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Reducing risks of infection

Amongst drug users

Collective Expert Report
Synthesis and Recommendations

Inserm
Institut National de la Santé et de la Recherche Médicale
(National Institute for Health and Medical Research)

This document presents the synthesis and recommendations of the group of experts brought together by the French National Institute for Health and Medical Research (Inserm) within the framework of the collective expertise procedure (Appendix), in response to the French Ministry for Health and Sport's request regarding the reduction of risks of infection amongst drug users. This work is based on the scientific data available during the first half of 2010. The information contained in almost 1,000 articles provides the basis for this expert report.

The Inserm Collective Expertise Center (Centre d'expertise collective de l'Inserm), linked to the Multi-Organism Thematic Institute for Public Health (Institut thématique multi-organismes Santé publique), co-ordinated this expert report.

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Foreword

The harmful health and social effects associated with the consumption of legal and illegal psychotropic substances, which are well documented in the majority of European countries, have for several years justified the setting-up of a policy to reduce these harmful effects.

In France, this has been set out as a risk reduction policy. Evidence of a high prevalence of HIV from 1985 onwards and then of HCV in the 1990s in drug users has prompted numerous initiatives by health associations and professionals in several countries, including France,with the aim of gradually obtaining public policies for risk reduction. Evidence of this is seen in the inscription of the risk reduction agenda in various public health government programs: the latest "addictions" program (2007-2011) and the national mission against hepatitis 2009-2012 program led by the French Health Ministry, and the governmental Interministerial Mission on Drugs and Drug Abuse (MiDLT) 2008-2001 program. The French Ministry for Health and Sports requested Inserm to carry out a Collective Expert Report, on the theme of "reducing risks of infection amongst drug users" with the objective of consolidating scientific knowledge on existing devices and programs on the international scene, the context of their set-up, evaluation of their impact and pilot projects. This expert report should contribute to defining guidance criteria in order to improve risk reduction tools, treatment methods and the practices of health care professionals. In response to this request, Inserm set up a multidisciplinary group of 14 experts, comprising epidemiologists, sociologists, economists, public health professionals, psychiatrists, hepatologists and addiction specialists. This group analysed over 1,000 articles and structured its review around the following questions:

- What are the concepts and definitions of risk reduction?
- What data is available in France and Europe on drug use and the associated health and social risks? Which uses are particulary problematic today?
- What is the epidemiological data on the risk of infection (HCV, HBV, HIV, etc.) amongst drug users? What developments are there in the prevalence of HCV, HBV and HIV infection in drug users in France?
- What are the methods of contamination in the population of drug users? What are the associated risk factors? What are the sources of contamination in relation to new practices and new products (crack/cocaine)?
- What is the impact on the incidence of HIV and HCV of the new types of contamination?
- What are the existing programs for risk reduction? What are the results of evaluations? On what criteria are they evaluated?
- What new tools, devices and treatments are currently in use? How well do these meet requirements? How are these utilized in existing programs?
- What is the cost-effectiveness of risk reduction programs?
- What is the data on screening and care for drug users? How can the practices of health care professionals be improved?

- What is the epidemiological situation in prison environments? What are the existing treatments, tools and devices? What evaluations are available on the impact of these tools?
- What data is specific to women? What data suggests that approaches to risk reduction take account of walks of life, risk taking and pregnancy?
- What is the availability of and access to risk reduction devices and programs? Who are the stakeholders in France? What is the acceptability of risk reduction policies to drug users and the public?
- How are initiatives, devices, and infection risk reduction programs integrated into overall policy on risk reduction, prevention and care?

The group of experts also heard from several speakers on the context of setting up a risk reduction policy in France and on the conditions facilitating the co-existence of a public health strategy and a national prevention strategy (for drug-related crime) with the example of Canada and the necessary co-operation of various stakeholders involved in this strategy.

Three discussion-meetings took place in 2009 and 2010 which developed the role played by associations in the set up and implementation of the risk reduction policy in France and envisaged development issues.

Synthesis

In order to minimize the risk of infections related to drug use, a risk reduction policy has been in place in numerous countries in Europe, North America and Australia for a little over twenty years. The concept of risk reduction corresponds to a variety of philosophical and political outlooks and gives rise to numerous debates concerning the place of abstinence, morality and the law. Furthermore, it has evolved over time, and definitions can vary according to the contexts of its application, as well as legal, philosophical and political positions. The semantic register used to qualify risk reduction policy differs according to country: vocabulary relating to the "reduction of damaging effects" is mostly used in Canada, whilst that of "risk reduction" is mainly used in France and in Switzerland. Use of the term "risks" evokes the notion of danger, whilst "damaging effects" relates more widely to ideas of harm, prejudice and problems. The issue of "damaging effects" or "harm" simultaneously incorporates risks to the individual and the consequences of drug use for the social environment in which drug users live, and their relationships with the rest of the population. The sense of "damaging effects" is closer than "risk reduction" to the original dimension of the English terminology of harm reduction. Reducing social and health inequalities amongst the population of drug users can also be placed at the center of risk reduction. Risk reduction can give rise to a policy centred exclusively on the drug user as an individual, widen to the drug user's network as a member of a "community", or be applied more generally to focus on the environment in which the individual develops and identifies his or her position in society. For some, the ultimate aim is abstinence, but to be reached gradually; for others, this objective is not a priority, unless the user expressly desires it. A gradualist policy allows risk reduction to be inscribed in a continuum (and not an opposition) with addiction care. The risk reduction policy encompasses strategies belonging to the prevention of psychoactive substance use (for example preventing initiation to injections), reduction of the risks linked to the use of such substances (for example preventing initiation to injections or preventing the risk of infection through access to sterile equipment), to treating addiction in all its forms (withdrawal, psychotherapy, opiate substitution treatment (OST), other treatments, etc.). Other objectives include facilitating access for alienated populations to care structures via the setting up of devices which go to the individual, and do not wait until users are ready to start the process. In France, the policy of risk reduction is enshrined by various decrees (Art. D. 3121-27 of the Public Health Code), orders and circulars which have been progressively adopted since 1987 along with the law passed on August 9 2004 relating to public health policy, which defined a frame of reference for activities relating to risk reduction (Art. D. 3121-33 of the Public Health Code). Devices for risk reduction (over-the-counter syringes, Steribox kits, substitution treatment and drop-in, care and risk reduction support centers, etc.) have been the subject of various legislative texts between 1987 and 2006 regarding their distribution. In order to be truly effective, risk reduction policy must take into account changing practices (products and consumption methods), consumer profiles and the contexts surrounding consumption. Furthermore, observation data are useful for evaluating the impact of implemented policies and their evolution.

Recent data regarding drug use in France

In France, tobacco and alcohol are the most widely consumed psychoactive substances. Alcohol is consumed, at least occasionally, by a very large majority of the population. Tobacco, which is equally widely used, is currently smoked by 3 out of 10 people living in France.

Amongst French people aged between 18-75 years, 27% have tried cannabis, and 7% of these have used it in the last year. Amongst this 7%, just over a third use cannabis regularly. Use of illegal drugs is marginal by comparison: 3% of the French population in the case of cocaine and magic mushrooms, 2% in the case of amphetamines and ecstasy and 1% in the case of heroin. Consumption of these various products over the last 12 months is even more rare.

Changing trends in drug consumption by the general population in France vary according to the product and age group studied. A downward trend can be observed for the two most frequently consumed products: tobacco and alcohol.

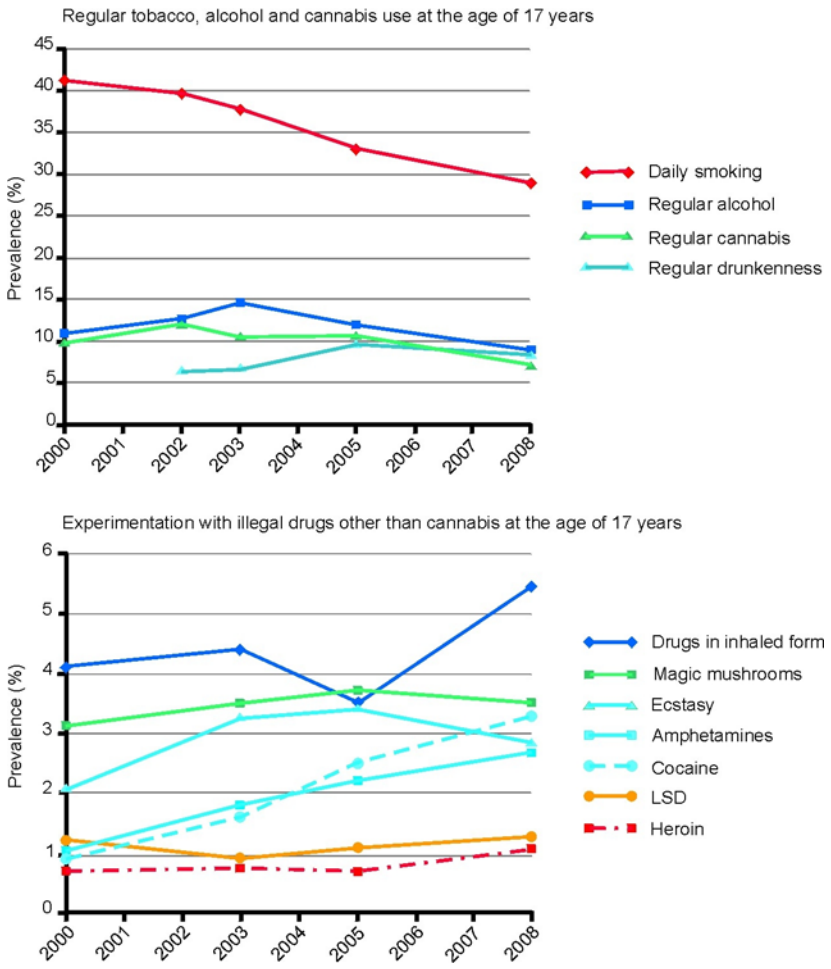
The decrease in alcohol consumption dates back a long way. Over the last 45 years, pure alcohol consumption per capita has been reduced by half (12.9 litres per capita aged over 15 years in 2006). This reduction is almost exclusively due to a decrease in wine consumption. This continuous decrease has changed France's historically marked position as a significant wine consumer within Europe, although it remains in the group of countries with the highest overall alcohol consumption. In correlation with the decline in average consumption quantities, the proportion of regular or daily consumers of alcohol has also declined.

The trend of alcohol consumption amongst young people, which is more difficult to establish, seems to be slightly on the increase in terms of drunkenness and excessive drinking sessions (over 5 glasses on the same occasion).

The decline in tobacco smoking is more recent, and has taken place over approximately the last twenty years. Observed since the 1980s amongst men, this trend has also been observed in recent years amongst women and young people. Whilst in 1999, they were amongst the most significant tobacco smokers in Europe, today smoking amongst French young people sits in the European average.

Consumption of other drugs is on the rise. This is the case with consumption of psychotropic medication, in particular antidepressants, the sales of which have doubled between 1990 and 2003. The rate of use of psychotropic medication in France is high, as is its overall medicinal drug consumption. Amongst young people, the level of consumption (consumption which does not always come under a medical prescription) recently seems to have stabilized.

Cannabis consumption is also on the increase amongst the general population. Nonetheless, after a decade (1990) of strong, steady increase that led to young French people figuring amongst the highest cannabis consumers in Europe, the most recent data indicates a stabilization and then the beginning of an inversion of this trend. Regarding other illegal, rarely consumed drugs, a growing diffusion of hallucinogenic drugs and stimulants has been noted, in particular of cocaine; the prevalence of cocaine experimentation at the age of 17 years increased from 1% to 3.2% between 2000 and 2008.



Changing drug consumption amongst young people aged 17 years between 2000 and 2008 (according to ESCAPAD survey, carried out by OFDT, the French observatory of drugs and drug dependency)

Overall, consumption of psychoactive substances is a male-dominated activity (except for smoking and psychotropic drugs), and this is especially true of regular consumption. Regular consumption of alcohol and psychotropic drugs significantly increases with age. Conversely, consumption of tobacco, cannabis and other illegal substances is more common amongst young people and then decreases with age. Drug-using behaviors frequently vary according to user's social and occupational status and level of education (or that of their parents for the youngest users).

Certain specific populations have very high rates of illegal drug consumption. They cannot be described using surveys of the general population, both because of the low prevalence of illegal drug consumption other than in the case of cannabis, and also because of the instability which can characterise these people and make them impossible to reach for such surveys.

In 2006, the number of problematic drug users (previously known as drug addicts) in France was estimated at between 210,000 and 250,000. This relates to injection drug users or long-term drug users and regular users of opioids, cocaine and/or amphetamines. This population is relatively young (around 35 years of age) but is ageing, very significantly male (4 men to 1 woman), and frequently suffering from psychiatric disorders and often social difficulties. Half of opiate consumers are receiving medical substitution treatments.

Estimate of the number of problematic drug users in France in 2006 (according to OFDT, 2008)

Estimated range	210,000-250,000
Rate/1,000 per capita aged 15–64 years	5.4–6.4
Central estimate	230,000
Rate/1,000 per capita aged 15–64 years	5.9
including:	
Active heroin users (month)	74,000
Rate/1,000 per capita aged 15–64 years	1.9
Intravenous users (life)	145,000
Rate/1,000 per capita aged 15–64 years	3.7
Active intravenous users (month)	81,000
Rate/1,000 per capita aged 15–64 years	2.1

Problematic drug use is defined by OFDT as: "the consumption of injectable drugs or long-term drug use/regular use of opioids, cocaine and/or amphetamines".

Observation of the use and users of illegal products shows that in recent years consumption of cocaine, as well as other stimulants such as ecstasy and amphetamines, is increasing, whatever the mode of use (injected, snorted or smoked). On the other hand, heroin consumption is stabilizing after having decreased. Other types of consumption are frequently associated, in particular alcohol, psychotropic medication and cannabis. Amongst populations using the first line of support for drug users (CAARUD - Reception and Harm Reduction Support Centers for Drug Users), cannabis use is the rule (86% during the previous month), with heroin and cocaine at the low end of the range of recently used products 34% and 40% respectively).

Another type of consumer is represented by individuals familiar with the techno party scene, whether "alternative" (free parties, rave parties and teknivals) or commercial (nightclubs, discotheques and private parties). Whilst many people within this scene are not drug users, the prevalence of drug use is observed to be higher than amongst people of the same age in the general population. Cocaine consumption increases to 35% within the previous 30 days, ecstasy consumption increases to 32%, whilst daily cannabis use is noted amongst 40% of individuals encountered on this scene. This population is not homogenous, but varies according to the places frequented and proximity to "techno culture".

Principal harm associated with drug use in France

In France, tobacco and alcohol are the psychoactive products that cause the most significant harm to health at the collective level. In 2000, smoking was considered responsible for around 60,000 deaths, or more than one in nine deaths. In 2007, the number of deaths attributable to alcohol in France was estimated at around 30,000.

In terms of the French population, harm to health linked to the consumption of illegal drugs is quantitively less than that related to tobacco and alcohol. This is due to the marginal character of illegal drug consumption compared to consumption of tobacco and alcohol. However, it must be noted that the characteristics of the populations affected are profoundly different, especially regarding age: harm to health linked to illegal drugs affects much younger populations than those affected by legal products.

In terms of mortality, only very partial data is available, which does not allow an overall estimation of the number of deaths attributable to illegal drug consumption in the same way as alcohol and tobacco. Nonetheless, a retrospective study shows that men questioned about heroin, cocaine and crack use have a risk of death 5 times that of other men the same age; for women, this additional risk is doubled. Despite their inability to document the true extent of mortality, routine data allow its development to be tracked. The number of drug addicts' deaths has fallen significantly since the mid-1990s, as indicated by the annual number of deaths from overdose recorded by the police, which went from over 500 in the mid-1990s to less than 100 from 2002. Nonetheless, the number of deaths linked to drug use recorded by Inserm (CepiDc - Epidemiological Center for Mortality by Medical Causes) increased by 30% from the year 2000 to reach 337 in 2007. The number of AIDS-related deaths amongst injection drug users also fell significantly between 1994 and 1997 (332 cases in 1997). This fall has continued, at a slower rate (69 cases in 2006).

In terms of illegal drugs, observed harm to health is mainly linked to the consumption of opiates and, to a lesser extent, of cocaine by intravenous methods.

Amongst drug users, intravenous injection of heroin was frequently practiced during the 1990s. Overall, this method of administration seems to be in regression today, even if its use is observed amongst some sub-groups of young and marginalized consumers. However, infectious harm (in particular chronic infection by HIV and/or HCV) linked to contamination from the use of injection equipment remains a major concern.

Injection drug users frequently suffer from other somatic problems, including: obstructed veins, bacterial or mycotic infections, and dental problems. These problems can sometimes lead to serious diseases such as: septicemia, endocarditis, and arthritis.

Psychiatric co-morbidities are frequent amongst drug addicts. Personality disorders, depression, anxiety and psychotic disorders can be pre-existing or can follow product consumption. Amongst drug users, 40% to 60% present a psychiatric co-morbidity. One in three patients who are dependent on heroin are depressed and a lifetime prevalence of depression amongst these patients is between 60% and 90%. Similarly, addictive co-morbidities are frequent amongst patients presenting chronic psychiatric disorders. The highest prevalences appear in schizophrenic and bipolar patients. Patients presenting a bipolar disorder are 5 times more at risk of presenting a disorder linked to substance use.

Drug users are characterized by a more unstable social situation than that of the general population, whether in terms of housing, income from employment or welfare cover. Amongst users who attended risk reduction structures in 2008, half were experiencing unstable housing conditions. A quarter had no legal source of income and resorted to begging, illegal resources and prostitution, and half were relying on universal medical coverage (CMU) for health insurance.

Risk reduction devices have observed, particularly since 2002, new unstable population groups using their services: "homeless youths", lacking any familial or institutional support or migrants without any resources, notably those originating from Eastern Europe. These new unstable users accumulate even more health risks as they distrust risk reduction practices and frequently resort to prostitution. In 2008, Trend, the French watchdog for the observation of recent trends and new drugs, indicated use of injections carried out collectively and in a great hurry (in order not to carry a product and thus be guilty of a criminal offence) amongst the most unstable groups, in horrendous hygiene conditions where contaminations seem inevitable. Finally, amongst disaffected youths, the growing female population (also observed by Trend since 2002) raises specific questions on a socio-sanitary level, such as violence, infections, unwanted pregnancy, and prostitution. Legal difficulties are often encountered by drug users. In 2008, 38% of drug users being treated in

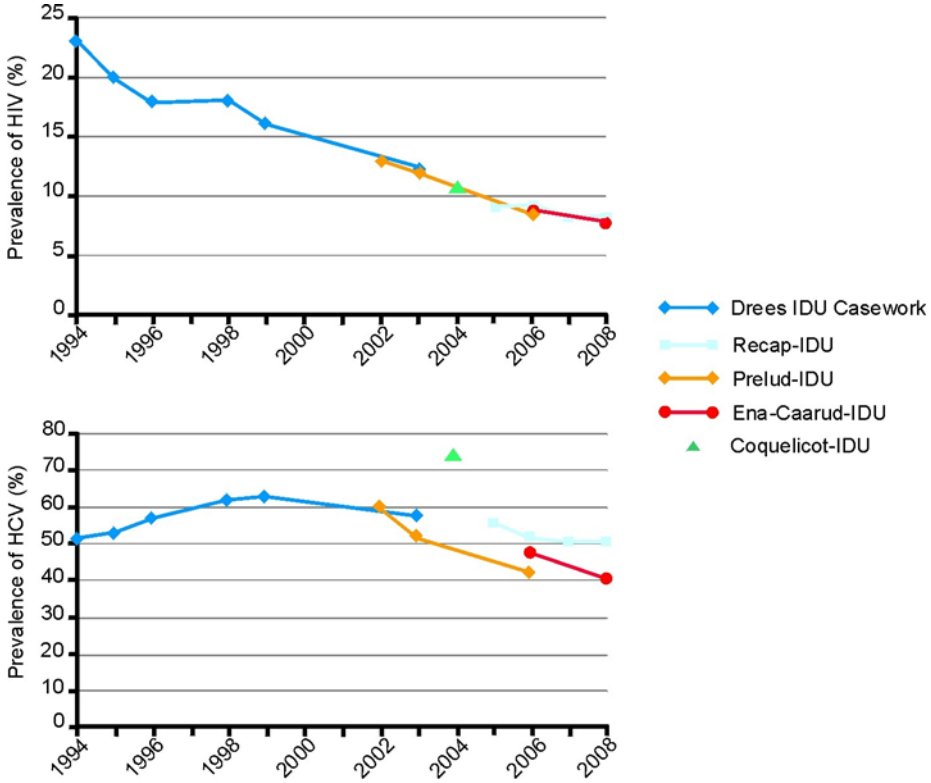
specialist drug addiction treatment centers (CSST) had previously served a prison sentence. In 2008, 17.4% of users who had attended a CAARUD center had served at least one prison sentence in the same year, an identical proportion to that recorded in 2006. This related to one in five men (19.9%) whilst only 8.7% of women had served prison sentences. According to evidence provided by socio-sanitary stakeholders, psychosocial or health treatment programs are frequently interrupted by such imprisonment.

Prevalence of HCV, HIV and HBV in drug users

There is great diversity of infectious harm amongst drug users. This may be linked directly to drug consumption (AIDS, viral hepatitis B and C, abscess, endocarditis, septicemia, ophtalmomycosis, tetanus, botulism, anthrax, etc.) or to users' living conditions (tuberculosis and pneumopathies, sexually transmissible diseases, hepatitis and AIDS). Whilst chronic infectious health risks (AIDS, viral hepatitis B and C) are privileged in this expert report, it should be noted that risk reduction strategies are equally important for other health risks.

In 2004, the prevalence of anti-HCV antibodies was less than 1% (0.84%) in the general population in France, or 367,055 people who were in contact with HCV.

In 2004, estimates of the prevalence of HCV in biological samples collected during the Coquelicot survey of 1,462 drug users (of which 70% had carried out injections in their lifetime) stood at 60%. In 2006, this estimate stood at 42% amongst 362 individuals who had injected at least once during their lives, compared with 7% amongst 138 users who had never injected. In 2007, amongst recently screened under-50 year olds, those contaminated by drug use (intravenous and/or nasal use) represented 57% of men and 36% of women.



Evolution of the prevalence of HIV and HCV amongst drug users frequenting specialist establishments (CAARUD or CSAPA - Support and Prevention Care Addiction Centers) between 1994 and 2008 (according to Drees, November Casework; OFDT, Recap, Ena-Caarud; InVS, Coquelicot)

In France, the prevalence of HIV in the general population is difficult to estimate. Studies on seroprevalence were carried out up until 1997, and the total number of people infected by HIV was estimated at 105,800 (89,000-122,000) including 27,000 intravenous drug users (26%) in 1997. In 2003, the estimated number was 97,000 (61,000-177,000).

In 2004, estimates of the prevalence of HIV, on the basis of the Coquelicot survey carried out amongst 1,462 drug users (of which 70% had injected during their lifetime), using biological samples stood at 11%. In 2006, this estimate stood at 8.5% amongst 484 individuals including 72% had injected at least once in their lifetime. The number of AIDS cases attributed to injection drug use reached its peak in 1993 (1,495 new cases) before declining to 51 in 2008.

Since 2003, throughout the European Union as in France, the number of new HIV contaminations has decreased. For less than two years, the prevalence of HIV amongst injection drug users has been less than 10% in 15 European Union member countries (including France) and above 10% in three European Union member countries.

A further decline in the prevalence of HIV has been observed since the beginning of the 1990s. This slowing of the epidemic linked to HIV could be explained, in particular, by the decrease in use of injection drugs and the development of risk reduction strategies (distribution of sterile injection equipment, substitution treatments).

In 2004, the prevalence of hepatitis B antigens (HBsAg) in the general population of Metropolitan France stood at 0.65% (280,821 people). This prevalence is higher amongst men (1.1%) than women (0.21%). In contrast to HIV and hepatitis C, drug users do not know their HBV status. In 2006, amongst 929 users of the first line of support services, 8% declared themselves contaminated, 16% non-contaminated, 40% vaccinated and 36% did not know their status.

Modalities of contamination and related factors

Between 1995 and 2005, the probable most frequent modalities of contamination amongst declared cases of individuals diagnosed with an HCV-related disease were use of injectable drugs and receiving a blood transfusion before 1991. According to a study on HCV cases in European countries diagnosed over the 2003-2006 period, injection as the probable contamination method was identified at between 74% and 100%.

Other than possible contamination factors applying to the whole population (blood transfusion and blood products before 1992, occupational exposure, nosocomial exposure, etc.), certain factors are specific to or more frequent amongst drug users. Amongst these factors, some are indisputable. Sharing of product preparation equipment or equipment used to carry out injections is the principal risk factor in HCV transmission amongst individuals injecting drugs. For non-injection drug users, rates of HCV prevalence are nonetheless higher than in the general population. For drug users consuming via nasal use, one hypothesis is that sharing consumption tools (straws) leads to transmission. For drug users who consume crack by smoking, the sharing of glass crack pipes, which are breakable and easily transmit heat, also forms a hypothesis for the transmission of HCV. In fact, HCV is present in the nasal mucositis of carriers of HCV, in blood and on drug-taking equipment. An association between HCV and tattooing is observed amongst non-injection drug users.

Poor social conditions are also risk factors. A Canadian study highlighted that unstable housing increased the risk of HCV contamination in drug users. In France, indicators associated with HCV contamination are receiving CMU and early school leaving.

Sexual transmission of HCV exists but remains much rarer than for HIV or HBV. Its occurrence is particularly low in strictly monogamous serodiscordant couples. However, certain factors seem to favor transmission: HIV infection, the concomitant presence of ulcerative sexually transmissible diseases and sexual practices that can lead to lesions (e.g. anal penetration). Studies regarding individuals with numerous sexual partners display a high prevalence of HCV. The possible recourse to prostitution by some drug users exposes them more particularly to sexual infections.

Furthermore, other methods used to consume psychoactive substances carry contamination risks (sniffing, exchanging injection material and crack pipes, etc.), as well as close contact between people in institutions (sharing of razors, toothbrushes, etc.), and should also be considered.

As with the hepatitis C virus, injecting is certainly responsible for a large amount of HBV contamination amongst injection drug users. Amongst non-injection drug users, multiple factors have been highlighted, such as sharing of equipment used to take drugs via nasal use or smoking, or high-risk sexual practices (high number of sexual partners, anal intercourse, practices that promote bleeding, etc.) The duration of drug use would also appear to be a factor frequently associated with HBV contamination, both amongst injection drug users and non-injection drug users.

Amongst injection drug users, it is the sharing of injection equipment (syringes, needles, accessories) that allows HIV contamination. Sexual promiscuity used to obtain drugs or money can also lead to contamination. In France, according to InVS, 60% of people who discovered that they were seropositive in 2008 were contaminated by heterosexual relationships, 37% by homosexual relationships and 2% by injection drug use. Amongst AIDS diagnoses in 2008 with a recorded method of contamination, heterosexual contamination was recorded for 64% of cases, homosexual contamination for 24% and injection drug use for 9%.

Drug users presenting associated psychiatric disorders present more behaviors which are considered high-risk for HIV (and HCV) contamination, such as sharing injection equipment or unprotected sex, than those not presenting psychiatric co-morbidities. Depression has been identified as an associated factor in syringe-sharing when injecting. In particular, a French study associated it with the misuse of high dosage buprenorphine via injection, as with history of suicidal thoughts or suicide attempts.

Alcohol consumption amongst drug users is higher and more frequent than in the general population. The alcohol consumption of nearly one in two people who use drugs is excessive. Alcohol consumption increases morbidity and mortality (outside of somatic complications resulting from drug use): violence, disputes (e.g. couples), accidents (road, domestic, occupational), suicide, overdose, etc. Excessive alcohol consumption is associated with increased risk behaviors: it increases overdose risk, reduces alertness and facilitates transition to a sexual act (sexual violence). By reducing precautions taken when injecting, it favors viral contamination (HIV, HBV and HCV). Alcohol consumption affects the natural history of infectious diseases with a quicker development of the disease, more frequent complications and a higher mortality (HIV, HCV). Amongst drug users, a decrease in alcohol consumption is associated with a decrease in injections and a decrease in high-risk sexual behaviors.

Contamination amongst crack smokers

Even though sharing of injection-related equipment (syringes, spoons, filters, water) constitutes the major risk for HCV transmission in the drug user population, a documentation review carried out in 2006 nonetheless highlighted a much higher prevalence of HCV amongst non-injection drug users (2% to 35%) than in the general population (less than 1%). These results led to investigation into the transmission vectors linked to drug use other than via injecting (sniffing, tattooing, straw, etc.). Ethnographical field observations have shown that use and sharing of tools linked to crack consumption (cutter, electric wire, glass pipe) could cause lesions to smokers' hands and mouths and constitute entry points for HCV transmission. Recently, in international literature, increasing numbers of articles have considered the implications of sharing crack pipes as HCV transmission vectors. This high-risk practice is particularly high and may concern up to 80% of crack consumers. Although discussed in other studies, the practice of crack pipe sharing seems to be one of the most plausible hypotheses for explaining both the high prevalence of HCV amongst non-injection crack consumers (45% in the Coquelicot survey) and a certain proportion of HCV cases which are unexplained by known exposure pathways.

Ethnographical data from international literature validates the additional HCV contamination risk linked to crack use, but this additional risk is little taken into account in risk reduction devices. Furthermore, the crack user population combines social, economic and health vulnerability factors, which are mutually consolidating.

The current debate on links between HCV and crack consumption highlights the necessity of taking into account the evolution of usage practices in risk reduction policies. The current priorities of authorities in this field, in France and at the international level, focus exclusively on injection practices, which constitute the major transmission vector for HCV and HIV in the drug user population.

Since the 1990s, products such as cocaine and crack/free-base and consumption methods such as smoking have constituted strong trends in Europe and North America. Little attention has been paid to these new consumption methods such as crack smoking and the profiles of these consumers.

Canada occupies an innovative place in the field of risk reduction linked to crack consumption, implementing specific equipment distribution programs. These "crack kit" distribution programs are controversial, following the example of Syringe Exchange Programs (SEP) at the time of their setting up and thus difficult to implement in the long term. Equipment aimed at crack users (distributed on a trial basis) includes a Pyrex tube, plastic caps, filters (in the form of metal grills), condoms, lip balms, alcohol swabs, hand wipes and chewing gum to salivate. Evaluation of these risk reduction programs has highlighted that they reduce crack pipe sharing practices and can indirectly contribute to the transition from injecting to smoking. These programs also facilitate the picking up of new drug user populations who did not attend the first line of support services, due to lack of equipment adapted to their needs.

Changes in HIV and HCV contamination since the 1990s

Changes in the number of new HIV and HCV contaminations each year (incidence) over a long period may provide an indicator of the impact of risk reduction programs. Incidence

can be directly measured prospectively within the framework of longitudinal monitoring of a cohort of seronegative drug users within the program. However, this type of study is difficult to conduct as the number of subjects lost to follow-up at the end of the observation period is generally very significant. Furthermore, biased representativeness is most difficult to avoid as the populations who are most at risk of viral contaminations are also the most difficult to include in epidemiological surveys due to a high level of dependence on the products and frequent social marginality. Incidence can also be measured indirectly and retrospectively using data regarding prevalence obtained amongst the youngest age ranges.

InVS's monitoring system indicates that the peak of declared AIDS cases amongst drug users in France was reached in 1993. Determined by a backcalculation based on the fact that the number of new AIDS cases is the result of a number of subjects previously infected by HIV after a given duration of incubation, the incidence of HIV amongst intravenous drug users would have reached its peak around 1985, followed by a rapid decrease to reach a very low annual contamination rate around the beginning of the 1990s. Thus in 1997, HIV-positive drug users under 25 years of age, and therefore probably contaminated after 1990, represented 2.5% of the total number of HIV-positive drug users, or around 700 subjects. In 2008, with an estimated 70 cases, people infected through intravenous drug use represented 1% of new contaminations.

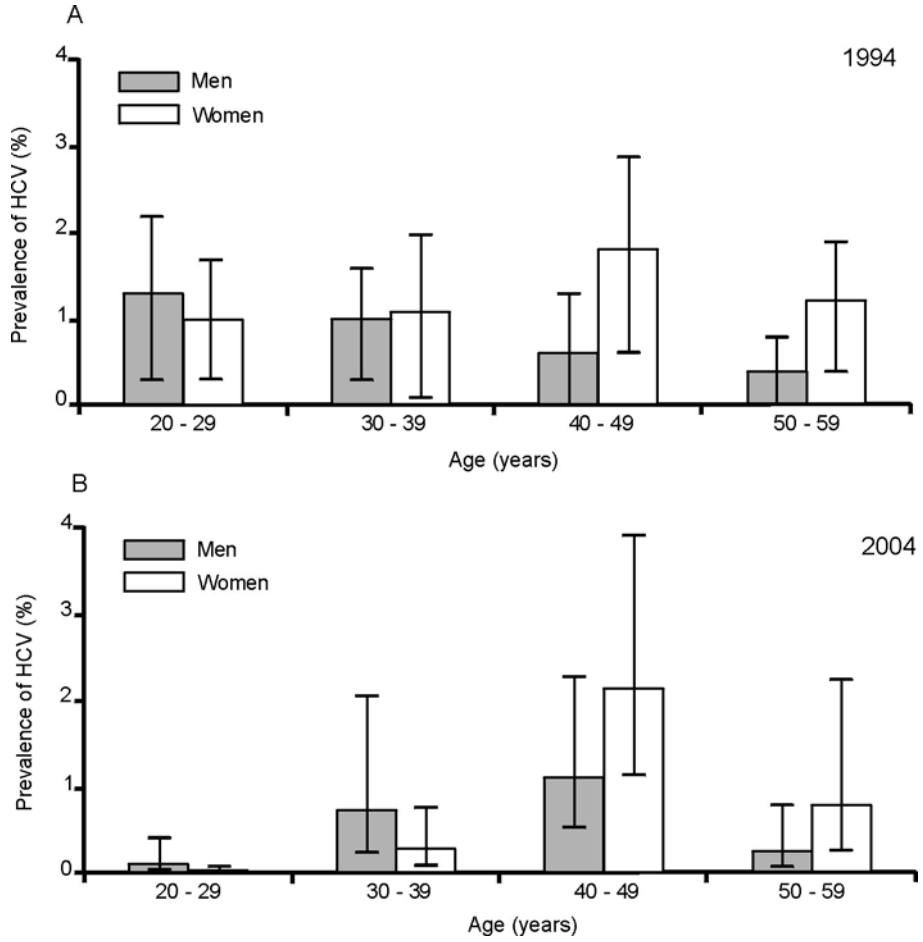
Modeling of the HCV epidemic in the general population had suggested a figure of around 15,000 cases as incidences of non-transfusion contaminations during 1990 of which around 70% had been secondary to drug use. A longitudinal study on the incidence of HCV infection in the drug user population between 1999 and 2001, carried out in the north and east of France, measured this incidence at 9 in 100 person-years and at 11 in 100 person-years amongst active drug users, i.e. those having injected at least once in the year preceding their inclusion in the study. An extrapolation of these results in active injection drug users who are presumed HCV-negative estimated that at that time 2,700 to 4,400 new contamination cases amongst drug users arose each year in France. This estimate would therefore indicate a significant reduction in the annual incidence of HCV amongst active drug users between 1990 and 2000.

Several sources issuing from surveys carried out in the general population but also amongst drug users attending treatment centers, general practices or first line support services appear to indicate a further decline in HCV incidence since 2000. The national survey on HCV prevalence in the population aged 18-80 years in Metropolitan France, carried out in 2004 (InVS), indicates a prevalence of HCV in those aged between 20 and 29 years of less than 0.1% (0.08%). Compared with the prevalence of over 1% observed in 1994, it is possible to conclude in favor of a decline in the incidence of infection between 1994 and 2004 in young adults, amongst whom drug use is the main mode of contamination.

However, in apparent contradiction with the previous results, most cross-sectional studies carried out between 1991 and 2004 amongst drug users found an HCV prevalence of between 50% to 80%. The stability at high levels of this prevalence despite a net incidence decrease could be explained by a very limited renewal of the drug user population monitored in treatment centers. For example, in the Coquelicot study carried out in 2004, 75% of all participants and 90% of HCV-positive subjects were born before 1975.

Whilst an apparent net decline in the incidence of HCV in drug users was observed between 1990 and 2000, changing trends between 2000 and today are more difficult to identify in the absence of recent longitudinal studies. However, a series of concurrent studies seems to indicate a decline of over 50% between 2000 and 2010. This would lead to a rough estimate of around 1,500 annual contaminations by drug use. It would be necessary to add to these estimates a number of HCV-positive subjects belonging to migrant populations, largely

originating from Eastern Europe and Caucasus. This number is difficult to specify. The decline in incidences of HCV in drug users observed over the last twenty years is confirmed by longitudinal studies encouraging the pursuit of prevention efforts and screening of new contaminations within the framework of risk reduction policies.



Prevalence of anti-HCV antibodies according to sex and age group in the two cross-sectional studies (InVS) carried out in France in 1994 (high) and 2004 (low) (according to Delarocque-Astagneau et al, 2009)

Preventing initiation into injecting and promoting "route transition" intervention

In literature, principally that originally written in English, themes on the prevention of initiation to injections and the "route transition" intervention were developed at the beginning of the 1990s around the issues surrounding the HIV epidemic.

Analysis of risk factors regarding initiation to injection indicates that dependencies (polyuse, intensity of use) and precocity of consumption (<18 years) are two factors strongly associated with starting injecting. However, some work also indicates that significant proportions of users (notably heroin users) consume via injection from the first instance, or that users consuming heroin via inhalation can develop a dependency without ever injecting. Women are generally considered less likely than men to inject. Instability and a marginal lifestyle are indicators often associated with injection, employed users being less likely to start injecting. Furthermore, there is much work that shows the occurrence of "deviant" behaviors (truancy, running away, trouble with the law, etc.) or traumatic events (sexual violence, psychological

or physical trauma, forced institutionalization) early in adolescence is more frequent amongst young injection drug users than non-injection drug users.

Amongst the factors examined in studies, the constant presence of drugs amongst relatives and the influence of an individual's social network are two factors which appear as determinants in starting injecting. Having friends, a family member or a sexual partner who inject themselves seems to influence starting injecting in various ways. The first injection is an event that individuals rarely carry out alone, instead taking ritual forms. From users' points of view, pleasure, the quest for a greater effect and curiousity about getting "high" are amongst the most frequently cited motivations. Availability, quality and varying cost of products on the market also seem to lead certain drug users to injecting.

Identification and study of all these factors are important to take into consideration when developing prevention programs. Drug intervention programs can be categorized according to two strategies. The first strategy aims to prevent non-injection drug users starting to inject, either through interventions directed at non-injection drug users to limit risks of initiation to injecting, or through initiatives directed at injection drug users (potential initiators) in order to try to reduce their influence on non-injection drug users. The second strategy aims to promote lower-risk injection techniques and procedures or even promote alternative (transition away from injecting) which are considered lower-risk than injecting.

There are two types of programs which have been set up responding to these two strategies. One of these types focuses on interventions via information, education and communication (responding to the IEC acronym). Another approach focuses on brief interventions.

IEC covers a range of approaches and activities; the best known are probably paper-based aids (leaflets, posters, flyers, etc.), videos, support groups, web platforms, media campaigns and other didactic materials. Despite their reach, there is little research on the effectiveness of these programs. Nonetheless, there is a level of consensus that merely delivering information is insufficient to bring about changes in behaviors.

Brief interventions are based on models derived from psychosocial theories explaining health-related behaviors. These are still little applied to infection risk reduction, in particular with regard to the problem of drug injecting and HCV. Regarding their effectiveness, some positive effects relating to changes in behaviors have been observed in the large majority of evaluated projects. More precisely, studies show a reduction in the number of non-injection drug users starting to inject, the number of injections and high-risk injection preparation practices. These interventions enjoy strong support from users who often demonstrate little interest in participating in long-term monitoring.

An example of a brief intervention program is the Break the cycle (BTC) program, which is distinguished by its focus on the individual and social aspects of product injection, in particular over the period when non-injection drug users begin injecting (increasing the ability to resist peer pressure to start injecting, or responding through educational methods regarding issues such as the physical, moral, psychological, social and legal consequences). Despite the paucity of available evaluation data, the pragmatic approach of this type of program makes it a promising tool for risk reduction.

In terms of prevention and reduction of HCV-related risks, literature reveals the common characteristics of effective interventions relating to injection drug users: interdisciplinary approaches or building on the complementarity and use of theoretical models to structure the progress of interventions. In order to be effective, approaches, messages and tools must be dynamic, adapted to the circumstances and individual practices, and take account of the social contexts and lifestyles of injection drug users.

Opiate substitution treatment (OST) using methadone and buprenorphine (HDB)

In France, there are currently two main therapeutic options for opiate dependency: treatments using methadone and high dosage buprenorphine (or Subutex ®). These two molecules are included on the WHO list of "essential medicines".

Methadone has been used to treat opiate dependency for over 40 years and since 1965 has become the main treatment alternative to withdrawal proposed to users of these drugs worldwide. In France, methadone was not introduced on a large scale until 1995 onwards. The initial prescription is carried out in a CSAPA (Support and Prevention Addiction Care Center) or in health institutions, with a relay with general practitioners possible after stabilization of the dosage. The geographical distribution of hospitals and CSAPA centers is not uniform, and a certain number of geographical areas lack these structures. A pilot project is currently studying the feasibility of the initial methadone prescription being issued by a general practitioner. In this way, methadone could become a first line treatment which would increase access to substitution for patients requiring this type of treatment.

The aim of treatment using methadone is to reduce opiate consumption but also to lead to a reduction and abandonment of conduits to associated risks of infection, social reintegration, and improvement in quality of life.

Although the impact of methadone on reducing the risk of HIV transmission is now acknowledged, few studies have shown the impact of methadone on the risks of hepatitis B or C transmission.

A study of a cohort of drug users in Amsterdam was able to show that access to methadone is associated with a reduction in the risk of seroconversion to HCV when combined with access to a syringe exchange program. In prison environments, a combined approach using OST, syringe exchange programs and peer education has proved effective, with a decline in the incidence of HIV as well as HCV. These results confirm that substitution treatments can play a crucial role in fighting the HIV and HCV epidemic if they are associated with other risk reduction tools.

The effect of treatments on high-risk behaviors remains limited amongst certain more vulnerable user groups, in particular those with alcohol problems, irrespective of their HIV status, and cocaine users.

Amongst patients infected by HIV, methadone substitution facilitates the start of combination therapy and also increases the observance of antiretroviral therapy. It also improves access to and observance of treatments of tuberculosis.

In general, scientific literature confirms an improvement in the health status and the social situation of drug users undergoing methadone substitution. In particular, a significant decline in criminality and an increase in employment rate has been observed.

According to several studies, the duration of methadone treatment plays a crucial role in reducing injection practices and improving social conditions. In particular, methadone's effectiveness, according to various criteria for judging effectiveness, would not be objectifiable for treatment duration of less than 90 days. A longitudinal study has shown that pursuing treatment, even in the presence of interruptions, influences the survival of patients beginning a treatment. The mortality rate could be multiplied by 8 if treatment stops prematurely.

Methadone carries a significant risk of overdose, in particular during the initial treatment phase, with the majority of deaths occurring during the first two weeks. The consumption of alcohol or other psychotropes at the same time can lead to harmful effects.

France was the first country to introduce high dosage buprenorphine (HDB) in opiate dependency treatment and currently has the most experience in this field. This has enabled demonstration of the first individual and public health benefits of wider access to HDB, in particular through general medicine. The most significant impact concerns the decline in heroin overdoses.

On the basis of several criteria for effectiveness, HDB appears comparable with methadone, except regarding treatment retention, for which methadone appears superior to HDB, in particular for patients presenting more serious dependency.

The Cochrane review published in 2008, which carried out a meta-analysis on the role of OSTs on infection risks, confirmed the positive impact of HDB and methadone on HIV seroconversion, injection frequency and high-risk behaviors regarding HIV and HCV transmission.

Two French studies, one based on two years of monitoring and the other on data collected retrospectively, also show a general decline in injection practices, an improvement in social conditions and a decline in criminal activities during buprenorphine treatment.

The "hijacking" of HDB is very quickly seen as one of the problems associated with the treatment, in the same way as overdoses are for methadone. This can be: a shift towards the black market (trafficking); use other than that recommended by the prescribing doctor (injection or sniffing or non-recommended co-use of other active substances); or misuse or "non-medical" use of unprescribed HDB (sublingual administration, injection or sniffing).

Misuse of HDB by injection concerns around 15% of patients undergoing treatment. Studies show that this affects a population with more serious dependency, consuming multiple products, often dependent on alcohol, affected by psychiatric co-morbidities and perceiving the posology to be inadequate. HDB injecting in France (amongst subjects undergoing treatment and others) is considered to be a practice which is responsible for HCV contaminations. Furthermore, complications linked to excipients contained in HDB tablets can appear around the injection site: abscess; tissue necrosis; massive degradation of the venous plexus; and indurated lymphatic edemas affecting the forearms and hands known as "Popeye syndrome". This can also relate to more serious health consequences for the user such as acute hepatitis, hypertension or pulmonary embolism.

For a homeless population, mobile devices such as the Bus Méthadone (Methadone Buses) in Paris and Marseilles and those used by Médecins du Monde have proved their effectiveness in several socio-cultural contexts. These devices simultaneously allow an almost daily supervised delivery of methadone or high dosage buprenorphine accompanied by care for of co-morbidities, counselling and distribution of single-use injection equipment.

Heroin prescription programs and other treatments

In the context of randomized clinical trials carried out in a number of countries, medically prescribed heroin appears as a therapeutic option for opiate dependent individuals and patients who are "resistant" to conventional treatments, i.e. for individuals suffering from a serious dependency and who have undergone several failed methadone or HDB treatments.

Treatment of opiate dependency by medically prescribed heroin is currently available in several countries (United Kingdom, Switzerland, the Netherlands, Germany, Spain and

Canada). Results of randomized studies comparing medically prescribed heroin to a conventional OST (such as methadone) repeatedly show the superiority of medically prescribed heroin on various levels: reduction in the use of street heroin and benzodiazepines, improvement in health status, social reintegration and superiority in terms of cost-efficiency.

The principle of medically prescribed heroin treatment is presented in the following way: amongst individuals presenting a serious opiate dependency, it is better to proceed in stages to gradually obtain changes. In fact, drug users with a serious dependency and multiple treatment failures have difficulties moving from a short-acting product (heroin) to a long-acting product (OST), or replacing an injectable substance with an oral substance. Until now, research has shown that these patients succeed at staying in medically prescribed heroin treatment more easily than other opiate substitution treatments, improving their health and social situations and reducing their drug-related criminal activities.

The therapeutic framework of medically prescribed heroin consists of full supervision of the treatment in specialist structures which the patient attends 2 to 3 times a day to carry out the injection of his or her heroin dose. Supervision guarantees several functions: the use of effective posologies, prevention of misuse of the drug and safety (in case of poisoning), and the installation and/or maintenance of a link with carers. Treatment programs using medically prescribed heroin often offer associated psychosocial care.

Together, the positive results of the latest studies have led the WHO to adopt a favorable position towards the introduction of medically prescribed heroin as a therapeutic option for serious dependency. This position regarding medically prescribed heroin can be summarized as follows:

- it relates to a medically feasible program which is safe, clinically responsible and acceptable to the community;
- treated patients have shown an improvement in their health status, social functioning and a decline in criminal activity.

Effectiveness is judged on criteria such as retention during treatment, decline in the use of illegal drugs, high-risk practices and HIV-HBV-HCV seroconversion, and an improvement in health and social integration.

Other formulations of HDB (injectable or inhalable) are currently being tested for their effectiveness and safety amongst different types of drug users (buprenorphine injectors, patients failing with methadone, multiple drug users, etc.). Treatments for psychostimulant dependency are also being evaluated for their impact on high-risk behaviors for HIV and HCV transmission. Finally, the identification of methods of prescription of morphine sulfate for opiate dependency and patients concerned could be envisaged in order to set up a new care framework.

Syringe exchange programs

Syringe exchange programs (SEPs) put sterile injection equipment and injection preparation equipment at the disposal of drug users. This may or may not be provided free of charge. According to the country, these programs are integrated into a coherent risk reduction system or take the form of an ensemble of regional or local programs. The organization and method of working of these programs can be very diverse in terms of localization (community, specific service, service in a treatment institution, pharmacies, fixed or mobile structures, automated distribution, etc.), accessibility and services offered.

Syringe exchange programs began in the mid-1980s in Europe, under the pressure of the HIV/AIDS epidemic, with the first programs being created in 1984 in Germany and the Netherlands. In 1990, 15 European countries were using these programs and in 2009 all the countries in the the European Union were involved. The majority of the early programs were financed by private funds, before obtaining public funding. In Australia, they were also initiated in the 1980s, whereas in the U.S.A. they took longer to develop due to a government ban, put into force in 1988, against using federal funds for this purpose. This ban was lifted in December 2009. Gradually, SEPs have developed in the U.S.A. with the use of public funds (towns, counties and states). In 2007, there were 185 SEPs in 36 states.

Several journals, a dozen meta-analyses and recent articles have evaluated these programs. Evaluations have measured the evolution of various indicators of results and impact. These indicators represent the programs' potential cascade of effects, from the most proximal (direct effects of intervention measured by changes in SEP user behaviors) to the most distal (final effect on the incidence of HIV and HCV in SEP users).

The practical and methodological difficulties of evaluations must be emphasized from the outset: drug users, in particular those who are the most marginalized (and at high risk), are a difficult population to recruit and retain for long-term studies with a strict protocol; SEPs co-exist with other risk reduction measures (sale of syringes in pharmacies, user advice programs, substitution treatments, etc.), making the attribution of causal links difficult; the low incidence of HIV and HCV is an additional problem for obtaining conclusive data. De facto, the crux of the accumulated evidence is based on observational studies, no experimental study having been carried out.

Potential effects of SEPs (according to Tilson et al, 2006)

Drug use-related behaviour	**Sexual behavior**
Decrease in frequency of use (+)	Number of sexual partners (?)
Decrease in injection frequency (+)	Frequency of unprotected sex (?)
Decrease in frequency of equipment sharing (++)	Sale of sex for drugs or money (?)
Increase in disinfectant use (+)	**Links between health services and social services**
Undesirable effects?	Orientation towards general and specific services (+)
Attraction of new injection drug users: No	Extent of use of services (+)
Increase in inappropriate disposal of equipment: No	**Incidence/prevalence**
Increase in prevalence of injection use or frequency: No	HIV (+/+)
Discouragement regarding beginning treatment: No	HCV (?/+) and positive effect on incidence in association with OST, suggested by recent data

+ /++: Existing evidence; ?: (As yet) insufficient evidence

Concerning high-risk behaviors (sharing injection equipment and injection frequency), all studies conclude that participation in a SEP reduces injection-related high-risk behaviors, in particular self-reported sharing of equipment but also reuse of equipment, and improves the safe disposal of used equipment. Some studies have reported a decline in injection frequency and an increase in use of disinfectants. Access to injection equipment via pharmacies carries an additional benefit which is specific to SEPs. The few studies carried out into sexual behaviors, which are not the main target of SEPs, do not allow for a conclusion on their impact.

Journals do not demonstrate undesirable side effects such as increase in injection frequency, drug use, loan of syringes to other users or discarded syringes. Nor is there mention of the attraction of new users, declining motivation to reduce use or increasing transition of non-injection drug users to injection, or increases in criminal offences linked to drug acquisition. Furthermore, referral towards both health and social services is improved, and use of other services by SEP users, whether general or specific, seems to increase.

In a journal from 2004, the authors concluded that "solid evidence of effectiveness, safety and economic advantages" could be found regarding the effect of SEPs on HIV transmission. Other recent and converging ecological studies indicate a modest effect on the prevalence of HIV and a limited and non-definitive effect on incidence.

Effects of SEPs on the incidence and prevalence of HCV are more difficult to establish. The authors of a journal from 2008 concluded that there was still insufficient evidence to confirm or eliminate the hypothesis of effectiveness of SEPs on HCV incidence. Furthermore, ecological studies have shown stable or declining prevalence rates associated with SEPs. The results of dynamic modeling studies have provided similar results.

In 2009, several pieces of work shed further light on the effects of SEPs regarding HIV or HCV transmission. A study carried out in 7 cities in the U.S.A. between 1994 and 2004 showed there was no significant relationship between the existence of SEPs and the probability of HCV seroconversion, but highlighted an effect on high-risk behaviors. The correlation between high-risk behaviors and HIV/HCV transmission therefore suggests an indirect effect. A modeling study carried out in Australia on the effect of SEPs on HIV and HCV transmission concluded that SEPs can have an effect on the incidence of HIV but not on that of HCV, which requires a larger intervention coverage. Finally, as previously mentioned following the data from a study carried out on a cohort of drug users in Amsterdam, "emerging positive evidence" exists regarding the effect of combining SEPs and OST on HCV incidence.

Even if evidence of the effectiveness of SEPs on HIV and HCV transmission according to recent journals is not as strong as that from previous studies or journals, the authors emphasize that this in no way implies a lack of effectiveness of SEPs or the existence of more effective alternatives. High-level evidence will be difficult to obtain and existing evidence is sufficient to recommend the establishment or extension of SEPs where it is possible and pertinent.

Complementary measures responding to specific requirements: supervised injection centers

Supervised injection centers (also known as supervised injection sites (SIS)) are structures where injection drug users can go to inject drugs – which they bring with them – in a safer and more hygenic way, under the supervision of qualified staff. Historically, supervised injection centers first appeared under pressure from several phenomena: the increase of injection drug consumption (heroin or cocaine), the arrival of the HIV (and HCV) epidemic, and the growing presence of drug consumers in extremely unstable social situations, often without fixed abode and consuming drugs via injection in public areas.

Currently, supervised injection centers exist in 8 countries: Germany, Australia, Canada, Spain, Luxembourg, Norway, the Netherlands and Switzerland. These centers work towards risk and harm reduction objectives for drug users and for the community, in the fields of public health and public order.

Certain information can be drawn from critical analysis of literature, including several in-depth journals, regarding the effects of supervised injection centers in terms of their objectives.

Objectives and effects of supervised injection centers (according to Hedrich et al, 2010)

Ensuring suitable coverage and operation
Reaching high-risk injection drug users (++)
Ensuring safer injecting (++)
Improving the health status of injection drug users
Reducing high-risk behaviors (+)
Reducing morbidity: HIV/HCV (?), abscess (+)
Reducing mortality (indirect, via avoided fatal overdoses) (+)
Improving access to healthcare (basic, general or specific) (++)
Reducing negative impact on public order
Reducing consumption in public places and associated nuisances (+)
Improving the perceptions of the population (+/-)
Not increasing consumption-related criminal offences (+)

+/++: Existing evidence; ?: (As yet) insufficient evidence; +/- : Variable effects (time and place)

Regarding the ability to reach high-risk users, studies show that supervised injection centers are able to reach very vulnerable injection drug users who are accumulating risks (without fixed abode, frequent injecting and/or injecting in public areas, recent previous overdose, carriers of infectious diseases, failure of dependency treatment, etc.), but also users in less unstable situations. Satisfaction surveys carried out amongst users show that supervised injection centers respond to their requirements. Supervised injection centers experience high rates of use when located in suitable locations (near drug user meeting places and dealing sites) and when they offer a good coverage of opening times.

All evaluated supervised injection centers have proved their ability to operate in a stable way and to guarantee good hygiene and safety conditions for users and staff.

Supervised injection centers have proved they assist in the reduction of morbidity and mortality associated with overdoses. They enable rapid and effective intervention in the case of overdose. No fatal overdose has been recorded in a supervised injection center, despite millions of injections having been carried out, and several estimates of the number of avoided fatal overdoses have been achieved.

Supervised injection centers ensure promotion of injection hygiene (handwashing, disinfection) and the provision of sterile equipment, as well as supervision of injections and sometimes the teaching of safer techniques. Studies clearly show a reduction in abscesses and other injection-related diseases and a reduction in high-risk HIV/HCV transmission behaviors (sharing used equipment or injection preparation equipment) amongst drug users, with a probable influence on the user community. It is not possible to draw conclusions on supervised injection centers' specific impact on HIV or HCV incidence. This is mainly due to a lack of studies, due to methodological difficulties (population coverage, low incidence, etc.). Furthermore, this is not the principal aim of supervised injection centers.

In addition to basic care provided in situ, health care professionals in supervised injection centers can direct users towards general care structures or dependency treatment, as well as towards social assistance. Although a significant proportion of users are or have already been receiving treatment, some studies show an increase in the number of users entering treatment for their dependency. The results of studies therefore suggest a complementarity between supervised injection centers and dependency treatment.

There is no evidence that the presence of supervised injection centers increases or reduces drug consumption amongst users or in the community although this presence does increase relapses amongst drug users receiving treatment. Studies have reported a decline in public injecting as well as a decline in discarded injection equipment and waste material in public areas, as supervised injection centers cover requirements (available sites, opening hours).

Two studies have explored the impact of supervised injection centers on criminal offences linked to the acquisition of drugs in areas where the centers have been introduced and have concluded an absence of any effect (positive or negative). The sporadic occurrence of nuisances such as gatherings of consumers or dealing in the immediate vicinity of supervised injection centers has been reported.

In several countries, opinion surveys have shown a favorable opinion and welcoming of supervised injection centers. However, the setting up of supervised injection centers has almost always given rise to debates and often to opposition, in particular from local businesses, residents and the police. In the majority of cases, these problems subside with time and are less pronounced if preparation for the opening and monitoring of the supervised injection centers is the subject of significant consultation.

The costs of setting up and running supervised injection centers are significant. However, two economic analyses of the supervised injection centers in Vancouver and Sydney concluded that opening supervised injection centers can contribute to reducing society's future financial burden, thanks to their effect on avoided fatal overdoses and HIV transmission. They constitute a potentially profitable investment.

Considering all these elements, supervised injection centers can be considered as a complementary measure (and not in competition) to others in the range of services offered to users which enable a response to specific injection-related risk reduction requirements. They constitute a place of refuge (safety, hygenic conditions for injecting, the opportunity to receive specific advice and instructions), access to basic care and a link to other services, for very high-risk users. They are also used by users who are receiving treatment and have not (yet) been able to give up injecting. Expectations of supervised injection centers should be realistic and take account of this specific and complementary nature.

It should be remembered that existing supervised injection centers operate in enviroments with variable services and ways of functioning. In order for supervised injection centers to be effective, it is necessary for them to respond to identified requirements, which can vary according to the context: level of significance of injecting in public, number of injection drug users who are not in contact with or are ceasing contact with care structures, number of fatal overdoses, existence of injection-related health problems, etc. Their integration within a wider system of services, with good communication between services, is also an element of their success. Finally, in order to guarantee suitable ways of operating, the setting up of supervised injection centers should be based on a consensus between local stakeholders: health, police, political and administrative authority stakeholders, the general population and immediate neighbouring population, and users themselves. An evaluation of the setting up phase is a very important element of the process of acceptance of supervised injection centers.

Care pathways for drug users

Mortality and morbidity linked to chronic viral infections (HIV, HCV, HBV) decline when early care is provided. This justifies the importance of early screening, in particular in order to act on co-morbidity factors, with alcohol consumption in first place. Regarding viral hepatitis, treatment of recent hepatitis is effective, hence the value of re-screening seronegative subjects. Contaminations appear very early in drug users and increase with the duration of drug use. In addition, high-risk practices do not stop with the setting up of OST and/or imprisonment. "Risk" periods in particular need of monitoring are the beginning of consumption(s), the re-starting of consumption(s) (on leaving prison), and lack of equipment

(in prison, significant instability). Adherence and response to treatments are identical to those of non-drug user patients receiving treatment. Recontamination after recovery can also be treated. There is insufficient data to evaluate the number of infected patients monitored in dedicated care structures: only a third of CSAPAs and UCSAs (Consultation and Outpatient Care Prison Units) can offer hepatology or infectious diseases consultations. Screening is offered in 3/4 of these structures and is rarely refused.

Screening of chronic viral infections relies on conventional serology, preferably combined with a simultaneous dosage of nucleic acids and hepatic enzymes in order to limit the number of blood samples. Within this population, there is interest in the use of saliva tests, the Western blot method or Quick Tests for HIV. This relates more to outreach methods than to true screening. For certain methods, validation has still not been obtained. It is essential to standardize biological assessments in order to avoid multiple samples after a first positive test in subjects with limited venous capital. For non-invasive evaluation of hepatic fibrosis, physical tests (fibroscan®) or biological tests (Fibrotest®, Fibromètre®) exist and can be privileged, also preferably on the same site.

Care can be taken charge of at all general medicine and specialist consultations, in particular at the point of OST prescription, as access to OST increases access to screening, evaluation and treatment of viral hepatitis. Care can also be taken charge of in sites where there is access to healthcare, where care is not initially dedicated to AIDS or hepatitis.

The significance of alcohol consumption amongst drug users has been observed: 16% to 40% of HCV-positive patients are alcohol-dependent and conversely 5% to 15% of alcohol-dependent patients are HCV-positive. Alcohol leads to a lifting of inhibitions which increases risk taking and polyuse (the level of which is in practice little-known). Alcohol aggravates fibrosis and seems to decrease adherence to treatments and response to treatments. In the case of viral hepatitis B or C, no alcohol consumption is without risk. However, a decline in alcohol consumption after hepatitis C diagnosis has been observed. Particularly vulnerable populations are subjects living in very unstable conditions, migrants, prisoners, women, prostitutes (male and female), psychiatric patients, and young people when starting drug-taking or in party environments.

A care pathway, from screening to treatment, is possible and feasible for drug users in different contact sites (CAARUD, CSAPA, UCSA, SAU[1], general practitioner, associations, etc). Health care professionals (doctors, nurses, social and association stakeholders, etc.) must be able to offer conventional or "rapid" screening, using conventional sampling methods or self-taking of samples or via capillary screening. Depending on the result, they can encourage preventative measures such as antiviral B vaccination or refer the patient to a specialist consultation (preferably on the same site). Co-morbidities, which are frequent (infectious co-morbidities, addictions, metabolic syndrome, being overweight, psychiatric illness, etc.), also need to be cared for.

Cost-effectiveness of risk reduction devices

The hepatitis C virus is indisputably the cause of a significant economic cost for national economies. In France in 2003, direct health costs linked to HCV pathologies attributable to drug use were estimated at between 239 and 249 million euros; costs of the same order of magnitude were indicated for HIV.

[1] SAU : Home emergency service

Due to the significant number of contamination in the drug user population and the cost that this epidemic represents for local authorities, it is expected that risk reduction devices will reduce the number of transmissions and lead to effective care for drug users infected by the virus. HCV prevention and care of infected drug users provided by devices such as syringe exchange programs, delivery of opiate substitutes and the setting up of "supervised injection centers" are economically evaluated in international experiments.

Cost-effectiveness studies only consider the point of view of direct financiers of devices and not the societal point of view when it comes to taking into account the costs generated by HCV: considering the probable signficance of the social cost of HCV, all evaluated devices are probably very cost-effective due to the economic savings they produce.

Following review of international literature on the subject, evaluated risk reduction devices can be arbitrarily grouped into three types: "medical" devices, i.e. those used following HCV screening and treatment; "field" devices such as syringe exchange programs or even supervised injection centers; and risk reduction devices aimed at imprisoned populations, like prisoners in penitentiary facilities.

It it important to clarify that treatment such as that used for HCV has been cost-evaluated for drug user populations. Under the constraints of adherence to treatment, of tolerance and of the risk of reinfection, analysis suggests that antiviral treatment for former or current injection drug users is shown to be cost-effective: these therapies strongly reduce the risks of developing liver complications, extend life expectancy and improve quality of life. Furthermore, it has been shown that the cost-effectiveness of HCV treatments was all the stronger when individuals were stabilized in their OST.

Generally, "medical" devices in the risk reduction policy show themselves to be cost-effective in fighting the HCV epidemic amongst drug users. More precisely, analyses of the cost-effectiveness of screening and treatment initiatives for infected individuals, also carried out in Canada, Italy, England and France conclude in favor of the cost-effectiveness of these measures. However, the cost-effectiveness of screening devices and setting up treatment if necessary varies according to the virus genotype and liver biopsy acceptance rate. This last point is today irrelevant thanks to non-invasive methods of diagnosis, whereas the first point relates explicitly to the difficulty of treating genotypes 1 and 4, which makes the ultimate cost-effectiveness of the device in question even better with regard to treating genotypes (as they lead to higher health costs).

Syringe exchange programs and supervised injection centers do not appear to be truly cost-effective in fighting HCV. It is, however, noted that these studies, carried out in different countries, agree on the undeniable cost-effectiveness of these devices in fighting HIV contamination. Whilst these risk reduction devices contribute strongly to reducing rates of syringe sharing, the cost of one avoided HCV infection as a result of these devices is clearly higher than that attributable to HIV: the greater infectious capacity of HCV compared to HIV explains this difference. However, with regard to supervised injection centers, it should be added that they contribute to the reduction of public nuisances linked to drug consumption, and thus can be seen to be cost-effective measures.

It is equally difficult to conclude on the cost-effectiveness of risk reduction policies aiming at screening and treating hepatitis C in imprisoned drug users. The length of imprisonment is a key factor in the measure's efficiency (HCV treatments requiring time), but another determining factor is the possibility for the prisoner to be able to undergo one or several screenings during his or her imprisonment, not solely on entry to prison.

Ultimately, whilst the risk reduction policy's cost-effectiveness in fighting HIV is proven, considering cost-effectiveness in the fight against HCV yields mixed results. Two reasons can

be advanced to explain this difference. The first reason is linked to HCV's very significant infectiosity. Subsequently, it is apparent that the implemented methods which have contributed to a decline in the rate of syringe sharing and to a reduction in HIV contaminations are insufficient to fight the HCV epidemic. Revitalizing this decline in the rate of syringe sharing leading to any effect on the HCV epidemic would then necessitate methods which would without a doubt be economically excessive. The second reason is that the most significant costs attributable to HCV pathologies, such as the necessity of liver transplants, only occur very late in the infected individual's case history, and therefore are of little value for Markov simulations; financiers having a strong preference for the short term.

Access to risk reduction devices in France

Risk reduction devices are simultaneously built on structures, programs and complementary initiatives. Their objective is preventing risks of infection by making available sterile injection equipment, distributing preventative messages, facilitating access to screening for high-risk populations, prescribing OST and supporting users in access to care, rights, housing and employment.

The following devices take part in these initiatives: general practitioners, pharmacies, the specialized medico-social device of CAARUDs (first line services) in complementarity with CSAPAs (specialized services), association stakeholders outside the medico-social field and municipal devices.

Points of intervention are diverse: dispensaries, medical practices, reception centers, on buses, on the street, in green spaces, in train stations, in squats, in prison or on the party or festival scene (large events, clubs, etc.). Methods of intervention are equally varied: fixed contact points, mobile teams, street teams, teams on the festival or party scene and teams working in prisons. Although more distanced from drug users, various institutions are involved in the field of information (INPES - the French National Institute for Health Education and Prevention, National Alert Cell) or device evaluation (OFDT, InVS).

Concerning the device in the form of dispensaries, data from 2003 indicates that 85% of pharmacists see at least one drug user per month in their dispensary requesting equipment (syringes or prevention kits) or OST. This figure stood at 54% in 1999. This activity is however limited to basic functions concerning distribution of syringes and/or substitution medication. Nearly 60% of pharmacists are not prepared to participate in a syringe exchange program.

In 2008, a little less than two thirds of general practitioners saw at least one opiate-dependent user in the course of the year; this proportion has clearly risen in the last few years. Doctors see at least 1.8 opiate-dependent users each month, which leads to an estimate of 110,000 patients seen each month on average for OST (without taking into account the fact that the patient could be monitored by several doctors).

In 2007, approximately 130,000 people in France received opiate substitution medication, of which HDB represented 75% to 80% of the total. In 2007, as in 2006, just over 60% of patients were receiving regular treatment. The rest of patients received prescriptions for substitution products irregularly or alternatively requested prescriptions for treatments most often with the aim of re-selling them. However, a downward trend has been observed in various predictive indicators regarding the potential "hijacking" or misuse of substitution medication, principally HDB. Thus, the proportion of people benefiting from a daily dosage over 32 mg/day has declined in recent years.

Today, a significant access differential persists in France between HDB, the initial prescription of which can be provided by a general practitioner, and methadone, which can be prescribed by practitioners in specialized centers or healthcare institutions. The structures which deliver this are not equally distributed over the national territory and furthermore can find themselves saturated by demand.

According to various information sources regarding injection equipment, it can be estimated that nearly 14 million syringes were sold or distributed to drug users in 2008. By relating this data to the 81,000 recent injection users, a ratio of around 170 syringes per year and per user is obtained. Partly due to the absence of reliable evaluation of requirements and partly taking account of probable geographical disparities (notably rural areas), this estimate remains difficult to interpret.

Despite a decline in recent years, sales of syringes to drug users in pharmacies constitute the main source of provision. CAARUDs currently account for just under a quarter of all syringes sold or distributed to drug users. The decline in the number of syringes distributed to drug users over the last ten years could be linked to the decline of injection drug users in drug user populations, with the exception of certain specific groups, or to the revival of sharing and re-use of syringes which has been observed amongst certain drug users, in particular those in the most unstable situations.

Although automated distribution accounts for just under 10% of the total of syringes sold or distributed in France, automatic distributors deliver injection kits such as Stéribox®, reaching a different population from that of other devices thanks to good accessibility to injection material (anonymity and 24 hour availability). In 2007, 255 prevention kit distribution points and 224 syringe collection points were counted, spread over 56 départements (French administrative authorities). Just over 40% of French départements are therefore lacking these points. This device is fragile because a quarter of distributors are ageing or in a bad condition.

Estimate of the number of syringes sold or distributed by various devices

2008	Number of syringes sold or distributed (in millions)
Pharmacy: single unit	4.3
Pharmacy: in a Stéribox®	5.2
CAARUD: single unit	2.3
CAARUD: in a Stéribox®	1.0
Automatic distributors	1.0*
Total	13.8

* 2007 data

In 2007, 97% of CAARUDs, medico-social institutions financed by social security, offered a fixed point of reception for drug users, 57% had street teams, of which 68% worked in squats and 33% had mobile teams, 36% worked on the festival or party scene and 20% had developed initiatives in prisons. They contribute to the distribution of clean injection equipment (3.3 million syringes in 2007) and other prevention equipment (accessory injection equipment, condoms, etc.). The main initiatives carried out by these structures include: assisting with basic hygiene and care, activities promoting health education, assistance accessing social aid entitlements, monitoring administrative and legal proceedings or searches for emergency shelter. Helping with access to OST and general care is an important mission for CAARUDs: 83% of CAARUDs report setting up initiatives for access to treatment (referral or monitoring).

In 2008, CAARUDs saw 48,000 people. The active patient register is, on average, around 200 people per structure but with very mixed realities: 41 structures have an active patient register of less than 200 people, whilst only 11 CAARUDs record over 1,000 people. Recently, more women and young people from the next generations have been seen by CAARUDs. A certain number of associations which are not labelled as CAARUDs operate in particular on the party and festival scene and, in this arena, play a central role in risk reduction. The role of CSAPAs in risk reduction, which is one of their missions, cannot be specified due to an absence of data caused by the short period of time the device has been in action. Anonymous and free information and screening centers (CIDAGs), which numbered 307 in 2006, plus 76 CIDAG satellite units in prisons, are a key device for the screening of viral infections in drug users.

Whilst the risk reduction devices system covers the majority of French territory, 25 départements do not have a CAARUD, and 2 of these do not possess a CSAPA either. Furthermore, there is a lack of facts available with which to draw conclusions on the relevance of their locations, namely, near drug user populations. In terms of social support and in particular access to housing, which is one of drug users' main requirements, the response offered does not seem to be at the level of demand by a population that is widely and significantly unstable.

The suitability of devices for drug users' requirements and the requirements of the public without medical coverage is a key element to take into consideration when addressing the issue of enlarging the range of responses proposed for risk reduction in France.

Conditions for setting up initiatives for risk reduction in France

In order to function as well as possible, risk reduction initiatives and programs require safe access for users, cooperation between stakeholders who are involved in the operating of these initiatives and programs, and the understanding of neighbouring populations.

Police presence and the risks incurred by users linked to the possession of risk reduction equipment has been seen to be a hindrance to access to healthcare and risk prevention. Police presence itself increases risk taking (rapid consumption, discarding equipment in public areas, etc.). The most marginalized users are the most exposed to police surveillance, leading these users to take more risks. The possibility or impossibility of consumption in private locations seems to be a discriminating factor in risk taking.

The discretion of devices is mentioned in several documents as favorable to use by users and guaranteeing their anonymity. This takes many forms, such as a wide range of opening hours, integration into the environment and not gathering around the tool.

Besides accessibility and user expectations, cooperation between stakeholders (notably within the socio-sanitary sector) and the existence of care networks appear as factors contributing to the success of programs offering better access to care for users and prevention of infectious diseases.

Risk reduction is practiced, in particular in France, by various stakeholders. The main stakeholders are: associations working against AIDS, associations or structures specializing in addiction care, so-called self-help groups, health stakeholders (pharmacists, private-practising physicians, general and specialist hospital services), certain stakeholders in the criminal field and social services. One of the issues in obtaining the most accurate information possible (taking account of available knowledge) on drug users, and thus the associated risks, is the initial and on-going training of these stakeholders. General training

aimed at non-specialist stakeholders should be distinguished from training aimed at stakeholders who are potentially in contact with users (pharmacists, private-practising physicians, etc.). According to some studies, these training initiatives (and accompanying initiatives), which are carried out in certain cities, yield good results in terms of improvements in the perception of drug users.

Work relating to cooperation between stakeholders in the criminal field and the health field, in particular at sites where risk reduction tools have been set up (CAARUDs, automated distributors, etc.), prove that cooperation greatly facilitates the implementation and development of measures, access to care for drug users, and the ability to maintain a coherent position when faced with potential critics.

Two recent examples of casework, one carried out in Marseilles and the other in Quebec, show that representations of users vary significantly between casework. The more casework considers drug usage as a problem relating to social and collective responsibility, the more tolerant it is of risk reduction. Conversely, the more casework defines drug usage as a matter of individual responsibility for the consumer, the more risk reduction is criticised, with other approaches being preferred (imprisonment, mandatory care, primary prevention). At the national level, when those surveyed are questioned about the appropriateness of the risk reduction policy, in general their opinion is positive. However, geographical proximity to risk reduction tools does not necessarily contribute to better acceptance.

In France, initiatives aimed at residents are most frequently devised after the setting up of devices and aim to confront disputes, with the aim of putting an end to them. Several studies describe these initiatives and try to point up the variables which enable disputes to become cooperation. The described disputes are often extremely violent (repeated complaints, damage, violence, and more rarely legal action) and lead to the involvement of political stakeholders (either to defend against or take the side of residents). Faced with long-lasting or recurrent disputes by residents, the types of mediations proposed are relatively varied (e.g. outreach work, public meetings, participation in on-site technical committees). There is no good practice guide.

Variables affecting the success of tool installation

Realistic representations of the problem
Commitment of local elected representatives and the local political community (especially at the municipal level)
Coherent position held by the various involved parties (elected representatives, outreach workers, police officers, street menders, etc.)
Frequency of meetings and explanations (not taking tolerance for granted)
Sharing knowledge (of residents and risk reduction stakeholders) as opposed to top-down approaches of explanations by professionals directed at residents
Mixed teams sent to meet with dissatisfied residents (mix of professions and area, similarity of position held by the various involved parties)
Discretion of tools and devices

Initially aimed at the most marginalized users, outreach or local intervention work can also be used as mediation tools. In fact, over the years they have been extended to protesting residents. The results of these initiatives have not received much evaluation, but the rare available casework highlights their necessity at installation sites where disputes are significant or even violent. The investigations also specify that these tasks rely on identifiable and transmissable skills. Technical committees or round table discussions can be used to bring together and share the knowledge of residents and risk reduction stakeholders. These

seem to produce better results than one-off public meetings. In the mid to long term, residents' continuous participation becomes a problem, as with other deliberative democracy processes. The quality of exchange (the impression of being heard or not) seems to be a determining factor in the length of residents' participation and their good will.

Risk reduction devices adapted to women

According to "Eurosurveillance" data, a third of opiate users in Europe are women. In certain European countries and the U.S.A., women represent around 40% of drug users. In Eastern Europe this figure is 20%. In France, data from specialist care centers (CSAPAs) shows that, apart from cannabis users, 22% of users in 2007 were women and one woman for every four men used CAARUDs. Approximately a quarter of reimbursements for OST involved women. National perinatal investigations do not question women who have given birth about their consumption of illegal products or opiate or benzodiazepine treatments. There appear to be differences between men and women in terms of their consumption trajectories and the prevalence of psychiatric co-morbidities. Furthermore, it does not seem that there is equality of access to healthcare, nor that women's specific requirements are taken into account in the majority of European countries.

Women are described as having sexual behaviors that expose them more to HIV. In Baltimore, casework showed that the incidence of HIV amongst female injection drug users more than doubled for those with a sexual partner who is an injection drug user. Frequently, women exchange sexual services for drugs, promises of protection, food or shelter. They are more likely to have a sexual partner who uses drugs. In all countries, casework shows that women report more high-risk behaviors than men, due to the fact of having a sexual partner who is a habitual injection drug user, or multiple casual partners. In addition, women are often initiated by men into injection practices in the context of intimate relationships, in particular during adolescence. In France, during the Coquelicot survey carried out between 2004-2006, the authors reported the same observations relating to the accumulation of risk taking linked to use and sexuality. In New York, out of more than 300 new injection drug users, the proportion of women initiated by a man is 62% compared to 19% new injection drug users initiated by a woman.

Women not only share injection equipment with their sexual partner, they also present more risks as injections may be administered by another person, notably their partner. This practice, which conveys domination and a loss of independence for women, contains more risk of injury, pain and psychological implications than self-injecting. Cohort monitoring in Vancouver of over 1,000 seronegative people showed an incidence rate for HIV which was doubled amongst those who had asked for help injecting. These people were three times more likely to be women.

Prostitution, violence and homelessness are acknowledged as risk factors for sexually transmissible diseases, HIV and hepatitis. The risk is significantly higher for women in the street or without fixed abode. Women admit much more than men to obtaining money or drugs in exchange for sexual services.

According to European estimates, amongst female problematic drug users 6.5% to 11% become pregnant each year, or 30,000 opiate users, risking the transmission of AIDS or hepatitis to their child. In France, Audipog data regarding drug addiction during pregnancy, intravenous or otherwise, estimated 2,400 to 5,000 affected births. In this context, the number of pregnant women using OST can be estimated at approximately 3,500. When other, non-

evaluated consumptions are added to this, approximately 1,600 women consume more than three glasses of alcohol per day during pregnancy (Audipog).

Rates of miscarriage and premature births are increased. Fetal abnormalities, restricted intra-uterine growth and withdrawal syndromes in newborns are amongst the most frequent consequences, besides the effects of alcohol on the fetus, notably fetal alcohol syndrome. A dead stop to consumption during pregnancy, in particular of opiates, can affect the fetus and lead to a withdrawal syndrome, the intensity of which can cause fetal death. For this reason, current recommendations are to never attempt opiate withdrawal during pregnancy but to propose a substitution treatment.

Interventions aiming for better medical supervision of pregnancy in women drug users should prevent the risks of vertical transmission of infectious diseases and/or enable immediate care of newborns. There is a major risk of vertical transmission for hepatitis B; this risk also exists for hepatitis C during pregnancy and at birth, but not through breast-feeding. A substitution treatment during pregnancy is the major interest for referring the mother to obstetrical monitoring and monitoring for her addiction. However, other aspects merit further examination, such as the risk of unwanted pregnancy under Subutex, due to the reprise of the menstrual cycle after heroin consumption has ceased, which necessitates a systematic consultation regarding contraception. Furthermore, debates on reducing the posology for a pregnant woman continue, in particular amongst users, as the general medical consensus is in favour of increasing dosages in order to take account of the mother's metabolism and in particular her weight gain. There are few proven links between the posology of OST and the severity of the withdrawal syndrome in the newborn, whereas the disadvantages of decreasing the posology seem more significant, notably because there is a risk of the mother finding a balance via consumption of more teratogenic products, in particular alcohol.

Withdrawal syndrome in the newborn is the major risk following exposure to opiates, benzodiazepines and, to a lesser extent, tobacco, cannabis or alcohol. This manifests itself a few hours or days after birth, through an ensemble of unspecific symptoms, informed by a severity score. In the most serious cases, children should receive pharmacotherapy, often using morphine hydrochloride, which may last from a few days to a few weeks. Moderate syndromes can be treated with nursing techniques and prolonged contact with the mother, sometimes including breast-feeding. The syndrome is more frequent under HDB than methadone, but in both cases affects at least half of children.

Another risk for children is passive exposure to products (tobacco, cocaine, etc.), but also accidental ingestion of legal or illegal substances in their parents' possession. Furthermore, the risks of negligence or abuse of children in a context of drug addiction and the lifestyle associated with this should not be underestimated. In the U.S.A., it has been possible to estimate that 40% to 80% of families with whom children's services become involved have problems regarding the use of alcohol or drugs.

A risk reduction policy aimed at women is based on work that highlights that addictions have specific causes and consequences for women. A punitive approach towards women who consume drugs during pregnancy has for a long time been the most common approach. Very recently, risk reduction programs have appeared which focus on mothers and pregnant women in order to offer them specific services. Forerunners of these services were the English, who in 1995 started having drug liaison midwives.

Research shows that fewer women present themselves to care centers of their own accord than men. The main reason appears to be that illegal use of narcotic drugs can constitute a legal basis for foster care of their children. However, keeping their children and protecting them is also a major motivation for mothers to enter a treatment program, and the presence

of children is an essential support for mothers to enter treatment. For these reasons, women tend not to attend specialist care centers and instead approach their general practitioner, even preferring to sort out the problem alone, without cure or treatment. The partner, himself a drug user, is generally described as an obstacle to treatment, as the couple is built on the relationship to the product.

There are very few mother and child reception centers in France, despite a problem of addictions amongst women. Such places are notoriously insufficient in the Paris region. This lack is even more striking in terms of reproductive health services aimed at drug users. In international literature, in the absence of specific care locations, programs offer times dedicated to women and adapted to family life, with child care services or consultations aimed at contraceptive or pregnancy monitoring, home help, or a transport service from the home to the care unit. Some integrated programs for comprehensive women's care simultaneously offer addiction care, somatic and mental health treatments, and some social services exist, but these focus too much on the period of pregnancy and so are not always adapted to long-term care of women and their children.

Risk reduction devices in prison environments

Imprisonment is frequent in a drug user's experience. Data (2004) from the Coquelicot survey shows that up to 61% of drug users (having sniffed or injected drugs at least once in their lifetime) attending specialist structures have been imprisoned at least once. Data from a survey carried out amongst CAARUD "users" in 2008 establishes that nearly 1 user in 5 said they had spent time in prison that year. Another survey carried out in 2008 amongst subjects attending CSAPAs shows that 38% of these heroin, cocaine and other substance consumers had been imprisoned at least once in their life, and for nearly 60% of these subjects the figure rose to 2 or more times.

Various studies carried out in Europe show that between 16% and 60% of injection drug user subjects continue to inject in prison. They do this less frequently than outside prison but take more risks in the process. At the international level, the prevalences of drug use vary according to the study and country, but are high on entry to prison, particularly amongst women. Data concerning drug use in prison is rarer. Where it exists, it shows frequent drug consumption practices (especially regarding cannabis).

Data concerning use of psychoactive substances amongst prisoners in France is old; the most recent dates from 2003. When compared with a similar study carried out in 1997, this data shows a decline in the use of opiates, drug and psychotrope polyuse and, to a lesser extent, cocaine on entering prison. Intravenous drug use or injections are also less frequent. On the other hand, the proportion of prisoners receiving OST on entering prison is increasing. There is no recent data on drug use within prison apart from data from the Coquelicot survey showing the frequent practice of injections and sharing of injection equipment.

Injection practices, especially regarding initiation to injection in prison have been described in all countries which have researched such practices, but at variable rates, reflecting the profile of the imprisoned subjects. In France, data from the Coquelicot survey showed that out of all drug users in care in the community, 12% of the 61% incarcerated at any time had at one point or another practised injecting in prison and among them, 30% said that they had shared their injection equipment at least once whilst in prison. There is no French data concerning sniffing drugs in prison (although this is probably the main method of drug misuse by prisoners receiving HDB substitution treatment).

Despite French and international data on this subject, injection practices continue to be the object of minimization reflecting reality: these are covert practices which are not tolerated, and are less frequent than outside prison but are carried out with considerable risk taking.

There is a high risk of infection in prisons, with a concentration of an unstable population which is frequently involved in drug use, presents high prevalences of HIV, HCV and HBV and has frequent revolving door with free society. The main factor associated with observation of seroconversions for HIV and HCV in prison remains drug use. Tattooing and piercing are also more frequent amongst drug using prisoners. In the national survey on the prevalence of HCV and HBV (2004), imprisonment constituted a risk factor in its own right: the relative HCV risk is multiplied by 10 and the relative HBV risk is multiplied by 4.

International and French data show that the prevalence of AIDS and of viral hepatitis is higher in prison environments than in free society, whatever country is studied. In France, the prevalence of hepatitis C amongst the prison population is close to 7%, that of hepatitis B is close to 3%, and that of HIV is above 1%. The incidence of new contaminations is not evaluated.

Screening for AIDS and viral hepatitis in prison environments in France is organized either by UCSAs (Consultation and Outpatient Care Prison Units) directly or by the intermediary of CIDAGs (Anonymous and free information and screening centers), which themselves depend either on the State or the département (General Council). According to practice casework, 2/3 UCSAs systematically offer this screening whatever the alleged practices. Consultations for delivering results are fairly systematic in the case of positive screening and less frequent in the case of a negative result. Offering the antiviral B vaccination should be systematic.

Since 1994, the organization of prisoners' care has been fully transferred from the French Ministry for Justice to the public hospitals service. The methodological guide relating to prisoners' healthcare, updated in September 2004, stipulates that: "The objective of the healthcare system for prisoners is to ensure an equivalent quality and continuity of care to that offered to the general population". The DGS/DH/DAP circular of 5 December 1996 "relating to the fight against human immunodeficiency virus in penitentiary environments" still determines the framework for prevention, screening, health treatment, preparation for leaving prison and staff training. Prevention and care initiatives are assigned to coordinating UCSAs where they are present, with SMPRs (regional medico-psychological services, totaling 26) and/or CSSTs/CSAPAs in prisons (totaling 16). Treatment and monitoring of HIV and viral hepatitis B and C necessitates a hepatology and/or infectious diseases consultation in situ; in practice, this is carried out in 1/3 UCSAs. Post-imprisonment monitoring remains insufficient.

In France, OSTs have been prescribed in prisons since 1996. Since 2002, the ability to initiate methadone prescription has been extended to all practitioners in public health institutions working in prisons. Whilst the proportion of prisoners receiving OST is progressively growing, there is still a significant heterogeneity from one institution to another regarding access to OST, linked to insufficient resources, deficiencies in training and medical non-disclosure by prison carers. Unsuitable practices (stealing of HDB, solution treatment, etc.) compromise the effectiveness of these therapies and reflect the difficulties experienced by teams working in prisons in situating themselves between care and security pressures.

The WHO considers OSTs as a first line measure in prisons and highlights their essential place in strategies to reduce risks of infection. These treatments have shown their effectiveness at reducing drug use, injecting, mortality and HCV and HIV contamination, as well as recurrence, but less consistently in the case of the latter. Various studies highlight the importance of sufficient OST posologies, treatment duration and comprehensive care in

order for the benefits to become significantly apparent. The importance of developing care strategies for users of stimulants, accompanying preparation for leaving prison and developing therapeutic alternatives, as well as alternatives for education and reintegration into criminal sentences in the case of infractions of legislation on narcotic drugs, is highlighted.

Besides OST and education initiatives, the actual risk reduction devices recorded in prisons in Europe are: syringe exchange programs, distribution of renewable drug use equipment other than syringes (straws, cotton, inhalation equipment, etc.), bleach and other disinfectants, sterile piercing and tattooing equipment, condoms, latex patches and lubricants. Except in Switzerland, there are currently no heroin prescription programs in prisons in Europe and the few existing "drug-free units" have not been subject to studies enabling conclusions on their ability to reduce risks of infection.

Bleach distribution is listed by the WHO as a second line measure, in particular compared with syringe exchange devices, and should not be considered as an alternative to such devices. Its effectiveness in a prison context is further brought into question concerning the prevention of HIV contamination and even more so concerning HCV. In France, bleach is delivered fortnightly to every prisoner by the prison administration. This delivery pattern is often not observed and the majority of the time no clear instructions for use are provided.

Access to condoms is fairly widespread in all French prisons but conditions of access remain inadequate (information for prisoners, confidentiality, discretion, and access often only at the point of care). Various reports record straw delivery for sniffing or occasional handing over by carers of injection equipment against all protocol. Syringe exchange programs are not available in France.

Finally, antiretroviral therapy for HIV and treatments for hepatitis C, by reducing the "viral reservoir", can be considered as contributing to infection risk reduction in prisons, where the prevalences of these viruses are high. Access to these treatments and to post-exposure treatment is described as satisfactory, although few data exist on effective use of the latter.

However, health requirements which should be addressed in specialist consultations (infectious diseases, hepatology, psychiatry, addictology, etc.) are important and are still not fully satisfied. Healthcare teams often suffer from inadequate staffing, with significant disparities between institutions. Additional dedicated resources are necessary in order to make progress.

The main observation is that such different risk reduction tools currently exist, outlined by the 1996 circular, that there is currently no real risk reduction policy in prisons in France. Experience in the field of infection risk reduction in prisons is older and/or more advanced in numerous countries and there is abundant literature showing the benefits of certain measures. Furthermore, the principle of equivalence between care and prevention measures in free society and prison, recommended in 1993 by the WHO, is not observed in France.

Recommendations

The risk reduction policy amongst drug users in France is founded on the setting up of widened access to injection equipment, opiate substitution treatment (OST), HIV screening and antiretroviral treatments, and has played an important role in reducing the incidence of HIV, reducing deaths linked to drug use and improving access to healthcare for drug users. However, inadequate results on HCV infection, the emergence of new populations that are not covered by the existing devices, the development of new high-risk practices and continued injecting by certain user groups, as well as the recent rise in the number of deaths related to drug use, highlight the limits of this strategy.

Risks and harmful effects linked to drug use, in particular the risk of transmission of HIV, HCV, HBV and other infectious diseases, are determined by several factors:

- epidemiological factors (HIV, HBV or HCV viral load, equipment sharing modalities, individual susceptibility);
- psychosocial factors (knowledge and attitudes concerning risk taking, cravings, intoxication), alcohol consumption, psychiatric disorders;
- environmental factors ("rushed" use in public areas, especially in the case of police pressure, lack of access to sterile equipment, prisons).

The injection of opioids (heroin, morphine, buprenorphine) or cocaine which entails frequent taking of the drug, the persistence of other high-risk practices such as sniffing, tattooing and piercing, and excessive consumption of stimulants and alcohol, which leads to risk taking, particularly in terms of sexual behaviors, significantly contribute to HIV, HCV and HBV transmission.

It is essential to document the impact of the programs available in France on indicators of risks and harmful effects linked to drug use, and to evaluate if other therapeutic strategies and health policies for risk reduction implemented abroad or in studies could be envisaged in order to reduce these indicators.

Risk reduction policies cannot be considered as the only provision of tools; they should be integrated into a more global strategy for reduction of social inequalities in the health sector.

To this end, a shared culture should be sought for all stakeholders involved in the field of drug addiction: health professionals (private-practising physicians, pharmacists, hospital doctors, etc.); associations; and stakeholders in the medico-social and social field. "Generalist stakeholders" carry out fundamental work by ensuring access to healthcare and rights, whilst "specialist professionals" work on specific elements for specific populations.

Define a framework for the development of risk reduction initiatives

DEVELOP A HEALTH AND SOCIAL AGENDA IN PUBLIC RISK REDUCTION POLICIES

Changes in practices and harmful effects reinforce the necessity of continuously adapting the societal response to identified "high-risk" behaviors. Risk reduction strategies, when not restricted by inappropriate, repressive policies, ensure social support for users and care for

their health. In this sense, the recent development of Reception and Risk Reduction Support Centers for Drug Users (CAARUDs) has been an important step, as has the boost to the risk reduction missions of Support and Prevention Addiction Care Centers (CSAPAs). The involvement of associations or active stakeholders that ensure interventions are as close as possible to where users live and meet their needs as closely as possible is important in order to help the most vulnerable populations such as homeless minors, migrants, women and prisoners. Treatment of drug users' health problems cannot be isolated from that of social problems.

The group of experts recommends promoting consistency and coherence between various public health, social and penitentiary policies in order to make the whole drug use-related risk reduction strategy effective. A collective approach to risk reduction should be able to address the diverse requirements of each drug user through an individualized response on the part of each care giver. A progressive policy enables risk reduction to be inscribed in the logic of a continuum and not an opposition with strategies for addiction care.

PROMOTE EQUALITY OF ACCESS TO RISK REDUCTION DEVICES FOR ALL DRUG USERS

Risk reduction devices are simultaneously built on structures, programs and complementary initiatives. Their objective is to prevent risks of infection by making available sterile injection equipment, distributing preventative messages, facilitating access to screening amongst a high-risk population, prescribing opiate substitution treatments (OSTs) and supporting users in accessing healthcare, their rights, housing and employment.

OSTs, predominantly prescribed in France with a low demand threshold through general practitioners, represent a major risk reduction device. In 2007, approximately 130,000 personnes received opiate substitution medication, of which high dosage buprenorphine (HDB) made up 75% to 80% of the total.

Mobilization of pharmacists in over-the-counter syringe sales has been strong, but some reluctance persists. Only a minority of pharmacists have accepted the installation of Stéribox® distributors at their dispensary storefront. Access to syringes and injection kits should be in place in 100% of French pharmacies.

Automatic distributors, vending machines, collection and exchange points for prevention kits are currently distributed throughout the national territory. Installed in public areas, managed by volontary associations and/or certain municipalities, these automatic collection and exchange systems enable 24 hour a day access to equipment. At the end of 2006, there were 255 Stéribox® type kit distribution points and 224 syringe collection points in 56 départements. This number is insufficient. A third are obsolete and in need of modernization.

Front-line structures (shops, CAARUDs, buses, etc.) are the contact points located closest to users. They are aimed at active drug users, some of whom are in very unstable situations, offering them various services: snack food, first aid medical attention, shower and clothes washing possibilities, and infection risk prevention equipment exchanges. These do not cover the national territory and are notably absent in the suburbs of provincial towns and cities and in rural areas. 25 départements do not have a CAARUD and 2 départements do not possess a CSAPA either. These devices are essentially most developed in Paris.

The group of experts recommends establishing equality of access to existing programs for all drug users, in particular the most marginalized, via the deployment of this device at national level. In particular, it recommends reinforcing and modernizing the network of automatic distributors by studying the possibility of combining it with several types of distribution

(condoms, syringes, etc.). It would also be judicious to integrate new tools adapted to changing practices with these devices upon their validation.

ADAPT RISK REDUCTION DEVICES TO THE SPECIFICITY OF POPULATIONS

Observation devices enable the regular identification of changes in user profiles and practices, the products consumed and the associated harmful effects. A new psychostimulant (cocaine, "free base" or crack, amphetamines, etc.) user population (young people aged 16-25 years) is emerging on the party and festival scene, as well as in low income districts and suburbs. Whilst this population is still mainly male, the proportion of women is increasing, and notably very young people in very unstable social situations. The fact that multiple drug use, including alcohol, is increasingly commonplace, tends to favor experimentation with new products.

For some years, an increase in cocaine use via injection has been reported in urban areas. Injecting can lead to compulsive drug-taking and health problems due to overdosing are increasingly visible: cardiac events, cerebrovascular accidents, pulmonary damage, psychiatric disorders, without forgetting risks of transmission of infectious diseases (HIV, HCV, etc.). In addition, treatment requests from these consumers only come very late.

Some socially unstable populations (certain migrant groups, homeless young people, etc.) living in shared squats, with various drug use practices, are particularly difficult to care for: illegal situations, language problems, etc. Some associations carry out outreach work known as "street work" which aims to establish dialogue with the most marginalized users, in order to gain their trust and accompany them to care structures or other reception centers. These associations should be supported.

The group of experts recommends taking into consideration the characteristics of user populations in order to define and adapt risk reduction devices, in particular concerning very young people, very marginalized migrants and users with psychiatric disorders. It is appropriate to make use of the know-how of mediation teams who reach out to these populations, and make them more visible. These teams also help with adapting devices to identified requirements, transmitting prevention messages and reinforcing links with professionals in the health and social field: specialist educators, social workers, doctors and nurses.

ADAPT RISK REDUCTION TOOLS AND APPROACHES TO CHANGING SUBSTANCES AND NEW MODALITIES OF CONSUMPTION

Risk reduction policies should be adapted to the development of new modalities of consumption. In recent years, crack inhalation and buprenorphine injection have constituted new sources of infectious contamination, in particular for HCV, leading to other effects on health. In addition, these consumptions concern an often marginalized and highly dependent population. Risk reduction tools should therefore continuously adapt to these developments in target populations.

Field observations enable the identification of sources of HCV contamination linked to drug use. Home-made pipes are used for crack smoking (alcohol dispensers used in cafés, converted soda cans, and filters fashioned from electric wire). The pipe is generally used several times. Problems reported by users are burns and injuries to the lips and hands. Much work has documented the implications of sharing crack pipes as an HCV transmission

vector. However, a prevention tool exists in the form of a Pyrex metering device, tips, filters and cicatrizing cream. These specific drug use-related kits (via smoking) are undergoing evaluation.

Buprenorphine (HDB) injection, in misuse of its design as a substitution treatment, is a fact for a population with severe dependency which is characterized by multiple product use, is often dependent on alcohol, presents depressive syndromes and is without fixed abode. Due to the excipients in HDB tablets, injecting can be accompanied by complications around the injection site: abscess, tissue necrosis and indurated edemas of the arms and hands, but also serious health consequences: acute hepatitis, hypertension, pulmonary embolism, etc. Single-use filters can eliminate, in particular, the particles responsible for fatal health events and minimize the risks associated with this practice. These tools should therefore be considered as part of the range of risk reduction measures available for drug users, whether they are receiving substitution treatments or not.

The group of experts recommends taking into account changing substance usage and consumption practices in order to improve existing measures and to distribute new tools (injection kits, single-use filters, crack inhalation kits, etc.).

ENLARGE THE RANGE OF MEASURES AND APPROACHES IN A COHERENT SYSTEM OF OFFERED SERVICES

Syringe exchange programs (SEPs) and distributors constitute a proven risk reduction measure for reducing high-risk behaviors with ramifications for infection risks (HIV, HCV). Some structures put sterile injection equipment and injection preparation equipment at the disposal of drug users, which may or may not be provided free of charge. This aims to reduce sharing and re-use of syringes, and reduce the number of used syringes discarded in public areas. Some studies indicate an increased impact on infection risk reduction when syringe exchange programs and substitution treatments are combined.

Furthermore, supervised injection centers have been tested in several countries and have been proven to reduce injection-related risks (injections in public areas, abscess, syringe sharing, fatal overdose, etc.) and improve access to healthcare.

The group of experts recommends strengthening links between various programs (SEPs, OST, supervised injection sites if applicable) in a consistent system. The group of experts recommends carrying out a study of requirements regarding the opening of a supervised injection center in order to define the specific objectives of this device (reduce fatal overdoses, reduce the number of abscesses, attract high-risk injection drug users in order to put them (back) in contact with treatment structures, etc.). The setting up of a supervised injection center can only be envisaged if this device responds to identified needs, taking into account changes in modalities of drug usage which can vary from one place to another: the level of injecting in public; the number of intravenous drug users who are not in contact or are breaking off contact with care structures; the number of fatal overdoses and complications linked to injecting (abscess). These centers, if proposed, should be able to meet these requirements. Their integration into a wider system, with good communication between services, is also indispensable. Finally, in order to guarantee proper functioning, their set up should be based on a consensus between local stakeholders: health, police, political and administrative authority stakeholders, the general population and immediate neighbouring population, and users themselves. This requires preparation, explanation and communication phases, taking account of the often negative representations that prevail for

this type of device. Evaluation of the setting up phase is an important element of the acceptance process for supervised injection centers.

PROPOSE THE THERAPEUTIC PLAN BEST ADAPTED TO IDENTIFIED INDIVIDUAL REQUIREMENTS

The relationship with the doctor forms the main support for the various stages of substitution treatment and all other treatments necessary for the user. It must meet expectations and overcome difficulties during the course of substitution treatment. This relationship, which is heavily invested in by users, presents itself as a space for negotiation, adjustments to treatment and for attention to be paid to the individual in their everyday difficulties.

For the doctor, the setting up of substitution treatment can target the stabilization of the user's health and social situation, bringing an end to consumption, and social and professional integration. The doctor-patient relationship adapts itself to the diversity and instability of users' situations during substitution treatment.

For the user, substitution treatment is not a long-term treatment like others. In order to deal with the hazards in their lives and their attempts to extricate themselves from these, users should benefit from treatment which is regularly readjusted, in particular in relation to dosages.

The group of experts recommends that the chronic dimension of dependency be taken into account more, along with the duration of its treatment and the stages of its care via the setting up of a true therapeutic plan. Regular reviews of the individual's situation and the treatment objectives should be carried out through dialogue with the doctor, in order to optimize care and to avoid "misuse".

ENLARGE THE RANGE OF THERAPEUTIC OPTIONS IN PARTICULAR FOR POPULATIONS PRESENTING SERIOUS DEPENDENCY

Methadone and buprenorphine are included in the WHO list of essential medicines. France was the first country to introduce high dosage buprenorphine (HDB) treatment on a wide scale via general practitioners. Currently, methadone treatment cannot be started by general practitioners in France.

In several countries, HDB (up to 32 mg per day) can be prescribed for drug users with serious dependency and those for whom a methadone prescription is not possible (drug interaction).

Some users presenting serious dependency and having undergone multiple therapeutic failures have difficulties progressing from a short-acting product (heroin) to a long-acting product (substitution treatment). They also experience difficulties replacing an injectable substance with an oral substance. Some countries have demonstrated the effectiveness of "medically prescribed heroin" via injection as a therapeutic option for users for whom substitution treatments have not worked.

The group of experts recommends adapting treatment of dependencies to the patient's identified requirements and being able to diversify therapeutic options in order to do so. Firstly, it recommends developing access to methadone in all départements. Contingent on the results of the Methaville trial, the initial methadone prescription could be issued by a general practitioner, using doctors who are willing, trained and appointed to issue this prescription. For patients with serious dependency, those most at risk of HIV, HCV or HBV

transmission and those who cannot be treated with methadone for medical reasons, the group of experts recommends considering (after evaluation), within a strict medical framework, other therapeutic options: higher dosages of buprenorphine, other formulations of substitution medication already used elsewhere (inhalation), as well as medically prescribed heroin as a treatment option via injection.

DEVELOP STRATEGIES FOR THE MEDICAL AND SOCIAL MONITORING OF USERS

The promotion and accessibility of HIV, HBV and HCV screening amongst both injection and non-injection drug users need to be integrated into the risk reduction strategy. The provision of HIV quick screening kits, microsampling for HCV, screening for sexually transmissible infections and a vaccination against hepatitis B are all proposals aiding users to enter the care pathway.

Other than chronic viral infections (HCV, HIV, HBV, HDV), alcohol and tobacco consumption, psychiatric disorders, and infection, especially skin infections, are co-morbidities which are frequent in the user population; their detection should be considered as a priority. A non-invasive measure of liver fibrosis can now be carried out using FibroScan and this measure can also constitute incitement to enter a care pathway.

The group of experts recommends systematically offering screening (and re-screening at least once a year) for HIV, HCV and HBV for all drug users in first-line devices as well as in all places frequented by users (and in particular at the time of OST prescription). Teams need to be made aware of screening for viral diseases and be trained in evaluating general typologies of psychiatric diseases and situations requiring psychiatric referrals.

The group of experts recommends suitable, concomitant and multidisciplinary treatments. In order to reach out to users, it recommends setting up "all-inclusive" outpatient consultation centers in all départements, to be integrated into CSAPAs and providing services ranging from screening to treatment for viral hepatitis and HIV infection and antiviral B vaccination.

The group of experts notes that treatment comes under global somatic, psychological and social care in order to improve the patient's personal, social and familial functioning. Accompanying psychosocial care should be considered as a supplementary and necessary aspect of all treatment.

PREVENT INITIATION TO INJECTION AND PROMOTE LOWER RISK METHODS OF ADMINISTRATION

Data from literature indicates that HIV/HCV contaminations occur early in users' trajectories, probably during the first two years of injections. In France, it has been observed that first injections are taking place at a younger age, which accompanies a diversification of socio-demographic characteristics, consumption profiles and modes of starting injecting amongst young users. The period of initiation is a particularly sensitive and critical period to the extent that the way in which a person is initiated influences their later practices and risk taking.

Taking account of the strongest contagiosity of HCV, the development of strategies aiming to reduce the frequency of injection, to prevent or defer the initiation of injection, and to ensure that injection takes place in lower risk contexts should enable support for a policy to fight HCV. Prevention of the initiation to injection, and promotion of lower risk administration methods, constitute complementary approaches within the existing system.

With this objective, several countries have tested an approach based on so-called brief intervention. The positive results observed translate into a change in behaviors (reduction in the number of initiations, reduction in the number of injections, decline in high-risk practices during injection preparation).

Complementing the conventional approaches of information, education and communication, the group of experts recommends developing brief interventions aimed at promoting the prevention of initiation to injection, injection-related risk reduction and transition to other administration methods which are judged to be lower risk. In order to be effective, these intervention strategies should be adapted and appropriate to individual circumstances and practices and should take account of users' social environments.

SPECIFY A RISK REDUCTION POLICY FOR WOMEN

Female drug user populations present particular risks: violence, prostitution, sexual risks, pregnancy. The number of young female drug users under the age of 25 years in first line structures is increasing. However, women with children present themselves less often than men at care locations, fearing their children will be taken away from them and preferring to "sort it out" themselves, without cure or treatment. The placement of children whose mother is a substance user, in the absence of specific accompanying measures, translates into pure and simple rupture of the link between mother and child.

All products are potentially dangerous during pregnancy and polyuse increases dangers for the fetus. Perinatal consequences are particularly serious: prematurity, fetal distress, fetal death, neonatal abstinence syndrome, sudden infant death syndrome, and mother-child relationship disorders. However, a dead stop, in particular of opiates, can be fatal for the fetus. It is therefore recommended to propose a suitable substitution treatment to favor better monitoring of the pregnancy and addiction. Reducing or interrupting this treatment risks leading to the taking of substances which are more dangerous for the fetus, such as alcohol (fetal alcohol syndrome). Previously, in 2004, a Consensus Conference recommended not reducing or stopping treatments during pregnancy: "Women should be stable in late pregnancy and in the postpartum period, even increasing the posology. An insufficient posology of substitution treatment favors consumption of other psychotropic products, particularly alcohol and tobacco. In addition, changes to the pharmacokinetics of methadone in late pregnancy can necessitate a transitional posology increase, helped if necessary by results of plasmatic dosages".

The group of experts recommends that women's requirements are recognised in first line devices and addiction care centers, in order to offer them services that take account of their specific risks such as unwanted pregnancies, having their children taken away from them, domestic violence and infectious risks, as well as the specific risks for the unborn child in case of pregnancy. It recommends developing global medico-social care programs for duration beyond pregnancy and mother-child reception centers.

DEFINE A CARE AND RISK REDUCTION POLICY IN PRISON ENVIRONMENTS

Reducing risks of infection in prison environments should be considered as an important public health issue. In 1993, the WHO highlighted the importance of guaranteeing the right to identical access to healthcare and prevention for every prisoner as that provided in free society. Since 1994, organization of healthcare for prisoners in France has been fully transferred from the French Ministry for Justice to the public hospitals service. The 1996

circular allowed the basics of a risk reduction device to be laid down in prison environments in France, with the introduction of opiate substitution treatments and advances in fighting AIDS.

However, the question arises of whether this device, as it currently functions, is adequate. Opiate substitution treatments have been prescribed in prisons in France since 1996, and are considered an essential measure in fighting infection risks in prisons. Studies carried out in prisons have shown an effect of treatments illustrated by a decline in the practice of injections and equipment sharing, a decline in mortality, a decline in the number of imprisonments, retention in a care pathway after imprisonment and a reduction in behavior problems in prison.

A very significant heterogeneity is observed in the dispensation of substitution treatments. The proportion of entrants to prison and prisoners receiving substitution treatment, which is on the increase, currently involves 10% of prisoners. In numerous penitentiary institutions, no initiation of opiate substitution treatments exists, neither via high dosage buprenorphine (HDB) nor methadone, despite the extension of initial methadone prescriptions to all practitioners in public health institutions. Current and growing crushing practices of high dosage buprenorphine, or even dilution of the treatment, compromise the effectiveness of these therapeutics and reflect the difficulties encountered by teams in prison environments when working between care and security pressures. The group of experts insists on the importance of initiating treatments on entry to prison and their dispensation without interruption during imprisonment. It recommends defining a therapeutic plan for each prisoner receiving treatment, adapted to the seriousness of his or her dependency with sufficient posologies and sufficiently long treatment durations to allow retention in a course of treatment after imprisonment. It recommends training initiatives for care-giving staff and an adequate workforce to reach greater homogeneity of treatments in prison environments.

Antiretroviral treatments for HIV and hepatitis C treatments, by reducing the viral reservoir, can also be considered as contributing to infection risk reduction as the prevalence of these viruses is high in prison. Screening for viral diseases remains limited in prison environments, with inadequate specialist consultations in many institutions (hepatology, infectious diseases, addictology, etc.). The group of experts is insistent that: screening strategies for HIV, HBV and HCV and sexually transmissible infections be improved; that it be possible to easily repeat this screening during imprisonment, in particular before exiting prison; and that hepatitis B vaccination for unprotected entrants to prison be proposed according to an accelerated immunization schedule.

Recent data from the Coquelicot survey (2006) show that practices carrying risks of infection continue in prison. Amongst drug users who have been imprisoned at least once, 12% have practised injection in prison and 1 out of 3 have shared injection equipment. Furthermore, tattooing and piercing are frequent in prisons amongst drug users. Distribution of bleach, other disinfectants and male condoms with lubricants is partially carried out in most prisons but most often without risk reduction information. Approximately 50 prisons (institutions with high concentrations of drug users) in 12 countries in eastern and western Europe have trialed provision of syringes (anonymous access or handover in person by care-giving staff or external professional health workers). In certain countries or institutions, distribution of renewable drug use equipment exists in addition to syringes (straws, alcohol swabs, inhalation equipment, etc.), sterile piercing and tattooing equipment and female condoms.

Firstly, the group of experts recommends, in accordance with the WHO's recommendations, that the principle of equal access to healthcare and risk reduction measures in prison and free society is applied. Furthermore, after an assessment of practices carrying risks of infection in prison environments, it recommends overcoming the deficiencies observed in France:

distribution of bleach without instructions for use, insufficient access to condoms, not taking into account risks of infection linked to certain behaviors which are frequent in prison environments (sniffing, tattooing, injections, etc.), and lack of access to sterile equipment.

Care-giving staff and prisoners' lack of awareness of the health issues associated with certain high-risk practices leads to the suggestion that all new risk reduction initiatives in prison environments be preceded by preparation and explanatory work aimed at identifying representations and amending them, as well as enabling adherence by various categories of carer. Training and sensitization initiatives for professionals working in prisons should also enable their adherence to a more global approach to risk reduction.

SENSITIZE, TRAIN AND COORDINATE VARIOUS STAKEHOLDERS INVOLVED IN THE RISK REDUCTION FIELD

The territorial location of the setting up of a device aiming to reduce drug use-related risks does not occur without prompting a debate between those who set up the public initiative and the residents living in the vicinity of this device. Furthermore, police forces working in the area of where a device is set up are often badly informed and can impede user access. Professionals working in the street (local agents, prevention leaders, outreach workers) are relay-stakeholders responsible for making contact with users who are outside the care system in order to re-register them in it, for the long term, in the common law system. At the same time, they must establish good relations with the neighbouring area and other professionals working with drug users at the neighbourhood level.

At the territorial level, some shared training for the various stakeholders in the health, social and legal fields should be organized. One of the missions of French regional public health agencies (ARS) is to define and finance initiatives aiming to promote health, educate the population about health and prevent diseases. Training of police forces, magistrates and employees of legal services should be organized within the risk reduction framework because, as studies have shown, strengthening repression is accompanied by an increase in harmful behaviors amongst drug users. ARS agencies should ensure territorial distribution of care offered in such a way as to satisfy the population's health requirements. To this aim, they implement a medico-social organization diagram. It seems important to have inter-professional regional leadership in the field of addictions: in training sessions, awareness of the evolution of products, usage (international, national and regional aspects), and prevention, risk reduction and care strategies could be tackled. The main objective is to provide a common culture by distributing validated data and avoiding barriers and the implementation of inappropriate initiatives (useless or dangerous) based on subjective opinions.

The group of experts recommends coordinating the stakeholders in France who are likely to intervene in this field: directory of networks, knowledge and approval of general practitioners and pharmacists, list of associations, etc. It also recommends making provision for mediation missions amongst local residents in order to facilitate the setting up and acceptance of the structures and initiatives undertaken.

To develop research

IMPROVE AND BUILD ON THE EXISTING SYSTEM FOR SUPERVISION

For approximately fifteen years, France has been endowed with an ensemble of drug consumption supervision tools which are amongst the best-performing in Europe: Baromètre Santé ("Health Barometer") (INPES); ESCAPAD survey (OFDT); ESPAD survey (European School Survey Project on Alcohol and other Drugs) (OFDT/Inserm); Recap survey (OFDT); ENA-CAARUD (OFDT); Trend-Sintes (OFDT); Coquelicot (InVS). This ensemble enables up-to-date documentation of significant changes in drug use and certain health and social consequences.

However, the majority of these surveys concern the evolution of consumed products and relate very little to evolutions in modalities of use. Furthermore, this supervision device only offers very little data on new injection drug users and infectious diseases other than that provided by statements made by users themselves.

The group of experts recommends building on the means necessary to maintain existing national devices. It recommends that new studies and suveys facilitate knowledge of the number of new injection drug users (those having started injecting less than two years ago) or injection drug users under the age of 25 years (according to the OEDT's survey standards).

In order to ensure rigorous monitoring of the prevalence of infectious diseases, in particular HCV, the group of experts recommends integrating the determination of this prevalence by biological markers into national supervision devices. As alcohol consumption has significant health consequences for hepatitis, the group of experts recommends systematizing questioning surrounding alcohol consumption in studies and surveys carried out amongst drug users.

Making comparisons between different studies and establishing evolving trends in the HIV and HCV epidemics in the drug user population is made difficult by the diversity of study periods, geographical origin, the populations studied, survey modalities, statistical analysis methods and also modalities of the presentation of results. The group of experts recommends using European conceptual and methodological standards in all study projects in France. It recommends that data-producing bodies work together and that data produced is made available (via the internet) with validated common indicators.

CONDUCT EPIDEMIOLOGICAL CASEWORK IN PRISON ENVIRONMENTS

No recent data exists on drug use in prison environments. The 1998-1999 Resscom survey carried out amongst prisoners leaving prison highlights the reality of psychoactive substance use in prison: illegal drug consumption (less frequent than in free society) and, above all, misuse of psychotropic medication and opiate substitution treatments (OSTs). In the Coquelicot study (2004), 12% of questioned subjects, who had been in prison, revealed injecting during imprisonment. Within the framework of the Pri2de study, 32% of institutions declared that they had provided care for abscesses linked to injecting (which could also have taken place prior to imprisonment).

The prevalence of HIV and HCV is higher in prison environments than in free society; however, the incidence of new contaminations is unknown. Numerous practices carrying

risks of infection exist in prison and are not limited to injecting. Imprisonment itself constitutes a full-fledged risk factor: the relative risk of HCV is multiplied by 10 and the relative risk of HBV is multiplied by 4.

The age of epidemiological data, the methodological bias encountered in its collection (self-declaration, aggregated data, limited samples), as well as the little knowledge held on the reality of high-risk practices in prison, leads the group of experts to recommend regular and methodologically reliable epidemiological casework to be carried out regarding the use of psychoactive substances on entry to prison and during imprisonment, as well as on the prevalence and incidence of viral and sexually transmissible infections. On a qualitative level, it would be useful to identify high-risk practices in prison by questioning prisoners but also professionals working in prisons. No data exists on drug sniffing in prison (although this is probably the main mode of misuse amongst prisoners receiving high dosage buprenorphine treatment). The group of experts recommends carrying out an assessment identifying and exploring the reality of high-risk practices in prison in order to trial interventions adapted to these practices.

DEVELOP KNOWLEDGE OF DRUG USERS' REQUIREMENTS VIA FIELD STUDIES IN ORDER TO ADAPT RISK REDUCTION TOOLS

Some studies show that certain drug user populations are particularly exposed to risks of infection and are faced with specific problems. This concerns, for example, women who are set against their partner, who is also a drug user; prisoners without access to risk reduction tools; unstable populations or homeless migrants; individuals with psychiatric co-morbidities and first-time injection drug users. These populations are difficult to identify or to reach because they have little contact with risk reduction and care devices. There are often linguistic or comprehension difficulties and little known living conditions.

For example, the requirements of drug addicted pregnant women and mothers have been little explored in the French context. Research that takes account of women's testimonies and explores their life trajectory, not only in terms of addiction and risks but also as women or mothers, should be promoted. Generally, parenthood amongst drug users, both men and women, would gain from being better understood, in order to evaluate the requirements involved and the most appropriate care.

The group of experts proposes privileging research that structures quantative and qualitative approaches which enable the contexts of existence, modes of life and life experiences of users to be tackled in order to define their requirements and respond to these via adapted interventions. The group of experts recommends developing research-initiatives based on the experience and knowledge of relevant stakeholders, associations intervening in the field and associations representing users. Networking with academic research teams is indispensable in order to evaluate risk reduction tools and strategies adapted to change.

EVALUATE NEW RISK REDUCTION TOOLS

In order to be effective, the risk reduction policy should take into account changing practices (products, modalities of consumption) and consumer profiles as well as the evolving contexts of consumptions.

In recent years, consumption of cocaine, ecstasy and amphetamines has increased, whatever the mode of use (injected, sniffed, smoked). Consumptions are frequently associated and

cannabis use is nearly always present. This diversity of consumptions is also observed on the party and festival scene, in particular on the "alternative" scene. The prevalence of HCV is higher in the non-injection drug user population than in the general population. This leads to questions on transmission vectors besides the practice of injecting. For example, sharing crack pipes and preparation steps (making the filter) are suspected as possible exposure pathways.

Risk reduction tools adapted to these new practices are therefore indispensable. The group of experts recommends evaluating new tools using a scientific approach. This evaluation should, in particular, have a bearing on the composition of risk reduction kits linked to crack inhalation.

Misuse of buprenorphine (HDB) in the form of injections concerns 15% of patients receiving treatment as well as other users. This practice can lead to serious health complications linked to the injected excipients. Single-use filters, in particular, eliminate the particles responsible for these fatal health events and minimize the risks associated with this practice. These tools therefore need to be evaluated in the range of risk reduction measures available for users, whether undergoing substitution treatment or not.

Various interventions concerning measures to accompany injection or injection-related risk education should also be the object of evaluation. These interventions are part of a participatory evaluation and knowledge sharing process, which favors the responsibility of the individuals concerned and the involvement of public authorities.

LEAD STUDIES TO EVALUATE DEVICES INCORPORATING AN ENSEMBLE OF VALIDATED TOOLS

When evaluated in isolation, risk reduction programs (syringe exchange programs, opiate substitution treatments) certainly present effectiveness regarding proximal parameters (high-risk behaviours) and much more modest effectiveness on distal parameters (HIV or HCV incidence/prevalence). Studies have shown that effectiveness is improved when several programs are associated. Recently, a study on a cohort in Amsterdam was able to show for the first time that combining syringe exchange programs with opiate substitution treatments had an effect on the incidence of HCV.

Interventions promoting transition to lower risk modes of drug administration are also to be integrated into the device and to be evaluated as supplementary aids. For approximately ten years, so-called "brief" interventions have been developed which are simultaneously aimed at individuals and social contexts through development of specific psychosocial skills. These interventions show positive results in terms of changing behaviours (reductions in number of injections and initiations, transitions to lower risk practices). The English program Break the cycle focuses on the psychosocial aspects of injection, in particular during the initiation period. Initially developed within the framework of an intervention structured around face to face meetings, this program is very flexible, in particular in view of a group or peer approach. For example, it encourages injection drug users to work with their non-injection drug user peers with a view to dissuading them from starting to inject.

The group of experts recommends evaluating different devices integrating several programs by researching the best combination of services in order to best repond to users' requirements and changes in their trajectory.

For the public policy maker, the economic argument can be a strong point for the setting up of health devices. The group of experts recommends that studies evaluating risk reduction tools and devices integrate an economic section, where their methodology allows for this. It

is thus expected that risk reduction tools and devices will be the object of cost-effectiveness, cost-utility and cost-benefit analyses with the aim of comprehending their economic merits.

EVALUATE MEDIATION PROGRAMS

Disputes surrounding the setting up of risk reduction initiatives are often extremely violent (repeated complaints, violence, and more rarely legal action) and lead to the involvement of political stakeholders (either to defend against or take the side of residents). If faced with long-lasting or recurrent disputes by residents, the types of mediations proposed are relatively varied (outreach work, public meetings, participation in on-site technical committees) but there is no good practice guide.

However, it seems necessary to identify and index the different forms of mediation which have been set up in France and Europe when faced with disputes regarding risk reduction initiatives, for example by comparing several districts which have experienced usage or establishment conflicts or by in-depth casework to identify progress from the emergence of conflicts until their possible mode of resolution.

The group of experts recommends evaluating mediation programs so that the acceptability of initiatives aimed at residents or the environment is assured.

DEVELOP RESEARCH CONCERNING PHARMACOLOGICAL TREATMENTS FOR SERIOUS DEPENDENCY

In France, there are principally two therapeutic options for opiate dependency: treatment using methadone or high dosage buprenorphine (Subutex). Other therapeutic options are indispensable for stimulant addictions and for serious opiate addictions that are resistant to conventional treatments.

The group of experts recommends pursuing research on pharmacological treatments for stimulant addictions (cocaine, amphetamines, crack) and setting up clinical and therapeutic research into co-dependencies. It also recommends evaluating the implementation of other treatments that are as yet unavailable in France, such as injectable or inhalable buprenorphine and/or methadone, and using randomized trials to compare medically prescribed heroin to oral methadone and to high dosage buprenorphine, in order to enlarge the range of therapeutic options for users presenting serious dependencies.

PROMOTE COORDINATED PUBLIC HEALTH RESEARCH IN THE FIELD OF ADDICTIONS AND RISK REDUCTION

Currently, research carried out in the field of addictions and risk reduction in France is fragmented, uncoordinated and lacking dedicated funding. France does not, like other countries (e.g. United Kingdom, Australia, U.S.A.), possess an institution capable of creating, initiating, coordinating and financing research projects in this field.

The group of experts recommends coordinating different teams (academic sector and relevant stakeholders) working in the field of addictions and risk reduction. This would enable evaluation of research requirements in the field of addictions and risk reduction linked to all forms of addictions (alcohol, tobacco, legal and illegal drugs, gambling, etc.), and the opening of consistent calls for proposals in epidemiology, human and social sciences, clinical medicine and fundamental research. The group of experts recommends that the

allocated budget for initiatives and structures in the field of addictions includes a part reserved for evaluation and research that takes into account the point of view of associations operating in the field and that of associations representing users.

APPENDIX

Inserm collective expertise: Methodology

An Inserm collective expertise[2] sheds scientific light on a given subject in the field of health on the basis of a critical analysis and synthesis of the international scientific literature. The collective expertise is implemented at the request of institutions wishing for access to recent research data pertinent to their decision-making process with respect to public policy. An Inserm collective expertise is to be considered as an initial stage that is necessary but most frequently not sufficient to result in decision-making. The conclusions of the collective expert review contribute to, but cannot replace, debate between the professionals involved or society debate if the questions addressed are particularly complex and sensitive.

At the request of an institution, the Inserm collective expertise may be accompanied by an 'operational' expertise addressing application of the knowledge and recommendations and taking into account contextual factors (existing programs, structures, players, training, etc.). The latter type of expert review elicits contributions from the players in the field able to respond to the feasibility aspects, representatives of the administrations or institutions responsible for promoting applications in the field involved, experts having contributed to the reviews, and representatives of patient associations. The sharing of varied cultures and experience enables a complementary approach to the collective expertise in an operational framework. Moreover, a variety of work (recommendations for good practices, public hearings, etc.) implemented under the auspices of the High Authority for Health (HAS) may follow an Inserm collective expertise.

Collective expertise has been an Inserm mission since 1994. Some sixty collective expert reviews have been implemented in numerous health fields. The Institute guarantees the conditions under which the expert review is implemented (exhaustiveness of the document sources, qualification and independence of the experts, transparency of the process).

The Inserm Centre for Collective Expertise organizes the various stages of collective expertise from the initial problem statement through to communication of the report, with the assistance of Inserm departments. The Centre team, consisting of engineers, researchers and a secretariat, implements the document searches, logistics and chairing of the expertise meetings. The team contributes to the scientific writing and to compiling the expertise products. Regular exchanges with other public organizations (EPST) implementing the same type of collective expertise have enabled similar procedures to be set up.

Problem statement

The problem statement phase enables definition of the institution's request, checking that accessible scientific literature on the issue raised is available and drawing up specifications which state the framework of the expertise (status report on the perimeter and main themes of the subject), its duration and budget, documented by a convention signed by the sponsor and Inserm.

[2] Inserm accredited label

During the problem statement phase, Inserm also organizes meetings with patient associations in order to ascertain the questions those associations wish to have addressed and the data sources available to them. The information is incorporated in the scientific program of the expertise. For certain subjects, exchanges with industrial partners are indispensable in order to obtain access to complementary data not available in the databases.

Expertise monitoring committee and assistance unit setup

A monitoring committee consisting of the institution and Inserm representatives is set up. The committee meets several times during the expertise to monitor the progress of the review, discuss any difficulties encountered in addressing the issues, ensure compliance with the specifications and examine any new factors in the regulatory and political context pertinent to the ongoing review. The committee also meets at the end of the expertise for presentation of the conclusions and prior to compilation of the final version of the report.

For expertises addressing sensitive issues, an assistance unit is also set up and consists in representatives of the Directorate General of Inserm, scientific board, ethical committee of Inserm, communication department, human and social science researchers and specialists in the history of science. The role of that unit is to identify, at the start of the expertise, the issues liable to have strong resonance for the professionals involved and civil society, and to suggest hearings of professionals in related fields, representatives of civil society and patient associations. In short, the unit is responsible for measuring the perception that the various recipients may have of the expertise. Before publication of the expert report, the assistance unit pays special attention to the wording of the synthesis and recommendations, including, if necessary, the expression of the various points of view. Downstream of the expertise, the unit is responsible for strengthening and enhancing the circulation of the results of the expertise, for instance by holding colloquia or seminars with the professionals of the field and players involved or holding public debates with representatives of civil society. Those exchanges are to ensure enhanced understanding and adoption of the knowledge generated by the expertise.

Literature searching

The specifications drawn up with the institution are translated into an exhaustive list of scientific questions reflecting the perimeter of the expertise with the assistance of referral scientists in the field and members of Inserm. The scientific questions enable identification of the disciplines involved and construction of a key-word arborescence employed in the systematic searching of international biomedical databases. The articles and documents selected on the basis of their pertinence with respect to answering the scientific questions constitute the document base, which is forwarded to the experts. Each member of the group is asked to add to the document base over the course of the expertise.

Institutional reports (parliamentary, European, international, etc.), raw statistical data, associations' publications and other documents from the gray literature are also inventoried (non-exhaustive) in order to complement the academic publications provided to the experts. The experts are responsible for taking or not taking into account those sources depending on the interest and the quality of the information supplied. Lastly, a review of the main articles in the French press is supplied to the experts during the expertise in order to enable them to follow developments on the theme and the social repercussions.

Constitution of the expert group

The expert group is formed on the basis of the scientific skills necessary for analysis of the bibliography collected and on the basis of the complementarity of the group members' approaches. Since an Inserm collective expertise is defined as a critical analysis of the academic knowledge available, the choice of the experts is based on their scientific skills certified by publications in peer-review journals and their recognition by their peers. The expert recruitment logic, based on scientific skills and not on knowledge in the field, is to be stressed in that it is a frequent source of misunderstandings when the expert reports are published.

The experts are selected from the French and international scientific community. They are to be independent of the partner sponsoring the expertise and recognized pressure groups. The composition of the expert group is validated by the Directorate General of Inserm.

Several scientists outside of the group may be requested to contribute occasionally to a particular theme during the expertise.

Expert review implementation lasts between 12 and 18 months, depending on the volume of literature to be reviewed and analyzed and the complexity of the subject.

Initial expert group meeting

Before the first meeting, the experts receive a document explaining their mission, the scientific program (issues to be addressed), schedule, the expertise bibliographic database to date and articles more specifically addressing certain experts on the basis of the skills.

During the first meeting, the expert group discusses the list of issues to be reviewed and completes or modifies it. The group also examines the document base and proposes supplementary searches with a view to enriching that base.

Expert critical analysis of the literature

During the meetings, each expert orally presents a critical analysis of the literature with respect to the aspect allocated to the expert in his/her field of expertise and communicates the accepted facts, uncertainties and controversies with respect to current knowledge. The questions, remarks and points of convergence or divergence elicited by the group analysis are taken into consideration in the section that each of the experts compiles. The analysis report, consisting of various sections, thus constitutes the state of the art for the various disciplines pertinent to the issue under review. The bibliographic references used by the expert are cited in and at the end of each section.

Synthesis and recommendations

The synthesis summarizes the broad lines of the literature analysis and identifies the main findings and principles. Contributions from contributors outside the group may be summarized in the synthesis.

The synthesis is more specifically intended for the institution and decision-makers with a view to use of the knowledge presented therein. The wording of the synthesis is to take into account the fact that it will be read by non-scientists.

As of report publication, the synthesis is posted on Inserm's website. The synthesis is translated into English and posted on the NCBI/NLM site (National Center for

Biotechnology Information of the National Library of Medicine) and Sinapse site (Scientific INformAtion for Policy Support in Europe, European Commission site).

If requested by the institution, certain collective expertises include 'recommendations'. Two types of 'recommendations' are formulated by the expert group. 'Principles for action' based on a validated scientific reference system with a view to defining future public health action (mainly in screening, prevention and management) but which are not under any circumstances to be considered 'operational' recommendations insofar as no economic or political components have been taken into account in the scientific analysis. 'Research orientations' are also proposed by the expert group with a view to filling in the gaps in scientific knowledge observed during the analysis. Once again, these proposals cannot be considered 'priority' research without their being put into perspective. That is the task of the pertinent authorities.

Critical review of the report and synthesis by prominent 'readers'

For certain expertises addressing sensitive subjects, a critical reading memorandum is requested from several prominent 'readers' selected on the basis of the scientific or medical knowledge and managing or evaluating French or European research programs or having contributed to ministerial working groups. Similarly, the report and synthesis (and recommendations) may be submitted to figures with good knowledge of the 'field' and able to grasp the socioeconomic and political issues associated with the knowledge (and proposals) presented in the expertise.

Presentation of the conclusions of the expertise and debate

A seminar open to the various sectors involved in the subject of the expertise (patient associations, professional associations, unions, institutions, etc.) enables an initial debate on the conclusions of the expertise. On the basis of that exchange, the final version of the synthesis document incorporating the various viewpoints expressed is compiled.