

How to prepare a case narrative ?

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Important element in reporting cases of DILI

- The data elements should include all the information needed for making a diagnosis and to assess causality in suspected drug-induced liver injury.
- Without this information, it may be impossible to tell whether or DILI is the cause of the liver injury.

History most important

- Did the intake of the implicated drug PRECEDE the “symptoms of liver injury”?
- Medicines might be taken to relieve first symptoms of “hepatitis”
- Latency period different for different drugs

Causality assessment-most important issues

- (1) Time from the start of treatment
- (2) Course after dechallenge
- (3) Exclusion of other causes
- (4) Rechallenge-numerous well reported cases with positive rechallenge

Essential information

When did intake of drug start?

What were the doses?

When was the treatment discontinued?

What happened with symptoms and liver tests when treatment was stopped?

Important issues

- In case reports and/or series, lack of elements may be because they were not performed or not available.
- The scientific value of the report depends on how well you can defend you against the criticism!

Exclusion of other causes

- Hepatitis A, B, C, CMV, EBV, Herpes, HEV
- ANA, SMA, IgG
- Alcoholic liver disease
- Hypotension
- Liver ultrasound (doppler), MRCP in cholestasis

Other investigations depend on the clinical context (cholestatic reactions others than ALF)

Causality assessment

- The most commonly used instrument is RUCAM (Roussel Uclaf Causality Assessment method)
- Takes into consideration:
 - Duration of drug therapy
 - Type of liver injury
 - Development of liver tests after cessation of drug
 - Exclusion of competing etiologies
 - Documentation of the hepatotoxicity of the drug
 - Documented rechallenge



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on Drug-Induced Liver Injury

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LiverTox provides up-to-date, accurate, and easily accessed information on the diagnosis, cause, frequency, patterns, and management of liver injury attributable to prescription and nonprescription medications and herbals. The LiverTox Website provides a comprehensive resource for physicians and their patients, and for clinical academicians and researchers who specialize in idiosyncratic drug-induced [hepatotoxicity](#). For complete information, see [About](#)

Björnsson Es, Hoofnagle JH. Categorization of drugs implicated in causing liver injury: critical assessment based upon published case reports.

Hepatology 2016; 51: 594-600.

- Category A: Drugs with > 50 cases reports
- Category B: Drugs with <50 and >12
- Category C: Drugs with >12 and <4
- Category D: 1-3 cases reported
- Category E: No convincing reports

Pro-Euro DILI template

CASE	
DILI Type	
Exposure	
Drug	
Time from drug intake until reaction	
Risk factors_Alcohol	
Risk factors_Age>55 y	
Course of reaction	
Concomitant therapy	
Exclusion of non-drug	
Previous information on hepatotoxicity	
Response to re-administration	
Total score	
Causality	

Conclusions

- Important elements need to be taken into consideration such duration of therapy, effects of dechallenge, exclusion of competing etiologies and knowledge of the known hepatotoxicity of the implicated agent
- Clinical judgment and experience in hepatotology can though not be overestimated