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Original Article

Cost-effectiveness and cost-utility analysis of type-2 diabetes screening in pharmacies in Iran

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Abstract

Background and purpose: Several studies have shown the effectiveness of screening programs in decreasing the costs and disutility of type-2 diabetes and related complications. As there is a growth in the incidence of type-2 diabetes amongst the Iranian population, the cost-effectiveness of performing type-2 diabetes screening tests in community pharmacies of Iran was evaluated in this study from the payer's perspective. The target population consisted of two hypothetical cohorts of 1000 people 40 years of age without a prior diagnosis of diabetes, for the intervention (screening test) and no-screening groups.

Experimental approach: A Markov model was developed to evaluate the cost-effectiveness and cost-utility of a type-2 diabetes screening test in community pharmacies in Iran. A 30-year time horizon was considered in the model. Three screening programs with 5-year intervals were considered for the intervention group. The evaluated outcomes were quality-adjusted life-years (QALYs) for cost-utility-analysis and life-years-gained (LYG) for cost-effectiveness-analysis. To examine the robustness of the results, one-way and probabilistic-sensitivity analyses were applied to the model.

Findings/Results: The screening test represented both more effects and higher costs. The incremental effects in the base-case scenario (no-discounting) were estimated to be 0.017 and 0.0004 (approximately 0) for QALYs and LYG, respectively. The incremental cost was estimated to be 2.87 USD/patient. The estimated incremental-cost-effectiveness ratio was 164.77 USD/QALY.

Conclusion and implications: This study indicated that screening for type-2 diabetes in community pharmacies of Iran could be considered highly cost-effective, as it meets the WHO criteria of the annual GDP per capita ($2757 in 2020).

Keywords: Cost-effectiveness; Cost-utility; Markov-model; Screening; Type-2 diabetes.

INTRODUCTION

Today, diabetes is known as one of the major problems in the healthcare sector. The number of people with this disease was reported to be more than 537 million worldwide in 2021 (1). It is estimated that this number will reach 783 million people by 2045 (2). About one out of every 10 people in the world have diabetes, of which 90% are type-2 diabetes (3).

Some previous studies have shown a faster rate of increase in diabetes than the global trend for Iran. According to a 7-year survey from 2005 to 2011, the prevalence of diabetes among the Iranian adult population was estimated at 11.4% (4.52 million) in 2011 which represented an average growth of 35.1% in 7 years. According to this growth rate, the number of people with diabetes in Iran was projected to be more than 6 million in 2017 (2). It is also estimated that by 2030, 9.2 million Iranians will have diabetes (4).

Diabetes is a chronic disease that can cause serious complications such as heart attack, stroke, kidney failure, blindness, and amputation. Uncontrolled diabetes can deteriorate the prognosis of diabetes complications (1).

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A study about diabetes in Iran reported about 38,000 diabetes-related deaths in 2009 and predicted an increase to 89,000 deaths by the year 2030 (4).

The prevalence of diabetes and prediabetes amongst Iranian people aged 18 years or more, were accounted to be 14.15% and 24.79% in 2021, respectively, representing a 45.5% increase in diabetes prevalence in comparison with 2016 (5).

Direct costs of diabetes, including outpatient care, medication, physician visits, and laboratory tests, for those who suffer one or more diabetes-related complications, have been estimated to be twice as people without diabetes. In 2009, the direct cost of diabetes in Iran was reported to be around $2 billion, almost half of which was due to the complications of the disease (4).

A study in 2014 on the cost of diabetes in Iran estimated a cost of $1914 per type-2 diabetic person which was significantly greater than the reported figure in 2009 ($1707) (6).

It has been shown in many studies that screening tests for diabetes can decrease the costs and disutility of diabetes and its complications. On the other hand, community pharmacists in Iran, although have a good geographic distribution and are easily available to the majority of people, are not actively involved in doing activities such as screening tests, vaccination programs, and monitoring of chronic diseases including diabetes. This study aimed to investigate the cost-effectiveness of a simple and available type-2 diabetes screening test amongst Iranian middle-aged people with no previous history of diagnosed diabetes in the community pharmacies of Iran.

MATERIALS AND METHODS

The population of this study included two hypothetical cohorts of 1000 people aged 40 years without a prior diagnosis of type-2 diabetes. The intervention group underwent 3 screening tests with 5-year intervals (at the 1st, 6th, and 11th year of the model), while the alternative group was not screened for type-2 diabetes. The screening test was considered to be performed using an ordinary and available glucometer to measure the fasting blood glucose of the volunteers visiting the community pharmacy. This study was conducted from the payer's perspective. Markov modeling technique was performed to evaluate the cost-effectiveness of type-2 diabetes screening in community pharmacies of Iran within a 30-year time horizon. For chronic diseases with recurrent events such as type-2 diabetes, particularly when the risk of the disease progression persists indefinitely, Markov modeling is generally the preferred choice (7). The major complications of diabetes evaluated in the current study included blindness, end-stage renal disease (ESRD), myocardial infarction (MI), stroke, lower extremity amputation (LEA), and death. The results are reported with no discount, a discount rate of 3% for both costs and effects (based on the recommendations of the WHO-choice) (8), as well as a scenario with a discount rate of 7.2% for costs (according to a domestic study) and 3% for effects (9,10). The main measured consequences were life-years-gained (LYG) and quality-adjusted-life-year (QALY). LYG is a measure of the benefits from the use of an intervention in terms of increased average life expectancy or delay in death amongst the population when compared with the alternative intervention (11).

QALY is used to illustrate the outcomes of health care programs by adjusting the LYG *via* an estimate of utility (utility weight), generally measured using a preference-based method (12). This model consisted of 12 different health states including diabetes, ESRD (1st year), sub-ESRD (subsequent years following the 1st year), amputation-LEA (1st year), sub-amputation-LEA (subsequent years following the 1st year), blindness (1st year), sub-blindness (subsequent years following the 1st year), MI (1st year), sub-MI (subsequent years following the 1st year), stroke (1st year), sub-stroke (subsequent years following the 1st year), and death. Individuals can stay in one health state or might develop one of the complications. As the cost of the treatment is different in the 1st year of the complication, compared to the following years, separated health states (*e.g.* MI and sub-MI) were considered in the model. Figure 1 demonstrates the health states considered in this model. As those without diabetes have similar costs and consequences, healthy people are not shown in the Markov diagram. It was assumed in the model that those with undiagnosed diabetes would start their treatment 4 years later than those with diagnosed diabetes (13).

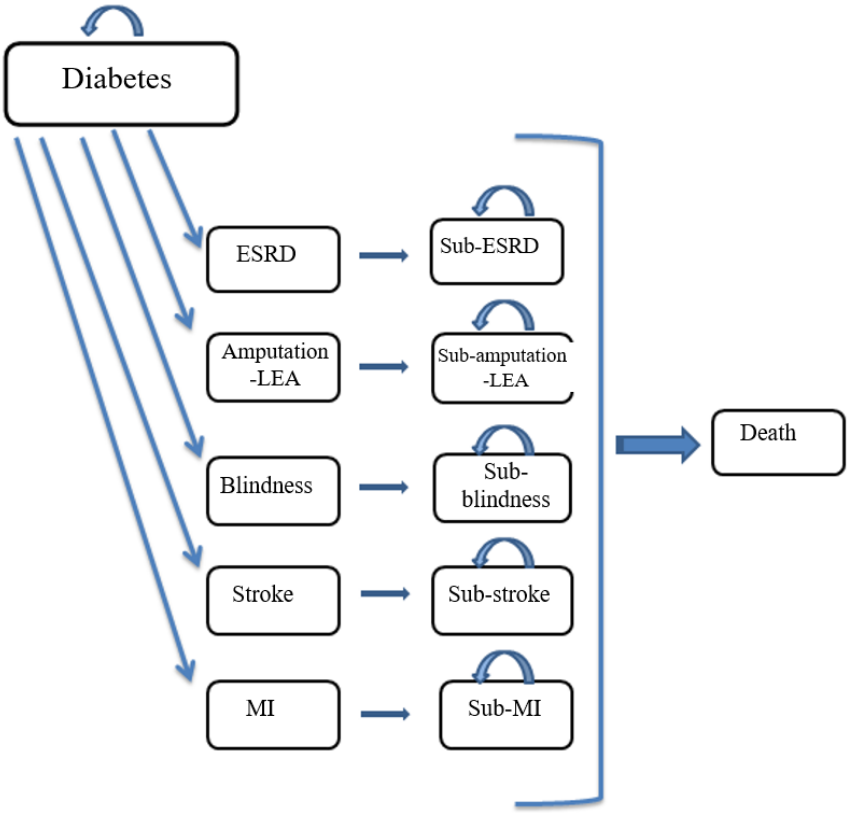

Fig. 1. The Markov model diagram

To confirm diabetes, two physician visits and a laboratory fasting blood sugar (FBS) test were considered following the referral of those patients who were recognized with high FBS in the screening test. Obviously, those diagnosed with confirmed type-2 diabetes would receive all the required treatments and controls for their disease. Direct costs including laboratory tests, para-clinical examinations, physician's visits, hospitalization, medicine and treatment, glucometer testing, test strips, and community pharmacist time costs were taken into account. Considering the adopted perspective, indirect costs were not considered in this study.

The treatment cost of diabetes and the related complications were sourced from a domestic study, published in 2020 in an Iranian journal (Tamine-Ejtemaie) (14). To calculate the costs of diabetes and its related complications in the Tamine-Ejtemaie study, the data related to diabetic patients under treatment in 3 major diabetes registration centers in Tehran, Iran have been acquired, using the micro-costing technique. These values included the dose of the medicines and the number and value of the services used or consumed for treatment and control of type-2 diabetes and its complications. These data were extracted from the files as well as the bills of the patients. Calculations have been made for each of the complications using a significant sample size of patients. Regarding the costs related to the years after the onset of the complication (subsequent years after the 1st year), the active files of the patients in the previous stage have been also used (14). The annual costs of the health states are presented in Table 1. The cost of one screening test for each patient, including a lancet, an alcohol pad, a glucometer test strip, a share of each patient for a glucometer and a battery (according to the average prices of 5 domestic wholesalers at the time of the study), and pharmacist charge (equal to a prescription delivery charge) were considered to be 1 $. The cost of diabetes confirmation in people with the elevated screening test result, including 2 physician visits, one laboratory admission fee, one sampling fee, and one FBS test estimated to be 12 $, according to the latest edition of the healthcare tariffs book at the time of the study.

Table 1. Data used in the model.

Relative risk of screening effect on type 2 diabetes complications	**Data**	**References**
Blindness	0.72	(13,16)
End-stage renal disease	0.8	(13,16,17)
Amputation-lower extremity amputation	0.78	(13,16)
Myocardial infarction	0.8	(16)
Stroke	0.91	(16)
Relative risk of type 2 diabetes effect on myocardial infarction and stroke		
Myocardial infarction	1.72	(18)
Stroke	1.54	
Relative risk of type 2 diabetes effect on all-cause mortality		
Age 40-59	2.855	(19)
Age 60-79	1.685	
Transition probabilities from type 2 diabetes with no complications of type 2 diabetes with complications		
Blindness	0.002	(20,21,22)
End-stage renal disease	0.002	(13,21,22)
Amputation-lower extremity amputation	0.007	(23)
Myocardial infarction	0.004	(24)
Stroke	0.005	(24)
Annual costs of type-2 diabetes complications per patient (USD)		
Blindness	434.91	(14)
Sub-blindness	144.97	
End-stage renal disease	2886.87	
Sub-end-stage renal disease	1934.49	
Amputation-lower extremity amputation	1363.57	
Sub-Amputation-lower extremity amputation	368.532	
Myocardial infarction	2609.39	
Sub-myocardial infarction	527.14	
Stroke	1650.99	
Sub-stroke	430.44	
Utility weights applied to the model		
Blindness	0.69	(13)
End-stage renal disease	0.61	
Amputationlower extremity amputation	0.80	
Myocardial infarction	0.76	(25)
Stroke	0.64	
Type 2 diabetes with no complication	0.95	(13)

An exchange rate of 42000 Rials for each USD was applied to the model, as it was the formal exchange rate used for decision-making in the health sector of Iran at the time of the study (15). However, the effect of uncertainty in these amounts was evaluated in the performed sensitivity analyses including univariate and probabilistic sensitivity tests. Cost-effectiveness-acceptability-curve (CEAC) was also reported for the evaluated intervention to illustrate the probability that an intervention (here screening) is more cost-effective compared to the alternative one, over a range of ceiling values (λ). Input parameters, including relative risks related to diabetes complications, transition probabilities, utility weights, costs, and the related sources are illustrated in Table 1.

Statistical analysis

Microsoft Excel was used for developing the model, performing the sensitivity analyses and producing tables, graphs, and charts.

RESULTS

The results of the outcomes were calculated as incremental-QALY and incremental-LYG. The QALY gained by screening with no discounting (base-case scenario) and with a 3% discount were estimated to be 0.017 and 0.01, respectively. The LYG gained in the explained scenarios was estimated to be 0.0004 and 0.0003, respectively. Table 2 represents the incremental effects. Costs were calculated separately for the two groups of screening and no-screening with different discount rates of 0%, 3%, and 7.2%. The results are demonstrated in Table 2.

Table 2. Final results of the model

Discount rate	Final costs (USD/patient)		Inc-cost	Effect (per patient)						ICERs (USD/ Effect)
				QALY			LYG			ICER for QALY
	No Screening	Screening		No Screening	Screening	Inc-QALY	No Screening	Screening	Inc-LYG	
0% (no discounting)	977.87	980.74	2.87	1.55	1.57	0.017	0.98	0.98	0.00	164.77
3% for both costs and effects	576.08	593.22	17.14	0.99	1.00	0.01	0.97	0.97	0.00	1766.65
7.2% for costs and 3% for effects	299.86	325.72	25.86	0.99	1.00	0.01	0.97	0.97	0.00	2666.00

Inc, Incremental; QALY, quality-adjusted life-years; LYG, life-years-gained; ICER, incremental-cost-effectiveness-ratio

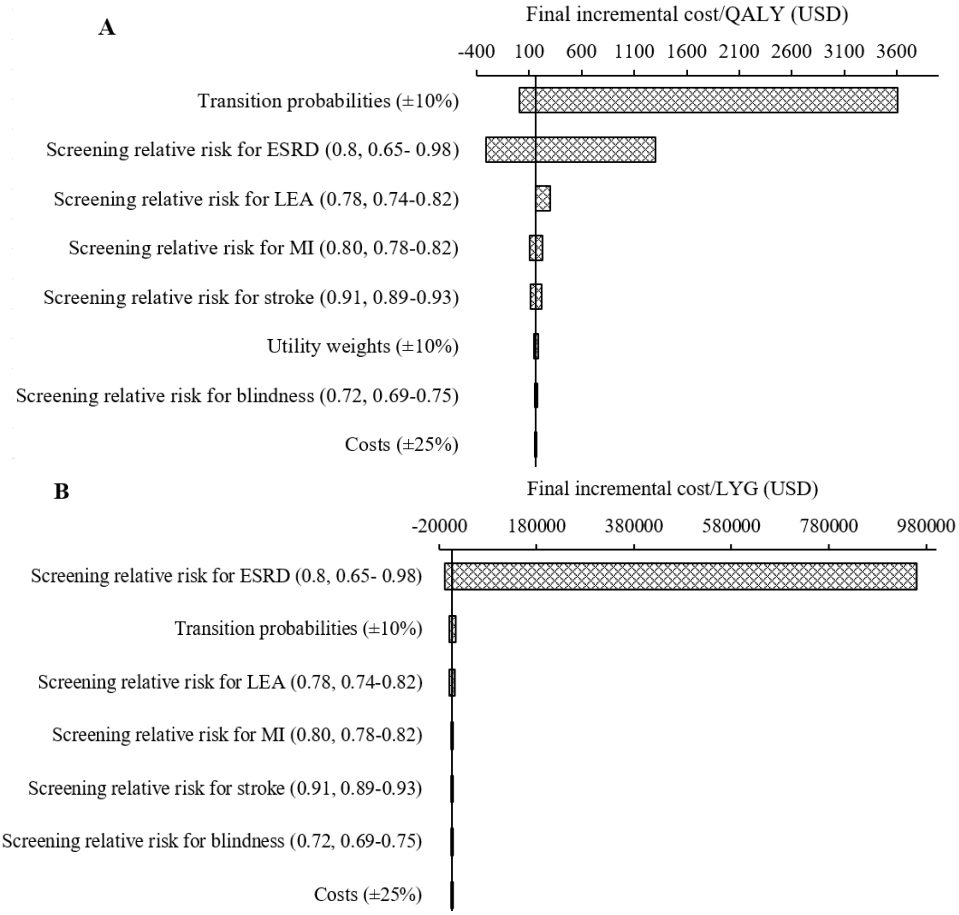

Fig. 2. Tornado charts for incremental cost per (A) QALY and (B) LYG. QALY, quality-adjusted life-years; LYG, life-years-gained; ESRD, end-stage renal disease; LEA, lower extremity amputation; MI, myocardial infarction.

As the calculated incremental LYG per capita was close to 0, no incremental-cost-effectiveness ratio (ICER) is reported for LYG. The final results (ICER) for QALY are shown in Table 2.

To deal with uncertainty, the effect of change in different applied parameters was examined through one-way (univariate) sensitivity analysis. Results from the one-way sensitivity analysis are presented as a Tornado chart. Figure 2 illustrates the Tornado chart for the one-way sensitivity analysis. The Tornado chart for QALY represented that the ICER is most affected by the transition probabilities and the relative risk of screening effect on ESRD.

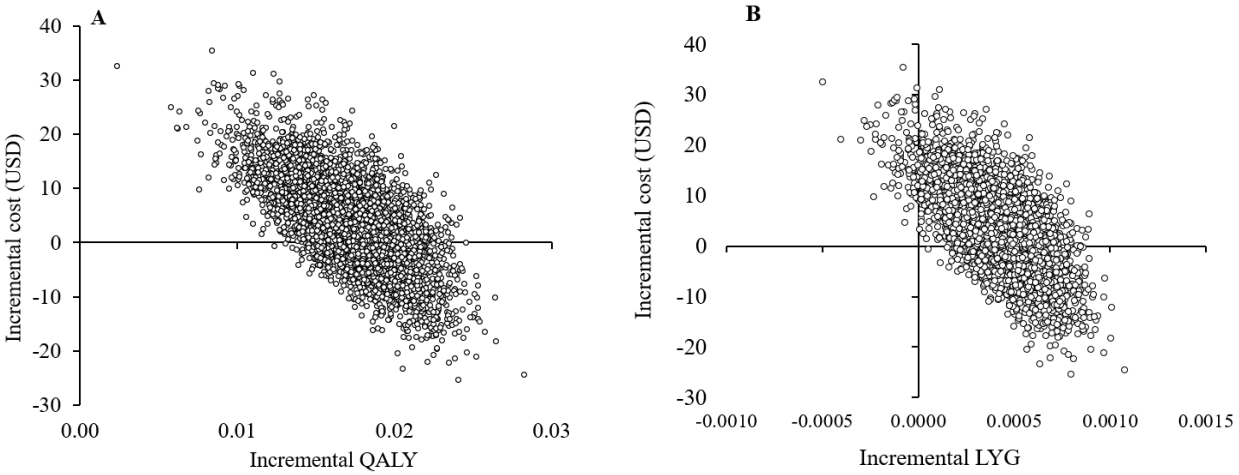

Fig. 3. Scatter plots of probabilistic-sensitivity-analysis for (A) QALY and (B) LYG. QALY, Quality-adjusted life-years; LYG, life-years-gained.

The Tornado chart for LYG revealed that the ICER is most affected by the relative risk of the effect of screening on ESRD, followed by transition probabilities applied to the model, and the relative risk of the effect of screening on LEA, respectively.

Probabilistic-sensitivity-analysis (PSA) was also performed, with 5,000 iterations, using lognormal distribution for relative risks and costs and beta distribution for transition probabilities and utility weights. The following parameters were evaluated in the PSA within the range of their reported 95% confidence intervals: relative risks for 1st and subsequent years of LEA, blindness, ESRD, MI, and stroke. Also, costs (±25%), transition probabilities (±10%), and utility weights (±10%) were assessed in the performed PSA to deal with uncertainty. Figure 3 represents the results of PSA as scatter plots of ICERs for QALY and LYG.

The performed PSA revealed that screening for type-2 diabetes, resulted in higher costs in 65% of the simulations, when compared to no screening. According to the performed PSA, the estimated incremental cost per QALY and LYG gained were $259.77 (95% CI: $-583.18- $ 1540.46) and $11785.88 (95% CI: $ -26388.90 - $ 188749.28), respectively (Fig. 3). The scatter plot of incremental cost/QALY represented that none of the cases fell in the negative area in terms of incremental effectiveness. The scatter plot of the incremental cost/LYG also showed that only 2% of the cases were located in the negative area in terms of incremental effectiveness, which was not considerable.

In addition, all the points of the PSA scatter graph fell below the recommended threshold of WHO for GDP per capita (the reported GDP per capita by the World Bank for Iran in 2020 was $2757) which means that the evaluated intervention in this study could be considered highly cost-effective. (26). Moreover, in 35% of the iterations, undertaking screening resulted in cost-saving.

A CEAC illustrates the probability that an intervention (here screening) is more cost-effective compared to the alternative intervention over a range of ceiling values (λ). The ceiling ratio represents the willingness-to-pay (WTP) for an additional unit of effectiveness ($/QALY). Figure 4 shows the CEAC for the evaluated intervention. A cross-over in acceptability between the scenarios is seen at a WTP of $175.38/QALY. This revealed the probability of no-screening for type-2 diabetes, being more cost-effective, compared to screening, is higher only if the WTP is less than this amount.

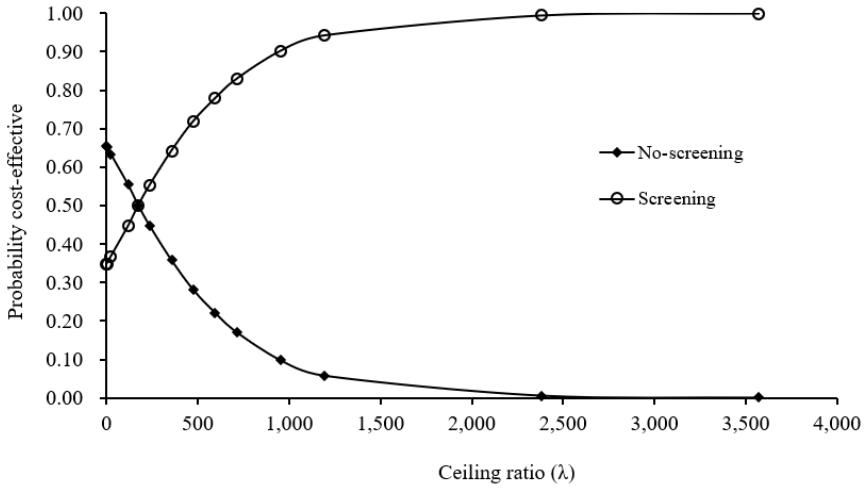

Fig. 4. Cost-effectiveness-acceptability-curve for the base-case scenario.

DISCUSSION

Taking into account, the WHO recommended threshold of GDP per capita for the incremental cost per QALY, the evaluated intervention could be considered highly cost-effective. According to the results of the PSA, screening for type-2 diabetes in community pharmacies could save costs in 35% of cases. In another 65% of the cases, screening costs are estimated to be higher. However, this increase in cost per QALY would not be more than the reported GDP per capita of the country. The results of this study also showed that the number of people who have died within the time horizon of the study due to death-causing complications such as ESRD, MI, and stroke, have not been large enough to represent a significant impact of screening on the patient's life expectancy, and therefore the increase in LYG is estimated to be close to zero. The results of the one-way sensitivity analysis, represented in the Tornado diagram of QALY, showed that screening for type-2 diabetes increased the quality of life of participants. In the base-case scenario (no discounting) the incremental QALY per patient has been reported to be 0.017. Providing services to improve patients' adherence to medicines or screening people in community pharmacies can prevent or postpone early complications of chronic diseases such as type-2 diabetes. These services could be provided by community pharmacists and even become mandatory on a regular basis. At the moment, community pharmacies are not actively involved in activities such as screening tests in Iran.

One of the main goals of this study was to demonstrate the benefits of expanding the role of community pharmacies and its potential effect on patients' quality of life. Increasing the role of community pharmacists and community pharmacy services can help control and/or prevent many complications.

Although some previous studies have been conducted to evaluate the cost-effectiveness of type-2 diabetes screening, studies that evaluate the cost-effectiveness of type-2 diabetes screening in community pharmacies using simple feasible methods (such as the use of ordinary glucometers) are very limited.

In a 2019 study in the UK, a total of 11 pharmacies and 336 volunteers were selected to evaluate the cost-effectiveness of type-2 diabetes screening. In this study, the screening method included initial risk assessment through a questionnaire. Patients at high risk were determined and were subjected to HbA1c testing. This study compared the cost-effectiveness of type-2 diabetes screening in pharmacies as opposed to screening in health clinics. The results of the study showed that the cost-effectiveness of screening in pharmacies was almost similar to the screening performed in health clinics. In the aforementioned study, unlike the present study, the Markov model method has not been used (27).

A study in 2014 in Japan inspected the cost-effectiveness of screening for type-2 diabetes in pharmacies. This screening was done by

measuring HbA1c in Japanese pharmacies. In this study, Markov modeling was used and the ICER regarding QALY has been calculated. The results of this intervention were compared to the results of screening in health clinics, and it was revealed that screening in pharmacies was more cost-effective. The results of this study showed that the greatest effect of early diagnosis of type-2 diabetes was on ESRD (28).

Due to the differences in the methods of analysis and screening, setting, and compared alternatives, the results of these studies were not comparable with the present study.

Limitations

Although major complications of diabetes including ESRD, blindness, LEA, stroke, and MI were considered in this study, due to limited available information and excessive model complexity, complications such as diabetic ulcers, nephropathy without ESRD and retinopathy without blindness were not modeled. Other risk factors such as smoking and high blood pressure that could contribute to the complications of diabetes were not considered in this study. As at the moment, the establishment of required instruments to measure HbA1c seems not to be feasible for the community pharmacies in Iran, a simple and available method to measure FBS was considered for the screening test in the current study. However, all the required interventions for the treatment and monitoring of the diagnosed diabetic patients have been taken into account. It was assumed that the population of this study would not undergo any diabetes screening test other than the mentioned screening test, within the time period of the study.

CONCLUSION

This study indicated that screening for type-2 diabetes in community pharmacies in Iran could be considered a highly cost-effective intervention with regard to the WHO criteria of the annual GDP per capita ($2757 in 2020).

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Conflict of interest statement

The authors declared no conflict of interest in this study.

Authors' contribution

M. Amirsadri contributed to the conception of the work, model design, data acquisition and analyses, interpretation of results and manuscript preparation; E. Torkpour was involved in data acquisition and analyses and manuscript preparation. All authors approved the final version of the manuscript.

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