinning a coherent strategy for evidence based action. The forthcoming redesign of the *Connect* initiative intends to fill this gap. It describes a framework and methodologies for assessing the extent to which, and how, the *Connect* service system, by expanding contraceptive choice and access, attains reproductive health for all. *Connect* has been launched with an experimental design that is motivated by the WHO sponsored framework for health systems strengthening (WHO 2007).

Our extension of the WHO framework is based on the following assumptions: affecting fertility preferences, unmet need, and contraceptive acceptability is essential, but its achievement at scale requires broad-based and enduring organizational change in the systems – public health and community – that comprise the means and strategies for bringing reproductive health services to the population. Secondly, although the available evidence indicates the interventions which these systems *should* adopt, the effectiveness of interventions depends on how implementation strategy adjusts for organizational and external contextual factors to impart lessons learned about what works and what fails to facilitate the coverage, quality and utilization of programs and which hinder them.

The theoretical framework for this project represents a synthesis of the WHO health systems strengthening framework with the framework of Easterlin and Crimmins (1985) and Easterlin (1988) for explaining the determinants of demand for family planning, as well as



those for studying organizational culture and context (Pettigrew & Whipp 1993) and analogous applied theoretical frameworks (e.g. Chen 1990; Pawson & Tilly 1997). The former is used to study the determinants of met need and contraceptive utilization as a function of individuals' interaction with services and the resultant changes in women's and couples' demand for fertility and perceptions of the benefits and costs of method uptake and continuation. The latter two frameworks attempt to combine work on the 'strategic management of change', the processes that define how systems absorb or resist the utilization of best practices, bringing into consideration social theory on social and institutional determinants of human behavior that are influenced by the interaction of special projects with contextual factors.

Integrating these perspectives into a single theoretical perspective is appropriate for adding family planning to *Connect* because the project is embedded into a district health management organization that is, itself, part of the social, cultural and organizational system where project implementation must be pursued. The outcomes of the project – coverage, quality and utilization of services – not only affect the demand for services and fertility preferences directly, but also catalyze organizational change to absorb evidence, adopt new practices, adapt and deliver services at scale (May *et al.* 2007). Figure 1 portrays this

interface between organizational and social systems. Efforts of the *Connect Project* to strengthen system functioning are posited to have direct organizational outputs that affect health behavioral outcomes. These outputs are factors that either influence demand for contraception or the supply of effective services, with supply factors influencing actual or perceived social and monetary costs of practicing family planning. Participant perceptions of the benefits and costs of uptake and continuation of family planning services then emerges as a function of the pilot program's success with consequent effects on unmet need. This, in turn, is posited to lead to sustained contraceptive use which affects fertility.

Connect: Study Design

The introduction, expansion and assessment of DMPA in the *Connect* service system will proceed in strategic phases. This process aims to facilitate 'learning by doing' at each stage and will be undertaken jointly between the project and stakeholders who will use evidence for action (Simmons and Shiffman 2007). Termed the "strategic approach", the process of introducing DMPA in *Connect* will start within a subset of intervention villages of one *Connect* district, Rufiji. Overtime, the innovation will be scaled up within Rufiji and later in *Connect's* two other districts, Kilombero and Ulanga (Table 1). The final product will be program with expanded family planning capabilities to be known as *Connect-FP*.

Table 1: Strategic phases of DMPA introduction

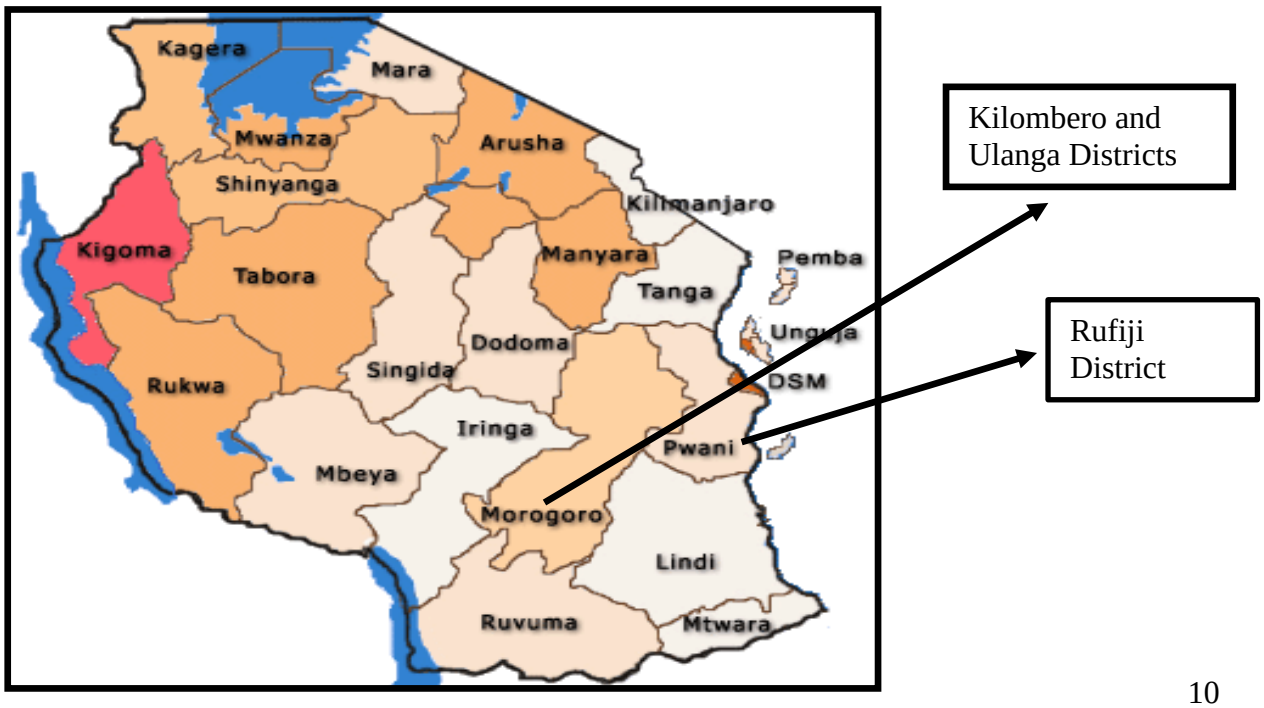
Phase	Micro-pilot and strategic planning	Expanded pilot based on evidence	Impact experiment	Project validation and expansion
Questions	What is feasible? What can succeed?	How does it work? Is it effective?	Can strategy be validated? Does it work?	Is scale up happening?
Approach	Micro-pilot and social research	Process evaluation; safety and quality of care assessment	Randomized cluster trial; operations research	Operations research, quantitative and qualitative system appraisal
Findings	Factors that facilitate or hinder program coverage, quality and utilization.	Quality of services; contraceptive continuity organizational change	Fertility and MDG 5 indicator impact.	Characteristics and processes of sustainability and scaling up.
Product	Alternative models for operationalizing MMAM.	Effective strategy for implementing MMAM.	Consensus for change; evidence of scale up potential.	MMAM-driven health systems reform.

Project Setting

The *Connect Project* is underway in Kilombero, Rufiji and Ulanga districts (Figure 2). The districts were chosen to represent the regional diversity of the country and to enable utilization of the Health and Demographic Surveillance System (HDSS) to monitor the outcomes and impact of the CHA service system. The total population of these expanded areas is estimated at approximately 375,000 in December 2011. Kilombero and Ulanga are isolated, impoverished districts that lie between 200 and 400 km from Dar es Salaam in the Morogoro Region of southwestern Tanzania. These areas are predominately rural with economies that rely primarily upon subsistence agriculture. The Rufiji district is located in Tanzania's Coastal Region, south of Dar es Salaam, and is also rural. Most inhabitants are subsistence farmers, though there is some trade in fishing and in wood products. Transportation and infrastructure in all three districts are poor.

In all, 101 HDSS villages were stratified by population and randomly allocated into 50 treatment communities where CHAs operate and 51 communities served only by the usual public health programs that operate in clinics and dispensaries. Of the 101 HDSS communities, 51 are located in Kilombero, 12 in Ulanga, and 38 in Rufiji. Analysis using the HDSS and cross sectional panel surveys in linked households has demonstrated comparability vis-à-vis other relevant health indicators. Since legacy data are available for the period since 1999, power calculations could be undertaken that attest to the feasibility of counterfactual comparison across intervention and comparison areas.

Figure 2: Connect Study Areas



Allocation of CHA to treatment villages was determined based on population size. Villages <1,000 have received a single, female CHA. Villages with a population between 1,000 and 3,999 (inclusive) have received 2 CHAs, one male and one female. Villages with a population between 4,000 and 6,999 (inclusive) have received 2 female CHAs and 1 male CHA. Villages with a population of 7,000+ have received 2 male and 2 female CHA.

Connect Intervention

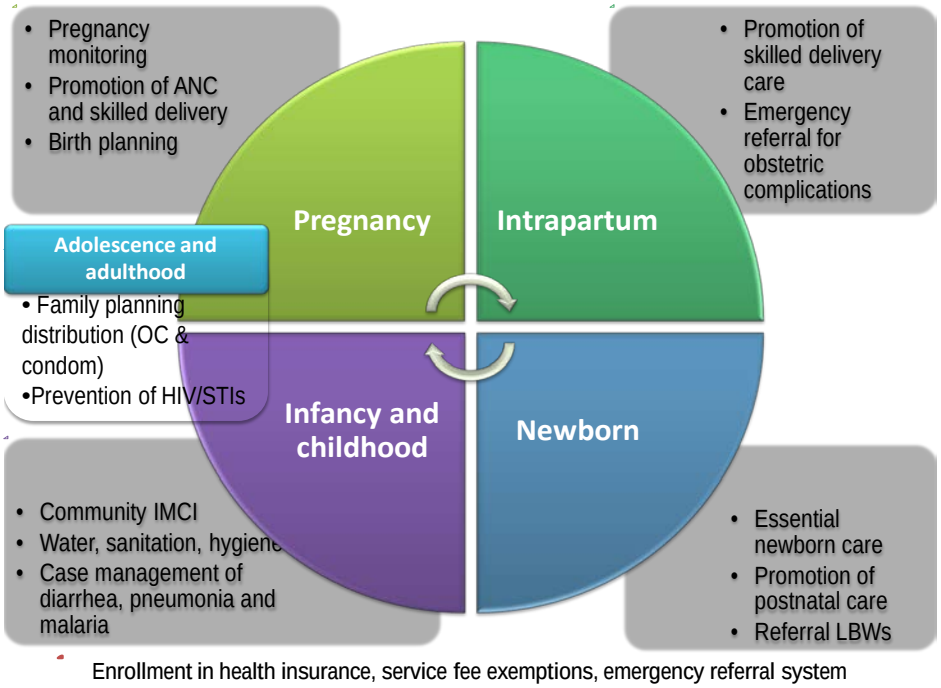
In 2010, the program commenced with the recruitment and selection of candidates. This was followed by a nine months training program leading to the designation of a new cadre known as Community Health Agents (CHA) who are formally trained and employed by the health system and provides a package of health services in the community, connecting households to facilities while engaging in risk identification and management, care for sick children and referral of maternal and child health emergences. CHA are members of the community where they work, selected by the community, and answerable to the community for their activities. But they are also frontline workers of the MOHSW MMAM initiative. Recruitment and selection of CHA tapped into village-level customs and procedures whereby local leadership committees, having understood the program, job description and qualification requirements, led the solicitation and review of applications, selected candidates to stand in a village wide election whereby all residents took part in choosing their CHA who were then sent for training. Apart from being fairly elected by their village, the minimum qualification for a CHA is completion of a secondary education.

During preparatory phase of the project, the IHI convened an advisory committee to design the CHA role and work package. This was based on the premise of task shifting MNCH services to CHA whose service package would develop both the home-to-hospital and lifecycle continuum of care by integrating behavior change communication, education, counseling and referral functions with actual delivery of appropriate MNCH services. The nine-month pre-service training is a residential competency-based program that allows CHA to pursue further training as a health provider. The training is divided into two levels to meet national accreditation requirements. National Training Accreditation level 1 is comprised of training in human biology, basic clinical skills, and community health skills, and NTA level 2 is a more rigorous course including training in advanced clinical skills, reproductive health and family planning, integrated management of childhood illness, essential newborn care, disease prevention and control, community entry and stakeholder networking. To meet

presumed manpower requirements for testing impact, *Connect* trained a total of 57 CHA in the first round of training and 56 CHA in the second round of training and deployed them to their home villages. Although CHA recruitment and training was financed with project resources, they are salaried contract employees of local Council governments. Their compensation, calculated according to government salary scales, is administered through local systems of payment and benefits enrolment.

During the training period, the Connect intervention team designed and prepared a program for ensuring the provision of health system support and linkages for the CHA. Clinical supervisors from catchment facilities as well as village government-selected supervisors representing intervention communities were recruited and trained to perform supportive supervision and report activities to the district and project. During the period of recruiting supervisors, the Connect intervention team primed village leaders and stakeholders for the arrival of the CHA, engaging them in the process of preparing storage and work areas for the CHA, community entry procedures and work planning and inculcating a firm understanding of the CHA role. Regarding health information, registers and reporting forms were developed and are being utilized by CHA based on their unique package of services. These forms will also be integrated into existing vital registration and district health information systems. CHA also receive a specially-designed kit of medicines, supplies and equipment, and re-supply mechanisms, which are being developed with the district governments. Additionally, they are linked to local governance structures, such as village

Figure 3: Community Health Agent Work Package



social service committees and health facility governance committees, in order to assist in mobilizing the communities, providing data for decision-making, advocating for community needs, as well as for supporting the CHA to provide care that is acceptable and attune to village realities. Training and health system linkage and support preparations were completed and the Connect service system was launched in August 2011.

DMPA introduction: phases in the scaling-up process

From its onset, the introduction of DMPA into the *Connect* service system will be an instrument of the health sector reform process rather than a discrete research study for generating scientific results. A sustained partnership between researchers and policymakers in Tanzania will carry this process forward from micro-pilot to regional scale up. Table 2 outlines the 'strategic approach' that has been customized in this instance in order to facilitate *Connect's* aim of re-positioning family planning in Tanzania within comprehensive community-based health services. It details what will be implemented and learned during each phase of the four phases, as guided by research questions, approaches and products contributing to national health sector reform.

Table 2: Research questions, approaches, and objectives associated with successive phases of *Connect-FP*

Treatment	Services	Question	Approach	Objectives	# villages
Phase 1: Strategic planning in Rufiji district:					
CHA with comprehensive FP	DMPA, Condoms/oral contraceptives	What is feasible?	Micro-pilot and social research	Develop a contextually appropriate and organizationally optimal strategy for integrating comprehensive FP services into community-based primary health care.	9
Restricted CHA	Condoms and OC				9
Comparison	Facility-based services only				18
Phase 2: Extending results of the strategy to all CHA villages in Rufiji					
CHA with comprehensive FP	DMPA, Condoms/oral contraceptives	How does it work?	Explanatory case study	Assess quality of CHA services, acceptability, and method continuity; develop health policy recommendations. Assess organizational change in health and community systems; develop procedures for scaling up the approach.	18
Comparison	Facility-based services only				18
Phase 3: Transfer of DMPA to intervention villages in Kilombero and Ulanga, experiment of expanding contraceptive choice through the Connect service System of MDG 5 targets					

CHA with comprehensive FP	DMPA, Condoms/oral contraceptives;	What is the impact at scale?	Randomized cluster trial	Evaluate the fertility and reproductive health impact of community-based distribution of comprehensive family planning & primary health care versus CBD of restricted FP Learn if community-based distribution of integrated MNCH-FP can be used to attain MDG 5.	25
Restricted CHA	Condoms and OC				25
Comparison (no CHA)	Facility-based family planning services				51
Phase 4: Utilize CHA experimental villages project organizational capacity to support and catalyze scale up.					
CHA will comprehensive FP services	DMPA, Condoms/oral contraceptives	Can it be validated?	Operations research	To understand the characteristics and processes of sustainable scaling up. Develop dissemination capabilities for evidence-based scale-up in *all* randomized villages Establish at least one replication and demonstration district in each region	101+[i]

Phase 1: Micro-pilot and strategic planning

Phase 1 will commence in the last quarter of 2012 by way of qualitative research amongst Rufiji district and community stakeholders. The purpose of this is to identify feasible alternatives for family planning promotion and service delivery and to illustrate how contextual factors and implementation variation affect the success of such programs. Findings will feed into episodes of strategic and participatory planning with community and health system stakeholders in which project scientists will facilitate the development of implementation strategy and processes in addition to establish essential health system supports and linkages for community-based activities. In order to generate consensus for introducing DMPA into the *Connect* service system, the micro-pilot will use 9 intervention villages where CHA will be initially trained to provide comprehensive family planning services, including DMPA, and 9 villages in which CHA family planning services are restricted to distribution of condoms and oral contraceptives. This will permit stakeholders to make a relative assessment of the feasibility and outcomes from micro-pilot activities. At the end of phase 1 they will make recommendations to improve the program and endorse it so as to enable the expansion of the micro-pilot to the 9 remaining intervention villages where CHA remain with a restricted method mix.

Prior to the launch of DMPA service delivery, in-depth interviews and focus group discussions will be convened in six villages of Rufiji districts ecological zones (delta, mainland-rural and urban) to gauge opinions about the design, contextual and implementation-related factors that shape reproductive health-related attitudes, decision-

making and service utilization, and the quality and acceptability of current community-based services. Particular attention will be directed to seeking guidance from women about their needs and advice on family planning service strategies. Men will also be sampled to capture perspectives on potential for marital and gender-related discord that may result and identify strategies for health promotion and service delivery that garners male support and participation. Village governance, traditional and religious leaders will also be interviewed to provide additional information on the social and cultural structure of high fertility, family size preferences and low contraceptive utilization

Additional interviews and semi-structured questionnaires will be administered to CHA, clinical service providers, village leaders, district planners and managers which elicit information on contextual factors in community and health system organizations that would affect the pilot and eventual acceptance and utilization of family planning services in the community. Research will emphasize leadership, decision-making and information-utilization at these levels, i.e. what is in place to sustain the process implementing the program; experienced and forecasted economic, political and administrative challenges, how they affected health care and are handled, i.e. feasibility for sustaining the program itself; factors in the environment that affect reproductive health; social, cultural, economic aspects of care-seeking; financing, human resources and management of programs, i.e. feasibility for sustaining the impact of the program. Key informant interviews with national level policymakers and stakeholders will also be used to assess the policy barriers and opportunities, and general political viability, of community-based health systems reform, MNCH-FP integration and expanded contraceptive choice at this level.

Activities that emerge from these data will be implemented in a micro-pilot in nine initial intervention communities in Rufiji district where CHA are currently operative. Accordingly, they will focus on practical and appropriate strategies for pilot success that are attuned to contextual realities. From them, guidelines will be formed for engaging the range of community and health system stakeholders in managing their program of work, subordinating technical aspects of health promotion and services to traditional and other local forms of governance. Local leaders, clinical supervisors and district coordinators will be oriented to tasks of securing community commitment to integrate CHA and family planning activities into their routine workings, and clarify the role and potential for community volunteerism, and vibrant social networks that are relevant in this setting.

From this experience, steps will be developed for modifying coverage areas for CHA and adapting their workflows for the introduction of DMPA, social mobilization and health

promotion activities. Field methods supporting CHA operations by project members, district and clinical supervisors will be formed as well as procedures for planning and coordination between CHA and clinical counterparts. These procedures will be articulated in the form of training content for CHA, village supporters and clinical supervisors. For the implementation strategies that emerge from this work, project scientists will revise current health information procedures to ensure that CHA record essential information about episodes of counseling, referral and service delivery. Simple monitoring and evaluation tools will also be developed which assess CHA adherence to clinical procedures, as well as CHA, supervisor and village stakeholder adherence to procedures formed during strategic planning.

Following pre-pilot research and program development CHA will be trained in comprehensive family planning. At this point orientations of village representatives, clinical supervisors and district focal persons will also ensue. CHA training, though mostly focused on the practice of safely delivering and disposing of the DMPA injectable, will aim to improve general counseling and education of family planning, appropriate client screening and impart strategies for carrying out the activities and procedures developed in the pre-pilot period. Clinical supervisors, district-management focal persons and village representatives will be oriented to the latter aspect of the CHA training.

Following the training, monthly focus group discussions and interviews with village, clinical and district stakeholders will be used to gauge reactions to strategies, point out problems and proffer solutions, permitting project scientists to revise operations accordingly. Project scientists will be deployed to micro-pilot villages during this period to monitor implementation fidelity, documenting factors that facilitate or hinder implementation and their consequences. At this point, quality of care assessments will commence involving project scientists and clinical counterparts. These will rapidly identify and correct technical problems and, thereby, address broad-based concerns over the safety of the controversial practice. After 3 months of strategic planning and 6 months of the micro-pilot and participatory assessment, project scientists and stakeholders will review findings jointly, concur on steps to improve operations and strategies for expanding the DMPA introduction into the 9 remaining *Connect* intervention villages in Rufiji.

Phase 2: Expansion of DMPA services and explanatory case study

The strategic review of findings from phase 1 will produce implementation milestones and process guidelines that will, in turn, be used to transfer the innovation developed during that period. At this point, the research focus will shift to the content of service delivery and

organizational change that emerges from the pilot. This will discover how the innovation works – what factors and practices facilitate coverage, quality and utilization of the CHA service system, and how effective is the intervention in terms of contraceptive continuity of the user and the structural changes health system and community organizations make to normalize the service system into its routine workings.

At this point, an multi-method explanatory case study will be undertaken (i.e. Koenig 2009) to assess the extended pilot and test the assumption that the implementation strategies identified in Phase 1 meet locally accepted quality standards (WHO 2009). Investigation will determine if CHA deployment is acceptable to users and providers (Malarcher *et al.* 2011) and if community based care more highly utilized than facility services (Bhatia *et al.* 1980; Azim 1994; Huber *et al.* 2010). Monitoring systems will determine if CHA operations differentially benefit under-served groups, a key aim of the MMAM initiative (i.e. Hatzell-Hoke *et al.* 2008). During this period, project scientists will also assess the effects the program on organizational behavior and implications of worker reactions to the system for improving the contribution of local governance and health care management to repositioning family planning in the system.

Investigation will utilize experience from Phase 1 to clarify the requirements milestones and processes associated with going to scale during phase 2. CHA and supervisors will summarize intervention activities in monthly summary forms that document volume of service delivery by method type, location and client characteristics, and episodes of counseling and educational service delivery, group health education, supervision interactions and coordination meetings with village stakeholders. Project scientists and district counterparts will also complete monthly reports to document management and research-related inputs and activities. These actors will be enrolled twice yearly in qualitative exercises to provide information on implementation-related decisions and actions they undertake and consequences. Data collection will focus on leadership and information utilization; economic, political or administrative challenges and how they are handled; financial, social and management-related consequences of the program.

To assess safety, quality and utilization the project will carry out sampling within two evaluation arms: intervention (i.e. CHA distribution of DMPA in community) and comparison (distribution of DMPA as per current policy, i.e. from facility providers). The rationale for the two-armed approach is to ascertain outcome measures of quality, acceptability and utilization that are relative the current health system standard. As discussed above, the actual onset of safety and quality assessments of community-DMPA delivery CHA directly

following the first CHA training during phase 1. Accordingly, intervention villages will be sampled purposively according to their status within the overarching *Connect* trial, and in two stages: in stage 1, 9 villages will be enrolled in the micro-pilot and, six months later, in stage 2, the remaining CHA from Rufiji will receive training and their 9 intervention villages also enrolled. The structure of this sample will be determined according to population size of villages and the number of CHA operative in them so that each village cohort will be comparable according to those aspects. The purpose of this is to permit a segment (stage 1) of observation during the micro-pilot that permit for comparing service quality, acceptability and utilization amongst users from (a) communities that do not have a CHA and can only get services from facilities in the comparison arm, (b) communities with CHA that can only provide condoms and oral contraceptives, and (c) communities with CHA that can provide condoms, oral contraceptives and DMPA. For every case village that is sampled during the two stages, a comparison case facility will be sampled. Comparison case facilities will be considered for selection provided that they are not located within an intervention community and that the facility is within the sentinel area of the HDSS. There will be 18 intervention cases (communities) and 18 comparison cases (facilities).

Within each case DMPA clients and providers will be sampled for assessments of quality and acceptability. Within community cases, relevant community members will also be sampled in order to provide information on the acceptability of the service to different segments of the village population (i.e. men, adolescents, opinion leaders, etc.). An equal number of clients will be enrolled from intervention villages and comparison facilities. Sampling of clients will commence upon the enrollment of the case into the study, i.e. in two stages, but procedures will be identical and the number of clients enrolled will be equal across stages. Actual enrollment of DMPA clients will take place at designated community or facility locations respectively during between 3 and 4 planned sessions when service utilization is expected to be ample. During these periods a trained data collector with a clinical background will perform informed consent, asking clients to agree to their observing her interaction with the provider, to participate in an exit interview and in a follow up interview which will occur four months following the observation. Sampling of clients will be compressed within the first six weeks of DMPA introduction in communities in order to facilitate comparability across cases.

Enrolled clients will be followed up after four months for data collection concerning their recall of their service encounter and decision to continue the method. Providers in intervention cases will be purposively selected: all CHA will be enrolled as participants. In

comparison cases, DMPA providers will be enrolled for the same regimen of data collection as CHA provided that the provider is a Clinical Assistant or above (i.e. recognized by the system as qualified to deliver DMPA). As discussed earlier, whereas providers and clients will be enrolled in cases to permit an examination of quality and acceptability based on their interchange and perspectives, within communities a wider range of actors will also be enrolled in order to gauge reactions and explore the climate of acceptability of community-based family planning. Sampling for these participants will be in two stages: the project will purposively identify sub-groups in the population whose views and perceptions are relevant to reproductive health care seeking in the community. Within those groups individuals will be selected randomly for participation in focus group discussions on these issues.

Assessment of community-DMPA service quality, acceptability and utilization will be carried out using observation checklists, client exit interviews immediately after receiving the service from CHA and a follow up questionnaire administered four months after receipt of the service. A module will be integrated into the HDSS regimen in order to capture information on method continuation. Checklists will be designed for the purpose of clinically-trained observers to rate the quality and safety with which CHA delivery DMPA to clients. Observations and ratings will be structured using the following quality indicators: correct use of screening checklist, safe injection technique, accurate and complete counseling and proper syringe disposal. Exit interviews will capture data on client recall of counseling and education messages during the interaction, their satisfaction with the service and perceptions of its quality. The aim of the follow up interview administered after four months will be to learn about clients' decision to continue the method and motivations behind that decision such as side-effects, fertility preferences, method failure, partner support, recall of counseling and education messages, satisfaction with the service and its quality.

For an extended exploration of contraceptive a Laing method calendar (Laing 1985) will be introduced into the HDSS that reaches all households in intervention and comparison villages. This will occur during the HDSS round that transpires during the period marking one year following the four-month follow up for clients enrolled in both sampling stages. Interviewers will ask all subjects for each month of the year period that just transpired if the client was using a contraceptive method. At instances where method uptake is indicated the interviewer will obtain information on method type, place where method was obtained and motivation for use. At instances where method continuation is indicated, the interview will record the method that had been discontinued and the motivation for discontinuation. Information obtained from clients upon enrollment in either the community or at comparison

facilities will be used to link exit interview and follow up questionnaire data to the information gathered from them at subsequent stages through the HDSS.

Findings from these activities will reviewed and distilled into accessible policy briefs. These documents will be customized for target audiences so that project scientists can use them to engage influential stakeholders in policy, district management and community settings twice-yearly in updates and evidence reviews. The consequences of this will subsequently be captured through a longitudinal process of 'qualitative systems appraisal'. For this, the project will use purposive case sampling. At the national-level, cases will be selected based on their relevance to reproductive and primary healthcare policymaking and healthcare research utilization and program design in Tanzania. Within Rufiji district participants will be sampled from the Council Health Management Team (CHMT), Community Health Services Board (CHSB), Health Facility Management and Governance Teams. Village-level bureaucratic and traditional structures comprise of village executive officers, chairmen and health committees that influence the climate of demand for health services in these settings will also be enrolled at these junctures. Data collection will comprise of in-depth interviews at these levels and focus on reactions to the extended-micro-pilot, information utilization and consequent changes in opinion-formation, decision-making, organizational learning and changes in organizational practice, foreseen economic, political and administrative challenges and strategies for handling them vis-à-vis implementation of the *Connect* service system and community-DMPA more specifically. Starting with the training of the second cohort of CHA, phase 2 will go on for a period of 18 months.

Phase 3: Randomized Controlled Trial

Prior to scaling up community-DMPA into the three-district randomization, project scientists will apply the theoretical perspectives discussed earlier on phase 1 and 2 findings. Triangulation of data will yield a rich picture of the factors that facilitate and hinder the coverage, quality and utilization of the CHA service system. Findings concerning innovation adoption and normalization at the community- and health systems-level, and contraceptive continuity of clients will be involved to understand more deeply the effectiveness of the pilot and the implementation-context interactions that led to those outcomes. This will involve quantitative and qualitative data analysis.

For quantitative data, primary analyses will be completed in order to establish relative measures of quality, safety and acceptability obtained from observation checklists, exit- and follow-up interview questionnaires from clients and providers in intervention and comparison

groups (i.e. CHA and facility-based DMPA service delivery). Whereas this will establish the relative safety and quality of community-based distribution, additional sub-analyses will be performed using intervention group data alone to identify variation in these outcomes that will be explored during later stages of analysis. Analysis of HDSS data will be used to determine rates of contraceptive prevalence in intervention and comparison communities, as well as continuity patterns and motivations amongst subjects from intervention and comparison groups respectively. Again sub-analyses will also be performed to identify variation across intervention villages to be explored more illustratively at later points. Review and analysis of intervention monitoring data will enrich comparative sub-analyses by providing a sense of what piloting processes and inputs explain variation on coverage, quality and utilization of CHA services. Qualitative data will be subject first to thematic content analysis following the procedure outline by Miles & Huberman (1984). 'Content analyses' and 'constant comparison' techniques (i.e. Glaser & Strauss 1967) will be applied across cases within the intervention arm and at different stages in implementation will be used to identify temporal and cross-case variation in program acceptability, individual and organizational change.

Using the quantitative and qualitative outcome measures, the 'context-process-outcome' analysis framework will be used to understand the determinants and processes of pilot success and effectiveness. Findings from the qualitative data on organizational change and contextual factors will be triangulated with data on implementation strategy to assess CHA service coverage, quality and utilization, and the effectiveness of the pilot on individual and organizational behaviors. Methods for this will draw on 'grounded theory' approaches developed by Glaser & Strauss (1967) and Strauss & Corbin (1998) and aim to derive inductively plausible explanations for complex outcomes – i.e. contraceptive utilization and continuity, quality of care, program coverage, innovation adoption – and their variation across cases using mixed sources of data on intervention strategy and context. This will support conclusions regarding the feasibility for sustainably scaling up the pilot into the *Connect* service system based on what is learnt about leadership, decision-making and utilization of evidence and information, experienced and/or foreseen economic, political and administrative challenges and how they will be handled as the program goes to scale.

Findings from these analyses will be shared with partners from the Ministry of Health and Social Welfare and *Connect* districts. Workshops will be held where evidence is distilled into comprehensible lessons learned. These will illustrate the changes required for expanding contraceptive choice and implementing community-based services more generally. Representatives from the Council Health Management Team in Rufiji will orient their peers

from Kilombero and Ulanga in the steps for changing operations from clinic-focused to community-based services. Together they will review the operational details and practical guidelines of phasing in the innovation to the workings of communities and the district in Rufiji, adapt and refine this model for relevance to circumstances in the other districts.

These peer exchanges will review and adapt the tools used in phases 1 and 2 for implementation process tracking as well as CHA coverage and service delivery in order to generate cheap and easy-to-use instruments that districts will use for generating evidence that guides their integration of the *Connect* service system into their routine workings. Whereas evidence of the quality and safety of CHA distribution of DMPA will be reviewed extensively, efforts to monitor CHA services will not be extended to the new districts with the same rigor owing to the evidence from phase 2. Supervisors from Rufiji district will instead orient their peers from scale up districts regarding their CHA supervision and performance monitoring strategies. This will facilitate the formation of strategies for improving implementation based on what is learned, and transferring the DMPA pilot to intervention villages in Kilombero and Ulanga districts. In turn, this will permit a full use of the existing experiment for randomized control trial of MDG 5 impact.

The scale up of community-based DMPA in this phase will be pursued incrementally in order to maximize potential for understanding the impact of different policy alternatives. At the outset, the pilot will be expanded to roughly 7 additional intervention villages in Kilombero district, for a total of 25 villages, including those in Rufiji, with CHA providing doorstep DMPA. The remaining 25 intervention villages will remain with CHA that provide the restricted regimen of family planning methods, oral contraceptives and condoms. The 51 remaining villages in the randomization will stay as comparison villages for the duration of the trial. Allocation of community-DMPA treatment will denote the formation of experimental cells within the existing counterfactual design (table 3). Baseline levels of overall and age specific fertility rates were calculated using HDSS data for the five year period preceding the deployment of CHA (July 2006 – 2011). It demonstrates no significant differences in TFR across the cells which stood at 4.7 births per woman of reproductive age in each randomized area. Neither did it indicate any significant differences in age specific fertility rates across cells. Baseline contraceptive prevalence rates were also calculated. These demonstrated baseline rates of 36% with no significant differences neither across treatment and comparison areas of the current randomization nor across the phase three cells.

Table 3: Cells in Experimental Design

DMPA is made available in…	Contraceptive services are made available….	
	In Health Centers and dispensaries only	**In health centers and dispensaries and by community-based CHA**
…Health Centers and dispensaries only	**Cell 1:** Comprehensive clinical care comparison communities 51 communities where all family planning is provided at facilities	**Cell 2:** Expanded access to family planning 25 villages where CHA provide OC and condoms.
… Health Centers, dispensaries and in villages and homes by CHA		**Cell 3:** Expanded family planning choice 25 villages where CHA provide OC, condoms and DMPA.

The substantive hypothesis of the study is as follows:

- H1: After Cell 3 population exposure to treatment conditions for a period equivalent to the baseline mean closed birth interval, the TFR in Cell 1 > Cell 2 > Cell 3;

… and the null hypothesis is:

- H0: TFR in Cell 1= Cell 2 = Cell 3.

Comparison of cells will provide answers to questions about the relative fertility impact of adding community-based family planning to a primary health care program versus broadening the regiment of community-based family planning to include the doorstep provision of DMPA. Results will test the proposition that comprehensive community-based care not only was possible to achieve, but also improves the quantity of family planning care and the impact of care on fertility (e.g. Phillips *et al.* 2006). Multivariate spline regression methods will be used to evaluate the hypothesis that the addition of DMPA to *Connect* will be associated with a disjuncture in the fertility time trend of Cell 3 relative to the fertility trend arising from the first two years of village exposure to Cell 2.[ii] Research will provide statistically rigorous evidence to support policy commitment to whichever model is shown to be the simplest variant that impacts on fertility. In studies conducted elsewhere, the rigor of experimental evidence has been a determinant of successful scaling-up elsewhere (Phillips *et al.* 1988). After the population has been exposed to the treatment condition for a period equivalent to the baseline mean closed birth interval, project impact against fertility, contraceptive prevalence and unmet need will be measured.[iii] Stakeholders will then be asked to convene again, review the findings, and decide if a scale up

should be undertaken to introduce DMPA to all intervention villages in the experiment, thereby closing one experimental cell and re-shaping the trial to have a three celled design.

The preceding section on the *Connect* study design provides additional relevant information on how project scientists will use the current experiment to measure impact on fertility and key MDG 5 indicators. Fertility and contraceptive prevalence rates will be measured continuously using the demographic surveillance platform which is operative in the entire study area and captures the required data thrice yearly. Information required for measuring impact on unmet need for family planning in the study population will be collected cross-sectionally using a customized module that is added to the DSS fieldworker regimen at first at baseline, again after the first assessment for fertility impact, and again at endline should the decision be taken to introduce DMPA in all 50 intervention villages.

In some important examples of health experimental research, Phase 3 has been extended to include replication research. In this approach, senior health officials from national, regional and district levels are involved in the design and implementation of transfer experiments, with the goal of resolving debate about the relevance of experimental results to the national program. Special studies often generate controversy about the sustainability and affordability of experimental approaches to large scale operations. However, replication research can test the proposition that operations are transferable to non-research settings and also clarify the steps and processes that optimize scale-up operations. In the case of experiments in Bangladesh and Ghana, replication studies were pursued as a distinct phase in the scale-up paradigm (Phillips *et al.* 2007). Dispersing experience with innovation addressed concerns about the relevance of the experiment to diverse social, ecological, and economic circumstances of each region of the countries where scale-up was pursued.

In the case of introducing of DMPA into *Connect*, the necessity for replication research is not yet determined. The aim of the research undertaken in phases 1 and 2 together with the district-driven innovation transfer in the current phase and ongoing economic evaluation is to provide critical information for initiating a national scale up process. It is possible that replication research will not be necessary provided that several conditions in phase 3 are met. These include adequate participation from MOHSW officials, leadership and constructive engagement between peers from pilot and scale up districts, and adherence of district actors to implementation and learning procedures established during the micro-pilot.

Phase 4: Scale up and validation of initiative in all study villages and demonstration areas

Results from the phase 3 trial will demonstrate the impact for increasing contraceptive choice within an integrated community-based primary health and that it is feasible to scale up the effects of the micro-pilot in districts that are socially, culturally and ecologically different from the setting of phases 1 and 2. Phase 3 will also document the process and effects of transferring the management and supervision of the pilot innovation through district-driven peer exchanges and adaptation of process evaluation techniques into practical, easy-to-use and cheap research tools. Evidence of MDG 5 impact will be paired with practical guidelines for program implementation that are associated with each cell. These will be discussed in a national steering committee meeting that has already been constituted for governing *Connect*. As consensus emerges that national implementation of the *Connect* service model is feasible, a secretariat will be constituted for guiding the scale-up process. This approach has been used in Tanzania to guide the institutionalization of insecticide impregnated bed net distribution (Hansen *et al.* 2008; Magesa *et al.* 2005; Njau *et al.* 2009; Semani *et al.* 2005; Bonner *et al.* 2011; Kikumbih *et al.* 2005; Mulligan *et al.* 2008). Three overarching features of this program govern its strategic design for scale-up: policy, evidence and action. The scale up during this phase will start in the 51 comparison villages in Rufiji, Kilombero and Ulanga districts and expand into demonstration districts throughout the country.

In the policy forum, conferences, field exchanges, policies, plans, and directives from headquarters from the *Connect* Steering Committee will catalyse and legitimize expansion at all levels of the service system. Field exchanges will be designed to build consensus and commitment for action. Newsletters will be disseminated to communicate to all district teams practical lessons and experience so that district plans benefit from advice from the field. National policies comprising the MMAM initiative, in turn, will be modified to legitimize the process of operational change, producing budgets and manpower assessments that respond to the requirements of a decentralized programme of action.

As the program marshals evidence to evaluate whether strategies developed by *Connect-FP* can be scaled up with replicable levels of success, regional and national staff meetings and Annual National Health Forum Conferences will be convened to provide mechanisms for discussion of monitoring and evaluation results among health managers at all levels of the national MOHSW program. Developments that transpire during the period preceding national expansion will dictate the type of data that will be generated to propel national expansion; however, it is likely that they would mirror the methodologies used to

studying systems change in phases 1 and 2. This would involve a qualitative systems appraisal involving community members, CHA, supervisors, district managers, local politicians and administrators to elicit perceptions of progress as well as incidence and reactions to economic, political and administrative challenges to the program, decision-making, leadership and information utilization, social, financial and management-related consequences of the program. Implementation checklists would be used to record the coverage, content and pace of national scale up vis-à-vis the practical guidelines developed in earlier phases; survey research to record key impact statistics in districts where *Connect* implementation is advanced. Data triangulation will illustrate the characteristics and processes of sustainability and scaling up. Where it points to problems, operations research will be designed to understand them, identify alternative solutions and assess what works instead.

Each region will be equipped with a demonstration district where the approach is adapted as needed. "Guided diffusion" will be employed to clarify the operational details of scaling-up (Glaser *et. al.* 1983; Rogers 1995; Mintrom 1997). The exchange process of transferring phase 1 and 2 operations to the scale up areas of phase 3 will provide a model of peer training to guide national expansion in phase 4. In this approach, structured interaction between district teams will prevent isolation of *Connect* innovations, offset confusion about the changes required to scale-up operations, and resolve ambivalence about the initiative.

Discussion

In this paper, we developed a systematic framework for accelerating the MMAM policy's attainment of MDG 5 in Tanzania by re-positioning family planning within comprehensive community-based health services. The framework determines how and why community-based family planning programs achieve success vis-à-vis coverage, quality and utilization measures, and effectiveness in terms of client method continuation and program adoption by community and local health systems. Furthermore, it links these plausibility explanations of program results with actual evidence of impact against indicators such as contraceptive prevalence and unmet need, as well as fertility reduction, which, accordingly would lead to declines in maternal deaths in Tanzania (Kanté *et al.* 2012).

Sustainably scaling up the *Connect* service system in Tanzania will be a process of organizational change that requires working in phases guided by evidence. The progressive agenda for 'learning by doing' informs the development of practical guidelines for expanding the introduction of DMPA across pilot sites, within the experiment and across demonstration

districts. These include applied procedures for monitoring and assessing the project and providing necessary health system supports and linkages to the community-based activities. District managers and implementers use these to normalize the pilot into their routine operations and scale up its implementation. As the role and type of research pursued shifts during the project, it will not only guide the continuous process of program expansion and development, but also identify problems and permit strategic change and improvements as scaling up progresses.

Nevertheless, large-scale expansion of the *Connect* service system, including comprehensive community-based family planning, will remain a complex task. It will require guidance by multiple sources of evidence and support from complementary strategies for communicating results to stakeholders. Monitoring and evaluation activities use a 'context-process-outcome' framework in order to produce scalable guidelines for program success and sustainability, while evidence of quality, safety and impact assuages decision-making in favor of embedding community-level expansion of the contraceptive method mix into the MMAM program of action. Thus, the pace of accumulating evidence should be matched by activities that foster decentralized planning, training and adaptive development of findings as well as centralized communication efforts for ensuring the results are put to use. If a committed and versatile group of health system scientists, managers and policymakers join forces and apply this framework together they make progress toward universal reproductive health.

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[i] All villages in Connect current randomization plus replication and demonstration villages throughout Tanzania

[ii] The term "Spline regression" is widely used to estimate the effect of "shocks" in economic systems. However, the technique has proved to be applicable to various studies where time trends are posited to be influenced by treatment effects (see, for example, DeGraff et al, 1986 and Kravdal, 2006.

[iii] Baseline analyses show that fertility rates in treatment and comparison areas are statistically equivalent. Consideration has been directed to the utilization of the Heckman (1986) "difference of differences" procedure. Current study power suggests that direct cell comparisons will suffice without imposition of the Heckman procedure. However, multi-level multivariate modeling is anticipated as a tool for researching the interaction of treatment effects with social and economic determinants of fertility (Phillips *et al.* 2012).