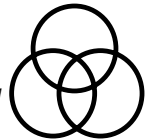# Epidemiological-based ROI in Disease Management: Case Studies

Disease Management Summit
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W i l s o n R e s e a r c h, L L C
Bringing epidemiology to the business of health care[SM]

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^{TM}."

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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[TM]

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

Health
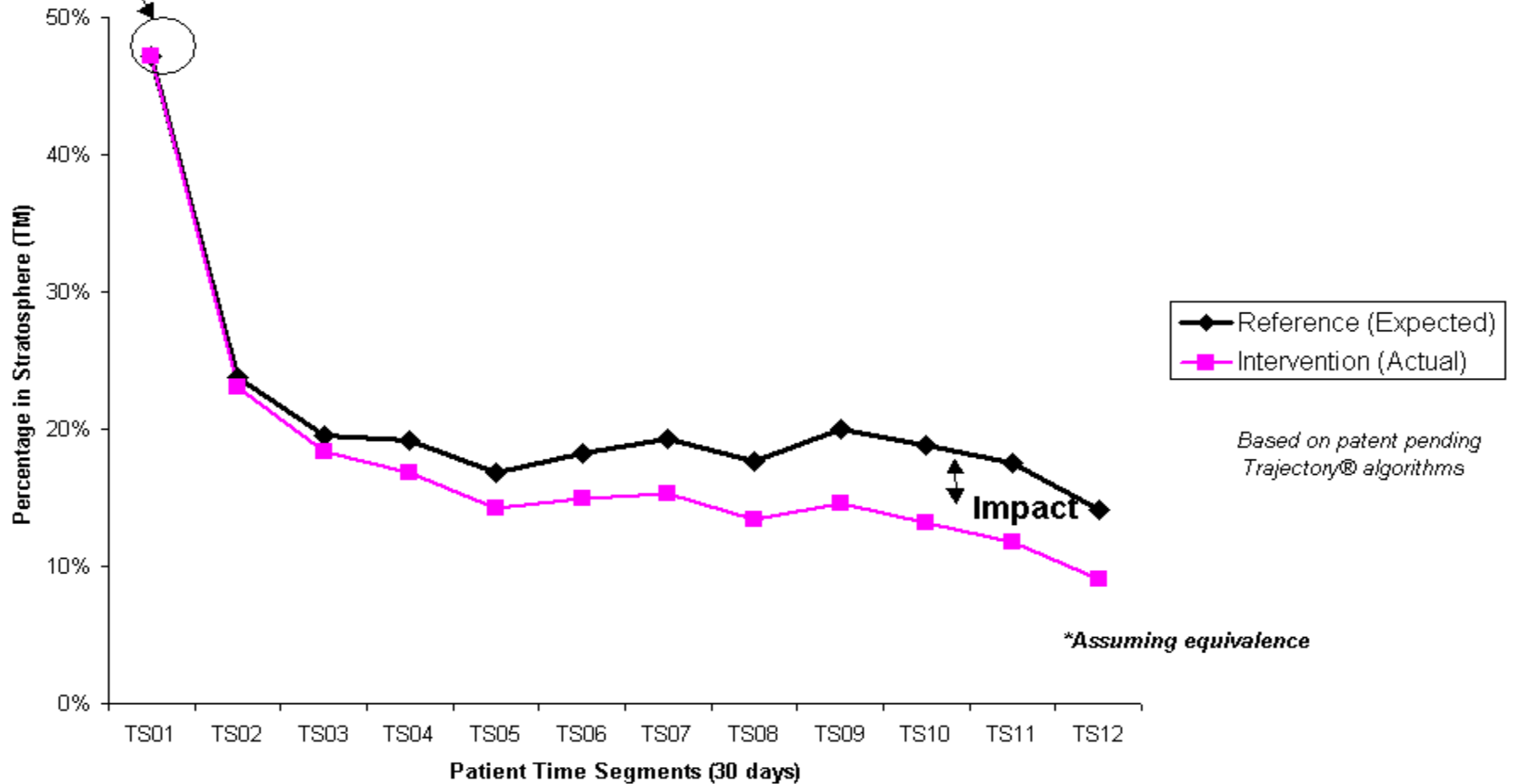
Economic
(ROI)

Perception

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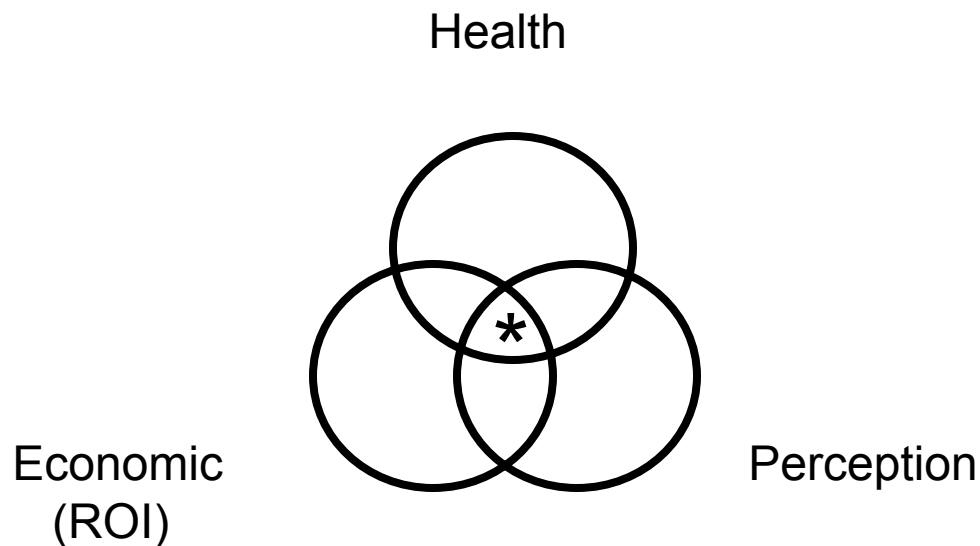
* *Ideal Target: Can be hit using Pragmatic Epidemiology Tools*

IMPACT
The Difference between the Intervention Group and the Reference Group*

Administrative Incidence (TM)

Percentage in Stratosphere (TM)

Patient Time Segments (30 days)

Legend:
- Reference (Expected)
- Intervention (Actual)

Impact

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**

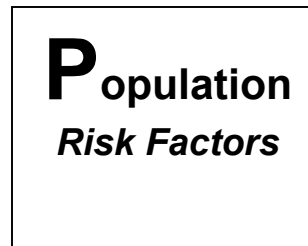### Pre-Post Type Design: Discussed Today

IV.   **Ecological**

V.   **Cross-Sectional**

VI.   **Case-Control**

VII. **Follow-up / Cohort**

Observational: Discussed Today

Numbering from: MacDowell & Wilson. Framework for Assessing Causality in Disease Management. Disease Management of America White Paper, 2002.

EQUIVALENCE

Disease Management Population

Population
Risk Factors

Equivalence?

At beginning | throughout

... Except for the Intervention

Population
Risk Factors

Reference Population

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?

Pre-Post Design
Equivalence Assumption

Pre-Period   Post-Period
                              without intervention

Sickness
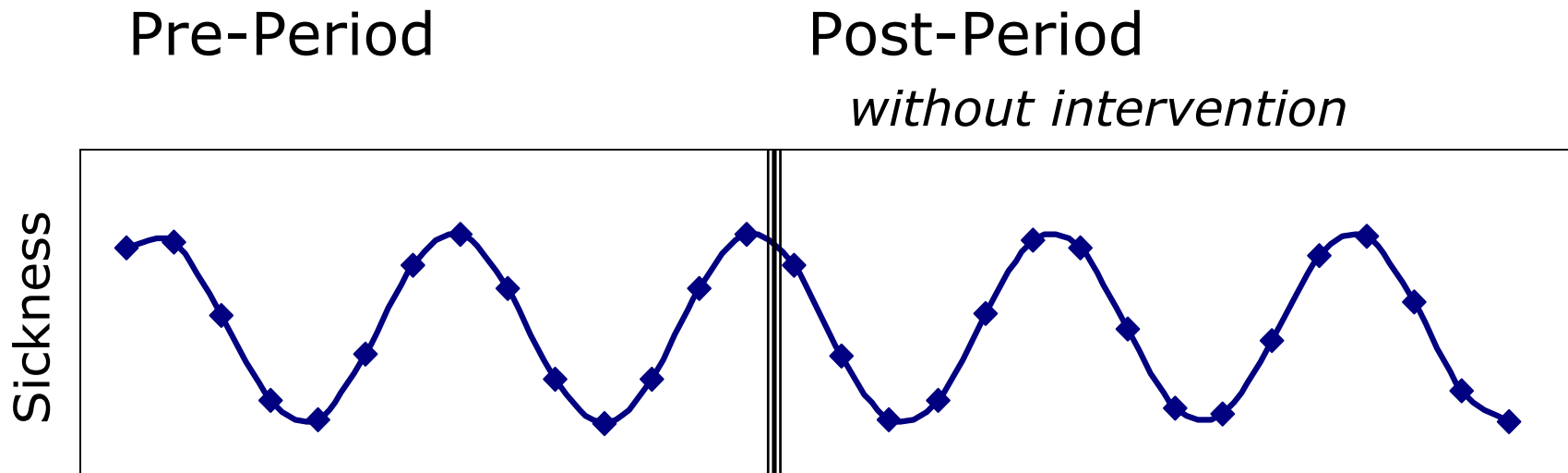
Thus, in a properly conducted pre-post study, any change detected in metrics in the post-intervention period could, arguably, be attributed to the DM intervention.
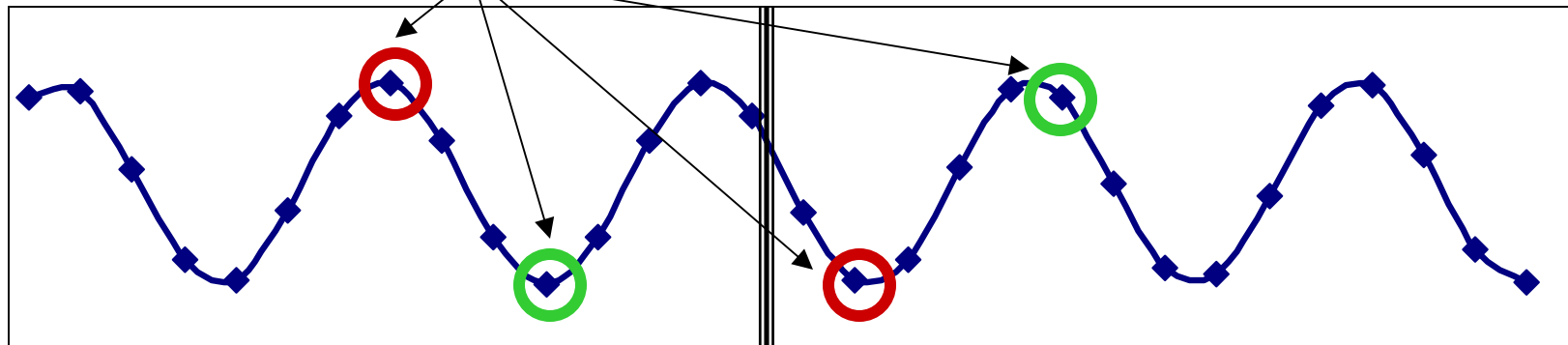
Pre-Post Design:

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

Pre-Period

Measurements

"Post-Period"

without intervention
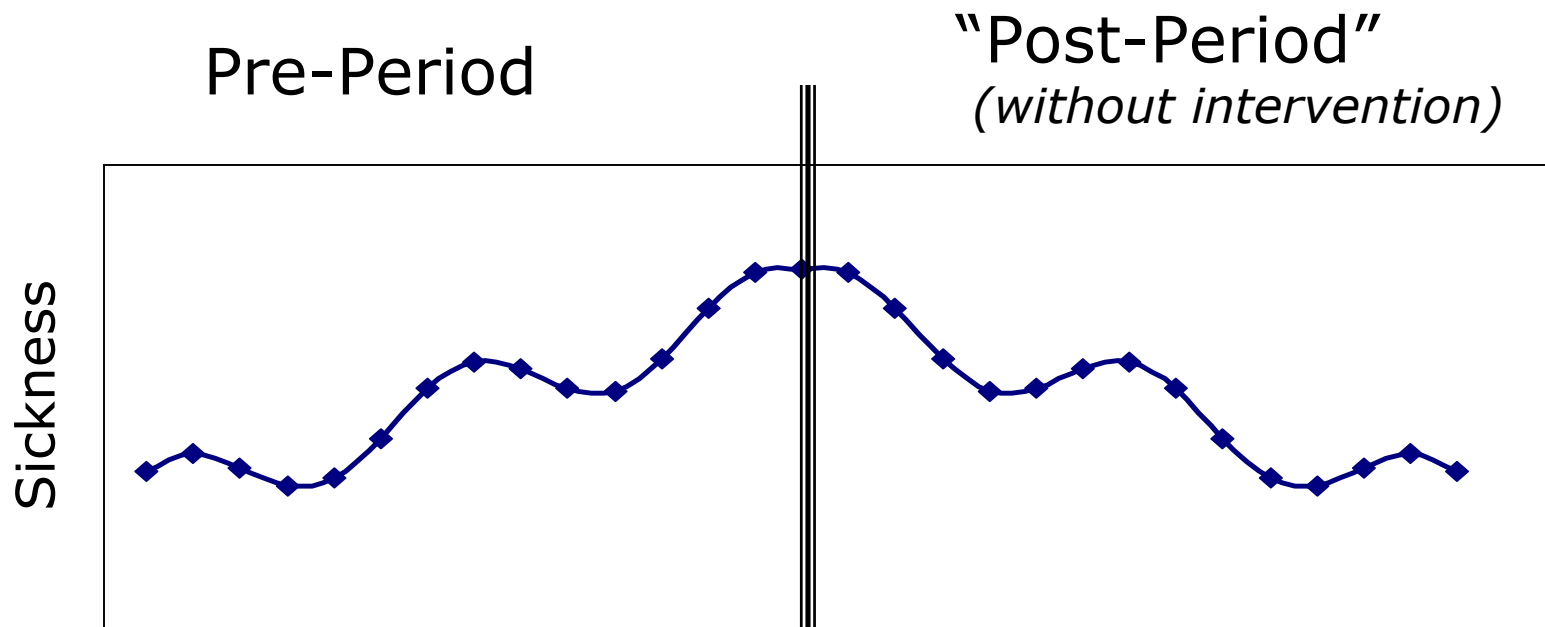
Sickness

🟢 **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.*
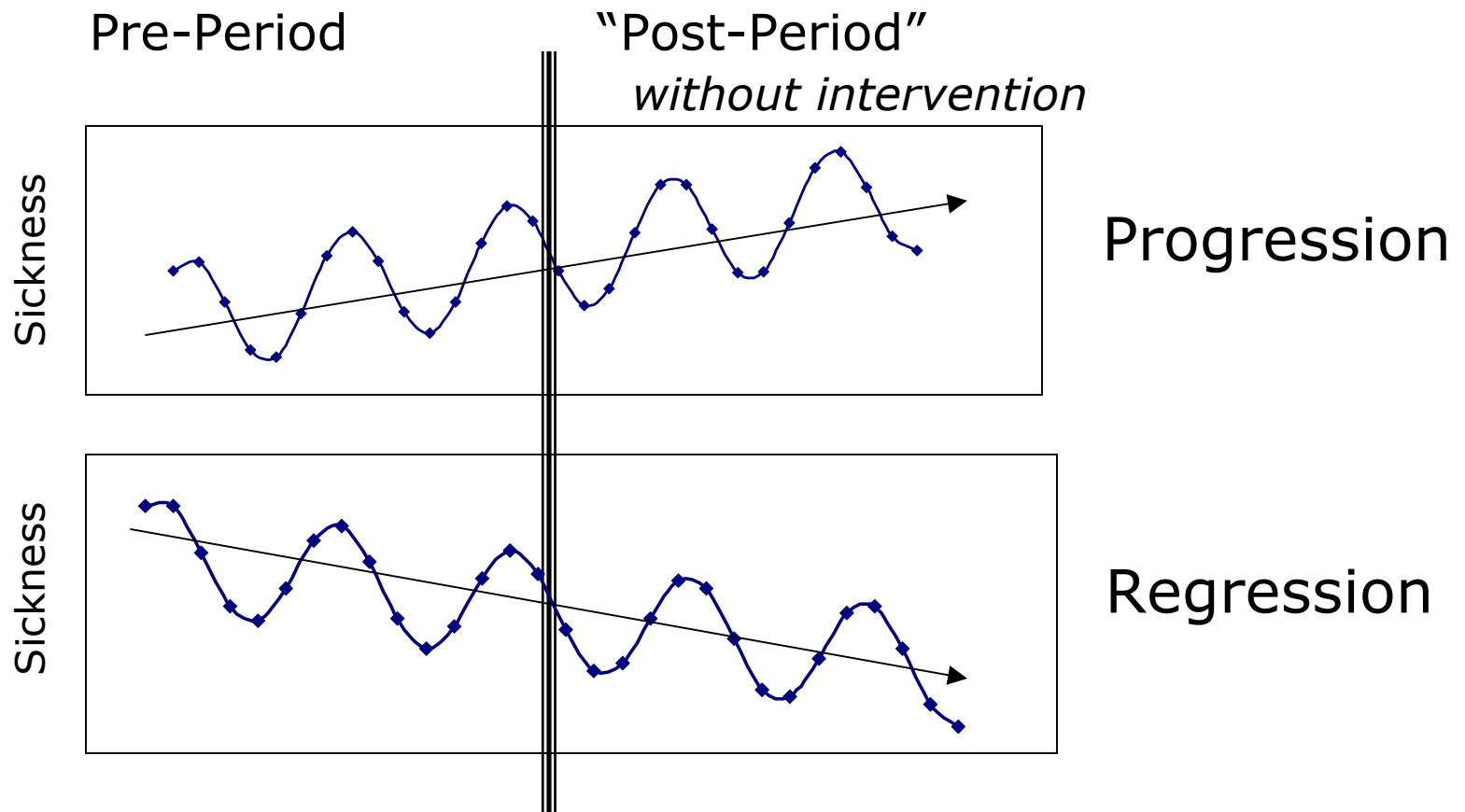
Pre-Post Design:
Past is NOT Prologue: One Situation where equivalence is not achieved

Pre-Period

"Post-Period"
(without intervention)

Sickness

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.
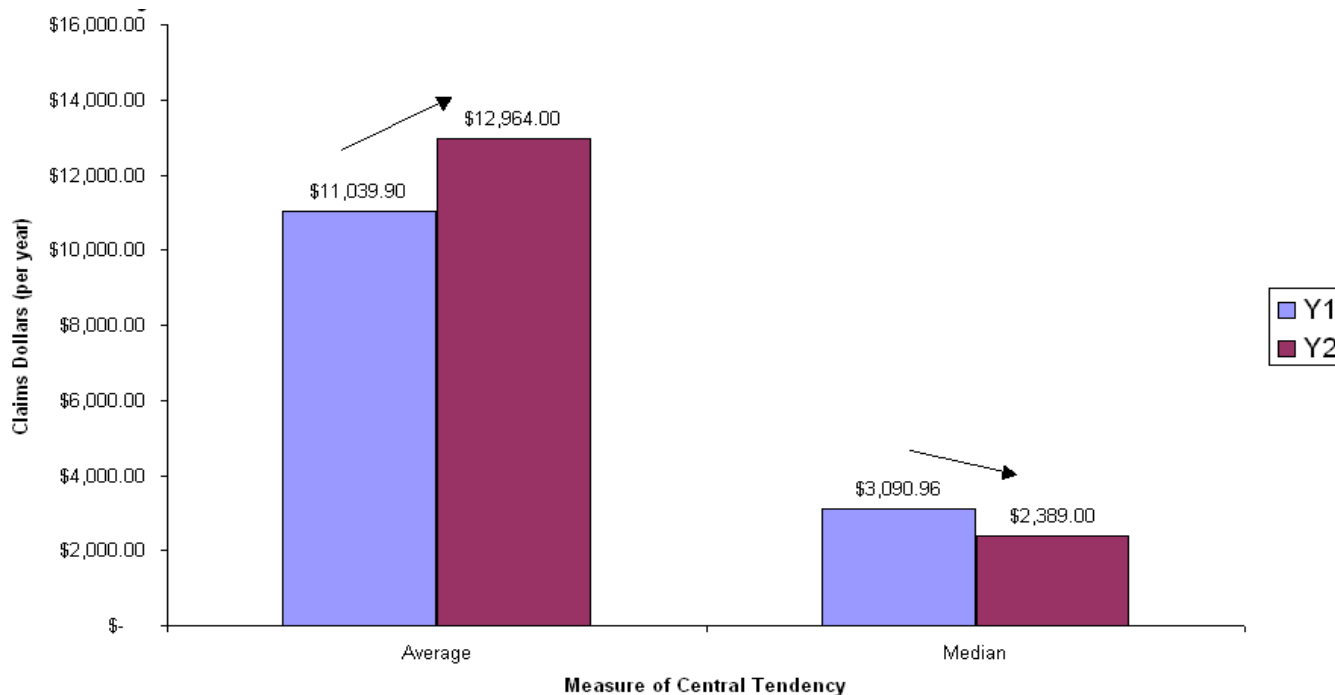
"Past is Prologue"
Two Situations where equivalence is achieved (as long as you are aware of it)

Pre-Period   "Post-Period"
without intervention

Sickness

Progression

Sickness

Regression

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

Patient-as-own-control: Pre-Post Comparisons #1 (Average) & #2 (Median):

**The difference in outcoes 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
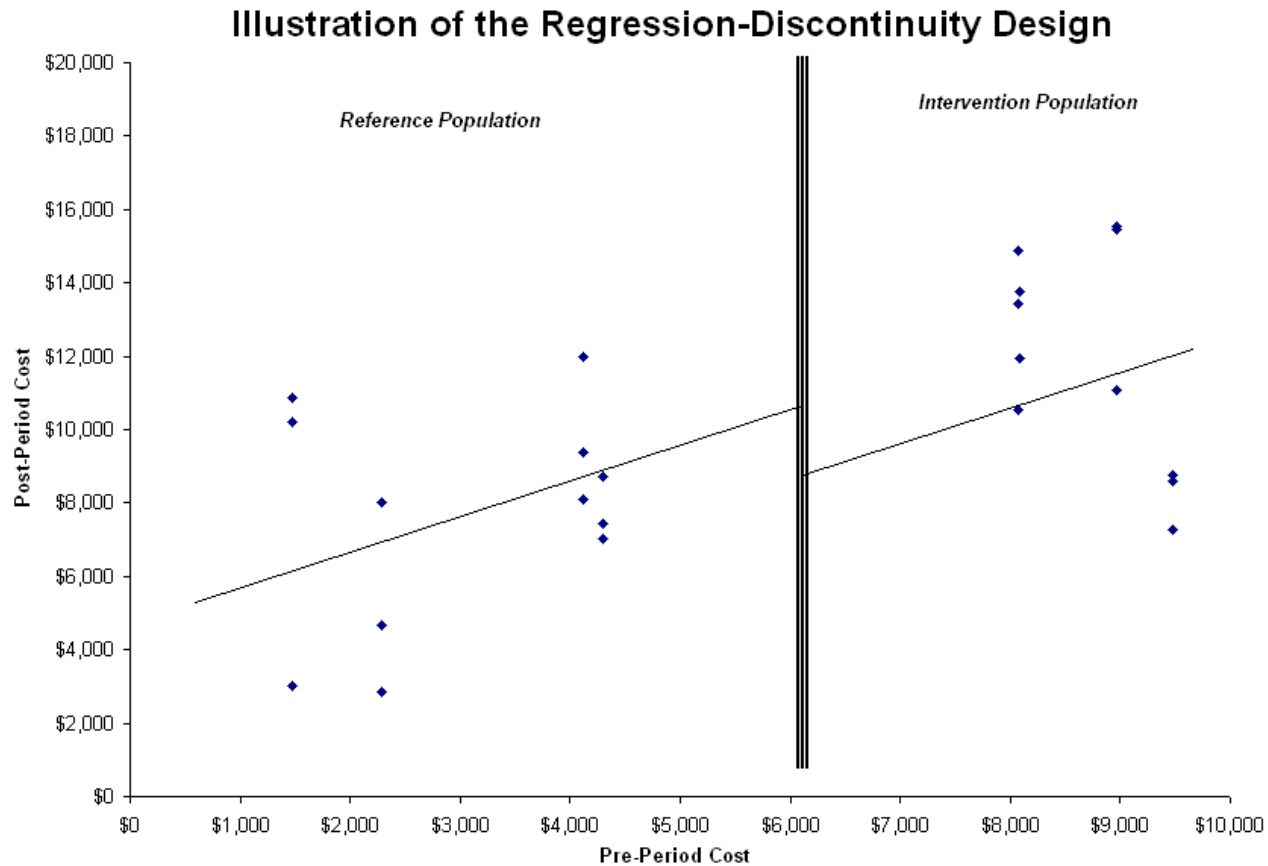
Regression-Discontinuity Design
Equivalence Assumption: Is it true?

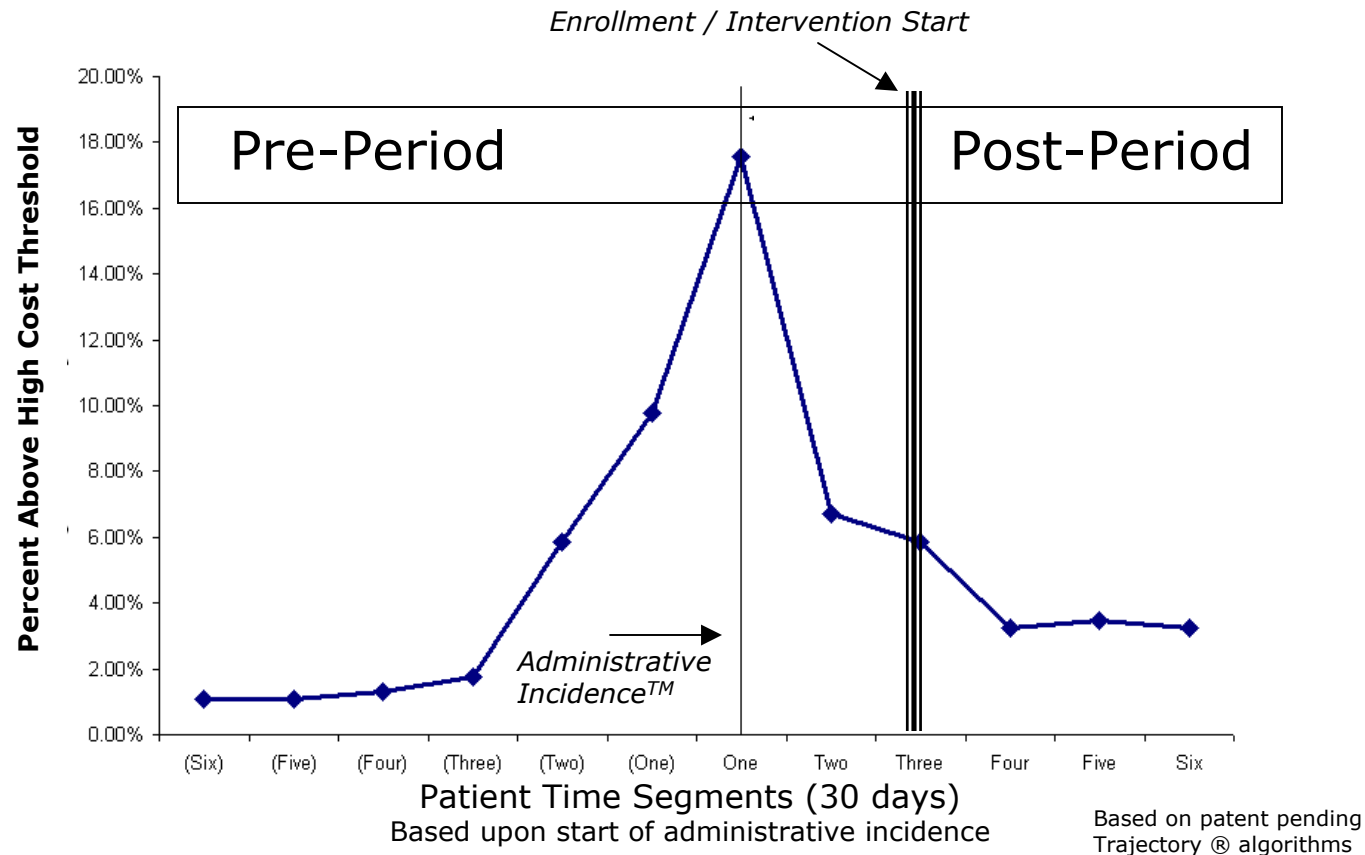**Equilavence Assumption of the Regression-Discontinuity Design**
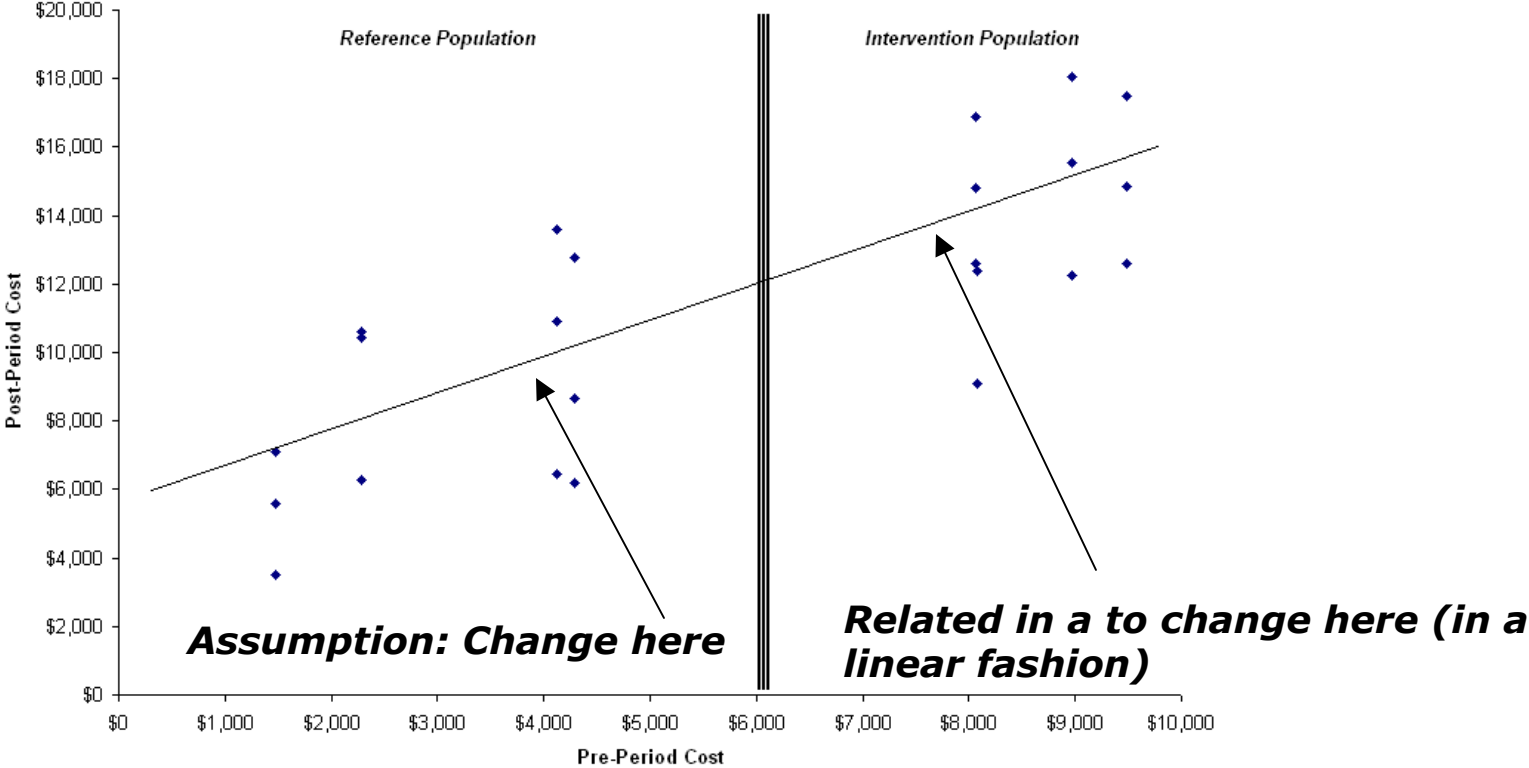
Time-Series Design:
Another Variation to Pre-Post

☐ **Characteristic: Multiple pre and multiple post measures.**

Time Series:
Example where equivalence assumption is problematic

Enrollment / Intervention Start

Pre-Period

Post-Period

Percent Above High Cost Threshold

20.00%
18.00%
16.00%
14.00%
12.00%
10.00%
8.00%
6.00%
4.00%
2.00%
0.00%

Administrative Incidence^TM

(Six) (Five) (Four) (Three) (Two) (One) One Two Three Four Five Six

Patient Time Segments (30 days)
Based upon start of administrative incidence

Based on patent pending
Trajectory ® algorithms

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 PERFECTY DESIGNED AND EXECUTED RANDOMIZED CONTROL TRIAL?*

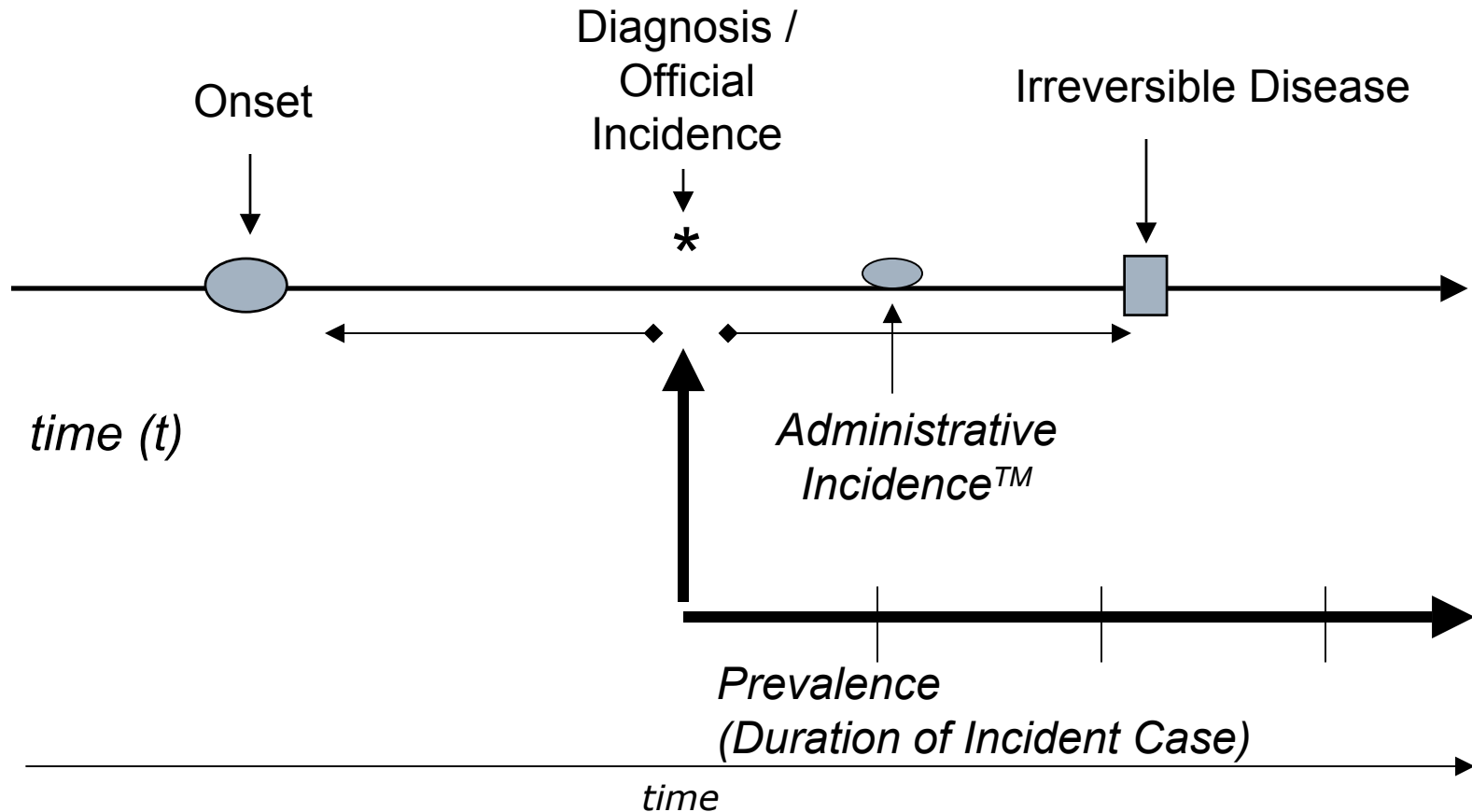   ☐ *YES!*

Observational Follow-up study
Where <u>population(s)</u> 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™"

Diagnosis /
Official
Incidence

Irreversible Disease

Onset

*

time (t)

Administrative
Incidence™

Prevalence
(Duration of Incident Case)

time

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 data base*
- *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^{TM}"*
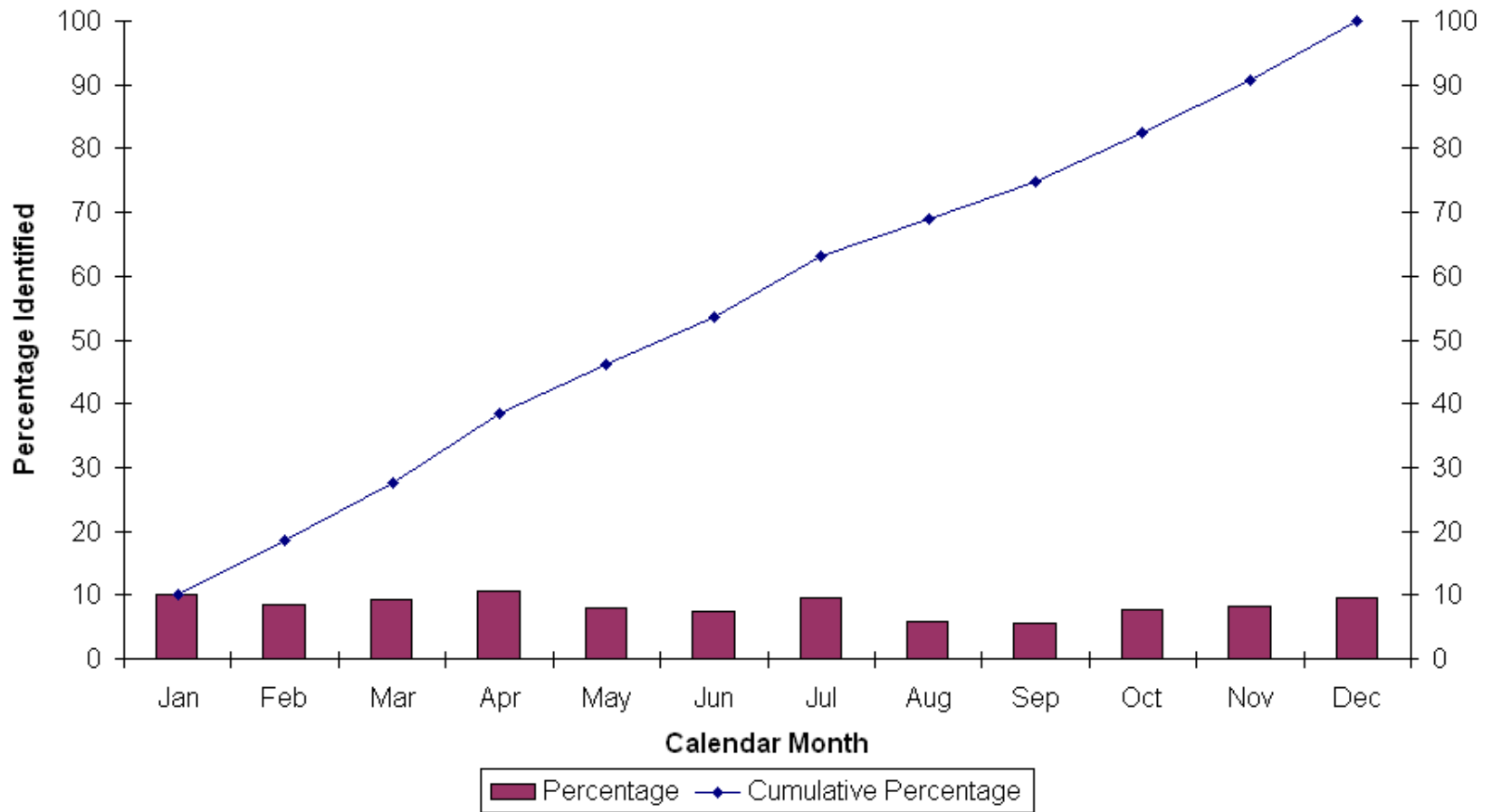
The Design in a Perfect World: *Case Study #1*

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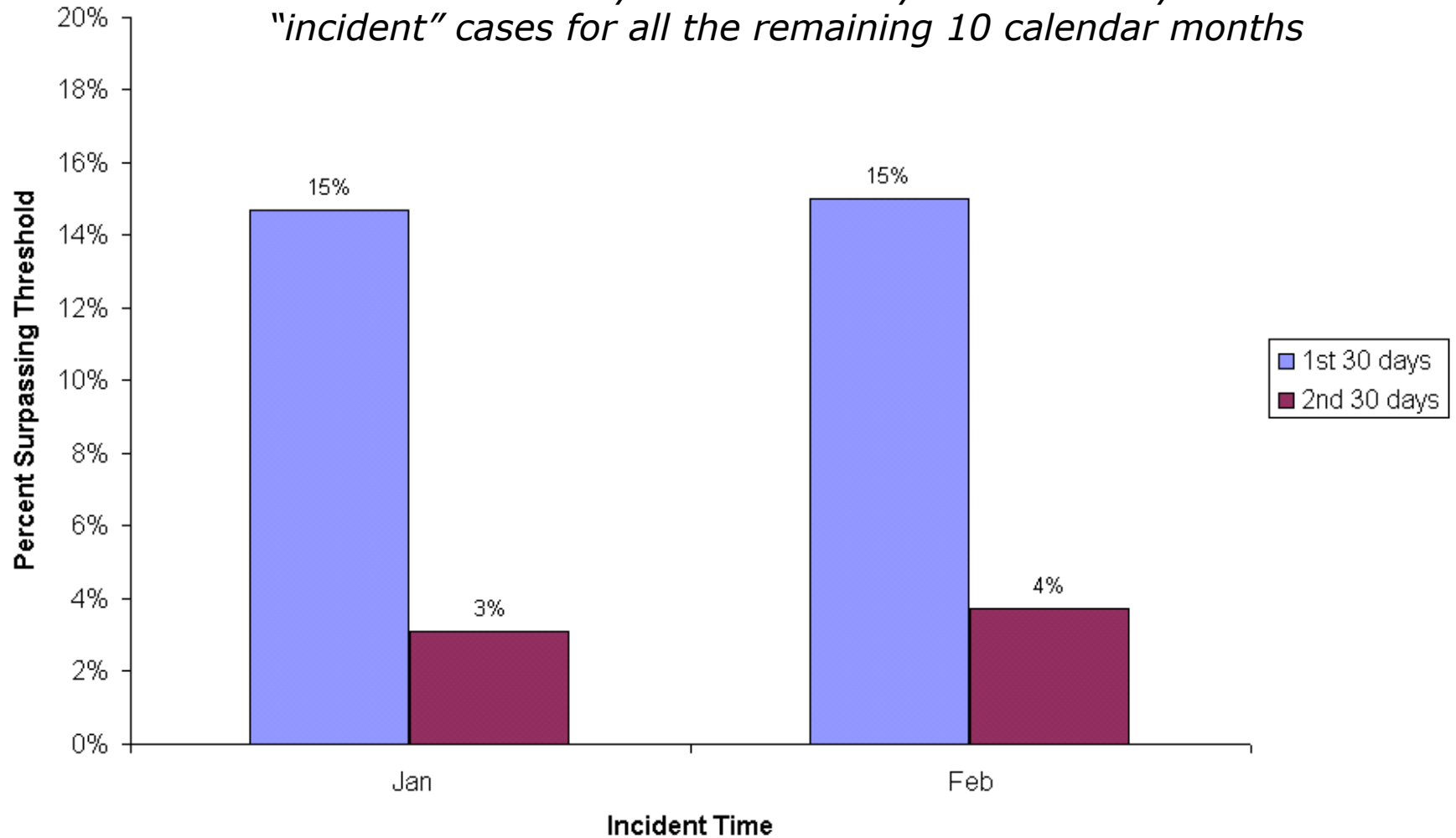(12 month continuous enrollment)
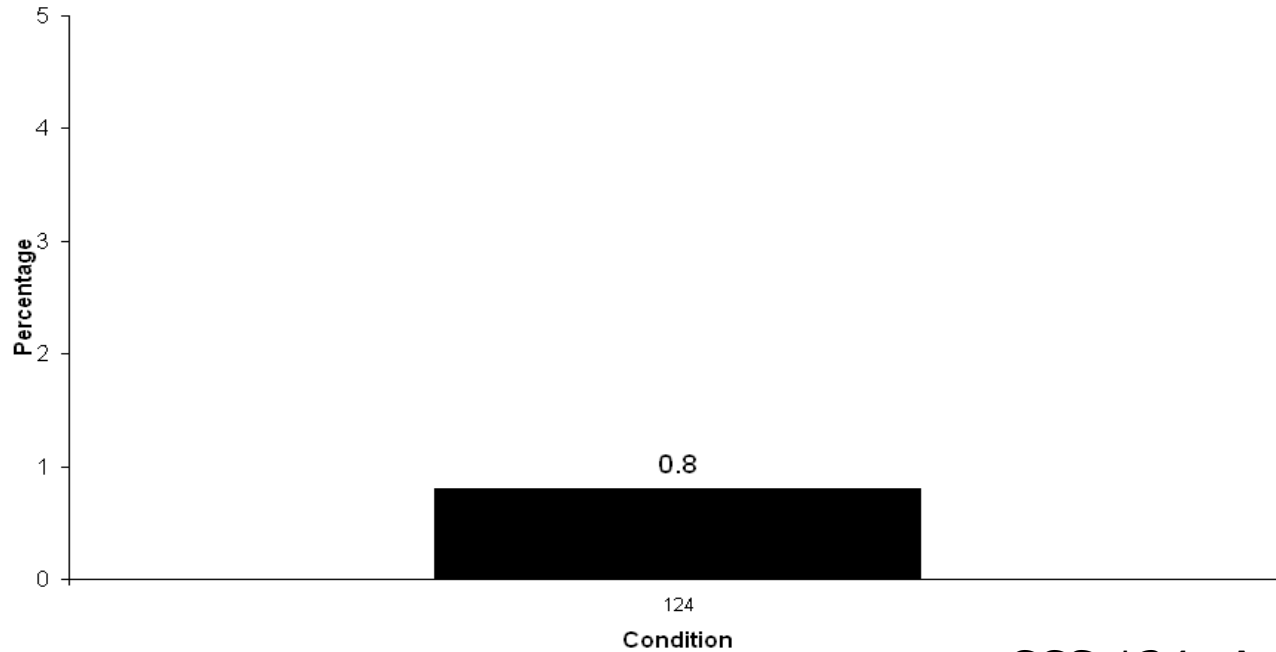
CCS 124=Appendicitis

Incident Month: First Indication of 124 Diagnoses (12 month continuous enrollment)
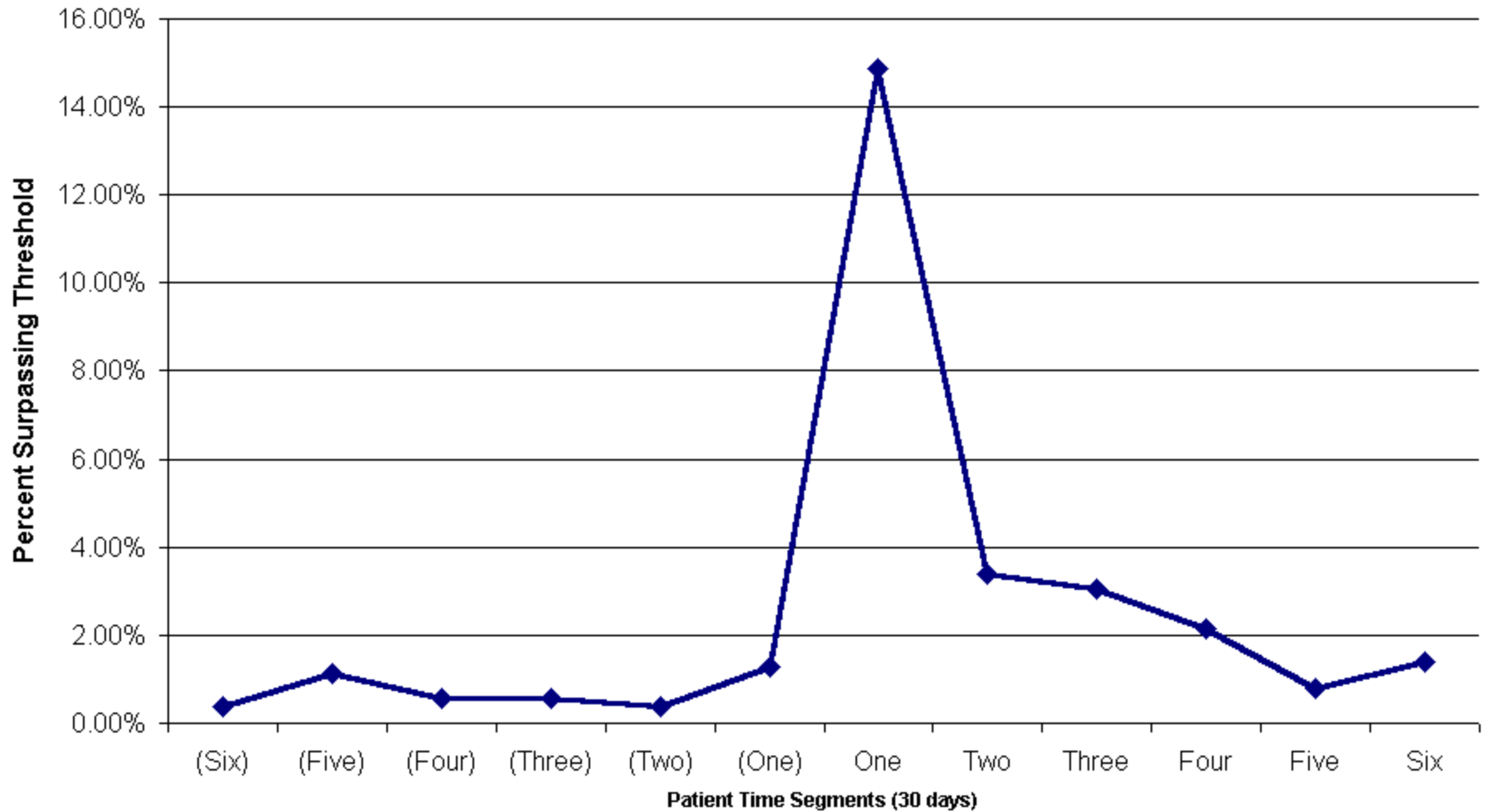
Cost Trends Per Start Time: 124

This trend from 1st 30 days to 2nd 30 days was virtually the same for "incident" cases for all the remaining 10 calendar months

Legend:
- 1st 30 days
- 2nd 30 days

Y-axis: Percent Surpassing Threshold (0% to 20%)
X-axis: Incident Time

Jan: 1st 30 days = 15%, 2nd 30 days = 3%
Feb: 1st 30 days = 15%, 2nd 30 days = 4%

Evaluation Design

☐ *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.*

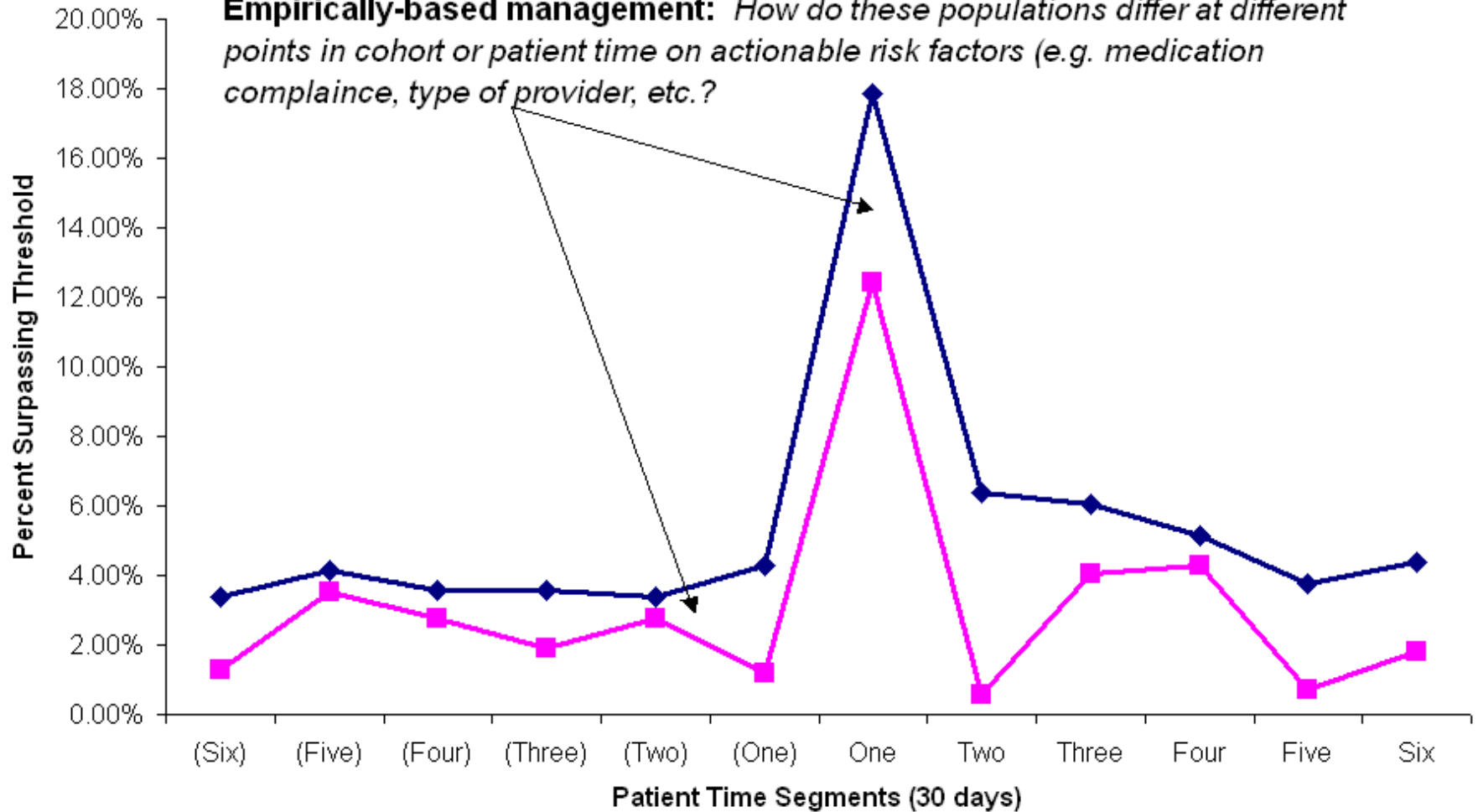# Retrospective | Prospective: Percent of 124s Surpassing Threshold.

Percent Surpassing Threshold (y-axis)

16.00%
14.00%
12.00%
10.00%
8.00%
6.00%
4.00%
2.00%
0.00%

Patient Time Segments (30 days)

(Six) (Five) (Four) (Three) (Two) (One) One Two Three Four Five Six

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***^{SM}***"***

Retrospective | Prospective: Percent of 124s Surpassing Threshold, Stratified by Different Cohort Time Cost Patterns.

Empirically-based management: *How do these populations differ at different points in cohort or patient time on actionable risk factors (e.g. medication complaince, type of provider, etc.?*

Y-axis: Percent Surpassing Threshold (0.00%, 2.00%, 4.00%, 6.00%, 8.00%, 10.00%, 12.00%, 14.00%, 16.00%, 18.00%, 20.00%)

X-axis: Patient Time Segments (30 days) — (Six), (Five), (Four), (Three), (Two), (One), One, Two, Three, Four, Five, Six

The Design in An Imperfect World: *Case Study #2*

"Incidence" of 128 in One Calendar Year
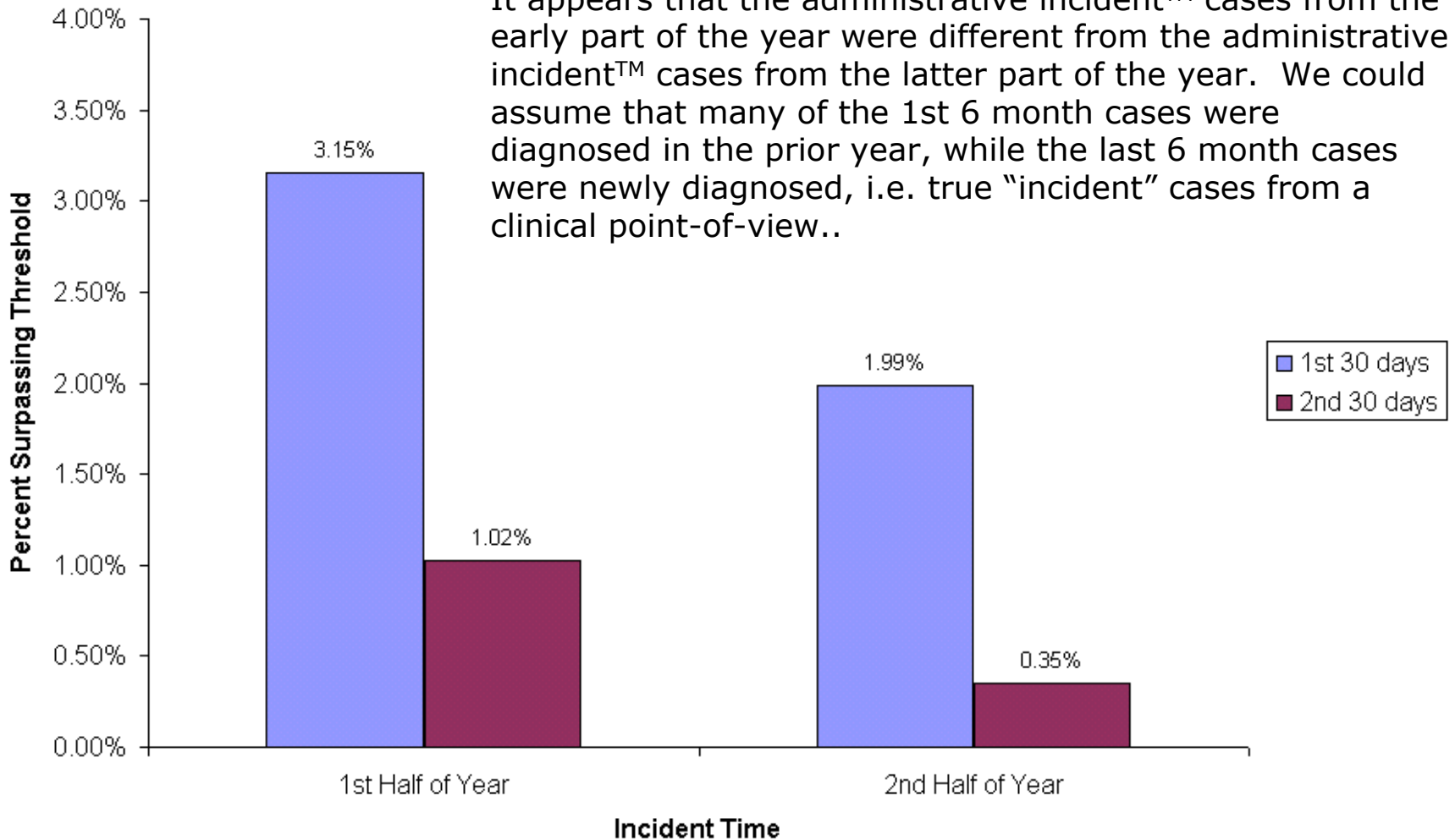(12 month continuous enrollment)

CCS 128=Asthma
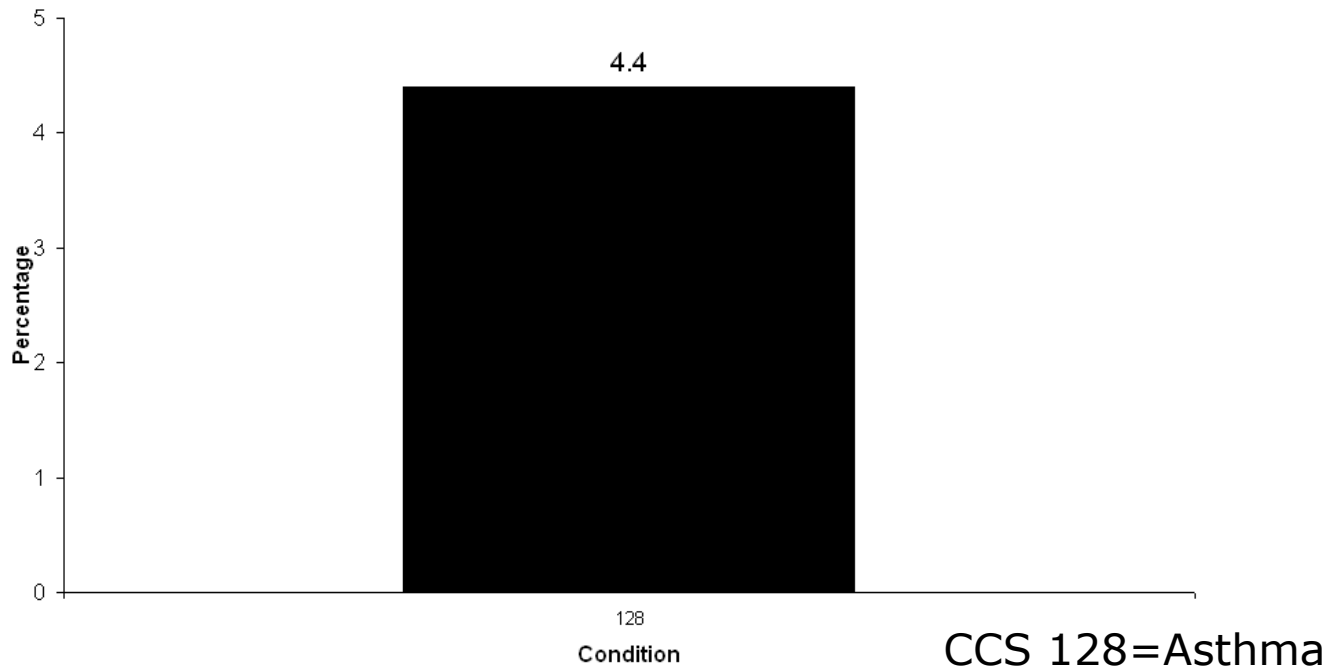
Incident Month: First Indication of 128 Diagnoses (12 month continuous enrollment)
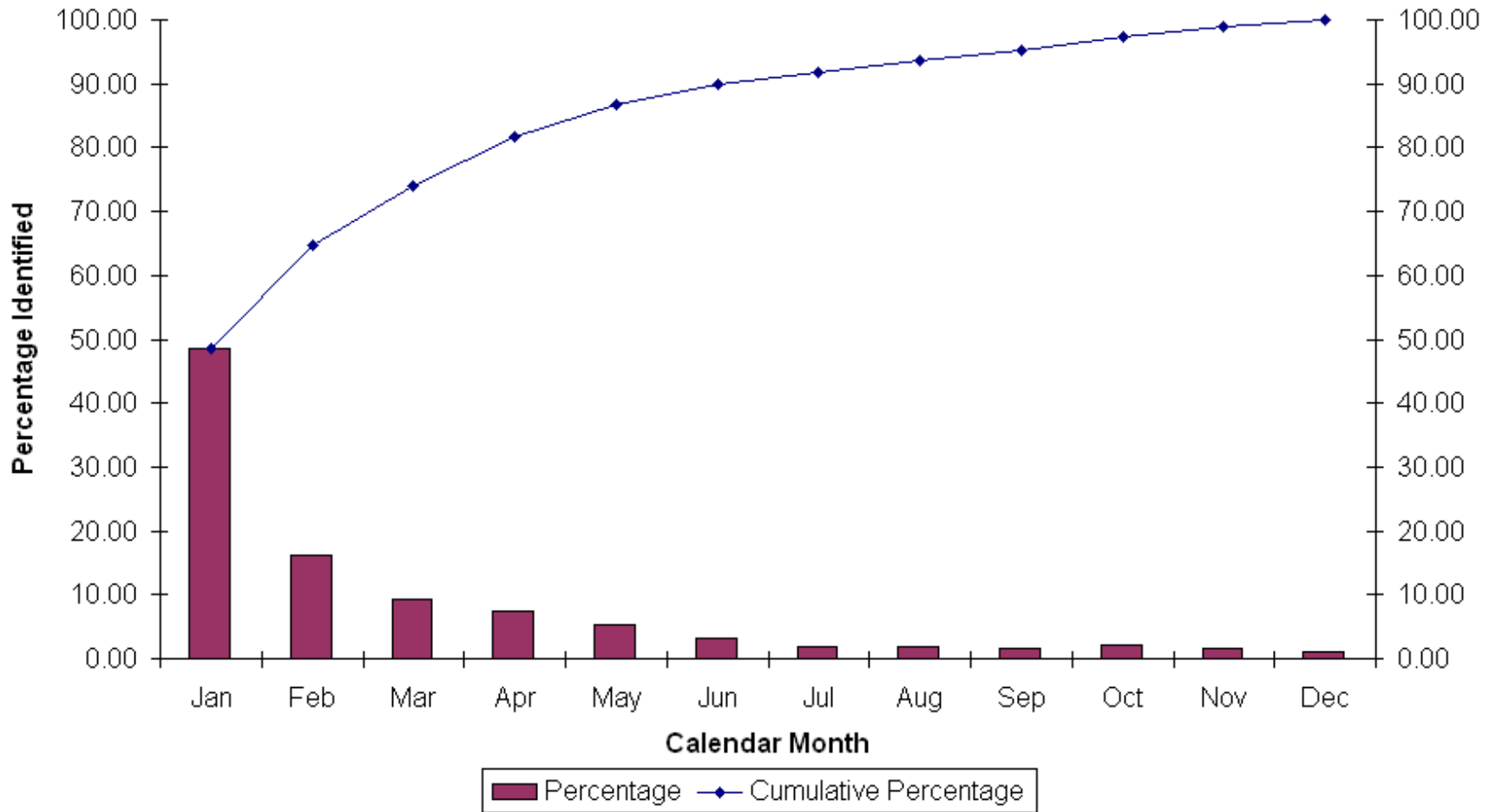
Cost Trends Per Start Time: 128

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..

Legend:
- 1st 30 days
- 2nd 30 days

Chart values:
- 1st Half of Year: 3.15% (1st 30 days), 1.02% (2nd 30 days)
- 2nd Half of Year: 1.99% (1st 30 days), 0.35% (2nd 30 days)

Y-axis: Percent Surpassing Threshold (0.00% – 4.00%)
X-axis: Incident Time

Evaluation Design

- *The Administrative Incidence^{TM} 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)

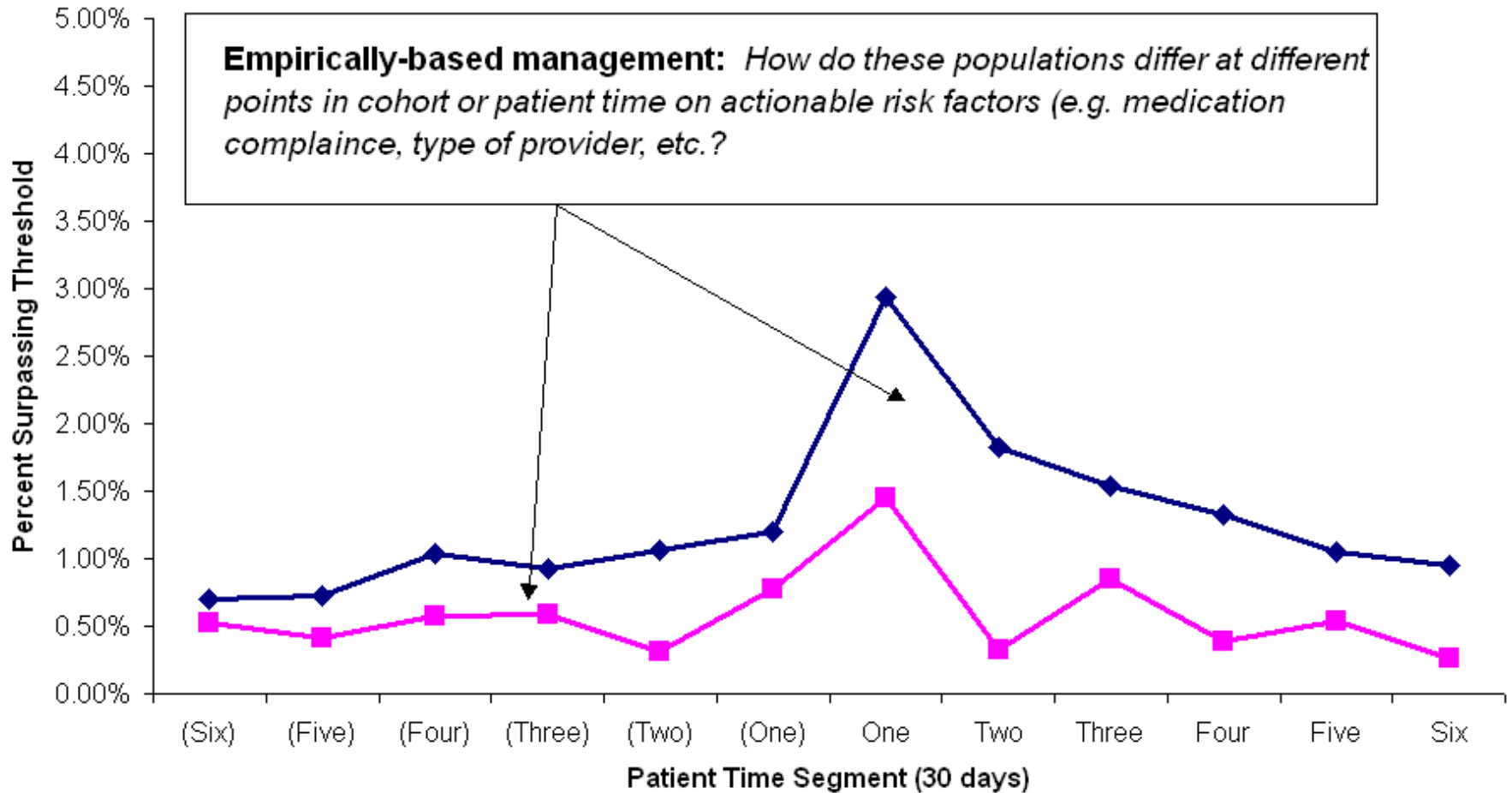## Retrospective | Prospective from Incident Date of First Diagnosis
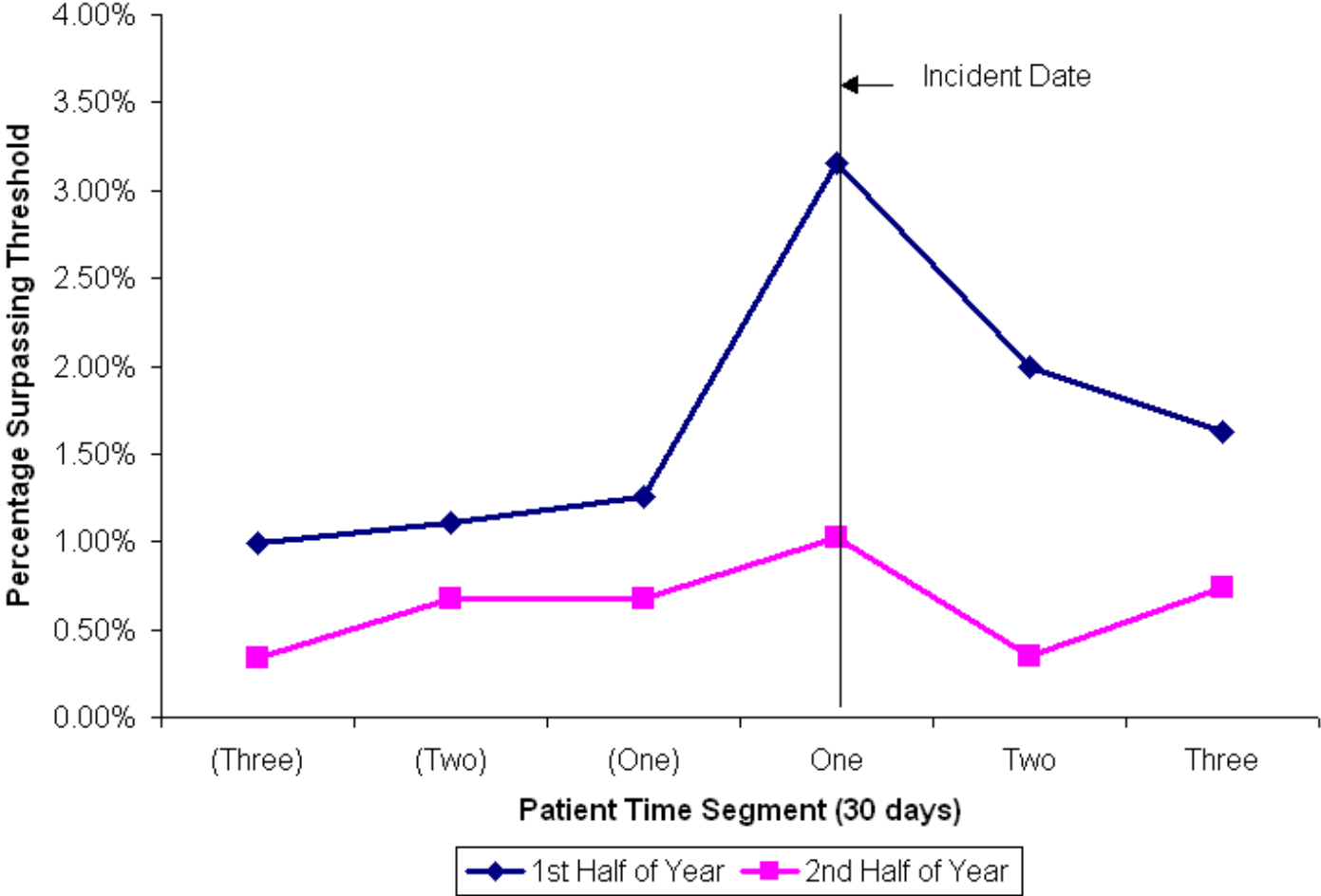
Management

- ☐ *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^{SM}*

Percent of 128 Population Surpassing Threshold Per 30 Day Patient Time Segment:
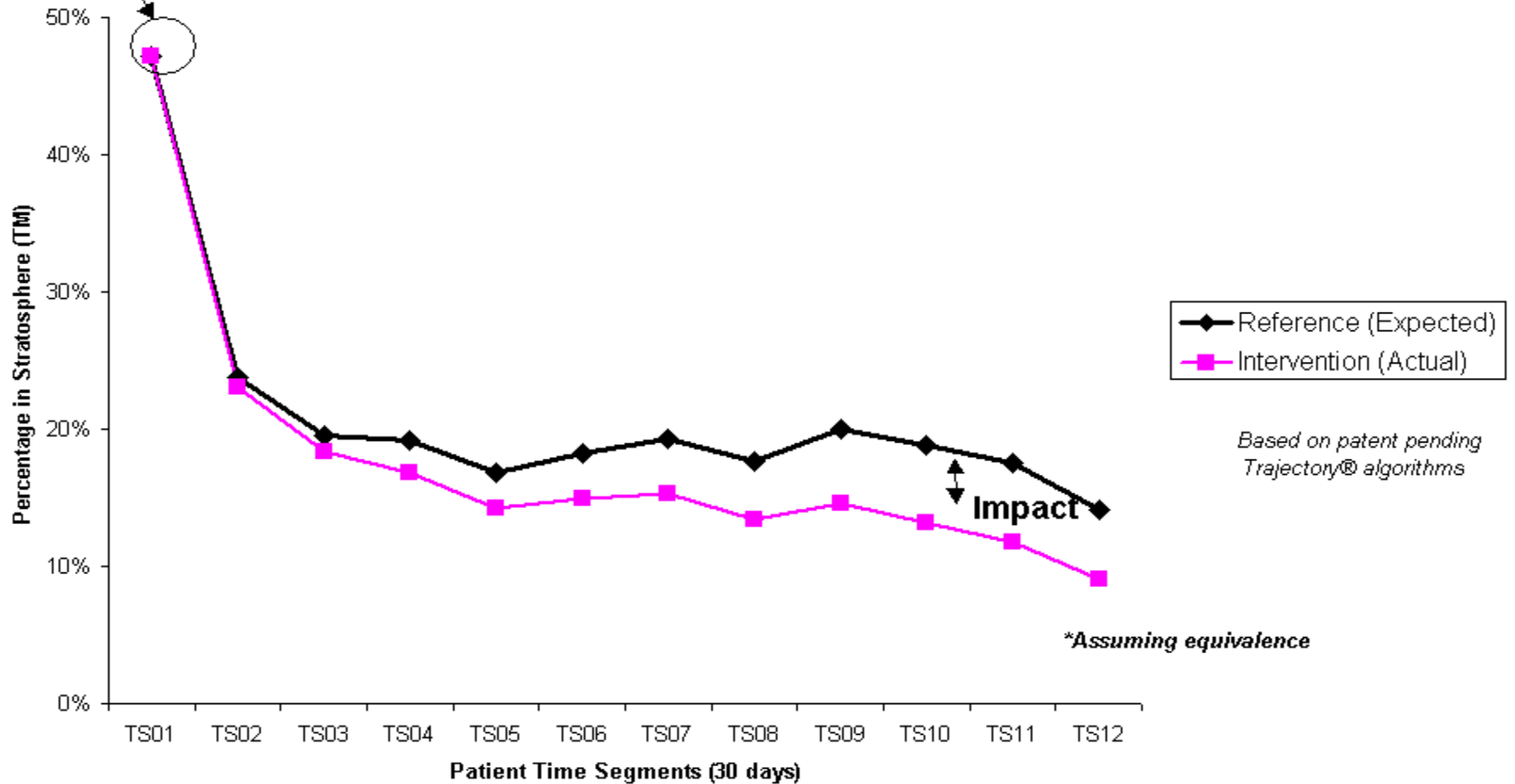## Retrospective | Prospective from Incident Date of First Diagnosis

Empirically-based management: *How do these populations differ at different points in cohort or patient time on actionable risk factors (e.g. medication complaince, type of provider, etc.?*

The Design and ROI (Retrospective Resource Modeling^{TM)}: *Case Study #3*

IMPACT
The Difference between the Intervention Group and the Reference Group*
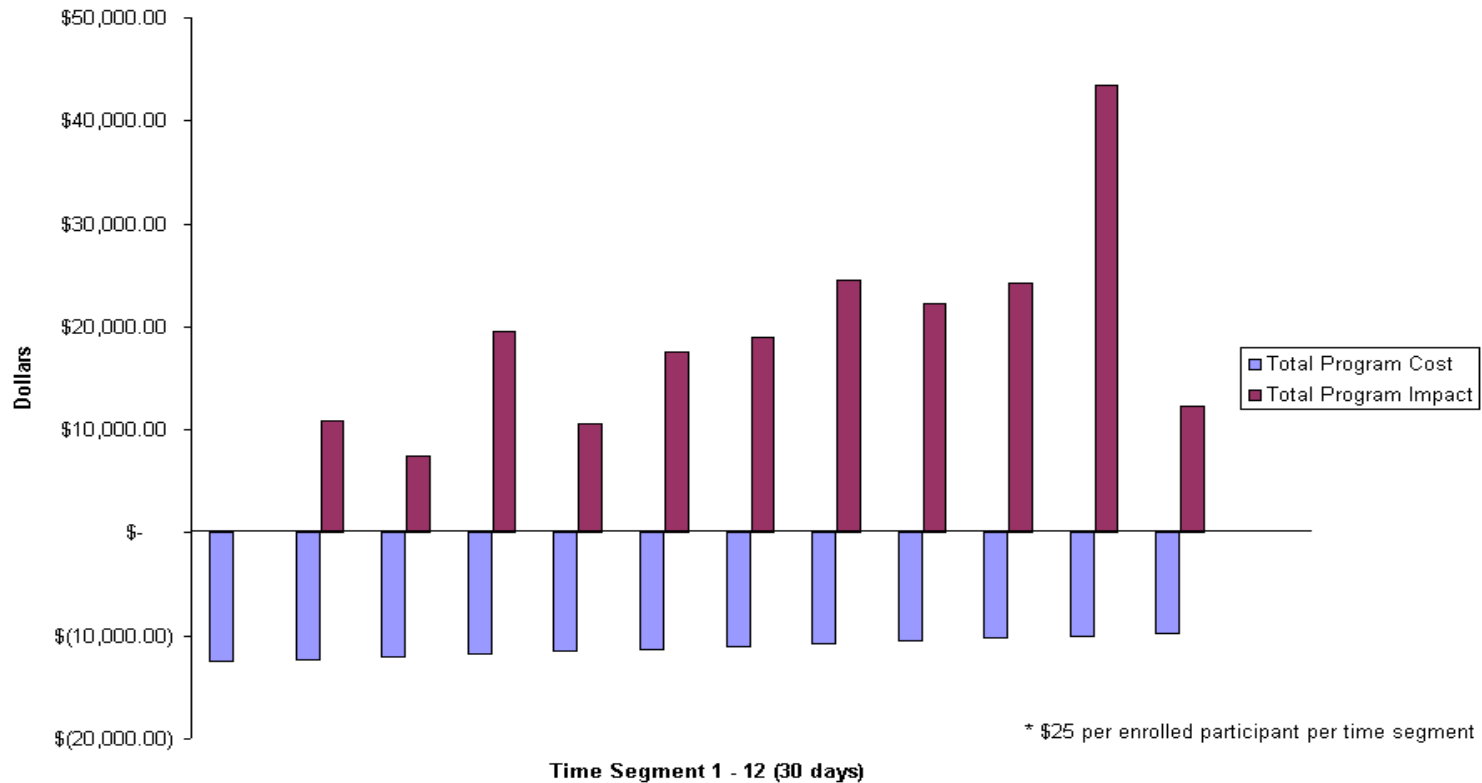
Administrative Incidence (TM)

Percentage in Stratosphere (TM)

Legend:
- Reference (Expected)
- Intervention (Actual)

Based on patent pending Trajectory® algorithms
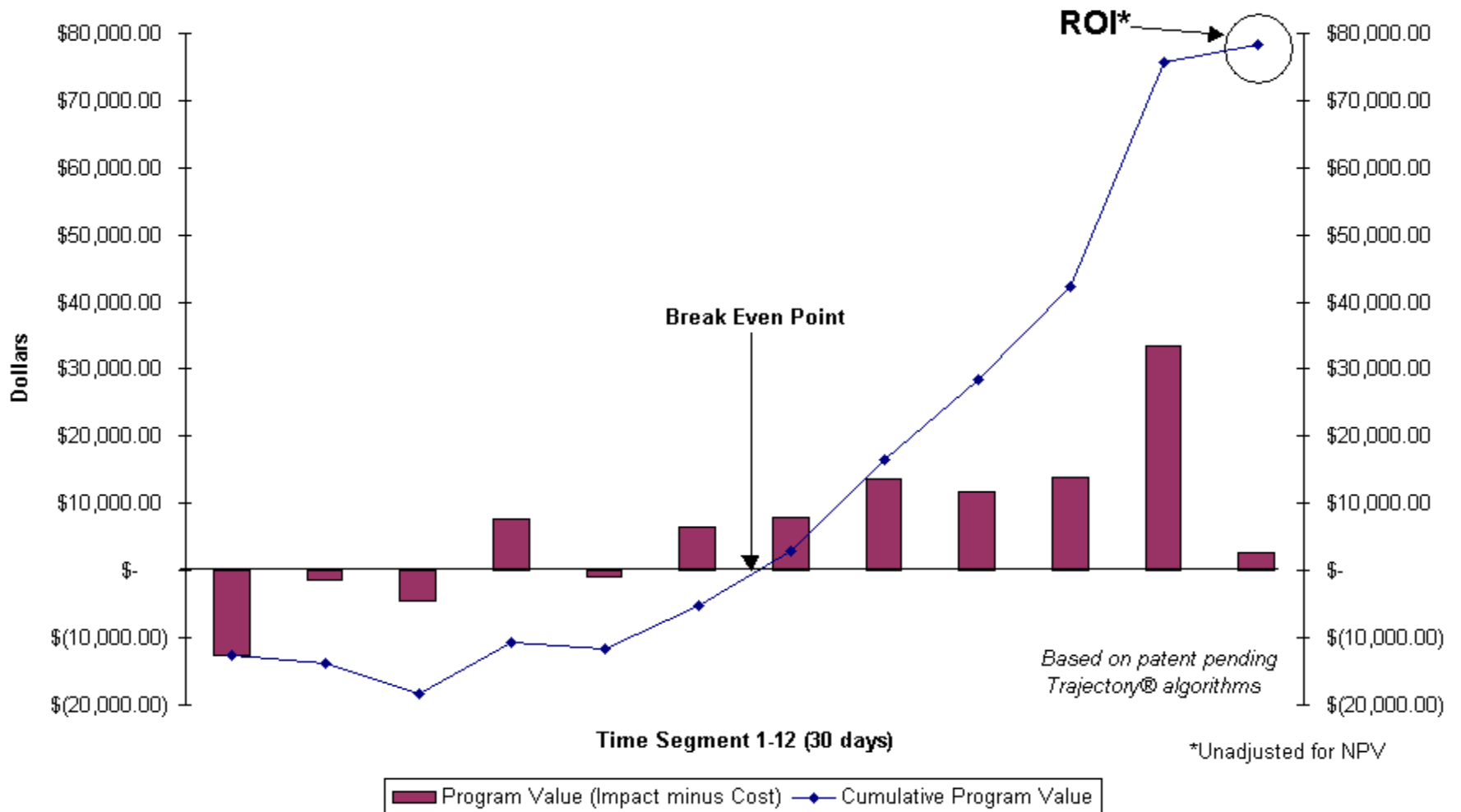
Impact

Assuming equivalence

Patient Time Segments (30 days)

Costs per Month | Impact per Month

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

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

ROI*

Break Even Point

Based on patent pending Trajectory® algorithms

Time Segment 1-12 (30 days)

Dollars

*Unadjusted for NPV

Legend: ■ Program Value (Impact minus Cost) ◆ Cumulative Program Value

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 ^{TM}**
- ☐ *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