A Systematic Review on the Extent and Quality of Pharmacoeconomic Publications in Egypt

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Abstract

Background: Egypt faces many challenges matching budget requirements with the available resources. Consequently, there has been an increasing interest in pharmacoeconomics as an aid tool in decision making in health policies to better allocate resources.

Objectives: To review and evaluate the extent and quality of the published pharmacoeconomic studies in Egypt.

Methods: A literature search was conducted using PubMed, Google Scholar, and Cochrane library to identify the published Egyptian pharmacoeconomic studies. Articles were included if they were original economic studies, written and published in English and conducted in Egypt. Each article was assessed independently by two reviewers using the 100-point Quality of Health Evaluation Studies (QHES) scale.

Results: Thirteen studies published between 2002 and 2016 were included in the review. Most of them were cost-effectiveness analyses (61.5%). The minority of the studies used secondary data (30.7%) or adopted modeling techniques (38.5%). The mean QHES score of the included studies was 69.6 ± 21.5 and approximately 38% of them had a QHES score of more than 80.

Conclusion: Pharmacoeconomic evaluations in Egypt are still at its inception. The Egyptian guidelines for economic evaluation should be adopted and the EQ-5D-5L value sets should be developed to increase the quality of economic research.

1. Introduction

Egypt is the most populous country in North Africa and the Arab world with an approximate population of 95,000,000 . It is classified as a lower middle-income country , where up to 27.8% of the Egyptian population is living below the poverty line . Since 2011, the country has witnessed two revolutions that resulted in dramatic political and economic instabilities. Therefore, Egypt is now facing major financial difficulties that make paying for healthcare services challenging. Compared to other middle-income countries in the region, Egypt's expenditure in health remains low; representing 6.2% of the Gross Domestic Product (GDP) and the Government health spending accounts for only 25% of the total health expenditure, whereas the regional average is 52%, as per 2009 data .

The Ministry of Health and Population (MoHP) and the Health Insurance Organization (HIO) are the main governmental bodies governing Egypt’s health care system. Egypt’s MoHP covers 17% of the population , and the HIO covers 58.2% of Egyptians . However, only 6% of Egyptians covered by HIO actually utilize its services because the coverage is dissatisfactory. According to the National Health Accounts, in 2008, up to 72% of total health expenditure in Egypt is paid out of pocket (OOP) by people seeking treatment. High OOP share presents a disease burden on the Egyptian population, particularly lower income brackets .

Currently, Egypt is working to improve the quality of its public healthcare system. New legislation has been implemented to establish a comprehensive insurance umbrella that was supposed to provide all Egyptians with both insurance and care by 2016. However, with increased healthcare costs, also due to inflation and currency devaluation, budget needs exceed available resources, as is the challenge with many healthcare systems. Simply, increasing healthcare budget is not an easy fix to narrow the gap between resources available

and actual spending, due to the paucity of resources available. Hence, a method to better allocate and utilize existing recourses is needed. Pharmacoeconomic studies could be of an important role at this crucial time as it offers the most cost-effective services (interventions / medications) that meet the country's budget and manage the scrutiny of resources and thus reduce the burden on Egyptian healthcare system. The concepts of pharmacoeconomic were introduced in western countries in the 1970s and formal pharmacoeconomic guidelines were first established in Australia and Canada about a decade ago . The significance of pharmacoeconomic studies relies on its ability to translate research findings into health care policies. They assist policy makers in the allocation of scarce healthcare resources and act as a guide to the health sector in implementing effective measures towards a sustainable and highly efficient health care system . They also ensure transparency in formulary decision making in health insurance programs . Pharmacoeconomics and Outcomes Research (PEOR) provide a great tool for decision making that is based on scientific evidence and actual figures. Countries that actually have or plan to implement universal healthcare coverage benefit more from PE implementation.

In Egypt, with growing awareness of the importance of pharmacoeconomic and the increasing need for optimizing the use of limited resources, the MoHP established a pharmacoeconomic unit to support and inform pricing and reimbursement decisions and the first recommendations for reporting pharmacoeconomic evaluation were conducted in 2013 . However, there is still a lack of available evidence about the quality of economic studies carried out in Egypt. A poorly designed and implemented pharmacoeconomic study can misguide decision makers. Hence, in order to enhance the decision making process in Egypt, high quality and well-designed pharmacoeconomic studies are a necessity. The first step to accomplish this is by reviewing and evaluating the current published pharmacoeconomic studies in Egypt.

2. Objectives:

To the best of our knowledge, no published study has systematically reviewed pharmacoeconomic studies conducted in Egypt over the years. Therefore, the objective of the present study is to investigate the state of pharmacoeconomics research in Egypt by evaluating the extent and quality of published articles in this field.

3. Methods

3.1. Information Sources and Research

A systematic search of the literature was conducted in November 2016 using PubMed, Google Scholar and Cochrane library to identify the published pharmacoeconomic studies conducted in Egypt. The following keywords were used alone and in different combinations: “pharmacoeconomics”, “economic evaluation”, “cost”, “effectiveness”, “cost effectiveness”, “cost-minimization”, “cost-utility”, “cost-benefit” and “Egypt”. Additional relevant articles were identified from the reference lists of the obtained articles. This continued for all the additional articles until no more articles could be identified.

3.2. Eligibility Criteria

We limited our search to studies written and published in English and conducted in Egypt. Studies had to be original economic studies including any of the health economic analyses of one or more health-related interventions (drugs, pharmaceuticals or treatment modalities). Studies were excluded if the cost was not the main topic of the study and if they compared multiple countries. Full peer-reviewed publication was required for a study to be included in this review; thus, meeting abstracts, letters to the editor, treatment guidelines or recommendations, expert opinion, and narrative reviews were excluded.

3.3. Study Selection

Article titles and abstracts of all the identified studies were screened independently by two different authors. In order to remove any duplicates, search results were imported into a Microsoft Excel and manually screened by the authors. Article titles were shortlisted for a detailed review of their abstracts. The authors then confirmed which met the inclusion and exclusion criteria. Full articles were then obtained for further evaluation.

3.4. Data Collection Process

A data collection questionnaire similar to the one developed by Gavaza et al. was used for this study. This form was also adapted from previous published economic guidelines and studies [13-16]. Moreover, the methodology used for data collection is similar to that used in

several previous studies [17-20]. The data collection form included two sections. First, the general information section included the total number of authors for the study, country of residence of the lead author, primary training of the lead author, year of publication of the study, journal in which the study was published, the country of the journal in which it is published and type of publication. Second, the economic information section included method of economic evaluation used in study, type of costs included, perspective of study, study design, primary outcomes, type of data, disease state investigated, whether economic evaluation was the primary study goal, funding source, type of medical function, and the decision reached on whether treatment was cost-effective.

3.5. Quality Analysis

Assessment of the full pharmacoeconomic studies (e.g. those studies that compared both costs and outcomes of interventions or conditions) were done using the Quality of Health Evaluation Studies (QHES) scale . The QHES scale is a 16-item scale covering evaluation of study objectives, perspective, economic model, study design, and methodology. Each criterion is weighted depending on its importance in assessing quality (range: 1 to 9 points for each criterion) and gets either a full score or zero. The QHES scale is a 100-point scale, with lower scores representing poor quality. In our study, a modified version of the QHES scale having three scoring points; full score, a mid-point score (lying midway between zero and the full score for the criterion), or a zero was used . Each article was assessed independently by two blinded reviewers. All disagreements between the reviewers on any of the items in the data collection questionnaire were resolved through discussions and assessment by a third reviewer. If the difference between the scores given by the two reviewers exceeded 10, it was passed to a third reviewer for further evaluation. In this case, the final score of the article was defined as the average score of the third reviewer and a closer score given by either reviewer.

Published articles were grouped by type of evaluation, and were considered to be (i) a cost-minimization analysis (CMA), if costs were compared with evidence of equal effectiveness, (ii) a cost-effectiveness analysis (CEA), if health outcomes were presented in intermediate terms e.g. disease prevented, (iii) a cost-utility analysis (CUA), if health outcomes were expressed in terms of QALYs or disability adjusted life-years (DALYs) (iv) a cost-benefit analysis (CBA), if health outcomes measured in monetary units.

3.6. Statistical Analysis

The Statistical Package for the Social Sciences (SPSS) software package version 22 was used for all analyses (SPSS Inc., Chicago, IL, USA). All nominal variables were represented by descriptive statistics as numbers and percentages. The normality pattern of QHES score was explored using Shapiro-wilk test of normality. It was found to be normally distributed ($P > 0.05$) and hence, parametric tests were adopted. The differences in QHES scale scores by variables (country of residence of the primary author, number of authors, type of publication, costs considered, type of data and study design; whether modelling is adopted or not) were compared using independent sample t tests. Pearson's correlation was used to test correlation between continuous variables. P-values less than 0.05 were considered statistically significant.

4. Results

4.1. Study selection

Around 1500 (1480) studies were identified using search engines after using the keywords formerly mentioned in the methodology section. Screening of all the identified studies was done at two different stages; the first was during the primary screening of titles and abstracts of the articles then the second stage was during the evaluation of the full articles.

Figure 1 shows the selection process of the included articles. The abstracts of 61 articles, after the removal of duplications, were examined for their eligibility to the study inclusion and exclusion criteria. Of the considered sixty-one articles: 14 studies were found to be non-pharmacoeconomic studies, 10 articles were not mainly concerned with costs, three studies were comparing more than one country, two studies were not conducted in Egypt and two studies were not an original research article studies. In addition, 10 more studies were excluded for which full text manuscripts could not be obtained. Twenty articles were found eligible and were considered for further assessment of the full article. Seven articles were further excluded and only thirteen articles met the inclusion and exclusion criteria and were finally included. The included articles were then evaluated using QHES scale score by two independent reviewers. The difference between the QHES scores of the two reviewers did

not exceed 10 to any of the included studies. Thus, the final score was calculated based on the average of both reviewers' score.

4.2. Study general characteristics

Upon the study of the included publications, we found that most of the first authors (61.5%) were residing in Egypt while 38.5% had a different country of residence. The majority of publications (84.6%) were medical while only 15.4% were of health economic publications. It was also noted that the majority of the publishing journals were based in United Kingdom (38.5%) while 15.4 % of the journals were American and 15.4% were Scandinavian. The remaining journals were based in Netherlands, Egypt, New Zealand and Edinburgh. Corresponding authors were contacted by e-mail to obtain information about the primary training they received. Unfortunately, only two authors responded, therefore this data was not included in our analysis. The general information of the included studies is represented in **Table 1**.

4.3. Economic characteristics of the included papers

When considering the economic data and analysis of the included studies, the majority (76.9%) focused on the study of direct costs only with only three studies (23.1%) including the indirect costs as well. The majority (61.5%) had the design of a cost-effectiveness analysis (CEA) while 30.7% were cost-benefit analysis. A minority of the studies carried out cost-utility analysis (15.4%) and cost-minimization analysis (7.7%). Equal proportions of the studies (30.7%) were economic evaluations of randomized controlled trials and prospective cohorts while 38.5% made modeling studies and only one study (7.7%) was a retrospective database. The studied interventions in the included studies were preventive (46.1%), treatment (53.8%) or diagnostic (7.7%). Also, the majority of the studies analyzed primary data (69.3%) and stated the funding source (53.8%). The economic data of the included studies are shown in **Table 2**.

The first study among those included was conducted in 2002 and the last was in 2016. Hepatitis C virus was the condition investigated in 30% of the studies owing to the high prevalence of Hepatitis C in Egypt and its high medical and economic impact.

. Only six studies determined a perspective for the economic evaluation which was a governmental perspective in most cases. The outcome measures varied from the consideration of cost and incremental cost-effectiveness ratio (ICER) in CEA, costs in CMA, benefit-cost ratio (BCR) in CBA and finally quality adjusted life years (QALY), disability adjusted life years (DALY) and life years gained (LYG) in CUA. Majority of the studies proved the treatment/intervention in question to be cost effective. The outline characteristics of the included studies are shown in **Table 3**.

4.4. Assessment of quality of the included articles:

The mean QHES score of the 13 studies was found to be 69.6 ± 21.5. Thirty-eight percent of the studies were of high quality with a QHES score of more than 80 out of 100. Although the QHES score was higher in the studies whose first authors were residing in countries other than Egypt, this did not reach statistical significance. More than 7 authors were found in 8 articles (61.5% of included studies). There was no statistical significance in the QHES score between the studies with less than seven authors and those with more than seven authors but it was observed that the QHES score of the included papers was found to be positively correlated with the number of authors in each article ($r = 0.565$, $P=0.044$, Pearson correlation). Also, QHES scores tended to be higher in medical economic publications than medical publications and in studies that assessed direct costs only than those which assessed both direct and indirect costs. However, none of these was statistically significant. Conversely, QHES score were significantly higher in studies that used secondary data than those with primary data as well as those that adopted modeling techniques versus those which do not perform it ($P < 0.05$, **Table 4**).

5. Discussion

The present study assessed and evaluated the quantity and quality of the pharmacoeconomic studies in Egypt. Based on the study inclusion and exclusion criteria, 13 studies were included. This limited number of included studies is comparable with setting such as Saudi Arabia , Nigeria , Bangladesh , Iran and Zimbabwi , but lagging behind other developing countries in conducting health related economic evaluations [17, 20, 25-27]. Sixty-nine percent of the included studies were published after 2013 **(Figure 2)**. This is

because the pharmacoeconomic education in Egypt till 2012 was in its infancy stage and started to develop in the last three years after the development of the Egyptian guidelines for reporting pharmacoeconomic evaluations . Also, the launch of ISPOR Egypt's chapter has helped raise awareness on pharmacoeconomics in Egypt. Through awareness campaigns and educational activities, there is more interest in adopting pharmacoeconomic principles amongst decision makers in Egypt.

Although 61.5 % of the primary authors resided in Egypt, 92% of the studies were published in foreign journals, all the studies that carried out modelling (N = 5) had high average QHES score (89.85 ± 7.04), authored by two or more foreign authors and were funded internationally. This could be attributed to the lack of data in the local hospitals and institutes and lack of experts in using such modelling techniques. About 61.5 % of the studies are cost effective analyses which is comparable to finding in other setting [12, 17, 18, 20, 22-27], as clinical benefit can be interpreted as naturalistic clinical outcomes and it is more straightforward and the preferred method for economic evaluation. Only two studies carried out CUA as the concept of QALYs is not well understood by the majority of the decision makers with the absence of the Egyptian tariff for the EQ-5D-5L. Limited studies performed CBA in its right meaning due to the lack of knowledge and experience in using this method in applying a monetary value for the human life. Seventy-seven percent of the studies included direct costs only due to the lack of the Egyptian data and information on indirect costs .

In this review most of the studies focused on the economic evaluation of infectious disease interventions which is comparable with lower middle-income countries . In addition, the economic evaluation publications for the rest of many major health problems in Egypt were absent indicating a poor distribution of research resources towards the determination of cost-effective interventions. Accordingly, there is more need for PE studies that address non-communicable diseases in Egypt, which also carry a significant disease burden.

Although the Egyptian guidelines for reporting pharmacoeconomic evaluations were published in 2013 , only one study adhered to these guidelines with a high QHES score . Fifty-three percent of the assessed studies had some technical limitations and weakness in reporting the pharmacoeconomic evaluation such as lack of sensitivity analysis, ICER

calculation and specifying the study perspective. This was in agreement with the economic evaluations conducted in other lower middle-income countries .

Finally, several recommendations to improve pharmacoeconomic evaluation in Egypt should be adopted. First, the recommendation of the Egyptian guidelines for economic analysis of health technologies should be adopted. This will improve the quality of the pharmacoeconomic studies and make the results more robust. Second, there is a great need to develop a value set for the EQ-5D-5L based on societal preferences in Egypt and support the implementation of cost-utility, cost-benefit analysis and health economics modelling by Egyptian academics and researchers to assist decision makers for appropriate allocation of health care resources. Third, in order to best address and quantify disease burden and assess cost effectiveness of our healthcare interventions, more pharmacoeconomic research/publications are needed in this field. Fourth, pharmacoeconomic capacity building efforts should be continued among relevant stakeholders. Finally, pharmacoeconomic research represents an opportunity for multi stakeholder collaboration in Egypt as there are efforts needed in raising awareness, conducting actual studies and transitioning towards decision making that further incorporates pharmacoeconomic studies and principles.

6. Limitations

Although the research has reached its aims, there were some unavoidable limitations. It is probable that some published articles were unintentionally eliminated or missed. Also, the review is focused only with studies found during the database search. This may mean that unpublished data like governmental reports, pharmaceutical company reports, and academic theses, were excluded. Additionally, the study may be subjected to publication bias, since only published articles were included and there is a greater tendency for studies with positive findings to be published compared to studies with negative outcomes. Finally, the methodology sections of many studies were ambiguous and the authors failed to explain what was carried out explicitly. This may have resulted in some difficulty encountered when classifying those studies and other readers may classify them differently.

7. Conclusion

Current economic evaluations in Egypt cannot be a useful source of information for the decision makers. The Egyptian guidelines for economic evaluation should be adopted to increase the quality of economic research in Egypt.

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