Abstract
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Drug free rehabilitation program for drug addicts and management of HIV and HCV infection

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Introduction:
San Patrignano is a drug free residential rehabilitation facility for the treatment of drug addiction, founded 30 years ago by Vincenzo Muccioli, in northern Italy, on the hills near the Adriatic sea.

Addiction is not treated as a psychiatric disease with biological basis, but as behavioural problem with multiple and variable social, cultural, educational, psychological causes, including psychiatric disease.

The therapeutic program, free of charge for families and also for Public Health, lasts about 4 years and is based on education and social rehabilitation of subjects. The main goal is essentially the progressive building of individual and social responsibility, self esteem, intrapersonal and professional skills and strengthening of relationships.

Substitutive therapy with methadone or buprenorphine is used for detoxification only in selected cases (pregnant women, AIDS patients or very sick subjects, etc.) and never as maintenance treatment.

Psychopharmacologic treatment is reserved to those subjects with a well defined psychiatric disease non related to withdrawal of drugs (about 20-25% of cases), with minimal prescription of addictive drugs (barbiturates, benzodiazepines, etc.).

Since 1984 (the first year of regular data collection) about 17.000 subjects entered in the Community. For most of these subjects a plasma sample has been stored and vital statistics, toxicological, and medical informations are available in the computerized data bank, for epidemiological analysis of drug related risk behaviour, and medical disease.

The Medical Center

The San Patrignano Medical Center has been created for the management of medical complications related to drug addiction: withdrawal syndrome, psychiatric diseases, sexually transmitted disease, infections associated with syringe use or exchange (HIV/AIDS, hepatitis C or B/cirrhosis, endocarditis, etc.), odontoiatric diseases, tuberculosis, pneumonia, etc.

Patients are followed in a multi function office with diagnostic instrumentation or in a 50 bed medical ward, depending on the severity of those complications. Inside the Medical Center an hospice and a long term rehabilitation center for AIDS patients without resources (homeless, illegal people, patients with neurological o psychiatric diseases, patients without access or unable to adhere to treatments, etc.).

Epidemiology of HIV and HCV infections.

Our data confirms that, in Italy, HIV infections diffused among intravenous drug users from 1980 to 1985 (data on about 13.000 subjects), beginning to decline thereafter, when the test became available. The prevalence of HIV infection was 10% in those admitted in1981, peaked to 56% in 1986, and returned to 10% in 1999. Unfortunately the prevalence remained stable to about 10% from 1999 to 2007, confirming the persisting of high risk behaviours in a subgroup of drug users.

Since 1981 to 1999 more than 90% of drug addicts have been exposed to HCV infection, and infection generally occurs very early, in the first years of intravenous drug use. Exposure is clearly associated with syringe use, but not necessarily to syringe exchange; probably some other injected related practice plays a role in the diffusion of HCV infection (sharing of spoons and/or filters? Front-loading or after-loading of syringes?).

The recent decrease of prevalence of HCV infection (< 60%), observed in those subjects entered in the Community in the last 3 years is clearly associated with increased numbers of addicts not injecting drugs (also heroin).

More detailed data on epidemiology of HIV and HCV infections, including the role of sexual transmission, will be presented.

The changing spectrum of risk behaviours in Italian drug user

Sharing of needles or syringes. During the years a decreasing percentage of intravenous drug users (IDVUs) reported "frequent" sharing (from about 40% in 1986 to 10-15% in the last ten years). Most of IDVUs continues to report "sporadic" sharing, that generally means sharing with the partner or with a trustworthy friend. The percentage of IDVUs referring that "never" shared syringes was below 20% before 1985 (the year of HIV serological test) and is stable (40-50%) in the last 10 years.

Use of syringes. The number of drug addicts through non parenteral route has gradually increased from below 5% (subject entered before 1997) to 30% (2007). Considering heroin addicts, less than 5% of those starting addiction before 1990 were non-injectors, whereas the percentage has increased thereafter: 10% for those starting in 1991, 23% for those starting in 1995, 42% for those starting in 2003, and 67% for those starting in 2007.

Sexual risk. We don't ask our guests about sexual orientation, so we have no data on this topic. "Casual" sexual intercourse is common in drug users (59% of males and 63% of females), independently from prostitution, and the percentage has remained quite stable in the years. Non using females often have enter into relationships generally with male drug users (85,7%), whereas only 38,8% of non using males have drug using female partners. Not considering prostitution, 12,7% of males and 8,6% of females reported regular prophylactic use, whereas 58,2% of males and 63,8% of females reported "never" using prophylactics. The percentage of regular use of prophylactic ha only partially increased in the years (below 10% before 1995 to about 20% in the last years).

We suggest that the diffusion of HIV infection occurs in drug users also through unprotected sexual intercourse: the prevalence of HIV infection is higher in females drug users than in males (26,9% vs 18,6%) and this higher risk has remained stable over the time. Moreover we have observed cases of HIV infection in non using syringes drug addicts, and the number of these cases are increasing in the last years.

Treatment of HIV and HCV infection in active drug users and in former drug users

To assess the access to, the adherence, and the efficacy of antiretroviral therapy in active and former drug users, we analyzed the data on about 3.000 HIV-infected patient, followed from 1985 to 2007.

Our data let us to conclude that, in Italy, drug users have a good access to antiviral therapy (ART). From 1990 to 1996 (the period of low efficacy therapy) a minority of patients entered in the Community have been previously exposed to anti-HIV drugs (10% in 1991, 40% in 1995), but an high percentage of them were unaware of HIV infection; during the HAART-era only few patients were unaware of HIV serostatus, and the percentage of ART-naïve decreased from 40% (1996) to 25% (1998 and thereafter). These very high percentages of ART-exposed subjects let us to suggest that most of these patients were over-treated, having started HAART sometimes too early.

Adherence is confirmed to be a great problem in activedrug users: of 196 drug users in HAART at the entry in the Community (from 1996 to 2006), 42,3% were in virological failure. Only 12% of failing patients had a wild type virus, whereas the others had genotypic resistance to one, two, or three class of antiretroviral drugs (respectively 21%, 40% , and 27%).

In the multivariate analysis virological failure resulted associated only with "active" drug use (virological failure= 53%), self reported adherence, and cumulative exposure to antiretroviral drugs.

In the same period (1996-2006) the incidence of virological failure was of 14,5% in 456 evaluable former drug users who received HAART during or after the residential therapeutic program (median follw-up of 39 monthes). In multivariate analysis the principal causes of virological failure were being in virological failure at entry in the

Community (p=0,005) and a reported low adherence. The risk of virological failure was very low (7,4%) in the 162 naïve subjects starting HAART during the therapeutic program; moreover, in these subjects the efficacy was non related to the pharmacological combination of HAART.

Also adherence was correlated with the risk of virological failure. Periods of low adherence were reported by 15% of former drug users; the major reasons were: depression and other psychiatric diseses (52.2%), non acceptance of HIVdisease (34.0%), simple dimenticance (28.3%), fear of side-effects (23.7%), and desire to leave off the therapeutic program.

Interferon-based treatment for HCV-infection is generally considered problematic in drug users because low adherence, high alcohol intake, and the high prevalence of psychiatric disorders, a contraindication to treatment.

In our experience a residential therapeutic program for drug addiction could be considered an ideal opportunity to treat HCV infection, having the wisdom to choose the right moment to start (not too early, not too late), and of treating (or also preventing) co-esisting psychiatric disease before hepatitis treatment. Data on tolerability and efficacy will be presented.

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