



HAUTE AUTORITÉ DE SANTÉ

A national scheme to ensure medication safety : the national certification system for computerized physician order entry (CPOE) in France

National Authority for Health (HAS)

Department of care coordination, appropriateness and quality of care

Links of Interest – Current activities

**Project manager for National Authority for Health / Haute
Autorité de Santé (HAS) - France**

Part-time hospital physician (ICU)

**Inspector for the French national accreditation body
(Cofrac)**

Regulatory mission

National certification system for Computerized Physician Order Entry (CPOE)

Mandatory certification

Goals :

- improving practices
- contributing to cost containment
- disseminating the use of the International Nonproprietary Name for drugs

Roles :

- software requirements : National Authority for Health (HAS, independent administrative authority)
- accredited certification body : conformity assessment

Schemes

Certification scheme for hospital CPOE systems (CPOE supported by hospital drug formulary, 2012)

Certification scheme for CPOE systems used in ambulatory care (2008, 2016)

Approval process for Pharmaceutical Data Bases (PDB) : requirement definition and conformity assessment by HAS

Only CPOE incorporating approved PDB are allowed to apply for certification

Consensus among user representatives, public stakeholders and representatives of software companies

Requirements for certified CPOE

Advertisement not allowed

Security checks for drug use with medical record data including maximum dosage, drug interactions, pregnancy, lactation, medical history and allergy

Allow to prescribe using International Nonproprietary Names with and without the pharmaceutical brand name, at users choice, same security checks

Price of drug, reimbursement rates by the national health insurance, cost of drug prescriptions

Updated, neutral and comprehensive drug information including information from the HTA process

Certified CPOE stockyard

1 accredited certification body

5 Pharmaceutical Data Bases (PDB) approved

66 certified “ambulatory CPOE” (October 4, 2016)

- 78% of CPOE used in primary care in France

- duration of the certificate : 3 years \approx 100 certifications

66 certified “hospital” CPOE (October 4, 2016)

- the most frequently used hospital CPOE in France

- extent of implementation not assessed as of this date

Conclusion

Certification scheme for community pharmacy-dispensing software (mandatory, December 2015)

HAS required to define a mandatory certification scheme for hospital pharmacy-dispensing software

Improving practices : security checks + therapeutic choices

Further improvements :

- biology order entry and results**
- mapping with HL7 standards**
- better use of French national data warehouses**

The team

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