Appropriateness of healthcare decisionmaking: what multicriteria decision analysis (MCDA) can bring?

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EVIDEM Collaboration - Board of Directors

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Overview
Healthcare decisionmaking continuum

Develop intervention and data
- Clinicians
- Industry
- Researchers

Authorize use
- Regulatory bodies

Prioritize/Reimburse/implement intervention
- Health systems & institutions

Prescribe intervention
- Clinicians

Receive/take intervention
- Patients

Addressing health need

→ Appropriateness: Which interventions contribute the most to health and to an equitable, efficient and sustainable healthcare system?
Structuring the natural thinking process

Apply the principles of Multicriteria decision analysis (MCDA)

- Identify criteria
- Systematize their consideration
- Qualitative/quantitative approaches

Efficacy
- Patient reported outcomes
- Historical context

Safety
- Feasibility
- System capacity
- Unmet needs
- Quality of evidence
- Ethics
- Population Priorities

Cost
- Affordability
- Disease severity
- Unmet needs
- Expert opinion
- Individual values
- Feasibility

Affordability
- Cost
- Affordability
- Disease severity
- System capacity

Finding the evidence for each criteria (scientific and colloquial)

⇒ Apply the principles of health technology assessment (HTA)
Bridging MCDA with HTA

⇒ EVIDEM framework

EVIDEM Collaboration*
A not-for-profit collaborative platform

Object: promote public health by developing efficient multicriteria-based solutions to healthcare decisionmaking

Board of Directors
Officers
Monika Wagner, Hanane Khoury
Developers at BioMedCom

Staff (part-time)
Michele Tony, Danielle Badgley

Membership
• Physicians & Healthcare professionals
• Policy makers
• Patients
• Researchers
• Health care industry
• Open source specialists

- Tools regularly upgraded based on academic research and feedback from users
- Registry populated with data generated by users

Community of multicriteria practice

Researchers/users:
Development, adaptation and application of tools

Open source philosophy: sharing, contributing and improving for benefit of all

Open source
multicriteria
decisionmaking
framework & toolkit

Open Web Registry
of “by-criterion” synthesized evidence

Discussion forum

*International collaboration registered under and structured according to the Canadian laws in January 2009
Last funding received for EVIDEM operations: Canadian Institutes of Health Research (CIHR)
Criteria & tools
EVIDEM conceptual approach

Generic framework to facilitate reflection on all aspects of healthcare decision across all stakeholders to assess interventions

- **MCDA principles**
  - criteria should be complete
  - with minimum overlap
  - mutually independent
  - Operationalizable

- **Includes an adaptable set of criteria***
  - **MCDA Core Model** (universally normative criteria)
  - **Contextualization Tool** (normative contextual and feasibility criteria)

*Criteria identified from extensive analysis of literature and decisionmaking processes, feedback from users and selected to fulfill MCDA principles; categorized based on WHO normative and feasibility principles
**EVIDEM MCDA Core Model**

*What should we do? Which interventions contribute the most to health and sustainable systems?*

Includes 15 universal **normative** criteria and assumes that:

- **Interventions that contribute the most are:**
  - For severe disease (D1)
  - For common disease (D2)
  - For disease with many unmet needs (C2)
  - Recommended by expert consensus (C1)
  - Conferring major improvement in efficacy/effectiveness over standard of care (I1)
  - Conferring major improvement in safety & tolerability over standard of care (I2)
  - Conferring major improvement of patient perceived health over standard of care (I3)
  - Either conferring major risk reduction (T1) or major alleviation of suffering (T2)
  - That results in savings in healthcare intervention expenditures (E1) as well as other medical and non medical expenditures (E3); **cost-effective (E2)**
  - For which there is sufficient data (Q1), that is fully reported (Q2) and valid and relevant (Q3)

*Cost-effectiveness is a composite of some elements of other criteria and does not comply with the non-redundancy design requirement of MCDA. It may be included in the framework since many decisionmaking processes currently rely on this composite measure.*


**EVIDEM Contextualization Tool**

*What is our context and what can be done?*

Includes 6 criteria

- **Define objectives of healthcare system & population priorities** - 2 contextual normative criteria
  - Alignment with scope and mission of health care system/plan (Et1)
  - Defining country/jurisdictional priorities for populations & access (Et2)

- **4 Feasibility criteria**
  - Exploring opportunity costs (forgone interventions) and affordability (Et3) (financial/budgeting exercise)
  - Verifying system capacity (e.g., infrastructure, skills) and appropriate use of intervention (O1)
  - Assessing political/historical context (e.g. cultural acceptability, precedence) (O2)
  - Realizing pressures/barriers from healthcare stakeholders (O3)
**EVIDEM framework**

**MCDA Core Model**
- **Normative criteria**
  - **Disease impact**
    - Disease severity (D1)
    - Size of population affected by disease (D2)
  - **Context of intervention**
    - Clinical guidelines (C1)
    - Comparative intervention limitations (C2)
  - **Intervention outcomes**
    - Improvement of efficacy/effectiveness (I1)
    - Improvement of safety and tolerability (I2)
    - Improvement of patient reported outcomes (I3)
  - **Type of benefit**
    - Public health interest (e.g., prevention, risk reduction) (T1)
    - Type of medical service (e.g., symptom relief, cure) (T2)
  - **Economics**
    - Budget impact on health plan (cost of intervention only) (E1)
    - Impact on other spending (e.g., hospitalization, disability) (E2)
    - Cost-effectiveness of intervention (E3)
  - **Quality/uncertainty of evidence**
    - Adherence to requirements of decisionmaker (Q1)
    - Completeness and consistency of reporting (Q2)
    - Relevance and validity of evidence (Q3)

**Contextualization tool**
- **Feasibility & normative criteria**
  - **E2 - Possible sub-criteria**
    - Impact on primary care expenditures
    - Impact on hospital care expenditures
    - Impact on long-term care expenditures
    - Impact on productivity
    - Financial impact on patients
    - Financial impact on caregivers

*Adapt to context*

*Includes an ethical framework based on WHO ethical principles of resource allocation*
Weights, scores & appraisal
Not all criterion are equal

Disease severity \[=\] Improvement of efficacy
Develop MCDA model
Weight elicitation technique*

- Capture individual perspective on relative importance of criteria independently of healthcare interventions
- No gold standard

→ Simple techniques
  - EVIDEM
  - EVIDEM

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Low</th>
<th>Weights</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example Disease severity</td>
<td></td>
<td>![1 2 3 4 5]</td>
<td></td>
</tr>
</tbody>
</table>

- Kepner-Tregoe Analysis (KTA)
- Direct point allocation

→ More complex
  - Analytical hierarchy process (AHP)
  - Best/worst scaling
  - (Conjoint analysis)

→ Adapt to user preference/context

  Clemen and Reilly. Making Hard Decision. 2001
Not all interventions are equal
Develop MCDA model
Scoring scale?

- Measure performance of intervention
- Need to define:
  - Type of scale/number of options
  - Scale anchors for each criteria
- Simple approach
  - EVIDEM

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Scoring scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example Disease severity</td>
<td>0 - not severe</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>3 - very severe</td>
</tr>
</tbody>
</table>

- More complex (e.g., more scale options, boolean operators for each option)

- Adapt to user preference/context
Applying the tools: appraise & rank interventions

Adapted MCDA Core Model

**Quantitative criteria**

\[ \sum N \text{Weights} \times \text{Scores} = \text{Value} \]

**Adapted Contextualization tool**

**Qualitative criteria**

- **Impact of context**
  - A
  - B
  - C
  - D

**Financial Exercise**

- B = $0.01M
- A = $1M
- C = $0.01M
- D = $1M

**What should we do?**

- Normative criteria

**What can we do?**

- Feasibility criteria

**Recommendation**

**Decision**

**Invest**

**AND**

**Disinvest**
“By-criterion”
HTA web report
Web registry

http://www.evidem.org/evidem-collaborative.php

Demo: Interactive prototype

https://www.evidem.org/tiki/?page=DEMO-main
Overview of intervention

**Last Update:** April 2009  
**Disease:** Turner syndrome (TS)  
**Intervention:** Growth Hormone (GH)  
**Setting:** Canada

**Drug class:** Polypeptide hormone  
**Indication:** treatment of short stature in girls with Turner Syndrome  
**Administration:** subcutaneous injection 3 to 7 days a week  
**Intervention duration:** Needs to be established. Initiate as soon as growth failure demonstrated until satisfactory height reached (6 years of treatment starting at 10 years)  
**Comparator(s):** No treatment  
**Economic burden of illness:** No data available

Interactive by-criterion HTA report – high level synthesis - excerpt

<table>
<thead>
<tr>
<th>Disease criteria</th>
<th>Highly synthesized information</th>
<th>Score</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease severity</td>
<td>Female-specific genetic disorder characterized by short stature, cardiovascular defects, absence of puberty, infertility, increased risk of diabetes, defects in visuospatial organization and nonverbal problem-solving, and decreased life expectancy. [see details]</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0 Not severe (minor inconvenience)</td>
<td>Low Score due to data specify</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 Very Severe</td>
<td></td>
</tr>
<tr>
<td>Size of population</td>
<td>Prevalence: 40/100,000 female adults.</td>
<td></td>
<td>Low Score due to data specify</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0 Very rare disease</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 Common disease</td>
<td></td>
</tr>
</tbody>
</table>

Context of Intervention

| Clinical guidelines | International guidelines (eg Canadian Guidelines: Candid GH treatment as seen - specify) | | |
|                    | || |
|                    | 0 No recommendation | | |
Interactive by-criterion HTA report
Details on evidence - example

**D1 - Disease severity**

Turner syndrome is a female-specific genetic disorder (complete or partial loss of one of the X chromosome) characterized by short stature and presenting a wide spectrum of abnormalities, including cardiovascular defects (17-45%), lymphedema, gonadal dysgenesis (90% requiring hormone replacement therapy to induce puberty), infertility, miscarriage, hypothyroidism (15-30%), risk of obesity, ophthalmic defects, hearing problems and ear malformations, gastrointestinal and renal manifestations (Bondy 2007, Sybert et al. 2004). Patients are at increased risk of impaired glucose tolerance and diabetes (Hjerrild 2008, Holl 1994). Overall, cancer risk appeared not to be significantly increased; increased risks were reported in some studies for brain and nervous system tumors, and for colon and rectal cancer (Stochholm 2006, Schoemaker 2008, Hjerrild 2008). Defects in visuo-spatial organization and nonverbal problem-solving affect most patients with TS; in addition, impaired psychomotor and social functioning have been reported (Bondy 2007, Sybert et al. 2004).

In young patients, psychosocial issues arise: impaired peer relationship, teasing, social isolation, anxiety, shyness, and poor self-esteem (Bondy 2007, Sybert et al. 2004, Schmidt et al, Busschbach et al. 1998). In audiotaped interviews, Turner Syndrome patients reported infertility as their biggest concern (range: 36% of girls aged 7–13 yrs to 74% of adults aged 20–39 yrs; Sutton et al. 2007). However, many Turner Syndrome patients of all ages reported to be bothered by short stature (36% girls, 44% adolescents and adults, 53% mature adults 40–59 yrs; Sutton et al. 2007); 44% of 25 adult Turner Syndrome patients reported short stature (Busschbach et al. 1998). Short stature is a defining feature of TS.

Life expectancy is decreased in women with Turner Syndrome (Stochholm et al. 2006; Sybert et al. 2004) (number of deaths / expected number of deaths = 1.1).

*Return to DEMO Scoring intervention (NCDA Manual)*

*Return to DEMO Menu*
### Interactive by-criterion HTA report

**Links to quality assessments - example clinical data**

<table>
<thead>
<tr>
<th>Intervention outcomes</th>
<th>Interventions limitations</th>
<th>limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement of efficacy/effectiveness</td>
<td>syndrome.</td>
<td>Limitations</td>
</tr>
<tr>
<td>Improvement of safety &amp; tolerability</td>
<td><strong>4 placebo controlled RCTs</strong> (2-year (toddlers) to 11-year treatments; N=42 to 104, 1 in Canada, 3 in USA): Final height of treated patients = 147 cm to 150 cm; difference with untreated = 7 cm</td>
<td></td>
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<tr>
<td></td>
<td><strong>Observational studies</strong> (2-year to 8-year treatments, N=26 to 123, 1 in Germany, 1 in Greece, 1 in Israel, 3 in Italy): Final height of treated patients = 148 cm to 151 cm; difference with controls = 2.1 to 6.3 cm. <a href="#">Example of critical analysis</a></td>
<td></td>
</tr>
<tr>
<td>Improvement of patient reported outcomes</td>
<td><strong>Common AEs</strong> (from RCTs - frequency at least twice of placebo): Surgeries (50%), ear problems (6% to 47%), joint (13.5%) and respiratory (11%) disorders, sinusitis (18.9%)</td>
<td>Limitations</td>
</tr>
<tr>
<td></td>
<td><strong>Serious AEs</strong> (from registries, no control data): Intracranial hypertension (0.2%), slipped capital femoral epiphysis (0.2 - 0.3%), scoliosis (0.7%), pancreatitis (0.1%), diabetes mellitus (0.2 - 0.3%), cardiac/aortic events (0.3%), malignancies (0.2%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Warnings:</strong> Scoliosis, slipped capital femoral epiphysis, intracranial hypertension, ear disorders, cardiovascular disorders, autoimmune thyroid disease, insulin resistance.</td>
<td>Limitations</td>
</tr>
<tr>
<td></td>
<td><strong>Inconclusive data:</strong> 1 RCT (2-year treatment data, N=28, Canada): higher rating on questionnaire by GH treated patients versus untreated for some domains but not for others</td>
<td>Limitations</td>
</tr>
<tr>
<td></td>
<td>2 observational studies: no significant differences on SF-36 dimensions in one study (5-year treatment, N=568, France) and significant differences in another (7-year treatment, N=29, Holland); other questionnaires, non significant differences</td>
<td>Limitations</td>
</tr>
<tr>
<td></td>
<td>Convenience: Subcutaneous injection 3 days a week or daily.</td>
<td>Limitations</td>
</tr>
<tr>
<td>Type of benefit</td>
<td>Public health interest</td>
<td>Limitations</td>
</tr>
<tr>
<td>T1</td>
<td>No data on <strong>risk reduction</strong> with GH treatment.</td>
<td>Limitations</td>
</tr>
</tbody>
</table>
# Interactive by-criterion HTA report

## Quality of evidence assessment - overall clinical data

<table>
<thead>
<tr>
<th>Relevance and validity – clinical data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Disease:</strong> Turner Syndrome (TS)</td>
</tr>
<tr>
<td><strong>Intervention:</strong> recombinant human growth hormone (GH)</td>
</tr>
<tr>
<td><strong>Setting:</strong> Canada</td>
</tr>
<tr>
<td><strong>Series of key studies</strong></td>
</tr>
<tr>
<td>Stephure et al, 2005: Canada - See full assessment</td>
</tr>
<tr>
<td>Quigley et al, 2002: US - See full assessment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of evidence</th>
<th>Question(s)</th>
<th>Rationale</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Efficacy/safety data</strong></td>
<td>How relevant is the research program with regard to efficacy and safety? Are conclusions valid over the range of studies (conclusions across studies consistent or conflicting)? Are individual trials relevant and valid? See assessment of individual studies below</td>
<td>Overall, randomized controlled trials consistently demonstrate that GH treatment promotes height gain in girls with Turner Syndrome. Some uncertainty remains on extent to which GH may affect final height. High attrition rates were noted in the Canadian clinical trial (Stephure 2005); 2 multiphase trials were missing a control arm (no GH treatment) and chose GH administration mode (frequency of injections) that did not correspond to current practice (Rosenfeld et al. 1998; Quigley et al. 2002). Safety data monitoring is generally limited, despite the numerous warnings and AEs associated with GH treatment in Turner Syndrome populations. (Humatrope PM, 2007; Saizen PM, 2007; Nutropin PM, 2006).</td>
<td>1 [ ] Low relevance/validity 2 [ ] 3 [x] 4 [ ] High relevance/validity</td>
</tr>
</tbody>
</table>
# Interactive by-criterion HTA report

## Quality of evidence assessment - excerpt single study

### Relevance and validity - clinical data - study 1

**Disease:** Turner Syndrome (TS)  
**Intervention:** recombinant human growth hormone (GH)  
**Setting:** Canada  

<table>
<thead>
<tr>
<th>Type of evidence</th>
<th>Question</th>
<th>Rationale</th>
<th>Score</th>
</tr>
</thead>
</table>
| **Efficacy/safety data** | Is the study question relevant (choice of comparator, time horizon, patient population, and outcome)? Is the design appropriate (setting & design, sample size, patient allocation, analyses, statistics)? See dimensions below | This is the only study reporting final height (standard measure of GH effect; (Baxter et al. 2007)) as the primary outcome. Although differences between GH treatment and no treatment are meaningful, high attrition rates, especially in the control arm (45%) might bias the study conclusions (Baxter et al. 2007). Authors report that supportive intent-to-treat analysis with conservative assumptions on missing data confirmed significance but no details are provided. | 1 [ ] Low relevance-validity  
2 [ ]  
3 [x]  
4 [ ] High relevance-validity |

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Question</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Target population</td>
<td>Is the target population relevant (age, gender, disease stage, comorbidities, inclusion criteria/exclusion criteria, setting etc)? Does it correspond to the actual population in which the intervention is envisioned to be used?</td>
<td>Target population is relevant and corresponds to the actual population in which the intervention is indicated; prepubertal Turner Syndrome girls (mean age: 10.3 ± 1.8 yrs; range: 7–13 yrs) with evidence of growth failure (height &lt; 10th percentile) (Gondy 2007). Canadian setting but there is no mention of number and location of centers involved.</td>
</tr>
<tr>
<td>2 Intervention &amp; comparators</td>
<td>Is the intervention in agreement with expected use? Does the choice of comparators reflect standard of care?</td>
<td>GH dose and schedule are in agreement with indication to treat short stature in Turner Syndrome girls (Humatrope PM. 2007; Saizen PM. 2007; Nutropin PM. 2006). Comparator is no treatment (standard of care).</td>
</tr>
<tr>
<td>3 Outcome measures</td>
<td>Are the selected outcomes measures (efficacy, safety and PRO) relevant? Are rationales for outcomes selection valid? Are the instruments/methods/units used to measure outcomes (efficacy, PRO, validity)</td>
<td>The primary outcome is final height (cm), which is the gold standard measure of GH effectiveness (Baxter et al. 2007). Other efficacy analyses are relevant to the assessment of short-term growth, and instruments/units used are valid: height age-specific Turner Syndrome standard deviation score (SDS; allows comparing to non-patient height); height while Turner</td>
</tr>
</tbody>
</table>
## Users & applications

<table>
<thead>
<tr>
<th>Users</th>
<th>Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>❖ Decisionmakers</td>
<td></td>
</tr>
</tbody>
</table>
| Policy (macro/meso) | ✗Priority setting  
✗Regulatory  
✗Reimbursement  
✗Implementation |
| Physicians & healthcare professionals | ✗Clinical practice guidelines (CPGs)  
✗Seamless access to evidence |
| Patients | ✗Access to clear, digested & validated information |
| ❖ HTA developers | ✗By-criterion HTA report  
✗Web-based multilevel evidence |
| ❖ Research | ✗Identify research questions/data needs  
✗Research planning  
✗Explore the decisionmaking process |
| ❖ Developers of new healthcare interventions/programs | ✗Development  
✗Positioning  
✗Data gap analysis |
| ❖ All | ✗Communication (evidence and values)  
✗Knowledge translation |
# Strengths and challenges

<table>
<thead>
<tr>
<th>Strengths to decisionmakers</th>
<th>Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adaptable to local context</td>
<td>Perception of complexity</td>
</tr>
<tr>
<td>Systematize decision process</td>
<td>Integration into existing processes</td>
</tr>
<tr>
<td>Quantitative and qualitative aspects combined</td>
<td>Degree of quantification</td>
</tr>
<tr>
<td>Identify criteria and perspectives at play in decisionmaking</td>
<td>Risk of using MCDA as a formula rather than as a support to decisionmaking/priority setting</td>
</tr>
<tr>
<td>Appraisal and priority setting based on wide range of criteria</td>
<td></td>
</tr>
<tr>
<td>Transparency</td>
<td></td>
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</tbody>
</table>

## Methodology

<table>
<thead>
<tr>
<th>Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pragmatic, user-oriented and modular</td>
</tr>
<tr>
<td>Open source development (benefit from others’ experience)</td>
</tr>
<tr>
<td>Criteria selection</td>
</tr>
<tr>
<td>Weighting process</td>
</tr>
</tbody>
</table>

## Data requirements

<table>
<thead>
<tr>
<th>Data requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comprehensive but modular</td>
</tr>
<tr>
<td>Open web registry (benefit from others’ work)</td>
</tr>
<tr>
<td>Data synthesis by criteria</td>
</tr>
<tr>
<td>Web registry in its infancy</td>
</tr>
</tbody>
</table>

## Capacity/training requirements

<table>
<thead>
<tr>
<th>Capacity/training requirements</th>
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</thead>
<tbody>
<tr>
<td>Testing package available in the toolkit</td>
</tr>
<tr>
<td>Community of users and developers building up</td>
</tr>
<tr>
<td>Limited MCDA expertise in healthcare</td>
</tr>
</tbody>
</table>
On the agenda

- **Methodological development** (e.g., sub-criteria, weighting elicitations techniques, data synthesis)
- **Field adaptation and implementation**
- **Discussion forum – community of multicriteria practice**
  - Collaboratively optimize open source framework & toolkit
  - Optimize resources, decisions, priority-setting and patient health
Acknowledgments

- Colleagues at BioMedCom
- Active members of the EVIDEM Collaboration

Thank you

www.evidem.org
Back-up slides
EVIDEM framework - overview

Framework structure adaptation

Standard set of criteria
MCDA CORE MODEL CONTEXTUAL TOOL

Contextualized framework

HTA report "by criterion"
- Step-by-step methodology for data synthesis by criterion
- Applicable to any interventions (drugs, devices, procedures)
  - Web-based

Evidence

Applications

Clinical practice guidelines
- Structure CPGs questions by criteria
- Facilitate deliberations

Health policy
- Appraisal of interventions with a contextualized tool
- Facilitate deliberations for
  - Reimbursement
  - Priority-setting

Recommendation Decision

Knowledge transfer & research planning