Epidemiological-based ROI in Disease Management: Case Studies

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Wilson Research, LLC
Bringing epidemiology to the business of health careSM
Disclosures

- Analyses based on patent pending Trajectory® system
- Study Design numbering from “Framework for Assessing Causality in Disease Management” (MacDowell and Wilson): 2002 Disease Management Association of America.
- Theory from book proposal entitled “The Epidemiology of Value™.”

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Organization

I) Pragmatic Epidemiology
II) Pre-Post Design: Problems
III) Follow-up Design: Practical Solution
IV) Case Studies
   A Perfect World: Case Study #1
   An Imperfect World: Case Study #2
   ROI in a Perfect or Imperfect World: Case Study #3
V) Recap & Implications
I: Pragmatic Epidemiology: Principles of Assessing Impact of Disease Management

- Definition
- Measuring Value and Impact.
Pragmatic Epidemiology: 
*Epidemiology of Value™*

The *scientific* study of the distribution and determinants of health-related *value* in defined populations, and the application of this study to the control of health-related *value* problems.
“Value”: Operational Definition
Person/Population

* Ideal Target: Can be hit using Pragmatic Epidemiology Tools
IMPACT

The Difference between the Intervention Group and the Reference Group

Administrative Incidence (TM)

Percentage in Stratosphere (TH)

Impact

Patient Time Segments (30 days)

Reference (Expected)

Intervention (Actual)

Based on patent pending Trajectory® algorithms

*Assuming equivalence
But where did that “expected” black line come from?

or...

How do we credibly determine the “expected”?

and...

How valid is the “expected”?
Let’s start with a Question

What would have happened to the DM population in the absence of the DM intervention?

KEY ANSWER: A “REFERENCE GROUP” IS NECESSARY.

... but there is more.
Key Study Designs

I. Post-Only (no reference)
II. Benchmark
III. Quasi-experimental

Pre-Post Type Design: Discussed Today

IV. Ecological
V. Cross-Sectional
VI. Case-Control
VII. Follow-up / Cohort

Observational: Discussed Today

EQUIVALENCE

Disease Management Population

Equivalence?  At beginning | throughout

... Except for the Intervention

Reference Population

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Classic Pre-Post
(Patient as their own control)

- **Characteristic:** The pre-period (e.g. last year) is used as a reference group for the post-period.

- **The key question (among many others) is:**

  *Is the pre-period a good indication of the experience in the post period in the absence of the intervention?*
Thus, in a properly conducted pre-post study, any change detected in metrics in the post-intervention period could, arguably, be attributed to the DM intervention.
**Pre-Post Design:**

*Past is NOT Prologue:* A Situation where equivalence is not achieved (if you’re Red or Green)

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**Spurious Progression:** Measured at low end of cycle in pre period and high end in post period

**Spurious Regression:** Measured at high end of cycle in pre period and low end in post period.
Pre-Post Design:
*Past is NOT Prologue:* One Situation where equivalence is not achieved

Not a good situation to conduct a pre-post design unless you are aware of this trend and take it into account in your results.
“Past is Prologue”

Two Situations where equivalence is achieved (as long as you are aware of it)

Pre-Period

“Post-Period”

without intervention

Progression

Regression

Sickness

Sickness
Patients as Their Own Control: Averages vs. Medians*

*The difference in outcomes is due to skewness of distribution of cost variable.
Regression-Discontinuity Design:
“Smart” Variation to Pre-Post

- Characteristic: Pre-Post change in low risk compared to pre-post change in high risk.
  *(Graphical representation to follow.)*
Regression-Discontinuity Design
Pre-Post change in low risk compared to pre-post change in high risk

Illustration of the Regression-Discontinuity Design

Reference Population

Intervention Population

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Regression-Discontinuity Design

Equivalence Assumption: Is it true?

Equivalence Assumption of the Regression-Discontinuity Design

Reference Population

Intervention Population

Assumption: Change here

Related in a to change here (in a linear fashion)

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Time-Series Design: Another Variation to Pre-Post

- **Characteristic:** Multiple pre and multiple post measures.
Time Series:
Example where equivalence assumption is problematic
Pre-Post Study Conclusion

- The model does not take into account the “natural history of disease”

- It makes the potentially inaccurate assumption that “past is prologue” (i.e., that the past period is equivalent to the post period without the intervention.)

- IS THERE A BETTER WAY WITHOUT SPENDING LOTS OF MONEY ON A PERFECTLY DESIGNED AND EXECUTED RANDOMIZED CONTROL TRIAL?

- YES!
Observational Follow-up study
Where population(s) serves as a reference

- This takes into account the natural history of disease in populations.
- The study design is “population-based;” it does not use the “patient as their own control”
- The model is based upon epidemiological / public health theory.
  - Reduce the incidence and prevalent burden.
    - Incidence burden: Fewer people, Lower costs
    - Prevalence burden: Shorter duration, Lower costs.

- The assumption (that can be tested) is that population pattern of costs among people with a disease over time is constant (can be a prior or concurrent period)
Pragmatic Epidemiological Thinking: Classic “Incidence” & “Prevalence”

Introducing a new concept invented for managed care: “Administrative Incidence™”

- Onset
- Diagnosis / Official Incidence
- Irreversible Disease
- Time (t)
- Prevalence (Duration of Incident Case)

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Undeniable Goals of Population Management

1) Reduce *Onset*
   - How?
     - Modification of Health Risks at Environmental, Social, and Individual Level. NOT DISCUSSED HERE.

2) Reduce *Incidence burden*
   - How?
     - Change proportion of new cases in a defined population
     - Change clinical and/or financial cost of an incident case

3) Reduce *Prevalence burden (i.e. “duration”)*
   - How?
     - Change the duration of a case in a defined population
     - Change the clinical and/or financial cost of an prevalent case
Methods:

- **Data sources:** Wilson Research/Trajectory® Benchmark database

  - Use of patent pending software to transform claims-line data set to
    - (a) **person calendar time-based data system of defined populations.**
    - (b) **person cohort time-based data system of defined populations.**

- Application of epidemiological methods to assess relationships between risk factors.

- For this demonstration, all individuals were continuously enrolled for one entire calendar year period (other applications will not employ this assumption as “lost-to-follow-up is an extremely important economic and clinical issue”).

- **KEY ISSUE:** Dealing with the “lag” time between “official incidence” and “administrative incidence™”
The Design in a Perfect World: Case Study #1

"Incidence" of 124 in One Calendar Year
(12 month continuous enrollment)

CCS 124 = Appendicitis
Incident Month: First Indication of 124 Diagnoses (12 month continuous enrollment)
This trend from 1st 30 days to 2nd 30 days was virtually the same for “incident” cases for all the remaining 10 calendar months.
We will make the defensible assumption that the overall patient-time trend is a good “prediction” of the experience a current population would have in the absence of an intervention.

To put it another way, we have “taken into account” the confounding potential of incidence distribution over calendar time. The “administrative incidence” is a perfect organizing principle.

The next slide shows the overall trend (retrospective and prospective) from incidence, in patient-time for the “pre” period. Thus, in this situation a pre-post study design could work extremely well.
Retrospective | Prospective: Percent of 124s Surpassing Threshold.
Management

- **When do we intervene?**
  - *The empirical data suggests that the intervention should occur during the incident time segment.*

- **What do we do?**
  1. **Try and reduce costs in incident month**
  2. **Intervention Option #1:** Incorporate practice guidelines and “evidence-based medicine”
  3. **Intervention Option #2:** Use epidemiological tools and determine how one sub-set of the population is different ON ACTIONABLE RISK FACTORS from another sub-set.

  *“Empirical-based management”*
Empirically-based management: How do these populations differ at different points in cohort or patient time on actionable risk factors (e.g. medication compliance, type of provider, etc.?)
"Incidence" of 128 in One Calendar Year
(12 month continuous enrollment)
Incident Month: First Indication of 128 Diagnoses (12 month continuous enrollment)
It appears that the administrative incident™ cases from the early part of the year were different from the administrative incident™ cases from the latter part of the year. We could assume that many of the 1st 6 month cases were diagnosed in the prior year, while the last 6 month cases were newly diagnosed, i.e. true "incident" cases from a clinical point-of-view..
Evaluation Design

- The Administrative Incidence™ Rate is not evenly distributed
- Cohort Time Trends differ depending on Calendar Time Segment
- Thus, the use of a pre-post design may be difficult to justify, unless we “adjust”
- Thus, we stratify the pre population by this “time of administrative incidence” to “adjust” for the potential confounding of this variable.
- The comparison of the post population must be similarly stratified.
- Thus, the next chart shows the stratified retrospective and prospective trends from time of administrative incidence.
Percent of 128 Population Surpassing Threshold Per 30 Day Patient Time Segment (Stratified by Calendar Date of Incident Event)

Retrospective | Prospective from Incident Date of First Diagnosis

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Management

- **When do we intervene?**
  - *Don’t know*: We could do before, during, or after incident month. Commonly, these cases are managed after the incident month, but there may be other “times” in which intervention would be successful.

- **What do we do?**
  - Follow practice guidelines
  - More investigation
    - How did the group with a higher cost pattern differ from those that had a lower cost pattern?
    - **Empirical-based management**
Empirically-based management: How do these populations differ at different points in cohort or patient time on actionable risk factors (e.g. medication compliance, type of provider, etc.)?
The Design and ROI (Retrospective Resource Modeling™): Case Study #3
IMPACT

The Difference between the Intervention Group and the Reference Group

Administrative Incidence (TM)

Percentage in Stratosphere (TM)

Patient Time Segments (30 days)

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Costs per Month | Impact per Month

Program Cost* and Program Impact Per Time Segment in One Defined Population

* $25 per enrolled participant per time segment

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Value (Impact - Cost) Per Time Segment and Cumulative Program Value (ROI) over All Time Segments

Break Even Point

ROI*

Based on patent pending Trajectory® algorithms

*Unadjusted for NPV

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VI (a): Recap

- **Pre-Post**
  - Equivalence assumption may often be violated.

- **Follow-up**
  - Dealing with issues of administrative incidence compared to official incidence.
  - Issues with new technologies would support a concurrent reference group in addition to a pre-group.
VI (b): Implications

- **Observational Follow-up Studies**
  - Improves prediction
  - Improves management
  - Improves evaluation
  - ... It's about time™

- **Benefits**
  - Resonates with Health Care Workers:
    - Looks at populations over “time” the same way doctors have diagnosed and managed patients since ancient times.
    - Looks at evaluation the same way researchers assess new treatment (e.g., drugs): Follow-up in a defined population (without randomization)
  - Intervene prior, during, or after incidence event? Depends on results of empirical investigations.
  - Pricing, budgeting, forecasting, evaluating
  - Population-based (where the individual is the unit of focus)
Discussion