A conceptual paper on Lahore-Pakistan pregnancy cohort study

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Abstract---Pakistan is among the countries with a high rate of fertility and maternal mortality, and it's in a contract with sustainable development goals (SDGs) to achieve its 5th goal (achieve gender equality and empower all women and girls). Remaining this rate high with the availability of evidence-based strategies for reducing maternal mortality and advances in medical technology in Pakistan, this study will attempt to explore the methodology of the Lahore Pregnancy Cohort Study (LPCS). The objectives of the study were to determine the nutritional status, environmental factors (socio-economic status and food insecurity) and psychological status (depression and anxiety) of pregnant women. Moreover, the study will be an ongoing two-year prospective cohort study of Pakistani pregnant women in their 2nd trimester from the outpatient department of Fatima Memorial Hospital Lahore, Pakistan. Meanwhile, during pregnancy, their interview was conducted three times in the 2nd and 3rd trimesters of pregnancy and postpartum.

Keywords---Cohort study, HFIAS, LPCS, Pregnancy.
1. Introduction

Khalid et al. (2017) identified that each year, it is estimated that 30000 women die due to obstetric complications and interpreting to death of one woman in every 20 minutes. Rural area and urban slums of Pakistan are most susceptible to these deaths. The yearly proportion of pregnant women in Pakistan is near to five million and out of those approximately 0.7 million (15%) are likely to face some medical and obstetrical complications. Deaths during pregnancy and childbirth occur due to certain complications such as low gestational weight gain, gestational diabetes mellitus, post-partum haemorrhage, preeclampsia, and many others. With such high prevalence of maternal mortality and low birth weight neonates in Pakistani population, characterization of health status of pregnant females is of great importance (Gebremichael et al., 2022)

Tyagi et al. (2017) Maternal malnutrition is the major determinants of adverse outcomes for mothers and offspring globally. A range of preventive and therapeutic nutrition specific interventions can potentially address these risks, ranging from nutrition education to fortification strategies at the population level and targeted supplementation among at risk population.

Tyagi et al. (2017) stated that nutrition has a great life-long influence on wellbeing, but it plays a particularly significant role in affecting fetal growth as well as birth performance. The main marker for the nutritional condition of neonates may be called maternal nutritional wellbeing, but the relationship between maternal diet and birth result is determined by multiple biological, socio-economic including demographic variables. The development of fetal tissues and other conception materials, such as emotional suffering, as well as the physiological changes that result from birth, cause significant stress that contributes to elevating the expecting mother's nutritional requirement (Tyagi et al., 2017).

Malnutrition influences the general wellbeing of mothers and infants, sustainability, human economic efficiency, balanced production and a child's growth. There is starvation, shortage of important micronutrients named minerals and vitamins; their scarcity contributes to severe health issues in mothers during pregnancy and stunting in infants after birth (Sciences et al., 2020).

Maternal malnutrition (including both under and over-nutrition) can have profound distresses for embryonic development & fetal growth and for subsequent infant growth and development during and beyond the breastfeeding period. The first three months of a child are most crucial for normal physical and conceptual development. Even cognitive and emotional potential start to develop early and so the base of intellectual, social and emotional competencies may have established during this time period (WHO, 2019).

The main objective of this LPCS is to investigate the maternal nutritional status, socioeconomic factors, psychological status and its possible effect on the maternal nutritional status. The overarching objectives of the LPCS are to advance empirical studies on the welfare of pregnant women in Pakistan in order to serve as a model for producing evidence-based results, turning them into guidelines for
culturally relevant and targeted practise and advocating a major improvement at the policy level. While possibilities are provided by the Pregnancy cohorts & life course designs, their execution is uniquely difficult. The objectives of this concept paper are: identify the LPCS’s architecture and methodology; address the study participants’ baseline demographic characteristics and examine the cohort’s problems and their respective response strategies.

The maternal nutritional status, depression, unavailability of food and many related factors might affect the mother’s health. So, operational strategies might help to protect the health of the mother. The application of such policies might help in improving their lifestyles and reducing the complications during pregnancy mentioned above.

2. Materials and Methods

LPCS will be the prospective cohort study in Pakistan to systematically explore the maternal nutritional status, environmental factors (socio-economics food insecurity) and psychological among Pakistani pregnant women, through integration of sociodemographic, dietary habits, anthropometrics, food insecurity and depression. The prospective cohort study design will be a strategy for examining diseases of public health importance because its inherent temporal nature renders it advantageous for studying early life influences on health outcomes and the importance of research questions of etiological.

Data will be collected from Pregnant women (2nd Trimester postpartum) visiting gynaecology and obstetrics Clinic and Outpatient Department (OPD) at Fatima Memorial Hospital, Lahore, Pakistan. The duration of the study will be 2 years. The sampling technique for the data collection will be cross sectional sampling.
Validated Questionnaires will be used to assess the data which includes demographics, health history, family strength, environmental factors, blood pressure, anthropometrics, biochemical and 24-hour recall data of Pakistani pregnant women will be analysed by using the questionnaire.

Pregnant women anthropometrics such as weight, height at 2nd and 3rd trimester and postpartum weight will be measured. Weight of the participants will be measured by Certeza living digital weighing scale and height by inches’ tape. Body Mass Index (BMI) will be calculated by using the WHO standard formula. Biochemical assessment will include Haemoglobin (Hb) Fasting and random Blood Glucose Monitoring. Secondary blood reports of participants will be assessed during 2nd, 3rd trimesters of pregnancy and postpartum. Right arm systolic and diastolic blood pressure of pregnant women will be measured using Certeza Arm Digital blood pressure monitor (BM-407) by a trained nurse during the 2nd, 3rd trimesters of pregnancy and postpartum.
trimester of pregnancy and Postpartum. Household Socio-demographics will include the information about their Socio-Economic Status, Family strength, Health history, Smoking history (Mother/father any other member of household).

Two days (Sunday & Tuesday) maternal diet history will be recorded using 24-hour recall. This assessment will be done during 2\textsuperscript{nd}, 3\textsuperscript{rd} trimester of the pregnancy and postpartum. The assistant nutritionist will use the specific household measurements such as cups, tablespoon and glass. It will help the research participants in approximating the amount of food and beverages they consumed (Savard et al., 2018).

Household food security will be assessed by Household Food Insecurity Access Scale (HFIAS) for Measurement of Food Access of pregnant women during 2\textsuperscript{nd}, 3\textsuperscript{rd} trimesters of pregnancy and postpartum. The HFIAS is composed of a set of nine questions that have been used in several countries and appear to distinguish food insecure from food secure households across different cultural contexts. The information generated by the HFIAS can be used to assess the prevalence of household food insecurity (access component) and to detect changes in the food insecurity situation of a population over time (Salarkia et al., 2014).

Urdu Translated DASS 21 by Naeem Aslam (National Institute of Psychology, Quaid-I- Azam University Islamabad, Pakistan) will be used to assess the psychological status of pregnant women during 2\textsuperscript{nd}, 3\textsuperscript{rd} trimesters of pregnancy and postpartum. The DASS 21 is a clinical assessment instrument that is used to measure the three negative emotions of an individual (Depression, Anxiety and Stress) (Oei et al., 2013).

2.1 Subject Criteria
2.1.1 Inclusion Criteria:
Mothers:
- Pregnant women of Age 19-40 Years
- Singleton Pregnancy
- 2\textsuperscript{nd} Trimester Pregnant women
- Healthy Pregnancy (including GDM and Preeclampsia)

2.1.2 Exclusion Criteria:
Mothers:
- Dizygotic Pregnancy (Twin Pregnancy)
- Pregnant women with existing chronic diseases (excluding Diabetes and Hypertension)
- IUGR

Sample size Estimation
Objective 1: To determine the effect of nutritional status through dietary habits of pregnant women.
According to National Nutrition Survey the 18 % pregnant females have poor nutritional status (NNS, 2018). The following simple formula would be used for calculating the adequate sample size

\[ n = \frac{Z^2 \cdot P \cdot (1 - P)}{d^2} \]

Where n is the sample size, Z is the statistic corresponding to level of confidence, P is prevalence and d is precision.
\[ n = \frac{(1.96)^2 \times 0.18 \times (1 - 0.18)}{(0.05)^2} \]
\[ n = 227 \]

As, this research will deal with a finite population. Therefore, the formula for sample size calculation will become:

\[ n = \frac{n}{n + \left(\frac{n-1}{\text{Population}}\right)} \]
\[ n = \frac{227}{1 + \left(\frac{227-1}{13095000}\right)} \]
\[ n = 226.6 \]

20 % drop out will be added in \( n = 227 \)
So, the sample size will be 272.

**Objective 2: To determine the environmental factors (Food insecurity and socioeconomic status) of Pakistani pregnant women.**

Nationally, more than half (67.6%) of the Pakistani households were reported to be food insecure in the National Nutrition Survey (NNS) conducted in 2018 (NNS, 2018). The following simple formula would be used for calculating the adequate sample size

\[ n = \frac{Z^2 \times P(1 - P)}{d^2} \]

Where \( n \) is the sample size, \( Z \) is the statistic corresponding to level of confidence, \( P \) is prevalence and \( d \) is precision.

\[ n = \frac{(1.96)^2 \times 0.67 \times (1 - 0.67)}{(0.05)^2} \]
\[ n = 339 \]

20 % drop out will be added in \( n = 339 \)
So, sample size will be 407.

According to National Nutritional Survey 2018 the socioeconomic status was estimated 55 % (NNS, 2018). The following simple formula would be used for calculating the adequate sample size

\[ n = \frac{Z^2 \times P(1 - P)}{d^2} \]

Where \( n \) is the sample size, \( Z \) is the statistic corresponding to level of confidence, \( P \) is prevalence and \( d \) is precision.

\[ n = \frac{(1.96)^2 \times 0.55 \times (1 - 0.55)}{(0.05)^2} \]
\[ n = 380 \]

20 % drop out will be added in \( n = 380 \)
So, the sample size will be 456.
**Objective 3: To determine the psychological status (depression and anxiety) of Pakistani pregnant women**

According to a study conducted at the antenatal clinic of a teaching hospital in Lahore, Pakistan, 25% of the women suffered from depression and 34.5% from anxiety during their pregnancy (Ghaffar et al., 2017). The following simple formula would be used to calculate the adequate sample size:

\[
 n = \frac{Z^2 \, p \,(1-p)}{d^2}
\]

Where \( n \) is the sample size, \( Z \) is the statistic corresponding to level of confidence, \( P \) is prevalence and \( d \) is precision.

\[
 n = \frac{(1.96)^2 \, 0.3 \,(1-0.3)}{(0.05)^2}
\]

\[
 n = 323
\]

20% drop out will be added in \( n = 323 \)

So, the sample size will be 388.

Sample size calculation for all objectives

<table>
<thead>
<tr>
<th>No</th>
<th>Objectives</th>
<th>Sample size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>To determine the effect of nutritional status through dietary habits of pregnant women</td>
<td>272</td>
</tr>
<tr>
<td>2</td>
<td>To determine the environmental factors (Food insecurity and socioeconomic status) of pregnant women.</td>
<td>456</td>
</tr>
<tr>
<td>3</td>
<td>To determine the psychological status (depression, anxiety and stress) of pregnant women.</td>
<td>388</td>
</tr>
</tbody>
</table>

Maximum number of sample size calculated = 456

**3. Data Analysis**

Statistical package for social sciences SPSS Version 22.0 will be used to calculate the descriptive statistics (Mean, Standard Deviation, Median and Frequency). Results will be presented in graphical and tabular form. Appropriate Statistical test will be applied to find out the relation.

**4. Ethical Considerations**

Research and ethical approval will be obtained from Institutional Review Board (IRB) of Fatima Memorial College of Medicine and Dentistry, Shadman Lahore, Pakistan. After that Approval from USM Human Research Ethics Committee will be obtained. After explaining the study purpose and procedure, a written consent will be taken from the pregnant women who agree to participate in the study.

Data confidentiality will be practiced at highest level possible. Where the questionnaire will be anonymous. The respondents will not be able to be identified by any means and they will be accounted for any responses that they gave. This will be able to eliminate reporting bias. Only researcher have the access to the data. Any information revealed cannot identify the individual case. Data will be presented as grouped data and will not identify the responders individually.
References


