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Guidelines for Health Technology Assessment, Ministry of Health, Sultanate of Oman

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BACKGROUND

Health Technology Assessment (HTA) is crucial for informing healthcare decisions, optimizing resource allocation, and shaping policy. A systematic, evidence-based HTA framework ensures consistent value judgments of health technologies and supports the integration of new technologies into the healthcare system.

OBJECTIVE

To create a tailor-made HTA framework that supports evidence-based policy decisions, aligned with best international HTA practices, and tailored to specific needs in the healthcare system of Oman. These guidelines are designed to assist HTA practitioners (the "doers" of HTA dossiers) in applying standardized procedures that provide credible and reproducible information, which decision-makers can rely on for resource allocation.

METHODOLOGY

The HTA methodology was developed through five steps:

1. **Learnings from international guidelines:** A targeted review was conducted independently from the Omani HTA initiative, focusing on guidelines available on the ISPOR website. Findings from this review informed the key features and main chapters of the Omani HTA methodological guidelines.
2. **Multistakeholder workshop:** In March 2024, a workshop was held in Oman with key stakeholders. The workshop concluded with recommendations for preferred health gain measures, economic evaluation methods, cost-effectiveness thresholds, methods for budget impact analysis, transferability of international evidence, and transparency in HTA reports.
3. **Multistakeholder survey :** Workshop participants completed an anonymous Mentimeter® survey to gather opinions on key methodological topics. The survey used a flowchart design, allowing questions to adapt dynamically based on previous responses, ensuring a relevant and structured voting process throughout.
4. **Guideline Preparation:** Based on workshop conclusions, a draft HTA guideline was developed with six sections: target indications, medical assessment, economic evaluation, budget impact analysis, social and ethical considerations, and transparency requirements.
5. **Guideline Validation:** The draft guidelines were circulated to decision makers in the Ministry of Health and HTA experts to ensure the practicality, credibility, and successful implementation within the Omani healthcare system. Based on their feedback, the recommendations were adjusted, resulting in a consensus on the structure and core components of the guideline.

RESULTS

Twenty-five multistakeholder agreed to establish local HTA methodological guidelines, to enhancing the quality of health technology assessments and facilitating informed healthcare decision-making.

Decision Problem The disease or health condition being assessed should be clearly outlined, including societal implications, risk factors, symptoms, and progression.
Targeted Indication Define the target population and patient number, in line with the summary of product characteristics in regulatory documents. **Subgroup Analysis**: is mandatory for diseases with varying severity or demographic differences.
Disease Area Clearly describe the disease, including its risk factors, symptoms, disease progression, and societal burden, as well as specific aspects of the condition targeted by the health technology.
Comparator The comparator must be authorized, reimbursed, and supported by robust scientific evidence. It should be endorsed by clinical guidelines and regularly used in clinical practice. Deviations from standard comparators must be justified.
Perspective **Mandatory**: Health care perspective (payer and/or provider). **Optional**: Societal perspective may be included in a supplementary analysis.
Resource use and cost inputs Align cost inputs with the healthcare perspective. Use Oman-specific unit costs ensuring transparency in all sources. Include all direct medical costs and consider out-of-pocket payments by patients. Exclude unrelated healthcare costs.
Type of economic evaluation If the investigational technology shows no significant improvement over the comparator, use cost-minimization analysis. For significant improvements, use **Cost-Utility Analysis (CUA)** with **QALYs** as the outcome measure.
Time horizon The time horizon must be long enough to capture the full cost and outcome implications of the health technology. Default to a lifetime horizon for chronic conditions unless a shorter period is justified for acute conditions.
Modelling Use appropriate models, such as **decision tree, Markov or simulation models** to evaluate long-term costs and outcomes. Clearly justify the choice of modelling approach, and ensure transparency in the inputs, assumptions, and uncertainty analyses.
Discounting Apply a **3% discount rate** to both costs and outcomes to reflect the time preference for health gains and costs occurring in the future.
Sensitivity analysis **Mandatory**: Deterministic sensitivity analysis must be conducted, varying key inputs by ±10%. **Recommended**: Probabilistic sensitivity analysis and scenario analyses should also be conducted to assess robustness.
CET Recommended baseline CET should equal 1x GDP per capita linked to the economic status of the country, with modifiers for significant health gains (max 3x), health policy priorities (2x) and technologies in rare diseases (2x).
Presenting cost-effectiveness results The presentation of results should clearly separate health benefits and costs for the technology and comparator. **ICER** (Incremental Cost-Effectiveness Ratio) must be calculated and presented transparently in a reproducible format.
Budget Impact Analysis **4-year time** horizon should be applied in BIAs**.** It must project direct medical costs and incorporate the gradual uptake of the technology. Costs should be aligned with local practices and pricing structures.
Transparency Conflicts of interest must be fully disclosed. Include details on the contribution of experts, contracted organizations, and any financial compensation. **A public version** of the HTA dossier without confidential details should be made available to enhance transparency.

TABLE: SUMMARY OF KEY FEATURES IN THE HTA GUIDELINES IN THE SULTANATE OF OMAN

The HTA methodological guidelines should be revised – updated if necessary – in every 3 years.

CONCLUSION

The newly developed HTA guidelines for Oman provide a structured, evidence-based approach for the value judgement of health technologies. These guidelines emphasize transparency, the use of local data, and adaptability to Oman's healthcare context, ensuring high-quality and consistent evaluations. Standardizing HTA processes not only improves decision-making but also ensures that healthcare investments are prioritized effectively, leading to better health outcomes and optimized resource allocation.

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