HIV/AIDS TREATMENT LITERACY

UNIVERSAL ACCESS TO PREVENTION, TREATMENT, CARE AND SUPPORT IN THE NEW MEMBER STATES AND NEW NEIGHBOURHOOD COUNTRIES.

TRAINING MANUAL

EATG
EUROPEAN AIDS TREATMENT GROUP

European AIDS Treatment Group

The EATG's mission is to achieve the fastest possible access to state of the art medical products, devices and diagnostic tests that prevent or treat HIV infection or improve the quality of life of people living with HIV, or who are at risk of HIV infection.

Founded in 1992, the European AIDS Treatment Group (EATG) is a European network of nationally based activists. As a European patient-led advocacy organisation, it has been at the forefront of the development of the civil society response to the HIV/AIDS epidemic in Europe. It represents and defends the treatment-related interests of people living with HIV and AIDS.

In responding to HIV, the EATG also considers diseases frequently seen as co-infection in people with HIV, as well as other health issues that increase the risk of HIV. For more information visit www.eatg.org.

This publication is a part of the project "Support to EATG in promoting UA in the new member states and New Neighbourhood countries – SUPPORT TO EATG" (Agreement no. 2008 32 77) which has received funding from the European Union, in the framework of the Health Programme.

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INTRODUCTION

by Ana Lúcia Cardoso

training coordinator

1.
INTRODUCTION

Treatment literacy is important, because it enables people living with HIV/AIDS to make more informed decisions about their treatment regimen, care and the general management of their condition. Treatment literacy also contributes to an increased likelihood of better adherence, management of the possible side effects from the ARVs and, generally, improved health outcomes. People, who understand their treatment, are empowered people. They are aware of what is happening to them and they are in a position to participate actively in improving and protecting their health. In addition, people, who are literate about their treatment, are able to mobilise other community members and affected individuals, which enhances the access to treatment, reduces stigma and thus increases testing and improves the effect of prevention.

Treatment information, disseminated from health care settings, leads to a better understanding of the epidemic, overcoming discrimination and in the long run reducing health inequalities. That is why we strongly believe that both people living with HIV and health care professionals must have access to up-to-date, objective and evidence-based information.

Based on this belief, we aim to reach as many people possible living with HIV/AIDS, their carers, representatives of the civil society, health care professionals, peer counsellors and everybody working in the field, in order to provide them with the opportunity to develop their treatment knowledge and skills in treatment literacy work. Our utmost ideal is a situation where all HIV-positive people have the best possible access to information on treatment and access to medicines, care and support.

This manual is a result of our work to reach the aforementioned goal. It is based on a training programme on HIV/AIDS treatment literacy developed by the European AIDS Treatment Group and it presents the methodology used, sessions delivered and bibliographic resources that may be of help to community trainers, PLWHA and their supporters when organising similar trainings.

EATG's training activities are based on a very rigorous needs assessment and address the gaps in knowledge. The sessions in this manual meet the needs of both members of the EATG, as well as the community representatives, mainly from Eastern and Central Europe. The EATG has a pool of dedicated trainers and a long and successful history of providing trainings on many different topics. Besides our educational role, we consider we have a supporting, enabling and empowering role.

Our strategic plan is to establish the organisation as one of the leading community organisations providing training, capacity building and treatment preparedness with a focus on reaching out to peer community organisations, as well as to provide training in other areas as appropriate.

In the coming years, we want to focus our training activities on Eastern Europe, where the prevalence is high, information is scarce and a sustainable dialogue with the main stakeholders is most of the times a very difficult task.

As a part of our strategic plan, we organised four training workshops for two different groups of participants in 2009 in Brussels. Group A included trainees from South Eastern Europe and Group B from the Russian Federation, Ukraine, Belarus, Central Asia, Central Europe and the Baltic states. Both groups undertook two training sessions: one on treatment literacy and a second one on treatment advocacy. This is the first of two manuals that were produced within this project. The second manual covers treatment advocacy topics.

The 2009 training workshops were interactive and participatory with group work as well as discussions in the plenary.

The feedback from the participants was positive, and challenging, and it will be interesting to learn whether subsequent workshops have a similar outcome. The highlights from the first workshops were as follows:

Many considered the session "What do PLWHA in my country lack" particularly important. In this session, participants from different countries got together to discuss main needs regarding treatment and care and it was interesting to see disparities between regions and to discuss barriers to overcome these disparities.

In terms of prevention, all groups agreed much more remains to be done to reach out to vulnerable groups, to promote free and anonymous testing and to ensure positive prevention. Also discussed were awareness programmes for doctors and other health practitioners.

When it comes to treatment, many countries do not have enough facilities (laboratories or centres) for monitoring or treatment.

Other topics were discussed in the sessions, such as the need of tailored communication between doctor and patient, better health care services involving psychologists, social workers and care givers (multi-disciplinary teams). Some of the participants also considered that often patients are not involved in the process and may feel confused about their treatment options.

Everyone agreed that there is still a long way to go to achieve universal access to treatment, prevention and care and that capacity building adapted to specific contexts is a step to ultimately achieve it.

The participants evaluated the seminars through evaluation forms. The levels of awareness, knowledge and competency about HIV treatment and advocacy strategies were evaluated through randomly performed interviews to selected participants.

This first training workshop was followed by a second one on treatment advocacy and as an outcome, a separate manual on advocacy has been produced, covering the following topics: advocacy definition, development of advocacy tools and actions, stakeholders identification and techniques to address stakeholders.

Both manuals are available free of charge (electronically and hard copy).

The EATG is a non-profit organisation and we are glad to grant permission for the use of this manual for non-commercial use. We encourage community-based organisations, people living with HIV/AIDS and all other people working in the field of the treatment, care and support for PLWHA to use the material as they may deem appropriate, including its adaptation to the local requirements, but the copyright of this manual stays with the EATG.

We hope you will be able to use this material in your advance, particularly, when organising your own training session in your country and wish you best of luck with the task.

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2

HISTORY OF TREATMENT ACTIVISM

by Stephan Dressler

2.
HISTORY OF TREATMENT ACTIVISM

Aims and objectives

The aim of this section is to present an outline of the history of HIV/AIDS treatment activism since its beginning in the mid-1980s. After reading this material, the trainer/trainee will have a general understanding of:

- History of ARV therapy
- Milestones in HIV treatment activism
- Successful community interventions
- Greater awareness of the important achievements of HIV treatment activism

In addition, the trainers will learn how to show the trainees how to identify milestones in HIV treatment activism in their own country, as well as milestones in their personal experience as activists.

Abstract

Over the last three decades, there have been numerous initiatives by HIV/AIDS treatment activists all over the world. Many of those happened in the US and Europe, but major activities were also organised on continents such as Africa and Asia. Activism during these years addressed a broad variety of themes: access to treatment, research ethics, clinical trials, community participation in the planning of clinical trials, and standards of care. Among the major achievements of HIV treatment activism are: parallel track programmes, expanded access programmes, expanded access to 3TC worldwide, research into combination therapies and others. Activists still face many challenges and problems that activists. Some of the most important ones are: access to treatment in underserved communities, improving the level of treatment, care and support, establishing a standard of care and ensuring an adequate funding for the HIV/AIDS sector.

How to deliver the material of this section

It is expected that the trainer uses a PowerPoint presentation, video or internet clips (downloaded either in advance or in real time), followed by group work to identify past and present issues for treatment activism on a local, country, or a larger geographical level.

The PowerPoint presentation should be delivered in a plenary session, after which the trainees should be divided into several groups (5-8 participants maximum per group), preferably by country or region.

Time of the session: 2 hours (45 minutes presentation, 60 minutes group work, 15 minutes feedback in the plenary).

> NOTE: The above description of how to deliver the session is only advisory. The methodology has already been used successfully, but the trainer should feel free to adapt it, according to the local training circumstances.

Detailed presentation material

1. Background and context

- 1981: first description of a new syndrome (today referred to as AIDS) by Gottlieb et al., 1981 June 5; 30: 250-252, followed by additional reports from the US and Europe
- 1981-1984: epidemiologic research; identification of a transmissible agent as a possible cause of the syndrome
- 1984: isolation and description of HIV by Montagnier et al.
- 1984 onwards: response in the US and in Europe starts; public health systems and other existing institutions start addressing the new disease; first information and prevention campaigns

Initially, the financial response was concentrated on virological, epidemiological and immunological research. Research on treatment was not considered. As a result, no antiviral treatment was available and the treatment options for the majority of the opportunistic infections were severely limited or often non-existent. The survival time of an infected person during these years between diagnosis with HIV-infection and death was ~12-15 months.

2. Patient initiatives for starting clinical trials

Desperate, because there was no treatment available and because of the prospect of eminent death, many people with HIV/AIDS experimented individually with a broad variety of compounds. Those included: compound Q, mistletoe, isoprinosine, ribavirine, phytotherapeutic preparations, etc. Some of these compounds were known to be highly toxic and some were illegally imported into the US and other countries. There were no evidence-based data on the effects of their use; individual results were not recorded and no stringent scientific criteria were applied at the point of use.

In this situation, community-based organisations took a lead and initiated the first clinical trials on HIV/AIDS treatment. These organisations were:

- Community Research Alliance (CRA), Project Inform, both in San Francisco, USA
- Community Research Initiative (CRI), New York

The trials raised public awareness of the need for a structured HIV/AIDS treatment research. This need was also highlighted by large demonstrations by gay men, a group that was particularly vulnerable to the new disease.

3. Treatment research

Small scale research into HIV/AIDS treatment had been conducted in various universities and other institutions in the US and Europe. Academic teams tested a variety of drugs (e.g., suramine) on a small number of HIV-positive people, without any groundbreaking results. A breakthrough only came after the pharmaceutical manufacturer Wellcome Burroughs, with the support of the US National Institutes for Health, developed azidothymidine (AZT, today known as zidovudine) and tested it in larger clinical trials in 1986/87. Even though the compound was initially considered as a possible cancer treatment, it became the first anti-AIDS drug with a proven effect and as a result it was approved in 1987 in the US and in 1989 in Europe.

The example of AZT showed that it was possible to develop antiretroviral drugs and thus served as an incentive for other pharmaceutical companies to look into the development of antiretroviral agents. In the following years, ddI and ddC (the latter no longer used) were developed. They were approved in the early 1990s.

AIDS activists demanded that pharmaceutical companies engage in HIV/AIDS, providing resources and checking again compounds that never made it to a clinical trial for possible antiretroviral effects. Only a limited number of companies took up the challenge, as AIDS was still regarded as a small market and a ''dirty' disease. Having an anti-AIDS drug in the portfolio was feared to taint a company's image.

4. Access to treatment

From 1987 until 1991, people with HIV/AIDS only had one treatment option: AZT. If they failed on AZT, or if they could not tolerate the then high doses of the medicine, they were left without any viable treatment option. The only solution for those people was to get access to a new compound under clinical research.

Clinical trials of ddI became a way to access a new experimental drug. However, the number of participants in those trials was limited, while the number of people in need of the new drug was much higher. The US authorities and Project Inform developed a so-called parallel track programme for ddI. It allowed people with AIDS, who could not participate in a clinical trial (because it was fully enrolled, did not run in their region, or because they did not meet trial inclusion criteria), to participate in the parallel programme and thus get access to ddI. These early programmes developed soon into what is now known as expanded access programmes (EAP), a widely used standard procedure not only in the field of HIV/AIDS, but also in oncology and some other treatment realms. The initiator for these programmes was Martin Delaney from Project Inform in San Francisco, USA.

5. The European situation in the late 1980s

- **Limited research**
  By the late 1980s, only a limited number of clinical studies had been initiated in (Western) Europe. University hospitals would typically run small clinical trials, and HIV/AIDS-focused research networks only slowly came into existence.

- **Delay in clinical trials initiation**
  There was a considerable time gap between the start of a clinical trial in the US and in Europe. Pharmaceutical companies would initiate clinical trials in the US and wait for the first results before making a decision of whether to then start the study in Europe. An example of this is ddI. The studies of the compound were at an advanced stage in the US, while Europe was still awaiting the start of the first ddI trial. In various European countries (France, Germany), AIDS activists stormed the offices of the manufacturer, demanding access to ddI.

- **Delay in approval of ARVs**
  Delays in national drug approvals for new ARVs added to the time gap between the US and Europe. In the early 1990s, drug approval in Europe was handled on a country-by-country basis, by the respective national authorities. This was a time-consuming and painstaking process, which sometimes resulted in one country approving a new treatment within months, while people with AIDS in other countries had to wait for more than a year.

- **AIDS activism**
  Community-based organisations and self-help groups were formed in most Western European countries from the mid-1980s (UK, France, Switzerland, Germany, etc.). Almost all of these organisations provided information on HIV/AIDS treatments, but as national (or sometimes even regional) organisations, none of them had been able to influence HIV/AIDS research on a European level, despite the need being clearly recognised.

  In early 1992, AIDS activists from 10 European countries met in Berlin to found an organisation, which aimed to overcome the aforementioned difficulties and accelerate access to experimental treatments in Europe. This was the foundation of the European AIDS Treatment Group (EATG). One of the aims of the EATG was that clinical trials would start simultaneously in all areas in the world and that new treatments would be registered with the authorities at the same time; a goal, which has now been achieved in the majority of the EU countries. One of EATG's first initiatives was a call for EU-wide ''Compassionate Use'' programmes.

6. Involvement of PLWHA in clinical trials

- **Inclusion/exclusion criteria**
  Clinical trials are typically designed to produce scientific results, and, in case of registrational studies, to produce data, which would potentially allow to apply for approval and registration of the researched medicine. In other words, clinical trials are not designed to meet people's need.

The issues around access to new treatments in clinical trials raised another question: Are the inclusion and exclusion criteria (the criteria which define what people are allowed in a clinical trial) appropriate? In many cases, they are not. HIV-positive people, who have previously received an antiretroviral therapy, have been excluded from trials with new drugs. Limits for laboratory values, like CD4 cell count and viral load, are often unacceptable. Often, entire population groups, such as people on drug maintenance treatment with methadone or buprenorphine, have been excluded.

- **Placebo**
  The use of placebo in clinical trials has probably been one of the most controversial issues in clinical research. While it was widely felt that the use of placebo in clinical trials for life-threatening diseases is unethical when a proven treatment exists, the use of placebo without an optimised background regimen, continued in the HIV/AIDS sector until the mid-1990s, not only in trials for new antiretrovirals, but also in trials for treatment of opportunistic infections, such as PCP and CMV. In 1989, ACT UP New York demanded an end to placebo-controlled trials that required "body counts" or a "death toll" to prove efficacy.

- **Combination therapy**
  Currently, the best treatment for HIV-infection is combination therapy, consisting of several antiretroviral drugs. Combination therapies prove to be the best option also in other diseases, such as many forms of cancer, viral hepatitis, tuberculosis, or certain forms of epilepsy. Establishing combination therapies in HIV treatment has been one of the most challenging tasks in AIDS activism and clinical research. Which drugs to choose for a combination? How to combine them? Also, how to test the combination in a clinical trial against a monotherapy? Or compare one combination with another?

  Data from early combination trials with AZT and ddI became available in 1995 and suggested that a drug combination could be superior to monotherapy. At the same time, clinical trials with a new class of drugs, the protease inhibitors, were already on their way. They had to compare the protease inhibitor against an AZT monotherapy. As the news about combination therapies spread, these clinical trials were facing the danger of seeing the participants abandoning the trials in favour of a combination therapy. Such evasion of trial participants jeopardised the protease inhibitor trials, and would have meant a significant setback in the development of the new medicinal class. AIDS treatment activists contributed significantly to rescue these trials by developing a roll-over concept for trial participants. Through those roll-overs, participants were allowed to receive combination therapies. The regulatory authorities also accepted this procedure.

- **Patient safety**
  Almost all ARVs and the combinations (HAART) have the potential for severe side effects, ranging from mild (i.e. nausea and headache) to severe (i.e. body composition disorders and even death). Some antiretrovirals are associated with serious drug-drug interactions. PLWHA were the first to identify these risks and asked for clinical trials, which to investigate the management of side effects or the prevention of toxicities.

AIDS activists have taken up this need, demanding that pharmaceutical companies conduct extensive pre-clinical studies on potential drug-drug interactions of investigational compounds and in vitro studies of potential toxicities.

The availability of HAART also allowed the establishment of evidence-based treatment recommendations and treatment standards. Thus, the need for experimental treatments declined in certain settings, especially where the well-established standard of care treatments was available.

7. Community participation and community-based organisations in the field of treatment

- **Denver Principles**
  In 1983, a group of people living with AIDS convened at a health conference in Denver, Colorado, and developed the Denver Principles. This statement included, amongst others, the following: *"We condemn attempts to label us as 'victims,' a term which implies defeat, and we are only occasionally 'patients,' a term which implies passivity, helplessness, and dependence upon the care of others. We are 'People With AIDS."*
  The Denver Principles are sometimes summarised in the slogan "Nothing Without Us", referring to the involvement and participation of people with AIDS in research.

- **Community Advisory Boards (CABs)**
  Since the early 1990s, activist groups have been discussing different issues with the sponsors of clinical trials, usually pharmaceutical companies, and have demanded access to the protocols of clinical trials, before the trial designs are finalised. On many occasions, activists had to protest against inappropriate criteria. From these interactions, the concept of Community Advisory Boards emerged. Community Advisory Boards (CABs) are groups composed of HIV-positive people, AIDS treatment advocates, and/or relatives and friends of HIV-positive people. The European Community Advisory Board (ECAB) was founded in 1997; similar CABs now exist in the US, Canada, France, the UK, Italy, Romania, the Russian Federation and Germany. CABs represent the interests of people living with HIV in clinical research and ask the questions that the community has an interest in, during the research process.

8. Achievements of HIV/AIDS treatment activism

The milestones of HIV/AIDS treatment activism in summary are:

- Parallel track programme for ddI in the US
- Expanded access/named patient programmes for ddI in Europe
- Expanded access to 3TC (lamivudine) worldwide. More than 30,000 people with HIV received the medicine as a result of that.
- Stopping the use of placebo without an optimised background regimen or standard of care in clinical trials
- Research into combination therapies
- Improving inclusion and exclusion criteria of clinical trials
- Improving patient's safety in clinical trials via alterations of the trial protocols

9. Past and present challenges for AIDS treatment activism

- **Access to treatments in underserved communities and/or regions**
  Depending on the country, there may still be underserved communities or regions where adequate HIV/AIDS treatment is not available. In certain settings women (especially, women with children), drug users, and, in some areas, heterosexual people and/or MSM, may not receive adequate care. In countries with clear regional differences and a centralised health care system, people living in rural areas may be underserved and have difficulties in accessing treatment and care.

- **Removal of barriers to treatment and care**
  While we are nearing the fourth decade of HIV/AIDS, there are still many barriers to treatment and care. While some of them (e.g., stigma and discrimination) are being dealt with in other sections of this manual, others are discussed here. For example, patent issues and intellectual property protection prevent the production of generic antiretroviral drugs at a cost affordable to poorer countries. It still seems that after nearly a decade of intense discussions with all stakeholders there is no easy solution to this problem. Other barriers, such as inappropriate allocation of resources to the HIV/AIDS sector, also need to be addressed.

- **Establishing a standard of care**
  Despite the existence of European Treatment Guidelines for HIV Infection (published by the European AIDS Clinical Society, EACS), a standard of care is not yet established in all European countries. In particular, in countries where people have limited access to treatment, the existing documents, published by EACS, may be helpful in setting an acceptable standard of care that nears the standard of more developed countries.

- **Involvement and active participation in research and clinical trials**
  The active participation of people with HIV in clinical trials remains a constant effort for AIDS treatment activists. This active participation is crucial for HIV/AIDS research, as it is the community of PLWHA that can best identify its main needs.

- **Continuous funding for HIV/AIDS treatment and care**
  Adequate financial resources for HIV/AIDS treatment and care are not only an issue for resource-limited countries, but also for the highly industrialised countries. With health budget cuts, high costs of new drugs and the current worldwide financial crisis, we are at risk of reducing the quality of treatment, care and support, as well as the access to treatment.

- **Access to information on therapies and treatment options**
  Information on treatment options and benefits and/or limitations of currently available therapies can be life saving for people with HIV. Therefore, providing information is an integral part of AIDS treatment activism. This information should be based on the best available sources, it should not be biased, or influenced by interests, other than the interest of reaching the best treatment and care for people living with HIV.

Group work: History of AIDS treatment activism

The aim of this part of the session is to allow participants to identify important milestones of AIDS treatment activism in their home countries or regions. Participants should be divided into working groups of approximately five-eight people each, according to countries / regions of origin.

1. Topics

- When was the first community-based AIDS organisation found in your country?
- What were important milestones in the involvement of NGOs in national or regional AIDS programme?
- Can you identify milestones of HIV advocacy in each country from your region?
- When did people with HIV/AIDS organise for the first time a public protest, press conference or other activity to express their needs in public in your country or region?
- What are your personal experiences in regards to HIV/AIDS treatment activism in your country/region?

2. Methodology

The working groups should produce a flip chart or poster, which provides a historical outline of key activities in their countries/regions. Following the group work, results will be presented to the plenary. Similarities and differences between various countries and regions should be identified and possibly underlying causes should be discussed.

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Further reading and internet resources

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Smith, Raymond A. (Ed.): The Encyclopedia of AIDS: A Social, Political, Cultural, and Scientific Record of the HIV Epidemic. Fitzroy Dearborn Publishers 1998

On the web

ACT UP Oral History Project http://www.actuporalhistory.org

AIDS Oral History Project http://history.nih.gov/NIHInOwnWords/
The Body
An extensive collection of articles from HIV newsletters and other publications from around the world, and an archive of historical newsletters. http://www.thebody.com

Various films and documentaries on AIDS treatment activism in the US and worldwide can be traced at http://www.youtube.com, for example:

1989 http://www.youtube.com/watch?v=q7BfwFqoicA runtime 1:25
ACT UP Demonstration, Vito Russo "Silence=Death"

1991 http://www.youtube.com/watch?v=By9kgVBuEok runtime 9:22
January 24, 1991: Hundreds of demonstrators flooded Grand Central Terminal during the height of rush hour. They demanded more research money for AIDS.

2004 http://www.youtube.com/watch?v=W0FpveJwm9o runtime 5:22
FrontAIDSPart. Documentary on Russian AIDS activists, Russian with English subtitles (part 1/3)
http://www.youtube.com/watch?v=Fh9urWFy5w8 runtime 3:15 (part 2/3)
http://www.youtube.com/watch?v=C6z6IgGWra8 runtime 5:03 (part 3/3)

2007 http://www.youtube.com/watch?v=qSpTdO4FBZI runtime 1:52
Novartis, a global pharmaceutical company, is challenging India's patent law. India supplies half of all AIDS medications used in poor countries. If Novartis wins its court case, access to AIDS treatment could be shut off for hundreds of thousands of people. Their lives hang in the balance.
On February 14, 2007, AIDS activists demonstrated outside Novartis offices in Cambridge, Massachusetts (USA), during a blizzard.

3

INTRODUCTION TO COMBINATION THERAPY

by Svilen Konov

3.
INTRODUCTION TO COMBINATION THERAPY

Aims and objectives

The aim of this section is to acquaint the reader with antiretroviral therapy, its use and the monitoring of its effects. After reading this material, the trainer/trainee will have a basic understanding of:

- Combination Anti Retroviral Therapy (CART)
- The HIV life cycle and the significance of it; how different antiretrovirals (ARVs) work
- Development and approval process of ARVs
- Currently approved ARVs and their use
- Monitoring tests used to assess the effect of the ARVs on HIV
- ARVs in development and novel approaches to treating HIV-infection

This section does not cover all aspects of CART, i.e. side effects, drug interactions, ARV use in specific subpopulations like hepatitis C and B co-infected people or people with tuberculosis, drug users, pregnant women, etc. This is because those issues are covered in different sections or publications of the EATG. Further information on the above-mentioned topics is given in the referral section of this chapter.

All acronyms used in this section are explained at the end of the manual.

Abstract

CART is Combination Antiretroviral Therapy. Its different components work at a different stage of the HIV life cycle. Creating a new ARV is a difficult process that may take up to 10 years or even more, before it is approved for marketing. The studies that are required before approval are divided into 4 main phases. To-date, there are more than 5 classes of approved ARVs. Each ARV is taken in a specific way. The effect of the ARVs on HIV is monitored with special tests, the main ones of which are the CD4 count and the viral load. There is a number of new ARVs in the pipeline and researchers are looking into new approaches to treating HIV-infection and possibly eradicating the virus.

How to deliver the material of this section

PowerPoint presentation with distribution of handouts during the talk. Duration: 40 minutes with 20 minutes questions and answers. As the topic may be particularly complicated for some of the trainees, we suggest questions to be taken as soon as they arise, as the presentation gradually progresses to a more complicated level. As a result, not understanding certain points in the beginning may turn out to be detrimental to the general understanding of the topic.

Detailed presentation material

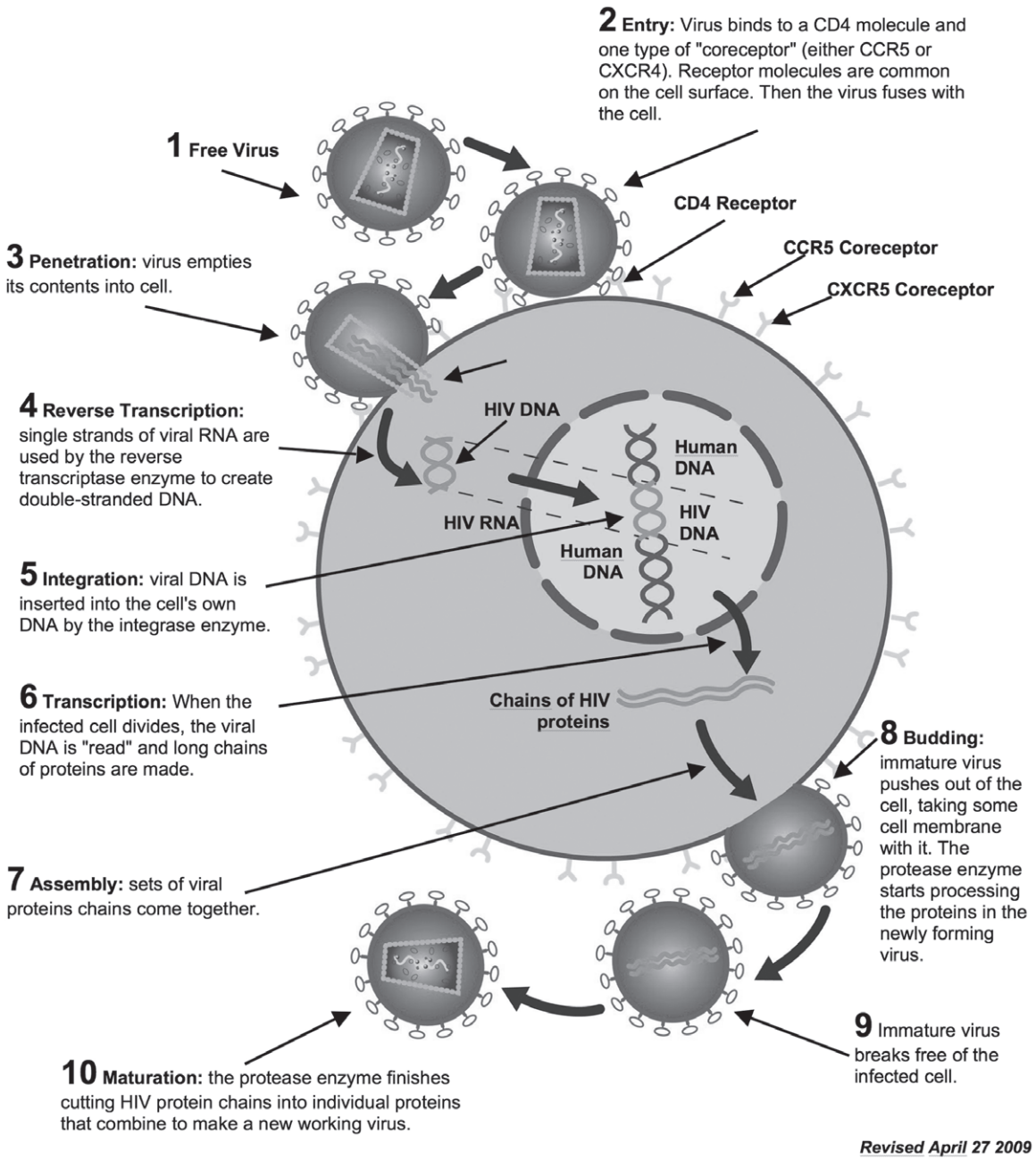
1. What is CART?

CART stands for Combination Anti Retroviral Therapy. It consists of 3 or more medicines and is used to treat HIV-infection. It is CART, because it is:

- Combination-consists of several elements (several medicines)
- Antiretroviral-fights retroviruses (HIV is a retrovirus). A retrovirus is an RNA virus (a virus composed not of DNA but of RNA). Retroviruses have an enzyme called reverse transcriptase that gives them the unique property of transcribing RNA (their RNA) into DNA. The retroviral DNA can then be integrated into the chromosomal DNA of the host cell to be expressed there.
- Therapy-treatment that goes on for a certain period of time or forever. So far, the therapy that is used to treat HIV infection needs to be taken for life.

Other terms used to describe CART are:
- ARV therapy (Anti Retroviral Therapy)
- Triple therapy or triple combination
- HAART (Highly Active Anti Retroviral Therapy)

2. HIV life cycle[1]



3. How the ARVs are developed and approved

To develop and get a new medicine on the market can take 10 years and in some cases even longer. There are 2 main methods to develop a new HIV medicine:

- Screening; when researchers are checking currently existing compounds for activity against HIV
- Rational drug design-after identifying a target in the viral life cycle, scientists design a compound that will attack the virus exactly at that point

[1] Diagram courtesy of www.aidsinfonet.org

If a promising new compound is found, then the pre-clinical stage of the development can be started. It involves work in laboratories (test tubes) and animal experiments with the new compound. If the results are encouraging(i.e. anti HIV activity is clearly proved and toxicity is low enough, so that application in humans can be considered), then the compound developer can start clinical trials (in humans), but only after an official permission of a regulatory body.

The clinical trials are generally divided into 4 major phases:

- **Phase I** - this phase looks into whether the new medicine will be safe for humans. All participants in this phase receive the new medicine, but it may be (and usually is) given in different dosages. All reported adverse events are closely monitored and described. The number of people who are enrolled in this phase is usually small-from 10 to 100. It is rare (but sometimes possible) HIV-positive people to be included at this stage of research. The participants are usually healthy volunteers or if they have HIV-infection, then they are treatment-naïve, meaning they do not need CART immediately or on the near future and their general health allows them to participate.
- **Phase II** - in this phase the side effects are recorded further and even in a more detailed way. The main purpose of this phase, however, is to check to what extent or how well the new medicine works against HIV. The duration is about 1-2 years and the number of participants can reach several hundred. In majority of cases these trials are randomised, masked (also known as blinded) and placebo controlled. Randomised means that participants are divided on a random basis, so that the groups can be similar in terms of age, sex, background and other important factors that may play a role in their response to the new medicine. 'Masked' refers to the fact that neither the medical professionals, nor the participants know what the HIV-positive person receives, i.e. the new medicine or placebo (a dummy medication that looks and tastes exactly like the active one, but does not have the effect). The presence of a placebo group makes the trial 'placebo controlled'. The control group is used as a comparison, so that researchers can avoid a situation where the participants have some effect from the new medication that is entirely psychological.
- **Phase III** - this phase often involves several clinics and may often be conducted in many different countries. It can involve several thousand participants and collects data on the drug's effectiveness and side effects on a much larger scale. Often, researchers may use the data from phase III for sub analyses that look into a particular side effect, co-morbidity or genetics. This study may last for a year or more and is normally randomised, blinded and placebo controlled. Only after completing Phase III and having acceptable results, the institution that develops the new medicine may apply to a regulatory body for marketing approval of the new medicine. This process is very stringent and often some manufacturers are required to provide an array of further information before their product is approved.
- **Phase IV** - this phase is also known as a 'post-marketing' phase. It is conducted after the new medicine is already is use and a larger number of HIV-positive people are using it. In recent years, the importance of these studies has grown tremendously, as some side effects of the ARVs may show only in the long run, long after the medicine has been approved (i.e. lipodystrophy). That is why in some parts of the world (EU, for example), the regulatory bodies have the power to withdraw marketing permission if the manufacturer does not meet the requirement for post-marketing studies.

4. Currently registered ARVs, how they work and how they are taken

To-date, there are more than 5 classes of ARVs. The following table shows how they work and gives some examples of ARVs that belong to the different classes:

ARV class	How it works	Examples
Nucleos(t)ide reverse transcriptase inhibitors (NRTIs), also known as 'nukes'	NRTIs block reverse transcriptase's enzymatic function and prevent completion of synthesis of the double-stranded viral DNA, thus preventing HIV from multiplying	AZT, ddI, d4T, 3TC, ABC, TDF, FTC
Non-nucleoside reverse transcriptase inhibitors (NNRTIs), also known as "non-nukes"	NNRTIs block reverse transcriptase by binding at a different site on the enzyme, compared to NRTIs. NNRTIs are not incorporated into the viral DNA but instead inhibit the movement of protein domains of reverse transcriptase that are needed to carry out the process of DNA synthesis	nevirapine, efavirenz, etravirine
Protease inhibitors (PIs)	PIs prevent viral replication by inhibiting the activity of HIV protease, an enzyme used by the viruses to chop up developing proteins for final assembly of new virions.	indinavir, ritonavir, saquinavir, nelfinavir, fosamprenavir, lopinavir/r, atazanavir, tipranavir, darunavir
Fusion (entry) inhibitors (EIs)	EIs interfere with the binding, fusion and entry of an HIV virion to a human cell.	enfuvirtide
Integrase inhibitors (INIs)	INIs block the action of integrase, a viral enzyme that inserts the viral genome into the DNA of the host cell	raltegravir, elvitegravir
CCR-5 inhibitors	They are designed to prevent HIV infection of CD4 T-cells by blocking the CCR5 receptor. When the CCR5 receptor is unavailable, 'R5-tropic' HIV (the variant of the virus that is common in earlier HIV infection) cannot engage with a CD4 T-cell to infect the cell	maraviroc, vicriviroc

The currently recommended doses for adults with HIV-1-infection (children's doses differ from the adults') are as follows (please note that specific sub-populations like pregnant women, people on substitution therapy, people with co-morbidities, etc. may require dose adjustments):

ARV	Daily dose (adults)	How to take and store	Possible side effects
NRTIs			
abacavir	2 (300 mg: 1, 2x/day or 2, 1x/day)	No food restrictions.	Hypersensitivity reaction in about 8% of people.
Combivir	2 (150 mg lamivudine + 300 mg zidovudine: 1, 2x/day)	No food restrictions.	Anaemia, nausea, vomiting, headache, fatigue, muscle aches, bone marrow toxicity.
didanosine	Buffered tablet: 4 (100 mg: 2, 2x/day or 4, 1x/day) Videx EC:1 pill daily; 400 mg for people over 60 kg/ 132 lbs; 250 mg if below.	Chew or dissolve in water; take on empty stomach; not within 1 hour of indinavir or 2.5 hours of ritonavir.	Diarrhoea, pancreatitis, abdominal pain, neuropathy, nausea & vomiting.
emtricitabine	1 (200 mg: 1, once a day)	No food restrictions.	Headache, diarrhoea, nausea and rash.
Kivexa	1 (600 mg abacavir + 300 mg 3TC; 1, once a day)	No food restrictions.	Nausea, vomiting, fatigue, headaches.
lamivudine	1 (600 mg abacavir + 300 mg 3TC; 1, once a day)	No food restrictions.	Nausea, vomiting, fatigue, headaches.
stavudine	2 (40 mg for people over 60 kg/ 132 lbs; 30 mg if below: 1, 2x/day)	No food restrictions.	Peripheral neuropathy, headache, chills & fever, diarrhoea, nausea.
tenofovir	1 (300 mg: 1, 1x/day)	No food restrictions.	Mild side effects; some nausea, vomiting, loss of appetite. May reduce bone mineral density.
Trizivir	2 (150 mg lamivudine + 300 mg zidovudine + 300 mg abacavir: 1, 2x/day)	No food restrictions.	See zidovudine (Retrovir,) lamivudine (Epivir) and abacavir (Ziagen) above.
Truvada	1 (300 mg tenofovir + 200 mg emtricitabine: 1, 1x/day)	No food restrictions.	Headache, nausea, vomiting, rash, loss of appetite.
zidovudine	6 (100 mg: 2, 3x/day) or 2 (300 mg: 1, 2x/day)	No food restrictions.	Anaemia, nausea, vomiting, headache, fatigue, muscle aches, bone marrow toxicity.

ARV	Daily dose (adults)	How to take and store	Possible side effects
NNRTIs			
efavirenz	3 (200 mg: 3, 1x/day) or 1 (600 mg; 1, 1x/day)	Take on an empty stomach before going to sleep.	Vivid dreams, anxiety, rash, nausea, dizziness, diarrhoea, headache and insomnia.
etravirine	4 (100 mg, 2, 2x/day)	Take after a meal.	Rash, nausea, abdominal pain
nevirapine	1 (200 mg; 1, 1x/day for the first two weeks) then 2 (200 mg: 1, 2x/day)	No food restrictions.	Skin rash, fever, headache, nausea
Combination medicines of 2 classes			
Atripla	1 (600 mg efavirenz + 200 mg emtricitabine + 300 mg tenofovir, 1x/day)	Take on an empty stomach before going to sleep.	Vivid dreams, anxiety, rash, nausea, dizziness, diarrhoea, headache and insomnia, vomiting, loss of appetite
PIs			
atazanavir	2 (300 mg: 1 plus 1 100mg ritonavir, or 3 (200 mg; 2, plus 1-100 mg ritonavir, once a day)	Take with food.	High levels of bilirubin. Nausea, headache, rash, stomach pain, vomiting, diarrhoea, tingling in hands or feet, and depression. Changes in heart rhythm.
darunanavir	6 (300 mg, 2 + 1 ritonavir, twice a day) or 4 (600 mg + 1 ritonavir, twice a day)	Take with food.	Diarrhoea, nausea, vomiting, headache and common cold. Rash which in rare cases may be serious.
fosamprenavir	4 (700 mg; 2, twice a day) or 4 (700 mg, 2 + 2 ritonavir, once a day; or 700 mg, 1 + 1 ritonavir twice a day)	No food restrictions.	Nausea, diarrhoea, vomiting, rash, numbness around mouth, abdominal pain. Increase in cholesterol and triglycerides.
indinavir	6 (400 mg: 2, every 8 hours, not 3x/day) or 9 (333 mg; 3 every 8 hours)	Take with lots of water, on empty stomach or with low-fat snack. Keep cool and dry.	Headache, nausea, abdominal pain, kidney stones.
lopinavir/ ritonavir	4 (200 mg lopinavir + 50 mg ritonavir: 2, 2x/day)	No food restrictions for tablets; take liquid with food. Keep at room temperature.	Diarrhoea, fatigue, nausea, headache. Increase in cholesterol and triglycerides.
nelfinavir	9 (250 mg: 3, 3x/day) or 10 (5, 2x/day or 4 (625 mg; 2, 2x/day)	Take with meals or a snack.	Diarrhoea, nausea, gas, abdominal pain, weakness.

ARV	Daily dose (adults)	How to take and store	Possible side effects
ritonavir	12 (100 mg: 6, 2x/day); small doses used to boost other protease inhibitors	Take with food if possible. Keep refrigerated. Take 2 hours apart from ddI.	Nausea, vomiting, diarrhoea, tingling & numbness around the mouth. Increase in cholesterol and triglycerides.
saquinavir	6(500 mg: 2 + 1-100mg ritonavir, 2x/day)	Take within two hours of a full meal or large snack. In hot climates, keep refrigerated.	Minimal nausea, diarrhoea, abdominal discomfort.
tipranavir	8 (250 mg, 2 + 2 ritonavir 100 mg, twice a day)	Take with food. Refrigerate, or keep at room temperature up to 60 days.	Diarrhoea, rash, nausea, vomiting, stomach pain, tiredness and headache. Worsening of liver problems. Increase in cholesterol and triglycerides.
EIs			
enfuvirtide	2 injections each day. 90 mg per injection for adult	No food restrictions.	Skin reactions where drug is injected, ranging from redness and itching to hard lumps.
CCR-5 inhibitors			
maraviroc	1 or 2 tablets twice each day. 150, 300 or 600 mg per tablet.	No food restrictions.	Cough, fever, upper respiratory infections, rash, sore muscles, abdominal pain, and dizziness. Can be hard on the liver.
INIs			
raltegravir	2 tablets (400 mg, 2x per day).	No food restrictions.	Diarrhoea, nausea and headache; elevated levels of creatine kinase (relates to muscle problems)

5. Monitoring tests used to assess the effect of the ARVs on HIV

When treating somebody with HIV, many and different monitoring tests are used. Some check for specific conditions, while others check the general health. Those may include: complete blood count, chemistry panel, blood sugar and fats, etc. There is a set of tests, however, that checks for specific aspects of the HIV-infection. They are used at different moments, depending on clinical necessity. Those tests are:

Viral load (PCR; b-DNA, NASBA) - Viral load is a measure of the severity of a viral infection, and can be calculated by estimating the amount of virus in a certain amount of body fluid. For example, it can be given in RNA copies per millilitre of blood plasma. There are different approved methodologies to check the viral load and the results may slightly differ from system to system.

CD4 count (flow cytometry) - CD4 counts measure the number of T cells containing the CD4 receptor. Results are usually expressed in the number of cells per microlitre of blood. While CD4 tests are not an HIV test in that they do not check the presence of viral DNA, or specific antibodies, they are used to assess the state of the immune system. People are often started on ARVs when the CD4 count reaches a low point, around 350 cells per ml3. CD4 count plus the viral load are the two main tests that are currently used to determine the efficacy of the treatment.

Genotype resistance tests – With this test, the genetic code of the sample virus is compared to the wild type virus. The code is a long chain of molecules called nucleotides. Each group of three nucleotides, called a "codon," defines a particular amino acid used to build a new virus. Mutations are described by a combination of letters and numbers, for example K103N. The first letter (K) is the code for the amino acid in the wild type virus. The number (103) identifies the position of the codon. The second letter (N) is the code for the "changed" amino acid in the mutant sample. Generally, the genotype resistance test helps to determine whether certain ARVs will work against the particular HIV type of the HIV-positive person.

Phenotype resistance tests – During this test, a sample of HIV is grown in the laboratory. A dose of one ARV is added. The growth rate of the HIV is compared to the rate of wild type virus. If the sample grows more than normal, it is resistant to the medication

Therapeutic drug monitoring – measures medicine levels in blood. Its main focus is on drugs with a narrow therapeutic range, i.e. drugs that can easily be under- or overdosed. In pharmacology, many medicines are used without monitoring of blood levels, as their dosage can generally be varied according to the clinical response. In a small group of drugs, this is impossible, as insufficient levels will lead to sub-optimal treatment or resistance, and excessive levels can lead to toxicity and damage. Using this test, the clinician can determine whether an HIV-positive person gets enough or too much amount of the ARVs to suppress the replication of the virus. This is a very important test for HIV-positive pregnant women and also children.

HLA-B*5701 - This is a genetic test that predicts the chance of developing a hypersensitivity reaction to abacavir. The gene is associated with drug-induced inflammatory disease of the skin. Not every negative result from the test means that there is no chance of developing the reaction. That is why, HIV-positive people who are taking abacavir require close monitoring, especially shortly after starting therapy.

Tropism test - The tropism test is helpful in deciding whether a CCR5 inhibitor will be useful in controlling a patient's HIV.

Framingham score – The Framingham score is used to estimate 10-year risk for "hard" coronary heart disease outcomes (myocardial infarction and coronary death.) Even though it is not an actual test to check the status of the infection, it has become very important in the recent years, as heart disease turned out to be one of the major health problems for HIV-positive people in the long run.

ARVs in development and novel approaches to treating HIV-infection[2]

With the enhanced understanding of the HIV life cycle, researchers are looking into more targets where the virus can be attacked. Even though the development of new compounds from the traditional classes is thriving, some scientists propose new approaches to treating the infection and some of them talk about eradication of the virus as well.

Among the new classes in development are:

- Maturation inhibitors-they inhibit the development of HIV's internal structures in a new virus
- Zink finger inhibitors-the inner core of HIV is called the nucleocapsid. It is held together by structures called "zinc fingers". Zinc finger inhibitors (or zinc ejectors) are drugs that can break apart these structures and prevent the virus from functioning. Scientists believe that the nucleocapsid core cannot mutate very easily, so a drug that works against zinc fingers might be effective for a long time. Unfortunately, zinc fingers are not only used by the HIV. Drugs that attack them could have serious side effects.
- Viral decay accelerators-this class encourages mutations in HIV to the point that the virus is no longer functional
- Gene therapy-different therapies are experimented with, notably therapies that produce CD4 cells that resist infection by HIV. Other promising gene therapies interfere with the viral protein vpr or with the HIV's tat gene.

References

AidsInfoNet ..... http://www.aidsinfonet.org/fact_sheets/view/106 - HIV life cycle
http://www.aidsinfonet.org/categories/view/2 - Laboratory tests
http://www.aidsinfonet.org/fact_sheets/view/401 - Taking current antiretrovirals
http://www.aidsinfonet.org/fact_sheets/view/470 - Other antiretrovirals in development
http://www.aidsinfonet.org/fact_sheets/view/105 - Phases of clinical trials
HIV i-Base ..... http://i-base.info/guides/starting - Introduction to combination therapy

Further reading and internet resources

Information on individual ARVs and comprehensive information on HIV
http://www.aidsinfonet.org/categories/view/5
http://i-base.info/ttfa/
http://www.aidsmeds.com/list.shtml
Side effects ..... http://i-base.info/guides/side
http://www.aidsinfonet.org/categories/view/17
HIV and pregnancy .... http://i-base.info/guides/pregnancy
Changing treatment ... http://i-base.info/guides/changing
Clinical trials ..... http://i-base.info/home/clinical-trials-community-guide-to-hiv-research/
Co-infections ..... http://i-base.info/guides/hepc
http://www.treatmentactiongroup.org/uploadedFiles/Projects/Hepatitis_C_-_HIV/HBVGuide09.pdf

[2] For more detailed information, including description of different compounds, please visit: http://www.aidsinfonet.org/fact_sheets/view/470

4

STANDARDS OF TREATMENT

WHAT DO PLWHA IN MY COUNTRY LACK?

by Svilen Konov

4.
STANDARDS OF TREATMENT

WHAT DO PLWHA IN MY COUNTRY LACK?

Aims and objectives

The purpose of this section is to present some internationally recognised guidelines on treatment of HIV infection with a particular emphasis on the guidelines produced by the European AIDS Clinical Society (EACS). After reading this section, the trainer/trainee will have an understanding of:

- When to start ART
- Which medicines to use
- What algorithm of monitoring of the infection should be followed
- What and how to use PEP(SE)
- Where to find additional information about state-of-the-art treatment algorithms

Abstract

Provision of HIV treatment is quite complex, as PLWHA have diverse needs and different countries have health care systems that are organised differently. Still, governments should provide access to optimal treatment for HIV according to needs. There are attempts to create a common standard of treatment across EU and Europe, but, to date, different countries decide on an individual basis how to organise PLWHA health care and what treatment to provide to them. The guidelines of the European AIDS Clinical Society make an attempt to take into account the availability of medical equipment and expertise on the one hand and the state-of-the-art medical science on the other in order to present a 'golden' standard algorithm for treatment that can be used throughout Europe. The guidelines' recommendations can be useful for new HIV activists, when questioning treatment regimes.

How to deliver the material of this section

It is expected that the trainer uses a PowerPoint presentation with distribution of handouts during the talk, followed by group work to identify the differences in the standards of provision of HIV treatment locally versus best practices in Europe. The PowerPoint presentation should be delivered in a plenary session, after which the trainees should be divided into several groups (5 participants maximum per group), preferably by country or region.

Time of the session: 2 hours and 30 min. (1 hour presentation, 1 hour group work, 30 min. feedback). As the topic may be particularly complicated for some of the trainees, it is suggested that

questions are taken as they arise, as the presentation gradually progresses to a more complicated level. As a result, failure to understand certain points in the beginning may turn out to be detrimental to the general understanding of the topic.

> NOTE: The above description of how to deliver the session is only advisory. The methodology has already been used successfully, but the trainer should feel free to adapt it, according to the local training circumstances.

Detailed presentation material

The provision of medical care for PLWHA is a very complex process that requires sophisticated organisation, expertise, substantial financial and human resource and many other components. As a result of the many specific aspects of HIV infection, PLWHA have quite diverse needs. Those needs are not only defined bio-medically, but also culturally, geographically, socio-economically, psychologically, etc.

The fundamental needs, however, ,are treatment, care, support and prevention of opportunistic infections and other medical conditions.

Generally, the healthcare system is expected to be scaled up for HIV treatment and care to everybody who needs it, prevent medical complications and allow the PLWHA to:

- Have access to optimal treatment for HIV according to needs
- Start HIV treatment in an optimal time
- Be able to switch HIV treatment at the optimal time
- Be able to manage side effects
- Plan long term HIV treatment
- Access treatment for any other than HIV-infection complications and prevention for those

Different countries' health care systems meet these expectations with varied success. The reasons for that are many and quite complex.

Some activists, doctors, decision-makers and other stakeholders have worked together for a long time in an attempt to reach a common standard of treatment, care and support, in the EU, at least, but, so far, it has not been universally accepted. The situation is still such, that some countries have their own concept for what is best in terms of treatment for their people with HIV infection and this is reflected in national guidelines on treatment (UK, France, etc.), while other countries rely on expert opinions of prominent local doctors.

There is, however, a pan European organisation of clinicians working in the field of HIV/AIDS called European AIDS Clinical Society. This organisation, via a panel of experts (including community representatives) produces Guidelines for the Clinical Management and Treatment of HIV Infected Adults in Europe. An attempt has been made in the EACS document to reflect the most advanced and evidence-based trends, thus becoming a 'golden standard' for treatment, and at the same

time to take into account the availability of some medical services in different countries of Europe. As many activists, particularly from Eastern Europe and Central Asia, still have questions about what is the 'best' treatment, combination, when to start and how to proceed with the management of the infection, the next part of this section will cover some of the main questions and hopefully will lead to a comparison and show some disparities between the treatment provided in the local settings and the one suggested on a European level.

The treatment algorithm proposed by EACS is used only as an example of an advanced way of providing treatment and also as one that reflects the latest development in HIV medical science.

1. What algorithm for assessment of the patient the doctors should use? What shall I receive in terms of monitoring, which tests and when?

Initial visit

- Complete medical history
- Physical examination, including height, weight, BMI, blood pressure, waist circumference
- Laboratory evaluation
    - Confirmation of HIV antibody positive
    - Plasma HIV RNA
    - Resistance testing (genotype) with determination of HIV subtype
    - CD4 absolute count + percentage (optional: CD8 and %)
    - Complete blood count, AST, ALT, Alk.phosphatase, calcium, phosphate, glucose, creatinine, calculated creatinine clearance
    - Antibody tests for toxoplasma, CMV, Hepatitis A, B and C and syphilis
    - Fasting blood glucose and lipids including fasting total LDL & HDL cholesterol, and triglycerides
    - Urine dipstick for protein and sugar
    - HLA B*5701 determination (if available)
    - R5 tropism (if available)
    - Cardiovascular risk assessment
- Sexually Transmitted Infection screen if appropriate
- Women: cervical pap smear
- Assessment of social and psychological condition: provide support and counselling if needed
- Consider HAV and HBV vaccination (depending on serology results) and pneumococcal vaccination
- PPD if CD4 above 400. Negative PPD does not exclude active or latent tuberculosis. T.SPOT.TB® (or QuantiFERON-TB Gold IT®) can be an alternative to PPD in selected high risk populations (if available)

Subsequent visits

(Asymptomatic patients not receiving antiretroviral therapy)

- At least every 6 months
    - Complete blood count, CD4 count and %
    - Plasma HIV RNA

- Every year
    - Physical examination
    - Evaluation of social and psychological support
    - Smoking cessation, diet evaluation
    - Repeat serologic testing (syphilis, CMV, toxoplasmosis, hepatitis B, hepatitis C) if previously negative
    - AST, ALT
    - Women: cervical pap smear
    - Fasting lipids
- Every 6 months
    - If cirrhosis (regardless of cause): alpha-fetoprotein + ultrasound examination

- Treatment initiation

- Assess and support patients' readiness to start combined ART (see specific Table)
- Physical examination, including height, weight, BMI, blood pressure, waist circumference
- Plasma HIV RNA
- Resistance testing (genotype), if not yet obtained
- CD4 count and % (optional: CD8 count and %)
- Complete blood count, AST, ALT, bilirubin, creatinine, calculated creatinine clearance, calcium, phosphate
- Fasting glucose and lipids
- Urine dipstick for protein and sugar
- Other laboratory parameters may be useful according to selected first-line regimen e.g. protein creatinine ratio, amylase, lipase
- Cardiovascular risk assessment

- Visits on therapy

- Plasma HIV RNA
- CD4 count and % (optional: CD8 count and %)
- Complete blood count, creatinine, calculated creatinine clearance, AST, ALT bilirubin
- Other laboratory parameters according to selected regimen
- Fasting glucose and lipids

2. When shall I start ART?

SYMPTOMATIC	• CDC stage B and C: treatment recommended • If OI, initiate as soon as possible*
ASYMPTOMATIC	• CD4 < 200: Treatment recommended, without delay. • CD4 201-350: treatment recommended. • CD4 350-500: - Treatment recommended if hepatitis C co-infection, hepatitis B co-infection requiring therapy, HIV-associated nephropathy or other specific organ deficiency; - Treatment should be considered if VL>105 c/ml and/or CD4 decline >50-100/mm3/year or age >50 or, pregnancy, high cardiovascular risk, malignancy. • CD4 > 500: - Treatment should generally be deferred, independently of plasma HIV RNA; closer follow-up of CD4 if VL > 105 c/ml. - Treatment can be offered if presence of 1 of the above co-morbid conditions (CD4 350-500). • Whatever CD4 and Plasma HIV RNA, treatment can be offered on an individual basis, especially if patient is seeking and ready for ARV therapy
RESISTANCE TESTING	Genotypic testing and subtype determination recommended, ideally at the time of HIV diagnosis, otherwise before initiation of first-line regimen If genotypic testing is not available, a ritonavir-boosted PI should be included in the first-line regimen
ADDITIONAL REMARKS	• Before starting treatment, CD4 should be repeated and confirmed • Time should be taken to prepare the patient, in order to optimize compliance and adherence**

* Pay particular attention to drug-drug interactions, drug toxicities, immunereconstitution syndrome and adherence, etc...

**See recommendation on "Assessing and supporting patients' readiness to start ART"

3. Which ARVs shall I use when I start?

SELECT 1 DRUG IN COLUMN A AND 1 NRTI COMBINATION IN COLUMN B

	A	B	REMARKS
Recommended	**NNRTI**		
	• EFV[1]	TDF/FTC	- TDF/FTC co-formulated
	• NVP[5]	ABC/3TC[2-3-4]	- ABC/3TC co-formulated
			- EFV/TDF/FTC co-formulated
	or ritonavirboosted PI		
	• ATV/r[6]		- ATV/r: 300/100 mg qd
	• DRV/r[6]		- DRV/r: 800/100 mg qd
	• LPV/r[7]		- LPV/r:400/100 mg bid or 800/200 mg qd
	• SQV/r		- SQV/r:1000/100 mg bid
Alternative	SQV/r	• ZDV/3TC[8]	- SQV/r: 2000/100 mg qd
	FPV/r	• ddI/3TC or FTC[8]	- FPV/r:700/100 mg bid or 1400/200 mg qd
	RAL[9]		- RAL: 400 mg bid
			- ZDV/3TC co-formulated

1 EFV: not recommended in pregnant women or women with no reliable and consistent contraception; not active on HIV-2 and HIV-1 group O
2 Contra-indicated if HLA B*5701 positive. Even if HLA B*5701 negative, counselling on HSR risk still mandatory
3 ABC + NVP contra-indicated, unless HLA B*5701 negative
4 Abacavir should be used with caution in patients with a high cardiovascular risk and/or patients with a viral load higher than 100,000 copies/ml.
5 NVP: Use with extreme caution in women with CD4 >250 and men with CD4>400/↔L; not active on HIV-2 and HIV-1 group O
6 Castle study (LPV/r vs. ATV/r) has shown better tolerability of ATV/r and Artemis study (LPV/r vs. DRV/r) better efficacy and greater tolerability of DRV/r.
7 ACTG 5142, randomised study showed lower virological efficacy of LPV/r vs. EFV. However no PI mutations were seen in the LPV/r failures.
8 Only if unavailable or intolerant to other recommended NRTIs
9 Raltegravir is indicated in combination with other anti-retroviral medicinal products for the treatment HIV-1 infection in adult patients. It has been studied only in combination with TDF/FTC in naïve patients with limited follow-up (48 weeks).

4. How do we use post-exposure prophylaxis?

	POST-EXPOSURE PROPHYLAXIS (PEP) RECOMMENDED IF	
	Nature of exposure	Status of source patient
Blood	Subcutaneous or intramuscular penetration with IV or IM needle, or intravascular device	HIV + Or serostatus unknown but presence of HIV risk factors
	• Percutaneous injury with sharp instrument (lancet), IM or SC needle, suture needle • Contact > 15 min of mucous membrane or non intact skin	HIV +
Genital secretions	Anal or vaginal sex	HIV + Or serostatus unknown but presence of HIV risk factors
	Receptive oral sex with ejaculation	HIV +
Intravenous drug user	Exchange of syringe, needle, preparation material or any other material	HIV +

- Rapid testing of the source patient for HCV and HIV (if HIV status unknown) recommended,
- If source patient HIV+ on ARV therapy, order genotyping testing if HIVRNA >1000 copies/↔L
- If prior resistance test available in source patient, individualize the PEP therapy accordingly
- PEP to be started ideally < 4 hours after the exposure, and no later than 48 hours
- Duration of PEP: 4 weeks
- Standard PEP regimen: TDF/FTC (alternative: ZDV/3TC) + LPV/r tablets 400/100mg bid
- Full sexual health screen in case of sexual exposure
- Follow-up:
    - HIV serology + HBV and HCV, pregnancy test
    - (Women) within 48 hours of exposure
    - Reevaluation of PEP indication by HIV expert within 48-72 hours
    - Assess tolerability of ARV PEP regimen
    - Transaminases, HCV-PCR and HCV serology at month 1 if source of exposure were HCV+ (observed or suspected)
    - Repeat HIV serology after 2 and 4 months, syphilis serology after 1 month if sexual exposure

Group work:
Standards of treatment: What PLWHA in my country lack

Ideally, groups should be divided on a national, or if the country is large with much of differences in treatment standards, regional basis. Each participant should receive a copy of the EACS guidelines, possibly in his/her native language, as the guidelines are translated into majority European languages. This is particularly important if the trainee is not a native speaker of the language in which the training is conducted or challenged by the terminology in the foreign language.

The trainer should prepare a list of 10 key questions from the EACS guidelines. The trainees should be tasked to identify first what the EACS recommendation is for each question. Then they should describe how the matter is actually handled in their local countries. The trainee groups should then identify 3 variances they consider to be most important, and the reasons for selecting them.

At the end of this workshop, the trainees should return to a plenary session and present their work, with the trainer seeking to identify common key variances from the EACS guidelines.

References

Clinical Management and Treatment of HIV Infected Adults in Europe-Version 5
http://www.europeanaidsclinicalsociety.org/guidelinespdf/1_Treatment_of_HIV_Infected_Adults.pdf

Further reading and internet resources

Published and approved British HIV Association (BHIVA) guidelines:
http://www.bhiva.org/PublishedandApproved.aspx

European AIDS Clinical Society (EACS) guidelines on different HIV/AIDS related topics:
http://www.europeanaidsclinicalsociety.org/guidelines.asp

The US Department of Health and Human Services guidelines:
http://www.aidsinfo.nih.gov/Guidelines/Default.aspx?MenuItem=Guidelines

5

HUMAN RIGHTS, STIGMA AND DISCRIMINATION

PATIENTS' RIGHTS AS HUMAN RIGHTS

by Ninoslav Mladenovic

5.

HUMAN RIGHTS, STIGMA & DISCRIMINATION

PATIENTS' RIGHTS AS HUMAN RIGHTS

Aims and objectives

This section of the training manual aims to shed light on the right to health in international human rights law and to summarise key legal and policy issues. After reading this material and finishing the exercises, the trainer/trainee will have a basic knowledge about:

- How laws and regulations can either underpin or undermine public health programmes
- Specific regulations and standards related to PLWHA
- Patient's rights that are under active consideration or are of particular interest to PLWHA
- Nations' obligations with respect to the right to health
- National, regional and international accountability and monitoring mechanisms

Abstract

Laws relating to many areas of our lives—from intimate physical conduct to international travel—can contribute to stigma, discrimination, and exclusion or, conversely, can help remedy these inequities. In order to create a supportive legal framework for responding to HIV/AIDS, it is important to effectively address gaps and other problematic aspects in national legislations and regulatory systems.

How to deliver the material of this section

It is expected that the trainer uses a PowerPoint presentation, followed by group work to discuss inequalities in health system. The PowerPoint presentation should be delivered in a plenary session, after which the trainees should be divided into several groups (up to 6 participants per group).

Time of the session: 1 hour (15 minutes presentation, 30 minutes group work, 15 minutes feedback in the plenary).

NOTE: The above description of how to deliver the session is only advisory. The methodology has already been used successfully, but the trainer should feel free to adapt it, according to the local training circumstances.

Detailed presentation material

The international human rights standards include: the right to the highest attainable standard of health; non-discrimination and equality before the law; human rights of women; human rights of children; right to marry and found a family; right to privacy; right to education; freedom of expression and information; freedom of assembly and association; right to work; the right to enjoy the benefits of scientific progress and its applications; the right to freedom of movement; right to an adequate standard of living and social security; the right to participation in political and cultural life; the right to seek and enjoy asylum; the right to liberty and security of person; freedom from cruel, inhuman or degrading treatment or punishment.

The right to health in international human rights law is enshrined in a number of articles. The most important ones of those are:

- International Covenant on Economic, Social and Cultural Rights, article 12
- International human rights treaties recognising the right to health
- Declaration of Alma-Ata, 1978
- Declaration of Commitment on HIV/AIDS
- Political Declaration on HIV/AIDS
- UNAIDS/UN OHCHR International Guidelines on HIV/AIDS and Human Rights

From a legal perspective the right to health is an inclusive right. It contains both freedoms and entitlements. Ideally, health services, healthcare goods and facilities must be equally and equitably available, accessible and of the best attainable quality.

There are common misconceptions about the right to health though. The right to health is not the same as the right to be healthy and is not a goal to be attained in the undefined future. The right to health is a right of the 'here and now'. Challenging economic conditions do not absolve governments from taking action to realise the right to health of their citizens and this includes PLWHA. The right to health applies in specific ways to different PLWHA categories. It reflects some of the needs, but not necessarily all PLWHA. Specific categories are covered in international agreements and laws. These are:

1. Children and adolescents
2. Migrants
3. Injecting drug users
4. Women
5. Sex workers
6. Men who have sex with men (MSM)

National governments have responsibilities in terms of achieving the right to health for its citizens. These responsibilities are described in the International Covenant on Economic, Social and Cultural Rights, article 2. The general obligations include: progressive realisation; taking steps to realise the right to health of the citizens. There is a proposed framework of indicators to assess the achievements of governments. The core minimum obligations of the state are: obligation to respect, obligation to protect, protect the right to health (this includes the patents and access to medicines), obligation to fulfil and support the health systems.

Other bodies that have a role in the human rights and right to health framework are:

- United Nations bodies and specialized agencies (WHO/UNAIDS/The World Bank)
- Regional bodies (OSCE/COE/EU instruments and mechanisms)
- The private sector (including pharmaceutical companies)

Accountability for monitoring these human rights is at a regional and international level. The main bodies in the EU and internationally with a major role in this are:

- European Commission
- European Parliament
- European Court of Justice
- European Court of Human Rights
- United Nations treaty bodies, i.e., United Nations Special Rapporteur on the right to the highest attainable standard of health

Group work: Patients' rights, stigma and discrimination

The objectives of this exercise are to: raise awareness of healthcare issues and develop knowledge about health rights as human rights; to develop skills of discussing and analysing health rights violations; to promote empathy and self-confidence; to underline the importance of taking a stand and promoting equality, justice and responsibility.

The trainer should divide the participants into small groups, provide them with the appropriate stationary (flipchart paper, pen, etc.) and hand out the discussions topics that he/she has printed in advance. Depending on the group, trainees may be divided into small groups that are either mixed or single-sex. Choosing single-sex groups often leads to more provocative conclusions and a richer discussion. Participants should be aware that discussions about some issues can be very personal and that no one should feel under pressure to disclose more than they want. At the end, participants should return to the plenary and move on to the evaluation and debriefing stage. The discussion here should cover how the group's work went. How realistic were the discussion topics and how relevant were the questions. Since different groups worked on different topics, each of the groups should present the outputs raised in their discussion, followed by an analysis of the different topics and their relevance to the real world. Debriefing questions about different aspects of health rights as human rights may bring up some controversial issues. This is especially relevant because it requires participants to be open-minded and to use their skills in critical thinking. It can also be a very good illustration of the inherent complexity of human rights. Some participants may have personal experiences. No one should feel under pressure to disclose more than they want.

The rights that are covered in the discussion topics are: the right to protection from violence, torture and degrading treatment; the right to equality and non-discrimination; the right to equal protection of the law; the right not be dismissed on the grounds of particular health status; the right to equal employment opportunities and remuneration.

Discussion topics

Discussion topic 1

The decentralisation of social expenditures has had a substantial effect on available resources for health protection. Some governments have introduced greater decentralisation of health system finance and governance in its new efforts to transfer responsibilities from central to local level, thus local governments have been given increased responsibility for health care and primary to tertiary prevention. Local healthcare providers have also been assigned considerable authority. Measured in terms of expenditure responsibilities, municipalities are responsible for a majority of all spending on health.

Nevertheless, economic recovery in the health sector is still not a reality. In many municipalities (particularly in the rural areas) local authorities are not allocated the financial resources to meet these new responsibilities and have few means to raise additional funds. The share of resources going to the health sector is coming from a public budget that has been greatly diminished. Faced by large falls in national income and by reduced tax revenues, state support for health protection has been sharply reduced in real terms. Doctors' wages (representing the largest share of the health budget) are still fixed by central authorities, and prices for pharmaceutical products are set by producers, which leaves local healthcare providers with limited autonomy over budgetary decisions. Nevertheless, state authorities have taken many concrete steps towards supporting the health reform. These reforms have focused on the area of health legislation, liberalisation of health services and decentralisation of governance and finance in the health sector. However, nationwide, the actual implementation of these reforms has been slow and often difficult.

Questions:

Is your country's healthcare system moving to a decentralised model, as per the example? What does decentralisation mean for the health rights of PLWHA?

If your country has embarked on a decentralised model, has it kept close central control of key expenditure items such as doctors' wages and the price of medicines? What are the good points of keeping central control? What are the implications of delivering the heath rights of PLWHA?

Discussion topic 2

In many countries there is still a lack of official government policy and commitment with regards to healthcare issues of PLWHA. Although many healthcare systems have recently undergone considerable reforms, focused to a great extent on restructuring of the healthcare services' provision and its funding mechanisms, with more attention being given to public health and health promotion, many present-day government programs and activities in the field of healthcare and human rights of PLWHA are still lacking serious commitment and clear strategies to address concerns in this field. This process is even more endangered by some governments' efforts to foster positive image and populist ideology to the general population, thus disregarding PLWHA and endorsing their social exclusion. In many Central and Eastern European countries, prevention and treatment programs are mainly implemented by NGOs and funded by international donors. Relevant institutional stakeholders as main actors in the process did not show readiness to embark upon dealing with healthcare issues of PLWHA.

Questions:
Why have governments been reluctant to specifically identify the health rights of PLWHA, and to communicate them? What are the health rights risks when HIV/AIDS prevention, education and treatment are led by NGOs and funded by international donors?

Discussion topic 3

The massive and disproportionate exclusion of marginalised and vulnerable groups from employment is still an undisputed reality in many developing countries. Mass unemployment affects these groups more than the general public. These people are thrown out of the labour market due to total lack of opportunity to adapt and respond to the demands of the newly rising labour market. This fact raises serious human rights concerns about the failure of the national governments (both at central and local level) to curb discrimination in employment as well as to undertake proactive measures to confront disadvantages facing marginalised and vulnerable groups at the labour market. The issue to be examined is the effectiveness of various approaches to tackling employment inequalities, as well as a range of other relevant issues (i.e. economy, employment, poverty reduction and social welfare).

Questions:
Which groups would you identify as being the most vulnerable and discriminated employment-wise? What would be your recommendations to the Government/NGOs/foreign institutions and donors regarding vocational trainings, civil service, and public work programs for identified groups? What priority measures should be undertaken by state authorities related to improvement of the socio-economic status of identified groups? What about PLWHA? Do you think special attention to HIV/AIDS dimension in the employment policies is needed? If yes, how would you promote incorporation of those issues on the national employment agenda?

Discussion topic 4

There are over 700,000 people living with HIV across the EU and discrimination against people with HIV is common in all EU member states. Discrimination can take many forms, from denial of employment, housing, healthcare, goods and services, through breaches of confidentiality, to harassment and hate crime. Protection against discrimination for people with HIV across the EU is currently inconsistent, often weak, and infrequently accessed. People living with HIV face particular barriers in accessing justice and legal redress, including loss of confidentiality in the legal process, lack of funds to fight cases, and legal systems with poor understanding of, and sometimes hostility towards, people living with HIV. It is hard for people with HIV to seek justice. Confusion as to whether the anti-discrimination laws protect or not PLWHIV makes the situation more difficult.

The EU is committed to respect and the protection of human dignity, equality before the law and non-discrimination [Articles 1, 20 and 21 EU Charter of Fundamental Rights]. Furthermore, with the Dublin Declaration on Partnership to Fight HIV/AIDS in Europe and Central Asia, the EU has committed itself to combating discrimination against people living with HIV, and this is reaffirmed in the Vilnius and the Bremen Declarations. Under Article 13 of the EU Treaty, the EU can legislate to combat discrimination across all EU member states on a number of defined grounds – sex, racial

or ethnic origin, religion or belief, disability, age or sexual orientation. HIV status is not explicitly mentioned, but it could be included within the concept of disability.

In brief, disability discrimination is already prohibited in relation to employment, social protection, social advantages, education, and access to goods and services, including housing, although current EU law does not define disability nor refer to the laws of member states for the definition of the concept. Some people may not naturally think of HIV infection as a disability but it is important to note how the concept of disability had developed significantly in recent years. In a recent survey of legislation and judicial systems in relation to HIV across the WHO European region, to which 36 countries responded, including 24 EU member states, 16 responses stated that people with HIV were protected from discrimination under disability legislation. Furthermore, national jurisdictions such as New Zealand, Australia, Canada, the United States and Hong Kong all include HIV infection within the concept of disability irrespective of symptoms or stage of infection.

Questions:
How can clear protection from discrimination for all people living with HIV from discrimination be ensured, within the EU, and in non-EU countries? Is HIV infection a disability in all circumstances, even when there are no symptoms or physical problems such as difficulties with mobility? But what if many people living with HIV do not think of themselves as 'disabled' and maybe do not want to be thought of as disabled? Do we need a clearer description of disability in implementing the principle of equal treatment between persons irrespective of religion or belief, disability, age or sexual orientation for the purposes of Article 13 EC?

References

OHCHR &WHO, Fact Sheet No. 31 on The Right to Health, United Nations Geneva, ISSN 1014-5567, GE.08-41061–June 2008, http://www.ohchr.org

The World Bank Global HIV/AIDS Program and Legal Vice Presidency, Legal Aspects of HIVAIDS - A Guide for Policy and Law Reform, Lance Gable, Katharina Gamharter, Lawrence O. Gostin, James G. Hodge, Jr., Rudolf V. Van Puymbroeck, ISBN 978-0-8213-7105-3, eISBN: 978-0-8213-7106-0, DOI: 10.1596 / 978-0-8213-7105-3, SKU 17107, www.worldbank.org/aids

UNAIDS &OHCHR, International Guidelines on HIV/AIDS and Human Rights (2006 Consolidated Version), http://www.unaids.org

OHCHR and UNAIDS (2007), Handbook on HIV and Human Rights for National Human Rights Institutions, HR/PUB/07/3, UNITED NATIONS PUBLICATION, Sales No. E.07.XIV.12, ISBN 978-92-1-154181-6

UNAIDS & Inter-Parliamentary Union, Handbook for Legislators on HIV/AIDS, Law, and Human Rights: Action to Combat HIV/AIDS in View of its Devastating Human, Economic, and Social Impact (Second reprint, May 2002), http://www.unaids.org

UNAIDS and Canadian HIV/AIDS Legal Network, Courting Rights: Case Studies in Litigating the Human Rights of People Living with HIV

OHCHR, Economic, Social and Cultural Rights: Handbook for National Human Rights Institutions

UNAIDS BEST PRACTICE COLLECTION: Protocol for the identification of discrimination against people living with HIV, UNAIDS/00.05E (English original, May 2000, Geneva, Switzerland), http://www.unaids.org

Further reading and internet resources

International treaties

Charter of the United Nations (1945)
Constitution of the World Health Organization (1946)
COE Convention for the Protection of Human Rights and Fundamental Freedoms 1950 European Social Charter (1961)
International Convention on the Elimination of All Forms of Racial Discrimination (1965)
International Covenant on Economic, Social and Cultural Rights (1966)
International Covenant on Civil and Political Rights (1966) and its two optional protocols (1966 and 1989)
Convention on the Elimination of All Forms of Discrimination against Women (1979) and its Optional Protocol (1999)
African Charter on Human and Peoples' Rights (1981)
Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (1984) and its Optional Protocol (2002)
Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (Protocol of San Salvador) (1988)
Convention on the Rights of the Child (1989) and its two optional protocols (2000)
ILO Convention No 169 concerning Indigenous and Tribal Peoples in Independent Countries (1989)
International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families (1990)
COE Framework Convention for the Protection of National Minorities (1995)
European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (1996)
Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1997)
European Charter of Patients' Rights (2002)
Convention on the Rights of Persons with Disabilities (2006) and its Optional Protocol (2006)

International declarations, norms and other standards (non-treaty documents)

Universal Declaration of Human Rights (1948)
Declaration of Alma-Ata, International Conference on Primary Health Care (1978)
Declaration on the Elimination of Violence against Women (1993)
Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care (1991)
Standard Rules on the Equalization of Opportunities for Persons with Disabilities (1993)
Amsterdam Declaration of the World Health Organization (1994)
Universal Declaration on the Human Genome and Human Rights (1997)
Jakarta Declaration on Leading Health Promotion into the 21st Century (1997)

Declaration on Commitment on HIV/AIDS, UN General Assembly Special Session on HIV/AIDS, New York 2001
The Framework for the Protection, Care, Support of Orphans and Vulnerable Children living in a World with HIV and AIDS (OVC Framework) 2004
Declaration of the World Medical Association (WMA) on the Rights of the Patients (2005)
Charter of the International Union of Lawyers on the Right to Health (2005)
International Guidelines on HIV/AIDS and Human Rights: 2006 Consolidated Version
Declaration of the International Alliance of Patients' Organizations (IAPO) on Patient-Cantered Health Care (2007)

General comments and recommendations by treaty bodies
Committee on the Elimination of Discrimination against Women, general recommendation Nº 15 (1990) on the avoidance of discrimination against women in national strategies for the prevention and control of AIDS Committee on the Elimination of Discrimination against Women, general recommendation Nº 19 (1992) on violence against women
Committee on Economic, Social and Cultural Rights, general comment Nº 6 (1995) on the economic, social and cultural rights of older persons
Committee on the Elimination of Discrimination against Women, general recommendation Nº 24 (1999) on women and health
Committee on Economic, Social and Cultural Rights, general comment Nº 14 (2000) on the right to the highest attainable standard of health
Committee on Economic, Social and Cultural Rights, general comment Nº 15 (2002) on the right to water
Committee on the Rights of the Child, general comment Nº 3 (2003) on HIV/AIDS and the rights of the child
Committee on the Rights of the Child, general comment Nº 4 (2003) on adolescent health and development in the context of the Convention on the Rights of the Child
Committee on the Elimination of Racial Discrimination, general recommendation Nº 30 (2004) on discrimination against non-citizens

Commission on Human Rights resolutions
Resolutions 2000/82 and 2001/27 on the effects of structural adjustment policies and foreign debt on the full enjoyment of all human rights, particularly economic, social and cultural rights
Resolution 2001/35 on the adverse effects of the illicit movement and dumping of toxic and dangerous products and wastes on the enjoyment of human rights
Resolutions 2002/31 and 2003/28 on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health
Resolutions 2001/33, 2002/32 and 2003/29 on access to medication in the context of pandemics such as HIV/AIDS

International conference outcome documents
Council of Europe, Committee of Ministers, Recommendation R (87) 25 to member States concerning a common European public health policy to fight AIDS, Strasbourg, 1987
London Declaration on AIDS Prevention, World Summit of Ministers of Health, 28 January 1988
Paris Declaration on Women, Children and AIDS, 30 March 1989
Recommendation on the Ethical Issues of HIV Infection in the Health Care and Social Settings, Committee of Ministers of the Council of Europe, Strasbourg, October 1989 (Rec. 89/14)
Declaration of Basic Rights of Persons with HIV/AIDS, Organizing Committee of the Latin American Network of Community-Based Non-Governmental Organizations Fighting AIDS, November 1989
World Declaration on the Survival, Protection and Development of Children and Plan of Action of the World Summit for Children (1990)
Declaration of the Rights of the People with HIV and AIDS, United Kingdom, 1991
Australian Declaration of the Rights of People with HIV/AIDS, National Association of People Living with HIV/AIDS, 1991
Prague Statement, Pan-European Consultation on HIV/AIDS in the Context of Public Health and Human Rights, November 1991
European Union, European Parliament and Council Decisions on "Europe Against AIDS" programme (including dec. 91/317/EEC and dec. 1279/95/EC)
Rio Declaration on Environment and Development and Agenda 21 of the United Nations Conference on Environment and Development (1992)
Rights and Humanity Declaration and Charter on HIV and AIDS, United Nations Commission on Human Rights, 1992
South African AIDS Consortium Charter of Rights on AIDS and HIV, 1 December 1992
Vienna Declaration and Programme of Action adopted by the World Conference on Human Rights (1993)

Cebu Statement of Belief, UNDP Inter-Country Consultations on Ethics, Law and HIV, the Philippines, May 1993
Cairo Declaration and Programme of Action, Report of the International Conference on Population and Development, Cairo (1994)
Dakar Declaration, UNDP Inter-Country Consultations on Ethics, Law and HIV, Senegal, July 1994
Phnom Penh Declaration on Women and Human Rights and the Challenge of HIV/AIDS, Cambodia, November 1994
Paris Declaration, World AIDS Summit, Paris, 1 December 1994
Malaysian AIDS Charter: Shared Rights, Shared Responsibilities, 1995
Copenhagen Declaration on Social Development and Programme of Action of the World Summit for Social Development, March 1995
Chiang Mai Proposal on Human Rights and Policy for People with HIV/AIDS, submitted to the Royal Thai Government, September 1995
Asia-Pacific Council of AIDS Service Organization's Compact on Human Rights, September 1995
New Delhi Declaration and Action Plan on HIV/AIDS, Interdisciplinary International Conference: AIDS, Law and Humanity, December 1995
Montréal Manifesto of the Universal Rights and Needs of People Living with HIV Disease
United Nations Millennium Declaration, adopted by the United Nations General Assembly "Millennium Assembly of the United Nations" (2000)
Beijing Declaration and Platform for Action of the Fourth World Conference on Women (1995) and its follow-up, Beijing + 5 (2000)
Istanbul Declaration and the Habitat Agenda of the Second United Nations Conference on Human Settlements (Habitat II) (1996), and the Declaration on Cities and Other Human Settlements in the New Millennium of the Special Session of the General Assembly for an overall review and appraisal of the implementation of the outcome of the United Nations Conference on Human Settlements (Habitat II) (2001)
Declaration of Commitment on HIV/AIDS, "Global Crisis—Global Action", adopted by the United Nations General Assembly at its special session on HIV/AIDS (2001)
Durban Declaration and Programme of Action of the World Conference against Racism, Racial Discrimination, Xenophobia and Related Intolerance (2001)
Political Declaration and Madrid International Plan of Action on Ageing of the Second World Assembly on Ageing (2002)
Rome Declaration on World Food Security and World Food Summit Plan of Action (1996) and its follow-up, Declaration of the World Food Summit: Five Years Later, International Alliance Against Hunger (2002)

On the web

Office of the United Nations High Commissioner for Human Rights, www.ohchr.org
United Nations human rights treaty bodies, http://www.ohchr.org
Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, including yearly reports and country visits, www.ohchr.org
Open-ended Working Group on an optional protocol to the International Covenant on Economic, Social and Cultural Rights, http://www.ohchr.org
United Nations Children's Fund (UNICEF), www.unicef.org
United Nations Population Fund (UNFPA), www.unfpa.org
United Nations Programme on HIV/AIDS (UNAIDS), www.unaids.org
World Health Organization (WHO), www.who.int

6

INEQUALITIES IN HEALTH SYSTEMS

AND PSYCHOSOCIAL CARE

by Stephan Dressler

6.

INEQUALITIES IN HEALTH SYSTEMS

AND PSYCHOSOCIAL CARE

Aims and objectives

The aim of this section is to acquaint the readers with health inequalities, health inequities, and inequalities in psychosocial care of PLWHA. After reading it, trainers/trainees will have a basic grasp of how to:

- Identify disadvantaged groups
- Find out how they are disadvantaged
- Determine the impact of inequalities on healthcare
- Identify possible points of intervention

The section closely relates to the section on human rights and the right to health.

Abstract

Health inequalities are disparities in health achievements of individuals or groups. Health inequities are those health inequalities that are considered unjust or unacceptable. Access to healthcare and prevention is a right of all citizens of the European Union, as described in the Lisbon Treaty. The diversity of health care system structures and welfare states in the European region may result in different level of access to HIV/AIDS treatment, care and support.

How to deliver the material of this section

It is expected that the trainer uses a PowerPoint presentation, followed by group work to identify health inequalities in different countries and/or regions. The PowerPoint presentation should be delivered in a plenary session, after which the trainees should be divided into several groups (6-8 participants maximum per group), preferably by country or region.

Time of the session: 2 hours (30 minutes presentation, 60 minutes group work, 30 minutes feedback in the plenary). The material to be used during the group work is case studies. Some examples are provided in this section

NOTE: The above description of how to deliver the session is only advisory. The described methodology has already been used successfully, but the trainer should feel free to adapt it, according to the local training circumstances.

Detailed presentation material

'Health inequalities' is the generic term used to designate differences, variations, and disparities in the health achievements of individuals and groups. 'Health inequities' refers to those inequalities in health that are deemed to be unfair, unacceptable or stemming from some form of injustice, such as health-damaging behaviour where the degree of choice of lifestyles is restricted, exposure to unhealthy, stressful living and working conditions, inadequate access to essential health and other public services, or health-related social mobility involving the tendency for sick people to move down the social scale (EuroHealthNet 2006).

Access to health care and prevention is a right of all citizens of the European Union, as prescribed by the Lisbon Treaty effective December 2009. It is, however, the responsibility of EU member states to protect and improve human health. Across Europe, and across the EU member states, there is a broad diversity of health care system structures and welfare states. This may result in different level of access to prevention, treatment and care for people at risk of HIV infection or people living with HIV/AIDS. The following factors contribute to health inequalities:

- Socioeconomic determinants
- Political factors
- Geographical and environmental factors
- Educational background
- Cultural influences

The 'life-course' theory suggests that long-term exposure to physical risks or adverse social and economic circumstances in childhood or concurrent adverse circumstances due to unfavourable living conditions in earlier life may lead to poor health, detrimental health behaviour, disease and even premature death. Albeit not developed in the context of HIV/AIDS, parts of the life-course theory on health inequalities are also applicable to the field of HIV/AIDS, in particular, vulnerable groups, such as marginalised populations, migrants, drug users and/or people who were exposed to unfavourable, discriminating or stigmatising life conditions. Therefore, biographical factors may also contribute to health inequalities.

Health inequalities and inequities in psychosocial care may have an impact on access to care for PLWHA, the quality of care, access to health information and prevention (including testing for HIV infection), and can result in stigma and discrimination towards PLWHA or people living with a risk for HIV infection (Atun 2008). The right to health as a human right includes the right to equal access to prevention and care. Unjust variations in health care can be tackled by using the public health and the health promotion approach as outlined in the "Ottawa Charter" (WHO 1986).

Group work: Identification of health inequalities

The aim of this session is to allow participants to identify health inequalities in their home countries, identify groups or communities which suffer most from health inequalities, explain causes for health inequalities and identify possible mechanisms of intervention

1. Topics

Questions and topics to be discussed can include:

- HIV/AIDS in special populations in Central and Eastern European countries, e.g. sex workers, migrants, mobile populations, MSM, drug users, women
- Structure of the welfare state
- Impact of economic factors
- Impact of the political environment in transitional societies

2. Methodology

The groups should work in a structured manner, preferably by using case studies or scenarios. After the group work, results should be presented in a plenary session. Similarities and differences between various countries and regions should be highlighted. Underlying causes should be discussed and possible solutions or recommendations should be identified. The following are sample case studies that have already been used successfully, but the trainer should feel free to introduce new or adapt the ones provided, according to the local training circumstances.

Discussion topic 1

In many Central and Eastern European countries the health care system and the welfare state are undergoing major restructuring. In almost all of those countries a previously state-subsidised health care system has been replaced by mechanisms of health insurance, co-payments, and self-payments. The overall cost for health care has increased considerably. In addition, the structure of the health care system has been altered: doctors in private practice have replaced some clinics and ambulatory services, and hospitals have been closed, etc.

Questions:

1. What were the major changes in the health care system in your country?
2. How do these changes affect the medical care for PLWHA?
3. Do patients have to contribute in form of co-payments? If so, in which disease areas or therapeutic fields?
4. Do PLWHA in general have access to medical and psychosocial care? If not, why not? Can you identify groups/communities that do not have equal access to care?
5. Is access to medical care free of charge for PLWHA? How is medical care funded?

Discussion topic 2

In many countries there is still an uneven geographical distribution of medical services across the country with major differences between urban and rural areas. In particular, in countries with a relatively low prevalence of HIV/AIDS, specialised medical centres can be rare, meaning that PLWHA may have to travel long distances in order to receive adequate medical care.

Questions:

1. Describe the availability and distribution of HIV services in your country.
2. Do geographical factors have an impact on access to care in your country?
3. Do PLWHA receive support (e.g., financial) to travel long distances to receive medical care?
4. Can you identify specific groups/communities that are most affected by geographical factors?
5. Are there initiatives (e.g. from governmental agencies or health care providers) to overcome geographical barriers in access to medical care?

Discussion topic 3

HIV/AIDS has a different impact on different populations and/or communities. While in some Central and Eastern European countries injecting drug users are affected most, there may be countries where no dominant epidemiological pattern can be observed, meaning that HIV spreads in various populations, thus making targeted interventions and prevention efforts sometimes more difficult.

Questions:

1. Can you describe the epidemiological pattern of HIV in your country?
2. Which populations/communities are affected by HIV/AIDS?
3. Do all populations have equal access to information, prevention, and care? If not, why not?
4. And if not, how can access to care be improved?
5. How are sex workers, MSM, migrants, women and drug user affected by HIV/AIDS in your country or region?

Discussion topic 4

Studies have demonstrated a twofold impact of socioeconomic factors on HIV/AIDS and care: A higher risk for acquiring HIV infection can be associated with a lower social status; and an HIV infection may result in socioeconomic disadvantages (i.e. as a result of unemployment due to medical conditions or stigma and discrimination).

Questions:

1. Can you describe the socioeconomic situation of PLWHA in your country?
2. Which impact does the socioeconomic status of a person have on access to medical care?
3. Are there any welfare programmes providing full and adequate support for PLWHA?
4. What interventions are needed to assure access to medical and psychosocial care for socioeconomically disadvantaged people?

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Further reading and internet resources

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Simić M, Rhodes T: Violence, dignity and HIV vulnerability: street sex work in Serbia. Sociol Health Illn. 2009 Jan;31(1):1-16. Epub 2008 Dec 16
Name: DETERMINE - an EU Consortium for Action on Socio-economic Determinants of Health
Website: http://www.health-inequalities.eu/
Description: The initiative, DETERMINE (2007-2010) establishes an EU Consortium for Action on the Socio-economic Determinants of Health (SDH), which aims to take forward the work of the WHO Commission on the SDH (CSDH) in an EU context. It brings together over 50 health bodies, public health and health promotion institutes, governments and various other organizations from 26 European countries.

On the web

Name: WHO Regional Office for Europe: Health Inequities
Website: http://www.euro.who.int/socialdeterminants/systems/20081128_6
Description: The European Union, Health and Consumer Protection Directorate General (DG-SANCO) and WHO Regional Office for Europe formed a partnership in 2007 to develop tools for assessment and information sharing for health system performance on socially determined health inequities in Europe.

Inequalities in Health System Performance and their Social Determinants in Europe – Tools for Assessment and Information Sharing (Action 2006WHO03) – the joint project – will run for 3 years and has 5 general objectives:

1. Improve availability of and access to evidence on the disparities in health system performance, including quality of care and the structural determinants of such disparities across countries and regions in Europe.
2. Provide additional information support to priority setting processes for equity-orientated policies at the national and regional levels in Europe.
3. Facilitate the evaluation of the equity impact of various policies within and outside health systems.
4. Collect and systematize good practice examples on effective policies to reduce inequalities in health through health systems action on tackling wider social determinants.
5. To develop tools and mechanisms for skills development to strengthen the human resource capacity to address such issues in countries.

7

STIGMA AND DISCRIMINATION

AS A BARRIER TO ACCESSING TREATMENT & CARE

by Anna Zakowicz & Tomislav Vurusic

7.

STIGMA AND DISCRIMINATION

AS A BARRIER TO ACCESSING TREATMENT & CARE

Aims and objectives

The aim of this section is to demonstrate how stigma and discrimination can hinder the access to treatment, care and support for people living with HIV/AIDS. After reading and/or participating in the session, the trainer/trainee will have a basic knowledge of how to:

- Create a sense of community and build openness and safety to be able to talk about HIV and stigma
- Identify different forms of stigma and discrimination as a barrier to access to treatment
- Share and describe personal experience of exposure to stigma
- Identify how stigma affects PLWHA and begin to identify some root causes of stigma

Abstract

Stigma and discrimination are present in every country of the world and are something we have been fighting against since the beginning of the epidemic. To successfully fight HIV, we need to address and reduce the stigma and the discrimination associated with the disease. The stigmatisation of and the discrimination against people living with HIV are a result of fear of the disease, lack of knowledge, misconceptions about the ways the HIV is transmitted and by prejudice against people who are at a higher risk of contracting the virus. Stigma and discrimination often deprive PLWHA of their rights to education, health care, employment, freedom of movement and the right to a dignified life. These factors bring about humiliation, unemployment, divorce, people being shut out of their families and communities, and cessation of education and training. Stigma and discrimination are major obstacles to effective HIV/AIDS treatment, prevention and care.

How to deliver the material of this section

This session is interactive and consists of small group workshops, followed by a whole-group discussion. The session has a logical order. It gradually introduces concepts and provokes the participants. The particular methodology of each exercise is explained step-by-step in the detailed presentation material (next part of this section). The themes that are covered in the different modules are: health, social rights, discrimination and stigma.

For best results, the working groups should not consist of more than 6 trainees. The total time of the session is 2 hours. The trainer should pace the activities accordingly.

> NOTE: The above description of how to deliver the session is only advisory. The described methodology has already been used successfully, but the trainer should feel free to adapt it, according to the local training circumstances.

Detailed presentation material

Modules step-by-step

I. Warm-up. Example:

Objective: To prepare a ground to talk openly about HIV and stigma by creating a sense of community and building openness and safety.

This should be conducted when the trainees already know each other and never as a first session of the overall treatment literacy training. The activity should focus on positive feelings and experiences that the trainees have already shared together and should strengthen the feeling of belonging to the group.

Materials: colourful paper for each participant (trainers included), safety pins, markers.

Methodology: The trainer explains and demonstrates the exercise.
The trainees help each other to pin a piece of paper onto each other's back. When this is done, everybody stands up with a marker in hand. Every participant should get to as many people in the room as possible and write on the paper things they like about the person. Everyone should write one sentence or word for one person. When it is done, the writer should look for the next person.

Allow 5 min for this. Each person should have at least 4-6 comments. The trainer should monitor very closely if some people are standing aside or have less comments than the others. If this happens, the trainer should go to those people and write something he/she likes about them.
At the end of the activity trainees help each other to unpin the paper. Let the trainees to sit down and allow 2 min for quiet reading of the comments.

The trainer should thank for all the comments, especially for the ones he/she received.

II. Introduction to the session: 11 steps to stop stigma

Objective: Introduction to the topic of the session and to the steps to stop stigma, with an emphasis on the first five steps that will be covered in the session.

The trainer shares the steps with the participants and introduces the session and the objectives of the session, which are closely related to the 11 steps to stop stigma.

Methodology: PowerPoint presentation

11 steps to stop stigma

1. Create a sense of community and build openness and a sense of safety to talk about HIV and stigma
2. Name the problem. Get people to talk about stigma in different contexts
3. Get people to own the stigmatising disease- "we are all a part of the problem"
4. Help people to see the effect of stigma on PLWHA
5. Analyse the root causes of stigma
6. Address fears and misconceptions connected with HIV
7. Challenge the judging and blaming built into stigma and help people to explore their own attitudes
8. Build commitment to changing attitudes
9. Help PLWHA to overcome self-stigma and build up self-esteem
10. Develop strategies and plans for taking action against stigma
11. Action and monitoring of the action

Based on Understanding and Challenging HIV stigma. Toolkit for Action. 2006

III. Workshop

Objectives:

- Identify different forms of stigma and discrimination as a barrier to access to treatment
- Describe personal experience connected with stigma
- Identify how stigma affects PLWHA and begin to identify some root causes of stigma

Methodology: small group work

Preparation:

1. As it is a very personal session (participants are expected to share their own experiences connected with stigma and discrimination), it is important that the trainer shares his/her personal experience related to stigma and discrimination with the group before asking the participants to do so.
2. Divide participants into small groups.
3. Ask the groups to share their personal experience of stigma and discrimination that may have had impact on people's HIV treatment and care. Be aware of issue of sensitivity and confidentiality/anonymity (some participants may have direct experiences). Make it clear to everyone that no one should feel under pressure to disclose more than they want.
4. Ask the groups to prepare a short drama based on the experience. The drama should be based on one story. The story can be a sum of the shared experiences or an invented story based on them.
5. Monitor the work of the groups; help when necessary.

Reporting back: role-play

Methodology: whole group activity

1. Gather together all the groups and let each group perform its drama.
2. After each role-play, discuss the following questions with the whole group. Let the members of the groups that were watching the role-play report and discuss their feelings first.
    - What happened in the story?
    - Why did it happen?
    - What were the attitudes there?
    - What were the contributing factors?
    - Does it happen in your country? If so, discuss similar examples.

Wrap-up of the session

Methodology: whole group activity

After all the role-plays, discuss/compare/evaluate the cases that the trainees presented. Use some of the following questions:

1. How was the exercise? What happened? What do we learn from this? How were you feeling?
2. What are some of the common features across the different scenarios?
3. What are the attitudes across the different scenarios towards PLWHA?
4. What are the effects on the people who have been stigmatised?
5. What are some of the root causes of stigma and discrimination?
6. How can we help to support each other to face the challenges?

The alternative approach for the session described above is to prepare case studies and have them discussed in small groups with feedback to the whole group. Examples of case studies are provided below, but the trainer should feel free to use real life cases from his/her setting or adapt the ones below according to the local training circumstances.

Case studies: Stigma and discrimination as a barrier to access to treatment

Themes: Stigma, discrimination, treatment
Group size: up to 6 participants per group
Time: 60min.

Overview: A small group exercise dealing with issues of stigma and discrimination in the context of HIV/AIDS and treatment

Related issues: Legal aspects, e.g., the right to protection from discrimination; the right to equality; the right to equal protection by the law; the right not be dismissed on the grounds of particular health status; the right to equal employment opportunities.

Objectives: To raise awareness of stigma and discrimination-related issues and develop knowledge about different levels of discrimination; to develop skills to analyse stigmatising or discriminating situations; to identify adequate responses to different levels of discrimination.

Materials: A large sheet of paper, flipchart paper or board; space for small group work; table and chairs, pen and paper.

Preparation: Divide participants into small groups, hand out proposed case studies and provide the necessary instructions for work.

Instructions (for the trainer)

1. Depending on the group, you may wish to divide the participants into small groups that are either mixed or consist of participants who may have special experiences with certain stigmatised populations. Choosing the second approach may lead to more provocative endings and a richer discussion.
2. Hand out the copies of prepared case studies and give the work instructions. Participants should be aware that discussions about these issues can be very personal and that no one should feel under pressure to disclose more than they want.
3. At the end, come into plenary and move on to the evaluation and debriefing.

Debriefing and evaluation (for the trainer)

1. Start with a short review of how the groups' work went. How realistic were the case studies and how relevant were the questions?
2. Since different groups worked on different case studies, let each of the groups present the outputs of their group discussion. Then let the groups' feedback on their analysis of the different cases. Then talk about how the cases relate to real-life experiences.
3. Bear in mind that the debriefing questions on different aspects of stigma and discrimination may bring up some controversial issues and/or attitudes.

Tip (for the trainer)

Be aware of issue of sensitivity and confidentiality/anonymity (some participants may have personal experiences). Make it clear to everyone that no one should feel under pressure to disclose more than they want.

Case study 1 deals with the intrapersonal level of discrimination. Counselling, self-help and support groups may be taken into consideration

Case study 2 deals with the interpersonal or individual level of discrimination and stigma. In this situation, care and support are essential strategies

Case study 3 deals with the community level of discrimination and stigma. Education, training, and contacts with other PLWHA can be considered as a strategy here

Case study 4 deals with the institutional level of discrimination. This can be addressed with training programmes and policy development

Case study 1

Karyna, a 27-year old woman living in a suburb of Kiev, Ukraine, had been injecting drugs for a few years starting when she was 18. At the age of 21, she met Konstantin and fell in love with him. Since then they have been a couple, and neither of them is using any drugs. During a hospital stay in 2006, due to unclear abdominal pain, Karyna learned about her HIV infection – she was part of a routine testing programme. Since the acute medical problem had been solved (it was not HIV-related), she has not received medical care for HIV. Karyna feels guilty about her HIV infection. She has disclosed the information about her infection to Konstantin, but to nobody else. She assumes that she will be considered as a burden to society by causing high costs for medical care and HIV treatment, and that her family and that friends will cease contact with her, if she were to disclose her HIV status.

Questions:

1. Has there been any discrimination or stigmatisation imposed on her by others?
2. What are the possible scenarios of what will happen to her in the future?
3. What could be possible steps to take in her situation?
4. What are realistic options for support in her situation?

Case study 2

Pavel, 42-years old gay man lives in a rural area of the Czech Republic. He was diagnosed HIV-positive 12 years ago. His doctor in the nearby little town knows about his HIV infection, but does not offer him any treatment. "Your laboratory results and CD4 count look fine", is the standard response from the doctor at each visit. The doctor declines to refer Pavel to a specialised centre in a larger city, even though he admits that he is not a specialist in infectious diseases or HIV. Pavel himself does not have private internet access and has only limited knowledge of English.

Questions:

1. What would be the best next steps for Pavel to take?
2. What should be done from a medical perspective?
3. Why the doctor does not take the necessary steps?
4. Is this case study realistic in other countries?

Case study 3

This case study is set in a city with a population of about 100,000 in a Central European non-EU country. The exact number of people with HIV/AIDS living in this city is unknown, because epidemiological statistics are only available at a national level. The estimated number is between 300 and 650. There is a general city hospital, a health office run by the local authorities, and, established in 2001, one association for people with HIV/AIDS, which is run by two people and it mainly deals with information about transmission routes and prevention education by publishing flyers and organising meetings in the organisation's rooms.

Eva. has been working with the city's HIV/AIDS association since its foundation. In 2005, the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM) announced that they would give a grant to the country to provide antiretroviral treatments. At World AIDS Day, 1 December 2005, Eva gave an interview to a local television station and mentioned the opportunity that now, people who need it most will soon have access to better HIV medication.

One week after World AIDS Day, Eva had an appointment at the dental practice where she has received dental care for more than ten years, ever since she was 14 years old. After a wait of 2 hours (which was rather unusual), she was told that because of an emergency the dentist could not see her on that day. She was asked by the dentist's assistant to go home and call in later for another appointment. When Eva called next day, she was told that unfortunately, there was no free date for a new appointment. A couple of days later, calling in again, she received the same answer. When she asked to speak to the dentist, she was told that he was busy treating a patient.

Questions:
1. Describe what happened.
2. What next steps should be taken?
3. What can be done to prevent similar situations in the future?
4. What would be your advice to Eva of what to do and how to find access to dental care?

Case study 4

Slava is a 36 year old IT expert, living in Riga, Latvia. He has been HIV-positive for many years, and receives his medical care from a specialised centre in Riga. In December 2008, his doctor talked with him about starting ART. He had already suggested it to Slava some while ago, but Slava had decide to postpone ART treatment.

In the current economic situation, Slava is afraid that there may be side effects from starting ART, resulting in more doctor visits and possibly work absence due to sickness. This could be a threat to keeping his job. Slava postpones the initiation of ART again.

Questions:
1. Do you think that Slava's fears and assumptions are realistic, in terms of the impact that an antiretroviral therapy may have on his ability to work?
2. What next steps can be considered in Slava's situation?
3. Is it helpful to inform his employer of Slava's HIV status?
4. Will medical support solve Slava's problems?

Further reading and internet resources

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HIV - Related Stigma, Discrimination and Human Rights Violations: Case studies of successful programmes; UNAIDS 2005, http://data.unaids.org/publications/irc-pub06/JC999-HumRightsViol_en.pdf
Reducing HIV Stigma and Discrimination: a critical part of national AIDS programmes; A resource for national stakeholders in the HIV response; UNAIDS 2007, http://data.unaids.org/pub/Report/2008/JC1521_stigmatisation_en.pdf
HIV/AIDS-related Stigma and Discrimination: A Conceptual Framework and an Agenda for Action; USAID 2002, http://pdf.usaid.gov/pdf_docs/Pnacq832.pdf
HIV/AIDS Stigma and Discrimination, USAID/AIHA/AS School of Public Health 2004, http://www.eurasiahealth.org/health/resources/81862/

On the web

Center of AIDS and Community Health: http://www.hivaidsstigma.org/
Gay Men's Sexual Health Alliance: www.hivstigma.com

8

GLOSSARY

ACRONYMS AND ABBREVIATIONS

Literacy Manual

8.

GLOSSARY

ACRONYMS AND ABBREVIATIONS

ARV	**A**nti**R**etro**V**iral
bDNA	**b**ranched DNA
CART	**C**ombination **A**nti**R**etroviral**T**herapy
DNA	**D**eoxyribo**N**ucleic **A**cid
EI	**E**ntry **I**nhibitor
EATG	**E**uropean **A**IDS **T**reatment **G**roup
HAART	**H**ighly **A**ctive **A**nti**R**etroviral **T**herapy
HCV	**H**epatitis **C** **V**irus
HIV	**H**uman **I**mmunodeficiency **V**irus
IDU	**I**njecting **D**rug **U**ser
IEC	**I**nformation, **E**ducation **C**ounselling
INI	**IN**tegrase **I**nhibitor
MARP	**MAR**ginalised **P**opulation
MTCT	Mother **T**o **C**hild **T**ransmission
NASBA	**N**ucleic **A**cid **S**equence **B**ased **A**mplification
NNRTI	**N**on**N**ucleoside **R**everse **T**ranscriptase **I**nhibitor
NRTI	**N**ucleos(t)ide **R**everse **T**ranscriptase **I**nhibitor
PI	**P**rotease **I**nhibitor
PCR	**P**olymerase **C**hain **R**eaction
PEP(SE)	**P**ost **E**xposure **P**rophylaxis after (**S**exual **E**xposure)
PMTCT	**P**revention of **M**other **T**o **C**hild **T**ransmission
RNA	**R**ibo**N**ucleic **A**cid

9

SUPPLEMENTS

9 / I
TREATMENT LITERACY TRAINING AGENDA

9 / II
TREATMENT LITERACY TRAINING EVALUATION FORM

Literacy Manual

9.

SUPPLEMENTS

I. TREATMENT LITERACY TRAINING AGENDA

FRIDAY

08:45 – 09:00	Registration
09:00 – 09:30	Welcome and introduction Presentation of the trainers Housekeeping announcements Moderator: Ana Lucia Cardoso
09:30 – 10:30	Presentation of participants Moderator: Ana Lucia Cardoso
10:30 – 10:50	Coffee break
10:50 – 12:00	History of treatment activism Trainer: Stephan Dressler and Tomislav Vurusic
12:00 – 13:00	Introduction to HIV therapy Trainer: Svilen Konov
13:00 – 14:30	Lunch
14.30 – 15:30	What do people living with HIV in my country need? Trainer: Svilen Konov and Stefan Stojanovik
15:30 – 16:00	Coffee break
16:00 – 17:00	What do people living with HIV in my country need? (continued) Trainer: Svilen Konov and Stefan Stojanovik
17:00 – 17:30	Debrief Group Work Moderator/trainer: Svilen Konov and Stefan Stojanovik Summary of the day Moderator: Ana Lúcia Cardoso

END OF THE FIRST DAY (Information on dinner will be given during the day)

SATURDAY

09:00 – 09:30	Introduction of the second day Moderator: Ana Lucia Cardoso
09:30 - 11:00	Barriers to access to treatment from the perspective of PLHA Moderator: Svilen Konov and Stefan Stojanovik Case studies – Working groups: 1. Doctor – patient relationship 2. Adherence 3. Access of services 4. KAP towards treatment (knowledge, attitudes and practices)
11:00 – 11:30	Coffee break
11:30 – 13:00	Debrief Group Work Moderator/trainer: Svilen Konov
13:00 – 14:30	Lunch
14:30 – 15:30	Human rights; stigma and discrimination Trainer: Stephan Dressler and Ninoslav Mladenovic
15:45 – 16:00	Coffee break
16:00 – 17:00	Inequalities in the health system Trainer: Stephan Dressler and Ninoslav Mladenovic
17:00 – 17:30	Debrief Group Work Moderator/Trainer: Stefan Dressler and Ninoslav Mladenovic Summary of the day Moderator: Ana Lucia Cardoso

END OF THE SECOND DAY (Information on dinner will be given during the day)

SUNDAY

09:30 – 11:45	Stigma and discrimination as a barrier to access to treatment Trainer: Anna Zakowicz and Tomislav Vurusic
11:45 – 12:00	Coffee break
12:00 – 13:00	Final debrief of the meeting Homework Presentation of CoPE Evaluation Moderator/trainer: all trainers/ Ana Lucia Cardoso
13:00 – 14:30	Lunch

END OF THE THIRD DAY

9.

SUPPLEMENTS

II. TREATMENT LITERACY TRAINING EVALUATION FORM

Evaluation form

HIV/AIDS Treatment Literacy

Please circle when appropriate a score between 1 and 5
in accordance with the following guidelines:

1 – Very poor
2 – Poor
3 – Adequate
4 – Good
5 – Very good

For example:

1	How relevant do you consider the seminar topic?	1 2 3 4 5

Content

1	How relevant do you consider the seminar topic?	1 2 3 4 5
2	How good are the seminar documents – printed materials	1 2 3 4 5
3	How well did the seminar meet your needs?	1 2 3 4 5
4	How well did the seminar fit your expectations?	1 2 3 4 5
5	How valuable was the seminar in increasing your knowledge?	1 2 3 4 5
6	How valuable was the seminar in increasing your skills?	1 2 3 4 5
7	How well will you be able to apply what you have learned?	1 2 3 4 5

8	Which sessions of the seminar were most useful to you?
9	Which sessions of the seminar were not useful to you?
10	What information or skills do you still lack?
11	Comments & suggestions

Methods

12	How did you like the methods used?	1 2 3 4 5
13	Was there sufficient participation/interaction?	1 2 3 4 5
14	How well did the methods fit your expectations?	1 2 3 4 5
15	What method did you not like?	
16	What method do you still look for?	
17	Comments & Suggestions	

Trainers

18	How good were the trainers in terms of knowledge?	1 2 3 4 5
19	How good were the trainers in terms of delivery skills?	1 2 3 4 5
20	How responsive/flexible were the trainers to your needs?	1 2 3 4 5
22	What was good about the trainers?	
23	What was bad about the trainers?	
24	Comments & Suggestions	

Practical arrangements

25	Communication/information before seminar	1 2 3 4 5
26	Support from seminar organizers	1 2 3 4 5
27	Hotel room and services	1 2 3 4 5
28	Seminar venue	1 2 3 4 5
29	Meals	1 2 3 4 5
30	Comments & suggestions	

General

31	How successful was the seminar in creating networking opportunities?	1 2 3 4 5
32	How are you planning to follow-up on the seminar? What is your action plan?	
34	Anything not addressed?	

Thank you for your feedback!

Acknowledgments

This manual was commissioned by the European AIDS Treatment Group (EATG) as part of an operating grant received by the European Commission – European Agency for Health and Consumer within the framework of the Health Programme.

Thanks are due to the following people: Alain Volny-Anne, Anna Zakowicz, Ninoslav Mladenovic, Stefan Stojanovik, Stephan Dressler, Svilen Konov and Tomislav Vurusic for their active contribution to the EATG training activities, namely, for the production of a training module, training material and delivery of training sessions.

Ana Lúcia Cardoso (EATG) provided guidance and support to the trainers group, as did Elizabeth Verhetsel (EATG) and Smiljka de Lussigny (EATG).

Farah Soussan, Julien Benali and Floriane Gloaguen (EATG) provided additional support for the organisation of the seminars.

Anna Zakowicz, Ninoslav Mladenovic, Stephan Dressler, Svilen Konov and Tomislav Vurusic wrote the chapters of this manual and delivered the respective training sessions. William Flynn (independent consultant) edited the document. SEVT Ltd. (www.sevt.info) translated it into Russian and Klaartje De Buck (letterwelf.be) designed the manual. We are also thankful to Floriane Gloaguen that provided kind assistance with the Russian version of the manual.

Our sincere thanks to all people who have contributed to the training activities of the EATG and in particular to those who worked on this manual.

Most thanks should go to the group of participants who openly shared their ideas, gave us their comments and actively contributed to an intense and fruitful discussion throughout the trainings.

HIV/AIDS TREATMENT LITERACY

**THE EUROPEAN AIDS TREATMENT GROUP (EATG)
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