

 中文标题 检索 跨刊检索

国内外不良反应因果判断原则及评价方法解读

投稿时间: 2012-07-15 责任编辑: [点此下载全文](#)

引用本文: 魏戊,谢雁鸣.国内外不良反应因果判断原则及评价方法解读[J].中国中药杂志,2012,37(18):2744.

DOI: 10.4268/cjmm.20121819

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基金项目:科技部“重大新药创制”科技重大专项(2009ZX09502-030)“中药上市后评价关键技术研究”

中文摘要:不良反应因果判断是药物警戒研究的通用程序,目前尚无统一的判断标准与分类标准。时间性、一致性、特异性、反应程度是不良反应因果判断应遵循的基本原则。不良反应因果判断评价方法众多,大致可分为标准化算法、专家判断法、贝叶斯法。部分评价方法分类标准之问定义模糊不清,病例资料的不完整,评价者临床应用时的不同理解均是造成评价结果不同的重要原因。几乎每一种方法均对不良反应因果判断进行分级,主要为5级分类,但评级方法间的基本原理、评价标准、特异度与敏感度有所差异。每一种方法均有其优缺点,尚无一标准化方法适用于所有的不良反应评价。

中文关键词:不良反应 个例评价 因果判断原则 因果评价方法

Principle of adverse drug reaction causality judgement and interpretation of causality assessment method both in China and abroad

Abstract: Adverse drug reaction(ADR) causality judgement is a routine procedure in pharmacovigilance, no unified judgement standard and categories standard are established. Temporal relations, consistency, specificity, intensity of reaction are the basic principle of ADR causality judgement we should abide by. There are many ADR causality assessment methods, which classifies standard algorithms, expert judgement, bayesian approaches. The implicit definitions of some categories standard, incomplete information from case reports coupled with vast differences in the application of clinical judgements are the major problems facing ADR evaluation. Almost every kind of method shares certain common feature, that is, causal relationship of ADR is classified about five categories. However, causality assessment methods differ in basic principle, evaluation standard, specificity and sensitivity. There are some advantages and disadvantages among methods, but no causality assessment method can be applied to all ADR evaluation to date.

Keywords: adverse drug reaction case-by-case evaluation principle of causality judgement causality assessment method

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