

The Changing Face of Diagnosing Illness in the Kingdom of Saudi Arabia

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The Middle East is going through a digital transformation and this is especially so in the Kingdom of Saudi Arabia ('KSA') in relation to the healthcare sector. This digital transformation is revolutionising the way patients are being diagnosed in a number of ways, from the implementation of electronic medical records through to cloud based diagnostic software and the growth of telemedicine. Gone are the days when a medical practitioner had to rely on just his knowledge, the expertise of his colleagues, and available medical text books.

Digital transformation in KSA

The digital transformation in KSA is the backdrop to the Crown Prince's Vision 2030, which plans to modernise the country and move away from its dependence on income from oil. One of the aims of Vision 2030 is the implementation of electronic medical records in all healthcare institutions to form a Unified Medical Record System ('UMRS'), which will enable institutions and the Ministry of Health ('MOH') to share information. The possibilities for utilising the UMRS are endless; one such application comes from a UMRS' ability to allow for accurate recording of the nation's health, thereby enabling the MOH to plan for the future, predict outcomes, and implement appropriate preventative healthcare programmes. There could be a time in the not so far future where software programmes analyse such information to diagnose illness, before symptoms become apparent, thereby allowing early intervention to achieve the best prognosis. A UMRS will minimise the risk of misdiagnosis as healthcare professionals ('HP') will have a wealth of information readily available and the aforementioned software will be able to analyse and highlight crucial information, which may have been previously overlooked by an HP.

In KSA, we are seeing a large number of cloud based diagnostic software ('CBDS') programmes enter the market place. This software utilises a cloud based platform, for analytic purposes, to support diagnostic and therapeutic decisions by HPs. From the cloud, HPs have access to sophisticated diagnostic tools not previously available, due to the prohibitive cost, as well as data aggregated from other HPs in order to provide comparative analyses. Through the use of CBDS, a diagnosis can be made relatively quickly, thereby alleviating patient anxiety as much as possible and enabling all involved to agree a course of action. This diagnostic tool will prove invaluable to HPs as it enables them to share knowledge and technology with their peers all over the world without the restrictions of time, language, and distance. CBDS programmes are developing at a record pace and are becoming available across many specialist areas, with developers and manufacturers keen to be at the forefront of this technology.

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Regulation of diagnostic software

For regulatory purposes in KSA, diagnostic software is considered a medical device. Such devices will be subject to the Interim Medical Devices Regulation and will require registration with, and market authorisation from, the Saudi Food and Drug Authority ('SFDA'). Furthermore, only Saudi nationals or Saudi wholly owned entities can distribute medical devices manufactured outside KSA. As a result, all foreign owned medical device manufacturers without a manufacturing facility within KSA must appoint a KSA owned distributor and representative, who in turn will need to be registered with the SFDA.

Telemedicine is becoming increasingly popular within KSA as more and more healthcare providers see the advantage of providing remote consulting services to their patients. There are two categories of telemedicine: the first being peer to peer consultation where HPs seek the opinion of an HP at another institution, often outside the jurisdiction through a commercial arrangement with the institution in question. Here the consultant HP at another institution has no access to the patient but has access to the patient's medical information and communicates his opinion and expertise to the enquiring HP; and secondly an element of telemedicine is where an HP based outside a particular healthcare institution has access to a patient at that institution through a commercial arrangement to provide his expertise. The outside HP directly deals with the institution's patient and provides his opinion and expertise directly to the patient, under the supervision of an HP based in that institution.

There is currently no regulation in place to regulate either element of telemedicine, yet, it is a tolerated practice as KSA is keen to cultivate the knowledge of its HPs and enhance the healthcare offering to its citizens. Healthcare education and development is a current growth area in KSA and one of the aims of Vision 2030. The only current stipulation is that all telemedicine must be carried out under the supervision of an appropriately licenced HP in KSA. It is not possible for a telemedicine providing enterprise to provide its services directly to patients in the country without the interaction of a KSA based HP. With that said, it is still entirely possible for KSA citizens to approach telemedicine providers outside the country, as the telemedicine provider is arguably not providing their services directly in KSA. Telemedicine regulations have been drafted and are currently under the consultation of the Shoura Council. Unfortunately, the proposed regulations are yet to be published so we cannot comment on whether they are sufficient for the purposes for which they were intended.

Looking forwards

Unified medical record systems, CBDS, and telemedicine bring about other considerations not previously thought to be part of traditional diagnostic methods, such as data protection and security breaches. Cloud security is taken very seriously in KSA, leading to the implementation of the Cloud Computing Regulatory Framework in March 2018. However, so long as a cloud provider has adequate security measures in place and healthcare institutions ensure they obtain patient consent as a matter of course in all their dealings, the risks associated with the new diagnostic methods can be negated to a large extent.

The method of diagnosing patients has fundamentally changed over the last few years. HPs worldwide have access to information and technology not previously imagined. Their knowledge is increasing, and accurate diagnoses are made more often than not. Patients are benefitting from this digital transformation as early diagnosis means there is more chance of recovery from illness. Another benefit of early diagnosis is that less medical care is required over a longer term than if illness is diagnosed at a later stage, thereby causing overall healthcare costs to decrease. In

relation to patient recovery, we have a lot to look forward to and we have the digital transformation to thank for it.

Al Tamimi & Company's KSA [Regulatory team](#) regularly advises on healthcare matters. For further information please contact [Julie Bassi \(j.bassi@tamimi.com\)](mailto:j.bassi@tamimi.com).