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Pharmacoeconomics Evaluation And Its Impact On Healthcare Logistics Cost-Effective: Evidence From Egypt

Abeir Moussa[1], Shada Tarek[2,] Amira Hasan Abada[3]

Assistant Professor in Finance[1], Teaching Assistant in Economics[2,] Hospitals Management Specialist, Clinical Pharmacist[3]

Department of Finance[1]
Arab Academy for Science, Technology, and Maritime Transport- Alexandria- Egypt[1]

Abstract: The purpose of this paper is to review the relevant previous literature to provide insights into maximizing the effectiveness of healthcare logistics through the application of pharmacoeconomics. It investigates pharmacoeconomic evaluation validity in Egypt by examining pricing, reimbursement, and evaluation of pharmacoeconomics. It helps to identify problems and areas for improvement. This paper reviews the prior literature, particularly on publications published after 2013 when the Egyptian Pharmacoeconomic Evaluation Unit was established. Considering the results of this study, Egypt appears to be off to a promising start in its pharmacoeconomic evaluation—additionally, the advancement of pharmacoeconomics aids in the optimization of healthcare logistics. This study provides recommendations on how Egyptian Pharmacy and Therapeutic (P&T) decision-makers can best utilize pharmacoeconomics to lower healthcare logistics costs and maintain a high level of service.

Index Terms **- Component, formatting, style, styling, insert.**

I. INTRODUCTION

Given the increasing demand for healthcare interventions and limited resources, economic evaluation is becoming increasingly critical to ensure that we make choices that maximize benefits from limited resources (Palmer and Torgerson, 1999). Pharmacoeconomics can be defined as the economic evaluation of pharmaceuticals. A formulary system should be developed and implemented in hospital settings to optimize patient care (ASHP, 2008). Many countries use cost-benefit evidence to support decisions on licensing, pricing, reimbursement, and addition to the formulary (Taylor et al., 2004).

In the healthcare system, drug management contributes a substantial portion of the costs since these products are expensive and require significant storage and control. Thus, reducing waste in the healthcare system and improving its efficiency are global challenges, emphasizing the need to identify potential improvement points and utilize all tools, techniques, methods, and technologies available to enhance the delivery of healthcare and services. Despite well-documented evidence of significant competitive advantages and cost reductions resulting from supply chain management (SCM) principles, the healthcare sector has been very slow to adopt them. There are numerous obstacles to implementing SCM principles, including the cost of goods used in medical treatments can be very high. As a result of the wide range of patient characteristics, it can be challenging to predict how and when products will be required for treatments. It may also be difficult to track inventory in medical emergencies due to the efficacy of the situation. An inability to track products handled through consignment procedures contributes to product expiration and tracking issues (Postacchini et al., 2016).

Due to its direct influence on human health and safety, the Pharmaceutical Supply Chain (PSC) is more complex and challenging than in other industries. Through the supply chain, from production to consumption, drug quality effectiveness must be guaranteed, at the appropriate time, quality, and point. Consequently, the PSC is responsible for ensuring not only the delivery of high-quality, safe products but also top-notch customer service and compliance with regulatory requirements. (Argiyantari et al., 2020)

Inventory of pharmaceuticals and medical supplies is a record of purchases, movements, and availability of medicines and medical supplies kept by the pharmacy at the hospital (Ingersoll BK., 2017). Pharmaceutical inventory management is imperative to ensure an adequate stock of drugs and supplies. Consequently, there is a smooth provision of healthcare services and profits from the sale of drugs. It has been reported that a pharmacy generates revenue from 50 percent of its operations (Suciati, Adisasmito. 2006). The clinical pharmacy is a pivotal component of the daily operations of a hospital (Dacosta- Claro I.2002), (de Vries J. 2011). Hence, an effective and efficient pharmaceutical inventory is imperative since poor management can result in a stagnant shortage of drugs (Ingersoll BK., 2017).

Since healthcare expenditures account for a considerable portion of countries' Gross Domestic Product (GDP), health economics is of significant importance. WHO (2015) reported that global health expenditures in 2012 accounted for 8.6% of global GDP, and total expenditures per capita were 1173 USD. The Organisation for Economic Co-operation and Development (OECD) conducted a study comparing pharmaceutical expenditures with healthcare expenditures. According to the OECD (2015), pharmaceutical expenditures in 2013 accounted for approximately 20% of total health expenditures across 35 OECD countries. Pharmacoeconomics significantly impacts the health care system as a whole, rather than just health economics, as stated in this study.

This direction, however, reduced incentives for drug development where the OECD (2015) noted that healthcare policymakers need to balance patient access to effective medicines with limited healthcare budgets; while at the same time providing the right incentives to manufacturers to develop new drugs.

According to the Ministry of Health of Egypt (2011), pharmaceutical expenditures account for 34.20 percent of total health expenditures. The percentage is significantly higher than the OECD average of 20%, which emphasizes the importance of pharmacoeconomics to health economics and the overall economics of Egypt.

To understand the cost-effectiveness of pharmaceutical products, the Egyptian Drug Authority established a Pharmacoeconomic department in 2013. In the same year, the newly established unit launched a pharmacoeconomic evaluation program which developed the first pharmacoeconomic guideline model for the Middle-East region.

This paper aims to provide insight into healthcare logistics optimization in Egypt to reduce healthcare costs effectively. The study examines the drug reimbursement process and pricing policy. Furthermore, the study analyzes the challenges and opportunities for improvement in pharmacoeconomic evaluations in Egypt eight years after the guidelines were issued. Moreover, the study examines how pharmacoeconomic evaluation models affect medicine reimbursement in Egypt. Also, it will provide recommendations on how to optimize healthcare logistics through pharmacoeconomics.

The key benefit of this study is that it offers pharmaceutical managers alternative solutions, particularly concerning drug inventory planning. Providing information to decision-makers will help the hospital plan its budget more efficiently.

II. Objectives of the Study

- Conduct a literature review of healthcare logistics cost, drugs pricing, medicine reimbursement process, and pharmacoeconomic effectiveness in developing counters such as Egypt.
- Propose recommendations for the decision-makers on the healthcare logistic drug system optimization through applying pharmacoeconomics to reduce the healthcare logistics cost.
- Emphasizing and providing suggestions for future research.

III. METHODOLOGY

This paper provides a review of the literature regarding healthcare logistics costs concerning pharmaceutical economics, as well as addresses the following objectives;

- Conducting a literature review of healthcare logistics costs, drug pricing, medicine reimbursement process, and pharmacoeconomic evaluation in developing countries such as Egypt.
- Using pharmacoeconomics, prescribe recommendations for decision-makers on improving the healthcare logistic drug system to reduce healthcare logistics costs effectively.
- Highlighting gaps and providing suggestions for further research.

This paper identifies scholars and their contributions to healthcare logistics costs, drug pricing, the medicine reimbursement process, and pharmacoeconomic evaluation. The literature search included published journals in Emerald, Science Direct, and Scopus.

A total of nineteen publications are listed and classified as journal papers in the fields of healthcare logistics costs and medical reimbursement, and pharmacoeconomics. In addition, we reviewed several comparative studies and operational research studies in the healthcare field. A wide range of academic publications was also included, including textbooks, unpublished working papers, and numerous case studies in the field of health economics. Furthermore, reports from the World Health Organization and the Egyptian Ministry of Health were reviewed, in the literature.

This paper reviews the literature on healthcare logistics and pharmacoeconomics with an application of medicine pricing and medicine reimbursement dating back to 2013 when the Egyptian Pharmacoeconomic Evaluation Unit was established. However, for the other variables, healthcare logistics, medicine pricing, and medicine reimbursement, the study reviews literature dating back to 1983. A literature survey was employed as the research methodology in the study to develop a framework. Literature was gathered from Logistics, Economics, Pharmaceuticals, and Finance journals. The reviewed papers are categorized according to the essential attributes as follows; healthcare logistics optimization, management of healthcare logistics costs, medicine pricing policies, medicine reimbursement process, and developing pharmacoeconomics systems.

IV. RESULTS AND FINDINGS

Considering the results of this study, Egypt appears to be off to a promising start in its pharmacoeconomic evaluation. Additionally, the advancement of pharmacoeconomics contributes to the improvement of healthcare logistics.

4.1 AN OVERVIEW OF GLOBAL HEALTH ECONOMICS

Economic growth is associated with healthcare expenditures. In a summary of this relationship, Venelnyi (2016) noted that more effective and strategic expenditure results in better health outcomes and, at the same time, better health leads to enhanced economic productivity. According to Drouin, Hediger, and Henke (2008), a comparison of healthcare spending to GDP revealed an interesting phenomenon where for nearly fifty years, healthcare expenditures have increased by two percentage points more than GDP growth in 35 countries that are members of the Organization for Economic Cooperation and Development (OECD). According to this trend, most OECD countries would spend a fifth of their GDP on health care by 2050, requiring policymakers to begin optimizing health care expenditure.

4.2 AN OVERVIEW OF HEALTH ECONOMICS IN EGYPT

The World Bank has classified Egypt's economy as a low-middle-income economy, according to Fantom and Serajuddin (2016). There are challenges associated with healthcare finance in Egypt based on the country's economic indicators. Pande et al. (2013) found that Egypt's total healthcare expenditures were on par with the world's low-middle-income economies and Middle East and North African countries. The figures for Egypt, however, indicate that government expenditures on health are the least, whereas out-of-pocket spending on health is the highest. Based on an analysis of the out-of-pocket trend in Egypt, Nakhimovsky et al. (2011) found 71.8% private expenditure on health in 2008/2009, a significant increase compared to the 60% spending in previous years.

According to the World Health Organization (WHO), health expenditures in Egypt have decreased from 5.4% of GDP in 2000 to 4.9% in 2012. This result contradicts the average for all WHO regions. During the same period, health expenditures as a percentage of GDP increased. This rise resulted in an increase in the overall global average from 2000 (7.7%) to 2012 (8.6%). By examining Egypt's total health expenditures, out-of-pocket spending paired with a 26.3% poverty rate and 13.2% unemployment rate, this analysis shows how much the healthcare system in Egypt struggles to reach Universal Health Coverage (UHC), which is one of the UN sustainable development goals, that all UN Member States have agreed to attempt to achieve by 2030. Healthcare constraints have made access to advanced health technologies more challenging in Egypt than in other countries.

4.3 Categorization of healthcare systems

Depending on the type of health insurance, healthcare systems can be classified into several categories. Anan (2014) summarized such categories into:

- Traditional sickness insurance: Fundamentally a private insurance market approach with state support (e.g., Germany).
- National health insurance: National-level health insurance systems (e.g., Canada, Finland, Norway, Spain, and Sweden).
- National health services: The State provides healthcare (e.g., Denmark, Greece, Italy, New Zealand, Portugal, Turkey, and the United Kingdom).

In the mixed systems, sickness insurance compromises with national health coverage (e.g., Switzerland and the United States). Those countries that fall into more than one category will be comprised in the global overview, also over the rest of the paper, which provides a comprehensive overview of healthcare systems in different countries.

According to Anan (2014), Egypt began as a national health service in the 1950s. However, now, it is considered to have a mixed system for healthcare. However, Egypt's national health system is fragmented and complex by nature.

A World Bank report (2015) outlines four key financing players in Egypt's health system: Social Health Insurance (SHI), the Ministry of Health and Population (MOHP), the Program for Treatment at the Expense of the State (PTES), and the Family Health Funds (FHFs). Each has its own coverage/health service package. These agencies were designed to complement each other. However, such fragmentation caused more complexity to the overall picture, as there was less integration between these organizations, and information about patients/diseases was scattered.

4.4 Methodologies used in economic evaluation and pharmacoeconomics

Economic evaluation is considered one of the most significant aspects of assessing health technologies. As a result of such an evaluation, policymakers will be better able to determine the most appropriate alternative available based on the efficiency of the various options. In the following sections, we highlight the most relevant methodologies for economic evaluation, along with their advantages and disadvantages from the perspective of policymakers.

4.4.1 Cost-benefit analysis

Cost-benefit analysis is used for evaluating and comparing different projects and products. Besides measuring the benefits and costs of each available project in monetary terms, it also considers all the periods over which the project will operate. Svensson, M. and Hultkrantz, L. (2017) explain that if the net present value of the benefits exceeds the costs of an investment, it will increase social welfare. Accordingly, projects are prioritized based on the ratio of benefits to costs, with social benefits obtained from a project being higher than its monetary costs.

Cost-Benefit Analysis (CBA) = B/C,

Where:
B presents the total monetary benefit and
C presents the total monetary cost.

Costs and benefits must be measured correctly, in monetary terms, to achieve the optimal outcome of this analysis. One of the difficulties considered a disadvantage is determining the monetary value of costs and benefits. This is especially true for those that do not have a price, such as vaccination against the flu. (Svensson, and Hultkrantz, 2017)

Harrington, Heinzerling, and Morgenstern (2009) pointed out another disadvantage of cost-benefit analysis where the criteria of choice of CBA differ from that of policymakers. While CBA directs investment toward equity in terms of risk outcomes, policymakers direct investment toward equity in terms of the cost per life saved. Thus, economists developed two approaches to deriving the value of human life, the human capital approach and the willingness to pay for risk avoidance. These approaches can provide a basis for measuring benefits and monetary variables.

The difficulties of measuring and linking each aspect to a monetary value led to the development of two approaches to economic evaluation. These approaches will be discussed in the following paragraphs.

4.4.2 COST-EFFECTIVENESS ANALYSIS

According to Jamison et al. (2006), Cost-Effectiveness Analysis is a method for evaluating the effects of different health interventions on health and costs, along with their direct financial and scientific implications. This approach is limited when the project's goal is clear, and the objective is to select the most appropriate option between two alternatives. There should be an equal comparison of the benefits of the two alternatives (for instance, the same level of morbidity or health status for the two alternatives). It is still necessary to quantify the costs in monetary terms. As shown in the equation, the analysis compares the incremental cost to the output.
Incremental Cost Effectiveness Ratio *(ICER) = (C1 - C2) / (E1 - E2),*

Where:
C1= cost of the new treatment,
C2= cost of existing treatment,
E1= Health outcome of a new treatment,
E2= Health outcome of existing treatment (for instance, number of events (strokes), number of cases detected, symptom-free days).

According to WHO (2014), ICER has the potential to benefit policymakers in the following three situations:
(i) When the health effect target is specified by policymakers and the cost-effectiveness analysis aims to minimize the expenditure needed to achieve that target.
(ii) When a budget constraint is specified by policymakers and the aim is to maximize the health benefits while keeping expenditure within budget.
(iii) When policymakers have specified an explicit standard or threshold for what should be considered cost-effective.

Compared to the CBA, the CEA is more practical because it avoids evaluating benefits in monetary terms; however, challenges remain associated with it. According to Goeree and Diaby (2013), the two main challenges are the occasional measurement of intermediate outcomes with uncertain implications for patient outcomes and the difficulty of comparing CEA outcomes across diseases and interventions when making healthcare resource allocation decisions.

4.4.3 COST-UTILITY ANALYSIS

WHO (2003) defines Cost-Utility Analysis (CUA) as the analysis used to determine the cost of utilities, specifically, quantity and quality of life. In contrast to cost-benefit analysis, cost-utility analysis is used to evaluate two different drugs or procedures that may contain various benefits. A project's evaluation is based on the incremental cost per Quality-Adjusted Life Year (QALY) gained by patients.

QALY= Σ Fi qi/(1+d)I, then (ICER) = (C1-C2)/(QALY1 – QALY 2),

Where:
C1= cost of the new treatment,
C2= cost of existing treatment,
QALY1= Quality-adjusted life year of a new treatment,
QALY2= Quality-adjusted life year of existing treatment.

One type of CEA would be utilized, which can be considered a health outcome. However, some studies (Jakubiak and Jakubczyk, 2014; Nas, 2016) still view a CUA as unique since QALYs generally combine multiple outcomes from a disease or intervention. It would then be possible for decision-makers to compare infections or interventions with each other based on such specialization.

Accordingly, CUA is the preferable tool for Health Technology Assessment (HTA) among decision-makers, and most economic evaluations are based on the measurement of QALYs. The literature, however, indicates that evaluating alternatives using QALY has some drawbacks and challenges. The key QALY challenge, according to Whitehead and Ali (2010), is its reductionist nature, which indicates that QALY cannot capture all the benefits of a given intervention. An example of uncaptured benefits would be the effect of an improvement in the health of a woman/man with children on their children's health.

According to Whitehead and Ali (2010), QALY does not give a higher weight to individuals who contribute the most to society, as opposed to other health measures such as Disability-Adjusted Life Year (DALY). which measures the relative impact of diseases and injuries on the loss of healthy life years, which gives an added weight to a year lived by a young adult.

Finally, QALY does not consider the susceptibility of vulnerable populations, such as children, severely ill people, and socioeconomically disadvantaged people, which stands against equity. According to Whitehead and Ali (2010), equity-weighted QALY maximization refers to the need for decision-makers to ensure distributional equity of health outcomes and to prioritize health care for disadvantaged groups, suggesting that further studies must be conducted before such an approach becomes a norm for economic evaluation.

Considering the above overview of various economic evaluation tools, we can conclude that each has its limitations, with the CBA having the most difficulty to be measured. There are limitations to generalizing CEA across the allocation of healthcare resources. Due to these limitations, CUA remains the preferred option for economic evaluation, with DALYs serving as the health measure of choice. Organizations like the World Bank and WHO frequently use the DALY approach to compare disease burdens internationally.

WHO (2014) highlighted the strategy promoted by the organization for selecting cost-effective interventions. According to the report, interventions that reduce disability-adjusted life years (DALYs) by less than three times the national GDP per capita are considered cost-effective. Interventions that cost less than one percent of the national annual GDP per capita would be classified as highly cost-effective.

4.5 MEDICINE PRICING STRATEGY IN EGYPT

The price of pharmaceuticals is driven by both demand and supply. However, market imperfections arise from both forces, supply and demand. According to Ruggeri and Nolte (2013), such defects on the supply side are caused by patent protection or regulatory approval processes. In terms of demand, it is composed of various factors, including physicians, pharmacists, patients, and third-party payers. The following sections will address the supply side of the equation and analyze Egyptian pricing strategies.

4.5.1 Club Medicine pricing and Medicine pricing strategy in Egypt

Different countries have different pricing strategies for pharmaceuticals. Ruggeri and Nolte (2013) examined the approaches of six high-income countries to pharmaceutical pricing; and concluded that price negotiation, external reference pricing, and price-volume agreements are the main strategies for innovative drugs, whereas internal reference systems and fixed portions of originator prices constitute the main strategies for generic medications.

Health technology assessment (HTA) is another critical strategy authorities use to determine the initial price and/or reimbursement status of innovative drugs. While HTA provides superior value for money compared to other pricing strategies, the process is more costly. Drummond et al. (2010) compared the significance of conducting HTA strategies with internal reference pricing strategies by comparing the prices of four drug groups in four European countries. While the study is limited to only four countries/drug groups, the study conclusion indicates that the most efficient method for drug pricing may be a combination of both policies; however, this was the only literature that examined this aspect of medicine pricing strategy.

In Egypt, pharmaceutical pricing is regulated by the health authorities; and it is mandatory. Since first legalized in 1960, it has evolved through several stages. The regulation has passed through three phases in the past few years: start with the cost-plus and mark-up regulation, then add external reference pricing in 2009, and finally combine external reference pricing with mark-up regulation as of 2012. (Wanis, 2014)

The Ministry decree (499/2012) on pharmaceutical drug pricing describes the pricing system for innovative and generic drugs in detail. According to the ministry decree, innovative medications' prices will be 10% lower than the lowest consumer price in the country where it is currently available.

There will be a fixed percentage markdown on the price of generic drugs. Based on the certifications obtained by manufacturers, the decree establishes three categories of generic medications. Products in the first category shall be priced 30% lower than brand medicines. They include those produced in facilities; that are licensed by the Egyptian Ministry of Health and certified by international agencies.

The second category consists of products with a price of 40% lower than brand medicines, including drugs made in facilities licensed by the Egyptian Ministry of Health but not certified by other organizations.

The third category of products must be priced at 60% below the brand of medicine. These are drugs owned by companies that have subcontracted the manufacture of the drugs to contract manufacturers.

4.6 Overview of pharmacoeconomic evaluation: Global perspective of

The Australian authorities were the first to mandate the economic evaluation of medicine in 1991, as stated by Drummond (2013); other authorities have since followed Australia's example and required economic analyses to varying degrees. Here is a list of the various pharmacoeconomic guidelines/recommendations from countries around the world: http://www.ispor.org/PEguidelines/index.asp. Based on the list of authorities, it appears that at least two countries on each continent require economic evaluations of pharmaceutical medicines, with Europe having the majority of such requirements.
The study by Drummond (2013) examined the application of economic evaluations in drug reimbursement in several authorities, demonstrating that some jurisdictions consent to the drug evaluation. However, their applications vary. In countries like Denmark, Italy, and Spain, where "value for money" is considered, manufacturers are not obliged to submit economic evaluations to authorities such as Scotland, which require all novel drugs to undergo economic evaluation. Some governments (such as England or Portugal) focus such evaluations on medications that have the potential to impact clinical or economic outcomes significantly.

Nevertheless, Drummond (2013) notes that authorities not in favor of economic evaluation still vary in their applications, ranging from those who oppose the use of cost or cost-effectiveness in denying access to medicine, as in the USA, to countries such as France & Germany that require only the assessment of "added clinical benefit" to determine the price of new drugs.

In a subsequent analysis, it seems that the economic evaluation by some opposing authorities still merits further investigation. According to Sorenson et al. (2012), the USA private insurance sector has shown interest in using the most cost-effective medicine and determining the level of co-payment based on the value of drugs. According to Nasser and Sawicki (2009), in Germany, the Institute for Quality and Efficiency in Health Care was mandated to develop methods for evaluating drug costs and benefits. The goal was to define a ceiling price for statutory health insurance and to encourage competition between providers.

According to this global overview, economic evaluation is becoming increasingly prevalent due to direct regulations mandated by health authorities who favor economic evaluation during drug submission, besides the design of public and private health insurance reimbursement schemes.

4.7 PHARMACOECONOMIC EVALUATION: EGYPT

Until recently, the deployment of pharmacoeconomic evaluation in Egypt was not well documented. Soliman, Hussein, and Abdulhalim (2012) investigated the foundation of the field of pharmacoeconomic assessment as well as the status of pharmacoeconomics education in Egyptian pharmacy schools. Based on the research findings, we can conclude that pharmacoeconomics education in Egypt was still in its infancy. There was an opportunity for talented individuals to provide structured pharmacoeconomics education to students, researchers, and stakeholders, specifically, to facilitate the establishment of an integrated scientific community to apply pharmacoeconomic evaluation to the decision-making process in healthcare.

Egypt released its first guidelines for pharmacoeconomic evaluation in 2013. A study conducted by Elsisi et al. (2013) emphasizes that the guidelines intend to focus on issues related to pharmaceutical pricing and/or reimbursement. However, the contribution of pharmacoeconomics to medicine pricing in Egypt is considered negligible. As an explanation, one could view the current pricing decree in Egypt (Decree 2012), which relies on external reference pricing, mark-up regulation, and markdown regulation without reference to pharmacoeconomic assessments. Because of these legislative conflicts, the pharmacoeconomic evaluation had a minimum impact on medicine pricing and a maximum on reimbursement requests.

Since 2013, when the pharmacoeconomic evaluation unit in Egypt was established, it has evaluated various technologies for their cost-effectiveness. Due to difficulties in calculating incremental effectiveness, some studies were not completed, while others were. Under the heading "Technology appraisal assessment," the Pharmacoeconomic evaluation unit issued a technical report for each evaluation describing the general objectives, detailed cost-effectiveness, and the evaluation conclusion.

To date, the Pharmacoeconomic evaluation unit has completed more than thirty technology appraisal assessments and published these assessments on the Pharmacoeconomic evaluation unit's website: http://www.eda.mohealth.gov.eg/Articles.aspx?id=167. A review of the completed technology appraisal assessments revealed that 52% of the studies were deemed "cost-effective," while 27% were determined to be "not cost-effective." A total of fifteen percent of the studies proposed "risk sharing," while six percent focused on the impact on the budget.

4.8 THE MEDICINE REIMBURSEMENT PROCESS: GLOBAL PERSPECTIVE

Barnieh et al. examined the reimbursement process for medicines in all OECD countries in 2014. Based on the general analysis of the 35 formulary systems reviewed by Barnieh et al. (2014), 94% of the formulary systems reviewed have expert committees that make decisions regarding drug reimbursement. A total of 31 expert committees either provided recommendations to an agency (often the Ministry of Health or another government agency) that made the final decision concerning medicine listing or decisions directly regarding the reimbursement of medicines.

Furthermore, the review revealed that 69% of the systems did not negotiate prices during the reimbursement phase, whereas 31% did. Seventy-one percent of the expert committees, which make recommendations/decisions, require the submission of cost-effectiveness. In addition, 74% of formulary systems have guidelines for preparing economic evaluations.

According to Barnieh et al. (2014), England and Germany have different healthcare systems from developed countries. During the reimbursement process, the expert committee for drug reimbursement in England

determined what medicines should be reimbursed, and it negotiated the prices during the process. Including clinical evidence in reimbursement submission is mandatory, which may come from the manufacturer or an independent evaluation. In England, economic evaluation guidelines recommend reporting cost per QALY since the threshold for cost-effectiveness is set at £30,000; per QALY.

Germany represents the "traditional sickness insurance" healthcare system and has an expert committee for drug reimbursement that makes recommendations to the Ministry of Health, which makes the final decision regarding medicine listing. In Germany, there is no price negotiation during the reimbursement process, as reimbursement submissions require clinical evidence, which is only obtained from the manufacturer. Although cost-effectiveness was not mandatory, Germany issued guidelines for economic evaluations. (Barnieh *et al.,* 2014)

Although pharmacoeconomic evaluation helps evaluate medicine reimbursement, each health system must determine the most appropriate arrangement for its specific needs. There is no universal model that can be replicated by developing countries.

4.9 THE MEDICINE REIMBURSEMENT PROCESS: EGYPT

The medicine reimbursement process in Egypt is summarized in the following flow diagram;

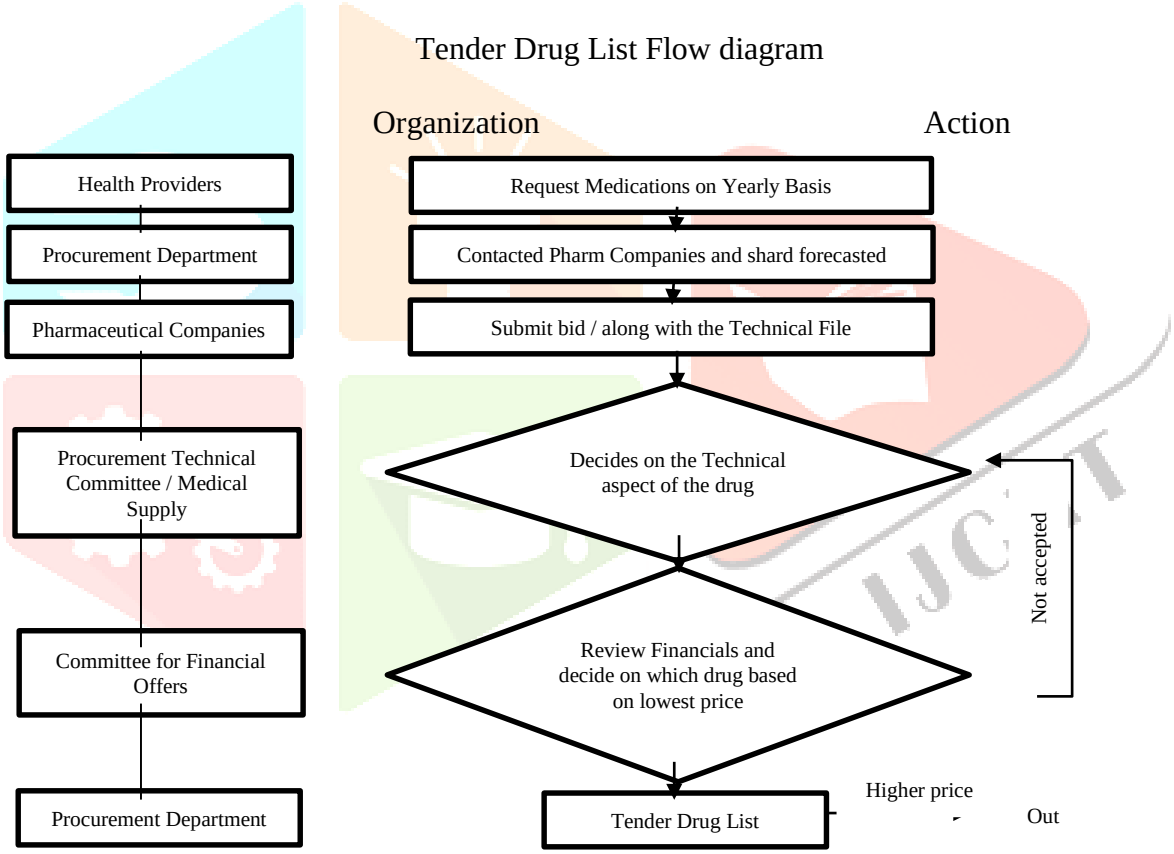

Figure 1: Process flow of Tender Drug List (TDL) for drug reimbursement in Egypt, the flow is similar for the issuance of the 3 TDLs (Main TDL, add-ons List, and TDL of HIO**)**- (Khalil, 2018).

The following figure clarifies the role of each stakeholder in the drug reimbursement process in Egypt along with the communication type between the various parties. This figure gives a good overview of stakeholders' interactions with the reimbursement process.

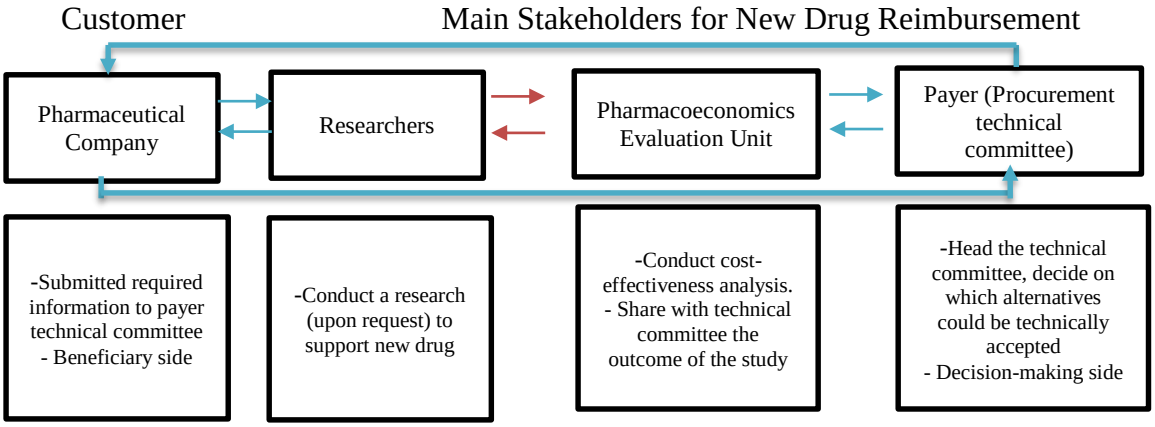

Figure 2 maps of main stakeholders for new drug reimbursement in Egypt with the role of each party along with the communication type between the various parties (Khalil, 2018).

→ Primary Communication

→ Secondary Communication

In Egypt, the healthcare system is fragmented with several authorities involved in healthcare management, funding, and service provision. Concerning the management system, the Ministry of Health and Human Services is the primary authority responsible for healthcare delivery. However, since many decentralized service providers are spread throughout Egypt's 27 governorates, decision-making processes are spread across the country. The health care system is financed by SHI, MOHP, PTES, and FHFs.

According to Phamax (2015), many parties are autonomous as health service providers but are under the MOHP's overall supervision. In addition to decentralized units, university hospitals, Health Insurance Organizations (HIO), Teaching Hospitals and Institutes Organizations (THIO), Curative Care Organizations (CCO), and private hospitals are all a part of MOHP. This applies to all Egyptian governorates. Other health providers include many ministries that have their hospitals. These include the Ministry of Interior, the Ministry of Transport, the Ministry of Agriculture, the Ministry of Religious Affairs, and the Ministry of Defense. The diversity of healthcare providers in Egypt confirms the complexity of the Egyptian healthcare system.

Further, Phamax (2015) clarifies that not all drugs that have been granted marketing authorization are covered by MOHP, but only those that appear on the Tender Drug List (TDL) are reimbursed by public sector hospitals. This study examined how reimbursement occurs in such a fragmented system.

Each two-year TDL is published by the Procurement Department of the Central Administration for Pharmaceutical Affairs (CAPA) based on requests from all health providers. The procurement department; then contacts pharmaceutical companies and shares forecast quantities to request a bid. Based on technical aspects, the procurement technical committee (made up of physicians, academic pharmacists, and legal affairs personnel from MOHP, makes a decision regarding the listing of the drug or not. Afterward, the application is directed to the MOHP committee for financial offers. This committee reviews the financial issues and selects the pharmaceutical company with the lowest price for each active medication. ISPOR (2012) summarized that reimbursement decisions should be based on acceptable technical offers and the lowest prices offered by drug manufacturers or wholesalers. (Khalil, 2018)

Upon receiving a projected unfavorable reimbursement decision (rejection), the Procurement Technical Committee informs the applicant of the decision, according to ISPOR (2012). Applicants may request a re-evaluation before the final reimbursement decision has been issued. The application submitted to the reimbursement process typically takes about eight months. Unlike the private sector, public sector entities follow MOHP regulations for reimbursement, but they are independent.

ISPOR (2012) consists of three tender drug lists. The first is the main list discussed above; the second is the "add-ons," which are provided when the key or first tender drug list does not address all of the hospital and primary care unit needs. Thirdly, there is the issue of the medical supply department at HIO. This department complements the procurement committee at MOHP, where not all the drugs requested by HIO are covered by

the procurement committee. HIO's medical supply department covers the remainder of the drugs on this third tender list. (Khalil, 2018)

The public healthcare system in Egypt is complex. It is challenging in the reimbursement process since there are multiple payers, multiple tender drug lists, and some entities wearing two hats at once (for instance, payers and providers). As a result of the implementation, the pharmacoeconomic evaluation would fit into the technical portion of reimbursement, the procurement technical committee decision step. The following section will analyze how far the pharmacoeconomic assessment has progressed; and its impact on the drug reimbursement process in Egypt. Also, the extent to which such evaluations are considered in the decision-making process for medical reimbursement.

V. DISCUSSION AND CONCLUSION

In this descriptive case study, the findings provide an in-depth understanding of the Egyptian pharmacoeconomic program, as well as the supply and reimbursement of medicines. Since few peer-reviewed papers examined healthcare financing in Egypt, most of the data came from gray literature, indicating the topic is under-reviewed.

According to the study, hospitals are currently seeking the most cost-effective method of managing pharmaceutical inventory. The inextricable relationship between patient care and cost has made inventory management a key challenge for hospitals (Vila-Parrish AR, Ivy JS, King RE, et al. 2012). By improving or changing the drug inventory management, excess investment in inventory can be avoided (Noel MW, 1984). In this case, the hospital should choose a method based on the main issue that needs to be addressed. Lacking design thinking frameworks and inventory management patterns, it will be more challenging to identify the problem (Chanpuypetch W, Kritchanchai D.2017). The costs associated with drug inventory are primarily comprised of (1) shortage costs, (2) carrying costs, and (3) replenishment costs (Hughes TF.1984). A computerized inventory management system enables hospitals to optimize their inventory performance using sophisticated technology (VanDerLinde.1983) (Holm MR, Rudis MI, Wilson JW.2015). It will likely be necessary to quantify the economic impact of efficient inventory management. The hospital can estimate its profit margins using the margin of return on investment (Parrish RH, Berger BA.1986).

Furthermore, the findings indicate that the Pharmacoeconomic evaluation unit should guide reimbursement decision-making using a science-based approach and changing the previous cost-based mindset and consultancy aspect of such economic evaluations. Stakeholders expect that the Pharmacoeconomic Program will yield positive results. Even if some technical committees do not include pharmacoeconomic evaluation, a payer may not be satisfied with the pharmacoeconomic evaluation where their opinions still rely on clinical drug effects, thus encouraging cost reimbursement.

Moreover, cost-effectiveness is an influential factor in the reimbursement decision. An indication that the Technical Committee considered pharmacoeconomic data when making the decision. However, no existing model includes various parameters in one equation; therefore, decision-makers deal with applications on a case-by-case basis. Furthermore, the political perspective affects decision-making processes.

According to the Pharmacoeconomic Unit (2015) for Enzyme Replacement Therapy for treating pediatrics with Type 1 Gaucher disease, the pharmacoeconomic analysis emphasized budget impacts rather than cost-effectiveness, which provides helpful information for medicine reimbursement decisions. However, the Pharmacoeconomic unit did not define a process when considering budget analysis during the unit's technical appraisals. Accordingly, this process is more on an ad-hoc basis.

Pharmacoeconomic evaluation plays the primary role in determining medical reimbursement (medicine inclusion) within the context of UHC. The payer, however, suggested that the pharmacoeconomic evaluation role should be extended to support pricing decisions and medicine inclusion. Currently, pricing decisions are part of medicine marketing authorization. The researcher proposes the same role as the regulator (Khalil, 2018).

Since better budget allocation has resulted from implementing pharmacoeconomic evaluation, medication availability has increased. Additionally, two years after the program implementation, pharmacoeconomic evaluation resulted in eighty million Egyptian Pounds (EGP) savings, which was utilized to purchase other medications.

Identifying priorities in a healthcare environment where demand outweighs the available resources is the most challenging aspect of healthcare decisions. A sustainable and efficient healthcare system depends on effective pharmaceutical pricing and reimbursement systems based on health technology assessments (HTAs), which include economic evaluations. Initially, the Egyptian Ministry of Health established a pharmacoeconomic unit to support pricing and reimbursement decisions. Egypt's reimbursement decisions are currently based on the lowest price after clinical review and approval by the Procurement Technical Committee of the efficacy and safety of the medication. MOHP hospitals and primary care units are reviewed by the Procurement Technical Committee for their medication requirements, while applications are submitted by drug manufacturers, particularly, for cost-minimization analyses (Brown, 2017).

A lack of clarity exists regarding Egypt's pharmacoeconomic studies (Bootman et al., 1996). No published paper has examined pharmacoeconomic studies conducted in Egypt systematically. As Arnold (2016) noted, pharmacoeconomic evaluations in Egypt do not contribute significantly to medicine pricing. It is due to the immaturity of pharmacoeconomics education in Egypt until 2012, which was initiated three years after the Egyptian guidelines for submitting pharmacoeconomic evaluations were published (Bootman et al., 1996).

CUA was conducted only in three studies since many Egyptian decision-makers do not fully understand the QALYs concept. There is no Egyptian tariff for EQ-5D-5L- the descriptive system for health-related quality of life states in adults, consisting of five dimensions (Mobility, Self-care, Usual Activities, Pain and discomfort, Anxiety & Depression). The lack of knowledge and experience required to apply CBA to a monetary value for human life led to few studies performing CBA correctly. Due to the lack of Egyptian data and information on indirect costs (Bootman et al., 1996), eighty percent of the studies included only direct costs.

High-quality economic evaluation studies should be integrated into the reimbursement decision-making process to accurately evaluate clinical and economic benefits and assess their acquisition costs. These evaluations will facilitate decision-making by prioritizing our resources and reducing our massive pharmaceutical expenditure, allowing us to allocate these resources to other cost-effective health technologies (Brown, 2017). Due to the rise in healthcare costs, inflation, and currency devaluation, in addition to healthcare needs that exceed available resources, increasing the healthcare budget does not provide an easy solution to constrict the gap between available resources and actual spending because of the scarcity of cash.

Pharmacoeconomic studies play a vital role at this critical time as they assess the cost-effectiveness of services (interventions/medications) (Bootman et al., 1996). The present study conducts a descriptive case study on medicine pricing, medical reimbursement, and pharmacoeconomic evaluation in Egypt concerning other global perspectives.

During conducting the review, we defined how far the pharmacoeconomic evaluation program had progressed in Egypt and clarified how the pharmacoeconomic evaluation impacted medicine reimbursement. Finally, recommendations were provided to further develop pharmacoeconomics implementation in Egypt.

In Egypt's health care system, payer fragmentation and lack of independence between payers and service providers are significant hindrances to reaching the Universal Health Coverage that Egypt committed to achieving by 2030.

As the direct beneficiaries/main customers of the drug reimbursement process, any upcoming research on Egypt's pharmacoeconomic evaluation should include pharmaceutical companies and patient feedback.

VI. RECOMMENDATIONS AND FUTURE RESEARCH DIRECTION

To enhance drug reimbursement decision-making, Egypt recently launched the pharmacoeconomic evaluation concept. Because this pharmacoeconomic evaluation is not yet mandatory, Egyptian health authorities have

not fully considered it when setting medicine reimbursement policies. Regionally, Egypt is the first country to utilize this science. The experience gained from this implementation could serve as an example for other countries in the region.

In Egypt, the availability of local clinical data hampers the completion of some pharmacoeconomic studies. As well as that, the country has not yet achieved the appropriate level of pharmacoeconomic education, especially for those who are responsible for the reimbursement of medicines. As a result of these issues, the progress of pharmacoeconomic evaluation has been challenging to date.

Pharmacoeconomic evaluation in Egypt has progressed despite a challenging healthcare environment. However, several improvements within the healthcare system had to be made before the full benefits of implementing the pharmacoeconomic evaluation program could be realized.

According to the World Bank (2015), the primary improvement required in the Egyptian public health care system is the reduction of the system's complexity. Four key financiers of Egyptian health care are Social Health Insurance, the Ministry of Health and Population, the Program for Treatment at the State's Expenses, and the Family Health Funds. Each plan offers its own coverage/health service package.

Unifying payers, using one list of drugs for local tenders, and separating payers from providers could reduce complexity. Furthermore, the MOHP needs to develop a clear vision and formulate and implement clear healthcare strategies. As opposed to existing initiatives, which are not necessarily connected or synchronized and are often changed based on changing political climates from time to time.

Second, it is necessary to develop capabilities within MOHP personnel and other relevant stakeholders to improve pharmacoeconomic excellence within the technical staff. This will ensure that competent evaluations can be provided. Furthermore, it would be beneficial to create a culture of pharmacoeconomics among healthcare stakeholders.

Thirdly, establishing guidelines on localizing international QALY data will improve the precision of pharmacoeconomic evaluation outcomes; and ultimately benefit pharmacoeconomic evaluation deployment. The fourth improvement area considers adopting ISPOR guidelines for budget impact analysis into local procedures. By doing so, a systematic approach would be maintained. This approach would help in evaluating upcoming technologies, economically, and when to conduct budget impact analyses, reducing the need for case-by-case scenarios.

The fifth improvement area is to reduce complexity by unifying payers, using only one drug list for local tenders, and separating payers from providers. Furthermore, the MOHP requires developing a clear vision of health care, formulating and implementing explicit strategies, and operationalizing electronic health records for data collection and analysis.

In addition to developing a cadre of trained consumers and producers, the sixth improvement area is to launch pharmacoeconomics teaching and training programs for students of the faculty of pharmacy. There is also a need for more pharmacoeconomics research and publications that require long-term funding and support of applied pharmacoeconomics research. Also, a pharmacoeconomics department at hospitals and successive staff education is a requirement.

Lastly, the development of an appropriate health information system aimed at creating an epidemiology profile for Egypt as well as detailed clinical data for the region is vital. A fact-based decision-making mechanism in the health care system is crucial when obtaining more valuable pharmacoeconomic evaluations and, therefore, a more reliable pharmacoeconomic evaluation. In addition, MOHP should work on establishing a comprehensive HTA program that would consider societal perspective parameters. All these improvements can be grouped under the UHC road map that Egypt committed to achieving by 2030.

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