APPENDIX 4: DATA ABSTRACTION FORM — CLINICAL EFFECTIVENESS, HARMS, DIAGNOSTIC TEST ACCURACY

DATA ABSTRACTION FORM: Clinical Effectiveness (Q1), Frequency of Harms (Q2), DTA (Q5)		
Reviewer		
RefID		
Author, date		
Study Characteristics		
Country setting		
Care setting		
Study design		
Study duration		
Inclusion and exclusion criteria		
Description of study population (e.g., HCV high-risk group)		
Q1 (clinical effectiveness), Q2 (harms): description of intervention; Q5 (DTA): description of index test		
Q1 (clinical effectiveness), Q2 (harms): description of comparator; Q5 (DTA): description of reference standard		
Q5 (DTA): timing of or interval between index test and reference standard administration		
Conflicts of interest (yes, no, none declared, not mentioned)		
Funding status		
Other		
Patient Characteristics		
	Intervention	**Comparator**
Number enrolled		
Number completing study		
Age (mean, SD)		
Female, n (%)		
Male, n (%)		
Other		
Clinical Effectiveness Outcomes (Q1)		
	Intervention	**Comparator**
Long-term outcomes: • Mortality due to HCV infection • Morbidity due to HCV infection • Compensated cirrhosis		

DATA ABSTRACTION FORM: Clinical Effectiveness (Q1), Frequency of Harms (Q2), DTA (Q5)		
• Decompensated cirrhosis • Hepatocellular carcinoma • Rate of liver transplantation • Quality of life		
Intermediate outcomes: • HCV transmission • Virologic response rates (RVR, eRVR, EVR, SVR12, SVR24) • Behavioural changes to improve health outcomes • Histological improvements		
Comments		
Frequency of Harms Outcomes (Q2)		
	Intervention	**Comparator**
• Overdiagnosis • Overtreatment • False positives • False negatives • Harms of follow-up tests (including biopsy) • Effect on insurance premiums • Labelling • Abuse or violence • Anxiety • Partner discord		
Comments		
DTA Outcomes (Q5)		
	Index Test	**Reference Standard**
• Sensitivity • Specificity • Positive predictive value • Negative predictive value • Positive likelihood ratio • Negative likelihood ratio • Diagnostic odds ratio • AUC • Detection rate		

DATA ABSTRACTION FORM: Clinical Effectiveness (Q1), Frequency of Harms (Q2), DTA (Q5)		
• Number needed to screen to detect 1 case		
Comments		

AUC = area under the receiver-operating characteristic curve; DTA = diagnostic test accuracy; eRVR = extended rapid virologic response; EVR = early virologic response; HCV = hepatitis C virus; n = number; PCR = polymerase chain reaction; RVR = rapid virologic response; SD = standard deviation; SVR12 = sustained virologic response at 12 weeks after treatment; SVR24 = sustained virologic response at 24 weeks after treatment.