# Patient safety in the era of the 80-hour work week:

## An evaluation of the ACGME duty hours policy

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# Background: Duty Hours

- Graduate medical education and work hours
  - Public perception of medical errors
  - New York State
  - ACGME
- Implementation of Duty Hours Policy
  - July 2003
  - July 2011

# Background: Patient Safety

- Freedom from accidental injury
- Avoiding injuries or harm to patients from care that is intended to help them
- Ensuring patient safety “involves the establishment of operational systems and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur.”

# Background: Duty Hours and Patient Safety

- ACGME –
  - Patient safety
  - Resident well-being

- Public perception – long work hours leads to a decline in the quality of patient care

# Study Question

- Has the 80-hour work week policy met its goals of improving patient safety?

# Methods

| | |
|---|---|
| Study Design | Interrupted time series analysis with concurrent control |
| Data Source | Nationwide Inpatient Sample (1998-2007) |
| Study Group | All inpatient discharges from teaching hospitals |
| Control Group | All inpatient discharges from nonteaching hospitals |
| Intervention | ACGME 2003 duty hours policy |
| Outcomes | Patient Safety Indicators |
| Analysis | Autoregressive moving average model |

# Study Groups

| Teaching Hospitals Discharges | Nonteaching Hospitals Discharges |
|---|---|
| 171,563,817 | 204,900,562 |

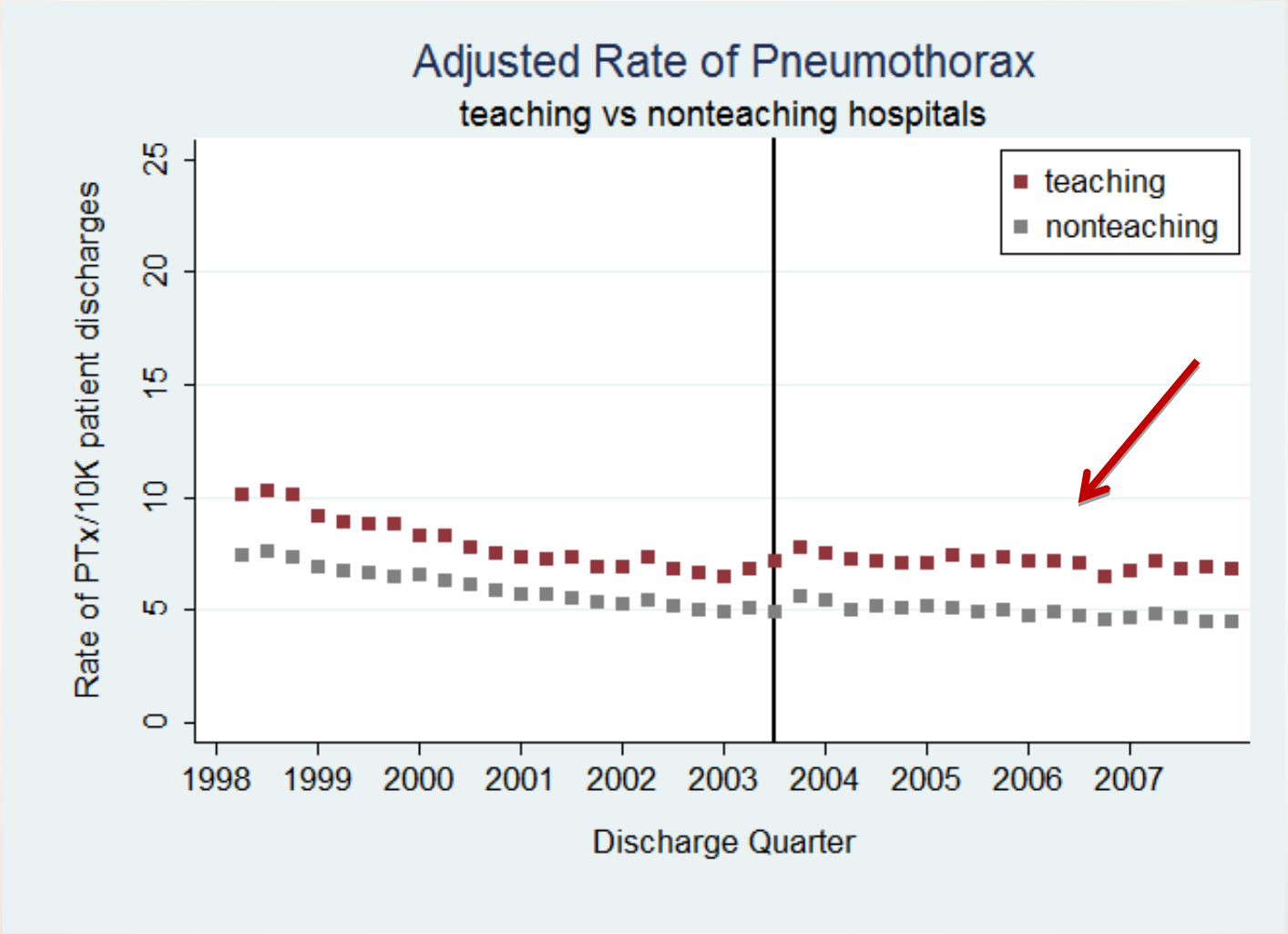
# Outcomes

- AHRQ Patient Safety Indicators
  - Pneumothorax (PTx)
  - Post-operative hemorrhage or hematoma (HH)
  - Post-operative wound dehiscence (WD)
  - Accidental puncture or laceration (aPL)
  - Post-operative physiologic and metabolic derangements (PMD)
  - Post-operative pulmonary embolus or deep vein thrombus (PE/DVT)

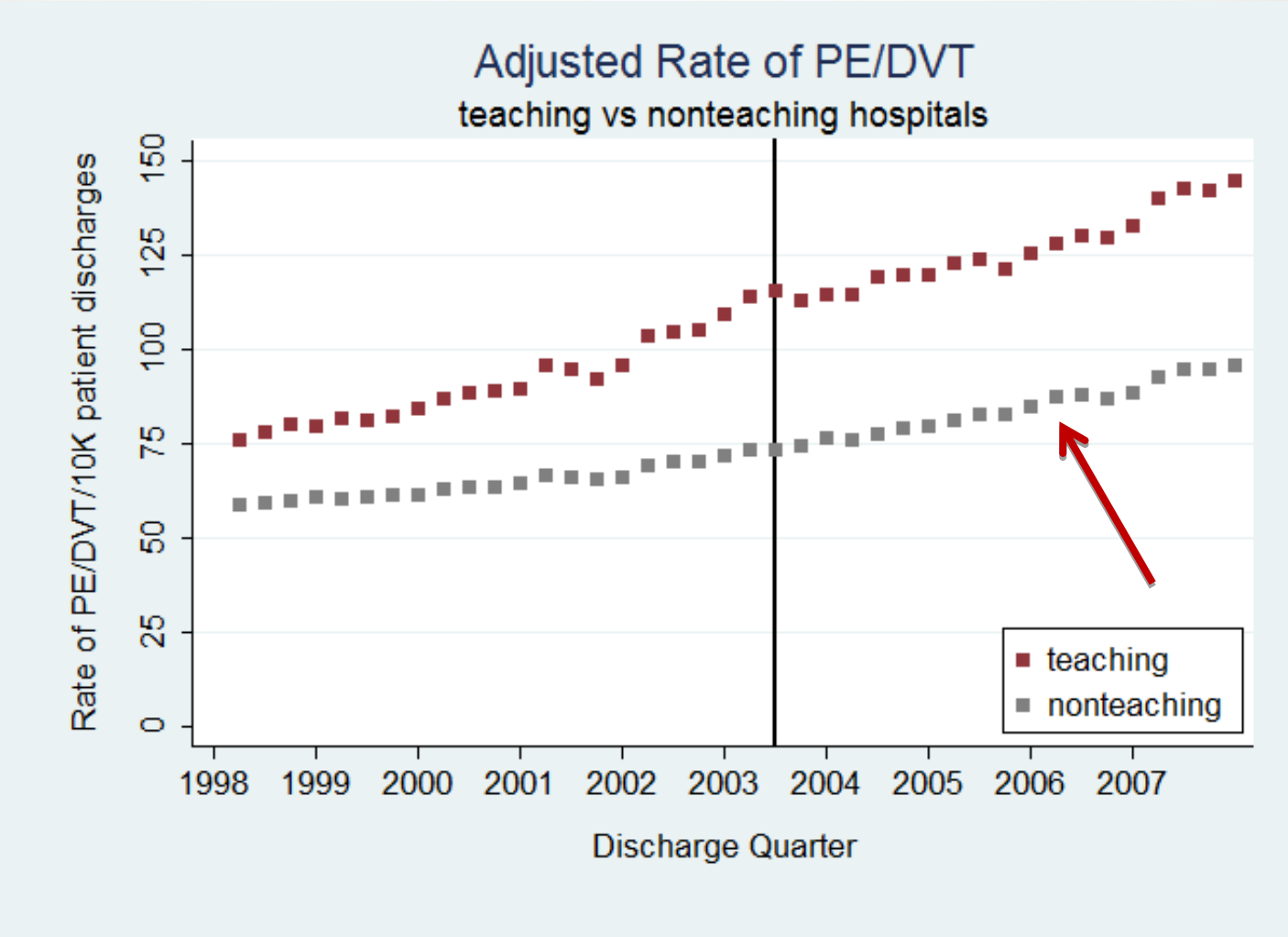
# Results: Patient Safety Indicators
## pre-intervention and post-intervention rates

| Patient Safety Indicator | Institution Type | Pre-intervention rate (event/10K pt discharges) | Post-intervention rate (event/10K pt discharges) | p-value |
|---|---|---|---|---|
| PTx - Iatrogenic Pneumothorax | NT | -0.13 | 0.08 | 0.14 |
| | T | -0.19 | 0.14 | 0.04 |
| PEDVT - Postoperative Pulmonary Embolus or Deep Vein Thrombus | NT | 0.65 | 0.59 | 0.01 |
| | T | 1.67 | 0.14 | 0.75 |
| HH - Postoperative Hemorrhage or Hematoma | NT | -0.12 | 0.04 | 0.71 |
| | T | -0.20 | 0.15 | 0.33 |
| PMD - Physiologic or Metabolic Derangement | NT | 0.05 | 0.15 | 0.18 |
| | T | 0.18 | 0.07 | 0.49 |
| aPL - accidental Puncture or Laceration | NT | -0.13 | 0.12 | 0.56 |
| | T | 0.20 | -0.53 | 0.17 |
| WD - Postoperative Wound Dehiscence | NT | 0.05 | 0.55 | 0.20 |
| | T | -0.01 | 0.72 | 0.07 |

# Results


Adjusted Rate of Pneumothorax
teaching vs nonteaching hospitals
Rate of PTx/10K patient discharges
0
5
10
15
20
25
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
Discharge Quarter
teaching
nonteaching

# Results


Adjusted Rate of PE/DVT
teaching vs nonteaching hospitals
Rate of PE/DVT/10K patient discharges
0
25
50
75
100
125
150
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
Discharge Quarter
teaching
nonteaching

# Results

- There were no significant differences in rate trends or in immediate effects of the policy change
  - Post-operative hemorrhage or hematoma (HH)
  - Post-operative wound dehiscence (WD)
  - Accidental puncture or laceration (aPL)
  - Post-operative physiologic and metabolic derangements (PMD)

# Conclusions

- Only PTx showed a significant effect after duty hour regulations in teaching hospitals; similarly, only PE/DVT showed a significant effect in nonteaching hospitals.
- Neither of these changes resulted in an improvement of the PSI.
- Due to the lack of consistent patterns of change, we conclude that there is no measureable effect of the policy change on these PSIs.

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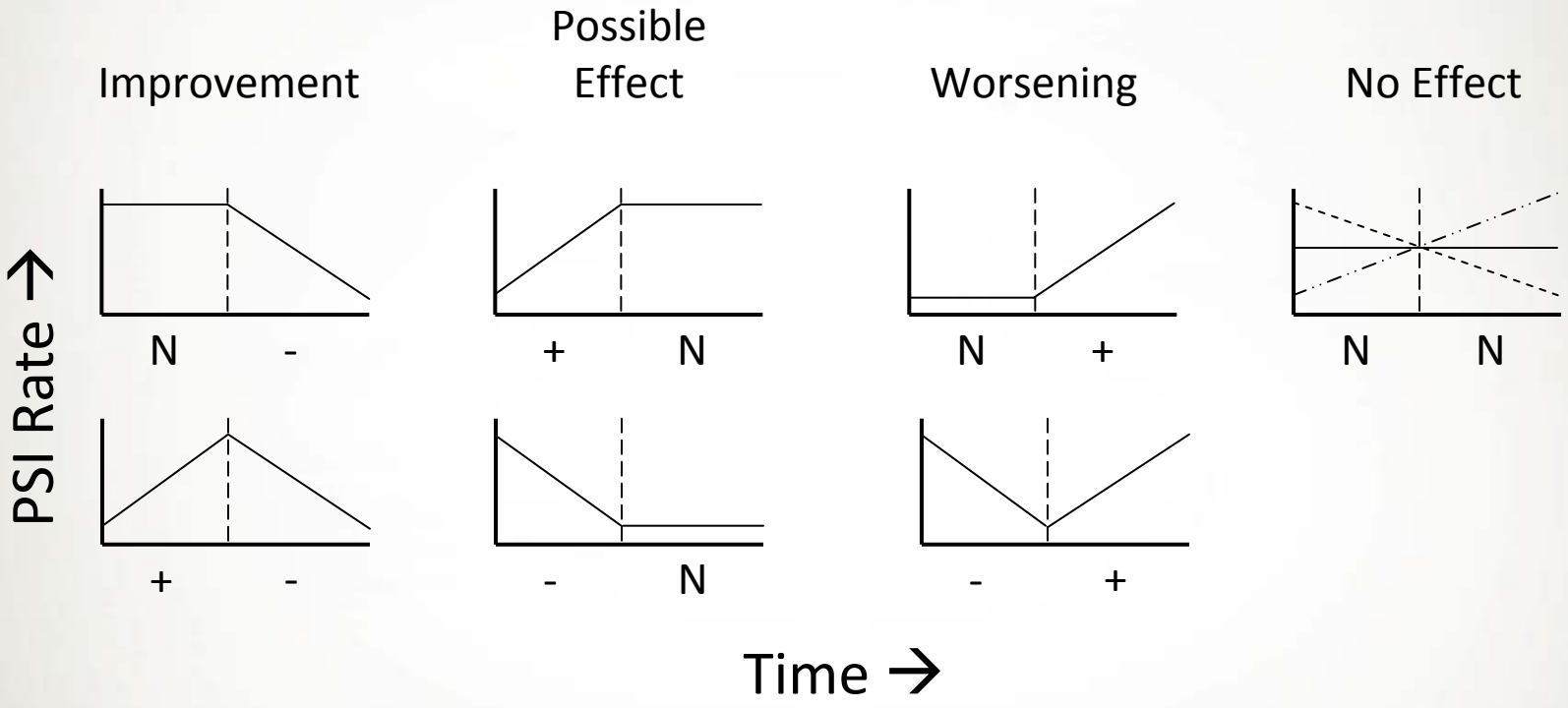
# Patient Discharges by Teaching Status

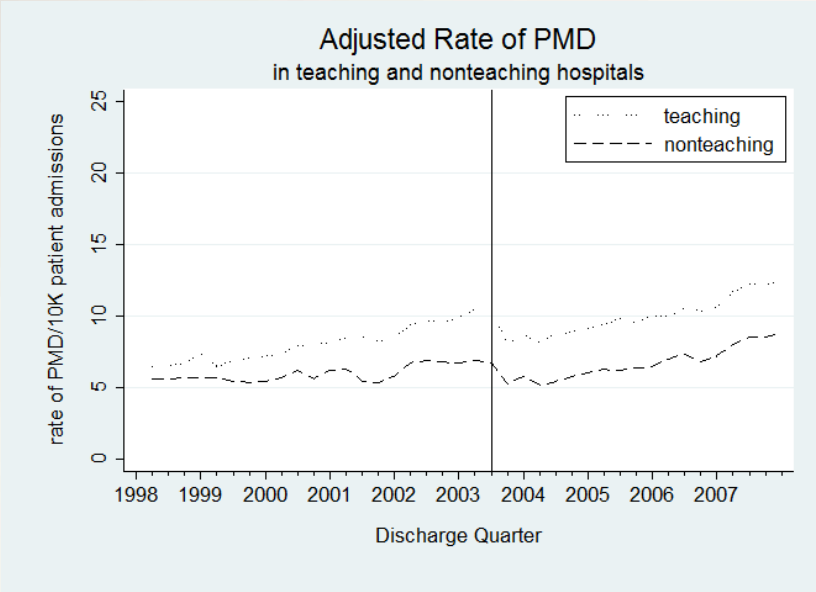
Table 1 – Total Yearly Patient Discharges by Teaching-Nonteaching Status

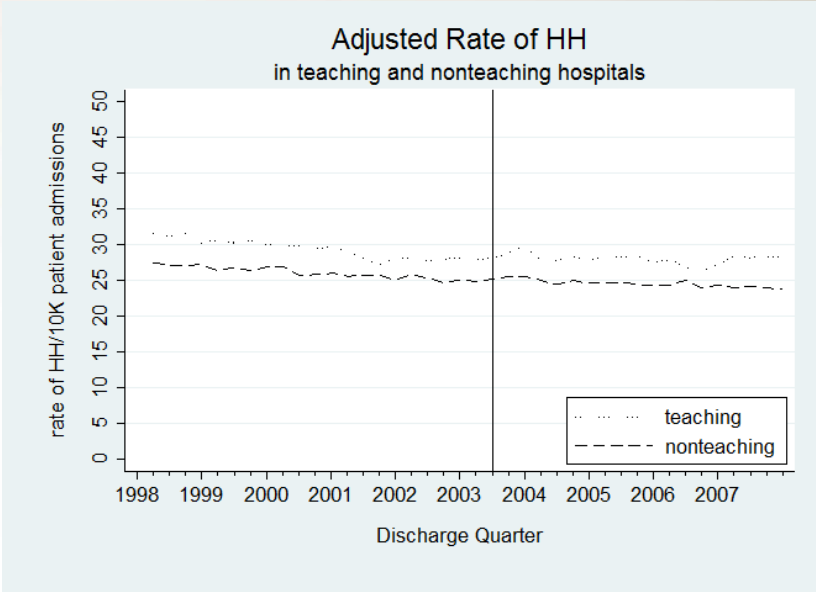
| Calendar Year | Participating States | Sample Hospitals | | Raw Discharges | | Weighted Discharges | |
|---|---|---|---|---|---|---|---|
| | | T* | NT* | T | NT | T | NT |
| 1998 | 22 | 195 | 787 | 3,132,644 | 3,668,527 | 16,815,005 | 17,938,471 |
| 1999 | 24 | 198 | 786 | 3,385,811 | 3,813,118 | 17,170,794 | 18,296,919 |
| 2000 | 28 | 172 | 821 | 3,195,481 | 4,243,926 | 15,795,383 | 20,569,365 |
| 2001 | 33 | 172 | 814 | 3,167,539 | 4,285,188 | 16,452,295 | 20,735,351 |
| 2002 | 35 | 178 | 817 | 3,530,994 | 4,322,988 | 17,130,943 | 20,673,111 |
| 2003 | 37 | 175 | 817 | 3,507,256 | 4,466,593 | 16,890,021 | 21,310,686 |
| 2004 | 37 | 175 | 828 | 3,598,070 | 4,406,501 | 17,266,656 | 21,395,130 |
| 2005 | 37 | 164 | 890 | 3,293,582 | 4,701,466 | 16,360,911 | 22,802,923 |
| 2006 | 38 | 198 | 844 | 3,804,142 | 4,254,173 | 18,920,907 | 20,450,041 |
| 2007 | 40 | 191 | 851 | 3,758,898 | 4,273,251 | 18,760,902 | 20,728,565 |

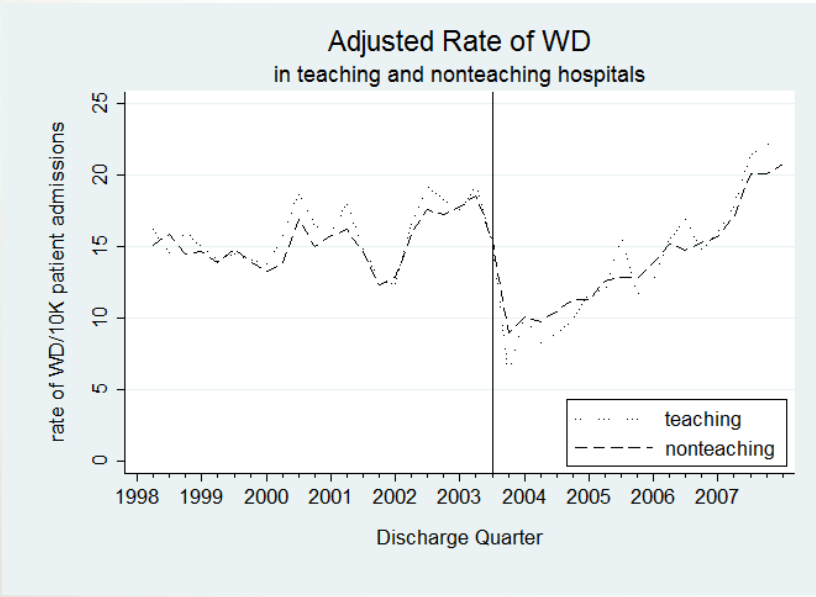
*Hospitals in the Nationwide Inpatient Sample (NIS) without a (T)teaching/(NT)nonteaching designation were excluded from this study.

# Interrupted Time Series




Adjusted Rate of PMD
in teaching and nonteaching hospitals
rate of PMD/10K patient admissions
0
5
10
15
20
25
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
Discharge Quarter
teaching
nonteaching


Adjusted Rate of HH
in teaching and nonteaching hospitals
rate of HH/10K patient admissions
0
5
10
15
20
25
30
35
40
45
50
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
Discharge Quarter
teaching
nonteaching


Adjusted Rate of WD
in teaching and nonteaching hospitals
rate of WD/10K patient admissions
0
5
10
15
20
25
1998
1999
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2001
2002
2003
2004
2005
2006
2007
Discharge Quarter
teaching
nonteaching

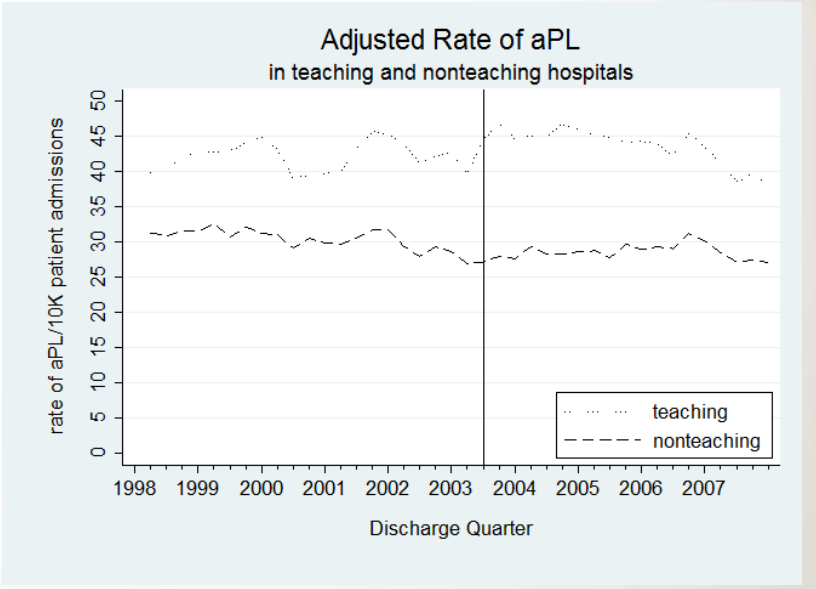
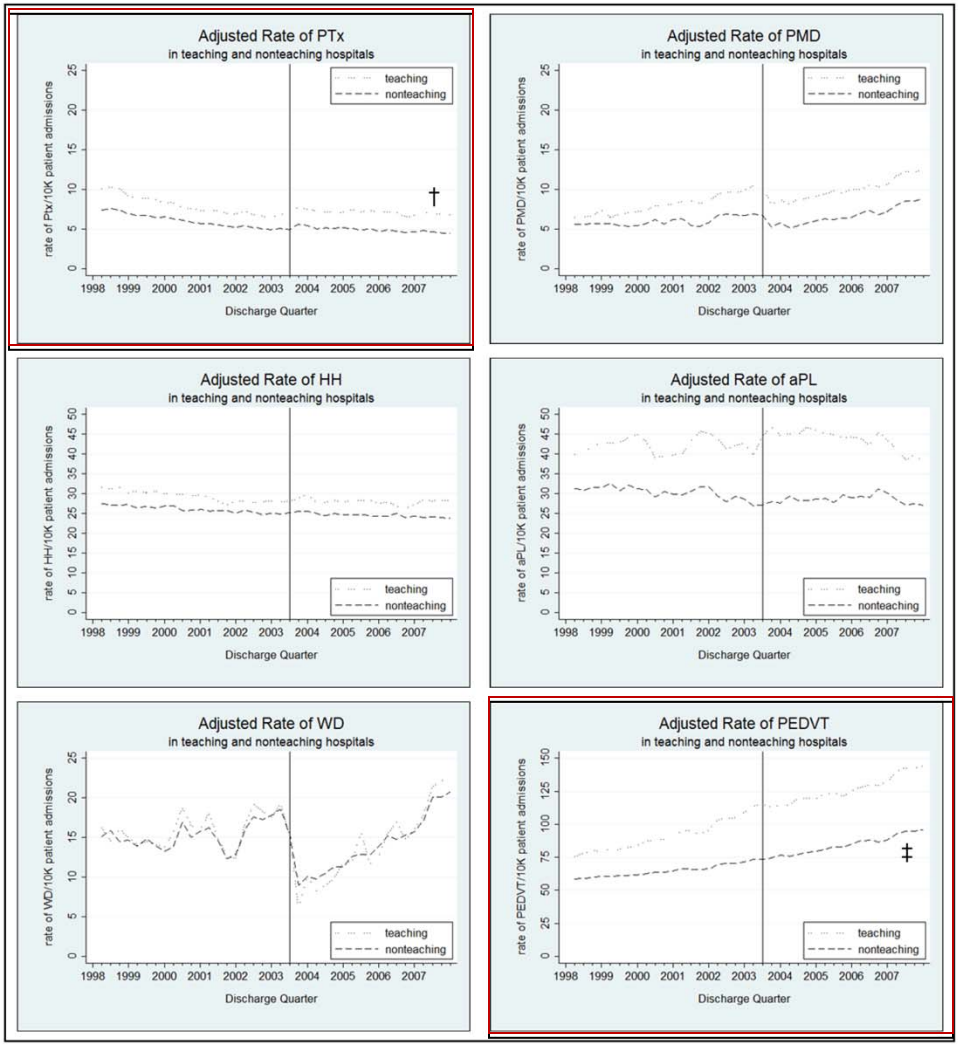

Adjusted Rate of aPL
in teaching and nonteaching hospitals
rate of aPL/10K patient admissions
0
5
10
15
20
25
30
35
40
45
50
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
Discharge Quarter
teaching
nonteaching

Figure 1 – Adjusted Rates of PSIs by Teaching Status




*PSIs per 10,000 admissions per discharge quarter: note different scales on y-axis.
Vertical line on each graph represents the implementation of 80 hour work week.
† PTx: Prior to the policy change, PTx rates had been declining in both teaching (T) and nonteaching (NT) institutions. This decline slowed significantly in T hospitals (p-value 0.04) after the implementation of the 80 hour work week.
‡PEDVT: Prior to the policy change, PEDVT rates were increasing in both T and NT hospitals. After the policy change the rates for PEDVT were noted to increase further in NT institutions p-value 0.01).

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# ACGME Policy: the 80-Hour Work Week

- ACGME Duty Hours
  - **Must promote patient safety and resident well-being**
  - 80 hours/weekly
  - No more than 24 hours of consecutive call
  - Plus 6 hours for administrative and educational duties and to maintain continuity of care
  - 10 hour rest period in between shifts and after in-house call
  - No new patients accepted after 24 hours of call

- ACGME Effect
  - >8700 programs
  - ~130 specialties
  - Nearly 110,000

- Program Implementation - July 2003

# Etiology of Suboptimal Care

- Sleep Physiology
- Fatigue
- Stress
- Culture of resident training
- Financial restrictions

- Implication: more hours → greater fatigue → increased provider errors → adverse patient events

# Inadvertent Outcomes

- Handoffs
  - Increased frequency
  - Poorly conducted
- Lack of familiarity
- Decreased resident education
- Decreased technical instruction or practice
- Decreased clinical knowledge

# Prior Work

- There is an ever growing body of “imperfect literature” regarding work hour restrictions and patient safety
- In a systematic review, Fletcher et al found 7 studies that addressed patient safety and duty hour restrictions
- Morrison and colleagues in their 2009 study addressed the question of Mortality and morbidity using the National Trauma Data Bank

- There are no studies that specifically address patient safety related to duty hour restrictions using national data

# Hypothesis

- The question remains: Has the 80-hour work week policy met its goals of improving patient safety?

- There has been no change in patient safety as a result of the policy implementation

# Standards

- IOM report
- The Agency for Healthcare Research and Quality (AHRQ) has established quality indicators (QIs) which have been designed to measure health care quality from readily available administrative data
- Patient Safety Indicators (PSIs) are one of these quality indicators and allow for identification of rates of adverse events during inpatient hospital stays
- In this study, we will define patient safety standards as the rate of adverse events of each selected patient safety indicator prior to the policy implementation
- These are Indicators – not definitive measures and they have limitations

3. White et al. , Medical Care. 2009 Dec;47(12):1237-1243.
4.Romano, et al., Health Services Research. 2009 Feb;44(1):182-204.
5.Haytham, et al. American Journal of Surgery 2009 198(Suppl to November 2009), S63–S68

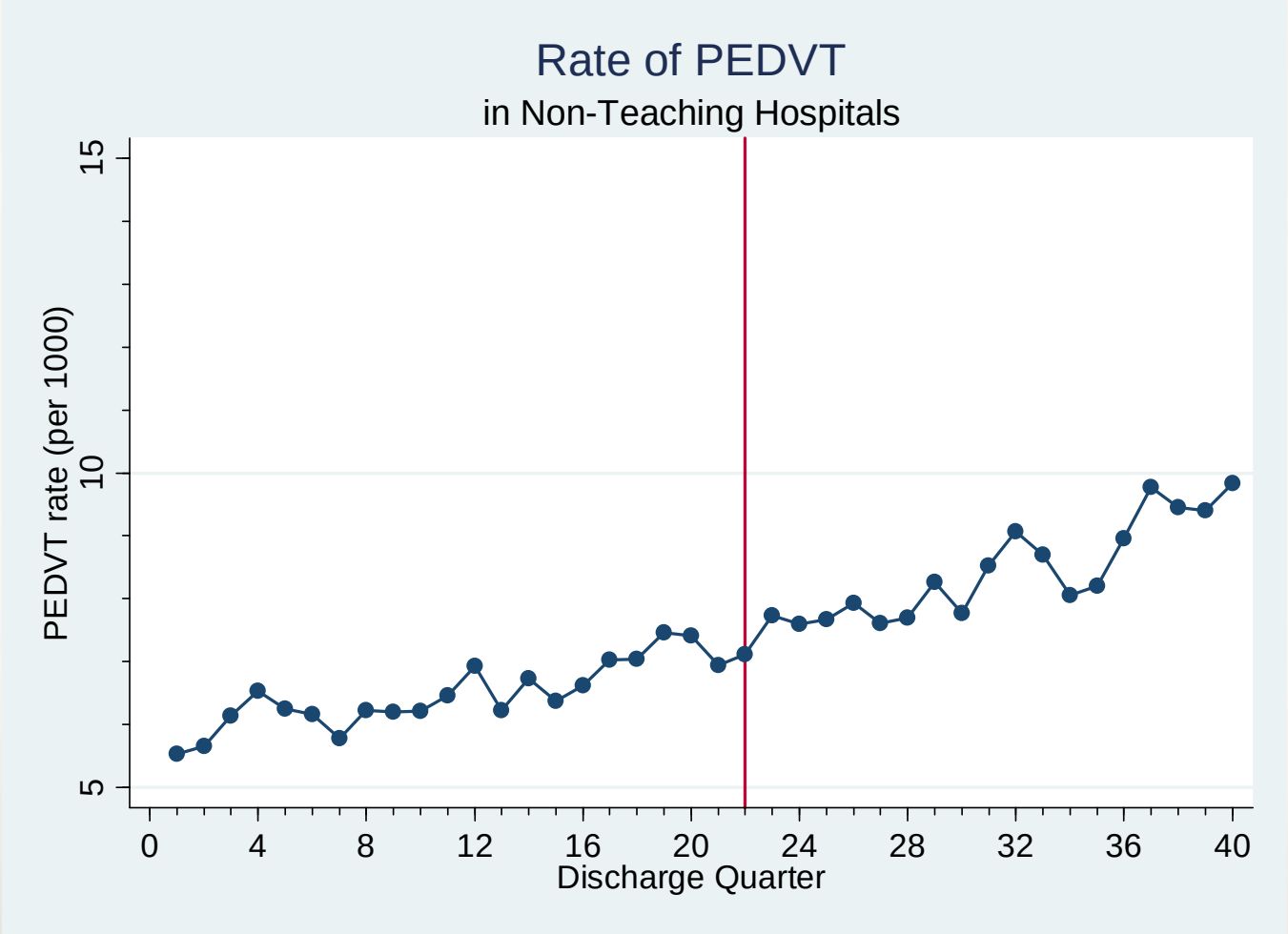
# Outcome Variables

- Foreign Body (FB)
- **Pneumothorax (PTx)**
- Post-operative hemorrhage or hematoma (HH)
- Post-operative physiologic and metabolic derangements (PMD)
- **Post-operative pulmonary embolus or deep vein thrombus (PE/DVT)**
- Post-operative wound dehiscence (WD)
- **Accidental puncture or Laceration (aPL)**

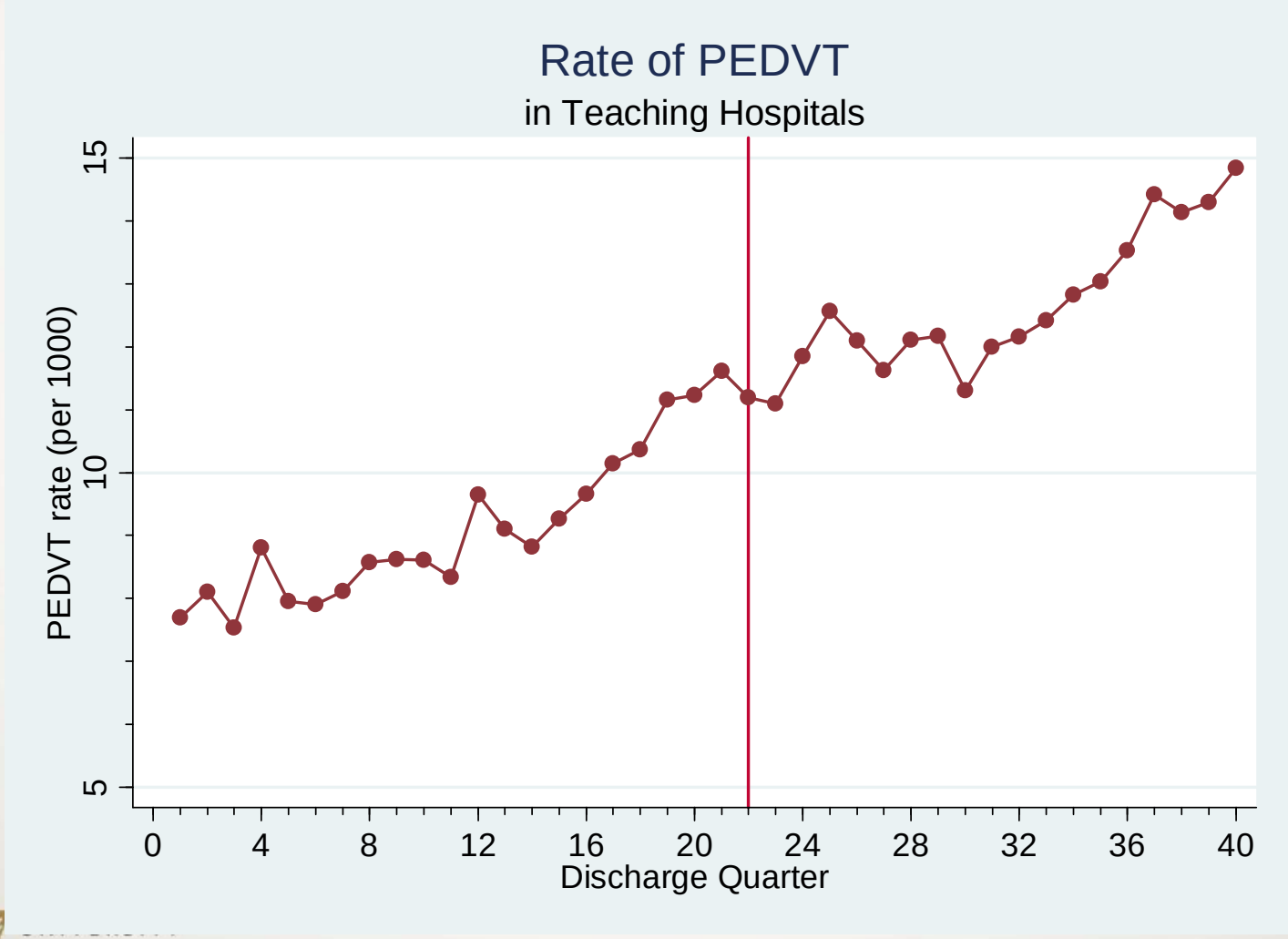
# Methods

- Nationwide Inpatient Sample (NIS)
- 1998-2007
- Interrupted time series analysis

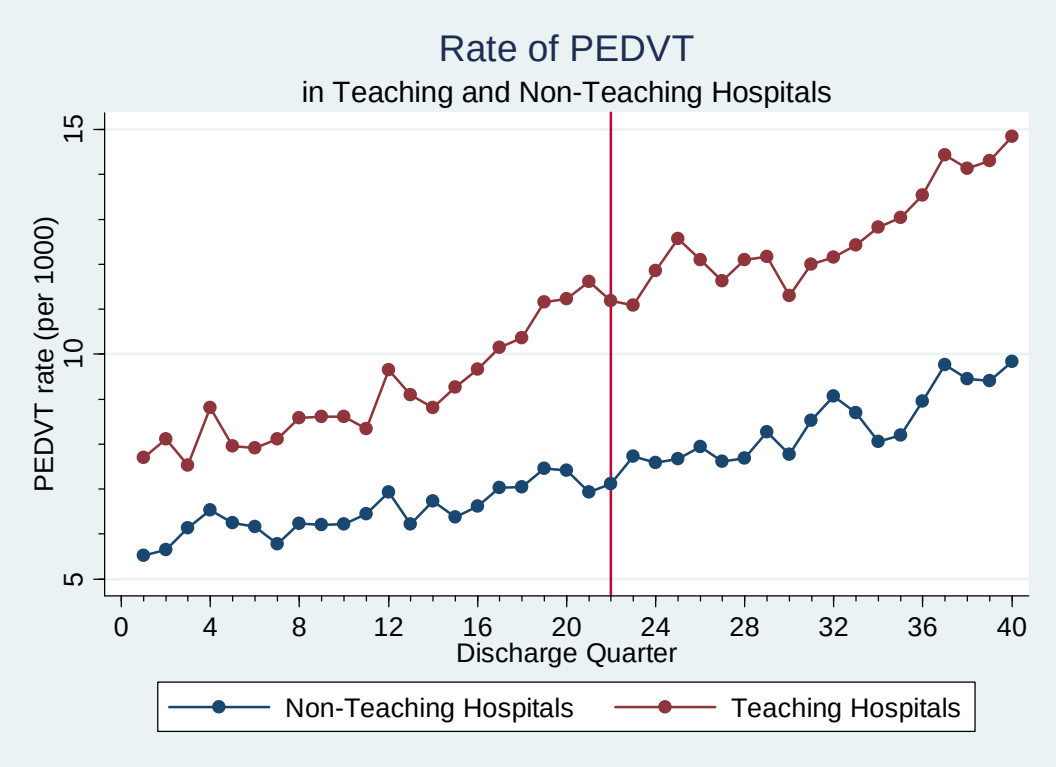
# Results: PEDVT



# Results: PEDVT



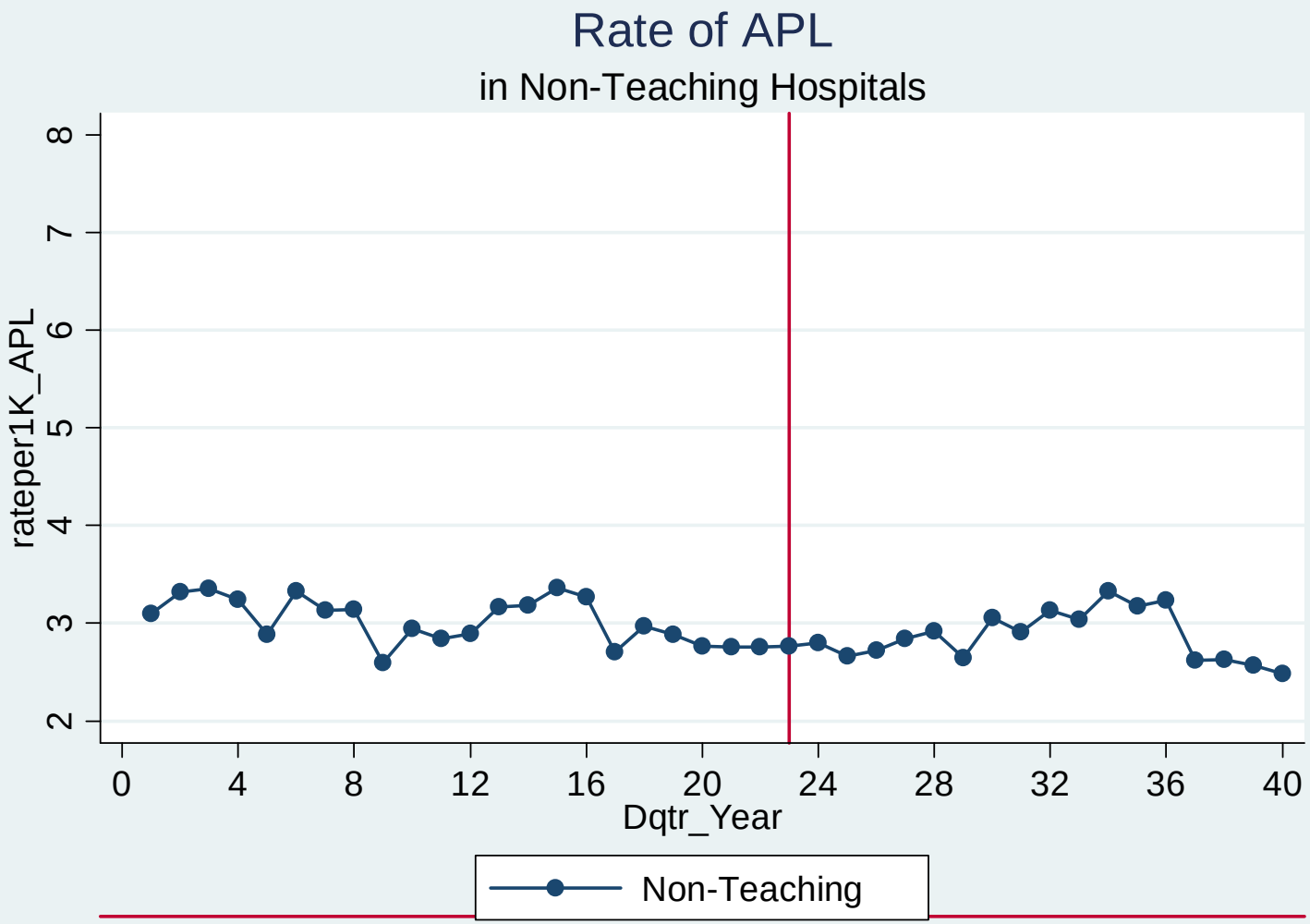
# Results: PEDVT



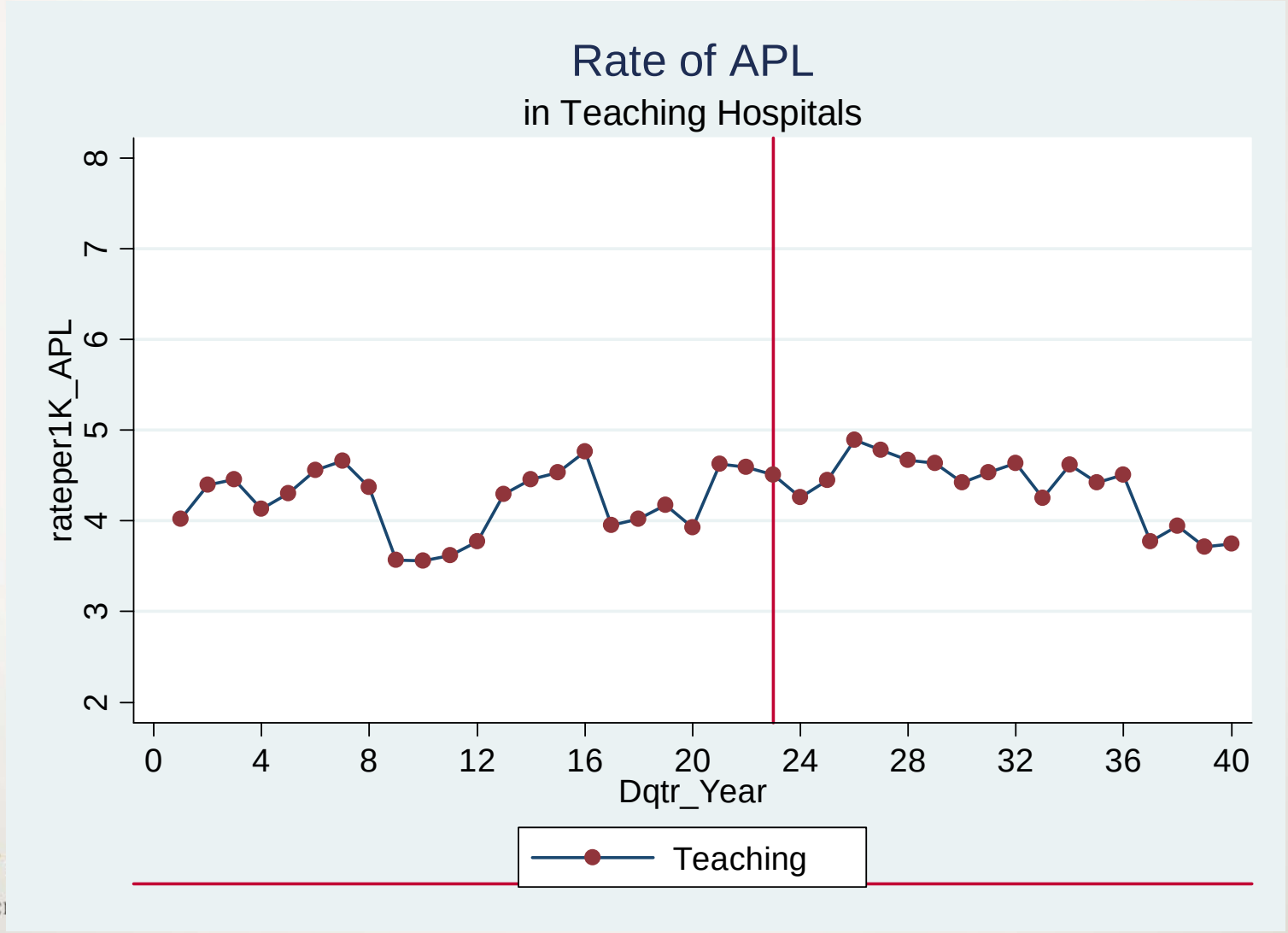
# Conclusions: PEDVT

- There is no significant change in the PEDVT rates as a result of the implementation of the ACGME duty hours policy

# Results: aPL


Rate of APL
in Non-Teaching Hospitals
rateper1K_APL
2
3
4
5
6
7
8
0
4
8
12
16
20
24
28
32
36
40
Dqtr_Year
Non-Teaching

# Results: aPL


Rate of APL
in Teaching Hospitals
rateper1K_APL
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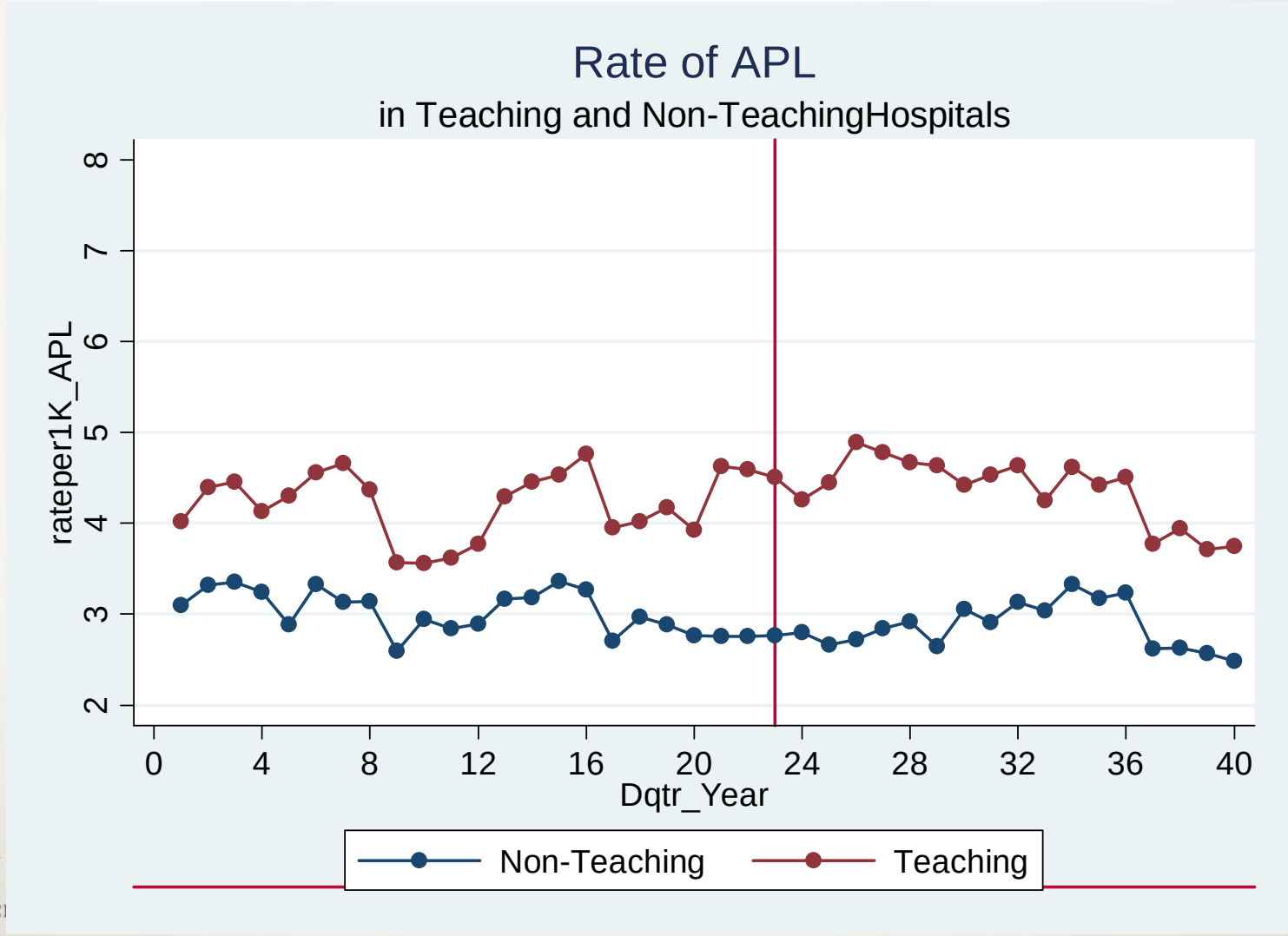
24
28
32
36
40
Dqtr_Year
Teaching

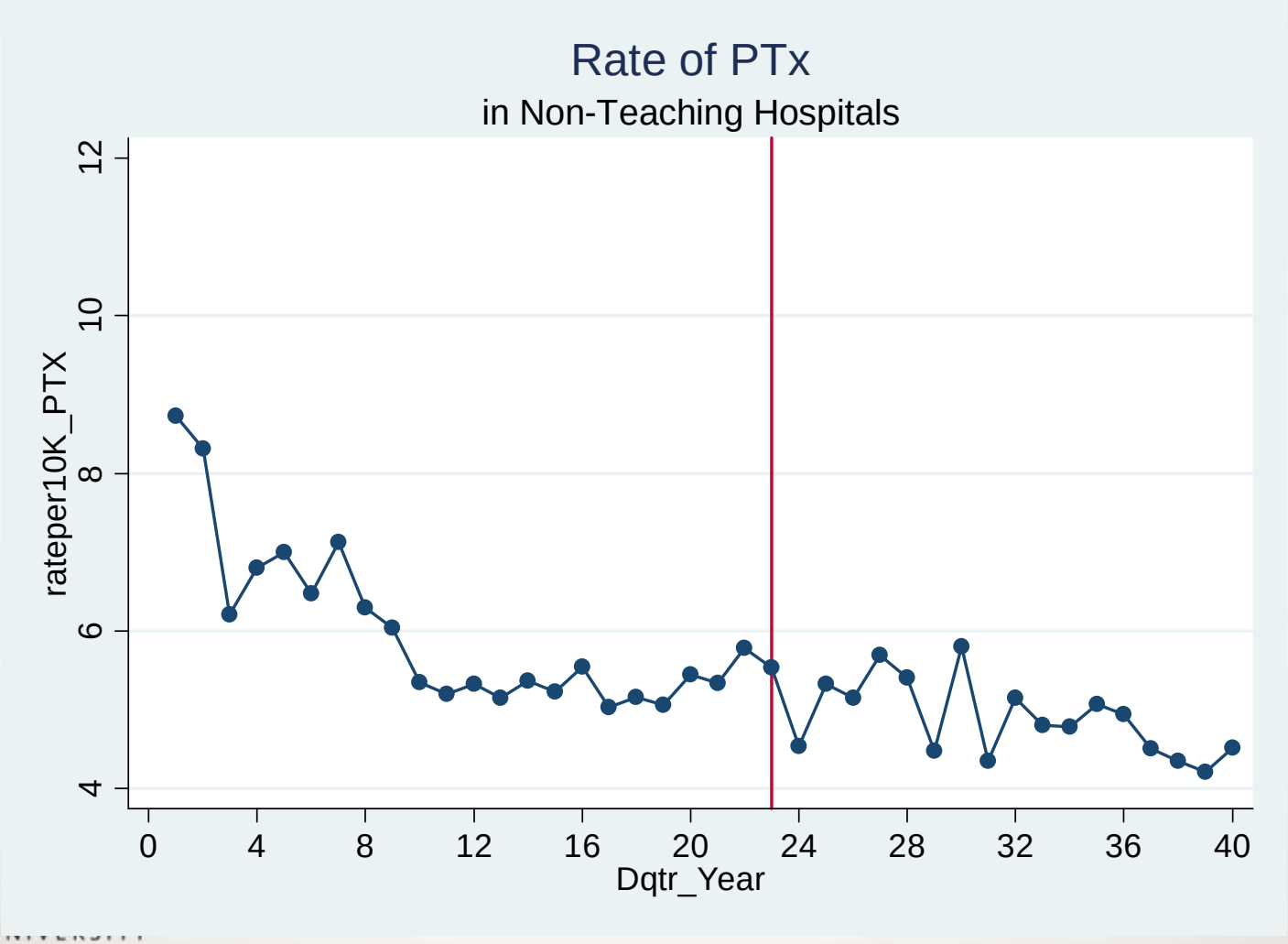
# Results: aPL


Rate of APL
in Teaching and Non-TeachingHospitals
rateper1K_APL
2
3
4
5
6
7
8
0
4
8
12
16
20
24
28
32
36
40
Dqtr_Year
Non-Teaching
Teaching

# Conclusions: aPL

- The rate of aPL does not change as a result of the intervention

# Results: PTx


Rate of PTx
in Non-Teaching Hospitals
rateper10K_PTX
4
6
8
10
12
0
4
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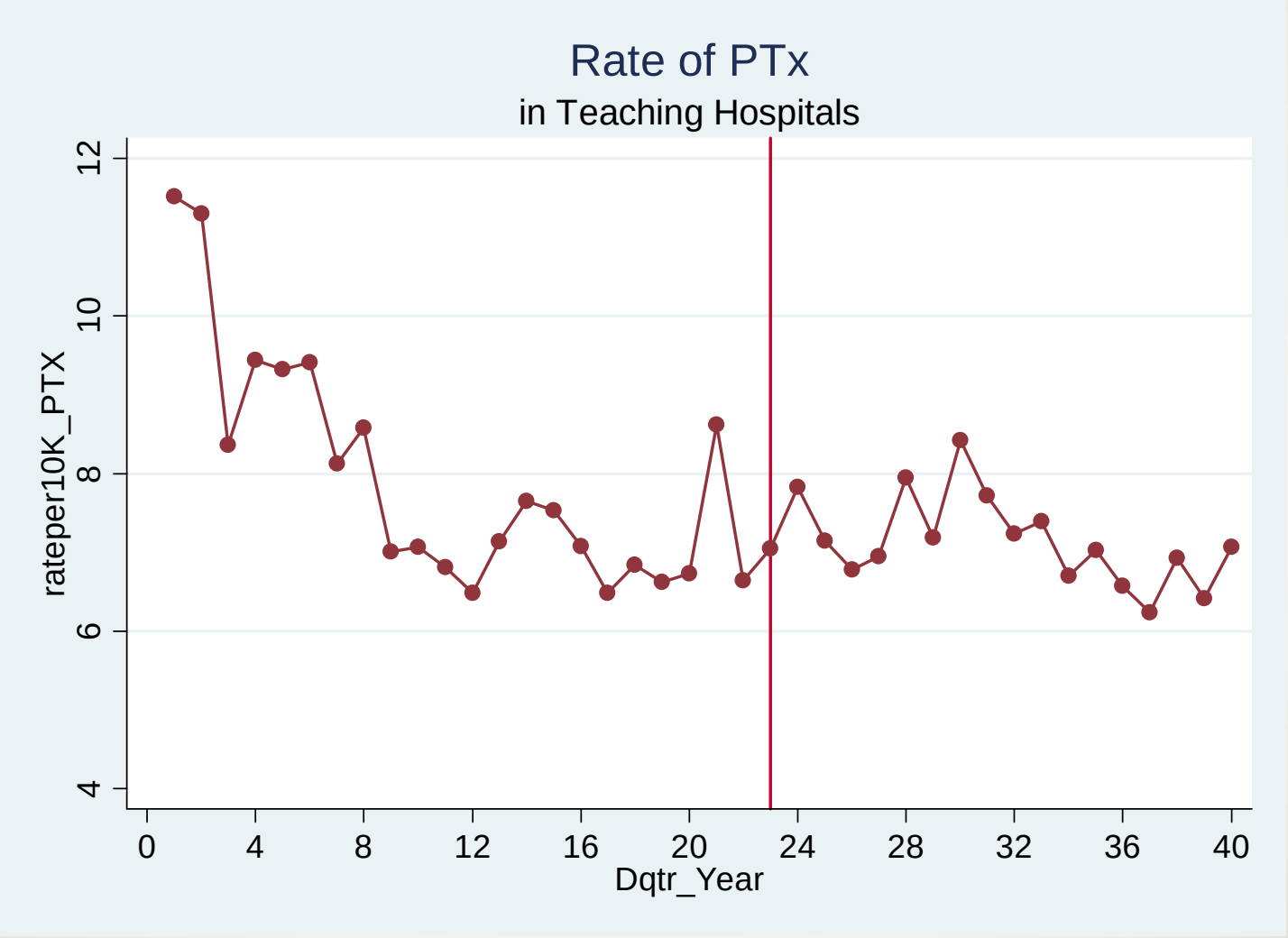
32
36
40
Dqtr_Year

# Results: PTx


Rate of PTx
in Teaching Hospitals
rateper10K_PTX
4
6
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12
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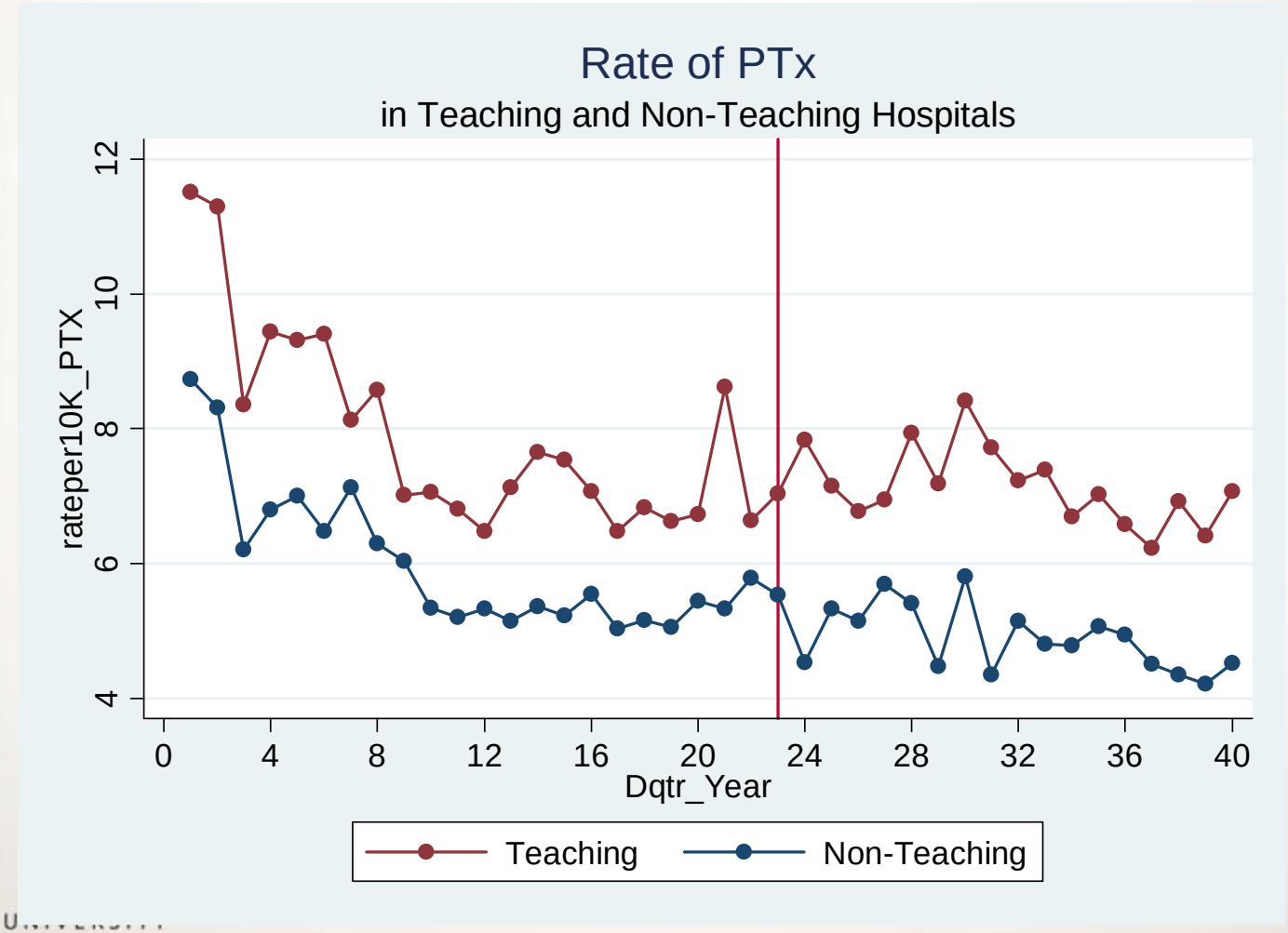
36
40
Dqtr_Year

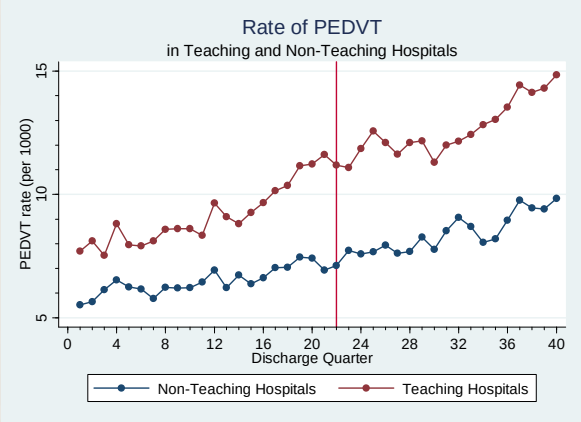
# Results: PTx

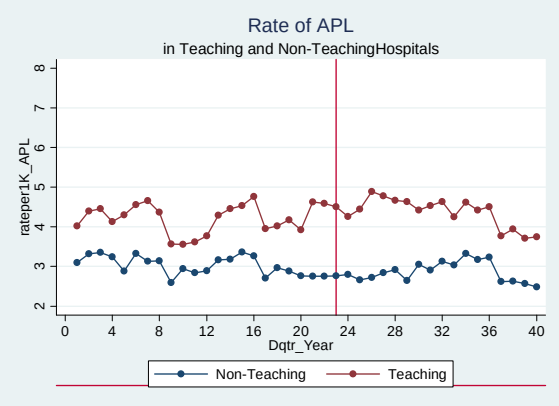

Rate of PTx
in Teaching and Non-Teaching Hospitals
rateper10K_PTX
4
6
8
10
12
0
4
8
12
16
20
24
28
32
36
40
Dqtr_Year
Teaching
Non-Teaching

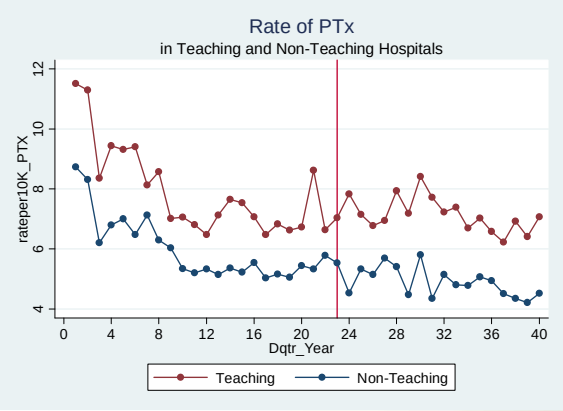
# Conclusions: PTx

- There is a non-significant trend toward lower rates of PTx in the Teaching Hospitals.

# Result Review

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# Study Limitations

- The events used to calculate PSIs are rare
- Definition may vary and thus affect coding
- Denominator not specific enough
- Underreporting → artificially low rate
- Screening → artificially high rate
- Case mix bias (should be addressed by propensity score)
- New York State is included in all years of our analysis

# Implications:

- Patient safety is multi-factorial
- Measures of patient safety may be inadequate
- It is difficult to implement effective, productive changes if we cannot adequately evaluate patient safety

# Next Steps

- Repeat Analysis for remaining PSIs
- Propensity Scores

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- Romano, et al., Health Services Research. 2009 Feb;44(1):182-204.
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**Table 1** List of the currently available nonobstetric PSIs

| PSI | Definition |
|---|---|
| 1. Complications of anesthesia | Cases of anesthetic overdose, reaction, or endotracheal tube misplacement per 1,000 surgery discharges. Excludes codes for drug use and self-inflicted injury. |
| 2. Death in low-mortality DRGs* | In-hospital deaths per 1,000 patients in DRGs with <0.5% mortality. Excludes trauma, immunocompromised, and cancer patients. |
| 3. Decubitus ulcer | Cases of decubitus ulcer per 1,000 discharges with lengths of stay ≥ 5 days. Excludes patients with paralysis or in MDC 9 or MDC 14 and patients admitted from long-term care facilities. |
| 4 Failure to rescue*,† | Deaths per 1,000 patients having developed specified complications of care during hospitalization. Excludes patients aged ≥75 years, neonates in MDC 15, patients admitted from long-term care facilities, and patients transferred to or from other acute care facilities. |
| 5. Foreign body left during procedure* | Discharges with foreign bodies accidentally left in during procedures per 1,000 discharges. |
| 6. Iatrogenic pneumothorax*,† | Cases of iatrogenic pneumothorax per 1,000 discharges. Excludes trauma, thoracic surgery, lung or pleural biopsy, or cardiac surgery patients and patients in MDC 14. |
| 7. Selected infections due to medical care | Cases of secondary ICD-9-CM code 9993 or 00662 per 1,000 discharges. Excludes patients with immunocompromised state or cancer. |
| 8. Postoperative hip fracture | Cases of in-hospital hip fracture per 1,000 surgical discharges. Excludes patients in MDC 8, patients with conditions suggesting fracture present on admission, and patients in MDC 14. |
| 9. Postoperative hemorrhage or hematoma | Cases of hematoma or hemorrhage requiring procedures per 1,000 surgical discharges. Excludes patients in MDC 14. |
| 10. Postoperative physiologic and metabolic derangements | Cases of specified physiologic or metabolic derangement per 1,000 elective surgical discharges. Excludes patients with principal diagnoses of diabetes and with diagnoses suggesting increased susceptibility to derangement. Excludes obstetric admissions. |
| 11. Postoperative respiratory failure | Cases of acute respiratory failure per 1,000 elective surgical discharges. Excludes patients in MDCs 4 and 5 and obstetric admissions. |
| 12. Postoperative pulmonary embolism or deep vein thrombosis* | Cases of DVT or PE per 1,000 surgical discharges. Excludes obstetric patients. |
| 13. Postoperative sepsis | Cases of sepsis per 1,000 elective surgery patients with lengths of stay > 3 days. Excludes principal diagnosis of infection or any diagnosis of immunocompromised state or cancer and obstetric admissions. |
| 14. Postoperative wound dehiscence*,† | Cases of reclosure of postoperative disruption of abdominal wall per 1,000 cases of abdominopelvic surgery. Excludes obstetric admissions. |
| 15. Accidental puncture or laceration*,† | Cases of technical difficulty (eg, accidental cut or laceration during procedure) per 1,000 discharges. Excludes obstetric admissions. |
| 16. Transfusion reaction* | Cases of transfusion reaction per 1,000 discharges. |

Adapted from AHRQ.[10]

DRG = diagnosis-related group; MDC = major diagnostic category (MDC 4 = respiratory system; MDC 5 = circulatory system; MDC 8 = musculoskeletal system and connective tissue; MDC 9 = skin, subcutaneous tissue, and breast; MDC 14 = pregnancy, childbirth, and puerperium; MDC 15 = newborn and other neonates [perinatal period]).

*Endorsed by the National Quality Forum.

†Adopted by the Centers for Medicare and Medicaid Services.

# PSI limitations

| PSI Name | Definition | Validity Concerns | Strength of Evidence |
|---|---|---|---|
| Foreign Body Left During Procedure (PSI 5) | Discharges with foreign body accidentally left in during procedure per 1,000 discharges | Rare<br>Stratification suggested<br>Denominator unspecific | 0 Coding<br>0 Explicit Process<br>0 Implicit Process<br>0 Staffing |
| Iatrogenic Pneumothorax (PSI 6) | Cases of iatrogenic pneumothorax per 1,000 discharges. Excludes trauma, thoracic surgery, lung or pleural biopsy, or cardiac surgery patients, and MDC 14. | Denominator unspecific | 0 Coding<br>0 Explicit Process<br>0 Implicit Process<br>0 Staffing |
| Postoperative Hemorrhage or Hematoma (PSI 9) | Cases of hematoma or hemorrhage requiring a procedure per 1,000 surgical discharges. Excludes MDC 14. | Stratification suggested<br>Case mix bias<br>Denominator unspecific | ± Coding<br>± Explicit Process<br>+ Implicit Process<br>0 Staffing |
| Postoperative Physiologic and Metabolic Derangement (PSI 10) | Cases of specified physiological or metabolic derangement per 1,000 elective surgical discharges. Excludes patients with principal diagnosis of diabetes and with diagnoses suggesting increased susceptibility to derangement. Excludes obstetric admissions. | Condition definition varies | – Coding<br>0 Explicit Process<br>0 Implicit Process<br>– Staffing |

# PSI limitations (continued)

| PSI Name | Definition | Validity Concerns | Strength of Evidence |
|---|---|---|---|
| Postoperative PE or DVT (PSI 12) | Cases of deep vein thrombosis or pulmonary embolism per 1,000 surgical discharges. Excludes obstetric patients. | Underreporting or screening<br>Stratification suggested | + Coding<br>+ Explicit Process<br>+ Implicit Process<br>± Staffing |
| Postoperative Sepsis (PSI 13) | Cases of sepsis per 1,000 elective surgery patients, with length of stay more than 3 days. Excludes principal diagnosis of infection, or any diagnosis of immunocompromised state or cancer, and obstetric admissions. | Condition definition varies<br>Adverse consequences | ± Coding<br>0 Explicit Process<br>0 Implicit Process<br>– Staffing |
| Postoperative Wound Dehiscence (PSI 14) | Cases of reclosure of postoperative disruption of abdominal wall per 1,000 cases of abdominopelvic surgery. Excludes obstetric admissions. | Case mix bias | 0 Coding<br>0 Explicit Process<br>0 Implicit Process<br>0 Staffing |
| Accidental Puncture or Laceration (PSI 15) | Cases of technical difficulty (e.g., accidental cut or laceration during procedure) per 1,000 discharges. Excludes obstetric admissions. | Underreporting or screening<br>Unclear preventability | ± Coding<br>0 Explicit Process<br>0 Implicit Process<br>0 Staffing |

# Policy: ACGME 80-hour work week

- National patient safety movement
- VA patient safety programs
- Sleep physiology/Sleep medicine
- Stress inoculation
- Joint commission
- Patient safety-Duty hours literature review:
  - Patient handovers
  - Impact of duty hour restrictions on educational outcomes
  - Resident safety and duty hour schedules

- Reiteration that patient safety is the "prime directive"[5]
  - Experiential learning of the resident is crucial to patient safety
  - Responsibility for safety and outcomes is shared within the microsystem of care. Oversight and redundancy assure prevention of errors



5. http://www.acgme.org/acWebsite/dutyHours/dh_index.asp. An open letter to the GME Community. Thomas J. Nasca, MD, MACP

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