सत्यमेव जयते

NATIONAL HEALTH MISSION

Operational Guidelines for Establishing Hospital Based Birth Defect Sentinel Surveillance System

June 2016

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

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

World Health Organization

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PREFACE

Birth defects are a hidden problem, but their impact is particularly severe due to high mortality and morbidity in babies particularly in newborns with serious birth defects. For those who survive, these defects can cause life-long mental, physical, auditory or visual disability.

Every year an estimated 15 lakh children – 6% of total births are born with a birth defect in India. 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 haemoglobinopathies, musculoskeletal disorders and others. There are many known risk factors associated with birth defects such as genetic factors; maternal conditions, behaviours and environmental exposures.

Adequate data and information on birth defects is not available in India. Depending on the presence or absence of these risk factors, the prevalence and spectrum of birth defects will vary among different communities and regions. Such information is important to understand the state-wise burden and to design prevention and management programmes accordingly. The initiative to establish the national capacity for surveillance and monitoring of common birth defects will provide the true scale of birth defects both nationally and regionally.

Many of the factors responsible for the birth defects are preventable and effective interventions are available – vaccination against rubella; folic acid supplementation; prevention and management of syphilis and diabetes in mother; fortification of staple foods with micronutrients (iodine and folic acid); controlling use of toxic chemicals; a timely identification of a family risk of inherited disease; and carrier screening with genetic counselling etc.

These guidelines aim to complement the existing maternal, newborn and child health programmes and surveillance information systems will inform robust policies and also allow evaluation of the existing interventions, such as vaccination, fortification of the food supply with folic acid etc. I am confident that the hospitals will take up the implementation of this initiative with full commitment.

(C.K.Mishra)

New Delhi
July 4, 2016

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PREFACE

Birth defects contribute to a significant proportion of perinatal, neonatal and child mortality. Major birth defects are diagnosed in nearly six percent of infants in their first year of life. Birth defects account for a significant proportion of mortality among infants and children, in particular in those areas where infant mortality due to other common causes has been reduced.

The impact of birth defects on the unborn child, on the child's family and on the community, is not restricted to mortality; it also involves the morbidity and disability experienced by those who survive. Birth defects are responsible for a high proportion on years of potential life lost, infant hospital admissions and medical costs.

Birth Defects Surveillance as a part of Child health programs represents an important source of information for monitoring the trends and the risk factors in a population. Birth defect surveillance by virtue of its ongoing systematic collection, analysis, and interpretation will support a robust outcome-specific data. The programme not only includes data collection and analysis, but also utilizes the application of this data to control and prevention activities by disseminating information to health program managers to support in planning, implementation and evaluation of various newborn interventions and programs.

The present operational guidelines are aimed at program managers and hospital staff with the purpose of providing practical guidance on how to establish sentinel surveillance for birth defects at the hospital level. Although these guidelines have been developed keeping in mind the tertiary hospitals/ medical colleges, it is hoped that the guideline can be used by any health facility that caters to high delivery load.

The guideline articulates how to set up system for collecting, coding and processing data on major birth defects. We hope it will lead to better information on birth defects and in turn, support the preventive interventions which reduce the incidence of death and disability due to birth defects.

(Ms. Vandana Gurnani)

New Delhi
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Acknowledgement

I would like to take this opportunity to acknowledge all the experts, academicians, public health experts from medical colleges who have contributed towards developing this guideline. I would also like to acknowledge my colleagues in Child Health and Maternal Health division especially Dr. P.K Prabhakar, DC (CH) for their valuable inputs. I sincerely thank the team at WHO SEARO and WHO India Country office to provide technical guidance throughout the development process. The contribution of Centers of Diseases Control (CDC) in development of these important operational guidelines is well acknowledged.

I am confident that the operational guidelines on Birth defects Surveillance is a step towards achieving single digit NMR target by 2030 in the country.

(Dr. Ajay Khera)
4/7/16

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Acronyms

ASD	Atrial Septal Defect
BD	Birth defect
C Section	Caesarean Section
CECT	Contrast-enhanced computed tomography
CHD	Congenital Heart Disease
DEO	Data Entry Operator
ICD	International Classification of Diseases
MRI	Magnetic resonance imaging
NTD	Neural Tube Defect
OT	Operation Theater
PPI	Pixels per Inch
SEAR-NBDD	South-east Asian region Newborn and Birth Defects Database
SOP	Standard Operating Procedure
TGA	Transportation of great arteries
USG	Ultrasonography
VSD	Ventricular Septal Defect
WHO	World Health Organization

1. Introduction

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. As estimated, 10% of neonatal deaths are due to congenital abnormalities. As per the available estimates 4-6% of children are born in India with congenital anomalies. With annual birth cohort of 2.6 crore, this amounts to approximately 15 lakh children with birth defects.

The birth defects spectrum involves different organ systems, the most common being congenital heart diseases (CHD), neural tube defects (NTD), Down syndrome followed by haemoglobinopathies, musculoskeletal disorders and others. Many risk factors are known to be associated with birth defects like genetic factors; maternal infections like rubella & syphilis, maternal conditions like diabetes, obesity and age & behavior 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 through legislation and policies support in the reduction of birth defects. Some of the effective interventions include vaccination against rubella; iodine and folic acid supplementation; fortification of staple foods with micronutrients, 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 India. Such information is important to understand the public health burden and help to design prevention and control programs in the country related to birth defects. The operational guidelines have been formulated to establish the surveillance mechanisms and improve data and information. To start with, India has initiated hospital-based surveillance for birth defects in selected medical colleges and district hospitals with high load of deliveries, in due course and with the experience gained, this could be expanded to health facilities at other levels, so that the data collected would be representative of the most of the regions in the country. Later, population based surveillance may be considered depending on the availability of resources.

2. Purpose of the operational guideline

This guideline is for public health managers and all health professionals involved in the establishment and roll out of the birth defect surveillance system and for setting up sentinel surveillance sites in hospital. Birth defect surveillance is a public health tool which includes continuous, systematic collection, analysis, and interpretation of birth defect data to support in planning, implementation and evaluation of essential health interventions for prevention and control of birth defects.

The specific objectives of birth defects surveillance are:

1. To define the magnitude and distribution of birth defects by time, person and place
2. To identify high-risk populations and clusters (aggregation of cases)
3. To monitor trends in the prevalence of different types of birth defects in a defined population

The general term 'birth defect' may take on a variety of meanings depending on the context in which it is used and the perspective of the person using it. 'Congenital abnormality', 'congenital anomaly', and 'congenital malformation' are terms often used as synonyms for 'birth defect'.

However, the word 'congenital' is to be focused. Any condition present at birth, regardless of its etiology or timing of occurrence is to be considered. In a broad sense, the term birth defect encompasses a diversity of conditions including physical malformations, sensory deficits, chromosomal abnormalities, metabolic defects, neurodevelopmental disorders, musculo-skeletal disorders and complications related to prematurity and low birth weight, among others.

Under the hospital based sentinel surveillance the following 8 major visible anomalies are to be reported. Individual hospitals may expand this list to include other defects listed as optional.

Table 1: Birth Defects Listed For Surveillance

Externally visible major birth defect(s)	*Optional birth defect(s)*
1. Neural tube defects including microcephaly 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. Tracheo-esophageal fistula 5. Exstrophy of bladder 6. Other defects

3. Steps for establishing birth defect surveillance system

(a) Identification of Institution and the team

Hospital-based surveillance will be initiated in selected medical colleges / hospitals with high load of deliveries. In due course and with experience this could be expanded to other hospitals, so that the data collected would be representative of the most of the regions in the country.

Head of Departments of Pediatrics / In-charge Neonatology and Head of Departments Obstetrics & Gynecology will be responsible to establish the birth defects surveillance mechanism in the hospital. As a first step a nodal officer (head/ in-charge) for birth defects surveillance would be designated by the head of the institution.

The nodal officer will further collaborate with the Pediatrics, Obstetrics & Gynecology department to identify all the personnel who will be involved in the surveillance, as under:

i. Reporters: They would be involved in identification of babies with birth defects (case ascertainment) and recording e.g. Doctors, resident doctors and nurses working in the Pediatric and Obstetrics & Gynecology Department; and
ii. Data entry operator : They would be responsible for data entry in SEAR-NBBD Database (Online) e.g. Resident doctor / nurse / medical record clerk / data entry operator for uploading on online system

(b) Screening for birth defects

For the purpose of surveillance, case ascertainment will include all births (live and still) which will be clinically screened as for presence of birth defects.
The inclusion criteria for screening include

i. All newborns in the institution – Inborn and Out-born babies
ii. Stillbirths- Babies delivered at a gestation period of 20 weeks or more, or a birth weight of at least 500g (when gestation period is not available)
iii. Babies in the postnatal ward up-to discharge (or death) from the hospital special units like NICU, SNCU etc.

(Case ascertainment is the process of identifying – from existing sources and using defined case definitions – embryos, fetuses, neonates, infants, and children who have a birth defect)

(c) Adoption of standard case definitions

For the purposes of generating uniform standard data, the case definitions are to be followed (not be deviated / modified).

Case definitions for the hospital based surveillance system for above mentioned defects are annexed [Refer Annexure 1a and 1b]

(d) Recording and reporting

i. Recording

If a baby is detected with birth defect(s), an abstraction form {standard recording form} (Annexure 2) will be filled. The abstraction form has the following information fields

- Basic information
- History of birth defect
- Type of birth defect(s)
- Additional information/ investigation, if any
- Photographs taken

This form should be attached alongwith the case sheet / records of the baby.

Correct information must be ensured by using case sheets of mother and baby and taking further history from the mother as required and enter the information in the abstraction form.

It is essential to provide complete physical description of the birth defects in the text box at the relevant field of the abstraction form. (Refer Annexure 3 for SOP).

The name, designation and signature of the reporter filling the abstraction form is compulsory.

As part of the recording the birth defect(s) will be photographed and attached to the abstraction form. The standard procedure for taking the photograph is detailed in Annexure 4.

Birth defects forms would be further completed in the following situations:

- After any confirmatory tests (like X ray, USG, MRI, CECT, karyotyping etc.) are dole
- A new, missed-out or additional defect is detected during the baby's stay in the postnatal ward or neonatal unit / pediatric ward, also needs to be entered in the form by the respective units.

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.

All records need to be stored at the facility both in hard copy and as a soft copy. At the time of discharge or death of the baby, the filled abstraction form should be detached from the case record and filed at the hospital with the Nodal Officer for birth defects surveillance.

This is important to keep the records for later need of confirmation and validation.

ii. Coding and Online data entry

After the abstraction form has been completed, coding of the birth defect will be done based on the recorded information, using a standardized set of rules and procedures for case ascertainment, the description provided and organizing the "cases" based on the clinical condition(s). For this purpose of coding, ICD – 10 classification will be used [Refer Annexure 1a and 1b].

Select the most appropriate ICD-10 code from the ICD 10 list to describe the birth defects identified , based on the description and photograph included in the form, which is to be entered in the online system, which can be selected through drop-down menus.

The complete list of ICD codes for birth defects is available at the web link: http://apps.who.int/classifications/icd10/browse/2015/en

- For the purpose of online reporting, computer and broadband connection will be required for online submission of the forms in the SEAR-NBBD database.
- Monthly reporting of all the birth defects detected has to be reported by the facility through the registered ID in the SEAR-NBDD database.
- Detailed procedure for registration and online reporting (login and the process of entering birth defects form) is annexed in Annexure 5 & 6.
- Mobile apps for smart phones (Android and iOS systems) are also available to facilitate online reporting under the SEAR-NBBD.

(e) Analysis and feedback

Nodal Officer of the hospital / sentinel site will analyze the data on birth defects among intra-mural births every month and discuss with the team in the hospital. They would also facilitate appropriate care, management and counseling of the case in the hospital or by referral, as feasible and report the same.

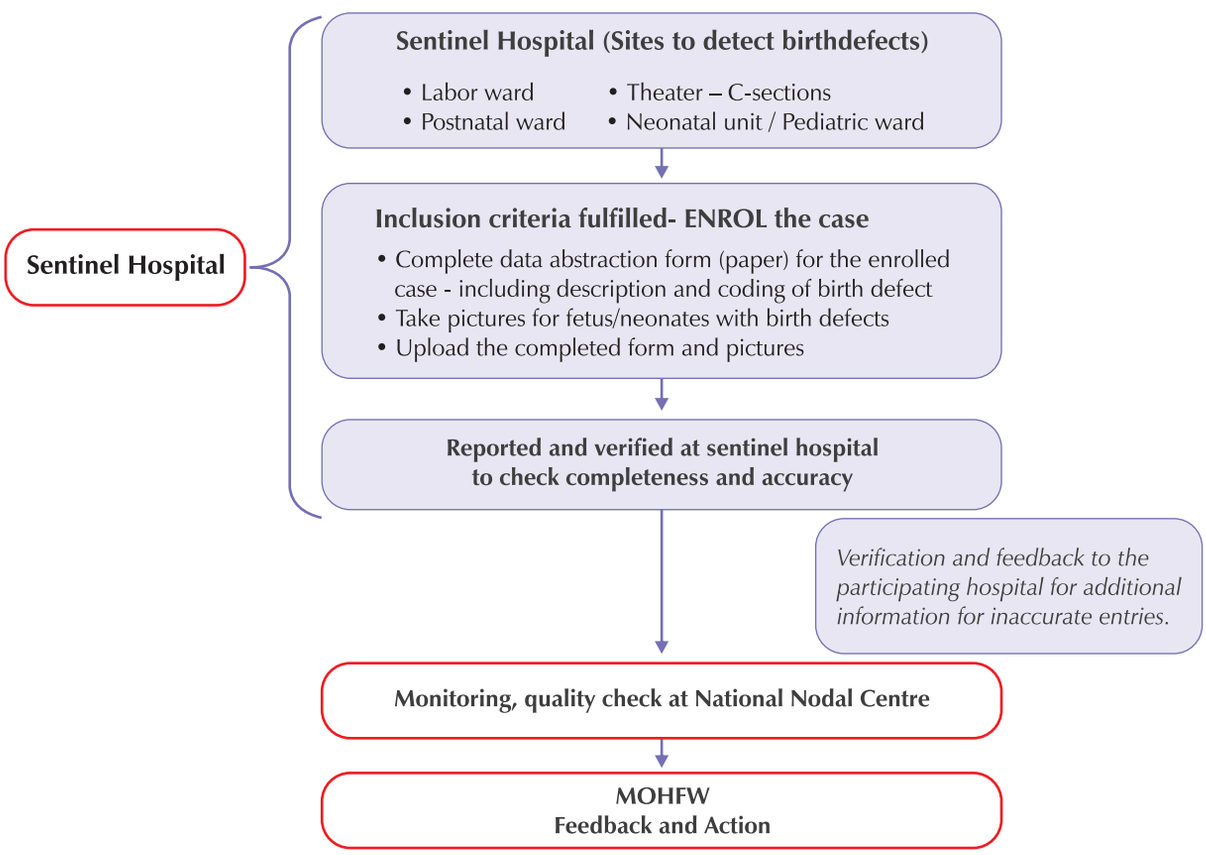
Quarterly analysis will be done by the State / UT, based on the birth defect surveillance data for:

- Prevalence of birth defects in live born and still born babies (separately) – at birth.
- Distribution of birth defects with reference to
    - Type of birth defect
    - Sex of the baby
    - Gestation period of the baby, and
    - Risk factors/ environmental factors
- Identify time trends in the prevalence, and occurrence of birth defects.

Quarterly and annual reports are to be shared with the Institution/State Program Manager and forwarded to National Program Manager.

At the national level the national nodal center will conduct timely quality check, analyze the state reports and provide feedback at the state and national level.

Flow chart for birth defect sentinel surveillance



4. Capacity building

Two day training on birth defects surveillance would be organized by the Ministry of Health for the representatives of the identified Institutions (one from each department - Department of Pediatrics / In-charge Neonatology and Department of Obstetrics & Gynecology).

After being trained, the Institution team shall convene a meeting in the hospital with relevant staff to plan for establishing surveillance of birth defects in the hospital and conduct an in-house orientation to the staff at the delivery points to enable recording of birth defects.

The Nodal officer will further collaborate with the departments, to identify all the personnel who will be involved in the case ascertainment and recording e.g. Doctors, resident doctors and nurses working in the Pediatric and Obstetrics & Gynecology Department and train them on the online reporting mechanism.

5. Quality Assurance

'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 on improvement that focuses on prevention of errors. As a result of QA procedures, high- quality data is created at the front end or at the designing stage.

- ***Quality control*** is a retrospective and reactive approach on improvement that focuses on identification of errors. 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.

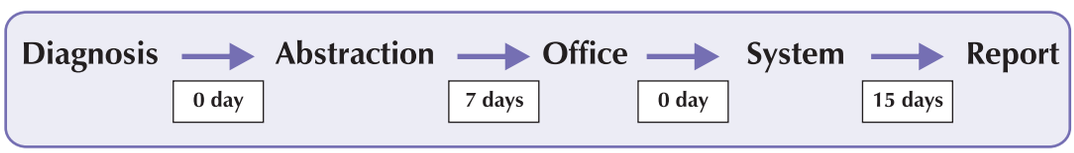
Quality data must have the following

- **Completeness :** The extent to which data is completedly captured and is 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 is accurately captured, with correct and valid information. Accuracy reflects the program's standard to conform on the

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 is rapidly diagnosed, promptly reported, and its response. For example, *a birth defect case should be ascertained or reported to the program immediately after diagnosis. With rapid case identification, reporting and analysis the program is able to provide timely intervention services.*



A simple checklist for quality check is annexed in annexure 11, which can be used for routine ongoing quality assurance by the Hospital Nodal Officer.

6. Role and responsibilities

i. Hospital Nodal Person

Training

a. The nodal officer in-charge will train / orient the identified personnel (resident doctors, nurses, and data entry operator) working in the Pediatric and Obstetrics and Gynecology Department on birth defect surveillance.

b. Orient the selected personnel regarding filling of the birth defects abstraction form- correctly and completely.

c. Provide ongoing support for skill building and problem solving.

Data quality management

a. Undertake quality check of the data - review the birth defects form for its completeness and accuracy, and confirm the diagnosis of the birth defect(s) before or after online submission. The total number of births (live and still) in a month must also be confirmed, verified and authenticated.

ii. Reporter of the institution

Record keeping

a. The doctors (Pediatrician/ Obstetrician) / nurses present in the delivery area (labour room/O.T.), post-natal wards and neonatal/pediatric units will be responsible to screen all the births.

b. They would ensure that babies (live and still born) are examined in the delivery rooms, operation theaters (for C Section), postnatal ward and neonatal unit/ pediatric ward in the hospital soon after delivery.

c. They would conduct a complete physical examination of all live-born / stillborn babies (>500 g / 20 weeks gestation), 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).

d. Refer the cases with birth defect(s) to the appropriate specialty for complete check-up and relevant investigations, to confirm the diagnosis, including karyotyping and genetic studies, and for further management.

iii. State Nodal Officer

a. Analyze the data on birth defects among intra-mural births on a monthly, quarterly and annual basis, and discuss with the team in the hospital with feedback.

b. Share the analysis with Institution /State / National Program Manager at quarterly / annual intervals.

c. Arrange for appropriate counseling, management and care in the hospital or provide further referral for management.

7. Annexures

Annexure 1a: Standard case definitions for major birth defects

Congenital malformations of the nervous system

Neural Tube Defects

1. 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.

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

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

4. Microcephaly (Q 02): Microcephaly is defined as occipito- frontal circumference less than the third percentile, based on standard growth charts (e.g., WHO growth curves) for sex, age, and gestational age at birth. For a diagnosis of microcephaly to be made, the occipito-frontal circumference should be disproportionately small in comparison with the length of the infant and not explained by other etiologies (e.g., other congenital disorders)

5. 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.

6. 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 thorough an incompletely closed spine. Includes: meningocele, meningomyelocele, myelocele, myelomeningocele, and rachischisis.

Cleft lip and cleft palate

Orofacial

Orofacial Clefts

1a. 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, sub-mucous cleft palate

2a 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

Other congenital malformations of the digestive system

Large intestine

Imperforate anus (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, that varies from fairly minor lesions, as well as complex anomalies

Congenital malformations of genital organs

Genitourinary

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.

Congenital malformations and deformations of the musculoskeletal system

Congenital deformities of feet

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).

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

Other congenital malformations of the digestive system

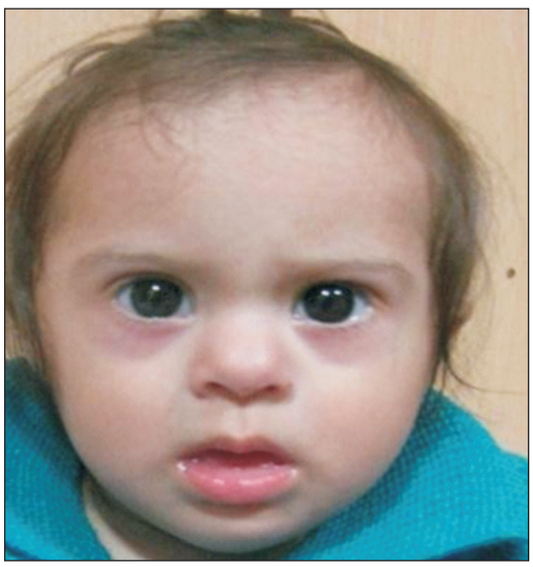
Exomphalos / Omphalocele (Q79.2)

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

Gastroschisis (Q79.3)

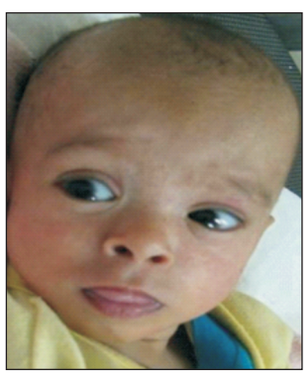
A congenital malformation characterized by visceral herniation usually through a right side abdominal wall defect to one side of an intact umbilical cord and not covered by a membrane. Excludes hypoplasia of abdominal muscles, skin covered umbilical hernia and omphalocele.

Annexure 1b: - Standard case definitions for optional birth defects

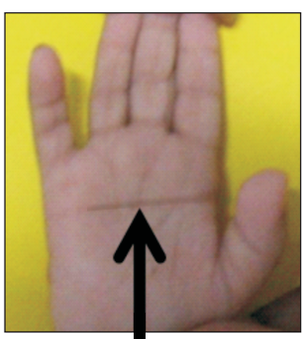


1. Down syndrome/ Trisomy 21 (Q90.0, Q90.1, Q90.2, Q90.9)

Down syndrome is a chromosomal disorder that is characterized by presence of flat facies, up-slant, 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



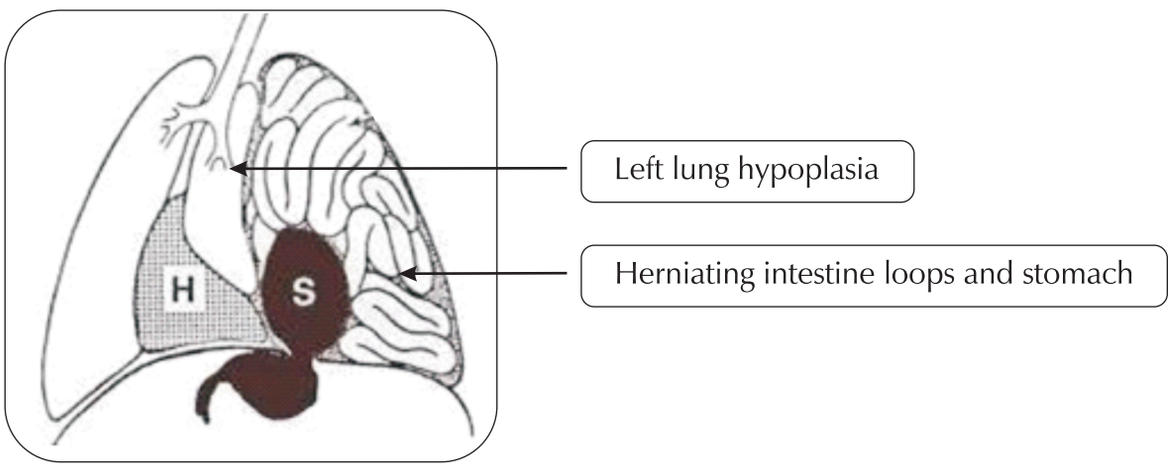
Simian crease

Short & broad hands and small fingers

Increased space between 1 & 2 toes - Sandal Gap

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

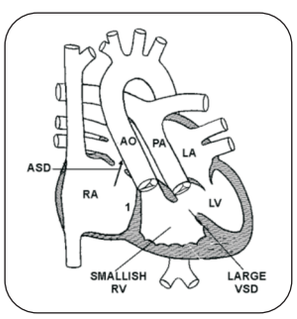
CDH occurs due to a defect in the formation of diaphragm through which gastrointestinal organs like stomach, intestines, liver can herniate into the chest causing poor development of the lungs resulting in life threatening breathing difficulties at birth. Picture shows right sided congenital diaphragmatic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



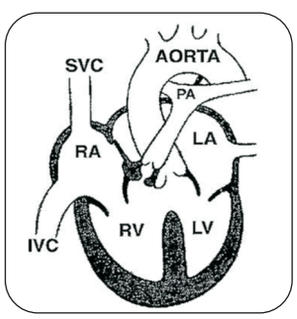
Congenital Diaphragmatic hernia

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

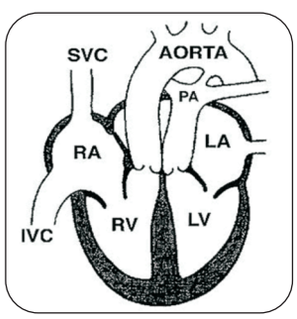
A congenital malformation of the structure of the heart can involve the walls or valves of the heart, and aorta or other large blood vessels near the heart. There are many types of congenital heart diseases; some of the common ones are atrial septal defect (ASD), ventricular septal defect (VSD), pulmonary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



ASD and VSD



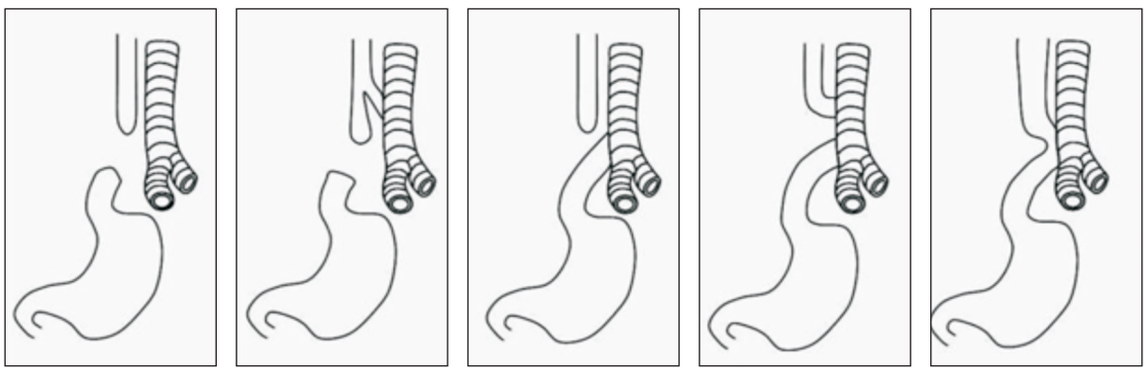
Tetralogy of Fallot



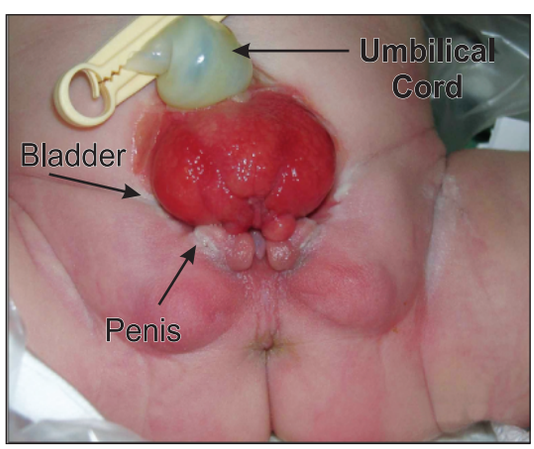
TGA with VSD

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

Tracheo-esophageal 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.



Type-I (8%) **Type-II (1%)** **Type-III (84%)** **Type-IV (3%)** **Type-V (4%)**



5. Exstrophy of bladder (Q64.1)

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

Annexure 2 - Birth Defects Abstraction Form

Center Name	Baby's Hospital Record No.	Mother's Hospital Record No.	NBBD Number
			1 2 3 4 5 6 7 8 9

Inborn ☐ **Out born** ☐

1. Basic information:

i.	Mother's Name		
ii.	Date of Delivery *	d d m m y y y y	
iii.	Time of Delivery * *(24 hr format)*	h h m 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	C or P #
i.				
ii.				
iii.				
iv.				
v.				

4. Additional information/investigation if any

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

1. Chromosomal Analysis (Karyotype) (Y/N)
2. Infantogram / Babygram (Y/N)
3. 2-D Echo (Y/N)
4. Ultrasound Abdomen (Y/N)
5. 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

Annexure 3 - Birth Defects Abstraction form - Definitions

FIELD TITLE	EXPLANATION / DEFINITION
Hospital Name	Name of hospital / center & 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 center name/code like; IND-PGIME- 123456789

S.N.	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 *(choose any one)*
v.	Time of Delivery	*(24 hr format)*
vi.	Gestation* *(in weeks)*	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").*
vii.	Baby's Gender *	Male / female / ambiguous *(choose any one option)*
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 *(decimel upto to units e.g. 29.69 cms)*
xi.	Mother's Age (Completed) *	Two digits field.; age in completed years
xii.	Father's Age (Completed) *	Two digits field.; age in completed years

* denotes mandatory fields

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 / Still Birth – Fresh/ Still Birth – Macerated (Choose anyone)
xv.	Autopsy (in case of still birth) *	Y/N (Mandatory in case of Still birth)

	2. HISTORY OF BIRTH DEFECT(s)	
i.	Previous termination of pregnancy for malformation	Y/N (*Describe in case of Yes)*
ii.	Previous Still birth Y / N	Yes; if any birth defect found
iii.	Previous spontaneous abortion(s)	Y / N

	3. TYPE OF BIRTH DEFECT(s)	
i.	Birth Defect	*Birth defects* are defined as structural changes that have significant medical, social, or cosmetic consequences for the affected individual, and typically require medical intervention. *Major structural abnormalities* are the conditions that account for most of the deaths, morbidity, and disability related to birth defects. *Minor abnormalities* are structural changes that pose no significant health problem in the neonatal
ii.	Description	Provide a full description for each birth defect identified.
iii.	Code	Code the congenital anomaly according Classification of Disease and Related Health Problems, Tenth Revision (ICD10).
iv.	C or P	C = Confirmed, P = Possible

* denotes mandatory fields

	4. ADDITIONAL INFORMATION / INVESTIGATION IF ANY
	Indicate what tests have been performed for the fetus/baby 1) Chromosomal analysis (Karyotype) 2) Infantogram 3) 2-D Echo 4) Ultrasound abdomen 5) 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	If Yes, attach photo If possible, take the following photographs: 1) all the birth defects present in a baby 2) the whole fetus or newborn from front view and back view 3) fetal face front and lateral view Mention the respective image description(s). This is important, since photographs explain the condition of the infant with great clarity.
	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*

Annexure 4 - Taking Photograph of Birth Defect

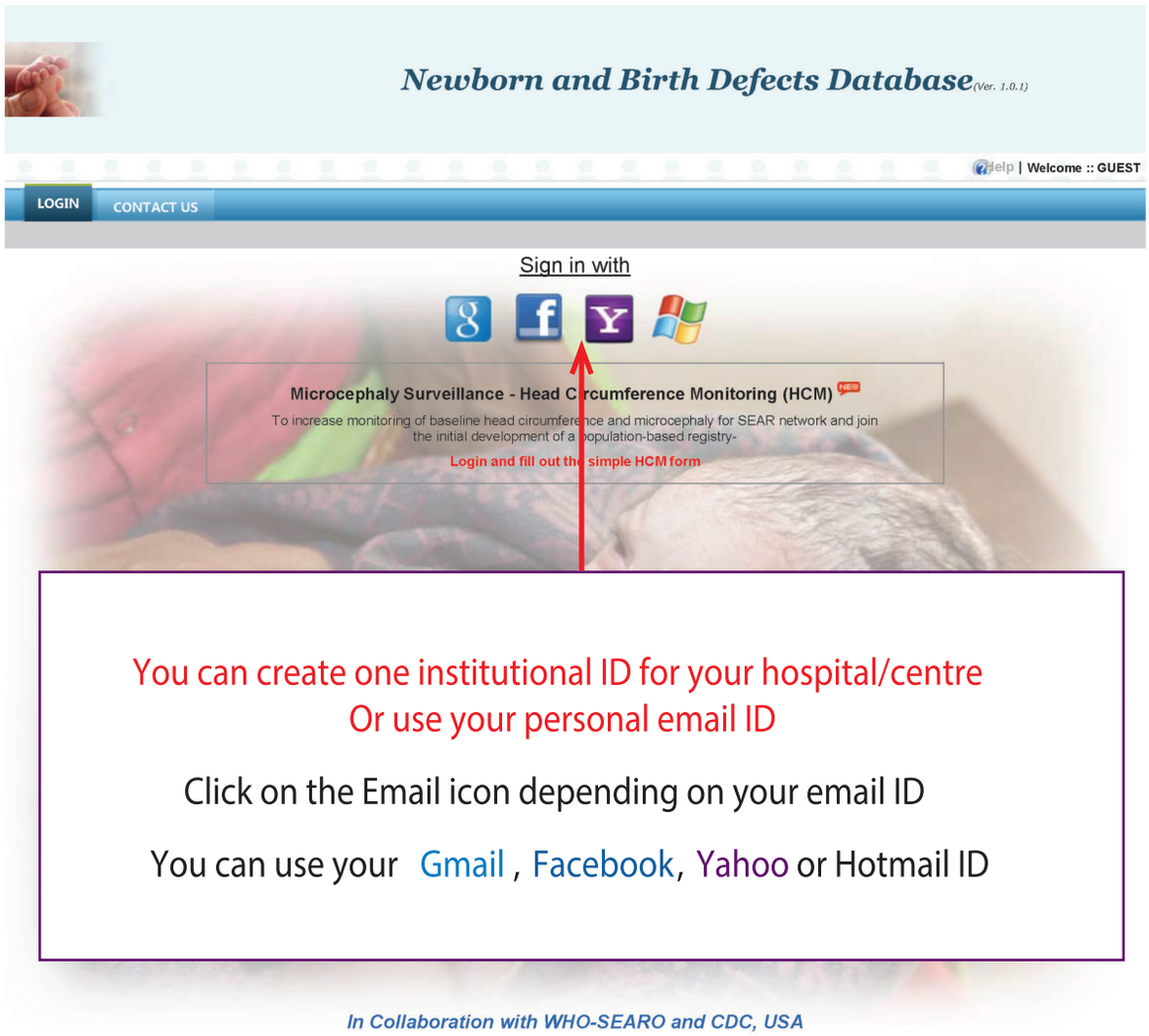
1. Make a label for the photograph on a piece of paper, adhesive tape available in hospital: Write in big and bold letters (so that these are legible in the photo) a unique identifier e.g. Date and time of birth, sex, name of mother if acceptable.
2. Place the label next to, but not touching, the fetus or neonate.
3. If more than one photograph is taken, make sure that all photographs can be identified with the label for that particular fetus or neonate.
4. Have a clean, simple, non-patterned light or dark blue background (no blankets or other things in the bassinet or on the examination table).
5. If there are objects on the examination table that affect the photograph, remove them before taking the photograph.
6. Take a view of the entire fetus or neonate, plus several focused views of the congenital anomaly/anomalies.
7. Take a separate view of the face, if possible.
8. Take a front or back view, or both, plus a side view, depending on the congenital anomaly.
9. Avoid taking photographs at an angle; i.e. take all photographs holding the camera at 90° to the fetus or neonate.
10. Ensure that there is adequate lighting and no shadows in the photograph. Use a flash if needed.

Consider the cost of photograph storage.

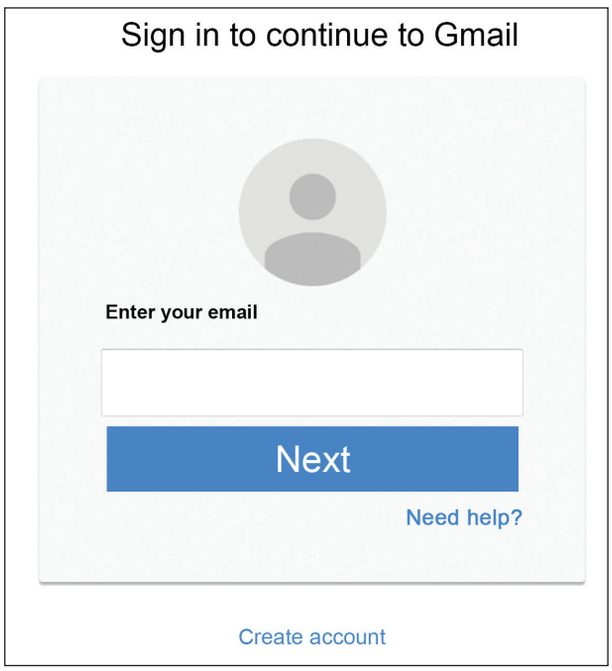
1. Use a digital camera with high resolution, at least 300 ppi (pixels per inch).
2. Review photographs quickly while on site and retake the picture if necessary.
3. Save the image in jpeg (jpg) format; make sure each photograph is transferred to a computer file or other secure storage before deleting it from the camera.
4. Tablets or smart phones can also be used to take photographs

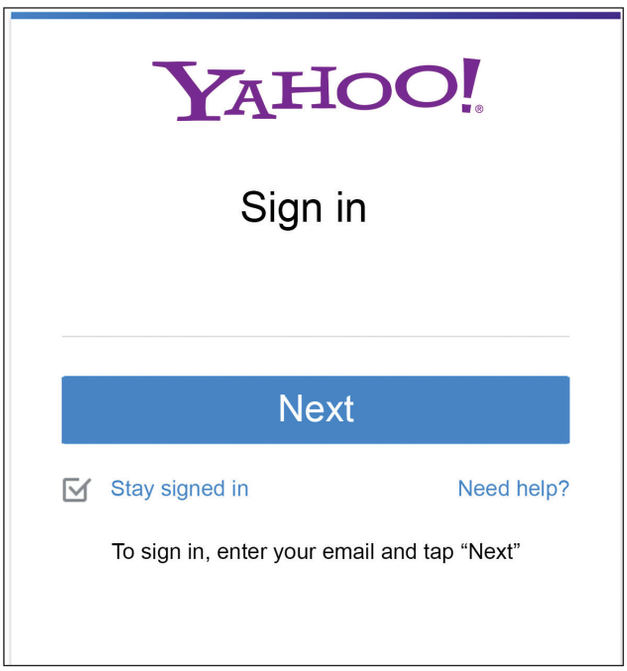
Annexure 5 - Standard Operating Procedure for online registration of the hospital

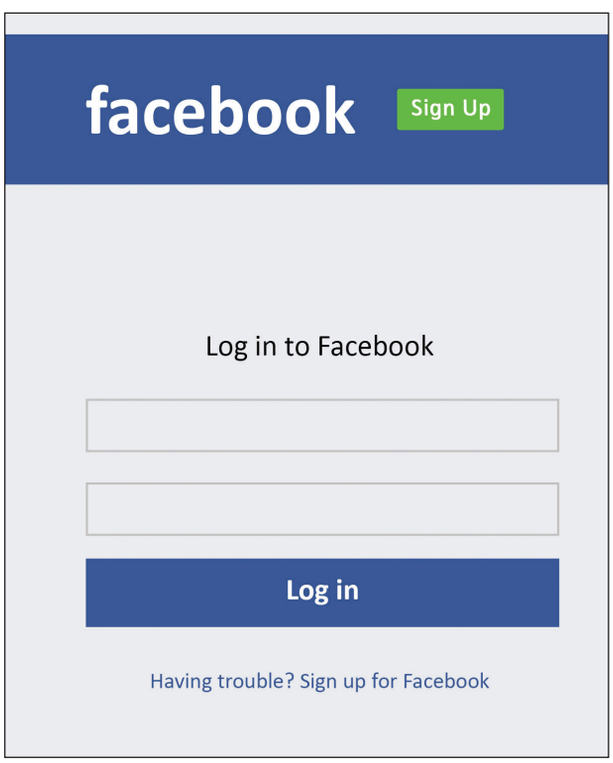
1. Go to site http://apps.searo.who.int/npn/

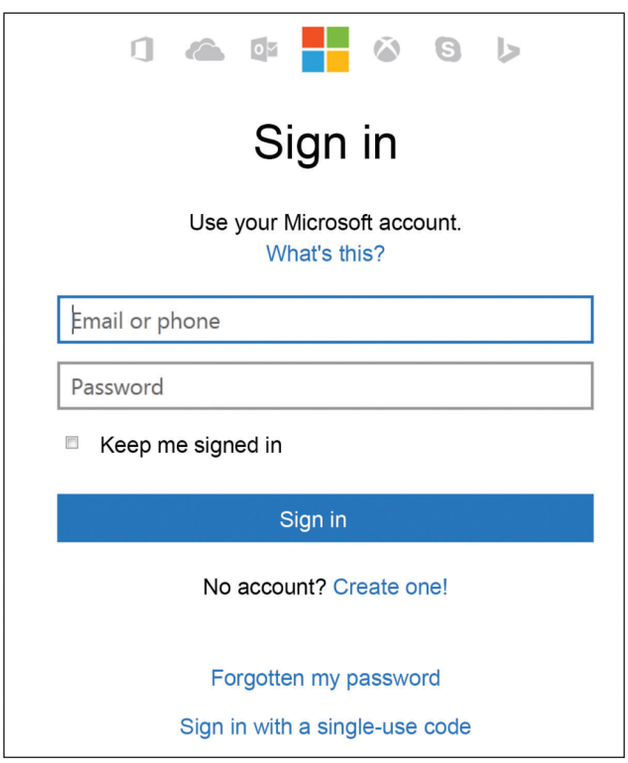


2. Provide your email and password

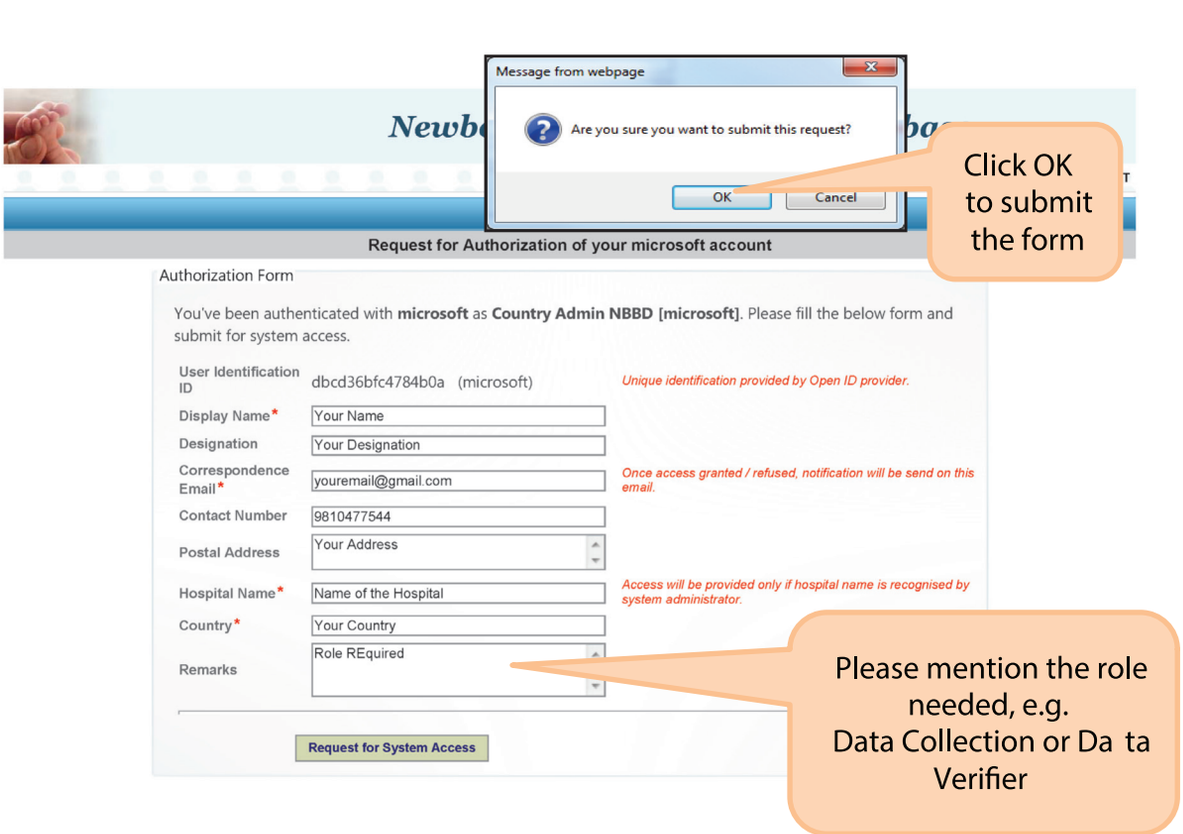








3. This will take you to the registration form; fill out the registration form



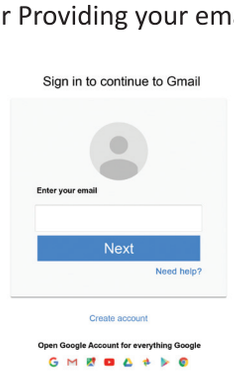
After submitting the registration form, the request will come to us for approval. Once approved, you will be informed by WHO-SEARO and then you will be ready to login.

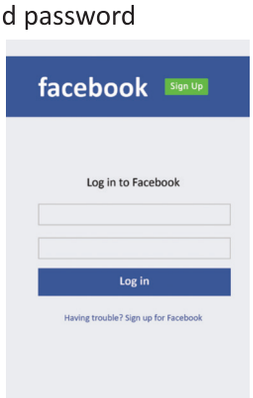
Annexure 6 - How to login and enter online birth defects form

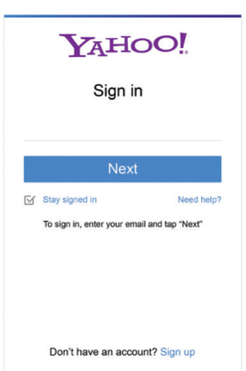
1. *How to login*

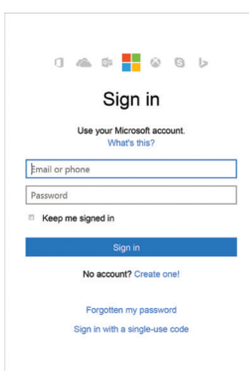
i. Once your ID is approved and assigned to a hospital and role: Login to the site http://apps.searo.who.int/npn

ii. After Providing your email and password









iii. The hospital is logged in the system and ready to report/submit data on Newborn and Birth Defects.

iv. 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.

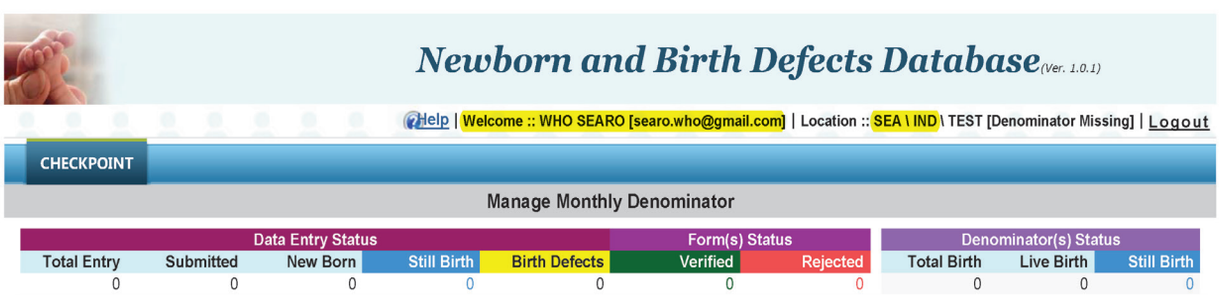
1. Limiting the description to final diagnosis only, without giving the full description of the birth defect. However, the surveillance system expects full description of the birth defects; giving the full description helps in better characterization of the birth defect.
2. Reporting multiple birth defects 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.

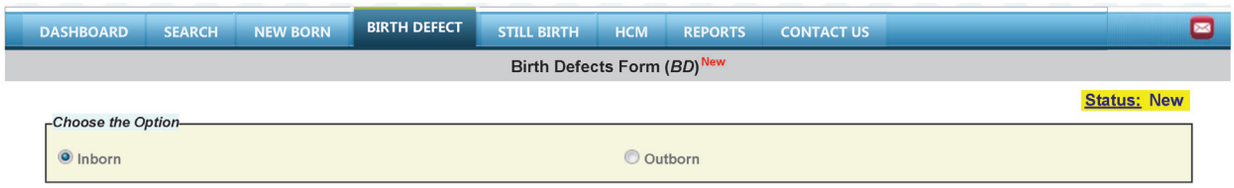
v. On the welcome screen, you can notice on top right side: Your Name, Email ID, Location and Role

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

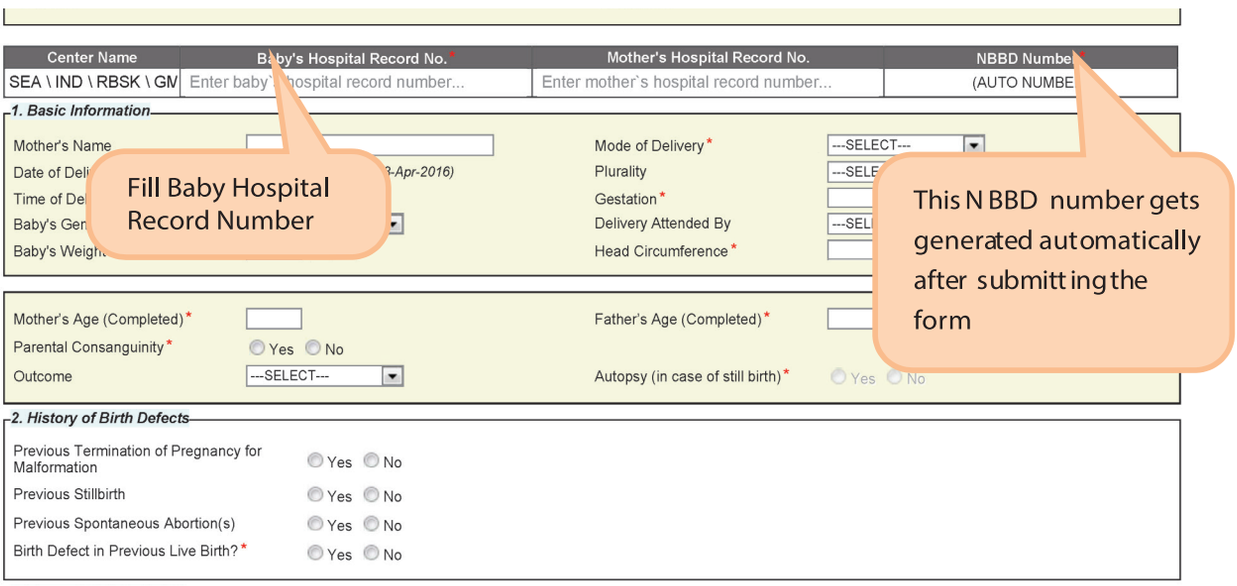


Birth defect form

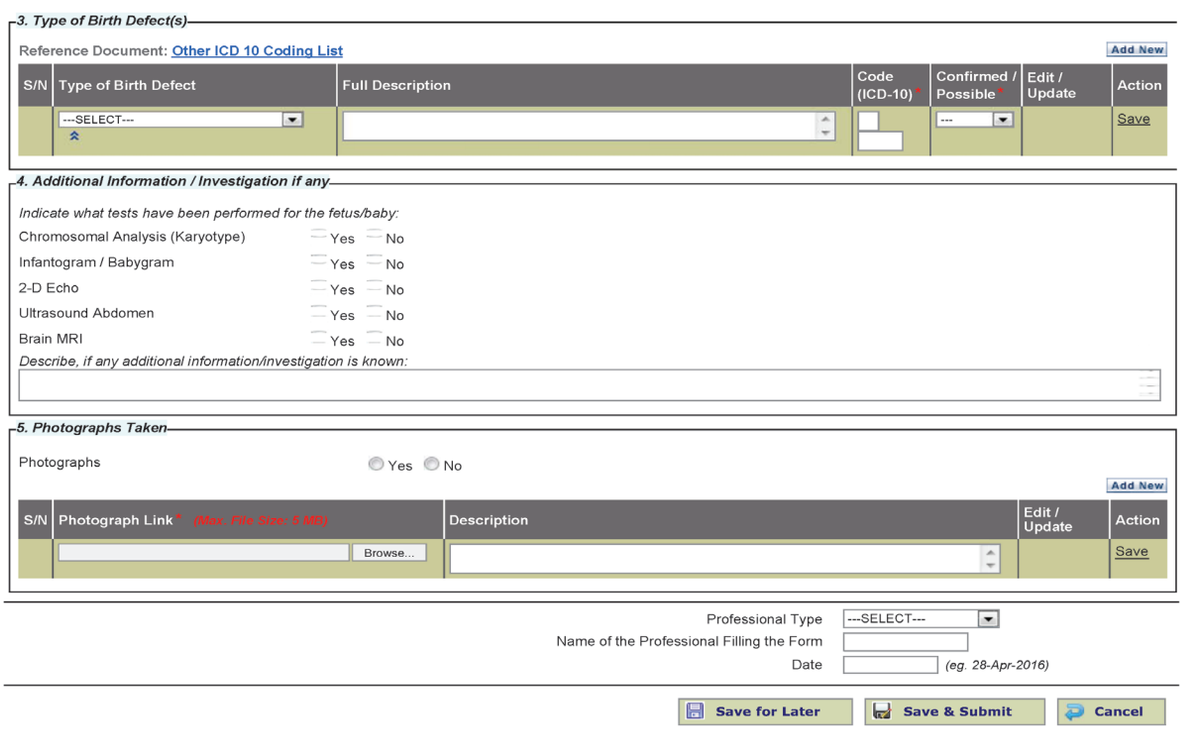
2. *How to fill the birth defect form*

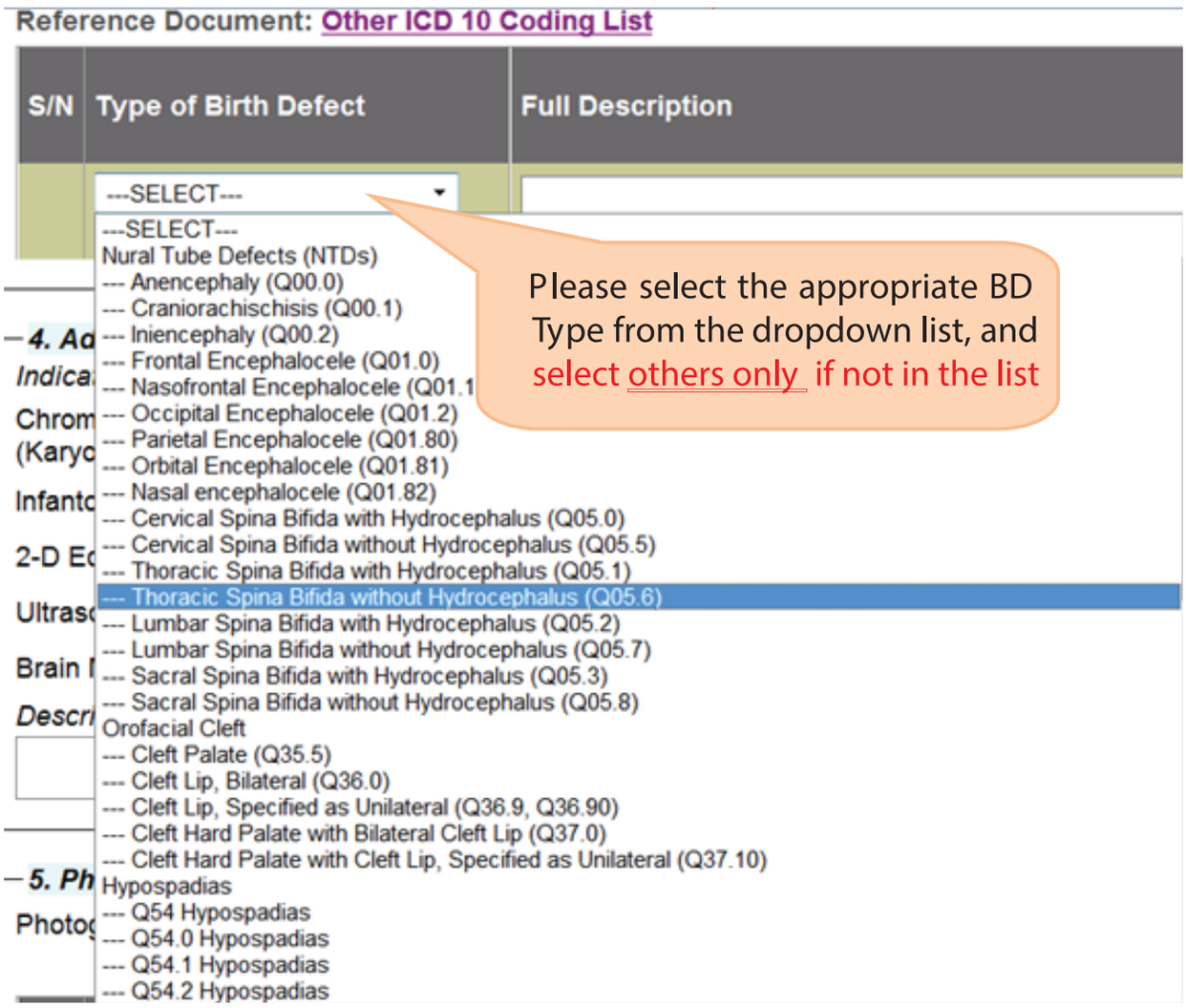


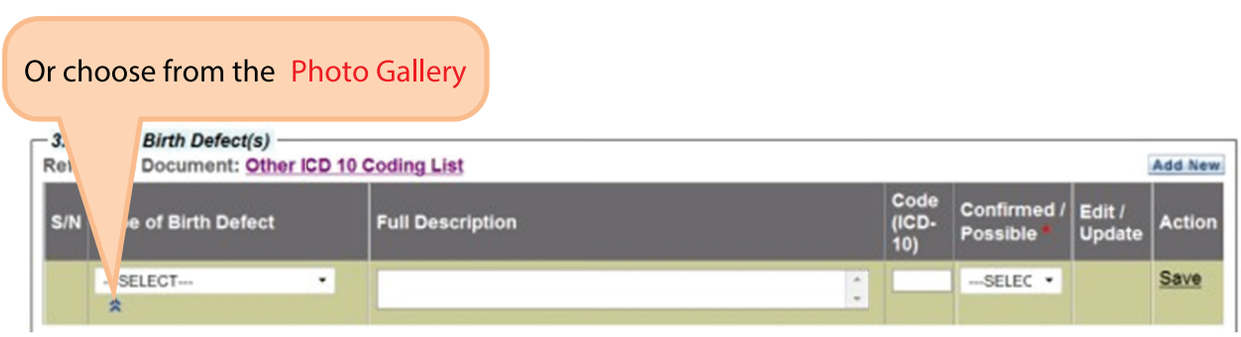
i. Click on Birth Defect and Select inborn live birth or outborn live birth



ii. Fill out the basic information and history of birth defects







iii. 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.*


iv. Provide full Description

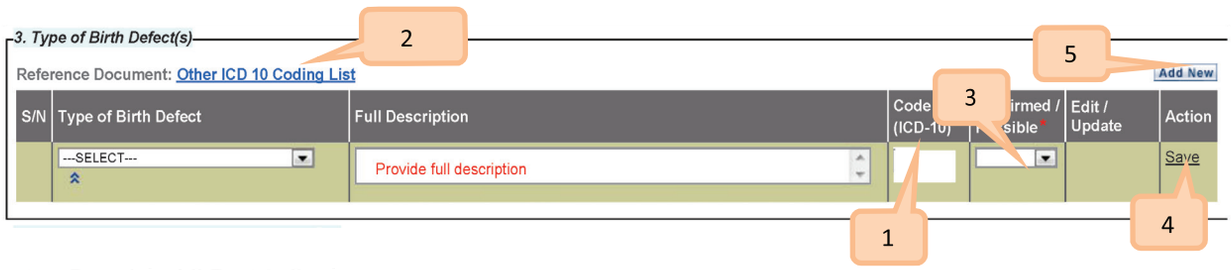
3. Type of Birth Defect(s)

Reference Document: Other ICD 10 Coding List — Add New

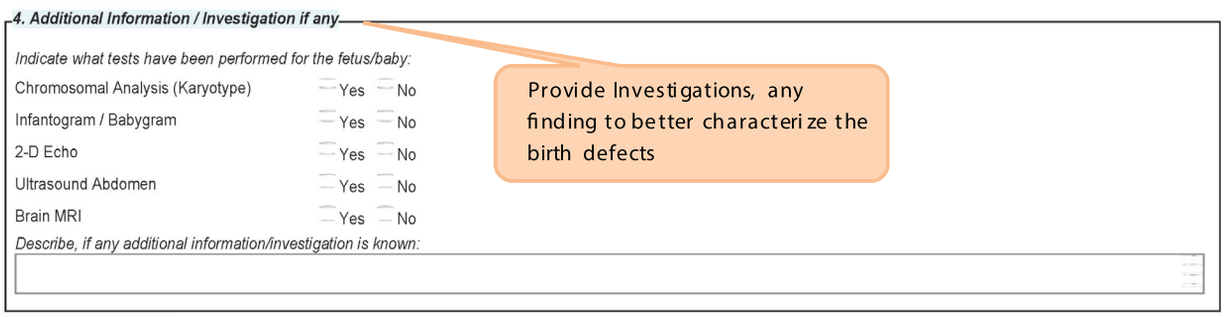
S/N	Type of Birth Defect	Full Description	Code (ICD-10)*	Confirmed / Possible*	Edit / Update	Action
	---SELECT---	Provide full description				Save

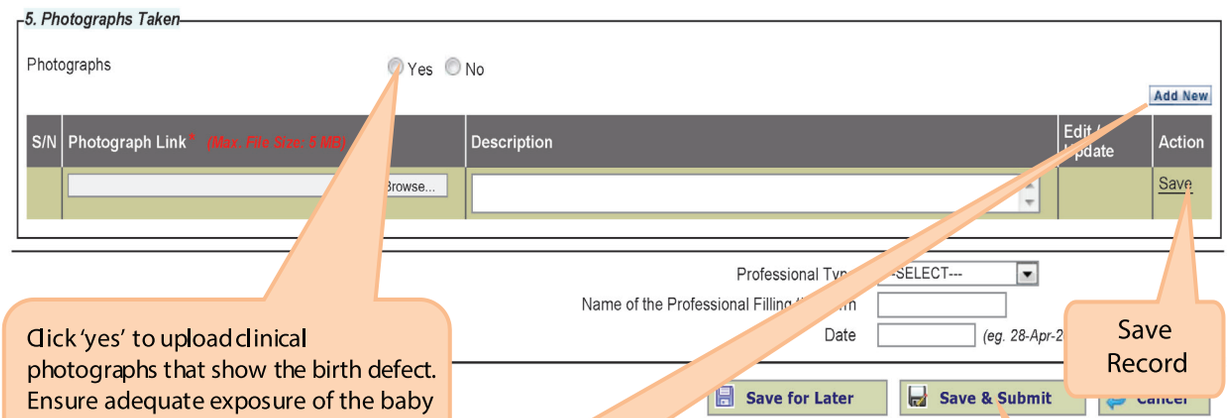
Please provide full description of the birth defect and not only the final diagnosis.

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 clini cal description: Forefoot and midfoot and heel are adducted , and there is a fixed plantar flexion (equinus position) of the ankle



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





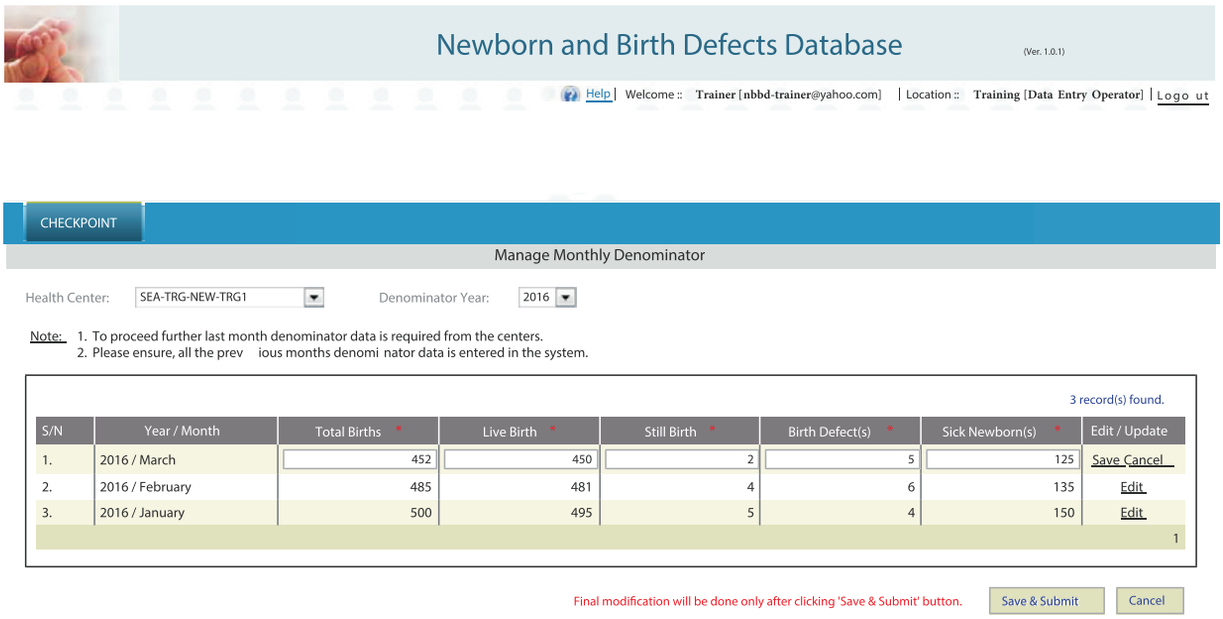
Click 'yes' to upload clinical photographs that show the birth defect. Ensure adequate exposure of the baby before clicking pictures.

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

Save Record

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

v. Check Point



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

Total Births (Including Multiple births)

Total Live Births

Total Stillbirths

Total Birth Defects

vi. 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.

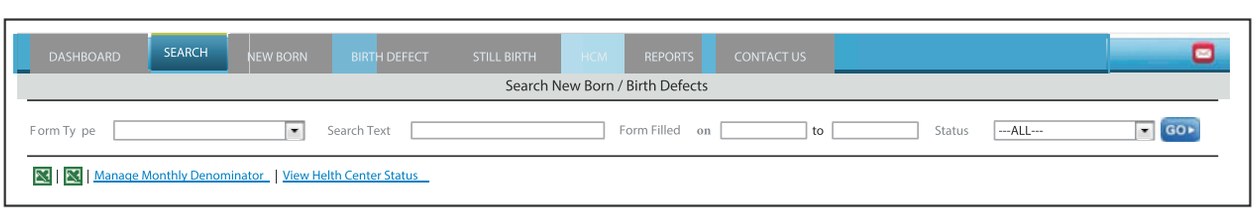
Alert 

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.

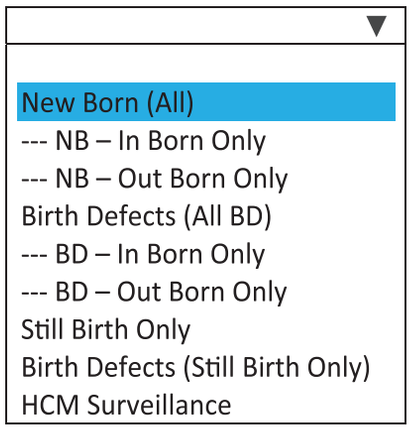
3. *Other functionalities*

i. Search

Go to Search Tab



1. Form Type

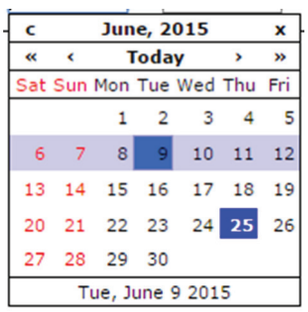


2. Search Text

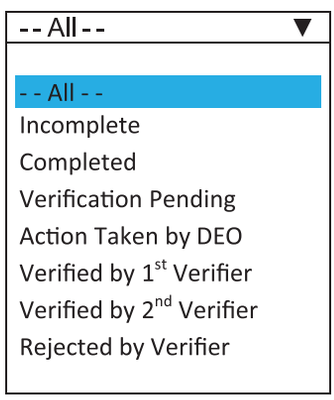
You can search records based on the baby hospital record number or the NBBD number that is generated automatically when you submit the form and can be seen immediately on top of search results. Any other criteria should not be selected in this case.

3. Forms filled on

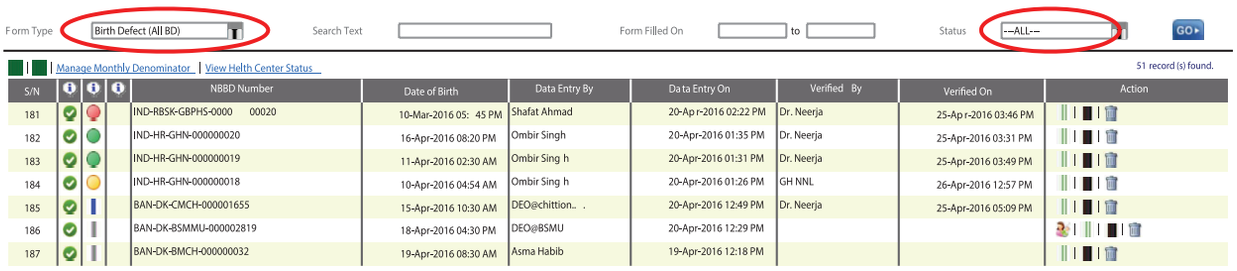
You can select the date range when the form was filled and submitted.



4. Status



Some examples of search based on the above criteria



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 Sing h	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 Sing h	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@chittion.. .	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

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

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			

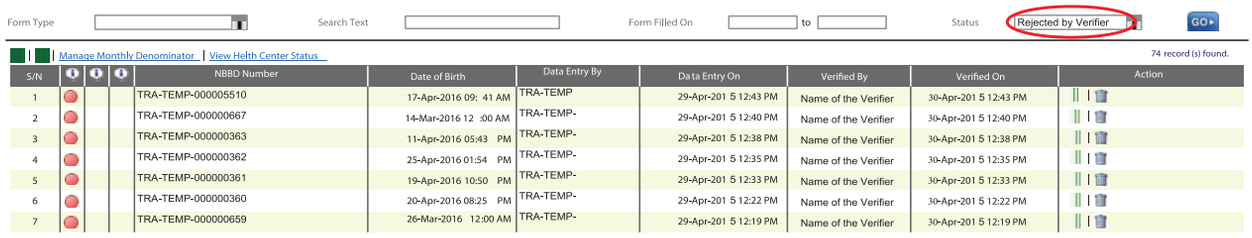
Verified by 1 st Verifier

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	

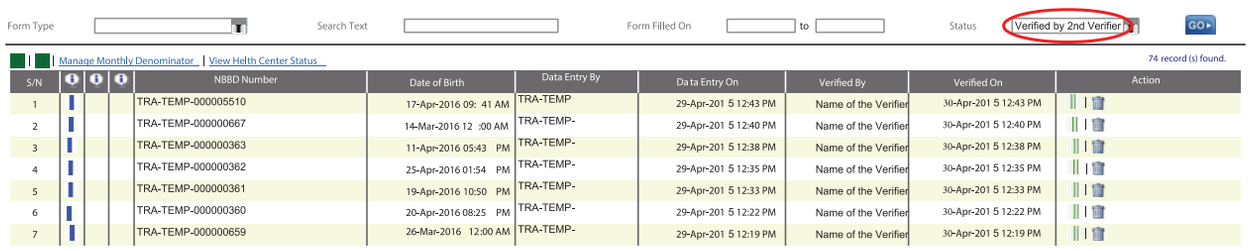
Verified by 2 nd Verifier

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



Action Taken by DRs/DEO



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.

Annexure 7 - Wall poster

LET'S COUNT AND PREVENT BIRTH DEFECTS

Essential Birth Defects

Neural Tube Defects


Anencephaly


Craniorachischisis


Meningocele


Encephalocele


Cervical spina bifida


Iniencephaly


Lumbar spina bifida


Sacral spina bifida


Thoracic spina bifida

Limb Defects

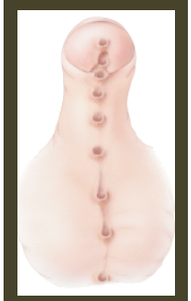

Congenital absence of both forearm and hand


Congenital absence of finger (s)and toes

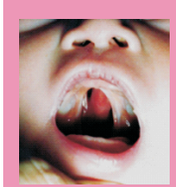

Amelia of lower limb


Talipes equinovarus

Hypospadias



Facial Defects

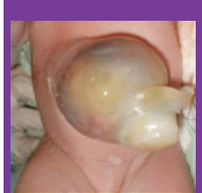

Cleft palate


Cleft lip, specified as unilateral


Cleft hard palate with cleft lip, specified as unilateral

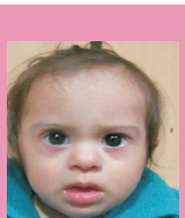
Imperforate anus

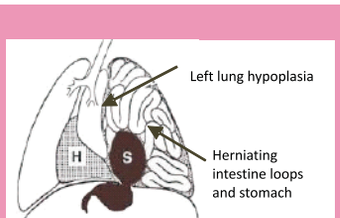
Abdominal wall Defects


Exomphalos /omphalocele

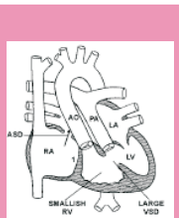

Gastroschisis

Optional Birth Defects

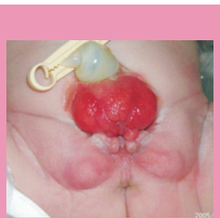

Down syndrome



Congenital diaphtragmatichernia


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

Annexure 8 - Recurrence risk of some birth defects

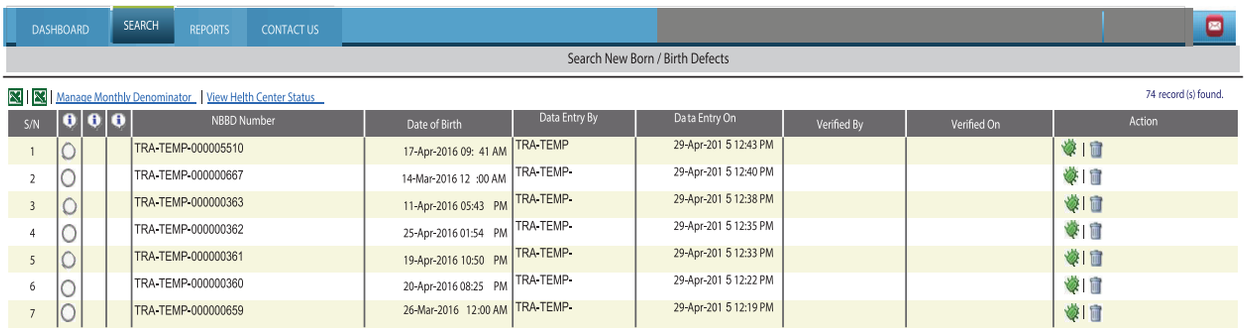
Defect	RECURRENCE RISK FOR		
	Normal Parents of One Affected Child	Future Males	Future Female
Cleft lip with or without cleft palate	4% - 5%*		
Cleft palate alone	2%-6%		
Cardiac defect (common type)	3%-4%		
Pyloric stenosis	3%	4%	2.4%
Hirschsprung anomaly	3%-5%		
Clubfoot	2%-8%		
Dislocation of hip	3%-4%	0.5%	6.3%
Nerual tube defects-anecephyaly, meningomyelocele	3%-5%		

(Adapted from SMITH'S Recognizable Patterns of Human Malformation, Seventh Edition)

Annexure 9 - 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.



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 clinking 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.
- Repeat same steps to identify the birth defects forms among the newborn and birth defect category by selecting the form type All NB + BD and Status Verification Pending from dropdown in the search option.

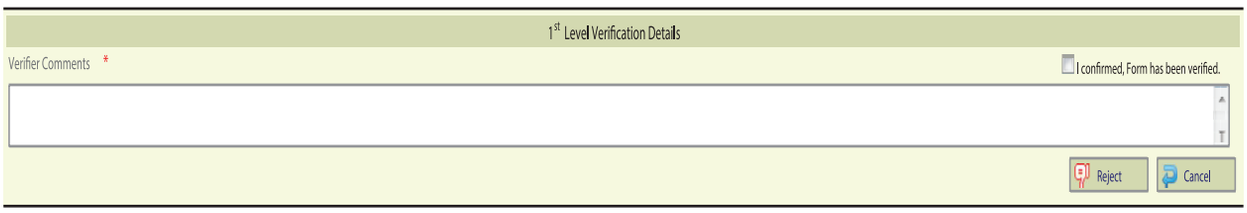
Steps in verification

i. 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 babys weight 500gms
- Make a note of history of birth defect section if not completed

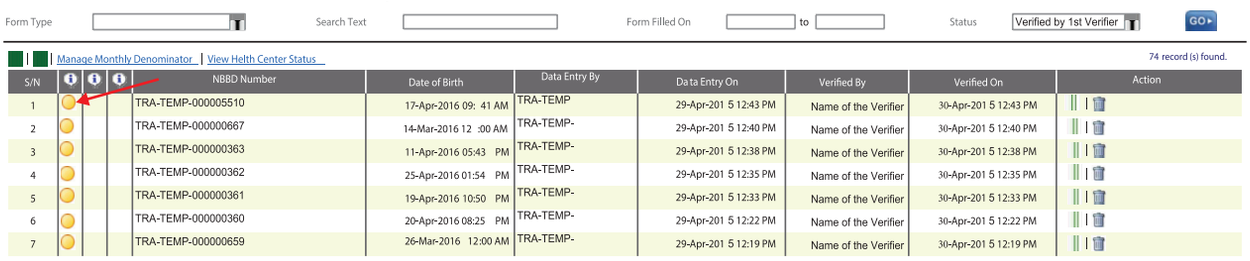
ii. Types of birth defect verification

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.



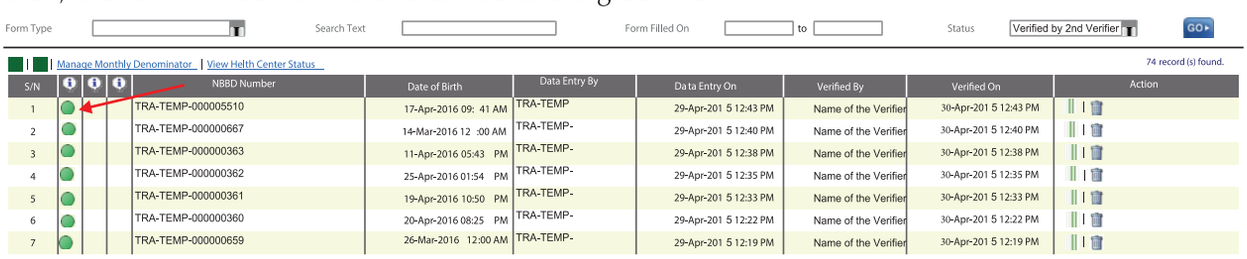
If you feel the form is incomplete or some fields are missing, you can write in the comment box and click the reject button and the form will be rejected, and the colour icon of this forms will turned to red, these rejected forms can be picked up DEO form search **Status** Rejected by Verifier

And you if feels 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.



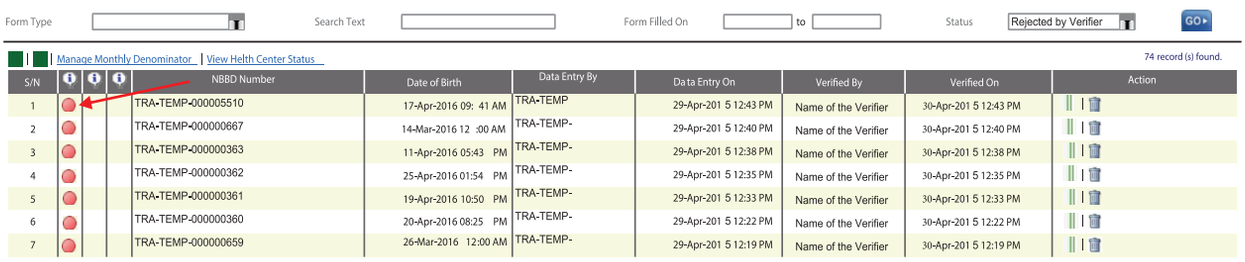
S/N	NBBD Number	Date of Birth	Data Entry By	Data Entry On	Verified By	Verified On	Action
1	TRA-TEMP-000005510	17-Apr-2016 09: 41 AM	TRA-TEMP	29-Apr-201 5 12:43 PM	Name of the Verifier	30-Apr-201 5 12:43 PM	
2	TRA-TEMP-000000667	14-Mar-2016 12 :00 AM	TRA-TEMP-	29-Apr-201 5 12:40 PM	Name of the Verifier	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.



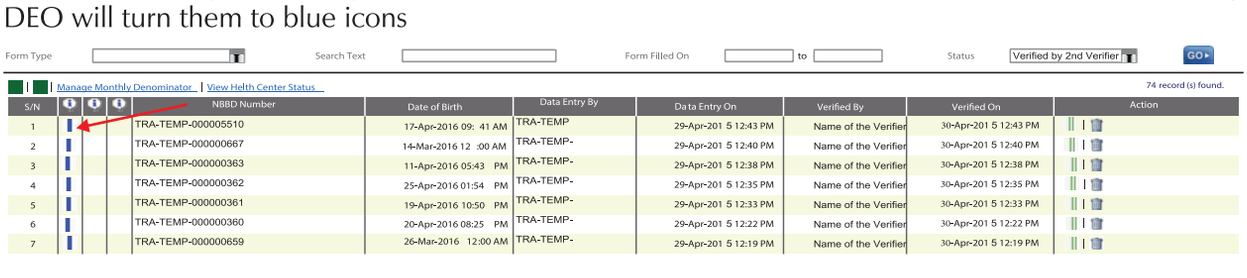
S/N	NBBD Number	Date of Birth	Data Entry By	Data Entry On	Verified By	Verified On	Action
1	TRA-TEMP-000005510	17-Apr-2016 09: 41 AM	TRA-TEMP	29-Apr-201 5 12:43 PM	Name of the Verifier	30-Apr-201 5 12:43 PM	
2	TRA-TEMP-000000667	14-Mar-2016 12 :00 AM	TRA-TEMP-	29-Apr-201 5 12:40 PM	Name of the Verifier	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	

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



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	

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



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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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.
- 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.
- 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.
- 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.

- 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 :

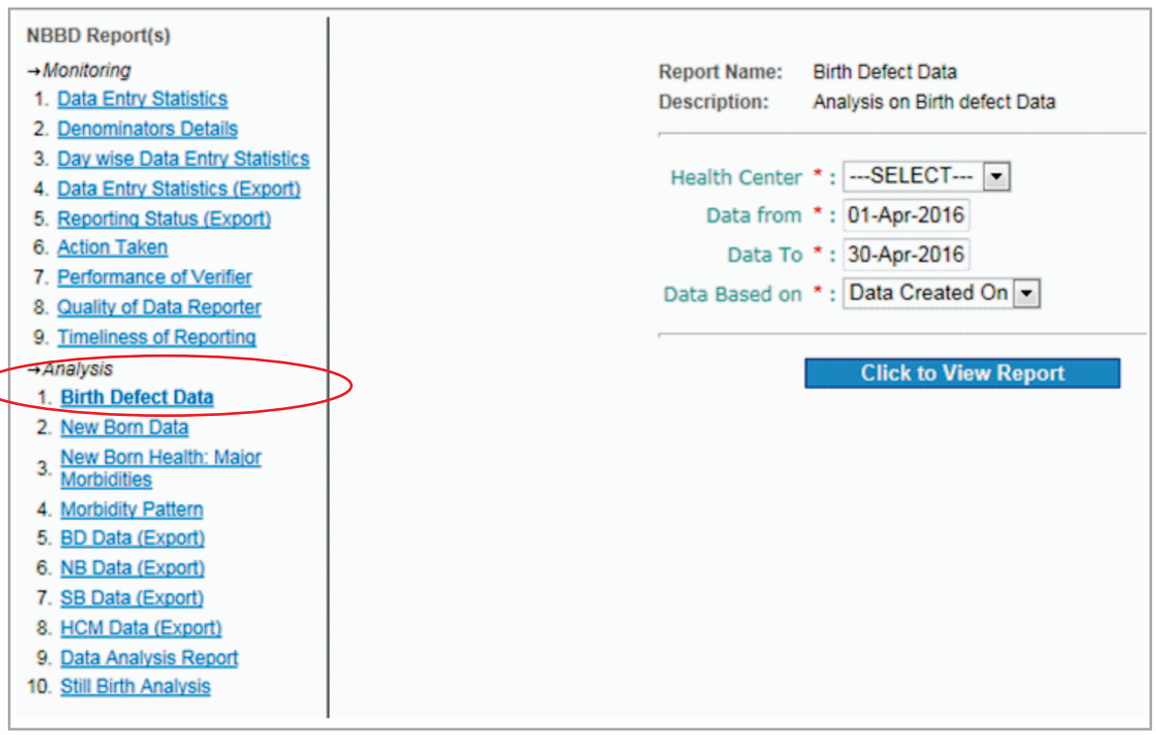
Period verified – : from to

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					

Data Analysis

Numerator

Under the report section and analysis category, you find the "Birth Defect Data Analysis" option. Then fill the dialup box using required the parameters for the data requested.



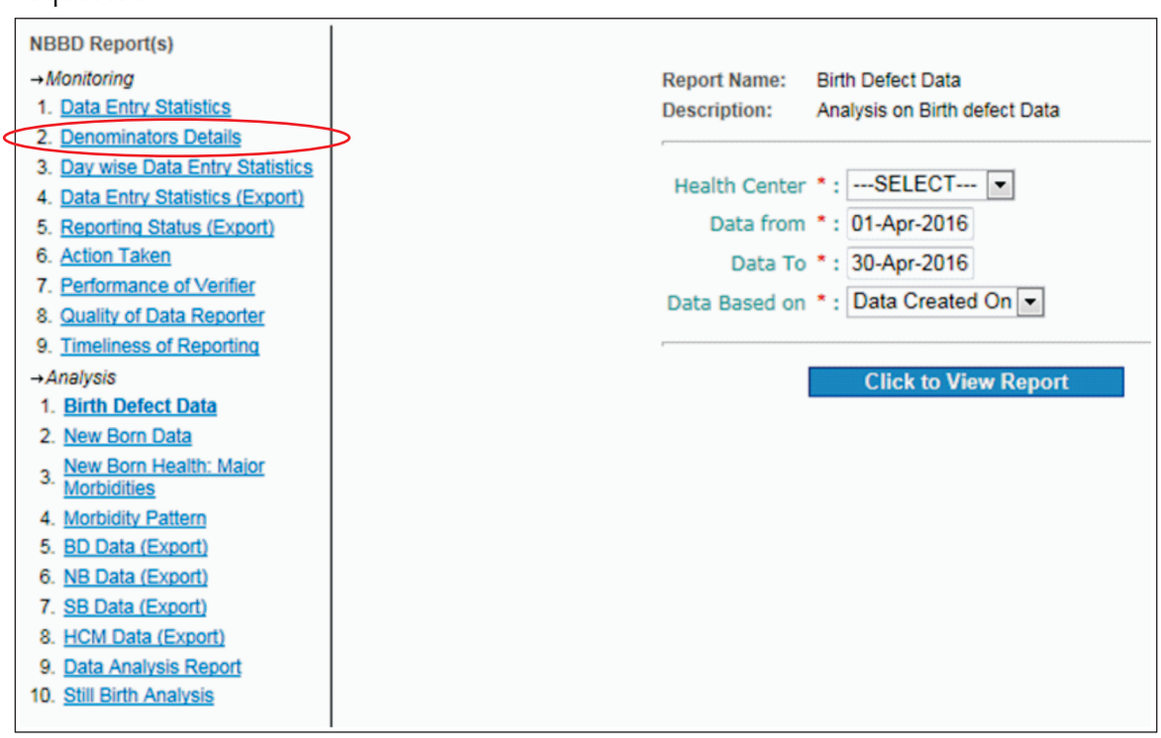
Data Analysis

You get the total number of all defects, major categories of defects and specific types of defects by **Term/Preterm and Male/Female**

Country	Network	Center	Birth Defect Category	Birth Defect Type	Ambiguous	Female		Male		Total
					Term	Preterm	Term	Preterm	Term	
Bangladesh (40)	Dhaka (40)	BIRRDEM (1)	Q38-Q45 Other congenital malformations of the digestive system	Q43.1 Hirschsprung's disease	0	0	1	0	0	1
				Total	0	0	1	0	0	1
			BIRRDEM: Bangladesh Institute of Research and Rehabilitation for Diabetes, Endocrine and Metabolic Disorder Total:		0	0	1	0	0	1
		BMCH (3)	Q65-Q79 Congenital malformations and deformations of the musculoskeletal system	Q65.9 Congenital deformity of hip, unspecified	0	1	0	0	0	1
				Q66.5 Congenital pes planus	0	1	0	0	0	1
				Q68.1 Congenital deformity of hand	0	1	0	0	0	1
				Total	0	3	0	0	0	3
			BMCH: Bangladesh Medical College Hospital Total:		0	3	0	0	0	3

Denominators

Under the report section and Monitoring category, you find the **"Denominators Details"** option. Fill the dialup box using required the parameters for the data requested.



			Denominators Reported						Status of Forms Filled			
Country	Network	Center	Month	Deliveries	Live Birth	Still Birth	Birth Defects	Updated by	Newborn	Sick Newborn	Still Birth	Birth Defect
BAN	DK	BIRRDEM	Nov	150	149	0	2	BIRDEM dhaka	130	1	0	0
			Oct	130	130	0	4	BIRDEM dhaka	145	5	0	0
			Sep	140	140	0	3	BIRDEM dhaka	139	2	0	0
			Aug	148	145	0	3	BIRDEM dhaka	128	3	0	0
			Jul	135	135	0	4	BIRDEM	162	5	0	0

Annexure 10 - Quality Check for Hospital based Birth Defect Surveillance

Date of Assessment:

General information:

1. Name of Hospital:
2. State & Country:
3. Nodal person:
4. Any new staff who needs to be trained:
5. Places of delivery in the hospital included for capturing BD case:

   Record the name/s and type/s of staff at each site

   a. Labour room:
   b. Operation theatre:
   c. Both:
6. Other places in the hospital where birth defects are to be captured in the in-born babies:

   Record the name/s and type/s of staff at each site

   a. Postnatal ward:
   b. Neonatal unit:
   c. Pediatric unit:
   d. Other area:
7. Are the pictures taken in all cases of birth defects: Yes / No

a. If no, please specify why:

8. Is the data first captured on the paper form (birth defects abstraction forms): Yes / No
9. Is the data captured directly on the online system (laptop, smart phone, Tablet): Yes / No

a. If yes, are photographs being saved into the laptop, smartphone, tablet in an orderly way (with proper identification)? Yes/ no

10. Are the filled up BD abstraction forms stored in the designated folder in the hospital: Yes/No

11. Checklist:

S. No.	Items	Response	Comments
1.	Are birth defects abstraction forms available at the identified sites? (Points 5-6 above)		
2.	Are birth defects recorded in the delivery / admission-discharge registers at the identified sites?		
3.	Is each baby delivered in the hospital examined clinically for detecting birth defects?		
4.	Are the babies also examined in postnatal ward / pediatric unit / neonatal unit for detecting birth defects?		
5.	Proportion of baby case records (10 records randomly selected) in which details of newborn clinical examination is recorded, including examination for birth defects		
6.	Is appropriate description of the birth defects written – Check 10 random BD forms		
7.	If pictures of birth defects are taken, is the quality as per the guidelines		
8.	Are the birth defects correctly coded (as per ICD 10) – Check 10 random BD forms		
9.	Time taken between identification of birth defect and filling the BD abstraction form: Same duty shift/ Same Day / Later		
10.	Time taken between filling the paper form and online entry: Same duty shift / Same Day / Later		
11.	Proportion of forms verified		
12.	Proportion of forms that required changes / completion		
13.	Are the birth defects correctly diagnosed – Check 10 random forms		
14.	Check the monthly denominator (Total births, live births and stillbirths in the hospital in a month) from the hospital record: Correct / Incorrect		
15.	When was the analysis of birth defects forms done?		
16.	Was the analysis shared with hospital team and district / state program managers?		

Assessment of Challenging factors:

Factors ↓ / Consequence →	Missing BDs	Delay in filling forms	Delayin online reporting	Poor data quality
High load of deliveries				
Insufficient Paper forms				
Insufficient staff				
Early discharges				
Baby being discharged without examination				
Poor internet availability				
Insufficient Knowledge / Training				
Insufficient supervision and support				

Summary of Assessment:

Main problems identified:

Plan to improve the quality: (Include timelines)

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