中国药物经济学评价指南
China Guidelines for Pharmacoeconomic Evaluations

（第八稿）

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Summary of the Draft China Guidelines for Pharmacoeconomic Evaluations (V8)

Note: The China Society for Pharmacoeconomics and Outcomes Research (Chinese Pharmaceutical Association Pharmacoeconomic Committee) developed a China Guidelines for Pharmacoeconomic Evaluations (V8) (written in Chinese only). This draft document was only available to the ISPOR Asia Consortium Working Committee for comment December 2010 and is not available to the public. A summary of the draft China PE Guidelines (V8) developed by the ISPOR Asia Consortium is given below. The final China PE Guidelines (in Chinese) will be available early 2011. The English version of the China PE Guidelines will be available early 2012. This summary given below is not to be used as an official document.

Executive Summary (Executive Summary)

The "Guide" includes an introduction, instructions, executive summary, text, references and appendices six parts. Among them, the body of pharmacoeconomic evaluation in accordance with procedures followed by the main research writing, consists of nine parts guide.

Guide 1 for study guide questions (Study Question)

Pharmacoeconomic evaluation of the first step is to clear research questions, including research background, research products (intervention), research perspective, the study population and research purposes and so on. Background should provide the following information: epidemiological profile of disease-related, the main means of intervention and the efficacy of drug intervention in domestic and foreign related economic evaluation of the status quo (the basic conclusions and remaining problems), and the value of this research (the need for major or innovation) and so on. For the study, interventions and control measures should be as detailed as possible description, including the types, specifications, quantity, treatment, combined medication and treatment background information. The choice of the control measures recommended indications the same conventional treatment or standard treatment. If the drugs are new therapeutic category, then select the closest indication of drug as a control. Researchers should study and report on targeted research perspective, and always consistent. Research needs specific target groups of drugs is recommended in patients with type description of epidemiological characteristics, such as the type and severity of disease, with or without other complications or risk factors, age, gender, socio-economic characteristics. Evaluation is usually carried out in the general population, may also need to be in the sub-group level.

Guide 2 for study design (Study Design)

According to the data source can be divided into Pharmacoeconomic evaluation of prospective studies, retrospective cohort study, mixed research design (clinical trial or a combination of retrospective data collection under actual conditions) and the secondary literature. Among them, the prospective studies and randomized clinical intervention, including research and prospective observational study. By analysis, economic evaluation of drugs can be divided into the point estimate method, modeling, and measurement analysis. Prospective observational study is the first choice for economic evaluation of drug design, but also can be used around the clinical stage / parallel clinical trial research and modeling studies, retrospective cohort study is also acceptable, mixed research design and the secondary literature. The study design or model to estimate the key assumptions made, researchers should fully explain the basis and reasonableness. In general, the drug economy evaluation of sample size should be slightly larger than the sample size of randomized clinical trials, pharmacoeconomics recommended formula for estimating the test sample. Description of study design should be based on time and. In general, the sample observation period should be long enough to get the major costs incurred interventions and outputs.
Guide 3 for cost (Cost)

Cost estimates include the cost of the main framework for the recognition, measurement cost, discount analysis, and uncertainty analysis. Pharmacoeconomic cost includes direct costs, indirect costs and hidden costs. Direct costs include direct medical costs and another direct non-medical costs. Cost recognition, the proposal includes all direct medical costs, but also include direct non-medical costs and indirect costs, hidden costs can be flexible. Cost determined by measuring range of needs and the angle consistent. Measurement, the proposed multi survival after treatment generated during the costs associated with this intervention include the cost of measuring range, excluding costs unrelated to treatment; in measuring adverse drug reactions (ADRs) costs, the proposed measure to avoid or to monitor ADRs ADRs arising after the occurrence of costs and for other costs arising from medical intervention. If the product has a suggested price of the use of medical insurance payments, if the product is not listed, recommended recommended price of manufacturer. On the time cost (including paid work time, non-paid work time and leisure time), the proposed use of human capital approach, that is calculated with reference to the average market wage for their time costs. Cost describes the recommended amount of resource consumption and unit price in the form of reports, not the total cost. Proposed one-year Treasury rate or the national guidance on discounted rates, the proposed scope of sensitivity analysis of the discount rate set at between 0-8%. Recommended the same discount rate and cost estimate of the health benefits and sensitivity analysis.

Guide 4 for health outcomes (Health Outcomes)

Performance metrics, the reality in a non-test under the conditions of treatment outcomes. Pharmacoeconomic evaluation of priority use the actual performance metrics. When the test conditions can be indicators of clinical efficacy of the proposed indicators will be adjusted effective performance metrics. If you cannot adjust, you can still use outcome measures, but under the experimental conditions should be stated and the actual use state of the possible differences and bias, and sensitivity analysis. Economic evaluation of drugs proposed as far as possible endpoints. If there are difficulties in access to end points can also be used in the middle of the key indicators, intermediate indicators and the need to explain the correlation between endpoints. Effectiveness indicators are generally used quality-adjusted life years (QALY) or quality-adjusted life expectancy (QALE). Report on the effectiveness of the indicators, the need to separately report the first survival time (life years or life expectancy) and health utility values, and then reporting QALY or QALE. Measuring effectiveness, when the target population for the healthy population, we recommend using a common measurement scale utility value. When the target population for the sick people, and there is value for measuring the effectiveness of the disease types of scales, it is recommended to use disease-specific utility value of the measurement scale. When the target population for the sick people, but there is no value for the effectiveness of the disease types of measurement scale, it is recommended to use common utility value of the measurement scale. Utility value of the measurement tools Health recommends the following major categories: direct measurement of the standard gamble method (SG), time trade-off method (TTO), visual analog scale method (VAS); indirect measurement of the European five-dimensional health questionnaire (EQ-5D), six-dimensional health measurement scale (SF-6D), health utility index (HUI) and the Health Quality of Life Scale (QWB) and so on. For the indirect measurement tools, the use of preferences based on his country's points into the crowd to be very cautious table. When using the EQ-5D suggested the utility of the United Kingdom or Japan, conversion tables, when using the SF-6D recommend the use of the United Kingdom or China, Hong Kong's utility value conversion table, while the sensitivity analysis. Efficiency unit of currency is the quantitative measurement of health outcomes, including direct benefits, indirect benefits and intangible
benefits of three parts. Recommend the use of human capital approach (HCA) and the Willingness to Pay Act (WTP) on the indirect benefits and intangible benefits were measured. Willingness to pay by law, with particular note of the assumptions, questioning approach, measuring the range of benefits, the question of language expression and so on.

**Guide 5 for the analysis (Analysis Method)**

Pharmacoeconomic analysis methods include cost analysis (CA), the minimum cost analysis (CMA), cost-effectiveness analysis (CEA), cost-utility analysis (CUA) and cost benefit analysis (CBA). When conditions permit, the proposed priority CUA, or CBA, can also be used CEA, CMA or CA, but it should explain its reasons. Researchers could also use two or more evaluation methods, or a way to evaluate other methods of combination. Model method using economic evaluation of drugs, researchers should model all kinds of causality, using extrapolation, the model scope, structure and data, the interpretation of the assumptions and explanations. The introduction of the model structure to express clearly, the proposed structure with the model on display. Researchers should systematically collect data used in the model, detailed model, all parameters of the source and the basis. For important assumptions, uncertainty analysis should be conducted. Econometric Analysis of the model can be used or the total cost of the health effects of parameter estimation and output factors, you can also use their estimated ICER, and get its associated interval estimates.

**Guide 6 for the difference and uncertainty (Variability and Uncertainty)**

Study the source of differences may be regional differences in background and treatment, treatment of diversity and differences between different patient subgroups. Sensitivity or scenario analysis can deal with the difference treatment, patients can be divided into smaller sub-group dealing with the homogeneity of the heterogeneity of patients. The uncertainty of the study mainly from two aspects of data and evaluation process, including sampling error, data collection, methods, assumptions and so on. Bootstrap method and Fieller recommended guidelines for calculating incremental cost effectiveness ratio of Ge 95% confidence interval sampling error handling, treatment is recommended sensitivity analysis assumptions and the uncertainty caused by data collection.

**Guide 7 as fair (Equity)**

The purpose of economic evaluation is to improve the efficiency of medical resource use and fairness, so when conditions permit, should consider the fairness of the evaluation results. Research methods in elucidating the fairness of the existing assumptions, sensitivity analysis should be appropriate to illustrate the fairness assumptions affect the results. If the information is complete, the main beneficiaries should be identified and disadvantages of sub-sub-group of the fairness of the relevant characteristics of groups, such as age, gender, race, region, socio-economic characteristics or health status of group identities. When the different subgroups benefited in varying degrees, and can selectively intervene in different sub-groups, you should report the cost of each sub-group - performance information.

**Guide 8 for extrapolation (Generalizability)**

Researchers need to prove from all countries other than China, the cost effectiveness and applicability of evaluation results in the country, and according to China's medical environment to validate the data.
If you need to adjust the data in the medical environment in China, you should describe the methods used and demonstrate its applicability.

Guide 9 for budget impact analysis guidelines (Budget Impact Analysis)

First 3-5 years of disease to predict the market size (total number of patients), disease prevalence and incidence rate of change, consider the natural factors (such as birth and death rates) and migration factors (such as immigration and migration) and so on. Secondly, two kinds of market conditions should be clear that the drugs not included in the directory of the market state reimbursement and drug reimbursement directory included in the market state. Two cases should take into account the expected changes in the market, including the listing of other new interventions, drugs removed from the market of similar and alternative treatment methods. Market capacity used in the study should come from a third party or government agency and investigation of health statistics, market share should be derived from this disease have been published or industry authority of the forecast, according to health care institutions can be assumed or third-party database. Drug prices can be obtained through various channels, not recommended discount and inflation included in the budget impact analysis. To evaluate the uncertainty caused by the assumptions, should be factors in the analysis of single or multi-factor sensitivity analysis to evaluate the model by changing parameters of one or more of the impact on the simulation results. The following parameters should be considered as a sensitivity analysis of the test object: both cases the drug market share; the market distribution of the two cases; new drugs from the competition to seize market share drugs; directory to be included in the drug reimbursement price.

Appendix

Appendix of this guide includes two parts: Pharmacoeconomic evaluation of Appendix 1 to the standard reporting format, Appendix 2, glossary of terms for drug economics.