Exploring and validating alternative methods of using multiple databases to answer complex longitudinal research questions

Is linking databases the only answer?

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Presenters

- Rolin Wade, RPh, MS
  - Principal, RWE/HEOR, IMS Health
  - US Practice Lead, Retrospective Database Research
  - Plymouth Meeting, NJ USA

- David Macarios, MBA (HSM)
  - Vice President, HEOR, Lifecell Corporation
  - Bridgewater, NJ USA
Background

- HEOR requires evaluating a longitudinal view of patient risk factors, details regarding medical interventions, and accurate cost/payment information.
- Complete granular detail has been unavailable or inaccessible except for tedious and expensive chart abstraction, patient and provider interviews etc.
- These methods were not practical and had many limitations.
- Our research is focused on implementing and validating methods of building a robust longitudinal view of the patient using multiple sources of retrospective data.

"It’s Just A Hernia"

Hernia surgery gets no respect !!

3.2 billion $ in 2011 spent on ventral “hernias” in USA¹

This does not include loss of work and disability issues

The Medical Challenge: Understanding A Subset Of All Ventral Hernia Repairs

Over 335,000 ventral hernia repairs (VHR) are performed in the US each year
- ~ 15% are considered 'complex' patients

The Complex Abdominal Wall Repair (CAWR) procedure is complicated and often includes:
- A large defect size, Multiple comorbidities, Prolonged OR time, Concomitant procedures, Component separation to restore ab wall function
- 5th most common procedure listed in surgeons applying for board recertification

No Consensus On Optimal Method Or Type Of Mesh In Specific Cases

There Is No Agreed Upon System To Characterize Patients

The Analytic Challenge: Insurance Claims Data Inadequate To Answer Analytic Challenge

- Cohort of interest not easily identifiable in claims records
  - Claims records can approximate case complexity, but cannot accurately capture
- What technique of repair
  - open, lap, CS, etc
- When is mesh needed?
  - Where to place the mesh?
  - What type of mesh? Biologic vs synthetic mesh? Permanent vs absorbable?
    - Can you even identify the type of mesh consistently in claims records?
- What is optimal post op management?
- What to do with infected mesh?
  - Timing of repair following removal infected mesh?
- Do all hernias really need to be repaired?
  - Is "watchful waiting" ok for some ventral hernias?
- Is hernia repair economically feasible for hospitals?

Making the Correct Decision!!

- Right operation
- Right patient
- Right timing
- Right mesh

The Current Fiscal Environment Demands We Guide Administers and Surgeons Regarding Choices in Optimal Patient Care
Understand Long term Consequences Critical, Starting With the Index Inpatient Surgery

Illustrative example: Total cost of care is \$74K due to multiple surgeries of increasing complexity (excludes QoL and Productivity)\(^1,2,3\).

Case example provided by George DeNoto III, MD, FACS, Chief, Division of General Surgery at St. Francis Hospital, Roslyn, NY & Clinical Associate Professor of Surgery, Hofstra North Shore-Long Island Jewish School of Medicine.


The Research Question

- Primary Objective: What is the overall cost of care in patients with ventral hernia repair using surgical mesh implant?
- Are there differences in outcomes based on the type of mesh used?
- How should patient risk factors influence choices?
- What is the prevalence of postoperative complications and their costs?
- Should we focus only on Grade 3 and 4 hernia repair (potentially contaminated or infected)
Previous Research on this Subject

Lifecell/IMS (data on file, 2012)

- Used open source OP claims and hospital charge master data
- 4332 patients (grade 2=2875, Grade 3=171, grade 4=488)
- Compared synthetic mesh and biologic implant
- Tracked complication rates through 90 days post-discharge
- Overall complication rates and costs were higher with biologic implant
- Results were mixed in grade 4 patients
- Limitations: grading based on billing codes, unknown missing data, charge versus cost estimates, long-term complications unknown

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DeNoto et.al. Open Access Surgery 2013:6 23-32

- Use of a very large US claims data set
- 744 patients with grade 3 (n=538) or 4 (n=206) hernia repair
- Compared primary repair, synthetic mesh and xenograft
- Complication rates
  - Grade 3: Synthetic mesh > primary repair > xenograft
  - Grade 4: Xenograft = primary repair
- Overall costs (hospital perspective)
  - Grade 3: $33K – 36K, NS difference between groups
  - Grade 4: $46K - $50K, NS difference between groups
- Limitations: grading approximated, specific product unknown, specifics of surgery unknown, uncertain coding of complications, no visibility to IP services used
Overcoming the Limitations of Previous Research

Full information is available – but in different places

- Details of surgical procedure
- Size of repair, accurate grading of hernia
- Specific size and type(s) of material used
- Patient risk factors identified

- Accurate accounting of costs
- Ability to track complications across multiple sites of care
- Longitudinal medical history

Back to the Research Question

- We have a registry of approximately 1000 patients having a ventral hernia repair at a regional medical center
- The type and severity of immediate complications are recorded, but it is known that complications can occur many months post-discharge
- Patient linking technology provides a method to track (at least some) of these patients for 18 months or more across multiple sites of care
- There are a variety of challenges in developing answers to the research questions
Approach #1 – Direct Patient Linking

- Synthetic identifiers will be created for the 1000 patients in the ventral hernia repair registry
- These identifiers can be linked to a variety of longitudinal data assets
  - PharMetrics Plus Administrative Claims database
  - IMS Patient-centric data warehouse (OP claims, Rx claims, Charge master)
  - Social Security Death Index
- A longitudinal analysis of the linked patients will be conducted
  - Pre-surgical history
  - Resource utilization and costs
  - Relevant medical events (infection, bowel obstruction, re-admission)
  - death

Data Linking Technology

- PATIENT: A single patient interacts with the healthcare system across multiple entry points
- MULTIPLE CHANNELS: Each interaction is captured at the de-identified patient level in the same manner across channels
- DE-IDENTIFICATION: All interactions are combined upon the common algorithm in place across channels
- PATIENT PROFILE: A singular view of the patient experience is represented
IMS utilizes a patented HIPAA compliant algorithm for linking patients across data sources

1. IMS and its technology partners deploy proprietary encryption tools to de-identify patient data at the source
2. De-identified patient data undergo a deterministic matching process to be assigned to a unique and persistent IMS Patient ID
3. Patient data with persistent IMS Patient ID’s are available from across sources for use in IMS products and services to inform patient-centric insights across “linkable” IMS data assets

Trusted Third Party

Name
DOB
ZIP
Data

Source Data with PHI from Data Supplier


Approach #2 – Population Matching

- The 1000 registry patients will be characterized by:
  - Age, Gender, Geography, Payer type
  - Index quarter of ventral incisional hernia repair
  - Index procedure codes, Secondary diagnoses for hernia repair
  - Primary/Secondary diagnosis at admission/discharge diagnosis
  - Length of index hospital stay, total allowed costs ($2500 increment)

- These patients will then be matched (versus linked) to patients in the longitudinal claims database

- A longitudinal analysis will be conducted as specified in Approach #1

- Can matching be a practical surrogate for linking?
Comparison of the Methods

**Linking**
- Patients from one database are directly linked to a 2nd database
- Expected match rate is low (5-20%)
- Sample size is small and may not be generalizable
- Outcome measures can be directly associated with clinical specifics
- Can provide a validation reference for alternative methods

**Matching**
- Patients in the 2nd database are chosen on multiple characteristics
- Matching elements are limited to administrative elements
- The sample size is large and may be generalizable
- Some outcome measures (re-admission, death) may statistically approximate the linked population outcomes

What Can We Learn in Further Analysis?

- What outcome measures can be credibly estimated when using a matched population?
- How influential are un-matchable confounders (such as hernia size) on our outcome estimates?
- Does using a combination of techniques to estimate outcomes provide a more robust answer or just add confusion?
- How many statistical consults will we need to satisfy the peer-reviewers?
Challenges Beyond Methodology

??? Who owns the data ???

Discussion

- Where do you see these methods being applicable to your work?
- What suggestions do you have for additional ways of utilizing diverse data sets in innovative ways?
- What techniques have you used to address the issues raised in this workshop?
- Have fun at the meeting!
Contact Information

- Rolin Wade
  - rwade@us.imshealth.com
- David Macarios
  - dmacarios@lifecell.com