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 débarrasse des humains...

Mediator 150 mg

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 porteurès
- 14 327 femmes ont eu une extraction de leur prothèse, dont 10 042 à Marseille
- Effets indésirables : ruptures observées chez 3 290 femmes, réactions inflammatoires chez 1 937 femmes
- 57 cas d'adénocarcinomes mammaires (cancers du sein) déclarés
- 5 127 plaintes déposées, dont 2 350 lancées à Marseille

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

Journal d'un surirradié d'Épinal

Nombre de portées :
- portées
- prothèses implantées

Le monde des prothèses :
- ROYAUME-UNI 40 000
- FRANCE 30 000
- ITALIE 4 300
- ESPAGNE 1 950
- PAYS-BAS 1 200
- ALLEMAGNE 7 500 à 10 000
- POLOGNE 2 200
- SUISSE 280
- AUTRICHE 100
- CANADA 50
- ÉTATS-UNIS 10
- JAPON 10
- AUSTRALIE 12 300
- BRÉSIL 25 600
- ARGENTINE 15 000
- MEXIQUE 4 500
- COLOMBIE 15 000
- ÉQUATEUR 5 000
- ÉTATS-UNIS 1 100
- CHILI 1 000
- VENEZUELA 33 000
- TUNISIE 743
- CHINE 570
- ÉGYPTE 732
- COSTA RICA 372

Source : ANSM

De 400 000 à 500 000 femmes seraient porteurès de ces implants dans plus de 65 pays.
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 monoxyd...)

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 Health Services Visits

On Call GP Association “SOS Médecins”

Call centre

NATIONAL SOS server

INSEE server

INSEER server

Electronic Death Certificates

INSEE server

NATIONAL PUBLIC HEALTH AGENCY SERVER

EDC
EDC
EDC

Town Hall

In Town Mortality

EDC
EDC
EDC

Town Hall

DC
DC
DC

GP

GP

GP

GP

GP

GP

GP

GP

GP

GP
Assessment of an alert

Regional capacities adequate?
  N
  REGIONAL ALERT + SPECIAL SUPPORT
  Y
  National info?
    N
    REGIONAL ALERT
    Y
    REGIONAL ALERT + NATIONAL INFO

Supra-regional extension risk?
  N
  Y
  NATIONAL ALERT
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
Players of the health monitoring system

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