

National Consultation on HIV and HCV Treatment Access Issues

NEW DELHI, INDIA



ORGANIZED BY:
INTERNATIONAL TREATMENT PREPAREDNESS COALITION – INDIA
(ITPC – India)



Strengthening Community Responses
to HIV Treatment & Prevention

INTERNATIONAL TREATMENT PREPAREDNESS COALITION - SOUTH ASIA (ITPC - SOUTH ASIA)

The International Treatment Preparedness Coalition (ITPC) which started focussing on South Asia in 2004 has supported over 95 community-based organizations in India, Pakistan, Nepal, Bangladesh and Sri Lanka in this region through its HIV Collaborative Fund. The ITPC's global Secretariat is based in Bangkok at the offices of the Asian Pacific Network of People Living with HIV (APN+). South Asia regional coordination of ITPC activities is managed by Loon Gangte, who is a noted treatment activist in India since 1997 and also a founder of the Delhi Network of People Living with HIV (DNP+).



Strengthening Community Responses
to HIV Treatment & Prevention

INTERNATIONAL TREATMENT PREPAREDNESS COALITION - INDIA (ITPC - INDIA)

To strengthen country-level treatment preparedness advocacy in India, ITPC-India was formed in September 2008. ITPC-India is a national coalition of people living with HIV, treatment activists, doctors, lawyers, academia, among others; all of whom have strong expertise in HIV, tuberculosis (TB) and hepatitis C (Hep-C) treatment and other related interventions.

The goal of ITPC-India is to “*Accelerate treatment access in India through advocacy and treatment literacy*”. ITPC-India plans to advocate and contribute to the national HIV programme by involving and providing scientific information and strategic direction.

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**WHEN A VIRUS (HIV)
AND A BACTERIA (TB)
CAN WORK SO WELL
TOGETHER –
WHY CANT WE?
MICHEL SIDIBE**

22 16:34

**Likewise when two viruses
(Hepatitis C and HIV) can work
so well together, why cannot the
national AIDS programmes and
other stakeholders work better
to strengthen coordinated
responses to HIV and HCV?**

ABOUT THIS CONSULTATION

In communities where sharing of injection equipment drives the HIV epidemic, a parallel epidemic of Hepatitis C often lurks quietly. Neglecting Hepatitis C leaves people with HIV vulnerable. Greater awareness about hepatitis C, more investment of resources, cheaper diagnostic and treatment services, and improved hepatitis-related treatment literacy, are all urgently needed by people co-infected with the hepatitis C virus and HIV.

ITPC-India invited people living with HIV (PLHIV), people who use drugs (PUD), treatment activists, clinical experts treating HIV and HCV, government representatives among others from across India to participate in a two days 'National Consultation on HIV and HCV Treatment Access Issues' in New Delhi (19-20 October 2011). A delegation of thirty judges and police officers (including those working in Jails) also attended and interacted with all participants on first day of this consultation.

Agenda of this consultation is attached along with the list of invitees at the end of this report.

In communities where sharing of injection equipment drives the HIV epidemic, a parallel epidemic of Hepatitis C often lurks quietly. Neglecting Hepatitis C leaves people with HIV vulnerable.

The consultation helped highlight the gaps in responses to HCV and potential areas where joining forces with HIV response among others could help improve services.

A delegation from this consultation then had a brain storming session with key UN agencies such as UNAIDS, WHO, UNICEF, UNDP, UNAIDS north-east regional coordinator, among others. A press conference was organized on 21st October in Delhi (press release and media coverage clippings attached at the end of this report) and also met officials and senior member of Planning Commission of the Government of India providing them with meeting documents for consideration to be fed into the next five year plan (12th FYP: 2012-2017).



SESSION 1

Hepatitis C: A Global Health Problem

Discussant:

LOON GANGTE

Delhi Network of Positive People (DNP+) and Regional Coordinator, ITPC - South Asia (Collaborative Fund for HIV Treatment Preparedness)

Hepatitis C (Hep C) is a blood-borne, infectious, viral disease that is caused by the hepatitis C virus (HCV). The infection can cause liver inflammation that is often asymptomatic, but chronic hepatitis can lead to cirrhosis and liver cancer. HCV transmission occurs when traces of blood from an infected

person enter the body of a HCV-negative person. Like HIV, HCV is spread through sharing injection equipment, through needle stick or other sharps injuries, or less frequently from infected mothers to their babies. HCV also spreads by using unsterilized injecting equipment (bad injecting practices in healthcare settings) or unsterilized equipment used for injecting drugs (such as spoons, filters), snorting drugs with shared straws or bank notes, tattooing or piercing with unsterilized needles or

ink, dialysis in healthcare settings where infection control is poor, needle-stick injury for healthcare workers, or having unprotected sex with a person having HCV. In India before 1992, blood was not screened for Hep C. So people who had blood transfusion before 1992 are at a possible risk for Hep C.

According to a WHO (1999) data, there are 3.4 million people with Hep C in US, 5 million in Western Europe, 10 million in Eastern Europe, 30-35 million in South-East Asia and 30-40 million in Africa. Overall, WHO estimated that there are 170-200 million people with Hep C worldwide.

HCV transmission rates are higher than that of HIV, and the condition is often more severe in drug users. People who share injection equipment are one of the populations more vulnerable to HCV and HIV infection.

The HCV mainly lives in the blood and in liver cells where it can cause damage. HCV can cause liver inflammation and scarring (known as fibrosis or when most serious, cirrhosis). This can reduce the liver's ability to perform essential functions. Liver damage from HCV usually takes many years.

According to a WHO (1999) data, there are 3.4 million people with Hep C in US, 5 million in Western Europe, 10 million in Eastern Europe, 30-35 million in South-East Asia and 30-40 million in Africa. Overall, WHO estimated that there are 170-200 million people with Hep C worldwide.

According to old data and very conservative estimates, there are 735,000 HIV-HCV co-infected people in Asia. It is noteworthy to mention that Asia Pacific is home to up to 9 million IDUs. Experts estimate about 60% to 90% of HCV co-infection among IDUs living with HIV.

Raising awareness about Hep C prevention and treatment is a key to improving the responses on the ground. Compared to Manipur, even doctors in another North-Eastern state Nagaland don't advise injecting drug users (IDU) to go for Hep C test.

Just like knowing how one got infected with HIV helps in preventing its further transmission, it is important for people with HCV to know how they got infected so that they can prevent its further spread. However many people will find it difficult to find how they got infected with HCV because they might be carrying the virus since past many years.

Since harm reduction programmes reaching out to IDUs for HIV prevention, treatment, care and support are also potential programmes to respond to HCV in the same population, it makes sense to get more value for every dollar spent to integrate them so as to respond to both: HCV and HIV in IDU populations.

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However, harm reduction is very much HIV centric and doesn't include specific measures to address HCV, such as programmes are providing clean needles and syringes but not providing swabs, cooker and other supplies that can put people at risk of contracting HCV.

DISCUSSION:

A participant (Leena) asked when it makes so much programmatic and public health sense, why are we not pushing for harm reduction programmes so that they can address to both conditions: HCV and HIV?

Another participant (Umesh) said that in a feedback meeting for the 12th five year plan being developed by the Planning Commission of the Government of India, they had strongly made the recommendation that HCV should be an important part of HIV programmes for IDUs.

HIV and HCV

Although transmission routes of HIV and HCV are similar (blood-borne) but HCV is more infectious (HCV is more transmissible than HIV) and a person can be cured of HCV unlike HIV. A person with HCV can get cured of HCV

either naturally (because of body's immune system) or by completing standard treatment for HCV. Once cured, HCV may not have long-term effect on a person's health.

HCV progresses more quickly in people who are also HIV-positive, and HCV treatment is less successful in PLHIV compared to people who are only infected with HCV (and HIV negative).

HCV adversely impacts antiretroviral therapy (ART) because the liver processes most drugs used in ART and HCV seriously damages the liver. But, the benefit of ART still outweighs the risk of side effects. The doses of some drugs used in ART can be individually adjusted for people with advanced, liver disease by measuring drug levels in a sample of blood.

According to some studies, more than 45% of HIV-negative people, and up to 20% of HIV-positive people clear HCV without treatment within the first few months of getting infected. But if body's immune system cannot clear HCV then it risks developing into chronic Hep C infection that can have a wide range of outcomes. Some people who develop chronic Hep C infection will never have any significant liver damage but some will have mild liver scarring and 20-30% of them will develop liver cirrhosis - a very serious condition. In a smaller percentage of such people, HCV can also cause liver cancer (Hepato-Cellular Carcinoma or HCC) and liver failure (a situation where a liver transplant is needed).

According to some studies, out of 85% of people who get HCV 20% will develop cirrhosis (and 25% of these people who develop cirrhosis, 20% of them will need liver transplant). Being co-infected with HIV or alcohol are some of the factors that exacerbate progression of HCV.

Although transmission routes of HIV and HCV are similar (blood-borne) but HCV is more infectious (HCV is more transmissible than HIV) and a person can be cured of HCV unlike HIV. HCV progresses more quickly in people who are also HIV-positive, and HCV treatment is less successful in PLHIV compared to people who are only infected with HCV (and HIV negative).

ARE PEOPLE AROUND ME NOW AT RISK?

HCV is a blood borne virus so unless anyone comes into contact with blood from HCV-infected person there is no risk of transmission. To prevent HCV transmission, it is advisable for HCV-infected people not to share anything that may have come into contact with their blood such as toothbrushes, razors, and manicuring tools.

Unlike HIV, HCV can live outside of the body for days to weeks.

Can I pass on HCV through sex?

The percentage of people who acquired HCV through sexual transmission is lesser than through injecting drug route.

DISCUSSION:

A participant (Luke Samson) said that we have under coverage of all IDU related services such as prevention, treatment, care and support. When India has 14 million people with HCV, government cannot close its eyes on them.

Another participant (Leena) said: Is men-who-have-sex-with-men (MSM) community also having these discussions to address HCV in their community?

Another participant said that according to a recent FHI study, HCV is going up in Maharashtra and Nagaland but HIV is going down in these states.

Another participant said (Luke): HCV is much more transmissible, and much more robust, that is why we have to do HCV programmes more stringently. We have to lobby with ministry of health's infectious diseases section as most programmes are likely to be rolled out through National Rural Health Mission (NRHM) in coming few years. We should not just look at IDU as a high risk community for HCV but also those across the country who are at risk of contracting infections such as HCV through bad injecting practices in health sector.

We should not just look at IDU as a high risk community for HCV but also those across the country who are at risk of contracting infections such as HCV through bad injecting practices in health sector.

Another participant said that unless community at risk of getting HCV or already dealing with HCV is aware of their condition and how appalling is the situation of HCV-related services in public health sector, not much could be achieved. Community mobilization is a key to build, develop and help sustain good programmes addressing HCV.

At policy level it is important to emphasize on National AIDS Control Organization (NACO) and also the Ministry of Health of the Government of India that they cannot ignore HCV because it is undermining HIV programme performance in populations co-infected with HCV, people are likely to get antiretroviral therapy (ART) but die of HCV, HCV is more infectious than HIV, transmission routes of HCV and HIV are similar, and a host of other public health, social justice and programmatic efficiency reasons that make it so obvious and a moral imperative to have a strong programme to address HCV in India.

According to Center for Disease Control and Prevention (CDC), 15% HCV transmission occurs through sexual route, 10% through blood transfusion (this figure has substantially come down since blood screening for Hep C was introduced), 60% through injecting drug use, and 5% through other routes such as healthcare workers getting infected due to poor infection control measures in healthcare settings (no universal precaution measures in place or needle prick injuries etc), mother to child transmission, among others.

There are vaccines against hepatitis B virus (HBV) but **no vaccine against HCV**. People infected with HCV are advised to get vaccinated against HBV but if they are co-infected with HIV then their HBV vaccine is likely to work only when CD4 count is high enough.

MOTHER TO CHILD TRANSMISSION OF HCV

Like HIV, HCV too can be transmitted from mother to child during pregnancy or at birth. The risk of mother to child transmission of HCV is 3-4 times higher if the mother is co-infected with HIV and HCV. Some studies estimate that there is a 20% likelihood of HCV transmission from mother to child route if mother is co-infected with HCV and HIV.

Factors that accelerate HCV progression include co-infection with HIV or hepatitis B virus (HBV), alcohol intake (greater than 60 ml a day), age, duration of infection, getting infected in older age (more than 40 years), among others.

HIV treatment dramatically reduces the risk of mother to child transmission of HIV, regardless of the mother's hepatitis C status, and it may also lower the risk of HCV transmission.

POINT TO REMEMBER: HCV treatment is not possible during pregnancy. This is because one of the HCV drugs (Ribavirin) causes birth defects, and the other (interferon) can cause brain and nerve damage in infants less than two years old.

Planned delivery by caesarean section (C-section) reduces the risk of mother-to-child HCV transmission among HIV-positive mothers.

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WHAT IS THE TREATMENT FOR HCV?

There are three types of tests for HCV, which all use polymerase chain reaction (PCR) technology:

HCV PCR viral detection test: This qualitative test is designed to detect the hepatitis C virus.

HCV PCR viral load test: This quantitative test estimates the level of HCV in the blood. It helps to monitor the effectiveness of treatment.

HCV PCR genotype test: This determines the specific genotype (genetic 'make-up') and subtype of HCV. This information is important in selecting a course of treatment. For example, treatment with interferon is more often effective for people with HCV genotype 2 or 3.

People co-infected with HCV and HIV should monitor indicators of HIV progression, such as their CD4 count. If the CD4 count falls below 200, then HCV treatment is less effective, and its side-effects may be more pronounced.

HCV can often be treated successfully, including among PLHIV, but the treatment is not easy to endure due to side effects. Treatment for HCV uses a combination of two drugs, and usually takes between six and twelve months. The two drugs are: pegylated interferon (PegIFN) and ribavirin (RBV).

There are two types of Interferon:

- (i) alpha-2a (manufactured by Roche, trade name 'Pegasys'). Pegasys is a liquid that comes in one vial and is stored in the refrigerator. Everyone uses the same dose of Pegasys, regardless of their weight.
- (ii) alpha-2b (manufactured by Schering Plough, trade name 'PegIntron' or 'ViraferonPeg').

Ribavirin comes in the form of pills or capsule.

PegInterferon (180 mg) injection is given once a week for 48 weeks. Ribavirin (800 (twice a day) pill or capsule is also given for 48 weeks.

DISCUSSION:

A participant (Umesh) points out that there is no standardized treatment protocol and clinical practice varies considerably between individual doctors. This can add to uncertainty and confusion for patients.

There is **no vaccine to prevent HCV** infection and even after successful completion of treatment, HCV re-infection can occur. During and after treatment, HCV PCR viral load testing is done at six month intervals to monitor HCV control.

CHALLENGES

The awareness at the individual and community level regarding Hep C is very low, even in communities at high risk of Hep C such as IDUs. The government's health programme doesn't address Hep C prevention, treatment, care and support services, even where it makes profound public health sense.

Surveillance system for Hep C is not at place within country, testing for HCV is not widely available and accessible.

Not only the populations at higher risk of Hep C but also the healthcare providers have very inadequate information regarding Hep C testing and treatment. As one of the fallouts, there is a clear dearth of enough physicians that are competent enough to manage Hep C.

The biggest challenge to access to Hep C services is the cost. The medicines are unaffordable (cost is up to INR 700,000-900,000) and due to patent restrictions on interferon, India cannot produce generic drugs.

India also needs a clear guideline for Hep C treatment.

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India needs a clear guideline for Hep C treatment

SESSION II

Safeguards in Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985 for people who use drugs

Discussant: Eldred Tellis

Founder-Director, Sankalp Rehabilitation Trust, Mumbai

There is a clear need that those working on targeted interventions (TIs) related to IDUs must be aware of and sensitised about the growing Hep C epidemic and appalling services related to Hep C in public sector. Sharing his experience, Eldred said that in trainings he finds only people from Sankalp Rehabilitation Trust are raising key issues related to Hep C. HIV interventions managed by Sankalp Rehabilitation Trust have integrated HCV component and provide clean distilled water, swabs among other supplies and most importantly raises awareness about Hep C and its management.

Since HCV is a stronger virus, and requires smaller quantity to infect somebody when transmitted, Sankalp Rehabilitation Trust looked at Hep C risk reduction recommendations for IDUs.

Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985 of the Government of India sets out the statutory framework for drug law enforcement in India. There is negligible information regarding the safeguards NDPS Act towards rights of people who use drugs.

For example, according to the NDPS Act, the Ministries of Social Justice and Empowerment (MSJE) and Health (MOH) are responsible for the demand reduction aspects of drug law enforcement which broadly covers healthcare and the de-addiction, rehabilitation and social reintegration of people who use drugs.

It needs to be noted, however, that while the powers to search, seize, arrest etc., are inherent in the NDPS Act, all these are subject to both the substantive and procedural safeguards mandated by the Code of Criminal Procedure, in relation, inter-alia, to the presence of **independent witnesses** at a search, the drawing up of search lists or *panchanamas*, and



the constitutional obligation to produce an arrested person before a Judge within 24 hours etc.

The NDPS Act also makes a distinction between possession for personal consumption and trafficking, the punishment for the former being limited to between six months and one year only. Also as per the NDPS Act it is the accused (and not the police) who will establish that the drug in question was meant for personal consumption and not for sale, distribution etc.

The NDPS Act also comes with **procedural safeguards and immunities** such as:

Personal search: Any person being searched has a right to be searched before a Gazetted Officer or a Magistrate (Section 50 of NDPS Act). The officer searching the person has to explain to the person that he has a right to be searched before a Gazetted Officer or a Magistrate and if the person wishes to be searched before a Gazetted Officer or a Magistrate he should be taken to the Gazetted Officer or the Magistrate and searched. However, if the officer has reason to believe that it is not possible to take him to a Gazetted officer or a magistrate without giving him a chance to part with the drug, controlled substance, etc., he can search him under Section 100 of the Cr. P. C. [Section 50(5) and 50 (6)].

Arrests: The person who is arrested should be informed, as soon as may be, the grounds of his arrest [Section 52 (1) of NDPS Act].

People who use drugs: The people who use drugs charged with consumption of drugs (Section 27 of NDPS Act) or with offences involving small quantities will be **immune from prosecution** if they volunteer for **de-addiction**. This immunity may be withdrawn if the addict does not undergo complete **treatment** (Section 64A of NDPS Act).

Juvenile offenders: Juvenile offenders (below 18 years of age) will be governed by the Juvenile Justice (Care and Protection of Children) Act, 2000.

Any person who uses drugs and is charged with an offence punishable under section 27 of NDPS Act or with offences involving small quantity of narcotic drugs or psychotropic substances, **who voluntarily seeks to undergo medical treatment for de-addiction** from a hospital or an institution maintained or recognized by the Government or a local authority and undergoes such treatment **shall not be liable to prosecution** under section 27 of NDPS Act or under any other section for offences

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involving small quantity of narcotic drugs or psychotropic substances, provided the person who uses drugs undergoes the complete treatment for de-addiction.

DISCUSSION:

A participant (Luke) said that it is **unacceptable** that a company is allowed to charge 10 or more times the price of drugs for Hep C when 14 million people are dealing with Hep C in India and struggling with unaffordable treatment. He also stressed on very low awareness regarding Hep C in the affected communities.

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Another participant (Loon Gangte) said that Georgia is the first country to be funded for HCV programme by the Global Fund to Fight AIDS, Tuberculosis and Malaria (The Global Fund).

Another participant (Leena) said that applying for the Global Fund grant to support Hep C programmes becomes more difficult with the national AIDS programme not taking any lead (or responsibility) on Hep C.

Another participant (Loon) said that when Hep C affected communities are themselves not taking any responsibility or raising any voice then even less can be done.

Another participant (Luke) said that treatment literacy on HCV is critical - and if we have treatment literate communities across India then we will have a widespread network of informed Hep C advocates nationwide which will be a powerful support for the Hep C programme.

Another participant (Eldred) said that Alert India (NGO that has done commendable work on leprosy) works on HCV.

Another participant (Dr Tokugha Yephthomi) said that a formidable challenge is to bring community on the table so that affected people can be equal partners in developing effective Hep C programmes in India that reach out to those most in need. He said that 14 million is a huge population of Hep C infected people in India and country has to do a lot more without delay to save lives and reduce human suffering related to Hep C. This includes legal reforms and supportive laws for health and social justice (death penalty is given in some countries on drug-use).

Another participant (Luke) who heads the Indian Harm Reduction Network (IHRN) gave full commitment on behalf of IHRN to support Hep C treatment literacy in affected communities. He added that if we are able to avert Hepatitis B virus (HBV) infection for someone living with HCV that will be less stress on the liver. He shared a personal experience of one of his team members undergoing treatment for liver cirrhosis in India's top rated public

hospital (All India Institute of Medical Sciences) where treating physician referred the patient for expensive Hep C tests. When there is no treatment available for hepatitis C in public healthcare setting and patient cannot afford INR 700,000 - 900,000 Hep C treatment what is the point of asking patients to spend considerable amount on Hep C diagnostics, asked the IHRN representative.

Another participant (Eldred) shared that although there are no robust studies to prove but homeopathic trials for Hep C have shown positive outcomes. Moreover if the client is cared for, then their feeling for living and love for life is better. The homeopathic trial for Hep C is for people who are HIV negative - and for now tests are showing excellent results, viral load is coming down, it is not costing anything and is done by an organisation called Life Force (since more than a year). The trial participants are doing well, feeling better, went back to work, are progressing, and clinically also results are good.

A participant shared a personal experience of one of his team members undergoing treatment for **liver cirrhosis** in India's top rated public hospital (*All India Institute of Medical Sciences*) where **treating physician referred the patient for expensive Hep C tests**. When there is no treatment available for hepatitis C in public healthcare setting and patient cannot afford INR 700,000 – 900,000 Hep C treatment **what is the point of asking patients to spend considerable amount on Hep C diagnostics**, asked the IHRN representative.

SESSION III

Treating HCV

Discussant:

Dr Tokugha Yepthomi
Senior Medical Officer
YRG CARE and ITPC-India



[Note: Since a lot of Hep C treatment was covered in previous session I, a lot is not being repeated here. **Please read session I along with this part**]

The risk of Hep C transmission through heterosexual route is less than 1 per cent. However for reasons why HIV is more transmissible through anal intercourse, possibility of Hep C transmission through anal intercourse is higher too. MSM programmes on HIV should integrate component for Hep C accordingly.

HCV diagnostics need a battery of tests during the course of treatment that includes:

- Serum liver enzymes
- Complete blood count
- Thyroid - stimulating hormone
- Antinuclear antibody
- Glucose
- Quantitative HCV RNA in serum
- HCV genotype
- Alpha-fetoprotein (only if cirrhotic)
- Pregnancy testing for female patients of childbearing potential

There are six known genotypes of HCV. Genotype 1 of HCV is common in US, however in India it is usually genotype 2. Standard treatment response for genotype 2 and 3 is very good.

DISCUSSION:

A participant (Loon) said that after getting infected with Hep C it takes 6 months for antibodies to show in blood (in HIV it takes 3 months). So that is why antibody tests might be repeated after 3-6 months to confirm Hep C diagnosis.

Another participant (Luke) said that the cost of diagnostics and tests mount up as we need aggressive or active monitoring of viral load, particularly for

those co-infected with HCV and HIV. The ART drugs are not liver friendly and HCV can aggravate morbidity and mortality in HIV-HCV co-infected individuals. That is why active monitoring of liver functions and viral load is required.

Another participant (Umesh) said that it is high time that we should have pre- and post- test counselling for Hep C as well just like we have it institutionalised in HIV programmes routinely. This will go a long way in increasing treatment literacy, adherence and mental health issues that might arise in due course, among host of other public health benefits.

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SESSION IV

Barriers to access to treatment

Discussant:

Leena Menghaney

Medecins Sans Frontieres (MSF)/ Doctors Without Borders

According to the WHO data 3 per cent of the world's population (170 million) is infected with Hep C. each year 3-4 million people get infected with Hep C (WHO 2010). 26-39 million people with Hep C will develop cirrhosis if left untreated.



According to a study (Prez 2006), there is a high risk for developing liver cancer (hepatocellular carcinoma or HCC) and liver failure in people with Hep C. 365,000 people die each year from HCV complications.

Globally 15-40% PLHIV are co-infected with HCV. In Myanmar, China and India, HCV infection among IDU populations is between 11-90% depending upon specific locations. HIV-HCV co-infection in Myanmar and China is estimated to be between 20-30%. There is not sufficient data on HCV rates in prison or congregated settings but since it spreads broadly through the same route as HIV, there is an alarming likelihood of high HCV rates in prison settings too.

Due to HIV-HCV co-infection, there is a faster progression to end-stage liver disease. Although ART improves survival but still there is a high mortality reported in HIV-HCV co-infected people.

HIV-HCV co-infected people have shown lower cure rate for HCV. HCV cure rate is 65-70% lower for those with HCV genotypes 2 and 3 and 35% lower for those with HCV genotypes 1 and 4.

Although HCV is curable if standard treatment is provided but there are side effects that are also a major cause of concern such as flu-like symptoms (muscle aches, headaches, low grade fevers), fatigue, injection

Although HCV is curable if standard treatment is provided but there are side effects that are also a major cause of concern such as flu-like symptoms (muscle aches, headaches, low grade fevers), fatigue, injection site reactions (redness, painful nodules or ulceration), neuropsychiatric effects, hair loss, among others.

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There are formidable challenges to universal access to Hep C treatment.

Firstly, given the population size of people with Hep C and its infectiousness among other public health and social justice reasons, government has still not included Hep C prevention, treatment, care and support services in its public healthcare services.

Also even those health programmes that are working with populations that are at high risk of Hep C and there is growing evidence of high Hep C rates in these populations such as IDUs, prison inmates or PLHIV, lack a component to address Hep C.

The cost of medicines for Hep C is very high and testimonies of people who have successfully completed Hep C treatment in India calculate it to be up to INR 700,000 - 900,000. Clearly Hep C treatment is affordable for most of the people with Hep C. Ironically India that supplies up to 90% of the ART drugs to the world with its robust generic drug manufacturing is not allowed to produce generic versions of Hep C medicines. This is because the first patent granted in India was on a Hep C drug in 2006 blowing away chances of generic production on the home turf. But it has not prevented generic medicine manufacturers in Egypt, Pakistan and Viet Nam to produce Hep C drugs but due to patent restrictions, India cannot even import these cheaper drugs for Hep C. This is one of the most impenetrable barriers to access when it comes to Hep C drugs.

Ironically India that supplies up to 90% of the ART drugs to the world with its robust generic drug manufacturing is not allowed to produce generic versions of Hep C medicines. This is because the first patent granted in India was on a Hep C drug in 2006 blowing away chances of generic production on the home turf

(Note: for more details on patent and intellectual property rights issues on Hep C drugs, see other sections of this report)

The side effects of Hep C treatment are severe at times and due to poor treatment literacy, care and support services and lack of pre- and post- test counselling provisions, it becomes all the more difficult for people with Hep C to deal with the side effects alone.

Due to high cost of Hep C medicines, lack of care and support services, proper management of side effects and quality counselling, maintaining adherence to Hep C treatment becomes another challenge.

The need for injections every week and long duration of treatment (6-12 months) are other challenges impeding HCV responses.

As it happens with other disease control programmes, people most-in-need of Hep C services are often left unreached by health programmes.

Management of co-morbidities (alcohol and drug use, depression, HIV, etc) is another challenge confronting us.

Despite sustained advocacy over years for provision of HIV-related harm reduction services for IDUs still the coverage is abysmally low. It is almost a public health and moral imperative to integrate HCV and HIV in programmes reaching out to most-at-risk-populations but coverage of these programmes must also be scaled up so as to reach every person who needs them.

There are lot of lessons to be learnt from HIV and tuberculosis (TB) or drug-resistant TB programmes when building an effective, integrated and sustainable programme for HCV. AIDS activists have been arguing it since years but recent HPTN 052 study results clearly show that early initiation of ART in HIV sero-discordant couples almost reduces the chances of HIV transmission to zero. Similarly it has been proven and WHO also recommends that if a PLHIV is co-infected with TB, then ART should be initiated regardless of CD4 count. Also if PLHIV are put on ART early on there is less likelihood of developing active TB disease. Clearly in terms of controlling number of new infections **treatment has proven to be prevention.**

There is a compelling need that WHO and other technical agencies should come up with a Hep C treatment protocol and programme guidelines, specific to resource limited settings.

For comprehensive integrated hep C care, Hep C programme has to look at harm reduction programme, drug substitution programme, chronic disease management and other possible areas where Hep C component can be integrated.

Due to unaffordable Hep C medicines and other barriers to access to services, people who have chronic Hep C infection, either they go in debt or are dead.

All people with Hep C must have access to generic low(er) cost pegylated interferon and ribavirin. The drug pipeline is promising which

In short run, we need to continue the negotiations with the drug companies to procure Hep C treatment at as low a price as possible. In long run, we have to find ways to encourage generic production of cheaper effective drugs for Hep C.

includes injectable free regimens. There is a need to boost research for new drugs for Hep C in low or middle income countries.

There needs to be a two-prong strategy to increase access to Hep C treatment. In short run, we need to continue the negotiations with the drug companies to procure Hep C treatment at as low a price as possible. In long run, we have to find ways to encourage generic production of cheaper effective drugs for Hep C.

In India the two companies (Roche and Schering) have patents over Hep C drugs. Past experience suggests that whether people negotiated with either of the companies, they got the medicines at the same discounted price. It appears as if the markets have been fixed. Although there is a cheaper generic Hep C drug getting manufactured in Egypt, Pakistan and Viet Nam, yet we cannot import it because of patent restrictions.

There is a clear **need for a more coordinated response to Hep C**. It also mandates ongoing collaboration with activists, academics, NGOs, cancer groups among others. If we need legal remedies such as filing of court cases to improve access to treatment then we should be doing that. Also since the Global Fund has supported a Hep C proposal for Georgia, India should come up with a proposal for the Global Fund to support an integrated and comprehensive Hep C programme where Hep C component is also built in HIV programmes that are reaching to most-at-risk-populations for Hep C and HIV both. Activists should consider measures such as breaking of patents.

DISCUSSION:

A participant (Nanao) who has successfully completed Hep C treatment said that he paid INR 18,300 per week for pegylated interferon.

In India the two companies (Roche and Schering) have patents over Hep C drugs. Past experience suggests that whether people negotiated with either of the companies, they got the medicines at the same discounted price. It appears as if the markets have been fixed. Although there is a cheaper generic Hep C drug getting manufactured in Egypt, Pakistan & Viet Nam, yet we cannot import it because of patent restrictions.

SESSION V

Personal testimonies of people who have completed HCV treatment

HAOBAM NANAO

Shared his personal experience of HIV and HCV

Haobam Nanao is an admirable AIDS activist from Manipur. He is living with HIV, has IDU background, and had contracted HCV twice. On the first instance in 2005, the doctors advised him to get treated for Hep C (genotype 3). The cost was high and he could get INR 100,000 from friends for Hep C treatment. Nanao could put only 30% of the money required for Hep C treatment from his own end. He completed the treatment successfully but relapsed into drug use.

He again contracted HCV in 2010 and this time his doctor connected him with the medical representative of a company producing Hep C drugs. Nanao got medicines at a 'subsidised' rate through company's stockist and had to go for liver function test and other tests every fortnight. The entire treatment costed him INR 900,000 which was completed in March 2011 (48 weeks duration). *"I feel very guilty because many of my friends are dying of HCV without proper treatment and care"* said Nanao.

Side effects were very bad. Friends were helping financially but no organisation was helping in terms of psychological needs among others, said Nanao.



NEINI WANDA E PAKMA

Shared her personal experience of HCV



Neini Wanda E Pakma is an inspiring HCV advocate and comes from Meghalaya. She has an IDU background and got infected with HCV. She tested negative for HIV. Side effects were very severe with the first injection itself for Hep C treatment which included loss of hair, bodyache, drowsiness, among others. After completion of Hep C treatment all side effects were gone.

She had to spend INR 580,000 for a 6 months duration Hep C treatment in Shillong, Meghalaya. Her parents paid for her treatment. **Her doctor encouraged her to speak with the company producing Hep C drugs** which agreed to support free HCV screening among IDUs in Shillong. Neini had also tried to treat Hep C four years back but then had not revealed her Hep C to her family. She tried to absorb treatment costs herself but due to high and mounting cost, soon ran out of money to buy weekly medicines and was forced to discontinue.



Thankfully her parents upon knowing of her HCV were in a position to absorb the cost and she successfully completed her Hep C treatment.

**Side effects
were very
severe
with the first
injection itself**

UMESH SHARMA

Shares his experience of Hep C

Note: This article was written in 2007 when HDN Key Correspondent Bobby Ramakant interviewed Umesh Sharma who shared his powerful testimony reproduced below. Umesh actively participated in this consultation and that is one key motivation to reproduce this article below:

NEGLECT OF HEPATITIS C LEAVES PEOPLE WITH HIV VULNERABLE

Bobby Ramakant, HDN Key Correspondent (2007)

In communities where sharing of injection equipment drives the HIV epidemic, a parallel epidemic often lurks quietly in the shadows. Greater awareness about hepatitis C, more investment of resources, cheaper diagnostic and treatment services, and improved hepatitis-related treatment literacy, are all urgently needed by people co-infected with the hepatitis C virus and HIV.

"Hepatitis C treatment is mostly left out since AIDS activists are so focused on ARVs [antiretroviral drugs] or other prevention and treatment services," said Umesh Sharma, who has just completed a course of hepatitis C treatment.

Hepatitis C is a blood-borne, infectious, viral disease that is caused by the hepatitis C virus (HCV). The infection can cause liver inflammation that is often asymptomatic, but chronic hepatitis can lead to cirrhosis and liver cancer. HCV transmission occurs when traces of blood from an infected person enter the body of a HCV-negative person. Like HIV, HCV is spread through sharing injection equipment, through needle stick or other sharps injuries, or less frequently from infected mothers to their babies.

HCV transmission rates are higher than that of HIV, and the condition is often more severe in drug users. People who share injection equipment are vulnerable to HCV and HIV infection, and in many places co-infection is not common.

“Hepatitis C treatment is mostly left out since AIDS activists are so focused on ARVs or other prevention and treatment services”

For Umesh the key was largely having access to the information he needed. Already aware of his positive HIV status, he went for a routine general health check-up during a trip to Manchester in 1995. He discovered he was also infected with HCV. Until then he had no symptoms of HCV. This is not an unusual story, up to 80% of people with HCV usually develop no

symptoms. Initial symptoms, when they appear, can include jaundice, fatigue, dark urine, abdominal pain, loss of appetite and nausea.

There are three types of tests for HCV, which all use polymerase chain reaction (PCR) technology:

- HCV PCR viral detection test: This qualitative test is designed to detect the hepatitis C virus.
- HCV PCR viral load test: This quantitative test estimates the level of HCV in the blood. It helps to monitor the effectiveness of treatment.
- HCV PCR genotype test: This determines the specific genotype (genetic 'make-up') and subtype of HCV. This information is important in selecting a course of treatment. For example, treatment with interferon is more often effective for people with HCV genotype 2 or 3.

"The cost of these PCR tests is prohibitive", says Umesh. He had to pay close to US\$100 for the tests.

People co-infected with HCV and HIV also need to monitor indicators of HIV progression, such as their CD4 count. If the CD4 count falls below 200, then HCV treatment is less effective, and its side-effects may be more pronounced. Umesh suggests that those people with HIV who are taking antiretroviral (ARV) drugs should consult their doctors to find out if they need to change their ARV combination before starting HCV treatment.

Another challenge is the limited availability of PCR tests. In India for example, the test is available in only one city (Mumbai), although blood samples are collected from other parts of the country and sent there for diagnosis. The results can take more than a month to be returned.

Over ten years after his initial diagnosis, Umesh has just completed a course of hepatitis treatment, but getting through the treatment was not without its challenges. "We clearly need more HCV diagnostic facilities", added Umesh. "Particularly in areas with high levels of injection drug use."

HCV can often be treated successfully, including among PLHIV, but the treatment is not easy to endure. Treatment for HCV uses a single drug, or a combination of two drugs, and usually takes between six and twelve months. Umesh points out that there is no standardized treatment protocol and clinical practice varies considerably between individual doctors. This can add to uncertainty and confusion for patients.

The treatment for HCV is also very expensive - costing on average approximately US\$250 per week. Interferon injections are given weekly, in addition to ribavirin tablets. The tablets may be provided free for people paying for interferon injections. On purchasing four interferon injections, one extra is often provided free as a 'discount'. But in countries such as India, people have to bargain with representatives of pharmaceutical

companies or doctors, remarks Umesh. A cheaper alternative is to use interferon injections alone, although this is reported to be less effective. Umesh comments that high-profile donor agencies including the Clinton Foundation and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) are yet to dedicate resources to providing treatment for HCV.

Another dispute among clinicians surrounds the diagnostic value of a liver biopsy. In well-resourced countries, a liver biopsy is usually performed to determine the extent of hepatitis-related liver damage, whereas in Asian countries such as India, China, Vietnam, and Thailand, doctors usually avoid this procedure. Consensus is needed around the diagnostic utility of liver biopsy, if nothing else in order to eliminate additional confusion for patients.

There is no vaccine to prevent HCV infection and even after successful completion of treatment, HCV reinfection can occur. During and after treatment, HCV PCR viral load testing is done at six month intervals to monitor HCV control.

Umesh says that people with HCV considering treatment should connect with those who have previously been through it. The initial days of the regime can be very frustrating and challenging, including loss-of-appetite and flu-like symptoms - it helps to talk to those who have completed the regimen before. Even after successful completion of HCV treatment, it is vital to keep the HCV viral load low. Umesh recommends that drug and alcohol use should be avoided in order to protect liver functions. Also people with HCV need to take care of their livers by avoiding spicy or fatty foods.

Umesh recalls, "I learnt from my doctor, Dr Samiran Panda, in the early 1990s, who taught me how to take care of myself and monitor my own health."

Umesh has proactively sought information over the years, in order to look after his own well-being as well as possible. As a result, he has developed a comprehensive understanding of issues around HIV, injection drug use, as well as HCV.

There is no vaccine to prevent HCV infection and even after successful completion of treatment, HCV re-infection can occur

Developing these kinds of self-management abilities is vital: To monitor and control symptoms of hepatitis C, to minimise other complications or opportunistic infections, or hopefully to prevent their onset entirely.

For people co-infected with HCV and HIV, self-management and treatment literacy skills may be all the more crucial.

(Reproduced from HDN: 2007)

SESSION VI

Interaction with 30 judges and police officials from Home Ministry, Government of India

A delegation from Home Ministry, Government of India consisting of thirty judges and police officials (also those who have been posted in prisons) interacted formally in a session with the participants of the National Consultation on HIV and HCV treatment access issues.

DISCUSSION:

A participant (Eldred) said that programme to address public healthcare needs of IDUs has grown because of the need of the clients. Clients (IDUs) came for opioid substitution therapy (OST) where service providers substituted drugs with buprenorphine sublingual on daily basis. There was a common observation as quite often clients used to disappear for few months. When investigated they found that clients were getting rounded up by police and put in jail every now and then, may be due to past bad petty crime records. These people who use drugs need OST and many of them are also PLHIV and were on ART (a lifelong treatment regimen). Not having access to ART for many days and missing out on OST is counterproductive in terms of public health. Also it can potentially lead to drug resistance to ART drugs.



Continuing treatment in prison is one of the challenges. Most of them are not educated and have been living on the streets. IDU is treated as someone lesser than normal human being. According to the NDPS Act Section 21, 27, there is a provision of continuing treatment but it is not even told to those imprisoned under NDPS Act. Section 7(a) of NDPS Act provides rehabilitation, treatment, and as per Sections 37 and 64 of NDPS Act they can volunteer to go to detoxification. Sankalp Rehabilitation Trust started a treatment centre in the jail itself. Police said to IDUs to accept their crime. But once they confessed then they were being repeatedly rounded up on several occasions. Lawyers' Collective provides legal aid to clients. IDUs should get the benefit of NDPS Act. The IHRN has opposed the compulsory death penalty which is quite archaic. It is important for law enforcers to recognize that bigger people in drug trade don't get caught, and it is usually the smaller drug users who get caught. Drug users are getting doubly convicted but peddlers are not. This is not justice.

Another participant (Manoj Pardeshi) said that he has been living positively with HIV since 18 years. He is also part of the team that filed two cases against the government of India to increase access to treatment. The government was not providing second line ART to everyone



eligible, however after a landmark Supreme Court order, every eligible PLHIV can have access to second line ART. The cost of treatment for hepatitis C is up to INR 900,000. Some people with Hep C sold their wife's ornaments, houses or other possessions to complete Hep C treatment. We believe in health and also want to contribute towards advancing public health. He has lived responsibly with HIV over the last 18 years and is proud to state that he has not passed on HIV to anyone.

Another participant (SPYM) said that health is fundamental right.

A delegate from Home Ministry asked: **How does HIV transmit?**

A participant responded that HIV is transmitted through blood, sharing needles (50% risk, one out of two times of sharing needle episode), mother to child, lowest risk of transmission (female to male 0.1%) and then male to female transmission (1%). 87% of PLHIV in India contracted through sexual route despite low efficacy. Silence around sex is a major obstacle as in a recent training for Anganwadi workers, they could tell routes of HIV transmission except sexual route.

Another delegate from Home Ministry asked: why are there no services for HIV or HCV in Himachal Pradesh?

A participant (SPYM) responded that the state of Himachal Pradesh has only recently started taking HIV seriously.

Another delegate from Home Ministry asked: How do you identify IDU or HIV in prison, because this is not reflected in prison registers and accessing this information is a problem anyways. There are so many barriers one has to cross to reach the inmate cells such as the gate, guard room, superintendent Jail, assistant superintendent jail (who is also the welfare officer), head constable, other officers, women cell, children cell, and then comes the convict cell. Even doctors are not allowed to go that inside of a prison as the doctor sits outside these cells and only attend to patients (inmates) who are brought by the constable to doctor's room.

A participant (Eldred) responded that he has a programme in Mumbai's Arthur jail. There is a denial by police as they say that there is no drug supply inside jail. However, sometimes the police don't even check him.

During *Ramzan* (holy month of fasting for Muslims), he has seen cartons of papaya and mobile etc being taken inside. He has seen drug peddlers too who have easy access inside the jail.

Another delegate from Home Ministry, who has been welfare officer (assistant jail superintendent) for 4-5 years, shared his experience that now it is mandatory as per law for the welfare officer to visit the jail once in three months, interact with the prisoners, ask about health, and welfare. But this is not done properly as the records show that there is hardly any complaint made by any prisoner. Premature release policy is there in prison for other inmates but not for convicts under NDPS Act, no matter how good their conduct is.

A participant (Loon) said that he has been to jail many times as an inmate and as per the law very limited and basic supplies are allowed inside such as blanket. However he has seen that everything can be made available inside the jail upon payment. He asked that since it is not possible for outsiders to go inside so easily and supply items not legally allowed and inmates cannot go outside to get their supplies, who are the people among jail officials who are supplying these legally prohibited items in jails?

Since it is not possible for outsiders to go inside so easily and supply items not legally allowed and inmates cannot go outside to get their supplies, who are the people among jail officials who are supplying these legally prohibited items in jails?

A participant (SPYM) said that 40% juvenile under-trials are also drug users. He shared his observation that guards or visitors supply the drugs inside.

Another delegate from Home Ministry asked again how can they see IDU in prisons.

A participant (SPYM) responded that once the government begins treatment centre in prison they will 'see' IDUs coming in for services.

The President of Indian Drug Users Forum (IDUF) Abou Mere from Nagaland said that he has worked in district jail of Kohima. Although the jail has on an average 5-6 inmates imprisoned under NDPS Act for every 100 inmates, but 50-60 are likely to be drug users. In the jail we do need services such as OST, detoxification, and other health services needed by IDUs. Most of the IDUs are not imprisoned under NDPS Act but because of petty crimes such as pick-pocketing, cheating, etc to support their addiction.

Another delegate from Home Ministry said that one challenge confronting healthcare in prisons is that there is no independent cadre of medical professionals to serve jail inmates. Rather medical officers on deputation

are posted in jails to serve healthcare needs of inmates and they are only allowed to provide healthcare service to the inmate brought by the constable. If they cannot treat such inmates brought to them then they can refer to zonal hospitals. If we had a dedicated cadre of medical professionals providing healthcare service to jail inmates then they could be sensitized and trained to improve public health in prisons.

Another delegate from the Home Ministry said that person who is taking drugs and person who is helping drug supply in prisons should be identified.

A participant (SPYM) responded that supply reduction has less impact, whereas demand reduction has major impact. For example in the following three states of India - Gujarat, Nagaland and Meghalaya, alcohol is banned (dry states) but despite stringent law alcohol is widely available and consumed. In countries such as Mexico or US authorities have realized that they should treat IDU as a patient - and if they are not providing health services to IDUs then they are making it more difficult.

Another delegate from Home Ministry said that “This is the problem, the more we try to hide the more it spreads or increases.”

A participant (SPYM) said that in Chittorgarh district of Rajasthan state, opium use is socially accepted, although government regulation exists. Person doesn't become bad just because they use drugs. There will be people who will continue using opium. The NDPS Act, 1985, has created more problems than it has solved. There is a lot of money in drug business. Majority of children who come to us now have been used as peddlers.

Children as young as 12-14 years have been used as drug peddlers. Somewhere we have to start thinking how to decriminalize drug use. Netherlands has decriminalised and up to a certain quantity of drugs it is not bothered. Drugs become an easy substitute to come out of issues related to conflict-ridden states or mental health problems. Just because a person uses drugs doesn't mean the person is bad. Former Minister of the Government of India Jaswant Singh was caught using and serving opium laced brew in a family function in Rajasthan (2007). Does this mean Jaswant Singh is a bad person?

in the following three states of India – GUJARAT, NAGALAND and MEGHALAYA, alcohol is banned (dry states) but despite stringent law alcohol is widely available and consumed. In countries such as Mexico or US authorities have realized that they should treat IDU as a patient – and if they are not providing health services to IDUs then they are making it more difficult.

A delegate from the Home Ministry agreed that opium ('afeem' in Hindi) is also given in every wedding in localities he comes from.

A participant (SPYM) responded that if these people using drugs in social gatherings are caught and presented in court should NDPS Act be slapped on them?

A participant (Abou Mere IDUF) said that demand for candles will be there when power supply is not good. If government provides full power supply candle supply will die down. If government doesn't supply enough power then despite restrictions and laws that criminalize, smuggling will go up. I request police and judges to also advocate for demand reduction.

Another participant (Leena) said that in 2006, India gave 20 years patent to ROCHE for Alpha-2a interferon and 20 years patent in 2007 to Schering Plough for Alpha-2b interferon which restricts generic production of Hep C drugs. There is an Indian company that made alpha 2b interferon and is currently being sued by Schering Plough for infringing patents. Sankalp Rehabilitation Trust has filed a court case against granting of patent on Alpha 2a interferon (patent is held by Roche). We need to decide what should we be doing to challenge the grant of patent on Alpha-2b interferon - should we file for generic production under compulsory licensing, file a case in court, or other options? It is difficult to import bio-equivalents of these Hep C medicines because these are cold chain drugs.

A delegate from the Home Ministry said that pressure building from different mechanisms should not be ruled out, and going to court is one option.

Somewhere we have to start thinking how to decriminalize drug use. Netherlands has decriminalised and up to a certain quantity of drugs it is not bothered. Drugs become an easy substitute to come out of issues related to conflict-ridden states or mental health problems. Just because a person uses drugs doesn't mean the person is bad. Former Minister of the Government of India Jaswant Singh was caught using and serving opium laced brew in a family function in Rajasthan (2007). Does this mean Jaswant Singh is a bad person?

SESSION VII

Access to medicines and treatment: critical to right to health framework

Discussant: Amritananda Chakravorty, Lawyers' Collective

The Constitution of India guarantees certain fundamental rights, for example: right to equality (Article 14), right to non-discrimination (Article 15), right to freedom of expression, assembly and association (Article 19), right to life and personal liberty including dignity, privacy, health and livelihood (Article 21).

When state actions are violating fundamental rights then such state actions can be struck down by courts (Articles 32 and 226). So going for legal remedy to protect one's fundamental right is always a choice. We can go to court if our fundamental right has been violated.

According to the fundamental right to health in domestic law, read into and interpreted as part of Article 21: "It is the constitutional obligation of the state to provide adequate medical service to the people" (Paschim Banga Khet Mazdoor Samiti vs state of West Bengal 1996).

The right to health as enshrined in domestic law is majorly boosted by International laws on right to health. For example right to health is an integral component of international human rights law instruments such as the Universal Declaration of Human Rights (UDHR), International Covenant on Civil and Political Rights (ICCPR), International Covenant on Economic, Social and Cultural Rights (ICESCR), Committee on the Elimination of Racial Discrimination (CERD), Committee on the Elimination of Discrimination Against Women (CEDAW), Convention on the Rights of the Child (CRC), among others.

The Article 12 of the ICESCR recognizes that: "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." It is substantiated by the Committee on Economic Social and Cultural Rights CESCR in its General Comment no.14 (2000).

It is defined as a right to enjoyment of variety of facilities, goods, services, and conditions necessary for the exercise of right to health and not as only confined to right to healthcare.

This includes socio-economic determinants of health such as food, nutrition, housing, safe and potable water, sanitation, healthy working conditions and environment. This also includes access to health-related education and information, community participation in all health related decision making,

and incorporates ‘freedom and entitlements’ such as right to control one’s health and body, right to be free from interference like torture, non consensual medical treatment, and entitlements include right to healthcare system such as that for Hep C prevention, treatment, care and support.

There are four elements of right to health that overlap and mean that healthcare facilities, goods and services including diagnostics, medicines and hospitals must be:

1. **AVAILABLE:** Hep C diagnostics and treatment should be available in public hospitals (Hep C drugs are not part of WHO list or national list of essential medicines (NLEM). Only *ribavirin* is mentioned in WHO list but for viral haemorrhagic fever only and not for Hep C. The screening for Hep C is recommended as mandatory for IDUs and those with transfusion-associated HIV infection in the ART guidelines of NACO (2007). So if Hep C screening is not being provided to IDUs who are living with HIV then it is not only violation of NACO ART guidelines but also of the right to health.
2. **ACCESSIBLE:** Health services should be accessible to people who need them in non-discriminatory manner. For example, if marginalised groups, such as HCV-HIV co-infected IDUs are facing stigma and discrimination in healthcare settings then it is a violation of this tenet. Healthcare facilities such as those for Hep C testing and treatment should be within safe easy reach (physical accessibility). They should be economically accessible (affordable) which clearly implies that Hep C testing and treatment should be available for all especially for most vulnerable populations such as IDUs. Also the information should be accessible to people such as IEC materials on Hep C, which hardly exist.
3. **ACCEPTABLE:** The healthcare services offered should be culturally appropriate and sensitive to populations. For example, new Hep C drugs approved by US FDA (Boceprevir and Telaprevir) have been tested only on Hep C genotype 1 whereas India has Hep C genotype 3 predominantly in our populations). To market in India they have to do the trial on Hep C genotype 3 first.
4. **OF HIGH QUALITY:** This implies that the healthcare services and medicines for example should be scientifically and medically

There are four elements of right to health that overlap and mean that healthcare facilities, goods and services including diagnostics, medicines and hospitals must be accessible, affordable, available and of high quality...

appropriate and of good quality. Complex side effects of pegylated interferon cause concern.

According to the right to health framework states should not interfere directly or indirectly with the enjoyment of right to health. This means that the states cannot deny or limit access to health services as punishment which is happening currently for those in detention and need ART and/or OST.

States have an obligation to ensure that right to health is realized by taking legislative, administrative, budgetary, judicial, promotional and other measures as appropriate, for example, setting up a national viral hepatitis Control Programme to ensure that the above mentioned four overlapping elements of right to health are enjoyed by every citizen.

There are international obligations too such as states must ensure that other international agreements don't violate right to health (for example, Free Trade Agreements (FTAs) between European Union and India will substantially increase prices of drugs which will violate right to health for millions of people).

We should not let government's unwillingness to act be mistaken as its inability.

In terms of putting more pressure on the government to take cognizance and respond to growing epidemic of Hep C, it is an advantage if Hep C drugs are included in WHO Essential List of medicines. Going to court is another legal remedy as state is clearly violating right to health for over a million people with Hep C in India.

DISCUSSION:

A participant (Leena) asked that who is going to take the responsibility and initiative to test the two new Hep C drugs approved by US FDA (Boceprevir and Telaprevir) cited above for Hep C genotype 2 and 3 which are predominantly found in India (as well as in China and Myanmar)? She asked if government will not step forward then who else will. For how long more people with Hep C have to wait to access latest drugs and treatment modalities? Four years ago we had people who had sold their property for Hep C treatment and are dead now. Even today after 4 years we don't have any legal strategy to bring in a change. As a strategy which court should we go to? Should we exhaust all our options and go to Supreme Court (SC) hoping for favourable order or go to High Court first and if so, then the next question should be which High Court?

States have an obligation to ensure that right to health is realized by taking legislative, administrative, budgetary, judicial, promotional and other measures as appropriate, for example, setting up a national viral hepatitis Control Programme to ensure that the above mentioned four overlapping elements of right to health are enjoyed by every citizen.

SESSION VIII

Patent barriers to affordable access to HCV medicines

Discussant: Prathibha Siva, Lawyers' Collective

When antiretroviral (ARV) drugs were discovered to work against HIV, cost of drug was USD 15,000 per patient per year. It was taken as a death sentence for millions of PLHIV in developing and least-developed countries because of unaffordable price tag on potentially life-extending treatment. The reason for this high price of ARV drugs was patents that restricted others to produce it at lower costs. The patent not only prevented production of cheaper drugs but also using, selling, offering for sale or importing drugs. Patents established a monopoly that led to monopolistic prices.



ABUSING PATENT EXTENSION and EVERGREENING

Patent should be granted for a new drug, not for an already existing drug with little or no change or for an already existing and patented drug with a new use. Companies have been abusing patent extension provision repeatedly. For example, Zidovudine was discovered and patented in 1964 and explored as an anti-cancer drug, but shelved. In 1984-85, its anti-HIV activity was discovered and this same drug which was already patented in 1964 for anti-cancer use was again patented in 1985 for anti-HIV use. Same happened in the case of Lamivudine which was patented for 20 years in 1989. Then later it was combined with Zidovudine and again patented for 20 years in 1992.

Similarly on 22 June 1999, Lopinavir was discovered and patent granted. On 30 July 1996, Ritonavir was discovered and patent granted. However on 14 August 2000, another patent was granted for a combination of Lopinavir and Ritonavir (soft gel).

In 1993 Imatinib was patented for 20 years. In 1995-96, Mesylate salt of imatinib was published. However in 1997, an application for different crystal forms of mesylate salt of imatinib was filed. It is noteworthy to mention that it is the same molecule that acts against or have anti-disease property but patented many times with some changes. Not only this

molecule was patented before but also it has been published before filing for patents.

On 30 December 1986, Tenofovir was granted patent. On 11 May 1993, Emtricitabine was patented. On 21 May 1996 Efavirenz was patented. However on 13 June 2006, Atripla which is a combination of these three drugs was granted patent.

Before the year 2005, there was no product patent in India for pharmaceutical companies. In 2005, India was required to comply with Trade-Related aspects of Intellectual Property Rights (TRIPS) and grant product patent protection for pharmaceuticals.

In India parliament deliberated on the issue of pharmaceutical patents and problem of evergreening. As is obvious patent should not be granted to discover a new property of an existing molecule. Also no patent should be granted for discovering a new use. This was reinforced through establishing public health safeguards through Patents (Amendment) Act.

The Section 3 (d) of Patents (Amendment) Act is a public health safeguard. It states: “The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use of a known substance...”

should not be granted patents. It further explains that “salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”

This public health safeguard was put in place to prevent frivolous patenting, prevent evergreening and promote access to life saving medicines.

Although India supplies 90% of AIDS medicines to the world through the Global Fund, ironically it cannot do so on Hep C as the first patent to be granted in India was on interferon which is used to treat Hep C.

The company ‘Roche’ was granted the patent for pegasys (pegylated interferon alpha a) used for the treatment of Hep C in May 2006. Cost of six months course of Pegasys costs INR 225,000 (USD 5625). Sankalp

The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use of a known substance...” should not be granted patents

Rehabilitation Trust filed a post-granted opposition on 18 May 2007, within a year of patent grant.

The section 25 (2) of the Indian Patents Act allows a “person interested” to file either pre-grant or post-grant opposition. The Sankalp had argued that the “patients’ group” is a “person interested” because patent would exclude other companies from manufacturing the medicine, patent would allow patentee to set high prices for the drug and grant of patent would put the drug out of the reach of millions who need it.

Pegasys, the brand name of Interferon alpha-a, is required to treat Hep C. It is a protein already existing biologically and is known for its antiviral and proliferation activities. However interferon alpha-a molecule had two problems - 1) rapid clearance from the human body system; and 2) breaks down in the body.

So interferon alpha-a molecule was combined with polyethylene glycol and called ‘Pegasys’ that prevents immediate breakdown of interferon alpha-a, and helps the drug stay in the body for longer duration.

This process is called pegylation. This process of pegylation is also not new, and is known since 1970 and widely published. It has been used for different enzymes which are used as medicines and is one of the techniques to make the drug stay in the body or increase solubility of the drug.

Also in 1995, an article published by Monfradini disclosed an identical structure to that of the pegylated interferon alpha-a.

The case filed by Sankalp argues that interferon had previously known anti-proliferative and antiviral activity and could not be used for Hep C treatment because of its rapid clearance from the system. Pegylation of interferon could improve these characteristics and Monfradini disclosed a particularly promising branched pegylated conjugate of interferon (published in 1995). Therefore, if not anticipated, alleged invention is obvious and **does not involve an inventive step**, argues Sankalp’s case. The case is still going on and next hearing is in Chennai, Tamil Nadu (January 2012).

Discussion:

A participant (Leena) said that the group should brainstorm if there is anything we can do to support the legal case.

The case filed by Sankalp Rehabilitation Trust argues that interferon had previously known anti-proliferative and antiviral activity and could not be used for Hep C treatment because of its rapid clearance from the system.

PEGYLATION of interferon could improve these characteristics and Monfradini disclosed a particularly promising branched pegylated conjugate of interferon (published in 1995). Therefore, if not anticipated, alleged invention is obvious and does not involve an inventive step, argues Sankalp’s case.

SESSION IX

Seeking the Phase out of Stavudine (d4T) – An Update

Discussant: Mihir Samson,
Lawyers' Collective

Stavudine or d4T is used extensively in national HIV programme (as part of the drugs used in ART) and approximately 200,000 people are on stavudine despite established evidence that Stavudine has serious long term and irreversible toxicity. Low price of Stavudine cannot justify the continued usage or refusal to provide more effective and better tolerated drugs like Tenofovir.

Sankalp Rehabilitation Trust had filed a case in 1999 seeking to address the rampant discrimination of PLHIV in health care settings. Scenario changed with the initiation of the ARV rollout in 2004. This case was used to address issues relating to access to treatment for PLHIV. Some orders that had profound public health and social justice outcomes for PLHIV include:

- On 1st October 2008, there was an order to realize the right to non-discrimination for PLHIV in healthcare settings and scale up ART centres, link ART centres, treatment facilities for opportunistic infections, and ensure universal precautions are practiced by healthcare providers.
- On 1st October 2010, the order said that doctors will follow NACO Protocol while prescribing ART - this addressed the issue of irrational use of ART drugs among others.
- On 16 December 2010, the order stated that the second line ART will be provided to all those who require it, irrespective of any other criteria.

There are a number of unresolved issues which already form part of the Sankalp's case such as:

- Expansion of the number of drugs in first line ART regimen

Stavudine or d4T is used extensively in national HIV programme (as part of the drugs used in ART) and approximately 200,000 people are on stavudine despite established evidence that Stavudine has serious long term and irreversible toxicity.

Low price of Stavudine CANNOT JUSTIFY the continued usage or refusal to provide more effective and better tolerated drugs like Tenofovir.

- Scale up of second line ART
- Involvement of PLHIV in the ARV rollout programme
- Provision of diagnostic tests
- Disaggregated data for marginalized groups (from AIDS programmes)

In addition, there are other pressing issues relating to access to treatment and the ARV rollout programme which could be taken up.

A national consultation was held in Bhubaneswar (June 2011) to prioritise key issues related to HIV response in India such as continued use of Stavudine in the ART rollout programme, use of Tenofovir as a preferred first line drug, repeated incidents of drug stock-outs, mechanism of referral to State AIDS Clinical Experts Panel (SACEP) for initiation of second line therapy among others.

In India there are two first-line ART combinations that are being provided currently: Zidovudine + Lamivudine + Nevirapine/Efavirenz; and Stavudine + Lamivudine + Nevirapine/Efavirenz. Better tolerated drug Tenofovir is an alternate first line drug, prescribed only when patient cannot take either Stavudine or Zidovudine.

Stavudine causes long term, cumulative, irreversible and often fatal toxicities. These toxicities unfavourably impact the health, well-being and quality of life of PLHIV and some of the toxicities also cause death.

Stavudine also causes lipodystrophy (re-distribution of body fat around the body) and lipoatrophy (fat wasting) due to which there is a loss of subcutaneous fat from one or more of several areas of body, including the face, torso, arms, legs and buttocks, with veins becoming prominent. Stavudine also causes lipohypertrophy which increases fat accumulation in the abdomen, breasts, or at the back of the neck often referred to as the “buffalo hump”. Since these are visible physical symptoms the PLHIV taking Stavudine face more stigma, discrimination and related mental health issues.

Stavudine also causes lactic acidosis and symptomatic hyperlactatemia (blood becomes too acidic due to presence of excess lactic acid). It can have severe effect on many organs and can also become fatal. High levels of lactic acidosis have been reported to have a high mortality rate (up to 50%).

Stavudine also causes peripheral neuropathy (disorder of nerves mostly in the feet and legs, causing tingling, numbness, unusual sensations, weakness, or burning pain which may lead to disability).

Stavudine also causes inflammation of the pancreas.

Studies show that women are more vulnerable to Stavudine related toxicities, especially lactic acidosis and symptomatic hyperlactatemia and are thereby disproportionately impacted.

Stavudine related toxicities, particularly lipodystrophy have psychological and psychosocial impact on PLHIV, contributes to stigma and has the potential to encourage PLHIV to discontinue ART.

Toxicities negatively impact adherence and lead to treatment interruptions, resistance and failure which have also been associated with high morbidity and mortality rates.

In 2006, the WHO had recommended reducing dosage of Stavudine from 40 mg to 30 mg. Concerns were expressed about toxicities associated with Stavudine. WHO noted that it is important to begin planning to move from Stavudine containing regimens so as to avoid or minimize toxicities.

In 2009 the WHO reviewed existing evidence on toxicities of Stavudine, and recommended withdrawal from the government programmes even in resource limited settings.

In 2010 the WHO revised guidelines and strongly recommended withdrawal of Stavudine from government treatment programmes.

Toxicities negatively impact adherence and lead to treatment interruptions, resistance and failure which have also been associated with high morbidity and mortality rates.

The WHO had expected countries will either immediately stop the use of Stavudine or take steps to progressively reduce the use of Stavudine in first line regimens of ART in national AIDS programmes.

India and other countries should have made an action plan to move towards first line regimens of ART consisting of Zidovudine or Tenofovir and away from Stavudine, and fully implement the WHO recommendations by 2012. With two more months to go for 2012, India is way behind implementing the WHO recommendations.

Two years after WHO recommendations and a decade worth of evidence, Stavudine continues to be used in ART rollout in India with no phase out plan evident so far.

The technical review group (TRG) of National AIDS Control Organization (NACO) had met on 19-20 August 2011, to discuss phase out of Stavudine. There was a general consensus and acceptance of WHO's recommendation that Stavudine causes serious toxicities and there was a need to phase it

out. The NACO had shared data from various Centres of Excellence that show the following: peripheral neuropathy (nearly 7%), lipodystrophy (5%) and lactic acidosis (0.9%). We should understand that the low incidence of lactic acidosis might be due to non-availability of serum lactic acid estimation facilities in most of the hospitals.

Instead of proactively phasing out Stavudine, the NACO rather went ahead and procured Stavudine for eighteen months.

In 2010, the main reason for not phasing out Stavudine immediately was that the existing stocks and those in the procurement pipeline would be wasted. But fresh procurement of Stavudine for next eighteen months causes serious concerns and creates a doubt that the phase out will be deferred on the same excuse that the newly procured “stocks will be wasted.”

One of the strong grounds to go for legal recourse against continued use of Stavudine is that it violates the right to health which is a part of the right the life guaranteed under Article 21. Low price of Stavudine cannot justify the continued usage or refusal to use better, well tolerated ART drugs, like, Tenofovir. Cost considerations are outweighed by the benefits of avoiding Stavudine associated toxicities and benefits of using Tenofovir.

Phasing out Stavudine is not only in the interest of the PLHIV but also in the interest of the national AIDS programme. Moving PLHIV to safer and better tolerated ART drug (such as tenofovir) will have positive impact on adherence, patient morale, longevity of PLHIV, simpler clinical interventions and overall better treatment outcomes.

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Once India starts making bulk purchase of Tenofovir (TDF), the economies of scale will automatically bring down the prices and address price concerns.

In the legal recourse, the directions sought include:

- Union of India should be stopped from purchasing more stocks of Stavudine (except small quantities for those who cannot tolerate Zidovudine or Tenofovir).
- In the alternative, Union of India should be permitted to procure stocks only for 6 months instead of 18 months. In the meanwhile the Union of India should develop a phase out plan for Stavudine in equal partnership with the PLHIV community.

- New patients should not be put on Stavudine based ART regimens and instead on Tenofovir and Zidovudine based ART regimens
- More than 200,000 patients who are already on Stavudine based ART regimens in India should be closely monitored to detect associated toxicities so that alternate regimens may be provided
- Stavudine should be phased out over a period of one year and should be completely withdrawn by 2012 and all the patients on Stavudine should be switched over to Tenofovir or Zidovudine based first line ART regimen by then.
- The national AIDS programme should put in place a pharmaco-vigilance, detection and monitoring system of Stavudine toxicities and Zidovudine induced anaemia

This application was filed in Supreme Court and came up on 5th August 2011. The Court had asked Petitioners to approach the NACO first. On 10th August 2011, a legal notice was sent to the NACO regarding the removal or phase out of Stavudine. Since no reply was given to this notice, another reminder notice was sent on 12th September and reply duly received on 27th September 2011.

Meantime DNP+ members who have been prescribed Stavudine are collecting affidavits to be used in this case.

The NACO's reply of 27 September 2011 states that the WHO guidelines (2010) recommend country adaptation based on health systems, HIV epidemic and available resources. The TRG had met in August 2010 regarding the need for the implementation of the WHO guidelines but expert opinion was divided.

Some experts felt that the incidence of toxicity is low and therefore does not warrant a phase-out as the drug is effective and requires little laboratory monitoring. Some experts didn't consider lipoatrophy a reason for phase out as it is a cosmetic issue and not many complaints have been received. Stavudine requires little monitoring which is another reason some experts supported its provision.

Other experts felt that due to serious, long term and irreversible side effects of Stavudine, the drug should be phased out from national ART programme.

There was an overall consensus in the TRG meeting that use of Stavudine should be reduced in the following manner:

- By substituting Stavudine with Tenofovir in patients with evidence of long term stavudine related toxicity
- By initiating new patients eligible for ART with baseline anaemia on Stavudine for 6 months and if haemoglobin levels improve, then switching to Zidovudine or Tenofovir
- Tenofovir based regimes require more rigorous monitoring which may not be possible
- The financial and logistical issues for implementing these guidelines have to be worked out
- Phase out will start from Nov-Dec 2011
- The TRG will meet again to review the status of the phase out.

DISCUSSION:

A participant (Dr Tokugha Yephthomi) said that he was one of the invitees to the TRG meeting. There was a disagreement on how prevalent are side-effects related to Stavudine. Also there were concerns regarding putting PLHIV eligible for ART on first-line regimens that will reduce options for second line regimens if required. Also toxicity such as peripheral neuropathy doesn't develop in 6 months and takes longer time, so if people on stavudine take it for 6 months they might continue taking it. He was also concerned on how many ART doctors will follow the recommendations such as phasing out of Stavudine or putting new people on Tenofovir or Zidovudine and phasing out those already on stavudine.

Another participant (Manoj Pardeshi) said that the Active Pharmaceutical Ingredient (API) to formulate ART drugs comes from China. Eferavine is most costly among ART drugs. Tenofovir API is cheaper. As production is increasing prices are going down. Presently Tenofovir might cost INR 184 per person per month. If the NACO goes for Tenofovir then this price of INR 184 will also come down.

Doctors don't have enough time to ask history for side effects, and patients think that side effects are part of life and may not share. So that is also one of the reasons why doctors are reporting very few patients with Stavudine-related side-effects

A participant (Dr Tokugha Yephthomi) said that the doctors don't have enough time to ask history for side effects, and patients think that side effects are part of life and may not share. So that is also one of the reasons why doctors are reporting very few patients with Stavudine-related side-effects. Human resource needs to be strengthened. All duties cannot be on the ART doctor.

A participant (Dr Jana) said that the standard design format to record side effects of drugs should be developed. Networks should be asked to record and report levels of poor adherence, and what are the reasons behind poor adherence.

A participant (Umesh) said that adherence is also important and it has two aspects. Having medication but not taking it timely is one aspect of adherence and another aspect is timely detection of problems, regular availability of stocks, and other factors that impact adherence.

A participant (Manoj Pardeshi) said that in India, entire ART is funded by the Global Fund - to put a certain number of eligible PLHIV on ART in a time bound manner. The NACO has spent all its energy in rolling out this programme. Now is the time to start demanding for quality. Some reliable sources suggest that the NACO is not able to spend USD 100 million of the multiple Global Fund grants. The Global Fund Round-4 money is still remaining to be utilized and the NACO has not even started utilizing Round-

6 money. When poor countries such as Kenya or Zimbabwe have phased out Stavudine and their first line ART regimen consists of Tenofovir then why is India facing so much of problem in doing something which is clearly a public health imperative?

A participant (Mihir Samson) said that when we asked PLHIV (DNP+ members) on ART whether the doctors told them about side effects associated with ART drugs the answer was no.

A participant (Aarthi Pai) said that despite WHO recommendations what is the guarantee that the counselling sessions will address issues such as side effects related to Stavudine, among other issues? There should be more community monitoring of these programmes and systems to feed into the overall monitoring and programme improvement.

A participant (Dr Jana) said that if quality is not maintained the objective of ART programme is compromised.

A participant (Manoj) said that over 530,000 people are on ART since India started rolling out ART in 2004. However, currently only 430,000 people are on ART. Where are the remaining 100,000 PLHIV on ART gone? The only official reply is “LFU” (Lost to follow up) because there is no system to record such critical and valuable information.

Over 530,000 people are on ART since India started rolling out ART in 2004. However, currently only 430,000 people are on ART. Where are the remaining 100,000 PLHIV on ART gone? The only official reply is “LFU” (Lost to follow up) because there is no system to record such critical and valuable information

A participant (Dr Tokugha Yepthomi) said that when we had an opportunity to raise these concerns with NACO, then community, NGOs, etc wanted to be in good books of the NACO and didn't speak up. The NACO needs to record, mortality, LFU, etc and we need to do better and people centric research in this country.

A participant (Manoj) said that the NACO is not allowing anyone to come and do any research in ART centre.

A participant (Aarthi Pai) said that the community involvement is negligible, forget about community-led monitoring. How do we prepare ourselves and our own community members to go into NACP-4 meetings, argue and bring their issues on the table? It relates very strongly to preparedness and advocacy.

A participant (Umesh) said that the discussion is coming back to quality and it relates to every component of AIDS programmes such as harm reduction,

outreach, services, etc and not just to ART. In our system accountability is a big missing link here. Without accountability we cannot call people and say they are responsible for providing a service and it is missing or suboptimal. Sustainability will only come when accountability is established. Since Centres of Excellence were mentioned by Mihir Samson, the participant mentioned his own experience of visiting a Centre of Excellence for children. He went to this centre of excellence for his CD4 count and was 16th in queue. Another person who came right after him from 40 km far distance was refused service because only 16 blood samples can be mounted at one time. Is this the quality of service at centre of excellence?

A participant (Bobby Jayanta Kumar) said that all ART drugs don't work for IDUs, such as Nevirapine is provided to IDUs when it is not indicated.

A participant (Eldred) said that the NACO is giving so much emphasis on data but how are they using this data to improve programme performance?

More discussion:

A participant (Bobby Jayanta Kumar) said that outside of Manipur laboratory technicians find it very difficult to take his blood and are not trained to take bloods of those with history of injecting drug use. At times he has to do it himself (take his own blood sample and hand it to the technician).

A participant (Dr Tokugha Yepthomi) responded that such issues should be brought in notice of the ART doctor and he is hearing such issues for the first time.

A participant (Eldred) said that this practice where laboratory technicians find it difficult to collect blood samples from PLHIV with injecting drug use history is old, and they have been facing it since past 15 years.

A participant (Bobby Jayanta Kumar) said that there is an ego problem too when he (patient or client) volunteers to take his own blood sample as the laboratory technician is failing to do so. The technicians have often injected him 9-10 times at 9-10 different places unsuccessfully for collecting blood samples. A laboratory technician thinks she or he knows best. Such ego problems should be resolved and existing healthcare workers must be well trained in providing services for clients with specific needs. Even the nurse is not well trained to provide service for IDUs.

Outside of Manipur laboratory technicians find it very difficult to take his blood and are not trained to take bloods of those with history of injecting drug use. At times he has to do it himself (take his own blood sample and hand it to the technician), said a participant. By that time, the technician has often injected him 9-10 times at 9-10 different places unsuccessfully...

A participant Aarthi Pai) said that first step was that extensive consultations were done to seek inclusion of Hep C in targeted interventions (TIs) of NACO. Then the second step was making the Hep C recommendations not only in the (currently-under development) 12th Five Year Plan (FYP) of the Planning Commission of the Government of India but also in the National Rural Health Mission (NRHM) so that Hep C programming is well integrated, comprehensive and well budgeted. The third step should be on how we want to input on Hep C into the efforts that are currently underway to develop a national drug policy.

A participant (Bobby Jayanta Kumar) said that the NACO has done its midterm review and based upon their report (December 2010) it had identified 4 SACS with administrative problems. It is almost a year now since then and no solution seems to be forthcoming.

A participant (Manoj) said that since the NACO and Ministry of Health both have not taken up Hep C programming, it appears as if it is an orphan issue affecting an alarming number of people in India

Since the NACO and Ministry of Health both have not taken up Hep C programming, it appears as if it is an orphan issue affecting an alarming number of people in India *(estimated to be 14 million)*

(estimated to be 14 million). There are so many issues that need to be addressed such as operational issues, development of new guidelines and standards among others and in absence of any coordinated response to Hep C “with no father or mother taking care of Hep C programme development”, not much can be achieved.

A participant (Umesh) said that the IDUs also need Ministry of Social Justice and Empowerment (MSJE) services at some point of time and that should be involved in these discussions too.

A participant (Eldred) said that he has done a recent study about 380 MSJE centres across the country and almost 50% of them were non-functional. It becomes a way to siphon out money. They don't have an email address, no computer, and when these centres were visited, many of them refused to take in people for provision of services. These are MSJE centres that are getting INR 1,700,000 a year to provide such services. 119 centres participated in this study.

A participant (Umesh) said that this is unacceptable that IDUs who are in detoxification are denied Hep C treatment. Why are the service providers waiting for IDUs to finish detoxification and then come back for Hep C treatment? Hep C services should be available in detoxification centres too.

A participant (Eldred) said that MSJE centres are taking selective people for services who can pay something for food etc and a significant number of them come here for alcohol de-addiction.

A participant (Loon) said that in terms of strategy eventually we all want treatment. This is our longer goal and for now it is important to hook the government. Let's ask for testing first as it is very feasible - and then voices will come out from affected communities that "why are you testing me and not giving me treatment?" Currently they are testing people for Hepatitis B, let's add Hep C. Testing can be the entry point as the programmes will never give treatment when they aren't even ready to test those with risk of Hep C.

A participant (Dr Tokugha Yephthomi) said that we should include Hep C and Hep B in guidelines for patients suffering from haemophilia, Thalassemia, PLHIV, among others and encourage service providers to take history of IDUs

A participant (Dr Jana) said that the short term strategy should focus on what is the space that has already been created or exists in the NACO, MSJE, NRHM, and other mechanisms for potential Hep C response.

A participant (Bobby Jayanta Kumar) said that the Indian Harm Reduction Network (IHRN) has done this advocacy in 2010 to include hep C and NACO said that Hep C is not part of NACP and thus they cannot invest so much of money in Hep C

An ITPC-India delegation had met the Executive Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria and he said the country has to decide *[on Hep C proposals]* and the Global Fund has no issues to supporting Hep C treatment.

A participant (Dr Jana) said that the WHO provides technical support for National Surveillance System and if we can include Hep C here then we will get more representative data from the country on Hep C. We also need to engage policy makers in the parliament, such as committee on HIV/AIDS. We need to involve media - and help them do some stories based on the evidence, activists, PUD, PLHIV, lawyers, etc

A participant (Ratan) said that just like there is mandatory screening in blood banks for diseases such as HIV, Hep C and Hep B, similarly Hep B and Hep C should be included in the national sentinel surveillance

A participant (Aarthi Pai) said that the Hep C briefs are way too technical and people outside the development sector just don't engage with it

A participant (Dr Jana) said that we have to collect more data and we need more studies such as sentinel surveillance or people attending to ART centres to get better information on Hep C. Why cannot the NACO undertake an independent study on Hep C?

A participant (Abou Mere - IDUF) said that we recommend that every PUD should be tested for Hep C. In Nagaland in some districts, HIV is 2% but Hep C is 40%. When we don't have treatment literacy how can we make noise? Treatment literacy is important for IDUF

A participant (Manoj) said that he along with Loon Gangte had met the Executive Director of the Global Fund and he said the country has to decide and the Global Fund has no issues to supporting Hep C treatment. The ball is back in our court.

A participant (Manoj) said that we need to push Hep C and phasing out of Stavudine (D4T) with the UN agencies

A participant (Luke) said that Lamivudine and Tenofovir manage both Hep C and HIV. Where there is HIV-HCV co-morbidity then person should be given these two ARVs on priority

A participant (Manoj) said that lot of people are failing the drugs, they go to SACEP and based on the report SACEP decides whether the person is eligible for 1st line or 2nd line ART. We should reach out to the people failing on ARVs much early on to improve quality of life and life span

SACEP was created by the NACO to control roll out of second line ART regimen but it is creating a problem (structural barrier to access) with long waiting time, etc

A participant (Loon) said that let's remove SACEP and ART doctor should be the one deciding when is the right time to shift from first line ART regimen to second line ART regimen

A participant (Luke) said that it is much easier and cheaper to monitor ALT and AZT than viral load. If there is high AZT and ALT then be very cautious. Stock outs should not happen especially in Manipur

A participant (Dr Jana) said that standardised drug side effect monitoring system should be in place

A participant (Dr Tokugha Yephthomi) said that the drug side effect monitoring system is there but doctors just 'fill it' for namesake and not really implement it in spirit and letter and that is why programme is missing the opportunity to collect this data genuinely and improve responses on the ground

A participant (Luke) said that if SACEP is not following their own guidelines they should be thrown out. INR 8000 crore is prevention budget of NACO NACP-III - the argument they don't have enough money is not true

A participant said that SACEP was created by the NACO to control roll out of second line ART regimen but it is creating a problem (structural barrier to access) with long waiting time, etc. We also need to strengthen universal precaution and studies should be initiated to ascertain causes beyond poor adherence

SESSION X

Brainstorming on listing out key advocacy issues and strategies for UN agencies, NACO, Planning Commission, media and other stakeholders:

The NACO has made a significant contribution in scaling up HIV programmes across the country over the past years. The NACO is credited with helping establish and continuing support to very successful HIV interventions, networks and has gained rich experience on HIV. People living with HIV are on ART if eligible but if co-infected with Hep C, likely to die of Hep C. That is why working on Hep-C is so important to maximise AIDS programme performance and also to save lives, and reduce human suffering.

The UN agencies can play a key role in supporting community research to bring out evidence and advocate with NACO and other agencies to build up a comprehensive and integrated response to Hep C.

WITH NACO

- Strengthen surveillance and testing of Hep C and Hep B in all sites - this can be scientifically justified
- Ensure Hep B and Hep C testing
- Short term strategies with spaces already open and available - go with NACO for now
- Testing of Hep B and Hep C is there as part of the give infections for donating blood - needs to be extended to HIV testing
- Need to gather enough evidence about the prevalence of Hep C and Hep B
- Propose to NACO to carry out independent studies on Hep C
- When a PUD is going for testing should go for Hep C testing compulsorily (hep C burden is very high) - include in the ICTC guidelines. With pre and post test counselling should be routinely offered
- IEC - prevention and treatment literacy is essential
- Building capacities of the members in treatment literacy
- Capacities in outreach, TI - with reference to Hep C - learning sites should take this up too (13 learning sites covering entire India supported by the Global Fund round 9).

OTHER STAKEHOLDERS

- Existing networks of PUD/ CBOs should prioritise Hep C - get ANGRY!
- Involve the media and other stakeholders - focus both from the angle of HIV and quality of life, how it can help LHIV, how it is important to achieve the targets
 - Develop a separate eGroup on Hep C
- Strengthen advocacy with donors on medicines, treatment

- Strengthen community forum so that they can raise issue at a local level/ state level - creating knowledge and awareness - Indian Drug User Forum
- Legal options - file a case/ PIL individually or as a community
 - Create awareness amongst the affected community on how to proceed legally - who will take the initiative and what is the roadmap? LC/HRLN
- Increasing alliances with other networks/ issues - cancer/ Thalassemia/ haemophilia

How?

- Creation of a simple brief on the issues (Hep C, patent, costing, lack of policy) which can be shared with emdia, lawyers, opinion leaders, ministries, MLAs)
- Bringing together community at regional level to create literacy on the issue
- Generate evidence of the impact of Hep C
- Document of cost of not intervening on Hep C

Issues to be placed before UN group:

- Treat Hep C as a co-infection
- Include Hep C within TI
- Integrate Hep C in existing outreach programmes/strategies
- Include Hep C within surveillance
- Include Hep C for MSM and FSW TIs also
- Include Hep C for pre and post test counselling
- Support evidence and research on Hep C - impact, numbers
- Initiate Hep C consultation at the regional and national level (by November)
- Recommend viral load testing every year in treatment guidelines for PLHIV

ANNEXURE I

National Consultation participants' list

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ANNEXURE II

PRESS RELEASE

21 October 2011

HEALTH GROUPS - WITHOUT PREVENTION PROGRAMME, MILLIONS AT RISK OF INFECTION

HIGH PRICES OF MEDICINES MEANS DEBT OR DEATH FOR PEOPLE WITH CHRONIC HEPATITIS C

New Delhi, 21 October 2011 - People living with hepatitis C, ITPC-India and treatment activists at a press conference openly questioned the silence maintained by the Indian Health Ministry on its response to the Hepatitis C virus (HCV), which is emerging as a growing public health threat.

According to the World Health Organization, hepatitis C virus (HCV) is a major cause of acute hepatitis and chronic liver disease. Globally, 3 to 4 million persons are newly infected each year. According to the health groups at the press conference, the burden of the disease in India will continue to rise in the absence of prevention and harm reduction measures with vulnerable communities.

"HIV and hepatitis viruses are transmitted in similar ways and it makes public health sense to link HCV prevention efforts to HIV programme" said Eldred Tellis, Director of Sankalp Rehabilitation Trust. "In addition to HCV screening in blood banks, prevention and harm reduction efforts for HIV and HCV with vulnerable communities should go hand in hand. Unless this is done, HCV infections will rise in India even though HIV transmission rates reduce, particularly among injecting drug users (IDU), the most vulnerable community," adds Tellis.

According to the health organisations, there are two main obstacles to an effective HCV response in the country. First is the absence of prevention efforts; second is the lack of political will to treat HCV-among policymakers in the Health Ministry.

Currently, HCV treatment is a combination of two drugs, pegylated interferon and ribavirin. For people who do not clear the virus spontaneously from their body and go on to develop chronic forms of the disease that affects the liver, treatment is currently unavailable in the public healthcare system and unaffordable in the private sector.

The high cost of HCV treatment in India is attributed to the absence of generic competition due to patent barriers. India, as part of its obligations under World Trade Organization's (WTO) international trade rules, had to introduce product patents on medicines in 2005.

Pegylated interferon alpha 2a and alpha 2b, used in the treatment of Hepatitis C, were among the first set of drugs to come under patent monopoly in India. The patents granted by the Indian Patent Office to two pharmaceutical companies - Roche and Schering-Plough, block the development of more affordable generic versions of the drug. As a result both these companies charge exorbitant prices from patients, ranging from Rs. 14,000 to 18,000 per dose.

"People living with HIV are increasingly being diagnosed with HCV co-infection. Hepatitis C, is the "silent killer," threatening to undermine HIV treatment efforts", said Loon Gangte, of the Delhi Network of Positive People (DNP+). "We need not only AIDS medicines but also access to HCV medicines from the government."

"I had to use all my savings and borrow heavily to pay over seven lakhs rupees for my 48 week HCV treatment, " said Nanao Haobam, sharing his experience of living with HCV/HIV co-infection. "The Indian Government's silence on this issue is more like telling us - I am sorry you will die because treating you is not cost effective."

Neini Wanda E. Pakma, who underwent HCV treatment this year, adds, "my family had to pay Rs. 5,78,000 over 24 weeks for just pegylated interferon. I am one of the lucky ones to have been successfully treated in India. The high cost of drugs makes it impossible for patients in India with chronic HCV to get the treatment they need."

"As a physician we have gone through the frustration of watching people die of AIDS even when effective antiretrovirals existed. But things changed with domestic production of affordable generic antiretroviral medicines," said Dr. Tokugha Yephthomi, of ITPC - India. "People are now dying because the price of the HCV drug that can save them is too high. Prohibitive pricing of lifesaving medicines by pharma companies is unethical and unacceptable."

According to the organisations, the government has been moving far too slowly on addressing the problems of patients who need HCV treatment. "When drugs are patented, and pharmaceutical companies fail to fulfil their obligation to make patented medicines available and affordable to patients, the only way to bring prices down is through examining the validity of the patent granted or compulsory licensing which allows generic production of more affordable versions," said Loon Gangte. "Instead of addressing the problem, it's like the government is pretending the death and the sickness that HCV causes are not happening."

This press briefing is being organized by International Treatment Preparedness Coalition - India (ITPC-India). ITPC-India was set up in 2008 as a national coalition of people living with HIV, treatment activists, doctors, lawyers and academia.

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NOTES FOR THE EDITOR:

Viral Hepatitis resolution adopted by the member states of the World Health Organisation on 23 January 2010 at the Sixty-third World Health Assembly, which recognises Hepatitis C as a public health issue. Available at
http://apps.who.int/gb/ebwha/pdf_files/EB126/B126_R16-en.pdf

Hepatitis C in India:
<http://www.ias.ac.in/jbiosci/nov2008/465.pdf>

Treatment protocol: Hepatitis C treatment is a combination of two drugs, pegylated interferon and ribavirin. Pegylation means that a small molecule has been attached to interferon to keep it in the body longer, to make dosing more convenient. There are two types of pegylated interferon (PegIFN) - alpha-2a and alpha-2b. Pegylated interferon alpha-2a is a liquid that comes in one vial and is stored in the refrigerator. Everyone uses the same dose of Alpha-2a, regardless of their weight. Pegylated interferon alpha-2b is a powder that has to be reconstituted with purified water, both of which come in separate vials. Alpha-2b is dosed by weight. For people living with HIV, who are co-infected with HCV, the usual course of HCV treatment lasts for 48 weeks, with ribavirin taken daily (pills) and pegylated interferon taken once a week by injection.

Patents: High prices due to the introduction of WTO's product patent regime in 2005 are starting to be experienced in India. On March 3rd 2006, Roche proudly announced it was becoming the first pharmaceutical company in India to receive a product patent under the new patent regime on peg-interferon alfa-2a (IN198952). Sankalp Rehabilitation Trust filed a post grant opposition to the patent, as the technology of combining interferon and other biologically active proteins with PEG has been known for years prior to the patents. The matter will be heard before the Intellectual Property Appellate Board in January 2012. Schering-Plough was granted a patent (IN 207233) on peg-interferon alpha-2b and has filed infringement suits in 2009 against Virchow Laboratories and Ranbaxy before the Delhi High Court. The infringement suit is scheduled to be heard next on 15 December 2011.

Compulsory licensing (CL): With CLs prices of medicines can be lowered effectively. The case of the CL issued by Thailand for the AIDS drug lopinavir/ritonavir in January 2007 clearly illustrates this. Over the course of one year, the price for LPV/r decreased by as much as 75%, from \$2,200 ppy to under \$900 in Thailand. As per the World Trade Organization's TRIPS Agreement and the 2001 Doha Declaration on TRIPS and Public Health, India's Patents Act too allows it to implement a progressive compulsory licensing policy in accordance with international trade rules.

ANNEXURE III

Meeting between ITPC-India and Planning Commission on 21st October 2011

A delegation led by ITPC-India met with the Dr Syeda Hameed, Member, Planning Commission of the Government of India, who is also the Chairperson of a forty-member steering committee for health which is currently formulating the health component of the Twelfth Five Year Plan (2012-2017) of the Planning Commission. The ITPC-India delegation had also met with Mr SM Mahajan, Adviser, Planning Commission (HIV/AIDS). Dr Hameed's sectoral responsibilities at Planning Commission include health and women and children.

Manoj Pardeshi informed Dr Hameed about Hep C related issues, and mountainous challenges in accessing affordable and standard prevention, treatment, care, and support services for Hep C.

Dr Hameed said that although even if one person is affected health services should be available, still she wanted to know about the numbers of people with Hep C in India. ITPC India delegates informed her of current estimates (14 million).

Dr Hameed also enquired about route of transmission, and other services. She asked her HIV/AIDS Adviser Mr Mahajan if Hep C services are included in HIV programme and the answer was 'no'. She further asked if it was included in general healthcare in public sector and the answer was another 'no'. She was visibly concerned and then listened to the personal experiences of dealing with Hep C shared by Neini Wanda E Pakma (Meghalaya). Neini shared her Hep C treatment testimony and also the cost she had to incur.

The ITPC-India delegation apprised her of country's first patent granted to one of the drugs (interferon) used to treat Hep C which has restricted generic production of cheaper drugs for Hep C treatment.

The ITPC-India delegation also apprised her how Hep C co-infection with HIV is undermining India's AIDS programme performance. Treatment outcomes are poorer and even if PLHIV are accessing ART they are likely to die of HCV if co-infected.

Dr Hameed accepted all documents handed over by ITPC-India team to her office and deputed Mr Mahajan to study the matter and in case it is found appropriate she said in clear terms to put NACO's NACP-4 proposal to be submitted for 12th Five Year Plan on a **conditional approval** so that Hep C component can be integrated for a coordinated response.

The list of forty-members of steering committee on health of the Planning Commission is online at:

http://planningcommission.nic.in/aboutus/committee/strgrp12/st_health.pdf

ANNEXURE IV

Meeting between ITPC-India and UN agencies on 20th October 2011

A delegation led by ITPC-India met with UNAIDS India, World Health Organization (WHO), UNICEF, UNDP, UNAIDS North East regional coordinator among others, at the meeting hall of UNAIDS India in New Delhi.

ITPC-India apprised the UN agencies of the national consultation on HCV and HIV treatment access issues held on 19-20 October. The consultation had focussed on HCV treatment issues, phasing out of Stavudine (d4T), introducing Tenofovir in first-line ART regimens among others.

ITPC-India raised the following issues:

- Hep C is not in the national surveillance system and should be included
- Hep C is not just an issue confined to North-Eastern States. FHI study in Maharashtra and other data is alarming on rising rates of Hep C across India. Even states reporting drop in HIV rates have recorded rising HCV rates
- There is a need to bring all different players on Hep C together for a well-coordinated and integrated response to Hep C in India
- India's AIDS programme should adhere to guidelines and standard practices and phase out Stavudine (d4T) and introduce Tenofovir in first-line ART regimens. The ART programme in India is at most becoming like a drug dispensing system and there is a long way to go in terms of improving quality of services

A delegate with ITPC-India (Eldred) raised the point that Hep C has to be taken onboard by existing targeted interventions (TIs) for IDUs. TIs should include Hep C and while giving distilled water, swabs etc they should also give other clean paraphernalia such as cookers. Hep C testing should be included in ICTC centres across India.

ITPC-India also raised the point of pre- and post- test counselling for Hep C while scaling up testing and providing treatment for Hep C.

A delegate with ITPC-India said that neither the NACO nor the Ministry of Health and Family Welfare, Government of India has taken leadership in developing a well-coordinated and integrated programme to respond to Hep C. Hep C is an orphan issue and government agencies are passing the buck around instead of acting upon to save lives and reduce human suffering due to Hep C.

UNAIDS India head Dr Charles Gilks said that the health department doesn't seem to recognize the correlation between HIV and HCV possibly because

they have too much to do. Hep C has fallen between lots of potential actors.

The WHO should push the Ministry of Health for a national response on Hep C and Hep B. India had signed a resolution 57 at the World Health Assembly (2010) committing to a 10 action points charter on Hep B and Hep C which is not only related to IDUs but to general population as well across the country.

There are MSM community that have reported Hep B and Hep C. It is very important for HIV community to act as a spearhead on building up Hep B and Hep C responses in the country but eventually it should be a broader agenda.

A delegate with ITPC-India (Eldred) said that Hep C is too big to miss with 80% incidence in some communities.

Dr Charles Gilks agreed that we should be pushing the government for a national surveillance policy on Hep C to feed into the national response to Hep C then.

The WHO should come up with guidelines for resource-poor countries for Hep C.

Dr Charles Gilks said that Hep B and Hep C testing and treatment provision should be available at the ART centres.

A delegate with ITPC-India (Leena) said that she has cases who had tested positive for Hep B but not for HIV so were refused free treatment from the programme (a person has to be HIV positive and Hep B positive too to receive free treatment from the programme). This doesn't make any public health sense and legal remedy is one way to challenge such policies.

Dr Charles Gilks suggested that we should be following up with the parliamentarians too on what is the progress India is making on WHA resolution 57 by which it committed to a 10 action points agenda on Hep C.

Dr Jana and UNICEF representative both said that we should be having regional consultations on Hep C and then a national consultation to mobilize better response.

A delegate with ITPC-India (Aarthi) said that will it make sense to have some consultative process before December 2011 when NACO and Ministry of Health will submit NACP-4 proposal to the 12th Five Year Plan currently being developed by the Planning Commission of the Government of India.

Dr Charles Gilks said that the NACO will not act alone. We should be going to the Planning Commission with the 10 action points on Hep C to which India committed by signing the WHA 57 resolution in 2010. Since India has

signed it, so it should be reflected in the 12th Five Year Plan of the Planning Commission.

India's essential list of medicines should include interferon and pegylated interferon and this will help in advocacy.

The risk groups for Hep B and Hep C should also include MSM, transgender populations, sex workers and IDUs.

India should also develop Hep C treatment guidelines before the national consultation on Hep C takes place.

Many MSM networks weren't aware that Hep B treatment is available under the national programme.

Dr Charles Gilks said that we should be engaging the MSM and transgender communities among others while planning for regional and national consultations on Hep B and Hep C.

Dr Charles Gilks said that there is a very good drug pipeline for Hep C which should be followed. Also it is unlikely that India will qualify for another round for the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) grant and even if it does, it is unlikely that the NACO will take a lead on Hep C proposal. Also Ministry of Labour of the Government of India has pulled out of being a Principal Recipient to the Global Fund round 9 grants which automatically disqualifies India for round 11 of the Global Fund (HIV component).

The viral load testing should be done at least once a year. The SACEP is becoming a barrier instead of being an asset and must be removed and current ART healthcare providers should be trained in second- and third-line treatment. Stock-outs are regular be it paediatric, adult or PPTCT ARV drugs.

A delegate from ITPC-India (Leena) said that we are losing more with drugs expiring in ware-houses. This is more of a shame with stock-outs happening in different states. The situation is grimmer in Bihar. The procurement and distribution system is in soup and there is no buffer stock.

ITPC-India chair (Naresh) shared his dialogue with the NACO on adopting latest WHO 2010 guideline. Dr BB Rewari from NACO said that if they follow the guideline then there will be additional 100,000 PLHIV eligible for ART and they cannot handle this situation at this moment. He was asked to wait till October 2011 but now have been asked to wait till December 2011.

A delegate from ITPC-India (Manoj) said that the ART programme in India is up to 2016 under which they provide treatment to 600,000 as promised and may add 300,000 more to ART. Phasing out Stavudine (d4T) is a key issue and instead of phasing out Stavudine the NACO had procured additional supplies for next eighteen months. The viral load testing should be done at

least once a year. The SACEP is not functioning well and instead of being an asset it has rather become a structural barrier to access to treatment.

Stock-outs are regular be it paediatric, adult or PPTCT ARV drugs.

A delegate from ITPC-India (Leena) said that we are losing more with drugs expiring in ware-houses. This is more of a shame with stock-outs happening in different states. The situation is grimmer in Bihar. The procurement and distribution system is in soup and there is no buffer stock.

A delegate from ITPC-India (Naresh) said that the NACO has ART guidelines of providing ART to those with CD4 count less than 350 but ART centres are not following it. When he raised the issue with the NACO then Dr BB Rewari said that if they follow the guideline then there will be additional 100,000 PLHIV eligible for ART and they cannot handle this situation at this moment. He was asked to wait till October 2011 but now have been asked to wait till December 2011.

A delegate from ITPC-India (Loon) said that the NACO had purchased more Stavudine instead of phasing out. They placed the orders in December 2010 to procure Stavudine stocks for next eighteen months for 400,000 PLHIV on treatment. Only if Ziduvudine - a drug used in the first-line ART regimen - doesn't work then only Tenofovir will be provided to the people.

A delegate from ITPC-India (Leena) said that India had done commendable work around Tenofovir in 2005. India continues to produce and ship tenofovir for rest of the world but its own people who need it cannot have it through our national ART programme.

A delegate from ITPC-India (Manoj) said that despite Supreme Court orders only 72 people have got second line ART regimens as NACO is coming up with new barriers. The Supreme Court had directed the Government to provide second line ART regimen to all those who need it without any condition (except medical eligibility).

A meeting with new Health Secretary Mr Pradhan was suggested.

ANNEXURE V

Major recommendations

Major recommendations from this National Consultation on HIV and HCV Treatment Access Issues are:

1. Include Hep-C in surveillance system
2. Initiate Hep-C testing through current ICTCs with proper pre- and post- test counselling
3. Provide free Hep-C treatment to people where medically it is indicated
4. Government must integrate a comprehensive and well-coordinated Hep-C programme within the National AIDS Control programme at NACO as both HIV and HCV interventions are going hand in hand and will maximise AIDS programme performance as well as save lives from Hep C
5. Phase out toxic Stavudine (d4T) from India's ART programme
6. Remove SACEP criteria from countries ART programme





Strengthening Community Responses
to HIV Treatment & Prevention

