The Pathway to Optimized PrEP

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Overview

Basic Principles
Where are we now?
Where might we be going?
Caution: Potential problems ahead!
Refining the Map
The Way Forward: Big Picture
Basic Principles

A variety of types of products and approaches are needed to reach key populations and make a real impact on the HIV epidemic.

Product specific PK/PD relationships are key. Products must reach the site of infection in sufficient quantities to prevent infection.
Where are we now?

• Coital topicals
  – TDF vaginal gel (results expected soon)
• Rectal Microbicides
  – Rectal specific TDF gel (in phase II testing)
• Long acting topicals
  – In efficacy testing (results likely early 2016)
    • Dapivirine ring
Where are we now?

• Other daily oral PrEP options
  – MVC (in phase II clinical testing – results expected in 2015)

• Long acting injectables (in phase II clinical testing – results expected late 2016)
  – TMC 278 LA
  – GSK 744 LA
Where might we be going?

- **Vaginal films?**
  - Easy to use and offers a shorter acting option than monthly or bimonthly

- **Pod IVRs?**
  - Ability to include varied products without as much concern about drug compatibility due to separation in ring

- **Implants?**
  - Already used in contraception, convenient for long term use and relatively easily removed
Where might we be going?

• Transdermal?
  – Thought be to be prohibitive due to inability to load enough drug for a reasonable sized patch - now being considered...

• Long acting tablets?
  – Long thought to be nearly impossible, but are they?
Where might we be going?

• Meeting varied needs by Multipurpose Prevention Technologies (MPTs)
  – HIV and contraception
  – May be able to include other STI prevention
  – Multiple options for delivery
    • IVRs
    • IUDs
    • Implants
    • Injectables
Where might we be going?

• Could Monoclonal Antibodies hold a place in the prevention repertoire?
  – Concept needs to be proven in an efficient and timely way
    • Issues currently include
      – Costs
      – Need for monthly IV infusion or large volume subcutaneous injections
  – Improvements being sought now
    • Subcutaneous injection with smaller volumes
    • Longer acting preparations
Caution: Potential Problems Ahead!

• Are there potential differences in drug levels between compartments?
  – Need good PK information in plasma and tissue

• Acceptability
  – What does that really mean?
  – How to more accurately assess?
Caution: Potential Problems Ahead!

- ADHERENCE
  - What decision making process occurs initially and can it be positively influenced?
  - What support is needed and feasible for long term adherence?
Refining the Map

• PK/PD
  – Set ideal properties for each type of PrEP delivery and include adequate PK information to be collected early in the development process.

• Reconsider what questions we ask in trials and what the information that we get really means?
  – What do we really need to know to understand context and product use?
Refining the Map

• Expand the multidisciplinary teams to optimize clinical trials
  – Demographers to help illuminate population dynamics such as migration patterns
  – Behavioral economists to help us understand the decision making process
  – Anthropologists to increase understanding of cultural influences and actual lived experiences of key populations
  – Community discussions to assist researchers in understanding their lives/needs/desires
The Way Forward: Big Picture

Be bold, yet discerning in our prioritization of products and strategies

• Push boundaries and think creatively
• Question the status quo
• Use objective criteria to select and down select products
• Keep in mind there are always opportunity costs
The Way Forward: Big Picture

Make Prevention Cool!

Include marketers and media experts in the expanded multidisciplinary team to influence desire for prevention products.
Thank you PSP Members:

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We have come a long way, but...

“The woods are lovely, dark and deep,
But we have promises to keep,
And miles to go before we sleep,
And miles to go before we sleep.”
Robert Frost
Thank you.

Questions?