

Implementation of a multi-city preconception care program in the Netherlands - within the Healthy Pregnancy 4 All program

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ABSTRACT

Backgrounds Programmatic preconception care was implemented in 10 municipalities in The Netherlands within the Healthy Pregnancy 4 All program. The program aimed to promote preconception health by 1) engaging municipal stakeholders 2) delivering a four-pronged recruitment strategy to promote uptake of preconception care consultations and 3) delivering standardized preconception care by general practitioners and midwives in the community. Aim of the current study was to evaluate implementation.

Methods Process evaluation was performed according to Saunders' guideline for process evaluation. Process implementation measures were scored by triangulating data from several program data sources. Qualitative analysis was performed to identify promoting and impeding factors for implementation.

Results Overall implementation was good but varied per component across municipalities. The program succeeded in engaging municipal stakeholders sufficiently in 9 municipalities. Implementation of the recruitment strategy was good regarding 3 of the 4 recruitment components. Regarding delivery of preconception care, participation was adequate in only 5 municipalities, but criteria for the delivery of standardized consultations were met in 9 municipalities. Factors that influenced implementation were lack of local networks, low sense of ownership, and training and logistical support to resolve the complexity of preconception care.

Conclusions Preconception care in a municipal healthcare setting is achievable but the landscape for preconception care needs (further) construction for optimal effectiveness. Dedicated networks between preventive and curative health care professionals are essential. Knowledge brokers need to provide continuous support whilst strategies are tailored locally. Concentration of the delivery of care amongst a few caregivers needs to be considered.

INTRODUCTION

Preconception care (PCC) is defined as a program or a set of interventions that aims to reduce biomedical, behavioral, and (psycho)social risks present amongst parents in order to improve the health of their future child.¹ Examples of risk factors are inadequate folic acid supplementation, obesity, medication and chronic medical conditions.

Rationale for PCC is that exposure to ‘preconception risk factors’ in the first trimester is associated with perinatal mortality and morbidity. Different pathways have been identified through which preconception risk factors influence embryonic health, new born health and health in adulthood.² Antenatal care is mostly too late for preventive measures because risk factors are likely to have negatively influenced fetal organogenesis and programming before the first antenatal consultation.³ Although the concept of PCC has taken flight as of the 1980’s, it is still only happening on a small scale.⁴⁻⁶

The Healthy Pregnancy 4 All (HP4All) program was initiated by the national Ministry of Health, Welfare and sports to reduce the relatively high perinatal mortality rates and inequalities in perinatal health in the Netherlands.⁷ The program selected 2 interventions: preconception care and a novel risk assessment approach during pregnancy. This manuscript focusses on the preconception care (sub)program, referred to as the Healthy Pregnancy 4 All (HP4All) – PCC program. Within the PCC program a community-based approach for preconception care was implemented within neighborhoods with disadvantaged perinatal health statistics.^{8,9} Parallel to performance of the PCC program, studies were conducted iteratively to evaluate the effectiveness of the program in terms of outreach and changes in preconception health risks and to evaluate the implementation process.^{10,11} This current study evaluates the implementation process of HP4All’s PCC program within the 10 participating municipalities. It aims to provide information about best practices on community-based PCC for formative purposes.

Backgrounds

The HP4All program is a structural intervention that aims to achieve changes in preconception health behavior by intervening within the environment of preconception women by 1) engaging municipal stakeholders 2) delivery of a recruitment strategy to promote uptake of PCC consultations and 3) delivery of standardized PCC by general practitioners (GPs) and midwives. The program is summarized graphically in **figure 1**.

Component 1: engaging municipal stakeholders

The importance of PCC was recognized at a national policy making level.¹² A national HP4All program team was formed within the Department of Obstetrics and Gynecology of the Erasmus MC. Within this team, two program directors, two program managers and one PHD student

were dedicated to the design, guidance of implementation and evaluation of the program. They functioned as organizational change agents to facilitate local stakeholders to implement the program. This strategy complies with knowledge brokering strategies, in which research generated knowledge is translated to the practice field.¹³ Municipalities with perinatal mortality and morbidity rates above the countries national average were selected for participation.⁹ To create commitment in the municipalities to participate, local Aldermen were informed about these rates in there municipality and the solution of implementing a PCC program. After participation was agreed upon, the municipality was asked to allocate a municipal program manager to guide local rollout of the program. The program chose this strategy to promote responsiveness and sustainability of the program. Based on perinatal mortality and morbidity rates and local health goals of the municipality neighborhoods were selected for local rollout of the program.

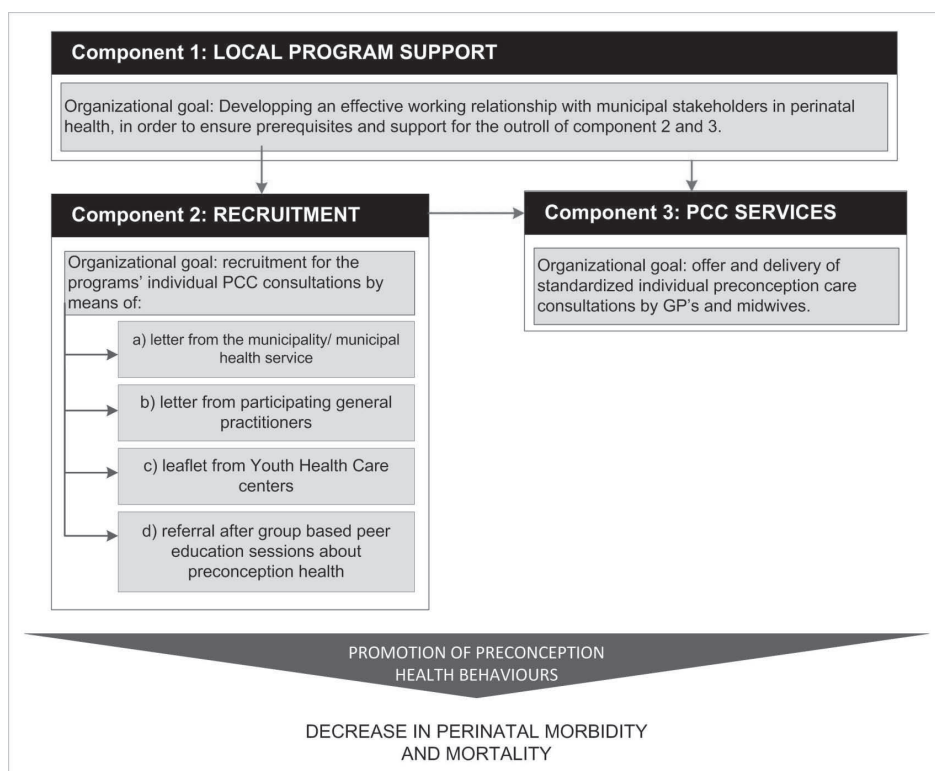


Figure 1: The program components in Healthy Pregnancy 4 All's – Preconception care sub-study

Component 2: delivery of a recruitment strategy

Several studies have shown that it is challenging to achieve uptake of PCC consultations.¹⁴⁻¹⁶ Therefore, a recruitment strategy was employed to create awareness about the availability of the PCC consultations amongst women of reproductive age.⁸ A four-pronged recruitment strategy was implemented: 1) an invitation letter sent by the municipal health service; 2) an

invitation letter sent by participating GPs; 3) provision of a leaflet by Youth Health Care providers to parents during routine check-ups of their six months old child; 4) referral by preconception health educators after group education sessions about preconception health. Money was allocated to implement the peer health education approach in six municipalities, whereas the other recruitment approaches were intended to be implemented in all municipalities.

Component 3: Delivery of individual preconception care consultations

PCC is delivered as individual consultations. The consultations consist of two visits. In the first visit risk assessment is performed and a plan is made to address risk factors conform the national guideline.¹⁷ Three months later, a follow-up visit takes place. The consultation is performed with existing tools: ‘the Preparing for Pregnancy’ questionnaire (‘Zwangerwijzer’ in Dutch) and the complementary software program ‘the Preconception Appointment Tool’ (‘PreconceptieWijzer’ in Dutch).¹⁸⁻²⁰ The questionnaire is filled in by couples on internet or paper prior to consultation. Consequently, the PCC provider can upload the emailed questionnaire into the corresponding Preconception Appointment Tool. This tool provides a summary of detected risk factors, relevant protocols and patient information leaflets. The tools standardize risk assessment and intervention. GPs and midwives known to deliver care in the neighborhoods were approached to participate as PCC delivery center. They were asked to appoint one or two PCC providers in their practice. They were provided with a face to face training about the use of the tools and a self-study about the contents of PCC. During the program, the national program team was available for remote support for the consultations. Consultations were reimbursed by the program.

Setting and context of the HP4All PCC program

The PCC program is set up within disadvantaged neighborhoods in ten municipalities (Almere, Amsterdam, Enschede, The Hague, Heerlen, Groningen (including five smaller municipalities: Appingedam, Delfzijl, Menterwolde, Pekela, Groningen City), Nijmegen, Schiedam, Tilburg and Utrecht). Five municipalities of Groningen were clustered in the study as one municipality, because they proved to be one implementation unit. Municipalities were selected after a geographical analysis of perinatal outcomes in the Netherlands.⁹ Characteristics of municipalities are displayed in **table 1**.

Table 1 Characteristics of the participating neighborhoods within participating municipalities

Characteristics	A	B	C	D	E	F	G	H	I	J	Total
Female residents 18-41years	45801	27030	11347	6492	4696	14594	21894	13081	15533	5147	165615
Deliveries / year	2896	2148	803	379	361	967	1359	734	1076	336	11059
Number of GP practices (participating)	46 (17)	50 (7)	17 (2)	5 (1)	4 (3)	18 (3)	16 (2)	15 (5)	3 (3)	9 (3)	183 (46)
Number of midwife practices (participating)	8 (7)	4 (2)	8 (7)	3 (3)	1 (1)	4 (4)	3 (2)	6 (6)	4 (4)	2 (2)	43 (38)

The program is rolled out within existing public health settings and curative health settings.

- *Municipal health services.* Participation in a PCC program is new for municipalities. Besides promotion of healthy lifestyle during pregnancy and breastfeeding, municipalities and their municipal health services have a very limited role in perinatal health in the Netherlands.¹² Municipal administrative records are used for preventive healthcare purposes (e.g. sending an invitational letter for the cervical cancer screening program and child vaccination program), but have not been used for PCC before.
- *Youth Health Care Centers (YHC):* YHC is a subdivision of the Municipal health service that effectuates screening and preventive health care for children aged 0 - 19 years (e.g. hearing tests and vaccinations). Therefore, YHC has a large outreach to parents for interconception care – or preconception care between subsequent pregnancies. Prior to our program YHC unfamiliar with PCC.
- *Peer health education:* *Peer health education* is defined as teaching or sharing of information with regards to health and healthcare by a peer.²¹ Prior to the program, some municipalities had peer health educators –predominantly targeting ethnic minorities - to deliver health promotion activities.²² They had not provided peer health education about PCC. It was foreseen that peer health educators had to be recruited and/or trained for delivery of peer health education about PCC. The national program team provided training to candidates selected by the municipalities.
- *General Practice* in the Netherlands can be considered as advanced. They are the gatekeepers to refer patients towards secondary and tertiary hospital-based care delivered by specialists. With regards to perinatal health care, GPs involvement in routine obstetric care is minimal and mostly limited to non-obstetric health issues during pregnancy. Women are not accustomed to visit a health professional when planning a pregnancy. The Dutch professional organization for GPs has provided a guideline for the contents of PCC.²³ GPs are familiar with sending letters about several preventive health services (e.g. influenza vaccinations). Sending invitational letters about PCC has only been implemented within studies.^{15, 24}
- *Midwives* are the primary caregivers in the perinatal health care system, which is tiered in the Netherlands. They provide perinatal health care (from care in the preconception phase to parturition and postpartum care) to low-risk women autonomously. Depending on the nature of (risk for) pathology they refer to Gynecologists or GPs. Midwives are mostly organized in community based practices. PCC has been integrated in midwives' curricula and certified trainings about PCC are available. A PCC guideline was published in 2005.²⁵

METHODS

This PCC process evaluation is based on Saunders step by step approach for process evaluation of complex interventions in organizational settings.^{26,27}

Development of the process evaluation plan

Basis for the process evaluation plan is the intervention and the mapping of the implementation strategy within its context (step 1). This is included in the background section. As Saunders recommends, we drafted a logic model to break the program strategy into actions that need to happen for the required event to occur. This logic model is presented in **Table 2a**. In a next step (step 2), we clustered process evaluation measures into implementation components: dose delivered, dose received, fidelity, and outreach (see **Table 2b**). Dose delivered (labelled 'input' in **Table 2a**) describes to what extent the HP4All team delivered the specified actions to initiate the implementation strategy. Dose received ('immediate impacts' in **Table 2a**) explains to what extent municipalities responded to the dose delivered. Fidelity ('short term impacts') explains to what extent the intervention was implemented as originally planned. In turn, this was expected to result in outreach of the program components ('organizational outcomes'). The process measures were chosen such that process evaluation would answer the following three broad implementation questions. Firstly, we aimed to assess to which extent the program succeeded in forming a local team to stimulate program adoption and implementation by local stakeholders (Component 1: staff) Secondly, we aimed to assess the extent to which local teams functioned effectively to employ the recruitment strategy (component 2: recruitment). Lastly, we aimed to evaluate the extent to which the program delivered PCC as intended (component 3: delivery of individual PCC consultations).

The process evaluation measures were evaluated by means of several formulated questions (step 3). These questions and the scoring system of the outcomes were formulated iteratively by the national program team.

Developing criteria for implementation

Desired implementation levels were formulated per process measure and per implementation component overall (dose delivered, dose received and fidelity and completeness) (step 4). We set the implementation criteria at 100% for dose delivered as these items concerned our own activities and at 60% for the other process evaluation components (dose received, fidelity and outreach). Our decision to apply a 60% criterion was based on a review by Durlak and Dupre, which states that program implementation rates above 80% are rare and rates of 60% produce an effective program.²⁸

Table 2a. Logic model: The inputs and their effects throughout various steps of the implementation process

Program component:	Inputs:	Immediate Impacts:	Short-term Impacts:	Organizational outcomes:	Individual Behavior Outcome
<p>1. HP4All local municipal program manager The HP4All staff serves as organizational change agents in the participating municipalities. They provide the resources and engage the networks to effectuate the other program components.</p>	<p>The national HP4All program team (of the Erasmus MC) will request a municipal program manager, as a local stakeholder in the perinatal health situation and interventions.</p>	<p>This will lead to allocation of resources to have a municipal program manager for the course of the project.</p>	<p>This will lead to the continuous availability of a municipal program manager that is involved as local spokesperson for the implementation and support of the program.</p>	<p>This will lead to an effective collaboration between municipal program manager and the national program team so the local health network can be mobilized to participate in their role as recruitment partners or preconception care providers. Positive effects of the program will be sustained in the future.</p>	
<p>2. The HP4All recruitment component a) the mailing of a municipal letter b) mailing of a letter to patients in participating General Practices. c) provision of information leaflets in the routine follow-up by Youth Health Care centers d) provision of peer group education sessions about PCC and referral to PCC</p>	<p>The national HP4All team will discuss recruitment methods with the municipal program manager. The national HP4All team will deliver resources for the effectuation of the recruitment process.</p>	<p>This will lead to agreement with the municipal program managers and the process to effectuate the recruitment process will be initiated firstly by approaching recruitment partners and agreeing on the recruitment approach. Where applicable recruitment partners will facilitate resources to effectuate the recruitment strategy.</p>	<p>Recruitment partners are ready to implement their recruitment role as predefined.</p>	<p>This will result in outreach towards the local population about the availability of PCC services in their community.</p>	<p>Uptake of individual PCC consultations at created PCC services</p>
<p>3. The HP4All individual PCC consultations Delivery of standardized individual PCC consultations responsive to needs of couples contemplating pregnancy</p>	<p><i>Participation:</i> The national HP4All team will collaborate with the municipal program manager to approach GP's and midwife practices to participate in the program as PCC providers. <i>Standardized PCC:</i> The national HP4All team will develop training, deliver tools and provide continuous support for the provision of standardized PCC consultations.</p>	<p><i>Participation and standardized PCC:</i> This will lead to availability of PCC service points, if GP's and midwives agree to participate in the program. PCC providers will be able to undergo training in order to be ready to deliver the PCC as intended.</p>	<p><i>Participation and standardized PCC:</i> PCC providers will be able to deliver PCC consultations as intended when (recruited) couples register for an appointment. They will evoke support where necessary, in order to do so.</p>	<p><i>Participation and standardized PCC:</i> This will result in delivery of PCC, and hence health promotion because of standardized individual risk assessment and formulation of an individual plan to improve the chances of a healthy pregnancy</p>	<p>Behavioral change regarding present risk factors will lead to improved health in the preconception period, which is likely to improve perinatal health outcome.</p>

Table 2b: Process measures: Measures of implementation throughout the various steps of the implementation process

Program component:	Dose delivered	Dose received	Fidelity and completeness	Outreach	Individual Behavior Outcome
1. HP4All local municipal program manager	<ul style="list-style-type: none"> The extent to which municipalities were approached to recruit a municipal program manager. 	<ul style="list-style-type: none"> The extent to which resources were allocated to appoint a municipal program manager. 	<ul style="list-style-type: none"> The extent to which there was availability and continuity of a municipal program manager. 	<ul style="list-style-type: none"> The extent to which the municipal program manager participated in the creation of local sustainable networks. 	<ul style="list-style-type: none"> uptake of the PCC consultation services amongst the target population.
2. The HP4All recruitment component	<ul style="list-style-type: none"> The extent to which the municipal program manager and the local recruitment professional were approached to discuss the recruitment strategy. 	<ul style="list-style-type: none"> Whether settlement was achieved with municipal program manager and the local recruitment professional to adopt the recruitment strategy. The extent to which prerequisites were met to effectuate the recruitment strategy. 	<ul style="list-style-type: none"> The extent to which each component of the recruitment strategy was effectuated as planned. 	<ul style="list-style-type: none"> Outreach of the recruitment strategy in terms of numbers of women reached. 	<ul style="list-style-type: none"> uptake of the PCC consultation services amongst the target population.
3. The HP4All individual PCC consultations	<p><i>Participation:</i></p> <ul style="list-style-type: none"> The extent to which practices are approached for participation. <i>Standardized PCC:</i> The extent to which training is developed and delivered to all PCC practices. The extent to which access to tools is provided. The extent to which measures were taken to reinsure the availability of continuous support for PCC care providers in their delivery of PCC. 	<p><i>Participation:</i></p> <ul style="list-style-type: none"> The extent to which approached practices agreed to participate as PCC providers. <i>Standardized PCC:</i> The extent to which PCC providers completed training. The extent to which PCC providers attended the tools training and felt competent to use the tools The extent to which PCC providers felt supported. 	<p><i>Participation:</i></p> <ul style="list-style-type: none"> The extent to which PCC consultations were available continuously. <i>Standardized PCC:</i> The extent to which PCC providers ensured continuous access to the tools The extent to which PCC providers evoked support when necessary. 	<p><i>Participation:</i></p> <ul style="list-style-type: none"> The extent to which PCC consultations were delivered. <i>Standardized PCC:</i> The extent to which the consultations were delivered with the 2 tools. 	<ul style="list-style-type: none"> The extent to which PCC consultations promoted behavioral change regarding PCC risk factors, amongst women that attended the PCC services.

Data collection and organization of data

Two authors (SVV and MS) extracted and triangulated data on the process evaluation questions into spreadsheets (step 5). They scored the extent to which items were implemented per municipality according to scoring criteria per item (see **Table 3**). In case data was collected on the level of practices, scoring was averaged on the municipal level (pooling GPs and midwives). In case of disagreement between the two, opinion of a third author (SD) was sought to reach consensus.

Data was collected between September 2011 to July 2015. We triangulated data from the following data collection sources for this process evaluation (also see **Table 3**):

- *Logs and program administration files* in which chronologic events were collected by the national program staff.
- *End of program interviews* held with all municipal program managers (response rate 100%), one purposively sampled peer educator per municipality (response rates 100%), one purposively sampled YHC coordinator per YHC organization in the municipalities (81,8% of the YHC organizations in 9/10 municipalities), one caregiver from each participating midwife practice (94,1% of midwife practices, covering 10/10 municipalities) and GP practice (response rate 61,7% covering 9/10 municipalities). The interviews were structured by the process evaluation measures of **table 2**. Additionally, we asked respondents about constraints and facilitating elements to identify factors that influenced the implementation. These answers were transcribed and organized per topic in a spread-sheet.
- *Registration forms for peer-health educators* were filled in by educators after each education session throughout the entire intervention. This provided data about the location and date of the given session, the number of participants and how the participants were recruited. Response rate was 100%
- *The HP4All- PCC database*: All women who applied for PCC within the HP4All program were registered in the HP4All database (Gemstracker data monitoring system) from inception of inclusion (February 2013) until the end of the program (December 2014).[11]

RESULTS

Table 3 Presents the summary results of the process evaluation (Step 6 and 7).

Component 1: To which extent did the program succeed in forming a local team to stimulate program adoption and implementation amongst local stakeholders?

Overall implementation criteria for the staff component were met in 9/ 10 municipalities (see **table 2**). In the municipality (I) that did not meet overall implementation criteria, this was due to lack of compliance with process measures within *dose received* and *organizational outcome*.

This municipality did not finance a program manager for the desired time; the available program manager did not participate in the promotion of participation amongst local GPs and midwives, and did not attend collateral meetings with program managers. The latter meetings were meant to strengthen collaboration and exchange best practices for the efficiency of the program.

A barrier for implementation was that the program could not expand on existing relationships but new relationships needed to be developed and for a new purpose: collaboration in perinatal health. Program managers were mostly unfamiliar with midwives and GPs. When they had collaborated with GPs before, it was not with regards to perinatal health. Setting up new collaborations required a larger time investment than planned. Where originally the program wanted local program managers to lead the recruitment of professionals for the program, the HP4All program team needed to step in to a bigger extent than planned. End of program interviews revealed that program managers found the new relationships with GPs and midwives with regards to perinatal health one of the most important things the program had brought them as a municipal health service or municipality.

Another barrier was the tug of war between the wish of local program managers on the one hand to adapt the program to the local setting and the need to adhere to the study design for evaluation purposes on the other. This was exemplified by the following statement of one of the program managers *“The project was top down, and there was hardly any room to locally adopt the program.”* Program managers generally felt a low sense of ownership regarding the research component as their main priority was achieving local effectiveness. The desire to adapt the program was most profound with regards to changing the recruitment strategies locally. In the end, it was accepted that municipalities participated without adopting all components of the recruitment plan. The process negotiation and adaption required more time than foreseen. Furthermore, selective adoption of a strategy can also provide negativity to some participants. As one program manager said *“There were municipalities that clearly wanted to effectuate their own variation of the plan ... not all cities were role models.”* Program meetings with all municipal program managers were generally felt as positive and are perhaps good media to centralize discussions about local adoption.

Component 2: To which extent did the local teams form and function effectively to employ the 4 components of the recruitment strategy?

The municipal invitational letter

The program intended to send the municipal invitational letter to the target population in all the participating municipalities. The letter was sent in 7/10 municipalities, resulting in mailing 110.199 invitational letters to women aged 18 up to and including 41years in the selected

neighborhoods. Overall process evaluation criteria were met in all 7 municipalities that sent the letter (municipalities A, C, E, F, H, I, J, see **table 3**). They scored maximal with regards to defined criteria for dose delivered, dose received and the organizational outcomes. Six of the 7 municipalities fulfilled criteria required for the process to send the letters (fidelity and completeness). One municipality (I) that sent the letter did not meet these criteria because they sent the letters too late (up to 8 months before the end of the enrollment period). Where overall process evaluation criteria were not met (B, D,G) this was because negotiation did not result in adoption to send the letter.

Main factors that impeded adoption of the municipal letters was a low belief in the effectiveness of the letter combined with moral constraints that the letter could hurt women's feelings (e.g. in case of infertility). The Erasmus Medical Ethics Board evaluated the invitational letter and incorporated a sentence to address this: *"Maybe you do not have the intention to become pregnant. If this letter is inappropriate or painful for you, we apologize. It is definitely not our intention to be hurtful"*. This did not resolve the issue for all municipalities. Some found that utilizing the municipal administrative records to acquire addresses to send the letters was unsuitable. They feared complaints. In response, a sentence was added to the letter to explain that it was sent to all women aged 18 up to and including 40 years residing in selected zip codes. Additionally, municipalities were asked to facilitate a local service women could call in case of questions or complaints. The 53 complaints in the course of the program were resolved sufficiently in all cases; mostly by explaining the program. Low beliefs in effectiveness brought one municipality to set up an alternative recruitment strategy (a local campaign).

The most important promoting factor for the municipal letters was that the intervention was part of the programs protocol which municipalities had agreed upon. In 3 municipalities, the city council set up a debate to decide whether the municipality should send the invitational letter. Explanation of the programs rationale and its evaluation led to agreement to adopt the municipal letter. One program manager said in convincing policy makers, it was crucial to frame preconception health as a public health issue.

The invitation letter from General Practices

The program required all participating GP practices to send all their patients aged 18 up to and including 41 invitational letters. 23304 invitational letters were sent in all 10 municipalities by 30 practices (65%). One of 10 municipalities (D) met overall implementation criteria for the mailing from participating GP practices. Implementation varied amongst municipalities. Dose delivered was only met in 2/10 municipalities (D, J). Only these municipalities fulfilled the criterion that the municipal program manager was involved in engaging practices to send the letter. Criteria for dose received were reached in most municipalities (8/10 municipalities). In municipalities that did not meet criteria for dose received (C, H), this was because of lack of

adoption of the mailing by 3 practices which withdrew participation. Only one municipality (I) met criteria for fidelity. Fidelity was compromised because majority of practices (23 practices) sent the letter to a selection amongst the predefined target group rather than all women aged 18 to 41 in their practice (8 practices). Fidelity was also compromised because the letters were sent out later than planned. The organizational outcome was achieved in 3 municipalities (B, D, and G).

A promoting factor for implementation was pre-existing working relationship between the municipal program manager and local GP practices. Preexisting working relationships were seen more often in smaller municipalities in which it might be easier to build up and maintain relationships with GP practices. GPs were generally positive with regards to the mailing. However, several GPs found that the efforts of sending the letter would not outweigh the expected uptake. This was heard more often in practices which had experienced low uptake of PCC during the program so far. Low uptake was reported as a demotivating factor to either set up or keep up the required logistics for PCC. This led to withdrawal from participation by some practices.

It proved to be an impediment that GPs wanted to send the letter to a selection of their patients. This required a change in the process and led to delay of the mailing. Performing a selection amongst women aged 18 – 41 proved to be time consuming and technically challenging. The HP4All program team needed to perform the selection for many practices. GPs were required to report exclusion reasons. Most reported reasons for exclusion were: expected fulfilled family, subfertility, pregnant or postpartum, sterilization, or having an episode of disease (unspecified). Factors that facilitated the selection were the better acquaintance with patients in smaller practices, having up to date medical records and working with ICPC codes.

The Youth Health Care component

It was intended that YHC centers would give all parents a PCC information leaflet when they came for the regular appointment with their child aged 6 months. Overall process evaluation criteria for the YHC component were met sufficiently in 6 municipalities (A, C, F, H, I, J). Criteria for negotiation for the adoption of the YHC component (dose delivered) were met in all municipalities except for 3 municipalities (E, I, and H). This was because the municipal project manager did not initiate collaboration with the YHC. Rather, the national program team had to seek collaboration. Dose received was compromised because 3 municipalities did not adopt the strategy (B, D, G) or because implementation was not monitored sufficiently in 5 municipalities (C, E, H, I, J). The intervention was conducted sufficiently (fidelity and completeness) in 5 municipalities (A, F, H, I, J). Only 2 municipalities (E, F) performed the intervention continuously throughout the program. Furthermore, 1 municipality (E) did not use the flyer to recruit women and 3 municipalities (E, C, F) did not adhere to the planned moment of the intervention: the 6

month follow-up consultation. Organizational outcome was met in all but 4 municipalities (B, D, G, and F).

Main reason for YHC not adopting the strategy were conflicting reorganizations and consequent time restraints to 'pick up' another project. YHC professionals recognized the importance of PCC (on a scale of 1-10 from not important to important they graded the importance of PCC between 7 – 8). Reasons to adopt the strategy that were mentioned in the interviews, were the urgency for prevention and the potential large outreach that YHC could fulfill. Providing information about PCC complies with elements of the aim of YHC such as prevention, attention for the family of the child and starting care before the child is born. Some YHC providers suggested that PCC should therefore be integrated more in YHC, which would facilitate adoption.

Several barriers for implementation were identified. Firstly, the HP4All approach did not fit the YHC habit of a demand driven or personalized approach. Professionals need to tailor information for time effectiveness and to satisfy patients. Secondly, YHC professionals were not familiar with PCC. Thirdly, referral with the flyer was not routine procedure because of other priorities. Furthermore, there was hesitancy to give the flyer to everybody at the set time. Feelings of mingling with the private subject of parents' pregnancy wish as early as 6 months after birth of their last child were barriers. Lastly, interviews showed that about half of the municipal project managers were not acquainted with YHC providers. This may explain lower affinity and involvement with effectuation of this component.

The peer health education approach

We intended to implement the peer health education approach in at least 6 municipalities. Implementation of this component was assessed within the 7 municipalities that adopted the peer health component (A, B, C, D, E, F, and G). The strategy led to delivery of 147 preconception health education sessions with a total of 1796 participants. Overall implementation criteria for the peer health education approach were met in 5 of the 7 municipalities that implemented the strategy (A, B, C, E, and G). All 7 municipalities met criteria for dose delivered because the strategy was negotiated by the HP4All staff with all municipalities. All 7 municipalities met overall criteria for dose received; meaning they met criteria for adoption and required prerequisites. Notably, the prerequisite that program managers invested in network relationships between peer educators and PCC providers was not met in 5 municipalities (municipalities A, B, D, F, and G). This is noteworthy because it was contemplated to be an important step in creating a referral network to PCC consultations. Four municipalities satisfied overall criteria for the extent to which they followed the process as intended (fidelity and completeness). Fidelity and completeness was mostly compromised because training was only taken up as intended in 1 municipalities (E) and because only 3 municipalities (B,E,G) were ready to deliver peer health education within the desired time frame. Despite of adequate overall implementation

regarding dose delivered, dose received, and fidelity, the organizational outcome was only achieved in 3 municipalities (C, E, and G). This was due to the fact that only these 3 municipalities delivered more than 10 peer education sessions and only 3 municipalities (A, E, G) reached more than 100 participants. Lastly, only 3 municipalities (B, C, and E) stated to always refer to PCC consultations during the group sessions.

Factors that impeded adoption of the preconception health education strategy were lack of governmental funding to deliver the training and concerns regarding feasibility within the planned timeframe of the study. Adoption of the strategy was promoted by the fact that peer education is an intervention that fits the approaches of municipal health services. Five of the 7 municipalities that adopted the strategy already had an existing form of peer education. At the same time this may have troubled implementation during the program. It required adaptation of the training because the peer educators that were already providing peer education felt the training was redundant. Adapting the training to the needs of the educators that had different backgrounds, proved to be time-consuming and delayed implementation. Secondly, the integration of preconception health education into existing peer education is questionable for the effectiveness of the program. End of program interviews and peer education registration forms showed that preconception health was added into existing health education sessions rather than provided amongst specifically recruited groups of women aged 18-41. Not having sufficient time was stated as a reason for this strategy. Educators felt there was not enough time to develop specific recruitment strategies. Program managers found the concept of reaching a target group indirectly (e.g. informing grandmothers about PCC to reach their grandchildren) an acceptably strategy. This raises a debate about how we desire strategies to be synergistic in different ways.

Lack of network between peer educators and PCC providers impeded referral. End of program interviews showed peer educators were unaware of the programs' PCC services to which they could refer women. Additionally, peer educators said to refer outside of the programs PCC providers when women lived outside of the geographic regions of the PCC center and wanted to visit her own (non-participating) GP.

Component 3: To what extent did the program succeed in delivery of standardized PCC?

GPs and midwives were encouraged to offer the individual PCC consultations (*participation*) in a standardized format with the risk assessment tools and follow-up consultation (*standardization*). With regards to participation, overall process evaluation criteria were met in 7/10 municipalities (A, C, D, E, F, I, J). 100% of the midwife practices (n=41) in the selected areas were approached for participation; whereas 89% of GP practices (183) in the selected areas were approached. This led to insufficient dose delivered in 2 municipalities (B and G), where 39%

and 50% of the GP practices instead of the required 100% was approached for participation. Overall, participation was 88% amongst approached midwives and 28% amongst approached GPs. See **table 1** for participation rates per municipality. Dose received was low because of participation rates (<40%) for GPs in 7 municipalities (A, B, C, D, G, H, J). Criteria for fidelity and completeness were met in all but 1 municipality (B). This municipality did not want to deliver and evaluate PCC as set up in the program. Fidelity was reduced in other municipalities because 1) enrollments were not always converted into planned appointments (in A, D, F); 2) it was not regular policy to delivered PCC in two visits (A, C); and 3) women were not contacted in case of no show (C). Organizational outcome criteria were met in 5 municipalities (D, E, F, I, J). The other municipalities did not meet the criteria because the majority of practices had less than 5 consultations planned during the course of the program and second consultations were planned insufficiently (<60%). Overall, 43% of practices had >5 appointments for consultations. Overall adherence to planning of a second consultation was 41%.

Overall process evaluation criteria for standardization were met in all municipalities, except in one municipality (B), where no data were available for evaluation, as explained above. Dose delivered was scored 100% in all municipalities, meaning that all practices were provided with training material, access to the tools and support during the program. Criteria for dose received were met in all 9 municipalities with available data. Where dose received was reduced this was because less practices reported their providers to have conducted the self-study component of the training and to feel competent in the use of tools. One municipality (I) did not meet the criteria for fidelity and completeness because practices did not ensure accessibility to the provided tools and there was insufficient continuity in who provided PCC during the program. One municipality (D) did not meet the criteria for the use of tools because neither ‘the Preparing for Pregnancy questionnaire’ nor the ‘Preconception Appointment Tool’ was used consequently.

In the interviews, training and support regarding tools and delivery of PCC were reported as prerequisites. Providers generally felt capable to deliver the consultations with the tools of the program and there was satisfaction with technical support from the national program team.

Several barriers were identified regarding the fidelity of using the tools. Firstly, respondents noted lack of user friendliness of the ‘Preconception Appointment Tool’. Users experienced problems with logins, importing the ‘Preparing for Pregnancy questionnaire’ into the ‘Preconception Appointment Tool’ and documentation in the tool. Secondly, low uptake was a problem to gaining routine in the use of tools. Thirdly, PCC providers felt it was undesirable that tools were not integrated into their daily archive system for prenatal care. Once patients were pregnant, midwives found themselves performing antenatal risk assessment entirely again. Integration between systems was mentioned as a prerequisite for continuity of preconception and antenatal care.

Interviews also revealed several factors that contributed to lower feelings of effectiveness of PCC. Firstly, low uptake of PCC by women was felt as a barrier for their efforts to set up and deliver PCC. Low uptake was a barrier for gaining routine in the delivery of PCC. We experienced that this barrier varies largely amongst health care providers. Secondly, some providers felt the effectiveness of their activities was lower because they felt they did not reach the population that needed PCC the most. This was mostly explained because *‘those you want to reach with high risks are not busy with preparing for pregnancy.’* This is a philosophical barrier as it brings up the debate who would benefit most rather than what the benefit is of consultations for those who do utilize PCC. Thirdly, PCC providers felt effectiveness of their activities was lower because they were frequently confronted with risk factors they did not feel capable to address because the risk factors were beyond their scope (e.g. after kidney transplantation) or because they did not know where they should refer to (e.g. genetic consultations in case of congenital heart disease).

PCC providers reported that delivery of standardized comprehensive consultations was impeded by specific patient desires rather than the specific request for a PCC consultation. *“Women come to a consultation with other questions than for which we [health care providers] intend to deliver a PCC consultation”* Cases of women wanting to discuss fertility preservation, contraception, infertility or only one specific risk factor were often mentioned. In response, some PCC providers abandoned the comprehensive approach to only address the single risk factor. This may have reduced the measured effectiveness of the program because providers reported that they often did not register these consultations because they were not performed according to the protocol. It is unclear how many consultations this concerned.

Interview data showed promoting and impeding factors for the extent to which providers adhered to the follow-up consultation. Practices that had good follow-up rates mostly presented the consultation to include two appointments. Attendance was best when the follow-up appointment was made at initial enrollment. This could not be realized by practices that could not plan 3 months ahead. Some providers felt a follow-up consultation was redundant. Furthermore, many providers said the fixed period of 3 months did not always suite the detected risk factors and the period should be individualized. Providers also reported that patient related factors impeded the occurrence of the follow-up consultation: many patients became pregnant or patients do not want to plan 3 months ahead, and high risk patients have a known high tendency for no-show. In case women became pregnant, some PCC providers encouraged women to come for consultation as adherence to the PCC recommendations is more important than ever and it provides the possibility to form a bridge towards antenatal care. Others simply canceled the follow-up consultation.

With the structured design of the HP4All program we contemplated that GPs and midwives would be more motivated when the program was set up from local initiatives with the municipality. Interviews showed that needs and preferences regarding municipal collaboration or ownership varied. Some PCC providers stated they did not need any collaboration at all while others would have appreciated (more) collaboration (e.g. facility of preventive services for specific risk factors e.g. smoking cessation clinics or in recruitment).

DISCUSSION

Main Findings

This study describes the process evaluation of a comprehensive PCC program that aimed to promote preconception health in 10 Dutch municipalities. The analysis of process measures showed that overall implementation was good as 5 of the 7 program components met the implementation criteria in the majority of municipalities. The evaluation also identified variation in implementation success between the program components and the different municipalities which could contribute to understanding the impact of the program. Firstly, the programs components that were implemented insufficiently were the invitational letters from GPs and participation of GPs and midwives to deliver PCC consultations. Secondly, differences between municipalities were often a result of municipalities not adopting all PCC recruitment strategies.

Qualitative analyses contributed to identifying factors that facilitated and impeded the implementation. This showed on the one hand that training and continuous support is important. On the other hand, barriers are the lack of ownership of PCC of the different stakeholders, the lack of a network to collaborate in for the recruitment and delivery of PCC, and the extensiveness of delivering PCC which requires a learning curve.

Altogether, our evaluation suggests that PCC promotion in a preventive municipal healthcare setting is achievable but challenging as the landscape for PCC still needs to be constructed or fine-tuned to meet local needs.

Comparability to prior findings

Prior literature regarding the effectiveness of PCC mostly focusses on evidence for standardized interventions addressing a single risk factor.²⁹ Implementation is not evaluated in these studies. Furthermore, a large body of literature has emerged often describing the - expected rather than the personally experienced – barriers and facilitators regarding effectuation of PCC.³⁰⁻³² Pitfall in these studies is that the way PCC is organized is often undefined, making it impossible to relate implementation factors with actual organizational approaches for PCC. To our knowledge the HP4All – PCC program is the first to evaluate implementation in practice of a standardized com-

prehensive PCC program within the organizational context it was performed in. It is remarkable that this information is typically not reported. Not evaluating implementation provides the scenario for making ‘type III errors’ - where programs are seen as ineffective whilst implementation was suboptimal.³³ Furthermore, only looking at effectiveness and neglecting contextual factors can give rise to introduction of interventions in settings while they will be ineffective because of (unidentified) contextual factors. This manuscript illustrates the complexity of the introduction of PCC in different contexts. Recently, a national multidisciplinary guideline on PCC has been developed which focusses on content and collaboration. It appoints stakeholders to promote sense of ownership whilst it encourages local stakeholders to develop local approaches that suite local organizational structures.

Strengths and limitations

Triangulation of data from several sources or stakeholders provided the opportunity to verify data and to gain a more complete understanding of contextual factors that influenced the program.

A limitation of our process evaluation approach is that it was performed by the national program team. This theoretically gives room for bias. For example, implementation may be overestimated in cases where stakeholders would feel there was not enough trust to be open about how things really went in the program. Ideally, we would have had an outsider perform the process evaluation. This was not feasible. As a result, dose delivered was only evaluated briefly – in terms of which starting point was necessary for municipalities to commence with the programs implementation.

As the program was performed iteratively, data collection for the studies within the program was required. This required extra efforts and involvement in scientific research in which many stakeholders did not have prior experiences. This extra effort is likely to have influenced implementation negatively. End of program interviews often showed that stakeholders experienced difficulties in participating in the data collection. This reduced goodwill for overall participation. The studies were also reported as a barrier because it made that standardization was necessary and adoption to local wishes was limited.

The program has different organizational stakeholders of which it is unknown how they influence each other. We chose to analyze implementation per municipality and assume similar relationships to explore contextual factors explaining variations in implementation. A limitation of this approach is that in smaller municipalities with lower number of practices, (in)sufficient implementation is inflated at municipal level. At the same time, we believe this approaches reality as the local community had to rely on a smaller number of sources for PCC.

Implications of findings

There is room for improvement of implementation to improve effectiveness of PCC programs. This mostly requires the following changes in the landscape for PCC:

- Guidance of implementation from a knowledge broker is essential to close the gap between 'what is known and what gets done in practice.' With regards to PCC, lack of networks between curative and preventive health care, lack of sense of ownership, complexity in terms of the logistics and the vast contents of PCC might explain the latent introduction into practice. Knowledge brokers could fasten implementation by addressing these factors.

At the same time, it is a misconception that standardized approaches are sufficient. The variation in implementation we found in this study shows that there is a need to tailor standardized approaches to local contexts. We recommend the use of blueprints and implementation and iterative evaluation. It is likely to differ which partnerships' work best where.

- Future implementation strategies need to invest in achieving continuity between preconception and antenatal care. Practical arrangements – such as facilitation with IT technologies are essential - besides achieving a continuous risk concept amongst PCC providers.
- Concentrating where and by who PCC is delivered should be considered to ensure that PCC providers can mount the learning curve that is required to deliver comprehensive PCC.

CONCLUSION

Delivery of programmatic PCC is feasible yet complex. We identified several factors which could contribute to better implementation and higher effectiveness. Implementation of programmatic PCC requires a local municipal tailored approach for optimal effectiveness.

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