

Signal Identification in Addictovigilance: the Functioning of the French System

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Abstract – The French addictovigilance network (addictovigilance: surveillance of addiction), composed of 13 Addictovigilance Centres, was set up in 1990 in order to achieve reliable surveillance and evaluation of abuse and dependence cases due to psychoactive substances (alcohol and tobacco excepted). The detection of safety signals is one of the roles of the addictovigilance centres. Signals from spontaneous reports need to be analyzed before further communication. In addictovigilance, signals may be linked to adverse effects (deaths, pathological signs), to products (new psychoactive substances with potentially dangerous effects) or to practices (new administration routes, new contexts of use). These signals are provided by numerous partners among whom the addictovigilance network has to raise awareness about information that may possibly be an alert signal. The watchful attitude of all partners will make it possible that signals will be, after analyze, considered as true alerts. The addictovigilance network collects data, assess the potential for addiction of psychoactive drugs to provide information on the risk of addiction and give opinions for public health decisions (harm reduction or prevention programs, psychoactive substances control, health alerts).

Abbreviations: see end of article.

1. Introduction

A “signal” can be generally considered as information or warning issued to indicate that something is to be done (“*signal: a gesture, action or sound that is used to convey information or instructions, typically by pre-arrangement between the parties concerned*”).^[1] This notion of the signal also calls on communication theories. Since the work by Shannon and Wiener, backed up by that by Weaver, there is a general theory of communication that enables an understanding of the different stages between the source of the information and the final receiver, in the course of which an element of information becomes a signal. According to this theory, the sender issues a notification on the basis of information he/she has noticed as being potentially important, and it is the receiver

who analyses it and gives it meaning. Detecting and identifying signals is one of the central issues for addictovigilance agents: they need to be able, at a some stage, to label a piece of information received as a signal.^[2,3] Signals suggesting a public health risk are collected and analysed in continuous manner in a surveillance process implemented by watchdog or public health structures, in a perspective of alert, anticipation and early action. In this framework, a signal is defined as a piece of information concerning a health phenomenon or exposure to a risk or hazard, which requires investigation in order to validate it and decide whether or not it should be considered as an alert.^[4]

In pharmacoepidemiology, reference is made to a signal when the value of a parameter (number of cases of an event, incidence rate, etc) exceeds what is expected or allowed. A signal,

once confirmed, is an alert, which should lead to decisions or the implementation of an appropriate investigation.^[5] In the area of addictovigilance, the notion of a threshold is very often lacking, and what launches a signal is generally the notification of an unusually serious event, or of an unexpected cluster of cases.

The signals observed in addictovigilance can be among the following:

- signals linked to human cases: unusual deaths, symptoms, syndromes or pathologies that are grouped in time or space, having suspected or obvious links with isolated or repeated use of a psychoactive substance or an association of such substances;
- signals linked to substances: psychoactive substances or associations thereof observed to be in circulation, found in seizures or already in use, substances that are atypical, dangerous, or liable to be life-threatening, or likely to have serious health consequences (presence of adjuvants, degree of purity, novelty of the substance or its usage, etc);
- signals linked to practices: new modes of administration, new settings of use.

The problem in addictovigilance is that there is a risk of missing a signal, since this area concerns rare or extremely rare phenomena for which there is considerable under-notification. Yet signals can be provided by many different sources, and these sources need to realise the need for awareness towards information that might provide a warning sign.

2. The sources of signals in addictovigilance

The French addictovigilance network, made up of 13 Addictovigilance Centres, was set up in 1990 under the auspices of the French Health Products Safety Agency (*Agence Française de Sécurité Sanitaire des Produits de Santé* [Afsaps]), which later became the French Medicines Agency (*Agence Nationale de Sécurité des Médicaments et des produits de santé* [ANSM]), in order to monitor serious addiction cases involving psychoactive substances, *i.e.* medicines, plantes or substances, illegal or not, with psychoactive effects, with the exception of alcohol and tobacco.^[6] At the time of the creation of this network, the information available for assessing abuse, dependence and misuse of these substances was based on fairly succinct data from animal studies, clinical trials, and spontaneous reports by health professionals of addiction cases related to psychoactive substances. Notification was inadequate, and the system restricted by considerable under-reporting. This phenomenon is frequently observed in surveillance systems,^[7] but it is aggravated in the area of addictovigilance by the difficulty in identifying the boundary between abuse and misuse, and in detecting misuse behaviours. In addition, the link between clinical profile and use of a psychoactive substance is rendered even more difficult to establish by the fact that the health professional, even when, he/she knows that the

effect observed can be attributable to one or several substances, is not necessarily aware of the exposure of the particular patient to the substances in question.

2.1. On-going specific pharmacoepidemiological programmes

To counterbalance the limitations of spontaneous notification by health professionals, despite the fact that it is an essential element in detecting signals and launching alerts,^[8] several pharmacoepidemiological programs were set up in France to complement the information provided by spontaneous notification, and to improve the assessment of the psychotropic medication's misuse.^[9] One advantage of these programs is that they use a wide range of partners (table I) which enables the exploration of different populations liable to present a disorder related either to the use of legal substances or the use of illegal substances with addictive potential. They are thus able both to identify emergent phenomena and signals at an early stage, and to provide elements to confirm a signal, as will be seen in different examples hereafter. With the exception of the programmes “*ordonnances suspectes indicateurs d'abus possible*” (OSIAP) and “*antalgiques, stupéfiants et ordonnances sécurisées*” (ASOS), which are addressed specifically to community pharmacies and concern medications, all these programmes enable the evaluation of psychoactive substances whether or not they are medications.

These programs, which are particularly complementary in the exploration of addiction potential or different substances, follow on from year to year, so that it is possible to observe evolutions addiction risk over time, going back, depending on the programs, up to ten or twenty years.^[10,11]

Thus France possesses observational surveillance programmes that are unique in Europe. While other European countries separate the surveillance of psychotropic medication (*via* national pharmacovigilance networks) from that of illegal drugs, the French addictovigilance system enables an approach that is both qualitative and quantitative to the use and abuse of psychoactive substances in general.^[12]

2.2. Other data sources

To complete these on-going programs, other systems have been established. They are used in more focal manner to respond to specific questions, and they are based on consumption data or medical-administrative databases such as those of the health insurance database (*système national d'informations inter-régimes de l'Assurance maladie* [SNIIR-AM]), or the computerisation of medical information (*programme de médicalisation des systèmes d'information* [PMSI]).^[13,14]

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