

Real World Evidence and Local Evidence Generation: How Should it Be Approached in Asia Pacific? - Korea

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Real World Data & Real World Evidence

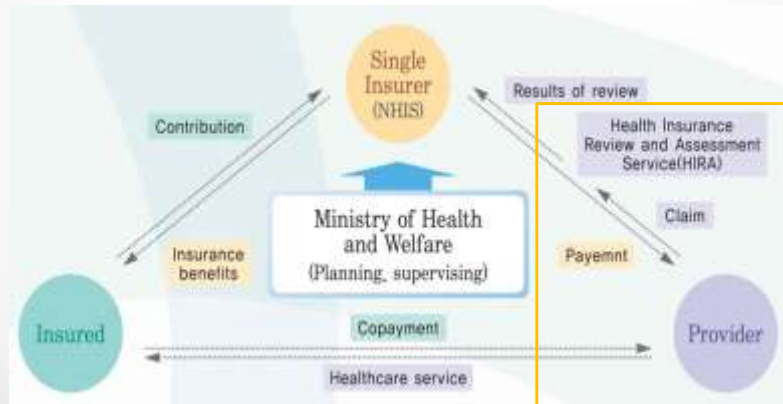
- Real World Data
 - The data relating to patient health status and/ or the delivery of health care routinely collected from a variety of sources
 - Electronic health records (EHRs)
 - Claims and billing activities
 - Product and disease registries
 - Patient-related activities in out-patient or in-home use settings
 - Health-monitoring devices
- Real World Evidence
 - The clinical evidence regarding the usage and potential benefits or risks of medical product derived from analysis of Real World Data

FDA. Real World Evidence.

<https://www.fda.gov/ScienceResearch/SpecialTopics/RealWorldEvidence/default.htm>

NHI system and Real World Data

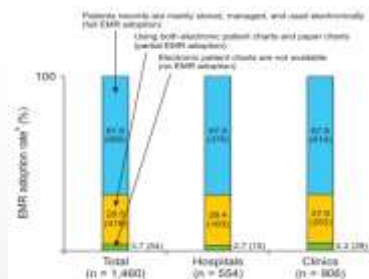
- National Health Insurance System
 - Operating based on Electronic Data Interchange and web-base claims submission



• 3

Real World Data

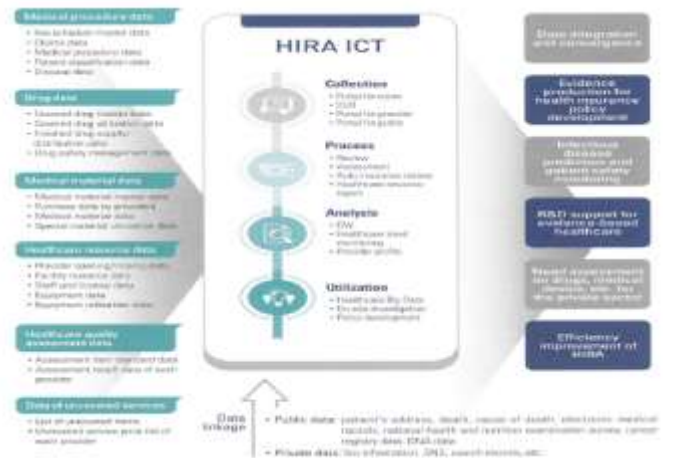
- Medical Record
 - Electronic Medical Record in Hospitals and Clinics
 - Facilitated by electronic National Health Insurance Claims Review and Assessment system building
 - Tertiary hospitals have been leading Electronic Medical Record and hospital Information and Communication System
 - Medium and small hospitals and clinics adopted EMR system around 97% in 2014



• 4

Real World Data

- National Health Insurance Information System
 - Electronic NHI Claims Review and Assessment System
 - Based on web-based claims submission



Real World Data

- National Health Insurance Information System
 - Research data sets from HIRA
 - HIRA-NIS: Inpatient dataset composed of 1M cases stratified systematically sampled (13%)
 - HIRA-NPS: Total patient dataset composed of 1.4M cases stratified systematically sampled (3%)
 - HIRA-APS: Elderly patient dataset composed of 1M cases stratified systematically sampled (20%)
 - HIRA-PPS: Children-Youth patient dataset composed of 1.1M stratified systematically sampled (10%)
 - ❖ Stratified by gender, age
 - ❖ Health service utilization data
 - ❖ Additional on-site Data
 - Other information from HIRA
 - Medical Equipment and facility, health personnel working in hospitals and clinics
 - Quality information on healthcare organizations

Real World Data

- National Health Insurance Information System
 - Research data sets from NHIS
 - Sample Cohort: 1M cohort, 2% of NHI and Medicaid enrollees (stratified sampled by gender, age, NHI/Medicaid, SEG, Region (2002~2015))
 - Eligibility, birth/death
 - Health service use details: Diagnosis, Prescription and dispensing..
 - Health check-up Cohort: 0.5M of 40~79 examinees (stratified sampled by gender, age, NHI/Medicaid, SEG, Region (2002~2015))
 - Eligibility, birth/death
 - General Check-up, Dental check-up
 - Elderly Cohort: 0.5M of 60+ NHI/Medicaid enrollees (2002~2015)
 - Eligibility, death
 - Health service use and health check-up details
 - Female Employee Cohort: 0.2M (2007~2015)
 - Infant Health Check-up Cohort: 5% of live birth from 2008~2012 (2008~2015)

Real World Evidence

- HTA, CER and ORs
 - Focusing on decision making for NHI Coverage and listing
 - Few for Risk Sharing for evidence generation of pharmaceuticals
 - Efforts for CER for anticancer drug therapy
 - nHTA for diagnosis, procedures and surgeries suffering from shortage of evidence
 - Public Researches in NECA and efforts for expanding local evidence generation to support policy makers, clinicians and patients

	Agency	Activities	Revenue
Korea	NSCR/NHCR (finished)	• CER and OR for healthcare Decision Making	8M/8.5M USD (per YEAR)
	NECA	• Evidence Generation and Synthesis for Healthcare Decision Making	10M USD
UK	NIHR	• EME, HTA, SR etc.	1160M USD
US	AHRQ	• HTA, EPC, Patient Safety and QI Researches and Planning	408M USD
	PCORI	• CER to Support Informed Choice	310M USD

Future

- Moon Jae-In Care needs more evidence to expand NHI coverage in Korea



● 9

Challenges

- Big data in Korea doesn't provide sufficient results and/or outcomes information
 - Diagnosis classifications accuracy is controversial
- Medical records need QUALITY upgrade and standardization
- RWE needs to be supported by experts of research methodologies to control confounding factors
 - Observational studies
 - Sample bias
 - Rare cases
- International cooperation for Asian patient registry and surveillance/ monitoring

● 10

Thank You!!

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