



ACT

TOOLKIT 2.0

ADVOCACY for COMMUNITY TREATMENT

Strengthening Community Responses to HIV Treatment and Prevention

About ITPC

International Treatment Preparedness Coalition (ITPC) is a worldwide network of community activists unified by our vision of a longer, healthier, more productive life for all people living with HIV (PLHIV). ITPC's mission is to enable communities in need to access optimal HIV treatment. As a grassroots movement based primarily in the Global South, ITPC is the community's voice on HIV treatment and is driven by and committed to the human rights of those most impacted by the HIV epidemic.

ITPC is a global coalition that includes eight regional networks in Africa, Asia, Latin America and the Caribbean, Eastern Europe, and the Middle East. Through its HIV Treatment Education program, ITPC is committed to providing accurate and timely HIV treatment information that can improve the lives of PLHIV. Many of the tools developed under this program are also intended to be used for advocacy initiatives. Additional information about ITPC is available at: www.itpcglobal.org.

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Introduction

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Welcome to the **Introduction** of the Advocacy for Community Treatment (ACT) Toolkit 2.0 of the International Treatment Preparedness Coalition (ITPC)

The aim of the **Introduction** is to explain what the ACT Toolkit is, what it contains and how it can be used.

Abbreviations

ACT TOOLKIT	Advocacy for Community Treatment Toolkit	FTA	Free Trade Agreement	LAM	Lipoarabinomannan	R&D	Research and Development
AFSU-EN	Association des Frères et Soeurs Unis du Cameroun	GAVI	Global Alliance for Vaccines and Immunizations	LGBT	Lesbian, Gay, Bisexual and Transgender	RNA	Ribonucleic Acid
AIDS	Acquired Immunodeficiency Syndrome	GHRN	Georgian Harm Reduction Network	LMIC	Low-and-Middle-Income Country	RR-TB	Rifampicin Resistant TB
AJWS	American Jewish World Service	GLOBAL FUND	The Global Fund to Fight AIDS, Tuberculosis and Malaria	LPA	Line-Probe Assay	SBP	Systolic Blood Pressure
AM	Amikacin	GNI	Gross National Income	LTBI	Latent TB Infection	START	Strategic Timing of AntiRetroviral Treatment
ARASA	AIDS & Rights Alliance for Southern Africa	HAV	Hepatitis A Virus	MDR-TB	Multidrug-Resistant TB	STI	Sexually Transmitted Infection
ART	Antiretroviral Therapy	HBV	Hepatitis B Virus	MIC	Middle-Income Country	TASP	Treatment as Prevention
ARV	Antiretroviral	HCT	HIV counselling and testing	MSM	Men Who Have Sex with Men	TAT	Turn-Around-Time
BP	Blood Pressure	HCV	Hepatitis C Virus	MTB	Mycobacterium Tuberculosis	TB	Tuberculosis
CAB	Community Advisory Board	HDV	Hepatitis D Virus	NCD	Non-Communicable Disease	TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
CCM	Country Coordinating Mechanism	HEV	Hepatitis E Virus	NGO	Nongovernmental Organization	TST	Tuberculin Skin Test
CDC	United States Centers for Disease Control and Prevention	HHV	Human Herpes Virus	NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor	UHRA	Uganda Harmonized Rights Alliance
CIFF	Children's Investment Fund Foundation	HIV	Human Immunodeficiency Virus	nPEP	Non-Occupational PEP	UN	United Nations
CL	Compulsory License	HPTN 052	HIV Prevention Trials Network Study	NRTI	Nucleoside/Nucleotide Reverse Transcriptase Inhibitors	UNAIDS	Joint United Nations Program on AIDS
CPT	Co-Trimoxazole Preventive Therapy	HPV	Human Papilloma Virus	NtRTIs	Nucleotide Reverse Transcriptase Inhibitor	UNDP	United Nations Development Programme
CSO	Civil Society Organization	IAC	International AIDS Conference	oPEP	Occupational PEP	UNESCO	United Nations Educational, Scientific and Cultural Organization
CSS	Community Systems Strengthening	IC	Infection Control	OSF	Open Society Foundation	UNGASS	United Nations General Assembly Special Session on HIV/ AIDS
CTAAP	Community Treatment Access Advocacy Program	ICF	intensified case finding	OST	Opioid Substitution Therapy	UNHCR	United Nations High Commissioner for Refugees
DAA	Direct-Acting Antiviral	IFFIM	International Finance Facility for Immunization	PCR	Polymerase Chain Reaction	UNICEF	United Nations International Children's Emergency Fund
DBP	Diastolic Blood Pressure	IGRA	interferon gamma release assay	PEP	Post-Exposure Prophylaxis	UNODC	United Nations Office on Drugs and Crime
DBS	Dried Blood Spot	ILO	International Labour Organization	PEPFAR	The President's Emergency Plan for AIDS Relief	USAID	United States Agency for International Development
DM	Diabetes Mellitus	IMF	International Monetary Fund	PI	Protease Inhibitors	VNP+	Vietnam Network of People Living with HIV
DNA	Deoxyribonucleic Acid	INSTI	integrase strand transfer inhibitor	PLHIV	Person(s) Living with HIV	WFP	World Food Programme
DR-TB	Drug-Resistant TB	IPRs	intellectual property rights	PMTCT	Prevention of mother-to-child transmission	WHA	World Health Assembly
DST	Drug-Susceptibility Testing	IPT	Isoniazid Preventive Therapy	PoC	point-of-care	WHO	World Health Organization
ECOSOC	United Nations Economic and Social Council	ICASA	International Conference on AIDS and STIS in Africa	PPK	Professionals in Pride Kenya	WTO	World Trade Organization
EJAF	Elton John AIDS Foundation	ITPC	International Treatment Preparedness Coalition	PREP	Pre-Exposure Prophylaxis	XDR TB	Extensively Drug Resistant TB
FDC	Fixed-Dose Combination	KS	Kaposi's Sarcoma	PWID	People Who Inject Drugs		
				PWUD	People Who Use Drugs		

What is the ACT Toolkit?

What is the aim of the ACT Toolkit 2.0?

The aim of the Advocacy for Community Treatment (ACT) toolkit is to support and train community activists to advocate effectively and passionately on access to treatment for people living with HIV, including those from key populations.

Such activists may be part of the International Treatment Preparedness Coalition (ITPC) (see box). Or they might be part of a wide range of other types of organizations, networks or campaigns related to HIV treatment throughout the world.

The 2.0 version of the ACT Toolkit updated the information contained in the first ACT Toolkit. In addition to revised facts and figures that reflect the most recent evidence, the ACT Toolkit 2.0 also includes new content on the World Health Organization's 2015 treatment guidelines, monitoring HIV treatment with routine viral load testing, and the Fast-Track global initiative to scale-up the HIV response and end the HIV epidemic by 2030. The ACT Toolkit 2.0 also contains new sections on HIV/TB co-infection and Hepatitis C virus, giving activists a comprehensive understanding of these diseases and their association with HIV.

Why is the ACT Toolkit needed?

According to the UNAIDS Fact Sheet of 2016, of the 36.7 million PLHIV, 17 million were accessing antiretroviral therapy in 2015.¹ This means that the previous global target of having 15 million people on HIV treatment by 2015 has been achieved. This is important progress and very welcome. However, it is not enough. It represents just 46% of the people who are eligible for ART according to the 2015 WHO ART guidelines.

In addition, even though access to treatment has improved, there are gaps which must be addressed. The rate of new HIV infections and AIDS-related deaths is still unacceptably high. In its publication to mark World AIDS Day 2015, UNAIDS states that 28 million new HIV infections and 21 million AIDS-related deaths could be averted between 2015 and 2030 if the response to the epidemic is accelerated.

In reality, access to HIV treatment – for many different community members in many different contexts – is still limited. This is due to a range of social, political and economic factors. Examples include the: cost of treatment; quality of treatment; political support for treatment; and where, how and by whom treatment is delivered. These challenges especially affect people from key populations (see box above) who experience inequitable and unacceptably low access to ART.

Community advocacy is crucial to bringing about change. Yet community activists often lack the knowledge and skills needed to raise their voices and communicate their needs in the local and national forums where decisions are made. The ACT Toolkit 2.0 contributes to addressing that gap.

What is ITPC?

ITPC is the world's leading community-based movement of people living with HIV (PLHIV), key populations and their supporters who are united in promoting access to treatment. The coalition members include community organizations, local NGOs, researchers and activists with strong expertise in HIV treatment, HIV co-infections, health systems and related issues. ITPC is engaged in treatment advocacy and literacy – ensuring that PLHIV are at the forefront of actively shaping their own futures and leading productive lives.

Who are key populations?

Key populations include LGBTI people, sex workers, men who have sex with men (MSM) and people who use drugs. Key populations live among every population in the world. However, national governments often ignore their responsibility to ensure access to health for these people. As a result, they are disproportionately affected by HIV. In addition to being more vulnerable to HIV, key populations are often victimized, criminalized, stigmatized and marginalized in society. This makes it difficult for people from key population to access HIV testing and treatment services.

How was the ACT Toolkit developed?

The ACT Toolkit 2.0 is based on the first edition of the ACT Toolkit, originally published in July 2014, which was developed by partners, staff and consultants of ITPC with extensive, practical experience of community advocacy on access to treatment. ITPC is grateful to all of the individuals and organizations that contributed. In particular, thanks are given to: Eleanor Whyte, Gerrit Giebel, Khairunisa Suleiman, Tracy Swan, Sam Avrett, David Barr, Kajal Bhardwaj, Abraham Siika, Allan Maleche, Sarah Middleton-Lee, David Traynor and Othoman Mellouk.

Drafts texts were tested and improved during training with community activists in four regions: Anglophone Africa, Asia, Eastern Europe and Central Asia, and Latin America. This Toolkit brings together all the lessons and suggestions from those experiences.

What does the ACT Toolkit contain?

PART	SECTIONS
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1 THE SCIENCE OF HIV INFECTION & HIV TREATMENT	<p>1.1 • What is HIV?</p> <p>1.2 • What is HIV Treatment?</p> <p>1.3 • Monitoring HIV Treatment</p>
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3 HIV TREATMENT INITIATIVES	<p>3.1 The History of Global Treatment Initiatives</p> <p>3.2 Fast-Track: Ending the AIDS epidemic by 2030</p> <p>3.3 HIV Treatment Guidance</p> <p>3.4 What are the Entry Points for Advocacy on HIV Treatment Initiatives</p>
4 HUMAN RIGHTS AND HIV	<p>4.1 What are Human Rights?</p> <p>4.2 How do Human Rights Relate to Access to Treatment?</p> <p>4.3 Advocacy for Human Rights and Access to Treatment?</p>
5 TRADE AND TREATMENT	<p>5.1 • What are Patents and Intellectual Property?</p> <p>5.2 • Why does Trade matter to HIV Treatment?</p> <p>5.3 • What are TRIPS and TRIPS Flexibilities?</p> <p>5.4 • How can you Advocate on Trade and Access to Treatment?</p>
6 FINANCING AND TREATMENT	<p>6.1 • How does Funding relate to Access to HIV Treatment?</p> <p>6.2 • What needs to happen to Increase Funding for HIV Treatment?</p> <p>6.3 • What are the Entry Points for Advocacy on Funding and Treatment?</p>

7	COMMUNITY ADVOCACY PLANNING FOR INCREASED ACCESS TO OPTIMAL HIV TREATMENT	<p>7.1 • What is Advocacy for Community Treatment?</p> <p>7.2 • What are your Opportunities and Barriers for Advocacy for Community Treatment?</p> <p>7.3 • What are your Opportunities and Barriers for Advocacy for Increased Access to Optimal Treatment?</p> <p>7.4 • How do you develop a Plan for Advocacy for Increased Access to Optimal Treatment?</p> <p>7.5 • How do you develop messages for advocacy for increased access to optimal treatment?</p> <p>7.6 • 'What works' for community advocacy on common barriers to increased access to optimal treatment?</p>
8	ACT CASE STUDIES	<p>1. Advocating Against Human Rights Abuses of Sex Workers Living with HIV, Uganda</p> <p>2. Advocating Against Barriers to CD4 Counts and ART for Key Populations, Ukraine</p> <p>3. Advocating Against Negative Attitudes of Treatment-Providers, Cameroon</p> <p>4. Addressing the 'Evidence Gap' for Advocacy on ART for Key Populations, Vietnam</p> <p>5. Advocating on the Lack of Appropriate Health Services for LGBT People, Kenya</p> <p>6. Advocating for the Involvement of People Who Use Drugs in ART Services, Georgia</p> <p>7. Advocating for Improved Provincial Procurement of ARVs, Russia</p> <p>8. Advocating Against Poor Quality ART for Women Living with HIV, West Africa</p>

What does each Section contain?

Each Section in the ACT Toolkit contains:

- **Section objective:** summarizing what community trainers can achieve by using the Section.
- **Training materials** providing a list of the resources and materials (such as PowerPoint presentations or flipcharts) needed to guide the participants through the session A PowerPoint presentation, to support training, is available for each section.
- **Training options** providing options for activities to help participants engage with the content of the section depending on the amount of time available for the session.

In each section, there is an:

Option A: Giving a short (60 minutes) and information-based option for training, such as through a PowerPoint presentation and discussion.

In some Sections, there is also:

Option B: Giving a longer (approx. 120 minutes) and more participatory option for training, such as through group work and activities
- **Useful resources:** Giving links to other useful documents or websites on the subject.
- **Key messages:** key 'take-home' messages for the participants that can also be used as part of an advocacy strategy for the issue in question

How can the ACT Toolkit be used?

Who can use the ACT Toolkit?

The ACT Toolkit is designed to be used by community trainers. These are people who work closely with community activists, such as PLHIV and members of key populations. The trainers might be community members or they might work or volunteer with nongovernmental organizations (NGOs), training groups or academic institutions. They should already have basic skills in participatory training.

How can the ACT Toolkit be used?

The ACT Toolkit is designed to be used flexibly – in whatever way is most useful to the trainer and community activists. For example, it can be used to develop a 3-5 day training workshop that includes all of the Modules. It can also be used for shorter and less formal initiatives – with trainers selecting a few of the Modules and Sections according to the number of participants, their needs and the time available.

The ACT Toolkit requires only basic training equipment - a laptop and projector, flipcharts and marker pens.

How can the ACT Toolkit support participatory training?

The ACT Toolkit works best if it is part of participatory training. This means training that puts the participants first and enables them to: share their own knowledge, experience and ideas; ask questions and have discussions; build their skills and confidence; and 'learn by doing,' such as through doing activities and analyzing case studies.

This Toolkit does not give detailed guidance on how to prepare or facilitate participatory training. However, trainers can find some tips on effective participatory training below.

TEN 'TOP TIPS' FOR FACILITATING A PARTICIPATORY WORKSHOP

1. PREPARE YOURSELF

- 'Do your homework' - reading the ACT Toolkit, researching access to treatment and having discussions about the key issues.
- Prepare each Section - considering the objective, activities and key messages. Ensure you are familiar with any materials, such as PowerPoint presentations.
- Don't present a session on a topic you don't know very much about (unless you have time to prepare very well). Instead, swap the session with another trainer or identify an external resource person.

2. ADAPT THE TRAINING

Adapt the content of the training to your community. This might involve considering the context in relation to:

- The scale of unmet needs for HIV treatment and the key barriers to access.
- Human rights and stigma, especially for key populations.
- Stakeholders involved in decision-making on HIV treatment.
- 'What works' in local HIV advocacy.
- National policies and laws related to HIV treatment.
- National and international funding for HIV treatment.

Make any necessary changes to the content of the training. For example, you might want to: add case studies on access to treatment in your community; refer to national guidelines and protocols in your country; or use different types of media (such as films about treatment by local campaign groups).

3. PREPARE THE PROGRAM

- Develop an outline program to share with the participants – showing what sessions will occur, when and for how long. Ensure you time the sessions in a way that will encourage hard work, but also take care of the participants (for example with adequate lunch breaks).
- Run through the full program with the participants at the start of the training. Then run through the program at the start of each day or Section – to show the flow of the training. If possible, provide the participants with an information pack to support the training. This might include copies of PowerPoint Presentations or national HIV treatment guidelines.

4. PREPARE THE SPACE

- Make the training venue as comfortable and energizing as possible. For example, if possible, choose a room with lots of windows (to give natural light) and plenty of space.
- Ensure that the venue is a ‘safe space’ that, for example, will enable people from key populations to maintain confidentiality.
- Arrange the room in a way that encourages sharing and participation. For example, have a circle of chairs rather than a classroom-style layout.
- Ensure that the equipment (laptop, projector, etc.) is ready and that you know how to work it.

5. USE AVAILABLE EXPERTISE

- Use the expertise that you have among the participants. Recognize that everyone comes with some experience and knowledge of access to HIV treatment.
- Work in partnership and identify external resource people to provide expert input into the training or to facilitate specific Sections. Examples might include representatives of networks of PLHIV, groups of key populations or the Ministry of Health.

6. SET AND ENFORCE GROUND-RULES

- At the start of the training, work with the participants to identify and agree on ground rules by which everyone will work. Examples include: keep to time; have mobile phones on silent; do not answer calls during the training; participate openly and honestly; and respect each other’s opinions.
- Ask the participants to help you enforce the ground rules throughout the training. For example, if someone is not participating, ask the others to encourage them to do so.
- Respect the ground-rules yourself. For example, if a rule is ‘keep to time,’ finish facilitating your sessions promptly. If you are running late, ask the participants if they would prefer to continue or to re-arrange the program.

7. ENCOURAGE PARTICIPATION

- Do not dominate sessions. Instead, facilitate the involvement of the participants.
- Respect participants’ different experiences and perspectives. For example, say: *“Thank you for that important contribution”* or *“It was great to hear your interesting example.”*
- If some participants are not participating, consider: using buzz groups (groups of 2-3 participants that provide a ‘safe space’ and encourage people to talk); or speaking to them in a break to check if there are any problems and encourage them to give input.
- If some participants are being dominant, consider: politely stopping them from making long interventions (for example by saying “Thank you ... and now I’d like to hear about other people’s experiences”); speaking to them in a break and encouraging them to keep engaged, but to speak less; or giving them a task to do (for example, being a rapporteur who will report back on the day at the beginning of the next morning).

8. WORK AS A TEAM

- If you are working with other trainers, work as a team – supporting each other and your roles. Ensure that everyone in the team is familiar with the whole program – so that they understand the flow of the training and can ‘jump in’ if there are emergencies.
- Where possible, co-facilitate sessions – to support each other and provide a variety of styles, inputs and energies.
- Support each other if there are crises. For example, if a session is not going well, ask for suggestions from the other trainers or take a short break.

9. ASK YOUR PARTICIPANTS

- Ask the participants their expectations at the start of the training and regularly re-visit those expectations to ensure you are on track.
- Keep in touch with your participants. For example, have a brief feedback session at the end of each day or each Section – for participants to share their ‘highs’ and ‘lows’ and any concerns. Or have informal discussions during the lunch break to check-in on how people are feeling.
- Check throughout the training that your participants have understood key terms and concepts. For example, ask: “Is that clear?” or “Shall I go through that again?”
- Respond to feedback from your participants – either making changes to the program or explaining why you cannot do so.

10. LEARN FROM EXPERIENCE

- Evaluate the training, such as through a form or activity to collect the participants’ feedback (for example on the quality of the sessions and the facilitation).
- After the training, carry out a debrief among the trainers to identify lessons learned and what could be done better or differently in the future.

More information about participatory training can be found in a number of other resources. Examples include:

- *A Facilitators’ Guide to Participatory Workshops with NGOs/CBOs Responding to HIV/AIDS*, International HIV/AIDS Alliance, December 2003. http://www.aidsalliance.org/includes/Publication/fge1101_Facilitators_guide_eng.pdf
- *100 Ways to Energize Groups: Games to Use in Workshops, Meetings and the Community*, International HIV/AIDS Alliance, December 2003. http://www.aidsalliance.org/includes/Publication/ene0502_Energiser_guide_eng.pdf

1

THE SCIENCE OF HIV INFECTION & HIV TREATMENT

Welcome to **Module 1: The Science of HIV Infection & HIV Treatment** of the Advocacy for Community Treatment (ACT) Toolkit 2.0 of the International Treatment Preparedness Coalition (ITPC)

The activist's aim of Module 1 is to build community understanding of the 'basics' of HIV, including how the virus interacts with the body, and how HIV is treated.

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SECTION 1.1. What is HIV?

SECTION OBJECTIVE

To build community activist's backwards understanding of the 'basics' of HIV, including: what it is, how it is transmitted, and how it is diagnosed.

TRAINING MATERIALS

PowerPoint presentation '1.1. What is HIV?'

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objective of the Section.
2. Divide the participants into 'buzz groups' of 2-3 people. Ask them to discuss and write down any questions that they have about 'What is HIV?' These might be things that they do not know or information that is unclear to them.
3. Present PowerPoint presentation '1.1. What is HIV?'
4. Ask the participants if they have any questions about the presentation. Check if you have answered all of the questions that they identified in their 'buzz groups.' If you have not, provide them with further information.
5. Ask the participants to summarize the section by developing advocacy messages about 'What is HIV?' Support their ideas by sharing examples of messages (see below).

KEY MESSAGES

To fight a good fight, it is important to understand one's enemy. In this case, it is important to understand the HIV, its life cycle and how it damages the immune system. This will help people understand that:

- Treating HIV early has great benefits for both people living with HIV and those not living with the virus.
- Access to key tools - such as viral load tests - are very important for monitoring HIV treatment (antiretroviral therapy). Routine viral load testing is a sure way to know that HIV treatment is working.
- Access to HIV treatment also requires access to treatment for opportunistic infections and non-communicable disease, such as cancers, that affect people living with HIV.

USEFUL RESOURCES

- *What is HIV/AIDS?* POZ.com. Available here: <https://www.poz.com/basics/hiv-basics/hivaids>
- *Am I at Risk of Getting HIV?*, (online guide) VERYWELL.com. Available here: <https://www.verywell.com/hiv-information-47874>
- *HIV in Our Lives: Book of Information Sheets for People Living With HIV, Support Groups and Clinics*, Treatment Action Campaign, 2013. Available here: http://www.tac.org.za/sites/default/files/publications/2014-10-31/TAC_IOL_web3_LR-1.pdf
- *HIV/AIDS 101: What is HIV?*, AIDS.gov. Available here: <https://www.aids.gov/hiv-aids-basics/hiv-aids-101/what-is-hiv-aids/#>

- *HIV Treatments Directory: A to Z of Antiretroviral Drugs*, Aidsmap, 2016. Available here: <http://www.aidsmap.com/drugs>
- *Activist Toolkit: Campaigning for Routine Viral Load Monitoring*, International Treatment Preparedness Coalition, 2016. Available here: <http://itpcglobal.org/wp-content/uploads/2016/05/ITPC-RVLT-Toolkit-English.pdf>

What is HIV?

The **Human Immunodeficiency Virus (HIV)** is a very small virus that cannot be seen with the naked eye. HIV affects a person's immune system (the system in the body which acts as a defense against diseases and infections). The immune system is made up of white blood cells, including CD4 cells. These are cells that act as the soldiers of the immune system and fight off infections, bacteria and viruses. HIV destroys these CD4 cells.

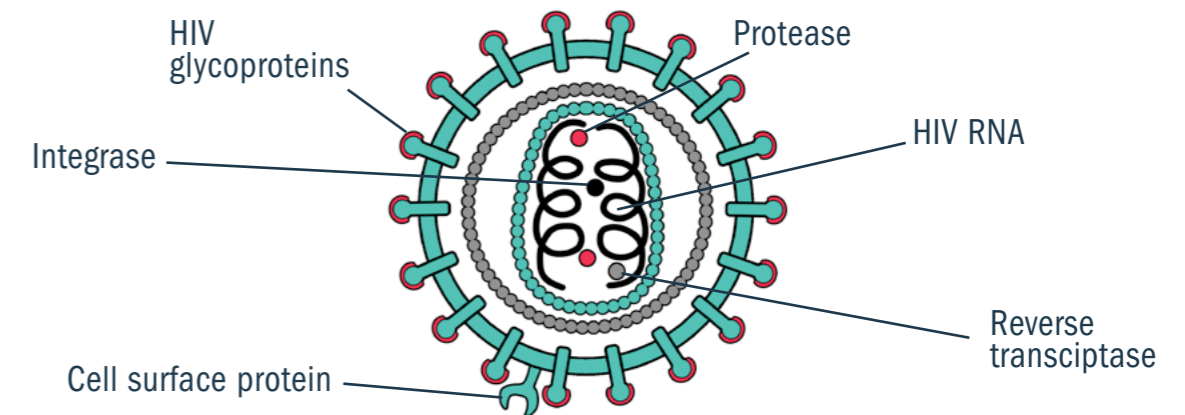


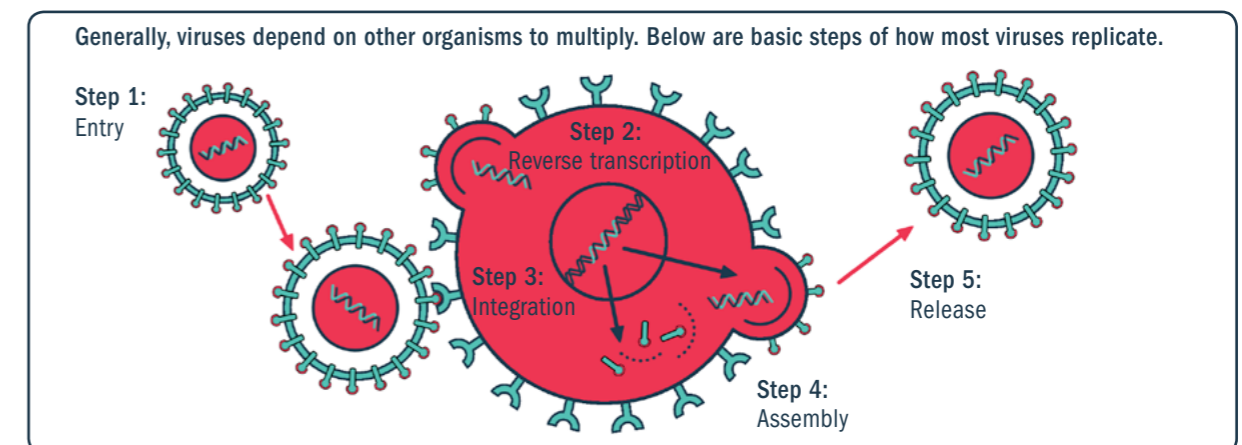
Figure 1: Diagram - Structure of a HIV cell

There are two types of HIV:

- HIV 1 is the most common. It is found all around the world. It has different groups, of which the most common is group M. Group M has several sub-types, named A–K.
- HIV 2 is less common. It is most often found in West Africa.

When a person living with HIV does not take antiretroviral (ARV) treatment, HIV eventually causes Acquired Immunodeficiency Syndrome (AIDS). This is where a person's immune system fails, allowing other infections and cancers to attack the body and make the person sick. These infections are called opportunistic infections.

How does HIV interact with the body?



When HIV enters the body, it first infects the cells. It then takes several hours for the newly infected cells to carry HIV to the lymph nodes, which are full of CD4 cells. HIV reproduces using the CD4 cell. The virus enters the CD4 cell and uses this cell to make more copies of the virus. During the next few days or weeks, HIV continues to multiply in the CD4 cells found in the lymph nodes and blood, as is illustrated in Figure 3 below.

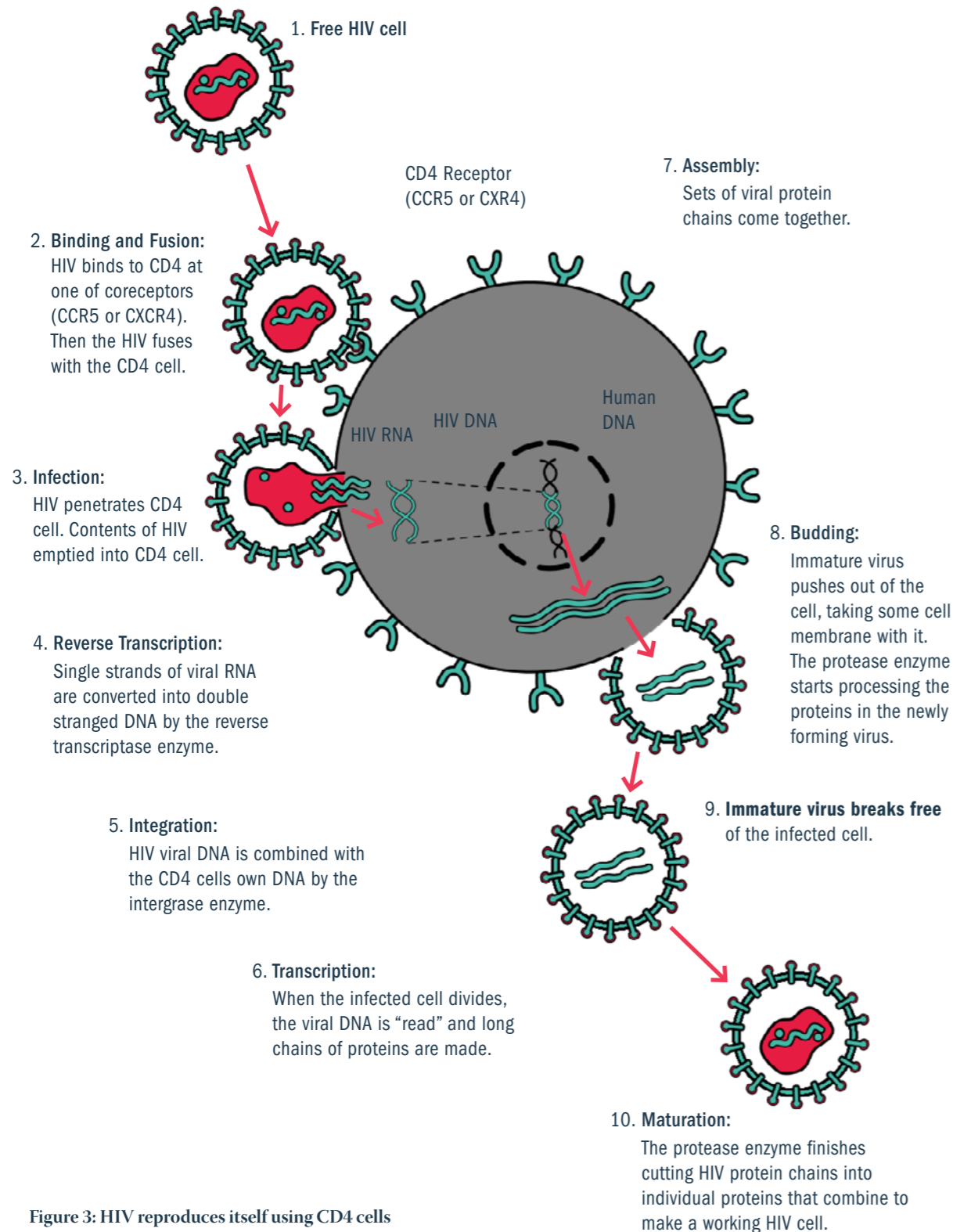


Figure 3: HIV reproduces itself using CD4 cells

How is HIV Transmitted?

HIV is transmitted through a person's body fluids. This includes, genital fluids such as vaginal fluids, semen, moisture in the rectum; blood; and, breast milk.

HIV can be transmitted (spread from one person to another) in different ways, including:

- A person having unprotected vaginal, oral or anal sex with someone who is living with HIV. Unprotected sex is sex without a condom.
- A mother who is living with HIV passing the virus to her baby during pregnancy, delivery or breast-feeding. This is sometimes referred to as 'vertical transmission,' 'mother-to-child transmission' or 'parent-to-child transmission.'
- A person sharing a needle, syringe or other injection equipment with a person who is living with HIV.
- A person having a transfusion of blood that is infected with HIV.
- A person having contact with needles, knives and other sharp objects that have blood infected with HIV on them.

There are factors that affect a person's risk of getting infected with HIV. The factors include:

- The viral load of the person who is living with HIV (i.e. how much of the virus they have in their body).
- The frequency of exposure (how often the situation that risks transmission occurs).
- The duration of exposure (how long the situation that risks transmission lasts).
- The condition of their protective barriers (whether the barriers are strong enough to stop the virus being transmitted through them). These barriers include skin and mucous linings (such as the skin in the vagina and anus).

These protective barriers can become damaged in different ways. Examples include through:

- Illness, such as if someone has a sexually transmitted infection (STI) which causes sores on their genitals.
- Accidents, such as if someone pricks themselves with a needle that has infected blood on it.
- Behaviors, such as if a man and woman have dry sex – where the natural lubrication of the woman's vagina is reduced and the lining might get ripped.

There are many ways a person can protect themselves from HIV, and make sure they don't transmit HIV to others:

- Condoms provide excellent protection against HIV transmission during sex.
- If you inject drugs, you can reduce the risk of HIV and other infections by not sharing needles or other injecting equipment.
- With the right treatment and care during pregnancy and birth, and by not breastfeeding, it's nearly always possible to prevent mother-to-child transmission of HIV.
- Effective HIV treatment, which reduces viral load, has been shown to reduce the risk of transmission.

How does HIV progress?

If a person is living with HIV, but is not on HIV treatment, their infection will get worse. The HIV will reproduce inside the body, making more and more copies of the virus, and destroying the immune system in the process. If a person then becomes infected by a germ (such as bacteria, fungus, virus, etc.), there will not be enough CD4 cells (the soldiers of the immune system) to fight off the infection. This will cause a person living with HIV to become ill, as illustrated in the diagram below.

This process, in which a healthy person is infected with HIV and slowly becomes very ill, is called the natural progression of HIV infection. The World Health Organisation (WHO) has described this progression in five stages. These stages help us to easily recognize how sick a person is. These five stages are described in Table 1, below.

The natural progression of HIV infection^{3,4}	
Stage 1: Acute (early) phase infection	<ul style="list-style-type: none"> • This is also known as acute retroviral syndrome. • It usually lasts up to six months. • The person usually develops a mild illness a few days or few weeks after becoming infected with HIV. They may have one or more of: sore throat; rash; enlarged lymph nodes; headache; malaise; fatigue; fever; poor appetite; vomiting; and muscle pain. • The person's viral load goes up dramatically for a few weeks. It then goes down. • Many scientists believe that this is an important stage at which to take action and achieve better outcomes. This is why it is important to start ARV treatment as early as possible.
Stage 2: Asymptomatic phase	<ul style="list-style-type: none"> • This is also known as chronic HIV infection. • It can last from a few weeks to many years. • On average, a person who becomes infected with HIV and does not start ARV treatment will be in this phase for 8 years. • The person is generally well, has a high CD4 count and a low viral load.
Stage 3: Early symptomatic phase	<ul style="list-style-type: none"> • During this stage, the person has simple illnesses (such as colds, flu or skin rashes) more often. • The person might start to lose weight. • The person will also start to get more minor infections such as mouth ulcers and nail infections.
Stage 4: AIDS stage	<ul style="list-style-type: none"> • This is marked by the start of the person's first AIDS defining illness or opportunistic infection. AIDS-defining illnesses tend to be very severe infections that are extremely rare in people healthy immune systems. Examples of AIDS-defining illnesses include Kaposi's sarcoma and Tuberculosis outside of the lungs. • Without treatment, the average length of time between the start of the AIDS stage and death is less than two years.
Stage 5: Death	<ul style="list-style-type: none"> • If the person does not receive treatment, HIV infection will lead to their death.

How is HIV diagnosed?

HIV is usually diagnosed through a blood test where a small amount of blood is taken from a person's arm or finger. Some tests use fluid from around the gums. An HIV test is the only way to know for sure whether or not a person has HIV.

If the test results are 'positive' the person has HIV, they are regarded as HIV-positive. If the test results are negative, the person does not have HIV, they are then regarded as HIV-negative. With some tests, you will need to have a follow-up test if you have a positive result, to confirm that the test was correct.

It is very important that a person's HIV is diagnosed because it means that the infected person will have the best chance of getting the treatment and care they need to fight the disease and stay well. Usually, the person performing the test will explain how the test works and what the results mean and will provide an opportunity for the person taking the test to ask questions.

A blood test for HIV looks for things indicative of HIV infection in the patient's blood.

These include:

- Antibodies that are produced by the body to fight HIV. Antibodies, are produced by the immune system to help stop viruses, bacteria and other organisms from harming the body.
- Proteins that are on the surface of the virus.
- Genetic material related to the virus, such as deoxyribonucleic acid (DNA) or ribonucleic acid (RNA).

There are a number of different types of HIV tests. Examples include:⁷

- **Antibody test** (such as the ELISA, Western blot and rapid test). This is the most common type of HIV test. It involves testing whether a person's blood sample contains antibodies to HIV. For most of these tests, the test results are available on the same day which is essential for early care and treatment initiation. When these tests are conducted during the window period (the period after a person has been exposed to the virus but before the test can find the antibodies) it may give a false-negative result. This is why it is often necessary to have a follow-up test to confirm a negative result.
- **Antigen/p24 marker test**. This is rarely used. It involves identifying whether a person's blood sample contains protein number 24 of the HIV virus.
- **Combined antibody and antigen test**. This test identifies if a person's blood sample contains both antibodies to HIV and protein number 24 of the HIV virus. This test is becoming more common because it can find infection earlier than tests that only detect antibodies. However, this test can only be used for testing blood and cannot be used in testing oral fluid.
- **Nucleic acid test** (also called RNA PCR test/viral load test). This is a complex and expensive test that is commonly used for children under the age of 18 months. It is a viral load test that identifies the presence and amount of the HIV virus in a body fluid.

SECTION 1.2. What is HIV treatment?

SECTION OBJECTIVE

To build community activists' understanding of the 'basics' of HIV treatment, including: what it is; how it works; when someone should start it; the current options for treatment; what adherence means; treatment as prevention; pre & - post exposure prophylaxis.

TRAINING MATERIALS

- PowerPoint presentation '1.2. What is HIV treatment?'
- Box or bag (to put small pieces of paper in).

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objective of the Section.
2. Present PowerPoint presentation '1.2. What is HIV treatment?'
3. Ask the participants to write down on a piece of paper any points from the presentation that were unclear or any questions that were not answered. Ask them to write one point or one question per piece of paper.
4. Ask the participants to put their pieces of paper in a box or a bag.
5. Take one of the pieces of paper out of the box or bag. First ask the participants for their answers, then, if necessary, provide additional information yourself.
6. Repeat the process for the other pieces of paper.
7. Ask the participants to summarize the session by developing advocacy messages about 'What is HIV treatment?' Support their ideas by sharing examples of messages (see below).

Option B (approx. 120 minutes)

1. Explain the objective of the Section.
2. Give the participants paper and ask them to each write down a questions they have about HIV treatment or a piece of information they know about HIV treatment Collect these pieces of paper.
3. Present PowerPoint presentation '1.2. What is HIV treatment?'
4. Divide the participants into groups of 4 or 5 people. Give each person one of the pieces of paper with questions and information written on them.
5. Let the groups discuss the questions and information on the pieces of paper – decide about the answer to the questions, and think about whether the information on the paper was true or false.
6. Bring all the participants together and form a large circle.
7. Go round the circle and ask each participant to read out their piece of paper. If what was written on the piece of paper is a question, the participant should answer the question. If he or she cannot, discuss the question as a group. If what was written on the paper was a piece of information, ask the participant to explain if that piece of information is true or false. If he or she cannot, discuss this as a group.
8. Continue until each participant has had a chance to discuss his or her piece of paper with the group.

Advocacy Messages

- HIV treatment is highly effective and critical to any response to HIV. HIV treatment allows people living with HIV to live longer, healthier lives.
- Just like other chronic diseases, such as diabetes, HIV is manageable with medication.
- HIV treatment must be part of a 'cascade' of steps that take people from HIV counselling and testing through to having a low, and stable viral load. HIV treatment must also be provided as part of a continuum of care that includes HIV prevention, care and support.
- It is important to start treatment early. The World Health Organization now recommends that all people living with HIV start ARV treatment as soon as possible, at any CD4 count.
- Starting ART early, will significantly decrease the chance of a person getting sick from an AIDS-related illness and decreases the chance of a person passing on the infection to others.
- ART should be taken at the same or similar times every day. It must be taken for life and should not be started and stopped. Taking your treatment at the right time every day is called adherence. The more adherent a person is, the better their HIV treatment will work
- The risk of an HIV-positive person passing on the virus to their uninfected sexual partner can be reduced by 93% if the infected person adheres to an effective ART regimen.

Useful Resources

- *HIV Treatment: Starting HIV treatment*, POZ, 2016. Available here: <https://www.poz.com/basics/hiv-basics/starting-hiv-treatment>
- *Guides: ARVs*, i-base. Available here: <http://i-base.info/guides/category/arvs>
- *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: What's New*, World Health Organisation, 2015. Available here: <http://www.who.int/hiv/pub/arv/policy-brief-arv-2015/en/>
- *Guideline on When to Start Antiretroviral Therapy and on Pre-Exposure Prophylaxis for HIV*, World Health Organisation, 2015. Available here: <http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en/>
- *ARV Flipchart*, Medicine Sans Frontieres, 2014. Available here: https://www.dropbox.com/sh/lkgjyfb6035wef/AABDyii-NZWLYI7b-Myxfbjfa/Annex%207_Patient%20education%20tools/MSF%20ARV%20Flipchart%20Dec2014.pdf?dl=0
- *Starting Antiretroviral Treatment for HIV*, Avert, 2015. Available here: <http://www.avert.org/living-with-hiv/starting-treatment>
- *Staying Healthy with HIV/AIDS: Opportunistic Infections*, AIDS.gov, 2010. Available here: <https://www.aids.gov/hiv-aids-basics/staying-healthy-with-hiv-aids/potential-related-health-problems/opportunistic-infections/>

What is HIV treatment?

Just like other chronic diseases, such as diabetes, HIV is treatable with medication. HIV treatment is also called Antiretroviral Treatment (ART). HIV treatment involves using drugs known as antiretrovirals (ARVs).

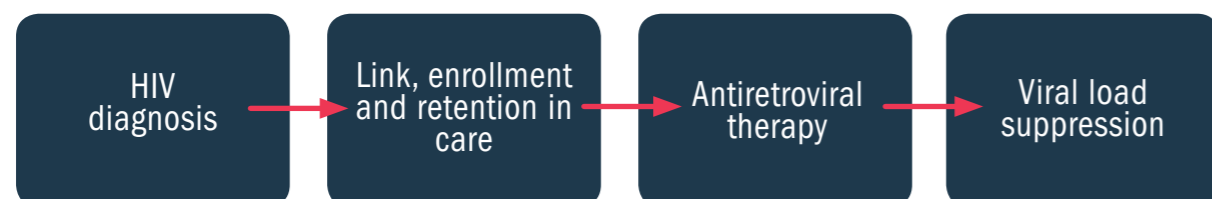
This treatment works by controlling the reproduction of the HI virus in the body, keeping the amount of virus in the body low. The amount of HI virus in a person's body is known as their viral load. When the amount of HI virus in the person's body is low, their immune system stays strong enough to fight off other infections. Keeping the HIV level low also helps to stop the HIV from being passed on to others.

HIV treatment should also include the treatment of opportunistic infections and Non-communicable diseases including cancers that affect people living with HIV (PLHIV) (see Module 2). Opportunistic infections are infections which take hold when a person's immune system has been weakened by HIV. ARVs help your body fight off these opportunistic infections by strengthening the immune system, increasing the amount of CD4 cells in the body.

HIV treatment should be part of a 'cascade' or 'continuum' of care that includes counselling, testing, treatment, and support.

The HIV treatment cascade

ART needs to be part of 'a package' of prevention, care, support and treatment for PLHIV. This also includes psychological, emotional, nutritional and social support – all of which are vital for HIV treatment to be effective.



In 2015, the WHO released new guidelines on when ART should be started. These guidelines recommend that any person living with HIV should start ARV treatment as soon as possible after they have been diagnosed.

Increasing access to treatment for PLHIV and those at a substantial risk of being infected with the virus is the cornerstone of new targets for 2020 which aim to end the AIDS epidemic by 2030.

WORLD HEALTH ORGANIZATION GUIDANCE ON WHEN PEOPLE SHOULD START ART

WHO SHOULD START ARV?	SPECIFIC RECOMMENDATION	START ARV AFTER TESTING
Adults (>19 years)	ART should be initiated in all adults living with HIV at any CD4 cell count	✓
	As a priority, ART should be initiated in all adults with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and individuals with CD4 count ≤ 350 cells/mm ³	✓
Pregnant and breastfeeding women	ART should be initiated in all pregnant and breastfeeding women living with HIV at any CD4 cell count. ART should be continued lifelong	✓
Adolescents (10–19 years)	ART should be initiated in all adolescents living with HIV at any CD4 cell count	✓
	As a priority, ART should be initiated in all adolescents with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and individuals with CD4 count ≤ 350 cells/mm ³	✓
Children (1 to <10) years old	ART should be initiated in all children 1 to <10 years old living with HIV at any CD4 cell count	✓
	As a priority, ART should be initiated among all children <2 years old and those with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and individuals with CD4% < 25% (if < 5 years old) or CD4 count ≤350 cells/mm ³ (if ≥5 years old)	✓
Children (<1 year old)	ART should be initiated in all children living with HIV younger than 1 year old at any CD4 cell count	✓
HIV-negative individuals at substantial risk of HIV infection	Oral PrEP (containing TDF) should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination prevention approaches	✓

How does HIV treatment work?

HIV treatment works by interfering with the life cycle and reproduction of the HI virus. ARVs slow down the reproduction of the virus, allowing the body's immune system to get back to normal and fight infection.

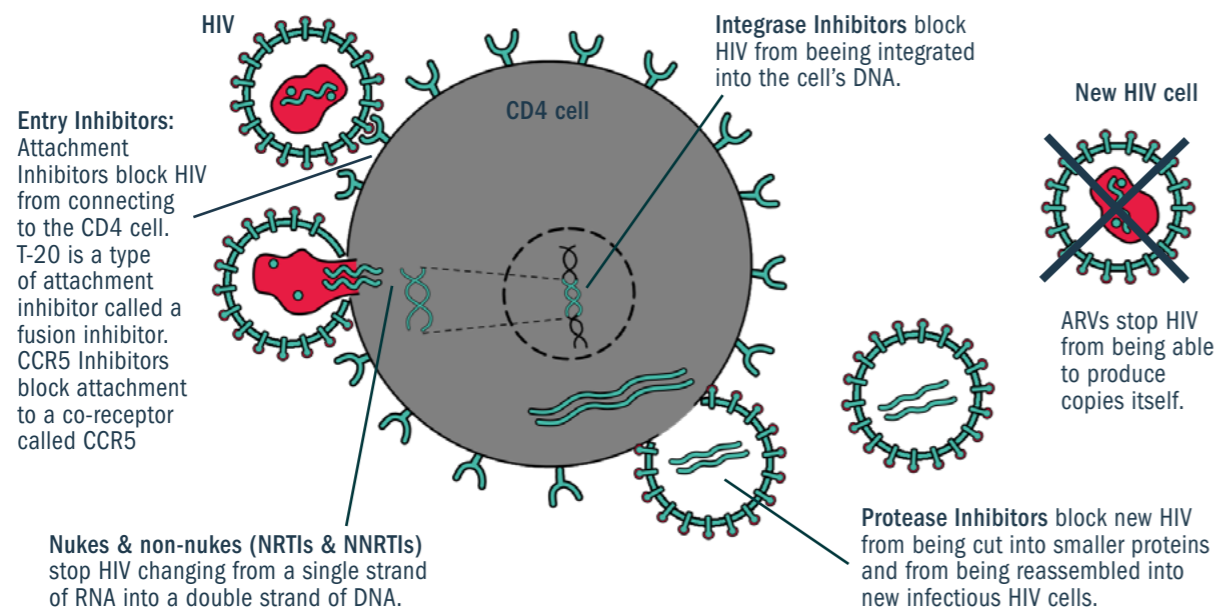
Over the years, important developments have taken place in areas of science related to HIV, such as vaccines and microbicides. However, currently, there is no cure or vaccine for HIV. Fortunately, ART stops HIV from multiplying, allowing the body's immune system to regain its strength, to be able to fight off infections. As such, ART – as part of a 'package' of HIV prevention, care, support and treatment – is the most important option available to save the lives of PLHIV. It is also – as described later in this Section – an increasingly important option for HIV prevention.

A combination of 3 or more antiretroviral drugs must be taken together for the reproduction of HIV to be suppressed. This is referred to as combination therapy.

When HIV enters the body and begins entering the CD4 cells to make copies of itself. ARVs work by stopping different parts of the process as is illustrated in Figure 3. Different ARV drugs target different parts of the HIV reproduction process. This is why it is important to take ARVs in combination. These are the ‘jobs’ different ARVs do to stop the reproduction of HIV:

- To reproduce, an HIV cell must enter and take over the internal machinery of a healthy CD4 cell. To do this, HIV uses reverse transcriptase enzymes to convert its RNA to DNA. This process is called reverse transcription. **Entry inhibitors** work by preventing HIV from entering CD4 cells by attaching themselves to proteins on the surface of CD4 cells or on the surface of the HI virus.
- After the reverse transcription of RNA into DNA is complete, HIV’s DNA must be incorporated into the CD4 cell’s DNA. This is known as integration. **Integrase inhibitors** work by blocking this process.
- After the HIV has converted its RNA into DNA using the DNA of the CD4 cell, it has to ‘programme’ the DNA to start making new HIV genetic material and HIV proteins. To do this, the proteins must be cut up by HIV protease – a special enzyme for cutting proteins. **Protease Inhibitors** work by blocking the activity of the protease enzyme, stopping the cell from producing new copies of the virus.
- **Nucleoside reverse transcriptase inhibitors (NRTIs)** and **nucleotide reverse transcriptase inhibitors (NtRTIs)** work in very similar ways. During reverse transcriptase, the HIV converts its RNA to DNA using ‘building blocks’ called nucleotides. NRTIs contain faulty or broken versions of these nucleotides (called NRTI or NtRTI triphosphate). When HIV tries to convert its RNA to DNA in the presence of NRTIs, it uses these faulty building blocks. This means that the new DNA cannot be built correctly. This means that the genetic material of the HIV cannot be incorporated into the DNA of the CD4 cell, and the virus cannot reproduce.
- HIV uses reverse transcriptase enzymes to convert its RNA to DNA. **Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)** attach themselves to reverse transcriptase enzymes and stop the enzyme from converting RNA to DNA by sticking to the enzyme. This means that HIV’s genetic material cannot be incorporated into the genetic material of the CD4 cell, and new copies of the virus cannot be produced.

Figure 4: How do ARVs work?



What are the current options for HIV treatment?

As we have discussed, when HIV enters the body and begins entering the CD4 cells to make copies of itself, ARV treatment works by stopping different parts of the process. The table below provides examples of the types of ARVs that are currently available. It states the type of ARV, describes how it attacks HIV and gives examples of drugs:¹⁹

TYPES OF ARVS CURRENTLY AVAILABLE

TYPE OF ARV	HOW THE ARV ATTACKS HIV	EXAMPLES OF DRUGS
Fusion or Entry Inhibitors	Prevents HIV from binding to or entering healthy CD4 cells in the body.	enfuvirtide (ENF) maraviroc (MVC)
Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs) - also known as nucleoside analogues or nukes	Interferes with an HIV protein called reverse transcriptase which the virus needs to reproduce itself	zidovudine (AZT, ZDV) didanosine (ddI) stavudine (D4t) lamivudine (3TC) abacavir (ABC) emtricitabine (FTC) tenofovir (TDF) zalcitabine (ddC)
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) - also known as non-nucleosides or non-nukes	Stops HIV replicating within cells by interfering with the reverse transcriptase protein	efavirenz (EFV) nevirapine (NVP) delavirdine (DLV) etravirine (ETR) rilpivirine (RPV) doravirine
Integrase Inhibitors	Interferes with the integrase enzyme which HIV needs to insert its genetic material into human cells	raltegravir (RAL) dolutegravir (DTG) elvitegravir (EVG)
Protease Inhibitors (PIs)	Inhibits protease - another protein involved in the replication of HIV	lopinavir/Ritonavir (LPV/r) nelfinavir (NLF) darunavir (DVR) atazanavir (ATZ) indinavir (IDV) triplanavir (TPV) saquinavir (SQV) fosamprenavir (FPV)

Recommended 1st line ARV regimens for adults and adolescents:

First-line therapy: **NRTI + NRTI + NNRTI** Space for requested examples of ARV

Alternative First-line therapy: **NRTI + NRTI + INSTI** Please provide examples of ARV

The preferred option (see Table 3 below) is usually TDF + 3TC/FTC +EFV. In a few cases, due to medical contraindications, one of these drugs may be substituted with the alternate option, but this is rare.

The following summarizes global guidance by WHO in 2015 on the preferred combination of different ARV for first-line regimens for different types of populations living with HIV. The drugs that are in bold type are the first choice combination for the regimen in question:

RECOMMENDED FIRST-LINE ARV REGIMENS

For adults and adolescents (10-19 years)	Recommended regimen
Preferred Option	TDF + XTC + EFV ₆₀₀
Alternate Options	AZT + 3TC + EFV ₆₀₀ AZT + 3TC + NVP TDF + XTC + NVP TDF + XTC + DTG (New) TDF + XTC + EFV ₄₀₀ (New)
First-line therapy for children less than 3 years of age	
Preferred Option	ABC or AZT + 3TC + LPV/r
Alternate Option	ABC or AZT + 3TC + NVP
First-line therapy for children 3 years to less than 10 years <35kg	
Preferred Option	ABC + 3TC + EFV
Alternate Options	ABC + 3TC + NVP AZT + 3TC + EFV AZT + 3TC + EFV TDF + XTC + EFV TDF + XTC + EFV

*XTC = 3TC or FTC

Sometimes HIV drugs stop working. This is called treatment failure. Treatment failure occurs when an antiretroviral (ARV) regimen is unable to control HIV infection. This happens when HIV develops resistance to one or more drugs in a regimen. This means that the drugs can no longer stop the HI virus from reproducing. Treatment failure can be identified if a person's viral load is increasing, CD4 count is decreasing and/or if clinical symptoms (such as opportunistic infections) return.

If a first-line regimen fails, a person should switch to a second-line regimen. There are also third-line regimens that one switches to if second-line fails, but these drugs are usually very expensive. Countries are usually left to determine case by case which options would be desirable. The following summarizes global guidance by WHO in 2015 on the preferred combination of different ARV for second-line regimens for different types of populations living with HIV.

Recommended 2nd line ARV regimens:

Second-line therapy: **NRTI + NRTI + PI**

RECOMMENDED SECOND-LINE ARV REGIMENS

Second-line therapy for adults	
Preferred Options	ARV regimen (fixed-dose combinations are preferable) 2 NRTI + ATV/r or LPV/r (heat stable FDCs of boosted PIs are the preferred approach). The following sequence of 2nd line NRTI backbone options is recommended: · If in 1st-line, failure was with TDF + XTC, use AZT + 3TC · If in 1st-line, failure was with AZT + 3TC, use TDF + XTC
Second-line therapy for children less than 3 years of age	No change is recommended unless there is advanced clinical disease progress or lack of adherence specifically due to poor palatability of LPV/r
Second-line therapy for children 3 years to less than 10 years (<35kg)	
Preferred Options	AZT + 3TC + EFV if ABC/AZT + 3TC + LPV/r was the first-line regimen ABC or TDF (only for children older than 2years) + 3TC + EFV if AZT +3TC +LPV/r was the first-line option
Alternate Options	AZT + 3TC + LPV/r ABC or TDF + XTC + LPV/r

Side-effects of HIV treatment

It is normal that most people will experience some side effects when they first start treatment. Side-effects are the unwanted and unpleasant effects of HIV treatment. All medicines can cause side-effects. Not everyone taking ARVs will get side-effects, and, even when people do experience side-effects, they are usually mild, temporary and treatable.²³

Common side effects of ART are:²⁴

- **Diarrhoea**
This is a possible side-effect of most anti-HIV drugs. Avoiding coffee, raw vegetables and spicy foods can help with diarrhoea. There are also treatments available to help control diarrhoea, such as the anti-diarrhoea medicine loperamide (sometimes called Imodium).
- **Nausea (feeling or being sick)**
This is a possible side effect of most ARVs. Nausea can be treated with anti-emetics which help to prevent vomiting. These side-effects tend to be worst in the first few weeks after you start treatment and then often lessen or go away completely.
- **Mood and sleep problems**
Efavirenz (an NNRTI) can cause problems with sleeping, vivid dreams, and depression and anxiety. Rilpivirine (also an NNRTI) can cause mood changes and depression. These side-effects usually go away after a few weeks. However, some people will struggle to cope with these side-effects and will switch to an alternative treatment regimen.
- **Rash**
A skin rash is a side-effect of a number of anti-HIV drugs especially Nevirapine (NVP). These side-effects usually go away by themselves, but it is still important to tell a healthcare worker if someone taking ARVs develops a rash. This is because a rash can be a sign of an allergic reaction to ARVs, which can be dangerous.
- **Sexual problems**
Sexual problems (such as losing interest in sex, delayed orgasm, or difficulty getting and maintaining an erection) can be a side-effect of HIV treatment, but can also have other causes. There are drugs to help men get and maintain an erection (such as Viagra, Levitra and Cialis). These drugs can interact with ARVs, so people taking ARVs will usually be given a lower dose.
- **Tiredness**
Tiredness is usually worse in the first few weeks after someone starts a new HIV treatment, and usually goes away over time. Getting enough sleep, eating a good diet, and exercising regularly can help with tiredness.

Some side-effects only develop months or years after a person starts taking ARVs. These long-term side-effects include:²⁵

- Kidney problems: TDF can cause kidney disease
- Metabolic changes: Protease inhibitors can cause metabolic changes
- Heart disease: Protease inhibitors can cause heart disease
- Liver problems: Some HIV treatments which are processed by the body, using the liver can cause liver problems.
- Lipodystrophy: d4T can cause Lipodystrophy
- Peripheral neuropathy: d4T can cause peripheral neuropathy
- Bone problems: TDF can cause bone problems

It is important to tell your healthcare worker if you develop these or other problems while you are on ARVs.

It is important that a person continues to take their medication even if they are having side-effects. People should discuss their side-effects with their health care provider. Usually there is something a healthcare worker can do to help.

Once a person is on treatment, it is important to stay in touch with a healthcare professional to monitor progress, manage side effects or change treatment, if necessary.²⁶ Treatments are constantly improving and becoming easier for PLHIV to cope with, so²⁷ even if someone is experiencing side-effects, there is usually a treatment option that will be easier for them to take.

What is treatment as prevention?

Treatment as prevention (TasP) is a term used to describe HIV prevention methods that use ART to decrease the chance of a person passing on HIV to others. With TasP, HIV treatment is used for the benefit of both the person living with HIV and to protect HIV-negative people from HIV infection.

ART reduces the risk of passing on HIV because it decreases the amount of the virus in the blood, semen, vaginal and rectal fluids.²⁸ This reduces the chances of them transmitting HIV to other people.

TasP has been used for almost 20 years in the prevention of mother-to-child transmission (PMTCT) of HIV. By treating HIV-positive women during pregnancy, delivery and breastfeeding, it has been found that the risk of mothers passing on HIV to their babies can be reduced by up to 90%.

However, the growing emphasis on the role of HIV treatment as a method of HIV prevention is one of the most significant developments in HIV prevention strategies in recent years. Many experts and advocates now believe that treating people with HIV might be one of the most important strategies for HIV prevention, and ending the HIV epidemic.

Two important studies, the Strategic Timing of AntiRetroviral Treatment (START) study and the *HIV Prevention Trials Network Study 052* (HPTN 052) demonstrate the effectiveness of ARV treatment as a strategy for HIV prevention.

The results of the start START study were released in 2015. They demonstrated that starting ART as early as possible (rather than waiting for the person's CD4 cell count to fall below a certain point) reduces the risk of death and serious AIDS-related illness by 57%. The START study also showed that starting ART early reduces the risk of non-AIDS-related illnesses such as cancer and cardiovascular diseases. The START study demonstrated that ART is an important strategy to prevent AIDS-related and non-AIDS-related illnesses and death in PLHIV.

In 2011, the HIV Prevention Trials Network Study 052 (HPTN 052) showed that using ART can also have significant benefits for HIV prevention. The study showed that starting ART early reduced the overall risk of HIV sexual transmission to uninfected partners by 93%. This means that if a person living with HIV is taking ART, there is a huge reduction in their risk of transmitting HIV to their HIV-negative sexual partner. The study looked at 1763 HIV-serodiscordant couples. A serodiscordant couple is a couple where one partner is HIV-negative and one partner is HIV-positive. For some of the couples, the HIV-positive partner was started on ART straight away. For others, the HIV-positive partner was started on ART only when his or her CD4 cell count dropped below 250 cells/mm³ or when he or she was diagnosed with an AIDS-related illness. The results showed that ART is highly effective at preventing the transmission of HIV in heterosexual couples.

Combination HIV prevention is prevention that combines different prevention strategies (such as those that are behavioral, biomedical and structural) and which work at different levels (such as individual, relationships, community and societal). TasP is seen as an important strategy for ending the HIV epidemic. It is a critical part of combination HIV prevention.

Particular emphasis is given to TasP in communities or groups of people that bear the greatest burden of HIV infection. These include serodiscordant couples, pregnant women and members of key populations.

Adherence

Adherence means taking the correct drugs at the right time every day, for as long as necessary – as recommended, for example, by a doctor or community health worker.

For ARV treatment to work, it is very important that people take their medication every day, at the same time. Adherence is the most important aspect in determining the success of taking HIV treatment.

In HIV treatment, people usually take a combination of three anti-HIV medications (which are often combined into one tablet/pill) as described in Section 1.2. Adherence to an HIV regimen gives HIV medicines the chance to do their job: to prevent HIV from multiplying and destroying the immune system.

ARVs should be taken every day as close to the same time as possible. Poor adherence occurs when people take their pills too late, when they forget to take a dose, when they do not take all their pills, or when they stop taking their treatment. Poor adherence can also be caused by health system factors, such as when ARVs are not reliably available at the health facility, or when patients are treated badly by health care workers.

If an infected person does not take their ARVs every day at a chosen time, they will not have enough ARVs in their body to stop HIV from multiplying. This will reduce the number of CD4 cells in the body to fight off infections. If the level of ARVs in the body is too low, HIV is able to transform itself (mutate) so that ARVs no longer affect it, and the virus will start multiplying again. This means that the HIV has become resistant to the ARVs which the person is taking.

ARVs do not cure HIV, they suppress the reproduction of HIV, allowing the body's own defense system to get strong enough to fight off infection. So, adhering to treatment is vital to treating and managing the HIV infection. HIV treatment is not like some other chronic illnesses like diabetes where good outcomes can be achieved even when a person misses a few doses of medication. Effective HIV treatment requires PLHIV to adhere strictly to their treatment schedule to avoid complications. A person living with HIV must take drugs for their whole life, without any interruptions.

Adherence to HIV treatment is very important for a person living with HIV. This is because it helps them to:

- Avoid giving the virus a chance to weaken their immune system.
- Improve their health over a longer period of time.
- Adherence also helps to avoid the development of an HIV virus that is resistant to the types of ARVs that are currently available.

The benefits of being and staying on HIV treatment include that it can:

- Save and improve the quality of life of a person living with HIV.
- Enable families to improve their social and financial situation, for example because a parent living with HIV can go to work.
- Reduce the transmission of HIV from a person living with HIV to their sexual partner (see later in this Section).
- Save and improve the quality of life of a mother living with HIV and also prevent transmitting HIV to her baby.

What is Pre-Exposure Prophylaxis?

Pre-exposure prophylaxis (PrEP) involves providing a medical intervention before someone is exposed to a disease. The aim is to prevent them from becoming infected. PrEP is when ARV drugs are used to prevent a HIV-negative person from exposure to HIV. When the treatment is taken correctly PrEP can be extremely effective.

PrEP is a method for HIV prevention. New WHO guidelines recommend that an oral (pill or tablet) which contains tenofovir disoproxil fumarate (TDF) should be offered to those at a substantial risk of becoming infected. Usually it is combined with emtricitabine FTC.

It is important that PrEP is used in addition to other prevention measures such as HIV testing and counselling, male and female condoms, lubricants, ARV treatment for partners with HIV infection, voluntary medical male circumcision, and harm reduction interventions for people who use drugs.

What is post-exposure prophylaxis?

Post-exposure prophylaxis (PEP) is an intervention that uses treatment to reduce the likelihood of HIV infection after possible exposure through, for example, accidental needle pricks, cuts with sharp contaminated objects or sexual intercourse. PEP is also used to treat people who may have been exposed to the HIV-infected fluids through events such as, sexual assault, unprotected sex or sharing injection needles. PEP is usually taken as a short-term ARV treatment.

There are 2 types of PEP. These include:

1. Occupational PEP (sometimes called "oPEP"), taken when someone working in a healthcare setting is potentially exposed to material infected with HIV
2. Non-occupational PEP (sometimes called "nPEP"), taken when someone is potentially exposed to HIV outside the workplace (e.g., from sexual assault, during episodes of unprotected sex or needle-sharing injection drug use).

For effective protection, PEP must be started within 72 hours of exposure, before the virus has time to multiply in the body.

PEP consists of a combination of ARVs that are taken for 28 days. Some researchers suggest retesting after 4 weeks and then after 12 weeks. National guidelines should be followed to ensure the effectiveness of treatment.

WHO recommends a three drug PEP regimen, but acknowledges that a two-drug PEP regimen is effective.

RECOMMENDED REGIMEN FOR PEP FOR ADULTS, ADOLESCENTS AND CHILDREN

Preferred antiretroviral regimen for PEP for adults and adolescents	An HIV post-exposure prophylaxis regimen with two antiretroviral drugs is effective, but three drugs are preferred. TDF + 3TC (or FTC) is recommended as the backbone regimen for HIV PEP in adults and adolescents. LPV/r or ATV/r are suggested as the preferred third drug for HIV PEP in adults and adolescents. Where available, RAL, DRV/r, or EFV can be considered as alternative options.
Preferred antiretroviral regimen for PEP for children ≤10 years	ZDV + 3TC is recommended as the preferred backbone for HIV PEP in children aged ≤10y. ABC + 3TC or TDF + 3TC (or FTC) can be considered as alternative regimens LPV/r is recommended as the preferred third drug for HIV PEP in children aged ≤10 y. An age-appropriate alternative regimen can be identified among ATV/r, RAL, DRV, EFV, and NVP.

Exposures that do not require HIV PEP include:

- If the exposed person is already HIV positive
- When the source is established to be HIV negative
- When a person has been exposed to body fluids that do not pose a high risk, e.g. tears, non-blood stained saliva, urine, and sweat

The exposed person should receive counselling on ways to limit future exposure even where PEP is not required. HIV testing may be provided if the person wishes to be tested, even though the test may not be required.

SECTION 1.3. Monitoring HIV Treatment

SECTION OBJECTIVE

To build community activists' understanding of the importance of HIV monitoring and how routine viral load testing is used to monitor HIV treatment. Community activists should be able to explain to PLHIV how they can tell if their HIV treatment is working, including: why viral load testing is important, what the World Health Organization recommends about viral load testing and the current situation regarding access to routine viral load testing.

TRAINING MATERIALS

To build community activists' understanding of the importance of HIV monitoring and how routine viral load testing is used to monitor HIV treatment. Community activists should be able to explain to PLHIV how they can tell if their HIV treatment is working, including: why viral load testing is important, what the World Health Organization recommends about viral load testing and the current situation regarding access to routine viral load testing.

- PowerPoint presentation '1.3. Monitoring HIV Treatment'

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objectives of the Section.
2. Present PowerPoint presentation '1.3. HIV Monitoring?'
3. Divide the participants into two groups. Ask each group to summarize the session in two or three key advocacy messages. Support their ideas by sharing examples of messages (see below).

Option B (approx. 120 minutes)

1. Explain the objectives of the Section.
2. Present PowerPoint presentation '1.3. HIV Monitoring?'
3. Ask the participants to divide into pairs and to discuss the key points of what they have learnt about monitoring HIV treatment, including:
 - What is the best way to monitor HIV treatment?
 - How often a person's viral load should be tested.
4. Ask the participants to summarize the session by developing advocacy messages about 'the importance of monitoring HIV treatment.' Support their ideas by sharing examples of messages (see below).

ADVOCACY MESSAGES

- The goal of taking ARV treatment is to have a suppressed (undetectable) viral load. An undetectable viral load is when there are so few copies of HIV in your blood, that it cannot be detected by the viral load test. This however doesn't mean you don't have HIV
- Once you have started treatment, it is important to check (monitor) if your ARV treatment is working. The best way to monitor your ARV treatment is to take a viral load test every 6-12 months.
- Adhering to HIV treatment, by taking your ARVs every day at the same time, is key to ensuring that the treatment works and that you are virally suppressed

USEFUL RESOURCES

- Activist Toolkit: Campaigning for Routine Viral Load Monitoring, ITPC, 2015. Available here: <http://itpcglobal.org/wp-content/uploads/2016/05/ITPC-RVLT-Toolkit-English.pdf>
- ITPC's Be Healthy, Know Your Viral Load campaign. Available here: www.knowyourviralload.org
- HIV/AIDS and antiretroviral treatment, Mediciens sans Frontieres, 2015. Available here: https://www.dropbox.com/sh/lkgjyf6035wef/AABDyii-NZWLYI7b-Myxfbjfa/Annex%207_Patient%20education%20tools/MSF%20ARV%20Flipchart%20Dec2014.pdf?dl=0
- Getting to Undetectable: Usage of HIV Viral Load Monitoring in Five countries, Mediciens Sans Frontieres. Available here: https://www.dropbox.com/sh/lkgjyf6035wef/AABuixtLGZvYfnFEbMv1ZRHa/Annex%206_Advocacy%20materials/HIV_MSF_IssueBrief_Getting%20to%20undetectable.pdf?dl=0
- Treatment Training for Advocates. Chapter 2: Virology, HIV and Viral Load, i-base. Available here: <http://i-base.info/ttfa/section-2/>
- The Need for Routine Viral Load Testing: Questions and Answers, UNAIDS, 2016. Available here: http://www.unaids.org/sites/default/files/media_asset/JC2845_en.pdf

WHY MONITOR HIV?

It is important to keep track of how well your body is fighting the HI virus. If a person has not yet started treatment, HIV monitoring can tell them that it is time to start taking ARVs. If a person is already on ARVs, HIV monitoring is important to make sure the treatment is working.

ARVs stop HIV from making copies of itself inside the body. When the ARV treatment is fighting HIV, there will be fewer copies of the virus in the person's body. The goal of ARV treatment is to have an undetectable viral load. This means that there are so few copies of the virus in the person's blood that HIV viral load tests can't detect any of them. This does not mean that the person is cured. There will still be some of the virus in the person's body, and if the person stops treatment, their viral load will start to increase and they will get sick. However, an undetectable viral load does mean that there are not enough copies of the virus in the person's blood to make them sick. When this happens, we say that person is virally suppressed. Taking ARVs is the best way to reach viral load suppression.

There are two ways to monitor HIV: CD4 testing and viral load testing.

1. CD4 testing

A CD4 count can be used to help decide when a person needs to start HIV treatment. Once the person has started treatment, the CD4 count will give an indication of how successful the treatment is.

A CD4 cell count tells you how strong the immune system is, by showing you how many CD4 cells ('soldiers') are in the body. A healthy person has between 600 and 1500 CD4 cells/mm³. A person who is sick with HIV has between 0 and 500 CD4 cells/mm³.

CD4 testing has been the most common way to monitor how well a person is responding to ARV treatment, especially in resource-poor settings. However, a **CD4 count test is a measurement of people's CD4 white blood cell count, not a direct measure of how much HI virus is in the blood.** This means that **CD4 tests do not paint an accurate enough picture of how a person is responding to ARV treatment.** CD4 testing should only be used to monitor HIV treatment if there is absolutely no viral load testing available.

2. Viral load testing

HIV infection can also be monitored through a person's viral load. **This involves counting how many copies of the virus are present in their blood.** The higher the viral load, the more the immune system is in danger of being weakened.

The best way to tell if your ARV treatment is working is to have regular viral load tests. This is because a viral load test shows how much HIV is still in the person's blood. It is used routinely in developed countries, but in many resource-limited countries, it is not available due to cost and other barriers.

WHAT DO VIRAL LOAD TEST RESULTS MEAN?

The viral load result is usually reported as the number of HIV particles (copies) per milliliter of blood (copies/ml). The test will indicate how many copies of the virus can be found in a very small amount of a person's blood.

The aim of taking ARV treatment is to have a low or undetectable viral load. This means that the HIV has stopped making more copies of itself in the body because of the effectiveness of ARV.

1. A low or undetectable viral load result:

A viral load of less than 1000 copies per ml, is a low viral load. An undetectable viral load (less than 50/40/20 copies per ml, depending on the machine) usually means that there is a lower number of HIV in your blood than what can be detected by the viral load test used.

An undetectable viral load does not mean that you have no HIV in your blood: it only means that there is so little HIV in your blood, that the current tests we have cannot detect it. This means that your HIV is not multiplying in your body and that your ARV treatment is working.

2. A high viral load result:

A high viral load is any result above 1000 copies per ml. A high viral load result means that HIV is multiplying, even though you are taking your treatment.

This could mean that the infected person is facing some problems in taking their treatment correctly every day (non-adherence). This has been found to be the most common reason for a high viral load. The infected person and their health care worker or peer supporter can address adherence problems early, which should bring the infected person's viral load down to low or undetectable.

In a few cases, you could be taking your ARV medication correctly (being adherent), but you have become resistant to your treatment. This means that the HIV has learnt how to multiply in your body, even when you are taking your treatment correctly. In this case, your health care provider can change your medication.

If a person's viral load hasn't fallen to undetectable levels within three to six months of starting HIV treatment, it means that the treatment is not working properly. This might be because the person is not staying adherent on their treatment, or because something else is preventing the treatment from working. It might be the case that the treatment is not working properly because the person is taking other drugs – including prescription, over-the-counter, herbal or recreational drugs – at the same time.

Not taking treatment regularly, or interactions with other drugs, can cause the levels of anti-HIV drugs in the body to be too low to work. A blood test may be necessary to check the level of anti-HIV drugs in the blood in order to find out whether the HIV has developed resistance to the treatment.

Treatment is said to failing when a person's viral load test result shows 1000 copies/ml for two consecutive viral load measurements after 3 months of ARV treatment, even when a person has been receiving adherence support.

WORLD HEALTH ORGANIZATION (WHO) RECOMMENDATIONS FOR MONITORING HIV TREATMENT

Guidelines for ART management issued by the World Health Organization (WHO) have recognized the importance of viral load monitoring; and in 2013, routine viral load testing was more strongly recommended as the monitoring strategy for ART than ever before. The 2015 guidelines recommendations built on this and are summarized below:

- **Routine viral load testing should be used instead of CD4 count testing**
- Viral load testing should be done 6 months after the person starts ARV treatment. After that, the person should do another VLT 6 months later and thereafter have a routine viral load once every 12 months.
- Every person should receive a viral load test once a year as part of the routine follow up of HIV-positive people on ART.
- If a person's viral load is found to be high (above 1000 copies/ml) through any of these tests, another viral load test should be taken 3 months later. Adherence support should be provided between viral load tests.

Viral load monitoring is important for monitoring how well the ARV treatment is working. It is the earliest indicator for showing whether the virus is reproducing. Only after the viral load has been increasing for some time does this lead to a drop in the CD4 cell count. As such, viral load is the preferred monitoring strategy for patients on ARV, over CD4 cell count.

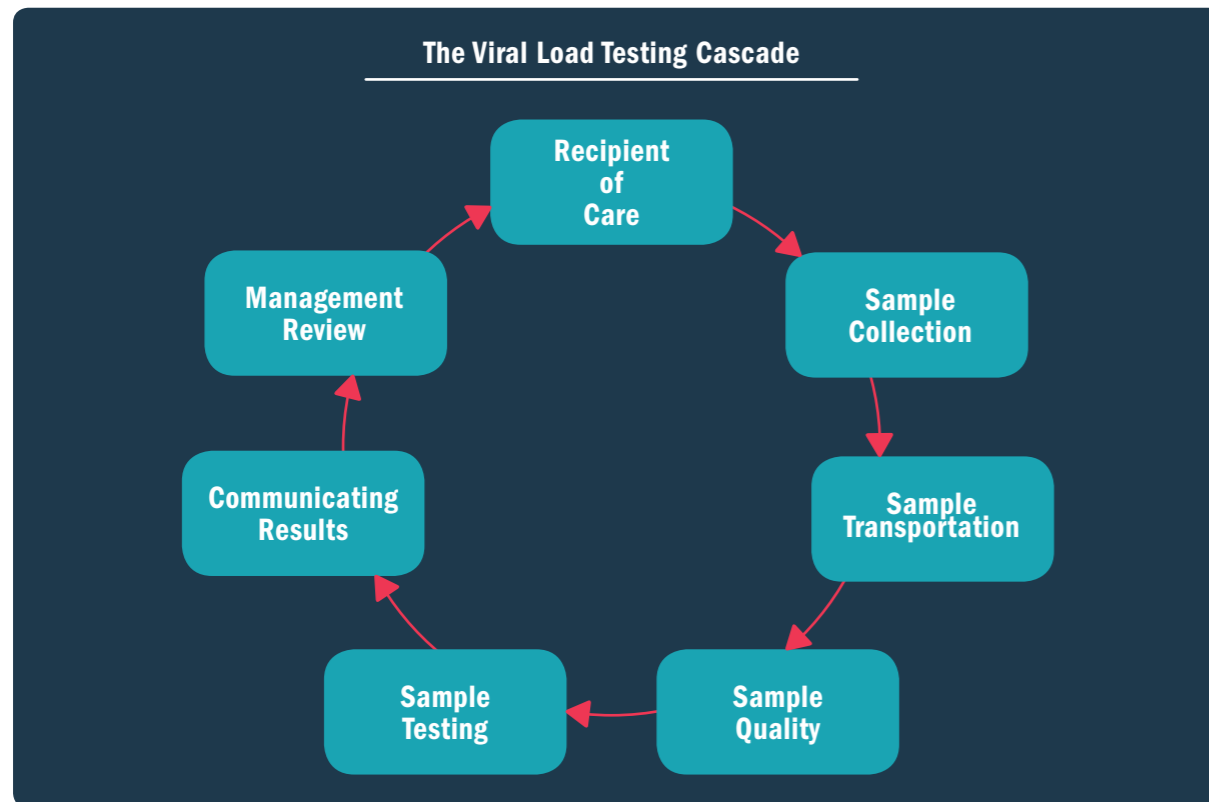
1. A high viral load result can be an indication (sign) that the person may be having difficulties with their treatment adherence. This allows an opportunity for adherence support. Providing adherence support to people with a high viral load often leads to viral suppression, according to data from MSF sites in South Africa.
2. Viral load testing also helps to identify people who are indeed failing their treatment and need to be switched to another set of medicines.

Viral load monitoring can identify these problems much sooner than CD4 testing. It is better to not wait for the body to reveal problems with the immune system or to show clinical signs of treatment failure. This misses an ideal opportunity to provide additional adherence counselling or, where necessary, to change to second-line treatment.

Viral load testing avoids people having a high viral load that stays high for a long time, and can prevent people from switching to more expensive and complicated regimens when it is not necessary. It also prevents illness and potential transmission of HIV.

TABLE 5: THE BENEFITS OF VIRAL LOAD TESTING

The benefits for viral load testing	
For people living with HIV	Knowing if their treatment is working. Receiving adherence support to reach an undetectable viral load, if necessary. Switching to a different ARV regimen early, before the person gets sick, if they have drug-resistance.
For treatment providers	Viral load testing means the health care provider will know if the treatment a person is taking is not working. The health care provider can then provide additional adherence support or switch the person's treatment, when necessary.
For programme managers	Better information about treatment adherence and health outcomes across the programme. Assists in identifying areas that need more attention.
For policy-makers and national governments	Monitoring of community-wide progress towards viral suppressions. Assists in identifying areas that need more attention. Allows for a decrease in unnecessary spending on incorrectly switching regimens.
For donors	Can reduce global HIV incidence by reducing viral transmission within communities. Allows for a decrease on unnecessary spending on incorrectly switching regimens.



HIV VIRAL SAMPLE PREPARATION AND LABORATORY TESTING

Samples for viral load testing collected from patients, can be sent from health facilities to the laboratory as whole blood or as a Dried Plasma Spot (DBS). Unlike whole blood samples, DBS samples have less strict requirements for transport and storage and are the preferred sample types for the scale up of HIV viral load testing. Nonetheless, only a handful of machines in the laboratory can accurately provide viral load results from DBS samples.

Currently, viral load testing is still largely conducted in central laboratories with sophisticated equipment and highly trained technicians. There are different techniques and machines available for measuring viral load. Most of the laboratory machines calculate HIV viral load based on the Polymerase Chain Reaction (PCR) technique; which quantifies HIV by amplifying the target nucleic acid. It is the most commonly used viral load testing technique.

Complexity and costs of reagents and machines have been barriers to scaling up viral load testing in developing countries. The turn-around-time (TAT) for a viral load result varies, according to: laboratories, availability of reagents, testing backlog and equipment function, amongst other factors. However, experience from MSF-supported laboratories has shown TAT of between 7 days to 14 days, depending on the area or country.

Viral load test blood samples are sent to a centralized laboratory that sends the results back to the health-facility. This can cause delays in getting results and can cause patients to be lost to healthcare workers, or fall out of the HIV treatment cascade because they need to return to the health facility on a different day to receive their viral load test results.

There is a global move to demand the development and implementation of a viral load test that can be

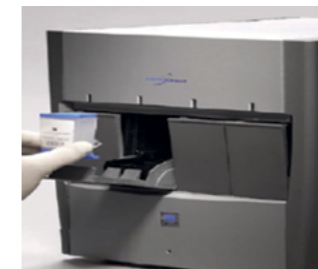
used and analyzed in health facilities (without being sent to the laboratory), in a decentralized manner. This is called point-of-care (PoC) viral load testing.

New viral load point-of-care diagnostics have been developed and others are under development. These new technologies hold the potential to simplify ARV treatment monitoring as they bring viral load testing closer to the patient, which could accelerate clinical decision-making. These PoC machines are less expensive, are smaller and less complicated to use.

According to the **WHO ASSURED** criteria, point of care testing should be:

- A: Affordable**
- S: Sensitive (never giving a negative response when the result is truly positive)**
- S: Specific (never giving a positive response when the result is truly negative)**
- U: User-friendly**
- R: Rapid and robust (must provide the results as soon as possible)**
- E: Equipment-free**
- D: Deliverable to those who need it**

Examples include:



A. GeneXpert HIV viral load testing



B. SAMBA PoC for viral load testing

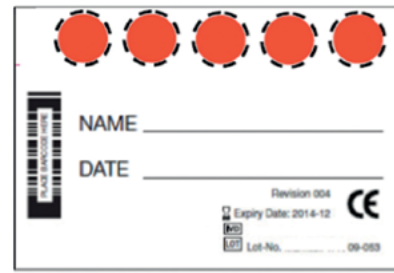


C. ALERE PoC Tool

WHAT PROCEDURES ARE FOLLOWED TO ADMINISTER A VIRAL LOAD TEST?

Trained medical staff draw blood from a vein with a syringe and use the following technique:

- a. Dried Blood Spot (DBS) sample:** blood collected using a syringe can be directly applied, gently, to fill each of the 5-circles of the DBS card as shown in the figure below. Care must be taken to make sure the circles do not touch each other when blood is being applied. The DBS card should be left to dry for 4 hours and the samples can be kept at room temperature for 1-2 weeks or for longer at lower temperatures, before being sent to the laboratory.
- b. Whole blood and/or plasma samples:** blood collected through a syringe should be immediately put into anti-coagulated tubes for preservation. The samples should reach the laboratory within 6 hours of collection, if kept at room temperature, or the sample can be separated into plasma (only in health facilities with small laboratories that can centrifuge the blood), which can be stored for up to 5 days at 4 degrees Celsius.



DBS Sample for HIV viral load enumeration



Anti-coagulated blood sample for HIV viral load enumeration

ISSUES WITH ACCESS TO ROUTINE VIRAL LOAD TESTING

Unfortunately, despite the 2013 World Health Organization recommendations of HIV viral load test as the preferred ARV monitoring tool, it is still not routinely available to many HIV-positive people, especially in low and middle-income countries. MSF, ITPC and their partners have been conducting surveys to assess the extent to which routine viral load testing is available in resource-limited settings.

MSF conducted an analysis of survey data on access to viral load testing across 47 MSF projects in 15 resource-limited countries. Only 61% of the projects had some access to viral load testing, but this was used mainly in a targeted way to confirm treatment failure, following clinical or immunological failure before switching to second-line ART. Another 2012 internal review of MSF data from 12 countries found that only 2% of patients had ever received a viral load test result.

ITPC and ARASA also conducted a survey of 12 African countries by community research teams. Eight of the countries reported the existence of a government policy of the WHO guidelines regarding routine viral load testing. However, the survey found that only three countries actually provided routine viral load monitoring. The survey also found that people were asked to pay for viral load testing in eight of the countries.

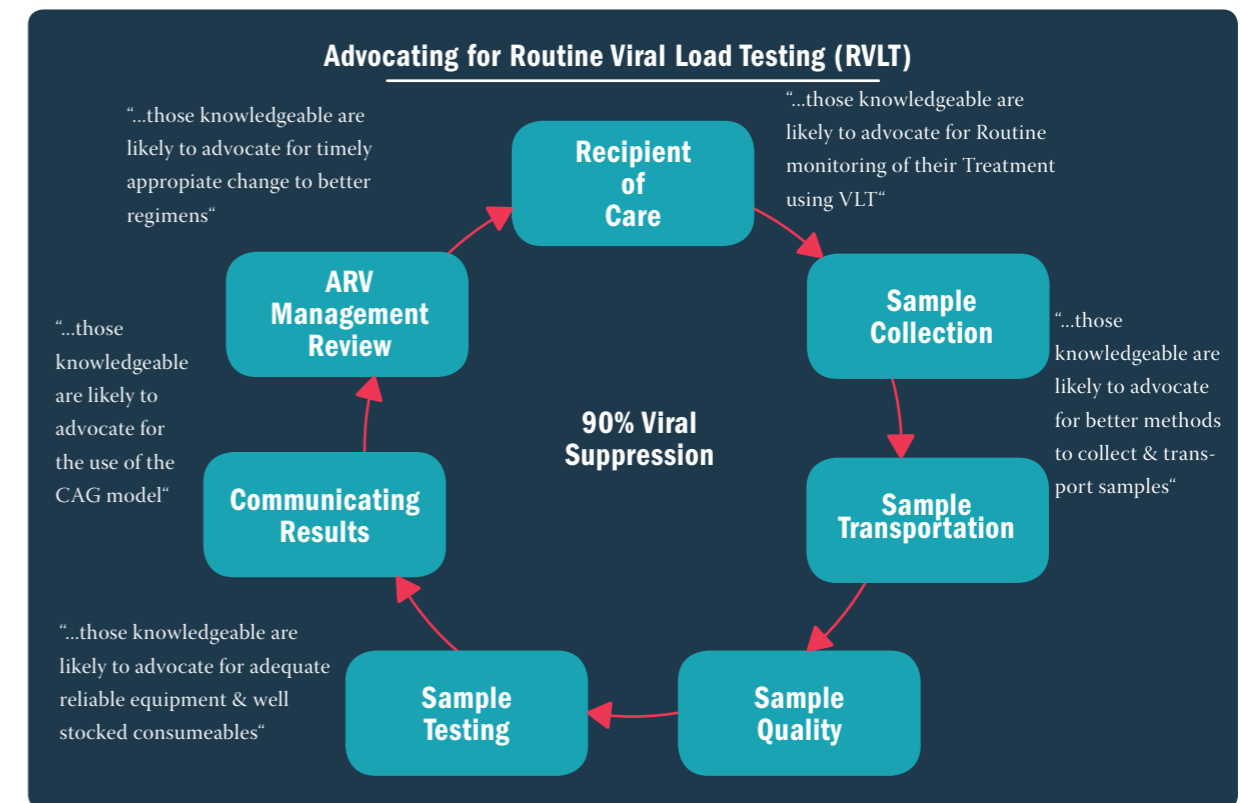
In addition, the survey found that in the majority of cases, viral load tests were only done when knowledgeable PLHIV requested them. This is problematic as very few people know about the importance of viral load testing, so most people will not request them. This finding is the basis for providing knowledge through various treatment education forums to strengthen communities to demand access to routine viral load testing.

WHY DO PEOPLE NOT HAVE ACCESS TO VIRAL LOAD TESTING?

There are many reasons why people do not have access to routine viral load testing. These reasons are different from place to place and will depend on the contextual factors.

- Viral load tests are often not available in HIV clinics.
- The high price of a viral load test (at US\$14-US\$85 per test) is unaffordable to most people who need it.
- The equipment for monitoring viral load is expensive and requires infrastructure, electricity and experienced laboratory technicians.
- The consumables, like reagents and other products, needed to carry out the tests often run out because of poor planning and re-stocking management.
- There is a low level of awareness among health practitioners and PLHIV, about the importance and availability of routine viral load monitoring.

It is important to know and understand why routine viral load testing is not available in your country, based on the context-specific issues. Mapping out these reasons will help inform the advocacy priorities you take on in your viral load campaigns.



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- ⁵⁰How Viral Load Testing can Improve HIV Treatment in Developing Countries, Médecins Sans Frontières, 2012. <http://www.msfacecess.org/content/undetectable-how-viral-load-monitoring-can-improve-hiv-treatment-developing-countries>
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2 HIV CO-MORBIDITIES

Welcome to **Module 2: HIV Co-morbidities of the Advocacy for Community Treatment (ACT) Toolkit** of the International Treatment Preparedness Coalition (ITPC).

The aim of Module 2 is to strengthen community activists' understanding of the common illnesses associated with HIV and the best ways to prevent and treat these illnesses in people living with HIV. Because HIV weakens a person's immune system, people living with HIV are vulnerable to certain infections and cancers. These include opportunistic infections (such as Tuberculosis, Hepatitis, oral thrush; malaria; and fungal pneumonia) and cancers (such as Kaposi's Sarcoma, Non-Hodgkin Lymphoma, and cervical cancer). This section will focus on Tuberculosis and Hepatitis C Virus.

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CHAPTER 2.1. What is TB/HIV co-infection?

CHAPTER OBJECTIVE

To build community activist's knowledge of Tuberculosis (TB) and how TB is linked to HIV/AIDS. This section will also discuss the methods for preventing, diagnosing and treating TB in people living with HIV, and the common issues facing people living with HIV and TB.

TRAINING MATERIALS

- PowerPoint presentation '2.1. What is TB/HIV co-infection?'
- Flipchart and pens (for training **option A**)
- Paper and bowl or basket for collecting pieces of paper (for training **option B**)

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objective of the Chapter.
2. Facilitate a discussion on TB. Encourage the participants to discuss what they know about TB, and about the link between TB and HIV.
3. Present PowerPoint presentation '2.1. What is TB/HIV co-infection?'
4. Facilitate a group discussion on TB prevention and treatment, and the issues affecting people who are co-infected with TB and HIV. Encourage the participants to think about what could be done to make things easier for these people.
5. Write these suggestions on the flipchart.
6. Ask the participants to summarize the session by developing advocacy messages about 'What is TB-HIV co-infection?' Support their ideas by sharing examples of messages (see below).

Option B (approx. 120 minutes)

1. Explain the objective of the Chapter.
2. Divide the participants into 'buzz groups' of 2-3 people. Ask them to discuss and write down on separate pieces of paper 2 or 3 things they know about TB, and 2 or 3 things people in their communities commonly believe about TB. These might be common misconceptions or misunderstandings about TB and how it relates to HIV.
3. Collect all the pieces of paper and put them in a bowl
4. Present PowerPoint presentation '2.1. What is TB/HIV co-infection?'
5. Read out the pieces of paper, and ask the participants to tell you whether the statement on the piece of paper is true or false. If the participants think something is true when it is not, explain further and vice-versa.
6. As a group, discuss the common misconceptions about TB and how it relates to HIV. Encourage the participants to think about how these misconceptions and misunderstandings affect people who are co-infected with HIV and TB.
7. Ask the participants to summarize the session by developing advocacy messages about 'What is TB/HIV co-infection?' Support their ideas by sharing examples of messages (see below).

KEY MESSAGES

- PLHIV are very vulnerable to TB infection, because they have weakened immune systems.
- The equipment and resources needed to test for TB, especially TB in PLHIV and drug-resistant TB, are often not available to those who need them.
- There are many ways to treat people who are co-infected with TB and HIV.
- Isoniazid Preventive Therapy, Intensified Case Finding and Infection Control, known as the 3 I's, are important ways to prevent TB in PLHIV

USEFUL RESOURCES

- *Leaflet: HIV and TB*, NAM. Available here: <http://www.aidsmap.com/TB-and-HIV/page/2258313/>
- *Facts: Tuberculosis*, WHO Global Tuberculosis Report 2015. Available here: http://www.who.int/tb/Global_TB_Facts.pdf?ua=1
- *Guidelines for Treatment of Tuberculosis: Fourth Edition*, WHO, 2010. Available here: http://apps.who.int/iris/bitstream/10665/44165/1/9789241547833_eng.pdf?ua=1&ua=1
- *Victory for TB Patients as Court Declares that TB is not a Crime*, KELIN, 2016. Available here: <http://www.kelinkenya.org/2016/03/victory-tb-patients-court-declares-tb-not-crime/>
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- *Two Diseases, One Fight: The TB-HIV Co-infection*, Stop TB Partnership. Available here: <http://www.stoptb.org/assets/documents/events/meetings/IAS2014/Stop%20TB%20Partnership%20TB%20and%20HIV%20Flier.pdf>
- *TB Tests: Skin Test, Sputum & Other Types of TB Test*, TBfacts.org. Available here: <http://www.tbfacts.org/tb-tests/>
- *An Activist's Guide to Tuberculosis Drugs*, Treatment Action Group, 2014. Available here: <http://www.treatmentactiongroup.org/sites/g/files/g450272/f/201406/An%20Activist%27s%20Guide%20to%20Tuberculosis%20Drugs%20V9.pdf>

SECTION 2.1.1. What is TB?

Tuberculosis (or TB) is a disease caused by a bacteria called Mycobacterium Tuberculosis (MTB). Unlike other bacteria, MTB is difficult to kill. It has a fatty cell wall, which is difficult for most drugs (antibiotics) to penetrate. The cell wall also means the bacteria can survive for up to a few weeks outside of the body. In figure 1, below, you can see the fatty cell wall (gray), protecting the inside of the cell (the plasma membrane in turquoise, and the ribosomes in light mint). MTB causes a disease called Tuberculosis.

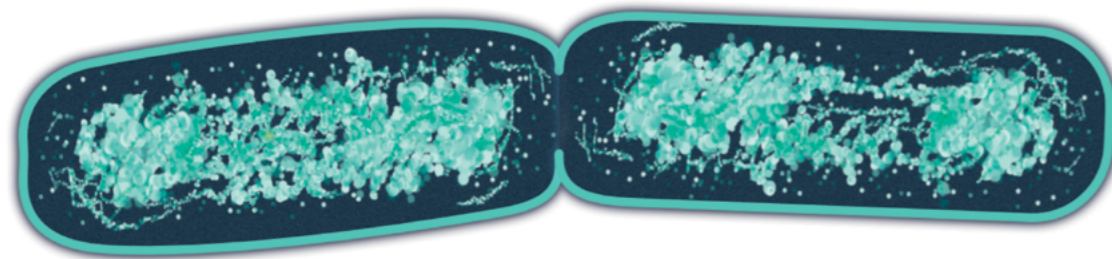


Figure 1: TB bacteria¹

TB is a preventable and treatable disease. However, for TB to be successfully treated, it has to be diagnosed correctly and timely way and treatment must be made available.²

TYPES OF TB INFECTION

There are two types of TB infection; latent TB and active TB. Although MTB can cause TB disease, many people who get infected with the TB bacteria do not get sick. This is because most people's immune systems are strong enough to prevent the bacteria from spreading throughout the body.

Latent TB

When somebody gets infected with MTB by inhaling it through the air, the bacteria infect a small part of the lung. Although the immune system cannot kill the bacteria, in most cases, the immune system is strong enough to stop the bacteria from spreading.³ This is called latent tuberculosis. When somebody has latent TB, they do have TB bacteria in their body, but they are protected by their immune system and do not become ill. Because latent TB is not TB disease, it cannot spread from person to person.

About one third of people in the world have latent TB. About 80% of people infected with TB will not develop TB disease.⁴

Active TB

Some people with latent TB will develop TB disease (active TB). This can happen years or decades after the person first got infected with TB.⁵ In other words their immune system is no longer preventing the bacteria from spreading. It is often older or very young people or people living with HIV who develop TB disease. This is because they have compromised immune systems. People that do have active TB are referred to as having active TB disease. About 10-30% of people infected with TB (latent TB) will develop active TB disease.⁶ When we say a person 'has TB', we usually mean they have active TB disease.

There are two types of active TB disease, pulmonary (where TB develops in the lungs) and extra pulmonary (where TB develops in organs outside the lungs).

How common is TB?⁷

Globally, in 2014, about 9.6 million people had TB, including approximately 1 million children. About 1.5 million people died of TB in 2014⁸. Of the people who died of TB, nearly a third (400 000) were PLHIV.



9.6 MILLION
People fell ill with TB
in 2014



1.2 MILLION
People living with
HIV developed TB

IN 2014
WITH 0,4 MILLION
ASSOCIATED DEATHS

Globally, the treatment success rate for people newly diagnosed with TB was 86% in 2013. However, many people with TB are not diagnosed and do not have access to treatment.

Factsheet: Tuberculosis, World Health Organisation, 2015

Pulmonary TB

Pulmonary TB is the most common type of TB. About 80% of reported TB cases are Pulmonary TB. Pulmonary TB is infectious, meaning it can spread from one person to another.

Pulmonary TB is transmitted (spread) through the air from person to person. This can happen when a person with active TB disease coughs, sneezes, talks, or sings. When this happens, MTB are released into the air, where they can be inhaled (or breathed in) by others. Those that inhale the TB bacteria can become infected with TB (latent TB)⁹. Figure 2 shows how this can happen when somebody with pulmonary TB sneezes.

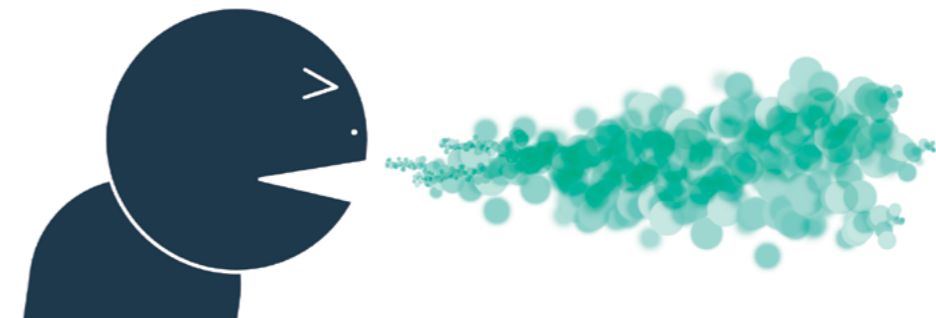


Figure 2: How is TB Spread?¹⁰

Extra-pulmonary TB

Sometimes the TB bacteria spreads to parts of the body other than the lungs, including bones, liver, spleen, or the lining covering the brain. This is called Extra-pulmonary TB. Extra-pulmonary TB is not infectious.

Drug-susceptible and drug-resistant TB

TB can usually be cured with a combination of antibiotics.¹¹ For the treatment to be successful, the patient must take the TB treatment for 6 months without missing any doses. TB bacteria can become resistant to common anti-TB drugs. This means that the TB bacteria are no longer affected by the drugs. This can happen randomly or when someone misses doses of their anti-TB treatment.¹²

The most commonly used, affordable and widely available TB drugs are called first-line TB drugs. TB that can be treated with these first-line drugs is called drug-susceptible TB. When the TB bacteria becomes resistant to one kind of TB treatment, it is called drug-resistant TB.¹³

Sometimes, TB bacteria become resistant to more than one of the common, first-line anti-TB drugs. Multi-drug resistant TB, or MDR-TB is when a person's TB is resistant to Isoniazid and Rifampicin, the two strongest and most commonly used TB drugs (usually taken with Ethambutol and Paryzinamide).

MDR-TB is very difficult to treat. The anti-TB drugs to treat MDR-TB are more expensive, have more side-effects, and are less effective. The drugs used to treat MDR-TB are called second-line drugs.¹⁴

Extensively drug-resistant tuberculosis or XDR-TB is TB that is resistant to all the first-line TB drugs, and at least one of the second-line TB drugs. Second-line TB drugs are the drugs used to treat multi-drug resistant TB.¹⁵

How do people get MDR-TB or XDR-TB

Many people think that when someone has MDR-TB or XDR-TB it is their own fault because they did not take their TB medication properly. It is important to remember that there are two ways people get MDR-TB and XDR-TB. They can develop MDR-TB or XDR-TB because they miss some doses of their treatment, which may not be their fault, or because their treatment doesn't work properly because of interactions with other drugs. People can also get infected with MDR-TB or XDR-TB from someone who already has MDR or XDR-TB.

Globally in 2014, an estimated 480,000 people developed multidrug-resistant TB (MDR-TB) and there were an estimated 190,000 deaths from MDR-TB. 123,000 people were diagnosed with MDR-TB in 2014, about a quarter of the total 480,000 new cases of MDR-TB that occurred in 2014.

HOW DOES TB INFECTION HAPPEN?

1. Somebody inhales (or breathes in) TB bacteria

- TB bacteria are very small and weigh very little. When TB bacteria are released (when somebody with active TB coughs or sneezes) they can float in the air for up to 8 hours.
- Infection occurs when a tiny drop of moisture containing the TB bacteria is inhaled by somebody and travels into their lungs. Inside the lungs are small air sacs called alveoli. These can be seen in Figure 3, below. The small red cells represent MTB or TB bacteria, and the large green cells are macrophages. When the TB bacteria reaches the alveoli it is surrounded by macrophages.

What is a macrophage?

A macrophage is a specialized cell. Its job is to recognize, surround and destroy infections or foreign cells in the body. It is a type of white blood cell, and it is usually found where there is an infection.

2. The immune system surrounds and attacks the TB bacteria

- At this stage, the macrophages are not active, so they surround the MTB but cannot kill it.

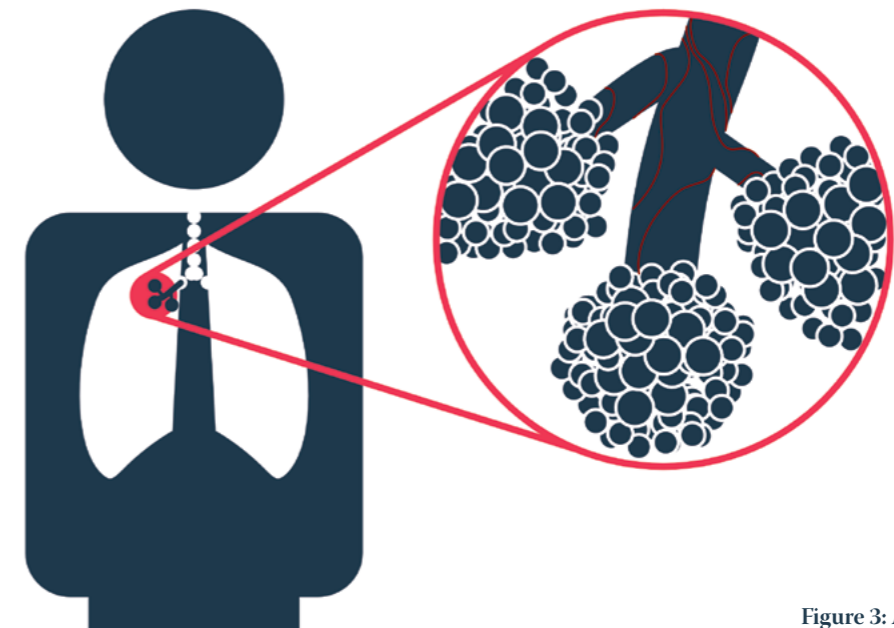
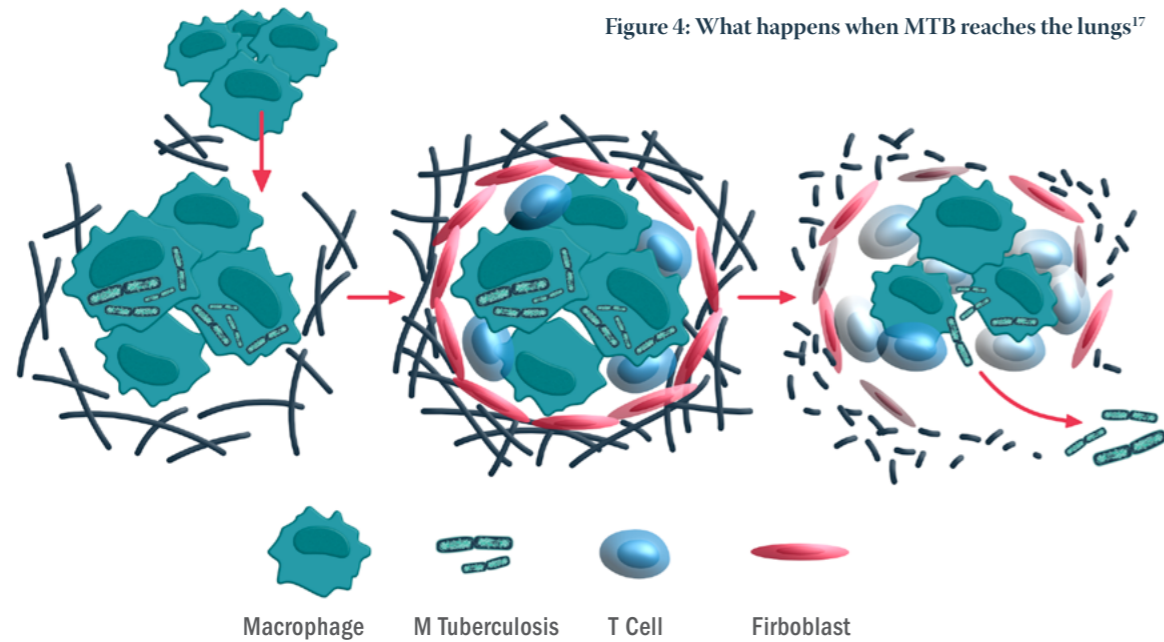


Figure 3: Alveoli in the lungs¹⁶

- Next, lymphocytes (or T cells) arrive at the site of infection. Lymphocytes are similar to macrophages – they fight infection – but macrophages are found in hard and soft tissue, while lymphocytes move around in the blood. The lymphocytes help the macrophages to kill some of the TB bacteria.



- The inside of the granuloma becomes soft, with a cheesy consistency. The TB bacteria cannot reproduce in this environment. In people with a strong immune system, more than 90% of the TB bacteria will be contained in this way (stay latent). In most cases the granuloma stops the TB from reproducing. When this happens we say the person has latent TB (see Figure 4 above).

3. In some cases, the TB bacteria start to reproduce.

- Sometimes, the TB bacteria multiply or reproduce. This causes the granuloma to grow and the inside of the granuloma becomes filled with air. TB bacteria can grow and multiply in the air pocket inside the granuloma (see Figure 4 above).

4. TB bacteria spreads to other parts of the body.

- When TB continues to multiply rapidly, the granuloma can break open and the TB bacteria spills into other parts of the lungs and body (see Figure 4 above).

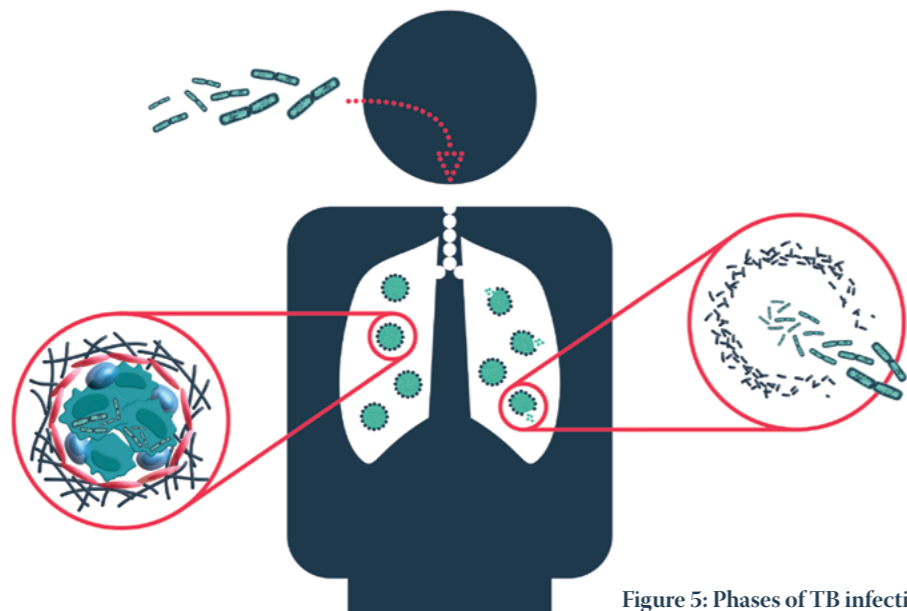


Figure 5: Phases of TB infection in the lungs¹⁸

SIGNS AND SYMPTOMS OF TB

The main symptoms for pulmonary TB are:

- Fever and chills
- Night sweats
- Loss of appetite
- Fatigue or tiredness
- Cough (persistent and productive – produces phlegm and lasts more than 2 weeks or coughing up blood)
- Unexplained weight loss

SUMMARY: WHAT IS TB?

- MTB, the TB bacteria, has fatty cell walls that protect it from drugs, which usually easily kill other types of bacteria
- There are two types of TB infection: latent TB and active TB
- There are two types of active TB: pulmonary TB (TB in the lungs) and extra-pulmonary TB (in other parts of the body)
- The main symptoms of pulmonary TB are fever, night sweats, cough, fatigue and unexplained weight loss

SECTION 2.1.2. TB and People Living with HIV

TB is an opportunistic disease meaning that it will mostly affect people who are immunosuppressed (people who have weak immune systems) such as people living with HIV (PLHIV). This is because when somebody has a weak or compromised immune system, latent TB can easily become active TB. This means that people with PLHIV, who have low CD4 counts, are very vulnerable to TB.

About a third of all PLHIV are also infected with TB, and TB is the most common cause of illness and death in people with HIV.¹⁹ PLHIV are 20 times more likely to develop TB than people who are HIV-negative.²⁰

TB infection can be prevented in PLHIV who have not had active TB before, by using a treatment called isoniazid Preventive Therapy (IPT) for 6-36 months. IPT is fully explained in the section called 'How can TB be prevented in PLHIV?', below.

TB and Antiretroviral Therapy

Extra-pulmonary TB mainly affects PLHIV. About 75% of people with extra-pulmonary TB are PLHIV.

It is very important that people co-infected with HIV and TB get treatment for both diseases. PLHIV and TB are much more likely to die from TB, than people who are HIV-negative, especially if they have a low CD4 count and are not on ARV treatment. This is because PLHIV have weaker immune systems.²¹ In addition, untreated TB in PLHIV increases viral load and worsens disease progression, meaning that these people get much sicker much more often.²² Fortunately, treating PLHIV and TB with ART and TB treatment, makes them much less likely to die from extra-pulmonary TB.

Co-trimoxazole Preventive Therapy

PLHIV who have TB should start taking co-trimoxazole preventive therapy (CPT) as soon as possible. This is because CPT is a broad-spectrum antibiotic. This means that it can be used to treat and prevent a wide range of bacterial infections, which can make people ill. In PLHIV who are co-infected with TB, CPT is used to help the body fight the TB bacteria, and prevent their TB disease from getting worse. Co-trimoxazole can also be used to protect PLHIV from other opportunistic infections. The World Health Organization treatment guidelines recommend that PLHIV who are co-infected with TB should continue to take CPT even after they have finished their TB treatment.²³

Antiretroviral Therapy and TB

Antiretroviral therapy (ART) is very important for PLHIV. ART helps PLHIV stay healthy, and significantly reduces their chances of developing opportunistic infections (OIs). ART is also very effective in preventing TB in PLHIV. ART decreases the chances of someone with HIV contracting TB by 90%, and for someone who has already had TB, it reduces the chance of the TB becoming active again by 50%.

All PLHIV who have TB should be on ART, but many PLHIV either do not know that they have TB, or do not have access to ART. ART should be started as soon as possible after someone with HIV gets infected with TB, regardless of whether their CD4 count is low or high. Although HIV testing of people with TB has increased, many PLHIV do not get diagnosed with TB. This is because the diagnostics (sputum and smear microscopy) used for TB are not as effective at diagnosing TB in HIV-positive people. These low TB detection rates prevent many PLHIV from starting ART, which could save their lives.²⁴

Sometimes the drugs used to treat TB interfere with the drugs used to treat HIV. This can stop the drugs from working properly, or can make the patient feel not well. WHO recommends first-line ART regimens for people with TB should be those that contain Efavirenz (EFV). This is because EFV is least likely to interact with anti-TB drugs.²⁵

The recommended strategies to prevent and treat TB/HIV co-infection are:

1. PLHIV who have TB should start ART, IPT and CPT as soon as possible.
2. PLHIV should be tested for TB often so that they can be diagnosed and start treatment as soon as possible.
3. Infants, children, prisoners, miners and healthcare workers should be screened for HIV and TB
4. Preventing TB from spreading in health facilities, through infection control measures, is very important.
5. Healthcare services for HIV and TB should be integrated so that PLHIV can get HIV-related care, and be screened, tested and treated for TB at the same time and place.²⁶

How can TB be prevented in PLHIV?

Because TB is very dangerous for PLHIV, and because TB/HIV co-infection is very difficult to treat, it is very important to do as much as we can to prevent TB in PLHIV. The WHO recommends a strategy called ‘The Three I’s’ for preventing TB in PLHIV. The Three I’s include: Intensified case finding (ICF), isoniazid Preventive Therapy (IPT), and Infection Control (IC).

Intensified Case Finding

Intensified Case Finding for TB means screening all PLHIV for the four main symptoms of TB (cough, fever, night sweats and weight loss).

Active screening (screening patients every time they come to the health facility or interact with a health-care worker) has many benefits:

- It leads to early diagnosis and treatment.
- It helps to prevent the spread of TB around health facilities and communities. This is because when people know they have TB, they can begin treatment and are no longer infectious. After a person has started TB treatment, it takes just 2 weeks before their TB is no longer infectious and those around them are protected. **It is still very important to finish TB treatment even though the person may no longer be infectious.**

The WHO recommends regular TB screening for PLHIV at every clinical visit. People in the health facility who do have symptoms of TB should be diagnosed as quickly as possible and, if they test positive for TB, should be started on TB treatment.

ICF is the most important step of the Three I’s because if you don’t know whether someone with HIV has TB or not, you cannot treat them for TB, or provide preventive therapies to protect them from getting TB.

There are other methods of ICF, such as screening all the household and other contacts of someone who has TB, doing door-to-door TB screenings, providing TB screening close to where people live and/or work, instead of waiting for them to come to the clinic.

Isoniazid Preventive Therapy

Isoniazid preventive therapy (IPT) is given to PLHIV who do not have TB, to protect them from getting TB. Isoniazid is one of the four first-line drugs used to kill TB. As it kills bacteria, isoniazid prevents the latent TB from becoming active TB disease. The WHO recommends giving IPT to children and adults who are HIV, whether or not they are on ART, for 6-36 months.²⁷

IPT is very effective in helping to prevent TB disease.²⁸ However, IPT can only be given to people with latent TB (TB that is not active) and it is very important that people with active TB are not given IPT.²⁹ If the patient does develop active TB while they are taking IPT, they should stop taking the IPT. PLHIV should be screened for TB before they start taking IPT to make sure they do not have active TB disease. Symptom screening should also be used to make sure that PLHIV who are taking IPT have not developed active TB disease.

Even though it should be, IPT is not available to everyone who needs it. In some countries, there are no clear regulations to allow the IPT to be implemented. There is need to advocate for policies and implementation of IPT use for PLHIV who do not have TB.

Another reason some PLHIV do not get IPT is that some healthcare workers worry that IPT could lead to isoniazid resistance. Isoniazid resistance is when TB bacteria become resistant to isoniazid, which means isoniazid could no longer be used to treat TB. However, we now know that giving IPT to PLHIV who do not have TB does not cause isoniazid resistance.³⁰

Infection Control (IC)

Infection control for TB are steps that healthcare workers and the public can take to make sure that TB is not spread from one patient to another through the air in communities and health facilities. It is important to focus infection control efforts on places where TB can most easily be spread from one person to another.

The 3 types of infection control are, administrative controls, environmental controls and personal controls.

Administrative controls try to prevent TB bacteria getting into the air at health facilities and other places.³¹ This is done by managing the movement of people around the facility, setting up IC committees for health care facilities and educating people about IC. Possible administrative controls for IC are:³²

- Screening of clients for cough as they enter the facility, either by asking the person if he or she has been coughing (while being sure to respect the person's privacy and to treat the person with kindness and dignity) or by watching to see whether the person is coughing. People who are coughing should be seen before others, to reduce the time they spend in the waiting room. It is very important that these IC measures do not make people with TB feel stigmatized or unwelcome in the health facility. All people in the health facility should be treated with kindness and respect, and healthcare workers should be sure to respect their privacy and confidentiality.
- Forming Infection Control committees at health facilities, who are responsible for ensuring that IC measures are implemented properly at the health facility.
- Educating people about the importance of coughing into your hand or a piece of cloth to prevent the TB bacteria from getting into the air.
- Doing sputum collection outside. Sputum collection (which is done for TB testing) can release TB particles into the air. To protect healthcare workers and others from becoming infected, sputum collection should be done outdoors.
- HIV and TB prevention and care for healthcare workers. Healthcare workers are vulnerable to TB infection because they work with people who have TB every day. It is important that healthcare workers know their HIV status (so they can be started on preventive therapy if necessary) and that they are screened for TB regularly (and started on treatment if necessary).

Stigma and Infection Control

It is important to remember that people with TB must be treated with dignity and respect and must not be made to feel ashamed that they have TB. Whether healthcare workers are asking people in the health facility about a persistent cough, asking people who are coughing to wait in a separate area, or conducting sputum collection outdoors, it is very important that everyone is treated with kindness and respect, and that the person's confidentiality and privacy are protected.

Environmental controls are the changes that can be made to the health facility to reduce the amount of TB bacteria in the air as much as possible. This can be done with ventilation, or with special lights that kill TB bacteria.

- Ventilation is the flow or movement of air around the facility. Health facility waiting areas and consultation rooms should be well ventilated. This can be done by making sure that there is a way for fresh air to enter the facility (such as an open window), that there is a way for stale air to leave the facility, and that the movement of air pushes the stale air (that might have TB bacteria in it) out of the facility. This can be done with fans, but these are expensive and can break. Another way is to open all the windows and doors and let the wind move the old, stale air out of the facility.

Personal controls are the things that each individual patient and healthcare worker can do to protect themselves and others from TB. Personal controls include surgical masks for people with infectious TB, and N95 respirators for healthcare workers.

- Clients in the health facility should wear surgical paper masks. Surgical masks do not stop TB particles from being inhaled, but they do stop TB particles from being released into the air when the patient coughs, talks or sneezes. Because it can be stigmatizing for people with TB to wear surgical masks, everyone in the facility should wear surgical masks.
- Nurses and other healthcare workers working with people with TB should wear N95 respirators. N95 respirators are different from surgical masks because they protect the wearer from inhaling TB bacteria. Figure 6 below shows the difference between surgical masks and N95 respirators.

Figure 6: Surgical mask (left) and N95 respirator (right)



SUMMARY: TB AND PLHIV

- TB affects those with weak immune systems, such as PLHIV
- Co-trimoxazole Preventive Therapy reduces infections in PLHIV and should be given to PLHIV during and after TB treatment
- Isoniazid Preventive Therapy, Intensified Case Finding, and Infection Control, known as the Three I's help to protect PLHIV from getting TB.
- IPT should be given to PLHIV for 6-36 months

SECTION 2.1.3. How is TB Diagnosed?

There are several types of tests used to diagnose TB. However, diagnosis of TB in PLHIV is difficult and diagnosis of drug-resistant TB is even more complex. In addition, even though rapid diagnostic tests for TB are available, many people still do not have access to them and have to wait to find out their test results. This can make some people reluctant to test for TB, and some people do not come back to get their results. There is a need for a fast, reliable, and affordable way to diagnose TB.

To diagnose active TB, it is necessary to find evidence of TB bacteria in the person's body. Some TB tests look directly for TB bacteria. Other TB tests, such as the chest X-ray, look for signs of the effect the TB is having on the person's body.³³

The most common ways to test people for TB are symptom screening (asking about TB symptoms), microscopy (using a microscope to look for signs of TB in the person's sputum) and chest X-ray (taking an X-ray of the person's lungs to look for signs of TB). It is very difficult to diagnose TB in HIV-infected people because:

- PLHIV are usually asymptomatic. This means that although they have TB, they do not have the symptoms of TB.
- Up to 30% of PLHIV will have a normal chest X-ray.
- About 50% of people who are co-infected with HIV and TB will test negative for TB in a sputum smear test.

Ways of diagnosing TB include:

- (1) Symptom screening
- (2) Microscopy
- (3) Chest X ray
- (4) Culture
- (5) DST

Sensitivity and specificity³⁴

A sensitive test is a test that is very good at identifying or 'finding' positive cases. In other words, if a test is very sensitive, it will be able to correctly identify almost all the people who are infected with TB. If a test is not very sensitive, or has low sensitivity, it will only be able to correctly identify some of the people who have TB. In other words, some people who are infected with TB, will not test positive for TB – they will receive a false negative test result.

A test that has high specificity is a test which will almost always give a negative result when the person really is negative. In other words very few patients who are not infected with TB will test positive for TB. If a test has low specificity, it might give a positive test result even when the person being tested is not infected with TB – a test with low specificity will give more false positive test results.

Symptom screening

Symptom screening is used to check if someone has active TB. The four main symptoms include night sweats (lasting 3 or more weeks), fever, weight loss and a cough. For TB symptom screening, it does not matter how long the person has been coughing. Looking for these symptoms helps healthcare workers identify 93% of TB cases. In other words, this is a very sensitive test, because it catches almost all the people who have active TB. However, symptom screening also identifies many people who don't actually have TB as being infected with TB. For this reason, it is important to use another testing method after symptom screening to confirm the result.³⁵

Microscopy

1. Sputum Smear Microscopy

Microscopy means using a microscope (seen in Figure 7, below). A sputum sample is collected by a person coughing up some sputum. Sputum is a thick fluid that is produced in the lungs. Usually two samples are taken on the same day for testing.³⁶ To do the TB test a very thin layer of the sputum sample is placed on a glass slide, this is called a smear.³⁷ Because the TB bacteria has thick fatty cell walls, it is easy to tell the difference between TB bacteria and other bacteria. Acid is used to stain the bacteria, so that it can be seen easily through the microscope.

Advantages of Microscopy

1. Sputum smear microscopy is simple, cheap and fast.
2. Microscopy can be done in all laboratories, whether they are large and well-equipped, or small.
3. Microscopy is widely available.
4. Microscopy can be done safely in a lab, protecting laboratory staff from getting infected with TB.³⁸
5. Microscopy can be used for treatment follow up of people with DS-TB
6. Low technology

Disadvantages of Microscopy

Sputum-smear microscopy cannot always identify TB in the sputum of someone who has TB. In other words, the test is not very sensitive. This is because quite a lot of bacteria (at least 5,000 bacilli per millimeter of sputum) has to be in the sputum for it to be seen under the microscope. The sensitivity of this test is even worse for samples from PLHIV, people who have extra-pulmonary TB, and samples from children.³⁹

It is difficult to diagnose TB in PLHIV because PLHIV who are co-infected with TB usually do not have enough TB bacteria in their sputum samples to test positive. About 66% of PLHIV who have TB, do not test positive for TB on a sputum smear test.⁴⁰ It is also difficult to diagnose TB in children using smear microscopy,⁴¹ usually because of the few TB bacteria found in the sputum samples of children. Sputum smear microscopy is only able to test for pulmonary TB. This is because of the low numbers of TB bacteria usually found in extra-pulmonary samples.

2. Light-emitting diode (LED) fluorescence microscopy

LED fluorescence microscopy and conventional fluorescence microscopy use special kinds of light to allow laboratory staff to see more through the microscope. LED fluorescence microscopy is a more accurate way to diagnose TB than conventional sputum smear microscopy discussed above. LED fluorescence microscopy is also more affordable than other fluorescent microscopy. The WHO recommends replacing conventional fluorescence microscopy with LED fluorescence microscopy.⁴²

Advantages of LED fluorescence microscopy

1. LEDs are an inexpensive light source for fluorescence microscopy⁴³
2. LED microscopes require less power than conventional fluorescence microscopes and can run on batteries⁴⁴
3. The bulbs used in LED microscopes last longer than conventional fluorescent bulbs⁴⁵

Disadvantages of Microscopy

1. LED microscopy cannot tell you if a person has drug-susceptible or drug-resistant TB.



Figure 7: Microscope⁴⁶

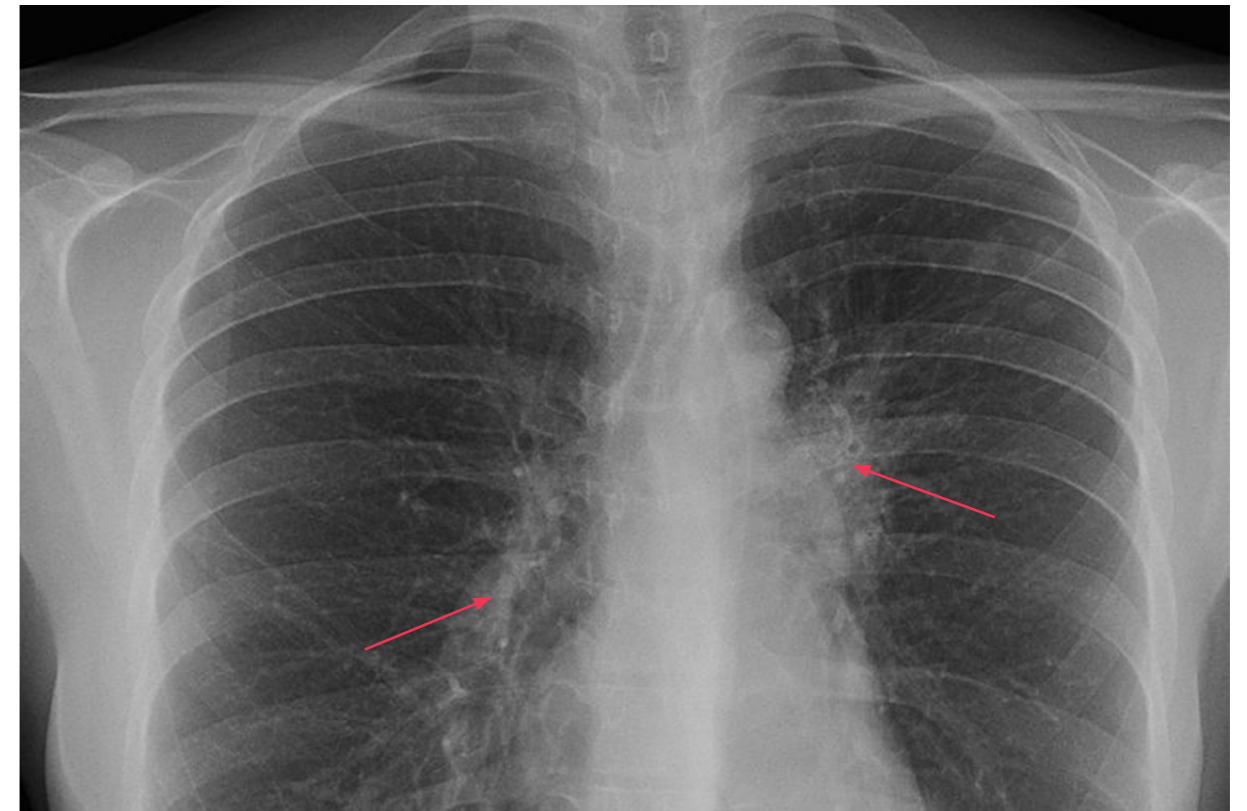


Figure 8: Chest X-ray of MTB infection, arrows show lesions⁵⁰

Chest X-ray

When somebody has pulmonary TB, they develop granulomas in their lungs. These granulomas, and the changes they cause in the lungs, are visible on a chest X-ray. When somebody has TB, you will be able to see granulomas (sometimes called lesions) in an X-ray of their lungs.⁴⁷

Advantages of Chest X-ray

1. Chest X-rays are a relatively cheap way to test for TB.

Disadvantages of Chest X-ray

1. Chest X-rays alone cannot confirm TB.
2. A chest X-ray will not identify TB in all TB cases. Some people with TB will have a clear chest X-ray.⁴⁸
3. Not all lesions or granulomas on the lungs are because of TB. This means that a chest X-ray might identify some people as having TB, even though they do not actually have TB.⁴⁹
4. Chest X-rays cannot easily identify TB in PLHIV

Drug Susceptibility Testing (DST)

Drug susceptibility testing (DST) is used to test whether the strain of TB the person has is susceptible to anti-TB drugs (the drugs kill the TB), or resistant to anti-TB drugs (the drugs cannot kill the TB). A result which shows that a sample is susceptible means that treatment with those drugs will usually be successful. A result showing that the sample is resistant to certain drugs means that there are high chances that treatment with those TB drugs will fail and other TB drugs should be used. DST is very important because it tells healthcare workers which drugs should be used to effectively treat the patient.⁵¹ Only DST can be used to confirm that the patient's TB is drug resistant.

First-line DST

Isoniazid and rifampicin are two of the most common, first-line anti-TB drugs. First-line DST, indicates whether the patient's TB is resistant to isoniazid and rifampicin.

People most at risk for DR-TB are people who live in areas where many people have DR-TB, and people who have missed doses or stopped taking TB treatment in the past. People at risk for drug resistant TB should be tested with first-line DST before other people. If DST results show resistance to both rifampicin and isoniazid then second-line DST should be performed.⁵²

Second-line DST

When someone has drug-resistant TB that is resistant to first-line drugs (the commonly used anti-TB drugs such as isoniazid and rifampicin), they can be treated with second-line drugs. Second-line drugs include second-line injectables (kanamycin, amikacin, capreomycin) and fluoroquinolones (ofloxacin, levofloxacin, moxifloxacin and gatifloxacin). A kind of DST called phenotypic DST can be used to test for resistance to second-line TB drugs.

Culturing bacteria to test for TB

Culturing is a method of studying bacteria by growing them in a laboratory.⁵³ The substance the TB bacteria are grown in is called a medium. Bacteria from sputum (in the case of pulmonary TB) or another sample (for extra-pulmonary TB) is grown in either solid or liquid media. Using a solid medium is less expensive, but the bacteria takes 28-42 days to grow in a solid medium. Liquid culture takes a shorter time (about 10 days), which reduces delays to diagnosis⁵⁴, allowing the patient to start treatment much sooner. Figure 9 below shows TB bacteria being grown in a solid medium.

Advantages of culturing bacteria to test for TB

1. Culture is more sensitive than microscopy because it can detect bacteria that are not detectable with microscopy. A test is sensitive if it correctly identifies most positive cases. For example, someone with TB might test negative for TB in a sputum smear test, but they could still test positive on a culture test, because a culture test is a more sensitive test.
2. Culture can also be used for drug susceptibility testing.⁵⁵
3. Culture can be used for patient monitoring – to check how well their treatment is working.

Disadvantages of culturing bacteria to test for TB

1. Culture is more complex and more expensive than microscopy.⁵⁶
2. Culture testing also takes longer than microscopy, which causes delays in treatment initiation.⁵⁷
3. Culture requires specialized facilities in the laboratory to prepare the media, process specimen and grow the bacteria.⁵⁸

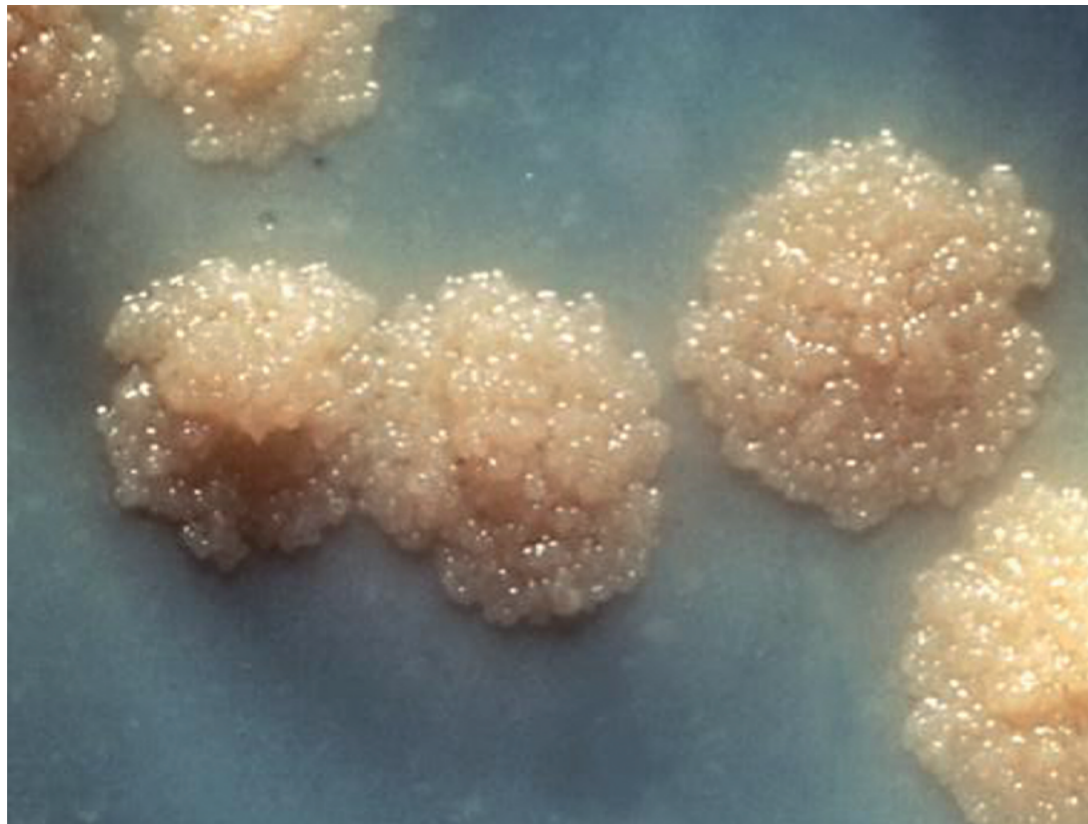


Figure 9: TB Cultures (Source: TBFacts.org)

Molecular Methods

Molecular tests look for the DNA of the *M. tuberculosis* bacteria. This is a relatively new kind of test, and it is an important development in TB testing because fast, accurate TB testing is still a significant challenge, especially in poorer countries.⁵⁹ This might be because the equipment needed for testing is very expensive, or because the test requires highly trained laboratory staff that are not available in many countries. The main advantages of molecular testing is that it is fast, it is safe for the people doing the tests, and it requires less specialized laboratory equipment. There are two approved types of molecular testing, Line probe assay and GeneXpert MTB/RIF.

Line Probe Assay (LPA)

The use of Line Probe Assay (LPA) was approved by the WHO in 2008.⁶⁰ LPA is used to test for drug susceptibility. It rapidly identifies mutations (changes) in the bacteria that indicate drug resistance. LPA can detect rifampicin resistant TB (RR-TB), as well as isoniazid resistant TB. This means it can be used to diagnose multi-drug resistant TB. Samples from culture or sputum smears can be used for LPA.⁶¹

LPA allows rapid detection (within 48 hours) of resistance to rifampicin and/or isoniazid. In addition, using LPA, it is possible to test up to 48 samples at a time, and several batches or samples can be tested each day.⁶² However, LPA cannot identify resistance to second-line injectable TB drugs. This means that LPA cannot be used to determine which second-line drugs the patient should be given. It is recommended that only sputum smear samples that have already tested positive for TB be used for LPA. This means that every sputum smear sample for LPA must first be tested using sputum smear microscopy. If TB is detected in the sample, LPA tests can be done.⁶³ Another disadvantage of LPA is that it requires sophisticated laboratory equipment, and specially trained laboratory staff.⁶⁴

Molecular LPA for the detection of resistance to second-line anti-TB drugs

In 2016 the WHO approved the use of a new type of molecular LPA testing to detect resistance to second-line anti-TB drugs.⁶⁵ This new test is called MTBDRsl. MTBDRsl identifies mutations in the DNA of the TB bacteria that indicate resistance to fluoroquinolones and injectable second-line TB drugs (kanamycin, capreomycin and amikacin).⁶⁶ MTBDRsl can diagnose MDR-TB and XDR-TB.

MTBDRsl only takes 24-48 hours. This is much quicker than detecting MDR-TB through cultures which takes about 3 months. However, this type of testing requires very sophisticated laboratories with special equipment, highly trained staff and strict safety standards.⁶⁷

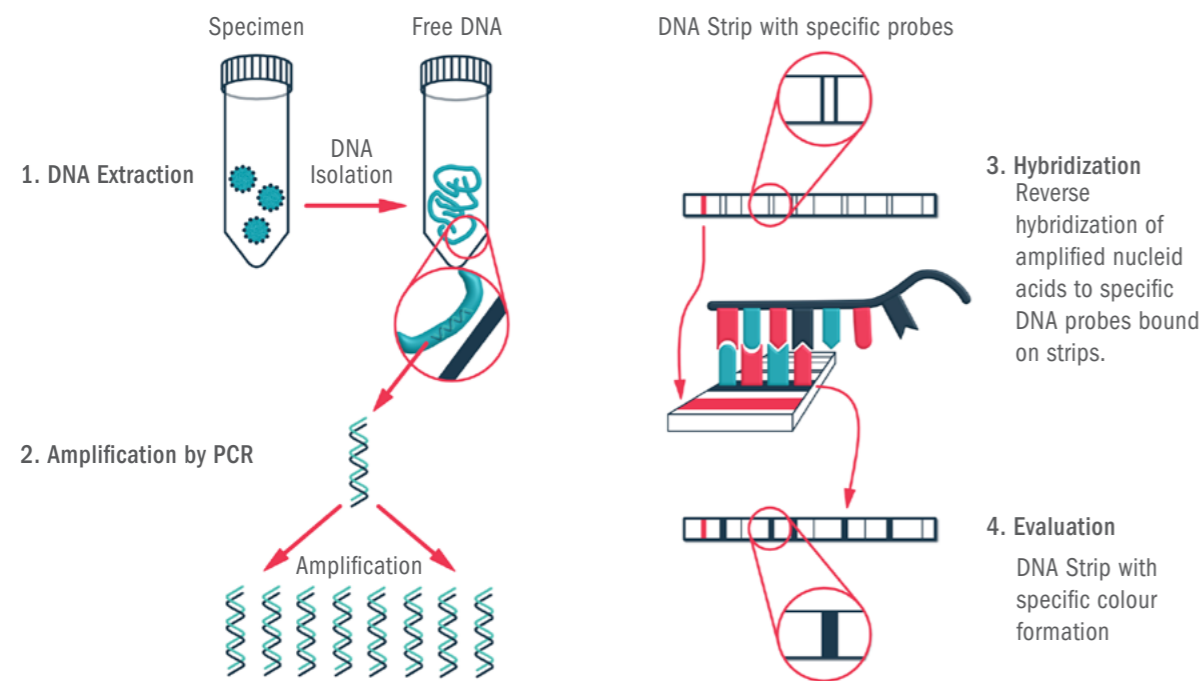


Figure 10: Molecular LPA test procedure

Xpert MTB/RIF Assay

The Xpert MTB/RIF assay is a new molecular test for TB which diagnoses TB by detecting the presence of TB bacteria, as well as testing for resistance to the drug rifampicin.⁶⁸ The WHO approved this test in 2010. Through a public-private partnership with the WHO, Xpert testing equipment is made available to national governments at affordable prices. At the end of 2014, 3763 Xpert instruments had been purchased by national governments at a reduced price.⁶⁹

Advantages of the Xpert MTB/RIF test.

- Direct sputum can be used in Xpert MTB/RIF. This means that unlike LPA, it is not necessary to test the sample with sputum smear microscopy first.
- Xpert MTB/RIF can also detect TB in certain extra pulmonary samples.⁷⁰
- Xpert MTP/RIF takes only 2 hours to detect both rifampicin and isoniazid resistance; it is the fastest test to detect MDR-TB
- Xpert MTP/RIF is a very sensitive and specific test. This means it catches almost all cases of TB, and doesn't give false positive results.
- Xpert MTP/RIF is better at detecting TB than microscopy, even in PLHIV.
- The test does not require specially trained laboratory staff, or very high safety standards in the laboratory. It can be done at local level laboratories and not only at central/reference laboratories.

Disadvantages of the Xpert MTP/RIF test:

- The test requires an uninterrupted power supply.
- The temperature in the room the equipment is in must not exceed 30°C.
- The cartridges used in the equipment can expire, so the supplies need to be carefully managed.⁷¹



Figure 11: GeneXpert instrument with additional laptop, UPS and printer
Source: Khairunisa Suleiman, Hanoi Vietnam, (2015)

Lipoarabinomannan (LAM)

Lipoarabinomannan (LAM) can be used to help diagnose TB in PLHIV with very low CD4 counts. LAM is a quick test, which can help detect TB in PLHIV that have signs and symptoms of pulmonary TB who have a very low CD4 count or are seriously ill. LAM should not be used as a screening test for TB in PLHIV.⁷² The test is done on a sample of the person's urine.

Advantages of Lipoarabinomannan (LAM)

1. A urine sample is easier to obtain than sputum
2. It is a rapid test with results obtained within 15 minutes
3. It is easy to use and does not require special training of healthcare workers

Disadvantages of Lipoarabinomannan (LAM)

1. It can only be used on PLHIV with low CD4 count, PLHIV with an unknown CD4 count, and PLHIV who are seriously ill.

Latent TB infection (LTBI) diagnosis

Latent TB Infection is when someone is infected with TB, but their immune system is fighting the TB bacteria, and protecting them from developing active TB disease. For people with latent TB who are HIV-negative, there is a 5-10% chance that the latent TB will develop into active TB. This is called TB reactivation. It usually happens within 5 years after TB infection.

There is no way to test for LTBI directly. Tuberculin Skin Test (TST) and Interferon Gamma Release Assay (IGRA) are indirect tests for latent TB. TST tests work by injecting a small amount of purified protein from the *M.tuberculosis* bacteria (also called TB antigen) under the patient's skin. If there is a visible reaction to the protein within 2 days, it means that the body's immune system has recognised the TB bacteria. This indicates that the patient is infected with TB.

In countries with low rates of TB, TST is often used to test for latent TB infection. TST cannot be used in countries with a high burden of TB. This is because TST cannot tell the difference between latent and active TB, and in countries with a high TB burden most people have latent TB.⁷³

The Interferon Gamma Release Assays (IGRAs), are a new type of more accurate TB test. IGRAs are blood tests that measure a person's immune system response to TB bacteria.⁷⁴ The WHO recommends IGRA in middle to high-income countries with low TB incidence. IGRA should not replace TST in low-income countries.

Advantages of Latent TB infection (LTBI) diagnosis

1. For IGRAs only one patient visit is required. Test results are available within 24-48 hours.
2. TST is widely available and is inexpensive. TST does not require specialized laboratory equipment or supplies.

Disadvantages of Latent TB infection (LTBI) diagnosis

1. IGRAs are expensive. They also require specialized laboratory equipment and well-trained staff.
2. For an IGRA test it is necessary to draw blood.
3. TST requires two visits to the health facility and results are only available within 48-72 hours. This means that some people with TB may be lost to follow-up.
4. TST is not a very sensitive test, especially for people who have received a TB vaccination, and people with weak immune systems, such as PLHIV.

SUMMARY: DIAGNOSTING TB

- There are several tests for diagnosing active TB:
 1. Symptom screening
 2. Microscopy
 3. Chest X-ray
 4. Culture
- To see whether a patient has drug-resistant TB, drug susceptibility testing (DST) can be done. There are two types of DST:
 1. Culture
 2. Molecular methods
- The molecular methods are Line Probe Assay (LPA) and GeneXpert. There is a new LPA test which can identify resistance to second-line anti-TB drugs (SL LPA)
- Lipoarabinomannan (LAM) helps to diagnose TB in PLHIV, who have very low CD4 counts
- Interferon Gamma Release Assays and Tuberculin Skin Tests are ways of diagnosing latent TB.

SECTION 2.1.4. How is TB Treated?

WHO groups anti-TB drugs according to how well they fight TB (how strong they are), and how safe they are to take (whether they often cause side-effects and how well tolerated they are). Group 1 drugs are the best, because they are very good at fighting TB, and they do not often cause side-effects.⁷⁵ TB drugs must be used in combination to make sure the TB doesn't become resistant to any of the anti-TB drugs used. This is why TB is treated with a combination of anti-TB drugs that each attack the TB bacteria in different ways. The combination of different drugs used, and how long they are used for, is called a treatment regimen.

There are always 2 phases to TB treatment: an intense first phase that includes more drugs to fight the infection, and a longer continuation phase to be sure the infection is gone.⁷⁶

WHO Anti-TB Drug Groups ^{77,78}	
Group	Drugs (abbreviations)
Group 1: First-line oral drugs Most potent and best tolerated.	isoniazid (INH) rifampicin (R) pyrazinamide (Z) ethambutol (E) rifabutin (Rfb)
Group 2: Injectable drugs These are used if the patient's TB might be resistant to the drugs in group 1.	kanamycin (Km) amikacin (Am) capreomycin (Cm) streptomycin (S)
Group 3: Fluoroquinolones	levofloxacin (Lfx) moxifloxacin (Mfx) ofloxacin (Ofx)
Group 4: Oral bacteriostatic second-line drugs	para-aminosalicylic acid (PAS) cycloserine (Cs) terizidone (Trd) ethionamide (Eto) protionamide (Pto)
Group 5: Drugs with unclear role in treatment of drug-resistant-TB	clofazimine (Cfz) linezolid (Lzd) amoxicillin/clavulanate (Amx/Clv) thioacetazone (Thz) imipenem/cilastatin (Ipm/Cln) high-dose isoniazid (high-dose H) clarithromycin (Clr)

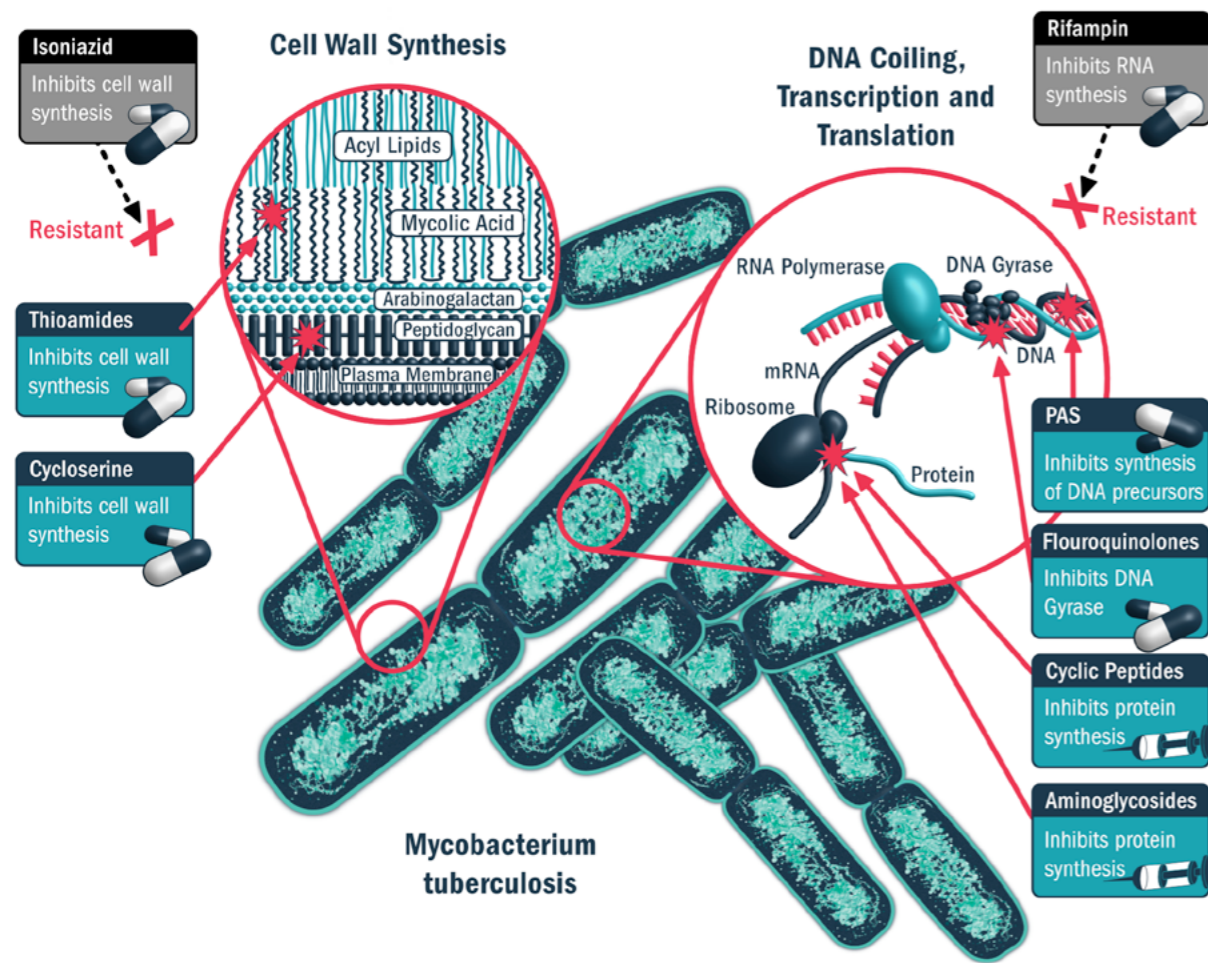


FIGURE 12: MDR-TB and possible effective treatments⁷⁹

First-Line TB Treatment

TB that is responsive to first-line drugs, the drugs most commonly used to treat TB, is referred to as **drug susceptible TB (DS-TB)**.

First-line treatment for TB includes:

- isoniazid (H)
- rifampicin (R)
- pyrazinamide (Z)
- ethambutol (E)

First-line TB treatment is often abbreviated as HRZE. All these drugs are in group 1. The WHO recommends that first-line TB treatment should be taken for 6 months.

This includes:

- 2 months of taking HRZE (2HRZE) and then
- 4 months of HR (4HR)

The treatment regimen for DS-TB treatment is abbreviated as 2RHZE/4HR⁸⁰.

Sometimes, to make it easier for people with TB to take their TB treatment, different drugs are combined into 1 pill or tablet. These are called Fixed Dose Combinations (FDC). FDCs of HRZE and HR are available in tablet form and have been recommended for use by the WHO since 1999.

Second-line TB Treatment

TB that is not affected, or not susceptible to first-line treatment is called **drug resistant TB (DR-TB)**. TB that is resistant to 2 of the first-line anti-TB drugs is called **multi-drug resistant TB (MDR-TB)**. MDR-TB is resistant to rifampicin and isoniazid. TB that is resistant to isoniazid, rifampicin (MDR-TB) and at least one fluoroquinolone (FQ), and one aminoglycoside (AG) is known as **extensively drug resistant TB (XDR-TB)**.

In 2016, the WHO released new guidelines for the treatment of MDR-TB. Treatment for MDR-TB should be taken for 9 months. The exact treatment the person should use depends on the guidelines of the country where the person lives, the person's medical history, and the results of DST. For treating people with MDR-TB the WHO now recommends:

- 4-6 months Km-Mfx-Pto-Cfz-Z-H_{high-dose}-E
- 5 months of Mfx-Cfz-Z-E⁸¹

This new recommendation is expected to benefit the majority of people with MDR-TB worldwide. However, there are serious risks of worsening drug resistance if this treatment regimen is used inappropriately.⁸² This treatment regimen should NOT be used if:

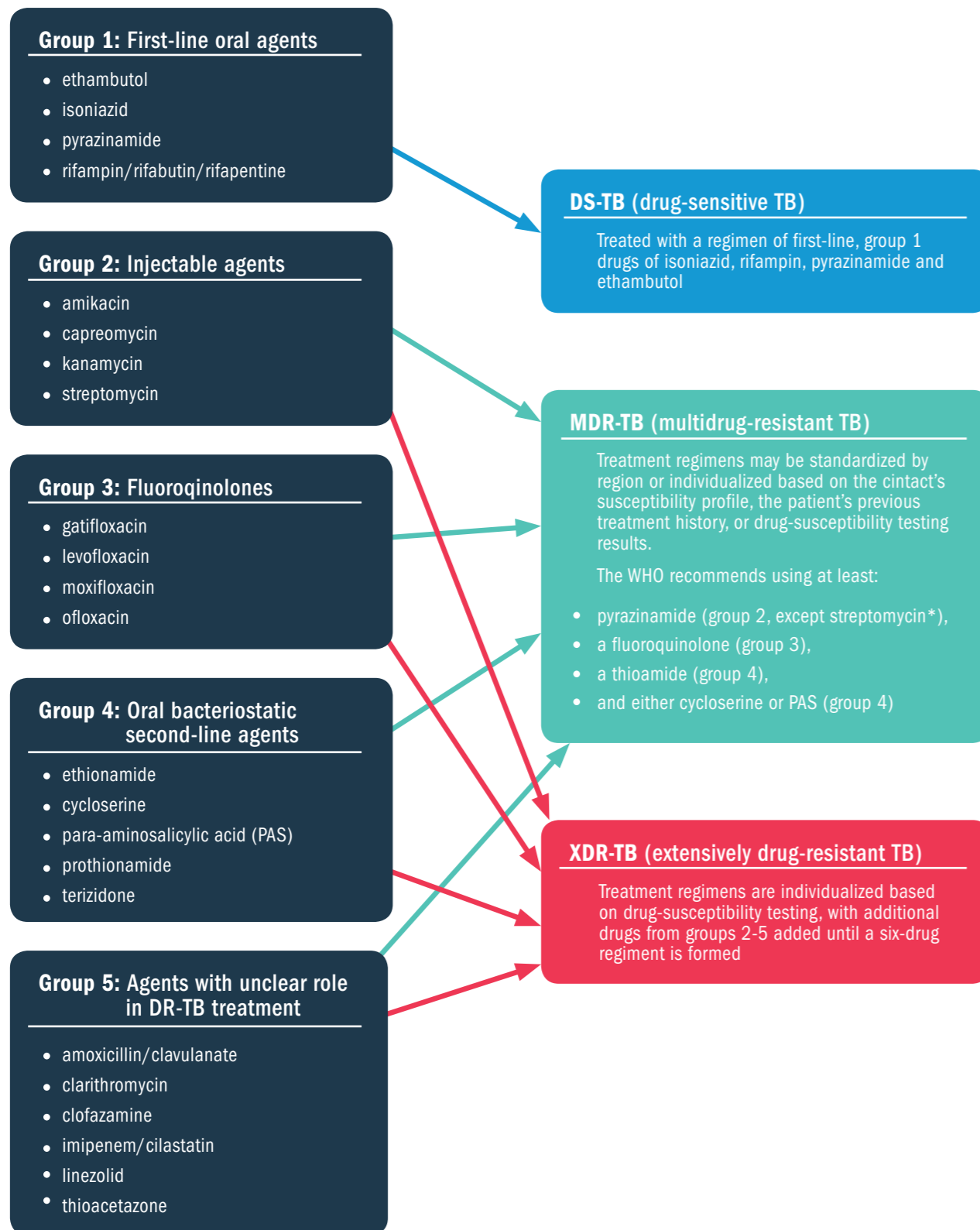
- the person's TB is, or might be, resistant to any of the drugs in this treatment option (other than isoniazid)
- the person has ever taken any of the drugs in the treatment regime for more than a month
- the person is pregnant
- the person has extra-pulmonary TB, or
- any of the drugs in the treatment regime are not available.

If the 9-month treatment option is inappropriate for the patient for any of these reasons, the patient should use a 20 month treatment option. The treatment option will depend on the country, the patient's history, DST, and how well they tolerate the drugs. The treatment option should include:

- At least 8 months of 4 or more second-line anti-TB drugs and then
- At least 12 months of 3 or more second-line anti-TB drugs.⁸³

For XDR-TB, the treatment regime must be personalized (i.e. different for every patient) depending on the DST profile. WHO recommends the use of drugs from groups 2, 3, 4 and 5. Anti-TB drugs from group 1 are not included due to drug resistance. The diagram below shows how to construct a TB treatment regimen using drugs from the different groups.

Figure 13: Constructing a TB Drug Regimen (Source: An Activist's Guide to Tuberculosis Drugs, Treatment Action Group, 2014)



Recently, two new drugs have been approved as TB treatment: bedaquiline and delamanid. In 2013 and 2014 the WHO released interim guidelines for the use of bedaquiline and delamanid. The WHO recommends the use of bedaquiline and delamanid in MDR-TB cases when the standard MDR-TB treatment regimen is not possible.⁸⁴ Frequent monitoring of the heart for arrhythmia and other side-effects is very important when using bedaquiline and delamanid.⁸⁵ Clinical trials to determine whether it is safe to take bedaquiline and delamanid concurrently (at the same time) are still underway. These trials will tell us whether it is safe to use bedaquiline and delamanid at the same time. Delamanid can be used for the treatment of XDR-TB, and it “may lower the need to include other drugs belonging to Group 5 which have unproven anti-tuberculosis activity or a lower safety profile.”⁸⁶ However, it might be dangerous to use delamanid with fluoroquinolone or a Group 5 drug. This is because these drugs can interact with each other and cause dangerous side-effects.⁸⁷

Anti-TB drugs, and their side-effects	
Drug	Possible Side effects
isoniazid	Peripheral neuropathy (vitamin B6 can help with this) Skin rash Hepatitis Sleepiness and tiredness Vision impairment (difficulty seeing properly)
rifampicin	Abdominal pain Nausea Vomiting Hepatitis Allergic reaction such as rash, itching
pyrazinamide	Joint pains Hepatitis Abdominal pain
ethambutol	Problems with vision/sight Pain in the eye (these are caused by retro bulbar neuritis - swelling in the nerves behind the eye)
streptomycin (considered a first line drug but is in group 2)	Problems with hearing (caused by auditory nerve damage) Renal nerve damage
Group 2: amikacin capreomycin kanamycin streptomycin	Kidney damage Hearing loss

Anti-TB drugs, and their side-effects	
Group 3: gatifloxacin levofloxacin moxifloxacin ofloxacin	Nausea Diarrhea Insomnia (inability to sleep)
Group 4: Ethionamide Cycloserine para-aminosalicylic acid (PAS) protionamide terizidone (PAS) protionamide terizidone	Convulsions (when Ethionamide is used with cycloserine)
Group 5: amoxicillin/clavulanate clarithromycin clofazamine imipenem/cilastatin linezolid thioacetazone	Clofazamine may cause: skin discoloration Linezolid may cause: Headaches Diarrhea and nausea Optic nerve damage
bedaquiline	Arrhythmia (abnormal heart beat)
delamanid	QT prolongation

Important factors for treating DR-TB

Although the drugs used to treat TB are very good, TB treatment, especially second-line treatment, can fail. This could happen because the drugs cannot kill the TB bacteria, because the treatment is not taken correctly or because the person's TB is too extensive or resistant to the stronger TB drugs. To make sure TB treatment is successful, it is important to consider the following factors:

Efficacy

The treatment of DR-TB involves second-line drugs which are less effective than first-line drugs. More effective, newer drugs and targeted regimens are needed.⁹⁰

Side effects

Second-line drugs used for DR-TB treatment are more toxic and less tolerable than first-line drugs. This means they often cause side-effects which make the patient feel ill, which makes it less likely that the patient will stay adherent to their treatment regime. Side-effects and non-adherence are some of the reasons for the high numbers of deaths due to XDR-TB.

For people co-infected with TB and HIV, side-effects can also be caused by interactions between TB drugs and HIV drugs. For example both ARVs and isoniazid cause peripheral neuropathy (weakness, numbness and tingling in the hands and feet). Taking ARVs and anti-TB drugs together can make these side effects more likely and more severe.⁹¹ HIV and TB drugs that do not interact with each other are needed for the effective treatment of both HIV and TB.

Fixed-dose combinations

Fixed-dose combinations (FDCs) are tablets/pills that contain the right amount of each of the drugs in the treatment regime. FDCs mean that the patient only has to take one pill at a time, instead of many separate pills. This makes TB treatment easier for people with TB and helps them to stay adherent. At the moment, FDCs are only available for first-line drugs. There are no FDCs for second-line drugs. FDCs also help people to make sure they are taking the correct dose of their treatment and is more patient-friendly. This is especially important for children. When treating children for TB, the dosage (how much of the drug they should take) depends on their weight. Often, children are given incorrect doses which can cause drug resistance and side-effects. FDCs for DR-TB are desperately needed.

Short regimen

People with TB have to take their treatment for a long time (a minimum of six months). This is because there are some types of TB bacteria that can survive for a long time, even when the person is on treatment. The problem is that it is very difficult for people to take their treatment correctly for a long period of time. Many people with TB struggle to stay adherent over time. Not taking your TB treatment properly can lead to drug resistance.

The recently approved shortened MDR-TB regimen is a very important change. The reduction of the treatment time from 20 months to 9 months will help many people stay adherent over the course of their treatment. Shorter treatment regimes also reduce the burden on the health system, allowing healthcare workers to see more new patients.⁹²

Affordable

Second-line treatment is much more expensive than first line treatment. Shorter treatment regimes are much cheaper than longer treatment regimes. The new 9 months treatment regime for and therefore the newly approved shortened regimen for MDR-TB treatment will translate to more affordable treatment.

Drug resistance

TB bacteria can become resistant to the all the drugs used to treat TB. For some drugs, this happens much faster than for others. Using a combination of different drugs (a treatment regime) helps to reduce the chances of the TB bacteria becoming resistant. This is because each different drug attacks the TB bacteria in a different way (see Figure 11, above). The best drug regimen decreases the chances of drug resistance.⁹³

The table above shows some of the common side-effects of each drug.

Researchers are working all the time to develop new anti-TB drugs that meet these requirements:

- The use of sutezolid in DS-TB is being investigated for efficacy when given to people with TB for 14 days⁹⁴ instead of the 6 months of standard DS-TB treatment.
- A study to understand the best dosing strategy for levofloxacin (that will be effective but not cause serious side-effects) is being done.⁹⁵
- The possibility of using an FDC containing pretomanid, moxifloxacin and pyrazinamide (PaMZ) to treat MDR-TB is being studied.⁹⁶
- A study is being done to see whether bedaquiline, pretonamid (both new drug classes) and pyrazinamide can be effective in a 3 month treatment regime for MDR-TB.⁹⁷

SECTION 2.1.5. Advocacy Issues for TB Testing and Treatment

THE NEED FOR ADVOCACY FOR TB TESTING AND TREATMENT

In some communities, levels of awareness of TB and its connection to HIV are still low. There is a need for more advocacy to raise awareness of TB, and the treatment and diagnosis issues associated with TB.

Studies from around the world, including Tanzania, India and the Pacific Islands, show the need for more advocacy and raising awareness around TB. These studies show that in some communities, people do not know what causes TB, or how TB is spread from one person to another.

In addition, many people don't know that they can get treated for TB free of charge at government health facilities. This is very important information for people to know because worries about the cost of treatment stops many people from getting tested and treated for TB. Better knowledge and understanding of TB will help to make sure that people go to the health facility sooner. This will allow them to get tested and start treatment before they become very sick. In some communities, people only go to the health facility when they are already very sick. In a community in Tamil Nadu, in India, only 54% of people visited public health facilities when they had a cough for more than three weeks.¹⁰¹

Even when people do seek care and treatment for TB, they often go to traditional healers, or try 'self-medication' (such as with over-the-counter drugs) before going to the health facility.^{102,103}

There are gender differences in TB treatment seeking behavior. Women generally seek TB testing and care much sooner than men. This means that advocacy efforts should pay particular attention to the needs and behaviors of men.

Barriers to TB testing

Not enough integration of TB and HIV health services

One of the things that make it more difficult for people to get the TB testing services they need, is the lack of integration between TB and HIV health services. Integration of TB and HIV services is very important because of the many links between TB and HIV. TB is an opportunistic infection, and many people who are ill with TB were vulnerable to TB infection because HIV/AIDS had weakened their immune systems. This means that many people who are sick with TB, are also PLHIV, and many PLHIV are co-infected with TB.

However, TB and HIV services are not always integrated. For example, some TB health centers do not offer HIV testing and treatment services, and some HIV facilities, do not offer TB testing and treatment. There is a need for advocacy for more integrated TB and HIV health services that are easy to reach for everyone in the community.

DR-TB testing services are located far away from the communities that need them

Another barrier people face is that DR-TB testing is not always available at community-level health facilities. This means that people might have to travel long distances to get tested for DR-TB, creating a barrier to testing and treatment.

No rapid test for TB

Currently, there is no rapid point of care TB test, i.e. a TB test where people can get tested and get their test results in one visit. This is very important because it allows people to start treatment as soon as possible and decreases the risk of people with TB being lost to follow-up after their TB test. There is a need to push for more investment to develop point of care TB tests.

Limited access to GeneXpert

GeneXpert (a fast test for MDR-TB) is not available in a lot of health facilities. In addition, when GeneXpert is available, it is often not available in those communities where there is most need for it. There is a need for advocacy to improve access to this kind of testing.

Activists often play an important role in making sure that new technology for health is affordable. In the past, advocacy organizations have been involved in negotiations with diagnostic manufacturers to bring down the prices of important health equipment and drugs. Usually, this advocacy strategy is to demand that prices are lowered after the company has made a certain amount of profit, or sold a certain amount of the equipment or drugs in question. This strategy has been used to lower the price of GeneXpert cartridges and instruments. For this reason, it is important for activists to keep track of how much of a certain product or equipment is sold. Activists must urge diagnostic manufacturers to regularly and openly report the numbers of drugs and equipment sold. Open reporting by manufacturers will allow activists to hold them accountable for the prices of the drugs and equipment.

The need for Advocacy for TB Treatment and Prevention

TB Prevention Issues

IPT is the best way of preventing TB in PLHIV. However, as was discussed earlier in this Module, many people still do not have access to IPT because many healthcare workers still believe that using IPT to protect PLHIV from TB will lead to drug resistance. There is a need for advocacy to create awareness among healthcare workers of the effectiveness of using IPT to protect PLHIV from TB.

TB Treatment Issues Patient-centered TB care

Patient-centered TB care is TB treatment that meets the needs and expectations of those who need it most. A more patient-centered approach is needed to improve treatment success rates. When a patient-centered approach is used more people will come to the health facility for TB testing and treatment, and more people will be able to stay adherent through the whole duration of their treatment. Advocacy organizations and community advocates play an important role in making sure that health services meet the needs and preferences of the communities that use them.

Reducing the price of anti-TB drugs

It is very important that TB drugs are affordable. Even when governments are buying drugs for treating people in government health facilities, the price of drugs can be a major barrier to their availability. In 2015, activists wrote a letter to the manufacturer of Bedaquiline, requesting for the prohibitive price reduction of Bedaquiline so that high prices do not hinder national roll-out of these drugs.

Better access to FDC for DS TB treatment

Some countries have been slow to make FDC for DS-TB treatment available in government health facilities. While policies state that FDCs for DS-TB should be available, health facilities are often very slow to implement the policies, creating a barrier to access for those with DS-TB. In the past, activists have taken action to urge governments to make FDCs for TB treatment available in public health facilities.

Better access to MDR-TB treatment

Throughout the world, treatment for MDR-TB is not always available for those who need it. For example, in India only 20,753 people with MDR-TB are started on MDR-TB treatment, but there are 35,585 people suffering from MDR-TB. More advocacy is needed to ensure that people suffering from MDR-TB have access to the treatment they need. This is important to improve the lives of those with MDR-TB, but it is also vital to protect others from getting infected with MDR-TB.

Ensuring access to new and repurposed TB drugs

Repurposed drugs for TB are drugs that used to be used to treat other health conditions, but have been found to be effective anti-TB drugs. Sometimes, even when new or repurposed drugs have been shown to be effective at fighting TB, they are not available in government health facilities. This is because government processes for testing and approving new and repurposed drugs can take a very long time.

Advocacy organizations play an important role in making sure that new drugs are approved by country governments as soon as possible, and that these new drugs are quickly made available in all health facilities.

Advocacy organizations also play an important role in making sure people have access to drugs through compassionate use programs. Compassionate use is a term used to refer to the practice of making these drugs available to people who desperately need them, even before they have been officially approved by government. Because access to new and repurposed drugs for TB (especially MDR and XDR-TB) is so important, drug manufacturers sometimes agree to make these drugs available for free or for a very low price. This is called a compassionate use programme, and it is a very good way of making sure TB drugs are available to those who need them most. Bedaquiline is a good example of a MDR-TB drug that was widely available under compassionate use before governments officially approved the drug.

However, some drug companies refuse to make their drugs available under a compassionate use programme, or take a very long time to do so. In cases like this, activists must work to push the drug manufacturer to make the drug available. In the past, activists have written letters to the company that manufactures the anti-TB drug delamanid to urge them to scale-up their compassionate use program.

TB AND HUMAN RIGHTS

In some countries people can be imprisoned for not adhering to their TB treatment. Governments might think that this strategy encourages people to adhere to their TB treatment regime. However, punishing people who fail to adhere to their TB treatment can make them very scared to start TB treatment, because they worry that if they are not able to stay adherent, they will be imprisoned. In this way such punishments become a barrier to TB treatment. In the past, activists in Kenya have been involved in successful advocacy efforts to protect the rights of TB patients. The advocacy organization won the case and patients who had been imprisoned were released. Imprisoning TB patients is a human rights violation.

SUMMARY: ADVOCACY ISSUES FOR TB TESTING AND TREATMENT

- TB awareness is generally low – many people don't know what TB is or how it affects PLHIV.
- There is not good integration of TB and HIV services
- Many PLHIV lack access to IPT because healthcare workers still believe that using IPT to protect PLHIV from TB will cause drug resistance.
- There is no rapid test for TB diagnosis that can be done at the health facility
- Equipment such as GeneXpert machines for TB diagnosis are often not found where they are most needed.
- Advocacy for fixed-dose combinations and increased access to better TB drugs is needed
- TB and HIV services should be integrated, and easy to reach for everybody in the community.

- Advocacy for compassionate use is very important to make sure people with TB have access to the anti-TB drugs they need
- Many people suffering from MDR-TB do not have access to MDR-TB treatment
- Human rights are an important aspect in TB treatment. The rights of people with TB must be protected.

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Chapter 2.2. What is the Hepatitis C Virus?

CHAPTER OBJECTIVE

To build community activists' knowledge of the Hepatitis C Virus (HCV) and how HCV is linked to HIV. This section will also discuss the methods for preventing, diagnosing and treating HCV in people living with HIV, and the issues HCV advocacy should address.

TRAINING MATERIALS

- PowerPoint presentation '2.2. What is Hepatitis C Virus?'
- Flipchart and pens (for training option A)
- Paper and bowl or basket for collecting pieces of paper (for training option B)

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objective of the Chapter.
2. Present PowerPoint presentation '2.1. What is the Hepatitis C Virus?'
3. Facilitate a discussion on HCV. Encourage the participants to discuss what they know about HCV, and to think about why they might know less about HCV than about HIV and TB.
4. Have a group discussion on the things it is important for healthcare workers, communities and activists to know about HCV. Write up the advocacy messages on the flipchart.
5. Support the discussion with the advocacy messages below.

Option B (approx. 120 minutes)

1. Explain the objective of the Chapter.
2. Divide the participants into 'buzz groups' of 2-3 people. Ask each group to write down on a small piece of paper 2 questions they have about Hepatitis C.
3. Collect all the pieces of paper and put them in a bowl.
4. Present PowerPoint presentation '2.1. What is Hepatitis C Virus?'
5. Give each group 2 questions from the bowl. Ask them to brainstorm the answers to the questions.
6. Altogether, discuss each question and the group's answer. Confirm whether or not the group's answer was correct. If not, discuss the answer to the question.
7. As a group, think about why the participants might know more about HIV and TB, than about HCV.
8. Ask the participants to summarize the session by developing advocacy messages about 'What is the global guidance on treatment?'
9. Support their ideas by sharing examples of messages (see below).

ADVOCACY MESSAGES

- Hepatitis means inflammation of the liver. Sometimes hepatitis is caused by a virus.
- The Hepatitis C Virus is the most common hepatitis virus. Worldwide, by 2015 about 185 million people were infected with HCV.¹ In 2016, nearly 2.3 million of these people were also HIV-positive.²
- PLHIV are vulnerable to HCV because they have weakened immune systems.
- Unlike HIV, HCV can be cured, using drugs known as Direct-Acting Antivirals (DAAs).
- More attention and resources must be devoted to HCV education, testing, treatment initiation and treatment support.

USEFUL RESOURCES

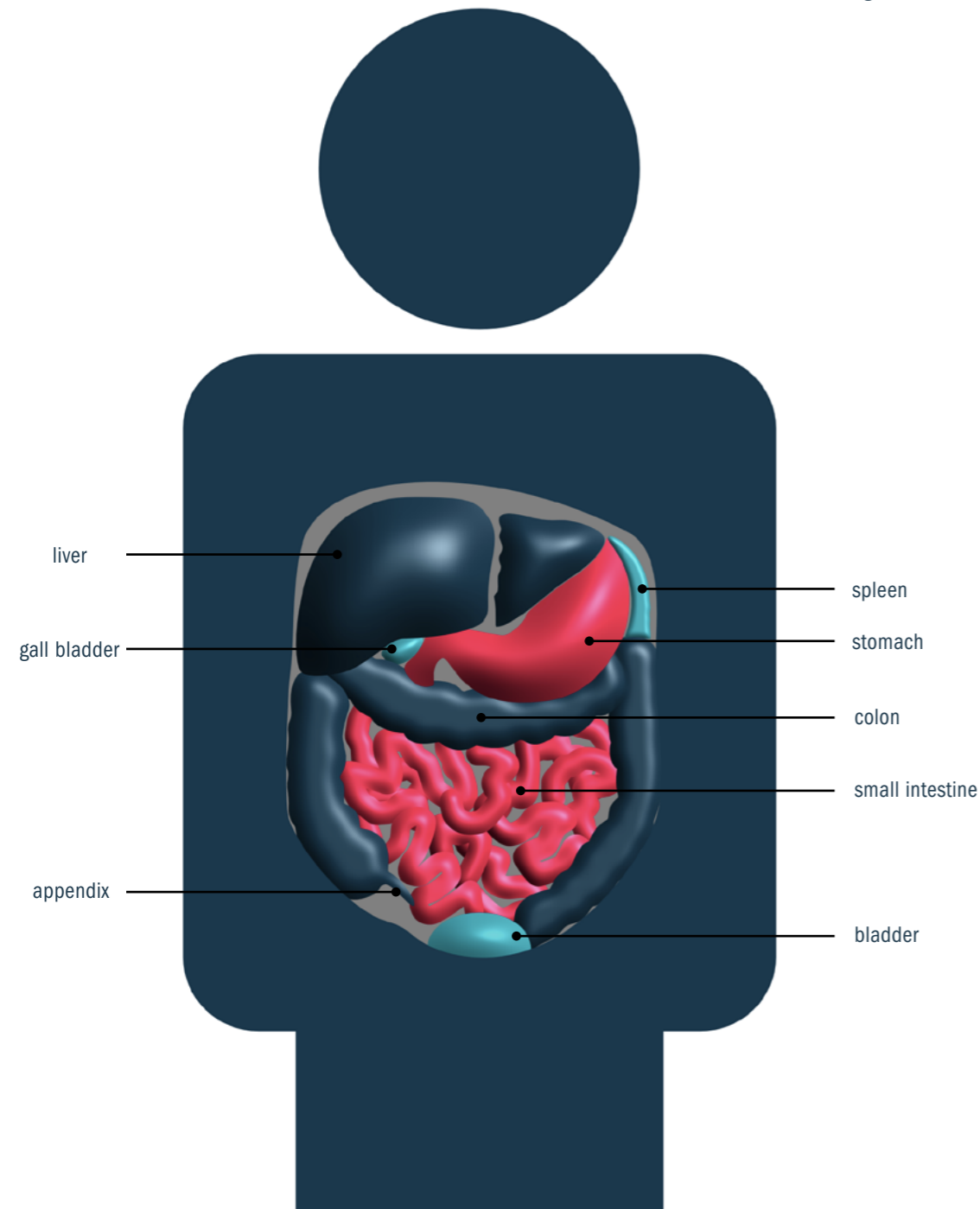
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- HCV Fact Sheets, Treatment Action Group, 2016. Available here: <http://cts.vresp.com/c/?TreatmentActionGroup/d0da6bcb45/a389dd96ef/4868b4f2b5>

SECTION 2.2.1. What is the Hepatitis C Virus?

What does the liver do?

The liver is one of the body's busiest internal organs. It acts as the body's filter by removing toxins from the blood. It also breaks down fat, medicines and alcohol; converts food into energy and makes proteins, including some that help blood to clot and keep fluid in the bloodstream. The liver also stores vitamins and minerals and regulates blood sugar. It is found on the right side of the body, under the ribs below the right lung. Figure 14 shows the location of the liver in the body.

Figure 14: The liver

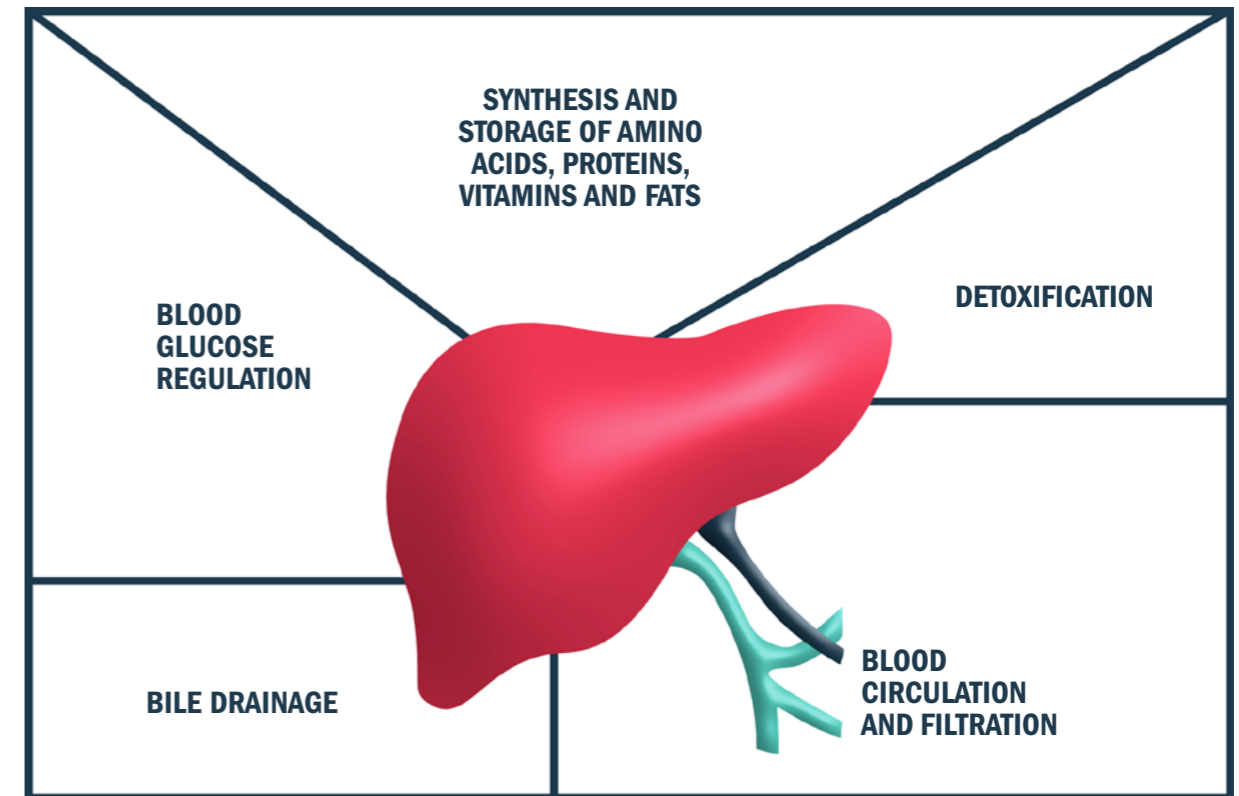


What is hepatitis?

Hepatitis means inflammation of the liver. Many things can cause hepatitis, including infections by bacteria and viruses, exposure to fumes and chemicals, certain medicines and drinking a large amount of alcohol over time.

Hepatitis can be acute or chronic. Acute Hepatitis infection is a short-term illness that occurs within the few months after someone is infected with the Hepatitis virus. For some types of Hepatitis (Hepatitis A virus) the body usually kills the infection after a short time.³ For other types of Hepatitis, the virus remains in the body resulting in long-term liver problems.⁴ This is called chronic Hepatitis disease.

Figure 15 The Liver



Types of Hepatitis Virus

How do you get it?	HAV can be spread through food or water that has feces in it -even amounts that are too small to see; from oral-anal sex (known as rimming) with a person who has HAV. Cooks with HAV who do not wash their hands after using the bathroom and caregivers who do not wash their hands after changing diapers can spread HAV. A person can only get HAV once.	HBV is spread through direct contact with infected blood, semen and vaginal fluid. This can happen during sex; from sharing syringes when; from reused, unsterilized medical, dental or tattooing equipment; from unscreened blood transfusions; and from a mother to her infant. A person can only get HBV once.	HCV is spread through direct contact with infected blood. This can happen from sharing equipment to inject drugs; from reused, unsterilized, medical, dental or tattooing equipment; from unscreened blood transfusions; during sex (mainly among HIV-positive men who have sex with men (MSM); and from mother to infant. A person can get HCV over and over again, known as reinfection.	HDV is spread through direct contact with infected blood. You can only get HDV if you have HBV, or if you get HBV and HDV at the same time.	HEV is spread by water or food that has feces in it- even amounts that are too small to see. It can also be spread through eating animals (pigs, chickens, deer, rabbits) that have HEV; from unscreened blood transfusions; and from mother to her infant. A person can only get HEV once.
How is it diagnosed?	Through blood tests				
Will I feel sick?	Children do not usually have symptoms; adults may have fever, joint pain, fatigue, appetite loss, stomach pain, nausea, vomiting, diarrhea, dark urine, grey feces, and yellowish skin and eyes. These symptoms can last for up to six months.	Most people do not feel sick, but HBV can cause fever, joint pain, fatigue, appetite loss, stomach pain, nausea, vomiting, diarrhea, dark urine, grey feces, and yellowish skin and eyes.	Most people do not feel sick during the first six months, but symptoms can include fever, joint pain, feeling tired, appetite loss, nausea and vomiting, dark urine, grey feces and yellowish skin and eyes. Many people who have chronic HCV feel tired; some also have memory loss ("brain fog") and depression. Other symptoms often don't appear until a person has serious liver damage.	Most people feel tired and weak, with appetite loss, nausea, dark urine, grey- colored feces and yellowish skin and eyes.	Children who have HEV usually do not feel sick; people who are 15 to 40 years old may have fever, stomach pain, appetite loss, nausea, vomiting, a swollen, painful liver, dark urine, grey feces, and yellowish skin and eyes.

How is it treated?	Rest, fluids and good nutrition	Oral drugs (tenofovir or entecavir) can suppress the virus and reduce the risk of cirrhosis and liver cancer. These drugs usually do not cure HBV. Treatment for HBV is lifelong.	HCV can usually be cured with a few months of treatment with oral drugs, called DAAs.	Although it is not very effective, interferon is the best available treatment for HDV. Research on other new treatments is being conducted.	Rest, fluids and good nutrition
Is there a vaccine?	Yes	Yes	No	No, but the HBV vaccine will prevent HDV	A vaccine is in development
What happens to people who have it?	HAV does not cause liver damage; most people recover within weeks or months. HAV can be life-threatening for people with other liver diseases and people over 50 years of age, although this is rare.	HBV becomes chronic (remains in the body) in: 80-90% of infants infected before they are one year old; in 30-50% of children infected before they are six years old; and in 5% of adults. HBV is more likely to become chronic in HIV-positive people. Untreated HBV can lead to liver failure and liver cancer in 30-50% of adults.	HCV becomes chronic (remains in the body) in 55-85% of people. Untreated HCV can lead to liver damage, including cirrhosis of the liver (serious scarring). People with cirrhosis from HCV are at risk for liver failure and liver cancer.	5% of people who get HBV and HDV at the same time (called co-infection) will develop chronic HDV (the virus remains in the body). 80% of people who already have chronic HBV when they get HDV (called superinfection) will develop chronic HDV. In some cases, HDV superinfection can lead to sudden liver failure and death – although this is rare. Chronic HDV can cause cirrhosis in 60-70% of people, leading to liver failure. The liver-related death rate is ten times higher for HBV/HDV co-infection than it is for people who have HBV alone.	Usually, HEV goes away by itself, in 4 to 6 weeks, but it can become chronic in people with weak immune systems. HEV can become serious, causing life-threatening liver failure in pregnant women, especially during the 3rd trimester. HEV can cause rapid and serious liver damage in HIV-positive people with a history of low CD4 cell count (although this is not common).

What is the Hepatitis C virus?

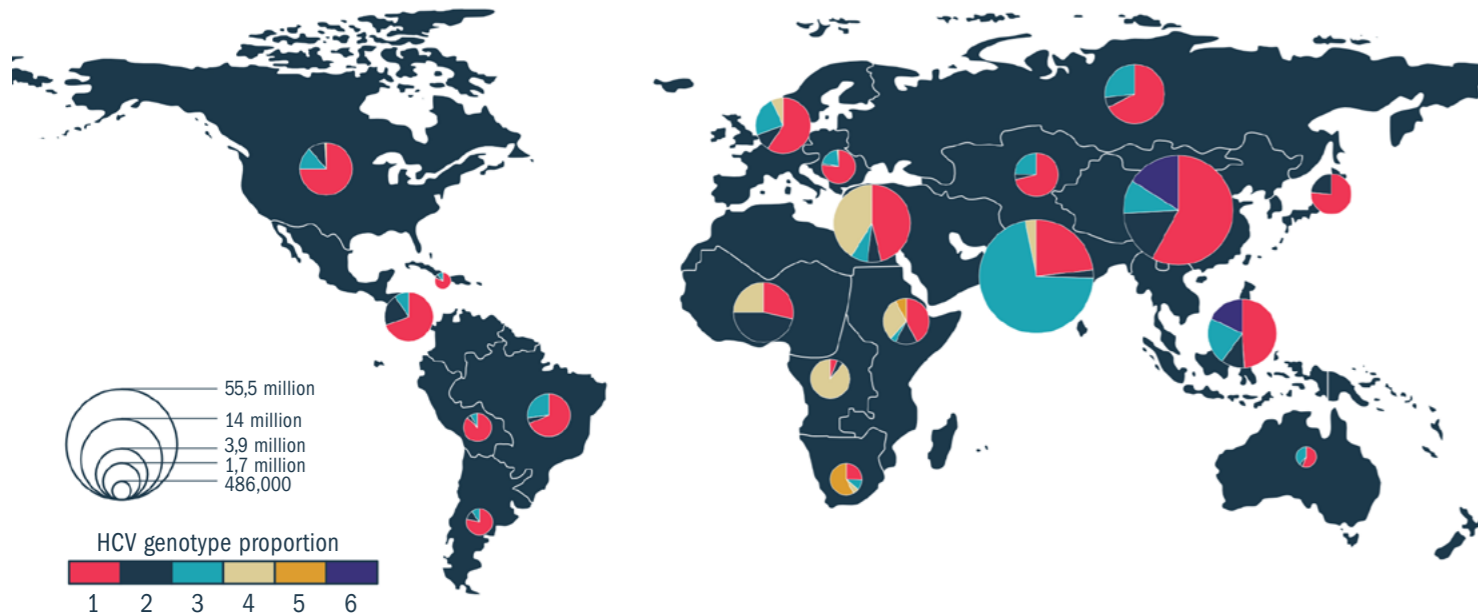
Hepatitis C virus is so tiny that it cannot be seen without a microscope. It is part of the flavivirus family of RNA viruses that can reproduce inside of human cells.

Are there different kinds of HCV?

There are 7 genotypes (or strains) of HCV. Each strain was given a number in the order that it was discovered. Each genotype has subtypes and are named alphabetically in the order that they were discovered. A person can be infected with HCV more than once, and some people have more than one strain of HCV.

Globally, HCV genotype 1 is the most common, followed by genotypes 3, 2, 4, 6, 5 and 7. Over 50% of people with HCV have a strain other than genotype 1. Genotype 4 and 5 are the most common in low- and middle-income countries.¹⁵ Most direct-acting antivirals (DAAs) were developed for genotype 1. DAAs are the drugs used to treat HCV. People with genotypes 4, 5, and 6 are often not included in clinical trials to test the effectiveness of DAAs. Therefore, the effectiveness of DAAs for treating people infected with Hepatitis C genotypes 4, 5 and 6 is not well known. DAAs are less effective for treating people with HCV genotypes 3 and cirrhosis of the liver (liver scarring).¹⁶ Treatment with DAAs for people with genotype 2 HCV has been shown to be effective, but many of the treatment options are very new, some are not yet approved, the drugs are expensive, and the effectiveness of many of the treatment options has only been tested in small numbers of people.¹⁷

Figure 15: Global distribution and prevalence of HCV genotypes



Source: Messina JP, Humphreys I, Flaxman A, et al. Global distribution and prevalence of hepatitis C virus genotypes. *Hepatology*. 2015 Jan;61(1):77-87. doi: 10.1002/hep.27259. Used with permission.

HCV genotyping (testing to see which strain the HCV is) is done with a blood test. This may not be necessary in the future, since some DAA combinations can be used to treat all genotypes. DAA combinations that can be used to treat all genotypes of HCV are called pan-genotypic DAAs. But for now, the type, length and outcome of HCV treatment depends on the HCV genotype (and sometimes the subtype), and whether or not a person has cirrhosis. For example, DAAs are less effective for people who have both genotype 3 and cirrhosis, but adding Ribavirin and/or extending treatment from 12 to 24 weeks can increase the likelihood of being cured.^{18,19,20} This means that it is very important to know which genotype and subtype of HCV a person has, before starting them on treatment.

How many people have HCV?

Worldwide, about 185 million people have been infected with HCV. Nearly 2.3 million of these people are also HIV-positive.^{21,22} It is hard to know exactly how many people have chronic hepatitis C, or how many more people become infected each year. Estimates are based on studies in small groups of people, such as blood donors, people who inject drugs, prisoners and pregnant women. Other estimates are based on information from clinics that treat PLHIV.

HCV is common among people living in poverty, PLHIV and some of the same key populations that are vulnerable to HIV/AIDS, including people who inject drugs, men who have sex with men (MSM), sex workers and prisoners. Stigma and criminalization (using legal punishments against these groups of

people) make them afraid to seek healthcare or other social services. People in key populations often lack access to healthcare and are unaware that they have hepatitis C. In addition, most people with HCV do not feel sick when they become infected. Because they don't feel sick, many people do not know they have become infected, and do not go to the health facility. For these reasons, HCV is often not diagnosed.

Many countries do not have government-funded testing programs for HCV. In addition, countries do not always collect the same, or any, information about the number of people who have HCV. There is no global standard for HCV surveillance - and more than one test is needed to confirm chronic HCV infection. This means that there is not good, accurate information on how many people are infected with HCV. Without national and local data on the number of people with HCV, it is difficult to know the amount of resources needed for preventing, diagnosing and treating HCV. It is also difficult to know where these resources are most needed.

How is HCV transmitted?

Hepatitis C is a tiny and tough virus that lives in the blood. It can survive for weeks outside the body in dried blood.²³ HCV is transmitted when infected blood enters a person's body. This can happen:

- When people are injecting drugs with shared, unsterilized needles, syringes, filters and other equipment,
- From unscreened blood transfusions,
- From a mother to her infant,
- During sex,
- During medical and dental procedures, including kidney dialysis and circumcision,
- From scarification (scratching, burning or cutting patterns into the skin) and tattooing with shared needles, ink and inkwells.

Hepatitis C can be transmitted from a mother to her infant, although when and how this happens is not well understood. The risk of a mother with HCV passing the virus on to her infant is about 3% to 10%.²⁴ This risk is much higher among HIV-positive mothers who are not receiving antiretroviral therapy. ART lowers the risk of mother-to-child transmission of HIV and HCV.^{25,26}

HCV can be transmitted during sex. Transmission of HCV among MSM has been increasing over the last 15 years.²⁷ The factors that make transmission of HCV between MSM more likely are:^{28,29}

- Being HIV-positive,
- Having another sexually transmitted infection (STI),
- Having multiple sex partners or group sex,
- Having unprotected, rough receptive fisting and anal sex,
- Sharing sex toys,
- Bleeding during anal sex, and
- Using recreational drugs that cause people to have more risky sex.

A higher risk of sexually transmitted HCV has been reported among HIV-positive women who have male partners that inject drugs.²⁴

What happens to people who have HCV?

Sometimes people have a strong immune response that will get rid of hepatitis C (called spontaneous viral clearance). This usually happens within the first six months after HCV infection.³⁰ This will happen for about 1 out of 4 people (or 25%)³¹ of people. Spontaneous viral clearance is most likely to happen in young women and people with the IL-28B CC genotype (which is most common among white people with European ancestry).^{32,33,34} Because PLHIV have weaker immune systems, they are less likely to spontaneously clear hepatitis C than HIV-negative people.³⁵

For most people, HCV becomes a chronic infection (an infection that lasts for a long time) although it is curable.

How does HCV cause liver damage?

After the hepatitis C virus gets into the bloodstream, it enters and infects liver cells. The immune system responds by walling off infected cells to protect healthy liver cells from HCV. Over many years, this immune response causes liver scarring (called fibrosis). Fibrosis can spread through the liver and worsen, leading to serious liver scarring (called cirrhosis) that makes it difficult for the liver to function. People with cirrhosis are at risk for liver failure and liver cancer. Each year, 700,000 people die from liver failure or cancer caused by HCV.^{36,30}

Figure 17: The stages of liver disease³⁷



There are two stages of cirrhosis. The first stage is called compensated cirrhosis - meaning that the liver can still function even though it is scarred. The second stage is called decompensated cirrhosis, or liver failure, meaning that the liver can no longer function. Sometimes, people with decompensated cirrhosis can be cured of HCV. However, some DAAs are not safe for people with second-stage cirrhosis or decompensated cirrhosis. This can make the HCV more difficult to treat. HCV treatment should be delivered or overseen by a specialist. Usually, a liver transplant is recommended.

HCV and TB

The groups of people that are at high risk of getting HCV, are the same groups that are at high risk of developing active TB. These include:

- PLHIV
- People who inject drugs
- Prisoners

The World Health Organization (WHO) recommends screening people with hepatitis C for active TB disease.³⁸ This is because it can be difficult to treat people who have TB and HCV. The medicines used to treat TB may cause damage to the liver, and the risk for liver damage from TB treatment is much higher for people with hepatitis C. For this reason, people with HCV who are being treated for TB should have regular check-ups and monitoring.^{39,40} In addition, people cannot take HCV treatment (DAAs) while they are being treated for TB. This is because anti-TB drugs interact with DAAs. Active TB disease should be treated first.⁴¹

HCV and HBV

HCV/HBV co-infection is when someone has hepatitis C and hepatitis B. HCV/HBV co-infection is common where HBV rates are high, including countries in Asia, sub-Saharan Africa and South America. Liver damage or liver disease sometimes develops more quickly in people who have HBV and HCV. HCV can be treated in people with HBV, but they may also need HBV treatment.

HCV and pregnancy

Hepatitis C can harm mothers and their infants. For some women with HCV, liver disease gets worse after they give birth.⁴² Maternal HCV infection (having HCV while pregnant) may increase the risk of pre-term delivery – when the mother gives birth too early, before the infant is ready. Having HCV while pregnant can also increase the risk of low birth weight (the infant weighs too little at birth), low Apgar score (the infant doesn't have a healthy appearance and breathing at birth), birth defects and infant mortality.⁴³

It is not known whether it is safe to take DAAs during pregnancy and breastfeeding, because DAAs have not been studied in pregnant and breast-feeding women. Sometimes, a drug called Ribavirin (RBV) is used to treat HCV. Women who are pregnant should not take Ribavirin as it can cause birth defects and miscarriage. Women who have been taking Ribavirin should try not to get pregnant for six months after finishing their Ribavirin treatment.

HCV and children

Although HCV is thought to develop slowly in children, it can cause serious liver damage. The longer the child has HCV, the worse their liver damage will get.^{44,45,46} Children who have had cancer have weakened immune systems. For this reason, children who have had cancer who also have HCV, are more likely to develop liver disease.⁴⁷

At the moment, the recommended treatment for children with HCV is pegylated interferon (PEG-IFN) and Ribavirin. Studies to test the safety and effectiveness of using DAAs to treat children with HCV are underway.

What can I do to prevent liver damage?

There are some factors that can worsen hepatitis C, but there are also many actions a person can take to help protect their liver from damage.

Alcohol is known to cause and worsen liver damage, even in people who do not have HCV. For this reason, the WHO recommends that people with HCV should be screened for alcohol use and moderate to heavy drinkers should be counseled to reduce their alcohol intake.⁴⁸ Drinking less alcohol, or avoiding alcohol completely is an important way to prevent liver damage. In addition, drinking at least two cups of caffeinated coffee per day lowers the risk of liver damage.^{49,50}

Some medicines are difficult for the liver to break down, but there are often more 'liver-friendly' versions of those medicines. When possible, people with Hepatitis C should switch to these liver-friendly medicines. Overweight people may have steatosis (fatty liver) that increases their risk for cirrhosis and liver cancer. Weight loss can improve this.⁵¹

Unfortunately there are other factors that cause liver damage from HCV, and that cannot be prevented. The longer people have HCV, the more likely they are to have liver scarring or cirrhosis. People who get HCV when they are over 40 years old will develop liver damage more quickly. People with a certain strain of hepatitis C (genotype 3) are at higher risk of cirrhosis and liver cancer.^{52,53} Estrogen, a female reproductive hormone, can help protect the liver from scarring. This means that males and post-menopausal women are at higher risk for HCV-related liver damage and liver cancer.⁵⁴

HCV outside of the liver

Hepatitis C can also cause health problems outside of the liver. These are called extrahepatic manifestations.⁵⁵ Possible extrahepatic manifestations HCV are:^{56,57}

- Type 2 diabetes
- Cardiovascular disease
- Anxiety
- Depression
- Fatigue
- Neuropathy (numbness or weakness in the hands or feet)
- Cognitive (feeling confused or 'foggy' thinking)
- Cryoglobulinemia (when abnormal proteins cause blood to thicken and damage blood vessels)
- Non-Hodgkins lymphoma (cancer of the lymph nodes)

Extrahepatic manifestations are not related to the severity of liver damage, meaning that the amount of liver damage a person has is not a sign of whether or not they will develop extrahepatic manifestations.⁵⁸ HCV increases the risk for type 2 diabetes and cardiovascular disease.⁵⁹ Being cured is known to lower the risk of developing type 2 diabetes, and it may also lower the risk for heart disease and stroke.^{60,61}

Being cured of HCV also improves or eliminates many other extrahepatic manifestations.

SECTION 2.2.2. HCV and People Living with HIV

PLHIV are six times more likely to have hepatitis C than HIV-negative people.⁶² HIV worsens hepatitis C, increasing the risk of serious liver damage, even for people who are on ART. PLHIV who have HCV are also likely to develop liver damage more quickly than HIV-negative people even on ART.^{63,64} In countries with widespread access to ART, liver disease from HCV has become a leading cause of death among HIV-positive people.⁶⁵

The highest rates of HCV/HIV co-infection are found among HIV-positive people who inject drugs. 82% HIV-positive people who inject drugs are HCV/HIV co-infected. 6.4% of HIV-positive MSM are co-infected with HIV and HCV.

DAAs are just as effective at curing HCV in people who are HIV/HCV co-infected as in those with HCV alone. However, interactions between DAAs and ARVs may make it more difficult to treat HCV in PLHIV.^{66,67,68}

SECTION 2.2.3. How is HCV diagnosed?

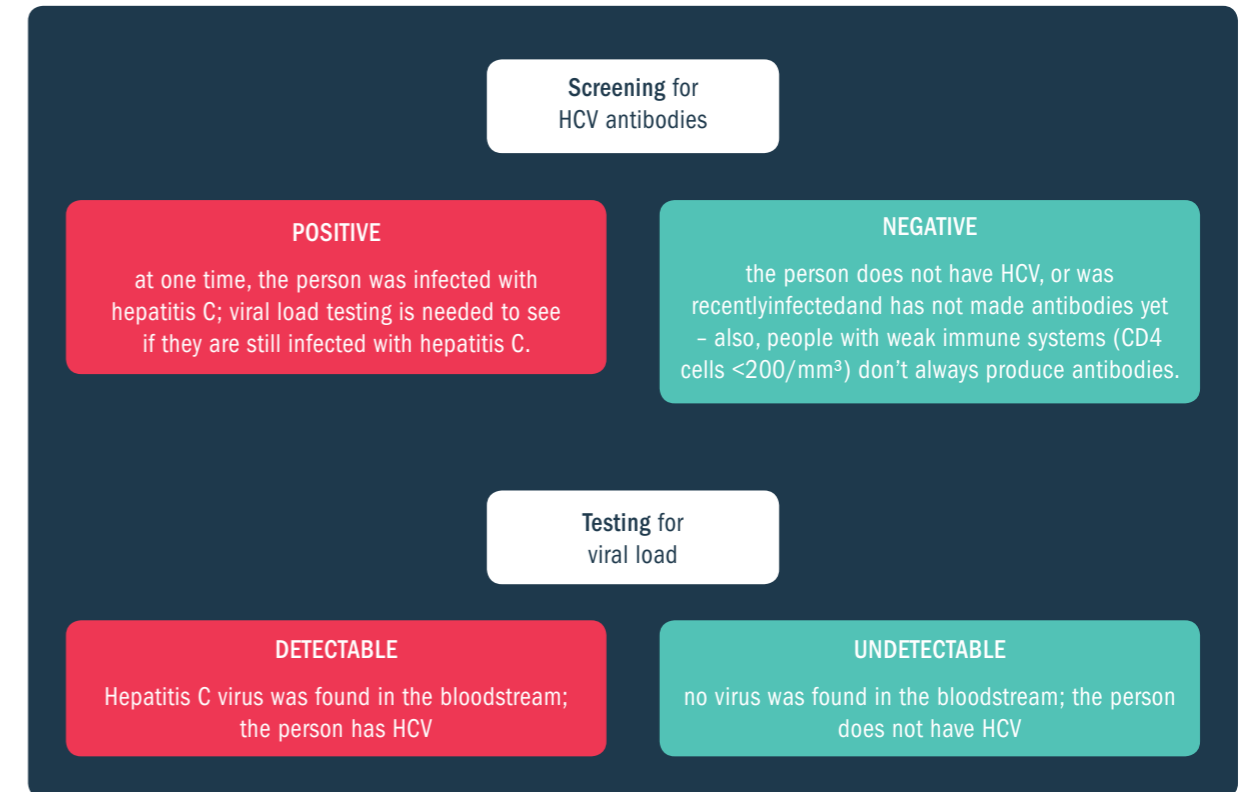
There have been huge improvements in HCV treatment in recent years, but technology for HCV diagnosis is developing more slowly. There are no rapid point-of-care tests suited for resource-limited settings currently available. At the moment, HCV testing is a two-step process. The first test, called screening, looks for antibodies to the virus. Antibodies are proteins made by the body's immune system. When the immune system identifies a virus or bacteria, it makes antibodies to fight the infection.⁶⁹ Almost everyone will produce antibodies within 12 weeks of becoming infected with hepatitis C.⁷⁰ Being HCV-positive does not mean that a person still has the hepatitis C virus, since some people have a strong immune response that will destroy the virus without treatment. This usually happens within the first six months after acquiring HCV.

People with a positive HCV antibody test result need another test that looks for the actual hepatitis C

virus, to confirm or rule out HCV infection. The WHO recommends that all people who have a positive antibody test result should undergo viral load testing.⁷¹ Hepatitis C virus can usually be detected in a person's bloodstream two weeks after she or he becomes infected.

HCV core antigen testing looks for a protein, the HCV core antigen, that is part of the virus. The HCV core antigen becomes detectable much faster than antibodies; it can be found two weeks after a person becomes infected with HCV. Core antigen testing may be a good option for resource-limited settings, since it is simpler and less expensive than viral load testing.

Figure 4: HCV – screening and testing



Who should be screened for HCV?

The WHO recommends that people who are part of high-prevalence group, or people with a history of HCV risk behavior should be screened with an HCV antibody test.⁷² These include:⁷³

- Persons who have had medical or dental interventions in health-care settings with poor infection control practices.
- Persons who have received blood transfusions at a time when testing blood donors for HCV was not done, or in countries where testing of blood donations for HCV is not done regularly.
- People who inject drugs (PWID)
- People who have had tattoos, body piercing or scarification procedures done where infection control practices are not good
- Children born to mothers infected with HCV
- PLHIV
- Persons who use/have used intranasal drugs
- Prisoners and people who have ever been in prison

How to test for liver damage

When treating HCV, it is very important to find out whether a person has liver damage, or scarring, called cirrhosis. There are several reasons why this is important. Since people with cirrhosis are at higher risk for liver-related illness and death, they may be prioritized for treatment if HCV access is limited. Also, people with cirrhosis may need to avoid certain DAAs, be monitored more often, and stay on treatment longer.

In the past, the best way to test for liver damage was an invasive test called a liver biopsy, which involved removing a piece of the liver using a long needle. This piece of liver is then examined under a microscope to look for scarring. Biopsies are expensive, can be painful (and in rare cases, dangerous) and are not always accurate.

Luckily, there are new, less invasive ways to test for liver damage, and to tell how badly the liver is damaged. These tests are good at identifying people with cirrhosis, but they are not good at identifying mild or moderate liver damage.

There are ways to identify mild and moderate liver damage. The WHO recommends Fibroscan or Fibrotest, when these tests are available. Fibroscan is a device that uses sound waves to assess liver damage, but the machines are expensive. Fibrotest is a combination of several blood tests that has been patented and must be performed in designated laboratories with specific quality standards.

An alternative, more affordable way to test for mild to moderate liver damage involved groups of simple and routine blood tests (FIB-4 and APRI). Although these are less accurate, the WHO has recommended them because they can distinguish cirrhosis from less serious liver damage and are inexpensive to perform.⁷⁴

SECTION 2.2.4. How is HCV Treated?

HCV can be cured. This is because, unlike HIV, hepatitis C does not insert itself into a cell's DNA.

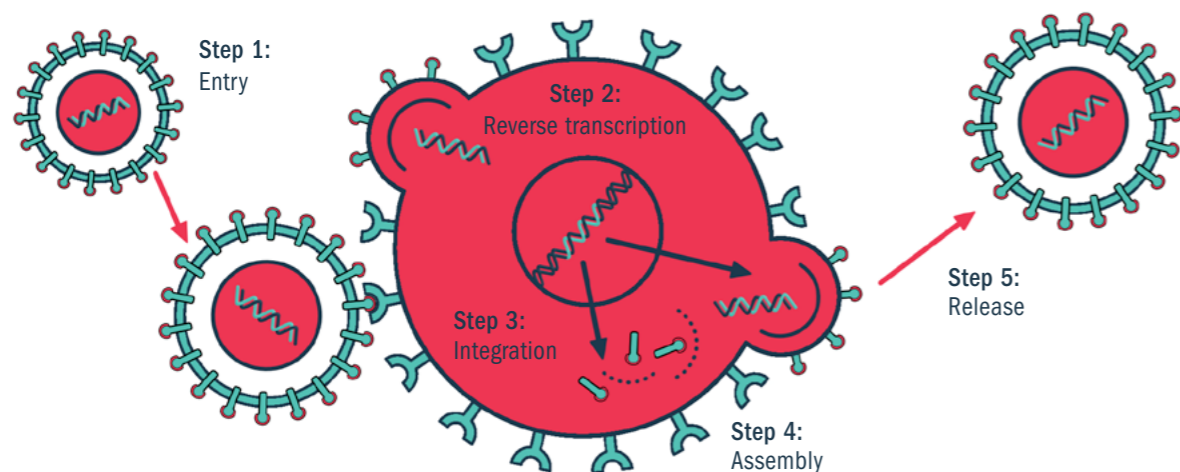
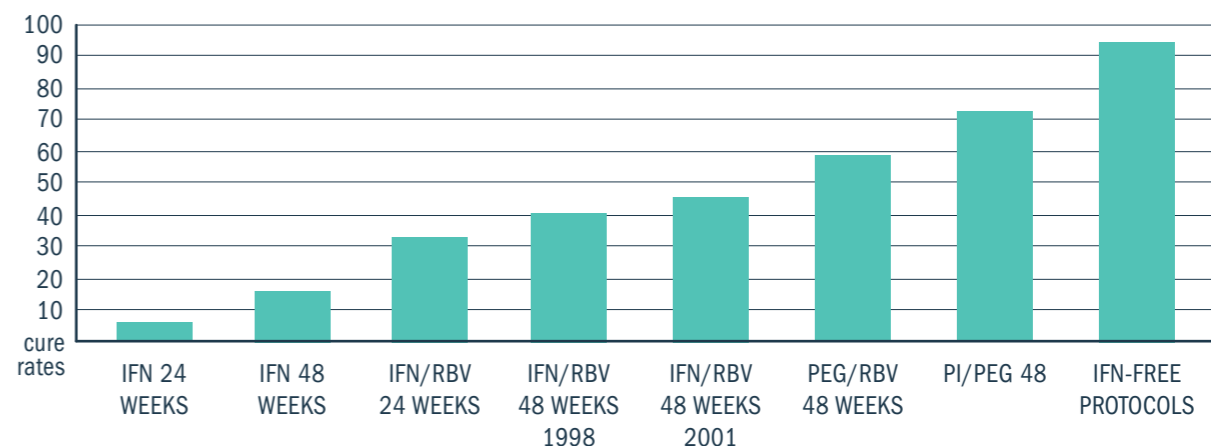


Figure 5: The life cycle of most viruses

The first medicines used to treat HCV were pegylated interferon (PEG-IFN) and Ribavirin (RBV). These drugs were not created to cure HCV. PEG-IFN and RBV can cure HCV in about 50% of people. In 2011, there were reports of the first people with HCV to be cured after 24 weeks of treatment with a pair of oral direct-acting antivirals DAAs.⁷⁵

Figure 6. Improvement of hepatitis C treatment



Source: <https://www2.med.psu.edu/medicalreport/gi/new-developments-in-the-rapidly-evolving-landscape-of-hepatitis-c-therapy/>

The same principles and technology that led to development of HIV antiretrovirals (ARVs) were also used for HCV DAAs. Some DAAs even target the same enzymes as ARVs. However, because DAAs were made specifically to work against hepatitis C virus, they do not work against HIV.

By 2013, it became possible to treat HCV – and usually cure it within 12 weeks – with oral, DAAs. DAAs have proven to be safe and effective, regardless of HCV treatment history, HIV status, or whether or not the person has cirrhosis of the liver.^{76,77,78,79,80}

DAAs are safer, simpler, more effective, and have fewer serious side-effects than treatment with interferon.⁸¹ In 2016, the WHO updated their HCV guidelines to recommend treatment with interferon-free regimens. Now, hepatitis C is treated with a combination of oral DAAs, for 8 to 24 weeks. In some clinical trials, DAAs have cured over 95% of people who were treated with them – and real life results have been similar.^{82,83,84,85,86}

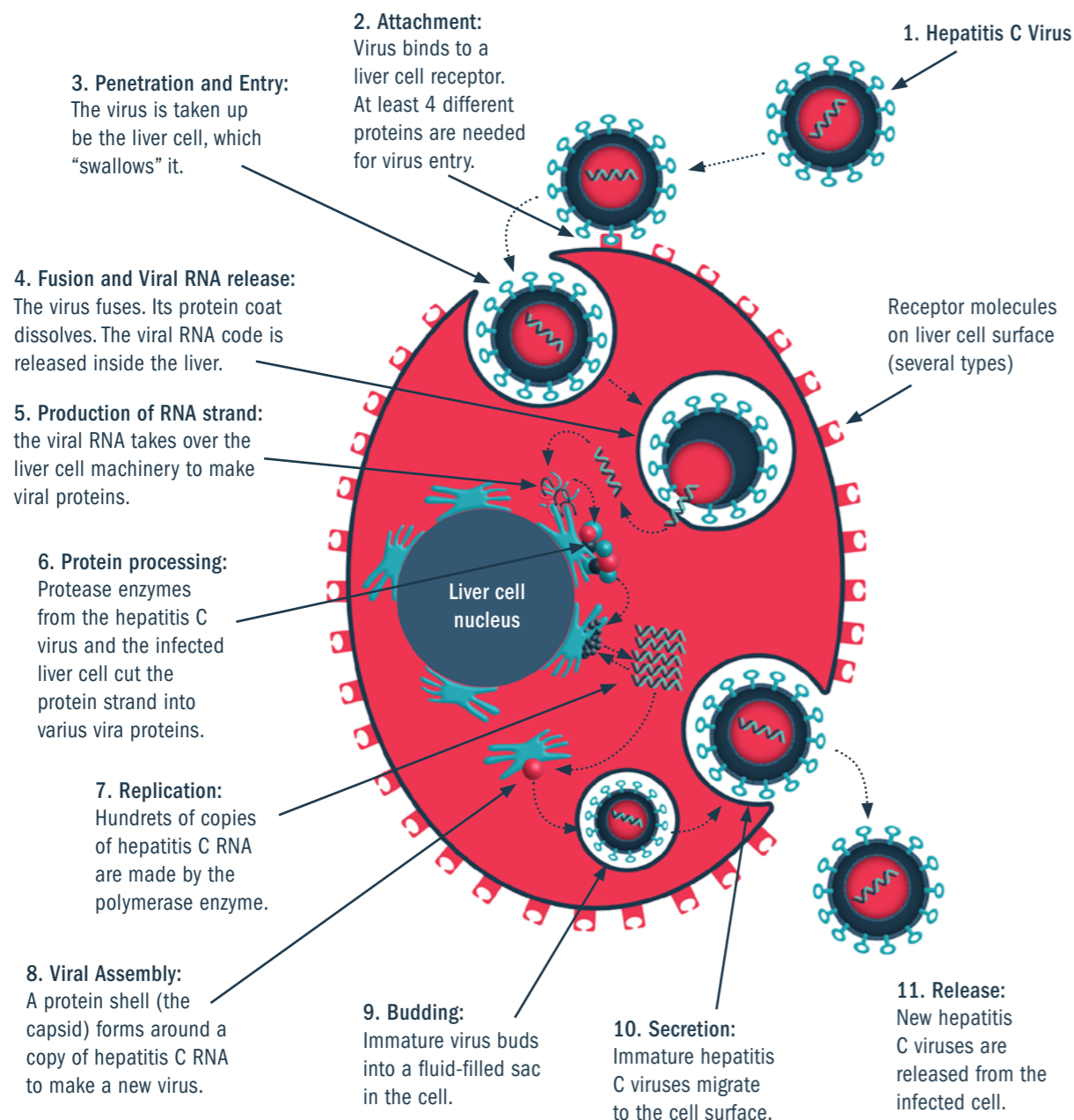
When is a person with HCV cured?

We say a person with HCV is 'cured' when the hepatitis C virus becomes undetectable during treatment and is still undetectable 12 weeks after they have finished treatment. This is called sustained virologic response (SVR). This means that the body's suppression of the virus is continuing even though the person has finished taking their treatment. In some people, liver damage lessens after they are cured. In long-term studies on people who are co-infected with HCV and HIV, SVR has reduced the risk of liver-related and non-liver related illness and death. Being cured also reduces the risk of AIDS-related illness and death.^{87,88,89}

How do DAAs work?

An individual hepatitis C virus is called a virion. Each HCV virion can make hundreds of thousands of copies of itself. Just like ARVs, DAAs work by blocking different steps of the HCV lifecycle. This prevents HCV from reproducing. DAAs stop new virions from being made. The remaining virus in a person's body dies off, usually within 12 weeks.⁹⁰

Figure 7. The HCV Lifecycle and DAA targets



There are four different classes, or families, of DAAs. These are:

- Non-nucleoside polymerase inhibitors,
- Nucleoside/nucleotide polymerase inhibitors,
- NS5A inhibitors, and
- Protease inhibitors.

HCV is treated with at least two DAAs, each from a different class. Sofosbuvir, a nucleotide polymerase inhibitor, has become the backbone of nearly all DAA combinations.

Table 2. WHO-recommended DAAs, by Class*

Class	How it Works	WHO-recommended DAAs	Genotypes	Characteristics
HCV protease inhibitor	These DAAs stick to the HCV protease enzyme so it cannot cut up viral proteins. This prevents the virus from reproducing.	simeprevir paritaprevir/r	1 and 4	Once daily. Can interact with other drugs.
HCV non-nucleoside polymerase inhibitor	These DAAs stick to different parts of the polymerase enzyme and change its shape	Dasabuvir	1	Twice-daily. No other DAAs from this class are being developed.
HCV nucleoside/nucleotide polymerase inhibitor	These DAAs inhibit HCV RNA synthesis by blocking the polymerase enzyme	Sofosbuvir	all	Once-daily. Few interactions with other drugs High barrier to resistance Has become the backbone of nearly all DAA regimens
HCV NS5A inhibitor	It is not clear exactly how these DAAs work; experts think they block more than one step in the viral lifecycle. They are thought to interfere with the function of NS5A protein that plays a role in HCV RNA replication. in steps 6 and 8 (seen in Figure 7 above)	Daclatasvir Ledipasvir ombitasvir	Most or all	Once-daily Some interactions with other drugs Low barrier to resistance

* some recently-approved DAAs are not included in WHO treatment recommendations. These are: Zepatier, a fixed-dose combination (FDC) of Elbasvir (NS5A inhibitor) and Grazoprevir (protease inhibitor) for HCV genotypes 1 and 4, which was approved in January 2016; and Eplclusa, a pan-genotypic, FDC of Sofosbuvir and Velpatasvir (an NS5A inhibitor), which was approved in mid-2016.

Who should be treated for HCV?

DAAs are expensive. For this reason many people living in low- and middle-income countries have limited access to DAAs (although affordable generic DAAs are becoming available). In addition, HCV is a global epidemic, and many poor and resource-limited countries do not have enough healthcare workers to screen, diagnose, and treat people. For these reasons, the WHO has released guidelines on which groups of people to prioritize for HCV treatment.⁹¹

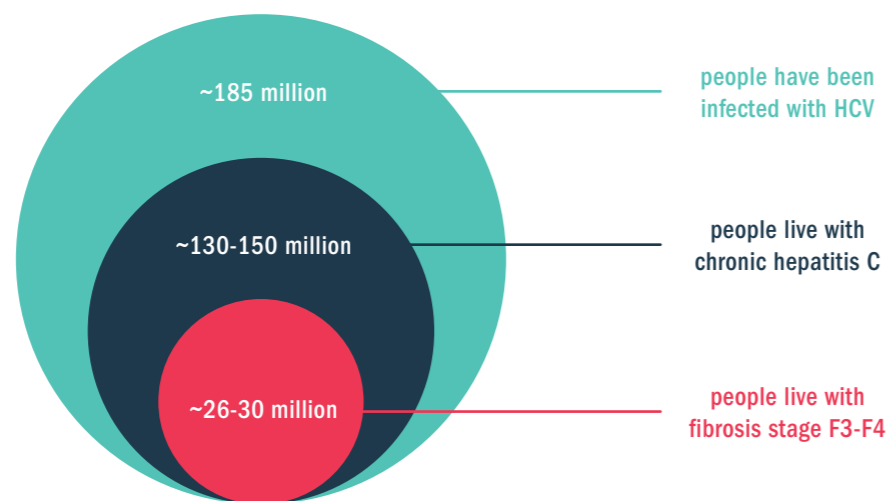
- People at increased risk of death
- This includes people who have advanced HCV-related liver disease, and people who have had a liver transplant but still need HCV treatment.
- **Risk of accelerated fibrosis**
- This includes people who are co-infected with either HIV or HBV, and people who drink a lot of alcohol.
- **Metabolic syndrome, extrahepatic manifestations and evidence of end-organ damage**
- This includes people who have serious symptoms such as debilitating fatigue, and people who are suffering psychologically due to stigma, discrimination, or fear of transmission to others.

- Maximizing reduction in incidence
- This is done by prioritizing treatment for PWID; MSM with HIV; prisoners; sex workers; women with childbearing potential; and health-care workers.

Although following these guidelines will help us to treat the people who are most in need of treatment, scaling-up HCV treatment to everybody with HCV will save people's lives, and prevent the virus from spreading. At the moment, it is estimated that 26 to 30 million people have advanced liver disease due to HCV. These people need treatment now to protect them from developing liver failure or liver cancer, and to stop the transmission of HCV to others. If only the sickest people get access to HCV treatment, the virus will continue to spread.

Between December 2013 and January 2015 only 770,000 people were treated with Sofosbuvir-based regimens.⁹² At this rate, it will take hundreds of years to eliminate the epidemic.

Figure 8. Who Needs Treatment



Source: Lavanchy. Clin Microbio Infect 2011.

What are the WHO guidelines for HCV treatment?

The WHO no longer recommends PEG-IFN and RBV for hepatitis C. This is because these drugs often cause side-effects, are not very effective, and are very complex.*⁹³ However, in some countries, PEG-IFN and RBV is the only HCV treatment available. Other countries still use PEG-IFN to treat certain genotypes. Some countries use PEG-IFN with a DAA, so that treatment is shortened to 12 weeks. However, many people cannot take PEG-IFN, and many others get side-effects from PEG-IFN, causing them to stop treatment.

In 2016, the WHO released updated treatment guidelines, recommending first-line DAA regimens according to HCV genotype and amount of liver damage (cirrhosis or no cirrhosis).

* Since no other treatment has been approved for children, the WHO still recommends treating HCV in children with PEG-IFN and RBV.

Table 3. WHO recommended first line HCV regimens, by genotype and cirrhosis status⁹⁴

	Daclatasvir/ Sofosbuvir	Daclatasvir/ Sofosbuvir/ RBV	Ledipasvir/ Sofosbuvir	Ledipasvir/ Sofosbuvir/ RBV	Sofosbuvir/ Ribavirin
Genotype 1	No cirrhosis: 2 weeks Cirrhosis: 24 weeks	Cirrhosis: 12 weeks	No cirrhosis: 12 weeks Cirrhosis: 24 weeks	Cirrhosis: 12 weeks	
Genotype 2					No cirrhosis: 12 weeks Cirrhosis: 16 weeks
Genotype 3	No cirrhosis: 12 weeks	Cirrhosis: 24 weeks			No cirrhosis: 24 weeks
Genotype 4	No cirrhosis: 12 weeks Cirrhosis: 24 weeks	Cirrhosis: 12 weeks	No cirrhosis: 12 weeks Cirrhosis: 24 weeks	Cirrhosis: 12 weeks	
Genotype 5			No cirrhosis: 12 weeks Cirrhosis: 24 weeks	Cirrhosis: 12 weeks	
Genotype 6			No cirrhosis: 12 weeks Cirrhosis: 24 weeks	Cirrhosis: 12 weeks	

A pan-genotypic regimen (a regimen that is effective against all the HCV genotypes) is ideal, because it simplifies HCV treatment procurement and delivery. Unfortunately, at the moment not enough is known about treating HCV genotypes 5 and 6 with Sofosbuvir/Daclatasvir. Although this once-daily regimen has been effective in the small numbers of people who were treated with it, larger studies must be done before we can be sure that it is safe and effective for people with HCV genotypes 5 and 6.⁹⁵

The duration of HCV treatment still varies by HCV genotype and presence or absence of cirrhosis. In the future, it is likely that there will be pan-genotypic regimens with a fixed duration of treatment for everyone. Until that time, the WHO recommends:⁹⁶

For people without cirrhosis:

- Daclatasvir/Sofosbuvir (12 weeks)
This is the preferred regimen for genotypes 1, 3 and 4, and an alternative regimen for genotype 2),
OR
- Sofosbuvir/Ledipasvir (12 weeks)
This is the preferred regimen for genotypes 1, 4, 5 and 6.

- Sofosbuvir/Ribavirin

This is the preferred regimen for genotype 2 (12 weeks) and genotype 3 (24 weeks)

For people with cirrhosis:

- Daclatasvir/Sofosbuvir (24 weeks)

This is the preferred regimen for genotypes 1 and 4

- Daclatasvir/Sofosbuvir/Ribavirin

This is the preferred regimen for genotypes 1 and 4 (12 weeks) and genotype 3 (24 weeks)

- Ledipasvir/Sofosbuvir (24 weeks)

This is the preferred regimen for genotypes 1, 4, 5 and 6

- Ledipasvir/Sofosbuvir/Ribavirin (12 weeks)

This is the preferred regimen for genotypes 1, 4, 5 and 6

- Sofosbuvir/Ribavirin (16 weeks)

This is the preferred regimen for genotype 2

What alternative treatment regimens are recommended by the WHO?

Alternative regimens are not preferred for various reasons. These reasons include limited data, complexity of the treatment regimen for the patient, the possibility of interactions with other drugs, limited effectiveness across all the HCV genotypes, and safety issues in people with decompensated (advanced) cirrhosis. However, some people will need alternative HCV treatment regimens. The WHO recommendations for alternative treatment regimens are:⁹⁷

- Simeprevir/Sofosbuvir (12 weeks)

This is the preferred alternative treatment regimen for genotypes 1 and 4.

- Daclatasvir/Sofosbuvir (12 weeks)

This is the preferred alternative treatment regimen for genotype 2

- Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir (12 weeks)

This is the preferred alternative treatment regimen for genotype 1

- Ombitasvir/Paritaprevir/Ritonavir/Ribavirin (12 weeks)

This is the preferred alternative treatment regimen for genotype 4

- Sofosbuvir/pegylated interferon/Ribavirin (12 weeks)

This is the preferred alternative treatment regimen for genotypes 5 and 6

What is second-line HCV treatment?

Sometimes, HCV treatment fails. The main reasons for HCV treatment failure are drug resistance (usually to NS5A inhibitors) insufficient length of treatment, interactions with other drugs, or poor adherence. There has been very little research done on the best way to treat people who have had treatment failure in the past.

All fixed-dose combinations (FDCs) for HCV contain an NS5A inhibitor. For this reason it is very important to do research on how to treat people with HCV that is resistant to NS5A drugs. A small retreatment study was done on 16 people who had experienced treatment failure with an NS5A-inhibitor-based combination. The study found that using a new class of DAA (in this case, a protease inhibitor) cured 14 of the 16 study participants.⁹⁸

Drug development for HCV

By mid- 2016, the first pan-genotypic, single tablet FDC for HCV will be approved. This FDC is a combination of Sofosbuvir and Velpatasvir (an NS5A inhibitor). Other pan-genotypic DAA combinations, including triple-class DAA regimens are being developed. Hopefully these new FDCs will simplify treatment, and shorten treatment duration. This will make it much easier for people with HCV to stay adherent and get cured.

Where are the gaps?

In recent years a lot of work has been done to make DAAs more affordable for the people who need them. However, the price of DAAs is not the only factor that prevents people with HCV from getting cured. Making sure that everyone with HCV gets treated will involve strengthening every step of the HCV treatment cascade. The treatment cascade is all the steps a person with HCV must take to get cured. For any disease, the treatment cascade includes counselling and education, testing, treatment initiation, and support to stay on treatment. Strengthening the treatment cascade involves raising awareness among healthcare workers and community members, increasing access to testing, using better diagnostic tools, making sure people who test positive are linked to treatment, and supporting people to stay adherent to their treatment and avoid treatment failure. Some of the problems at the moment include a lack of information among communities and healthcare providers, little or no access to prevention, screening, testing, care and treatment, and little political will to address HCV.

SECTION 2.2.5. Advocacy for HCV Treatment

It is very important for activists to be well-informed. This way, they will know exactly what to demand for from policy-makers and government. If your government does not collect information about the number of people with HCV, it cannot address the epidemic. It is very important that government records and collects accurate data on the HCV epidemic.

However, HCV services have to do more than just collect data: they need to provide information, diagnostics, care and treatment. Issues that will need to be addressed in a national plan for HCV treatment and prevention include: access to information, harm reduction and drug decriminalization policies, the capacity of the healthcare system, and how the national regulatory system functions.

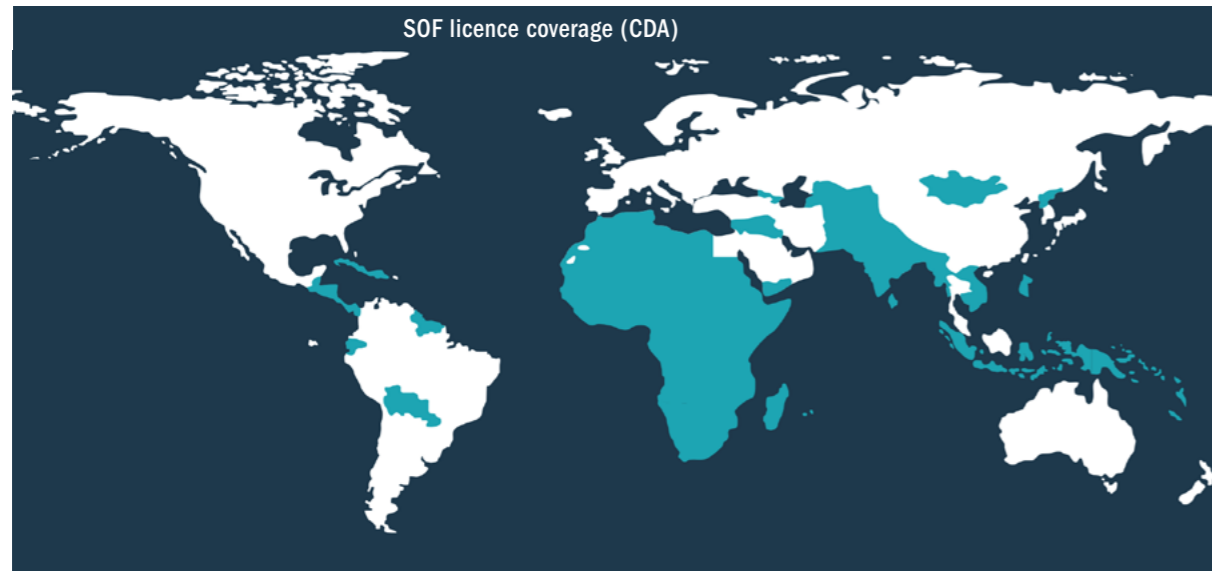
Activists have used research to inform and support their campaigns. A group of researchers looked at all the steps and raw ingredients needed to make HCV DAAs. They found that generic DAAs could be sustainably and affordably mass-produced. For example, a 12-week course of Sofosbuvir and Daclatasvir could be produced for \$102 (\$86.00 and \$16, respectively) including packaging and a 50% profit margin.⁹⁹ This information has strengthened advocacy for affordable HCV treatment.

Where is HCV treatment needed most?

Unlike HIV, hepatitis C mainly affects middle-income countries (MICs)¹⁰⁰ A voluntary license is an agreement by a patent holder (usually the manufacturer of the drug) to allow another company to produce and sell the drug, even while it is under patent. These agreements make drugs much more affordable. However, most MICs are not offered a voluntary license for DAAs. Instead, they are forced to pay high prices to drug developers. Some of the countries with the largest number of people suffering from HCV do not benefit from voluntary licenses. For this reason, millions of people in MICs do not have access to the first pan-genotypic regimen, Sofosbuvir and Daclatasvir – because they live in countries that are excluded from voluntary licenses, and they cannot afford to pay the high prices of the drug developer.

For example, Figure 9 below shows the countries where Sofosbuvir and Sofosbuvir/Ledipasvir (produced by the drug manufacturing company Gilead) are available at affordable prices through a voluntary license agreement (green), and the countries where these drugs are not available through a voluntary license agreement (red). 48,013,610 people with HCV, or 60%, have affordable access to these drugs under a voluntary license agreement, while 32,159,170, or 40%, do not.

Figure 9. Gilead: Sofosbuvir and Sofosbuvir/Ledipasvir voluntary license coverage



Source: Hill et al, World AIDS Conference, Durban, July 2016

Similarly, throughout the world, 43,132,760 people with HCV (or 54%) have affordable access to Daclatasvir through a voluntary license agreement with Bristol-Myers Squibb (the company that produces Daclatasvir), while 37,040,720 people with HCV (or 46%) do not have affordable access to Daclatasvir under a voluntary license agreement.¹⁰¹

Who is working to improve HCV treatment access?

The international response to the HCV epidemic is very different to the response to the HIV epidemic. With AIDS activism, the concept of a global community is firmly established. For more than two decades, activists have fought for life-saving research and access to affordable generic drugs, healthcare and, above all, human rights. AIDS activism has empowered people to address economic and geographic inequality, racism, sexism, homophobia, structural and institutional barriers to health, stigma, discrimination and criminalization, and other social problems driving the epidemic. A chronic disease has been transformed from deadly to manageable, and treatment and prevention continue to improve.

With hepatitis C however, community building has been difficult. This is probably because HCV is curable. In addition, HCV is common among poor and marginalized populations. These populations often have more immediate needs, which get more attention. However, outrage over high DAA prices has sparked a global movement. AIDS activists have joined forces to remove access barriers that prevent people with HCV from being cured.

In many countries around the world, people are fighting for access to HCV treatment. In Thailand, activists have:

- Protested the high price of Sofosbuvir
- Pressured their government to provide universal access to HCV treatment
- Filed a patent opposition for Sofosbuvir (which was granted)

In India, activists have:

- Filed patent oppositions for Sofosbuvir and Daclatasvir
- Launched a successful campaign to speed up registration for Sofosbuvir by waiving the requirement for local clinical trials
- Fought for HCV treatment access via compassionate use

In Spain, activists have:

- Occupied a hospital for months, to demand access to HCV treatment
- Brought legal action to the country's Supreme court, demanding an end to treatment rationing

In Australia, activists have:

- Demanded that the country's Pharmaceutical Benefits Advisory Committee provide unrestricted HCV treatment access, including for people who inject drugs; this became a reality in 2016.

In the US, activists have:

- Fought at local and national levels to demand an end to HCV treatment rationing
- Taken legal action against public and private payers that have withheld access to treatment

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Chapter 2.3. Non-Communicable Diseases (NCDs) in People Living With HIV (PLHIV)

CHAPTER OBJECTIVE

To build community activists' understanding of the 'basics' of Non-Communicable Diseases (NCDs), including: what are NCDs; the three main types of NCDs (diabetes, hypertension and cancer); NCDs in PLHIV, and the prevention, diagnosis and treatment of NCDs.

TRAINING MATERIALS

- PowerPoint presentation '2.3. What is a non-communicable disease?'
- Flipchart and pens (for training **option A**)
- Paper and bowl or basket for collecting pieces of paper (for training **option B**)

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objective of the chapter.
2. Divide the participants into 'buzz groups' of 2-3 people. Ask them to discuss and write down any questions that they have about NCDs in general, or one of the four main types of NCDs: cardiovascular disease; cancer; chronic lung disease or diabetes. These might be things that they do not know or information that is unclear to them.
3. Present Powerpoint presentation '2.3. What is a non-communicable disease?'
4. Ask the participants if they have any questions about the presentation. Check if you have answered all of the questions that they identified in their 'buzz groups'. If you have not, provide them with further information.
5. Ask the participants to summarize the chapter by developing advocacy messages about NCDs.
6. Support their ideas by sharing examples of messages (see below).

Option B (approx. 120 minutes)

Explain the objective of the chapter.

1. Divide the participants into 'buzz groups' of 2-3 people. Ask each group to write down on a small piece of paper two questions they have about NCDs in general, or one of the four main types of NCDs: cardiovascular disease; cancer; chronic lung disease or diabetes.
2. Collect all the pieces of paper and put them in a bowl.
3. Present PowerPoint presentation '2.3. What is a non-communicable disease?'
4. Give each group two questions from the bowl. Ask them to brainstorm the answers to the questions.
5. Altogether, discuss each question and the group's answer. Confirm whether or not the group's answer was correct. If not, discuss the answer to the question.
6. As a group, think about the complications of NCDs for PLHIV.
7. Ask the participants to summarize the session by developing advocacy messages about NCDs
8. Support their ideas by sharing examples of messages (see below).

KEY MESSAGES

- NCDs are chronic diseases – diseases that last a long time and generally can't be cured by medication
- PLHIV are at higher risk of developing some NCDs
- The four main types of NCDs are: diabetes, cardiovascular disease, cancer and chronic lung disease
- NCDs can cause severe life threatening complications (and even death) if poorly managed or diagnosed late in the course of illness
- Lifestyle and behavior are key contributing factors to NCDs
- It is essential that PLHIV have knowledge of NCDs and their causes, prevention strategies, diagnoses and treatments
- Some NCDs are treatable or controllable through healthy diet, exercise or medication
- Treatment for NCDs is generally lifelong

USEFUL RESOURCES

- *Prevention and Control of Noncommunicable Diseases: Guidelines for primary health care in low-resource settings*, World Health Organization, 2012. Available here: http://apps.who.int/iris/bitstream/10665/76173/1/9789241548397_eng.pdf
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SECTION 2.3.1. What are non-communicable diseases (NCDs)?

A non-communicable disease (NCD) is a medical condition or disease that is non-infectious and non-transmissible among people. This means that NCDs are not passed on from person to person. Most NCDs are chronic diseases. A chronic disease is a disease that persists for a long time. By definition, a chronic disease lasts three months or more. Chronic diseases generally cannot be prevented by vaccines or cured by medication. Chronic diseases don't go away over time. A person's chance of contracting a chronic disease tends to increase with age. The majority of people above the age of 65 years have at least one chronic disease.

Currently, NCDs are the leading causes of death and disease burden worldwide. Disease burden is the impact of a health problem as measured by indicators like financial cost and mortality.

The four main types of NCDs are:

1. Cardiovascular disease
2. Cancer
3. Chronic lung disease
4. Diabetes

The most common NCDs in the world are:

- Arthritis
- Cardiovascular disease (such as heart attacks and strokes)
- Cancer (such as breast and colon cancer)
- Diabetes
- Asthma and other chronic lung diseases
- Epilepsy and seizures
- Obesity
- Oral health problems

Between 1990 and 2010 the NCD burden increased from 43% to 54% of the total disease burden in the world. Currently, NCDs are directly responsible for 30 million deaths every year. Half of these deaths occur in people younger than 70 years. The majority (82%) of these deaths occur in low- and middle-income countries. The WHO projects that NCDs will cause 73% of global deaths and 60% of the burden of disease by 2020. It is projected that the majority of these deaths will occur in low- and middle-income countries. Population growth and population aging have contributed substantially to the expanding NCD burden trends. Population growth and aging are rapidly occurring within low- and middle-income country populations.

Health-damaging behaviors, especially cigarette smoking, lack of physical activity and poor eating habits, are major contributors to the leading NCDs. PLHIV are as much, or even more at risk of NCDs than they used to be. This is because PLHIV are living longer due to the widespread use of antiretroviral therapy (ART). For this reason PLHIV are getting exposed to risk factors for NCDs for longer.

PLHIV have also been found to have greater exposure to some of the risk factors for NCDs, such as smoking and infectious diseases like some viral infections. Some PLHIV are also particularly at risk of developing NCDs as a consequence of some of the antiretroviral (ARV) medicines that they are using, such as protease inhibitors. It is therefore essential that PLHIV have some knowledge of NCDs, especially the causes, prevention strategies, diagnoses and treatments available. This knowledge will help PLHIV to reduce their chances of acquiring NCDs or quickly seek treatment if they develop NCDs. This chapter will discuss some of the NCDs that are common in the general population, as well as NCDs that are common in PLHIV.

SECTION 2.3.2. HIV and Diabetes

Diabetes (also called diabetes mellitus) is a group of diseases characterized by the body's inability to use the energy found in the foods that we eat. Diabetes is a lifelong NCD. The main symptom of diabetes is a high level of sugar (glucose) in the blood. This is caused either by reduced insulin production or by the body's inability to use insulin properly. Insulin is a hormone in the bloodstream produced by the pancreas (a gland found in the abdomen). Insulin helps to regulate blood sugar. It acts like a key that opens cells in the body, allowing glucose to be taken into the cells so that it can be used to make energy. When cells do not take up glucose it floods the blood stream. This causes high blood sugar (too much glucose in the blood, also known as hyperglycemia). High levels of blood sugar cause many problems, both in the short and long term.

Types of diabetes

All types of diabetes have something in common. Normally, your body breaks down the sugars and carbohydrates you eat into a special sugar called glucose. Glucose fuels the cells in your body. But the cells need insulin to take in the glucose and use it for energy. With diabetes, either your body doesn't make enough insulin, or it can't use the insulin it produces, or a combination of both these things happen. Because the cells can't take in the glucose, glucose builds up in the blood. High levels of blood glucose can damage the tiny blood vessels in the kidneys, heart, eyes, or nervous system. That's why diabetes, especially if left untreated, can eventually cause heart disease, stroke, kidney disease, blindness and damage to nerves.

Type 1 diabetes

Type 1 diabetes is also called insulin-dependent diabetes mellitus. In people with type 1 diabetes, there is complete absence of insulin in the body. Type 1 diabetes occurs more frequently in people younger than 30 years. It is an autoimmune disease, which means the body attacks itself, destroying the cells in the pancreas that produce insulin. It is not very well understood why the body does this, but it may be because the body's immune system thinks that the cells in the pancreas are 'foreign' cells.

Type 2 diabetes

This is the most common type of diabetes. More than 95% of all diabetes in the world is type 2 diabetes. With type 2 diabetes, the pancreas usually produces some insulin but either the amount produced is not enough for the body's needs, or the body's cells are resistant to it. Therefore, there is a relative absence of insulin. Either way, there is an inability of the body's cells to take up the glucose from the bloodstream. Type 2 diabetes occurs more commonly in persons above the age of 30 years and more so in those who are obese.

Gestational diabetes

This is diabetes that is triggered in women when they are pregnant. An estimated 2 – 10% of pregnant women develop gestational diabetes. It usually resolves on its own after birth. However, it may persist in some to become type 2 diabetes. It is often diagnosed in middle or late pregnancy.

High blood sugar levels in a mother cross through the placenta to the baby during pregnancy. Therefore gestational diabetes must be controlled to protect the baby's growth and development. With gestational diabetes, risks to the unborn baby are even greater than risks to the mother. Risks to the baby include abnormal weight gain before birth, breathing problems at birth, and higher obesity and diabetes risk later in life. Risks to the mother include needing a caesarean section due to an overly large baby, as well as damage to heart, kidney, nerves, and eye.

Risk factors for diabetes

The risk factors for developing diabetes include:

- Being overweight
- Being over 40 years of age
- Having a parent, sibling or child with diabetes
- Having a history of elevated glucose readings in blood sugar testing
- Having a history of diabetes during pregnancy
- Having hypertension
- Having high cholesterol or fats

In addition to these risk factors, PLHIV are at greater risk of developing diabetes than people who are HIV negative. This is explained further below.

HIV and diabetes

Some anti-HIV drugs increase a person's risk of high blood glucose and type 2 diabetes. Some ARV medicines in the nucleoside reverse transcriptase inhibitor (NRTI – Didanosine; Stavudine; Zidovudine) and protease inhibitor (PI – Indinavir; Lopinavir/Ritonavir) drug classes may increase the risk of diabetes. These ARVs seem to make it harder for the body to respond to and use insulin (insulin resistance). Insulin resistance leads to high blood glucose levels, which can result in type 2 diabetes.

Signs and symptoms of diabetes

The major signs and symptoms of diabetes are:

- Increased thirst (polydipsia)
- Increased urination (polyuria)
- Urination at night (nocturia)
- Increased hunger (polyphagia)
- Extreme fatigue and irritability
- Blurring of vision
- Weight loss
- Tingling or numbing in the hands and feet
- Multiple infections or infections which take longer to heal

How is diabetes diagnosed?

Diabetes is diagnosed by measuring the blood sugar levels using a special machine called a glucometer. A person has diabetes if:

Fasting blood sugar (blood sugar levels taken after fasting overnight) is greater than 7mmol/L

or

Random blood sugar (blood sugar taken at any time) is greater than 11.1mmol/L

A periodic test called the Hb A1C blood test estimates glucose levels in your blood over the previous three months. It is used to help identify overall glucose level control and the risk of complications from diabetes, including organ damage.

How is diabetes treated?

There is no cure for diabetes. However, the disease can be controlled, and people with diabetes can live normal and healthy lives if managed well.

Treatment for type 1 diabetes

Treatment for type 1 diabetes involves taking insulin, which needs to be injected through the skin into the fatty tissue below. The methods of injecting insulin include:

- Syringes
- Insulin pens that use pre-filled cartridges and a fine needle
- Jet injectors that use high pressure air to send a spray of insulin through the skin
- Insulin pumps that dispense insulin through flexible tubing to a catheter under the skin of the abdomen

Treatment for type 1 diabetes involves significant lifestyle changes that include:

- Frequent testing of your blood sugar levels
- Careful meal planning
- Daily exercise
- Taking insulin and other medications as needed

Treatment for type 2 diabetes

Treatment for type 2 diabetes is with oral medications. There are several classes of oral anti-diabetes medicines. Examples of medications used in the treatment of diabetes include:

- **Alpha-glucosidase inhibitors:** (e.g. Acarbose and Miglitol) help the body break down starchy foods and table sugar. This lowers blood sugar levels. For the best results, these drugs are taken before meals.
- **Biguanides:** (e.g. Metformin) decrease how much sugar the liver produces. They decrease how much sugar intestines absorb, make the body more sensitive to insulin, and help muscles absorb glucose.
- **Dopamine agonist:** (e.g. Bromocriptine) it is not known exactly how this drug works to treat type 2 diabetes. It may affect rhythms in the body and prevent insulin resistance.
- **DPP-4 inhibitors:** (e.g. Alogliptin, Linagliptin, Saxagliptin and Sitagliptin) help the body continue to make insulin. They work by reducing blood sugar without causing hypoglycemia (low blood sugar). These drugs can also help the pancreas produce more insulin.
- **Glucagon-like peptides (incretin mimetics):** (e.g. Albiglutide, Dulaglutide, Exenatide and Liraglutide) are similar to the natural hormone called incretin. They increase B-cell growth and how much insulin the body uses. They decrease appetite and how much glucagon the body uses. They also slow stomach emptying.
- **Meglitinides:** (e.g. Nateglinide and Repaglinide) help the body release insulin. However, in some cases they may lower blood sugar too much.
- **Sodium glucose transporter (SGLT) 2 inhibitors:** (e.g. Dapagliflozin, Canagliflozin and Empagliflozin) work by preventing the kidneys from holding on to glucose. Instead, the body gets rid of the glucose through urine.
- **Sulfonylureas:** (e.g. Glimepiride, Gliclazide, Glipizide, Glyburide, Chlorpropamide, Tolazamide, Tolbutamide) are among the oldest diabetes drugs still used today. They work by stimulating the pancreas with the help of beta cells. This causes the body to make more insulin.
- **Thiazolidinediones:** (e.g. Rosiglitazone and Pioglitazone) work by decreasing glucose in the liver. They also help fat cells use insulin better.

Oral medications used in treatment of type 2 diabetes like those listed above work by helping the body cells take in the blood sugar from the blood stream, or by encouraging the pancreas to produce more insulin.

The kind of medication that a diabetic person needs is determined by their doctor after taking into account several factors. Sometimes insulin may be needed to maintain the blood sugar levels below normal if the oral medications do not work as well as intended.

Other factors that help in managing diabetes include:

- Diabetes nutrition therapy
- Diabetes education
- Physical activity
- Complementary and alternative therapy

It is also essential to have the blood sugar levels monitored regularly as prescribed by the doctor. Also, whether a person is on insulin or oral medications or any other form of treatment, it is absolutely essential that they adhere to their treatment schedule as prescribed by the doctor.

Complications of diabetes

Untreated or poorly treated diabetes may result in complications, some of them life threatening. Complications of diabetes are divided into acute (short term) and chronic (long term).

Acute complications

- Diabetic keto acidosis (DKA) occurs when the blood sugar rises to very high levels, usually due to poor medication adherence. The patient may go into coma (a state of unconsciousness), and if left unattended for long, the patient may die.
- Hypoglycaemia refers to a very low blood sugar level. It may occur a person takes medications without eating, or after an overdose of medication. Patients feel drowsy, hungry, sweat a lot, have tremors, and if not attended to, become confused and may go into coma and even die.
- Hyperosmolar non-ketotic coma (HONK) is similar to DKA but tends to occur in older people with diabetes.
- Lactic acidosis is an accumulation of excess acid in the patient's blood as a result of high sugar levels. It may also lead to coma and death.

Chronic (long term) complications

People with diabetes are at risk of experiencing long-term problems affecting the eyes, kidneys, heart, brain, feet, and nerves.

Eyes:

Eye problems that can occur with diabetes include:

- Cataracts: a clouding of the lens of the eyes
- Glaucoma: increased pressure in the eye
- Retinopathy: eye changes with the retina in the back of the eye

Symptoms of eye problems include:

- Blurred vision
- Spots or lines in your vision
- Watery eyes
- Eye discomfort
- Loss of vision

It is recommended that people with diabetes see an eye doctor every year for a dilated eye exam – so that the doctor can examine important tissues at the back of the eye

Kidneys:

Protein in the urine is a sign of kidney disease. High blood pressure might also lead to kidney disease. Your blood pressure should be checked when you see your health care provider.

Symptoms of a kidney problem include:

- Swelling of the hands, feet, and face
- Weight gain from edema
- Itching and/or drowsiness (this can occur with end stage kidney disease)

Prompt treatment may slow the changes with kidney disease. People with diabetes should have their urine checked for protein at least once a year.

Heart and brain:

All people with diabetes are at increased risk of developing heart disease and strokes. Heart disease is the major cause of death in people with diabetes. It is important to control other risk factors such as high blood pressure and high fats (cholesterol), as well as blood sugar to prevent heart disease.

Symptoms of a heart attack include:

- Shortness of breath
- Feeling faint, feeling dizzy
- Sweating
- Nausea
- Chest pain or pressure
- Pain in the shoulders, jaw, and left arm

Warning signs of a stroke include:

- Sudden numbness or weakness in the face, arm, or leg, usually on one side of the body
- Sudden nausea
- Fever
- Vomiting
- Difficulty speaking or understanding words or simple sentences
- Sudden blurred vision or decreased vision in one or both eyes
- Difficulty swallowing
- Dizziness
- Loss of balance or loss of coordination

- Brief loss of consciousness
- Sudden inability to move part of the body (paralysis)
- Sudden intense headache

Feet:

High blood sugars can lead to poor blood flow and nerve damage. This can lead to slow healing of sores. People with diabetes experience severe pain in their feet, and may also lose feeling in their feet. In serious cases, this can lead to amputation of a toe(s), foot, or leg.

Nerves:

High blood sugars can affect all of the nerve endings in the body. Nerve damage can cause many problems.

- Symptoms of nerve damage include:
- Burning pain
- Numbness
- Tingling or loss of feeling in the feet or lower legs
- Constipation and diarrhea
- Problems with sexual function in both men and women

Neuropathy:

Neuropathy is a disorder of the nervous system that can affect people with diabetes. There are different forms of neuropathy, including:

- Peripheral neuropathy: damage to the peripheral nervous system
- Autonomic Type I: damage to the nerves of internal organs
- Gastroparesis: movement of food through the stomach slows or stops
- Postural hypotension: drop in blood pressure due to change in body position
- Uncontrolled diarrhea

Preventing diabetes

Diabetes can be prevented by avoiding or minimizing the risk factors explained before such as:

Improving diet

- Use less fat in cooking (eat less fried foods, do not add cream to food)
- Reduce portion sizes
- Eat at least five servings of fruit and vegetables per day
- Eat whole grains and rice
- Eat more fish and lean meats, legumes, fat-free or low-fat dairy products

Exercise

Try to exercise 3 to 5 times per week for at least 30 minutes

Early detection of pre-diabetes

People at risk must undergo regular screening and manage their risk of developing diabetes.

SECTION 2.3.3. HIV and Hypertension

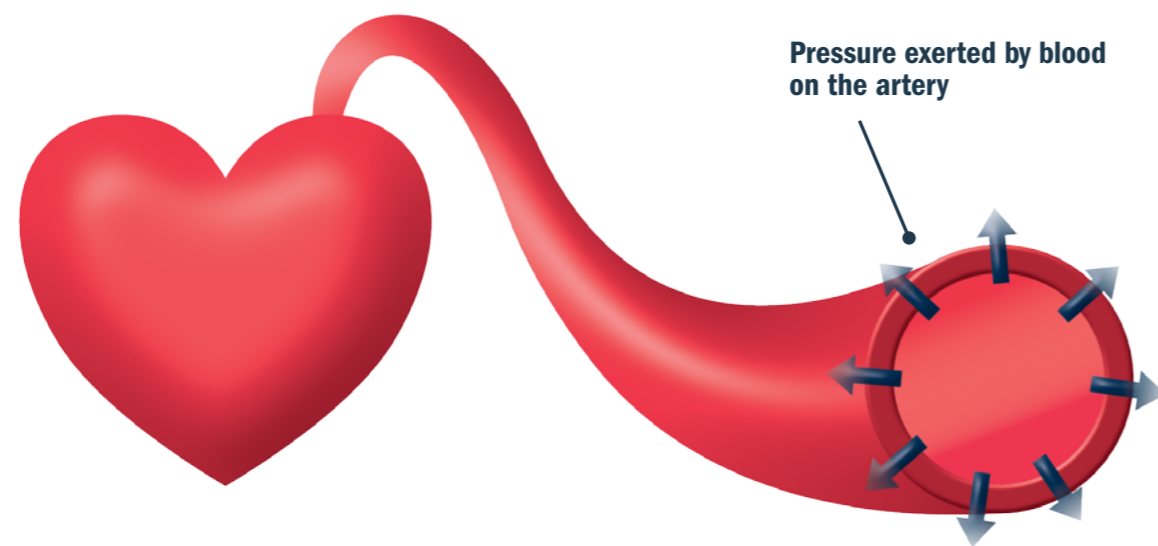
What is blood pressure (BP)?

Blood pressure (BP) is the force exerted on the arteries (vessels that carry blood in the body) by blood as it flows from the heart through the vessels. It is measured in millimetres of mercury (mmHg).

A person's BP is defined by two measurements:

- Systolic BP (SBP): pressure in the arteries produced when the heart contracts
- Diastolic BP (DBP): pressure in the arteries during relaxation of the heart

BP is reported as the systolic pressure over diastolic pressure (for example, 120/70 mmHg or 120 over 70 mmHg)



What is hypertension (high BP)?

Hypertension is blood pressure that is higher than normal.

Normal:

SBP <120 mmHg

or

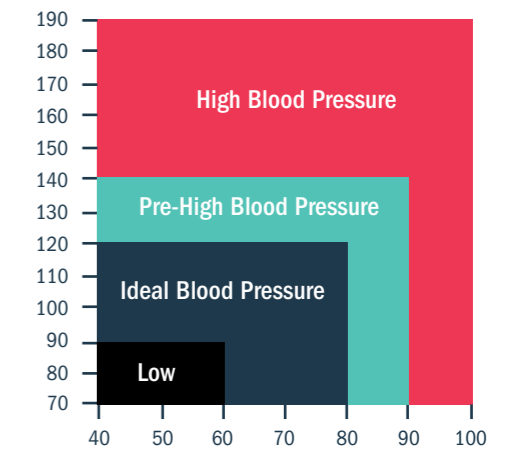
DBP <80 mmHg

Hypertension:

SBP >140mmHg

or

DBP >90mmHg



Hypertension occurs when the arteries (vessels that carry blood from the heart to the rest of the body) stiffen. There are many reasons why this might happen. Some of these reasons are provided below.

Causes and risk factors of hypertension

The cause of hypertension is unknown in the majority of cases. However, there are some medical conditions that may cause high BP. These are regarded as secondary causes of hypertension and include:

- Kidney disease
- Hormonal imbalances
- Blood vessel disease
- Drugs such as oral contraceptives, steroids, caffeine, cocaine
- Psychological factors
- Some diseases of the nerves

HIV and hypertension

Some HIV drugs, particularly protease inhibitors, can cause increases in blood fats, similar to those caused by a fatty diet. High fat content in the blood leads to stiffening of the arteries. Because of this, people taking HIV treatment may be at increased risk of hypertension, particularly if they have other risk factors such as a family history of the condition, a fatty diet, drink a lot of alcohol, smoking or not exercising. ARV medicines can also interact with other medicines to affect blood pressure, and this can be harmful.

Signs and symptoms of hypertension

In early disease, and in general, there are no signs of hypertension. This makes hypertension a very dangerous disease. No wonder it has been called a silent killer! When symptoms are present, they indicate complications related to high BP such as heart failure, heart attack, blindness, stroke and kidney failure.

How is hypertension diagnosed?

The diagnosis of hypertension is made based on several readings of blood pressure above the acceptable (healthy) limits. Generally, BP should be measured in a quiet and comfortable room and when you are in a relaxed mood.

How is hypertension treated?

Lifestyle modification

Living a healthy life is the beginning of preventing hypertension. This includes, but is not limited to:

- Avoiding becoming overweight
- Reducing any excess weight
- Eating more fruits and vegetables
- Reducing salt intake
- Increasing physical activity
- Taking alcohol in moderation (small quantities)
- Avoiding smoking

Medications (anti-hypertensives)

People with high BP often need medicine to lower blood pressure. Several types of anti-hypertensive medicine are available. Different types of anti-hypertensives act in different ways to lower the BP. Some examples of antihypertensive medicines are:

- **Diuretics:** Diuretics (such as thiazides, potassium-sparing diuretics and loop diuretics) are also called water pills. Diuretics help the kidneys get rid of excess water and salt (sodium). This reduces the volume of blood that needs to pass through the blood vessels, and as a result, blood pressure goes down. Diuretics in the thiazide group generally have fewer side effects than the others, particularly when taken at the low doses generally used in treating early high blood pressure.
- **Beta-blockers:** Beta blockers (such as Acebutolol, Betaxolol, Metoprolol, Penbutolol) help the heart beat with less speed and force. The heart pumps less blood through the blood vessels and blood pressure decreases.

- **Angiotensin converting enzyme (ACE) inhibitors:** ACE inhibitors (such as Benazepril, Captopril, Enalapril, Fosinopril, Lisinopril) help the body produce less of a hormone called angiotensin II, which causes blood vessels to narrow. These medications decrease blood pressure by helping blood vessels expand which lets more blood through. ACE inhibitors include:

Angiotensin II receptor blockers: (e.g. Candesartan, Eprosartan, Irbesartan, losartan potassium, telmisartan, valsartan) protect the blood vessels from angiotensin II. To narrow blood vessels, the hormone must bind with a receptor site on the blood vessels. These medications keep that from happening. Consequently, blood pressure decreases.

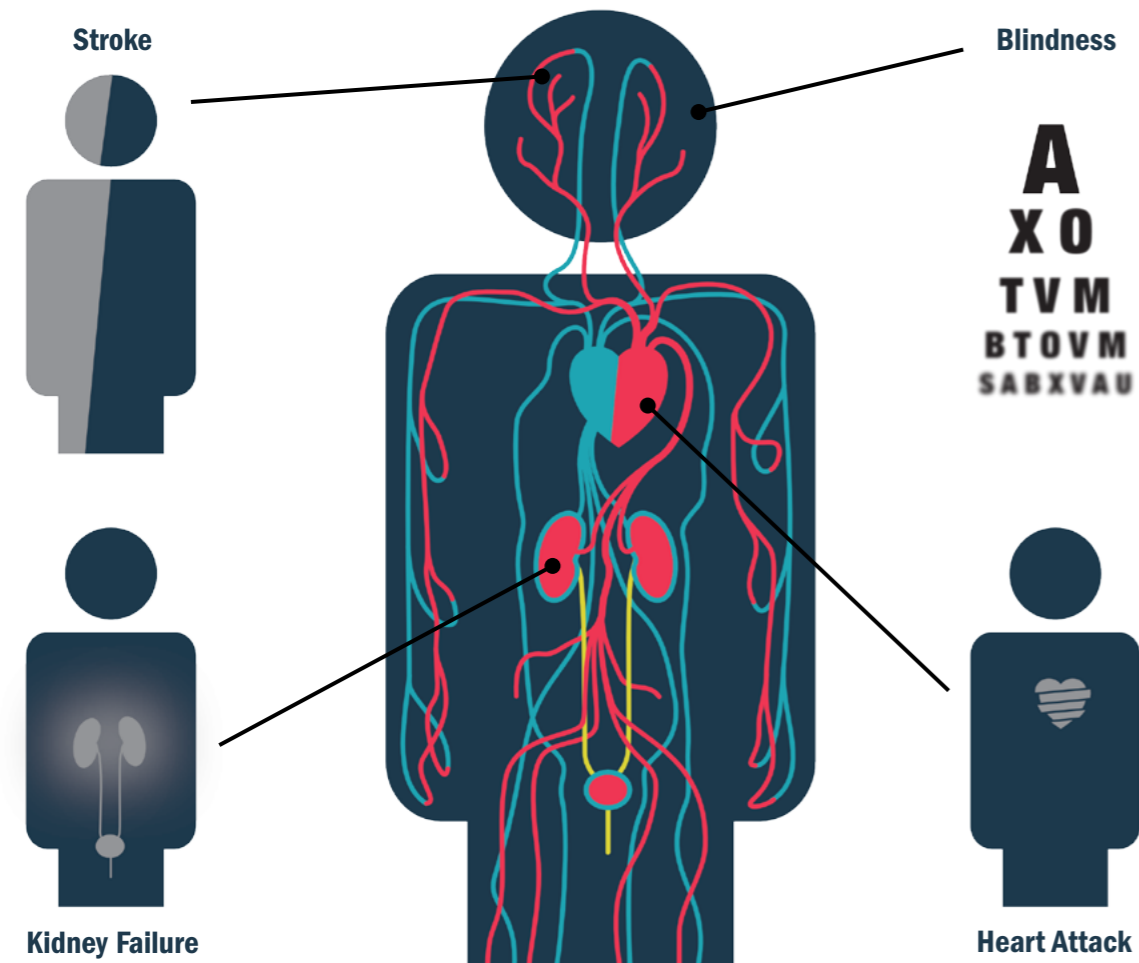
- **Calcium channel blockers:** Calcium channel blockers (such as Amlodipine, Felodipine, Isradipine, Verapamil) keep calcium from entering the smooth muscle cells of the heart and blood vessels. This makes the heart beat less forcefully and helps blood vessels relax. As a result, blood pressure decreases.
- **Alpha-blockers:** Alpha-blockers (such as Doxazosin, Prazosin, Terazosin) help blood to flow through the blood vessels more easily. The body produces a type of hormone called catecholamine when under stress, or chronically in some disease states. Catecholamine, along with norepinephrine and epinephrine, cause the heart to beat faster and with more force. They also constrict blood vessels. These effects raise blood pressure, and occur when these hormones attach to a receptor. The muscles around some blood vessels have what are known as alpha adrenergic receptors. When catecholamine binds to an alpha receptor, the muscle contracts, the blood vessel narrows, and blood pressure rises. Alpha-blockers prevent binding to alpha receptors, so blood is able to flow through the blood vessels more freely, and blood pressure decreases.
- **Alpha-beta-blockers:** Alpha-beta-blockers (such as Carvedilol and Labetalol) have a combined effect. They block the binding of catecholamine hormones to both alpha and beta receptors. They can decrease the constriction of blood vessels like alpha-blockers, and slow down the rate and force of the heartbeat like beta-blockers.
- **Alpha-2 receptor agonists:** Alpha-2 receptor agonists (such as methyl dopa) reduce activity in the sympathetic nervous system, which decreases blood pressure. The main difference between alpha-2 receptor agonists and other alpha-blockers is that they target only one type of alpha receptor. They are a first choice treatment during pregnancy because they generally pose few risks to the mother and fetus.
- **Central agonists:** Central agonists (such as Alpha Methyl dopa, Clonidine, Guanabenz, Guanfacine) keep the brain from sending messages to the nervous system that would release catecholamines and speed up heart rate and tighten blood vessels. The heart doesn't pump as hard and blood flows more easily, so blood pressure decreases.
- **Peripheral adrenergic inhibitors:** Peripheral adrenergic inhibitors (such as Guanadrel, Guanethidine, Reserpine) work to block certain chemical messengers inside the brain, which in turn prevents the smooth muscles from constricting. These medications are generally used only if other medications aren't effective.
- **Vasodilators:** Vasodilators (such as Hydralazine and Minoxidil) relax the muscles in the walls of blood vessels, especially small arteries (arterioles). This widens the blood vessels and allows blood to flow through them more easily. Blood pressure falls as a result.

The kind of anti-hypertensive medication a patient should take is determined by the doctor. After treatment is initiated, BP should be rechecked in one month. Further drug adjustments like increasing the dose of BP medicine or adding other antihypertensive medications are made if the target BP has not been met.

PLHIV should have their BP monitored regularly if on ART, especially protease inhibitors. HIV clinics should do this at least once a year, as part of routine care for PLHIV. Remember that there is no cure for hypertension and that one must continue using medicines for a very long time to control BP.

Complications of hypertension

Debilitating complications may occur as a result of uncontrolled blood pressure. The most common include:



- Coronary artery disease (this disease affects the arteries of the heart and may lead to heart attack)
- Stroke
- Heart failure
- Kidney failure
- Gangrene of the toes and feet
- Poor vision or loss of eye sight

Preventing hypertension

Living a healthy lifestyle can help to prevent hypertension. Living a healthy lifestyle includes:

- Reduce salt intake
- Lead an active lifestyle
- Reduce alcohol intake
- Eat more vegetables and fruits
- Avoid stress
- Avoid smoking
- Maintain a healthy weight

SECTION 2.3.4. HIV and Cancer

What is cancer?

Cancer refers to the abnormal growth of cells in the body. Cancer can start in any part of the body.

Normal cells divide in an orderly way. They die when they are worn out or damaged, and new cells take their place. In the case of cancer, cells start to grow out of control. The cancer cells keep growing and reproducing (making new cancer cells). These cells crowd out the normal cells. Usually the cancer cells don't function like normal cells. Sometimes cancer cells even produce harmful chemicals. This causes problems in the part of the body where the cancer started. Sometimes cancer cells also cause problems in other parts of the body due to the circulating harmful chemicals.

Cancer cells can also spread to other parts of the body. For instance, cancer cells in the lung can travel to the bones and grow there. When cancer cells spread, it is called metastasis. When lung cancer spreads to the bones, it is still called lung cancer. The cancer cells that have moved from the lung to the bones, or any other part of the body look exactly the same as the cells in the lungs.

Most cancers form a lump called a tumor or a growth. But not all lumps are cancerous. When doctors discover a lump, they take out a piece of the lump and look at it to find out if it is cancer. This is called a biopsy. Lumps that are not cancer are called benign. Lumps that are cancer are called malignant. There are some cancers, like leukemia (cancer of the blood), that don't form tumors. They grow in the blood cells of the body.

HIV and cancer

PLHIV can get cancer. They are actually more likely to get some types of cancer than people who do not have HIV. Some types of cancer occur so often in people with AIDS that they are considered AIDS-defining conditions. In other words, the presence of these types of cancer in PLHIV is a clear sign that full-blown AIDS has developed.

Although not considered to be AIDS-defining, some other cancers are also more common in PLHIV than in people who are HIV negative. It is not always understood why this is the case. It may be that some of these cancers are able to develop and grow more quickly because of a weakened immune system brought on by the infection. In other cases it may be because PLHIV are more likely to have certain other risk factors for cancer, such as being smokers. Many cancers are no more or less common in PLHIV than in people who are HIV negative.

Cancer in PLHIV

The burden of cancer in PLHIV has been changing as HIV treatment with ARVs has increased worldwide. Some AIDS-defining cancers have become less common because more people are on ART. As PLHIV are now living longer, they are also developing other types of cancer that are more common in older people. The use of ART has also led to better cancer survival rates for PLHIV, as more and more people are now able to get full doses of chemotherapy and other standard cancer treatments, which may not have been possible in the past.

The most common cancers associated with HIV infection are

- Kaposi's sarcoma
- Cancer of the cervix
- Lymphoma

Other types of cancer are also more likely to develop in PLHIV than in people who are HIV negative, including:

- Anal cancer
- Melanoma (skin) cancer
- Liver cancer
- Lung cancer
- Mouth and throat cancers
- Testicular cancer
- Squamous cell and basal cell skin cancers

The link between HIV and these cancers is still not fully understood. Some of these cancers have been linked to infections with different viruses. These viruses can cause cancer in PLHIV and without HIV. However, the risk might be higher in PLHIV because their immune systems are less able to control the viral growth.

For some cancers, the higher risk in PLHIV may be because of other risk factors these people are more likely to have, rather than the HIV infection itself. For example, mouth, throat, and lung cancers are strongly linked with smoking, which is more common in PLHIV. The link between these cancers and HIV becomes much weaker if smoking status is taken into account. Cancers of the liver, mouth, and throat (as well as some other cancers) are linked with heavy alcohol use, which is also more common in PLHIV.

As PLHIV are now living longer, they are also developing other cancers that are not clearly linked to HIV but are more common in older people – such as breast, colorectal, and prostate cancer.

KAPOSI'S SARCOMA (KS)

What is KS?

In this section, we will describe the AIDS-related KS, also known as epidemic KS. KS is a cancer that develops from the cells that line lymph or blood vessels. There are four different types of KS:

1. AIDS-related KS (epidemic KS)
2. Classic KS
3. African cutaneous type KS
4. Immunosuppression-related KS

KS was once an uncommon cancer that mainly affected older men of Mediterranean, Eastern European, or Middle Eastern ancestry, organ transplant patients, or young men in Africa. But in the past few decades, most KS cases have been linked to HIV infection. These cases are called epidemic KS (or AIDS-related KS).

With the growth of the AIDS epidemic in the early 1990s, the burden of KS increased significantly. With the advent of ART the disease is now rare in the developed world but is still seen mostly in PLHIV. In the United States, KS is much more common in men than in women, and it is rarely seen in children. It is also more common in African Americans than in white people.

In some parts of Africa, both HIV and HHV-8 (the virus that causes KS) are common. In these areas there is a high burden of KS – including HIV-associated KS and other types of KS. KS occurs in men, women and even children.

What causes KS?

KS is caused by a virus. This virus is called human herpesvirus 8 (HHV-8). HHV-8 is also known as KS-associated herpesvirus (KSHV). The HHV-8 virus is found in saliva and other body fluids. Sharing of bodily fluids might be how the HHV-8 virus is transmitted from one person to another.

How does HHV-8 lead to KS?

HHV-8 infects the cells that line blood and lymphatic vessels (called endothelial cells). After infecting the cells, the virus integrates itself within the genetic material of the cell and starts expressing abnormal genes that cause the cell to divide more often and live longer. These types of changes may eventually turn the cells into cancer cells.

Most people who develop KS have a weak immune system. While HHV-8 seems to be more common in PLHIV, not all PLHIV with HHV-8 develop KS. Those who do usually have a very weak immune system (CD4 count < 200/ml). KS may also develop in:

- People who have had an organ transplant (about 1 in 200 transplant patients in the United States get KS).
- Elderly people

HIV and KS

In most healthy people, HHV-8 does not cause KS. Studies have found that infection with HHV-8 is more common in PLHIV than in the general population. HHV-8 infection is especially common in PLHIV who are men who have sex with men. HHV-8 can also be transmitted between men and women.

The percentage of people infected with HHV-8 varies in different places around the world. In the United States, studies have found that less than 10% of people are infected with HHV-8. In some areas of Africa, however, more than 90% of the population show signs of HHV-8 infection.

Signs and symptoms of KS

In most cases, KS causes painless dark purplish or red or brownish spots (called lesions) on the skin or in the mouth. These lesions can be flat and not raised above the surrounding skin (patches), flat but slightly raised (plaques), or bumps (nodules). The skin lesions of KS most often develop on the legs or face, but they can also appear in other areas.

Lesions on the legs or in the groin area can sometimes block the flow of fluid out of the legs. This can lead to painful swelling in the legs and feet. KS may also affect the lymph nodes and other organs, such as the digestive tract, lungs, liver, and spleen.

When they are first diagnosed, some PLHIV and KS have no other symptoms, especially if their only lesions are on the skin. But some have other symptoms, such as swollen lymph nodes, unexplained fever, or weight loss. Over time, KS spreads throughout the body. If it involves a lot of the lung or intestine, it can be fatal.

How is KS diagnosed?

Unlike many other cancers which start in one place, KS tends to form in several areas at the same time. Even when only one skin lesion is visible, many people already have other areas of KS that are just too small to be seen, or that are hidden within the body.

There are no recommended routine screening tests to look for KS in people who are not at increased risk of the disease. When a lesion is found, additional tests may be requested to confirm the diagnosis. These tests include:

- **Biopsy:** Involves the removal of cells from the suspected site which are sent to a lab for testing.
- **Chest X-ray:** To look for signs of KS in the lungs
- **Upper digestive tract endoscopy:** A procedure for viewing the inside of the upper digestive tract (including the esophagus and stomach) and taking biopsies or tissue samples by using a tube with a camera and a biopsy tool on the end
- **Bronchoscopy:** An endoscopy of the lungs to look for KS lesions in the lungs

How is KS treated?

Today, treatment for KS is much more effective than it was in the past. Choices about the best treatment options for each patient are based on the function of the immune system as well as the number, location, and size of the KS lesions. The patient's general health is also considered.

There are various ways of treating people with KS. Some of these are explained in brief below. In some patients, two or more of these treatments are used at the same time. For patients with severe immune suppression, the most important treatment is to keep the immune system strong (using ART) and to keep any related infections under control.

Local therapy

Local therapy is used to treat a few skin lesions in one spot. The disadvantages of local therapy are that it doesn't treat lesions anywhere else in the body and it can't keep new lesions from developing. Some of the local treatments available include:

- **Topical retinoid treatment:** Alitretinoin, a drug related to vitamin A, is available as a gel (Panretin)
- **Cryosurgery (cryotherapy):** liquid nitrogen is applied to the tumor to freeze and kill the cells
- **Surgery (removal):** when a person has only a few, small Kaposi sarcoma lesions, one option may be to remove them with surgery
- **Intralesional chemotherapy:** a small amount of a chemotherapy drug is injected directly into the KS lesions. The most common drug used for intralesional chemotherapy in KS is Vinblastine. Sodium Tetradecyl sulfate (STS or Sotradecol) can also be used.
- **Photodynamic therapy (PDT):** this treatment uses a special liquid drug that is applied to the skin. The drug collects in the tumor cells over several hours or days and makes the cells sensitive to certain types of light. A special light source is then focused on the tumor(s), and the cells die.

Radiation therapy

This is a form of cancer treatment that uses high-energy x-rays or other types of radiation to kill cancer cells or keep them from growing. There are two types of radiation therapy:

- External radiation therapy uses a machine outside the body to send radiation toward the cancer.
- Internal radiation therapy uses a radioactive substance sealed in needles, seeds, wires, or catheters that are placed directly into or near the cancer.

The way the radiation therapy is given depends on the type and stage of the cancer being treated.

Biologic therapy (immunotherapy)

Biologic therapy (also known as immunotherapy) uses chemicals made naturally by the body (or man-made forms of these chemicals) to help the immune system attack cancer cells. Interferon Alfa, is an example of biologic therapy. For KS, Interferon is injected daily into a muscle or under the skin. Interferon seems to work by preventing viruses from reproducing and by activating immune system cells that attack and destroy the virus.

About half of patients with good immune function get better when given high doses of these drugs. However, Interferon is not often an effective treatment for KS in patients with fevers, infections, weight loss, or low CD4 counts. Even when this treatment does work, it can take several months or more. Interferon Alfa is not often used now because of its side effects and because it doesn't work well in many patients with AIDS.

Chemotherapy

Chemotherapy, also referred to as 'chemo,' is a cancer treatment that uses drugs to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing.

When chemo is taken by mouth or injected into a vein or muscle, the drugs enter the bloodstream and can reach cancer cells throughout the body. When chemo is placed directly into an organ or a body cavity such as the abdomen, the drugs mainly affect cancer cells in those areas (regional chemo). How the chemo is given depends on the type and stage of the cancer being treated.

Preventing KS

Since there are no preventative vaccines, the only way for PLHIV to reduce the chances of getting KS is to minimize the chances of getting infected with HHV-8. General measures to prevent acquiring HHV-8 and eventually KS include:

- Avoid unprotected sex – always use a condom

For PLHIV infected with HHV-8, avoiding severe immune suppression will significantly reduce the chances of getting KS. This can be done by:

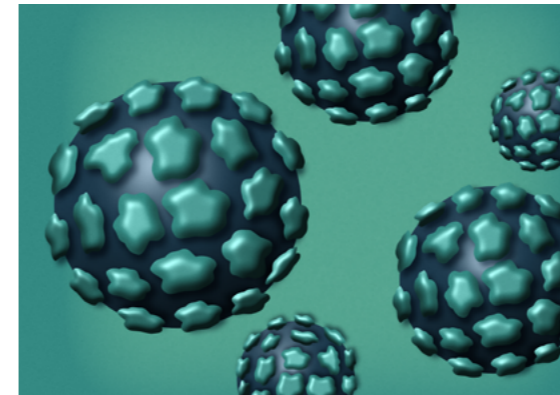
- ART (building the immune system reduces the risk of developing KS)
- Treating infections that commonly occur in PLHIV
- PLHIV who take drugs to treat herpesvirus infections (such as Ganciclovir or Foscarnet) are less likely to develop KS because these drugs also work against HHV-8

CANCER OF THE CERVIX

Cervical cancer is a cancer of the cervix – the lower part of the uterus (womb). An estimated 500,000 women are diagnosed with cancer of the cervix every year. Roughly 250,000 women die from complications of the disease every year.

What causes cancer of the cervix?

Almost all cases of cancer of the cervix are caused by the Human papillomavirus (HPV). There are more than 100 types of HPV. HPVs infect skin and other skin-like surfaces in the body (such as cervical, anal and genital surfaces). At least 30 different types of HPV target the mucous membranes that line the genitals and some internal organs. 15 of these types of HPV cause cancer. Types of HPV that cause cancer are known as oncogenic HPV.



HPV infections are very common. Every sexually active woman is at risk of acquiring an oncogenic HPV infection, which may cause cervical cancer. In general:

- Up to 80% of women will acquire an HPV infection in their lifetime
- While most HPV infections go away on their own, there is currently no way of predicting which infections will persist

New HPV infections can be acquired at any age. Prevalence of infection is greatest in women less than 25 years of age. Although new infections decrease with age, the risk of an HPV infection persisting increases with age.

How does HPV lead to cervical cancer?

There are several steps between becoming infected with HPV and developing cervical cancer. Once the virus enters the body cells, it integrates with the host cell's genetic material and produces genes that cause cellular instability. In other words, the virus causes cells to mutate which, in turn, leads to uncontrolled dividing and multiplication of cells. Eventually the cells become cancerous.

Other factors that increase the risk of cancer development after HPV infection include:

- Environmental factors, e.g. smoking
- Sexual exposure, e.g. becoming sexually active at a young age
- Hormonal factors e.g. long-term use of oral contraceptives
- Immunosuppression e.g. PLHIV, transplant recipients, long-term systemic steroid users

Relationship between HIV and cancer of the cervix

HIV-infected women are around four times more likely to develop genital lesions and cervical cancer. About 20 to 60% of HIV-infected women show signs of pre-cervical cancer. One of the major causes of pre-cervical cancer is HPV infection. Around 75% of women with HIV also have HPV. Women with HIV have a weakened immune system, which allows HPV to survive in the cervix and cause pre-cancerous lesions.

Signs and symptoms of cervical cancer

The symptoms of cervical cancer are non-specific. All women, including those living with HIV, are encouraged to consult a doctor if they have any of the following:

- Vaginal bleeding
- Pain during sexual intercourse
- Unusual vaginal discharge
- Pelvic pain

How is cervical cancer diagnosed?

Pap smear

This is a procedure to collect cells from the surface of the cervix and vagina. A piece of cotton, a brush, or a small wooden stick is used to gently scrape cells from the cervix and vagina. The cells are viewed under a microscope to find out if they are abnormal. This procedure is also called a Pap test.

HPV Test

This is a laboratory test used to check DNA (genetic material) for certain types of HPV infection. Cells are collected from the cervix and checked to find out if an infection is caused by a type of HPV that is linked to cervical cancer. This test may be done if the results of a Pap smear show certain abnormal cervical cells. This test is also called the HPV DNA test.

Colposcopy

This is a procedure in which a colposcope (a lighted, magnifying instrument) is used to check the vagina and cervix for abnormal areas. Tissue samples may be taken using a curette (spoon-shaped instrument) and checked under a microscope for signs of disease.

Biopsy

If abnormal cells are found in a Pap smear, a sample of tissue is cut from the cervix and viewed under a microscope by a pathologist to check for signs of cancer.

Pelvic exam

This refers to an exam of the vagina, cervix, uterus, fallopian tubes, ovary and rectum. The doctor or nurse inserts one or two lubricated, gloved fingers of one hand into the vagina and places the other hand over the lower abdomen to feel the size, shape, and position of the uterus and ovaries. A speculum is also inserted into the vagina and the doctor or nurse looks at the vagina and cervix for signs of disease. A Pap test of the cervix is usually done. The doctor or nurse also inserts a lubricated, gloved finger into the rectum to feel for lumps or abnormal areas.

How is cervical cancer treated?

Three types of standard treatment are used. These include surgery, radiation therapy and chemotherapy.

Surgery

- This is sometimes used to treat cervical cancer by removing the tumor in an operation. The following surgical procedures may be used:
- Conization: This is a procedure to remove a cone-shaped piece of tissue from the cervix and cervical canal. A pathologist views the tissue under a microscope to look for cancer cells. Conization may be used to diagnose or treat a cervical condition. This procedure is also called a cone biopsy.
- Total hysterectomy: This is a type of surgery to remove the uterus, including the cervix. If the uterus and cervix are taken out through the vagina, the operation is called a vaginal hysterectomy. If the uterus and cervix are taken out through a large cut in the abdomen, the operation is called a total abdominal hysterectomy. If the uterus and cervix are taken out through a small incision in the abdomen using a laparoscope, the operation is called a total laparoscopic hysterectomy.

Radiation therapy

This is a cancer treatment that uses high-energy x-rays or other types of radiation to kill cancer cells or to prevent them from growing. There are two types of radiation therapy:

- External radiation therapy uses a machine outside the body to send radiation toward the cancer.
- Internal radiation therapy uses a radioactive substance sealed in needles, seeds, wires, or catheters. These are placed directly into or near the cancer.

The way the radiation therapy is given depends on the type and stage of the cancer being treated.

Chemotherapy

Chemotherapy, or chemo, is a cancer treatment that uses drugs to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. When chemo is taken by mouth or injected into a vein or muscle, the drugs enter the bloodstream and can reach cancer cells throughout the body. How the chemotherapy is given depends on the stage of the cancer being treated.

Preventing cervical cancer

There are lots of things a person can do to reduce her risk of developing cervical cancer. These are:

- Avoid known risk factors for cancer such as smoking
- Avoid risk factors for the acquisition of HPV
- Regular Pap smears can reduce the risk of developing cancer of the cervix due to early identification of changes in the cervix with early treatment intervention
- Vaccination with HPV vaccine
 - All boys and girls ages 11 or 12 years should get vaccinated
 - Catch-up vaccines are recommended for males up to age 21 and for females up to age 26 who were not vaccinated when they were younger
 - The vaccine is also recommended for gay and bisexual men (or any man who has sex with a man) up to age 26
 - The HPV vaccine is also recommended for men and women with compromised immune systems (including PLHIV) up to age 26 who were not get fully vaccinated when they were younger

HIV-ASSOCIATED LYMPHOMA

Lymphoma is a group of cancers that spread from the body's lymph system. The lymph system is a series of lymph nodes and vessels that move lymph fluid through the body. Lymph fluids contain infection-fighting white blood cells. Lymph nodes act as filters, capturing and destroying bacteria and viruses to prevent infection from spreading. While the lymph system typically protects the body, lymph cells called lymphocytes can become cancerous.

There are many types of lymphoma but they are usually classified into two groups:

- Hodgkin's lymphoma
- Non-Hodgkin's lymphoma

In general, lymphomas are more likely to occur in PLHIV than in people who are HIV-negative. However, the majority of people with lymphoma are not HIV-infected. Today, fewer PLHIV are developing lymphoma because ART is now in common use.

What causes lymphoma?

It is not known what causes lymphoma. However, there are certain risk factors that increase a person's chances of developing the disease. These include:

- **Viral infections:** Infection with certain viruses including the Epstein-Barr virus (EBV), Human herpes virus 8 (HHV-8) and Human T-lymphotrophic virus (HTLV-1) seem to increase the likelihood of lymphoma developing. Some of these viruses have also been linked with other cancers. For instance, HHV-8 is linked with Kaposi's sarcoma.
- **Age:** People of any age can be diagnosed with Hodgkin disease, but it is most common in early adulthood (ages 15 to 40, especially in a person's 20s) and in late adulthood (after age 55).
- **Gender:** Hodgkin disease occurs slightly more often in males than in females.
- **Geography:** Hodgkin disease is most common in the United States, Canada, and northern Europe. It is least common in Asian countries. Burkitt's lymphoma is most common in Africa.
- **Family history:** Brothers and sisters of young people with this disease have a higher risk of developing Hodgkin disease. The risk is very high for an identical twin of a person with Hodgkin disease.
- **Socioeconomic status:** The risk of Hodgkin disease is greater in people with a higher socioeconomic background. The reason for this is not clear. One theory is that children from more wealthy families might be protected from type of infection (such as the Epstein-Barr virus), while children from less wealthy families might be exposed from a young age.
- **HIV infection:** The risk of Hodgkin disease is higher in PLHIV.

What is the relationship between HIV and lymphoma?

In the 1980s, it became apparent that the PLHIV have a much higher risk of lymphoma than HIV-negative people. Before ART was available to treat HIV, PLHIV were sixty to a hundred times more likely to get lymphoma than HIV-negative people. This risk was even higher, up to a thousand times higher, for certain types of lymphoma such as primary central nervous system (CNS) lymphoma. The widespread availability and uptake of ART since 1996 has significantly reduced this risk.

Certain factors might increase the risk of PLHIV developing lymphoma. These include:

- Duration and degree of immunosuppression
- Opportunistic infections with oncogenic herpesviruses such as EBV and HHV8

Common types of lymphoma in PLHIV include:

- Primary CNS lymphoma
- Burkitt's lymphoma
- Hodgkin's lymphoma
- Diffuse large B-cell lymphoma

Signs and symptoms of lymphoma

Lymphoma can cause many different signs and symptoms, depending on where it is in the body. In some cases it might not cause any symptoms until it grows quite large. Common signs and symptoms include:

- Enlarged lymph nodes
- Swollen abdomen
- Feeling full after only a small amount of food
- Chest pain or pressure
- Shortness of breath or cough
- Fever
- Weight loss
- Night sweats
- Fatigue (extreme tiredness)
- Low red blood cell counts (anemia)

Additional signs and symptoms depend on where the tumor is. For instance, CNS lymphoma can cause seizures, facial paralysis, confusion and memory loss.

How is lymphoma diagnosed?

There is currently no screening test for lymphoma. Many symptoms of lymphoma are not specific enough to say for certain if they are being caused by cancer. Most of the symptoms can also be caused by non-cancerous problems, like infections, or by other kinds of cancers. For example, enlarged lymph nodes are more often caused by infections than by lymphoma. If the doctor suspects lymphoma, they will ask for additional tests that might include:

Biopsy

Different types of biopsies can be conducted in order to diagnose lymphoma. Doctors choose which one to use based on each patient's situation.

- **Excisional or incisional biopsy:** This is the most common type of biopsy if lymphoma is suspected. In this procedure, a surgeon cuts through the skin to remove either the entire node (excisional biopsy) or a small part of a large tumor (incisional biopsy).
- **Fine needle aspiration (FNA) or core needle biopsy:** In a FNA biopsy, the doctor uses a very thin, hollow needle attached to a syringe to withdraw (aspirate) a small amount of tissue from an enlarged lymph node or a tumor mass. For a core needle biopsy, the doctor uses a larger needle to remove a slightly larger piece of tissue.
- **Bone marrow aspiration and biopsy:** These procedures are often done after lymphoma has been diagnosed to help determine if it has reached the bone marrow. The two tests are often done at the same time. The samples are usually taken from the back of the pelvic (hip) bone. In some cases they may be taken from the sternum (breast bone) or other bones.

Lumbar puncture (spinal tap)

This test looks for lymphoma cells in the cerebrospinal fluid (CSF), which is the liquid that surrounds the brain and spinal cord. Most people with lymphoma will not need this test. But doctors may request it for certain types of lymphoma, or if a person has symptoms that suggest the lymphoma has reached the brain.

Pleural or peritoneal fluid sampling

Lymphoma that has spread to the chest or abdomen can cause fluid to build up. Pleural fluid (fluid inside the chest) or peritoneal fluid (fluid inside the abdomen) can be removed by placing a hollow needle through the skin into the chest or abdomen. Often, an ultrasound is used to guide the needle. The fluid is then withdrawn and looked at under the microscope to check for lymphoma cells.

Lab tests on biopsy samples to diagnose and classify lymphoma

All biopsy samples and fluids are looked at under a microscope by a pathologist who studies the size and shape of the cells and how they are arranged. This may indicate if the person has a lymphoma, and also what type of lymphoma it is.

Pathologists can sometimes tell what kind of lymphoma a patient has by looking at the cells, but usually other types of tests are needed to confirm the diagnosis. These tests might include:

- **Immunohistochemistry:** In this test, a part of the biopsy sample is treated with special antibodies (man-made versions of immune system proteins) that attach only to specific molecules on the cell surface. These antibodies cause color changes, which can be seen under a microscope. This test may be helpful in distinguishing different types of lymphoma from one another, and from other diseases.
- **Flow cytometry:** Like immunohistochemistry, this test looks for certain substances on the outside surface of cells that help identify what types of cells they are. A flow cytometry test can look at many more cells than immunohistochemistry.
- **Cytogenetics:** This technique allows doctors to evaluate the chromosomes (long strands of DNA) in the lymphoma cells. The cells are looked at under a microscope to see if the chromosomes have any abnormalities. Some lymphoma cells may have too many chromosomes, too few chromosomes, or other changes such as a translocation (where part of one chromosome breaks off and attaches to another chromosome). These changes can help identify the type of lymphoma.
- **Molecular genetic tests:** These tests look more closely at lymphoma cell DNA. They can detect most changes that are visible under microscope in cytogenetic tests, as well as others changes that can't be seen. The disadvantage is that these tests can only be used to look for specific changes, so the doctor has to know what he or she is looking for.
- **Fluorescent in situ hybridization (FISH):** FISH uses special fluorescent dyes that only attach to specific genes or parts of chromosomes. FISH can find most chromosome changes (such as translocations) that can be seen under a microscope in standard cytogenetic tests. FISH can also find some gene changes too small to be seen with usual cytogenetic testing. FISH can be used on regular blood or bone marrow samples. It is very accurate and can usually provide results within a couple of days, which is why this test is now used in many medical centers.
- **Polymerase chain reaction (PCR):** PCR is a very sensitive DNA test that can find gene changes and certain chromosome changes too small to be seen with a microscope, even if very few lymphoma cells are present in a sample.

Blood tests

Blood tests measure the amounts of certain types of cells and chemicals in the blood. They are not used to diagnose lymphoma, but they can sometimes help determine how advanced the lymphoma is.

Patients with known or suspected lymphoma undergo a complete blood count (CBC). This test measures the different cells in the blood, such as the red blood cells, the white blood cells, and the platelets. In patients already known to have lymphoma, low blood cell counts can mean that the lymphoma is growing in the bone marrow and affecting new blood cell formation. Many patients will also have blood chemistry tests to look at kidney and liver function.

If lymphoma has been diagnosed, another blood test called lactate dehydrogenase (LDH) may be checked. LDH levels are often higher in patients with lymphomas. For some types of lymphoma or if certain treatments may be used, doctors may also advise other blood tests to check for infection with certain viruses, such as the hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV). Infections with these viruses may affect treatment.

Imaging tests

Imaging tests use x-rays, sound waves, magnetic fields, or radioactive particles to produce pictures of the inside of the body.

In someone with known or suspected lymphoma, these tests might be done to look more closely at an abnormal area suspected of containing lymphoma, to learn how far the lymphoma has spread, or to find out if treatment has been effective.

- **Chest x-ray:** The chest might be x-rayed to look for enlarged lymph nodes in this area.
- **Computed tomography (CT) scan:** The CT scan is an x-ray test that produces detailed, cross-sectional images of the body. Instead of taking one picture, like a regular x-ray, a CT scanner takes many pictures as it rotates around the body. A computer then combines these pictures into a single image.
- **CT-guided needle biopsy:** In some cases, CT can be used to guide a biopsy needle into a suspicious area. For this procedure, the patient remains on the CT scanning table while a radiologist moves a biopsy needle through the skin and toward the location of the mass. CT scans are repeated until the needle is within the mass. A biopsy sample is then removed to be looked at under a microscope.
- **Magnetic resonance imaging (MRI) scan:** This test is not used as often as CT scans for lymphoma. However the MRI is very useful for looking at the spinal cord and brain. This is very important in cases where the lymphoma might have spread to the spinal cord or brain. Like CT scans, MRI scans provide detailed images of soft tissues in the body. But MRI scans use radio waves and strong magnets instead of x-rays. The energy from the radio waves is absorbed by the body and then released in a pattern formed by the type of body tissue and by certain diseases. A computer translates the pattern into a very detailed image of parts of the body.
- **Ultrasound:** Ultrasound uses sound waves and their echoes to produce a picture of internal organs or masses. In the most common type of ultrasound, the skin is lubricated with a gel and a small, microphone-like instrument called a transducer is placed on the skin. The transducer emits sound waves and picks up the echoes as they bounce off the organs. The echoes are converted by a computer into a black and white image that is displayed on a computer screen. Ultrasound can be used to look at lymph nodes near the surface of the body or to look inside the abdomen for enlarged lymph nodes or organs such as the liver and spleen. It can also detect kidneys that have become swollen because

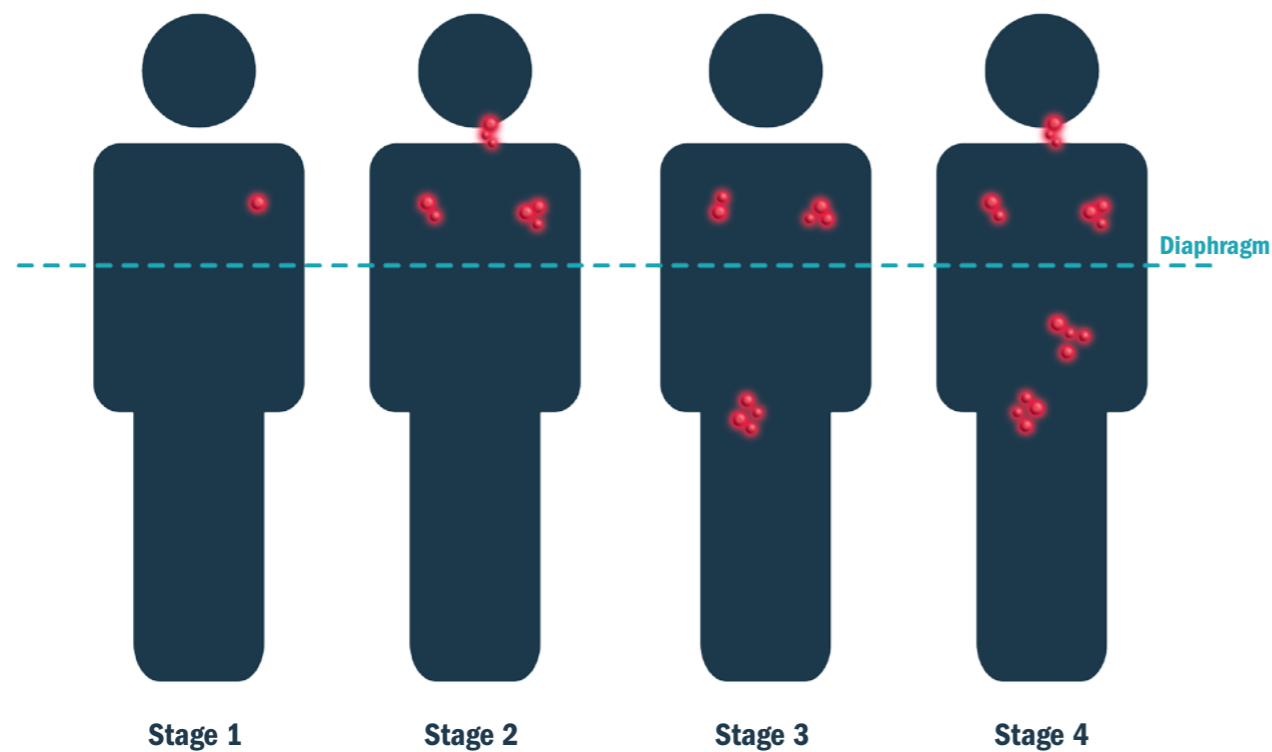
the outflow of urine has been blocked by enlarged lymph nodes. Ultrasound cannot be used to look at lymph nodes in the chest because the ribs block the sound waves. This is an easy test to have done, and it uses no radiation. For most ultrasounds, the patient simply lies on a table, and a technician moves the transducer over the part of the body being examined.

- **Positron emission tomography (PET) scan:** For a PET scan, a form of radioactive sugar (known as fluorodeoxyglucose or FDG) is injected into the blood. Because cancer cells in the body grow rapidly, they absorb large amounts of the radioactive sugar. After about an hour, the patient is moved onto a table in the PET scanner. The patient lies on the table for about 30 minutes while a special camera creates a picture of areas of radioactivity in the body. The picture is not finely detailed like a CT or MRI scan, but it can provide helpful information about the whole body:
 - PET scans can help tell if an enlarged lymph node contains lymphoma
 - It can also help spot small areas that might be lymphoma, even if the area looks normal on a CT scan.
 - PET scans can be used to tell if a lymphoma is responding to treatment. Some doctors repeat the PET scan after one or two courses of chemotherapy. If the chemotherapy is working, the lymph nodes will no longer take up the radioactive sugar.
 - PET scans can also be used after treatment in helping decide whether an enlarged lymph node still contains lymphoma or is merely scar tissue

Often, for patients with lymphoma, a machine that combines the PET scan with a CT scan (PET/CT scan) is used. This lets the doctor compare areas of higher radioactivity on the PET scan with the more detailed appearance of that area on the CT.

- **Gallium scan:** For this test, a liquid containing slightly radioactive gallium is injected into a vein. It is attracted to lymph tissue in the body. A few days later a special camera is used to detect the radioactivity, showing the location of the gallium. The gallium scan will not detect most slow-growing lymphomas but will find many fast-growing (aggressive) lymphomas. This test is no longer commonly used – many doctors do a PET scan instead. However, a gallium scan can still be useful in finding areas of lymphoma that the PET scan may miss. It can also help distinguish an infection from a lymphoma when the diagnosis is not clear.
- **Bone scan:** For bone scans, a radioactive substance called technetium is used. After being injected into a vein, this substance travels to damaged areas of the bone. Lymphoma often causes bone damage, and a bone scan will detect this. But a bone scan may also pick up non-cancerous problems, such as arthritis and fractures. This test is not usually done unless a person is having bone pain, or unless lab test results suggest the lymphoma may have reached the bones.

Tests of heart and lung function



These tests are not used to help diagnose non-Hodgkin lymphoma. But they may be done if the patient is going to get certain chemotherapy drugs (commonly used to treat lymphoma) that may affect the heart or lungs.

- Heart function may be checked with an ultrasound of the heart (called an echocardiogram or a MUGA scan)
- Lung function may be checked with pulmonary function tests, in which the patient breathes into a tube connected to a machine

Stages of lymphoma disease

The severity of lymphoma disease can be described by the stage of the disease. The stage of lymphoma describes the spread of the disease to other parts of the body and by how much it has spread. In addition to a good clinical examination, some tests are done to determine the stage of the disease. These tests include:

- Biopsies of enlarged lymph nodes or other abnormal areas
- Blood tests
- Imaging tests, such as CT scans
- Bone marrow aspiration and biopsy (often but not always done)
- Lumbar puncture (spinal tap – this may not need to be done)

Details of these tests are provided above.

How is lymphoma treated?

Lymphoma can be treated very well for many people. In fact, today more people than ever before lead full lives after cancer treatment.

The outcome for patients with AIDS-related lymphoma depends on the type of lymphoma and on the person's immune function, the stage of the disease as well as other factors. People with advanced lymphoma, a low CD4 count, or who are not on ART don't usually do as well as people without these factors.

Some of the treatment options for lymphoma include:

Chemotherapy

Depending on the type and the stage of the lymphoma, chemo may be used alone or combined with immunotherapy or radiation therapy. Doctors give chemo in cycles of a period of treatment, followed by a rest period to allow the body time to recover. Many chemo drugs are useful in treating lymphoma patients. The number of drugs, their doses, and the length of treatment depend on the type and stage of the lymphoma. Often drugs from different groups are used in combination. Most chemo drugs given systemically – into the veins (intravenously) or by mouth – cannot penetrate the spinal fluid and tissues around the brain and spinal cord. Therefore, chemo may also be given into the spinal fluid (cerebrospinal fluid). This is called intrathecal chemo.

Immunotherapy

Immunotherapy is treatment that either boosts the patient's own immune system or uses man-made versions of the normal parts of the immune system. These treatments may kill lymphoma cells or slow their growth. Immunotherapy includes treatments such as monoclonal antibodies (proteins made by the body's immune system to help fight infections).

- **Monoclonal antibodies:** An example of a monoclonal antibody drug is Rituximab, which is often used along with chemotherapy, either as part of the initial treatment or as part of a second-line regimen, or by itself.
- **Immunomodulating agents:** These work against certain cancers by affecting parts of a person's immune system, although exactly how they work is not known. Immunomodulating agents are sometimes used to help treat certain types of lymphoma, usually after other treatments have been tried. An example of such drugs is Thalidomide.

Radiation

If the lymphoma is still in the early stages, radiation might be used as the main treatment option because these tumors respond very well to radiation. For more advanced lymphomas and for some lymphomas that are more aggressive, radiation is sometimes used along with chemotherapy. Patients who get a stem cell transplant (see below) may get radiation to the whole body along with high-dose chemotherapy, to try to kill lymphoma cells throughout the body.

Stem cell transplant

Stem cell transplants are sometimes used to treat lymphoma patients who are in remission or who have a relapse during or after treatment. Although only a small number of patients with lymphoma are treated with this therapy today, this number is growing.

Stem cell transplants allow doctors to use higher doses of chemotherapy to kill the cancer than normally would be tolerated. Radiation is sometimes given as well. This treatment can kill the cancer cells but also destroys the bone marrow, which prevents new blood cells from being formed. This would be fatal if stem cells weren't given back to replace the ones in the bone marrow. The stem cells used for the transplant can come from blood, bone marrow, or umbilical cord blood. In most cases, stem cells from the blood are used.

Preventing lymphoma

Most people with lymphoma have no risk factors that can be changed, so there is no way to protect against these lymphomas. The best way to reduce the risk for lymphoma is to try to prevent known risk factors such as immune deficiency.

3 HIV TREATMENT INITIATIVES

Welcome to Module 3: HIV Treatment Initiatives of the Advocacy for Community Treatment (ACT) Toolkit of the International Treatment Preparedness Coalition (ITPC)

Module 3 focuses on a number of global initiatives (such as frameworks and guidelines) that shape the HIV treatment ‘world’ and influence access to HIV treatment in communities and countries.

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CHAPTER 3.1 The history of global treatment initiatives

CHAPTER OBJECTIVE

To provide participants with information on the historical global initiatives to give a deeper understanding of the role of global treatment initiatives in ensuring that the needs of people living with HIV are met.

TRAINING MATERIALS

- PowerPoint presentation '3.1. The history of global treatment initiatives.
- Copies of the Useful Resources.
- Flipchart and pens.

TRAINING OPTIONS

Option A (approx. 60 minutes)

For this activity, it is helpful to give participants copies of resources on the initiatives in advance and ask them to read them.

1. Explain the objective of the Section.
2. Present PowerPoint presentation '3.1. The history of global treatment initiatives
3. Encourage the participants to ask questions about the initiatives addressed in the presentation and to share any experiences of advocacy related to them. Also ask them to add any other global, regional or national initiatives that they know of that are relevant to HIV treatment.
4. Facilitate a discussion about the opportunities and challenges presented by the initiatives in terms of community advocacy on access to HIV treatment. Encourage the participants to focus on issues affecting access for people from key populations, such as sex workers, people who use drugs, and lesbian, gay, bisexual, transgender and intersex (LGBTI) people.
5. Ask the participants to summarize the session by developing advocacy messages about 'What are the historically important initiatives for HIV treatment?' Support their ideas by sharing examples of messages (see below).

Option B (approx. 120 minutes)

For this activity, it is necessary to give participants copies of resources on the initiatives in advance and to ask them to read them.

1. Explain the objective of the Section.
2. Present PowerPoint presentation '3.1.
3. Encourage the participants to ask questions about the initiatives addressed in the presentation. Also ask them to add any other global, regional or national initiatives that they know of that are relevant to HIV treatment.
4. Divide the participants into four groups, with each focused on a different historical, global initiative:
Group 1: Treatment 2.0 – launched in June 2010; an initiative of the World Health Organization (WHO) and Joint United Nations Program on AIDS (UNAIDS)

Group 2: Treatment 2015 – launched by the United Nations Joint Program on AIDS (UNAIDS) in July 2013. A framework to accelerate action to meet the target set by the 2011 United Nations Political Declaration on HIV/AIDS – having 15 million people on antiretroviral therapy (ART) by 2015

Group 3: Community Systems Strengthening

Group 4: Investment Framework

5. Ask each group to discuss their initiative and identify the opportunities and challenges that it would have presented for community advocacy on access to HIV treatment.
6. Bring all of the participants back together. Ask Group 1 to present a summary of the opportunities and challenges that they identified. Encourage the other participants to ask questions and make additional points.
7. Repeat the process for Groups 2, 3 and 4.
8. Ask the participants to consider the feedback from Groups 1, 2, 3 and 4. Ask them to pick out the opportunities and challenges that especially affect access to HIV treatment for key populations, such as sex workers, people who use drugs and LGBTI people.
9. Ask the participants to summarize the session by developing advocacy messages about Support their ideas by sharing examples of messages (see below).

ADVOCACY MESSAGES

- All global treatment initiatives have emphasized that it is not only about what needs to be done (the priority areas of work), but how it needs to be carried out. For example, Treatment 2.0 outlined principles – such as equity and accessibility – that are vital, especially for ensuring access to treatment for key populations.
- Community mobilization, involvement and systems are fundamental to achieving all key global initiatives related to HIV treatment. They are not 'optional'.
- Community involvement and systems not only make programmatic sense – such as for reaching marginalized groups, such as key populations. They are also central to cost-effective, investment approaches to increasing access to HIV treatment.
- Community organizations and systems do not 'just happen.' They require funding and other resources to play their full role in increasing access to HIV treatment.

USEFUL RESOURCES

- *Treatment 2015*, UNAIDS, 2013. Available here: www.unaids.org/sites/default/files/media_asset/JC2484_treatment-2015_en_1.pdf
- *Community Systems Strengthening Framework: Revised Edition*, The Global Fund to Fight AIDS, Tuberculosis and Malaria, 2014. Available here: www.theglobalfund.org/documents/core/framework/Core_CSS_Framework_en/
- *Community Systems Strengthening and Key Populations: A Policy Discussion Paper*, Global Forum on MSM and HIV, 2013. Available here: http://23.91.64.91/~msmgf/wp-content/uploads/2015/09/CSS_and_Key_Populations_3oct2013.pdf

- *Investing for Results. Results For People: A People-Centered Investment Tool Towards Ending AIDS*, UNAIDS, 2012. Available here: http://www.unaids.org/sites/default/files/media_asset/JC2359_investing-for-results_en_1.pdf
- *Smart Investments*, UNAIDS, 2013. Available here: http://www.unaids.org/sites/default/files/media_asset/20131130_smart-investments_en_1.pdf
- *Global AIDS Report*, UNAIDS 2013. Available here: http://www.unaids.org/sites/default/files/media_asset/UNAIDS_Global_Report_2013_en_1.pdf
- *Fact Sheet 2016*, UNAIDS. Available here: http://www.unaids.org/sites/default/files/media_asset/20150901_FactSheet_2015_en.pdf
- *Global Plan towards the Elimination of New HIV Infections among Children by 2015 and Keeping Their Mothers Alive 2011-2015*. UNAIDS. 2011. Available here: http://www.unaids.org/sites/default/files/media_asset/20110609_JC2137_Global-Plan-Elimination-HIV-Children_en_1.pdf

Treatment 2.0

Treatment 2.0 was launched in June 2010 as an initiative of the World Health Organization (WHO) and Joint United Nations Program on AIDS (UNAIDS). The Treatment 2.0 Framework for Action: *Catalyzing the Next Phase of Treatment, Care and Support* was published in 2011.

The '3 by 5' initiative

Treatment 2.0 built on the foundation of the '3 by 5' initiative.¹ At the start of the 21st Century, three major international events laid the foundation for a decade of global action in response to the HIV epidemic. Firstly, in 2000, at the XIII International AIDS Conference in South Africa, global leaders, donors and public health experts called for an end to inequity in access to treatment between developing and developed countries. Shortly thereafter, in 2001, leaders and policy-makers gathered at the United Nations General Assembly Special Session on HIV/ AIDS (UNGASS). In 2002, The Global Fund to Fight AIDS, Tuberculosis and Malaria (The Global Fund) – which would become one of the largest funders of the HIV response (as discussed in Module 6) – was established.² On World AIDS Day in 2003, WHO launched the '3 by 5' Initiative, which aimed to get 3 million people on ART by 2005. At the time the initiative was launched, over 30,000,000 people were living with HIV in low-and-middle-income countries, and only 400,000 had access to ART.³

To support country partners in achieving this goal, the WHO developed a set strategic guidelines, called the 'Public Health Approach to ART', specifically for HIV programs in developing countries.⁴ Key elements of the public health approach included:⁵

- Making ART accessible for as many people as possible given the resources available
- Involving people living with and affected by HIV in program design
- Good management and support for healthcare workers providing treatment

Although the '3 by 5' targets were not met, between 2001 and 2009 the HIV response expanded dramatically. Funding from bilateral agencies, multilateral agencies, and private organizations increased US\$1.6 billion to US\$15.9 billion, and by the end of 2010 approximately 6.6 million people in low-and-middle-income countries were receiving ART, 22 times as many as in 2001.⁶

The '15 by 15' Initiative

In 2012, UNAIDS and partner organizations launched the '15 by 15' initiative, aiming to get 15 million

people on ART by 2015. Coming on the heels of the successes of the '3 by 5' initiative, the '15 by 15' initiative sought to catalyze global partners to redouble their efforts and reach an ambitious target within a limited timeframe.⁷ To do this, UNAIDS called for focused global action to scale-up HIV treatment, focus on those most in need, and develop innovative HIV testing and treatment approaches.⁸

Between 2011 and 2015:⁹

- Political leaders around the world demonstrated strong political commitment to the target. The commitment of political leaders was matched by the engagement and leadership of civil society organizations and people affected by the epidemic.
- Funding for HIV testing and treatment services increased. Country governments increased domestic allocations for HIV testing and treatment programmes, and international donors provided much-needed financial assistance.
- The number of people living with HIV (PLHIV) who knew their status increased dramatically. In 2014, for the first time ever, more than half of all people living with HIV knew their HIV status.
- Prices for antiretroviral regimens and important diagnostic tools declined.
- The quality of HIV treatment programmes improved.
- Innovative service delivery models improved the quality of treatment programs and made treatment programs accessible to many more people. Globally, innovative service models, many of which are community-driven, are showing that it is possible to expand treatment access while saving money.
- HIV-related stigma has declined.

The '15 by 15' Initiative was very successful. On the 14th of July 2015, the target of getting 15 million people on ART by 2015 was reached.¹⁰ This was the first time ever that a major global treatment target had been reached by the deadline.¹¹

Treatment 2.0

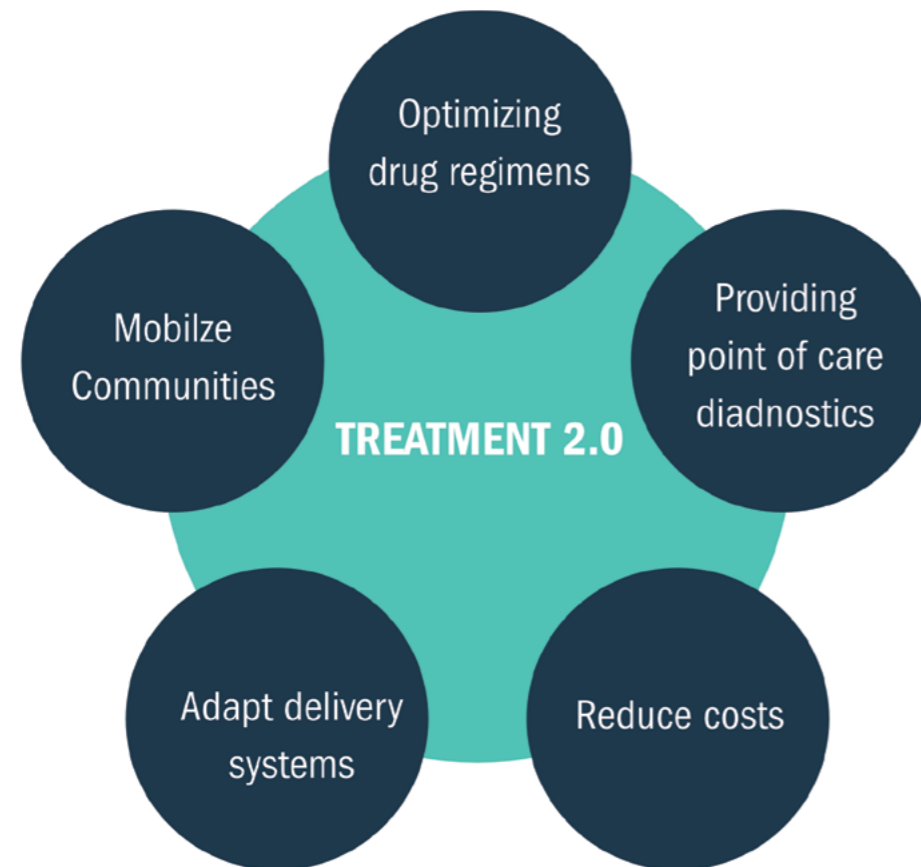
Treatment 2.0 aims to catalyze the next phase of scaling-up HIV treatment by promoting innovation and efficiency. It helps countries to reach and sustain the goal of universal access to HIV treatment and also to make the most of the prevention benefits of ART.

Treatment 2.0 is based on a set of principles:

- Simplification
- Innovation
- Efficiency
- Effectiveness and cost-effectiveness
- Accessibility
- Affordability
- Equity
- Decentralization and Integration
- Community involvement

Treatment 2.0 focuses on five priority areas of work. These are illustrated below and also described, with the relevant goals for 2020 (using the exact wording of the Framework):

DIAGRAM: The Five Priority Areas of Work of Treatment 2.0



PRIORITY AREA	GOAL FOR 2020
Optimize drug regimens	<p>2020 Goal: Effective, affordable, one pill, once daily potent ARV regimens, suitable for most populations with minimal toxicities or drug interactions and high barrier to resistance are available in low-and-middle-income countries (LMICs).</p> <ul style="list-style-type: none"> · Regimens should be easy to use, with little side effects without compromising quality · Regimens should be standard across all populations
Provide point-of-care (POC) and other simplified diagnostic and monitoring tools	<p>2020 Goal: A package of simple, affordable, reliable, quality-assured POC and other simplified diagnostics are available and accessible in LMICs.</p> <ul style="list-style-type: none"> · Diagnostics to initiate and monitor treatment should be simple, efficient and easily accessible to all
Reduce costs	<p>2020 Goal: High-quality HIV prevention, care and treatment programs are available at the lowest possible cost with optimal efficiency to all in need in LMICs.</p> <ul style="list-style-type: none"> · Cost of care should not be a barrier to accessing treatment
Adapt service delivery	<p>2020 Goal: HIV care and treatment programs are decentralized and appropriately integrated with other HIV and non-HIV health services, with increased community engagement in service delivery and improved retention in care.</p> <ul style="list-style-type: none"> · Services should be closer to the people with communities actively involved in the delivery system
Mobilize communities	<p>2020 Goal: People living with HIV and key populations are fully involved in the demand creation, planning, delivery and evaluation of quality-assured, rights-based HIV care and treatment programs in all LMICs.</p> <ul style="list-style-type: none"> · Active and meaningful engagement of PLHIV & key populations in the leadership and service delivery of HIV care

The full involvement of PLHIV and key populations, and the groups that represent them, has been central to the success of Treatment 2.0. The work of these individuals and organisation has been vital to:

- Driving demand for more and better treatment services. This included advocating for: fair prices for medicines; better quality services; full access to services, including for key populations; and the rights of people living with HIV.
- Identifying 'what works' – for example for treatment optimization – by documenting and learning from the real life experiences of people living with HIV, including those from key populations.
- Decentralizing the delivery of treatment services – bringing them closer to community members and ensuring that they are accessible (practically, financially, socially, etc.).
- Providing the 'wrap-around' services that are needed for ARVs to be effective, such as treatment literacy for communities and adherence counselling for people living with HIV.
- Addressing specific 'bottlenecks' and inequities in treatment, such as for key populations.
- Promoting practical ways for Treatment 2.0 to be a reality. For example, by using funding opportunities for Community Systems Strengthening through the Global Fund) (see Section 6.1).

- Advocating for ‘nothing about us without us’ and ensuring that the voices of communities, including people living with HIV and key populations, are heard in decision-making on treatment.

However, the realization of Treatment 2.0 also required resources – like funding and technical support – that allow communities to play their full role.

The Treatment 2015 Framework

Treatment 2015 was launched by the United Nations Joint Program on AIDS (UNAIDS) in July 2013. It is a framework to accelerate action to meet the target set by the 2011 United Nations Political Declaration on HIV/AIDS – of having 15 million people on antiretroviral therapy (ART) by 2015. It built on the Treatment 2.0 initiative and the 2013 WHO Consolidated ARV Guidelines.

Treatment 2015 called for intensified efforts in the 30 countries that are home to 9 out of 10 of the people with an unmet need for HIV treatment.

Priority Countries for Treatment 2015

Africa	Angola, Cameroon, Central African Republic, Chad, Cote d'Ivoire	Democratic Republic of the Congo, Ethiopia, Ghana, Kenya	Lesotho, Malawi, Mozambique, Malawi, Mozambique, Nigeria	South Africa, South Sudan, Togo, Uganda, Tanzania, Zambia, Zimbabwe
Asia	China, India, Indonesia, Myanmar, Thailand, Vietnam			
South America	Brazil, Colombia			
Eastern Europe	Russian Federation, Ukraine			

Treatment 2015 addresses three main areas:

1. DEMAND.

This focused on:

- Creating demand for HIV treatment that was led by people living with HIV, as well as key populations, and was sustained by civil society and the international community.
- Having strategic actions that would increase the demand for HIV testing and treatment services. This included:
 - Re-thinking HIV testing by adopting multiple, proactive strategies to encourage people to know their HIV status.
 - Investing in treatment literacy initiatives in communities.
 - Removing barriers to access to HIV treatment.
 - Emphasizing the prevention, as well as treatment, benefits of ART.

2. INVEST.

This focused on:

- Mobilizing sustained investment, giving priority to innovation and using available resources as strategically as possible.
- Having strategic actions to mobilize enough resources to cope with the scale-up of treatment and to enhance the effectiveness and efficiency of spending. This included that:
 - Domestic and international contributions should increase.
 - Continued efforts be made to improve the efficiency of HIV treatment programs.
 - Strengthening of health and community systems.
 - Programmatic innovation that would speed up scale-up be encouraged.
 - The means to manufacture ARVs in Africa should be created.

3. DELIVER.

This focused on:

- Ensuring that health and community systems, infrastructure, laws and policies were in place to deliver treatment to all people living with HIV who were eligible for it.
- Having strategic actions to close gaps in the HIV treatment continuum. This included:
 - Implementing efficient and innovative delivery models.
 - Taking steps to ensure equitable access to treatment.
 - Promoting accountability through rigorous measurement of outcomes.
 - Forging strategic partnerships that made best use of the unique experience and expertise of diverse stakeholders involved in treatment.

Treatment 2015 was important because it represented a high-level commitment by UNAIDS, its 11 UN agencies (known as co-sponsoring organizations) and other partners. It was also important because it aimed to build on existing lessons and tools to provide a ‘push’ to achieve the 2015 target for treatment.

Community Systems Strengthening (CSS)

Community systems strengthening is a term that has evolved over the last several years to encompass how communities (or people affected by a disease/issue) and their organizations (such as community-based organizations) engage in health service-delivery, health-related decision-making and other critical health system functions.

The goal of community systems strengthening (CSS) is to develop the roles of key affected populations and communities, community organizations and networks, and public or private sector actors that work in partnership with civil society at community level, in the design, delivery, monitoring and evaluation of services and activities aimed at improving health outcomes.

Community systems strengthening strategies often focus on building the capacity of civil society organizations (such as through improved human and material resources), with the aim of enabling communities and community actors to play a full and effective role alongside health and social welfare systems.

Since community organizations and networks engage regularly with affected communities, they are uniquely positioned to react quickly to community needs and emerging health concerns. These organizations can also provide direct services to communities not reached through the traditional national

health care sector (such as a peer outreach program for adolescents or people who use drugs). They also advocate for improved programming and policy environments.

Example of CSS in practice: In 2009, the Global Fund introduced the concept of community systems strengthening (CSS) to its funding model. This built on the existing understanding of many agencies about the vital role of communities in action on HIV. However, it aimed to articulate and strengthen that role in a more systematic way. The CSS Framework was updated in 2014¹² Its goal is to achieve improved health outcomes by developing the role of key populations, communities and community-based organizations in the design, delivery, monitoring and evaluation of services and activities related to prevention, treatment, care and support for HIV, tuberculosis and malaria.

The Global Fund CSS Framework has six core components or ‘building blocks’:

1. Enabling environments and advocacy – including community engagement and advocacy for improving the policy, legal, and governance environments and for affecting the social determinants of health.
2. Community networks, linkages, partnerships and coordination – enabling effective activities, service delivery and advocacy, maximizing resources and impacts, and coordinated, collaborative working relationships.
3. Resources and capacity building – including: human resources with appropriate personnel, technical and organizational capacities; financing (including operational and core funding); and material resources (infrastructure, information and essential commodities, including medical and other products and technologies).
4. Community activities and service delivery – accessible to all who need them, evidence-informed and based on community assessments of resources and needs.
5. Organizational and leadership strengthening – including management, accountability and leadership for organizations and community systems.
6. Monitoring and evaluation (M&E) and planning – including M&E systems, situation assessment, evidence-building and research, learning, planning and knowledge management.

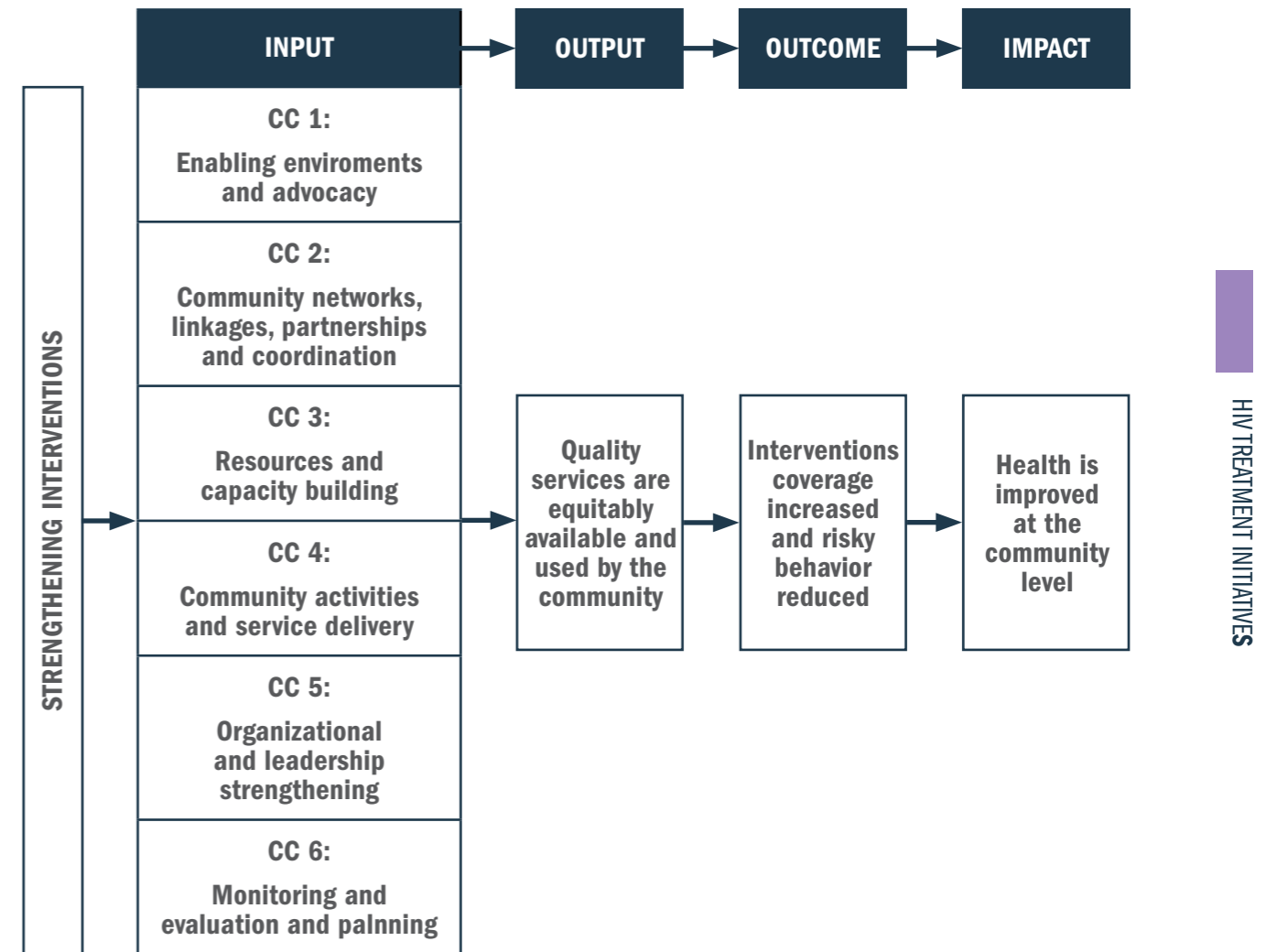
How Community Systems Strengthening Improves Responses to Health

The CSS Framework can be used by all those who have a role in dealing with health challenges and have an interest in community involvement and action. This includes community actors, governments, donors and partner organizations.

CSS is vital for achieving the HIV treatment initiatives described in this Module of the ACT Toolkit. If the global targets of 90-90-90 and ending the AIDS epidemic by 2030 are to be achieved, community actors must be mobilized and supported.

The six core components (building blocks) add up to ensure increased results for action on HIV:

CSS – DIAGRAM



CSS is also a particularly important opportunity to recognize and strengthen the role of groups, organizations and networks by and for key populations, such as sex workers, people who use drugs and LGBTI people. Such groups have often faced particular challenges - such as hostility towards their programs and lack of opportunities to get funding and build their capacity. CSS provides an important ‘entry point’ for community advocacy on access to HIV treatment. For example, a meeting convened by the (ITPC) identified the following activities that community-based organizations are uniquely placed to deliver and which, through advocacy, should receive the resources to do so:

TABLE Examples of Community System Contributions to Expanding HIV Treatment¹³

HIV treatment	HIV advocacy
<ul style="list-style-type: none"> • Support for adherence to HIV treatment. • HIV counselling and testing (HCT). • HIV treatment literacy. • Linkages to HIV care and support services. • Linkages to harm reduction services for people who use drugs. • Management of a person's health and psycho-social needs following HCT. • Support for disclosure of HIV status. • Delivery of HIV treatment (extending the role of community organizations). • HIV case management. • Nutritional support for people living with HIV. 	<ul style="list-style-type: none"> • Monitoring and accountability (of health systems, government responses, abuses of human rights, etc.). • Quality assurance of health services. • Anti-stigma, anti-discrimination and decriminalization efforts (including legal support, law reform and lobbying). • Policy analysis around access to and development of essential medicines. • Ensuring the meaningful involvement of people living with HIV in policy and program development.

The Investment Framework

The Investment Framework was initially developed by individuals working at different global health agencies and published in the Lancet medical journal in June 2011. The framework was proposed to facilitate more focused and strategic use of scarce resources by concentrating investments strategically and cost-effectively through resourcing in evidence-based interventions suitable for each country's epidemic scenario, while also emphasizing a human rights approach. The framework estimated that its application could avert 12.2 million new infections and 7.4 million AIDS-related deaths between 2011 and 2020.

Since the initial Lancet article the term and concept have been adapted by many global health institutions – such as UNAIDS and the Global Fund to Fight AIDS, TB and Malaria. In 2011, UNAIDS published *A New Investment Framework for the Global HIV Response*. In 2012, this was complemented by *Investing for Results, Results for People: A People-Centered Investment Tool towards Ending AIDS*.

What are the basics of the Investment Framework?

The framework provides a road map for accelerating progress on the global response to HIV to:

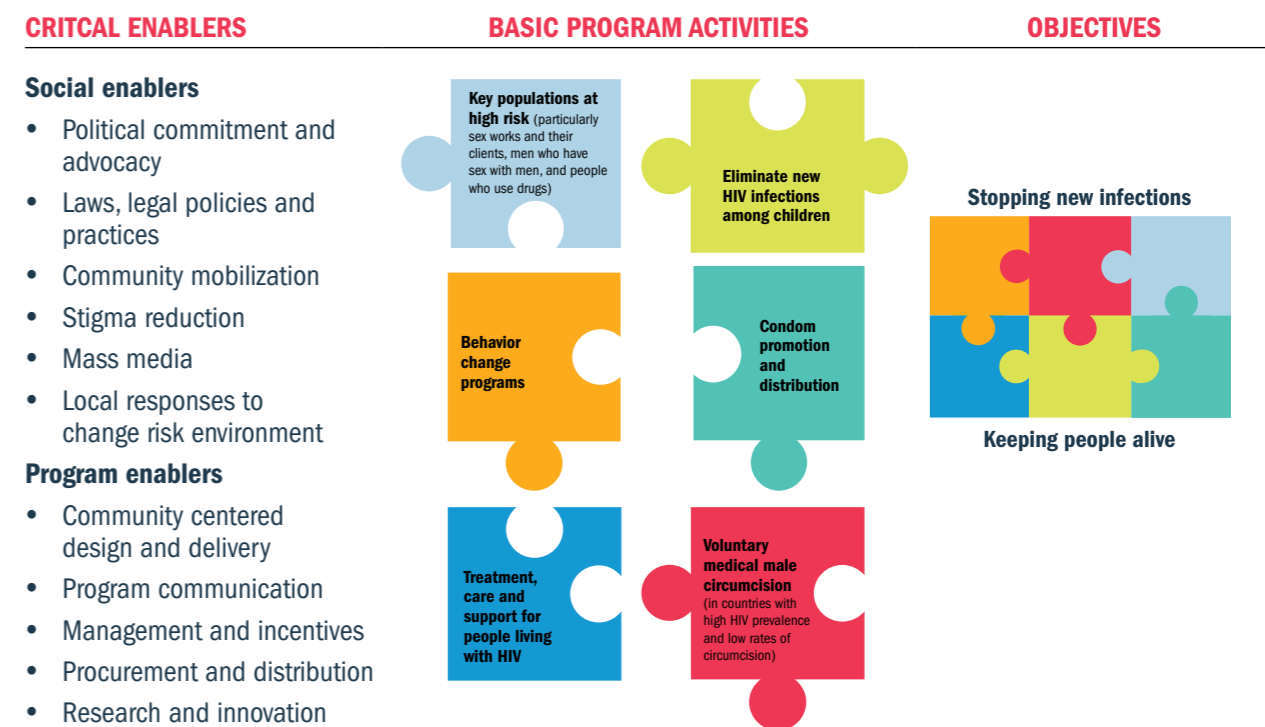
- Maximize the benefits of the HIV response.
- Support more rational resource allocation based on country epidemiology and context.
- Encourage countries to prioritize and implement the most effective programmatic activities.
- Increase efficiency in HIV prevention, treatment, care and support programming.

As shown by the graphic below, the Investment Framework focuses on:

- **Scaling up basic program activities** that have a direct effect on HIV risk, transmission, sickness and death and that **should be delivered as a comprehensive package** – such as:
 - Programs on key populations at higher risk (particularly sex workers and their clients, men who have sex with men, and people who inject drugs)

- ♦ Elimination of new infections in children
 - ♦ Programs that focus on the reduction of risk of HIV exposure through changing people's behavior and social norms
 - ♦ Procurement, distribution and marketing male and female condom programs
 - ♦ Treatment, care and support for people living with HIV
 - ♦ Voluntary medical male circumcision in countries with high prevalence of HIV and low rates of male circumcision
- **Supporting critical enablers** that are crucial to the success of programs – such as support for human rights based health service delivery. **Social enablers** create environments conducive to rational HIV responses – such as stigma reduction and human rights advocacy, while **program enablers** create demand for programs and improve their performance, such as VCT, treatment literacy, psycho-social support services and adherence support.
 - **Synergies with development sectors** – recognizing that HIV programs are not implemented in isolation and should, for example, support a country's wider development objectives and social, legal and health systems. Relevant development sectors include: social protection, education, legal reform, gender equity, poverty reduction and gender-based violence.

DIAGRAM The Investment Framework¹⁴



SYNERGIES WITH DEVELOPMENT SECTORS

Social protection, Education, Legal reform, Gender equality, Poverty reduction, Gender-based violence, Health systems (incl. STI treatment, Blood safety, Community systems, and Employer practices).

The Investment Framework has informed the development of an Investment Approach and Investment Cases (see below). These are increasingly critical for how countries express their needs and mobilize their resources. For example, they can be used in proposals to the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Investment approaches and investment cases¹⁵

An investment approach moves the focus from costs and expenditure to investments which will result in returns. This approach applies a long term outlook (10 years or more) and is a process that must be supported by analysis and an understanding of existing resources.¹⁶

An Investment Approach:

- Makes the best use of investments in action on HIV.
- Focuses on combinations of actions that will make the biggest difference.
- Improves the equity and impact of actions by focusing efforts on the populations and places that need them most.
- Improves the efficiency of HIV prevention, treatment, care and support programs.
- Uses evidence and models to identify priorities and gaps.
- Supports sustainable funding for HIV programs.
- Provides a framework for aligning government and donor funding.

An Investment Case:

- Is a way to make strategic decisions about resource allocation, resource mobilization, service delivery and funding.
- Can be articulated in different ways, based on a country's specific contexts and needs.
- Is a way to show national leadership in the response to HIV.
- Brings together different stakeholders including: Ministries of Finance, Health, Development and Planning; civil society; people living with HIV; and international partners.
- Communicates a joint effort to identify program gaps and bottlenecks and create a roadmap for action.

SECTION 3.2.

Fast-Track – ending the aids epidemic by 2030

SECTION OBJECTIVE

To build community activists' understanding of the UNAIDS *Fast-Track: Ending the AIDS Epidemic by 2030* initiative and why the fast track approach is important.

TRAINING MATERIALS

- PowerPoint presentation '3.2: Fast –Track: Ending the AIDS epidemic by 2030'
- Copies of the UNAIDS *Fast-Track: Ending AIDS by 2030*
- Flipchart and pens

TRAINING OPTIONS

Option A (approx. 60 minutes)

For this activity, it is helpful to give participants copies of the UNAIDS 'Ending AIDS by 2030' document to read.

1. Explain the objective of the session.
2. Present PowerPoint Presentation '3.2: Fast-Track: Ending the AIDS epidemic by 2030'.
3. Encourage the participants to ask questions about the initiative addressed in the presentation and to share any experiences of advocacy related to them.
4. As a group, ask participants to:
 - Explain why it is important to use the fast track approach to ending the AIDS pandemic,
 - Explain the 90-90-90 concept and the 95-95-95 concept,
 - Brainstorm the opportunities and challenges presented by this initiative,
 - Give examples of innovative funding methods,
 - Discuss the types of strategies which would have to be used to ensure that 90% of all people living with HIV know their status,
 - Brainstorm the indirect benefits of investments into AIDS programmes.
5. Ask the participants to summarize the session by developing advocacy messages about the 'Fast-Track: Ending AIDS by 2030' initiative.

Option B (approx. 120 minutes)

For this activity, it is necessary to give participants copies of the UNAIDS 'Ending AIDS by 2030' document and ask them to read it before the session.

1. Explain the objective of the Section.
2. Present PowerPoint Presentation '3.2: Fast-Track: Ending the AIDS epidemic by 2030'.

3. Encourage the participants to ask questions about the Fast-Track: Ending the AIDS epidemic by 2030 initiative.
4. Divide the participants into three groups. Ask the groups to choose a representative, and to discuss a different aspect of the Fast-Track Initiative:

Group 1: How countries can align to the fast track process and what some of the barriers might be.

Group 2: Mobilizing the correct resources, including the Abuja Declaration and how this could be used for this initiative.

Group 3: Explain the targets contained within the UNAIDS, 'Fast-track. Ending the AIDS epidemic by 2030', document.
5. Ask the representatives from the groups to present their topic to the all the participants. Encourage the participants to ask the representatives questions. If the representatives cannot answer the questions, discuss the answer as a group.
6. Altogether develop key advocacy messages on the Fast-Track: Ending the AIDS epidemic by 2030 Initiative. Support the discussion with the advocacy messages below.

ADVOCACY MESSAGES

- Without fast scale-up of treatment and prevention the HIV epidemic will continue.
- There is global consensus to aim for 90% of PLHIV knowing their status; 90% who know their status receiving treatment; and, 90% of those on treatment achieving a suppressed viral load. These targets include people in all population groups.
- There is global agreement that the scientific breakthroughs and the experiences gained over the last 10 years of scaling up treatment will make it possible to end the AIDS epidemic.
- HIV treatment is effective in preventing HIV transmission and extending the lifespan of those living with HIV. However, there are other ways of preventing the disease which do not involve medicines and which have proven themselves effective in decreasing rates of infection. These include, condom education and training; behavior change; voluntary medical male circumcision; and training and education with key populations.
- HIV programs are more effective when combined with social and structural approaches.
- A fast-track approach to HIV response in LIMC could mean that 28 million infections; 21 million AIDS-related deaths; and, 5.9 million infections among children will be prevented between 2015 and 2030.
- The fast-track approach will mean that US\$ 24 billion of additional costs for HIV treatment will be avoided.
- Although many achievements have been realized through global initiatives, some key populations are not benefitting from these gains. These groups include, sex workers; men who have sex with men and people who inject drugs
- Financing the fast-track approach will mean that LMICs will have to increase domestic funding for the programme. African countries who have signed the Abuja Declaration on committing 15% of their national budgets for health are encouraged to use this funding for fast-tracking the response to HIV.

USEFUL RESOURCES

Fast-track. *Ending the AIDS epidemic by 2030*. UNAIDS. 2014. Available here: http://www.unaids.org/sites/default/files/media_asset/JC2686_WAD2014report_en.pdf

The Fast-Track: *No Scale-up versus Rapid Scale-up*, UNAIDS, 2014. Available at: http://www.unaids.org/sites/default/files/20141118_WAD2014report_infographic_02_fasttrack_en.pdf

The Abuja Declaration: Ten Years On, WHO, 2011. Available at: http://www.who.int/healthsystems/publications/abuja_report_aug_2011.pdf?ua=1

HIV treatment – the big picture

While significant gains have been achieved over the past ten years to scale-up access to HIV treatment, many people still do not have access to treatment. The statistics are stark: In 2012, there were 35.3 million people living with HIV globally, and in the same year 1.6 million people died of AIDS. In 2015, there were 36.7 million people living with HIV while in the same year, 1.1 million people died from AIDS-related diseases.¹⁷

How many people are eligible for treatment? As of 2013, about 28.6 million PLHIV were eligible for ART under the World Health Organization (WHO) Consolidated ARV Guidelines of 2013. The updated WHO Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV, published in 2015, states that antiretroviral therapy (ART) should be started in everyone living with HIV at any CD4 cell count. The guidelines also recommend the use of daily oral pre-exposure prophylaxis (PrEP) for prevention for people who are at substantial risk of HIV.

How many are receiving treatment? By the end of 2012, 9.7 million people in low and middle-income countries were on ART. This represented 61% of all who were eligible under the 2010 WHO HIV treatment guidelines. Antiretroviral coverage among pregnant women living with HIV reached 62% in 2012. By 2014, 13.6 million people in low and middle income countries were receiving treatment.¹⁸ According to the UNAIDS Fact Sheet of 2016, of the 36.7 million PLHIV, 17 million were accessing antiretroviral therapy in 2015.¹⁹ This means that the previous global target of having 15 million people on HIV treatment by 2015 has been achieved.

Where are the gaps? Some countries have been able to accelerate treatment scale-up while others lag behind. Treatment gaps also remain for certain populations – for example, in lower- and middle-income countries, ART treatment rates were lower amongst children than adults who needed it. 32% of children needing ART were on treatment in 2014 compared with 41% of adults.

Regrettably, there is no data available on treatment coverage for key populations – LGBTI individuals, people who use drugs, and sex workers – or adolescents aged 10 – 19. As of 2013, HIV was the second leading cause of death among adolescents worldwide. According to the UNAIDS Gap Report published in 2014, there were 12 populations which, for a number of reasons, lagged behind in terms of treatment rates. These populations included:²⁰

- **PLHIV**
Only 2 out of 5 PLHIV have access to antiretroviral therapy.
- **Adolescent girls and young women**
Gender-based violence and limited access to health care and education prevent adolescent girls and young women from being able to protect themselves against HIV.
- **Prisoners**
People who use drugs (PWUDs), sex workers, and gay men and other men who have sex with men (MSM) are overrepresented in prisons. Overcrowding increases vulnerability to infections such as HIV, tuberculosis and hepatitis.

- **Migrants**
Migration can make people more vulnerable to HIV, and undocumented migrants often lack access to healthcare
- **People who inject drugs (PWIDs)**
PWIDs face legal punishments and human rights abuses. They also often lack access to health services. These factors increase their risks of acquiring HIV
- **Sex workers**
HIV rates are much higher among sex workers than among others. Stigma and discrimination, violence and legal punishment make sex workers very vulnerable to HIV.
- **Gay men and other MSM**
Rates of HIV are much higher among gay men and MSM than among other people. . Stigma and discrimination, violence and legal punishment make gay men and MSM very vulnerable to HIV.
- **Transgender people**
Many transgender people experience social exclusion and marginalization.
- **Children and pregnant women living with HIV**
HIV is the leading cause of death among women of reproductive age. Without treatment, about 1 out of 3 children living with HIV die by their first birthday, and 1 out of 2 die by their second.
- **Displaced persons**
Emergencies can leave people homeless and disrupt care and treatment for PLHIV
- **People with disabilities**
People with disabilities experience stigma that can result in violence and sexual abuse. This, combined with a poor understanding and appreciation of their sexual and reproductive health needs, makes people with disabilities vulnerable to HIV.
- **People aged 50 years and older**
The number of people aged 50 and older living with HIV is growing. Like younger people, people aged 50 and older also need HIV services, but their needs are often neglected or ignored.

Issues with testing and retention in care: Nearly 26 million people were living with HIV in the Sub-Saharan African region in 2015, which is the region most affected by the pandemic.²¹ Only 52% of people within the African region knew their status and only 43% of people needing treatment were receiving it in 2015.²² Treatment and care for key populations, young children and adolescents were still lagging, while social stigma, discrimination and punitive laws continued to have a negative influence on communities. The WHO stated that their target was to have ‘90% of people living with HIV know their status, 90% of people diagnosed with HIV are offered antiretroviral therapy and ensure that 90% of people living with HIV on treatment achieve viral load suppression’²³

Even when PLHIV began treatment, not all remained on treatment – reducing the proportion of people living with HIV who achieved viral suppression and other treatment benefits. There is considerable variation in retention rates between countries. However, according to the UNAIDS Gap Report, knowledge of HIV status amongst those living with HIV has increased: 86% of people in Sub-Saharan Africa who know their status are receiving ART and about 76% of those have achieved viral suppression.²⁴

Dwindling international resources for treatment: In 2012, US\$ 18.9 billion was available for HIV programs in low- and middle-income countries – leaving a resource gap of approximately US\$ 3.1 – 5.1 billion.²⁵ Encouragingly, domestic spending has increased for HIV. Still, in 2012, 51 countries looked to international sources for more than 75% of HIV-related spending. In 2014 an estimated US\$19.2 billion

was made available in low- and middle-income countries.²⁶

Estimates are that US\$26.2 billion will be needed in 2020, with this amount decreasing to US\$22.3 billion for the UNAIDS target of ending the HIV epidemic as a public health threat by 2030.²⁷

Fast-Track: Ending the AIDS epidemic by 2030

There is global consensus that by 2020, the 90-90-90 target could be reached. The 90-90-90 target aims at 90% of people knowing their status; 90% of those who know their status receiving treatment; and 90% of those on treatment achieving a suppressed viral load by 2020. It also aims at reducing the number of new infections to 500,000; and achieving no discrimination. In its document, entitled ‘*Fast-track. Ending the AIDS Epidemic by 2030*’, UNAIDS reports that, with rapid ‘scale-up’ of responses to the AIDS epidemic, the target of ending the AIDS epidemic could be achieved by 2030.

UNAIDS reports that the learnings, scientific breakthroughs and experiences of the past decade of treating HIV have created an ideal platform on which the targets can now be ‘fast-tracked.’ Without this ‘scale-up’ the AIDS epidemic will outrun the current response rate and result in a longer term need for treatment and increased costs. With this scale-up, the global health threat brought about by the AIDS epidemic could be ended.²⁸

The fast-track approach builds on the investments and gains already made in the fight against AIDS. These gains include that there are that:

- An increasing number of people are on treatment
- The number of pregnant women on treatment has increased (in line with the Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive)
- More men in priority areas within sub-Saharan Africa being circumcised
- The use of condoms among adults is increasing
- Knowledge of HIV is increasing
- The number of young people initiating sex before the age of 15 is decreasing, and
- The number of adults having multiple sex partners is decreasing.

However, key populations, such as sex workers, MSM, and PWIDs are not benefitting as much from these gains and there is a need to place more focus on these populations.

There have also been gains in the resources being made available for AIDS programmes. While international support has begun to level out in some regions, countries have been mobilizing their own resources and are taking an investment approach where resources are channeled to areas where they will result in the most gains and where the need is greatest. However, more funding will be needed to end the epidemic by 2030.

Achieving the 90–90–90 targets by 2020 would still mean that 27% of PLHIV would have unsuppressed viral loads.²⁹ This is because, if 90% of PLHIV know their status, there are still 10% who do not. 90% of those who do know their status will be on treatment, which means that 10% of those who know their status will not be on treatment. This means that only 81% of PLHIV will be on treatment. Of those who are on treatment, 90% will be virally suppressed, but 10% of those who are on treatment will not be virally suppressed. This means that 73% of PLHIV will be virally suppressed. In other words, even if the 90-90-90 target is reached by 2020, there will still be 27% of PLHIV will not be virally suppressed.³⁰

If the target of ending aids by 2030 is to be reached, preventing, testing and treatment efforts will have to be scaled up - increased resources will have to be channeled towards proven prevention strategies. These strategies include

- Enrolling all people living with HIV on ART for their own health and to prevent the transmission of HIV
- Condom education
- Behavior change
- Voluntary medical male circumcision, and
- Programmes with key populations.

The fast-track approach also calls for increased mass-media and face-to-face and outreach programmes in high-prevalence settings. An expansion of biomedical prevention tools will be needed and access to PrEP must be ensured for key populations. Higher levels of ART will be needed amongst pregnant mothers to eliminate new HIV infections amongst children. All barriers to accessing services on an ongoing basis, including social and structural barriers, must be addressed for HIV programmes to be more effective. In addition, mobilizing communities and engagement with development sectors, such as health, social protection, gender equality and education, will be required to ensure improved access to HIV prevention, testing and treatment.

UNAIDS-commissioned projections have indicated that if the AIDS epidemic is to be brought to an end, a more rapid approach is required. If the 2020 targets are only reached by 2030, there would be 3 million more new HIV infections and 3 million more AIDS-related deaths between 2020 and 2030. The fast-track approach would mean that the AIDS epidemic would be reversed by 2020. If the response carries on 'as usual' then the epidemic would worsen, resulting in an even greater global health burden and increased costs.

The strategic approach outlined by UNAIDS will require commitment to principles of global solidarity and shared responsibility. The required resources, as stated by UNAIDS, will provide treatment to double the amount of people in low-and-middle income countries in 2020 than in 2015. Financing the fast-track approach will mean that LMIC will have to increase domestic funding for the programme. All except low-income countries must work towards self-funding of the programme. Other, innovative methods of funding the initiative will have to be explored, for instance through, special tax levies. African countries who have signed the Abuja Declaration on committing 15% of their national budgets for health are encouraged to use this funding for fast-tracking the response to HIV.³¹

Because of the extra effort which will be required by nations to end the epidemic, optimal service delivery and the efficient use of funds will be critical. Apart from this, other strategies, such as price reductions and community-based service delivery will have to be employed.

In view of the increase in life expectancy, improved health and economic productivity, and the savings resulting from avoiding healthcare expenditure on those who will never become infected and the reduction in number of orphans due to AIDS, UNAIDS estimates a 15-fold return on investment due to this fast-track approach to ending the epidemic. Although the economic benefits will extend to every region, sub-Saharan Africa will benefit the most from this approach.

If the fast-tracked targets are to be realized, service delivery will have to be scaled-up and innovative service delivery strategies will have to be used. Multiple strategies for testing will need to be employed and will need to be strategically focused to those at the greatest risk. Where currently, 95% of testing is facility based, it will be necessary for countries to employ strategies such as community-based; provider initiated and self-testing to reach the target of 90% of PLHIV knowing their status.

The scaled-up investment into ending the AIDS epidemic by 2030 will provide indirect benefit to the broader health systems in that they will provide capacity for nations to address other health priorities, such as NCDs, maternal and child health, infectious diseases and emerging diseases or outbreaks. A good example of this is Rwanda where their early focus on HIV treatment and support has strengthened their primary health care system.

UNAIDS suggest that although the epidemic could be beaten with the tools currently available, investment into research and development of aspects such as longer-lasting and more potent therapies and curative vaccine is required.

UNAIDS warns that if existing levels of coverage continue, there will be an additional 28 million people living with HIV and an extra 21 million lives will be lost by 2030. In addition, an additional US\$ 24 billion will be spent every year for antiretroviral therapy by 2030.³²

The United Nations General Assembly High-Level Meeting on Ending AIDS – June 2016

In 2016 UNAIDS hosted a High-Level Meeting on Ending AIDS to focus the world's attention on the importance of a Fast-Track approach to the AIDS response.³³ High-level meetings are important because ending the AIDS epidemic will require global solidarity, partnership and commitment from international, national and local partners.

At the High-Level Meeting, held in New York, United Nations Member States committed to implementing a bold strategy to end the AIDS epidemic by 2030. At the meeting, which was attended by Heads of State and Government, ministers, PLHIV, civil society organization (CSO) representatives, representatives from the private sector, scientists and researchers, UN member states adopted an actionable Political Declaration.³⁴ The progressive Political Declaration included specific, time-bound targets and actions that must be achieved by 2020 if the world is to end the AIDS epidemic by 2030.

In addition to reaffirming previous commitments relating to the Fast Track approach to ending the AIDS epidemic, by adopting the Political Declaration Heads of State and Government, and representatives of States and Governments formally:³⁵

- Reaffirmed their commitment to end the AIDS epidemic by 2030
- Reiterated concern that Africa, in particular sub-Saharan Africa, remains the region worst affected by HIV/AIDS, and recognized that urgent action is required to curb the devastating effects of the AIDS epidemic
- Emphasized that the meaningful involvement of PLHIV and populations at high risk of HIV facilitates a more effective AIDS responses
- Expressed concern at the unacceptably low rates of testing and treatment coverage among children in developing countries, which are a result barriers including low rates of early infant diagnosis, inadequate case-finding for children, and poor linkage to treatment for children
- Expressed concern women and girls are still the most affected by HIV/AIDS and that they bear a disproportionate share of the caregiving burden. It was also noted that progress towards gender equality and the empowerment of women and girls has been unacceptably slow, and that their ability to protect themselves from HIV is undermined by gender inequalities, including unequal power relations, unequal legal, economic and social status, and insufficient access to health-care services
- Noted that many national HIV-prevention, testing and treatment programmes provide insufficient access to services for women and girls, migrants, and key populations at higher risk of HIV, such as PWID, sex workers, MSM, transgender people, and prisoners
- Expressed concern regarding the lack of global progress in reducing transmission of HIV among PWID, and called attention to the insufficient coverage of substance use treatment programmes that improve adherence to HIV drug treatment services. Member states also recognized the continued marginalization and discrimination against PWID through the application of restrictive laws which hamper access to HIV services

- Expressed concern that discrimination against PLHIV continues to be reported, and that restrictive legal and policy frameworks, including laws related to HIV transmission, continue to prevent people from accessing prevention, treatment, care and support services
- Recognized that there are still gaps in financing for HIV/AIDS and the need to further improve access to medicines in developing countries
- Committed to targets for 2020 to work towards reducing the global numbers of people newly infected with HIV to fewer than 500,000 per annum and people dying from AIDS-related causes to fewer than 500,000 per annum, as well as to eliminate HIV-related stigma and discrimination

At the meeting, Armenia, Belarus and Thailand joined Cuba in receiving official certificates from the WHO to congratulate them for eliminating new HIV infections among children. Thailand is the first country with a major HIV epidemic to accomplish this.³⁶

SECTION 3.3.

HIV treatment guidance

SECTION OBJECTIVE

To build community activists' understanding of the most recent World Health Organization (WHO) Antiretroviral Therapy (ART) Guidelines* and why they matter for access to HIV treatment.

TRAINING MATERIALS

- PowerPoint presentation '3.3. What is the global guidance on treatment?'
- Copies of *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: What's new*, November 2015 http://apps.who.int/iris/bitstream/10665/198064/1/9789241509893_eng.pdf?ua=1
- Flipchart and pens.

TRAINING OPTIONS

Option A (approx. 60 minutes)

For this activity, it is helpful to give each participant a copy of the *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: What's new*, November 2015 in advance and to ask them to read it. You can find it here: http://apps.who.int/iris/bitstream/10665/198064/1/9789241509893_eng.pdf?ua=1

1. Explain the objective of the Section.
2. Facilitate a group discussion, asking the participants what they know about the ART Guidelines and how they can ensure access to HIV treatment in their communities.
3. Present PowerPoint presentation '3.3. What is the global guidance on treatment?'
4. Compare the participants' discussion and the content of the presentation. For example: Were there any differences in understanding or opinions about what the guidelines say? Were there any examples of countries or areas where these guidelines were not being implemented?

6. Encourage the participants to ask additional questions for clarification.
7. Ask the participants to summarize the session by developing advocacy messages about 'What is the global guidance on treatment?'
8. Support their ideas by sharing examples of messages (see below).

Option B (approx. 120 minutes)

For this activity, it is necessary to give each participant a copy of the:

- *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: What's new*, November 2015 in advance and to ask them to read it. You can find it here: http://apps.who.int/iris/bitstream/10665/198064/1/9789241509893_eng.pdf?ua=1, and
- *Summary of New Recommendations, 2013* (this is a summary of the Consolidated Guidelines on the use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach, June 2013). You can find the summary here: <http://www.who.int/hiv/pub/guidelines/arv2013/intro/summarynewrecommendations.pdf>.

If possible, you should give the participants copies of these guidelines in advance, so they have time to read them before the session.

1. Explain the objective of the Section.
2. Present PowerPoint presentation '3.3. What is the global guidance on treatment?'
3. Provide a general introduction to the ART Guidelines (2013 and 2015). For example, summarize who produced the guidelines, what they cover and who can use them.
4. Divide the participants into two groups, each with a question to focus on:

Group 1: What do the guidelines recommend about who should have access to HIV treatment?

Group 2: What do the guidelines recommend about how HIV treatment should be provided?

Optional: Group 3. If there are participants from different countries at the training session, make a third group with one participant from each country. Ask Group 3 to discuss how the guidelines are implemented differently in different countries.
5. Give the groups about 45 minutes to discuss their question. Encourage them to base the answer to their question on the specific recommendations in the 2013 and 2015 ART Guidelines.
6. Bring the two (or three) groups back together. Ask each group to briefly report back on the answer to their question. Encourage the other participants to make additional points.
7. Facilitate a group discussion on the aspects of the ART Guidelines that matter most to communities. For example, which recommendations will make the greatest difference in access to treatment for:
 - People living with HIV (in general)?
 - People living with HIV who are from key populations, such as sex workers, people who use drugs and lesbian, gay, bisexual, transgender and intersex (LGBTI) people?
8. Support the participants to identify about four priorities in the ART Guidelines from the perspective of communities. Write the priorities on a flipchart.

9. Ask the participants to summarize the session by developing advocacy messages about ‘What is the global guidance on treatment?’
10. Support their ideas by sharing examples of messages (see below).

ADVOCACY MESSAGES

- HIV treatment is highly effective at stopping HIV from multiplying. Treating HIV with ART reduces the amount of virus in the body (viral load) and allows for the immune system to recover.
- Starting ART early will decrease the chance of a person’s HIV multiplying and increasing the person’s viral load. This decreases the risk of HIV being transmitted to a partner or infant.
- The latest WHO ART Guidelines are a vital opportunity to follow good practice and achieve universal access to HIV treatment for all people living with HIV, including those from key populations.
- The ART Guidelines emphasize the crucial role of communities in delivering HIV services and increasing access to treatment. However, that role can only be fulfilled if such groups have access to resources and are able to participate in decision-making.
- Implementing the WHO ART Guidelines and achieving universal access is not only about scaling-up ART. It is about the ‘whole package’ of HIV services. For example, attention must be paid to: the quality of ARV drugs, treatment for co-infections, the availability of 2nd and 3rd line treatment options, and adherence support services.

USEFUL RESOURCES

- *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach*, WHO, 2013. Available here: http://apps.who.int/iris/bitstream/10665/85321/1/9789241505727_eng.pdf
- *Consolidated Guidelines on the use of Antiretroviral Drugs for Treating and Preventing HIV Infection: What’s New*, WHO, November 2015. Available here: http://apps.who.int/iris/bitstream/10665/198064/1/9789241509893_eng.pdf?ua=1
- *Fact Sheet: HIV Treatment and Care. What’s new in HIV Treatment*, WHO, 2016. Available here: http://apps.who.int/iris/bitstream/10665/204347/1/WHO_HIV_2015.44_eng.pdf?ua=1
- *Policy Brief: WHO Expands Recommendation on Oral Pre-exposure Prophylaxis of HIV Infection (PrEP)*, WHO, 2015. Available here: <http://www.who.int/hiv/pub/prep/policy-brief-prep-2015/en/>
- *News Release. Treat All People Living with HIV, offer Antiretrovirals as Additional Prevention Choice for People at “Substantial” Risk*, WHO, 2015. Available here: <http://www.who.int/mediacentre/news/releases/2015/hiv-treat-all-recommendation/en/>
- *HIV Testing Services: Fact sheet to the WHO Consolidated Guidelines on HIV Testing Services*, WHO, 2015. Available here: http://apps.who.int/iris/bitstream/10665/179931/1/WHO_HIV_2015.20_eng.pdf?ua=1
- *Global Health Sector Response to HIV, 2000–2015. Focus on Innovations in Africa*. WHO. November 2015. http://apps.who.int/iris/bitstream/10665/198148/1/WHO_HIV_2015.40_eng.pdf?ua=1
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Who is responsible for global guidance on health?

Global guidance on health issues and diseases is provided by the World Health Organization (WHO). The WHO is a United Nations (UN) agency based in Geneva, Switzerland. WHO provides UN member states with access to essential information about health and health care delivery in order to improve health outcomes in their countries. WHO guidance aims to ensure that all people have equitable access to essential healthcare and stay as healthy as possible.

WHO is governed by the World Health Assembly (WHA) – the world’s highest body for health policy-making. The WHA is attended by delegations from 194 member states. The WHA approves the WHO work program and budget and elects WHO’s Director General.

WHO’s responsibilities include:

- Providing leadership on global health matters and engaging in country partnerships where joint action is needed
- Shaping the health research agenda and stimulating the generation, translation and dissemination of valuable knowledge
- Setting health norms and standards and promoting and monitoring their implementation
- Articulating ethical and evidence-based health policy options
- Providing technical support to countries
- Monitoring and assessing health trends
- Developing guidelines and recommendations on clinical, public health, and policy interventions guide policy-makers, healthcare providers and patients

The Joint United Nations Programme on HIV/AIDS (UNAIDS) is a leading advocate for global action against HIV/AIDS. UNAIDS was established in 1994 by the United Nations Economic and Social Council (ECOSOC). UNAIDS is composed of eleven United Nations organizations, including: WHO, United Nations High Commissioner for Refugees (UNHCR), United Nations International Children’s Emergency Fund (UNICEF), World Food Programme (WFP), United Nations Development Programme (UNDP), United Nations Fund for Population Activities (UNFPA), United Nations Office on Drugs and Crime (UNODC), UN Women, International Labour Organization (ILO), United Nations Educational, Scientific and Cultural Organization (UNESCO), and the World Bank.³⁷ As well as developing prevention and treatment guidelines for HIV/AIDS, UNAIDS gathers evidence to track the spread of the HIV epidemic and assess the effectiveness of various interventions. UNAIDS works closely with national governments and other partners to end the AIDS epidemic by 2030.³⁸

What does WHO say about HIV treatment?

WHO has produced guidelines on the use of antiretroviral therapy (ART) since 2002 and updates these regularly. In June 2013, the WHO released an important document containing guidelines on ART treatment for HIV, called the *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach*.¹ In the ACT Toolkit, they are referred to as the ‘2013 WHO ART Guidelines.’

Although most of the information in the 2013 ART Guidelines is still correct, in 2015, the WHO updated its recommendations about when to start ART. The new recommendations about when to start ART are in a document titled *Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV*.² In the ACT Toolkit, they are referred to as the ‘2015 WHO ART Guidelines.’ This means that to get the best information about ART for HIV, it is important to use both of these documents.

The WHO ART Guidelines address the use of ARV drugs for HIV treatment and prevention across all age groups and populations in terms of education, testing, linking to care, and adherence support. The WHO provides:

- Evidence-based clinical recommendations – focused on countries with limited financial resources for health, and limited numbers of skilled healthcare workers and managers
- Guidance on key service delivery issues that need to be addressed to increase access to HIV services
- Guidance for governmental decision-makers and planners on setting priorities, implementing clinical and operational recommendations, monitoring implementation and evaluating impact.

The WHO ART Guidelines are for use by all stakeholders involved in HIV treatment. This includes Ministries of Health, health program managers, health workers, PLHIV and key populations. The 2013 ART Guidelines are very detailed – totaling over 250 pages – but a shorter summary version is also available.ⁱⁱⁱ The 2015 Guidelines on When to Start ART updates the 2013 guidelines with new information based on an extensive review of existing evidence. The 2015 Guidelines on When to Start ART were also influenced by experience from country programs, and consultations with communities.³⁹

What communities should know about the WHO ARV guidelines

The target audience for the WHO Guidelines are, national HIV program managers; national HIV treatment and prevention decision-makers; clinicians and other health service providers; people living with HIV and community-based organizations; and international and bilateral agencies and organizations that provide financial and technical support to HIV programmes in resource-limited settings.⁴⁰ The guidelines are an important tool for communities and community activists – enabling them to know what treatments and services they are entitled to so they can demand them.

This section of Module 3 highlights the elements of the WHO Guidelines that are most important for community activists to be aware of.

HIV testing: The beginning of a successful implementation of these guidelines is scaling up HIV testing. Efforts to scale up HIV testing should be community-driven, so that communities are aware of their rights can demand HIV testing and treatment.

When to start ART: The new recommendations support starting ART in all adults, adolescents and children with HIV, regardless of CD4 cell count or disease stage. This means that everyone who is diagnosed with HIV is eligible to start ART. The new guidelines also include specific recommendations for adolescents (10 to 19 years old) around when to start ART.

Lifelong treatment for pregnant women: Pregnant women should have the opportunity to access lifelong HIV treatment under option B+ (see table below), which ensures prevention of vertical transmission but also protects the health of the patient.

Making treatment easier for patients: The guidelines encourage the use of fixed-dose combinations and once-daily regimens.

Eliminating toxic regimens: The 2015 WHO ART Guidelines reiterate the recommendation that Stavudin (d4T) should not be used in first-line regimens. The 2015 Guidelines also recommended ART regimens for adults and children should include a smaller dose of Efavirenz. This is to reduce the risk of side-effects, reduce the costs of treatment, and allow the option of using the integrase inhibitor class of drugs in first-line ART.⁴¹

Treatment beyond HIV: Co-infections and other illnesses are common among people living with HIV. Implementing the WHO ART Guidelines also requires the management and treatment of co-infections, including Tuberculosis (TB), Hepatitis C and sexually transmitted infections (STIs). The WHO Guidelines offer guidance across the range of care required in managing the common co-infections and comorbidities in people living with HIV. The 2015 WHO ART Guidelines include new recommendations on diagnosing active TB.⁴²

The role of communities in supporting health: There is acknowledgment in the Guidelines that communities are essential in the implementation of the new guidelines through treatment and rights literacy, creating demand for treatment, linking communities to health services, reaching those hardest to reach to increase impact, and providing supporting behavioral interventions at healthcare facilities (e.g. through peer education and counselling).

The following table provides further examples of the WHO's recommendations that are particularly relevant to community activists.

How communities get involved in guideline development

Communities can and should play a central role in the development of guidelines. Communities and CSOs can be involved in guideline development in the following ways:

1. Community Advisory Boards (CABs) for scientific studies. Treatment guidelines are based on evidence collected through clinical trials and studies. These studies involve large number of people, some of whom are PLHIV. CABs ensure that the community perspectives and preferences of community members are respected, that the study is responsive to the needs of the community, and that the community has the information they need to benefit from the study. The recommendations made by CABs during the study are ultimately reflected in the guidelines.
2. Guideline development reference groups: Communities should be consulted in the development of global guidelines. At national level, CSOs are often invited to participate in various steps of the guideline development process. This gives them a chance to ensure that the preferences and needs of communities are addressed by guidelines. Often, those responsible for developing national guidelines will also consult directly with communities and community leaders before finalizing the guidelines.
3. Critiquing existing guidelines and advocating for the development of new guidelines. Communities and CSOs will often comment publically on guidelines when they are released. This is especially important when guidelines are not responsive to the needs of communities, or when national guidelines are not in keeping with global guidelines and evidence. Sometimes CSOs will call for the development of new guidelines, often to meet the treatment and care needs of a specific key population.
4. Participate in the development of consumer guidelines: Usually, the Ministry of Health puts together a guideline development committee to oversee the process of developing treatment guidelines.⁴³ This stage of the policy development is usually too technical for the involvement of communities to be beneficial. However, PLHIV, their families and representative organizations can be involved in reviewing consumer guidelines related to HIV treatment guidelines.⁴⁴ The opinion and perspectives of these groups can be collected through focus-group discussions.⁴⁵
5. Participate in the process of adapting guidelines to national or local contexts: Communities, community leaders and CSOs can play an important role in advocating for any changes or further research necessary to ensure that the guidelines are appropriate to the local context.⁴⁶

HOW CIVIL SOCIETY ORGANIZATIONS CONTRIBUTE TO GUIDELINE DEVELOPMENT

The International Treatment Preparedness Coalition (ITPC), AIDS & Rights Alliance for Southern Africa (ARASA) and the Asia Pacific Network of People Living with HIV/AIDS (APN+) welcomed the new 2015 WHO ART Guidelines, as they had done for the 2013 as well. They view the Guidelines as an important tool to increase access to life-saving ART.⁴⁷ However, the Coalition highlighted three issues in response to the 2015 Guidelines. In the opinion of ITPC, these issues create barriers to ongoing progress.

These issues of concern are:

1. Community-led treatment education is not sufficiently supported and should enjoy more focus. Although they welcome the new ‘test and offer to treat’ attitude adopted by the WHO to ensure early treatment of HIV, ITPC suggest that more education is needed to ensure that patients are knowledgeable about their choices. ITPC emphasise the importance of community-led treatment education and urge the international community to provide this education as a vital aspect of the treatment expansion.
2. ITPC is concerned that access to affordable medicines, such as dolutegravir, will be denied to people living in middle income countries. The antiretroviral drug, dolutegravir, recommended in the guidelines is more effective, has fewer side effects and has a lower risk of resistance for patients than previous drugs. However, ITPC are concerned that it will be unavailable for most people in middle-income countries who need it, due to patents and the drug’s exclusion from a voluntary license issued by its manufacturer in 2014. ITPC has urged governments to increase access to affordable essential medicines by making use of compulsory licensing and other public health protection measures.
3. While ITPC support the Guideline’s recommendation of routine viral load monitoring, ITPC calls on governments to speed up implementation of this recommendation in the interest of better health outcomes. In 2014, a year after the WHO released guidelines recommending routine viral load testing, ITPC conducted a global survey involving 760 PLHIV in 16 countries to find out how well the routine viral load testing guidelines were being implemented.⁴⁸ According to ITPC, the survey (which was part of the Be Healthy – Know your Viral Load campaign) found that many countries in Africa, Asia and Latin America have not adopted recommendations associated with routine viral load testing and only recommend viral load test following signs of treatment failure.

SECTION 3.4.

What are the Entry Points for Advocacy on HIV Treatment Initiatives?

SECTION OBJECTIVE

To build community activists’ understanding of the entry points and ‘what works’ for advocacy on treatment initiatives.

TRAINING MATERIALS

PowerPoint presentation ‘3.4. What are the entry points for advocacy on treatment initiatives?’

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objective of the Section.
2. Ask the participants to think about the HIV treatment initiatives that have been addressed in Part 3.1; 3.2 and 3.3. Ask them to identify some examples of entry points for advocacy on those initiatives. Explain that an entry point is an opportunity to ‘get started.’ It might, for example, be a process (that provides an opportunity to influence decision-making) or a crisis (that provides an opportunity to achieve urgent change).
3. Present PowerPoint presentation ‘3.4. What are the entry points for advocacy on treatment initiatives?’
4. Ask the participants to share other lessons learned about advocacy on treatment initiatives – based on their own experiences.
5. Summarize what has been discussed and agreed during the session.

Option B (approx. 120 minutes)

1. Explain the objective of the Section.
2. Explain to the participants what is meant by an entry point for advocacy on treatment initiatives – in terms of an opportunity to ‘get started.’ For example, an entry point might be a process (that provides an opportunity to influence decision-making) or a crisis (that provides an opportunity to achieve urgent change).
3. Divide the participants into groups of about 5 people. Ask the participants to identify 1-2 entry points for advocacy on treatment initiatives that relate to their community.
4. Bring all of the participants back together. Ask each group to present their examples of entry points. Encourage the other participants to ask questions and make comments.
5. Ask the participants to think about what type of advocacy they could carry out for the entry points that they have identified. Facilitate a discussion on: What do we know about ‘what works’ in advocacy on treatment initiatives?

6. Encourage the participants to identify the lessons learned from their own experiences. Write their inputs on a flipchart.
7. Summarize what has been discussed and agreed during the session.

What needs to happen to increase access to treatment for all in need?

In order to increase treatment access, there must first be increased demand for treatment from people living with HIV, other affected communities and their allies. People living with HIV who do not know their status must be supported to access testing and links to treatment, preferably through community-based initiatives that ensure a rights-based approach.

National strategies need to include and support communities to be involved in all aspects of HIV prevention, treatment and care. Community treatment literacy programs (aimed at improving treatment seeking behavior and adherence as well as promoting the prevention benefits of treatment) must also be recognized and supported by national HIV policies and strategies as well as be adequately funded.

Countries must also immediately adopt the new WHO ART Guidelines with clear strategies of how to mobilize the necessary resources to meet the new recommendations. The inclusion of civil society/expert patients/ community members in national treatment guideline task forces is mandatory to ensure that the adoption and use of the new guidelines is fast tracked.

At the same time, laws and policies that infringe on the right to life and health that deter persons in need of testing and treatment – such as laws that criminalize HIV transmission or exposure, laws that criminalize behavior such as same-sex relations, sex work and drug use – must be eliminated.

At the end of the day, treatment scale-up can only happen with more investment and political will. To help mobilize this, communities can:

1. Champion innovative financing mechanisms based on a strategic investment approach.
2. Be the watchdog of budgetary allocation and expenditure of resources to ensure appropriate prioritization and allocation of resources; identify and report misappropriation, diversion, misuse and wastage of resources; and ensure accountability and transparency is always in place in procurement and supply of medicines, equipment and supplies.
3. Demand utilization of TRIPS and voluntary licensing flexibilities to minimize costs of medicines and expand access to affordable generic ARVs and other essential medicines, such as HPV treatment.
4. Advocate for more investment in the development of optimal ARV regimens (easy to use, minimal side effects, more potent, affordable).
5. Advocate for capacity building for drug manufacturing in Africa, creating new supply chains and less dependency on drug producers elsewhere through developing the local production capacity for pharmaceuticals.

Treatment scale-up also needs efficient and robust treatment delivery systems. To help achieve this, communities can:

1. Be involved in the establishment and management of Primary Treatment Delivery Points so that treatment services can be brought closer to where people live.
2. Focus on training community health workers including PLHIV to be part of a country's task shifting strategy.
3. Be involved in treatment outreach programs, especially for key populations and other groups not often reached by mainstream health services.

What are entry points for advocacy on treatment initiatives?

For community activists, there are many different entry points that can be used for advocacy on treatment initiatives. An entry point is an opportunity to 'get involved,' 'get going' and 'make a difference.' It is an opportunity to start discussions, influence opinions and achieve change.

For example, an entry point might be a process (that provides an opportunity to influence decision-making) or a crisis (that provides an opportunity to achieve urgent change). More examples of entry points can be seen in the experiences of ITPC partners and other organizations throughout the world:

TABLE Examples of Entry Points for Advocacy on HIV Treatment Initiatives

Examples of entry points	Examples of advocacy actions
<p>The District AIDS Plan does not recognize or fund the role of community groups in providing HCT and mobilizing local people to 'know your status' and access treatment.</p> <p>(For example, as called for in the 2013 ART Guidelines)</p>	<ul style="list-style-type: none"> • Gathering data on how many people community groups have provided HCT to in recent years. In particular, highlighting 'hard to reach' groups – such as key populations – that might, otherwise, not access HCT. • Asking for a meeting with the District Health Director to present the data and advocate for a change to the Plan. • Working with the District Health Authority to draft new text for the Plan that recognizes – and allocates a budget to – the role of community groups.
<p>The country's Investment Case – for inclusion in a proposal to the Global Fund – does not use community data about HIV treatment or include community knowledge about 'what works', especially in relation to reaching key populations.</p> <p>(For example, as called for in the Investment Framework)</p>	<ul style="list-style-type: none"> • Gathering examples of community data about HIV treatment and lessons on 'what works' for increasing access for key populations. • Implementing an e-campaign - with community groups throughout the country mobilized to send e-mails to the coordinators of the Investment Case to call for the inclusion of community data. • Using all relevant contacts – such as the community sector representatives on the Country Coordinating Mechanism – to promote advocacy messages that neglect of community data and lessons is unacceptable and argue for why their inclusion will produce a stronger and more accurate Investment Case.
<p>The country is not investing in the development of high quality ARV regimens - that, for example, have drugs that are easy to use, affordable and have minimal side effects.</p> <p>(For example, as called for in Treatment 2.0 and the new WHO ART Guidelines)</p>	<ul style="list-style-type: none"> • Working with other stakeholders – such as the country office of the World Health Organization (WHO) – to raise understanding of the logic and benefits of Treatment 2.0 and the new WHO ART Guidelines among the Ministry of Health and Ministry of Finance. • Preparing case studies of community members living with HIV – to show why a high quality ARV regimen will both improve their quality of life and improve the efficiency of treatment. • Arranging meetings between people living with HIV, the Ministry of Health and pharmaceutical companies to present the 'human face' of why investing in high quality ARV regimens matter.

<p>The National Guidelines do not reflect the most recent WHO Treatment Guidelines.</p> <p>(For example, the 2015 WHO ART Guidelines which state that all PLHIV are eligible to start ART as soon as possible).</p>	<ul style="list-style-type: none"> Working with other stakeholders – such as the country office of the World Health Organization (WHO) – to raise understanding of the logic and benefits of early treatment initiation. Developing evidence on the cost of implementing the recommendation and the money that will be saved by preventing opportunistic infections that happen when PLHIV start ART at a lower CD4 count. Presenting the evidence for early treatment initiation to policy-makers in an easy to understand and compelling way, such as with infographics.
<p>The Provincial Health Authority supports task-shifting (from government clinic staff to community health workers) for providing HIV treatment and supporting adherence. But it will not fund the training of the community health workers.</p> <p>(For example, as called for in relation to Community Systems Strengthening)</p>	<ul style="list-style-type: none"> Asking for a meeting with the Director of the Provincial Health Authority and promoting the initiatives (such as the 2013 ART Guidelines and Community Systems Strengthening) that call not only for task-shifting, but also for the funding and support of community systems. Developing a proposal for bringing together the Provincial Health Authority and community groups to provide a joint training program for the community health workers – that can be replicated in the future. Where possible, involving people living with HIV – including those from key populations – as trainers.

What works in advocacy on HIV treatment initiatives?

Many lessons have been learned - including by ITPC's partners - about 'what works' in advocacy on HIV treatment initiatives. The following presents examples that apply to different contexts:

'What works' in advocacy on HIV treatment initiatives

USING GLOBAL 'PEER PRESSURE'

- For example, using the existence of global initiatives – such as the WHO ART Guidelines – to advocate to the government on why and how action on access to HIV treatment needs to be increased and improved in your country.

IDENTIFYING WHAT CAN AND CANNOT BE CHANGED

- For example, identifying what aspects of treatment initiatives (such as the WHO ART Guidelines and Treatment 2.0) can or cannot be adapted within your country and, therefore, what aspects are worth advocating on.

FOCUSING ON YOUR PRIORITIES

- For example, identifying 2-3 key community issues to advocate on within national consultations on treatment initiatives (which may be complex and address many different areas).

DOING YOUR HOMEWORK

- For example, researching the specific process and stages for adapting and rolling out the latest treatment initiatives in your country – so that you can identify the best entry points for advocacy.

SUPPORTING YOUR MESSAGES WITH EVIDENCE

- For example, gathering data and case studies that demonstrate why Treatment 2.0 (with its emphasis on simplification, equity, etc.) will increase access to HIV treatment for 'real life' people living with HIV in your community.

'SPEAKING THE LANGUAGE'

- For example, using the language of the Investment Framework - such as 'critical enablers' and 'value for money' - to convince decision-makers (such as in the Ministry of Finance) about why action on issues such as stigma represents a good investment for scaling-up access to treatment.

USING EXAMPLES FROM OTHER CONTEXTS

- For example, using an Investment Case from another country - that addresses the treatment needs of key populations and has contributed to a successful proposal to the Global Fund – to advocate for why such a case is needed in your country.

Endnotes

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- 35 Political Declaration on HIV and AIDS: On the Fast-Track to Accelerate the Fight against HIV and to End the AIDS Epidemic by 2030, United Nations General Assembly, 2016. http://www.unaids.org/sites/default/files/media_asset/2016-political-declaration-HIV-AIDS_en.pdf
- 36 Press Release: *Bold New Political Declaration On Ending Aids Adopted In New York*, UNAIDS, 2016. http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2016/june/20160608_political-declaration
- 37 *Joint United Nations Programme on HIV/AIDS*, UNAIDS, 2016. http://www.unaids.org/sites/default/files/sub_landing/20160426_PCB_Members_1January2016_EN.pdf
- 38 *The Governance Handbook*, UNAIDS, 2009. http://www.unaids.org/sites/default/files/media_asset/JC1682_GovernanceHandbook_March2011_en.pdf
- 39 *Policy Brief: Consolidated Guidelines on the use of Antiretroviral Drugs for Treating and Preventing HIV Infection: What's New*, WHO, 2015. http://www.avac.org/sites/default/files/resource-files/guidelines_Nov2015.pdf
- 40 Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach, WHO, 2013. http://apps.who.int/iris/bitstream/10665/85321/1/9789241505727_eng.pdf
- 41 *Policy Brief: Consolidated Guidelines on the use of Antiretroviral Drugs for Treating and Preventing HIV Infection: What's New*, WHO, 2015. http://www.avac.org/sites/default/files/resource-files/guidelines_Nov2015.pdf
- 42 *Policy Brief: Consolidated Guidelines on the use of Antiretroviral Drugs for Treating and Preventing HIV Infection: What's New*, WHO, 2015. http://www.avac.org/sites/default/files/resource-files/guidelines_Nov2015.pdf
- 43 *Developing HIV/AIDS Treatment Guidelines*, UNAIDS, 1999. http://data.unaids.org/publications/irc-pub03/developingkm_en.pdf
- 44 *Developing HIV/AIDS Treatment Guidelines*, UNAIDS, 1999. http://data.unaids.org/publications/irc-pub03/developingkm_en.pdf
- 45 *Developing HIV/AIDS Treatment Guidelines*, UNAIDS, 1999. http://data.unaids.org/publications/irc-pub03/developingkm_en.pdf
- 46 *Driving the HIV Response, Global Network of People Living with HIV, International HIV/AIDS Alliance, and STOP AIDS NOW!*, 2014. <http://www.gnpplus.net/assets/Community-Guide-final1-copy.pdf>
- 47 *Response to Who HIV Treatment Guidelines, International Treatment Preparedness Coalition*, 2015. <http://itpcglobal.org/response-to-who-hiv-treatment-guidelines/>
- 48 *Be Healthy Know Your Viral Load*, ITPC, 2015. <http://www.knowyourviralload.org/language/en/the-campaign/>

4 HUMAN RIGHTS AND HIV

Welcome to Module 4: Human rights and HIV of the Advocacy for Community Treatment (ACT) Toolkit of the International Treatment Preparedness Coalition (ITPC).

Module 4 focuses on human rights and how they affect access to HIV treatment.

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SECTION 4.1 What are human rights?

SECTION OBJECTIVE

To build community activists' understanding of what human rights are and why they matter for advocacy for community treatment.

TRAINING MATERIALS

- PowerPoint presentation '4.1 What are human rights?'
- A list of the key regional, national and international agreements and other instruments (such as policies and guidelines) that your country has committed to for human rights and the right to health.

TRAINING OPTIONS

Option A (approx. 60 minutes)

- 1 Explain the objective of the Section.
- 2 Facilitate a discussion on:
 - What are human rights?
 - Why do human rights matter?
- 3 Present PowerPoint presentation '4.1 What are human rights?'
- 4 Encourage the participants to ask questions about anything in the presentation that is unclear.
Facilitate a group discussion on:
 - In our country, what are the regional, national or international agreements and other instruments (such as policies and guidelines) that commit to:
 - Human rights (in general)?
 - The right to health (specifically)?
- 6 Write lists of these commitments and instruments on a flipchart. If necessary, add to the participants' inputs (based on your own research for this Section).
- 7 Ask the participants to summarize the session by writing advocacy messages about 'What are human rights?' Support their ideas by sharing some examples of advocacy messages relating to human rights (see below).

Option B (approx. 120 minutes)

- 1 Explain the objective of the Section.
- 2 Divide the participants into small groups of about 5 people. Start by giving each group 10 minutes and asking them to discuss:
 - What are human rights?

- 3 Give the groups another 10 minutes and ask them to discuss:
 - What types of human rights are there? (An example might be 'the right to life' or 'the right to education')
- 4 Give the groups a further 10 minutes and ask them to discuss:
 - Who has human rights and who should protect them?
- 5 Bring all of the participants back together. Go through each of the three questions and ask the groups to share their ideas.
- 6 Facilitate a discussion on:
 - What do we mean by health?
 - What is the right to health?
- 7 Write the participants' ideas on a flipchart.
- 8 Divide the participants into the same small groups of about 5 people. Ask each group to discuss:
 - In your country what are the regional, national or international agreements and other instruments (such as policies and guidelines) that commit to:
 - Human rights (in general)?
 - The right to health (specifically)?
- 9 Bring all of the participants back together. Ask one of the small groups to present their work. Ask the other participants to share any additional information or ideas that were raised in their own groups.
- 10 Write a list on a flipchart of the country's agreements and instruments that commit to human rights and the right to health – as identified by the participants. If necessary, add to the participants' inputs (based on your own research for this Section).
- 11 Ask the participants to summarize the session by writing advocacy messages about 'What are human rights?' Support their ideas by sharing some examples of advocacy messages relating to human rights (see below).

ADVOCACY MESSAGES

- Human rights – such as the right to life, equality and non-discrimination – are not 'optional'. They are essential principles that all governments must respect and protect for all people, including people living with HIV (PLHIV) and people from key populations.
- Every human being has the right to health. This right is not just about having enough health facilities, services and products. It is also about ensuring that health facilities are accessible and of a high quality.
- All governments have made commitments to human rights, including those human rights related to health. Governments must promote and protect those rights, including the rights of PLHIV and members of key populations.

USEFUL RESOURCES

- *The Universal Declaration of Human Rights*, United Nations, 1948. Available here: <http://www.un.org/en/universal-declaration-human-rights/>
- *The Right to Health* (website page), World Health Organization, December 2015. Available here: <http://www.who.int/mediacentre/factsheets/fs323/en/>
- Fact Sheet No. 31: *The Right to Health*, World Health Organization and Office of the United Nations High Commissioner for Human Rights, 2008. Available here: http://www.who.int/hhr/activities/Right_to_Health_factsheet31.pdf
- Chapter 2: HIV, *Health and Human Rights in Health and Human Rights Resource Guide*, FXB Centre for Human Rights, Harvard School of Public Health, November 2013. Available here: <https://www.hhrguide.org/2014/03/05/471/>
- *HIV/AIDS & Human Rights in Southern Africa: An Advocacy Resource and Training Manual*, AIDS and Rights Alliance for Southern Africa, 2008. Available here: http://www.arasa.info/files/4813/9056/2374/arasa_training_manual_english.pdf
- *Handbook on HIV and Human Rights for National Human Rights Institutions*, OHCHR and UNAIDS, 2007. Available here: http://www.ohchr.org/Documents/Publications/HandbookHIV_NHRIsAug2007.pdf

What are human rights?

Human rights are values and principles that are essential to human dignity. They are laid out in law and protected by law. Human rights are universal. This means that they apply equally and to everyone – regardless of a person's sex, religion, social status, etc. Human rights have other common characteristics. They are:

- 1 Inherent – meaning that you are born with these rights because you are human; they are not granted to you by a person or authority.
- 2 Fundamental – meaning that without these rights, life and dignity would be meaningless.
- 3 Inalienable – meaning that they cannot be taken away, given away or denied.
- 4 Indivisible – meaning that they cannot be divided and are all equally important.
- 5 Interdependent – meaning that fulfilling one right cannot happen without fulfilling other human rights.

Who has human rights and who should protect them?

Important terms relating to human rights:

- Rights-holders: individuals or groups that have human rights.
- Duty-bearers: individuals or institutions that are responsible for ensuring that individuals or groups can claim their rights.
- The duty-bearers are government officials and bodies. Their role is to:

Respect human rights. They must not do anything that violates (abuses) the rights and freedoms of individuals or groups.

Protect human rights. They must prevent others from violating the rights and freedoms of individuals or groups.

Fulfill human rights. They must make it possible for all citizens to claim their rights and needs.

What types of human rights are there?

Human rights have been defined in a number of international agreements (also called commitments, conventions, covenants or treaties). The first of these agreements was the Universal Declaration of Human Rights, which was agreed by the United Nations in 1948. The Declaration listed a broad range of rights, such as:

- The right to equality and dignity
- The right to non-discrimination
- The right to life
- The right to health
- The right to privacy
- The right to marry and start a family
- The right to participation
- The right to education
- The right to freedom from arbitrary arrest or detention

The Declaration emphasized that all of these rights apply to all people “without distinction of any kind, such as race, color, sex, language, religion, political or other opinion, national or social origin, property, birth or other status”. Therefore, the rights clearly apply to PLHIV and members of key populations.

Since the Universal Declaration of Human Rights was drafted, countries have made more detailed or specific commitments to:

- Sets of human rights, such as through the International Covenant on Economic, Social and Cultural Rights (1966).
- Types of human rights violations, such as through the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (1984).
- The human rights of particular groups of people, such as through the Convention on the Rights of the Child (1989) and the Convention on the Elimination of All Forms of Discrimination against Women (1979).

How are human rights enforced?

All of the agreements listed above – and many other examples – are legally binding on the states that have committed to them. In other words, states that sign to these agreements are required by law to respect or protect the provisions laid out in them. For this reason, such international agreements are often reflected in regional agreements and/or national laws.

Human rights are also committed to in other types of instruments at the country, district or local level. Examples include guidelines, codes of conduct and sets of principles. These documents are not legally binding. However, they provide important tools to support and encourage action on human rights.

Ultimately, governments are responsible for enforcing human rights. However, many other individuals, institutions and sectors have an important role to play. Examples include the judiciary, the police, parliamentarians, local leaders and community members.

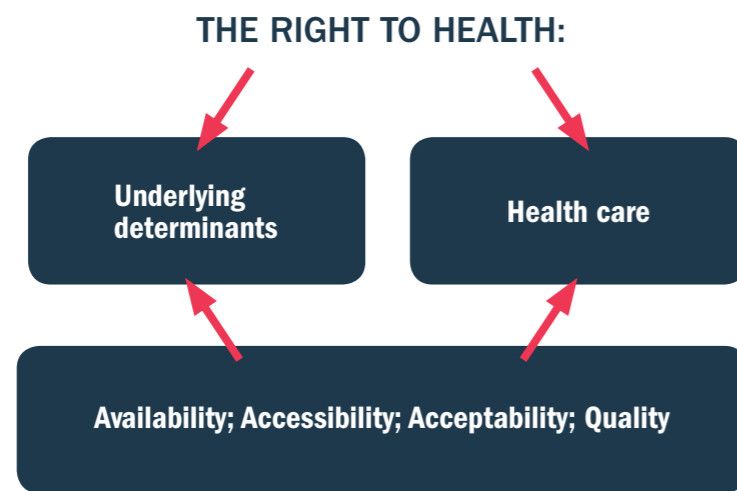
By 2014, every country in the world had agreed to at least one international agreement that addresses rights related to health.¹

The right to health is also specifically addressed in a number of regional agreements and national laws. For example, it is recognized in the Constitution of at least 115 countries.

What is the right to health?

The right to health was first formally described in the Constitution of the World Health Organization (WHO) in 1946. The WHO Constitution defined health as a state of “complete physical, mental and social well-being.”

In 2000, the definition of health was further clarified through a General Comment on the Right to Health by the United Nations Committee on Economic, Social and Cultural Rights. As shown in the diagram below, this definition emphasizes that the right to health is not only about providing healthcare; it is also about addressing the underlying determinants of health. The ‘underlying determinants’ of health are the factors – such as education, housing and nutrition – that affect the quality of people’s health.



As Also shown in the diagram, the General Comment states that the right to health requires a comprehensive (holistic) approach. A comprehensive approach involves attention in four areas:

- 1 Availability: Ensure that there are enough health facilities, services and commodities to serve the people in a specific area.
- 2 Accessibility: Ensure that the available health facilities, services and commodities are accessible to everyone. This means that they are:
 - Non-discriminatory (people can use them without fear of being treated badly).
 - Physically accessible (people can reach them).
 - Economically accessible (people can afford them).
 - Information accessible (people can get health information in a language and style that they can understand).

- 3 Acceptability: Ensure that all health facilities, services and commodities are respectful of medical ethics, local cultures and customs, and issues related to gender and age.
- 4 Quality: Ensure that all health facilities, services and commodities are of a high quality medically and scientifically speaking.

Importantly, the General Comment also states that in order to fulfill a person’s right to health, he or she must have access to:

- Prevention, treatment and control of diseases.
- Essential medicines.
- Maternal, child and reproductive health.
- Health-related education and information.
- Participation in health-related decision-making at national and community levels.

SECTION 4.2

How do human rights relate to access to treatment?

SECTION OBJECTIVE

To build community activists’ understanding of how human rights relate to access to treatment for PLHIV, including those from key populations

TRAINING MATERIALS

- PowerPoint presentation ‘4.2 How do human rights relate to access to treatment?’
- Brief profiles of local PLHIV, including some from key populations. These should provide key information about the person – such as his or her sex, age, location and economic situation. The profiles should not be of real people.

TRAINING OPTIONS

Option A (approx. 60 minutes)

- 1 Explain the objective of the Section.
- 2 Facilitate a discussion on:
 - Why do human rights matter for action on HIV?
- 3 Present PowerPoint presentation ‘4.2 How do human rights relate to access to treatment?’ Ask the participants if they have any questions about the presentation or additional points to raise.
- 4 Return to the PowerPoint slide that shows the table of human rights and examples of violations in relation to access to HIV treatment.
- 5 Facilitate a discussion on:
 - In your country, which international or national agreements, policies or laws should protect PLHIV – including those from key populations - against such violations of their rights in relation to access to treatment?

- 6 Ask the participants to summarize the session by developing advocacy messages about ‘How do human rights relate to access to treatment?’ Support their ideas by sharing some examples of advocacy messages (see below).

Option B (approx. 120 minutes)

For this activity, it is necessary to develop brief profiles of local PLHIV, including some from key populations

- 1 Explain the objective of the Section.
- 2 Divide the participants into discussion groups of 3 to 4 people. Ask each group to discuss:
 - Why do human rights matter for action on HIV?
- 3 Bring all of the participants back together and facilitate a discussion of the question.
- 4 Present PowerPoint presentation ‘4.2. How do human rights relate to access to treatment?’ Ask the participants if they have any questions about the presentation or additional points to raise.
- 5 Divide the participants into small groups of about 5 people. Give each group a different profile of a local person who is living with HIV.
- 6 Ask each group to think about their person and discuss the challenges that he or she might face in relation to access to HIV treatment.
- 7 Ask each group to identify whether their person might experience violations of their human rights in relation to access to treatment. Remind the groups that there are a broad range of human rights, such as the right to life, health, equality and participation.
- 8 Bring all of the participants back together. Ask one of the groups to present the key points from their discussions. Encourage the other participants to ask questions or make additional points.
- 9 Facilitate a discussion about:
 - In our country, which international agreements or national policies or laws should protect the rights of PLHIV to access treatment?
- 10 Is this protection any different for members of key populations living with HIV – such as sex workers, people who use drugs, and lesbian, gay, bisexual, transgender and intersex (LGBTI) people?
- 11 Ask the participants to summarize the session by developing advocacy messages about ‘How do human rights relate to access to treatment?’ Support their ideas by sharing some examples of advocacy messages (see below).

ADVOCACY MESSAGES

- Human rights and HIV are closely connected. Action to prevent the spread of HIV will not be effective without action to promote human rights.
- Every day, a wide range of human rights violations prevent PLHIV from accessing life-saving HIV treatment. The situation is especially serious for people from key populations.
- Governments have made formal commitments to addressing human rights in response to HIV. Such commitments are not optional. They must be fulfilled now for PLHIV to access life-saving treatment.

USEFUL RESOURCES

- *The Equity Deficit: Unequal and Unfair Access to HIV Treatment, Care and Support for Key Affected Communities*, Report by the NGO Delegation to the Programme Coordinating Board of UNAIDS, December 2013. Available here: http://files.unaids.org/en/media/unaids/contentassets/documents/pcb/2013/pcb33/agendaitems/presentations/1.4-NGO_report.pdf
- *HIV/AIDS & Human Rights in Southern Africa: An Advocacy Resource and Training Manual*, AIDS and Rights Alliance for Southern Africa, 2008. Available here: http://www.arasa.info/files/4813/9056/2374/arasa_training_manual_english.pdf
- *HIV and the Law: Risks, Rights & Health, Global Commission on HIV and the Law*, 2012. Available here: <http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf>

Why do human rights matter for action on HIV?

Human rights have been a vital part of the response to the fight against HIV since the HIV epidemic began over 30 years ago. The relationship between human rights and HIV is a two-way relationship:

- In areas where human rights are not respected or protected, HIV tends to spread more rapidly. For example, if a person’s right to non-discrimination is not protected, they may be more likely to take risks and become infected with HIV. They may also be less likely to have access to effective antiretroviral therapy (ART).
- The spread of HIV limits progress on human rights. For example, HIV epidemics are often accompanied by specific challenges – such as discriminatory or stigmatizing attitudes – that prevent people from realizing their human rights.

It has become increasingly clear, and widely agreed, that action on HIV will not be effective without action on human rights. This is especially the true for members of key populations who often have the greatest need for HIV prevention, treatment, care and support, but whose rights are often disrespected or violated.

What is a human rights-based approach to HIV?

Growing attention has been given to a ‘human rights-based approach’ to HIV. This is an approach that considers and addresses human rights at all levels and in all processes of action on HIV.

Some of the characteristics of a human rights-based approach include that it²

- Uses human rights as a framework.
- Addresses any policy or program’s impact on human rights.
- Makes human rights a key element of the design, implementation, monitoring and evaluation of policies and programs.

A human rights-based approach can be part of a response at all levels of action on HIV. For example, it can be part of community advocacy work or part of core national policies, such as the National AIDS Strategy.

Human rights and the WHO antiretroviral therapy (ART) guidelines

Human rights are central to all global initiatives on HIV treatment (as summarized in Module 3). For example, in the 2015 ART Guidelines, the WHO states that:

“Implementation of the guideline needs to be accompanied by efforts to promote and protect the human rights of people in need of HIV services, including by ensuring informed consent, preventing stigma and discrimination in the provision of services and promoting gender equity.”³

In the 2013 ART Guidelines, the WHO states that:

“Global and national commitments require providing HIV treatment and prevention to everyone in need, following the human rights principles of non-discrimination, accountability and participation Key ethical principles of fairness, equity and urgency should also be observed in the process of reviewing and adapting guidelines. The design of effective and equitable policies implies that strategies should focus comprehensively on addressing barriers to access testing, prevention and treatment services, particularly those faced by key populations.”⁴

Action on human rights is seen as a ‘critical enabler’ of investment approaches to HIV (described in Section 3.1). Investment approaches focus resources where they will make the biggest difference, as promoted by the United Nations Joint Program on AIDS (UNAIDS) and other agencies. Such approaches – and programs that actively address human rights, including in access to treatment - are increasingly welcomed by donor mechanisms. A key example is the New Funding Model of the Global Fund to Fight AIDS, Tuberculosis and Malaria.

What types of human rights are relevant to access to treatment?

Access to treatment for all PLHIV – including those from key populations – requires the full range of rights listed in the Universal Declaration of Human Rights. Access to treatment does not only involve the right to health. It also involves the right to:

- Privacy: For example, ART services that respect people’s confidentiality
- Non-discrimination: For example, key populations having access to the same quality of treatment counselling as others
- Participation: For example, involving PLHIV in decision-making about how treatment is managed and funded.

In practice, however, violations of human rights against PLHIV are still common. This presents a major barrier to access to treatment. The table below focuses on the same rights from the Universal Declaration that were listed in Section 4.1. It provides examples of how these rights are violated in the context of access to treatment for PLHIV, including those from key populations.

TABLE: Rights & HIV Treatment Violations

HUMAN RIGHT	EXAMPLES OF VIOLATIONS IN RELATION TO HIV TREATMENT
Right to equality and dignity	<ul style="list-style-type: none"> • PLHIV have to wait until all other patients have been seen at a clinic before they are given their Antiretroviral drugs (ARVs). • Members of key populations with HIV receive poorer quality ART services than other PLHIV.
Right to non-discrimination	<ul style="list-style-type: none"> • PLHIV who seek treatment experience judgmental attitudes by health care providers at ART services. • Members of key populations, such as people who use drugs, are denied ART because they are assumed to be ‘unreliable patients’.
Right to life	<ul style="list-style-type: none"> • PLHIV who are eligible for treatment are denied ART. • Key populations face multiple, routine barriers to all health care – resulting in those living with HIV not being able to access treatment until they are seriously ill.
Right to health	<ul style="list-style-type: none"> • PLHIV are denied treatment for life-threatening opportunistic infections, such as TB. • PLHIV are denied access to affordable, life-saving medicines due to their government’s patent laws or trade agreements.
Right to privacy	<ul style="list-style-type: none"> • PLHIV have their confidentiality breached (violated), for example by ART counsellors. • Young PLHIV cannot access ART services without permission from their parents.
Right to marry and found a family	<ul style="list-style-type: none"> • Women living with HIV are forcibly sterilized (in other words, made unable to have children), rather than offered a range of HIV prevention and treatment options. • Women living with HIV are given a minimal package for prevention of mother-to-child transmission (PMTCT) that only provides them with treatment until after birth.
Right to participation	<ul style="list-style-type: none"> • PLHIV are not asked their opinions about the quality and effectiveness of treatment services. • PLHIV, including those from key populations, cannot influence decision-making on treatment, such as decisions made by district health services.
Right to education	<ul style="list-style-type: none"> • PLHIV are not given enough information about treatment to make good decisions about which treatment options to take. • PLHIV are not given opportunities to ask questions about the side effects of different treatment options.
Right to freedom from arbitrary arrest and detention	<ul style="list-style-type: none"> • Key populations that are criminalized - such as sex workers - fear recognition and arrest at health facilities and do not access ART services. • Key populations, such as people who use drugs, experience imprisonment which stops their access to treatment.

As seen above, some violations relating to access to treatment are due to a lack of action to promote and protect human rights. Other violations are the result of harsh measures by governments, such as laws that criminalize and punish key populations.

The relationship between human rights and HIV treatment is constantly changing. For example, new developments – such as treatment as prevention (described in Section 1.2) – raise important ethical questions about the right to ART for PLHIV ‘versus’ the right to ART for people who are at risk of HIV, but who are not currently infected.

How are human rights addressed in HIV commitments?

As seen in Section 4.1, all countries are committed to at least one international agreement that addresses rights related to health.

Countries have also made specific commitments to address human rights within their approach to fighting HIV. For example, the Political Declaration on HIV and AIDS, which was agreed by the United Nations in 2011, specifically addresses human rights, including in relation to access to treatment.

COMMITMENTS TO HUMAN RIGHTS IN THE POLITICAL DECLARATION ON HIV AND AIDS (2011)⁵

Article 32: Recognize that access to safe, effective, affordable, good quality medicines and commodities in the context of epidemics such as HIV is fundamental to the full realization of the right of everyone to enjoy the highest attainable standard of physical and mental health.

Article 38: Reaffirm the commitment to fulfill obligations to promote universal respect for and the observance and protection of all human rights and fundamental freedoms for all in accordance with the Charter, the Universal Declaration of Human Rights and other instruments relating to human rights and international law; and emphasize the importance of cultural, ethical and religious values, the vital role of the family and the community and, in particular, of people living with and affected by HIV, including their families, and the need to take into account the particularities of each country in sustaining national HIV and AIDS responses, reaching all people living with HIV, delivering HIV prevention, treatment, care and support and strengthening health systems, in particular primary health care.

Article 39 Reaffirm that the full realization of all human rights and fundamental freedoms for all is an essential element in the global response to the HIV epidemic, including in the areas of prevention, treatment, care and support, recognize that addressing stigma and discrimination against people living with, presumed to be living with or affected by HIV, including their families, is also a critical element in combating the global HIV epidemic, and recognize also the need, as appropriate, to strengthen national policies and legislation to address such stigma and discrimination.

Commitments to human rights – including in relation to access to treatment – can also be found in many key national policies on HIV. For example, human rights are often a guiding principle of a country's National AIDS Strategy. Also, many countries have a Bill of Rights (a formal declaration of the right to equality, human dignity, life etc.) that is enshrined in their Constitution.

Similarly, commitments can be found in important regional policies. For example, the Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infections Diseases (2010) commits members of the Organization of African Unity to respect human rights, including the rights of PLHIV.

Global and national commitments are supported by a growing amount of evidence about why human rights matter and why further action must be taken to promote and protect human rights. For example, the Global Commission on HIV and the Law published a groundbreaking report in 2012.⁶ This report provides evidence and recommendations about a range of issues related to human rights and access to treatment. Examples include discrimination, criminalization of HIV transmission, and intellectual property. The report also contains specific sections on the rights of key populations. It is an important advocacy tool.

SECTION 4.3

Advocacy for human rights and access to treatment

SECTION OBJECTIVE

To build community activists' understanding of the entry points and 'what works' for advocacy on human rights and treatment.

TRAINING MATERIALS

- PowerPoint presentation '4.3 Advocacy for human rights and access to treatment'

TRAINING OPTIONS

Option A (approx. 60 minutes)

- 1 Explain the objective of the Section.
- 2 Ask the participants to think about the human rights and treatment issues that have been addressed in Sections 4.1 and 4.2. Ask them to identify some examples of entry points for advocacy. Explain that an entry point is an opportunity to 'get started.' An entry point for advocacy might, for example, be a process that provides an opportunity to influence decision-making, or a crisis that provides an opportunity to achieve urgent change.
- 3 Present PowerPoint presentation '4.3 Advocacy for human rights and access to treatment'
- 4 Ask the participants to share other lessons learned about advocacy on human rights and treatment – based on their own experiences.
- 5 Summarize what has been discussed and agreed during the session.

Option B (approx. 120 minutes)

- 1 Explain the objective of the Section.
- 2 Explain what is meant by an entry point for advocacy on human rights and treatment – in terms of an opportunity to 'get started.' For example, an entry point might be a process that provides an opportunity to influence decision-making, or a crisis that provides an opportunity to achieve urgent change.
- 3 Divide the participants into groups of about 5 people. Ask the participants to identify 1 or 2 entry points for advocacy on human rights and treatment that relate to their community.
- 4 Bring all of the participants back together. Ask each group to present their examples of entry points. Encourage the other participants to ask questions and make comments.
- 5 Present PowerPoint presentation '4.3 Advocacy for human rights and access to treatment'
- 6 Ask the participants to think about what type of advocacy they could carry out for the entry points they have identified. Facilitate a discussion on:
 - What do we know about 'what works' in advocacy on human rights and treatment?
- 7 Encourage the participants to identify the lessons learned from their own experiences. Write their inputs on a flipchart.
- 8 Summarize what has been discussed and agreed during the session.

USEFUL RESOURCES

- *Key Programmes to Reduce Stigma and Discrimination and Increase Access to Justice in National HIV Responses: Guidance Note*, UNAIDS, 2012. Available here: http://www.unaids.org/sites/default/files/media_asset/Key_Human_Rights_Programmes_en_May2012_0.pdf
- *HIV and Human Rights: Good Practice Guide*, International HIV/AIDS Alliance and ARASA, 2014. Available here: http://www.arasa.info/files/1714/1215/9968/Alliance_GPG-HIV_and_human_rights.pdf

How can community activists protect the rights of people living with HIV?

Community activists can help to ensure that PLHIV do not face stigma and discrimination, and that the rights of PLHIV are protected. In 2012, UNAIDS suggested key programs or interventions that activists can implement in their communities in order to protect rights and promote universal access to health care services in the context of HIV, AIDS and TB.⁷ These programs can also help to reduce stigma and discrimination and to strengthen access to justice for people in HIV treatment programs.

Stigma and discrimination reduction programs:

These programs help to reduce stigma and discrimination against PLHIV by addressing the causes of stigma. Research has shown that the causes of stigma include ignorance about the harm of stigma, irrational and misguided fears about becoming infected with HIV, and moral judgments against PLHIV.⁸

Stigma training in practice:

In Zambia, Alliance Zambia's Regional Stigma Training Program integrates stigma and discrimination reduction within existing HIV programs. Training addresses key factors that drive stigma, including a lack of understanding of stigma and discrimination; misguided fears of becoming infected with HIV, and attitudes that link HIV with 'immoral' behaviour. Participatory exercises can be used to build participant's empathy and understanding, and prevent stigma and discrimination against PLHIV.⁹

Legal support services:

Legal support services involves providing services such as legal information/education, legal advice, and legal representation. Legal support services ensure that PLHIV have access to justice when their rights have been violated, for example if:¹⁰

- Healthcare workers disclose their HIV status, ignoring their right to privacy
- They are discriminated against by employers or potential employers due to their HIV status
- They are denied access to education or social services due to their HIV status

Legal support services in practice:

In 2001, the Treatment Action Campaign (TAC) and the AIDS Law Project took legal action against the South African minister of health for failing to roll-out antiretrovirals in national prevention of parent-to-child transmission (PPTCT) programs.¹¹ The judge ruled in favor of TAC and ordered the Department of Health to make Nevirapine available in all public hospitals and clinics. The victory demonstrates that legal action is an important advocacy mechanism.

Legal literacy:

Legal literacy programs, such as 'Know Your Rights' campaigns, teach PLHIV about their rights, and the national and international laws that protect their rights. This increases access to justice for PLHIV by making sure PLHIV know when and how their rights are being violated. Legal literacy programs can form part of other HIV services, such as information and education campaigns and peer support groups.¹²

Legal literacy in practice:

In South Africa, the South African National AIDS Council (SANAC) has partnered with Legal Aid South Africa to develop a Legal Advice Helpline for people with HIV and TB. The Helpline will give people information about their rights. It will also refer them to legal support services in cases where their human rights have been violated.

Monitoring and law review and reform:

Laws, regulations and policies relating to HIV affect the lives of PLHIV. For this reason, it is essential to monitor laws, regulations and policies so they support access to HIV and other health services.¹³ Community activists play an important role in reviewing laws, monitoring their enforcement, and campaigning for laws to be changed. This helps to ensure that the legal environment is protective of the rights of PLHIV.

Law review and reform in practice:

In Mozambique, an HIV law was developed in 2009 that had many protective provisions. But it also criminalized HIV transmission. In 2013, a process was started to review and reform this law. The law was reviewed by civil society organizations working in partnership with UN agencies, parliamentarians and academics. The amended law was finally passed by Parliament to exclude the provision that criminalized HIV transmission.

Sensitizing law makers and law enforcement officials:

Sensitizing law-makers (such as parliamentarians), law-enforcers (such as Ministers of Justice, police, prosecutors, judges, lawyers, and religious leaders) and service providers (such as healthcare workers and teachers) involves making sure they are aware of how their policies and behaviors impact the lives of PLHIV, and the importance of appropriate laws to the HIV response.¹⁴ This helps to ensure that the rights of PLHIV are respected when they access treatment and care, and that new policies are sensitive to the rights and needs of PLHIV.

Sensitizing officials in practice:

In Nairobi in 2013, 43 law enforcement officers from Kenya, Lesotho, Malawi, Swaziland, Tanzania and Zambia participated in a regional capacity building workshop on HIV and the law. Participants discussed the status of the HIV epidemic in Eastern and Southern Africa; stigma and discrimination and its role in HIV prevention and treatment among law enforcement officers; human rights and the law etc. At the end of the workshop, the officials developed country action plans that sought to strengthen HIV workplace programs, and create and enable legal environments that minimize human rights violations.

Training for health care workers:

Training programs for healthcare workers improves healthcare workers' knowledge of their own rights and the rights of their patients. This helps to reduce stigmatizing attitudes in healthcare facilities and to provide healthcare workers providers with the skills they need to ensure patients' rights to informed consent, confidentiality, appropriate treatment and non-discrimination.¹⁵ It also helps them to gain a better understanding of the needs and experiences of PLHIV.

Training in practice:

In Southern and East Africa, health care worker training programs often include: training on HIV, TB and human rights; discussions between health care workers and PLHIV and key populations to discuss the impact of discrimination on people's rights; training for health administrators on the rights of health care workers with HIV.

What are entry points for advocacy on human rights and treatment?

For community activists, there are many different entry points that can be used for advocacy on human rights and treatment. An entry point is an opportunity to 'get involved,' 'get going' and 'make a difference.' It is an opportunity to start discussions, influence opinions and achieve change. As explained above, an entry point might be a process (that provides an opportunity to influence decision-making) or a crisis (that provides an opportunity to achieve urgent change). See the table below for examples of entry points that can be seen in the experiences of ITPC partners and other organizations throughout the world.

TABLE Examples of entry points for advocacy on human rights and treatment

EXAMPLES OF ENTRY POINTS	EXAMPLES OF ADVOCACY ACTIONS
<p>Health workers at a government Health Centre discriminate against PLHIV by making them wait until last for their treatment</p> <p>(For example, denying the right to life of PLHIV)</p>	<p>Gathering evidence of the discrimination carried out by the health workers against PLHIV.</p> <p>Gathering information about relevant national laws and local policies that state people's rights to equality, health and life.</p> <p>Asking for a meeting between PLHIV and the manager of the Health Centre.</p> <p>Using your evidence and information to advocate for changes to the practices of health workers.</p>
<p>People who use drugs – who are criminalized in the country - refuse to access ART services due to fear of arrest and imprisonment</p> <p>(For example, denying the right to freedom from arbitrary arrest or detention for PLHIV)</p>	<p>Gathering evidence of the fears and concerns of the people who use drugs.</p> <p>Holding briefings with the local Police Chief and Health Director to explain the problem and how it denies people their right to health. Working together to identify a practical solution - such as the police 'allowing' people who use drugs to access ART services.</p> <p>Providing feedback to the sex workers and people who use drugs and encouraging them to access ART services and monitor the implementation of the agreement.</p>
<p>Women living with HIV are only offered ART if they take specific action – such as being sterilized or terminating their pregnancy.</p> <p>(For example, denying women the right to marry and found a family)</p>	<p>Gathering evidence of the scale and nature of the denial of treatment for women living with HIV.</p> <p>Partnering with human rights, women's and HIV organizations to hold a demonstration outside the Local Government Office – highlighting that denying treatment is denying women's human rights (to health, life and to marry and found a family).</p> <p>Using the demonstration to get media attention on the issue and providing a platform for women living with HIV to advocate for their needs, where they are happy to speak publicly</p>

<p>The District Health Authority is carrying out a Mid-Term Review of the principles, services and budget for HIV treatment.</p> <p>(For example, presenting an opportunity to use a human rights-based approach)</p>	<p>Making a formal request to the District Health Authority to have community representatives – including from key populations - involved in the Mid-Term Review process.</p> <p>Gathering evidence of 'what's working' and 'what's not working' in relation to a human rights-based approach to HIV treatment – including for PLHIV in the District, including those from key populations.</p> <p>Using the evidence to advocate for stronger principles, services and budget allocations to HIV treatment services that, for example, are equitable, confidential and non-discriminatory.</p>
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What works in advocacy on human rights and treatment?

Many lessons have been learned – including by ITPC's partners - about 'what works' in advocacy on human rights and treatment. See the examples below that apply to different contexts:

DO YOUR HOMEWORK

- For example, if you are advocating on the lack of confidentiality in ART services for PLHIV, it is important to gather and document evidence – such as examples of where and when this has taken place and how many people have been affected.

ADDRESS BOTH RIGHTS-HOLDERS AND DUTY-BEARERS

- For example, if you are advocating for a new law to protect the rights of all PLHIV to access treatment, it is vital to also advocate for who should have responsibility for applying this law.

USE A RANGE OF ACTIVITIES AND MESSAGES

- For example, if you are advocating on the denial of ART to PLHIV, it may be effective to use direct methods (such as demonstrations) with some targets and indirect methods (such as briefing papers) with others. It might also be effective to use 'rights' messages with some stakeholders and 'public health' messages with others.

USE INTERNATIONAL AND NATIONAL COMMITMENTS

- For example, even where a government criminalizes key populations, arguing that the government has to protect the right to life and health of those living with HIV because they have formally committed to do so.

USE HUMAN RIGHTS EXPERTISE

- For example, partnering with a legal company or human rights organization to bring knowledge and experience to your advocacy work of how to understand the human rights system properly in order to achieve change.

PROTECT PEOPLE'S CONFIDENTIALITY

- For example, while PLHIV should be supported to participate in all stages of advocacy, they should not be forced to disclose their identity or status during advocacy action.

'PUSH' THE LEGAL SYSTEM THROUGH LITIGATION

- For example, 'testing' laws and their protection of human rights, such as by taking the government to court for denying access to ART for PLHIV. This can bring about changes in the legal system, as well as important publicity.

Endnotes

- 1 *Fact Sheet No. 31: The Right to Health*, World Health Organization and Office of the United Nations High Commissioner for Human Rights, 2008. http://www.who.int/hhr/activities/Right_to_Health_factsheet31.pdf
- 2 Adapted from: *HIV/AIDS & Human Rights in Southern Africa: An Advocacy Resource and Training Manual*, AIDS and Rights Alliance for Southern Africa, 2008. http://www.arasa.info/files/4813/9056/2374/arasa_training_manual_english.pdf
- 3 *Guideline on when to Start Antiretroviral Therapy and on Pre-Exposure Prophylaxis for HIV*, World Health Organization, 2015. http://apps.who.int/iris/bitstream/10665/186275/1/9789241509565_eng.pdf
- 4 *Consolidated Guidelines on the use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach*, World Health Organization, 2013. http://apps.who.int/iris/bitstream/10665/85321/1/9789241505727_eng.pdf
- 5 *Political Declaration on HIV and AIDS: Intensifying Our Efforts to Eliminate HIV and AIDS*, United Nations General Assembly, 2011. http://www.unaids.org/sites/default/files/sub_landing/files/20110610_UN_A-RES-65-277_en.pdf
- 6 *HIV and the Law: Risks, Rights & Health*, Global Commission on HIV and the Law, 2012. <http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf>
- 7 *Guidance Note: Key Programmes to Reduce Stigma and Discrimination and Increase Access to Justice in National HIV Responses*, UNAIDS, 2012. http://www.unaids.org/sites/default/files/media_asset/Key_Human_Rights_Programmes_en_May2012_0.pdf
- 8 *Guidance Note: Key Programmes to Reduce Stigma and Discrimination and Increase Access to Justice in National HIV Responses*, UNAIDS, 2012. http://www.unaids.org/sites/default/files/media_asset/Key_Human_Rights_Programmes_en_May2012_0.pdf
- 9 *HIV and Human Rights: Good Practice Guide*, International HIV/AIDS Alliance and ARASA, 2014. http://www.arasa.info/files/1714/1215/9968/Alliance_GPG-HIV_and_human_rights.pdf
- 10 *Guidance Note: Key Programmes to Reduce Stigma and Discrimination and Increase Access to Justice in National HIV Responses*, UNAIDS, 2012. http://www.unaids.org/sites/default/files/media_asset/Key_Human_Rights_Programmes_en_May2012_0.pdf
- 11 *HIV and Human Rights: Good Practice Guide, International HIV/AIDS Alliance and ARASA*, 2014. http://www.arasa.info/files/1714/1215/9968/Alliance_GPG-HIV_and_human_rights.pdf
- 12 *Guidance Note: Key Programmes to Reduce Stigma and Discrimination and Increase Access to Justice in National HIV Responses*, UNAIDS, 2012. http://www.unaids.org/sites/default/files/media_asset/Key_Human_Rights_Programmes_en_May2012_0.pdf
- 13 *Guidance Note: Key Programmes to Reduce Stigma and Discrimination and Increase Access to Justice in National HIV Responses*, UNAIDS, 2012. http://www.unaids.org/sites/default/files/media_asset/Key_Human_Rights_Programmes_en_May2012_0.pdf
- 14 *Guidance Note: Key Programmes to Reduce Stigma and Discrimination and Increase Access to Justice in National HIV Responses*, UNAIDS, 2012. http://www.unaids.org/sites/default/files/media_asset/Key_Human_Rights_Programmes_en_May2012_0.pdf
- 15 *Guidance Note: Key Programmes to Reduce Stigma and Discrimination and Increase Access to Justice in National HIV Responses*, UNAIDS, 2012. http://www.unaids.org/sites/default/files/media_asset/Key_Human_Rights_Programmes_en_May2012_0.pdf

5 TRADE AND HIV TREATMENT

Welcome to **Module 5: Trade and HIV Treatment** of the Advocacy for Community Treatment (ACT) Toolkit of the International Treatment Preparedness Coalition (ITPC).

Module 5 focuses on trade and how it affects access to HIV treatment.

INTRODUCTION

THE SCIENCE OF HIV

HIV CO-MORBIDITIES

HIV TREATMENT INITIATIVES

HUMAN RIGHTS AND HIV

TRADE AND HIV TREATMENT

FINANCING AND HIV TREATMENT

COMMUNITY ADVOCACY PLANNING

ACT CASE STUDIES

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3

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5

6

7

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Section 5.1. What are patents and intellectual property?

SECTION OBJECTIVE

To build community activists' understanding of what patents and intellectual property (IP) are and why they matter for access to HIV treatment.

TRAINING MATERIALS

PowerPoint presentation '5.1 What are patents and intellectual property?'

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objective of the section.
2. Divide the participants into 'buzz groups' of 2-3 people. Ask each group to discuss:
 - What is intellectual property?
 - What is a patent?
3. Ask the participants to write down questions they might have about intellectual property and patents. If the participants do not know what intellectual property and patents are, ask them to this down as a question.
4. Present PowerPoint presentation '5.1 What are patents and Intellectual Property?' Check-in with the participants about whether the presentation has answered any questions that they wrote down.
5. Ask the participants to share any examples they know of that show how issues relating to patents and intellectual property affect access to HIV treatment. Ask them, in particular, to share examples of where advocacy has helped to overcome such barriers.
6. Ask the participants to summarize the session by developing advocacy messages about "What are patents and intellectual property?" Support their ideas by sharing examples of messages (see below).

Option B (approx. 120 minutes)

1. Explain the objective of the section.
2. Divide the participants into 'buzz groups' of 2-3 people. Ask each group to discuss:
 - What is intellectual property?
 - What is a patent?
3. Ask the participants to write down questions they might have about intellectual property and patents. If the participants do not know what intellectual property and patents are, ask them to this down as a question.
4. Present PowerPoint presentation '5.1 What are patents and Intellectual Property?' Check-in with the participants about whether the presentation has answered any questions that they wrote down.
5. Divide the participants into 'buss groups' of 2-3 people again. Ask each group to discuss:
 - Who or what is intellectual property designed to protect?
 - What are the possible negative consequences of intellectual property and patents?

- Who might these negative consequences affect?
 - Examples of issues relating to patents and intellectual property and their affect on access to HIV treatment
 - Examples of where advocacy has been used to tackle issues relating to intellectual property, patents, and access to HIV treatment.
6. Altogether, ask the participants to report back on their groups discussions. Ask them in particular to share their thoughts on intellectual property and patents as they relate to HIV treatment.
 7. Ask the participants to summarize the session by developing advocacy messages about 'What are patents and intellectual property?' Support their ideas by sharing examples of messages (see below).

ADVOCACY MESSAGES

1. Patents – such as for HIV drugs - should be for the 'public good.' The people and companies that create inventions have the right to benefit from them, but not at the expense of the human rights of others.
2. Generic medicines are central to ensuring all people living with HIV have access to affordable and high quality medicines. Patents and other systems that protect intellectual property should not be a barrier to their benefits.

USEFUL RESOURCES

- *Access Campaign*, Médecins Sans Frontières. Available here: <http://www.msfacecess.org/>
- *Access Challenges for HIV Treatment among People Living with HIV and Key Populations in Middle-Income Countries*: Policy Brief, GNP+, NSWP, INPUD, MSMGF and ITPC, 2013. Available here: http://www.gnpplus.net/assets/Access_Challenges_for_HIV_treatment_among_PLHIV_and_KAPs_in_MICs_Policy_brief-copy.pdf
- *Lives on the Edge: Time to Align Medical Research and Development with People's Health Needs*, Médecins Sans Frontières, 2016. Available here: http://www.msfacecess.org/sites/default/files/MSF_assets/Innovation/Docs/R&D_report_LivesOnTheEdge_ENG_2016.pdf
- Gagnon, M A and Lexchin, J. *The cost of pushing pills: A new estimate of pharmaceutical promotion in expenditures in the United States*. Plos Medicines (2008), 5(1):29-33
- *Untangling the Web of Antiretroviral Price Reductions*: 17th Edition. Médecins Sans Frontières. 2014. Available here: https://www.msfacecess.org/sites/default/files/MSF_UTW_17th_Edition_4_b.pdf

What is intellectual property?

Intellectual property refers to work or inventions that are the creation of people's minds. Examples include inventions, songs, or a new medicine. The creations are 'property' because they are produced at a cost and have a commercial value.

Intellectual Property Rights (IPRs) are the legal rights of the owner of IP. They are exclusive – meaning that they can only be used by that person. Others cannot use the creation without permission or payment.

There are different types of Intellectual property rights: Copyright, Trademark, Patents and Industrial design. The type of IPRs that are most relevant to HIV treatment are patents and trademarks. Intellectual property rights are typically granted by a state's national institutions (e.g. a patent office), are only valid in the country in which they are granted, and are only valid for a limited period of time. However, some countries have opted for regional patent offices for example the African Intellectual Property Organization known as OAPI that serve as patent office for 17 countries in west and central Africa (Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Côte d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Union of the Comoros and Togo).

What is a patent?

A patent is an exclusive right granted to the inventor of a product or a process that prevent other people from making, using, selling, offering to sell, or importing the invention without authorization of the patent holder for a limited period of time. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement) rules require countries to protect medicines with patents like they would for any other invention. Patents on medicines can be granted for the product or for the process of production. Under TRIPS, protection through a patent is effective for a period of twenty years. In order for a patent to be granted, the invention must satisfy certain criteria, known as ‘patentability criteria’ (for more information, please see Section 5.3).

Patents are given through Patent Offices at the national level or regional level by governments and intergovernmental organizations. There is no such thing as a global patent. Each country can decide which criteria it uses for giving and using patents. This means that, for example, a drug that is patented in one country may or may not be patented in another.

In theory, the patent system is supposed to balance private rights of the patent holders and the public interest. The reason for granting patents is that they benefit society by encouraging inventors to disclose their research to the public and to give the public access to new products or technologies. In exchange, the inventor is rewarded for this disclosure. However, in the health sector, patents have allowed the companies that manufacture and sell drugs to create monopolies. A company or individual is a monopoly if they alone control the supply and trade of a certain commodity, in this case drugs. When a single company monopolizes the supply and distribution of a certain drug, this drives prices up and reduces availability. This means that in the health sector, patents have had a negative influence, leading to higher prices and reduced availability of many drugs.

Patents are supposed to protect genuine innovation. However, in many cases, companies apply for new patents to protect existing drugs, often with only minor modifications – this is known as ‘evergreening’. Companies might also apply for a new patent when a drug is shown to be effective to treat a different disease than the one the medicine was initially registered for.

For example, the first ever medicine to treat HIV, Zidovudine (AZT), was originally registered as a treatment for cancer but once it became clear that it would also be an effective HIV treatment, a new patent was registered in the late 1980s, even though the drug was developed in the 1960s. It is these kinds of practices that indefinitely extend the patent protection period, which allows patents to become a real obstacle to access for medicines for those most in need. This often creates unsustainable cost burdens in the country of the patent as well as for national governments in other countries due to Free Trade Agreements (which will be discussed later).

Very often, multinational pharmaceutical companies argue that the key barrier to access to medicines is not patents, but the weak health systems in developing countries, ‘as well as a lack’ of infrastructure to produce high quality medicines. But this argument ignores how consumers get medicines in developing countries – not always from public distributors, but often using their own money to pay for medicines directly. This may be because medicines are not available through the public sector, or even if they are, the public health system might experience stock outs, or the drugs might be inaccessible for other reasons.

Another argument used by pharmaceutical companies is that strong protection of IPRs is an incentive for research and development (R&D) for new medicines. In general, patents are most effective at attracting investment in products that have commercial prospects, leaving important gaps where R&D is the most commercially risky. The diseases and conditions that affect people in the world’s major markets largely determine where the pharmaceutical industry’s investments go. Of the 1,393 new chemical entities developed globally between 1975 and 1999, only 16 were for the treatment of tropical diseases and tuberculosis, which primarily affect people in developing countries. The Global Forum for Health Research notes that only 10% of global R&D spending is directed to the health problems that account for 90% of the global disease burden: the so-called 10/90 gap.

It is also important to put the profits generated by commercial companies into perspective, noting that much of this profit is used to market drugs in ‘profitable markets.’ For example, one study from 2008 (highlighted in the Useful Resources section) analyzed the United States of America’s pharmaceutical market and concluded that pharmaceutical company’s spending on marketing is almost twice their spending on R&D.

In practice patents can create monopolies. This is because they give all the power to one individual or company. In the case of HIV drugs and diagnostics, they can lead to less competition, higher prices and reduced availability.

What is a trademark?

A trademark is a sign (like a word or a symbol) that is used to distinguish the goods or services of one person or company from another’s. Often, a company will put a small ‘TM’ next to the name or symbol that it has trademarked.

The same drug – such as for HIV treatment – can be sold by different companies using different trademarks.

What are the different types of medicines?

There are two different types of medicines:

1. ORIGINATOR/INNOVATOR/BRANDED MEDICINE

This is the first version of a medicine developed by a company after it has been authorized for marketing worldwide. It has met the standards for efficacy, safety and quality, according to requirements at the time of authorization. It is also known as an ‘originator medicine.’ It is usually a patented product and has a brand name (although this might vary between countries). A branded medicine is often more expensive than other options.

2. GENERIC MEDICINE

This medicine is a pharmaceutical product that is the same as a brand/reference listed drug product in every way, including: dosage form, strength, route of administration, quality and performance characteristics, and intended use. A generic medicine is interchangeable with the originator brand product, and may be manufactured with or without a license from the originator manufacturer. This category includes pharmaceuticals whose patents or other exclusivity rights have expired, pharmaceuticals that have never been patented, and copies of patented pharmaceuticals in countries where the drug is not patented or where a compulsory license (CL) has been granted. These medicines are identical to the innovator product, but mostly cost significantly less. Generic medicines are made by companies that do not hold the patent for them. The generic market is highly price competitive because buyers can choose among several sources of chemically identical medicines.

Often we also hear the term ‘counterfeit’ or ‘counterfeit medicines.’ It is important to understand what this term means because it is often incorrectly used in the context of generic medicines: generic medicines have nothing to do with counterfeit medicines.

Counterfeits: WHO defines counterfeit medicines as a pharmaceutical product whose origin and/or identity specifications have been deliberately and fraudulently modified, regardless of whether it is a pharmaceutical product protected by a patent or whether it concerns a generic drug. This commonly accepted meaning falls within the broader concept of substandard medicines.

Counterfeit medicines may be:

- Products containing the same active ingredients and the same excipients of the original pharmaceutical agent, correctly packaged and labeled, but illegally imported into a country.
- Products containing the same ingredients of the genuine medicine, with genuine packaging, but containing incorrect amounts of ingredients.
- Products that – despite being identical from an external point of view and having genuine packaging – do not contain any active ingredients.
- Products externally similar to original products with genuine packaging, but containing harmful substances instead of the same active ingredients.
- Products with counterfeit packaging and correct amounts of active ingredients.
- Products with counterfeit packaging, but with different amounts of active ingredients.
- Products with counterfeit packaging that contains a different active ingredient.
- Products with counterfeit packaging that do not contain active ingredients.

EXAMPLE OF HOW ANTI-COUNTERFEIT LAWS THREATEN ACCESS TO MEDICINE:

In Kenya, an anti-counterfeit law was proposed in 2008. Although the law intended to combat counterfeit drugs, there were significant problems with the legislation, which failed to categorically distinguish between counterfeit and generic drugs. As a result, the legislation would have negatively impacted the importation and production of generic drugs, affecting people living with HIV and others.

To fight the legislation, a civil society coalition, including the International Treatment Preparedness Coalition (ITPC) Eastern Africa, took the Kenyan government to court for drafting ambiguous legislation that made dealing with substandard drugs even more difficult by widening the scope to include generic medicines. The petitioners sought to have the Anti-Counterfeit Act 2008 declared unconstitutional, on the grounds that it infringed on their right to health. In court, the judge ruled in favor of the civil society coalition and against the Kenya Anti-Counterfeit Act 2008. In her ruling, the judge said that the Anti-Counterfeit Act was more concerned with seeking extra-territorial enforcement of IPRs at the expense of access to medicines. The decision in this case was a landmark – it was the first legal challenge in Africa against a new push for anti-counterfeit legislation that is widely expected to also appear in other East African countries.

Section 5.2. Why does trade matter to HIV treatment?

SECTION OBJECTIVE

To build community activists' understanding of why trade matters to access to HIV treatment, the role of the World Trade Organization and the impact of Free Trade Agreements on access to medicines.

TRAINING MATERIALS

PowerPoint presentation '5.2 Why does trade matter to HIV treatment?'

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objective of the Section.
2. Facilitate a group discussion on:
 - Why does trade matter to HIV treatment?
3. Encourage the participants to share their experiences – or stories that they have heard – about how issues related to trade can make access to HIV treatment better or worse.
4. Present PowerPoint presentation '5.2 Why does trade matter to HIV treatment?'
5. Check if the participants have further points or questions about the subject.
6. Ask the participants to summarize the session by developing advocacy messages about 'Why does trade matter to HIV treatment?' Support their ideas by sharing examples of messages (see below).

Option B (approx. 120 minutes)

1. Explain the objective of the Section.
2. Present PowerPoint presentation '5.2 Why does trade matter to HIV treatment?'
3. Divide the participants into groups of 3 or 4 participants
 - Why does trade matter to HIV treatment?
 - Ask the participants to share any experiences they may have had, or stories they might have heard, related to issues around trade and access to HIV treatment.
 - Encourage the groups to explore the trade-related causes of these issues.
5. Back in a big group, ask the participants to share an aspect of their group discussion.
6. Facilitate a group discussion on how different people might experience the impact of trade on their access to treatment differently. For example, someone with a lot of money might not be negatively affected by the influence of trade on access to medicines.
7. Once everyone has had a chance to share their thoughts with the group, ask the participants to summarize the session by developing advocacy messages about 'Why does trade matter to HIV treatment?' *Support their ideas using the advocacy messages below.*

ADVOCACY MESSAGES

- 1 Issues relating to trade can make a significant difference to whether community members living with HIV have access to HIV treatment and other essential medicines.
- 2 Trade issues not only affect how much medicines cost. They also affect their quality, availability and accessibility.
- 3 Fair trade – that is not restricted by agreements, and where there is healthy competition – is vital to ensuring access to life-saving HIV drugs and diagnostics for all.

USEFUL RESOURCES

- World Trade Organization (website). Available here: <http://www.wto.org/>
- *Access Challenges for HIV Treatment among People Living with HIV and Key Populations in Middle-Income Countries*: Policy Brief, GNP+, NSWIP, INPUD, MSMGF and ITPC, 2013. Available here: http://www.gnppplus.net/assets/Access_Challenges_for_HIV_treatment_among_PLHIV_and_KAPs_in_MICs_Policy_brief-copy.pdf
- *The Potential Impact of Free Trade Agreements (FTAs) on Public Health*, UNAIDS, 2012: http://www.unaids.org/sites/default/files/media_asset/JC2349_Issue_Brief_Free-Trade-Agreements_en_0.pdf
- *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, World Health Organization, 2013. Available here: http://www.who.int/phi/promoting_access_medical_innovation/en/
- WHO Director-General (Dr Margaret Chan) Addresses Symposium on Intellectual Property and Trade. World Health Organization, 2015. Available: <http://www.who.int/dg/speeches/2015/intellectual-property-trips/en/>
- Empty Gestures: The EU's Commitments to Safeguard Access to Medicines, Médecins Sans Frontières, 2015. Available here: http://www.msaccess.org/sites/default/files/Access_HAI-MSF-report_2015.pdf
- Decisions around HIV Treatment in 2015: Seven ways to Fail, Derail or Prevail, Médecins Sans Frontières, 2015. Available here: http://www.msaccess.org/sites/default/files/HIV_Brief_HIV_Fail_Derail_or_Prevail_ENG_2015.pdf

Why does trade matter to HIV treatment?

Trade refers to the buying and selling of goods and services. In this ACT Toolkit, it particularly refers to the buying and selling of:

- HIV-related drugs, such as antiretrovirals (ARVs) and medicines to prevent and treat opportunistic infections and co-infections (e.g. TB, Hepatitis C)
- HIV-related diagnostics, such as HIV tests and equipment for CD4 count tests and viral load tests
- Resistance tests

Trade matters to HIV treatment because it can affect:

- How much drugs and diagnostics cost
- The quality of drugs and diagnostics (because the quality of drugs and diagnostics provided by treatment programs is very often linked to affordability)
- Tests for HIV resistance
- Where and by whom drugs and diagnostics can be made
- Where and by whom drugs and diagnostics can be sold and distributed

For HIV treatment to be affordable it has to have the “right cost” – one that countries, health systems and people can afford. National, regional and global markets drive the cost of HIV drugs and diagnostics. These markets are in turn driven by trade. Trade that is fair and ethical is important to ensure access to HIV treatment for all people living with HIV. For example, ideally, markets should not be driven by monopolies – where only one company has control over the market of a particular product, and is therefore able to set a high price. Instead, there should be competition between drug manufacturers – as this can drive down the costs of medicines, while also increasing the quality of medicines.

The buying and selling of goods and services should take place in an environment that regulates trade and promotes ‘fair play.’ Without regulation, there is the risk of monopolies and other bad practices – which reduce people’s access to essential products, such as medicines.

The impact that market regulations and, in particular, intellectual property regulations can have on access to medicines is easily understood when we look at the incredible price reductions that occurred for ARVs through generic competition from 2003 onward. The cost of the first generation of first-line ARVs dropped by 99%, which led to a 20-fold increase of people living with HIV being on antiretroviral therapy since 2003.

Only 690 000 of the estimated 28.6 million of PLHIV received ART in 2000, but by mid-2015 this number had risen to 15.8 million people, thanks to the increase in generic medicines entering the market, and new sources of funding.¹

What is the World Trade Organization (WTO)?

The World Trade Organization (WTO) is an international body. It was set up to regulate trade between countries and to ensure fair trade. It started in 1994 and now has 155 member countries.

The WTO is based on agreements that are signed by all of its members. These legally bind the countries to take actions at a national level to support global trade. The agreements require governments to make changes in their laws and policies relating to trade in goods, services and IPRs (described in the Section 5.1). In terms of IPRs, WTO sets a minimum standard of protection for patents, copyright, trademark and industrial design in an agreement called TRIPS which stands for Agreement on Trade-Related Aspects of Intellectual Property Rights (described in the Section 5.3).

TRIPS is only one trade agreement among many, and all agreements are open to interpretation. In practice, some developed countries choose to interpret agreements in a way that protects their companies’ IP rights over the rights of developing countries to access medicines; these developed countries then use a range of strategies and tactics to enforce WTO Agreements.

For example, the United States of America and the European Union try to avoid multilateral negotiations over intellectual property issues, where developing countries can act as a block to resist or challenge IP claims, instead preferring bilateral or regional trade agreements. These enable certain countries to exploit unequal power relationships, link intellectual property with other trade issues, divide developing countries and create norms that can then be imposed on the rest of the world.

What is a Free Trade Agreement?

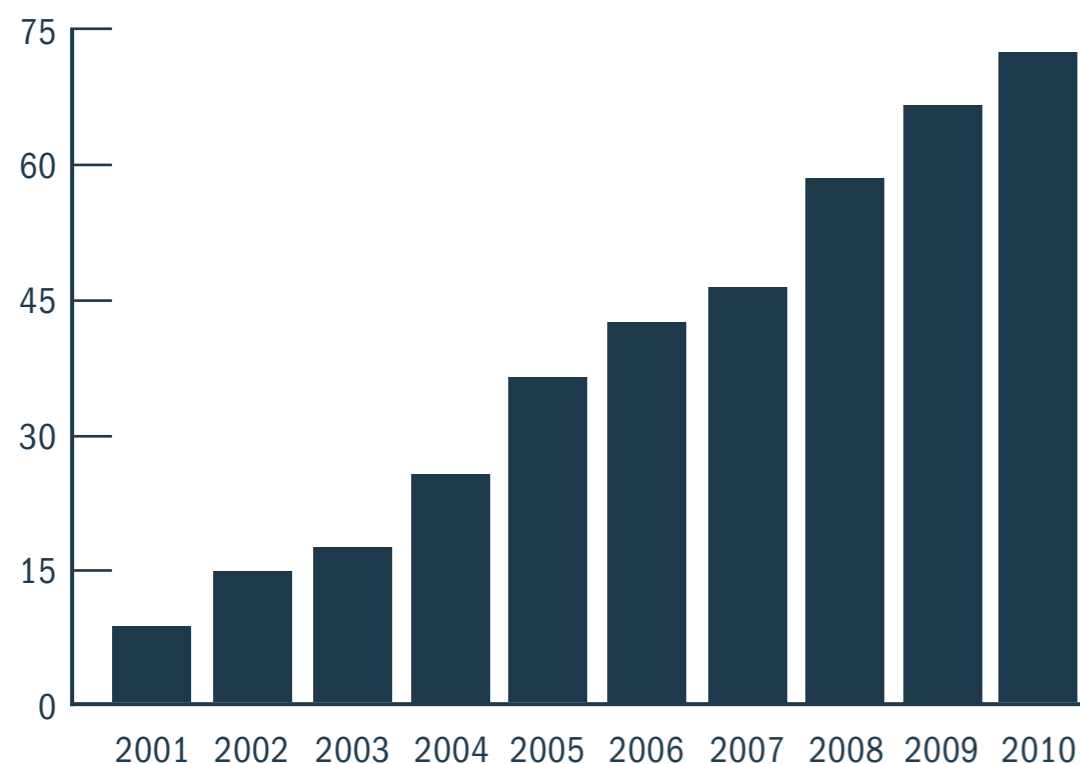
A Free Trade Agreement (FTA) can be negotiated between individual countries or blocs of countries in a region. It is an agreement through which the countries can trade goods and services between them without tariffs (taxes or duties) or other barriers. Developed governments typically propose FTAs to derive an economic benefit from the cheaper flow of goods between countries as well as to ensure their products (including patented medicines) are profitable in other countries. FTAs can also be known as Regional Trade Agreements or Economic Partnership Agreements.

Developed countries sometimes use FTAs to get even greater commitments to 'free trade' than those agreed through the WTO. Often, developed countries insert stringent intellectual property regulations into FTAs that are in contradiction to the WTO TRIPS Agreement and threaten to block access to affordable medicines. Meanwhile, developing countries often have less power to resist or control the terms of FTAs, since they may be in need of increased economic revenue or other benefits that the developed countries can provide.

For example, the United States-Jordan Free Trade Agreement, which was fully implemented on January 1, 2010, has had disastrous results for public health. As a result of the FTA, Jordan has witnessed an increase in the price of medicine; over 25% of the Ministry of Health's budget is now spent on buying medicines, data exclusivity has delayed the introduction of cheaper generic versions of 79% of medicines and higher medicine prices are threatening the financial sustainability of government public health programs.

FREE TRADE, MOUNTING CONSTRAINTS

Number of free-trade agreements with intellectual property clauses, 2001-2010



How free trade agreements undermine access to HIV treatment and other essential medicines *

TRIPS-Plus FTAs and Economic Partnership Agreements generally

- Include clauses to extend patent terms beyond the twenty-year minimum required by TRIPS.
- Limit the use of compulsory licenses (CLs).
- Require data exclusivity that restricts the use of clinical data by national drug regulatory authorities to approve generic production for a certain time period.
- Prevent countries from restricting evergreening or allowing pre-grant oppositions.
- Prevent or ban the use of pre-grant opposition
- Prevent or the use of parallel imports of patented medicines
- Create linkage between patent protection and marketing approval

As a result, countries should:

- Develop/amend national patent laws in order to protect and promote the right to health and guarantee access to affordable essential medicines, by adopting the full range of TRIPS flexibilities including:
 - high patentability criteria – patents should only be granted for real and meaningful innovation and not for evergreening;
 - explicit language allowing for the use of CLs and parallel imports;
 - the opportunity for the public, generic manufacturers, and civil society to challenge patents through pre- and post-grant patent opposition provisions.
- Low and middle-income country governments must: Reject, from the outset, any provisions in all trade-agreements that in any way impact affordable access to essential medicines, including TRIPS-Plus provisions and investment protection provisions
- Guarantee access to safe, effective and affordable generic medicines, including developing manufacturing capacity where possible, by broadly and boldly using the TRIPS flexibilities.

* Excerpted from Zaidi, Sarah. 2013. Access Challenges for HIV Treatment among People Living with HIV and Key Populations in Middle-Income countries. Read the full report here: http://www.gnpplus.net/assets/Access_Challenges_for_HIV_treatment_among_PLHIV_and_KAPs_in_MICs_Policy_brief-copy.pdf

Section 5.3 What are TRIPS & TRIPS Flexibilities?

SECTION OBJECTIVE

To build community activists' understanding of TRIPS and the TRIPS agreement, and why they matter to access to HIV treatment.

TRAINING MATERIALS

PowerPoint presentation '5.3 What is TRIPS?'

Flipchart and pens

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objective of the Section.
2. Ask the participants what they know about:
 - TRIPS
 - TRIPS-Plus
 - TRIPS Flexibilities
3. Ask them to, in particular, share any examples of where situations related to TRIPS have threatened or improved access to treatment for people living with HIV. Write the ideas on a flipchart.
4. Present PowerPoint presentation '5.3 What is TRIPS?' Check if the participants have any further questions.
5. Ask the participants to build on the previous discussion and identify any additional ways in which situations related to TRIPS could threaten or improve access to HIV treatment in their community. Add the ideas to the flipchart.
6. Ask the participants to summarize the session by developing advocacy messages about 'What is TRIPS?' Support their ideas by sharing examples of messages (see below).

Option B (approx. 120 minutes)

1. Explain the objective of the Section.
2. Divide the participants into 3 groups. Give each group a topic as follows:
 - Group 1: TRIPS
 - Group 2: TRIPS-Plus
 - Group 3: TRIPS Flexibilities
3. Ask each group to brainstorm everything they know or think they know about their topic. This can be anything they have heard or read.
4. Altogether, ask each group to report back on their discussion.
5. Present PowerPoint presentation '5.3 What is TRIPS?' Check if the participants have any further questions.

6. Ask the participants to reflect on whether they had a good understanding of TRIPS, TRIPS-Plus and TRIPS Flexibilities before the PowerPoint presentation, including things they may have been incorrect about, and things they did not know.
7. Ask the participants to share any examples of where situations related to TRIPS have threatened or improved access to treatment for people living with HIV.
8. Ask the participants to summarize the session by developing advocacy messages about 'What is TRIPS?' Support their ideas by sharing examples of messages (see below).

ADVOCACY MESSAGES

1. TRIPS presents a significant threat to access to life-saving treatment for people living with HIV. For example, it can block access to new medicines, promote monopolies and keep prices of medicines unaffordable.
2. The threats are even greater under TRIPS-Plus. Practices (such as Patent Term Extension, evergreening and data exclusivity) risk protecting the rights of foreign businesses at the cost of public health.
3. TRIPS flexibilities present a vital opportunity to focus on what matters most – in terms of access to essential medicines that protect public health and deal with health crises, such as HIV.

USEFUL RESOURCES

- *TRIPS and Health: Frequently Asked Questions*, (webpage), World Trade Organization. Available here: https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm
- *Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement*, UNDP, 2010. Available here: <http://apps.who.int/medicinedocs/documents/s17762en/s17762en.pdf>
- *Access Challenges for HIV Treatment among People Living with HIV and Key Populations in Middle-Income Countries: Policy Brief*, GNP+, NSW, INPUD, MSMGF and ITPC, October 2013. Available here: http://www.gnpplus.net/assets/Access_Challenges_for_HIV_treatment_among_PLHIV_and_KAPs_in_MICs_Policy_brief-copy.pdf
- *Voluntary Licensing Practices in the Pharmaceutical Sector: An Acceptable Solution to Improving Access to Affordable Medicines?*, Tahir Amin for Oxfam, 2007. Available here: <http://apps.who.int/medicinedocs/documents/s19793en/s19793en.pdf>
- *Trends in Compulsory Licensing of Pharmaceuticals since the Doha Declaration: A Database Analysis*, Reed Beall and Randall Kuhn, 2012. Available here: <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001154>
- *Bulletin of the World Health Organization. Using TRIPS Flexibilities to Facilitate Access to Medicines*, World Health Organization, 2013. Available here: <http://www.who.int/bulletin/volumes/91/7/12-115865/en/>
- *Technical Brief: Doha+10 TRIPS Flexibilities and Access to Antiretroviral Therapy: Lessons from The Past, Opportunities for the Future*, UNAIDS, 2011. Available here: http://www.unaids.org/sites/default/files/media_asset/JC2260_DOHA%2B10TRIPS_en_0.pdf

What is the TRIPS agreement?

The TRIPS agreement is an agreement under the World Trade Organization (WTO). It outlines minimum standards for many types of regulations for IPRs but leaves space for countries to include in their national laws safeguards to protect public health. TRIPS requires members of the WTO to change their national laws in order to provide protection of IPRs. Countries have to give the same protection to nationals and foreigners. Under TRIPS the term of a patent, including patents on medicines, is 20 years. TRIPS includes an enforcement mechanism through economic sanctions for countries that fail to comply with the minimum standards for protecting IPRs.

One of the challenges of TRIPS is that, through its high level of protection for IPRs, it can block access to new products, promote monopolies and keep prices high for essential medicines.

Different deadlines for the implementation of TRIPS were set depending on the level of economic development, financial, administrative and technological constraints to conforming and previous existence of patents on pharmaceutical products:

- 1995 for developed countries.
- 2000 for developing countries who grant patents on pharmaceuticals before joining the WTO.
- 2005 for developing countries that had not introduced patents for pharmaceuticals before joining the WTO.
- 2016 for pharmaceuticals for “least developed countries (LDCs).” The TRIPS agreement includes a certain number of flexibilities that allow countries to break or work around patents to ensure balance between monopolies and public health goals. This transition period for LDCs has now been extended to 2021.

What are TRIPS flexibilities?

A TRIPS Flexibility is an amendment to the TRIPS Agreement. It allows members of the WTO to avoid patent rights for the sake of better access to essential medicines. It ensures that TRIPS does not prevent countries from taking steps to protect public health and, in particular, deal with health crises.

TRIPS Flexibilities create a supportive environment for WTO members to exercise their right to promote access to medicines for all. Examples of Flexibilities include:

STRICT PATENTABILITY CRITERIA

Member states may set high patentability criteria, denying new patents on new uses, forms, formulations or combinations of known medicines. This prevents “evergreening” of patents – where pharmaceutical companies will obtain new patents by making minor changes to the medicine to extend its monopoly period.

TRANSITION PERIOD

Least developed countries are not obliged to grant patents on pharmaceutical products until 2021 and should take advantage of this transition period.

COMPULSORY LICENSING (GOVERNMENT USE)

A CL is a government order allowing other persons or companies to use, make, sell, offer for sale or import the patented product or process without the consent of the patent holder. Under the TRIPS Agreement, countries are free to determine the grounds on which a CL should be issued. Patent holders still have the right to be compensated for the use of their patent rights by competitors and generic producers have to pay royalty on the sales of the generic versions of the medicines made under the CL.

In Africa, for example, Ghana, Eritrea, Zambia, Mozambique and Zimbabwe have issued CLs for generic ARVs. Some more examples are in the table below.

TABLE 1

COUNTRY & DATE OF ISSUE	TYPE OF LICENSE & NAME OF MEDICINE	IMPACT OF COMPULSORY LICENSE
INDIA March 2012	Compulsory license to locally produce general Sorafenib Tosylate to treat kidney cancer and liver cancer	Price set by India's Patent Controller will result in 97% reduction
ECUADOR April 2010	Compulsory license to import and, if necessary, locally produce generic Ritonavir	Resulted in a patent holder reducing price of brand medicine by 70%
THAILAND January 2008	Government-use license for import of generic Letrozole used to treat breast cancer	Projected aggregate price reduction of 96.8%
BRAZIL May 2007	Compulsory license issued by government to import generic Efavirenz	Resulted in a 71.8% price reduction
THAILAND January 2007	Government-use order to import or locally produce generic Lopinavir/ Ritonavir	Projected price reduction of 80.2% expected
INDONESIA October 2004	Government-use order to locally manufacture generic Lamivudine, Nevirapine	Resulted in price reduction of 53.3%
MALAYSIA November 2003	Government-use order for the production of combination of generic Stavudine + Didanosine + Nevirapine	Resulted in price reduction of 83%

PARALLEL IMPORTATION

Allows countries to import a patented medicine from other countries where it is produced and sold by the patent holder or an authorized party at a lower price than in the domestic market. This can happen without the permission of the intellectual property owner.

EXCEPTIONS TO PATENTS RIGHTS

TRIPS allows states to establish limited exceptions to the exclusive rights of a patent owner, as long as they do not unreasonably prejudice his or her ownership rights. For example, the Bolar Exception – an ‘early working’ exception which allows for research and experimental use of products still under patent. This allows generic versions to promptly enter the market directly after the patent expires.

PATENT OPPOSITIONS

Countries may permit any person to oppose patent applications before the patent is granted by filing a case in court (pre-grant opposition). Under certain circumstances, a patent can be challenged after it has been granted by filing a case in court (post-grant opposition). Patent oppositions ensure higher scrutiny of patent applications before and after they are granted to ensure a novel, inventive step.

LIMITS ON DATA PROTECTION

TRIPS does not require countries to grant exclusivity of clinical trials data. This should only be protected from “unfair commercial use”. Registration of a generic medicine is not considered an unfair commercial use.

What are voluntary license mechanisms?

A pharmaceutical company that holds patents on a product can offer, of their own accord, a license to a third party (usually a generic producer) to produce, market and distribute the patented product. In exchange, the patent holder will usually request a royalty on the net sales made by the licensee. This is also referred to as 'out-licensing.' Other types of licenses granted by patent holders to generic companies could be marketing licenses (or distribution agreements), where a company may simply sell the branded version of the product.

However, very often the patent holders impose some restrictions, such as:

- Geographical restrictions – on where the licensee can sell the product
- Restrictions on the price the product may be sold at
- Create a monopoly and control on sales of raw materials for local production (active pharmaceutical ingredients known as API)

Patent holders can, and often do, also apply any other terms or conditions.

In general, multinational companies negotiate the terms of voluntary licenses directly with generic companies, and the terms are usually kept secret. In 2010, however, the Medicines Patent Pool was created to increase access to more affordable HIV/AIDS medicines in developing countries.² Patent holders, such as pharmaceutical companies, are encouraged to share their drug patents with the Patent Pool. This allows other manufacturers to produce more affordable, generic versions of the drug.³ In return, the patent holder receives a royalty payment. In theory, this process allows for competition among manufacturers, which may drive down the price of drugs.

One of the particular aims of the pool is to facilitate the development of fixed-dose combinations (FDCs) which combine multiple medicines into one pill.⁴ FDCs can be more easily developed through the Patent Pool, because the patent pool means that patents on the individual drugs do not stop drug manufacturers from combining them.

However, there are some limits to what the patent pool can achieve. Firstly, the patent pool is a voluntary mechanism, so it can only achieve its objective if patent holders are willing to participate.⁵ Also, the licenses agreed on so far have the same limits in term of geographical coverage and other issues. This means that, in practice, the Medicine Patent Pool has no real leverage for negotiation.

In conclusion, voluntary licenses could help in reducing prices when there is no alternative. However, governments and health authorities have no control over them. Voluntary licenses do not necessarily create the competition needed for progressive price reductions: some voluntary licenses effectively replace one monopoly with another monopoly. Furthermore, voluntary licenses do not guarantee the availability of medicines on the market. In fact, several voluntary licenses have not yet led to the production of actual medicines. Some multinational companies use voluntary licenses only to prevent governments from using other TRIPS flexibilities (like CLs) or to limit local production of generics by controlling production and sales of raw materials or selecting few competitors. For example, most VLs of the medicine patent pool are exclusively signed with Indian producers which makes local production of recent drugs impossible in Africa.

What is the Doha Declaration?

The Doha Declaration is a joint agreement endorsed by all WTO countries that gives countries the right to take wide-ranging actions to protect the health of their citizens. The 2001 WTO Doha Declaration states: "The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. ... [W]e affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."⁶

The Doha Declaration reaffirmed countries' rights to use TRIPS Flexibilities to overcome patent barriers in order to increase access to medicines, including specifying that the grounds for issuing a CL are unlimited and can apply to any disease or public health situation (for example, emergencies as well as chronic health issues).

What is TRIPS-Plus?

"TRIPS-Plus provisions" refer to those measures related to intellectual property that go far beyond what governments are required to do under TRIPS. This includes efforts to extend patent periods beyond the twenty-year TRIPS minimum, limit compulsory licensing in ways not required by TRIPS, limit exceptions that facilitate the prompt introduction of generics, and grant clinical data needed for registration of medicines during a period of exclusivity.

Many developing countries have been forced to include such provisions in their national laws after signing a Free Trade Agreement. However, some did so voluntarily because of a lack of expertise when drafting their national laws or as a result of technical assistance provided by developed countries.

Examples of TRIPS-Plus measures include:

- Expansion of the patentability criteria (second use, new formulation, etc.).
- Exclusion of patent pre-grant opposition.
- Restrictions of grounds for patent revocation.
- Extension of the term of patent protection.
- Data exclusivity for data submitted to regulatory authorities.
- Limitations on compulsory licenses.
- Limitations or interdictions on parallel importation.
- Linkage between patent status and market approval.

Two TRIPS-Plus measures are of particular interest:

EVERGREENING

Refers to a variety of legal and business strategies by which technology producers with patents over products that are about to expire retain royalties from them, by either taking out new patents (for example over associated delivery systems or new pharmaceutical mixtures) for longer periods of time than would normally be permissible under the law or by buying out or frustrating competitors.

Used to refer to the myriad of ways in which pharmaceutical patent owners use the law and related regulatory processes to extend their high rent-earning IP rights particularly over highly profitable (either in total sales volume or price per unit) "blockbuster" drugs

DATA EXCLUSIVITY

This refers to a different type of monopoly on medicines separate from patents. Data exclusivity refers to the period during which the data of the original marketing authorization holder relating to (pre-) clinical testing is protected. A country's drug regulator will be prohibited from registering an effective generic medicine as long as the exclusivity over the clinical trial data submitted by a pharmaceutical company lasts – this can be up to 10 years.

Section 5.4.

How can you advocate on trade and access to treatment?

SECTION OBJECTIVE

To build community activists' understanding of the entry points and 'what works' for advocacy on trade and access to treatment.

TRAINING MATERIALS

PowerPoint presentation '5.4 How can you advocate on trade and access to treatment?'

Flipchart and pens

TRAINING OPTIONS

Option A (approx. 60 minutes)

- 1 Explain the objective of the Section.
- 2 Ask the participants to think about the information on trade and HIV treatment that has been addressed in Sections 5.1-5.3. Ask them to identify some examples of entry points for advocacy. Explain that an entry point is an opportunity to 'get started.' It might, for example, be a process (that provides an opportunity to influence decision-making) or a crisis (that provides an opportunity to achieve urgent change).
- 3 Present PowerPoint presentation '5.4 How can you advocate on trade and access to treatment?'
- 4 Ask the participants to share other lessons learned about advocacy on trade and access to treatment based on their own experiences.
- 5 Summarize what has been discussed and agreed during the session.

Option B (approx. 120 minutes)

- 1 Explain the objective of the Section.
- 2 Explain to the participants what is meant by an entry point for advocacy on trade and HIV treatment – in terms of an opportunity to 'get started.' For example, an entry point might be a process (that provides an opportunity to influence decision-making) or a crisis (that provides an opportunity to achieve urgent change).
- 3 Divide the participants into groups of about 5 people. Ask the participants to identify 1-2 entry points for advocacy on trade and access to treatment that relate to their community.
- 4 Bring all of the participants back together. Ask each group to present their examples of entry points. Encourage the other participants to ask questions and make comments.
- 5 Ask the participants to think about what type of advocacy they could carry out for the entry points that they have identified. Facilitate a discussion on: What do we know about 'what works' in advocacy on trade and access to treatment?
- 6 Encourage the participants to identify the lessons learned from their own experiences. Write their inputs on a flipchart.
- 7 Summarize what has been discussed and agreed during the session.

USEFUL RESOURCES

- *Success story: The Case of TDF in Brazil*, Patent Oppositions Database, 2012. Available here: http://www.patentoppositions.org/da/case_studies/4f106d0504a7f92f5b000003
- *Global Commission on HIV and the Law: Risks, Rights and Health* – Chapter 6: Medicines For Whom? Intellectual Property Law and the Global Fight for Treatment, UNDP, 2012. Available here: <http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf>
- *Don't Trade Our Lives Away: Networks Striving for Equitable Access to Medicines*, (website). Available here: <https://donttradeourlivesaway.wordpress.com/>
- *TRIPS in Question during Social Forum Discussion on Access to Medicines*, Global Commission on HIV and the Law, 2015. Available here: <http://www.hivlawcommission.org/index.php/news/news/424-trips-in-question-during-social-forum-discussion-on-access-to-medicines>
- Patent Opposition Database (website). Available here: <http://www.patentoppositions.org/>

How Can You Advocate Around Trade Issues And HIV Treatment?

For community activists, there are many different opportunities to get involved on trade and access to treatment and make a difference. Advocacy is about starting discussions, influencing opinions and achieving change.

While advocacy on trade might sound like a complicated concept, there are many "entry points" for advocacy that provide the opportunity to get involved, such as a process (that provides an opportunity to influence decision-making) or a crisis (that provides a chance to achieve urgent change). Examples of advocacy opportunities can be seen in the experiences of ITPC partners and other organizations throughout the world:

TABLE Examples on How to Advocate on Trade and Access to Treatment

Advocacy opportunities:	Examples of advocacy actions:
1 - Call for law reform for better inclusion of TRIPS flexibilities in your national law	<ul style="list-style-type: none"> • Analyze your national intellectual property law and highlight all provisions that could undermine the use of TRIPS flexibilities • Assess the impact of such provisions on access to medicines • Draft amendments to integrate safeguards • Meet with legislators and parliamentarians to explain your position and why it's in their interest to support law reform • Mobilize communities and the media to build support
2 - Develop a "post license strategy" if your country has been excluded from a voluntary license	<ul style="list-style-type: none"> • Issue a press statement • Push your Ministry of Health to protest against such exclusion • Analyze if there are potential sources of generic supply or local capacity for production • Call on your government to issue a CL or call for amendment of the voluntary license to include your country • Explore the possibility of opposing the patent • Mobilize communities, engage with the media and build support

3 - Call on your government to issue a compulsory license (CL)	<ul style="list-style-type: none"> • Make the case for why a CL is urgently needed in your country through research and personal stories of people who would be affected by the CL • Rally public opinion to your side through media outreach, demonstrations and other advocacy actions. • Seek the support of legal experts and experts in other countries who helped achieve CLs to ensure your government feels comfortable proceeding • Rally decision-makers to your side through targeted lobbying meetings and if they are elected officials, through pressure from their constituents through public rallies, petitions and so on
4 - Oppose an abusive patent	<ul style="list-style-type: none"> • Do research and analysis to identify abusive patents or applications that hinder generic competition • Build arguments for a case to oppose the abusive patent • Communicate with the patent office to explain why a patent should not be granted • File an opposition according to your national legislation • Mobilize communities and gain media coverage to build support
5 - Influence your government as it debates entering a Free Trade Agreement (FTA)	<ul style="list-style-type: none"> • Analyze the impact the FTA would have on medicines in your country. • Publicize your analysis so others can be informed • Rally public opinion to your side through media outreach, demonstrations and other advocacy actions. • Rally decision-makers to your side through targeted lobbying meetings and if they are elected officials, through pressure from their constituents through public rallies, petitions and so on

In 2012, the Global Commission on HIV and the Law issued recommendations on what needs to change with regards to trade and IP to ensure the right to health is protected. You can also advocate for their recommendations, which included:

- High-income countries, including donors such as the United States, European Union, the European Free Trade Association countries (Iceland, Liechtenstein, Norway and Switzerland) and Japan must immediately stop pressuring low- and middle-income countries to adopt or implement TRIPS-Plus measures in trade agreements that impede access to life-saving treatment.
- All countries must immediately adopt and observe a global moratorium on the inclusion of any intellectual property provisions in any international treaty that would limit the ability of countries to retain policy options to reduce the cost of HIV-related treatment.
- High-income countries must stop seeking to impose more stringent TRIPS-Plus intellectual property obligations on developing country governments. High-income countries must also desist from retaliating against countries that resist adopting such TRIPS-Plus measures so that they may achieve better access to treatment.
- Individual countries may find it difficult to act in the face of political pressure; they should, to the extent possible, incorporate and use TRIPS flexibilities, consistent with safeguards in their own national laws.

- Low- and middle-income countries must not be subject to political and legal pressure aimed at preventing them from using TRIPS Flexibilities to ensure that infants, children and adolescents living with HIV have equal access to HIV diagnosis and age-appropriate treatment as adults.
- WTO members must indefinitely extend the exemption for LDCs from the application of TRIPS provisions in the case of pharmaceutical products. The UN and its member states must mobilize adequate resources to support LDCs to retain this policy latitude.
- TRIPS has failed to encourage and reward the kind of innovation that makes more effective pharmaceutical products available to the poor; including for neglected diseases. Countries must therefore develop, agree and invest in new systems that genuinely serve this purpose, prioritizing the most promising approaches including a new pharmaceutical R&D treaty and the promotion of open source discovery.

You can read the full report here: <http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf>. The relevant chapter for advocacy on trade and treatment is Chapter 6.

WHAT WORKS IN ADVOCACY ON TRADE AND ACCESS TO TREATMENT?

Many lessons have been learnt - including by ITPC's partners - about 'what works' in advocacy on trade and access to HIV treatment. The following presents examples that apply to different contexts:

EXAMPLE 1: OPPOSING A FREE TRADE AGREEMENT BETWEEN THE U S AND SOUTHERN AFRICA

In early 2000, the U.S. engaged in parallel free trade negotiations with various developing countries and regional trading blocs. Among these were South Africa and its Southern African Customs Union (SACU) partners, commonly referred to as the BNLS countries (Botswana, Namibia, Lesotho and Swaziland). Shortly after the negotiations started, civil society groups began organizing against the potential free trade agreement. For people opposing the FTA, the main concern was that certain elements proposed by the U.S. for inclusion would be detrimental to the developmental aspirations of the SACU countries, while also putting public health, food security and service delivery in the region at risk.

For example, the U.S. sought extensive IPRs in the agreement, which would have constrained the region's ability to provide medical care to its people. Eventually, the negotiators failed to reach a consensus on many of the contested issues, and the talks collapsed. In the end, civil society groups and activists were successful in averting a FTA that could have had disastrous consequences for the Southern African region.

EXAMPLE 2: SUPPORTING THE GOVERNMENT OF THAILAND TO ISSUE COMPULSORY LICENSES

In 2004, 500,000 people were reported to be living with HIV in Thailand, and some were beginning to develop resistance to the available first-line treatment regimens. Second-line treatment at the time was unaffordable at \$2,200 per person. The Thai government estimated that if it distributed second-line ARV therapy to people who could not afford it 8,000 lives per year would be saved. As a result, between October and January 2007, the Thai government used lawful flexibility under the TRIPS Agreement to issue CLs for four drugs, including Abbott's ARV Kaletra. There was a backlash towards the Thai government from Abbott, other pharmaceutical companies and the U.S. government, but even Abbott's investors denounced the backlash as unethical. For more information, please see: www.uaem.org/cms/asests/uploads/2013/03/uaemconference2008-compulsory-licensing

EXAMPLE 3: ITPC SOUTH ASIA RALLIES AGAINST A POTENTIALLY HARMFUL FREE TRADE AGREEMENT BETWEEN INDIA AND THE EUROPEAN UNION

In 2007, the European Union began secret talks with India on a potential FTA. When the Delhi Network of People Living with HIV (DNP+), ITPC South Asia and others learned of the talks, they began asking questions on the terms of the FTA and were rebuffed. As a result, they began forming a coalition of diverse civil society groups that would be affected by the FTA – including groups focused on health, agriculture, environment and trade unions – and began organizing public protests. As a result of their first protest in

March 2009, they were granted a meeting with Indian government negotiators. As talks continued, the coalition has kept up public pressure through additional protests (some of which resulted in police abuse and detention), media actions and letters to public officials. Activists also publicly presented Carla Bruni, the wife of the then French President Nicolas Sarkozy and an ambassador for the Global Fund to Fight AIDS, TB & Malaria with 5 ml of blood to symbolize the deaths that would occur under an FTA that protects IP over people's health. The protests spread outside India to other parts of Asia, Africa and Latin America – regions that would be affected if India was no longer able to produce generic drugs and export them. Increasingly, the Indian government began making public statements indicating that it would not trade away IP rights.

On the 30 March 2016, ITPC indicated that it expected an announcement at the 13th EU-India summit that the European Union and India Free Trade Agreement negotiations would resume. In response to this, PLHIV presented a letter to the European Commissioner for Trade, highlighting two key areas of concern. The first is a request to the EC to remove harmful intellectual property provisions from the trade agreement, while the second, calls for the EC to adhere to their own policies of transparency regarding the EU-India FTA. You can find more information on ITPC's advocacy on this issue here: <http://itpcglobal.org/message-to-europe-hands-off-our-medicines/>

EXAMPLE 4: OPPOSING A QUESTIONABLE PATENT IN BRAZIL

In Brazil, the drug Tenofovir Disoproxil Fumarate (TDF) is widely used as part of first- and second-line HIV treatment regimens. However, this was not always the case. In 1998, the pharmaceutical company Gilead filed a patent application for TDF in Brazil, and while the patent was under examination by the Brazilian Patent Office, the lack of competition in Brazil allowed Gilead in 2003 to charge US\$3,300 per person per year (ppy). In 2006, a coalition of non-governmental organizations (NGOs) known as the Working Group on Intellectual Property from the Brazilian Network for the Integration of Peoples (GTPI/REBRIP) utilized a pre-grant opposition to prevent the patent from being granted and encourage competition to reduce the drug's price. In August 2008, the patent office in Brazil rejected the patent application on TDF on the grounds that it lacked inventiveness. The Brazilian government has since announced the start of local production of TDF through a partnership between public and private manufacturers in Brazil. Gilead is still appealing its patent application [number PI9811045], in the Brazilian courts. To read more, please access the full document here: http://www.patentoppositions.org/dadrugs/4f1081fb04a7f937af000019/patent_oppositions/512339c0cab5a10002000002

EXAMPLE 5: DEVELOP NATIONAL STRATEGIES TO REMOVE PATENT BARRIERS ON ACCESS TO MEDICINES

A consortium of four middle income countries (Argentina, Brazil, Thailand and Ukraine) with the support of ITPC and I-MAK have developed national strategies to address IP barriers on access to HIV treatment. The strategies are based on the following pillars:

- Advocating for patent law reform to promote the use of TRIPS flexibilities
- Opposing and preventing TRIPS Plus provisions through free trade agreements
- Supporting a public health approach to patent examination to prevent the granting of abusive patents (evergreening)
- Opposing unmerited patents
- Campaigning on selective use of compulsory licenses when needed.

For more information about this initiative please see: www.makemedicinesaffordable.org

'WHAT WORKS' IN ADVOCACY ON TRADE AND ACCESS TO HIV TREATMENT

FOCUSING ON WHAT YOU CAN HELP CHANGE:

Depending on your skills, focus your advocacy on areas where you have the ability to affect change. For example, if you identify that in your country, some aspects of trade and treatment are difficult and take a long time to change (such as patent law), you may decide to focus instead on advocating for a compulsory or voluntary license.

KNOWING WHO TO TARGET:

Identify who makes and influences decisions on trade in your country and target them with your advocacy. These may be stakeholders – such as the Ministry of Trade – that are not your usual targets for HIV advocacy.

SHOWING THE 'HUMAN FACE':

For example, developing case studies that tell the story of real people living with HIV and how trade-related issues have affected their access to treatment.

FORMING ADVOCACY COALITIONS:

For example, joining forces with other organizations – such as ones focused on different aspects of health and development – to do joint campaigning on harmful aspects of trade, such as the impact TRIPS-Plus would have on people's health.

ACCESSING EXPERTISE:

You don't have to do advocacy work alone! There are many people and organizations working on these issues who can assist you. For example, you could call on free legal expertise to confirm that your advocacy 'asks' about patents and HIV treatment are accurate and possible within your country's legal and policy system.

Endnotes

- 1 Global Health Observatory (GHO) Data: Antiretroviral Therapy (ART) Coverage among all Age Groups. World Health Organization, 2016. http://www.who.int/gho/hiv/epidemic_response/ART_text/en/
- 2 Spotlight on: Patent Pool, Médecins Sans Frontières, 2016. <http://www.msfaaccess.org/spotlight-on/patent-pool>
- 3 Spotlight on: Patent Pool, Médecins Sans Frontières, 2016. <http://www.msfaaccess.org/spotlight-on/patent-pool>
- 4 Spotlight on: Patent Pool, Médecins Sans Frontières, 2016. <http://www.msfaaccess.org/spotlight-on/patent-pool>
- 5 Spotlight on: Patent Pool, Médecins Sans Frontières, 2016. <http://www.msfaaccess.org/spotlight-on/patent-pool>
- 6 Doha WTO Ministerial 2001: TRIPS, World Trade Organization, 2001. https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

6 FINANCING AND HIV TREATMENT

Welcome to **Module 6: Financing and HIV Treatment** of the Advocacy for Community Treatment (ACT) Toolkit of the International Treatment Preparedness Coalition (ITPC)

Module 6 focuses on funding and how it affects access to HIV treatment.

INTRODUCTION	
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SECTION 6.1

How does funding relate to access to HIV treatment?

SECTION OBJECTIVE

To build community activists' understanding of how funding relates to access to treatment for people living with HIV.

TRAINING MATERIALS

- PowerPoint presentation '5.1. How does funding relate to access to HIV treatment?'

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objective of the Section.
2. Facilitate a discussion on:
 - Why does it 'make sense' to fund HIV treatment?
 - Who could and should fund HIV treatment in our country?
3. Present PowerPoint presentation '6.1 How does funding relate to access to HIV treatment?' Ask the participants if they have any questions or comments.
4. Ask the participants to summarize the session by developing advocacy messages about 'How does funding relate to access to HIV treatment?' Support their ideas by sharing examples of messages (see below).

Option B (approx. 120 minutes)

1. Explain the objective of the Section.
2. Divide the participants into small groups. Ask each group to discuss why it 'makes sense' to fund HIV treatment. Ask them to develop 2-3 advocacy messages that they could use to convince advocacy targets, such as the Ministry of Finance or an international donor.
3. Bring the participants back together. Ask each group to share one of their advocacy messages. Encourage the other participants to provide feedback.
4. Present PowerPoint presentation '6.1 How does funding relate to access to HIV treatment?' Ask the participants if they have any questions or comments.
5. Facilitate a discussion on:
 - What are the sources of funding for HIV treatment in our country?
 - What is the current status of each of those sources? (For example: How much support do they currently provide? Is their funding increasing or decreasing? Are there specific challenges?)
6. Ask the participants to summarize the session by developing advocacy messages about 'How does funding relate to access to HIV treatment?' Support their ideas by sharing examples of messages (see below).

ADVOCACY MESSAGES

1. Funding HIV treatment is a cost-effective way to prevent illness, death and further HIV infections. Increasing investment now will save money in the future.
2. Globally, at US\$22 billion per year is needed in low-and-middle-income countries if governments are to achieve their commitment to providing universal access to HIV prevention, treatment, care and support.¹
3. All stakeholders – including national governments, international donors and community members – play a vital role in providing and/or advocating for increased funding for HIV treatment.
4. As donor financing for health and HIV treatment dwindles and transitions to other sectors, many, many countries will be forced to move towards more sustainable, domestic financing. As this shift occurs, it is vital to ensure that financing gaps are not filled by households paying out-of-pocket. This will increase inequities in access to health care and push more households into poverty.

USEFUL RESOURCES

- *Financing the Response to AIDS in Low and Middle-Income Countries: International Assistance from Donor Governments in 2014*, UNAIDS and Kaiser Family Foundation, September 2015. Available here: <https://kaiserfamilyfoundation.files.wordpress.com/2015/06/7347-11-financing-the-response-to-aids-in-low-and-middle-income-countries.pdf>
- *UBRAF Thematic Report: Closing the Resource Gap*, UNAIDS, 2014. Available here: https://results.unaids.org/sites/default/files/documents/ClosingResourceGap_Oct2014_final.pdf
- *Smart Investments*, UNAIDS, 2013. Available here: http://www.unaids.org/sites/default/files/media_asset/20131130_smart-investments_en_1.pdf
- *Fast-Track Update on Investments Needed in the AIDS Response*, UNAIDS, 2016. Available here: http://www.unaids.org/sites/default/files/media_asset/UNAIDS_Reference_FastTrack_Update_on_investments_en.pdf
- *Sustaining the Global HIV Response: Innovative Financing Options*, amfAR, 2014. Available here: http://www.amfar.org/uploadedFiles/_amfarorg/Articles/On_The_Hill/2014/IB%20Innovative%20Financing%20-%20Final.pdf
- *Domestic Innovative Financing for Health: Learning From Country Experience*, USAID and HFG, 2014. Available here: <https://www.hfgproject.org/domestic-innovative-financing-healthlearning-country-experience/>

Why does funding matter for action on HIV treatment?

Worldwide, approximately 37 million people are living with HIV.² According to the 2015 World Health Organization Guidelines (WHO) ART Guidelines (see Section 2.1), 15 million people living with HIV (PLHIV) were receiving antiretroviral therapy (ART) in 2015. This is only 46% of those who should be provided with ART under the 2015 WHO ART Guidelines.³ In addition, only about a quarter of those on ART are achieve a suppressed viral load. As explained in Module 1, a person is virally suppressed, or has an undetectable viral load, when there are too few copies of the virus in the person's blood to make them sick, or to be found by a viral load test. In sub-Saharan Africa, 76% of PLHIV who are on ART have achieved viral suppression.⁴

The fact that only 41% of PLHIV who are eligible for ART are on treatment, and many people on ART are not virally suppressed indicates that there is a treatment gap. There are many reasons for the treatment gap, including access issues, but funding is one of the main reasons. Globally, US\$22 billion is needed per year in low-and-middle-income countries for governments to achieve their commitment to providing universal

access to HIV prevention, treatment, care and support.⁵

Why does it make sense to fund HIV treatment?

There are many reasons why it makes good sense to fund HIV treatment. These include that:

1. HIV TREATMENT IS AN EFFECTIVE WAY TO PREVENT ILLNESS, DEATH AND FURTHER HIV INFECTIONS

For most people, HIV treatment is relatively simple, effective and safe. For PLHIV who are taking treatment and achieving viral suppression, their expected life span is now near normal.⁶

When most PLHIV in a community are on treatment and virally suppressed, the amount of the virus in the community overall is lower. By reducing viral load of individuals within a community, and therefore reducing the amount of the virus circulating within a community or population, scaling-up ART helps to reduce the number of new HIV infections. Between 2010 and 2015 4,870,000 deaths were averted due to ART.⁷

Scaling-up HIV treatment to the 22 million people who need it is a fundamental part of a strategy to end the HIV pandemic.

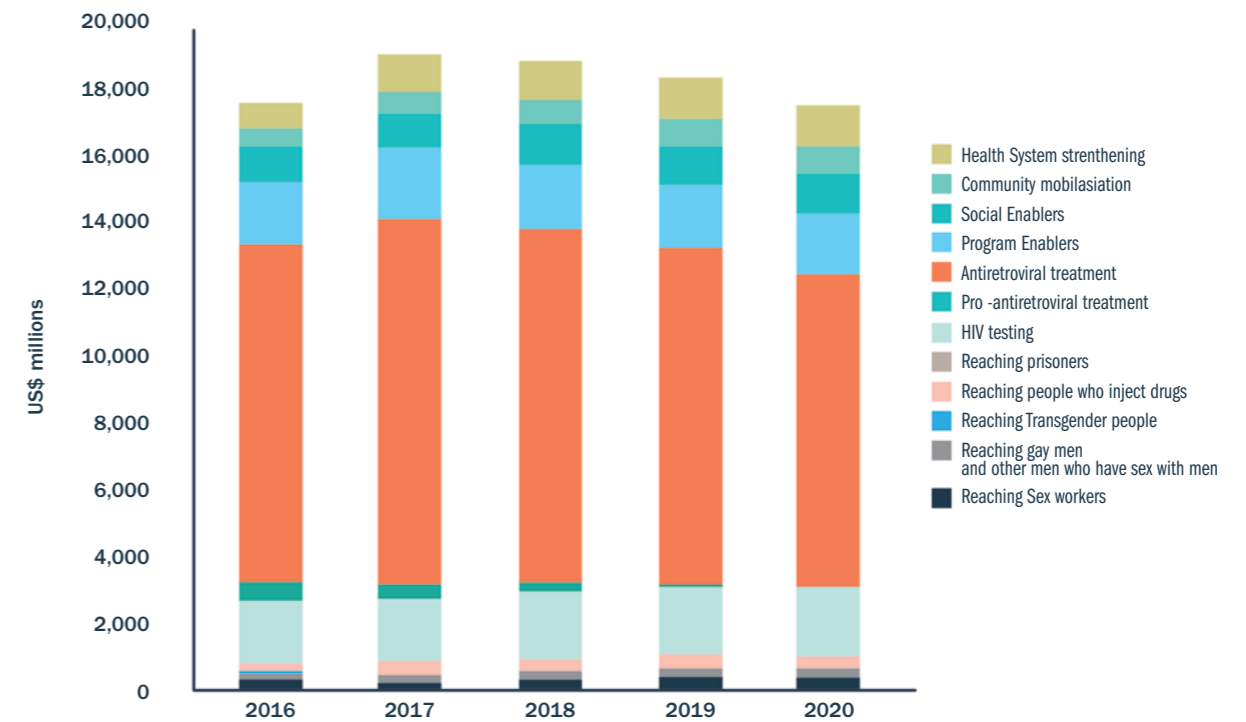
2. EXPANDING HIV TREATMENT IS A COST-EFFECTIVE STRATEGY AGAINST POVERTY

In today's global economy, wealth and development depends on more than natural resources (such as oil or land) and infrastructure (such as roads or buildings). Economic development depends on people and, specifically, on healthy, skilled and productive people. Studies in countries as diverse as Mexico and Singapore have shown a link between improved health and economic growth. When a community has a lot of people who are sick, their families are more likely to: stop work; take children out of school to nurse sick relatives; deplete their savings to pay for healthcare; and have fewer resources for food and education. These factors slow economic development, and keep people in poverty.

3. INCREASING FUNDING FOR HIV TREATMENT NOW IS A KEY WAY TO SAVE MONEY IN THE FUTURE

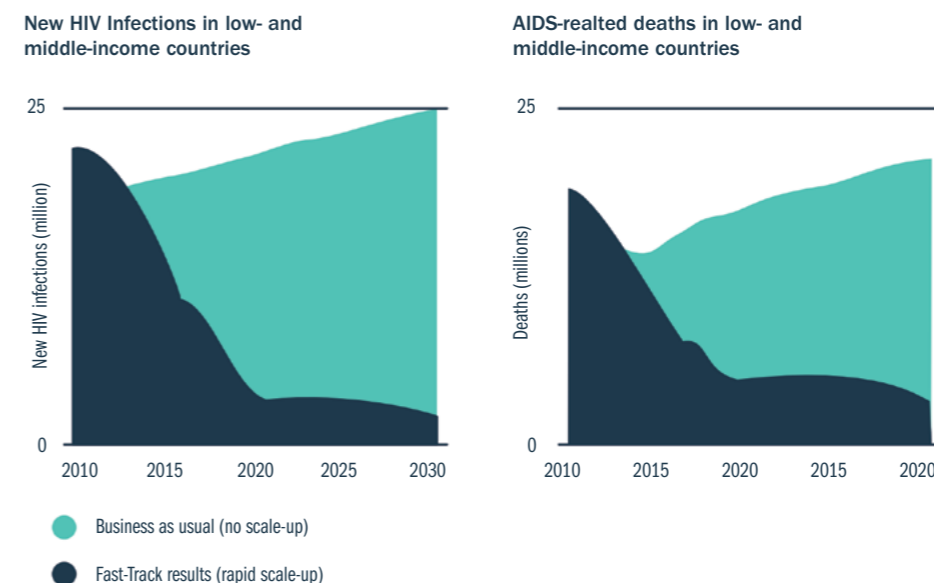
Increasing investment in HIV treatment to reach targets for universal access as soon as possible will not only save lives and reduce infection rates. It will also save money over the long-term. The graph below provides estimates of the costs of scaling-up HIV services to meet the current global targets by 2020. The costs peak in 2017 and then begin to come down.

Resources needed to achieve the 90-90-90 treatment target by 2020⁸



The following two graphs show the impact that increased investment could have on the rates of new HIV infections and AIDS-related deaths (shown in dark blue) compared to the current level of investment (shown in light blue). The graphs show that increasing funds for HIV treatment now will drastically reduce illness, death and new infections in the future, which will save money in the long term. By 2030, the Fast-Track approach will avert 28 million new infections, and will result in global savings of 15 times the initial investment.⁹

GRAPHS IMPACT OF FAST-TRACK ON RATES OF NEW HIV INFECTIONS AND AIDS-RELATED DEATHS



What level of funding is needed?

The Joint United Nations Program on AIDS (UNAIDS) estimates that globally US\$ 26.2 billion will be required for the AIDS response in 2020, with US\$ 23.9 billion required in 2030.¹¹ The largest share of these investments, US\$ 15.8 billion in 2020, will be required in sub-Saharan Africa.¹² By 2020, annual international HIV assistance should be at least US\$ 12.7 billion (or 40% of the total HIV resources needed in low- and middle-income countries). This is compared to the US\$ 8.75 billion in international funding for HIV assistance in 2014.¹³

UNAIDS estimates that, in 2013, global HIV funding available from all sources — domestic public and private spending, donor governments' bilateral assistance, multilateral organizations and private philanthropic groups — totaled US\$19.1 billion.¹⁴ Therefore, the total resources available in 2013 were well below what is needed to achieve the Fast-Track targets.

The cost of antiretroviral (ARV) drugs has been reduced drastically over the past 8 years. In 2015, first-line regimens now cost an average of approximately US\$100 per patient per year in developing countries.¹⁵ Even costs for second-line regimens are being reduced — with some costing as little as US\$300 a year. However, overall, second-line regimens remain too expensive for many countries.

To achieve universal access, funding also needs to be used effectively and efficiently. Every year, more and more people are being reached with each amount of funding that is raised for HIV treatment. This is because programs are scaling-up and gaining experience. After the initial cost of establishing HIV treatment programs, governments and community organizations are able to enroll and support additional people with increasing efficiency and effectiveness.

Who pays for the response to HIV?

Many different entities provide funding for HIV care, treatment, prevention and support.

Of the estimated US\$18.9 billion spent in 2012, US\$10 billion (53% of the total spent in low- and middle-income countries) came from domestic in-country resources (i.e., spending by individuals, communities and their governments). In 2014, the percentage of funding coming from in-country sources had risen to 57%.¹⁶ This mirrors the overall pattern of funding for all health programs. For example, in sub-Saharan Africa, more than two-thirds of general health spending comes from domestic sources.¹⁷

Additional HIV funding comes from donor governments, which in 2014 contributed US\$8.64 billion.¹⁸ In 2012, private foundations contributed approximately US\$640 million. Donor funding to address HIV increased by only 1% (after adjusting for inflation).¹⁹ Funding from nine of fourteen donor governments assessed either declined or remained flat in 2014; while funding from five governments increased.²⁰ Overall, funding for HIV has been relatively flat for the past three years.

In reality, people living with HIV carry the biggest financial burden of all.

In Africa and elsewhere, people living with HIV and their families and communities spend a large amount on healthcare, spending from their income, savings or borrowed funds. Researchers suggest that this spending accounts for 15-45% of total national spending on HIV-related treatment and care. This means that people living with HIV — and their families and communities — are likely to be the single largest 'funder' of HIV-related health care in many countries.

Payments for HIV-related care and treatment can be a leading cause of financial catastrophe and impoverishment for people living with HIV. It can also force people to choose between borrowing money to stay healthy or waiting — people who wait eventually get sick and needing more intensive, and expensive, healthcare.

To ease the burden on individuals and communities, governments have a responsibility to provide accessible and affordable healthcare. Because HIV treatment can prevent serious illness and reduce the risk of HIV transmission, there are also important public health, ethical and financial reasons for governments to ensure easy access to HIV treatment.

Private health insurance is another way to ease the burden of healthcare costs for individuals and households. Health insurance is a mechanism that collects and pools funds for healthcare from a group of people, and then finances health services for members of the group when they need it. As such, national schemes have a potential to generate resources for HIV services, redistribute resources from rich to poor, and help people avoid impoverishment as a result of catastrophic spending on healthcare. Private and pre-paid health insurance is widely used in Europe, North America, Latin America and in countries such as Namibia, South Africa and Thailand. However in many countries in Africa and Asia, private and pre-paid health insurance is only now starting to expand.^{21,22} In Africa, where national health insurance schemes are being introduced in countries such as Rwanda, these efforts are associated with considerable improvements in the use of health care services.²³

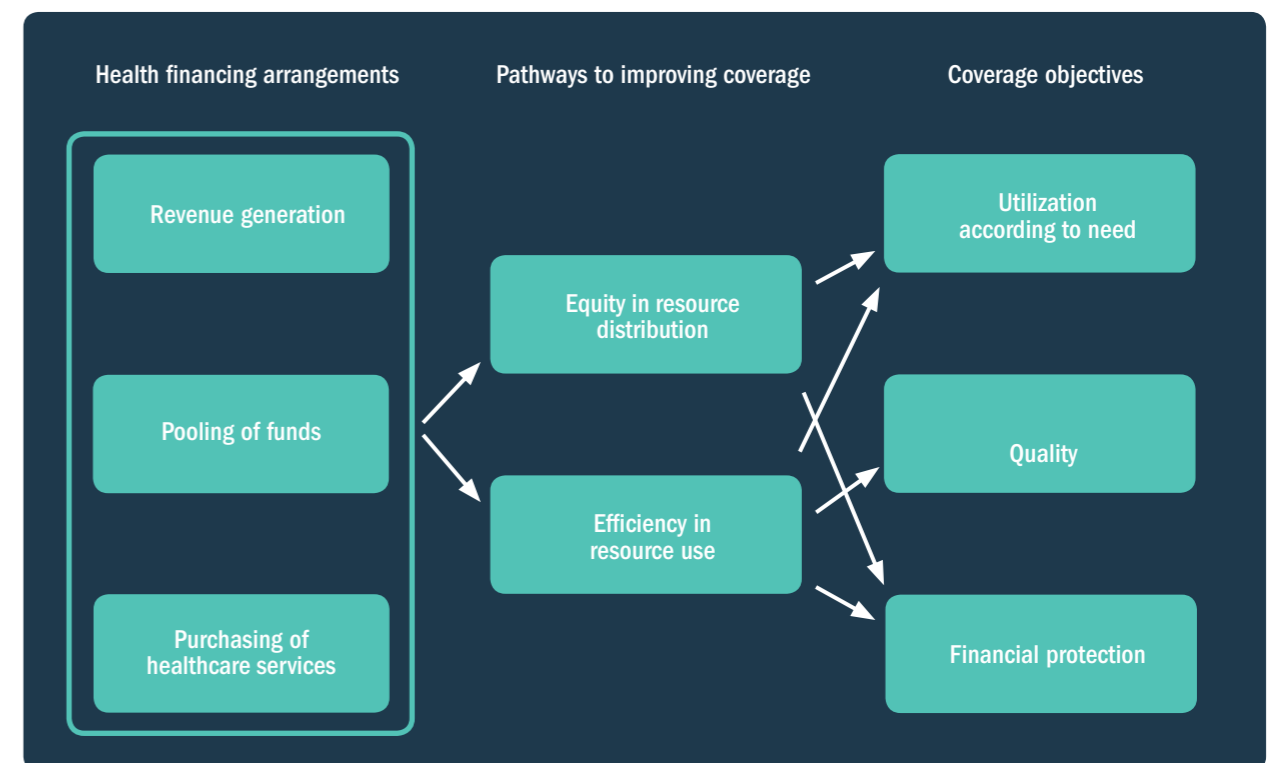
To ensure that health financing needs are met in an equitable and sustainable manner, governments and donor organisations are exploring Domestic Innovative Funding (DIF) models for health. DIF models seek to raise extra funds for health spending. Innovative funding models can take the form of taxes, e.g. taxes on income or profit; taxes on goods and services; options for increasing private sector contributions to the financing of healthcare service delivery; or through debt instruments.

According to the WHO, it is the role of national health systems to improve the health status of the population equally and fairly. Health financing, either innovative or traditional, enables these goals to be met by generating the necessary funds.

Universal health coverage links the three key pillars of a health system, i.e. revenue generation; pooling of resources; and purchasing of services. The objective of universal health coverage is improving equity in resource distribution and improving efficiency in the use of resources, which can lead to greater accessibility to quality healthcare with utilization linked to need rather than ability to pay.

See diagram below:

Financing Universal Coverage



Source: Adapted from Kutzin (2013)

SECTION 6.2

What needs to happen to increase funding for HIV treatment?

SECTION OBJECTIVE

To build community activists' understanding of what needs to happen to increase funding for HIV treatment, and the stakeholders that will play key roles.

TRAINING MATERIALS

- PowerPoint presentation '6.2 What needs to happen to increase funding for HIV treatment?'

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objective of the Section
2. Facilitate a discussion on
 - What needs to happen to increase funding for HIV treatment? For example, what kind of steps need to be taken by:
 - Local and national governments?
 - International donors?
 - Private sector donors?
3. Present the PowerPoint presentation '6.2 What needs to happen to increase funding for HIV treatment?' Encourage the participants to ask questions and make comments
4. Ask the participants to summarize the session by developing advocacy messages about 'What needs to happen to increase funding for HIV treatment?' Support their ideas by sharing examples of messages (see below)

Option B (approx. 120 minutes)

1. Explain the objective of the Section
2. Facilitate a discussion on
 - What needs to be done to increase funding for HIV treatment? For example, what kind of steps need to be taken by:
 - Local and national governments?
 - International donors?
 - Private sector donors?
3. Present PowerPoint Presentation '6.2 What needs to happen to increase funding for HIV treatment?' to add to the points raised by the participants in the discussion

4. Divide the participants into four groups. Ask each group to focus on a different type of funder for HIV treatment
 - Group 1: Local government
 - Group 2: National government
 - Group 3: International donors
 - Group 4: Private sector

Ask each group to:

- Discuss the current opportunities and challenges for mobilizing funding for HIV treatment from their funder.
 - Identify actions that community activists could take to advocate for greater funding for HIV treatment from their donor.
5. Bring all of the participants back together. Ask each group to present its work. Encourage the other participants to ask questions and make comments
 6. Ask the participants to summarize the session by developing advocacy messages about 'What needs to happen to increase funding for HIV treatment?' Support their ideas by sharing examples of messages (see below)

ADVOCACY MESSAGES

1. The current level of funding for HIV treatment is too low. Increased investment will be needed in the next few years to meet the 90-90-90 targets in 2020.
2. Funding for HIV treatment must be increased at all levels:
 - National and local governments must step-up their funding
 - All wealthy country governments must contribute their fair share
 - The private sector must continue to play its crucial role

USEFUL RESOURCES

- Financing the Response to AIDS in Low and Middle-Income Countries: International Assistance from Donor Governments in 2014, UNAIDS and Kaiser Family Foundation, 2015. Available here: <http://files.kff.org/attachment/report-financing-the-response-to-aids-in-low-and-middle-income-countries-international-assistance-from-donor-governments-in-2014>

What needs to happen to increase funding for HIV treatment?

To increase funding for HIV treatment, action is needed at three levels:

1. National and local governments must increase their funding
2. All wealthy country governments must contribute their fair share of HIV funding
3. The private sector must continue to play a central role in HIV funding
4. Greater exploration of opportunities for domestic innovative financing suitable to the country context

Each of these are described below

NATIONAL AND LOCAL GOVERNMENTS MUST STEP-UP THEIR HIV FUNDING

A total of 135 countries include the right to health – or a commitment to health – in their national constitution. Of those, 95 state that people have the right to access health facilities, goods and services, and 111 mandate the right to equal treatment or freedom from discrimination.²⁴

Those national governments have a constitutional and legal obligation to fulfill the right to health and to protect their populations from illness.

The International Monetary Fund (IMF) has set a benchmark of 15% GDP as the lower limit for government investment in health in low-income countries. To date, however, progress has been limited. For example, in Africa, only 9 countries have met this target (Lesotho, Liberia, Madagascar, Malawi, Rwanda, Swaziland, Togo, and Zambia). Several countries with large HIV epidemics – including Botswana, Kenya, South Africa, Namibia, and Zimbabwe – have not met the target.²⁵

In 2001, heads of state of African Union countries met to sign the Abuja Declaration, pledging to strive towards the target of allocating at least 15% of their government budget to the health sector.²⁶ However, in 2011, only 6 countries had been able to meet this target, including: Rwanda, Liberia, Malawi, Zambia, Togo, and Madagascar.²⁷

International donors are increasingly looking to national governments to match investments in health programs. For example, for HIV spending:

- The President's Emergency Plan for AIDS Relief (PEPFAR) now requires cost-sharing assurances of 25% from governments.
- The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) now requires governments to provide 5-60% counterpart financing, depending on the country's income.

Studies on government spending in some African countries - such as Kenya, Rwanda and Zambia - show that government spending for HIV still accounts for less than 25% of the country's total HIV expenditure, and needs to be increased.²⁸

ALL WEALTHY COUNTRY GOVERNMENTS MUST CONTRIBUTE THEIR FAIR SHARE OF HIV FUNDING

International resources for HIV – spending by donor governments, multilateral organizations and the private sector – totaled an estimated US\$8.9 billion in 2012. This was 47% of total spending on HIV programs.

More than 20 high-income countries have the potential to contribute to the global response to HIV. These include the United States of America and Canada, the countries of Western Europe, Japan, Australia and New Zealand. Many wealthy and emerging economies also have the potential to contribute, including Brazil, China, India, Mexico, Russia, South Korea and Saudi Arabia.

However, in the last few years, only five countries accounted for most (approximately 87%) of the total donor support for HIV. In 2014 (as in 2012) the U.S. was the largest donor contributing approximately two-thirds (64.5%) of donor government disbursements for HIV (US\$5.6 billion).²⁹ The U.K. was the second largest donor (12.9%), followed by France (3.7%), Germany (3.2%), and the Netherlands (2.5%).³⁰

Most international assistance for HIV is still provided bilaterally, even though bilateral funding for HIV has declined in recent years.³¹ Bilateral funding is funds that are given by high-income country governments directly to low- and middle-income countries in the form of international development aid.³² Bilateral funding accounted for 73% of HIV funding from donor governments in 2014 (US\$6.3 billion).³³ This was down \$100 million less than in 2013 (US\$6.4 billion).³⁴ The USA and UK are the largest funders of direct bilateral aid.

The remaining international government assistance (27% or US\$2.3 billion in 2014) for HIV is provided through multilateral mechanisms such as the Global Fund, UNITAID and other United Nations agencies.³⁵ In 2012, the Global Fund received US\$1.7 billion in contributions from governments and UNITAID received US\$135 million.³⁶ Four donor governments provided a majority of their funding through the Global Fund and UNITAID: Canada (65%), the European Commission (70%), France (85%) and Japan (90%).³⁷

As a result of a United Nations resolution in 1970, most of the wealthiest countries in the world have agreed to spend a target of 0.7% (US\$7 for every US\$1,000) of their Gross National Income (GNI) on international development aid. However, few countries have ever met this target, with the exception of Denmark, Luxembourg, the Netherlands, Norway and Sweden.

High-income country governments have not significantly increased international funding for HIV since 2008. In 2014, HIV-related funding from most donor governments either decreased (Australia, Canada, Denmark, France, Ireland, Sweden, and the European Commission) or remained the same (Germany and the U.S.). Increased funding for HIV programs will be needed in the 90-90-90 targets are to be met and the AIDS epidemic ended by 2030. High-income country governments have an important role to play in providing the funds to make these ambitious targets possible.

Advocacy is needed in all high-income countries to convince politicians and voters that international aid is needed. It is important to emphasize that:

- International aid is a small expenditure compared to overall national budgets. An increase in donor funding for HIV by high-income country governments and emerging economy country governments would help to end the global HIV epidemic.
- Among the many crises facing the planet - including political instability and environmental disasters - health and infectious diseases (such as HIV) remain a priority.
- Many countries - particularly in Latin America and the Caribbean, Eastern Europe and the Middle East, but also across Africa and Asia - have growing economies and are, therefore, rising into 'middle-income' status. However, due to inequality within those countries, millions of people still live in extreme poverty and desperately need international assistance.

Advocacy is also needed to create new dedicated tax revenues and private investment opportunities for international health, particularly to benefit the Global Fund, UNITAID and the Global Alliance for Vaccines and Immunizations (GAVI). GAVI already raises US\$3.7 billion each year from a financing program at the World Bank called the International Finance Facility for Immunization (IFFIm). UNITAID raises \$580 million from an airline ticket tax. Since 2010, HIV activists have been working in collaboration with many partners to get the US and the European Union to adopt a Financial Transaction Tax (or 'Robin Hood Tax') to raise as much as \$400 billion per year for international aid.

THE PRIVATE SECTOR MUST CONTINUE A CRUCIAL ROLE IN HIV FUNDING

International funding from the private sector – including foundations (charitable and corporate philanthropic organizations), corporations, faith-based organizations, international non-governmental organizations (NGOs), and individuals³⁸ – is another important source of support for HIV programs. Private philanthropic organisation provided US\$592 million towards the global HIV response in 2013, largely through foundations, faith-based organizations and international NGOs.³⁹ This was an 8% decrease from 2012.⁴⁰

The United States of America is the country with the largest number of private sector grant-makers and the largest total amount of investment. In 2012, 209 funders gave \$467 million to HIV programs. Of this amount, \$150 million was directed internationally to HIV programs not in the US. In 2013, US-based philanthropic organizations contributed 73% of the total philanthropic aid for HIV.⁴¹

In recent years, including 2012 and 2013, the Bill and Melinda Gates Foundation has been the largest US-based funder of international HIV programs, investing \$47 million in 2012.⁴² In 2013, the Gates Foundation provided 49% of all US HIV-related philanthropic funding.⁴³ Today, the Gates Foundation has donated more than US\$2.5 billion to tackling the global HIV epidemic.⁴⁴

After the Gates Foundation, the MAC AIDS Fund, Ford Foundation, Open Society Foundation (OSF), ITPC and the American Jewish World Service (AJWS) were the five largest non-pharmaceutical grant-makers, investing \$31 million in 2012. Meanwhile, AbbVie, ViiV, Johnson & Johnson, Merck and Bristol-Myers Squibb were the five largest pharmaceutical grant-makers, investing US\$39 million.

Also in 2012, a total of 38 European private sector grant-makers invested approximately US\$100 million in international HIV programs and HIV programs outside of Western and Central Europe. The largest European grant-makers were AIDS Fonds Netherlands, Children's Investment Fund Foundation (CIFF), Elton John AIDS Foundation (EJAF), Foundation la Caixa, Monument Trust, Sidaction, ViiV and Wellcome Trust.

DOMESTIC INNOVATIVE FINANCING (DIF)

As dialogue on sustainable health financing becomes prominent in the debate of long-term sustenance of national HIV-services and programs, opportunities for domestic innovative financing need to be explored.

Innovative financing for health is one part of the revenue generation function of a health system.

Domestic innovative financing (DIF) options are financing solutions and tools that will increase revenue for the health system. Types of DIF include:

- Taxes on income and profits
- Taxes on goods and services, e.g. VAT; excise tax; sin tax; trade tariffs
- Options that increase private sector participation in the financing and delivery of health services
- Debt instruments
- Other DIF for health, e.g. health lottery, crowd funding.

DIF options have the following characteristics:

Domestic: This option sees funding generated from sources within the country and managed within the country. These can include, public agencies, like ministries of health, national insurance agencies, or non-state entities who have a role to play in the health system.

Innovative: Where funding is generated by financing solutions or design change. Note, that innovative in one country may not be innovative in another.

Health: Where the funding has a health objective which, according to WHO, is an activity whose primary purpose it is to promote, restore or maintain health. This funding does not necessarily go to the health system.

ASSESSING DIF

Assessment of DIF options may be undertaken in various sections, which group related topics and questions, as follows:

DIF option definition and context:

- Understanding the particular country context
- Understanding the design features specific to that country
- Reasons for undertaking the DIF options
- Factors leading to the design
- How revenue was spent

Effectiveness and sustainability:

- How much did the DIF option generate?
- How much was additional to the health sector?
- Was it significant for the health sector?
- Time period?
- Will revenue continue at similar levels into the future?

Governance and efficacy:

- Are revenue collection structures simple or burdensome?
- Are revenue collection structures transparent?
- What costs are associated with collecting new/additional revenue through the DIF option?
- Are there institutional barriers to corruption?

Progressivity:

- Who bears the burden of supplying the additional revenue pooled and allocated to health? Is it the rich or the poor? (A 'flat' DIF option places equal burden on the rich and the poor, while a 'progressive' DIF option places a smaller burden on the poor and a larger burden on the rich).
- To what extent are similar socio-economic households burdened?

Macro-economic impact – referring to the effect of the DIF option outside of the health sector:

- How did the burden on various economic entities affect employment and competitiveness in the market?
- Was it counter to national development strategies of low and middle-income countries?
- Will the DIF option result in social welfare loss, i.e. where revenue gained through DIF options is less than that which would have been generated without an intervention?

SECTION 6.3

What are the entry points for advocacy on funding and treatment?

SECTION OBJECTIVE

To build community activists' understanding of the entry points and 'what works' for advocacy on funding and treatment.

TRAINING MATERIALS

- PowerPoint presentation '6.3 What are the entry points for advocacy on funding and treatment?'

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objective of the Section.
2. Ask the participants to think about the funding and treatment issues that have been addressed in Sections 6.1 and 6.2. Ask them to identify some examples of entry points for advocacy. Explain that an entry point is an opportunity to 'get started.' It might, for example, be a process (that provides an opportunity to influence decision-making) or a crisis (that provides an opportunity to achieve urgent change).
3. Present PowerPoint presentation '6.3 What are the entry points for advocacy on funding and treatment?'
4. Ask the participants to share other lessons learned about advocacy on funding and treatment – based on their own experiences.
5. Summarize what has been discussed and agreed during the session.

Option B (approx. 120 minutes)

1. Explain the objective of the Section.
2. Explain to the participants what is meant by an entry point for advocacy on funding and treatment. Explain that an entry point is an opportunity to 'get started.' It might, for example, be a process (that provides an opportunity to influence decision-making) or a crisis (that provides an opportunity to achieve urgent change).
3. Divide the participants into groups of about 5 people. Ask the participants to identify 1 or 2 entry points for advocacy on funding and treatment that relate to their community.
4. Bring all of the participants back together. Ask each group to present their examples of entry points. Encourage the other participants to ask questions and make comments.
5. Ask the participants to think about what type of advocacy they could carry out for the entry points that they have identified. Facilitate a discussion on:
 - 'What works' in advocacy on funding and treatment?

6. Encourage the participants to identify the lessons learned from their own experiences. Write their inputs on a flipchart.
7. Summarize what has been discussed and agreed during the session.

What are entry points for advocacy on funding and treatment?

For community activists, there are many different entry points that can be used for advocacy on funding and treatment. An entry point is an opportunity to 'get involved,' 'get going' and 'make a difference.' It is an opportunity to start discussions, influence opinions and achieve change.

An entry point might, for example, be a process (that provides an opportunity to influence decision-making) or a crisis (that provides an opportunity to achieve urgent change). Examples of entry points can be seen in the experiences of ITPC partners and other organizations throughout the world:

TABLE EXAMPLES OF ENTRY POINTS FOR ADVOCACY ON FUNDING AND TREATMENT

Examples of entry points	Examples of advocacy actions
The national government has not met the Abuja Declaration target of allocating 15% of its national budget to health.	<ul style="list-style-type: none"> • Documenting the experiences of countries with similar economies that have met the 15% target, and using them as the basis for advocacy materials. • Disseminating case studies that show the difference meeting the 15% target could make to access to treatment for people living with HIV. • Collaborating with other health organizations to present a petition to the government, urging it to meet the Abuja Declaration target.
The District Health Authority has merged its HIV budget and health budget – making it impossible to assess what funding is allocated to HIV treatment.	<ul style="list-style-type: none"> • Facilitating a meeting between the District Health Authority and people living with HIV – to explain why transparent budgeting is important. • Advocating to the Director of the District Health Authority to provide an annual breakdown of how the health budget is allocated, including the process of budgeting for the HIV response.
The national government refuses to go beyond the minimum amount of domestic funding required to receive an HIV grant from the Global Fund.	<ul style="list-style-type: none"> • Presenting the government with examples of other countries (with similar economies) that have increased their national contributions to Global Fund programs. • Facilitating meetings between the Country Coordinating Mechanism and people living with HIV to identify how and when to encourage the government to increase its domestic funding. • Sharing examples of innovative financing – to encourage the government to identify creative ways in which it could raise further funds for HIV programs. Explore examples where DIF options have been successfully used.
An international donor is going to stop direct funding for HIV work in your country as it is classified as a "middle-income country".	<ul style="list-style-type: none"> • Advocating to the donor on why funding for HIV is still needed in a Middle Income Country, such as for treatment for people living with HIV who are from marginalized groups and would, otherwise, be neglected. • Advocating to the donor to maintain or increase its support to multi-lateral funding mechanisms (such as the Global Fund).

The District Health Authority provides ARVs for free, but does not pay for other services related to treatment, such as CD4 counts.

- Compiling a breakdown of the average annual costs for a community member living with HIV – to show the level of ‘extra’ costs involved.
- Holding meetings with the District Health Authority to advocate for full funding of all treatment-related services and commodities.
- Partnering with national networks of people living with HIV to advocate for ‘treatment funding’ to always include the full package of services and commodities that are needed.

What works in advocacy on funding and treatment?

Many lessons have been learned – including by ITPC’s partners – about ‘what works’ in advocacy on funding and treatment. The following presents examples that apply to different contexts:

‘What works’ in advocacy on funding and treatment

- **DOING YOUR HOMEWORK**
For example, researching – and being able to speak confidently about – how funding for treatment has changed and/or reduced in recent years in comparison to the needs of people living with HIV.
- **SHOWING THE ‘HUMAN FACE’**
For example, translating what reduced funding for treatment means for the health and quality of life of real people living with HIV.
- **PROVIDING FINANCIAL EVIDENCE**
For example, gathering data from community groups about why their areas of work – such as treatment programs for key populations – are cost-efficient and a good investment of resources.
- **EMPHASIZING DOMESTIC AS WELL AS INTERNATIONAL FUNDING**
For example, advocating to local or national governments to fund treatment as well as advocating to international donors to maintain or increase their investments.
- **‘TALKING THE TALK’ OF FUNDING**
For example, talking about the funding of treatment in terms of ‘front-loading investment’ and ‘value for money’, as emphasized in key approaches to HIV supported by donors, such as the Fast-Track approach.
- **ENCOURAGING FLEXIBLE AND INNOVATIVE FUNDING**
For example, not always ‘demanding more money’, but advocating for how funding for treatment could come from a wider range of sources or how it could be used more efficiently.
- **PARTNERING WITH FUNDING ALLIES**
For example, identifying the stakeholders that make decisions about funding for treatment and identifying partners that can help you to get their attention and influence their understanding of the issue and how to solve it.
- **BUILDING SKILLS AND INVOLVEMENT IN BUDGET TRACKING**
For example, becoming familiar with processes for national budgeting on health, and identifying when and how the process can be influenced.

Endnotes

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7 COMMUNITY ADVOCACY PLANNING FOR INCREASED ACCESS TO OPTIMAL HIV TREATMENT

INTRODUCTION	
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Welcome to **Module 7: Community Advocacy Planning** of the Advocacy for Community Treatment (ACT) Toolkit of the International Treatment Preparedness Coalition (ITPC)

The aim of **Module 7** is to support community activists to build on the previous modules of the ACT Toolkit – by making the HIV treatment world relevant to their specific context, identifying their priorities and developing a community advocacy plan.

Section 7.1

What is advocacy for community treatment?

SECTION OBJECTIVE

To build community activists' understanding of what is meant by advocacy for community treatment and how it benefits people living with HIV (PLHIV), including those from key populations.

TRAINING MATERIALS

- PowerPoint presentation '7.1 What is advocacy for community treatment?'
- Flipcharts and pens

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objective of the Section.
2. Facilitate a brief group discussion on:
 - What does 'advocacy for community treatment' mean?
3. Present PowerPoint presentation '7.1 What is advocacy for community treatment?' As you get to each question, ask the participants if anything is unclear, or if they have anything to add.
4. Facilitate a group discussion about the participants' own experiences of doing community advocacy for treatment or similar issues. Ask them to share examples of their work and to identify the factors that made their work successful or unsuccessful. Write the 'success factors' on a flipchart.
5. Ask the participants to summarize what has been discussed and agreed during the session.

Option B (approx. 120 minutes)

1. Explain the objective of the Section.
2. Facilitate a group discussion on:
 - What does 'advocacy for community treatment' mean?
3. Put sheets of flipchart paper on the wall in three different places in the room. Write one question on top of each sheet:
 - What type of activities does advocacy for community treatment involve?
 - What type of stakeholders does advocacy for community treatment target?
 - What benefits does advocacy for community treatment bring?
4. Give the participants marker pens. Ask them to move around the three places in the room and write their ideas underneath each question.
5. Bring all of the participants back together. Go through the answers that they have written to the three questions.
6. Divide the participants into small groups of about 5 people. Ask the members of each group to share their real life examples or stories of successful community advocacy on treatment or similar issues. Ask them to think about what factors contributed to the success of the work.

7. Bring all of the participants back together. Ask them to briefly summarize what they discussed in their groups and to share the factors that contributed to the success of their community advocacy work.
8. Write the 'success factors' on a flipchart – to provide a guide that the participants can use to support their work.
9. Summarize what has been discussed and agreed during the session.

USEFUL RESOURCES

- *HIV, Health & Rights: Sustaining Community Action*, International HIV/AIDS Alliance, 2016. http://www.aidsalliance.org/assets/000/002/457/FINAL_Strategy_2016-2020_WEB_original.pdf?1457345491
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What Does 'Advocacy for Community Treatment' Mean?

There is no one agreed definition of community advocacy. However, in general, it involves:

- Community members coming together and taking action.
- Identifying priority issues that affect access to treatment for PLHIV.
- Identifying what change is needed, such as in policies, laws and services – to address those priority issues
- Working with other individuals and groups that have similar concerns.
- Targeting individuals, groups and institutions that can influence change.
- Achieving results that make a difference to the people most affected by HIV-related issues.

Community advocacy is about caring for an issue deeply enough to stand up and say that something needs to change. In practice, almost all community activists do some type of advocacy work - even if they don't use the word 'advocacy'!

Advocacy by communities has been key to action on HIV throughout the world. In particular, advocacy by PLHIV – including those from key populations - has brought about dramatic changes and improvements in antiretroviral therapy (ART).

What Type of Activities does Advocacy for Community Treatment Involve?

Community advocacy can take many forms, depending on the needs of the community and the political and financial context. It can involve a wide range of activities. Examples include:

- **PARTICIPATING IN DECISION-MAKING FORUMS**
Examples include: Community Advisory Boards, District Planning Communities, Country Coordinating Mechanisms or National AIDS Councils.
- **LOBBYING**
Examples include: holding meetings with parliamentarians or the District AIDS Director.
- **USING ADVOCACY MATERIALS**
Examples include: developing a position paper on an issue and handing it to selected decision-makers.
- **USING CAMPAIGNING METHODS.**
Examples include: handing petitions (signed by community members) to decision-makers or organizing marches or public rallies.
- **WORKING THROUGH THE MEDIA**
Examples include: writing a press release, doing a media interview or writing a blog.

What Type of Stakeholders Does advocacy for Community Treatment Target?

Advocacy for community treatment can involve action at many different levels – community, district, regional, national and global.

It can also focus on a range of different targets – for instance, individuals or organizations that are in a position to make a difference to the issue and influence the change that is needed. Examples include:

- Community leaders and decision-makers
- Community health services
- Local government departments
- Religious institutions
- Members of Parliament
- National government Ministers, Ministries or Departments
- Law-making agencies
- Donor organizations
- Law-enforcement agencies, such as the police
- Businesses, including pharmaceutical companies
- International non-governmental organizations (NGOs)
- Trade unions
- United Nations agencies

What Type of Benefits does Advocacy for Community Treatment Bring?

Advocacy for community treatment can bring about important changes. Depending on the context – and on factors such as the time and resources available – these changes might be small or large. However, they all benefit those who need access to treatment – namely, PLHIV, especially those from key populations.

Some of the many benefits that advocacy for community treatment can bring include:

- Lowering the cost of antiretrovirals (ARVs) and medicines for opportunistic infections, such as by pushing for cheaper prices from pharmaceutical companies.
- Ensuring appropriate funding for ART, such as by advocating for adequate resources for HIV treatment in the District Health Strategy.
- Increasing the quality of ART, such as by educating people on the dangerous side effects of low quality drugs.
- Ensuring wider availability of ART, such as by advocating for treatment to be integrated with sexual and reproductive health services.
- Ensuring better access to treatment for key populations, such as by campaigning for the removal of policies that discriminate against these groups.
- Ensuring non-stigmatizing ART services, such as by advocating for training on human rights for local health workers.

What are the Characteristics of Successful Advocacy for Community Treatment?

The experiences of ITPC and its partners around the world show that there are specific factors that contribute to successful advocacy for community treatment. Examples of these 'success factors' include advocacy work that is:

- **BASED ON EVIDENCE** – so that it responds to the real needs of community members, especially PLHIV and key populations.
- **OWNED AND RUN BY COMMUNITY ACTIVISTS** – so that activists feel committed to and in control of the work.
- **CARRIED OUT BY A GROUP OF ACTIVISTS** – so that the work is not over-dependent on one or two individuals.
- **WELL-PLANNED** – so that it is strategic and makes the best use of the resources available, especially where those resources are limited.
- **FOCUSED** – so that it makes (or recommends) concrete changes, even if they are small.
- **REALISTIC** – so that it focuses on changes that are actually possible within the local context and with the resources that are available.
- **CREATIVE** – so that it suits community advocacy and makes the best use of local ideas.

SECTION 7.2

What are your opportunities and barriers for advocacy for increased access to optimal treatment?

SECTION OBJECTIVE

To support community activists to make the treatment world relevant to their specific context and to analyze their opportunities and barriers for advocacy for community treatment.

TRAINING MATERIALS

- PowerPoint presentation '7.2 What are your opportunities and barriers for advocacy for increased access to optimal treatment?'
- Flipchart and pens

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objective of the Section.
2. Present PowerPoint presentation '7.2 What are your opportunities and barriers for advocacy for increased access to optimal treatment?' Stop the presentation on the last slide – showing the chart of opportunities and barriers.
3. Facilitate a discussion to fill in the chart, either by typing text into the PowerPoint slide or by drawing the chart on flipcharts on the wall. Go through each of the four areas addressed in Parts 3-6 of the ACT Toolkit and ask the participants to identify the opportunities and barriers.
4. Summarize what has been discussed and agreed during the session.

Option B (approx. 120 minutes)

1. Explain the objective of the Section.
2. Divide the participants into four groups. Give each group one of the areas addressed in the previous modules of the ACT Toolkit:
 - Treatment initiatives
 - Human rights and treatment
 - Trade and treatment
 - Financing and treatment
3. Ask each group to recall the 'headlines' for their area (i.e. what key issues it addressed and why it is important for access to treatment).
4. Ask each group to draw the following chart on a flipchart:

PART	OPPORTUNITIES	BARRIERS
------	---------------	----------

5. Ask each group to write their Part in the first column.

6. Then ask each group to discuss the key 'opportunities' and 'barriers' that their area presents for access to HIV treatment in their community. Explain that:
 - An opportunity is a time or set of circumstances that makes it possible to achieve positive change. It is a 'chance,' 'entry point,' 'right time' or 'good moment.'
 - A barrier is something that makes it difficult or impossible to achieve positive change. It might also make the current situation worse. It is an 'obstacle,' 'obstruction,' 'bottleneck' or 'blockage.'
7. Ask each group to write their opportunities and barriers in the second and third columns of their chart.
8. Bring all of the groups back together. Ask each group to provide feedback on their work – first sharing the 'headlines' from their area, then their chart of opportunities and barriers.
9. Place the four charts together on the wall – as a giant chart of opportunities and barriers. Facilitate a discussion about the giant chart. For example, ask the participants:
 - What does it show us about the number of opportunities versus the number of barriers?
 - What does it tell us about which areas have the largest number and/or more significant opportunities or challenges?
10. Ask the participants to summarize what has been discussed and agreed during the session.

USEFUL RESOURCES

- *The Equity Deficit: Unequal and Unfair Access to HIV Treatment, Care and Support for Key Affected Communities*, Report by the NGO Delegation, 33rd Meeting of the UNAIDS Programme Coordinating Body, December 2013. Available here: http://files.unaids.org/en/media/unaids/contentassets/documents/pcb/2013/pcb33/agendaitems/20131206_PCB-NGO-report.pdf
- *It Takes a Village: Empowering Communities to Fight HIV*, USAID, July/August 2013. Available here: <https://www.usaid.gov/news-information/frontlines/economic-growth/it-takes-village-empowering-communities-fight-hiv>
- *Policy Brief: Access Challenges For HIV Treatment Among PLHIV and Key Populations in Middle-Income Countries*, Global Network of PLHIV, Global Network of Sex Work Project, International Network of People Who Use Drugs, Global Forum on MSM and HIV and ITPC, October 2013. Available here: http://www.gnpplus.net/assets/Access_Challenges_for_HIV_treatment_among_PLHIV_and_KAPs_in_MICs_Policy_brief-copy.pdf

How do you make the Treatment World Relevant to Your Own Context?

Modules 3-6 of the ACT Toolkit focused on four of the key areas that make up today's 'treatment world':

1. Treatment initiatives
2. Trade and treatment
3. Human rights and treatment
4. Financing and treatment

Each of these areas is complex. Each area involves many different issues, levels and stakeholders.

It is important to understand what each of these areas - and the 'treatment world' as a whole - means for you and your community. For example: Are all of the areas important? Are any of the areas in crisis? Which of the areas are open to change? Which areas make the biggest difference to the lives of PLHIV, including those from key populations?

What are the major **opportunities** and **barriers** for advocacy for community treatment in your context?

An **opportunity** is a time or set of circumstances that makes it possible to achieve positive change. It is a ‘chance,’ ‘entry point,’ ‘right time’ or ‘good moment.’

A **barrier** is something that makes it difficult or impossible to achieve positive change. It might also make the current situation worse. It is an ‘obstacle,’ ‘obstruction,’ ‘bottleneck’ or ‘blockage.’

Different communities face different opportunities and barriers for access to HIV treatment. These might depend on factors such as:

- The stage of the HIV epidemic
- The level of resources available
- The human rights situation
- The political environment

One way to start making the ‘treatment world’ relevant to your context is to identify your community’s major opportunities and barriers for access to treatment. This can be done by using a simple chart, such as this one:

CHART OPPORTUNITIES AND BARRIERS IN THE ‘TREATMENT WORLD’

	Opportunities	Barriers
Treatment initiatives		
Trade and treatment		
Human rights and treatment		
Funding and treatment		

SECTION 7.3 What are your priorities for advocacy for increased access to optimal treatment?

SECTION OBJECTIVE

To enable community activists to identify clear and strong priorities for their advocacy for community treatment.

TRAINING MATERIALS

PowerPoint presentation ‘7.3 What are your priorities for advocacy for increased access to optimal treatment?’

Option A (approx. 60 minutes)

1. Explain the objective of the Section.
2. Present PowerPoint presentation ‘7.3 What are your priorities for advocacy for increased access to optimal treatment?’ When you have finished, keep the final slide showing – that provides a checklist for identifying priorities. Ask the participants if they have anything to add to the checklist.
3. Ask the participants to consider everything that they discussed in Section 7.2 and to re-cap the opportunities and barriers that they identified. Ask them to identify the opportunities or barriers that stand out for them – in other words, the most important barriers and opportunities that make the biggest difference to access to treatment in their community.
4. Support the participants to use the checklist that was included in the presentation to consider the ‘top’ opportunities and barriers that they have identified. Participants should then select a priority for their advocacy for community treatment.
5. Ask the participants to confirm their decision by clearly and simply stating:
 - Their priority issue for advocacy for community treatment
 - Their reason for choosing this issue as the priority issue
6. Ask the participants to summarize what has been covered and agreed during the session.

Option B (approx. 120 minutes)

1. Explain the objective of the Section.
2. Facilitate a discussion about:
 - “Why it is important” to identify priorities for advocacy for community treatment.
3. Divide the participants into small groups of about 5 people. Ask each small group to develop a checklist of criteria for identifying priorities for advocacy for community treatment. Explain that a checklist has criteria (key questions) to support the selection of the clearest and strongest priorities.
4. Bring all of the participants back together. Ask each small group to share its ideas for a checklist. Use the different ideas to develop a joint checklist. Write the checklist on a flipchart.

5. Ask the participants to consider everything that they discussed in Section 7.2 and to re-cap the opportunities and barriers that they identified. Ask them to develop a short-list of issues for advocacy – in other words, the issues that ‘stand out’ as the most important and likely to make the greatest difference in their community.
6. Ask the participants to use the joint checklist to analyze their shortlist and identify a priority for advocacy for community treatment.
7. Present PowerPoint presentation ‘7.3 What are your priorities for advocacy for increased access to optimal treatment?’ Ask the participants to discuss whether the presentation caused them to change anything about their priorities.
8. Ask the participants to confirm their decision by clearly and simply stating:
 - Their priority issue for advocacy for community treatment
 - Their reason for choosing this issue as the priority issue
9. Ask the participants to summarize what has been covered and agreed during the session.

USEFUL RESOURCES

- *EMPowerment for Advocacy (EMPAD), International HIV/AIDS Alliance, 2014.* Available here: http://www.aidsalliance.org/assets/000/000/409/90667-Empowerment-for-Advocacy-Framework_original.pdf?1405586678
- *Measuring Up - A Guide for Learners: HIV-related Advocacy Evaluation Training for Civil Society Organisations, International Council of AIDS Services Organisations and International HIV/AIDS Alliance, 2010.* Available here: <http://www.icaso.org/publications/2011/Measuring-up-learners-30.09.10.pdf>

Why do we Need Priorities for Advocacy for Community Treatment?

Communities often face many different types of opportunities and barriers in accessing treatment, especially for key populations. However, they can rarely address all of these issues at once. That is why it is important to set priorities.

Having clear priorities enables community activists to work towards these priorities and make the biggest difference. It also enables activists to make the best use of their resources – including their energy, time, skills and funding).

How do you Select Priorities for Advocacy for Community Treatment?

One way to set priorities is to develop a checklist. This has criteria (key questions) to support the selection of the clearest and strongest priorities possible. See the example below:

CHART CHECKLIST FOR SELECTING ADVOCACY PRIORITIES

	Criteria (key question)	Y or N
1	Will the issue bring benefits to PLHIV?	
2	Is the issue clear ? (For example, will we be able to explain it to people easily?)	
3	Can the issue be solved through advocacy ?	
4	Do we have ideas about who could bring change to the issue?	
5	Do we have ideas of what could be done to make a difference to the issue?	
6	Do we have the right resources (such as expertise/skills) to advocate on the issue?	
7	Are we the right people to advocate on the issue? (For example, will our work be respected or should we support the advocacy of other stakeholders instead?)	

SECTION 7.4 How do you develop a Plan for Advocacy for Increased Access to Optimal Treatment?

SECTION OBJECTIVE

To build community activists’ skills in developing a plan for advocacy for community treatment.

TRAINING MATERIALS

- PowerPoint presentation ‘7.4 How do you develop a Plan for Advocacy for Increased Access to Optimal Treatment’
- Handout of the advocacy cycle
- Handout of the advocacy planning chart
- Flipchart and pens

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objective of the Section.
2. Facilitate a brief group discussion on:
 - Why does planning for advocacy for community treatment matter?
3. Present PowerPoint presentation '7.4 How do you develop a Plan for Advocacy for Increased Access to Optimal Treatment?' After you have completed it, return to the slide showing the advocacy planning chart.
4. Remind the participants of the advocacy priority that they identified in Section 7.3.
5. Go through each part of the advocacy planning chart and ask the participants to complete it. Remind them to make sure that everything in the chart:
 - Contributes towards their advocacy priority (and makes a difference to PLHIV)
 - Is appropriate for advocacy work
 - Is feasible (in other words, is realistic considering their resources)
6. Complete the advocacy planning chart – either by typing the information into the PowerPoint slide or drawing the chart on a flipchart.
7. When the advocacy planning chart is complete, ask the participants to review it. For example, ask them:
 - Is this plan something that we want to and will achieve?
 - Will this advocacy work make a difference to PLHIV in our community?
8. Ask the participants to summarize what has been covered and agreed during the session.

Option B (approx. 120 minutes)

1. Explain the objective of the Section.
2. Facilitate a group discussion about:
 - Why does planning for advocacy for community treatment matter?
3. Encourage the participants to briefly share the lessons they have learned about the importance of planning other types of action to address HIV-related issues.
4. Divide the participants into small groups of about 5 people. Give each participant a handout of the advocacy cycle. Ask each group to look at the cycle and discuss what each step might involve.
5. Bring all of the groups back together. Go through the advocacy cycle, asking the participants to share what their groups discussed about each step.
6. Present PowerPoint presentation '7.4 How do you develop a Plan for Advocacy for Increased Access to Optimal Treatment?' to support the information provided by the participants. Check if the participants have any further questions or issues to clarify about the advocacy cycle.
7. Divide the participants into the same small groups. Give each participant a handout of the advocacy planning chart. Ask each group to look at the chart and discuss what each part might involve.
8. Bring all of the participants back together.
9. Remind the participants of the advocacy priority that they identified in Section 7.3.

10. Go through each part of the advocacy planning chart and ask the participants to complete it. Remind them of the need to ensure that everything in the chart:
 - Contributes towards their advocacy priority (and will make a difference for PLHIV)
 - Is appropriate for advocacy work
 - Is feasible (in other words, is realistic considering their resources)
11. When the advocacy planning chart is complete, ask the participants to review it. For example, ask them:
 - Is this plan something that we want to and will achieve?
 - Will this advocacy work bring an important change to PLHIV in our community?
12. Ask the participants to summarize what has been covered and agreed during the session.

USEFUL RESOURCES

- *Advocacy in Action*, International HIV/AIDS Alliance, 2003. Available here: http://www.aidsalliance.org/assets/000/000/790/adv0602_Advocacy_toolkit_eng_original.pdf?1407150117
- *Measuring Up - A Guide for Learners: HIV-related Advocacy Evaluation Training for Civil Society Organisations*, International Council of AIDS Services Organisations and International HIV/AIDS Alliance, 2010. Available here: <http://www.icaso.org/publications/2011/Measuring-up-learners-30.09.10.pdf>
- *Invest in advocacy: Community participation in accountability is key to ending the AIDS epidemic*, UNAIDS, 2016. http://www.unaids.org/sites/default/files/media_asset/JC2830_invest_in_advocacy_en.pdf

Why does planning for advocacy on community treatment matter?

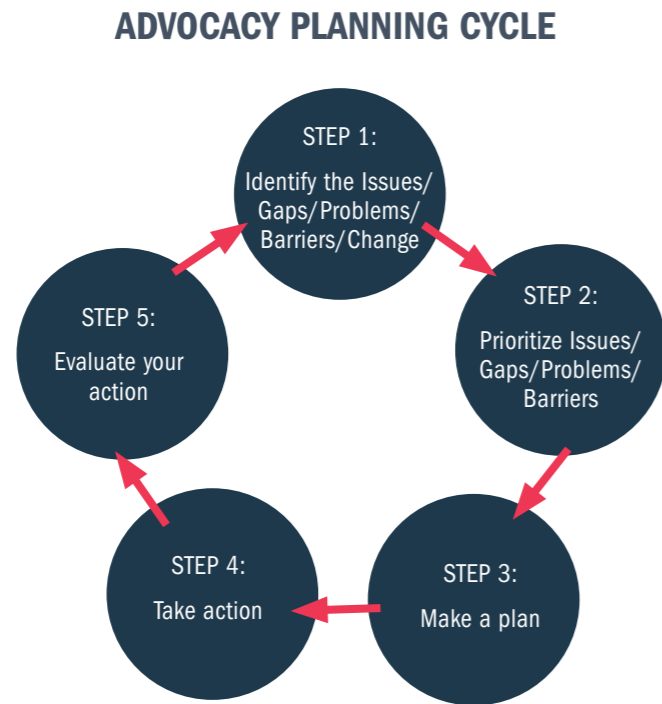
As with all action on HIV, it is important to plan advocacy work. If your work is planned carefully, it is more likely to:

- Be carried out efficiently (in other words, without wasting time and effort)
- Make the best use of your resources (such as your funding)
- Achieve its goal – because your activities will be specifically selected to meet your objectives.

What does an advocacy cycle look like?

There is no one fixed way to develop an advocacy plan. Where possible, activists should use planning frameworks that they already know, from previous experience doing program and project work.

One way to think about this type of work is as an advocacy cycle. As shown below, this takes you through five planning steps:



Step 1: Identify the issues, gaps, problems and barriers

Before any advocacy work begins, you must know the extent of the problem. You could read documents and reports, but these do not always give a true reflection of the nature of the problem, or they may not contain specific information about your area.

You could ask questions, such as:

- What are the issues, gaps, problems and barriers?
- What are the causes of these issues, gaps, problems and barriers?
- What are the effects of these issues, gaps, problems and barriers?

Note that the process of identifying the barriers for access to treatment was addressed in Section 7.2.

Step 2: Prioritize the issues, gaps, problems and barriers to deal with

This involves exploring questions such as:

- Which opportunities and barriers are the most important?
- Which are we best placed to advocate on?
- How can we bring the greatest benefit to PLHIV?

Priority setting was addressed in Section 7.3.

Step 3: Make a Plan

This involves setting out what you want to achieve and how you will do it. This can be done using an advocacy planning chart:

GOAL: THIS IS THE LONG-TERM RESULT THAT WE WANT TO ACHIEVE

For example, see the advocacy planning chart below which addresses the following issue: 'Sex workers living with HIV have full and equal access to ART at local government clinics'

Objectives	Activities	When	Targets	Partners	Resources
This is a short-term goal that contributes to achieving your long-term goal	These are the advocacy actions that you will take to achieve your objective	This is the time period when the advocacy actions will take place	These are the people, organizations or institutions that you will target to help us bring about the change that we want	These are our supporters who you will work with to carry out your advocacy	These are the resources (such as people, time, money and skills) needed to do your advocacy

Step 4: Take Action

This involves putting your advocacy plan into action. As described in Section 7.4 it might involve strategies such as lobbying parliamentarians, holding demonstrations or working with the media.

Step 5: Evaluate Your Work

This involves exploring questions such as: How effective has our advocacy been? What are the results? What did and did not work? Should anything have been done differently?

SECTION 7.5.

How do you Develop Messages for Advocacy for Increased Access to Optimal Treatment?

SECTION OBJECTIVE

To build community activists' skills in developing strong and clear messages to support their priorities for advocacy for community treatment.

TRAINING MATERIALS

- PowerPoint presentation '7.5 How do you Develop Messages for Advocacy for Increased Access to Optimal Treatment?'
- Flipchart and pens

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objective of the Section.
2. Present PowerPoint presentation '7.5. How do you Develop Messages for Advocacy for Increased Access to Optimal Treatment?' When you have finished, keep showing the last slide that lists the characteristics of a good advocacy message.

3. Remind the participants of the advocacy priority that they identified (see Section 7.3) and the advocacy plan that they developed, including their targets (see Section 7.4).
4. Support the participants to use the characteristics of a good advocacy message to develop messages for their advocacy priorities.
5. Write the advocacy messages on a flipchart. Give the participants feedback on ways that they could strengthen their messages.
6. Summarize what has been discussed and agreed during the session.

Option B (approx. 120 minutes)

1. Explain the objective of the Section.
2. Facilitate a discussion on:
 - What is an advocacy message and how can it be used?
3. Ask the participants to suggest the characteristics of a good advocacy message. Write their ideas on a flipchart.
4. Remind the participants of the advocacy priorities that they have identified (see Section 7.3) and the advocacy plan that they have developed, especially their targets (see Section 7.4).
5. Divide the participants into small groups of about 5 people. Ask each group to use the characteristics that they identified to develop a message for their advocacy priority.
6. Bring all of the participants back together. Ask each group to present their advocacy message. Support the participants to decide which of the messages is the clearest and strongest.
7. Ask for two participants to volunteer to take part in a role-play. Ask the first volunteer to play the part of a community activist (i.e. themselves). Ask the second volunteer to play the advocacy target (i.e. the person or organization that was identified in the advocacy planning chart in Section 7.4).
8. Facilitate a role-play where the community activist uses his/her advocacy message during a meeting with the advocacy target.
9. Ask the other participants to give feedback to the volunteers, such as on how the advocacy message could have been used more effectively.
10. Repeat the role-play with other pairs of volunteers and with different types of advocacy targets.
11. Present PowerPoint presentation '7.5. How do you Develop Messages for Advocacy for Increased Access to Optimal Treatment?' and summarize what has been discussed and agreed during the session.

USEFUL RESOURCES

- *Advocacy in Action*, International HIV/AIDS Alliance, 2003. http://www.aidsalliance.org/assets/000/000/790/adv0602_Advocacy_toolkit_eng_original.pdf?140715011

What is an Advocacy Message?

Messages are an important tool for advocacy work. They summarize what community activists are asking for and communicate it to their target audience.

Advocacy messages can be communicated in a number of different ways. These include in briefing papers, media interviews, speeches, blogs and meetings with decision-makers.

Developing an Advocacy Message

Some of the characteristics of a good message for advocacy for community treatment are that it is:

SHORT – it can be said in under 20 seconds

- **FOCUSED** – it is clearly related to the advocacy priority
- **SIMPLE** – it uses straightforward language and avoids specific terminology/jargon
- **TARGETED** – it is appropriate and relevant to the advocacy audience
- **POWERFUL** – it convinces stakeholders that the issue matters and why they must take action
- **AGREED** – it is supported by all those who need to use it

SECTION 7.6.

Advocating for treatment monitoring using routine viral load testing

SECTION OBJECTIVES

The aim of this section is to learn how to demand Routine Viral Load Testing in your community, through advocacy. This section will examine the advocacy cycle, discuss entry points for advocacy, share existing advocacy resources and provide you with an opportunity to develop your own advocacy plan for access to routine viral load testing.

TRAINING MATERIALS

PowerPoint presentation 7.6: Advocating for treatment monitoring using routine viral load testing

TRAINING OPTIONS

Option A (approx. 90 minutes)

Explain the objective of the Section.

1. Show the MSF HIV Status: Undetectable video
2. Show the ITPC Be Healthy, Know your Viral Load video.
3. Facilitate a discussion with participants about why routine viral load testing is needed.
4. Present PowerPoint presentation 7.6: Advocating for treatment monitoring using routine viral load testing.
5. Break away sessions: Divide participants into groups, according to their organization, country or region. Ask each group to develop an advocacy plan (30 minutes) and to present back to the group (5 minutes each).

Option B (approx. 120 minutes)

1. Explain the objective of the Section.
2. Show the MSF HIV Status: Undetectable video.
3. Show the ITPC Be Healthy, Know your Viral Load video.
4. Facilitate a discussion with participants about why routine viral load testing is needed.
5. Present PowerPoint presentation 7.6: Advocating for treatment monitoring using routine viral load testing.
6. Break away sessions: Divide participants into groups, according to their organization, country or region. Ask each group to develop an advocacy plan (30 minutes) and to present back to the group (5 minutes each).
7. Allow for discussion at the end of each presentation, where groups can give feedback on each other's advocacy plans.
8. Ask the participants to summarize the session by developing advocacy messages about the importance of monitoring HIV treatment.

ADVOCACY MESSAGES

- It is important to understand your current situation before starting an advocacy intervention. This will help you identify the barriers that exist, and will help you to decide what issues to address first.
- Demand routine viral load testing. It is your right to know if your ARV treatment is working.
- By investing in routine viral load testing now, overall treatment costs can be reduced because fewer people would be unnecessarily switched to more expensive second-line treatment. Costs could also be reduced if viral load testing completely replaced CD4 testing.
- Working in partnership with organizations that have similar goals to your organization can be an effective way of sharing tasks and increasing the impact of your work.
- If evidence shows that a specific model of care works effectively in one place, you can advocate for it to be implemented in another part of the world, where the context is similar.
- Using personal stories about the impact of an advocacy issue can be an effective way to demonstrate the importance of such an issue to decision-makers.

USEFUL RESOURCES

- Video: *HIV Status: Undetectable*. A film by Médecins Sans Frontières. Available here: <http://www.msf.org/en/article/video-hiv-status-undetectable>
- Video: *Be Healthy, Know Your Viral Load*. A film by ARASA and ITPC. Available here: <https://www.youtube.com/watch?v=y3efVSfRBUC>
- Resources from the *Be Healthy: Know Your Viral Load campaign*. Available here: <http://www.knowyourviralload.org/language/en/resources/>
- *Advocacy in Action: A Toolkit to Support NGOs and CBOs Responding to HIV/AIDS*, International HIV/AIDS Alliance, 2002. Available here: http://www.aidsalliance.org/assets/000/000/790/adv0602_Advocacy_toolkit_eng_original.pdf?1407150117

- *Undetectable: How Viral Load Monitoring can Improve HIV Treatment in Developing Countries*. Médecins Sans Frontières. Available here: http://www.msfaccess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/MSF_ViralLoad_Report_FINAL_Sept2012_webres.pdf
- *Measuring Up: A Guide for Learners: HIV-Related Advocacy Evaluation Training for Civil Society Organisations*. International Council of AIDS Services Organisations and International HIV/AIDS Alliance, 2010. Available here: <http://www.icaso.org/publications/2011/Measuring-up-learners-30.09.10.pdf>

What is Viral Load?

A viral load test measures the number of HIV viral particles per milliliter of blood. A low viral load indicates that treatment is effective. A high viral load in a person on treatment indicates either that the medication is not being taken properly or that the virus is becoming resistant to the medication. The goal of antiretroviral therapy is viral suppression—viral load that is so low that it cannot be detected by viral load tests.¹

What does Advocating for Routine Viral Load Testing Mean

Community advocacy is about caring for an issue deeply enough to stand up and say that something needs to change. Advocacy by communities, and by PLHIV in particular, has been key to improving access to HIV treatment and care throughout the world. Advocacy has also brought about significant improvements in antiretroviral therapy.

Just as activists and communities fought for their right to access the best medicines for HIV, we now have the opportunity to demand that routine viral load testing be made available to all.

Characteristics of Successful Advocacy for Routine Viral Load Testing

We have already discussed the characteristics of successful advocacy for community treatment above. These are key factors that contribute to successful advocacy. These factors are equally important for advocacy for routine viral load testing. Advocacy work should be:

- **BASED ON EVIDENCE** – so that it responds to the real needs of community members, especially PLHIV and key populations.
- **OWNED AND RUN BY COMMUNITY ACTIVISTS** – so that activists feel committed to and in control of the work.
- **CARRIED OUT BY A GROUP OF ACTIVISTS** – so that the work is not over-dependent on one or two individuals.
- **WELL-PLANNED** – so that it is strategic and makes the best use of the resources available, especially where those resources are limited.
- **FOCUSED** – so that it makes (or recommends) concrete changes, even if they are small.
- **REALISTIC** – so that it focuses on changes that are actually possible within the local context and with the resources that are available.
- **CREATIVE** – so that it suits community advocacy and makes the best use of local ideas.

Creating an Advocacy Plan for Routine Viral Load Monitoring

The process for creating an advocacy plan for community treatment was discussed in Section 7.4. The same process can be used to develop an advocacy plan for Routine Viral Load Monitoring. The suggested steps are provided below.

Step 1: Conduct baseline research – identify opportunities & barriers

Step 2: Select a priority

Step 3: Make an action plan

Step 4: Take action

Step 5: Evaluate action

STEP 1: CONDUCT BASELINE RESEARCH – IDENTIFY OPPORTUNITIES AND BARRIERS

Before any advocacy work begins, you must know the extent of the problem. You could read documents and reports, but these do not always give a true reflection of the nature of the problem, or they may not contain specific information about your area.

Instead, you could ask questions, such as:

- What do my country's ARV guidelines say about making routine viral load testing available?
- Do our guidelines meet the recommendations made by the World Health Organization?
- Is viral load testing offered free of charge or is there a cost involved to the person living with HIV?
- Have PLHIV in my community/country been able to access a viral load test, if they request one?
- Is viral load testing routinely done by health care providers?
- Is there a stable supply of viral load tests available?
- Does my country/community have the laboratory infrastructure required to provide viral load test results?

Community monitoring is another way of finding out what the current state of access to viral load testing is in your community. Community monitoring takes place when members of a community conduct research themselves about an issue. It can involve asking other community members about their experience of accessing a service.

Below is a list of questions you could ask PLHIV at a health service:

1. Do you know what a viral load test is? Do you know what it measures?
2. Have you ever been offered a viral load test by your healthcare provider?
3. Have you ever taken a viral load test?
4. How often is your viral load tested?
5. Have you ever had a problem accessing viral load testing?

Answers to these questions will give you an idea of the following:

- If viral load testing is available in your community
- If viral load testing is done routinely in your community
- If there are any supply issues in terms of accessing viral load testing in your community
- If PLHIV in your community are well-informed about routine viral load testing

Once you know the extent of the problem, you can identify opportunities and barriers for change. This involves asking questions such as: What are the specific opportunities and barriers to advocating for routine viral load testing? What are the reasons routine viral load testing is not available?

An opportunity is a time or set of circumstances that makes it possible to achieve positive change. It is a 'chance,' 'entry point,' 'right time' or 'good moment.' For example, an opportunity to advocate for routine viral load testing could be when the World Health Organization announces guidelines that recommend routine viral load testing. Another opportunity could be when a new scientific article shows the benefits of routine viral load testing.

A **barrier** is something that makes it difficult or impossible to achieve positive change. It might also make the current situation worse. It is an 'obstacle,' 'obstruction,' 'bottleneck' or 'blockage.'

Your **opportunities** and barriers might depend on factors such as: the scale of the HIV epidemic; the level of resources available; the human rights situation; the political environment.

List all your potential opportunities and barriers for advocating for routine viral load testing.

Challenges for scaling up routine viral load testing:

It is important to understand why routine viral load testing is essential. This understanding will help you to advocate for viral load testing to be made available to all PLHIV. You also need to understand the challenges for scaling up routine viral load testing – in other words, increasing the accessibility of this testing. This will help inform the advocacy plan you decide to implement.

- Viral load testing can be expensive for governments. However, it is important to note that by investing in routine viral load testing, overall costs of HIV treatment can be reduced because it means that fewer people are unnecessarily switched to more expensive second-line treatment. Costs could also be reduced if viral load testing completely replaced CD4 testing.
- The infrastructure required to conduct viral load testing is complex. This infrastructure includes laboratory equipment and trained staff to analyze results. A point-of-care viral load test is needed – in other words, a test that requires no electricity, operates via finger-prick whole blood, requires no refrigeration, is battery operated, requires simple training, can be operated by a community health worker, and with a lower cost of testing compared to laboratory-based tests.
- Health care providers are not always motivated to follow protocols and there may be a shortage of skilled healthcare workers to do the VL test and counsel the patients.
- Many PLHIV and health care providers do not know of the importance of viral load testing for monitoring HIV treatment. Many people still believe that CD4 testing is the best way to monitor if HIV treatment is working. However, PLHIV on antiretroviral therapy with routine viral load monitoring have better health outcomes than people monitored only with CD4 testing.²

STEP 2: SELECT A PRIORITY

This involves exploring questions such as:

- Which opportunities and barriers are the most important?
- Which are we best placed to advocate on?
- How can we bring the greatest benefit to PLHIV?

Communities often face many different types of opportunities and barriers in accessing treatment. However, they can rarely address all of these issues at once. That is why it is important to set priorities.

Having clear priorities enables community activists to work towards these priorities and make the biggest difference. It also enables activists to make the best use of their resources – including their energy, time, skills and funding.

One way to set priorities is to develop a checklist. A checklist has criteria (key questions) to support the selection of the clearest and strongest priorities possible. See the example next page:

Table: Checklist criteria

Criteria	Yes	No
Will the issue bring positive benefits to people living with HIV?		
Is the issue clear? (For example, will we be able to explain it to people easily?)		
Can the issue be solved through advocacy?		
Who could bring change to the issue?		
What could be done to make a difference to the issue?		
Are we the right people to advocate on the issue? (For example, will our work be respected or should we support the advocacy of other stakeholders instead?)		

STEP 3: MAKE A PLAN

This involves setting out what you want to achieve and how you will do it. This can be done using an advocacy planning chart:

Advocacy Planning Chart

Objectives	Activities	When	Targets	Partners	Resources
This is a short-term goal that contributes to achieving your long-term goal	These are the advocacy actions that you will take to achieve your objective	This is the time period when the advocacy actions will take place	These are the people, organizations or institutions that you will target to bring about the change that you want	These are supporters who you will work with to carry out your advocacy	These are the resources (such as people, money, time and skills) needed to do your advocacy

STEP 4: TAKE ACTION

This involves putting our advocacy plan into action. This might involve strategies such as lobbying parliamentarians, holding demonstrations or working with the media.

Advocacy for HIV treatment monitoring involves: Community members coming together and taking action.

- Identifying priority issues that affect access to routine viral load monitoring for PLHIV.
- Identifying what change is needed for those issues – such as in policies, funding, infrastructure and services.
- Partnering with other individuals and groups that have similar concerns.
- Targeting individuals, groups and institutions that can influence change.
- Achieving results that make a difference to the people most affected by the issues.

Community advocacy for viral load testing can take many forms, depending on the needs of the community and the political and financial context. It can involve a wide range of activities, including:

- **Campaign methods:** handing petitions (signed by community members) to decision-makers; organizing marches, demonstrations or public rallies.
- **Raising awareness:** through peer-to-peer education, workshops, training sessions and treatment literacy.
- **Lobbying:** holding meetings with decision-makers and influencing people who can bring about change.
- **Working through the media:** writing a press release, doing a media interview, using social media.
- **Participating in decision-making forums:** representing the views of your community at meetings where decisions are made. For example, Community Advisory Boards, District Planning Communities, Country Coordinating Mechanisms or National AIDS Councils.
- **Monitoring access:** conducting community-led monitoring surveys to assess if people have access to services and/or their human rights.

STEP 5: EVALUATE YOUR WORK.

This involves exploring questions such as:

- How effective has our advocacy been?
- What are the results?
- What did and did not work?
- Should anything have been done differently?

Developing an advocacy message

As with any advocacy work, it is important to develop key messages for your advocacy. Advocacy messages summarize what community activists are asking for and communicate it to their target audience. You can use your advocacy messages in your briefing papers, media interviews, speeches, blogs and meetings with decision-makers.

Advocacy messages should be:

- Short
- Focused
- Simple
- Targeted
- Powerful
- Agreed upon/supported

SECTION 7.7

'What works' for community advocacy on common barriers to increased access to optimal treatment?

SECTION OBJECTIVE

To build community activists' understanding of 'what works' and 'what doesn't work' – by sharing real life case studies of advocacy for community treatment.

TRAINING MATERIALS

Module 7: ACT case studies of the ACT Toolkit

TRAINING OPTIONS

Option A (approx. 60 minutes)

1. Explain the objective of the Section.
2. Ask the participants to re-cap the priority that they have identified for their advocacy for community treatment (see Section 7.3) and the plan that they have made (see Section 7.4).
3. Ask the participants to identify which of the following case studies might give them the most useful ideas for implementing their advocacy plan:
4. Give each participant a copy of the case study that they have selected. Give them time to read the case study.
5. Facilitate a discussion to identify:
 - What are the key lessons from the case study? In other words, 'what worked' and 'what didn't work' in the advocacy for community treatment?
 - How could those lessons be adapted to your context and your own advocacy for community treatment?
6. If you have time, repeat the process for other case studies.
7. Summarize what has been discussed and agreed during the session



ACT CASE STUDIES

Welcome to **ACT Case Studies**

The aim of the **Case Studies** is to provide real world examples of advocacy for community treatment from a range of ITPC partners working in different contexts and countries.

INTRODUCTION	
THE SCIENCE OF HIV	1
HIV CO-MORBIDITIES	2
HIV TREATMENT INITIATIVES	3
HUMAN RIGHTS AND HIV	4
TRADE AND HIV TREATMENT	5
FINANCING AND HIV TREATMENT	6
COMMUNITY ADVOCACY PLANNING	7
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ACT CASE STUDY 1: UGANDA

Advocating Against Human Rights Abuses of Sex Workers Living With HIV

What is the context?

In Uganda, HIV prevalence is estimated at 7.1%.³ In 2015, 834,931 PLHIV were provided with antiretroviral therapy (ART) – less than a fifth of the PLHIV who are all eligible for treatment under the 2015 WHO ART Guidelines.^{4,5} HIV prevalence among sex workers in Uganda is 34.2%.⁶ However, their access to ART is believed to be very low, despite efforts to increase the number of sex workers who have access to ART.⁷

What is the organization?

The Uganda Harmonized Rights Alliance (UHRA) is a coalition of human rights organizations that support sex worker activism.

What was the barrier to treatment?

Sex workers living with HIV were experiencing a number of practical and legal barriers to access to treatment. These included that they could not freely pick up their antiretroviral drugs (ARVs) at clinics (due to the stigma of being sex workers); access clinics during opening times (due to their work hours); or take their ARVs while in police cells (following frequent arrests).

What were the advocacy actions and messages?

UHRA's advocacy actions included:

- Advocating at a national level for policies to promote and protect the human rights of sex workers. This included drawing attention to the right to health, non-discrimination and a safe working environment (free from arrest, abuse and violence).
- Carrying out public demonstrations, with banners stating that sex workers have equal rights to other Ugandans.
- Carrying out meetings with health care providers and officials to call for changes to the systems of clinics – such as with longer opening hours and with other people allowed to pick up ARVs on behalf of sex workers.
- Holding a protest whenever a sex worker was arrested and negotiating with the police for her release, so that she could take her ARVs.
- The advocacy work was based advocacy messages such as: 'sex workers are Ugandans'; and 'Sex workers living with HIV have the right to treatment.'

What were the advocacy results and lessons?

The results of UHRA's advocacy included sex workers living with HIV being released from police cells (and being able to take their ARVs) and the agreement of a system whereby people can collect ARVs from clinics on behalf of sex workers.

UHRA's lessons included that:

- A country's Constitution – combined with international laws – can provide a strong tool for advocacy if, for example, it states that everyone has the right to health.
- It is best to try 'advocacy through talking' before taking other action. For example, UHRA found that sometimes, when they did demonstrations, their members were themselves arrested and beaten.
- Working through one advocacy target can enable you to reach another. For example, by working with the media (such as informing newspapers and radio stations when a sex worker was arrested), UHRA achieved action by police – who did not want their stations to be a focus of attention and, therefore, released the women.



ACT CASE STUDY 2: UKRAINE

Advocating Against Barriers to CD4 Counts and ART for Key Populations

What is the context?

In Ukraine, HIV prevalence in adults is estimated at 0.9%.⁸ In 2015 HIV prevalence among people who inject drugs (PWID) is 21.9%.⁹ In 2011, 31% of new infections were associated with injection drug use.¹⁰ In 2015, 60,753 PLHIV were provided with antiretroviral therapy (ART).¹¹ This is about 28% of those eligible for treatment under the new WHO guidelines.¹²

What is the organization?

Kirovograd is a regional department of the All-Ukrainian League LEGALIFE. It aims to provide access to timely CD4 testing and treatment for PLHIV who are prisoners, people who use drugs (PWUD), sex workers, and people from remote areas or small towns.

What was the barrier to treatment?

LEGALIFE was concerned about a group of related issues. Firstly, PLHIV were unable to access ART if they could not register a place of residency, such as if they were homeless. Secondly, those with a place of residence experienced interruptions to their treatment – and resistance to ARVs – if they had to travel to another area and were not permitted to use local ART services. This affected groups such as migrant sex workers. In addition, in some locations – especially small towns and detention centers – there was poor access to equipment for CD4 testing. This was due to the lack of mobile testing equipment. Despite the fact that there are manufacturers of CD4 testing equipment in the country, production was held-up due to protocols not being approved. As a result of these barriers, there were increases in mortality among PLHIV.

What were the advocacy actions and messages?

LEGALIFE took a range of advocacy actions to address the different issues. These included:

- Gathering evidence – including by analyzing legislation related to access to ART for PLHIV who chose to move away from their registered place of residency.
- Sending letters of enquiry to AIDS Centers about people whose treatment was interrupted due to challenges related to registration/residency.
- Mobilizing the government and community organizations to be interested in the issue of mobile CD4 testing. Activities included:
 - a speech to the Ukrainian Community Advisory Board

- meetings with civil society leaders, including the All-Ukrainian Network of People Living with HIV
- a roundtable discussion with representatives of communities, government medical services and laboratories
- Advocating to Alere and Partec – the companies producing mobile CD4 equipment – to lower the price of equipment.
- Holding a national conference – involving United Nations agencies, the Ministry of Health, NGOs (from Ukraine and Russia), AIDS Centers, sex workers and organizations of PLHIV – on sex work and HIV. The conference drew particular attention to the issue of migration and reliable access to ART.
- The advocacy work was based on messages such as: 'quality diagnosis = early treatment'; and 'life depends on timely diagnosis.'

What were the advocacy results and lessons?

- The results of the advocacy included an agreed way forward for distributing mobile CD4 equipment and an agreement with the manufacturers regarding lower prices for CD4 testing equipment. The advocacy efforts also resulted in better access to ART for PLHIV regardless of their place of registration and residency.
- The advocacy lessons were:
 - It is important to mobilize all relevant stakeholders for your cause – especially for an issue such as CD4 testing which stakeholders may not immediately recognize as a vital part of HIV treatment.
 - Before carrying out public events (such as roundtables) with different stakeholders, it is vital to understand the interests of each one and, in some cases, to conduct individual meetings beforehand.



ACT CASE STUDY 3: CAMEROON

Advocating Against Negative Attitudes of Treatment-Providers

What is the context?

In Cameroon, HIV prevalence is estimated at 4.5%, with some 620,000 PLHIV.¹³ In 2015, 168,249 people were receiving ART.¹⁴ This represents only 27% of those now eligible for ART according to the 2015 WHO ART Guidelines.

What is the organization?

Association des Frères et Soeurs Unis - Extrême Nord (AFSU-EN) is based in Maroua in the Farth North region. It is a network of activists that works with over 15 community based organizations of PLHIV, including women and young people. AFSU-EN is supported by the International Treatment Preparedness Coalition (ITPC) Central Africa.

What was the barrier to treatment?

AFSU-EN identified that the negative attitudes of some health workers at a Treatment Centre were a major barrier to access to ART for the community. The staff had poor attitudes to their work, and often arrived late to work or were absent. They also had very negative attitudes towards PLHIV, and would insult them and discriminate against them. Some healthcare workers were also involved in the illegal sale of ARVs. As a result of these problems, some PLHIV were discouraged from going to the Treatment Center and stopped taking ART. In addition, some that continued to go to the Centre did not receive their drugs on time.

What were the advocacy actions and messages?

Over a period of fifteen months (August 2012 – October 2013), AFSU-EN's advocacy actions included:

- Holding focus group discussions with community members, facilitated by ITPC Central Africa. These discussion aimed to better understand and gather evidence about the issues faced by PLHIV.
- Writing a letter from the community (and supported by ITPC Central Africa) to the health authority. The letter formally complained about the attitudes and behavior of the health workers and outlined the impact of these negative attitudes on the health and wellbeing of PLHIV.
- Holding a meeting between the community and the management of the Treatment Centre, including the health workers that had shown negative attitudes. During this meeting, community members denounced the workers' attitudes and spoke about the harmful impact of stigma and discrimination on the lives of PLHIV.

- Getting legal support for the community from a lawyer. The lawyer helped the community to prepare a report containing evidence of the problems they were facing. This led to the director of the Treatment Centre suspending two health workers who had demonstrated negative attitudes.
- In its letter, meeting and dossier, AFSU-EN used advocacy messages, such as stating that: 'the mistreatment of patients living with HIV is a flagrant violation of human rights'; 'the sale of ARVs is illegal. It is also unacceptable'; and 'access to high quality and sustained treatment, care and support for PLHIV is critical not only to individuals, but to public health.'

What were the advocacy results and lessons?

After its advocacy action, AFSU-EN found that:

- Health workers at the Treatment Centre became more attentive to the needs of PLHIV
- Access to treatment improved for PLHIV – due to an end to the illegal sale of ARVs
- PLHIV became more motivated to go to the Treatment Centre, to get their drugs and to receive medical attention

AFSU-EN's lessons included that:

- Before starting advocacy, it is crucial to ensure that community members are concerned about the issue, and committed to the advocacy. Community members should be involved in every step of the advocacy process, including gathering evidence.
- For high quality advocacy, your information and evidence must be genuine and accurate. At the start, AFSU-EN found that some of its information was false. By fact-checking the data, AFSU-EN ensured that they had the correct data to use as evidence.
- Involving an expert at the right time can make a vital contribution to successful advocacy. For AFSU-EN, working with a lawyer enabled them to take the formal action that was needed to achieve change.



ACT CASE STUDY 4: VIETNAM

Addressing the 'Evidence Gap' for Advocacy on ART for Key Populations

What is the context?

In Vietnam, HIV prevalence among adults is 0.5%¹⁵ among the general public, but much higher among key populations, such as sex workers (2.7%), PWID (9.3%) and men who have sex with men (MSM) (5.1%).¹⁶ In 2015, 106,373 PLHIV were provided antiretroviral therapy (ART).¹⁷ This represents about 42% of those eligible under the 2015 WHO ART Guidelines. A study of the 'treatment cascade' found that many individuals are lost at various stages in the HIV treatment continuum – reducing the number of PLHIV who achieve viral suppression and other benefits from ART.

What is the organization?

The Vietnam Network of People Living with HIV (VNP+) is an organization run by and for PLHIV. It fights stigma and discrimination and advocates for the rights of HIV-positive people (such as to treatment, care and support), including those from key populations.

What was the barrier to treatment?

Stigma and discrimination were presenting a significant barrier to ART for PLHIV. Fear of disclosing their HIV status was thought to be the main factor preventing community members from accessing treatment. However, there was a lack of evidence to demonstrate the extent of the problem to decision-makers.

What were the advocacy actions and messages?

The advocacy actions of VNP+ included:

- Implementing the People Living with HIV Stigma Index in 2012 – to gather concrete data on the situation for PLHIV and provide evidence about the impact of stigma and discrimination. PLHIV were involved throughout the process.
- Using the findings of the Stigma Index to inform a pilot program of the Treatment 2.0 Framework, supported by the United Nations Joint Program on AIDS (UNAIDS) and World Health Organization (WHO).
- Sharing the findings of the Stigma Index with the government – resulting in the Ministry of Health using the data during presentations at the National AIDS Conference.
- Since 2013, developing and running a treatment literacy program for groups of PWUD, sex workers and MSM. The program is run by PLHIV and involves monthly meetings to share information, especially about the importance of accessing treatment and staying healthy.

- Carrying out further research to identify the opportunities and barriers to access to treatment, care and support for PLHIV.
- The advocacy work used messages such as: 'AIDS can be treated'; and 'no one needs to die of HIV, but they are dying from stigma and discrimination.'

What were the advocacy results and lessons?

The results of VNP+'s work included that:

450 people were informed about HCV/HIV co-infection, ARV treatment adherence and other HIV-related health services.

180 clients were successfully referred to additional health services, including treatment for Hepatitis C, voluntary counselling and testing services, and treatment for sexually transmitted infections.

The lessons learned of VNP+ included that:

Concrete data and evidence are vital foundations for successful advocacy work. Evidence and data increase the power of advocacy messages and help to persuade decision-makers.

Advocacy on access to treatment needs to be accompanied by work within communities – such as treatment literacy and peer education – to encourage and support PLHIV to overcome their fears and to access treatment.



ACT CASE STUDY 5: KENYA

Advocating on the Lack of Appropriate Health Services for LGBT People

What is the context?

In Kenya, HIV prevalence among adults is estimated at 5.9%¹⁸, but estimated to be much higher among key populations – such as 18.3% among PWID, and 18.2% among MSM.¹⁹ In 2015, 897,644 PLHIV were on ART²⁰ – this is about 59% of those eligible for ART under the 2015 WHO ART Guidelines.²¹

In Kenya, homosexuality is criminalized. The punishment for those convicted of homosexuality is up to 14 years imprisonment. There is evidence that MSM do not seek health services – such as for sexually transmitted infections – due to fear and stigma.

What is the organization?

Professionals in Pride Kenya (PPK) support the lesbian, gay, bisexual and transgender (LGBT) community, including those living with HIV.

What was the barrier to treatment?

There were no 'LGBT-friendly' health services in most clinics in Kenya, including the capital Nairobi. Few doctors or nurses had any understanding of the specific health issues affecting MSM, such as anal infections. In addition, LGBT people faced criminalization. For this reason many PHIV felt unable to discuss their health care needs with healthcare workers, for fear of disclosing their sexuality or sexual orientation.

What were the advocacy actions and messages?

PPK's advocacy activities included:

- Holding meetings with government officials, including the Kenya National AIDS and STI Control Program. During these meetings, PPK shared their concerns about the dangers that their community members are exposed to as a result of the lack of LGBT-specific health facilities. They highlighted the needs of those living with HIV – for ART and also for commodities (such as condoms and lubricants) for HIV prevention.
- Holding demonstrations to build awareness among the public of the needs of LGBT people and to demand the rights of Kenyan homosexuals and MSM are protected.
- Building partnerships with stakeholders prepared to support the LGBT community. For example, some pastors publicly supported PPK during radio interviews.

The advocacy work focused on messages such as: 'gay rights = human rights'; and 'no judgment based on my sexual orientation'

What were the advocacy results and lessons?

The results of PPK's advocacy include that:

- LGBT people can now go on the media and talk about their issues without fear of arrest.
- Other civil society organization have increased their understanding of LGBT issues and joined PPK in their fight for rights.
- PPK's lessons include that:
 - It is important to base advocacy on evidence and existing, supportive resources. For example, PPK used relevant sections of the national Constitution, HIV Bills, HIV policies, and quotes from the President and Minister of Health.
 - It is vital to get the media interested in your case and 'on your side.' If there is a lot of publicity, it is hard for your advocacy targets to make the wrong decisions – because everyone is watching.
 - As well as targeting decision-makers, it is important to educate the general public about the issue. This creates understanding and – even if not everyone agrees with you – enables you to increase the scale of your advocacy work, and build support for the issue.



ACT CASE STUDY 6: GEORGIA

Advocating for the Involvement of People Who Use Drugs in ART Services

What is the context?

In Georgia, HIV prevalence in adults is estimated at 0.4%.²² Prevalence is much higher among key populations, such as PWID (2.2%) and MSM (20.7%).²³ In 2015, 3,044 PLHIV were receiving ART.²⁴ This is about 32% of those eligible under the 2015 WHO ART Guidelines.

What is the organization?

The Georgian Harm Reduction Network (GHRN) is a national network of 26 organizations from across the country. It is based in the capital (Tbilisi) and supports PWUD.

What was the barrier to treatment?

Georgia has a program supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria that provides the treatment component of services related to ART, opioid substitution therapy (OST), Tuberculosis (TB) and co-infection of HIV and HCV. However, major barriers still prevent PWUD from accessing such treatment. These barriers include criminalization, discrimination and stigma from both the public and healthcare workers. In addition, PWUD have not been involved in the design, planning and implementation of the services.

What were the advocacy actions and messages?

GHRN's advocacy activities included:

- Carrying out advocacy campaigns – such as on access to treatment for HIV, HCV and OST – with the involvement of PWUD and PLHIV
- Bringing community members together with decision-makers. For example, GHRN supported PLHIV, PWUD and LGBT people to become members of the Country Coordinating Mechanism and its oversight committee. This was done through a transparent election processes coordinated by community-based organizations.

The advocacy work was based on messages such as: 'ART = health can be bought' (to promote government funding of ART); and 'health is not a luxury' (to draw attention to the impact of HCV).

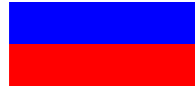
What were the advocacy results and lessons?

The results of GHRN's advocacy included that:

- PWUD and PLHIV experience increased access to treatment services and quality of life – such as through the launch of a state program to address HCV and reduced price of drugs to treat the disease.

- Through involvement in the Country Coordinating Mechanism, representatives of community-based organizations are able to influence national decisions about policies and programs that affect them.

GHRN's lessons include that community involvement is essential to advocacy – as it gives issues a 'human face' to your issues and makes targets more like to support them



ACT CASE STUDY 7: RUSSIAN FEDERATION

Advocating for Improved Provincial Procurement of ARVs

What is the context?

In contrast to many other countries, the HIV situation in the Russian Federation is getting worse, rather than better – with increased numbers of new infections each year. There are now an estimated 1.5 million PLHIV²⁵ – however, in 2012, only 157,000 of these people were on ART.²⁶ This is about 10% of those who are eligible for ART under the 2015 WHO ART Guidelines. Access to ART is known to be especially challenging for PWUD.

What is the organization?

The International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPCru) was established in 2005. It is an initiative of people who are united by common ideas. Its objectives are to ensure universal, adequate and equitable access to HIV care, treatment and prevention for all people living with and at risk of HIV; and their greater input in decision-making that affects their lives.

What was the barrier to treatment?

ITPCru was concerned that PLHIV – including PWUD – frequently lacked access to ARVs due to drug stock-outs. This issue came to a head in 2013 with the decentralization of ARV procurement, when each of the country's 83 provinces given responsibility for organizing its own ARV program.

What were the advocacy actions and messages?

ITPCru's advocacy actions included:

- Training and supporting a team of 15 local activists to analyze about 2,000 tenders for ARVs in the 83 provinces. The work was based on a simple methodology for monitoring electronic tenders and analyzing the relevant data, such as the prices of drugs. The problems identified included:
 - Late announcement of tenders
 - Exorbitantly high prices of ARVs
 - Purchase of single pills instead of FDCs
 - Cancellation of tenders due to there being no bids
- Publishing the activists' results, including a report²⁷ that combines information on stock-outs (and their impact) with an analysis of the federal government procurement of ARVs.

Activists identified problems with the tendering process in various provinces and carried out advocacy activities such as street rallies, press conferences and round tables – all with good media coverage. These activities were supported by a database of advocacy tools, including

samples of advocacy letters and press releases, and instructions for organizing street-level actions. In total, over 100 activities were conducted.

The advocacy work was based on messages such as: 'treatment is needed for all PLHIV'; and 'access to high quality ART is not optional – it is the human right of all PLHIV.'

What were the advocacy results and lessons?

The results of ITPCru's advocacy included the successful analysis of approximately 2,000 tenders for ARV medicines in 83 provinces in Russia. This monitoring led to the development of advocacy tools, including sample letters, press-releases, and instructions for organizing street actions, that can be used in addressing late tender announcements and the annulment of tenders due to the absence of bids

The lessons learned included that:

- Practical tools – such as a methodology for analyzing tenders – are key to scaling-up advocacy as they can be used by different people in different locations, adding up to a large-scale initiative. They also, however, benefit from re-adjustment. For example, while very useful for individual contexts, ITPCru's methodology did not serve to identify systemic stock-outs of ARVs as a result of decentralization.
- The media is a vital 'ally' for advocacy. For example, ITPCru gained media coverage for many of its activities – which served to mobilize stakeholders and also document the work. Many examples can be seen on YouTube.¹
- To be effective, advocacy objectives must constantly be updated. For example, ITPCru's work now also includes advocacy for the inclusion of community activists in local tender committees – an opportunity that arose from a new law on procurement that started at the end of January 2014.

¹ July 2013: <https://www.youtube.com/watch?v=Ey4MPLwdYAs> and April 2013: <https://www.youtube.com/watch?v=6WQsxSAWZTI>



ACT CASE STUDY 8: WEST AFRICA

Advocating Against Poor Quality ART for Women Living with HIV

What is the context?

In West and Central Africa, HIV prevalence among adults is 2.2%.²⁸ There are about 6,500,000 PLHIV in the region, and 1,830,710 on ART.²⁹ This is 28% of those eligible for ART under the 2015 WHO ART Guidelines. Great progress has been made in the region through the Global Plan Towards the Elimination of New HIV Infections Among Children by 2015 and Keeping Their Mothers Alive (the Global Plan).³⁰ However, in 2013 two thirds of pregnant women living with HIV did not receive ART for their own health.³¹

What is the organization?

The International Treatment Preparedness Coalition (ITPC) West Africa is a regional network of treatment activists based in Abidjan, Côte d'Ivoire. It works with communities of PLHIV – including those from key populations - as well as all other stakeholders involved in the response to HIV.

What was the barrier to treatment?

In 2011, single-dose Nevirapine was being prescribed to pregnant women living with HIV in five countries in West Africa. The drug prevents the vertical transmission of HIV from a mother to her baby. However, using it alone is not as effective as triple therapy and has great potential to result in resistance. The Global Plan recommended that single-dose Nevirapine should be rapidly phased out, and replaced by triple therapy as suggested in option B+.

What were the advocacy actions and messages?

ITPC West Africa launched a campaign to put an end to use of single-dose Nevirapine and make African countries provide high quality ART to pregnant women living with HIV. The campaign included:

- Distributing postcards during the International Conference on AIDS and STIs in Africa (ICASA) in Addis Ababa, Ethiopia, in 2011. The postcards were signed by over 2,000 people and handed to the Chairperson of the African Union through the Social Affairs Commissioner.
- Distributing postcards during the International AIDS Conference (IAC) in Washington DC, United States of America, in 2012.
- Seeking an appointment with the representative of the Africa Union in Cote d'Ivoire after the IAC to discuss the problem of single-dose Nevirapine in the region.

- The campaign focused on messages such as: 'Africa: Say no to single-dose Nevirapine'; and 'full ART for HIV-positive women.'

What were the advocacy results and lessons?

As a result of the advocacy:

- Many people, including women living with HIV gained knowledge about PMTCT issues. As a result, they were able to share this knowledge when they returned to their communities.
- Important stakeholders at the African Union were sensitized to PMTCT issues after they were inundated with 1,500 postcards demanding the AU prioritize PMTCT.
- The lessons included that:
 - Regional and international events (such as AIDS conferences) provide important advocacy opportunities – they enable access to both advocates (for example, to sign campaign postcards) and advocacy targets (such as policy-makers).
 - International policy initiatives – such as the Global Plan - provide important advocacy tools to put pressure on regional decisions-makers about why they must make changes to policies related to HIV treatment.



ACT CASE STUDY 9: MALAWI

Thyolo Community ART Groups and Education about Viral Load Testing

What is the context?

In Malawi, HIV prevalence among adults is 9.1%³², one of the highest HIV prevalence rates in the world.³³ There are about 980,000 PLHIV, and 595,186 on ART.³⁴ This means that about 61% of those eligible for ART under the 2015 WHO ART Guidelines are receiving treatment. In 2009 many PLHIV in the Thyolo district in Malawi did not have access to viral load testing

What is the organization?

Médecins Sans Frontières (MSF) is an international medical humanitarian organisation that delivers aid to people affected by conflict, epidemics, natural disasters and exclusion from healthcare.³⁵ For many years Médecins Sans Frontières (MSF) has been supporting the Malawian Ministry of Health to strengthen its HIV response through staff training and technical support.³⁶

What was the barrier to treatment?

In order for more people to access and demand viral load testing, they need to understand the importance of monitoring HIV treatment. Community education can lead to a change in health policy as more people demand a specific service, as illustrated in the example of the Thyolo Community ART Groups (CAGs).

What were the advocacy actions?

From 2012 to 2015, MSF collaborated with Thyolo District Health office to pilot a community model for ART distribution called Community ART Groups (CAGs). CAGs are self-formed groups of stable PLHIVs who are on ART, who take turns attending the health facility to receive a clinical assessment and monitoring tests, while collecting drugs for themselves and the other members of the CAG.

The main objective of the CAG model of care is to reduce the workload of the existing health providers in the health facilities, reduce the number of visits to the health facility by PLHIVs and to improve long-term retention in care, by reducing access barriers and enhancing the role of the ART client in the management of their HIV.

What were the advocacy results?

CAGs helped to improve PLHIV's access to ART by addressing barriers to accessing health facilities such as long distance, transport costs and spending long hours at the health facility. CAGs also reduce the workload for health workers.

One of the requirements for one to join a CAG is to have a viral load of less 1000 copies/ml of blood. This means that before one joins a CAG, he or she must get his or her viral load tested. This means that PLHIV have to be provided with treatment literacy about the importance of viral load testing in order to join the CAGs. The CAG program ensured that many more people know about the importance of viral load testing, and knew their viral load.



ACT CASE STUDY 10: PEPFAR COP

The President's Emergency Plan for AIDS Relief Country Operational Plan: Influencing people who can bring about change.³⁷

What is the organization?

AVAC is a global advocacy organisation for HIV prevention. AVAC works to accelerate the development and roll-out of HIV prevention tools. Through education, policy analysis, and advocacy work, AVAC supports efforts to deliver HIV prevention tools, demonstrate new HIV prevention options, and develop long-term solutions to end the HIV epidemic.

What is the context?

One crucial way that civil society organizations can advocate for routine viral load monitoring to be made available, is by influencing key donors who fund HIV programmes. The United f President's Emergency Plan for AIDS Relief (PEPFAR) is a key donor that funds routine viral load monitoring in resource-limited settings.

What were the advocacy actions?

In the majority of countries where they work, the PEPFAR program completes an annual Country Operational Plan (COP) that describes national PEPFAR targets, goals, implementing partners and budgets. According to their own policies, PEPFAR must engage with civil society when reviewing their COP. This is an important opportunity for advocacy organizations to have significant impact. There are many ways that civil society can influence COPs, such as:

- Writing to and/or requesting a meeting with the PEPFAR Coordinator, and heads of relevant agencies in your country.
- Ask to review the targets in the draft COP. Look to see what the targets related to routine viral load testing in your country are.
- Craft a clear, specific set of recommendations about what PEPFAR should commit to fund: targets, funding levels, etc. Provide any evidence you can. The most effective recommendations will be very specific and will tackle what PEPFAR does or could fund and provides ideas about what should change.
- Lobby national decision-makers to enact policy through national strategic plans or commitments that can be used to leverage more ambitious routine viral load testing targets.
- Share questions and advice with other advocates working on similar campaigns.



ACT CASE STUDY 11: ZAMBIA

Creating demand for routine viral load testing: An example of the implementation of an advocacy plan is the launch of ITPC's 'Be Healthy, Know your Viral Load' campaign

What is the context?

In Zambia, HIV prevalence in adults is 12.9%.³⁸ Prevalence is much higher among key populations, such as sex workers (56.4%).³⁹ In 2015, 758,646 PLHIV were receiving ART.⁴⁰ This is about 62% of those eligible for ART under the 2015 WHO ART Guidelines.

By as early as 2013, the World Health Organization had recommended that routine viral load testing be used to monitor HIV treatment. It is the gold standard (the best method) for checking if a person's ARV treatment is working in resource-rich countries, but is unavailable in many resource-poor settings. This is because of the cost of routine viral load testing and the infrastructure and human resources needed to set up a system for delivering routine viral load testing to all PLHIV.

What was the barrier to HIV treatment?

A survey by ITPC and ARASA also found that in the majority of cases, viral load tests were only done when knowledgeable PLHIV requested them. This is problematic as very few people know about the importance of viral load testing and may be requesting them. This finding is the basis for providing knowledge through various treatment education forums to encourage communities to demand viral load testing.

What were the advocacy actions?

- ITPC conducted the survey as a way of gathering information on the lack of RVL in 12 countries in Africa. The information gathered from this survey formed the basis of all the advocacy actions.
- To increase the demand for viral load testing, ITPC made a short film about the personal impact of viral load testing on the daily lives of two PLHIV.
- A website was developed with information about viral load testing for PLHIV about the importance of routine viral load testing and to encourage people to demand viral load testing to know if their treatment is working. This included a template letter that could be sent to decision-makers, demanding that routine viral load testing be made available to all PLHIV.
- An information leaflet for PLHIV and decision-makers was developed, outlining the benefits of viral load testing for people living HIV and the HIV response.
- In October 2015, a march was held in Lusaka, Zambia, to mark the launch of the campaign, as a pan-African campaign for improving access to RVL.

What were the advocacy results and Lessons?

As a direct result of the Be Healthy, Know your viral load campaign launch held in Lusaka and subsequent meetings with the Treatment Advocacy and Literacy Campaign (TALC), the Zambian Ministry of Health issued a directive to all ART facilities, instructing the immediate uptake of viral load testing. In support of the anticipated increase in viral load testing, the Ministry has committed to procuring viral load testing machines for all provinces (outside of the sole machine currently in use in a private laboratory in Lusaka). As of March 2016, several clinics have already reported the scale up of routine viral load testing.

Lessons include that:

- Conducting baseline research (sometimes known as a situational analysis) is useful to inform your advocacy campaign.
- Sharing personal stories about the effect of viral load testing helps other PLHIV relate to the issues and can motivate them to take action.
- Developing targeted advocacy tools that people can adapt and use throughout the campaign gives partners tools to begin using as soon as they are ready to embark on the campaign.

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