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

2

■ Government-led

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

3

■ 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

4

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

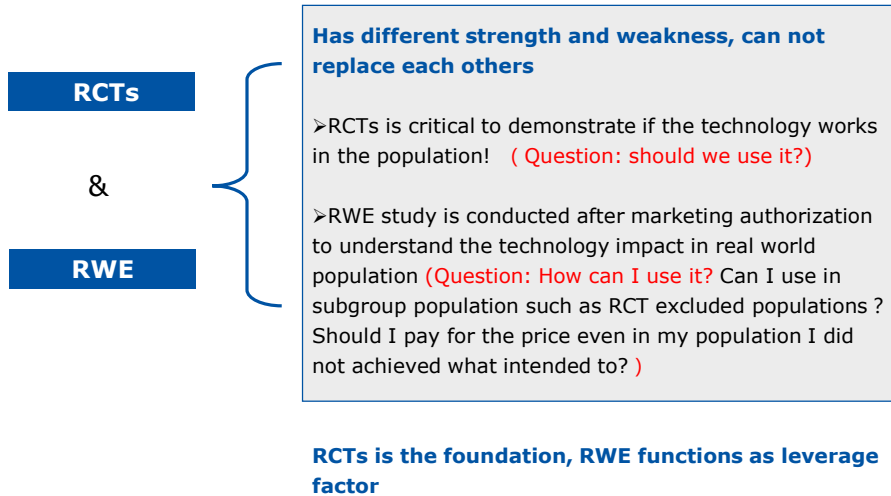Demonstrating the value of innovation is an essential part of HTA

Clinical 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

RCTs

&

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

9

Demonstrating the value of innovation is an essential part of HTA
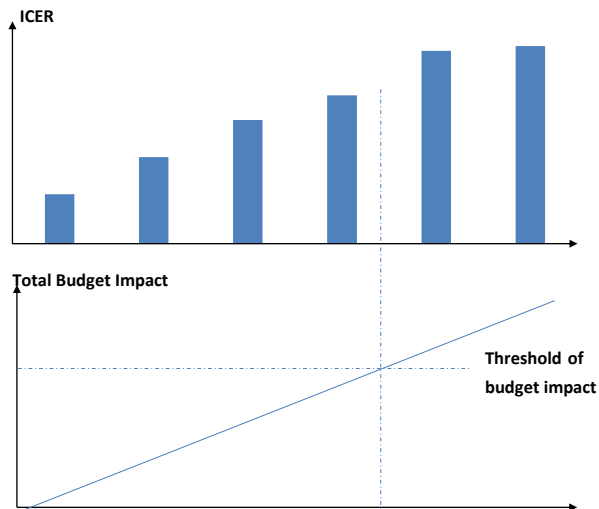
Economic Value

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.

10

Budgetary Impact：

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

Ref:
1.陶立波，宣建伟.经济学评估在医保准入决策中的意义及其应用机制探讨.中国医疗保险8期

Centennial
Scientific

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**

  BIA on affordability

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

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

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1
3

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**
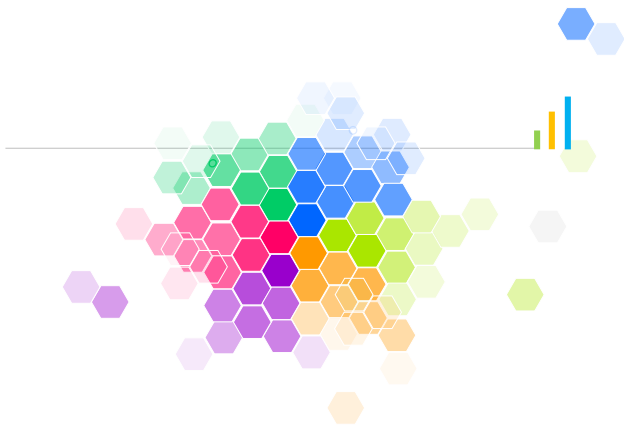   **the RWD.**

14

China	1	2
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 include the inpatient and outpatient data of different level hospital from the Tier 1 hospital (23.08%), Tier 2 hospital (64.96%) to tertiary hospitals 11.97%);	• The Health Insurance database include the Urban Employee Basic Medical Insurance database and the Urban Resident Basic Medical Insurance 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 detailed information about inpatient's disease diagnosis, treatments and medication utilizations and costs.
Data sources (inpatient, outpatients…)	Inpatient and outpatient	Inpatient and outpatient
Type (EMR, Claims…)	EMR data	Government Claims data
Starting year	The earliest records of database is in 2000 and the data from 2012 is high quality	2002
Number of patients in 2017	12,341,313 patients (including inpatients and outpatient)	11.62 million in 2017
Number of unique patients/records in total in database	Number of unique patients: 81,960,352; Number of inpatient records: 9,254,991; Number of outpatient records: 191,859,905	11.62 million in 2017
Population coverage (%)	10.29% (81960352/796180000)	98%
Length of follow-up (Average)	Not clear	Not clear, longitudinal data
Patient demographics • birth day • weight, height, BMI • insurance type • Age distribution (%) ○ <65 ○ >=65	Birth day: Yes; weight, height: Yes, BMI:No Insurance type: Yes; age: Yes The Variables above have missing value	Birth day: Yes; weight, height: Yes, BMI:No Insurance type: Yes; age: Yes The Variables above have missing value
Diagnostic code • ICD code (yes or no) • If yes, ICD 9 or ICD 10? • Date of diagnosis	ICD code: ICD-10 Date of diagnosis: Yes	ICD code: ICD-10 Date of diagnosis: Yes
Procedure code • ICD code (yes or no) • If yes, ICD 9 or ICD 10? • Date of procedure	ICD code: No Date of procedure: Yes	ICD code: No Date of procedure: Yes
Medication\pharmacy (yes or no) • Drug name • Dosing • Dates of prescription	Drug name: Yes Dosing: Yes Dates of prescription: Yes	Drug name: Yes Dosing: Yes Dates of prescription: Yes
Hospitalization • Admission date • Discharge date • Discharge status	Admission date: Yes Discharge date: Yes Discharge status: Yes	Admission date: Yes Discharge date: Yes Discharge status: Yes
Lab test • Lab codes • Lab test date • Lab test results	Lab codes: Yes Lab test date: Yes Lab test results: Yes	Lab codes: No Lab test date: Yes Lab test results: No
Publication records	INDENTIFY THE TEMPORAL MEDICATION PATTERN IN THE HYPERTENSIVE PATIENTS USING SEQUEENTIAL PATTERN MINING AND RELATE THE PATTERNS TO THE OUTCOMES AND COST	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, Real World Data Clinical, Effectiveness Study, Health economics study Burden of disease	Cost Study, Health economics study, Burden of disease
Case study examples	• A retrospective EMR（Electronic Medical Record）database analysis to understand disease burden and healthcare resource utilization of RA Patients with designated drugs in China • Rational use of antifungal agents in department of Hematology	Research on the impact of policy change on hepatitis B drugs Association of COPD Medication Adherence with Resource Use AND Cost among COPD Patients
Contact person	Yin Wu, grace.wu@suvalue.com,	Contact Information available upon request

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

16

谢谢！
THANKS!

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