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Fourth Pharmacoeconomics International Masterclass: Vital Initiative

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Abstract-- The annual Pharmacoeconomics International Masterclass has been organized by Global Healthcare Activities Academy (GHAA) every year since 2017, to enrich the knowledge of healthcare professionals and provide them with the necessary tools to maximize the quality of the healthcare services provided around the world.

The topics discussed in the Masterclass were choosen to cover as many aspects as possible from different stakeholders whether they were healthcare practitioners, academics, pharmaceutical companies or policy makers. The masterclass is divided into four main session topics, each including more specific sub-topics. The main session topics are the novel values in health economics, the alternative access models for innovative treatment, the pharmaceutical pricing techniques and lastly, the role of academia in PE development.

As the principles of pharmacoeconomics gain more appreciation and acceptance around the world, the Arabic world is starting to take steps towards the implementation of these principles, with countries starting to establish official HTA organization and publishing official guidelines. Taken these changes into account, defining "value" in an accurate, inclusive manner is vital to assure maximum benefit and cost-containment. More concepts regarding quality adjusted life years, novel values, gene replacement therapy values, managing entry agreements, reference and value-based pricing were discussed.

The Pharmacoeconomics International Masterclass is a vital and important element for the introduction and development of pharmacoeconomics principles in the Middle East. The benefit of the masterclass comes from the fact that year after year, more in-depth issues are discussed, and bigger challenges are tackled. From the introduction to pharmacoeconomics principles in the 1st masterclass to the discussion of novel values and optimizing the healthcare services provided, each year the topic is more relevant and more crucial for the application of health economics principles in the area. With two paper already published based on discussions and recommendations in the previous masterclasses, the 4th Pharmacoeconomics International Masterclass is expected to produce many fruitful insights and helpful recommendations.

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1. BACKGROUND

The annual Pharmacoeconomics International Masterclass has been organized by Global Healthcare Activities Academy (GHAA) every year since 2017, in an effort to enrich the knowledge of healthcare professionals and provide them with the necessary tools to maximize the quality of the healthcare services provided around the world.

Global Healthcare Activities Academy (GHAA) is an organization of healthcare professionals, aiming to acknowledge and address pressing healthcare problems, new innovative fields, and their possible applications through expanding the horizon and knowledge of healthcare professional around the world.

Since the Pharmacoeconomics International Masterclass was first held in 2017, its main purpose remains to spread the knowledge about the pharmacoeconomics and its important application in the management of resources and improving the patient's outcome and quality of life.

In addition to that, the masterclass provides an optimum environment for expanding one's professional network and share experiences and knowledge on different topics which leads to different perspectives on many obstacles and potential solutions.

The 1st Pharmacoeconomics International Masterclass was held on December 16, 2017. The main focus of the masterclass was introducing the basics of pharmacoeconomics and health technology assessment (HTA) such as the different types of economic evaluations, clinical outcomes, assessment of the quality of life and modelling. The concepts learned in that masterclass were necessary to pave the way to better interpret, understand and conduct economic evaluations.

The 2nd Pharmacoeconomics International Masterclass was held on October 24, 2018. This masterclass focused more on the practical aspect of the pharmacoeconomic science with practical examples of budget impact and cost-effectiveness analyses. Furthermore, different approaches to pricing and the

critical appraisal of different pharmacoeconomic studies were discussed.

The 3rd Pharmacoeconomics International Masterclass was held on December 14, 2019. After learning the theoretical and the practical basics of pharmacoeconomic. The third masterclass dived more into issues and obstacles that are met in the real world. Among the topics discussed were the challenges faced in the rare diseases including the high prices of medications and the lack of real-world data to build a model for an economic evaluation. And with goal of knowledge sharing in sight and based on the recommendations shared in that masterclass, the hoped results started to materialize and a paper was published in Global Journal of Medical Therapeutics (GJMT), discussing the challenges of reimbursing orphan drugs, especially in the Arabic world health technology assessment organization is not yet established [1]. The paper discusses the challenges of evaluating orphan drugs with the guidelines used for other drugs and also includes prevalence of rare conditions in Saudi Arabia and possible solution to face current challenges in evaluating specialty drugs [1].

Another important paper materializes discussions and recommendations exchanged in the Pharmacoeconomics International Masterclass. This paper discussed the challenges in the application of the pharmacoeconomic concepts in hospitals in the presence of an elite selection of healthcare professional and pharmacoeconomic specialists [2]. Based on the discussion occurred between different stakeholders, the problems were identified and possible solutions were set by the experts [2].

Now more than ever with the limitation of the resources increasing, and the economic aspect of new interventions being a crucial determent in the realistic ability to adopt them into any healthcare system, the application of HTA is vital to guide policy maker to the best possible decision to ensure maximum patient benefit and satisfaction. With pharmacoeconomic and HTA taking on a new role and a newfound importance, the cost aspect is now not the only cornerstone of an economic evaluation, but it has to be weighed against the added value of the intervention or service being evaluated.

Accordingly, it was decided that the 4th Pharmacoeconomics International Masterclass is to be held on December 26, 2020. The masterclass focuses on the value assessment in the healthcare policy, novel values, and alternative agreements for innovative treatments.

There were debates and differences between scientists on how to define value. For instance, Michael porter defines value as “health outcomes achieved per dollar spent” [3]. To further specify the meaning of value, ISPOR Special Task Force Report stated that the gross value is what a person would be willing to pay for a good or an intervention [4]. While the net value removes the opportunity, costs utilized to obtain the gross value [4]. Regardless of what the definition is, it remains agreed upon that what qualifies as value depends on the perspective and the context of the study.

2. Organization of the Masterclass

Given that the subject of the 4th Pharmacoeconomics International Masterclass which is value is such a broad area with a lot of aspects to cover. The topics to be discussed were chosen to cover as many aspects as possible from different stakeholders whether they were healthcare practitioners, academics, pharmaceutical companies or policy makers. The masterclass is divided into four main session topics, each including more specific sub-topics. The main session topics are the novel values in health economics, the alternative access models for innovative treatment, the pharmaceutical pricing techniques and lastly, the role of academia in PE development.

The first main topic is the novel values in health economics and it includes orientation of the new values that may have emerged in the health economics field and then a specific dive in the new values that are now considered in gene therapy. The second main topic is the alternative access models that could be used for innovative treatment introduction into a country, which includes risk sharing agreement or performance-based agreements. Both access models are to be discussed along with the challenges and benefits of each and previous interventions that were introduced with said agreement, in addition to discussing the challenges and methodology of reimbursing a new innovative treatment. The third main topic is the pricing techniques used to price a new pharmaceutical intervention, which includes a general orientation of the different principles and approaches utilized in pharmaceutical pricing and a more focused review of reference-based pricing and value-based pricing. Each pricing technique was discussed in detail mentioning the implications of their use and the challenges expected in attempting to apply them. The fourth main topic is the role of academia in pharmacoeconomic development in which the difference between pharmacoeconomic in curriculums and in practice was discussed from an international point of view.

After each one of the main sessions, a Q&A session was conducted to allow for an environment of knowledge sharing and exchanging of expertise. During the Q&A sessions, attendees are encouraged to share their questions and their point of view in an effort to generate new perspective on the topics discussed.

3. Discussion

As the principles of pharmacoeconomics gain more appreciation and acceptance around the world, the Arabic world is starting to take steps towards the implementation of these principles, with countries starting to establish official HTA organization and publishing official guidelines. Egypt for instance, published official guidelines for reporting pharmacoeconomic evaluations in 2013 [5]. Taken these changes into account, defining “value” in an accurate, inclusive manner is vital to assure maximum benefit and cost-containment.

Novel values are a central topic in the masterclass. The ISPOR Task Force concluded that in order to decide what value should entail, the perspective should be determined [4]. Whether the usual health payer, the patient, the provider, the manufacturer governmental regulators or societal perspective,

the value is to determined accordingly as an any of these stakeholders could be the perspective for a cost-effectiveness study for different purposes [4].

3.1 Quality-adjusted life years

Traditionally the gain from an intervention is measured from the patient's point of view or it could be measured from the perspective of all of the society, however different components need to be considered such as the impact on the patient's mobility, pains experienced, life years gained or lost and their quality [6]. In order to address these benefits, quality adjusted Life years (QALYs) were implemented into health economics [7]. A QALY is the portion of a perfectly healthy life-year remaining after considering for the damage due to an illness or a condition [6]. For instance, based on surveys, consumers stated that one year of blindness is equivalent to six months of health, this proportionality or fraction is called utility, which is used to build cost-utility models that are model that uses QALYs [6].

3.2 Novel Values

But as QALYs only capture a portion of the real values, there is a need to introduce new values such as productivity. Productivity is not included in the QALYs calculations but many researchers and organizations included loss or gain of productivity in the work place as a separate value input. Contrary to some scientists, it is widely believed that the traditional utility measurements do not capture productivity as it is a separate gain than that included in QALYs, which could be important, especially for studies conducted from employer or government perspective [6]. Another value to be considered is the effect of the new therapy on patient compliance, such as simplifying dosing regimens or using different routes of administrations, which in turn would improve the outcome for the patients and should be considered as an added value for the new intervention [8]. Additionally, the severity of the disease should be included in calculating value, patients near end of life or starting from a poor prognosis would add more value in health gains than other patients [9]. Another novel value arises when the patient does not only focus on increasing QALYs but is willing to take risks, which is the value of hope [10].

Since the COVID-19 pandemic, this value is more relevant than ever, which is the fear of contagion. Although usually evaluations of interventions for infectious disease "externality", the fear associated with these infectious diseases affect the patient's quality of life and should be taken into consideration. Fear of contingency could be measured using surveying method to establish the amount a patient is willing to pay to eliminate the fear of contacting this disease [6]. Lastly, a novel value that is known but not sufficiently developed, is scientific spillover. Which is the effect of a new technology on the future generations and their wellbeing, while for instance, a new mechanism of action would not be particularly valuable to the patient, it could be a path for greater benefits in the future, which should be considered [11].

3.3 Gene replacement therapy values

As an example of how the value could affect the final outcome, novel value in gene replacement therapy (GRT) was discussed. Gene therapy is defined by the European Medicines Agency (EMA) as a "medicinal product is a biological medicinal product contains an active substance that contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence and has therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence" [12]. GRT usually target younger population with cognitive damage and thus concerns about the under quantification of utility and quality of life. Therefore, a factor for QALYs inflation could be used or higher willingness to pay threshold when evaluating GRT [13]. Or as a novel value, saved young life equivalents (SAVE) as an alternative to QALYs is now being utilized [13].

3.4 Managed entry agreements

After thoroughly discussion the importance of novel values in health economics and their application in published models, the new alternative ways to assess innovative treatment offering unique and make them available to the patients was discussed. Managed entry agreements (MEAs) are a new way to introduce innovative treatment to the market and it is defined as "any arrangement between a manufacturer and payer/provider that enables access to a health technology subject to certain condition" [14]. MEAs have been previously used when the effectiveness evidence on the new intervention were not sufficient [15]. MEAs are also known as patient access schemes (PASs), especially in the UK as models causing a reduction in the effective price [15]. In an effort to control the expenses of the healthcare sectors and optimized the allocation of the budget, risk-sharing agreements (RSAs) were utilized by many policy makers. RSAs are agreements between manufacturers and payers that allows the patients to access an innovative treatment even though the clinical evidence on its effectiveness and cost-effectiveness is not sufficient or mature [16]. The drug is introduced to a portion of the patients where it would be the most beneficial to, allowing for more evidence collection on the real-world clinical outcomes of the intervention, therefore the reimbursing of the intervention depends on its effectiveness in real-world clinical practice [16]. Furthermore, then the intervention is only introduced to the subgroup that would benefit from it the most, its impact on the budget is limited, thus the RSAs ensure that the price of the intervention is compatible with outcome gain it provides [16]. One of the methods for risk sharing between manufactures and payer is performance-based MEAs, that can be defined as "schemes between health care payers and medical product manufacturers in which the price, level, or nature of reimbursement are tied to (future) measures of clinical or intermediate endpoints ultimately related to patient quality or quantity of life" [17]. Performance based MEAs are a way of applying value-based pricing to limit the price of an intervention to how beneficial it is. The main rationale behind implementing performance

based MEAs is for interventions that satisfy an unmet need for the patients which makes the policy makers agree on that an unconventional method of pricing specially if the intervention does not have enough clinical evidence to allow for evidence based reimbursing decision [17].

Challenges concerning the implementation of MEAs and reimbursing innovative treatments was discussed. Based on a study conducted in 2018, only a few MENA countries utilize MEAs due to the limited health economic knowledge in the area and the difficulty in measuring relevant indicators [18]. Therefore, the urgency to consider these agreements, in the current situation of restricted healthcare budgets to optimize the provided healthcare service, is crucial.

3.5 Pricing Challenges

Other than MEAs, pricing pharmaceuticals in general is being widely discussed among researchers and stakeholders. Pricing is the financial value for an item for consumption while during its transaction between different stakeholders [19]. Many elements affect the pricing of pharmaceuticals including the novelty of the intervention, the competing technologies, the effect on the budget and the accessibility of the intervention [20]. The determined price has an impact on many aspects, for instance it determines the ability of the patients to afford it, the economic impact on payers and furthermore, the motivation of pharmaceutical companies to develop new innovations [21].

3.6 Reference-based pricing

Among the methods used for healthcare expenditure containment is reference-based pricing. Reference-based pricing refer to the state where a payer set an upper limit to how much they are willing to pay for a certain medication or services, while allowing the manufacturers to set the prices for their product and the treating physicians and the patients to choose the product they desire, thus minimizing the pharmaceutical expenditure without affecting the healthcare service provided to the patient [22]. Though a valid way to reduce drug costs, reference-based pricing has its drawbacks including, discouraging pharmaceutical companies to manufacture new products, inserting the economic aspect to the relationship between the physician and the patient, while undermining the ability of the physician to make a treatment plain specific for each patient and determining the level of treatment access based on the economic background of the patient [23].

3.7 Value-based pricing

Another highly approved pricing strategy is value-based pricing. As the general awareness of the importance of profit sustainability increased, it became increasingly important to identify the elements that are considered as added value for the patient, and aim to achieve customer satisfaction through determining pricing policies while considering the value the intervention has to offer [24]. Value-based pricing basically depends on how much the payer is willing to pay for the value the product provides, which increases the competition between manufacturers not just to lower the prices of their products but to invest in innovative ways to increase the value of their products to satisfy unmet need [25].

Finally, in an attempt to ensure the practical application of discussed topics, previous experiences and challenges in implementing pharmacoeconomic concepts in practices were discussed.

Lastly, On December 26, 2020, the 4th PEMC was held by GHAA with the participation of a selected group of distinguished professionals and various stakeholders. The topics discussed in this masterclass were of critical importance to decision makers. In such times of high load on healthcare systems around the world, these discussions about novel values and optimum cost allocation are not only of vital economic importance, but are also absolutely vital to insure better treatment and better healthcare services to patients worldwide. In the time of COVID-19 pandemic, this masterclass served as a guidelight for policy makers on the importance of evidence-based decisions and their benefit for the society and the economy.

4. CONCLUSION

The Pharmacoeconomics International Masterclass is a vital and important element for the introduction and development of pharmacoeconomics principles in the Middle East. The benefit of the masterclass comes from the fact that year after year, more in-depth issues are discussed, and bigger challenges are tackled. From the introduction to pharmacoeconomics principles in the 1st masterclass to the discussion of novel values and optimizing the healthcare services provided. Each year the topic is more relevant and more crucial for the application of health economics principles in the area. With two paper already published based on discussions and recommendations in the previous masterclasses, the 4th Pharmacoeconomics International Masterclass is expected to produce many fruitful insights and helpful recommendations.

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