

Establishing National Neonatal Perinatal Database and Birth Defects Registry Network – Need of the Hour!

NEERJA GUPTA, MADHULIKA KABRA AND *SEEMA KAPOOR

*From Division of Genetics, Department of Pediatrics, AIIMS, New Delhi and *Division of Genetics, Maulana Azad Medical College, New Dehi, India.*

Correspondence to: Dr Neerja Gupta, Assistant Professor, Division of Genetics, Department of Pediatrics, All India Institute of Medical Sciences, New Delhi 110 029, India. neerja17@gmail.com

Early detection and prevention of birth defects is necessary to further reduce neonatal morbidity and mortality. A birth defect registry or surveillance system is necessary to assess the exact magnitude, profile and modifiable risk factors for birth defects. We review the existing efforts and suggest possible options for addressing this important issue. Connecting birth defects registry with the pre-existing programs such as National Neonatal Perinatal Database could be one of the option.

Keywords: Birth defects, Network, Registry.

Birth defects contribute significantly to perinatal, neonatal and under-five morbidity and mortality. Due attention as an important public health problem by various funding agencies is lacking, particularly in the developing world. This could partly be due to the other pressing issues such as infection and malnutrition. Lack of epidemiological data further prevent inclusion of birth defects under the purview of preventive strategies. With gradual improvement in the management of prematurity, asphyxia and sepsis through tertiary care newborn units across the country, birth defects are likely to emerge as a major cause of neonatal and intrauterine deaths. Several neonatal morbidities and birth defects share many risk factors and require common interventions such as maternal folic acid and iron supplementation, rubella immunization, screening for congenital syphilis, and adolescent health programs to promote healthy lifestyles. A substantial decline in few birth defect categories may be expected with effective implementation of these preconceptional care programs. However, to assess the actual burden of the birth defects, to quantitate the effect of such interventions, and to identify additional risk factors or any emerging trends, it is important to have a national level birth defect surveillance system or birth defect registry.

BIRTH DEFECTS: DEFINITION AND CAUSES

Birth defect is defined as the presence of a structural or functional abnormality, that is present at birth and has medical, social or cosmetic consequences. It includes structural malformation(s), inborn errors of metabolism,

single gene disorders, developmental disabilities, intrauterine growth retardation (IUGR) and prematurity [1]. The incidence of birth defects is higher in early abortions and stillbirths (15-20%) as compared to live births (2-3%). Etiology of birth defects could be genetic (30-40%) or multifactorial (7-10%). In about 50% of the cases the etiology remains unknown. The issue of still births is another neglected area where these factors may be causative.

BURDEN OF BIRTH DEFECTS

According to the March of Dimes Global Report (2006), though the infant mortality rate is showing a downward trend worldwide; there is a constant rise in the percentage of infant deaths due to birth defects. Various hospital-based prospective Indian studies have shown a prevalence of birth defects ranging from 1.6-3.2% in live births and 5-16.4% in stillbirths [2-5]. Worldwide about 7.9 million children (6%) annually are born with a serious birth defect [1]. India, with its vast population of 1.2 billion and approximately 27 million births per year, possibly contributes to about one fifth of these defects. Various risk factors that are associated with birth defects are advanced maternal age, maternal nutritional status, infections, medical illnesses such as diabetes, maternal exposure to teratogenic drugs, and consanguinity [4-6]. Most of the available Indian studies, including the data available from Birth Defect Registry of India (BDRI) [7] show that the common systems involved in birth defects are central nervous system, musculoskeletal system and cardiovascular system, with neural tube defects being the commonest [8].

IMPACT OF BIRTH DEFECTS ON PUBLIC HEALTH

Birth defects can be incompatible with life or may have long term disability depending upon the type and severity. The incapacitation is not limited to the child alone but affects the entire family due to lack of state-funded health insurance systems. Collectively, they pose a significant economic burden to the community, society and the health care system. Impact of birth defects on public health is expected to be huge, as apart from preventing a decline in neonatal mortality, it would also affect the economy due to the cost involved in the medical care, rehabilitation and education of affected individuals. The health impact of birth defects is expected to be even higher in the developing countries like India because of a lack of adequate services for the care of affected infants, and a higher rate of exposures to infections and malnutrition.

BIRTH DEFECT SURVEILLANCE AND REGISTRY – CURRENT STATUS IN INDIA

A birth defect surveillance program is an ongoing, regular, systematic collection, analysis and interpretation of birth defect data in a sustainable, standardized and efficient way [9]. An effective surveillance program is helpful in identifying the magnitude and profile of the birth defects, modifiable risk factors, changing trends and high-risk populations. It assists the policy makers in implementing evidence-based advocacy and prevention programs to improve the overall standard of care across different life stages at various health system levels. Surveillance programs are either population-based or hospital-based. Case ascertainment for surveillance can be active or passive, or a hybrid of two. In a population-based surveillance, the outcomes with birth defects occurring among a population in a defined geographical area are included, whereas a hospital-based surveillance includes birth outcomes with birth defects occurring in selected hospitals.

In India, although few individual groups are collecting data from their center or states, but so far, there has been no national birth defect surveillance system or registry in India. There are few parallel databases within the country like Birth defect Registry of India (BDRI) which is hospital-based passive reporting system that includes all the live births, intrauterine deaths, and medical termination of pregnancy. This registry is functional for past 13 years and about 309 hospitals are contributing to passive reporting of birth defects. The participation in this registry is voluntary and depends upon the motivation of participating centers. Another web-based entry system

(www.scnumponline.org) for special newborn care units under National Rural Health Mission at the district level care across Madhya Pradesh State targets mainly sick newborn babies. It includes few congenital malformations and does not have the primary aim of birth defect surveillance. Indian Council of Medical research (ICMR) supported an initiative of funding National Neonatal Perinatal Database (NNPD), including 18 institutions throughout the country in the pilot phase [10]. This hospital-based database centered on common neonatal morbidities but included some data on birth defects. However, there is a lack of uniformity, inclusion criteria and systematically collected data with respect to birth defects. No brainstorming on sustainable plan for data collection on birth defects, their risk factors, and further preventive strategies has taken place.

Accurate reporting of birth defects requires clear criteria and case definition, a good knowledge about the congenital anomalies, and skills in dysmorphology. For effective surveillance of birth defects, it is mandatory to have data on medical termination of pregnancy for birth defects, and still births. Postmortem evaluation further improves the yield [11]. Now-a-days, with the availability of clinical geneticists, improved dysmorphology expertise, facilities for fetal autopsy and various advanced imaging and molecular cytogenetic techniques, early detection of birth defects is possible. Appropriate reporting for birth defects requires a liaison between neonatologists, clinical geneticists, pediatric surgeons, pediatric cardiologists and the fetal medicine specialists through a robust but common national neonatal and perinatal network, rather than several vertical programs.

INITIATIVES TAKEN

Some initiatives have already been taken by the WHO and ICMR in this direction. ICMR constituted a Task force on Birth Defects to plan a nationwide surveillance system in India, including some research objectives. Four WHO-South East Asia Region (SEAR) Birth Defect Meetings in New Delhi, India; Bangkok, Thailand; and Colombo, Srilanka; have been organised over past 18 months. The last WHO meeting in New Delhi focused on integrating the NNPD with the birth defects surveillance. The main focus of all these meetings has been developing an effective birth defect surveillance system and provide a broad framework for the prevention and control of birth defects in SEAR.

Government of India (GOI) under the National Rural Health Mission (NRHM) of the Ministry of Health and Family Welfare has taken a major initiative last year and has launched a national programme on 'Child health

screening and early intervention services (*Rashtriya Bal Swasthya Karyakram*) for universal screening, early detection and management. This program targets approximately 270 million children with an objective to improve the overall quality of life through early detection of 4Ds (birth defects, diseases, deficiencies, development delay including disabilities). This program covers nine common structural birth defects (neural tube defect, Down syndrome, cleft lip and palate club foot, developmental dysplasia of the hip, congenital cataract, congenital deafness, congenital heart diseases and retinopathy of prematurity). It also includes few important disorders such as developmental delay, congenital hypothyroidism, sickle cell anemia, and beta-thalassaemia. These programs can serve as a platform to effectively launch a robust birth defect surveillance system across India.

THE WAY FORWARD

As mentioned above, birth defects can be prevented through the implementation of better periconceptional and antenatal strategies. This could be possible if we have good epidemiological data on the prevalence and types of birth defects. To gather good epidemiologic data, we need to develop a robust birth defect surveillance or registry network. Implementation of Birth defect registry network (BDRN) would promote early and accurate identification of birth defects, facilitate prevention and will be helpful in the planning of a service delivery system.

The existing NNPD network of India across 18 centers can be rejuvenated and further strengthened for addressing both the newborn health and birth defects in a convergent manner (**Fig. 1**). We may start with four easily recognizable birth defects and then expand as program gains experience and resources. **Fig. 2** shows the conceptual framework for functioning of hospital

based NNPD-BDRN in a particular state and region where all the fetuses or newborns with birth defects born to mothers in participating hospitals are included and finally report to the state nodal centers at specified intervals where data is verified for completeness, coding and duplication. The coding, in order to be uniform, should be in ICD system which will maintain uniformity across the globe. This data then can be compiled at regional coordinating center for different states of that region. Finally, the national coordinating center compiles all the data from the country which is then used for dissemination, research and referrals. This framework can be further expanded to the district level and peripheral health centers.

The successful launch of NNPD-BDRN system in our country would need the following-

- Voluntary enrolment should be done for building up a national network in a phased manner. This would need identification of champions and commitment from already enrolled NNPD centers followed by enrolment of more centers for birth defect registry across various states; merging the neonatal and birth defect source data sheet with the daily hospital record sheets for sustainability to avoid duplication of daily work or extra work; and connecting genetics centers to the nearest NNPD centers for services.
- Capacity building
- Raising awareness about various birth defects and their prevention strategies using effective media, campaigns, workshops amongst public, primary health care workers and health professionals.
- Education and training of Accredited Social Health Activists (ASHAs), paramedics and health professionals about birth defects.

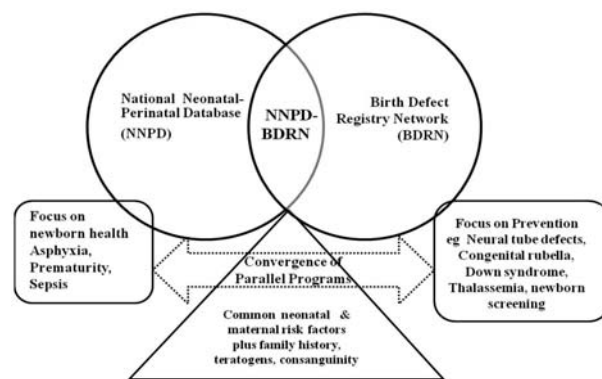


FIG. 1 Convergence of National Neonatal Perinatal Database Network (NNPD) with Birth Defect Registry Network (BDRN).

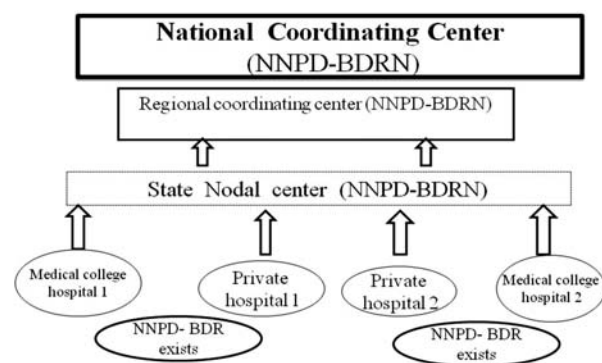


FIG. 2 Conceptual framework of functioning of a hospital based NNPD-BDRN program.

- Incentive-based birth defect reporting through integration with preexisting national programs such as *Janani Suraksha Karyakaram* (JSK), and *Janani Shishu Suraksha Karyakram* (JSSK).

Anticipated challenges include the identification of dedicated units and staff, committed health professionals, financial and personnel resources for sustainability, and quality control of NNPD-BDRN data.

CONCLUSIONS

Most major birth defects pose a huge burden to the family, community, and the society. As the majority of the causes of neonatal mortality share common risk factors, a vertical approach is not optimal. There is a need to initiate an effective birth defect surveillance system and connect it to the preexisting neonatal-perinatal databases to understand the profile of burden and the modifiable risk factors. This strategy would be helpful in successfully implementing the effective preventive strategies through various life stages.

Acknowledgements: Prof VK Paul, Dr Neena Raina (WHO), and Dr Rajesh Mehta (WHO) for their valuable suggestions.

Contributors: NG: conceived, planned and wrote the manuscript. MK, SK: revised the manuscript for important intellectual content. The final manuscript was approved by all the authors.

Funding: None; *Competing interests:* None.

This manuscript incorporates some of the relevant discussion points that emerged during WHO meetings related to birth defects surveillance.

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