Evolving Methods for Staging Patient Registries in Mature & Emerging Markets

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inVentiv Health

Workshop Leaders

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Workshop Objectives

- General objective is to compare and contrast traditional versus novel methods for the conduct of patient registries

- Specific objectives include:
  - Describe how electronic medical records (EMRs) can impact study planning, patient identification & recruitment, and data capture
  - Provide a case study of a recent disease registry conducted in the AsiaPac region using traditional methods
  - Present a hospital-based EMR database in China and demonstrate how it could be used to facilitate conduct of observational studies

Patient Registries: Traditional vs Novel Methods

Traditional paper-based approaches to patient identification & data collection

Newer electronic approaches to patient identification & data collection

EMRs & Registries: Square Peg in Round Hole?

Characteristic	EMRs	Registries
Data collected for …	Individual patient health tracking & physician orders support	Population research
Patients included	All in practice	Selected based on protocol
Provider-induced variability in data collection	Lots	None
Practice-based customization of data collection	Yes	No
Data formats	Structured & unstructured	Structured & controlled vocabularies
Timing of data collection	Tied to patient encounters	Tied to protocol
Data quality assurance	Limited	Research specific validation rules
Data standards	HL7	CDISC

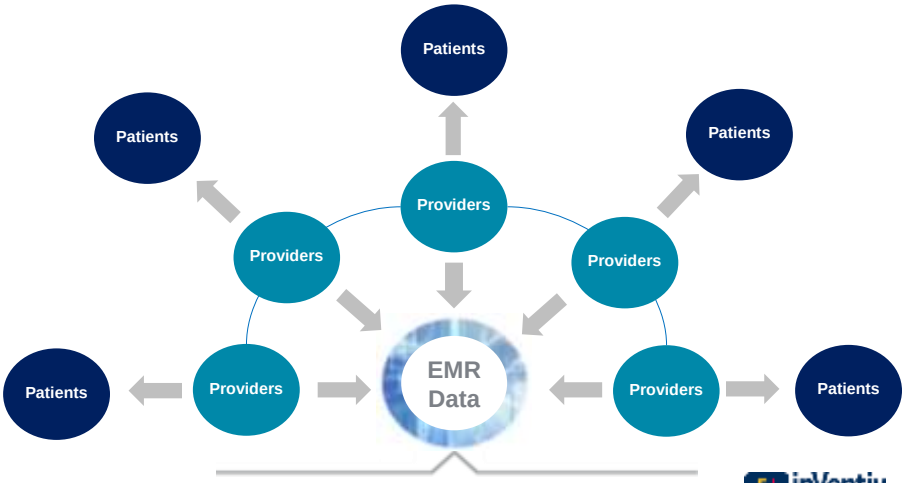
Role of EMRs in Registries

- EMR databases can be used to assess protocol feasibility
- EMR databases can be used to prescreen patients for eligibility

- EMR networks can be tapped into to identify potential investigators based on current patients
- EMRs can be used to remind providers of registries
- EMRs can be programmed with pop-up boxes indicating potential patient eligibility

- Registry CRFs can be programmed into EMRs to facilitate data capture
- EMRs can autofeed data to registry CRFs

EMR Systems Create Provider/Patient Networks



Retro-to-Prospective Hybrid Study Designs

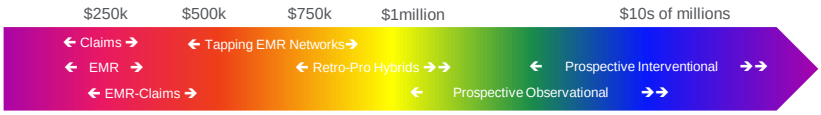
Combine insights from retrospective analyses of EMR data

With prospective data collection from patients iin these analyses

As well as the physicians who treated them

To reduce longitudinal follow-up & overall costs of study execution

A Cost Spectrum of Study Designs



- Studies involving different kinds of data sources naturally array across the cost spectrum according to time & effort in data collection
- Historically, much has been done on either end of the spectrum, but not much in the middle
- Novel approaches leveraging EMR databases for data analysis & patient outreach are providing design alternatives in mid-range of costs

Case Study

Technology @ Present

Presenter - Linda Liong

Primary Objective

To measure the comparative efficacy of double and triple oral therapies:

- metformin + sulfonylurea,
- metformin + sulfonylurea + TZD (Thiazolidinediones) and
- metformin + sulfonylurea + DDP-IV (DiPeptidyl Peptidase – 4) inhibitor,

on glycemic control from baseline over a 24-week treatment period in patients with type 2 diabetes mellitus using defined clinical laboratory measurements

Protocol Inclusion/ Exclusion Criteria – Highlights

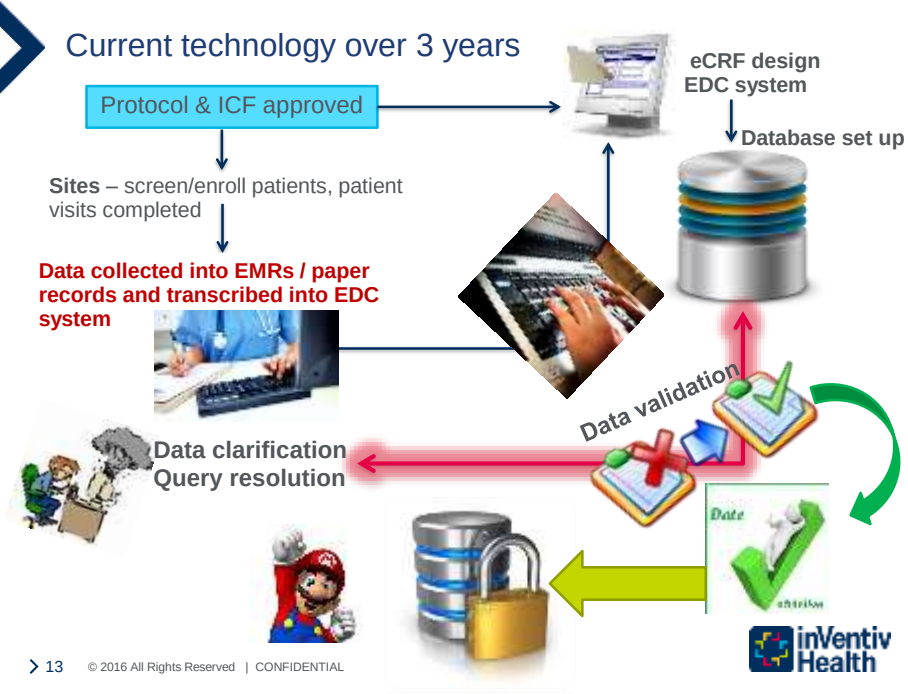
Inclusion criteria

- Patients with a history of clinical diagnosis of established type 2 diabetes mellitus defined by the ADA criteria 2012
- Patients with stable double oral therapy of metformin + sulfonylurea, triple oral therapy of metformin + sulfonylurea + TZD and triple oral therapy of metformin + sulfonylurea + DDP-IV inhibitor for at least 12 weeks at the screening visit

Exclusion criteria

- Patients with type 1 diabetes mellitus or secondary forms of diabetes
- Patients who have been treated with insulin for ≥7 days within 3 months prior to the screening visit
- Patients with a history of acute diabetic complications such as diabetic ketoacidosis
- Patients taking concomitant gemfibrozil or other strong cytochrome P450 (CYP)2C8 inhibitors

Current technology over 3 years



Current Challenges & Novel Technology Solutions

Current Challenges	Novel Technology Solutions
Investigator selection • based on clinical trials/research experiences • Investigator's interest in research participation • Patient recruitment - pre-screen patients for eligibility as quick assessment (accuracy?)	• EMR databases can be used to assess protocol feasibility • EMR databases can be used to prescreen patients for eligibility • EMR networks can be tapped into to identify potential investigators based on current patients
• Patient selection in accordance to protocol full I/E criteria – limited number of eligible patients • Patient pool saturation • Screen failures • For this registry, 2 protocol amendments to reduce sample size • Enrollment rate calculations based on estimated number of available eligible patients (& referrals) = Extended enrollment period (Still a great struggle)	• EMRs can be programmed with pop-up boxes indicating potential patient eligibility – speed up identification process • After informed consent taken, eligible patient data is readily available

Current Challenges & Novel Technology Solutions

Current Challenges	Novel Technology Solutions

Site resources needed
• Screen and recruit patients, manage study activities
• Post study (patient) visits: Perform
  • Data transcription from EMRs/paper medical records = data entries into eCRFs
  • Data cleaning – query resolution
• Site staff- training and re-training on the use of EDC (slows down DE & DC)
Due to other "priorities" from existing workload for clinical trials (higher investigator fees & SC fees) – Limited site resources
 	
Limited number of on-site monitoring visits & remote monitoring by CRAs = reduced site interactive time to motivate site teams & getting site resources
	• Registry CRFs can be programmed into EMRs to facilitate data capture
	• EMRs can autofeed data to registry CRFs – No data entries required
	• Minimal site resources needed
	• Minimal CRA resources needed
	• Entire registry duration reduced
	
	All adds up to significant cost savings

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Medical Big Data Analysis to Support Real World Patient Registry Studies - China Example

Jianwei Xuan, PhD.

Professor, Health Economic Research Institute, Sun Yat-shen University

Singapore, 09, 2016

SuValue EMR Database

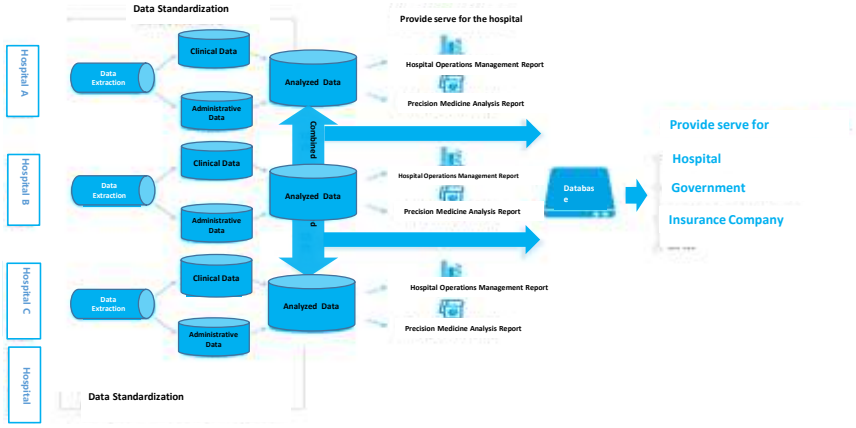
——Medical Big Data In the Cloud

Brief Introduction of SuValue database

SuValue is a medical RWD database provider which obtains the *complete HIS/EMR data* from independent hospitals in various provinces/cities of China.

- ✓ Up to the July, 2016, completely cleaned and *structured data* from *15 hospitals* were included in the database.
- ✓ It is estimated that the database will cover 50 hospitals by *the end of 2016* in various provinces/cities of China.
- ✓ It will reach the amount of *500* hospitals *within 3 years*.

Database Structure



SuValue Healthcare

Quality of SuValue database:

All the raw data collected from all hospitals have been cleaned and de-identified before transfer to research database (final database).

- ✓ All variables had been standardized as *structured data* follow by well-known *standard coding system(ICD-10, ATC code).*
- ✓ Medical records from same patient have been integrated in order to provide *longitudinal record.*

Data Components:

- ✓ The database include the inpatient and outpatient data of different level hospital from the *Tier 2 hospital (80%)* to tertiary hospitals (20%).
- ✓ This database includes all EMR data elements form the *HIS, LIS and PACS* systems. It incorporates all the following detail information:
  - ✓ Patients' demographics, and insurance information
  - ✓ Provider information
  - ✓ Diagnostic (ICD-10), comorbidities, and treatment outcomes
  - ✓ Lab details,
  - ✓ Prescription information
  - ✓ Hospitalization information
  - ✓ All health care resource utilization and cost information.
  - ✓ Others

Typical research questions that can be addressed by the data source

- Cost, Burden of Illness Study
- Real World Clinical Effectiveness Study
- Real World Patient Registry……

Real World Patient Registry Studies – ideal situation

- ✓ Large Sample Size
- ✓ Fast Recruitment
- ✓ Ability to recruit patients who are more likely to react to particular treatments or potentially have less side effects
- ✓ Ability to generate real world effectiveness information

Real World Patient Registry Studies – Big Data Example

Study Objectives:

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Real World Patient Registry Studies – Big Data Example :

Type of Encounter	Diabetic Patients	Hypertension	Hyperlipidemia
Ambulatory	188,269	325,652	12,995
Hospitalizations	5,001	9,742	336

Real World Patient Registry Studies – Big Data Example

Big Data Analysis to Support Real World Patient Registry Study:

1. Ability to identify patients by applying the inclusion and exclusion criterial in the Suvalue database to identify right patients
2. Ability to assess the feasibility of the study
3. Potentially can trace these patients to the site and work with site investigators to recruit patients under considerations
4. Running risk factor analysis to identify which inclusion and exclusion criterial could potentially have more impact on the recruitment of the patients.
5. Identify subgroup patients who are more likely to react particular treatments
6. Identify subgroup patients who are more likely have less ADRs

End Results: Improve Efficiency and Effectiveness to Run the Study

Thanks!