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

Korea

Sukyeong Kim, PhD
Senior Research Fellow, International Cooperation Advisor
Evidence-based Healthcare Research Division

Real World Data & Real World Evidence

- Real World Data
  - The data relating to patient health status and/or the delivery of healthcare 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
  o Operating based on Electronic Data Interchange and web-base claims submission

Real World Data

• Medical Record
  o 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
Real World Data

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

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

<table>
<thead>
<tr>
<th>Agency</th>
<th>Activities</th>
<th>Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Korea</td>
<td>NSCR/NHCR (finished)</td>
<td>CER and OR for healthcare Decision Making</td>
</tr>
<tr>
<td></td>
<td>NECA</td>
<td>Evidence Generation and Synthesis for Healthcare Decision Making</td>
</tr>
<tr>
<td>UK</td>
<td>NIHR</td>
<td>EME, HTA, SR etc.</td>
</tr>
<tr>
<td>US</td>
<td>AHRQ</td>
<td>HTA, EPC, Patient Safety and QI Researches and Planning</td>
</tr>
<tr>
<td></td>
<td>PCORI</td>
<td>CER to Support Informed Choice</td>
</tr>
</tbody>
</table>
**Future**

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

**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
Thank You!!

sukyeong.kim@neca.re.kr