REVIEW ARTICLE

ADHERENCE TO DIABETES MELLITUS TREATMENT GUIDELINES FROM THEORY TO PRACTICE: THE MISSING LINK

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Diabetes mellitus is a complex multisystem disease that requires high quality care. Clinical practice guidelines help physicians and patients make the best possible health care decisions and improve health care management of diabetic patients. These guidelines provide the norms for clinical management as well as monitoring of diabetes care. They are not simple algorithms but are based on structured evidence based diabetic management protocols developed from randomized controlled trials. Despite the widespread availability of this diabetic guideline, their use is suboptimal at best. There are several factors blamed for contributing to this missing link from available theoretical guideline recommendations to practical applications of these guidelines. We present a brief review based on available literature review for an ongoing interventional study being done by authors in two tertiary care hospital in Lahore Pakistan for improving adherence to diabetes guidelines. We will discuss guideline implementation cycle and also present a framework encompassing various factors involved in adherence to guidelines. Until recently the emphasis to improve the guideline adherence targeted the factors relating to individual health care professionals in reference to their knowledge, attitude practice of the guidelines. However, we will discuss that broader range of health care systems, organizational factors, and factors relating to patients which may also significantly impact the adherence to the guidelines. The framework emphasises that it is important to understand the factors that act as barriers and contribute to the missing link between theory and practice of diabetic guidelines. This will help plan appropriate strategies in the pre-implementation stage for effective and improved diabetes guidelines adherence and management.

Keywords: Diabetes mellitus; Diabetes management; Diabetic guidelines; Adherence to guidelines

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INTRODUCTION

Diabetes is a disease characterized by hyperglycaemia which can increase the risk of microvascular complications (retinopathy, nephropathy and neuropathy) and as well as macrovascular complications (ischemic heart disease, peripheral vascular disease and stroke).[1] Diabetes mellitus has been blamed as the leading cause of morbidity and mortality.[2] Its global prevalence was about 8% in 2011 and is predicted to rise to 10% by 2030.[3] Several reasons are cited for this increasing trend including a change in life-style, rapid urbanization and increase in the aging population.[4] In 2012 diabetes was noted to be directly responsible for about 1.5 million deaths. More than 80% of these diabetes related deaths occurred in low and middle income countries.[5] South Asian countries have been estimated to see an increase of type 2 diabetes 150% between 2000 and 2035.[6]

According to International Diabetic Federation data from 2011 the prevalence of diabetes in the world was 8.3%. Diabetes prevalence showed variation in different countries from 9.5% in Australia to 23.4% in Saudi Arabia and 7.8% in Pakistan[7], which is one of the countries with a high prevalence of diabetes and recent data from 2015 from International Diabetic Federation showed prevalence of diabetes in adults aged 20–79 years was 6.9% and it is estimated that this number will increase to 11.5 million people by 2025.[8]

Diabetes Mellitus management and the role of Diabetic Guidelines:

Diabetes is a complicated disease which affects multiple organs requiring multiple treatments and preventive strategies to prevent long term complications associated with it. The management of diabetes mellitus is therefore often difficult to coordinate and requires structured plans to adequately control this multisystem disease and prevent associated morbidity.[9] Implementing structured plans has been shown to improve overall diabetes management.[10]

Structured care plans in the form of various diabetic guidelines have been developed by various organizations. These guidelines are based on evidence based strategies that were developed out of recommendations from various randomized control trials and finalized by diabetic expert consensus. The guidelines recommend both clinical and preventive strategies for diabetes management and are regularly

updated. They are used not only for clinical management of the disease but also for the monitoring of ongoing care with predefined laboratory check-ups at regular intervals, life style counselling about diet, exercise, smoking and referral services to various specialists including ophthalmologist, dietician, and podiatrist. The guidelines are used to prevent the diabetic related morbidity by preventing complications related to diabetes including diabetic retinopathy, diabetic nephropathy, and diabetic neuropathy.[11–13]

Studies have shown that when diabetic guidelines were used HbA1c[14], lipid levels[15], and diabetic patients' satisfaction levels to their diabetes related care[16] showed more improvement than when they were not used. Research also has revealed diabetes guidelines may make diabetes management more cost effective by preventing unnecessary use of certain medications and procedures that have been not shown to be beneficial based on the evidence based data. This could be very important for many developing countries with limited healthcare budgets and increased burden of diseases including diabetes. Diabetic guidelines have also been found useful in planning diabetic health services because of predefined standards of care which health care policy makers and health care mangers may use to plan the required resources to implement those standards of care. This may include planning availability of physical, human resources, and developing organizational structure at the system level to implement these guidelines effectively.[17,18]

Adherence to the Diabetes Guidelines:

Despite the widespread availability of the diabetic guidelines many studies have revealed inconsistent and suboptimal adherence rates of patients to the diabetic management guidelines. The adherence rates varied from proper medication use in 78–83% of patients to less than 40% to dietary recommendations as per diabetic guidelines.[19]

A survey in the USA looked at about 5000 self-reported diabetics data from 1988 to 2010 to see if the patients were getting diabetic care according to the American Diabetes Association's (ADA) recommended targets. It was noted that only 18% of the patients had achieved all the recommended ADA guidelines targets for HbA1c level, blood pressure and LDL levels.[20] Another study done in Israel also revealed that only 13% of the diabetics had achieved all the three goals for diabetes management (HbA1c, LDL-C, Blood pressure levels) according to the diabetic guidelines.[21]

Similar results were noted in a survey done in Australia among 600 diabetics. Only 63% of patients reported that their diabetes mellitus was well controlled and over one third of patients had diabetes related complications. Even though majority of them had blood pressure and serum creatinine checked, only 42% had the recommended foot exanimation and only 20% had lifestyle management recommendations as per diabetic guidelines.[22] Similarly data from a retrospective study done in four diabetic clinics in Karachi Pakistan in 2005 showed that only 44% patients had lower leg examination, 30% had eye examination, and HbA1c levels was recorded in only 44% of the patients. The authors also noted that a large proportion of the patients did not achieve the care according to the diabetic guideline standards.[23] Another descriptive study done in Azad Kashmir Pakistan in 2012-13 showed that 39% of patients had not received information about life style changes and 68% of patients had never or rarely received information about diabetic complications.[24]

Factors affecting adherence to Diabetic Guidelines:

Several factors have been noted to affect the implementation and adherence to diabetic guidelines. These factors can be categorized into four major groups. Group one includes factors related to the intrinsic attributes of the guidelines themselves and factors related to guideline implementation process, group two includes physician's related factors, group three includes patient related factors, and finally the group four includes factors related to health care system affecting diabetic guideline implementation and adherence.[25–27] These groups are discussed below individually.

Factors related to the guideline are multidimensional and are related to the intrinsic attributes guidelines as well as several other factors that can affect their implementation. Implement ability of guidelines is noted to be dependent on various factors including whether the guidelines are valid, reliable, applicable, and if they are disseminated to all the relevant stakeholders in an effective manner.

Additionally, health care systems related factors including availability of trained human resources, physical infrastructure availability, financial resources, policy and organizational setup are also important determinants for effective implementation of the guidelines.[26,27] Literature review and adaptation of Knowledge-to-action' (KTA) cycle[28] is used to describe the guideline implementation process framework as depicted in figure-1. This model describes various steps which are important in developing, disseminating, implementing and finally evaluating the guidelines. Successful implementation of diabetes guidelines will require that each of these attributes of the guidelines are examined and factors that either hinder or facilitate the implementation process are addressed before actual implementation process start.[28]

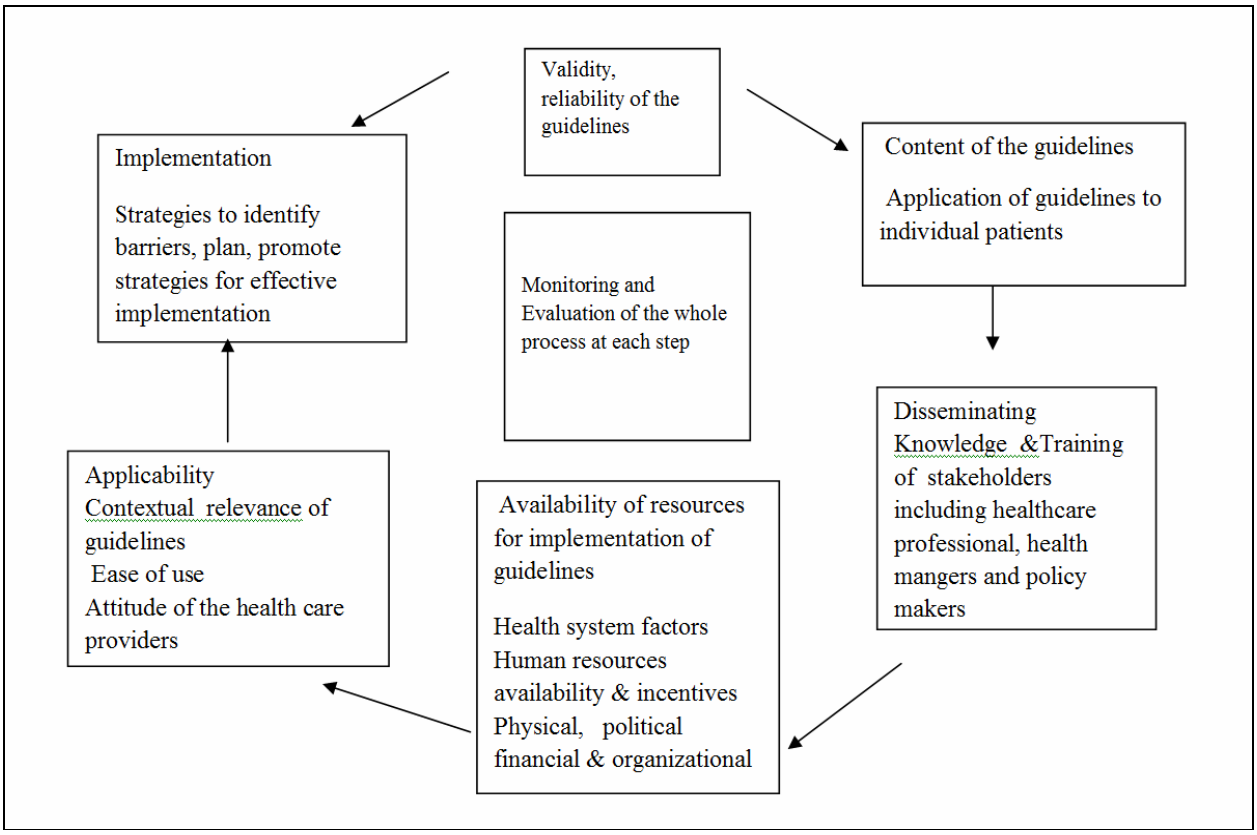

Figure-1: Framework of guidelines implement ability using knowledge-to-action' (KTA) cycle

Additionally, an instrument also has been developed called. The Appraisal of Guidelines Research and Evaluation (AGREE) instrument which is used to assess guidelines using various factors. The indicators used include the process of development of the guidelines, the extent of the stakeholder involvement, and applicability of the guidelines in various contexts.[29] This instrument can be used to check if a particular diabetic guideline whether it is from American Diabetic association, World health organization or International Diabetic Federation will be implementable in a particular health care setting. The contextual constraints including availability of resources both physical and human resources and health system capacity to implement a particular guideline will be just as important as the intrinsic attributes of the guidlines.[27]

Physicians have been noted to use clinical guidelines inconsistently and variably.[30] Several reasons have been blamed to explain this lack of adherence to the guidelines by the physicians. The foremost is that physicians are not convinced of the utility of international guidelines. The concern is that most of the guidelines are based on recommendations from emerging evidence based data which are often obtained from randomized controlled trials (RCTs). These trials however are done in very controlled environments with strict inclusion/exclusion criteria, treatment protocols and sometimes excluding patients with comorbidities. The physicians are concerned that these trial participants do not represent either the patient population or the practice setting that they usually practice. The physicians therefore have difficulty translating the results based on these randomized controlled trails into their routine practice because of their contextual constraints.[31] Other physician factors which are important and can affect their adherence to diabetic guidelines, include their lack of knowledge and training about the guidelines[32,33], work overload[29,33,34], time constraints[29,33,35,36], lack of incentives[29,33,35,36] and lack of consensus about using diabetic guidelines[29,30,37–39].

Physician's attitude and individual motivation can also have an impact on their adherence to the guidelines. This was noted in a systemic review done in 2002 in which it was seen that 70% of physicians believed that the diabetic guidelines did have an impact upon the quality of diabetes care and improved it. It was also noted that about 71% of clinicians thought that they were good educational tools. However, 30% of physicians were also concerned about the utility of using guidelines in

individual patients. Another 23% thought they were impractical. Physicians also shared their concern that since these guidelines specifically demanded certain well defined diabetes management protocols which may not be possible in every single patient and in every single clinical practice setting. Any deviation of care from these guidelines could be used for malpractice and litigation against the physicians. However, it has been noted both in the UK and the USA that even though clinical practice guidelines may define the standards of care they could not be used for regulatory purposes in a court of law. In fact, it is conjectured that adhering to the guidelines may offer some protection against litigation as physicians may demonstrate that they were following the standard of care as defined by the guidlines.[40,41] However which international guideline can be followed in different context remains to be decided and individual physicians are left to make that decision if there are no country specific diabetic guidelines that they can use. This can lead to variation in the diabetic care by physicians even if they were following a particular international diabetic guideline. Research studies to look at local adaptation of international diabetic guidelines may help in the implementation and adherence of these guidelines by the physicians.

Diabetic patients are especially prone to problems with adherence as the management of diabetes which is a multidimensional disease and requires multisystem complex treatment and preventive strategies.[42] Patient factors like patient refusal to follow the guidelines will limit the ability of physicians to implement diabetic care according to the guidelines.[43] There are several factors that are patient related that can affect their ability to adhere to the diabetic guidelines. These include demographic factors, psychosocial factors, relationship with the health care provider/medical system, and disease related factors.[44] It has been noted that patients with low education and low socioeconomic status had difficulty with adhering to the diabetic regimens and consequently were noted to have high diabetes related morbidity.[45]

Patients who had history of depression, anxiety, and eating disorders also had problems with adhering to the diabetic guidlines.[45] Self-perceived efficacy is also important for adherence to diabetic guidelines. It has been seen that although different personality traits had no effect on the adherence rates, patients who had higher stress levels had more difficulty adhering to the guidelines.[46]

Psychological factors which can affect adherence include the patient health belief model which essentially is based on the patient's belief about the severity of their diabetes mellitus and if they can make sense of the treatment and if they believe that spending money on the treatment to get the required health benefits will be worthwhile.[47] Social support is very important for adherence and it has been seen that diabetics who had good family support, better communication skills with their family and social support did better with adherence. Spousal support especially was considered to be very important in helping diabetics adhere to the diabetic treatment regimens.[45,46] Despite the importance of psychological effect on diabetes adherence it was concerning to note that many health care providers were unable to identify or provide the necessary psychological to their patients. Additionally, it has been noted that patients treatment regimens that are simpler have better adherence than complex ones.[48]

Healthcare economic and organizational constraints will affect the adherence to the guidelines.[25] Studies have shown that good quality patient physician relationships are integral for adherence to diabetic regimens by the patients.[48] It has been seen that multifaceted healthcare organization interventions including an improved data monitoring system, healthcare team support which is well coordinated and adequately trained is also important to achieve good quality of diabetic care by physicians. Consistent use of guideline related standardized protocols for implementation, monitoring and evaluating will also help ensure effective guideline implementation goals.[49]

System level factors are important as seen in the Translating Research into Action for Diabetes (TRIAD) Study which was done to study association between system related factors and the diabetic patient outcomes. The system level factors identified in this study included health system structure, disease management strategies like physician patient reminders, manpower training, referral care coordination, resource allocations, incentives and data monitoring as important determinants in diabetic patient management and outcomes.[50] Organizational strategies including setting clear goals, training appropriate health care personnel and adequate communication among the team members are also important factors that can impact on the implementation of diabetic guidelines and effectiveness of diabetes management (Figure-2).[51]

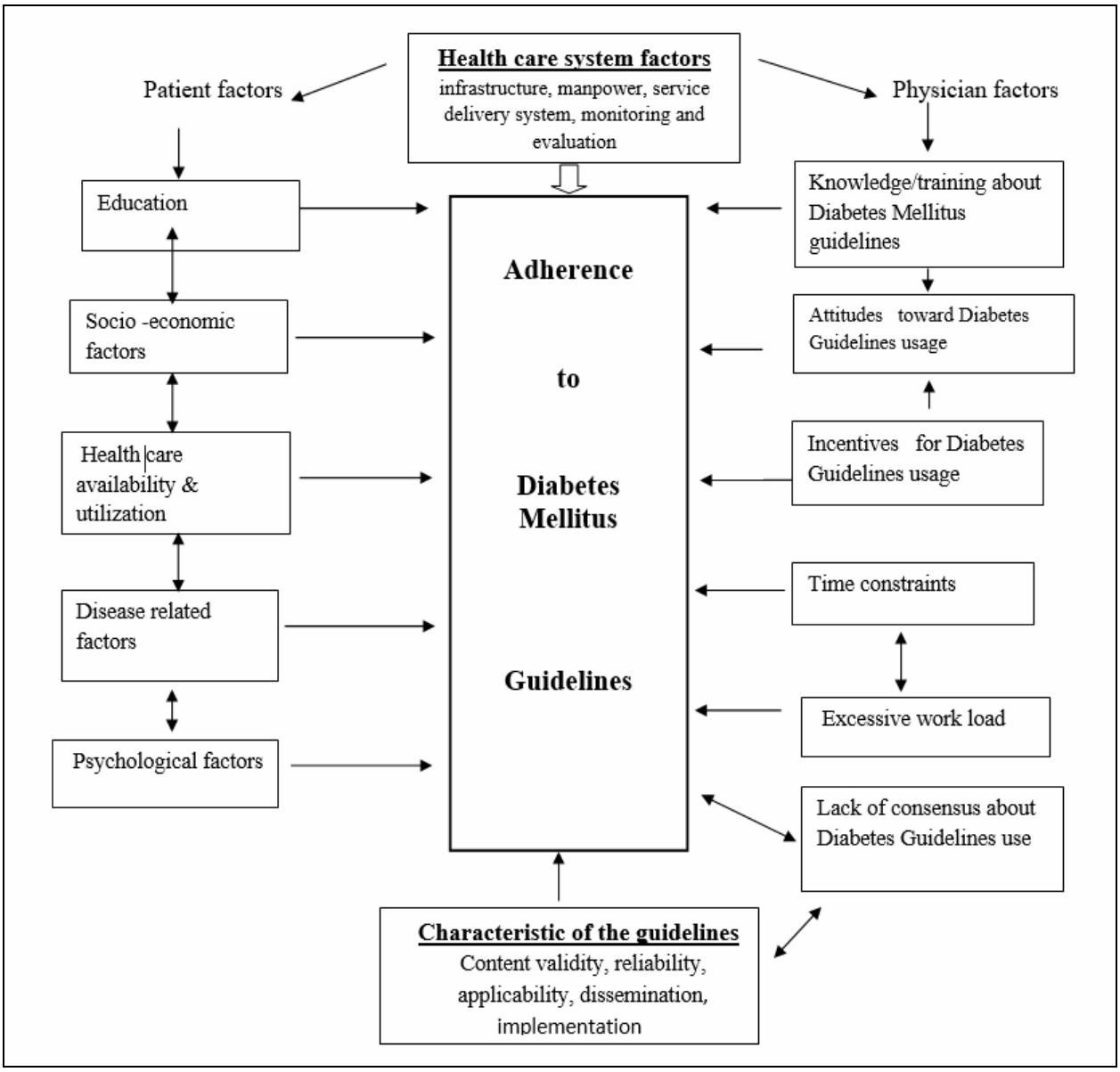

Figure-2: Theoretical framework: Determinants of adherence to diabetes mellitus guidelines

CONCLUSION

Diabetes is a multisystem disease with complex clinical management and preventive issues. Implementing structured evidence based care using diabetic guidelines is an important strategy to improve the management of this disease. There are several factors affecting the diabetic guideline adherence including characteristics of guideline themselves, physician factors, patient factors and wider healthcare system/organizational factors. We have presented a framework to understand these various factors and their dynamic interaction with each other. This will help identify barriers to implementation of guidelines and plan strategies in the pre-implementation phase for effective guideline implementation. The available international diabetic guidelines do not have cross-cultural references making it difficult for individual physicians in different countries with no local diabetic guidelines to determine which guidelines will work best for their patient population. It is important to identify the contextual factors that might affect the implementation of the guidelines. Expert opinion should then develop local consensus for diabetic guidelines that will work for that society given its resources and socio-cultural constraints. Input from the physicians, healthcare policy makers, healthcare mangers and patients may help in making these guidelines more user friendly and improve adherence.

Dissemination of the guidelines once developed and agreed upon by all the stakeholders, monitoring and evaluation will be integral to the success of such program.

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