

Patient safety activities in France: an overview

Context

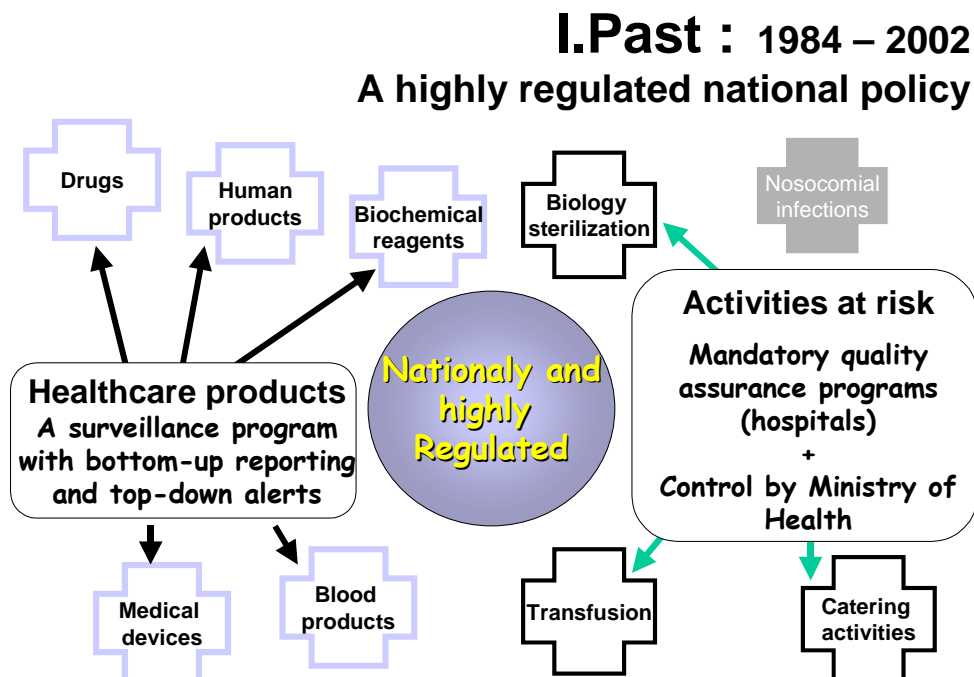
In France, implementation of patient safety activities mainly developed after the “contaminated blood crisis” in the mid-eighties, when a large number of patients contracted HIV after transfusion of unsafe blood; healthcare professionals and politicians (including the prime minister and the minister of health) were pursued. Individual and organisational errors in the healthcare system were, for the first time in France, largely published. This crisis highlighted the lack of safety culture and of barriers protecting the individuals and the system from errors at all, macro, meso and micro, levels.

This crisis was one of the main reasons why patient safety activities became product-oriented, and politically-driven by the mean of numerous laws.

1984-2002: a highly regulated and healthcare product oriented patient safety program

A national safety surveillance program was launched and progressively included different healthcare products. Historically, the first concerned drugs (1984) ; then blood products; now, medical devices, biochemical reagents and human products are involved too.

For all risks, voluntary health professionals are trained as technical referees in each private and public hospital. They are in charge of organising the different safety tasks, surveillance, coordination and implementation of regulation and good practices guidelines. These professionals (doctors or nurses) are not full-time; they also have clinical activities. At the regional level, supportive units coordinate these activities. In 1999, the AFSSAPS national agency was created (Agence Française de Sécurité Sanitaire des Produits de Santé) for evaluating and controlling the security, quality and efficacy of the healthcare products. It provides surveillance (a framework for reporting), healthcare product safety recommendations and alert dissemination.

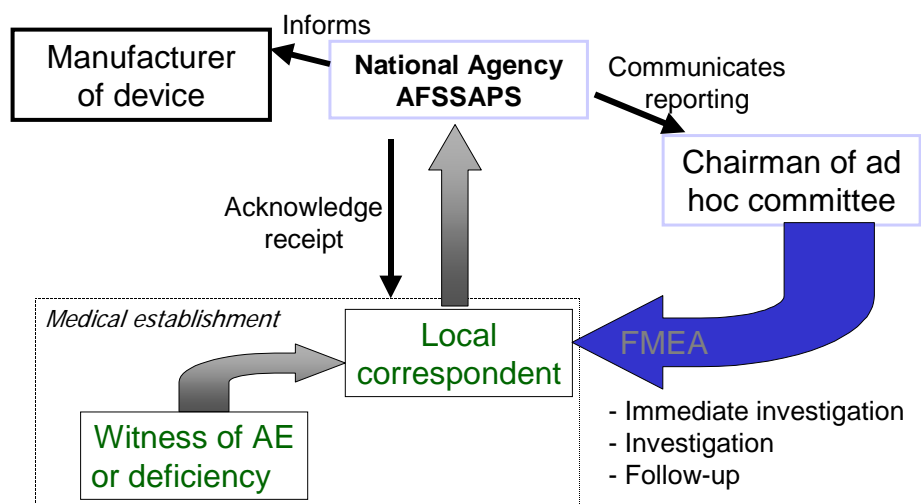


Hospitals' organisation for controlling risks as nosocomial infections or sterilization has also been regulated. Specifically for the nosocomial infection control, budgets have been provided to the hospitals in order to set up a structure with dedicated professionals. Five inter-regional structures and a national committee have been set up to coordinate these activities.

Good practice procedures are now defined in addition to the legal requirements and, during the last decade, mandatory quality assurance programs were launched in all biology and sterilization units and for transfusion and catering activities in healthcare organizations. Finally, the technical conditions for performing some activities as anaesthesia, ambulatory surgery or perinatal care, have been precisely described by the Ministry of health, which is also in charge of controlling the compliance of hospitals with these requirements

The surveillance is based on bottom-up reporting and top-down alerts. The type of events to be reported, and the process of reporting, may differ slightly according to the risk. We here describe the organisation of medical device surveillance as an example. The witness of an adverse event related to a medical device has to inform either the local correspondent, when available, or directly the national Agency (AFSSAPS). A major objective of the local correspondent is to act as a filter and to select among the declarations of events those to be transmitted without delay or quarterly to the Agency, and those to be registered only locally. Within 48 hours the national Agency: a) returns an acknowledgement with instructions how to proceed with the involved device; b) communicates the declaration to the chairman of the ad hoc committee; c) informs the manufacturer of the device. In 2002 for example, 2675 adverse events related to a medical device were declared. The chairman decides on the degree of severity (major event requiring an immediate investigation, event requiring an investigation, event to be entered into a follow-up program). In the first two cases, an investigation using the failure mode and effects analysis method is undertaken by one or several members of the committee together with the manufacturer and the professional who declared the event. Conservative measures can be undertaken to prevent the re-occurrence of an event either with the involved and/or with similar devices and to facilitate the investigation.

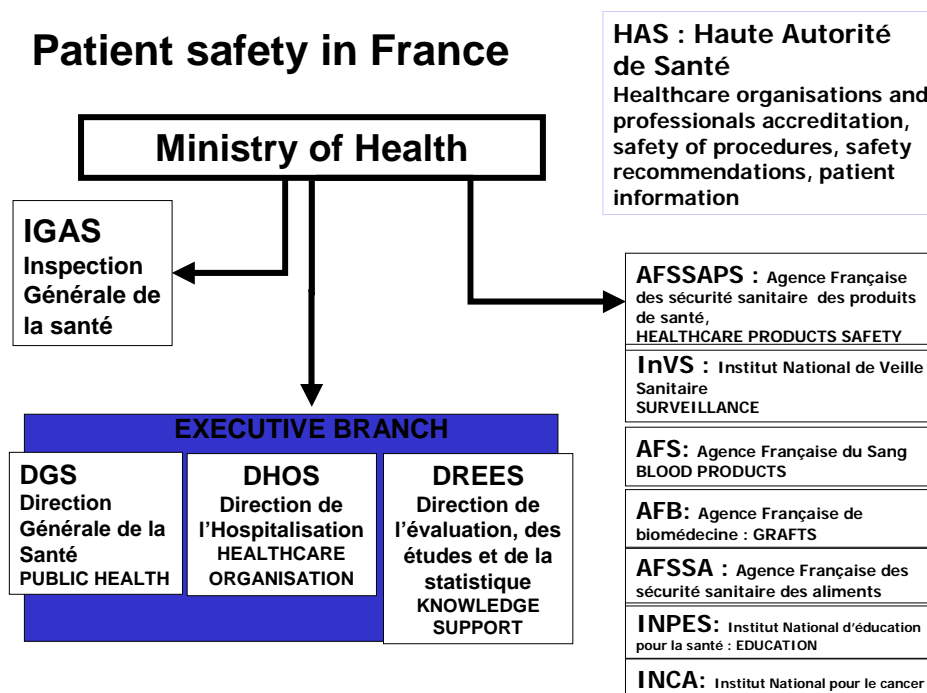
Organization of the surveillance program: the case of medical devices



The main strength of this organization is a very effective alert system, with top-down and bottom-up “red flags”.

However, the limitations are numerous:

- An extremely regulatory approach can be a strength in pushing hospitals and health professional to more preventive practices. Nevertheless, compulsory quality assurance systems may not be sufficient to continuous quality improvement. The director of the French national transfusion Agency, Dr. Herve stated for instance in 1999 that “transfusion was historically characterized by its ambivalence: it was the first medical discipline which integrated Quality Assurance concepts, it was also the first which proved unable to respond adequately in the face of uncontrolled risks”.
- A compartmentalization of the vigilance activities according to products, without bridges between each other, within the hospitals, at the regional and at the national levels;
- A limited leadership and too many actors
- Limited information on other iatrogenic injuries than injuries directly related to healthcare products
- A lack of a proactive approach
- A limited knowledge of organizational defects and other latent causes of adverse events in hospitals



2002-2007: toward a more integrated system

Since 2002, a huge effort has been made to enlarge the scope of patient safety and to improve its effectiveness. A national survey on all adverse events is being carried out in 71 hospitals, 292 wards and 7500 patients. It aimed at assessing the incidence of adverse event and at realising a root cause analysis of the most frequent and prominent events in order to find out the frequency of the main contributory factors related to their occurrence.

Two laws were published in 2002 with the main following consequences:

- The surveillance system will no longer be restricted to the adverse events related to healthcare products and to nosocomial infections, and will cover all types of adverse events. The national agency InVS is currently developing the principles of adverse event reporting.

- The patient must be told the occurrence of an adverse event within 15 days after its identification.
- Patients may receive financial compensation even if malpractice is not proven.

Finally, the 2004-2008 national public health program for France, released by the Ministry, include, for the first time, quality and safety indicators. The five first safety indicators, defined and tested in 2004, are in the field of nosocomial infections.

In brief, patient safety management was first developed in France as parallel efforts in reducing risks related to different products and risky activities. Now, efforts are being devoted to reorienting the hospital organization of patient safety activities and to setting up a national reporting system. The Ministry of health and the HAS published two guidances on organisational patterns and methods principles of patient safety and risk management.

The five missions of HAS regarding patient safety

The **accreditation program of healthcare organisations** evaluates the implementation of all patient safety activities

The **accreditation program of professionals** and of medical teams with risky activities is based on a near misses reporting and learning system.

A department dedicated to **patient information and mediation** has a strong commitment for the information and orientation of individual patients who are seeking advices.

The **procedure evaluation department**, while evaluating the performance of procedure, identifies “risky procedures” (for example carotid artery stenting), makes recommendations in terms of professional qualification and training requirements, and of technical environment needed to perform the procedure.

In line with the most frequently reported near misses (HAS) and adverse events (InVS), the clinical guidelines department will produce **risk reduction recommendations**

The state of development is heterogeneous: the first mission is in place since 1999, the second and third one are currently being implemented and the procedure evaluation department is working on the methods of doing recommendations.

In addition, HAS leads the development of a European network on patient safety activities for the 27 countries (EuNetPaS).

Conclusion: a French singularity?

Probably linked with a global public satisfaction vis-à-vis healthcare delivery (full coverage social security, limited waiting lists and open access to healthcare, the pressure on the system is limited: the patient’s organisations and the medias are not aggressive, the increase in litigations is small and the development of patient safety remains largely in the hands of national authorities and care givers. This is a unique opportunity to drive a politics focused on the development of a safety culture among healthcare professionals.

However, the low pressure explains that the system gave an intensive focus on product security, and poorly focused on errors and contributory factors. There is still place for a strong leadership which, under the political , could be taken by HAS.