INTRODUCING A NOVEL CONCEPT TO OBSERVATIONAL RESEARCH IN THE ASIA-PACIFIC REGION: ENRICHED REAL-WORLD DATA (RWD) STUDIES

Workshop
ISPOR 7th Asia-Pacific, Singapore

6th September 2016
Discussion Leaders

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Associate Professor, National University of Singapore (NUS)

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## Today’s discussion

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<tr>
<th>Time</th>
<th>Session Title</th>
<th>Presenter</th>
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<tr>
<td>16:00</td>
<td>Welcome and introductions</td>
<td>Laura Garcia Alvarez</td>
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<tr>
<td>16:05</td>
<td>How electronic medical record (EMR) systems can be implemented?</td>
<td>Ong Leong Seng</td>
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<td>16:20</td>
<td>What research can we do using EMR?</td>
<td>Joanne Yoong Su-Yin</td>
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<td>16:35</td>
<td>What’s next? Enriched RWD Studies</td>
<td>Josh Hiller</td>
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<td>16:50</td>
<td>Moderated Q&amp;A</td>
<td>Laura Garcia Alvarez</td>
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Although the RWE landscape in the Asia-Pac region is currently immature, it has the potential for future evidence generation.

Historically, there is heavy reliance in data collected through surveys in observational research.

Current landscape is evolving towards structured data capture providing opportunities for use of RWD in observational studies.

In this workshop, we will cover the following topics:

- EMR infrastructure implementation
- Usage of RWD data in research
How electronic medical record (EMR) systems can be implemented in Asia?
EMR/EHR Implementations in Singapore Opportunities, Challenges and Lesson Learnt

Ong Leong Seng
Chief Architect & Group Director
Architecture & Innovation
About IHiS

Transforming Healthcare with IT Innovation

- **Vision:** To be the trusted technology partner in healthcare
- **Mission:** To lead and deliver technology for excellence in healthcare
- **Goals:**
  - Drive Service Excellence and Value at Healthcare Institutions
  - Integrate Care Delivery across Healthcare Continuum
  - Innovate to Transform Healthcare
Key Healthcare Statistics

- Increasing demands on healthcare
  - Population trends
  - Capacity
  - Chronic illnesses
  - Case complexity

- Currently serving
  - 380,000 hospital admissions
  - 970,000 accident + emergency
  - 4,500,000 specialist outpatient clinics
  - 4,650,000 polyclinics

- 63 percent of all deaths
  - Diabetes
  - Respiratory heart disease
  - Hypertension
  - Stroke
  - Cancer

- Multi-disciplinary care team
  - Clinician, social worker, therapist
  - Family support caregiver training community
  - Access to facilities treatment rehabilitation

- Requires:

- Expansion
  - 1,120 more nursing home beds by 2015
  - 3,700 more acute & community hospital beds by 2020
  - 20,000 more healthcare professionals by 2020
Singapore Healthcare 2020 and Beyond

- Acute Hospital
- Acute Care
- Family Physician
- Polyclinic
- Primary Care
- Patients
- Screening / Prevention
- Rehab Centre
- Health Promotion Board
- Intermediate / Long Term Care
- Nursing Homes
- Community Hospital
- Hospice
- Palliative Care

Screening / Prevention

Health Promotion Board

Primary Care

Polyclinic

Acute Care

Acute Hospital

Family Physician

Patients

Rehab Centre

Intermediate / Long Term Care

Nursing Homes

Community Hospital

Hospice

Palliative Care
Increasingly fragmented by independent procurement for new corporate entities. Some aging systems present softer targets for consolidation.
Consolidation Roadmaps with dependencies

Logical Application

- Application (cluster A, cluster B)
- Application (cluster C)
- Application (cluster D)
- Application (cluster D,E)
- Various systems
- Various systems (clusters A,B)
- Various systems (clusters C,D)
- Various systems
- Various systems

2015

- Review after 12 months
- Review of Application
- Procurement & Implementation
- New Application
- Procurement & Implementation
- Procurement & Implementation
- Procurement & Implementation
- Procurement & Implementation
- Procurement & Implementation

2016

- Migrate functionality over
- New Application
- Go live for Cluster A
- All clusters on new system
- Upgrade capability of existing system
- New common system
- Integration with private sector
- Integration with private sector
- Integration with private sector
- Integration with private sector

2017

- Migrate functionality over
- Review of Application
- Go live for Cluster A
- All clusters on new system
- Upgrade capability of existing system
- Integration with private sector
- Integration with private sector
- Integration with private sector
- Integration with private sector

2018

- All clusters on new system
- Integration with private sector
- Integration with private sector
- Integration with private sector
- Integration with private sector
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- Integration with private sector
- Integration with private sector

2019

- Integration with private sector
- Integration with private sector
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- Integration with private sector

2020

- Integration with private sector
- Integration with private sector
- Integration with private sector
- Integration with private sector
- Integration with private sector
- Integration with private sector
- Integration with private sector
- Integration with private sector
- Integration with private sector

Procurement & Implementation

Common Rule Engine

Integration with private sector

National Rule Engine

Go-live for first institution

Process Transformation Blueprint

New National System

Review after 12 months

Go live for Cluster A

All clusters on new system

Take over functionality from the other system
Use of process analysis to identify fit with existing/planned IT systems
Illustration of architecture options to implement a process
## Applying Architecture Trade-off Analysis Method (ATAM)

### Attributes

<table>
<thead>
<tr>
<th>Attributes</th>
<th>Common System</th>
<th>Distributed/Local System</th>
<th>Hybrid 2-Tier Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of Acceptance</td>
<td>User B are unwilling to use another system other than their EMR this process</td>
<td>User A are generally neutral regarding whether function is done in local EMR’s or on a separate central system.</td>
<td>User A are generally neutral regarding whether function is done in local EMR’s or on a separate central system.</td>
</tr>
</tbody>
</table>

**Best (4)  Good (3)  Average (2)  Poor (1)  Worst (0)**

[http://www.sei.cmu.edu/architecture/tools/evaluate/atam.cfm](http://www.sei.cmu.edu/architecture/tools/evaluate/atam.cfm)
HIMSS EMRAM Stage 6 Hospitals Awards

First in Asia
Four Public Hospitals

Singapore General Hospital
SingHealth

National University Hospital

Tan Tock Seng Hospital

STAGE 6 & 7 AWARDS
Khoo Teck Puat Hospital And National Heart Centre Achieve Global Benchmark For Advanced IT To Improve Patient Care

Singapore, September 10, 2014 – HIMSS Analytics Asia Pacific announced today that Khoo Teck Puat Hospital (KTPH) and National Heart Centre Singapore (NHCS) have achieved HIMSS EMRAM Stage 6, an international benchmark for the use of advanced IT to improve patient care.

24-Aug-2016

Institute of Mental Health Achieves Global Recognition with HIMSS Analytics EMRAM Stage 6

- First Psychiatric Hospital outside of North America to be Awarded Stage 6

Singapore, 24 August 2016 – The Institute of Mental Health (IMH), will be awarded Stage 6 under the HIMSS Analytics EMR Adoption Model (EMRAM) later this evening at HIMSS Asia Pacific Awards Dinner at Westin Grande Sukhumvit Bangkok in Bangkok, Thailand. The collaborative efforts of IMH and Integrated Health Information Systems (IHiS) to implement several high performance systems such as the Closed Loop Medication Management (CLMM) and Clinical Documentation (C-Doc) systems enabled the institution to be the first psychiatric hospital outside of North America to achieve this global benchmark.

Photo: Institute of Mental Health

Singapore, October 16, 2013 – HIMSS Analytics Asia Pacific announced today that Changi General Hospital (CGH) has achieved HIMSS EMRAM Stage 6, an international benchmark for the use of advanced IT to improve patient care.

Changi General Hospital's Medication Management System with QR Codes

Photo: Institute of Mental Health

Singapore, October 16, 2013 – HIMSS Analytics Asia Pacific announced today that Changi General Hospital (CGH) has achieved HIMSS EMRAM Stage 6, an international benchmark for the use of advanced IT to improve patient care.
Critical Success Factors

- **Strong leadership and governance**
  - Require from all aspects: Clinical, Business, Operations
  - Important for adoption and change management
  - Need to set strategic goals, objectives and direction
  - Need to be actively involved, not just saying it
  - Be prepared to make hard decisions, if necessary
  - EMR implementation is never an IT project

- **Objectives of implementing the EMR**
  - Need to define upfront with SMART KPIs
  - Use as guidance for decision making, prioritization
Challenges & Lessons Learnt

➤ Scope of implementation
  • Is it really just the EMR or it extends to the ancillary and supporting systems/capabilities, e.g. Patient Management, Patient Accounting, Pharmacy, ID Admin
  • Do not forget to ensure these areas are able to handle the new capabilities: network, access control, downtime, production support, users roles and workload

➤ Data governance
  • Is the institution data policy updated to support EMR roll out?
  • Important to ensure every data field has a unique and global definition, e.g. unique lab test code for each test, unique drug code for each drug

➤ One size does not fit all
  • Harmonize and standardize global definitions, master data, DB schema
  • Allow and plan for localization, e.g. process, workflow, template
Patient safety must be 1\textsuperscript{st} priority
- Is this function compromising patient safety, e.g. copy and paste
- How do we ensure sufficient test coverage?

Do not photocopy the AS-IS UI, processes, workflow, templates
- Especially true if it is from manual and paper to electronic
- BPR is required to streamline and optimize how it should work in electronic, which may require right siting of work among roles (e.g. Orders now placed by doctors instead of nurses prior to CCOE roll out), re-define/new user roles access rights (e.g. VVIP access)
- Every function and report request must have justifications and create value

Data migration and roll out strategy
- Do we really need to migrate all past data into the EMR?
- Should we do a big bang roll out or roll out by specialties, in-patient then out-patient, by user roles, etc?
What research can we do using EMR?
Using EMR in Health Services Research in Singapore: Lessons and Looking Ahead

Joanne Yoong

Senior Economist, Center for Economic and Social Research, University of Southern California
Associate Professor, National University of Singapore
Deputy Director, Center for Health Services and Policy Research, NUHS
Honorary Senior Lecturer, London School of Hygiene and Tropical Medicine
Better Analytics, Better Healthcare

- Predictive Analytics
- Diagnostic Analytics
- Descriptive Analytics
- Prescriptive Analytics

Tom Davenport, Five Types of Analytics for The Internet of Things, Deloitte University Press
We used 73182 blood glucose measurements from 3673 patients between November and December 2013 in the EH to monitor adherence to timely measurement protocol.

• Can a goal-directed program improving weight loss outcome when compared to standard program after sleeve gastrectomy?

• We identified patients from 3 bariatric centers between April 2010 and July 2013 in the electronic health records (EHRs), and compared the center that has a goal-directed program with the other 2 centers.

Example III: Predictive Analytics

- Which patients are most likely to enroll into a program to co-ordinate patient care between specialists and family physicians (FPs)?

- We identified 220 patients enrolled into the program between August 2010 to December 2012 in the EHRs.

- Private class patients and patients seeing private FPs are more likely to continue, but diagnosis, comorbidities and meds surprisingly not significant.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Odds ratio (95%CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at enrolment in years</td>
<td>1.00</td>
<td>0.250*</td>
</tr>
<tr>
<td>First quartile: ≤44</td>
<td>1.08 (0.47–2.51)</td>
<td>0.854</td>
</tr>
<tr>
<td>Second quartile: 45–56</td>
<td>2.17 (0.94–5.04)</td>
<td>0.071</td>
</tr>
<tr>
<td>Third quartile: 57–65</td>
<td>1.20 (0.51–2.81)</td>
<td>0.677</td>
</tr>
<tr>
<td>Fourth quartile: ≥66</td>
<td></td>
<td></td>
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<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1.16 (0.59–2.27)</td>
<td>0.666</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
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<tr>
<td>Chinese</td>
<td>1.00</td>
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</tr>
<tr>
<td>Malay</td>
<td>0.39 (0.16–0.94)</td>
<td>0.037</td>
</tr>
<tr>
<td>Indian/Others</td>
<td>0.85 (0.27–2.64)</td>
<td>0.776</td>
</tr>
<tr>
<td>Patient class</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subsidised</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Private</td>
<td>4.18 (1.49–11.74)</td>
<td>0.007</td>
</tr>
<tr>
<td>Shared care with FP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMC-FP</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Private FP</td>
<td>4.30 (2.23–8.30)</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>

*Overall p value for categorical variables with more than two groups

Example IV: Prescriptive Analytics

- Using EMR of 10678 diabetic patients between January 2010 and December 2011, we proposed a well-calibrated risk score that identifies the top spenders using previous year’s records including sociodemographic, biochemistry, comorbidity and healthcare utilization variables.

- Application: Patients to be assigned based on a more refined score to complex case management within a Patient-Centered Medical Home (PCMH) model

<table>
<thead>
<tr>
<th>Cut-off</th>
<th>Optimal Youden’s J statistic</th>
<th>90-th percentile of the risk score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specificity</td>
<td>69 (9.9)</td>
<td>92.1 (0.2)</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>61.6 (10)</td>
<td>29.7 (1.9)</td>
</tr>
<tr>
<td>Accuracy</td>
<td>68.3 (7.9)</td>
<td>85.9 (0.4)</td>
</tr>
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You say EMR, I say HSR …

Striking a balance between EMR to support hospital management and clinical care and the conduct of health services research is challenging

- Rich clinical data versus other information
- Ease of entry and process needs versus ease of use and research needs
- Too little vs too much automation
- Data safety and protection versus facilitation and interoperability
Tantalus in the Age of the EMR - Moving Towards Novel Enriched Studies
What’s next? Enriched RWD Studies
Historically, researchers must trade-off benefits and limitations based on data collection mechanism.

<table>
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<th>Pros</th>
<th>Cons</th>
<th>Retrospective analysis</th>
<th>Prospective data collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pros</td>
<td>Cons</td>
<td>Large data sets</td>
<td>Control around collected data, confounders, sample size</td>
</tr>
<tr>
<td>Real-life patterns</td>
<td>Data verification/quality issues</td>
<td>Analysis can uncover new insights</td>
<td>Focus on hypothesis</td>
</tr>
<tr>
<td>Analysis can uncover new insights</td>
<td>Incomplete data</td>
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<td></td>
<td>Time lags</td>
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<tr>
<td></td>
<td>Coding issues</td>
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<tr>
<td></td>
<td></td>
<td>Costly, time-consuming</td>
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<td></td>
<td></td>
<td>Smaller sample sizes</td>
<td>Delays in initiation due to recruitment</td>
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<td>Delays in initiation due to recruitment</td>
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Enriched Real-World Data (RWD) Studies are observational studies that combine existing EMR with prospective data.

**Existing EMR data**
- Data on events collected during standard medical practice
- EMR are being aggregated to create researchable database filled with clinical information from patient record
- Retrospective analysis to support study design and planning

**Prospective data**
- Collected via patient reported outcomes (PRO) and directly from physician (e-CRF)
- Allows for gathering targeted data not available in any standard data sets over time
- Traditional paradigm of market research and CROs

**Enriched RWD Studies**
Enriched RWD Studies use integrated multi-source data to provide a comprehensive view of the patient

**EMR data**

**Other Existing Datasets (e.g. claims)**

**EMR Data**
- Aids patient recruitment
- Provides core patient information

**Study Planning**

**Recruitment**

**Study Execution**

**Types of Enrichment**
- E-CRF and PRO provide supplementary data on variables not in EMR, including QoL

**Data collected directly from MD (e-CRF)**

**Patient reported outcomes (PRO)**

**Study database**
- Linkage and de-ID patient information
- Final study database linking all data sources
Throughout the lifecycle of an observational study, EMR data can enhance the design and delivery of the study.

**Observational study lifecycle**

<table>
<thead>
<tr>
<th>Study planning</th>
<th>Identify site &amp; physician</th>
<th>Patient recruitment</th>
<th>Data collection &amp; monitoring</th>
<th>Data integration &amp; analysis</th>
</tr>
</thead>
</table>

- **Traditional Capabilities**
  - Site list generation
  - IRB
  - Contracting and training physicians
  - Performance forecast
  - Informed consent support
  - Physician support and motivation
  - Review patient records
  - Electronic data capture tools
  - Query management
  - Data validation
  - Site support
  - Data management
  - Statistical services
  - Publication services

- **RWD Driven Enhancements**
  - Clinical expertise
  - Epidemiology (sample size calculation)
  - Site list generation
  - IRB
  - Contracting and training physicians
  - Performance forecast
  - Study planning
    - I/E criteria testing
    - Routine care evaluation
    - # sites and time to recruit
  - Targeted physician list
    - High patient density based on I/E (EMR)
    - High likelihood based on Rx
  - Assisted patient identification
    - Program to analyze patient data offline (cold)
    - Pop-up identification real time in EMR (hot)
  - Linkage to EMR
    - Assisted population of CRF
    - Reduced physician burden
  - Continued follow-up
    - On-going extraction of EMR data
    - Long-term outcomes

**imshealth™**
Applying Enriched RWD Studies

Situations where Enriched RWD studies may be applicable:

- **Strong foundational data**, where most of the data is complete but key variables are not collected electronically; can enrich for the last 10-20% of data, rather than gathering all the data through eCRF
- **TAs** where the patient perspective through capture of PROs is critical; enable linkage of PROs to clinical data
- **Chronic diseases** where long-term follow-up is required to evaluate outcomes; electronic follow up reduces drop-out and is less costly
- **Data from disparate sources required**, such as deep clinical information combined with full healthcare resource utilization costs

**Key Benefits**

- Stronger evidence
- Enhanced study value
- Improved probability of success
- Efficiency
Example 1: Optimizing study design and planning

Challenge: Planning a multi-year observational study there was concerned that some elements in the protocol would make patient recruitment more difficult. To ensure efficient study deployment and generalizable results, it chose to use study planning analysis to inform important decisions around key variables, recruitment timelines and the distribution of physicians to target by specialty.

Approach: Use EMR databases to evaluate inclusion and exclusion criteria to determine number of sites required. Evaluate capture of routine data to determine budget and timelines for ensuring all variables were collected in study.

Impact:
- Ensure accurate budgeting
- Informed recruitment planning and forecast
- Refined I/E criteria and patient stratification

Results presented in poster **PRM20: FEASIBILITY OF ELECTRONIC MEDICAL RECORDS IN AUSTRALIA, CHINA, AND JAPAN TO SUPPORT NOVELTY (A NOVEL OBSERVATIONAL LONGITUDINAL STUDY OF PATIENTS WITH ASTHMA AND/OR COPD)**
Example 2: Site targeting to drive recruitment

**Challenge:** Desired patient cohort needed for multi-year observational study in diabetes proved to difficult for investigators to estimate accurate numbers of patient meeting criteria, putting recruitment targets and timelines at risk

**Approach:** Apply inclusion and exclusion criteria to EMR data bases to identify physicians with high populations of patients meeting study criteria. Prioritise recruitment of physicians with high patient populations for participation in study

**Impact:** Reduced timeline for recruitment by ~5 months, creating efficiency and reduced resource need to meet target recruitment
Conclusions

• Real-world data driven approach to study design and planning enables a fact based assessment of study feasibility prior to expensive and time consuming engagement with investigators.

• Recruiting investigators (where possible) from a universe that is heavily populated with patients meeting study criteria can greatly reduce recruitment timelines.

• Linkage of EMR data to physician or patient collected data enables the creation of a more comprehensive study database to be used for analysis.

• As with any design, an Enriched RWD approach provides more benefit in particular situations.
If you have any questions, please contact us

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