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NATIONAL HEALTH MISSION

Operational Guidelines for Establishing Sentinel Stillbirth Surveillance System

June 2016

Child Health Division
Ministry of Health and Family Welfare
Government of India

Developed for Ministry of Health & Family Welfare by
World Health Organization Country Office for India

OPERATIONAL GUIDELINES FOR ESTABLISHING SENTINEL STILLBIRTH SURVEILLANCE SYSTEM

June 2016

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PREFACE

As part of the national and international commitments, India is steadfast in its resolve to reduce Neonatal Mortality Rate (NMR) to single digit by year 2030. Going by the past trends in the reduction of Infant Mortality and Neonatal mortality, India seems to be on the right track. However, we need to capitalize on the ground gained and consolidate what has been achieved. Post 2015, the world will focus on achieving the Sustainable Development Goals (SDGs). India Newborn Action Plan (INAP) clearly spells out that we need to continue working on reducing NMR to much lower levels; we also need to focus on stillbirths which is not only an adverse pregnancy outcome but also affects the health of the mother and the family.

Stillbirth surveillance at the facility level will provide opportunity to not only count but review the circumstances, risk factors and leading determinants resulting in a stillborn baby. By analyzing the surveillance information, the variation in antenatal and intrapartum care and its outcomes will inform the implementation of the evidence based interventions. It should not, however, be seen as an isolated intervention but be an integral part of maternal and newborn care. In addition to implementation of surveillance activities, I encourage teams at the sentinel sites to use surveillance as a tool to address burden of stillbirths by improving health systems and clinical care at the health facilities.

These guidelines are being brought out at a very opportune moment, addressing a need that is being felt not just at the national but at the global level. I am confident that with these guidelines, the States will take up the implementation of this initiative with full vigour and commitment.

(C.K.Mishra)

New Delhi
July 4, 2016

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PREFACE

India has made substantial gains in tackling direct obstetric complications however the indirect causes that put a substantial proportion of our mothers and children at risk of mortality & morbidity need to be reviewed. Stillbirth surveillance that will provide better information for its causes is important to address the silent burden of stillbirths. Annually, approximately 6 lakhs stillbirths happen in the country resulting mostly from complications during pregnancy and childbirth occurring in India. Most maternal and perinatal deaths are preventable or treatable if life-saving preventive or therapeutic known and effective interventions are provided at the right time.

India's commitment to achieve single digit Stillbirth Rate under India Newborn Action Plan (INAP) by Ministry of Health and Family Welfare is a step forward towards achieving our national and international commitments for its newborns. Establishing sentinel surveillance system in India through institutions will enable assessment of the magnitude of stillbirths and compel policy-makers and decision-makers to give the problem the attention it needs and plan for interventions to prevent stillbirths.

I would like to congratulate the Child Health Division in preparing the Operational Guidelines for establishing Sentinel Stillbirth Surveillance System in collaboration with the World Health Organization and other partners. This guideline is the first step towards reviewing every stillbirth at the facility level and will guide the nation to take steps to significantly reduce maternal and neonatal mortality and morbidity. I am hopeful that the designated centers will take cognizance of these new guidelines and incorporate stillbirth surveillance as an integral component of the quality care at birth.

(Ms. Vandana Gurnani)

New Delhi
July 4, 2016

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(Dr. Ajay Khera)
4/7/16

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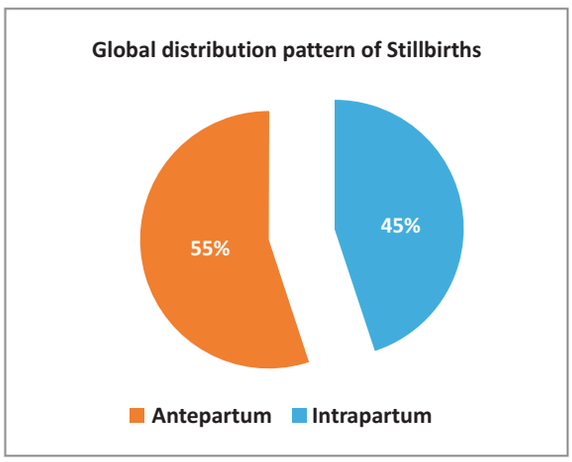
Acronyms

CHL	Crown-heel length
CODAC	Causes of death and associated conditions
HMIS	Health Management Information System
ICD	International Classification of Disease
SRS	Sample Registration System
WHO	World Health Organization

I. Introduction

Stillbirth or intrauterine fetal death is an unfavorable pregnancy outcome and is defined as complete expulsion or extraction of baby from its mother where the fetus does not breathe or show any evidence of life, such as beating of the heart or a cry or movement of the limbs. WHO defines stillbirth for international comparison as a baby is born with no signs of life at or after 28 weeks' gestation. The birth weight is often used in defining stillbirth if the gestational age is unknown.



Globally, an estimated 2.6 million stillbirths occur each year which account to nearly 7,200 babies stillborn each day. Ten countries alone including India account for two-thirds of all global stillbirths >28 weeks. Amongst the total 1.19 million (45%) are intra-partum and 1.46 million (56%) are antepartum. Current global stillbirth rate is 18.9/ 1000 total births and the average annual rate of global decline in stillbirths between 1995 and 2009 has been 1.1%, much slower when compared to the decline in maternal and child mortality.

In India, estimated 6 lakh stillbirths occur every year. As per the estimations made by Lancet (2011) the current stillbirth rate is 22 per 1000 total births, there are wide interstate variations. As per the national HMIS 3,03,857 stillbirths were reported for the year 2015-16.

Largely, the causes of many stillbirths are unknown as discerning the actual cause of stillbirths is a challenge. There are number of risk factors that are directly and/or indirectly associated with stillbirth. The known causes of stillbirth fall into following three broad categories;

1. Fetal and neonatal causes (birth defects or genetic problems, Small for gestational age)
2. Placenta or umbilical cord related issues (abruption placenta)
3. Maternal causes (uncontrolled diabetes, high blood pressure, or obesity, syphilis etc.)

Other contributing factors that may increase the risk for a stillbirth include adolescent pregnancy, maternal age-35 years of age or older, multiple pregnancies, H/O of previous pregnancy loss/ stillbirth, smoking during pregnancy. These factors are also associated with other adverse obstetric outcomes, such as preterm birth.

The stillbirth rate is a key indicator of quality of care during pregnancy and childbirth, which is defined by WHO as: 'the extent to which health care services provided to individuals and patient populations improve desired health outcomes. In order to achieve this, health care needs to be safe, effective, timely, efficient, equitable, and people-centred[1]'.

India's Newborn Action Plan has articulated MOHFW vision and goal of "Ending preventable stillbirths to achieve "Single Digit SBR" by 2030, with all the states to individually achieve this target by 2030 with 4.4% average annual reduction rate (ARR) of Still Birth Rate. Preventing stillbirths along with neonatal deaths are integral strategy within the India Newborn Action Plan (INAP) with their specific targets and interventions.

At present there is an unmet need in the country to establish standard stillbirth assessment, recording and reporting as a vital event and understand the determinants over time and health system response capacity. Measuring and counting stillbirths is vital to advance the agenda of both maternal and newborn survival which is crucial to achieve targets under INAP.

Therefore establishing a robust surveillance system for identification and recording of all stillbirths using a uniform classification system is an important step towards improved data and evidence based planning. Sentinel surveillance will also document events which are not being captured by the regular HIMS reporting system and will be able to identify causes and the associated risk factors contributing to stillbirths.

The purpose of the guideline is to assist the program managers and health functionaries of sentinel hospitals/ health facilities to support establishment of surveillance and guide planning and implementation of interventions to reduce stillbirths.

II. Case definitions adopted for Sentinel Surveillance Purposes

Surveillance is an ongoing and systematic collection, analysis, interpretation, and dissemination of data, it is important to use standard case definitions. Definitions of the stillbirths vary from country to country as survival of a viable fetus is directly dependent upon the functionality of the existing neonatal health care system within a country.

a) Definitions commonly used for recording stillbirths are as follows;

- **ICD-10** defines a fetal death as death prior to the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such

1 *Tuncalp, Were, WM, MacLennan, C et al. Quality of care for pregnant women and newborns-the WHO vision. BJOG. 2015;* ***122****: 1045–1049*

separation the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles without specification of the duration of pregnancy. The denominator is all live births plus late fetal deaths.

- For inter country comparisons, **World Health Organization** defines that stillbirth is a baby born with absolutely no signs of life at or after 28 weeks gestation, weight ≥ 1000 g, crown-heel length (CHL) ≥ 35 cm.
- Under India's **HMIS** a stillbirth has been defined as "complete expulsion or extraction of baby from its mother where the fetus does not breathe or show any evidence of life, such as beating of the heart or a cry or movement of the limbs"

b) For the purpose of sentinel surveillance in the country the following definitions will be used

- **Early fetal deaths:** An early fetal death is death of a fetus weighing at least 500 grams (or, if birth weight is unavailable, after 20 completed weeks gestation, or with a crown-heel length of 25 centimeters or more).
- **Late fetal deaths** (stillbirths): A late fetal death is defined as a fetal death weighing at least 1000 grams (or a gestational age of 28 completed weeks or a crown-heel length of 35 centimeters or more).
- **Fresh stillbirth** or Intra partum stillbirths are defined as stillbirths occurring after the onset of labour 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 ocurred before the initiation of labour. A "macerated" fetus shows skin and soft-tissue changes (skin discoloration or darkening, redness, peeling, and breakdown).

India also considers less than 28 weeks gestation fetus as not viable; however the reporting for stillbirths will be done for 20 weeks onwards.

III. Steps for establishing sentinel surveillance system

This section provides standard guidance to operationalize sentinel stillbirth surveillance at the medical colleges / large district hospitals/ institutions.

a) Identification of sentinel institution and it's team

In consultation with state, medical college will be identified as the institution to carry out stillbirth surveillance activities. As far as possible, these medical colleges will be the ones identified already as state resource centers for Birth Defect Surveillance system and the sites will be strengthened to enhance surveillance data on stillbirths.

This approach will utilize the existing infrastructure already in place for birth defects surveillance program to incorporate surveillance data on stillbirths. Intensifying surveillance on stillbirths likely will increase the identification and ascertainment of birth defects and vice versa

List of the first 50 medical colleges to be covered in the initial phase is annexed (refer annexure 1). The other medical colleges/ district hospitals will be covered in a phased manner to allow any mid- course corrections if any depending on the lessons learned from the implementation activities in the first phase.

As a first step faculty or the Head of department of Obstetrics & Gynecology Department would be designated as the nodal officer and will be responsible for all surveillance related activities. Service providers at the facility who will be involved will be identified and include all obstetricians and gynecologists, pediatricians, resident doctors, medical officers, nurses, other staff including pathologist of the institution.

The designated health staff will be trained on the standard operating procedure on stillbirth surveillance related activities.

b) Data collection using history and examination

For the purpose of surveillance a standard and consistent format for data collection and collation needs to be used. After a stillbirth is diagnosed, data collection will be done for every stillborn using a standard history taking and examination of both mother and the baby. The details for the following are recorded in a standard format.

- **Basic Information**
- **Maternal History including obstetric history, past medical illness and personal history**
- **History of present pregnancy**
- **Antepartum complications**
- **Examination of the mother (physical, abdominal, vaginal)**
- **Investigation of the mother done for the present pregnancy including any fetal screening if any**
- **Details of labor for the present delivery**
- **Delivery details**
- **Baby details**

- **Investigations of the baby**
- **Placenta examination**
- **Autopsy of the baby is done where the obstetrician feels the need.** *Specific indications for autopsy are referred to in the format(field 51)*
- **Family history**

The team at the sentinel site will be trained in filling a standard recording format (Annexure 2) with uniform protocols to enter the requisite fields.

c) Assigning cause of stillbirth and associated risk factor

After the nodal officer receives the complete documentation of the mother and baby, the cause of stillbirth is assigned by him/her. Sometimes in – case of uncertainty, team would be required to review the details and discuss with the family to identify the cause of stillbirth.

The cause of stillbirth is categorized under the following;

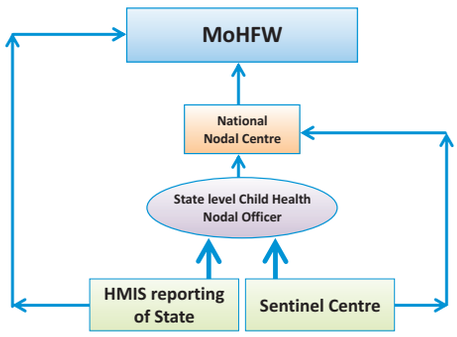
- **Infections during pregnancy**
- **Intra-partum complication**
- **Fetal cause**
- **Cord complications**
- **Placental causes**
- **Maternal**
- **Unknown**

The associated risk include

- **Fetal**
- **Maternal**
- **Any other**

This simplified surveillance tool utilizes the modified CODAC classification to assess the cause of stillbirth. Medical cause of stillbirths is to be ascertained using modified CODAC classification. This classification enables categorization of important information to explain stillbirth for the purposes of counselling and prevention through audit, epidemiology and research.

d) Reporting and feedback



For the purpose of reporting, computer and broadband connection will be required for online submission of the forms to SEAR-NBBD database. Monthly all the stillbirths detected will be reported by the facility through a registered id to SEAR-NBDD database.

Each sentinel site will have its own login id

and password for online reporting. All enrolled sites will be responsible for online uploading of the information, conducting analysis and using information for action. Regular reporting from the unit will be a mandatory activity. Even if no stillbirths have occurred during the month "Nil reporting" is indicated. Each site will be reporting to the National Nodal Centre for Stillbirth Surveillance and State Child Health Nodal Officer monthly. All 'Detailed Investigations' using the standard formats should be filled at the institution and retained.

A detailed quarterly report detailing the cause and associated risks will be shared by the medical college with the State Child Health Nodal Officer and onward with national State Child Health Nodal Officer.

In addition, the reporting should be ensured in regular reporting systems as well e.g. HMIS.

e) Quality validation

National nodal institution along with the sentinel institution will oversee the accuracy of reporting, timeliness and validated information on the causes of stillbirths. Refer role of National Medical College/ nodal center.

IV. Role and responsibilities

Team at the institution

- ✓ Nodal officer - S/he will report, review and supervise all surveillance activities and allocate the causes of stillbirth.
- ✓ Designated Neonatologist/Pediatrician will examine and confirm the diagnosis of stillbirth.
- ✓ Pathologist will carry out the autopsy of indicated cases, thereby helping arrival at a final diagnosis.
- ✓ Obstetricians & gynecologists/Resident doctors/ nurses/ - To fill up the standard recording format with uniform protocols to enter the requisite fields in case of stillbirth. Refer Annexure 3 for standard protocol for filling up the stillbirth form
- ✓ A Data Manager will maintain the records of all stillbirths & its information in a separate register at the medical college/hospital.
- ✓ Data should be managed electronically in order to facilitate a faster transmission of the same.

State child health nodal officer

The surveillance activities in a state will be under overall guidance of the State Child Health Nodal Officer. They will ensure

- ✓ S/he will facilitate the process of surveillance establishment at the sentinel centers but will also coordinate that the team is trained and the completed reports are submitted timely. The action taken report at the sentinel center following the surveillance will also be shared with her/him.
- ✓ S/he will also identify the new sentinel sites in the states for expanding surveillance network. S/he will be the link between the sentinel center and National nodal center and MoHFW.
- ✓ The state nodal program officer person will also ensure that all the facilities are regularly reporting stillbirths in the facilities under HMIS monthly format Section 4.1.2.
- ✓ The action taken report by the sentinel site to be shared with the state nodal officer

National Nodal Center

A National Nodal Center will provide clear leadership and technical guidance for ensuring uniform, high quality implementation of sentinel surveillance. This designated National Nodal Center will be responsible for coordinating the activities of the sentinel center

The national nodal center will be responsible to

- ✓ Conduct training for the staff at the sentinel health facilities/ medical colleges
- ✓ Review and analyze the reports
- ✓ Mentor and support the existing and new centers enrolled in the surveillance system. Hand –hold for continuous quality improvement and verification will of the sentinel centers at regular intervals
- ✓ Monitor the progress and quality of stillbirth surveillance and provide recommendations to the MOHFW to improve the implementation and make course corrections
- ✓ Provide recommendations on mechanism to scale the surveillance system across the country

Regular review of the progress will be undertaken by the GoI's Technical Advisory Committee on Stillbirths to take informed decisions, plan and make modifications if required.

V. Approaching a family for the autopsy of a stillbirth

The reference of autopsy is often awkward and may be painful to the family. Stillbirths being rare and autopsy even rarer, there are high chances of refusal to provide a consent for the procedure. It is the right of the family to accept or reject the request for autopsy. Immediately following the stillbirth, families are often in a very intense grieving period. The investigator discussing autopsy should ideally should established rapport with the parents. The investigator should have detailed knowledge and experience of the autopsy procedure.

It is important to take written consent for conducting an autopsy. It may useful to discuss with the parents: the value of an autopsy, issues related to retained fetal tissues, the possibility that a cause may not be found, cost (if any) to the parents of the autopsy, appearance of the baby following autopsy, the likely timeframe for results to become available and arrangements for communicating results (e.g. appointment following results availability)

Annexures

Annexure 1: List of sentinel surveillance sites

S. No.	State's name		Name Of the Medical College
1	Andhra Pradesh	I.	Government Medical College, Anantapur
		II.	Guntur Govt Medical College
		III.	Gsl Medical College, Rajahumndry
		IV.	Sri Padmavathi Medical College For Women , Alipiri Road, Tirupati
2	Bihar	I.	Indira Gandhi Institute Of Medical Sciences,
		II.	Patna Nalanda Medical College Hospital ,
		III.	Patna Jawarlal Nehru Medical College, Bhagalpur
3.	Chhattisgarh	1.	Government Medical College, Jagdalpur
		2.	Government Medical College, Rajnandgaon
4	Goa	I.	Goa Medical College, Bambolim, Panaji
5	Gujarat	I.	Government Medical College, Bhavnagar Government Medical College, Surat
6	Jammu & Kashmir	I.	Government Medical College, Jammu
		II.	Government Medical College, Srinagar
7	Jharkhand	I.	Mahatma Gandhi Memorial Medical College, Jamshedpur
		II.	Patliputra Medical College And Hospital , Dhanbad
		III.	Rajendra Institute Of Medical Sciences, Ranchi
8	Karnataka	I.	Banglore Medical College And Research Institute, Banglore
		II.	Jawaharlal Nehru Medical College , Belgaum
		III.	Karnataka Institute Of Medical Sciences , Hubli
		IV.	Kasturba Medical College, Mangalore
9	Kerala	I.	Government Medical College, Kozhikode
		II.	Government Medical College, Malappuram
		III.	Government Medical College, Thrissur
		IV.	Government Medical College, Palakkad
10	Maharashtra	I.	Armed Forces Medical College, Pune
		II.	Grand Medical College And Sir Jj Group Of Hospitals, Bombay
		III.	Mahatama Gandhi Institute Of Medical Sciences
		IV.	Government Medical College, Aurangabad
11	Madhya Pradesh	I.	Gandhi Medical College, Bhopal
		II.	Mahatama Gandhi Memorial Medical College, Indore
		III.	Netaji Subhash Chandra Bose Medical College, Indore
12	**O**disha	I.	Mkcg Medical College And Hospital, Brahmapur, Odisha
		II.	Shri Ramchandra Bhanj Medical College, Cuttack
13	Puducherry	I.	Jawaharlal Institute Of Postgraduate Medical Education & Resarch **Institute**
		II.	Mahatama Gandhi Medical College & Research Intitute
14	Rajasthan	I.	Dr. S.N. Medical College, Jodhpur
		II.	Government Medical College, Kota
		III.	Rabindranath Medical College, Udaipur

15	Tamil Nadu	I. II. III.	Madras Medical College And Research College And Reserch Insitute, Park Town, Chennai Government Kilpauk Medical College, Chetput (Chennai) Government Vellore Medical College, Adukamparai, Vellore
16	Telangana	I. II.	Gandhi Medical College Government Medical College, Mahaboobnagar
17	Uttar Pradesh	I. II. III.	Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh Government Medical College, Orai Jalaun Government Medical College, Kannauj
18	Uttarakhand	I.	Government Medical College, Srinagar, Pauri Garhwal, Srinagar
19	West Bengal	I. II.	Calcutta National Medical College, Kolkata Murshidabad Medical College, Berhampore, Murshidabad

Annexure 2: Stillbirth Review Proforma

Stillbirth Review Proforma

Center ☐☐ S. No. ☐☐☐☐	Hospital Record No._____	Date of Admission_____

A. Basic information

		Mother	Father
1	Name		
2	Age	☐☐ yrs	☐☐ yrs
3	Education	Illiterate/Pri. /middle/high/graduate/PG/Prof.	Illiterate/Pri. /middle/high/graduate/PG/Prof.
4	Occupation	Unemployed/Semiskilled/Skilled/Professional	Unemployed/Semiskilled/Skilled/Professional
5	Income per capita(Rs.)	Total monthly family income ☐☐☐☐☐☐☐ No of family members ☐☐	
6	Residential Address	Contact no._____	
7	Type of area	Urban /Rural / Slum	

B. Maternal History

8	Obstetrical history	Gravida ☐ Para ☐ Abortion ☐ living children ☐ Previous still birth Y/N Previous Birth defects Y/N if Yes, Details_____ Previous cesarean Y/N if Yes, Details_____
9	Past Medical illness	Yes/No- ***(if Yes, Specify (√) the appropriate & if No ,move to no.10)*** Anemia ☐ Infections ☐ Cardiovascular ☐ Endocrinal ☐ Neurological ☐ Pulmonary ☐ Hematological ☐ Auto-immune ☐ None ☐ Others ☐ If any of the above is yes, details _____
10	Personal History	Tobacco / Smoking /Alcohol / Consanguinity /Rubella Vaccination**(√) If yes, details** _____
11	Family History	Diabetes /Hypertension/ Birth Defects / None/ Others **(√) if yes,specify,** _____

C History of present pregnancy *(√) the appropriate* *LMP -*_____

12	Iron/Folic acid intake(periconception)	Yes /No
13	Antenatal visits(minimum 4)	Yes / No
14	Place of ANC	SC/ PHC/ DH/ Private Nursing Home/ Medical College
15	Last visit before diagnosis of IUFD	☐☐ Days ago
16	History of drug intake	Yes / No Details_____
17	History suggestive of rubella (Fever+Rash)	Yes / No

D. Antepartum complications						
18	Disease	Yes/No	Type(√) the appropriate	Diagnosed at(wks)	Treatment (specify)	Dose
18.1	Anemia		Mild /Moderate / Severe/ very severe			
18.2	Infection		Syphilis/ HIV /hyperpyrexia, if others, Specify_____			
18.3	Hypertension		Chronic/Gestational/ PE/ Eclampsia			
18.4	Diabetes		Type I/Type II/GDM		Diet / Insulin/ Oral	
18.5	IUGR		Mild/Severe			
18.6	APH		Placenta Previa/ Abruptio			
18.7	Preterm labor					
18.8	PROM		PT/ Term/ Chorioamnionitis			
18.9	Cholestasis					
18.10	Multiplepreg.		Twins/Triplets/Higher			
18.11	Trauma		RTA/Fall/domestic violence			
18.12	IUFD		Second/Third trimester			
18.13	Others					

E.Examination of the mother at admission					
19	Physical examination		20	Abdominal examination	
19.1	Weight / Height(Kg/cm)	☐☐ / ☐☐	20.1	Fundal height	Corresponding/less/more than POG
19.2	Pulse rate(beats/minute)	☐☐☐	20.2	Fetus	Singleton / Multiple
19.3	Blood pressure Systolic/Diastolic(mmHg)	☐ / ☐	20.3	Presentation/ Lie	Cephalic/Breech/Transverse
19.4	Respiratory Rate	☐☐	20.4	FHS	Present/ Absent
19.5	Temp(Degree Celsius)	☐☐	20.5	Ut/ scar tenderness	Yes / No
19.6	Pallor	Yes/No	21	Vaginal examination	
19.7	Oedema	Yes / No	21.1	Bleeding PV	Yes / No
19.8	Cardiovascular system	N /Abn	21.2	Liquor	Clear/Meconium/ Foul smelling
19.9	Respiratory system	N/ Abn	21.3	Cord Prolapse	Yes /No

F. Investigations of the mother						
22	Investigations		23. Prenatal screening		TICK (√)	If Abnormal, specify findings.
22.1	Hb (gm/dl)	☐☐	1st trimester	Dual marker	N/Abn/ND	
22.2	Urine albumin / sugar Microscopy	☐ / ☐ N / Abn	1st trimester	Ultrasound for Nuchal translucency & nasal bone	N/Abn/ND	
22.3	Blood group & ,Rh typing if negative ICT	☐☐☐ +ve / -ve	2nd trimester	Triple test	N/Abn/ND	
22.4	VDRL/TPHA	+ve / -ve	2nd trimester	Anomaly scan (level 2 ultrasound)	N/Abn/ND	
22.5	HIV	+ve / -ve	3rd	Latest Growth scan	N/Abn/ND	
22.6	GTT/ GCT	N / Abn	3rd	Days ago	☐☐	
22.7	Others, specify		3rd			

G. Details of labor (√) the appropriate		
24	Period of Gestation (weeks) ☐☐	Calculated by - LMP/LMP+UPT/LMP+USG/Unknown
25	Type of labor	Spontaneous / Induced ***if spontaneous, move to 28***
26	Indication for Induction of Labor	HT /Diabetes/IUGR/Cholestasis/PROM/ ,If others specify _____
27	Method of induction of labor	Oxytocin / Prostaglandins / Foley's catheter / ARM
28	Partograph used	Yes / No **if Yes**, Normal / Abnormal
29	Fetal Monitoring intrapartum	Manual /CTG / Both
30	Last CTG/ Manual record prior to IUFD	☐☐ Hours/prior

*** Duration of rupture membranes ____/___ hrs**

H. Delivery Details (√) the appropriate Date & time _____		
31	Intrapartum Complications	Non progress of labor ☐ Prolonged second stage ☐ Fetal distress ☐ Obstructed labor ☐ Cord complications ☐ Fever ☐ Rupture uterus ☐ Chorioamnionitis ☐ Others ☐ Abruptio ☐ Eclampsia ☐
32	Mode of delivery	Vaginal / instrumental / Abdominal
32.1	Vaginal	Normal / Breech
32.2	Instrumental	Forceps/ Vacuum / Destructive Operation
32.3	Abdominal	Elective CS./ Emergency / Laparotomy for rupture uterus
32.3.1	Indications of cesarean /instrumental delivery	Previous cesarean ☐ Breech ☐ Dystocia ☐ APH ☐ Fetal distress ☐ if others ,specify _____
32.3.2	Decision to delivery interval	☐☐ Min.
33	Duration of 1st , 2nd & 3rd stage	☐☐ Hrs ☐☐ Min ☐☐ Min
34	Duration of rupture membranes	☐☐ Hrs
35	Who Conducted the delivery	Doctor / Nurse
36	Maternal outcome	Alive and well ☐ Alive but with serious morbidity ☐ Death ☐

I. Baby details Live birth/ Fresh stillbirth/ Macerated stillbirth (Refer to ANNEXURE-1)				
37	Birth weight(gms) ☐ OFC(cm) ☐ Length(cm) ☐ APGAR Score 1min ☐ 5min ☐			
38	Sex (Male-M/Female-F/Ambiguous-A) ☐			
39	Birth defect Yes/No Description of Birth defect Isolated ☐ Multiple ☐ Syndromic ☐			
40	If Birth Defect is yes in above option; Fill BD form at the end of this forms			
41	**Organ**	**Size(cms)**	**Consistency , tick (√)**	**Any other mass** yes/no , **if Yes, describe** _____
A	Liver		soft/firm/hard	
B	Spleen		soft/firm/hard	

J. Investigations of baby		
42	Cord blood Done/Not done/Not available	Blood group ☐ Hb (gm %) ☐ Bilirubin (mg %) ☐ **(specify value)** DCT ☐ VDRL ☐ TPHA ☐ Rubella ☐ Toxoplasma ☐ CMV ☐ Parvovirus ☐ Karyotyping ☐ **(indicate +ve/-ve)** others(specify) _____
43	Infantogram (whole body x-ray) abnormal:	Yes / No /Not done if 'yes', describe: _____

	K. Placenta examination				
44	Weight(gm)	☐☐☐☐	**48.**	Chorionicity of Multiple Pregnancy	DADC/ DAMC/MAMC
45	Morphology	N / Abn.	49	Membrane culture	Neg./Post//ND
46	Cord Insertion	N / Abn.	**50**	Histopath. Done /not done	Suggestive of syphilis Yes /No
47	Infarct	Yes / No		Report_____	

	L .Autopsy Done ☐ Not done ☐	
51	External exam. only / conventional /minimally invasive **(√) the appropriate**	Details

M. Family interview
52. Sociocultural factors and care seeking ,details(if available) –

53	N. Cause of Fetal Death (Modified from CODAC SIMPLIFIED) (√) the appropriate	
53.1	Infections	Syphilis / Malaria / Hepatitis /others Specify _____
53.2	Intra-partum	Mal-presentation /prolonged labor/ Obstructed labor /Fetal distress
53.3	Fetal	Birth Defects / Isoimmunization / Hydrops / Extreme prematurity / Congenital Rubella Syndrome / Unknown
53.4	Cord complications	Knots / loops /Abnormal insertion / Cord Prolapse
53.5	Placental	Abruptio / Infarction / Thrombi / Previa / Insufficiency
53.6	Maternal	Hypertensive disorder /Diabetes /Infections / Others
53.7	Unknown	Unexplained / Multiples / unclassifiable
	Associated conditions	
53.8	Fetal	IUGR / Multiple pregnancy
53.9	Maternal	Anemia/ Poverty /Smoking / Trauma /Alcohol

56	O. Expert's opinion- SB Preventable Yes / No	
56.1	Level of care	Optimal / suboptimal
56.2	Patient reported late to health facility	Yes / No
56.3	Referred to appropriate centre	Yes / No
56.4	Reached appropriate referral centre (in hours)	☐☐☐☐
56.5	Whether fetal heart present at the time of admission to referral Centre	Yes / No
56.6	Cause of IUD at referral centre if FHS present at the time admission	

57. Any other information _____

_____

_____

_____

58. Person filling the proforma (designation)_____

_____

Annexure 3: Standard operating protocol for stillbirth surveillance

S. No	Field	Explanation
	Case Identification	
	Centre ID	Unique ID of the sentinel site
	S. No	Serial number of the Stillbirth
	Hospital record no.	
	Date of admission	
	MCTS No.	
A	**Basic Information**	
1	Name of mother and father	Indicate stillborn' s mother's name and father's name
2	Age of mother and father	Two digit fields.; age in completed years
3	Education of mother and father	Illiterate/ Primary/ Middle/ High school/Graduate/ Post graduate/ Professional
4	Occupation of mother and father	Choose one -Unemployed/semiskilled/ skilled/ professional
5	Income per capita	Sum total of monthly income of all members (in rupees)/ No of family members
6	Residential address	Current residential address with contact details If rural (note name and details of the ASHA worker)
7	Type of area	Urban / Rural / Slum
B	**Maternal History**	
8.	**Obstetrical history**	History of the present pregnancy
8.1	Gravida	Total number of times a woman has been pregnant irrespective of period of gestation (POG)
8.2	Para	The number of viable births.
8.3	Abortion	The number of pregnancies that were lost for any reason, before 20 weeks of gestation including induced abortions, miscarriages or ectopic pregnancy.
8.4	Living children	No. of living children at present
8.5	Previous Still birth (Yes/No)	Yes, if history of birth of a baby born with no signs of life at birth.
8.6	Previous Birth Defect (Yes/No)	Yes, Birth defect is an abnormality of body structure or function that are present at birth and are of prenatal origin
8.7	Previous Cesarean (Yes/No)	Yes, if history of previous Cesarean if present.
9	**Past medical illness**	Include already diagnosed conditions

9.1	Anemia:	Mild (9-10.9 gm %), Moderate (7 – 8.9 gm %), Severe (4-6.9gm %), Very severe (< 4 gm %)
9.2	Infections:	Either documented history or investigations – positive VDRL, HIV,TPHA Malaria parasite etc. If VDRL/HIV positive specify. Status of the partner.
9.3	Cardiovascular disease:	Hypertension, Heart disease Rheumatic or congenital Heart Disease (RHD/ CHD), If others , specify
9.4	Endocrinal:	Diabetes (Type I / II), Thyroid diseases, if others specify
9.5	Neurological:	Epilepsy, Tumors, Aneurysms, if others specify
9.6	Pulmonary:	Tuberculosis, Asthma, Chronic Airway, obstructive disease, if Others Specify.
9.7	Hematological:	ITP, Lymphoma, Leukemia, APLA, Thrombophilia, if others Specify
9.8	Auto-immune:	SLE, Rheumatoid arthritis, if others specify
9.9	Any other	Specify
10	**Personal History**	**Yes/ No, if yes details**
10.1	Substance abuse	Tobacco / Smoking / Alcohol
10.2	Consanguinity	If the couple share at least one common ancestor
10.3	Rubella vaccination	History of rubella vaccination
11	Family History	Yes / No If yes specify otherwise mark none
11.1	Diabetes	Yes / No If yes specify otherwise mark none
11.2	Hypertension	Yes / No If yes specify otherwise mark none
11.3	Birth defects	Yes / No If yes specify otherwise mark none
11.4	Others	

C	History of present pregnancy	L.M.P _____
12	Iron / Folic acid intake (peri-conception)	History of intake of iron ,specifically folic acid 4-6 weeks prior to pregnancy
13	Antenatal visits (Minimum 4)	Antenatal visits minimum 4 or more qualifies the pregnancy as supervised pregnancy.
14	Place of ANC (Choose any one)	SC / PHC / DH / Private Nursing Home / Medical College
15	Last visit before diagnosis of IUFD	Note the details
16	History of drug intake	Write details of drugs (category,dose,duration,specifically mention, if taken, in the first trimester
17	History suggestive of rubella	History suggestive of rubella (fever +rash)
D	**Antepartum complications**	
18	Disease	Mention Y/ N; if Y details as appropriate including diagnosed at weeks, specific treatment taken with dose details
18.1	Anemia [Classify according to the Hb level]	Mild (9-10.9 gm %), Moderate (7 – 8.9 gm %), Severe (< 7 gm %), Very severe (< 4 gm %)
18.2	Infection [Either documented history or investigations – positive]	VDRL, HIV, Malaria parasite etc
18.3	Hypertension [Systolic blood pressure ≥ 140mm/Hg, Diastolic ≥ 90 mm/Hg on two separate occasions 6 hours apart]	**Chronic HT** - Presence of HTN prior to 20 weeks pregnancy or before pregnancy **Gestational** – HTN diagnosed ≥ 20 weeks pregnancy in the absence of proteinuria. **Preeclampsia-** HTN diagnosed ≥ 20 weeks pregnancy with presence of proteinuria **Eclampsia** – Preeclampsia plus convulsions
18.4	Diabetes	**Type I-**insulin dependent, **Type-II** noninsulin dependent **Gestational diabetes** – Diagnosis of diabetes during pregnancy • *GCT Blood sugar - > 140 mg% (screening test using 50 gm glucose)* • *OGTT (100 gm) > 105/190/165/145 mg %) – Two or more abnormal (75 gm) – 92/180/153 – Any one abnormal*
18.5	IUGR [Diagnosis of Intrauterine growth retardation made clinically by fundal Height less than period of Gestation and/ or ultrasound parameters lesser than period of gestation]	**Mild** if the disparity is up to 4 weeks. **Severe** if more than 4 weeks when fetal weight is < 10 centile of the average weight of gestation.

18.6	APH [Bleeding from vagina after 20 weeks of pregnancy till delivery of the baby]	**Placenta Previa** – Bleeding from a low lying placenta **Placenta Abruptio** – Bleeding due to separation of normally situated placenta before birth of baby.
18.7	Preterm labor	Delivery before 37 completed weeks of pregnancy
18.8	PROM	**PPROM-** Rupture of membranes ***before 37 completed weeks of gestation***, before onset of labor. **PROM**- Rupture of membranes ***after 37 weeks of gestation*** but before onset of labor **Chorioamniotis**- Infection of placental membranes elicited by history of rupture of membranes fever, high TLC count, local uterine tenderness or foul smelling discharge.
18.9	Cholestasis	Diagnosed by itching with more than normal liver enzynes.
18.10	Multiple Pregnancy	Complications like abnormal chorionicity, discordancy, twin to twin transfusion Syndrome (TTTS) monoamniotic twins, conjoint twins' etc.or due to higher order Multiple Pregnancies
18.11	Trauma	History of fall or injury/domestic violence/road side accidents etc. to the maternal abdomen during pregnancy.
18.12	IUFD	Fetal death during second / third trimester
18.13	Others	Any other complications.

E	Examination of the mother on admission (taken from the medical records of the mother)	
19	**Physical examination**	[Normal / If Abnormal] Specify i.e. pallor, edema, increased or decreased blood pressure, tachycardia, tachypnea
19.1	Weight / Height	
19.2	Pulse rate	
19.3	Blood pressure	
19.4	Respiratory rate	
19.5	Temperature	
19.6	Pallor	
19.7	Edema	
19.8	Cardiovascular system	Normal / Abnormal
19.9	Respiratory system	Normal / Abnormal
20	**Abdominal Examination**	
20.1	Fundal height (choose any one) **Corresponding / less / More than POG**	Taken in cm from symphysis pubis to fundus, usually correspond to POG after 28 weeks of gestation ,, disparity of 4 weeks is taken significant
20.2	**Fetus** (choose any one) Singleton /Multiple	As diagnosed ultra-sonologically
20.3	**Presentation/Lie** Cephalic/ Breech / Transverse	As confirmed from clinical examination and sonogram
20.4	**Fetal Health Sound** (choose any one) Present / Absent	As confirmed from clinical examination, through CTG or sonologically
20.5	**Uterus / Scar tenderness**	Yes / No
21	**Vaginal examination**	
21.1	**Bleeding per vaginal**	Yes/No
21.2	**Liquor** Clear/ Meconium/ Foul smelling	As confirmed from clinical examination
21.3	**Cord Prolapse**	Sudden coming out of cord through vagina spontaneously or after leakage or trauma

F	Investigation of the mother	
22	**Investigation**	
22.1	Hb (gm/dl)	Record from details provided in file
22.2	Urine albumin / sugar Microscopy	Present/Absent. If present then mention the severity
22.3	Blood group & Rh typing If Negative ICT	+ ve / -ve, ABO
22.4	VDRL/TPHA	+ ve / -ve
22.5	HIV	+ ve / -ve
22.6	GTT/GCT	Normal / abnormal
22.7	Others, specify	
23	**Fetal screening**	
23.1	**1st trimester** **[**Note down the risk of malformation and if high risk on dual (11-13 weeks) or triple screening (16-18 weeks) whether confirmed on chorion villus sampling/amniocentesis]	
23.1a	**Dual marker**	Normal /Abnormal /Not Done If abnormal, specify finding
23.1b	**Ultrasound for Nuchal translucency & nasal bone**	Normal /Abnormal /Not Done If abnormal, specify finding
23.2	**2nd trimester** [note down any abnormality in growth parameters ,amount of liquor, location of placenta, no. of blood vessels in the umbilical cord or any congenital malformation in the fetus and its details]	
23.2a	**Triplet test**	Normal /Abnormal /Not Done If abnormal, specify finding
23.2b	**Anomaly scan (level 2 ultrasound)**	Normal /Abnormal /Not Done If abnormal, specify finding
23.3	**3rd trimester**	
23.3a	Latest Growth Scan	Normal /Abnormal /Not Done
23.3b	Days ago	Date of ultrasound

G	Details of labor	
24	Period of Gestation (weeks)	Period of Gestation (POG) in week to be verified from history of last menstrual period (LMP), examination and early ultrasonography (where available). In case LMP is not known the dates need to be ascertained by detailed history specifically in the regional context. E.g. in reference to a local event, festival, calendar month etc.
25	Type of labor	Spontaneous – Onset of labor pains on its (***own if spontaneous move to 28)*** Induced – Artificial labor pains induced for termination of pregnancy
26	Indication for Induction of labor [Indicate the condition for which pregnancy was terminated]	HT/ Diabetes / IUGR/ Cholestasis/ PROM/ others specify
27	Method of induction of labour	Oxytocin / Prostaglandins
28	Partograph used[Partograph whether available in records]	Yes/ No if Yes, Normal / Abnormal
29	Intra-partum Fetal monitoring	Manual / Cardiotocograhy (CTG) / Both
30	Last CTG / manual record prior to IUFD	__ / __ hours / prior
H.	**Delivery Details**	Date and time _____
31	Intra-partum Complications (choose any one)	Non progress of labor/Prolonged second stage/ Fetal distress/Obstructed labor/Cord complications/ Fever/Rupture uterus / Chorioamnionitis/Others/ Abruptio/Eclampsia
32	Mode of delivery	Select appropriate from vaginal/instrumental/ abdominal
32.1	Vaginal	Delivery per vaginum
32.2	Instrumental	**Instrumental** - delivery by Forceps, outlet or midcavity/ventouse **Destructive operation**-craniotomy/cleidotomy/ decapitation *Destructive operation-procedures to diminish the bulk of the fetus so as to facilitate easy delivery through the birth canal, includes craniotomy (perforation on fetal head to evacuate cranial contents, cleidotomy (division of clavicle to reduce the bulk of shoulder girdle), decapitation (severing of the head from the trunk and delivering head and trunk separately).*
32.3	Abdominal	**Cesarean**–Delivery of baby by surgical opening of the abdomen and uterus. **Elective**-when operation is performed at a prearranged time during pregnancy **Emergency-** when operation is performed due to unforeseen or acute obstetric emergency. **Laparotomy** –Opening of abdominal cavity as in rupture uterus

32.3.1	Indications of cesarean/ Instrumental delivery	Dystocia –difficult labor characterized by abnormally slow progress. Include indications like non-progress, prolonged second stage obstructed labor, cephalo-pelvic disproportion, under this heading. APH-ante partum hemorrhage, specify placenta previa or abruption Fetal distress include irregularities of fetal heart, meconium, non-reassuring NST
33	Duration of 1st, 2nd, & 3rd stage	First stage – from start of labor pains till full dilatation of cervix. Second stage – From full dilatation of cervix till delivery of baby. Third stage-From delivery of the baby till delivery of the placenta.
34	Duration of rupture membranes	from the timing of rupture of membranes till delivery of the baby
35	Who Conducted the delivery	Doctor/Nurse (choose any one)
36	Maternal outcome (choose any one)	Maternal outcome –alive & well, alive but with serious morbidity like acute renal failure, post Stroke deficit etc.or died.
I	**Baby Details**	**Live birth/ Fresh stillbirth / Macerated Stillbirth**
37	Birth weight	Note down birth weight in grams,OFC and length in cms, apgar score
38	Sex	Male-M/Female-F/Ambiguous-A
39	Birth defect	Birth defect to be categorized as • Isolated-if it involves singe organ or system. • Multiple- if it involves multiple organs or systems. • Syndromic-if it fits in to some syndrome
40	If birth Defect is yes in above option; Fill BD form at the end of this form	
41	Examination	Tick whether normal (N)/abnormal (AbN.)/not done (ND)
41 a	Liver (size in cms & Consistency)	Size in cms ; Soft / Firm / Hard
41 b	Spleen (size in cms & Consistency)	Size in cms ; Soft / Firm / Hard
41c	Any other mass, if yes describe	Size in cms ; Soft / Firm / Hard

J	**Investigations of baby**	
42	Cord blood (choose any one)	Done/Not done / Not available
i.	Blood Group	
ii.	Hb (Gm%)	
iii.	Bilirubin Mg %	
iv.	DCT	
v.	VDRL/ TPHA	
vi.	Rubella	
vii.	Toxoplasma	
viii.	CMV	
ix.	Parvovirus	
x.	Karyotyping	
xi.	Others, specify	
43	Infantogram (whole body X-ray) abnormal:	Yes / No /Not done ; If yes describe
K.	**Placenta examination**	
44	Weight(gm)	Weight of placenta in grams.
45	Morphology	Normal /Abnormal
46	Cord Insertion	Normal /Abnormal
47	Infarct	Yes/No
48	Chronicity of Multiple Pregnancy	Select from DADC/DAMC/MAMC
49	Membrane culture	Membrane culture-positive-if there is growth of any organism
50	Histopathology	Done /not done Suggestive of syphilis Y/N, mention accordingly
L	Autopsy	
51	External exam. only / conventional / minimally invasive *Autopsy may be done where the obstretrician feels the need.* *Autopsy is not needed if adequate and obvious maternal problems are present like –eclampsia,hyp ertension,abruption,placenta previa,cervical incompetence,scar rupture,ruptured uterus,maternal illness to account for still birth*	Describe the method followed by the details of the report. Consent has to be taken from the parents.Placenta should be sent along with the baby for examination. Ideal is to do a complete autopsy with the removal of brain and study of placenta. **Autopsy is mandatory in the following cases** 1. Congenital malformations 2. Recurrent fetal death-after the obstretician has investigated thoroughly for a cause and found none. 3. Hydrops fetalis-all cases of non immune hydrops 4. Cases of IUGR where no cause is detactable 5. Suspected infections 6. Any Unexplained event e.g. failed resuscitation 7. Term still birth/intrapartum death-unsuspected CMF's

M	Family history	
52	Sociocultural factors and care seeking behavior for e.g. I Delay in recognizing the complication ii. Delay in decision to seek help iii. Delay in organizing the transport/or arrival of transport v. Delay in initiating treatment **Other social factors** Poverty, adherence to traditional rituals ,Unawareness, Heavy work during pregnancy, Domestic violence, Poor health infrastructure vi. Others (specify)	If patient is still admitted or family can be contacted, note down the details.On sociocultural factors and care seeking during pregnancy. TICK the appropriate one or more than one if required to finally arrive at the final conclusion
N	**Cause of Fetal death**	
53.1	Infections (choose any one)	Syphilis/ Malaria / Hepatitis /others Specify
53.2	Intrapartum (choose any one)	Mal-presentation/prolonged labor/Obstructed labor/ Fetal distress
53.3	Fetal (choose any one)	Birth defects/Iso-immunization /Hydrops/Extreme prematurity/Congenital Rubella Syndrome / Unknown
53.4	Cord complications (choose any one)	Knots/Loops/Abnormal insertion/Cord Prolapse
53.5	Placental (choose any one)	Abruption/Infraction/Thrombi/Previa/Insufficiency
53.6	Maternal (choose any one)	Hypertensive disorder/Diabetes/Infections/Others If others, specify
53.7	Unknown (choose any one)	Unexplained
	Associated conditions	
53.8	Fetal (choose any one)	IUGR/ Multiple pregnancy
53.9	Maternal (choose any one)	Anemia/Poverty/Smoking/Trauma/Alcohol
53.10	Any other	
O	**Experts Opinion – Still Birth - Preventable (Yes/ No)**	
56.1	Level of care	Level of care to be ascertained critically from interview of the patient, family,health Care personnel and records
56.2	Patient reported late to health facility	
56.3	Referred to appropriate center	
56.4	Reached appropriate referral center (in hours)	
56.5	Whether fetal heart present at the time of admission to referral center	
56.6	Cause of IUD at referral center if FHS present at the time of admission	

Attachment:Stillbirth surveillance guidelines - MoHFW.pdf

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