



A pilot study to assess the feasibility and acceptability of a relationship-based early parenting add-on package to support early child development in KwaZulu-Natal

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EXECUTIVE SUMMARY

The project: This project is a pilot study to explore the feasibility and acceptability of the Ibhayi Lengane intervention. Feasibility research is an important step in intervention science which aims to determine whether an intervention is appropriate for further testing before undertaking large scale evaluations or controlled studies. The aim of this research project was to provide both the donor (Ilifa Labantwana) and the proposed service provider (The Department of Health) with information which would help them assess whether or not the Ibhayi Lengane intervention is acceptable, feasible to deliver within the public health system and likely to have the impact expected.

The partnership: This project is the result of a partnership between Dlalanathi, the implementation partner who developed the Ibhayi Lengane add-on, the Human Sciences Research Council, who provided technical support for the scientific aspects of the project, and the Department of Health who delivered the intervention as part of the pilot study, using their human resources (community caregivers) within their routine services (primary health care).

Overview of report structure: In this report we outline the findings of the pilot study. We start by outlining the rationale for the pilot study and the proposed hypothesis. We describe the Ibhayi Lengane add-on and the additions and revisions which were made in consultation with stakeholders and the Department of Health. Thereafter, we provide feedback on the training process which was undertaken with the Department of Health employed community caregivers. We explore the facilitators to training, making recommendations for how this training should be structured within public health systems, and highlighting the potential pitfalls to be avoided. We report feedback on the community caregiver's experiences of the training and the content of the programme prior to and after training, and post-intervention. We present feasibility and acceptability aspects of the project based on implementation data and present the results of the pilot study measures collected pre and post intervention. We provide patient engagement data on the participating mothers' experiences and perceptions of the intervention and we present case studies to illustrate the potential impact of the intervention on morbidity and mortality risks at community level. Finally, we present a preliminary costing exercise to outline

the estimated costs associated with various approaches to intervention delivery. We conclude the report with recommendations for further implementation science.

Summary of results: We demonstrate that Ibhayi Lengane is not only feasible but also highly acceptable to both provincial and district health stakeholders; to the community caregivers delivering it; and to the mother's receiving it. We demonstrate that the intervention has the effect that we expect it to have, based on the proposed hypothesis, and that the results demonstrate potential to show a positive impact if tested at a larger scale. Likewise, we find that our proposed measures are adequate and reliable for assessing the impact of the intervention. While we are able to estimate an indicative costing for varying approaches to delivery, and in particular to show the potential savings gained by targeted approaches, a full costing exercise is not possible without a controlled study which demonstrates the effects of the intervention relative to a standard of care control condition.

Recommendations: The report makes four recommendations:

1. Test the Ibhayi Lengane intervention at a larger scale in a controlled study in partnership with district Department of Health to determine effect size and relative benefit.
2. Undertake a full economic costing of a range of delivery approaches to determine the optimal model, based on the controlled study outcomes.
3. Establish systems to extend the supervision systems developed for Ibhayi Lengane for broader use in existing health structures to enable higher quality support for referrals.
4. Expand the Ibhayi Lengane package to include an implementation planning module to guide district managers and primary health care coordinators on implementation approaches.

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BACKGROUND

Enormous gains have been made in the last few years towards recognizing that nurturing, protective and supportive care for children in their earliest years of life is critical to achieving sustainable change in the world¹.

ADVANCES IN EARLY CHILD DEVELOPMENT SCIENCE AND POLICY

Tireless advocacy by the child development community² and a growing body of evidence provided by the scientific community³ have led global policy makers to an understanding that tackling poverty in a meaningful way requires investment in human developmental potential^{4,5}. There is now overwhelming scientific evidence that the parent-child relationship, in particular responsive sensitive care in the first 1,000 days of life, is critical to children's development⁶. The benefits of responsive caregiving and early stimulation have been demonstrated across all domains of child development including in the development of secure attachments, which in turn are critical to healthy relationships later in life, and in attention and language skills which are key to later school achievement and ultimately economic productivity in the adult years^{3,7}.

SUSTAINABLE DEVELOPMENT GOALS (SDGs)

The pinnacle of these achievements over the past decade has been the inclusion of early child development (ECD) as a Sustainable Development Goals (SDG) target^{4,8}. The SDG were preceded by the Millennium Development Goals (MDG)⁸ in 2000 which focused on targets to ensure child survival, and which was broadly successful⁹. The SDG Target 4.2 to '*ensure that all girls and boys have access to good-quality early childhood development*' alongside global strategies such as the '*Survive, Thrive, and Transform*' goals of the Global Strategy for Women's, Children's and Adolescent Health provide the impetus to governments and all concerned stakeholders to begin to take action to deliver ECD services^{6,10}. There is also growing evidence to suggest that programmes aimed at supporting child development by training caregivers on early stimulation and responsive care, such as the World Health Organization's (WHO) Care for Child Development (CCD) program, are successful to implement across a variety of settings, including very low resource contexts^{4,11}. This, together with the impetus of the SDG targets and a

commitment to *'leave no one behind'* has brought a heightened commitment to the delivery of ECD services in the first 1,000 days¹⁰.

NURTURING CARE FRAMEWORK

The Lancet series *Advancing Early Childhood Development: from Science to Scale (2017)*^{1,4,6} highlighted the importance of nurturing care in the first 1,000 days – from conception to age two – as the foundation for child development. Major stakeholders to the delivery of the SDG for children including WHO, UNICEF and the Partnership for Maternal, Newborn & Child Health and the ECD Action Network, have developed an umbrella framework called the *Nurturing Care Framework*¹² set to be launched at the 71st World Assembly in 2018.



Figure 1 Nurturing Care Framework (WHO, 2017)

This framework argues that there is an indivisible cluster of interventions related to health, nutrition, responsive caregiving, safety and security, and early learning which are critical to improving child outcomes, and that these must be achieved together if progress is to be made^{12,13}. Furthermore, the nurturing care framework emphasises the importance of cooperation and integration among sectors in ensuring the reach and impact of ECD services, but also recognizes that the health sector has a

particularly important role to play given its regular interface and reach to children and caregivers during this most critical time period^{4,12,14}.

EARLY CHILD DEVELOPMENT IN SOUTH AFRICA

In South Africa significant progress has been made towards achieving the targets of the MDGs^{8,15,16} over the past decade however, young children and their mothers (and/or caregivers) still face a myriad of risks as a result of poverty, violence and disease¹⁷. These conditions pose immediate risks to the mother and child's safety and health, and can impact on the longer term development of the child. South Africa has developed an Early Childhood Development Policy¹⁸, and in responding to the need to shift towards the '*thrive*' rather than '*survive*' agenda, significant investments are being made (by both the public and the private sector) to scale up ECD services in South Africa¹⁹. This includes initiatives to increase access to ECD centres, play groups and other out-of-home activities, however, few programs have focused on in-home support, leaving a critical gap in the earliest years of life which are known to be both formative and essential in securing the longer terms gains of early investment¹³.

There is general consensus globally²⁰ that in-home-activity support, delivered by community health care workers or other community based human resources, is critical to ensuring that parents are able to provide a nurturing, stimulating and supportive care environment for the young child⁶. This is particularly so in the early developmentally sensitive window period of the first 1,000 days of life, when the child is unlikely to access ECD support outside the home^{13,20}. Not only is there a shortage of public sector in-home support programs, but there are a dearth of successful examples illustrating integration of ECD with other maternal and child health services²⁰.

The South Africa Department of Health (DOH) faces its own unique set of challenges²¹, in part due to historical inequities and in part given the high burden of disease brought about by the HIV epidemic^{16,17}. Community based human resources have been critical to the expansion of health services in South Africa^{22,23}. Historically, these human resources have included multiple cadre's including community health care workers formally employed and trained by DOH, and lay counsellors and community caregivers in stipend or volunteer services linked to national programmes or linked to the not-for-profit sector²³. More recently, in provinces such as KwaZulu-

Natal where this research takes place, efforts have been made to integrate these lay professional cadres within DOH under the title “community caregivers” or CCG’s.

In general the support programmes which are delivered by DOH in South Africa, which make use of community based human resources, tend to focus more heavily on the provision of health and nutritional information, an area in which great successes have been evidenced²⁴. However, these CCGs do not currently provide support and training around early child development, responsive caregiving or early stimulation, representing a potentially significant missed opportunity²⁰.

A review of several ECD programs by this team, prior to this pilot study, found that there were many home visiting programmes being delivered in South Africa. Most were made possible by support from private donor funding and delivered through the non-governmental organisations (NGO) and community based organisations (CBO). Again many of these programmes focused exclusively on providing the mother or caregiver with important information on child survival, nutrition and health, and more recently many have begun to focus more exclusively on ECD without any integration of health or nutrition, resulting in missed opportunities in both areas. ECD programmes delivered in-home by NGO supported parallel services to DOH tend to be costly and unsustainable, hence there is a growing need to integrate in order to scale²⁵. The review also found that in most cases (both in the NGO and the public sector) information on early stimulation is provided primarily in a didactic approach and few approaches focus on the training required by CCGs to enable their capacity to deliver such services, nor curriculum which used a relationship-based framework in the first 1,000 days.

EARLY CHILD DEVELOPMENT AND THE HEALTH SECTOR

A further challenge identified in the South African context prior to this pilot study, which informed the approach taken in this study, was that the South African ECD policy¹⁸ places specific responsibilities on the health sector in delivery of these early childhood services, in particular for high risk families. This is challenging given the current burden on health services¹⁶, and the concurrent service delivery pressure placed on community based health sector personnel^{17,22}. In order for the implementation of ECD services to be operationalized, integrated and scaled up within the health sector, there is a need to develop curriculum and materials to

support the training of CCGs and a need to pilot the methodology by which such an additional or “add-on” service by CCGs can be integrated into ‘real life’ settings and systems within the DOH service sector.

It is in this context that the Dlalanathi and Ilifa Labantwana project teams, supported by a research team at the Human Science Research Council (who have led the development of several successful family based interventions in KwaZulu-Natal) developed an “add-on intervention package” aimed at responding to this gap.

STUDY RATIONALE

Hypothesis testing is critical to ensuring rigorous intervention research²⁶. Developing a hypothesis helps researchers and implementers understand what characteristics, variables or processes might impact on the desired intervention outcome²⁷. In the earlier formative stages of intervention research, our knowledge of relationships may be based on theoretical understandings or on existing evidence about relationships between variables from settings different to our research context²⁸. This may help in the formulation of our hypothesis, and in testing it within our context. Large scale testing of a hypothesis in controlled studies is still necessary, but it is also expensive and should be informed by feasibility research to increase the prospect of intervention success^{28,29}.

A good working hypothesis stresses that it should be able to be tested^{26,27}. To meet this criterion the hypothesis must be operationalised - meaning that concepts employed in the hypothesis must be measurable, or more simply put, it is important to establish that one can measure the change one expects to achieve through intervention. In the case of Ibhayi Lengane, reported on here, enough theoretical and research evidence exists from other settings to help the formulation of a meaningful hypothesis about how the intervention will impact on responsive caregiving and ultimately child developmental outcomes.

However, research is required to ensure that the intervention approach is acceptable and feasible to deliver; salient and engaging enough to ensure uptake by the target population; and safe to deliver in the context²⁷⁻²⁹. It is also important to test that the expected relationships hold in the environment under study and to ensure that the variables of interest used as outcome measures are measurable and reliable to use in a larger scale study^{26,28,30}.

RESEARCH HYPOTHESIS

The Ibhayi Lengane intervention was developed to respond to key challenges in delivering ECD services in the first 1,000 days in South Africa. It draws on the existing evidence base and is designed to enhance parenting skills, reduce mental health symptoms and increase family support amongst high risk mothers in order to ensure mothers have both the emotional and practical capacity to be responsive and

provide stimulation to their children. These established expected theoretical relationships are illustrated below.

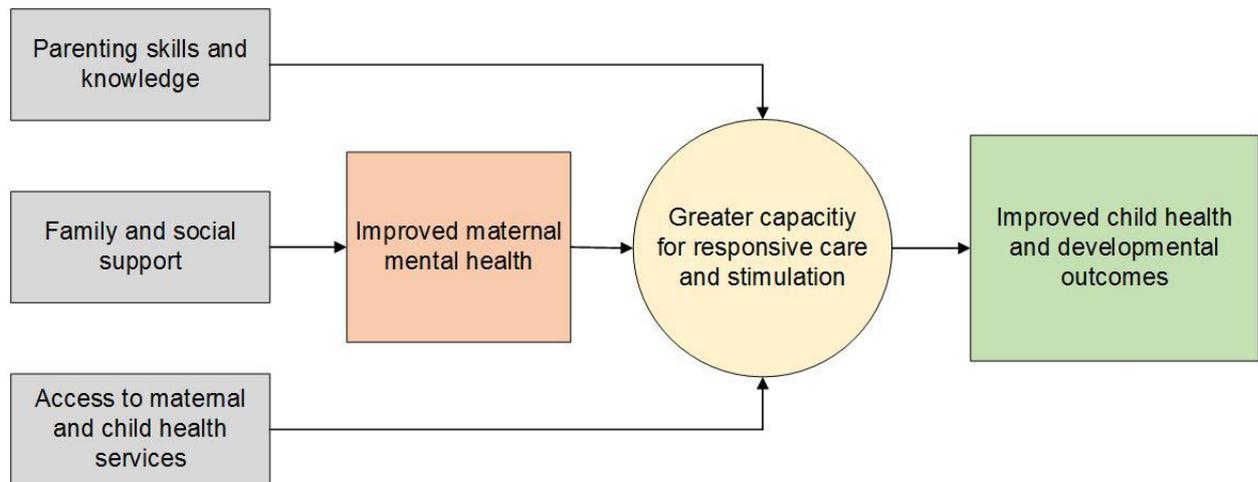


Figure 2 The theoretical pathway to enhanced early child development

We start from the premise that in the context of poverty and inequality, unplanned pregnancies (which are very common in South Africa) can lead to significant stress in both partner and family relationships. Further, we acknowledge that this is often confounded by other pregnancy related risk variables such as HIV, maternal depression and domestic violence. We hypothesise that these health, family and partnership stressors are key variables that disrupt maternal mental health and coping both in pregnancy and the postnatally, and can lead to social isolation and a lack of support which likely impacts negatively on maternal health behaviours, the quality of the parent-child relationship, and access to health care - all of which in turn have downstream effects on child development.

In the intervention design (described in detail in the next section) we hypothesise that in a controlled study receiving services from an Ibhayi Lengane trained CCG employed by the DOH, at optimal dose and fidelity, we will improve family relationships and support; improve maternal mental health; have a positive influence on maternal capacity for responsive care and stimulation; will reduce parenting stress and improve the quality of the mother-infant relationship; and increase access to health care support, which together will lead to improvements in infant development at 12 and 24 months, as compared to the standard of care.

In the research reported on here, we prepare for a larger scale testing of this hypothesis in a controlled study. An important aspect of this research project was the

engagement of DOH as an intervention partner. Doing so allowed an assessment of the realistic potential for integration; it provided an opportunity to review and augment lbhayi Lengane content to suit delivery by CCGs employed by DOH; and to test the feasibility and acceptability of the integrated intervention with both CCGs and mothers.

RESEARCH APPROACH

Pilot studies are an important and crucial first step in the design and testing of interventions which are expected to be implemented at a large scale²⁷⁻²⁹. They can improve and enhance aspects of the intervention design before embarking on a larger scale implementation, evaluation or controlled testing. Furthermore, there is growing recognition that participant or patient engagement and involvement in intervention development and evaluation can improve outcomes³¹. It is argued that the success of complex interventions at scale are strongly associated with the extent to which participants of the intervention (both those receiving and those delivering the intervention) report feeling engaged in the intervention and consider it to be responsive to a clearly identifiable, salient need.

The qualitative research in this project can help researchers understand - at least indirectly - whether the intervention can be delivered in the manner conceptualised; what aspects might facilitate or impede its success; and whether these barriers exist either within the health system which will deliver it - or the family system where it is delivered. In this sense, qualitative methods are central to our piloting phase^{28,29} and while piloting does not guarantee success in the larger scale implementation of an intervention, it is an important tool to substantially increase the likelihood of later success²⁷.

Pilot studies are also an important ethical imperative where intervention resources are limited and demands high, such as in public health²⁷. In these contexts pilot studies can help ensure accountability around larger scale investments, rather than relying on theoretical assumptions about potential impact at scale within the intervention design. Pilot studies thus provide an opportunity for the best possible intervention approach to be determined before a large amount of time, resources and effort are invested. They can also provide realistic and thorough estimates of the

additional costs of an intervention as a means towards supporting an investment case.

When conducted carefully pilot studies can also elicit important information on unanticipated practical problems which might affect intervention delivery and outcomes at scale.

RESEARCH AIMS

The primary aim of this project was to conduct a pilot study to test the acceptability and feasibility of the Ibhayi Lengane program as an add-on to existing Department of Health services.

The primary aim was operationalised through the following three research objectives:

- i. Operationalise the Ibhayi Lengane add-on based on input from Department of Health.
- ii. Pilot the delivery of the Ibhayi Lengane add-on by Department of Health community caregivers with 40 families.
- iii. Determine the resource inputs and costs associated with various models of delivery of the Ibhayi Lengane add-on.

INTERVENTION APPROACH

Ibhayi Lengane is designed as an ‘add-on’ intervention to augment the existing programme of health care and nutritional programmes currently being delivered by CCGs working for the Department of Health in South Africa.

THE RATIONALE FOR THE DESIGN OF THE IBHAYI LENGANE ‘ADD-ON’

The add-on was developed against the backdrop of the South African Early Child Development Policy, which includes home visiting for at-risk new mothers – with differing duration depending on assessed risk. The policy indicates that the DOH will take responsibility for this component. The DOH, while expressing support for the policy has expressed concern about the creation of a *new* cadre of staff to conduct these home visits. It is therefore probable that the policy will be implemented by existing staff within the health sector. This means, it will invariably become what can be termed an add-on program. An add-on program is conceptualised as a specific discrete addition of training, content and practice, which is integrated into the existing role of DOH employed CCGs.

There are, however, limited examples of how such an add-on would work and how successful it could be. There is a clear need to develop, pilot, and test approaches for add-on interventions, not least of which to test their feasibility. Likewise in the not-for-profit sector while many programmes have been sensitively developed, they tend, given capacity restraints, to only deliver limited components of integrated interventions, resulting in missed opportunities. Without promising examples of how an ECD add-on could work, it is unlikely that funding will be forthcoming from Treasury. Thus, this add-on intervention has significant national relevance.

An important opportunity to reach the ‘hard to reach’

The Ibhayi Lengane add-on does not propose to replace well established maternal and child health primary health care services delivered by CCGs (such as breastfeeding or nutritional support). Nor does it propose to replace ECD programs such as Care for Child Development (CCD) – which is designed to be delivered in group sessions at primary health care clinics and other community settings from birth to 3 years, and which has been shown to improve maternal capacity for responsive

care and stimulation at scale in a multitude of settings. However, the Ibhayi Lengane add-on acknowledges that high risk mother-child dyads may be socially isolated and may thus have limited access to centralised health care and ECD services. It operates on the assumption that the most effective way to identify such high risk mothers would be through community level services such as home-based care.

The targeting approach of an add-on also acknowledges that home-based health care services are heavily burdened, and that scalable models for delivery of ECD services at a population level will likely require centralised integrated services and group based delivery. But because high risk mothers may have lowered access to these centralised services, the Ibhayi Lengane add-on aims to address the needs of a smaller population of high risk mothers who may warrant additional intervention (at home and centre based) particularly during vulnerable periods or critical transitions, in order to ensure they have adequate social support and health care access.

Therefore, Ibhayi Lengane attempts to work within existing home-based services, as a means to augment existing centralised services, with the ultimate aim of lowering risk factors and improving child development by providing additional '*activating*' supports which bring high risk families into closer contact with health and educational services. It is designed to be responsive to high risk families in order to disrupt the negative influence of risk factors on the mother and the infant, and to provide greater linkage to existing services. Factors considered to make mothers high risk include but are not limited to; extreme poverty, young age, HIV status, maternal depression, domestic violence and migrant status. Given existing estimates in KwaZulu-Natal it is expected that at least a third of women at a community level might warrant these additional services.

The goal of designing the Ibhayi Lengane add-on is to ensure that the intervention is suited to low resource settings, in that it is: **scalable** and can be delivered through task-shifting and; **targeted** in that it focuses on a smaller population of high risk mothers with less access to routine health care and social welfare services.

Relationship based frameworks to secure both health and ECD outcomes

The central principle guiding Ibhayi Lengane is that fostering the responsive care framework which is needed for child development, requires at its core, that the helper or home visitor should role model the same sensitive and caring approach towards the mother that they expect a mother to provide to her child.

The assumption of a relationship-based framework is that the relationship itself (between the helper and the helped; the mother and the baby) is the catalyst for change, particularly in contexts of high adversity. It is proposed that without a relationship-centred approach, knowledge and skills alone have limited power to effect change for mother and baby, particularly when the desired change in the mother is for a responsive relationship with her baby.

The intervention approach specifically values the mother and/or caregiver as a critical force in the child's life and prioritises attending to and addressing the mother or caregiver's independent needs, as a means to ensuring that the mother or caregiver is psychologically available and able to be responsive to the infant.

The CCG is thus initially primarily focused on supporting the mother in order to increase her family support and psychological well-being. Once this capacity is established, the CCG is then able to focus more on the parenting and health education using the Ibhayi Lengane curriculum which educates mothers using very simple empowering activities and tasks to increase knowledge in support of child development and maternal and child health.

In this way the add-on has both a *dual target* - because it aims to improve both the mothers own health along with the child's health and developmental outcomes; and it uses a *temporal approach* - in that it works on the assumption of needing to address family support and mental health first, with parenting, skills training and referrals to follow, as a *pathway to change* in maternal capacity and maternal and child health, as illustrated in Figure 3.

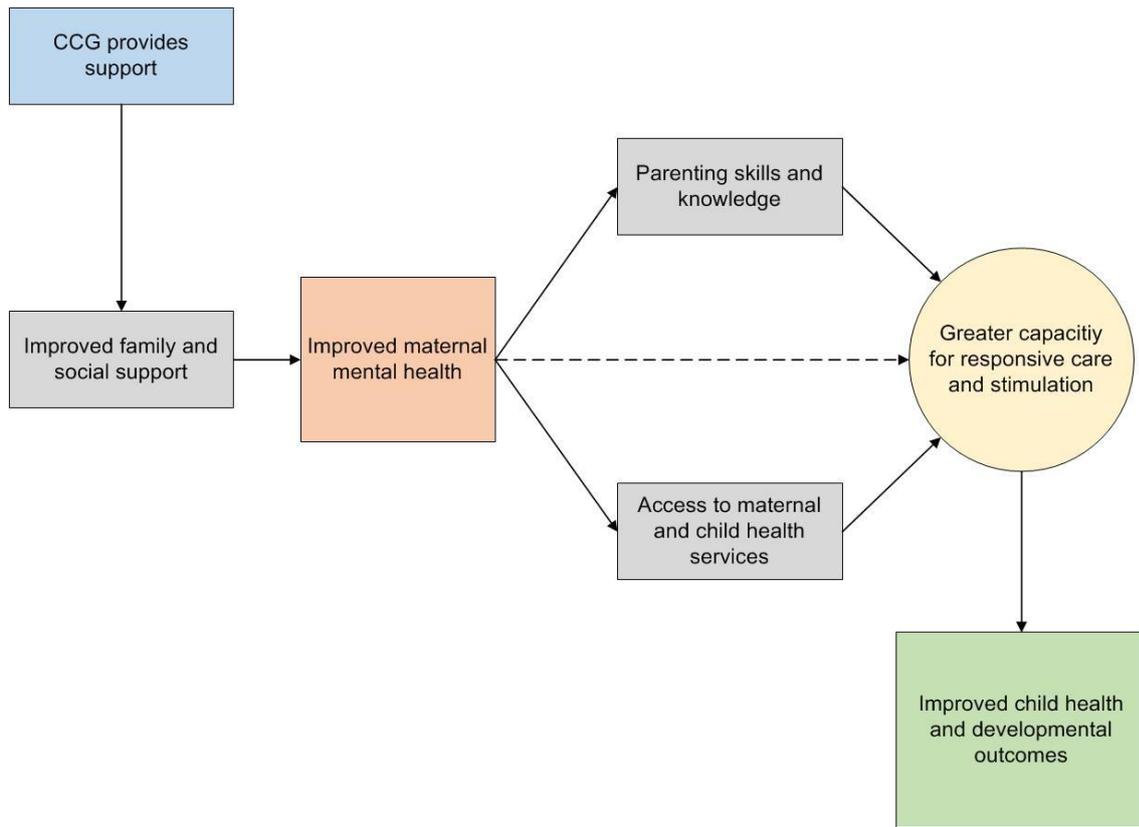


Figure 3 Pathway to increased capacity for responsive parenting health

THE IBHAYI LENGANE INTERVENTION

To achieve this relationship-based approach the intervention targets change in both the CCG and in the mother. The methodology for this change is operationalised through experiential learning and activity. The Ibhayi Lengane add-on includes two components:

- i. Firstly, it provides *training and appropriate supervision for CCGs* to enable and empower them to work from within a relationship-based approach to deliver maternal and child health care, responsive care and stimulation training,
- ii. Secondly, it provides *curriculum for 12 home-based sessions* with activities and materials to support the CCG to deliver programming content in support of the first 1,000 days in a community setting context.

The activities embodied in the curriculum take a specific and novel approach to behaviour change, by embodying change in the CCG, the mother and the child within each activity. Ibhayi Lengane activities thus reflect the behaviour change one wants to achieve, providing the child with an opportunity to reinforce positive parenting behaviour, and allowing the CCG to model the behaviour change towards responsiveness desired in the mother. The activities themselves also act as guidance and fidelity checks for the CCG. In this way, the mother and the CCG become the transformation that is expected through the session activities which are then reinforced through practice and homework, in a positive and empowering way. While the curriculum is structured, the relationship is sensitive and thus allows for flexibility in supporting goals in a variety of familial contexts.

The Ibhayi Lengane curriculum content itself is not particularly innovative, nor is it intended to be; instead it reflects mainstream ECD content which is evidence based. It draws on well validated content, such as the World Health Organization (WHO) Care for Child Development (CCD) presented in a more succinct form, in order to remain low intensity. Where it does innovate is:

- i. By providing content in areas where little content exists as in the case in providing pregnancy support and in dealing with partner and family conflict.

- ii. By providing content through non-didactic activity based learning which can be delivered during home visiting as opposed to centre based activities.
- iii. By incorporating contextually specific and culturally sensitive information, for example addressing cultural myths which are barriers to health and ECD in the South African context.
- iv. By using content developed for the South African context through careful participatory formative work.

The Ibhayi Lengane intervention proposes that the quality and effectiveness of a mother's responsive care for her baby is influenced primarily by her emotional well-being, her skills, confidence and capacities, as well as by the support of those close to her (in most cases her partner and family). This is even more so in families facing many cumulative and concurrent risks that may reduce their capacity to engage in out-of-home activities. Without a supportive relationship between a home visitor and a mother, and mother and family, interventions delivered in the home are unlikely to be effective.

Ibhayi Lengane CCG training component

The training is delivered in two sessions. The first is a specific, short and scalable experiential training (3 days) aimed at providing a CCG with a relationship-based framework from which to provide care and offer support at a community level. The second is an additional training (2 days) covering curriculum specific to the first 1,000 days, with information and materials to support mothers and to guide home visitors. This curriculum includes materials and activities for three structured home visits over four developmental phases: Pregnancy; birth to six months; six to twelve months; and twelve to twenty four months. The initial three day training is a rich experiential training based on the Dlalathathi 'play for communication' training which aims to provide an understanding of the importance of a relationship-based approach and skills relevant to practicing a relationship-based approach. The first training provides a framework by which CCGs can approach their relationships with high risk mothers and begin to address the difficult task of supporting them by focusing on three things:

- i. The potential of the transformative influence of a supportive relationship between the CCG and the mother, for high risk mothers

- ii. The significance of the mothers nurturing relationship with her baby to buffer the negative influence of high risk context
- iii. The simplicity, accessibility and empowering process of play and communication to strengthen relationships between the mother, her infant and her family.

The second training then focuses on the application of this understanding to the content and specific skills needed for each of the sessions, to allow for practise and preparation for home visits through role play, and to consider approaches to managing both family support and health care support in an integrated way.

Ibhayi Lengane curriculum

Each Ibhayi Lengane session has relationship based goals around the caregiver-mother relationship; the mother-baby relationship and the mother-family relationships as illustrated in Figure 4.

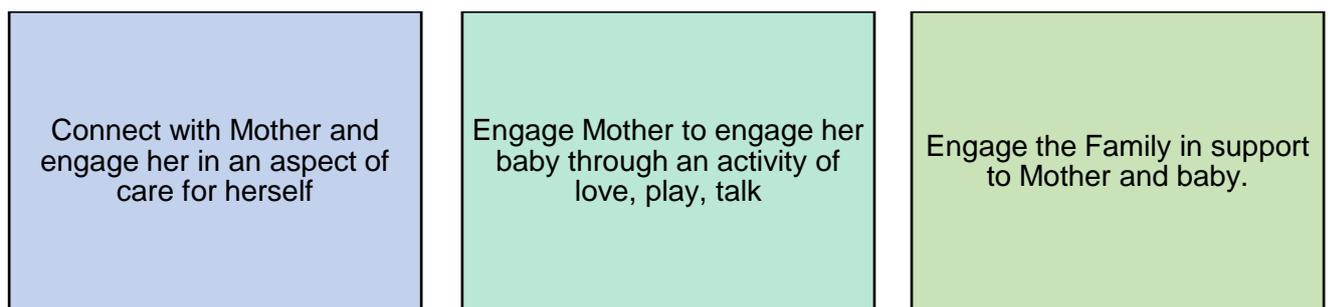


Figure 4 Relationship-based goals for CCGs within each session

As summarised in Figure 5 over the page, the intervention starts in pregnancy and includes 12 sessions over the first 24 months of life. Sessions are delivered at home as part of routine care by lay professional CCGs. The sessions are between 1-2 hours, some are mother focused and others are family focused. The program was designed to include simple, user-friendly materials as part of the curriculum to guide training/facilitation and to support sustaining the activities at home.

	Pregnancy 3 rd trimester	Early Postnatal 0 to 6 months	Late Postnatal 6 to 12 months	Child 1-2 years 12 to 24 months
Session 1 Mother	<ul style="list-style-type: none"> Relationship-building between CCG and Mom Mom identifies a healthy action to strengthen Mom identifies support circles - friends, services, family 	<ul style="list-style-type: none"> Introducing Love, Play, Talk Sharing the story of birth Introducing interactions and 2-way communication between mom and baby Affirm healthy actions to support breastfeeding Enjoying play time with baby Strengthen support from family and household 	<ul style="list-style-type: none"> Mom describes her journey with baby so far Relationship responds to development The importance of play, making a toy Activities for baby on the move, and for small and big muscles Play with toys and everyday safe objects 	<ul style="list-style-type: none"> Relationship responds to development Affirm healthy actions for Mom and baby Discuss parenting and emotions Coping with baby's growing independence Positive parenting The importance of learning through experiences
Session 2 Mother and family	<ul style="list-style-type: none"> Affirm healthy actions for Mom Relationship-building between CCG and family members Introduce warmth, welcome and wisdom Seek ways to strengthen support Family discuss support for mom and baby 	<ul style="list-style-type: none"> Introducing Love, Play, Talk to family (i.e. the people in the home) Establishing a responsive rhythm Introducing the importance of two-way communication between mom and baby and baby and family members 	<ul style="list-style-type: none"> Games and play with family Keeping baby on the move safe Learning through senses – exploring the world at home Encouraging movement Baby's development over time 	<ul style="list-style-type: none"> Baby's development, learning and growth in the family Family learning and limit setting Highlight the importance and adventure of learning Family support for positive parenting To introduce how learning and limit setting go together
Session 3 Mother and baby	<ul style="list-style-type: none"> Relationship with baby begins Mom connects with baby through decorating of baby blanket Relationship-building between mom and home visitor Thinking about ways to cope with overwhelming emotions Thinking about ways to soothe my baby 	<ul style="list-style-type: none"> Sharing joy between mom and baby through Love, Play, Talk Coping with overwhelming emotions Thinking about ways to soothe baby Review of the past six months Baby's development over time (Vroom cards) 	<ul style="list-style-type: none"> Reviewing the first year of baby's life Affirm healthy actions for Mom Seek ways to strengthen support for mom Coping with emotions – mother and baby Setting limits through talking Taking a 'sensory' - Love, Talk, Play – walk outside 	<ul style="list-style-type: none"> Affirming mom in her journey with baby so far Noticing baby's development over time (Vroom cards) Affirming relationship skills learned to be responsive to baby's further growth Recapping everything learned Saying goodbye to mom and baby

Figure 5 Overview of the intervention curriculum

The content of the Ibhayi Lengane intervention is structured around a central metaphor of ‘the baby’s blanket’ which provides a culturally, emotionally, and physically resonant organising concept which runs as a golden thread throughout all sessional content. The metaphor of the blanket captures the support embodied in the CCG support, the mother’s support and protection of the baby, and the family’s support of the mother. The metaphor sets the tone of relationship as warm, embracing and gentle, but also as strong and protective.

The blanket frames the boundaries of the respective roles between mom and home visitor: *‘I (Home Visitor) am your blanket of support; you (mom) are your baby’s blanket of support; your family and your culture is the support for you and your baby’*. The metaphor of the blanket was developed through careful formative work and was selected from a range of content not only because of its simplicity and ability to reflect the central principles of all intervention content from pregnancy to two years postpartum, but also because of its cultural tradition and acceptability.

Using the blanket across sessions and activities, the CCG is able to address several content areas using the same supportive framework. In the pregnancy phase the metaphor is used to illustrate the support and care which the CCG provides for the mother. The blanket is then linked into a family activity in session two which includes the use of the blanket to address issues of conflict in the family. The activity builds on the cultural practice of mothers providing their daughters with a blanket before the baby's arrival, and on family engagement around the naming a child. The blanket provides a concrete focus which supports the family to feel validated in their anger or frustration over an unplanned pregnancy and the burden it places on families, but also elicits positive emotions and cultural responsibilities. In the third session the blanket is used to provide a simple narrative to the mother around how she provides a protective blanket for the child in her womb and to facilitate discussion around how the experience of the mother (stress and worry) and the mother's health behaviour (eating, resting) can affect the fetus in positive or negative ways. The blanket is not only a supportive metaphor; its presence in the home is also a daily reminder of the behaviour change the mother and family need to practice.

Throughout the intervention the blanket narrative is expanded on through the content. For example, the blanket is used to explain the importance of exclusive breastfeeding by presenting this as an extension of the protection the mother provides in the womb to the protection she can offer in the early postpartum: *'During pregnancy you are a blanket for your baby as they are growing in your womb. Your body knows exactly what to do to grow your baby until it is ready to be born. Once your baby has been born, your body continues to be a blanket of support in a different way for your baby. Your breast milk is produced by your body automatically, providing the exact type of sustenance for your baby to grow while they are outside the womb. In this way, breastfeeding extends a blanket of support around your growing infant to protect them'*. Likewise, the metaphor is extended to later stages of development to illustrate the protective nature of immunisation and later to illustrate the child's safety needs as they grow and become more independent of the mother. Formative work found this metaphor and the conceptual framework of Ibhayi Lengane to be highly acceptable to mothers, families and CCGs.

METHODOLOGY

RESEARCH DESIGN

We undertook a pilot study to examine the feasibility and acceptability of the Ibhayi Lengane add-on intervention in one clinic catchment area in the Msunduzi Municipality of KwaZulu-Natal.

Pilot studies are particularly beneficial for the following reasons:

- i. Firstly because they provide valuable information to assess the feasibility, acceptability, resource requirements and cost of the proposed intervention;
- ii. Secondly they provide information on potential adverse effects or unexpected impacts of the intervention;
- iii. Thirdly, pilot data allows for an estimation of effect size (statistical variability) in order to determine an appropriate sample size for a larger evaluation study.

The pilot study included stakeholder consultations with DOH; the training and preparation of CCGs; the implementation of the programme with mothers; and collation of the pre-post evaluations and qualitative data collection with CCGs and mothers; and the costing exercise. The methodological approach for each of these is described below, after the description of the context in which the pilot study was undertaken.

Ethical approval was sort from both the Department of Health and the HSRC (REC 13/22/03/17).

RESEARCH CONTEXT

The KwaZulu-Natal province has the second highest number of births in South Africa (213 992 births in 2015), after Gauteng (273 410 in 2015). Most women living in KwaZulu-Natal face a myriad risks to their health and to their pregnancies. Not only is KwaZulu-Natal at the epicentre of the HIV epidemic³², it also has high rates of unemployment, poverty³³, intimate partner violence³⁴ and maternal mental health problems^{35,36}. This context calls for more decentralised support for mothers during both the antenatal and postnatal periods and also for their children.

It is within this context that HSRC and Dlalanathi embarked on a pilot study to assess the feasibility and acceptability of a relationship-based, early parenting add-on package to support ECD. The study was implemented within The Msunduzi Municipality, the smallest of seven municipalities in the uMgungundlovu District (District Council DC22) of KwaZulu-Natal (See Figure 6). The Municipality covers formal settlement areas with relatively high income along the main transit routes with access to services, as well as poorly serviced areas such as Dambuza, Slangspruit, Sinathingi and Ematharen. There are also outlying rural areas within the municipality such as Slangspruit, Noshezi and Sinathingi which have very limited access to facilities. The Greater Edendale area of the municipality is serviced by 7 health facilities (see Figure 7): Edendale Hospital, the main referral facility, Imbahlenhle Community Health Centre, 2 Primary Health Clinics (Caluza and Nzalabantu), and 3 satellite Primary Health Clinics (Azalea, Sinathingi and Willowfountain). Our programme was implemented with women accessing services from the Caluza Clinic.



Figure 6 Msunduzi Local Municipality and Health Facilities

Caluza Clinic serves as the primary health care facility for the catchment area, which includes residents of both Ward 20: Caluza and Ward 1: Mpumuza (see Figure 6).

The clinic provides HIV and TB-related treatment, care and support services. Caluza clinic has a community oriented primary health care programme that monitors and proactively works towards the improved health and well-being of families in the area through CCGs who are directly linked to this facility.

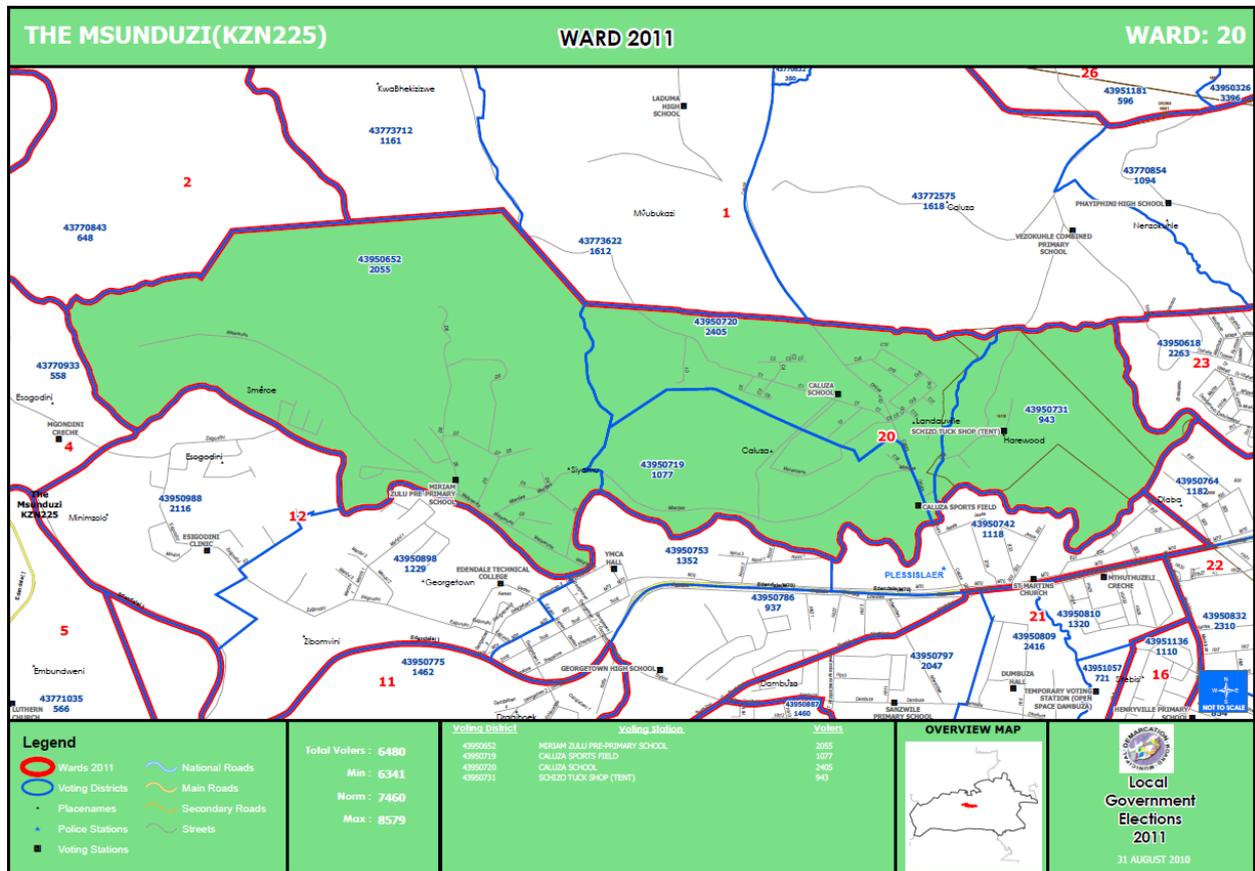


Figure 7 Map of Caluza Ward 20 and part of Mpumuzi Ward 1

STAKEHOLDER CONSULTATION

Success in a larger scale roll-out of Ibhayi Lengane would require substantial integration of services within the DOH – who would ultimately deliver the add-on. Thus, an important aspect of the participant engagement in this project included collecting qualitative data from those delivering or expected to deliver the program.

In undertaking consultation as part of the pilot study the researchers and implementation team attended a number of DOH forums and workshops to present the Ibhayi Lengane add-on and elicit feedback.

Timing of data collection: The meetings occurred prior to, during and after the pilot study.

Participants: The team attended meetings which involved stakeholders at provincial, district and clinic level, as well as attended ECD forums and presentations. They also consulted with a range of non-governmental services and potential implementers and referral sources.

Measurements: The data collection focused on capturing the following three key pieces of participant engagement data:

1. Programme engagement: Understanding stakeholders' views on the programme and what might affect their participation and engagement, this included data on salience, relevance and interest, or lack thereof.
2. Content of the programme: Whether the focus areas of Ibhayi Lengane were valuable, whether the materials seemed usable, whether the dose (number of sessions) was appropriate and manageable.
3. Integration of the programme: What the barriers to implementation might be, what facilitators needed to address to ensure success, what delivery approach might be most appropriate (either a full integration add-on for all CCGs and all families, or add-on for select cadres of CCGs for targeting high risk families only)

Data collection: The data collected at these meetings and presentations were captured in the form of minutes and notes kept by the Dlanathi and HSRC team. In discussion with DOH audio recording was not considered appropriate and might have introduced resistance to speak openly or may have introduced social

desirability bias. It was agreed that researchers could capture field notes on the content of the meetings in the focal areas of the research as outlined above, but that content of meetings would be anonymised, and where necessary the researchers could report feedback associated with particular roles (i.e. CCG versus nurse) but that individual names would not be reported.

In order to ensure all main points were captured with as much accuracy as possible - two team members attended all meetings, with one team member focused on note taking while the other presented and facilitated the discussion. Following the meeting, notes were circulated and the facilitator assisted with clarifications and additional information.

PILOT IMPLEMENTATION OF IBHAYI LENGANE

The pilot study was operationalised in two parts, the first involved the training component with CCGs and the second the implementation of the programme by CCGs to a sample of mothers in the research community. Methodology used to collect data for both are outlined below.

Training and CCG supervision

At the start of the pilot study we conducted training with DOH CCGs in relationship-based approaches and in the Ibhayi Lengane curriculum in order to test the feasibility, acceptability and efficiency of the training approach. The data collected in this stage of the research included pre- and post-evaluations of the training, supervision notes and case studies, and several feedback workshops with CCGs.

Timing of data collection: The training component was implemented over a period of one month. The pre-post evaluation was collected at the start and end of the training of CCGs; supervision meetings were conducted on a monthly basis during implementation while the feedback workshop was held at the end of implementation. Follow up telephonic interviews were conducted with all participating CCGs several months post-pilot.

Participants: The total number of CCGs working in the selected geographic area, which was linked to two primary health care clinics, was 20. These 20 CCGs were identified for participation by the DOH and were given permission to participate. No

selection criteria were applied to the CCGs except that they were currently working in the identified geographical area. All 20 CCGs were requested to participate in a meeting to learn about the training and program. The attendees of this meeting were then invited to participate in the training. While DOH encouraged CCG participation there was no obligation to participate, instead the CCGs were given the choice to participate in training and implementation. Only CCGs who completed the full training programme were included in the implementation of the pilot with mothers. The post-implementation workshop included all the CCGs who had implemented the programme.

Measurement: As with the data collected as part of the stakeholder consultation, the data collection focused on capturing three key pieces of participant engagement data from CCGs perspectives:

1. Programme engagement: Understanding the CCGs' perspectives on the programme and what factors might affect their participation and engagement. This included data on salience, relevance and interest, or lack thereof.
2. Content of the programme: Whether the focus areas of Ibhayi Lengane were valuable, whether the materials seemed usable, whether the dose (number of sessions) was appropriate and manageable.
3. Integration of the programme: What the barriers to implementation might be, what facilitators needed to address to ensure success, what delivery approach might be most appropriate (either a full integration add-on for all CCGs and all families or, an add-on for select cadres of CCGs for targeting high risk families only,) whether the add-on was feasible in terms of other commitments and whether supervision structures provided were adequate.

Data collected: This included a training survey and trainer reports and reflections, observations of supervision, and qualitative feedback collected from CCGs in a qualitative workshop.

The pre-post evaluation included a short survey to establish knowledge before and after the training. The survey covered knowledge on the first 1,000 days, the importance of mother-child interaction, and the importance of support for the mother and the child from family, CCGs, clinic and the community at large. All evaluations

were administered solely by the research team and were conducted independent of the trainer.

The trainers provided a daily sheet of reflections on the process of training identifying what had gone well and what had not gone well and capturing any adjustments made to the content or process of the training in response to training challenges.

Data was also collected at the CCGs' monthly group supervision session, which lasted on average 2 hours. Here trainers responded to feedback from implementation work and addressed any concerns raised by the CCGs. The supervision sessions were conducted in a group, and in order to collect data while maintaining the integrity of the supervision process, an observer from the Dlanathi team completed field notes using participant observation methodology. The same observer was present at all supervision sessions. Supervision notes were anonymised to protect confidentiality.

Finally, at the end of implementation a qualitative workshop was held and the workshop was audio recorded and transcriptions were analysed by the research team. Two members of the research team completed the initial analysis to establish categories and codes amongst the data linked to the workshop guide. These two researchers had not taken part in any of the other fieldwork activities and were thus independent of the implementation team. Thereafter these categories were verified and discussed in a data analysis workshop with the research and implementation leads. Once complete the results, along with selected example quotations, were presented to the implementation team for feedback and discussion to support interpretation. Individual follow-up interviews were conducted with a random selection of 50% of CCGs 6 months post-intervention. This final interview was restricted to 50% of CCGs given time constraints related to the close out of the project.

Implementation of pilot intervention

On completion of this training, the trained CCGs implemented Ibhayi Lengane. Given the resource and time constraints the four stages of the intervention could not be tested consecutively (as this would require a 24 month follow up period) and instead were tested concurrently with a group of high risk families. Data was collected

directly from participating mothers through surveys and a workshop. Direct observation of content delivery was observed for all CCGs by an independent observer and CCG reports on mother's participation, understanding and response to the interventions were also collected.

Timing of data collection: The implementation was completed over a period of four months. Data from participating mothers was collected at the start and end of their participation. Data from participating CCGs were collected during implementation (at monthly supervision meetings) and observations were completed linked to when visits were occurring. The workshop with participating mothers was completed at the end of implementation.

Participation: Each CCG aimed to recruit 4 mothers, one from each of four groups (either pregnancy; post-natal 0-6; postnatal 6-12; postnatal 12-24). Each mother received the 3 sessions suited to her stage of pregnancy or motherhood and each CCG delivered all 12 sessions across 4 different mothers within a limited time period.

Measurements: Each mother then completed a pre-post evaluation which included three psychometric measures, including:

Edinburgh Postnatal Depression Scale (EPDS) – maternal depression symptoms were measured using this well validated screening scale³⁷. This screening tool has been validated for use in South Africa and is used widely amongst both clinical and population based sample, in both the antenatal and postnatal periods. The measure is scored on a severity scale (0-3) which is totalled for a maximum score of 30. A score ≥ 13 is considered the gold standard cut-off for probable depression³⁸. We analysed this data using both mean scores per group, as well as individual participant's scores in order to understand trends in depressive symptoms.

Parenting Stress Index Short Form (PSI-36) - Parenting stress was measured using PSI-36 consisting of 36 questions which are organised into 3 different scales with 12 questions each. These include the parental distress, the parent-child relationship, and the difficult child scale. The scales can be analysed individually or together. We used the mean scores from pre- and post-intervention to identify changes within the different domains of parenting stress.

McMaster Family Assessment Device (FAD) - Aspects of family relationships were measured using the FAD. It is a 60-item instrument, and is made up of seven scales which measure Problem Solving, Communication, Roles, Affective Responsiveness, Affective Involvement, Behaviour Control and General Functioning³⁹. In the analysis of this measure, we used both continuous scores, and recommended clinical cut-offs in order to examine the patterns and changes in family relationships, on an individual level and within the 4 sub-groups within the intervention.

Data collection: The implementation team directly observed at least one of the three sessions of all four components with each of the CCG to establish competency and fidelity to the intervention content. Data included participant observation notes and the completion of a fidelity checklist. Data was also collected as part of the supervision of CCGs as described above, at monthly meetings. All mothers completed the evaluation before starting to receive sessions and all post intervention session evaluations were completed only when all 3 sessions from each component had been completed, and within two weeks of the last of the three sessions being completed.

As with the CCGs, a qualitative workshop was held at the end of implementation using the same methodology as the CCG workshop. The workshop was audio recorded and transcriptions were analysed by the research team. Two members of the research team completed the initial analysis to establish categories and codes amongst the data linked to the workshop guide. These two researchers had not taken part in any of the other fieldwork activities and were thus independent of the implementation team. Thereafter these categories were verified and discussed in a data analysis workshop with the research and implementation leads. Once complete the results along with selected example quotations were presented to the implementation team for feedback and discussion to support interpretation.

COMPLETION OF A COSTING EXERCISE

We conducted an iterative cost analysis of the potential scale up of Ibhayi Lengane scale-up in Msunduzi Local Municipality. The key component to be costed was the provision of training and intervention materials, given that DOH provides human resources. In terms of the training cost we examined approaches which used expert trainers for all training versus a train-the-trainer approach.

Thereafter, two approaches to delivery were modelled – one approach used a *generalist* strategy where Ibhayi Lengane is provided to all families by all CCGs, and the other a *specialist* approach whereby Ibhayi Lengane is provided to only high risk families by a selection of CCGs per ward.

Timing of data collection: The costing data collection was concurrent to implementation of the intervention as part of stakeholder consultations. Costing inputs were finalised post-intervention with feedback on implementation available to inform this. The cost of Ibhayi Lengane training and materials for roll-out were collected from Dlalanathi and local service providers (printers and other suppliers) at the end of intervention, taking into consideration operational changes that occurred in the pilot.

Participants: The Head of Paediatrics and Child Health in KwaZulu-Natal DOH and the KwaZulu-Natal DOH Coordinator for CCGs were selected to provide information on the DOH CCG program in KwaZulu-Natal. The District Heads of Mental Health and Maternal and Child Health were selected to be part of this exercise based on their knowledge of the number of CCGs involved in their portfolios and to also provide a work process – in terms of the hierarchy and responsibilities. The primary health care (PHC) outreach team were selected to be part of the costing exercise because they monitor and supervise CCGs. The CCGs were selected to provide a clear understanding of the needs, requirements and the exact costs, in monetary terms as well as amount of time spent conducting the intervention.

Measurement: In conducting the costing exercise, a number of factors were taken into consideration. Because the add-on would aim to target mothers and children at high risk, risk was defined to cover three highly prevalent variables which are common in pregnancy and the postnatal and are known to affect health outcomes of mothers and children. These included:

- HIV infection: Estimated antenatal HIV prevalence of 40% in the province.
- Domestic violence: Estimated prevalence of 36% in the province.
- Maternal depression: Estimated prevalence ranging from 18% to 47% for antenatal depression and from 32% to 35% for postnatal depression nationally.

Prevalence estimates were taken from published reports. This is based on recent statistics showing that 21% of ever-partnered women 18 years and older had ever experienced physical violence by a partner⁴⁰, and maternal depression in this vulnerable population ranges from 30 to 45% depending on the type of measurement used⁴¹⁻⁴⁴. Once the criteria for risk were defined, a mean prevalence was calculated, and a high risk population of approximately 30% of the general population was established. In this exercise the general expected population was estimated at a ward level by reviewing the number of pregnancies and live births occurring annually for the past three years.

Information from the DOH's 2011 provincial guidelines for the implementation of the three streams of PHC re-engineering was used.

The cost of materials included in the models includes the estimated costs of production, as well as district level adaptation and translation.

Data collected: In the pre-pilot phase of the project discussions with the Head of Paediatrics and Child Health in KwaZulu-Natal DOH and the KwaZulu-Natal DOH Coordinator for CCGs were undertaken, focusing on the different levels of training amongst CCGs and numbers of CCGs in a district or province. Discussions on how the scale-up of Ibhayi Lengane might occur were also conducted during these meetings. The meetings with District Heads of Mental and Maternal and Child Health; and interviews with the PHC outreach team and CCGs also collected information on the roles of CCGs, their reporting structure (work process) and the average number of families they service, in order to get an estimate of the resources required to implement Ibhayi Lengane in communities. Population statistics for models were sourced from STATS SA.

RESULTS

STAKEHOLDER CONSULTATIONS

Table 1 over the page provides a summary of the meetings completed and the main outcomes of these meetings in terms of the engagement, content and integration of the programme.

Across all stakeholders and all levels of DOH from provincial leadership to the CCG's acceptability of the programme was high, with strong support for the need for such services in current health services. There was a high level of concordance among all stakeholders across meetings that DOH CCGs were the best human resources to effectively deliver the programme. The content was considered highly relevant, low intensity and user friendly for CCGs, however in consultation with DOH it was recognised that the programme needed to be augmented in some key areas to add content which aligned to health messages in DOH in the areas of nutrition (including breastfeeding) and immunisation. This was easily integrated into the package that was tested in the pilot.

Prior to implementation there were substantial concerns about logistical and time barriers given demands on CCGs and an uncertainty about whether taking a generalist (train all CCG to deliver to all mothers) or add-on approach (train some CCG for only high risk mothers) or a mixed approach (train all CCG but deliver to only high risk mothers) would be best. In terms of integration approaches, district leadership were inclined to support a generalist or mixed approach for simplicity of implementation, despite acknowledging that this would likely be resource intensive, while provincial leadership and the CCGs agreed that an add-on for high risk mothers was feasible and most appropriate, while acknowledging it might require adjustments to CCG management systems and approaches.

The reticence towards a specialist add-on approach by district appeared to reflect the sheer demand on implementation resources at a district level, which made it challenging for managers and coordinators to conceptualise how such an add-on process could be adequately managed and monitored. Hence the inclination towards a generalist strategy was more centrally to keep the system simple, rather than to keep the system cost and resource effective. This potentially reflected a need for

capacity building to strengthen district management capacity to conceptualise or gain consensus on *which cadres* of CCGs would be trained to support *which families* if a high risk specialist add-on model was adopted.

To address this, the scalable programme package should include some guidance for selection and recruitment of CCGs and set clear guidance for the selection of either a generalist or a specialist approach, so that implementation plans could be more easily structured and be responsive to district needs and systems which are not entirely uniform. If a specialist approach were taken, systems for work sharing and referral amongst those providing Ibhayi Lengane, and those not, would need to be established and monitored. Some discussion about the potential of providing electronic resources and mobile platforms to support such an implementation structure were positively viewed by DOH. Stakeholders acknowledged that a specialist approach had particular benefits over a generalist one in the case of the Ibhayi Lengane add-on relative to other health content because the content is driven to address high risk families, and the additional burden of delivering such a specialist service to all families was likely unwarranted and unfeasible.

Following the successful implementation of the pilot, both district and provincial leadership were interested in exploring further scale up and it was acknowledged that some of the process variables in the delivery of Ibhayi Lengane (e.g. the approach to training, scheduling of visits, supervision) might also be useful more generally since CCGs received too little support and supervision in these areas.

At the close of the project during feedback meetings on results, the District DOH management expressed an interest in partnering with Dlananathi to further test the intervention at a larger scale with a larger geographical area using DOH CCGs in the district. It was felt that this was needed particularly to establish and test the systems for selection, training and supervision of CCGs, to test implementation of generalist versus specialist approaches and to improve the ease with which CCGs could allocate families for visits and make appropriate referrals. While DOH could provide the CCG workforce as a resource – additional resources would be needed to provide for training, supervision, materials and the research component of the evaluation.

Table 1 Summary of DOH consultation by key categories

Date	Purpose and participation	Summary of outcomes
<p>May 2016 <i>Round table discussion on general acceptability and feasibility within DOH structures and willingness to partner in the pilot study</i></p>	<p>Provincial DOH Project specific meeting with participation from both tertiary and primary health care representatives.</p>	<p><u>Programme engagement:</u> Programme is relevant and salient to our population. <u>Content:</u> Training will be key, possibility of adding health information training to this and a need to link outcomes to maternal and infant morbidity and mortality. <u>Integration of services:</u> As there is only 1 cadre of community health workers, the programme should be implemented as an add-on. Home visitors are currently not adequately supervised by DOH. Concerns raised about where it will be delivered – identified that there is a gap in home visiting services.</p>
<p>July 2016 <i>Presentation of full proposal and Ibhayi Lengane materials to district leadership structures</i></p>	<p>District DOH Routine district management meeting with participation from both mental health and primary health care coordinators</p>	<p><u>Programme engagement:</u> Programme valuable and unique in that it restores connection between families. Impressed that programme aims to capacitate CCGs so that they can engage mothers in health services and care. <u>Content:</u> Materials and the blanket tool will be useful in family conflict identification and resolution. Mental health content is important and not possible to deliver through routine mental health services which were centralised. <u>Integration of services:</u> DOH Mental Health Programme does not have direct contact with CCGs in terms of intervention and do not have adequate resources in reaching into the community through home visiting, in this way the programme has the advantage of integrating both primary health and mental health. Outlining of the permission process – contact the District Head of DOH for site permission.</p>
<p>August 2016 <i>3 separate meetings to operationalise the pilot study and finalise site selection and implementation protocol</i></p>	<p>District DOH Ad hoc project specific planning meetings - participation of managers and</p>	<p><u>Programme engagement:</u> Positive feedback on the relevance and need for the programme in all consultations. Focus is highly salient and relevant and currently very poorly addressed in primary health care. Particular preference for preventive approaches. <u>Content:</u> Materials and content highly acceptable, and intensity feasible at scale. Importance of linkage in to other programmes for the aspects which the programme does not address</p>

	coordinators of CCGs but not CCG themselves)	<p>(e.g. other health services such as HIV services or programmes outside health such as ECD or Social Welfare). Could be used to strengthen breastfeeding and immunisation practises, in particular could reach and reduce barrier to these at a community level and therefore this information will be added to the curriculum materials to strengthen them. Given that CCG already have basic maternal and child health training, it is helpful that this programme is so specific and complimentary. There is an understanding that added this to CCG home visiting could maximise the opportunity at the home.</p> <p><u>Integration of services:</u> Discussion of intervention sites – some CCGs employed by DSD and others by DOH. However consensus that health CCG’s were the best placed to deliver content. Caluza Clinic chosen as CCGs in this ward are DOH employed and had been trained in maternal and child health.</p>
<p>October 2016 <i>District meeting to review protocol and formalise request for approval to proceed</i></p>	<p>District DOH Routine district management meeting participation by all district leadership</p>	<p><u>Programme engagement:</u> Positive feedback on the relevance and need for the programme. <u>Content:</u> Sessions are well aligned to critical DOH contact periods. <u>Integration of services:</u> Agreement that DOH is key point of contact for maternal and child services, other departments (DSD) will be involved through referrals when applicable.</p>
<p>December 2016 <i>District launch: Orientation to Ibhayi Lengane and invitation to participate in the pilot study</i></p>	<p>District DOH Ad hoc meeting by invitation of district to 20 CCG and their coordinator</p>	<p><u>Programme engagement:</u> “High risk” women for whom the programme will be particularly salient were identified – foreigners, pregnant teenagers, HIV positive women, those with substance abuse problems and child headed households. Concerns were raised about time and burden. <u>Content:</u> CCG’s were positive about the content, very user friendly, CCG found the branding attractive and felt it would be helpful to encourage use. <u>Integration of services:</u> Assistance is needed in scheduling this into routine services. Specific help is needed to ensure referrals are managed. Important to acknowledge the limited ‘power’ CCG have in the system in order to advocate for patients. This particularly challenging in emergency situation and when referrals need to occur across departments.</p>

<p>March 2016 <i>Implementation launch: allocation of families and provision of intervention tools</i></p>	<p>District/Ward DOH Ward coordinators and CCGs to plan implementation post training</p>	<p><u>Programme engagement:</u> All CCG able to readily identify high risk women for each of the four components <u>Content:</u> Additional content on breastfeeding and VROOM cards are very user friendly. CCG felt confident about content post training. <u>Integration of services:</u> Scheduling for pregnancy needs to be different to other components and sessions need to occur within a shorter period of time, perhaps weekly instead of monthly as it is in other stages.</p>
<p>August 2017 <i>First feedback post intervention on operational aspects of delivery</i></p>	<p>Provincial/District DOH Routine district meeting with provincial representative in attendance</p>	<p><u>Programme engagement:</u> The programme is easy to relate to for mothers and was acceptable and something that families felt is important. It is something that the community wants and that CCG enjoyed. <u>Content:</u> The value in the programme is that it supports relationships and communication between parents, their children and families and strengthens the relationship between CCG and families. The blanket and the images are useful in portraying the messages of the intervention and help families understand the CCG role in the community and also to see their own responsibilities. <u>Integration of services:</u> There is a need for Ibhayi Lengane to be scaled up across the whole District but that operational planning would be needed. This planning could only take place if the programme showed some efficiency on the psychological measures.</p>
<p>25 October 2017 <i>Feedback on programme content and implementation to a broader set of invested stakeholders</i></p>	<p>Provincial and district DOH, DSD and DOE Routine ECD forum meeting provided opportunity to more broadly disseminate</p>	<p><u>Programme engagement:</u> Interest shown in scaling up the programme to different districts. Strongly complementary of other programmes such as Phila Mtwana but important in its focus on mothers and caregivers as other programmes were generally child centric and health focused. <u>Content:</u> Participants at this meeting valued the curriculum and materials. ECD centre participants reiterated the importance of providing this in the early years (infancy) so that stimulation of children started earlier before ECD centres. Recognition that parents need practical simple guidance and the importance of engaging parents was highlighted. <u>Integration of services:</u> Discussion on the importance of having a community asset</p>

		<p>mapping process at the start of implementation to support CCG to have referral sources, and suggestion that ECD centres and ECD forum meetings could become part of the operational structure which supervises and support the CCGs in this work. Important that ECD forums include stakeholders from health and DSD and NGO and intended to have good relationships with community leaders so this would be helpful to CCGs.</p>
<p>December 2017 <i>Feedback on programme implementation and results to the district management team</i></p>	<p>District DOH Presentation at routine district meeting and an additional ad hoc meeting with district manager to report the results of the intervention</p>	<p><u>Programme engagement:</u> Recognition that the programme is a success and clearly meets an important need in the community and fills an important gap in health services</p> <p><u>Content:</u> Encouraging that low intensity and relatively simple support can have a substantial effect for mothers. Important to acknowledge that relationship based approaches lead to greater utilisation of services and more understanding of healthy behaviours by mothers which can have a strong preventative effect.</p> <p><u>Integration of services:</u> Acknowledgement that add-on approach has particular benefits; however concerns still exist in how you would manage that process at scale since all CCG were supposed to cover all things in their households. More implementation science would be required to develop this new approach for high risk families only at scale.</p>

PILOT STUDY PARTICIPANTS

Figure 8 provides a consort for the sample of participating CCGs and the participating mothers linked to each of them in the pilot study.

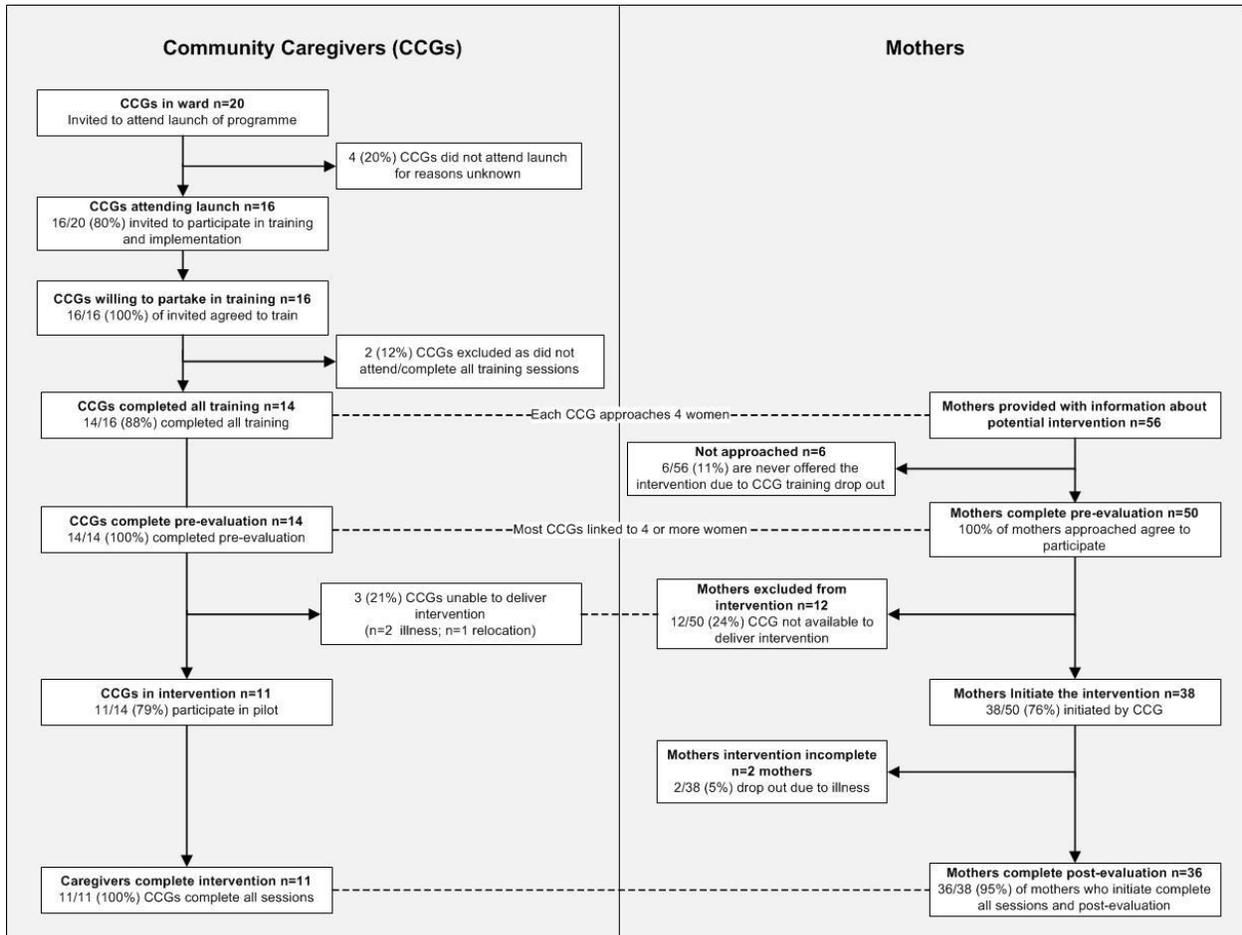


Figure 8 Consort flow-diagram to show recruitment of CCGs and mothers

Of the pool of 20 CCGs based in the geographical area who were invited to attend an orientation meeting, high numbers (16/20 or 80%) attended the orientation meeting. While all 16 expressed an interest in being trained only 14 of those were able to attend all the required training sessions in order to be accredited to deliver the Ibhayi Lengane add-on as part of the pilot.

Hence, from the overall pool of available CCGs, 70% (14/20) were recruited and trained all the way through to accreditation. Importantly, amongst CCGs who were orientated to the project, interest in training was high and retention in training was high once it began

(88% completion rate). This would suggest that if CCGs were targeted for training (in either a specialist or a generalist approach) a recruitment/training dropout rate of at least 10% and potentially up to 30% should be expected from recruitment to accreditation.

Importantly in the implementation of this pilot study, CCGs were supported to recruit and deliver the intervention in a specialist approach only – in other words the pilot study focused on CCGs recruiting high risk families in their catchment area, rather than delivery to all families, given time and resources available. Results show that CCGs were able to recruit and retain families, suggesting that it is feasible for a CCG to identify high risk families (using specific criteria) and engage them in the intervention. Retention of mothers in each component (Pregnancy; 0-6; 6-12; 12-24) was unproblematic and there were no participant refusals, suggesting the program was acceptable for both CCGs and mothers alike.

The highest risk to retention once training was completed and families were initiated related to illness and capacity to participate, where either the CCG or the mothers became ill. Given the likely burden of illness and other risk factors in heavily burdened communities this should be expected, and will likely affect at least 10-15% of CCGs and participants. As compared to the short timeframe of the pilot study, at scale CCGs and mothers would have the opportunity to continue the program once illness and other barriers are resolved. It is important that implementation guidance should be provided for managing situations where CCGs become ill in the course of delivering the programme, to ensure continuing support to mothers who have started the intervention but need to pause participation on account of illnesses or hospitalisations.

Importantly, among the 50% of CCGs who were approached for follow-up interviews 4-6 months post intervention, all (100%) reported that they had continued to see the participants after the pilot was completed and had delivered components which participants had not yet received as part of the intervention. That CCGs continued to use the intervention in their daily practice, despite the research project being over, speaks volumes in favour of its salience and acceptability, at least in this sample.

OUTCOMES OF THE IBHAYI LENGANE TRAINING INTERVENTION

Training was conducted from 25-27 January 2017 (first training) and from 9-10 February 2017 (second training).

CCG knowledge and attitudes prior to training

Of concern, at baseline the assessment of CCG knowledge showed that almost all the CCGs could not articulate a clear understanding of the importance of mother-child interaction in the first 1,000 days of life. This is a concern since all CCGs in the group had completed the DOH maternal and child health training module. This suggests that potentially, training and support in the area of the first 1,000 days may reflect a common need amongst the CCG workforce.

The pre-training surveys also highlighted many other challenges faced by CCGs when conducting home visits in their community. This was exasperated by CCGs working in the same community where they lived – meaning that they themselves were facing similar realities to the families they serve. While this could increase empathy, it also meant that CCGs often felt overwhelmed and powerless to affect change within very high risk, high burdened families. Many CCGs at baseline reported that often these very high risk households would be avoided during their community work because they as CCGs would not know what to do in the face of such adversity, and therefore felt it was better not to go and make false promises or give false hope.

Most CCGs reported feeling that the mothers in their community were not doing enough to provide care and support for their children. CCGs felt negative towards mothers and did not view themselves as a support system for mothers, but rather as a lifeline for the child. CCGs said things like *“Mothers don’t listen” “Mothers don’t care”* or *“Mothers are not interested to learn from us”*. Adding to this, many CCGs said they did not feel welcome in families, and therefore expected that intervention content might be viewed badly. One CCG stated *“Families don’t accept us; how am I going to ask the family to*

play?” and another added, “Do you think they will do these things, how are we going to be allowed to be in the home to do these things?”

CCG knowledge and attitudes post training

In the post-training surveys CCGs responded more positively to their training and expressed more confidence in their ability to implement the programme and to respond to the needs of their community. The comments post-training suggested that the support and encouragement trainers had provided (in the face of CCG resistance and scepticism) was an important factor in the changing of attitudes post training. Many CCGs cited the care and consideration with which the trainers responded to their concerns and frustrations as central to their acceptance and enjoyment of the training process. This highlights the importance of the experience and expertise required by the trainer who implements the training as part of the ‘recipe’ for success. This is an important consideration in how a train-the-trainer model is developed to ensure a high standard of training is maintained through the cascades of training. Another success was that post-training survey results also highlighted significant improvement in CCGs’ understanding of the importance of the parent-child bond in the earliest stages of life and in their knowledge of the importance of the first 1,000 days.

In examining how memorable and relatable the content of the intervention was, post-training surveys suggest that CCGs had retained knowledge of the Ibhayi Lengane content and that CCGs overwhelmingly endorsed the intervention as valuable, as something they were looking forward to, and something which they felt enabled to deliver. Importantly, there was also a marked shift in the expressed empathy for mothers by most CCGs, with a shift from seeing the mother as a problem, to seeing the mother as a person who needed support and who had the potential to be a good mother in spite of difficult circumstances. There was also evidence that CCGs acknowledged the value of not focusing on the child alone and could see the value in supporting both the mother and her family to provide more consistent care and support for the child than they themselves could provide on infrequent visits to the home.

Lessons learnt in the training process

The training notes and reflections suggested that the initial training process itself was fraught with difficulties. While it was agreed that DOH would provide a training venue, the trainers had discovered immediately prior to training that the venue DOH provided was not adequate for training. They also discovered that no transport had been allocated to CCGs even though the venue was a substantial distance from the area in which CCGs worked and it was not feasible to walk to. The training team quickly intervened to find a more suitable venue, which had adequate facilities and was more accessible for CCGs, and also assisted with CCGs' transportation needs.

Training reflections and notes suggested that this lack of attentiveness towards the minimum training facilities required (by the DOH organisers) had conveyed a lack of respect to the CCGs. This seemed to be a common experience for the CCGs and had set a particularly negative tone to the training before it had even begun. Trainers felt that this group of CCGs was quite empowered, in that it emerged that in the previous year the group had gone on strike to protest the lack of provision of personal protective equipment such as TB masks and gloves, and also for non-payment of stipends. It was clear that they did not feel valued or appreciated for the heavy burden of responsibility placed on them and any show of disrespect elicited a strong response which could destabilise efforts to offer training and support.

In reflecting on this issue, trainers raised the caution that this particular challenge may be exasperated in groups of CCGs who were not as empowered as this group, and could lead to CCGs participating - but passively resisting the programme and not finding the training experience a supportive one. Trainers reported that a large part of the first day of training was spent debriefing the CCGs and helping them to feel supported and respected in the training process. The trainers recognised that specific time should likely be given on the first day of training in order to understand the perceptions of CCGs with regards to their role within the DOH, and to work through concerns about the addition of this intervention to their workload. Because the CCGs in this programme felt particularly unsupported by the DOH in their own roles and function, this needed to be addressed in order to ensure that they were receptive to training. Equally it may be helpful for the first

day of training to include a DOH line manager or supervisor so that concerns and challenges could be appropriately addressed in other forums thereafter. Importantly this regard, training notes and reflections indicated that the bulk of the frustration and resistance of CCG in the initial training sessions was not with the training process itself, or the content, but rather with their role and function, in particular the large expectations placed on them by community members and the concurrent lack of support from DOH.

The trainers reported that once the CCGs were provided space to report their frustrations there was a substantial improvement and openness to the training. However, having done all these preparatory steps, there was still strong resistance from the CCGs to the anticipated challenges of implementation at the end of the first training, with many CCGs lamenting *“In theory this should work, but the reality on the ground is different.”* Trainers accepted that this resistance is a healthy response to real change, and an indicator that participants were actively engaging, as opposed to passively accepting what is said to them or expected of them in the training situations, with little intention to make any real changes.

Trainers made some recommendations on common barriers faced by CCGs within DOH structures which would need to be addressed within the broader system if add-on interventions like Ibhayi Lengane were to be successful. One of the most salient challenges reported by CCGs was the absence of a platform for CCGs to contact anybody in DOH for supervision or advice in high risk or emergencies situations. The burden of this responsibility therefore falls on CCGs alone while their ability to deal with the situation is constrained by their limited training and the limited resources made available to them. This leads CCGs to feel isolated, helpless and overwhelmed. There was also little awareness by CCGs of other supports which might be available within the community. Hence, an important part of the training content might need to include a mapping exercise to map services available in a particular community – not only health services, but also CBOs and NGOs such as Life Line. CCGs also found it particularly challenging that it was very difficult to follow up on referrals they had made, especially when families were asking for feedback, while they had no way to know whether or not the case had been successfully picked up by the appropriate individual. This situation

was particularly difficult when the referral involved cross department referral, i.e. from DOH to DSD. Importantly, all of the issues raised by CCGs reflect a strong investment in their care for families in their communities which would suggest that not responding to these practical requests would result in substantial missed opportunities in utilising the CCG as a community asset within the health system.

In attempting to mitigate the resistance to training and implementation expressed during the initial training, the trainers introduced into the second training a peer mentorship session where an experienced implementer from an NGO, who had previously delivered the Ibhayi Lengane intervention (at Ethembeni) as part of the first field test in the formative work, was invited to join a session in order to share experiences with CCGs peer-to-peer. One of the lead implementers, (Thunyiwe Sokhela) also brought along a mother who had participated in the intervention. Trainers reported that this was a very successful approach to overcoming initial concerns and resistance. Both spoke very powerfully to the CCGs about their personal experiences of engaging with Ibhayi Lengane, sharing examples of their success and their failures and speaking to the overall value of the intervention and how it had changed their approach, and the way in which they engaged in a helping relationship in their community. This was an important activity to help CCGs grow in their confidence of how this intervention could work in practice. After the second training, CCGs reported feeling confident that they had the tools and support needed to implement Ibhayi Lengane in their community.

Fidelity and supervision of the intervention

Supervision sessions were conducted on a monthly basis and were important as trainers were able to respond to any problems encountered by CCGs while in the field, and give additional input on salient issues as they arose. Feedback from both trainers and CCGs on supervision sessions was that the supervision was important to building positive working relationships and in building the CCGs' confidence over time. Overall, CCGs reported far more support and less frustration in their role as a consequence of the ongoing support and guidance.

Fidelity observations found that all CCGs were delivering the intervention with high fidelity to content, all CCGs scored >85% on fidelity checks.

OUTCOMES OF IBHAYI LENGANE IMPLEMENTATION

The measurements administered as part of the pre-post evaluation of participating mothers had two central objectives.

- i. Firstly, they aimed to assess the suitability of three measures (depression, parenting stress and family relationships) for use as outcome measures of the intervention in a larger intervention.
- ii. Secondly, they aimed to assess change in scores pre- and post-intervention in order to establish ceiling and change effects, to assist with sample size calculations and to determine if the intervention change was in the direction expected, and to assess whether the outcomes measured indicated preliminary efficiency of the intervention to impact on the desired outcomes

Each of these is addressed in turn in this section of the results. Of mothers completing the post intervention assessment n=8 were in the pregnancy group; n=11 were in the 0-6 months group; n=8 were in the 6-12 month group and n=9 were in the 12-24 month group.

Piloting of measures of depression, parenting stress and family relationships.

All three measures were found to be suitable for data collection in the context of this pilot study. Administration time for all three measures ranged between 20 and 30 minutes. Data collectors reported the measures to be user-friendly and understandable to mothers, and that available translated measures did not create any difficulties in the field.

We assessed the reliability of the measures using Cronbach alpha (α) tests. Cronbach's alpha is a measure of internal consistency, that is, it measures how closely related a set of items on a scale are to each other and to one another as a group. This is an indicator that the scale as a whole measures a single construct, and that items have consistent relationships to each other across participants who complete it. High reliability suggests

that the measure operates as it intends to, supporting its use as a standalone measure for the construct measured (i.e. depression or parenting stress). Table 2 presents the reliability scores for the three measures. The general recommended alpha for a good standalone measure is $\alpha \geq 0.75$.

Table 2 Reliability scores of the three measures pre and post intervention

	Pre-intervention	Post-intervention
	α	α
EPDS	0.76	0.87
PSI	0.79	0.87
FAD	0.90	0.95

**EPDS – Edinburgh Postnatal Depression Scales, FAD – McMaster Family Assessment Device, PSI – Parenting Stress Index.*

We conclude that all three measures had good internal consistency and reliability at both pre- and post-intervention time points and are suitable to use as standalone measures of these outcomes in an evaluation.

Change in depressive symptoms pre- and post-intervention

We analysed the EPDS data using both mean continuous scores per group, as well as individual participant's change scores in order to understand the changes in depressive symptoms over the course of the intervention. We also use the gold standard cut off for probable depression (EPDS ≥ 13) to determine cases and examine changes in probable depression pre- and post-intervention to explore whether changes are the same or different for women with mild to moderate symptomology and those with more severe symptomology. Importantly, the sample size is small and not adequately powered to determine the efficiency of the intervention for changing depression, but it does provide a general indication that variance exists (meaning there is change) and that results are in the direction that one would expect (the intervention decreases symptoms rather than increases them).

When examining group scores, the number of depressive symptoms (measured as changes in the mean of continuous scores) decreases from pre-intervention to post-

intervention for mothers in the pregnancy, early and later postnatal groups but increases for mothers in the 12-24 month group. The decrease was particularly marked in 6 to 12 month group of mothers, whose mean EPDS score decreased from 17 to 14. Overall the scores decrease, suggesting that the intervention has either a neutral or a positive effect and that changes are in the direction expected. Variations in scores may also be accounted for by outliers in this small sample.

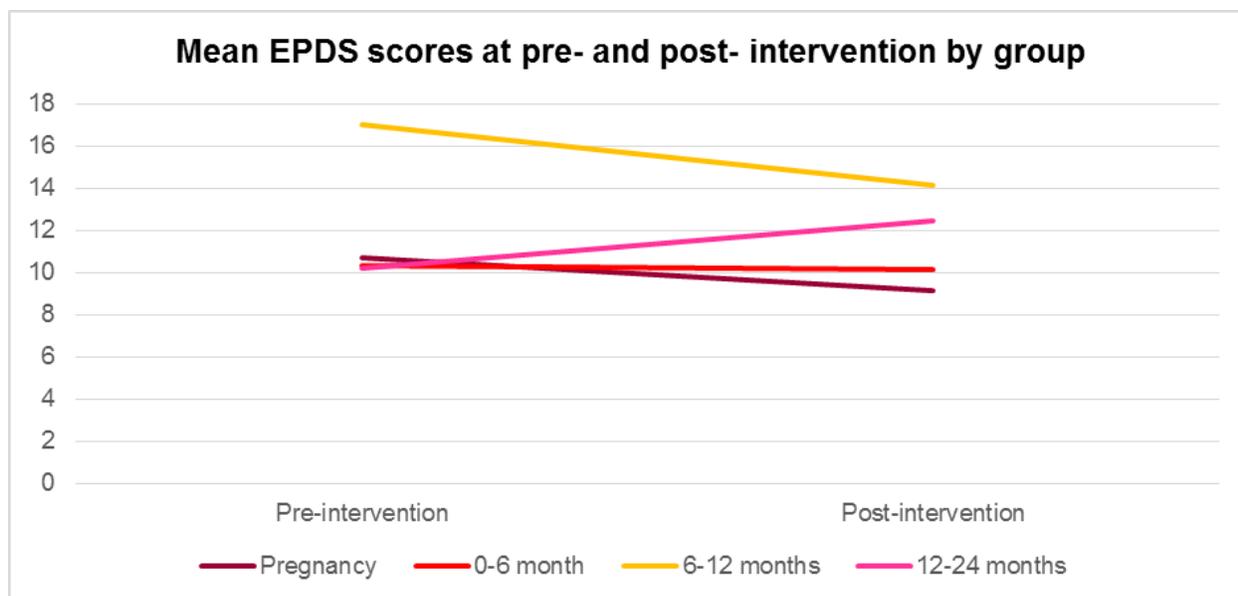


Figure 9 Group mean depression scores pre and post intervention

The increases in the 12-24 month group may indicate several things including that:

- i. this is a particularly stressful period for mothers and stress may increase over time regardless of the intervention;
- ii. the intervention dose may be too low to impact at this developmental stage given it covers a 12 month rather than a 6 month range as do other components;
- iii. that interventions which only start post infancy may require greater efforts to have a positive impact;
- iv. that the intervention content may increase attention to stressors and thus increase depression.

To interrogate this further we examined individual differences scores for the n=36 mothers who completed the intervention. Here we calculated the difference between

each mother's pre- and post-score, and determined if it reflected a positive change (decreased scores to reflect decreases symptoms) or a negative change (increased scores reflecting increased symptoms). As shown in Figure 9 we see that scores decreased more in first 2 groups (pregnancy and 0-6 months) and also show a trend towards decreasing in the third group (6-12 months) although less so. Then as shown in the group, difference scores were more inclined to increase in the last group (12-24 months).

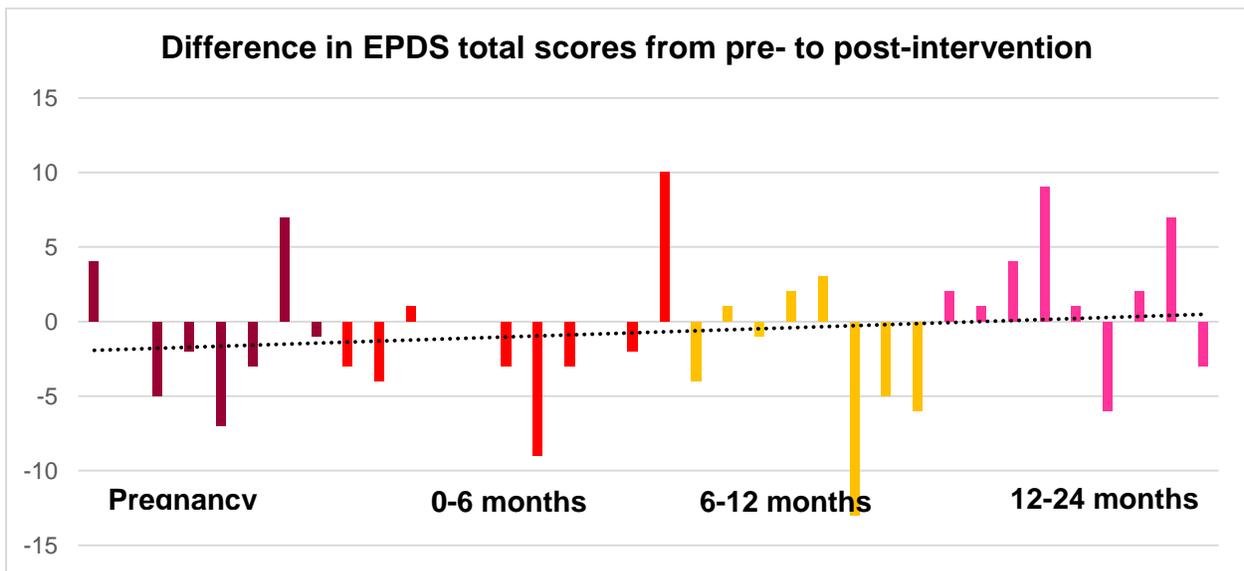


Figure 10 Individual difference scores on depression pre and post intervention

This suggests that the intervention had more positive effect when started in the pregnancy and early postnatal period than when started 6 months postnatal, and was not particularly helpful in reducing depression scores if only started after 12 months postnatal. It is noteworthy that all groups have outliers who have particular increases or decrease in scores which are opposite to the trend of the group. This is to be expected in a small sample and may explain the reduced effect in the 0-6 month and 6-12 month groups where outliers are particularly extreme. It is also possible that the short intensity (3 sessions per group of mothers receiving each component) - related to the concurrent delivery of the components i.e. that mothers were not followed across the stages and only benefited from one component – may also have reduced the impact of the intervention. Despite this, the trendline suggests that overall the intervention has a positive effect in reducing depression scores in pregnancy and the early and later

postnatal periods, but only has a neutral effect when delivered after 12 months postnatal. Importantly this effect is achieved despite a relatively low dose intervention.

In examining depression cases pre- and post-intervention, we see that depression prevalence at baseline is high in all groups, but particularly so in the first year postnatal. As shown in Table 2 we do see a trend towards decreases in numbers of cases pre- and post-intervention but this change is somewhat marginal, and prevalence post-intervention remains alarmingly high. We also see that in the 12-24 month group there is an increase in the number of depression cases.

Table 3 Depression prevalence (≥ 13) “cases” pre and post intervention

Pre intervention depression cases			Post intervention depression cases		
Group	n	%	Group	n	%
Pregnancy	4	28	Pregnancy	2	25
0-6 months	7	47	0-6 months	4	36
6-12 months	8	75	6-12 months	5	63
12-24 months	4	31	12-24 months	4	44

It is common in psychological studies to observe an increase in reporting of symptoms amongst mothers who are particularly distressed, as they become more acutely aware of symptoms and emotions which are made salient through both the intervention and the assessment. However, even when taking this into account it seems noteworthy that if a mother is already 12 months postnatal and is already somewhat depressed the intervention does not have as much positive effect than if she is supported earlier in the first 1000 days – this trend reiterates the importance of the early intervention which can be facilitated by delivering an add-on such as Ibhayi Lengane through CCGs.

Equally, one should consider two cautions in interpreting these results, firstly the intervention outcomes are not benefiting from the cumulative gain which would likely be observed if each of the components were delivered consecutively and secondly, the intervention was not designed to treat depression per se and so it would be unreasonable to expect it to have a significant impact on depression “caseness” given it

does not use any depression treatment strategies in its content, and given that the concurrent implementation only provided 3 sessions per mother, a dose which is unlikely to impact on severe depression. These results also suggest that is important for CCGs to have referral pathways for more severe cases of depression.

Change in parenting stress pre- and post-intervention

The Parenting Stress Index measures total stress and include three subscales which measure:

- i. Parental distress (emotional distress as result of parenting role)
- ii. Parent-child relationships dysfunction (the quality of the parent-child relationship)
- iii. Difficult child (negative parental perceptions of the child)

In pregnancy, since the child is not born, only the parental distress scale was administered, while postnatally all subscales were administered and a total stress score calculated.

In pregnancy we see a marked decrease in parental distress, and this is encouraging given the intervention content in this group focuses on the reduction of conflict over the pregnancy and in supporting the mother to adjust to pregnancy.

However, using the group mean for continuous scores of total parenting stress postnatally we see an increase across all the groups. The total increase in mean scores on the parenting stress index pre- and post-intervention across groups was 91.7 to 94.7 - and although this is a small difference it is a significant one (t test $p= 0.025$). There is an expectation that parenting stress will increase over time in the parenting role, in particular as the child becomes more independent. Also it is known that parental distress is cumulative (meaning it worsens in the absence of intervention and over time) and so these results may again reflect the important need to start early (in pregnancy) in order to see a cumulative and preventative effect over time. Equally, it is noteworthy that the baseline levels of parenting stress are particularly high in later developmental stages, which is concerning since parenting stress is strongly associated with child neglect and abuse. When examining the scores by subscale in the early and later

postnatal period one sees some evidence of a trend towards decreasing and or neutralising scores on the parent-child relationship and difficult child scales (in the context of overall increasing total scores) however in the 12-24 month period we again see a particular vulnerability around parental distress and perceptions of the child but no particular increase of scores on the parent-child dysfunction scales. The context of overall increases would suggest some mitigation effect of the intervention, although this effect seems to be limited by the high levels of stress at baseline. It is most likely that these scores are worsened by the concurrent delivery (low dose per mother) and late start amongst this group of high risk mothers. Nonetheless, greater attention needs to be paid toward strategies to reduce parenting stress, in particular in mothers with older children.

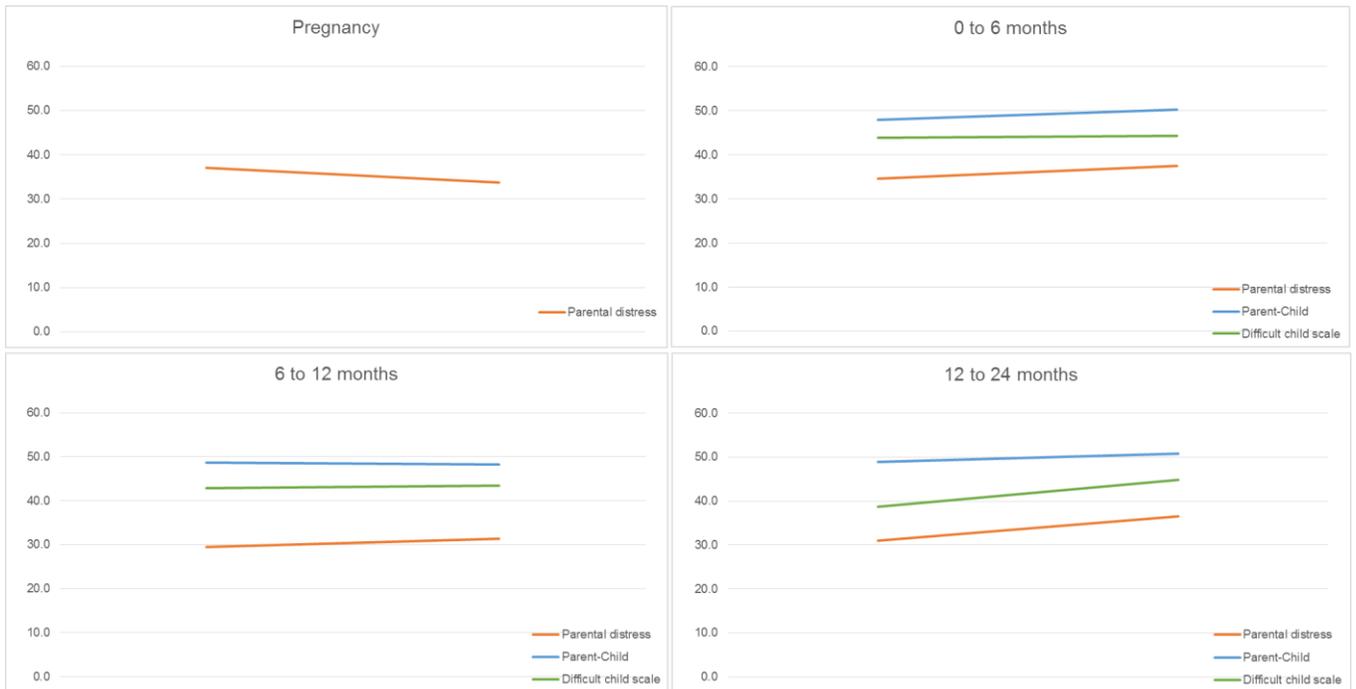


Figure 11 PSI subscale by group pre/post intervention

Changes in family relationships pre and post intervention

This intervention specifically targets improvements in family functioning as a key mechanism to increasing support for pregnant women and high risk mothers. As shown in Figure 12, we see positive trends (higher scores indicate better functioning) across all groups pre- and post-intervention, as indicated by change in mean scores in the General Family Functioning subscale of the Family Assessment Device. Although we see increases in family functioning across all groups, these differences were not statistically significant in t tests, but as with the depression scores there appears to be a particular strong effect in pregnancy and the early postnatal.

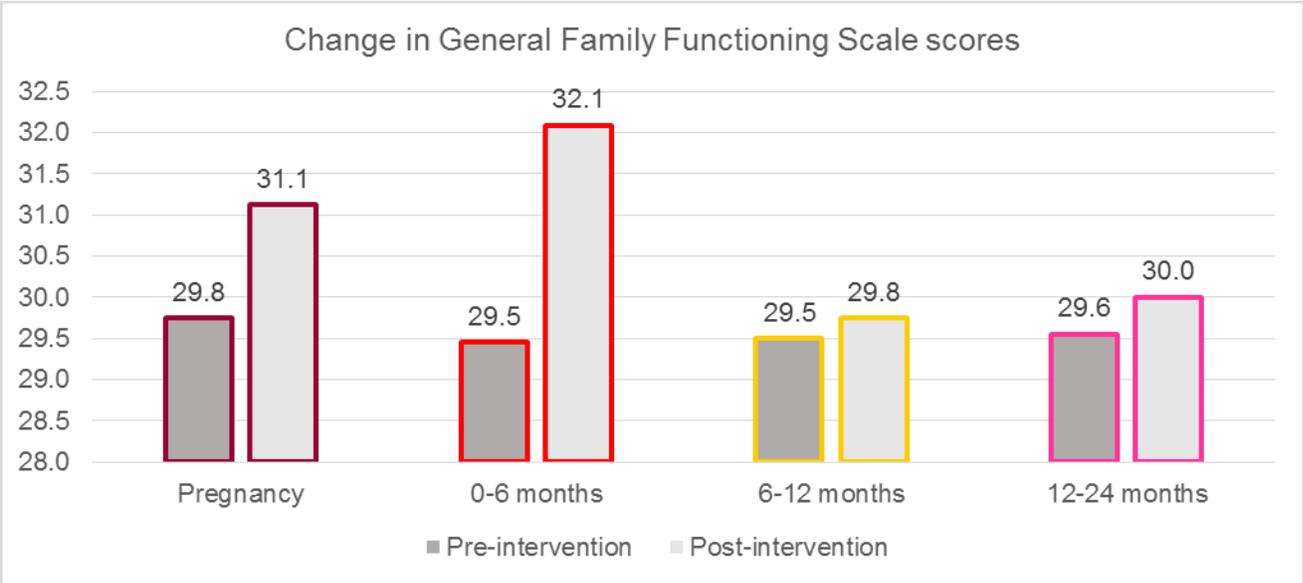


Figure 12 General Family Functioning by group pre/post-intervention

In examining the specific areas where family function and relationships had the more significant improvements we find that:

- Families showed more affection to one another (p=0.042)
- Confided in each other more (p=0.017)
- More able to talk about sadness to each other (p=0.049)
- Family members became less self-centred (p=0.048)
- There were less 'bad feelings' in the family (p=0.048)
- Improvements in communication and "saying what we mean" (p=0.013)

- Mothers feeling more accepted by the family for who they are (p=0.048)
- Families became more reliable in doing things they were asked to do (p=0.050)
- Families being more vigilant in holding to rules and standards (p=0.037)
- Better problem solving within the family (p=0.014)

CCG experiences of the intervention change

Although the sample size is too small to infer efficacy, the generally positive results on the three psychological measures were validated by the qualitative feedback provided by both CCGs and mothers.

The change in family relationships was also supported by qualitative data from the CCG post interventions.

“Seeing families where they were when we arrived, there was no relationship and now the families are more connected and have support for each other.”

CCG’s reported that the knowledge and skill transfer was also extended to the mother’s family, and that this increased the amount of support that mom’s had from the family.

“The family enjoyed the activities and they were very supportive of the mother and me when I visited them.”

“It was also encouraging to see that the family engaged with what they had learnt even without me there”

Equally CCGs felt that their relationships with mothers benefited from the program, suggesting that this relationship would likely have a potent effect with continued support over time.

“The relationship with the moms grew a lot over the duration of the process and moms acquired a lot of new information”

The improvement in the relationship between the CCG and the mother in the intervention is critical to the hypothesised pathway to change. Achieving this improvement in the quality of the relationship likely led to important opportunities to exchange information and learning, and provision of support. The high quality of CCG-

to-mother relationship not only positions the CCG as a credible and trustworthy information source, but also allows for a two-way exchange of information between CCG and mother which facilitates joint problem solving and responsiveness in the support provided by the CCG, allowing the intervention resources to be directed in an efficient way based on a particular mothers most salient and pressing needs. All CCG's reported there had been a notable shift in the type and quality of relationships that they had with mothers.

"They were able to open up and share the challenges that they were facing at that time with us that showed that they trusted us with their feelings"

"The relationship with the mom is very positive, the mom really saw the value in the knowledge we were sharing with them so much"

CCGs also acknowledged that the relationship based approach had changed the openness of the mother to the information the CCG could provide and results in a more productive helping relationship.

"Mothers are listening to us now, where before they did not"

"The relationship with the moms has strengthened significantly; our ability to be there to help the mom has meant that we have developed good working and personal relationships with each other"

"It changed in terms of them doing everything that we were teaching them. The information we gave them, they took it and used it."

CCGs also noted changes in mothers and the ways in which they interact with their children and reported this was one of the most enjoyable rewards of delivering the intervention.

"Seeing the mom connect with her child and also seeing the moms' growth and development in terms of how she interacts positively with her baby"

An additional challenge facing many pregnant women and new mothers relates to engagement of the child's father in the pregnancy or in the child's life. While a growing

body of evidence from the literature suggests that father involvement is beneficial for maternal and child outcomes, the engagement of fathers is somewhat problematic in primary health care and other clinical settings. Given how common this challenge is the intervention worked specifically to include fathers in is this respect there were both success and barriers noted.

“Some men did not involve themselves at all in the intervention and the family members that did participate were mostly women”

The CCGs identified some of the reasons why it was difficult to have fathers engage in the intervention. One of these reasons is that a man is not allowed to live with his partner unless he has paid *lobola* which resulted in the father not having regular or any contact with the mother or family. This made the father somewhat difficult for the CCG to reach, unless they made specific efforts to do so outside of the scope of the regular DOH home visits. There were a number of ‘success’ stories – where CCGs could engage fathers, either in the home or through inviting fathers outside the home to participate, where participation helped the father identify with the importance of the intervention thus increasing his interest and support towards the mother and baby.

“He is very supportive now and takes an active role in taking care of the child... he has taken over responsibilities”

“He was so excited that he made extra effort making sure that the mom had nutritious food to eat. Even though he worked, on the days he was available he would join the sessions.”

Mothers experiences of the intervention change

Mothers reported that the intervention was salient and responded to specific needs, and resulted in improvements in their ability to respond appropriately to their children’s cues, or needs.

“I did not know how to play with my child or to create a bond”

“I couldn’t comfort baby when she was crying”

“I didn’t care about pregnancy and now I love my baby”

“The big change from Ibhayi Lengane is that I am now able to play with my child as this was not happening before because when my child cries I usually get angry but now I play with my child so that he is going to stop crying and play. I couldn’t comfort baby when she was crying. I changed and spent more time with my child, and I know when they are hungry”

The intervention was particularly salient for first time and young mothers.

“It was useful since it was my first time to have a child and I am lucky to get someone else to provide advice about how to raise a child.”

Mothers’ skills and knowledge about stimulation and responsive care also improved – notably in their understanding of what children need to grow and develop well.

“Now I know that my child does not only need nappies, food so that he will grow but he needs me and love.”

Mothers reported substantial changes in their understanding of the value of communication and building a positive relationship with the child from pregnancy – regardless of negative circumstances which may surround the pregnancy.

“I learnt that you have to love your baby from when it is still in your tummy”

“I enjoyed learning that I could talk with my child in my tummy”

“Touch your tummy and tell your child about stories that are happening around”

This increased understanding of the value of communication for children’s development was true also evidenced in the postnatal period:

“It is good to share with your baby stories that are happening around in life, it helps them grow and learn”

Mothers also recognised the value of communicating with other adults around you when you need support.

“It encourages me to have someone I can talk to as I was not in a good position”

Mothers also reflected on the change in their families as a result of the intervention.

“We became closer and we would share everything.”

Mothers consistently validated the importance of the CCG-to-mother relationship in particular in periods of isolation and crisis.

“She supported me as it was not easy to tell my problems with the family members and it was easy to tell CCG, I remember the day I was trying to commit suicide, she supported me and she helped a lot during that day. My family members were not helpful to me and the CCG helped me”

The vast majority of the mother’s feedback in the qualitative workshop centred on the positive relationships they had developed with the CCGs as part of the intervention, identifying CCG’s as source of credible information and an important emotional support for them.

“The CCG helped me in so many ways that I was able to talk to her about everything I need to talk about without any fear of rejection.”

“CCG was a good person as we have a good relationship because we went through my challenges together she was doing check-ups and I was able to talk to her about everything that was bothering me.”

“They were like a parent to me.”

Mothers also reported that the CCG support was extended to both health and social welfare referrals, confirming the important role that CCG in the health sector can play at a community level when they are trained to use a relationship-based framework and build positive helping relationships, thus ensuring that high risk mothers access relevant support.

“I did get support even if I don’t have anything to eat, I will go to the CCG will help me and she will get me something to eat so the support is good”

“The CCG she encourage me even when I am sick to go to the hospital as it is important to go and I remember the day she told me to go and it is helpful to have someone to talk to and encourage you”

“The CCG she supported me when the baby is sick as she will tell me when it is time to go to the hospital”

Potential for reducing maternal and child morbidity and mortality

Despite the small sample, two case studies demonstrate the important role that a relationship-based community level intervention can play in accentuating the role CCG and families can play in ensuring access to health and social services in communities.

The first case study illustrates how repairing and strengthening the family relationship can have particular benefits in identifying risks early enough to access treatment and prevent morbidity and mortality. In the absence of such attentive relationships many at risk mothers might not receive the medical help needed on time. Families and CCGs are important participants in leveraging care for vulnerable women, especially in periods of illness or high risk. In this instance the attentiveness of the grandmother, the information she had received as part of the intervention, and the response of the CCG and the support of the local nurse who was managing the CCG referral ensured this pregnant women’s access to timely life-saving care.

The second case illustrates the important role that CCG can play in identifying serious psychological risks such as suicide ideation, and how a system which connects the CCG to services is able to support referrals and prevent morbidity and mortality. The case highlights the important asset that CCG represents for the health sector because of their role as a community member, who is trusted and accepted – and also their role as a health care worker who is knowledgeable and able to advocate for her patients and is highly accessible to families.

In both these cases the CCG noted throughout their feedback workshop on Ibhayi Lengane that the fact that the clinic nurse was available and had provided them with her cell phone number for emergency was particularly helpful.

These cases reiterate the critical role CCGs play given their proximity to community and provide strong justification for increased investment in their training and supervision.

CASE STUDY 1: ASSISTING WITH PREGNANCY COMPLICATIONS

Mantombi is 19, this is her second pregnancy and she became pregnant shortly after her first child turned 2 years of age. She joined the intervention in her second trimester. At the first meeting the CCG noted that there was a lot of anger in the house, with Mantombi's mother and grandmother both in the house with no-one talking to each other. Mantombi shared how afraid she was of talking to the family about this pregnancy, they were already not happy about the added burden of this new pregnancy on the family and to add to her stress at her last antenatal visit she had just discovered she was expecting twins. The CCG encouraged her to tell her family Mantombi felt she could try and do this if the CCG supported her, and they agreed the time for a family session to include Mantombi, her mother Busi* and Gogo Sihle*. Mantombi's mother and grandmother agreed to the family sessions facilitated by the CCG. When the CCG brought out the baby blanket as part the family session, Mantombi asked for two blankets, this is how she opened and shared with her mother and grandmother that she was expecting twins. Mantombi's mother Busi shared how angry she felt holding the blanket because she felt that it was forcing her to accept these children and she did not want to. Her grandmother shared that it was difficult to hold the blanket in your hands and still remain angry because it was like being angry at the child which was not easy. Mantombi reports that after the 3 CCG visits her family became much more supportive and forgiving towards her. In the family session the CCG also shared the mother's journey through pregnancy (images of mom's healthy activities, 'heathly eating, rest and sleeping, activity, self-care, gentle exercise and friendship' with the message 'Everything that keeps me healthy, also supports my baby's development'). A few weeks later Gogo Sihle came to find the CCG, bringing with her the Ibhayi Lengane Pregnancy poster, she used the poster to talk about her granddaughter's health and reported that she felt something was wrong because while it is healthy to sleep Mantombi was sleeping too much and she feared something was wrong. The CCG visited mom and took her to the clinic, at the clinic a doctor saw her and referred her directly to hospital. It transpired that one of the twins had died in Utero. Mantombi was able to get the medical treatment required and managed to carry the second twin to term and delivered a healthy baby girl who is growing well. Mantombi thanks God that she had the courage to tell her family that she was expecting twins because they can share the grief of the loss of the one baby and the joy of her healthy baby and she does not have to carry this alone. She is also very thankful that her grandmother intervened when she did, and that she had someone to go to who could help. If it was not for the CCG and the poster her family might not have noticed there was something wrong until it was too late.*

CASE STUDY 2: ASSISTING WITH SUICIDE IDEATION

Sindi was a pregnant mom who enrolled in the Ibhayi Lengane interventions. She is in her early 20s and had become pregnant unexpectedly when her first child was only just a year old. At the time she joined the intervention in her second trimester, her first child was 15 months old and her family relationships are difficult, strained and largely unsupportive. The news of her second pregnancy was not well received by her family members, in particular since the first pregnancy had been a cause of conflict also, and she had been completely rejected by her family. Both the CCG and fieldworker who completed Sindi's pre intervention survey raised concerns about her mental health. The CCG had learnt that when she was 3 months pregnant, she tried to terminate her pregnancy, and had also tried to harm herself and despite being referred for assistance she had not taken up the referral. The CCG approached the supervisor to help with a referral for the mother. At that time, an immediate referral was made to LifeLine and transport money was provided (from project resources) to help facilitate attendance at the first two sessions. However, Sindi was very anxious about attending the appointment on her own and before her first appointment became available, she again tried to commit suicide by overdosing on ARVs. She was treated at Edendale Hospital who suggested on discharge that she be referred to Townhill, but again she was resistant and said she preferred to go to Life Line as had been the original plan. At this stage the CCG suggested that she thought it would be helpful if she accompanied Sindi to the first appointment as it seemed that she needed support if she was going to take the step to get help. Transport money was provided to enable the CCG to accompany Sindi to Life Line. This caused a major shift in Sindi's engagement with mental health care. She attended two sessions at Life Line where it became clear that she needed further psychological support. A referral was made to Townhill Hospital for Sindi to see a State psychologist. She was provided with an emergency appointment and a second appointment a few weeks later. For the first appointment, she was accompanied by the fieldworker who had initially detected that she had depression, having had this additional support in attending services, by the second appointment Sindi indicated that she was comfortable returning on her own for her next appointment, which she did. Three months later she gave birth to twins, and has attended a further three sessions at Townhill without assistance by the CCG or fieldworker to attend, and the Psychologist has told her that she was doing much better and didn't need to return.*

**pseudonyms*

The second case study illustrates that significant resources are required for a CCG to effect referrals to tertiary level care. The referral process entailed over 15 telephone calls and assistance with transport costs which most CCGs would not be able to provide without support from the health system. Equally in the face of such challenges, and the absence of a strong relationship, the CCG may well have given up with potentially disastrous consequences for both cases. While highlighting the important potential that lies in the relationship between CCG and high risk women these cases also bring to our attention that an absence of resources and communication challenges might prevent a CCG from being effective in such cases if they are unable to access adequate clinical support from nursing and medical teams at their local clinic.

CCGs did report that a number of referrals were successfully made during intervention. These referrals were not limited to the mother and child, but extended to her family and covered a wide variety of diagnoses. Within their normal scope of work, CCGs have a target number of referrals to make each month, and therefore by reaching so many individuals (by intervening with the family) during the intervention visits, they were able to lessen the stress/ burden of this workload. Mothers reported that CCGs would remind them of clinic dates as well as make appropriate referrals for both them and their families and children.

CCGs reported that the clinic nurse being interested, engaged and being willing to receive referrals – as demonstrated concretely to the CCGs by her willingness to provide her cell phone number for emergencies – had an impact on their confidence in making referrals and seeking advice when needed.

COSTING EXERCISE

Many factors influence an add-on costing, and these may change over time and vary across communities and by the approach taken to training (expert vs train-the-trainer) and the delivery approach (generalist vs specialist). This iterative costing of the training and delivery components is based on the assumption that the intervention would be managed by the DOH as the government department with the necessary infrastructure to support this add-on.

Regardless of whether the Ibhayi Lengane add-on intervention was delivered in a generalist or specialist approach, a substantial investment in training would be required. The costing exercise estimates the cost of implementing Ibhayi Lengane either using an expert trainer approach or using a train-the-trainer model which cascades down to CCGs through PHC outreach structures, with less direct expert input. We estimate the costs of implementing the training using two potential scenarios with the numbers of CCGs needing training adjusted in each scenario (either a generalist or specialist delivery approach).

Expert training versus train-the-trainer models

While we are able to make an estimate of the relative cost benefits of these two training approaches we were unable to test the fidelity or success of a train-the-trainer model for this training, within the scope of this pilot. We can hypothesise that potentially higher quality training can be delivered by experts, and that expert training may result in time to service provision being reduced, however this benefit falls away over time. Equally we can expect that with adequate up front investment high quality train-the-trainer models can be developed which deliver high quality training which can scale up at lower cost within a 12 month period.

Scenario 1 Expert training

1. **Generalist**: An expert training approach where trainers from Dlalanathi conduct training directly with larger generalist cadre of all CCGs in a district.

2. Specialist: An expert training approach where trainers from Dlalanathi conduct training directly with a smaller specialist cadre of CCGs sufficient to meet demand in the district.

Scenario 2 Train-the-trainer

3. Generalist: A train-the-trainer approach where trainers from Dlalanathi train the number of DOH trainers required to cascade the training down in a generalist approach to all CCGs
4. Specialist: A train-the-trainer approach where trainers from Dlalanathi train the number of trainers required to cascade the training down to a smaller specialist cadre of CCGs.

To complete this exercise we make assumptions based on the existing DOH structures for the catchment areas of CCGs and the management of the PCH teams in the ward and district under study. Each PHC facility is reported to include a team of at least two PHC outreach personnel (who provide supervision and training to the CCGs) and 6-10 CCGs who target the ward population, managing approximately 250 households per CCG. For the purposes of consistent calculations we work on a median of 8 CCGs per ward.

Our calculations are based on assumption of 1 supervisor to 8 CCGs per ward based on a median with at least 1 required supervisor. We then assume that each approach will require a smaller or larger number of trainees trained by either an expert (directly) or a DOH trainer (CCG supervisor). Importantly all DOH trainers require expert training in the train-the-trainer model in first instance.

Based on input from Dlalanathi, and quotations from suppliers, the cost of training varies from R350 per person trained per day (or R1750 for the 5 days training) when delivered by an expert trainer to 50% of that cost or R175 per person per day (or R875 for the 5 days training) in the train-the trainer cascade approach.

The cost of the Ibhayi Lengane training manual and materials (R350) stays constant to the number of persons trained and accredited – given these numbers will remain low in all scenarios economies of scale are less likely at a provincial level. Conversely, when

examining delivery models, we can expect some economies of scale in the cost of materials used in delivering the intervention to mothers (R50) is also kept constant but is based on production of materials at scale (minimum service to 10,000 women per annum) provincially. Since this variable can vary dramatically by service provision approach it is not estimated in training costs by rather as part of the delivery approach costs.

In both training scenarios (expert versus train-the-trainer) the number of trainees is determined by the total number of CCGs and their supervisors across wards. In the train-the-trainer approach training costs vary by cascade, reducing costs by 50% by the second cascade of training.

Based on data from the Msunduzi Local Municipality we expect to service 39 wards with an estimated population prevalence of risk 30%, thus we estimate the number of CCG needing training to be 30% of all CCGs while the supervisor variable stays constant given this is a minimum requirement.

The estimates for numbers to be trained then vary by approach as follows:

Generalist CCG training numbers - in a ward, based on current service delivery variables we assume that at least 9 people (1 PHC outreach supervisors, and 8 CCGs) require training for a generalist approach.

We estimate approximately 351 persons be trained, made up primarily of the 312 CCGs (39 wards with 8 CCGs each) and an additional 39 CCG supervisors (minimum 1 per ward) who can either be an outreach nurses or health promotion and environmental officers trained in order to deliver training and provide supervision during implementation.

Specialist CCG training numbers - in a ward, we estimated that 30% of the population would need the Ibhayi Lengane services and that therefore 30% of CCGs would require training to respond, but that all wards should have access to at least one trained CCG (30% is approximately 2/8 per ward) hence the number of supervisors at 39 remains constant to the number of wards served as each ward requires a supervisor. If

supervision was centralised this would save training costs, but introduce ongoing travel costs to CCGs.

This approach requires 94 CCGs (30% of all CCGs) to be trained along with 39 supervisors (assuming that the specialist cadres are spread across all wards) and CCGs are supervised by at least 1 supervisor per ward.

The cost of each scenario is outlined in Tables 4 and 5.

Table 4 Scenario 1 Expert training to generalist/specialist cadres

Scenario	Required inputs	Unit costs	Quantity	Year	Per annum
<i>All training is delivered by expert trainers</i>					
Expert (generalist)	Training	1750.00	351	1	R 614,250.00
	Manuals	350.00	351	1	R 122,850.00
Total					R 737,100.00
Expert (specialist)	Training	1750.00	133	1	R 232,750.00
	Manuals	350.00	133	1	R 46,550.00
Total					R 279,300.00

Table 5 Scenario 2 Train-the-trainer to generalist/specialist cadres

Scenario	Required inputs	Unit costs	Quantity	Year	Per annum
<i>Experts train supervisors who train CCG</i>					
Train-the-trainer (generalist)	Training (supervisors)	1750.00	39	1	R 68,250.00
	Training (CCG)	875.00	312	1	R 273,000.00
	Manuals	350.00	351	1	R 122,850.00
Total					R 464,100.00
Train-the-trainer (specialist)	Training (supervisors)	1750.00	39	1	R 68,250.00
	Training (CCG)	875.00	94	1	R 82,250.00
	Manuals	350.00	133	1	R 46,550.00
Total					R 197,050.00

This exercise helps to demonstrate the cost effectiveness of a train-the-trainer model even in cases where all CCGs would be trained in delivery. While the benefit of the train-the-trainer approach is greater in the generalist approach (cost savings of R273,000 or 40% less) relative to the specialist approach (cost savings R82,250 or 30% less), the overall cost of training is lowest when a train-the-trainer model is applied to a

specialist cadre (R197,050) as compared to the generalist one (R464,100), with cost savings of R267,050 or 57%. Importantly, in both scenarios the trainer-the-trainer model eliminates the need for further investment in expert training which has longer term advantages and cost savings.

Generalist versus specialist approaches to delivery

Greater specificity, a control group, and a larger costing exercise would be required to determine the cost versus benefit of delivering the intervention to all mothers versus high risk mothers only, and this falls outside of the scope of this research project.

However using available broad population parameters we can illustrate the extent to which one approach is more resource intensive than the other, and we can provide an indication of how these training investments can be expected to be distributed over services delivered on a per annum basis within each approach. We are also able to outline the variable which should weigh into consideration around each scenario for future costing exercises.

Keep our assumption of number of CCGs constant (8 CCGs per ward) we use the estimates for number of residents and numbers of households are available from STATS SA. Making all other population statistics equal for the purpose of the exercise, we can make some estimates using the number of residents in the Msunduzi Municipality, the number of wards, the number of females, estimated fertility rate and age of first parity amongst 15-24 years and the potential additional burden of second parity which may occur amongst 25-34 year olds are included in the larger population of 15-34 year olds. Given these are broad (and somewhat flawed) parameters we offer costings by a range of both a low and high estimate for illustrative purposes.

Importantly, in reality these wards and variables will not be equal, in fact most, if not all of these vary substantially across the population. This is therefore an illustrative example only and should not serve to underestimate the degree of specific planning which will be required at a ward and district level to conduct a full costing exercise.

Parameters used for estimations

- 618,539 people reside in 163,993 households in Msunduzi.
- If households are equally distributed by 39 wards, each ward has approximately 4200 households per ward.
- We expect each ward to have a median of 8 CCGs (total of 312 CCGs across the 39 wards).
- Distributing these CCGs over 4200 households we estimate each CCG to attend to 525, noting that this is double the number reported in guidance from DOH (which is 250 households per CCG).
- Based on estimated sex ratios for KwaZulu-Natal one would expect approximately 52% of the population to be female.
- The proportion of female population in these age brackets are estimated to be 5.2 (15-19) 5.9 (20-24) 5.7 (25-29) and 4.3 (30-34) respectively.
- Age of first parity is most commonly between ages 15-24 years and the rate of first parity by 24 years is 4-5%.
- National fertility rate is estimated at approximately 2.5%, this is used to estimate the % of potential second parities in women 25-34 years.

Given these parameters one could assume that approximately 21% of all females will be aged 15-34 and at least 2.5-7.5% of those will have a child in any given year. Thus we can estimate that 321,640 of the 618,539 residents in Msunduzi are female of which 67,544 are aged 15-34 years. Amongst these 67,544 women we would also expect that approximately 35,702 are aged 15-24 years while 31,842 are 25-34 years.

Using the estimate of 5% first parity by 24 years we estimate that 1785 (5% of women aged 15-24) have their first parity by this age. The lower limit estimate of 1785 pregnant women for Msunduzi is a very conservative approach as it reflects only estimates of first parity by 24 years. Using estimates of overall parity and fertility rates across all the wider child bearing age (15-34 years) where second parity likely occurs the parameters can shift. The national fertility rate is approximately 2.5% across the child bearing years 15-34. We use this 2.5% to estimate additional second parity rates in the 25-34 age

group. Increasing the age band to 15-34 years and the estimated pregnancies to 7.5%, we would increase our proportion of women to be 5065 of the 67,544 women of child bearing age. This is a high estimate (higher than the delivery rate for most wards) and so for the purposes of this exercise we use the expected parity 5% across all ages to provide a more realistic estimate. This lead us to expect that the upper limit of pregnancies (5% parity/fertility rate) could be as high as 3377 per annum.

Thus using these parameters we can expect between 1785 and 3377 pregnancies per annum in this population aged 15-34 years. Working on the assumption that between 1785-3377 pregnancies occur across 39 wards with 8 CCG per ward (312 CCGs) we would expect a ratio of either:

- Lower estimate 1 CCG to 6 pregnant women
- Higher estimate 1 CCG to 11 pregnant women

Estimates of human resource demands by approach

Using these parameters we can now apply the generalist versus specialist approaches to estimate the resource intensity of:

Generalist – all CCGs (312) target either all (100%) pregnant women OR all CCGs target only number of expected high risk (30%) pregnant women.

Specialist – Some CCGs (94) target all (100%) pregnant women OR all CCGs target only number of expected high risk (30%) pregnant women.

In each of these scenarios we assume that each CCG will deliver 12 session to any one mother in a one year cycle, bearing in mind this is an overestimate (because the add-delivers 12 sessions over 24 months, hence mothers only receive 6 sessions in any one year cycle) however estimating at 12 sessions per annum allows us to account for second and third cohorts of mothers who may join in the programme throughout the year, and those who will be receiving additional services from years 2 onwards to a maximum of 12 per annum.

Generalist approach: Table 6 outlines the resource burden of the specialist approach.

Table 6 Resource burden generalist approach (case estimation 30-100%)

Pregnancies (Risk)	Sessions per annum	Distributed by 94 CCGs	Per CCG per month	Per CCG per week	Hours per week
Low Estimate 1785 (100%)	1785 x 12 sessions = 21,420 sessions	21,420/312 CCG = 69 sessions per CCG per year	69/12 months = 6 sessions per month	6/3 weeks = 2 sessions per week	2 x 1.5 hours = 3 hours per week
High Estimate 3377 (100%)	3377 x 12 session 40, 524 sessions	40, 524/312 CCG = 130 sessions per CCG per year	130/12 months = 11 sessions per month	11/3 weeks = 4 sessions per week	4 x 1.5 hours = 5 hours per week
Low Estimate 535 (30%)	535 x 12 sessions = 6,420 sessions	6,420/312 CCG = 21 sessions per CCG per year	21/12 months = 2 sessions per month	1/3 weeks = 0.5 per week	1 x 1.5 hours = 45 minutes per week
High Estimate 1013 (30%)	1013 x 12 session = 12,156 sessions	12,156/312 CCG = 40 sessions per CCG per year	40/12 months = 3 sessions per month	3/3 weeks = 1 sessions per week	1 x 1.5 = 1.5 hours per week

This approach assumes 12 CCGs were to deliver these sessions to either to 100% (if all pregnant women meet the criteria for being high risk) or delivering to 30% (only a third of mothers are high risk) and require the intervention. For both the high and the low estimate the burden on CCGs to deliver the service to 100% of pregnant women remains relatively low 3-5 hours per week. This is reduced to 45 minutes to 1.5 hours per week if only high risk women are targeted.

This makes the generalist approach feasible to deliver for high risk mothers but also makes it reasonable to consider delivery to all mothers (half a day a week additional workload). While acknowledging that the current burden on CCGs high, importantly the add-on may have benefits in other areas (allowing for the better integration CCGs work tasks, service to multiple families members at a time, higher rates of appropriate referrals) which may ultimately also streamline and reduce overall work burden, and increase productivity per hour spent.

Additional costs which must be considered include the cost of materials (R50) and the cost of supervision and delivery. In a generalist model using low (1785) and high (3377) estimates this could and additional R89,250-R168,850 per annum for mothers materials if delivered to all (100%) of mothers. If delivered to only high risk (535-1013 or 30%)

mothers R26,750-R50,650. In this model supervision is not likely to add additional costs or resources, as CCG can be supervised in the current system, and will see mothers within their geographical service areas without needing additional transport costs.

Specialist approach: Table 7 outlines the resource burden of the specialist approach if 94 CCGs were to deliver these sessions either to 100% (all pregnant women turn out to meet the criteria for being are high risk) or delivering 30% (only a third of mothers are high risk) and require the intervention.

Table 7 Resource burden specialist approach (case estimation 30-100%)

Pregnancies (Risk)	Sessions per annum	Distributed by 94 CCGs	Per CCG per month	Per CCG per week	Hours per week
Low Estimate 1785 (100%)	1785 x 12 sessions = 21,420 sessions	21,420/94 CCG = 228 sessions per CCG per year	228/12 months = 19 sessions per month	19/3 weeks = 6 sessions per week	6 x 1.5 hours = 9 hours per week
High Estimate 3377 (100%)	3377 x 12 session 40, 524 sessions	40, 524/94 CCG = 431 sessions per CCG per year	431/12 months = 36 sessions per month	36/3 weeks = 12 sessions per week	12 x 1.5 hours = 18 hours per week
Low Estimate 535 (30%)	535 x 12 sessions = 6,420 sessions	6,420/94 CCG = 68 sessions per CCG per year	68/12 months = 6 sessions per month	6/3 weeks = 2 sessions per week	2 x 1.5 hours = 3 hours per week
High Estimate 1013 (30%)	1013 x 12 session = 12,156 sessions	12,156/94 CCG = 129 sessions per CCG per year	129/12 months = 11 sessions per month	11/3 weeks = 4 sessions per week	4 x 1.5 = 5 hours per week

In this model the smaller cadres of CCGs delivering the service to all mothers would increase the time burden on those CCGs substantially – between 9 and 18 hours per week, which would mean they would have at least 2 fewer days in the week available to deliver other CCG related services. However if these specialist CCG were only delivering the service to high risk women the additional burden is 3-5 hours per week, making this equivalent to the burden placed on all CCG seeing all mothers in the generalist model but with significant lower training costs. As such this approach holds particular advantages over the generalist approach delivered to all mothers and is relatively close to the burden of the generalist approach delivered to only high risk mothers.

However the advantage is that these 30% are serviced by a smaller cadre of CCG's so distributing this by smaller group by the 94 specialist CCGs the number of session delivered (68-129 sessions by 94 CCGs) is almost identical to the resource burden to the generalist approach (69-130 sessions by 312 CCGs) while only needing to invest in training a smaller cadre of CCGs. If additional workload could be feasibly shared with non-specialist CCGs supporting on more general health tasks, this approach seems most favourable.

Relative costing advantages of varying approaches

While the specialist approach requires a much smaller training and supervision investment, delivering approximately the same number of sessions per person trained, it is also based on the expectation that demand for service is constant at 30% of the population. In a worst case scenario if all women were high risk in any given year, this would require 94 CCGs to deliver 21,420 - 40,524 per annum. However even in this case, this would equate to 227-431 sessions per CCG per annum, 19-36 sessions per CCG per month. This would add a workload of 10-18 hours per week (1.25 to 2.25 days) a work load which in itself is potentially feasible if systems for workshare could be established between generalist and specialist cadre within wards. Furthermore, the relative cost of training and supervision of 94 (R197, 050) versus 312 CCG (R464, 100) is an important factor determining the most potentially effective approach.

If these training costs are allocated to the number of sessions delivered in year 1 then the cost of per high risk women serviced by a specialist CCG is R194 per mother if the maximum numbers of mother (n=1013/3377 pregnant women aged 15-34 years) require this service. Over a 3 year period, expecting that 3039 women benefit from the service per year, the cost per women serviced reduces dramatically to R65 per women and over a 5 year period, with 5065 women benefitting from the service per year, the cost per women serviced reduces to R39 per women serviced. If the training costs are allocated to the number of sessions delivered in year 1 in a generalist model then the cost of servicing the maximum number of mothers (n=3377 of women 15-34 years)

would be R137 per mother per year, reducing to R46 and R27 for years 3 and 5 respectively.

Thus while there is only marginal benefit in the actual costs saved in delivering the service to mothers in the specialist cadre in monetary terms (R137 versus R194 per pregnant women, the additional burden on a larger cadre of generalist CCD is substantially higher (312 CCG working an additional half a day per week as opposed to 94) and the relative gain is likely low since the greatest gain is likely to evidence among the smaller population of high risk women, as compared to all women.

This is particularly so when one considers that the specificity of the generalist approach is likely only 30% (i.e. only 30% of all women who receive the intervention in the generalist approach are likely to actually need it based on population statistics) in which case the cost of training all CCGs (312) to deliver services to only high risk women (1013) is much higher in year 1 (R458), year 3 (R153), and year 5 (R92).

We conclude that the train-the-trainer specialist approach is by far the most resource effective to target high risk pregnant women in the current system. However a specialist approach would require an adjustment of CCG workloads, systems of management, and may have hidden costs in terms of the time and transport costs for a smaller group of CCGs to work in a larger geographical area, than the local area in which CCGs currently deliver generalist services within the communities where they live.

Establishing systems of work between generalist and specialist CCGs – may in itself have additional costs to establish and maintain. Importantly DOH express a clear preference for generalist systems suggesting that there may be resistance to alternative approaches and this may raise acceptability and feasibility challenges for scale up and sustainability.

Importantly, it is also plausible, if one considers it to be more important to make an investment in *wellbeing over risk reduction*, that the additional initial investment in a generalist approach (more investment in training all CCGs) which saturates the

community with these specialist skills may have benefits beyond initial resource assessments. These include that:

1. The benefits of this higher skill and saturation may help to go beyond the targeted outcomes – in that it may increase the quality of all care delivered to all households;
2. That costs will likely equalise over time between the two approaches in particular if one considers that with each passing year, this skill will be utilised more readily for an ever increasing population, and will create opportunities for preventative interventions;
3. That a generalist approach may allow for greater retention of training investment across all CCGs and may in the longer term reduce morbidity and mortality which themselves are associated with high costs.
4. That the costs of establishing workshare systems are minimised, and the risk of missed referrals from generalist to specialist cadre's is minimised.

However regardless of whether a generalist (easier to deliver and manage but more resource intense approach) or a specialist (less resource intense but more complex approach to established and deliver) it is clear that the only circumstances where Ibhayi Lengane is feasible to deliver is where it is only delivered to high risk women, since delivering to all women is likely unfeasible.

RECOMMENDATIONS

All levels of stakeholders in DOH found the programme acceptable and identified that it meets a critical need. Most stakeholders hold concerns about the integration aspects of the implementation model, and this likely reflects concerns that will emerge in most districts if the programme is scaled. The implementation guide needs to provide clear guidance on potential operational models for delivery and the cost of resources required. Providing the cost versus benefit information would be critical to encouraging districts to endorse the programme. In this regard, since districts could be quite diverse some flexibility for districts to deliver the programme in either a generalist or specialist approach dependent on the (public and private sector) resources available to them, and the population profile of their communities (degree of risk factors amongst pregnant women).

The training and implementation of the intervention was a success, and the intervention shows potential to improve both maternal mental health and family relationships and support. The pilot study shows adequate potential for the intervention to be warrant being tested on a larger scale and the measures identified would likely be adequate. The preliminary psychometric outcomes and important qualitative findings provide sufficient data to suggest that the intervention works in the way it is expected too, and that it does not have any hidden risks or particular barriers to intervention which could not be addressed with careful planning. Sufficient data is also provided to estimate sample size in future research. Given the established prevalence and changes in depression scores, if this were a target outcome, a larger controlled study would require a sample size of approximately 100-120 women per arm to provide >90% power to detect a five point difference in depression scores.

The add-on approach for high risk populations is not only feasible and acceptable, but it is also likely to be reasonably cost effective, and investment gain increases in a relatively short period of time. However, many variables would need to be considered in determining whether generalist (all CCGs) or specialist (a select cadre) of CCGs were trained to deliver the intervention; and/or whether all CCGs were trained to only deliver to a small group of high risk mothers and if so what approach is formalised to defining

high risk. Given that all approaches have relative advantages and disadvantages in either in the short, medium or long term, it is clear that establishing the best model requires a full detailed costing exercise using accurate and specific estimates, which goes beyond the scope of this pilot study. However, we recommend that district health services will need support and guidance on how to structure the-add on within current more generalist management approaches should the recommendation be to shift away from this model.

In conclusion, this pilot study demonstrates that if integrated successfully into DOH structures, Ibhayi Lengane has the potential to increase the quality of CCG work at a community level, to improve maternal mental health, and could act as an important early warning system for highly vulnerable families. Intervening in these highly vulnerable populations has large potential to improve maternal and child health, reduce morbidity and mortality, and in the longer term to improve child development. Furthermore, the levels of risk amongst these families also make the delivery of Ibhayi Lengane achievable at a reasonable cost, relative to the expected gains.

The recommendations following this pilot study are:

1. Given DOH support, and positive preliminary results, we recommend proceeding to test the intervention at a larger scale in a controlled study.
2. Given the identified gap around ward and district level implementation systems and approach we recommend that the Ibhayi Lengane package be augmented to include an implementation planning module to guide district managers and primary health care coordinators on implementation approaches.
3. Given the importance of determining the best model of investment in CCG delivered services such as Ibhayi Lengane, we recommend that a full economic costing of a range of models be undertaken before determining the recommended model of delivery.
4. Given the importance and success of a simple low intensity supervision system, we recommend that the supervision systems proposed for Ibhayi Lengane be better integrated into the existing health structure to broaden the scope and content of supervision of CCG and to enable higher quality support for referrals.

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