

# Conflict of Interest Statement

- I have no commercial relationships to disclose.
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# Safety Warnings about Power Morcellation in Hysterectomy: A Simulation of National Impact

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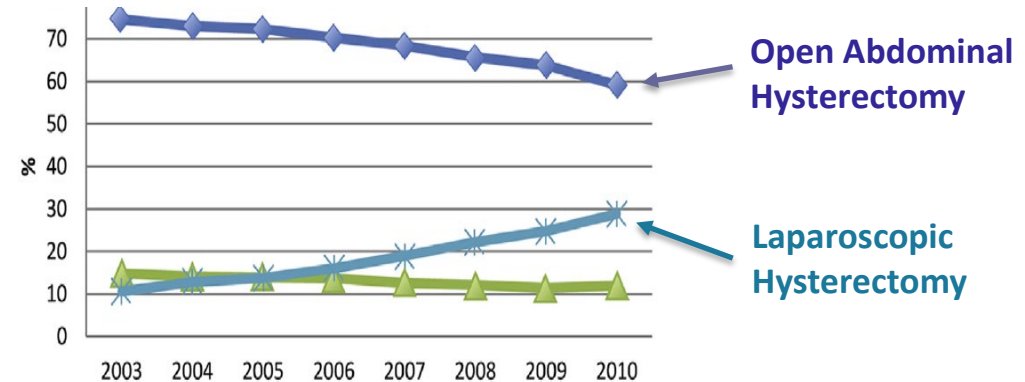
Department of Obstetrics, Gynecology and Reproductive Sciences

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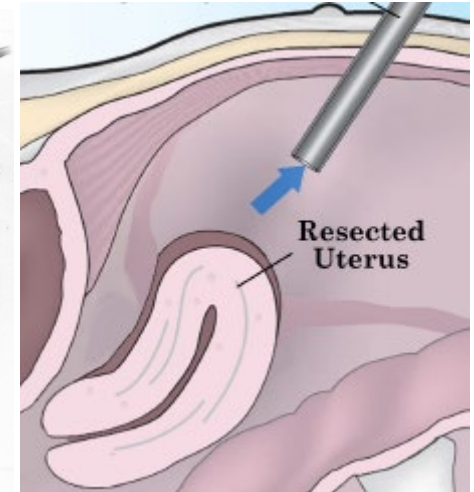
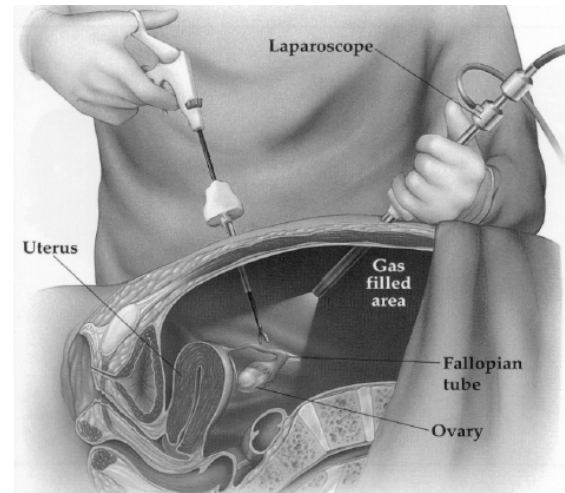
# Hysterectomy

- Hysterectomy: surgical removal of the uterus
  - 600,000 procedures/year
  - Mostly for benign indications
- Increased use of laparoscopic hysterectomy over time
  - Small incisions <2 cm
  - Lower complication rates
  - Faster recovery



# Laparoscopic Power Morcellation

- Facilitate removal of the uterus via small incisions in abdomen
  - When uterus is large or when the cervix is preserved
- A process that involves an electromechanical device with a cylindrical blade – rapidly rotates, cuts uterine tissue into smaller fragments, and extracts



# FDA Warning about Power Morcellation (April 2014)

The screenshot shows the FDA website header with the logo and navigation links. The main content area is titled "Medical Devices" and features a breadcrumb trail: Home > Medical Devices > Medical Device Safety > Safety Communications. A sidebar on the left lists "Medical Device Safety", "Safety Communications", "Information About Heparin", and "Medical Device Safety Archive". The main article title is "Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication", dated April 17, 2014.

**FDA** U.S. Food and Drug Administration  
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**Medical Devices**

Home > Medical Devices > Medical Device Safety > Safety Communications

Medical Device Safety

Safety Communications

Information About Heparin

Medical Device Safety Archive

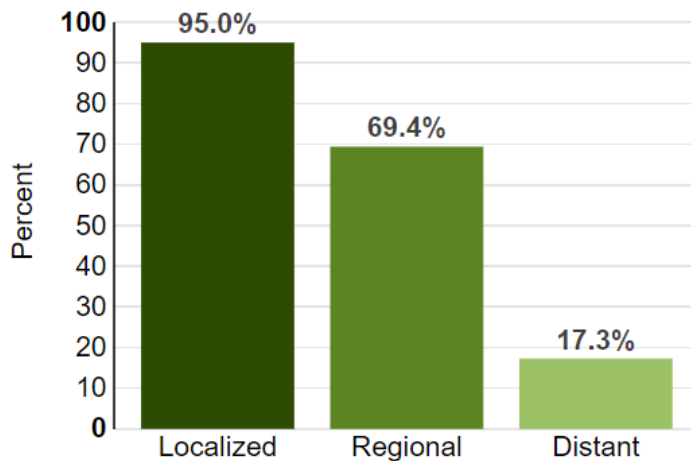
**Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication**

**Date Issued:** April 17, 2014

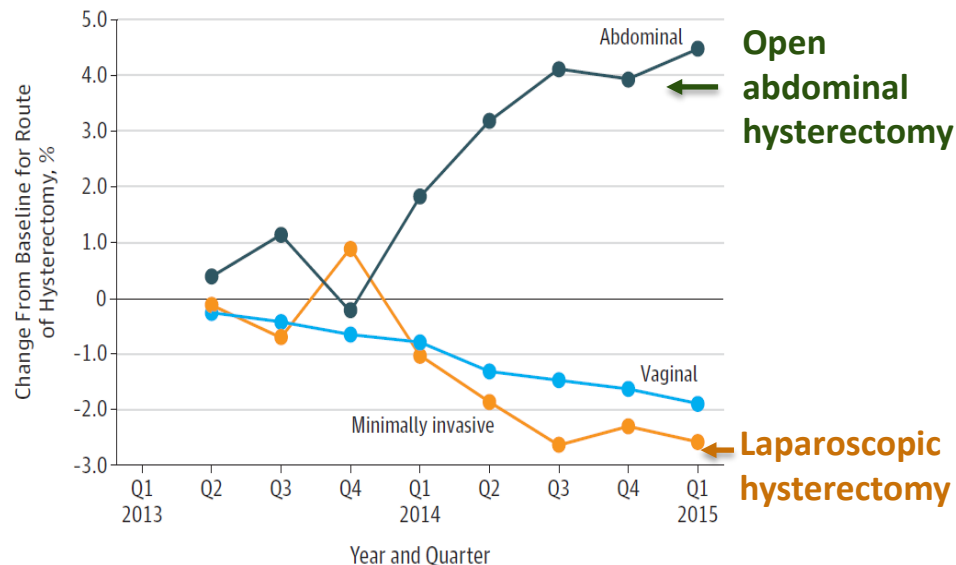
“If laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma, there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient’s likelihood of long-term survival. ....., the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids.”

<https://wayback.archive-it.org/7993/20170406071822/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm393576.htm>

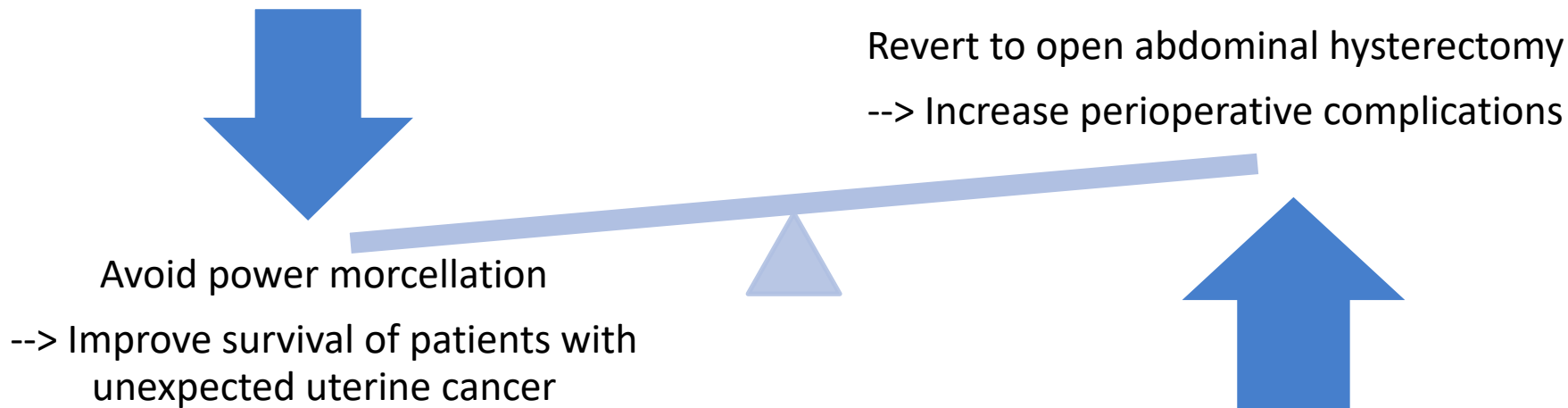
## 5-Year Relative Survival, Uterine Cancer by Stage



<https://seer.cancer.gov/statfacts/html/corp.html>



Wright et al. JAMA. 2016;316(8):877-878.

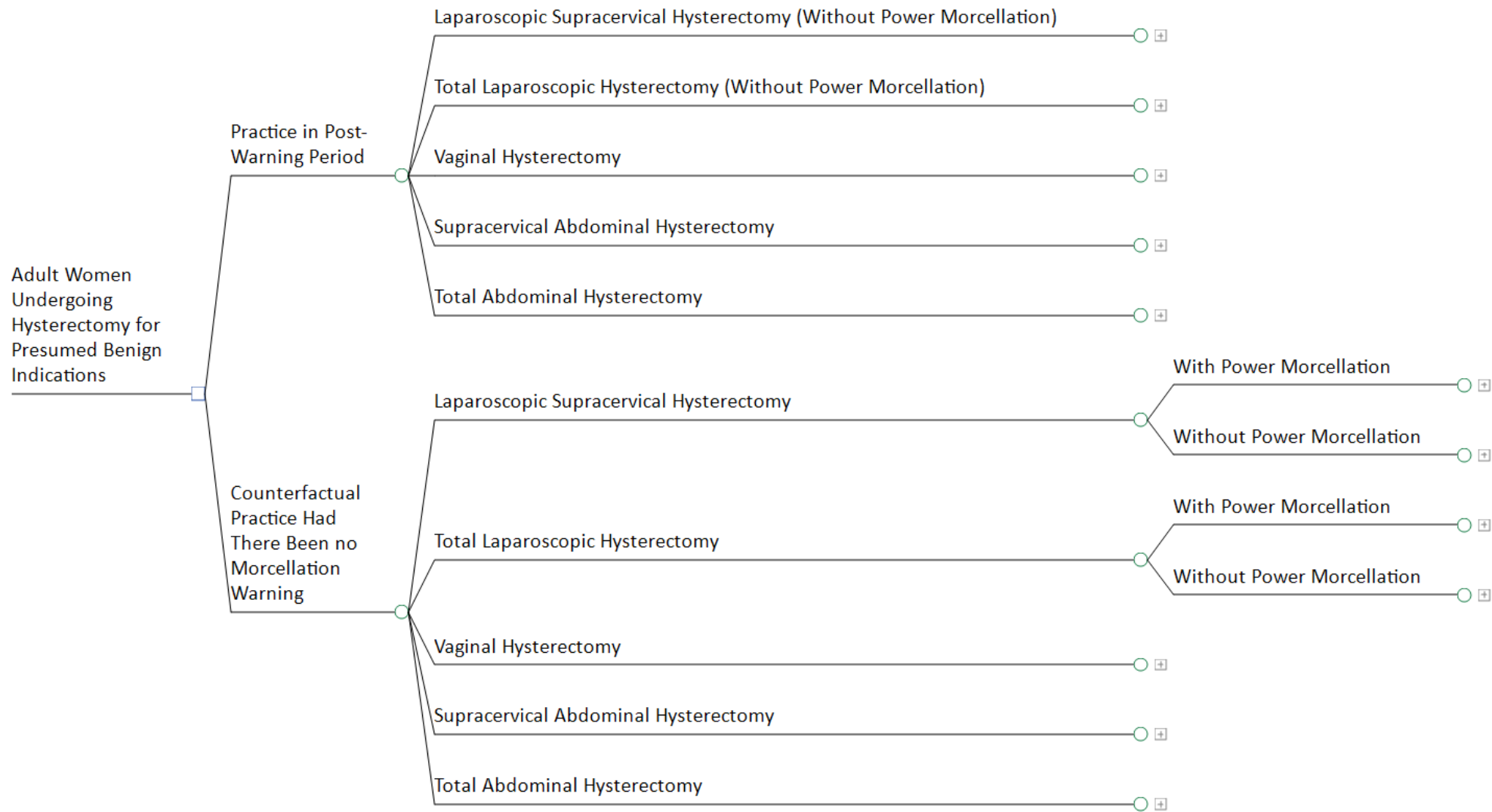


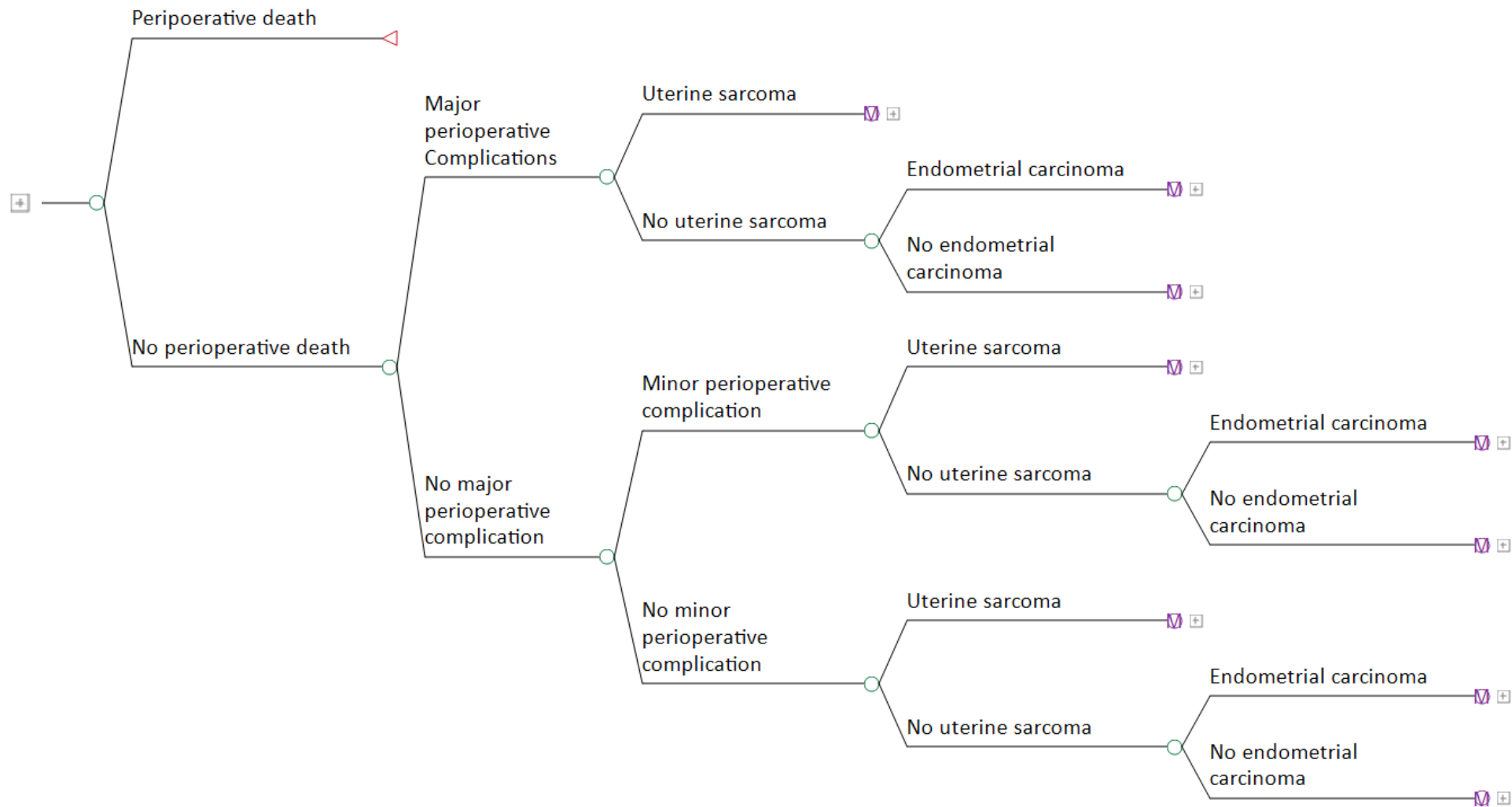
# Research Objective

To examine the cost-effectiveness of hysterectomy practice with versus without the power morcellation warning in the national population, while accounting for both hysterectomy- and occult uterine cancer-related outcomes.

# Overall Study Design

- A decision analytic model comparing:
  - Hysterectomy practice in the post-warning period, vs.
  - Counterfactual hysterectomy practice had there been no morcellation warning
- Societal perspective
- Lifetime horizon
- Study Population: N=353,567 women nationwide who were  $\geq 18$  years of age and underwent a hysterectomy for presumed benign indications





# Data Sources

- Inpatient & outpatient discharge data from 12 states
  - State Inpatient Database (SID)<sup>1</sup> & State Ambulatory Surgery and Services Database (SASD)<sup>1</sup>: Florida, Iowa, Kentucky, Michigan, Minnesota, Nebraska, New Jersey, North Carolina, Oregon, Vermont, and Wisconsin
  - New York Statewide Planning and Research Cooperative System (SPARCS)<sup>2</sup>
- Data from the New York State Cancer Registry (NYSCR)
- Published literature

<sup>1</sup> From the Agency for Healthcare Research and Quality Healthcare Cost and Utilization Project (HCUP).

<sup>2</sup> This publication was produced from raw data purchased from or provided by the New York State Department of Health (NYSDOH). However, the conclusions derived, and views expressed herein are those of the author(s) and do not reflect the conclusions or views of NYSDOH. NYSDOH, its employees, officers, and agents make no representation, warranty or guarantee as to the accuracy, completeness, currency, or suitability of the information provided here.

## SID+SASD+SPARCS Data (12 States)

Post-Warning (2014Q3-2015Q3)

Apply clinical characteristics of patients in the post-warning period

- Hysterectomy route
- Age distribution
- Risk of intraoperative mortality and morbidities
- Cost of hysterectomy, by route and mortality/morbidity status

Pre-Warning (2013Q1-2013Q4):

- How clinical characteristics relate to hysterectomy route

- Counterfactual distribution of hysterectomy route had there been no morcellation warning

**SPARCS+NYSCR Linked Data**  
(2003-2013)

- Impact of morcellation on occult uterine cancer survival

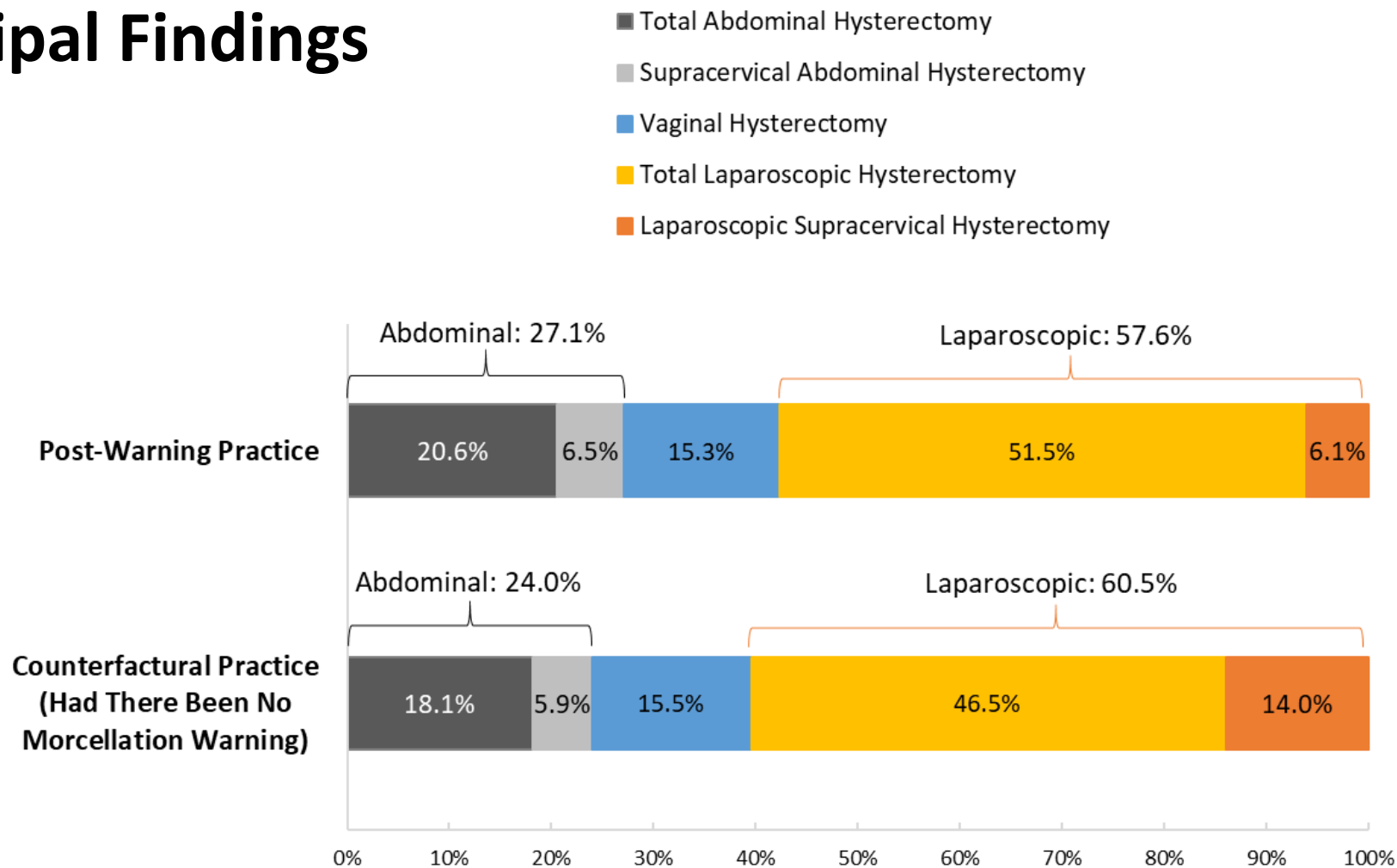
**Published Literature**

- All other parameters, e.g., utility, cost of cancer care

## National Simulation

- Extrapolate to national population (females age  $\geq 18$ )
- Assume practice pattern in the 12 states is generalizable

# Principal Findings

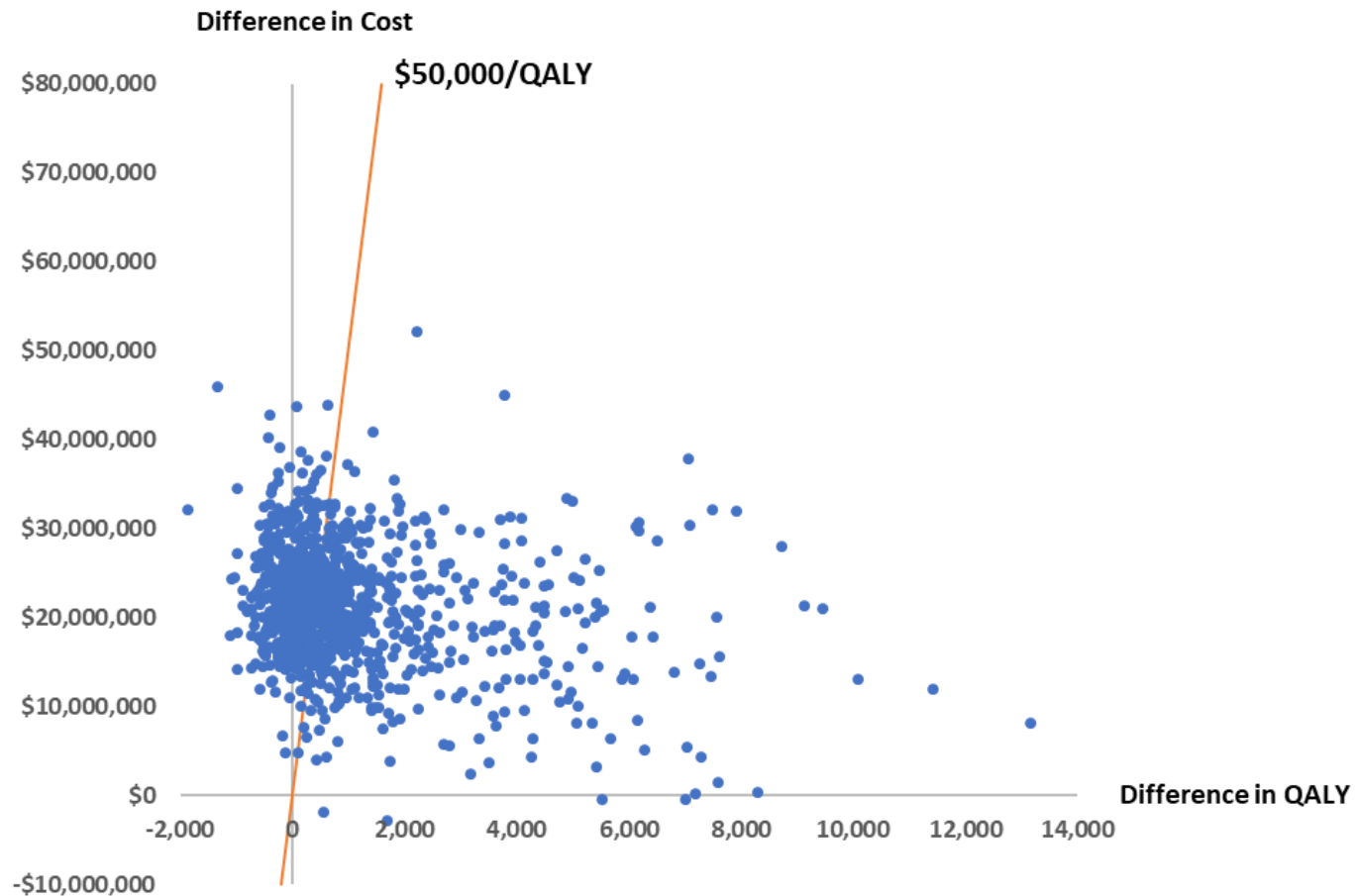


# Principal Findings

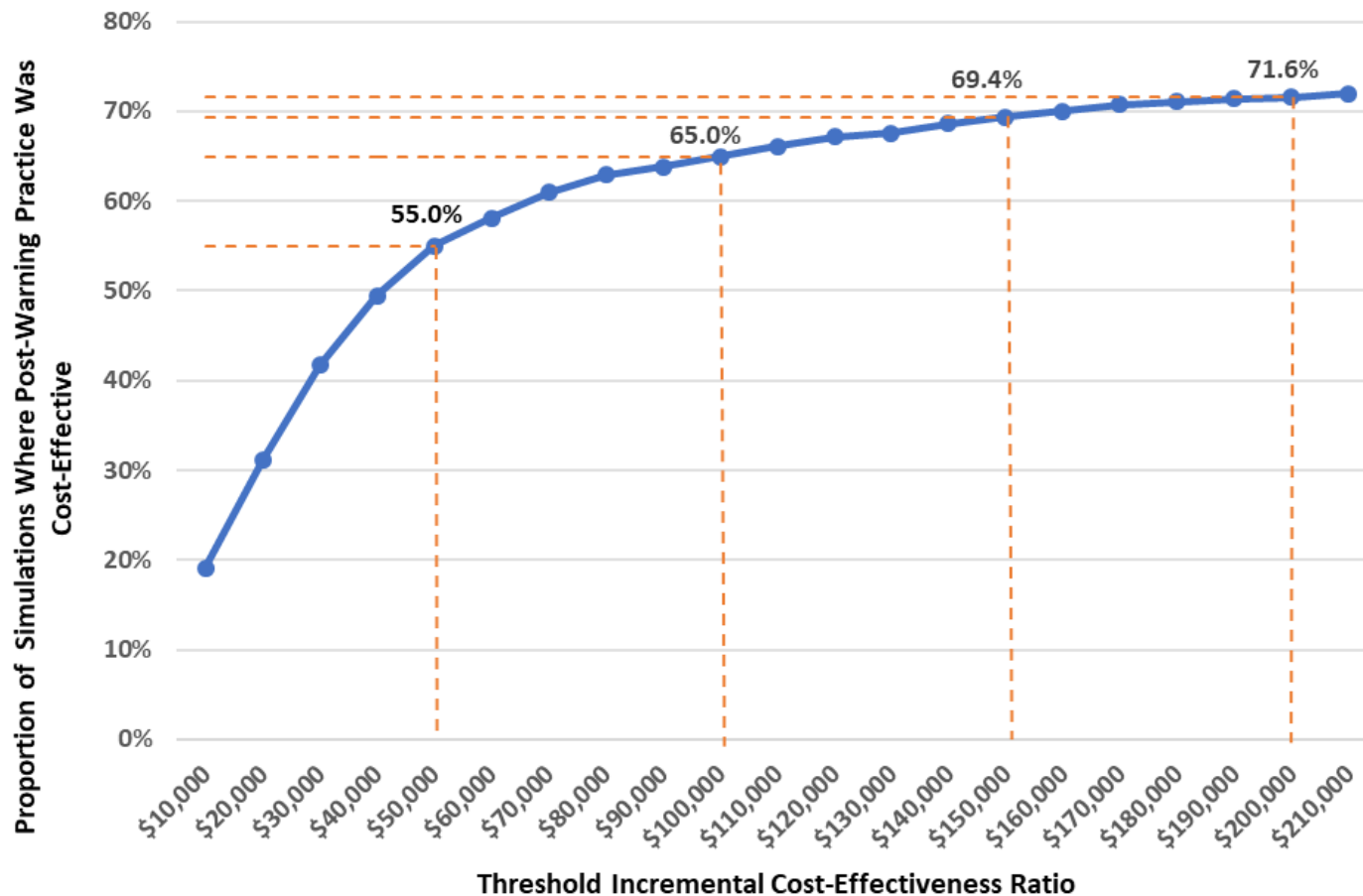
| Outcomes                                          | Post-Warning    | Counterfactual<br>(without warning) | Difference   |
|---------------------------------------------------|-----------------|-------------------------------------|--------------|
| Hysterectomy-related outcomes                     |                 |                                     |              |
| # deaths                                          | 31              | 30                                  | 1            |
| # major complications                             | 24,819          | 23,411                              | 1,408        |
| # minor complications                             | 7,634           | 7,486                               | 148          |
| Occult cancer-related outcomes                    |                 |                                     |              |
| # occult endometrial carcinoma morcellated        | 0               | 333                                 | -333         |
| # occult uterine sarcoma morcellated              | 0               | 115                                 | -115         |
| Expected total quality adjusted life years (QALY) | 7,610,775.61    | 7,610,104.66                        | 670.95       |
| Expected total cost                               | \$4,938,725,733 | \$4,914,964,373                     | \$23,761,360 |
| Incremental cost-effectiveness ratio              | \$35,414/QALY   |                                     |              |

Costs are reported in 2015 USD.

# Principal Findings



# Principal Findings



# Conclusions

- Morcellation warning led to changes in hysterectomy practice
  - Mostly affected laparoscopic supracervical hysterectomy
- An increase in hysterectomy-related mortality/morbidities, but avoided morcellation of occult cancers -> Net gain in QALYs but higher costs
- Aggregate impact is expected to be cost-effective in base-case analysis

# Discussion

- Morcellation warning did not substantially shift practice away from minimally invasive hysterectomy
- Morcellation warning is expected to improve QALYs in overall population
- Limitations: administrative data, model assumptions
- Future directions:
  - Further research on key parameters: prevalence of occult uterine cancer, impact of morcellation on cancer survival, utility weights
  - Safety of new specimen removal techniques (e.g., in-bag morcellation)

# Thank You!

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