

Sweet Turns Sour

Bindhya Cariappa of ClinTec International reviews the rising prevalence of diabetes clinical trials in India and the Gulf region

As the prevalence of diabetes grows at an alarming rate worldwide, particularly in the developing economies, many initiatives to impede this growth are being considered and implemented in the affected countries. While prevention, detection and management form the cornerstones of most national diabetes programmes, a large number of clinicians and patients are now looking at clinical trials as an opportunity to access new treatments prior to their availability on the market.

According to the WHO, the prevalence of diabetes in developing countries will continue to rise in the 21st century. At present, more than 70 per cent of people with diabetes live in low and middle income countries. Mortality attributable to diabetes in 2010 shows a 5.5 per cent increase compared to 2007.

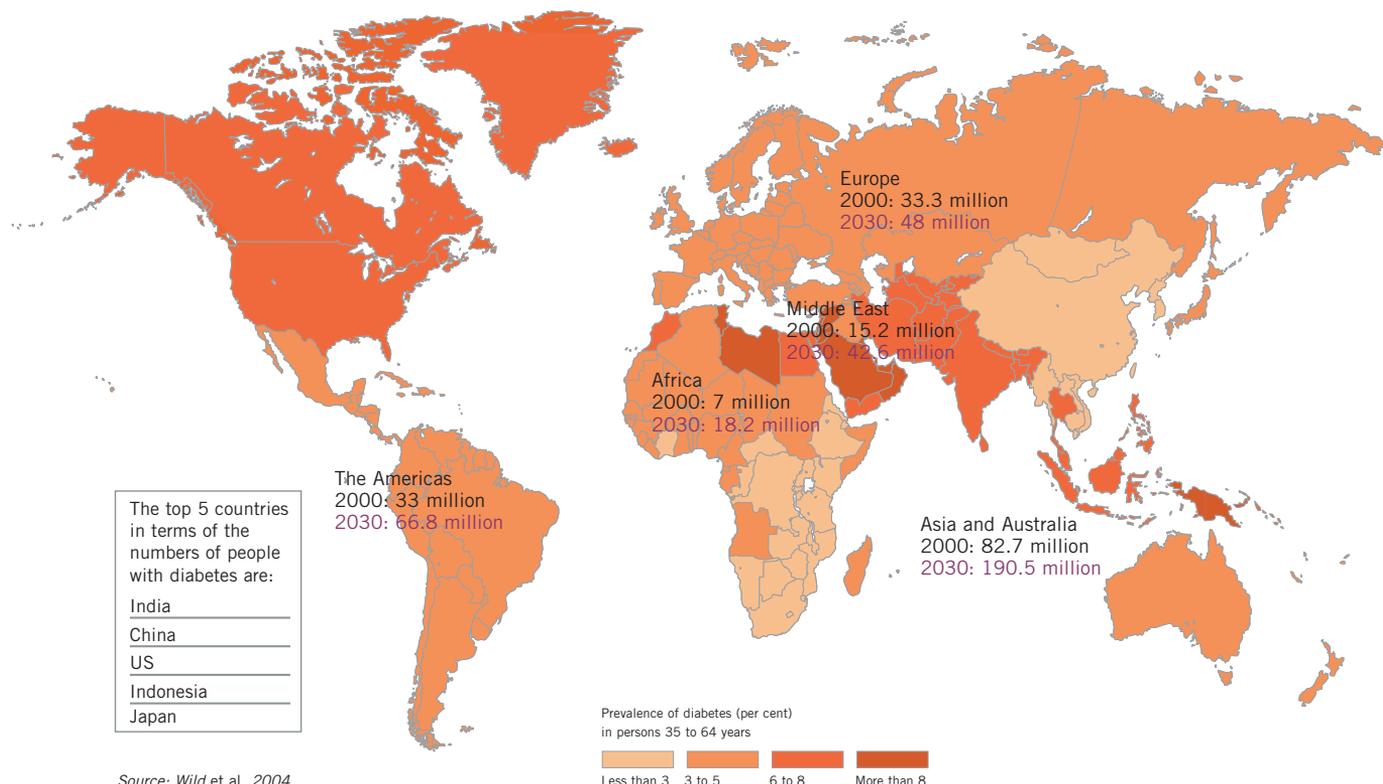
India and the Gulf countries are two regions of growing concern due to the significant morbidity associated with diabetes. While India for several years now has been listed as one of the countries with the highest number of diabetetic patients, the prevalence of diabetes in the Gulf countries has been significantly greater than predicted, with more than eight

per cent of the adult population affected. These statistics have made both regions important destinations for the conduct of clinical trials in diabetes.

INDIA

India has the highest number of diabetetic patients in the world, with the International Diabetes Federation (IDF) reporting 50.8 million people suffering from the disease. Government, non-government agencies, as well as large corporations, are actively involved in community health campaigns highlighting the importance of diabetes intervention and education. In late

Figure 1: Prevalence of diabetes





As India enters a new era of healthcare, there are a large number of community-based programmes that are being implemented. Although there are very little data on the level of awareness and prevalence about diabetes in developing countries like India, it is vital to plan community health programmes to provide important education.

2008 the UK, acknowledging the increasing disease burden in the country, sent a team of diabetes experts to share expertise and collaborate with Indian institutions and companies. The team was led by the UK Minister for Health Services, Ann Keen, who highlighted the pressing need to target the prevention and management of diabetes, stating data from the Diabetes Atlas published by the IDF, which projected that every fifth person in the world with diabetes will be Indian.

As India enters a new era of healthcare, there are a large number of community-based programmes that are being implemented. Although there are very little data on the level of awareness and prevalence about diabetes in developing countries like India, it is vital to plan community health programmes to provide important education. The Diabetes Foundation of India

conducted a study to identify, investigate and evaluate knowledge and practice. The study reported limited knowledge and awareness about diabetes in rural India, and recommended the need for increasing diabetes awareness activities in the form of mass campaigns in both urban and rural settings.

The World Diabetes Foundation has been reaching out to more than 94 hospitals, 544 doctors and 124 diabetic nurse educators who were trained on diabetes all over the country. There are several other such community-based programmes which have been funded in India over the last decade, and there has been a rise in community-based programmes that reflect lifestyle modifications such as dietary changes and increased physical activity. Pharma companies have also implemented various initiatives to spread awareness to target

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audiences, including the use of mass media such as television and radio.

The last decade has seen the medical community actively developing infrastructure, resources and competencies for the management of diabetes. This has resulted in the establishment of a large number of specialised diabetes hospitals and clinics, which in turn is promoting better diabetes care.

The significant morbidity, favourable regulatory reforms and growing capabilities have led to the inclusion of India in the clinical development plans of global pharma companies running diabetes trials. From a couple of trials being conducted in the late 1990s, there are 28 diabetes clinical trials currently reported to be recruiting in India as per the US NIH trial registry. These trials have established India as their preferred location for diabetes trials due to the recruitment potential and ability to provide regulatory compliant data. They have also provided treatment options to the patients participating in these trials that are currently unavailable to them at their local pharmacies.

The diabetes clinical trials being conducted in India are becoming increasingly complex, reflecting the local clinical capabilities and expertise that made the trial possible.

THE GULF REGION

In the Middle East, lifestyle changes including high calorie diets and increasingly sedentary lifestyles have been linked to the tripling in the rate of diabetes and other related disorders in last 20 years. As Arab nations deal with a growing incidence of obesity, inadequate awareness will continue to fuel the increase in diabetes in the coming years. A study conducted in 2004 reported abnormal glucose tolerance in 78 per cent of obese individuals in some Arab countries.

Epidemiological data demonstrates that in the Gulf states approximately 18 million people annually experience cardiovascular diseases, where diabetes and hypertension are the leading predisposing factors. Statistical data in the Gulf states have shown that diabetes has emerged as an epidemic and its prevalence is reported to be as high as 25 per cent in the Kingdom of Saudi Arabia, Sultanate of Oman and the Kingdom of Bahrain.

Recent data reported in the Diabetes Atlas of the IDF estimates the diabetes prevalence in the Gulf population aged 20 to 79 years to be between 10.8 per cent and 14.4 per cent (with the exception of Iran, where the estimates are reported to be lower at 6.1 per cent). The highest prevalence has been reported in Bahrain (14.4 per cent) followed by Saudi Arabia (13.6 per cent).

There are several initiatives being considered in the Gulf today with the objective of curbing the morbidity and mortality associated with diabetes and its complications. In December 2006, the Gulf region adopted the United Nations Resolution on Diabetes, which acknowledged the growing healthcare threat posed by the disease in the region.

About the author



Bindhya Cariappa is responsible for the development of ClinTec International's operations within India, Middle East and Africa. She joined ClinTec in 2002 as the Head of Medical and Scientific Services, bringing with her over seven years of experience in clinical research, and is currently responsible for the efficient management of various clinical development verticals including clinical operations, regulatory affairs, medical writing, quality assurance and training. In addition, she has managed all aspects of regulatory affairs for studies in India, Nepal and Bangladesh. Bindhya studied at Bangalore University, graduating with a Master of Pharmacy majoring in Pharmaceuticals. Prior to joining ClinTec she worked for various pharmaceutical companies and CROs, as well as working as a freelance consultant for multiple clinical trials. **Email:** bcariappa@clintec.com

In line with the growing awareness and concern in the Gulf region, Dubai will play host to the 21st IDF World Diabetes Congress in December 2011. The congress offers all stakeholders an opportunity to discuss issues and strategies to combat the growing prevalence of diabetes worldwide. Most countries are also aggressively investing resources in developing specialised healthcare infrastructure to combat diabetes. The opening of the Harvard-Affiliated Joslin Diabetes Center in Dubai is a sign of development in this direction.

Compelling epidemiological data on diabetes also makes this region relevant to the evaluation of drugs and medical devices in clinical trials. While the infrastructure and medical expertise are not the same across the Gulf countries, UAE and Saudi Arabia are emerging as countries frequently included in diabetes clinical trials. Clinical trial regulations in the region are evolving and many countries do not require regulatory approval for the conduct of clinical trials. As such, approvals are primarily obtained from central or local Ethics Committees, while Phase I trials are not permitted.

The Gulf region has been involved in over 30 diabetes clinical trials in the last three years, including observational and interventional drug and medical device trials. This emerging region has great potential due to the expanding availability of expertise, access to the large patient pool, regulatory agencies that are keen to build capabilities and the active efforts of the pharma companies and local CROs. This is reflected in the increased number of diabetes trials from five in 2007 to 15 in 2009 as reported in the US NIH trial registry.

THE FUTURE

Diabetes has reached epidemic proportions in India and, as a result of increased life expectancy and urbanisation, the number of diabetes patients is estimated to double within 20 years in the Gulf region based on IDF and WHO forecasts. While this burdens the healthcare system and has enormous economic repercussions, the clinical trial data emerging from these markets should help fuel the development of better products in the prevention, detection and management of diabetes in the years to come.