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An evaluation of the quality care for type 2 diabetes patients in the primary healthcare using the lot quality assurance sampling technique

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Abstract

Background Diabetes is the most prevalent metabolic disease globally. Correct and effective healthcare management requires up-to-date and accurate information at the local level. This level of information allows managers to determine whether the health system has achieved its desired goals in this area. This study aimed to evaluate the adequacy and quality of care for Type 2 diabetes mellitus (T2DM) patients using the Lot quality assurance sampling (LQAS) technique to provide evidence for decision-making at the local level, prioritizing and allocating resources.

Methods A descriptive-analytical study was conducted in 12 supervision areas (SAs)/health facilities in northwestern Iran involving 240 patients with T2DM in primary health care. The selection of patients and determination of SAs were done randomly using the LQAS technique. Glycated Hemoglobin (**(**HbA_1c) was used to evaluate patients' blood sugar control in each SA. Multiple linear regression analysis was used to estimate predictors of HbA_1c in T2DM.

Results The overall average of HbA1c value was 7.84%. The HbA_1c level was > 7% in 148 (61.6%) of the patients. Among the 12 SAs, the LQAS identified unacceptable quality of care in 5 SAs. In the final analysis, each unit increase in fasting blood sugar (FBS), High-density lipoprotein (HDL), Low-density lipoprotein (LDL), and Thyroglobulin (TG) values resulted in an increased in HbA_1c levels by 0.43, 0.183, 0.124, and 0.182 times, respectively. However, with a one-unit increase in the care of a family physician and nutritionist, along with regular physical activity, HbA_1c levels decreased by − 0.162, -0.74, and − 0.11 times, respectively.

Conclusions The quality of care for diabetic patients needs improvement in some SAs. Findings indicated that the LQAS technique effectively identifies centers/areas with substandard diabetes care quality and efficiently allocates resources to those in need. It is recommended to implement corrective measures in areas with inadequate care quality.

Keywords Diabetes Mellitus, Quality of Health Care, Epidemiology, Health system, Blood glucose

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Introduction

Diabetes is the most common metabolic disease in the world, characterized by high blood glucose levels. Annually, four million deaths worldwide occur due to this disease, accounting for 9% of all deaths [1]. The prevalence of Type 2 diabetes mellitus (T2DM) in Iran and worldwide has been increasing. Without proper intervention, it is estimated that by 2030, the number of people with diabetes will almost double, affecting nearly 530 million people [2]. The pooled prevalence of retinopathy for T2DM patients in Iran, on the basis of meta-analysis, has been reported at 37.8% [3].

Improving blood sugar control in diabetic patients reduces the occurrence of chronic complications [4]. Evidence shows that optimal blood sugar control reduces the occurrence of diabetic retinopathy by 67%, nephropathy by 45%, and neuropathy by up to 60% [5, 6].

Measuring glycosylated hemoglobin (HbA1c and/or A_1c) in diabetic patients is clinically important, reflecting the average blood glucose level over the past 2 to 3 months. It provides a valuable tool for monitoring the treatment and care of diabetic patients and their long-term glucose status [7, 8]. The results of this test indicate the percentage of blood hemoglobin combined with glucose, with a higher percentage indicating elevated average blood sugar levels. A significant correlation has been reported between diabetes complications and HbA1c levels [9].

Several methods have been used to evaluate the quality of diabetes care [1, 10–12]. However, these evaluations exhibit three significant shortcomings. Firstly, there is a lack of a standardized quality assessment cut-off point or criterion for evaluating care. Most previous studies have reported blood sugar control status in diabetic patients using blood parameters and indices. Secondly, the applicability and implementation of the findings from such studies for health managers and professionals, especially at the primary healthcare management level, are very limited and not tangible. There is a need to identify centers or regions with unsatisfactory quality of care for diabetic patients to make management decisions, design operational plans in healthcare systems, and allocate resources. For example, in a set or a specific number of diabetic patients from a health center or clinic or region, what is the minimum acceptable threshold of the desired quality in diabetes patient blood sugar control must be met by a certain number of individuals to say that the quality of diabetes care is satisfactory? Thirdly, the previous studies require a considerable sample size, which increases the costs of these studies [13–15].

The Lot Quality Assurance Sampling (LQAS) technique solves the above defects. This sampling method was previously used in industry for quality control of production and was first used by Dodge and Roming in 1920. It was later used in public health and healthcare, particularly for monitoring and evaluating healthcare practices and services [16]. The LQAS method, similar to cluster sampling, selects supervision areas (SAs) or lots and has two states (acceptable or not) for each lot depending on the pre-determined threshold. This level of information enables managers to determine whether the health system has achieved its goals in that area. For attaining quick and economical access to this information, the LQAS technique can be ideal [17].

Therefore, the present study aims to assess the quality and adequacy of care for T2DM and their blood sugar control using the LQAS technique in the primary healthcare system of Malekan County northwest Iran.

Methods

Study design and setting

A cross-sectional analytical study was conducted in 2023 using the LQAS technique to assess the quality of care and blood sugar control in T2DM patients receiving care from family physicians in primary care. The target population included T2DM patients with medical records in the primary healthcare system in Malekan County. The study sample will consist of 450 T2DM in urban and rural healthcare centers in Malekan. The sampling method and data analysis were done using the LQAS technique which is presented below.

Eligibility criteria

Inclusion criteria were age range of 30 to 76 years, availability of test results for blood sugar, HbA1C, lipids, blood fats, and other blood indices for at least the past six months, and having T2DM. Exclusion criteria included having type 1 diabetes, gestational diabetes, neoplasms, and chronically disabled patients requiring home care.

Data collection and quality assessment index

Data were collected from electronic medical records of T2DM in primary care. In the Iranian health system, all socio-demographic characteristics, clinical and paraclinical statuses, and all care provided to T2DM patients were registered in the electronic system, allowing for the reporting of care details and test results for the patients [18]. In addition to the above indicators and indices, the average blood sugar level over the past three months using the HbA1c level, was is regarded as one of the key indicators [19] as it reflects the average blood sugar level during the last two to three months [20].

Sampling and quality assessment in the LQAS

In the present study, each health center in Malekan County was considered a lot in the LQAS technique. Next, we randomly selected 20 T2DM patients (as normal size in LQAS) with medical records from each lot.

The selection of samples within each lot was done randomly in two stages: in the first stage, the probability proportionate to the size of each lot was determined. In the second stage, the sample was randomly selected (without replacement).

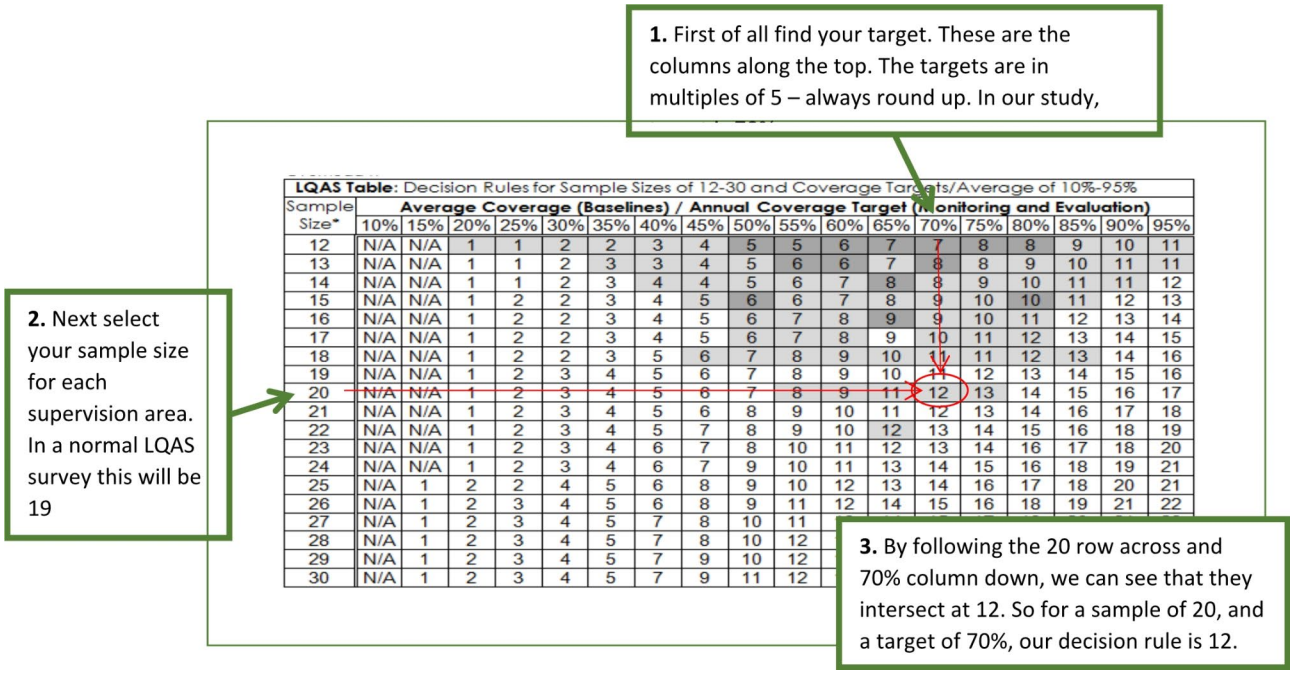
The next step was determining the decision rule (DR) for each lot and/or SA. The DR is the maximum acceptable number of failures (in this study, HbA1c level above 7%) in each lot. That is, considering the guidelines and recommended criteria, how many diabetic patients out of the 20 selected in each lot should have a tolerable blood sugar level (HbA1c) below 7% or above 7%? If the cases above 7% exceed the recommended value, the lot will be rejected, indicating unacceptable quality of service in that lot [17].

The DR in the LQAS technique is determined based on two items: (1) sample size within each LQAS category: the number of samples within each LQAS category is either 19 or 20 based on the standard tables of this method. (2) Upper and lower threshold values: The threshold value is a specific ratio or percentage for evaluating a category. Two threshold values are proposed in LQAS. One is the upper threshold, and the other is the lower threshold. Details for determining DR and the maximum allowable number of failures in each lot are shown in Fig. 1.

Statistical analysis

Using the decision rule, the LQAS technique divides the patients in each supervision area (healthcare centers) into two categories: acceptable and unacceptable (requiring intervention and improvement) regarding the quality of care and blood sugar control. Considering the upper and lower thresholds of 70% and 40% as per the standard LQAS table, the minimum acceptable number of diabetes patients with HbA1c levels below 7% is 12 (DR=12). This indicates that in each group of 20 T2DM patients, if the count of diabetes patients with HbA1c below 7% falls short of 12 cases, the group will be rejected [15] (Fig. 1).

In addition to the LQAS analysis, based on HbA1c levels, the patients were classified into two categories below and above 7%., The relationship between demographic, clinical, and blood biochemical variables with the HbA1c level was evaluated. The chi-square test will be used for categorical variables, and an independent t-test will be used for quantitative variables. If the data does not follow a normal distribution, the equivalent non-parametric test, such as the Mann-Whitney test, will be used. Linear regression analysis will be used to estimate the standardized coefficient of the relationship between related factors and predictors of HbA1c levels (continues variable) in T2DM patients. For modeling, all independent variables were initially evaluated through simple linear regression. Subsequently, variables with a p-value below 0.2 underwent further analysis via multiple linear regression employing the *Enter* method. A significance level of less than 5% will be considered in all tests. Data analysis was done using SPSS (version 22.0, Chicago, IL, USA).



LQAS Table: Decision Rules for Sample Sizes of 12-30 and Coverage Targets/Average of 10%-95%

Sample Size*	Average Coverage (Baselines) / Annual Coverage Target (Monitoring and Evaluation)																	
	10%	15%	20%	25%	30%	35%	40%	45%	50%	55%	60%	65%	70%	75%	80%	85%	90%	95%
12	N/A	N/A	1	1	2	2	3	4	5	5	6	7	7	8	8	9	10	11
13	N/A	N/A	1	1	2	3	3	4	5	6	6	7	8	8	9	10	11	11
14	N/A	N/A	1	1	2	3	4	4	5	6	7	8	8	9	10	11	11	12
15	N/A	N/A	1	2	2	3	4	5	6	6	7	8	9	10	10	11	12	13
16	N/A	N/A	1	2	2	3	4	5	6	7	8	9	9	10	11	12	13	14
17	N/A	N/A	1	2	2	3	4	5	6	7	8	9	10	11	12	13	14	15
18	N/A	N/A	1	2	2	3	5	6	7	8	9	10	11	11	12	13	14	16
19	N/A	N/A	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
20	N/A	N/A	1	2	3	4	5	6	7	8	9	11	12	13	14	15	16	17
21	N/A	N/A	1	2	3	4	5	6	8	9	10	11	12	13	14	16	17	18
22	N/A	N/A	1	2	3	4	5	7	8	9	10	12	13	14	15	16	18	19
23	N/A	N/A	1	2	3	4	6	7	8	10	11	12	13	14	16	17	18	20
24	N/A	N/A	1	2	3	4	6	7	9	10	11	13	14	15	16	18	19	21
25	N/A	1	2	2	4	5	6	8	9	10	12	13	14	16	17	18	20	21
26	N/A	1	2	3	4	5	6	8	9	11	12	14	15	16	18	19	21	22
27	N/A	1	2	3	4	5	7	8	10	11								
28	N/A	1	2	3	4	5	7	8	10	12								
29	N/A	1	2	3	4	5	7	9	10	12								
30	N/A	1	2	3	4	5	7	9	11	12								

Fig. 1 Determining the maximum acceptable number of failures in each lot based on the LQAS standard table

Table 1 Baseline characteristics and healthcare status of patients with T2DM in primary health care

Variables		Total ($n=240$; %)	HbA1c categories		*P*-value
			<7 92 (38.3%)	>7 148 (61.6%)	
Age (year)	Mean ± SD	57.33	57.3 ± 10.9	57.4 ± 10.4	0.952
Sex	Female	153 (65.7)	58	95	0.387
	Male	80 (34.3)	35	45	
Education	Primary school	188 (80.3)	68	120	0.041
	Secondary school	40 (17.1)	23	17	
	Academic	6 (2.6)	2	4	
BMI	Mean ± SD	29.1 ± 4.3	28.8 ± 4.4	29.3 ± 4.3	0.496
Diabetes morbidity (year)	Mean ± SD	6.23 ± 7.07	6.04 ± 9.0	6.4 ± 4.5	0.696
Number of family physician cares*	Mean ± SD	2.7 ± 1.6	2.06 ± 1.5	1.8 ± 1.4	0.026
Having high blood pressure	yes	165 (71.0)	66	99	0.755
	no	67 (29.0)	26	41	
Current smoking	yes	18 (7.8)	8	10	0.059
	no	214 (92.2)	83	131	
Physical activity (at least 30 min per day)	yes	84 (36.4)	43	41	0.006
	no	147 (63.6)	48	99	
Cared by ophthalmologist**	yes	109 (48.2)	57	52	0.637
	no	122 (52.8)	49	73	
Cared by Nutritionist **	yes	60 (26.0)	30	30	0.051
	no	171 (74.0)	61	110	
Any complications	yes	14 (6.1)	8.76 ± 2.16		0.045
	no	216 (93.9)	7.80 ± 1.85		

* In the last 12 months

* During the last 12 months

Table 2 Glycosylated hemoglobin (HbA1c) value and blood biochemical parameters in T2DM patients

Variables	HbA1c categories		Total ($n=240$)	*P*-value
	<7 92 (38.3%)	>7 148 (61.6%)		
Glycated hemoglobin (HbA1c)	6.18 ± 0.87	8.93 ± 1.47	7.84 ± 1.8	0.001
Fasting blood sugar (FBS)	139.8 ± 55.2	210 ± 74.9	174.8 ± 75.0	0.001
Blood sugar (BS)	203 ± 247	296 ± 152	251 ± 209	0.002
High-density lipoproteins (HDL)	51.6 ± 20.6	70.6 ± 62.2	61.5 ± 47.0	0.025
Cholesterol	179 ± 38	189 ± 46	184 ± 42.8	0.105
Thyroglobulin (TG)	173 ± 84	240 ± 151	207.7 ± 126.0	0.001
Low-density lipoproteins (LDL)	85 ± 30	105 ± 58	97.2 ± 48.5	0.022
Blood pressure (systole)	119 ± 11	118 ± 10	121 ± 11.2	0.761
Blood pressure (diastole)	72 ± 9	73 ± 8	73 ± 8.8	0.265

Results

Table 1 shows the demographic characteristics and healthcare status of T2DM in the primary healthcare system of Malekan County in 2023. A total of 240 T2DM patients, with an average age of 57.3 years, participated in the study. Among them, 92 (38.3%) had an HbA1c level of less than 7%. The average duration of diabetes in patients exceeded six years. More than 65% of patients were female. The majority of patients (80%) had a primary school education. The average body mass index (BMI) of patients was over 29. No significant associations were found between age, sex, and BMI with an HbA1c level above 7% ($P>0.05$). However, a significant association was observed for education level ($P=0.041$).

As shown in Table 1, the average frequency of family physician care in the past six months was 2.7 ± 1.6 times. A significant association was found between an increase in patient care times and a decrease in HbA1c levels ($P=0.026$). Significant associations were also observed between physical activity and current smoking with changes in HbA1c levels ($P<0.05$). Likewise, a mild significant association was found between the number cares of nutrition specialist consultation and HbA1c levels ($P=0.051$). While no significant associations were found between eye cares and high blood pressure with HbA1c levels ($P<0.05$). Regarding diabetes-related complications, 14 (6.1%) had any diabetes complications. The average HbA1c level in patients with complications was 8.76, whereas in those without complications, it was 7.8, which was statistically significant ($P=0.045$) (Table 1).

Table 2 indicated the HbA1c levels and blood biochemistry parameters in T2DM. The average HbA1c level was reported to be above 7%, averaging 7.84% ± 1.8%. Nearly 62% of patients had A1c levels exceeding7%. In other words, only 38% had desirable blood glucose control (HbA1c less than 7%). The average fasting blood glucose, 2-hour glucose, High-density lipoprotein (HDL), Low-density lipoprotein (LDL), and Thyroglobulin (TG) levels were 174, 251, 61.5, 97.2, and 207.7 mg/dl, respectively. Statistically significant associations were observed between these indices and HbA1c levels ($P<0.05$). However, no significant association was found between

cholesterol levels and HbA1c levels ($P>0.05$). The average systolic and diastolic blood pressures were 121 and 73 mm Hg, respectively, with no significant differences in HbA1c levels ($P>0.05$).

Table 3 shows the adequacy and quality of care for T2DM patients using the LQAS. All patients in the county were categorized into 12 management/health center regions (lots), and 20 diabetic patients were randomly selected from each lot. Among the 12 health centers, five were found to have an unacceptable quality of diabetes care, with fewer than 12 patients out of the selected 20 having HbA1c levels below 7%. The names of centers with unacceptable diabetes care quality (requiring care, educational, and operational interventions) are presented in Table 3.

Table 4 shows the linear regression results for predictors of HbA1c levels in T2DM after adjusting for the potential confounders. The final analysis indicated that A1c levels increased by 0.182, 0.124, 0.183, and 0.43 for a one-unit increase in FBS, HDL, LDL, and TG values, respectively. Additionally, HbA1c levels in T2DM were linked to diabetes-related complications. Furthermore, for a one-unit increase in family physician care, and nutrition specialist, and regular physical activity of at least 30 min per day, HbA1c levels decreased by -0.162, -0.74, and −0.11, respectively.

Table 3 Care quality and adequacy of T2DM patients in primary health facilities using LQAS technique

Lots (Health facilities)	Lot size	Number of patients with HbA1c < 7	Quality of care
Urban center 1	**20**	6	Reject
Urban center 2		9	Reject
Esmaeilabad		18	Accept
Bayghout		12	Accept
Goorijan		12	Accept
Shahrak		11	Reject
Shirinkand		14	Accept
Aroogh		13	Accept
Mobarkabad		7	Reject
Urban 3		6	Reject
Tooraghay		13	Accept
Aghmenar		12	Accept

Table 4 Linear regression analysis to estimate variations of HbA1c in T2DM patients

Variables	Standardized Coefficients (B)	t	95% CIs	*p*-value
FBS	0.43	5.44	0.007–0.15	0.001
HDL	0.183	2.21	0.001–0.016	0.029
LDL	0.124	1.50	−0.002–0.014	0.136
TG	0.182	2.30	0.001–0.005	0.023
Any complications	0.133	1.67	−0.17–2.1	0.090
Family physician care	−0.11	−1.27	−0.315–0.07	0.207
Nutritionist care	−0.74	−0.89	−0.93–0.35	0.373
Physical Activity	−0.162	−2.07	−1.25 - −0.26	0.41

* Adjusted for age, sex, BMI, current smoking, blood pressure, and cholesterol

Discussion

The current study aimed to assess the quality and adequacy of care for T2DM patients within the primary healthcare system using the LQAS technique. The overall average HbA1c value was 7.84, with 148 (61.6%) of the patients exhibiting levels above 7%, indicating that the quality of patient care requires improvement and intervention. The study revealed that a unit increase in fasting blood sugar, HDL, LDL, and TG values corresponded to increases in HbA1c levels by 0.43, 0.183, 0.124, and 0.182 times, respectively. Conversely, there was an inverse correlation between the number of visits to a family physician and nutritionist, as well as regular physical activity, with HbA1c levels of -0.162, -0.74, and −0.11 times, respectively.

The LQAS technique indicated that among the 12 evaluated health centers (lots or SAs), quality and adequacy of diabetes control were deemed to be unacceptable in five health centers/lots, falling short of the expected coverage target. Compared to other related research, the main advantage of this study is the use of the LQAS technique for local-level management decision-making. Our findings offer valuable insights for healthcare managers to evaluate the status and quality of care for each supervision area (health center) at a local level. This finding can be highly effective in designing interventions and implementing operational and corrective programs to enhance the quality of diabetes care in centers or regions with unsatisfactory conditions. The LQAS technique achieves this with the smallest sample size, cost savings, and optimal accuracy [21]. International organizations such as World Health Organization (WHO) and the World Bank have utilized this method to evaluate the quality of healthcare services worldwide [14, 22]. Statistical concepts relevant to this work have been presented in other articles [23]. The recommendation of the LQAS technique for areas with unsatisfactory status is that corrective interventions should be implemented. These interventions may encompass educational initiatives for patients or healthcare providers, the formulation of action plans, enhancements in care and equipment, etc., tailored to the specific issue or disease being addressed.

The average HbA1c in this study for all evaluated patients evaluated was 7.84, with only 38% of patients having HbA1c levels below 7%. In contrast, the ADA recommends HbA1c control below 7%. In addition, the average HbA1c measurement in diabetic patients with complications was higher than in patients without

complications. The average HbA1c in the present study is consistent with national study results. In the study by Moradi et al. conducted nationally, the average HbA1c was reported to be 8%. While 33% of patients had desirable blood sugar control with HbA1c below 7%, slightly better than our study. Consistent with our findings, a study by Davari et al. on diabetic patients in five provinces and 15 centers in Iran found that 33% of patients had HbA1c below 7% [24]. Another study in Iran by Yazdanpanah et al. showed that mean (±SD) of HbA1c was 8.5% (±1.8) and 72.1% of the patients had poor glycemic control [25]. In a study of 400 T2DM referring to the primary healthcare system in Saudi Arabia, the mean HbA1c was 8%, similar to ours. However, the percentage of patients with HbA1c less than 7% was lower than in our study at about 25%. In another study in South Africa, the average HbA1c was reported to be 6.8% [26].

Other important indicators for proper care of diabetic patients are fasting blood sugar, two-hour blood sugar, and blood lipid indices, most of which were reported as higher than desirable standards in the present study. In our regression analysis, we found a significant correlation between increasing levels of these indicators and an increase in HbA1c levels, with an increase of one unit in them significantly increasing the A1c level. These findings are consistent with the studies by Mousavi and Davari in Iran [24, 27].

In the present study, the frequency of visits to family physicians, specialized nutrition care, and regular daily physical activity significantly reduced HbA1c levels. On average, patients in our study were cared for 2.7 times by a family physician, at least once by a nutrition specialist and an eye doctor, and the frequency of family physician visits was associated with a decrease in HbA1c levels. The average number of family physician visits in the study by Azizi et al. (in this County) was similar to our study at 2.63 times per year [28]. Although we did not identify a significant relationship between the blood pressure levels of patients and HbA1c levels, strict control of blood pressure in diabetic patients is recommended.

Limitations and strengths

The main strength of the present study was using the LQAS technique to assess the quality and adequacy of diabetes care at the local level for each health center to provide evidence for managerial and clinical decision-making and to implement intervention programs only for centers with unsatisfactory conditions. Therefore, this method will optimize health system costs as well as utilization.

Many clinical and para-clinical variables may influence HbA1c levels; therefore, we carried out multiple linear regression analysis to adjust for the effects of other potential confounding variables in predicting changes in HbA1c levels. Our study primarily relied on medical records, and registration inaccuracies were among the common concerns. Nevertheless, this information served as the most reliable and accurate source for collecting and evaluating the diabetes care system in this region.

Conclusion

Our results using the LQAS technique indicated that in some health centers, the quality of care and blood sugar control are unacceptable. Our findings suggest that the LQAS method is effective in locating primary healthcare facilities where diabetic patients are not receiving adequate treatment. As a result, the system's financial, human, and material resources will be directed to the problematic centers and areas. Corrective interventions are recommended for centers with unsatisfactory conditions.

Abbreviations

ADA	American diabetes association
BMI	Body mass index
DR	Decision rule
T2DM	Type 2 diabetes mellitus
LQAS	Lot quality assurance sampling
HbA1c and/or A1c	Glycated hemoglobin
PHC	Primary health care
SA	Supervision area
FBS	Fasting blood sugar
HDL	High-density lipoprotein
LDL	Low-density lipoprotein
TG	Triglycerides
WHO	World Health Organization

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Author contributions

HA has designed this study. All the authors conceived and developed the protocol that led to the manuscript or played an important role in the acquisition, analysis, and interpretation of the data or both. All authors contributed to the manuscript development and/or made substantive suggestions for revision. All authors approved the final submitted version.

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Data availability

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Tabriz University of Medical Sciences (Ref No. TBZMED.REC.1402.125) and grant number of 70469. Written informed consent was obtained from all the participants before the interview. The authors were state to confirm that all methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication

Not applicable.

Competing interests
The authors declare no competing interests.

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