The Context of Biomedical Prevention for Youth

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Consultation on the Inclusion of Adolescents in HIV Prevention Clinical Trials

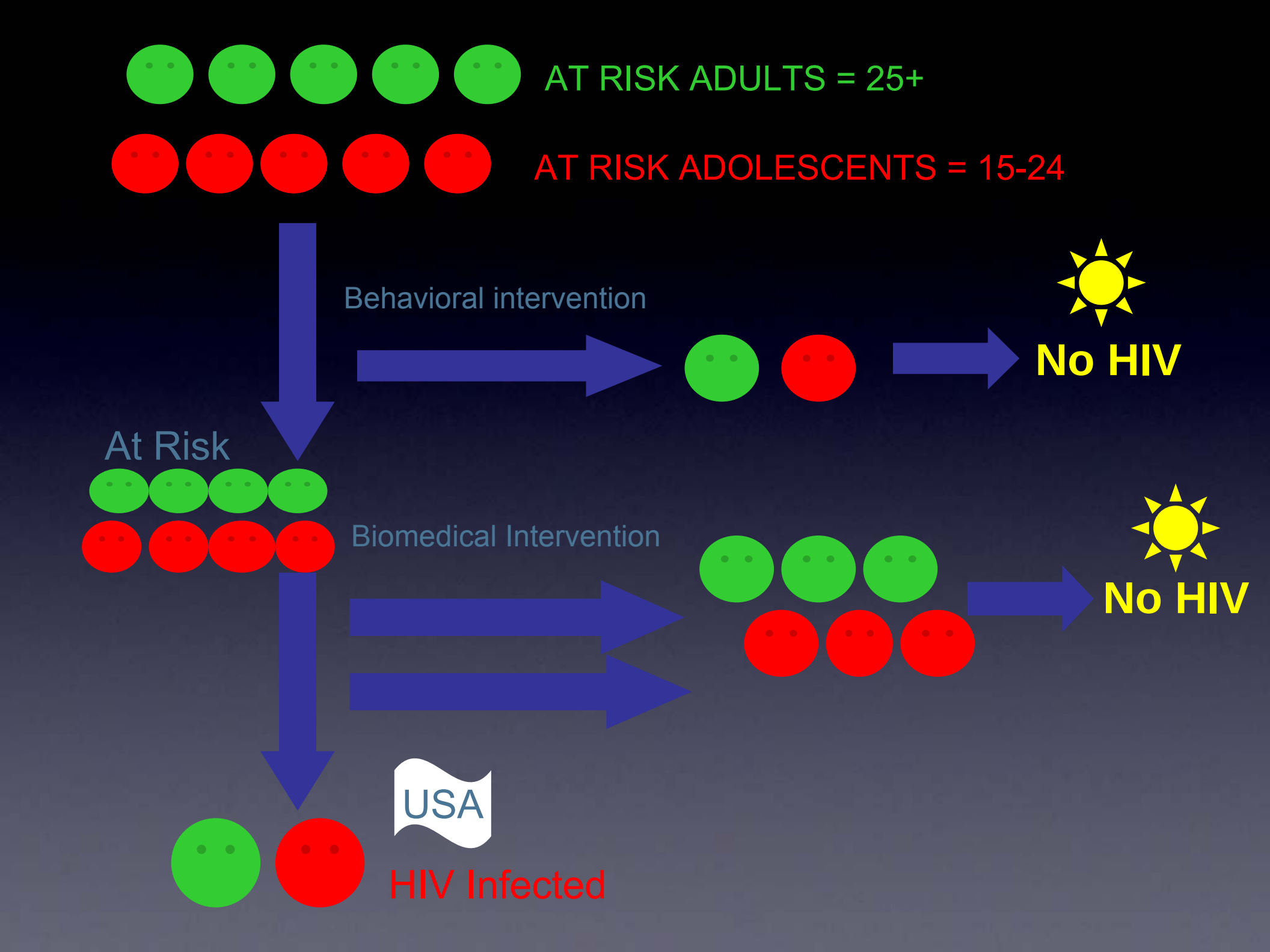
What we know: Adolescents and HIV prevention

- Adolescents in the US and worldwide are a priority population for HIV prevention.
- Adolescents make prevention decisions in a complex risk environment.
- One size does not fill all for effective prevention (not all youth at equal risk).
- Youth need prevention options:

Biomedical Interventions.

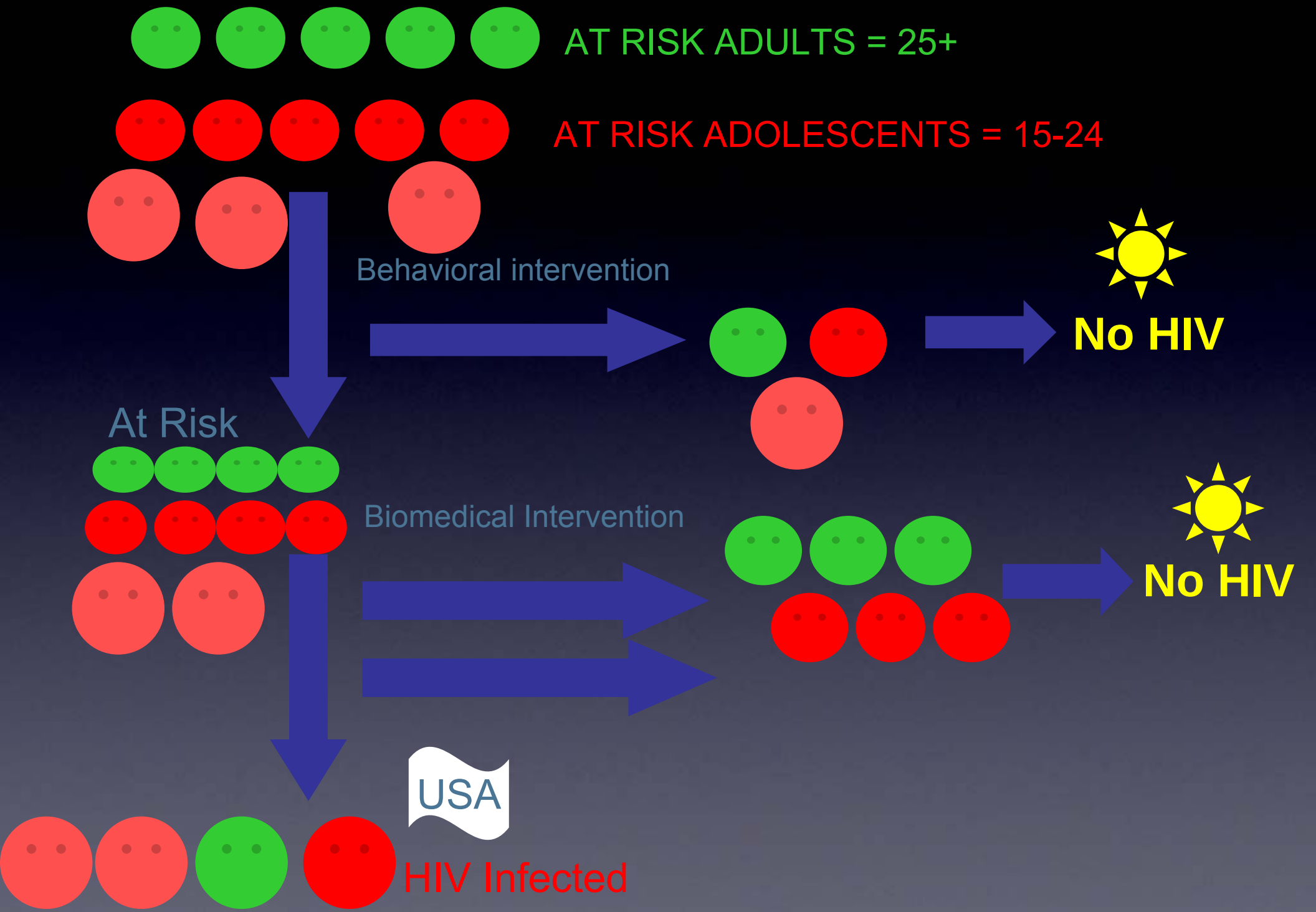
Why include biomedical prevention for adolescents?

- Delivery of a safe, effective product to adolescents before sexual debut is best hope to curb epidemic.
- Current behavioral, community, and structural interventions are limited in reach and efficacy.
- Biomedical prevention may catch adolescents who do not participate in or fully benefit from current behavioral programs.
    - Vaccines, microbicides, PrEP, circumcision.
    - HPV vaccine as example of an effective biomedical intervention.


AT RISK ADULTS = 25+
AT RISK ADOLESCENTS = 15-24
Behavioral intervention
No HIV
At Risk
Biomedical Intervention
No HIV
USA
HIV Infected

≥ 18

AT RISK ADOLESCENTS = 15-24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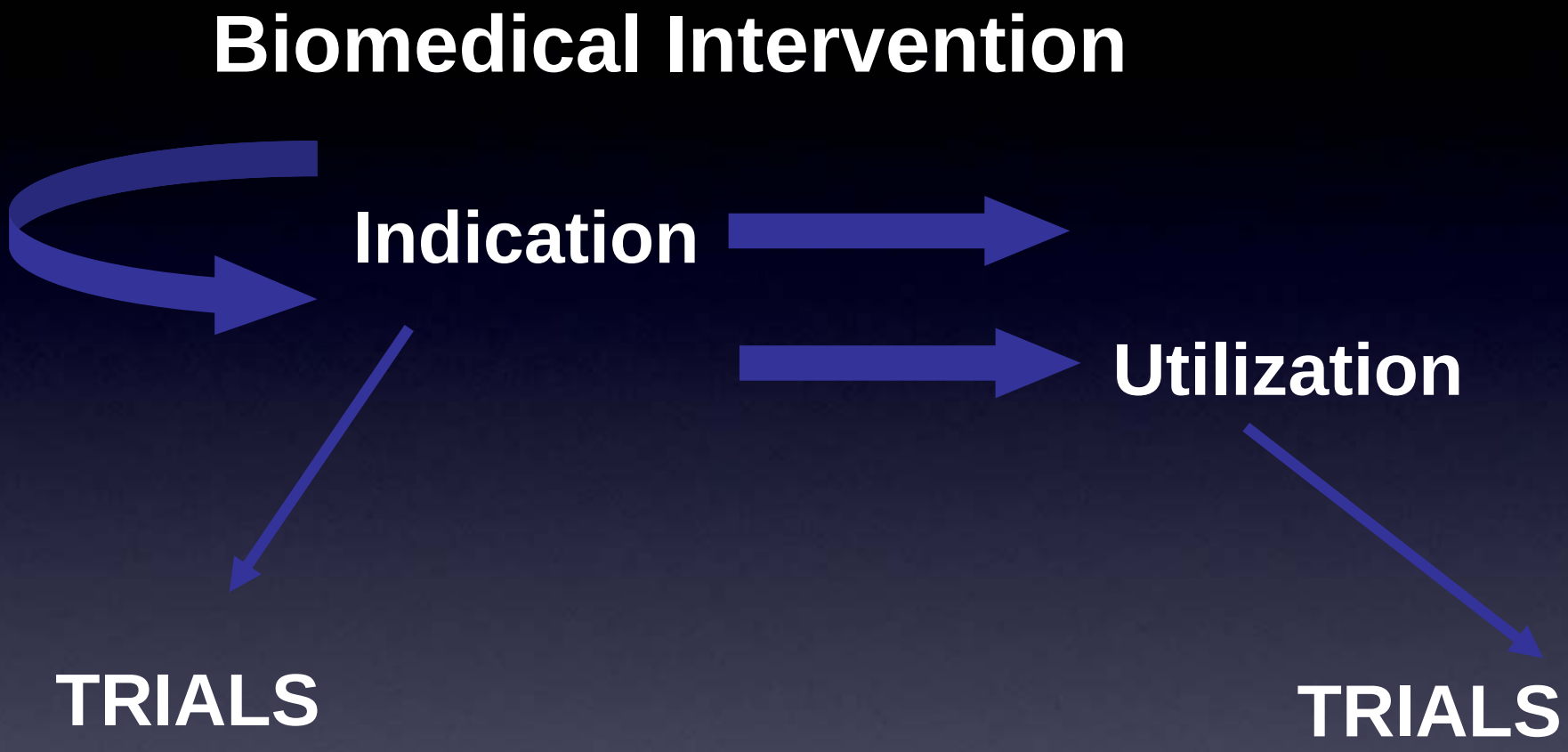
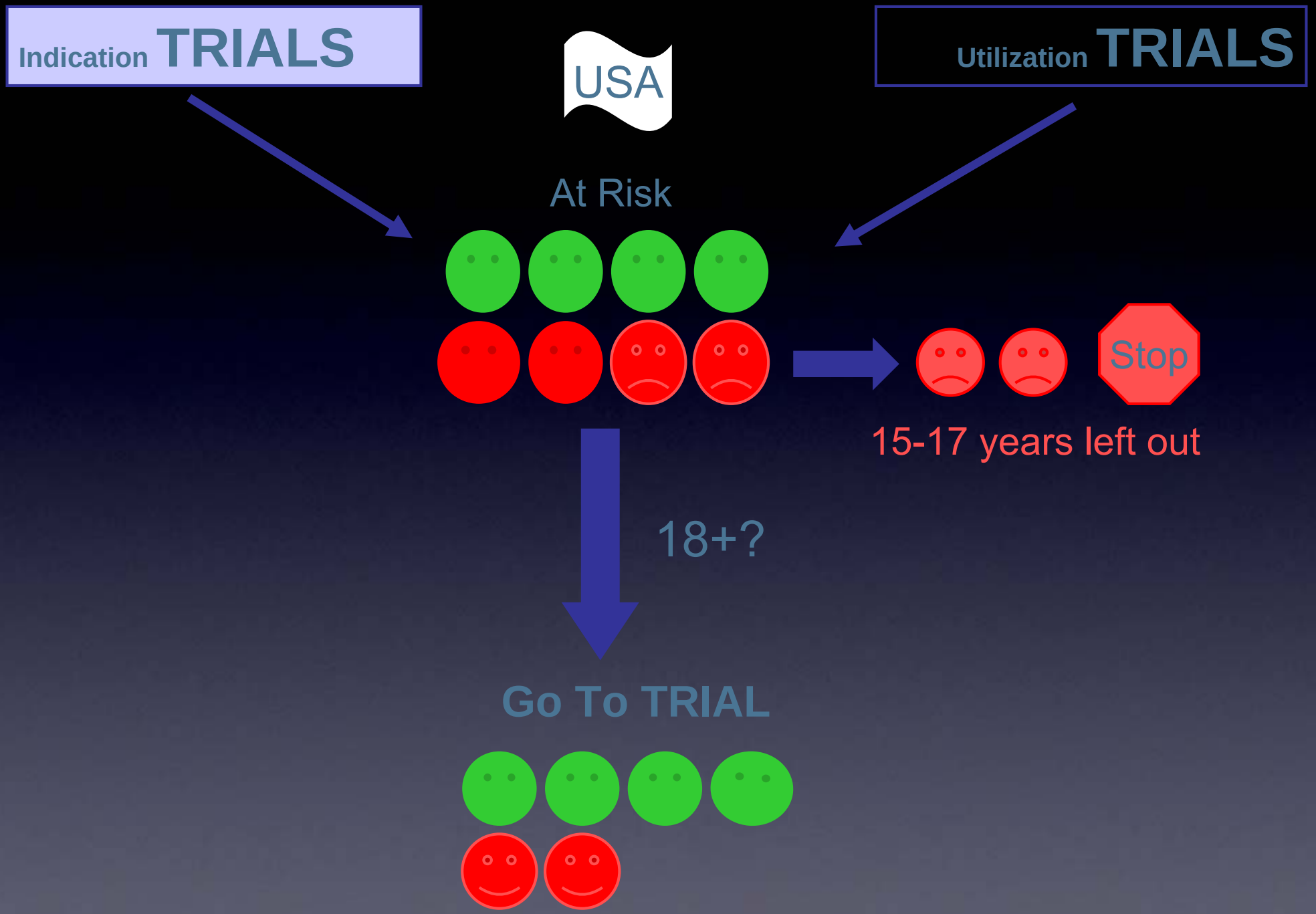
Goals and Planning

- General Goal: Develop safe, efficacious biomedical interventions that prevent HIV infection.
    - -- May be vaccines, microbicides, or PrEP
- **Specific Goal: Newly licensed biomedical interventions will have an indication for use in at risk adolescents.**
- How do we prepare so we can provide ready dissemination to adolescents under 18 ?


Biomedical Intervention
Indication
Utilization
TRIALS
TRIALS


Indication TRIALS
USA
Utilization TRIALS
At Risk
Stop
15-17 years left out
18+?
Go To TRIAL

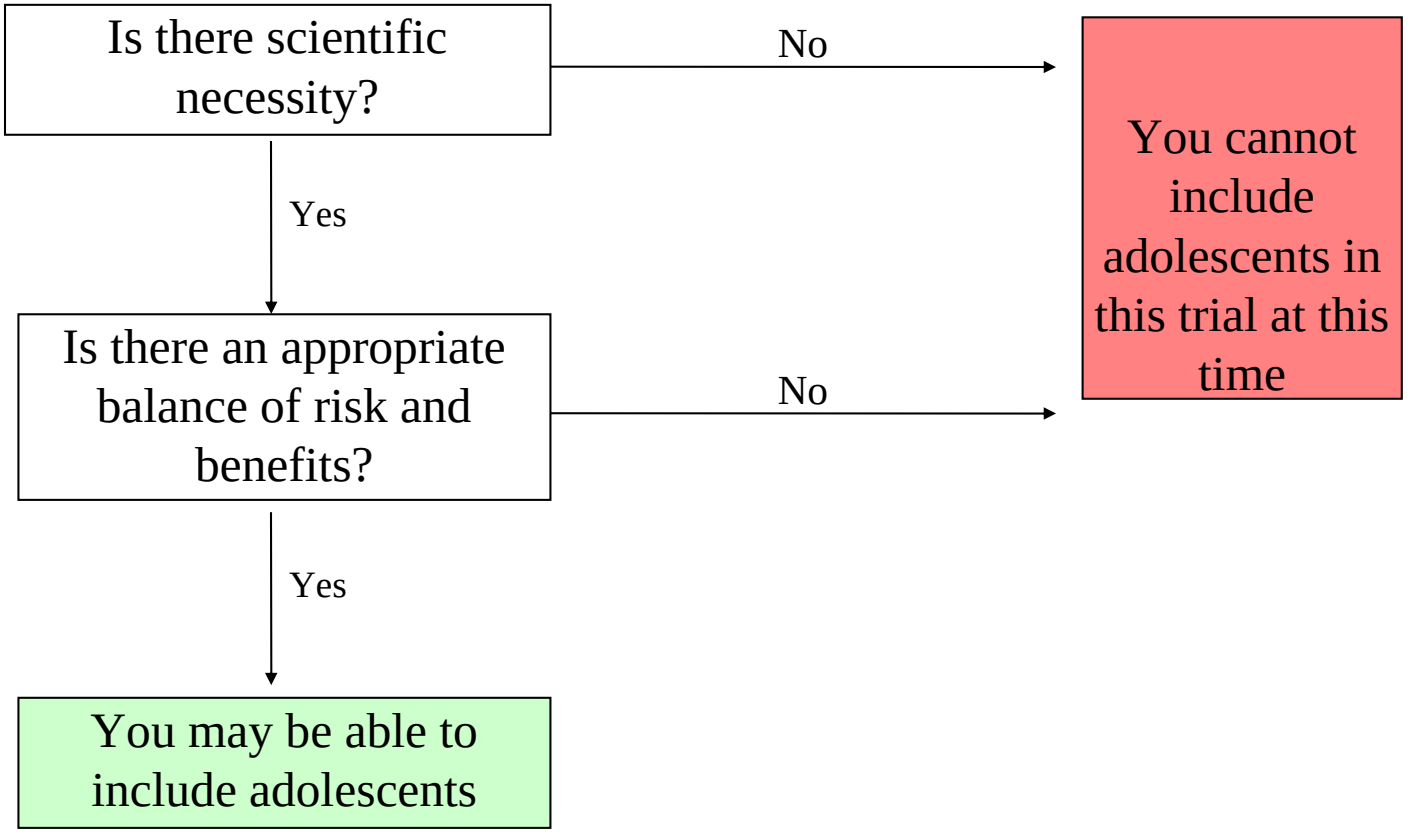
Laws in the US

- CFR codifies the regulations
- More recent laws recognize the importance of studying younger populations

What are the CFR regulations?
Appropriate balance of risk and benefit

	Prospect of Direct Benefit	No Direct Benefit
Minimal Risk	A	B
More than Minimal Risk	C	

When can we include adolescents in clinical trials?



Question 1: Scientific Necessity?

- Is there a scientific question we need answered to safely and effectively apply product to adolescents?
- Can data be extrapolated from adults?
  - If yes, no necessity.
- Is there regulatory necessity?
  - Do we need to include adolescents in this study to get an indication on the initial license? If so, how do we navigate the regulatory pathways?

Question 2: Adequate Risk and Benefit Ratio?

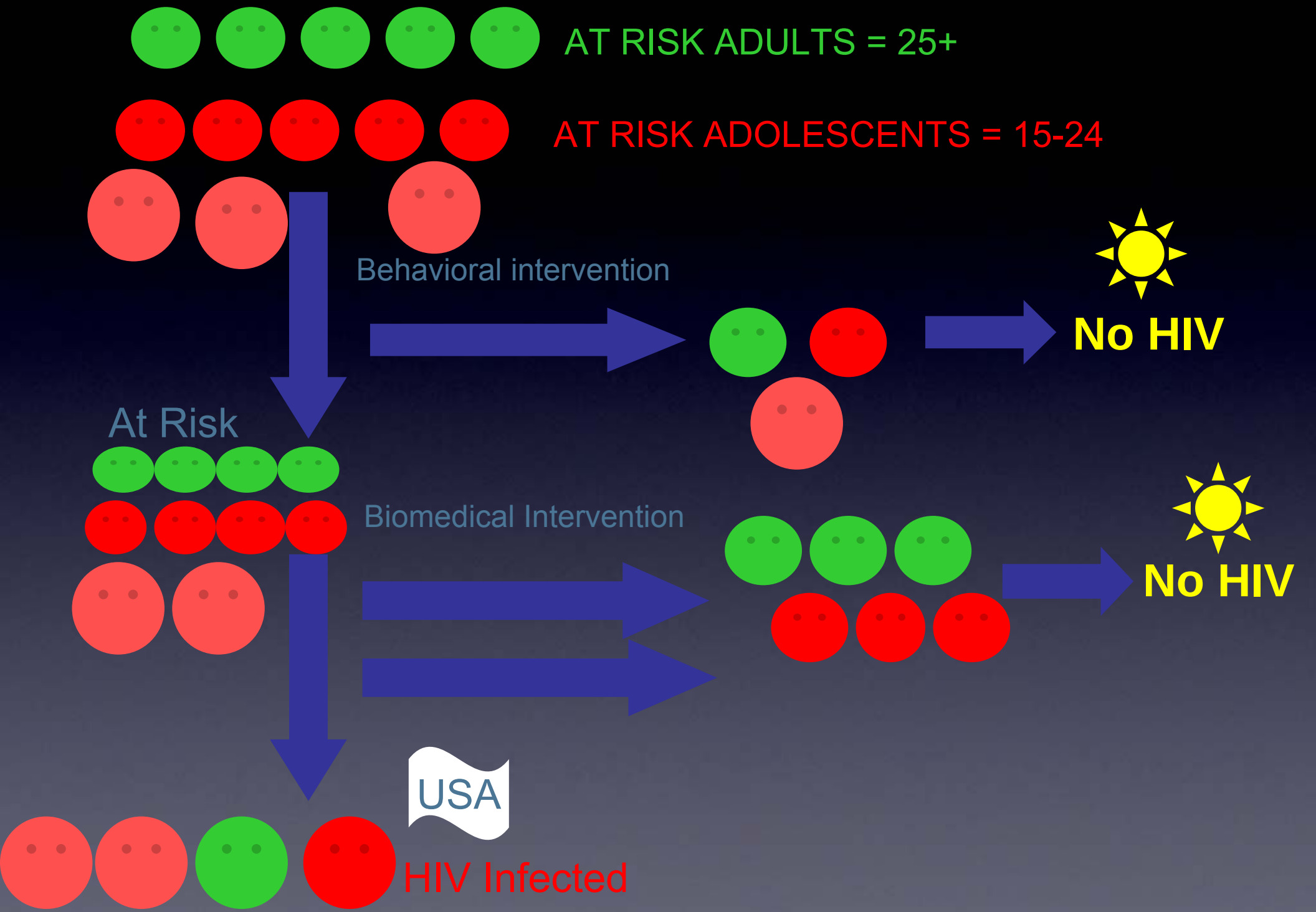
- What are the risks and benefits to adolescents for their participation?
- Do they understand them?
- Do we need to demonstrate direct benefit specific to adolescents to justify more than minimal risk? Define ‘prospect of direct benefit’?
- Need for consensus among legal, ethical, and physiological perspectives.

Reasons to include adolescents

- Efficiency: Greater "bang for your buck."
- Immunogenicity
- Not yet acquired HSV or other factors
- Practical: Adolescents 15-17 will need biomedical interventions too.
- Ethical: Protect vulnerable populations: Excluding adolescents because of potential risks may cause more harm than good.

Making connections between Vaccines, Microbicides, and PrEP.

- Despite differences in method, biomedical interventions will have **common barriers** to enrolling adolescents in trials.
- Different biomedical interventions will have in **common need to evaluate** safety, efficacy, acceptability, feasibility, and delivery.
- Work with regulatory bodies to get direction, identify scientific questions, and anticipate required data for approval/licensure in youth.
- Collaboratively address operational issues, informed consent, recruitment and retention, behavioral disinhibition, adequate prevention counseling, and other legal and ethical issues.
- Include behavioral interventionists in planning to optimize willingness to participate and uptake.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