Israel Very Low Birth Weight Infant Database

FORM 1 –Maternal Data

Birth Details:

1. Record the **name of the hospital** where the baby was born.
   The hospital of birth will be recorded as the one in which the baby was first admitted, including home births or birth in ambulance.

2. **Place of birth:** Hospital/ Ambulance/ Home. Mark the correct option in event of baby being born alive at home or in an ambulance.

3. **Date of birth** as recorded in live birth registration certificate.

Mother's information:

4. **Mother's identification number** as recorded in live birth certificate.
5. Mother's **first name**
6. Mother's **surname**

7. **Multiple birth:** yes/no.
   If "yes", record the total **number of fetuses** at this birth and **birth order** of the current infant.
   If there were also **stillbirths** at this birth, mark "yes" and record the number of stillbirths. For this purpose "stillbirth" is defined as a fetus weighing more than 500 grams or if weight is unknown, gestational age is at least 20 weeks or 22 weeks from the date of last menstrual period.

8. **List of infants:**
   For **each** live born infant in the present birth record the **birth order**, **identification number**, **gender** and **birth weight**
   Infants who died shortly after birth who received an identification number and for whom a live birth certificate was completed must be recorded.
   All 9 digits of identification number must be recorded, including control digits.
   Infants weighing over 1500 grams, born at same birth, must also be recorded.

9-23. **Parental Demographic Information**:
   Record **parents details as they are registered in live birth certificate.**
   It is recommended to use the live birth certificate for this information. Completion of the birth certificate is done according to the Ministry of Interior protocol, including checking the parents ID cards. The information is generally accurate. Care must be taken to ensure that the documents are compatible.

9. Residential address (Town)
10. Single mother (yes/no)
11. Father's **ID number**
12. Father's **first name**
13. Mother's **year of birth**
14. Father's **year of birth**
15. Mother's **country of birth**
16. Father's **country of birth**
17. Mother's **nationality** (Jewish, Arab, Druze, other)
18. Father's **nationality** (Jewish, Arab, Druze, other)

19. Mother's **profession**
20. Father's **profession**
21. **Country of birth** of mother's father
22. Mother's **years of education**
23. Father's **years of education**

Present pregnancy

24. **Gestational age**
    Record gestational age according to the best medical assessment based on: last menstrual period, obstetric history and gynecological exams, pre-natal ultrasounds and a post birth clinical evaluation.
    Record complete weeks only (28 and 5 days = 28 weeks)

25. **Prenatal care:** yes/no
    Record gestational week at initiation of prenatal care by physician or "family health clinic".
    If mother did not receive prenatal care, or if the first examination following complications (such as contractions or membrane rupture) that ended in birth, record "no prenatal care".

26. **Infertility treatment:** yes/no. Mark "yes" if current pregnancy was as a result of infertility treatment.
    If "yes", record the **primary treatment** (only one): Ovulation induction/IVF/other.
    IVF includes all accepted methods, micromanipulation and methods used for male infertility.
    "Other" treatments include all methods not including ovulation induction or IVF, such as tuboplasty or artificial insemination. Record the specific treatment
    In event of past surgical treatments such as tuboplasty, and the current pregnancy was achieved by IVF, record only IVF.

27. **Cigarette Smoking:** yes/no
    Mark "yes" in event of the mother smoking cigarettes during pregnancy, regardless of number of cigarettes and for how long.

28. **Previous obstetric history:**
    This section **does not include the current pregnancy and its outcome.**
    Record **number of previous pregnancies** and their outcomes
    Record **number of live births**
    Record **number of still births** (a fetus weighing more than 500 grams or if weight is unknown gestational age is at least 20 weeks or 22 weeks from date of last menstrual period).
    Record **number of miscarriages** (spontaneous termination of pregnancy prior to 20 weeks gestational age or 22 weeks LMP, or when fetal weight is less than 500 grams)
    Record number of **induced terminations of pregnancy** (induced terminations as per maternal request following maternal or fetal reasons)
    Record **number of live born infants weighing less than 2,500 grams**. These infants are included in the total number of live births.
    Record **number of infant deaths before the age of 1 year**. These infants are included in the total number of live births.

Medical Conditions and Treatment during current pregnancy

29. **Cervical suture:** yes/no
    Mark "yes" in event of a cervical suture being done at any stage of the pregnancy.
30. **Selective fetal reduction:** yes/no
    Mark "yes" in event of a deliberate intervention to reduce number of fetuses in a multi-fetal pregnancy.

31. **Amniocentesis:** yes/no
    Mark "yes" if an amniocentesis was performed during any stage of the pregnancy for the purpose of genetic testing only.
    (Does not include amniocentesis for assessing fetal lung maturity, diagnoses of ruptured membranes, OD testing in cases of isoimmunization, cord blood sampling or intra-uterine blood transfusion etc.)
    Record **gestational week** when procedure was performed.

32. **Diabetes mellitus:** yes/no
    Mark type of diabetes:
    Pre-gestational diabetes
    Diabetes treated with insulin or hypoglycemic therapies AND was diagnosed pre LMP of current pregnancy.
    Gestational diabetes
    Diagnosed by 2 pathological values during 100 gram glucose tolerance test performed during the current pregnancy (according to the values published by the international work group in 1985: 0,105; 1,190; 2,165; 3,145) without diagnosed pre-gestational diabetes (unless during previous pregnancies).

33. **Hypertension:** yes/no
    If "yes" mark type of hypertensive disorder:
    Pregnancy induced hypertension (PIH)
    Hypertension (systolic BP equal or greater than 145 mm mercury or diastolic BP equal or greater than 95 mm mercury as measured on at least two separate measurements , with at least 4 hours between them) , which first occurred **after** the 20^{th} week gestation of current pregnancy.
    This includes both proteinuric PIH and non - proteinuric PIH.

    Chronic Hypertensive Disorder
    Hypertension (as defined in PIH) that first appeared before 20^{th} week of the current pregnancy or beginning of the pregnancy. Hypertension presenting **after** the 20^{th} week of pregnancy of a previous pregnancy is **not** included in this definition.

    In event of PIH on the background of an existing chronic hypertensive condition, record only "chronic hypertensive disorder". Do not record both PIH and chronic hypertensive disorder.

34. **Eclampsia:** yes/no
    Tonic-clonic seizures during third trimester of pregnancy or during the first 10 days post partum, in a woman with hypertension pre or post contractions, and who does not suffer from a known chronic convulsive disorder.

35. **Other chronic disease:** yes/no
    Mark "yes" in event of woman suffering from chronic illness during current pregnancy (**not** including diabetes or hypertension) and **specify primary diagnosis.**

Perinatal Complications and Treatments

36. **Preterm labor:** yes/no

a. First contractions appear before 35th week of pregnancy, at a frequency of 4 or more in 30 minutes.

AND b. Cervical effacement of over 50% and cervical dilation without contractions greater then 1 cm in primipara and greater than 2 cm in multipara

Mark "yes" only if both a and b are present.

37. **Cervical incompetence:** yes/no

EITHER a. Previous or current pregnancy characterized with cervical dilation in second trimester (weeks 14-26) without premature contractions.

OR b. Cervical incompetence diagnosed by radiological studies of uterus or other examination of the cervix.

38. **Premature rupture of membranes:** yes/no

Membrane rupture starting prior to onset of contractions.

39. **Prolonged membrane rupture:** yes/no

Membrane rupture occurring 12 or more hours prior to delivery.

If "yes" then mark length of PROM: 12-24 hours/24-48 hours/>48 hours/

If more than 48 hours record number of days.

It is possible to have prolonged membrane rupture without premature rupture (ie membrane rupture after onset of contractions, for more than 12 hours). In this case mark "no" for premature rupture of membranes and "yes" for prolonged rupture of membranes.

40. **Amnionitis:** yes/no

An oral temperature of more than 37.8 º or rectal temperature of more than 38.0 º, measured at least twice in a one hour period:

a. During birth, after amniotic sack has ruptured

OR b. During the first 6 hours after birth

AND c. No other proven source of fever such as urinary tract infection, respiratory infection, etc.

41. **Placental abruption / Placenta previa:** yes/no

Placental abruption: Vaginal bleeding (not associated with placenta previa) with clinical symptoms of abruption, an US exam demonstrating an area of abruption or post partum demonstration of a definite area of abruption.

Placenta previa: Placenta shown to be partially or fully covering cervix by US, C-Section or manual prenatal exam.

42. **Induced delivery:** yes/no

If "yes", mark primary reason for induction:

Suspected fetal distress or Intra Uterine Growth Retardation

Mark if the primary reason for delivery was suspected fetal distress or IUGR

OR

Induction for maternal medical reasons

Mark if primary reason for delivery was for maternal medical reasons.

This section relates to medical conditions in which continuing the pregnancy could have endangered the mother's health such as heart disease, eclampsia. The primary reason for induction was directly related to mother's heath and not for a fetal problem.

Mark the primary cause. Do not mark both fetal distress and maternal causes.

43. **Live birth resulting from termination of pregnancy**: yes/no
Mark "yes" if infant was born alive following a pregnancy termination, according to the Pregnancy Termination Law, and a live birth certificate was registered.

44. **Antenatal steroid therapy:** yes complete/ yes partial/ none
Mark "**yes complete**" in event the birth was more than 24 hours and less than 7 days after start of steroid treatment.
Mark "**yes partial**" in event the birth was less than 24 hours after first dose or more than 7 days after final dose of antenatal steroids.
Mark "**none**" in the event no antenatal steroids were given.

45. **Tocolytic therapy during pregnancy:** yes/no
Mark "yes" only in the event of the tocolytic therapy being given for at least 12 hours.
In the event of the mother being treated for only a shorter period of time, or with a single treatment (such as Indomed) less than 12 hours prior to the delivery, mark "no".
Mark the type of treatment received (beta-mimetic/indomed/magnesium/other).
More than one medication may be recorded but only medications fulfilling the above criteria.
Mark only treatment given in order to stop contractions: eg do not record magnesium given for treatment of hypertension.

46. **Notes**:
Record notes (free text) that may be important for clarifying data registered on the form.

FORM 2- Infant data

Infant identification data:

1. **Infant's identification number**
2. **Infant's birth hospital**
3. If transferred to another hospital – **name of hospital to which transferred**
4. **Date of birth**
5. **Mother's identification number**
6. **Mother's first name**
7. **Mother's surname**

Infant's birth data:

8. **Location of birth** – record if born in hospital, ambulance, home or other.

9. **Type of delivery** – Mark cesarean section / vaginal accordingly.

10. **Apgar score 1 min** – record apgar score at age 1 minute

11. **Apgar score 5 min** – record apgar score at age 5 minutes

    Apgar scores as recorded in delivery room documentation.

12. **Birth weight** – record birth weight in grams, as registered in delivery room documentation. If not weighed in the delivery room, record first weight on admission to neonatal department

13. **SGA / LGA / AGA** – according to weight for gestational age at delivery.
    Record appropriate (AGA), small (SGA), or large (LGA) according to Kramer et al gender specific birth weight /gestational age percentiles (Pediatrics 2001; 108: E35)

14. **Length at birth** – if measured, record length in cm (including $1\backslash 10^{th}$) as registered upon admission.

15. **Head circumference at birth** – if measured, record circumference in cm (including $1\backslash 10^{th}$) as registered upon admission.

16. **Intervention** (forceps / vacuum) – mark "yes" if forceps or vacuum were used during delivery. Mark "yes" also if the attempted intervention failed.

17. **Presentation** (vertex / breech / other) – record infants presentation as registered in delivery room records. For this purpose presentation is defined as the one infant is in during birth or C/S prior to any intervention aimed at changing the presentation.

18. **Cord blood gases** – Mark "yes" if cord blood was taken for blood test AND a result was given. In the event of cord blood being taken and the test not successful (because of technical or other reasons), or if blood was tested for other purposes (such as blood groupe, hemoglobin), mark "no".
    Record pH, bicarbonate, base excess (including +\- in marked place)

19. **Resuscitation in delivery room** yes/no
If "yes" record all treatments:
"Oxygen" – if infant received supplemental oxygen in delivery room.
"Ventilation (mask)" – if infant received positive pressure ventilation via face mask
"Intubation and ventilation"- if infant was ventilated via ET tube. If infant was intubated for purpose of suction only and the infant was not ventilated – do not mark.
"Cardiac massage"
"Epinephrine"

Infant's disposition

Record **infant's disposition**:

20. If **died in delivery room** record only infant's birth data (ITEMS 1-19) AND if **congenital malformations** were observed at birth list specific malformations (Item 51).

21. If **died before 24 hours** of age record date of death and age of death in hours.

22. If **died after 24 hours** of age record date of death and age of death in days.

23. If **discharged** record date of discharge and age at discharge in days
Record all **discharge information**:
28. **Address** – residential address, area code and telephone number at discharge.
29. Record **name of discharging hospital**
30. Record **weight at discharge** (in grams)
31. Record **length at discharge** (in cm)
32. Record **head circumference at discharge** (in cm)
33. Mark all **treatments and\or support** infant was given upon discharge:
Supplemental oxygen / Steroids / Methylxanthines / Anticonvulsant therapy / Monitor/ Gastrostomy/ Tracheostomy / Stoma / Ventriculo-peritoneal shunt
Mark "monitor" only if used according to medical instruction.

24. If **still admitted in hospital** when completing data form, record date.

25. If **transferred to another hospital before age 24 hours**, record hospital name, date of transfer and age in hours.

26. If **transferred to another hospital after age 24 hours**, record hospital name, date of transfer and age in days.

27. **Reason for transfer**: Record primary reason for transfer
Mark "intensive care\special" in event of infant is being transferred because of a need for intensive care or specialized treatment not available at your hospital
Mark "surgery" (specify type) in event of infant being transferred in order to undergo surgery (ie cardiac, neurosurgery) even if surgery was not performed.
Mark "medical or diagnostic consult" in event of infant being transferred for consultation, even if consult results in surgery.
Mark "Shortage of beds in referring hospital" in event infant was transferred to a different ward for intensive care\special or surgery even if these exist in your ward\hospital, and the only reason for transfer was lack of beds\full capacity.
Mark "Chronic treatment" in event infant was transferred for prolonged chronic treatment.
Mark "Growth\discharge planning" in event infant was transferred to another hospital for continuing treatment before discharge home.

Infant's Hospitalization- Diagnoses and Treatment

34. **Respiratory Diagnoses**

Mark "yes" or "no" for each of the respiratory diagnoses as defined:

Respiratory Distress Syndrome

a. $PaO_2 < 50$ mmHg in room air, central cyanosis in room air, or requiring supplemental oxygen to maintain $PaO_2 > 50$ mmHg.
AND b. A chest radiolograph consistent with RDS (low lung volumes and reticulogranular apperarance of lung fields, with or without air bronchograms).

Transient Tachypnea of the Newborn

a. Tachypnea (> 60 breaths/minute) during the first day of life.
AND b. $PaO_2 \leq 50$ mmHg in room air or central cyanosis in room air or requiring supplemental oxygen to maintain $PaO_2 > 50$ mmHg.
AND c. Chest X-ray showing hyperinflation and perihilar or pleural fluid with no evidence of hyaline membrane disease.
If another reason for respiratory distress was diagnosed, such as pneumonia, meconium aspiration, etc. mark "no"

Pneumothorax

Extrapleural air diagnosed by chest X-ray or needle aspiration
If free air was present on a chest X- ray taken immediately after thoracic surgery and was not treated with a chest tube, mark "no"

Pulmonary Interstitial Emphysema

a. Chest X-ray showing radiolucent interstitial air.
AND b. Deterioration in respiratory status as defined by an increase in ventilatory requirement (either FiO_2, rate or pressure).

Apnea of Prematurity

a. Apneic spells of $\geq$ 20 seconds.
OR b. Apneic spells of $\geq$ 10 seconds associated with bradycardia (< 100 beats/min) or central cyanosis or $SaO_2 < 88\%$ or $PaO_2 < 50$ mmHg.
AND c. Necessity for therapy including methylxanthines, CPAP.
AND d. No other clinical or laboratory diagnosis as cause of apnea including sepsis, PDA, seizures, intracranial hemorrhage, etc.

Other Respiratory Disorders

Including pneumonia, aspiration syndromes, persistent pulmonary hypertension, etc.
Do not include congenital malformations such as pulmonary hypoplasia, adenomatous malformation, diaphragmatic hernia, etc. Do not include BPD

35. **Respiratory assistance during hospitalization**

Mark "yes" or "no" for each of the respiratory therapies:

For each therapy record total number of days the treatment was given throughout the hospitalization.

Did not receive respiratory assistance

The infant never received supplemental oxygen, nasal CPAP or any form of assisted ventilation (conventional or high frequency) at any time after leaving the delivery room.

Oxygen

The infant was given supplemental oxygen at any time after leaving the delivery room. Includes supplemental oxygen administered during ventilation/CPAP.

Nasal CPAP

The infant was given continuous positive airway pressure via nasal prongs at any time after leaving the delivery room.

IMV

The infant was given intermittent positive pressure ventilation with a conventional ventilator (IMV rate < 240/minute) at any time after leaving the delivery room.

HIFV

The infant received high frequency ventilation (IMV rate ≥ 240/minute) at any time after leaving the delivery room.

Surfactant

Record type and number of doses.
Record exogenous surfactant at administered at any time during hospitalization

36. **CRIB score**

The following data are required for calculation of CRIB score:
Record most appropriate FiO2 prior to age 12 hours
Record BOTH highest and lowest values

The most appropriate FiO2 is defined as FiO2 given:
a. When PaO2 (arterial or through skin) is within the range 50-80mm Hg
OR b. When FiO2 is over 25%, the FiO2 needed to maintain saturation (SaO2) is within 88-95% range
OR c. When FiO2 is between 21-25%, the FiO2 needed to maintain saturation over 88%.

Record highest (worst) base deficit measured prior to age 12 hours

37. **Maximal ventilation on day 3 (age between 48-72 hours)**

Record the maximal respiratory parameters at age 48-72 hours:
Maximal FiO2 (between 21-100), PIP, PEEP, PaO2 and Oxygenation Index
Oxygenation Index calculated: $\frac{100 \times FiO2 \times MAP}{PaO2}$

38. **Bronchopulmonary Dysplasia** yes/no
Mark "yes" only if all 4 criteria present according to definition of Banclari et al. (J Ped 1979, 95:819)
a. Positive-pressure ventilation in the first week of life for a minimum of 3 days.
AND b. Clinical signs of chronic respiratory disease, including tachypnea, chest retractions, and rales beyond 28 days of age
AND c. Requires supplemental oxygen to maintain PaO2 beyond 28 days of life.
AND d. Chest X-ray demonstrating persistent strands of densities alternating with areas of hyperinflation.

Record the **FiO2** (21-100) infant received at **age 28 days**.
Record the **FiO2** (21-100) infant received at **corrected age of 36 weeks**

Steroid treatment for chronic pulmonary disease: yes/no
Mark "yes" if received steroids for treatment for BPD/chronic pulmonary disease.
Mark "yes" if preventive steroid therapy was given.
Record FiO2 and steroid treatment even if pulmonary disease does not comply with BPD definition as stated.

39. **Patent Ductus Arteriosus** yes/no
Mark "yes" only if PDA diagnosed as defined by Bandstra et al (Pediatrics 1988;82:533):
Heart murmur compatible with a PDA and/or Doppler evidence of left-to-right ductal shunting and 2 or more of the following:
a. Bounding peripheral arterial pulses
b. Hyperdynamic precordial pulsation
c. Radiographic evidence of cardiomegaly or pulmonary edema
d. Inability to decrease ventilator settings (pressure, rate, FiO2) after 48 hours from the time of birth. (If one or more of these parameters can be consistently decreased, an infant does not meet this criterion).
If PDA "yes" then record **treatment** :
Medical (Indomed\Neurofen) and/or surgical treatment

40, 41 **Sepsis**

40. **Early** – before age 72 hours: yes/no
Mark "yes" if bacteria\fungus present in blood culture taken before age 72 hours.
Record name of pathogen.

41. **Late** – age 72 hours or more: yes/no
Record all episodes of sepsis from age 72 hours until discharge.
For each episode record **age** in days and **name of pathogen**.
Record "Staph Coagulase Negative" only if sepsis was diagnosed according to **all 3 of the following**:
a. A positive culture for Staph Coagulase Negative
b. Clinical signs of sepsis
c. Intravenous antibiotic treatment for 5 or more days after taking the culture OR until date of death, in the event of death occurring less than 5 days after taking the culture.
In event of another pathogen as well as Staph Coag Neg being isolated on same occasion, record only the other pathogen.

42. **Meningitis:** yes/no
Mark "yes" if bacteria\fungus was present in spinal fluid culture, taken during a spinal tap or brain ventricle tap or shunt.
Record **name of pathogen**.

43. **Necrotizing Enterocolitis:** yes/no
Mark "yes" only in cases of NEC diagnosed according to following definition:
a. One or more of the following clinical signs present:
1. Bilious gastric aspirate or emesis
2. Abdominal distension
3. Occult or gross blood in stool (no fissure)
AND b. One or more of the following radiographic findings present:
1. Pneumatosis intestinalis
2. Hepato-biliary gas
3. Pneumoperitoneum

Record level of severity as 2 or 3 according to Bell et al (Ann Surg 1978;187:1-8):

Stage	Clinical Findings	Radiographic Findings
1. Suspected NEC	Mild abdominal distention Poor feeding Gastric residual Vomiting (may be bilious) Occult blood	Mild ileus Distension
2. Definite NEC	The above plus Marked abdominal distention GI bleeding	Significant ileus Pneumatosis intestinalis Portal vein gas
3. Advanced NEC	The above plus Deterioration of vital signs Septic shock Marked hemorrhage	The above plus Pneumo-peritoneum

Suspected NEC (level 1) is **not** included in the NEC definition and only levels 2 or 3 should be recorded.
Mark if **surgical treatment** for NEC was performed.

44. **Retinopathy of prematurity (ROP)**
Fundus Examination: yes/no
If exam was performed – record **maximum degree of severity of ROP** for each eye according to International classification or ROP (Pediatrics 1984;74:127):
Stage 0: No evidence of ROP
Stage 1: Presence of demarcation line (± abnormal vascularization)
Stage 2: Presence of intraretinal ridge
Stage 3: Presence of a ridge with extraretinal fibrovascular proliferation
Stage 4: Retinal detachment

Plus Disease: yes/no - presence of posterior vascular dilatation and tortuous arterioles

Treatment: Cryotherapy\Laser Treatment\Avastin injection – mark "yes" if done. Record treatment for each eye separately.

45. **Periventricular - Intraventricular Hemorrhage (PVH)**
Cranial ultrasound exam done before age 28 days: yes/no
If multiple exams were done or PVH was diagnosed during autopsy record the **maximal severity of bleeding. Record maximal grade for each side separately:**

Grade 0: No subependymal or intraventricular hemorrhage
Grade 1: Subependymal germinal matrix hemorrhage only
Grade 2: Intravenricular blood, no ventricular dilation
Grade 3: Intraventricular blood, ventricular dilation
Grade 4: Intraparenchmal hemorrhage

46. **Cystic Periventricular Leucomalacia (PVL)**
Cranial ultrasound exam done after age 28 days: yes/no
Record if **PVL** was observed.
PVL includes Multiple Small Periventricular cysts
Excludes a. Periventricular echogenecity without cysts
OR b. Porencephalic cyst in the area of a previously identified intraparenchymal hemorrhage

47. **Post hemorrhagic hydrocephalus**
Mark "yes" if diagnosed according to definition:
a. Diagnosis of intraventricular hemorrhage (according to item #45)
AND b. Ventricular dilation as measured by a ventricular index ≥ 4mm above the 97th percentile for corrected age (gestational age plus chronological age), according to Levine (Arch Dis Childh. 1981;56:900).

48. **Ventriculostomy or VP shunt:** yes/no
Mark "yes" if either or both procedures performed

49. **Seizures:** yes/no
Mark "yes" if any seizures were observed during hospitalization.
Anti-convulsive treatment: yes/no
Mark "yes" if any anti-convulsive treatment was administered, including single dose or preventative therapy.

50. **Bilirubin**

Record **highest total bilirubin** level measured during hospitalization in mg\100 cc **or** in mmol\l.

Exchange transfusion: yes/no

Mark "yes" only if performed as a treatment for hyperbilirubinemia .

51. **Major birth defects**

Record birth defects diagnosed during hospitalization according to the Ministry of Health list of reportable birth defects on birth certificate (see MOH directive)
Record all specific defects and their ICD-9 codes.

52. **Notes**

Record notes (free text) that may be important for clarifying data registered on the form.