含毒性饮片口服中成药说明书的临床不适用性评价体系构建与应用Δ

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摘　要　目的　构建含毒性饮片口服中成药说明书的临床不适用性评价体系，为该类药品说明书的修订完善和新药说明书制定提供参考。**方法**　通过收集与说明书注册、修订相关的政策文件及文献等资料，确定初始指标框架；对25名专家进行两轮德尔菲函询，完善与优化指标体系；通过层次分析法构建判断矩阵获得指标权重。将指标综合权重换算成百分制，对本课题组所在医疗机构的11份含毒性饮片口服中成药说明书进行评价。**结果**　两轮函询的平均问卷回收率为96%，专家权威系数分别为0.87、0.88，肯德尔协调系数均有统计学意义（$P<0.001$）。最终构建的评价体系涵盖4项一级指标（毒性标识缺陷、剂量信息缺陷、风险警示缺陷和信息指导缺陷）和24项二级指标（如未在【警示语】中对毒性饮片进行标注、未标明全部饮片组成、无用药疗程规定等）。11份口服中成药说明书的总评分范围为15.50～50.87分，主要临床不适用性问题包括无用药疗程规定及存在“十八反、十九畏”的饮片未在【注意事项】等项目进行警示等。**结论**　构建的指标体系可满足含毒性饮片口服中成药说明书临床不适用性的评价要求。应用该指标体系评价的说明书均存在一定的临床适用性缺陷，药品生产企业应根据政策要求和临床需求对说明书进行修订。

关键词　毒性饮片；口服中成药；药品说明书；指标体系；德尔菲法；层次分析法

Construction and application of clinical inapplicability evaluation system for instructions of oral Chinese patent medicines containing toxic decoction pieces

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ABSTRACT　OBJECTIVE To construct a clinical inapplicability evaluation system for the instructions of oral Chinese patent medicines containing toxic decoction pieces, so as to provide references for the revision and improvement of such drug instructions and the formulation of instructions for new drugs. **METHODS** The initial indicator framework was determined based on policy documents and literature related to instruction registration and revision. Two rounds of Delphi consultation were conducted among 25 experts to refine and optimize the indicator system. The analytic hierarchy process was employed to construct judgment matrices and obtain indicator weights. The comprehensive weights were converted into a 100-point scale to evaluate 11 instructions of oral Chinese patent medicines containing toxic decoction pieces from the medical institution of the research team. **RESULTS** The average questionnaire recovery rate of the two rounds of consultation was 96%. The expert authority coefficients were 0.87 and 0.88, respectively, and the Kendall's W was statistically significant ($P<0.001$). The final evaluation system comprised 4 first-level indicators (defect of toxicity identification, defect of dosage information, defect of risk warning, and defect of information guidance) and 24 second-level indicators (e.g., failure to label toxic decoction pieces in【warnings】, failure to indicate all decoction piece compositions, absence of medication course specifications, etc.). The total scores of the 11 oral Chinese patent medicine instructions ranged from 15.50 to 50.87 points. The main clinical inapplicability issues included the absence of medication course specifications and the failure to provide warnings in items such as【precautions】for decoction pieces involving the "eighteen incompatibilities and nineteen mutual antagonisms". **CONCLUSIONS** The constructed indicator system can meet the requirements for evaluating the clinical inapplicability of instructions for oral Chinese patent medicines

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