states representing severe, moderate and mild ED. The ED-specific values from Scale 1 are transferred onto a second “dead to perfect health” scale. Fifteen subjects with ED and 25 adults without ED participated in pilot testing the instrument. The 15 ED subjects participated in additional domain ranking and content relevance exercises, and were asked to suggest additional domains they considered relevant to the HRQL impact of ED. Minor modifications were made, and the resultant instrument was implemented in a clinical trial of 160 ED subjects. Full validation analysis of feasibility, reliability, responsiveness and validity is ongoing.

RESULTS: Initial analysis demonstrates the instrument is feasible, with only 13% of subjects making errors in the most complex step (Scale 1). Preliminary evidence suggests that the instrument is valid, measuring what it claims to measure, with one subject suggesting the addition of one domain. One domain deletion was suggested. 94% of subjects felt the domains and levels appropriately assessed the impact of ED on HRQL. The marker states (mild, moderate, and severe) were correctly ranked and fully understood by 100% of subjects. Responsiveness is currently being assessed.

CONCLUSIONS: A HRQL instrument, for use in ED subjects, which combines disease-specific and preference-based approaches, has been successfully developed, pilot tested and is currently undergoing validation analysis.

VALIDATION OF VAGINAL CONTRACEPTION ACCEPTABILITY QUESTIONNAIRE
Novak A1, Aberz L2, de la Loge C3
1NV Organon, Oss, Netherlands; 2Mapi Values, Cheshire, UK; 3Mapi Values, Lyon, France

OBJECTIVE: To validate an acceptability questionnaire for a vaginal ring contraceptive.

METHODS: A 21-item questionnaire was developed covering: ease of use (ring/package); clarity of instructions; sexual comfort; menstruation; compliance, and satisfaction. A total of 2393 women completed the questionnaire after 3, 6 and 12 months of using a vaginal contraceptive (NuvaRing®, Organon, Oss, The Netherlands). The robustness and predictive value of the questionnaire were assessed using cycle three data. The quality of completed questionnaires, item content analysis, construct validity, internal consistency reliability, known-group validity, and predictive value were evaluated.

RESULTS: Excluding non-ordinal items, on average 0.6% of data was missing. Principle component analysis of 15 ordinal items indicated that linked domains gave consistent results. Hence, ‘ease of package use’ and ‘clarity of instructions’ were combined. Item-convergent validity, the degree of correlation between two measures of the same construct, was excellent for ‘ease of use’ and ‘satisfaction’, moderate for ‘clarity of instructions’ and ‘sexual comfort’ and poor for ‘menstruation.’ Item-discriminant validity, the uniqueness of information, was excellent for all domains. Women without adverse events and completers responded to the questionnaire most positively. The likelihood of early discontinuation was linked to the occurrence of adverse events (odds ratio (OR) 2.42), and having started this method because of problems with other methods (OR 1.46). Factors predicting continuation were: compliance; age over 30 years; childlessness, and positive evaluation of NuvaRing after three months.

CONCLUSION: The acceptability questionnaire has good psychometric properties and can predict early discontinuation of the method. The questionnaire could be used in general practice to monitor user compliance.

AN ANALYSIS OF THE USEFULNESS AND TRANSPARENCY OF COST-EFFECTIVENESS LITERATURE FOR SURGICAL DEVICES AND PROCEDURES
Basskin LE, Chan J
Butler University College of Pharmacy and Health Sciences, Indianapolis, IN, USA

OBJECTIVES: Published cost-effectiveness literature regarding surgical devices and procedures should be valid, useful, and transparent. Since users often need to be able to substitute local costs or resource utilization into economic models, publications need to disclose sufficient information about the methodology and costs of resources used rather than simply aggregate or average cost per case data. The primary objective of this study was to examine the extent of useful disclosure of reported dollars per health-care resource (HCR) in surgery performed in all patient populations. The secondary objective was to determine the extent to which economic principles and disclosure (i.e., validity) existed.

METHODS: “Dollars per HCR” were obtained from literature searches conducted in two databases using the search terms “surgery”, “cost”, and “cost effectiveness”. Mean, standard deviation, and confidence intervals were determined for each type of HCR. All articles were individually critiqued for internal and external validity based on ten created problem categories.

RESULTS: After eliminating 122 articles that contained no cost information or analysis, twenty-five percent of 138 articles contained usable dollars per HCR data. All descriptive statistics will be reported for each category. Over 74 percent of the articles were missing one or more of the following definitions or disclosures: fixed versus variable costs; dollars per HCR; perspective, and sensitivity analysis. The greatest number of articles was found to have five problems, while the lowest number had one problem. Lack of transparency was also evident.

CONCLUSIONS: Published cost-effective literature cannot be relied on nor easily utilized due to the lack of availability of dollars per HCR and the weak validity of such literature. Relying on invalid and useless published literature can lead to unwarranted conclusions and an in-