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Dr. Nada Abu-Shraie gives her insights into the evolving drug evaluation processes in Saudi Arabia, including the progress made on the path towards striking value-based agreements, where the country stands in terms of patient registries and epidemiological data, and Vision 2030's potential impact on the medicine reimbursement landscape.

Can you begin by introducing your background and current role to PharmaBoardroom's international audience?

I work as a consultant clinical pharmacist at the Drug Policy and Economic Centre (DPEC) at King Abdulaziz Medical City (KAMC), Ministry of National Guards – Health Affairs (MNGHA), Riyadh, Saudi Arabia. Before that, I worked as a consultant clinical pharmacist for King Faisal Specialist Hospital & Research Centre (KFSH&RC), also in Riyadh.

I hold a Doctor of Pharmacy degree from Nova Southeastern University, USA, have a pharmacy general practice residency certificate from King Faisal Specialist Hospital & Research Centre (KFSH&RC), Saudi Arabia & Saint-Louis College of Pharmacy, USA and I lately earned a drug information specialty residency certificate from Yale-New Haven Hospital and Boehringer Ingelheim Pharmaceutical Inc., USA.

My main specialization is in drug information, formulary management systems, and the development of drug-use policies and clinical practice guidelines. At the DPEC, I have a clinical role, including developing drug-use policies and clinical guidelines, and reviewing medications protocols. Part of my role is focused on evaluating requested medications for formulary additions and deletions based on evidenced-based evaluation, which is usually done in collaboration with our pharmacoeconomic team, and I also contribute to reviews of internal departmental policies and procedures.

What is the purpose of the Drug Policy and Economic Centre (DPEC) within the MNGHA and the Saudi health ecosystem in general?

The DPEC analyses and identifies costs and outcomes associated with providing pharmaceutical products and related services. This can be achieved by assessing the clinical and pharmacoeconomic data on drug therapies and determining the most cost-effective drug of choice based on different factors. In addition, the DPEC oversees the MNGHA Drug Formulary management system through active involvement with the Corporate Pharmacy and Therapeutics' (CP&T) Committee and other related subcommittees. We select the medications to be included or deleted from the MNGHA Formulary; develop drug-use policies and clinical practice guidelines; conduct various types of pharmacoeconomic analysis and medication utilization evaluations (MUEs); as well as many other activities.

How does the DPEC interplay with the work done by other governmental entities such as the Ministry of Health (MoH) and Saudi Food & Drug Administration (SFDA)?

Our centre is one of the first of its kind to be established in the Kingdom of Saudi Arabia. We are nationally recognized as a leader in the application of innovative collaboration pharmaceuticals policies development program that is powered by applied pharmacoeconomics and outcomes analyses. The DPEC predominantly serves the pharmacoeconomic needs of the MNGHA, but we also collaborate with all other national sectors if needed in assessing the value of pharmaceutical products to support decisions and policymaking around drug use.

We also play an active role in contributing to taskforce groups and committees such as the "National Expensive Medications Committee" at the Saudi Health Council (SHC). The committee has a multidisciplinary team of experts with various specialties from different healthcare sectors in

Saudi Arabia. The main function of the members of the committee is to conduct extensive clinical and pharmacoeconomic evaluations for any submitted medications to be used by the MoH and other Saudi healthcare sectors. Most of the medications that we have evaluated so far were indicated for uses in the treatment of rare diseases. These medications usually have a very high cost and require a thorough evidence-based evaluation by an expert team of clinicians and pharmacoeconomists. We also have contributed to many committees at the SFDA for evaluating the cost of therapies.

What are the fundamental tools that the DPEC utilises in its work?

We analyse both clinical and economic information in clinical trials and outcomes research, whether they are published or available on-file sources. Our pharmacoeconomic team, in collaboration with the clinical team, can build economic models and conduct different types of analysis as needed such as:

1. Cost-effectiveness analysis (CEA) to compare competing therapeutic alternatives that differ in therapeutic outcomes where cost is measured in monetary terms and consequences in units of effectiveness or natural units
2. Cost-benefit analysis (CBA) to compare the costs and benefits of therapeutic treatment alternatives when costs and benefits are expressed in monetary terms, particularly when deciding how to allocate scarce resources
3. Cost-utility analysis (CUA) to compare therapeutic alternatives using terms of patients, preference, or quality of healthcare, or when outcomes cannot be expressed in monetary terms

Other types of analysis can be conducted if needed such as budget impact analysis, sensitivity analysis, and decision analysis to choose between competing therapeutic alternatives.

Various software programs can be utilised in the building of these economic models and the manufacturing companies can also help during the development of these models by providing some data.

Our clinical team, which I am part of, oversees data analysis activities and contributes by collecting clinical data for feeding the economic model. This activity can assist them later on in developing drug-use policies and clinical guidelines based on the clinical and economic evaluations conducted. The clinical team is also responsible for developing reports after reviewing retrospective data for

the purpose of MUEs and oversees the evaluation process of medications that have requested to be added to the MNGHA formulary. Such a systematic process ensures that all requested medications undergo an extensive scientific evaluation of all comparative data related to efficacy, safety, and cost.

Both teams can also contribute to developing value-based agreements in collaboration with different manufacturing companies based on needs.

What has the MNGHA's experience been thus far in terms of striking value-based agreements?

We have moved forward with value-based agreements with manufacturers. There is no clear approved policy for value-based agreements or risk-sharing agreements (RSAs) in the Kingdom yet, but we recently developed our own internal policy and procedures at MNGHA for establishing such agreements and we have a total of eight (8) RSAs so far. Most of these agreements are formulated for oncology medications that are expensive and/or have uncertain clinical outcomes. These agreements are either financially- or outcome-based where we link the outcome of the medications to the reimbursement. For outcome-based agreements, the clinical team at the DPEC has to set the clinical criteria for reimbursement and response. I consider our experience to be successful so far and hopefully, it will be soon published.

Health outcomes is a science that is best guided by quality data from patients and population. At what stage is Saudi Arabia in terms of patient registries and epidemiological data today?

In Saudi Arabia, the SHC oversees registry development for different diseases. Additionally, the Public Health Authority is working on developing epidemiological data for various diseases. These registries cover chronic diseases such as cardiovascular; rare and neurological diseases; cancer, and many others.

KAMC at MNGHA already has several registries in place developed by the treating physicians/services. The treating physicians usually contribute to national disease management registries if they exist. Currently, we extrapolate data that we get from international studies and real-world diseases management registries or use in our local registries, if they are available, to build our pharmacoeconomics models. We are still progressing in this field. Some epidemiology

data on certain diseases is lacking but we expect this field to improve more within the next five years. With the recent establishment of the Saudi Health Technology Assessment (HTA) agency, we expect this to grow faster.

In which epidemiological areas does Saudi Arabia most need to reformulate its approach in terms of access and impact?

There is no easy answer to this question. While data on chronic diseases that increase the risk of mortality such as cardiovascular, obesity, and diabetes is, of course, essential, ensuring the availability of epidemiological data on rare and genetic diseases, which are very prevalent in Saudi Arabia, is equally important. The clinical and economic evaluations of medications used to treat these diseases are very difficult due to a lack of international data and the limited availability of evidence. Nevertheless, the evaluation of medications used for rare diseases involve considerations that differ from those used of more prevalent conditions. Many of these considerations are based on practical challenges with evidence development, high cost of medication, and the small number of people that participate in these trials.

For example, the use of randomized, controlled trials (RCTs) is often not feasible with rare diseases. Additionally, the fact that the treatment of rare conditions often fails to meet the cost-effectiveness thresholds used to consider what reasonable value would be for other conventional therapies raises important ethical questions of fairness. International Health Technology Assessment (HTA) agencies have developed special frameworks for decision-making, thresholds for economic impact, and reimbursement policies for medications used for treatment of rare diseases that differ from those for other conventional medications.

In Saudi Arabia, due to the limited local epidemiology and patient registry data, it can be very difficult to fairly evaluate medications indicated for orphan and rare disorders since most trials for these new medications have not been conducted locally. Having local epidemiology data and patient registries on rare and genetic diseases would definitely facilitate better assessment and balance between the economic and societal burden that these diseases cause compared to the cost of the medication.

How has the reimbursement landscape worked traditionally in Saudi Arabia and how are you seeing it evolving?

We have both governmental and private healthcare systems in Saudi Arabia, with the governmental sectors accounting for the majority of healthcare systems. KAMC at the MNGHA is considered to be a governmental healthcare sector and has its own budget that differs from that of the MoH. In the governmental healthcare system, Saudi citizens are treated free of charge, but in the private sector, private medical insurance is used and both Saudi and non-Saudi citizens can be treated. The MoH is the main regulator for both the government and private sectors.

We hope that our new Saudi HTA agency, with the help of all other stakeholders such as our DPEC, will soon be fully functioning and generating its own outcomes. It is expected that it will take the lead in the Middle East and North Africa (MENA) region in identifying the pharmacoeconomic and reimbursement outcomes on medication use.

Which impact do you foresee the Vision 2030 economic transformation programme having on the way that drugs are assessed in Saudi Arabia?

All Saudi healthcare systems will be still regulated and accredited by the MoH but will no longer be directly operated by it. A National Centre for Health Insurance will be used by each sector and the MoH will be billed for the sectors under its umbrella. Other governmental sectors such as KAMC at the MNGHA are usually billed separately under their own budget.

Until then and until the Saudi HTA agency is fully operational, it is expected that each healthcare system will independently continue to identify the most cost-effective medications to be included in their healthcare system formularies and avoid unnecessary drug expenditures resulting from the use of expensive medications that do not provide additional value or outcomes in comparison to the existing ones. We are defining ‘cost-effective medication’ as:

1. Less expensive, and at least as affective as the comparator; or
2. More expensive while providing an additional benefit worth the additional cost; or
3. Less expensive and less effective when the extra benefit is not worth the extra cost

Therefore, the most-effective medication is not necessarily the cheapest medication.

In a broader sense, do you feel that Vision 2030 is set to change many socio-economic aspects of the Kingdom?

By 2030, we will have good epidemiological infrastructure data and well-structured disease registries which will affect the Kingdom's budget and socio-economic aspects. In addition, the healthcare initiatives that form part of Vision 2030 such as promoting quitting smoking; vaccination; increasing life expectancy; and reducing traffic accidents are focused on preventing risks and providing early and proper management of diseases.

Recently, the Agency of Preventive Health at the MoH launched a huge educational campaign around women's health and the human *papillomavirus* (*HPV*) *vaccine*. More than 100 countries, including Saudi Arabia, have started using the vaccine as part of World Health Organization (WHO) plans to get close to eliminating cervical cancer.

Many other initiatives have been set out by Vision 2030 such as the shift towards the digital transformation of our systems; the use of artificial intelligence applications and software; new governance systems; partnerships with private healthcare sectors; and increasing the capacity and efficiency of the healthcare system. **All these amazing initiatives will give healthcare workers a greater chance to show care and empathy** to patients. In addition, these initiatives will have a huge economic impact, can assure financial sustainability, and reduce unnecessary spending. Eventually, this will definitely improve Saudi citizens' quality of life.

How do you believe these changes will impact women in Saudi society, especially given that they traditionally play a key role on healthcare issues within their households?

I believe that the real benefit that women will bring to the Saudi healthcare system is in the diversity that they offer, especially given the education, knowledge, and experiences they have nowadays. The high sense of responsibility that Saudi women possess is the real added value, which is reflected within society. In traditional Saudi culture, women have a leading and influential role and today they are showing more strength with added knowledge, and the empowerment provided by Vision 2030.

Believe me, all Saudis (male and female) are very optimistic about Vision 2030 and it is obvious that all Saudi healthcare systems are working hard towards achieving its goals. King Salman Al Saud once described his ultimate goal as "making our country a role model and a pioneer in all fields," and this is a goal that all Saudis share.

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