

OBSTETRICS & GYNECOLOGY

These unmet clinical needs were identified following an 8-week clinical immersion that was conducted by a team in Obstetrics and Gynecology. The clinical immersion was conducted in high volume tertiary care centres in South India. We observed what's done and how it affects the provider, the patient, and the system. This was followed by a peripheral immersion to numerous primary, secondary and tertiary health care centres across India. The clinical needs found in the tertiary care hospital were validated in other large centres and new primary and secondary specific unmet needs were added on. At the end of 2 months of clinical immersion, the team had over 100 detailed observations with significant negative outcomes and 150 unmet clinical needs. These needs were then filtered using objective parameters, detailed below:

THE FILTERING PROCESS: 3 STAGES OF FILTERING

Level 1: The level 1 filter eliminated those needs which are redundant, pharmaceutical related or process related.

Level 2: This level of filtering focused on the severity of clinical condition (in the perception of observers and clinicians) as well as the epidemiology of the disease and the frequency of the negative outcome. This data was then validated by a comprehensive literature review of incidence and prevalence data. A scoring system of 1 – 3 – 5 was used through the process.

Epidemiology

- Frequency of problem as per clinician (number of cases per month)
 - < 5 patients per month =1
 - 6-12 patients per month =3
 - >13 patients per month =5
- Frequency of problem as per observers (number of cases seen per month during the clinical immersion)
 - < 2 patients per month =1
 - 2-5 patients per month =3
 - >5 patients per month =5

Criticality

- Short lasting, reversible: Not resulting in death, disability, hospitalization, or socioeconomic stress = 1
- Resulting in death, hospitalization >3 days, disability/ handicap (> 6 months), large financial burden to the patient/family = 5
- Needs in between 1 and 5 = 3

Observed Epidemiology and criticality score: 3 (Frequency of clinician) + Frequency of observer + 3 (Criticality score)

Target patient population in a given year: We used data wherever available for India. However, in many cases due to the dearth of validated health statistics, certain assumptions had to be made using a combination of data from India and global epidemiological data.

- <100,000 patients/year = 1
- 100,000 – 500,000 patients/year = 3
- >500,000 patients/year =5

Secondary research based epidemiology and criticality score: Target patient population * Criticality score

Filter 2 score: Subjective epidemiology and criticality score + secondary research based epidemiology and criticality score

Level 3: The third level of filtering evaluated the technical complexity of the solutions available, the regulatory landscape and the buyer environment.

Number of predicates: This was made based on the solutions which currently exist as per guidelines and those being used in the Indian clinical setting. Both at prevailing practice as well as gold standards were considered.

- High number of predicates i.e. >5 = 1
- Medium number of predicates i.e. 1 to 5 = 3
- No predicates = 5

Technical complexity of predicates: This filter considered the technology behind the solution as well as the expertise needed to implement it in current clinical practice. A medium complexity solution is rated the highest, followed by low complexity and lastly by a highly complex solution.

- High =1
- Medium =5
- Low =3

Regulatory and clinical trial complexity: This filter was based on the regulatory hurdles and clinical trials one would have to conduct for a particular solution. It was a judgment call based on the current predicates in the system and the classification of devices as per the Global Harmonisation Task Force classification (Class A - Low Risk, Class B - Low to Moderate Risk, Class C - Moderate to High Risk, Class D - High Risk)

- High (Class D) =1
- Medium (Class C) =3
- Low (Class A & B) =5

Buyer environment: This filter was based on the eventual buyer of a particular medical solution. This in turn depended on which level in the healthcare system the particular condition was treated. The peripheral immersion helped understand, more thoroughly, the referral system in India which defined this filter.

- High (Tertiary Care Centre) = 5
- Medium (Secondary Centre) = 3
- Low (Individual/Primary centre) = 1

Filter 3 score = Number of predicates score + Regulatory and clinical trial complexity score + Buyer environment score

Final Score= Filter 2 score + (Filter 3)/4

NEED SPECIFICATION DOCUMENTS

1. FETAL DISTRESS & INTRAUTERINE FETAL DEATH

INTRODUCTION

Fetal Distress (FD) is a complication of labor. It occurs when the fetus does not receive enough oxygen. Fetal distress may also occur when the pregnancy lasts too long (post maturity).

Usually, doctors identify fetal distress based on an abnormal fetal heart rate pattern. In such cases, the fetus' heart rate is monitored continuously. It is usually monitored continuously with electronic fetal heart monitoring or, a hand-held Doppler ultrasound device may be used to check the heart rate every 15 minutes during early labor and after each contraction during late labor.^[1]

OBSERVATION

Female, 24 years, pregnant for the third time and currently at 40 weeks gestational age. The first and second pregnancy were both full term vaginal deliveries. The second baby had a congenital heart defect. Patient arrives on a stretcher to the high-risk pregnancy (HRP) labor ward of an urban tertiary healthcare center at noon with complains of severe abdominal pain and leak per vagina since the night before. The patient is accompanied by her sister.

History:

Five days ago, patient visits the out-patient department of the same urban tertiary care center for her regular antenatal checkup. On examination, her blood pressure was found to be 110/70, no pallor, edema negative and fetal heart sounds positive. Estimated delivery date (EDD) given was two days ago. The doctor told her that since she is 2 days past her due date, she should get admitted immediately to the clean labor ward.

The patient was not yet in labor. From her experience of her previous two pregnancies where she had gone into labor after her EDD, she decided not to get admitted and went back home. Four days late, patient experienced severe lower abdominal pain. The patient goes to the same tertiary care center the next morning.

Day of admission:

Patient visits the OPD where her per abdominal examination was done and no fetal heart sound was detected. The patient is sent to get an ultrasound scan and report to the Septic Room Labor Ward (SRLW). As the scanning room is very crowded at the hospital, the patient's family take her outside to a private diagnostic center for scanning and return. She goes to the Septic Room Labor Ward (SRLW) as directed. From there she is sent to the clean labor ward (CLW). At the Clean Labor Ward, they check her file and send her to the HRP labor ward in view of intrauterine death (as seen in the scan). Patient is very tired and frustrated on arrival at the HRP at noon. Patient says that she could feel the baby's movements since the night before.

On arrival to HRP, BP was 150/110. No pallor, no edema.

At noon the membrane is artificially ruptured and meconium stained liquor is found. The patient is injected with oxytocin - 10 units intramuscular and 10 units intravenous. On per vaginal examination patient has dilated 6 cms. Labor is accelerated with oxytocin. One hour later, patient delivers a fresh dead female baby weighing 2.5 Kgs.

CURRENT SCENARIO

Undetected (asymptomatic) fetal distress in pregnant women post term.

Pregnant women currently monitor fetal health at home by maintaining a chart of fetal movement through the day. This is inaccurate due to its subjective nature, especially in primigravidae. Also, non-compliance by pregnant women is fairly common. There is currently no method to monitor the fetal heart rate at home and doctors monitor the fetus only during routine check-ups.

NEED STATEMENT

An accurate (Equal to NST) and low skill (any pregnant female at term should be able to use) way to detect fetal distress in women who are not in labor, used at home to avoid Intrauterine fetal death (IUFD).

FILTERING PROCESS

Final Score = 14

Rank =1

MARKET POTENTIAL

Number of deliveries annually: 25,000,000

Number of IUFDs and stillbirths in the system: 5,00,000

There are on an average 40 intrauterine fetal deaths for every 1000 live births recorded.

COMPETITIVE LANDSCAPE

There is currently no solution within India available to detect asymptomatic fetal distress in a home setting. Hand held dopplers that are available, are recommended to be used only by trained clinicians.

In rural India, a comprehensive mother and child registration booklet called the THAYI card is distributed ward wise. Regular visits are made by Accredited Social Health Activists (ASHA workers) to check maternal and fetal health. These checks include review of the baby movement chart. However, the workers are not provided with hand held dopplers to measure fetal heart rate and hence all pregnant women must visit their nearest health care center for antenatal checks.

In urban India, there is a surplus of government, aided, charitable and private maternity hospitals, though no solution for accurate home monitoring is available. Even in urban India, the daily baby movement chart is advised and is the only measure of fetal health from a home setting.

A Non-Stress Test (NST) and CTG are used to monitor women in early and active labour. A state of the art NST machine costs around Rs. 3-4 lakhs.

AVAILABLE OPTIONS FOR FETAL HEART MONITORING

EXTERNAL MONITORING

- **Pinard Stethoscope** - It is a gynecological instrument which allows the heartbeat to be heard in a quick and easy manner. The Pinard stethoscope is helpful when expensive tools such as ultrasound machines may not be available.^[2]
- **Electronic Hand-Held Doppler** - monitoring through a fetal Doppler is similar to that of a fetal stethoscope. An advantage of the Doppler fetal monitor over a fetal stethoscope is the electronic audio output, which plays out the fetal heart sound through an inbuilt speaker.
- **Electronic Fetal Heart Monitors** - It keeps track of the heart rate of the baby (fetus). It also checks the duration of the contractions of the uterus. The associated tests are called a non-stress test and cardiotocography. Electronic monitors may be ultrasound devices or electrocardiogram devices.

INTERNAL MONITORING

Fetal Scalp Electrode - For internal monitoring, a sensor is strapped to the thigh. A thin wire (electrode) from the sensor is put through the cervix into the uterus. The electrode is then attached to the baby's scalp. The baby's heartbeat may be heard as a beeping sound or printed out on a chart.^[3]

IDEAL SOLUTION

The solution must be designed such that it is simple to use for a pregnant woman without any assistance. It must also be able to communicate the fetal heart rate in an understandable method to the user. The solution must also give accurate results that are comparable or better than the existing solutions.

NEED CRITERIA

MUST HAVES

- Fetal heart rate output must be equal to available solutions
- Audible / Visual output of fetal heart rate
- Easy to use for a non-clinician
- Non-invasive
- Robust form

NICE TO HAVE

- Cost effective for easier adoption in rural settings
- Wire-free
- Light weight <200 grams
- Easy to use and store at a home setting

REFERENCES

1. <http://www.msmanuals.com/home/women-s-health-issues/complications-of-labor-and-delivery/fetal-distress>
2. <http://www.blacksmithsurgical.com/gynecology-instruments/pinard-stethoscope>
3. <https://myhealth.alberta.ca/Health/pages/conditions.aspx?hwid=hw214546>

2. UTERINE FIBROIDS - MONITORING

INTRODUCTION

Uterine fibroids are benign smooth muscle tumors of the uterus. Most women have no symptoms while others may have painful or heavy periods. Diagnosis can be performed by pelvic examination or medical imaging. Medications of the gonadotropin releasing hormone agonist class may decrease the size of the fibroids but are expensive and associated with side effects. If greater symptoms are present, surgery to remove the fibroid or uterus may help. Uterine fibroids are the most common reason for surgical removal of the uterus.

OBSERVATION

32-year-old Female, from a rural area, with two prior pregnancies both of which were live deliveries arrives at a major urban tertiary health center (THC) at the outpatient department (OPD), 8 months ago, with history of heavy menstrual bleeding and clots associated with abdominal pain since the past 3 months. Patient complains of heavy bleeding for 15 days per month and changes 3-4 sanitary pads per day.

The advice from the gynecologist at the OPD is to conduct a pelvic ultrasound scan and blood work of the patient. The scan is conducted at the same THC and shows a submucosal uterine fibroid of dimensions 1.5 x 2 centimeters (cm) along with thickening of the endometrial layer of the uterus. After consulting the scan, doctors conclude that the fibroid is still small at this point and an invasive removal procedure can be avoided.

In order to manage the endometrial layer thickening, the patient is admitted into the Obstetrics and Gynecology (OBGYN) ward at the hospital. The patient is transfused with 2 units of Packed Red Blood Cells (PRBC) and a Dilation and Curettage (D&C) procedure is done. Patient is sent home and is counselled that the procedure done should control her heavy bleeding cycles. Patient is advised to get regular ultrasound scans done to continuously monitor the development of the fibroid.

Patient 's bleeding was in control for the next 6 months. The patient goes to the local health clinic to get an ultrasound scan to monitor the fibroid as per advice but the local clinic does not have ultrasound equipment or a radiologist to conduct the scan. Since she is not facing any symptoms and her heavy bleeding is in check she does not bother much about it. In the 7th month, the patient experiences heavy blood flow and severe abdominal pain. She immediately goes to the local clinic where she is referred to get an ultrasound scan. For the scan, the patient arrives at the urban THC after travelling a large distance. The scan shows that the fibroid has grown and is 4.2 cm x 4.3 cm in size. She was referred to the OBGYN ward for a surgery.

At the urban THC, patient is admitted and underwent a total abdominal hysterectomy under general anesthesia (GA). The patient is in the fertile age group and has lost her ability to conceive.

CURRENT SCENARIO

Presently, uterine fibroids in women are diagnosed with an Ultrasonography (USG) Scan when the woman presents with symptoms. If the fibroid is small, it is treated with medication and the patient is advised to get regular scans to monitor it. However, majority of the health centers in rural and semi urban parts of India do not have USG equipment. Some centers, which have the

equipment, do not have a radiologist and hence cannot conduct these regular scans. Due to this, large number of fibroid cases go unmonitored and have to be managed through a hysterectomy when the fibroid grows too large.

NEED STATEMENT

An accessible and low skill (without a radiologist, any doctor should be able to use) way to monitor asymptomatic uterine fibroids in fertile women at primary healthcare centers to prevent infertility and risks of hysterectomy.

FILTERING PROCESS

Final Score = 13

Rank = 2

MARKET POTENTIAL

There are an estimated 20 million cases of asymptomatic uterine fibroids annually in India. [2] Approximately 10% of these patients have access to health centers where USG facilities and radiologists are available to monitor. This estimates the patient pool to approximately 2 million people annually.

Although Ultrasonography is an obvious solution to monitor fibroids, the absence of a radiologist in most parts of the country nullifies its effectiveness. Another issue of an ultrasound machine in rural India is its use to determine the sex of the baby which is a step back in combating female infanticide in India. These two mutually exclusive factors present a large market for a possible device solution.

COMPETITIVE LANDSCAPE

Ultrasonography: Ultrasonography is a diagnostic imaging technique based on the application of ultrasound. [3] General Electric (GE) Healthcare is the gold standard for USG equipment. In India, the cost of an Ultrasound Machine ranges from INR 250,000 to INR 3,000,000 depending on the brand and range of product. Another key factor in determining the price of USG equipment is if it is first hand equipment or certified refurbished by an authorized dealer.

In the private healthcare setting, the cost of a pelvic ultrasound scan can range from INR 450 to INR 1,500 depending upon healthcare setting such as private clinics or tertiary care centers.

Magnetic Resonance Imaging (MRI): The cost of an MRI Machine in India ranges from INR 10,000,000 to INR 70,000,000 depending upon the strength of magnetic field and brand. Certified refurbished 3 Tesla (3T) MRI Machines cost an average of INR 25,000,000.

The average cost of an MRI Scan in the private healthcare setting in India can range from INR 4,000 to INR 10,000.

IDEAL SOLUTION STATEMENT

An ideal solution should have the following:

- Ideally, the solution should be able to monitor the presence and growth of uterine fibroids at centers where an ultrasound machine, gynecologist or a radiologist is unavailable (accessible and low skill).
- It should be able to indicate when a uterine fibroid can be ignored and when it needs management.

NEED CRITERIA

MUST HAVE

- Usable by an General Physician
- Low cost: Patient should pay less than INR 100 per session

NICE TO HAVE

- Usable by Nurse or paramedic
- Indicates exact dimensions of fibroid
- Indicates when fibroids can be ignored or when it required surgical intervention

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1. "Uterine fibroids fact sheet". Office on Women's Health. January 15, 2015. Archived from the original on 7 July 2015. Retrieved 26 June 2015.
2. Asymptomatic Uterine Fibroids. (2018, 30 January). Retrieved from <http://www.sciencedirect.com/science/article/pii/S1521693408000205>
3. Badea, R.; Ioanimescu, Simona (2012). "Ultrasound Imaging of Liver Tumors – Current Clinical Applications".
4. "Magnetic Resonance, a critical peer-reviewed introduction". European Magnetic Resonance Forum. Retrieved 17 November 2014.

3. PREVENTION OF SEIZURES IN PRE-ECLAMPSIC/ ECLAMPSIC WOMEN

INTRODUCTION

Pre-eclampsia (PE) is a disorder of pregnancy characterized by the onset of high blood pressure and often a significant amount of protein in the urine. When it arises, the condition begins after 20 weeks of pregnancy. In severe disease there may be red blood cell breakdown, a low blood platelet count, impaired liver function, kidney dysfunction, swelling, shortness of breath due to fluid in the lungs, or visual disturbances. Pre-eclampsia increases the risk of poor outcomes for both the mother and the baby. If left untreated, it may result in seizures at which point it is known as eclampsia. [1]

OBSERVATION

18-Year-old female is 33+3 weeks gestational age (33 weeks and 3 days into her pregnancy) and Primigravida (First pregnancy). Patient arrives at the Out Patient Department (OPD) at an urban Tertiary Health Centre with per vaginal mild white discharge and pelvic pain. On further questioning, it is found that her regular ante-natal (pre-labor) check-up scan was not done. The patient's blood pressure is taken, BP 145/112 (High). Patient was advised to get admitted, however patient's family is unwilling. Patient goes back home. Two weeks later, Patient comes into the emergency room at 5 a.m. with a history of 2 episodes of seizures. Her Family is unwilling to give a proper clinical history. On admission, her Pulse Rate (PR): 80, Blood Pressure: 130/100 (high). Fetal heart sounds not localized. She is diagnosed with eclampsia and MgSO₄ (Magnesium Sulphate) given according to Pritchard regimen (standard protocol for Magnesium Sulphate dosage). Prior to being treated with Magnesium Sulphate, patient is on Labetalol 100 mg (vasodilating drug used to manage high blood pressure) twice a day (1-0-1). When she is being moved from high risk pregnancy (HRP) side-ward to HRP Labor Ward, she had another episode of seizure. Uterus was term sized and relaxed. Pelvic Scan reveals Single Live Intra-Uterine Gestation (Fetus was alive inside the uterus) with Cephalic presentation and adequate Liquor. At 6:40 am, Patient is not responding to oral commands, very irritable. PR: 100, BP: 120/70. She had a tongue bite overnight (Sign of seizure overnight). She had pedal Edema (swelling due to accumulation of fluid (symptom of pre-eclampsia)). At 2:30 pm, Labor was induced (current protocol to manage uncontrolled pre-eclampsia and eclampsia) and she delivered (vaginally) a female at 2kg (pre-term). At 10am: Post-delivery, patient appeared weak. She fainted while being shifted from one bed to another. Patient was mildly anaemic. Immediately after delivery, baby was in the Neonatal ICU for observation, and then shifted out within 3-4 hours. Post-delivery maternal heartrate 86, BP 155/112 (high).

CURRENT SCENARIO

Currently, management of pre-eclampsia before the onset of labor includes close monitoring of maternal and fetal status, medical management of hypertension through vasodilating drugs such as labetalol and seizure prophylaxis with Magnesium Sulphate (which has risk of Magnesium toxicity in the patient). However in large number of cases, delivery remains the ultimate treatment which leads to risk of seizures pre-Labor, during Labor and post Labor.

NEED STATEMENT

An effective (MgSO₄ fails to prevent seizures + Mg toxicity) way to prevent seizures in pre-eclampsic/ eclampsic women at secondary care centres and above to prevent high risk of brain damage and/or Magnesium toxicity.

FILTERING PROCESS

Final Score = 13

Rank = 3

MARKET POTENTIAL

Out of the 30 million pregnancies reported annually in India (which come into the healthcare setting), there are 25 million reported live births. 50 out of 1000 live births have a reported case of pre-eclampsia progressing into eclampsia. As a result, there are 1.25 million cases of eclampsia and seizures during pregnancy annually in India. [2]

Currently there exists only one protocol to manage pre-eclampsia and ultimate treatment in premature medical termination of pregnancy and delivery. This possesses high risk to both mother and the baby. Hence a potential solution, which may enable the pregnancy to be carried to term, will have a large potential market.

COMPETITIVE LANDSCAPE - AVAILABLE TREATMENT OPTIONS

MANAGEMENT OF BLOOD PRESSURE (HYPERTENSION)

The World Health Organization (WHO) recommends that women with severe hypertension during pregnancy should receive treatment with anti-hypertensive agents. Labetalol, Hydralazine and Nifedipine are commonly used antihypertensive agents for hypertension in pregnancy.

The goal of treatment of severe hypertension in pregnancy is to prevent cardiovascular, kidney, and cerebrovascular complications. [3]

PREVENTION OF ECLAMPSIA

The intrapartum and postpartum administration of Magnesium Sulphate is recommended in severe pre-eclampsia for the prevention of eclampsia. Further, Magnesium Sulphate is recommended for the treatment of eclampsia over other anticonvulsants. Magnesium Sulphate acts by interacting with NMDA receptors. [3]

INDUCTION OF LABOR

The definitive treatment for pre-eclampsia is the delivery of the baby and placenta. The severity of disease and the maturity of the baby are primary considerations. Treatment can range from expectant management to expedited delivery by induction of labor or Caesarian section, in addition to medications. [4]

In the private healthcare setting in India, the overall management of pre-eclampsia including anti-hypertensive medication, Magnesium Sulphate, medical termination of pregnancy and delivery can cost anywhere between INR 25,000 to INR 80,000.

IDEAL SOLUTION STATEMENT

An ideal solution should have the following:

- Should be able to manage the blood pressure effectively
- Avoid progression into eclampsia and seizures.

NEED CRITERIA

MUST HAVE

- Should cost as much or lesser per session use as compared to Magnesium Sulphate.

NICE TO HAVES

- Usable by a nurse or paramedic.
- Allow pregnancy to be carried to term.

REFERENCES

1. Pre-eclampsia: Symptoms, risks, treatment and prevention. (2018, January 30). Retrieved from <http://americanpregnancy.org/pregnancy-complications/preeclampsia/>
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4. UTERINE FIBROIDS - MANAGEMENT

INTRODUCTION

Uterine fibroids are benign smooth muscle tumors of the uterus. Most women have no symptoms while others may have painful or heavy periods. Diagnosis can be performed by pelvic examination or medical imaging. Medications of the gonadotropin releasing hormone agonist class may decrease the size of the fibroids but are expensive and associated with side effects. If greater symptoms are present, surgery to remove the fibroid or uterus may help. Uterine fibroids are the most common reason for surgical removal of the uterus. [1]

OBSERVATION

32-year-old Female, who comes from a rural area, with two prior pregnancies both of which were live deliveries arrives at a major urban tertiary health center (THC) at the outpatient department (OPD), 8 months ago, with history of heavy menstrual bleeding and clots associated with abdominal pain since the past 3 months. Patient complains of heavy bleeding for 15 days per month and changes 3-4 sanitary pads per day.

The advice from the gynecologist at the OPD is to conduct a pelvic ultrasound scan and blood work of the patient. The scan is conducted at the same THC and shows a submucosal uterine fibroid of dimensions 1.5 x 2 centimeters (cm) along with thickening of the endometrial layer of the uterus. After consulting the scan, doctors conclude that the fibroid is still small at this point and an invasive removal procedure can be avoided.

In order to manage the endometrial layer thickening, the patient is admitted into the Obstetrics and Gynecology (OBGYN) ward at the hospital. The patient is transfused with 2 units of Packed Red Blood Cells (PRBC) and a Dilation and Curettage (D&C) procedure is done. Patient is sent home and is counselled that the procedure done should control her heavy bleeding cycles. Patient is advised to get regular ultrasound scans done to continuously monitor the development of the fibroid.

Patient 's bleeding was in control for the next 6 months. The patient goes to the local health clinic to get an ultrasound scan to monitor the fibroid as per advice but the local clinic does not have an ultrasound equipment or a radiologist to conduct the scan. Since she is not facing any symptoms and her heavy bleeding is in check she does not bother much about it. In the 7th month, the patient experiences heavy blood flow and severe abdominal pain. She immediately goes to the local clinic where she is referred to get an ultrasound scan. For the scan, the patient arrives at the urban THC after travelling a large distance. The scan shows that the fibroid has grown and is 4.2 cm x 4.3 cm in size. She was referred to the OBGYN ward for a surgery.

At the urban THC, patient is admitted and underwent a total abdominal hysterectomy under general anesthesia (GA). The patient is in the fertile age group and has lost her ability to conceive.

CURRENT PROBLEM

Presently, uterine fibroids in women are diagnosed with an Ultrasonography (USG) Scan when the woman presents with symptoms and managed by performing a hysterectomy which is a surgery with high risk of post-operative complications and which also leads to infertility in fertile age group women. A safer treatment of fibroids is laparoscopic myomectomy which is an

expensive procedure that required a high skilled surgeon and high resource operation theatre.
[2]

NEED STATEMENT

A safer (uterus sparing procedure) and low skill (any obstetrician/ gynecologist should be able to perform) way to manage uterine fibroids in women at secondary care hospitals and above to prevent risks of hysterectomy.

FILTERING PROCESS

Final Score = 12.5

Rank =4

MARKET POTENTIAL

At any given time in India, 10% of the 100 million women in fertile age group of 20-35 years have uterine fibroids. That accounts for a prevalence of 10 million cases of fibroids. Out of these, an estimated 10% of women have access to a gynaecologist. This results in an patient pool of 1 million women in the fertile age group alone. Out of the post-menopausal age women who have access to a gynaecologist, fibroids are prevalent in 1.5 million patients. This accounts for a total of at least 2.5 million cases of fibroids in women in the present healthcare setting. [3][4]

The dearth of Laparoscopic equipment, OB-GYN surgeons trained in laparoscopy as well the high costs of laparoscopic surgery are all factors in the limited prevalence of myomectomy as a solution to manage fibroids. This leaves hysterectomy as the only solution. The high risks and long recovery period of hysterectomy and the high costs of myomectomy are key factors in ensure a large market potential for a possible solution.

COMPETITIVE LANDSCAPE

Hysterectomy: Hysterectomy is the surgical removal of the uterus. Hysterectomy is a permanent solution for fibroids, and is an option if other treatments have not worked or are not appropriate. [5] In the private healthcare setting in India, the average cost of a hysterectomy ranges from INR 150,000 to INR 300,000. Charitable trust hospitals charge INR 25,000 to INR 60,000 for the procedure and government tertiary care centers do it free of charge.

Laparoscopic Myomectomy: Refers to the surgical removal of uterine fibroids using laparoscopic instruments. [5] Laparoscopic Myomectomy can cost anywhere between INR 260,000 to INR 400,000 in the private healthcare setting.

Medicine choices: Gonadotropin-releasing hormone analogue is used to shrink fibroids before surgery and to temporarily relieve symptoms. GnRH-a therapy puts the body in a state like menopause, which shrinks the uterus and fibroids. GnRH-a therapy is used for only a few months, because it can weaken the bones. It may also cause unpleasant menopausal symptoms. Fibroids grow back after GnRH-a therapy is stopped. [5]

IDEAL SOLUTION STATEMENT

An ideal solution should have the following:

- Manage the uterine fibroid without removing the uterus
- Usable by any OBGYN surgeon
- Inexpensive
- Executable in a low resource operation theatre setting

NEED CRITERIA

MUST HAVE

- Usable by any OBGYN surgeon
- Usable in low resource operation theatre setting such as a district hospital
- Should retain the uterus irrespective of the size of the fibroid
- Should cost the patient less than INR 150,000

NICE TO HAVE:

- Non-Invasive method
- Should be able to be done under local or spinal anesthesia
- Usable in minor operation theatre setting

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5. ECTOPIC PREGNANCY

INTRODUCTION

Ectopic Pregnancy (EP) is a complication associated with pregnancy, where in the embryo get implanted in the Fallopian Tube (most commonly) and starts growing there [1]. Ectopic Pregnancy can occur in the ovary, cervix, vagina, body of the uterus or even in the peritoneum. When the Embryo grows, the tube gets severely stretched leading to abdominal pain and vaginal bleeding. In many extreme cases, the tube ruptures leading to severe internal and vaginal bleeding. This is an emergency condition and requires quick surgical intervention to prevent hemorrhagic shock.

OBSERVATION

32-year-old female, presented in her third pregnancy at 8 weeks and 5 days of gestation. Her first pregnancy ended in a normal full-term vaginal delivery, while her second pregnancy ended in an ovarian ectopic pregnancy leading to a unilateral Salpingo-Oophorectomy (removal of tube and ovary). She had come into an Emergency Unit in a tertiary care hospital with heavy vaginal bleeding and severe left lower abdominal pain. She was rushed to the Operating Theatre (OT) for a suspected ruptured tube/ovary. She is put under General Anesthesia (GA) and a lower segment laparotomy was performed. Her ovary had ruptured due to an ectopic pregnancy growing on the ovary. A unilateral Salpingo-Oophorectomy was performed. The patient was infertile (sterile) due to removal of both her ovaries. She was unaware of her pregnancy for two months. Ovarian Ectopic Pregnancies are extremely rare. More commonly, the tube ruptures are treated with a Salpingectomy. In addition, the woman cannot conceive normally if both the tubes are removed. [2]

CURRENT PROBLEM

Early detection of Ectopic Pregnancy is extremely difficult especially since most pregnancies, especially in India are unplanned. In most of cases, females become aware of the pregnancy around 6-8 weeks of gestation. A woman's chances of fertility are severely reduced after the tube is removed on one side, and is reduced to zero if both tubes are removed.

NEED STATEMENT

A safer (preserving tubal functionality) way to manage tubal rupture (ectopic pregnancy) in women at secondary care hospitals and above to preserve the normal fertilization pathway.

FILTERING PROCESS

Final score = 11.5

Rank =5

MARKET POTENTIAL

Annually, India has 4 recorded EPs per 1000 pregnancies. India has an estimated 30 million pregnancies annually, implying at least 100,000 annual cases of EPs leading to Salpingectomy are recorded in India. ^{[3][4][5]}

COMPETITIVE LANDSCAPE - AVAILABLE TREATMENT OPTIONS

DIAGNOSIS

- **β -HCG (Beta-Human Chorionic Gonadotropin) test:** This hormone is produced in the body after implantation. However, since the implantation is not particularly complete in a tubal gestation, the HCG levels in the blood may not be high enough to be detected on a Urine Pregnancy Test (UPT). Hence, false negatives are common. The HCG blood test is a more definitive test than a UPT. The cost is approximately Rs. 600.
- **Ultrasonography:** A Transvaginal Ultrasound (TVS) is known to detect Tubal Pregnancy well (high specificity). It ranges from Rs. 300 to Rs. 2,000 depending on the scanning center.

DRUG TREATMENT

Drug treatment is effective in managing EPs if it is caught early and the fetus is still small in size. Methotrexate is given as a single shot or in regular doses to stop rapidly dividing cells.

MANAGEMENT OF RUPTURED TUBE

Laparotomic or Laparoscopic Salpingectomy is inevitable once the fetus is more than 5-7 weeks of gestation. Laparoscopy can be opted for in non-emergency situations. ^[6] The lower end of the price range for the surgery would be Rs. 20,000 with costs going up to Rs. 50,000 in some centers.

IDEAL SOLUTION STATEMENT

An ideal solution should be able to stop the bleeding and remove all the products of conception without losing tubal functionality. The solution should stop the bleeding within a maximum of an hour of the patient entering the healthcare setting.

NEED CRITERIA

MUST HAVE

- Stop the bleed within 60 minutes of entering the hospital
- Can be used by any OBGYN
- Should maintain tubal functionality

NICE TO HAVE

- Completely stop the bleed within 30 minutes
- Can be used by any Emergency Doctor
- Should not cost more than INR 10,000 to the patient

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6. POSTPARTUM HEMORRHAGE

INTRODUCTION

Postpartum Hemorrhage (PPH) is defined as the loss of more than 500 ml of blood within 24 hours after childbirth (post 2nd stage of labour) [1]. This is an emergency scenario that requires active intervention of a trained midwife or obstetrician. If too much blood is lost, the woman can go into hemorrhagic shock.

OBSERVATION

A 25-year-old female with a history of one normal vaginal full-term delivery, pregnant at 41 weeks and 1 day of gestation at the time, was admitted from the OPD of a tertiary care centre to the high-risk pregnancy labour ward with high Blood Pressure (BP) of 140/100 mmHg and a post-dated pregnancy. The patient was not in labour. A urine Albumin test indicated 3+, and a diagnosis of Pre-Eclampsia was made. She had no history of Pregnancy Induced Hypertension (PIH) or any other comorbidities. She had done her regular Ante-natal Checkups (ANCs) at urban private clinic. An ultrasound showed the Amniotic Fluid Index (AFI) as 4 cm. A decision was taken to induce labour using Intra-Venous Oxytocin and Dinoprostone Gel. The patient went into labour at 1am and delivered a live female baby of 2 kgs weight at 10:25am. Placenta was completely expelled and all clots were removed. Uterus failed to contract and bleeding continued till 10:40 am. One more dose of Oxytocin and methergine was given. Bimanual compression of the uterus along with fundal massage was performed. Bakri Balloon was inserted and in place at 10:45am. At 11am, the bleeding did not reduce. Non-pneumatic Anti-shock garments (NASG) were wrapped around lower limbs at 11:10am. Carbetocin and misoprostol was given, yet at 11:30am, the patient was still bleeding. Patient's family was told to arrange 2 units of Packed Red Blood Cells (PRBCs). At 12:10pm, the patient was in hemorrhagic shock and had a weak pulse with heart rate of 130 bpm. Patient had lost an estimated 2 litres of blood. The bleed was slightly controlled with the Balloon, but had not stopped completely. Patient had started to desaturate with Blood Oxygen Saturation (SpO₂) of 90%. A senior doctor took a decision to perform a Total Abdominal Hysterectomy (TAH) at 12:30pm. Patient was transfused 4 units of PRBCs and blood products intra-op while under General Anesthesia (GA). Patient was on a ventilator (Synchronous Intermittent Mechanical Ventilator (SIMV)) support in the Intensive Care Unit (ICU). Patient was very weak and still unresponsive 24 hours later. Her SpO₂ had risen to 95%, Respiratory rate 25/min and Pulse rate 90/min. [2]

CURRENT PROBLEM

The inability to manage a Postpartum Hemorrhage over 3 hours with uterotonic drugs, bakri balloon tamponade and NASGs lead to a Total Abdominal Hysterectomy (TAH). An early hysterectomy has several risks associated such as long recovery time, pelvic adhesions, vaginal prolapse, early menopause etc. In addition, the woman permanently lost her fertility at an early age due to uterus removal.

NEED STATEMENT

An effective (faster, low skill, uterus sparing, and affordable - compared to embolization) way to manage post-partum hemorrhage in women at Primary Health Centres and above to avoid hypovolemic shock and high risk of maternal death (when hysterectomy is neither possible nor desirable).

FILTERING PROCESS

Final score = 11

Rank =6

MARKET POTENTIAL

5-8% of deliveries end up in PPH. That accounts for more than 1 million cases annually. Out of these, at least 1 in 10 cases (10%) cannot be managed by uterotonic drugs or Bakri Balloon Tamponade. Annually, this leaves around 100,000 - 200,000 mothers at high risk for severe morbidity or mortality. [3] [4]

COMPETITIVE LANDSCAPE - AVAILABLE TREATMENT OPTIONS

Uterotonic/Oxytocic Drugs: Oxytocin, Ergometrine and Carbetocin help the uterine muscles to contract. They also increase the production of prostaglandins which in turn help in uterine contraction. Misoprostol acts by binding to myometrial, leading to contractions.

Bi-manual Uterine compression: Fundal massage and bimanual uterine compression help in mechanically compressing the uterus.

Uterine Balloon Tamponade: A deflated uterine balloon (most commonly a bakri balloon) is inserted into the uterus and inflated using sterile saline. These balloons normally have a minimum capacity of 500 ml. The tamponade action of the balloon pressing against the myometrium helps in stemming blood flow. The commercially available uterine-specific devices are designed with an intrauterine drainage port but have a prohibitively high cost. Low resource settings have to rely on lower cost adaptations like a condom balloon tamponade which is the most cost-effective second-line management option. Successful in 92% of cases as a second line approach.

Non-Pneumatic Anti-Shock Garments (NASG): This involves compressing and tying the limbs in a suitable cloth to reduce perfusion to the extremities. In this method, blood flow to the critical organs (heart, brain, lungs, liver and kidneys) is maintained.

Aortic Compression: This is a technique used while waiting for Operating Room facilities. The descending aorta is compressed at the umbilicus by applying vertical compression in the form of a clenched fist. The pulse is checked at the femoral artery to ensure that aortic compression is successful (pulse should be absent).

Compression Uterine Suture (B-Lynch): This requires an obstetrician and OT facilities. A couple of sutures are placed through the uterus in such a way (over the fundus), that the entire uterus is compressed mechanically. This is a laparotomic surgery.

Uterine Artery Embolization: This surgery requires OT facilities and an interventional radiologist (catheterization laboratory). Embolizing agents are delivered into the uterine artery while the patient is under mild sedation.

Peripartum Hysterectomy: If all techniques have failed, the last resort is to remove the uterus. This is a final and definitive way to stop the bleeding. ^[5] ^[6] The cost ranges from Rs. 50,000-200,000 for the procedure.

IDEAL SOLUTION STATEMENT

Ideally, bleeding should be stopped or significantly reduced within one hour of onset of the 3rd stage of labour (beginning of expulsion of placenta). The solution should be non-surgical and should be able to be used by any doctor or trained midwife (low skill).

NEED CRITERIA

MUST HAVE

- Significantly reduce bleed within 1 hour
- Can be used by any doctor or midwife
- Non-surgical method
- Cost to the patient should be under INR 2,000

NICE TO HAVE

- Completely stop the bleed within 1 hour
- Non-invasive method
- Cost to the patient should be under INR 1,000
- Any trained nurse should be able to use

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7. NEONATAL SEPSIS

INTRODUCTION

Neonatal sepsis is a blood infection that occurs in an infant younger than 90 days old. Early-onset sepsis is seen in the first week of life and occurs after 1 week and before 3 months of age. It can be caused by bacteria such as Escherichia coli (E.coli), Listeria, and some strains of streptococcus. Group B streptococcus (GBS) has been a major cause of neonatal sepsis. [1]

Neonatal sepsis may be categorized as early-onset or late-onset. Of newborns with early-onset sepsis, 85% present within 24 hours, 5% present at 24-48 hours, and a smaller percentage present within 48-72 hours. Onset is most rapid in premature neonates. [2]

OBSERVATION

23-year-old Primigravida complains of abdominal pain at 8 months.

History: Scan shows AFI 19 cm and fetal heart rate (FHR) 154 bpm at gestational age of 25+6 weeks. Scan shows mild right hydroureteronephrosis and fetal heart rate 136 bpm at gestational age of 32 weeks.

Day of Out Patient Department (OPD) visit:

Noon:

Patient arrives at urban tertiary healthcare center (THC) OPD with a case of abdominal pain and headache since 2 days. Heart Rate is 120 bpm. Blood Pressure is 170/100. Everything else is normal. She is given Nifedipine 10mg and is advised admission to high risk pregnancy labor ward (HRPLW). Patient's family refuse admission as they want her to get admitted to urban THC Hospital #2 which is in closer proximity to their residence. The urban THC #2 refuses to take her in and she is sent back to urban THC #1.

Evening:

Patient is admitted and is referred to a dermatologist in view of Pustular Lesions on the abdomen; and general medicine and psychiatry in view of breathlessness and psychosis. Systolic Blood Pressure fluctuating between 150-160 (although she was on Labetalol). Case of severe pre-eclampsia. MgSO4 administered according to Pritchard's regimen. Despite this, she has a seizure.

Three days later:

Obstetrics scan shows Amniotic Fluid Index (AFI) 20 cm, FHR 142 bpm, right lateral ventricle of fetus is 1 cm in size and very prominent. Blood work was normal. Two days later delivery is induced with dinoprostone, misoprostol, foley's catheter and artificial rupture of membranes (clear liquor). She is induced preterm at 35 weeks. She delivers an alive braindead male baby of 1.5 Kg the next day. This is inferred due to unnatural pupil dilatation. Baby doesn't cry immediately after birth. Shifted to neonatal intensive care unit NICU. Baby contracts sepsis the following day (baby prone to sepsis due to poor environmental condition in the NICU, as well as underweight and pre-term nature of the baby). Baby is in distress and oxygen saturation has not been maintained. Baby does not respond well to surfactant. Baby at high risk of death due to sepsis and low birth weight. Doctor claims that in a better equipped NICU (such as a private hospital) the baby would not have contracted sepsis and would have a higher chance of survival.

PROBLEM STATEMENT

MgSO₄ treatment for the prevention of seizures in eclampsia was ineffective. This led to the patient's condition worsening into eclampsia. As the patient was in risk due to eclampsia, she was induced preterm, this put the baby (preterm baby) at risk. Preterm babies are at a greater risk of getting sepsis due to their weaker immune system and underdeveloped lungs. NICUs must initiate treatment for sepsis immediately on detection due to the relative immunosuppression of the neonate and also be equipped to treat for the overwhelming systemic effects of the disease.

NEED STATEMENT

An affordable way to reduce the incidence of sepsis in neonates at primary care centers and above to avoid neonatal death.

FILTERING PROCESS

Final Score = 11

Rank = 7

MARKET POTENTIAL

Number of live births annually: 25,000,000

Number of cases of sepsis in the system: 200,000

7 neonates per 1000 live births have Sepsis within a month of birth.

COMPETITIVE LANDSCAPE

Sepsis in neonates is treated in hospitals with a functioning NICU where they have a wide variety of staff on site, including neonatologists, neonatal nurses, and respiratory therapists. NICU cost to the patient is around Rs. 15,000 per day.

CURRENT TREATMENT

Early detection of sepsis - through early laboratory testing, Lumbar Puncture and CSF Analysis, Radiography, CT, MRI, and Ultrasonography.

Antibiotic Therapy - includes combined IV aminoglycoside and expanded-spectrum penicillin antibiotic therapy.

Considerations for Meningitis - Infants with bacterial meningitis often require different doses of antibiotics and longer courses of treatment.

Investigational Therapies - Additional therapies that have been investigated for the treatment of neonatal sepsis include Granulocyte transfusion, IVIg infusion, Exchange transfusion and Recombinant cytokine administration.

Diet - Because of gastrointestinal (GI) symptoms, feeding intolerance, or poor feeding, it may be necessary to give the neonate nothing by mouth (nil per os; NPO) during the first days of treatment. [3]

IDEAL SOLUTION STATEMENT

The solution must be affordable for use in all rural and urban primary care settings. It must be acceptable for use in current NICUs and add value to the current treatment protocol. It should aid in prevention and/or management of sepsis, taking into consideration all the touchpoints for possible source of infection.

NEED CRITERIA

MUST HAVE

- Affordable for rural primary care centers
- Acceptable to use in rural tertiary care NICUs
- Prevent and manage incidence of sepsis in first 24 hours of birth OR manage late-onset of sepsis

NICE TO HAVE

- Multi-functional for very crowded NICUs (support more than one neonate at a time)

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8. CERVICAL CANCER

INTRODUCTION

Cervical cancer is one of the leading causes of cancer mortality in India, which alone accounts for more than 25% of the worldwide burden of cervical cancers [1]. Despite high disease burden, there is no nationwide government-screening program directed towards early detection of cervical cancer. This in turn enhances incidence of advanced stage cancer.

OBSERVATION

A 54-year-old female with a history of 3 pregnancies, all of which ended in normal full-term deliveries came into the OPD of a District Hospital with complaints of heavy vaginal bleeding. She had extremely painful lower abdominal pain, especially during her periods and would pass several clots. She had normal bleeding until 6 months ago, when her bleeding began to increase significantly along with increased abdominal pain. Prior to this, she had no known comorbidities. She also complained of dyspareunia and constipation. She was severely anemic and was transfused with 2 unites of Packed Red Blood Cells (PRBCs). On per speculum examination, a large cervical mass was found. A CT scan revealed a 9 x 9 cm mass with milk hydronephrosis. The biopsy revealed a well-differentiated carcinoma at IIIB stage. She received daily pelvic radiation therapy. Over few days of treatment, the bleeding had reduced and her stomach pain was no longer present. However, the patient keeps complaining of increased overall fatigue and severe shortness of breath. The patient is permanently under palliative care. [2]

CURRENT PROBLEM

In India, delayed presentation and thus diagnosis of cervical cancer cases add huge burden of mortality (approximately 132,000 new cases diagnosed and 74,000 lives claimed annually). [3] In a country where healthcare expenses are largely borne by the patient and no screening programs are run for an early detection of cervical cancer, a solution which can introduce high compliance to early screening would be required to detect cervical cancer cases in initial stages.

NEED STATEMENT

An accurate (compared to a pap-smear) and low skill (any doctor should be able to use) way to detect cervical cancer in women at primary healthcare centers to reduce the incidence of false negatives and late diagnosis.

FILTERING PROCESS

Final score = 9

Rank =8

MARKET POTENTIAL

Cervical cancer in India is very prevalent and approximately 132,000 new cases are diagnosed per year with 74,000 deaths annually reported due to cervical cancer, accounting for more than

1/4 of the global cervical cancer deaths. Indian women face a 2.5% cumulative lifetime risk and 1.4% cumulative death risk from cervical cancer.

COMPETITIVE LANDSCAPE

The Pap (Papanicolaou) Test- In this test, the cells are gently scraped from the outside of cervix and vagina by the doctor for testing. Traditional Pap tests can be hard to interpret as the cells can dry out, but Improved Pap test methods have made it easier for doctors to find cancerous cells. Recently, the liquid-based cytology tests, often referred to as ThinPrep or SurePath, transferring a thin layer of cells onto a slide after removing blood or mucus from the sample, have been used.^[4] The sample is preserved, so other tests can be performed at the same time, such as the HPV test. Computer screening, often called AutoPap or Focal Point, uses a computer to scan the sample for abnormal cells. Cost of a Pap smear test to patient could be between INR 200 – 1,500, depending upon in which area of the country the test is being performed.

Human Papilloma Virus (HPV) DNA Test- An HPV test is performed on a sample of cells from patient's cervix and it is similar to a Pap test. It is usually performed with the Pap test or after Pap test results show abnormal changes in patient's cervix. Many women have HPV, but do not have cervical cancer. New generation of HPV DNA assays combines qualitative detection of 12 high-risk HPV genotypes with HPV-16 and HPV-18 genotyping.^[5] HPV testing alone is not an accurate test for cervical cancer. It can cost between INR 2,000-7,000 in Indian settings.

Endocervical Curettage or Cone Biopsy with Cytology- Endocervical Curettage (ECC) is performed when the doctor wants to check an area inside the opening of the cervix that is not visible during a colonoscopy. In this procedure, to scrape a small amount of tissue from inside the cervical opening, doctors use a small, spoon-shaped instrument called a curette. Conization (a cone biopsy) removes a cone-shaped piece of tissue from the cervix. Conization may be done as treatment to remove a pre-cancer or an early-stage cancer. It can cost between INR 2,000-10,000 in Indian settings.

Imaging techniques to visualize tumor size- CT scan or MRI scan scan can be used to measure the tumor's size, once the above stated tests show positive results. A CT machine can cost INR 50 Lakh- 1.5 Crore in Indian settings depending upon which versions are being used and per scan, the amount charged to patient can vary from Rs. 3000-8000. An MRI machine can cost between INR 1.5-2.5 Crore and per scan cost to patient can be anywhere between INR1,500 – 25,000, depending upon the body part being tested and the area in which the test is conducted.

IDEAL SOLUTION STATEMENT

Ideally, the solution should be able to detect early stage cervical cancer with high fidelity. It should be very low cost, with an ability to enhance compliance amongst women towards regular screening for cervical cancer. The solution should be non-surgical and easily interpretable.

NEED CRITERIA

MUST HAVE:

- Ability to diagnose cervical cancer in early-stage
- High portability
- Easy to interpret
- Minimal false-positive and false-negative rate
- Non-surgical method
- Cost to the patient should be under INR 1000

NICE TO HAVE:

- Non-invasive method
- Any trained technician should be able to perform the test
- Cost to the patient under INR 500

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9. SURGICAL SITE INFECTIONS

INTRODUCTION

Any surgery that causes a break in the skin can lead to an infection. These infections are Surgical Site Infections (SSIs) because they occur on the part of the body where the surgery took place. An SSI typically occurs within 30 days after surgery. 3 types of surgical site infections:

1. **Superficial Incisional SSI.** This infection occurs just in the area of the skin where the incision was made.
2. **Deep Incisional SSI.** This infection occurs beneath the incision area in muscle and the tissues surrounding the muscles.
3. **Organ or Space SSI.** This type of infection can be in any area of the body other than skin, muscle, and surrounding tissue that was involved in the surgery. This includes a body organ or a space between organs. [1]

OBSERVATION

Female, 23-year-old, sent to the minor operation theater of an urban tertiary healthcare center (THC) with an infection on her lower segment Caesarean Section (LSCS) incision site. She is currently on post-operative day 3.

At the Minor OT: Suture is removed using a pair of tweezers and without administering local anesthesia. Infected pus is cleaned out using Hydrogen Peroxide. An antiseptic is applied to the wound. Remaining pus and the dead cells are removed using a blade. The wound is dressed. The wound has to heal for a week so that new cells would generate (granulation tissue). After this, a re-suturing will be done. Patient will need to remain in the ward for at least a week for the wound to heal and for re-suturing.

PROBLEM STATEMENT

Infections are caused by bacteria that enter the surgical wound through various touch points such as from contact of the caregiver, surgical instrument contamination, air and environment or through germs already in the body. SSI is a major cause of morbidity in post-operative procedures and also leads to prolonged hospitalization, re-suturing and incurred costs of services.

NEED STATEMENT

A better (current way causes infections) way to prevent Suture Site Infections in open abdominal/pelvic surgeries at District Hospitals and Tertiary Healthcare Centers to avoid re-suturing of incision and risk of sepsis.

FILTERING PROCESS

Final Score= 8

Rank =9

MARKET POTENTIAL

Number of live births annually: 25,000,000

Total number of SSI cases from C-section operations annually: 200,000 (40 per 1000 C-sections. 1 in 5 deliveries are C-sections.)

Total number of laparotomy procedures annually: 10,000,00

COMPETITIVE LANDSCAPE

The number of variables that can influence SSI rates is large. Preoperative planning and intraoperative technique become important in prevention of SSI. In addition, the appropriate use of preventive antibiotics in an appropriate fashion is very important. C-sections cost the patient upto Rs. 1 lakh based on the hospital. Costs of all precautionary and preventive measures taken are included in the total cost.

Preoperative Planning - The site of the surgical incision should be managed prior to the actual arrival of the patient in the operation theater. Many surgeons instruct their patients to shower and scrub the surgical site with antiseptic soap on the evening prior to the procedure. Also, the site of the planned incision should not be shaved or clipped the evening before the operation.

Prevention of SSI in the operation theater - Prevention in the OR begins with the skin preparation of the operative site. The site is cleansed with chlorhexidine or povidone iodine. Prevention also requires the use of caps, gowns, masks, and sterile surgical gloves. Double gloving is also recommended.

Preventive Antibiotic Therapy - The antibiotic should be administered preoperatively, but as close to the time of the incision as is clinically practical; antibiotics should be administered before induction of anesthesia in most situations.

Increased Oxygen Delivery - Experimental evidence has favored the concept that increased oxygen delivery has a favorable influence in the prevention of infection.

Optimizing Core Body Temperature - Better intraoperative and postoperative temperature control of the patient may reduce the risk of SSI.

Blood Glucose Control - Better control of blood glucose appears to have value in the reduction of SSI. [2]

IDEAL SOLUTION STATEMENT

The solution must aim to measurably reduce the incidence of SSI in open abdominal/pelvic surgeries done rural and urban district hospitals and above.

NEED CRITERIA

MUST HAVE

- Better than current solutions
- Acceptable for use in rural and urban district hospitals

NICE TO HAVE

- Low cost implementation
- Non-invasive

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10. PLACENTAL ABRUPTION

INTRODUCTION

Placental Abruption is a condition when the placenta separates from the uterus before childbirth. This is a dangerous condition where the fetus is supplied lesser blood than required. This can lead to severe fetal morbidity and even death. Common risk factors include Hypertensive Disease of Pregnancy (HDP), physical trauma, short umbilical cord, prolonged rupture of membranes etc. [1]

OBSERVATION

A 28-year-old female at 31 weeks and 5 days of gestational age, with history of one normal full-term vaginal delivery, went to a Primary Health Centre (PHC) complaining of severe lower back pain. She was referred to a Taluk Hospital where she was asked to get a scan done and come with the report 3 days later. On the 3rd day morning, she did not feel any fetal movements. Patient experienced heavy bleeding and goes back to the Taluk Hospital, where she was asked to immediately go to a government Tertiary care centre due to a suspected placental abruption.

In the urban hospital, on examination, she had positive pallor and bilateral pedal edema. She was shifted to the high-risk pregnancy labour ward at 11am. Atleast 150 grams of clotted blood was removed vaginally, amounting to a blood loss of 600 ml. The patient's family was asked to arrange for Packed Red Blood Cells (PRBCs) from the blood bank. At 12 noon, a Non-Stress Test (NST) was done and good fetal heart sounds were detected with a Fetal Heart-rate (FHR) of 140/min. Doctor decided to induce labour (terminate the pregnancy) since the extent of abruption was too severe. Membranes were ruptured artificially and blood-stained liquor was observed. An immediate C-Section was planned, provided 2 units of PRBCs were made available. Blood was not available at 2 blood banks as of 5pm. The mother had progressed to stage 2 Hypovolemic shock with a heart-rate of 110/min. There was less than 300 ml urine output over 12 hours. Meanwhile, the patient progressed into labour and delivered a female baby of weight 1.5 kgs at 6pm. The baby was not breathing. She was ventilated on ambu-bag and shifted to the Neonatal Intensive care unit (NICU). The pediatrician diagnosed the baby as severely hypoxic with a blood oxygen saturation (SpO2) of 85%. Baby was intubated and put on a ventilator. The doctor said the delay in arranging of blood resulted in the baby being asphyxiated. At 10pm, blood was arranged for and transfused. The mother was out of danger post transfusion. [2]

CURRENT SCENARIO

The delay in arranging blood from the blood bank due to unavailability of blood led to the delay in performing the Cesarean Section. This led to the fetus being hypoxic which lead to asphyxia.

NEED STATEMENT

An accessible and affordable way to manage placental abruptions in women when blood is unavailable, at District Hospitals and above to prevent hypovolemic shock and fetal asphyxia.

FILTERING PROCESS

Final score = 8

Rank =10

MARKET POTENTIAL

Annually, India has around 10 recorded Placental Abruptions per 1000 live births. India has an estimated 25 million deliveries annually. This implies that India has at least 250,000 annual cases of Placental abruptions. Currently, India falls short by 10% on availability of blood and blood products. Hence, we can estimate around 25,000 annual cases of placental abruptions where blood is unavailable.

COMPETITIVE LANDSCAPE

Differential Diagnosis to confirm placental abruption vs placenta previa (if time permits).

Blood tests to check blood clotting parameters, Liver Function Tests (LFTs), Renal Function Tests (RFTs), Serum Urea and Electrolytes etc.

The standard guidelines for a severe placental abruption (hypovolemic shock) is to deliver the baby as soon as possible via Lower Segment C-Section (LSCS) while transfusing blood pre-op and intra-op. [3] [4] [5] Cost of Packed Red Blood Cells (PRBCs) is around Rs.200 - 1000 per unit. LSCS can cost upto Rs. 1 lakh.

IDEAL SOLUTION STATEMENT

An ideal solution should be able to deliver the baby as soon as possible when blood and blood products are not available for transfusion. The solution should be usable by any nurse. It should be inexpensive to the patient. Expensive solutions exist for autologous blood transfusions. These need to be made affordable.

NEED CRITERIA

MUST HAVE

- Easy to use (any nurse)
- Less than INR 2,000 cost to patient
- Should enable immediate Cesarean Section
- Should restore blood parameters (volume, WBCs, platelets, hematocrit) to an adequate level within 1 hour (Hb >10 gms/dL)

NICE TO HAVES

- Less than INR 1,000 cost to patient
- Should restore normal blood parameters (volume, WBCs, platelets, hematocrit) within 30-45 minutes (Hb >12 gms/dL)
- Portable Solution

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