Directory of Genetic Test Services and Counselling Centres in India

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ABSTRACT The conservative birth defects and genetic disorders estimate from India indicates that every year 6,78,000 infants with congenital anomalies, 22,477 with metabolic disorders, 34,000 with Down syndrome, 16,700 with β-thalassemia and sickle cell disease, 10,900 with congenital hypothyroidism and 2,700 with Duchene muscular dystrophy and 2,700 with spinal muscular atrophy are born; which suggests how acute the burden is in India. The total number of individuals who are at a higher risk of being afflicted with a genetic disease and consequently requiring diagnosis and counselling would thus be mind boggling. In this paper the researchers have created a state-of-the art directory of genetic test services and counselling centres in India to facilitate access to a comprehensive, accessible, and trust worthy web based genetic information and resources which will prove helpful to the physicians; academicians; scientists and the researchers requiring the above facility for better healthcare.

INTRODUCTION

India is the seventh largest country of the world in size and with a population of 133,17,84,905 (1.33 billion) (http://www.census-india.gov.in) has the distinction of being the second most populous country in the world, housing 17.5 percent of all the humans (http://www.prb.org). More than 50 percent of India’s current population is below the age of 25 and over 65 percent is below the age of 35. Multiple events of migration, invasions and trade interaction from the north-western and the eastern sides have led to the population admixture giving rise to the highly heterogeneous population groups in this country. India has more than two thousand ethnic groups. Presently there are believed to be four main ethno-racial groups in India, which are the Indo-European, Dravidian, Austro-Asiatic and Tibeto-Burman (Lewis 2009). India is a home of 300-400 languages and 1,652 mother tongues, according to the linguistics. It is no surprise that India has 23 official languages (Mahanty 2007). Hindus are nominally about 80 percent of the population in India. Muslims are nominally about 14 percent and are a majority in Kashmir. The 23 million nominal Christians have a 2.2 percent share of the national population (Wood 2016). The rate of population growth between 2001 and 2013 was 20.22 percent and the predicted population size for 2030 is 1.46 billion. About 68.8 percent of the population lives in the villages and the rest 31.2 percent in the urban areas.

The total fertility rate is 2.3 births per woman. Life expectancy at birth is 68.89 years (67.46 years for men; 72.61 years for woman) (Census and Sample Registration System, O/o Registrar General of India). Infant mortality rate was 58 per 1000 live births in 2005, which came down to 40 in 2013. The under-five mortality rate in 2005 and 2013 were 74.3 and 49 per 1,000 live births respectively. The maternal mortality ratio in 2013 was 167 per 1,00,000 live births.

As is in the developing countries, India is facing an accelerating demographic switch to non-communicable diseases. In the cities, congenital malformation and genetic disorders are important causes of morbidity and mortality.

Objectives of the Study

To create a state-of-the art directory of genetic test services and counselling centres in India, to facilitate access to comprehensive, accessible, and trust worthy web based genetic information and resources which will prove helpful to the physicians; academicians; scientists and the researchers requiring the above facility for better healthcare.
OBSERVATIONS AND DISCUSSION

Health Services in India

The health services in India are available as a public service which are provided by the Government of India under the Ministry of Health and Family Welfare as well as a private service which is provided by the various corporate organizations in addition to the individual practice (Balarajan et al. 2011). Social development coupled with scientific advances and health care have led to a decrease in the mortality rates and the birth rates (Statement on National Health Policy). India spends 1.3 percent of its GDP on health, and provides completely free or highly subsidized health services to the economically deprived groups through the public health system.

Genetic Disorder

Genetics diseases are classified as chromosomal (numerical or structural), Mendelian or single-gene disorders, multifactorial/polygenic (complex) diseases, congenital anomalies or diseases associated with specific mitochondrial gene mutations. Apart from chromosomal disorders, essentially all genetic disorders result from some form of alteration or mutation occurring in a specific gene (single gene) or involving multiple loci spread across the human genome (Polygenic). Chromosomal disorders, where the entire chromosomes, or the large segments of chromosome are missing, duplicated, or otherwise altered (Kumar 2008).

Congenital and Genetic Disorder’s Burden

Genetic disorder and birth defects are relatively common in India. According to the March of Dimes Report, 17,22,404 infants are born every year with birth defects due to genetic or environmental causes, that is, 64.3 infants per 1000 live births (Christianson et al. 2006). The conservative birth defects and genetic disorders estimate from India indicates that every year 6,78,000 infants with congenital anomalies; 22,477 with metabolic disorders; 34,000 with Down syndrome; 16,700 with β-thalassemia and sickle cell disease, and 10,900 with congenital hypothyroidism are born (Verma and Kumar 2012).

Genetic disorders and birth defects are relatively common in India and, are due to the fact that many communities marry consanguineously. Consanguinity rates in India vary from as low as 1 percent to 4 percent in the northern regions to as high as 40-50 percent in the southern regions (Bittles 2008). Indeed due to the large number of births per year (20.22 births/1000 population), March of Dimes Report estimated that India had the largest number of infants born with birth defect in the world.

Genetic Services

Genetic disorders are emerging as an important group of medical ailments requiring attention at a priority level. Clinical genetic and cytogenetic services developed in India in the late 1980s in a few premier cities as multicentric research programs for the prevention of mental retardation and neural tube defect. These services have progressively expanded over the last 35 years and many trained Medical and Clinical geneticists practice all over the country at present. The growing significance of molecular genetics and cytogenetics in diagnosis as well as the management of various cancers have led to the expansion of genetic diagnosis and counselling services in the country. The main aim of this research is to collect data from a well researched and exhaustive study and to prepare a directory of genetic test services and counselling centres in India in the field of human genetics which can be used as a desk reference.

Availability of Genetic Services

Diagnostic laboratory facilities are available both as part of an integrated medical genetics department/centre or as an independent facility (See Annexure). Newborn screening, diagnostic testing, carrier testing, prenatal testing, predictive and presymptomatic testing, forensic testing are all available in most of these centres. Recent years have seen a marked expansion of private laboratories in the field of genetic diagnosis services. Pre-implantation genetic diagnosis and pharmacogenetics testing are also available in some of the laboratories.

Newborn screening shortly after birth for inborn errors of metabolism and hearing loss offers the opportunity to begin treatment or intervention for these serious disorders as soon
as possible. Diagnostic genetic testing, like other types of diagnostic testing, is used to confirm or rule out an known or a suspected genetic disorder in a symptomatic person. Although there are often other methods to make a diagnosis, DNA-based testing may provide the same information at a far lower cost and often with less risk to the patient. Carrier testing is used to identify individuals who have a gene mutation for a disorder inherited in an autosomal recessive or X-linked recessive manner. Usually the carrier does not have symptoms of the disease itself but seeks the information to make informed reproductive choices. Prenatal testing is used to identify the genetic status of a pregnancy at risk for a genetic disorder. Current prenatal testing options include maternal serum screening and the invasive procedures of amniocentesis and chorionic villus sampling, which are widely available, and also the more highly specialized techniques of placental biopsy and periumbilical blood sampling (Pagon 2008). Non-invasive prenatal testing (NIPT) is an advancement in the detection of fetal chromosomal aneuploidies that analyses cell-free fetal DNA in the blood of a pregnant woman. NIPT is more accurate than serum screening and produces fewer false positives, but is not currently diagnostic. Predictive testing is used to clarify the genetic status of an asymptomatic family member at risk for a genetic disorder (Allye 2015). Predictive testing is presymptomatic or predispositional. Forensic testing is used for identification, not to identify individuals at risk for a genetic disease. Forensic testing is performed for legal purposes such as criminal investigations, questions of paternity, and identification after catastrophic events. Preimplantation genetic diagnosis (PGD) is used to select early embryos for implantation that have been conceived by in vitro fertilization. Testing determines whether the embryos are free of a particular genetic condition and provides an alternative to prenatal diagnosis and termination of pregnancy. Pharmacogenetic testing provides information about a patient’s likelihood to have an adverse response and/or a therapeutic response to a medication, enabling the potential for a tailored and personalized approach to medication therapy (Haga et al. 2013). Very few genetic service centres are available in the rural areas, apart from a few outreach clinics provided by the academic/private centres, but referral to the tertiary care level can be made by the secondary and primary levels.

There is a growing interest in the Birth Defect Registries in India (BDRI). In Chennai a BDRI has existed from 2001 and currently receives data from 700 hospitals all over India. So far, 10,00,000 deliveries have been analysed. BDRI has associated with the Federation of Obstetricians and Gynaecologists of India to extend coverage of other hospitals. Regulation of genetic diagnostic services is presently governed by the IC-MR’s Ethics Guidelines for Biomedical Research as no separate standards are available for the same. Prenatal diagnostics services are more stringently regulated by the preconception and prenatal diagnostic techniques (PNDT) Act, 1994, which is primarily intended to curb prenatal sex determination.

**Genetic Counselling**

The early diagnosis of many genetic diseases, coupled with a timely interventional therapy, can prevent several disease associated disabilities. The predictive genetic testing, pre-natal diagnosis and timely genetic counselling can help to prevent the recurrence of genetic diseases. Genetic counselling deals with the human problems associated with the occurrence, or the risk of occurrence, of a genetic disorder in a family (Ad Hoc Committee). Genetic counselling is essentially a communication process about the medical facts, the contribution of heredity to certain conditions, the interpretation of test results, and the options available. It also involves supportive counselling to enable the patients to make decisions and to make the best possible adjustment to the presence or to the risk of a genetic disease. Genetic counsellors play an important role in providing expert genetic services. In educating and counselling about genetics, the counsellors convey the varying nature of genetic risk and our varying ability to predict such risks. Our ability to predict genetic risk varies with the mode of inheritance, severity of the disorder, and other essential factors, such as environmental and/or combinations of genetic factors that must be present before the genetic susceptibility is expressed as a disease. The prediction of genetic risk also depends on the sensitivity and the specificity of the test itself and the quality of laboratory procedures.
CONCLUSION

There is tremendous variability in genetic counselling as provided today and as envisioned for the future. As genetic testing expands with the growth of new genetic tests, genetic counselling and education will need to adapt to new modes and settings for the delivery of genetics services, without sacrificing quality. It is hoped that this directory would highlight the existing genetic laboratory and counselling centres in India. The researchers endeavour would be to continuously update this directory and make it more comprehensive, accurate and include more about the kind of test services that are available in each of the centres. The efficient registries, databases and continued investment in genetic research are the key to successful public health interventions.

REFERENCES

ANNEXURE

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<td><strong>Department of Pathology</strong></td>
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<td>Adyar Cancer Institute, No. 38, Sardar Patel Rd, Gandhi Nagar, Adyar, Chennai - 600020</td>
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<td><strong>Gharbbaha Rakshambigai Fertility Center</strong></td>
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<td><strong>Swagene</strong></td>
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<td>28, KR Ramasamy Nagar,</td>
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