FAQs in HIV Care

Christopher B. Hurt, MD, FIDSA

Webcast Wednesday

02 August 2023

AETC AIDS Education & Training Center Program Southeast

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Disclosures

- This program is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number U1OHA30535 as part of an award totaling $4.2m. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit: https://www.hrsa.gov

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Dr. Hurt is supported by the Health Resources and Services Administration (HRSA-17-039, U1OHA30535) and the National Institute of Allergy and Infectious Diseases (P30AI50410, R61AI174285, UM1AI069423, UM1AI068619).

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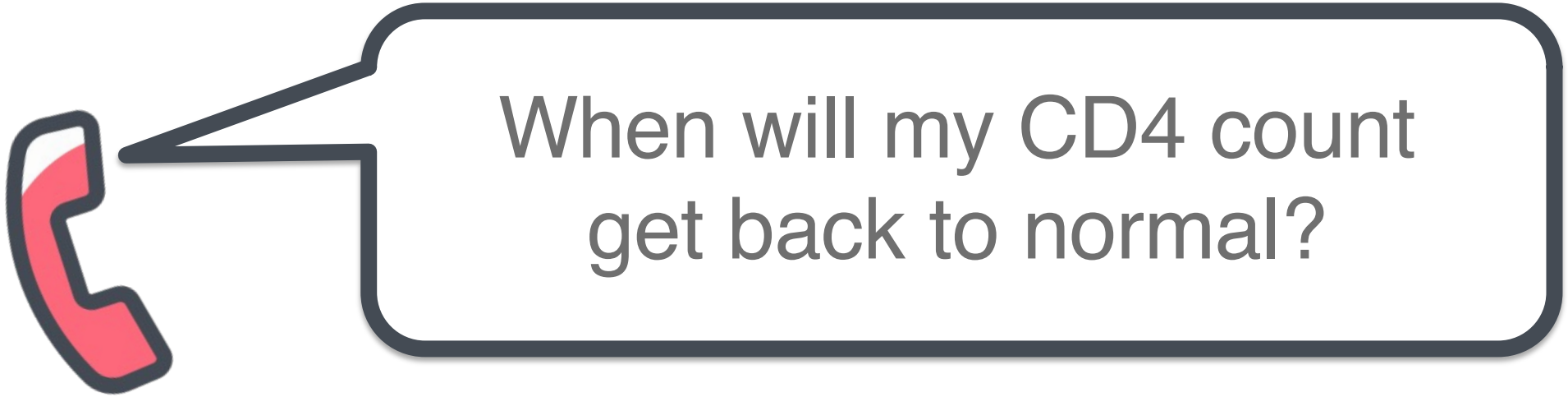
Objectives

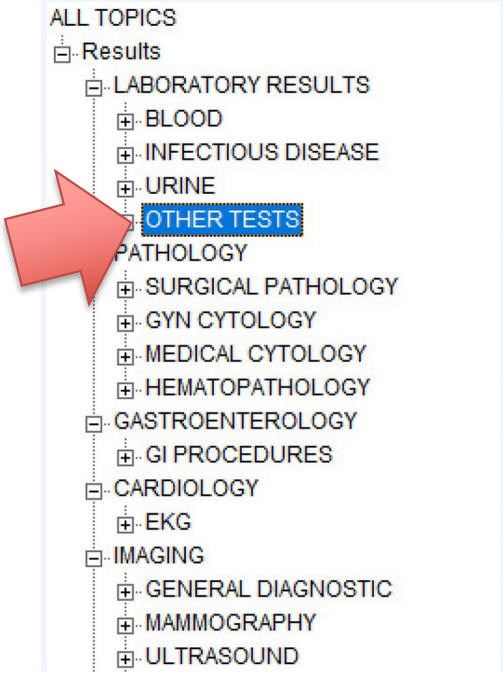
- Improve knowledge to address common questions patients have about HIV medications, adherence, and complications

- Recognize some “red flag” issues that should prompt you to discuss the patient’s question with a pharmacist or the patient’s provider


When will my CD4 count get back to normal?

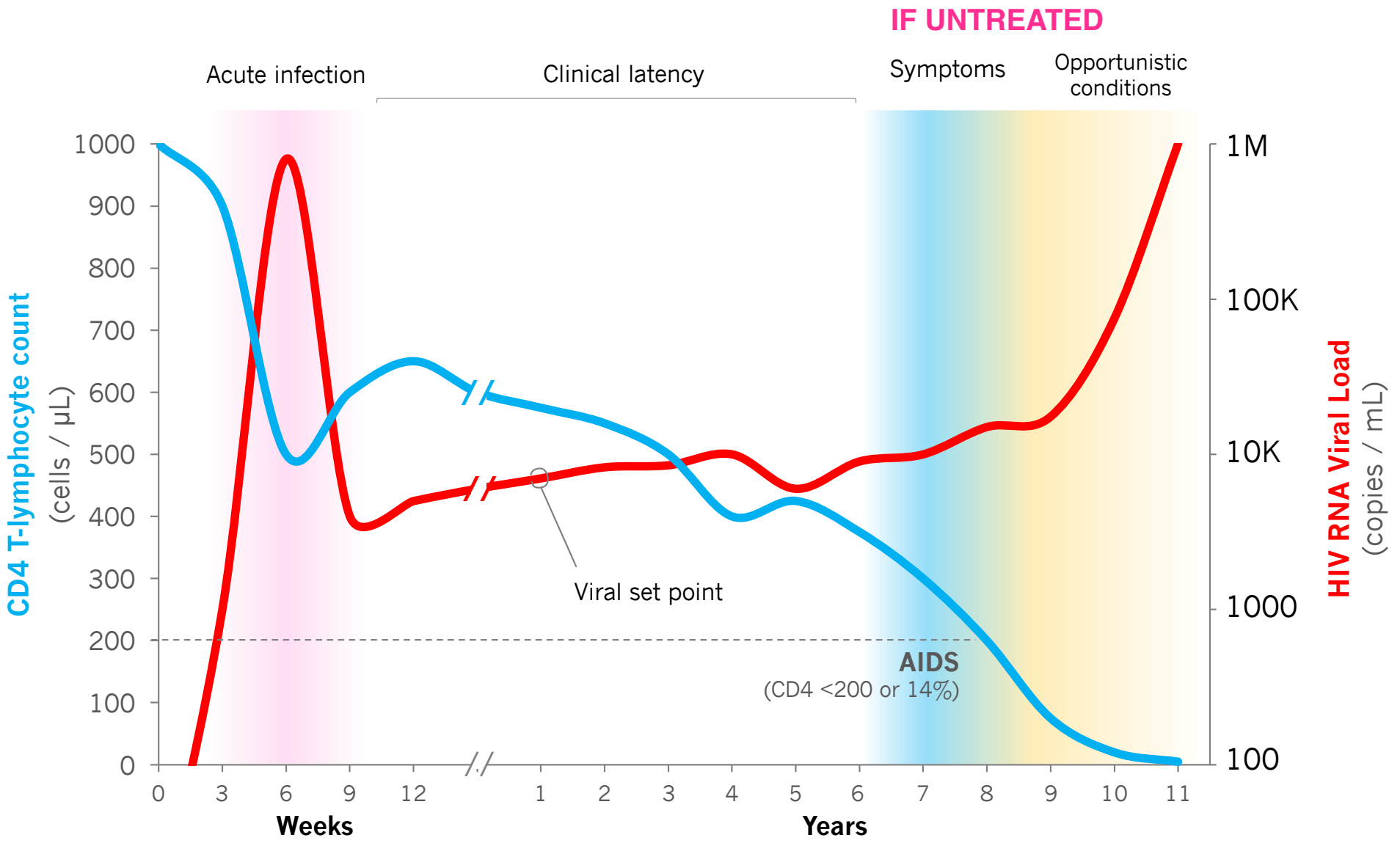
and look up their most recent <u>absolute</u> CD4 count!

Absolute CD4 counts



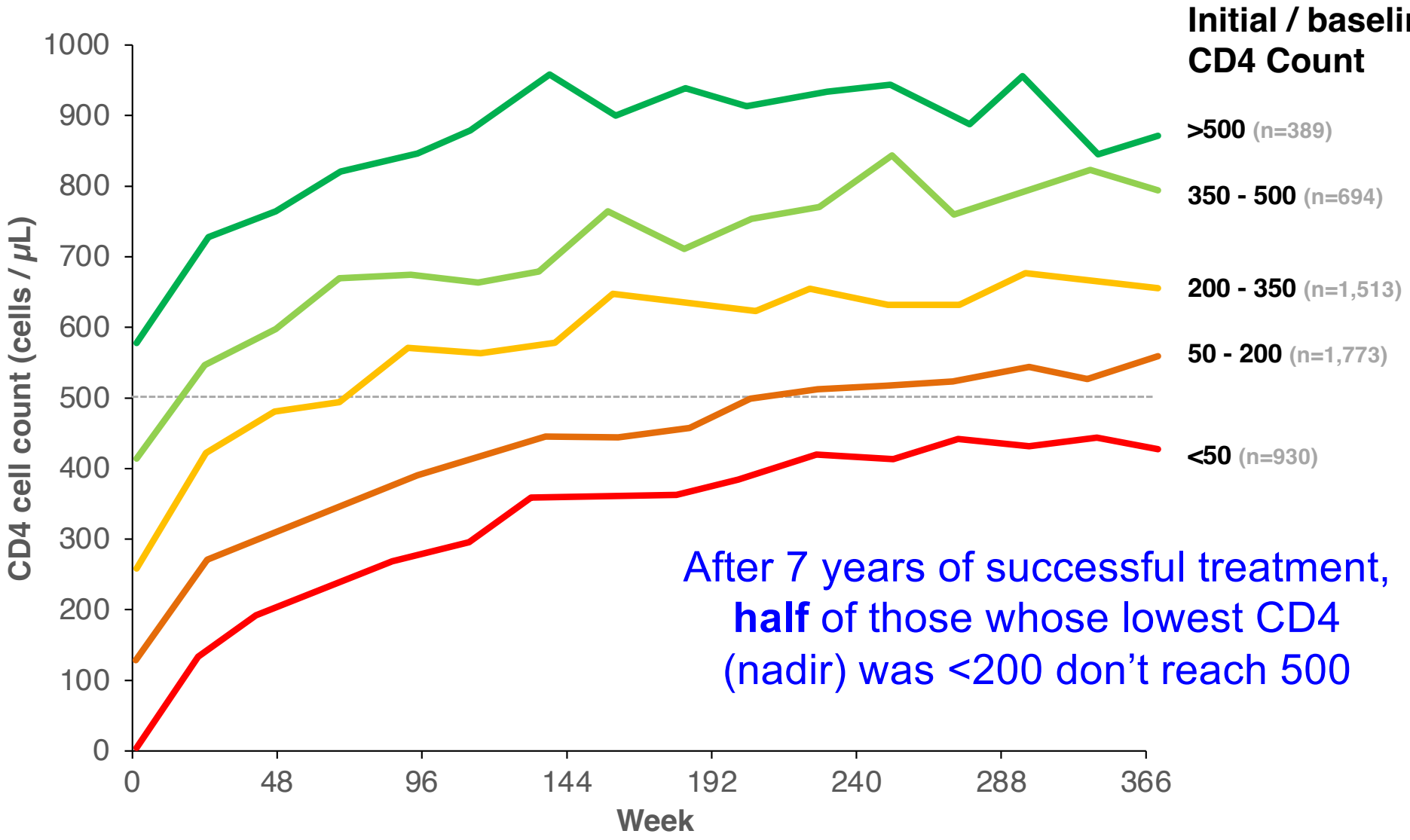
	1 1/30/2020 1106	2 8/22/2019 1028	3 8/2/2018	4 7/16/2018	5 1/19/2017 1447	6 4/14/2016 1359	7 8/24/2015 0922
FLOW CYTOMETRY							
Lymphocyte Marker						:*	:*
CD3% (T Cells)		67			72	72	73
CD4% (T Helper)		33			34	35	31
CD8% T Suppressor		33			35	36	40
Absolute CD3 Count		1,235			1,475	1,479	1,115
CD4%(T HELPER)			32.7 *	33.3 *			
Absolute CD4 Count		609	687 *	666 *	696	719	474
Absolute CD8 Count		609			717	739	611
CD4:CD8 Ratio		1.0			1.0	1.0	0.8
CD4/CD8 Ratio	1.02						
% CD 4 Pos. Lymph.	34.5						
% CD 8 Pos. Lymph.	33.7						
Absolute CD 4 Helper	690						
Absolute CD 8 (Supp)	674						

Timeline after infection: CD4 and viral load



Adapted from: Fauci AS, et al. *Ann Int Med* 1996;124:654-63

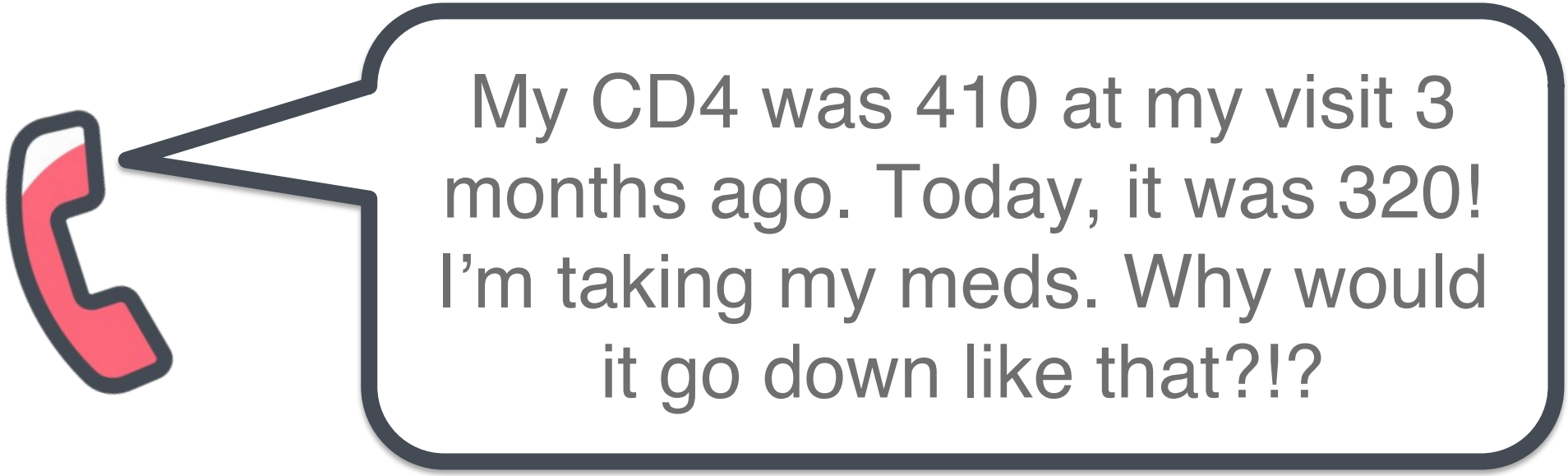
CD4 at entry to care "predicts" recovery



ATHENA Cohort – Gras L, et al. *JAIDS.* 2007;45:183–192.

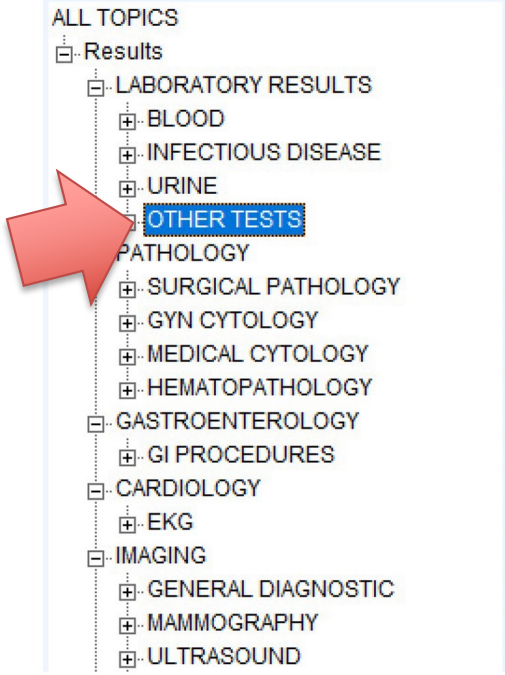
When will my CD4 count get back to normal?

How much your CD4 comes up depends on a lot of things. For now, keep taking your meds. I'll ask your provider to talk with you more about this, soon.


My CD4 was 410 at my visit 3 months ago. Today, it was 320! I'm taking my meds. Why would it go down like that?!?

and look up their most recent CD4 counts and CD4 percentages

Absolute CD4 counts



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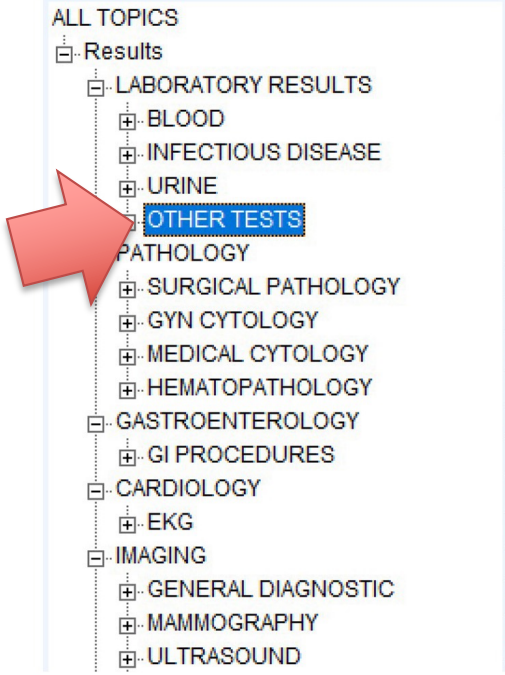
Absolute CD 4 Helper	690						
Absolute CD 8 (Supp)	674						

CD4% = % of lymphocytes that are CD4+



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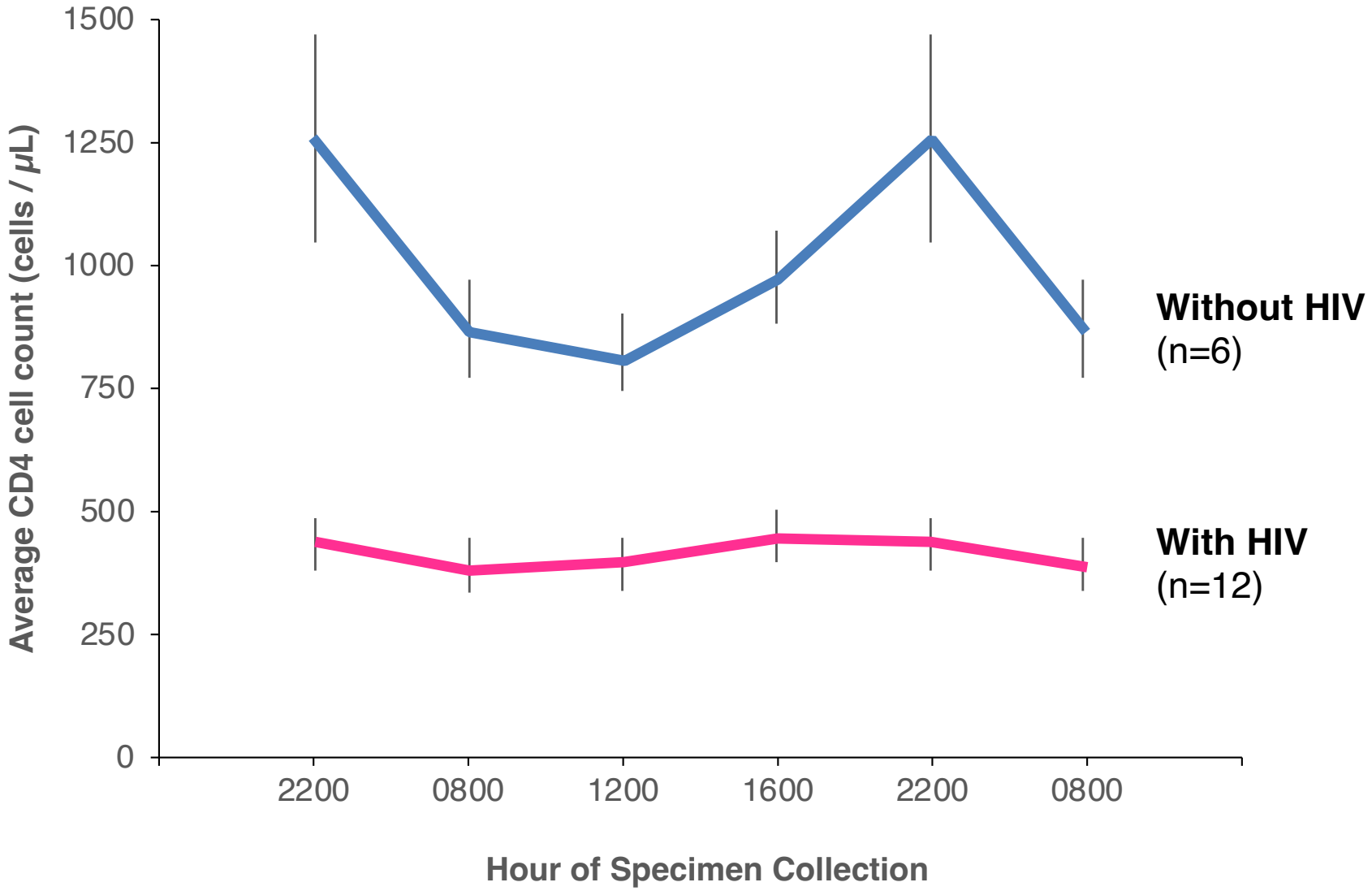
https://clinicalinfo.hiv.gov/en/glossary/cd4-percentage

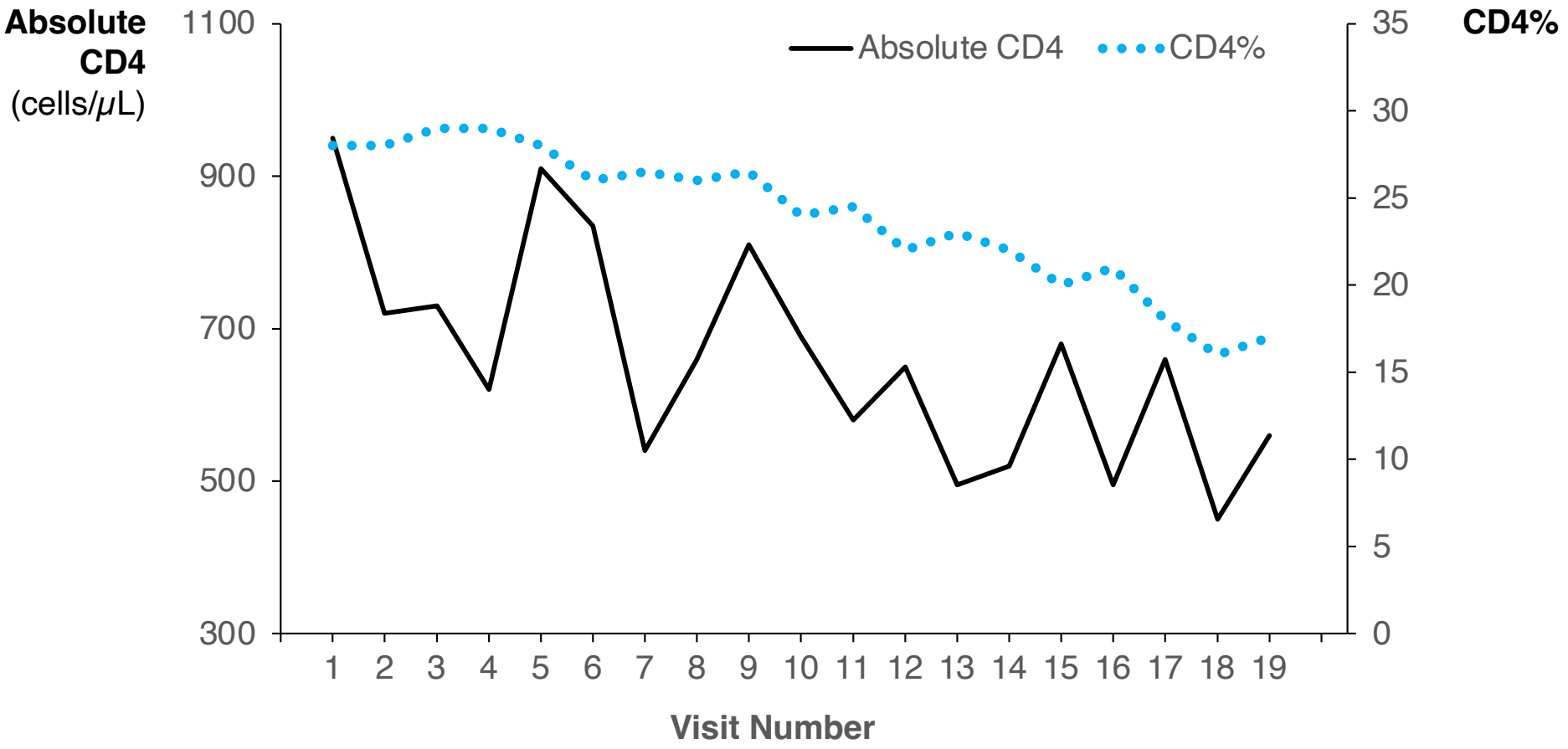
Absolute CD4 counts fluctuate during the day



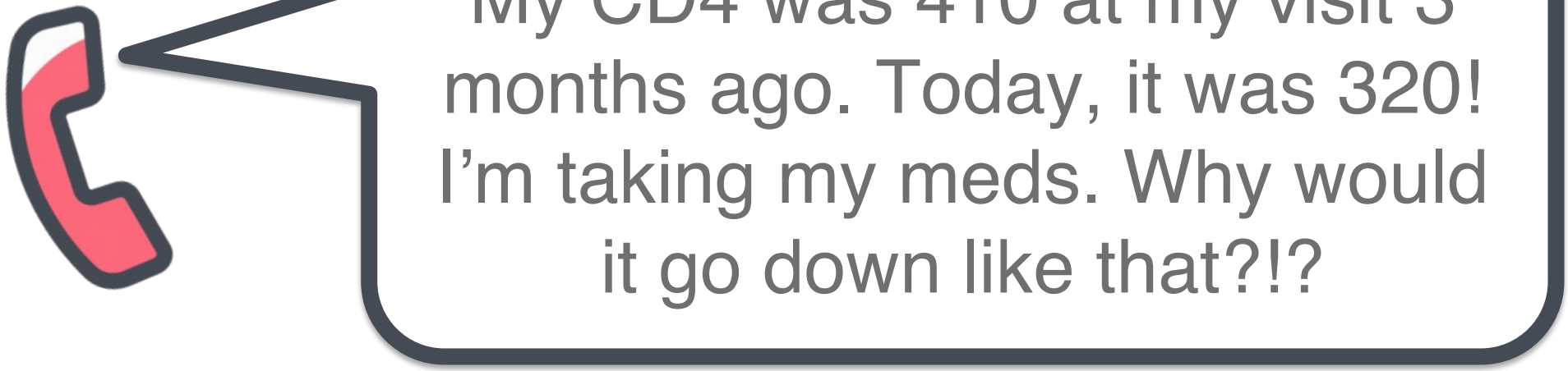
Adapted from: Malone JL, et al. JAIDS. 1990;3(2):144-51

CD4% is “smoother” over time

Trends in Absolute CD4 and CD4% in an Untreated Patient



Adapted from: https://www.hivbook.com/tag/cd4-t-cells/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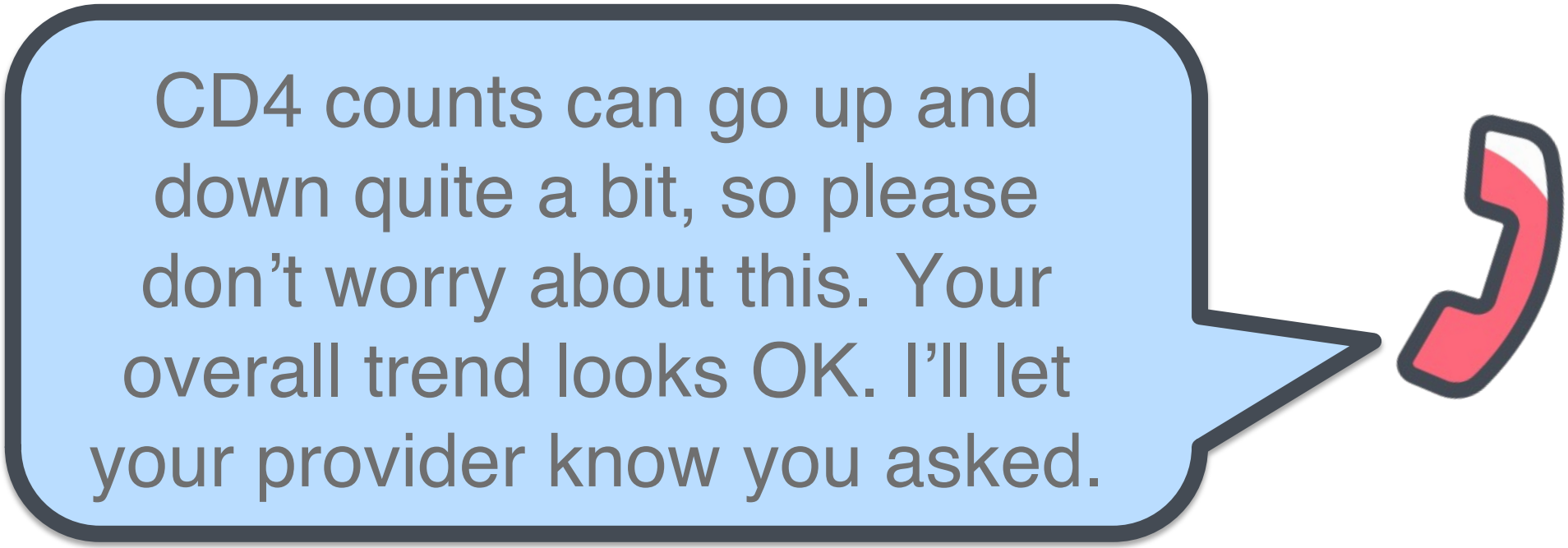
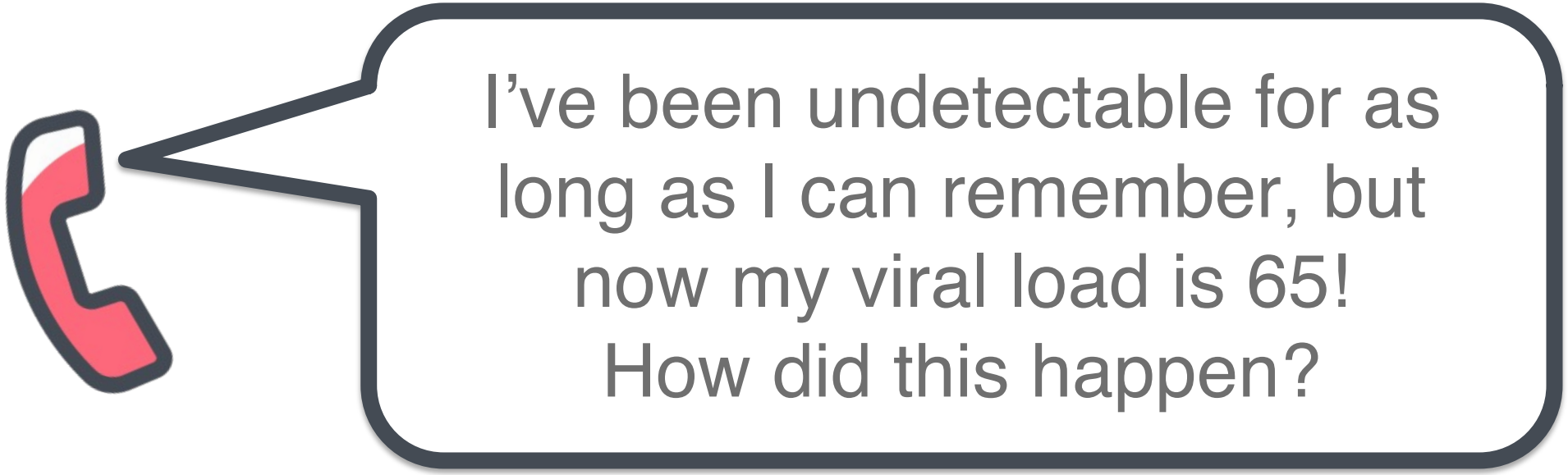
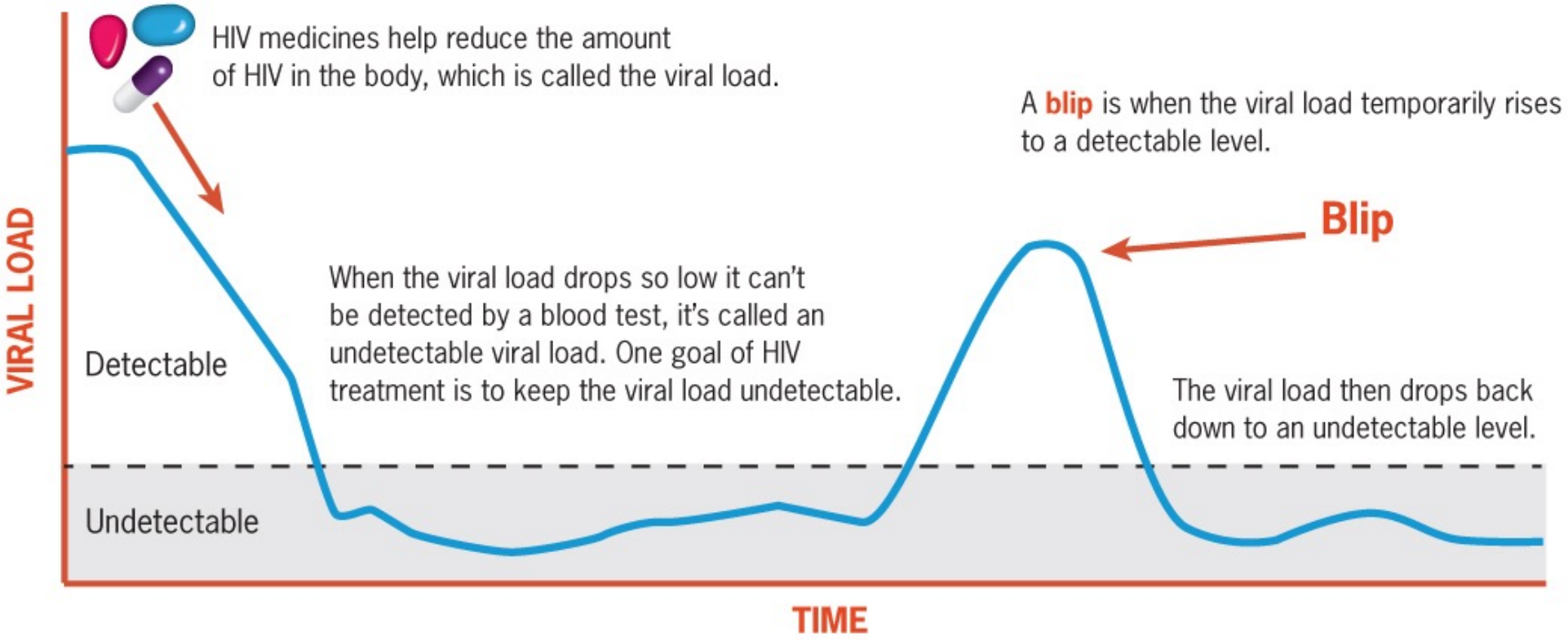

CD4 counts can go up and down quite a bit, so please don't worry about this. Your overall trend looks OK. I'll let your provider know you asked.


I’ve been undetectable for as long as I can remember, but now my viral load is 65! How did this happen?

What's a viral load "blip"?



https://hivinfo.nih.gov/understanding-hiv/infographics/whats-blip

Dealing with blips

Don’t panic!

Frequent blips can be a sign of trouble, but occasional blips are OK.

Were they sick recently?

If the immune system is stressed, the viral load may transiently rise.

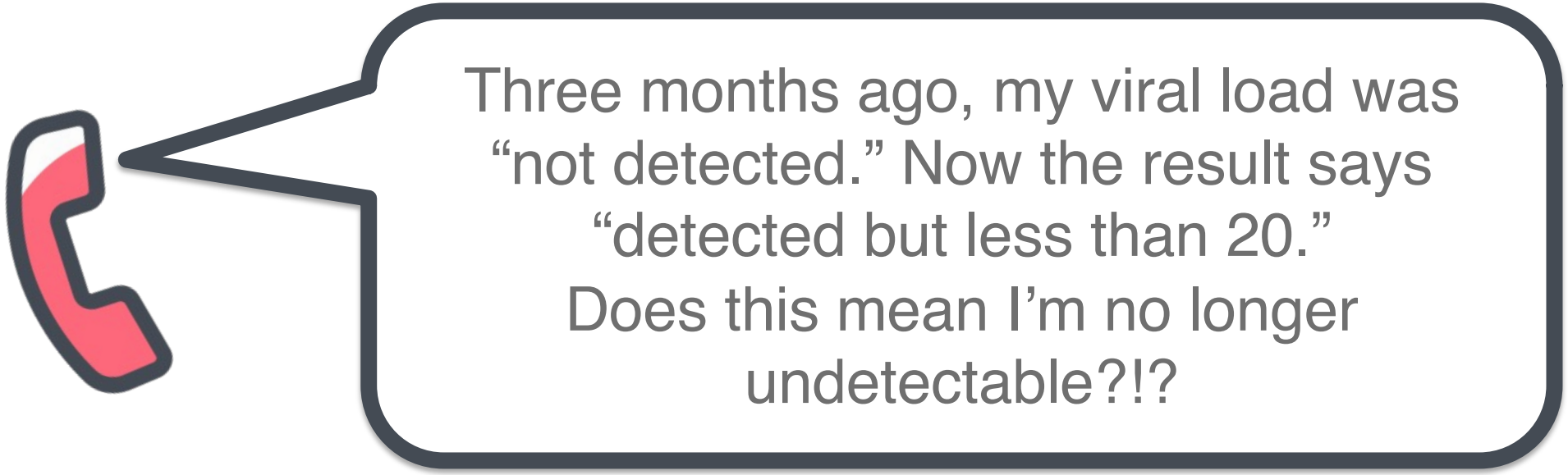
Missed any doses?

Skipping doses (intentionally or unintentionally) can cause blips.

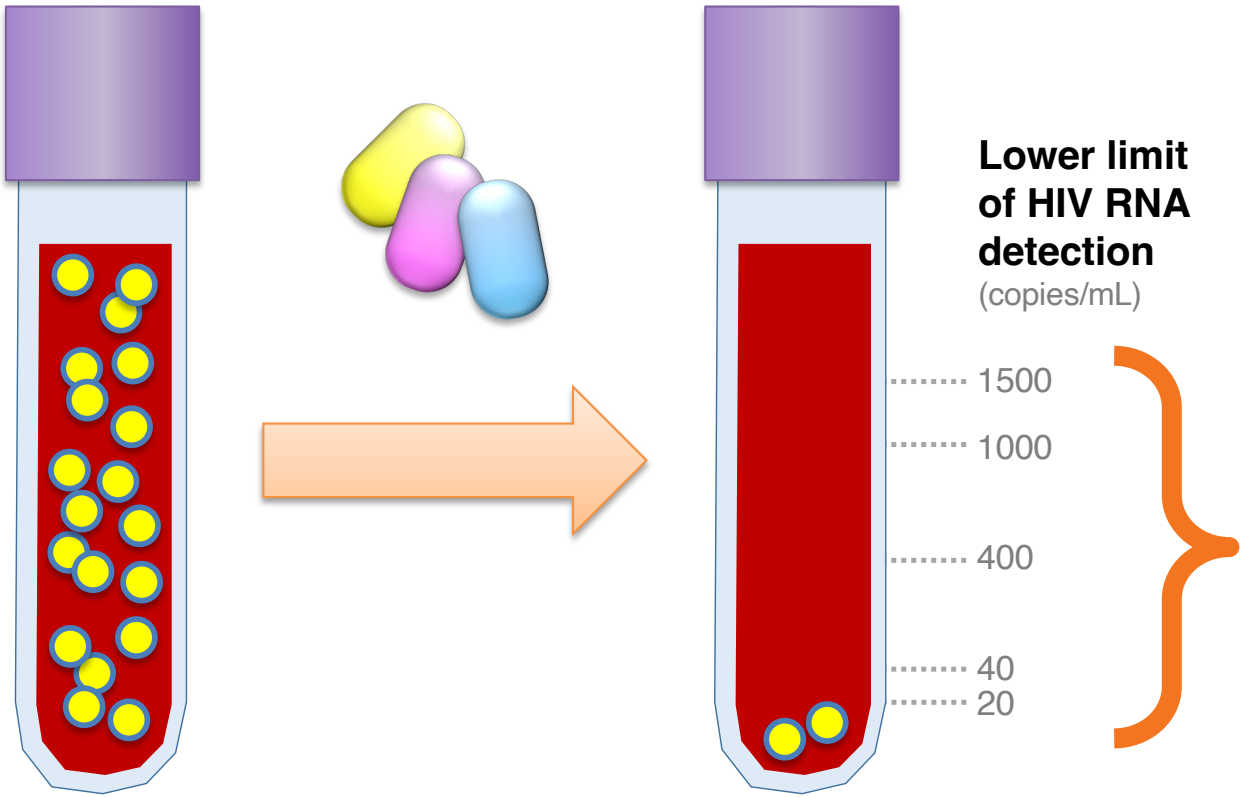
https://hivinfo.nih.gov/understanding-hiv/infographics/whats-blip
Animated emojis from → https://emojipedia.org/microsoft-teams/1.0/

I've been undetectable for as long as I can remember, but now my viral load is 65! How did this happen?

It can be normal to see a very small amount of HIV, from time to time. It's called a "blip," and it's nothing to worry about if you're taking your meds. Your provider may want to recheck your viral load. I'll let them know you called.


Three months ago, my viral load was “not detected.” Now the result says “detected but less than 20.” Does this mean I’m no longer undetectable?!?

Defining “undetectable” and the LLOD



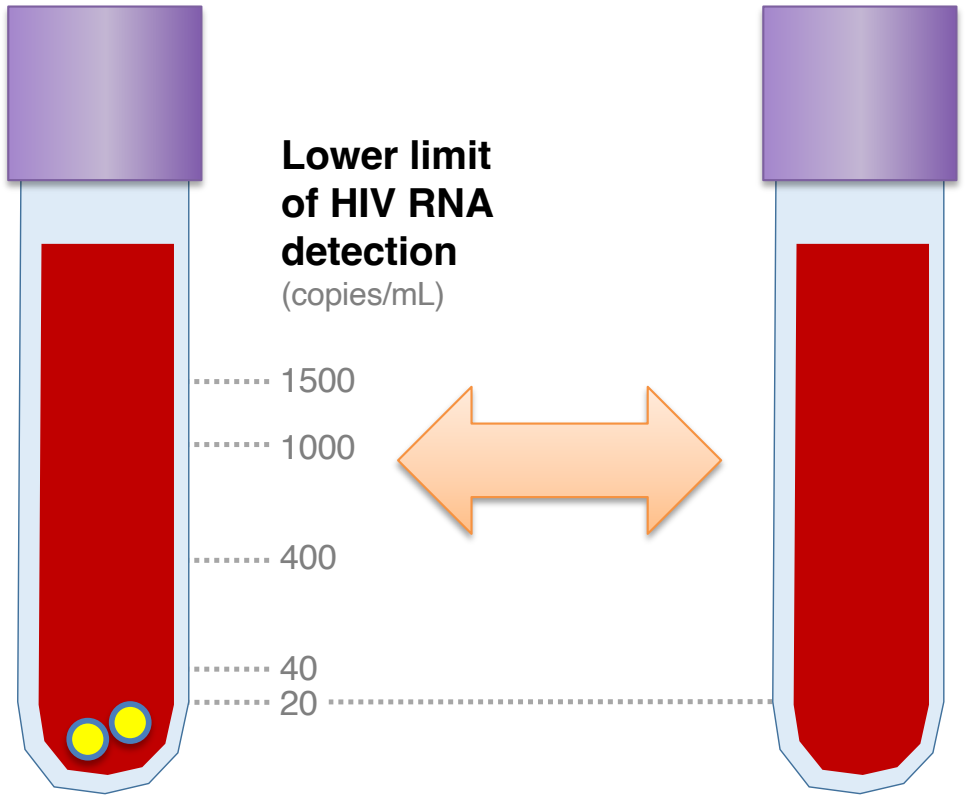
Lower limit of detection “goal posts” have moved as lab technology has become more sensitive.

This means we’re able to quantify (count) smaller amounts of virus more precisely.

Sometimes there's no virus in a specimen

Lab machines sometimes can detect that there's some HIV present, but the amount is too small to accurately count. This is reported as "detected but less than…"

Other times, there's no "target" seen in the sample at all.



Detected but less than 20

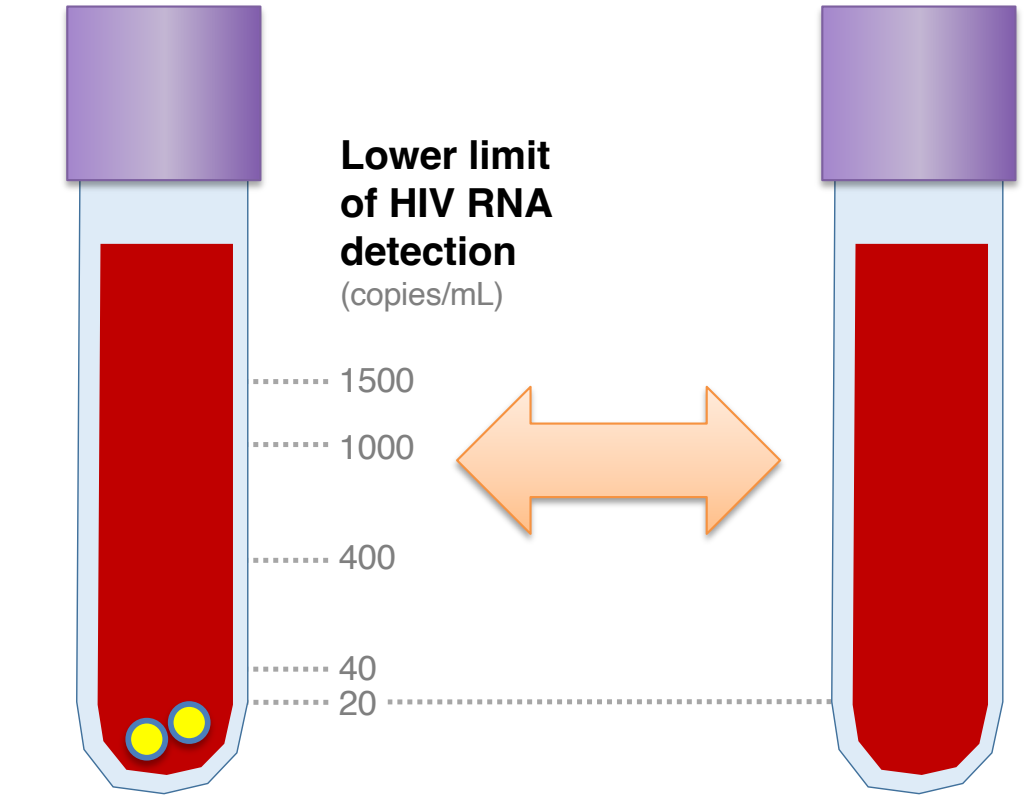
HIV RNA not detected

“Undetectable” is a poor descriptor*

* but we’re stuck with it

Clinically, we use “below the lower limit of detection” and “undetectable” interchangeably – even though their meanings differ.

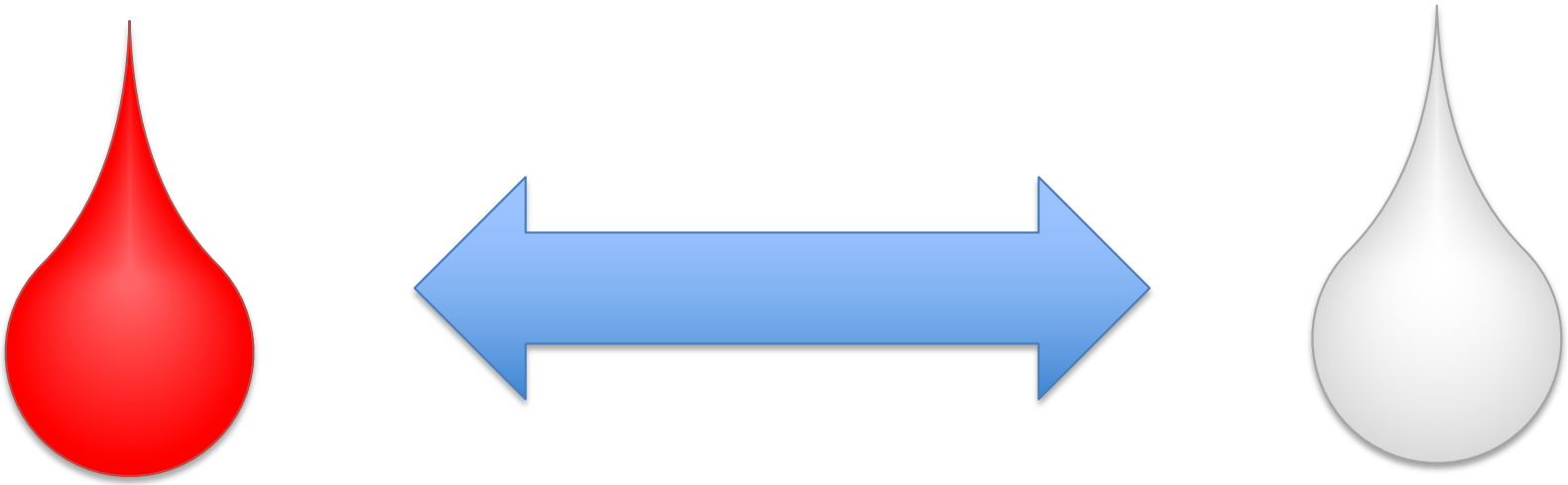
This leads to a great deal of confusion among patients when they see their lab results.



Both of these are considered “undetectable”

What does this mean for “U=U”?

Virus can be detected in different “compartments.”



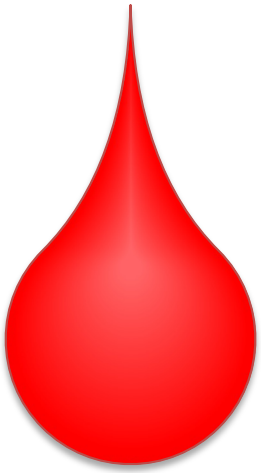
Blood

Genital fluids

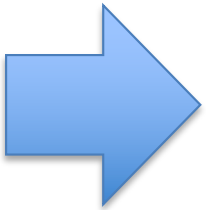
Viral loads in blood are related to sexual transmission risk.

What does this mean for “U=U”?

Data from 415 heterosexual couples in Uganda showed:



below
1,500
copies/mL



0
transmissions

The Rakai study provides a key piece of data:
if RNA ≤1500, there’s little-to-no risk
for sexual transmission to others.

*only data are for heterosexuals

Quinn TC, et al. N Engl J Med. 2000 Mar 30;342(13):921-9

What does this mean for “U=U”?

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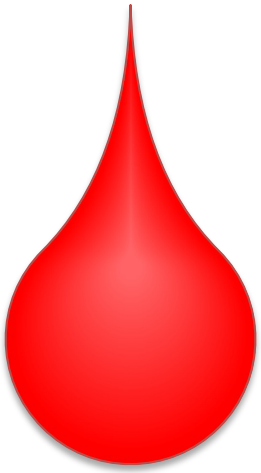

below
1,500
copies/mL

0
transmissions

Most patients who express concerns will have viral loads <u>well below</u> 1,500 copies – “detectable less than” or “not detected.”

*only data are for heterosexuals

Quinn TC, et al. N Engl J Med. 2000 Mar 30;342(13):921-9

WHO weighs in…

(IAS 2023 - Brisbane)

Articles

The risk of sexual transmission of HIV in individuals with low-level HIV viraemia: a systematic review

Laura N Broyles, Robert Luo, Debi Boeras, Lara Vojnov

Summary

Background The risk of sexual transmission of HIV from individuals with low-level HIV viraemia receiving antiretroviral therapy (ART) has important public health implications, especially in resource-limited settings that use alternatives to plasma-based viral load testing. This Article summarises the evidence related to sexual transmission of HIV at varying HIV viral load levels to inform messaging for people living with HIV, their partners, their health-care providers, and the wider public.

Methods We conducted a systematic review and searched PubMed, MEDLINE, Cochrane Central Register of Controlled Trials, Embase, Conference Proceedings Citation Index-Science, and WHO Global Index Medicus, for work published from Jan 1, 2010 to Nov 17, 2022. Studies were included if they pertained to sexual transmission between serodiscordant couples at various levels of viraemia, the science behind undetectable=untransmittable, or the public health impact of low-level viraemia. Studies were excluded if they did not specify viral load thresholds or a definition for low-level viraemia or did not provide quantitative viral load information for transmission outcomes. Reviews, non-research letters, commentaries, and editorials were excluded. Risk of bias was evaluated using the ROBINS-I framework. Data were extracted and summarised with a focus on HIV sexual transmission at varying HIV viral loads.

Findings 244 studies were identified and eight were included in the analysis, comprising 7762 serodiscordant couples across 25 countries. The certainty of evidence was moderate; the risk of bias was low. Three studies showed no HIV transmission when the partner living with HIV had a viral load less than 200 copies per mL. Across the remaining four prospective studies, there were 323 transmission events; none were in patients considered stably suppressed on ART. Among all studies there were two cases of transmission when the index patient's (ie, patient with previously diagnosed HIV infection) most recent viral load was less than 1000 copies per mL. However, interpretation of both cases was complicated by long intervals (ie, 50 days and 53 days) between the transmission date and the most recent index viral load result.

Interpretation There is almost zero risk of sexual transmission of HIV with viral loads of less than 1000 copies per mL. These data provide a powerful opportunity to destigmatise HIV and promote adherence to ART through dissemination of this positive public health message. These findings can also promote access to viral load testing in resource-limited settings for all people living with HIV by facilitating uptake of alternative sample types and technologies.

Funding Bill & Melinda Gates Foundation.

Published Online July 23, 2023 https://doi.org/10.1016/S0140-6736(23)00877-2

See Online/Comment https://doi.org/10.1016/S0140-6736(23)01519-2

Global Health Impact Group, Atlanta, GA, USA (L N Broyles MD, R Luo MD, D Boeras PhD); WHO, Geneva, Switzerland (L Vojnov PhD)

Correspondence to: Dr Lara Vojnov, WHO, Geneva 1211, Switzerland

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Introduction

Viral load testing is the gold standard for monitoring the response to HIV antiretroviral therapy (ART) with the goal of durable suppression of viraemia to both promote health and longevity and decrease the risk of transmission. As access to ART and viral load monitoring has increased, data from various settings show that a small minority of people living with HIV on ART have viral loads that are detectable but below the threshold for virological failure (ie, 1000 copies per mL).[1–3] The clinical significance and management of this low-level viraemia has been an ongoing topic of debate. At the individual level, low-level viraemia has been associated with virological failure, HIV drug resistance, and worse clinical outcomes; however, data on these outcomes in patients taking integrase inhibitors are scarce.[4,5]

From a public health perspective, low-level viraemia can also have implications in disease transmission risks and thus affect messaging for people living with HIV, including undetectable=untransmittable (U=U) campaigns.[6] Although it is generally accepted that HIV viral loads of less than 200 copies per mL are associated with zero risk of sexual transmission and this threshold is used for U=U messaging in many high-income settings,[7]

Among 7,762 serodiscordant couples from 25 countries across eight studies:

below **200** copies/mL → **0** transmissions

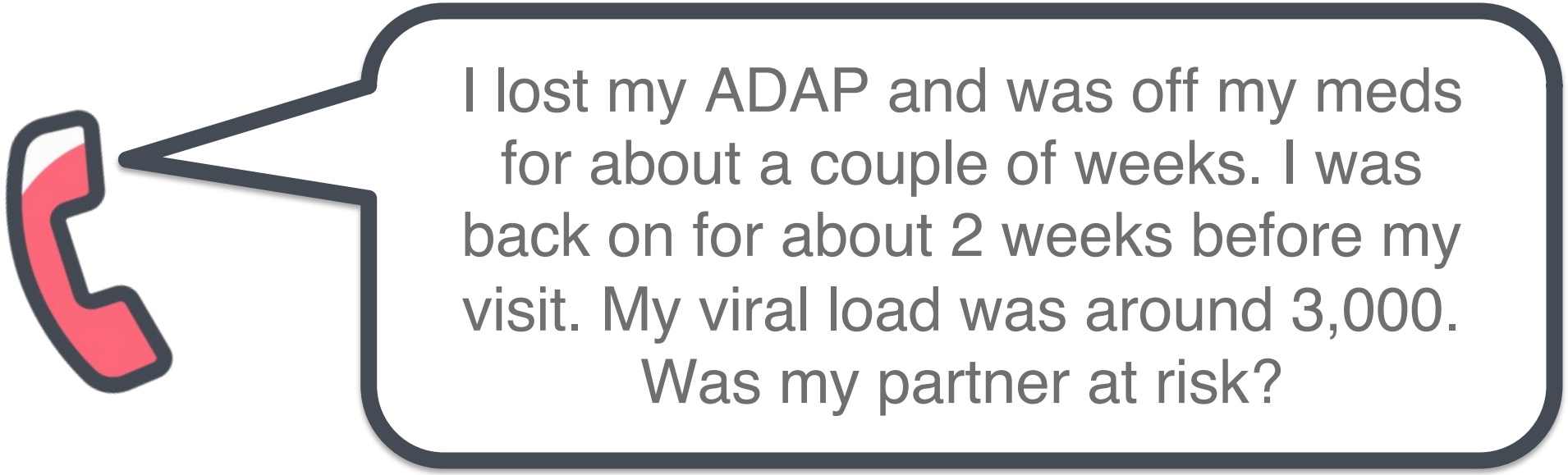
below **1,000** copies/mL → **2** *possible* transmissions

Broyles LN, et al. Lancet. 2023 Jul 21:S0140-6736(23)00877-2

Three months ago, my viral load was "not detected." Now the result says "detected but less than 20." Does this mean I'm no longer undetectable?!?

We're getting this question a lot, but there's nothing for you or your partner(s) to worry about. Since your viral load is less than 20 copies, there's ***effectively no risk*** of passing the virus anyone else.

A similar question…



Risk is a difficult concept for most people

Event/act with HIV+ partner	Per-Event/Act Probability (%)	One transmission approximately every…
Blood transfusion	88.3 -100	**1 transfusion[1,2]**
Bottoming (RAI)	0.73 - 1.7	**140 encounters[2-5]**
Shared needles / works	0.63 - 2.4	**160 injections[1]**
Vaginal sex (M-to-F)*	0.08	**1,250 encounters[2,3]**
Topping (IAI)	0.06 - 0.62	**1,700 encounters[2,5-7]**
Vaginal sex (F-to-M)*	0.04	**2,500 encounters[2,3]**
Oral sex (fellating)	0.01 - 0.17	**10,000 encounters[6,8]**

1 Baggaley *AIDS* 2006;20(6):805-12 2 Patel *AIDS* 2014;28(10):1509-10 3 Boily *Lancet ID* 2009;9(2):118-29
4 Baggaley *Int J Epi* 2010;39(4):1048-63 5 Scott *JAIDS* 2014;65(1):115-21 6 Vittinghoff *Am J Epi* 1999;150(3):306-11
7 Jin *AIDS* 2010;24(6):907-13 8 Baggaley *Int J Epi* 2008;37(6):1255-65 * **high-income / low-prevalence countries**

Relative risk may be a little easier to conceptualize

A person with untreated HIV performing oral sex on someone with a penis who is wearing a condom is the reference for all other categories

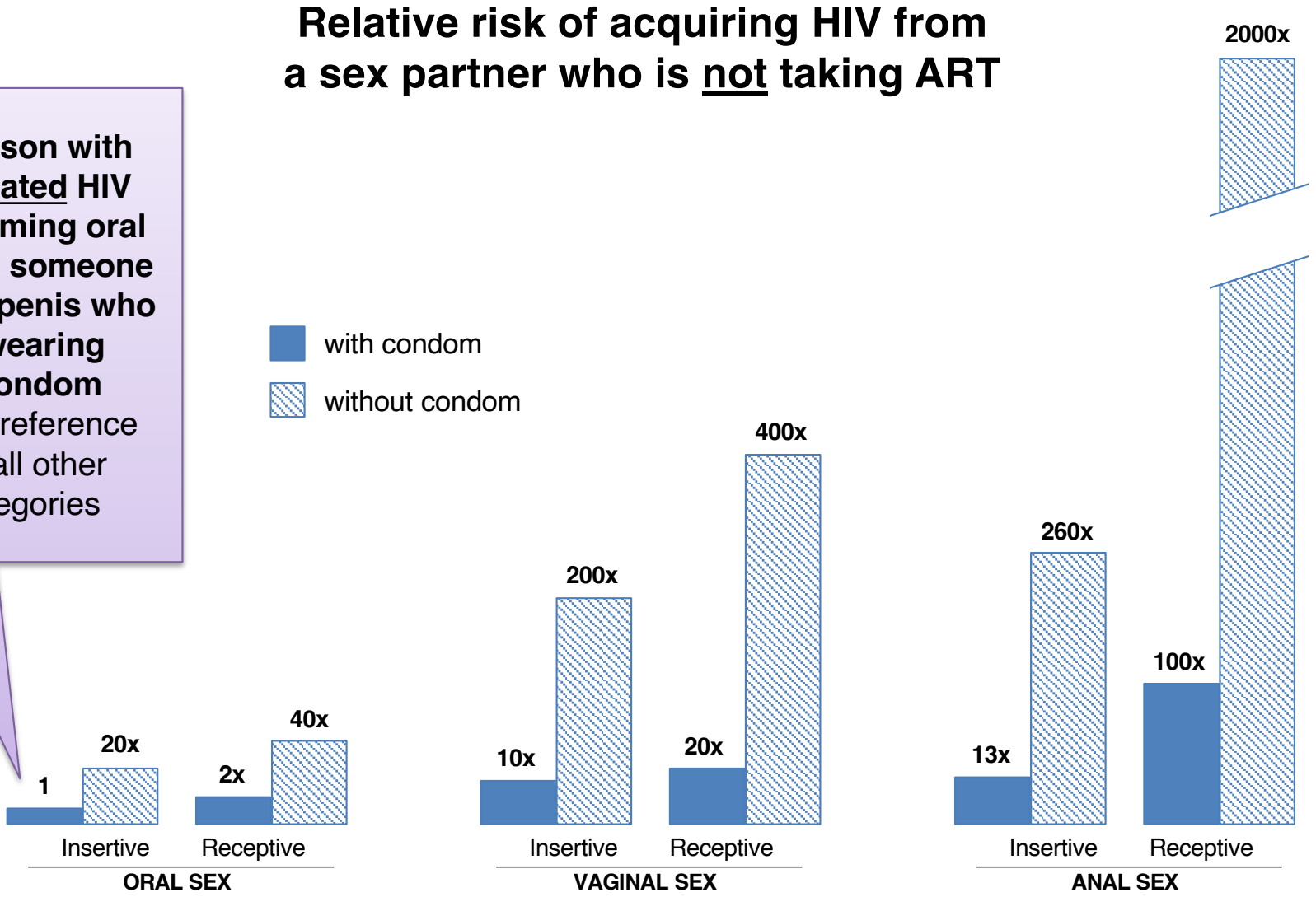
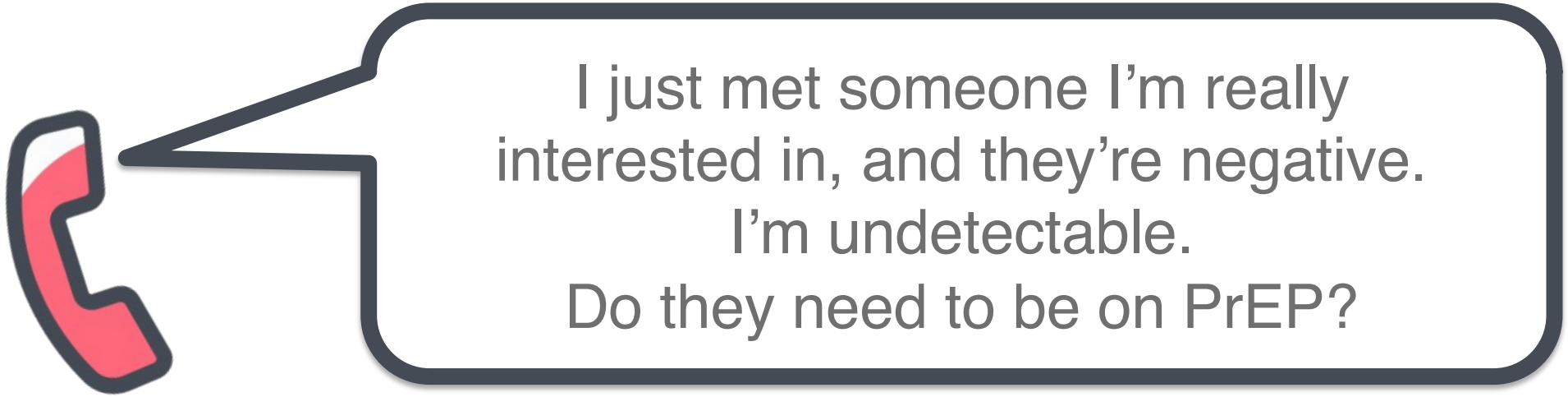


Illustration by Christopher Hurt

Adapted from CDC Prevention Is Care Campaign, v1.0

I lost my ADAP and was off my meds for about a couple of weeks. I was back on for about 2 weeks before my visit. My viral load was around 3,000. Was my partner at risk?

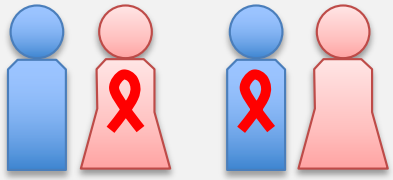
It's hard to know, and a lot depends on the kind of sex you had, when it was, and whether you used a condom or not. I'll let your provider know you'd like to talk more about this.


I just met someone I'm really interested in, and they're negative.
I'm undetectable.
Do they need to be on PrEP?

Treatment as prevention is a proven fact

HPTN 052

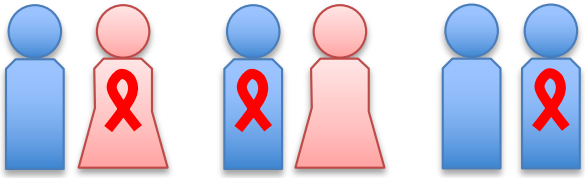
2007-2010
Botswana, Malawi, South Africa, Zimbabwe, Brazil, India, Thailand (& US)



93% * reduction
8509 couple-years f/u
Upper CI bound: 1.1/100 couple-years

PARTNER1

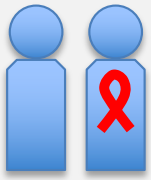
2010-2014
Europe (888)



100% reduction
1238 couple-years f/u
Upper CI bound: 0.3/100 couple-years

Opposites Attract

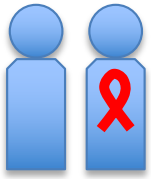
2012-2016
Australia (153), Thailand (97), Brazil (93)



100% reduction
588.4 couple-years f/u
Upper CI bound: 1.59/100 couple-years

PARTNER2

2014-2018
Europe (782)

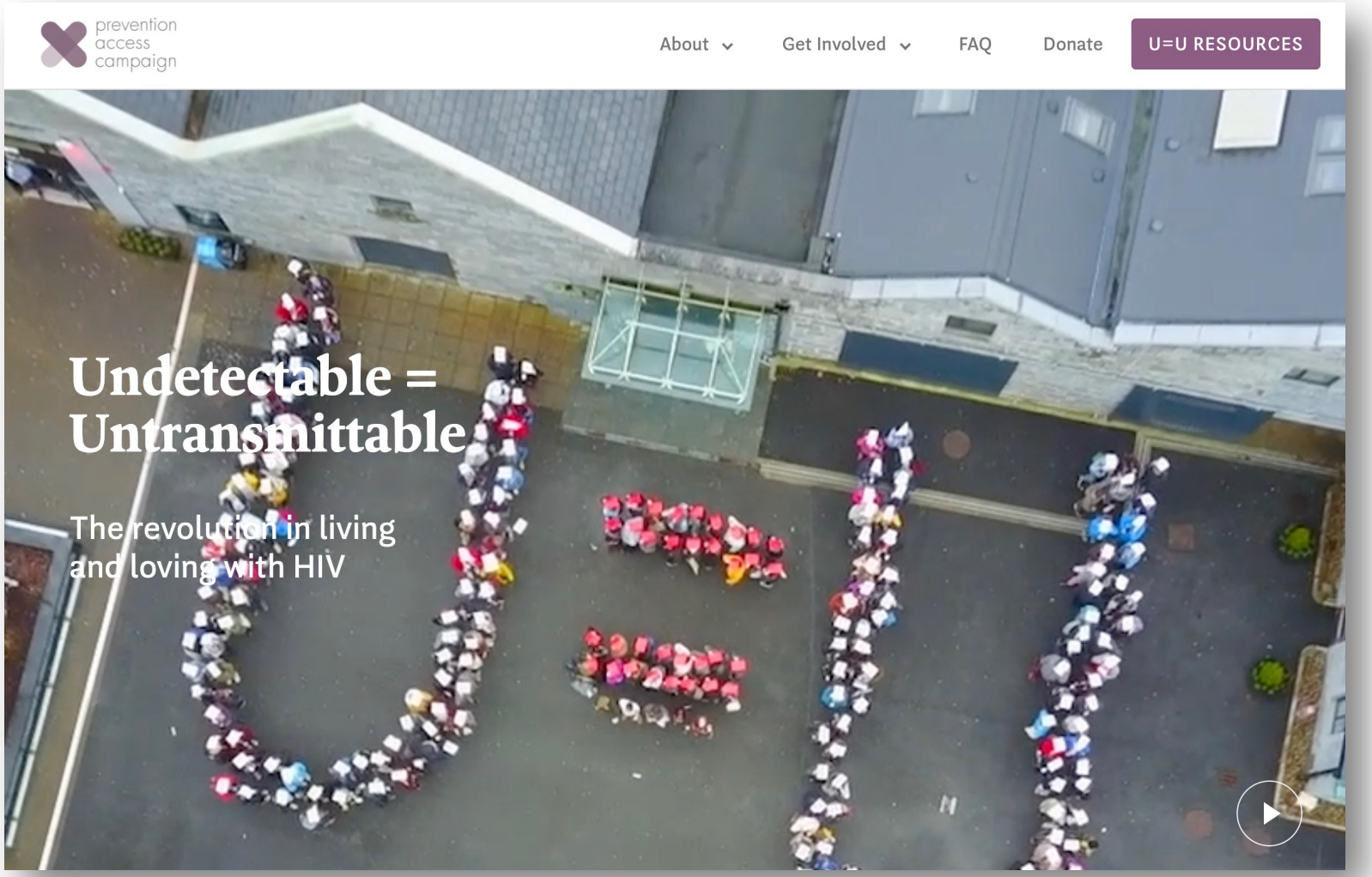


100% reduction
1593 couple-years f/u
Upper CI bound: 0.23/100 couple-years

* linked transmissions were from sources who had not yet become undetectable or had lapses in treatment

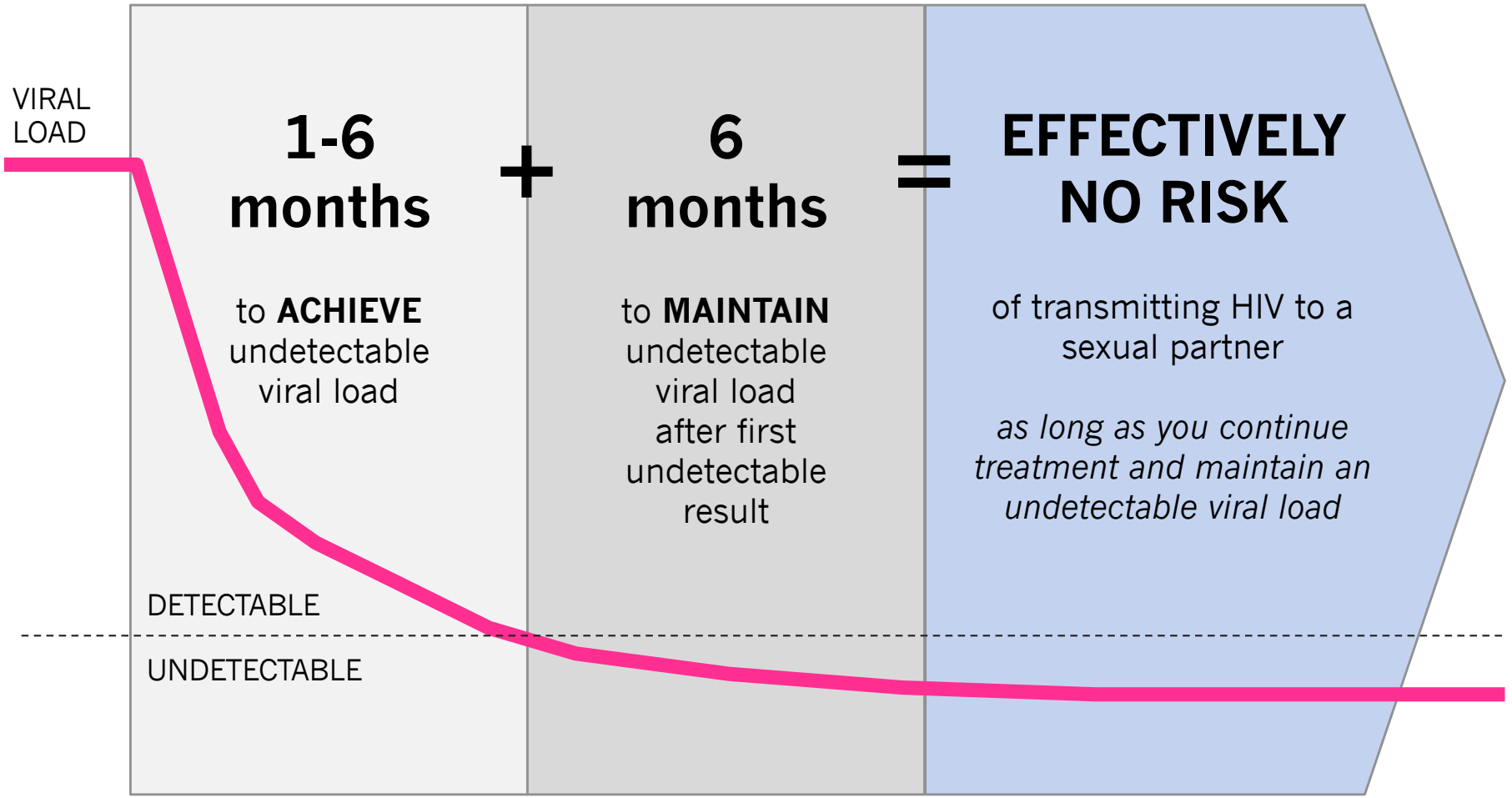
HPTN 052: Cohen MS, et al. *New Engl J Med.* 2016;375(9):830-839.
Opposites Attract: Bavinton BR, et al. *Lancet HIV.* 2018 ;5(8):e438-e447.
PARTNER1: Rodger AJ, et al. *JAMA.* 2016;316(2):171-181.
PARTNER2: Rodger AJ, et al. Lancet. 2019;393(10189):2428-2438.

The “U=U” campaign launched in 2016



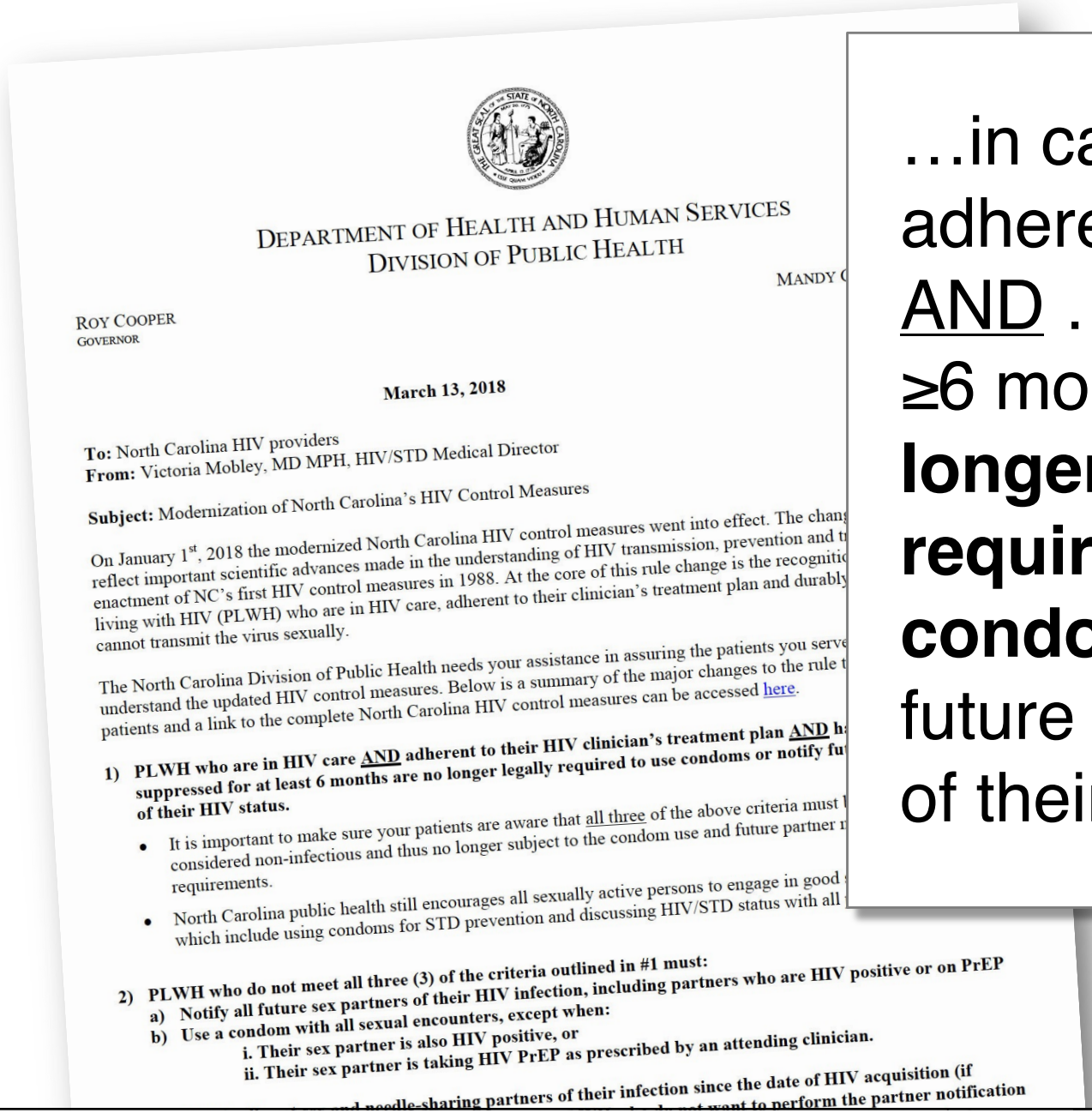
https://www.preventionaccess.org/

Federal guidelines onboard with U=U since 2017



Adapted from: https://www.niaid.nih.gov/news-events/10-things-know-about-hiv-suppression

NC modernized control measures in 2018



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH

ROY COOPER
GOVERNOR

March 13, 2018

To: North Carolina HIV providers
From: Victoria Mobley, MD MPH, HIV/STD Medical Director

Subject: Modernization of North Carolina's HIV Control Measures

On January 1st, 2018 the modernized North Carolina HIV control measures went into effect. The chang
reflect important scientific advances made in the understanding of HIV transmission, prevention and t
enactment of NC's first HIV control measures in 1988. At the core of this rule change is the recognitio
living with HIV (PLWH) who are in HIV care, adherent to their clinician's treatment plan and durably
cannot transmit the virus sexually.

The North Carolina Division of Public Health needs your assistance in assuring the patients you serve
understand the updated HIV control measures. Below is a summary of the major changes to the rule t
patients and a link to the complete North Carolina HIV control measures can be accessed here.

1) **PLWH who are in HIV care AND adherent to their HIV clinician's treatment plan AND h**
suppressed for at least 6 months are no longer legally required to use condoms or notify fu
of their HIV status.
   - It is important to make sure your patients are aware that all three of the above criteria must
   considered non-infectious and thus no longer subject to the condom use and future partner n
   requirements.
   - North Carolina public health still encourages all sexually active persons to engage in good
   which include using condoms for STD prevention and discussing HIV/STD status with all

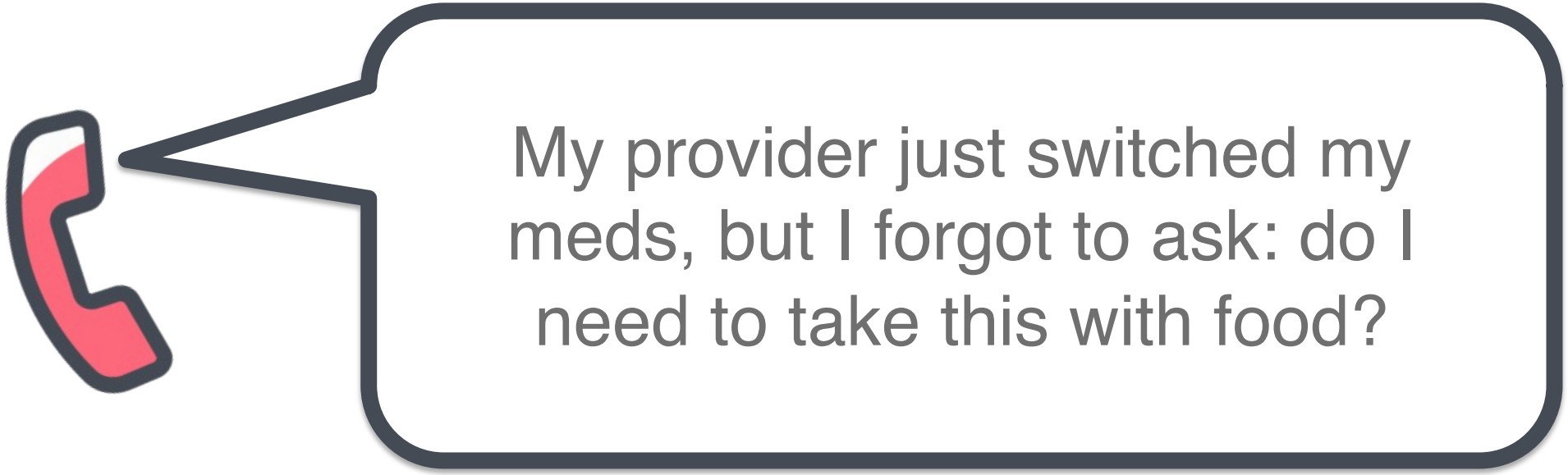
2) **PLWH who do not meet all three (3) of the criteria outlined in #1 must:**
   a) **Notify all future sex partners of their HIV infection, including partners who are HIV positive or on PrEP**
   b) **Use a condom with all sexual encounters, except when:**
      i. **Their sex partner is also HIV positive, or**
      ii. **Their sex partner is taking HIV PrEP as prescribed by an attending clinician.**

needle-sharing partners of their infection since the date of HIV acquisition (if
want to perform the partner notification

…in care, AND adherent to [ARVs], AND … suppressed ≥6 months… **no longer legally required to use condoms** or notify future sexual partners of their HIV status.

I just met someone I'm really interested in, and they're negative. I'm undetectable. Do they need to be on PrEP?

If your viral load has been undetectable for more than 6 months, then the risk of passing HIV to your partner through sex is **effectively zero**. But you and your partner might feel more comfortable with PrEP. Would your partner like to talk to a provider about it?


My provider just switched my meds, but I forgot to ask: do I need to take this with food?

and check to see what meds they're supposed to be taking

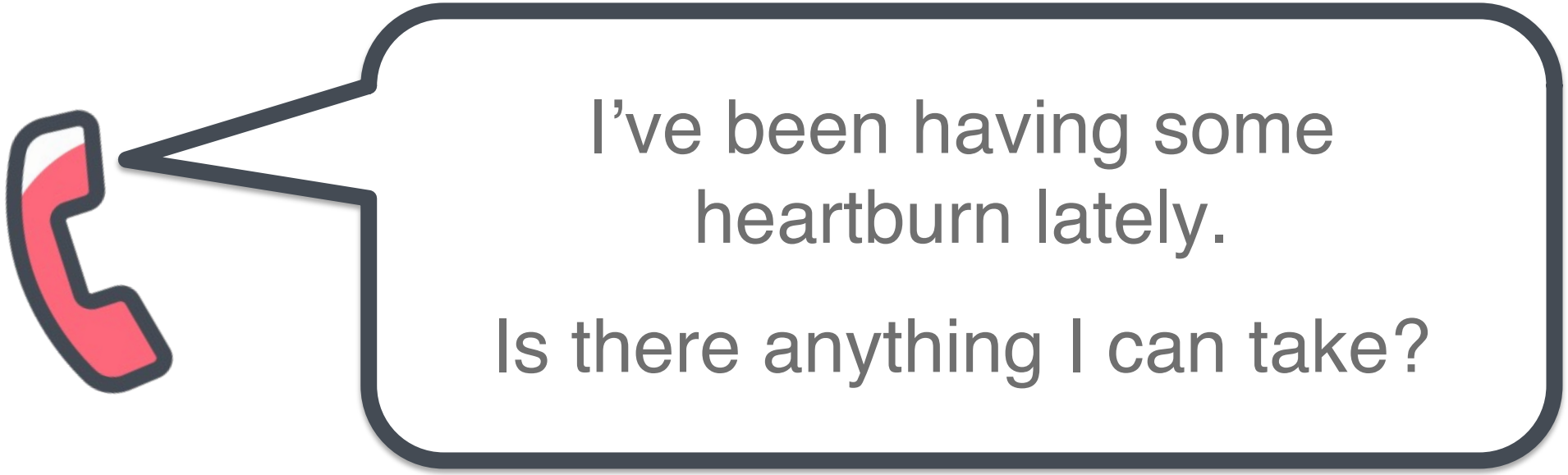
Which meds should be taken with food?

Antiretroviral Agent	Should take with food	MUST take with food	Take on an empty stomach
efavirenz (EFV/FTC/TDF or 3TC/EFV/TDF)			X preferably at bedtime
elvitegravir (EVG/c/FTC/TDF or EVG/c/FTC/TAF)			
rilpivirine (FTC/RPV/TDF, FTC/RPV/TAF, or DTG/RPV)			
FTC/TDF			
atazanavir (ATV/c)			
darunavir (DRV/c, DRV/c/FTC/TAF)			

Rilpivirine's absorption is HIGHLY dependent on a low stomach pH (acidic), so any regimen that contains rilpivirine MUST be taken with food.

My provider just switched my meds, but I forgot to ask: do I need to take this with food?

It’s generally a good idea to take your meds with at least a little bit of food. Would you like to talk to one of our pharmacy experts?


I’ve been having some heartburn lately.
Is there anything I can take?

and check to see what meds they're supposed to be taking

Managing heartburn safely

Antiretroviral Agent	Cationic (Tums, Maalox, Gaviscon, Mylanta, Mag Citrate)
atazanavir	← ! → Separate by ≥ 2h
bictegravir (BIC/FTC/TAF)	← ! → Take bictegravir 2h BEFORE
dolutegravir (DTG/RPV)	← ! → Take dolutegravir 2h BEFORE or 6h AFTER
elvitegravir (EVG/c/FTC/TDF, EVG/c/FTC/TAF)	← ! → Separate by ≥ 2h
raltegravir	AVOID
rilpivirine (DTG/RPV)	← ! → Take the antacid ≥ 2h BEFORE or ≥ 4h AFTER

Absorption of atazanavir and rilpivirine is dependent on stomach pH (acidic), so be cautious about recommending acid suppressing meds!

https://www.hiv-druginteractions.org/prescribing_resources

Integrase inhibitors & cations don't get along

Antiretroviral Agent	Cationic (Tums, Maalox, Gaviscon, Mylanta, Mag Citrate)
atazanavir	← ! → Separate by ≥ 2h
bictegravir (BIC/FTC/TAF)	← ! → Take bictegravir 2h BEFORE
dolutegravir (DTG/RPV)	← ! → Take dolutegravir 2h BEFORE or 6h AFTER
elvitegravir (EVG/c/FTC/TDF, EVG/c/FTC/TAF)	← ! → Separate by ≥ 2h
raltegravir	AVOID
rilpivirine (DTG/RPV)	← ! → Take the antacid ≥ 2h BEFORE or ≥ 4h AFTER

Generally should also apply to supplements taken for iron, calcium, magnesium, or zinc replacement

Absorption of atazanavir and rilpivirine is dependent on stomach pH (acidic), so be cautious about recommending acid suppressing meds!

https://www.hiv-druginteractions.org/prescribing_resources

Managing heartburn safely

Antiretroviral Agent	Cationic (Tums, Maalox, Gaviscon, Mylanta, Mag Citrate)	H2 blockers (ranitidine, famotidine)
atazanavir	← ! → Separate by ≥ 2h	← ! → Take H2 blocker at SAME TIME or ≥10h AFTER
bictegravir (BIC/FTC/TAF)	← ! → Take bictegravir 2h BEFORE	**OK**
dolutegravir (DTG/RPV)	← ! → Take dolutegravir 2h BEFORE or 6h AFTER	**OK**
elvitegravir (EVG/c/FTC/TDF, EVG/c/FTC/TAF)	← ! → Separate by ≥ 2h	**OK**
raltegravir	AVOID	**OK**
rilpivirine (DTG/RPV)	← ! → Take the antacid ≥ 2h BEFORE or ≥ 4h AFTER	← ! → Take H2 blocker 12h BEFORE or ≥ 4h AFTER

Absorption of atazanavir and rilpivirine is dependent on stomach pH (acidic), so be cautious about recommending acid suppressing meds!

https://www.hiv-druginteractions.org/prescribing_resources

Managing heartburn safely

Antiretroviral Agent	Cationic (Tums, Maalox, Gaviscon, Mylanta, Mag Citrate)	H2 blockers (ranitidine, famotidine)	PPIs (omeprazole)
atazanavir	← ! → Separate by ≥ 2h	← ! → Take H2 blocker at SAME TIME or ≥10h AFTER	← ! → Take PPI 12h BEFORE
bictegravir (BIC/FTC/TAF)	← ! → Take bictegravir 2h BEFORE	OK	OK
dolutegravir (DTG/RPV)	← ! → Take dolutegravir 2h BEFORE or 6h AFTER	OK	OK
elvitegravir (EVG/c/FTC/TDF, EVG/c/FTC/TAF)	← ! → Separate by ≥ 2h	OK	OK
raltegravir	AVOID	OK	OK
rilpivirine (DTG/RPV)	← ! → Take the antacid ≥ 2h BEFORE or ≥ 4h AFTER	← ! → Take H2 blocker 12h BEFORE or ≥ 4h AFTER	X DO NOT TAKE PPIs WITH RILPIVIRINE

Absorption of atazanavir and rilpivirine is dependent on stomach pH (acidic), so be cautious about recommending acid suppressing meds!

https://www.hiv-druginteractions.org/prescribing_resources

I've been having some heartburn lately.

Is there anything I can take?

Just to confirm, you're taking <MED>, right?

Follow recs in the table shown ***or*** *ask pharmacy to help.*

Questions?

Christopher Hurt, MD

churt@med.unc.edu

https://www.wikiart.org/en/keith-haring/stop-aids-1989