FOGSI - ICOG

Good Clinical Practice Recommendations

GCPR

PREVENTION AND MANAGEMENT OF STILLBIRTHS

Convenor – Seetha Ramamurthy Pal Co-Convenor – Kiran Pandey

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GENETICS AND FETAL MEDICINE COMMITTEE

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Disclaimer: These recommendations for "Prevention and Management of Stillbirths" have been developed, to be of assistance to obstetricians, gynecologists, consulting physicians, and general practitioners by providing guidance and recommendations for managing women and families, who experience a stillbirth. The recommendations included here should not be viewed as being exclusive of other concepts or as covering all legitimate strategies. The suggestions made here are not meant to dictate how a particular patient should be treated because they neither set a standard of care nor do they guarantee a particular result. To diagnose patients, choose dosages, and provide the best care possible, while also taking the necessary safety precautions, clinicians must rely on their own experience and knowledge. The writers or contributors disclaim all responsibility for any harm and/or damage to people or property resulting from the use or operation of any techniques, goods, guidelines, or ideas presented in this content.

BACKGROUND AND EPIDEMIOLOGY

Stillbirth, the death of a baby before birth or during labor, is a world epidemic with greatly underestimated prevalence. Stillbirth has been neglected by the global health agenda until recently. However, we need to understand the medical, economic, and psychosocial consequences of stillbirth, and address these issues in the context of the Indian population. Stillbirth has a pervasive impact on families and its impact continues during the subsequent pregnancies. The consequences of stillbirth are far and wide and include significant physical, mental, and emotional trauma, and delayed involution, challenging issues of questioning self-worth, social issues involving marital discord and acceptance, not to forget sexual disharmony. The overall rate of stillbirth has remained largely unchanged due to the interplay of factors decreasing stillbirth on the one hand including improved antenatal and intrapartum care with the reduction of some modifiable risk factors and the early detection of congenital anomalies and an increased incidence of important risk factors, such as obesity, and advanced maternal age on the other hand. In 2015, 2.6 million stillbirths have been recorded with 98% occurring in low- and mid-income countries.[1,2] with India having the highest number of stillbirths with the largest burden.

Intent: The guidelines are a reference of recommended care and not an endpoint of clinical care. The guidelines are subject to evolution with advances in scientific knowledge and technology.

PURPOSE AND SCOPE

The primary objective of this GCPR is to provide consensus statement and to guide professionals, postgraduates, midwives, and pediatricians about clinical practice and recommendations for antenatal care, intrapartum care, and the psychosocial considerations necessary in the care of pregnant women with a history of stillbirth.

METHODOLOGY

These good clinical practice recommendations (GCPR), given by the Federation of Obstetric and Gynaecological Societies of India (FOGSI), followed the process mentioned in the Royal College of Obstetricians and Gynaecologists (RCOG) "Guideline for guideline development - 2020". The topic was selected and approved and a task force was formulated. The core group was identified and the time lines were discussed and communicated. The scope of the guideline was drafted, objectives were framed, and the stakeholders were listed and incorporated in the scope. A systematic review of the literature was conducted to provide the best possible evidence base for the GCPR. Existing guidelines, meta-analyses, systematic reviews, and key articles relating to blood transfusion were reviewed by the core group and recommendations relevant to the Indian scenario were framed. These recommendations review the available evidences in the field by the members of the task force, which include eminent obstetricians, gynecologists, and transfusion specialists of repute. The guideline was peer reviewed by experts, multiple times, and feedback was incorporated. No conflict of interest and good standing was appropriately expressed by all concerned for professional, personal, or nonpersonal interest, either financial or nonfinancial. The committee evaluated recommendations and evidence using the methodology of the United States Preventive Service Task Force (USPSTF), on the basis of the strength of evidence and the magnitude of net benefit (benefits minus harms).

GRADE

Grading	*Recommendation*	
A	Strongly recommended	At least one randomized controlled trial (RCT) as part of a body of literature of overall good quality and consistency that addresses the specific recommendation
B	Suggested	Availability of well-controlled clinical studies, but no RCTs are available on the topics of recommendation
C	Unresolved	Evidence obtained from the expert committee reports of opinions and/or clinical experiences of respected authorities, which indicates an absence of directly applicable clinical studies of good quality
CPP	Clinical practice points	Evidence not sought. A practice point has been made by the guideline development group, where important issues arose from the discussion of evidence-based or clinical consesus recommendations

LEVEL OF EVIDENCE

Level	
I	High quality prospective cohort study with adequate power or systematic review of these studies
II	Lesser quality prospective cohort, retrospective cohort study, untrated controls from an RCT, or systematic review of these studies
III	Case control studty or systematic review of these studies
IV	Case series
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research or "first principles"

1. DEFINITION

World Health Organization (WHO): Stillbirth – A newborn ≥28 weeks of gestation with no signs of life at birth, weight ≥1000 g, crown-heel length (CHL) ≥35 cm.[3]

For the purpose of surveillance, the following definitions will be used:

- **Fresh stillbirth or intrapartum stillbirths** are defined as stillbirths occurring after the onset of labor in less than 12 hours before delivery with no skin changes weighing more than 1,000 grams and more than 28 weeks of gestation, but excludes severe lethal congenital abnormalities.
- **Macerated stillbirth or antepartum stillbirth** is a baby born with all the changes, which occur in a fetus retained in utero after death and the death occurred before the initiation of labor. A "macerated" fetus shows skin and soft-tissue changes (skin discoloration or darkening, redness, peeling, and breakdown).

2. PREVALENCE

Global

Worldwide, the stillbirth rate has been falling from approximately 21.4 deaths at ≥28 weeks of gestation per 1000 births in 2000 to approximately 13.9 deaths per 1000 births in 2019.[4]

India

- National average of stillbirths in 2017–18, 2018–2019, and 2019–2020 are 13.4 [4.2–24.2], 13.1 [4.2–22.2], and 12.4 [3.7–22.5], respectively.
  Of the 1.9 million stillbirths globally, India recorded 0.34 million stillbirths in 2019.
  Though there was a 53% reduction from 2000, they have not declined as rapidly as maternal and newborn mortality.[5]

Stillbirth Target

Based on the *Every Newborn* Action Plan to improve newborn health and prevent stillbirths, a stillbirth target of 12 or less stillbirths per 1000 total births for all countries by 2030 has been set, with a focus on addressing inequalities and the use of audit data to track and prevent stillbirths.[6]

3. CAUSES

The WHO has recently adapted the International Classification of Diseases (ICD-10) for use in perinatal mortality (ICD-PM). The ICD-PM provides a standardized system for classifying perinatal mortality (including stillbirths) based on the time of death (antepartum or intrapartum) into fetal and maternal causes, thereby enabling comparisons within and between diverse settings and contexts **(Table 1)**. [7]

Table 1 Main perinatal cause of death ICD-PM groups

Antepartum death		***Intrapartum death***		***Neonatal death***	
A1	Congenital malformations, deformations, and chromosomal abnormalities	I1	Congential malformations, deformations, and chromosomal abnormalities	N1	Congenital malformations, deformations, and chromosomal abnormalities
A2	Infection	I2	Birth trauma	N2	Disorders related to fetal growth
A3	Antepartum hypoxia	I3	Acute intraprtum event	N3	Birth trauma
A4	Other specified antepartum disorder	I4	Infection	N4	Complications of intrapartum events
A5	Disorder related to fetal growth	I5	Other specified intraprtum disorder	N5	Convulsions and disorders of cerebral status
A6	Antepartum death of unspecified cause	I6	Disorders related to fetal growth	N6	Infection
		I7	Ibntraprtum death of unspecified cause	N7	Respiratory and cardiovascular disorders
				N8	Other neonatal conditions
				N9	Low birth weight and prematurity
				N10	Miscellaneous
				N11	Neonatal death of unspecified cause

Abbreviation: ICD-PM: International Classification of Diseases for Perinatal Mortality

4. RISK FACTORS

Many complex factors interplay that may contribute to stillbirth varying with gestational age. Recurrent fetal death in a subsequent pregnancy may be influenced by risk factors, etiology, and the underlying mechanism of the prior stillbirth.

Table 2 identifies maternal, fetal, and sociodemographic risk factors associated with stillbirth. Some of them have been identified as risk factors for stillbirth in subsequent pregnancy.

Table 2 Factors which can increase the risk of stillbirth in a subsequent pregnancy

MATERNAL FACTORS	*FETAL FACTORS*	*SOCIODEMOGRAPHIC FACTORS*
Diabetes mellitus	Multiple pregnancy	Advanced maternal age
Essential hypertension	Low birth weight (<3rd centile/ <10th centile)	High body mass index
HIV/AIDS	Short for gestation age baby	Smoking
Pre-eclampsia	Post-term pregnancy >42 weeks	Antenatal care
Severe preeclampsia		Low socioeconomic status
Previous stillbirth		Illicit drug use

Abbreviations: AIDS: Acquired immunodeficiency syndrome; HIV: Human immunodeficiency virus

Table 3 Identifies risk factors, which may recur in subsequent pregnancy.

Table 3 Risk of recurrence

Etiology with previous stillbirth	*Recurrence risk*
Congenital anomalies	Depends on types of anomaly
Abruption	9–15%
Vasa previa/Umbillical cord abnormality	Undetermined
Turner syndrome	Sporadic
Trisomy -21, 18, 13	Full mutation: 1–2%
Autosomal recessive disorders	25%
X-linked disorders	Increase in male offsprings
Infections	Varies
Pre-eclampsia	14%
IUGR	20%
Thrombophilia	
APLA, isoimmunization	

Abbreviations: APLA: Antiphospholipid antibody; IUGR: Intrauterine growth restriction

1. ***HISTORY OF PRIOR STILLBIRTH***: Risk of stillbirth in next pregnancy is increased [odds ratio (OR): 3.38; 95% confidence interval (CI): 2.61–4.38][8] (level 1).
   - Women with a first stillbirth at **early gestation** (22+0 until 27+6 weeks), had the highest risk of recurrent stillbirth (15.0 per 1000 versus 8.4 per 1000; adjusted OR: 2.25; CI: 0.62–8.15).[9]
   - The risk of stillbirth increases with the **number of subsequent pregnancies** for women, who had a stillbirth, compared to women who had a live birth[10] **(LEVEL II, GRADE C)**.
2. ***MATERNAL AGE:*** Maternal age at first pregnancy resulting in stillbirth had an impact on the outcome of subsequent pregnancy[10] **(LEVEL II, GRADE B)**.
   - Less than *20 years*: Risk of stillbirth in subsequent pregnancy [adjusted hazards ratio (aHR): 1.63; 95% CI: 1.49–1.77]
   - *20–24 years* (aHR: 1.25; 95% CI: 1.16–1.33)
   - ≥*40 years*: (aHR: 1.68; 95% CI: 1.09–2.58).
2. ***SMOKING***: Risk of stillbirth in subsequent pregnancy was 1.12 times higher in women, who had a stillbirth in previous pregnancy[10] **(LEVEL I, GRADE B)**.
3. ***SOCIOECONOMIC STATUS:*** Women belonging to low-socioeconomic status in a first pregnancy were also at increased risk of subsequent stillbirth.[10] (the criteria of socioeconomic status may vary between countries and may result in heterogeneity)
4. ***PRE-EXISTING DIABETES***: Women with pre-existing diabetes were 2.42 times more likely to experience stillbirth in subsequent pregnancy[10] **(LEVEL I, GRADE B)**.
5. ***PREECLAMPSIA:*** women with a history of preeclampsia in previous pregnancy had a 1.42 times higher risk of experiencing stillbirth in subsequent.

6. ***PLACENTAL ABRUPTION:*** Placental abruption leading to stillbirth in previous pregnancy has a hazard ratio of 1.41[10] (95% CI: 1.12–1.44) **(LEVEL II, GRADE C)**.
7. ***HISTORY OF GROWTH RESTRICTION:*** A significant increased risk of stillbirth has been observed in subsequent pregnancy amongst women with previous history of fetal growth restriction irrespective of the outcome of previous pregnancy (aHR: 1.59; 95% CI: 1.39–1.81)[10] (LEVEL II, GRADE B).
8. ***NO INCREASED RISK:*** Women with pre-existing hypertension, placenta previa, or antepartum hemorrhage were not at increased risk of subsequent stillbirth[10] (LEVEL I, GRADE B).
9. ***UNEXPLAINED:*** Many cases of stillbirth may remain unexplained despite extensive investigations.[11] (LEVEL II, GRADE C).

5. MANAGEMENT OF STILLBIRTH

1. Diagnosis

Practice Points

1.1. Diagnosis of stillbirth should be confirmed by real-time ultrasonography (Level III, Grade C).

1.2. If the couple wishes, a second opinion may be offered to reconfirm the diagnosis (CPP).

Discussion: When an intrauterine fetal death (IUFD) is suspected, this must be confirmed by 2D ultrasound at the earliest opportunity. If the diagnosis is suspected in the community setting, then the mother should be referred to a hospital for confirmation.

It is advisable to obtain a second opinion from a suitably trained person, whenever possible, although it is recognized that this may not always be possible in emergency situations.

2. Counseling

Practice Points

2.1: The news should should be broken in a sensitive fashion preferably first involving the partner and family when present. (**LE 3, Grade C)**.

2.2:

- Parents and family should be counseled regarding need for further investigations in the mother, fetus, and the placenta.
- A systematic approach is required to evaluate fetal death and to determine the underlying etiology **(LE 1, Grade A)**.
- Investigations are needed to assess maternal condition, determine the cause of the stillbirth, and to determine the risk for future pregnancies **(LE2, Grade C)**.
- Even with full investigation, parents should be advised that a specific cause for death. may not be found in approximately 45–50% of cases **(LE3, Grade B)**.

Discussion: Breaking bad news can be difficult, but this should be done with sensitivity, compassion, and empathy with the patient and the family together.[12-14] All information should be provided in an honest and transparent manner using clear and understandable language. Investigations are necessary to assess maternal well-being and the management of critical conditions such as severe pre-ecclampsia or abruption. Furthermore, tests are needed to make a diagnosis, which allows more prognostic accurate information for future pregnancies, and parents should be adequately counseled regarding the same. Parents should be advised that no specific cause is found in almost half of stillbirths.[15]

2.3: Clinicians should explain to parents that a full autopsy remains the gold standard (**LE1, Grade A).** A full postmortem examination should be strongly recommended as it has the strongest diagnostic yield. Parents should be informed about the possibility of missing an important finding, when a full autopsy is not undertaken.

2.4: A plan regarding time, place, mode of delivery, and disposal of the fetus should be made and discussed (**CPP**).

2.5: Everything that has been discussed with the parents should be documented (CPP).

3. Investigations

Practice Points

- A systematic approach is required to evaluate fetal death and to determine the underlying etiology (**LE 1, Grade A**).

- Comprehensive maternal (medical, social, family) and pregnancy history should be taken following all perinatal deaths. (**LE 1, Grade A**).
- **The following core investigations should be adopted for all stillbirths (Table 4) (LE1; Grade A).**

Table 4 Core investigations for all stillbirths

	Test	***Reason***
Maternal	CBC, renal and liver profile Thyroid function Bile acids HbA1c	Pre-eclampsia Cholestatsis GDM
	Blood group and antibody screen	Rh incompatibility
	Coagulation studies	DIC
	LA, ACLA, and anti-B2 glycoprotein	APLA
Fetal	External examination	Gross defects
	Clinical photographs	For future use as memories for parents
	Full/Partial Postmortem	
Placenta and cord	HP CMA	 Chromosomal analysis and DNA storage

Abbreviations: APLA: Antiphospholipid antibody; CBC: Complete blood count; CMA: Chromosome microarray; DIC: Disseminated intravascular coagulation; DNA: Deoxyribonucleic acid; GDM: Gestational diabetes mellitus; HP: Human placenta; LA: Lupus anticoagulant

3.1 Fetal Autopsy

- Comprehensive external examination of the baby performed by the attending clinician, is an essential component of the investigation of a stillbirth (**LE 3, Grade C**).
- Clinical photographs of the baby and X-rays should be taken for every stillborn baby.
- A detailed macroscopic examination of the placenta and cord and documentation of the normal and abnormal finding should be recommended irrespective of the autopsy (**LE 3, Grade B**).
- Umbilical cord knots or tangling should be noted but interpreted with caution, as cord entanglement occurs in approximately 25% of normal pregnancies and most true knots are found after live births.
- The placenta, membranes and cord should be sent fresh and unfixed for macroscopic and histological examination (**LE 3, Grade C**).

Discussion: The clinical photographs should be clearly labeled and filed in the medical record. When a full autopsy is performed, it should follow published guidelines and protocols for perinatal autopsy.[16] Umbilical cord knots or tangling should be noted, but interpreted with caution, as cord entanglement occurs in approximately 25% of normal pregnancies and most true knots are found after live births.

3.2 Sample Collection

- Skin biopsy - 1 cm length, deep, from upper fleshy part of thigh.
- Placenta biopsy - 1 cm diameter from fetal surface, close to cord insertion as most viable tissue.
- Specimen for cytogenetic testing should be collected in a sterile container with normal saline with a few drops of gentamycin and kept at room temperature and should be processed as soon as possible, preferably within 48 hours.
- Formalin fixed tissue is NOT suitable for cytogenetic investigation.
- All specimens must be clearly labeled and following should accompany for autopsy examination. (**LE 3, Grade C).**
- The following should accompany the infant for autopsy examination (LE 3, Grade C).
  - Autopsy consent form
  - Placenta (fresh and unfixed)
  - Comprehensive maternal (medical, social, family) and pregnancy history
  - Copies of the death certificate and copies of all antenatal ultrasound reports
  - Copy of prenatal karyotyping results if available
  - Findings from initial external examination performed at birth by attending clinician

- Sampling of cord and placental tissue for chromosomal analysis. If a prenatal karyotype has already been performed, these samples should still be taken for DNA extraction and storage (**LE 3, Grade C**).

3.3 Cytogenetics (Chromosomal Microarray or Karyotype)

- Genetic analysis should ideally be performed in all cases of stillbirth and chromosomal microarray (low resolution) is preferable (LE1, Grade A).

Discussion: Chromosome microarray (CMA), in contrast to conventional culture karyotyping, uses DNA and does not require viable cells, which means that chromosomal abnormalities can be detected in macerated stillbirth also. Microarray is also superior to karyotype as it can detect additional genetic abnormalities, including microdeletions and microduplications.[17]

- Targeted genetic testing using fetal and/or placental DNA (e.g., for monogenic disorders) will always have a role, where a specific phenotype is suspected, or when the family history is informative (LE 3, Grade B).

3.4 Further sequential and/or selective investigations on the basis of information gained from core investigations, clinical scenario, and comprehensive history

- **Congenital infections** : Routine testing of all stillbirths for infection is no longer recommended. Targeted investigation should be undertaken if infection is suspected on the basis of maternal history, autopsy and/or placental findings and early-onset fetal growth restriction (LE 3, Grade C).
- **Maternal thrombophilia screen**: Testing for antiphospholipid syndrome is strongly recommended and if positive must be confirmed after repeat testing after 12 weeks. However, testing for inherited thrombophilias is not recommended.[18]
- **Parental blood for karyotyping**: Parents' blood can be tested to look for balanced translocations or mosaicism if fetus found to have unbalanced translocation and in the cases of recurrent fetal losses.

3.5 Alternative investigations: When permission for full autopsy is not obtained

- If permission for a full autopsy is not obtained, a limited autopsy can be done by an external examination, X-ray (babygram), and clinical photos (LE 2, Grade B).
- Magnetic resonance imaging (MRI), if available, should be offered to parents, who decline an autopsy. MRI may be diagnostic in some cases, where intracranial abnormalities are suspected (LE 3, Grade C).
- Other alternatives to a full postmortem examination including post-mortem needle biopsy; laparoscopic autopsy, and small incision access for focused investigation of suspected abnormalities (LE 3, Grade C).

4. Delivery

Practice Points

- Patients should ideally be admitted and delivered preferably in a place separate from the busy antenatal or postnatal ward (CPP).
- Respectful antenatal care should be provided and patient and family well supported (CPP).
- The presence of a birth companion or family member should be allowed and encouraged (CPP).
- Timing and mode of delivery should be customized according to the presenting condition, and other patient characteristics including past obstetric and medical history (LE3, Grade B).

4.1 Timing

Practice Points

1. Immediate delivery required if there are signs of pre-eclampsia, sepsis, placental abruption, or membrane rupture, and if the laboratory tests are suggestive of disseminated intravascular coagulation (DIC) (Level 3, Grade B).
2. Expectant management may be considered for a short-term period, as the risk for coagulopathies and infections for up to 48 hours is low[19] (Level 3, Grade C).
3. However, the mother should be informed that waiting can reduce the diagnostic yield of postmortem examination (LE3, Grade B).

Discussion: Spontaneous delivery occurs within 3 weeks from the fetal demise in the majority of cases. Although most patients desire prompt delivery, the timing of delivery is not critical; coagulopathies associated with prolonged fetal retention are uncommon.

4.2 Mode of Delivery

Vaginal birth is the recommended mode of delivery for most women, but cesarean birth will need to be considered with some.

Unscarred uterus:

1. Induction of labor (IOL) is the recommended method of delivery of a stillborn fetus (LE3, Grade B).
2. Cesarean delivery may sometimes be considered depending on maternal wish and medical condition, always taking into consideration the increased risk of maternal complications and the absence of fetal benefit following this approach (LE 5, Grade CPP).

Discussion: Vaginal birth should be aimed for and it can be accomplished within 24 hours of IOL in 90% of stillbirth cases.[20] Vaginal birth has the advantage of quicker recovery and early return to home. Ceserean birth might occasionally be needed and this demands a careful and sensitive discussion with informed choice making. The implications of cesarean section on future childbearing should also be discussed.

4.3 Method

A. Unscarred uterus

Practice Points

- Combination of Mifepristone and Misoprostol is preferred (LE 1, Grade A).
- Although the optimal dosage of misoprostol and the frequency of administration have not been ascertained to date, recommended dose is according to the gestational age (LE 3, Grade C).

Single 200 mg dose of mifepristone, followed by **(Table 5)**:

Table 5 Optimal dosage of misoprostol

	Gestation	***Misoprostol***	***Dose***	***Comments***
Unscarred uterus	24–26+6 weeks	200 µg	PV/SL/PO 4-6 hourly	If not effective, discuss with senior colleague - consider repeat misoprostol at least 12 hours after the last dose
Unscarred uterus	27–27+6 weeks	100 µg	PV/SL/PO 6 hourly	If not effective, discuss with senior colleague - consider repeat misoprostol at least 12 hours after the last dose
Unscarred uterus	>27+6 weeks	50 µg	PV/SL/PO 6 hourly	If not effective, discuss with senior colleague - consider repeat misoprostol at least 12 hours after the last dose

- Oxytocin infusion can be considered as a safe alternative to a combined mifepristone-misoprostol treatment (LE IV, Grade C).

Discussion: Mifepristone can be considered as an adjunct to misoprostol given at a single dose, 48 hours before IOL in women with stillbirth as it reduces the induction-to-delivery interval by 7 hours compared to other regimens.[20] A meta-analysis of 14 randomized controlled trials (RCTs) showed that among women with a stillbirth, both vaginal and oral misoprostol are highly effective in achieving uterine evacuation within 48 hours, although the latter is more effective within the first 24 hours.[21]

B. Scarred uterus

Practice Points

a. Induction of labor is not contraindicated (LE 2, Grade B).
b. Mechanical methods of induction like Foley catheter for cervical ripening can be used in patients with low Bishop score after 28 weeks and a history of previous cesarean section (LE 2, Grade B).
c. Use of oxytocin for induction or augmentation is not contraindicated in women undergoing a trial of labor after cesarean. However, the use of oxytocin is associated with an increased risk of uterine rupture and should be used carefully after appropriate counseling (LE 2, Grade B).

d. Medical induction with Prostaglandin gel or Misoprostol is associated with high risk of uterine rupture and should not be used (LE2, Grade B).

Discussion: There is an increase (between 3% and 12%) in the risk of uterine rupture in women with IUFD, who have had a previous cesarean section.[22] Discussion about safety and the benefits of IOL should be undertaken by a Senior Obstetrician.

A retrospective study concluded that IOL using a transcervical Foley catheter is not associated with an increased risk of uterine rupture, although having a lower rate of success in achieving vaginal birth after cesarean section.[23]

Oxytocin may be used and studies show a trend for improved vaginal birth after cesarean (VBAC) rates, when oxytocin is used for augmentation compared to its use for induction.[24]

Misoprostol, though an effective cervical ripening agent, its use has been associated with a higher incidence of uterine rupture, when used in women with previous cesarean section; and until further randomized studies are completed, misoprostol is not recommended as a method of induction or cervical ripening in women with previous cesarean delivery at term.[24]

4.4 Antibiotic Prophylaxis and Pain Relief

Practice Points

1. Routine antibiotic prophylaxis may be offered to all women in labor with a stillbirth (LE V, Grade CPP).
2. In the cases of maternal sepsis, intravenous broad-spectrum antibiotics should be administered as the stillborn fetus can become a focus of secondary infection and can result in DIC (LE 3, Grade B).
3. It is crucial that all patients with stillbirth are offered adequate analgesia.
   Epidural anesthesia can also be considered, if no evidence of DIC or sepsis (LE 2, Grade B).

4.5 Baby Memories

Practice Points

- Parents should be offered the choice of seeing and holding their baby (CPP).
- Photographs of the baby may be provided too (CPP).
- Mementos can be offered such as a lock of hair, or hand and foot prints, and a piece of cord (CPP).

6. POSTPARTUM

6.1: Lactation Suppression

Practice Points

1. Dopamine antagonists, such as bromocriptine, successfully suppress lactation in more than 90% of women without major side effect and are significantly more efficient than breast binders (LE 1, Grade A).
2. Cabergoline is equally effective in preventing puerperal lactation; while at the same time, it has considerably a lower rate of rebound breast activity and adverse events, as well as simpler administration schedule[25] (LE 1, Grade A).

6.2 Contraception

Practice Point

- Adequate contraception should be discussed (CPP).

Discussion: Contraception should preferably be discussed and offered. There is no recommended regimen for the right interpregnancy interval after a stillbirth. It is reasonable to advise patients to delay conception until they feel they have achieved the psychological closure of the previous pregnancy loss, which typically takes at least 6–12 months.[26]

6.3 Ongoing Support

Practice Points

- Parents can be informed about various support groups to help them overcome the loss and give psychological support (CPP).

6.4 Follow-up

Practice Point

- A 6-week follow up visit should be scheduled to assess recovery, review the investigations performed and counsel regarding future pregnancies (LE 2, Grade B).

Discussion: Follow-up of patients, who had a stillbirth, is a key element of care, with an opportunity to assess maternal recovery from the event, both physical and psychologically, as well as to convey information about investigations performed. Risk factors can be reviewed with lifestyle counseling and the modification of risk factors. In addition, the psychological well-being of both parents should be asked about and additional help offered if needed.

7. MAINTENANCE OF RECORDS

Practice Point

- All records of the stillbirth event should be maintained and stored for medicolegal purposes for at least 5 years (CPP).

Antenatal Interventions and Surveillance in Pregnancy Following Stillbirth

Several studies have reported that parents receive inconsistent advice regarding management options following stillbirth and management of subsequent pregnancy. Hence, we aim to provide certain recommendations regarding antenatal interventions and surveillance in pregnancy following stillbirth to optimize pregnancy outcomes.

1. **PRECONCEPTION ADVICE/GENETIC COUNSELING**

   Practice Points

- Review records
- Discuss possible etiologies and the work-up of the previous stillbirth
- Determine recurrence risk
- Obtain a detailed medical and obstetric history
  (LEVEL II, GRADE B)
- Optimize maternal medical conditions
- Change potentially modifiable risk factors
  (LEVEL I, GRADE B)
- Smoking/alcohol/illicit substance use discontinuation
- Weight loss in obese individuals[27]
- Genetic counseling where indicated[28] **(LEVEL III, GRADE B)**
- Support and reassurance[28] **(LEVEL II, GRADE A).**

2. **INITIAL BOOKING VISIT**

   Practice Points

- No universal tests are recommended.
- Clinical history and work-up should be used to guide testing on a case-to-case basis.[2]
  (LEVEL II, GRADE B).
- If the previous stillbirth was unexplained or related to fetal anomalies, we screen for diabetes early in pregnancy and, if normal, repeat screening at 24–28 weeks. The odds of gestational diabetes are 4-fold higher after an unexplained stillbirth[29] **(LEVEL II, GRADE B)**.

3. **ROLE OF SPECIALIZED CARE**

- Informed, sensitive, and specialized care may have a powerful positive influence on women, who are pregnant following stillbirth (CPP).

4. **ROLE OF LOW-DOSE ASPIRIN**

   Practice Point

- Low-dose aspirin may reduce the risk of perinatal death in women at risk for placental insufficiency[30] **(LEVEL II, GRADE A)**.

Discussion: Pre-eclampsia and fetal growth restriction are both associated with stillbirth; hence, low-dose aspirin can be considered in women at risk of developing pre-ecplamsia. In the absence of high-risk factors for pre-eclampsia, prophylactic low-dose aspirin is not recommended for the prevention of stillbirth.[31]

5. **FIRST TRIMESTER**
   Practice Points
- Dating ultrasound by crown-rump length (CRL)
- First trimester screen: pregnancy-associated plasma protein-A (PAPP-A), human chorionic gonadotropin (hCG), and nuchal translucency
- Diabetes screen
- Antiphospholipid antibodies/thrombophilia work-up (where specifically indicated)
- Support and reassurance.

6. **SECOND TRIMESTER**
- Fetal anatomic survey at 18–20 weeks
- Quadruple screen: Maternal serum alpha-fetoprotein (MSAFP), hCG, ESTRIOL, and inhibin-A
- Uterine artery Doppler studies at 22–24 weeks
- Support and reassurance.

7. **THIRD TRIMESTER**
   Practice Points
- Serial ultrasounds to rule out fetal growth restriction, starting at 28 weeks.[27]
- Antenatal fetal surveillance starting at 32 weeks or 1–2 weeks earlier before gestational age of previous stillbirth if occurred before 32 weeks [27] **(LEVEL V, GRADE C)**.
- Support and reassurance.

Discussion: A history of prior stillbirth is associated with a significantly higher frequency of preterm birth (PTB), fetal growth restriction, pre-eclampsia (OR: 3.1; 95% CI: 1.7–5.7), and abruption (OR: 9.4; 95% CI: 4.5–19.7).[32] In women with a history of prior stillbirth associated with fetal growth restriction and/or the evidence of uteroplacental insufficiency, ultrasound examination can be offered both at 24 weeks and 30 weeks.[33]

8. **ROLE OF FETAL KICK COUNTING**

Practice Point
- The effectiveness of fetal movement counting in preventing stillbirth is uncertain and routine formal fetal movement counting should not be offered[34.35] **(LEVEL II, GRADE B)**.

Discussion: Mindfetalness, a method to examine whether a method for raising women's awareness of fetal movements, can affect pregnancy outcomes, was studied in a cluster-randomized controlled trial and they concluded that mindfetalness did not reduce the number of babies born with an Apgar score <7. However, Mindfetalness was associated with the health benefits of decreased incidence of cesarean section and fewer children born small-for-gestational-age.[36]

9. **DELIVERY**
   Practice Points
- A plan of the termination of pregnancy should be charted at the beginning of pregnancy and subsequently discussed and modified during the course of pregnancy.
- Elective induction at 39 weeks or earlier if clinically indicated **(LEVEL II, GRADE C)**.
- Early-term delivery can be planned in cases where clinical situation in current pregnancy demands for it.
- Birth at a specialist maternity unit is recommended **(CPP)**.

10. **POSTPARTUM PERIOD**
    Practice Points
- Women might have a tendency of experiencing postpartum depression despite a live birth following previous stillbirth, particularly for women who conceive within less than 12 months from an IUFD[37] **(LEVEL II, GRADE B)**.
- Unresolved maternal grief may result in the disorganization of attachment with future babies[38] **(LEVEL II, GRADE C)**.

11. **PSYCHOSOCIAL IMPACT**
    Practice Points
- Various psychological sequelae associated with pregnancies after stillbirth, include depression, post-traumatic stress, and anxiety.
- Women and families should be provided with opportunities for support during pregnancy and postpartum.
- Care providers should promote family strengths and provide psychocial screening, targeted follow-up, referrals, and treatment as appropriate[37] **(LEVEL I, GRADE A)**.

12. **ADDITIONAL CARE AND SUPPORT**

Practice Point

- Specialized antenatal classes for bereaved parents; peer support programs and grief counseling; and additional antenatal visits or therapies to address anxiety, depression, and maternal-infant attachment (CPP).[39]

8. STILL BIRTH AUDIT

A stillbirth audit is a step-wise process of gathering information on the magnitude of stillbirth and deliberating on these cases with a view to critically appraise the quality of care received and consciously look for the avoidable causes from clinical, administrative, and logistic perspectives in a multidisciplinary setting, essentially with the aim of learning from the past and improving systems to create better outcomes in the future. The ultimate goal is to strengthen the civil registration and vital statistics system and improve the overall quality of care.

1. Multidisciplinary Perinatal Audit Committee comprising obstetricians, midwives, maternal-fetal medicine specialists, neonatologists, radiologists, one member of the administration, and one member of the legal system
2. Instruments for data collection **(Annexure 1)**
3. Identifying key modifiable variables:
   a. Delay in seeking care
   b. Delay in reaching care
   c. Delay in receiving optimum care.
4. Drafting minutes of meeting to include: strategies to avert; personnel responsible fortask; time frame; and date of next review.
5. Tenets to remember: Anonymity/confidentiality/legal obligation to report/indemnity from legal action based on audit outcomes. It must be reiterated that the cardinal principle of audit is to review cases with the sole aim of learning from the past and improving the future. Any tendency to find who to penalize, negates this very purpose and must be avoided to maintain the sanctity and utility of the process.

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ANNEXURES

ANNEXURE 1

STILLBIRTH AUDIT FORM

2. Pregnancy Care

Obstetric history:	☐ Gravida	☐ Para	☐ Abortion	
Past history:	☐ Anemia	☐ Urinary infection	☐ TORCH	☐ Obesity
	☐ Hypertension	☐ Under nutrition	☐ Gestational	☐ Diabetes Mellitus
	☐ Unknown			
Previous stillbirth	☐ Yes	☐ No		
Previous malformation	☐ Yes	☐ No		
Previous cesarean	☐ Yes	☐ No		
Rh negative	☐ Yes	☐ No	☐ Unknown	

Antenatal care received: None/at least 1/minimum 4/>4 visits/>8 visits/Unknown

TT vaccination: TT1/TT2/TT Booster/Not needed/Not given/Unknown

Iron folic acid: ( ) Given / ( ) Not given / ( ) Unknown

Syphilis test: ( ) Positive, ( ) Negative, ( ) Not done

HIV status: ( ) Positive, ( ) Negative, ( ) Not done

Prenatal ultrasound: ( ) Anomaly detected, ( ) Normal, Not done

Center name: Mother hospital record number Baby hospital record number

3. Examination: Labor and Birth Examination on Admission

HIV Status: HIV-positive/ HIV-negative/ Not done/ Unknown Pre-Natal Ultrasound: Anomaly (BD) detected/ Normal/ Not done! Unknown

Fetal Heart Sound: ( ) Present ( ) Absent ( ) Unknown

" Blood Pressure" ( ) Done ( ) Not Done

Per Vaginal Bleeding ( ) Yes ( ) No

Fever ( )Yes ( ) No

Delivery Details

Partograph: Used Not Used

Type of Labor: Spontaneous/Induced

Mode of Delivery: Normal Vaginal Delivery/ Breech Delivery/ Instrumental Delivery/ Emergency Cesarean Section/ Elective Cesarean Section

Birth Details

Baby Weight (in gram) Gestation Age (weeks & days)

Sex of the Baby Male/Female/Ambiguous

Confirmation of Gestation Age by: Last Mensuration Period LMP/Ultrasound USG/Unknown

4. Details of Stillbirth

Type of Stillbirth" Ante-Partum/Macerated Stillbirth (MSB) OR Intrapartum/Fresh Stillbirth (FSB)

M-Maternal Conditions

4.1- Maternal Condition Associated with Fetal Death (M)

[] M1 Complications of Placenta, Cord & Membranes

[] M2 Maternal Complications of Pregnancy

[] M3 Other Complications of Labor and Delivery

[] M4 Maternal Medical & Surgical Conditions: Noxious Influences

[] M5 No maternal condition identified (healthy mother)

Refer the PDF for suboptions

4.2-Fetal Death Main Cause (Ante-Partum Death (MSB) (A)] A-Antepartum Deaths

[] A1 Birth Defect

[] A2 Infection

[] A3 Antepartum Hypoxia

[1] A4 Other Specified Antepartum Disorder

[1A5 Disorders Related to Fetal Growth

[] A6 Unspecified Cause of Antepartum Death

Refer the PDF for suboptions

4.2-Fetal Death Main Cause (Intrapartum Death (FSB) (1)]" 1- Intrapartum Deaths

[] 11 Birth Defect

[] 12 Birth Trauma

[] 13 Acute Intrapartum Event

[] 14 Infection

[] 15 Other Specified Intrapartum Disorder

[116 Disorder Related to Fetal Growth

[] 17 Other

4.3-Other Associated Conditions:

1. Critical Delay: [] Delay in Recognizing [] Need for Care Delay Seeking Care [] Delay Receiving Care

Modifiable Factors:
1-Family Related: Late or no antenatal care/Cultural inhibition to seeking care/No knowledge of danger signs/Financial constraints/Partner restricts care-seeking/Use of traditional herbal medicine/Smoking/drug/alcohol abuse/Attempted termination/Other

2-Administration Related: Neonatal facilities/Theater facilities/Resuscitation equipment/Blood products/Lack of training/ Insufficient staff numbers/Anesthetic delay/No antenatal documentation/Other

3-Provider Related: Partogram not used/Action not taken/Inappropriate action taken latrogenic delivery/Delay in referral/ Inadequate monitoring/Delay in calling for assistance/Inappropriate discharge/Other

4-Unknown

Name of the Professional Filling the Form:

Date:

Disclaimer - These recommendations for “PREVENTION AND MANAGEMENT OF STILLBIRTHS” have been developed, to be of assistance to obstetricians, gynecologists, consulting physicians and general practitioners by providing guidance and recommendations for managing women with anemia and suffering from hemorrhagic conditions. The recommendations included here shouldn't be viewed as being exclusive of other concepts or as covering all legitimate strategies. The suggestions made here are not meant to dictate how a particular patient should be treated because they neither set a standard of care nor do they guarantee a particular result. To diagnose patients, choose dosages, and provide the best care possible while also taking the necessary safety precautions, clinicians must rely on their own experience and knowledge. The writers or contributors disclaim all responsibility for any harm and/or damage to people or property resulting from the use or operation of any techniques, goods, guidelines, or ideas presented in this content.