HTA Practice, Value Frame Work, and RWE in China

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Agenda

1. China HTA Initiative
2. Value Frame Work to Support HTA Evaluation
3. ISPOR Asia Consortium RWE Initiative
In 2017, the NRDL was readjusted by the government. And the first time employed negotiation mechanism. At the end of March 2017, letter of invitation for negotiation was issued to the manufacturers of the selected 44 drugs.

Request Letter for submission of related products was issued to manufacturers:

- Companies must submit enterprise qualification documents, product price information, pure budgetary impact
- In addition, the company can also submit supporting materials (self choice)
- An executive self-assessment report of the product is mandatory

Top Priority: Clinical Value and Economic Value

Submission Contents

**Self Choice Document**

The following can be submitted if available:

- Clinical efficacy
- Cost effectiveness analysis
- Budgetary impact analysis (Allow you include efficacy component)
- Any other information you deem necessary
Impact On the Future:

**Value, Value, Value!**

Can you tell a straight value story?? Why Should I Pay???

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Demonstrating the value of innovation is an essential part of HTA.

Clinical Value
Economic Value
Patient Value
Society Value

Foundation of all economic value, focus on if the technology is innovative, can it better meet patient needs. Key evidence is clinical research data submitted to FDA and supplemented by real world evidence.
**RCTs Vs. RWE**

Has different strength and weakness, can not replace each others

- RCTs is critical to demonstrate if the technology works in the population! (Question: should we use it?)
- RWE study is conducted after marketing authorization to understand the technology impact in real world population (Question: How can I use it? Can I use in subgroup population such as RCT excluded populations? Should I pay for the price even in my population I did not achieved what intended to?)

RCTs is the foundation, RWE functions as leverage factor

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Demonstrating the value of innovation is an essential part of HTA

**Economic Value**

Translate clinical value into economic value. Includes two components:

- One is a comprehensive CEA to determine if worth to pay
- The second is a BIA to assess if enough resource available to pay.
Budgetary Impact:

Evidences required:
- Clinical efficacy
- Cost-effectiveness
- Budget Impact analysis

Summary

➢ Reimbursement decision will be based on:

➢ **Clinical Value**: RCT as base, RWE as Adjustment factors

➢ **Economic Value**: CEA based on RCT and RWE as comparisons

➢ **Patient Value**: QOL, impact on all aspects of life

➢ **Society Value**: Real world population impact, Productivities, Others

Ref:
1. 周立波，宣建伟. 经济学评估在医保准入决策中的意义及其机制探讨. 中国医疗保险
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Landscape Evaluation of Real World Data in Asia

- To provide a data source platform to support RWE/RWD research in the region

- To conduct a landscape evaluation on the availability of various real world data (RWD) source currently existing in Asia

- To understand the availability, accessibility, general quality and contents of each type of the RWD.
### Database name
- **Suvalue EMR database**
- **The XXX City Health Insurance database**

### Brief description of data
- **By May 11, 2018,** Suvalue EMR database contains 117 hospitals EMR data in 17 different provinces of China; The database includes patient and outpatient data of different levels of hospitals from Tier 1 (23.08%), Tier 2 (64.96%), to tertiary hospitals (11.97%).
- **The Health Insurance database includes the Urban Employee Basic Medical Insurance database and the Urban Resident Basic Medical Insurance database before 2014.** After the Urban Resident Basic Medical Insurance and the New Rural Cooperative Medical Scheme had been combined to the Urban and Rural Resident Basic Medical Insurance in 2014, it had all the three insurance databases. It contains valuable information about patients' disease diagnoses, treatments and medical utilization and costs.

### Data sources (inpatient, outpatient...)
- Inpatient and outpatient

### Type (EMR, Claims...)
- EMR data
- Government Claims data

### Starting year
- The earliest records of database are in 2000 and the data from 2012 is high quality

### Number of unique patients/records in database
- **Number of unique patients:** 81,960,352; **Number of inpatient records:** 9,254,991; **Number of outpatient records:** 191,859,905

### Population coverage (%)
- **10.29% (81960352/796180000)**

### Length of follow-up (Average)
- Not clear, longitudinal data

### Patient demographics
- **Birth day:** Yes; **weight, height:** Yes, **BMI:** No
- **Insurance type:** Yes; **Age:** Yes

### Diagnostic code
- **ICD code (yes or no):** Yes
- **If yes, ICD 9 or ICD 10?:** ICD 10

### Procedure code
- **ICD code (yes or no):** No
- **If yes, ICD 9 or ICD 10?:** ICD 10

### Medication
- **Drugs name:** Yes
- **Dosing:** Yes
- **Dates of prescription:** Yes

### Hospitalization
- **Admission date:** Yes
- **Discharge date:** Yes
- **Discharge status:** Yes

### Lab test
- **Lab codes:** No
- **Lab test date:** Yes
- **Lab test results:** No

### Publication records
- None

### Access requirements/restrictions
- Data cut and review the data on site

### Cost to access
- Depended on the quantity of data the project need

### Utilities
- Cost Study, Health economics study, Burden of disease

### Case study examples
- A retrospective EMR (Electronics Medical Record) database analysis to understand the disease burden and healthcare resource utilization of RA patients with different drugs in China.
- Research on the impact of policy change on hepatitis B drugs. Association of COPD medication adherence with Resource Use AND Cost among COPD Patients

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### Landscape Evaluation of Real World Data in Asia

Countries and regions will include China, Japan, South Korea, Taiwan, Australia etc.

Details to be reported in Sept. 2018 in Tokyo ISPOR Conference
谢谢！
THANKS!
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