Stillbirth Society of India

Preventing death before birth

Consensus Statement 2023

for

Evaluation after Stillbirth

STILLBIRTH
SOCIETY OF INDIA

Team Lead
Uma Ram

Convenor
Tamkin Khan

Co-ordinator
Ayesha Ahmad

List of Contributors
[in alphabetical order]

Anita Kaul
Clinical Director, ACFM,
Indraprastha Apollo Hospital, Delhi

Asna Ashraf
Director & Consultant ObGyn
Ujala Medical Centre, Lucknow

Ayesha Ahmad
Professor, ObGyn
ELMCH, Lucknow

Bharti Sharma
Asst. Professor, ObGyn, PGIMER,
Satellite Center, Sangrur, Punjab

Deepak Chawla
Professor, Neonatology
PGIMER, Chandigarh

K Aparna Sharma
Professor, ObGyn
All India Institute of Medical Sciences,
Delhi

Mandakini Pradhan
Professor and Head, Maternal and Reproductive
Health, SGPGIMS, Lucknow

Neelam Aggarwal
Professor, ObGyn
PGIMER, Chandigarh

Nuzhat Aziz
Lead Consultant, Obstetric Emergencies
Dept.,Fernandez Hospitals, Hyderabad

Pratima Mittal
Professor and Head, ObGyn
Amrita Institute of Medical Sciences, Faridabad

Seema Chopra
Professor, ObGyn
PGIMER, Chandigarh

Shubha Phadke
Professor and Head, Medical Genetics,
SGPGIMS, Lucknow

Sujata Siwatch
Associate Professor, ObGyn
PGIMER, Chandigarh

Sunil Jaiman
Section Head, Placental Pathology Perinatology
Research Branch, NICHD. Asst. Professor,
Pathology, Hutzel Women's Hospital, Wayne State
University School of Medicine, Detroit, MI, USA.

Tamkin Khan
Professor, ObGyn
JNMC, AMU, Aligarh

Uma Ram
Director and Lead, ObGyn
Seethapathy Clinic and Hospital, Chennai

Message from President SBSI

Stillbirth is one of the most devastating life events with substantial physical, psycho social impacts on women, families & society. It's a huge public health concern. In 2019, globally an estimated 1.9 million babies were stillborn and India topped the wrong charts with maximum number of still births. They are invisible due to social taboos, stigma, isolation etc. There are no formal organizations in our country for raising voices of these bereaved parents & families. Every unborn baby has the right to receive best care. All bereaved parents must have the highest quality respectful bereavement care. It has been my proud pleasure to lead the Stillbirth Society of India --- the first formal organization dedicated to stillbirths in India.

I am very hopeful that through the medium of these consensus statements we will help in reducing preventable stillbirths and improving the care provided to parents following stillbirths.

These consensus statements will be released in the First Conference of The Stillbirth Society of India by joint efforts of SBSI and Department of Obstetrics & Gynecology, PGIMER, Chandigarh. We hope to focus on awareness, advocacy, dissemination, skill building, public forum, bereavement support on the subject of stillbirths.

"The temptation to quit will be greatest just before you are about to succeed." —Bob Parsons . Let's continue to work on this neglected tragedy.

Neelam Aggarwal
President Stillbirth Society of India
Professor Dept. of Obstetrics & Gynaecology
PGIMER, Chandigarh

Message from Vice - President SBSI

Greetings to each one of you. Thank you for joining us in the effort to prevent all preventable stillbirths. We find huge disparity in the rates of stillbirths across the world varying from 2/1000 to 40/1000, with India at 13/1000. A closer look gives a direct relationship with economic development. Low-income families, societies, and countries have high stillbirth rates with a high proportion of intrapartum stillbirths, again reflecting resources in the intrapartum period. Majority of stillbirths are preventable. The causes of stillbirths are very well known, preventable aspects have been studied. Success stories from countries, institutions have shown that there are effective interventions. Time has come for each one of us, at individual, institutional and regional levels, to plan pathways in antenatal care and audit any adverse outcomes to learn and review. Every stillbirth must be evaluated completely at birth. There will be gaps in resources, training and implementation. Our priority will be to provide a training facility for the gaps; example placenta histopathology and autopsy as it's a major missing step in evaluation of stillbirth due to lack of expertise.

Creation of the Stillbirth Society of India has the sole central aim of preventing stillbirths. This is the first annual conference of the society, and we hope you will benefit for the scientific content and create networks across India to promote this initiative. A BIG thank you to the PGI Chandigarh team, for the entire conference, concept to creation, for making this possible.

Leaving you with a quote from Atul Gawande that fits the stillbirth prevention pathways; 'Better is possible. It does not take genius. It takes diligence. It takes moral clarity. It takes ingenuity. And above all, it takes a willingness to try.'

We thank you for joining our efforts to be better.

With best wishes
Nuzhat Aziz
Vice President, Stillbirth Society of India
Lead Consultant, Obstetric Emergencies Department,
Fernandez Hospitals, Hyderabad, India

Message from Secretary SBSI

It is with immense pride and a shared sense of purpose that I present the Consensus Statements on Safe Baby Bundle and Evaluation of Stillbirth Cases, from the Stillbirth Society of India. This document stands as a testament of our commitment of understanding and addressing the complex issue of stillbirths. The journey towards formulating this consensus statement has been a harmonious symphony of collaboration, exchange of knowledge and experience, and perseverance. The process involved a team of experts who evaluated different National and International guidelines, published literature from south-east region of the world, other LMICs and the Indian subcontinent to arrive at these consensus statements.

We are indebted to our distinguished team leaders Professor Manju Puri and Dr Uma Ram who skillfully steered us towards a harmonious convergence of ideas and clear cut recommendations. They ensured seamless communication and balanced diverse viewpoints. They also tapped into the reservoir of personal journeys of our experts and their empathy and wisdom derived from their clinical practice and research. This has enriched the document to answer questions where the data was missing or not applicable to our settings. I thank each and every member of the two groups for their contributions.

We were extremely fortunate to have two dedicated coordinators, Dr Asna Ashraf and Dr Ayesha Ahmad who helped in organising zoom meetings, keeping minutes and sending timely emails. Later we discovered their passion for detail, aversion to typos and spellos, expertise in editing and formatting, and their aesthetic sense which brought the document into its final shape. I request each one of you to use and disseminate this document as guidance for healthcare providers, researchers, policymakers, and families, as we collectively strive to unravel the mysteries surrounding stillbirth and pave the way for a future marked by healthier pregnancies and brighter beginnings. With deepest gratitude to all contributors and an unwavering commitment to the cause.

Sincerely,
Tamkin Khan
Secretary Stillbirth Society of India
Professor Dept. of Obstetrics & Gynaecology, JNMC, AMU, Aligarh

Foreword

Stillbirth is a devastating pregnancy outcome where one is left encountering death when one is anticipating a new life. It is a clinical situation that has to be managed with sensitivity and empathy while ensuring a safe delivery for the mother who is fully supported.

In this document we have addressed different aspects of evaluation and management when one encounters a stillbirth. We have put together the key recommendations for practice based on evidence and international guidelines wherever available, keeping in mind that India is a vast country of varying health systems.

Uma Ram

Team Lead, Consensus Statement 2023 for Evaluation after Stillbirth
Director and Lead, Dept. Of Obstetrics and Gynaecology
Seethapathy Clinic and Hospital, Chennai

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1. Introduction

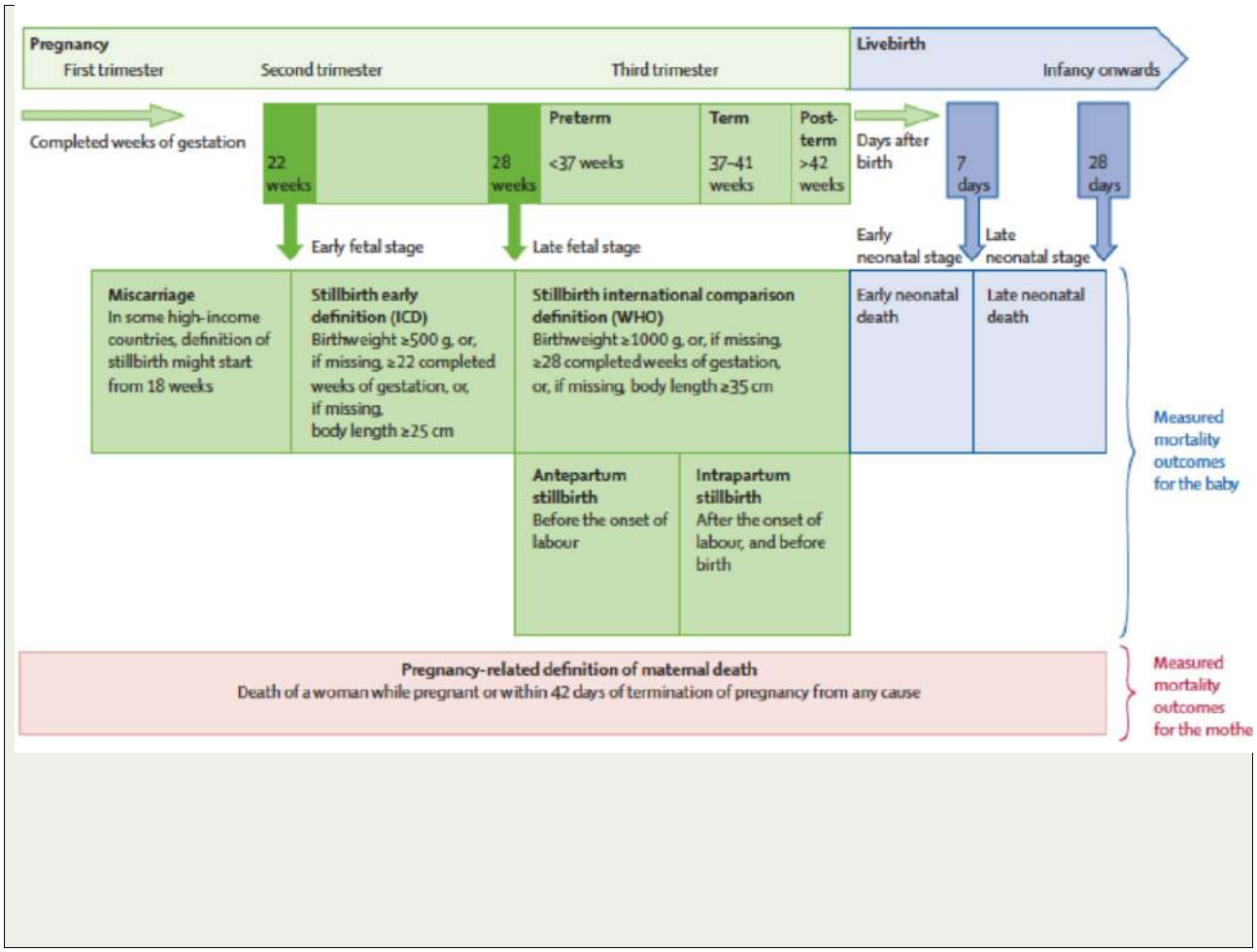
Stillbirth is defined as a baby delivered with no signs of life at or after 28 weeks of gestation. 2.6 million stillbirths are estimated to occur worldwide each year with the incidence being higher in the developing nations compared to the western world and the rate now compared to the year 2000 has reduced 2-3% on average. [1] Stillbirth can be an antepartum or intrapartum event and the aetiology for both are different.

The causes of stillbirth vary between different countries and in over half of the cases the aetiology is unexplained [fetal death that cannot be attributed to an identifiable fetal, placental, maternal, or obstetric aetiology due to lack of sufficient information or because the cause cannot be determined at the current level of diagnostic ability].

Antepartum stillbirths: The important causes of a baby dying in the womb before labour are maternal conditions [hypertension, diabetes], fetal growth restriction, birth defects, maternal infections [syphilis], placenta or cord related events and a small proportion of unexplained stillbirths. Many of these babies at risk of dying can be identified and timely intervention taken.

Intrapartum stillbirths: Intrapartum deaths are extremely rare in countries with low stillbirth rate, suggesting that improvement in intrapartum care will have a major impact on reducing the stillbirth rates. Early neonatal deaths within one week of birth also have a high proportion of deaths due to birth asphyxia. Intrapartum events are believed to be responsible for 19.2% of all the neonatal deaths in India.[2] Almost all deaths [97.8%] due to asphyxia occur in the first week of life, with 70% of them occurring within the first 24 hours of life [day 0].[2]

For international comparison, WHO uses stillbirth to mean the ICD definitions of late fetal deaths [i.e., birthweight of 1000 g or more with an assumed equivalent of 28 weeks' gestation. The figure below shows the continuum of pregnancy loss within which stillbirth sits.



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2. Classification of Stillbirths

The purpose of classification of deaths is to recognize, differentiate the underlying cause and to categorize so that relevant information can be gathered which further helps in reducing number of still births. In 1986, Whitfield et al proposed that the 'purpose of any classification should be to identify the deficiencies in health care provided, to focus attention where improvement is possible and where new development will lead to further advances.[1]

Thus, the primary goal of all these classification systems is to provide information on the cause of still birth to allow targeting of interventions at both the individual and public health level to reduce still birth and to conserve this data for regional and international comparison, health care quality improvement and for further research. In India, classifying stillbirths is more challenging, only 21% of women gets complete antenatal care, and even if investigations are available at the time of the stillbirth it is nearly impossible to have a complete postnatal work up to know the exact cause of any still born baby. [2]

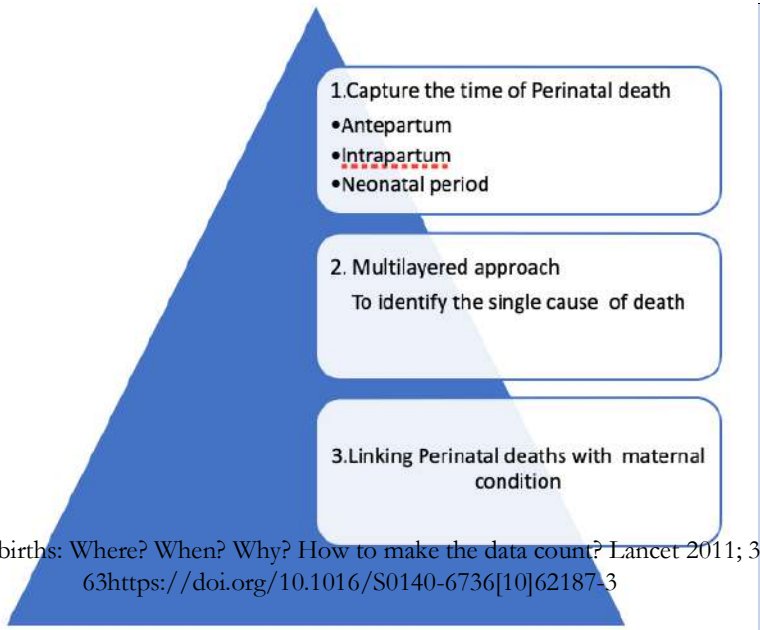
As per the systematic review published in 2016, Eighty-one systems were found to be used to classify stillbirth worldwide.[3] In terms of global effectiveness none of the system had alignment with "ease of use" among all system.[4]

WHO recommends the use of the International Classification of Disease [ICD] to classify deaths at any age, including stillbirths. However, the variation in the application of ICD-10 to still births limited the comparability of cause of still birth across different settings and it was clear that further guidance would be needed. Therefore in 2016, WHO developed revised guidance on the application of ICD 10 for perinatal deaths i.e., during pregnancy, child birth and puerperium- the ICD PM classification, seeking to create the first guidance on a global system for classifying still births.[5,6]

The ICD PM classification is a multilayered approach to identify the single cause of death and it actually captures the time of perinatal death i.e., Ante partum, Intrapartum & Neonatal period. It also links the perinatal deaths with maternal condition [Figure 1].[7] A job aid adapted from MPDSR training module can be used to classify each death in labour room or operation theatre for reporting [figure 2]

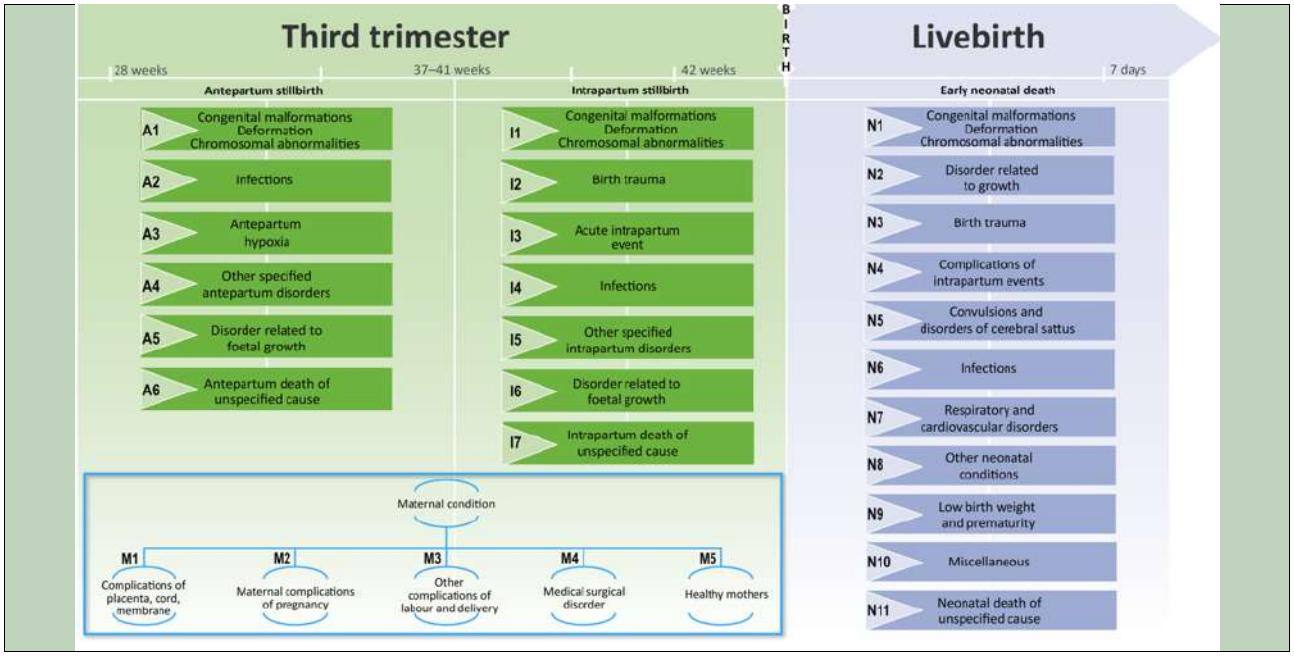
In our country, There is no uniformity in the classification system followed , as per the latest systematic review and mainly three classifications systems were used, which include cause of death – associated condition system [CODAC], Relevant condition at death [ReCoDe] and ICD PM system.[8]

Figure 1: ICD PM system of classification



Lawn et al Stillbirths: Where? When? Why? How to make the data count? Lancet 2011; 377: 1448–63https://doi.org/10.1016/S0140-6736[10]62187-3

Figure 2: ICD PM system of classification for perinatal death [Job aid adapted from MPDSR training module]



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3. Diagnosis and Initial Response to a Stillbirth

Diagnosis [1]

- Real-time ultrasound is essential for accurate diagnosis of intrauterine fetal death. It allows direct visualisation of fetal heart, and corroborating features such as collapse of fetal skull with overlapping bones, hydrops, maceration, intrafetal gas [within heart, blood vessels and joints].
- Doppler can be used additionally in case of technical difficulties with imaging such as maternal obesity, abdominal scars and oligohydramnios.
- Passive movements in case of IUFD may sometimes be felt by the woman. It is good practice to have another operator to confirm the absence of fetal heart before confirming diagnosis to the woman and family.

Breaking the News [1]

- Breaking the news of intrauterine fetal demise is a challenging situation to be handled with sensitivity and empathy by the doctor. The senior most team member should break the news to the family
- If the woman is alone, she should be offered to call in partner, relatives or friends.
- It is important the news is broken in quiet, comfortable surroundings, free of interruptions using an empathetic approach.
- Long explanations with jargon should not be given. It is important that the information that the baby is dead be communicated without the use of vague terms or euphemisms.
- It is important to give time for the information to be absorbed and for the woman / couple to come to terms with the significance of what has just been communicated to them.
- It is better to deal with questions or statements from her as they emerge. Any feelings of blame and self-censure should be countered with reassurance that she is not at fault.
- In case the woman desires a second scan for confirmation, she should be encouraged to do so.
- Most of the time we are unsure at that point of what may have caused the stillbirth and this also needs to be communicated while mentioning the need for testing to help identify the cause.
- We should give opportunity for them to come back with any questions and discussion The discussion should end with a care-plan based on the patient's wishes.

Reference:

1. Royal College of Obstetricians and Gynaecologists. Green-top Guideline No. 55: Late intrauterine fetal death and stillbirth. London: RCOG; 2010

4. Work up of a Case of Stillbirth

Maternal Investigations

A detailed history, clinical examination and laboratory tests should be recommended to evaluate the cause of stillbirth, risk of recurrence and possible preventive measures. It is critical to assess every stillbirth carefully to assign a cause of death, both for the parents as well as the care givers, with the intent of avoiding a recurrence in a future pregnancy.

Evaluation following a stillbirth can be discussed under the following categories

- Detailed History
- Maternal examination
- Maternal Investigations
- Placenta, fetal autopsy

This document will address the first three evaluations. Genetic testing and fetal autopsy are addressed in subsequent documents.

History

History should comprise details of pregnancy associated with stillbirth, previous obstetrical history, maternal medical history, family history and socio-economic and occupational history. A comprehensive history of present or previous pregnancies with fetal loss helps to determine the cause of the stillbirth. Though many a times history does repeat itself, multifactorial or sporadic causes of fetal loss may be seen in different pregnancies. The evaluation must consist of history taking and review of medical records of the pregnancy regarding the following:

- Maternal age
- Smoking, alcohol, or substance abuse
- Environmental factors : maternal education, socio-educational status, access to healthcare
- Past obstetric history
- Review of antenatal records: visits, care received, investigations

- Complications in pregnancy : Anemia, HDP*, HIP*, FGR*, cholestasis APH
- Multiple pregnancy : chorionicity, complications
- Fever and symptoms / evidence infections in pregnancy

Delivery details:

- Gestational age,
- induced or spontaneous labor,
- malpresentations
- Amniotic fluid : colour, evidence of APH or chorioamnionitis
- Nature of delivery spontaneous, instrumental or cesarean
- Preterm premature rupture of membranes
- Birth weight,
- maceration, malformations, or hydrops [See examination of newborn]
- Family history including a 3-generation pedigree, medical illnesses, hereditary syndrome and consanguinity should be recorded.[1]

Examination of the mother may also suggest contributory causes of stillbirth. This would include the following

- BMI
- Evidence of any rash : suggestive of autoimmune disease or infections
- Acanthosis
- Goitre
- Anemia

- Pedal edema or facial puffiness

Investigations: Investigations of stillbirth are varied and detailed in Table 1.[1, 2]

- All women who have a stillbirth will benefit from the tests listed below. others can be obtained as appropriate based on the clinical situation.

1. Kleihauer test to detect large fetomaternal haemorrhage as major fetomaternal haemorrhage is a silent cause of IUFD/SB.
2. Maternal complete blood count, liver and renal function tests when there is pre-eclampsia, Multiorgan failure in sepsis or haemorrhage Coagulation screen to be done to rule out DIC.
3. Hb A1c and blood sugars to rule out occult Diabetes and GDM.
4. Maternal thyroid function tests to rule out occult thyroid disease.
5. Screening for maternal infections including Toxoplasmosis, CMV, Rubella, Herpes simplex, malaria and Parvovirus B19
6. Serum bile acid if there is suggestion of obstetric cholestasis.

The availability of all tests throughout all resource settings may not be feasible, but a careful clinical assessment and the knowledge of prevalence of various causes of stillbirth in the Indian context may help to efficiently direct the investigations to identify the likely and contributory causes of the stillbirth.

Condition	**Category**	**Investigations**	**Suggested Indications**
Thrombophilias	APLA syndrome[2]	LA, B2 Glycoprotein, acLa antibodies- IgG/ IgM	History of early onset FGR, preeclampsia, abruption, recurrent abortions, placental insufficiency
	Inherited thrombophilias	0-8 weeks postpartum- Factor V, MTHFR 6-8 weeks- Factor VIII, Protein C/S, Plasma homocysteine [6]	Not routinely recommended. [1] Family history, DVT, recurrent fetal growth restriction, preeclampsia

Endocrine Causes	Diabetes- Preexisting DM, Gestational diabetes[7-10]	OGTT, FBS, HBA1c	Universal screening for Indian ethnicity, Family history of diabetes, glycosuria, polyhydramnios, macrosomia
	Hypo and hyperthyroidism may be associated with stillbirths[7-9]	Thyroid stimulating hormone	Features of hypothyroidism
Hematological Diseases	Fetomaternal hemorrhage Rh isoimmunisation[9]	Kleihaeur betke test, flow cytometry Blood group, antibody screen[8, 9]	Recommended[2] Fetal hydrops, anemia and jaundice in affected fetus/ baby
	Anaemia- moderate to severe anaemia Thalassemia Alloimmune Thrombocytopenia[2]	Complete blood count [7, 8] HPLC/ Electrophoresis[8] Fetal cord blood for platelets	Fetal growth restriction and demise Baby hydropic in alpha thalassemia Rare. History of intracranial bleed in baby
Infections	Chorioamnionitis TORCH serology, Parvovirus B19, Syphilis[7-9] Tropical illness Leptospirosis, Malaria, Dengue, scrub typhus, Listeria	Blood and urine culture, vaginal/ cervical swab, membrane culture[4, 7-10] Serology Serology	Preterm labor, preterm rupture of membranes, urinary tract infections Fever and rash in pregnancy, flu like symptoms, Fetal growth restriction with malformations Fever with rash, jaundice, diarrhoea

Maternal Medical Disease	Intrahepatic Cholestasis of pregnancy[9] Other hepatic diseases like Hepatitis E, AFLP	Fasting bile acids [>40umol/l] Liver function tests Liver function tests	History of itching, decreased fetal movements, Meconium stained liqor, and fetal demise. Fever, Jaundice, vomiting, coagulopathy
	Chronic Hypertension Hypertensive disorders of pregnancy Renal disease	Platelets, liver function tests, renal function tests	Fetal growth restriction, abruption, preeclampsia
	SLE	ANA, anti Ro, anti La, APLA work up	Maternal features of SLE, evidence of antenatal Fetal bradycardia, Non- immune hydrops, Endomyocardial fibroelastosis, AV nodal calcification on fetal autopsy
Toxins	Smoking, alcohol, cocaine, cannabis, drugs abuse[1, 7-9] like amphetamine, hydrocodone, NSAIDS- premature closure of PDA	Levels in serum/ breath	History of substance abuse, Abruption, Psychiatric illnesses, drug intake
Genetic	Genetic disorders	Karyotype, chromosomal microarray	Sudden unexplained fetal demise, Maternal congenital heart disease, recurrent fetal losses, Genetic abnormality in fetal tissue

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5. Examination of a Stillborn Fetus

It is crucial not only to quantify stillbirths but also understand their causes which helps in counselling parents and assessing future pregnancy risks.

The examination includes:

1. External examinations of the fetus and placenta
2. Photography
3. Radiography
4. Autopsies
5. Microscopic Analysis
6. Karyotyping, and genome sequencing

- A comprehensive investigation can identify the cause of stillbirth in about 90% of cases.
- Among these methods, the external examination of the fetus is the most informative and feasible, even in settings without access to fetal autopsies or genetic analysis.
- A structured approach to this examination is vital to avoid overlooking significant findings.

1. **Maceration and intactness:** The first component of the examination is to assess the degree of maceration of the fetus. The degree of maceration can be graded as following:

Grade	Desquamation	Skin and tissue color
0	None	Normal
I	< 1% of the surface are	Red/pink and fresh with focal discoloration Brown-red discoloration of umbilical cord stump
II	1-5% of the surface area	Red/pink and fresh with focal discoloration Serous fluid collection

III	>5% of the surface area	Red/pink mixed with brown
IV		Total brown skin discoloration
V		Mummification

If the fetus is not delivered intact, the fetal components should be separated from the placenta, counted, identified and examined.

2. **Anthropometric measurements:** The following measurements should be performed using a calibrated weighing machine, non-stretchable plastic tape and a caliper.

A. Fetal weight
B. Crown-heel length
C. Crown-rump length
D. Head circumference
E. Biparietal diameter
F. Chest circumference at the level of nipples
G. Abdominal circumference at the level of umbilicus
H. Toe-heel length
I. Hand length

These measurements when compared with gestation-based charts help in identification of fetal growth restriction [FGR]. Disparity between measurements [e.g., weight and crown-heel length or head circumference] can help in identifying the time of onset of FGR [early or late]. Toe-heel or hand length can be useful in cases when a fragmented fetus is delivered.

Some additional measurements that can help in identification of dysmorphic fetus include:

A. Ear position - low-set ears [both sides]
B. Inner canthal distance
C. Outer canthal distance
D. Inter-pupillary distance
E. Philtrum length
F. Inter-nipple distance

3. **External examination:** A detailed examination must be performed from head to toe. All the abnormalities should be noted in detail. The details include location, number, severity, and description of each identified abnormality.

A. General examination

(a) Trauma including lacerations, dismemberment, and fragmentation
(b) Bruising and petechiae - presence and distribution
(c) Amniotic bands
(d) Localized or generalized discoloration including icterus, pallor, or cyanosis
(e) Meconium-staining of skin, nails, umbilical stump. If meconium present - thick or thin
(f) Localized [e.g., nuchal], partial, or generalized edema [hydrops fetalis]
(g) Skin rash

Head

(h) Anencephaly
(i) Acrania
(j) Encephalocele - location
(k) Large head [hydrocephalus]
(l) Abnormal head shape
(m) Low hairline
(n) Size of anterior and posterior fontanelle
(o) Overlapping sutures
(p) Craniosynostosis and sutures affected
(q) Any other abnormality

Eyes

(a) Synophrys
(b) Palpebral slant
(c) Epicanthal folds
(d) Cyclopia
(e) Cataract
(f) Coloboma
(g) Blue sclerae
(h) Microphthalmia
(i) Any other abnormality

Ears

(a) Absence or abnormality of auricle [anotia/microtia]
(b) Ear tag
(c) Any other abnormality

Nose

(a) Proboscis
(b) Choanal atresia
(c) Depressed nasal bridge
(d) Any other abnormality

Mouth

(a) Cleft lip or cleft palate
(b) High-arched palate
(c) Natal teeth
(d) Micrognathia
(e) Tongue - size and abnormality
(f) Oral mass
(g) Any other abnormality

Neck

(a) Short neck
(b) Nuchal thickening
(c) Cystic hygroma
(d) Fistula
(e) Mass
(f) Any other abnormality

Chest

(a) Pectus
(b) Ectopia cordis
(c) Any other abnormality

Abdomen

(a) Abdominal wall defect - gastroschisis
(b) Abdominal wall defect - omphalocele
(c) Prune belly
(d) Exstrophy
(e) Abdominal mass or distension
(f) Any other abnormality

Anus

(a) Imperforate anus
(b) Fistula
(c) Displacement
(d) Any other abnormality

External genitalia

(a) Ambiguity
(b) Hypospadias/epispadias
(c) Undescended testes
(d) Clitoromegaly
(e) Vaginal opening
(f) Abnormality of labia majora and minora
(g) Any other abnormality

Upper limbs

(a) Short
(b) Missing part [e.g., phocomelia]
(c) Contractures
(d) Digit abnormalities including syndactyly, absent digits, extra digits
(e) Palmar crease
(f) Any other abnormality

Lower limb

(a) Short
(b) Missing part [e.g. phocomelia]
(c) Fused
(d) Contractures
(e) Toe abnormalities including syndactyly, absent toes, extra toes
(f) Talipes - presence and type
(g) Rocker bottom foot
(h) Any other abnormality

Spine

(a) Neural tube defect
(b) Any other defect

Skeletal system

(a) Fractures
(b) Any other abnormality

4. **Photography:** Following photographs may be obtained for records: anterior, posterior and lateral views of the body, anterior, posterior and lateral views of head, and close-up views of any abnormality. The views should be labeled for laterality and a scale should be placed alongside the body at the time of photography. Examination should be documented with date, time, and the person performing the examination.

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6. Genetic Testing of Stillborn Baby

Introduction

When stillbirth is diagnosed the need for investigating the cause of stillbirth and the utility, availability, cost and timing of investigations should be discussed with the couple. They should be given adequate time to discuss, decide and give informed consent. It is recommended that a comprehensive pre- and post- test counselling of the couple should be done by a trained health care provider with expertise in genetics who can explain the benefits, limitations and results of tests. The following principles can be followed when deciding investigations for genetic testing in case of stillbirth.

1. Intrauterine fetal demise diagnosed with an ongoing pregnancy

(a) Obtaining fetal sample

- Chorionic villous sampling [less than 16 weeks], Amniotic fluid [more than 16 weeks]
- Amniotic fluid is collected into two sterile tube [10ml each] without adding any chemicals/media.

(b) Genetic test to be ordered

Without malformation or hydropss

- Karyotype: in more than 50% cases it may fail to grow and hence may not be possible to obtain a report. [1]
- Chromosomal microarray [CMA]: This test should not be ordered without informed consent. Which should include discussion of the potential to identify findings of uncertain significance, non-paternity, consanguinity and rarely adult onset disease. The need for further testing of couple may be emphasised. [1]

With malformation or hydrops detected on Ultrasound

- CMA: it is expected that all unbalanced karyotype abnormality responsible for malformation will be picked up by CMA
- Polymerase chain reaction [PCR] of Toxoplasma, cytomegalovirus and Rubella

2. Still birth detected at delivery

(a) Obtaining fetal sample

- 2 ml Cord blood collected in EDTA vial, fetal placental tissue or fetal skin that can be obtained after delivery
- Collection of Fetal placental tissue: with aseptic precaution 1cm^3 placental tissue should be collected away from the cord insertion, without any prominent vessels into a container with culture media obtained from the laboratory.
- Collection of fetal skin: with aseptic precaution, a 5X2 cm approximate skin with dermis and epidermis should be collected from the medial aspect of the delivered baby and put into the culture media bottle from the laboratory.

(b) Genetic test to be ordered

- Haemoglobin, total leucocyte count, Platelet count
- IgM for Toxoplasma, cytomegalovirus and Rubella
- PCR for Parvo-B19 [if non-immune hydrops fetalis]
- CMA as explained above
- Whole exome sequencing in case of skeletal dysplasia, syndrome, non-immune hydrops or suspected single gene disorder [2, 3]

3. **Previous history of Still birth**

Examination of the couple for any malformation, neurological defect, skin lesion especially café-au-lait spot, single incisor, blue sclera etc.

(a) Genetic test to be ordered

<u>With prior history of malformation:</u>

- Karyotype of the couple
- If karyotype is normal, then whole exome sequencing may be considered [no recommendation as yet]

<u>Without history of malformation:</u>

- Consider karyotype of the couple after ruling out other causes of stillbirth
- Carrier testing for spinal muscular atrophy by MLPA of one partner
- Fragile -X carrier testing of the women
- Whole exome sequencing may be considered for one partner. No recommendation as yet. [2,3]

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7. Timing and Mode of Birth for Intrauterine Fetal Demise after 24 weeks

Introduction

Diagnosis of intrauterine fetal demise [IUFD] is devastating news for every woman and most desire a prompt delivery. Women need time to make decisions and need counselling about the advantages of vaginal birth, the available methods of inducing labour and pain relief. [1,2,3,4]

Timing of delivery

Many women fear of complications due to delay in delivery of the dead fetus. Disseminated intravascular coagulation [DIC] is a rare complication of delayed delivery of IUFD with a reported incidence of 2%. However, it is a dreaded sequelae with risk of heavy bleeding and maternal mortality.[5]

- If women chose to wait beyond 48 hours of stillbirth, then DIC screen should be done twice weekly.[2] This includes estimation of total platelet count, prothrombin time and serum fibrinogen levels.
- Prompt delivery is required in the event of sepsis, abruption, pre-eclampsia, ruptured membranes or any evidence of DIC.[2]

Mode of Delivery

- Vaginal birth is the preferred mode of delivery as cesarean section [CS] is associated with potential maternal morbidity without any fetal benefits.[1,2,3,4]
- CS is limited to adherent placenta syndromes or previous multiple uterine surgeries in the past.
- CS may also be needed in placental abruption or previa with profuse bleeding with maternal compromise.
- Labour can be induced depending on the gestational age, degree of cervical ripening and history of previous CS, hysterotomy or uterine surgery.
- Induction with Misoprostol was found to be better than other methods with vaginal route of administration being better than sublingual.[6,7,8] Addition of Mifepristone [200 to 600 mg] was found to reduce the induction-to-delivery interval. Examples of different regimens are given in table 1.[9,10] Mechanical dilatation with transcervical catheter can be added for those with unfavorable cervix or as a primary method in those with scarred uterus.

- Women who have increased risk of rupture of uterus and who opt for induction of labour should do so with the understanding that induction and prostaglandins use is associated with higher rates of rupture.[1]
- Vast majority of women [87.5%] delivery within 24 hours, remainder deliver in the ensuing 24 hours. When delivery does not occur at 48 hours, the options of surgical intervention, or repeat regimen after a gap of 24 hours should be discussed in the context of urgency of delivery and the woman's desires.[9]
- Routine antibiotics are not recommended.
- Anti D should be given to Rh negative women at presentation.
- All pain relief options including epidural labour analgesia should be offered.
- Post-birth, the third stage of labour is similar, except that spontaneous expulsion of placenta is awaited rather than traction.
- Care should be taken as there is higher incidence of retained products.
- Women should be provided bereavement support, medications for suppression of lactation, complete documentation of stillbirth evaluation should be given to the woman.

Table 1 : **Regimens for induction of labour**

Regimen A [9]	
24 to 34 weeks	**More than 34 weeks**
Step 1: Mifepristone 200 mg **Step 2:** 24 to 48 hours later- Misoprostol 200 mcg vaginal, then maximum of four ORAL doses of 200 mcg every 3 hours	**Step 1**: Mifepristone 200 mg 24 to 48 hours later **Step 2:** 24 to 48 hours later- Misoprostol 100 mcg vaginal, then maximum of four ORAL doses of 100
Regimen B [10]	
20 to 26 weeks	**More than 26 weeks, unscarred uterus**
Misoprostol 100 mcg every 6 hours for four doses. Dose to be doubled if no response with first. Maximum daily dose should not exceed 800 mcg.	Misoprostol 50 mcg every 4 hours for maximum of 6 doses. Dose to be doubled if no response after first dose. Maximum daily dose should not exceed 600 mcg.

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8. Post-partum Care of a Woman Following Stillbirth

Introduction

Care for a woman who has experienced stillbirth must include emotional support in addition to a clear explanation of the process to be followed and results. Communication must be clear, honest and given in a culturally appropriate manner. [1]

Important Considerations [1,2,3]

- The baby must be treated with respect and parents given the opportunity to see and hold the baby. Their preferences about cremation or burial need to be discussed, respected and facilitated. [2]
- Assessment of risk for venous thrombosis must be made as per standard recommendations.
- Lactation suppression is to be offered. This is usually done by prescribing Cabergolin 1 mg as a single dose. Women are advised not to express milk and to use cold compress for pain relief. [3]
- We must be aware that the women and family are going through a very difficult time and how much information they want to know may vary in the immediate post-partum period. [1,2,3]
- Also, we must be aware that all the information we give may not be retained. It is therefore important that a time is set for a review fairly soon in a quiet and undisturbed environment to go over the events and address queries and concerns. [1,2,3]
- Women who have had stillbirth have gone through a significant loss and are at risk of postpartum depression. The mother / couple must be given the option to meet someone trained in bereavement care. They must be aware that they can reach out and meet the appropriate person if they should feel the need for psychological support. [1,2,3]
- In the review visit, one must also address any additional tests that need to be done and the timelines for results of tests already performed.
- Contraception should be discussed. The pros and cons of different modes of contraception should be explained to enable the woman to make an informed choice. It is important to emphasize that pregnancy be delayed until the investigations are completed and appropriate pre-pregnancy counselling and planning discussed based on the outcome of the investigations. [1,2,3]

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9. Investigations in a Case of Stillbirth

The most frequent causes of stillbirth are attributable to placental pathology and umbilical cord abnormalities. Gross and microscopic examination of the placenta, umbilical cord, and fetal membranes by a trained pathologist is the single most useful test in evaluation of stillbirth.

Fetal autopsy [1]

It is one of the most useful diagnostic tests in determining the cause of stillbirth. Prior to autopsy, permission from the parents should be taken on a consent form. The fetus should be at least 11 weeks' gestation for performing autopsy. The entire placenta with membranes and attached cord should be sent along the fetus. Complete autopsy is the most thorough investigation and provides most information. This includes both gross and internal examination of fetus, relevant radiographic and genetic tests along with placental evaluation.

Applicable to all autopsies

Examination of placenta: Gross and microscopic examination of placenta, umbilical cord and fetal membranes by a trained pathologist yields extensive information about etio-pathogenesis of stillbirth. [2]

Gross Examination of placenta, cord and membranes

It includes placental weight, dimensions, odour, presence of retroplacental clot and recording any gross structural variants [succenturiate/circumvallate/bipartite placenta and insertion of cord such as eccentric/central/marginal/velamentous]. Umbilical cord should be measured in entirety, noting the number of cord vessels, presence of any knots and appearance of cord [thin/thick/ meconium stained]. The umbilical coiling index is calculated as a ratio of the number of coils to the length of the cord. [2]

Gross examination of the fetus

It consists of fetal measurements [weight, head circumference and length of fetus] and documentation of any external malformations and dysmorphic facies. [2]

Clinical photography

It includes standard full body frontal and side view of face in all cases with selected additional close ups for specific abnormalities in dysmorphic babies with gross abnormalities. [2]

Radiographs

X-ray is recommended for suspected skeletal dysplasia, multiple malformations and unexplained stillbirth, and in particular clinical settings such as suspected fetal growth restriction. [3]

Internal examination

(a) Transport of the fetus: Ideally fetus and placenta should be transported in sterile normal saline, preferably in an ice box if the referral lab is located within the city.

(b) If the fetus has to be transported to a lab outside the city- Fetus should be preserved in 10% formalin. Samples for genetic testing should be collected before putting formalin in placenta. The skin incision should be midline and inverted Y- shaped or I-shaped and a systematic examination should be performed including all organs of the body. [3]

References

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10. Pre-conceptional and Antenatal Care for Subsequent Pregnancy: Principles of Care

Introduction

Evidence on management of pregnancy after a stillbirth is still not robust. The risk attributable to modifiable factors can be minimised by targeted interventions. However, there is insufficient evidence regarding effective interventions in women with a history of stillbirth. [1]

The recommendations have been graded according to the level of evidence [Table 1].

The components of care for subsequent pregnancy includes:

1. Counselling for risk of stillbirth recurrence
2. Planning Antenatal Care
3. Antepartum surveillance
4. Fetal kick counting for women with history of unexplained stillbirth
5. Timing of delivery

Counselling for risk of stillbirth recurrence

- A previous stillbirth may remain unexplained despite extensive investigations. [2]
- There is an increased risk of stillbirth in women with a history of stillbirth irrespective of the cause. The reported pooled OR, 4.83;95% CI, 3.77-6.18. [3]
- It is difficult to quantify the risk of stillbirth subsequent to previous unexplained stillbirth. However, it has been reported to have a risk between 3.11 [95%CI.0.72-13.5][4] to up to 4.18 [95% CI 1.36-12.89][5]
- The patient will require counselling and extra support in the subsequent pregnancy despite counselling about risk of recurrence.[6]
- If an etiology for stillbirth has been identified, it is easier to quantify the risk [Table 2].

Table 2: Estimated risk of stillbirth with background maternal conditions [6]

Condition	Risk/1000 live births
Diabetes	
On diet	6-10
On Insulin	6-35
Hypertension	
Chronic hypertension	6-25
Preeclampsia	9-51
SLE	40-150
Renal Disease	15-200
Cholestasis of Pregnancy	12-30

Planning antenatal care [7]

Pre-conceptional and Early Pregnancy Care

- Evaluation by :
    - Detailed medical and obstetric history
    - Review of work up of previous stillbirth
    - Diabetes screening
    - Acquired thrombophilia testing
- Determining the recurrence risk
- Lifestyle modification
    - Smoking cessation
    - Weight loss
- Genetic consultation: based on family history and past history
- Counseling and support

First trimester

- Dating ultrasonography
- Aneuploidy screening in first trimester
- Counselling and support

Second trimester

- Anatomy scan
- Genetic consultation [If not done earlier]
- Counseling and support

Third trimester

- Monitoring for fetal growth
- Fetal surveillance starting 32 weeks
- Counseling and support

Antepartum surveillance

There is no evidence on optimal time for starting monitoring for fetal growth and well-being. Hence, it should be based on local protocols considering the following:

- Serial assessment of fetal growth should start around 28 weeks' gestation with consideration for the gestation of the previous loss [i.e., an earlier loss at 24−26 weeks should indicate earlier monitoring].
- The frequency of monitoring for growth should not be more than 2 weekly. [8]
- Data does not support routine use of ultrasound biophysical profile in women with a history of stillbirth.[9]

- However, in pregnancies with background morbidities, monitoring can be according to the protocol for that condition. In general , for a history of stillbirth at more than 32 weeks , surveillance can begin at 32 weeks. For earlier stillbirths, the monitoring plan must be individualised.

- Increased frequency of scans are associated with increased patient anxiety. [10] A compassionate approach, presence of a companion and sensitive communication can help allay anxiety.

- The evidence on routine use of biophysical profile and non-stress test are conflicting. [11] However, patient perceptions towards Non stress test have been reported to be positive. [12] These tests can be offered according to the existing local protocols.

Fetal kick count for women with history of unexplained stillbirth

- There is no evidence that routine formal fetal monitoring based on a fetal movement count reduces perinatal mortality. [13,14]
- The best practices regarding fetal movement involve educating women about fetal movement and self-monitoring to report a reduction in fetal movement to care providers, who then perform an NST and an ultrasound scan to assess fetal biometry and amniotic fluid. "Fetal awareness" seems to be more relevant than an actual numerical fetal movement count. [15]

Timing of delivery

- There is no evidence about the timing of birth to address maternal stress and anxiety in women who have experienced a stillbirth in a prior pregnancy.
- Early term birth may be an option for women with a previous stillbirth, in those cases where the clinical situation necessitates these measures.
- Charting a clear path from early pregnancy for planning a delivery around 38-39 weeks can help alleviate the patient's anxiety. [10] [Level of Evidence 2+; Grade C]
- Timing of birth must be considered taking into account the conditions of previous stillbirth, clinical picture in the current pregnancy and the emotional state of the couple. Any decision for delivery before 39 weeks must be taken after considering the risks to the neonate. The decision making has to shared.

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11. Institutional Stillbirth Audits

Introduction

The global burden of neonatal deaths is 2.7 million and stillbirths is 2.6 million. About 98% of these deaths occur in low-income and middle-income countries [LMICs].[1,2]

Stillbirth and neonatal death audit is the process of collecting information on the cause of death and analysis of quality of care received by the parturient and neonate. Understanding the number and causes of death is key to decreasing the disease burden. According to WHO, mortality audit for stillbirths and neonatal deaths may help contribute to global goals and is covered under two of the five objectives in the 'Every Newborn Action Plan: to address quality of care at birth and to generate data for decision-making and action. [3]

It is important that every obstetric unit puts in place a protocol for reporting and auditing stillbirths. In order to bring about change, one needs improved qualitative and quantitative data on births and perinatal deaths, from different health care providers and departments.

Regional Audit System for Stillbirth improves the registration of stillbirth and allows to define its cause, identify the group of recipients who would benefit from preventive measures in future. Audits should be interdisciplinary and maintain a no-blame approach.

Data collection includes: Maternal information and Diagnostic work-up after still birth.

Measures to be taken

- Identify a team of specialists: Maternal fetal medicine [MFM] specialists, Histopathologist, Microbiologist.
- Quality of care: Pre- and post-audit, Comparison with national and international standards.
- Interdisciplinary Meetings: monthly, area wise -6 monthly, annual for trends.[4]

Six-Step Cycle of Auditing Deaths at Facility Level

Step One: Identify Cases for Review

- Aim: To record all births, stillbirths, and neonatal deaths,
- Questions to Ask: Which deaths do we want to collect more detailed information on?

Step Two: Collect Information

- Aim: To empower designated staff to collect a standardized set of information
- Questions to Ask: What kinds of records exist for every death?

Step Three: Analyze Information

- Aim: To identify problems in the system
- Questions to Ask: Trends over time? What modifiable factors ? additional analyses ?

Step Four: Recommend Solutions

- Aim: specific, measurable, attainable, relevant and time-bound [SMART] solutions.
- Questions to Ask: What changes are needed in each unit, within linked health services, in the community, or at an administrative level?

Step Five: Implement Solutions

- Aim: To take immediate, medium-term, or long-term actions .
- Questions to Ask: influence factors beyond our immediate sphere of control?

Step Six: Evaluate Both Process and Outcomes, and Refine as Needed

- Aim: To look back at what worked and what did not
- Questions to Ask: How efficient is the system? Staffing issues influence review meetings? [3]

Assisting in implementing audit as a tool for quality improvement can help parents to understand why the death occurred and to assist in future pregnancy planning, improving clinical practice and appropriate research. [5]

There is a set of questions for assessing the implementation and maintenance of the audit system, or example- how can the feedback to service providers and senior management in the facility and outside the facility be improved.[6]

Recommendations emanating from the audit process should follow the Plan, Do, Study, Act [PDSA] and SMART cycles. Completing the audit cycle by implementing recommendations is crucial to improving perinatal outcomes. [7]

Despite all system levels being of value, facility-level activities are central to the successful implementation of stillbirth and neonatal death audits. Even auditing a single death is useful in the process of improving care at the facility level. Completing the audit cycle by implementing recommendations is crucial to improving perinatal outcomes. [4]

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