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This will be one of the largest healthcare transformations in the world in terms of number of centres, size of population served, and complexity

11.10.2021

Tags: Saudi Arabia, Ministry of Health, Vision 2030, Healthcare, Regulation

Prof. Ahmed Aljedai, assistant deputy minister of therapeutic affairs for support services at Saudi Arabia's Ministry of Health (MoH) outlines how the Saudi healthcare system is being restructured in line with the country's Vision 2030 economic transformation programme and the three goals of improving access, improving quality, and improving value.

Ministries of Health have different roles depending on the country and healthcare system which they serve. How wide is the MoH's remit in Saudi and how is it shifting in line with the country's Vision 2030 transformation plan?

The healthcare system in Saudi Arabia is governed by multiple bodies. Pharmaceuticals, medical devices, food, supplements, and herbal products are governed by the Saudi FDA. The FDA oversees the review, registration, and classification of these products, but also their pricing and assuring their quality.

In terms of healthcare practices, the MoH is the regulator for both the government and private sectors. In the national governmental healthcare system citizens are treated free of charge and we have about eight governmental healthcare sectors. There is also a private sector, which today

accounts for about 20 to 25 percent of the whole market, a number that is expected to reach 35 percent by 2030. The MoH accounts for 80 percent of the governmental sector and 60 percent of the overall healthcare sector. Then we have other healthcare sectors such as National Guard Health Affairs, Ministry of Defence Health Affairs, Ministry of Interior, King Faisal Specialist Hospital General organization, ARAMCO, and many others.

The MoH, as the largest healthcare sector, provides three main functions. The first is provision of care through a network of healthcare systems, including about 300 hospitals, about 2200 to 2400 primary healthcare centres and other specialized centres like oncology, cardiology, eye specialist hospitals, nephrology, and dialysis centres. MoH is also the regulator of the healthcare sector as a whole, however the other governmental healthcare sectors have some governance within their sectors. The MoH is the payer for these healthcare costs. In total, therefore, *currently, the Saudi MoH is the provider of care, the regulator, and the payer*.

Within the healthcare transformation in Vision 2030, which has been ongoing since 2018, we are going to separate these functions. MoH is going to be the only regulator of health, including all governmental healthcare sectors, and all other healthcare systems will be under its governance, not operationally but in terms of regulatory and auditing standards and accreditation credentials etc.

In terms of provision of care, we are giving this up to 20 ‘accountable care organisations’, which will include primary, secondary, and tertiary care healthcare centres. These organisations will provide care to Saudi citizens free of charge and will then bill the government through an independent payment centre, currently called PHAP but eventually to be known as the National Centre for Health Insurance. These organisations are not really private in that they are initially owned by a holding company that is owned by the government. The overall super-regulator of health will remain the MoH by 2030. This will be one of the largest healthcare transformations in the world in terms of number of centres, size of population served, and complexity.

Saudi citizens will continue to get free healthcare through the government, but via a more corporatized provision of care. This will help remove both complexity and conflicts of interest.

Can you introduce your remit within the Saudi Ministry of Health (MoH) and in which projects are you currently participating for the betterment of healthcare provision?

I am assistant deputy minister for medical support services, where I oversee multiple clinical aspects, including drug policy and control, pharmaceutical care, clinical nutrition, nutrition services, and radiology, among others. Part of my role is to focus on the selection of *evidence-based* pharmaceutical products, as well as other health technologies. In the MoH, we are responsible for building, maintaining, and developing a national formulary of medications. We have been implementing state-of-the-art formulary management practices under the scientific therapeutics committee that reviews, evaluates, and approves new medications and manages the formulary.

I also take care of all health technologies related to radiology, nutrition, or pharmacies in general. This is in line with the healthcare transformation part of Saudi's Vision 2030, which focuses on improving patient access to care, improving the quality of care that is provided, and finally providing value-based healthcare. This represents a huge change from what went before.

Additionally, we also conduct economic evaluations and health technology assessments, review the best available evidence, and create clinical practice guidelines, clinical pathways, and protocols. Moreover, we also conduct economic models in terms of budget impact analysis, cost effectiveness studies, and establishing a national cost effectiveness threshold, which we will publish soon. Another ongoing project is a very large study estimating the cost utility valuation based on EQ-5D-5L for which we are working with the EUROQOL which will hopefully be completed by mid-2022.

We improve access to care by providing the best health technologies available, including pharmaceuticals, and also work to improve the quality of care. We do this not by only providing the best available medications, but also the most rational and cost-effective therapies. This is coupled with making sure that clinical guidelines and protocols are implemented and auditing the healthcare systems within MoH in terms of implementation and adoption.

The fact that the Saudi FDA will retain its pricing remit is quite unusual given that national regulators tend to focus solely on efficacy and safety.

That is true. The FDA is responsible for safety, efficacy, and quality, but also pricing. Other medicine regulators like the US FDA, EMA, MHRA, and TGA do not price medications; this comes from different entities. In Saudi, there is a legal requirement for all medications to be priced for out-of-pocket spending. These prices are higher than the cost of medications in national tenders and represent the maximum that a company can sell its products for.

Healthcare budgets are constrained across the world, including in Saudi. How does this budget management piece fit into your healthcare transformation strategy?

The three goals of our healthcare transformation are improving access, improving quality, and improving value. We are looking at healthcare services that provide value to society and this includes making sure that we are utilizing the most cost-effective approaches, treatment modalities, and diagnostic modalities to our patients.

Healthcare expenditure is continuously increasing and no healthcare system in the world can completely accommodate the ever-increasing costs of medications, diagnostics, and devices. That is one of the reasons we want to link the payment for healthcare services to the outcomes. *The National Centre for Health Insurance* will reimburse the 20 accountable care organizations based on outcomes such as length of stay, surgery outcomes, and treatment outcomes, with certain clinical metrics and KPIs that are set in advance for all of these healthcare systems, where we reward those who excel and provide care with extra support payments and penalise those who underperform by not giving them the full reimbursement.

This will encourage improvements in the quality of, access to, and efficiency of care. Treating cancer patients a few months after they are diagnosed is different to treating them immediately, for example. That is why it is very important to bundle quality, access, and efficiency into a payment model that rewards good performers and underpays underperformers.

Is Saudi Arabia yet in a position to have a detailed epidemiology agenda, with national plans in areas like cancer, chronic diseases, rare diseases and any others with budgets attached to them?

This is still a work in progress. The Saudi Health Council, the umbrella for all healthcare systems is charged with registry development of different diseases, and we already have several registries in place. These registries cover chronic diseases, such as cardiovascular – the number one killer in our country – as well as other areas such as tumours.

We also have the Saudi CDC which is called now the public health authority, which focuses on disease prevention and control, and which is working on developing epidemiological data. The MoH has some epidemiological data on the most prevalent chronic diseases such as diabetes and obesity, for which we are, unfortunately, one of the top countries globally in terms of prevalence.

Within our healthcare transformation plan we created several models of care, one of which focuses on chronic diseases, another on maintaining the health of those in good health and preventing diseases by encouraging lifestyle modifications in terms of diet, exercise, and smoking cessation.

One of our Vision 2030 KPIs is improving the average life expectancy of Saudis from 76 to 80. Another target is to reduce the mortality from road traffic accidents, a major issue here which were able to reduce over the past three years by about 50 percent.

There are multiple initiatives within the healthcare transformation plan, but we still lack the detailed epidemiology data that exists in North America and Europe. This is not to say that we don't have data on the prevalence; we have data on diabetes, obesity, hypercholesterolemia, tumours, cardiovascular disease, but very specific data in areas such as metabolic genetics and neurological diseases are not readily available today, although we are in the process of developing this.

How much of a burden is medicine spending on the overall Saudi healthcare budget today and what steps have been taken to better assess value?

Last month, we established a Health Technology Assessment Centre which is charged with conducting HTA of different technologies, starting with medications, before moving onto medical diagnostics, devices, medical supplies, and procedures. We have conducted multiple economic evaluations and HTAs at the MoH even before the creation of this new centre, making the MoH a leader not just in Saudi Arabia but across the region on budget impact and cost effectiveness analysis.

The MoH has also led the way in registry development, developing multiple disease registries. Also, when it comes to evaluation of the safety and efficacy of different classes of medications, we are establishing for the first time, the cost effectiveness threshold or the health opportunity cost for Saudi Arabia, as well as the cost utility valuation based on the EUROQOL 5D-5L-5Q

At the same time, we have moved forward with value-based agreements with manufacturers. We had already established managed entry agreements based on risk sharing on a volume or financial basis and have now also established several outcome-based agreements where we link the outcome of the medication to the reimbursement. Currently, we have eight signed value-based agreements for different expensive medications, including gene therapy and we are moving forward with another ten, five of which we hope will be signed before the end of 2021. We have

currently implemented four of the eight signed agreements and are generating the data, linking them with the drug-disease registries with electronic platforms, so we can actually monitor and follow up these patients and decide their response to these treatment modalities. We have already set the clinical criteria for reimbursement and response. Hopefully our experience will soon be published; we consider ourselves leaders in this region of the world.

What approach is the Saudi MoH taking to these value-based agreements?

Our approach is to firstly evaluate this new technology or medication from the point of view of safety, efficacy, and clinical compatibility with other agents in the same therapeutic class. Then we conduct budget impact analysis based on our epidemiological figures, factors, healthcare related costs, and healthcare payment model. Then, once we establish that the budget impact is in favour of introducing this into our practice, we construct a value-based model based on Phase III randomized clinical trial cut off efficacy points adjusted for real world practice before the payment is linked to the surrogate marker or clinical variable we are after.

For example, with a medication for multiple sclerosis, after giving the medication for 12 months, we linked the payments to an MRI and clinical evaluation every six months. If there is a stabilisation of the lesions, a continuation of patients being in clinical remission, no new lesions, and no new attacks, then we continue to pay for 100 percent. However, if the patient develops new lesions or new attacks, then we get reimbursed for the last six months.

Another model that we took with familial hypercholesterolemia was to link the payment to LDL level and cardiovascular outcomes. For patients who achieve the percentage of LDL reduction despite maximally tolerated doses, we give them 100 percent of the reimbursement. For those patients within 80 to 100 percent of the response, then we get 80 percent reimbursed for free goods from the manufacturer. For patients between 50 to 80 percent, we get 50 percent. For patients less than 50 percent we don’t pay anything and get 100 percent reimbursed. There are multiple models.

This seems like an interesting opportunity to bring more clinical trials to Saudi Arabia. Is that the intention?

Yes, definitely. We are establishing the HTA Centre but also this year we established the Saudi National Health Institute, which is charged with the governance of all clinical trials in the health

field, promoting clinical research, and approving these clinical trials in terms of IRB and ethics.

In countries like the US, there is a tendency to heavily reward the first in class drug, while the second or third medicines for the same indication are somewhat left behind in terms of pricing and coverage, leading to less competition and higher drug prices. What HTA approach will you take in Saudi?

We have been taking the opposite approach. One of the reasons for manufacturers to get involved in value-based agreements is that when they come up with a first-in-class drug, they know that within six to 12 months another me-too drug will be introduced to the market and if they do not engage in such value-based agreements in the beginning, they will lose a huge market penetration opportunity. This happened with several medications where the sponsor was very hesitant about value/outcome-based agreements. Other agents within the same class have been introduced and we had to negotiate with everybody.

We open the door to all comers. Once we select the medication and sign the value-based agreement it is usually for or a minimum of two to three years. In many cases is we selected the second or third comer instead of the first because the value-based agreement that we constructed with them was more beneficial to us.

As a Saudi, what are your hopes and expectations for the transformation that Vision 2030 can bring to your country's healthcare?

I am very optimistic about Vision 2030 and am keen to work with all stakeholders towards achieving its goals. We believe that by 2030, we will have better control of certain non-communicable diseases such as obesity, diabetes, hypertension, hypercholesterolemia; the four most prevalent non-communicable diseases here. We will put communicable diseases through vaccination programs and have already been doing a great job in this aspect. Also, we will invest in Saudi citizens' health in terms of preventing health risks in several areas, from road traffic accidents to obesity, smoking, and other chronic diseases, and extending the average life expectancy to a minimum of 80 years. This ageing population is a challenge; we will have more seniors about 65 and need to take care of them, which will put pressure on the budget. Nevertheless, it is good to take care of healthy seniors.

We are also very optimistic about introducing value to our healthcare, only paying for what really works. Saudi Arabia is nicely equipped for this push, with well trained, highly qualified, and ambitious Saudi nationals, many of whom have experience in North America and Europe, who are eager to help achieve Vision 2030. Moreover, we are fortunate to have government support in achieving the Vision. While it will be challenging, it *is* achievable. We have the right infrastructure, the right governance, and we know the direction in which we are going.

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