Adherence to the American Diabetes Association standards of care among patients with type 2 diabetes in primary care in Saudi Arabia

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ABSTRACT

الأهداف: تقييم مدى الالتزام بحوالي 11 معيار من معايير الجمعية الأمريكية للسكري والرعاية الصحية بمرضى السكري.

الطريقة: أُجريت هذه الدراسة الاستطلاعية التاريخية على مدار عام كامل وذلك خلال الفترة من أكتوبر 2010م إلى سبتمبر 2011م. شملت الدراسة 450 مريضاً مصابا بالسكري من النوع الثاني والذين تتم علاجهم في مركز للرعاية الصحية بالمملكة العربية السعودية. واعتمدت الدراسة على التعريف الصادر من معايير الجمعية الأمريكية للسكري النسخة 2010 لتقديم الرعاية الصحية اللازمة لمرضى السكري وأهدافها المرجوة.

النتائج: شملت الدراسة 450 ملفاً طبياً مما كانت بياناتها كاملة ومطابقة لشروط الدراسة. وتبين أن نسبة الالتزام بالمعايير الإجرائية لجمعية السكري الأميركية لقياس الهيموجلوبين السكري كانت 68.7%، و 92.9%بالنسبة لضغط الدم، و 80.2% بالنسبة لنسبة الدهون في الدم. وكان الالتزام بالفحص الدوري متدنياً بالنسبة لاعتلال الكلى (35.6%)، فيما كان الالتزام الأعلى بالنسبة للقدم السكرية (72%). وتراوح الالتزام بتناول الأدوية ما بين 82.2% فيما يخص مضادات الصفائح الدموية، و92.4% بالنسبة لأدوية اعتلال الدهون. وفيما يتعلق بمعايير الأهداف المرجوة من الرعاية الصحية فقد تبين أن 24.2% من المرضى قد وصلوا إلى نسبة الهيموجلوبين السكري المستهدفة (≤7%)، فيما وصل 32.2% منهم إلى ضغط الدم المستهدف (<130/80 mm Hg)، وحقق 58.5% منهم النسبة المستهدفة للبروتينات الدهنية منخفضة الكثافة. ووصل 7.2% من المرضى إلى النسب المستهدفة للسكري بالدم، وضغط الدم، ومستوى البروتينات الدهنية منخفضة الكثافة مجتمعة. كما أشارت النتائج إلى حدوث تحسن واضح من الناحية الإحصائية في نسب المرضى (≤7%) الذين حققوا المستوى المستهدف للسكر بالدم خلال فترة المتابعة(p=0.003).

الخاتمة: تشير النتائج إلى أن الالتزام بمعايير جمعية السكري الأميركية لرعاية السكري بين المرضى الذين يعانون من مرض السكري من النوع 2 في مركز للرعاية الصحية الأولية في المملكة العربية السعودية أقل من المستوى المطلوب. كما أن تحقيق معايير أهداف الرعاية الصحية ، إما منفردة أو مجتمعة، هي أقل من معدلات الالتزام. ومع ذلك فإن الأرقام أشارت إلى حدوث تحسن واضح من الناحية الإحصائية في نسب المرضى الذين حققوا المستوى المستهدف للسكر بالدم خلال فترة المتابعة.

Objectives: To assess adherence to 11 American Diabetes Association (ADA) standards of diabetic care.

Methods: We conducted this one-year historical prospective study between October 2010 and September 2011 on 450 adult type 2 diabetes patients in a primary care center in Saudi Arabia. We used the definitions of the 2010 ADA standards of diabetic care processes and targets.

Results: Four-hundred and fifty medical files were valid. The adherence to ADA process standards of measurement of glycated hemoglobin (HbA1c) was 68.7%, 92.9% for blood pressure, and 80.2% for serum lipids. Screening was lowest for nephropathy (35.6%), and highest for diabetic foot (72%). Adherence to medications ranged between 82.2% for antiplatelets, and 92.4% for dyslipidemia. For outcome standards, 24.2% of the patients had an HbA1c ≤7%, and 32.2% had controlled blood pressure (<130/80 mm Hg); and 58.5% achieved targeted low-density lipoproteins (LDL). Only 7.2% had glycemic control in addition to controlled blood pressure and targeted LDL level. An increasing trend of patients achieving glycemic control (≤7%) was shown throughout follow-up (p=0.003).

Conclusions: We found suboptimal adherence with many ADA standards of diabetic care among patients with type 2 diabetes treated at a primary care center in Saudi Arabia. The achievement of outcome standards, either singly or combined, is lower than the adherence rates. However, the figures show improvement in adherence during the follow-up period.

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Diabetes mellitus is a chronic disease that can cause devastating secondary complications, reducing the quality and length of life as well as increasing medical costs for the patient and society.[1-3] Saudi Arabia has one of the highest diabetes prevalence rates worldwide. The International Diabetes Federation estimates that 8.3% of the world's adult population (20-79 years) have diabetes, with Saudi Arabia one of the top countries affected (20%).[4] Additionally, a national study estimated the overall prevalence of diabetes in Saudis aged 30-70 years at 23.7% (26.7% in women, and 21.5% in men).[5]

Diabetes care is a complex process requiring ongoing patient self-management, education, and support to prevent acute complications, and to reduce the risk of long-term complications.[6] Compelling evidence from clinical trials shows that intensive glycemic control effectively delays the onset and slows the progression of diabetic complications, such as nephropathy, retinopathy, and neuropathy.[7-9] Likewise, substantial evidence shows that control of associated risk factors such as hypertension and dyslipidemia is protective against undesirable outcomes in patients with diabetes.[10-14] The American Diabetes Association (ADA) put together a set of diabetic care standards that are annually revised.[15] However, despite the availability of convincing evidence and clear guidelines, many studies throughout the world reported suboptimal adherence to diabetic care standards.[16-19] Only a few studies have examined the quality of diabetic care among Saudi patients in a primary care setting,[20] outpatient clinics of internal medicine,[21,22] and specialized diabetic care centers.[23] These studies covered one or more of the screening, diagnostic, and therapeutic components of the ADA standards of diabetic care. However, the extent to which these standards are met at primary care settings was not comprehensively studied. Moreover, the degree to which multiple ADA processes and outcomes are simultaneously achieved was also not studied. Therefore, we aimed to assess the adherence of primary care patients to 11 ADA standards of diabetic care including glycemic control, blood pressure control, and lipid management, singly and combined.

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Methods. This record-based study used a historical cohort design covering a one-year follow-up of eligible patients with diabetes. The "historical prospective" design combines many of the advantages of prospective and retrospective designs. It is retrospective in the sense that the data are already present and the outcomes already happened. It is prospective in the sense that the direction of the data manipulation is from exposure to outcome. Since the follow-up is carried out on records, it is called "historical" to differentiate it from a "concurrent" follow-up design.[24] The study was conducted in Al-Wazarat Healthcare Center (WHC), Riyadh, Saudi Arabia. This is a big family medicine center accredited by the Joint Commission International (JCI). It provides charge-free service to all military personnel and their families, as well as for its staff. The total population served in 2011 was 303,682. The center consists of 32 general clinics, specialized primary care clinics, a pharmacy, laboratory, treatment room, and radiology room. It is staffed by approximately 80 physicians and receives approximately 1000 patient visits daily. The chronic disease unit provides care to approximately 16,000 patients, most having diabetes. The unit is staffed by senior family physicians who are board certified and/or specialized in diabetes care, a board certified clinical pharmacist, dietitians, diabetic educators, and health educators. The unit receives on average 120 chronic disease patients daily. The care provided is the standard care as per ADA guidelines,[15] but intensified with consideration of individual patient's clinical and social factors.

Any adult (18 years or older) type 2 diabetes patient who attended the chronic disease unit during a 2-week period of recruitment (end of September and beginning of October 2011) was eligible for inclusion in the study sample. The inclusion criteria were receiving primary care at the chronic disease unit during the preceding year, and having at least 2 visits 3-6 months apart during this period. Patients with known hemoglobinopathies such as sickle cell anemia or any blood disorders that may affect the accuracy of glycohemoglobin (HbA1c), a history of recent acute blood loss, or end stage renal disease were excluded from the study.

The sample size was calculated to estimate the prevalence of adherence to any of the ADA criteria of 25% or higher, with an absolute precision of 2%, at the 95% level of confidence. The required sample size was calculated as 450 participants using the Epi-Info 6.04 software package. This was increased to 500 to account for a dropout rate of approximately 10%.

Eligible patients were invited to participate in the study after being briefed on its purpose and procedures,

anonymity, and confidentiality, and the rights to refuse or withdraw. Those who agreed signed an informed consent to review their medical files. Trained pharmacist interns collected the required data over the last year from the patients' charts and laboratory records using a pre-designed abstraction sheet. The historical follow-up period was from October 2010 to September 2011. The study was carried out according to the principles of the Helsinki Declaration, and its protocol was approved by the Research and Ethics committee of Prince Sultan Military Medical City, Riyadh, Saudi Arabia.

We collected data on 11 ADA process standards of diabetic care: 1) HbA1c at least twice/year in patients meeting treatment goals and quarterly in those not meeting goals; 2) blood pressure measurement at every routine diabetes visit; 3) fasting lipid profile measurement at least annually with more measurements if starting/changing lipid lowering medications; 4) annual measurement of urine albumin and serum creatinine with more measurements to assess progression of kidney disease and response to therapy; 5) use of medications that optimize blood pressure and reduce the risk of nephropathy such as angiotensin converting enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARBs); 6) use of lipid lowering agents with statins as first-line pharmacologic therapy; 7) use of antiplatelet agents such as aspirin or clopidogrel; 8) annual retinopathy screening after an initial dilated and comprehensive eye examination; 9) annual comprehensive foot examination including inspection, assessment of foot pulses, and testing for loss of protective sensation (10-g monofilament plus testing any one of: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold); 10) annual administration of influenza vaccine; 11) and at least one lifetime administration of pneumococcal vaccine.

The outcome standards measured included the percentages of patients with: 1) HbA1c ≤7% 2) blood pressure control: both systolic blood pressure <130 and diastolic blood pressure <80 mm Hg 3) low-density lipoprotein (LDL), cholesterol <2.6 mmol/l (100 mg/dl), high density lipoprotein (HDL) cholesterol >1.0 mmol/l (40 mg/dl) in males and >1.3 mmol/l (50 mg/dl) in females, triglycerides <1.7 mmol/l (150 mg/dl), total cholesterol <5.2 mmol/l (200 mg/dl) 4) urine microalbumin-to-creatinine ratio (ACR) <2.0 mg/mmol in males, and <2.8 mg/mmol in females. In case of multiple measurements of HbA1c, we calculated the average of the best 2 values; however, if the most recent value was >7% the patient was considered non-adherent. A low risk lipid profile (controlled blood lipids) was defined as achieving the targets of LDL, HDL, and triglycerides.

Statistical methods. We used the Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, USA) version 16 for the data analysis. Any missing data in the patient's records pertaining to the measured standards was considered as "not done" as a more conservative approach. The changes in the proportions of patients with glycemic control across the 4 follow-up visits were tested using the Mantel-Haenszel extended chi-square (for trend). The association between the level of HbA1c and the type of diabetic medication at each of the 4 visits was tested using ANOVA test. A 2-tailed *p*-value <0.05 was considered as statistically significant.

Results. The study sample included 450 type 2 diabetes patients (90% response rate). Slightly less than half of the sample were men (44.2%) of 60 years or older (48%) as shown in **Table 1**. The mean BMI was 31.4, with 57.9% being obese (BMI ≥30). As for therapy, 56.4% of the patients were on combined insulin and oral hypoglycemic medications, while 2.2% were not receiving any medications for DM during the follow-up period.

Adherence to ADA process standards of diabetic care shows a wide variation from as high as 92.9%

Table 1 - Demographic characteristics and diabetic medications of 450 type 2 diabetic patients attending a primary care center in Saudi Arabia.

Characteristics	Frequency (%)
Age (years)	
<40	31 (6.9)
40-49	65 (14.4)
50-59	138 (30.7)
60-69	136 (30.2)
≥70	80 (17.8)
Mean±SD	58.5±12.2
Gender	
Male	199 (44.2)
Female	251 (55.8)
*Body mass index**	
Underweight (≤18.5)	2 (0.5)
Normal weight (18.5-24.9)	50 (11.3)
Overweight (25-29.9)	134 (30.3)
Obesity (≥30)	256 (57.9)
Mean±SD	31.4±4.4
Medication	
None	10 (2.2)
Oral hypoglycemic only	170 (37.8)
Insulin only	16 (3.6)
Both	254 (56.4)

*8 wheel-chaired patients could not have this measurement

Table 2 - Adherence to processes of the ADA standards of diabetic care among 450 type 2 diabetic patients attending a primary care center in Saudi Arabia.

ADA process standards	Frequency (%)
Glycemic control: HbA1c measurement	309 (68.7)
Blood pressure measurement	418 (92.9)
Lipid profile measurement	
LDL	313 (69.6)
HDL	254 (56.4)
Triglycerides	361 (80.2)
Total cholesterol	355 (78.9)
Nephropathy screening	160 (35.6)
Hypertension/nephropathy medications: ACEI or ARBs	377 (83.8)
Lipid lowering medications: statin	416 (92.4)
Antiplatelet agents: aspirin or clopidogrel	370 (82.2)
Referral for fundus examination	291 (64.7)
Foot care	
Foot examination	324 (72.0)
Monofilament testing	230 (51.1)
Influenza vaccine	207 (46.0)
Pneumococcal vaccine	208 (46.2)

ADA - American Diabetes Association, HbA1c - glycohemoglobin, LDL - low-density lipoprotein, HDL - high density lipoprotein, ACEI - angiotensin converting enzyme inhibitors, ARBs - angiotensin receptor blockers

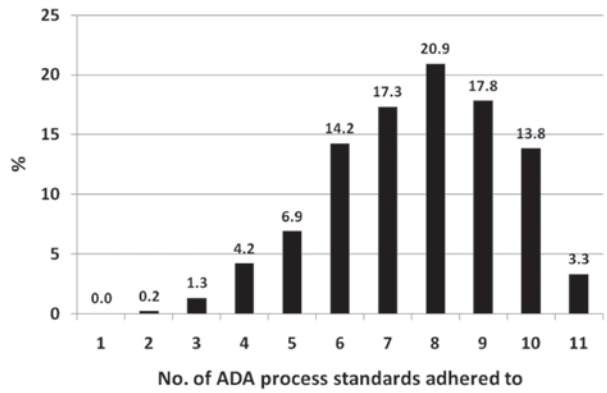


Figure 1 - Percentage of adherence to multiple processes of the American Diabetes Association (ADA) standards of diabetic care among 450 type 2 diabetic patients attending a primary care center in Saudi Arabia.

for blood pressure measurement, to as low as 35.6% for assessment for nephropathy (**Table 2**). Generally, the adherence to medications is high (82.2-92.4%), compared with lab testing, especially HDL (56.4%), and HbA1c (68.7%) measurements. Even lower rates of adherence are shown regarding influenza (46%) and pneumococcal (46.2%) vaccinations.

Looking at the rates of adherence for combined ADA process standards, **Figure 1** demonstrates that only 3.3% had all the 11 processes carried out according to standard, and another 13.8% had all but one of these

Table 3 - Adherence to targets of the ADA standards of diabetic care among 450 type 2 diabetic patients attending a primary care center in Saudi Arabia.

ADA standards	Number examined	Adherence number (%)
Individual targets		
Glycemic control - HbA1c <7%	450	109 (24.2)
Controlled blood pressure - SBP <130 & DBP <80 mm Hg	450	145 (32.2)
Low risk lipid profile	388	182 (46.9)
LDL <2.6	388	227 (58.5)
HDL >1.0 in males and >1.3 in females	388	125 (32.2)
Triglycerides <1.7	413	258 (62.5)
Total cholesterol <5.2	388	320 (82.5)
Low ACR (mg/mmol) - <2.0 in males & <2.8 in females	318	151 (47.5)
Combined targets		
Glycemic and blood pressure control	450	45 (10.0)
Glycemic and LDL control	388	64 (16.5)
Glycemic and lipid control	388	54 (13.9)
Blood pressure and LDL control	388	80 (20.6)
Blood pressure and lipid control	388	64 (16.5)
Glycemic, blood pressure and LDL control	388	
None		92 (23.7)
One		169 (43.6)
2		99 (25.5)
All 3		28 (7.2)
Glycemic, blood pressure and lipid control	388	
None		117 (30.2)
One		158 (40.7)
2		91 (23.5)
All 3		22 (5.7)

ADA - American Diabetes Association, HbA1c - glycohemoglobin, SBP - systolic blood pressure, DBP - diastolic blood pressure LDL - low-density lipo-protein, HDL - high density lipo-protein, ACR - albumin creatinine ratio

processes carried out. Overall, more than half of the patients had at least 8 of the 11 processes carried out. Regarding patients' achievement of the targets of the ADA standards of diabetic care, **Table 3** indicates that the goal of glycemic control is the least achieved (24.2%), followed by control of hypertension (32.2%). As for lipid control, it ranges between 32.2% for HDL, and 82.9% for total cholesterol. The figures for combined targets are even lower, with only 10% of the patients having glycemic control in addition to controlled blood pressure, 7.2% having glycemic control in addition to controlled blood pressure and targeted LDL level, and 5.7% having control of all parameters.

As **Figure 2** illustrates, the percentages of patients achieving glycemic control (≤7%) show a statistically significant increasing trend across the 4 patients' visits (p=0.003). It has almost doubled from the first to the

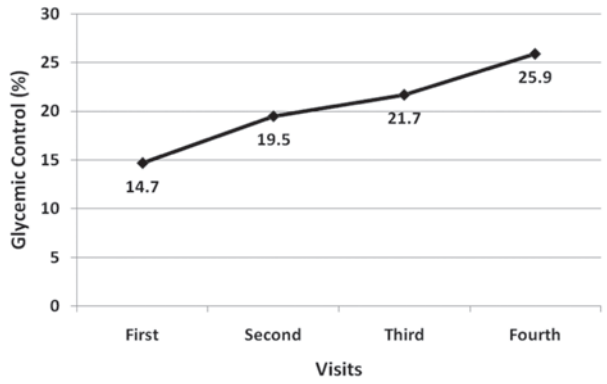
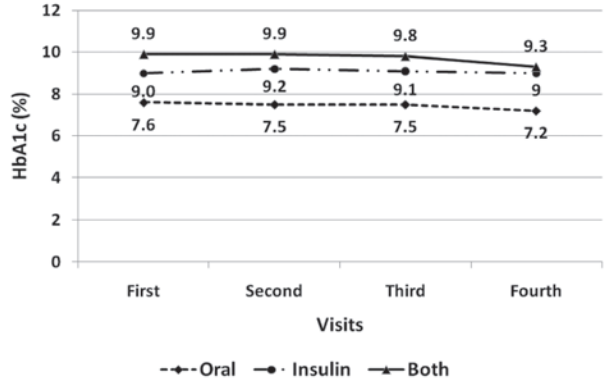


Figure 2 - Glycemic control with HbA1c ≤7% across the patients' 4 follow-up visits (Chi-square for trend: 9.125, p=0.0025). Number of patients per visit: First n=143, Second n=287, Third n=438, and Fourth n=437. HbA1c - glycosylated hemoglobin



Medications	Number of patients			
	Visit 1	Visit 2	Visit 3	Visit 4
Oral only	53	113	163	165
Insulin only	6	11	16	16
Both	84	160	250	248
P-value (ANOVA among medications)	<0.001	<0.001	<0.001	<0.001

ANOVA - Analysis of Variance

Figure 3 - Glycemic control with HbA1c ≤7% across the patients' 4 follow-up visits by type of medications. HbA1c - glycosylated hemoglobin

last visit. The improvement tends to be more evident in patients on oral hypoglycemic medications with or without insulin, but not in those on insulin alone (**Figure 3**). It is also noticed that at all 4 visits, the level of HbA1c (%) is significantly lower among those receiving oral hypoglycemic medications, compared with those on insulin alone or combined with oral hypoglycemic medications as tested by ANOVA (p<0.001).

Discussion. Although glycemic control is a strong predictor of long-term diabetes complications,[7-9] around two-thirds of the current study cohort show adherence to it according to ADA guidelines, and slightly less than one-fourth have actual control. Our figure for adherence to the process (68.7%) lies almost midway between the upper and lower boundaries of the rates reported in previous studies in Saudi Arabia (30-92%),[21-23] and is closer to the figures reported in facilities providing specialty care (80%).[25] This relatively high rate of adherence to process standards might in part be explained by the fact that the service is offered free of charge. Our rate of target achievement (24.2%) is higher than the rates reported in all these studies (8-24%).[20,23] This might be explained by the integrated care approach, which has been applied in our center over the last 2 years, and which seems to be more effective in reaching the goal. This is also confirmed by the improving trend of glycemic control throughout the follow-up period. In congruence with this, the importance of a multidisciplinary approach in diabetes care,[26] and the effectiveness of care planning in its control[27] have been emphasized. Nonetheless, our figures still lag behind those reported in the US.[28,29] and Europe,[30] where 37-41% of their patients are achieving the HbA1c target.

The levels of HbA1c in the current study are lowest among patients on oral medications only, and highest among those on combined insulin and oral medications. This is quite plausible, and can be explained by the severity of diabetic disease, which dictates the therapeutic approach. However, the improvement in glycemic control seems to be better in the combined therapy patients compared with those on insulin alone.

The discrepancy between process and outcome criteria is even wider regarding control of hypertension. Although almost all of our patients have their blood pressure checked according to ADA guidelines, only around one-third had their blood pressure controlled. This can be attributed to the ease of the process, which is routinely carried out by the nurse upon receiving the patient, and the difficulty of achieving the outcome, especially in patients with diabetes.[25,31] Nevertheless, our figures are close to those from local[21-23] and international[17,28,30] studies.

As for lipids, no wide discrepancy is noticed between the adherence to process standards and the achievement of goals, especially for LDL. While our percentage of adherence to LDL testing (69.6%) is similar or slightly lower than reported in local studies (70-87%), our achievement of the recommended LDL target (58.5%)

is better compared with these studies (28-56%),[20-23] and is near to the higher end of the range of international figures (33-64%).[17,18,30] This high percentage of goal achievement might be related to the high percentage of adherence to lipid lowering medications, exceeding previously reported local figures.[21]

Looking at the achievement of combined goals, only a small proportion (7.2%) of our patients have glycemic control in addition to controlled blood pressure and targeted LDL level. While this very low compliance with multiple targets is expected given the low compliance with individual components, it reflects the real challenge of adherence to ADA standards of diabetic care at a primary care setting. Unfortunately, data on simultaneous achievement of multiple ADA outcome standards of diabetic care are lacking, and several authors have pointed out that these standards are difficult to practice or even sometimes unrealistic.[32,33] Nonetheless, the aim of treating a patient with diabetes should not be limited to achievement of glycemic control, but should have a more holistic approach, and this is one of the main functions of primary care. To foster this concept in our setting, we use a flow chart for each chronic disease, and we apply integrated care and case management to reduce fragmentation, and to achieve improved outcomes for chronic disease patients at acceptable cost as previously reported in a study carried out in our setting.[34] These approaches are expected to improve the achievement of combined goals in our patients, and their effectiveness has been shown in local studies.[35,36]

Our data suggest suboptimal provider compliance regarding adherence to recommended screening for diabetic complications such as nephropathy, retinopathy, and diabetic foot examination, as well as influenza, and pneumococcal vaccination. However, we need to differentiate between lack of provider adherence to standards (no referral), and lack of patient adherence (not attending scheduled referral). Regarding vaccination, the low figures are certainly due to lack of documentation, since many patients take these vaccines in other settings and do not report it. Although our figures are better than those reported in local studies,[20,23] they still need to be improved. Possible barriers such as inadequate accessibility or efficiency of the services at the center,[37,38] inadequate laboratory facilities,[39] incompetent structure and process of health education programs,[40] and poor referral systems[41] need to be identified and addressed properly. However, we believe, we have adequate resources at our primary care center. An important limitation in this study, as in many record-based ones, is the dependence on recorded data, which may be lacking or incomplete. For instance, the vaccination seems to be under-documented in patients' files, and we considered the "missing" as "not done," which may have led to lower adherence rates. The use of a prospective cohort design would avoid this limitation. Other limitations include the non-probability convenience sampling and the lack of data concerning co-morbidities. Lastly, the sample may be biased towards more compliant patients since it included only patients with at least 2 visits 3-6 months apart during the preceding year; however, this inclusion criterion was essential in order to have at least 2 readings to compare during the historical record-based follow-up period of one year.

In conclusion, in a high diabetes prevalence country with sufficient resources, we are reporting a suboptimal adherence to many ADA standards of diabetic care among patients with type 2 diabetes treated at a primary care center. The figures are even lower when considering simultaneous adherence to multiple standards. Nevertheless, our figures are better compared with local studies, which may be attributed to implementation of case management and integrated care approaches. Therefore, a wider application of these integrated approaches is planned in our center with assessment of their effectiveness. Further in-depth investigation of the relation between adherence to process indicators and the achievement of outcome indicators is suggested.

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