

2023



SPIRE

SPIRE is an independent initiative by sensitive and aware inhabitants of our planet. It stands for Social Action for Progressive Innovation, Research and Education. SPIRE works as a collaborative initiative of NEAD Foundation, <https://neadfoundation.com/> Whats App text contact: 00923219801238 and Email: info@neadfoundation.com & palwasha.bibi@gmail.com

MEMORANDUM OF UNDERSTANDING: **NEAD-SPIRE & PROPOSING RESEARCHER/AGENCY**

SPIRE recognizes the sanctity of research data and specimens. All information/data/specimens collected under this MOU will be used solely for the purpose outlined in this MOU and treated as highly sensitive and privileged information, not to be released to third parties without permission from SPIRE team. A breach of this statement may lead to disciplinary/legal action by NEAD-SPIRE team as well as by the participating individual/agency.

1. Name of proposing/collaborating Individual/Independent Consultant/agency: (Official name is required with proof of registration by appropriate government/non-governmental offices.

2. Name/s along with highest educational qualification and official position of Individual/Independent Consultants/appointed representative/s by the proposing agency:

3. Title of project: SPIRE-OBS-ANEST – 04/2023

4. Purpose of SPIRE-OBS-ANEST: Multicenter study to compare maternal and fetal/neonatal outcomes in regional versus general anesthesia in emergency LSCS cases.

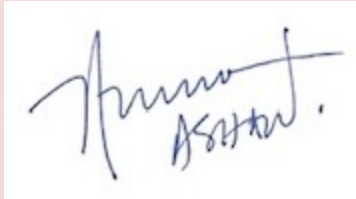
5. Name, educational qualification, whether acting or permanent position holder, of the appointed Head/MD/CEO/Director of agency/office/hospital/college/university. (Not required in cases of MOU for Individual/Independent Consultants:

MEMORANDUM OF UNDERSTANDING:
NEAD-SPIRE & PROPOSING AGENCY

SPIRE Representatives Present, (at least 02):

Afshan H. Khattak, Director SPIRE
Sana Alauddin, Program Coordinator

Signatures and CNIC Numbers, (attach scanned copies):

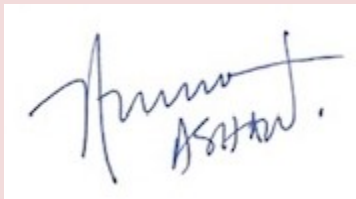


Individual/Independent Consultant: AGENCY, (second party):

Signatures and CNIC Numbers, (attach scanned copies):

Site and Date of Signing:

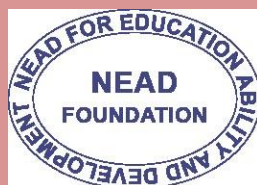
Lead Person: Chairperson, SPIRE, Signature & Date:



Afshan H. Khattak, Director, SPIRE
DATED: September 1st 2023

INSTITUTIONAL ETHICAL REVIEW COMMITTEE REPORT

S. No	Query	Comments
1.	Title of study	Effects of Anesthetic Techniques/Medications on Maternal/Fetal/Neonatal Outcomes in Emergency LSCS for Fetal Distress Query - Cleared
2.	Background Justification	Query - Cleared
3.	Material & Methods	Cross-sectional. Primary datasets Human subjects – Consent included. No unique identifiers in database Addresses will be anonymized. Investigators' names will be coded at the source. Query - Cleared
4.	Data sharing	Data is open to vetted and cleared participants and participating institutions. Query - Cleared
5.	Publication	All participants providing 20 data points will be eligible for authorship in publication/s.
6.	Funding for study	NEAD Foundation through SPIRE initiative. https://neadfoundation.com/ Query – Cleared
7.	Conflicting Interests	None to be declared. Query – Cleared



Project SPIRE-OBS-ANESTH:

Title:

Effect of Anesthetic Technique/Medication on Maternal/Neonatal
Morbidity/Mortality in Emergency Caesarean Section for Fetal Distress

Background Introduction:

Obstetric cases leading to emergency caesarean section are testing for the obstetrician as well as the anesthetist. These cases are typically associated with life-threatening conditions for both the mother and the fetus. For women requiring emergency caesarean section, a 30-minute decision-to-delivery interval (DDI) has become the standard target in clinical practice, [1]. Royal College of Obstetricians and Gynecologists (RCOG) guidelines suggest that caesarean section should be carried out “with an urgency appropriate to the risk to the baby and the safety of the mother”, as soon as the target DDI is established [1]. Given the limited time and increased risk, both maternal and fetal outcome depend on the skill, coordination and vigilant teamwork between obstetrician and anesthetist. The selection of appropriate anesthetic agents and technique is of paramount importance.

For elective caesarean section, regional anesthesia is preferred over general anesthesia, as there is less risk of aspiration and maternal compromise with regional anesthesia. This choice also carries no risk for intubation-related injury and complications [2]. Evidence suggests that general anesthesia may depress the 1-minute neonatal APGAR score, [3–5]. For emergency caesarean section, regional anesthesia is used given that there is sufficient time available for safe administration and maternal monitoring, [6,7].

Regional anesthesia has emerged as the preferred anesthetic technique in caesarean sections performed in well staffed maternal care centers and good hospitals. Although many emergency caesarean sections are performed each year, however, limited data are available regarding safe and effective choices of anesthetic agents and practices for mothers facing fetal distress. Fetal asphyxia, typically referred to as fetal distress, can lead to hypoxic-ischemic injury of the fetal brain. Compensatory physiologic mechanisms involving the redistribution of blood to vital organs enable the fetus to survive asphyxia, provided that the duration of asphyxia can be, somehow, controlled or limited through supportive measures from the obstetric, anesthesia and neonatal support teams, [6].

An estimated 289000 mothers died during pregnancy and childbirth, across the globe in any given year. Pakistan contributed nearly 8000 maternal deaths to this number in 2013, [7]. Fact is that maternal and fetal mortality is unacceptably high in developing countries, and the practice of obstetrics and anesthesia has significant effect on such outcomes. In order to prevent unacceptable and preventable maternal morbidity and mortality, consortia and think tanks among most professional organizations, throughout the world have devised and issued guidelines and protocols for obstetric anesthesiologists. These organizations include Obstetric Anesthetists Association; OAA, Royal College of Anesthesiologists UK, Difficult

Airway Society (DAS), Association of Anaesthetists in Great Britain and Ireland (AAGBI) and many more. OAA recommends that departments of obstetrics and anesthesiology should have written guidelines, setting out local standards of care, [8].

A review of literature in Pakistan does not provide the investigator with much data about the issue of maternal and fetal morbidity and mortality in setting of emergency cesarean sections. Provision of such data is deemed difficult and often considered detrimental and defaming for the healthcare facility. It is therefore easy to appreciate that few well designed studies have been done in our country that successfully investigated neonatal morbidity related to proven fetal distress in cases of mothers undergoing emergency caesarean section. Almost all the research done in last decade in Pakistani centers is focused on decision to delivery time validation and outcomes, [9, 10], that does not provide one with any plausible information and way-forward in outcomes research.

SPIRE proposes the present study and invites collaborators from obstetrics, anesthesia and neonatology to identify the most suitable anesthetic agents and techniques for mothers undergoing emergency cesarean sections for documented fetal distress.

Primary aim of our study is to investigate the effect of the anesthetic agent/s and techniques (i.e., regional or general anesthesia) on neonatal morbidity in emergency caesareans.

Length of hospitalization, and umbilical cord pH values, success/failure of early lactation are expected as secondary outcomes.

Materials & Methods:

Study Design: Prospective, observational, Descriptive study

Study Location: Departments of Obstetrics/Gynecology and Operating Theatres of collaborating institutions.

Study Duration: SIX months, (Pilot followed by expanded duration data collection)

Study Tool: Questionnaire based data collection after obtaining patient consent. Data will be anonymized for institutional privacy and patient confidentiality purposes.

Study tool is included in this document. Data will be entered in Google Form designed for this study and analyzed using SPSS to calculate the statistical significance of the differences in maternal and neonatal parameters observed between regional versus general anesthesia groups by applying students t-test to calculate p-value.

Inclusion criteria:

1. Diagnosis of Fetal Distress in a laboring woman at or above 38 weeks gestational age by the treating team.
2. Maternal Age – 18 – 40 years.

Exclusion Criteria:

1. Maternal neuropsychiatric illness being treated with medicines through last trimester of pregnancy.
2. Maternal BMI > 40 kg/m².

3. Known hypersensitivity to any of the anesthetic agents used in emergency cesarean section protocols.

Project SPIRE-OBS-ANESTH: 004/2023

Effect of Anaesthetic Technique/Medication on Maternal/Neonatal

Morbidity/Mortality in Emergency Caesarean Section for Fetal Distress

Patient Consent:

Cesarean section is a surgical procedure to help you bring your baby into this world safely and without harm. As already explained to you, cesarean section has its own complications. We are doing this research to help reduce the risk of those complications for mothers like you.

All information collected through this data tool is property of the research team. Your name or any other personal detail will not be collected through this tool. All medical information collected through this tool will be kept anonymous and confidential.

Your data will not be shared with a third part without your written consent.

سیزرین سیکشن جراحی کا طریقہ ہے جو آپ کو اپنے بچے کو محفوظ طریقے سے اور بغیر کسی نقصان کے اس دنیا میں لانے میں مدد کرتا ہے۔ جیسا کہ آپ کو پہلے ہی سمجھایا جا چکا ہے، سیزرین سیکشن کی اپنی پیچیدگیاں ہیں۔ ہم یہ تحقیق آپ جیسی ماؤں کے لیے ان پیچیدگیوں کے خطرے کو کم کرنے میں مدد کے لیے کر رہے ہیں۔

اس ڈیٹا ٹول کے ذریعے جمع کی گئی تمام معلومات ریسرچ ٹیم کی ملکیت ہیں۔ آپ کا نام یا کوئی اور ذاتی تفصیلات اس ٹول کے ذریعے جمع نہیں کی جائیں گی۔ اس ٹول کے ذریعے جمع کی جانے والی تمام طبی معلومات کو بے نام اور خفیہ رکھا جائے گا۔

آپ کی تحریری اجازت کے بغیر آپ کا ڈیٹا کسی کے ساتھ شیئر نہیں کیا جائے گا۔

Date:	Time:	Location:
Age:	Gestation in weeks:	Fetal Position:
Fever: Yes/No	ROM: Yes/No	Duration of Labor:
Decision to Delivery interval: min	Operation time: min	
Anesthesia Used:	Anesthetic agents used:	

○ Epidural ○ Spinal ○ General ○ Notes:			
Indication/s for LSCS: <u>Non-Reassuring FHR</u> ○ Late Decelerations ○ Fetal Bradycardia ○ Fetal tachycardia ○ Variable Decelerations ○ HELLP syndrome ○ Fetal anomaly ○ Multiple gestations ○ Uncontrolled bleeding	○ Meconium ○ Uteroplacental insufficiency ○ Placental previa ○ Abruptio placentae ○ Oligohydramnios ○ Malpresentation ○ Umbilical cord prolapsed ○ PROM ○ PPRM ○ Other:		
Maternal parameters: MAP 0 minutes: ----- 10 minutes: ----- 20 minutes: ----- 30 minutes: ----- Upon recovery: -----	Maternal Parameters: Heart Rate 0 minutes: ----- 10 minutes: ----- 20 minutes: ----- 30 minutes: ----- Upon recovery: -----		
Fetal/Neonatal Parameters: To be recorded on-site by Pediatrician or Anesthetist			
A-P-G-A-R Scores	1 minute	5 minutes	10 minutes
Appearance 0 - Blue/Pale face 1 - Pink face, Blue extremities 2 - Pink			
Grimace/Expression 0 - No expression 1 - Facial scowl 2 - Crying			
Pulse/Heart Rate 0 - No heart beat 1 - 60-80 2 - 80 - 100			

Activity/Movements 0 – Limp/floppy 1 – Limb flexion 2 – Active & vigorous			
Respirations: 0 – No respirations or gasping 1 – Breaths noted 2 – Crying actively			
Condition of baby after 20 minutes: ○ Stable in skin to skin contact with mom ○ Under observation in delivery room ○ Oxygen requirement in delivery room ○ Transferred to NICU/Nursery			
Condition of baby after 30 minutes: ○ Stable in skin to skin contact with mom ○ Under observation in delivery room ○ Oxygen requirement in delivery room ○ Transferred to NICU/Nursery			
Breastfeeding offered: ○ Yes ○ No ○ 25% D/W feeding ○ Formula feeding			
Outcome of baby: ○ Stable with mom ○ Under observation in Nursery ○ Admitted in NICU on oxygen ○ Critically ill on life support ○ Expired within 72 hours			

References:

1. Royal College of Obstetricians and Gynaecologists, Royal College of Anaesthetists. Classification of Urgency of Caesarean Section—A Continuum of Risk. Available from <http://www.rcog.org.uk/classification-of-urgency-of-caesarean-section-good-practice-11>
2. Algert CS, Bowen JR, Giles WB, Knoblanche GE, Lain SJ, Roberts CL. Regional block versus general anaesthesia for caesarean section and neonatal outcomes: a population-based study. BMC Med 2009; 7: 20 PMID:19402884
3. Reynolds F, Seed PT. Anaesthesia for Caesarean section and neonatal acid-base status: a meta-analysis. Anaesthesia 2005; 60: 636–653 PMID:15960713
4. Fox GS, Houle GL. Acid-base studies in elective Caesarean sections during epidural and general anaesthesia. Can Anaesth Soc J 1971; 18: 60–71 PMID:5545736
5. James FM 3rd, Crawford JS, Hopkinson R, Davies P, Naiem H. A comparison of general anesthesia and lumbar epidural analgesia for elective cesarean section. Anesth Analg 1977; 56: 228–235 PMID:557920
6. Afolayan JM, Olajumoke TO, Esangbedo SE, Edomwony NP. Spinal Anaesthesia for Caesarean Section in Pregnant Women with Fetal Distress: Time for Reappraisal. Int J Biomed Sci 2014; 10: 103–110 PMID:25018678
7. World Health Organization. 2014. Trends in maternal mortality: 1990 to 2013. Estimates by WHO, UNICEF, UNFPA, The World Bank and the United Nations Population Division. WHO Geneva 2014
8. Obstetric Anaesthetists' Association, Association of Anaesthetists of Great Britain & Ireland. OAA/AAGBI guidelines for obstetric anaesthetic services 2013. Available at; <http://www.oaa-anaes.ac.uk/content.asp?ContentID=580>
9. Shoukat R, Momon F, Rajpur S, Shaikh M; Perinatal outcome of women who delivered within 30 minutes of taking decision versus after 30 minutes undergoing emergency cesarean section; J Soc Obstet Gynecol Pak. 2022; Vol 12. No. 3

10. Chukwudi OE, Okonkwo CA. Decision delivery interval and perinatal outcome of emergency caesarean sections at a tertiary institution. Pakistan journal of medical sciences. 2014 Sep;30(5):946

TERMS & CONDITIONS OF MOU

1. This Memorandum of Understanding between NEAD-SPIRE and Individual/Independent Consultant/AGENCY is valid from DATES, September 1st, 2023 – December 31st, 2023, (PROBATIONARY) and extendable till September 30th 2024
2. It is renewable yearly after mutual agreement and revisions, (if any) of term and conditions.
3. SPIRE reserves the right to revoke this MOU with ONE-week notice period and ONE-week grace period. The Individual/Independent Consultant/Agency may opt out of the terms and conditions of this MOU after giving a one-week notice of mediation followed by a two-week notice of termination via registered mail.
4. In the event of a breach of Disciplinary policy of SPIRE, MOU can be revoked without notice and with no grace period through official letter via registered mail.
5. Terms & conditions of this MOU are confidential between SPIRE and Individual/Independent Consultant/AGENCY. No press release, media coverage and other social media releases are allowed under this MOU without prior scrutiny by and approval of Chairperson, NEAD and Director, SPIRE.
6. SPIRE reserves the privilege to make press releases and media statements about events jointly arranged by SPIRE and AGENCY after clearance from appointed representatives of AGENCY.
7. All research work, publishable output and funded projects resulting from collaboration through this MOU are to be further processed through members of SPIRE team and Individual/Independent Consultants/appointed members of AGENCY team/s. AGENCY cannot publish/reproduce/use part of or entire piece of work without prior approval from Chairperson, NEAD and Director, SPIRE. (Re: Disciplinary Policy of SPIRE; Authorship Rights).
8. SPIRE accepts the responsibility to provide logistic/media and qualified human resources for events arranged jointly after this MOU is signed.
9. AGENCY accepts the responsibility to assist SPIRE in arranging ONE event/month in institutions where AGENCY holds focal persons and professional linkages.

SPIRE: Support Systems: ALLOWED by this MOU

1. SPIRE Office/s located at Peshawar University Campus and F-10 Islamabad
2. IT support
3. Logistic support for local events
4. Qualified human resource/workshop facilitators/teachers/scientists for events
5. Proof reading and publishing support
6. NEAD Website
7. NEAD email

AGENCY: Support Systems: REQUIRED by this MOU

1. SPIRE Focal persons in respective institutions
2. Individual/Independent Consultants/Agency Website: (Provide web link)
3. Agency press department: (Provide contact details)
4. Agency publications: (Provide links to at least 03 Publications about the said title given in this MOU that came out of your institution in last ONE year.)

**External/Internal Research Linkages – REQUIRED from AGENCY
(Check those that you have available since January 2023)**

- Local government university
- Local government medical colleges
- Local private medical colleges
- Local paramedical training school/s
- Local nursing schools
- College of Physician & Surgeons of Pakistan
- Post Graduate Medical Institute
- Institutional Review Committee
- Institutional Ethical Committee
- Institutional Review Board
- Pakistan Medical Research Council
- Pakistan Science Foundation
- Any other research collaboration/s:

Human Resource OFFERED by SPIRE

Research degrees (PhD qualified faculty members in various clinical and basic sciences departments)

Physical Resources

Outlined above.

Financial Support Offered by SPIRE

1. R&D Fund of NEAD-SPIRE
2. Funded projects of SPIRE