FRENCH VIGILANCE ORGANISATION

FROM A BIRD’S POINT OF VIEW…

“At the national level, States Parties are required to assess all reports of urgent events within their territories within 48 hours by applying a specific algorithm” International health regulations (2005) WHO

Félix FAUCON
General Inspector
General Inspectorate for social affairs and health
The scope of vigilance

- Human, animal and vegetal health,
- Products on the market and out of the market (mushrooms collected in the forest, kitchen gardens, private orchards...),
- Practices (use of medical equipment emitting ionising radiation...),
- Not only for patients or users, or consumers, but also for providers
A growing concern

La grippe aviaire est arrivée en France
Pourvu que cela nous débarrasse des pigeons...
Pourvu que cela nous débarrassse des humains...

Pilule de troisième et quatrième génération : le scandale atteint la France

Le scandale des prothèses mammaires PIP
Un procès hors normes aura lieu du 17 avril au 17 mai à Marseille.

Situation en France (à fin oct. 2012)
- 30 000 femmes portees
- 14 327 femmes ont eu une exploration de leur prothèse, dont 10 042 a été prouvée

Effets indésirables:
- ruptures observées chez 3 290 femmes, réactions inflammatoires chez 1 837 femmes
- 57 cas d’adénocarcinomes mammaires (cancers du sein) déclarés
- 5 127 plaintes déposées, dont 2 200 étrangères

Nombre de cas d’encéphalopathie spongiforme bovine (ESB) signalés au Royaume-Uni (1987-2008)

Jour de la main-courante - Journal d’un surirradié d’Épinal
Health monitoring building blocks

- **Routinely collected data (monitoring via specific surveillance):** priority and well known risks; population health status (reportable diseases, incidence threshold crossing), living environment (concentration of a pollutant in the air), various zoonotic infections (avian mortality, equine encephalitis...)

- **Systems able to collect signals of all kinds and origins (vigilance via non specific surveillance)** concerning different types of threat: abnormal clinical profile, complaint from a neighbouring resident of a polluted site, disease peak in a community etc...
Examples of diseases surveillance networks

- **Specific mortality and morbidity**: notifiable diseases; hospital acquired infections;

- **Medical test laboratories**: gonococcal infection; chlamydia; haemophilus influenza; HCV; HIV; rubella; streptococcus; pertussis etc.

- **Hospital services**: paediatrics; asthma; influenza; Creutzfeldt-Jacob...

- **National centres of reference** (44) and associated laboratories

- **Environmental surveillance**: heatwave; poisoning (lead, carbon monoxide...)
Examples of diseases surveillance networks

- **Sentinel / GPs under the umbrella of the INSERM** (national institute of health and medical research): seasonal surveillance (influenza, acute diarrhoea), and permanent surveillance on an annual program basis (currently 8 diseases);

- **Regional surveillance**: West Nile, Lyme disease, dengue fever, leptospirosis...

- **Sentinel / occupational physicians**: specific diseases

- **European and international networks**: legionnaires (ELDSNET), antimicrobial resistance (EARSS), influenza (EISN), vaccine preventable diseases...
Examples of risk exposure indicators (surveillance networks)

- Quality of drinking and human uses water
- Quality of bathing water
- Quality of the air
- Radioactivity
- Aerobiological inspection
- Weather events
- Phytosanitary products exposure
- Sectoral or general exposure matrix for occupational risks
Emergency and death surveillance information system architecture

- **Emergency H Services Visits**
  - HES
  - Call centre

- **On Call GP Association “SOS Médecins”**
  - GP

- **National SOS server**
  - Call centre
  - GP

- **Regional server**
  - HES

- **National Public Health Agency Server**
  - INSERM server
  - INSEE server

- **Electronic Death Certificates**
  - EDC

- **In Town Mortality**
  - Town Hall
  - DC

- **Call centre**
  - GP
Assessment of an alert

Regional capacities adequate?

Supra-regional extension risk?

National info?

N: REGIONAL ALERT + SPECIAL SUPPORT

Y: NATIONAL ALERT

N: REGIONAL ALERT

Y: REGIONAL ALERT + NATIONAL INFO
A gradual construction of a legal framework...and a complex system

- Born out from public health crisis (HIV contaminated blood, mad cow crisis, asbestos contamination...)
- And sentences against the State because of its deficiencies: Like all kinds of safety, sanitary safety is a State responsibility
- Then, a lot of legislators’ interventions from 1993 to now (last law in 2016)
- Each crisis brings its specific agency; and some have since been merged
Players of the health monitoring system

The DGS / General Directorate for health (Ministry of Health) in charge of:

- Health monitoring
- Alert response
- Sanitary crisis management in cooperation if necessary with the Ministry of Interior (inter-ministerial role of the Prefects)

It includes the national operational centre for sanitary and social emergency responses

IHR (2005) Focal point for WHO
Players of the health monitoring system

6 thematic national agencies (some having regional offices)

Overarching principle: risk assessment done by the agencies; risk and crisis management done by the State (regional and/or national level);

Exceptions: health products (human and veterinary uses) decisions on behalf of the State done by the CEO (ANSM or ANSES)

- HAS (National authority for health): vigilance related to drug prescription and dispensing assistance softwares
6 thematic national agencies:

- **ASN** (nuclear safety authority): vigilance related to radioprotection significant incidents

- **ANSP** (public health national agency): transversal action closely linked with the DGS; epidemiological surveillance; prospective watch on sanitary risks; preparation and response to health threats, alerts and crisis;

- **ABM** (biomedicine agency): biovigilance (organ, cell and tissue implantation), vigilance related to medically assisted reproduction;
Players of the health monitoring system

6 thematic national agencies:

- **ANSM** (medicine and health products and devices agency): pharmacovigilance; medical device vigilance; hemovigilance; reagent vigilance; addictovigilance; cosmetovigilance; tattoo product vigilance; biomedical trial vigilance

- **ANSES** (Food, environment and occupational health agency): toxicovigilance; food vigilance; veterinary pharmacovigilance (effects on humans); agrochemical product vigilance (effects on humans)
Players of the health monitoring system

17 ARS (regional health agencies, in mainland and overseas France):

- Health monitoring, emergency responses, crisis management in respect of Prefect attributions;
- Organisation of the description, notification and alert collection;
- Coordination of a regional network gathering entities involved in safety and quality of patient care;
- Coordination of a regional network gathering entities involved in health monitoring and vigilance;
- Coordination of investigations and local responses in the case of sanitary alert;
An historical stratification
Since 2013, reports to prepare a reform

Assessment:

- A fragmented functioning;
- A dense territorial network, but regionally varied and unclear (heterogeneity of the local organisations);
- Multiple and not communicating tools;
- A weak notification culture (fear of sanction);
The 2016 reform objectives

- Facilitate and promote the AE notification: web portal (see second presentation); whistle blower protection; non sanction hospital charters; recognition of the health providers contribution to the public health service

- Improve the regional organisation: promotion of the regional agencies leading role over all the local and regional entities involved in surveillance and vigilance;

- Improve overall steering and management: clarify roles and responsibilities; urbanize the information systems related to surveillance, alert and crisis management
THANK YOU FOR YOUR ATTENTION