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Legal aspects of perinatal loss

© Vitaly F. Bezhenar¹, Lidia A. Ivanova², Dmitry O. Ivanov³

¹ Academician I.P. Pavlov First St. Petersburg State Medical University, Saint Petersburg, Russia;

² Military Medical Academy named after S.M. Kirov, Saint Petersburg, Russia;

³ Saint Petersburg State Pediatric Medical University, Saint Petersburg, Russia

BACKGROUND: Perinatal death is the death of the fetus, starting from 22 weeks of pregnancy and in childbirth, as well as the death of a newborn in the first seven days of life. Despite the fact that reducing perinatal losses is one of the most important tasks of contemporary medicine, the level of perinatal mortality in Russia in recent years has been about 7.5 ‰.

AIM: The aim of this study was to analyze documentation related to the legal aspects of perinatal loss.

MATERIALS AND METHODS: The article analyzes the main federal laws, agency regulations, orders, methodological letters, recommendations, and materials on the Internet concerning the main aspects and questions that most often arise among doctors, as well as postpartum women who have undergone perinatal loss and their family members.

RESULTS: The article provides data on:

- the medical criteria for birth, basic documentation issued in case of stillbirth, the birth of a live child who died in the perinatal period, and the rules for their issuance;
- the rules and procedure for notifying state bodies in case of perinatal death, the rules for registering a stillborn and a child who died in the first 168 hours of extrauterine life;
- the types of perinatal death certificate;
- the rules for conducting a pathological autopsy and the possibility of refusing it;
- the issues of burial of children who died perinatally;
- the rules for handling material obtained during termination of pregnancy up to 22 weeks.

CONCLUSIONS: The legislative framework was analyzed and answers were given to the most frequently asked questions regarding the legal aspects of perinatal loss.

Keywords: infant; newborn; stillbirth; perinatal death; autopsy; burial; documentation.

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Юридические аспекты перинатальных потерь

© В.Ф. Беженарь¹, Л.А. Иванова², Д.О. Иванов³¹ Первый Санкт-Петербургский государственный медицинский университет им. акад. И.П. Павлова, Санкт-Петербург, Россия;² Военно-медицинская академия им. С.М. Кирова, Санкт-Петербург, Россия;³ Санкт-Петербургский государственный педиатрический медицинский университет, Санкт-Петербург, Россия

Обоснование. Перинатальная смерть — гибель плода начиная с 22 недель беременности в родах, а также гибель новорожденного в первые 7 сут жизни. Несмотря на то что снижение перинатальных потерь является одной из ведущих задач современной медицины, уровень перинатальной смертности в России в последние годы составляет около 7,5 ‰.

Цель — проанализировать документы, касающиеся юридических аспектов проблемы перинатальных потерь.

Материалы и методы. В статье рассмотрены основные федеральные законы, приказы министерств и ведомств, распоряжения, методические письма и рекомендации, материалы сети Интернет в отношении основных аспектов и вопросов, наиболее часто возникающих у врачей, а также родильниц, перенесших перинатальную потерю, и членов их семей.

Результаты. В статье приведены данные о:

- медицинских критериях рождения, основной документации, выдаваемой при мертворождении, рождении живого ребенка, погибшего в перинатальном периоде, и правилах их выдачи;
- правилах и порядке оповещения государственных органов в случае перинатальной гибели, правилах регистрации мертворожденного и ребенка, погибшего в первые 168 ч внеутробной жизни;
- видах медицинского свидетельства о перинатальной смерти;
- правилах проведения патологоанатомического вскрытия, возможности отказа от него;
- вопросах погребения детей, погибших перинатально;
- правилах обращения с материалом, полученным при прерывании беременности до 22 нед.

Заключение. Была проанализирована законодательная база и даны ответы на наиболее часто возникающие вопросы о юридических аспектах перинатальных потерь.

Ключевые слова: новорожденный; мертворождение; перинатальная смерть; вскрытие; захоронение; документация.

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BACKGROUND

Perinatal death is fetal death starting from 22 weeks pregnancy in childbirth, as well as the death of a newborn in the first 7 d of life. Despite the fact that perinatal losses reduction is one of the leading tasks of modern medicine, the level of perinatal mortality in Russia in recent years has been about 7.5% [1]. In addition, perinatal mortality rates are steadily decreasing in subjects of the federation in particular and in the country as a whole, mainly due to the decrease in early neonatal mortality and insignificant changes in the number of stillbirths for a long time [2].

This study aimed to analyze the documents related to the legal aspects of perinatal losses problem.

MATERIALS AND METHODS

The article discusses the main federal laws, orders of ministries and departments, orders, methodological letters and recommendations, and materials on the Internet on the main aspects and issues that most often arise among doctors, as well as postpartum women who underwent perinatal loss and their families.

RESULTS

According to the Order of the Ministry of Health and Social Development of the Russian Federation dated December 27, 2011 No. 1687n of Moscow "On medical criteria for birth, the form of a birth document, and the procedure for issuing it" [3], the medical criteria for birth are 22 weeks of gestation and more; child's body weight at birth of 500 g or more (or <500 g for multiple births); and child's body length at birth of 25 cm or more (if the child's body weight at birth is unknown). If a newborn has signs of live birth (breathing, heartbeat, pulsation of the umbilical cord, or voluntary muscle movements) at the time of separation from the mother's body, he is considered live born. In the absence of a newborn with a body weight of 500 g or more (or <500 g in case of multiple births), born at a gestational age of 22 weeks and more, signs of live birth at the time of separation from the mother's body, he is considered stillborn.

A medical birth certificate is issued for newborns who are born alive to their parents (one of the parents), and to a relative of one of the parents or another authorized person if the parents are unable to personally obtain a medical birth certificate. A medical certificate is required for state registration of birth, carried out in accordance with the Federal Law of November 15, 1997 No. 143-FZ "On acts of civil status" [4]. A child born alive but died in the first 168 hours of extrauterine life is issued with a medical birth certificate and a medical certificate of perinatal death.

According to Article 20 of the Federal Law of November 15, 1997 No. 143-FZ (as amended on April 24, 2020) "On acts of civil status," [4] the obligation to declare to the civil registry office (ZAGS) about the stillbirth or birth and death of a child in the first week of life is assigned to the head of the medical organization in which the childbirth took place or in which the child died, or to the medical organization (an individual entrepreneur carrying out medical activities), a doctor who established the fact of stillbirth or the fact of death of a child on the first week of life from childbirth outside the medical organization. Thus, the medical workers are obliged not only to issue the necessary documents (birth, death, and perinatal death certificates), but also report this fact to the registry office, whereas the parents or other representatives of the newborn to the registry office with a statement stillbirth/perinatal death is not reported. In addition, the above-mentioned federal law regulates that a statement on stillbirth or on the birth and death of a child in the first week of life must be made no later than 3 d from established date of the stillbirth or the fact of death of a child on the first week of life.

State registration of the birth of a dead child is carried out on the basis of a document on perinatal death issued by a medical organization or an individual entrepreneur carrying out medical activities, in the form and manner established by the federal executive body performing the functions of developing and implementing state policy and regulatory, legal regulation in the field of health care.

A birth certificate for a dead born child is not issued. In addition, state registration of the death of a dead born child is not carried out. Parents, at their request, can be issued with a document confirming the fact of state registration of the birth of a dead child. If the child died in the first week of life, a state registration of his birth and death is made (based on the certificate of perinatal death).

The issuance of a medical certificate of perinatal death is regulated by the Order of the Ministry of Health and Social Development of the Russian Federation of December 26, 2008 No. 782n "On the approval and procedure for maintaining medical documentation certifying cases of birth and death" (with amendments and additions) [5]. The medical certificate of perinatal death (Form No. 106-2/-08, Appendix No. 3 of the above law) is filled out in accordance with the recommendations presented in the letter of the Ministry of Health and Social Development of the Russian Federation dated January 19, 2009 No. 14-6/10/2-178 "On the procedure issuing and filling out medical certificates of birth and death" [6]. According to the above recommendations, this document is issued by the medical organization whose doctor provided medical care during childbirth, or those whom the mother contacted after childbirth, or a private practitioner during childbirth outside the medical organization; the document is filled in by a doctor and in

his absence, a paramedic or midwife. However, in practice, a medical certificate of perinatal death is usually issued by the organization in which the death of the child was diagnosed, i.e., in the event of a stillbirth or death in a maternity facility, the medical organization whose doctor provided assistance during childbirth. When a transfer to a children's hospital, perinatal center, etc. has already taken place, and the child dies a few hours/days after birth, a medical certificate of perinatal death is issued by the medical organization in which the child died.

A medical certificate is issued with the mark "final," "preliminary," "instead of the preliminary," and "instead of the final." For doctors-obstetricians and gynecologists, this is a very important point: it is necessary to understand that on the basis of this document, state statistics on the causes of death are formed. Bodies of children who died perinatally are sent for pathological examination, and an extract from the protocol (card) of pathological examination is filled in, which is transferred to a medical organization where a stillbirth took place or the child died in the first 168 hours of life. A medical certificate is issued by this medical organization, whereas the section "Causes of death" is filled in in accordance with the conclusion of a pathologist [6].

Accordingly, it is more correct to initially issue a medical certificate marked "preliminary." After receiving the pathological examination results (no later than 45 d after the established cause of death), the forensic expert or pathologist draws up a new medical certificate marked as "instead of the preliminary one" or "instead of the final one." In cases where a medical certificate marked as "final" was issued in an obstetric (or other) institution, but later an error in the cause of death was discovered, a new medical certificate is filled in and marked as "instead of the final."

Thus, for a stillbirth, one certificate is issued: a certificate of perinatal death, and two documents for a live birth who died perinatally: birth certificate and perinatal death certificate. In addition, the organization in which the death of a child is recorded: maternity, children's hospital, etc., informs the registry office about the perinatal death (within 3 d), and the medical institution where the birth took place (or a private practitioner) issues a certificate of perinatal death.

The next question, which was partly raised above is whether a woman can refuse to open a child who died perinatally. This aspect is regulated by the Order of the Ministry of Health of the Russian Federation of June 06, 2013 No. 354n "On the procedure for conducting pathological autopsies" [7]. According to this document, an autopsy of a child who died perinatally is carried out in all cases, without exception, despite the protests of the woman, relatives, or including those expressed in writing, in front

of witnesses, for any reason, etc. The order states that the postmortem autopsy is not carried out for religious reasons, at the will of the deceased, etc., with the exception of cases: clause 5: pregnant women, women in labor, parturient women (including the last day of the postpartum period), and children under the age of 28 d of life inclusive; point 6: the birth of a still child. During the pathological examination, any study (histological, biochemical, etc.) of any organ can be carried out, and the consent to conduct these studies is not required from the relatives. Referral to pathological autopsy is organized by the head of the department of the medical organization where the patient was at the time of death, and in his absence, by the doctor on duty.

According to the order of the Ministry of Health of the Russian Federation dated June 06, 2013 No. 354n "On the procedure for conducting pathological autopsies," [7] "card of a newborn, history of the child's development, medical card of an outpatient, containing the results of laboratory and instrumental diagnostic studies, cards of anesthetic and resuscitation aids, protocols of surgical interventions, final clinical diagnosis indicating the diagnosis code in accordance with the International Classification of Diseases 10th revision, and postmortem epicrisis." However, in practice, medical documentation is not always "present" at the autopsy. In most cases, when referring to an autopsy, the attending physician applies a referral for an autopsy, a referral for the study of the placenta, a postmortem epicrisis with an extract from the birth history, and a history of the newborn development with cards of resuscitation and anesthetic benefits. Furthermore, the very history of childbirth remains at this time in the obstetric institution.

This practice has existed for the entire duration of Order No. 354n [7], an autopsy is performed in the absence of a birth history; if necessary, the pathology bureau (department) requests this document (and a number of others, for example, exchange card, outpatient card for the mother, etc.) later, after the autopsy, and the final documents are formed: the autopsy protocol, an extract from the protocol, etc. The attending physician (doctor-obstetrician-gynecologist, neonatologist), paramedic, midwife, or head of the department of the medical organization in which he was located is invited to autopsy the patient at the time of death. Thus, the attending physician has the right to be present at the autopsy, but is not obliged to. Presence of the attending physician at the autopsy is desirable for the pathologist can contact him for necessary clarifications.

Pathological autopsy of the fetus should be carried out within 3 d after delivery (ascertaining the death of a newborn) and refers to an autopsy of the second category of complexity, i.e., equated to conditions in which a clinical diagnosis has been established, including complications of the underlying disease, with certainty in the interpretation of the mechanisms and causes of death. The fact that the

autopsy of a child who died perinatally belongs to the second category of complexity, unfortunately, initially suggestion on the cause of death must be given. In this type of research, macroscopic (examination) and microscopic (histological examination) methods are used.

A number of pathological bureaus (departments), in particular the Leningrad Regional Pathological Bureau, each time justifies and classifies the autopsy of perinatally dead fetuses as an autopsy of the fifth category of complexity—cases when the autopsy is performed with an unknown clinical diagnosis of the underlying disease, in the presence of difficulties in interpreting the nature pathological process and causes of death. Using additional immunohistochemical, molecular biological, and electron microscopic research method is necessary when carrying out an autopsy of the fifth category of complexity, and if possible conduct virological studies, etc. Thus, the obstetrician-gynecologist must be prepared for the fact that according to Order No. 354n [7] during an autopsy of a child who died perinatally, only histological examination of standard micropreparations will be carried out. In addition, he will not receive an answer to the question as to why the perinatal loss occurred. In addition, it should be borne in mind that an obstetrician-gynecologist cannot require a pathologist to use additional research methods at will; additional studies (genetic, virological, immunohistochemical, etc.) may be denied to him on the basis of the order of the Ministry of Health of Russia [7]. What can be the way out of this situation? It is possible to send fetuses and newborns that died perinatally to pathological bureaus (departments) that deal specifically with pathological autopsies of children, including stillborn babies.

The order of the Ministry of Health of the Russian Federation of March 24, 2016 No. 179n "On the rules for conducting pathological studies" [8] regulates the complexity categories of intravital pathological studies of biopsy (surgical) material and classifies the research of successions in the second category of complexity, equating them to complicated forms of nonspecific acute or chronic inflammation, dystrophic processes, and malformations.

Based on the postmortem examination results, form No. 013/y-1 "Protocol of postmortem dissection of the fetus, stillborn, or newborn" is filled out [7]. Not later than 30 d after the autopsy completion, the pathologist finalizes the autopsy protocol, and also enters the pathological diagnosis and clinical and anatomical epicrisis into the above-mentioned medical documentation. A copy of the autopsy protocol is attached to the medical documentation—a medical card of an inpatient, after which all documentation is returned to the medical organization. The conclusion about the cause of death and diagnosis of the disease is issued to parents at their request. The body can be handed over to the parents for burial after the autopsy is complete.

According to the Federal Law of January 12, 1996 No. 8-FZ (as amended on 08.12.2020) "On Burial and Funeral Business" [9] in the Russian Federation, every person after death is guaranteed the right to burial. Thus, a child born during a 22-week pregnancy can be buried and more, and weighing 500 g or more, for which the relevant documents are drawn up (certificate of perinatal death for a stillborn, birth certificate, and certificate of perinatal death for a child born alive and died perinatally). This is indirectly indicated by Article 9 of the Law on Burial and Funeral Affairs, which states that the cost of services for the burial of a dead child born after 154 d of pregnancy is determined by the local authorities and reimbursed to a specialized service for funeral affairs within 10 d from the date of the appeal of this service at the expense of the budget of the constituent entities of the Russian Federation.

Article 8 of the above-mentioned law regulates the provision of the possibility of finding the body of the deceased in the morgue free of charge up to 7 d from the moment the cause of death is established. In addition, this period can be increased to 14 d with circumstances that complicate the implementation of the (for example, the mother is in a serious condition, postoperative complications, etc.). Thus, a woman (family) has the right to bury a child, including stillborn.

However, another question arises: can a family refuse to be buried, is it legal, and does it entail any material obligations? The answer to this question is given by Article 6 of this law: in the event of a reasoned refusal by the relatives or legal representatives of the deceased from burial, it is carried out by a specialized service for the funeral business. Consequently, in the history of childbirth, it is necessary to point out the "motivated refusal" from burial: usually the puerperant notes that she refuses burial for personal reasons. On the basis of this document, burial rights of the child are transferred to a specialized service, which carries out the burial within 3 d from the moment the cause of death is established (Article 12) [9]. In this case, the body can be buried (burial in a grave) and cremated (cremation with subsequent burial of the urn). In each subject of the federation, this service is established by the order of a specific subject, for example, in St. Petersburg it is the state unitary enterprise "Ritual Services" (GUP RU). In St. Petersburg and Leningrad regions, bodies are interred (buried). In some cases, after a certain time (months, years), a woman may have a question: can I find the burial place of my child? Yes, she can find this burial, for this she needs to contact the archives of the service, which at that time was engaged in "the burial of the dead (deceased) in the absence of a spouse, close relatives, other relatives, or legal representative of the deceased (deceased) or if they were unable to carry out the burial."

Another question that a doctor may face: is it possible to get a burial for a fetus born before 22 weeks, including when a pregnancy is terminated for medical reasons? According to all the normative acts given above, a fetus born before 22 weeks is not viable, “child,” or “person,” the corresponding documentation cannot be drawn up on it, and cannot be buried.

End of uterine pregnancy before 22 weeks is considered a miscarriage. The tissue obtained as a result of miscarriage (including the embryo/fetus) should be sent for histological examination [10]. After histological examination, the tissues should be disposed of as Class B waste (epidemiologically hazardous waste). This type of waste also includes organic operating waste (organs, tissues, etc.). Further actions with specific types of waste, including Class B, are regulated by the decree of the chief state sanitary doctor of the Russian Federation dated December 09, 2010 No. 163 On approval of SanPiN 2.1.7.2790-10 Sanitary and epidemiological requirements for the management of medical waste [11]. According to this document, pathological and organic operating waste of Class B waste (organs, tissues, etc.) is subject to cremation (incineration) or burial in cemeteries in special graves in a specially designated area of the cemetery. Control over compliance with the rules of waste management lies with the organization that carries out their storage, disinfection, transportation, etc. [11].

However, when analyzing sites on this topic on the Internet, you can find a variety of stories, which is especially typical for forums of women who have suffered perinatal losses. Usually, problems arise precisely with miscarriages: when a child is born with a gestational age of >22 weeks (as mentioned above), his official burial is possible. If the pregnancy is terminated before 22 weeks, it is not officially possible to obtain the material from the miscarriage. However, we read: “But then my husband unofficially agreed” [12]. Unfortunately, we can only guess what will happen next. Someone buries in a grave with relatives, or someone buries in the forest outside the city, but some records states: “One of my friends buried her baby in the sea, letting him go on a homemade boat ...” [13].

Omitting the ethical side of the issue and not discussing the situation, what will happen if this homemade boat with

a half-decayed corpse is found by children playing on the beach, the legal side of the issue will be discussed. This situation is regulated by Article 247 of the Criminal Code of the Russian Federation “Violation of rules for the circulation of environmentally hazardous substances and waste” [14]. Part one of this article reads: “Production of prohibited types of hazardous waste, transportation, storage, burial, use, or other handling of radioactive, bacteriological, chemical substances, and waste in violation of established rules, if these acts created a threat of causing significant harm to human health or the environment, shall be punishable by a fine in an amount of up to two hundred thousand rubles, or in the amount of the wage or salary, or any other income of the convicted person for a period of up to eighteen months, or restraint of liberty for a term of up to two years, or compulsory labor for a term of up to two years, or imprisonment for the same term. The second part of article [14] states that the same act that caused harm to human health “are punished with a fine in the amount of one hundred thousand to three hundred thousand rubles or in the amount of wages or salary or other income of the convicted person for a period of one to two years, either forced labor for up to five years, or imprisonment for the same period.” Accordingly, the doctor who issues the miscarriage material to a woman or her relatives realizes that this material cannot be buried legally, and its transportation, storage, and burial will be carried out in violation of the established rules by persons who do not have the right to do so, and, based on the foregoing, is an accomplice in a crime, for which he can be prosecuted.

Thus, a doctor has no right to give a woman or relatives the material obtained from a miscarriage; this material must be sent for histological examination and then disposed of.

CONCLUSIONS

An analysis of the legal framework for legal aspects of perinatal losses will allow a practicing obstetrician-gynecologist to get answers to the most frequently asked questions regarding routine practice in the field of perinatal losses.

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AUTHORS INFO

Vitaly F. Bezhenar, MD, Dr. Sci. (Med.), Professor;
ORCID: <https://orcid.org/0000-0002-7807-4929>;
eLibrary SPIN: 8626-7555; e-mail: bez-vitaly@yandex.ru

***Lidia A. Ivanova**, MD, Cand. Sci. (Med.), Assistant Professor;
address: 6 Akademika Lebedeva Str.,
Saint Petersburg, 194044, Russia;
ORCID: <https://orcid.org/0000-0001-6823-3394>;
eLibrary SPIN: 1569-8842; e-mail: lida.ivanova@gmail.com

Dmitry O. Ivanov, MD, Dr. Sci. (Med.), Professor;
ORCID: <https://orcid.org/0000-0002-0060-4168>;
e-mail: doivanov@yandex.ru

ОБ АВТОРАХ

Виталий Федорович Беженарь, д-р мед. наук, профессор;
ORCID: <https://orcid.org/0000-0002-7807-4929>;
eLibrary SPIN: 8626-7555; e-mail: bez-vitaly@yandex.ru

***Лидия Алексеевна Иванова**, канд. мед. наук, доцент;
адрес: Россия, 194044, Санкт-Петербург,
ул. Академика Лебедева, д. 6;
ORCID: <https://orcid.org/0000-0001-6823-3394>;
eLibrary SPIN: 1569-8842; e-mail: lida.ivanova@gmail.com

Дмитрий Олегович Иванов, д-р мед. наук, профессор;
ORCID: <https://orcid.org/0000-0002-0060-4168>;
e-mail: doivanov@yandex.ru