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A New System for Determining the Causes of Stillbirth

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Abstract

OBJECTIVE—To describe the methods for assigning the cause of death for stillbirths enrolled in the Stillbirth Collaborative Research Network (SCRN).

METHODS—A complete evaluation, including postmortem examination, placental pathology, medical record abstraction, and maternal interview was available on 512 stillbirths among 500 women. These 512 stillbirths were evaluated for cause of death using the definitions outlined in this report. Using the best available evidence, SCRN investigators developed a new methodology to assign the cause of death of stillbirths using clinical, postmortem, and placental pathology data. This new tool, designated the Initial Causes of Fetal Death, incorporates known causes of death and assigns them as possible or probable based on strict diagnostic criteria, derived from published references and pathophysiologic sequences that lead to stillbirth.

RESULTS—Six broad categories of causes of death are accounted for, including maternal medical conditions; obstetric complications; maternal or fetal hematologic conditions; fetal genetic, structural, and karyotypic abnormalities; placental infection, fetal infection, or both; and placental pathologic findings. Isolated histologic chorioamnionitis and small for gestational age were not considered causes of death.

CONCLUSION—A new system, Initial Causes of Fetal Death, to assign cause of death in stillbirths was developed by the SCRN investigators for use in this study but has broader applicability. Initial Causes of Fetal Death is a standardized method to assign probable and possible causes of death of stillbirths based on information routinely collected during prenatal care and the clinical evaluation of fetal death.

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For a list of criteria used to assign causes of fetal death in the SCRN cases, see Appendix 1 on page 260. For a fully referenced version of Initial Causes of Fetal Death, see Appendix 2 online at <http://links.lww.com/AOG/A186>.

Financial Disclosure

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The Stillbirth Collaborative Research Network (SCRN) is a consortium of five academic health centers, one data coordinating and analysis center, and the Pregnancy and Perinatology Branch at the *Eunice Kennedy Shriver* National Institutes of Child Health and Human Development (NICHD). The Stillbirth Collaborative Research Network has conducted a population-based study of stillbirth with the specific aims being 1) to obtain a geographic population-based determination of the incidence of stillbirth defined as fetal death at 20 or more weeks of gestation; 2) to determine the causes of stillbirth using a standard stillbirth postmortem protocol to include review of clinical history, protocols for postmortem and pathologic examinations of the fetus and placenta, and other postmortem testing; and 3) to elucidate risk factors for stillbirth. Between March 2006 and August 2008, the SCRN investigators recruited and enrolled women who had stillbirth (defined as fetal death at 20 or more weeks of gestation) while residing in five geographically defined regions. Women were recruited in 59 hospitals, including academic health centers and community hospitals. These geographically defined areas included the counties of Bexar, Brazoria, and Galveston in Texas; Salt Lake County in Utah; DeKalb County in Georgia; Bristol County in Massachusetts; and the entire state of Rhode Island.

A major aim of SCRN is to determine the cause of fetal death using the best available evidence including all available clinical and pathologic data. For the more than 500 stillborn neonates enrolled in this study on whom a complete postmortem examination was performed, we sought clinical, pathologic, and pathophysiologic findings that might be considered the cause of death. To classify these findings, the SCRN investigators developed the following tool to assign a cause of death for stillbirth cases ascertained and enrolled during the course of this study.

MATERIALS AND METHODS

The SCRN Initial Causes of Fetal Death has been devised to provide a structured system so that the definitions used to ascertain the most likely cause of fetal death are uniform and that those reviewing the potential cause of fetal death can communicate using a common language. An important goal of this system is to use the best available evidence and rigorous definitions determined before case review when assigning a cause of death.

Among the 663 women with stillbirths enrolled in the study, 620 delivered a single stillborn neonate, 42 delivered twins (13 sets with 2 stillborn neonates and 29 sets with 1 stillborn and 1 liveborn neonate), and 1 delivered triplets (1 stillborn and 2 liveborn neonates), for a total of 676 stillborn neonates (707 total neonates). A complete evaluation, including postmortem examination, placental pathology, medical record abstraction, and maternal interview was available on 512 stillbirths among 500 women. These 512 stillbirths were evaluated for cause of death using the definitions outlined in this report. One novel aspect of SCRN is that we also recruited and enrolled 1932 women with live births to serve as contemporaneous women in a control group. These women underwent the same study protocol (except the postmortem examination) as women who had stillbirth. Therefore, an important aspect of this system is the ability to consider potential newly discovered causes or risk factors for fetal death. As a result, one of our major goals will be to compare the initial clinical cause of death data with our final cause of death once all data from the study are available.

During the course of the study, causes of death were reported to individual participants as they became evident. Only the finding of carcinoma of the placenta was reported back to control participants. This study was reviewed and approved by the institutional review boards at each of the academic centers, the data coordinating center (RTI International), and all of the participating hospitals.

The SCRN investigators recognize the difficulty of assigning a cause of fetal death with a significant degree of certainty, especially before the availability of all laboratory evaluations. The cause of death can be assigned with certainty in a relatively small proportion of cases (eg, hydrops fetalis due to Rh isoimmunization, direct catastrophic fetal trauma). However, in most cases, defining the precise cause of death is a complex and iterative process. Given the degree of uncertainty in the majority of cases regarding the event or condition that led directly to fetal death, we adopted a hierarchical system wherein a condition that was a potential cause of fetal death was graded as being a *present* condition, a *possible* cause of death, or a *probable* cause of death.

To better define the approach to ascertaining the cause of death, we created subcommittees in specific areas: Surveillance and Epidemiology, Maternal Disease Mechanisms, Genetics, Immunology and Infectious Diseases, and Placenta/Postmortem Evaluation. These subcommittees were charged with reviewing available evidence to develop a working classification system for case reviews of each stillbirth enrolled in SCRN. The goal of Initial Causes of Fetal Death is to provide common definitions of conditions that may be potential causes of death so that the investigators in the study could use a common language in determining the most likely cause of death in each specific case.

As more definitive data come to light during the analytic phase of the SCRN study, we anticipate that Initial Causes of Fetal Death likely will need to be revised, refined, and updated. This current version of Initial Causes of Fetal Death is based on clinically available data, not on the extensive genetic, microbiological, and biochemical data that will be analyzed over the course of the study. Over time, as new tests become available or new questions raised, the SCRN cases will be evaluated for potentially novel causes of stillbirth and Initial Causes of Fetal Death will be modified to reflect these new insights. The original system, as well as any modifications, will be available on the publicly accessible area of the SCRN web site (<https://scrn.rti.org>).

In the development of this system, each subcommittee reviewed the literature and used individual and group expertise in identifying conditions of interest. A *condition of interest* is a maternal, fetal, or placental condition that might be a potential cause of fetal death and therefore must be evaluated in relation to a *probable* or *possible cause of death*. If, from evidence collected by medical record review, maternal interview, or pathologic evaluation, the condition of interest is present, then the following criteria are used to further classify a condition as a *probable* or *possible cause of death*:

1. Probable Cause of Stillbirth.

The identified condition is, with high likelihood, the cause of the fetal death. For example, maternal diabetes would be the probable cause of fetal death for a case in which the mother has type 1 diabetes mellitus with a stillbirth that occurred during an episode of diabetic ketoacidosis.

2. Possible Cause of Stillbirth.

The identified condition cannot with high likelihood be considered the cause of death, but there is reasonable certainty that this condition may be involved in a pathophysiologic sequence that led to the fetal death. For example, a fetal death occurs in a woman with poorly controlled type 1 diabetes mellitus and an elevated hemoglobin A1C with normal fetal growth. A fetal death in this circumstance cannot be definitely considered caused by the diabetes, as there are many other potential conditions that may affect this outcome.

Notably, not all *conditions of interest* can be further classified as a *probable* or *possible cause of death* based on the best available evidence or even expert opinion. In this

circumstance, the condition would be considered *present*. For example, a fetal death case in which the mother had well-controlled gestational diabetes would be identified as “gestational diabetes present,” as there is no evidence to suggest that well-controlled gestational diabetes is a cause of fetal death. In the course of data analysis for SCRN, future studies may indicate that such a condition might be considered a cause of death. In this circumstance, a specific case may be re-coded in the future as having a possible or probable cause of death. For the most part, “present” conditions are potential risk factors for, rather than causes of, stillbirth.

After the SCRN subcommittees created the first version of the Initial Causes of Fetal Death instrument, each case of stillbirth that underwent postmortem examination was reviewed by one of five teams of physicians who have been involved in the study. Each team consisted of two physicians who would independently review the abstracted medical records and autopsy records, along with a narrative of each case including pertinent hospital records and pathology reports. After independent review, the two investigators in each team reviewed the cases together and then completed the Initial Causes of Fetal Death instrument.

After the initial cause of death review, the first version of Initial Causes of Fetal Death required modification to account for new findings and nuances that were not readily evident before performing the initial review. Through this iterative process, all investigators involved in SCRN provided input into Initial Causes of Fetal Death based on the best available scientific evidence. The stillbirth cases were then reviewed a second time in a similar fashion as described, and causes of death assigned as appropriate for each case using the version of Initial Causes of Fetal Death presented in this report. The data from these reviews will be presented in other forthcoming reports.

RESULTS

Initial Causes of Fetal Death is divided into six sections, correlating with six general categories identified by the SCRN subcommittees that describe a constellation of findings that could be a potential cause of fetal death. Appendix 1 is an example of the system that we used to assign cause of death in the cases collected during SCRN, in this instance the criteria for assigning fetal death due to maternal or fetal infection (section 5 in Appendix 2). A fully referenced version of Initial Causes of Fetal Death is available in Appendix 2 online at <http://links.lww.com/AOG/A186>. As can be noted in Appendix 1, we end the section allowing for “other” as a cause of death so that investigators may expand this list as new conditions are described, characterized, and defined.

The medical conditions included in Appendix 2 are the most common medical complications during pregnancy. A medical condition described as present requires that the condition be diagnosed using standard criteria (eg, definitions by professional organizations, common definitions established in the medical literature) before the stillbirth or that the condition be diagnosed during the evaluation of the stillbirth. For a condition to be considered a possible cause of stillbirth, literature showing an association of the condition with stillbirth must be present and referenced. For a condition to be considered a probable cause of stillbirth, medical literature showing pathophysiology leading to fetal death must be referenced.

Many noninfectious obstetric conditions can be a direct cause of fetal death. These conditions are not associated with other medical conditions in the mother or fetus and have no other specific known placental or fetal cause.

When considering fetal-maternal hemorrhage (FMH) as a cause of death, we made the following assumptions:

1. Fetoplacental blood volume=125 mL/kg fetal weight
2. FMH red cell volume=maternal blood volume×maternal hematocrit×% fetal red blood cells in maternal sample
3. FMH whole blood volume=(FMH red cell volume)/(fetal hematocrit)

Conditional on these assumptions, we chose to define a FMH of greater than 40% of fetal blood volume before delivery as sufficient to cause fetal death.¹

We list specific hematologic conditions separate from the broader category of maternal medical conditions, because they are of contemporary interest as potential causes of fetal death. In addition, many of these conditions represent unique interactions between the mother and fetus via the maternal immune system.

A variety of fetal conditions have been implicated as causes of fetal death. These conditions are intentionally general, as specific abnormalities may be part of a syndrome or sequence such that detailed listing of all associated anomalies would likely be incomplete.

To better clarify the relationship between various infections and stillbirth, we defined three potential mechanisms by which infections are thought to cause stillbirth and provide criteria by which each of these mechanisms may be considered a present condition, or rise to be considered a possible or probable cause of stillbirth. We are aware that not all cases in which an infection causes stillbirth will fit exactly into one of these mechanistic categories. If an infection is considered a possible or probable cause of a specific stillbirth, yet the mechanism is not clear, the infection is classified as an infectious cause of death of other or unknown mechanisms.

Although placental pathologic findings are characteristically found in many of the conditions in Initial Causes of Fetal Death (eg, fibrosis or infarcts in association with antiphospholipid syndrome), placental conditions were included as an independent condition for those cases in which placental findings predominate and without a previously diagnosed maternal or fetal condition. When the placental findings occur in association with a maternal or fetal condition, then the condition itself is considered to be a possible or probable cause of death, rather than the placental anatomic abnormality.

Histologic chorioamnionitis with funisitis is a special condition that requires more thorough consideration, as funisitis indicates a fetal inflammatory response to an infectious process. Defined by extensive polymorphonuclear cell invasion of the membranes and umbilical cord, respectively, these conditions are believed by some authors in some cases to be causal for stillbirth.² In the case of funisitis with extensive polymorphonuclear cell invasion, we agree with this opinion. However, we have chosen to consider isolated histologic chorioamnionitis as a *present condition*, as there is insufficient evidence to include this pathologic diagnosis as a probable or possible cause of death.

Small for gestational age will not be treated as a cause of death but rather as a confirmatory finding that the maternal or placental condition adversely influenced fetal well-being. Although SGA is commonly associated with fetal death, it can only be considered as a consequence of other intrinsic conditions that are possible or probable causes of fetal death and cannot be considered to be a proximate cause of death. In this regard, SGA is a common modifier of other underlying maternal and fetal conditions, but not a specific condition itself. For the purpose of this algorithm SGA will be defined as a birth weight below the 10th percentile for gestational age based on population norms.³ Gestational age at delivery is based on last menstrual period and ultrasound criteria in an algorithm used by the Maternal-Fetal Medicine Units Network,⁴ and the gestational age of the stillbirth at death is adjusted

for the difference between the time when the fetus was last alive and time of diagnosis of death, using pathologic criteria to most accurately determine the time of death. We feel this is an improvement over arbitrarily using the time of delivery to reflect the time of death, as a significant proportion of fetuses (usually preterm) die days or weeks before the actual delivery. If unknown, the time of fetal death will be based on postmortem examination. In the future, we plan to assess the influence of using individualized fetal growth curves to identify SGA fetuses.⁵⁻⁷

DISCUSSION

The SCRN Initial Causes of Fetal Death has been developed to provide a common set of definitions that can be applied to each case of fetal death enrolled in the SCRN study. By using strict diagnostic criteria, we assigned cause of death based on pathophysiologic evidence acquired from the postmortem examination, placental evaluation, and maternal evaluation. In many cases, a probable cause of death was not assigned because we lacked conclusive evidence of a specific pathologic sequence that meets these strict criteria.

Many classification schemes for assigning cause of fetal death are currently used throughout the world.^{1,8-14} These classification schemes have recently been thoroughly reviewed by Gordijn et al.¹⁴ They listed the 35 different classification systems that have been reported in the medical literature since 1954 and noted that each system was created with a specific purpose by the investigators. These systems have the common theme of attempting to assign a cause of death but also to reveal trends in perinatal mortality and to guide prevention strategies and audits of perinatal care. One area of weakness of these systems identified by Gordijn et al.¹⁴ is the problem of incomplete registration or incomplete ascertainment of all women who suffered stillbirth in the population of study. In SCRN, we addressed this problem by developing a surveillance program designed to identify more than 90% of potentially eligible women over the time of enrollment on a population basis.

Another weakness noted by Gordijn et al.¹⁴ is the lack of clear and uniform definitions and guidelines in at least half of the currently available classification systems. They advocated developing a multilayered classification system to encompass all perinatal mortality including stillbirth and neonatal death. Because neonatal death was beyond the scope of SCRN, we developed our system to address only stillbirths at 20 or more weeks gestation. When developing our system, we incorporated the three key aspects of an evaluation of fetal death recommended by these authors. Our system includes consideration of three important features: 1) “when,” with an analysis of the clinical condition of the pregnancies at the time of stillbirth; 2) “what,” with a detailed and systematic pathologic protocol for postmortem examination and placental evaluation; and 3) “why,” or the reason for the fetal death taking into account all clinical and pathologic characteristics of the stillbirth. These features were then evaluated using Initial Causes of Fetal Death to determine the cause of death in as many cases as possible using rigorous and standardized definitions.

We developed our system after a workshop convened by the *Eunice Kennedy Shriver* National Institutes of Child Health and Human Development¹² where commonly used classification systems were discussed and evaluated. Numerous issues came to light in the course of the workshop. Perhaps most evident was that determination of the precise cause of death, from a pathophysiologic perspective, can be very complex and often there is no unequivocal cause of death. Second, the classification systems that are currently in use were designed for a variety of purposes including serving as public health tools that are intended to catalog as many cases of stillbirth as possible. Third, none of the classification systems currently in use or previously reported were deemed sufficiently complete to account for the quantity and depth of data being collected during the course of the SCRN study. The SCRN

investigators desired an instrument in which we could assign causes of death based on the best available evidence. In exchange for potentially greater certainty regarding causes of death, Initial Causes of Fetal Death may leave a substantial proportion of cases as unexplained or unclassified, while providing a more accurate depiction of the multifactorial nature of many cases of stillbirth. Moreover, many stillbirths may not have only a single cause of death. Instead, there may be a cumulative effect of several risk factors leading to multiple potential causes of death. Rigorously defining causes of death should facilitate both the clinical and experimental investigation of unexplained cases.

In addition to facilitating our research, providing rigorous definitions and more accurately attributing the cause of fetal death have useful clinical implications beyond the scope of SCRIN. For example, the opportunity to find the actual cause of death may be missed by assigning causation to any associated conditions that are also present in many live births (eg, maternal thrombophilias). Accurately assigning a probable cause of fetal death is critically important for counseling grieving families.

The SCRIN Initial Causes of Fetal Death is not designed to be static, rather it is intended to be flexible so that new conditions can be added as they become evident. In addition to the 512 cases of stillbirth with complete evaluations, we enrolled approximately 1,932 women with live births as a contemporaneous control group. Assays of biospecimens and detailed statistical analyses of the case-control data are ongoing. Should evolving results from the case-control study provide information regarding new possible and probable causes of fetal death, we may need to modify the coding criteria and revise some of the causes of fetal death that were initially assigned to specific cases. Conditions may be changed from each general assignment as present, possible cause of death, or probable cause of death as new information comes to light. For example, if we find that a specific genetic polymorphism may be present, but in the case-control study is strongly associated with fetal death, then the assignment for that polymorphism would change our level of certainty. Any modifications to the SCRIN Initial Causes of Fetal Death will be available online on the public portion of the SCRIN web site (<https://scrin.rti.org>).

Even with modifications, Initial Causes of Fetal Death may remain useful in stillbirth cases where extensive evaluation is not available. Most cases of stillbirth do not undergo all the tests that will be analyzed and used in future iterations of Initial Causes of Fetal Death. In these cases, this initial version of Initial Causes of Fetal Death may be used as it relies on clinically available tests and the postmortem examination.

In conclusion, we have devised a structured system to assign the causes of fetal death based on the best available evidence using a detailed protocol encompassing clinical, pathologic, and pathophysiologic data obtained through a rigorous study process. We anticipate that Initial Causes of Fetal Death will be useful for the researcher and clinician when faced with determining and explaining the cause of a fetal death.

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Appendix 1. Cause of Death Review

SCRN		Version 04 / December 21, 2009		Form 91A	
Review Case ID	Member	Review Number	Form Completion Date		
_____	_____	_____	mm	dd	yyyy

Instructions:
Code findings according to the + designation where 01=present, 02=possible cause of death, and 03=probable cause of death. Use the highest code for a finding with the criteria met. For example, if there is systemic lupus erythematosus disease activity (flare) during pregnancy and abortion/placental, the SLE should be coded as 1c3 (probable cause).

	01=Present	02=Possible	03=Probable
5. Placental and/or Fetal Infection (Excluding Fetal Membranes)			
a. Fetal infection involving vital organs: brain, heart, lung & liver (Positive bacterial or viral culture, or viral-specific PCR – examples: listeriosis, group B streptococcus, Escherichia coli, other viruses, protozoa) Specify organism, if known _____			
1) Culture or PCR proven infection in vital organs with no documented histologic signs of infection	•		
2) Culture or PCR proven infection in vital organs with signs of infection in the placenta but not organs		•	
3) Histologic evidence of infection in vital organs without culture or PCR proven infection in vital organs			•
4) Histologic evidence of infection in vital organs with culture or PCR proven infection in vital organs			•
5) Pathognomonic pathologic findings in fetus with or without culture or PCR proven infection			•
b. Fetal infection that causes congenital anomaly or other fetal condition (Fetal infection with a teratogenic organism – examples: parvovirus, varicella, CMV, toxoplasmosis) Specify organism, if known _____			
1) Organism known to cause fetal anomaly/condition, anomaly/condition is present, timing of infection not consistent with specific anomaly/condition	•		
2) Organism known to cause fetal anomaly/condition, anomaly/condition is present, timing of infection is unknown		•	
3) Organism known to cause fetal anomaly/condition, anomaly/condition is present, timing of infection consistent with expected anomaly (including neonatal injury or calcifications)			•
4) Pathognomonic pathologic findings in fetus or placenta with or without culture or PCR proven infection			•
c. Placental infection – organism likely to lead to decreased placental function (Maternal infection with organism known to decrease placental function – examples: malaria, syphilis) Specify organism, if known _____			
1) Culture or PCR proven infection without placental histologic changes characteristic of infection or in the absence of placental histology	•		
2) Culture or PCR proven infection and placental histologic changes characteristic of infection such as villitis and placentalitis (minimal placental involvement)		•	
3) Culture or PCR proven infection and placental histologic changes characteristic of infection such as villitis and placentalitis (extensive placental involvement)			•
4) Pathognomonic pathologic findings in placenta with or without culture or PCR proven infection			•
d. Infection-related fetal death by other or unknown mechanisms (placental or fetal infection, possible mechanism different from other categories) Specify organism, if known _____			
1) Presence of maternal or fetal infection, no clear pathophysiologic sequence leading to fetal death	•		
2) Presence of maternal or fetal infection, plausible pathophysiologic sequence leading to fetal death		•	
3) Presence of maternal or fetal infection, likely pathophysiologic sequence leading to fetal death			•
4) Pathognomonic pathologic findings in fetus or placenta with or without culture or PCR proven infection			•

Appendix 2

Dudley

SCRN		CAUSE OF DEATH REVIEW		Form 91A	
Version 04 / December 21, 2009					
Review Case ID	Member	Review Number	Form Completion Date		
_____	_____	_____	mm	dd	yyyy

Instructions: Complete the Cause of Death (CoD) Review Form for each stillbirth case reviewed. For multiple births complete a separate form for each stillborn baby using the Member ID (e.g., 1, 2, 3) – consistent with chart abstraction Member ID designation.

A. Reviewer

1. Reviewer category _____
01=Assigned team 02=Alternate team 03=Individual reviewer 04=Other

2. If other than team assigned by the DCAC (i.e., the assigned team), list last name of reviewers below.
a. _____ b. _____
c. _____ d. _____

B. Comprehensive Review of Findings Pertinent to Cause of Death

Instructions:
Code findings according to the + designation where 01=present, 02=possible cause of death, and 03=probable cause of death. Use the highest code for a finding with the criteria met. For example, if there is systemic lupus erythematosus disease activity (flare) during pregnancy and abortion/placental, the SLE should be coded as 1c3 (probable cause).

	01=Present	02=Possible	03=Probable
1. Maternal Medical Conditions during Pregnancy			
a. Hypertensive disorder of pregnancy (1-4)			
1) Hypertensive disease alone	•		
2) Hypertensive disease with <u>at least ONE</u> of the following (specify if present):		•	
a) SGA (<10%) _____ 01=Yes, 02=No _____			
b) Absent or reversed end diastolic flow of umbilical vessels _____ 01=Yes, 02=No _____			
c) Maternal hypertensive crisis _____ 01=Yes, 02=No _____			
3) Hypertensive disease with [isolated clinical diagnosis of abruption (no retroplacental clot or pathologic evidence of abruption)] OR [hypertensive disease with isolated retroplacental clot or pathologic evidence of abruption (no clinical evidence of abruption)]		•	
4) Hypertensive disease with <u>at least TWO</u> of the following (specify if present):			•
a) SGA (<10%) _____ 01=Yes, 02=No _____			
b) Absent or reversed end diastolic flow of umbilical vessels _____ 01=Yes, 02=No _____			
c) Maternal hypertensive crisis _____ 01=Yes, 02=No _____			
5) Hypertensive disease with antepartum clinical diagnosis of abruption and <u>at least ONE</u> of the following (specify if present):			•
a) Retroplacental clot _____ 01=Yes, 02=No _____			
b) Pathologic confirmation with extensive parenchymal infarction _____ 01=Yes, 02=No _____			
c) Maternal blood transfusion _____ 01=Yes, 02=No _____			
d) Massive bleeding with rupture of membranes noted in records _____ 01=Yes, 02=No _____			
e) Eclampsia _____ 01=Yes, 02=No _____			
Specify most appropriate category of the disorder from below _____			
01=Preeclampsia			
02=Gestational hypertension			
03=Chronic hypertension			
04=Chronic hypertension with superimposed preeclampsia			
05=Eclampsia			

Instructions: Code findings according to the • designation where 01=present, 02=possible cause of death, and 03=probable cause of death. Use the highest code for a finding with the criteria met. For example, if there is systemic lupus erythematosus disease activity (flare) during pregnancy and abruptio placentae, the SLE should be coded as 1c3 (probable cause).				01=Present	02=Possible	03=Probable
b. Diabetes during pregnancy (5-8)						
1) Gestational diabetes				•		
a) Abnormal 2' GTT with FBS >105 or unknown with or without LGA (>90%)					•	
b) Abnormal 2' GTT with FBS >105 and LGA (>90%)						•
2) Pregestational diabetes (type 1 or type 2)						
a) HgA1C unknown during pregnancy and normal fetal growth				•		
b) HgA1C <6.5 during pregnancy and normal fetal growth				•		
c) HgA1C <6.5 during pregnancy or unknown, abnormal fetal growth [SGA (<10%) or LGA (>90%)]					•	
d) Diabetic ketoacidosis						•
e) Diabetic embryopathy with lethal anomalies						•
3) Poorly controlled diabetes with majority of blood sugars > 250 mg/dl or if noted in clinical record						•
4) Diabetic fetopathy with significant birth trauma or fetal pathologic changes (e.g. islet cell hyperplasia)						•
c. Systemic lupus erythematosus (9-12) (SLE) (SLE diagnosed by ARA criteria)						
1) Diagnosed SLE, but no disease activity during pregnancy				•		
2) SLE disease activity (flare) during pregnancy					•	
3) SLE disease activity (flare) during pregnancy associated with <u>at least ONE</u> of the following (specify if present):						•
a) Antiphospholipid syndrome (APS) _____ 01=Yes, 02=No _____ [] []						
b) Abruptio placentae _____ 01=Yes, 02=No _____ [] []						
c) Severe preeclampsia _____ 01=Yes, 02=No _____ [] []						
d) Eclampsia _____ 01=Yes, 02=No _____ [] []						
e) SGA (<10%) / oligohydramnios _____ 01=Yes, 02=No _____ [] []						
d. Intrahepatic cholestasis of pregnancy (13,14) (Generalized pruritis with bile acids increased [≥40 μmol/L])						
1) Bile acids 40-70 μmol/L					•	
2) Bile acids >70 μmol/L						•
e. Thyroid disorders during pregnancy (15-17) (Diagnosis of hyper or hypothyroidism)						
1) Medical management and clinically euthyroid				•		
2) Clinical symptoms of hyperthyroidism or hypothyroidism					•	
3) Thyroid storm						•
f. Renal disease during pregnancy (18-20) (Elevated serum creatinine)						
1) Serum creatinine 1.3-1.9 mg/dL, without SGA (<10%)				•		
2) Serum creatinine >1.9 mg/dL, without SGA (<10%)					•	
3) Serum creatinine >1.3 mg/dL, with SGA (<10%)						•
g. Severe maternal infection (21-24) (Maternal infection – examples: influenza, polio, varicella pneumonia, pyelonephritis, appendicitis). Specify organism, if known						
1) Hospital treatment and fever >100.4 F, or IV antibiotics, or surgery, or ventilatory support >2 weeks prior to the stillbirth or timing not known				•		
2) Hospital treatment and fever >100.4 F, or IV antibiotics, or surgery, or ventilatory support within 2 weeks prior to the stillbirth					•	
3) Hospital treatment and fever >100.4 F, or IV antibiotics, or surgery, or ventilatory support within 48 hours prior to the stillbirth, or hypotension						•
h. Shock during pregnancy (25-27) (Precipitating event leading to shock presentation not sepsis)						
1) Corrected with fluid replacement					•	
2) Need for pressor agents						•

Instructions: Code findings according to the • designation where 01=present, 02=possible cause of death, and 03=probable cause of death. Use the highest code for a finding with the criteria met. For example, if there is systemic lupus erythematosus disease activity (flare) during pregnancy and abruptio placentae, the SLE should be coded as 1c3 (probable cause).				01=Present	02=Possible	03=Probable
i. Asthma during pregnancy (28,29) (Clinical diagnosis of asthma)						
1) No evidence of exacerbation, with or without medications				•		
2) Uncontrolled exacerbation or uncontrolled asthma					•	
3) Status asthmaticus, with or without hypoxia documented						•
j. Seizure disorders during pregnancy (30,31) (Diagnosed seizure disorder)						
1) Seizure activity during pregnancy absent or <1 seizure/month, with or without anti-epileptics				•		
2) Seizure disorder not controlled by medications, occurring >1 seizure/month					•	
3) Status epilepticus						•
k. Maternal substance abuse (32-34) (Evidence of substance abuse by history or laboratory evaluation)						
1) Positive drug screen without SGA (<10%) or history of drug use with negative drug screen				•		
2) Positive drug screen with SGA (<10%)					•	
3) Narcotic withdrawal						•
l. Other maternal medical condition (Specific maternal condition)						
Specify condition _____						
1) Condition is diagnosed with no consequences on pregnancy				•		
2) Condition is associated with possible fetal consequences					•	
3) Condition has clear pathophysiology that most likely caused fetal death						•
2. Obstetric Complications						
a. Fetal maternal hemorrhage (35-38) (Kleihauer-Betke test positive or flow cytometry positive)						
1) Positive Kleihauer-Betke or flow cytometry <5%				•		
2) 5% to <40% of fetoplacental blood volume					•	
3) >40% of fetoplacental blood volume with signs of anemia in the fetus or in the placenta (yellow)						•
b. Cervical insufficiency (Sonographic evidence of short cervix or evidence on cervical examination) with antepartum death						
				•		
c. Preterm labor (spontaneous preterm labor diagnosed before or after antepartum fetal death)						
				•		
d. Preterm premature rupture of membranes (PPROM diagnosed before or after antepartum fetal death)						
				•		
e. Clinical chorioamnionitis (diagnosed before or after antepartum fetal death)						
				•		
f. Intrapartum fetal death with labor-associated asphyxia (<26 weeks) (39-44)						
						•
Specify associated conditions present:						
1) Cervical insufficiency _____ 01=Yes, 02=No _____ [] []						
2) Abruptio placentae _____ 01=Yes, 02=No _____ [] []						
3) Preterm labor _____ 01=Yes, 02=No _____ [] []						
4) Preterm PROM _____ 01=Yes, 02=No _____ [] []						
5) Clinical chorioamnionitis _____ 01=Yes, 02=No _____ [] []						
6) Histologic chorioamnionitis _____ 01=Yes, 02=No _____ [] []						
g. Hypoxic intrapartum fetal death (>26 weeks) (45-49) (Intrapartum fetal death)						
1) Clinical or pathology evidence of fetal asphyxia (by fetal heart rate monitoring or clinical evaluation)						•
Specify any contributing maternal or fetal condition _____						

Instructions:
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	01=Present	02=Possible	03=Probable
h. Abruptio placentae (50-52) (Clinical diagnosis and/or retroplacental clot on pathology)			
1) Retroplacental clot noted at any time, but no clinical diagnosis of abruptio	•		
2) Clinical diagnosis without retroplacental clot or pathologic confirmation		•	
3) Antepartum clinical diagnosis of abruptio placentae with at least ONE of the following (specify if present):			•
a) Retroplacental clot 01=Yes, 02=No [] []			
b) Pathologic confirmation with extensive parenchymal infarction 01=Yes, 02=No [] []			
c) Maternal blood transfusion 01=Yes, 02=No [] []			
d) Massive bleeding 01=Yes, 02=No [] []			
i. Complications of multiple gestation (53-57) (Clinical diagnosis of multiple gestation)			
1) One or all fetuses dead, no SGA (<10%) or evidence of uteroplacental insufficiency, intervening membranes noted	•		
2) One or all fetuses dead, with SGA (<10%) and/or evidence of uteroplacental insufficiency, intervening membranes noted		•	
3) Complications of monochorionic multiple gestation (e.g., twin to twin transfusion syndrome, TRAP sequence, monoamniotic twinning)			•
j. Uterine rupture (58,59) (Separation of uterine scar noted at surgery)			
1) Uterine dehiscence with no extrusion of fetus or cord, no evidence of uteroplacental insufficiency	•		
2) Uterine dehiscence with no extrusion of fetus or cord, with evidence of uteroplacental insufficiency		•	
3) Uterine rupture			•
k. Maternal trauma during pregnancy (60-63) (Maternal trauma documented in medical record)			
1) No evidence of maternal or fetal injury from the trauma	•		
2) Evidence of maternal injury with no abruptio placentae, but with presence of fetal cephalhematoma or skull fracture		•	
3) Evidence of maternal injury with abruptio placentae or direct fetal trauma (e.g. subdural hemorrhage)			•
l. Uteroplacental insufficiency (64-66)			
1) Isolated SGA (<10%)	•		
2) AGA (10-90%) with at least ONE of the documented findings specified below	•		
3) SGA (5-10%) with at least ONE of the documented findings specified below		•	
4) SGA <5% with at least ONE of the documented findings specified below			•
Specify documented findings present for 2-4 above:			
Sp. a) Oligohydramnios: AFI <5 cm with intact membranes 01=Yes, 02=No [] []			
Sp. b) Abnormal Doppler: Absent or reversed end diastolic flow of umbilical vessels 01=Yes, 02=No [] []			
Sp. c) Category III fetal heart tracing or a biophysical profile score <6 01=Yes, 02=No [] []			
m. Other obstetric condition (Specific obstetric condition)			
Specify condition _____			
1) Condition is diagnosed with no consequences on pregnancy	•		
2) Condition is associated with possible fetal consequences		•	
3) Condition has clear pathophysiology that most likely caused fetal death			•

Instructions:
Code findings according to the • designation where 01=present, 02=possible cause of death, and 03=probable cause of death. Use the highest code for a finding with the criteria met. For example, if there is systemic lupus erythematosus disease activity (Item) during pregnancy and abruptio placentae, the SLE should be coded as 1c3 (probable cause).

	01=Present	02=Possible	03=Probable
3. Maternal or Fetal Hematologic Conditions			
a. Heritable thrombophilias (67-71)			
1) Positive test only	•		
2) Positive test with SGA (<10%)		•	
Specify tests documented positive for 1-2 above:			
Sp. a) Factor V Leiden 01=Yes, 02=No [] []			
Sp. b) Prothrombin Gene 20210A 01=Yes, 02=No [] []			
Sp. c) Antithrombin III deficiency 01=Yes, 02=No [] []			
Sp. d) Protein S deficiency 01=Yes, 02=No [] []			
Sp. e) Protein C deficiency 01=Yes, 02=No [] []			
b. Antithrombotic syndrome (APS) (72-74)			
1) Positive test for APS, no SGA (<10%) or oligohydramnios present	•		
2) Positive test for APS with SGA (<10%) or oligohydramnios present		•	
Specify tests documented positive for 1-2 above:			
Sp. a) Lupus anticoagulant 01=Yes, 02=No [] []			
Sp. b) Anticardiolipin antibodies 01=Yes, 02=No [] []			
c. Red cell isoimmunization (75-78) (Maternal antibodies against RBC antigen [a, b, 1, 15] except for any titer Kell antibody)			
1) No hydrops or fetal anemia	•		
2) Fetal anemia, without hydrops, extramedullary hematopoiesis present		•	
3) Hydrops fetalis			•
d. Platelet alloimmunization (79-81) (Maternal antibodies vs. pertinent fetal platelet antigen present)			
1) Parental platelet incompatibility with normal fetal platelet count and no fetal intracranial hemorrhage	•		
2) Fetal thrombocytopenia		•	
3) Fetal thrombocytopenia with intracranial hemorrhage			•
e. Other maternal or fetal hematologic conditions (Specific maternal or fetal hematologic condition)			
Specify condition _____			
1) Condition is diagnosed with no consequences on pregnancy	•		
2) Condition is associated with possible fetal consequences		•	
3) Condition has clear pathophysiology that most likely caused fetal death			•
4. Fetal Genetic, Structural, and Karyotypic Abnormalities			
a. Chromosomal anomalies (82-84)			
1) Aneuploidy, specify _____		•	
2) Unbalanced translocation, deletions		•	
3) Confined placental mosaicism with SGA (<10%)			•
b. Autosomal recessive disorders (85-88)			
1) Alpha thalassemia causing hydrops		•	
2) Storage disease causing hydrops		•	
3) Amino acid disorders		•	
4) Peroxisomal disorders		•	
c. X-linked dominant disorders in males (89)	•		

Instructions:
Code findings according to the * designation where 01=present, 02=possible cause of death, and 03=probable cause of death. Use the highest code for a finding with the criteria met. For example, if there is systemic lupus erythematosus disease activity (flare) during pregnancy and abruptio placentae, the SLE should be coded as 1C3 (probable cause).

	01=Present	02=Possible	03=Probable
d. Structural anomalies without chromosomal anomaly (90-102)			
1) Pentology of Canaliculoplasia cordis			*
2) Cardiac anomaly with no hydrops	*		
3) Cardiac anomaly causing hydrops (structural defects/dysrhythmias)			*
4) Intrathoracic anomaly causing hydrops (neoplasia)			*
5) Urogenital anomaly causing anhydramnios (prune belly, bilateral renal agenesis, cloacal dysgenesis)			*
6) Non-immune hydrops (diagnosed prior to fetal death, any cause)			*
7) Lethal type skeletal dysplasia			*
8) Fetal or placental tumors causing hydrops. specify _____			*
9) Abdominal wall defects			*
10) Neural tube defects, with no evidence of brain stem compromise		*	
11) Neural tube defects, with evidence of brain stem compromise		*	*
12) Other structural neurologic abnormalities, specify _____		*	
13) Fetal lung abnormalities (CCAM, hypoplasia), with or without congenital diaphragmatic hernia		*	
14) Endocrine gland agenesis, hypoplasia, or dysfunction		*	
15) Neuromuscular disorders (myotonic/muscular dystrophies)		*	
16) Any structural abnormality without chromosomal anomaly (1-15 above) with hydrops (if not already specified) or major structural abnormality likely leading to death. specify _____			*
e. Fetal metabolic disorders (103-104): Specify _____			
1) Inborn errors of metabolism: systemic effects			*
2) Inborn errors of metabolism: degenerative neurologic disease			*
f. Other chromosomal, genetic or structural abnormality Specify, if known _____			
1) Condition is not likely associated with fetal consequences	*		
2) Condition is associated with possible fetal consequences		*	
3) Condition has clear pathophysiology that most likely caused fetal death			*
5. Placental and/or Fetal Infection (Excluding Fetal Membranes)			
a. Fetal infection involving vital organs: brain, heart, lung & liver (105-118) (Positive bacterial or viral culture, or viral-specific PCR - examples: listeriosis, group B streptococcus, Escherichia coli, other viruses, protozoa) Specify organism, if known _____			
1) Culture or PCR proven infection in vital organs with no documented histologic signs of infection	*		
2) Culture or PCR proven infection in vital organs with signs of infection in the placenta but not organs		*	
3) Histologic evidence of infection in vital organs without culture or PCR proven infection in vital organs		*	
4) Histologic evidence of infection in vital organs with culture or PCR proven infection in vital organs			*
5) Pathogenomic pathologic findings in fetus with or without culture or PCR proven infection			*
b. Fetal infection that causes congenital anomaly or other fetal condition (116-119) (Fetal infection with a teratogenic organism - examples: parvovirus, varicella, CMV, toxoplasmosis) Specify organism, if known _____			
1) Organism known to cause fetal anomaly/condition, anomaly/condition is present, timing of infection not consistent with specific anomaly/condition	*		
2) Organism known to cause fetal anomaly/condition, anomaly/condition is present, timing of infection is unknown		*	
3) Organism known to cause fetal anomaly/condition, anomaly/condition is present, timing of infection consistent with expected anomaly (including neonatal injury or calcifications)			*
4) Pathogenomic pathologic findings in fetus or placenta with or without culture or PCR proven infection			*
6. Pathologic Placental Conditions (124-136)			
a. Placental Disc (137-141)			
1) Implantation site abnormalities			
a) Placenta previa		*	
b) Placenta percreta, increta, accreta			*
2) Abnormal development of villous parenchyma			*
a) Delayed villous maturation		*	
b) Accelerated villous maturation		*	
c) Partial mole			*
b. Placental membranes (142)			
1) Circumvallate, velamentous, or funicular cord insertion with compromise		*	
2) Early amnion rupture sequence			*
3) Amnion nodosa	*		
c. Umbilical cord (143-149)			
1) Vasa previa		*	
a) With no bleeding		*	
b) With bleeding			*
2) Umbilical cord entrapment (includes nuchal cord, body cord, shoulder cord or other evidence that umbilical cord is constricted by the fetus)		*	
a) With no evidence of occlusion	*		
b) With evidence of cord occlusion		*	
c) With evidence of cord occlusion and fetal hypoxia			*
3) True knots, false knots, torsions, strictures			*
a) With no thrombi or other obstruction	*		
b) With thrombi or other obstruction			*
4) Cord prolapse			*

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	01=present	02=possible	03=probable
d. Fetal membranes and placental inflammatory disorders (150-157)			
1) Histologic chorioamnionitis with antepartum fetal death	*		
2) Histologic chorioamnionitis and funisitis with antepartum fetal death		*	
3) Histologic chorioamnionitis and funisitis with intrapartum fetal death > 26 weeks gestation		*	
e. Circulatory disorders (158-177)			
1) Compromised maternal circulation: vascular lesions			
a) Extensive decidual vasculopathy	*		
b) Extensive villous (parenchymal) infarcts			*
c) Extensive intervillous thrombus (hematoma)		*	
d) Massive subchorionic hematoma			*
e) Subamniotic hemorrhage	*		
2) Compromised maternal circulation: nonvascular lesions			
a) Minor perivillous parenchymal fibrin deposition	*		
b) Massive perivillous parenchymal fibrin deposition			*
c) Maternal floor fibrin deposition (maternal floor infarct: covers parenchyma with ≥1 cm deposition of basal plate)			*
3) Compromised fetal microcirculation			
a) Thromboembolism of umbilical vein or large fetal vessels, no evidence of or partial obstruction		*	
b) Thromboembolism of umbilical vein or villous fetal capillaries and avascular villi, with evidence of obstruction		*	
4) Compromise of maternal/fetal circulations			
a) Placental and/or fetal hydrops			*
f. Other placental abnormalities (Specific placental abnormality diagnosed)			
Specify condition _____			
1) Condition is diagnosed with no consequences on pregnancy	*		
2) Condition is associated with possible fetal consequences		*	
3) Condition has clear pathophysiology that most likely caused fetal death			*
7. Other Pertinent Condition Not Specified in Sections 1-6			
Specify condition _____			
1) Condition is present that is pertinent to the evaluation of the fetal death	*		
2) Condition is associated with possible fetal consequences		*	
3) Condition has clear pathophysiology that most likely caused fetal death			*

C. Synopsis

1. Review complete 01=Yes, 02=No [] []

If NO →

a. Are there questions for the clinical site? 01=Yes, 02=No [] []

If YES → Specify

b. Are there questions for a pathologist? 01=Yes, 02=No [] []

If YES → Specify

c. Are there questions for a geneticist? 01=Yes, 02=No [] []

If YES → Specify

d. Is any additional input required? 01=Yes, 02=No [] []

If YES → Specify

2. Are there key data found in narrative reports that are not found or that are entered incorrectly in the SCRN database? Q1=Yes, Q2=No ☐ ☐

If YES → Specify

3. Provide a narrative in the space below

Narrative