Medication-related burden among patients with diabetes mellitus and its relation to diabetic control parameters: an observational study [version 1; peer review: awaiting peer review]

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Abstract

Background: Diabetes mellitus (DM) refers to a group of metabolic abnormalities that are linked with significant morbidity, death, and health-care costs. Management options for patients with chronic illnesses such as diabetes are growing more complicated, which may result in a therapeutic burden for patients. The purpose of this research was to quantify the forms of concerns diabetic individuals have with medication that influence overall burden, as well as to examine the sociodemographic and clinical factors linked with negative medication use experiences and increased levels of burden.

Methods: The present research was a cross-sectional study of diagnosed diabetes patients who attended the Specialized Center for Endocrinology and Diabetes between 1st of December 2021 and 30th April 2022 in Baghdad, Iraq. The Living with Medicines Questionnaire (LMQ) was used to assess medication-related burden (MRB).

Results: The study recruited 193 patients with diabetes mellitus. The participants were adults with an average age of 50±15 years. More than half (52.8%) of the participating patients were women, and more than half (51.3%) also had one or more other chronic diseases. Additionally, 23.3% of patients had polypharmacy (≥ 5 medications). More than one-third had diabetes complications: neuropathy (45.6%) or retinopathy (38.9%). The mean LMQ score was (122.8±15.5). The research revealed that most of the DM patients experienced a moderate degree of medication burden (72.5%), followed by high burden (14.5%), minimum burden (12.4%), and no burden at all (0.5%) with no patient experiencing extremely high burden (0.0 %). Patients with uncontrolled blood glucose (high HbA1c), neuropathy, or retinopathy had a significantly higher medication burden.

Conclusions: The MRB among diabetic patients is at a very high level. This information may be helpful to health care professionals and
policymakers seeking to understand MRB for patients with diabetes. Future studies should focus on developing interventions that help reduce such burdens.

**Keywords**
Diabetes mellitus, medication-related Burden, Living with Medicines Questionnaire, diabetic control parameters, Iraq

This article is included in the Sociology of Health gateway.
Introduction
Diabetes is a series of metabolic abnormalities characterized by hyperglycemia which are caused by abnormalities in insulin activity, production, or even both. Type 1 and type 2 diabetes are the most common types of diabetes. Type 2 diabetes is a chronic disease defined mostly by insulin resistance and high blood glucose levels, which may lead to increased morbidity and mortality. Type 1 diabetes is characterized by autoimmune destruction of the pancreas' beta cells, leading to absolute insulin deficiency. Diabetes constitutes a severe public health care issue. According to the international diabetic federation, in 2021 the total global number of adult diabetic patients was 537 million, which represents 9.8% of the total population; 73 million live in the Middle East and North Africa (MENA), which include the highest regional prevalence of 16.2%. In Iraq, studies suggested the prevalence of diabetes (13.9%). However, some Iraqi cities have a high diabetes mellitus (DM) prevalence of as much as one in five adults.

Many patients find it burdensome to take many medications for long-term diseases. This burden is complex and influenced by various aspects, such as medicine formulation, regimen, adverse outcomes, socioeconomic burden, and healthcare influences. Medicine has been demonstrated to make patients' everyday life more difficult, including medication administration, controlling, and traveling. Medication-related burden (MRB) affects patients' health and well-being, as well as their views and behaviors regarding treatments. Diabetes is a non-communicable chronic disease that needs lifelong treatment, mostly with more than one medication to achieve the target blood glucose. The prevalence of many comorbidities and diabetic complications increase the number and burden of medication use. Extra medication and much more complicated prescription programs have been associated with poorer patient outcomes, notably higher patient non-adherence. Increased medication complexity or burden has also been associated with higher HbA1c, healthcare costs, and death rates among elderly individuals.

The purpose of this research was to quantify the sorts of concerns diabetic people have with medication that relate to total burden, as well as to examine the socio-demographic and clinical factors related with unfavourable medication use situations and high levels of burden.

Methods

Ethical approval
On March 23, 2021, the scientific and ethical committee of Baghdad University's College of Pharmacy reviewed and approved the research proposal that explains the aims of the present study as well as the anticipated procedures for data collection (ethics board approval code: 2615). Additionally, on November 11th, 2021, clearance was acquired from the Iraqi Ministry of Health (ethical board approval code: 110483). Before giving the questionnaire, the investigator described the goal of the research to each participant and got written consent to participate in the study. The participants were not offered any incentives.

Study design
This research was a descriptive cross-sectional study carried out on individuals who had been diagnosed with diabetes.

Setting
This study was carried out at a single location, and participants were recruited from patients who were seen at the Specialized Center for Endocrinology and Diabetes at the Al-Rusafa Health Directorate in Baghdad, Iraq, during the period from the first of December 2021 to the end of April 2022.

Sample size
The statistical tool G*Power (RRID:SCR_013726) edition 3.1.9.7 was utilized to determine the sample size. To a 95% confidence level, the following have been the calculated results: Df = 194, noncentrally parameter = 3.3087, critical t = 1.6527 The sample size required to be in the range of 196 individuals (f).

Eligibility criteria
The inclusion criteria of the study were diabetic patients aged 18 years and above of either sex that were diagnosed with DM at least one year before this study and used at least one pharmacological treatment for DM and were able to communicate and willing to participate in the study.

Exclusion criteria
The study's exclusion criteria were patients with cognitive, hearing, or speech deficits that affect their understanding level, pregnancy or lactation, and patients who give incomplete information.
Bias
Sampling error may arise throughout sample selection. This is especially noticeable in retrospective cohort studies when exposure and result have already occurred. In this research, sampling error is less likely. In order to get the desired conclusion, the ideal research population is well-defined, accessible, highly reliable, and reasonable. To avoid bias, participants were recruited in such a way that persons with hearing, speech, or cognitive problems that restrict topic understanding were excluded. We also used standard words to prevent confusion.

Study questionnaire
The study questionnaire is divided into two parts. The first part contains questions about patients' demographical and clinical information, including gender, age, duration of illness, social status, education level, residence, diabetes type, other chronic diseases, monthly income, emergency attendance, and several chronic medications currently used. The second part is the Living with Medicines Questionnaire (LMQ). The Arabic version of LMQ version 3 was used to measure MRB experienced by the DM patients. The LMQ-3 consists of 41 items about which participants expressed their overall degree of agreement using a 5 Point Likert scale [ranging from (strongly agree) through to (strongly disagree)]. It contained eight domains: interactions and communication with health care providers (HCPs) regarding medications (five items), practical difficulties (seven items), medications cost burden (three items), side-effects burden of drugs (four items), belief about the efficacy of medicines (six items), concern about medicine use (seven items), interferences of medications with daily life (six items), and control of drug use (three items). The sum of domain scores yields a total scale score (LMQ-3 overall score) measuring the general degree of MRB, varying from 41 to 205, with higher values suggesting greater pharmaceutical loads.

Questionnaire administration
The researcher gathered all of the data needed for this study. After briefly describing the goal of the research and obtaining an informed consent form, the patients completed the questionnaire, which took around 15-20 minutes.

Laboratory and clinical examination
Additionally, the researcher (after patients' permission) ordered blood sample withdrawal for the analysis of glycosylated hemoglobin in all patients involved in this study. Also, the researcher requested examining the patients for diabetic neuropathy using United Kingdom Screening Test, while eye examination was performed by dilated fundus examination by a specialist physician.

Statistical analyses
During the statistical analysis, version 25 of the IBM SPSS Statistics (RRID: SCR 016479) software for Microsoft Windows was used. All research items were analyzed using descriptive statistics (means, standard deviations, frequencies, and percentages). The association between biological parameters and MRB Score was determined using Pearson correlation. Using independent T-tests and one-way analysis of variance (ANOVA) testing, the effect of patients' demographical and clinical features on MRB was determined (total LMQ Score). Furthermore, an independent T-test was employed to assess the associations between medication burden (total LMQ score) and DM control/complications (neuropathy & retinopathy). A P-value below 0.05 was considered statistically meaningful.

Results
The study recruited 193 patients with diabetes mellitus. The participants were adults with an average age of (50.15±13.6 years). More than half (52.8%) of the participating patients were women, and more than three-quarters were married with primary/secondary school education. In addition, the majority (95.3%) have lived in urban areas and had low income (65.8%) (Table 1).

The mean disease duration was (9.32±7.33 years). More than three quarters (83.4%) of the participating patients had type 2 DM, and more than half (51.3%) also had one or more chronic diseases. Additionally, 23.3% of patients had polypharmacy (≥ 5 medications). Less than one-quarter (16.1%) were admitted to the emergency room during the last 12 months. More than one-third had diabetes complications: neuropathy (45.6%) or retinopathy (38.9%) (Table 2).

The mean LMQ score was (122.8±15.5). The findings showed that most of the DM patients experienced a moderate degree of medication burden (72.5%), followed by a high burden (14.5%) and a minimum burden (12.4%), and no burden at all (0.5%), with no patient experiencing extremely high burden (0.0 %) as illustrated in Table 3.

Four LMQ domains had the lowest mean of burden scores (below the average): domain 1 (relationships with HCPs), domain 2 (practical difficulties in using medicines), domain 5 (effectiveness of prescribed medications), and domain 6 (concerns about drugs use). In other words, the patients had good relationships with HCPs, low practical difficulties in
### Table 1. The sociodemographic characteristics of the patients.

| Subcategory          | Frequency (N) | %   |
|----------------------|---------------|-----|
| **Gender**           |               |     |
| Male                 | 91            | 47.2|
| Female               | 102           | 52.8|
| **Education level**  |               |     |
| Illiterate           | 22            | 11.4|
| Primary school       | 89            | 46.1|
| Secondary school     | 59            | 30.6|
| College degree       | 23            | 11.9|
| **Social status**    |               |     |
| Single               | 25            | 13.0|
| Married              | 154           | 79.8|
| Divorced             | 2             | 1.0 |
| Widowed              | 12            | 6.2 |
| **Living place**     |               |     |
| Urban                | 184           | 95.3|
| Rural                | 9             | 4.7 |
| **Cigarette smokers**|              |     |
| Yes                  | 31            | 16.1|
| No                   | 162           | 83.9|
| **Monthly income**   |               |     |
| Less than 0.5 million ID | 127     | 65.8|
| 0.5-1 million ID     | 50            | 25.9|
| More than 1 million ID| 16         | 8.3 |
| **Alcohol drinker**  |               |     |
| Yes                  | 2             | 1.0 |
| No                   | 191           | 99.0|
| **Age (years)**      | Minimum       | Maximum | Mean | Std. Dev |
|                      | 18            | 77       | 50.15| 13.6     |

ID: Iraqi dinar.

### Table 2. The clinical characteristics of the patients.

| Clinical characteristic          | Subcategory          | Frequency (N) | %   |
|----------------------------------|----------------------|---------------|-----|
| **DM type**                      | Type 1 DM            | 32            | 16.6|
|                                  | Type 2 DM            | 161           | 83.4|
| **No. of other chronic diseases**| 0                    | 94            | 48.7|
|                                  | 1                    | 65            | 33.7|
|                                  | 2                    | 31            | 16.1|
|                                  | 3                    | 3             | 1.6 |
| **Emergency admission in the last 12 months** | Yes | 31 | 16.1 |
|                                  | No                   | 162           | 83.9|
| **No. of emergency admission in the last 12 months** | 1 | 8 | 4.1 |
|                                  | 2                    | 15            | 7.8 |
|                                  | 3                    | 3             | 1.6 |
|                                  | ≥3                   | 5             | 2.5 |
| **No. of chronic medications**   | 1                    | 18            | 9.3 |
|                                  | 2                    | 58            | 30.1|
|                                  | 3                    | 42            | 21.8|
|                                  | 4                    | 30            | 15.5|
|                                  | 5                    | 20            | 10.4|
|                                  | 6                    | 13            | 6.7 |
|                                  | ≥7                   | 12            | 6.2 |
using medicine, reasonable belief in their effectiveness, and shared concerns about medicine use. On the other hand, four domains had the highest mean of burden scores: domain 3 (cost related burden), domain 4 (side effects of medicines), domain 7 (impact of using medications on daily life), and domain 8 (autonomy to vary regimen). In other words, the patients had difficulty with medicine costs, could not change their regimen, and their medicine impacted their daily life (Table 4).

There were no significant differences in medication burden (total LMQ) according to patient demographic characteristics (Table 5).

Patients who were admitted to the emergency department (ED) last year had a significantly (P-value <0.05) higher medication burden (total LMQ) compared to not admitted patients (Table 6).

### Table 2. Continued

| Clinical characteristic | Subcategory                  | Frequency (N) | %  |
|-------------------------|------------------------------|---------------|----|
| Neuropathy              | Without Neuropathy           | 104           | 53.9 |
|                         | With Neuropathy              | 88            | 45.6 |
|                         | Examination not accomplished | 1             | 0.5  |
| Retinopathy             | Without retinopathy          | 113           | 58.5 |
|                         | With retinopathy             | 75            | 38.9 |
|                         | Examination not accomplished | 5             | 2.6  |
| DM duration (years)     | Minimum                      | 1.00          | 9.32 |
|                         | Maximum                      | 38.00         | 7.33 |
|                         | Mean                         | 9.32          | 7.33 |

DM: diabetes mellitus.

### Table 3. Perceived MRB using LMQ in patients with diabetes.

| LMQ overall score (mean ± SD) | 122.8±15.5 |
|-------------------------------|------------|
| Degree of burden              | The range of each category | Number of patients | %      |
| No burden                     | (41-73)    | 1           | 0.52   |
| Minimum burden                | (74-106)   | 24          | 12.44  |
| Moderate burden               | (107-139)  | 140         | 72.54  |
| High burden                   | (140-172)  | 28          | 14.50  |
| Extremely high burden         | (173-205)  | -           | -      |

LMQ: Living with Medicines Questionnaire; MRB: medication-related burden; SD: standard deviation.

### Table 4. Descriptive statistics of LMQ domains.

| LMQ themes                               | Minimum | Maximum | Mean   | Std. deviation |
|------------------------------------------|---------|---------|--------|----------------|
| Domain 1: Relationships with HCPs        | 6.00    | 20.00   | 12.52  | 2.26           |
| Domain 2: Practical difficulties in using medicines | 9.00    | 29.00   | 20.10  | 3.88           |
| Domain 3: Cost-related burden            | 4.00    | 15.00   | 11.41  | 2.63           |
| Domain 4: Side effects of medicines      | 4.00    | 19.00   | 12.68  | 3.25           |
| Domain 5: Effectiveness of prescribed medications | 8.00    | 22.00   | 14.29  | 3.08           |
| Domain 6: Concerns about medicines use   | 14.00   | 35.00   | 22.45  | 3.77           |
| Domain 7: Impact of using medicines on daily life | 6.00    | 28.00   | 19.20  | 3.92           |
| Domain 8: Autonomy to vary regimen       | 5.00    | 15.00   | 10.20  | 1.73           |

HCPs: health care professionals; LMQ: Living with Medicines Questionnaire.
### Table 5. Influence of patients’ demographics on medication burden (total LMQ).

| Characteristics  | N     | Mean  | Std. deviation | P-value |
|------------------|-------|-------|----------------|---------|
| **Total LMQ**    |       |       |                |         |
| Age <65 years    | 169   | 123.03| 15.52          | 0.661   |
| ≥65 years        | 24    | 121.54| 15.79          |         |
| **Gender**       |       |       |                |         |
| Total LMQ Male   | 91    | 122.20| 15.41          | 0.586   |
| Total LMQ Female | 102   | 123.42| 15.67          |         |
| **Residence**    |       |       |                |         |
| Total LMQ Urban  | 184   | 122.92| 15.74          | 0.749   |
| Total LMQ Rural  | 9     | 121.22| 10.52          |         |
| Total LMQ No     | 191   | 122.95| 15.55          |         |
| **DM type**      |       |       |                |         |
| Total LMQ Type 1 | 32    | 125.47| 15.41          | 0.296   |
| Total LMQ Type 2 | 161   | 122.32| 15.54          |         |
| **Social status**|       |       |                |         |
| Total LMQ Without spouse | 39 | 123.95| 15.39          | 0.62    |
| Total LMQ With spouse | 154 | 122.56| 15.59          |         |
| **Income**       |       |       |                |         |
| Total LMQ <0.5 million ID | 127 | 123.36| 15.62          | 0.518   |
| Total LMQ 0.5-1.0 million ID | 50 | 122.88| 13.35          |         |
| Total LMQ >1.0 million ID | 16 | 118.63| 20.78          |         |
| **Education**    |       |       |                |         |
| Total LMQ Illiterate | 22 | 128.32| 14.03          | 0.057   |
| Total LMQ primary school | 89 | 123.47| 14.44          |         |
| Total LMQ Secondary school | 59 | 122.56| 15.23          |         |
| Total LMQ University | 23 | 115.91| 19.67          |         |

ID: Iraqi dinar; LMQ: Living with Medicines Questionnaire.

### Table 6. Influence of patients’ clinical characteristics on medication burden (total LMQ score).

| Clinical characteristics | N     | Mean  | Std. deviation | P-value |
|--------------------------|-------|-------|----------------|---------|
| **DM type**              |       |       |                |         |
| Total LMQ Type 1         | 32    | 125.47| 15.41          | 0.296   |
| Total LMQ Type 2         | 161   | 122.32| 15.54          |         |
| **ED admission last year**|     |       |                |         |
| Total LMQ Yes            | 31    | 130.65| 11.83          | 0.002*  |
| Total LMQ No             | 162   | 121.35| 15.72          |         |
| **Chronic disease**      |       |       |                |         |
| Total LMQ No             | 94    | 122.10| 16.49          | 0.515   |
| Total LMQ Yes            | 99    | 123.56| 14.59          |         |
| **No. of chronic medications** | |       |                |         |
| Total LMQ ≤5             | 168   | 122.48| 15.72          | 0.394   |
| Total LMQ >5             | 25    | 125.32| 14.17          |         |
There were significant (P-value <0.05) differences in medication burden in terms of total LMQ scores according to diabetes control (HbAlc) and complications (neuropathy and retinopathy). In other words, patients with uncontrolled blood glucose (high HbA1c), neuropathy, or retinopathy had a significantly (P-value <0.05) higher medication burden (total LMQ) (Table 7).

**Discussion**

Diabetes is a chronic condition requiring long-term medical treatment. Whenever lifestyle adjustments alone fail to achieve or maintain the desired glycemic control, the majority of patients are routinely recommended prescription medicine. The vast majority of published studies have understood the biological viewpoint of MRB as the quantity of pills or treatments frequently taken by specific patients to treat their conditions, ignoring the patient’s views. To our knowledge, no published research has quantified MRB amongst diabetic patients in Iraq. Consequently, the purpose of this research was to assess the problems diabetic patients encounter with drugs that contribute to the overall MRB and the variables that affect them.

The current study indicated that nearly all the participants (99%) suffered from varying degrees of MRB. A study in Qatar found that 90% of DM patients were suffering from MRB. Utilization of prescription medication to manage glucose levels and manage concomitant illnesses is an important aspect of diabetes therapy and might even greatly contribute to the MRB for this disease. The most frequent degree of MRB in the current study was moderate burden (72.5%); however, inconsistent with the results of the present study, most DM participants in Qatar were of minimum burden (66.8%). The high level of services administered to DM patients in Qatar at low cost and in one clinical setting may explain such findings.

Four domains had the highest mean of burden scores: cost-related burden, side effects of medicine, the impact of using medication on daily life, and autonomy to vary regimen. Traditionally the focus of guidelines for clinical practice on specific diseases, the growing coexistence of various chronic conditions, and the lack of systematic strategies for addressing issues related with the implications of therapies supposed that patients with long-term illnesses such as DM had to deal with complex medication-related instructions and tasks for the remainder of their lives. Dealing with the unpleasant effects of medication and needing to adjust daily activities to meet the requirements of therapeutic interventions imposes an additional stress on individuals. On the other hand, the patients had good relationships with HCPs, low practical difficulties in using medicine, reasonable belief in their effectiveness, and shared concerns about medicine use. The preponderance of patients with T2DM in Iraq (76.3%) according to a prior research were adamant

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**Table 6. Continued**

| Disease duration | N  | Mean  | Std. deviation | P-value |
|------------------|----|-------|----------------|---------|
| Total LMQ ≤5 years | 73 | 120.60 | 14.35 | 0.118 |
| >5 years         | 120| 124.21 | 16.10 |         |

*Significant (P-value <0.05) according to independent T-test; DM: diabetes mellitus; ED: emergency department; LMQ: Living with Medicines Questionnaire.

**Table 7. The relationships between medication burden (total LMQ) and DM control/complications (neuropathy & retinopathy).**

| Medication burden parameter | HbA1c | N  | Mean  | Std. deviation | P-value |
|-----------------------------|-------|----|-------|----------------|---------|
| Total LMQ ≤7               | 35    | 115.06 | 15.09 | 0.001*         |
| >7                         | 157   | 124.65 | 15.14 |             |

| Neuropathy | No | 104 | 119.60 | 14.33 | 0.001* |
|------------|----|-----|--------|-------|--------|
| Yes        | 88 | 126.84 | 16.05 |       |        |

| Retinopathy | No | 113 | 120.55 | 15.21 | 0.009* |
|-------------|----|-----|--------|-------|--------|
| Yes         | 75 | 126.49 | 15.26 |       |        |

*Significant (P-value <0.5) according to independent T-test. DM: diabetes mellitus; HbA1c: haemoglobin A1c; LMQ: Living with Medicines Questionnaire.
about the requirement of anti-diabetic therapy for ensuring constant glycemic control (scores of specific-necessity were more significant than the score of specific-concern).29

There were no significant differences in medication burden (total LMQ) according to patient demographic characteristics. However, a study in Qatar found that unmarried, female gendered DM patients demonstrated significantly higher scores of medication burden.19 Patients admitted to ED last year had substantially higher MRB (total LMQ) compared to not admitted patients. Previous studies showed that high MRB leads to decreased medication adherence,19,22 and the non-adherence to medication increases emergency room visits and hospitalization.30 Patients with uncontrolled blood glucose (high HbA1c), neuropathy, or retinopathy had significantly higher medication burdens. Diabetes-related microvascular and macrovascular complications in many patients with type 2 diabetes result in polypharmacotherapy and a high pill burden.31,32

The limitations of the present research demand examination. First, an MRB measurement was patient-reported and hence subjective. The research sample was limited to a single site; therefore, the results may not be representative of the population of individuals with DM in Iraq. Thirdly, due to the cross-sectional design of the research, we were unable to examine how these patient experiences evolved over time.

Conclusions
The medicine burden for diabetic people is at a very high level. This knowledge may assist pharmacists, doctors, nurses, and other clinicians, as well as policymakers, in comprehending MRB for people with diabetes. Accordingly, future studies should continue to measure MRB while moving the science toward developing interventions aimed at reducing such burdens.

Data availability
Underlying data
Zenodo: Demographic details, as well as questionnaire responses, https://doi.org/10.5281/zenodo.6968395.33

This project contains the following underlying data:

- Article’s data.xlsx (Demographic details, as well as questionnaire responses)

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

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