Translated from ***Rev Prescrire*** **December 2011; 31 (338): 915**

In France, healthcare products are involved in about half of all serious adverse events related to healthcare

● **These adverse events generally involve a drug, sometimes a medical device, and more rarely a labile blood product.**

In 2009, 8269 patients hospitalised in France were included in the Eneis 2 study and followed for an average of 4 days to collect data on serious adverse events related to healthcare.

A total of 374 serious healthcare-related adverse events were identified, 177 (47.3%) of which were considered preventable. 214 serious adverse events occurred during hospitalisation, while 160 had led to hospital admission. 171 serious adverse events were identified in general medicine wards and 203 in surgical wards.

Healthcare products involved in about half of all serious healthcare-related adverse events. In the Eneis 2 study, 175 (47%) of the 374 serious healthcare-related adverse events involved a healthcare product (**a**).

In our literature search, we found no data about the severity of the totality of serious adverse events involving healthcare products.

The French drug regulatory agency gave a presentation that only dealt with the preventable serious adverse events involving healthcare products (1).

54% of the serious adverse events involving healthcare products appeared to be preventable. About 54% of the 175 serious adverse events involving healthcare products that were observed in the study appeared to be preventable.

123 (32.9%) of the 374 serious healthcare-related adverse events involved drugs, 63 of which were preventable; 42 (11.2%) involved medical devices, 23 of which were preventable; and 3 (0.8%) involved labile blood products, 2 of which were preventable (1).

39 (58%) of the 67 serious adverse drug reactions that led to hospital admission appeared to be preventable (1): 26 (66%) were prescription-related, including 15 cases of "inappropriate" prescribing, 5 of which involved an "inappropriate" dose (no other details provided); 6 were related to "inappropriate" treatment monitoring (1); 3 were associated with self-medication and 3 with "poor compliance" (1).

Of the 56 serious adverse reactions involving a healthcare product that occurred during hospitalisation, 24 (43%) appeared to be preventable (1). 17 were prescription-related: 9 involved inappropriate prescribing, 5 an inappropriate dose, and 3 failure to prescribe treatment or preventive measures. One adverse event involved an administrative error, 4 were related to treatment monitoring, and 2 were patient-related (self-medication or incorrect drug use).

In the Eneis 1 study conducted in 2004, only 47% of the serious adverse drug reactions were considered preventable (2).

Even more elderly patients hospitalised for serious adverse drug reactions. The proportion of serious adverse drug reactions occurring in patients over the age of 65 years increased between 2004 and 2009.

The proportion of patients aged 80 to 90 years who were hospitalised for serious adverse drug reactions also increased, from about 18% to about 26% (1).

3.8% of the inpatients aged over 65 years were admitted because of an adverse drug reaction, versus 1.27% of patients aged 16 to 65 years. 71% of the hospitalisations caused by adverse drug reactions involved patients over the age of 65 years. These results are similar to those of the Evisa study (3).

About 2.2 serious adverse drug reactions occurred per 1000 bed days among patients over 65 years of age, versus 1.2 for patients aged 16 to 65 years.

16% of the serious adverse drug reactions were reported in geriatric wards.

One-third of adverse drug reactions involve anticoagulants. Anticoagulants were responsible for one-third of the serious adverse drug reactions that led to hospitalisation or that occurred during hospitalisation (1). These results are similar to those reported in 2004.

Low molecular weight heparins (LMWHs), including *fondaparinux*, were responsible for 50% of the serious adverse reactions caused by anticoagulants, and 1 out of 6 serious adverse drug reactions overall (1).

Vitamin K antagonists were responsible for almost 50% of the serious adverse reactions caused by anticoagulants and one-sixth of the total serious adverse drug reactions (1).

We found no data about other drug classes in our literature search.

Serious adverse drug reactions still responsible for many hospital admissions. The proportion of patients admitted to hospital for serious adverse drug reactions increased slightly between 2004 and 2009, from 3.8% to 4.5%, although the difference was not statistically significant (4).

The lack of decline in the proportion of preventable serious adverse drug reactions occurring during hospitalisation shows that medication safety has not improved (1).

a- Healthcare products include drugs, implantable medical devices (prostheses, implants), other medical devices (e.g. lasers, infusion sets, electric scalpels), labile blood products, organs, tissues and cells, and other therapeutic products (e.g. dietetic products, extemporaneously compounded preparations) (ref 4).

Selected references from Prescrire's literature search.

1- Castot A "La sécurité du patient: évènements indésirables associés aux soins et politique de réduction des risques. Zoom sur le médicament: évolution des pratiques en matière de gestion du risque" Présentation du 24 novembre 2010: 16 pages.

2- Prescrire Rédaction "L'étude épidémiologique française Eneis approche la part de l'évitable à l'hôpital et en soins ambulatoires" + "2005: les effets indésirables graves des soins médicamenteux recensés par l'étude Eneis" *Rev Prescrire* 2005; **25** (267 suppl.): 896-901 + 909-910.

3- Prescrire Editorial Staff "Ambulatory care in France: too many adverse events" *Prescrire Int* 2012; **21** (124): 40-41.

4- Direction de la recherche, des études, de l'évaluation et des statistiques "Les évènements indésirables graves associés aux soins observés dans les établissements de santé. Résultats des enquêtes nationales menées en 2009 et 2004" *Dossiers Solidarité et Santé* 2010; **17**: 18 pages.