

Value Assessment & Access to Innovative Medicines In Saudi Arabia

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Saudi Health Care System

- ✎ Health care services are mainly provided by governmental health care sectors (MOH, MNGHA, MOD, MOI, University Hospitals, KFSHRC)
- ✎ Total population 32.6 M: 20.5 M Saudi & 12.1M Non-Saudi
- ✎ Healthcare expenditures in 2019: \$46 B (SAR 172 B)
 - Public expenditures 74.2%
 - Private expenditures 25.8%
- ✎ Pharmaceutical expenditures represent 21.2% of healthcare expenditures: ≈ \$9.7B
- ✎ Pharmaceuticals are regulated by Saudi Food & Drug Authority (SFDA)
- ✎ Unified Procurement through National Unified Procurement Company (NUPCO) for Pharmaceuticals & Medical Supplies
- ✎ Private Insurance Beneficiaries: 10.9 M
 - 68% of expatriate
 - 13.4% of Saudi
- ✎ Key causes of death: non-communicable diseases account for 68% of deaths

Saudi Vision 2030

- Objectives of the National Transformational Program (NTP) 2020, which was developed to help fulfil Vision 2030 include:
 - Increase the efficient utilization of available resources
 - Achieve efficiency of government spending
 - Privatize Health care through increasing private sector share of spending in healthcare through alternative financing methods and service providers

HTA Evolution in Saudi Arabia

- Governmental healthcare sectors independent decision-making through P&T Committees
 - Comparative Effectiveness,
 - Budget Impact Analysis
 - Localization of International HTA & CEA reports
- Value Assessment & Access to Cancer Medications
 - Example: CDK4/6 Inhibitors reimbursement decision-making process.
 - **Only cost-effective with price reduction**
 - Price negotiation of two competing products
 - **Price was extensively reduced**
 - **Recommended in combination with an aromatase inhibitor for first-line treatment of HR-positive HER2-negative locally advanced or metastatic breast cancer**
 - Value Assessment Methods for Cancer Medications
 - HTA based Multi-Criteria Decision-Making that use cost/QALY Incremental Cost Effectiveness Ratio (ICER) and other criteria (e.g., NICE End of Life Rule)
 - European Society for Medical Oncology (ESMO) Magnitude of Clinical Benefit Scale.
 - American Society of Clinical Oncology (ASCO) Value Framework □ National Comprehensive Cancer Network (NCCN) Evidence Blocks

Facing the Global Challenges of Access to Cancer Medication

executive summary

INTRODUCTION

Recent articles and an editorial¹⁻³ published in *Journal of Global Oncology* have broached the question of affordability of modern anticancer medication and suggested that “the financial challenge presented by the rising cost of care will create a barrier to its delivery.” Booth and Del Paggio,² as well as Del Paggio et al,⁴ applied both the European Society for Medical Oncology (ESMO) Magnitude of Clinical Benefit Scale and the ASCO Value Framework and concluded that many of these recently approved agents offer only marginal value.

Access to cancer treatment is a major challenge that is encountered in all countries in different forms, such as lack of insurance coverage, copayment, and unavailability of medication in governmental hospitals in countries with a national health coverage system because of lack of approval by Health Technology Assessment (HTA) bodies that is compounded by the inability of the patient to cover the cost by out-of-pocket

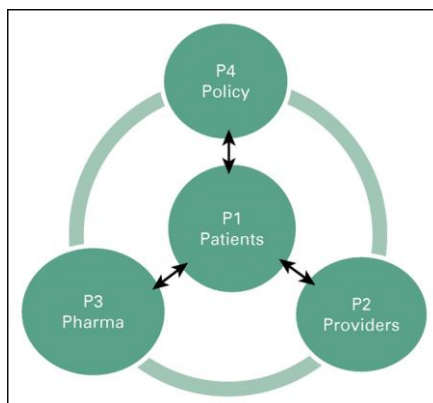
customer, not the supplier. Value must also be measured by outputs, not inputs. Hence it is patient health results that matter, not the volume of services delivered. But results are achieved at some cost. Therefore, the proper objective is to deliver good patient health outcomes relative to the total cost (inputs). Efficiency, then, is subsumed in the concept of value.⁶ Using this definition and relying on all major stakeholders, we suggest potential value-based solutions to overcoming the global challenge of high-quality cancer care delivery.⁶

P1: PERSONAL AND POPULATION APPROACHES TO THE PATIENT

The main focus of discussion with the patient should be about setting goals of care—taking into account the treatment outcome and the patient’s preferences, needs, and abilities to comply with treatment demands, toxicities both medical and financial, as well as inconvenience. Rather than sweeping cost under the carpet,

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The 4P Model: Stakeholders in Access to Medications



Access to Cancer Medication Matrix

Table 1. Access to Cancer Medication Matrix

Factor	Stakeholders	Expectations	Needs
P1: patients	1. Patient	Transparent communication	Financial counseling in the clinic
	2. Family member	Shared decision model	Access to various assistance programs from the community and pharmacy
	3. Care provider	Participatory approach to setting and prioritizing goals of care	
	4. Patient advocacy groups	Be informed about the financial responsibilities	
P2: providers	1. Physicians and other clinicians	Make the community, politicians, and others hear the concerns of patients	Access to guidelines
	2. Pharmacists	Understand different outcomes and be able to explain them to patients	Training on guidelines adaptation
	3. Investigators		
	4. Pharmaceutical manufacturers	Lower pricing and transparent pricing process	Managed entry agreements
P3: pharma	1. Medication vendors, wholesalers, and brokers	Partnership with all other stakeholders to improve access	Tiered pricing
	2. Research organizations	Design better studies with meaningful outcomes	Better risk-sharing models
	3. Governments and health care authorities	Adopt policies that assure delivery of the treatment that has the best outcome, taking into account the society resources and the particular setting status	Discount and individual patient help
	4. Health care organizations	Define what value is	Health Technology Assessment
P4: policies/payers	1. Payers and insurance companies	Ensure value (outcomes relative to cost), eg, cost per quality-adjusted life years incremental cost-effectiveness ratio, cost relative to clinical benefit and toxicity, or cost relative to the impact on overall survival and disease-free survival in curative disease.	Education and training programs to providers, patients, public, and politicians
	2. Community and public	Coverage and resource allocation decisions should maximize value to the patient.	Collaborations between entities to create easily adaptable framework
	3. Professional and scientific societies		
	4. Lobbies and advocates		
	5. Legal systems		

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Health Policy Analysis and Perspective

Implementation of Country-Wide Pharmacoeconomic Principles in Cancer Care in Developing Countries: Expert-Based Recommendations

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Abstract

Background: Cancer care is a major challenge to health care and for optimal outcomes, health systems need to align policy across many areas of public life. The recognition that even the wealthiest nations can fail optimum outcomes indicates a need for increased efficiency in cancer control programs. Fundamental to this is the efficient direction of resources—a process that can be optimized through economic measures. This article contains expert recommendations on how decision makers can implement pharmacoeconomic principles at national level in developing countries. **Methods:** A multidisciplinary panel of 10 experts was formed of oncologists, clinical pharmacists, health economists, and chronic disease control and public health experts from different countries and health-care sectors. The panel developed consensus recommendations for different stakeholders using a framework analysis method. **Results:** Recommendations were categorized as national level, hospital level, industry level, and public-community level to support decision makers in implementing pharmacoeconomic principles in a systematic way. The recommendations included having proper well-structured, data-driven processes with a specific role for each stakeholder. We proposed required structures and processes in such a way that they can be customized based on individual country plans. **Conclusion:** The expert panel recommendations will serve as a guide to relevant stakeholders at a national level. Adaptation of these recommendations to each setting is important to accommodate the situation and needs of each country.

Keywords: Cancer care, cost of cancer care, health economics, pharmacoeconomics

INTRODUCTION

countries, especially in the Middle East Region, with

HTA Evolution in Saudi Arabia

- ✎ National committees:
 - High Cost Medication Committee under Saudi Health Council
 - National Pharmaceutical Advisory Committee under NUPCO
- ✎ Ministry of health new HTA entity
 - Already budgeted in 2019
 - Two stakeholders workshops were held in 2019

Local Experts Expectation for HTA Entity

- ✎ Vision & Remit
 - Overwhelmingly supportive of HTA
 - HTA essential to enable consistent, harmonized coverage of health technologies across regions and hospitals
 - Fit-for-Purpose process
 - Need for national mandate
 - Need for independence
- ✎ Services provided and technologies covered
 - Full scope of health technologies, but “build-up should be progressive”
 - Focus in high impact technologies – but hard to define
- ✎ HTA process & method
- ✎ Implementation and practical considerations

What local experts expect from a health technology assessment (HTA) entity in Saudi Arabia: workshop conclusions. Expert Review of Pharmacoeconomics & Outcomes Research, 2019 Apr; 29:1-6

Local Experts Expectation for HTA Entity

- ✎ HTA in Saudi Arabia is essential to enable the consistent, harmonized coverage of health technologies across regions and hospitals.
- ✎ HTA in Saudi Arabia should focus on high-impact technologies.
- ✎ Expert felt that it would be important to focus on core HTA services such as HTA reports and horizon scanning.
- ✎ Experts highlighted on the importance of deliberation in providing the right context for more analytical methods of assessment
- ✎ HTA should establish strong partnerships, within a clear governance framework, with existing entities such as SFDA, the SHC, leading hospitals and Ministry function.

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Common Challenges for HTA Implementation in Middle East & Africa

- ✎ Fragmented health care systems
- ✎ Few number of local experts
- ✎ Country level price negotiation
- ✎ Limitation of local data for RWE
- ✎ Lack of local utility data
- ✎ Price driven tenders
- ✎ Achieving independence of a centralized HTA entity
- ✎ Establishing appropriate relation between centralized HTA entity and private plans
- ✎ Utilization management
- ✎ Limited cooperation between key stakeholders

Implementation of HTA in the Middle East & North Africa: Comparison between the Current and Preferred Status

Manuscript

Abstract

INTRODUCTION

Implementation of health technology assessment (HTA) is still in the early stage with some heterogeneity in the Middle East and North Africa (MENA). Our objective was to assess the current and future status of HTA implementation in the MENA region by focusing on regional commonalities.

METHODS

Preparatory discussions for the first ISPOR conference in the MENA region indicated some potentially generalizable trends of HTA roadmaps. To widen the perspective, a policy survey was conducted among conference participants by applying an HTA implementation scorecard. Discussion group members helped to validate key conclusions during and after the conference.

RESULTS

Health policy experts in MENA countries would like to facilitate HTA implementation and expect significant changes with some generalizable directions in the next 10 years. HTA capacity building has to be strengthened by more graduate and postgraduate programs. Increased public budget and enhanced institutionalization are necessary success factors of HTA implementation. The scope of HTA has to be extended from pharmaceuticals to non-pharmaceutical technologies and to revision of previous policy decisions. Although cost-effectiveness with explicit threshold remains the most preferred HTA criterion, several other criteria have to be considered, maybe even by applying an explicit MCDA framework. The role of local evidence and data has to be strengthened in MENA countries, which translates to the extended use of local patient registries and payers' databases. Duplication of efforts can be reduced if international collaboration is integrated into national HTA implementation.

DISCUSSION

Our results should be viewed as an initial step in a multi-stakeholder dialogue on HTA implementation. Each MENA country should develop its context-specific HTA roadmap, as such roadmaps are not transferable without taking into account country size, economic status, public health priorities and adopted systems of health care financing.

The study manuscript has been submitted to a Journal for publication and will be published soon

Thank You