prerequisites in the regulatory and healthcare system to ensure and monitor the benefit-risk balance across the product life cycle. A focus group of medicines regulators and healthcare system experts was established to discuss the existence of these measurements within the Egyptian regulatory framework and healthcare system context. Finally a list of policy recommendations will be set for the safe introduction of medicines approved by "adaptive pathway" to the Egyptian market. **RESULTS:** Health system decision makers and the Egyptian Drug Authority should ensure that the following measurements will be in place before starting the introduction of "Adaptive licensing" medicines: Vigilance regulation is fulfilled; Regulatory bodies closely monitor the promotion practice and prescribing practice to prevent off-label use; The Egyptian Drug Authority should revisit the definition of unmet medical need; Payers and health insurance organization should reconsider their reimbursement mechanisms and shift to payment-for- performance scheme; The MOH should ensure the availability of unbiased clear information for patients; Patient Registry systems in MOH and University tertiary hospitals should be strengthened and there should be a mechanism in place to compensate patients for any resulted harms from the therapy. **CONCLUSIONS:** Medicines approved by "adaptive pathway" should get a market authorization in Egypt only if there is an unmet medical need.

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DRIVING UHC IN EMERING EMERGING: AN EGYPTIAN CASE

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OBJECTIVES: Health Insurance Organization (HIO) is the governmental health insurance in Egypt, since 1964, covering specific population segments in the community, as salaried public and private sector employees, pensioners, widows, school students, pre-school children, female headed households and farmers. The current population coverage rate is 58% of the (around 50 million people). HIO is expected to lead the transition to universal health coverage (UHC), planned in 2020. However, HIO is facing many challenges that could hamper this leading role. Those challenges affect all the five Control Knobs of the health system, identified by World Bank, fading the financial situation of HIO. Consequently, quality of service provision (both clinical and service aspects) is affected, and ultimately jeopardizing beneficiary satisfaction and financial protection. This paper discusses the process of driving a policy change, led by HIO, mandatory on the road to UHC, in Egypt, as a model for challenging emerging markets. **METHODS:** A cross-functional task force representing the medical, financial, administrative and legal departments, in HIO, was formed to identify and analyze environmental factors, using DEPLESET model, and identify and analyse stakeholders. A multi-criteria decision analysis (MCDA) was conducted to develop evidence. Kotter's model for change was used to develop a policy change plan to convince key stakeholders with the required changes. **RESULTS:** Improving HIO financial viability will strengthen the purchasing power of the organization, which will help advance reimbursement of healthcare providers and pharmaceutical and medical suppliers, expand the contracting capacity of HIO, which in turn, will enhance patients' choice through competition between healthcare providers. Nevertheless, the road to reaching a political consensus, even for the most righteous decisions, requires thorough and scientific navigation process. **CONCLUSIONS:** Getting such a politically critical decision to be implemented, especially in economically struggling economies, requires a systematic approach to driving change.

HEALTH CARE USE & POLICY STUDIES – Risk Sharing/Performance-Based Agreements

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HPV VACCINATION POLICIES IN LATIN AMERICA: ACHIEVEMENTS AND PENDING MATTERS

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OBJECTIVES: To describe processes and policies behind the HPV vaccine introduction in LAC. To identify inequalities in the HPV vaccine introduction processes in LAC. **METHODS:** We reviewed national and regional sources of information to identify the following aspects: LAC countries with HPV universal vaccination, year of introduction of universal HPV vaccination by country, type of HPV vaccine and vaccination scheme used by country, age groups targeted by country, and coverage level reached by country. Inequalities in HPV introduction were assessed comparing the rates of cervical cancer between countries with and without vaccination. Information on cervical cancer incidence and mortality by country were extracted from GLOBOCAN 2012. **RESULTS:** More than 20 countries in LAC have introduced universal HPV vaccination among women but they differ in the type of vaccine used and vaccination policies. Most countries, excepting Ecuador and Peru, use the quadrivalent vaccine; and all of them, but Mexico and Ecuador, use a three doses scheme though they differ in the recommended time interval between doses. Also, they target different age groups with Argentina, Uruguay and Panama vaccinating one-year wide cohorts (11, 12, and 9 years old respectively), while Brazil, Colombia, Ecuador, and Paraguay selected multiyear cohorts (9-13 years, 9-17 years, 9-11 years, and 9-10 years severally). Vaccination coverage with 2 doses at least ranged from 86% in Mexico to <30% in Peru. The average incidence rate of cervical cancer for LAC was 21.2 per 105 inhabitants in 2012. Ten out of twelve countries which, so far, has not intorduced the vaccine have incidence rate above the LAC average. **CONCLUSIONS:** Inequalities in HPV vaccination persist in the Region because countries with the highest rate of cervical cancer have been unable to afford for the vaccine. Monitoring impact on HPV infection is needed to assess whether differences in vaccination policies lead to differences in clinical outcomes.

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THE FUTURE OF HTA IN EVOLVING HEALTH CARE SYSTEMS: DEVELOPING HTA STRATEGY FOR THE UNITED ARAB EMIRATES

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OBJECTIVES: 1) What lessons can be applied from established HTA systems in various OECD countries to the UAE? 2) What form may a HTA strategy devised for the UAE take? 3) What impact could the system have on the UAE health system? **METHODS:** Literarture review of national health systems and HTA sytems among OECD nations, and interview of officials from the UAE Ministry of Health, the Health Authority of Abu Dhabi and the Dubai Health Authority. **RESULTS:** The UAE health system is uniquely charecterised by central government (Ministry of Health) and local governent (Health Authority Abu Dhabi and Dubai Health Authority) agencies, each with varrying and often overlapping levels of jurisdiction and impact on reimbursement and pricing decisions. Private insurers also play a small, but significant and growing, role in health care coverage in the UAE. In this regard it differs from the centraly governed national health systems with their own national HTA policy (UK, France, Netherlands, Japan, Israel ect..). To date there is no official HTA and Health Economic strategy at the national level in the UAE. **CONCLUSIONS:** Creation of new National HTA Authority, with specialist health economic and clinical subcomittees. Predominantly advisory role to inform decisions of reimbursment and pricing of new health technologies by central government, individual emirate (local) health systems or private insurers.

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COVERAGE OF PHARMACOGENOMIC TESTS AMONG MINNESOTA HEALTH INSURANCE PLANS

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OBJECTIVES: To determine the type and level of insurance coverage, and identify specific pharmacogenomic tests that are covered or excluded from coverage by Minnesota health plans. Pharmacogenomics is a growing area that identifies an individual's drug response based on their genetic profile and can aid in choosing the most appropriate treatment for an individual. **METHODS:** Major health plans in Minnesota were included in the study if they were listed under "Individual plans as licensed by the State of Minnesota" and were a member of the Minnesota Counsel of Health Plans. Once health plans were selected, a Google search was performed to identify specific coverage policies using key words "Pharmacogenomic Testing Policy", "Pharmacogenetic Testing Policy", "Genetic Testing Policy", "Pharmacogenomics Coverage Policy", "Pharmacogenetics Coverage Policy", and "Genetics Coverage Policy". The most recent coverage policies were reviewed and analyzed as of July 2015. **RESULTS:** Five health plans were selected for review and analysis. As of July 2015 the five plans provided coverage for an average of 12 different pharmacogenomic tests ranging from 4 to 24. Across all plans pharmacogenomic tests were covered for eight different disease categories. Cancer had the highest number of covered pharmacogenomic and biomarker tests covered at a total of 20 different tests across the five plans. Four health plans provided coverage for non-cancer conditions with an overall coverage of eight different tests. **CONCLUSIONS:** Contrary to the common perception, some plans provided coverage for a vast range of pharmacogenomic tests, while others provided limited coverage. This review helped in identifying the growth and gaps in pharmacogenomic testing among major health plans in Minnesota. To address the limitations of this study of using only publicly available online information, the next step is to directly contact the health plans and confirm their coverage policies.

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PRICING AND REIMBURSEMENT OF INNOVATIVE TECHNOLOGY IN MENA AND THE DEVELOPMENT OF MANAGED ENTRY AGREEMENT

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OBJECTIVES: The main objective of this descriptive study analysis was to assess the access regulations applied in the MENA countries and examine how Managed Entry Agreement projects are implemented in the MENA these recent years. **METHODS:** To provide a comprehensive description of Pricing and Reimbursement regulation used in MENA region: We focused on the pharmaceutical policy in six countries: Algeria, Lebanon, UAE, KSA, Jordan, and Egypt. The analysis involved reviewing the literature in each country: First we reviewed the pricing and reimbursement procedures for the innovative drugs Secondly, we focused the review on the use in the regulatory process of MEA. Third we examined the agreements achieved in these region. **RESULTS:** We noticed that there are a lot of similarities and differences in principles of pricing and reimbursement of pharmaceuticals in the six countries studied are similar. The Pricing decision is taken at national level by a reimbursement committee within an institutional context (Ministry); most countries take into account the price levels prevailing in other countries, external price referencing) e.g. KSA, UAE, Algeria, or for alternative therapies (internal reference pricing) e.g. Egypt, Lebanon, Algeria. The Reimbursement is an administrative negotiation between the relevant committee and the manufacturer. In the regulatory process we didn't find explicitly the possibilities for MEA. Based on the case studies, it appears that some countries practice the MEA especially in KSA, Egypt, and Lebanon. **CONCLUSIONS:** In the MENA region, there are still important legal and structural obstacles for the implementation of risk sharing agreement and only few agreements have been implemented. Mainly financial-based, and the scientific literature on such schemes in the MENA countries is still sparse. However, as a response to uncertainty associated with new high cost of innovative drugs, we believe that the Managed Entry Agreement will increase in the MENA regions.

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DATA GOVERNANCE FOR REAL-WORLD EVIDENCE: CROSS-COUNTRY DIFFERENCES AND RECOMMENDATIONS FOR A GOVERNANCE FRAMEWORK