

Hospital-based Birth Defects Surveillance

A Guide to establish and operate



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Hospital-based birth defects surveillance: a guide to establish and operate.

1. Congenital Abnormalities 2. Hospitals 3. Data Collection 4. Counseling

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Background

Birth defects (also called congenital anomalies) are defined as abnormalities of body structure or function that are present at birth and are of prenatal origin. Birth defects contribute to a significant proportion of perinatal, neonatal and child mortality.

Globally, about 7.9 million children are born annually with a serious birth defect of genetic or partially genetic origin, as per the estimates provided by March of Dimes Report (2006). WHO estimates that out of 1 million neonatal deaths in 2012 in the South-East Asia Region, about 46 000 (4.6%) were caused by birth defects.

The birth defects spectrum involves different organ systems, the most common being congenital heart diseases (CHD), neural tube defects (NTDs), and Down syndrome followed by hemoglobinopathies, musculoskeletal disorders and others. Many risk factors are known to be associated with birth defects such as genetic factors; maternal conditions, such as diabetes and obesity; maternal age; and behaviours and environmental exposures. The prevalence and spectrum of birth defects varies among different communities and regions depending on the presence or absence of these risk factors.

Since many of these factors are preventable, a wide range of preventive approaches are possible through legislation and policies. Some of the effective interventions are vaccination against rubella; folic acid supplementation; fortification of staple foods with micronutrients (iodine and folic acid); prevention and management of syphilis and diabetes in mother; controlling use of toxic chemicals; a timely identification of a family risk of inherited disease; and carrier screening with genetic counseling, etc.

Adequate data and information on birth defects is not available in many countries of the South-East Asia Region. Such information is important to understand the public health burden and to design prevention and management programmes in the country. To improve data and information, there is a need to develop surveillance mechanisms. In the Region, it has been considered to establish hospital-based surveillance for birth defects to begin with, initially starting in selected hospitals with a high load of childbirths. In due course and with experience, this could be expanded to other hospitals, so that the data collected would be representative of most of the regions in the country. Later, population-based surveillance may be considered depending on availability of resources.

Basic Concepts of Birth Defects Surveillance

A. Birth Defects Surveillance:

Public health surveillance is defined as an ongoing, systematic collection, analysis and interpretation of health data essential to the planning, implementation and evaluation of public health practice. This is closely integrated with the timely dissemination of these data to those who need to know. The final link of the surveillance chain is the application of the data and information to prevent and control birth defects.

Objectives of birth defects surveillance:

- (1) To define the magnitude and distribution of birth defects by time, person and place
- (2) To identify high-risk populations or identify clusters (aggregation of cases)
- (3) To refer affected infants to appropriate services in a timely manner
- (4) To monitor trends in the prevalence of different types of birth defects in a defined population.

It is proposed to begin with hospital-based surveillance for birth defects, initially starting in selected hospitals with a high load of childbirths. In due course and with experience, this could be expanded to other hospitals, so that the data collected would be representative of most of the regions in the country.

B. Inclusion Criteria:

The following will be the inclusion criteria for a newborn to be enrolled in the hospital-based birth defects surveillance.

- Fetus/baby (live births and stillbirths) delivered in the hospital
- Birth defects identified at birth or until 7 days of life
 - Babies delivered at a gestation period of 22 weeks or more, or a birth weight of at least 500g when gestation period is not available
 - Live births and stillbirths born with a birth defect. Under SEAR_NBBD initial focus is on the following major structural birth defects. No baby born in hospital with any of these birth defects should be missed.

Externally visible major birth defects (Essential)	Other birth defects (Optional)
1. Neural tube defects 2. Oro-facial clefts: Cleft lip/cleft palate 3. Talipes equinovarus – Club foot 4. Limb reduction defects 5. Hypospadias 6. Exomphalos / Omphalocele 7. Gastroschisis 8. Imperforate anus	1. Down syndrome 2. Congenital diaphragmatic hernia 3. Congenital heart disease 4. Tracheoesophageal fistula 5. Exstrophy of bladder 6. Other defects

All hospitals must identify and report the essential list of externally visible major birth defects at the minimum. These are easy to diagnose without many investigations and have major consequences or need urgent treatment.

Depending on the expertise and resources, hospitals should consider **optional birth defects** that are associated with major consequences, need urgent treatment but may need investigations to diagnose.

It is understood that hospitals may like to record any other birth defects (minor and major) that are detected in babies to provide appropriate counseling and services. These are not to be reported in the SEAR-NBBD database.

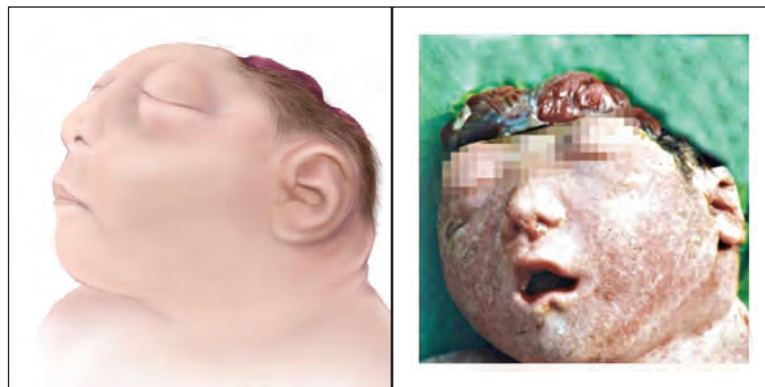
C. Case definitions:

The following standard case definitions will be used for the listed major birth defects:

Externally visible major birth defects (Essential)

1. Neural Tube Defects

Anencephaly (Q00.0): A congenital malformation characterized by the total or partial absence of the cranium vault, the covering skin and the brain missing or reduced to small mass.



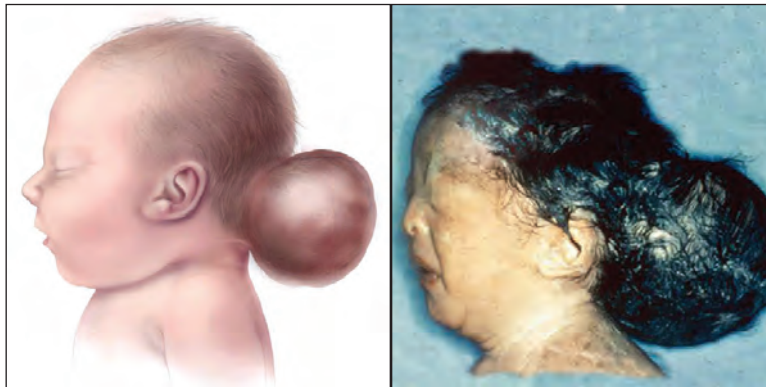
Craniorachischisis (Q00.1): Refers to the presence of anencephaly with a contiguous spine defect without meninges covering the neural tissue (rachischisis).



Iniencephaly (Q00.2): Iniencephaly is a rare and complex NTD involving the occiput and inion, resulting in extreme retroflexion of the head variably combined with occipital encephalocele or rachischisis of the cervical and thoracic spine. In iniencephaly, the cranium is always closed.



Encephalocele (Q01.0-Q01.2, Q01.8-Q01.9): A congenital malformation characterized by herniation of the brain and/or meninges through a defect in the skull. Encephalocele is not counted when present with spina bifida.

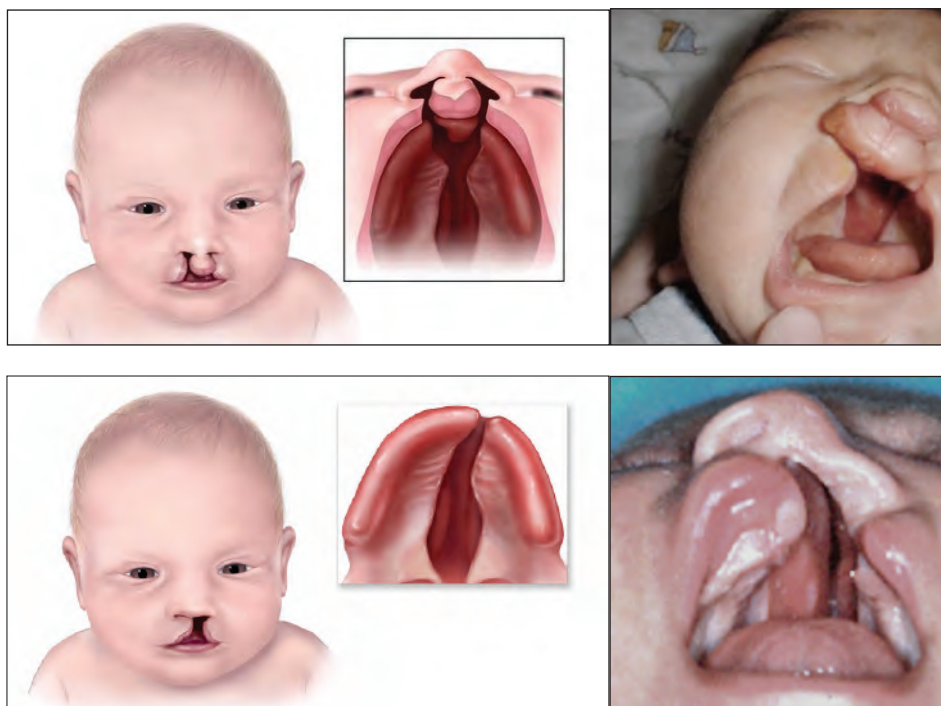


Spina bifida (Q05.0-Q05.9): Defects in the closure of the spinal column characterized by herniation or exposure of the spinal cord and or meninges through an incompletely closed spine. Such defects include: meningocele, meningomyelocele, myelocele, myelomeningocele and rachischisis.

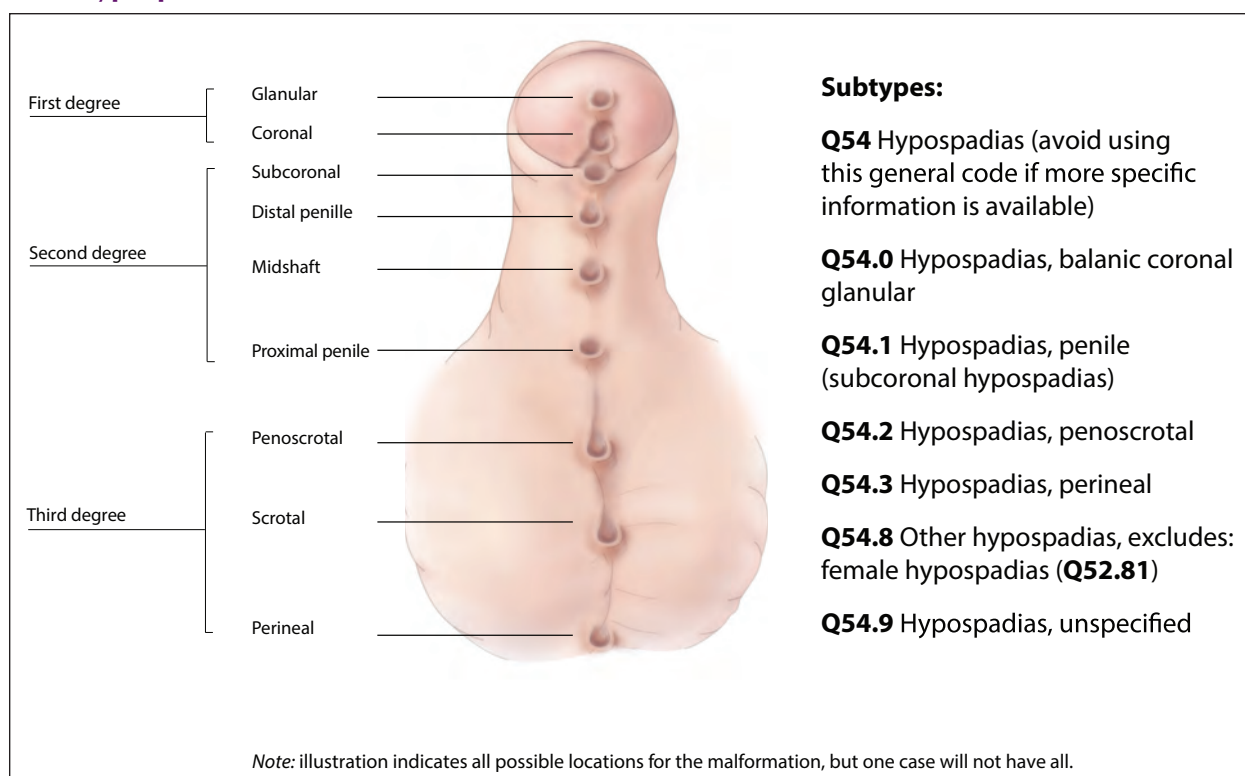


2. Orofacial Clefts

- **Cleft palate alone** (Q35.1-Q35.9, Q38.5, Q87.0): A congenital malformation characterized by a closure defect of the hard and/or soft palate behind the foramen incisivum without cleft lip. Includes submucous cleft palate
- **Cleft lip with or without cleft palate** (Q36.0, Q36.9), (Q37.0-Q37.9): A congenital malformation characterized by partial or complete
- clefting of the upper lip, with or without clefting of the alveolar ridge or the hard palate



3. Hypospadias (Q54.0-Q54.3, Q54.8-Q54.9):



A congenital malformation characterized by the opening of the urethra on the ventral side of the penis, distally to the sulcus. It includes penile, scrotal and perineal hypospadias. Excludes ambiguous genitalia.

4. Talipes equinovarus/clubfoot (Q66.0, Q66.8):



A complex deformity of the foot, with three basic characteristics: 1) the affected foot points downward (plantar or equine flexion); 2) the toes point inward (adduction of the foot); and 3) the sole is angled inward (varus deformity of the entire foot).

5. Limb reduction deficiencies (Q71.0-Q73.8):



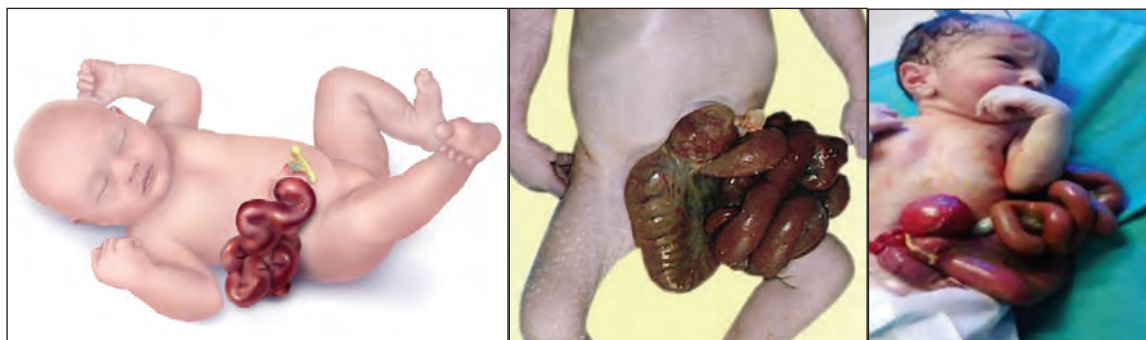
A congenital malformation characterized by total or partial absence or severe hypoplasia of skeletal structures of the limbs.

6. Exomphalos / Omphalocele (Q79.2):



A congenital malformation characterized by herniation of abdominal contents through the umbilical insertion and covered by a membrane which may or may not be intact. Excludes gastroschisis, hypoplasia of abdominal muscles, and a skin covered umbilical hernia.

7. Gastroschisis (Q79.3):



A congenital malformation characterized by visceral herniation usually through a right side abdominal wall defect to one side of an intact umbilical cord and not covered by a membrane. Excludes hypoplasia of abdominal muscles, skin covered umbilical hernia and omphalocele.

8. Imperforate anus (ICD code – Q42.3)



An **imperforate anus** or **anorectal malformations (ARMs)** are birth defects in which the rectum is malformed. ARMs are a spectrum of different congenital anomalies in males and females, which varies from fairly minor lesions to complex anomalies.

Optional birth defects

1. Down syndrome/ Trisomy 21 (Q90.0, Q90.1, Q90.2, Q90.9)

Down syndrome is a chromosomal disorder that is characterized by the presence of flat facies, upslant, depressed nasal bridge, hypertelorism, small ears, hypotonia, protruded tongue, simian crease and space between big toe and second toe (sandal gap). These babies have varying degrees of intellectual disability



Dysplastic middle phalanx of 5th finger-Clinodactyly



Simian crease

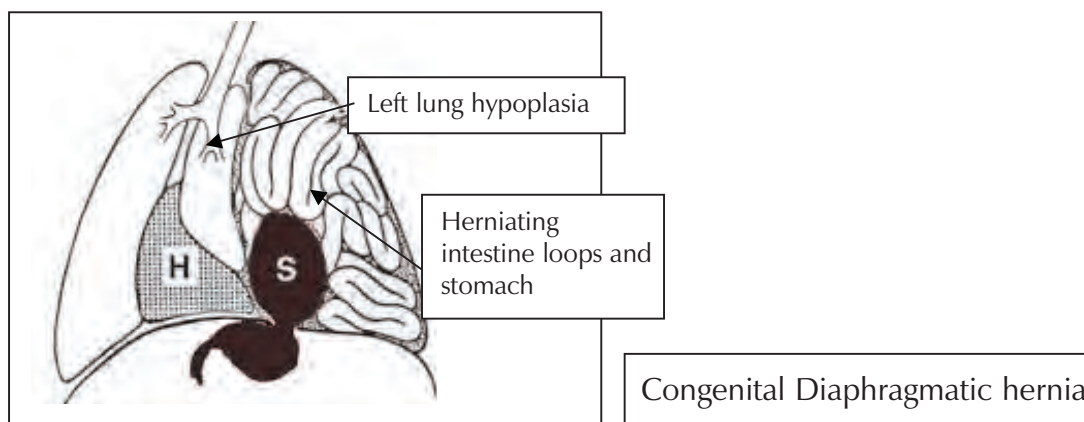
Short and broad hands and small fingers



Increased space between 1 and 2 toes- Sandal Gap

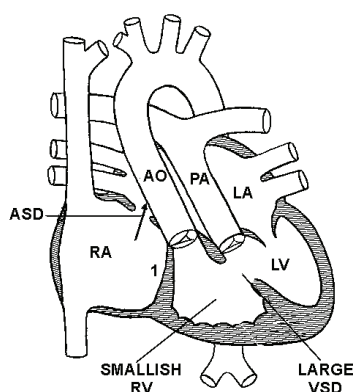
2. Congenital Diaphragmatic Hernia (Q79.00, Q79.01, Q79.1, Q79.10, Q79.11, Q79.12)

CDH occurs due to a defect in the formation of diaphragm through which gastrointestinal organs like stomach, intestines and liver can herniate into the chest causing poor development of the lungs resulting in life threatening breathing difficulties at birth. Picture shows right sided congenital diaphragmatic hernia.

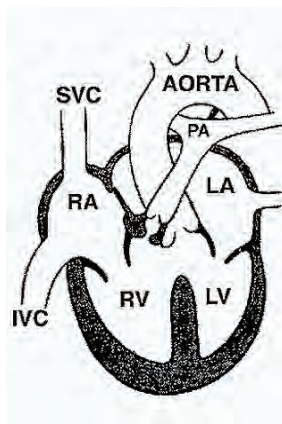


3. Congenital malformations of cardiac chambers and connections (Q20-Q28)

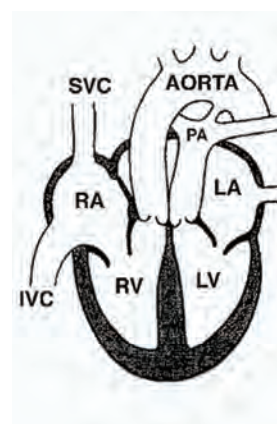
A congenital malformation of the structure of the heart can involve the walls or valves of the heart, and aorta or other large blood vessels near the heart. There are many types of congenital heart diseases; some of the common ones are atrial septal defect (ASD), ventricular septal defect (VSD), pulmonary (valvular) stenosis, aortic stenosis, coarctation of the aorta, Tetralogy of Fallot, and Transposition of the great arteries (TGA).



ASD and VSD



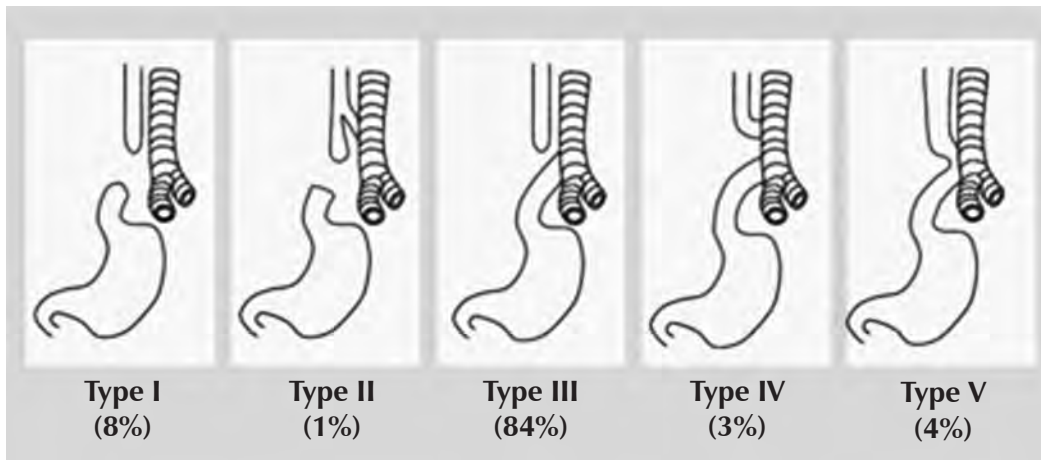
Tetralogy of Fallot



TGA with VSD

4. Tracheo-oesophageal fistula (Q39.0, Q39.1, Q39.10, Q39.11, Q39.2, Q39.20, Q39.3)

Tracheo-oesophageal fistula (TEF) is an abnormal connection between the food pipe (esophagus) and the wind pipe (trachea) which presents in a newborn by copious salivation associated with choking, coughing, vomiting and cyanosis with the initiation of feeding.



5. Exstrophy of bladder (Q64.1)

Bladder exstrophy is a congenital anomaly in which the bladder is incomplete and protrudes out through a defect in the abdominal wall.



D. Case Ascertainment:

All births (live and still) must be clinically screened for presence of birth defects, at birth and before discharge (or death) from the hospital.

- The doctors (pediatric/OBG) and or nurses present in the delivery area (labour room/O.T.), postnatal wards and neonatal/pediatric units will be responsible to screen all the births.
- They will conduct a complete head to toe examination of the live newborn /stillbirth (>500 g / 22 weeks gestation) by examination of head, face, ears, back, abdomen, pelvis, limbs, genitals and anus and note the birth defects, if present.
- The cases with birth defects will be referred to the appropriate specialty for full clinical work up and relevant investigations for confirmation of diagnosis, including karyotyping and genetic studies, as required as well as for treatment and care.

Establishing BD Surveillance in Hospitals

Administrative arrangements in hospitals

- Head of Departments of Pediatrics / In-charge Neonatology and Head of Departments Obstetrics
- and Gynaecology would collaborate and coordinate to establish birth defects mechanisms in hospitals. They will be receiving training for birth defects surveillance organized by the Ministry of Health.
- One of them may be assigned as the nodal officer for birth defects surveillance at the hospital.
- After being trained, the Head of Departments of Pediatrics / In-charge Neonatology and Head of Departments Obstetrics and Gynaecology would convene a meeting in the hospital with relevant staff to:
 - Plan to establish surveillance of birth defects in the hospital
 - Identify personnel for:
 - Data collection: doctor/resident doctor /nurse
 - Enter the data online to the SEAR-NBBD Database: resident doctor /nurse / medical record clerk/data entry operator
 - Share the SOPs to be followed to manage the surveillance system in the hospital
- The nodal officer (who has received training in birth defects surveillance) would further train the identified personnel (resident doctors, nurses, working in the Pediatric and Obstetrics and Gynaecology Department; and data entry operator) regarding the filling of the birth defects abstraction form including standardized coding.
- Adequate number of copies of birth defects abstraction forms would be made available in hospital delivery (labour) rooms, operation theaters, postnatal ward and neonatal units.
- Manual and Atlas of birth defects surveillance and wall posters (ANNEXURE I) on birth defects will be made available in these sites.
- Computer and a broadband connection will be required for online submission of the forms to the SEAR-NBBD database. Mobile apps for smart phones (Android and iOS systems) would be available soon for data entry under the SEAR-NBBD.

Essential tasks

Filling the data abstraction form

- If a baby is detected with birth defect/s, the standard data abstraction form (ANNEXURE II) will be filled and attached to the case sheet/records of the baby.
- All the fields in the abstraction form must be filled completely. (Refer to ANNEXURE III for SOPs for the form.) It is especially important to provide a complete physical description of the birth defects in the text box.

- Complete and correct information must be ensured by using case sheets of mother and baby and taking further history from the mother as required.
- In cases when birth defects are missed at the time of delivery, they may be detected after babies are transferred to the postnatal ward or neonatal unit/pediatric ward. In such cases, the form will be filled there.
- Photographs of birth defects should be taken as per the standard procedure (ANNEXURE IV).
- At the time of discharge or death of a baby, the filled form will be taken out of the case sheet and stored in the designated folder available with the hospital nodal officer for birth defects surveillance. It is important to keep these records for later need of confirmation/validation.
- Details of the birth defect/s in each baby will also be recorded in the labour room/OT register, admission and discharge /death registers maintained by the hospital.

Confirmation and coding of birth defects

- Birth defects forms would be further completed in the following situations:
 - After any confirmatory tests (like Xray, USG, MRI, CECT, karyotyping, etc.).
 - A new or additional defect is detected during the baby's stay in the postnatal ward or neonatal unit/pediatric ward.
- Select the most appropriate ICD-10 code selected from the ICD-10 list to describe all birth defects observed (based on the description and photograph included in the form). The online system provides the support for assigning the ICD codes for several birth defects through the dropdown menus. (Complete list of ICD codes for birth defects is available at the web link: <http://www.who.int/classifications/icd/en/>)

Uploading the data on the online SEAR-NBBD system

- First-time registration: Refer to ANNEXURE V for online registration to SEAR-NBBD
- Refer to ANNEXURE VI for logging in and entering birth defects form
- Upload the photograph of the birth defect/s.

Management of birth defects

- Upon identification of a birth defect, it is essential to provide appropriate services:
 - Immediate management and referral within or outside the hospital by referral.
 - Information about the risk of recurrence. A couple with isolated fetal birth defects is given a recurrence risk of about 5 % in the next pregnancy (ANNEXURE VII).
 - Information on preventive measures to prevent that defect in that family in future.

Quality assurance of surveillance at the hospital level

- Nodal person/s responsible for birth defects surveillance in hospitals are responsible for quality assurance of data and information on each baby that should cover three aspects:
 - Completeness
 - Accuracy
 - Timeliness

- Ensure that all babies delivered in the hospital (live births and stillbirths) are clinically examined for detection of birth defects at the earliest opportunity after their delivery.
- Ensure that the birth defects form for each baby born with birth defect/s is filled completely and accurately before discharge or death.
- Ensure that the completed BD form is uploaded to the SEAR-NBBD as soon as possible.
- Each filled out birth defects form is checked for completeness and accuracy and taken out of the baby's case sheet before it is dispatched to the hospital records section.
- All filled out birth defects forms are stored in the designated folder under lock and key.
- In addition, scanned copies of filled out birth defects forms as well as photographs (that are appropriately labeled) are electronically stored in the computer that is password protected.
- Quality assurance applies to the paper forms as well as the online data submitted from the hospital (ANNEXURE VIII).

Analysis and interpretation

- Nodal person/s will tabulate and analyse the data every month, quarterly and yearly.
- Analysis is done for:
 - Birth prevalence of birth defects in live born and stillborn babies separately.
 - Distribution of birth defects in relation to its type, sex of the baby, gestation of the baby, and risk factors included in the birth defects form.
- Time trends are to be determined as the time passes.
- Nodal person/s will arrange briefings of the whole team: hospital superintendent, staff in Pediatrics and Obstetrics and Gynaecology Departments, and data reporters.
- Quarterly and annual reports are to be shared with the district/state programme manager and onward with the national programme manager.

Assessment for quality of birth defects surveillance at a hospital

The nodal officer for birth defects surveillance at the hospital is expected to do a periodic assessment of quality of the surveillance. This could preferably be done once every month for ongoing quality assurance.

In addition, the district /state programme manager is expected to undertake quality assessment at the participating hospital. This could be done once every quarter.

A simple and short checklist is provided in ANNEXURE IX. This can be used both for routine ongoing quality assurance as well as less frequent external assessment for improving the quality of the database.

Roles and responsibilities

A. Data reporters (personnel assigned and responsible for data collection and uploading on the online system):

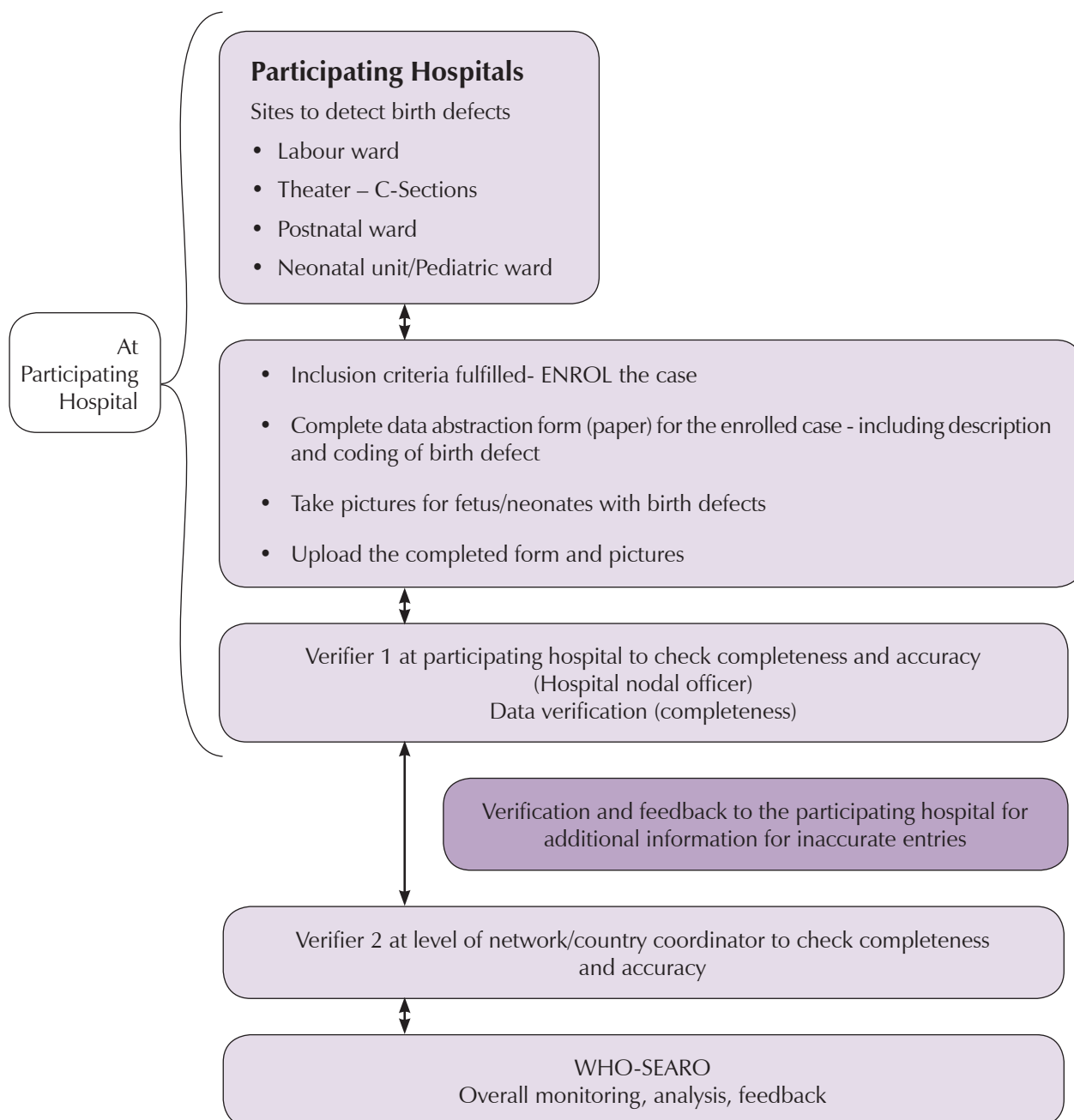
- She/he will ensure that babies (live and stillborn) are examined in the delivery rooms, operation theaters (for C-Section), postnatal ward and neonatal unit/ pediatric ward in the hospital soon after delivery.
- She/he will conduct a complete physical examination of all live born/stillborn babies including examination of the head, face, mouth, ear, chest, back, abdomen, pelvis, upper and lower limbs, genitalia and anus to detect any birth defect/s.
- If a baby (live born or stillborn) is identified with a birth defect, she/he will completely fill the birth defects abstraction form including complete description of the birth defect/s.
- In addition to completing the form, she/he will take standard photographs of the birth defect/s.
- She/he will select the most appropriate ICD-10 code for all birth defects observed by using the Birth Defects atlas.
- When there is difficulty in identifying the diagnosis of a case, final classification and diagnosis will be done by more experienced staff with confirmatory tests.
- She/he will also record the birth defect(s) in the delivery, admission and discharge/death register/ log books maintained in the hospital.
- She/he will be responsible for entering the data from the paper form into the online system, making sure that all the fields are filled accurately.
- After completion, the form will be submitted by clicking the submit button.
- On submission to the online system, a unique id number is automatically generated by the SEAR-NBBD system.
- Write this unique id number on the paper form of the baby for the records.
- Provide total number of births (live and still) that took place in the hospital in every month, by the 10th day of next month. This will serve as the denominator for the analysis.

B. Hospital nodal person/s for birth defects surveillance (including role of verifier)

- Orient personnel (residents, nurses) working in the Pediatric and Obstetrics and Gynaecology Department regarding correctly and completely filling out the birth defects abstraction form.
- Provide ongoing support for skills-building and problem solving.
- Undertake quality check of the data (for verifier role, see ANNEXURE VIII): Review the birth defects form for completeness and accuracy, and confirm the diagnosis of the birth defect/s before or after submission online. The total number of births (live and still) in a month must also be confirmed and verified.

- Analyse the data on birth defects among intra-mural births every month, quarterly and annually, and discuss with the hospital team.
- Share the analysis with district/state/national programme manager at quarterly /annual intervals.
- Arrange for appropriate care, management and counseling in the hospital or by referral, as feasible.

Flow of birth defects surveillance at a participating hospital



Annexes

Annex 1

Sample of Wall poster

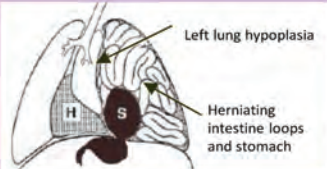
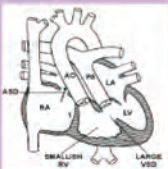
LET'S COUNT AND PREVENT BIRTH DEFECTS

Essential Birth Defects

Neural Tube Defects					Limb Defects		Hypospadias
							
Anencephaly	Craniorachischisis	Meningocele	Encephalocele	Congenital absence of both forearm and hand	Congenital absence of finger (s) and toes		
							
Cervical spina bifida	Iniencephaly	Lumbar spina bifida	Sacral spina bifida	Amelia of lower limb	Talipes equinovarus		

Facial Defects			Imperforate anus	Abdominal wall Defects	
					
Cleft palate	Cleft lip, specified as unilateral	Cleft hard palate with cleft lip, specified as unilateral		Exomphalos/omphalocele	Gastroschisis

Optional Birth Defects

				
Down syndrome	Congenital diaphragmatic hernia	Congenital heart defect	Tracheoesophageal fistula	Exstrophy of bladder

IF ANY LIVE BABY/STILL BIRTH WITH THE ABOVE BIRTH DEFECTS IS BORN PLEASE INFORM TO:

Dr. _____ (Medical Officer) Department of Gynaecology and Obstetrics, Mob: _____

Dr. _____ (Medical Officer) Department of Paediatrics, Mob: _____

Prepared by: WHO Collaborating Centre for Genetics, AIIMS, New Delhi

Acknowledgement-Figures are adapted from Atlas on selected congenital anomalies by WHO, CDC, ICBDSR

Annex 2

Birth defects abstraction form

Birth Defect

Center Name	Baby's Hospital Record No.	Mother's Hospital Record No.	NBBD Number
Inborn ☐	Out born ☐		
1. Basic information:			
i.	Mother's Name		
ii.	Date of Delivery * d m y		
iii.	Time of Delivery * (24 hr format) h m		
iv.	Mother's Age * (Years Completed)		
v.	Father's Age * (Years Completed)		
vi.	Parental consanguinity *	Y / N	If Yes Please Explain
vii.	Baby's Gender *	Male / Female / Ambiguous	
viii.	Baby's weight (g) *		
ix.	Head Circumference * cm		
x.	Mode of delivery * Vaginal / Cesarean section / Instrumental		
xi.	Plurality Single / Twin / Triplet / Higher order		
xii.	Gestation * (in weeks)		
xiii.	Delivery attended by Doctor / Nurse / ANM / Midwife		
xiv.	Outcome Alive / Died / Still Birth – Fresh/ Still Birth – Macerated		
xv.	Autopsy (in case of still birth) * Y / N		
2. History of birth Defects:			
i.	Previous termination of pregnancy for Malformation	Y / N	If Yes, Please describe (type of birth defects)
ii.	Previous Still birth	Y / N	In case of Yes; Check for any Birth Defect? * Y/N If yes Please describe type of birth defects
iii.	Previous spontaneous abortion(s)		Y/N
iv.	Birth Defect(s) in previous Live Birth *		Y/N
3. Type of birth defect(s): *			
S / N	Type of Birth Defect	Full description *	Code ICD-10
i.			
ii.			
iii.			
iv.			
v.			
4. Additional information/investigation if any			
Indicate what tests have been performed for the fetus/baby: - Chromosomal Analysis (Karyotype) (Y/N) - Infantogram / Babygram (Y/N) 2-D Echo (Y/N) - Ultrasound Abdomen (Y/N) - Brain MRI (Y/N) Describe, if any additional information/investigation is known: _____			
5. Photographs taken		Y / N	Attach Photo (if yes selected)
Name of the professional completed the physical form		Physician / Nurse / Other	
Date:			

C = Confirmed, P = Possible * Mandatory Fields

Annex 3

Definitions of fields in the birth defects abstraction form

Field title	Explanation/definition
Centre Name	Name of centre and country
Baby's Hospital Record number	This is the hospital registration number given to a baby when baby is born or admitted
Mother Hospital Record number	This is the hospital registration number given to mother when mother is admitted
NNPD number	This is a system-generated 9-digit UNIQUE number pre-fixed by county name abbreviation and health centre name/code like; BAN-24754-123456789 or IND-PGIME- 123456789

S. No.	Field title	Explanation/definition
1. Basic information		
i.	Mother's Name	Indicate mother's Name
ii.	Mode of Delivery*	Vaginal / Cesarean section / Instrumental (choose any one)
iii.	Date of Delivery *	dd/mm/yyyy format
iv.	Multiple Birth	Single / Twin / Triplet / Higher order (<i>choose any one</i>)
v.	Time of Delivery	(24 hr format) (hh-mm)
vi.	Gestation* (<i>in weeks</i>)	Gestational should be calculated from the following in this order of priority • First day of last menstrual period (LMP) • First trimester ultrasound • By Expanded New Ballard score (ENBS) If ENBS has been expressed as range, then enter the average e.g. if ENBS is coming as 30-32, enter as "31". Only completed weeks are to be entered, e.g. if born at 35+3 weeks, enter "35".
vii.	Baby's Gender *	Male / female / ambiguous (<i>choose any one option</i>)
viii.	Delivery Attended By	Doctor / Nurse / ANM / Midwife
ix.	Baby's Weight*	Baby's Weight is the weight of baby taken soon after the birth or within 24 hours of birth. The birth weight of 2.35 kg is to be written as 2350.
x.	Head Circumference*	Baby's Head Circumference in Centimeters
xi.	Mother's Age (Completed)*	Two digits field.; age in completed years
xii.	Father's Age (Completed) *	Two digits field.; age in completed years
xiii.	Parental consanguinity	Enquire about any biological relationship between parents. Choose any Y/N Consanguinity is defined as a consanguineous relationship between individuals who are second cousins or closer.

xiv.	Outcome	Alive / Died / Stillbirth – Fresh/ Stillbirth – Macerated
xv.	Autopsy (in case of stillbirth) *	Mandatory in case of Stillbirth and choose Y/N
2. History of birth defects		
	Previous termination of pregnancy for malformation	Describe in case of Yes
	Previous Stillbirth Y / N	Yes; if any birth defect found
	Previous spontaneous abortion(s)	Y / N
3. Type of birth defect(s)		
	Birth Defect	<i>Birth defects</i> are defined as structural changes that have significant medical, social, or cosmetic consequences for the affected individual, and typically require medical intervention. <i>Major structural abnormalities</i> are the conditions that account for most of the deaths, morbidity and disability related to birth defects. Examples include cleft lip and spina bifida. <i>Minor abnormalities</i> are structural changes that pose no significant health problem in the neonatal period and tend to have limited social or cosmetic consequences for the affected individual. Examples include single palmar crease and clinodactyly. Initially major structural birth defects are included. ICD-10 coding is done only for major defects. Select the name(s) of the birth defect (s) from the list.
	Description	Provide a full description for each birth defect identified.
	Code	Code the congenital anomaly according to the International Classification of Disease and Related Health Problems, Tenth Revision (ICD10). Follow Appendix 1
	C or P	C = Confirmed, P = Possible
4. Additional information / investigation if any		
	Indicate what tests have been performed for the fetus/baby 1) Chromosomal analysis (Karyotype) 2) Infantogram/babygram 3) 2-D Echo 4) Ultrasound abdomen	
	Brain MRI If abnormal, mention the precise report in the corresponding box. Include any other relevant comments. Describe if any additional information/investigation is known.	

5. Photographs taken	
Y/N	Attach photo if selected Yes If possible, take the following photographs: 1) all the birth defects present in a baby 2) the whole fetus or newborn from front and back 3) fetal face front and lateral view Mention the respective image description(s).
Name of the professional completing the physical form	Identify the name and the profession of the individual completing the physical form.
Date:	System should pick the date when the form is filled and submitted.

*** (Mandatory Field)**

Annex 4

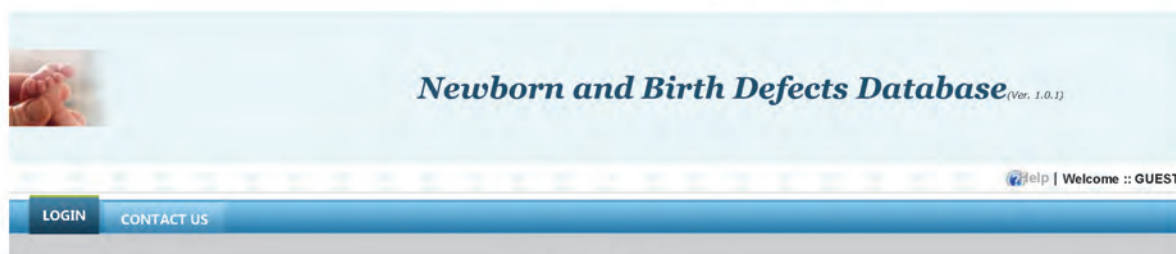
Taking photograph of birth defect

- Make a label for the photograph on a piece of paper, adhesive tape available in hospital: Write in big and bold letters (so that these are legible in the photo) a unique identifier; e.g., date and time of birth, sex, name of mother if acceptable.
- Place the label next to, but not touching, the fetus or neonate.
- If more than one photograph is taken, make sure that all photographs can be identified with the label for that particular fetus or neonate.
- Have a clean, simple, non-patterned light or dark blue background (no blankets or other things in the bassinet or on the examination table).
- If there are objects on the examination table that affect the photograph, remove them before taking the photograph.
- Take a view of the entire fetus or neonate, plus several focused views of the congenital anomaly/anomalies.
- Take a separate view of the face, if possible.
- Take a front or back view, or both, plus a side view, depending on the congenital anomaly.
- Avoid taking photographs at an angle; that is, take all photographs holding the camera at 90° to the fetus or neonate.
- Ensure that there is adequate lighting and no shadows in the photograph. Use a flash if needed.
- Consider the cost of photograph storage.
- Use a digital camera with high resolution, at least 300 ppi (pixels per inch).
- Review photographs quickly while on site and retake the picture if necessary.
- Save the image in jpeg (jpg) format; make sure each photograph is transferred to a computer file or other secure storage before deleting it from the camera.
- Tablets or smart phones can also be used to take photographs.
- Please be careful about privacy and data security issues related to patient information including pictures.

Annex 5

SOPs for online registration at your hospital

Go to site → <http://apps.searo.who.int/npn/>



Sign in with



Microcephaly Surveillance - Head Circumference Monitoring (HCM)

To increase monitoring of baseline head circumference and microcephaly for SEAR network and join the initial development of a population-based registry.

Login and fill out the simple HCM form

***You can create one institutional ID for your hospital/centre
Or use your personal email ID***

Click on the Email icon depending on your email ID

You can use your [Gmail](#), [Facebook](#), [Yahoo](#) or Hotmail ID

In Collaboration with WHO-SEARO and CDC, USA

Provide your email and password

Sign in to continue to Gmail



Enter your email

Next

[Need help?](#)

[Create account](#)

YAHOO!

Sign in

Next

☒ Stay signed in [Need help?](#)

To sign in, enter your email and tap "Next"

facebook [Sign Up](#)

Log in to Facebook

Log in

[Having trouble? Sign up for Facebook](#)



Sign in

Use your Microsoft account. [What's this?](#)

☒ Keep me signed in

Sign in

No account? [Create one!](#)

[Forgotten my password](#)

[Sign in with a single-use code](#)

This will take you to the registration form; fill out the registration form

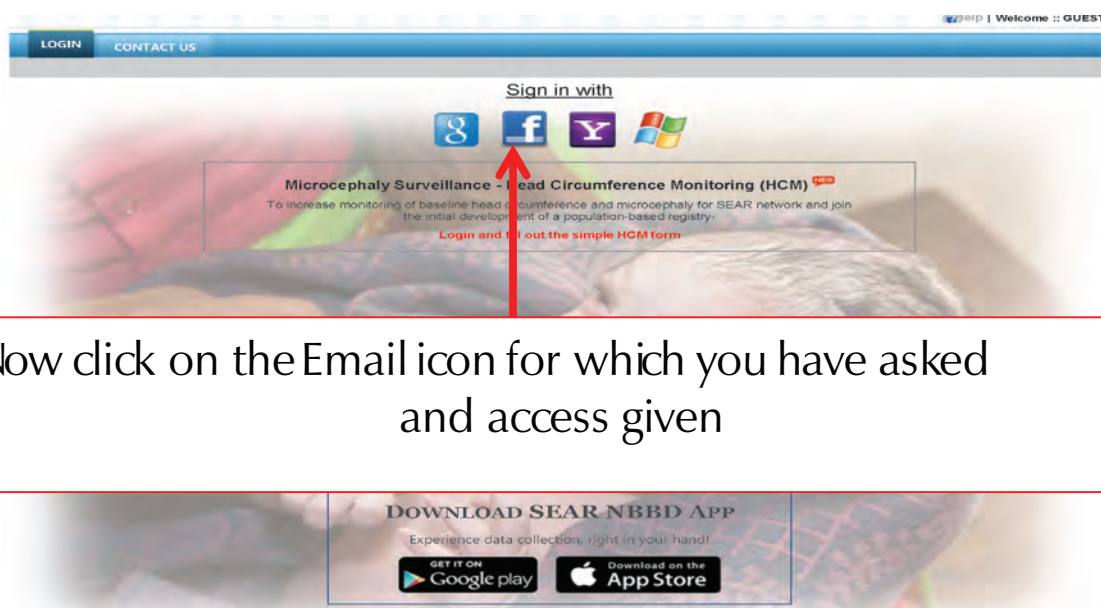
The screenshot shows a web page titled "Request for Authorization of your microsoft account". At the top, there is a "Message from webpage" dialog box asking "Are you sure you want to submit this request?" with "OK" and "Cancel" buttons. An orange callout bubble points to the "OK" button with the text "Click OK to submit the form". Below the dialog, the form is titled "Authorization Form". It contains a message: "You've been authenticated with **microsoft** as **Country Admin NBBB [microsoft]**. Please fill the below form and submit for system access." The form fields are: "User Identification ID" (pre-filled with "dbcd36bfc4784b0a (microsoft)" and a red note "Unique identification provided by Open ID provider."), "Display Name" (text box), "Designation" (text box), "Correspondence Email" (text box, pre-filled with "youremail@gmail.com" and a red note "Once access granted / refused, notification will be send on this email"), "Contact Number" (text box, pre-filled with "9810477544"), "Postal Address" (text box), "Hospital Name" (text box, pre-filled with "Name of the Hospital" and a red note "Access will be provided only if hospital name is recognised by system administrator."), "Country" (text box, pre-filled with "Your Country"), and "Remarks" (text box, pre-filled with "Role REquired"). An orange callout bubble points to the "Remarks" field with the text "Please mention the role needed, e.g. Data Collection or Data Verifier". At the bottom of the form is a button labeled "Request for System Access".

After submitting the registration form, the request will come to us for approval. Once approved, you will be informed by WHO-SEARO and then you will be ready to login.

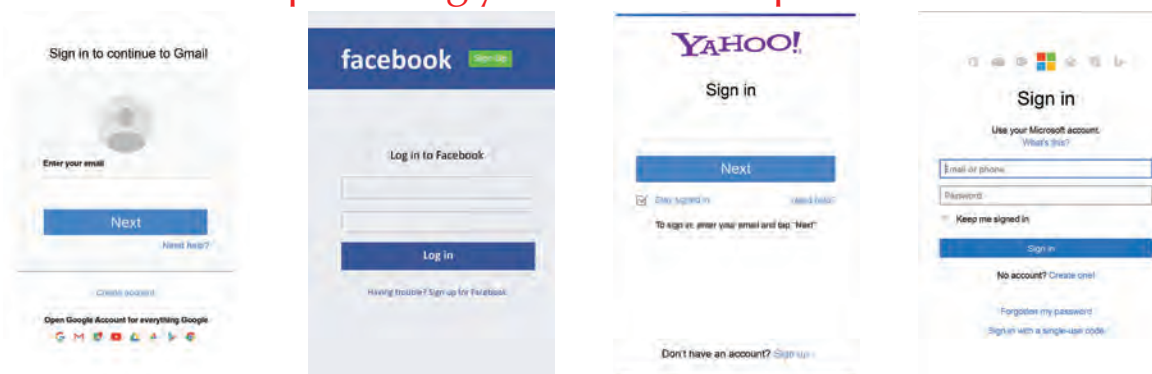
Annex 6

How to login and fill out the birth defects form

Once your ID is approved and assigned to a hospital and role: Login to the site <http://apps.searo.who.int/npn>



After providing your email and password



You are in the system and ready to report/submit data on Newborn and Birth Defects

A pop-up message window appear on the screen, where we send communication messages; please read these message and close the window.

Sample message

Message to all

Message to all

As part of quality monitoring system, we are examining every birth defect form uploaded into the system to enhance the quality of the data. The following are our observations and recommendations -

Observations:

After verification we noticed the following issues with reporting of the birth defects among many centers.

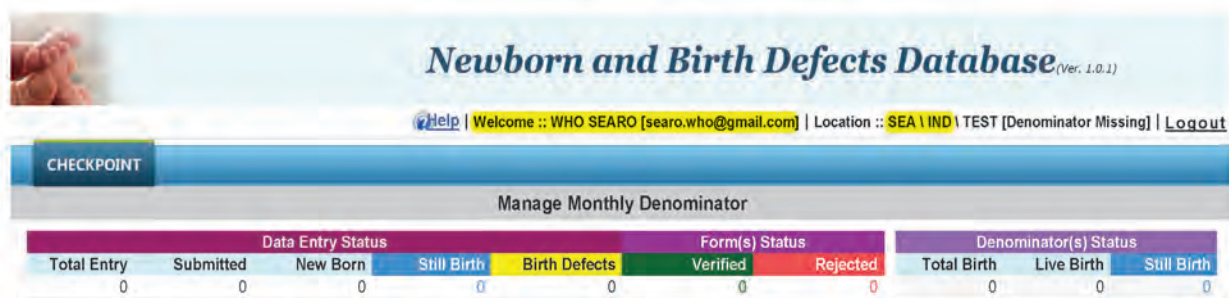
1. Limiting the description to final diagnosis only, without giving the full description of the birth defect. However, the surveillance system expects full description of the birth defects; giving the full description helps in better characterization of the birth defect.
2. Reporting multiple birth defects in the same description box.
3. Not selecting the proper heading and coding of the birth defects.
4. Classifying the Birth defects types under "others" option; while categories are already there in the drop down list for coding birth defects.
5. Not uploading appropriate good quality clinical photographs of the birth defects.

Recommendations:

1. Please provide full description of the birth defect and not only the final diagnosis. E.g. when describing a case of Talipes deformity of the foot, describe as unilateral or bilateral and whether it is rigid or only positional along with the full clinical description.
2. Please enter multiple birth defects in separate rows (by clicking on the add new icon).
3. Please select the appropriate heading from the drop down menu.
4. Please select birth defects type "other" option from drop down list, only if it is not there in the drop down menu of six main categories of visible birth defects. Please provide full description and select ICDS-10 code for each birth defect. We have uploaded ICD-10 coding list of birth defects for your reference.
5. Upload clinical photographs that show the birth defect. If needed, upload more than one picture with different angle of view. Ensure adequate exposure before clicking pictures.

On the welcome screen, you can notice on top right side: Your Name, Email ID, Location and Role

Welcome :: WHO SEARO [searo.who@gmail.com] | Location :: SEA \ IND \ TEST [Data Entry Operator]



Newborn and Birth Defects Database (Ver. 1.0.1)

Help | Welcome :: WHO SEARO [searo.who@gmail.com] | Location :: SEA \ IND \ TEST [Denominator Missing] | Logout

CHECKPOINT

Manage Monthly Denominator

Data Entry Status					Form(s) Status		Denominator(s) Status		
Total Entry	Submitted	New Born	Still Birth	Birth Defects	Verified	Rejected	Total Birth	Live Birth	Still Birth
0	0	0	0	0	0	0	0	0	0

Birth defect form

The screenshot shows the top navigation bar with links: DASHBOARD, SEARCH, NEW BORN, BIRTH DEFECT, STILL BIRTH, HCM, REPORTS, and CONTACT US. Below the navigation bar is the title "Birth Defects Form (BD)" with a "New" status indicator. On the right, there is a "Status: New" label. Below this, there is a section titled "Choose the Option" with two radio buttons: "Inborn" (selected) and "Outborn".

Click on Birth Defect and Select inborn live birth or outborn live birth

The screenshot shows the main form section. It includes fields for "Center Name" (SEA \ IND \ RBSK \ GM), "Baby's Hospital Record No." (with a callout "Fill Baby Hospital Record Number"), "Mother's Hospital Record No." (with a callout "This NBBD number gets generated automatically after submitting the form"), and "NBBD Number" (AUTO NUMBER). Below these are sections for "1. Basic Information" and "2. History of Birth Defects". The "Basic Information" section includes fields for Mother's Name, Date of Delivery (28-Apr-2016), Time of Delivery, Baby's Gender, Baby's Weight, Mode of Delivery, Plurality, Gestation, Delivery Attended By, Head Circumference, Mother's Age (Completed), Father's Age (Completed), Parental Consanguinity (Yes/No), Outcome, and Autopsy (in case of still birth) (Yes/No). The "History of Birth Defects" section includes checkboxes for Previous Termination of Pregnancy for Malformation, Previous Stillbirth, Previous Spontaneous Abortion(s), and Birth Defect in Previous Live Birth? (Yes/No).

Fill out the basic information and history of birth defects

The screenshot shows the bottom section of the form. It includes a section titled "3. Type of Birth Defect(s)" with a reference document link "Other ICD 10 Coding List" and an "Add New" button. Below this is a table with columns: S/N, Type of Birth Defect, Full Description, Code (ICD-10), Confirmed / Possible, Edit / Update, and Action. The table has one row with a dropdown menu for "Type of Birth Defect" and a "Save" button. Below the table is a section titled "4. Additional Information / Investigation if any" with a text area for "Indicate what tests have been performed for the fetus/baby:" and a table with columns: Test, Yes, No. The tests listed are Chromosomal Analysis (Karyotype), Infantogram / Babygram, 2-D Echo, Ultrasound Abdomen, and Brain MRI. Below this is a section titled "5. Photographs Taken" with a "Photographs" checkbox (Yes/No) and a table with columns: S/N, Photograph Link (Max. file size: 1 MB), Description, Edit / Update, and Action. The table has one row with a "Browse..." button and a "Save" button. At the bottom, there are fields for "Professional Type" (dropdown), "Name of the Professional Filling the Form", and "Date" (with a date picker showing 28-Apr-2016). There are also buttons for "Save for Later", "Save & Submit", and "Cancel".

Reference Document: [Other ICD 10 Coding List](#)

S/N	Type of Birth Defect	Full Description
	---SELECT---	
	---SELECT---	
	Nural Tube Defects (NTDs)	
	--- Anencephaly (Q00.0)	
	--- Craniorachischisis (Q00.1)	
	--- Iniencephaly (Q00.2)	
	--- Frontal Encephalocele (Q01.0)	
	--- Nasofrontal Encephalocele (Q01.1)	
	--- Occipital Encephalocele (Q01.2)	
	--- Parietal Encephalocele (Q01.80)	
	--- Orbital Encephalocele (Q01.81)	
	--- Nasal encephalocele (Q01.82)	
	--- Cervical Spina Bifida with Hydrocephalus (Q05.0)	
	--- Cervical Spina Bifida without Hydrocephalus (Q05.5)	
	--- Thoracic Spina Bifida with Hydrocephalus (Q05.1)	
	--- Thoracic Spina Bifida without Hydrocephalus (Q05.6)	
	--- Lumbar Spina Bifida with Hydrocephalus (Q05.2)	
	--- Lumbar Spina Bifida without Hydrocephalus (Q05.7)	
	--- Sacral Spina Bifida with Hydrocephalus (Q05.3)	
	--- Sacral Spina Bifida without Hydrocephalus (Q05.8)	
	Orofacial Cleft	
	--- Cleft Palate (Q35.5)	
	--- Cleft Lip, Bilateral (Q36.0)	
	--- Cleft Lip, Specified as Unilateral (Q36.9, Q36.90)	
	--- Cleft Hard Palate with Bilateral Cleft Lip (Q37.0)	
	--- Cleft Hard Palate with Cleft Lip, Specified as Unilateral (Q37.10)	
	Hypospadias	
	--- Q54 Hypospadias	
	--- Q54.0 Hypospadias	
	--- Q54.1 Hypospadias	
	--- Q54.2 Hypospadias	

Please select the appropriate BD Type from the dropdown list, and select **others only** if not in the list

Or choose from the **Photo Gallery**

3. Birth Defect(s)

Reference Document: [Other ICD 10 Coding List](#) [Add New](#)

S/N	Type of Birth Defect	Full Description	Code (ICD-10)	Confirmed / Possible	Edit / Update	Action
	---SELECT---			---SELEC		Save

Then the Atlas of selected BDs will appear- you can choose the defect type from the atlas as well by clicking the  icon.

Atlas of Selected Congenital Anomalies

Birth Defect: ---SELECT---

---SELECT---

Search

Text:

GO

52 record(s) found.

1. Abdominal Wall Defects / Exomphalos/omphalocele (Q79.2)

Description: Congenital anomaly of the anterior abdominal wall, in which the abdominal contents (gut, but at times also other abdominal organs) are herniated in the midline through an enlarged umbilical ring. The umbilical cord is inserted in the distal part of the membrane covering the anomaly. The herniated organs are covered by a membrane consisting of the peritoneum and amnion (but this membrane can be ruptured).



2. Abdominal Wall Defects / Gastroschisis (Q79.3)

Description: Gastroschisis is a congenital anomaly of the anterior abdominal wall, accompanied by herniation of the gut and occasionally other abdominal organs. The opening in the abdominal wall is lateral to the umbilicus, and the herniated organs lack a protective membrane. Note that the extruded abdominal contents can be matted and covered by a thick fibrous material, but this membrane does not resemble skin.



3. Type of Birth Defect(s)

Reference Document: [Other ICD 10 Coding List](#)

Add New

S/N	Type of Birth Defect	Full Description	Code (ICD-10)	Confirmed / Possible	Edit / Update	Action
	---SELECT---	Provide full description				Save

Please provide full description of the birth defect and not only the final diagnosis.

E.g. when describing a case of Talipes deformity of the foot, describe as unilateral or bilateral and whether it is rigid or only positional along with the full clinical description: Forefoot and midfoot and heel are adducted, and there is a fixed plantar flexion (equinus position) of the ankle

3. Type of Birth Defect(s)

Reference Document: [Other ICD 10 Coding List](#)

S/N	Type of Birth Defect	Full Description	Code (ICD-10)	Confirmed / Possible	Edit / Update	Action
	--SELECT--	Provide full description				Save

Buttons: Add New

- 1 Provide ICD-10 Code
- 2 In case of Others, take the reference from ICD-10 code list
- 3 Select confirm or possible
- 4 Save record
- 5 Add New for Multiple Types of birth defects

4. Additional Information / Investigation if any

Indicate what tests have been performed for the fetus/baby:

Chromosomal Analysis (Karyotype)	Yes	No
Infantogram / Babygram	Yes	No
2-D Echo	Yes	No
Ultrasound Abdomen	Yes	No
Brain MRI	Yes	No

Describe, if any additional information/investigation is known:

Provide Investigations, any finding to better characterize the birth defects

5. Photographs Taken

Photographs ☒ Yes ☐ No

S/N	Photograph Link [*] (Max. File Size: 5 MB)	Description	Edit / Update	Action
	Browse...			Save

Buttons: Add New

Professional Type: --SELECT--

Name of the Professional Filling the Form: _____

Date: _____ (eg. 28-Apr-2018)

Buttons: Save for Later, Save & Submit, Cancel

Save Record

Click 'yes' to upload clinical photographs that show the birth defect. Ensure adequate exposure of the baby before clicking pictures.

Click 'Add New' to Upload more than one picture with different angle of view.

The person filling up the form provides details as name, professional type, date etc. and clicks 'Save and submit'

Monthly Denominator (Check Point)



Newborn and Birth Defects Database

(Ver. 1.0.1)

[Help](#) | Welcome :: [Trainer \[nbbd-trainer@yahoo.com\]](#) | Location :: [Training \[Data Entry Operator\]](#) | [Logout](#)

CHECKPOINT

Manage Monthly Denominator

Health Center: Denominator Year:

Note: 1. To proceed further last month denominator data is required from the centers.
2. Please ensure, all the previous months denominator data is entered in the system.

S/N	Year / Month	Total Births	Live Birth	Still Birth	Birth Defect(s)	Sick Newborn(s)	Edit / Update
1.	2016 / March	452	450	2	5	125	Save Cancel
2.	2016 / February	485	481	4	6	135	Edit
3.	2016 / January	500	495	5	4	150	Edit

3 record(s) found.

1

Final modification will be done only after clicking 'Save & Submit' button.

A set of fields appears on the 10th day of every month Asking for

- Total Births (Including Multiple births)
- Total Live Births
- Total Stillbirths
- Total Birth Defects

Without filling these denominator details, you cannot move ahead to fill out the form, so please get these details from hospital records in first week of every month.



Alert

An Auto Email Alerts goes on the first day of every month to the DRs/DEO and hospital/network admins if there is no form uploaded in the last month.

Search Records

Go to Search Tab

DASHBOARD

SEARCH

NEW BORN

BIRTH DEFECT

STILL BIRTH

HCM

REPORTS

CONTACT US

Search New Born / Birth Defects

Form Type Search Text Form Filled on to Status

[Manage Monthly Denominator](#) | [View Health Center Status](#)

1. Form Type

▼

New Born (All)

--- NB – In Born Only

--- NB – Out Born Only

Birth Defects (All BD)

--- BD – In Born Only

--- BD – Out Born Only

Still Birth Only

Birth Defects (Still Birth Only)

HCM Surveillance

2. Search Text

You can search records based on the baby hospital record number or the NBBD number that is generated automatically when you submit the form and can be seen immediately on top of search results. Any other criteria should not be selected in this case.

3. Forms filled on

You can select the date range when the form was filled and submitted.

c	June, 2015							x
« < Today > »								
Sat Sun Mon Tue Wed Thu Fri								
1 2 3 4 5								
6 7 8 9 10 11 12								
13 14 15 16 17 18 19								
20 21 22 23 24 25 26								
27 28 29 30								
Tue, June 9 2015								

4. Status

-- All --

▼

-- All --

Incomplete

Completed

Verification Pending

Action Taken by DEO

Verified by 1st Verifier

Verified by 2nd Verifier

Rejected by Verifier

Some examples of search based on the above criteria

Form Type: **Birth Defect (All BD)** Search Text: Form Filled On: to Status: **ALL** 51 record(s) found.

S/N			NBBD Number	Date of Birth	Data Entry By	Data Entry On	Verified By	Verified On	Action
181			IND-RBSK-GBPHS-0000 00020	10-Mar-2016 05: 45 PM	Shafat Ahmad	20-Apr-2016 02:22 PM	Dr. Neerja	25-Apr-2016 03:46 PM	
182			IND-HR-GHN-000000020	16-Apr-2016 08:20 PM	Ombir Singh	20-Apr-2016 01:35 PM	Dr. Neerja	25-Apr-2016 03:31 PM	
183			IND-HR-GHN-000000019	11-Apr-2016 02:30 AM	Ombir Singh	20-Apr-2016 01:31 PM	Dr. Neerja	25-Apr-2016 03:49 PM	
184			IND-HR-GHN-000000018	10-Apr-2016 04:54 AM	Ombir Singh	20-Apr-2016 01:26 PM	GH NNL	26-Apr-2016 12:57 PM	
185			BAN-DK-CMCH-000001655	15-Apr-2016 10:30 AM	DEO@chitt...	20-Apr-2016 12:49 PM	Dr. Neerja	25-Apr-2016 05:09 PM	
186			BAN-DK-BSMMU-000002819	18-Apr-2016 04:30 PM	DEO@BSMU	20-Apr-2016 12:29 PM			
187			BAN-DK-BMCH-000000032	19-Apr-2016 08:30 AM	Asma Habib	19-Apr-2016 12:18 PM			

Incomplete Forms

Form Type: Search Text: Form Filled On: to Status: **Incomplete** 2974 record(s) found.

S/N			NBBD Number	Date of Birth	Data Entry By	Data Entry On	Verified By	Verified On	Action
1			THA-URA-CBH-000005510	17-Apr-2016 09: 41 AM	Thanatda yoo...	29-Apr-2016 12:43 PM			
2			IND-CH-PGIMER-Z.000000667	14-Mar-2016 12 :00 AM	DEO_PGIMER	29-Apr-2016 12:40 PM			
3			IND-DL-MAMC-000000363	11-Apr-2016 05:43 PM	Maulana Azad...	29-Apr-2016 12:38 PM			
4			IND-DL-MAMC-000000362	25-Apr-2016 01:54 PM	Maulana Azad...	29-Apr-2016 12:35 PM			
5			IND-DL-MAMC-000000361	19-Apr-2016 10:50 PM	Maulana Azad...	29-Apr-2016 12:33 PM			
6			IND-DL-MAMC-000000360	20-Apr-2016 08:25 PM	Maulana Azad...	29-Apr-2016 12:22 PM			
7			IND-CH-PGIMER-Z.000000659	26-Mar-2016 12:00 AM	DEO_PGIMER	29-Apr-2016 12:19 PM			

Verification Pending

Form Type: Search Text: Form Filled On: to Status: **Verification Pending** 74 record(s) found.

S/N			NBBD Number	Date of Birth	Data Entry By	Data Entry On	Verified By	Verified On	Action
1			TRA-TEMP-000005510	17-Apr-2016 09: 41 AM	TRA-TEMP	29-Apr-201 5 12:43 PM			
2			TRA-TEMP-000000667	14-Mar-2016 12 :00 AM	TRA-TEMP-	29-Apr-201 5 12:40 PM			
3			TRA-TEMP-000000363	11-Apr-2016 05:43 PM	TRA-TEMP-	29-Apr-201 5 12:38 PM			
4			TRA-TEMP-000000362	25-Apr-2016 01:54 PM	TRA-TEMP-	29-Apr-201 5 12:35 PM			
5			TRA-TEMP-000000361	19-Apr-2016 10:50 PM	TRA-TEMP-	29-Apr-201 5 12:33 PM			
6			TRA-TEMP-000000360	20-Apr-2016 08:25 PM	TRA-TEMP-	29-Apr-201 5 12:22 PM			
7			TRA-TEMP-000000659	26-Mar-2016 12:00 AM	TRA-TEMP-	29-Apr-201 5 12:19 PM			

Verified by 1st Verifier

Form Type: Search Text: Form Filled On: to Status: **Verified by 1st Verifier** 74 record(s) found.

S/N			NBBD Number	Date of Birth	Data Entry By	Data Entry On	Verified By	Verified On	Action
1			TRA-TEMP-000005510	17-Apr-2016 09: 41 AM	TRA-TEMP	29-Apr-201 5 12:43 PM	Name of the Verifier	30-Apr-201 5 12:43 PM	
2			TRA-TEMP-000000667	14-Mar-2016 12 :00 AM	TRA-TEMP-	29-Apr-201 5 12:40 PM	Name of the Verifier	30-Apr-201 5 12:40 PM	
3			TRA-TEMP-000000363	11-Apr-2016 05:43 PM	TRA-TEMP-	29-Apr-201 5 12:38 PM	Name of the Verifier	30-Apr-201 5 12:38 PM	
4			TRA-TEMP-000000362	25-Apr-2016 01:54 PM	TRA-TEMP-	29-Apr-201 5 12:35 PM	Name of the Verifier	30-Apr-201 5 12:35 PM	
5			TRA-TEMP-000000361	19-Apr-2016 10:50 PM	TRA-TEMP-	29-Apr-201 5 12:33 PM	Name of the Verifier	30-Apr-201 5 12:33 PM	
6			TRA-TEMP-000000360	20-Apr-2016 08:25 PM	TRA-TEMP-	29-Apr-201 5 12:22 PM	Name of the Verifier	30-Apr-201 5 12:22 PM	
7			TRA-TEMP-000000659	26-Mar-2016 12:00 AM	TRA-TEMP-	29-Apr-201 5 12:19 PM	Name of the Verifier	30-Apr-201 5 12:19 PM	

Verified by 2nd Verifier

Form Type: Search Text: Form Filled On: to Status: **Verified by 2nd Verifier** 74 record(s) found.

S/N			NBBD Number	Date of Birth	Data Entry By	Data Entry On	Verified By	Verified On	Action
1			TRA-TEMP-000005510	17-Apr-2016 09: 41 AM	TRA-TEMP	29-Apr-201 5 12:43 PM	Name of the Verifier	30-Apr-201 5 12:43 PM	
2			TRA-TEMP-000000667	14-Mar-2016 12 :00 AM	TRA-TEMP-	29-Apr-201 5 12:40 PM	Name of the Verifier	30-Apr-201 5 12:40 PM	
3			TRA-TEMP-000000363	11-Apr-2016 05:43 PM	TRA-TEMP-	29-Apr-201 5 12:38 PM	Name of the Verifier	30-Apr-201 5 12:38 PM	
4			TRA-TEMP-000000362	25-Apr-2016 01:54 PM	TRA-TEMP-	29-Apr-201 5 12:35 PM	Name of the Verifier	30-Apr-201 5 12:35 PM	
5			TRA-TEMP-000000361	19-Apr-2016 10:50 PM	TRA-TEMP-	29-Apr-201 5 12:33 PM	Name of the Verifier	30-Apr-201 5 12:33 PM	
6			TRA-TEMP-000000360	20-Apr-2016 08:25 PM	TRA-TEMP-	29-Apr-201 5 12:22 PM	Name of the Verifier	30-Apr-201 5 12:22 PM	
7			TRA-TEMP-000000659	26-Mar-2016 12:00 AM	TRA-TEMP-	29-Apr-201 5 12:19 PM	Name of the Verifier	30-Apr-201 5 12:19 PM	

Rejected by Verifier

Form Type Search Text Form Filled On to Status **Rejected by Verifier**

[Manage Monthly Denominator](#) | [View Health Center Status](#) 74 record(s) found.

S/N				NBBD Number	Date of Birth	Data Entry By	Data Entry On	Verified By	Verified On	Action
1				TRA-TEMP-000005510	17-Apr-2016 09: 41 AM	TRA-TEMP	29-Apr-201 5 12:43 PM	Name of the Verifier	30-Apr-201 5 12:43 PM	
2				TRA-TEMP-000000667	14-Mar-2016 12 :00 AM	TRA-TEMP-	29-Apr-201 5 12:40 PM	Name of the Verifier	30-Apr-201 5 12:40 PM	
3				TRA-TEMP-000000363	11-Apr-2016 05:43 PM	TRA-TEMP-	29-Apr-201 5 12:38 PM	Name of the Verifier	30-Apr-201 5 12:38 PM	
4				TRA-TEMP-000000362	25-Apr-2016 01:54 PM	TRA-TEMP-	29-Apr-201 5 12:35 PM	Name of the Verifier	30-Apr-201 5 12:35 PM	
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6				TRA-TEMP-000000360	20-Apr-2016 08:25 PM	TRA-TEMP-	29-Apr-201 5 12:22 PM	Name of the Verifier	30-Apr-201 5 12:22 PM	
7				TRA-TEMP-000000659	26-Mar-2016 12:00 AM	TRA-TEMP-	29-Apr-201 5 12:19 PM	Name of the Verifier	30-Apr-201 5 12:19 PM	

Action Taken by DRs/DEO

Form Type Search Text Form Filled On to Status **Verified by 2nd Verifier**

[Manage Monthly Denominator](#) | [View Health Center Status](#) 74 record(s) found.

S/N				NBBD Number	Date of Birth	Data Entry By	Data Entry On	Verified By	Verified On	Action
1				TRA-TEMP-000005510	17-Apr-2016 09: 41 AM	TRA-TEMP	29-Apr-201 5 12:43 PM	Name of the Verifier	30-Apr-201 5 12:43 PM	
2				TRA-TEMP-000000667	14-Mar-2016 12 :00 AM	TRA-TEMP-	29-Apr-201 5 12:40 PM	Name of the Verifier	30-Apr-201 5 12:40 PM	
3				TRA-TEMP-000000363	11-Apr-2016 05:43 PM	TRA-TEMP-	29-Apr-201 5 12:38 PM	Name of the Verifier	30-Apr-201 5 12:38 PM	
4				TRA-TEMP-000000362	25-Apr-2016 01:54 PM	TRA-TEMP-	29-Apr-201 5 12:35 PM	Name of the Verifier	30-Apr-201 5 12:35 PM	
5				TRA-TEMP-000000361	19-Apr-2016 10:50 PM	TRA-TEMP-	29-Apr-201 5 12:33 PM	Name of the Verifier	30-Apr-201 5 12:33 PM	
6				TRA-TEMP-000000360	20-Apr-2016 08:25 PM	TRA-TEMP-	29-Apr-201 5 12:22 PM	Name of the Verifier	30-Apr-201 5 12:22 PM	
7				TRA-TEMP-000000659	26-Mar-2016 12:00 AM	TRA-TEMP-	29-Apr-201 5 12:19 PM	Name of the Verifier	30-Apr-201 5 12:19 PM	

Icons

- Import the search results in Excel for record keeping purpose
- Newborn form
- Birth Defects form
- Discharge Summary
- Incomplete Forms
- Completed Form / Submitted
- Verification Pending
- Action Taken by DRs/DEO
- Verified by 1st Verifier
- Verified by 2nd Verifier
- Rejected By Verifier

By clicking on these icons that appear in search results, you can edit the forms and delete the unwanted forms and generate the discharge summary.

Annex 7

Recurrence risk of some birth defects

Type of Birth defect	Recurrence risk after one affected child
Neural tube defect	3-5%
Cleft lip/palate	4-5%
Common cardiac defects	3-4%
Club foot	2-8%

(Adopted from SMITH's Recognizable Patterns of Human Malformation, Seventh Edition)

Annex 8

Standard Operating Procedure (SOPs) for birth defect verification at hospital

Forms Verification

Go to Search Tab and identify the birth defect forms to be verified by selecting the **form type** as “Birth Defects (All BD)” and status as “Verification Pending” from the dropdown list and press GO button to get list of forms *to be verified*.

DASHBOARD SEARCH REPORTS CONTACT US									
Search New Born / Birth Defects									
Manage Monthly Denominator View Health Center Status 74 record (s) found.									
S/N			NBBD Number	Date of Birth	Data Entry By	Data Entry On	Verified By	Verified On	Action
1			TRA-TEMP-000005510	17-Apr-2016 09: 41 AM	TRA-TEMP	29-Apr-201 5 12:43 PM			
2			TRA-TEMP-000000667	14-Mar-2016 12 :00 AM	TRA-TEMP-	29-Apr-201 5 12:40 PM			
3			TRA-TEMP-000000363	11-Apr-2016 05:43 PM	TRA-TEMP-	29-Apr-201 5 12:38 PM			
4			TRA-TEMP-000000362	25-Apr-2016 01:54 PM	TRA-TEMP-	29-Apr-201 5 12:35 PM			
5			TRA-TEMP-000000361	19-Apr-2016 10:50 PM	TRA-TEMP-	29-Apr-201 5 12:33 PM			
6			TRA-TEMP-000000360	20-Apr-2016 08:25 PM	TRA-TEMP-	29-Apr-201 5 12:22 PM			
7			TRA-TEMP-000000659	26-Mar-2016 12:00 AM	TRA-TEMP-	29-Apr-201 5 12:19 PM			

Now export the search results in Excel file by clicking the first excel icon

- Save this Excel sheet and use it as your Log file for record-keeping purpose and future reference and follow-up (refer detail on “Record-keeping” section below for more details on Log file format).
- Select each case one by one from the search results by clicking the icons to verify the data entered.

Steps in verification

Background information verification

- Once a case form is selected, check those basic information entered to find any extreme findings
- Check for logical conflicts in data; Ex: POA-39 and baby’s weight 500gms
- Make a note of history of birth defect section if not completed

Types of birth defect verification

While checking and verifying, you will reach the bottom of the form where you need to provide your comments and reject or verify the form.

1st Level Verification Details

Verifier Comments * ☐ I confirmed, Form has been verified.

If you feel the form is incomplete or some fields are missing, you can write in the comment box and click the reject button and the form will be rejected, and the colour icon of this forms will turned to red, these rejected forms can be picked up DEO form search **Status** **Rejected by Verifier**

And if the form is ok in all aspects then click the check box ☐ I confirmed, form has been verified the reject button will now turn to **Verify** click on the verify button. And the colour icon of these forms will turn to yellow. 🟡

Form Type Search Text Form Filled On to Status **Verified by 1st Verifier**

[Manage Monthly Denominator](#) | [View Health Center Status](#) 74 record(s) found.

S/N	☐	☐	☐	NBBD Number	Date of Birth	Data Entry By	Data Entry On	Verified By	Verified On	Action
1	☐	☐	☐	TRA-TEMP-000005510	17-Apr-2016 09: 41 AM	TRA-TEMP	29-Apr-201 5 12:43 PM	Name of the Verifier	30-Apr-201 5 12:43 PM	
2	☐	☐	☐	TRA-TEMP-000000667	14-Mar-2016 12 :00 AM	TRA-TEMP-	29-Apr-201 5 12:40 PM	Name of the Verifier	30-Apr-201 5 12:40 PM	
3	☐	☐	☐	TRA-TEMP-000000363	11-Apr-2016 05:43 PM	TRA-TEMP-	29-Apr-201 5 12:38 PM	Name of the Verifier	30-Apr-201 5 12:38 PM	
4	☐	☐	☐	TRA-TEMP-000000362	25-Apr-2016 01:54 PM	TRA-TEMP-	29-Apr-201 5 12:35 PM	Name of the Verifier	30-Apr-201 5 12:35 PM	
5	☐	☐	☐	TRA-TEMP-000000361	19-Apr-2016 10:50 PM	TRA-TEMP-	29-Apr-201 5 12:33 PM	Name of the Verifier	30-Apr-201 5 12:33 PM	
6	☐	☐	☐	TRA-TEMP-000000360	20-Apr-2016 08:25 PM	TRA-TEMP-	29-Apr-201 5 12:22 PM	Name of the Verifier	30-Apr-201 5 12:22 PM	
7	☐	☐	☐	TRA-TEMP-000000659	26-Mar-2016 12:00 AM	TRA-TEMP-	29-Apr-201 5 12:19 PM	Name of the Verifier	30-Apr-201 5 12:19 PM	

Now this verified form by the first verifier will be again verified by WHO-SEARO and if everything is ok, the form will be verified and turned to the green icon.

Form Type Search Text Form Filled On to Status **Verified by 2nd Verifier**

[Manage Monthly Denominator](#) | [View Health Center Status](#) 74 record(s) found.

S/N	☐	☐	☐	NBBD Number	Date of Birth	Data Entry By	Data Entry On	Verified By	Verified On	Action
1	☐	☐	☐	TRA-TEMP-000005510	17-Apr-2016 09: 41 AM	TRA-TEMP	29-Apr-201 5 12:43 PM	Name of the Verifier	30-Apr-201 5 12:43 PM	
2	☐	☐	☐	TRA-TEMP-000000667	14-Mar-2016 12 :00 AM	TRA-TEMP-	29-Apr-201 5 12:40 PM	Name of the Verifier	30-Apr-201 5 12:40 PM	
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4	☐	☐	☐	TRA-TEMP-000000362	25-Apr-2016 01:54 PM	TRA-TEMP-	29-Apr-201 5 12:35 PM	Name of the Verifier	30-Apr-201 5 12:35 PM	
5	☐	☐	☐	TRA-TEMP-000000361	19-Apr-2016 10:50 PM	TRA-TEMP-	29-Apr-201 5 12:33 PM	Name of the Verifier	30-Apr-201 5 12:33 PM	
6	☐	☐	☐	TRA-TEMP-000000360	20-Apr-2016 08:25 PM	TRA-TEMP-	29-Apr-201 5 12:22 PM	Name of the Verifier	30-Apr-201 5 12:22 PM	
7	☐	☐	☐	TRA-TEMP-000000659	26-Mar-2016 12:00 AM	TRA-TEMP-	29-Apr-201 5 12:19 PM	Name of the Verifier	30-Apr-201 5 12:19 PM	

Otherwise it will be rejected with comments and the colour icon will turn red.

Form Type Search Text Form Filled On to Status **Rejected by Verifier**

[Manage Monthly Denominator](#) | [View Health Center Status](#) 74 record(s) found.

S/N	☐	☐	☐	NBBD Number	Date of Birth	Data Entry By	Data Entry On	Verified By	Verified On	Action
1	☐	☐	☐	TRA-TEMP-000005510	17-Apr-2016 09: 41 AM	TRA-TEMP	29-Apr-201 5 12:43 PM	Name of the Verifier	30-Apr-201 5 12:43 PM	
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3	☐	☐	☐	TRA-TEMP-000000363	11-Apr-2016 05:43 PM	TRA-TEMP-	29-Apr-201 5 12:38 PM	Name of the Verifier	30-Apr-201 5 12:38 PM	
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6	☐	☐	☐	TRA-TEMP-000000360	20-Apr-2016 08:25 PM	TRA-TEMP-	29-Apr-201 5 12:22 PM	Name of the Verifier	30-Apr-201 5 12:22 PM	
7	☐	☐	☐	TRA-TEMP-000000659	26-Mar-2016 12:00 AM	TRA-TEMP-	29-Apr-201 5 12:19 PM	Name of the Verifier	30-Apr-201 5 12:19 PM	

The data reporter is required to correct these forms and the colour icon of these edited forms by DEO will turn them to blue icons

Form Type Search Text Form Filled On to Status **Verified by 2nd Verifier**

[Manage Monthly Denominator](#) | [View Health Center Status](#) 74 record(s) found.

S/N	☐	☐	☐	NBBD Number	Date of Birth	Data Entry By	Data Entry On	Verified By	Verified On	Action
1	☐	☐	☐	TRA-TEMP-000005510	17-Apr-2016 09: 41 AM	TRA-TEMP	29-Apr-201 5 12:43 PM	Name of the Verifier	30-Apr-201 5 12:43 PM	
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3	☐	☐	☐	TRA-TEMP-000000363	11-Apr-2016 05:43 PM	TRA-TEMP-	29-Apr-201 5 12:38 PM	Name of the Verifier	30-Apr-201 5 12:38 PM	
4	☐	☐	☐	TRA-TEMP-000000362	25-Apr-2016 01:54 PM	TRA-TEMP-	29-Apr-201 5 12:35 PM	Name of the Verifier	30-Apr-201 5 12:35 PM	
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7	☐	☐	☐	TRA-TEMP-000000659	26-Mar-2016 12:00 AM	TRA-TEMP-	29-Apr-201 5 12:19 PM	Name of the Verifier	30-Apr-201 5 12:19 PM	

Points to Remember:

- Each BD type should be filled in a separate row from major defects to minor defects and crania to chordae order.
- Make a note of disparity in classification of major and minor birth defects. (A list of minor birth defects are included as Annex 1.)
- Type of birth defect should have been selected from the dropdown menu.
- Then each defect should be described precisely to distinguish it from another type of birth defect and birth defects with another ICD-10 category. Check for the consistency using the checklist provided in Annex 2. It highlights the significance of those descriptions and its use.
- Appropriate ICD code should be entered in the relevant cage and should match the ICD code selected in the dropdown menu.
- If there is any discrepancy, it should be corrected by selecting exact BD from the list or selecting the “Others” option.
- Check for possible or confirmed status and you may follow them up.
- Check for accuracy and relevance of investigation findings in the “investigation” section.
- Encourage data provider to enter relevant details of investigation to support the birth defect detected.
- Check for photograph uploads and encourage doing so.
- If uploaded, open it to check for adequacy of exposure, clarity and relevance to the BD selected.
- Identify any discrepancy with the description given above.
- Finally, based on the complete understanding of the birth defect, select appropriate categorization of the birth defect in the single/multiple/sequence/syndrome category.
- In the conclusion, make a verifier comment in the relevant cage.
- This comment should give a useful and supportive feedback on this birth defect form submitted by the data provider. Avoid making judgmental statements and premature conclusion in the verifier comments.
- Make sure to include all queries you have noted regarding this birth defect form.
- Copy your comments and the details entered by the data provider to your Log Excel file for record-keeping and follow-up (use format given in Annex 3) .
- If the information given is adequate and precise in describing the birth defect correctly, then you may select “Form has been verified” and save your comments by pressing the “Verify” icon at the end of the form. This will freeze the data entered into the system and prevent further alteration.

Record-keeping and follow-up

- Create a separate Log file for verification purpose for each calendar month. Include the fields relevant for your verification activity.
- A minimum of the ID number of the baby, date of verification, birth defect description given, comments of the verifier and follow-up details should be included (model table is shown in Annex 3). You may use Excel software for this purpose.

- Add the ID numbers of cases exported from the web page for verification into this Log Excel file when beginning each session. This will help to compile all records verified during that month.
- Copy the ICD code and description of birth effects given by the data provider and your comments as a verifier against the correct ID number of the form selected in this Log file.
- Log files should be submitted to the WHO-SEARO verifier on the 1st of every following month.
- Correspond and follow up with the data provider in a week's time on those forms that were not accepted as verified and notified as rejected, for correction.

Model table of the Log file for verifier

Name of verifier :

Verification station :

Period verified – : from to

NNPD Number	Date of verification	Observations in the birth defect form	Verifier comments	Date of follow-up	Follow up on correction made
HLN-CK-XXXX-00000		Sacral spina bifida and club foot.	Please mention multiple birth defects in separate rows and code them separately after giving full description of each birth defect. And please upload appropriate pictures of the birth defects.		
HLN-CK-XXXX-00000					

Annex 9

Quality Assurance and Quality Control Guidelines for NBBD

Introduction:

'Quality control' (QC) and 'quality assurance' (QA) can be defined as a set of methods, activities and procedures designed to improve the results of specific outcomes.

Quality assurance is a proactive approach to improvement that focuses on prevention of mistakes. Programme functions are designed and activities are planned in advance to avoid inaccurate or deficient data. As a result of QA procedures, high-quality data are created at the front end or design stage.

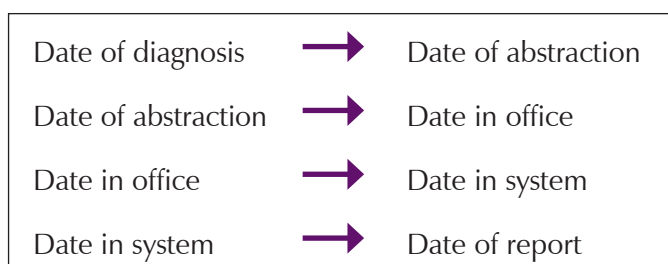
Quality control is a retrospective and reactive approach to improvement that focuses on discovery and detection of mistakes. Deficiencies and inaccuracies are found, resolved and fixed so that final results or outcome measurements are accurate. As a result of QC procedures, high-quality data are created at the back end. In QC, the emphasis is on checking, investigating, containing and adjusting.

Data must be – Complete, Accurate and Timely

Completeness. The extent to which data are all-inclusive and comprehensive. For example, are all the cases of birth defects that occur among all the hospital births (live births and stillbirths) identified? Are all the fields in the BD abstraction form completely filled?

Accuracy. The extent to which data are exact, correct and valid. Accuracy reflects the programme's standard to conform to agreed-upon case definitions. For example, are all the fields in the BD abstraction form appropriately filled? Are the birth defects correctly diagnosed and coded as per the ICD-10 system?

Timeliness. The extent to which data are rapid, prompt and responsive. For example, a birth defect case should be ascertained or reported to the programme shortly after diagnosis. With rapid case identification, reporting and analysis, the programme is able to provide timely intervention services. See example of timeliness below.



A simple checklist is provided below. This can be used both for routine ongoing quality assurance by the hospital nodal officer as well as less frequent external assessment for improving the quality of the database.

Annex 10

Assessment Form for Quality Check of Hospital-based Birth Defect Surveillance

Date of Assessment:

Name and Designation of assessor:

General information:

1. Name of Hospital:
2. State and Country:
3. Hospital nodal person:
4. Any new staff that needs to be trained: Mention names, etc.
5. Places of delivery in the hospital included for capturing BD case:
 - Mention the name/s and type/s of staff at each site:
 - Labour room:
 - Operation theatre:
 - Both:
6. Other places in the hospital where birth defects are to be captured in in-born babies:
 - Mention the name/s and type/s of staff at each site
 - Postnatal ward:
 - Neonatal unit:
 - Pediatric unit:
 - Other area:
7. Are the pictures taken in all cases of birth defects: Yes / No
 - If no, please specify why:
 - If yes, are photographs being saved to laptop, smartphone, tablet in an orderly way (with proper identification case by case)? Yes/ No
8. Are the data captured directly on the online system (laptop, smartphone, tablet)? Yes / No
9. Are the data first captured on the paper form (Birth defects abstraction form)? Yes / No
 - If Yes, are the filled out BD abstraction forms stored in a designated folder in the hospital? Yes / No

Checklist:

S No	Items	Response	Comments
1.	Are blank birth defects abstraction forms available at all the sites where BDs are captured? (Points 5-6 above)	Yes / No	
2.	Is each baby delivered in the hospital examined clinically for detecting birth defects?	Yes / No	
3.	Are the babies also examined in postnatal ward/pediatric unit/neonatal unit for detecting birth defects?	Yes / No	
4.	Are birth defects recorded in the delivery room register and admission-discharge registers at all the sites where BDs are captured? (Points 5-6 above)	Yes / No	
5.	Proportion of mother/baby case records (10 randomly selected records) in which details of newborn clinical examination is recorded, including details of birth defects.		
6.	Is appropriate description of the birth defects written in the BD forms? Check 10 random forms and state the proportion with appropriate description.		
7.	If pictures of birth defects are taken, is the quality as per the guidelines? Check stored pictures in the laptop.	Yes / No	
8.	Are the birth defects correctly coded as per ICD-10? Check 10 random BD forms and state proportion with correct codes.		
9.	Time taken between identification of birth defect in a case and filling the paper BD abstraction form.	Same duty shift / Same day / Later	
10.	Time taken between filling out the paper form and online entry.	Same duty shift / Same day / Later	
11.	Proportion of BD forms verified by the hospital nodal person.		
12.	Proportion of verified forms that required changes/completion.		
13.	Check the monthly denominator (total births, live births and stillbirths in the hospital in a month) from the hospital records.	Correct / Incorrect	
14.	When was the last analysis of birth defects forms done? Mention the date.		
15.	Was the analysis shared with hospital team and district/state programme managers?	Yes / No	

Assessment of challenging factors:

Factors ↓	Consequence →	Missing BDs	Delay in filling forms	Delay in online reporting	Poor data quality	Others
High load of deliveries						
Early discharges						
Baby being discharged without examination						
Insufficient paper forms						
Poor Internet availability						
Insufficient staff						
Insufficient knowledge / training of staff						
Insufficient supervision and support from country coordinator						

Summary of Assessment:

- **Main problems identified:**
- **Plan to improve the quality: (Include timelines)**
- **Follow-up:**
To confirm if each planned action for improvement has been completed for this cycle of quality check.



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