Real world evidence and local evidence generation: Taiwan perspectives

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The term “real-world evidence” … refers to information on health care that is derived from multiple sources outside typical clinical research settings, including electronic health records (EHRs), claims and billing data, product and disease registries, and data gathered through personal devices and health applications.
The 21st Century Cures Act (Cures Act): signed into law on Dec 13, 2016, is designed to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently.

Real-world evidences play an important role.


Real-world evidences in life cycle:
Should we have local RWE?
Apparentyes

• **World is different!**
• Different in genomics, environments, life style/risk factor behaviors, medical practice and accessibility

Mortality for Breast cancer by WHO

![Mortality chart](chart)

- More developed regions
  - Western Europe
  - Australia
  - Canada and Eastern Europe
- Less developed regions
  - Asia
  - Central America

Generating RWE in Taiwan (1): NHI-RD
Claim data with other database

- **Taiwan NHI**: single payer, 99% coverage rate with 93% providers contracted.

### Health and Welfare Data Center (MOHW)
- NHI claim data (NHIRD, 1995~)
- Other National Health Registry:
  - Cancer registry, Death certification, DM registry

### Researcher’s own database:
Primary biological data, medical records/information, community survey, etc.

- For research only
- Mostly outcome research
- Some for utilization with adapted PE parameters

![Health survey](survey)
- National health interview survey, Triple-high status survey, Low-income health survey, Taiwan smoking behavior survey, Handicapped life requirement survey

![Graph](graph)
Generating RWE in Taiwan (1): NHI-RD
Intervention in follicular lymphoma as an example

- Pivotal PRIMA study
- Adult advanced follicular lymphoma
- Open-labeled RCT
- Rituximab maintenance vs. observation
- PFS as primary endpoint: success
- Indication approved, but....
  OS benefits not demonstrated

- Data from Taiwan NHIRD + Cancer registry
- Adult stage II-IV follicular lymphoma
- Rituximab maintenance vs. observation
- OS benefits demonstrated
- Most beneficial population: stage IV and elder patients


Generating RWE in Taiwan (2): EMR

- Almost all hospital and clinics are digitalized in medical records in Taiwan.
- Hospital-based database for EMR is already established in some medical centers.

Huang, HH. et al. Cancer Med., (in revision)
Generating RWE in Taiwan (2): EMR
Linking claim-based EMR on the way

EMR exchange center

- All contracted Hospitals fully linked
- Claim data from all contracted clinics/hospitals are available

NHIA

Clinics

Hospital

Record system

Order system

Download

Inquiry

Requests

MP IC card + NHI IC card informed consents

Informed consents

NHI-VPN

Institute card

Image and lab reports

Index bank

NHIA

Order system

MP IC card + NHI IC card informed consents

Informed consents

NHI-VPN

Institute card

Download

Generating RWE in Taiwan (2): EMR
Health Bank system, with linked EMR

NHI Medi-Cloud System

Medication Records
(3 months)

Surgical Records
(6 months)

Examination Results
(6 months)

Chinese Medicine Records
(3 months)

Discharge Summary
(6 months)

Dental Care
(24 months)

Examination Records
(6 months)

Rehabilitation Records
(12 months)

Allergic Substance
(Forever)

(6 months)

Care List for Specific Drugs
Controlled medications / specific drugs
(coagulation and orphan drugs)
Generating RWE in Taiwan (3): Registry
National Registry for Hepatitis C

- Funded by government, and co-run with NGO (Taiwan Liver Research Foundation)
- Prospective and compulsory registration when use reimbursed anti-HCV DAA treatment: part of reimbursement plan

Generating RWE in Taiwan (3): Registry
Academic society-based stroke registry: large-sized disease

- Started from 2006, run by Taiwan Stroke Society
- Nation-wide registry, with 39 participating hospitals
- >100,000 cases till 2014, in growing still
- Prospective, web-based registration (5 pages), paid per case as incentives
- With external auditing
Generating RWE in Taiwan (3): Registry
Academic society-based BMT registry: small-sized disease

- Started from 2012, run by Taiwan BMT Society
- Nation-wide registry, with 17 participating centers
- Prospective and retrospective registration
- Data collected by 5 data managers
- With internal auditing

Challenges in RWE generation in Taiwan (1):

- Data collection/maintenance:
  - Claim data can be biased
  - Maintaining and auditing a registry can cause a lot for academic society

- Data accessibility
  - Ethical problems/Privacy, and other issues
  - HWDC data: only for research use
  - Health Bank: only for personal inquiry and government use
  - Hospital-based databank: only for research use
  - Academic registry data: allow more collaboration
Challenges in RWE generation in Taiwan (2):

- Big data: How we integrate and analyze them?
  - Brand-new data from other devices??

Challenges in RWE generation in Taiwan (3):

- How RWE integrate with trial data?
  - Proper methodology is a universal issue.
  - Weighted by region, or not?

- How RWE impacts healthcare decision and medical practice?
  - Regulatory issue: commitment for RWE generation?
  - Stockholders’ consensus
  - Healthcare providers’ viewpoints
Any questions?  
Your input is critical.

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