PATIENT REGISTRIES

CLINICAL RESEARCH EDUCATION SERIES

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OBJECTIVES

• Describe Patient (Disease) Registries
• Describe Setup and Maintenance of Registries
• Describe Typical Use and Access of Registries
• Describe Human Subjects Regulations
• Definition of a Patient Registry
  • “Register” a patient
  • Can refer to a list of patients with a common condition
  • Typically includes a collection of secondary data on patients with a common diagnosis
    • The choice of secondary data points can be critical in determining the “usefulness” of a registry
REGISTRY DEVELOPMENT

• Registry design is typically determined by the research question or program goal
  
  • Entry Criteria must be relevant and data points available
  
  • Data points must be pertinent to the topic and anticipate questions that will be asked regarding the population or program
  
  • Examine existing registries for similarities and potential to upscale data

• Provided common definitions are established, registry data is scalable from provider to facility to state or regional levels

  • National Trauma Data Bank pools data from over 697 trauma centers and contains over 5 million records (source NTDB Annual Report 2011, American College of Surgeons)
REGISTRIES

• Patient entry can be voluntary, self registered or abstracted by care providers or staff

• Topics/goals can be widely varied
  • Prosthetics, diagnosis (Stroke, STEMI), condition (Trauma), Characteristics (Twins)
  • Product performance evaluation, program performance, system performance, disease progression research, treatment efficacy…
PROGRAM IMPROVEMENT

- Ideal for monitoring a center of emphasis or population with standardized protocol for care
- Secondary data points can be chosen to evaluate system performance
  - Stroke programs are closely monitored for “door to CT time.”
- Performance reporting can be “automated” to run on a combination of pre-programmed data points
  - ED Length of stay > 2 hours with BP< 90 and ED disposition to the OR
- Ad hoc questions of performance
  - Mortality among patients that receive a thoracotomy in the ED
- Complication rates can be monitored in the chosen population
  - Instances of pneumonia, VTE, mortality…
Program improvement and performance

- Generally raw numbers, no identifiers
- Typical reports may include:
  - Monthly volumes and instances of an injury type
  - Specific procedures performed per month
  - Mechanism of injury
- Monitoring of complications
- Monitoring of outcomes
  - Mortality
  - Discharges to skilled nursing facilities
REGISTRY USE IN RESEARCH

• Often identified or patient identifiable information is provided

• Observation of “real world care”
  • Not protocolized as with RCT’s

• Useful when clinical trials are not practical or ethically possible

• Determination of the natural history of a disease
  • Cancer registries may follow patients that meet prescribed entry criteria for years
  • Long term evaluation of care and disease progression
• Retrospective Analysis
• Population bias
  • These patients are “chosen” based on entry criteria for the registry
• Limited study design based on available data
• Patient confidentiality considerations
  • Human Subjects regulation are specific based on research design and report criteria
  • Is this reasonably identifiable information?
EMS AND TRAUMA SYSTEM DEVELOPMENT

• Vietnam Era development of State Trauma Systems
  • Chicago – Cook County Hospital 1969
  • Illinois State EMS and Trauma System 1971

• Trauma Center Designation/Verification Requirements
  • Clinical, facility, staffing and resource availability requirements
  • Mandated to perform facility based performance evaluation and participate in regional and state wide QI
    • Necessitated the maintenance of facility based trauma registries
    • Required submission of data to a statewide registry for system analysis
  • Injury prevention program requirement
  • Highest level centers are responsible for research to improve the standards of care and practice
EMS AND TRAUMA SYSTEMS

• Systems should monitor all aspects of trauma care
  • Pre-hospital verification
  • Hospital Facility
  • Rehab
  • Research
  • Injury Prevention

• State system analysis
  • What should be collected/monitored?
  • What information would be submitted to state and national levels?
  • How will this data be analyzed and reported back to facilities?
• Facility, State and National reporting structure
  • Ensure common platform
• Fields collected
  • State WAC’s
  • Mandatory reporting to state registry
• Voluntary reporting to national registry data set
• Regional Councils
  • Allows performance information to be shared at a local level based on state analysis
  • Includes evaluation of pre-hospital care and transport
• Monitoring of facility performance
  • Mortality rates among Level I, II and III
  • ED time prior to transfer for Level II-V

• System Level
  • Specialty service coverage in remote regions
    • Do we have enough orthopedic coverage in a given region?
  • Pediatric splenectomy
• Passage of the Trauma Care Systems Act 1990
• First facility designation in 1993
• Pediatric designation in 1995
• State registry submissions
• Entry Criteria
  • Dx ICD-9 800-959.9
  • Admission 48 hours or more
  • All Deaths (that reach the facility)
  • Transfers in or out of the facility
• System/Software
  • Collector – Provided to designated trauma facilities by WA State
  • Other commercially available products are available
• Data fields
  • Common throughout the state
  • Facilities are free to add additional fields as they desire
• Abstraction process
  • Manual
• Link to funding
POTENTIAL FOR 400+ DATA POINTS

• Injury mechanism and location
• Transport/arrival mode
• Transport from scene versus another facility
• Arrival time
• Injuries
• Transfers out of the facility, to where and why
• Movement throughout hospital
• Care providers
• Operations
• Complications
• Outcome/disposition (Home, Rehab, SNF)
• Patient charges
• Funding sources
HARBORVIEW

• Level I adult/pediatric facility
  • 5 facility designation levels in WA State
• Only level I facility for 4 state region
• Obligation to participate/lead program improvement and QI processes
  • Assist with facility and state level QI
• Benchmarking
  • Both regional and national
• Research
HARBORVIEW’S TRAUMA REGISTRY

- Commercial product software - TraumaBase
  - Secure data
  - Password protected
  - Abstraction error checker
  - Potential for electronic downloads from EMR
- Manually abstracted with some downloaded elements
  - 6000 records are abstracted annually
  - Time from patient arrival to registry record completion is approximately 2 months
    - Long delays in record completion impact registry use for effective QI/PI
HARBORVIEW’S TRAUMA REGISTRY

• Expensive
  • 1FTE per 850 records
• National Benchmarking Mandates high level abstractor training and accuracy
  • Inter-rater reliability
  • Abstractor training and competencies
REGISTRY USES AT HMC

• Program Monitoring
• Performance Benchmarking
• Community injury prevention
  • Fireworks, window falls, bicycle helmets, distracted driving, elderly falls
• Community information
  • Sports injuries and return to play recommendations
• Outcome monitoring
REGISTRY USES AT HMC

- Research
  - Frequently involves identified information
- Registry can be used to provide abstracted data on an identified group
- Registry can be used to provide an identified group with a common set of characteristics
- Human Subjects/IRB approval is required for any research use of registry information
  - Requirements may range from informed consent to destruction of any identifiable information after the evaluation is complete
• Initial research questions
  • Requests for general numbers may be processed when evaluating research question but any identified or potentially identifiable data must have IRB approval
NOTABLE RESEARCH

• Using nationally scaled registry data
  • National examination of survival benefit for trauma patients cared for a Designated Trauma Centers vs. Non-Trauma facilities
  • Examination of care of survival benefit for trauma patients cared for at high volume versus low volume trauma centers
    • Nathans, AB; Jurkovich, GJ; Maier, RV; et al, (2001). Relationship between trauma center volume and outcomes, JAMA, 285, 1164-1171
  • Using linked registry information with additional registries (CHARS)
    • Comprehensive Hospital Abstract Reporting System (CHARS)
      • Risk adjusted look at the survival of discharged trauma patients based on location (Home vs. Rehab. vs. SNF)
FUTURE QUESTIONS

• Any number of possibilities!
• Trending mechanism and demographics surrounding injury allows us to identify populations at risk and target injury prevention programs to meet need.
  • Elderly fall victims
    • Increasing population of elderly people being treated with anti-coagulation medication
    • Multiple co-morbidities can lead to high potential for syncope and falls.
  • Prevention strategies
THANK YOU!

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