Data Analytics and Methodological Review of a Research Study for COPD Patients at Atrium Health

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Clinical trials.gov, Study ID: NCT03207776
Objectives

- Why conduct research in a healthcare setting

- Review an Institutional Review Board approved research study aimed at decreasing post-hospitalization acute care encounters for patients admitted with an AECOPD

- Discuss software and accessing electronic medical record data, the iterative process of interfacing with clients and changing requirements, scaling reporting, and the process of disseminating results
Size and Scope of Atrium Health

- 25+ cancer locations
- 28+ urgent care locations
- 65,000+ teammates
- 47 hospitals across three states
- 35 emergency departments, including freestanding
- $9.03 billion net operating revenue
- 8,700+ licensed beds
- 6.5% population growth in Charlotte region

Atrium Health
Population health is defined as:

- **the health outcomes of a group of individuals**
- **including the distribution outcomes within the group.**
Changing healthcare environment... Value

Triple Aim

1. Improved patient experience
2. Reduced cost
3. Improved population health

Source: Institute for Healthcare Improvement
Pragmatic Trials

- Fit seamlessly with care delivery
- Real-world applicability
- Leverage existing data
- Compare effects: A | B
- Very few exclusions for patients to be in study

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Before we act...

- Define question/hypothesis & outcome(s)
- Look at the existing evidence
- Apply rigorous evaluation methods
- Measure the good, the bad, and unintended
- Continuously adapt based on lessons learned
- Disseminate → contribute to the science

Defined by Institute of Medicine 2015
Defining the question/hypothesis & outcome(s)

• Offer consistent treatment to COPD patients and reduce post discharge utilization

• Meet with leaders to specify the population we’re targeting

• COPD patients
  • Daily patient list and identification post discharge from billing

• Details around the implementation of the clinical pathway,
  • Explicitly defining the intervention. All the care a patient with COPD should receive from time of admission to post discharge

• Defining the outcome
  • 60 day all cause, unplanned utilization – assess using a mixed model
Evaluation Methods

• Develop a protocol
  • Signed off by leadership and the research team

• Submit an intent to do research application to the IRB
  • Pull historical data for a power calculation

• Submit an application to the IRB

• Begin developing code to pull data
# Project Management

<table>
<thead>
<tr>
<th>Key Responsibilities</th>
<th>Critical Resources</th>
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<tbody>
<tr>
<td>• Coordination of multidisciplinary collaborations</td>
<td>• Bread and butter tools of PMing</td>
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<tr>
<td>• Focus on timelines, milestones and executing deliverables</td>
<td>• Business Case ~ Intake request</td>
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<td>• Reducing administrative burden</td>
<td>• Timeline (GANTT charts)</td>
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<tr>
<td>• Project Managers with research experience and <em>niche</em> expertise</td>
<td>• Project Charter</td>
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<td></td>
<td>• Other org. documents</td>
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<td>• Communicating with judgement</td>
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## Regulatory Affairs & Compliance

- Ethical and Feasible review~ IRB (ongoing)
- Reporting to responsible parties
- The *essence of trust*
- Other federal, state, and local reqs.

## Financials

- Budget development
- Contract negotiation and review (where applicable)
- Monitoring financials
• Jack of all trades, but master of some

• ‘Don’t project manage to death’

• Flexibility

• Value Add effort vs. Waste
  • Busy work

  • The allure of over-organization

  • Standard documents, processes, and tools
Statistical Analysis Plan

• Statistical Method: Mixed Effects Model

• Measures:
  o Dependent Var: 60 day acute care utilization
  o Independent Variable:
    ✓ Fixed Effects: Time and Intervention
    ✓ Random Effect: Utilization after intervention (slope effect)

• Model Variance accounted for participants nested in facilities
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Power Calculation

- Due to varying Cluster Size, we added 25%
- 74 patients per hospital every 2 months

*\(D\) = Difference in utilization between intervention and control period
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Dissemination of results

• Publishing results in a scientific journal

• Sharing results with key stakeholders and study team

• Presenting results at grand rounds and national conferences
Accessing data

- Compliance training

- Submitting business case for approval

- Software:
  - SAS, Aginity Workbench, and BusinessObjects

- Databases:
  - Netezza, Oracle, and REDCap
Healthcare data

• Sources:
  • Cerner, Epic, STAR, IDX, and others

• Clinical data:
  • Real time and historical data from the electronic medical record

• Billing data:
  • Historical data on claims
Interfacing with key stakeholders

• Gathering requirements

• Develop code and validate findings

• Share progress and finalize requirements

• Communicate updates and share deliverable
Creating a scalable data process

- Understanding requirements and desired output (dataset, email, etc.)

- Developing code and validating results

- Utilizing loops and user defined variables

- Maintenance of the process including error handling
Data Management support for COPD study

• Daily patient lists to ensure pathway compliance

• Daily, weekly and monthly reports across 8 facilities

• Maintenance of processes

• Preparing dataset for the final statistical analysis
Initial requirements – daily patient lists

• Requirements:
  • Identify all patients that met criteria
  • Daily patient list with 3 tabs
  • Ability to add and remove clinicians from report
  • Receive report via email and directory pathway
Desired views – daily patient lists

- Active patients – 18 variables

- Discharged patients – 15 variables

- Report – 5 counts by 4 patient status types:
Data sourcing – daily patient lists

• Identify patients through pre-existing report
  • Had to submit business case for credentials

• Clinical data sources:
  • Oracle and Netezza databases

• Utilizing SAS for data processing

• Managing shared drive folders where study files are stored
Developing process – daily patient lists

- Types of output (datasets, emails, and Excel files)

- Defining common variables and pathways for macro variables

- Writing code and validating results to identify patient population

- Focusing on 1 facility – then scaling across facilities
Updated requirements – daily patient lists

• Updated requirements:
  • Integrating clinician feedback to remove patients from list
  • Renaming variable names within output files

• Repurpose shared drives to include a file to remove patients
  • Added a unique id in the patient lists
  • Clinician adds unique id to file to remove patients
  • SAS would check this file during every execution for new records

• Scheduling code in production environment
Maintaining process – daily patient lists

• Including additional facilities as the study progresses

• Providing support to over 100+ clinicians

• Investigating and resolving process failures:
  • Server and database availability
• We covered the design of an IRB study in a healthcare setting

• We explored challenges and solutions of utilizing electronic medical record data

• We shared the iterative process of interfacing with clients and changing requirements, scaling reporting, and the process of disseminating results

• The processes discussed reflect a shifting approach to evaluate quality improvement initiatives through randomized trials
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Questions