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ORIGINAL ARTICLE

Validation of a Malay Language Questionnaire Assessing Direct and Indirect Cost Among Caregivers of Individuals with Type 2 Diabetes Mellitus at Public Primary Healthcare

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ABSTRAK

Diabetes merupakan penyumbang utama kepada kadar kematian dan ketidakupayaan di seluruh dunia, dengan diabetes mellitus jenis 2 (T2DM) menjadi gangguan metabolik yang paling lazim. Peningkatan kes T2DM bukan sahaja mengurangkan jangka hayat pesakit secara signifikan tetapi juga memberikan beban ekonomi yang besar kepada pesakit dan penjaga mereka. Kajian ini telah mengesahkan soal selidik dalam Bahasa Melayu yang relevan dari segi budaya untuk menilai secara komprehensif kos langsung dan tidak langsung yang ditanggung oleh penjaga bagi individu dengan T2DM dalam tetapan penjagaan kesihatan primer di Malaysia. Dengan menggunakan reka bentuk keratan rentas, proses pengesahan melibatkan pengesahan kandungan oleh panel pakar dan pengesahan muka bersama penjaga. Soal selidik akhir terdiri daripada 36 item merentasi empat domain: tempoh penjagaan, kos perubatan secara langsung, kos bukan perubatan langsung dan kos secara tidak langsung. Kesahan kandungan, yang diukur melalui indeks kesahan kandungan, mencapai skor 0.89, manakala indeks kesahan muka melebihi 0.8, mengesahkan kejelasan dan perkaitan. Data sosiodemografi mendedahkan bahawa kebanyakan penjaga berada pada usia pertengahan, bekerja dan berkahwin, dengan tanggungjawab penjagaan yang berpanjangan dan sumber kewangan yang terhad. Hasil kajian menunjukkan kos langsung yang ketara seperti perbelanjaan perubatan dan pengangkutan, serta kos tidak langsung seperti kehilangan produktiviti akibat tugas penjagaan. Penemuan ini menggariskan multidimensi dalam beban penjagaan yang diperkuatkan oleh komplikasi berkaitan diabetes dan amalan perubatan sendiri. Soal selidik yang telah disahkan ini berfungsi sebagai alat yang sesuai untuk menilai kesan ekonomi terhadap penjaga dan menangani jurang dalam penyelidikan ekonomi kesihatan yang khusus kepada konteks budaya dan landskap penjagaan kesihatan di Malaysia.

Kata kunci: *Beban ekonomi; diabetes; kos; penjaga, pesakit luar*

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ABSTRACT

Diabetes is a major global contributor to mortality and disability, with type 2 diabetes mellitus (T2DM) being the most common metabolic disorder. Its increasing prevalence notably decreases life expectancy and creates a significant economic burden for patients and their caregivers. This study validated a culturally relevant Malay-language questionnaire to comprehensively assess direct and indirect costs incurred by caregivers of individuals with T2DM in Malaysian public primary healthcare settings. Employing a cross-sectional design, the validation process involved content validation by an expert panel and face validation with caregivers. The final questionnaire comprised 36 items across four domains: caregiving duration, direct healthcare costs, direct non-healthcare costs and indirect costs. Content validity was measured via the content validity index, achieved a score of 0.89, while the face validity index exceeded 0.8, affirming clarity and relevance. Sociodemographic data revealed that caregivers were predominantly middle-aged, employed, married, with prolonged caregiving responsibilities and limited financial resources. Results highlighted significant direct costs, such as medical expenses and transportation, and indirect costs like productivity losses due to caregiving duties. These findings underscore the multidimensional caregiving burden, amplifying by diabetes-related complications and self-medication practices. This validated questionnaire serves as a robust tool for evaluating economic impacts on caregivers and addressing gaps in health economics research specific to Malaysia's cultural and healthcare landscape.

Keywords: Carer; cost; diabetes; economic burden; outpatient

INTRODUCTION

Diabetes ranks among the primary contributors to mortality and disability globally (GBD 2021 Diabetes Collaborators 2023). Type 2 diabetes mellitus (T2DM) is the most prevalent metabolic disorder, with a rising incidence that can substantially reduce life expectancy (Lin et al. 2020). The Eastern Mediterranean Region and South East Asia Region (low- and middle-income nations) exhibit a greater prevalence of diabetes compared to high-income countries (World Health Organisation 2016). In 2018, Malaysia was ranked highest in the Western Pacific Region in terms of the prevalence of diabetes at 16.8%, with approximately 3.6 million of the adults within the population (Ganasegeran et al. 2020). Although considerable focus has been directed towards the direct healthcare expenses related to the management of T2DM, the direct and indirect costs borne by caregivers remain poorly understood.

Individuals with T2DM can benefit from having a family caregiver (Kristaningrum et al. 2021). A family caregiver is a person within the patient's immediate family who delivers primary care or aids in fulfilling the patient's needs (Golbeck 2015). A relative, spouse, adult child, friend or neighbour may possess a personal connection with the family. There exists individuals who extend their support through unpaid caregiving to those incapacitated by various disabilities, encompassing physical, mental or cognitive challenges (Schulz et al. 2020). Caregivers also face a multitude of obstacles in providing assistance to T2DM patients who require physical, emotional and financial support due to their inability to independently care for themselves as a result of disease, injury or disability (Annisa 2016). Provision of meticulous care is related to a high economic burden as a consequence of increasing healthcare costs and loss of employment (Butt et al. 2022).

A validated tool tailored to the Malaysian context is crucial to quantify these costs comprehensively. Caregivers of individuals with T2DM in Malaysia often face unique challenges shaped by cultural norms, socioeconomic factors and healthcare system dynamics. Existing instruments used to assess direct and indirect costs are predominantly developed in non-Malay contexts, limiting their applicability in Malaysia. Recognising these gaps, this study

sought to develop and validate a Malay-language questionnaire that captured the direct and indirect costs of caregiving while ensuring cultural and linguistic relevance. This questionnaire was called as Caregiver Cost for Type 2 Diabetes Mellitus (COST2DM-Malay).

MATERIALS AND METHODS

Study Design and Population

This study utilised a cross-sectional design to validate the newly developed questionnaire. The validation process was conducted in two phases: content validation with an expert panel and face validation with caregivers.

According to National Diabetic Registry Clinical Audit Report 2023, Pahang Barat exhibited the highest percentage (60%) of uncontrolled T2DM cases within Pahang, indicating considerable challenges for caregivers in effective diabetes management. Hence, the study population included caregivers of individuals diagnosed with T2DM residing in Pahang Barat which consisted of four districts (Bentong, Raub, Kuala Lipis and Cameron Highland) managed at primary healthcare and were seen by Family Medicine Specialist (FMS).

Inclusion criteria for caregivers were (i) Malaysian citizens aged 18 years and above; (ii) providing care for the individual with T2DM for a minimum of six months; (iii) residing with or near the individual with T2DM; (iv) responsible for assisting with medication, treatments, daily activities and financial support; (v) proficient in Malay or English; and (vi) provided informed consent to participate in the study. Caregivers were excluded if they have (i) a history of current or previous psychiatric illnesses or other severe medical or surgical conditions; (ii) care for more than one chronically ill patient; and (iii) care for individuals with T2DM who are pregnant or diagnosed with gestational diabetes mellitus (GDM).

While, the inclusion criteria for individuals with T2DM were (i) Malaysian citizens aged 18 years or older; (ii) diagnosed with T2DM for three or more years; (iii) receiving multiple oral hypoglycaemic agents with or without insulin treatment; (iv) HbA1c level must be 7.0% or higher; and (v) attending follow-ups at public primary health clinics for at least six months under the care of FMS. Exclusion criteria were being pregnant or diagnosed with GDM and having debilitating medical or surgical conditions such as cancer or psychotic or cognitive disorders.

A dual sampling method was employed in this study. Initially, proportionate sampling was used to determine the number of caregivers required from each district based on the distribution of individuals with uncontrolled T2DM managed by FMS at primary health care (PHC). This approach aimed to ensure a representative sample across different districts. However, due to a poor response rate in certain districts, purposive sampling was subsequently applied to recruit additional caregivers who met the study's inclusion and exclusion criteria. This allowed the study to achieve the required sample size while ensuring that all caregivers who participated were actively involved in caregiving for adults with T2DM in PHC settings. In cases where the targeted number of caregivers from a specific district was not met, eligible caregivers from other districts were included to compensate for the shortfall.

Ethics Statement

Ethical approval for this study was secured from the Universiti Kebangsaan Malaysia Research Ethics Committee (UKM-PPI/111/8/JEP-2024-225) as well as from the Medical Research and Ethics Committee of the Malaysia Ministry of Health [NMRR ID: 24-00952-HBY (IIR)]. The respondents' data were kept confidential, and their identities were not revealed in the findings.

Data Collection

A meeting was conducted prior to the data collection process with the individual responsible for each clinic to clarify and outline the study's procedures and requirements. The recruitment

process commenced with the gathering of a list of T2DM patients who fulfilled the study's inclusion criteria. Information was collected from the selected patients to identify their primary caregivers, who were subsequently screened to confirm they met the inclusion criteria. Caregivers who met the criteria were reached out to, and personal meetings were scheduled at the appropriate PHC, where they were provided with a detailed overview of the study's purpose, objectives and procedures.

The data collection process took place from October to November 2024. A pre-test was conducted with 30 carers of individuals with T2DM from the target population. All participants provided their informed consent. In the course of the interview, the respondent was prompted by the interviewer, either verbally or through an open-ended question, to provide further insights on their thoughts regarding each item in the questionnaire.

Item Development for the Direct and Indirect Cost

Information about the cost was gathered using self-administered questionnaire in Malay language. Group of experts consisted of health economist, public health specialist, FMS, dietitian, diabetic educator and pharmacist developed the questionnaire.

The expenses were categorised into direct costs and indirect costs. The direct cost represented the opportunity cost of resources allocated to caregiving and treating individuals with T2DM. This cost includeed both direct healthcare costs and direct non-healthcare costs. Direct healthcare costs encompassed expenses related to outpatient visits, laboratory tests, medications, hospitalisation and consumables. The direct non-healthcare costs included expenses for transportation and lodging. Direct cost data were obtained from records of individuals with T2DM and interviews with carers. Transport costs were gathered from a carer for round trips and the frequency of visits to each care provider or hospital. Lodging costs were derived from caregiver-reported expenses and the duration of hospital stays for carers of individuals with T2DM.

Approaches for Direct and Indirect Cost Estimation

The cost of illness analysis undertook from the societal perspective. The primary outcome variable of the study was the overall expenditure associated with diabetes management and treatment incurred by caregivers. The cost of T2DM illness was the cost spent by caregivers as the consequence of T2DM illness (that was the cost for treatment and care of diabetes). Direct healthcare costs which were not government subsidised are categorised as Out of Pocket (OOP). The OOP expenses was calculated from the drugs purchased, private laboratory, clinic visit charge, complementary treatments and medicines which were purchased for the patients and not reimbursed by the government (Pharmaceutical Services Division, Ministry of Health Malaysia 2015). The overall expense associated with illness encompasses both direct and indirect costs. The assessment of direct and indirect expenses relied on the records of carers and their recollections during interviews. Costs were measured in Ringgit Malaysia (RM).

The direct cost was estimated using a micro-costing or bottom-up approach (Rice 1967; Rice 2000). In order to determine the direct and indirect cost of treating T2DM by their caregiver, the following components were measured and calculated (Azzani et al. 2016; Ministry of Health Malaysia 2022; Pharmaceutical Services Division, Ministry of Health Malaysia 2015; Zawudie et al. 2022):

(A) Direct healthcare cost

(i) Consultation fee

The consultation fee referred to the costs associated with a patient's visit to a physician, whether in public or private healthcare facilities. In Ministry of Health (MOH) public facilities, the fee for an ambulatory consultation with a

doctor was RM1.00, while the fee for a specialist consultation was RM5.00. Consultations with chemists or dietitians in MOH facilities were provided at no cost. In cases of missing costs, the information was verified against the types of consultations (either with a doctor or specialist), and fees were allocated in accordance with the Fee Act (Bahagian Kewangan, Kementerian Kesihatan Malaysia 2017).

(ii) Cost of drug

Drug costs referred to the total expenditure on all medications prescribed or acquired within private healthcare settings. These were classified as OOP expenses. The cost of the drug was determined by multiplying the prescribed quantity by the unit cost, as per the price list from Pharmacy Services Programme, Ministry of Health Malaysia (Program Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia 2023) if caregiver unable to show the receipt. In cases of missing data regarding the quantity of drug prescribed, the quantity was estimated by calculating the average dose prescribed over a one-month period (30 days).

(iii) Cost of laboratory tests and investigations

Laboratory and investigation costs referred to the total expenses associated with all tests and procedures, such as blood tests performed in private healthcare facilities.

(iv) Cost of hospitalisation

The cost of hospital admission was defined as the total of the admission fee, laboratory and investigation expenses and medication costs in a private hospital. The calculation of drug costs and laboratory costs had been outlined above.

(v) Cost of consumables

Healthcare supplies (e.g. needles, alcohol swabs, lancets, glucometers, dressing sets), dietary items (e.g., oats, diabetic milk), dietary supplements (e.g., multivitamins, fish oils, glucosamine), and ancillary items (e.g., exercise gear, diabetic shoes) contributed to the overall cost of consumables.

(B) Direct non-healthcare cost

(i) Cost of food and drink

Food and drink cost were defined as the sum of money paid for buying food and drink during caregiving individual with T2DM while seeking treatment or following-up at healthcare facilities.

(ii) Cost of transportation

All healthcare facility round-trips, including parking and tolls, were included in transportation expenses. When the exact cost of driving a car or motorbike was not specified, it is calculated by multiplying the total distance travelled in kilometres by the relevant mileage rate. Motorbikes were subjected to a charge of RM0.55 per kilometre and vehicles to a rate of RM0.85 per kilometre (Perbendaharaan Malaysia 2024). The costs associated with public transport (e.g. taxi, train and bus) was determined based on the ticket price per person.

(iii) Cost of lodging

The costs of lodging are defined as the total expenditure incurred by carers who must accompany individuals with T2DM to receive treatment away from their homes.

(iv) Cost of home help

The costs of home help encompassed the total expenditure associated with hiring a maid (either hourly or monthly), nursing care, laundry services and physiotherapy or massage services.

(C) Indirect cost

The indirect cost represents the productivity loss associated with caregiving for individuals with T2DM, quantified by the productive time lost by carers during travel and consultations

with healthcare providers. The human capital approach quantifies the productivity time lost (Jiang et al. 2022) while the value of carers' time is assessed through the opportunity cost method.

(i) Cost due to absenteeism from work

The cost of absenteeism from work attributable to taking care individual with T2DM was estimated by multiplying the total time spent in healthcare facilities by the daily or hourly income. The daily income was determined by multiplying the upper limit of the monthly carer income range by 12, then dividing the result by 52 and five, based on the assumption that the carer worked five days a week for 52 weeks each year (Pharmaceutical Services Division, Ministry of Health Malaysia 2015). This study posited that a single working day comprised eight working hours. Thus, the hourly income was calculated by dividing the daily income by eight (Ng et al. 2001).

$$\text{Cost per day due to days away from work} = \frac{\text{Monthly wage}^* 12}{52 \text{ weeks}^* 5}$$

The indirect cost associated with the care of individuals with T2DM during hospitalisation was determined by multiplying the length of stay in days and the number of medical leave days by the daily income. The expense associated with absenteeism in primary care activities was determined by multiplying the total hours spent in facilities by the income generated per hour. The indirect costs associated with unemployed carers and individuals not in the labour force were excluded, as the opportunity cost of their time, according to the human capital approach, was deemed to be zero. All direct and indirect cost data was gathered in RM.

Validity of the Item

(A) Content validity

To evaluate the content validity of each individual question, the panel of subject matter experts (SMEs) assessed whether the component measured by the question was classified as "essential," "useful, but not essential," or "not necessary" for measuring the construct (Nikolopoulou 2022). A greater consensus among panellists regarding the essential nature of a specific item correlated with an increased level of content validity for that item.

(i) Calculating content validity ratio and content validity index

To assess the content validity, we employed the content validity ratio (CVR) and the content validity index (CVI). The formula outlined below was utilised to determine the CVR for each question: The formula for calculating the CVR was as followed: (ne - N/2)/(N/2), where ne represents the number of SME panellists who indicated "essential," and N denoted the total number of subject matter expert panellists involved. This formula produced values that span from +1 to -1. Values exceeding 0 suggested that a majority of SMEs concurred that the question held significant importance. A value approaching +1 indicated an increased level of content validity.

The CVI served to assess the content of the complete questionnaire. The CVI represented the mean CVR score across all items in the questionnaire, with values approaching 1 indicating greater content validity (Nikolopoulou 2022; Polit et al. 2007).

(B) Face validity

The questionnaire underwent pre-testing with 30 carers of individuals with T2DM from the target population (Yusoff 2019). In the course of the interview, the respondent was prompted by the interviewer, either verbally or through an open-ended question, to provide a detailed explanation of their thoughts regarding each item on the questionnaire and the associated response mean. This method was designed to eliminate any ambiguity when responding to the questionnaire.

(i) Conducting response process validation

The respondents were requested to provide their opinions regarding the clarity and comprehension of each item using the following scale: 1 = the item is not clear and understandable; 2 = the item is somewhat clear and understandable; 3 = the item is clear and understandable; and 4 = the item is very clear and understandable (Yusoff 2019).

(ii) Reviewing item and provide score for each item based on clarity and comprehension

The respondents were asked to evaluate all items and subsequently assign a score to each one. Respondents were invited to offer verbal or written feedback to enhance the clarity and understanding of the items. All feedback was considered to enhance the items.

(iii) Calculating face validity index

Two forms of face validity index (FVI) were identified which was FVI for item (I-FVI) and FVI for scale (S-FVI) (Yusoff 2019). To calculate S-FVI, two methods were employed: (i) the average of the I-FVI scores for all items on the scale (S-FVI/Ave) and (ii) the proportion of items on the scale that received clarity and comprehension ratings of 3 or 4 from all raters (S-FVI/UA). To calculate FVI, the clarity and comprehension rating should be recoded as 1 for a scale of 3 or 4, and as 0 for a scale of 1 or 2. UA represented a universal agreement, where a score of '1' indicated that the item received 100% agreement from all respondents, while a score of '0' signified not all respondents rated the item with a '1'. The minimum acceptable value for FVI was 0.8. (Lau et al. 2018; Mohamad Marzuki et al. 2018; Polit et al. 2007).

RESULT

Sociodemographic Data of Caregivers

Table 1 showed sociodemographic profile of 30 caregivers for individuals with T2DM who participated in this pre-test questionnaire. The average age of caregivers was 46.63 years, with males comprising 60.0% of the respondents and females accounting for the remaining 40.0%. In terms of ethnicity, the majority of caregivers were Malay (60.0%), followed by Indian (20.0%), Chinese (16.7%), and a small proportion from the Orang Asli community (3.3%). The highest level of education attained by most caregivers was secondary school (66.7%), while 16.7% had a diploma and 13.3% was primary school. A minority reported hold a degree (3.3%). Employment data indicated that 76.7% were employed, while the rest were either self-employed (3.3%), pensioners (6.7%) or unemployed (13.3%).

Most caregivers earned less than RM 4,850 per month (86.7%), with 13.3% earning between RM 4,850 and RM 10,970. None reported an income above RM 10,970. The marital status of the majority was married (83.3%), with 16.7% being single or divorced. Regarding the caregiver-patient relationship, 43.3% were partners of the patients (spouse), while 26.7% are sons and 23.3% were daughters. The average number of family members in the household was 4.9, and the mean caregiving duration was approximately 59.7 months. These findings underscored the caregiving burden borne by middle-aged, predominantly married caregivers from lower-income backgrounds, many of whom had prolonged caregiving responsibilities within multigenerational households.

Characteristics of Individual with T2DM

Table 2 showed characteristics of individuals with T2DM who being taken care by their caregiver. Most individuals (66.7%) had follow-up at public health clinics in Bentong, with smaller proportions from Raub (20.0%) and Kuala Lipis (10.0%), while the Cameron Highlands accounts for only 3.3%. On average, individuals had been diagnosed with T2DM for 9.03 years, with 33.3% reported at least one diabetes-related complication. All individuals were on a combination of oral hypoglycemic

TABLE 1: Sociodemographic profile of caregivers of individual with T2DM (n = 30)

Profile		Frequency (n)	Percentage (%)
Age (mean ± SD)		46.63 (15.06)	
Sex	Male	18	60.0
	Female	12	40.0
Race	Malay	18	60.0
	Chinese	5	16.7
	Indian	6	20.0
	Orang Asli	1	3.3
	Others	0	0.0
Education level	Primary school	4	13.3
	Secondary school	20	66.7
	Diploma	5	16.7
	Degree	1	3.3
Employment	Self-employed	1	3.3
	Employed	23	76.7
	Pensioner	2	6.7
	Unemployed	4	13.3
	Student	0	0.0
Monthly income	< RM 4850.00	26	86.7
	RM 4850.00 - 10970.00	4	13.3
	> RM 10970.00	0	0.0
Marital status	Married	25	83.3
	Single	5	16.7
	Divorcee	0	0.0
Relationship with patient	Son	8	26.7
	Daughter	7	23.3
	Parent	2	6.7
	Partner	13	43.3
Number of family members (mean ± SD)		4.9 (1.52)	
Duration of caregiving (mean ± SD) in months		59.70 (46.78)	

TABLE 2: Characteristics of individual with T2DM (n=30)

Profile		Frequency (n)	Percentage (%)
Public Health Clinic	Bentong	20	66.7
	Raub	6	20.0
	Kuala Lipis	3	10.0
	Cameron Highland	1	3.3
Duration of diagnosed with T2DM (mean ± SD) in years		9.03 (6.92)	
Diabetes related complication	No complication	20	66.7
	At least 1 complication	10	33.3
Medication	OHA only	0	0.0
	OHA with insulin	30	100
Other disease beside T2DM	Yes	30	100.0
	No	0	0.0
History of admission for the past 1 year	Yes	12	40.0
	No	18	60.0

Continued...

...continuing

Profile		Frequency (n)	Percentage (%)
History of seeking treatment at healthcare facilities (private or public) in the last 6 months	Yes	21	70.0
	No	9	30.0
Frequency visited the pharmacy at any hospital/clinic (government/ private) in the last 6 months to get medications for T2DM and its complications (mean ± SD)		3.80 (4.17)	
History of seeking treatment for T2DM or its complications in the last 6 months from any alternative/ traditional medical practitioner	Yes	5	16.7
	No	25	83.3
History of purchased or obtained any self-medication without a doctor's prescription from a pharmacy for T2DM in the last 6 months	Yes	17	56.7
	No	13	43.3

OHA: Oral hypoglycaemic agent; T2DM: Type 2 diabetes mellitus

agents and insulin therapy, with none solely reliant on oral medication. Additionally, 100% of the individuals had other chronic diseases apart from T2DM, which may present complexity in management of comorbidities.

Regarding healthcare utilisation, 40% of individuals had at least one hospital admission in the past year, and 70% sought treatment at healthcare facilities in the past six months. The average frequency of visiting pharmacies for medications during this period was 3.8 times. Interestingly, 16.7% of individuals sought alternative or traditional medical treatment for T2DM, and 56.7% reported purchasing or obtaining self-medication without a doctor's prescription in the last six months. These findings underscored significant healthcare-seeking trends, highlighting a reliance on public clinics and the prevalent use of self-medication and alternative treatments among T2DM patients.

Content Validity

Group of experts consisted of Doctor of Philosophy Health Science (Health Economy) with 6 years' experience, Public Health Specialist with 6 years' experience, FMS with 24 years' experience, dietitian with 14 years' experience, diabetic educator with 10 years' experience and pharmacist with 13 years' experience.

The content validation process yielded a CVI score of 0.89 (Table 3), indicating excellent agreement among experts on the questionnaire's relevance and clarity. Experts highlighted areas for improvement, particularly in the phrasing of items related to direct and indirect costs, which were revised to enhance specificity and cultural sensitivity. For example, within the domain of direct healthcare costs, experts provided a detailed list of treatment types to prevent misunderstandings and to encompass all practices across cultures. This included (i) traditional treatments utilising natural ingredients like turmeric (widely used among Indians), aloe vera, sea cucumber or herbal remedies among indigenous people; (ii) complementary treatments such as acupuncture (a common practice among the Chinese), chiropractic care, traditional massage (prevalent among the Malays), homeopathy, and herbal therapy. These revisions ensured that the questionnaire items comprehensively captured the cost of caregiving.

Face Validity

The face validity process involved 30 caregivers, representing diverse socioeconomic backgrounds and caregiving experiences. Respondents

TABLE 3: Content validity of COST2DM-Malay

Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	CVR
1	e	n	e	e	e	e	0.67
2	e	e	e	e	e	e	1.00
3	e	u	e	e	e	e	0.67
4	e	u	e	e	e	e	0.67
5	e	e	e	e	e	e	1.00
6	e	n	e	e	e	e	0.67
7	e	u	e	e	e	e	0.67
8	e	e	e	e	e	e	1.00
9	e	e	e	e	e	e	1.00
10	n	n	e	u	u	n	0
11	e	e	e	e	e	e	1.00
12	e	n	e	e	e	e	0.67
13	e	n	u	e	e	e	0.67
14	e	e	e	e	e	e	1.00
15	e	e	e	e	e	e	1.00
16	e	e	e	e	e	e	1.00
17	e	e	e	e	e	e	1.00
18	e	e	e	e	e	e	1.00
19	e	e	e	e	e	e	1.00
20	e	e	e	e	e	e	1.00
21	e	e	e	e	e	e	1.00
22	e	u	e	e	e	e	0.67
23	e	e	e	e	e	e	1.00
24	e	e	e	e	e	e	1.00
25	e	e	e	e	e	e	1.00
26	e	e	e	e	e	e	1.00
27	e	e	e	e	e	e	1.00
28	e	e	e	e	e	e	1.00
29	e	e	e	e	e	e	1.00
30	e	e	e	e	e	e	1.00
31	e	e	e	e	e	e	1.00
32	e	e	e	e	e	e	1.00
33	e	e	e	e	e	e	1.00
34	e	e	e	e	e	e	1.00
35	e	e	e	e	e	e	1.00
36	e	e	e	e	e	e	1.00
						CVI	0.89

e: Essential; u: Useful but not essential; n: Not necessary; CVR: Content validity ratio; CVI: Content validity index

TABLE 4: Face validity

Item	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10	R11	R12	R13	R14	R15	R16	R17	R18	R19	R 20	R 21	R22	R23	R24	R 25	R26	R27	R28	R29	R30	Raters in agreement	I-FVI	UA
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1
2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1
3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1
4	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1
5	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1
6	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1
7	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	0	1	1	1	1	1	27	0.9	0
8	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1
9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1
10	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1
11	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1
12	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1
13	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1
14	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1
15	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1
16	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	0	1	1	1	1	1	27	0.9	0
17	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1
18	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1
19	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1
20	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	0	1	1	1	1	1	27	0.9	0
21	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	30	1.0	1

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Item	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10	R11	R12	R13	R14	R15	R16	R17	R18	R19	R 20	R 21	R22	R23	R24	R 25	R26	R27	R28	R29	R30	Raters in agreement	I-FVI	UA
22	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1.00	1	1	1	1	1	30	1.00	1.00
23	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	0	1	1	1	1	1	27	0.90	0
24	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1.00	1	1	1	1	1	30	1.00	1.00
25	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1.00	1	1	1	1	1	30	1.00	1.00
26	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1.00	1	1	1	1	1	30	1.00	1.00
27	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1.00	1	1	1	1	1	30	1.00	1.00
28	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	0	1	1	1	1	1	27	0.90	0
29	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1.00	1	1	1	1	1	30	1.00	1.00
30	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1.00	1	1	1	1	1	30	1.00	1.00
31	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1.00	1	1	1	1	1	30	1.00	1.00
32	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1.00	1	1	1	1	1	30	1.00	1.00
33	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1.00	1	1	1	1	1	30	1.00	1.00
34	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1.00	1	1	1	1	1	30	1.00	1.00
35	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1.00	1	1	1	1	1	30	1.00	1.00
36	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1	1	1.00	1	1	1	1	1	1	1	1.00	1	1	1	1	1	30	1.00	1.00
																															S-FVI/ Ave	0.99	
*	1	1	1	1	1	1	0.86	1	1	1	1	1	1	1	1	1	0.86	1	1	1	1	1	1	1	0.86	1	1	1	1	1	S-FVI/ UA		0.86

Average proportion of item judged clarity and comprehension across 30 raters = 0.98
*proportion clarity and comprehension

reported that the questionnaire was clear and easy to understand, with an FVI score more than 0.8 (Table 4). Minor adjustments, such as simplifying technical terms with proper examples, were made based on respondent feedback to improve readability.

The finalised version of the questionnaire comprised 36 items from 40 items across four domains: (i) information regarding seeking medical attention within a specified duration; (ii) direct healthcare costs; (iii) direct non-healthcare costs; and (iv) indirect costs (Table 5). These domains were deemed highly relevant by both experts and caregivers, ensuring the instrument's comprehensiveness and applicability in the Malaysian context. The high CVI and FVI scores reflected the instrument's robustness in capturing the multidimensional nature of caregiving burdens. These results underscored the importance of stakeholder involvement in developing contextually appropriate tools.

DISCUSSION

The findings from both caregivers and individual with T2DM characteristics highlight potential challenges related to the direct and indirect costs caregivers bear when supporting individuals with T2DM. Majority of caregivers were received education up to secondary school but minority of them were primary school education. The level of education is significantly associated with health literacy, as individuals possessing higher educational attainment typically demonstrate enhanced abilities to access, comprehend and utilise health information (Jaafar et al. 2021).

TABLE 5: List of questionnaires to measure direct and indirect cost incurred by caregiver of individual with T2DM managed at public primary healthcare

Bil	Domain	Item
A.		Seeking medical attention within a specified duration
1		Have you received T2DM treatment in the last 6 months from a specialist clinic or as an outpatient at a hospital/clinic (government/private)? Yes/No
2		Have you been hospitalised in the last year due to T2DM or its complications?
3		How many times have you visited the pharmacy at any hospital/clinic (government/private) in the last 6 months to get medications for T2DM and its complications? If yes, how many times?
4		Have you sought treatment for T2DM or its complications in the last 6 months from any alternative/traditional medical practitioner? Yes/No
5		Have you purchased or obtained any self-medication without a doctor's prescription from a pharmacy for T2DM in the last 6 months? Yes/No
B.		Direct healthcare cost
6		Types of consultations (list): Examples: doctor, pharmacist, dietitian, exercise specialist, traditional healer, Chinese medicine practitioner, and others.
7		Types of treatments (list): Examples: modern treatment (lab-created drugs), traditional treatment (natural ingredients like turmeric, aloe vera, sea cucumber), complementary treatment (acupuncture, chiropractic, traditional massage, homeopathy, herbal therapy), dialysis, blood tests, wound care, etc.
8		Types of medical needs (list): Examples: medications, supplements, herbs, vitamins, diabetic-specific nutritional foods like brown rice, medical devices, disposable items like insulin needles, syringes, etc.
		(I) Ward Admission Costs
		(i) Ward Admission
9		- Reason for admission
10		- Diagnosis
11		- Type of hospital (government/private)
12		- Duration/days admitted

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Bil	Domain	Item
		(ii) Travel to Hospital
13		- Distance to hospital from home (km)
14		- Mode of transportation used (motorbike/car/taxi/bus/Grab)
15		- Travel time to the hospital (minutes/hours)
16		- Total travel cost to the hospital from home (fuel, meals, drinks, etc.)
		(iii) Return Journey from Hospital
17		- Distance from hospital to home (km)
18		- Mode of transportation used (motorbike/car/taxi/bus/Grab)
19		- Travel time to the hospital (minutes/hours)
20		- Total travel cost to the hospital from home (fuel, meals, drinks, etc.)
		(iv) Others
21		- Number of nights stayed (if applicable)
22		- Accommodation cost/night
23		- Meal/drink expenses while taking care of the patient (until discharge)
		(II) Cost of traveling to a health clinic:
24		Distance to the health clinic from home (km)
25		Travel time to the clinic from home (minutes)
26		Waiting time at the clinic (from registration to seeing the medical officer) (minutes/ hours)
27		Total time spent at the clinic (hours)
C.		Direct non-healthcare cost
28		Additional Support: To be filled in if there are expenses for additional support at home due to: (a) T2DM and its complications; (b) Difficulties faced by the patient because of T2DM and its complications. Examples of support: Laundry, patient care assistance (nursing care/private clinic/ pharmacy) – foot care, wound care, medication management, bathing assistance, etc., physiotherapy or massage, cleaning/housekeeping assistant, cooking/catering services.
D		Indirect cost
29		Estimated salary/month
30		Daily working hours
31		Number of working days/week
		Frequency of accompanying the patient for treatment:
32		(i) Appointments at health clinics/private clinics
33		(ii) Appointments at hospitals.
34		(iii) Other appointments (e.g., physiotherapy/diabetic educator/dietitian/fundus camera/ traditional/complementary treatments).
		Number of leave days or time-off taken for this activity:
35		(i) Accompanying the patient for treatment at health clinics/private clinics/hospitals
36		(ii) Staying with the patient during hospitalisation

Effective management of T2DM significantly depends on sufficient health literacy, which affects glycaemic control and diabetic self-management (Mohd Rawi & Ibrahim 2024). Thus, poor health literacy among caregivers may heighten the difficulty of managing T2DM, resulting in suboptimal care and higher expenses.

Direct costs areevident in the healthcare-seeking patterns and medication use of individuals with T2DM. Despite 70.0% seeking treatment at healthcare facilities, a significant number (56.7%) also resorted to self-medication, which could increase out-of-pocket expenses for caregivers. Additionally, the frequent visits to pharmacies (3.8 times on average in six months) may burden caregivers financially, particularly those from lower-income households, as indicated by 86.7% of caregivers earning less than RM4,850 per

month. Furthermore, managing diabetes-related complications (33.3% of patients) and prolonged caregiving durations (59.7 months on average) increase medical expenses, transportation costs and other ancillary expenses, such as special diets or medical supplies. This is supported by study in Punjab, where the direct costs of T2DM patients accounted for almost 93% of the total costs of T2DM in 2021, mainly under outpatient care. The greatest contributor was medical expenditure, followed by direct non-medical costs including transportation, food and other materials after diagnostic expenditure (Kansra & Oberoi 2023), which may have been contributed by caregivers' fees. Another study by Bermudez-Tamayo et al. (2017) also supports this. It showed that the average direct non-medical costs paid to carers of people with DM were USD 0.2 and USD 0.5 for people without DM and DM, respectively, with a mean difference of USD 0.3.

Indirect costs are equally significant, as caregiving responsibilities often demand substantial time and effort. Caregivers, who are mostly employed (76.7%), may face challenges balancing work and caregiving duties, potentially leading to reduced work hours or absenteeism, thus affecting income. The average household size of 4.9 members suggests a multigenerational caregiving burden, intensifying stress and time constraints. The reliance on caregivers for transportation and healthcare navigation, particularly for those with complications, increases the opportunity cost of time spent away from other responsibilities. The long caregiving duration also contributes to emotional exhaustion, impacting caregivers' productivity and overall well-being. In Thailand, the typical duration allocated to caregiving amounted to 112.38 hours each month. This could influence the engagement of individuals in the labour market within Thai society (Chatterjee et al. 2011). A study by Bermudez-Tamayo et al. (2017) reported that the mean caregiver productivity loss cost was USD 7.1 for individuals without DM and USD 36.7 for individuals with DM, resulting in a mean difference of USD 29.6. These financial and non-financial burdens underscore the importance of targeted interventions, such as caregiver support programs and subsidies, to alleviate both direct and indirect costs (Sezgin et al. 2022).

Content validity that established through expert review by aligning the instrument's items with the study's objectives, it ensures clarity, relevance and comprehensiveness, avoiding gaps or irrelevant inclusions, making it suitable for the target population while reducing bias (Roebianto et al. 2023).

While, face validity is a non-statistical method of evaluation, meaning it does not rely on quantitative techniques for its assessment. However, when other quantitative methods of questionnaire validation are impractical due to nature of the research, the type of questionnaire or limited resources, face validity becomes an essential approach. This approach offers a pragmatic and significant method to guarantee the overall reliability and suitability of the research instrument, instilling confidence that the tool effectively assesses what it is designed to evaluate, as perceived by experts or intended users (Desai & Patel 2020).

There was no reliability test conducted for this questionnaire. The questionnaire employed consists of open-ended questions without a scale. In the context of open-ended questions, validity testing is typically prioritised over reliability testing due to the inherent challenges in reliably measuring reliability in free-form responses (Kindle 2017). Unlike standardised Likert-scale instruments that assess fixed constructs, cost-related responses vary based on individual caregiving situations, making it challenging to assess consistency across respondents, which is the key aspect of reliability testing (Middleton 2019). However, to ensure the accuracy of the received information, the provided expenses will be verified in accordance with the circular. For example, the pricing of medications will be verified against the price list from the Pharmacy Services Programme, Ministry of Health Malaysia (Program Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia 2023).

The validation of COST2DM-Malay questionnaire represents a significant contribution to the study of caregiver burdens in Malaysia. The CVI score of 0.89 underscores the expert consensus on the questionnaire's ability to accurately assess the direct and indirect cost of caregiving. The FVI score more than 0.8 further confirms its usability and acceptability among the target population.

Face and content validity are particularly suitable tools for validating questionnaires designed to gather information on costs due to their focus on ensuring clarity, comprehensiveness and relevance in the instrument's content. Cost-related data often encompasses diverse components, such as direct and indirect costs, which require careful item construction to capture all relevant aspects accurately. Face validity ensures that the questionnaire appears appropriate and logical to respondents, increasing their confidence in providing accurate cost-related data. Meanwhile, content validity ensures that the instrument comprehensively addresses all facets of costs, aligning with the study objectives and the complexity of economic evaluations.

The dual focus on direct and indirect costs ensures a holistic understanding of the direct and indirect cost faced by caregivers of individual with T2DM who managed at primary healthcare setting. Direct costs, such as medical expenses and transportation, are often readily quantifiable, while indirect costs, including lost productivity, require nuanced assessment tools. By incorporating both dimensions, this instrument provides a comprehensive framework for evaluating caregiver burdens.

On the other hand, COST2DM-Malay is culturally suitable, having been meticulously tailored to the Malaysian context, thereby ensuring its relevance and precision in evaluating caregiver burden. The utilisation of the Malay language enhances accessibility for the majority of caregivers, while validation through expert reviews and pre-testing with caregivers substantiates its clarity and comprehensibility.

Globally, prevalence use of traditional and complementary medicine is high (Lee et al. 2022). In Malaysia, more than 50% of population using traditional and complementary medicine which associated with strong ethnic identity and cultural significance (World Health Organisation 2020). For example, Malaysia's multicultural background leads many caregivers to employ diverse traditional and complementary treatments, including Malay traditional massage, Chinese acupuncture, and Indian or indigenous people used herbal remedies (Lokman et al. 2024; Park et al. 2022). The questionnaire effectively captures all caregiving expenses through the incorporation of these aspects. Thus, these findings align with previous research emphasising the need for culturally relevant tools in health economics research.

On top of that, the validated questionnaire holds substantial implications for caregivers, PHC, and governmental bodies or policy makers. This tool offers caregivers a systematic approach to evaluate their financial burden, encompassing both direct and indirect costs. This information aids caregivers in effectively planning their finances and advocating for financial assistance or support programs. PHC or healthcare providers can utilise the data obtained from the questionnaire to identify the primary cost-related challenges encountered by caregivers. This facilitates the optimisation of resource allocation, ensuring caregivers obtain essential education and support. Understanding the financial strains faced by caregivers allows PHC or healthcare providers to implement policies like priority consultation slots and reduced waiting times for those accompanying T2DM patients.

Furthermore, the findings of the COST2DM-Malay can inform health policy development at the governmental level by emphasising the economic burden experienced by caregivers. This evidence supports the justification for funding caregiver incentives, including subsidies or tax relief, and informs healthcare policies aim at reducing out-of-pocket expenses for caregivers. For example, in Singapore, caregivers benefit from a Home Caregiving Grant of SGD up to 400 per month (Ministry of Health Singapore

2024) and ElderCare Leave, which allows them to take up to six days of unpaid leave per year for caregiving duties (Singapore Human Resources 2024). Thus, a comprehensive understanding of caregiver costs can facilitate the development of cost-effective interventions aim at reducing financial strain and enhancing patient outcomes.

Strenghs and Limitations

One of the major strengths of this study is that it provides a culturally validated instrument for assessing caregiver burden in Malaysia. The high CVI and FVI ratings demonstrate the questionnaire's dependability and comprehensiveness. COST2DM-Malay questionnaire also considers both direct and indirect costs, providing a more complete picture of caregiving spending. An interdisciplinary team, comprising public health specialists, family medicine experts, nutritionists and pharmacists, also contributed to the questionnaire's development, ensuring that all essential components of caregiver expenses are addressed. Another advantage is its practical application for caregivers themselves, PHC or healthcare providers, and government or policymakers, where it provides valuable insights for decision-makers seeking to assist caregivers.

However, the study had certain limitations. One of the limitations is the absence of reliability testing, as the questionnaire contains open-ended questions that make it difficult to determine response consistency over time. Furthermore, self-reported statistics may introduce bias, since caregivers may underestimate or overestimate their expenses. Besides that, while integrating proportionate and purposive sampling allowed the study to balance representativeness and data relevance, this approach may have introduced geographic distribution bias and selection bias because caregivers who were easier to reach or more willing to participate were included through purposive sampling. Last but not least, the study was conducted in Pahang Barat, suggesting that the findings may not fully capture the experiences of caregivers in urban areas such as Kuala Lumpur, where the cost of caregiving could vary. Future studies ought to broaden their geographic scope to enhance their applicability across diverse contexts.

CONCLUSION

In conclusion, this study makes a substantial contribution by creating a validated questionnaire in Malay to evaluate the financial burden faced by caregivers of individuals with T2DM in Malaysia. The cultural significance and thorough cost evaluation render it an essential resource for caregivers, healthcare professionals and policymakers. The questionnaire demonstrates robust content validity (CVI = 0.89) and face validity (FVI > 0.8), effectively capturing both direct and indirect caregiving costs within public primary healthcare settings. Although reliability testing was not performed because of its open-ended characteristics, the responses related to costs were verified in accordance with official guidelines. This tool establishes a basis for additional investigation into financial burden among caregiver and can be broadened to examine wider economic effects, ultimately improving assistance for caregivers in Malaysia.

Data availability statement: The data are available upon request to the corresponding author.

Author contributions: Conceptualisation: SBMR, RI; Data curation: MNN, AMS, MAAH, IYD, AAG, NACD, SV, MFA; Formal analysis: SBMR, RI; Methodology: SBMR, RI, NA; Expert panel: CD, NAAT, MYMA, RAR, WHJ, RI; Manuscript-draft and editing: SBMR; Manuscript-critical review and guidance: RI. All authors have approved the final manuscript.

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