HTA341

ISPOR Europe 2023

November 12-15 2023, Copenhagen, Denmark

Egyptian Guidelines for Pharmacoeconomic Evaluations: toward Standardization of Drug Reimbursement Applications

Gihan Hamdy Elsisi [1,2], Mary Gergis [3], Amal Samir [3,4], Ahmed Elagamy [3], Ahmed Seyam[5], Mariam Eldebeiky [3], Randa Eldessuoki [6]

[1]HTA Office, LLC, Cairo, Egypt, [2]Department of Economics, American University in Cairo, Cairo, Egypt, [3]Health Technology Assessment Department, Egyptian Authority for Unified Procurement, Medical Supply and Management of Medical Technology (UPA), Egypt, [4]Faculty of Medicine, Cairo University, [5]Universal Health Insurance Authority, Cairo, Egypt, [6]Faculty of Medicine, Elfayoum University

Introduction

To improve resource allocation within our health care system, the Egyptian Authority for Unified Procurement, Medical Supply and the Management of Medical Technology (UPA) and Universal Health Insurance Authority (UHIA) established a joint economic evaluation process to support UHIA reimbursement decisions and UPA procurement decisions. The main objective of this study is to describe the developed pharmacoeconomic guidelines in Egypt, especially for reimbursement and procurement for pharmaceuticals.

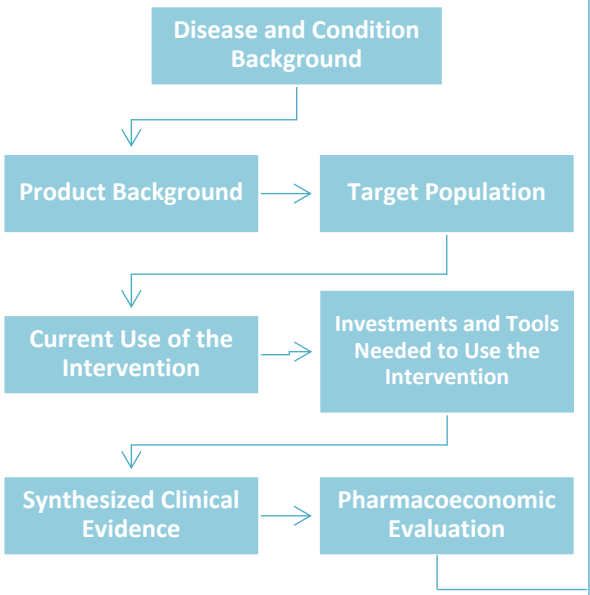
Methods

A focus group was formed as a national initiative activity by governmental authorities in Egypt. The aim of this focus group was to develop national pharmacoeconomic guidelines for the evaluation of innovative and high-budget pharmaceutical products. This group consisted of various stakeholders with experience in health economics, outcomes research, public health, and pharmacy practice.

Results

To develop our national pharmacoeconomic guidelines, three steps were taken. First, the focus group reviewed the EUnetHTA methods for health economic evaluations for pharmaceuticals as well as the Canadian Agency for Drugs and Technologies in Health (CADTH) guidelines and the Academy of Managed Care Pharmacy (AMCP) Format for Formulary Submissions. Second, the focus group used the EUnetHTA guideline as a reference and adapted it to our local context. The focus group added the value assessment component using the CADTH and AMCP guidelines. Third, the focus group collected input and feedback from key stakeholders by using the quasi-Delphi panel approach. Economic evaluation is a core element of HTA; therefore, the UHIA and UPA were encouraged to produce unified joint pharmacoeconomic guidelines for innovative products as an initial step in their commitment to implement the use of HTA in decision-making.

Pharmacoeconomic guidelines for innovative and high-budget pharmaceutical products



Perspective: study should be conducted from payer perspective. In Egypt, multiple payers exist.

Comparator: SOC, or most used product, preferably the currently reimbursed drug. Intervention and comparator should be in the same line of therapy.

Time horizon: should be long enough to capture all relevant outcomes, all clinical parameters and costs should be applied to the same time horizon "1". If a short time frame was chosen, a justification should be included. If the time horizon must be longer than the study and extrapolations must be made, assumptions on disease progression and intervention effects in the extrapolated period should be outlined.

Market share: only in BIA (The market share(s) of the comparator(s) should be identified, and then the planned rate of uptake of the intervention should be stated throughout the chosen time horizon.

Outcome measure: Only in CUA, preferably a primary endpoint is chosen, but if an intermediate marker is chosen, it must have a clear correlation to the final endpoint. HRQoL is the preferred outcome measurement for reimbursement. HRQoL is usually expressed in QALY or DALY "3". HRQoL could be constant over time or variable over course of disease. Variation in the health state should be reported by the patient or his or her caregiver "4".

Resource use and cost inputs: Identifying resource utilization and unit costs is a must "5". Prospective real-world data collection from Egypt is the main source for resource use data. Secondary sources could be accepted if primary are unavailable. All direct medical costs should be included. Indirect costs, if reported separately, should include the loss of productivity whether for the patients or the primary care givers multiplied by the annual wages (from published Egyptian GDP per capita). Direct non medical costs aren't needed. Macro-costing is the preferred method for cost calculation "6". All parameters of costs and outcomes used beyond one year should be discounted. The chosen discount rate for Egypt is 3-5%.

Modelling: should be simple, clear, and reflect real-world practice, with detailed documentation of the model structure and the input data. The modeling type chosen should be justified and validated "7". Unless it is a key feature of the model (e.g., mortality, adverse events, etc.), the time horizon should also be appropriate for the nature of the disease.

Assumptions and extrapolations: The data used to build the model are extracted from different sources, so there is a potential risk for bias and uncertainty. Therefore, all assumptions used in the model should be documented and justified.

Presenting results: The incremental cost-effectiveness ratios (ICERs) must be calculated. Interventions should be presented in the order of increasing costs, excluding pharmaceutical products that are more costly and less effective than the alternatives from the calculations based on simple dominance. The initial ICER should then be calculated by comparing each product with the one above it, excluding those products that are dominant. The final ICER is then calculated after eliminating products that are subject to extended dominance.

Sensitivity analysis: must be conducted on critical variables using best-case and worst-case scenarios. The results of the sensitivity analyses should be presented in a diagram. DSA uses variable point estimates to test the change in the results by varying a parameter, and it is the method of choice for performing SA. However, PSA is optional, as it is more complicated to interpret.

Validation: To test the external validity of the study, the results are to be compared with the results of other clinical trials, and if there are any differences between them, they should be justified. Cross-validation should include comparing the model results with those of other models. The face validity of the study must include expert panel validation "8".

Real-world evidence: If the model has uncertainty in its parameters, real-world evidence (RWE) could be used on an appropriate sample size if available. Sources of real-world data and limitations must be stated.

Conclusion

The standardization of guidelines not only ensures transparency but also guarantees an accurate and transparent process to support evidence-based decision-making. These guidelines are expected to help decision-makers improve their process and attain better health outcomes for Egyptian patients.

***Address correspondence to:**
Gihan Hamdy El-sisi, MSc, PhD
Managing Director, HTA Office, Middle East and North Africa
Health Science Policy Council Advisor, ISPOR
Assistant Professor_Health Economics, American University in Cairo
Founder and Former Head of Pharmacoeconomic Unit, CAPA, MoH, Egypt
Health Economics Consultant, World Health Organization EMR Office & USAID
Email: Gihan.elsisi@htaoffice.com

Acknowledgment:
Yousra Hamid, MSc, Research assistant, HTA Office, Middle East and North Africa.

References:
1. Website of International Society for Pharmacoeconomics and Outcomes Research: http://www.ispor.org/PEguidelines/source/HTAGuidelinesfortheEconomicEvaluationofHealthTechnologies-Canada.pdf
2. Berger ML, Bingefors K, Hedblom EC, et al. Health care cost, quality, and outcomes: ISPOR book of terms (1st Ed.). NJ: ISPOR, 2003.
3. Drummond M. Introduction to Pharmacoeconomics. European Journal of Hospital Pharmacy Practice 2008;14:17-9.
4. Elliot R, Payne K. Essentials of Economic Evaluation in Healthcare (1st Ed.). London: Pharmaceutical Press, 2005.
5. Hay JW, Smeeding J, Carroll NV, et al. Good Research Practices for Measuring Drug Costs in Cost Effectiveness Analyses: Issues and Recommendations: The ISPOR Drug Cost Task Force Report-Part I. Value in Health 2009;13:3-7.
6. Rascati KL. Essentials Of Pharmacoeconomics. Philadelphia: Lippincott Williams and Wilkins, 2009.
7. Weinstein MC, Brien BO, Hornberger J, et al. Principles of Good Practice for Decision Analytic Modeling in Health-Care Evaluation: Report of the ISPOR Task Force on Good Research Practices—Modeling Studies. Value in Health 2003;6:9-17.
8. D. M. Eddy, W. Hollingworth, J. J. Caro, J. Tsevat, K. M. McDonald, and J. B. Wong, "Model transparency and validation: A report of the ISPOR-SMDM modeling good research practices task force-7," Med. Decis. Mak., vol. 32, no. 5, pp. 733–743, 2012, doi: 10.1177/0272989X12454579.