

WHO国际药物监测中心对可疑不良反应的因果关系如何分级？
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WHO国际药物监测中心将可疑不良反应的因果关系分成如下级别：1.certain 2.probable/likely 3.possible 4.unlikely 5.conditional/unclassified 6.unassessible/unclassifiable 实际上，主要是4级，即肯定（certain），很可能（probable/likely），可能（possible），不太可能（unlikely）。conditional/unclassified

和unassessible/unclassifiable均不属于因果关系的正式术语，前者是指报告资料有待作进一步的补充和评价，然后再决定其级别；后者是由于报告资料不考试，大网站收集足或存在矛盾而无法评价。WHO因果关系评价的具体内容如下：

CERTAIN A clinical event，including laboratory test abnormality，occurring in a plausible time relationship to drug administration，and which cannot be explained by concurrent disease or

chemicals. The response to withdrawal of the drug（dechallenge）should be clinically plausible. The event must be definitive

pharmacologically or phenomenological，using a satisfactory

rechallenge procedure if necessary. PROBABLE/LIKELY A clinical event，including laboratory test abnormality，with a reasonable time sequence to administration of the drug，unlikely to

concurrent disease or other drugs or chemicals，and which follows a clinically reasonable response in withdrawal（dechallenge）。

Rechallenge information is not required to fulfil this definition.

POSSIBLE A clinical event , including laboratory test abnormality , with a reasonable time sequence to administration of the drug , but which could also be explained by concurrent disease or other drugs or chemicals. Information on drug withdrawal may be lacking or unclear. **UNLIKELY** A clinical event , including laboratory test abnormality , with a temporal relationship to drug administration which makes a causal relationship improbable , and in which other drugs , chemicals or underlying disease provide plausible explanations. **CONDITIONAL/UNCLASSIFIED** A clinical event , including laboratory test abnormality , reported as an adverse reaction , about which more data is essential for a proper assessment or the additional data are under examination.

UNASSESSIBLE/UNCLASSIFIABLE A report suggesting an adverse reaction which cannot be judged because information is insufficient or contradictory , and which cannot be supplemented or verified."

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