

**III CONFERENCE ON HIV/HCV COINFECTION:  
THE SOCIAL APPROACH IN SOUTHERN EUROPE**

**FINAL REPORT**

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**Feat**



**ITXAROBIDE**



## **Organizing committee:**

Spanish Forum of HIV Treatment Activists (FEAT)  
Anti-AIDS Commission of Bizkaia, Bilbao  
T-4 Association, Bilbao  
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## **Session 1: Liver Transplantation in HIV/HCV coinfecting Patients: Lessons Learned**

### ***THE SPANISH EXPERIENCE***

#### **Liver Transplantation in HIV/HCV-coinfecting Patients**

*Miguel Montejo*

*Infectious Diseases Unit of the Hospital Tres Cruces (Bilbao)*

Observation of available research data is required in order to know the clinic experience of liver transplant in HIV/HCV-coinfecting people.

A Spanish study describes the clinical baseline features and the evolution of Spanish patients infected with HIV-1 (n=89) who received a liver transplant in the era of highly active antiretroviral therapy (HAART), specifically in the period between 2002 and 2005.

Patients' HIV data (stage of infection, CD4 cell count, HIV viral load in plasma, antiretroviral treatment), liver disease data (etiology, stage) and baseline features before and after liver transplant were collected. Each centre used the same prophylaxis and immune suppression protocols as those used in HIV negative people.

The following criteria must be met by a coinfecting person in order to be eligible for a liver transplant:

- Liver: the same criteria as those required in HIV negative people;
- HIV: no occurrence of an AIDS-related opportunistic infection other than TB, *Pneumocystis jirovecii* pneumonia, and oesophagus Candidiasis); a CD4 cell count above 100 cells/mm<sup>3</sup> and undetectable HIV viral load in plasma (< 50 copies/ml) at the moment of liver transplantation, or detectable if viral suppression is achieved by using HAART after liver transplantation.
- Use of substances: A minimum of two years of drug abstinence (heroin and cocaine); avoiding alcohol "abuse" for at least six months.

97 % of the 89 patients who received a liver by transplantation between 2002 and 2005 were Caucasian, 74 % were male (n=65), their median age being 42 years (interquartile range 39-46); 78 % (n=69) had acquired HIV through intravenous drug use.

As regards the etiology of the cirrhosis of the liver, 83 % (n=74) was due to HCV infection, 6 % was due to HBV infection (n=5) and 11 % was due to HCV and HBV (n=10) [there were 6 cases of hepatitis Delta coinfection].

18 % (n=16) had hepatocellular carcinoma; 8 cases registered alcohol consumption and 1 case registered porphyria. The share of the HCV genotype was of 67 % (n=57) for types 1/ 4 and 21 % (n=18) for types 2/ 3. In 10 cases the genotype was not defined.

Child-Pugh classification was: 12 % in Stage A (n=11); 51 % in Stage B (n=45); 37 % (n=33) in Stage C. The median for the MELD<sup>1</sup> index was of 14 (interquartile range: 10 -19).

Prior to transplantation, the 89 patients were taking the following antiretroviral regimens: 48 % (n=43) were taking efavirenz; 19 % (n=17) were taking a protease inhibitors regime. The median CD4 count was of 288 cells/mm<sup>3</sup> (interquartile range: 165-486) and 64 % (n=54) had a viral load below 200 copies/mL.

The median period on a waiting list was of 3 months (interquartile range: 1-7). Once a patient is included in a list, the application is processed and conditions are the same for everyone, irrespective of HIV status, although some variations may be observed across transplant centres.

98 % of patients received a cadaver liver and 2 % received it from a living donor. The median monitoring period was of 16 months (interquartile range: 8-29).

22, 5 % (n=20) of patients receiving liver transplants died, 35 % of which (n=7) were early deaths (less than 6 months after transplantation); and 65 % (n=13) were late deaths (after 6 months). The main causes for early mortality were: post-operative complications (n=3), severe cholestatic hepatitis HCV (n=2) and Others (n=2); causes for late mortality were: HCV re-infection (n=5), chronic refusal (n=3) and Others (n=5).

Patient survival (according to Kaplan-Meier estimates) was of **90 % one year after transplant, 74 % after 2 years, and 67 % after 3 and 4 years**. Graft survival (according to Kaplan-Meier estimates) was of **89 % one year after transplant, 73 % after 2 years, 66 % after 3 years and 62 % after 4 years**.

Median hospitalization time was of 21 days (interquartile range: 16-37). 13 receiving patients (15 %) had surgical complications.

The rate of acute rejection was of 43 % (n=38) and chronic rejection was of 7 % (n=6). The rate of opportunistic infections following transplantation was only of 7 % (n=6).

The immune suppression guidelines to avoid refusal included cyclosporine A or tacrolimus, either combined or with other agents. The rate of acute rejection with either drug was similar (54 % versus 35 %).

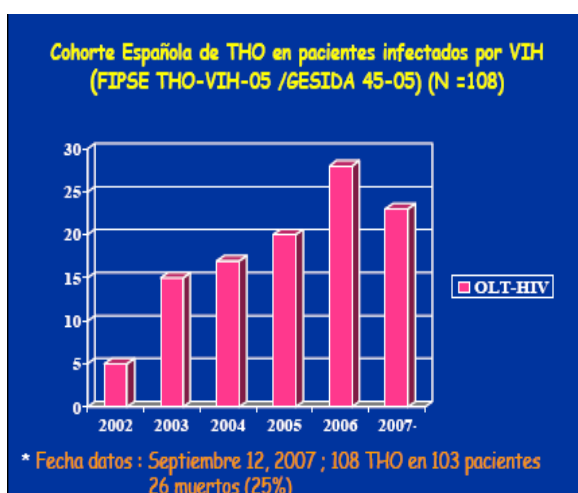
Six AIDS cases following transplantation occurred. All receiving patients resumed antiretroviral treatment following a median of 10 days of

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<sup>1</sup> Acronym for Model End Stage Liver Disease, a disease severity scoring system for adults with liver disease, designed to give priority to organ allocation in transplantation in candidates with chronic liver failure. The MELD score is based on a scale of 6 to 40 to estimate chances of survival over a period of 3 months (less than 3 months in patients with a score of 40). Although the MELD score required for receiving an organ varies across countries and according to the number of waiting candidates, as a general rule, any patient presenting the usual complications of liver disease and/or a MELD score of 10 should be referred to assess transplant eligibility.

transplantation (range: 5-21). 11 % (n=10) had to suspend treatment due to toxicity and 14 % (n=13) had to change treatment. Drug interactions between protease inhibitors and immune suppressor agents were very frequent.

To conclude, this study reports that the first liver transplant on HIV infected patients in Spain was carried out in January 2002 and 89 transplants have been carried out in 17 centres of Spain (90 %) to date. Most transplants were related to HCV infection in patients with an intravenous drug use record. In the medium-term, transplant in patients with HIV infection is safe and effective in the HAART era. Finally, HCV reinfection is the main problem for transplanted patients.



The chart shows the transplants carried out over the period from 2002 to 2007: 108 transplants in 103 patients (12 September 2007).

26 patients (25 %) of the Spanish cohort of 103 transplanted patients died (FIPSE THO-VIH-05/GESIDA 45-05); 29 patients were on a waiting list.

Since the recurrence of HCV following transplantation is an important cause of liver loss and death, and preliminary studies pointed at a worse survival rate after 3 years in HIV/HCV coinfecting patients than in monoinfected HCV patients, Spanish specialists compared the survival rates after 3 years in transplanted HIV/HCV coinfecting patients and in HCV monoinfected patients.

The results of this prospective case-control study (FIPSE THO-VIH-05/GESIDA 45-05) involving all HIV transplanted patients in Spain were presented in the 47th ICAAC conference (Chicago, U.S.A., September 2007). 51 patients were HIV/HCV cases while the control group involved 1.177 HCV patients.

Most transplanted patients were male (75 % were coinfecting patients against 70 % monoinfected patients). The median age for coinfecting patients was of 41 years (interquartile range: 38-45) and 56 years (interquartile range: 46-72) for monoinfected patients ( $p < 0,05$ ). 16 % of coinfecting patients (n=8) had hepatocellular carcinoma as compared to 32 % (n=376) in monoinfected patients.

The replantation rate was of 4 % (n=2) in monoinfected patients and of 32 % (n=38) in coinfecting patients, while the mortality rate was of 24 % (n=12) and 23 % (n=273) respectively.

Survival rates of transplanted patients after 3 years are shown below:

	HIV/HCV Receiving Patients (n=51)	HCV Receiving Patients (n=1.177)	p Value
After 1 year	88 %	81 %	NS
After 2 years	75 %	74 %	NS
After 3 years	64 %	69 %	NS

Survival rates after 3 years of liver transplantation are shown below:

	HIV/HCV Receiving Patients (n=51)	HCV Receiving Patients (n=1.177)	p Value
After 1 year	82 %	72 %	NS
After 2 years	72 %	71 %	NS
After 3 years	61 %	65 %	NS

*NS: Not significant*

Risk of mortality associated to age, sex and existing hepato cellular carcinoma as liver transplant indicator did not show any difference between coinfecting patients and monoinfected patients (IC95%: 1,74 [0,70-4,35] ).

To conclude, this study shows a similar mid-term (3 years) survival rate for patients and transplants in the Spanish cohort of liver transplantations, both in the case of HIV/HCV coinfecting patients and of HCV monoinfected transplanted patients. The results of the Spanish case are better than the ones obtained in the U.S. and in some European countries (France, and the U.K.). A longer period is required to confirm the results in the Spanish cohort.

### **Transplantation from a Community Perspective**

*Ramón Espacio*

*Chair, CALCSICOVA, Valencia Anti-AIDS Committee*

I have been a HIV/HCV coinfecting patient for many years, so I am going to talk about liver transplantation in HIV infected people from a community perspective. I hope my views will show the perspective of those living with the HIV/HCV coinfection and who bear witness of the slow passing away of friends and peer users.

First of all, I should mention that depending on the standpoint of the observer, the magnitude of this problem may change. As we are close witnesses, we regard it as a huge problem. We know that there are around 77.000 HIV/HCV coinfecting people in Spain, 7.000 HBV infected people, and that over 6.000 patients have developed liver cirrhosis. According to Joseph Maria Miró, an

estimated 1.142 people need a liver transplant urgently. We have known that for years that liver failure is the main cause of mortality amongst people with HIV. However, it is paradox that we do not know to date the exact figure of deaths for this cause in spite of our insistence in demanding such data in order to assess the size of the problem. Nonetheless, in the course of the daily work carried out by our associations we know we can give names and surnames to this problem, which sometimes reminds us of those days back in the late eighties or the early nineties. We believe this epidemic is being silenced, perhaps because we are not so young or because the media find it lacks impact, but also because we do not know the figures.

According to my data, 106 patients with HIV have received 110 liver transplants in Spain to date. Short and long-term survival results are similar to those in people without HIV that have liver disease with a similar etiology. Without doubt, this is good news: 106 transplant recipients over a five-year period seem to be a good figure if we compare it to other countries around us; but it is clearly insufficient if we consider that this figure does not even meet 10 % of the current demand.

On the other hand, we would like to have data regarding patients who did not undergo transplantation because they were late referrals or they did not meet the inclusion criteria or died while they were on a waiting list. We do not want to know this data to complain, but to act upon it: to see what is going wrong and how it can be improved.

I would like to summarize the last 10 years of liver transplants for people with HIV in Spain by referring to the ways in which community action took us to the point where we are now.

In 1997 HIV infection was an absolute criterion to exclude a patient from receiving a transplant because of uncertainty in his/her life expectancy. HAART had only been introduced a year before, hence such criteria gradually became pointless.

In September 1998 Jordi Riba, a person with HIV who suffered from advanced chronic liver disease and who was also a physician, founded in Barcelona the ATOS association for organ transplants in people with HIV with the aim of reviewing the absolute exclusion criteria and promoting a pilot study to assess survival in transplant recipients with HIV in the new context of HAART. Six months later, and following ATOS' public denunciation of discriminatory practices which had great media impact, Jordi Riba died of liver failure.

The community in Catalonia rallied round in demonstrations outside the Catalan Autonomous Government and the Central Government buildings.

Meanwhile, a number of meetings with health authorities were held and in June 1998 a first meeting with the Catalan Government's Health Department and the Spanish Ministry of Health took place in order to address the issue. From the beginning, our claim was endorsed by HIV specialists, while hepatologists and

surgeons in transplant centres were largely reluctant to accept the possibility of liver transplants in people with VIH, an idea which nowadays they are not easily persuaded about yet. In February 1999 health authorities began to give way and the first draft of a protocol was prepared.

Supposedly, it was a hard negotiation, since it took 18 months to complete the research protocol. In addition, the health authorities withdrew from the negotiations and Catalan hospitals were left alone on their side of the table. Finally, the first patient with HIV received a transplant in the Hospital de Bellvitge in Barcelona, which in view of the good short-term results gradually led to other transplant centres to follow the example of Catalonia.

Local associations are still putting pressure to this process. We could not accept that the right to receive a transplant was being limited by geographical factors. In Valencia, my hometown, where there is a transplant centre in which the largest number of daily transplants is carried out, they were still undecided. Local NGOs joined forces with infectious diseases doctors and demanded a meeting with the transplantation team, which eventually resulted in an action protocol. Finally, on 24 June 2004 the first HIV patient received a transplant in the Hospital de la Fe in Valencia.

The publication in March 2005 of a consensus document regarding solid organ transplantations in HIV infected patients in Spain could be regarded as the culmination of this process. The document was subscribed by GESIDA/GESITRA-SEIMC, SPNS and ONT and it establishes the criteria for inclusion and exclusion of transplantations with regard to HIV infection. It was the first of its kind ever to be drafted worldwide. Input from community groups such as FEAT and CACSIDA is reflected in the document, which allowed for an improvement of the final document.

The number of transplant centres and of HIV transplant recipients is growing every year. We now know that survival rates in people with HIV are similar to the rate of HIV negative people, and that the main complication is hepatitis C reinfection and the way it rapidly and aggressively progresses.

How can we improve the current situation?

- By doing away with geographical inequalities. In Spain there are 22 transplant centres for adults, 16 of which have carried out transplants, mostly in Bilbao, Madrid and Barcelona. Three Autonomous Communities with only one transplant centre have not carried out any transplants to date: Canary Islands, Castilla-Leon and Navarre. We are trying to change this with CESIDA and the local NGOs. In the Canary Islands, it is difficult to refer patients to distant hospitals in the Peninsula and it requires patients to move there in order to be included in a waiting list.
- To reduce the mortality rate in the waiting lists and change inclusion criteria. The waiting list mortality rate was of 62 % in coinfecting individuals and of 10 % in HCV monoinfected individuals between 1999 and 2005. We know that in some cases referrals are being ordered late

and that the time of survival following the first episode of liver decompensation is considerably shorter in coinfecting patients; hence, we believe that early referrals should allow for a more timely assessment.

- In Barcelona's Hospital Clinic, for instance, 57 % of coinfecting patients did not meet the inclusion criteria. Opportunistic infection criteria should be reassessed. In Spain AIDS-defining opportunistic infections are criteria for exclusion except in the case of TB, oesophagus Candidiasis or *Pneumocystis jirovecii* pneumonia. In the U.S. the exclusion criteria only includes progressive multifocal leukoencephalopathy (PML), cryptosporidiosis and systemic KS, the only infections for which there is no treatment. The Spanish criteria are too restrictive and conservative and should be reviewed.

To conclude, the pressure exerted by the community is very important and necessary, not only as a means to put our claims forward but also to monitor the way in which they are implemented. All HIV+ patients should be guaranteed equitable access to transplantation irrespective of the Autonomous Community in which they live. The Consensus Document should be revised with regard to the moment of referral and to C events. Transplantation is the last option and a large number of patients can recover from hepatitis. Thus, existing treatments should be optimized as well as research on new treatments for coinfecting individuals, which should be urged and be a priority in the agendas of activists, the pharmaceutical industry, and also among researchers and health authorities.

### **Social and Psychological Support to Coinfecting People on Waiting Lists**

*Udiarra García*

*Itxarobide Association (Bilbao) / FEAT*

Although the work done by doctors and activists alike is important, is there anyone helping coinfecting people in the meantime? 20 years of hepatitis C's natural history have led NGOs to rethink the services they make available to users. We had to train ourselves on such topics and to "manage" death once again, as we did in the early years of the HIV epidemics.

In our local association, Itxarobide, we have a support project specifically aimed at coinfecting individuals. We implemented it after we saw there was a number of cases that showed up and also were being referred to us. Coinfecting individuals receive the same kind of emotional support as mono-infected individuals do, although we take into account their specific features and perhaps give them closer support.

We believe in peer assistance and in the need of bringing together both the personal experience and professional aspects into assistance. Our organization gives great importance to psychological support and also to our members' continuing vocational training, which are key aspects in any successful intervention. We also believe in coordination and in putting pressure to health authorities and politicians in order to be able to change the state of affairs.

It is essential to listen to people who are about to be included in a transplant waiting list or to those who already have undergone transplant. By showing respect and a non-judgmental attitude we try to provide them with the tools or the keys that will ensure a good outcome for them. Some of these aspects cannot be provided by doctors or psychologists: only peers can do it. We try to get our users in contact with other people in their same situation or who have gone through a similar process.

We are aware that situations in which people have to wait for a transplant are a source of anxiety, anguish and this may also create controversy. Is there inequality in the access to transplants?

In Itxarobide we believe we should continue giving social and psychological support to people who are on a waiting list for a transplant. We need more resources from the administration; our associations also need more people with specific training in coinfections.

If we all contribute to this issue, we can achieve a stronger network whose ultimate goal is to save lives.

## **SESSION 1: DISCUSSION**

**Question:** How is alcohol or drug “abuse” defined in the Spanish exclusion criteria. Are people on a methadone programme eligible for transplantation?

**Miguel Montejo (MM):** Alcohol consumption criteria are the same as the one applied for HIV negative people: no consumption in the six months prior to the transplantation. It is difficult and controversial to determine the exact amount for this. Each individual case should be assessed and I would not be overly restrictive about this. Methadone is not regarded as a contra-indication and the psychologist is free to make an assessment of the candidates and take all these aspects into account. Cannabis consumption is not a reason for exclusion in our protocol.

**Question:** I read some research that shows that coinfecting patients have shorter survival rates than mono-infected ones when the first decompensation occurs. Is possible to have this in mind in those cases so that they have to wait less and thus increase their chances of survival?

**MM:** That is right. In the Tres Cruces Hospital we try to start the process as soon as patients experience their first decompensation. This does not mean they are going to skip places on the waiting list, but rather, that their process and assessment is initiated earlier. Nonetheless, some patients are still dying while on a waiting list.

**Question:** Would a patient in a pain centre taking a morphine treatment – due to a neuropathy, for instance -- be a candidate for a liver transplant?

**MM:** This would require assessing the cause of the neuropathy and whether the candidate is suitable or not. Morphine would not in itself be an obstacle; it would require studying the baseline pathology.

**Ramón Espacio:** Morphine in itself would not be a contra-indication for transplantation, which in any case would be based on an assessment of the pathology.

**Question:** Could you specify a little more about the amount of alcohol that is considered an abuse?

**MM:** I do not know exactly. We are currently based on the specifications established in the Consensus Document with regard to heroin, cocaine and alcohol consumption. We probably would have to revise it.

**Question:** I would like to know about the donors. What is the Spanish experience with regards to living donors? On the other hand, I would also like to make a statement about the exclusion of heroin and cocaine users. I believe this responds to the legislation currently in place: there is no scientific reason to justify this exclusion; it is a matter of moral criteria and prejudice, of moral criteria rather than scientific criteria.

**MM:** To answer your question, there were no living donors in the Tres Cruces Hospital, only in Catalonia.

**Question:** If we want to see an increase in the number of transplants for people, we will also need an increase in the number of donors and in the efficiency of the service. Portuguese legislation is complicated in this respect: many people who are willing to donate their organs don't do it because we lack effective reception centres. We should work on raising people's awareness of the issue of donation because we will not be able to carry out transplants without them. At the same time, we need new protocols with exclusion and inclusion criteria based on scientific evidence.

**MM:** I am not very knowledgeable about the willingness of donors. Spain is a country of donors, though -- but we still need to improve. And even though Euskadi is the pioneer, we still have a shortfall. With regard to Spanish hospitals, they have gradually introduced transplantation, some of them earlier and others later on until all of them integrated it. It is important to underscore that those in charge of transplants are highly aware.

**Ramón Espacio:** The Document of Consensus is an open document and it is open to revision. Two current studies – the Spanish cohort study by FIPSE and the Roland's American study. Once we get the long-term data for these cohorts, we will be able to revise the documents. There is also the criterion of social exclusion, that is, of people that would not cope with the post-transplantation period and thus would be excluded. This should also be revised.

**MM:** Transplant monitoring is a very important issue. The receiving patient has to cope with immune suppressing treatment, antiretroviral treatment and Hepatitis C treatment.

**Question:** Did toxicologists and drugs experts take part in the preparation of the protocol?

**MM:** I don't know. I did not take part in the drafting of that part of the document, but I should think they did.

**Ramón Espacio:** I am not sure, although the document establishes that the assessment team should include a drugs expert. I don't know whether there was one when the document was being drafted.

## **THE EUROPEAN EXPERIENCE: ITALY, FRANCE AND PORTUGAL**

### **Italy**

*Alessandra Cerioli*

*LILA, Italian Anti AIDS League, Italy*

My name is Alessandra Cerioli and I am a coinfecting person living with HIV/HCV. I am currently under an HCV treatment with ribavirin and interferon. I am a treatment activist and national health coordinator at LILA. I would like to explain my perspective on the current situation of liver transplantation from cadaver donors to people with HIV in Italy.

In 2001, the experts from the National Transplantation Centre and the Ministry of Health's National AIDS Commission drafted a pilot project for liver transplantation to people with HIV which concluded by the year's end. The pilot programme is based on a national protocol for liver transplantation for the general population, that is, people without HIV.

The criteria to select hospitals that would be entitled to carry out transplantations on people with HIV were established in 2002. It was decided that only the clinics that were associated to infectious diseases departments with experience in HIV/AIDS in the same hospital premises would be able to carry out transplants. In this context, "experience" meant that there was a group of 400 people with HIV that were actively receiving antiretroviral treatment.

Inclusion criteria for the pilot programme were:

- **To have an absolute CD4 cell count above 200 cells/mm<sup>3</sup> or above 100 cells/mm<sup>3</sup> in patients with decompensated cirrhosis** (first difference from the Spanish case, where the CD4 cell count is above 100 cells/mm<sup>3</sup>).
- Undetectable **viral load** while taking ARVT (no difference with Spain).
- **No opportunistic infections in the previous year.** *Pneumocystis jiroveci*, TBC and esophageal candidiasis are assessed on a case-by-case basis, while they are not exclusion criteria in Spain and in the U.S.
- The National Transplantation Centre established that **the use of legal or illegal substances** while on substitution therapy with methadone and buprenorphine, for instance, should be a general exclusion criterion, which also includes the general population (HIV-). Unfortunately, I was unable to find the national protocol in order to verify if any other substances were also not permitted (benzodiazepine and others).

I wrote an e-mail to the National Transplantation Centre with the following question: “Can a person that meets all the necessary requirements to receive a new liver, but who is also on a methadone treatment, be eligible for liver transplantation?”

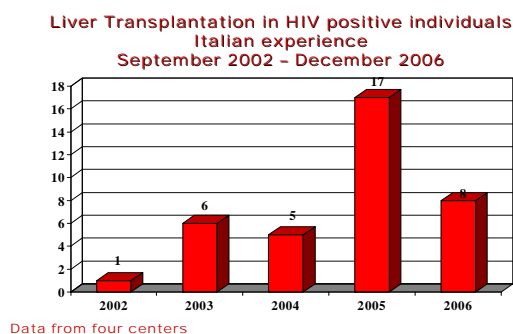
They wrote me back with the following reply:

“The use of methadone implies a dependency on drugs and this factor – if unresolved – can be an exclusion criterion for transplantation. The success of transplantation is measured by the patient’s survival and this depends greatly the patient’s ability to adhere, collaborate and pay attention to correct therapy administration.”

So this is what they think at the National Transplantation Centre about people who are on substitution therapy: they cannot adhere, therefore “they are unreliable.”

Nonetheless, the Centre at Modena is carrying out transplants on people who are on methadone programmes or who tested positive in the tetrahydrocannabinol test (THC); consequently, it is clear that the exclusion criteria is not based on scientific or ethic reasoning but that it depends on opinion, or rather, physicians’ medical prejudice towards users of legal and illegal substances. This is unacceptable!

The graph shows the number of transplants carried out in the five-year period since the beginning of the pilot programme, which is currently coming to a close (2 more transplants are left to begin to write the report on the data for the five-year period).



This detailed chart for December 2006 breaks down by hospitals that are entitled to carry out transplants within the pilot programme.

Although we are still focusing on the pilot programme, we can see already that some aspects are not going well and that they must be improved.

Of the 7 centres that are entitled to carry out transplants, there are 3 that have not done it yet and nobody understands why. Most of them are located in the north of Italy.

Bologna (my hometown) and Modena, both cities in the Emilia Romagna region, have a very high mortality rate in waiting lists. The

reason for this is the different criteria applied across regions and in single regions in liver allocation for donors. The criteria used are the MELD index and the Child scale. MELD is more restrictive while the Child scale and its results are not always comparable.

This could explain why Bologna, where the MELD index is employed (the rest of regions use Child) there is a difference in the way candidates are placed in the waiting list.

Internal auditing data from the pilot programme show that primary and secondary assessment criteria were reached. The main assessment criterion was survival while the secondary criterion was not to develop opportunistic infections. 14 HIV/HCV coinfecting people underwent liver transplant. Survival after transplantation was of 71, 4 % with a median monitoring period of 11, 2 months (range: 0, 1 – 23).

All liver recipients experience a recurrence of HCV after transplant but none developed opportunistic infections.

One of the biggest problems is the high mortality rates in waiting lists.

As member of the Italian community, I believe we cannot continue to be excluded from the issue of transplants. We want to be involved in a new process that is to conclude at the end of next year, when liver transplants are included in the healthcare standards for people with HIV/HCV.

I managed to collect all this information because I am a member of the Health Ministry's AIDS Commission.

A few months ago, in the National Commission we were informed that **a project aimed at unifying European criteria on liver transplants in people with HIV is envisaged; Spain and Italy will be the reference countries in the context of the Seventh European Framework Programme for Research.**

**SPERIMENTAZIONE TRAPIANTI IN PAZIENTI CON HIV**  
**LISTE DI ATTESA E REPORT ATTIVITA' A DICEMBRE 2006**

LIVER				KIDNEY	
CENTRI TRAPIANTO	of waiting lists (status attivo)	Drop out W.L	transplant carried out	CENTRI TRAPIANTO	PAZIENTI LISTA – Tx
ROMA IFO Reg. Elena	1	1 (dead 1)	12	VARESE	3-2
MODENA	14	4 (sosp 1: dead 3)	9	MODENA	0-0
UDINE	5	1 (sosp 1)	10	BRESCIA	2-0
BOLOGNA	4	6 (sosp 1: dead 5)	6	GENOVA	0-0
GENOVA	1	0	0	ANCONA	0-0
MILANO Ist.Tum.	0	0	0	PARMA	0-0
ANCONA	2	0	0		
<b>TOTALI (Pz. 74)</b>	<b>25</b>	<b>12</b>	<b>37</b>	<b>TOTALI (Pz.7)</b>	<b>5-2</b>

As members of the community we shall monitor the development and compliance of this important project while we also expect that Italy will find solutions and ways to improve its existing problems if it is to be a country of reference, like Spain, a country which most surely has a lot more to teach to other countries in the field of transplants.

## **France**

*Dominique Blanc*

*TRT-5*

Initially, France only had one centre that was entitled to carry out transplants on coinfecting people, and although it was a positive experience, the centre was unable to meet the existing demand. Around 50 people received transplants in this centre.

Other centres opened after the first centre was established and we currently have 5. There are some networks that work jointly with the first centre and ensure that transfer of knowledge.

The main problems detected were:

- Doctors take a long time to include coinfecting people in a transplant waiting list, and many people never make it because they are not referred and die while they are waiting to be included in a waiting list.
- There is a great lack of organs from donors. There is no policy in place to encourage organ donations. Generally speaking, there is a lack of education in society about transplants.
- We do not have really effective transplant centres because most of the existing ones were late in carrying out transplants on coinfecting people.

On the positive side, though, methadone is not an exclusion criterion because most studies have shown that people on substitution treatment usually have a better adherence. On the other hand, opportunistic infections are not an exclusion criterion.

## **Portugal**

*Luis Mendão*

*Portuguese Group of HIV/AIDS Treatment Activists (GAT)*

In Portugal the situation is different from the rest of countries. We recently had the first liver transplant. In my country there is no document that establishes HIV as criteria for exclusion from liver transplant. However, there is a lack of transparency with regard to the transplantations situation for coinfecting people, and the community has not been included in the process to draft a protocol.

GAT and EATG tried to ensure that this discussion topic be included in the national agenda. We did some lobbying among prominent physicians and

decisions makers at the political level, and there are some signs of change. We have seen more people being included in the waiting lists.

The problem is that we are lacking donors and organs. I would like to propose to do some international networking around this issue. We need to foster debate and we need a European consensus document. There is enough scientific evidence and other evidence from the community to bring about change, and this would improve the situation.

We also need to promote closer cooperation between physicians for different specialties and raise awareness about the importance of the waiting lists and of the appropriate way to be included in one. In Portugal we do not know about formal waiting list application procedures, and physicians are not informed about this because they believe their patients will never be eligible for a transplant.

Another problem we have detected in Portugal is that people receive a liver that is not in a good condition; they receive this kind of liver because presumably they will not survive; if they do, they are replanted another liver.

## **SESSION 1: DISCUSSION**

**Dominique Blanc:** We are going through the same situation of donation of damaged livers in France.

**Maria Jose Campos:** It should be clear for us that there are 3 problems with regard to transplants:

1. People in need of a transplant are not appropriately identified by their physicians and are not being referred to the system. In Portugal they have to be referred to a special group of hepatologists. The main problem is that most physicians that treat people infected with HIV share these beliefs and they won't carry out a transplant on a person with HIV. They are not willing to go against the system in order to refer their patient to a waiting list.
2. The MELD index seems to be the most appropriate to encourage transplants from living donors. There is also MELD plus, which is even better for people with HIV as they are included in the waiting list according to their real situation.
3. There is no common legislation about transplants in Europe.

Fostering transplants from living donors is another important matter. We have the Spanish experience and we should explore more about this possibility.

**Dominique Blanc:** I do not agree with you entirely on what you first said. I don't think discrimination is for being HIV positive but for being drugs users. On the other hand, many infectologists don't want to realize that the progress of HCV is much faster in people with HIV; they believe that progression is similar to the one in monoinfected people and they are not in a hurry. Finally, if I'm not

mistaken, the assessment systems we are discussing here are not adapted for coinfecting people.

**Joan:** To further explain what Ramón Espacio has just told us, two things proved useful in Catalonia to overcome this reluctance to carry out transplants in people with HIV: on the one hand, the Catalan Government was politically determined to see transplants happen on people with HIV. There even was the threat of beginning disciplinary proceedings on physicians who refused to carry out transplants, especially hepatologists and surgeons. On the other hand, since the ethical arguments were not convincing enough, physicians felt challenged by the insinuation that they were refusing to do it because they didn't know or couldn't do it or lacked the capacities to do it. This was a blow for their personal pride and they finally agreed to do it. Maybe in spite of the lack of ethics, they showed they had an ego.

**Ramón Espacio:** Regarding this issue of refusing to carry out transplants in people with HIV, there is another reason: physicians' fear of being infected. On the other hand, there is still a discrimination problem. Prejudice towards people with HIV -- and even among the HIV community -- towards those who are faced to the additional challenge of being in prison, and we know this by documented facts.

**Joan Tallada:** Fear is an important issue. In the first discussions with physicians, they said they would carry out transplants on people with HIV only if they had a big insurance premium. Since the Catalan Government did not want to pay the insurance premiums, the transplants issue was assumed as a political responsibility.

**Miguel Melo:** In France there is a lack of organ donors. According to legislation, any person can be an organ donor unless they specifically state before dying that they don't want to donate. But in practice, physicians generally ask the relatives, and it is them who eventually have the last word. Another way of solving this lack of organs is that people with HIV or HCV were allowed to be donors if they managed to clear the virus. We have asked doctors about this but they say it is very difficult for various reasons. But we should think about this issue and explore it.

**Alessandra Cerioli:** As transplants activists, have you established contact with national transplant associations?

**Luis Mendao:** We talked directly to the experts who work on liver transplants, with physicians rather than with associations. We worked in this direction in Portugal. We held a meeting with experts in April to foster debate on the issue.

**Ramón Espacio:** In the Spanish case, the National Transplants Organisation was involved but it was ATOS, a community-based organisation, who began to mobilize around the issue.

**Joan Tallada:** The job that was begun by ATOS was later followed by the Catalan NGO community. The strategy was always to demand a political

decision from the Health Department. It was important for us that the Catalan Government showed its agreement with carrying out transplants on people with HIV, that it showed its commitment with the issue by making the different stakeholders accept and implement a programme. Public authorities had to assume their responsibility by promoting a political decision.

**Ramón Espacio:** In the Autonomous Community of Valencia our strategy was to sit with infectologists and hepatologists at a negotiation table, but this happened later, once it was ethically unacceptable for them to keep refusing to do it.

**Esthe Inés:** I agree with Luis Mendao in that we see the interest of working together and united at the European level. We may feel we are privileged, but there are still many things to be achieved. Personally, I feel bad when I hear what the situation is like in the neighbouring countries; their situation is much worse than ours, should I complain?

**Alessandra Cerioli:** To take up the idea of working together at European level, it would be important to have a community representative in the European Transplant Registry.

## Session 2: Living with HIV and HCV (Part 2)

### Therapeutic Treatment of HCV: Innovative Studies

*Joan Tallada*  
*FEAT, Spain*

The standard therapy for hepatitis C in HIV/HCV coinfecting people is currently pegylated interferon (IFN-Peg) and ribavirin (RBV). Among the existing studies, Roche's APRICOT is the main study; this study established that taking IFN-Peg and RBV was better than taking standard IFN plus RBV or only IFN. Although this study is not perfect and it can be criticized, in practice it marked a watershed in the approaches to hepatitis C treatment in HIV/HCV coinfecting people.

The chart shows sustained viral response (SVR) in each of the arms of the APRICOT study:

Group	IFN-Peg + RBV	IFN-Peg + placebo	IFN + RBV
All	40%	20%	12%
Genotype 1	29%	14%	7%
Genotype 2 or 3	62%	36%	20%

In spite of the improvement achieved, we are still far from finding an optimal solution, since only 40 % of people who took IFN-Peg + RBV achieved a SVR; this percentage was even lower (29 %) in people with genotype 1, which is the most frequent in Spain. And it should be pointed out that participants who enrolled in this study were probably in better condition than the overall

coinfected population. According to this study, and being optimistic, only one third of coinfecting people could derive a benefit from this therapy.

What happens to people who do not achieve SVR through the standard therapy? What can be done? The studies showed that people who had a rapid virologic response (RVR) at week 4 of their treatment had more chances of achieving a SVR, which is called a positive predictive value.

The doctors' hypothesis was that there are better chances to be eventually "cured" of hepatitis C if an undetectable viral load for HCV is achieved early on. The first thing attempted was an **induction treatment** by trying to clear HCV viral load quickly with high doses (much higher than a usual dose) of IFN-Peg during the first four weeks. The usual dose of IFN-Peg is then resumed and viral levels are tested at week 12 to check for undetectable levels or at least a decrease of 2 log in HCV viral load, a sign that an Early Virological Response (EVR) was achieved.

The best-known study regarding this strategy is CORAL-1, which compared a first group of patients that took induction therapy for 4 weeks (270 mcg/week of IFN-Peg + 1.000-1.200 mg/day of RBV) followed by the standard dose of IFN-Peg with a second group that took the standard dose from the beginning (180 mcg/week of IFN-Peg + 1.000-1.200 mg/day of RBV). The aim of the study was to assess whether the first group achieved a better RVR than the second one. However, results showed that out of 58 people taking induction treatment, 25 % achieved RVR at week 4 while the percentage for those who took the standard doses was of 23 %, a difference which is statistically not significant. At week 12, 68 % of those who took induction treatment achieved EVR while 68 % of those who took a standard therapy from the beginning also achieved EVR. In other words, induction therapy did not improve chances of achieving SVR.

The authors of this study believe that it would be possible to carry out a study in different terms in order to improve results and this is being now done with CORAL-2, which uses higher doses of RBV (a maximum of 1.600 mg/day) and erythropoietin (EPO) to mitigate the side effects of this therapy. This study is under way and it is not clear yet whether induction therapy will be effective; improvements are envisaged by increasing the dose of ribavirin.

Another strategy to improve results in coinfecting patients is to **extend the treatment of hepatitis C with a higher dose of ribavirin**. This was the aim of the PRESCO study, which showed that people with genotypes 1 and 4 who took HCV treatment for 18 months (instead of 12 months) and people with genotypes 1 and 3 who were on HCV treatment for 12 months (instead of 6 months) responded better. These people achieved 50 % of SVR, but they had a high drop out rate. It can be a useful strategy for a number of patients, particularly if psychological, social and family support helps them relieve treatment over a longer period.

Another strategy is to **give IFN-Peg and RBV treatment again** to people who previously failed suboptimal treatments. This is the goal of the Spanish PILOT study on 51 coinfecting individuals who did not respond well (74 %) or

experienced relapse (26 %) following a monotherapy of pegylated interferon, standard interferon plus ribavirin or pegylated interferon plus 800 mg/day of ribavirin.

All the patients in this study were treated with IFN-Peg plus 1.00-1.200 mg/day of RBV depending on their body weight. EVR rates by week 12 were of 93 % for genotypes 1/4 and 98 % for genotypes 2/3 among those who relapsed after the previous treatment, while rates in patients without any previous therapeutical reponse were of 52 % for genotypes 1/2 and 75 % for genotypes 2/3. HCV undetectable levels by week 24 in the four groups were of 65 % and 69 % for those who experienced a previous relapse and of 48 % and 75 % for those who did not respond previously. According to the results of this study, the likeliness of success by re-treating people who once responded but relapsed could be slightly better when compared with those who did not respond to a previous treatment. Plasma concentration of ribavirin was the main prediction factor to check for therapeutic effects at week 24. Again, we see that achieving high levels of RBV – a highly toxic drug – is essential to achieve treatment success.

**Maintenance treatment** for people who failed in their standard treatment, particularly due to tolerance, has also been considered as a strategy; in this case, administering low doses of IFN could stop or delay liver damage. Although this treatment would not clear HCV, it would stop the progression of fibrosis. The ENDURE study assessed this strategy by monitoring clinical progression with the use of low doses of IFN-Peg. The drawback of this study was that it required carrying out a number of biopsies in participants to examine progression. The company cancelled the study because it lacked participants something, which was a disappointment for the community who had high hopes on the assay results that were expected to be promising for this group of patients.

To conclude, IFN is still the baseline therapy for hepatitis C although the dose of ribavirin is still the key. Longer treatments increase the likelihood of achieving a SVR, but this is less tolerated and does not work for everyone. Induction by initial high doses of IFN-Peg is still in an experimental phase. Re-treating patients with IFN-Peg and RBV could be useful for those patients who had a relapse (FVR but no SVR) with standard IFN but perhaps not for those who did not respond to treatment before. Maintenance therapy with low doses of interferon has not been tested yet.

We need new IFN formulations that are potent, easy and comfortable, and less toxic. We need new and less toxic ribavirin formulations. The role of EPO must be clarified, as well as other growth factors that can mitigate the impact of adverse effects and allow for more tolerance to therapy. We need new drugs for hepatitis C that are safer, more effective and tolerable for the diversity of people with hepatitis C and HIV/HCV coinfecting people.

### **Managing the Side-effects of HIV/HCV Therapeutic Treatment**

*Dominique Blanc*  
*TRT-5, France*

An estimated 4 - 5 million people are HI/HCV coinfecting.

The number of people who receive treatment varies across countries. According to physicians, access to treatment is not in a bad situation, but we have a different opinion.

We believe there is a number of reasons and obstacles for which coinfecting people do not have access to treatment: due to discrimination towards drugs and alcohol users, for instance. Not all patients know their viral hepatitis serostatus, and very often patients who know it are not offered treatment by their physicians, who even fail to refer them to hepatologists. Likewise, physicians do not take into account a number of factors regarding their mental, social, or psychological conditions. A key issue is that doctors do not anticipate the development of potential side-effects in order to be able to manage them in time.

Why doesn't treatment work well? Many people stop taking it, particularly when side-effects begin to appear. It is necessary to find a way of dealing with side-effects without having to interrupt treatment.

Doctors put all their efforts in achieving their patients' treatment adherence through an optimal dose of IFN-Peg and RBV and managing side effects by using EPO and growth factors, anti-depressants and so on.

From the standpoint of the patient, the difficulty of enduring treatment is related to side effects such as tiredness, depression, irritability, lack of concentration, skin and hair problems, anorexia, weight loss and other anomalies. Consequently, tolerance to treatment is low and it affects patients' quality of life.

A very interesting experience was carried out in France. A study to show the ways in which HCV treatment affects ways of expressing and controlling rage in HIV/HCV coinfecting people. The study demonstrated that people receiving HAART and an HCV treatment showed more frequent spells of rage and irritability than those who did not follow treatment. Consequently, treatment of coinfecting people requires a closer follow-up in order to control such aspects.

The community can provide information and support to face the problems that may occur during treatment. Quality of life can be improved if adequate information is offered to users, along with psychological support and tools to manage social problems that affect treatment and pose difficulties to it. In a large number of countries, patients do not have access to treatment because they cannot afford it. Peers support in this respect is also fundamental.

To conclude, a genuinely holistic, multidisciplinary and holistic approach to health care is necessary. Physicians must use EPO and other growth factors. They must anticipate side effects in order to deal with them in time and, above all, focus adequately on psychological disorders. It is essential to get all stakeholders involved in the treatment of HIV/HCV coinfecting patients in a coordinated manner.

### **HCV Medicines in the Pipeline: Its Implications for Coinfection**

*Tracy Swan*  
*Treatment Action Group (TAG), New York*

I have some good news and also not so good news. The not so good one is that we are going to have to continue working and battling with IFN-Peg and RBV because there is no other treatment envisaged for the time being, so it is very important to assess the different ways of taking it and to help people bear it.

The good news is that there are some new products under research that seem promising. We don't know what the treatment strategies are going to be in the future; pharmaceutical laboratories want their products to be approved as quickly as possible but we, our community, want to find the best and most efficient treatment strategy. Both requirements are possible as long as they are combined adequately. On the one hand, business participation in the development of more efficient and less toxic drugs and, on the other, the role of the community and its defence of coinfecting people's rights.

In a U.S. committee in which I sit, there were discussions about who should take part in clinical trials for new HCV drugs. Sponsors did not want mono-infected people to take part in them, but the panel recommended to carry out interaction studies in coinfecting people to confirm whether the use of experimental compounds are safe for this population, who would therefore also receive the benefits of early access to them.

This same idea is stated in the Sitges Declaration, a document drafted during an inter-disciplinary meeting held in 2007, which establishes that therapy trials for HIV/HCV coinfecting people should be started before the approval for its use in mono-infected people with hepatitis C. This can be done as soon as Phase IIb studies are released and there are enough indicators on the preliminary studies on toxicity, pharmacokinetics and pharmacological interactions of the agent or agents being studied which do not show any significant pharmacological interactions or relevant toxicity with regard to HIV.

New forms of interferon which are expected to be more potent and less toxic are among the latest drugs in the pipeline. There are also hepatitis C polymerase inhibitors and protease inhibitors. But as it happens with HIV, HCV could also develop resistance mutations to the new drugs under research, so they will need to be combined with existing standard treatment.

Also in the pipeline, there are a couple of vaccines to prevent fibrosis from developing. Luckily, vaccine research is also continuing and some research around prophylactic vaccines is currently being done.

## **SESSION 2: DISCUSSION**

**Luis Mendao:** We should count on more information about each and every participant whenever a new trial is carried out. This would allow us to assess results in a much better way, depending on the individual features, and it would enable us to predict which strategies are more effective.

**Joan Tallada:** Trial drop out rates are associated to side effects. An improved management of side effects is always based on the strengthening of therapeutic measures, for instance, by previously taking prophylactic treatment (antidepressants), or using EPO... To me, the fact is that any coinfection treatment must not only be approached from a health perspective. At present, we are lacking a good practices model for a bio-psycho-social approach. We are only referring patients to NGOs or groups, and in my opinion, a comprehensive approach would help reduce the drop out rate.

**Ernesto Delgado:** With regard to therapeutic failure in coinfecting people, in the Canary Islands some patients are offered maintenance therapy and I positively know that they are also offered a 1.500 mg/day dose of ribavirin. Do you have any information about this?

**Joan Tallada:** I never of 1.500 mg/day doses of RBV for maintenance therapy before. What I do know is that there is a growing consensus that in standard RBV treatment, patients who can tolerate high doses of RBV have more chances of achieving SVR. Studies have produced evidence in this respect. The problem with RBV is that it is too toxic. What can we do about this? Each hospital has its own way of dealing with this: some reduce the doses, others give up treatment and there are some others who try to support their patients with growth factors to reduce anaemia.

**Miguel de Melo:** Extending the treatment period to 18 months in coinfecting patients with previous failure could be more successful than increasing the RBV dose.

**Udiarraga García:** Maybe, but in my experience it is difficult to re-treat coinfecting people with an extra 18 months of IFN-Peg. On the other hand, I agree with Joan in that holistic bio-psycho-social approaches are essential in order to treat HIV/HCV coinfecting people in a successful way. We are lacking resources and support from institutions.

**Igor Santos:** However, every time we insist before institutions about the holistic psycho-social health approaches we lack the qualitative data that could specifically draw a picture of what the current situation is.

**Joan Tallada:** That is a very important point, you are right. In our discussions with public authorities on resource allocation we always try to position ourselves on the ground of human rights, while they position themselves on the ground of public health management. I'll give you an example: in the PRESCO study it is established that extending HCV treatment to 18 months increases patients' chances for a successful treatment; so in terms of cost-effectiveness it is more reasonable to pay a good psycho-social service than to spend all that money on transplants for every person in need of one. A multidisciplinary service would be a lot cheaper than paying liver transplants for all; this is a fact that we can show to public policymakers.

**Alessandra Cerioli:** With regard to IFN-Peg related psychiatric side effects, we know that a course of antidepressants is usually offered prior to beginning (and

during) HCV treatment. I don't know whether there are any studies about hepatitis C treatment drop out rates due to this factor, either by taking prophylactic treatment with antidepressants or not before beginning HCV therapy. With regard to IFN-Peg, I believe that there are more strategies to manage side effects in comparison with RBV, which offers fewer strategies. For instance, I take 1.000mg/day of RBV. When it became known that potential interactions with abacavir were likely, I began to take a 1.200mg/day dose and obviously I experienced a decrease in my quality of life. I just cannot imagine what it would be like if I had to take a dose of 1.500mg/day of RBV. The fact of the matter is that the use of EPO to mitigate the side effects related to RBV also has a number of side effects, so it isn't the best solution.

**Dominique Blanc:** I don't know whether there are any studies on the subject that Alessandra is bringing up. According to experts, a psychiatrist's opinion should be sought before beginning treatment. I don't think antidepressants work for everyone, and in any case, they should be prescribed by a psychiatrist. In coinfecting people, the main problems are due to interaction between RBV and other medicines taken at the same time such as antidepressants, antiretrovirals and so on. Therefore, treatment options are narrowed.

**María José Campos:** I agree with Dominique. I don't think that taking antidepressants is such a good solution for everyone in terms of prophylaxis. Another important issue is that we don't know much about interactions between multiple drugs taken at the same time. In my case, as a physician I tend to be very cautious when it comes to adding a new medicine to my patients' prescriptions because this means you are also adding the side effects that go along with each drug.

### **SESSION 3: The Social Context of HIV/HCV Coinfection**

#### ***Drug Use, Social Exclusion and Facts about HIV/HCV Coinfection in the Streets of Southern Europe***

*Alessandra Cerioli*

*LILA, Italian Anti-AIDS League*

Cocaine, crack and methamphetamines are giving rise to new ways of transmission. Transmission can occur through blood contact, by sharing equipment such as crack smoking pipes and sniffing tubes. HCV coinfection rates are increasing among drug users and this requires a new prevention approach.

HCV treatment access is another problem in IDUs. In spite of the changes and to more openness in the criteria employed, a number of aspects specifically affecting these patients make their treatment different: psychological problems, consumption, non-adherence, etc. The European Conference's conclusions established that drug use should not be an exclusion criterion for access to treatment; in spite of this, we still see some doctors excluding those who use drugs. The main argument for this is that drug users show similar adherence as non-users.

Another argument used is that there is a risk of HCV re-infection. However, the argument is not strong enough to refuse giving treatment. Therefore, equal access to treatment is a human rights issue because adherence is verifiable as long as a drug-substitution therapy is in place. Likewise, there is no substantial evidence to argue more side effects than in non-drug users.

To conclude, it appears that the approach to coinfection treatment in the context of social exclusion would require the setting up of a multidisciplinary team with mental health, HIV and HCV experts and other substance abuse experts.

### **Care and Access to Treatment for Drug Users**

*Bizkaia Anti-AIDS Commission, Euskadi*

It is important for drug users to know when they are coinfecting. A number of difficulties emerge, given the users' priorities; they have a low risk perception and they do not regard treatment as a solution or as an accessible option. They fear the side effects and there is also a lot of mythology around treatment.

For instance, the myths about one's own treatment: some people don't even know there is a treatment available; others have unclear ideas about it ("ART cures HCV", "IFN makes your liver turn round", "there a lot of different treatments for HCV") and yet others are afraid of side effects. This situation is causing a slow but steady number of deaths among coinfecting people. It is everyone's responsibility to break such myths.

It is important to meet those needs regarding more information, the creation of round-the-clock treatment centres, and of tailored treatment and care. It is also important to avoid exclusion of drug users, and to reach a consensus between patient and doctor. The latter should show greater medical involvement.

To conclude, it is necessary to raise infected people's awareness, to get more medical involvement and foster the training of social and health services personnel on coinfection by providing more information on HCV. Likewise, it would be also desirable to create safe and enabling socio-sanitary spaces for treatment follow-up and to include drug users in research.

### **Is There a Socio-sanitary Space in Response to Coinfection?**

*Alvaro Ortiz de Zarate*

*T4 Association, Euskadi*

There appear to be a number of socio-sanitary spaces to address the effects of coinfection in an *ad-hoc* manner, but there is still a lack of socio-sanitary spaces to address coinfection in a holistic and specific manner. Apparently, existing spaces are cheaper than the spaces that we would appear to need.

Coinfection implies a great deal of social vulnerability and insecurity. Any protection intervention would require support, company, help, care and learning. If we talk about social services, society at large should be involved; hence, it is everyone's business. We are in a system that does not protect coinfecting people.

Socio-sanitary spaces are still elusive. But we should not only criticize other people's work. We should also reflect on what we are doing ourselves. Are we being proactive?

We should therefore make use of all the resources available until we achieve comprehensive counselling. If we are counselling specialists, we should be consistent and think of our groups in terms of creating in them the kind of socio-sanitary spaces that we demand.

### **Reviewing Research on Drug Users under Treatment**

*Tracy Swan*

*Treatment Action Group (TAG), Nueva York*

According to a number of studies there are very few drug users who have access to HCV treatment. It is necessary to break barriers and to do this we need to prepare the system and people alike. The system is denying treatment to those who are most in need of it.

Strategies to do this include a change in treatment guidelines, paying attention to counsellors' concerns and conducting research that provides data that will enable us to change treatment guidelines. In New York this is done on a case by case basis: drug users are not excluded from treatment. How can we assess active drug consumption?

If we really read the studies, we will see that consumers do not respond any worse than non-consumers. Any decision regarding treatment should lie on the patient, and a number of different treatment options should be proposed.

Treatment eligibility criteria should be flexible, but if they choose to be treated they must be made aware of the importance of attending their appointments and of the risks involved. Networking among peers appears to be very important.

Some problems emerge because doctors don't feel comfortable working with drug users (this could be avoided through appropriate training). Besides, harm reduction in the context of drug use is needed. A relapse in drug use should not necessarily imply a drop out from treatment because the response to treatment is similar. It is also possible to give treatment to people with psychiatric problems (by carrying out an assessment and having access to mental health care). Opinions held by doctors with regard to drug users' non-adherence to treatment present an additional barrier. It is worth inquiring: if drug users adhere to consumption, why would they not adhere to treatment?

### **SESSION 3: DISCUSSION**

**Question:** Many doctors do not know about drug-substitution treatments.

**Tracy Swan:** Substitution treatment is given in the U.S., the dose is increased if necessary in order to avoid a relapse.

**Question:** Are doctors afraid of increasing the doses of methadone?

**Tracy Swan:** Sometimes they feel guilty for having to increase it.

**Question:** Is it necessary to ask the doctors about one's own liver? Or do they actually inform you?

**Answer:** It is often the case. One has to ask.

**Question:** Are there any drug users on HCV treatment in Euskadi?

**Answer:** There are some cocaine and hashish consumers but not heroin consumers, apparently.

**Marta Pastor:** Apparently some progress has been made with regards to the care of HCV people under treatment. However, this is not the case when considering treatment for homeless people. It would not be responsible to offer treatment to someone who know there is one, but who doesn't care for asking, knowing that it is someone who lives in the streets.

Public authorities should be held responsible for the creation of socio-sanitary spaces.

#### **SESSION 4: Living with HIV and HCV (Part 2)**

*José Muñóz (psychologist)*

*Hospital Trias i Pujol, Barcelona*

The psychological, psychiatric and neuropsychological impact (the central nervous system functions) of coinfection (as well as HIV and HCV infections taken in isolation) on the person also occurs with IFN-Peg + RBV treatment. The current research fields include psychology, psychiatry, treatments, neuropathogenesis and neurocognitive impact.

Three lines of research have been taken in neurocognitive research:

- AIDS-related dementia (at late stage). Currently of low incidence but with an unchanged prevalence.
- Asymptomatic person (despite past controversies, we know that nearly half these people experience changes in central nervous system performance) Some result tests in people complaining of neurocognitive impairment point at HIV, but in other situations where neurocognitive change occurs patients do not complain.
- Treatment effects (it seems that a number of patients improve their condition, with specific treatment). In the context of treatment effects a there currently is a concern for avoiding neurocognitive impairment or for how to revert it when it occurs.

We know that with current treatments there is greater incidence of minor sub-clinical disorders. Other risk factors of neurocognitive impairment include: length of infection, length of ART, ART interruptions, nadir value of CD4 cells, as well as age and coinfection.

A number of motor-cognitive brain areas may be damaged by HIV infection (a front-subcortical pattern) and by HCV infection (especially the areas for attention, verbal fluency, motor function and voluntary activities). In fact, 3 kinds of HIV-related disorders are currently being discussed, which can be extrapolated to the case of coinfection: sub-clinical cognitive impairment, minor motorcognitive disorder and AIDS dementia complex.

Research data from Richardson (2005), Parson (2006) and Heaton (2004) were presented to validate neurocognitive changes, along with other authors' data which demonstrate that neurocognitive impairment can be a predictor of a decrease in life quality, low adherence to ART, etc.

A number of strategies to alleviate or prevent impairment were explained, such as ARTs, HCV treatment, cognitive rehabilitation (which, according to a study, does not result in substantial improvement), alternative drugs and bearing in mind other risk factors.

### **The Role of Psychology in NGOs**

*Asier Gurruchaga (Psicólogo)*

*T4 Association, Bilbao*

The psychological support model of T4 Association was presented in this session. Psychological assessment is a key component in any intervention aimed at helping individuals. This is done through a preliminary interview around the subject's perceptions of the disease, the reasons for requesting counsel, the length of infection, ART adherence, the quality of social and family relations and fantasies arising from therapy. There is also a diagnostic interview (collection of personal life details) and a stage of devolution (with the aim of directing the patient and the therapist towards a psychotherapeutic pathway and in a specific framework).

An assessment is necessary in order to know the person internally and be able to uncover psychiatric pathologies and to achieve a realistic perspective for each case.

Self-support and psychotherapy are used in T4 as complementary techniques in aid of self-knowledge and to avoid internalized victimization and self-exclusion.

The psychological goals of an NGO are, among others, to come to terms with illness; achieve greater autonomy; improve social skills; achieve motivation and the strengthening of the individual; and pay attention to the body-mind feedback.

### **SESSION 4: DISCUSSION**

**Question:** How can one tell the difference between neurocognitive impairment caused by coinfection and the one caused by the use of substances?

**José Muñoz (JM):** Consuming drugs causes neurocognitive impairment but it is very difficult to assess it. It is difficult to know the causes, so perhaps it would be better to talk about influencing factors. The idea is to attempt to control this

factor by avoiding actual consumption (even when there was consumption in the past).

**Question:** Why do you think people don't improve with neurocognitive rehabilitation?

**JM:** It is advisable to do it although it is not a generally recommended strategy for everyone. Besides, theoretically rehabilitation should be multidisciplinary and include a variety of exercises which are currently not done in ideal conditions. All this could have led to results that show no improvement.

**Question:** Many coinfecting people feel they are victims (they have real political and social reasons for it) How could we make an individual revolution bring about a social revolution?

**Asier Gurruchaga (AG):** NGOs act like mothers, what is really interesting is to provide resources to these people so that they can function in the real world. These people often feel absolutely vulnerable and victimization is what originates this. Ideally, these people should be able to perceive themselves in a different way (as active agents and not only as passive subjects or recipients), and hence be able to take part in a social revolution. To do this they need to mark some defence lines.

- The idea that HIV positive people are regarded by society as a lethal weapon is very popular in the gay community. At T4 they try to normalize the situation of people who go to the group by trying to avoid self-victimisation.

**Question:** We must also consider the therapist-educator's fantasy and the difficulties some professionals have in saying "good-bye" or "I'll see you in some time" (taking holidays from the relation), which would be the most appropriate thing to do at certain moments, especially with chronic pathologies.

**Asier Gurruchaga:** It seems, though, that one could always expect an improvement. As far as possible, professionals should avoid fantasies and adjust to patients' reality as closely as possible. It is essential to be prepared in advance to say good-bye.

- We should prevent NGOs from working as "mothers" of HIV positive people in order for them to function better in society.

**Question:** Perhaps language is authoritative for people. People have a right to feel weak and they should be protected socially and politically. We should not be telling them how they should feel ethically. Shouldn't the therapist and the patient reach an agreement to decide on the latter's well-being?

**JM:** One must strike the balance between both things and only intervene if people wish us to.

**AG:** Very often patients have an idealized perception of the therapist. Assessment is essential in order to have specific goals set between them.

- In the Anti-AIDS Commission of Bizkaia we work on change processes even when they do not work out in consultations. Change is brought about by all members of the team, it is induced. Professionals themselves go through mourning, victimization and so on.

**Question:** Some people prefer some interventions to others (i.e. group interventions rather than individual ones) Do you have any comments on the way young people perceive the concept of help?

**AG:** Anyone is entitled to being helped.

## **SESSION 5: Determining the Needs of the Community and Representation**

GESIDA is the experts' working group that prepares the treatment guidelines in Spain which are adopted by Spain's National AIDS Plan. GESIDA does not count on community members and it also decides which research lines should be given priority.

The National AIDS Plan's Clinic Advisory Board is not meeting currently although a member of the community sits in it.

Doctors also take advantage of the fact that the concept of community is not clear.

**Joan Tallada:** It is impossible to represent the community but it would be possible to represent community values and interests. Every time the members of the community meet they demand the same kind of values: transparency, feedback, continuous consultations... There is a problem with supposedly assuming that community opinion is what any single member of the community has to say, and this is not correct.

- We must devote some time to train people interested in coinfection by introducing the issue and motivating inquiries.
- What do we understand by the community? We don't seem to agree on this.
- Set the topics that we are going to focus on. Many topics are related but we cannot respond to every single one.

**Tracy Swan:** In the U.S: a national HIV coalition was formed, in which they agree on the statements to be issued. Representation can mistakenly make us think that a community statement is shared by everyone.

- There should be transparency in the criteria established, perhaps along with rules on how these representatives should get community feedback and disseminate it later.
- We should strive for participation of all members of the community including drugs users...

**Joan Tallada:** I believe the problem is not in the ways in which we elect these members but in what they uphold. And asking for explanations is considered improper. We must also do more fundraising for coinfection.

**Tracy Swan:** We must try not to make the community overburdened with work. Representatives should be able to “translate” community knowledge and also accept that we don’t know it all. We should talk from a common sense perspective and based on our own experience.

**Joan Tallada:** It would also be necessary to detect those needs about which no research is being carried out.

**Alexandra Cerioli:** In Italy we don’t have people who are receiving training. Treatment activism has evolved into human rights activism.

**Joan Tallada:** We should stop thinking that activists have an answer for everything, we must be able to recognize that we have limited resources and that activists are human beings.

- There is no democracy in our groups. We must distinguish between delegating and representing and decide what we are going to focus on.

**Wim Vandevelde:** There is a lack of democratic perspective in the way we embrace some values which emerge spontaneously. Knowledge is power and some activists are determined to cling to power. We should try to get science to work for the benefit of the community.

**Tracy Swan:** We should try to think more about the future and attract younger men, women and diverse people. Once we become representatives we must think about those who are going to take our place.

- Acknowledging that as NGOs we do not use the same democratic framework which our political representatives use;
- The health system does not respond to the basic needs of the ill. NGOs should respond to such basic needs;
- We should be strict about our groups’ stated aims;
- Are human rights with regards to HIV being defended?
- What do we mean by a greater involvement of people with HIV in decision making? It is not enough to have a person with HIV sitting in each group.

**Joan Tallada:** Participation means that we actually express our concerns to people who represent us, and to hold them accountable and demand answers to our questions. This often happens with the media. A person’s serostatus makes him/her a person with HIV who automatically represents everyone, and this is not so. There ought to be structures in support of activism, the reason being that activists sometimes don’t have the time, money, or health condition to attend all the group meetings where they feel they should be.

## **SESSION 6: Challenges and Future Action**

**1.- A study on the reasons why coinfecting people in need of a transplant are not referred or are referred too late.** A geographical study is proposed (a

mapping?) in order to know where the problems are. Data are to be used for political action.

2.- Set up a coalition or network around the issue of coinfections in Southern Europe.

Core group:

GAT (Portugal)

FEAT and CESIDA (?) (Spain)

LILA (Italy)

TRT-5? And CHV? (France)

Each group is committed to disseminating the discussions at national level.

3.- To encourage an improvement and harmonization of the HCV treatment liver transplant guidelines for coinfecting people. This should also include a discussion and addressing the issue of the different existing scoring systems for hepatic fibrosis progression and ways of harmonising it. **Preparing a document on the community needs with regard to coinfection such as prevention, treatment, transplants and so on.** The document could be presented during next April's EASL conference in Milan.

Lobbying in the scientific, social and political realms.

4.- **To obtain more information about the European liver transplant register on coinfecting people and ensure community participation.** Since Spain and Italy are leaders in this field, researchers from these countries should be contacted.

5.- Collect data from NGO services and programmes which reflect the impact of coinfection.

6.- Make a survey of the ways in which organ donations work in each country and explore the possibility of bringing about a change of mentality leading to increment the number of donations. Disseminate best and successful practices. Collect information about resources devoted and assess whether they are enough.