IMPORTANT NOTICE - SUMMARY

Please read before using EVIDEM

EVIDEM is a reflective multicriteria approach designed to support the culture of reasonable decision-making by promoting procedural and substantive legitimacy; this includes selection of representative decisionmakers, relevance of reasons for the decision, publicity, appeal, and implementation – based on the ethical framework of accountability of reasonableness (A4R).

To help ensure that decisions are based on relevant reasons (substantive legitimacy), EVIDEM provides a set of generic decision criteria derived from the ethical imperatives that underlie the common goal of healthcare and its ultimate motivation: compassion. This represents a generic interpretive frame (MCDA reflective grid) that can be used to elicit individual values and facilitate sharing of diverse perspectives during committee deliberations or for other applications (e.g., patient-clinician shared decisionmaking). These generic criteria can be further concretized to reflect specificities of therapeutic areas or types of interventions. EVIDEM also provides a common structure for all members to express their interpretation of the evidence for each criterion and thereby share their reasoning with others. These interpretations can be expressed quantitatively through interpretive scores (quantitative criteria), qualitatively through impacts (qualitative criteria) as well as narratively through comments (all criteria).

To pursue its objectives, EVIDEM was designed to reduce constraints of the natural decision and deliberation process by ensuring that: all relevant generic criteria are included (whether they are considered qualitatively or quantitatively); scientific and colloquial evidence relevant to each criterion is made available through an efficient synthesis methodology; and face validity is checked at each step of the process (weights, scores and corresponding narratives, aggregated measures) to ensure that visual representations of quantitative outputs reflect the reasoning of individuals or, for system level decisions (e.g., for HTA or MoH), of the committee within and across assessments.
Although EVIDEM does use some features of MCDA, its roots are not in the methodology itself but rather in the natural decision and deliberation process. Its goal is to stimulate reflection, deliberation and reasonable decisions rather than algorithms approaches that traditional MCDA tends to promote. Each aspect of its design is geared to support the natural thinking process. It is built to minimize constraints of the natural reasoning in decisionmaking by providing a generic interpretive frame that can be shared across policy committee members, patients and physicians, and healthcare stakeholders at large.

**CRITERIA**

Criteria are selected to support the substantive legitimacy of the decision with regard to the common goal of healthcare systems. The goal is articulated in three normative aspects (ethical imperatives): 1 - alleviate/prevent suffering of patients; 2 - prioritize those who are worst off while ensuring greatest good for greatest number; and 3 - ensure sustainability. This is combined with the wisdom of making decisions informed by knowledge and adapted to context (feasibility aspect). These aspects are expressed in 20 criteria in agreement with MCDA methodological principles of non-redundancy, independence, operationalizability and completeness. This creates a generic interpretive frame which, by design, is a reminder of the common goal of healthcare.

THIS SHOULD BE BORNE IN MIND WHEN ADAPATING THE FRAMEWORK BY REMOVING/ADDING GENERIC CRITERIA

*Note 1: Attempts to limit the number of generic criteria for methodological reasons may constrain the reasoning and compromise the integrity of the comprehensive interpretive frame on which EVIDEM is built.*

*Note 2: For each generic criterion, a number of subcriteria are proposed in EVIDEM, which can be broken down further and integrated to reflect specificities of therapeutic areas or types of interventions.*

**REASONING LEADING TO A DECISION**

In the interpretive frame, the narratives and insights of the natural reasoning are structured by criteria and are complemented by qualitative and possibly quantitative outputs and visualization to facilitate their sharing and support the deliberation process.

**Evidence for Healthcare interventions**

When evaluating specific interventions, the goal of evidence synthesis and presentation (scientific and colloquial) is to provide for each criterion the best available and most relevant evidence in a clear format and ensure that the reflection is as unobstructed as possible by irrelevant or biased data.

**Qualitative approach** The framework can be applied in a qualitative mode that uses the interpretive frame (multicriteria grid) to capture interpretations of the available evidence for each criterion in a narrative form and uses implicit weights to arrive at a decision. A qualitative approach is recommended until a culture of the non-conventional use of numbers that EVIDEM proposes is well established in users.

**WHEN USING THE QUANTITATIVE ASPECTS OF THE FRAMEWORK BEAR IN MIND THEN THEY ARE MEANT TO HELP VISUALIZE AND SHARE THE REASONING**

**Mixed-Quantitative - Qualitative approach:**

**Qualitative considerations**

Since some criteria are not suitable for scoring (e.g., cultural and historical context) but nonetheless are an integral part of the reasoning, the framework provides a simple qualitative assessment tool to consider the impact of these criteria (positive, neutral or negative) on the value of interventions.

**Quantitative considerations involve weight and score elicitation and their aggregation.**

**Value system elicitation (Weights) for generic criteria:** Weighting of generic criteria is approached in EVIDEM as a way to explore the value systems (values) of individuals. Since its objective is to stimulate reflection on what matters most to each individual, direct (rather than indirect) weight elicitation methods are proposed, combined with a narrative and face validity exercise to confirm that the weights reflect the value system of the individual.

**Preferences (Weights) for specific subcriteria:** subcriteria that are specific to a therapeutic area or type of intervention can be elicited within a generic criterion (e.g., growth hormone: efficacy/effectiveness subcriteria: height [outcome 1], metabolism [outcome 2] etc.); the weights assigned to these represent individual preferences.

**Scores:** Reflective multicriteria analysis encourages the user to reflect on the evidence and make a judgment on its meaning using an interpretive scoring scale and also to provide a narrative to explain the reasoning that underlies the score. (Scores are thus a quantitative representation of an interpretation of the evidence, not a mathematical transformation of data.) These narratives can be summarized for each criterion at the group level for committees deliberations. Face validity of the visual representation of the scores is essential to ensure that the scores reflect the reasoning.

**Weights and scores aggregation:** Simple linear aggregation models are applied to create as little mental distance as possible between the measurement and the reasoning. To check face validity, users are presented with a visual representation of the aggregated measurement along with the contribution of each criterion and the associated narratives.

**Modulation by qualitative criteria:** the impact of each qualitative criteria on the aggregated measurement is considered. Face validity is checked at the group level, with a visual representation and associated narratives.

**Last criterion for consideration:**

After the evaluation based on all the other criteria is completed, the criterion "Opportunity cost and financial feasibility" is considered through a budgeting exercise, the committee performs a final deliberation on all aspects brought up and the decision is made.

**Ranking**

As the committee performs multiple assessments, face validity checks are carried out to ensure that the ranking based on the modulated aggregated measures does reflect the group reasoning within and across assessments. Adaptation of the framework is carried out as applicable over time.
VISUALIZATION OF THE FRAMEWORK

1 - GENERIC GOAL: HEALTH

- Goal is further defined in 3 normative aspects:
  - Patient: imperative to prevent/ameliorate suffering
  - Population: prioritize those who are worst off and greatest good to greatest number
  - Sustainability: ensure sustainable healthcare system
- Combined with practical wisdom to make decisions adapted to context (context awareness, feasibility aspect)
- These four aspects are further defined into 20 generic criteria

2 - CRITERIA

### 3 - VALUE SYSTEM ELICITATION & WEIGHTS

<table>
<thead>
<tr>
<th>Quantitative</th>
<th>Minimize mental distance</th>
<th>Scientific and colloquial</th>
<th>Interpretive scales</th>
<th>Narratives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease severity</td>
<td>Direct rating scale</td>
<td>Turner syndrome: Female specific; genetic disorder characterized by reduced life expectancy, (details)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Etc</td>
<td>Tool EVIDEM Adapt and pilot</td>
<td>Tool EVIDEM Evidence matrix</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Qualitative</td>
<td>NA</td>
<td>Scientific and colloquial</td>
<td>Non-numerical impact</td>
<td></td>
</tr>
<tr>
<td>System capacity</td>
<td>Risk of inappropriate use of growth hormone for Turner syndrome due to</td>
<td>(details)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Etc</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

OUTPUT: Pragmatic multicriteria evidence matrix to support reasoning & deliberation

6 - VISUALISATION OF REASONING

### QUANTITATIVE CRITERIA VALUE OF INTERVENTION A

Criteria contribution to value & insights

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harm reduction</td>
<td>B</td>
</tr>
<tr>
<td>Side effects</td>
<td>C</td>
</tr>
<tr>
<td>Comparative efficacy</td>
<td>A</td>
</tr>
<tr>
<td>Comparative safety</td>
<td>A</td>
</tr>
<tr>
<td>Comparative quality of life</td>
<td>A</td>
</tr>
<tr>
<td>Total value to society</td>
<td>A</td>
</tr>
<tr>
<td>Quality of evidence</td>
<td>A</td>
</tr>
</tbody>
</table>

### QUALITATIVE CRITERIA IMPACT ON VALUE OF INTERVENTION A

Impact of criteria & insights

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative impact</td>
<td>B</td>
</tr>
<tr>
<td>Positive impact</td>
<td>A</td>
</tr>
</tbody>
</table>

OUTPUT: Face validity of reasoning at group level

7 - RANKING, CONSIDERATION OF OPPORTUNITY COSTS & DELIBERATION

### RANKING OF INTERVENTIONS

Based on best overall value

- Value of interventions
- Qualitative criteria

### CONSIDERATION OF CRITERIA “OPPORTUNITY COST” BASED ON FINANCIAL IMPACT

<table>
<thead>
<tr>
<th>Financial Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0.1M high value</td>
</tr>
<tr>
<td>$1M invest</td>
</tr>
<tr>
<td>$0.15M low value</td>
</tr>
<tr>
<td>$1M disinvest</td>
</tr>
</tbody>
</table>