



Faculty of Family and Community Sciences
The Maharaja Sayajirao University of Baroda

**Institutional Ethics Committee for Human Research (IECHR)
FACULTY OF FAMILY & COMMUNITY SCIENCES, BARODA**

Date: 20/12/2018

CERTIFICATE

Mr. Sanket Dhirubhai Charola has been allotted ethical approval Number IECHR/2018/20 for his Doctoral (Ph.D.) study entitled "Ethnobotanical practices in Antenatal and Postpartum Indian women and its evaluation" for the year 2018 - 2019.

Prof. Mini Sheth
Member Secretary
IECHR
Faculty of Family & Community Sciences
Baroda.

Through:

Prof. Meenakshi Mehan
Head, Dept. of Foods and Nutrition

Prof. & Head
Dept. of Foods and Nutrition

Consent Form

Informed consent form for the participants for the research entitled “Ethnobotanical practices in antenatal and postpartum Indian women and its evaluation”

Research Guide: Prof. Susy Albert

Research Student: Sanket Charola

Name of Organization: Department of Botany, Faculty of Science, The Maharaja Sayajirao University of Baroda

This informed consent form has two parts:

1. Information Sheet (To brief you about the study)
2. Certificate of Consent (for you to participate in this study)

You will be given a copy of the full consent copy.

Part 1: Information sheet:

Introduction:

Ethnomedicines are used for variety of diseases from common cold, cough, and fever, diarrhea to more complex clinical problems like arthritis, bronchitis, cancer and neurological disorders. During pregnancy various physiological changes takes place, which needs clinical observation and intervention. Various home remedies are practiced during this period by many pregnant women. Such ethnobotanical practices are perceived as safe, effective and accessible remedies. Due to such reasons, ethnobotanical practices during pregnancy are commonly reported worldwide.

Purpose:

In India, various herbs are reported useful in infertility, contraception, antenatal, and parturition, and postpartum. Many such herbs are used by pregnant women based on their family traditions and previous knowledge. Such ethnobotanical practices though have been reported from other parts of the world, is not been recorded for Indian population. Hence this work is focusing on the documentation of such practices.

Efficacy of the ethnobotanical practices and safety is always a concern when it comes to the mother care and infant care. In order to establish the clinical outcomes of various herbal medicines during pregnancy and then postpartum recovery of the mother, the proposed study will be of great importance. Further, the animal experimentation will provide support to the clinical outcomes from population data.

Voluntary participation:

Your participation in this study is entirely voluntarily. You have all rights to discontinue at any point of time.

Procedure:

If you agree to participate in the study, you will be asked to answer some questions about yourself and your family, your knowledge about herbal medicine use. The interview with you will take about 15 minutes. Apart from Questionnaire, your clinical information will be obtained from the consultant. The study will explore about the use and correlates of herbal medicine use during pregnancy.

Duration:

The interview will take 15 to 30 minutes.

Benefits:

No harm or monetary benefits are there for participants. However, by helping in this study you will help us to document ethnobotanical practices and its evaluation.

Confidentiality:

The information received from you is solely for research purpose. Your personal information and identity will not be revealed in actual form to anyone. Outcomes from this study will be published to scientific community in coded form only.

In case of any difficulty faced, you may contact us at:

Sanket Charola (M: 7046776364)

Part 2: Certificate of Consent:

I have been asked to give consent in this research study which will involve me completing interview including questionnaire and clinical investigation. I have read the foregoing information, or it has been read to me. I have /had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this study.

Name: _____

Signature: _____

Date: _____

If illiterate: Participants who are illiterate should include their thumb print in the presence of any witness after reading out above information to them.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Thumb impression of Participant:

Name and Address of witness: _____ Age: _____ Date: _____

Statement by the researcher/person taking consent:

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the person understands risk and benefits. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been forced into giving consent, and the consent has been given freely and voluntarily. A copy of this Informed Consent Form has been provided to the participant.

Signature of Researcher: _____ Date: _____

A research Questionnaire

Ethnobotanical practices in antenatal and postpartum Indian women and its evaluation

IECHR No: IECHR/2018/20

Date: _____ Time: _____

Participant's Name: _____ DOB: _____

Name of Clinic: _____ Clinician: _____ Address: _____

Address: House no. _____ Area _____ Town _____ Dist. _____

Contact Number: _____ email: _____

Part 1: Socio-demographic Information of Participants

1 Demographic Information:

Religion: _____ Caste: _____ Birthplace (state): _____

2 Marital status

☐ Married & living with Partner ☐ Married but not living with Partner
☐ Single ☐ Divorced ☐ Widowed

3 Size of Family

☐ Nuclear ☐ Joint ☐ Extended

4 Time of Residence in Gujarat State

☐ By birth ☐ for 5 years ☐ for 10 years ☐ >10 years

5 Kuppaswamy scale:

☐ Education: _____
☐ Occupation: _____
☐ Per capita income: _____

6 Parity (in numbers) and age of child (in months)

☐ 1 _____ ☐ 2 _____, _____ ☐ >3 _____, _____, _____

7 Presence of major Health Problems not related to gestation

☐ Diabetes ☐ Thyroid issues ☐ PCOS
☐ Blood pressure ☐ Malnutrition ☐ Obesity
☐ More than one ☐ None of the above

8 Regular Diet

☐ Vegetarian ☐ non-vegetarian or mixed

9 Diet restrictions if any followed during pregnancy (Any special food item).

☐ Yes ☐ No

Please specify, if yes _____

Part 2: Attitude towards herbs usage of the Participants

10 Practiced any herbal drugs/traditional practices during your gestation period?

☐ Yes ☐ No

Help:

Which of the following have you taken during maternity period?

☐ Used more nuts/clarified butter/protein foods ☐ Taken castor oil
☐ Used Jeera, Saunth, Ganthoda, Gokhru, Ajwain etc. ☐ Used specific grains
☐ Methi/Vasanu Laddus ☐ Churna/Bhasma/decoction ☐ Herbal Lep/Bath
☐ None of the above

11 Do you think herbal drugs are cheaper than other medicines?

☐ Yes ☐ No

12 Do you believe that herbal drugs /traditional medicines are safe way of medication?

☐ Yes

☐ No

13 Do you think that herbal/traditional practices can be utilized during pregnancy period?

☐ Yes

☐ No

14 Do you believe herbal drugs are more effective?

☐ Yes

☐ No

15 Are herbal drugs or traditional practices easily available and accessible to you?

☐ Yes

☐ No

[discontinue questionnaire if answer to que 10 is 'No']

Part 3: Knowledge and practice of traditional medicine of the Participants

16 Which of the following classes of medicines have you taken during maternity along with allopathic medicines?

☐ More than one of the following

☐ Ayurvedic medicines

☐ Homeopathic medicines

☐ Unani/Siddha medicines

☐ Traditional practices

☐ Naturopathy/other complementary medicines

17 During which period of pregnancy have you used any herbal product?

☐ Antenatal

☐ Parturition

☐ Postpartum

☐ More than one

18 Do you know any other individuals using same practices/plants/herbs?

☐ Family members

☐ Members of the same ethnicity

☐ Members of another ethnicity

☐ Ethnically distant known person

19 What is your satisfaction level using traditional practices?

- ☐ Very satisfied
- ☐ Somewhat satisfied
- ☐ Neither satisfied nor dissatisfied
- ☐ Somewhat dissatisfied
- ☐ Very Dissatisfied

20 Have you experienced any side effects or adverse results while using traditional practices?

- ☐ NO ☐ YES

Specify the practice used: _____

Side effect experienced/noticed: _____

Part 4: Documentation of traditional practices

21 Choose purpose for which traditional practices were followed:

<p><u>Common problems to mother</u></p> <ol style="list-style-type: none"> 1. <input type="checkbox"/> Nausea and vomiting 2. <input type="checkbox"/> Constipation 3. <input type="checkbox"/> Body ache/back pain 4. <input type="checkbox"/> Legs/body parts edema 5. <input type="checkbox"/> Cold/cough/fever 6. <input type="checkbox"/> Diarrhea 7. <input type="checkbox"/> Urinary tract infection 8. <input type="checkbox"/> Gas trouble/Acidity 9. <input type="checkbox"/> Lethargy/Mood disorders 	<p><u>Parturition related issues</u></p> <ol style="list-style-type: none"> 10. <input type="checkbox"/> During delayed labor 11. <input type="checkbox"/> Labor induction 12. <input type="checkbox"/> Painless delivery 13. <input type="checkbox"/> Dilate birth canal 14. <input type="checkbox"/> Reduce blood loss 15. <input type="checkbox"/> Improves chance of normal delivery
<p><u>Recovery of mother</u></p> <ol style="list-style-type: none"> 16. <input type="checkbox"/> Food supplement 17. <input type="checkbox"/> Galactagogues (Lactation) 18. <input type="checkbox"/> Regularization of menses 19. <input type="checkbox"/> Improves immunity 	<p><u>Child health issues</u></p> <ol style="list-style-type: none"> 21. <input type="checkbox"/> Sedative 22. <input type="checkbox"/> Constipation/diarrhea 23. <input type="checkbox"/> Intestinal parasites/Vermes 24. <input type="checkbox"/> Improves health and immunity

20. <input type="checkbox"/> Blood purifier and booster	25. <input type="checkbox"/> Cold/cough/fever
	26. <input type="checkbox"/> Child growth and memory
	27. <input type="checkbox"/> Skin diseases
	28. <input type="checkbox"/> Strengthen bones and muscles
	29. <input type="checkbox"/> Teeth and Gums

22 Fill-in the following table for detailed description of traditional practices:

23 Provide detailed description of traditional practices:

Purpose										
Taken by (Mother /child)										
Practice used (refer to Key)										
Pure form /Mixture/ locally available packet (mention name and company) of herbs										
Name of herbs used (Local name)										
Part used (refer to key)										
Form of plant used (Fresh/Dry)										
Administration (Internal /external)										
Quality (std. packed / local packed/ loose)										
Period of usage (refer to Key)										
Dosage (gm/day or ml/day)										

Key:**Practice used:**

1. Flour balls (Laddu)
2. Flour slurry (Sheera)
3. Decoction
4. Extract- water
5. Extract –oil
6. Extract –milk/other media
7. Juice
8. Paste
9. Powder/capsule
10. Syrup (Honey /sugar based)
11. Pills/lozenge
12. Baths/Lep

Part used:

1. Stem
2. Stem bark
3. Rhizome
4. Gum/resin
5. Root
6. Flower/inflorescence

7. Fruit

8. Seed

9. Stem tuber

Period of usage:

1. First trimester of pregnancy
2. Second trimester of pregnancy
3. Third trimester of pregnancy
4. Upto 3 months postpartum
5. Upto 6 months postpartum
6. Throughout maternity
7. Only when required

Questionnaire

Ethnobotanical practices in antenatal and postpartum Indian women and its evaluation

IECHR No: IECHR/2018/20

Date: _____ Time: _____

Participant's Name: _____ DOB: _____

Name of Clinic: _____ Clinician: _____ Address: _____

Address: House no. _____ Area _____ Town _____ Dist. _____

Contact Number: _____ email: _____

Part I: Demographic details of the participants.

Sr. No.	Questions	Choice /Answers
101	Date of Birth	_____ (DD/MM/YYYY)
102	Birth Place (State)	District _____ and State _____
103	Time of residence in Gujarat state	1. By birth 2. <2 yr; 3. 2-5yr; 4. 6-10 yr; 5. 11-30 yr
104	Mother tongue	1. Gujarati; 2. Hindi; 3. Marathi; 4. _____
105	Marital status	1. Married & living with a partner 2. Married but not cohabiting 3. Single/Divorced/widow
106	Religion	1. Hindu; 2. Muslim; 3. Christian; 4. Sikh; 5. Jain; 6. Other, specify _____
107	Size of family	1. Nuclear; 2. Joint; 3. Extended
108	Socio-economic status	Per capita monthly income (INR): Occupation: Education level:
112	Parity	1. One; 2. Two; 3. Three or more
113	Age of each child (in months)	

Part II: Traditional practices use.

201	Have you used herbal medicine during pregnancy?	1. Yes; 2. No
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202	If you have not used herbal medicine, why not?	1. Lack of belief in the benefits of herbs 2. Afraid the side effect 3. Not required
203	Why have you used herbal medicines?	1. Family, tradition or culture 2. Belief in effectiveness of herbal medicines 3. Herbal medicines are cheap and accessible 4. Treatment of other medical problems 5. Safe in pregnancy
204	What type of herbal medicines have you used? More than one answer is possible	1. Liquid form 2. Solid form 3. Other forms
205	Antenatal period where herbs were used:	1. First trimester; 2. Second trimester; 3. Third trimester; 4. More than one of the above
206	What is your source of information about herbal medicines?	1. Families, friends and relatives 2. Media (internet, television, radio, book) 3. Health practitioner 4. Friend 5. Others, specify _____ Specify the ethnicity of the person from whom information was taken: _____
207	Any untoward condition faced?	1. Yes 2. No
208	In general, how could you rate the advantage you get from using herbal medicines use?	1. Very satisfied 2. Somewhat satisfied 3. Neither satisfied nor dissatisfied 4. Somewhat dissatisfied 5. Dissatisfied
209	Specify duration of use for each of the herbs practiced (in terms of month of pregnancy)	
210	Discomfort reported by participant	
211	Were you pressurized to follow cultural or family norms in use of herbs?	1. Yes 2. No

End of Questionnaire

Clinical Proforma

“Ethnobotanical practices in antenatal and postpartum Indian women and its evaluation”

Inclusion criteria	Exclusion criteria
Age: 20 to 35 years	Participants with H/o Abortion and miscarriage
Indian Women of any religion, caste, or socio-economic background	Sickle cell disease, Thalassemia major or any other systemic disease
Women taking contraceptives or drugs for systemic illness, any Nutritional supplements other than Batrisu vasanu/ Methi-laddu.	Participant with H/o hormonal supplements and other such treatments for pregnancy
	Participants with occupational hazard which may affect outcomes of the study

ID No: _____ Hospital Name: _____ Consultant: _____

Part I: Antenatal case (At time of recruitment to the study) Date: _____

1. Name: _____
2. Age: _____ years
3. Contact details: _____
4. Date of examination: _____
5. Gestation period: ____/____ (week/day)
6. Chewing tobacco: Yes / No (Specify duration)
7. Smoking tobacco: Yes / No (Specify duration)
8. Alcohol status: Yes / No (Specify duration)
9. Regular diet: Vegetarian / Non-vegetarian or mixed
10. Past history:
 1. Any Infertility treatment: Yes / No
 2. Use of contraceptives: Which types and frequency of usage
 3. Consanguineous marriage: Yes / No
 4. Any other disease: 1. Diabetes, 2. Tuberculosis, 3. Hypertension, 4. Jaundice, 5. Rheumatic fever in childhood, 6. Rickets or osteomalacia and 7. Syphilis
 5. H/o any pelvic surgery, accidents affecting pelvic bones: Yes / No
 - Specify if yes _____
 6. H/o any major hospitalization or h/o blood transfusion: Yes / No

Specify if yes _____

7. Family History of diabetes, hypertension, tuberculosis, hemoglobinopathies, twins, post maturity and genetic disorders: Yes / No

Specify if yes _____

11. Personal history

1. Diet: 1. Veg; 2. Non-veg (Mixed)
2. Appetite: 1. Pica: Yes, Specify _____ / No; 2. Dyspepsia: Yes/ No
3. Bowel: 1. Normal (1 or 2 times); 2. Constipation (lesser than once a day); 3. Diarrhea (more than 3 times a day)
4. Bladder: 1. Normal (5 times or more) 2. Infection (5 times with pain); 3. More than 5 times
5. Tobacco street habits: Yes / No
6. Physical activity: 1. No activity; 2. household activity; 3. Occupation related activity; 4. Physical exercise like walking etc
7. Allergens

12. General examination

1. Build: 1. Well-built 2. Fairly Built 3. Poorly built
2. Nutrition: 1. Well-nourished 2. Fairy nourished 3. Malnourished
3. Height (in cm): _____
4. Weight (in kg): _____

13. Vital data

1. Pulse: _____
2. BP (mmHg): _____; _____
3. Temp (°F): _____
4. Respiration rate: _____
5. Edema over body parts (Name parts) 1. None; 2. Medial malleolus; 3. tibia
6. CVS/ RS/ CNS: 1. Normal, 2. Abnormal

14. Obstetric Examination- Antenatal case:

1. Per abdominal examination (P/A):
 - a. Fundus height (in cm): _____
 - b. Estimated Fetal weight (in gm): _____
 - c. Fetal Heart sound (FHS): At _____ site; _____ rate (per min)
State whether- 1. Normal; 2. Abnormal
 - d. Uterine enlargement: 1. Longitudinal; 2. Transverse / oblique; 3. Undue distension

- e. Fetal Growth: 1. Normal; 2. Physiologically small Fetus; 3. Small for gestational age fetus (FGA); 4. Pathologically Intrauterine growth restriction (IUGR)
2. Breasts examination: 1. Normal; 2. Abnormal (specify if treated)
3. Pelvimetry: 1. Pelvis adequate; 2. Pelvis inadequate; 3. Pelvis not assessed
4. Chief complaints: 1. Nausea, 2. Common cold, 3. morning sickness, 4. Heartburn, 5. Urinary tract infection, 6. Constipation, 7. backache, 8. tiredness, 9. sleeping problems 10. If any
5. Any adverse conditions reported:
6. Immunity of Mother: 1. Good; 2. Average; 3. Poor

Part II: Parturition report **Date:** _____ **Doctor name:** _____

1. Duration of Labour (in min): _____
2. Modes of delivery: 1. Spontaneous vaginal delivery (SVD); 2. Caesarean section; 3. Instrumental and destructive delivery
3. Intrapartum blood loss (in ml): _____
4. 1-minute APGAR score: _____
5. 5-minute APGAR score: _____
6. Gestational age at delivery (w/d): _____
7. Weight of the baby (kg): _____
8. Sex of the baby: _____

Part III: Postpartum report **Date:** _____ **Doctor name:** _____

Number of day postpartum _____

1. Delivered on date: _____, Time: _____ with weight (kg) _____
2. Menstrual history: PaMP: _____, LMP: _____, EDD: _____
3. Diet: 1. Veg; 2. Non-veg (Mixed)
4. Appetite: 1. Pica: Yes, Specify _____/ No; 2. Dyspepsia: Yes/ No
5. Bowel: 1. Normal (1 or 2 times); 2. Constipation (lesser than once a day); 3. Diarrhea (more than 3 times a day)
6. Bladder: 1. Normal (5 times or more) 2. Infection (5 times with pain); 3. More than 5 times
7. Physical activity: 1. No activity; 2. household activity; 3. Occupation related activity; 4. Physical exercise like walking etc.
8. General examination:
 - a. Pulse: _____
 - b. BP (mmHg): _____

- c. Temperature (degC): _____
- d. Tongue/conjunctive/nails pallor: 1. Mild; 2. Moderate; 3. Severe
- e. Edema legs: 1. Present (report reason _____); 2. Absent
- 9. Per abdominal examination (P/A):
 - a. Fundus height (in cm): _____
 - b. Uterus (At ____ week): 1. Firm, Contracted; 2. Abnormal
- 10. Lochia (At ____ week): 1. Lochia rubra; 2. Lochia serosa; 3. Lochia alba
- 11. Episiotomy stitches (At ____ week): 1. Normal 2. Edema 3. Induration 4. Discharge
- 5. Wound gap
- 12. Breasts examination:
 - a. Nipples: 1. Normal; 2. Abnormal (specify cracked / fissures/ retracted)
- 13. Colostrum: 1. Present; 2. Absent
- 14. New born examination:
 - a. Weight (kg) _____
 - b. Reflexes: 1. Normal 2. Abnormal (specify _____)
 - c. Temperature(degC): _____
 - d. Cry: 1. Normal 2. Abnormal (specify _____)
 - e. Feeding: 1. Breast feeding; 2. Other milk sources _____
 - f. Skin: 1. Normal pink; 2. Blue; 3. Jaundice yellow; 4. Erythema toxicum
 - g. Eyes: 1. Normal, 2. Conjunctivitis, 3. Jaundice
 - h. Umbilical cord stump: 1. Dry; 2. Infected
 - i. Urine: 1. Passing 5-8 times a day, 2. Passing lesser than 1; 3. Passing more than 1
 - j. Stool: 1. Normal (atleast once); 2. Abnormal (specify _____)
 - k. Hemoglobin (g/dl): _____
 - l. Blood group: _____

Part IV: Postnatal care by mother:

- 1. Adequate rest : Hours of total bedrest _____; Hours after total bedrest allowed to sit and walk _____; Hours after complete activity permitted _____
- 2. Early ambulation : _____earliest days
- 3. Perineal care (at ____ week): 1. Normal; 2. Painful
- 4. Nutritious diet:
 - a. Frequency of food intake: Meals: _____; snacks: _____
 - b. approximate calories taken (Cal): _____
 - c. Diet restrictions advised:

5. Post natal exercises: Kinds: Pelvic floor muscle/bladder tone and Abdominal muscle; Times: ____ done; for ____ days.
6. Hematinic supplements advised: _____
7. Galactagogue prescribed: 1. No; 2. Yes (Name _____ Dosage: _____)
8. Lactation inhibition drugs prescribed: 1. No; 2. Yes (Name _____ Dosage _____)
9. Any adverse conditions reported: _____

Part V: Other relevant details:

1. Puerperium : 1. pain, 2. Backache, 3. Perineal pain, 4. bladder and bowel problems, 5. Psychological problems
2. Regularization of menses: from _____ month
3. Newborn health: 1. Normal; 2. Skinrashes; 3. Vomiting; 4. Feeding problems; 5. Constipation; 6. Diarrhea; 7. Physiological jaundice; 8. Dehydration fever; 9. Excessive crying or sleeping; 10. Infections
4. Medication prescribed with dosage: _____
5. Supplements prescribed with dosage: _____

End of proforma

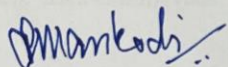
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Project No. MSU-Z/IAEC04/16-2020

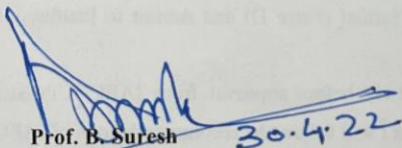
CERTIFICATE

This is to certify that the project proposal no. MSU-Z/IAEC04/16-2020 entitled **Ethnobotanical practices in antenatal and postpartum Indian women and its evaluation: Safety evaluation of selected botanicals using rats** submitted by Prof. Suresh Balakrishnan has been approved / recommended by the IAEC of The Maharaja Sayajirao University of Baroda, Vadodara in its meeting dated 30/04/2022.

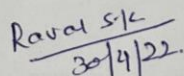
Authorized by



Prof. P.C. Mankodi
Chairman


30.4.22

Prof. B. Suresh
Member Secretary


30/4/22.

Prof. Sunant Kantilal Raval
Main Nominee of CPCSEA

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by Office)