Data Management

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Disclosures

• None
Objectives

• History of data management in medicine
• Review of data management use in medicine
• UMMC Apheresis database
  – What works
  – What doesn’t work
• Future
Introduction

• Clinical registries will have an increasing role in health-care as information technology is more accessible and there are higher demands for quality improvement

• Registries can be used for quality assessment, research, review productivity, regulatory purposes and more
History of Data Management

• Empirical observations have been around for some time
  – Acute diseases (short periods of time between onset, intervention, and outcome) become case reports, series, etc.
  – Chronic diseases benefit the most from data management

• Impact of the computer
  – Link observations made by many practitioners across long periods of time
  – Narrow as a specific disease or device, broad as the whole medical record

• Exact date of first data entry unknown
  – 1887, NIH with multiple divisions thereafter
  – 1969, Duke databank for Cardiovascular Disease
History of Data Management

• Apheresis registries are more recent
• 1994, The Italian Registry
• 2005, The Italian Pediatric Registry
• 2003, World Apheresis Registry (3 centers, 2 European countries)
• 1993, Swedish Apheresis study group
• 2000, Turkish Registry (single center)
Review: Examples of Successful Data Bases

• The Medical Record (TMR)
  – The most important and thorough document within the delivery of healthcare
  – Tracks course of patients care
  – Communication tool
    • Current, past, future medical history
    • Reviewing and reimbursement of insurance claims
    • Review utilization and quality of care
• Origin: replacing paper chart with computerized record, satisfying needs of practicing physicians
TMR Contents

• Face sheets, encounters for each visit
• Vital Signs
• Physician's orders
• History and Physical, Progress, and Discharge
• List of Medical Problems
• Medication Lists
• Authorization Forms
• Diagnostic and Laboratory Testing
• Reports, Operative and Pathology
TMR Contents

• Documentation (specifics on what to include)
• Legibility (scanned documents)
• Verbiage (NOT “doing well, appeared” etc., too ambiguous)
• Claims reimbursement (medical necessity)
• Correcting errors
• Telephone calls
• Counter-signatures
• Abbreviations (only standard abbreviations should be used)
• Records: retention, release, ownership
  – facility owns record, patient owns information within the record, rights differ between states
• Legal
Review: Examples of Successful Data Bases

• Examples of medical record information systems
  – COSTAR, Regenstrief Medical Record System, HELP, STOR, PROMIS

• Specific data base applications:
  – The Duke Databank for Cardiovascular Disease
  – The Boston Collaborative Drug Surveillance Program (BCDSP)
  – Mayo Clinic Data Base
  – National Heart, Lung, and Blood Institute of percutaneous transluminal coronary angioplasty (NHLBI-PTCA)
UMMC Apheresis Data Base
UMMC Apheresis Data Base

• 2005: informatics student needed a project
• Took our log book
  – Productivity
  – Records for inspectors
  – Statistical purposes
  – Good for recording
  – Bad for query (inefficient and error prone)

Microsoft Access (readily available)
UMMC Apheresis Data Base

• All charting went into data base (2005 through March, 2011)
  – Volumes, access (line v. peripheral)
  – Medications, anticoagulants, blood products (primes, plasma)
  – Reactions (classification)
  – Allergies

• Data entry was time consuming

• March 2011, Epic went live (Epic is not queryable), now using a scaled back version of the data base
**Patient Record - LEDMAN1**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Name:</td>
<td>Patient</td>
</tr>
<tr>
<td>First Name:</td>
<td>Test</td>
</tr>
<tr>
<td>Sex:</td>
<td>Male</td>
</tr>
<tr>
<td>Birthdate:</td>
<td>02/12/1960</td>
</tr>
<tr>
<td>Adult/Ped:</td>
<td>Adult</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
</tr>
</tbody>
</table>

**Course of Therapy Details**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Apheresis Diagnosis:</strong></td>
<td>Myasthenia gravis</td>
</tr>
<tr>
<td>Referring Physician</td>
<td>Day</td>
</tr>
<tr>
<td>Referring Service</td>
<td>Neurology</td>
</tr>
<tr>
<td>Apheresis Physician</td>
<td>Morgan</td>
</tr>
<tr>
<td>Begin Date</td>
<td>01/14/2013</td>
</tr>
<tr>
<td>End Date</td>
<td>01/23/2013</td>
</tr>
<tr>
<td>Number of Procedures</td>
<td>5</td>
</tr>
<tr>
<td>Frequency of Procedures</td>
<td>every other day</td>
</tr>
<tr>
<td>Primary Diagnosis</td>
<td></td>
</tr>
<tr>
<td>Comorbid Conditions</td>
<td>Ace Inhibitors</td>
</tr>
<tr>
<td>Height (cm)</td>
<td></td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td></td>
</tr>
<tr>
<td>Blood Volume (ml)</td>
<td></td>
</tr>
</tbody>
</table>

**Edit Course Data**

- **Save Updates**
- **Add New Course to Record**

**View/Edit Related Data**

- **View Procedure Details**
- **View Outcome Details**

**Record:** 1 of 1
Creating a Query
<table>
<thead>
<tr>
<th>Patient MR</th>
<th>Procedure Date</th>
<th>Comorbid Cond.</th>
<th>NotableEventCode</th>
<th>NotableEventDescr</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>01/17/2005</td>
<td>Ace Inhibitors</td>
<td>Itching</td>
<td></td>
</tr>
<tr>
<td></td>
<td>01/08/2005</td>
<td>Ace Inhibitors</td>
<td>citrate toxicity</td>
<td>tingling in lips and fingers</td>
</tr>
<tr>
<td></td>
<td>01/11/2005</td>
<td>Ace Inhibitors</td>
<td>transfusion reaction</td>
<td>pt. chilled, high HR, temp 100.4, proc stopped</td>
</tr>
<tr>
<td></td>
<td>01/17/2005</td>
<td>Ace Inhibitors</td>
<td>citrate toxicity</td>
<td>slight tingling</td>
</tr>
<tr>
<td></td>
<td>01/27/2005</td>
<td>Ace Inhibitors</td>
<td>Headache</td>
<td></td>
</tr>
<tr>
<td></td>
<td>01/27/2005</td>
<td>Ace Inhibitors</td>
<td>citrate toxicity</td>
<td>slight tingling in hands and feet</td>
</tr>
<tr>
<td></td>
<td>06/02/2005</td>
<td>Ace Inhibitors</td>
<td>Other</td>
<td>GEL-FOAM USED</td>
</tr>
<tr>
<td></td>
<td>06/04/2005</td>
<td>Ace Inhibitors</td>
<td>Other</td>
<td>TOOK 50 MIN FOR HEMOSTASIS</td>
</tr>
<tr>
<td></td>
<td>08/11/2005</td>
<td>Ace Inhibitors</td>
<td>fever</td>
<td>PRE=100.2 F, POST=100.4F</td>
</tr>
<tr>
<td></td>
<td>06/26/2005</td>
<td>Ace Inhibitors</td>
<td>Other</td>
<td>gel-foam used</td>
</tr>
<tr>
<td></td>
<td>06/20/2005</td>
<td>Ace Inhibitors</td>
<td>Other</td>
<td>gel foam used</td>
</tr>
<tr>
<td></td>
<td>09/23/2005</td>
<td>Ace Inhibitors</td>
<td>Other</td>
<td>gel foam used</td>
</tr>
<tr>
<td></td>
<td>09/27/2005</td>
<td>Ace Inhibitors</td>
<td>Other</td>
<td>GEL-FOAM USED</td>
</tr>
</tbody>
</table>
What Works

• Characteristics of most clinical databases

• Information
  – Collected
  – Entered
  – Stored
  – Recalled/Queried (for individuals or groups)
What Works: Data Collection

• Physician and IT work together
  – Which variables collected, how collected, how long they will be collected
  – Decide what types of information you would query to determine what fields you are interested in
  – Make sure you can capture what it is you want
• Danger with too much or too little data (maximum gain/minimum pain)
• Remember: the busier you are, the more data to enter, database can get behind
What Works: Data Collection

• Data bases functions can change
• Two ways to collect clinical information
  – Part of patient care process
    • Broad focus
    • Advantages are prospective, existing quality control, reduced cost
  – Separate data base
    • Narrow focus
    • Focus is not part of the patient care process
What Works

• General demographics
  – MR#, DOB, name, Adult vs. pediatric, sex, diagnosis, requesting physician, requesting service, TM physician initiator, start/stop date, # of procedures, schedule (daily, QOD), comorbidities

• Course of Therapy (COT)
  – Date, procedure, emergent or not, IP or OP, stability, start time and duration, access, instrument, anticoagulant, frequency (sometimes different), blood products
What Doesn’t Work

• Putting everything in (people get too excited at first)
• Avoid free text
  – Difficult to query
  – Takes longer to enter the data
What would be nice

• Adverse events
  – Could rate them 1-5 depending on a scale or non-severe, severe, life-threatening, death, not-determined
  – Imputablity (definite → ruled out, not-determined)
  – # of rxns and X% managed by a nurse per SOP

• Pertinent labs (TTP)
  – Could say platelet count rises by day X
  – Fibrinogen decreases by day X
Future

• Registry data vs. randomized clinical trials (RCT)
• Registry data is gold standard for observational data, but second best to RCT data
• Despite advances in statistical methods, a registry is not a replacement for a well-designed RCT

• RCT
  – Advantages:
    • Confounding variables accounted for by randomization
  – Limitations:
    • Expense and resource requirements to run them
    • Narrow patient cohorts may not reflect general target population
    • Some diseases too rare, prevalence unknown, or change in diagnosis
Registry Data vs. Randomized Clinical Trials (RCT)

- **Registry data**
  - **Advantages:**
    - Reflect common practice and the general target population
    - Can be used to validate or augment RCTs
    - Can be superior for monitoring long-term outcomes that exceed study window of a RCT
    - Can accelerate research for rare diseases
    - Facilitate collaboration and sharing of data
  - **Disadvantages:**
    - Limitations in collection fields means unmeasured confounders and potential selection bias
Future: Record Linkage

• Registry data linked to other data sources
  – Administrative databases
  – Official census records (e.g. Office for National Statistics)
  – National medical council databases (e.g. General Medical Council)

• More research possibilities, but also new legal and ethical challenges (mismatched data and patient ID potential)
Future: Commercial Value

• Registries require resources, infrastructure, and sustained funding for long-term benefits

• Funding:
  – Government budgets
  – Professional societies
  – Local health commissioners
  – Hospital
Conclusion

• Success of a registry:
  – Database completeness
  – Accessibility of information
  – Proven usefulness

• Benefits:
  – Advances in research
  – Improved patient decision making

• Most effective registries combine clinical input and data management expertise
References


