

**Methods.** A pragmatic literature search was conducted to identify and review key documents outlining reimbursement, pricing, and coverage policies in China, Taiwan, Korea, and Japan.

**Results.** Therapies for rare diseases in Japan and those for ultra-rare diseases in Korea are exempt from cost-effectiveness evaluations. Taiwan provides full financial coverage for rare disease therapies. China has no special considerations for rare diseases. Drugs included in the medical insurance list are reimbursed at varying levels depending on the “class” of the listing. Unlike prior variations at provincial levels for coverage of off-the-list drugs, new national policy has introduced consistency in coverage.

**Conclusions.** Access and reimbursement processes vary between markets in Asia. New HTA guidelines in Japan allow for easier access to therapies targeting rare diseases by eliminating cost-effectiveness analysis for price determination. On the other hand, a value dossier including an economic evaluation is necessary for rare diseases in Korea. However, manufacturers can provide risk-sharing schemes for rare diseases. China has not yet introduced any specific evaluations or reimbursement criteria for therapies targeting rare diseases. Policies for rare diseases are evolving rapidly to improve access and affordability.

### PP369 Development Of A Dysmenorrhea Quality Of Life Scale Based On Traditional Chinese Medicine Theory: A Mixed-Methods Study

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**Introduction.** It is difficult to generalize health technology assessment in the field of traditional Chinese medicine (TCM). The lack of an outcomes evaluation system based on TCM theory is one of the important reasons. Studies conducted in menstruating women have shown that the prevalence of primary dysmenorrhea varies from 45 to 95 percent. As a debilitating condition for many women, dysmenorrhea is one of the leading causes of absenteeism from school or work, which has a negative effect on quality of life (QoL). TCM has obvious advantages in treating dysmenorrhea. This study aimed to develop a dysmenorrhea QoL scale based on TCM theory.

**Methods.** We conducted focus group discussions and in-depth interviews with TCM gynecologists and patients, and adapted items from previously published scales. We generated an initial pool of forty-one items with eight domains. The Delphi method was used for preliminary item selection. Then, we administered the items to a sample of adolescent girls ( $n = 200$ ). The distribution of survey items, discrete trend, factor analysis, correlation coefficient, and Cronbach's  $\alpha$  coefficient were used to select items.

**Results.** After two rounds of expert consultation, a total of thirty items were included in the dysmenorrhea QoL scale. And after sample analysis, four items' frequency distribution was skewed, five items' standard deviation (SD) was  $<0.8$ , four items' factor

loading was  $<0.4$ , five items' score correlation coefficient with a related domain was  $<0.4$ , and three items' deletion would cause their domain's Cronbach's  $\alpha$  coefficient increased. The items were deleted when they met more than two above standards.

**Conclusions.** A total of twenty items with eight domains were included in the dysmenorrhea QoL scale. The methods to select the dysmenorrhea QoL scale items based on TCM theory were preferable. Given the paucity of research in this area, this new dysmenorrhea QoL scale may provide opportunities for patient-reported outcome evaluation in the field of TCM.

### PP382 Research On The Second-Line Anti-Tuberculosis Drugs Supply Based On Stakeholder Theory Of China

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**Introduction.** China is one of the twenty-seven countries with a high burden of Multidrug-resistant tuberculosis (MDR-TB) in the world. Of the new TB patients in China in 2017, about 63,000 are MDR-TB patients, accounting for one-third of the number of new MDR-TB patients worldwide. In the latest “China's 13th Five-Year Plan” national TB prevention and control plan promulgated in 2017, it is clearly emphasized that all regions should gradually incorporate TB into the payment catalogue of special outpatient medical insurance, according to local conditions. However, for this special group of MDR-TB patients, there is no specialized prevention and control policy at the national level, and there are also blind spots in the medical security policy. Responding to the drug needs of MDR-TB patients, it is necessary to provide patients with stable and affordable second-line anti-TB drugs. It is also necessary to understand the overall drug demand for second-line drugs nationwide to guide further policy formulation and budget research.

**Methods.** Through semi-structured group interviews and key informant interviews, five provinces and cities were investigated. Qualitative analysis was conducted based on stakeholder theory selected doctors and staff from Centers for Disease Control.

**Results.** Through investigations in this study, problems like low purchasing price, insufficient purchasing volume, low drug supply efficiency, and monopoly producers were found. Through the analysis of roles and relationships among the major stakeholders in the second-line drug supply system, together with the motivation and resistance factors, it was found that all stakeholders have the motivation to solve the problem and face their dilemmas and obstacles at the same time.

**Conclusions.** Patients with MDR-TB still have difficulties in obtaining medicines. The interests of various stakeholders need to be balanced to improve drug accessibility and affordability. It is recommended to take advantage of the country's centralized procurement, encourage the development and listing of new anti-tuberculosis drugs and generic drugs, and improve the supervision system to ensure the supply of drugs to benefit more patients with tuberculosis.