

HIV Drug Resistance: Community Concerns

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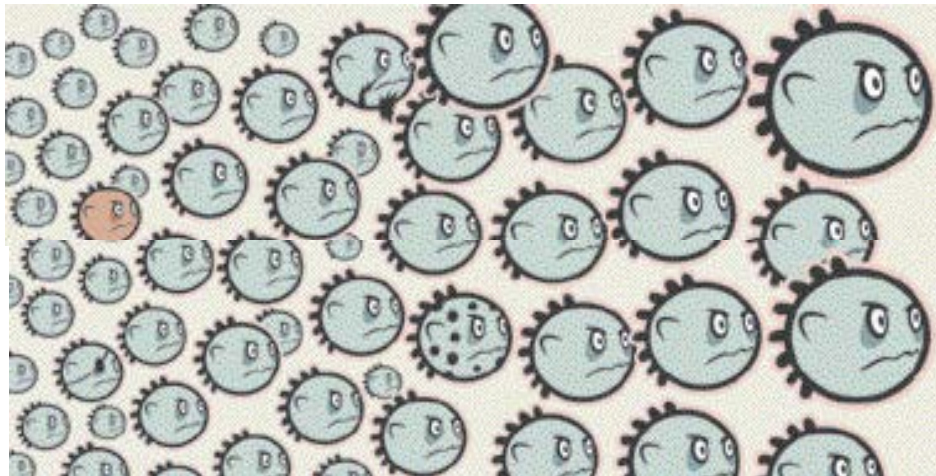
Outline of Session

1. Review of Basic Concepts in HIV Drug Resistance
2. Drug Resistance Quiz
3. 3 Case Scenarios: Resistance in VOICE
4. Discussion about risk in research

WE NEED YOUR ACTIVE PARTICIPATION!

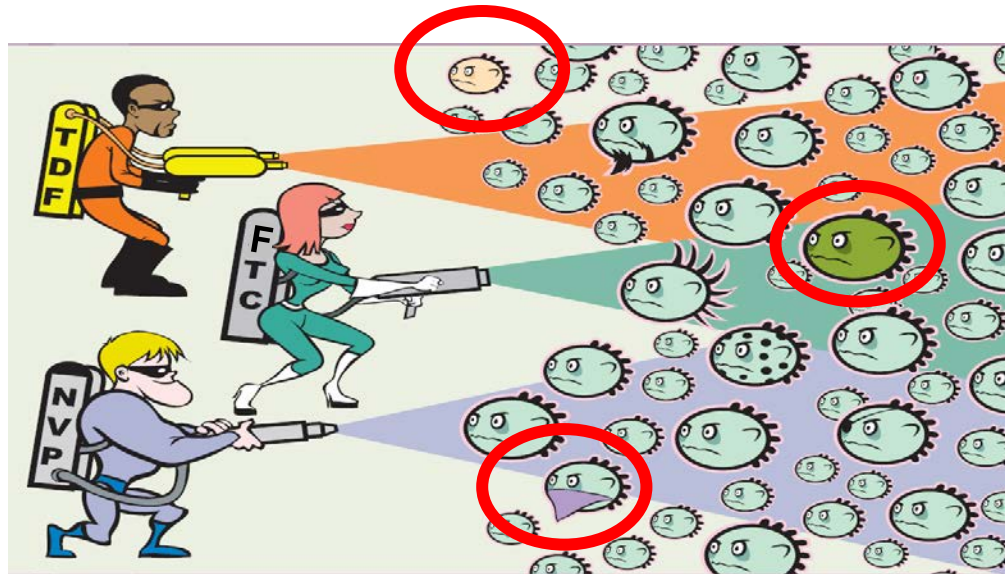
What is HIV drug resistance?

- ❑ **Drug Resistance** = loss of effectiveness of one or more ARVs (a drug used to treat HIV)
- ❑ Drug resistance is caused by changes in HIV's genetic material
- ❑ These changes are called **MUTATIONS**



How Drug Resistance Occurs

- HIV medications are best at treating the “wild-type” (regular) not the mutated virus
- HIV makes mistakes each time it copies itself, creating mutations



- If a mutation differs in just the right way, it can render an HIV medication less effective or useless.

How might a participant get drug resistance?

- She could get it...
 - from her partner if he is HIV infected and has drug resistance
 - if she becomes infected on an active product and she keeps taking the product
 - If she becomes infected and starts ARV but the ARV is not effective in stopping the virus from making copies.

How can drug resistance occur?

- **Question:** Is it possible for someone to be resistant to HIV medications if they have never taken them?
- **Answer:** Most likely, the person they got HIV from may have been on HIV treatment and his or her virus may have become resistant to one or more HIV medications

How can the same drug be used for prevention and treatment?

- For TREATMENT, at least 3 DRUGS must be used
 - Eg. Tenofovir, FTC, Efavirenz
 - An untreated infected person usually has lots of virus in their blood
 - One drug is not enough to stop the virus from making copies
 - If an infected person uses only 1 or 2 drugs, she is at risk for drug resistance

How can the same drug be used for prevention and treatment?

- For PREVENTION, 1 or 2 drugs may be sufficient
 - VOICE and ASPIRE are trying to find this out
 - An uninfected person has no virus
 - One or two drugs may be enough to prevent a person who is exposed to HIV from becoming infected
 - If a person becomes infected and continues to use only 1 or 2 drugs, she is at risk for drug resistance

Tips for Resistance Counseling

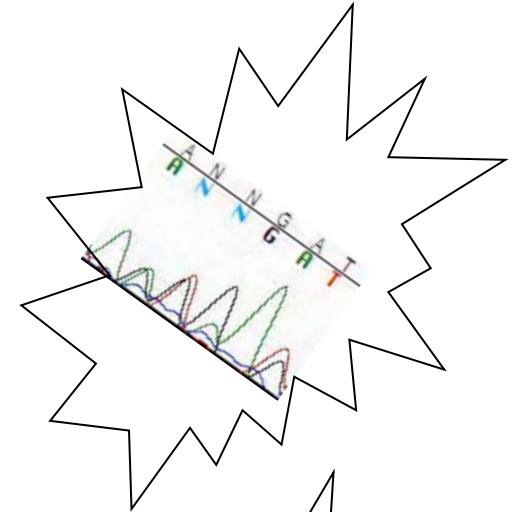
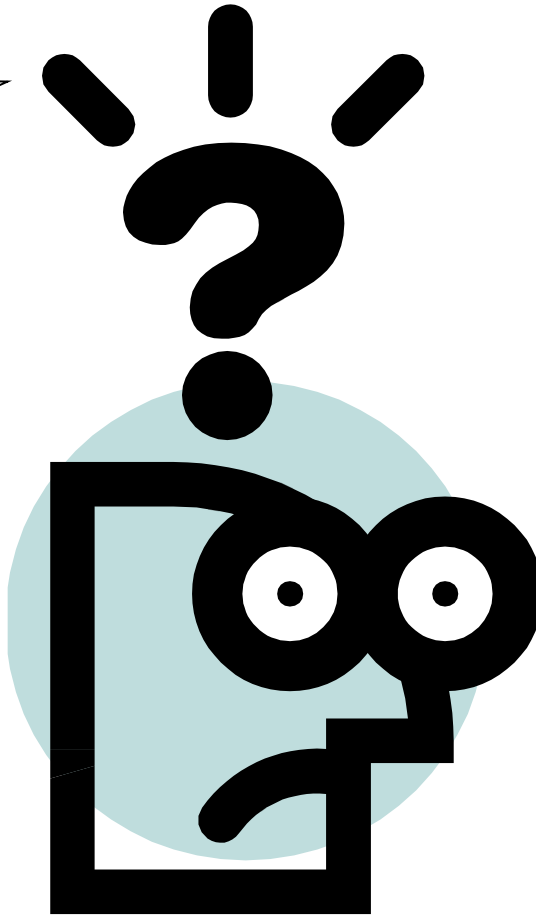
- Resistance could be hard to understand, encourage the participant to ask questions. Assess participant's understanding

- Emphasize the importance of:
 - using the study product as counseled
 - never sharing their study product
 - never using someone else's product

Questions?



ATTCTGGACATAAGACAAGGACCAAAG
AACCCCTTAGAGACTATGTAGACCGGTT
TATAAAACTCTAAGAGCCGAGCAAGCTT
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AACCTTGTGGTCCAAAATGCGAATGG
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ATTGTGGCAAAGAGGGCACATAGCCA



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Resistance Concepts Quiz

1) What is HIV Drug Resistance?

1. Something about the person makes the HIV drugs not work as well
2. The virus has changed to make the HIV drugs not work as well
3. The drug has changed to not work as well
4. All of them

2) What are ARV?

1. AIDS Related Virus = another name for HIV
2. AIDS Relief Vitamin = an herbal medicine to help those with HIV
3. Anti Retro Viral = a kind of drug used to treat HIV
4. ASPIRE VOICE = an acronym for the acronyms for the two MTN efficacy studies

3) If a participant becomes HIV infected, she will automatically be resistant to the products used in VOICE or ASPIRE.

1. True

2. False?

4) If a person has HIV drug resistance:

1. She can no longer take any ARV
2. She can take some specific ARVs depending on the kind of resistance she has
3. She can take all ARVs
4. She resists HIV and cannot get infected

5) Which statement is true?

1. A VOICE participant could get drug resistance if she seroconverts while taking the product
2. A VOICE participant can get drug resistance by just taking the study product
3. A VOICE participant can never get drug resistance
4. A VOICE participant can get drug resistance even if she is HIV negative

6) If a woman has resistance to tenofovir:

1. She can no longer use nevirapine because she has drug resistance
2. She can no longer use any HIV drug ever
3. All of the above
4. None of the above

7) A person who is not infected with HIV can still become resistant to ARVs

1. True

2. False?

8) An infected person can become drug resistance if...

1. An infected person does not take ARV
2. Her viral load is high and there is not enough drug to stop the virus from making copies
3. her viral load is undetectable
4. An infected person's partner has resistance

More than one answer can be correct.



What are your questions?



Case Scenarios

For each case, consider...

- Could the participant have HIV drug resistance?
 - If yes, how would she get it?
 - If no, why not?
- Does her risk of resistance depend on which study arm she was on?
- How could she prevent getting drug resistance in this case?

CASE 1

- Participant A's husband is HIV-infected and on first-line therapy, but he is not good at remembering to take his medication. He was able to get a viral load from his doctor, and his result was high.
- Could Participant A's husband have drug resistance? What are the signs?

Case 1, continued – Part 2

- Participant A is on the gel arm.
- She was confirmed to be HIV infected at visit 8.2

- Could she be drug resistant?
- How would she get it?
- Does it depend on whether she was on the placebo gel or tenofovir gel?

CASE 2

- Participant B is on an oral arm. She had two positive rapid tests at visit 5.0, and was told by the clinic to stop her medication.
- However, she was worried about stopping her medication so she kept taking it. When she ran out, she got more medication from her sister who was on the study. She didn't come back for her sample 2 until 2 months after her sample 1 visit.

CASE 3

- Participant C's friend Mary is HIV infected. Mary's doctor told her she has drug resistance, and switched Mary from first line to second line therapy.
- Now Participant C is worried, and wonders if she should switch her study medication. She had two negative rapids at visit 5.0, but would like to get a drug resistance test.

PART 3: DISCUSSION OF RISK

- What does RISK mean?
 - RISK is the chance that a bad effect may happen

- What are some examples of risk in your life?
 - Getting into an accident while driving or riding in a car
 - While cooking – getting burned using the stove, or getting cut using a knife

Risk in VOICE

- Using study product
 - a bad effect could happen such as getting nausea, vomiting, vaginal itching or burning
 - It does not mean it WILL happen
 - There is a chance that it COULD happen

- When is DRUG RESISTANCE a risk in VOICE?

Messages to Participants and Communities

- While taking study products there is the risk or possibility that you may develop resistance
- Resistance is a risk only if you seroconvert
- Sharing your product with someone else could increase the chance of that person developing resistance

Messages to Participants

- To avoid resistance, the clinic staff conducts HIV testing on regular basis. If participant test positive for HIV, product is stopped immediately to avoid resistance.
- If you seroconvert, it is important that you stop using study product and follow guidance provided by staff

Next Steps

- Ensure all staff are familiar with this information
- Provide counseling to participants as part of your counseling procedures
- Assess participant's understanding of this information and clarify any questions participants may have
- Ensure communities understand the risk of resistance in the context of research