

“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. Morals are mainly derived from religious practices and are not open to arguments or logic. Ethics on the other hand are intellectually derived by a particular profession (Medicine, law etc) 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. Over the centuries, Hippocratic Oath has been rewritten often to suit the values of different cultures. The oath was restructured in 1947 by International Doctors Association at the Declaration of Geneva and a new International Code of Medical Ethics was conceived. In India registration by MCI is necessary for practice and doctors have to submit a duly signed declaration instead of Hippocratic Oath. 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.

### DIABETES: AN OVERVIEW

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.

### DIABETES: ETHICAL ISSUES

An increase in the number of diabetics is likely to have a serious impact on our country’s health-care system raising many ethical and social issues related to diabetes. Performing research and preventing, diagnosing, and treating diabetes raises ethical, legal, social and policy issues. Issues raised by diabetes include understanding and addressing barriers to research, such as analyzing the impact of patents on genes related to diabetes or of statutes that restrict certain types of research; assessing the challenges of bringing new diabetes-related technologies through the government 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. Other topics include assuring people’s access to appropriate services and healthcare; preventing discrimination 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.

### Primary prevention strategies: Ethical Issues

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.

Scientific evidence of efficacy must also be considered before the allocation of limited healthcare resources. Primary prevention strategies which limit or delay the onset of diabetes are likely to be most desirable and cost effective. The question of dividing funds between primary prevention and pure research is likely to cause intense political, social and ethical debates. In a society like ours, the fascination for technologically-intensive, hospital based care is likely to take precedence over more cost-effective measures.

At present, bureaucratic controls, corruption and a lack of motivation are some factors responsible for the abysmal quality of primary health care in India compromising the primary prevention strategies for diabetes, sparking ethical debates.

### Primary Prevention of T2DM by Lifestyle Intervention: Ethical Issues

All of the major efficacy studies of lifestyle for primary prevention of diabetes were restricted to persons with glucose intolerance or very high risk for T2DM. However, the effectiveness of lifestyle intervention for persons at lower risk for diabetes is unknown. Is it ethical to await results of a new, extensive series of randomized controlled trials to evaluate intervention efficacy in groups at lower risk for diabetes or is it acceptable to infer intervention efficacy in these groups?

Despite high interest on the part of the public and media in lifestyle approaches and support from respected authorities, the public is becoming overburdened with health recommendations, many of which are unclear, inconsistent, and impractical. Disease prevention programs that do not work in the real world, even if grounded in science, may erode public confidence in lifestyle change as a worthy goal. This creates ethical implications of translating diabetes prevention by lifestyle intervention into clinical practice.

Possible harm associated with health recommendations has recently received considerable attention initiating debate that do broad, population-based programs require less evidence of efficacy than do individual clinical interventions or even greater proof is necessary in population-wide health promotion than in clinical care. Evidence that health promotion aimed at the general public will improve health needs to be even stronger than evidence for treating sick patients. Implementation of lifestyle programs for primary prevention of diabetes without full consideration of the effect on resources needed for other proven, effective diabetes treatment programs could set back efforts to reduce the overall burden of diabetes and initiate an ethical debate. So health professionals must ensure that the ethical mandate of nonmaleficence, *primum non nocere*—first, do no harm—applies to health promotion and disease prevention programs as well as to clinical medicine.

### Self-management of diabetes: Ethical Issue

Patient self-management (SM) of chronic diseases like diabetes is an evolving movement. Potential benefits from proper preparation and maintenance of patient SM skills include quality care tailored to the patient's preferences and life goals, and increase in skills in problem solving, confidence and success, generalizable to other parts of the patient's life. Four ethical issues arise with SM. 1) insufficient patient/family access to preparation that will optimize their competence to SM without harm to themselves, 2) lack of acknowledgement that an ethos of patient empowerment can mask transfer of responsibility beyond patient/family competency to handle that responsibility, 3) prevailing assumptions that preparation for SM cannot result in harm and that its main purpose is to deliver physician instructions, and 4) lack of standards for patient selection, which has the potential to exclude individuals who could benefit from learning to SM. Addressing these ethical issues require more evidence

about feasibility of SM and to optimize the benefits of SM while assuring that potential harms are controlled.

### Market-driven research in Diabetes: Ethical Issues

As the number of diabetic patients' increases, the private health sector will find new and lucrative market opportunities. Given the present government's economic and social philosophy, the market is take precedence over the patient's interests. 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, compartmentalisation within medical education and in the medical profession prevents scientific research in traditional medicines. Such issues of market influences generate ethical debates relating market influences of diabetes care.

### Costly therapy and diabetic complications: Ethical Issue

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 ethical dilemma faced by 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. For example, foot gangrene is one of the most dreaded complications of diabetes. It is often possible to salvage the foot, but only 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, even affecting one's employment. The difficult decision to amputate is often based on social and economic factors. Similarly, in the case of end stage renal disease, where renal transplant is not feasible and the patient has multisystem failure, the question is how long should hemodialysis be continued in view of increasing costs and an almost certain unfavorable outcome. Such dilemmas are likely to increase as the number of diabetics with complications increases and the resource crunch becomes severe leading to a wider debate on ethical, social and economic issues related to management of diabetic complications. One cost-effective strategy for the treatment of diabetic complications is to develop effective home care by a cadre of health workers. Another area which needs attention is the development of special footwear for diabetic patients. Today, despite the many patients with foot problems, cost effective and scientifically devised footwear is not available even in urban areas. This presents another ethical dilemma to the

744 practitioner who salvages a foot at great economic and social costs — only to see the patient’s feet damaged by the lack of effective footwear. The development of effective footwear is a low-tech labor-intensive industry. It is also probably not very profitable, and hence neglected.

### Diabetes and Driving Safety: Ethical issues

Driving is a common yet highly complex task and requires multitasking incorporating visual, motor, and cognitive abilities. Safe operation of a vehicle has significant implications for the physical and financial well-being of both our patients and the general public and it becomes a medical, public health and ethical issues for health care professionals regarding risk of both acute and chronic effects of diabetes like proliferative and advanced non-proliferative retinopathy may cause significant loss of peripheral vision and visual acuity (particularly in dim light situations or night driving). Peripheral neuropathy may result in significant lower limb proprioceptive defects, interfering with safe use of the pedals. Acute complications like significant hypoglycemia and hyperglycemia may impair perceptual, motor, cognition, awareness, and judgment. In light of the legal and ethical issues surrounding these growing scientific findings, the American Diabetes Association released a Position Statement on diabetes and driving which states that people with diabetes should be assessed individually, taking into account each individual’s medical history as well as the potential related risks associated with driving. Health care professionals, have a responsibility to discuss driving safety with patients who may have compromised driving ability secondary to diabetes and counseling them on preventive measures.

### Diabetic Clinical Trials: Ethical Issues

The Declaration of Helsinki, an international document that describes 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.

Another ethical issue 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.

### Predictive Genetic Testing for Diabetes: Ethical Issues

T2DM is a prevalent, chronic condition associated with

extensive morbidity, decreased quality of life, and increased utilization of health services. The polygenic nature of T2DM has been a major challenge to identifying genes involved in the pathogenesis of this disease knowledge that could give rise to new treatments and tests. 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 diabetes. As new predictive genetic tests for T2DM are developed and commercialized, it will be critical to consider the potential ethical implications they raise and steps to prevent or ameliorate harms.

Genetic susceptibility testing services for T2DM is available but experts are not convinced of its current clinical validity and utility generating an ethical issue. The variability of the severity of T2DM poses difficulties for the ethical evaluation of susceptibility testing for the disease. From a precautionary perspective, it could be argued that T2DM 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 T2DM implies a potential for medical benefits to be obtained from susceptibility testing. As a consequence, 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 definitely raise ethical issues, such as psychological harms: at-risk children who do not adhere to lifestyle recommendations and develop the disease later in life may blame 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. There is currently insufficient evidence to support an offer of genetic susceptibility testing for T2DM to children or minors.

### Type 1 DM Research with Children: Ethical Issues

HLA genotyping can be used to identify children at increased risk for type 1 diabetes mellitus (T1DM) and research studies to evaluate this testing strategy are currently being implemented. Research involving children raises significant questions, and families may need guidance in considering the risks and benefits of participation.

### Embryonic stem cells: Ethical issue

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. Cloned embryos may one day allow the customized replacement of damaged tissues and organs. The ethical aspects of such a research are hotly debated. 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.

### Surgical treatment of T2DM: Ethical Issues

International conferences on bariatric surgery for T2DM have concluded that bariatric surgery is an effective treatment of T2DM in morbidly obese subjects (body-mass index (BMI)  $> 35 \text{ kg/m}^2$ ) and recently bariatric surgery has been launched as an attractive treatment alternative for patients with T2DM and BMI  $< 35 \text{ kg/m}^2$  generating ethical debate because of limited evidence on the effect and safety of bariatric surgery in persons with BMI  $< 35 \text{ kg/m}^2$  particularly in those with T2DM. Some critics argue that even with high quality evidence for morbidly obese persons, we cannot uncritically extrapolate results on T2DM from persons with BMI  $\geq 35 \text{ kg/m}^2$  to those with

BMI  $< 35 \text{ kg/m}^2$ . A lack of high quality evidence on the effect of bariatric surgery for the treatment of T2DM in patients with BMI  $< 35 \text{ kg/m}^2$  poses a wide variety of ethical challenges, which are important for decisions on the individual patient level, on the management level, and on the health policy making level. Other ethical dimension is that strong preferences among surgeons and patients may hamper high quality research.

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