in regard to public funding criteria. The following main types of restrictions were identified either because of the target public funding parameter affected or because of the reasoning: a) "because of lack of evidence"; b) "because it is the only effective treatment" (rule of rescue); c) "to improve efficacy"; d) "to improve efficacy-safety relationship"; e) "to improve cost-effectiveness"; f) "to limit budget impact". CONCLUSIONS: The limiting conditions should be perceived as tools to enable positive public funding decision when the current scope of financing is just behind the hypothetical threshold. Exploring and further analyzing methods and aspects concerning generating public funding restrictions is important for: 1) decision makers, so they be more aware of the consequences and impact of their decisions on the people/patients they serve, and could make more transparent decisions; 2) HTA analysts, to focus their interest on the subsequent use of HTAs to help decision makers explore all potential options to minimally fund projects; 3) Market Access managers, so they used the identified mechanisms and methods to better foresee the public funding decisions concerning their drugs.

**OBJECTIVES:** Since economic evaluation has been enforced to be considered for new drug reimbursement decisions in 2007, the structure and constituents of decision body, "Drug Reimbursement Evaluation Committee", as well as the pharmacoeconomics reporting have been modified by Health Insurance Review Assessment Board and were modified in Korea. These changes reflect deficiency in systematic adoption of economic evaluation and disinterest among stakeholders. Recently, the fair and reasonable process and criteria have been highly emphasized at every level of policy administration and clinical development with concerns of increasing public demands for the public practices and political acceptance of the importance of public accountability. Now, imminent practical task is how to connect the conceptual framework and feasible practice for publicly accountable drug reimbursement decisions. METHODS: Using data from a qualitative study of public accountability published in the European Governance Paper, we analyzed qualifications of drug reimbursement policy as "accountable" and appraised the public accountability. We also performed interviews with ten key stakeholders from democratic, constitutional and learning perspectives. And then, recent reimbursement decision papers on two new drugs were analyzed to examine concrete shape of the accountability frameworks. RESULTS: Following scope of improvement would be suggested: (1) clear and reasonable standards for coverage decision; (2) relevance of the standards to population's health needs and health equity impacts; (3) disclosure of data used for decision, procedure and results to public; and (4) the procurement of due process of challenging decisions. CONCLUSIONS: Given value pluralism in democratic liberalism, it is matter of course that formal or procedural justice is given prominence. Conclusively, an explicit discussion for formal criteria and procedure is the essential component of the ongoing policy process. Accountable drug policy administration is impossible without accountable policy process which is impossible without transparent criteria for all decision stages.

**ASSESSING PUBLIC ACCOUNTABILITY OF KOREAN DRUG REIMBURSEMENT DECISION PROCESS**

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**OBJECTIVES:** We examined the effect of economic evaluation on health policy decisions in Korea. Our study was a follow up of the previous study conducted in Korea. These changes reflect the deficiency in systematic adoption of economic evaluation and disinterest among stakeholders. Recently, the fair and reasonable process and criteria have been highly emphasized at every level of policy administration and clinical development with concerns of increasing public demands for the public practices and political acceptance of the importance of public accountability. Now, imminent practical task is how to connect the conceptual framework and feasible practice for publicly accountable drug reimbursement decisions. METHODS: Using data from a qualitative study of public accountability published published in the European Governance Paper, we analyzed qualifications of drug reimbursement policy as "accountable" and appraised the public accountability. We also performed interviews with ten key stakeholders from democratic, constitutional and learning perspectives. And then, recent reimbursement decision papers on two new drugs were analyzed to examine concrete shape of the accountability frameworks. RESULTS: Following scope of improvement would be suggested: (1) clear and reasonable standards for coverage decision; (2) relevance of the standards to population's health needs and health equity impacts; (3) disclosure of data used for decision, procedure and results to public; and (4) the procurement of due process of challenging decisions. CONCLUSIONS: Given value pluralism in democratic liberalism, it is matter of course that formal or procedural justice is given prominence. Conclusively, an explicit discussion for formal criteria and procedure is the essential component of the ongoing policy process. Accountable drug policy administration is impossible without accountable policy process which is impossible without transparent criteria for all decision stages.

**DEVELOPMENT SCHEMES: PRACTICAL EXPERIENCES IN SEVERAL WESTERN JURISDICTIONS**

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**BACKGROUND:** The Dutch reimbursement procedure for expensive hospital drugs requires the submission of a baseline cost-effectiveness analysis together with a research plan for the period of temporary reimbursement in order to estimate the real-life cost-effectiveness after 4 years. In this situation, a Value-of-Information (VOI) analysis might identify the critical parameters that need to be studied in such outcome study. OBJECTIVES: To identify when a VOI analysis alongside sensitivity analysis is warranted, and when such VOI analysis will not impact the decision making process. METHODS: We used a hypothetical Markov model with three groups of parameters: costs, utilities and transition probabilities. We studied different configurations of input parameters, forcing the outcomes into different directions on the CE-plane. For each input configuration we performed a multivariate sensitivity analysis (MSA) and a probabilistic sensitivity analysis (PSA). In the MSA, sensitivity was measured as percentage change from baseline INSM. Additionally, we analyzed the expected value of perfect information (EVPI) and the expected value of partial perfect information (EVVPI). Analyses were done for a range of threshold ICERs. RESULTS: For each situation it was possible to predict the shape (but not the absolute value) of the EVPI curve based on the PSA findings. When the PSA plot covered both northern quadrants, MSA and EVVPI came to the same ranking of the groups of parameters. When the outcomes were in the northeast quadrant the ranking differed: MSA indicated costs as most important parameters, for EVVPI this was utilities. When outcomes were in the southwest quadrant, costs were most important in MSA and EVVPI. For both other quadrants, MSA and EVVPI were close to each other. CONCLUSIONS: Whether MSA and EVVPI come to a different priority setting for future research depends both on the threshold ICER and on the location of results on the CE-plane.

**STAKEHOLDER PERCEPTIONS OF CLINICAL DRUG TRIALS**

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**OBJECTIVES:** To identify stakeholder perceptions of sponsored clinical trials in a publically funded New Zealand hospital, and then to identify the similarities and differences in perceptions across these stakeholder groups. The stakeholders are: 1) participants involved in clinical trials; 2) management and the multidisciplinary team; 3) the larger South Auckland community; 4) government and decision makers; and 5) the pharmaceutical industry. METHODS: We used purposive sampling to select representatives of the stakeholder groups, which provides 109 respondents. We gather data using focus groups, in-depth interviews, telephone interviews and surveys. Many of the respondents represent more than one stakeholder group. While there is consensus across the stakeholders on some costs and benefits such as developing safe medicines and collecting useful data there are marked differences in perceptions in other areas, such as those indicated below. Most stakeholders perceive the risk of adverse reactions as the greatest cost to trial participants but the participants themselves do not regard this as significant. Pharmaceutical representatives, management and the multidisciplinary team feel that gaining access to new medicines motivates trial participants to participate in a trial. Trial participants feel that the support they receive from the multidisciplinary team is more important to them than the medication. Most researchers and staff believe trial involvement increases their job satisfaction, motivation, knowledge and skills while a few have concerns that sponsor control leads to the loss of their flexibility and independence. Generally there is a perception that New Zealand based clinical trials assist in the process of obtaining registration and subsidization of new drugs in New Zealand. However, this perception may be erroneous as location of trials is apparently not considered in the drug registration process. CONCLUSIONS: We find that most stakeholders are satisfied with the conduct of clinical trials in New Zealand and they believe the benefits outweigh the costs.