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SYSTEMATIC REVIEW

The Use of EQ-5D in the Middle East and North Africa Region: A Systematic Literature Review

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Abstract

Introduction The EQ-5D is the most commonly used preference-based measure of health-related quality of life. There is limited evidence about the use of the EQ-5D in the Middle East and North Africa (MENA) region. This study aimed to systematically identify, review, summarize, and synthesize the published literature on using the EQ-5D in this region.

Methods A systematic literature review was conducted, according to the PRISMA 2020 guidelines, using PubMed, Cochrane, PsycINFO, and CINAHL and covering the period up to 30 August 2024. Studies using any version of the EQ-5D in adults or youth in the MENA region were included. Pilot studies, guidelines, study protocols, and reviews were excluded. Key study characteristics and outcomes assessed included study design, clinical area, population, type of EQ-5D data reported, reference value set used, and mode of administration. Title/abstract screening was conducted independently by two reviewers to assess eligibility for inclusion. Two researchers completed full-text screening and extracted data using a standardized form. Disagreements were referred to a third reviewer if not resolved by discussion. Results were summarized in systematic evidence tables.

Results After removing duplicates, 18,034 references were considered for title/abstract screening. In total, 184 studies were included with a total sample size of 128,164 subjects. Of the included single-country studies, 42% were reported in Iran, 20% in Saudi Arabia, and 11% in Jordan. Patient populations were investigated in 86% of the studies, 23% of which targeted endocrine diseases. Study design was observational in 57% and experimental in 14% of the studies. Only 10% of the included studies applied the EQ-5D in an economic evaluation. The EQ-5D-3L version was used in 40% of the studies. However, the trend is towards a greater use of the 5L version in more recent years. Twenty percent of the studies reported EQ-5D results using the index score, frequencies of severity levels per dimension, and visual analog scale scores. EQ-5D modes of administration and funding sources were not reported in 16% and 20% of the studies, respectively.

Conclusion There is an increased use of the EQ-5D in the MENA region, especially since 2020. In the region, the use of the EQ-5D is more prevalent in clinical studies than in economic evaluation studies. The reporting heterogeneity indicates the need for guidance in reporting EQ-5D study results in this region.

1 Introduction

With increased life expectancy and budget constraints, measuring and valuing health-related quality of life (HRQoL) is essential for developing value-based healthcare systems and implementing health technology assessment (HTA). Several instruments are used to measure HRQoL; some are disease-specific, while others are generic. Certain tools generate health profiles, whereas others produce an index score reflecting HRQoL [1]. Tools that generate index scores may be preference-based or non-preference-based measures [1]. Selecting an appropriate HRQoL instrument depends on the purpose and desired outcomes.

Generating health state preferences values, commonly called 'utilities', typically involves the use of generic preference-based measures (GPBMs) to value health states and summarize health-related quality of life as a single index number, which allows the calculation of quality-adjusted life years (QALYs) [1]. This is a metric that combines mortality and morbidity, requiring two components for its calculation: life years and HRQoL values to adjust life years [2]. QALYs can be used to measure the burden of diseases, but also to assess the relative effect of health technologies in comparative effectiveness studies or economic evaluations [3, 4]. Health economic evaluation—specifically, cost-utility

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Key Points for Decision Makers

The EQ-5D is primarily used in the Middle East and North Africa (MENA) region for clinical purposes as a patient-reported outcome rather than for utility calculation in economic evaluations.

Reporting guidelines are needed for studies that use the EQ-5D or any other generic preference-based measures for clinical or economic evaluation purposes.

In the absence of national value sets, the EQ-5D-3L UK value set is the most commonly used scoring algorithm for calculating EQ-5D index scores in the MENA region.

analysis—is a major component of HTA, and it aligns with value-based healthcare principles [4]. Cost-utility analysis is a subtype of health economic evaluation that uses QALYs as the primary health outcome instead of natural health outcomes, such as survival or complications avoided [2, 4, 5]. Although QALYs are suitable for benefit–harm assessment [6], they are more frequently used in economic evaluation studies using modelling techniques to assess the effect of an intervention during a sufficiently long time horizon [7].

The EQ-5D is by far the most commonly used GPBM in cost-utility analyses [8]. It has been applied in a wide range of health conditions and treatments, including chronic disorders such as diabetes mellitus, asthma, and cancer [9–12], but also to assess the effect of treatments [13] and vaccination programs against infectious diseases [14]. It provides a simple descriptive profile and a single index value for the health status that can be used in benefit–harm assessments, economic evaluations of health care, clinical studies, population health surveys, and routine outcome measurements [15–17].

The EQ-5D consists of five health dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression [18, 19]. The EQ-5D-3L version considers three levels of severity, while the EQ-5D-5L version considers five levels of severity for each dimension [18, 19]. In addition, there is a separate 3L version for children and adolescents older than 3 years of age and the 5L version is forthcoming [20]. The EQ-5D-5L has refined 'granularity' with the increased severity levels from three to five. This resulted in 3125 possible health states for the 5L version compared with 243 for the 3L version. The refinement from 3L to 5L has improved sensitivity and precision compared with the 3L version [21].

Several modes of administration (MoAs) are available to complete the EQ-5D questionnaire, including a self-reported version, interviewer-administered version, face-to-face interviews, telephone interviews, and proxy versions. EQ-5D data can be collected digitally using platforms or using a paper version [22].

Health profiles (states) at a given point in time are described by answering the EQ-5D questionnaire through selecting the severity level under each dimension that matches the respondent's health status at that time, or as described in a hypothetical scenario. After answering all questions, a five-digit code ranging from 1 to 3 or 1 to 5, depending on the EQ-5D version used (3L or 5L), will be generated, describing the health state of that respondent. For a cost-utility analysis, it is necessary to value those health states by using a scoring algorithm (value set) that translates each health state into a single index number (i.e., utility), where 1 represents perfect health, 0 represents death, and negative values indicate a health status worse than death [18, 19].

Despite the widespread use of EQ-5D, little is known about its use in the Middle East and North Africa (MENA) region in different types of health service research studies (e.g., QALYs calculation for cost-utility analyses, outcome measure in clinical studies, a health indicator in population surveys, or an outcome in real-world evidence studies). The MENA region is shaped by diversity and transformation. It includes 19 countries from North Africa, through the Levant area, to the Arabian Peninsula. It has a strategic location, with a total population of 490,477,399 in 2023 [23] and it is responsible for 40% of the world's oil exports [24]. The MENA countries share some similarities in language, religion, and cultural aspects. However, there is variation in countries' income levels, available resources, and healthcare system development. Some countries in the region are experiencing political instability, hindering their economic growth and social development [25, 26]. The region's epidemiological transition, coupled with the rapid population growth and inefficiencies in healthcare spending within such a diverse context, imposes challenges to healthcare systems' sustainability. Cardiovascular diseases, cancer, and diabetes are the drivers of one third of the disease burden in the region [26, 27]. However, despite high spending on health care as a percentage of the gross domestic product (GDP) in some MENA countries, this spending is not always translated into positive health outcomes [28]. As a result, there is increased investment in healthcare system reforms, and a transition toward value-based healthcare [29, 30]. Moreover, most countries in the MENA region are committed to achieving universal health coverage (UHC) by 2030 [29]. To support this goal, they are increasingly adopting priority-setting tools such as HTA to identify health technologies and benefit packages that provide the greatest value to patients and healthcare systems [31, 32, 33].

Understanding the areas of EQ-5D application in the MENA region will reflect on the level of HTA development, provide insights into the use of patient-reported outcomes, and highlight how EQ-5D studies are implemented in the MENA region. Therefore, in this systematic review, we aim to systematically identify, review, and synthesize the published literature on the use of EQ-5D in the MENA region.

2 Methods

2.1 Study Design

A systematic literature review was conducted through August 30, 2024. The study was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [34] and adapted some aspects of a previously published systematic review of the use of the EQ-5D in Central and Eastern Europe (CEE) [35]. The study aimed to answer the following specific research questions:

1. In which clinical areas has the EQ-5D been used in MENA countries?
2. What was the Mode of Administration (MoA) used for the EQ-5D questionnaire?
3. Which EQ-5D version was used? EQ-5D-3L, EQ-5D-5L, or EQ-5D-Y
4. How was the quality of life reported? As a utility index score, frequency of reported levels per each dimension, visual analog scale (VAS) value, or other approaches?
5. Which tariff (or value set) was used in the utility calculation?
6. Which type of study design was applied?
7. Whose utilities/health-related quality-of-life profiles have been collected—patients, healthcare workers, general population, or caregivers?

2.2 Inclusion and Exclusion Criteria

Studies using any version of the EQ-5D in adults or youth in the MENA region as defined by the World Bank were included [36]. Pilot studies, guidelines, study protocols, and reviews were excluded. Table 1 provides the review's inclusion and exclusion criteria in more detail within the context of population, intervention, comparator, and outcomes (PICO). The systematic search code included the combination of one search domain coding any terms or synonyms for EQ-5D, quality of life, or economic evaluation with a second domain comprising the MENA region countries. We defined the included MENA countries based on the definition of the World Bank [36]. The detailed literature search code is presented in Electronic Supplementary Material (ESM) 1.

2.3 Databases

Four main electronic databases were searched: PubMed, Cochrane, PsycINFO, and CINAHL. Language was limited to English, French, and Arabic, being the three main languages in the MENA countries. A hand search of the reference lists from included studies was conducted to complement the database search.

2.4 Study Selection

Title and abstract screening were conducted independently by two out of a pool of three reviewers (AAR, SP, RS) to assess eligibility for inclusion. Two researchers (AAR, SP) completed the full-text screening. Disagreements were solved by discussion between the two reviewers. If the disagreement could not be resolved, a third reviewer (FAS) was consulted to make a final decision. All references were collected using the Endnote 21 reference manager [37]. The number of excluded articles and reasons for exclusion were documented in the PRISMA flow chart on the level of full-text screening. An R package linked to a Shiny application was used to produce the PRISMA 2020 flow diagram [38].

2.5 Data Extraction

Data were extracted and double-checked by two reviewers (AAR, SP) using a defined standardized data extraction form. The EviAtlas tool was used to produce a visualized evidence map of the systematic review results [39].

The International Statistical Classification of Disease and Related Health Problems, 10th Revision (ICD-10) was used to standardize disease names [40]. We collected the following information: year of publication, multi-country (MC) or a single-country (SC) study, countries, World Bank income classification, funding source, study design, sample size, disease area, EQ-5D version, type of study population, tariff (value set used), value set elicitation method, additional HRQoL tools and their names, and the reporting method of EQ-5D data (i.e., mean/median EQ-5D index score, mean/median EQ-5D VAS score, frequency of severity level, or a combination of these reporting methods.

2.6 Data Synthesis

We applied narrative synthesis rather than meta-analysis due to the high heterogeneity in the included studies. Also, our interest was in exploring the use of the EQ-5D in the

Table 1 Systematic review inclusion and exclusion criteria

Selection criteria	Inclusion	Details
Population	Adult and pediatric patients, general public, healthcare providers in the MENA region countries	MENA region countries: Algeria, Bahrain, Djibouti, Egypt, Iran, Iraq, Jordan, Kuwait, Lebanon, Libya, Morocco, Oman, Palestine, Qatar, Saudi Arabia, Syria, Tunisia, United Arab Emirates, Yemen Multi-country studies that include countries from the MENA region, along with countries from other regions, are included if the results for the MENA countries are reported separately
Intervention	Use of EQ-5D, all versions (3L, 5L, and youth)	
Comparators	There is no comparator	
Outcomes	EQ-5D version, clinical areas, value sets (tariffs) for utility calculations, study types, study population (patients, general population, caregivers, healthcare workers), results reporting method: number, percentages, or scores (VAS, index, dimensions), mode of administration	
Study design	Randomized controlled trials, observational studies, valuation studies (population surveys), cost-utility analyses along clinical trials, decision-analytic modeling studies	We included both randomized and non-randomized study designs because HRQoL is usually included as an endpoint under these designs Excluded: Qualitative studies, pilot/feasibility studies, protocols, reviews or systematic reviews, guidelines Modeling studies were included only if the utilities were collected directly from the study population as input parameter for the model
Language	Arabic, English, and French	These are the three main languages in the MENA region
Other	Full texts and abstracts, time period: from inception up to August 30, 2024	

HRQoL health-related quality of life, *MENA* Middle East and North Africa, *VAS* visual analogue scale

MENA region, rather than producing estimates of particular health state values. While developing the initial synthesis, our study primarily relied on textual descriptions of studies and applied tabulation, clustering, and grouping tools and techniques [41]. Descriptive analysis was conducted using Microsoft Excel and R version 4.4.1.

2.7 Risk-of-Bias Assessment

The primary aim of our review was to identify how the EQ-5D has been utilized in the MENA region rather than estimating treatment effects or specific outcomes. Therefore, the quality of each included study was not assessed.

3 Results

Identified and selected studies are shown in the PRISMA 2020 flow diagram in Fig. 1. Our systematic search identified 19,517 studies. An additional eighteen studies were identified through hand searching, and five studies through citation snowballing. After title and abstract screening and removing duplicates, 404 studies were considered for the full-text screening. Finally, 184 studies fulfilled the inclusion criteria and entered the data extraction phase with a total sample size of 128,164 subjects.

3.1 Study Characteristics Results

We identified 184 published studies using the EQ-5D in the MENA region. Of the included studies, 96% were SC studies, and 4% were MC studies. Publication of EQ-5D studies in the MENA region started in 2011 with only one MC study and two SC studies from Lebanon [41–44]. Figure 2 shows the trend of EQ-5D publications in the MENA region. From 2011 to 2013, the number of studies remained stable, followed by a slight annual increase from 2014 to 2016. Between 2017 and 2019, the number of published studies fluctuated. However, starting in 2020, the region witnessed a significant rise in the use of EQ-5D in applied research, with 74% of the studies published between 2020 and 2024, peaking in 2021 with the highest number of EQ-5D publications.

In SC studies, three countries (Iran, Saudi Arabia, and Jordan) contributed to 73% of the total publications in the MENA region. Around 42% of the included studies were conducted in Iran (Fig. 3). The EQ-5D was further used in Algeria, Oman, Libya, and Yemen as part of an MC study [42]. Saudi Arabia is the main contributor to MC EQ-5D

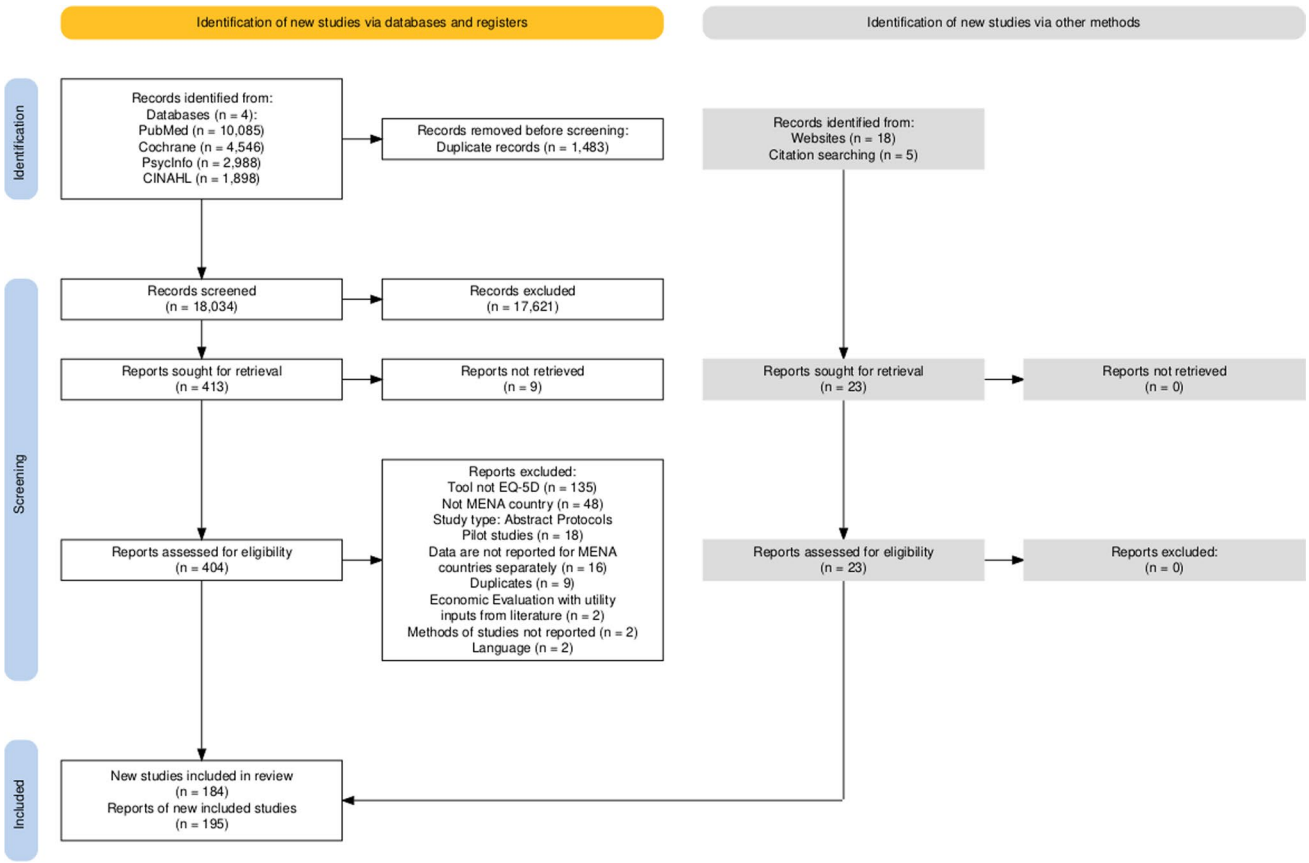

Fig. 1 PRISMA 2020 flow chart. Produced using Haddaway et al, R package and Shiny app for producing PRISMA 2020-compliant flow diagrams. *MENA* Middle East and North Africa

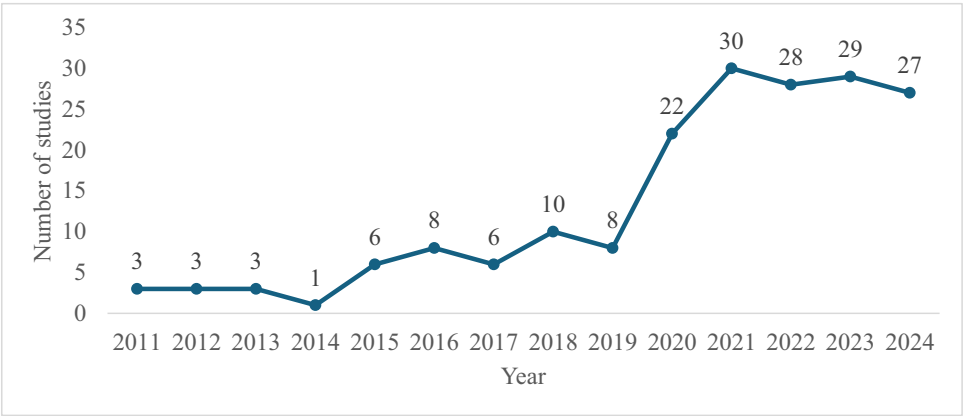

Fig. 2 Trend of EQ-5D published studies in MENA region (2011 to August 2024). *MENA* Middle East and North Africa

studies in the MENA region. No published studies using the EQ-5D were found in Djibouti and Iraq. Most of the SC studies were conducted in low- and middle-income countries (LMICs) (Iran, Egypt, Jordan, Syria, Lebanon, Palestine, Algeria, Tunisia, and Morocco). In contrast, 43 SC studies were conducted in high-income countries (HICs), including primarily Saudi Arabia, as well as Qatar, Kuwait, and United Arab Emirates (UAE). Stratifying studies by included countries per year, we found that Iran contributed to most of the reported studies from 2021 to 2024. Figure 4 shows the trend of published SC EQ-5D studies per country.

Universities funded 31% of the included studies, while the funding source was not mentioned or not clearly reported

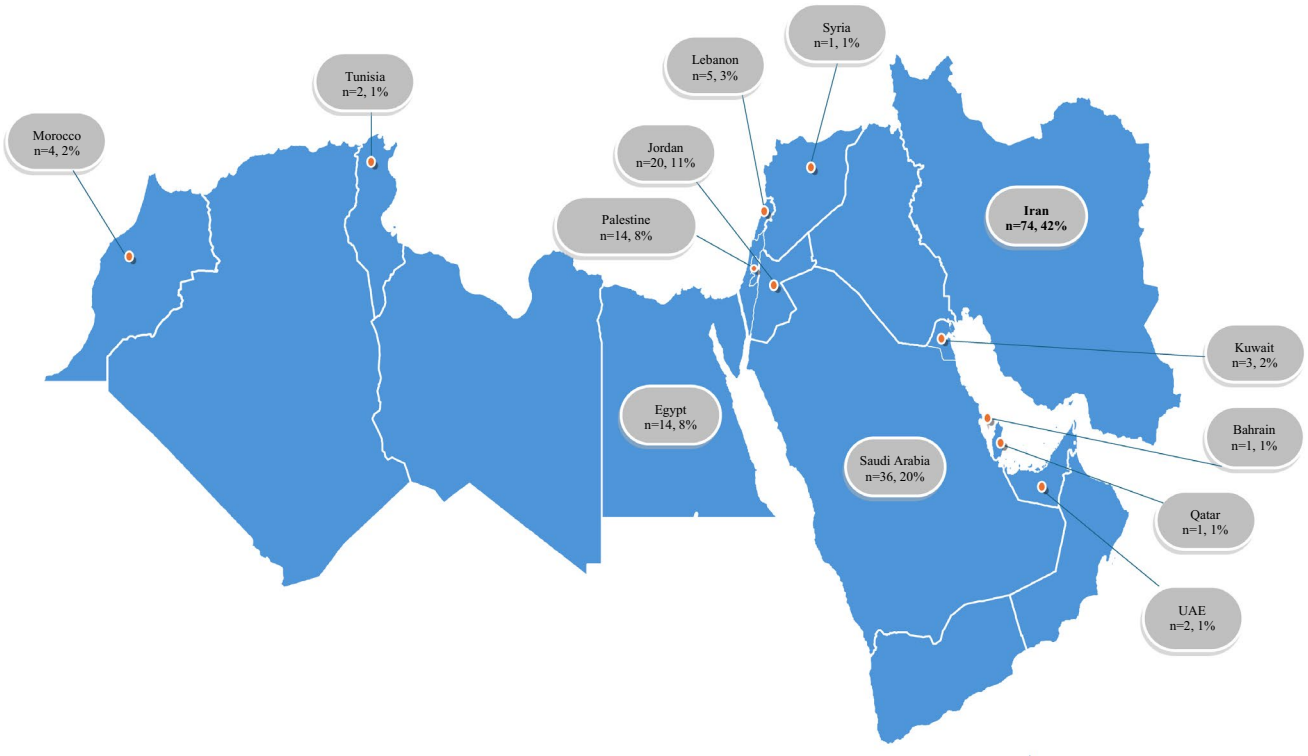

Fig. 3 MENA region map showing the number and percentage of studies per single-country studies. *MENA* Middle East and North Africa

in 20% of the studies. Pharmaceutical companies funded 5% of included studies, half of which were MC studies. The remaining half comprised three studies conducted in Iran [44–47] and two in Saudi Arabia [48, 49]. Only a limited number of studies were funded by non-university research institutes, hospitals, or external funds, and 31% were conducted without reporting any external funding.

3.2 Methodological Aspects of the Studies

3.2.1 Study Population

Most of the studies focused on patients (86%). Fourteen percent of the studies targeted the general population, with most conducted in Iran, followed by Egypt, Saudi Arabia, and Lebanon, each with two studies. Moreover, 23% of the studies targeting the general population are EQ-5D valuation studies. The value set of Tunisia, published in 2021 [50], is based on the EQ-5D-3L. The value sets of Egypt (2022) [51] and Saudi Arabia (2024) [49] are based on the EQ-5D-5L. Iran published three value sets. The first one was published in 2016 using the VAS method to generate weights for EQ-5D health states [52]. The second value set was published in 2019, which used the time trade-off (TTO) method, and was specific to the general population in Iran's capital city [53]. The third value set, published in 2023, used the TTO method for the EQ-5D-5L and was nationally representative, covering the entire country [54].

The pediatric population was included in five studies despite not using an EQ-5D-Y value set [55–59]. Three studies focusing on caregivers were conducted in Jordan, Saudi Arabia, and Iran [56, 60, 61]. One study targeted addicted individuals in Jordan [62], while another focused on Syrian refugee patients in Jordan [63].

3.2.2 Studied Disease Areas

Endocrine diseases (mostly type 2 diabetes mellitus) were the most studied disease area (23%), followed by musculoskeletal diseases (mostly osteoarthritis), diseases of the nervous system (mostly multiple sclerosis), neoplasms (mostly breast and colorectal cancers), and diseases of the circulatory system (mostly hypertension) (Fig. 5).

3.2.3 Study Designs

The most commonly applied study design is the observational study design (57%), with cross-sectional studies dominating (90%). Around 14% of the studies were randomized control trials (RCTs), mostly conducted in Saudi

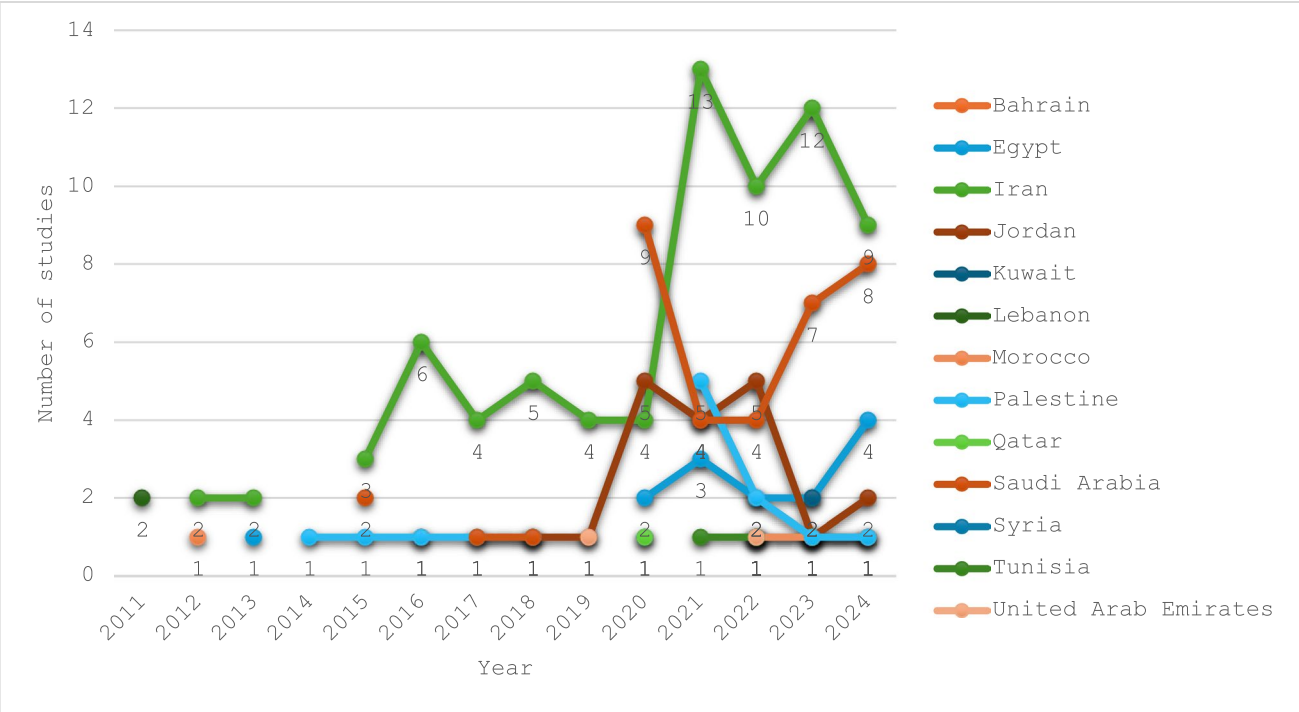

Fig. 4 Trend of EQ-5D published single-country studies per year and country (2011 to August 2024)

Arabia, followed by Egypt. RCTs were mainly conducted in patients with diseases of the musculoskeletal system and connective tissue. Almost 10% of the included studies are economic evaluations, including 6% cost-utility analyses alongside clinical trials [45, 55, 57, 63–71], and 4% decision-analytic modeling studies that used utility scores primarily collected for the economic evaluations [59, 71–78]. Iran conducted 89% of the included economic evaluation studies. Details of study designs per country are reported in Table S1 of ESM 2.

About half of the included studies (57%) have a sample size between 101 and 500 participants, and 10% of the included studies have surveyed more than 1000 participants. Studies targeting the general population had larger sample sizes and accounted for 47% of the total sample in our systematic review. Details of sample size per country are reported in Table S1 of ESM 2.

3.2.4 Intervention: EQ-5D Version

The version of the EQ-5D (3L or 5L) was explicitly mentioned in 65% of the studies, while 16% reported using EQ-5D without mentioning the specific version used. One percent of the studies used only the EQ-VAS [43]. However, the trend is towards a greater use of the 5L version in more recent years. The EQ-5D youth version was not used in any of the included studies, and none of the MENA countries have a EQ-5D-Y value set. A closer look showed that the 3L version was used more in studies focusing on the general population, while the 5L was used more in patient populations. Furthermore, in Iran, the EQ-5D-3L (50%) version was used more than the EQ-5D-5L (24%) version; however, the version was not reported in 22% of the published studies from Iran. Since 2019, the use of the EQ-5D-5L version started to increase, becoming more prevalent than the EQ-5D-3L version. Figure 6 shows the trend of the use of the EQ-5D versions in the MENA region. Details of the EQ-5D version used per country are reported in Table S1 of ESM 2.

3.2.5 Data Collection and Mode of Administration

The MoA was not reported in 16% of the studies. Interviews were reported in 13% of the studies as the MoA without mentioning the specific mode of interview administration (face-to-face, virtual, or telephone interview). The most frequent MoA was face-to-face interviews (29%). A combined MoA was applied in 10% of the studies included, with face-to-face interviews and telephone interviews being the most common MoA. Details of MoA per country are reported in Table S1 of ESM 2.

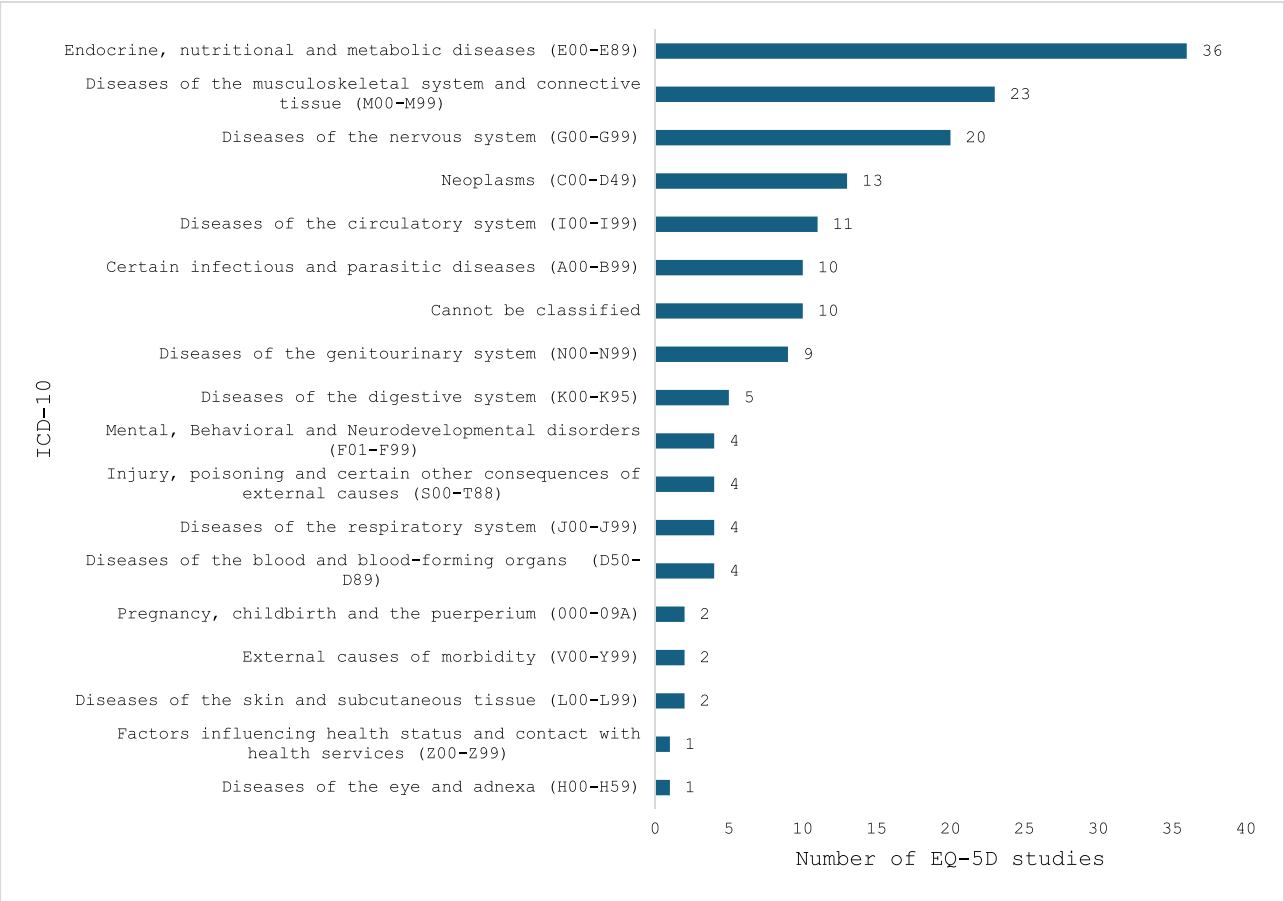

Fig. 5 EQ-5D use per clinical area. *ICD-10* International Classification of Diseases, 10th Revision

3.2.6 Value Set Use and Calculation of Utility Index Score

In studies reporting EQ-5D results as utility index scores, the country-specific value set used was not reported in 28% of the studies. The UK value set (TTO) was used in 21% of the studies, with the 3L version being the most commonly used value set, while 22% used other value sets. For example, studies using data from Iran mostly applied the national value set. However, the value sets used differed in terms of elicitation method (TTO versus VAS), as more than one national value set is available for Iran [51–54]. One study from Iran [84], two studies from Palestine [85, 86], and one multi-country study (Saudia Arabia and Kuwait) [87] used the United States value set. One study from Jordan used the Tunisian value set [88], and one study from Saudi Arabia used the value set from Thailand [89]. Two studies conducted in Egypt used the value set from Zimbabwe [90, 91], while two Egyptian studies applied the national value set [92, 93]. Further details of the EQ-5D value sets used in the MENA region are reported in Table S1 of ESM 2.

3.2.7 Use of Additional HRQoL Tools

Almost 19% of the studies used at least one other disease-specific HRQoL tool, such as the EORTC QLQ-C30 scale, the Osteoarthritis Knee and Hip Quality of Life instrument (OAKHQoL), and/or another generic tool (e.g., SF-36, Health Utility Index) in addition to the EQ-5D to measure health-related quality of life.

3.3 Reporting of EQ-5D Results

The study results on the EQ-5D were reported as index scores (mean or median), EQ-VAS score (mean or median), descriptive frequencies per each domain-specific severity level, or a combination of the three descriptors depending on the study objectives.

Approximately 20% of the studies jointly reported utility index scores, EQ-VAS scores, and frequencies of severity levels. Results were reported as index scores only in 17% of the studies, 16% as index scores and EQ-VAS scores, and 8% reported EQ-VAS scores only. Figure 7 shows the different ways of reporting EQ-5D results.

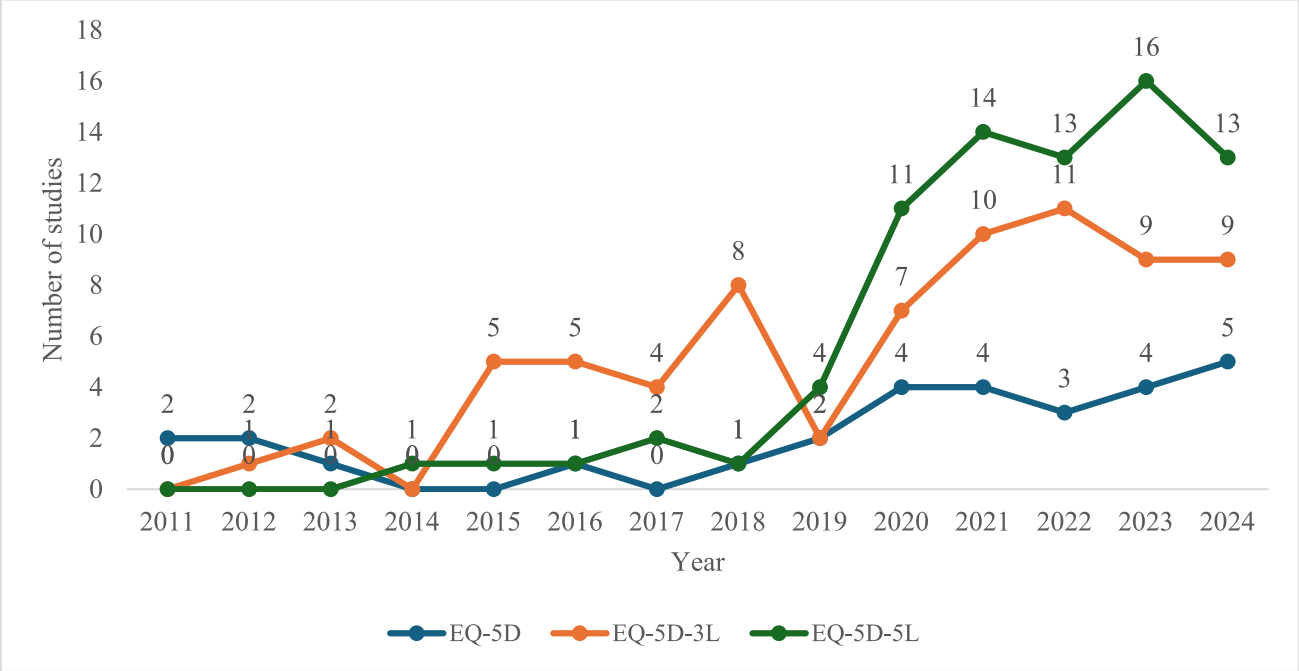

Fig. 6 Trend for EQ-5D version used in the MENA region (2011 to August 2024). *MENA* Middle East and North Africa

Around 11% of the studies' reports showed the EQ-5D results using atypical analysis methods. For example, some studies applied a Likert scale to the EQ-5D profile or used the sum scores of EQ-5D severity levels (Fig. 7).

4 Discussion

We performed a systematic review to identify, summarize, and synthesize the published literature on using the EQ-5D in the MENA region. Our review followed the PRISMA guidance [34] and resulted in 184 studies corresponding to 195 reports. This section will focus on seven themes from our systematic review based on identified trends and patterns.

4.1 Single-Country versus Multi-Country EQ-5D Studies

Multi-country studies have identified some of the regional challenges in HRQoL research, highlighted the most studied diseases, and showed which countries are primarily involved in such studies. Multi-country studies cover larger sample sizes, making their results more generalizable compared with SC studies. However, MC studies might not reflect the specific context of each country, which could influence the interpretations of results. Nevertheless, MC studies highlight the diseases where the EQ-5D is most commonly applied in the MENA region. For example, the A1chieve observational study was a large MC study that included most of the countries in the MENA region [42]. Published in 2011, it generated several reports that incorporated EQ-5D data. It is an international, prospective, multi-center, open-label, observational study that measured the HRQoL of patients with type 2 diabetes mellitus using insulin-analogue therapies. This study also highlighted a major limitation: the lack of HRQoL publications in the MENA region to serve as a reference for comparisons with the A1chieve study [42].

Moreover, 71% of the MC studies in our review were funded by pharmaceutical companies, in contrast with only 3% of the SC studies. This emphasizes the importance of encouraging more MC observational studies in the region, as they attract funding and facilitate collaboration between LMICs and HICs. Also, our results showed that Saudi Arabia is more involved in MC studies than other countries in the region, likely due to its large market size.

4.2 Pattern of EQ-5D Studies Within the MENA Region Countries

Our study shows an increased trend in the use of the EQ-5D tool in the MENA region. Around 74% of all included studies were published between January 2020 and August 2024. On the aggregate level, the use of the EQ-5D-3L version was comparable to the use of the EQ-5D-5L, even though the 5L

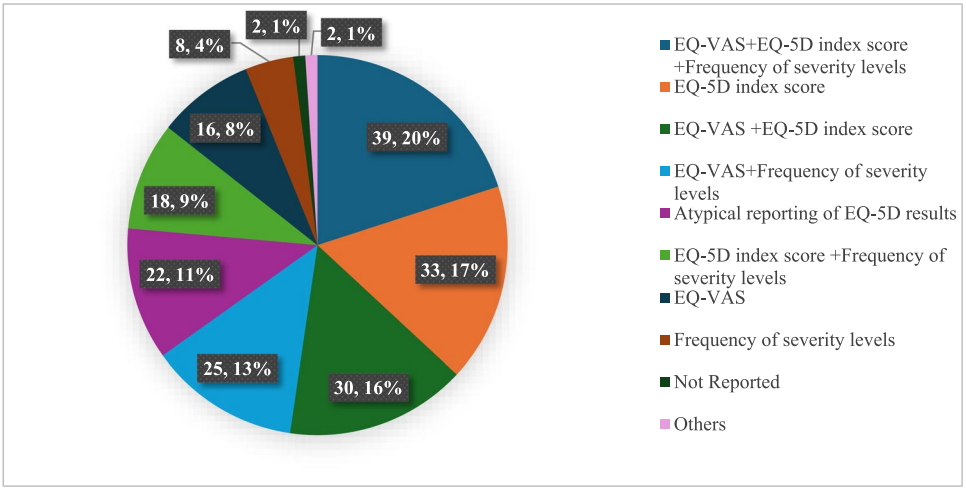

Fig. 7 Reporting patterns of EQ-5D results. *VAS* visual analogue scale

version was introduced in 2009 [15]. However, the trend is towards a greater use of the 5L version in more recent years.

Furthermore, the availability of EQ-5D versions translated in various languages, along with different MoAs and platforms, likely contributed to the growth in EQ-5D publications [94].The first Arabic self-reported EQ-5D-5L paper version was introduced in Jordan, the United Arab Emirates, and Lebanon in 2014. In Iran, the Farsi EQ-5D-5L paper version was introduced in 2015 [15, 94]. Moreover, the use of the EQ-5D in the MENA region is driven by studies from LMICs, which account for 75% of the studies. This is explained by the contribution of studies from Iran, an LMIC with a GDP of US$4466 and a total life expectancy at birth of 75 years [95, 96]. We created a bubble plot showing the relationship between GDP, life expectancy at birth, and number of studies across the MENA countries (Fig. 8). The rationale behind this pattern can be attributed to the development of HTA in Iran, which dates to the late 2000s. HTA development in Iran started earlier than in most other countries in the region [97]. The first master's study program in HTA was established in 2010, and the infrastructure for HTA was developed at universities [97]. Academia, government, and research centers have played a central role in HTA development in Iran. Iran conducts various types of HTA, one of which is known as 'type three' [97]. This type is considered the most advanced type that requires generating local utility and cost data for HTA according to the economic evaluation guidelines in Iran [97]. Furthermore, Iran has invested significantly in health outcomes valuation, publishing three EQ-5D value sets in 2016, 2019, and 2023, respectively [51–54]. Before 2016, Iran relied on the UK EQ-5D-3L value set to generate utility index scores.

Similar to Iran, the rise of EQ-5D publications (2000–2015) in Central and Eastern European countries was attributed to the growing interest in HTA across Europe, as explained by a systematic review [35]. Therefore, with the growing interest in HTA and the recent publication of EQ-5D value sets, it is expected that EQ-5D publications in the MENA region will continue to increase in the coming years.

Furthermore, with increased life expectancy in the MENA region, we are seeing an increasing interest in patient-reported outcome measures (PROMs). Since 2020, EQ-5D publications have increased in other MENA countries, alongside Iran, with a particular rise in Saudi Arabia. A systematic review published in 2021 on the use of the EQ-5D in Saudi Arabia showed that the first EQ-5D publication in the country appeared in 2015, with approximately two-thirds of EQ-5D studies published after 2020 [98]. This rise reflects Saudi Arabia's growing interest in measuring patients' HRQoL. Additionally, Saudi Arabia's 2030 vision, launched in 2016, has prioritized value-based health care [30, 98, 99]. This initiative introduced a national PROMs strategy to improve healthcare quality and link patients' outcomes to spending efficiency [99].

In general, the research output in different fields in the MENA region has followed an increasing trend since 2003, peaking in some countries around 2020–2021 [100]. Moreover, Iranian and Saudi Arabian research output in health sciences is among the highest in the region [101] and this trend was also seen in the EQ-5D research output.

Only a limited number of studies in the MENA region targeted caregivers and refugees. However, there is a need to know more about HRQoL in these populations, especially because the healthcare system in the MENA region is fragmented, with predominantly informal caregiving of critically ill patients. Therefore, the socioeconomic characteristics of the region and the political context require more research

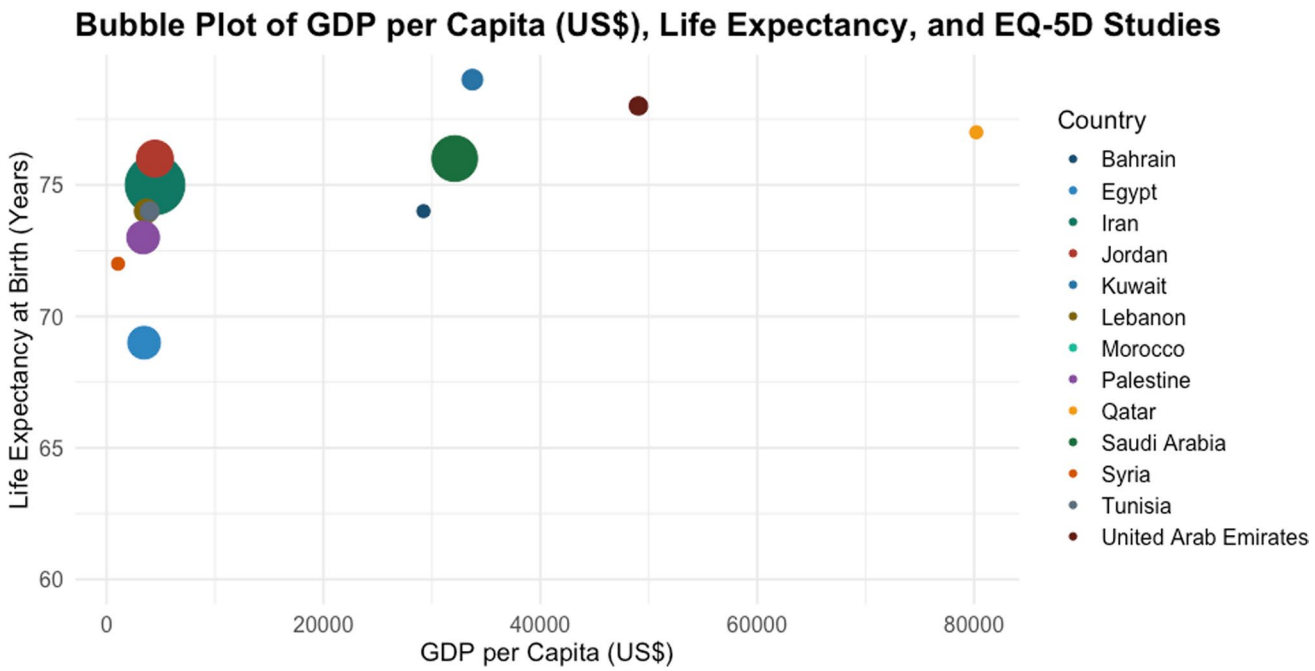

Fig. 8 EQ-5D study clusters per income and life expectancy. *GDP* gross domestic product

efforts to measure the HRQoL and health state valuations of different societal subgroups like refugees and caregivers.

4.3 Use of EQ-5D for QALYs Generation and HTA

In our systematic review, only 10% of the included studies used EQ-5D utility data for economic evaluations, either alongside a clinical trial or for decision-analytic modeling, with the majority of studies from Iran. A systematic review in 2022 on economic evaluations in the MENA region by Nagi et al. [102] showed that the number of economic evaluation studies in the region is low in quantity but with high to excellent quality [102]. Cost-utility analyses represented 71% of the included studies [102]. Nevertheless, utility scores were mostly taken from international sources outside the MENA region. Consistent with our review, the authors reported that Iranian studies were the major contributors to economic evaluation studies in the MENA region [102].

Approximately 25% of the included studies that reported EQ-5D results as index scores used the UK EQ-5D value set to generate these scores, referred to as utilities or values. Most of the studies used the 3L version, with some applying the UK EQ-5D crosswalk calculator to generate values for the 5L version.

In the Central and Eastern European (CEE) region, the UK value set was also used in the absence of national value sets. However, the availability of national value sets in the MENA region is new compared with the CEE region [35]. As previous evidence has shown, the value set used to generate utilities for QALY calculation could impact the incremental cost-effectiveness ratios (ICERs) and, ultimately, reimbursement decisions [103, 104]. Therefore, it is important that future economic evaluation guidelines clearly specify which value set is expected to be used and the rationale behind it.

Most MENA countries are still in the early stages of HTA development within a fragmented healthcare system [105]. Movement towards UHC by 2030 is considered a key driver of the regional HTA agenda [105, 106]. Several HTA road maps have been published in recent years [33, 107]. Furthermore, more interest in EQ-5D valuation studies is seen in the region as the QALY measure is expected to be the selected health outcome measure for future use in cost-utility analyses within HTA processes [102, 108]. Our systematic review included six valuation studies from Iran (3), Tunisia (1), Saudi Arabia (1), and Egypt (1) [48–54]. However, three additional value sets were recently published: the EQ-5D-3L valuation study for Jordan [109], the EQ-5D-5L valuation study for UAE [110], and the EQ-5D-5L for Morocco [111].

Pharmacoeconomic submission guidelines were released in Tunisia and Iran, and pharmacoeconomic reporting guidelines were published in Egypt [108, 112, 113]. These three countries identified the cost-utility analysis as the preferred analytical technique. In Egypt, the preferred method to derive utility is the direct use of EQ-5D, SF-6D, or similar generic measures [108]. Recommendations in Tunisia emphasize the preference for indirect measures of utility, without specifying particular tools, and advise using utility

values that are recent and representative of the Tunisian population [112]. In Iran, both direct and indirect methods (HUI, EQ-5D, and SF-36) can be used to derive utility; however, using national preferences is recommended [113].

4.4 The Use of EQ-5D and Patient-Reported Outcomes Research in the MENA Region

The results show that the use of the EQ-5D tool in the MENA region was more prevalent in clinical (non-economic) research. The EQ-5D was mainly used to collect the HRQoL data of patients, reflecting a clinical interest in the tool. This finding was in line with what was reported by Wang et al. (2022) about the frequent use of EQ-5D in non-economic research [114]. The dominance of using the EQ-5D in clinical studies to generate patient-reported outcomes, rather than for calculating QALYs for economic studies in the MENA region may reflect the region's growing emphasis on patient-centered outcomes. For example, Saudi Arabia has prioritized value-based health care since launching its 2030 vision in 2016 [99]. This initiative introduced a national PROMs strategy aligning with its broader objectives.

The interest in using EQ-5D in clinical research (without an economic component) in the region might also be explained by considering previous work done in the region in translating the EQ-5D tool to Arabic and validating it in different disease areas. For example, in Jordan, the EQ-5D-3L was translated into the Arabic language, followed by testing the tool's validity and reliability in a pilot study back in 2009 [115]. Later on, in 2018, the EQ-5D-3L was validated in Saudi Arabia [116]. These psychometric studies were conducted in academia with a primary focus on using the EQ-5D questionnaire to measure patients' HRQoL as a health outcome in clinical trials. Furthermore, the development of the Economic, Clinical, and Humanistic Outcomes (ECHO) model in the 1990s [117] to comprehensively assess the value of pharmaceutical products might have played a role in generating more evidence on HRQoL in the clinical pharmacy discipline. The humanistic outcomes included quality of life and patients' adherence to treatments [117].

The use of the EQ-5D was also triggered by investigations in specific disease areas where health-related quality of life plays a crucial role. The area of endocrine diseases, specifically type 2 diabetes mellitus, was the most studied disease area in the MENA region, followed by diseases of the musculoskeletal system, nervous system, neoplasms, circulatory system, and infections. Studied disease areas are also consistent with the disease burden in the region. The prevalence of type 2 diabetes in the MENA region is among the highest in the world [118]. The CEE region had a similar pattern of studied diseases, with cardiovascular disease at the top of the list [35]. Similar to our findings, the systematic review from Saudi Arabia reported that the EQ-5D was mainly applied in type 2 diabetes mellitus and musculoskeletal system diseases [98].

4.5 EQ-5D Use in the MENA Region Compared with Global EQ-5D Literature

On the global level, the application of the EQ-5D is expanding beyond its traditional use in HTA, especially through its integration as a PROM in routine clinical practice [15]. A similar trend is emerging in the MENA region. For example, Saudi Arabia has launched its national PROMs strategy as part of its transition to a value-based healthcare system [30, 99]. Also, the UAE has launched the EJADAH program to implement a value-based healthcare system in the Emirate of Dubai [119].

Interest in HTA has grown steadily, supported by increasing governmental efforts to institutionalize HTA since 2018 [105] and the commitment toward achieving UHC by 2030 in the MENA region [120]. Most countries in the region are moving toward QALY-based HTA systems. Between 2019 and 2024, five national EQ-5D value sets were published, with more expected in the near future [48–51, 53, 54]. This reflects a growing interest in the EQ-5D and its use for generating quality-adjusted life years.

Furthermore, the use of the EQ-5D-5L version in the MENA countries is increasing. This trend aligns with the global direction of EQ-5D use [15]. However, the use of the EQ Health and Wellbeing instrument, as well as EQ-5D bolt-ons, remains limited in the region.

4.6 Funding HRQoL Research in the MENA Region

The primary funding source for EQ-5D studies in the MENA region differed from that of the studies identified in the systematic review in the CEE region [35]. In the MENA region, universities were the main funding source, while in the CEE region, governmental organizations were the main driver, followed by the pharmaceutical industry. In the MENA region, where 74% of the studies were conducted in LMICs, only 5% of the studies were funded by the pharmaceutical industry. The difference in the HTA institutionalization levels between the MENA and the CEE regions may explain the difference in the primary funding source of EQ-5D studies in both regions [35]. However, considering the funding spectrum for research in the MENA region, we see that it is primarily driven by universities and governmental institutions with limited contributions from industry [121]. With the development of HTA institutionalization in the MENA region [105], governmental organization funding might increase. Furthermore, positioning HTA within countries' research agendas is important to engage academia in the

application of HTA and to link research to policy decision making.

With the growing interest in HTA in the MENA region, there is an increased need to have more funding directed toward generating real-world evidence in terms of effectiveness and health-state utilities, especially with the availability of national value sets. However, investing in clinical trials, particularly real-world evidence studies that cover a sufficient spectrum of health states over a long enough follow-up period, is essential to collect utility data under different health conditions for use in economic evaluation studies.

4.7 Reporting of EQ-5D Results and Impact on Use in Decision Making

Our review found significant heterogeneity in how EQ-5D results were reported. Some studies focused on describing health profiles with or without EQ-VAS, others concentrated on generating a single utility index score, while some used all three methods of reporting: percentages of reported problems per dimension, EQ-VAS, and the utility index score.

Nancy Devlin, David Parkin, and Bas Janssen, in their book "Methods for Analyzing and Reporting EQ-5D Data", emphasize the importance of standardizing the collection and reporting of EQ-5D data [122]. Such standardization guides how EQ-5D data should be analyzed and reported. For example, using EQ-5D index scores in clinical studies without considering profile data might fail to capture sufficient information about patients' significant health problems. Conversely, reporting EQ-5D results solely as patients' profile data may not be useful if the purpose is to generate QALYs for economic evaluation.

This heterogeneity in EQ-5D data reporting creates challenges. In some cases, results cannot be utilized for HTA purposes if utility index scores are not reported. Similarly, studies reporting only index scores may provide insufficient information for clinical decision making. This situation highlights the need for clearer guidelines on how the EQ-5D should be used for specific purposes and for educational sessions to support researchers in their reporting practices. Without such guidance, the usefulness of EQ-5D studies' results in clinical decision making and HTA becomes limited.

Moreover, using the EQ-5D as a PROM under healthcare reforms, such as in Saudi Arabia and the UAE [99, 119], requires a thorough understanding of how EQ-5D data should be collected and interpreted. In such cases, a combination of utility index scores and patient profile data may be necessary. Furthermore, when using a utility index score, a reference threshold may need to be defined to make results more meaningful. The utility index score results in our review demonstrated that health is valued differently across MENA countries. However, there is heterogeneity in several aspects including studied diseases, characteristics, the EQ-5D version used and the value set used. For instance, the utility scores for type 2 diabetes mellitus ranged from 0.58 in Bahrain [123] to 0.90 in Saudi Arabia [48]. Even in the same country, there were differences in the valuation of health. For example, in studies that targeted the general population, which mostly were conducted in Iran using the EQ-5D-3L version, the utility index scores ranged from 0.65 to 0.87 [124, 125]. This finding might be due to using different value sets in Iran.

5 Limitations and Strengths

Regarding the limitations of our review, we restricted our search to studies published in peer-reviewed journals. As HTA dossiers of pharmaceutical companies in the MENA region are not necessarily published, we could not include them. Moreover, we did not include information about registered, but not yet published EQ-5D studies from the MENA region in the EuroQoL foundation database. Therefore, there might be some information about EQ-5D use in the MENA region that we could not capture, which may have led to some publication bias.

In terms of categorization of reported outcomes, we did not differentiate if measuring HRQoL was a primary or secondary outcome in clinical trials. Therefore, we could not rank the importance of HRQoL as an outcome in clinical research in the region. In addition, we used EndNote [37] as our main reference manager. However, specialized software for systematic reviews could have better supported the screening process.

Our study also has several strengths. This is the first systematic review that assessed and summarized the evidence on the application of EQ-5D in the MENA region. Our work is very comprehensive as we screened more than 18,000 records and extracted and summarized the information of 184 published studies. We applied strict systematic screening steps with parallel evaluation by two independent screeners following the PRISMA guidelines [34], and standardized extraction criteria. Another important and unique feature of our work is that our report, including the identified studies, represents a source for utility input data for future economic evaluations in the MENA region for some specific disease areas. However, mapping techniques might be needed to make those utilities region-specific based on recently released value sets in the region. Finally, with the increased application of artificial intelligence (AI) in HTA and the trend towards having living HTA, we can build on this systematic review and maintain it with updated evidence from the region using the living systematic review approach [126].

6 Recommendations

In this section, we highlight some recommendations on how to improve the use of the EQ-5D in the MENA region, addressing some of the gaps identified in our systematic review.

Our systematic review showed some reporting challenges of the EQ-5D results that should inform future guidance. Twenty-eight percent of the studies did not report the value set used, and funding sources were not reported or not clearly mentioned in 20% of the studies included in our review. The EQ-5D version was not clear in 17% of the studies, and the method of tool administration was not mentioned in 16% of the studies. This aligns with the study of Rencz and colleagues in CEE from 2016 [35]. Our study underlines the need for improvement in the reporting of EQ-5D results. There are guidelines for reporting valuation studies (CREATE) [127], and we also recommend reporting guidelines for clinical and economic studies using EQ-5D. These guidelines will improve understanding, appraisal, and utilization of the results for health economic and non-health economic studies. Finally, how EQ-5D data are analyzed requires clarification, as authors used atypical ways to report EQ-5D results. Some studies reported results as means of EQ-5D severity levels or compared them with a threshold without explaining how it was defined and derived. It is worth mentioning that there is a need to add to the future EQ-5D reporting guidelines a section about how to report results based on EuroQoL recommendations that were published in some guidance documents and in a specialized book for reporting and analyzing EQ-5D data [18, 19, 122]. As more EQ-5D value sets are now available in the MENA region, there is a need to create awareness about them and provide capacity building programs about EQ-5D and its utilization.

Pharmaceutical companies in collaboration with research institutions could play a role in generating real-world evidence (RWE). They can fund establishing PROM registries and invest in information technology infrastructure, such as data platforms, to facilitate efficient data collection for RWE studies. For example, the ONCOVALUE project [128] in Europe serves as a collaborative consortium of cancer institutes to advance value-based oncology care. Its supports cancer clinics and hospitals in the real-time collection and analysis of high-quality real-world data using an AI-driven framework. Learning from the ONCOVALUE initiative could be very useful for the MENA region to establish similar frameworks to collect real-world HRQoL data and utility values. As healthcare systems in the region continue to move toward value-based healthcare models, increased investment in innovative outcomes-based agreements, which link reimbursement to improved HRQoL, could create significant opportunities for utilizing RWE in decision making.

Additionally, our systematic review showed the limited use of the EQ-5D in the pediatric population. Therefore, we recommend developing more youth value sets in the region to be able to value health at different ages.

As the EQ-5D was developed in Europe, the addition of bolt-ons to EQ-5D tools to better reflect cultural aspects of the MENA region might be tested by researchers from the region. Also, conducting more psychometric studies is important to test the measurement properties of EQ-5D instruments in the MENA region. Furthermore, generating EQ-5D population norms and investing in longitudinal observational studies is essential.

7 Conclusion

There is an increasing trend in the application of the EQ-5D in the MENA region, largely driven by studies conducted in Iran, Saudi Arabia, and Jordan. However, the reporting mode and quality remain heterogeneous, calling for guidance towards improvement. The use in clinical (non-health economic) research is still dominating. This is important and supports benefit(–harm) assessments for new technologies. However, this might change with the development of HTA in the region—including more economic evaluations—and will likely be paralleled with an increased generation of national EQ-5D value sets.

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Declarations

Author contributions Abeer Al Rabayah: concept and design, searching screening, full text review, data extraction, analysis, interpretation of data, drafting the manuscript. Sibylle Puntscher: concept and design, screening, full text review, data extraction, analysis, interpretation of data, critical revision of the paper for important intellectual content. Fatima Al Sayah: concept and design, served as third reviewer in case of disagreement between the other two reviewers, interpretation of data, critical revision of the paper for important intellectual content. Razan Sawalha: screening, data extraction validation, analysis, critical revision of the paper for important intellectual content. Elly Stolk: concept and design, interpretation of data, critical revision of the paper for important intellectual content. Judit Simon: concept and design, interpretation of data, critical revision of the paper for important intellectual content. Michael Drummond: concept and design, interpretation of data, critical revision of the paper for important intellectual content.

Uwe Siebert: concept and design, interpretation of data, critical revision of the paper for important intellectual content, and supervision.

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Ethics approval This is a systematic literature review, and an ethics or Institutional Review Board (IRB) approval is not required.

Data availability Data available from the corresponding author upon a reasonable request.

Code availability Not applicable.

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