



Feasibility Study of the Pregnancy Risk Assessment Monitoring System in Iran

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Abstract

Background: A surveillance system helps to detect epidemics and the pattern of the incidence of the problems in the community and is important for evidence based decision making. This study was conducted to determine the feasibility of the Pregnancy Risk Assessment Monitoring System (PRAMS) in Iran.

Methods: PRAMS feasibility was assessed in a cross-sectional study in the city of Shahriar, located in the west of Tehran in 2013. In this study, 811 women within 2 to 6 months postpartum who had a live or still birth were selected from thyroid screening forms and hospital records through a systematic simple random sampling method. Trained interviewers collected the data via calling mothers from health centers or through home visits. The outcome was tested on the "TELOS" model including technical, economic, legal, operational and schedule feasibility components.

Results: Thirty-seven health volunteers collected the data in this study. Many prevalence estimates were comparable with national and Tehran data (technical feasibility). A home based completed questionnaire cost 2.45 and a phone cost 1.89 USD (economic feasibility). The project was consistent with legal requirements (legal feasibility). The participation rate was 92.8% (95%CI: 92.7-95.3) for home visits and 90.9% (95% CI: 87.3-93.6) for the phonemethod. Over 80% of different sections of the questionnaire were completed (operational feasibility). All data collection processes took 35 days (schedule feasibility).

Conclusion: The adapted PRAMS could be considered feasible in Iran. Its widespread and periodic implementation can provide valuable maternal and child health information in the country.

Keywords: Feasibility study, Surveillance, Pregnancy, Iran

Introduction

During the past few decades, maternal and child health indicators have shown significant improvements in Iran. However, there are still some differences with developed countries. In Iran, maternal and child health data are collected using the

monthly health centers reports, census, civil registration, original studies, and rarely population based studies (1). Although the data covers very important indices of the country, some required data is not accessible from this database (2). On

the other hand, monitoring of the trend over time, evaluation of health systems performance, and achievement of valid and reliable indicators require a surveillance system (3).

The surveillance system is an essential component of evidence-based decision-making. It can help to estimate the prevalence and geographic distribution of health problems and to diagnose epidemics. This information should be reported to the authorities who are in charge of decision making in key situations as outside observers to recognize the requirements for planning and evaluating the health care system (4-6). The surveillance of maternal experiences and behaviors is essential to promote the maternal and society health (7). The maternal mortality surveillance system has been active in Iran since 2001 and was revised in 2006 (8), but it focuses on maternal mortality and not on pregnancy risks while according to a study, the most common risk factors in Iranian pregnant women are behavioral risk factors (9). Therefore, there has been a gap between existing surveillance system and a surveillance system with the goal of measuring maternal behavioral risk factors.

The Pregnancy Risk Assessment Monitoring System (PRAMS) is the only epidemiologic and population based surveillance system, which has been designed to monitor maternal experiences and behaviors among a sample of women who have had a recent live birth. This system was installed in 1987 by the Center for Disease Control and Prevention (CDC), aiming to reduce the infant mortality and low birth weight in the US. CDC considers this system as a successful program and has increased its fund to expand it over the years (10). For instance, the impact of health interventions on the breastfeeding rate (11), unintended pregnancy (12), and the achievements of Healthy People 2010 (13), Healthy People 2020 (14), and Millennium Development Goals (15) has been assessed based on this system.

Recently, the PRAMS feasibility was investigated in Europe and the US. In Ireland, hospital registration files have been used instead of birth certificates and the results have shown that the system is feasible in terms of the participation rate, costs, and schedule. Researchers in the US have reported

that this system is feasible at the local level more than the state level based on the participation rate, costs, and schedule of the new system (7,16,17). To the best of our knowledge, the PRAMS feasibility has not been assessed in Iran. The PRAMS data can be used by policy makers and health planners and to identify health inequalities. Moreover, establishment of the system makes it possible to track the progress and improvement of the outcomes due to health interventions and changes in the policies and programs in the areas of maternal and child health (18).

Therefore, this study was conducted to determine the feasibility of the PRAMS in Iran.

Materials and Methods

A feasibility study is the assessment of the potential impact of a project based on a research to help decision-making on doing or not doing it (19). Project feasibility is usually tested on "TELOS" (Technical, Economic, Legal, Operational and Schedule) components (20). PRAMS feasibility components were reviewed in a cross-sectional study as follows and a summary is shown in Fig. 1.



Fig. 1: Pregnancy Risk Assessment Monitoring System (PRAMS) feasibility study and each component's criteria

Technical feasibility means that what are the software and hardware prerequisites of the project. The PRAMS protocol was studied and the protocol components were specified. A panel of six experts in various areas of social medicine, epidemiology, obstetrics and gynecology, internal medicine, pediatrics, and reproductive health was held in order to adapt the PRAMS system and methods in Iran. Then, input containing information about similarities and differences of the two communities on the pregnancy risks and outcomes, prenatal care organization and protocol components was presented to the experts, and appropriate approaches for any difference were proposed by experts. The solutions were combined and the best ones were chosen.

Sampling: The sampling frame was constructed at first and the cases were then selected randomly. Thyroid screening forms were collected from all health centers in Shahriar, in the west of Tehran, where thyroid screening was performed. Hospital registration forms were searched for all stillbirths or infants who died shortly after birth in all hospitals of the city and 33 dead infants were included in the sampling frame.

The records of the Department of Health were searched further for the cases that might not have been registered. From this frame, 4120 live or dead children were identified from 4059 mothers. Systematic simple random sampling was used to select the cases (Fig. 2).

Inclusion criteria: Mothers within 2 to 6 months postpartum who had a live or still birth in Shahriar.

Exclusion criteria: Only one sibling of multiple births was included and multiple births containing four or more siblings were excluded. Adopted infants whose mothers' names were recorded as the adopting mother were excluded. Surrogate births were also excluded. If the name of the carrier was available, she could participate in the study.

No tools were used for measuring the outcomes of this study. The latest version (2009) of the core PRAMS questionnaire was adapted for using in future program. The cross-cultural adaptation, reliability and validity of the questionnaire were assessed in 5 steps as follows (21):

Step one: Forward translation. The instrument was translated by two independent translators from English to Persian.

Step two: Synthesis. Two translators and one recording observer synthesized the results of the translated instrument.

Step three: Backward translation. This version of the instrument was translated back to English by two independent translators from step one. Then, the instrument was sent to one of the main designers of the questionnaire in CDC in 2009 to confirm the consistency of the translated questionnaire with the original questionnaire.

Step four: Review of the experts committee. The instrument was assessed by experts and after collecting the experts' feedback, corrections and modifications were applied.

Step five: Pretest. The final version of the questionnaire was tested on 30 eligible women with a tool named "Question Appraisal System" (18); and unclear questions were modified. The reliability of the final version of the questionnaire was confirmed by test re-test in a period of two weeks with a kappa coefficient of 0.71 for qualitative variables and Pearson coefficient 0.74 for quantitative variables.

Economic feasibility discusses the project's operation costs and its reasonability.

The project's operation costs included instrument preparation costs, collecting the sampling frame, sample selection and packaging questionnaires, health volunteers' education and data collection costs and subsequent costs related to data processing. The reasonability of the costs was determined based on the comparability of the data with national and provincial information.

Legal feasibility addresses any inconsistency between the project and legal requirements. In this section, consistency between the project and legal requirements was assessed. Each question was examined in this regard. In addition, in order to obtain the necessary permissions for implementing the project, the project method and instrument were reviewed and accepted by the security system of the Iran University of Medical Sciences and Social Security Organization.

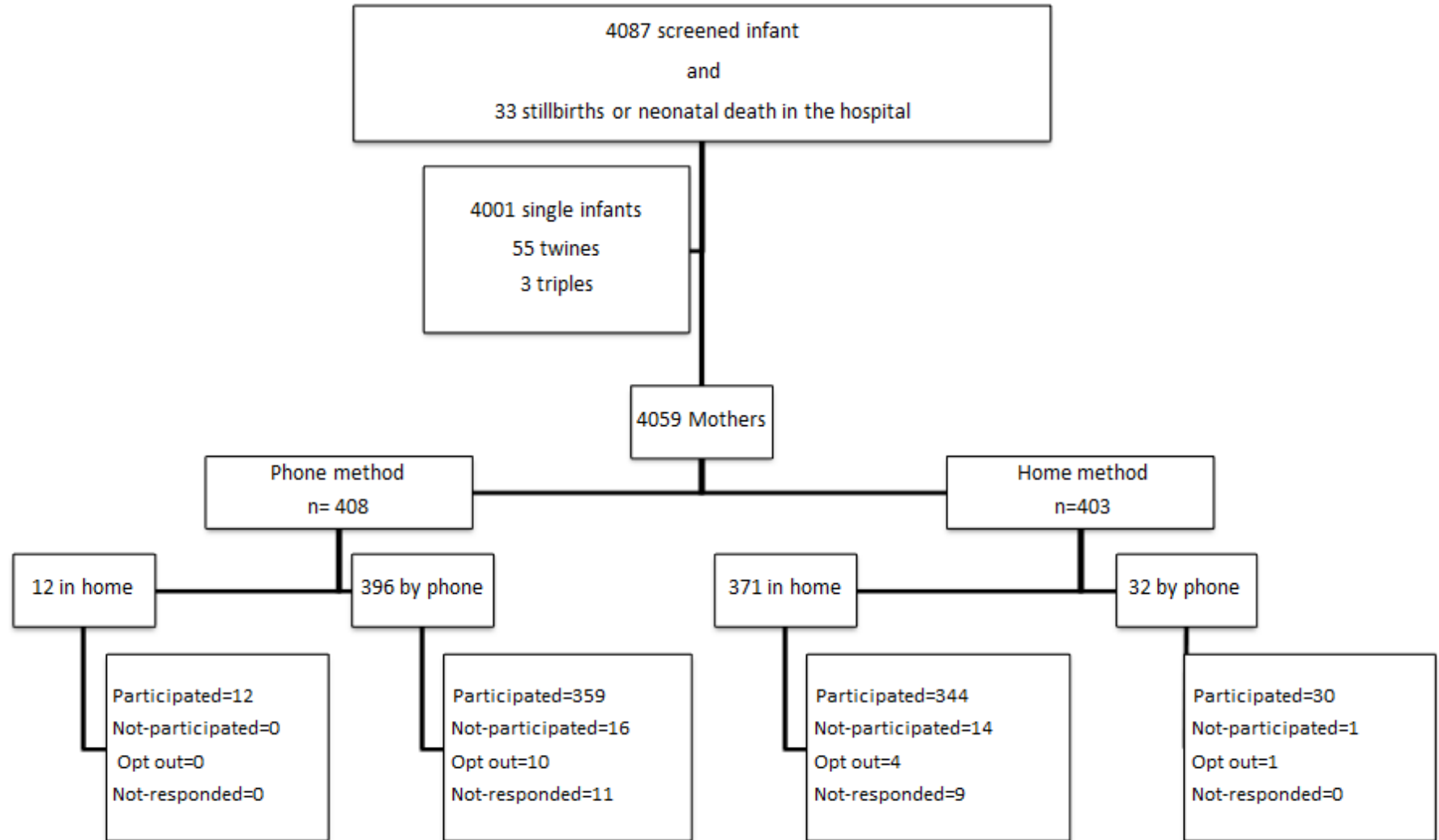


Fig. 2:Flowchart of the study participants

During the project implementation, the confidentiality and privacy of the mothers was maintained while the health volunteers contacted the mother's family or friends. Before completion of the questionnaire, the health volunteer read an informed consent text with introduction to the participant and asked clearly whether they wished to participate in the study and recorded the mother's consent. The study protocol was approved by Shahroud University of Medical Sciences and Health Services, No. 920,168.

Operational feasibility discusses whether the project is appropriate for the current environment with regard to the cultural participation, and current health practice and procedures.

For data collection, the necessary conditions were first prepared. Posters were placed at all health centers to inform people about the project and how to contact the main investigator. The address of each study sample and the related health centers where she lived was determined. The health centers officials were contacted and asked to introduce some health volunteers for data collection based on the number of samples in each center. Financial incentives for cooperation of health volunteers were considered. In coordination with health department, ID cards with a photograph were issued for the health volunteers. The health volunteers were trained in two sessions in the health department. Data collection was performed between November and December 2013.

Landline and mobile phone numbers of the mothers, husbands, or other family members and their mail address were retrieved from hospital records and thyroid screening forms in order to access the samples when there were troubles with the telephone call or if the telephone number was changed. In the telephone method, the participants were contacted up to 15 times in different times of the day and on different days of the week. Health centers phones were used for contacting in working hours. Date, time and results were recorded in the phone checklists. In home visits, health volunteers went to the houses and completed the questionnaires through face-to-face interview.

Schedule Feasibility discusses whether the project can be implemented on time.

According to the protocol, in order to maintain data integrity, data collection should not take more than three months, and the questionnaires, which are completed after nine months of birth, should not be accepted because of the probability of recall error. By timely sampling and implementing data collection procedures, very few cases, if any, should be completed after six months of birth. The duration of data collection was calculated from health volunteers training until returning the completed questionnaires and check lists.

Analysis

The participation rate of the mothers, duration of data collection, and costs of each method were assessed with descriptive analysis. Using the data in the sampling frame, samples were compared with the population, and participants were compared with non-participants. Chi-square or Fisher exact test were used for qualitative variables and independent t-test or Mann-Whitney test were used for quantitative variables. The rate of missing data for each question was calculated descriptively to determine the completeness of responses per question. Some comparable results of this study were compared with the results of "Islamic Republic of Iran's Multiple Indicator Demographic and Health Survey (IrMIDHS)", a national survey conducted in all provinces (22). Because Shahriar is a city in Tehran Province, the results of this study were compared with Tehran and national population in the IrMIDHS study descriptively.

Sample size: Assuming that at least 50 percent of the samples had good participation and to evaluate which of the two methods of data collection, i.e. home visit or phone methods, was better with a minimum difference of 10%, confidence interval of 95% and power of 80%, approximately 400 samples were required in each group.

Results

Technical feasibility: Thirty-seven health volunteers from different parts of Shahriar collected

data with the instrument described in the Methods section. The mean age of the health volunteers was 34.6 years (Standard Deviation 7.5). They had high school diploma, 94.5% of them were housewives and the majority of them (86.5%) were married. The mean age of the participants was 27.6

(5.2) years, 17.8% of them had primary school education or were illiterate, most of them were housewives (92.7%), many of them lived in rented houses (52%) and owned a vehicle (51.5%). About 57% of the mothers received prenatal care in non-governmental sectors (Table 1).

Table 1: Characteristics of the study participants

Variable	Number	Percent
Mother's age (year)*	27.6	5.2
Mother's job (housewife)	689	92.7
Mother's educational level ^a		
Illiterate or elementary school	130	17.8
middle school or high school	192	26.3
Diploma and higher	407	55.8
Type of housing ^b		
Homeowner	295	39.7
Rent	386	52
Others ^c	62	8.3
Car ownership (yes)	383	51.5
Multiparity (yes)	390	52.5
Pregnancy intention (yes)	499	64.2
Location of receiving prenatal care ^d		
Governmental	261	35.1
Non-governmental	420	56.6
Both	57	7.7
Not at all	6	0.8

* Mean \pm SD/a, b, d The number of subjects was not exactly 745 because of missing subjects
c other includes living in father in law's or mother in law's house

Economic feasibility: The total costs of the study were approximately 2166.69 USD. Non-staff costs were 198.61 USD and the rest of the costs were staff costs. Each phone based completed questionnaire cost 1.89 USD and each home based completed questionnaire cost 2.45 USD. It should be noted that these costs could be different depending on the market prices.

The participants of this study did not differ with the national population in the literacy rate, receiving midwife-led care and breastfeeding initiation while the health insurance rate, unmet needs of family planning, caesarean section and smoking hookah were more than national and Tehran pop-

ulation. In addition, they gave birth at home and had low birth weight infants less than the national population (Table 2).

Legal feasibility: The project was consistent with legal requirements.

Operational feasibility: Out of 403 home samples, 374 (92.8% participation rate 95%CI: 92.7-95.3) and out of 408 phone samples, 371 (90.9% participation rate 95% CI: 87.3-93.6) participated in the study. There was no statically significant difference between the two groups. Thirty-two questionnaires (7.9%) were completed by phone calls in the home group due to the unsafe or very far location of the house.

Table 2: Comparison of the characteristics of the study participants with Islamic Republic of Iran's Multiple Indicator Demographic and Health Survey (IrMIDHS)*

Variable ^a	Iranian PRAMS	National data	Tehran data
Literacy	96.3	96.8	99
Having insurance	83.1	53.1	75.3
Unmet need of family planning	8.3	5.6	5.6
Prenatal care provider			
Gynecologist	43.4	58.9	60.2
Midwife	54.4	53.9	44.5
Others ^b	6.1	37.6	10.6
Cigarette smoking	1.9	0.7	1.4
Hookah smoking	11.1	5	6
Home birth	0.1	3.7	No data
Method of delivery			
Normal vaginal delivery	39.4	54.4	41.6
Caesarean section	60.6	45.5	58.3
Low birth weight infant	6.3	7.7	No data
Breastfeeding initiation	98.5	97.4	96.2

* Rashidian A, Khosravi A, Khabiri R, Khodayari-Moez E, Elahi E, Arab M, et al. (2012). Islamic Republic of Iran's Multiple Indicator Demographic and Health Survey (IrMIDHS) 2010. Ministry of Health and Medical Education. Tehran./ a Values are percent/b other includes general practitioner and health worker

One of the health volunteers completed 12 questionnaires (2.9%) in the phone group by home visits because of the lack of full understanding of the questions over the phone by the participants (Figure 2). Approximately, 42.1% of the participants participated in the study with one phone call, 90.4% with 10 phone calls and 90.9% with 13 phone calls. Calling for 14 or 15 times did not add any participants to the study (Fig. 3).

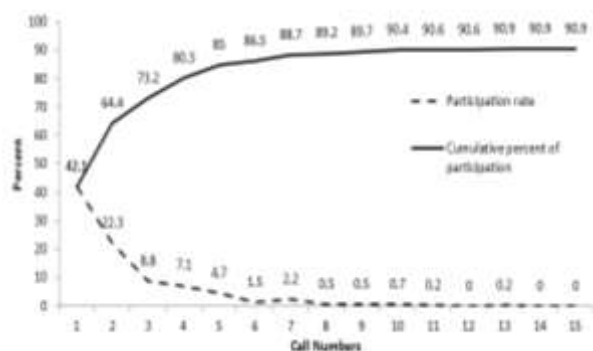


Fig. 3: Cumulative percent of participation based on the number of phone calls

After collecting the sampling frame of the study, all records were individually reviewed to see if they were eligible and to make sure that records of the eligible samples were not eliminated. The sample size was approximately 19.9% of the population and based on the protocol, this population was oversampled and the Finite Population Correction (FPC) could be applied for reducing the sample size. However, since it was decided to compare the two methods of data collection, the sample size did not change. The questionnaire did not have a lot of missing data; and there were not any significant differences between the samples and population and between participants and non-participants in the available data in the sampling frame; therefore, weighting of the data was not required. The minimum number of completed questions revealed that over 80% of all sections of the questionnaire were completed. Among them, the least completed section was the pre-pregnancy history and the most completed section was the pregnancy history and stressors of pregnancy (Tables 3 and 4).

Schedule feasibility: The sampling frame was prepared within about two weeks. Selecting the samples and packaging the questionnaires lasted about 12 hours and training the health volunteers lasted about two days (3 hours per day). Each questionnaire took an average of 22.8 (95% CI: 22.3-23.2)

minutes to complete at home and 16.7 (95% CI: 16.1-17.2) minutes on the phone.

It took 35 days from training the health volunteers and giving them the questionnaires until completing data collection. The mean age of the infants when the questionnaires were completed was 135.9 (35.3) days with a range of 63 to 211 days.

Table 3:The minimum completion rate of the questionnaire

Section	Number of questions	Minimum completion percent
Pre-pregnancy history	17	82.8
Pregnancy history and stressors of pregnancy	18	97.8
Prenatal care	38	95.7
Smoking during pregnancy	9	90.3
Childbirth	3	87.2
Time after birth	15	90.4
Demographic characteristics	10	91.7
Total	110	90.8

Table 4: Comparison of the characteristics of the population with samples and participants with non-participants

Variable ^a	Population n= 4120	Sample n= 811	P Value ^b	Participants n= 745	Non-Participants n= 66	P Value ^b
Infant's sex (girl)	1564 (47.8)	362 (44.7)	0.11	338 (45.6)	25 (38.5)	0.26
Multiple infant (yes)	103 (3.1)	16 (1.9)	0.08	13 (1.8)	1 (1.5)	0.89
Infant's age at sampling (days)	4 (3-5)	4 (3-5)	0.55	4.6 (2.7)	5.1 (2.8)	0.14
TSH Levels (unit/liter)	1 (0.6 to 2)	1 (0.5 to1.9)	0.69	1 (0.5 to1.9)	1.1 (0.6 to 2.2)	0.59
Phenylketonuria (mg/dl)	1.47 (0.6)	1.46 (0.5)	0.53	1.46 (0.5)	1.48 (0.5)	0.80
G6PD deficiency (yes)	56 (1.8)	21 (2.7)	0.10	18 (2.5)	3 (4.8)	0.27

a. Values are number (percent), mean (SD) or median (percentile 25 – percentile75).

b. Chi-square or Fisher exact test were used for qualitative variables and independent t-test or Mann-Whitney test were used for quantitative variables.

Discussion

The feasibility study showed different aspects of the technical, economic, legal, operational, and schedule feasibilities of the PRAMS in Iran. The study also showed that if the system was installed and data was collected periodically, the project could be considered an adapted surveillance system in Iran.

Participation of all individuals is essential for solving problems and achieving an acceptable level of health at the community level. The health volunteers are a bridge between the health system and

the community (23). The health volunteers collected data in this study. The health volunteers may already be acquainted with the participants, which may increase the participation rate on the one hand but may result in under reporting the undesirable social behaviors like cigarette or hookah smoking on the other hand. In this study, as expected, there was a high participation rate but these behaviors were not reported less than the national population; on the other hand, hookah smoking was reported even more than national and Tehran information. The reason could be that in the city, unlike villages and small towns, health

volunteers do not know the neighbors. In this study, 52% of the participants did not own a house, which implies that they were tenants and probably immigrants. Therefore, there might not have been any acquaintance between the health volunteers and the study population and as a result; the participants were not concerned about their behaviors. Also, 56.6% of the participants in this study received care in non-governmental centers. Similar to this study, Esmailnasab et al. indicated that 53.8% of the women used non-governmental health services (24). Therefore, data from the health centers alone cannot provide complete and comprehensive information for planning and policy making.

If the sample size is calculated based on the participation rate and the prevalence of the risk factors, according to the results of this study, 75 samples per month and 900 samples per year are needed, and the annual cost is about 6.1 million dollars which is acceptable because of the lack previous epidemiologic data. The cost of each completed questionnaire was much less than the cost reported in a study by Dozier et al. (16), which may be due to economic differences between the two countries. Home and phone based methods of data collection instead of postal method, without using any incentives for the participants, caused a decrease in study costs. Of course, part of the costs including the costs of translating the questionnaire will not repeat. In the future, using online surveys or applications such as Computer Assisted Telephone Interviewing (Web-CATI), which enters data into the software during the interview, can even reduce the costs more. However, it is not clear if these approaches could lead to a high participation rate in less educated and lower socioeconomic groups (17). Considering the lower cost of using the telephone method and the less required time to complete the questionnaire, it seems that the telephone method is more suitable for widespread implementation of this system in Iran in the future. About 90% of the women participated in the study with 10 or fewer telephone calls so it appears that 10 calls are appropriate for widespread implementation of the system.

The minimum acceptable participation rate in the PRAMS is considered 70% to analyze the data. The actual participation rate in the study was more than 90% for both methods of data collection. This participation rate was more than the previous PRAMS feasibility experiences in the US and Ireland (7, 16,17) which may be due to the contact from the health centers and the participants' trust in them. In addition, the methods which were used in this study may lead to a higher participation rate and more completed questionnaires than the postal method (25-27) since more than 80% of the different sections of the questionnaires were completed. Moreover, using the postal method leads to the elimination of low-literate and illiterate groups who are more likely to have worse pregnancy outcomes. About 18% of the participants in this study were low-literate and illiterate. It seems that unsafe or very distant location of some of the houses or changing the living place in the low socioeconomic group will provide challenges for widespread implementation of the home based method in the future. The participation rate showed no significant difference between home visit and phone methods and the power of the study was acceptable for detection of a 10% difference between the two groups (0.79), which could support the use of the phone method of data collection due to its lower costs.

The short sampling time of 35 days in this study was much shorter than three months recommended by the protocol, showing the very good schedule feasibility of the project. This sampling time is also much shorter than the prior studies in the US and Ireland (7, 16, 17), which may be due to the data collection method in this study. Over method decreased the probability of recall error. The PRAMS instrument asks risk factor questions before outcome questions in the most parts; therefore, the decrease in information error is expected, as well. In addition, there were not any significant differences between the sample and the population, which showed successful random sampling and control of selection bias.

Establishment of the system could provide valuable maternal and child health information for policy makers and health planners and could also be

used to identify health inequality, health, ethnic, and socioeconomic risk factors, adverse pregnancy outcomes, etc. (18). One of the limitations of this study was the lack of a birth registration system. In addition, the demographic characteristics of the mothers were not recorded in the hospital records; therefore, its use was not an advantage. More than 98% of the births are registered in thyroid screening forms; as a result, this system better represents live births in Iran before a birth registration system is operational and the parents' address and telephone number are registered. On the other hand, the demographic characteristics of the mothers were not recorded in the thyroid screening forms so other recorded data in the sampling frame were used for comparison. These limitations will be overcome once a birth registration system is operational in Iran. Since an interventional study could evaluate the effectiveness of a new program, it is suggested to conduct a randomized controlled trial to study the effectiveness of this methodology on pregnancy outcomes.

Conclusion

The PRAMS (a widespread surveillance system about maternal behaviors and experiences) could be considered feasible in Iran and its results could be generalized to the population of women with recent live or still births as there were no significant differences between the samples and the population. Furthermore, due to the insignificant difference in the participation rate between the phone call and home visit methods, the acceptable power of the study, the lower costs of the phone method, and the difficulty of the home visit method due to unsafe or very distant location of some of the houses or changing the living place in the low socioeconomic group, the telephone method is more suitable for widespread implementation of this system in Iran in the future. This system may suggest a potential solution for some data deficits in Iran. Although the lack of a birth registration system was a limitation of our study, the results may be important for researchers and policy makers who are interested in using

CDC valid methodologies to achieve their required population based information.

Ethical considerations

Ethical issues (Including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc.) have been completely observed by the authors.

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