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# A Tour of Pragmatic Study Design: Pragmatic Cluster-Randomized Trial

**Study Team:**

**University of Colorado AMC**

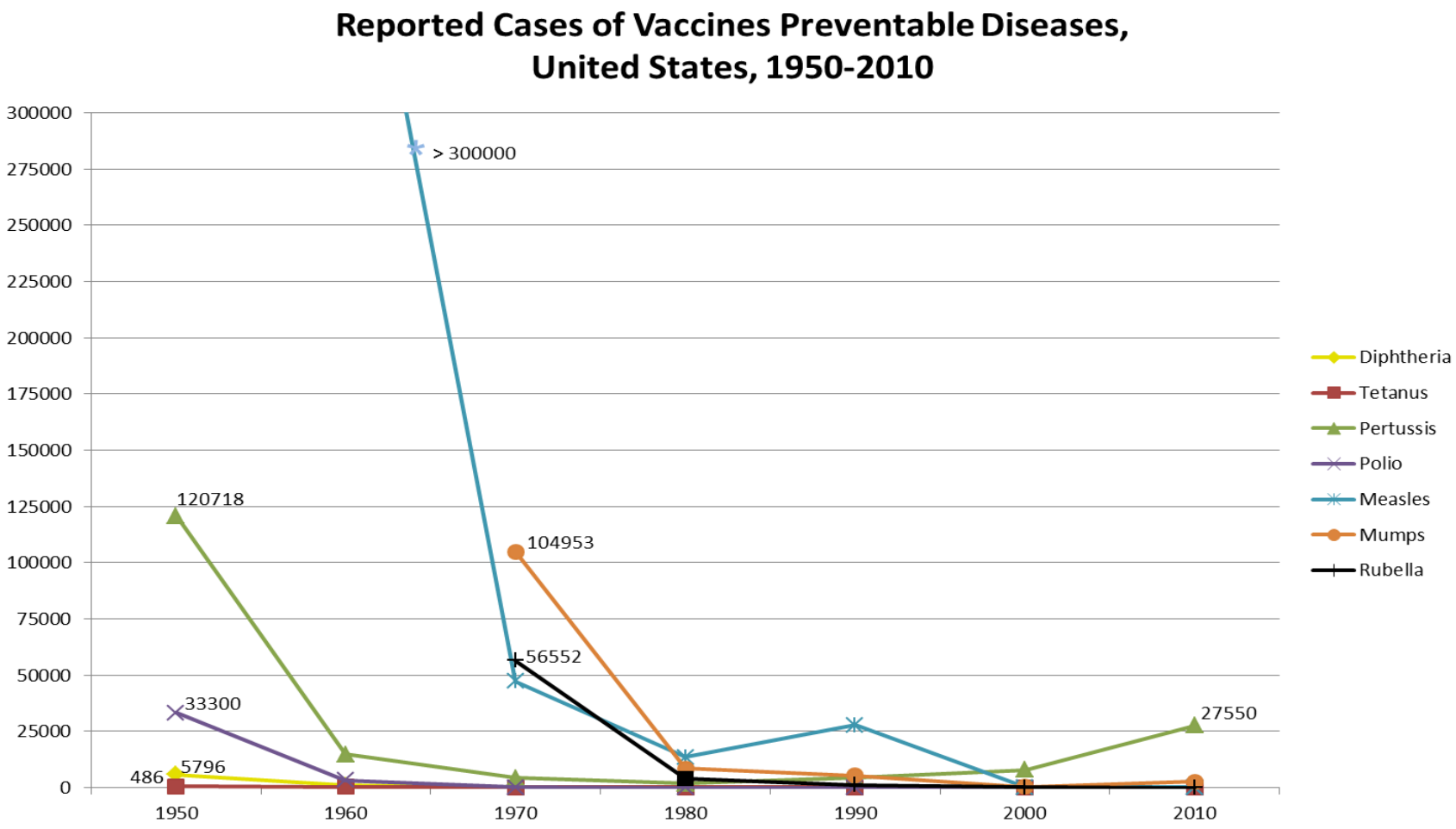
Principal Investigator – Allison Kempe, MD, MPH

- Alison Saville, MSPH, MSW
- L. Miriam Dickinson, PhD
- Brenda Beaty, MSPH
- Sheri Eisert, PhD
- Karen Albright, PhD
- Eva Dibert, MHA
- Vicky Koehler, MPH

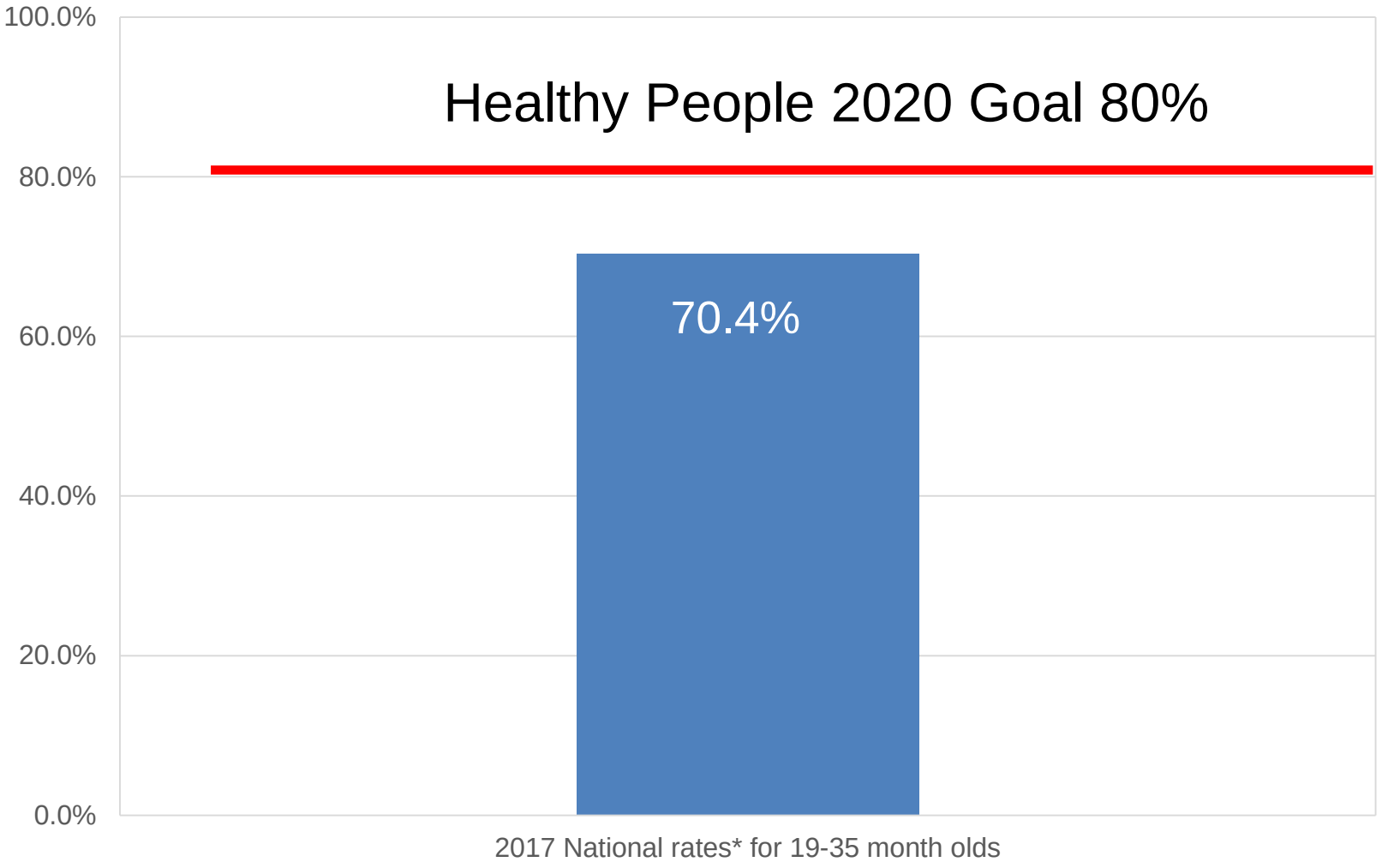
**CDPHE & CIIS Collaborators**

- Ned Calonge, MD
- Joni Reynolds, RN, MSN
- Diana Herrero, MS

# Immunizations Second Only to Clean Water!



# So How Are We Doing?




*Routinely recommended vaccines: ≥4 doses of DTaP/DT/DTP, ≥3 doses of poliovirus vaccine, ≥1 doses of measles-containing vaccine, full series of Hib (3 or 4), ≥3 doses of HepB, ≥1 dose of varicella vaccine, ≥4 doses of PCV

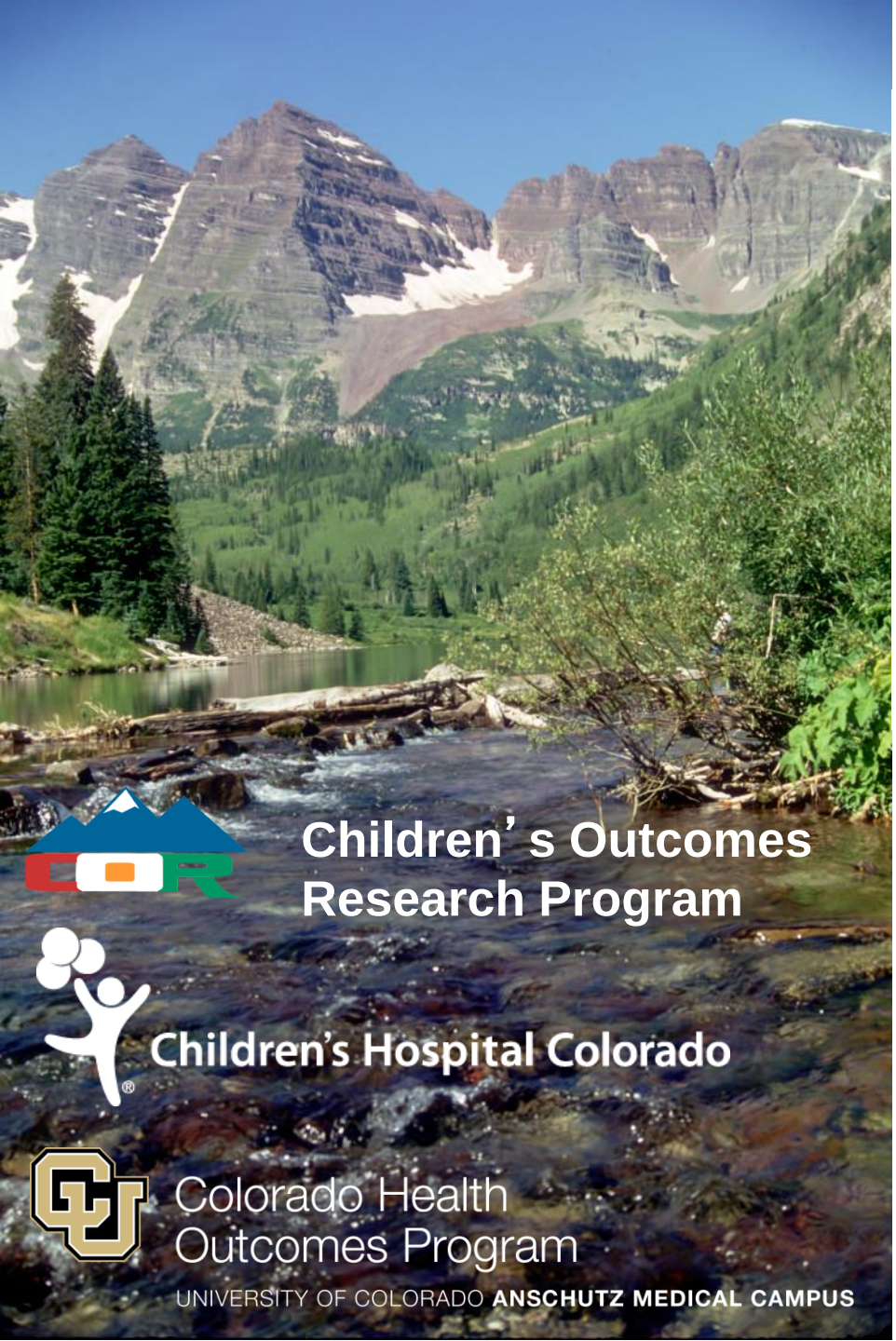
# What's the Problem?!

Barriers to optimal immunization delivery

- Financial
- Access to care issues
- Lack of awareness
- Infrastructure and regulatory issues
- Complexity and expansion of vaccination schedule
  - # of vaccines more than doubled in past 25 years
  - By18 months of age U.S. children recommended to receive vaccines against 14 different diseases, requiring up to 26 different vaccine doses
- Vaccine hesitancy
  - Misinformation
  - Safety concerns

# One Solution: Reminder/Recall

- Reminder/recall (R/R): postcards, letters, phone calls, texts to inform patients they are due or overdue for immunizations
- Can be automated using Immunization Information System (IIS)
- R/R conducted by practices shown effective in increasing rates but <20% of physicians nationally are conducting
- Population-based R/R conducted centrally by public health departments could offer advantages of:
  - Reducing burden of conducting R/R by practices
  - Reaching children without usual source of primary care




# Population-based vs. Practice-based Reminder/Recall: a Pragmatic Comparative Effectiveness Trial

Allison Kempe, MD, MPH

# Objectives

To compare the *effectiveness* and *cost-effectiveness* of conducting R/R using two methodologies:

1. ***Population-based R/R:*** conducted centrally by the State Health Department using the Colorado Immunization Information System (CIIS)

2. ***Practice-based R/R:*** conducted at the level of the primary care practice using CIIS

# Planning the Study Design

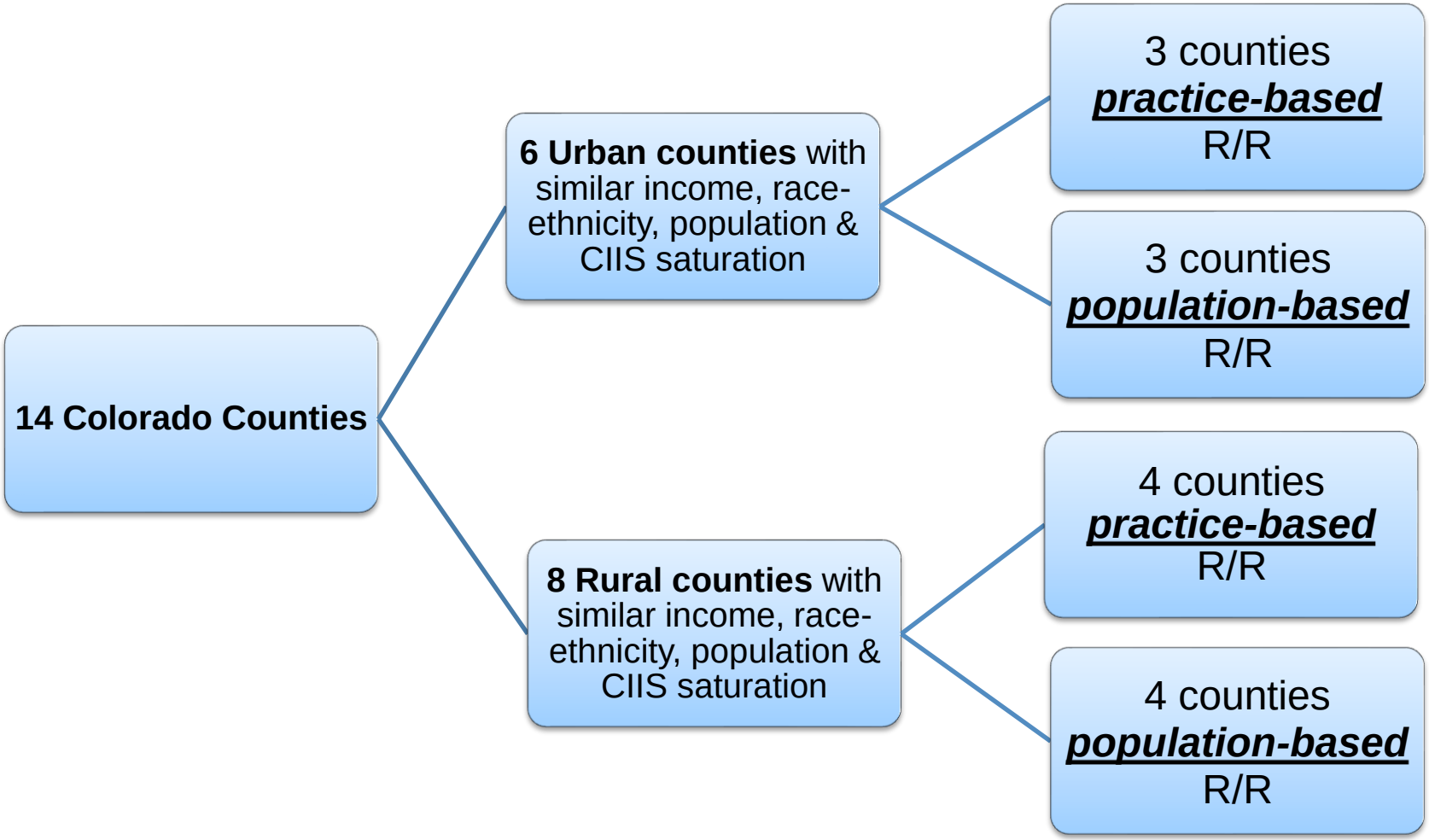
- Randomization needed to be at the level of the county in order to compare interventions occurring at the level of multiple practices vs centrally at the county population level
- Outcomes at the level of the patient with clustering within practices and counties
- Needed best approximation of total denominator of children at the county level
- Wanted to assure balanced randomization because of limited number of counties

# Randomization Procedures

- Counties first stratified into Urban or Rural based on Colorado Rural Health Center Designation
- Within these strata, covariate constrained randomization used to optimize balance between study arms with respect to baseline variables of <u>counties</u> including:

  - % Minority race and ethnicity
  - % 19-35 month olds with ≥2 Iz in IIS
  - # Pediatricians, # FM, Pediatric/FM ratio
  - Median income
  - # Children 19-35 months
  - # Community Health Centers

# Methods: Randomization of Counties



# Study Populations for Both Intervention Arms

Patient names, addresses and immunization data automatically uploaded from Birth Vital Statistics to

Colorado Immunization Information System (CIIS)

Downloaded names and addresses of children 19-35 months old needing ≥1 immunization within all 14 counties

# Methods: Intervention Strategies

- Population-based recall counties:
  - Centralized R/R conducted by the State Public Health Department June – September 2010
  - Up to 3 mailings to children 19-35 months needing immunizations
  - R/R notices suggested patients go to primary care provider for immunization or, if they did not have one, to public health immunization site

# Methods: Intervention Strategies

- Practice-based recall counties:
  - All practices invited to attend web-based R/R training in May/June 2010
  - R/R methodology suggested
    - 3 mailings to children 19-35 months needing immunizations
    - June – September 2010
  - Financial support for mailings offered to practices who did R/R in this timeframe

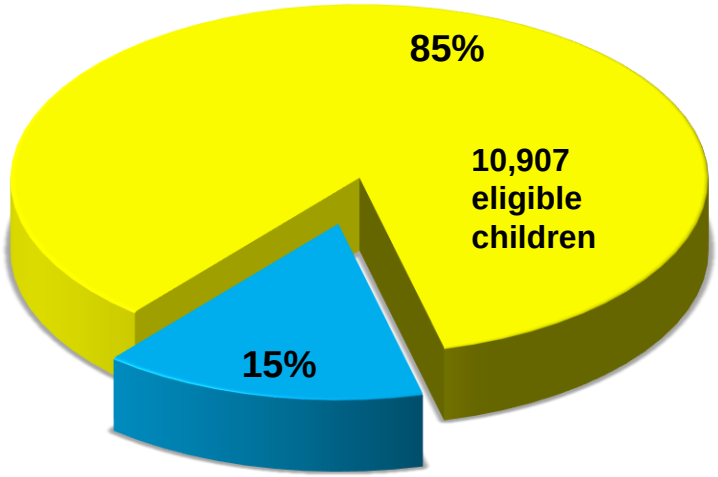
# Methods: Cost Assessment

- Population-based R/R (performed centrally)
  - Staff time for training and implementation
  - Staff time for updating bad mailing addresses
  - Mailing and printing costs for up to 3 mailings
- Practice-based R/R (performed differently at each practice)
  - Staff time among practices conducting R/R
  - Mailing costs or costs of phone calls

# Comparison of "Reach" of Intervention

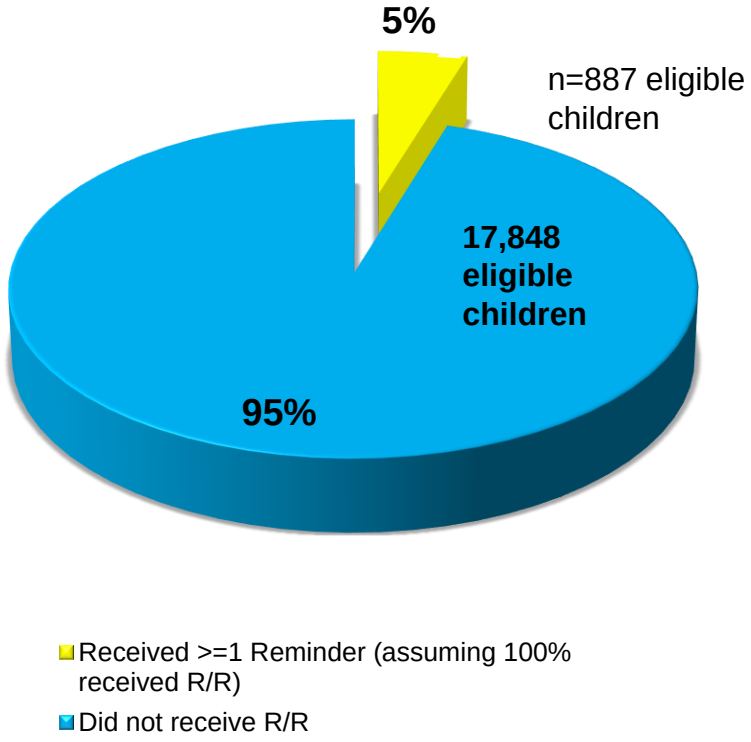
Population-based R/R Reach

188 practice sites

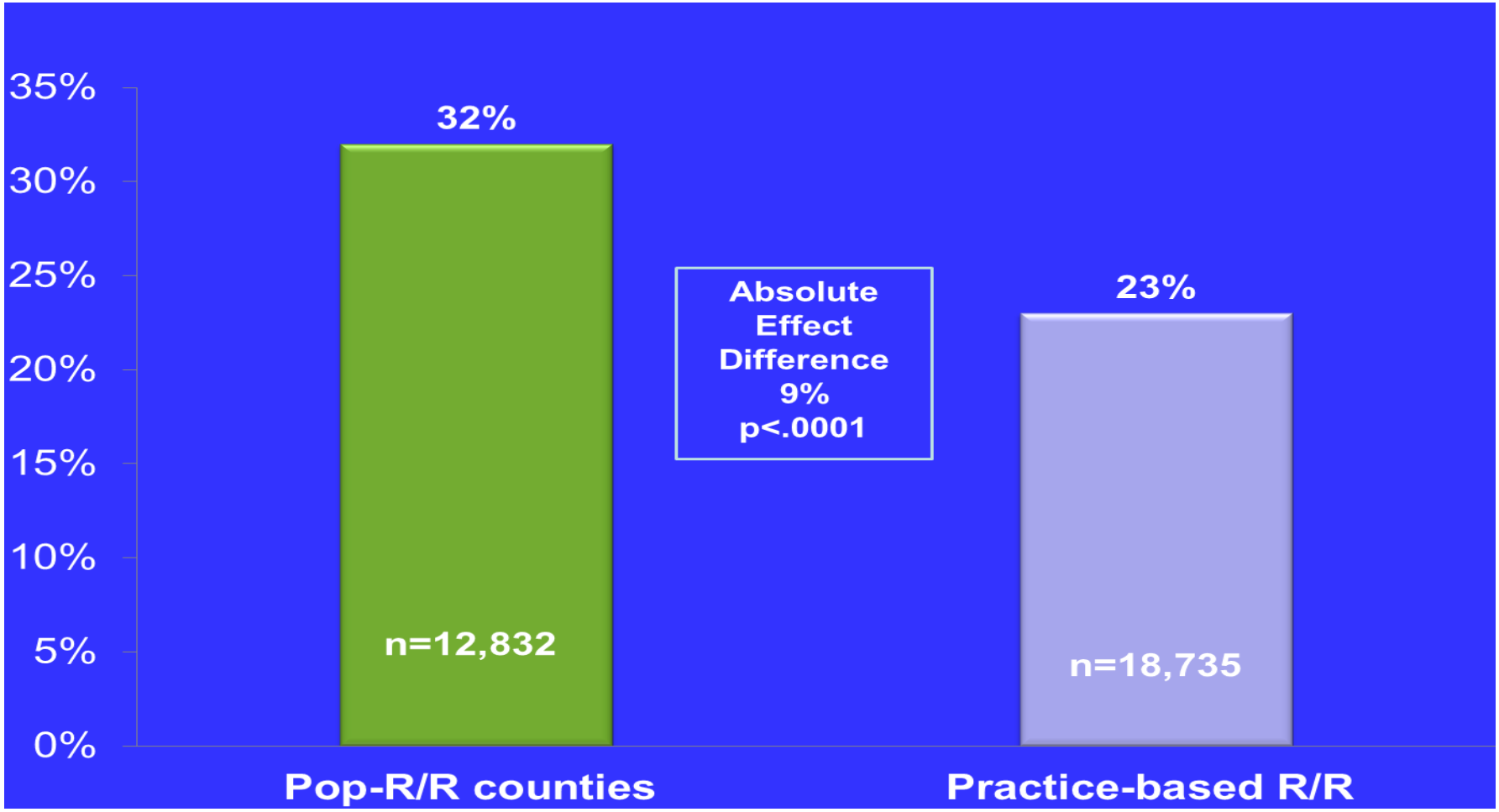



Practice-based R/R Reach

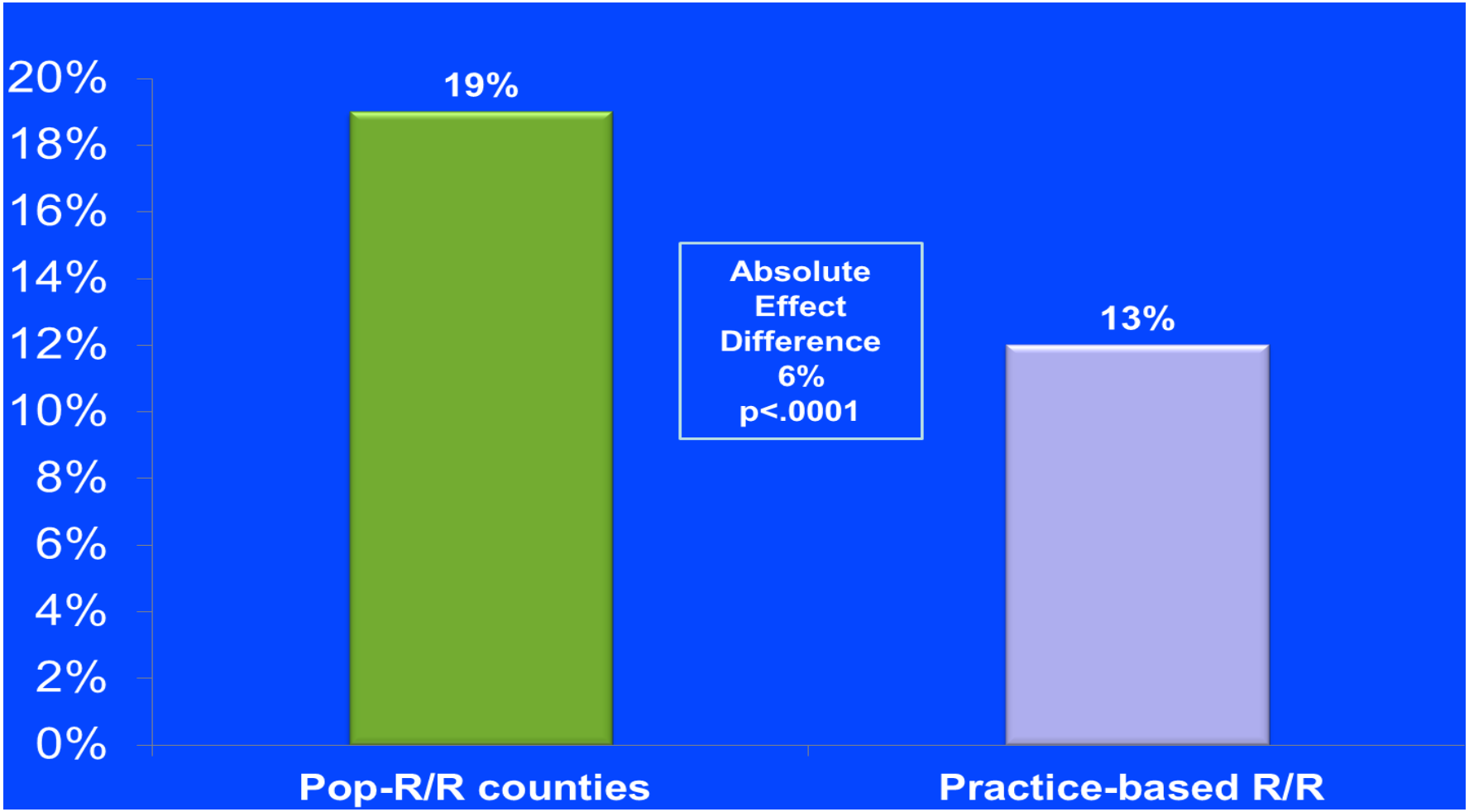
195 practice sites—10 did R/R



# Percent Receiving Any Vaccine within 6 months
## (of those needing vaccines at baseline)



# Percent Brought Up-to-Date within 6 months
## (of those needing vaccines at baseline)



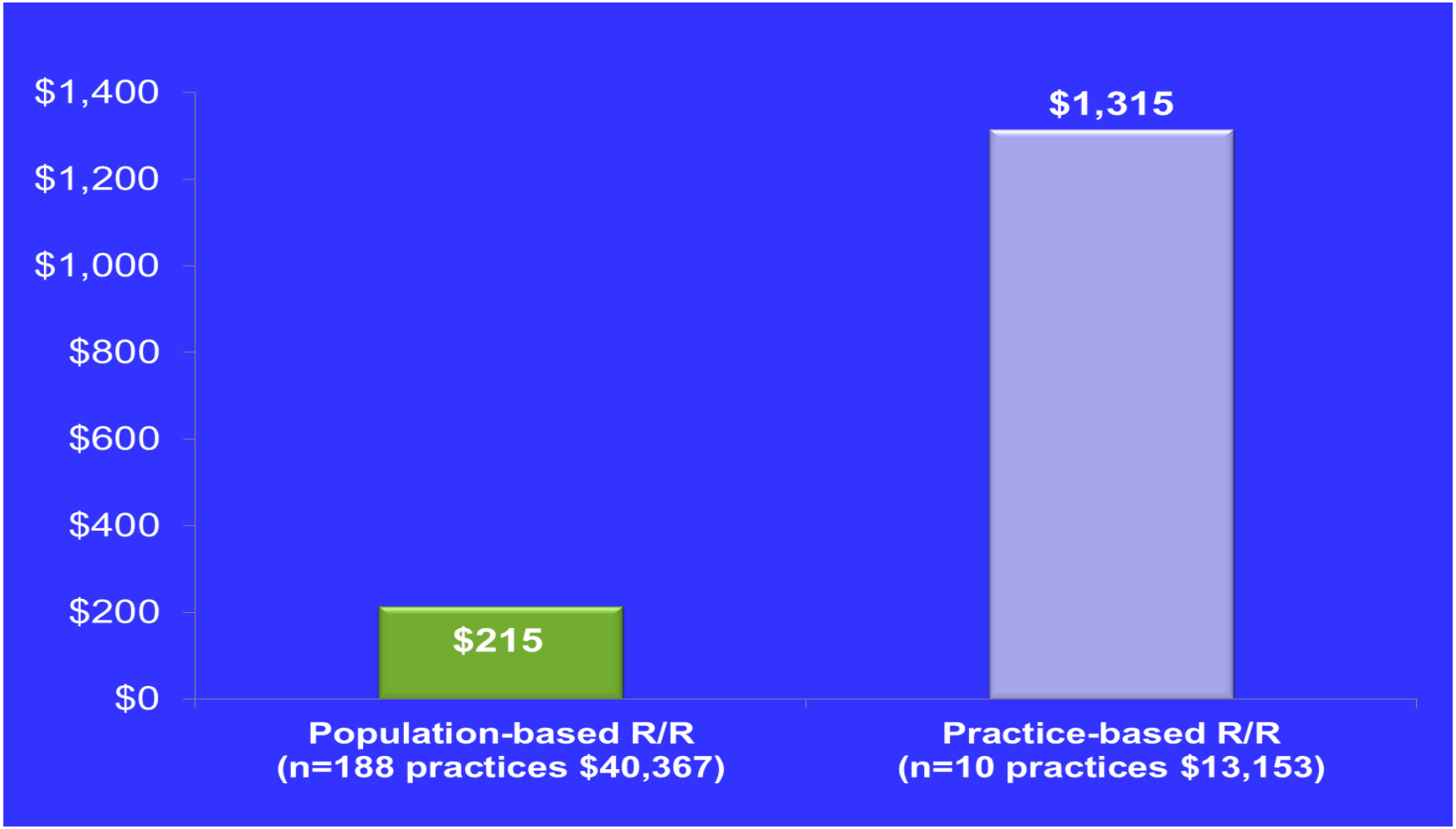
# Results: Multivariable Models

Association of Intervention Group with Two Outcomes

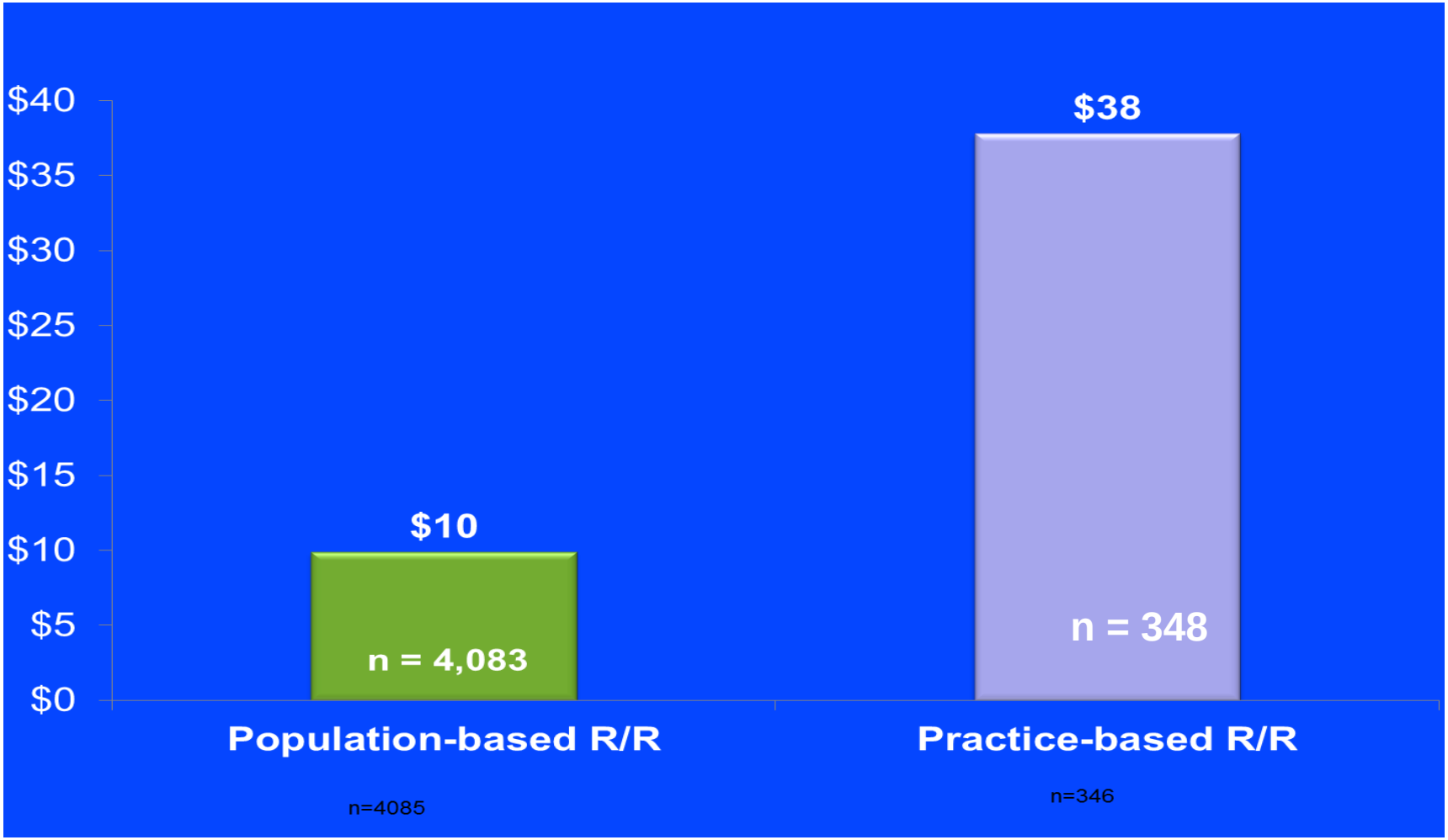
| Outcomes Modeled | Adjusted OR (95% CI) | P-value |
|---|---|---|
| Becoming up-to-date in population-based versus practice-based county | 1.24 (1.11-1.38) | .0002 |
| Receiving any vaccine in population-based versus practice-based county | 1.27 (1.15-1.39) | <.0001 |

*Other variables included in the model were baseline county UTD rate, rural/urban status of county, site of last service and whether or not site of last service did R/R, all of which were not statistically significant*

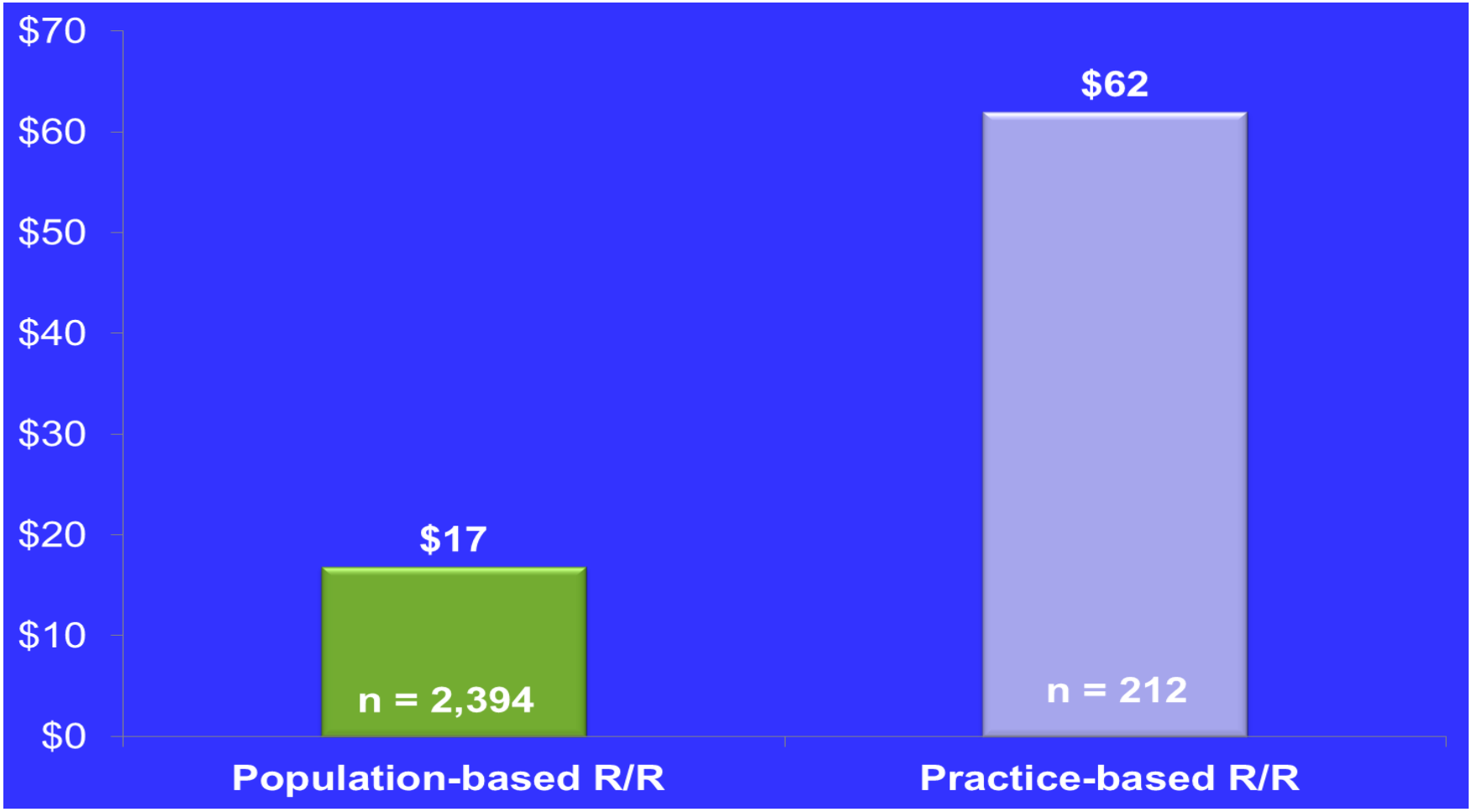
# Cost of Conducting R/R per Practice



# Cost of R/R Per Child who Received ≥1 Vaccine



# Cost of R/R Per Child Brought Up-to-Date



# Limitations

- Population impossible to accurately denominate in all counties—but same method of approximation used in both intervention arms
- Population-based R/R hampered by many inaccurate addresses from vital statistics
- Practices may have conducted R/R after the 6 month period of F/U despite incentives
- Costs were based on personnel report, rather than direct observation

# Conclusions

- Both practice-based and population-based R/R effective—practice-based slightly more effective when practices participated
- Overall, at a county level population-based R/R was more effective than practice-based R/R because of lack of participation of practices even when incentives provided
- Costs per practice or per child vaccinated were much lower for population-based R/R

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The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Library of Medicine or the National Institutes of Health.

# Now…lets delve

Let's talk amongst ourselves…….

Discuss…….