

Editorial

Ethical Issues associated with Diagnosing and Managing Diabetes

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The worldwide prevalence of diabetes is estimated to increase from 4% in 1995 to 5.4% by 2025. The increase will be sharpest in developing countries, where the number of diabetics will almost triple from 84 million to 228 million. The developing world will be responsible for more than 75% of diabetics in 2025, up from 62% in 1995. Among developing countries, the highest increase in prevalence will be in China followed by India. However, the greatest increase in numbers will be seen in India, where the number of diabetics will rise from 19 million in 1995 to 57 million in 2025, heading the list of countries with the greatest numbers of diabetics [1-2].

The World Bank estimates that diabetes will account for 1,870,000 Disability Adjusted Life Years in India, with a per capita health expenditure of \$21. Already, some two-three per cent of the health-care budget is spent on diabetes-related problems. An increase in the number of diabetics is likely to have a serious impact on our country's health-care system [3]. This scenario raises many ethical and social issues related to diabetes. Long term care for chronic diseases like diabetes goes beyond the traditional boundaries of medicine and single sector responsibility. One of the main characteristics of chronic diseases is the involvement of caregivers and other professionals from many disciplines. At the same time, there are medical and social implications in the need for long-term care for chronic diseases. One major goal of diabetes care is to achieve a condition of wellbeing in the presence of chronic disease and, often, disability. In this context, the harmful effects of medicalizing chronic care need to be recognized [2]. In most developed countries, such medicalization increases health-care costs without meeting the recipient's non-medical psychosocial needs. India must avoid this trap.

“Ethics” stands for a set of philosophical beliefs and practices concerned with the distinction between right and wrong or system of moral values or code of conduct relating to morals in human beings. Ethical principles are intellectually derived by a particular profession for its specific needs and may / can be changed or modified as per needs of the society or community. Medical ethics refers chiefly to the rules of etiquette adopted by the medical profession to regulate professional conduct with each other, with individual patients, with society, including considerations of the motives behind that conduct. In modern era, traditional medical ethics changed into an interdisciplinary field involving theologians, lawyers, philosophers, social scientists and historians, as well as physicians and other health professionals because of increasing impact of science and technology, public expectations from new medicines and surgical techniques, changes in the financing and delivery of health care. With more stakeholders, such as medical devices companies, pharmaceutical companies, diagnostic clinics, insurance companies, clinical trial organizations and other service providers entering the field, there was a need to expand the scope of the definition of ethics within the field of medicine. Now the terms “bio-medical ethics”, “bio-pharmaceutical ethics”, and “health care ethics” are gaining importance

Ethical Issues with managing Diabetes

An increase in the number of diabetics is likely to have a serious impact on a country's health-care system raising many ethical and social issues related to diabetes. Performing research and

preventing, diagnosing, and treating diabetes will raise ethical, legal, social and policy issues. The Issues raised by diabetes can surround the understanding and addressing of identified barriers to research, such as analyzing the impact of patents on genes related to diabetes; assessing the challenges of bringing new diabetes-related technologies through the regulatory approval process; conflicts of interest in research and medicine; and understanding and protecting the rights of human subjects in diabetes research, including genetics based research on collected or stored tissue samples. The place of distributive justice related assuring population's access to appropriate services and healthcare; preventing discrimination and stigma against people who have diabetes, a predisposition to diabetes, or family members with diabetes; and analyzing the effects of direct marketing to patients on diagnosis, prevention, and treatment.

Ethical issues with Primary prevention interventions

The burden of diabetes in the next 25 years is likely to sharpen the ethical dilemma of access to primary care as opposed to technologically-intensive care for complications. There is an urgent need to consider public health interventions to reduce the burden of diabetes and to contain its economic and social costs. Without primary prevention strategies at the public health level, the number of undiagnosed and uncared-for diabetics will increase, as will the number of complications requiring a higher technological input. This in turn will limit access to health care for large numbers of patients impacting on the ethical issues around access and distributive justice. Scientific evidence of treatment efficacy must also be considered before the allocation of limited healthcare resources. Primary prevention population health initiatives which limit or delay the onset of diabetes are the direction that will be effective and cost effective. The question of dividing funds between primary prevention and pure research is likely to cause intense political, social and ethical debates. The appetite for technologically-intensive, hospital based care in some regions will ensure that these interventions will take precedence over more cost-effective measures. At present, bureaucratic regulation, corruption and a lack of motivation are some factors responsible for the poor quality of primary health care in India. Thus, compromising the primary prevention strategies for diabetes leads to several ethical issues that shall come up.

Ethical Issues in Market-driven research in Diabetes

As the number of diabetic patients' increases, the private health sector will find new and lucrative market opportunities. Market-driven research can deprive patients of cost effective treatment modalities. For example, companies have stopped production of cheaper forms of insulin (Bovine and Pork) arguing that human insulin is more physiological. Now there is promotion of analogs as compared to human insulin. However, the cost difference is phenomenal. There is ample evidence that health related strategies, including those in the development of newer drugs, tend to be driven by the market rather than by people's needs. Traditional medicines can contribute significantly towards the development of cost effective treatment modalities, guided by evidence based research. Currently, compartmentalization within medical education and in the medical profession prevents scientific research in traditional medicines. Such issues of market influences generate ethical deliberations relating market influences of diabetes care.

Research for new modalities for the prevention or treatment of complications must consider the fact that certain research such as for diabetic peripheral neuropathy and diabetic ulcer, cannot be done on animals. Therefore, research in various treatment modalities for these problems must have stricter ethical controls and independent reviews. Market-driven research can deprive patients of effective treatment modalities. In the worldwide economic liberalization, the interests of the private sector are likely to take precedence over the needs of the healthcare system. This must be countered by vigilant patient interest/consumer groups and the medical profession. Another area is in regard to traditional medicines, which can contribute significantly towards the development of effective treatment modalities, guided by evidence-based research. Currently, compartmentalization within medical education and in the medical profession prevents scientific research in traditional medicines. This is also seen as an ethical issue that needs to be contended

in the management of diabetes. An open debate about various ethical, social, economic aspects of diabetes, with the involvement of all sectors of society.

Ethical Issues related to Diabetic Clinical Trials

The Helsinki Declaration 2013 updated version, ethical principles to be used in clinical investigations, states that “In any medical study, every patient, including those of a control group, if any, should be assured of the best proven diagnostic and therapeutic method”. But many of the placebo-controlled trials currently being performed to assess new oral diabetic therapies do not meet this ethical standard. Comparing an experimental drug with a placebo is perfectly ethical when no proven effective therapy exists and when the risk-to-benefit ratio needs to be assessed. However, when effective therapy exists, the use of placebo control subjects does not meet the ethical standard because efficacy and safety of the experimental medication should be tested by blindly randomizing to an existing drug that has been shown as effective and safe and not to placebo. Ethical issue that should be considered is, how long can hyperglycemia be permitted to continue in diabetic subjects undergoing trial? Prolonged hyperglycemia or more than 6 months hyperglycemia has the potential to exacerbate macrovascular complications and will have an adverse effect on the quality of life creating an ethical dilemma

Ethical Issues in Genetic susceptibility testing services

Genetic susceptibility testing is available but experts are not convinced of its current clinical validity and utility generating an ethical issue. With the rising number of individuals affected with diabetes and the significant health care costs of treatment, the emphasis on prevention is the key to controlling the health burden of this disease. Several genetic and genomic studies have identified genetic variants associated with increased risk to diabetes. As a result, commercial testing is available to predict an individual's genetic risk. Although the clinical benefits of testing have not yet been demonstrated, it is worth considering some of the ethical implications of testing for this common chronic disease. From an ethical perspective, several issues should be considered during the translation of predictive testing for diabetes, including familial implications, improvement of risk communication, implications for behavioral change and health outcomes, the Genetic Information Nondiscrimination Act, direct-to-consumer testing, and appropriate age of testing.

The variability of the severity of Type 2 Diabetes Mellitus poses difficulties for the ethical evaluation of susceptibility testing for the disease. From a precautionary perspective, it could be argued that Type 2 Diabetes Mellitus should be viewed as a severe disease and require high levels of genetic counseling and psychological support or hardly causes any psychological harm or emotional impact at all. There may be discrepancies between the severity of a disease as perceived by medical professionals and the severity of the same disease as perceived by other publics. There are both therapeutic options and well-established preventive strategies available for diabetes for children as well as for adults, at the level of lifestyle improvements. Existence of preventive options for Type 2 Diabetes implies a potential for medical benefits to be obtained from susceptibility testing. Therefore, if false reassurance occurs, it may lead to harm. Individuals who are found to be at decreased risk may wrongly feel assured that they will remain free from disease, regardless of their lifestyles. They may fail to understand that general health recommendations are relevant to the whole of the population, including low-risk subgroups. Low-risk individuals may ignore these recommendations and consequently put their health conditions at risk. In presence limited or moderate clinical validity burdensome or too strong preventive measures will raise ethical issues, such as psychological harms: at-risk children who do not adhere to lifestyle recommendations and when they develop the disease later in life, blame may be attributed to themselves or be blamed by others. Such ‘victim-blaming’ or feelings of guilt will not always be justified in the context of a multifactorial disease for which susceptibility testing is of moderate predictive ability: some at-risk individuals may develop the disease even if they take appropriate measures, whereas other at-risk individuals may not fall ill despite their failing to take preventive action.

Ethical Issues with costly therapy and diabetic complications

Various scientific trials have shown the enhanced benefits of aggressive insulin therapy to control and delay the onset of complications in severe diabetes, but intensive therapy with insulin is costly. So, the ethical dilemma faced by many doctors is whether to start costly, intensive therapy with expensive human insulin to prevent future complications or to continue traditional therapy which could lead to early complications. Medical practitioners are often faced with an ethical dilemma rooted in economics. An example would be foot gangrene, a dreaded complication of diabetes. It is often possible to salvage the foot, but at great expense. The family must incur heavy debts for this high-technology treatment. The alternative to taking on this economic burden may be amputation. In young diabetics, the loss of a limb can be crippling, affecting one's employment. The difficult decision to amputate is often based on social and economic factors. The similar can be considered in a case of end stage renal disease, where renal transplant is not feasible and the patient has multisystem failure. The issue might well be as to how long hemodialysis should be continued given the costs and an almost certain unfavorable outcome. Such dilemmas are likely to increase as the number of diabetics with complications increases and the resource availability becomes scarce leading to a wider debate on ethical, social and economic issues related to management of diabetic complications.

Ethical issues with Embryonic stem cell research in diabetes

Stem cell research could provide a means of replacing damaged tissue in patients with diabetes and embryos are a potentially rich source of viable stem cells. Mesenchymal stem cells (MSCs) are multipotent, self-renewing cells that can be found in almost all postnatal organs and tissues. The main functional characteristics of MSCs are their immunomodulatory ability, capacity for self-renewal, and differentiation into mesodermal tissues. The ability of MSCs to differentiate into several cell types, including muscle, brain, vascular, skin, cartilage, and bone cells, makes them attractive as therapeutic agents for several diseases including complications of diabetes mellitus. Thus, MSCs has the potential as new therapeutic agents in the treatment of diabetic cardiomyopathy, diabetic nephropathy, diabetic polyneuropathy, diabetic retinopathy, and diabetic wounds.

Cloned embryos may one day allow the customized replacement of damaged tissues and organs. The ethical aspects of such a research are varied and debatable. A philosophically coherent approach to embryo research would acknowledge the intrinsic value accorded by people to all human life. Society must find a way to reconcile these intuitive concerns with the utilitarian desire to maximize the benefits of stem cell research.

Conclusions

Non-communicative diseases are the challenge of the current and foreseeable time. To face this challenge, we need an optimally trained, aware and motivated medical profession, demedicalization of chronic disease health care and a proportional allocation of health-care resources geared to the needs of the poor. With more stakeholders, such as medical devices companies, pharmaceutical companies, diagnostic clinics, insurance companies, clinical trial organizations and other service providers entering the field, there was a need to expand the scope of the definition of ethics within the field of medicine. Now the terms "bio-medical ethics", "biopharmaceutical ethics", and "health care ethics" are gaining importance. From the varied ethical and social issues that are to be contended, we require an open deliberation on the various ethical, social, economic aspects of diabetes, and with the involvement of all stake holder and sectors of society.

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Acknowledgements–Nil
Source of Funding – Nil
Conflict of Interest – Nil