PrEP for HIV Prevention
Adherence to PrEP Testing Guidelines in the U.S.

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Disclosures

Only FTC/TDF (Truvada), FTC/TAF (Descovy), and CAB-LA (Apretude) are approved by the U.S. Food and Drug Administration (FDA) and only for use in some, but not all, populations. This talk may include discussion of non-FDA approved strategies for HIV prevention.

Disclaimer

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Adherence to HIV Pre-Exposure Prophylaxis Testing Guidelines in the United States

- PrEP guidelines exist but little is known about guideline adherence and quality of U.S. PrEP care.
- No data are available as to what factors might be associated with better quality of care (e.g. PCP v ID, # of PrEP patients).
- These associations might identify ways to inform interventions to improve care.

(And I wanted to explore issues related to guideline adherence, the FDA package insert, and the “standard of care.”)

McCormick et al, AIDS Patient Care and STDs, 2023 (37): 1-14.

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Adherence to HIV Pre-Exposure Prophylaxis Testing Guidelines in the United States

Methods

- Pharmacy-based records
  - Insured individuals
  - Claims for inpatient admissions, outpatient services, and medications
- Patients who started PrEP 2011-2019.
  - Because pharmacy claims do not have provider names, the provider was assigned who made claims related to PrEP care closest to first PrEP prescription, prioritizing PCP/ID doctors and claims prior to PrEP start.
  - All subsequent tests were assigned to that provider.
  - Dichotomized providers as having 1 versus >1 PrEP patient.

McCormick et al, AIDS Patient Care and STDs, 2023 (37): 1-14.

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Methods

- Tests for PrEP care were identified using broad CPT codes.
- Adherence = HIV test within 7d of PrEP start, 14d of anticipated visit
- “Higher quality” = providers who had claims for >60% of tests.
- Many sensitivity analyses.

McCormick et al, AIDS Patient Care and STDs, 2023 (37): 1-14.

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US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2021 UPDATE

A CLINICAL PRACTICE GUIDELINE

Source: https://www.cdc.gov/hiv/guidelines/preventing.html

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Results

- 29,660 patients who started PrEP during study period.
  - 12,083 (41%) were linked to a provider.
- 70% of providers were linked to only one patient.
- 6% of providers met definition of “higher quality.”
  - 32% had no testing claims within the baseline (7d) or follow-up (14d) windows.
  - 40% had no claims for HIV testing within the windows.

“Higher quality” providers were more likely:

PCPs > ID (OR 1.64, 0.93-2.90)

Only 1 PrEP pt (OR 0.42, 0.3-0.59)

McCormick et al, AIDS Patient Care and STDs, 2023 (37): 1-14.

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Limitations

- Population represents only insured patients, 2011-19.
- Challenges of the database
  - Linking patients and providers
  - Includes only testing that resulted in claims

McCormick et al, AIDS Patient Care and STDs, 2023 (37): 1-14.

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Conclusions?

- Do providers with only 1 PrEP patient follow guidelines more?
- Do more experienced providers do same day PrEP and don't ensure that testing is completed?
- Are pts of more experienced providers more likely to use insurance for medications but seek free HIV/STI testing?
- This sort of assessment is challenging…

McCormick et al, AIDS Patient Care and STDs, 2023 (37): 1-14.

Clinical Practice Guidelines

- Clinical practice guidelines improve patient outcomes.
- Institute of Medicine report to standardize guidelines (1990, updated 2011). CPCs should be:
  - Based on systemic review of evidence,
  - Be developed by knowledgeable, multidisciplinary panel of experts and representatives from key affected groups,
  - Consider important patient subgroups and preferences, if appropriate,
  - Have an explicit and transparent process to minimize bias and conflicts of interest,
  - Provide ratings of both quality of evidence and strength of recommendations,
  - Be revised as appropriate.

Murad MH. Clinical Practice Guidelines: A Primer on Development and Dissemination, Mayo Clin Proc 2017; 92(3) 423-433.

Clinical Practice Guidelines Issues

- CPG development
  - Quality of evidence
  - Bias and conflicts of interest
  - Obsolescence
- CPG implementation
  - Challenges in dissemination
  - Problems if multiple guidelines with conflicting recommendations
  - Desire for physician autonomy
  - Rarely consider rare conditions
  - Guidelines don’t allow for individual variation or preference

Clinical Practice Guidelines
Do you have to follow guidelines if evidence is weak?

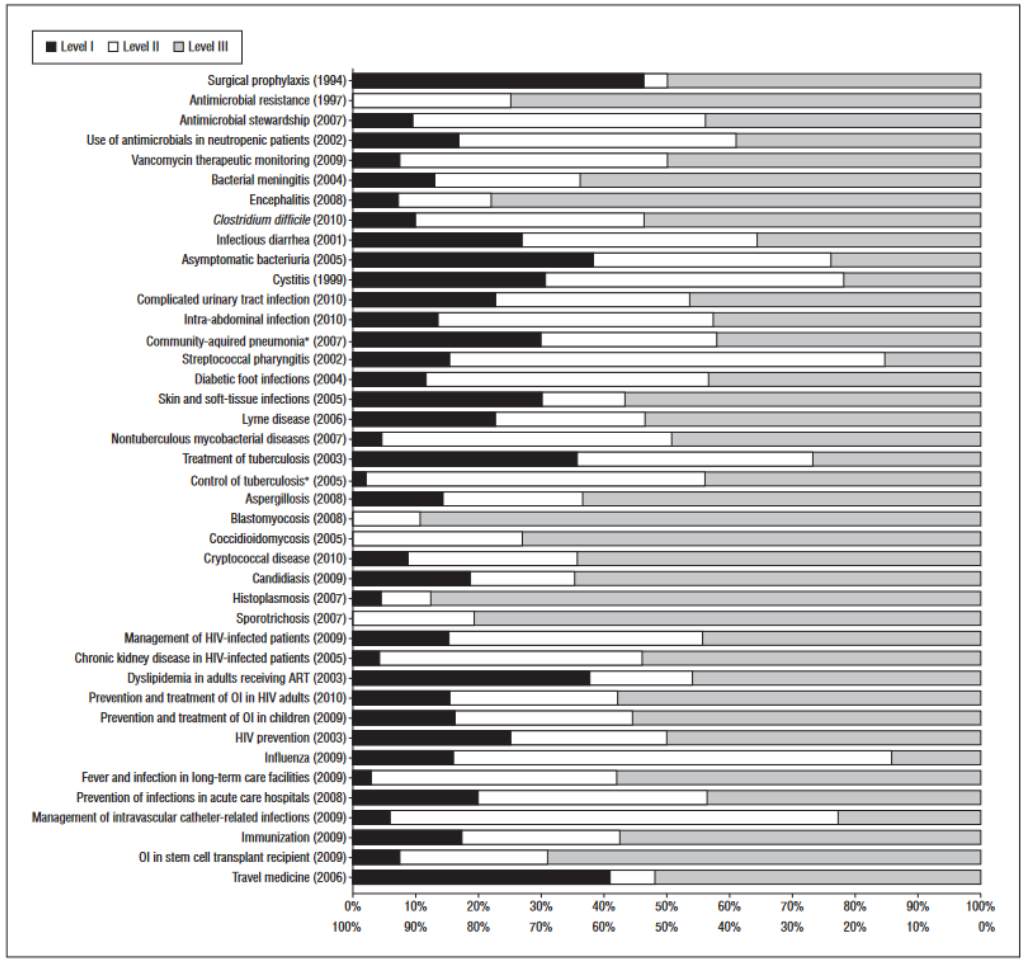

Figure 1. Comparison of 41 guidelines using percentage distribution of quality of evidence underlying individual recommendations. ART indicates antiretroviral therapy; HIV, human immunodeficiency virus; and OI, opportunistic infection. *Used a grading system that constituted a modification of the standard Infectious Diseases Society of America evidence-grading system.

- 41 IDSA guidelines issued 1994-2010
- 4218 individual recommendations
  - 14% level I (at least 1 RCT)
  - 31% level II
  - 55% level III (expert opinion only)
- Among class A recs (good evidence)
  - 23% based on level I evidence
  - 37% based on level III

This is an old example…

Lee & Vielemeyer, JAMA Internal Medicine 2011

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Clinical Practice Guidelines
Should you follow guidelines that are out of date?

2016 HHS Nonoccupational PEP Regimens for Adults and Adolescents
Preferred Regimen
Dolutegravir + Tenofovir DF-Emtricitabine
Raltegravir + Tenofovir DF-Emtricitabine
Alternative Regimen
Darunavir + Ritonavir + Tenofovir DF-Emtricitabine
Regimens for Patients with CrCl <60 ml/min
Replace Tenofovir DF-Emtricitabine with Zidovudine plus Lamivudine*
*Adjust doses for degree of renal impairment

Source: 2016 HHS Nonoccupational PEP Guidelines

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Clinical Practice Guidelines
Do their use impact litigation and malpractice claims?

- "Clinical practice guidelines … are designed to improve care, not to define standard of care."
- No set standard whether CPGs can/cannot be used in litigation.

Moffett and Moore Wes J Emerg Med 2011; 12: 109-112.

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FDA approvals and package inserts
Do you have to follow them?

"The FDA does not regulate the practice of medicine..."

- Do you *have* to follow the package insert?
  - E.g. at least quarterly HIV testing for TDF/FTC (Truvada) for PrEP or HIV NAT for CAB
- Off-label use of FDA-approved medicines is perfectly legal and can represent the standard of care.
- States differ whether the package insert is considered the standard of care.
- FDA does prohibit manufacturers from promoting/supporting off-label use.

www.fda.gov

Thornton RG. Package inserts and the standard of care. Proc Bay Univ Med Center 2003; 16(4): 502-4.

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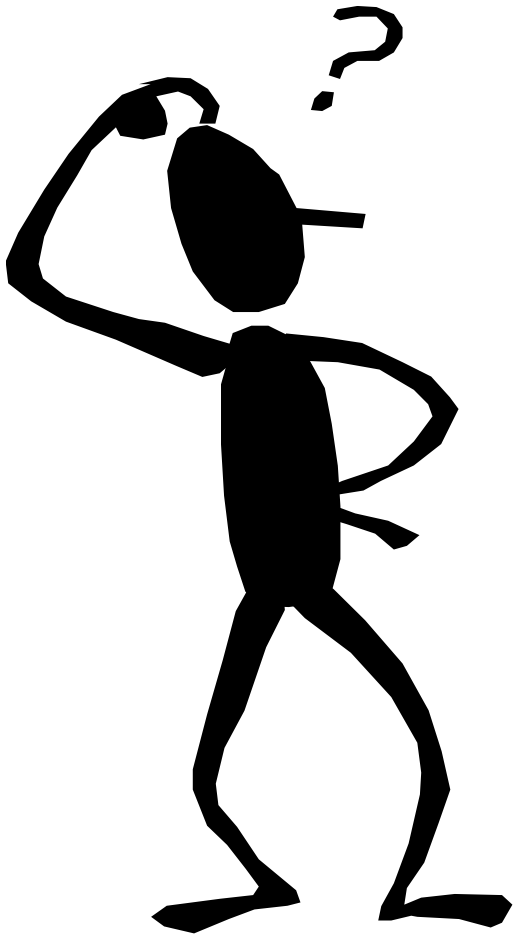
Questions?



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