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AIDS 2010:
News from the 18th World AIDS Conference

Contents

This supplement is a non-technical review of some of the most interesting studies presented at this meeting.

Technical reports from the conference are published in HIV Treatment Bulletin, available online and to order in print from the i-Base website (www.i-Base.info). Hyperlinks in this PDF file link directly to each abstract or session.All abstracts and webcasts can be seen online: http://www.aids2010.org

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Introduction to the World AIDS Conference

The International AIDS Society (IAS) World AIDS Conferences are the largest international conferences and they cover widely different aspects of HIV research.

These summaries cover some of the most interesting news.

The topics at this meeting ranged from basic science and early drug discovery to treatment and treatment access; from global funding to human rights and international law; from studies mapping the patterns of HIV transmission to strategies for HIV prevention (which neatly connects back to a key benefit from treatment).

This is probably the most community-focussed of all the medical conferences and and it is held every two years. For all the research–more than 6000 studies were presented–the meeting is always most memorable for the chance to meet people from different countries. Most are working in very difficult circumstances: when the conference ends, they return home to countries without many of the resources that in the UK we take for granted.

It is ten years since this meeting was held in Durban in South Africa. This was the first time that this international conference had been held in a country where the majority of people had no access to treatment. Since then, the most important news will always be treatment access. The good news is that more than five million people now access treatments that were originally only ever developed for Western countries. The bad news is that treatment only reaches less half of those who need it. Less than half of HIV-positive pregnant women access treatment that would reduce the risk of transmission to the baby. In some countries where the epidemic is driven by injecting drug use, less than 10% of former or current drug users have access to HIV drugs.

Access to high quality generic medications, together with international funding, has driven this access to treatment. The overwhelming concern during the meeting was how these programmes will continue.

Globally, the largest providers of treatment are the Global Fund and PEPFAR. The economic crisis has reduced the funding from Western countries to these and other programmes. Treatment on public health programmes is now capped in some countries. New patients, even if they are sick, are added to a waiting list.

In October 2010, the Global Fund is going into a new three-year funding cycle. Wealthier countries need to increases their promises for funding. The stand-still budget is $12 billion but in both 2008 and 2009 were under $9 billion. For a programme that treats people acoording to the World Health Organisation (WHO) guidelines, this needs to reach $18-20 billion.

At the conference we heard that countries that receive funding broadly agreed in 2001 to increase the proportion of their budget spent on healthcare to at least 15%. Very few countries achieved this. Many have made little attempt to change.

Getting undiagnosed people to test is central to reducing transmission, but people will not test if there is no prospect of treatment. Luckily ARV treatment is also increasingly recognised as perhaps the most effective way to prevent HIV transmission. Reducing viral load is effective prevention–and this was another important conference theme. Treatment and prevention cannot be separated.

In Vienna, the mosquitos biting delegates each humid evening were joined by mosotos. MOSOTOS (More Of the Same Old Talk, Opinions, Speeches) was used by one group to highlight how slowly things change, especially in response to TB. This group adapted the ACT-UP ‘silence=death’ slogan to MOSOSTOS=DEATH and ACTION=LIFE for badges and stickers. They had a spoof newsletter with headlines like “TB screening among PLWHA increases 400%” to highlight that increasing from 1% to 4% still leaves 96% HIV-positive people who are not being screened. And yet we are about to see the first new TB for over 40 years, and there are exiciting advances in new tests to diagnose TB more effectively and accurately.

The meeting included sessions that looked at the problems of homophobic legislation in many African countries from a human rights perspective. Other notable sessions looked at gender-based violence, access to care for drug users and research from the UK on the perspective of older HIV-positive people. HIV and ageing is an increasingly important issue.

The Vienna declaration was a statement issued at the conference calling for scientific evidence to determine health policies for drug users. Access to opiate substitution therapy (methadone and buprenorphine) and needle-exchange are proven health interventions that are currently available to a minority of drug users, with some countries, including Russia, refusing to approve methadone as a legal treatment.

Probably less than 10% of active drug users globally access ARV treatment. This is despite numerous studies showing that with appropriate support the effectiveness of ARV treatment is comparable to non-drug using populations.

Currently at 16,000 signatories, read the declaration online and sign on:

http://www.viennadeclaration.com/

Tenofovir gel reduces HIV infections

In terms of conference headlines, the biggest breakthrough news came from the results of a study called CAPRISA 004. But as with lots of research, the details were more interesting and important than the headlines...

This was a South African study–CAPRISA stands for Centre for the AIDS Programme of Research in South Africa.

This study reported women using a gel containing 1% tenofovir (called a microbicide) had a 39% reduced risk of catching HIV. [1] Previous microbicides (that were not based on HIV drugs) have not worked. A positive result, no matter how limited, was likely to be important. When the results were presented, some people in the audience gave the presenters a standing ovation.

The theoretical benefit from using an HIV drug in a gel is similar to the use of pre- and post-exposure prophylaxis (PrEP and PEP). The gel make sure that drug is absorbed in the body tissues that are first exposed to HIV. This hopefully reduces the risk of infection.

As with many studies, the complexity of the results is in the details. The presenters cautioned that these early results primarily showed the urgency of additional research.

Women were asked to use the gel twice; (1) up to 12 hours before sex' **and** (2) 'as soon after sex as possible'. No more than two doses were used any single 24 hour period. This is not as complicated as it sounds. There was no fixed timing, just a better chance of the gel working if it was been applied any time both before and after sex. Tenofovir drug levels are stable in cells for over 12 hours, meaning that one application will give you theoretical protection, no matter how many times you have sex during the day. The gel was applied using a pre-filled plastic applicator, similar to a tampon tube.

This study was in 899 women aged 18–40 years, attending two South African clinics in a region where the risk of HIV is high. By age 24, around 50% of women have become HIV-positive. One site was in Durban and the second was in a rural location 90 miles from the city. Half the women used the active gel and half used a placebo gel – without knowing which group they were in. Free condoms and counseling on the importance of safe sex were provided to all women, with monitoring every month.

Of the 98 women who became HIV-positive over 12–30 months, 38 were in the active gel group and 60 were in the placebo group. This was calculated as an overall protection rate of 39% from using the active compared to placebo gel. However, this calculation involves an estimate called the 95% confidence interval (95%CI). This calculates how likely it is that the results are real findings – and that they didn't occur by chance. The more narrow the difference between the lower and upper limits of the confidence interval, the more reliable the study results.

In the Caprisa 004 study the 95%CI limits were 6%–60%, which is wide. In statistical terms the results are still significant, but we need further studies.

There were no worrying side effects, including in the 54 unplanned pregnancies, or any increases in risky behaviour.

Although over 90% of women reported mild side effects, this was the same in both the active and placebo groups. This shows both the importance of having a placebo arm, and of the potential to report often unrelated events as a side effect. Mild diarrhoea was reported in 16% people using the active gel compared to 11% of the placebo group.

Importantly, no safety concerns were seen in people with hepatitis B (HBV). In the small numbers of women who entered the study with active hepatitis B (less than 20 in each group) or who caught HBV during the study (22 women, 19 of whom cleared the virus without needing treatment), there were no flares in liver enzymes.

Women who became HIV-positive were enrolled in programmes for monitoring for their HIV care. None of the women showed evidence of drug resistance to tenofovir. However the study design meant that this risk would have been very low (because HIV was tested for every four weeks).

Adherence (reporting both applications of the gel) was 70%. For women who used the gel more than 80% of the times that they had sex, the protection increased from 39% to 55%. For women where adherence was less than 50% the protection dropped to only 28%. Although this looks like a clear trend, and is plausible, the study did not have power to prove reduced protection below 80%.

An unexpected finding was that women in the tenofovir gel group had a lower risk of catching HSV-2 (the virus responsible for genital herpes). This was stronger than the protections against HIV. Out of over 400 women were HSV-2 negative at the beginning of the study, 29 caught the herpes virus in the active gel group compared to 58 in the placebo group. Because genital herpes increases the risk of catching HIV, these results are complicated to understand. Although tenofovir has not shown protective effects against HSV-2 in mouse and test-tube studies, drugs with a similar structure to tenofovir are active against HSV-2.

The next studies will focus on dosing, adherence and other factors. Does 100% adherence provide 100% protection? How does the viral load of the HIV-positive partner affect protection?

Further information:

http://www.caprisa.org

New drugs and formulations

At every conference we want to know about new drugs and how they might improve future care. In Vienna we learnt about new NNRTIs, an integrase inhibitor, a new CCR5 inhibitor and a new 3-in-1 pill.

Rilpivirine: an new NNRTI, a new 3-in-1 combination and a formulation for children

Rilpivirine is the name of a new NNRTI that was known as TMC-278 during its early development. The first results from the large studies used for drug approval (called phase 3) were presented in Vienna. [2]

The potential advantages of rilpivirine is that is uses a low dose (25mg) making it easier to develop as a fixed dose combination but that it may have an easier side effect profile compared to efavirenz. The question from using this low dose is whether it achieves optimum drug levels for all people.

The combined results from these two large randomised international studies were presented as late-breakers. This is the word for last-minute results that are important enough to be squeezed in to the programme.

The combined results showed that rilpivirine and efavirenz are similar, but there were important differences. Efavirenz was slightly better at reducing viral load and not developing resistance in people whose combinations failed. Rilpivirine had fewer side effects, especially less rash, psychiatric, sleep disturbance and dizziness.

Rilpivirine has also been co-formulated into a single once-daily combination pill with tenofovir/FTC. Another study showed that this had equivalent drug levels to each medication taken separately. [3] Both rilpivirine and the triple combination have now been submitted for approval–a process that may take as little as six months.

Because getting viral load undetectable is more important in the short-term, Atripla may continue to remain the first-line choice, with the 3-in-1 rilpivirine/tenofovir/FTC pill used as a switch option for people who get side effects to efavirenz.

It was also good to see an early study of a paediatric formulation of rilpivirine. Usually formulations for children–in this case granules that can be easily dissolved in water–are developed far more slowly. [4]

Nevirapine XR: a new once-daily formulation

The conference also included a presentation on a new formulation of nevirapine. [5]

Approved in 1996, nevirapine is now rarely prescribed for new patients in Western countries because of the low risk of very serious side-effects. However, because it is available in many generic formulations, it is still widely used as first-line therapy in developing countries. After the two-month risk period for initial side effects, nevirapine is very well tolerated, and has a good effect on cholesterol. The new formulation produces more stable drug levels. The highest levels are lower and the low dips are kept higher. Potentially this might make the XR formulation safer and more effective. It is also a once-daily formulation (even though the current twice-daily version is widely used once-daily).

A large randomised international study compared the current twice-daily formulation to the new formulation. The study enrolled over 1000 people starting treatment for the first time.

In a 'late-breaker' presentation, the new formulation was shown to be technically be 'non-inferior'. This is a research term to say they were basically the same. The study could not prove if there were any clinical advantages from the new formulation.

The presenter included no specific details on the most serious side effects: a potential fatal rash called Steven's Johnson Syndrome (SJS) and liver toxicity, and laughed when the question came from a doctor afterwards. In fact, five people (0.5%) discontinued due to SJS, which is higher than the rate of approximately 0.3%. Three of these cases were during the initial two-week lead in period and two occurred later in the old formulation group. During the first two weeks, everyone used a reduced dose of the old formulation.

It is frustrating that the study was not designed to show any differences between the two formulations because this is what we ultimately need to know. Even with a study this large, there were not enough serious events for the analysis to be able to prove whether one version was better than the other. In terms of getting a new formulation approved, a company only has to show that it is broadly the same as the existing drug.

A new integrase inhibitor and new entry inhibitor in development

Early results were also presented for a new integrase inhibitor, currently called GSK572.

A study in 200 people looking at three different doses compared to efavirenz, showed a rapid drop in viral load and fewer side effects. [6]

Other studies with this compound focussed on drug resistance, and whether this will work for people who have developed resistance to raltegravir. [7, 8] Based on small numbers, early resistance might be overcome by the new drug, but extensive resistance would not be. This would be a reason to consider stopping raltegravir if it has not reduced your viral load to undetectable levels – so that you can benefit from the newer drug, if and when it is approved.

Very early results were also presented on a new CCR5 inhibitor. This is a type of drug that stops the virus before it infects a new CD4 cell. This new compound called TBR-652 has the advantage of being dosed once-daily. After 10 days monotherapy (using only TBR-652) four of the five doses studied reduced viral load by 1.2–1.6 logs. [9]

Studies with current drugs

Several studies looked at new treatment strategies: using nuke-free combinations and switching boosted-PIs to raltegravir. Another study looked at when to start treatment.

Maraviroc plus atazanavir

Results from a pilot study of a boosting protease inhibitor (atazanavir/ritonavir) plus a CCR5 inhibitor (maraviroc) without nukes seemed to suggest that this was not as good as atazanavir/ritonavir plus two nukes (tenofovir plus FTC). [10]

Although the results didn't look impressive, the study was too small to be able to prove whether the differences were real or by chance. A larger study with the same combinations is currently ongoing and will hopefully be able to do this. These results are a caution not to use maraviroc with only atazanavir/ritonavir until that study is completed.

Unboosted atazanavir plus raltegravir

Another nuke-sparing regimen that used atazanavir as a twice-daily drug without ritonavir boosting with the integrase inhibitor raltegravir, failed to out-perform atazanavir/ritonovir plus two nukes (tenofovir plus FTC). In this case the study was stopped early due to increased side effects from the atazanavir. [11]

Lopinavir/r (Kaletra) plus raltegravir

A third nuke-sparing study compared lopinavir/r (Kaletra) plus raltegravir to Kaletra plus tenofovir/FTC in about 200 people starting treatment for the first time. [12]

After a year, approximately 10% of patients in each group had left the study, and just over 80% had viral load suppressed to less than 40 copies/mL. Although the study included a wide range of people. Some people were very advanced and other who were very well (the CD4 count range was from 5 to 750), the average CD4 count was about 300 and the average viral load was still very low (less than 20,000 copies/mL).

Generally people who did well reported few serious side effects but the few people with treatment failure (4 in one group and 3 in the other) were more likely to develop resistance if they were taking raltegravir.

Full study results will be available in another year, when all participants have been followed for two years. This will include results from DEXA scans and body measurements to look for differences in rates of lipodystrophy.

Switching to raltegravir

Two Spanish studies looked at switching people on stable PI-based treatment to raltegravir.

The first study (called ODIN) included 220 people on stable treatment who switched the boosted PI (mainly atazanavir, Kaletra or fosamprenavir) to raltegravir. [13]

Raltegravir was dose once-daily (149 people), or twice-daily (73 people). After three months half the twice-daily group switched to once-daily. By 24 weeks, more people had viral load rebound in the once-daily group (6% vs 3%) but the difference was not significant (perhaps because it was not a large enough study). Other studies looking at once-daily raltegravir are ongoing.

More importantly, a much bigger difference in failure rates was seen in people who had a previous history of resistance to nukes: 16 % vs less than 1%. This was from any previous virological failure and especially if previous nuke-resistance was documented. Lipids (cholesterol and triglycerides) generally improved slightly after the switch.

The second study (called SPIRAL) randomised 273 people on stable treatment to either continue on their boosted-PI or switch the PI to raltegravir. [14]

After a year, just over 10% of people in each group had changed treatment but less than half of these cases were due to virological failure. In this study lipids improved more significantly after switching from a boosted-PI to raltegravir perhaps because more people were switching from lopinavir/r (Kaletra). This reduced the number of people needed lipid lowering drug based on guidelines.

When to start treatment

The debate about what CD4 count to start treatment was the focus for one main session, and several studies looked at this question. This is a good session to watch online.

This is an important subject because several treatment guidelines changed in the last year. On this question different experts interpret the same research differently. In the US, the benefits of treatment are believed to outweigh the risks, recommending treatment at any CD4 count under 500 and the option to use treatment at any count above this. European guidelines generally remain at 350 until greater evidence of the benefits can be proven, although some countries including France have followed the US change.

A study in Vienna from a network of database studies called CASCADE included almost 10,000 people who had been diagnosed in early infection between 1994–2009. [15]

The researchers looked at health outcomes depending on whether treatment was started or deferred at different CD4 counts and used complicated analysis to adjust for other factors that might affect the results.

Starting at a CD4 count below 50 or at 50-200 was linked to really clear benefits. So was starting at 200-350 and 350-500 but the differences between these groups was less dramatic, at least over three years. The study found no benefit from starting at counts over 500.

In summary, the researchers talked about the limitations from this kind of study. Database studies can show a link between different factors but they cannot prove that one thing causes another (i.e. that earlier treatment leads to better health).

This can only be seen in a randomised study and the researchers supported the importance of the ongoing START study to answer the question more definitively.

Other studies

New CD4 test: real time 'point of care'

One of the most exciting developments, with the potential to radically change the standard of care in developing countries, was a new CD4 test that was prompted by the US treatment activist Gregg Gonsalves and has been developed by an international research group based in the UK. [16]

Instead of taking a syringe of blood that then has to be transported to a laboratory, the new test has been developed to run without additional chemicals or the need for electricity. A finger prick of blood is mixed and spun in a sealed unit that doesn't need batteries or electricity. It then produces a CD4 count similar to reading temperature on a thermometer.

Many resource-limited countries have little or no access to CD4 counts or viral load. When available, this can delay access to treatment, and make it more difficult to identify early treatment failure.

It is easy to see how this technology could be used in Western countries too.

Vaccine protects young men from genital warts and anal cancer

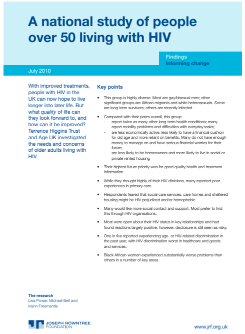
The meeting saw the first presentation of results from a study of an vaccine against the Human Papilloma Virus (HPV). This vaccine was initially tested and approved for young women. [19]

There are over 100 HPV viruses and this vaccine is highly effective at preventing four: HPV 6 and 11 which cause genital warts and HPV 16 and 18 which increase the risk of cervical and anal cancer.

The vaccine only works if it is used before you come into contact with these viruses. This means that for the protection to work, young adolescents need to take the vaccine before they become sexually active.

The study included over 4000 young men from 18 countries and over two years the vaccine was found to significantly reduce the risk of genital lesions, HPV infection and abnormal cells linked to anal cancer.

HIV and ageing



Several sessions looked at HIV and ageing, including a community meeting that included results from a THT survey of 325 gay men in the UK. [17, 18]

Many Western countries, including the UK, expect that by 2015 approximately half of all people living with HIV will be over 50 years old. This includes people who have been living with HIV for many years and are now surviving into older age and people who only become HIV-positive at a later age.

Over the last year there has been an increasing interest from researchers into the medical complications relating to HIV, ageing, medication and age-related illnesses. This session also focused on the social implications, including the risk of greater isolation, poorer financial status (pension planning was not a priority prior to treatment), mental health issues, being able to care for oneself and long-term health complications.

Drugs for the future: nanotechnology and searching for a cure

A poster from the first day of the conference reported a new technology for for using HIV drugs like AZT, d4T and efavirenz.

Nanotechnology work on the tiniest of particles that are hundreds of times smaller than the width of a human hair.

The requires only a small fraction of the active materials and results in formulations that might only need dosing every 2–4 weeks. Because the amount of active drug is reduced, this should dramatically reduce cost, reduce side effects, improve adherence and enable more people to be treated for the same amount of money.

The research is still in early stages, but this is an area to watch…

Finally, the long-term hopes for a cure are becoming a new focus of research again.

Immediately prior to the main conference, a two-day meeting brought together leading researchers to focus on the obstacles to finding a cure. This included approaches to target resting CD4 cells that are infected with HIV but which current drugs are not able to reach.

Many of the presentations are available online, together with a report from the meeting. Although the meeting was not webcast one of the lectures from the opening session of the main conference provides and overview of this research, and this is available online.

The online conference

As with previous IAS conferences, much of the conference material is available online and HTB reports include appropriate hyperlinks.

Getting to watch these presentations yourself is well worth overcoming the navigation difficulties outline below.

Locating the appropriate files, presentations, webcasts, transcriptions or even the basic abstracts is more challenging. Access is routed through the 'Programme at a glance' link on the conference homepage. This requires a free software plug-in called Silverlight, but an automatic download button should come up if you do not already have this installed.

Conference homepage

http://www.aids2010.org/

Programme at a glance

http://pag.aids2010.org/

The search facility requires selecting one of the seven options directly under the search bar ie to search the abstracts, you need to first click 'abstract' which when selected has the tiny white triangle in the red block turn to face down. Then search as you would normally by entering a keyword in the search box and clicking search. Results come up listed below.

The abstract books are available to download as free PDF files, but only for each day, so searching the whole conference requires repeating each search four times.

Download abstract books

http://www.aids2010.org/Default.aspx?pageId=322

Although you can browse sessions by day and time, this is not so easy if you are looking for a specific session but don't know when it was presented because there is not a programme that just shows the sessions. For example a search for 'late breaker' brings up no results whether searching 'programme at a glance', 'abstracts', or 'oral sessions'.

When you find a session page, you then have to find and click the yellow 'more info' button at the bottom right of an empty box, and then you finally get to a page that makes sense. Don't be entirely fooled. The 'abstract' link for each study seems to work, but 'slides with audio' are not always available and the 'powerpoint' link doesn't work at all. For powerpoint presentation slides, scroll further down the page where slides that are available are posted under the 'powerpoint presentations' heading.

The audio works but you need to manually download the powerpoint slides to really follow the presentation.

To make things more confusing, some webcast presentations are provided by Kaiser Foundation on a different website.

http://globalhealth.kff.org/AIDS2010

These webcasts only show the presenter, with no slides and no easy links to slides, so you need to get the slides from the main IAS site for them to make sense. Kaiser provide rough transcripts of the sessions that can be more useful with the slide set, than the webcast, though many medical terms have not been proof edited.

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Unless stated otherwise, all references are to the Programme and Abstracts of the 18th International AIDS Society World AIDS Conference, 18–23 July 2010, Vienna, Austria.

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21. Sharon Lewin S. State of the Epidemic: Strategies for a Cure. Opening Plenary.
http://pag.aids2010.org/session.aspx?s=570
Webcast:
http://globalhealth.kff.org/AIDS2010/July-18/Opening-Session-LIVE-WEBCAST.aspx
22. Katata L et al. Spray dried PCL-efavirenz nanoparticles for improving the current HIV/AIDS treatment. Poster abstract MOPE0031. Link includes ePoster.
http://pag.aids2010.org/Abstracts.aspx?AID=13785

For more information about any of these studies, call the i-Base information phoneline.

0808 800 6013

Mon, Tues, Wed 12.00 noon – 4pm

All calls are free and in confidence.

or email:

questions@i-Base.org.uk

i-Base publications and services

HIV i-Base is an HIV-positive led treatment information service. We produce information both for clinicians and other health workers and for people with HIV.

Our publications are used and have been adapted in many countries and settings.

Our fully searchable website is designed to be fast to access, easy to use, and simple to navigate.

All i-Base publications are available online.

http://www.i-base.info

i-Base produce five non-technical treatment guides.

http://www.i-base.info/guides

- Introduction to combination therapy
- A guide to changing treatment
- Avoiding & managing side effects
- HIV, pregnancy & women's health
- Hepatitis C for people living with HIV

The site also includes a web-based Q&A section to ask questions about treatment:

http://www.i-base.info/questions

Recent questions include:

- How can I lose weight without it affecting my CD4 count?
- Do ARVs act on other viruses apart from HIV such as herpes?
- Does Viagra react with tenofovir, 3TC and efavirenz?
- Does stress and lack of sleep effect your CD4 count?
- What can I do about the fat gain in my tummy and breasts?
- Can I have a child if I have HIV?
- Why does my CD4 count increase but not my CD4%?
- Can people be re-infected with different strains of HIV?
- Will anal warts lead to cancer?

Glossary

abstract - a short summary of a study (usually about 350 words)

antiretrovirals - common name for all HIV drugs

ARVs - abbreviation for 'antiretrovirals'

boosted-PI - a protease inhibitor taken with a small dose of ritonavir

cholesterol - a type of body fat measured in blood

HPV - Human Papilloma Virus

HSV-2 - Herpes Simplex Virus-2

late breaker - last minute study results - like 'late-breaking news'

log - when measuring viral load, 1 log is a drop by 90%, 2 logs by 99% etc

lipids - medical name for fat

microbicide - a gel that may protect against HIV infection

monotherapy - using only one drug

nanotechnology - science working on the scale of molecules

Stevens–Johnson Syndrome - a type of severe rash

DEXA - scan to estimate your proportions of body fat, bone and muscle

point of care - in your doctors office (or wherever you access care)

prophylaxis - taking a drug to protect you against a potential illness

randomised - when neither you or your doctor chose which group you join in a research study

triglycerides - a type of fat produced and regulated by your liver

viral rebound - when your viral load has been under 50 copies/mL and then becomes detectable