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SERIOUS ADVERSE EVENTS IN FRANCE: A REPORTING AND LEARNING SYSTEM

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What was the context?

The French National Authority for Health (HAS) is in charge of collecting and analyzing data on serious adverse events related to health care (SAE-HC) to give practical recommendations for improving patient safety at a national level.

Definition
Serious adverse events related to health care (SAE-HC) = events which led to death, disability, or other health threats)

What were the findings?

In France, reporting SAE-HC is mandatory since 2002. The French monitoring and health safety system was built over several years with successive strata and in response to health crises. Importantly, reporting SAE-HC and safety culture in healthcare remain underdeveloped. The last two French crises (Mediator®, PIP® prosthesis) have highlighted the need to review the organization of the vigilance system, from the reporting of incidents to their operational management.

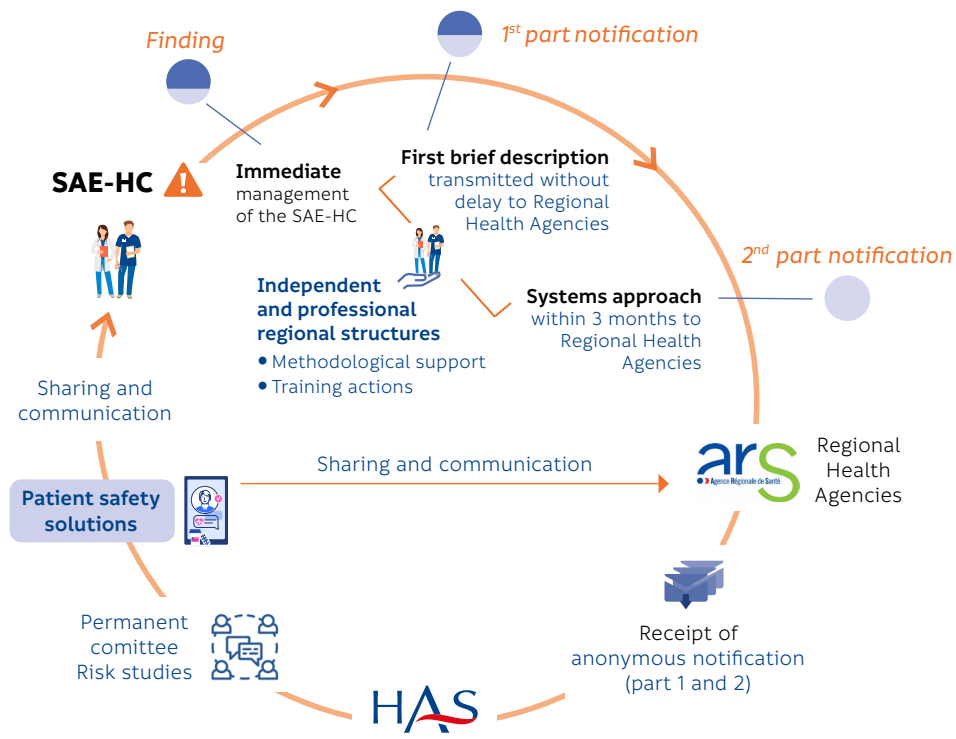
What was the French strategy?

The French Ministry of Health has decided to implement a single on-line platform for reporting adverse health events (signalement-sante.gouv.fr). It has been operational since March 2017 and allows reporting SAE-HC and also adverse events associated with the use of a drug, product or device. It also allows patients, carers or family members to declare any events themselves.

The SAE-HC notification process is built on 2 levels (cf. diagram 1) with specific features:

- the **regional level**: a first brief description transmitted to the regional health agencies for implementing immediate actions; then a second more detailed description with a systems approach in order to identify causes and barriers. Independent regional and professional structures carry out training actions and can help professionals to complete SAE-HC notifications.
- the **national level**: a permanent committee of 22 experts (selected by the HAS) who help analyze SAE-HC notifications and provide feedback based on their own professional experience. The HAS sets up risks studies and publishes educational stories, practical safety tools and annual reports.

At both levels, the objective is to share and communicate on feedback by grouping similar SAE-HC into specific types of risk situations.



The National Authority for Health

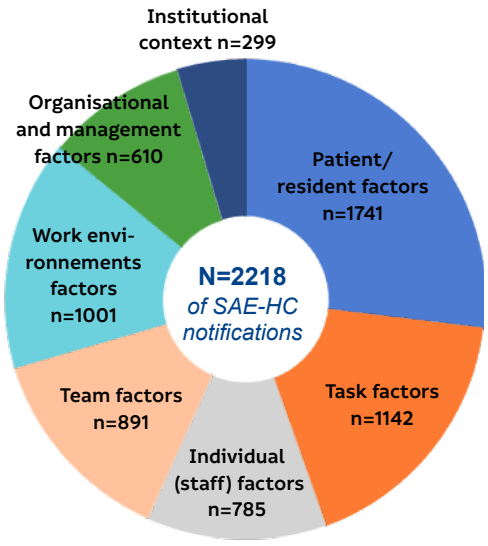
Diagram 1: The French SAE-HC notification process

What about this reporting system in figures?

→ **Between March 2017 and February 2020, the HAS has received 2,218 SAE-HC notifications**

Descriptive analysis

- → SAE-HC notifications come principally from health care facilities (80%), medico-social institutions (14%) and primary care (4%) (2% other).
- → Consequences of SAE-HC for the patient are: death (51%), disability (16%), and other public health threats (33%).
- → In 25% of notifications, no immediate cause is identified.
- → The predominant category of root causes described is patient/resident factors (cf. diagram 2).



N= number of SAE-HC notifications
n= number of root cause selection

Diagram 2: Selected root causes distribution (several possible answers per SAE-HC were possible)

Qualitative analysis

The permanent committee considers that root causes analysis is not done properly in 50% of SAE-HC notifications (cf. diagram 3).

Effects of changes

The volume of SAE-HC notifications is increasing. However, an important under-reporting compared to the literature is observed. The French national survey ENEIS estimated that between 5.1 and 7.3 SAE-HC occurred per 1,000 hospital days in 2009 (i.e. between 275,000 and 395,000 SAE-HC *per year*). The systems approach in notification remains poor in quality.

"Root causes analysis has been done properly":

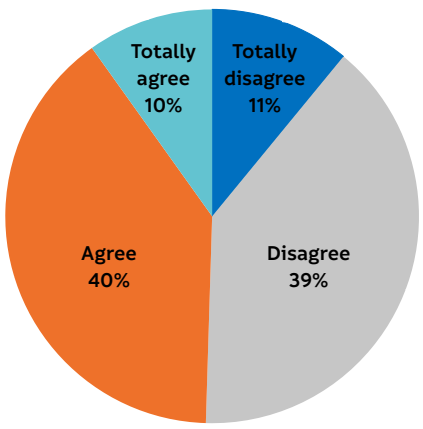


Diagram 3: Expert opinion on quality of route causes analysis

Principal characterization of notifications

To date, different types of errors have been highlighted in the database *(NB: several types of error could be found per event)*:

- related to diagnostics (error or delay in diagnosis, failure to act on results of monitoring or testing, ...) (n=42),
- related to treatments (error in administering the treatment, error in the dose or method of using a drug, ...) (n=194),
- related to failure of communication, lack of organization, system failure (n=342).

Two major risks themes, rather related to patient conditions, have been identified:

- patient suicide (N=413), patient falls (N=270).

What lessons have been learnt?

- → The systems approach requires a shift from a blame culture, where health care staff hides errors for fear of punishment, to a safety management with a just culture, to avoid future SAE-HC.
- → The French system needs to grow and mature but it contributes to develop patient safety through engagement with patients, the public, healthcare professionals and organizations.
- → Reporting systems can be designed differently but their principal purpose should be learning and improvement.

The process of acculturation and changing safety culture takes time. With 2 years of hindsight, we observe that lines and mindsets are evolving. Safety culture is gradually spreading but remains fragile.