

# PHS Guidelines 2014 and Implementing PrEP in the United States

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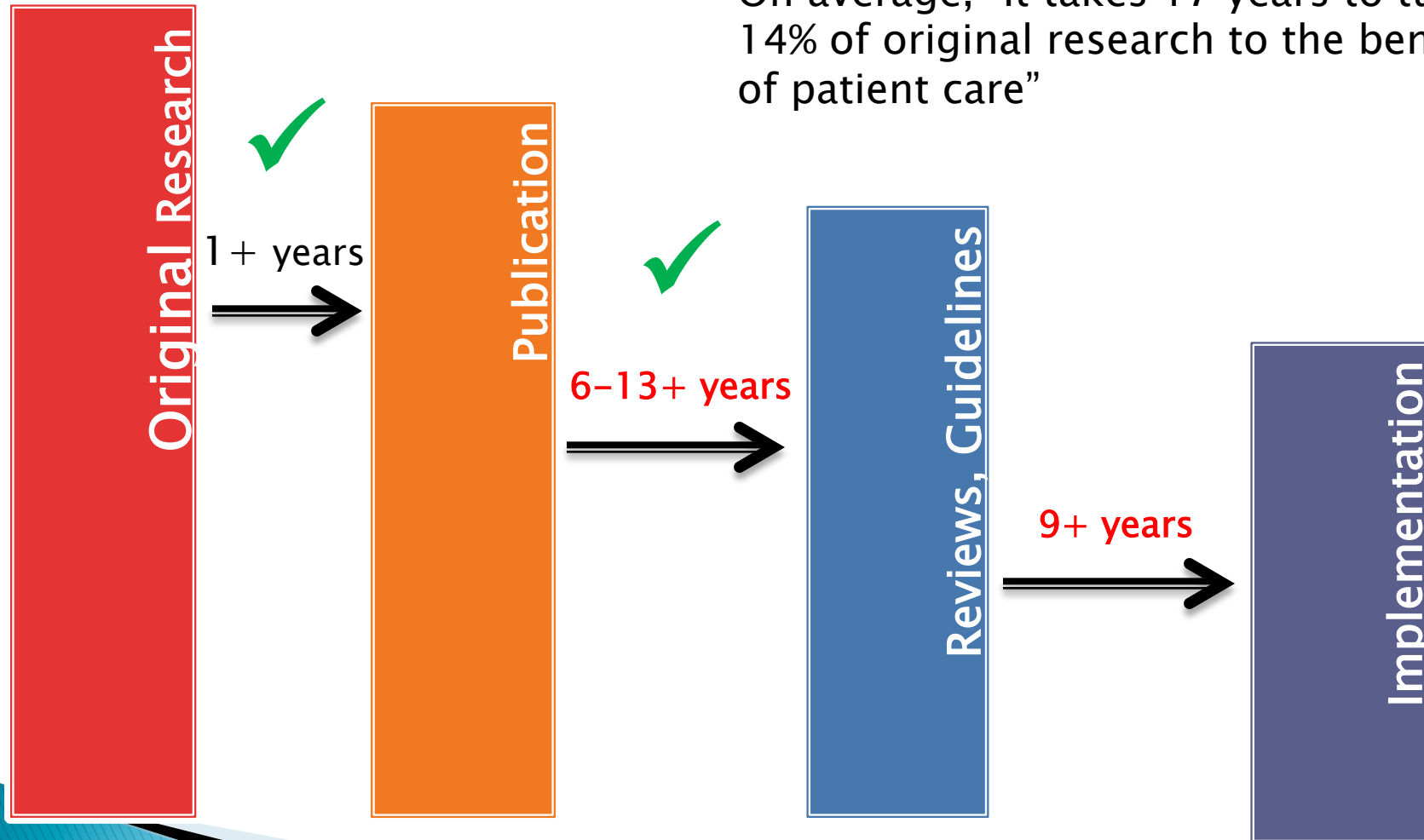


*"The findings and conclusions in this presentation have not been formally disseminated by the CDC and should not be construed to represent any agency determination or policy"*

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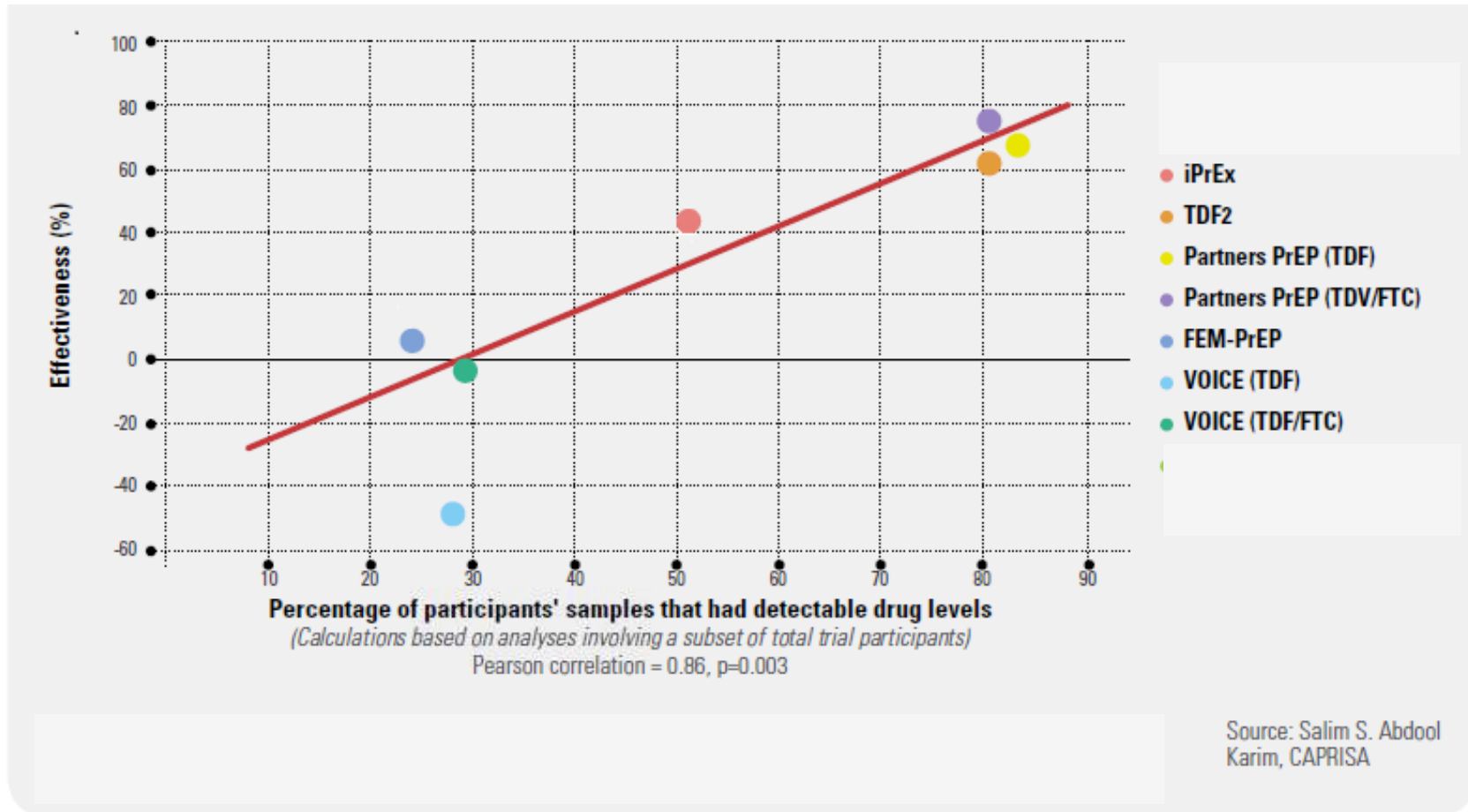
# Where Have All the Data Gone?

On average, “It takes 17 years to turn 14% of original research to the benefit of patient care”



Source: Balas EA, Boren SA. Integrating clinical knowledge for health care improvement. Yearbook of Medical Informatics 2000: Patient-centered Systems. Stuttgart, Germany: Schattauer, 2000: 65–70

# Drug levels and Efficacy in Oral PrEP Trials



# External Stakeholder and Expert Engagement

## Guidelines Work Groups

- ▶ Clinical Care
- ▶ Clinic-based Counseling
- ▶ PrEP integration with other prevention services
- ▶ IDU
- ▶ MSM
- ▶ Heterosexual men
- ▶ Women
- ▶ Adolescents

## Technical Expert Meetings

- ▶ Public Health Ethics
- ▶ Monitoring and Evaluation
- ▶ Financing/Reimbursement
- ▶ HIV discordant couples and conception/pregnancy
- ▶ Network Science
- ▶ Public Health Law
- ▶ Insurers



# Clinical Practice Guideline

- ▶ Provides comprehensive
  - Review of efficacy and safety evidence
  - Guidance on identifying patients with
    - Indications for PrEP
    - Contraindications for PrEP
  - Guidance on prescribing, laboratory testing, and follow-up care
  - Guidance on supporting medication adherence and risk reduction
  - Guidance on reporting HIV infection and PrEP use in pregnancy



# Clinical Providers' Supplement

- ▶ **Materials for providers**
  - Patient/provider checklist
  - Information for counseling about PrEP during conception, pregnancy and breastfeeding
  - MSM HIV incidence risk index
  - Supplemental counseling information
    - Medication adherence
    - HIV risk reduction
  - PrEP related billing codes
  - Potential PrEP practice quality measures
- ▶ **Information sheets for patients in English and Spanish**
  - PrEP
  - Truvada
  - Acute HIV Infection and PrEP



# Summary of Key Messages

- ▶ **Daily, oral PrEP with Truvada**
  - Is recommended as one prevention option for persons at substantial risk of HIV infection including:
    - Sexually-active MSM
    - Heterosexually active men and women
    - Injection drug users
  - Should be discussed with HIV discordant couples for use during conception and pregnancy
  - Use should be weighed carefully for adolescent minors
- ▶ **Support medication adherence and risk reduction practices**

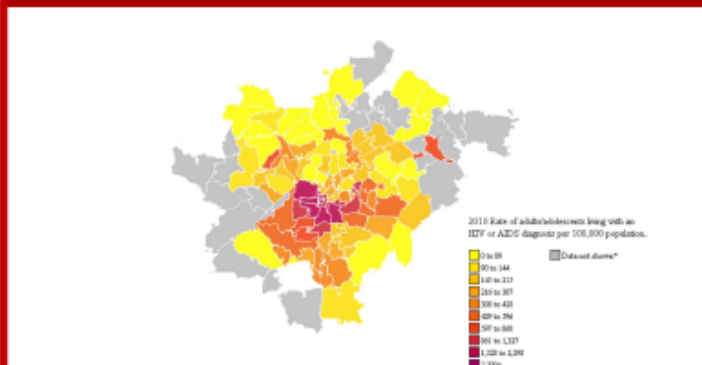
# Indications for PrEP Use by Subpopulation

	Men Who Have Sex with Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection	<ul style="list-style-type: none"> <li>• HIV-positive sexual partner</li> <li>• Recent bacterial STI</li> <li>• High number of sex partners</li> <li>• History of inconsistent or no condom use</li> <li>• Commercial sex work</li> </ul>	<ul style="list-style-type: none"> <li>• HIV-positive sexual partner</li> <li>• Recent bacterial STI</li> <li>• High number of sex partners</li> <li>• History of inconsistent or no condom use</li> <li>• Commercial sex work</li> <li>• In high-prevalence area or network</li> </ul>	<ul style="list-style-type: none"> <li>• HIV-positive injecting partner</li> <li>• Sharing injection equipment</li> <li>• Recent drug treatment (but currently injecting)</li> </ul>

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Rates of Females Living with an HIV or AIDS Diagnosis, by ZIP Code, Atlanta, 2010



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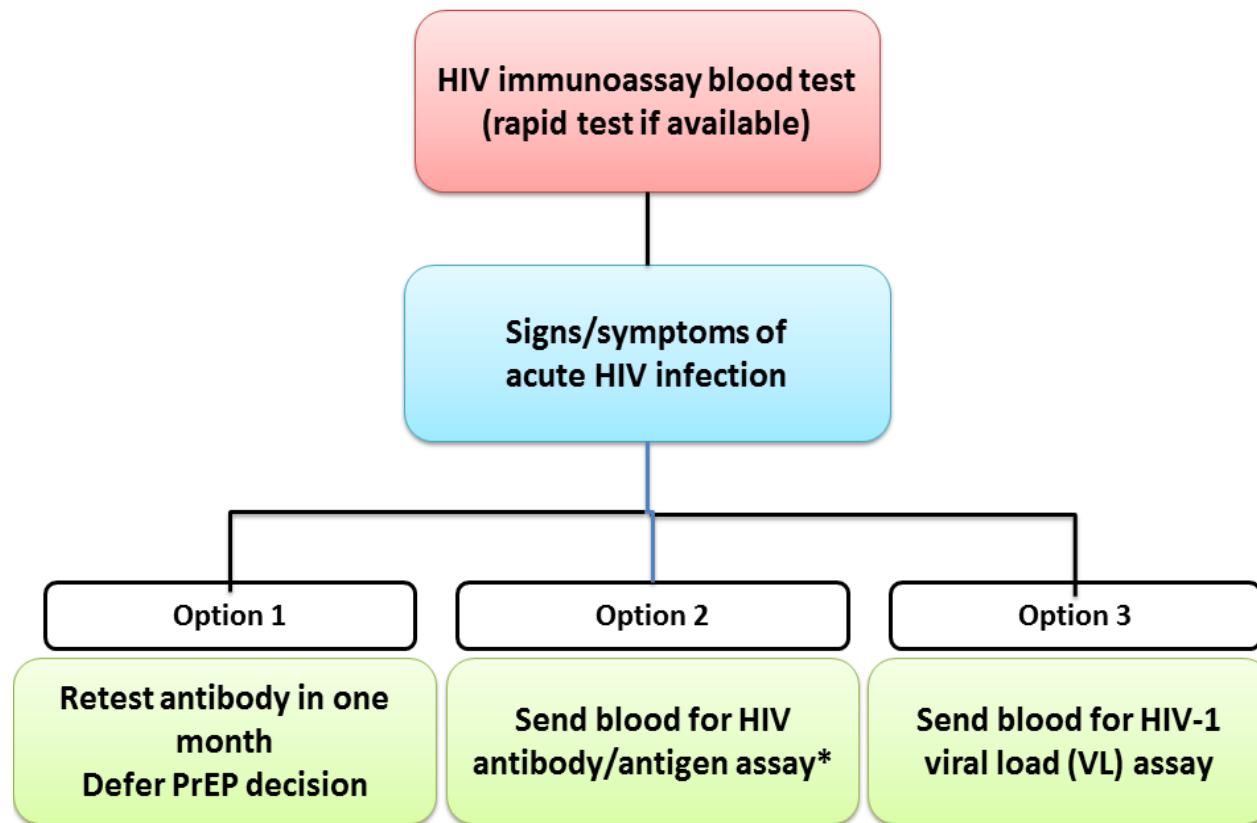
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# Assessing for Contraindications and Prescribing PrEP

	Men Who Have Sex with Men	Heterosexual Women and Men	Injection Drug Users
Clinically eligible	<ul style="list-style-type: none"><li>• Documented negative HIV test result before prescribing PrEP</li><li>• No signs/symptoms of acute HIV infection</li><li>• Normal renal function; no contraindicated medications</li><li>• Documented hepatitis B virus infection and vaccination status</li></ul>		
Prescription	<ul style="list-style-type: none"><li>• Daily, continuing, oral doses of TDF/FTC (Truvada®), ≤90-day supply</li></ul>		

# Excluding Acute or Established HIV Infection



\* Use only HIV antigen/antibody tests that are approved by FDA for diagnostic purposes

# Follow-up Visits While Prescribing PrEP

	Men Who Have Sex with Men	Heterosexual Women and Men	Injection Drug Users
Other services	<p>Follow-up visits at least every 3 months to provide the following:</p> <ul style="list-style-type: none"> <li>• HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment</li> <li>• At 3 months and every 6 months thereafter, assess renal function</li> <li>• Every 6 months, test for bacterial STIs</li> </ul>		
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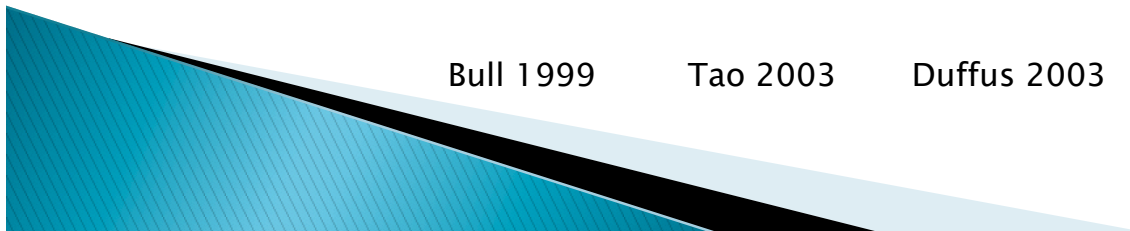
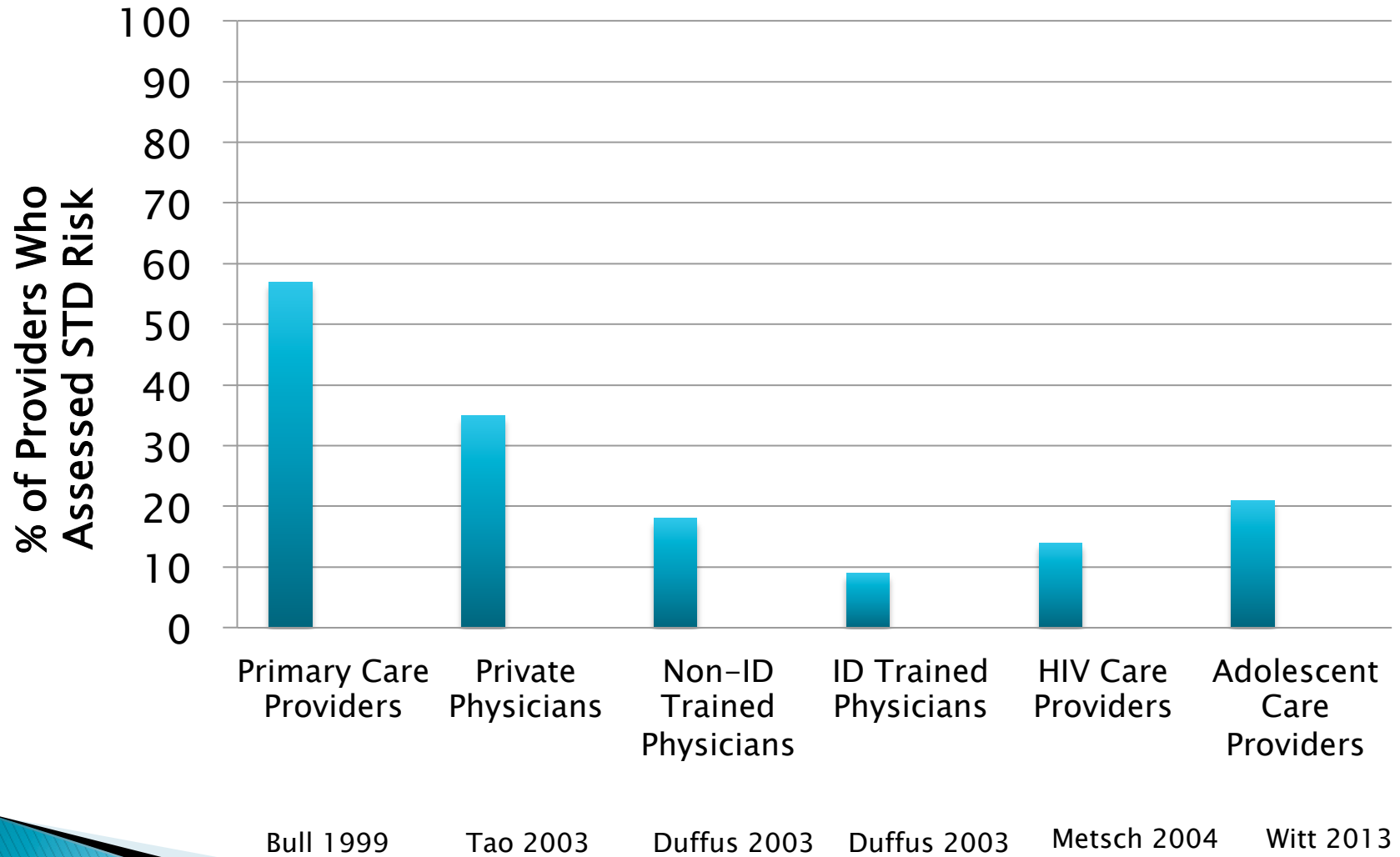
## ▶ Patient factsheets

- PrEP
- Truvada
- Acute HIV infection

## ▶ Provider materials

- Patient/Provider checklist
- Information on PrEP during conception, pregnancy, and breastfeeding
- HIV incidence risk index for MSM
- Potential PrEP practice quality measures
- Supplemental counseling information

# Do Providers Routinely Ask About Risk?



# Tools for Use in Clinical Practice

## ▶ Risk screening tools


Choose an ARCH tool

<b>IDU</b> An injection drug user. <b>Start</b>	<b>MSM</b> Men who have sex with men. <b>Start</b>	<b>HIV Discordant</b> Couple in which one partner has tested negative for HIV and the other tested positive. <b>Start</b>
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## ▶ Materials for persons considering PrEP

## ▶ Guide for billing codes

**HOW TO TALK TO YOUR DOCTOR ABOUT PrEP**



**Before Your Visit**

**Make an appointment** with your health care provider. Your doctor can help you to decide if PrEP would be a good choice for you.

**Do research.** Make a list of reasons that you think that PrEP would be a good choice for you.

**Think about your routine,** especially things that might make it easy or hard to take a daily medication.

**Make a health history list** for your doctor. That includes any past illnesses or concerns you have, as well as a list of your current medications (including supplements, herbs, etc.).

**Make sure a translator is available or bring someone who can translate** if you would prefer to speak a language other than English during your appointment.

**During Your Visit**

**Be clear.** Take out your notes and tell your doctor that you are interested in PrEP right away.

**Do not be shy.** Give your doctor all the details about your life that could be important to your health. Don't worry about being judged.

If your sex life is a hard topic to talk about, say that to your doctor. It will help to start the conversation.

**Ask questions.** You want to be sure that you understand what your doctor is telling you.

**Take notes** during your visit so that you can remember what your doctor said.

**After Your Visit**

**Review** your notes or any information provided by your doctor.

**Consider your options.** Your doctor gave you a lot of information. Now it is up to you to make the right decision for you.  
<http://www.cdc.gov/hiv/risk/behavior/index.html>

**Call your doctor** if you have more questions. Ask to speak to a nurse if your doctor is unavailable.

**Schedule tests** or follow-up appointments your doctor requested.

**Get your results** if you had tests done at your appointment.

**If you feel comfortable,** you may want to discuss this choice with your partners, family, or friends.

# Mitigating PrEP Costs

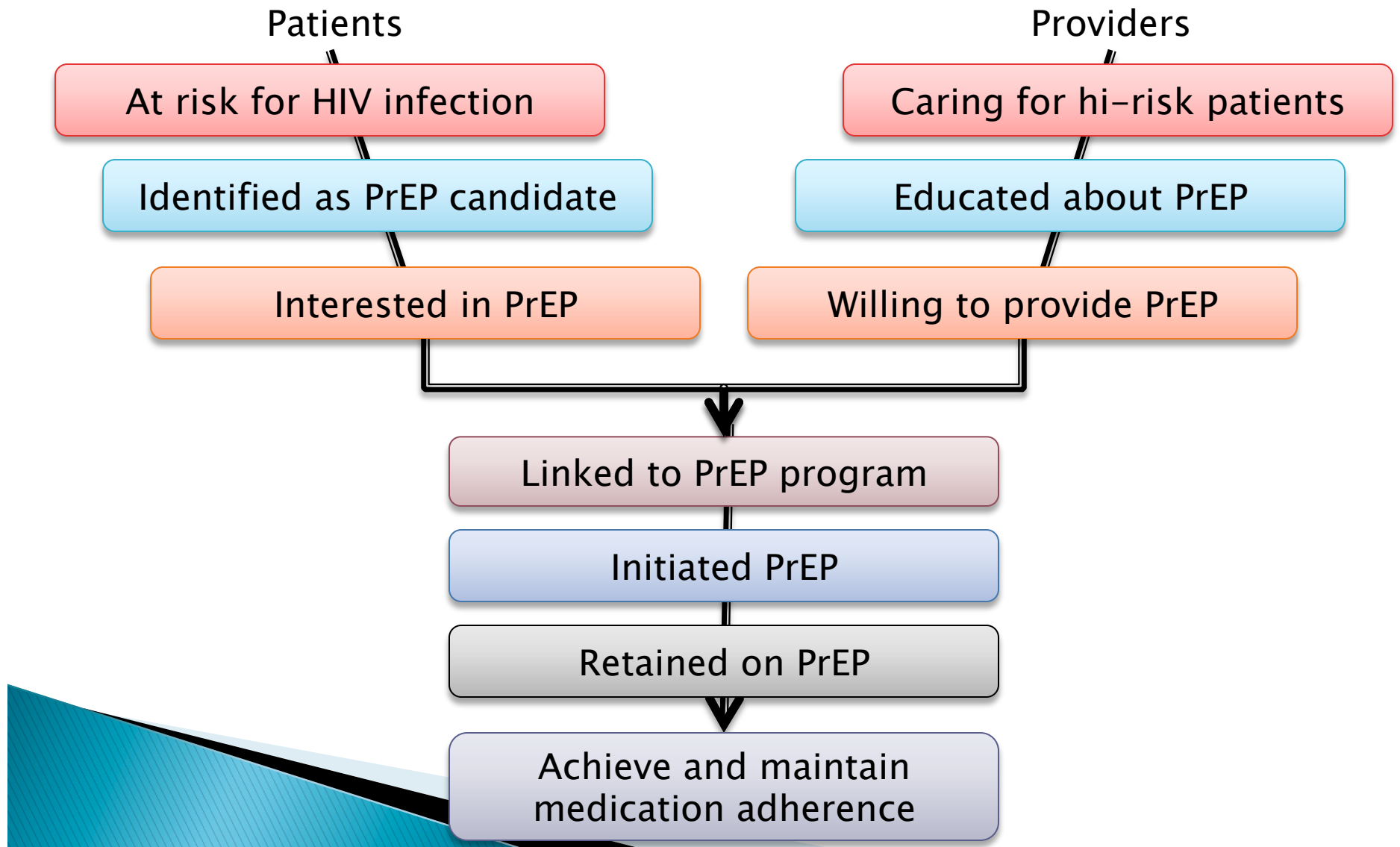
- ▶ PrEP covered by most private employer, school-based and public insurers (e.g., Medicaid)
  - Medication co-pay assistance available
- ▶ For those with low income and no insurance coverage
  - Gilead Sciences
    - Medication assistance program provides free drug to provider
    - Free condoms and HIV testing can be provided
    - Free hepatitis B screening, and HIV resistance testing for those who seroconvert on PrEP
  - Washington State Drug Assistance Program

# Clinician Resources

Public Health Service Guidelines	<a href="http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf">www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf</a>
Providers' Supplement	<a href="http://www.cdc.gov/hiv/pdf/guidelines/PrEPProviderSupplement2014.pdf">www.cdc.gov/hiv/pdf/guidelines/PrEPProviderSupplement2014.pdf</a>
REMS clinician materials	<a href="http://www.truvadapreprems.com/truvadaprep-resources">www.truvadapreprems.com/truvadaprep-resources</a>
Medication Assistance Programs	<a href="http://www.nastad.org/docs/PrEP%20and%20PEP%20PAP%20fact%20sheet.pdf">www.nastad.org/docs/PrEP%20and%20PEP%20PAP%20fact%20sheet.pdf</a>
Co-Pay Assistance Program	<a href="http://www.gileadcopay.com/">www.gileadcopay.com/</a>
Free condoms for patients	<a href="https://start.truvada.com/individual/truvadaprep-patient-resources">https://start.truvada.com/individual/truvadaprep-patient-resources</a>
Free HIV testing for patients	<a href="https://start.truvada.com/hcp#">https://start.truvada.com/hcp#</a>
Adolescent Law Analysis	<a href="http://www.sciencedirect.com/science/article/pii/S0749379712007118">www.sciencedirect.com/science/article/pii/S0749379712007118</a>
CDC NCHHSTP Atlas	<a href="http://www.cdc.gov/nchhstp/atlas">www.cdc.gov/nchhstp/atlas</a>
AIDSVu HIV data and maps	<a href="http://aidsvu.org/">aidsvu.org/</a>



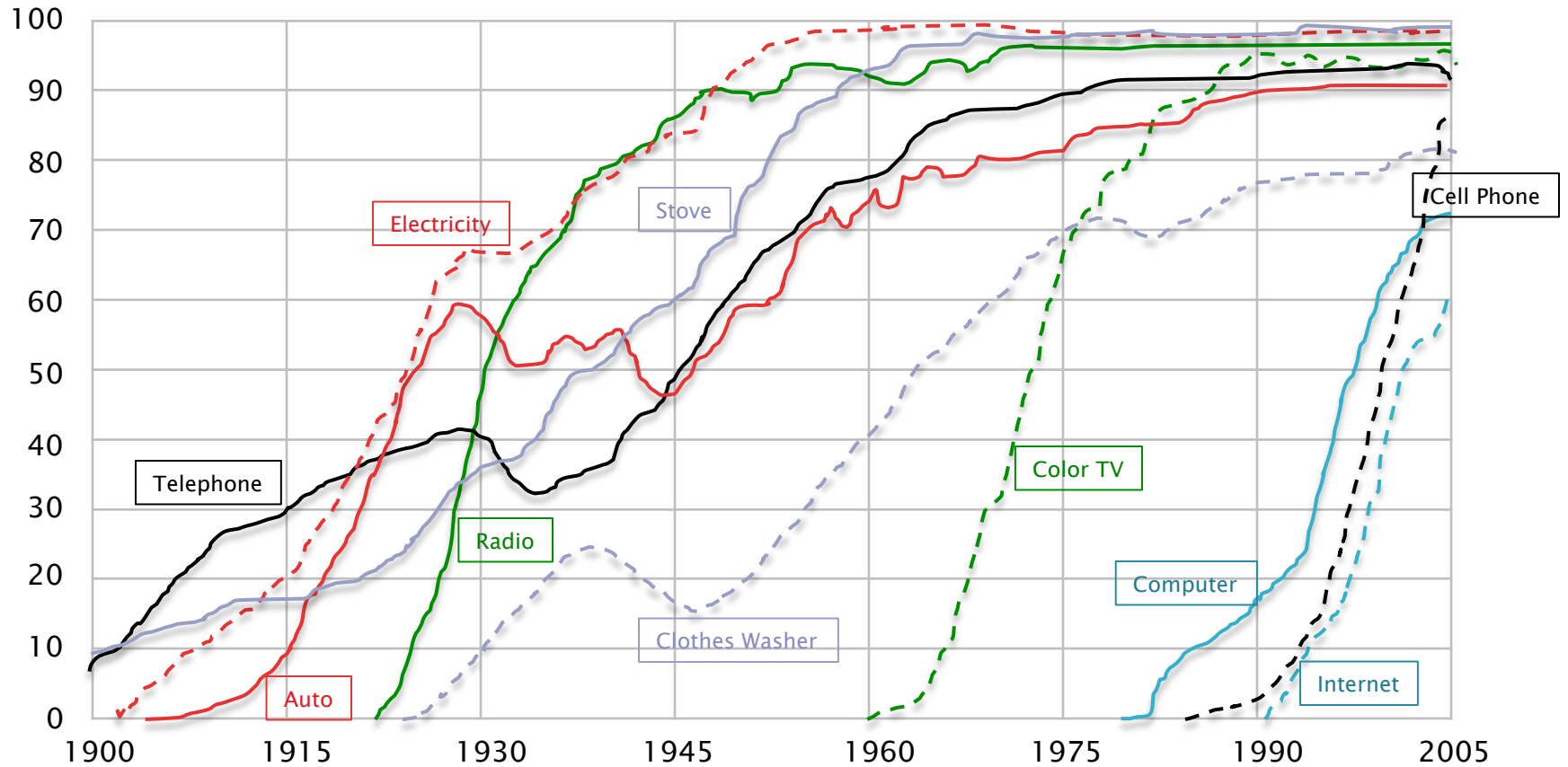
# PrEP Cascade





# Innovation Adoption Curves

% US Households



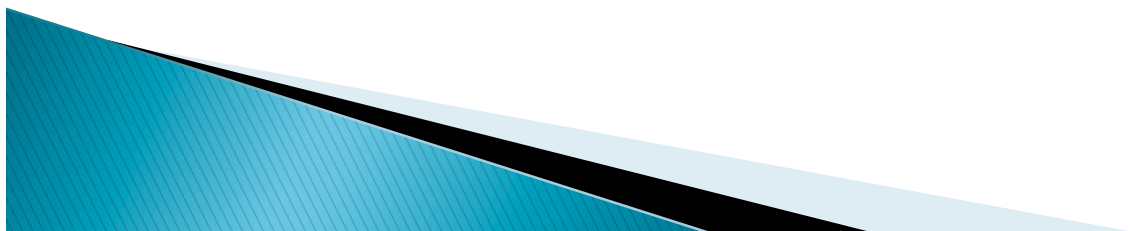
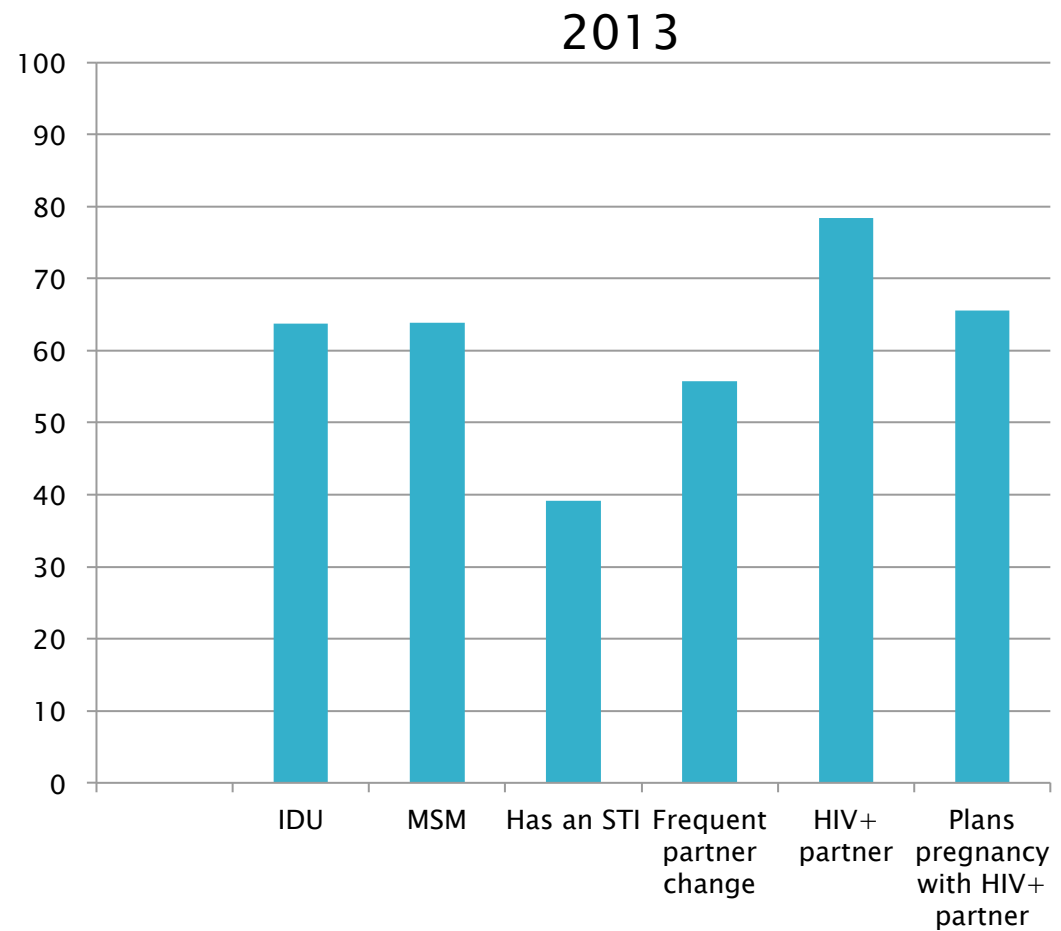
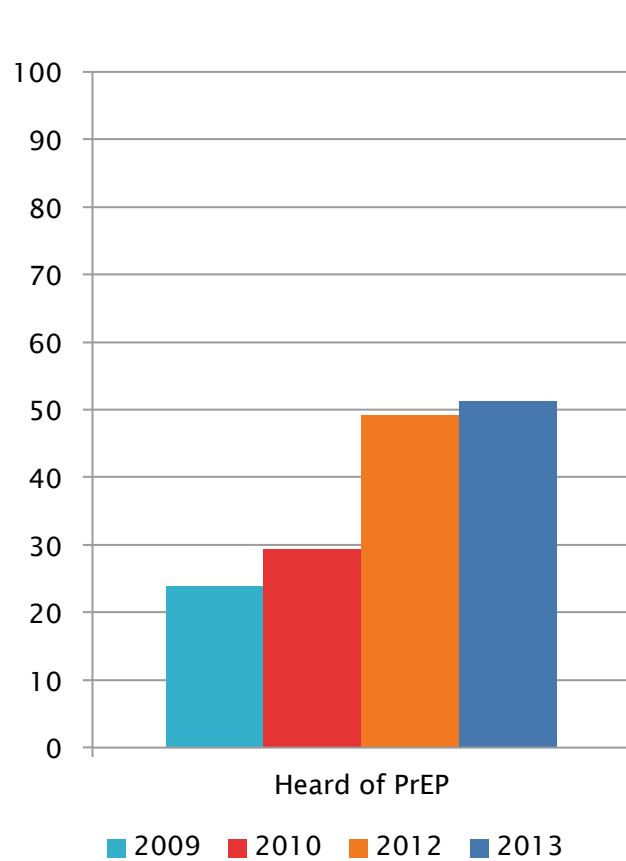
# Time to Adoption of New Clinical Practices

Clinical Procedure	Year of Landmark Trial	Years Elapsed	Rate of Use in 2000
Flu Vaccine	1968	32	55%
Pneumococcal vaccine	1977	23	36%
Beta blockers after MI	1982	18	62%
Mammography	1982	18	70%
Diabetic foot care	1993	7	20%

Source: Balas EA, Boren SA. Integrating clinical knowledge for health care improvement. Yearbook of Medical Informatics 2000: Patient-centered Systems. Stuttgart, Germany: Schattauer, 2000: 65–70

# DocStyles

## National Survey of Primary Care Clinicians

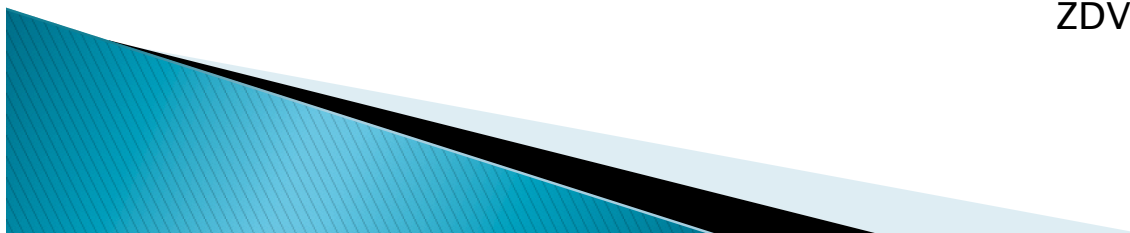
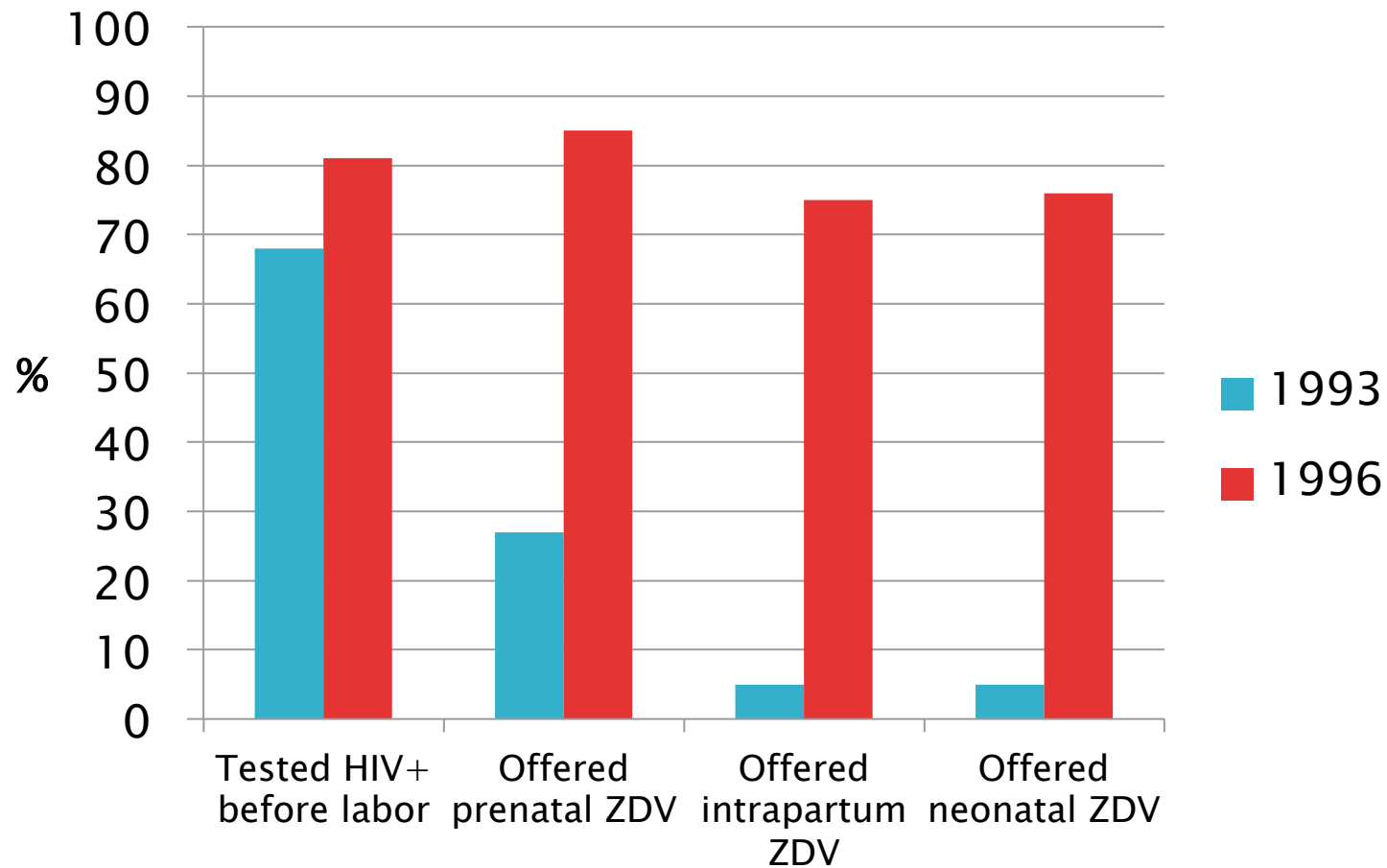


Unpublished data

# Estimating Early PrEP Uptake

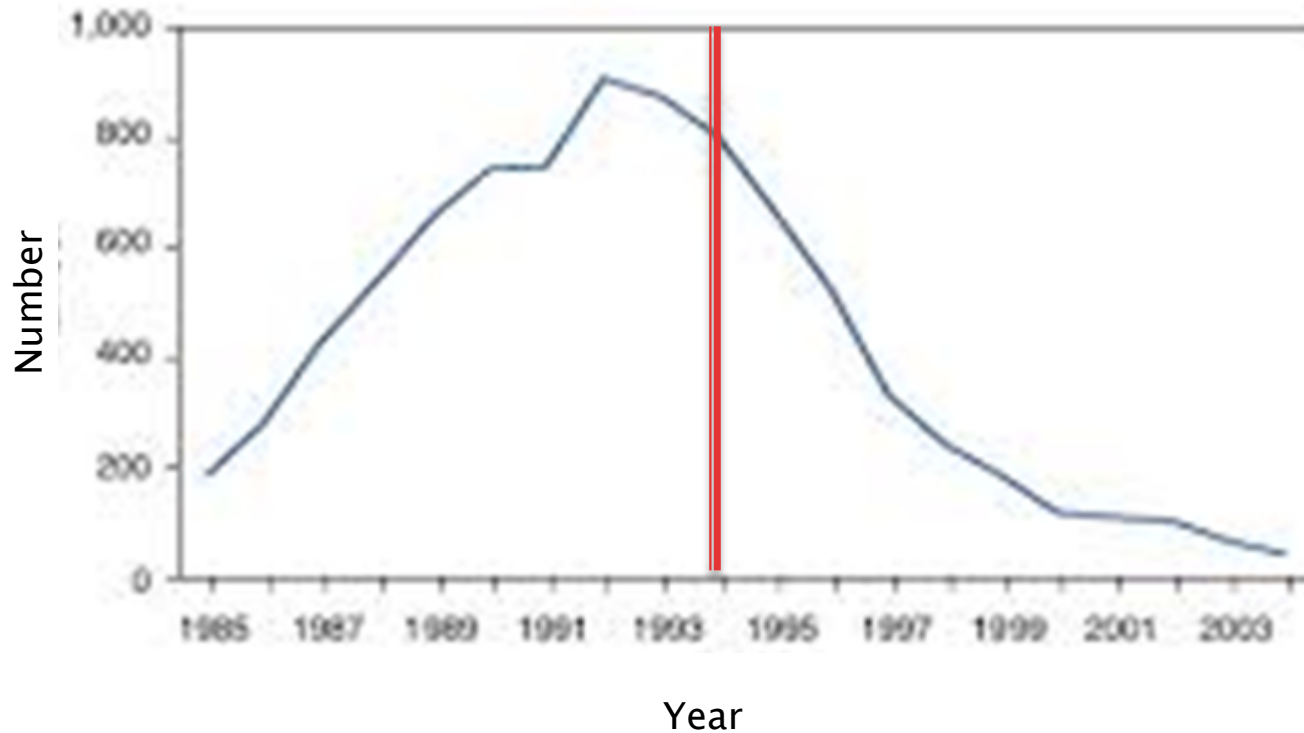
- ▶ Analysis of a commercial pharmacy database
  - Includes 55% of U.S. prescriptions
- ▶ PrEP prescribers in ~700 US cities, 49 states
  - 31% family practice and internal medicine
  - 17% non-physician prescribers (NP and PA)
  - 14% emergency medicine
  - 12% infectious disease
- ▶ Prescriptions rose 8.5-fold
  - 150 in 2011
  - 1274 in 2012

# 1994 Perinatal Guidelines Impact



# Impact of Perinatal Prophylaxis

Estimated number of cases of perinatally acquired AIDS, by year of diagnosis – United States, 1985–2004





# Next Steps

## ▶ With what we know now:

- Increase awareness and linkage to clinical care for persons who might benefit from PrEP use
- Increase awareness and training for providers interested in offering PrEP to their patients
- Increase systematic monitoring of PrEP use and its health impact

## ▶ With what we will learn soon:

- Incorporate lessons learned from OLE and demonstration projects
- Continue implementation research
- Continue clinical research





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