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.

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.


