How to use research to improve your hospice performance improvement projects

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Disclosures

• Consulting fees from Merck & Co., Inc. and Shionogi, Inc.
• Research grants from Merck & Co., Inc.

• Nothing relevant to this presentation.
Session Description

• Every hospice is supposed to have at least one “Performance Improvement Project” (PIP) as part of their ongoing Quality Improvement activities. Many hospices have several PIPs going at once. Some hospice and palliative care programs struggle with the how to interpret results or may ask “What do I do with this information?”. This session will review
  • how to create PIPs,
  • how to collect the data
  • make it useful for comparisons with research data.

• The session will assist programs in determining how to ask the right questions when collecting data about present performance to facilitate using the results for comparative/benchmarking purposes.
Session Objectives

- Attendees will review hospice requirements to meet the CMS Hospice Conditions of Participation for Performance Improvement projects.
- Attendees will be able to identify how to design data collection tools to facilitate the use of their data in benchmarking and how to assess for “measurable progress” as required by the COPs.
- Attendees will be able to identify how to employ research methods to strengthen the conclusions from quality improvement projects.
Outline

• Review CMS Hospice PIP Requirements
• Key principles in the conduct of clinical research
• Quick Review of Epidemiologic Study Designs
  • Quasi-experimental Studies
  • Mixed Methods
• Statistical Considerations
  • Absolute versus Relative Differences
  • Statistical Power
• Practical Tips (Plan, Do, Check, Act)
• PCRC
CMS Requirements (§418.58(d))

• Beginning February 2, 2009, hospices must develop, implement, and evaluate performance improvement projects.

• §418.58(d)(1) - The number and scope of distinct performance improvement projects conducted annually, based on the needs of the hospice’s population and internal organizational needs, must reflect the scope, complexity, and past performance of the hospice's services and operations.

• §418.58(d)(2) - The hospice must document what performance improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

Interpretive Guidelines

• There is no requirement for hospices to conduct a specific number of performance improvement projects. They must select the number and topics of projects based on the results of their quality monitoring and other quality information such as the results of State or accreditation surveys. Performance improvement projects must be documented in written form and include the elements outlined in the standard.

• Procedures and Probes §418.58(d)(2)

• Do the number and scope of performance improvement projects conducted by the hospice accurately reflect the scope, complexity and past performance of the hospice? Are all performance improvement projects appropriately documented?
Choosing PIP topics

• Hospice scope, complexity, past performance
• Based on quality monitoring and/or results of State or accreditation surveys

• High-risk, high-volume, or problem-prone areas
• Processes that affect patient or caregiver outcomes, patient safety, and quality of care

• Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospice.
Hospice must document

• What performance improvement projects are being conducted

• Reasons for conducting these project

• Measurable progress achieved on these projects
Hospice Item Set (HIS) Quality Metrics

- Patients treated with an opioid who are given/offered a bowel regimen
- Pain assessment
- Dyspnea screening
- Dyspnea treatment
- Preferences for life sustaining treatments
- Spiritual/religious beliefs/concerns addressed
- Hospice visits when death is imminent

CAHPS® Hospice Survey Metrics

• Communication with family
• Getting timely help
• Treating patient with respect
• Emotional and spiritual support
• Help for pain and symptoms
• Training family to care for patient
• Hospice rating/willing to recommend

Hot topics

• Staff burnout
• Burdensome transitions to hospital, ED
• Caregiver support
• Adverse events (e.g. medication errors, falls)
Key principles in the conduct of clinical research
Research

- Rigorous methodological investigation to test a hypothesis or answer a question

- Important to be question-driven and not methods-driven
Underlying goals of research

• Identify and quantify causal relationships
  • Causal inference

• Collect information that can be applied to other patients and healthcare systems
  • Generalizability
Why apply research methods to PIPs?

• Advantages of incorporating research methods
  • More convincing data
    • Better ability to attribute changes to interventions
    • Better able to identify areas of high/low performance
    • Support cost output by showing ROI
  • Reproducibility
    • Present/publish methods and results to help improve healthcare quality beyond program
      • Greater recognition for your efforts and hospice program!
Terminology

• “Outcome”
  • Project’s outcome of interest
    • May be a process measure, assessment of time expenditure, quantity of wasted medications, etc.

• “Intervention”
  • The process, program, policy, etc. being evaluated

• “Control”
  • Data being used for comparison

• “Observed effect”
  • The improvement made in the outcome or measured change in the outcome
Study Validity

Hospice Program
[Reference Population]

Data for Evaluation
[Study Sample]

Intervention data

Control data

Generalizability
(External validity)

Internal Validity

Adapted from Gordis Epidemiology 2nd ed.
Internal Validity

• Are observed effects truly due to the intervention of interest
  • Determined through assessments of threats
  • Study has high internal validity when there are few or low magnitude threats to internal validity
Generalizability

• How much can the conclusions be extended beyond the sample/target population
  • Dependent upon internal validity
    • Study conclusions can only be generalized to other populations if they are believed to be internally valid
Threats to Internal Validity

1. Was the study large enough?
   • Could observed effects be due to chance?

2. Was the observed effect due to something other than the intervention?
   • Due to confounding?
Threats to Internal Validity

3. Could the observed effects be due to how we selected the data for comparison?
   • Is there some systematic difference that may lead us to see an effect that is not there?
     • **Systematic bias**

4. Was the outcome measured accurately and precisely?
   • Could errors in data measurement be responsible for the observed effect?
     • **Information bias**
Assessing Generalizability

• Based upon the patient population, healthcare model, etc., in which the intervention was deployed, would the same results be expected if the intervention were deployed elsewhere?

• Would the same effects occur/continue in the future?
Understanding your Research Question

• Distill your project down to a research question and hypothesis

• Design your study to answer that question
  • Think about the optimal (i.e. most powerful, minimally-biased) study design
  • Then determine what you can do with your available resources
  • Knowing the difference between the optimal design and your design (and how these differences may affect your observed results) will aid in interpretation of your results
Hypothesis

- Precise, testable statement regarding the relationship between your exposure(s) and outcome(s) of interest

- Key variables, which should be explicitly defined
  - Population
  - Exposure (often an intervention)
  - Outcome
  - Comparison
  - Direction
Hypothesis: Population

- Patient or provider population that you plan to study
- Demographics
  - Age, sex
- Key inclusion criteria
  - Disease state (e.g. cancer pts, pts with positive blood cultures)
  - Home versus inpatient hospice
- Sampling Strategy
  - How are you go to identify these patients (diagnosis code, lab value, etc)
  - Time frame
Hypothesis: Exposure

- Usually treatment or intervention
- But could be any variable of interest

- Must be able to clearly differentiate between exposed versus unexposed subjects

- Misclassification by exposure status
  - Usually dilutes observed effect of the exposure
Exposure: Examples

• Posaconazole formulation (tablet versus suspension)

• Guideline-concordant empiric antibiotic therapy for intra-abdominal infections

• Informatics alert for increased risk for opioid overdose
Process measures versus outcome measures

• Many studies often look at process measures in addition to or instead of outcome measures.

• Study on the effect of an intervention on prenatal mortality.

• Process measures
  • Percent of mothers receiving prenatal care prior to 12 weeks gestation
  • Percent of mothers taking prenatal vitamins
  • Percent of smoking mothers counseled to quit

• Outcome measures
  • Neonatal mortality rate
  • Pre-maturity rate
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Hypothesis: Comparison and Direction

• Be specific about your comparison group
  • Is it just patients lacking of exposure of interest
  • More specific patient group
  • Pre-intervention group

• You should decide \textit{a priori} whether your exposure of interest will be associated with increased or decreased risk of your outcome
Measurement of exposures and outcomes (and key confounders)

• Explicitly define

• Type of data:
  • Categorical or Discrete (Ordinal and Nominal)
  • Continuous

• Data Source
  • Electronic health record data
    • Discrete fields
    • Qualitative abstraction of notes

• Time of measurement
Types of Data

• Data type for key variables may already be determined for you based on available data

• If not, choose wisely based on biological plausibility, clinical utility, or ease of interpretation

• Age:
  • Continuous (mean age)
  • Categorical (<65 versus 65+)
Types of Data: Example

Continuous

Ordinal

Nominal

Less Information

Systolic blood pressure
145 mmHg

Blood pressure
Normal (SBP <120)
Prehypertension (120-139)
Stage 1 (140-159)
Stage 2 (>160)

Hypertension?
1=yes
0=no
Hypothesis Example

• Research question: What characteristics are associated with receiving antithrombotic therapy on discharge to hospice care?

• Study Population: Adult (age ≥18 years) patients discharged directly from OHSU to hospice care between January 1, 2011 and December 31, 2014.

• Primary Exposures: History of cancer, stroke, or atrial fibrillation (defined using discharge diagnosis codes) or receiving active treatment for DVT/PE on the index admission (defined as antithrombotic medications and a new diagnosis code for DVT/PE) in patients’ EPIC electronic medical records.
Hypothesis Example (cont’d)

• Primary Outcome: Outpatient prescription for antithrombotic therapy (e.g. warfarin, heparin, low molecular weight heparin, clopidogrel, ticlopidine, prasugrel, ticagrelor, cangrelor, direct thrombin inhibitors (Argatroban, Bivalirudin, Dabigatran), Xa inhibitors (Idraparinux, Idrabiotaparinux, Rivaroxaban), Apixaban, Edoxaban, Otamixaban, or aspirin) in the patient’s discharge summary.

• Hypothesis: Among adult (age ≥18 years) patients discharged directly from OHSU to hospice care between January 1, 2011 and December 31, 2014, patients with a history of cancer, stroke, or atrial fibrillation, or patients receiving active treatment for DVT/PE treatment on the index admission, will be more likely to receive an outpatient prescription for antithrombotic therapy compared to patients without these exposures.
Types of Epidemiologic Study Designs

• Observational
  • Cross-sectional Studies
  • Case-control Studies
  • Cohort Studies (Retrospective and Prospective)

• Experimental
  • Randomized controlled trials

• Quasi-Experimental Studies

• Mixed methods
Quasi-Experimental Studies

• Interventional studies in which the intervention is not randomized

• Sometimes called before-after or pretest-posttest studies

• Used when logistically difficult or unethical to randomize patients to an intervention
  • Quality Improvement projects
  • Infection control or informatics interventions
Key Aspects of Quasi-Experimental studies

• Intervention=Exposure

• Number of before (pretest) measurements can vary from 0 to many

• Strategies to improve inferences from quasi-experimental studies
  • Non-equivalent dependent variables
  • Non-equivalent control groups
  • If no changes in these variables/groups post intervention, supports that effects on outcomes of interest were due to intervention
Example: Design Options

- Intervention: Computerized decision support system to improve antibiotic prescribing
- Posttest (no pretest)
- Pretest-Posttest
- Multiple Pretests or Posttests
- Non-equivalent dependent variable: analgesic prescribing
- Non-equivalent control group: unit not using the system
Quasi-experimental studies: Common Pitfalls

• Lack of randomization can result in confounding

• Different measurement of outcomes and confounders before and after intervention

• Regression to the mean: extreme values tend to come back to normal on their own

• Maturation: natural changes that occur over time
Mixed Methods

• Studies that use of both qualitative and quantitative methods to answer complex questions

• Qualitative
  • Interviews or focus groups with key stakeholders
  • Hypothesis generating
  • Do not utilize statistics

• Quantitative
  • Numerical data from survey, clinical repositories, etc
  • Hypothesis testing
  • Summarized and analyzed using statistics
Mixed Methods Designs

• Sequential
  • Explanatory
  • Exploratory
  • Transformative

• Concurrent
  • Triangulation
  • Nested (Embedded)
  • Transformative

Interpreting your results: Absolute versus relative differences

- Very different data can yield the same results

<table>
<thead>
<tr>
<th>Incidence of Outcome</th>
<th>Absolute Difference</th>
<th>Relative Difference</th>
<th>Relative Risk</th>
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<tr>
<td>Group A</td>
<td>Group B</td>
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<tr>
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<td>.1%</td>
<td>.1%</td>
<td>50%</td>
</tr>
</tbody>
</table>
Statistical Power

- Based on hypothesis testing

- Null hypothesis is that there is no difference in outcomes between comparison groups
  - No difference in treatment outcomes (%) between Drugs A and B
  - No difference in staff burnout (e.g. before and after intervention)
Statistical Power

• Ability to observe (or detect) statistically significant differences when they occur

• Statistically this means your ability to reject the null hypothesis when it is false

• When you have a non-significant p-value (usu. <0.05), there either could really be no difference or you could be “underpowered” to see the difference

• Not rejecting the null hypothesis when the null hypothesis is false is called Type II error
When performing a power calculation:

• Really calculating
  • Number of subjects needed to observe a statistically significant difference
  OR
  • Given a number of subjects, what is the smallest statistically significant difference (effect size) that I’ll be able to detect

• Statistical significance ≠ clinical significance
Strategies and Tips
Plan-Do-Act-Check

- The research strategies to be discussed complement existing QI strategies
- Forethought and organization is key in all steps

“Learn from the mistakes of others. You can never live long enough to make them all yourself.”

Groucho Marx
Planning

• Review the literature
  • Support the development of your intervention with other success stories
  • Identify if others could learn from your project
    • Would disseminating your work provide a model for other institutions?
      • Would it lead to improved or more efficient healthcare for patients?

• Provide more global context for your work
  • Background for future presentations/publications
Planning

• Consider IRB/Ethics board approval
  • If your project is human subjects based
    • Includes data collected as part of patient healthcare
  • Need approval prior to disseminating
  • Level of oversight varies by program/health system
  • A letter documenting your compliance with HIPAA and institutional policies is best
Planning

• Think *now* about how you will evaluate to avoid future headaches
  • What are you trying to impact/change
    • How will you measure it
    • What do you expect to see?
  • What do you need to demonstrate to convince your director/C-suite
Planning

• If you hadn’t implemented your intervention what would your outcome look like?
  • What would the medication error rate be? Amount of wasted medication? Compliance with medication reconciliation? Costs?

• Use control data to assess impact of intervention on outcome by comparing intervention data to control data
Planning: Control

• Many different options for control data
• To select best/most appropriate control consider:
  • Characteristics of the intervention and control
  • Available data and timeframe
  • Desired ROI
Planning: Control

• Before and After comparisons
  • Typically most readily available data
  • Whenever possible investigate time trends

![Graph showing medication error rate over time](image)
Planning: Control

• Will your intervention be rolled out/phased in?
  • Consider rolling out intervention thoughtfully to allow for intermediate comparisons
Planning: Control

• Non-dependent outcome
  • Another variable that would be unaffected by intervention, but would be affected by other outside forces that would affect your outcome of interest
  • Ex: Antimicrobial stewardship intervention to reduce vancomycin utilization
    • Non-dependent outcome: piperacillin-tazobactam
Planning: Control

• What to do in lieu of control?
  • *A priori* goals and targets
  • Assess frequency goals are achieved
    • Monthly/Quarterly basis
    • Is the effect sustained?
Planning: Control

• What happens if your intervention is revoked/not sustained?
  • Can compare intervention and removed intervention period
    • If intervention was beneficial, expect worsened outcomes after removal
    • Note that some intervention have sustained impacts
      • E.g. effects of an educational campaign
Planning: Data Collection

• Data Collection
  • What are your sources of data?
  • Ensure you have what you need
    • Or plan for an alternate strategy
  • Be sure data are in a format you can work with
Planning: Data Collection

• Plan your data collection
  • To minimize data management
    • To minimize headaches and problems during analysis

• If you have to merge data
  • Be sure to collect primary key fields necessary

• If you have to collect your own data
  • Be systematic & document
    • Data dictionary
  • Use consistent data formats
    • Keep numbers as only numbers
    • Use consistent categorization
Planning: Data Analysis

• Plan ahead for desired data analysis and presentation
• Can best prepare if you anticipate your needs
Planning: Data Analysis

- Create mock data tables and graphs

<table>
<thead>
<tr>
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<th>2012</th>
<th>2013</th>
<th>T-test p-value</th>
</tr>
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<tbody>
<tr>
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<td>Mean (SD)</td>
<td>P&lt;0.05</td>
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<td>Gen Surg</td>
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<td>Hem/Onc</td>
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<td>Critical Care</td>
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<tr>
<td>Pip/Tazo DDD</td>
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<td>Mean (SD)</td>
<td>P&gt;0.05</td>
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</tbody>
</table>
Doing

- Documentation is key
  - Describe intervention in sufficient detail to allow for reproducibility
    - Engagement
    - Training
    - Audit/Feedback
  - Track intervention deployment/roll-out dates/locations
    - Supports evaluation efforts
  - Track concurrent events that may impact outcome
    - Drug shortages, policy changes, opening of a new hospital wing, etc.
Checking

• Explore the data
  • Logic checks
  • Unanticipated effects
  • Data cleaning

• Enact the analysis plan
  • Summarize data
  • Use graphics
  • Perform statistical comparisons
Checking

• Summarize project results
  • Outlay for intervention
    • Cost, time, etc.
  • ROI
    • Effect size: Change in DDD, Cost savings, etc.
• Projections for future
Acting

• Decision making is up to you, Hospice Director, C-suite
• Well thought out P-D-C will provide strong evidence to support decision making
• Your decision making is your interpretation of data
  • This is of value to others
Dissemination of results
Dissemination

- Multiple options
  - Presentation at regional hospice and palliative medicine/nursing meetings
  - Company newsletter
  - Presentation at national professional meetings
    - Hospice and palliative medicine/nursing
    - Geriatrics
    - Quality
- Publication
  - Hospice and palliative medicine/nursing or quality literature
Dissemination

Professional Societies
• American Association Hospice and Palliative Medicine (AAHPM)
• Hospice and Palliative Nurses Association (HPNA)
• American Geriatrics Society (AGS)
• National Association for Healthcare Quality (NAHQ)
• Pharmacy Quality Alliance (PQA)
• .....
Dissemination

Journals

• Journal of Hospice and Palliative Medicine
• Journal of Palliative Medicine
• Journal of the Hospice and Palliative Nurses Association
• American Journal of Medical Quality
• Journal for Healthcare Quality
• Quality & Safety in Healthcare
Palliative Care Research Cooperative Group (PCRC)

- Become a member
- Annual Meeting (February in Denver)
- Methodological Cores and Centers
- Investigator development center
- Training videos

https://palliativecareresearch.org/
“Research Issues in Multi-Morbidity and Advanced Illness”

Host: Mike Steinman, MD will be leading the October webinar, titled: Research Issues in Multi-Morbidity and Advanced Illness. Dr. Steinman is Professor of Medicine, Co-Director for Research, Director of Research Training, and T32 research fellowship director for the Division of Geriatrics at the University of California, San Francisco.

When: Monday, October 22nd, 2018 at 3:00pm Eastern Time

https://palliativecareresearch.org/
Resources

• ASHP Quality Improvement Resource Center
  • http://www.ashp.org/menu/PracticePolicy/ResourceCenters/QII.aspx

• AHRQ Quality and Patient Safety

• Davidoff et al. Publication guidelines for quality improvement studies in healthcare: evolution of the SQUIRE project. BMJ 2009; 338: a3152


• Health Care Association of NJ PIP Template


• Palliative Care Research Cooperative Group (PCRC) https://palliativecareresearch.org/

• Free statistical tools
  • www.openepi.com
    • Online statistical calculator
  • PS: Power and Sample Size Calculation (biostat.mc.vanderbilt.edu/wiki/Main/PowerSampleSize)
    • Free download of power/sample size calculation program
  • Epi Info (www.cdc.gov/epiinfo/)
    • Free download of statistics program from CDC
Acknowledgements

- Brie Noble
- Jessina McGregor
- Erik Fromme
- Jennifer Tjia
- Seiko Izumi