Under-recognised ethical dilemmas of diabetes care in resource-poor settings

SAURAV BASU, NANDINI SHARMA

Abstract

Ineffective diabetes management results in suboptimal glycaemic control and adverse health outcomes. In resource-poor settings, a combination of high burden of medication nonadherence in patients and therapeutic inertia amongst clinicians is largely attributed to the failure to achieve glycaemic targets in diabetic populations. The potential health risks from intensification of medical therapy for aggressive lowering of glucose levels in Type 2 diabetes patients represents an ethical dilemma between averting risk from overtreatment and preventing future harm from raised blood glucose levels. However, the ethical dilemmas experienced by clinicians in most of the developing world when contemplating prescription of additional oral hypoglycaemic agents or initiating insulin have received little attention from the medical community. Such ethical dilemmas unique to resource-poor settings often emerge from poor availability of drugs, diagnostics and physician consultation time for diabetic patients. Furthermore, existing evidence-based guidelines for diabetes management assume a standard of care which is lacking in such settings. This often compels the developing world clinicians when confronted with such diabetes-related ethical dilemmas to rely solely on their clinical judgement which could be ethically unjust and medically prone to error. Newer research needs to generate evidence to develop best practice guidelines for optimal therapeutic outcomes, while acknowledging the reality of limited healthcare services available in resource-poor settings.

Optimal glycaemic control as a therapeutic outcome is essential for delaying the onset and progression of microvascular and macrovascular complications in diabetes patients (1). Diabetes complications are associated with premature mortality, reduced quality of life and enormous economic costs. Measurement of glycated hemoglobin (HbA1c) is considered the gold standard for assessment of glycaemic control in diabetics with a value of <7% usually considered as good control (2). Large scale studies have found poor glycaemic control to be a major public health problem, especially in the developing world. The A1chieve study reported a mean HbA1c of 9.2% in a large cohort of 20,554 diabetes patients in India (3). A facility-based study in Kerala among 1200 diabetics undergoing treatment reported HbA1c > 9% in 45% patients (4). The lack of effective diabetes management resulting in poor glycaemic control in a diabetic population is suggestive of a high prevalence of nonadherence to medication intake and therapeutic inertia. Medication non-adherence occurs when the patient's medication intake does not correspond to agreed recommendations from a healthcare provider, a major problem in chronic diseases which require lifelong medication intake (5), as in diabetes mellitus (DM). Therapeutic or clinical inertia is the failure to intensify the treatment of a diabetic patient who is not at his/her HbA1c goal as per standard guidelines (3). For instance, the American Association of Clinical Endocrinologists (AACE) 2016 guidelines recommend intensification of anti-diabetic therapy every three months, culminating in initiation of insulin on failure to achieve the HbA1c target (6). However, intensification of therapy is associated with health risks to patients which cannot be always predicted. In this regard, the ethical dilemma encountered by clinicians when considering intensification of therapy in Type 2 DM patients in attempting to balance their desire to achieve glycemic targets promptly with the need for averting risk to the patient from overtreatment (non-maleficence) has been previously reported in the context of the developed world (7). Yet, the ethical dilemmas which mediate the widespread clinical inertia in resource constrained settings of the developing world have received little attention from the medical community.

Clinicians when treating diabetic patients with suboptimal glycaemic control while also lacking social support and financial protection may experience a dilemma in strictly advocating insulin therapy, considering the difficulty in its acquisition and safety during regular application (8). The ethical challenge of balancing desire for beneficence (improved glycemic control) while avoiding harm (inadequate therapy, hypoglycaemic episodes) to patients is well established. Some other related ethical dilemmas also emerge when considering intensification of medical therapy in patients who are at risk of medication non-adherence. Patients lacking financial resources can struggle to meet their anti-diabetic medicinal requirements especially in dysfunctional healthcare systems (5,9,10). Medication non-adherence in these vulnerable populations may also occur on adding new generation Oral Hypoglycemic Agents to the patient regimen that are unavailable through government supply or when lacking inexpensive generic equivalents. Moreover, any intensification of therapy prior to correction of preexisting medication non-adherence involves the risk of further lowering

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adherence due to issues with drug acquisition and factors like increased regimen complexity (11). However, in high patient load and resource-poor settings, a correct assessment of medication adherence in chronic diseases like diabetes can be challenging for the clinician due to the shorter time available for patient consultation. Furthermore, patients often tend to over-report their levels of medication adherence due to self-desirability bias (12). The clinician considering all scenarios may continue with existing treatment while awaiting improved glycaemic outcomes from an anticipated improvement in medication adherence and lifestyle modifications. Such a clinical decision is apparently consistent with the non-maleficence principle which prioritises patient non-harm over beneficence. However, paradoxically the deliberate decision of opting for therapeutic inertia in a poorly controlled diabetic may aggravate an earlier onset of diabetic complications, endangering the physician's ethical compliance with the non-maleficence principle.

In an alternative situation, the diabetic patient may express unwillingness to accept the intensified medical therapy recommended by the clinician. Patients may lack the necessary self-efficacy for conforming to an insulin regimen due to their fear of pain, side effects, nervousness about correct application, and the drug costs. Such patient-directed clinical inertia involves the ethical challenge of respecting patient autonomy and also upholding the clinician's duty towards advancing beneficence.

Another possibility involves the inability of the physician to confidently identify the presence of clinical inertia in the poorly glycaemic controlled diabetic patient. This can occur when health facilities lack an HbA1c testing facility, or when patients irregularly test plasma glucose levels, or fail to self-monitor blood glucose due to inability to afford a glucometer and recurring cost of strips which precludes valid glycaemic control assessment. The physician preference for a conservative approach favouring non-maleficence over an uncertain beneficence is observed in these situations.

It could also be argued that most of these ethical dilemmas are ultimately an outcome of resource deprivation of the public health system, especially primary healthcare, leading to a denial of justice for diabetic patients dependent on it. We do realise that the achievement of a system of universal health coverage which ensures high quality diabetes care in the outpatient setting, inclusive of drugs and diagnostics, can largely eliminate diabetes related ethical dilemmas encountered by the clinician in existing resource-poor settings. The global NCD targets for 2025 are also directed towards enhancing the affordability, availability and assured delivery of essential medicines, counselling and basic technologies required for control of diabetes, cardiovascular diseases and stroke (13). The incorporation of e-Health and m-Health components for easing clinical decision making for healthcare providers in remote areas and promoting health education in patients can also facilitate the achievement of these targets.

There exist additional ethical dilemmas in diabetes care in resource-poor settings which relate to patient diet and lifestyle management. The challenge of selecting a healthy, culturally appropriate and affordable dietary plan for a largely poor, semi-literate and culturally diverse population can be daunting even for a skillful dietician. Similarly, recommendations of physical exercise can remain unmet due to lack of sufficient open recreational spaces or in the presence of sociocultural resistance against these health practices among younger women in certain orthodox communities (14). Conventional strategies for effective diabetes management overlook the enormity of such sociocultural, socioeconomic and environmental challenges which are pervasive over much of the developing world (15).

In conclusion, both overt and subtle ethical dilemmas influence diabetes management by the clinician. Existing evidence-based guidelines for diabetes management assume a standard of care which is lacking in much of the developing world and thereby inadequate for ameliorating the ethical dilemmas arising during diabetes care in these settings. This increases the clinician's vulnerability towards exercising his or her clinical judgement which could be ethically unjust and medically prone to error. Newer research needs to prioritise the focus in generating evidence for developing best practice guidelines to achieve optimal therapeutic outcomes while acknowledging the realities of the limited public healthcare services and the socioeconomic vulnerability of diabetic populations living in these resource-poor settings.

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Social responsibility and global health: Lessons from the Rio Olympics Zika controversy

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Abstract

The outbreak of Zika virus infection in the Americas and its possible association with microcephaly raised several concerns among global health authorities regarding the organisation of the Olympic and Paralympic Games scheduled for August and September 2016, in the city of Rio de Janeiro, Brazil. It generated an international controversy over the continuation of the Games with debates on the ethical principle of social responsibility. Based on the principles of social responsibility and health in the Universal Declaration of Bioethics and Human Rights, the present comment ponders on the application of such principles in the context of mega-events and global health.

The year 2016 started on the disturbing note of a possible Zika virus pandemic in the Americas, as reported by the World Health Organisation(WHO) (1). Following the news of the infection, the US Centers for Disease Control and Prevention advised pregnant women to refrain from traveling to the sites affected by Zika virus due to a possible association between the infection and microcephaly (2). The Zika virus epidemic caused great concern among global health authorities, given the fact that the Olympic and Paralympic Games were scheduled to be held in August and September 2016, in Rio de Janeiro, Brazil. Subsequently, a heated international controversy erupted, based on the principle of social responsibility, over whether the Games should be held in Brazil or not.

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The disagreement within the international scientific community intensified in May 2016 when a group of 177 scientists, mostly from the areas of bioethics and public health, from 28 different countries, including one from Brazil, sent an open letter to the WHO (3). The authors of the letter, led by Amir Attaran, argued that holding the Games in Rio would be "unethical" and proposed that "in the name of public health" the 2016 Olympic Games should be transferred from the country or postponed due to the uncertainties regarding the threat of Zika virus (3).

The WHO responded on May 28 that "there is no public health justification for postponing or canceling the Games". This was because the vast majority of healthy individuals who had become infected by Zika virus were asymptomatic, or the period in which the Olympics would be held in Brazil is not considered as endemic to the transmission of diseases caused by *Aedes aegypti* such as Zika, dengue and chikungunya (4). Thus, according to the WHO and, soon after, the International Olympic Committee, to cancel or change the location of the 2016 Olympics would not significantly alter the international spread of Zika virus (4).

Also, in response to the open letter from Attaran and colleagues, the Brazilian scientists immediately presented epidemiological information to state that "Zika is not a reason for missing the Olympic Games in Rio de Janeiro" (5). Immediately after this, the Brazilian Society of Bioethics (SBB) issued a critical note based on epidemiological, immunological and ethical arguments stating that, with all due respect to the possible good intentions of the scientists, it clearly disagreed with the proposal (6). Among other arguments, the SBB recalled a similar concern during the dengue epidemic preceding the Football World Cup held in Brazil in 2014, when the situation had been more severe. Besides, there was no scientific evidence of increased prevalence in other countries related to the return of tourists after that event (6). After the events reported above, in June 2016, a new epidemiological study attested that arguments for cancellation, postponement or transfer of the games "are not based on evidence, and they largely ignored current