Structural Heterogeneity in Health Economic Modelling Approaches for HCV and HDV Diagnostics: Need for Harmonization

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KEY MESSAGE

Health economic modelling of HCV and HDV diagnostics is methodologically heterogeneous. Best-practice guidance on modelling approaches is needed to improve the quality of health economic evidence, reduce structural bias and uncertainty, and strengthen comparability of future diagnostic evaluations.

BACKGROUND

Viral hepatitis is the second deadliest communicable disease[2]. Hepatitis C Virus (HCV) and Hepatitis D Virus (HDV) are associated with chronic infection, cirrhosis, hepatocellular carcinoma, and progression to liver-related death globally[1,3].

Health economic modelling (HEM) of diagnostic tests is crucial to inform value-based screening and testing policies in HCV and HDV. However, variability in the methodological approaches used to assess their economic value has been reported in the literature.

OBJECTIVES

- **Review** recent economic models of diagnostic strategies for HCV and HDV.
- **Assess** key modelling approaches and their ability to capture economic impact.
- **Identify** opportunities to harmonize methods, reduce structural uncertainty, and recommend best practices.

METHODS

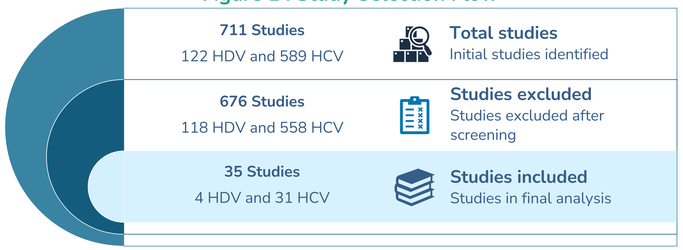
- A targeted literature search was conducted in PubMed from 1 January 2023 to 1 January 2026) to identify studies evaluating the economic value of diagnostic approaches for HCV or HDV. Detailed inclusion criteria are described in Table 1.

Table 1: PICOS Criteria for the Targeted Literature Review

Element	Inclusion Criteria
Population	Eligible subjects for testing with suspected HCV or HDV infection
Intervention	General-population or risk-based testing strategies for HCV or HDV
Comparator	General-population or risk-based testing strategies for HCV or HDV
Outcomes	Clinical and economic outcomes related to diagnostics and treatments
Study Design	Full economic evaluations based on analytical decision models

- Data were extracted on population, interventions and comparators, model perspective, economic analysis type, model structure (including health states), time horizon and cycle length, uncertainty analyses, and key modelling limitations.
- The search identified 122 HDV and 589 HCV records; 4 HDV and 31 HCV studies met the inclusion criteria, as shown in Figure 1.

Figure 1 : Study Selection Flow

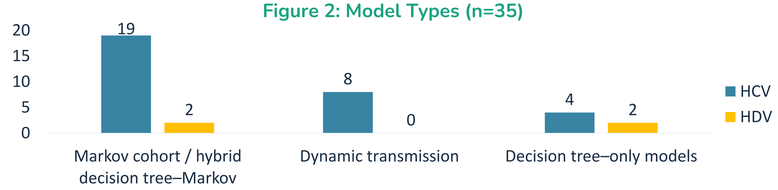


RESULTS

Key Specifications

- Studies covered 17 geographic settings, most frequently the US (6/35; 17%) and China (5/35; 14%).
- Markov cohort / hybrid decision tree-Markov models were most common (21/35; 60%), followed by dynamic transmission models (8/35; 23%), and decision tree-only models (6/35; 17%), as shown in Figure 2.
- The healthcare system perspective was most common (16/35; 46%), followed by payer/insurance (8/35; 23%), provider (4/35; 11%), and others/unspecified (7/35; 20%).
- Lifetime or long-term horizons (≥20 years) were used in 26 studies (74%), compared with 9 studies (26%) with short-term horizons. Annual cycles were most common (12/35; 34%), followed by monthly (5/35; 14%), and other/unspecified (18/35; 51%).
- Uncertainty analyses were reported in 34 studies (97%), most commonly probabilistic sensitivity analysis with other methods (28/35; 80%), and others/none (7/35; 20%).

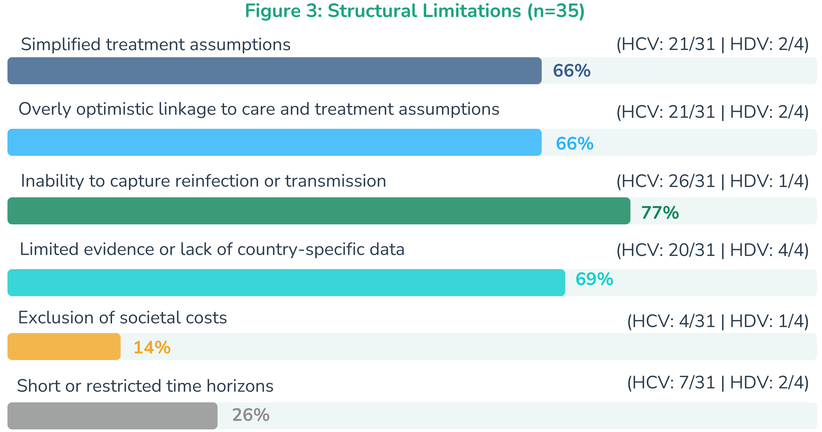
Figure 2: Model Types (n=35)



Key Structural Limitations

- Structural limitations were common across HCV and HDV models, as shown in Figure 3.
- Frequently identified issues included simplified treatment assumptions (single treatment and fixed uptake) and uncertainty in assumptions regarding the proportion of patients linked to care and treatment following diagnosis (e.g., perfect or high linkage to care, treatment completion, high treatment uptake, and no loss to follow-up).
- Models often did not fully capture reinfection and transmission, or broader societal costs. Some models were constrained by limited evidence or non-country-specific inputs, and shorter time horizons.

Figure 3: Structural Limitations (n=35)



CONCLUSIONS

The current HEM evidence for HCV and HDV diagnostic strategies is heterogeneous, with notable structural and methodological limitations. Key issues include simplified treatment pathways, assumptions regarding post-diagnosis linkage to care and treatment, and limited consideration of transmission and real-world constraints.

RECOMMENDATIONS

Based on the identified structural patterns and limitations, several recommendations for modelling practices are presented below. These considerations may help ensure that the impact of diagnostics on long-term patient outcomes is not underestimated in economic evaluations.

Identified Limitation	Recommendation
Lack of clear linkage between diagnosis and treatment pathways	To capture the long-term impact of diagnostics, models could include: • A diagnostic component that tracks active infections and their subtypes. • A treatment component that follows patients' treatment pathways after a confirmed diagnosis.
Limited or non-country-specific data	Epidemiological data on infection prevalence and transmission dynamics are key determinants of model outcomes and are highly context-specific.
Studies unable to capture reinfection and transmission dynamics	Consider dynamic transmission models to explicitly estimate the force of infection.
Short or restricted time horizons	• Use lifetime horizons. • Incorporate complete disease progression pathways (fibrosis → cirrhosis → hepatocellular carcinoma → transplant → death) to capture the full progression of the infection and disease.
Societal costs excluded in studies across both HCV and HDV	Adopt a broader analytical perspective incorporating non-healthcare costs that may be relevant to both patients and carers.

References:

1. Hepatitis D: Key facts. Geneva: World Health Organization; 2025.
2. Global hepatitis report 2024: Action for access in low- and middle-income countries. Geneva: World Health Organization; 2024.
3. Hepatitis C: Key facts. Geneva: World Health Organization; 2025.

A complete list of included studies is provided in the supplementary material.

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