A. Cover page:

Title: **Supporting Clean Air for Babies: An organizational strategy to reduce perinatal smoking**

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Goal:

To reduce the prevalence of smoking before and during pregnancy and the first postnatal year among members of Meuhedet & their families.

Target population:

1. Women who are pregnant or planning a pregnancy, and their significant others, who are at risk of exposing their child to tobacco smoke during pregnancy and during the first year of life.
2. Physicians and health care providers in Primary Health clinics, Women's Health Centers, Fertility Clinics, Well Baby clinics, and telephone services

Methods

We will restructure and enhance the management of perinatal care related to smoking cessation and maintenance by increasing awareness, knowledge and self-efficacy among physicians, nurses and other caregivers who interact with women before, during and post pregnancy. In this way we are building long term capacity within the organization.

Using our existing computerized medical records database we will develop algorithms to identify our target audience. The stages of this program are:

1. Identification of women who planning a pregnancy
2. To design, implement and evaluate a training program for physicians and health care providers in the following settings:
    a. Women's health centers
    b. Fertility clinics
    c. Well Baby clinics
    d. Gynecologists visits
    e. Telephone services
3. To establish and disseminate tailored solutions for smoking cessation for women and their significant others, including relapse prevention services.

Assessment

This project will undergo evaluation at all stages: formative evaluation to maximize the potential of our intervention, process evaluation to allow in-depth analysis of all approaches, and outcome evaluation to assess efficacy and effectiveness.

B. Table of Contents

C. Reviewer Comments- there were no reviewer comments

D. Main Section of the Proposal

1. ***Overall Goal and Objectives***

The goal of this program is to reduce the prevalence of smoking before and during pregnancy and the first postnatal year among members of Meuhedet & their families.

The long-term strategy adopted by Meuhedet in 2012 is defined as "Being Healthy and Staying Healthy" and focuses on disease prevention. We have previously launched several projects aligned with this agenda. In 2012 we launched a telephone support service in the areas of weight loss and physical activity – the Active Health Call Center- together with a media campaign to encourage service use. The call center assisted hundreds of members to improve their lifestyle in the first year of service. In 2014 we launched Israel's first "Well Child Visits" program. We trained 200 pediatricians to perform health and development assessments and health promotion counseling during 30 minute visits, and refer children to developmental services, follow-up or parent group counselling if required. Children aged 2-6 years are proactively invited to their pediatrician for these visits, and since July 2014 we have conducted over 12,000 visits.

The strategic goals for 2016 include focus on women and children, as our organization has a relatively young membership and includes a large proportion of Arab and Jewish Ultra-orthodox populations, with high fertility rates. Establishing a long term strategy for smoking cessation before or during pregnancy is in alignment with both our long term strategy and our current goals.

Throughout the world we have seen an increase in smoking among women over the past decades, particularly among women in lower socioeconomic tiers, in contrast with a decrease among men in most developed countries. Across interventions, data are sparse to evaluate sustained cessation among pregnant and postpartum women. Approaches that combine multiple components will have the best likelihood of success. Selecting which components to include is more complex and should be based on the particular considerations of the clinical setting, including patient characteristics and resource allocation, but incentives demonstrated the greatest effect among components studied. Infant outcomes are limited to data collected at time of birth; no studies assessed longer term or child outcomes. Harms data were rarely reported[1]. Although there are smoking cessation programs that are appropriate for women, few of these address perinatal smoking.

If our program proves to be successful, we will be able to disseminate materials and methods for the reduction of environmental tobacco smoke among babies both in utero and during infancy to other countries with similar community health infrastructures.

Objectives

1. To increase awareness and motivate caregivers to address the issue of smoking and child health.
2. To improve knowledge, skills and self-efficacy related to smoking cessation counselling among caregivers who are in contact with women before and during pregnancy.
3. To increase documented smoking cessation counselling among caregivers during the perinatal period.
4. To decrease reported smoking among women and their significant others during pregnancy and the post-natal period.

2. ***Current Assessment of need in target area***

Active Smoking before, during and after pregnancy affects the mother and her child and can cause: reduced fertility, premature rupture of the membranes, placenta previa, and placental abruption, preterm delivery and shortened gestation, fetal growth restriction and low birth weight., congenital malformations, infant mortality, child physical and cognitive development and sudden infant death syndrome. [2]
There are currently no established programs or processes for the prevention of exposure to secondhand smoke of infants during pregnancy of after birth in Israel. According to an Israeli Ministry of Health report[3], 20% of Israeli women are smokers immediately before pregnancy, and 13% continue to smoke throughout the pregnancy. By the time the baby is 6 months old, 15% of mothers smoke. This is similar to figures reported for other countries[4]. As in some Israeli cultures, such as Arabs or Ultra- orthodox Jews, it is unacceptable for women to smoke, but smoking is common among men, it is not surprising that at the age of 2 months 25% of Jewish infants and 52% of Arab infants are reportedly exposed to environmental tobacco smoke[3].

Although smoking cessation is discussed during clinical interactions, this is done sporadically, and there is no organized referral pathway for pregnant women or for women planning a pregnancy. Most physicians and other health care professionals who care for women and children (gynecologists and pediatricians, nurses) have not had any formal training regarding smoking cessation counselling, nor are they formally and systematically encouraged to discuss these issues during healthcare encounters.

This program aims to establish a computerized, educational and organizational infrastructure that makes the identification, referral, counselling and follow-up of all women who smoke, or whose significant others smoke during their pregnancy in order to make smoking cessation during pregnancy part of routine primary care in the community.

Data on smoking among members are routinely collected by physicians and nurses using coded fields in our computerized medical records. According to our quality indicators we have data regarding smoking practice for 60% of our members, and 19% of them are documented smokers. We do not currently have the ability to

document smoking in pregnancy, or smoking among family members, and this will be part of the upgrade to our computerized medical record database for this project.

3. ***Target audience***

Meuhedet cares for 250,000 women of childbearing age. We have approximately 30,000 births annually. Of these women, about 10% smoke during pregnancy (Lower than the population rate due to cultural differences). In addition, approximately 30% of spouses are smokers. This leaves a target population of 3,000 women and 10,000 men who need to be approached. We envisage that we can reach most of these at least once during the perinatal period, and 300 women and 1,000 men will be referred for cessation interventions.

The target audience will be proactively recruited by all health care providers and administrative staff who come in contact with them. Every pregnant woman has an obstetrician who she visits several times during her pregnancy. Every year approximately 2,500 women are treated in our fertility clinics, 2,000 are treated at our high-risk pregnancy clinics, we conduct 180,000 obstetric ultrasounds, and approximately 6,000 have genetic counselling when planning a pregnancy. All of these interactions will serve as assessment and recruitment opportunities for our program.

The assessment and recruitment model within our program will serve any other services for women of childbearing age within Israel and in other countries. In addition to this, the infrastructure we build for the program will provide opportunities for other health promotion interventions for this population, such as nutrition, physical activity, child safety etc.

4. ***Project design and methods***

The stages of this program are:

1. To establish a process for the identification and targeting of women who are planning a pregnancy and are at risk of exposing their child to tobacco smoke during pregnancy and during the first year of life. The identification process will begin using data mining and text identification processes on our database.
2. To design, implement and evaluate a training program for physicians, health care providers and administrative staff in the following settings:
    a. Women's health centers
    b. Fertility clinics
    c. Well Baby clinics
    d. Obstetrics services
    e. Maternal support nursing services

    The education program will rely on existing smoking cessation experts within the organization who will undergo specific training related to smoking and pregnancy, and our 120 health promotion coordinators throughout the country.

3. To establish and disseminate tailored solutions for smoking cessation for women and their significant others who are planning a pregnancy, during pregnancy for women including relapse prevention services. Treatment will be provided by our broad base of smoking cessation experts.
4. Throughout all stages we will conduct internal marketing campaigns advertising the project at all organizational levels, using our organizational internal website, and Above and Below the Line advertising methods at our clinics, in order to increase awareness and cooperation from all staff.
5. Throughout all stages we will conduct data collection for the evaluation process as detailed below.
6. All educational materials developed within this program will be made available publicly at no cost.

5. Evaluation design

1. Formative evaluation: qualitative research methods (Focus groups and interviews with obstetricians and nurses and potential women) will be conducted to understand their needs and expectations of the program. All materials for patients will be validated with patient test groups.
2. Process evaluation:
    a. Education: Proportion of staff undergoing training for each group will be collected using routine computerized attendee methods used by our Human Resources Education department.
    b. Behavior change - staff: Data collection from our computerized medical records will include documentation of smoking status by providers, referrals to smoking cessation interventions, smoking cessation medication prescriptions and purchases and any other relevant information related to target population (All fields already exist in the records).
    c. Intervention process: Target population participating in smoking cessation groups will be obtained from our existing health promotion activities database.
3. Outcome evaluation The proportion of our target population who stopped or reduced smoking levels during the program will be obtained from several sources: patient medical records (part of the program changes to medical record code fields will include smoking cessation), documented status at the end of the group sessions within the health promotion database and a telephone survey of a random sample of participants throughout the project.

Approximately 50% of participants in our smoking cessation groups remain smoke free at 1 year. We expect, as our target audience is expected to be highly motivated due to upcoming parenthood a smoking cessation rate of 70% at the completion of the groups and 60% will remain smoke-free at our final evaluation. We envisage that this intervention will affect other family members and people who work or interact socially with our intervention group[6], so the program will have a greater impact than that on the initial target audience.

Upon completion of this project we will present the results and disseminate the report at all organizational levels. We will endeavor to present at national conferences (Health promotion, Obstetrics and Gynecology, Primary health Care, Nursing, Quality and Safety), and at appropriate international conferences.

6. Detailed Workplan and Deliverables Schedule

The project will be conducted over a period of 2 years. Initially we will prepare all the resources required for our intervention- educational materials for physicians, nurses, administrative staff, patients and the general public; we will make the required changes to our computerized medical records and our business information collection procedures to maximize data collection and evaluation procedures; we will prepare an internal marketing campaign with our in-house marketing department. During the second stage we will conduct education sessions for all relevant staff, and the first round of marketing, to increase awareness; we will also commence recruitment procedures. The third stage is the intervention itself, and over a period of 12 months we will conduct continuous smoking cessation groups and individual sessions. The last stage is the evaluation and reporting stage. This will be completed by our project team together with our in-house statistician in the Clinical Quality department.

The following table describes the project timeline:

Stage	**Topic**	**Deliverable**	**Q 1**	**Q 2**	**Q 3**	**Q 4**	**Q 5**	**Q 6**	**Q 7**	**Q 8**
Preparation	Materials	Course materials for health care providers	X							
	Materials	Course materials for administrative staff	X							
	Materials	Course materials for obstetricians	X							
	Materials	On line and printed materials for patients and family	X							
	Marketing	Internal campaign materials	X							
	IT	Adaptation to medical records infrastructure	X	X						
	IT	Establishing recruitment database of target audience in BI	X	X						

Stage	Topic	Deliverable	Q 1	Q 2	Q 3	Q 4	Q 5	Q 6	Q 7	Q 8
Staff education	Group workshops	Health providers education program		X	X	X				
	Frontal courses	Administrative staff program		X	X	X				
	Frontal courses	Health promotion coordinator program		X	X	X				
	Frontal courses	Maternity telephone support center nurses		X	X	X				
	Group workshops	Smoking cessation councilors update		X	X					
	Small group education	Obstetricians education program		X	X	X	X	X	X	X
Intervention	Internal marketing	Organizational awareness Campaign		X	X		X			
	Recruitment	Active patient recruitment from database		X	X	X	X	X	X	X
	Cessation support	Smoking cessation intervention group for patients and family				X	X	X	X	X
	Cessation support	Individual counseling sessions				X	X	X	X	X
	Cessation support	Telephone support nurses				X	X	X	X	X
Evaluation	Process	Staff participation in education programs, smoking documentation and patient recruitment and referral.			X	X	X	X	X	X
	Process	Patient participation in cessation support activity				X	X	X	X	X
	Outcome	Data collection of smoking cessation				X	X	X	X	X
		Data analysis								X
Reporting		Completion of report								X

E. References

1. Smoking Cessation Interventions in Pregnancy and Postpartum Care, Evidence Report/Technology Assessment, Number 214, Agency for Healthcare Research and Quality.
2. Surgeon General's Reports on Smoking and Tobacco Use, 2014
3. National Health and Nutrition Survey- Birth to 2 years. 2009-2012. Israeli Center for Disease Control, Ministry of Health, Israel, 2014. [Heb]
4. Chamberlain, C. et al, Psychosocial interventions for supporting women to stop smoking in pregnancy, Cochrane Database Syst Rev. 2014.
5. Park, ER. Et al. Primary Care Provider-Delivered Smoking Cessation Interventions and Smoking Cessation Among Participants in the National Lung Screening Trial. JAMA Intern Med. 2015 Sep;175(9):1509-16.
6. Christakis, NA & Fowler, JH, The Collective Dynamics of Smoking in a Large Social Network. N Engl J Med 2008; 358:2249-2258, May 22, 2008