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RESEARCH AND EVALUATION REPORT

Analysis of Effectiveness and Cost-effectiveness of Adding Collaborative Improvement to a Conditional Cash Transfer Program in Guatemala

AUGUST 2011

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ABBREVIATIONS

BCG	Bacillus Calmette-Guerin
CAP	*Centro de atención médica permanente* (24-hour care health center)
CAIMI	*Centro de atención integral materno-infantil* (integrated maternal and child health care center)
CCT	Conditional cash transfer
CEA	Cost-effectiveness analysis
CENAPA	*Centro de atención a pacientes ambulatorios* (ambulatory care center)
EMCC	*Equipos de mejoramiento continuo de la calidad* (continuous quality improvement teams)
ENSMI	Fertility and Health Survey, Guatemala
EONC	Essential obstetric and newborn care
GOG	Government of Guatemala
HCI	USAID Health Care Improvement Project
HIV	Human immunodeficiency virus
ICE	Incremental cost-effectiveness
ICEFI	*Instituto Centroamericano de los Estudio Fiscales*
ICER	Incremental cost-effectiveness ratio
MCH	Maternal and child health
MMR	Mumps, measles and rubella vaccine
MOH	Ministry of Health
PDSA	Plan, Do, Study, Act improvement cycle
ProCONE	*Promoción del cuidado obstétrico y neonatal esencial* (promotion of essential obstetric and newborn care)
QI	Quality improvement
SES	Socio-economic status
URC	University Research Co., LLC
USAID	United States Agency for International Development
VCT	Voluntary counseling and testing for HIV
VDRL	Venereal Disease Research Laboratory blood test for syphilis

EXECUTIVE SUMMARY

Introduction

Conditional cash transfer (CCT) programs seek to improve health outcomes for the poor by providing incentives for specific target groups to seek care. However, if the quality of care provided at facilities where CCT program beneficiaries seeking services is poor, a CCT program may have limited impact overall. This study provides information to decision makers regarding the effectiveness and cost-effectiveness of combining a specific quality improvement intervention known as collaborative improvement with a CCT program. The objective of the study was to understand if implementing improvement activities in the context of a conditional cash transfer program improves compliance with clinical norms. A secondary objective was to determine how much the improvement collaborative costs and how cost-effective it is.

Guatemala initiated a large-scale CCT program during 2008. The United States Agency for International Development (USAID) Health Care Improvement Project supported quality improvement (QI) activities among underserved populations in several municipalities also covered by the CCT program during the same period. Hence Guatemala provides a natural setting for measuring the costs and effectiveness of combining a QI intervention with conditional cash transfers to families in priority underserved areas.

Conditional cash transfer program: In an effort to address severe maternal and child health (MCH) problems, the Government of Guatemala has undertaken a conditional cash transfer program as a means of increasing demand and use of MCH services at health facilities. CCT programs, first implemented in Latin America in the late 1990s, provide money to poor households conditional upon their complying with a number of program requirements (Handa and Davis 2006). Beneficiaries are required to use maternal and child preventive health, nutrition, and care services, and to enroll and maintain school-age children in school. The CCT program is intended to improve health and nutrition behaviors by conditioning payment on the use of preventive health care services. Some programs also provide a micronutrient-fortified food supplement. The overall aim is to reduce household vulnerability in the short term and break the intergenerational transmission of poverty by investing in human capital and reducing out-of-pocket expenditures and opportunity costs.

The health effects of CCT programs in Latin America include more visits to health services, less illness and less stunting (Glassman et al. 2009). Beneficiaries of CCT programs also have more direct control over intra-household resources and care of their children, as a result of behavior changes and empowerment.

The Government of Guatemala expects to reduce maternal and child mortality (including neonatal mortality) and chronic malnutrition through preventive activities led by the *Consejo de Cohesión Social* (Council for Social Cohesion) and involving the Ministry of Health and the Ministry of Education. The CCT program, *Mi Familia Progresa*, or "My Family is Making Progress", was launched in April 2008 to provide economic incentives to the poorest of the poor, especially those living in communities located in the highlands of Guatemala. The objective of the CCT program in Guatemala is to increase demand for MCH services and reduce maternal and child mortality. The notion is that once mothers are accustomed to using MCH services, they will continue to utilize the services without conditional payments. By June 2010, 187 municipalities in 20 departments were covered by the CCT program, serving 591,570 beneficiary families.

Maternal and newborn care improvement collaborative: Because CCT is a demand-side program in which beneficiaries are required to use maternal and child preventive health services in order to obtain the cash benefit, the supply side must meet the increased demand for services for the program's effects to be realized. Since 2008, the USAID Health Care Improvement Project (HCI) has provided technical assistance to the Ministry of Health (MOH) of Guatemala to define national standards of MCH care, improve compliance with those standards, and measure key service quality indicators. A central activity

of this assistance has been a maternal and newborn care improvement collaborative known by its Spanish acronym, ProCONE (promoting essential obstetric and newborn care). An improvement collaborative provides a structure for leveraging the work of many improvement teams, all focused on the same aim (HCI 2008). At the health facility level, the ProCONE collaborative organized and supported QI teams to introduce changes to increase compliance with clinical norms and improve maternal and newborn outcomes. HCI supported teams with training and coaching, provided educational and behavior change communication materials, and organized collaborative learning sessions to facilitate the sharing of successful changes in practice among QI teams from different health facilities. This context provided an excellent opportunity to study how quality of care is affected when demand for health care increases because of the CCT.

The ProCONE collaborative began with a pilot phase in 2007 in the San Marcos Health Area. It was expanded to seven additional health areas in 2009 based on lessons learned from the pilot. The pilot only focused on maternal and neonatal health care improvement. Child health care was added to the expansion phase so that the services covered by the quality improvement activities coincided with the entire spectrum of MCH services supported by the CCT program.

Methodology

A quasi-experimental design was used to test the effect on compliance with clinical norms of implementing the ProCONE quality improvement collaborative at centers covered by the CCT program. The analysis compared differences in compliance between 38 centers covered by both the QI collaborative and the CCT program and 12 centers covered only by the CCT program.

Compliance with clinical norms: Data were obtained through direct observations of provider-client interactions while providing prenatal care and child health services, using checklists completed by trained observers who were also health professionals. Data collectors were not able to observe and record enough neonatal and postpartum cases during their visits, so those observations were dropped from the analysis. Multivariate linear regression was applied to test the statistical significance of differences in compliance between the two study groups while controlling for confounding factors, such as number and type health center staff and socio-economic status of the client population.

Results

Compliance with selected criteria of prenatal care norms

Compliance in the two research arms (collaborative and non-collaborative sites) was measured three ways: 1) each selected criterion, 2) additive or cumulative scale of compliance, and 3) full-compliance with all selected criteria. The cumulative scale adds up the number of criteria correctly performed to derive an additive compliance scale, and results are presented as percent compliance.

Compliance with process criteria: For six out of 13 prenatal care process criteria, compliance was statistically significantly higher in CCT+collaborative sites compared to CCT-only sites. Even though CCT+collaborative facilities present higher levels of prenatal care compliance, additional improvements are needed for voluntary counseling and testing for HIV, counseling on planning for birth emergencies, and breastfeeding counseling. Thus, the study found that many pregnant women are not receiving valuable information during prenatal counseling sessions in both research groups.

Cumulative compliance scale: The percent of compliance with prenatal care norms (based on 11 criteria: nine clinical criteria, one criterion on counseling on emergency plan, and one criterion on filling out a clinical record) was 10 percentage points higher in the CCT+collaborative group (94%) compared to CCT-only facilities (84%).

Full compliance scale: Full compliance, defined as when all 10 technical criteria (excluding the counseling criterion) are performed in a clinical visit, was 58% at CCT+collaborative sites and 0% of the CCT-only sites.

Multivariate analysis controlling for confounding factors: Multivariate regression was used to control for confounding factors that might affect the association between the effects of the QI collaborative and compliance in CCT sites.

Cumulative compliance scale (measured as relative percent): The difference in levels of compliance was statistically significantly higher by 8.5% in CCT+collaborative facilities.

Full compliance scale (measured as an odds ratio): When compliance with all 10 technical criteria is considered, the likelihood of full compliance was 17.8 times higher in CCT+collaborative sites compared to CCT-only facilities.

Compliance with selected criteria of child preventive health care norms

Compliance with preventive child health care norms was also measured and compared between collaborative and non-collaborative health facilities.

Compliance with process criteria: Collaborative sites show statistically significantly higher levels of compliance with norms for child health consultations than the other non-collaborative sites within the CCT. Most non-collaborative facilities scored very low, demonstrating the need for major improvements in child health service quality in those sites.

Cumulative compliance scale: The proportion of cumulative compliance with child health criteria, based on nine criteria, was 36 percentage points higher in the CCT+collaborative group (86%) compared to CCT-only facilities (50%).

Full compliance scale: Considering full compliance as performance of all eight technical criteria for a child health visit (excluding the counseling criterion), CCT+collaborative sites achieved 60% full compliance, compared to 12% in CCT-only sites.

Multivariate analysis controlling for confounding factors: Multivariate regression analysis was applied to control for confounding factors that might affect levels of compliance independent of the effect.

Cumulative compliance scale: CCT+collaborative facilities had statistically significantly higher compliance at 38.9% compared to the CCT-only sites.

Full compliance scale: The likelihood of full compliance in CCT+collaborative sites was 17.9 times higher than in CCT-only facilities. Once potential confounding factors were controlled, collaborative sites had much higher levels of full compliance with norms for prenatal care and health services for children under two years of age.

The multivariate analyses demonstrate the effectiveness of QI collaboratives in achieving full compliance and suggest that the addition of QI to CCT facilities could readily increase the percent of compliance with norms, leading to full compliance by MCH health providers.

Cost-effectiveness of CCT+collaborative and CCT-only

The total cost of the QI collaborative from January 2009 to June 2010 was $293,385. The number of prenatal and child health visits provided in the sites during that period was over 375,000, giving a per-patient cost of the collaborative at $0.78. The highest cost item for the collaborative, at 29% of the total, was travel, including transportation and accommodation for the learning session participants and for the coaching visits to individual sites. For the total expenditure, there were 60,102 additional prenatal care consultations done to full compliance with clinical norms and 122,900 additional child health consultations done to full compliance. This is an additional cost per prenatal visit delivered in full compliance with norms of $1.25 and an additional cost of $1.78 per child health visit in full compliance

with norms. These are conservative estimates given that the collaborative addressed neonatal and delivery visits as well as prenatal care and child health. The most important driver in the result is the effectiveness as measured by the difference in the probability of full compliance with clinical norms.

Recommendations

The following recommendations are based on the study's findings and HCI's experience in designing and implementing QI collaboratives with health facilities in countries like Guatemala.

Carry out advocacy and marketing of the QI collaborative results with the MOH and CCT stakeholders: HCI should actively engage the MOH at the central and local levels to apply improvement strategies in other health areas of Guatemala. This would involve developing an action plan with shared funding from the MOH and donors, including the USAID Health Care Improvement Project. Advocacy with stakeholders in Guatemala's CCT program will also be important, to demonstrate the synergy between improvement and CCT objectives.

Promote community-based strategies to increase early postnatal and neonatal care: HCI should engage the MOH in other strategies to complement facility-based postnatal and neonatal care, such as community mapping of all pregnant women with probable date of birth and home visits during the first 24 hours after delivery. Due to geographic barriers and cultural beliefs, postpartum women and their neonates are not likely to use facilities before one month after delivery, and this only to assure vaccination of the newborn and a health card, which is sometimes required for birth registration.

Demonstrate the cost-effectiveness of QI collaboratives: Advocacy efforts should draw upon the findings of the cost analysis to advocate for investing in QI and collaborative interventions. Information in this report is important for decision-makers to evaluate to decide whether expanding collaboratives to other health facilities is feasible in the short-term and sustainable in the long-term.

Conduct additional studies on the effectiveness and cost-effectiveness of QI collaboratives: While this study focused on the integration of a CCT program and a quality improvement intervention, there remains a need to study the effect of QI interventions in lieu of a CCT program. The study's results suggest QI collaboratives should be implemented nationally to improve quality of care, even in facilities without a CCT program.

I. INTRODUCTION

Conditional cash transfer (CCT) programs seek to improve health outcomes for the poor by providing incentives for specific target groups to seek care. CCT programs have been successful in several Latin American countries (Mexico, Brazil, and Honduras, among others) and are increasingly being implemented in several countries in Asia (Rawlings and Rubio 2005). A Cochrane Review of CCT programs concluded that although these programs do increase service utilization, their impact on health outcomes is not consistent (Huntington 2010). CCT programs are based on the assumption that good quality health and social services are readily available and their utilization would be substantially increased by providing incentives and removing monetary barriers. However, raising demand for services by introducing a CCT program alone does not overcome the problem of poor quality of services. In fact, the low quality of services can be considered a supply-side constraint that can present a major weakness in a CCT program. Recognizing this issue, some countries have invested in combining conditional cash transfers with an improvement in the services provided. Examples include ensuring provision of essential resources as implemented in Mexico and incentivizing teachers for better performance as implemented in Nicaragua (Rawlings and Rubio 2005). CCT programs themselves are a substantial financial investment, and it is important to evaluate whether the addition of supply-side interventions improves service quality and whether it does so cost-effectively.

The process of providing care in developing countries is often poor and varies widely. A large body of evidence has documented the gaps in service provision in countries across the globe. In a study for the Disease Control Priorities Project, an international team used clinical vignettes to measure quality in China, El Salvador, India, Mexico, and the Philippines. The study found that compliance with evidence-based criteria varied widely among practitioners (Peabody et al.). Yet, the science of improvement offers a proven method which allows health care providers to analyze their own processes of care and improve compliance with standards.

The USAID Health Care Improvement Project (HCI) and its predecessor USAID projects , implemented by University Research Co., LLC (URC), have been applying quality improvement methods in over 40 countries for the last 25 years—methods which have demonstrated rapid and sustained improvements in the quality of care, at scale. Quality improvement is based on empowering teams to test changes in care processes and measuring whether the change has led to improvement in care. One method HCI is using is a collaborative improvement approach in which a large number of teams work together to share ideas for change. This approach has been shown to be very effective. An analysis of the work of more than 1,300 quality improvement teams in 27 countries demonstrated that teams were able to achieve performance levels of 80 percent or higher for 88 percent of the indicators studied, and 76 percent reached performance of 90 percent or higher, even though two-thirds had baseline performance below 50 percent (Franco and Marquez 2011).

Guatemala provided a good setting to study the combination of a CCT program with a quality improvement initiative. The Government of Guatemala initiated a large-scale CCT program in April 2008 which, by June 2010, covered 187 municipalities and 591,570 beneficiary families. At the same time, URC had successfully supported the Guatemala Ministry of Health in implementing collaborative improvement to strengthen essential obstetric and neonatal care, family planning and sexually transmitted infection diagnosis and treatment services. The situation in Guatemala provided the opportunity to study the added benefits and cost-effectiveness of combining CCT with a quality improvement strategy. The two objectives of the study are as follows:

Primary objective: The principal objective of the study was to understand if implementing a quality improvement (QI) intervention (in this case, a maternal and child health improvement collaborative) in the context of a CCT program added value in achieving CCT objectives, by increasing the quality of care

to CCT clients (as measured by adherence to clinical norms), and therefore increasing the likelihood of achieving the health objectives of the CCT program.

Secondary objective: A secondary objective of the study was to measure the *incremental cost-effectiveness* (ICE) of adding a QI collaborative intervention to a CCT program in order to improve the quality of MCH services (prenatal, neonatal, postnatal and child health care).

The following sections of the report describe the health situation in Guatemala, the country's conditional cash transfer program, the MCH quality improvement collaborative, the research methodology, findings from the study, and recommendations for applying the findings in Guatemala.

II. HEALTH SITUATION IN GUATEMALA

Guatemala has a population of approximately 14 million, the highest of any nation in Central America. Although classified as a middle-income country, it still faces significant social problems and is among the ten poorest nations in Latin America. More than half the population lives below the poverty line, and 15% live in extreme poverty (CIA). Its health indicators show limited progress, especially with regard to maternal health, and without concentrated efforts Guatemala is unlikely to meet the Millennium Development Goals. Figure 1 lists some health indicators for Guatemala and gives a sense of the challenges facing the country.

Figure 1: Guatemala Health Indicators

Infant mortality rate is among the highest in the Central America at 30 per 1000.

Guatemala has the third highest rate of chronic malnutrition (stunting) in the world: 54.5%.

Fertility rates remain high at 4.2.

Prenatal coverage is high, with 84% women accessing care at least once during pregnancy

Proportion of births assisted by skilled birth attendants: around 40%.

60% of all newborns receive breast milk within one hour of birth, but only 51% of infants under six months are exclusively breastfed.

Source: UNICEF 2008.

III. CONDITIONAL CASH TRANSFER PROGRAMS

A. CCT Programs in Latin America

Conditional cash transfer programs were first designed and implemented by the Government of Mexico in the late 1990s and since then have been implemented in Brazil, Nicaragua, Colombia, Honduras, Chile, Costa Rica, Ecuador, El Salvador, Panama, and Guatemala. Mother/child pairs receive cash each month if they meet specific conditions related to their participation in health and education programs. Beneficiaries are required to use maternal and child health, nutrition, prevention, and care services and to enroll and maintain school-age children in school. CCT programs use cash payments that bring about behavior changes in the use of social services and empower women within their household and community. CCT beneficiaries have more direct control over intra-household resources and care of their children, as a result of behavior changes and empowerment. The overall aim is to reduce household vulnerability in the short term and break the intergenerational transmission of poverty by investing in human capital.

The beneficial effects of CCT program have been increased utilization of health services, reduced illness, and decreased prevalence of stunting (Glassman et al. 2009, Handa and Davis 2006). Based on a review of CCT programs in Central America, four conditions for the success of a CCT program have been identified: inter-institutional coordination (coordination between the central government and local governmental bodies); improvement in the quality and supply of health services; careful monitoring of

compliance with CCT conditions and audit of financial management; adapt the CCT program to local ethnic and cultural contexts (ICEFI 2010).

B. The CCT Program in Guatemala

Guatemala leads most countries in Latin America in social inequity and exclusion, which is reflected, among other areas, in its poor health and nutritional situation. Poor families in Guatemala face resource constraints, long waiting lines, language barriers, low-quality services, and other barriers to the use of essential health care. Distance to health facilities, lost income associated with illness, costs of care-taking and care-seeking, facility fees and other out-of-pocket costs all contribute to limit access to health care and information, particularly for preventive measures, by those who need it most. These costs also have an impact on the financial security of affected individuals and their families.

In an effort to address the health problems described above, the Government of Guatemala expects to reduce maternal and child mortality (including neonatal mortality) and chronic malnutrition through preventive activities led by the *Consejo de Cohesión Social* (Council for Social Cohesion) and involving the Ministry of Health and the Ministry of Education. A CCT program called *Mi Familia Progresa*, or "My Family is Making Progress," was launched in April 2008 to provide economic incentives people living in extreme poverty, especially in communities located in the highlands of Guatemala.

CCT program coverage: In the first phase of the CCT program, residents of selected communities in the 45 poorest municipalities received the cash incentives; during the second phase currently underway, residents of an additional 80-85 municipalities were added as beneficiaries. According to official figures, a total of 20 departments were covered by the CCT program as of June 2010, with 187 municipalities and 591,570 beneficiary families. Of these families, 542,647 (91.7%) are reported to have complied with conditions such as attending health services at required times (four visits for pregnant women and monthly for children under two years of age and quarterly thereafter).

Services covered under the CCT program: Specifically, the CCT consists of providing 150 *quetzales* (US$18.70) per month – provided every two months – to parents of children under age six, conditional on performance of activities such as care-seeking for essential health and nutrition interventions and another 150 *quetzales* for school attendance of children 6 to 15 years. Nutritional support revolves around infant and child growth monitoring, counseling, and health talks to mothers. In some municipalities, children are starting to receive sprinkles, a micronutrient supplement that is sprinkled over the child's food. Pregnant women, lactating mothers (up to six months postpartum), and children 3-36 months of age also receive a food supplement called Vitacereal. CCT-supported primary health care services follow a life cycle approach and include the basic package of maternal and child health services, as shown in Table 1.

Categories of heath facilities in the CCT program: The CCT program covers several types of health facilities within the MOH. Table 2 gives a description of the different levels of health facilities included in the CCT program. Initially the CCT program only covered the first four types (hospitals, integrated care centers, 24-hour care centers, and ambulatory care centers). The CCT program is now being expanded to include health posts and reinforced health posts.

The CCT program has established its own processes, personnel (regional coordinators, municipal promoters, and community representatives) and education activities, largely dealing with the CCT program objectives and conditions (e.g., some counseling materials on nutrition have been provided to health providers). Although the CCT program has provided ambulances to all 24-hour care health centers in priority municipalities and hired additional medical personnel (such as health educators, shift doctors, and nurses), limitations on availability of drugs and other inputs have continued. The current financial crisis of the Ministry of Health is reflected in a lack of funds for hospitals and for the Extension of Coverage program. Limitations on resources for staff salaries, transport, per diem and materials for community outreach staff have constrained the government's ability to respond to national emergencies.

Table 1: Basic package of maternal and child care services tied to cash transfers

Stage in the life cycle	Preventive health care
Pregnancy	Prenatal care
	Micronutrients (iron and folic acid)
	Vaccination (tetanus toxoid)
	Counseling
Postpartum	Postnatal care
	Micronutrients (iron and folic acid)
	Vaccination (tetanus toxoid)
	Counseling
Newborn	Newborn care
	Vaccination (BCG)
	Counseling on immediate and exclusive breastfeeding
Infant and young child	Growth monitoring (weight and height measures)
	Vaccination (polio, Pentavalente-3, DPT, MMR)
	Micronutrients (vitamin A, iron, folic acid)
	De-worming, starting at 2 years
	Counseling on breastfeeding and complementary feeding

Table 2: Categories of health facilities providing health care to CCT beneficiaries

Type of facility	Services offered
Outpatient services of **hospitals** and Integrated maternal and child health care center (*Centro de atención integral materno-infantil,* **CAIMI**)	Outpatient services of these third level facilities provide basic care and receive emergency referrals from other health services
24-hour care health center (*Centro de atención permanente*, **CAP**)	These centers provide care 24 hours a day; most of them have started to attend normal births, perform initial management and refer complications to CAIMI and hospitals. As municipalities were incorporated into the CCT program, Type A health centers (with beds) were ordered to provide health services 24 hours a day and were given ambulances, reinforced with additional health providers (shift physicians, auxiliary nurses, and health educators) and administrative staff in order to deal with expected increased demand.
Ambulatory care center *(Centro de atención a pacientes ambulatorios,* **CENAPA**)	Health center with extended schedule. These are Type B health centers (no beds) that have extended the number of hours they provide services from eight to 12 or 24 hours.
Reinforced health post	Reinforced health posts have two auxiliary nurses and/or a community facilitator.
Health post	Health posts are located in small villages and are attended by an auxiliary nurse.
Extension of coverage convergence and community centers	These are services provided by mobile teams (ambulatory physician or nurse, institutional facilitator, health educator) and community health workers (community facilitator, health promoter and traditional birth attendant) of NGOs hired by the government to provide health care.

IV. THE MATERNAL AND NEWBORN CARE QUALITY IMPROVEMENT COLLABORATIVE

Because CCT is a demand-side program, in which beneficiaries are required to use maternal and child preventive health services, the supply side must meet increased demand for services for the program's desired results to be achieved. With increased demand, the potential exists for the quality of care to decrease, even lower than the already low quality of maternal and child care that has been documented. Although some efforts to improve quality were made, such as increasing staffing and upgrading the level of the facilities, no systematic attention was given to improving the quality of service delivery.

URC has been working in the field of quality improvement in health care service delivery for over 25 years and has pioneered the collaborative improvement approach in developing countries to facilitate rapid and sustained improvements in quality. In an *improvement collaborative*, a large number of teams or sites work together for a 12- to 24-month period to achieve significant improvements in a specific area of care. The collaborative organizes regular sharing of results among teams through learning sessions in which teams learn from each other about which changes have been successful and which were not. This results in a dynamic improvement strategy in which many teams working on related problem areas can learn from each other in a way that facilitates rapid dissemination of successful practices (HCI 2008).

The Maternal and Newborn Care Improvement Collaborative was developed by the MOH with the technical and financial support of the USAID Health Care Improvement Project to reinforce Guatemala's commitment to achieving Millennium Development Goal 4 to reduce by two thirds the under-five mortality rate and Millennium Development Goal 5 to reduce by three quarters, the maternal mortality ratio, between 1990 and 2015. Specific interventions include health promotion and communication and clinical interventions dealing with essential obstetric and newborn care (EONC). Known by its Spanish acronym, ProCONE (*promoción del cuidado obstétrico y neonatal esencial,* or promoting essential obstetric and newborn care) the improvement strategy has three main line of action: a) Community ProCONE: community support (focusing on pregnant women, families and communities), b) Basic ProCONE: basic health services (normal prenatal, delivery, postpartum and neonatal care with early detection and initial treatment of obstetric and neonatal complications), and c) Complications ProCONE: comprehensive services for the management of obstetrical and newborn complications. The initial improvement effort linked with the CCT program was focused on basic ProCONE—improvement of basic maternal and newborn ambulatory care services and compliance with clinical norms.

A. Demonstration and Expansion Phases of the Basic ProCONE Collaborative

Guatemala started implementing the improvement collaborative during 2007 in the Health Area of San Marcos where 22 "continuous quality improvement teams" (*equipos de mejoramiento continuo de la calidad* or EMCC) were formed in health centers to improve the prenatal, perinatal, and postpartum care of the mother and of the newborn.

In January 2009, based upon the success of the first phase and the great interest shown by other Health Areas and the Ministry of Health, the Basic ProCONE improvement collaborative was expanded from San Marcos to an additional 135 ambulatory health centers and 24-hour health centers in seven other Health Areas that were also participating in the CCT program. In order to ensure an overlap in the services addressed by the improvement collaborative and those covered by the CCT program, child preventive health care (growth monitoring and promotion and immunization of children under two years of age) was added to the aims of the Basic ProCONE collaborative approach in the expansion phase.[1] Therefore collaborative improvement activities covered prenatal, neonatal, postpartum, and

[1] These child health services were not addressed in the demonstration phase of the ProCONE collaborative in San Marcos.

child health care. (A complete description of the steps involved in preparing and implementing the expansion phase of the Basic ProCONE improvement collaborative is provided in the Annex.)

B. Quality Improvement Team Training and Activities

QI teams were formed in a sample of 37 health centers to support improvement activities. The initial training of QI teams included: basic concepts of continuous quality improvement (CQI) and collaborative learning; objectives of the ProCONE collaborative (clinical processes covering prenatal, postpartum, neonatal, and child care); organizational structure of the QI team (coordinator and 5-6 team members selected from health providers); standards and indicators for each type of care that defined what providers were supposed to do; and instruments for measuring quality indicators (clinical records and monitoring sheets, instructions to conduct a baseline, and an Excel database in which to record data). Subsequent learning sessions addressed the following topics: preparation of storyboards (called *salas situacionales* in Spanish, or situational rooms) to present baseline data and subsequent changes; the Plan-Do-Study-Act (PDSA)[2] cycle and planning matrices; change ideas for improving services that had been shown to work in the demonstration phase in San Marcos; tools for documenting changes and measures of quality improvement; on-the-job facilitation and tutoring skills; and communicating results within each facility and with other teams.

Teams within the collaborative used a common set of core indicators to measure compliance with norms for prenatal, neonatal, postpartum, and child care. Each team collected data on the indicators during more than one year to measure whether the changes it was making were resulting in improvement. Data were collected monthly through a random sampling of patient records for prenatal, neonatal, postnatal and child care (20 records for each type of MCH care). The records were reviewed, checked for compliance with selected criteria of clinical norms, and the results recorded on a monitoring checklist. If all criteria on the checklist were met, the clinical record was said to comply with the quality indicator (the standard of care). QI teams tested changes to inputs and processes in order to achieve improvements so that consistent quality of care was provided to clients. The changes made by QI teams were documented in order to identify those that were more effective in producing improved health care. A document summarizing those interventions was produced and shared among health facilities. Effective changes included: assuring the availability of inputs used in providing MCH services (micronutrients, reagents for lab, clinical records, etc.); organization of clinical and community-outreach services; using behavior change communication materials with groups and individuals (both clinical and community settings); and strengthening human resources (i.e., skill development and support through coaching).

Teams met monthly to review and analyze clinical records. Within each health facility, the QI teams share results from the record review with the rest of the facility's staff and reinforced the importance of complying with norms and completing clinical records. Changes implemented and results, based on the measurement of indicators, were shared with other QI teams during learning sessions and during meetings at the Health Area level. QI teams also received regular supervisory and coaching visits from the Health Area, as well as HCI technical support.

These quality improvement activities were very successful in improving compliance with clinical norms. For example, in the expansion sites in seven new Health Areas, compliance with the prenatal care indicator increased from 22% to 80% and more in eleven months from January to November 2009, and has remained above 80% thereafter. The quality improvement methods introduced in facilities have

[2] Also known as the Shewhart cycle, PDSA is part of the model for improvement taught by HCI that guides teams through an iterative process of defining the aim for improvement, deciding on measures that will show whether that aim has been met, and then testing changes to determine which of them yield improvement. PDSA refers to the steps of design and testing a change, studying whether it leads to improvement, and acting on that result.

been enthusiastically embraced by providers, who are beginning to apply quality improvement to other areas with little additional assistance from HCI. The initial efforts were focused on obstetric and newborn care but have now expanded to include essential nutrition actions and family planning.

This context provided an excellent opportunity to study the impact of deliberate efforts to improve quality of care under conditions of increasing demand for health care services due to the CCT program.

V. METHODOLOGY

The study measured and compared health care improvements achieved by adding collaborative activities to a CCT program and the additional costs of implementation of the improvement collaborative. The research methodology involved two major objectives: 1) comparative analysis of the effectiveness (i.e., compliance with clinical norms); and 2) analysis of the relative cost effectiveness of the *CCT+collaborative improvement* and *CCT-only* intervention modes. The notion is to measure the cost of adding collaborative improvement activities to a CCT program. This will answer the question of whether investments made in QI have led to increased compliance with clinical norms and whether it is cost-effective to combine a quality improvement strategy to a CCT program.

A. Research Model

Research hypothesis: The research model utilized statistical hypothesis testing, where the null hypothesis is "no difference between CCT-only and CCT+collaborative improvement groups" in terms of effectiveness (compliance with clinical norms) and cost-effectiveness. The notion is to either *reject*, or *not reject* the null hypothesis (of no difference). Rejecting the null hypothesis means there are statistically significant differences in effectiveness and cost-effectiveness between CCT-only and CCT+collaborative improvement groups.

The research model outlines two components for statistical hypothesis testing which are discussed in detail later:

- MCH service improvement and effectiveness: Analysis of MCH compliance with clinical norms using direct observation checklists
- Incremental cost-effectiveness analysis of adding a quality improvement collaborative to a CCT program.

Research design: A quasi-experimental research design was used because CCT-only (comparison or control group) and CCT+collaborative (treatment group) sites could not be randomly selected.

A post-test-only design with nonequivalent comparison groups was selected in order to improve validity by selecting similar CCT-only sites, by matching them to the CCT+collaborative group on socio-economic status (SES), demographic characteristics, ethnic profile, and urban/rural composition.[3] This design is appropriate for testing the statistical difference in compliance with MCH norms between CCT-only and CCT+collaborative research arms.

Given the quasi-experimental research design, selection of research sites was based on two research criteria: 1) implementation of CCT-only or CCT+collaborative activities, and 2) populations with similar SES and ethnic composition. As noted, the CCT program began in April 2008, while CCT+collaborative interventions were expanded beyond the San Marcos demonstration site in January 2009.

[3] When random or "matched pair" assignments are not feasible, attempts are made to control statistically by measuring and using as covariates all variables thought to affect the dependent variables (e.g., compliance with standards and use of health services). In the research protocol, these are referred to as "confounders" or control variables when applied to multivariate analysis.

Research sites: CCT+collaborative activities focus on health centers, which are the highest level of clinical care in a district health system, and their surrounding catchment areas. Since the CCT+collaborative effort focuses largely on health centers, research sites include municipality-level health centers and their surrounding catchment area. Thus research sites implemented CCT-only or CCT+collaborative in a health center which serve the central municipal capital and outlying *aldeas* and *caseríos* of the municipality. The number of sites (health centers and catchment areas in the same municipality) is relatively small: CCT-only includes only 12 sites that met the research criteria, while CCT+collaborative includes 38 sites. Of these 38 sites (all included in the first phase of the CCT program), there was one site, Cahabon in Alta Verapaz, where we were unable to collect the full set of data because remodeling in the clinic was taking place and members of the QI team had been temporarily reassigned and were unavailable. Therefore, the characteristics of the QI teams were determined from a sample of 37 CCT+collaborative sites.

The numbers of health facilities by category included in the study are shown in Table 3. A total of 50 health centers are covered by the study and segmented into collaborative and non-collaborative groups.

Table 3: Numbers and types of collaborative and non-collaborative facilities included in the study

Category of services	CCT+collaborative	CCT-only
District Hospital (outpatient clinic)	1	
CAIMI (Integrated Maternal and Child Health Care Center, outpatient clinic)	2	1
CAP (Permanent Health Care Center)	32	11
CENAPA (a Type B Health Center with 12-hours of service per day)	1	
Regular Type B Health Center (with 8 hours of service per day)	2	
Total	38	12

B. Analysis of Compliance with MCH Norms

1. Data collection

Compliance with clinical norms (both technical and communication norms) was measured through the direct observation of health provider-client interaction in health centers. Observation checklists were completed for each of the four MCH care processes in all 12 CCT-only and 38 CCT+collaborative research sites.

Table 4 presents clinical norms for prenatal, neonatal, postpartum, and child health care that were directly observed by a health professional and recorded on a checklist, to measure compliance with MCH norms and compare compliance in CCT+collaborative and CCT-only health centers.

2. Data analysis

Both basic descriptive statistics and multivariate regression were used to measure the effect of complementing a CCT program with an improvement collaborative.

Scoring compliance to norms: Each checklist item receives a binary score (1= compliance with norms, 0=non-compliance with clinical norms). Cumulative (or additive) and full compliance scores were derived for each observation.[4] This approach permits the calculation of compliance as proportion of the

[4] This part of the study does not include pre- and post- comparison data. Data collection using direct observation by health professionals using checklists in the 12 CCT-only sites began in 2010.

criteria met or a dichotomous measure of whether all criteria were met or not for each of the four MCH services, as well the measurement of each norm within an MCH process. Individual (by criterion), cumulative and full compliance scores were calculated for each provider-client encounter which permitted comparisons between collaborative and non-collaborative study sites.

Table 4: Key MCH indicators and criteria for measuring quality of care

Indicator	Selected criteria
Percentage of pregnant women who received prenatal care according to selected criteria in the norms	1) Determined gestational age 2) Examined to detect danger signs 3) Measured blood pressure 4) Evaluated fetal heart rate 5) Performed Leopold maneuvers, if applicable 6) Ordered lab tests for syphilis 7) Provided iron pills 8) Provided folic acid pills 9) Applied tetanus vaccine, if applicable 10) Provided counseling on relevant topics (according to visit. HIV testing, birth emergency planning, breastfeeding, etc.) 11) Filled out the clinical record – this was added in this study because the methodology involved direct observation
Percentage of postpartum women who received postnatal care according to selected criteria in the norms	1) Examined to detect danger signs 2) Measured blood pressure 3) Measured body temperature 4) Examined breasts 5) Examined uterine involution 6) Provided iron pills 7) Provided folic acid pills 8) Applied tetanus vaccine, if applicable 9) Verified exclusive breast feeding 10) Provided counseling on relevant topics 11) Filled out the clinical record
Percentage of newborns who received neonatal care according to selected criteria in the norms	1) Examined to detect danger signs, infection and malformations 2) Examined for diarrhea and ARI 3) Evaluated nutritional status 4) Applied BCG vaccine 5) Provided counseling on relevant topics 6) Filled out the clinical record
Percentage of children 29 days to 24 months who received preventive health and nutrition actions according to selected criteria in the norms	1) Administered vitamin A 2) Provided iron 3) Provided folic acid 4) Weighed the child 5) Evaluated feeding problems 6) Classified growth 7) Applied vaccines, according to age 8) Provided counseling on relevant topics (exclusive breastfeeding 0<6 months, complementary feeding 6<24 months, feeding during and after illness) 9) Filled out the clinical record

3. Multivariate regression

Compliance with norms at health centers may also be related to characteristics of health facilities and their surrounding population (e.g., staff types and numbers, ethnic composition, and socio-economic composition) and vary between research arms. Hence multivariate regression enables estimation of the influence of the QI collaborative intervention on compliance with norms between research arms while controlling for confounding factors.

Variables considered as potential confounders in the association between the collaborative and levels of compliance with quality indicators are the mean number of health educators at the site, the mean number of community health educators working in the service area of the site, the total catchment population covered by the site, the percentage of those covered by the site who are enrolled in the CCT program, the mean number of full-time doctors working at the site, the mean number of shift doctors contracted to provide 24-hour coverage at the site, and the mean numbers of professional and auxiliary nurses.

The proportion of children under the age of three years who have stunting has been used as a valid proxy measure of socio-economic status in Guatemala. (Personal communication: Hernan Delgado, August, 2010). This is because a strong inverse association between SES and risk of stunting has consistently been found in this population (Allen 1995, Lee et al. 2010, Neel and Alvarez 1991). Therefore we considered SES a potential confounder and included it as one of the variables in the analysis.

4. Statistical significance

Fisher's exact tests were used to determine if the proportions of correctly performed tasks observed in the two independent groups (CCT+collaborative and CCT-only) were statistically significant. The p-level reported in Table 5 is the probability of error associated with rejecting the hypothesis of no difference between the two categories of observations (corresponding to the groups) in the population when, in fact, the hypothesis is true. P-values less than 0.05 mean that there is a 95% probability that the proportions (or percents) between the two research arms are different. The same statistical methodology is used for comparing compliance with child health care norms.

C. Cost-effectiveness Analysis

Cost data were collected from the accounting records of URC's Guatemala office. The costs of participation by MOH staff in the collaborative in the training session were covered by the travel expenses and per diem paid by HCI. Because no additional expenses were incurred by the MOH for their staff's participation, these were not included in the calculations. Also not included were the costs of the MOH staff participating in the coaching sessions and QI team meetings because these were considered part of their regular activities and did not constitute additional direct costs to the MOH.

We used decision tree analysis to calculate the incremental cost-effectiveness ratio comparing the CCT+collaborative sites to the CCT-only sites. This is the standard measure used to determine the relative cost-effectiveness of two strategies. The numerators are the differences in cost between the two strategies and the denominators are the differences in measures of effectiveness of the two strategies. The two denominators used were prenatal care visits and child health visits done to full compliance with clinical norms (Figure 2). Therefore the incremental cost-effectiveness represents the additional cost per additional prenatal care visit provided that was in full compliance with norms or per additional child health visit provided that was in full compliance with norms. In this case, the lower the incremental cost-effectiveness, the better the relative cost-effectiveness of the care delivered by collaborative sites compared to non-collaborative sites. A positive number means that additional expenditure is required to achieve better quality performance. A negative number would indicate that collaborative sites cost less than non-collaborative sites and also had better quality performance.

The equation for the incremental cost effectiveness ratio is:

> Incremental cost-effectiveness ratio = (difference in costs between the two strategies) ÷ (difference in effectiveness of the two strategies)

Figure 2: Cost-effectiveness decision tree

The process goal of the collaborative is to increase the probability of full compliance with clinical norms for patients receiving care at participating facilities. Therefore we can express the equation as:

> Incremental cost-effectiveness ratio = (cost at collaborative sites – cost at non-collaborative sites) ÷ (probability of compliance at collaborative sites – probability of compliance at non-collaborative sites)

Based on the assumption that the collaborative did not change the cost of clinical services in collaborative sites, the cost in those collaborative sites was due only to the collaborative itself. The incremental cost at the non-collaborative sites is therefore 0. We can rewrite the equation:

> Incremental cost-effectiveness ratio = (cost of collaborative) ÷ (probability of compliance at collaborative sites – probability of compliance at non-collaborative sites)

Given that the difference in the probability of compliance with standards was estimated using a sample, there is a sampling distribution associated with the point estimate that must be accounted for to determine a confidence interval around the point estimates for the additional cost per additional service delivered to compliance. We used Monte Carlo simulations of repeated sampling from the binomial distributions of the probabilities of compliance to create a distribution for the additional costs per additional service delivered to standards.

To determine the relative effect that each of the variables had on the additional cost per additional service delivered to standards, we increased each input in turn by 1% and recorded change in the relative cost-effectiveness.

VI. RESULTS

A. Characteristics of Study Sites

Characteristics of the two groups of sites (CCT-only vs. CCT+collaborative) are listed in Table 5. The size of the populations covered by the sites was the same in collaborative and non-collaborative sites, as was the proportion of that population covered by the CCT program. The proportion of children classified with stunting was significantly higher in the collaborative group (p=0.038).

There was a statistically significantly higher mean number of health educators and professional and auxiliary nurses in the collaborative sites (p=0.003, p=0.003, and p=0.005, respectively). The numbers of community health educators were the same in both groups of sites. The mean number of full-time doctors was about the same in collaborative and non-collaborative sites, but the mean number of shift

doctors—those available to cover the clinic 24 hours per day—was greater in collaborative sites (p=0.006).

The higher mean numbers of health workers at the collaborative sites may have led to higher levels of compliance with quality of care indicators regardless of the effect of the collaborative itself. Therefore these were included in the regression equations as potential confounders that we controlled for. Because *percent of children with stunting* has been used as a proxy measure of socio-economic status, it appeared that the families in the collaborative sites were poorer than those in the non-collaborative sites. We considered this a potential confounder in the relationship between the effects of the collaborative and compliance with indicators and therefore included this in the multivariate regression equation.

Table 5: Characteristics of CCT+collaborative and CCT-only sites

	CCT program group			
	Collaborative (n=38)	No collaborative (n=12)	Difference	p value
Mean number of health educators	3.11	1.67	1.44	0.003**
Mean number community health educators	3.08	2.67	0.41	0.690
Total population in covered area	33,365	32,748	617	0.959
% covered by CCT	43.9	40.7	3.20	0.670
Mean number of doctors (full-time)	1.95	2.33	0.39	0.480
Mean number of shift doctors	5.42	3.08	2.34	0.006**
Mean number of professional nurses	4.34	1.75	2.59	0.003**
Mean number auxiliary nurses	17.2	10.2	6.93	0.005**
% of children with growth retardation	63.5	56.5	7.02	0.038*

*Statistically significant: p<0.05 **Statistically significant: p<0.01

B. Compliance with MCH Technical Norms

The following analysis presents results obtained through direct observations of prenatal and child consultations carried out by health professionals (using a checklist) in 50 health centers located in six MOH Health Areas. Data collectors were able to observe only a very few cases of neonatal and postpartum care at health centers, so these services are not included in this analysis. Thus, results for compliance with norms are only presented for prenatal care and child health. Compliance is measured for each selected criterion, as well as cumulative and full compliance scales.

1. Prenatal care

In this section, compliance with each selected task associated with prenatal care is examined, followed by an analysis of cumulative and full compliance scales. When the three types of prenatal counseling observed are taken separately, 13 separate criteria were measured (see Table 4 above). To measure cumulative compliance with prenatal care, just one of the counseling criteria—counseling on birth emergency planning, which is critical for maternal mortality reduction and has been actively promoted in Guatemala—was used to represent appropriate counseling. Thus, 11 individual criteria were included in the cumulative compliance scale.

Table 6 presents the number and percent of provider-client encounters that comply with prenatal care criteria. Statistically significant differences between CCT-only and CCT+collaborative sites are found for six of the 13 prenatal criteria. Among all the criteria with statistical significance, compliance was higher for CCT+collaborative sites compared to the CCT-only facilities.

Table 6: Comparison of compliance with quality prenatal care criteria between collaborative and non-collaborative health centers

Action observed	CCT+collaborative n[a]= 90 encounters observed		CCT-only n=29 encounters observed		p value
	n[b]	%	n[b]	%	
1) Determined weeks of pregnancy	89	99	28	97	0.395
2) Evaluated danger signs	84	93	25	86	0.229
3) Measured blood pressure	82	91	26	90	0.814
4) Evaluated fetal heart rate, if applicable (n=65; n=16) [c]	64	99	14	88	0.038*
5) Conducted Leopold maneuvers, if applicable (n=36; n=7)	35	97	7	100	0.656
6) Asked for a VDRL test (n=45; n=18)	38	84	12	67	0.115
7) Provided ferrous sulfate	81	90	26	90	0.957
8) Provided folic acid	82	91	26	90	0.814
9) Applied anti tetanus vaccine, if applicable (n=38; n=17)	34	89	10	59	0.009**
10) Counseled on VCT (n=56; n=19)	31	55	4	21	0.010**
11) Counseled on emergency plan	59	66	5	17	0.000**
12) Counseled on exclusive breastfeeding	22	25	1	3	0.013*
13) Filled out clinical record	85	94	20	69	0.010**

*Statistically significant: p<0.05 **Statistically significant: p<0.01

[a] N refers to the number of health centers where provider-client interactions were observed and compliance recorded.

[b] The number of **observations** that complied with the criterion.

[c] In parenthesis is the number of observations in which the norm was applicable for the CCT+collaborative and CCT-only arms, respectively.

Only one pregnant woman was observed to have received breastfeeding counseling during her prenatal visit among the 12 non-collaborative health centers staffed with professionally trained health providers.

Prenatal compliance scales[5]: The percent of compliance with prenatal norms (based on nine clinical criteria, one counseling criterion, and the criterion of completing the consultation form) was 10 percentage points higher in the CCT+collaborative group (94%) compared to CCT-only facilities (84%). When full compliance (all 10 technical criteria performed–excluding filling out the clinical form–for a given case) is examined, a large difference is found between the two research arms, with CCT+collaborative observations at 58% full compliance, whereas 0% of the observations in CCT-only sites achieved full compliance (Table 7).

[5] Two scales of prenatal care compliance were developed to measure the effect of adding a QI intervention to CCT sites and to compare the statistical significance between the two research arms (collaborative versus non-collaborative health centers): 1) additive scale consisting of nine prenatal clinical criteria, one counseling criterion, and completion of the prenatal clinical record (0-11), and 2) full compliance scale, consisting of meeting all nine clinical criteria and the counseling criterion but excluding completion of the prenatal clinical record (0-1).

Table 7: Compliance with prenatal care criteria in the CCT+collaborative and CCT-only groups

Prenatal care criteria	CCT+ collaborative n=90	CCT–only n=29	p value
Cumulative compliance scale: Percent of 11 criteria met (based on direct observations of care)	94%	84%	0.048*
Full compliance: Percent that complied with all 10 technical criteria (based on observations)	58%	0%	<0.001**

*Statistically significant: p<0.05 **Statistically significant: p<0.01

Multivariate analysis of compliance with prenatal care norms: Multivariate regression analysis was used to compare the two compliance scales, while controlling for confounders and testing for statistical significance. Confounding variables included in the multivariate regression were: number of professional health staff (physicians and nurses), socio-economic status of the district, and number of health educators involved in outreach and in-clinic services. Results of the multivariate analysis of the two prenatal compliance scales are presented in Table 8.

Cumulative compliance scale (measured as relative percent): The difference in levels of compliance was statistically significant, with CCT+collaborative facilities 8.5% higher than CCT-only.

Full compliance scale (measured as odds ratio): When compliance with all ten technical criteria are considered, difference in full compliance was also statistically significant, with CCT+collaborative sites 17.8 times higher than CCT-only facilities. That is, patients are almost 18 times more likely to receive care in full compliance with norms in CCT+collaborative health centers than in the facilities without the added quality improvement intervention.

Table 8: Prenatal care compliance with norms (controlling for confounders)

Measures: Percent difference and odds ratio		p value
Percent difference between collaborative and non-Collaborative sites	8.5%	0.007**
Odds ratio of full compliance, collaborative versus non-collaborative sites	17.8	0.003**

**Statistically significant: p<0.01

2. Child health care

The same procedures (direct observation of child health encounters and completion of a checklist) were followed to measure compliance with child health care. Compliance with each selected task associated with preventive child health care was examined, followed by an analysis of cumulative and full compliance scales. For the compliance scale with child preventive health care, all eight technical criteria were included (see Table 4 above). In addition, the criterion "filled out the clinical record" was included in the cumulative scale, but not in the calculation of full compliance.

Table 9 presents the number and percent of provider-client encounters that comply with each of the nine criteria regarding preventive child health and nutrition actions. Statistically significant differences were found for all nine criteria. Collaborative sites show substantially higher levels of compliance during child health consultation than the other non-collaborative sites within the CCT. Most of the criteria in non-collaborative facilities scored very low, demonstrating the need for major improvements in training, behavior change communication materials, and on-the-job support and supervision.

Table 9: Comparison of compliance with quality preventive child care criteria between collaborative and non-collaborative health centers

Action observed	CCT+ collaborative n[a]=104 encounters observed		CCT-only n=32 encounters observed		p value
	n[b]	%	n[b]	%	
1) Administered vitamin A, if applicable (n=19; n=8) [c]	14	73.7	0	0	<0.001**
2) Provided ferrous sulfate, if applicable (n=20; n=10)	13	65	1	10	0.004**
3) Provided folic acid, if applicable (n=20; n=10)	13	66	1	10	0.004**
4) Weighed and plotted weight for age on graph	80	76.9	4	12.5	<0.001**
5) Evaluated feeding problems	98	94.2	11	34.4	<0.001**
6) Classified growth (based on weight gain)	73	70.2	6	18.8	<0.001**
7) Verified and applied vaccine, if applicable (n=101; n=32)	93	92.1	21	65.6	<0.001**
8) Counseled on feeding, appropriate to age and growth classification	94	90.4	22	68.8	0.002**
9) Filled out infant/child clinical record	73	70.2	10	31.3	<0.001**

*Statistically significant: p<0.05 **Statistically significant: p<0.01

[a] N refers to the number of health centers where provider-client interactions were observed and compliance recorded.

[b] Is the number of **observations** that complied with the norm.

[c] In parenthesis is the number of observations in which the norm was applicable for the CCT+collaborative and CCT-only groups, respectively.

Child health compliance scales[6]: The percent (based on the nine criteria in Table 4) of cumulative compliance with child health criteria was 36 percentage points higher in the CCT+collaborative group (86%) compared to CCT-only facilities (50%). When full compliance (all eight technical criteria performed but excluding filling out the clinical form) is examined, a large difference is found between the two research arms, with CCT+collaborative sites at 60% full compliance, compared to only 12% in CCT-only sites (Table 10).

Table 10: Compliance with preventive child care criteria in the CCT+collaborative and CCT-only groups

Preventive Child Care Indicator	CCT+collaborative n=104	CCT-only n=32
Cumulative compliance: Percent of nine criteria met, including filling out the record (observations)	86%	50%
Full compliance: Percent that complied with all eight technical criteria (observations)	60%	12%

[6] Two scales of child health care compliance were developed to measure the effect of adding a QI intervention to CCT sites and to compare the statistical significance between the two research arms (collaborative versus non-collaborative health centers): 1) additive scale consisting of eight key child health criteria plus the completion of the children health clinical record (0-9), and 2) full compliance scale, consisting of meeting all eight clinical criteria but excluding completion of the prenatal clinical record (0-1).

Multivariate analysis of compliance with young child (under two years) health care norms: Results of the multivariate regression analysis of the two child health compliance scales (while controlling for confounders) are presented in Table 11. Confounding variables included in the multivariate regression were: number of professional health staff (physicians and nurses), size of population and socio-economic status of the district, and number of health educators involved in outreach and in-clinic services.

Cumulative compliance scale: The difference in levels of compliance was statistically significant, with CCP+collaborative facilities much higher at 38.9% compared to the CCT-only sites.

Full compliance scale: When compliance with all eight criteria is considered, the difference in full-compliance is also statistically significant, with full compliance in CCT+collaborative sites 17.9 times higher than CCT-only facilities. That is, some 18 times as many child health consultations in CCT+collaborative health centers comply with all of the eight technical criteria compared with the facilities without the QI intervention.

Table 11: Preventive child health care compliance with norms (controlling for confounders)

Measures: Percent and Odds Ratio		p value
Percent difference between collaborative and non-collaborative sites	38.9%	0.001**
Odds ratio of full compliance, collaborative versus non-collaborative sites	17.9	0.003**

**Statistically significant: p<0.01

C. Cost-effectiveness Analysis of Adding Collaborative Improvement to a CCT Program

1. Costs

The costs of the QI Collaborative to HCI were collected from January 2009 at the start of the intervention to June 2010 (Table 12). Travel and per diems for learning sessions and coaching visits was the highest category expense, comprising more than 30% of the total cost over the whole period. The cost of learning sessions and education materials were also significant contributors to the overall expenditure for the collaborative. All costs are reported in $US.

Table 12: Costs of HCI support for the ProCONE Collaborative from January 2009 to June 2010

Type of support	Cost	%
Personnel	6,167	2.1
Printing	15,860	5.4
Education materials	60,486	20.6
Travel (transport / hotel)	87,506	29.8
Per diems (Traveling HCI staff)	23,707	8.1
Area level meetings	73,076	24.9
Workshop for coaches / supervisors	26,583	9.1
Total	293,385	100.0

2. Cost-effectiveness

The cost of a prenatal care visit in a non-collaborative site was $5.25. The proportion of those visits in full compliance with quality standards was 6.9%, giving a cost-effectiveness of $76 per prenatal visit done to full compliance with standards. In collaborative sites, there was the additional cost of the QI intervention of $0.78 per service provided so the total cost per visit was $6.03 in collaborative sites.

However, the proportion of visits fully compliant with quality standards was 70% so the collaborative site's cost-effectiveness was $8.62 and the additional cost was $1.24/per additional prenatal care visit in full compliance. The same calculations for child health visits gave an additional cost of $1.78 per additional child care visit in full compliance (Table 13). The difference in proportion of full compliance with clinical norms prenatal and child health visits is the driver of the incremental cost-effectiveness. The confidence intervals derived from Monte Carlo simulations are given in Table 14.

Table 13: Cost per service for collaborative and non-collaborative sites and incremental cost-effectiveness ratios (ICERs)

Service	Collaborative	Cost	Incremental Cost	Probability of compliance	Incremental probability of compliance	Cost / effect	ICER
Prenatal care	No	$5.25		0.069		$76.12	
	Yes	$6.03	$0.78	0.7	0.631	$8.62	$1.24
Child health	No	$6.25		0.061		$102.04	
	Yes	$7.03	$0.78	0.5	0.439	$14.06	$1.78

Table 14: Incremental cost-effectiveness ratios and confidence intervals

Prenatal care	
Incremental cost-effectiveness	$ 1.24 / additional prenatal care visit done to full compliance with norms
95% Confidence interval	$1.13 - $1.37
Preventive child health care	
Incremental cost-effectiveness	$ 1.78 / additional child health visit done to full compliance with norms
95% Confidence interval	$1.55 - $2.07

Among all input variables in the decision tree model, the main driver of the result is the probability of compliance with quality standards in the collaborative sites. A 1% increase in this measure of effectiveness of the collaborative is associated with1.14% decrease in the additional cost per fully compliant service provided (or a 1.14% increase in the cost-effectiveness of the collaborative sites compared to the non-collaborative sites). The magnitude and direction of the effects of an increase in the other input variables of 1% is given in Table 15.

Table 15: Relative effect of a 1% increase in input variables on cost-effectiveness

Variable	Magnitude of effect (%)	Direction of effect on the ICER
Probability of compliance (collaborative sites)	1.140	Decrease
Total cost of collaborative	1.000	Increase
Patients served in collaborative sites	1.000	Decrease
Travel (transport and hotels) [travel/per diem]	0.300	Increase
Area level meetings	0.250	Increase
Educational materials	0.210	Increase
Probability of compliance (non-collaborative sites)	0.140	Increase
Workshop coaching / supervision	0.091	Increase
Per diems	0.081	Increase
Printing	0.054	Increase

3. Summary of cost-effectiveness findings

For a total cost of $293,385 for the QI collaborative from January 2009 to June 2010, there were 60,102 additional prenatal care consultations done to full compliance with clinical norms and 122,900 additional child health consultations done to full compliance. This is an additional cost per prenatal visit delivered in full compliance of norms of $1.25 and an additional cost of $1.78 per child health visit in full compliance with norms.

In this study we have used a process measure (full compliance with clinical norms) as the outcome of interest. Had we used health outcome data (neonatal mortality, child mortality/morbidity indicators) to measure the effect of the collaborative in CCT sites compared to non-collaborative sites, we could have used those outcomes as the denominator in the cost-effectiveness analysis. Alternatively, if we knew the relationship between health outcomes and either full compliance with norms compared to less than full compliance, then we could have linked this result to the direct effect on the lives of the patients. As the result is presented, we can only say that the collaborative achieved a high level of full compliance with clinical norms for a per-patient cost of $0.78 per patient served in the collaborative areas. This information is useful itself because it provides a baseline from which all other cost and cost-effectiveness studies of different quality improvement interventions in Guatemala can be measured.

The total cost of the collaborative to HCI was divided by the number of patients given prenatal care and child health services, a total of over 375,000 patients. However, other clinical care provided by facilities in the collaborative was not included in this denominator because outcome data were not available for those individuals. These include deliveries and post-natal care visits. Inclusion of all of the clinical areas that the collaborative worked with would have decreased the cost per patient served of the collaborative. This lower cost would have made the collaborative seemed even more cost-effective compared to non-collaborative sites than our results show.

It was not the purpose of this study to consider any downstream benefits to the health system of having better trained and more highly engaged and motivated clinical staff as a result of the collaborative. However, it is reported that QI collaboratives have other benefits, such as improved health provider engagement, increased trust among providers, better staff relationships, and application of QI methods to other areas within the facilities (Ayers et al. 2005, Bradley et al. 2002).

There is a paucity of literature on the cost-effectiveness of QI programs in both developed and developing countries. We found none in the peer-reviewed publications on Central American programs. The $0.78 per service cost of this intervention is one quarter of the cost of an essential obstetric and newborn care collaborative implemented in Niger from 2006-08 at $2.43 per service provided (Edward Broughton, unpublished data). The results of $1.25 and $1.78 per additional service provided to compliance with norms for prenatal and child health visits, respectively, are also lower than in Niger for compliance with essential obstetric and neonatal services. The additional cost in that setting was $3.48 per additional mother treated to compliance with active management of the third stafe of labor and $3.13 per additional infant treated to compliance with essential newborn care standards. While there were substantive differences between the collaboratives in Guatemala and Niger in the services targeted, the population served, the size of the country, the time frame of the intervention, and the logistics of conducting the collaborative, this comparison at least indicates that the overall cost per service and cost-effectiveness of the intervention is similar.

Information presented in this report is important for MOH decision-makers to determine whether spreading the collaborative to other sites in the CCT program is possible given budgetary constraints. Using projections based on this study, the cost of implementing collaboratives in other CCT Health Areas can be estimated.

If the MOH was to undertake the collaborative improvement intervention, it could be more cost-effective because the cost of the intervention would be lower (e.g., fewer transport costs, fewer

personnel, since some of the personnel in this intervention were needed for program development which would not have to be repeated). Coaching and supervision could be largely transferred to the Health Area teams and supervisors with training in QI and collaborative functions. HCI could provide technical support to support the transfer and institutionalization process, based on its lessons learned, tested training methods, and QI tools.

VII. CONCLUSIONS AND RECOMMENDATIONS

This section summarizes significant findings and provides recommendations to guide the scale-up of QI collaboratives by the MOH, institutionalization of support for QI interventions, additional research and cost analyses, and the scope of QI teams in health facilities.

A. Conclusions

This study provides information to decision makers and donors regarding the incremental effectiveness and cost-effectiveness of implementing QI collaboratives in areas in Guatemala where the conditional cash transfer program is operating. The objective of the study was to understand if implementing a quality improvement intervention results in improved compliance with clinical norms. A secondary objective was to measure the incremental cost-effectiveness of adding a QI collaborative to a CCT program. The findings are based on quality measures in 38 district health centers where the CCT program was operating and 12 facilities where the CCT program was operating but no quality improvement collaborative was in place. We compared the effectiveness and cost-effectiveness in the two types of facilities.

Heath centers participating in a QI collaborative presented higher levels of compliance with clinical norms when compared with non-collaborative sites. Cumulative and full compliance scales were developed to measure differences in compliance between the two study groups. Cumulative scores, percent of criteria performed correctly, for both prenatal care (+8.5%) and child health (38%) were significantly higher in health centers with the QI intervention. When full compliance scores were compared between the two research groups, full compliance with norms was almost 18 times higher for both prenatal care and child health in the collaborative sites. Thus some 18 times as many consultations in health centers participating in the QI collaborative complied fully with the clinical norms, compared with non-collaborative facilities. Even though CCT+collaborative facilities present higher levels of prenatal care compliance, there is still a need for additional improvement in voluntary counseling and testing for HIV, emergency birth planning, and promotion of exclusive breastfeeding.

The conservative estimate of the additional cost of the collaborative was $0.78 per service delivered. This is low compared to QI collaboratives in other countries. The intervention cost $1.25 per additional prenatal service provided in full compliance with norms and $1.78 per additional child health service in full compliance.

Given the modest cost and the high level of effectiveness in improving compliance with clinical norms for prenatal and child health services, we conclude that expansion of the ProCONE improvement collaborative to other health facilities in areas where the CCT program is operating is a cost-effective strategy for improving maternal and child health in Guatemala.

B. Recommendations

The following recommendations are based on the study's findings, our experience in introducing and expanding QI interventions with the MOH, and best practices documented worldwide by HCI.

Advocacy and marketing of QI collaborative results to the MOH: This study provides good evidence that improvement interventions like QI collaboratives are an important value-added strategy to obtain better MCH outcomes and cost-effective allocation of resources. HCI should actively engage the MOH at central and local levels in order to spread collaborative improvement to other Health Areas of

Guatemala. This process should begin with a presentation of results showing the effectiveness and cost-effectiveness of QI interventions, plus a discussion of mechanisms and feasibility of scale-up with decision-makers. The goal of the presentation would to persuade the MOH and directors of *Mi Familia Progresa* of the utility of integrating CCT and QI collaborative efforts and to obtain initial commitment to do so. A workshop format with breakout groups could be used to initiate group discussions, followed by a plenary session to present the results of breakout groups. Based on these results, a follow-on workshop could be scheduled to develop an implementation plan and budget for scaling up QI collaboratives in various types of health facilities.

Prior to undertaking the foregoing advocacy and marketing effort, it is important that HCI prepare a strategy for advocacy, buy-in workshops, and options for scaling up, including possible costs that can be shared between the MOH and donor funds. The scale-up strategy should consider three questions: 1) What are we trying to scale up? 2) To whom do we want to scale-up, and by when? and 3) How will we scale-up and expand to other areas and types of health facilities? (See Massoud et al. 2010 for an in-depth discussion of planning for scale-up.) These questions should be addressed prior to the first advocacy workshop and then introduced in the workshop's discussion groups.

The findings of this study, and other methods and materials should be packaged to optimally illustrate the QI collaborative model and its effective integration into a CCT program. For example, QI team members can present their favorable experiences with collaborative improvement and the changes in quality of service that resulted, including a presentation of facility level run charts.

In summary, HCI should develop an advocacy strategy and plan for adoption and scale-up of QI collaboratives that can be used during workshops with decision makers, managers, and donors and adapted based on feedback and buy-in from workshop participants and key decision-makers in the MOH.

Promote community-based strategies to increase early postnatal and neonatal care: As mentioned, data collectors were not able to observe and record enough neonatal and postpartum cases to include in the analysis. Due to geographic barriers and cultural beliefs and practices, postpartum women and their neonates are not likely to use facilities before one month after delivery and then only to guarantee vaccination of the newborn and a health card, which is sometimes required for birth registration. Therefore, HCI should engage the MOH in community-based strategies to complement facility-based postnatal and neonatal care. Community ProCONE is including among its interventions community mapping with probable date of birth of all pregnant women and home visits by traditional birth attendants during the first 24 hours after delivery. To achieve the reduction of maternal and neonatal mortality, extending coverage of key health services is as important as improving their quality.

Demonstrate the cost-effectiveness of QI collaboratives: The advocacy effort should draw upon the findings of the cost analysis to demonstrate the utility of investing in quality improvement interventions. Information in this report is important for decision-makers to evaluate whether expanding collaboratives to other health facilities is feasible given MOH budgetary constraints and financial and technical support of donors. Using projections based on the results of this study, the cost of expanding the ProCONE collaborative to CCT sites not currently participating in the collaborative can be estimated. HCI should add to the current study by making estimations of what it would cost to spread to the rest of the CCT sites, by phases and types or levels of health services.

We also recommend that future evaluations of QI programs be designed to capture patient outcomes as measures of effectiveness. A measure of incremental cost-effectiveness in terms of a specific health outcome would have allowed valid comparisons of this intervention with other health interventions. From such a measure, the relative efficiency of the intervention could have been reported in disability-adjusted life years or deaths or other adverse events averted and therefore compared with any other health intervention for which a comparable cost-effectiveness evaluation has been conducted.

Additional studies on the effectiveness and cost-effectiveness of QI collaboratives: While this study has focused on the integration of CCT and collaborative improvement interventions, there remains a need to study the effect of QI interventions in lieu of CCT. Also there is a need to broaden the scope of studies and examine the effect of QI collaboratives in rural health facilities and on the Extension of Coverage program.

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ANNEX: EXPANSION PHASE OF THE PROCONE IMPROVEMENT COLLABORATIVE

The preparation and implementation of the expansion phase of the ProCONE improvement collaborative, to expand the demonstrated best practices to seven additional regions, entailed four steps:

1. Advocacy

The first step in the expansion phase was advocacy visits to the seven Health Areas to be covered in the ProCONE expansion. Theses visits provided an opportunity to introduce the following topics:

- Concepts, principles and dimensions of quality
- Methodology for quality improvement: define, measure and improve quality
- Norms and standards to define the quality of maternal, neonatal and child care
- Indicators and criteria to measure quality of maternal, neonatal and child care
- Best practices of the demonstration phase to improve quality of maternal, neonatal and child care
- Facilitation processes and responsibilities
- Replication of learning sessions to reach 120 second level health centers and outpatient centers of the 15 hospitals, following a plan and methodological guidelines
- Formation of continuous improvement teams in 120 second level health centers and outpatient centers of the 15 hospitals
- Training and provision of basic inputs (e.g., clinical records and monitoring sheets with indicators and criteria) to conduct a baseline in participating health facilities.

2. Dissemination Workshop

A workshop for the dissemination of the methodology and achievements of the demonstration phase of the ProCONE collaborative to technical and administrative personnel of seven additional Health Areas was carried out following the advocacy visits. In each of the seven health areas, teams were formed involving the following staff: Health Area Director, Health Area Epidemiologist, Departmental Hospital Director, Directors of Obstetrics-Gynecology and Pediatrics of the hospital, Area professional nurse, hospital head nurse, hospital Obstetrics-Gynecology and Neonatology nurses, head of the Area Reproductive Health team, Area social worker (coordinator of health promotion), and hospital social worker.

3. Learning Sessions and Action Periods

The collaborative was rolled out in a sequence of learning sessions followed by action periods. Health Area teams replicated the workshop with 120 Health District teams and 15 hospital teams in the first learning session. This session served to strengthen the formation of facility-level QI teams and present indicators and criteria to be measured through the review of clinical records.

After the first learning session, facility QI teams conducted their baseline measurement of the indicators. At the second learning session, teams presented their baseline results, best practices from the demonstration phase in San Marcos were presented to QI teams from the expansion sites, and teams planned the improvements they would make in the second action period. The agenda of the second learning session included:

Distribution and analysis of the document on best practices of the demonstration phase in San Marcos to be used in planning improvement changes

The Plan-Do-Study-Act cycle and its steps

- Continuous measurement of indicators in order to show that the changes have resulted in improvements.

During the subsequent action period, QI teams received direct support in measuring and implementing changes from the central and Health Area teams, together with the HCI advisors.

Facility QI teams continued monitoring indicators in 120 second-level facilities and outpatient centers of 15 hospitals for several months. During the third learning session, emphasis was placed on the documentation of interventions. By the fourth measurement of indicators, QI teams attained acceptable levels of quality (indicators $\geq$ 80%) similar to those obtained in San Marcos over a longer period of time.

4. Transition Phase of the Collaborative

The expansion phase of the Maternal, Neonatal and Child Health QI Collaborative after 18 months of implementation will now enter into a transition phase. Next steps include determining which indicators will continue to be measured, the frequency of measurement, and what continuing support health facility teams will continue to receive. Also, successful interventions will be compiled and added to the list of interventions derived from the demonstration phase in San Marcos. Efforts will be made to expand the use of improvement methods, best practices, and lessons learned nationwide during 2011.

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