THE FRENCH NATIONWIDE SYSTEM FOR ADVERSE EVENT REPORTING BY PUBLIC, PATIENTS AND HEALTHCARE PROFESSIONNALS

From a hospital-based reporting of health-care-associated infection to a universal reporting system for adverse events

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AN EXTENDED REPORTING SYSTEM

Unique portal for reporting any adverse event within all and every field of regulated vigilances and HCAE

Associated with the use of a drug, product or device
- Medication
- Material (instrument, implanted medical device, dressings, prosthesis...)
- Blood derived product (transfusion)
- Food additive
- Addictive substance
- Cosmetics
- Tattoo product
- Other products ...

Healthcare-associated
- Healthcare-associated infection
- Serious adverse event (associated with death, disability, or other public health threat)
THE CONSTRUCTION PROCESS

A CO-CONSTRUCTION WITH REPRESENTATIVES OF ALL STAKEHOLDERS: REGISTRANTS AND ASSESSORS

- PATIENT ASSOCIATIONS
- HOSPITAL AND IN-TOWN HCP
- REGIONAL ENTITIES FOR VIGILANCE AND SUPPORT
- NATIONAL AGENCIES, REGIONAL HEALTH AGENCIES
- MINISTRY OF HEALTH

A PERMANENT DIALOGUE AND CONCERTATION

- 20 COLLABORATIVE WORKSHOPS
- MODEL CONSTRUCTION, PROTOTYPES AND TESTS
- JOINT CONTENT DEVELOPMENT
- FOCUS GROUPS AND INDIVIDUAL FEED BACK
OBJECTIVES AND PRINCIPLES OF THE WEB PORTAL

A single window for all types of registrants
• Web portal offers an ergonomical and simple access for all kinds of vigilance

Facilitating Serious Adverse Events notification
• Directing registrant through a guidance module aiming the identification of the relevant type of vigilance
• Orienting automatically to the existing notification tools, or enabling the online filling for non equipped types of vigilance

Promoting sanitary safety monitoring and notification initiatives
• Through a simplified information
• And a feed back to the registrant issuing an acknowledgement of receipt for every notification

Facilitating the transmission of information to the assessors
• Addressing automatically and immediately the notification to the relevant assessors
• Using email or interconnected messaging
A FIRST VERSION DELIVERED IN 2016 PROGRESSIVELY ENRICHED BY FURTHER DEVELOPMENTS

- Integration into hospital and in-town practitioners specific software
- Mobile phone applications
- Unique authentication

V1 (2016)
- Regulated Vigilances
- Form Simplification
- IS Interconnection

- Enlargement to the whole regional notifications
- Interconnection with sanitary agencies ‘IS and software

- Forms harmonisation and convergence

- Interconnection with sanitary agencies ‘IS and software
- Mobile phone applications
- Unique authentication

- Forms harmonisation and convergence
A GUIDE THROUGH REPORTING

Directs the reporter to the alert system corresponding to his/her context

- Simple, non-technical questions
- Directed to the relevant alert system
- Web-based reporting via online forms
- Does not substitute existing tools

3 possible pathways for reporting:

- Direct reporting
- Via an HCP
- Existing on-line system
THE ONLINE FORM

Evénement

Date de début:

Date de fin:

Département de survenue:

Code postal / commune de survenue:

Région de survenue:

Précision sur le lieu de survenue:

Type de l’événement:

Description de l’événement:

Nombre de personnes concernées:

date de survenue indésirable

date de l’hypothèse de...

toute précision sur le lieu ou (domicile, etc.)

Événements indésirables associés aux soins

...
From an historical stratification...
TO A TWO STEP MONITORING AND FEEDBACK PROCESS

Regional Health Agency

- Regional subsidiaries of health agencies providing expertise and support to HCP and ARS

Medicines agency
- ansm
  - CEIP
  - CRPV
  - CRH
  - CRMV (exp)

Biomedicine agency
- OMEDIT
  - Adverse Drug Events
  - Drug use monitoring

Nuclear medicine
- DIV
  - ASN

Health Authority
- SRA
  - HC Safety & Quality
  - SAE & HCAI

Public Health
- CPIAS
  - Infection Prevention & Control and AMR
- CIRE
  - Epidemiology

Regional Health Agency
- CAPTV
  - Poison Control Centre
- ansses
  - Food & environment
FOCUS ON PHARMACOVIGILANCE

**Notification**
- Notification of a drug adverse event

**Sending**
- Either downloaded or email notification
- Or using the specific HCP secure messaging

**Assessment**
- Reception by the concerned regional centre of pharmacovigilance (CRPV)

*The web portal doesn’t substitute for existing tools, such as notification websites yet used by some CRPV, or hospitals.*
FOCUS ON A NOTIFICATION ORIENTED TO A REGIONAL HEALTH AGENCY

Notification
- Health care adverse event

Sending
- Automatically interconnection with the regional vigilance and sanitary safety IS

Assessment
- Receipt by the regional agency team (regional focal point)

INDIVIDUAL

HEALTH CARE PROVIDER
- Severe Adverse Event notification
- Outpatient health care associated infection
- Health care adverse event
FOCUS ON TOXICOVIGILANCE

Notification

- Notification of a Poisoning resulting from an everyday life product

Sending

- Either downloaded or email notification
- Or using the specific HCP secure messaging

The individual is notified that:

- In an emergency or a need of medical assistance, he has to contact the poison control centre or the medical emergency services
- In the case of calling a poison control centre, it is not necessary to notify the adverse event, because the poison control centre systematically carries out the notification

Assessment

- Reception by the concerned regional poison control centre
Expected benefits from the extended web-based reporting system: Promoting a safety culture

**HCP**
- Incentivises healthcare professionals to report HCA–AE
- Provides support
- Prevents blame (charters for reporting)

**Patients**
- Enables patients to report their experience
- Extends the reporting system to all healthcare settings, incl. outpatient care

**Organisations**
- Enables hospital management to analyse feedback from all HCA-AE
- Provides support and expertise via regional QS units
THANK YOU FOR YOUR ATTENTION
Real-time tracking of Flu vaccination campaign

Flu epidemiology tracking in 2015

Public Health Indicators

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Couverture vaccinale contre la grippe saisonnière des 65 ans et plus.

<table>
<thead>
<tr>
<th>Objectif</th>
<th>03/01/2017</th>
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<td>75%</td>
<td>52%</td>
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Couverture vaccinale
2015/2016: 53%
Taux au 03/01/2016: 52%
Longitudinal data for practices monitoring and real time surveillance system

Follow-up of the drugs deliveries for each patient (with all details)
Use Case - L’impact des mesures de sécurité

L’évolution des patients sous VALPROATE vers une thérapie alternative

- Un recours aux traitements alternatifs spécifique aux femmes …
- mais limité avec seulement 12% de femmes concernées vs. 6% d’hommes

n = 2 430 Femmes 15 – 49 ans

Impact des mesures de sécurité

Lettre aux PS
26 -05-15
Conférence de presse & 2ème lettre aux PS
11-15
Fiche mémo
01-01-16
Nouvelles conditions de prescriptions et de délivrance