Quantifying the Level of Knowledge of Health Risks for New Tobacco Products: Development of a Measurement Certainty Index

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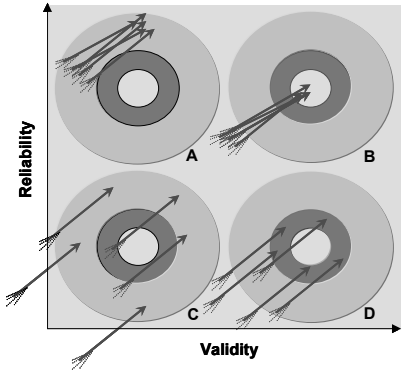
Background

Epidemiological risk assessment of potential reduced-risk tobacco products (RRTP) relates use of these products to morbidity and mortality risks. It quantifies the probability of developing a disease under specific exposure conditions. Although an epidemiological approach is the benchmark for health-risk assessment of tobacco products, it is often not applicable for risk assessment of new and innovative products where it is necessary to provide reliable predictive estimates of comparative risk prior to launch on a market. This is especially true when there is a long latency period between exposure and health outcome.

Objective

The aim of this paper is to introduce the Measurement Certainty Index (MCI) as a method based on objective rules to determine the level of certainty provided by a given dataset in a risk assessment context. The level of certainty depends on methodological aspects as well as on the underlying data; the two core dimensions of the MCI are reliability and validity.



Measurement Certainty Index (MCI)

	Measurement Precision (P)	Study Quality (Q)	Study Design (D)	Measurement Impact (I)
5	Established standardized measurement procedure, nearly completely precise	All major and most minor quality criteria fulfilled	Collection of consistent cohort and/or case control health-outcome studies	Parameter proximate to health outcome (established clinical endpoint)
4	Established standardized measurement procedure	Study conclusive; not all major quality criteria fulfilled	Health-outcome study (cohort or case-control)	Parameter associated with organic functioning (established surrogate endpoint)
3	Standardized measurement principle, literature evidence supporting reliability	Study partially conclusive; some major quality criteria fulfilled	Experiment in humans (clinical study) or observational study on biological parameters	Parameter related to organic functioning or established consistent literature evidence (established biomarker)
2	Standardized and practical measurement principle, internal evidence supporting reliability	Study partially conclusive; serious methodological flaws	Animal study	Parameter associated with pathogenetic mechanism; some literature evidence on functional relevance (new biomarker)
1	Standardized and practical measurement principle. Insufficient evidence on reliability available	Some but inconsistent evidence; replication required	Experiment in vitro	Parameter associated with pathogenetic mechanism; lack of evidence on functional relevance (new assay)
0	None of the above	None of the above	None of the above	None of the above

9-Box-Model of the Measurement Certainty Index

Reliability / Validity	0-8/ low	9-15/ medium	16-25/ high
0-8/ low	0-64 C=low	0-120	0-200
9-15/ medium	0-120	81-225 C=medium	144-375
16-25/ high	0-200	144-375	256-625 C=high

Max. C of Studies with the Highest Reliability

Experiment in vitro: C= 25x (1x3) = 75, C*= 0.12, **low**
Animal experiment: C= 25x (2x3) =150, C*= 0.24, **low**
Clinical Study: C= 25x (3x5) =375 , C*= 0.60, **medium**
Cohort/Case-Control Study:
C= 25x (4x5) =500, C*= 0.80, **high**

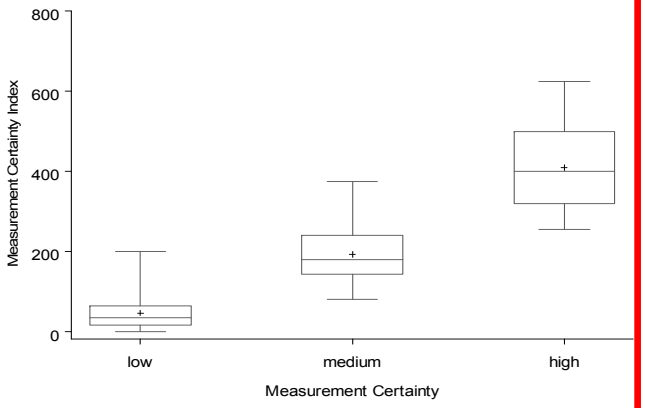
Multiple Health-Outcome Studies:
C= 25x (5x5) =625, C*= 1, **high**

Dimensions of the Measurement Certainty Index (C)

Categories of Reliability und Validity
Reliability (R):
-Study Quality (Q): 0/1 – 5
-Precision of the Measurement (P): 0/1 – 5
Validity (V):
-Study Design (D): 0/1 – 5
-Impact on Health Outcome (I): 0/1 – 5

MCI: C = R x V =D x I x Q x P = 0/1 – 625
Normalized: C*= 0-1 (0% - 100%)

Distribution of the *Measurement Certainty Index*



Conclusion

The MCI is a quantitative measure of empirical evidence weighting different criteria of reliability and validity with respect to the level of certainty of a risk assessment. **Application of such an index can help with both the retrospective assessment of existing data sets and the prospective design of assessment strategies to determine the probability of harm reduction prior to launch (and subsequent collection of epidemiological data).**

Pilot Study on Inter-Individual Variation of the MCI

We evaluated inter-individual variation for the proposed measurement certainty index in a " Proof of concept" study. In February/March 2007 internal assessors with diverse scientific backgrounds assessed different internal study reports. The results were relatively homogenous. The biggest variation was observed in the assessment of the measurement impact to health-outcome and the study quality. These results showed that training and a detailed description of the scoring system is necessary to achieve homogenous assessments.

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