Using EMR Data: Methods, Epidemiology and Biostat

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Common Research Uses for EMR Data

- Identify cohort for manual chart review
  - Eligibility for randomized trial
  - Case-control or cohort studies
- Large-database epidemiology, long-term outpatient followup
  - Large simple trials, survival
  - Caveat: JHM is NOT a closed system, lousy survival/outcome data, lots of flawed impossible research proposals
- EMR system develop/engineering
  - Forms, decision support modules, .DLL, BPA
  - Profile/improve provider experience/behavior
- Big Data, Machine Learning, Artificial Intelligence, Natural Language Processing

Sipping from the EMR Fire Hose: The Data Minefield

- Junk science is easy
  - Load an Epic report into stat package-- voila!!
  - Ignore all underlying assumptions/confounding/bias, systematic/secular variability, unexplained heterogeneity, coding errors
- Honest solid EMR-based research is hard
  - Manual chart review is easier to design/control
- Force yourself to be cautious, hypervigilant
  - Everyone makes mistakes; good analysts constantly explore the data, re-test, extend, correct.

Don’t Start with Data!! Learn Clinical Workflow—How Data Gets Into EMR

- Visit units/clinics. Befriend senior RNs. Talk to end-users at every level, patient to CMA to attending.
- Learn how each individual data element gets into the system, by site, user, temporal epoch.
- Get screenshots!! Lots!!!
- Don’t re-invent the wheel.
  - Partner with QA/QI analysts, advanced RN projects, Armstrong Institute.
  - Seek out legacy reports/code.

Workflow Data Pitfalls (I)

- Varying usage of same form/data element
  - Site- or unit-specific variability (eg BMC vs JHH)
  - Varying time/scenario for completion (ED vs floor, pre vs post-op)
  - Overloaded operators: Variable usage (eg pre/post-event)
  - Completed variably by different users (triage, RN, CMA, MD)
- Undocumented events
  - CAUTI, CLABSI—lines get slammed in, fall out
- Undocumented knowledge
  - Scanned documents—pharmacogenomics in rheum
  - Ignored sepsis alerts—because sepsis already Dx + Rx

Workflow Data Pitfalls (II)

- Unrecognized dependencies/intercurrent events—timing is critical!!
  - Hgb pre vs. post-transfusion
  - Pain assessment scores interact with narcotic dosing
  - Identifying unbiased events/measures is hard
- Confounding by indication
  - Anemia, transfusion and PCI

EMR Data Quality/Complexity Vastly Complicate Good Research

- Analysis needs static data; EMR is a moving target
  - Data elements constantly re-defined—even labs
    - New assay, analyzer—different code
  - ICD9 coding NOT fairly comparable to ICD10
  - Private vs faculty providers
  - Decision support (CDS/BPAs) constantly evolving
    - Revised triggers, targets, wording, actions

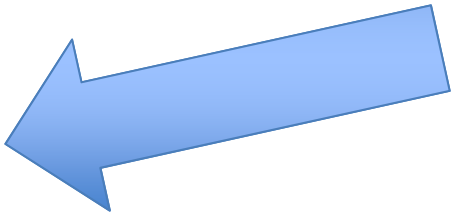
Coding (ICD/CPT) Gotchas

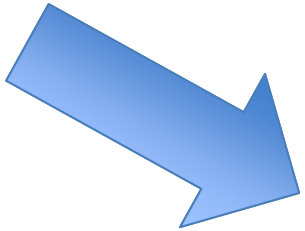
- ICD (Dx/procedure) and CPT (professional fee) codes are key basics, BUT:
- Don’t blindly query for ICD codes
  - Code existence doesn’t mean it’s used (or used accurately)—especially outpatient
  - Always compare to actual DB code frequency
- CPT limitations
  - Won’t capture unbilled house-staff procedures
  - Won’t capture private-physician charges
- Temporal evolution—codes get discontinued/superseded annually

EMR/Epic Data Nuances

- Always expect/test for missing/bad data
  - SQL “group by” query on every variable, by month/year
- Understand/analyze underlying source data structures, not just extract
  - Lab components may have different units, names by site and/or temporal epoch
  - Compound meds have recursive data structure
  - Flowsheets need intermediate data structures/joins
- Don’t blindly rely on orders
  - Orders not always completed, often modified by ancillary (esp radiology, pharmacy), timing uncertain
  - Focus on hard events—med admin, lab results, flowsheets

From DB to Analytic File





Data Cleaning/Management: 90% of Work (Analysis Is Easy!!)

- Use robust database tools that enforce data typing and primary keys, NOT Excel
- Start with separate files—labs, meds, vitals, imaging, whatever
- Use endogenous Epic classes rather than individual identifiers if possible
  - Lab component groups, pharm class and subclass
  - Using specific labels inevitably misses key data
- Carry primary keys throughout data transform steps
- Try multiple methods. Do they get the same cohort/result?
- Annotate code, document the whole ETL (extract-transform-load) process

Methods/Epi/Biostat Considerations

- Bias/confounding ubiquitous in EMR data. Address them.
  - Reviewers are getting smart about data science, shred sloppy work
- Methods section needs to describe in detail data cleaning, inclusion/exclusion criteria, missing data rates
  - Critical flaws typically buried in data cleaning, not fancy stat methods
- Fully describe (with table) excluded patients/observations, with reasons
- Test/prove robustness with multiple methods:
  - Vary propensity criteria, use alternate controls
  - Sensitivity analysis--“what-if” methods
- Don’t focus on AUC (area under curve) or sensitivity/specificity—low bars, no practical utility
  - Use reclassification indexes, predictive value (PPV/NPV), number needed to treat (NNT).

Creating an Flat File For Multivariate Analysis

- Begin by creating a single huge file of every conceivably useful variable; subset later
- Use explicit, defensible selection criteria for 1-to-many possibilities
- Create indicator/dummy variables for context/method/qualifier
  - Who entered data, where, interval (eg pre/post-op, ED/floor), intercurrent events (eg transfusion), datetime intervals
    - Missing data often has meaning; use dummy variables
- Explore/test surrogates for key unmeasured traits—frailty, survivability, nutritional/cognitive status, 6-minute walk
- Don’t use stepwise regression

Cautions

- Don’t use MRN as primary key-unstable
  - Use Epic enterprise id (E-ID) or study ID instead
- Don’t extract large DB directly to flat file
  - No redo capability, no inclusion/exclusion control
- Separate raw and analytic (no PHI) files
  - Calculated intervals, no dates/identifiers
- Beware of lead-time, lag-time and surveillance bias

Notes on Clinical Decision Support (CDS)

CDS cartoon

Be Realistic

- Maintainability
  - Everyone builds custom CDS. No one maintains.
  - If Epic has a reasonable native tool, enterprises will (and should) use that—even if yours is better.
- Bolt-on modules need 2-way data interfaces
  - Develop with Epic Clarity (or DW), not HL7/web services
  - Never use data polling—always event-driven model
  - Plan from the outset to feed real-time data back to Epic (often via hidden flowsheet rows). Systems that hoard data in standalone silos are stillborn.

User-Centric CDS Design

- Pop-ups are by definition bad decision support
  - Better to have users do things right the first time
  - Embed in-line CDS in workflow—relevant results, defaults, decision trees
- Generic “be careful” or “consider” guidance is useless (and annoying)
  - CDS needs to provide specific, transparent actions, links, buttons, ordersets
- Don’t expect users to enter data