

# The Impact of Third Party Payment Policies on Trial Enrollment: What Does the Evidence Say?

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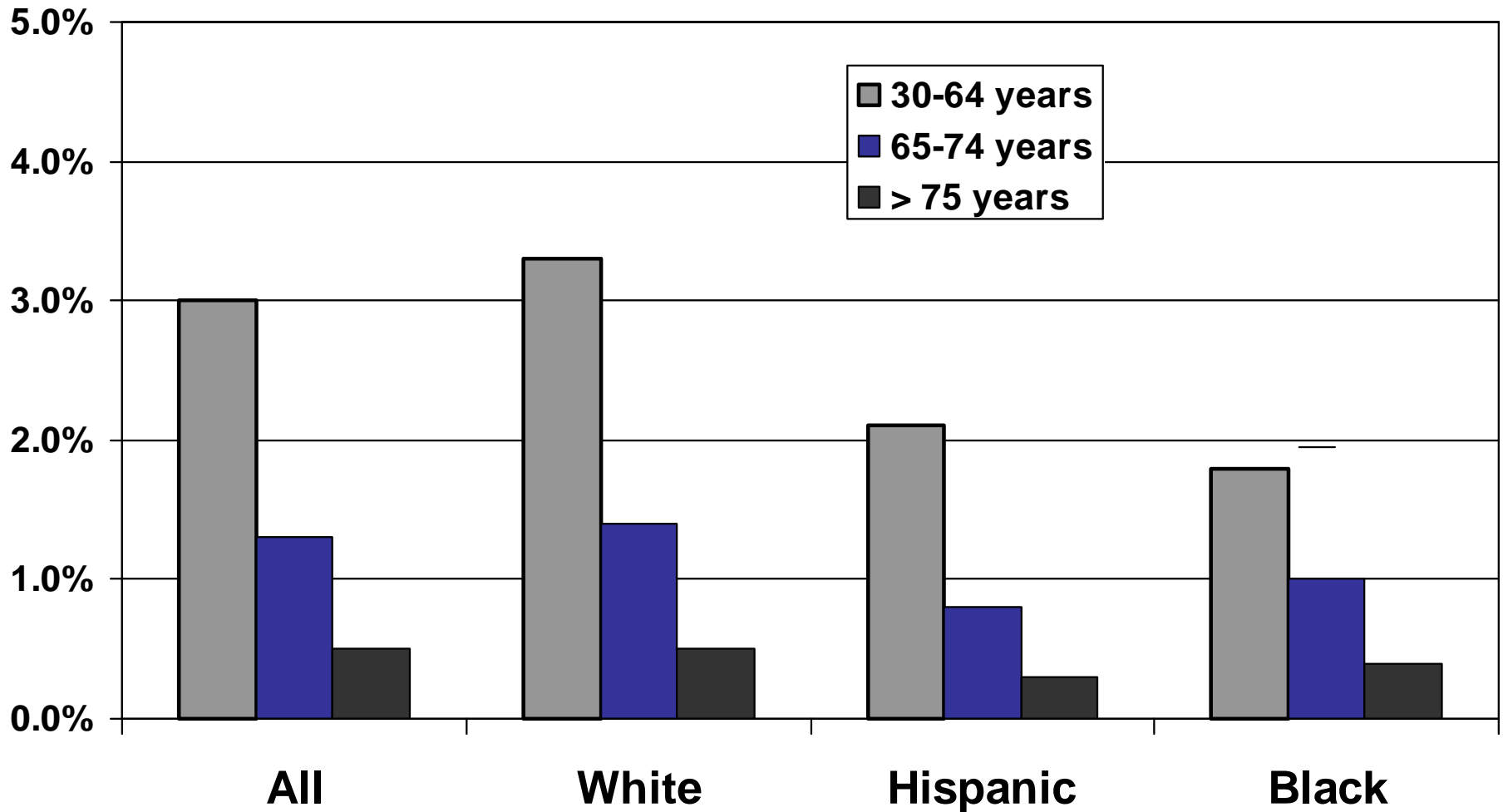
# Overview

- Background: paying for trials
- Empiric analyses of payment policies
- Summary

# Background

- Cancer trial enrollment is inadequate

# Trial Enrollment According to Race and Age



# Background

- Cancer trial enrollment is inadequate
- Numerous barriers to enrollment
  - Patient
  - Clinician
  - Researcher
  - Health System

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Access to cancer care

Access to cancer research center

Cost of trial enrollment

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# Incremental Costs Associated with Trial Enrollment

How much \$\$?

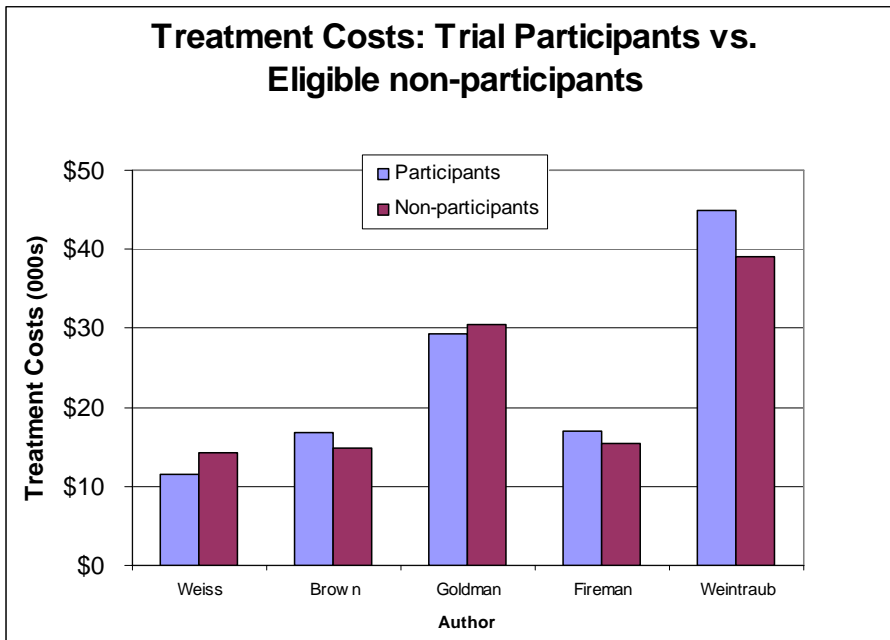
Who Pays?



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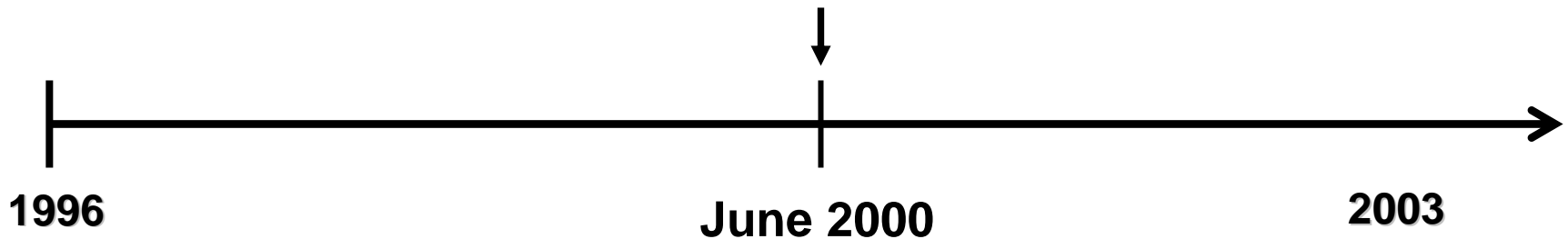
Administration  
mandates:  
Medicare

States mandate:  
Private payers

Did the enrollment of older persons in cancer trials increase after the Medicare policy change?

# Medicare Policy Revision

Clinton orders the revision of the Medicare program to pay for routine patient care costs associated with all clinical trials.



## Our approach

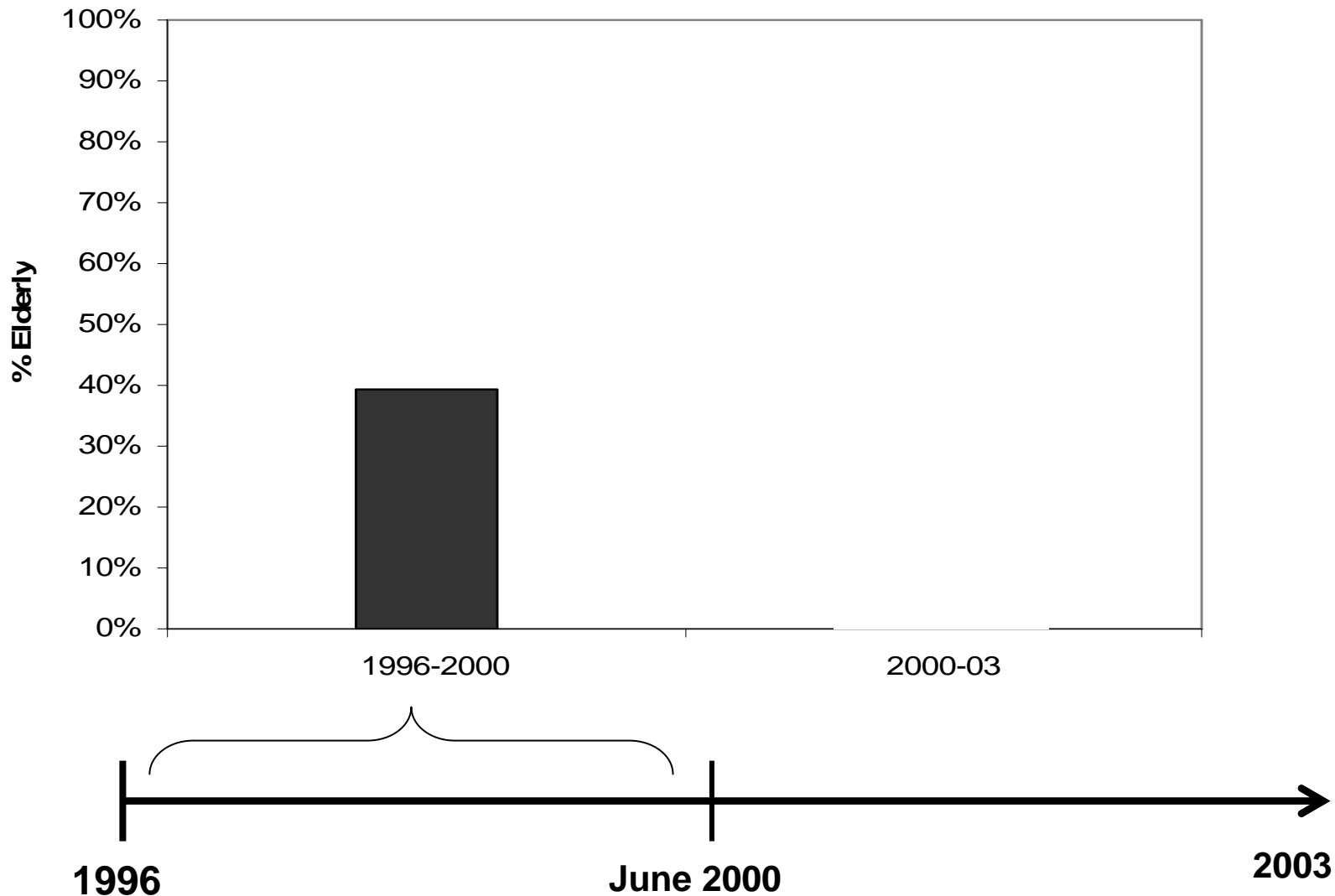
Participants in 23 NCI trials

Recruiting 1/96 – 7/03

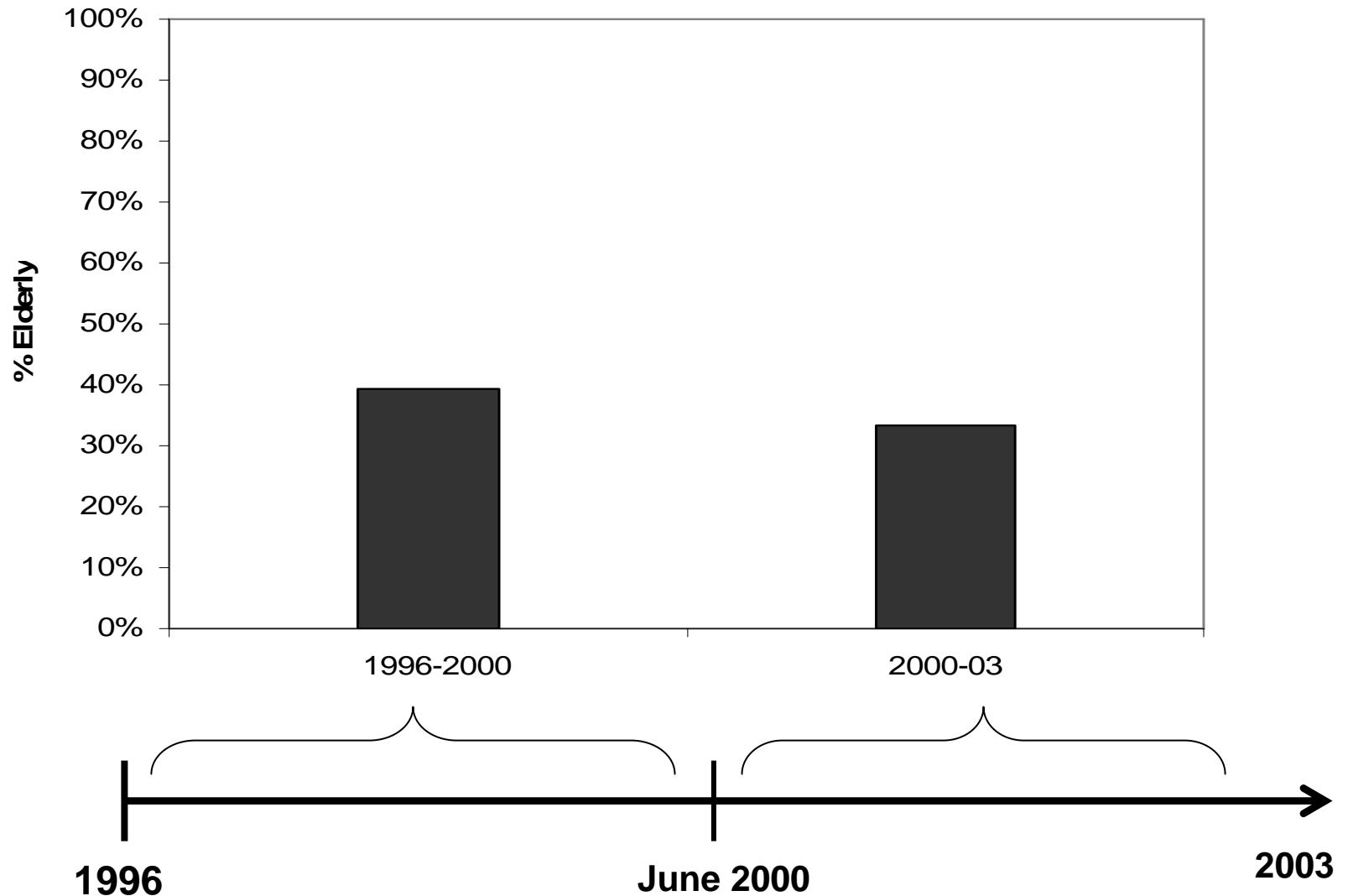
Lung, breast, colorectal, & prostate

↓ ↓ ↓  
% Elderly before vs. after June 2000

# Enrollment of Older Patients, pre- and post-Medicare policy change

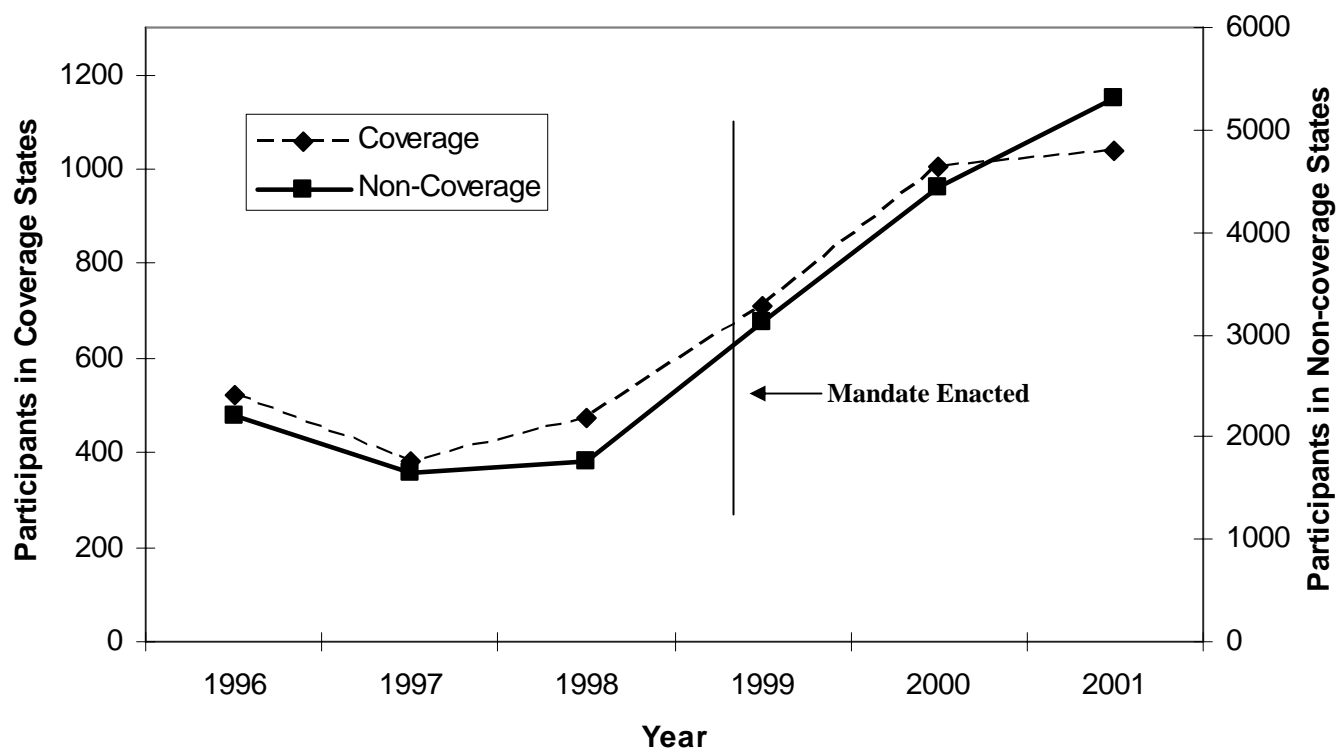


# Enrollment of Older Patients, pre- and post-Medicare policy change



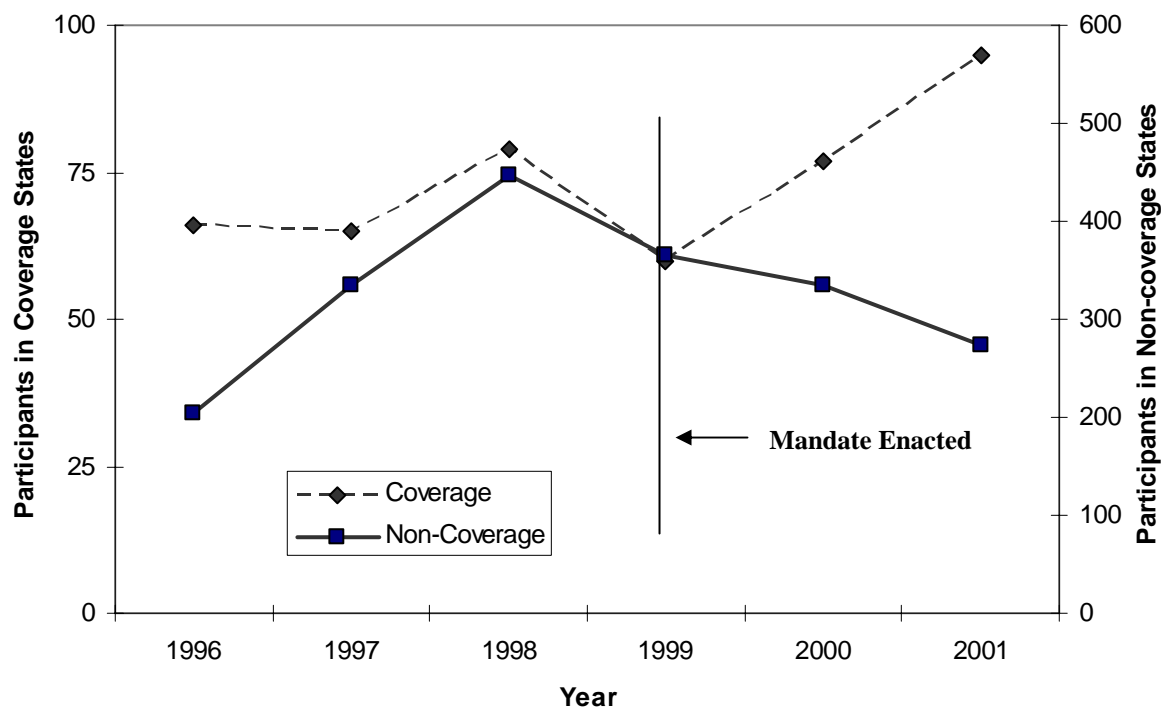
Was state-mandated coverage associated with an increase in cancer trial enrollment?

# Annual Number of Trial Participants in Coverage and Non-coverage states in phase III trials





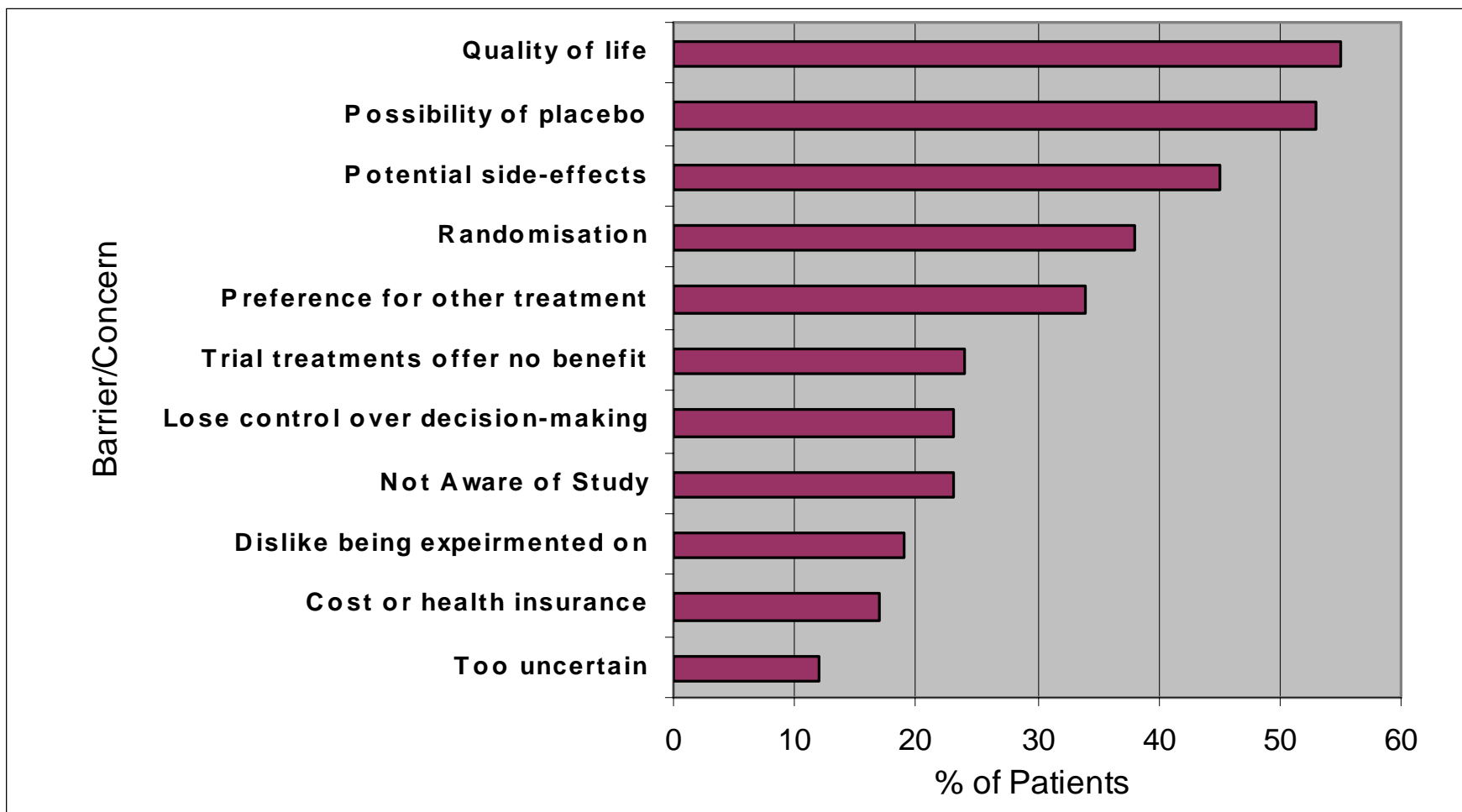
# Annual Number of Trial Participants in Coverage and Non-coverage states in phase II trials



# Summary

- Existing evidence does not support major role of payer policy changes in enhancing enrollment

# Concerns and Barriers cited by patients (recent systematic review)



# Acknowledgements

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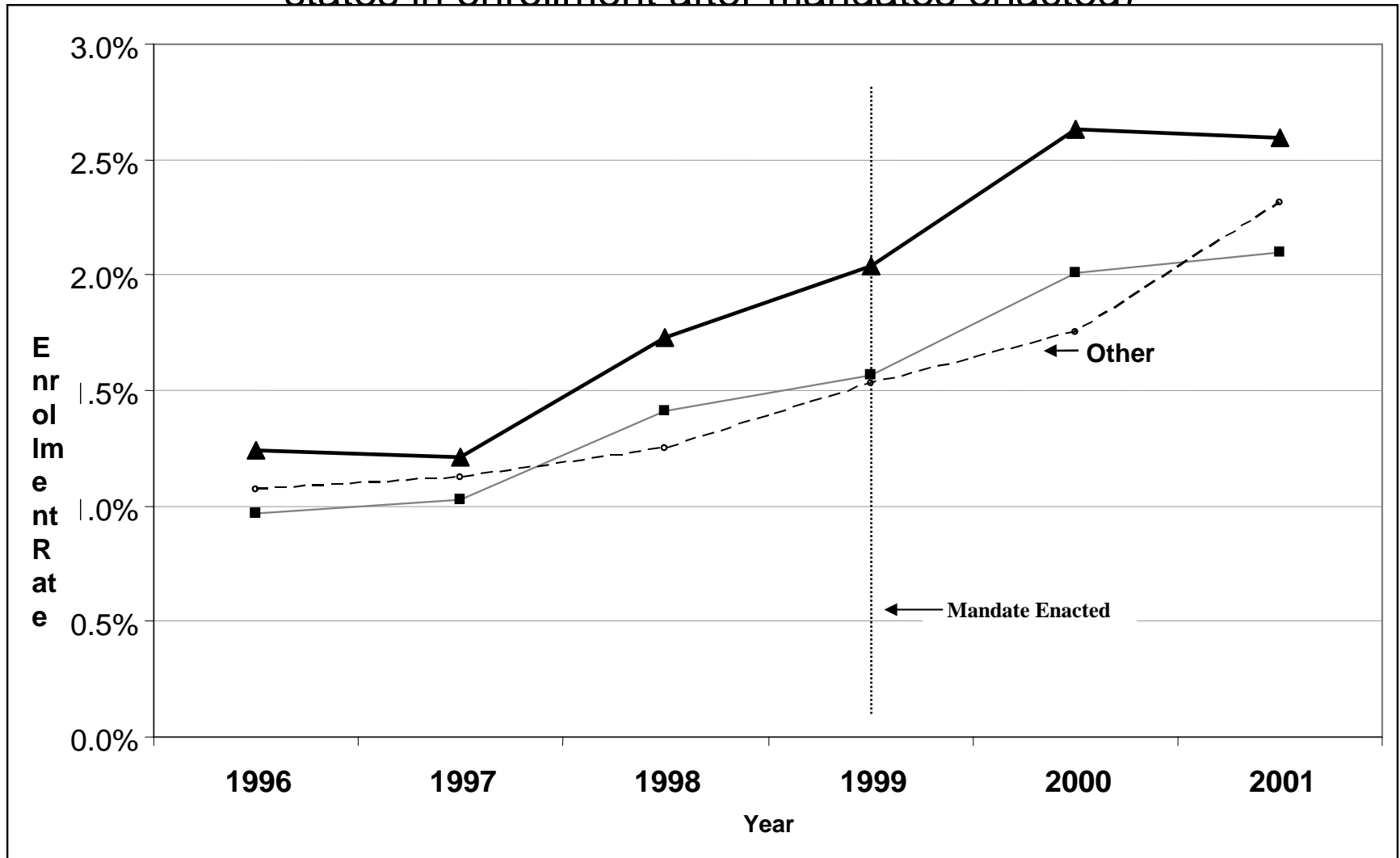


# Summary

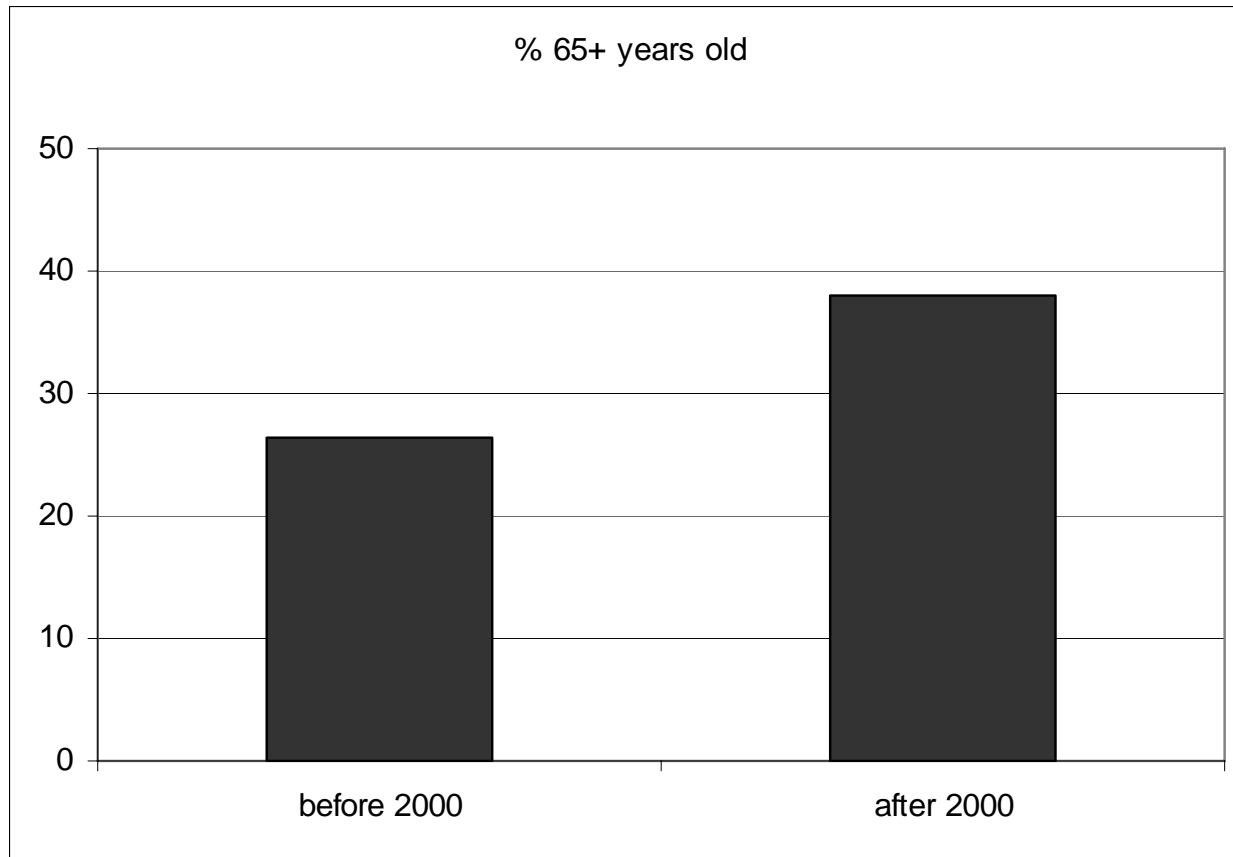
- Limited Evidence about effectiveness of payer policy changes
  - Existing evidence does not support major role of payer policy changes in enhancing enrollment
  - Policy changes necessary but not sufficient
- Other barriers more salient
- Next steps
  - Appreciation that practical evidence improves quality:
    - Coverage with Evidence Development
    - Comparative Effectiveness Research
    - “Traditional” Clinical Trial accrual

# Overall enrollment rate

(mandate states – top line – did not have faster increase than control states in enrollment after mandates enacted)

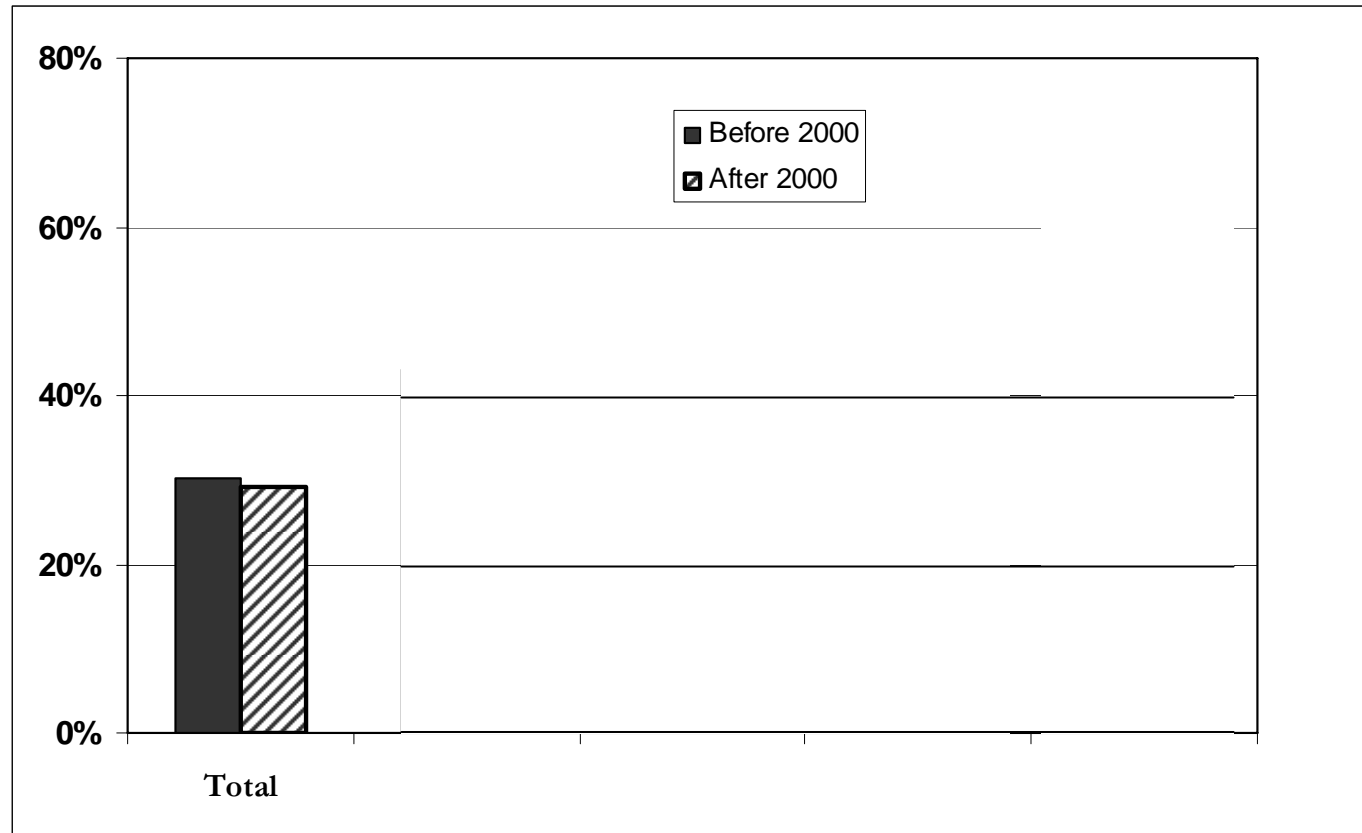


# % of SWOG Trial Participants 65+ years old





# % of NCI Cooperative Group Trial Participants 65+ years old



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