- Current cautions about drug development in treatment naive populations
  - more risk than potential benefit
    - other safe and effective options available
  - more vulnerable
    - “naive” about HIV & Tx options
  - other undefined/unspoken attitudes?
    - more pristine?? more innocent??
    - treatment experienced more expendable??
- but treatment naive
  - are less susceptible to side effects?
    - maybe less tolerant too?
  - are more likely to have virologic success
  - have more options in event of v-failure
  - use simpler regimens – fewer interactions

~27 million treatment naive people with HIV

unmet need: simple, cheap, tolerable, durable, all-in-one ARV meds

"Treatment naive" commonly associated with newly diagnosed and/or early in disease progression

- Late disease/newly diagnosed
  - significant proportion of new HIV dx in U.S.
    - increasing with "Test & Treat" roll out?
  - Concern with vulnerability
    - inappropriately enrolled in trials
      - risk of low dose and progression in phase II
- Some treatments ideally tested in early disease/treatment naive population
  - CCR5 inhibitors
  - viral mutagenesis promoters
  - eradication research

Emerging issues

- Research that requires stopping ARVs to get readout
  - eradication
  - viral mutagenesis
  - tropisim switch?
  - PEP impact on immunity?
- Is stopping treatment safer in early infection?
  - How do you research this question?
- How do you study toxic drugs with no likely benefit?
  - important for advancing cure research?
  - altruism: some eager to participate in cure research