

Real world evidence and local evidence generation: Taiwan perspectives

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Real-World Evidence — What Is It and What Can It Tell Us?

Rachel E. Sherman, M.D., M.P.H., Steven A. Anderson, Ph.D., M.P.P., Gerald J. Dai Pan, M.D., M.H.S., Gerry W. Gray, Ph.D., Thomas Gross, M.D., M.P.H., Nina L. Hunter, Ph.D., Lisa LaVange, Ph.D., Danica Marinac-Dabic, M.D., Ph.D., Peter W. Marks, M.D., Ph.D., Melissa A. Robb, B.S.N., M.S., Jeffrey Shuren, M.D., J.D., Robert Temple, M.D., Janet Woodcock, M.D., Lilly Q. Yue, Ph.D., and Robert M. Califf, M.D.
N Engl J Med 2016; 375:2293-2297 | December 8, 2016 | DOI: 10.1056/NEJMSb1609216

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.

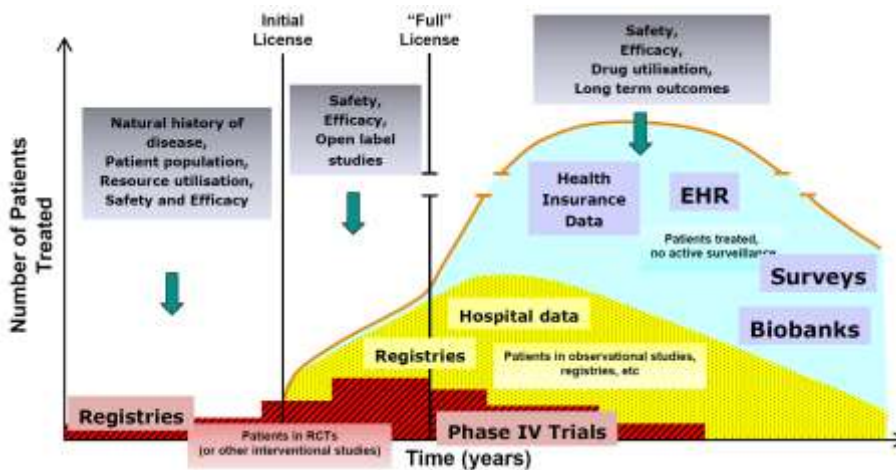


The 21st Century Cures Act (Cures Act): signed into law on Dec 13, 2016, is designed to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently.

Real-world evidences play an important role.

<https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentsTotheFDCAAct/21stCenturyCuresAct/default.htm>

Real-world evidences in life cycle:



Should we have local RWE?

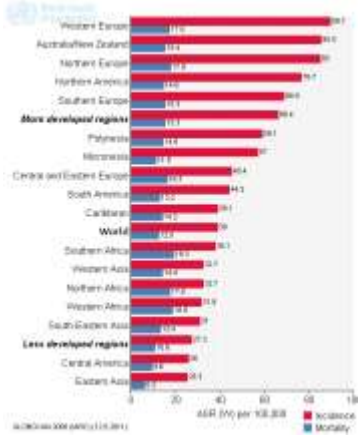
Apparently yes



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



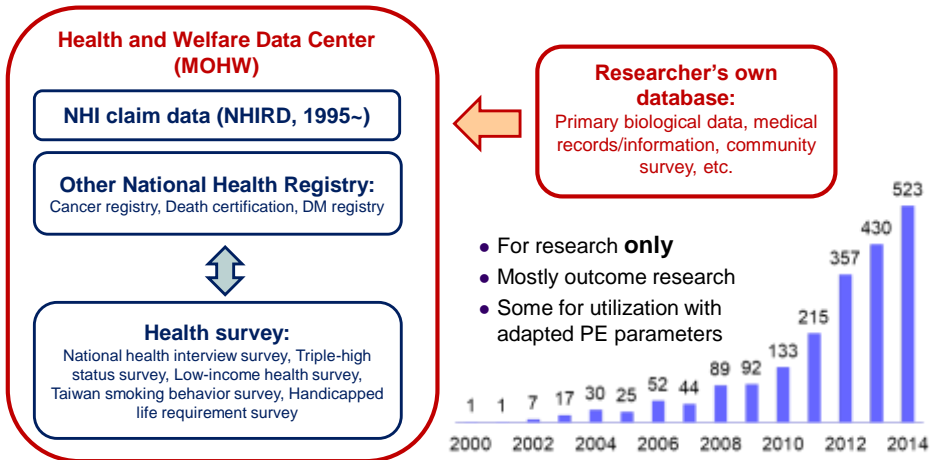
Mortality for Breast cancer by WHO



Generating RWE in Taiwan (1): NHI-RD

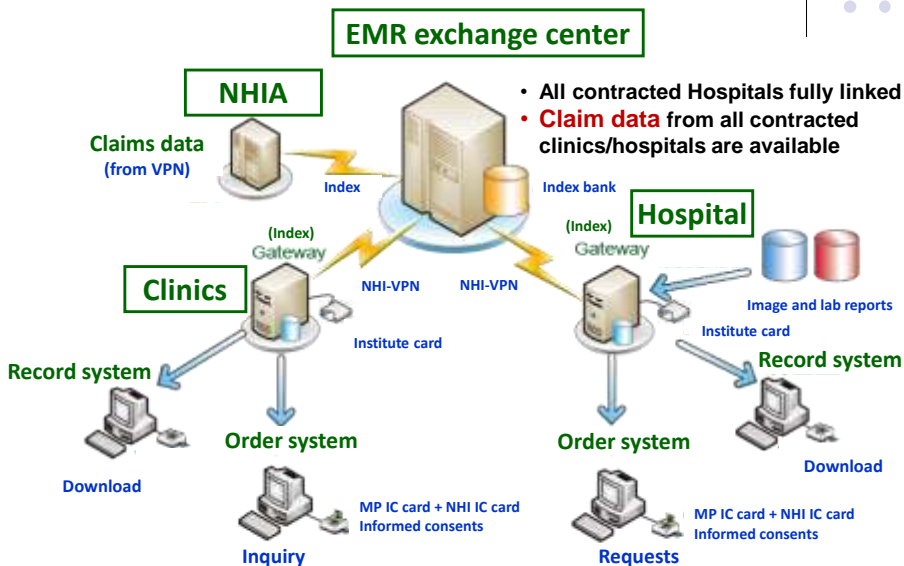
Claim data with other database

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



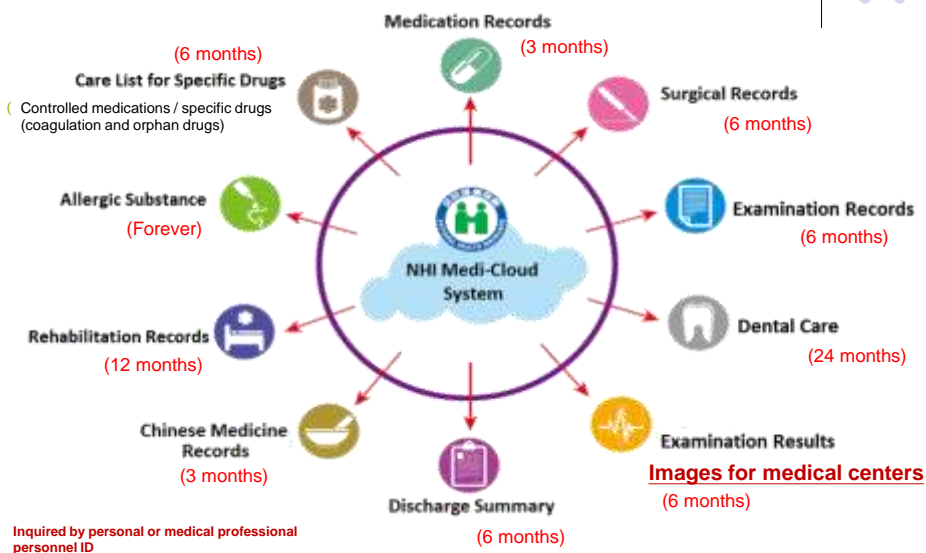
Generating RWE in Taiwan (2): EMR

Linking claim-based EMR on the way



Generating RWE in Taiwan (2): EMR

Health Bank system, with linked EMR



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

National Hepatitis C Program (NHCP) Office set in Taiwan, 2016

Strategies toward HCV Elimination at National Level

- **Prevent new HCV infection**
 - With universal educational programs for general population & health-care providers by NGO/GO
- **Increase rates of diagnosis/awareness**
 - With multi-proposed, integrated programs of community survey by NGO
 - With free check-up of HBV and HCV markers for adults with age > 45 years by GO
- **Increase accessibility**
 - Provide "point-of-care" service with specialized professionals in rural areas
- **Scale-up treatment uptake**
 - With reimbursement of DAA regimens at a fixed price of 8,300 USD per SVR achieved by Taiwan National Health Insurance, whatever DAA regimens
 - Prioritizing treatment by prior treatment experience and liver fibrosis status of HCV patients

Yu ML, 2017 World Hepatitis Summit

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

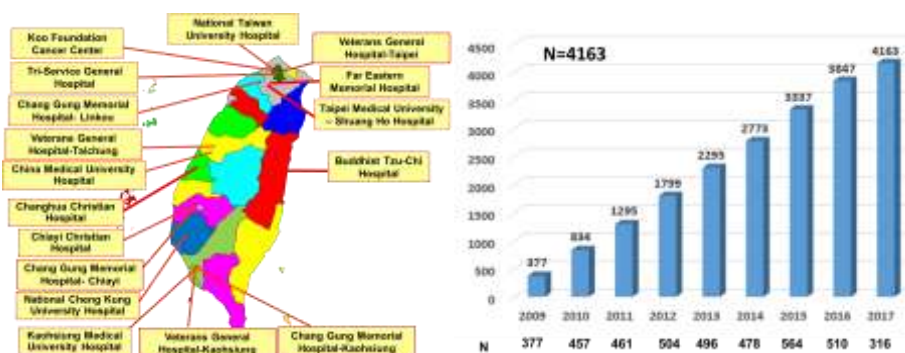


Generating RWE in Taiwan (3): Registry

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):

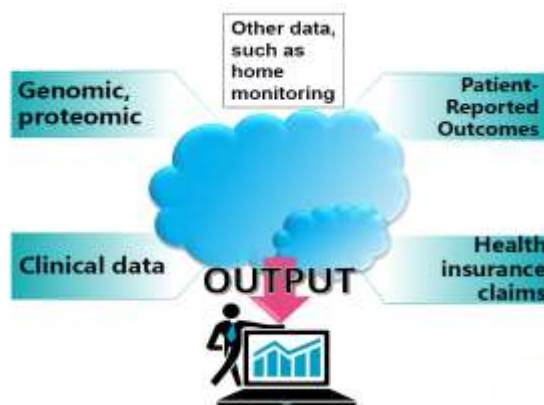


- Data collection/maintenance:
 - Claim data can be biased
 - Maintaining and auditing a registry can cause a lot of academic society
- Data accessibility
 - Ethical problems/Privacy, and other issues
 - HWDC data: only for research use
 - Health Bank: only for personal inquiry and government use
 - 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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