

## **Review on the contribution to evaluating the policy for health risk reduction in intravenous drug users**

The Institut national de veille sanitaire (IVS) (*National Institute for Health Monitoring*) recently published a two volume report entitled “Contribution to the Evaluation of the Policy for Risk Reduction: SIAMOIS”. This acronym describes the system for information about accessibility to pharmacy materials for injection and replacement.

A “risk reduction” policy was developed in France around ten years ago. Its aim is to prevent the development of health and social problems associated with drug use, particularly AIDS and Hepatitis B and C (HBV and HCV) infections from syringe sharing among intravenous drug users (IVDU). It is based both on improving access of IVDU who cannot or do not wish to give up this type of drug consumption, to sterile syringes, and on reducing injections for other users. In order to achieve these goals, sterile syringes have been sold without prescription in pharmacies since May 1987 or have been distributed free by more than one hundred associations since March 1995. substitution substances designed for oral use have been prescribed in primary care since March 1995 (méthadone) and February 1996 (Subutex®).

Evaluation of accessibility to these risk reduction instruments is based principally on:

- measuring the adoption level of this policy from the sale of sterile syringes and replacement substances in pharmacies.
- assessing whether the distribution of these risk reduction instruments is appropriate for the local situation.
- measuring the impact of accessibility from the national to local scales using specific indicators associated with drug use.

We present here a database which helps to monitor the sales of risk reduction (RR) instruments and then examine the major trends which have emerged from this follow up between 1996 and 1999 by comparing these with specific indicators for both risk and health and social problems associated with drug addiction.

### **A database: SIAMOIS**

The materials used to meet the objectives of this evaluation is a database christened SIAMOIS: “Information about accessibility to pharmacy materials for injection and replacement”. The information listed consists of sales of syringes and replacement substances in the 23,000 French pharmacies. These data are collected and have been sent to

the Institut national de veille sanitaire (InVS), monthly, by the Groupement pour l'élaboration et la réalisation de statistiques (GERS) (*Statistical design and application group*) since January 1996, by dividing France into 509 geographical analytical units corresponding to the catchment areas for the wholesale distributors, which may be re-grouped on a departemental and regional level. This system also enables an annual database of these sales figures to be compared to indicators for drug use, and morbidity and mortality associated with drug use.

The injection materials consist of syringes sold to IVDU packaged in a kit since 1995 (Stéribox® containing 2 syringes) or dispensed in units since 1987 (1 ml, 2 ml). The 1 ml syringe in batches of 30, Becton-Dickinson® (BD) brand are principally designed for diabetics (and represent 82% of syringe sales in pharmacies) and is the most widely used by the IVDU. These constitute 11 to 16% of total sales of 1 ml/301 syringes. In order to answer the specific sales need for which they were designed, Becton-Dickinson® marketed a single syringe in a blister pack at the end of 1995<sup>1</sup>. In addition, 2 ml syringes sold in batches of 20 and designed principally for diabetics are also used by IVDU (16 to 20% of sales), for injection of medicinal products amongst other things.

The replacement substances monitored are Subutex® tablets, prescribed almost exclusively in primary care, and methadone syrup, prescribed in the context of primary care follow on treatment for users who were initially treated in the specialist drug addiction care centres (CSST).

Indicators for drug use and mortality associated with drug use provided by the Central Office to Deter the Illegal Trafficking of Narcotics (OCRTIS, Ministry of the Interior) are determined from the annual number of legal infringements for narcotics (LIN) for use/use-re-sale of heroin and crack cocaine<sup>2</sup> and from the annual number of deaths due to overdose reported by the de-centralised services of the Ministry of the Interior.

## **IMPORTANT CHANGES**

In order to combat the major health consequences associated with drug use, accessibility to injection materials is designed specifically to reduce sharing and re-use. This should result in an increase in the number of syringes dispensed between 1996 and 1999. The replacement policy should conversely lead to a fall in heroin consumption, resulting in a progressive fall in infringements due to heroin use and fatal overdoses over the same period.

### **Accessibility to syringes**

The figures listing all of the sources of sales or distribution of syringes to IVDU (see table below) show that accessibility to syringes has continued to increase since 1995 (+ 15% from to 1999).

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<sup>1</sup> National survey by the BD company in a representative sample of 400 pharmacies in 1996 (unpublished). These proportions relate overall to BD 1 ml/30 (11 - 16%) or to BD 2 ml/20 (16 - 20%) sold in pharmacies without prescription.

<sup>2</sup> Crack is a smokable cocaine derivative which is not consumed much on mainland France, except on the Paris/close surrounding area and in Marseille.

## *Sterile syringes consumed by IVDU from 1995 to 1999 (SIAMOIS/InVS)*

<b>Syringes consumed by IVDU</b>	<b>1995</b>	<b>1996</b>	<b>1997</b>	<b>1998</b>	<b>1999</b>
From pharmacy sales of Stéribox®	3,888,656	3,832,654 (-1.4%)	4,614,032 (+20%)	5,440,032 (+18%)	5,759,374 (+6%)
From pharmacy sales of BD 1 ml unit	0	161,790	122,823 (-32%)	206,009 (+8%)	312,996 (+5%)
From pharmacy sales of BD 1 ml/30	7,139,800	6,479,966 (-9%)	6,433,436 (-1%)	6,076,369 (-5.5%)	7,379,847 (+21%)
From pharmacy sales of BD 2 ml/20	1,061,532	965,306 (-9%)	921,072 (-5%)	869,466 (-5.5%)	933,984 (+7%)
From pharmacy sales of other brands <sup>3</sup>	2,050,333	1,901,765 (-7%)	1,869,333 (-1.5%)	1,787,961 (-4%)	2,156,632 (+21%)
From the distribution of syringes through syringe exchange programmes (SEP)	1,512,502? (< 1996)	1,512,502 ( PES survey)	1,512,502? (> 1996)	1,512,502? (> 1996)	1,512,502? (> 1996)
Total annual number of syringes consumed by IVDU <sup>4</sup>	15,652,823	14,853,983 (-5%)	15,473,972 (+4%)	15,852,339 (+3%)	18,055,035 (+14%)

The increase in accessibility to sterile syringes should be accompanied by a fall in high risk injection behaviour (sharing, re-using syringes) and by a fall in HIV and HCV infections.

### **Changing usage behaviour**

Although they do not relate to the same populations of drug users, dividing the information available about high risk behaviour and viral infections associated with the use of drugs (see table opposite) shows that overall the IVDU have changed their syringe sharing and re-using practices. However, in addition to persisting high risk practices in the context of a still high prevalence of the AIDS virus (HIV) the reduction in syringe sharing alone (to which risk reduction was initially mostly limited), was not associated with a fall in the prevalence of hepatitis C (HCV).

### **Access to substitution treatments**

Since first marketed, sales of Subutex® packs have experienced very strong growth in the country. Using the maximum case scenario that users comply strictly with treatment at a dosage of 8 mg per day, these sales represent an average of 20,000 users/month in 1996, 40,000 in 1997, 52,000 in 1998 and 66,000 in 1999 (see table opposite).

The national increase in methadone consumption has not been as great as that of Subutex®, the availability of which depends only, apart from the number of users, on the local number of pharmacies, in contrast to methadone sales which also, and particularly, depend on the number and activities of specialist local care organisations. The SIAMOIS survey which started 10 months after methadone was first marketed (March, 1995) showed a very strong growth in prescriptions in primary care between 1996 and 1997 (table 3), followed by a slow rising phase for the substance, indicating more limited access to this type

<sup>3</sup> Other brands of syringes sold to IVDU represent 20% of the volume of BD sold to IVDU (survey by the BD company).

<sup>4</sup> For the purposes of obtaining exhaustive data, information obtained from SIAMOIS was supplemented by the volumes of syringes distributed in parallel by the *circuit associatif* (1996 estimate performed to establish a sounding database in the context of the PES enquiry "social characteristics, consumption and risk in drug users frequenting the PES in France"). InVS-Inserm report, J. Emmanuelli, F. Lert, M. Valenciano). As the number of PES has continued to increase since the start of the 1990s it is assumed that the number of syringes distributed is less than or equal to this value prior to 1996 and greater to or equal to this value after 1996.

of treatment. Changes in the growth rates of primary care prescriptions and CCST prescriptions would suggest that a still larger number of follow up prescriptions are started in primary care.

Against all expectations, the massive distribution of substitution treatments has not slowed down or even stabilised the national increase in sales of syringes in pharmacies. This suggests that the messages for risk reduction have not yet fully reached their objectives (non-sharing or even non-re-use of the syringe). It is also likely that many problem drug users alternate or even combine taking Subutex® with substance injection (Subutex® and/or others).

### **Fall in infringements and deaths**

The fall in heroin LIN for use/use-re-sales which has been identified since 1995 increased considerably from 1996 changing from 17,328 to 6,141 in 1999.

In its latest report, OCRTIS estimates that this trend indicates a persisting disinterest in heroin. It explains this by the impact of risk reduction messages, the development of multiple drug addition for some (ex) heroin addicts during treatment, for which cannabis, cocaine or even ecstasy offer a degree of attraction, and especially by the large extension of substitution treatments.

Comparing the sales data for Subutex® against heroin LIN for the years 1996 to 1999 shows that the consumption of Subutex® has increased, whereas heroin LIN has fallen in parallel. There is therefore a clear association between Subutex® and heroin. We cannot confirm, however, that the effect is causal in nature (even if this is likely), as other factors not taken into account in our analysis will be involved in the fall of heroin LIN.

Although it has been preceding distribution of substitution substances, the national growth in cocaine rose in parallel with the effective introduction of primary care methadone follow up, increasing further (+ 60%) with the distribution of Subutex® (from 1084 in 1995 to 3397 in 1999).

### **Indicators of behaviour and infection in IVDU from 1988 to 1998**

<b>Indicators of behaviour and infection among IVDU</b>	<b>Sources</b>	<b>1988</b>	<b>1991</b>	<b>1993</b>	<b>1996</b>	<b>1997</b>	<b>1998</b>
Sharing syringes	IREP	48%	33%	-	13%	-	-
	InVS/INSERM	-	-	-	-	-	20%
Re-using syringes	IREP	75%	75%	-	75%	-	-
	InVS/INSERM	-	-	-	-	-	45%
Prevalence of HIV <sup>5</sup>	IREP	40%	34%	-	20%	-	-
	CESES	-	-	29%	14%	19%	-
	DREES (SESI)	-	-	-	23%	14%	14%
	InVS/INSERM	-	-	-	-	-	19%
Prevalence of HCV <sup>6</sup>	IREP	-	-	-	47%	-	-
	CESES	-	-	43-51%	60%	58%	-
	DREES (SESI)	-	-	-	66%	60%	63%
	InVS/INSERM	-	-	-	-	-	58%

<sup>5</sup> Strictly, HIV prevalence is not the best indicator to examine the effects of the risk reduction policy as it depends both on the number of new cases (incidence, not available in France) and on the carrier period for the disease (monitoring infected people). As the treatments available since 1996, however, have tended to "increase" the number of sero-positive patients by reducing their death rate, a fall in prevalence indicates a fall in incidence partly due to the effects of prevention (cf report).

## *Accessibility of IVDU to substitution treatments from 1995 to 1999*

<i>Accessibility of IVDU to Substitution treatments from 1995 to 1999</i>	1995	1996	1997	1998	1999
Mean number of users/month on Subutex® 8 mg/d in primary care (SIAMOIS)	0	20,156	40,357 (+ 100%)	52,546 (+30%)	66,244 (+ 26%)
Mean number of users/month on Methadone 60 mg/d in primary care (SIAMOIS)	< 1,000	1,332	2,013 (+55%)	2,532 (+ 25%)	3,502 (+ 38%)
Mean number of users/month on Methadone 60 mg/d in CSST (DGS)	> 1,700	2,580	3,426 (+ 33%)	4,160 (+ 21%)	4,905 (+ 18%)
Mean number of users/month for all replacement treatments combined (Subutex® + methadone)	> 2,500	24,068	45,796 (+ 90%)	59,238 (+ 29%)	74,651 (+ 26%)

According to OCRTIS this sustained increase is explained by penetration of the substance beyond the field of business and arts into the population of heroin addicts who are using cocaine in association with heroin (particularly heroin replacement users). The combined increase of Subutex® and cocaine however shows a less close relationship than the more "natural" inverse growth link between synthetic opiates (Subutex®) and heroin.

Finally, in 1999 deaths due to overdose have fallen dramatically since 1995, reaching their lowest national level since 1979, when deaths fell from 465 in 1995 to 118 in 1999. Heroin consumption is still the most common cause, although an increasing number of deaths involving other substances, usually combined (alcohol, medicinal products) are seen. According to OCRTIS, the fall which started before 1996 and accelerated between 1996-1997 and 1997-1998 is due to the visible disinterest in heroin use, to the development of replacement treatments and to improvement in health and social management.

## **CONCLUSION**

The spearhead of the risk reduction policy, offering syringes and replacement treatments, has continued to expand since 1996, increasing the trend towards improved health of IVUD started several years previously. On a national scale, this improvement relates above all to mortality associated with drug use. In parallel to the very considerable increase in the availability of replacement substances (+60%), there has been a very profound fall in fatal overdoses (-70%) from heroin use (-58%) the major cause and, more hypothetically, in the number of injections. Apart from the fall in syringe re-use (-60%) improvement in availability has, above all, contributed to the stabilisation of rates of sharing and HIV prevalence (between 15 and 20%) following a large fall between 1998 and 1996 (-40% and -50% respectively).

This rapid advance in the risk reduction policy appears on the other hand to have had no effect on HCV prevalence, which remains very high. Although we do not yet have a detailed evaluation, the widespread distribution of replacement products, in the opinion of many observers (and of the people affected themselves) has helped to provide medical and

<sup>6</sup> As applies to HIV, the continued high prevalence of HCV is not the best indicator to examine the limits of the effectiveness of risk reduction. This applies particularly because it may mask a fall in the incidence of new infections (data which are not available in France). A collection of assumptions made from assorted foreign studies, including transverse (prevalence and longitudinal incidence) studies, tends to show that accessibility to syringes on its own appears to have no effect of the spread of hepatitis virus in IVDU (see report).

social stability for a not insignificant number of drug users. By reducing the use of heroin, however, the development of the availability of replacement treatments also appears to be accompanied by (and to have produced) changes in behaviour and uses, which in turn produce new problems. An example of this is the reverse use of Subutex® intravenously and its consumption in the context of dangerous multiple drug addictions.

Secondly, the large growth in cocaine consumption (+144% in 4 years) has made a management instrument, based historically on opiate use, obsolescent. It raises threatening questions about the major health gains of the risk reduction policy by de-stabilising preventative behaviour and by complicating the management of the IVUD.

The persisting practices of sharing and re-use of syringes whilst the prevalence of HIV remains high in IVDU drives us to continue our efforts in improving accessibility. We have to arrive at single individual use for all materials. Limits of accessibility to syringes force us to develop or increase other actions, particularly directed towards vulnerable, difficult to reach populations: young users, for which innovative approach strategies need to be used, or the IVDU in prison for whom management and prevention of risks must be improved whilst they are in prison.

We should also take into account the dimension of risks from sexual contact in the IVDU which are undoubtedly partially responsible for residual HIV infections, through the first line organisations. The availability of substitution substances must continue. However, thought must be given to possibly diversifying the pharmaceuticals of the substances (their presentation) or even making alternative substitution products available (morphine sulphate, etc.). Similarly we must consider broadening the prescription of methadone or putting it into the same context as that of Subutex®. In any situation, the benefits and risks of substitution therapy must be evaluated in more details.

In addition to propelling these initiatives, it is essential to maintain this type of monitoring in order to help to evaluate the policy and to detect possible trends and new developments. It is important therefore in parallel with collecting and analysing SIAMOIS data, to re-conduct surveys among the IVDU to monitor change in consumption behaviour, risk taking and their context<sup>7</sup> and to describe the different populations of vulnerable IVDU in order to adapt risk reduction measures to take account of the diversity of needs and changing situations.

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## **Methodological landmarks**

The Public Authorities have been undertaking risk reduction measures for the risks of HIV and Hepatitis transmission among intravenous drug users (IVDU) for ten years. In order to evaluate this policy the Institut de veille sanitaire (InVS) has developed a system which can provide indicators for the application of these measures, in order to monitor them and compare them with indicators of risks associated with drug use.

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<sup>7</sup> InVS-ANRS study project for 2001-2003 on the risks of blood and sex born HIV and HCV in IVDU (frequency and determinants of high risk practices in injectors).

The system was started by the General Directorate of Health following the proposal by Inserm 88 and was developed by the Institut de veille sanitaire. It was designed in 1996 to monitor trends in access to sterile injection materials available in pharmacies, and to substitution medicinal products. These findings are sent by the statistical studies design and application group for the pharmaceutical industry.

By comparing these findings in the 20-39 year old age group, which contains 80% of drug users, we get indicators allowing comparisons to be made between regions and départements (*counties*). These indicators may be compared to the new cases of AIDS, deaths due to overdose and convictions for infringement of the narcotic legislation in the same age group.

SIAMOIS collects sales data from all french pharmacies for products destined for IVDU (Steribox®, syringes, Subutex®, methadone) and compares these to “social and health” indicators for risk in IVDU (deaths due to overdose, new cases of AIDS and infringements of the narcotic legislation. In addition to measuring national trends SIAMOIS constructs rates from these data to compare départements (counties) and regions with each other.

### **For more information**

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