A Nationwide System for Adverse Events Reporting

By Patients and HeathCare Professionnals

Contributing to develop patient safety through engagement with patients, the public, healthcare professionals and organisations.

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Challenges and incentives for making safer care a key component of quality initiatives

- Increasingly complex pathological processes
- New treatments/procedures
- Emerging AMR threat
- Limited resources

SAFER CARE

- Strong leadership
- Governance & regulations
- Education & training
- Improved use of information & data sharing

INCIDENT REPORTING
The French Nationwide web-based Adverse events Reporting system

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

https://signalement.social-sante.gouv.fr/psig_ihm_utilisateurs/index.html#/accueil
The HCAI web-based EWRS
Implemented 2013
The EWRS for HCAI
No. Episodes of Colonization/ infection with Carbapenem-R Enterobacteriaceae, France 2009 – 2015 (N= 2 376)

Monthly No.

No. Episodes/year

Interregional spread

Avant 2009

2010-2012

2013-2015
Incidence study of SAE

81 hosp, 251 units, 8259 admissions (Apr-Jun 2009)

On-admission SAE (% admissions)

- Medicine:
  - Preventable: 2.1, 3.2
- Surgery:
  - Preventable: 1.7, 1.7
- Overall:
  - Preventable: 1.9, 2.6

In-hospital SAE (incidence p.1000 d)

- Medicine:
  - Preventable: 2.3, 2.4
  - Incidence: 6.3, 2.9
- Surgery:
  - Preventable: 2.9
  - Incidence: 2.6
- Overall:
  - Preventable: 3.6
  - Incidence: 6.3

Preventable Events category

- Procedure: 17% (Medecine 6%, Surgery 76%)
- Drug-medication: 46% (Medecine 29%, Surgery 75%)
- HCA Infection: 42% (Medecine 19%, Surgery 41%)

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)
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 formularies
- Does not substitute existing tools

3 possible pathways for reporting:

Direct reporting
Via an HCP
Existing on-line system
The online formulary
The Scope and pathways for reporting and analyses: Patients-Public and Healthcare Professionals

- Drug-medications
- Medical devices
- Tests
- Addictive drugs
- Cosmetics, tattooing
- Blood products, transfusion
- Household products, gardening
- Food additives
- Veterinary drug
- Assisted Medical Reproduction
- Tissue graft
- Medical Imaging
- Radiation therapy

AE associated with a product / substance

Healthcare associated AE

Drug agency

Food & environment

Biomedicine

Regional Health Agency

Infections & other SAE
Monitoring and feedback

Regional Health Agency

Medicines agency

Adverse Drug Events

Drug use monitoring

Biomedicine agency

Nuclear medicine

Regional subsidiaries of health agencies providing expertise and support to HCF and ARS

Health Authority

HC Safety & Quality

SAE & HCAI

Public Health

Infection Prevention & Control and AMR

Epidemiology

Centre antipoison & toxicovigilance

Food & environment

A two-step process for reporting, analysis and feedback on SAE
Expected benefits from the extended web-based reporting system: Promoting a safety culture

**HCP**
- Incentivize 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. ambulatory care

**Organisations**
- Enables hospital management to analyse feedback from all HCA-AE
- Provide support and expertise via regional QS units