سلطنة عُمان
Sultanate of Oman
وزارة الصحة
Ministry of Health

Guidelines for Health Technology Assessment

First Edition
2024

Guidelines
for
Health Technology Assessment

These guidelines aims to support the Ministry of Health in the value judgement of health technologies, facilitating evidence-based decision-making in healthcare. The guidelines cover various aspects of HTA and offer a structured approach for HTA practitioners with different educational background and experience.

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Suggested Citation:

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

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LIST OF ABBREVIATION

Description	Term
Health Technology Assessment	**HTA**
Central Bank of Oman	**CBO**
Central Drug Registration for the Gulf Cooperation Council countries	**CDRGCC**
Cost-Effectiveness Threshold	**CET**
Gulf Cooperation Council countries	**GCC**
Deterministic Sensitivity Analysis	**DSA**
European Medicines Agency	**EMA**
European Network for Health Technology Assessment	**EUnetHTA**
Gross domestic product	**GDP**
Gulf Health Council	**GHC**
Incremental Cost-Effectiveness Ratio	**ICER**
Incremental relative QALY gain	**IRQG**
International Monetary Fund	**IMF**
Life Years	**LY**
National Centre for Statistical Information	**NCSI**
Not applicable	**N/A**
Omani Rial	**OMR**
Probabilistic Sensitivity Analysis	**PSA**
Purchasing Power Parity	**PPP**
Quality-adjusted life years	**QALY**
US Food and Drug Administration	**FDA**
World Health Organization	**WHO**
Best Supportive Care	**BSC**
Budget impact analysis	**BIA**

I. PREFACE

Ensuring the effective allocation of resources is a priority for the Ministry of Health. The Health Technology Assessment (HTA) Methodological Guidelines represents a significant step in reinforcing evidence-based decision in our healthcare system. It provides a structured framework to evaluate the clinical effectiveness, cost-effectiveness, affordability and broader implications of health technologies, ensuring that our healthcare investments translate into tangible benefits for our population.

In an era of rapid medical advancements and increasing demands on healthcare resources, will eventually require an enormous budget. While the available resources are scarce, HTA serves as a tool in guiding decisions and prioritizing investments. It enables us to assess the value of pharmaceuticals, medical devices and healthcare interventions.

The development of this guideline is a result of collective efforts, including contributions from healthcare professionals and policymakers, integrating best practices and international standards in this failed . It reflects our dedication to fostering a transparent, inclusive and scientifically robust assessment process that aligns with global healthcare advancements while addressing Oman's unique healthcare needs.

These guidelines align with Oman vision 2040 and our unwavering commitment to ensure the sustainability of the health care system, I am pleased to endorse the Oman Guidelines for HTA. Ministry of Health can ensure better health outcomes, financial sustainability, and patient-centered care while fostering a modern evidence-based, and transparent decision-making process by implementing these guidelines.

I would like to express my appreciation to all those involved in the preparation of these guidelines. Your dedication and expertise have been invaluable in shaping the healthcare framework that prioritizes efficiency, effectiveness, and patient well-being.

Dr. Hilal bin Ali Al-Sabti

Minister of Health

II. FOREWORD

Health technology assessment (HTA) plays a crucial role in guiding decision-making processes about the value of health technologies and services across various facets of healthcare. Whether it involves prioritizing investments in healthcare, evaluating the benefits of pharmaceuticals, medical devices or other health care services, shaping health research strategies, HTA serves as a valuable tool in informing policy-makers.

HTA implementation is based on i) systematic and evidence-based methods for the value judgement of health technologies, ii) a clearly defined process for the critical appraisal of submitted assessments, and iii) a strategy for integrating key conclusions into health policy decisions. These three foundational elements serve as the cornerstone for establishing a robust HTA framework.

In March 2024, a workshop was convened in Oman, bringing together key stakeholders to deliberate essential considerations for a future HTA system in the country. The workshop aimed to set guidelines for HTA in Oman, addressing vital aspects such as preferred measures for health gain, economic evaluation methodologies, cost-effectiveness thresholds, budget impact analysis frameworks, the transferability of international evidence, and the transparency of HTA submissions and appraisals.

This collaborative effort underscores Oman's commitment to advancing healthcare through evidence-based decision-making and sets the stage for the development of a comprehensive HTA framework tailored to the country's specific needs and priorities.

III. METHODOLOGICAL GUIDELINES

The Methodological Guidelines chapter provides a detailed overview of the essential guidelines that must be followed when conducting HTA. These guidelines are particularly crucial for HTA doers, predominantly pharmaceutical and medical device companies, when preparing reimbursement applications for new health technologies.

SECTION 1 : TARGETED INDICATION

1. Therapeutic area targeted by the investigated health technology

The target indication, target population, and the number of patients within the target population seeking reimbursement must be clearly defined. The target indication for reimbursement may be more specific but not broader than the approved indication e.g. outlined in the summary of product characteristics by the Central Drug Registration for the Countries of the Cooperation Council (CDRGCC), or if not available in CDRGCC, in the market authorization by the US Food and Drug Administration (FDA) or European Medicines Agency (EMA).

The population in the HTA dossier cannot differ from the targeted patient population in the reimbursement application. When the population in the HTA dossier is narrower than the population in the reimbursement application, evaluating the generalizability of the conclusions is essential.

SECTION 2: MEDICAL ASSESSMENT

1. Disease area

The disease or health condition being assessed should be clearly outlined with a focus on the following areas:

- Identified risk factors associated with the disease or health condition;
- Symptoms and impact of the disease or health condition on the patient;
- Natural progression of the disease (including onset age, average duration, prognosis based on subgroups, gender variations, relapse frequency, spontaneous recovery rates, mortality rates, average survival time, comorbidities, etc.);
- Societal implications of the disease or health condition;
- Specific aspects of the disease consequences/ burden that are targeted by the technology under evaluation.

For additional details, follow the "Health Problem and Current Use of the Technology (CUR)" section in the HTA Core Model V3.0 by the EUnetHTA

a. Epidemiology (incidence, prevalence)

Epidemiological details within which the investigated health technology will be used has to be described, with special focus on disease incidence and prevalence, age and gender distribution, socio-economic conditions, contextual health status, and potentially stratification of patients based on disease severity levels (mild, moderate, moderate- severe and severe patient). Furthermore, it is imperative to highlight the evolving disease trends and population demographics over the past 5-10 years to understand the dynamic healthcare landscape.

When local data is unavailable, international epidemiological references are acceptable with a preference for data from GCC countries, the Gulf Health Council (GHC), the Middle East, especially if they are published either by the World Health Organization (WHO), or the Global Burden of Disease initiative or reputable academic institutions specializing in epidemiology, considering the need for potential adaptations to account for variations in population demographics, health access environments, and legal and cultural frameworks relative to the Omani healthcare setting.

b. Current management of the condition

- Provide detailed information on the current standard diagnosis, treatment, and care practices for the specified indication, where possible supported by published local and international guidelines or other reliable sources.
- Describe currently available patient pathways for the disease or health condition, specifying the settings in which the care is provided (e.g., primary care, outpatient and in-patient specialist care, home care).
- Include relevant details about service provision, such as outpatient turnover, number of hospital admissions, etc., in a verifiable manner.

- Present trends related to the current therapy data and care services in a way that can be easily verified.

c. Unmet health needs

- Clearly articulate the specific public health need that is not fully addressed by standard technologies, highlighting areas such as early detection, low cure rates, therapy resistance, adherence issues, severe side effects, etc.
- Demonstrate how the investigated health technology has the potential to address the gaps in meeting the identified public health need effectively.

d. Current reimbursement status

An overview of the reimbursed technologies in the target indication should be provided.

2. Description of the comparator health technology and justification of choice

It is essential to provide a detailed overview of the characteristics of the chosen comparator health technology and thoroughly justify the selection within the framework of the health technology assessment.

In reimbursement submissions, the comparator is typically an authorized and reimbursed health technology that may be substituted by the investigated health technology. The comparator may be a different type of technology, e.g. a pharmaceutical can potentially replace a surgical intervention. Both the investigated and comparator health technologies must address the same indication and patient population targeted in the health technology assessment.

The selection of the comparator in a health technology assessment is guided by national and international clinical practice guidelines and takes into account financial considerations regarding reimbursement. Typically, the comparator is a health technology that meets the following criteria:

1. Authorized for use in the investigated indication and treatment line,
2. Reimbursed in the investigated indication and treatment line,
3. Supported by robust scientific evidence demonstrating efficacy, effectiveness, and safety as documented in reputable international medical literature,
4. Endorsed within the existing clinical practice guidelines,
5. Regularly employed in routine clinical practice.

If multiple health technologies could serve as potential comparators, one of those routinely used or standard care reimbursed technologies should be chosen for conducting relative effectiveness and cost-effectiveness analyses, which will be most likely replaced by the investigated health technology. In some cases, may include more than one relevant, widely used alternative for the same indication. Budget impact calculations typically involve a basket of health technologies for assessment.

When the investigated health technology is an add-on therapy, the comparator should reflect the base treatment without the investigated add-on technology.

In cases where no effective therapy is currently available or reimbursed for the specific indication (e.g. in advanced stages of progessive diseases or rare diseases without orphan medicines), Best Supportive Care (BSC) should be utilized as the comparator.

Any deviations from these recommendations should be clearly outlined and justified.

3. Investigated health technology

A comprehensive review of the investigated health technology, including its therapeutic indications and contra-indications, should be presented, focusing on the targeted health conditions and populations, the intended purpose of the technology, its current utilization, existing variations in practice, and the anticipated patient eligibility criteria.

For additional details, follow the “Description and technical characteristics of technology (TEC)” section in the HTA Core Model V3.0 by the EUnetHTA

a. Overview of the investigated health technology

The overview of the investigated health technology should encompass specific elements that provide detailed insights into the technical aspects and characteristics of the health technology under evaluation. Key components to be included are as follows:

1. Clearly identify the health technology, specifying its commercial name, generic name, classification (e.g., pharmaceutical, medical device), and any relevant codes or identifiers (e.g., product code, identification number).
2. Provide a comprehensive description of the technology, outlining its components, technical specifications (if applicable), and any unique properties that distinguish it from similar technologies.
3. Explain the health procedure that can be performed using the health technology.
4. Present a detailed description of all authorized indications for the investigated health technology, with a specific focus on the indication to be assessed in the economic evaluation.
5. Specify the intended purpose or use of the technology, including its clinical indications, targeted patient population, and the conditions or diseases it is designed to manage.
6. Include information on the technical performance characteristics, such as accuracy, precision, sensitivity, specificity, reliability, durability, usability, and interoperability, along with any other pertinent performance metrics (if applicable).
7. Detail how the technology is administered, delivered, operated, or applied, including the dosing regimen (for pharmaceuticals), application procedure (for medical devices), route of administration, or any specific usage instructions.
8. Describe how the investigated technology impacts existing patient pathways.
9. Provide details on the current utilization of the investigational technology in Oman, along with its reimbursement status in other indications within Oman (if applicable).

10. Utilize the Gulf countries Joint Clinical Assessment as the primary source of evidence for the investigated health technology, if available.

b. Clinical and health outcome measures

A comprehensive list of measured clinical and health outcomes what was used to demonstrate the benefits and the safety of the investigated health technology has to be summarized.

c. Clinical trials and real-world studies

The clinical benefits of the investigated health technology can be evaluated through clinical trials and real-world studies. A comprehensive review of the clinical benefits supporting the technology should be provided, incorporating the following elements:

1. Present an overview of the clinical trials and real-world studies conducted to assess the health technology, including objectives, endpoints, inclusion and exclusion criteria, study duration, and methodology used.
2. Describe the characteristics of the patient population participating in the clinical trials and real-world studies, and clearly outline the intervention or utilization of the health technology in these studies, detailing dosing regimens (if applicable), treatment protocols, and any variations observed across studies.
3. Provide information on the control groups, comparator technologies, or standard-of-care treatments utilized for comparison, emphasizing how the new technology was evaluated against existing alternatives.
4. Highlight the primary and secondary outcomes evaluated in the clinical trials and real-world studies, encompassing clinical efficacy and safety endpoints, as well as patient-reported outcomes.
5. Discuss the strengths and limitations of the clinical evidence, emphasizing factors such as study design, sample size, study duration, patient demographics, biases, uncertainties, and potential sources of error or confounding variables.
6. Include details on the publication status of the studies and any regulatory submissions associated with the health technology.
7. Analyze the efficacy observed in clinical trials and the real-world effectiveness documented in observational studies related to the investigated health technology.

d. Evidence on safety

Safety information, in conjunction with data concerning efficacy and effectiveness, serves as a crucial foundation for any subsequent evaluations of a health technology; hence, substantiated data on these aspects are essential. The presentation of hazards (whether direct or indirect harm) associated with the health technology on patients, staff, and the environment should be evidence-based, accompanied by strategies to mitigate the risk of these hazards. Key elements that must delineate the safety profile based on available evidence include:

1. Summary of safety data pertaining to the health technology, sourced from clinical trials, observational studies, post-market surveillance, adverse event reporting systems, and other relevant resources.

2. Description of adverse events, side effects, adverse reactions, and any untoward incidents linked to the use of the technology.
3. Identification of known safety issues, risks, warnings, contraindications, precautions, and specific populations where safety concerns may be heightened (e.g., paediatric, elderly, pregnant individuals).
4. Exploration of dose-dependent effects, toxicity profiles, overdose risks, or any documented safety concerns concerning dosage, administration, or exposure to the technology.
5. Explanation of risk minimization strategies, risk management plans, or implemented measures to enhance safety.
6. Consideration of safety aspects in specific populations, including patients with comorbidities and vulnerable groups.
7. Utilize the Gulf countries Joint Clinical Assessment as the primary evidence source for safety-related information, if available

For additional details, follow the “Safety (SAF)” section in the HTA Core Model V3.0 by the EUnetHTA.

e. Health gain

In assessing the health gain anticipated from the utilization of the health technology, the evaluation of health benefits should primarily focus on policy-relevant outcomes, including mortality, morbidity, and quality of life. The examination of health benefits should encompass the following elements:

1. Mortality: Evaluation of the expected positive impact of the health technology on mortality rates.
2. Morbidity: Assessment of the influence of the health technology on disease or health condition symptoms, severity, frequency of morbidity, and disease progression (or recurrence).
3. Health-related quality of life: Examination of the effect of the health technology on both generic and disease-specific aspects of quality of life.
4. Function: Analysis of the impact of the health technology on body functions, work capacity, resumption of previous living conditions, and activities of daily living.
5. Patient satisfaction: Exploration of the satisfaction levels of patients with regard to the health technology.
6. Benefit-harm balance: Evaluation of the overall benefits and harms associated with the health technology in terms of health outcomes.

The assessment of health gain should be based on the below principles:

1. Scientific evidence on health benefits should be researched, evaluated, and presented according to international methodological recommendations for evidence-based medicine and systematic literature reviews. The methodology of the literature search, including the search terms, the literature databases (e.g., Medline, Embase, Scopus, Cochrane Library, etc.) and the inclusion and exclusion criteria, is recommended to be presented.
2. Utilize the clinical assessment reports published by reputable HTA agencies (e.g. Joint Clinical Assessment reports according to the European HTA regulation) as the primary evidence source of evidence on the health gain, if available.
3. It is important to give the sources of clinical data and the details of the calculations in a detailed, transparent, and reproducible manner.
4. Indirect evidence may also be considered in the health technology assessment, if the comparator and the investigated technologies are compared to a common technology (or technologies) in clinical trials. In this case, both direct and indirect evidence should be presented separately.
5. If several randomized clinical trials are accessible, meta-analysis (considering only direct comparative trials) or network meta-analysis (considering both direct and indirect comparative studies) are recommended to aggregate their results. The methodology of the meta-analysis and the specific relative effectiveness/efficacy indicators from the included studies should be presented in detail.
6. If only one clinical trial's results are used in the health technology assessment, the explanation of the choice should be presented.
7. If the analysis uses international scientific evidence from routine practice, its transferability should be investigated and presented as part of the analysis.
8. It is also important to describe the endpoints used to assess relative health gain. The appropriateness of the hierarchy of endpoints (primary and secondary) powered appropriately to demonstrate efficacy, is determined by the target patient population, the main characteristics of the disease and the purpose of the treatment.

SECTION 3 : ECONOMIC EVALUATION

1. Overview of economic evaluation

The economic evaluation must be meticulously detailed, starting with a clear delineation of the objective, including the patient population, the investigated health technology, the comparator health technology, and the method for measuring health benefits. Subsequently, the rationale for the chosen type of economic evaluation should be elucidated. Finally, key elements such as the perspective adopted, the modeling methodology employed, the defined time horizon, and the discount rate utilized should be explicitly disclosed. It is imperative that the economic evaluation is explicitly tied to the target population under scrutiny in the analysis.

a. Types of economic evaluations

In health economics, the comprehensive economic evaluations known as full evaluations involve the comparison of two or more alternative health technologies, assessing both costs and outcomes. The four primary types of full economic evaluations in health economics are cost-minimization analysis, cost-effectiveness analysis, cost-utility analysis, and cost-benefit analysis.

Cost-minimization analysis: The presumption is that the efficacy/effectiveness and safety of the two compared health technologies do not exhibit significant differences, bolstered by medical evidence. In such instances, comparable outcomes are assumed, enabling the deemed cost-effectiveness of the assessed health technology if its costs do not exceed those of the comparator. It is recommended to employ cost-minimization analyses exclusively when evidence substantiates outcome parity. Standard guidelines suggest that if the investigational technology does not demonstrate statistically significant enhancements in primary endpoints vis-à-vis the comparator in clinical trials, implying no discernible health gain, the application of cost-minimization analysis is warranted.

Cost-effectiveness analysis: Is a methodology that characterizes outcomes in natural clinical units, excluding measurements related to quality of life. Examples of natural units include alterations in laboratory parameters or gains in life years without adjustments for quality of life, etc.

The final result of cost-effectiveness analyses is presented as a ratio:

$$ICER = \frac{(Cost_{new} - Cost_{comp})}{(Outcomes_{new} - Outcomes_{comp})} = \frac{\Delta Costs}{\Delta Outcomes}$$

Where costnew is the overall cost of using the assessed health technology, costcomp is the overall cost of using the comparator health technology, outcomesnew is the overall outcomes resulting from using the assessed health technology, outcomescomp is the overall outcomes resulting from using the comparator health technology.

In the literature, the term “cost-effectiveness analysis” is often used to refer to economic evaluations in general. In the Economic Guidelines, a CEA refers to a specific type of economic evaluation in which the outcomes are measured in natural (health) units, such as life- years gained, lives saved, or clinical event avoided or achieved.

Cost-utility analysis: The holistic outcomes arising from the utilization of the compared health technologies are articulated in metrics that encompass both the longevity of life and the quality of life of patients, quantified in quality-adjusted life years (QALY).

The final result of cost-utility analyses is presented as the incremental cost-effectiveness ratio (ICER):

$$ICER = \frac{(Cost_{new} - Cost_{comp})}{(QALY_{new} - QALY_{comp})} = \frac{\Delta \text{Costs}}{\Delta QALY}$$

Where cost new is the overall cost of using the assessed health technology, cost comp is the overall cost of using the comparator health technology, QALYnew is the overall QALYs resulting from using the assessed health technology, QALYcomp the overall QALYs resulting from using the comparator health technology. Cost-utility analysis is the preferred method for cases where the outcomes are not assumed to be equal.

Cost-benefit analysis: Involves the conversion of all health outcomes into monetary units, with the comparison solely focusing on the two resulting sums. Owing to substantial ethical and methodological controversies surrounding the validity of such conversions, the utilization of cost-benefit analyses for health economic assessments is not favored.

Cost-Consequences Analysis: Is a form of analysis that presents both the costs and consequences of the compared health technologies without calculating specific ratios. However, due to the inherent limitations in providing comprehensive information, the preference is not to utilize cost-consequence analyses for health economic calculations.

Other types of analyses: Other types of analyses, such as cost-of-illness analysis, are available, but to ensure comprehensive and accurate cost-effectiveness assessments, there is a notable preference for the utilization of full economic evaluations.

As a general rule,

- If the investigational technology shows no statistically significant improvement in the main endpoints in clinical trials to the comparator technology, no health gain can be assumed, hence cost-minimization analysis should be applied.
- If the investigational technology shows statistically significant improvement in the main endpoints in clinical trials to the comparator technology, the health gain should be calculated in quality adjusted life years (QALYs), and cost-utility analysis should be applied.
- Cost-effectiveness analysis should typically be reserved for exceptional cases where health gains cannot be effectively quantified in QALYs. In such exceptional scenarios, a clear rationale must be provided to elucidate why cost-utility analysis was infeasible to implement.

b. Patient population

The patient population included in the economic evaluation should align with the intended reimbursed indication, and any deviations from this standard practice must be clearly explained and well-justified.

c. Perspective of the analysis

In economic evaluations, two primary perspectives can be used: the health care perspective and the societal perspective.

The health care perspective (payer OR provider) is mandated as the base-case, encompassing all direct health care costs within the health care system i) regardless whether they are covered by the health care payer, health care providers or patients, and ii) associated with the disease and its routine management, such as pharmaceutical expenses, hospitalization costs, diagnostic costs, medical management expenses, nursing costs, and palliative care costs etc.

The societal perspective, on the other hand, can serve as supplementary analysis to the health care perspective. An evaluation conducted from the societal perspective includes a broader range of costs and outcomes, both within and beyond the health care system, such as transportation costs, caregiver burden, productivity impacts, school performance effects, etc.

d. Time horizon

It is important to emphasize that the time horizon utilized in the analysis must be sufficiently extensive to effectively capture the cost and outcome implications related to use of the investigated health technology. An inadequate time horizon could introduce bias into the decision analysis process. Consequently, extrapolation of clinical results (e.g. primary data RCTs) is frequently necessary, a process that typically involves the utilization of modelling techniques (refer to next sub-section).

- The selection of the time horizon should be tailored to the disease area and the treatments under consideration to ensure comprehensive capture of all pertinent cost differentials and outcomes.
- The general mortality of the overall population and the disease-specific mortality should also be considered when choosing the length of the time horizon.
- The average age of the modelled population in the analysis should be clearly specified.
- Analysts are advised to default to using a lifetime time horizon for chronic conditions such as diabetes or cardiovascular disease, or when the treatment options have varying impacts on mortality rates.
- If a shorter period is used (e.g., for acute illnesses), justification should be provided.
- It is recommended to utilize scenario analysis in assessing the robustness of results by exploring different time horizons.

Costs and outcomes often occur in distinct timeframes. (e.g., in an economic evaluation of immunization programs, costs are typically immediate, while the benefits may manifest over a lifetime. This scenario involves upfront expenditure with delayed outcomes, aligning with the ‘time preference concept). Therefore, when analyzing over an extended period, it is essential to incorporate a discount rate for adjustment, encompassing both costs and outcomes.

Key considerations:

- If the time horizon is 5 years or less, general mortality is not obligatory, especially for a younger population (average age <50 years), yet with an older patient population (e.g., average age >50 years), general mortality must also be considered.
- If the time horizon exceeds 5 years (e.g., 10 years or more), general mortality must be incorporated into the model regardless of the average patients age.

e. Modelling

The economic evaluation of health technologies typically entail building and utilizing models to integrate evidence and assumptions from various sources, aiming to estimate the long-term incremental costs and outcomes associated with novel therapies.

There is a diverse array of modelling type available, such as decision trees, Markov cohort models and simulation models, etc., each potentially suitable for specific cases.

The following specific recommendations should be considered:

- The formulation of the study question is crucial in model development. Once the question is established, the analyst can assess whether modeling is the optimal approach to address the issue and identify the most suitable techniques to employ.
- The rationale for modelling should be clearly articulated and supported.
- The scope (i.e., the boundaries) of the model should be explained and justified.
- The feasibility of building a model should be assessed before coding it.
- The choice of modelling methodology should be aligned with the unique characteristics of the indication and the health technologies under comparison.
- All model inputs, including beyond cost and outcomes inputs (e.g., transition probabilities), must be transparently outlined, with clear references provided for all sources.
- The model's scope, framework, and variables should align with the study's inquiry and the requirements of the intended audience.
- Models should support the type of economic evaluation pertinent to the research question and allow for a comprehensive evaluation of uncertainties surrounding the study findings.
- Justification for the model's structure, data values, and sources for each input parameter should be provided.
- Reasoning behind assumptions and subjective judgments concerning the model structure (e.g., relationships, included variables, distributions) should be provided to enable users to assess their validity.
- The model's structure should be congruent with the underlying theory of the condition, should encompass the effects of the intervention and alternatives, and should be pertinent to the research question.

- The model structure should be explicated and visually represented through a schematic figure.
- The economic model should be included with the HTA dossier to facilitate critical appraisal by the official HTA body and ensure the appropriateness of calculations can be thoroughly examined.

f. Discounting

In consideration of the time preference element, it is essential to discount all future costs and outcomes at a rate of 3% to facilitate the comparison of present values. The formula for discounting costs should be the following:

$$\sum_{i=1}^{t} Cost_i * \frac{1}{(1+r)^{(i-1)}}$$

Where r is the discount rate, t is the number of years in the analysis, i is the particular year in question, and $Cost_i$ is the costs occurring in $year_i$. The formula for discounting outcomes should be the following:

$$\sum_{i=1}^{t} Outcome_i * \frac{1}{(1+r)^{(i-1)}}$$

Where r is the discount rate, t is the number of years, i is the particular year in question, and $Outcome_i$ is the outcomes occurring in $year_i$.

2. Cost and resource use data

Given the pivotal role of cost and resource use data as primary inputs for conducting both cost-effectiveness and budget impact analyses, meticulous attention should be directed towards the transparent, clear, and reproducible presentation of this data. Unit cost data, denoting monetary values such as cost of one unit of a medicine, cost of a general practitioner visit, cost of one hospitalization event, etc., are to be portrayed exclusively in Omani Rial (OMR) to ensure consistency and accuracy in the economic evaluation process.

Within this context, resource use data encompasses inputs that are not represented in monetary terms but instead denote the average frequency of utilization of specific resources along the patient pathway associated with the investigational or comparator technologies. Examples of such data include the quantities of medications, the frequency of hospital events, the number of general practitioner visits, etc. and similar metrics reflecting the consumption of healthcare resources throughout the treatment process.

The key recommendations are the following:

- The alignment of costs and resource use perspective with the analytical standpoint is essential. In cases where the healthcare perspective is adopted, the inclusion of costs should be limited to direct medical costs within the analysis.

- It is essential to include all direct medical costs to the analysis regardless of who is paying for the included health care services or technologies. For example, include the cost of necessary molecular diagnostics for personalized medicines, even if the cost of diagnostic technology is not covered by the public health care system.
- Use full prices for the health technologies included in the comparison, including patient copayments, taxes, and relevant fees.
- It is imperative that all cost and resource use components are meticulously detailed, explicitly specifying the source of each cost element (unit costs) and resource usage figure. Thorough documentation of all local input data is essential for comprehensive evaluation.
- All unit costs utilized in the analysis should be specific to Oman, with monetary values sourced exclusively from Omani Ministry of Health resources. Whenever feasible, utilizing public databases, such as the National Center for Statistical Information (NCSI), for specific types of costs covered by the healthcare payer is recommended as source for the analysis.
- The unit cost data should be considered constant throughout the time horizon of the economic evaluation. Nevertheless, if substantial price erosion of the comparator technology is anticipated within two years following the HTA submission due to patent expiration, the projected price reduction of the comparator technology must be taken into account in the analysis.
- In instances where a confidential discount is implemented for the comparator technology or is expected for the investigational technology, the base case analysis should incorporate the published list price for the comparator technology and the anticipated list price for the investigational technology.
- The primary source country for resource use data is Oman. However, in cases where no significant variances are presumed to exist between the healthcare systems of Oman (inclusive of pathways of care, available services, applied guidelines, patient population, etc.) and another country, the utilization of resource use data from that country may be permissible. Nevertheless, even under such circumstances, the monetary values of cost inputs (i.e., unit costs) should be exclusively sourced from resources within Oman.
- Unit cost data for identical resources should remain consistent between both arms of the analysis.
- The resource use data can be different between the arms of the analysis. It is recommended to present the resource use data side-by-side to enhance clarity and comparability.
- Resource use data utilized in the analysis should align with the standard therapeutic practices implemented in Oman, which may deviate from the resource use reported in the outcomes of a clinical trial. It is essential to transparently declare and support these discrepancies. Whenever feasible, validation of resource use data by clinical experts in Oman is recommended to ensure credibility and accuracy in the analysis.

- Unit cost and resource use data should be current to the greatest extent feasible. In cases where secondary data sources offer the most reliable evidence, cost values should be adjusted for relevant inflation rates, if required, to ensure the accuracy and currency of the data.
- When cost or resource use data is sourced through a database query, the methodology of the database query should be elucidated in the analysis to provide transparency and understanding of data retrieval processes.

Costs stemming from health care and societal factors associated with conditions unrelated to the indication or health technologies under examination (including other diseases diagnosed during the life years gained, such as elderly diseases) should be excluded from the economic evaluation.

3. Presentation of the results of the health technology assessment

a. Detailed description of the results

Health benefits and costs incurred throughout the time horizon of the health technology assessment should be meticulously detailed for both the health technology and the comparator separately. The calculation presentation should be transparent, traceable, and reproducible, with all input data references clearly provided to ensure transparency and reliability of the analysis.

In cost-utility or cost-effectiveness analyses, it is imperative to compute the Incremental Cost-Effectiveness Ratio (ICER). This ratio represents the relationship between the incremental cost and the incremental health effect of the investigated health technology compared to the comparator. The ICER calculated during the cost-utility analysis should be clearly presented in a tabular format for enhanced visibility and interpretation.

Table 2.: Summary of the results of the cost-utility analysis

	Cost	Expected health effect	Incremental cost	Incremental health	ICER
Health benefit expressed in life years					
Investigated health technology	XXX OMR	XXX LY	XXX OMR	XXX LY	XXX OMR /LY
Comparator health technology	XXX OMR	XXX LY			
Health benefit expressed in QALYs					
Investigated health technology	XXX OMR	XXX QALY	XXX OMR	XXX QALY	XXX OMR /QALY
Comparator health technology	XXX OMR	XXX QALY			

The investigated health technology is deemed cost-effective under the following conditions:

- If it provides health benefits and reduces costs compared to the comparator health technology (termed as a dominant alternative).
- If it offers equivalent or greater health benefits compared to the comparator without escalating costs.
- If its ICER does not exceed the cost-effectiveness threshold.

b. Cost-effectiveness threshold

The ICER should be compared with the appropriate threshold value, which is based on cost per QALYs and linked to the economic status of Oman. The baseline CET is equal to the latest 1x GDP per capita expressed in Omani Rial (OMR) and sourced from the Central Bank of Oman (CBO) or NCSI. It is essential to note that the conversion of GDP per capita into international currencies (e.g., USD, EUR, Purchasing Power Parity (PPP)) from international databases like WHO, IMF, or the World Bank databases, act. is not deemed suitable as a reference value.

The cost-effectiveness threshold should align with healthcare priorities, acknowledging that the willingness to pay for a QALY gain is higher for i) orphan medicines, ii) medicines in other priority diseases (initially cancer) and iii) technologies offering substantial relative benefits.

The CET is thus calculated using the following formula:

$$CET\ (localcurrency) = 1 \times GDP/Capita \times Multiplier$$

The threshold multiplier related to the relative health gain should be calculated based on the incremental relative QALY gain (IRQG) based on the below formula:

$$IRQG = (QALY_{new\ technology} - QALY_{comparator\ technology}) / QALY_{new\ technology}$$

The threshold multiplier for relative health gain is a continuous variable between 1 and 3. For example, if the IRQG

- is equal with 0.1 (i.e. minor relative health gain), the cost-effectiveness threshold needs to be multiplied by 1 + (0.1 x 2) = 1.2
- is equal with 0.25 (i.e. moderate health gain), the cost-effectiveness threshold needs to be multiplied by 1 + (0.25 x 2) = 1.5
- is equal with 0.5 (i.e. major health gain) the cost-effectiveness threshold needs to be multiplied by 1 + (0.5 x 2) = 2

Fixed multiplicator of 2 is selected for both orphan drugs and medicines in priority diseases (i.e. cancer).

In the HTA submission the relevant cost-effectiveness threshold should be presented in the format summarized in Table 3.

Table 3: Cost-effectiveness threshold

Most up-to-date GDP per capita (in OMR)	Baseline threshold (in OMR)	Threshold multipliers				Calculated cost-effectiveness threshold (in OMR)
		Incremental relative QALY gain (IRQG)	Disease rarity designation (yes or no)	Disease priority (yes or no)	Aggregate threshold multiplier (based on IRQG, disease rarity and priority	

4. Sensitivity and scenario analyses

Given the inherent limitations of cost-effectiveness analyses, it is advisable to assess the reliability of the results through sensitivity and scenario analyses. A deterministic sensitivity analysis is a mandatory component of the analysis to account for uncertainties. While conducting a probabilistic sensitivity analysis and scenario analyses are not compulsory, they are recommended as supplementary methods to strengthen the comprehensiveness and robustness of the evaluation.

a. Deterministic sensitivity analysis

In HTAs prepared to support reimbursement applications it is mandatory to conduct deterministic sensitivity analysis (DSA). DSA involves modifying the input values of the health economic model individually by predetermined percentages. The impact of these adjustments on the final outcome (such as the ICER value) is documented and evaluated to assess their influence on the analysis results.

For deterministic sensitivity analyses, it is recommended to perform one-way analyses on inputs, altering each input value individually by increasing and then decreasing it by 10%. If an input value adheres to specific limits (e.g., utility values capped at 1), these constraints should be factored into the sensitivity analysis. Inputs dictated by regulations (e.g., discount rates) need not be included in the deterministic sensitivity analysis.

The optimal method for displaying the outcomes of a deterministic sensitivity analysis is through a tornado diagram illustrating at least ten inputs that significantly influenced the final results of the health economic model. This graphical representation depicts a bar chart where the variations in model results (e.g., alterations in the ICER value) are shown on the horizontal axis, with the top ten most impactful input parameters presented vertically. The chart is structured in a manner such that the widest bar is positioned at the top, showcasing the parameters with the most significant influence.

If substantial price erosion of the comparator technology is anticipated due to patent expiration within two years of the HTA submission, the uncertainty surrounding the expected price reduction should be examined in a distinct sensitivity analysis.

In cases where a confidential discount is applied for the comparator technology or is anticipated for the investigational technology, a two-way deterministic sensitivity analysis should be conducted across plausible ranges of confidential discounts for both the comparator and investigational technologies.

b. Probabilistic sensitivity analysis

In HTAs prepared to support reimbursement applications it is optional to conduct probabilistic sensitivity analysis (PSA). PSA involves altering the input values of the health economic model based on a probability function. The impact of adjusting the input values according to these functions on the final result, such as the ICER value, is documented and evaluated.

The preferred approach for conducting probabilistic sensitivity analyses involves a multi-way analysis on inputs, adjusting multiple input values simultaneously. Each input must have a clearly defined probability function. Standard deviations should be set within sensible bounds, with the base-case value typically serving as the expected value for each input parameter. Constraints on valid input values, such as utility values capped at 1, should be considered during the probabilistic sensitivity analysis. Inputs subject to fixed regulations (e.g., discount rates) need not be included in the analysis. Standard error is assumed to be 10% of the mean, ensuring a robust estimation of variability within the collected data.

Different distributions may be more suitable for specific input types (e.g., Beta distribution for utilities, Log-normal distribution for relative risks). As probabilistic sensitivity analysis yields varied results with each iteration, it is recommended to present the result of at least 1,000 runs in a cloud diagram and summarize the average result.

The optimal method for presenting the outcomes of a probabilistic sensitivity analysis is through a cloud diagram illustrating the results of multiple runs on the cost-effectiveness plane, with a highlight on the average result. Additionally, a Cost-Effectiveness Acceptability Curve can be constructed to display the likelihood of the ICER falling below the cost-effectiveness threshold for various threshold values.

c. Scenario analysis

In certain instances, exploring the effects of setting specific inputs to designated values, altering particular health economic model settings, or modifying assumptions used in the analysis may be beneficial.

All inputs, settings and assumptions included in the scenario analysis should be clearly described. This entails providing details on the base-case values, alternative cases, and elucidating how the analysis results were influenced during the scenario analysis.

SECTION 4 : BUDGET IMPACT ANALYSIS

Alongside economic evaluation, the budget impact analysis constitutes another critical component of health economic computations within health technology assessment. The primary goal of the budget impact analysis is to address questions of affordability for the payer by estimating the overall costs and the number of patients impacted.

1. Methodological requirements for budget impact calculations

From the payer's perspective, the following general key considerations should be adhered to when conducting a budget impact analysis:

1. The analysis should employ the same assumptions and input data as the cost-effectiveness analysis for corresponding details.
2. All inputs utilized in the budget impact analysis should be transparently presented, with clear referencing of the sources for all inputs.
3. Unit costs should originate from Oman, and epidemiological factors should align with the Oman setting to the greatest extent feasible.
4. The budget impact analysis should be projected over a period of 4 years following the introduction of the therapy into the reimbursement system.
5. Discounting should not be applied to the budget impact analysis.
6. When feasible, the budget impact analysis should strive to include new patients gradually (e.g., by assuming a gradual increase in patient numbers rather than an instantaneous influx of 1200 new patients at the start of the year, may be with 100 new patients incorporated monthly).
7. The budget impact analysis should solely consider the costs covered by the healthcare payer for health technologies and services. Exclude direct payments paid by patients, such as the cost of over-the-counter medicines, copayments and fees paid for non-reimbursed health care services.
8. In situations where a confidential discount is enacted for the comparator technology or anticipated for the investigational technology, the base case analysis should utilize the published list price for the comparator technology and the projected list price for the investigational technology.
9. If there is a possibility of replacing more than one other health technology with the evaluated health technology, the budget impact analysis should consider the costs of those therapies, factoring in their market shares. Any alternative calculation method chosen should be explicitly stated and supported
10. Sensitivity analysis is a necessary component of the budget impact analysis. Among the different types, conducting a deterministic sensitivity analysis is obligatory, while the optional inclusion of probabilistic sensitivity analysis and scenario analyses is advisable.

11. In cases where substantial price erosion of the comparator technology is anticipated due to patent expiration within two years of the HTA submission, the budget impact analysis should include an assessment of the uncertain impact related to the expected price reduction of the comparator technology through a separate sensitivity analysis.

12. If a confidential discount is applied for the comparator technology or is expected for the investigational technology, a two-way deterministic sensitivity analysis should be conducted across plausible ranges of confidential discounts for both the comparator and investigational technologies within the budget impact analysis.

2. Estimated patient population

When estimating the patient population, who will be potentially treated with the investigated technology, the following factors should be taken into account:

1. Disease Incidence: The annual number of new patients is a fundamental input for budget impact calculations.

2. Disease Prevalence: The inclusion of patients previously diagnosed and possibly receiving standard therapy must be considered upon the introduction of the assessed health technology.

3. Subgroup Analysis: In scenarios focused on specific patient subgroups, the proportion of these patients compared to the overall disease population should be detailed transparently, with subgroup delineations based on biologically or clinically relevant criteria.

4. Estimation of Diagnosed and Treated Patients: An accurate estimation of the diagnosed and treated patient counts from the target population is crucial for the analysis.

5. Market Share Estimations for the Investgated Health Technology: Yearly estimates of the market share are vital for understanding patient distribution within the target population.

3. Budget impact analysis results

The budget impact analysis must calculate and present the total of all direct medical costs reimbursed by the healthcare payer for whole population who might receive treatment with the examined health technology, accounting for the availability or non-availability of the investigational technology over the ensuing 4 years. The disparity between these two totals should be computed and presented for each year and cumulatively over the 4-year period (net budget impact). Drug costs and non-drug costs for each year should be itemized separately.

The results of the budget impact analysis should be transparently and clearly presented, incorporating at least the following details:

Table 4: Summary of the Budget Impact Analysis

	Year 1	Year 2	Year 3	Year 4	Total
Annual number of patients (in the relevant subgroup)					N/A
Annual number of diagnosed patients (in the relevant subgroup)					
Annual number of treated patients (in the relevant subgroup)					
Annual market share of the investigated technology from treated patients					
Number of patients treated with the investigated technology					
Expected sales of comparator technologies					
Expected sales of the investigated technology					
Impact of the investigated technology on the pharmaceutical budget					
Expected direct medical costs related to the use of comparator technologies					
Expected direct medical costs related to the use of the investigated technology					
Impact of the investigated technology on direct medical costs					
Total budget impact of the investigated technology					

SECTION 5 : OTHER ASPECTS

1. Ethical aspects

To align the evaluation of health technologies with ethical standards and uphold individual rights, the consideration of the following areas is recommended:

1. Engage patient perspectives in health technology assessments by facilitating patient participation.
2. Provide information that supports patient autonomy.
3. Ensure the protection of patient privacy and confidentiality in data handling, storage, and dissemination adhering to legal and ethical norms.
4. Acknowledge the needs of vulnerable groups to ensure equitable healthcare access, particularly for conditions like rare diseases.
5. Address disparities in healthcare access, taking into account socioeconomic, cultural, and geographical factors specific to Oman.
6. Transparency and effective management of conflicts of interest within the health technology assessment process to maintain unbiased and evidence-based decisions.
7. Advocate for evidence-based methodologies encompassing not just clinical evidence but also ethical considerations, societal values, and broader implications on the healthcare system.

2. Organisational aspects

Organizational aspects of a health technology should be carefully examined within the health technology assessment. An understanding of resource needs and allocation requirements is essential for policymakers at the national level and stakeholders within the healthcare system. This comprehension can significantly impact the overall effectiveness of a health technology assessment.

Optional considerations encompass:

1. Health Delivery Process:

- Analysis of the impact of the investigated health technologies on service delivery and patient pathways.
- Evaluation of workflow modifications and the integration of the investigated health technology into healthcare settings.
- Assessment of training, communication, and quality assurance requirements within the healthcare system necessitated by the investigated health technology.

2. Dependency on Human Resources and Healthcare Infrastructure:

- Evaluation of the essential human resources or healthcare infrastructure crucial for the effective utilization of the investigated health technology.

- Understanding how the benefits of the investigated health technology could be impacted by limited human resources or healthcare infrastructure.

3. Process-Related Costs:

- Assessment of additional costs (e.g., training, equipment depreciation) associated with integrating the assessed health technology.

4. Management:

- Evaluation of the criteria determining access to the assessed health technology.
- Identification of barriers and effective management strategies for successful implementation.

5. Culture:

- Understanding the consideration of other interest groups during the planning/ implementation of the technology.
- Assessment of cultural factors influencing the acceptance of the investigated health technology.

3. Patient and social aspects

Patients are integral participants across various contexts, and their interaction with health technologies can influence their capabilities and experiences within home, work, and healthcare environments. The utilization of health technologies may impact patients' abilities and burdens, shifting their daily routines in both positive and negative ways, impacting both patients and caregivers. Health technology assessment should extend beyond clinical and cost effectiveness to encompass evidence on patient perspectives.

Optional aspects that could be considered in health technology assessment include:

1. Patients' Perspectives:

- The burden of the disease or health condition on caregivers.
- Patients' experiences of living with the target condition.
- Expectations concerning the investigated health technology.
- The role of patient organizations in facilitating the effective use of the investigated technology.

2. Social Group Aspects:

- Identification of vulnerable patient groups lacking adequate access to current therapies.
- Identification of factors impeding a group or individual from accessing the investigated health technology.

3. Communication Aspects:

- Communication strategies for explaining treatment choices to patients.
- Specific issues that may require communication to enhance patient adherence to treatment protocols.

SECTION 6 : TRANSPARENCY OF HEALTH TECHNOLOGY ASSESSMENT

1. Transparency about conflict of interest

The declaration of conflicts of interest pertaining to the development of HTA should be transparently disclosed in the HTA dossier. The following protocol is recommended for detailing the involvement of each contracted organization in the preparation of the Oman HTA dossier, including consultant firms, academic institutions, and patient organizations:

1. Listing of Contracted Organizations: Each organization involved in the preparation of the HTA dossier should be listed explicitly.
2. Contribution of Individual Experts:
   - The contribution of individual experts from within and outside the contracted organizations should be outlined.
   - Details specifying the relevant chapters of the HTA dossier associated with each expert should be provided.
3. Financial Compensation Details: Financial compensation details for individual experts engaged in the preparation of the HTA dossier should be included.
4. Grouping of Experts from the Same Organization: In cases where multiple experts from the same organization participate in the creation of an HTA dossier, they should be grouped together in the same row for clarity and coherence.

Table 5: Conflict of Interest

Name of the expert(s)	Contracted organization (if applicable)	Direct payment to the contracted organization	Direct payment to the individual expert	Reimbursement of expenses	Indirect compensation (e.g. sponsorship of conference participation)	Non-financial compensation / other types of conflict of interest (please provide details)

2. Transparency about scientific evidence related to investigational technology

Ensuring transparency regarding the scientific evidence related to investigated health technology is paramount to educate the public, particularly clinicians, patients, and researchers who are not directly engaged in the HTA process but will be impacted by the introduction of new technologies. This practice enhances accountability, fosters informed decision-making, and promotes public trust in the assessment of new health technologies.

To achieve this, the following details contained in the HTA dossier should be made public:

- The HTA submission should be prepared in two documents for dissemination.
- The “Full Version” should be accessible exclusively to experts and decision-makers

involved in critical appraisal, pricing, and reimbursement processes.

- The "Published Version" of the HTA dossier should be made available to the wider public, with potential confidential information concealed by the submitting organization (e.g., pharmaceutical or consulting company).

The below details of the HTA dossier should be published.

Table 6: Details of the HTA dossier to be published

HTA dossier chapters	Publication of details
Epidemiology of the target indication (incidence, prevalence)	Mandatory
Current patient pathways with highlights on unmet medical need	Mandatory
Efficacy and safety of the new technology	Mandatory
Methodology of calculating the health gain by the new technology	Mandatory
Estimated health gain	Mandatory
Methodology of cost calculations	Mandatory
Estimated current resource use and treatment costs of patients	Mandatory
Proposed price of the new technology	No publication
Estimated resource use and treatment costs of patients with the new technology	No publication
Economic modelling methodology (model type, time horizon, discount rate)	Mandatory
Cost-effectiveness results (incremental health gain, costs and ICER)	Recommended
Sensitivity analysis results for the cost-effectiveness analysis	Recommended
Methodology of budget impact calculations	Mandatory
Current treatment mix of patients	Mandatory
Estimated patient numbers and market share of new technology in next 4 years	Recommended
Budget impact of the new technology	Recommended

3. Update of the methodological guidelines

As HTA methodologies are advancing swiftly, it is imperative to regularly review and potentially update the appropriateness of HTA methodological guidelines and the associated critical appraisal checklist. It is recommended that these guidelines and checklists be reviewed and, if necessary, revised every three years to ensure alignment with current best practices and evolving standards in HTA methodology. This proactive approach supports the continued relevance, accuracy, and rigor of HTA processes, promoting the quality and reliability of assessments conducted within the healthcare sector.

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رؤية عُمان 2040