FIELD TESTING OF A MULTICRITERIA DECISION ANALYSES (MCDA) FRAMEWORK FOR COVERAGE OF A SCREENING TEST FOR CERVICAL CANCER IN SOUTH AFRICA

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Background

- Healthcare decisionmaking is a complex process that involves scientific assessment of available evidence and requires application of value judgment.[1,2]
- There is growing recognition that accessibility to the information on which decisions are based, together with transparent and explicit approaches to decisionmaking are necessary to legitimize and improve decisions.[3-5] This recognition has led to a number of approaches in this direction, including the 6-STEPPPs approach and other multicriteria models.[6-14]
- The EVIDEM framework was developed as a comprehensive set of components of decision for which data is made available using a multicriteria decision analysis (MCDA) approach, with the aim of supporting transparent and efficient healthcare decisionmaking.[15]
- Objective: To field test the EVIDEM framework, initially developed in the Canadian drug formulary context, in the South African context for the assessment of a screening test.

Methodology

- A collaborative team was established with a private health insurer in South Africa (Discovery Health). Liquid based cytology (LBC) for cervical cancer screening was selected as an intervention requiring a coverage decision which would benefit from an MCDA framework such as EVIDEM.
- Data for each MCDA Value Matrix component (intrinsic value) was collected and synthesized using a simplified EVIDEM methodology. Disease impact data was obtained from the public domain. Clinical data, was derived from a CADTH meta-analysis of trials comparing LBC with conventional cytology (CC). Cost-effectiveness and impact on other spending were based on a CADTH economic evaluation of LBC, using selected screening strategies most applicable to the Discovery Health setting. Budget impact data was based on information provided by the insurer.
- Quality of evidence was assessed using the Quality Matrix instruments for two types of evidence (clinical and economic evaluation) and for two criteria of quality ("completeness and consistency or reporting" and "relevance and validity of evidence").
- The intrinsic value of LBC was assessed by the decisionmaking committee by assigning to each value component weights (independent of intervention) and scores based on the synthesized evidence presented in the MCDA Value Matrix. Normalized weights and scores were combined using an MCDA linear model to derive a value estimate.
- Components affecting the extrinsic (or system-related) value of LBC in the Discovery Health setting were explored by participants.
- Participants were surveyed on components of decisions to be considered and outcomes of approach.

Results

Extrinsic value

Extrinsic value components*	Should this be considered? Would it impact positively or negatively on value of intervention?
Impact on future decisions	Decision to fund LBC coverage although not considered cost-effective will be setting a precedent as LBC technology will be expanded to other cytology tests Considered as negative impact on value
Relationship with pathology providers	Ongoing negotiations with the pathology groups in other areas may be impacted Considered as a positive impact on value
Impact on screening intervals	Screening interval may be extended to 2 to 3 years than annually Considered as a positive impact on value
Patient expectation	Discovery Health members expect that their pap smears will be paid in full and are likely to resist any benefit design which implements a co-payment for a more expensive technology Considered as a negative impact on value

*Extrinsic value components may include: appropriate use; opportunity cost; organizational structure required; stakeholder pressures; political context; population priorities & access; regulatory status of intervention etc…

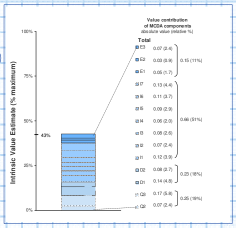
Intrinsic value

MCDA Value Matrix

- Value of LBC in current context (with conventional cytology available) was estimated at 43%
- Main contributors to value were relevance and validity of evidence, disease severity and type of medical service

For an intervention to achieve close to 100% on this scale, it would have to cure a severe endemic disease, demonstrate a major improvement in safety, efficacy and PRO compared to limited existing approaches, and result in major healthcare savings.

An intervention that scores low would be for a rare disease that is not severe, with limited data showing small improvement in efficacy & major safety and PRO issues over existing alternatives, & resulting in major increases in healthcare spending



Quality of evidence

Full assessment – example Q3-clinical

Clinical data – relevance and validity of evidence			
Disease: Cervical cancer **Intervention:** Liquid-based cytology **Setting**: Discovery Health - South Africa		**Study:** Krahn M et al..Meta-analysis of LBC accuracy (sensitivity and specificity). In Liquid-based techniques for cervical cancer screening: systematic review and cost-effectiveness analysis. http://cadth.ca/index.php/en/publication/799 –	
Type of evidence	**Question**	**Comments**	**Score**
Efficacy/safety, effectiveness, or PRO 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)?	The study question is relevant with regard to comparator (conventional cytology (CC); however, it does not assess the most relevant outcome, morbidity and mortality due to cervical cancer that would occur with screening programs using these technologies. The design is appropriate for the study question. (*See details below*)	1 ☐ Low relevance/validity 2 ☐ 3 ☒ 4 ☐ High relevance/validity

	Dimension	Question	Comment
1	Target population	Is the target population relevant (age, gender, disease stage, comorbidities, inclusion criteria/exclusion criteria etc)? Does it correspond to the actual population in which the intervention is envisioned to be used?	Target population (sexually active women ≥15 years of age) is relevant. The studies included were carried out in different countries and settings, although most of them were done in Europe and the USA.
2	Intervention & comparators	Is the intervention in agreement with expected use? Does the choice of comparators reflect standard of care?	Yes, CC is standard of care for screening for cervical cancer in the South African private healthcare sector.
3	Outcome measures	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*) valid?	Although the specificity and sensitivity of LBC compared to CC is a relevant primary outcome measure when comparing the technical performance of these two interventions, the most relevant outcome measure would be morbidity and mortality due to cervical cancer (no data available on these outcomes – only modeled in economic evaluation).
4	Study design	Was the sample size appropriate? Is the design appropriate? For RCTs, this includes: randomization; patient allocation concealment; blinding as appropriate; completeness of follow up; avoidance of carry-over effects. For observational studies (cross-sectional, cohort, or case-control) this includes adequate methods of selection of participants and control of confounding.	Literature search procedure and study inclusion criteria appropriate with regard to scientific standards. Sample size for the 20 studies pooled for the primary outcome analysis was large (28,736 women for LBC and 39,377 for CC). The primary outcome analysis included only studies directly comparing LBC to CC (2-cohort or split-sample studies), which is appropriate.
5	Adverse events	Are methods for monitoring the occurrence of adverse events and assumptions with regard to which adverse events are related to the intervention(s) relevant and valid in light of previous experience with similar interventions / populations? Are all relevant adverse events reported (deaths, serious, common, discontinuations), both treatment-related and all-cause?	Adverse events not addressed. Since the procedure for obtaining the sample from the patient is the same for both LBC and CC, incidence of adverse events is assumed to be the same.
6	Time horizon	Is time horizon long enough to capture all meaningful differences in key outcomes between the intervention and comparators? (e.g., Was the study stopped prematurely because of observed benefits or harms?)	Time horizon is not applicable for the outcome measures assessed (comparative accuracy of two screening tests).
7	Analyses	Are the analyses appropriate and comprehensive with sound and relevant statistics (e.g., intention-to-treat; missing data; control of confounding; subgroup analyses)?	Data analyses appear to be scientifically appropriate and comprehensive with relevant statistics.
8	Results (precision and strength of effect)	Are differences observed meaningful (clinically and statistically)? Is there evidence of a dose-response relationship?	Observed differences between the two screening methods not statistically significant.

Decision

Extrinsic value

Intrinsic value

MCDA Value Matrix

Cluster	Value component (alphabetical by cluster)	Weight	Synthesized evidence	Score	Evaluator comments	Value contri-bution
Quality of evidence						
Q1	Adherence to requirements of decisionmaking body		Quality Matrix			
Q2	Completeness and consistency of reporting evidence					
Q3	Relevance and validity of evidence					
Disease impact						
D1	Disease severity					
D2	Size of population affected by disease					
Intervention						
I1	Clinical guidelines on interventions or similar alternatives					
I2	Comparative interventions limitations					
I3	Improvement of efficacy/effectiveness					
I4	Improvement of safety & tolerability					
I5	Improvement of PROs, convenience & adherence					
I6	Public health interest					
I7	Type of medical service *(e.g., cure, symptom relief)*					
Economics						
E1	Budget impact of reimbursing intervention on health plan					
E2	Cost-effectiveness of intervention					
E3	Impact on other spending					
Total	Value estimate (sum of all value contributions; MCDA linear model)					

Synthesized Evidence

For each component of decision

Health technology assessment report

Quality of Evidence

Quality Matrix

Evidence available

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Liquid based cytology for screening cervical cancer in South Africa

Survey

Components of decision

Question: Indicate whether you feel components of the MCDA Value Matrix should be considered in the decisionmaking process (intrinsic value components)

Component	Total number of responses	Distribution of responses (%) Always	Sometimes	Never
Quality of evidence				
Adherence to requirements of decisionmaking body	9	33	67	0
Completeness and consistency of reporting evidence	9	89	11	0
Relevance and validity of evidence	9	89	11	0
Disease impact				
Disease severity	9	89	11	0
Size of population affected by disease	9	67	33	0
Intervention				
Current clinical guidelines	9	89	11	0
Current interventions limitations	9	78	22	0
Improvement of efficacy/effectiveness	9	89	11	0
Improvement of safety & tolerability	9	78	22	0
Improvement of PRO, convenience & adherence	9	44	56	0
Public health interest (prevention & risk reduction)	9	78	22	0
Type of medical service	9	89	11	0
Economics				
Budget impact on health plan	9	100	0	0
Cost-effectiveness of intervention	9	89	11	0
Impact on other spending	9	78	22	0

Question: Indicate whether components listed below should be considered in the decisionmaking process (extrinsic value components)

Component	Total number of responses	Distribution of responses (%) Always	Sometimes	Never
Appropriate use	9	89	11	0
Opportunity costs	9	78	22	0
Organizational structure	9	22	78	0
Stakeholder pressures	9	33	67	0
Political context	9	11	89	0
Population priorities and access	9	22	78	0
Regulatory status of intervention	9	56	44	0

Process outcomes

Question: Indicate how EVIDEM approach compares to existing process you are familiar with on the attributes listed below

Attributes	Total number of responses	Distribution of responses (%) Improved	Same	Worse
Intervention under scrutiny				
Understanding of intervention	8	50	50	0
Access to evidence on intervention	8	25	75	0
Access to quality assessment of evidence on intervention	8	50	50	0
Deliberative process				
Considering all key elements of decision	8	50	50	0
Expressing personal/expert opinion	9	11	89	0
Sharing & discussing values among committee members	9	22	78	0
Communication of decision				
Transparency of decision	9	56	44	0
Understandability of decision by stakeholders	9	56	44	0
Acceptability of decision by stakeholders	7	43	57	0

Discussion and conclusion

- The EVIDEM framework is applicable to the assessment of value of a screening intervention in the Discovery Health (South African private payer) context and provides a practical tool integrating an HTA report with a MCDA approach to support decisionmaking.
- Available clinical evidence was fairly relevant and valid. Partial reporting of disaggregated data in the published economic evaluation limited its usefulness.
- The MCDA Value Matrix provided a comprehensive measure of the intrinsic value of LBC in current context, i.e., relative to existing technology (conventional cytology), reflecting minor improvement at a significant cost, but also captured importance of absolute elements of value such as disease severity, type of medical service and quality of evidence. Non quantifiable extrinsic value components of decision were also identified and considered.
- Participants indicated that most MCDA Value Matrix components should be always considered.
- A majority of participants reported that EVIDEM would improve: understanding of intervention; access to quality of evidence; consideration of key elements of decision; transparency of the decision; and understandability of decision by stakeholders.
- Further field testing and instrument validation is needed to collaboratively advance this framework and contribute to more transparent and efficient healthcare decisionmaking.

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The EVIDEM Collaboration
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