

M & V Causality Assessment Scale

I. Temporal Relationship Between Drug Intake and the Onset of Clinical Picture	
A. Time from drug intake until the onset of the first clinical or laboratory manifestations	Score
a. 4 days to 8 weeks (or less than 4 days in cases of reexposure)	3
b. Less than 4 days or more than 8 weeks	1
B. Time from withdrawal of the drug until the onset of manifestations	
a. 0 to 7 days	3
b. 8 to 15 days	0
c. More than 15 days*	-3
C. Time from withdrawal of the drug until normalization of laboratory values**	
a. Less than 6 months (cholestatic or mixed patterns) or 2 months (hepatocellular)	3
b. More than 6 months (cholestatic or mixed patterns) or 2 months (hepatocellular)	0
II. Exclusion of Alternative Causes	
Viral hepatitis (HAV, HBV, HCV, CMV, EBV), alcoholic liver disease, biliary tree obstruction, pre-existing liver disease, other (pregnancy, acute hypotension)***	
<input type="radio"/> Complete exclusion	3
<input type="radio"/> Partial exclusion	0
<input type="radio"/> Possible alternative cause detected	-1
<input type="radio"/> Probable alternative cause detected	-3
III. Extrahepatic Manifestations	
Rash, fever, arthralgias, eosinophilia (>6%), cytopenia	
<input type="radio"/> 4 or more	3
<input type="radio"/> 2 or 3	2
<input type="radio"/> 1	1
<input type="radio"/> None	0
IV. Intentional or Accidental Reexposure to the Drug	
<input type="radio"/> Positive rechallenge test	3
<input type="radio"/> Negative or absent rechallenge test	0
V. Previous Report in the Literature of Cases of DILI Associated with Drug	
<input type="radio"/> Yes	2
<input type="radio"/> No (drugs marketed for up to 5 years)	0
<input type="radio"/> No (drugs marketed for more than 5 years)	-3
TOTAL (add the 7 scores)	

*Except cases of prolonged persistence of the drug in the body after drug withdrawal (e.g. Amiodarone)

**Normalization = decrease to values below two times the upper limit of normal values

***Using exclusion criteria considered appropriate in each case

Modified from: Maria VAJ, Victorino RMM. Development and validation of a clinical scale for the diagnosis of drug-induced hepatitis. Hepatology 1997; 26: 664-9.