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Comparing Methodological and Reporting Standards for Health Economic Evaluation – *Insights from NICE TSD 15, ISPOR Good Practices, and CHEERS 2022 Guidelines*

Gaind N, Ivkovic L, Balasubramanian G, **Shajarizadeh A**, Fazeli MS

Evidinno Outcomes Research Inc., Vancouver, BC, Canada

Contact: AShajarizadeh@Evidinno.com

Disclosures

- All authors report employment with Evidinno Outcomes Research Inc. (Vancouver, BC, Canada).

Background

- Health economic (HE) evaluations play a critical role in health technology assessment (HTA) and reimbursement decision-making
- However, analysts often face challenges when navigating multiple methodological and reporting frameworks, as methodological and reporting expectations vary across jurisdictions and evaluation contexts
- This variability can create uncertainty in model development, documentation, and reporting, potentially affecting the acceptability and comparability of submissions across HTA bodies
- To support consistency, transparency, and methodological rigor, several guidance documents have been developed. These include jurisdiction-specific methodological guidance such as:
  - National Institute for Health and Care Excellence (NICE) – Technical Support Document (TSD) 15
  - International Society for Pharmacoeconomics and Outcomes Research (ISPOR) – Society for Medical Decision Making (SMDM) – Good Research Practices
  - Consolidated Health Economic Evaluation Reporting Standards (CHEERS) 2022
- Understanding the similarities and differences between these frameworks can help analysts develop and report HE models that meet expectations across multiple HTA settings

Objective

To compare methodological and reporting guidance from NICE TSD 15, ISPOR-SMDM Good Research Practices, and CHEERS 2022, and identify areas of alignment, divergence, and complementarity.

Methods

Study Design

- Structured qualitative review of three publicly available guidance frameworks was conducted:
  - NICE TSD 15 – jurisdiction-specific methodological guidance
  - ISPOR–SMDM Good Research Practices – international methodological best practices
  - CHEERS 2022 – consolidated reporting standards for economic evaluations

Selection of Methodological Domains

- Seven domains were selected based on relevance to key components of lifecycle of HE modelling as shown in Figure

Data Extraction, Analysis and Reporting

- Guidelines were systematically reviewed across seven domains to extract recommendations, validation approaches, and reporting requirements, with key similarities, differences, and gaps synthesized
- Focus remained on principles affecting credibility and reproducibility, rather than on jurisdiction-specific technical preferences

Figure: Lifecycle of HE Model

Results – Overview of Guidelines

NICE TSD 15

- Developed by the NICE Decision Support Unit
- Provides detailed, hands-on step-wise guidance on designing, implementing, and reporting patient-level simulations (discrete event simulations) for HE evaluations in technology appraisals
- Includes practical, illustrative example models, equations for calculating

ISPOR–SMDM Good Practices

- A set of expert consensus guidelines developed jointly by the ISPOR and the SMDM to standardize HE modeling
- Reports provide best practices across the full modelling lifecycle, for designing, conducting, validating, and reporting simulation models to inform healthcare decisions

CHEERS 2022

- CHEERS 2022 used ISPOR Good Practices Task Force reports as well as guidance developed by the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) network
- An updated 28-item checklist and reporting guideline designed to ensure HE evaluations are transparent, consistent, and useful for decision-making
- Expands 2013 guidance by incorporating new analytical approaches, broader intervention contexts, and greater emphasis on stakeholder and patient involvement

Results – Decision Context & Study Design

NICE TSD 15

- Emphasizes alignment between economic model and the **decision problem** defined in the HTA scope
- Stresses that the **choice of modeling framework must align with decision problem**, particularly when patient heterogeneity, complex pathways, or history-dependent events are present
- Highlights that patient characteristics influencing outcomes must be considered when selecting the modelling approach; these relationships should ideally be assessed before model construction
- States that when selecting the appropriate modelling approach there should be clearly distinguish between **patient heterogeneity, stochastic uncertainty, and parameter uncertainty** to avoid confusion

ISPOR–SMDM Good Practices

- Recommends explicit definition of the **decision problem and modeling objective** prior to model development
- Stresses clear articulation of **perspective** of analysis, **target population, interventions, outcomes** and **time horizon** to guide model design
- No explicit emphasis on handling heterogeneity and parameter uncertainty at decision context stage

CHEERS 2022

- Requires **detailed reporting** of the **study perspective, target population, comparators, time horizon, setting**, and objective's practical relevance for decision-making in policy or practice to ensure **transparency and reproducibility**
- Requires reporting of subgroup analyses and justification for subgroup definitions but not explicitly at decision context stage

Key Takeaways

- **NICE TSD 15**: Provides a strong emphasis on decision problem alignment and handling heterogeneity and uncertainty in early stages
- **ISPOR-SMDM**: Strong emphasis on structured conceptualization before model building
- **CHEERS 2022**: Requires transparent reporting of study design and decision context

Results – Model Structure & Conceptualization

NICE TSD 15

- Focuses on **appropriate model structure** for the decision problem and emphasizes clear justification of modeling approach and assumptions **underlying disease progression and treatment pathways**
- Emphasizes the **importance of conceptual models before technical implementation**, describing two types of models (Problem-oriented conceptual models and Design-oriented conceptual models); to support justification of structural assumptions in the final model; in **conjunction with clinical experts** who practice within the disease service
- Provide detailed steps to structure the patient-level simulation models

ISPOR–SMDM Good Practices

- Provides **detailed guidance on conceptual model development**, recommending systematic identification of health states, causal pathways, and structural assumptions before model implementation
- **Distinguish between conceptualizing the decision problem vs. conceptualizing the model structure**
- **Engage stakeholders** and subject experts early to ensure the model reflects real-world clinical pathways; also **provides best practices references**

CHEERS 2022

- Requires **clear reporting of the model type, structural assumptions**, **rationale for model choice**, and **graphical depiction of the model structure,** where appropriate

Key Takeaways

- **NICE TSD 15**: Provides a strong emphasis on choosing appropriate model structure and importance of conceptual model alignment
- **ISPOR-SMDM**: Strong emphasis on model conceptualization and validating with stakeholders
- **CHEERS 2022**: Requires comprehensive reporting of model structure and justification

Results – Evidence Identification & Model Inputs

NICE TSD 15

- **Does not** specify explicitly how to **identify evidence, review it, synthesize it, or choose model inputs**
- Focus remains on **implementing patient-level simulation** after model inputs have been selected
- **No guidelines for systematic evidence** review or parameter sourcing

ISPOR–SMDM Good Practices

- Recommends **systematic identification and synthesis of model inputs:**
  - Including clinical data, epidemiology, utilities, and costs
- Emphasizes **justification of data sources and parameter assumptions**

CHEERS 2022

- Requires **transparent reporting of all data inputs:**
  - Including sources, estimation methods, assumptions
- Requires **justification of parameter values** used in the analysis

Key Takeaways

- **NICE TSD 15**: Offers limited direction on evidence sourcing, focusing instead on model implementation once inputs are selected
- **ISPOR-SMDM**: Strong emphasis on systematic identification of inputs and providing justifications
- **CHEERS 2022**: Prioritizes transparent reporting of inputs, ensuring assumptions and data sources are clearly documented, but without prescribing evidence identification methods

Results – Model Implementation & Internal Verification

NICE TSD 15

- Strong emphasis on the **technical implementation and internal verification** of economic models:
  - Including checking model equations, testing calculations, debugging code
- Provides **explicit guidance on internal verification**

ISPOR–SMDM Good Practices

- Emphasizes **rigorous and transparent model implementation** as part of good scientific practice
- Recommends careful translation of conceptual models into operational models with **systematic testing of algorithms and calculations** to ensure internal consistency

CHEERS 2022

- Focuses primarily on **transparent reporting rather than methodological guidance on implementation**
- Requires clear reporting of analytical methods, computational approaches and description of modeling techniques sufficient to support interpretation of results

Key Takeaways

- **NICE TSD 15**: Strong and most explicit emphasis on technical implementation and internal verification, including code checking and calculation testing
- **ISPOR-SMDM**: Reinforces internal consistency and validity as core principles, emphasizing systematic testing during translation from concept to computation
- **CHEERS 2022**: Prioritizes reporting transparency rather than implementation guidance, requiring disclosure of analytical methods but not verification procedures

Results – Model Validation & External Consistency

NICE TSD 15

- Encourages a **pragmatic approach to model validation and external consistency** by:
  - Comparing results with **alternative data sources**
  - Seeking **independent expert review**
  - Assessing **face validity** of outputs
  - **Testing model predictions** against external evidence, where possible

ISPOR–SMDM Good Practices

- Provides the **most structured** and **comprehensive framework** for model validation and external consistency
- Recommends **face validity checks, internal validity testing, cross-validation with other models, and external validation** against empirical data

CHEERS 2022

- Prioritizes **transparent reporting** over prescriptive methods
- Requires **clear description of validation activities, justification of model credibility and consistency with external evidence**

Key Takeaways

- **NICE TSD 15**: Emphasizes proportional validation to support decision credibility rather than rigid methodological requirements
- **ISPOR-SMDM**: Offers the most explicit and methodologically detailed guidance on validation and external consistency
- **CHEERS 2022**: Focuses on transparency and justification, ensuring consistency and validation are clearly reported

Results – Uncertainty & Sensitivity Analysis

NICE TSD 15

- Recommends **explicit exploration of uncertainty** to support robust decision-making
- Recommends **exploring parameter uncertainty through probabilistic sensitivity analyses** and assessing the impact of structural assumptions on results
- Provide description to ensure sufficient simulation runs to minimize Monte Carlo error
- Mention to **clearly distinguish between patient heterogeneity, stochastic uncertainty, and parameter uncertainty** to avoid confusion

ISPOR–SMDM Good Practices

- Provides **detailed guidance** on **characterization of parameter, methodological**, and **structural uncertainty** using **sensitivity analyses** and **probabilistic modeling approaches**
- Introduced **uncertainty as a core principle for decision modelling, not optional**

CHEERS 2022

- Requires **clear reporting of uncertainty analyses conducted**, including **methods** used, **parameter values, ranges and distributions** used in uncertainty analysis, **results**, and **interpretation of their implications** for decision-making

Key Takeaways

- **NICE TSD 15**: Emphasizes proportionate, decision-focused uncertainty analysis with clear interpretation for HTA decisions
- **ISPOR-SMDM**: Offers the most detailed and rigorous methodological guidance, defining uncertainty analysis as a foundational requirement
- **CHEERS 2022**: Prioritizes transparency and interpretability, ensuring uncertainty and its implications are clearly reported

Results – Transparency & Reporting

NICE TSD 15

- Encourages **clear and transparent reporting** to facilitate HTA review by:
  - Explicitly describing **model structure, assumptions,** and **key inputs**
  - Presenting results clearly and consistently
  - Supporting **independent scrutiny** and **expert review**
  - Demonstrating face validity through transparent articulation of modeling choices

ISPOR–SMDM Good Practices

- Emphasizes **transparency as a cornerstone of good modeling practice** by recommending:
  - Transparent reporting of **model objectives, conceptual framework, and design**
  - Detailed **documentation of data sources**, **assumptions**, and **parameter values**
  - Clear reporting of **validation activities and uncertainty analyses**
  - Sufficient detail to enable reproducibility, peer review, and critical appraisal

CHEERS 2022

- Provides a **standardized and comprehensive framework for transparent reporting** by requiring:
  - Adherence to a **detailed reporting checklist** for economic evaluations
  - Clear documentation of **study design, model structure, inputs, methods, uncertainty, and limitations**
  - Explicit reporting of **assumptions and analytical choices**
  - Structured presentation to support consistent interpretation across studies

Key Takeaways

- **NICE TSD 15**: Emphasis is on enabling efficient and informed HTA appraisal rather than exhaustive reporting
- **ISPOR-SMDM**: Focuses on methodological transparency to support reproducibility and peer review
- **CHEERS 2022**: Provides the most structured and comprehensive reporting standards, serving as the primary reporting benchmark

Alignment, Differences & Complementarity Across HE Guidelines

Areas of Alignment
Shared Principles

- Clear articulation of the decision problem & study design
- Appropriate model structure
- Exploration of uncertainty
- Justification of assumptions & analytical choices

All of the frameworks emphasizes credibility and transparency

Areas of Difference
Methodological Focus

NICE TSD 15
- HTA-focused approach
- Real-world application

Model Building

ISPOR–SMDM
- Detailed methodological guidance

Conceptual Designing

CHEERS 2022
- Reporting-focused
- Does not prescribe methodology

Reporting

Complementary Roles
Working Together

NICE TSD 15
- HTA-relevant application

ISPOR–SMDM
- Rigorous methods and validation

CHEERS 2022
- Transparent reporting

Together, these frameworks produce models that are HTA-relevant, methodologically rigorous and transparent

Discussion & Conclusions

- The three frameworks demonstrate **substantial alignment across key domains of HE modelling**, including model conceptualization, evidence inputs, uncertainty analysis, and validation, with a shared emphasis on transparency, credibility, and clear definition of the decision problem
- **NICE TSD 15** adopts an HTA-focused approach, prioritizing decision relevance, early alignment with the decision problem, patient heterogeneity, proportional handling of uncertainty, and rigorous technical implementation and verification
- **ISPOR–SMDM** provides comprehensive methodological guidance, positioning uncertainty and heterogeneity as core principles across model development, analysis, and validation
- In contrast, **CHEERS 2022** serves as a standardized reporting framework, ensuring transparent and reproducible reporting of inputs, assumptions, uncertainty analyses, and subgroup results without prescribing analytical methods
- Together, these frameworks play **complementary roles** across the modelling lifecycle, and **researchers or modelers** can align early on with **NICE guidelines to ensure decision relevance, ISPOR for supporting methodological rigor**, and **CHEERS for enabling reporting clarity**
- **HTA stakeholders and reviewers** can leverage these frameworks collectively to **guide** expectations across submission, appraisal, and reporting stages
- **Integrating these approaches across the modelling lifecycle can** ultimately **strengthen the credibility**, **transparency**, and **policy relevance** of HE evaluations across diverse HTA settings

Presenter Information

Presenter Contact Information
Ali Shajarizadeh, PhD
Evidinno Outcomes Research Inc.
AShajarizadeh@Evidinno.com

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Abbreviations

CHEERS, Consolidated Health Economic Evaluation Reporting Standards

ISPOR-SMDM, International Society for Pharmacoeconomics and Outcomes Research - Society for Medical Decision Making - Good Research Practices

HE, Health Economics

HTA, Health Technology Assessment

NICE TSD 15, National Institute for Health and Care Excellence Technical Support Document 15