REDUCTION OF BIAS OR A BURDEN? THE USE OF INDIVIDUAL-PATIENT MODELS FOR SUBMISSION TO HTA AUTHORITIES

ERG perspective

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Evidence review group (ERG)

- NICE TA program
  - Independent group
  - Critically assess (cost-)effectiveness evidence
  - Minority individual patient models
    - Personal experience: ~1/7
  - Output: ERG report (including analyses)
  - Time: 2 months

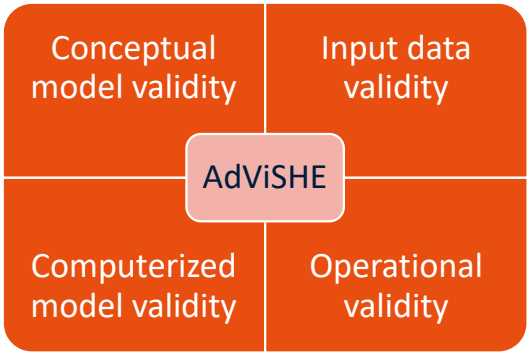
Objectives

1. Review challenges
2. Develop preliminary recommendations

Methods – Three individual patient model cases

- AAP: Abiraterone for metastatic castration-resistant prostate cancer (NICE TA387)
  - Discrete event simulation (pathway structure)
- Tica: Ticagrelor after myocardial infarction (NICE TA420)
  - Individual-patient state transition
- NB32: Naltrexone + bupropion for managing overweight and obesity (NICE TA494)
  - Discrete event simulation (according to DICE principles and structure)

Methods - AdViSHE



Conceptual model validity

- Individual-patient level approach appropriate (3/3)
  - to reflect the natural progression of disease
  - to incorporate non-linearity in the model
- Model structure overcomplicated (AAP & NB32)
  - Some phases had no clear contribution to the outcome (e.g. waiting time before starting chemotherapy)

Input data validity

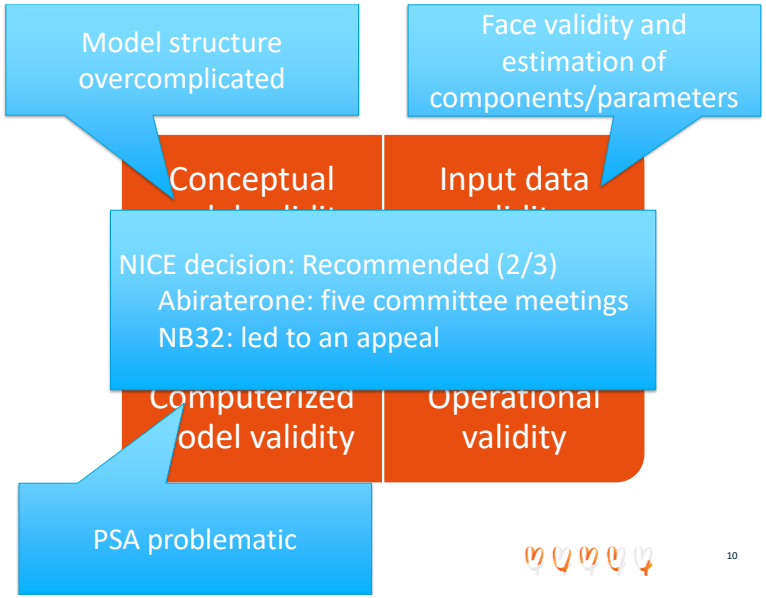
- Face validity
  - Lack of face validity for phases (AAP)
  - Not assessed for all components/input data
- Estimation of parameters
  - >15 parametric models (AAP & Tica)
    - Large amount of judgments required
    - Predefined statistical procedure not always adhered to

Computerized model validity

- Implementation of PSA problematic (Tica & NB32)
  - Based on single selected patient
  - Not feasible to perform (determ runtime: ~6 hours)
    - Internal validation challenging
- Lack of updating event (NB32)
  - Average time between BMI updates >10 years

Operational (model outcome) validity

- Operational validity diminished (3/3)
  - Input data validity
  - Computerized model validity



Recommendations (to all models ☺)

- A priori define (and consistently apply) procedures to estimate input parameters
- Validate different components/input parameters of the model separately
- Focus on transparent and efficient implementation
  - If really needed use mathematical approximations to conduct PSA

Future perspectives

- Ideally, standardized templates should be developed, validated and approved by all stakeholders
  - Ensure transparent and efficient implementation
  - Might increase familiarity and trustworthiness

Discussion statement

The use **of standardized templates that are approved by all stakeholders should be developed and used** to ensure the **transparent and efficient** implementation of the computerized model and **accelerate the external review of individual-patient models**