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The dynamic and context specific value of a medical test – A health economic perspective

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Background & Objectives

Health technology assessments (HTAs) focus primarily on the strictly regulated pharmaceutical industry. With the introduction of the Medical Device Regulation and In-Vitro Device Regulation, the medical device industry is rapidly evolving and the importance of HTAs is increasingly being recognized, especially for medical tests. A medical test is often assessed on its cost, rather than the value it brings[1]: a formal market access process is lacking and a test should fit within current reimbursement structures. A medical test should (in line with pharmaceuticals) be assessed on the health and economic impact.

However, quantifying the full health economic impact of medical tests is challenging. Simply applying pharmaceutical-focused health economic modelling approaches will fail to capture the actual value of a medical test. The effect of a medical test is highly dynamic and context specific, which should be accounted for in the model design and the selection of the most appropriate input variables. Drawing on the review of relevant literature and recent study cases, we highlight key themes that indicate the difference between the economic evaluation of pharmaceuticals and medical tests, illustrated with a decision tree analytical model for a screening test.

Proposed definition of a medical test: "Any method for obtaining information on an individual's health status for the purpose of informing potential medical decisions in relation to a disease(s)"

Main findings

Theme	Drugs	Medical tests	Translation into model design/input
Technology effectiveness	Effectiveness of drug depending on individual's characteristics (genotype, phenotype, health status) and disease stage	Effectiveness is highly dependent on external variables including test characteristics (sensitivity and specificity)[2] and operator-level variability	Include impact of true and false test results Include "operator effect" based on inter/intra-rater variability
Epidemiology	Prevalence considered for budget-impact	Prevalence influencing the predictive values and budget-impact of a test	Include multiple, clinically relevant prevalence levels[3]
Disease characteristics	Drugs influence the pathological process and are often more effective in early disease stages	Medical tests aim to detect and quantify the pathological process. Early detection could benefit the subsequent treatment pathway.	Include disease stage specific sensitivity and specificity[4] Consider natural disease progression in addition to the disease progression under treatment to model the effect of early detection
Clinical implementation	New treatment becomes part of disease specific clinical pathway with potential interplay affecting the drug effectiveness (i.e., targeting sub-population)	New test becomes part of a test algorithm with substantial interplay affecting test effectiveness: - Test-to-test interdependencies - Test adherence	Assess the effect of test-to-test interdependency on the positive and negative predictive values[5] Include adherence as important model variable: - Clinician adherence - Medical decision adherence by patient - Adherence to follow-up tests or screening programs
Consequences	Direct and indirect effects as a result of treatment (i.e., cost and health)	Direct effects as a result of testing (i.e., cost and health) and indirect cost and effects due to subsequent treatment pathways	Include subsequent treatment pathways for true and false positives

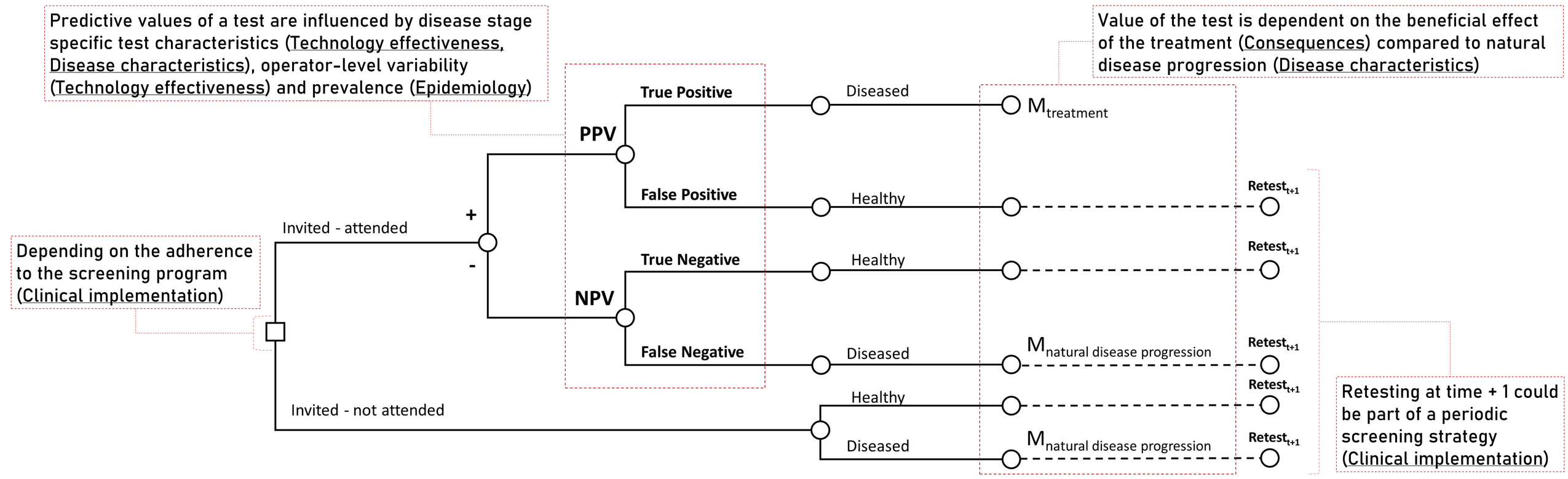

Figure 1. Example of decision tree decision analytical model for a screening test. Red arrows and boxes indicate the model parameters are affected (with the respective theme between brackets). M = Markov model; PPV = Positive Predictive Value; NPV = Negative Predictive Value.

Conclusion

The health economic assessment of medical tests should not be purely viewed as an adaptation of therapeutic assessments. Applying pharmaceutical-oriented health economic models to medical tests will fail to capture the dynamic and highly context specific value, rendering their guidance unreliable and misleading. A uniform approach towards health economic modelling of medical tests can contribute to the urgently needed evidence base to inform policy decisions and implementation on the value of medical tests in clinical practice.

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