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Review article

Computerization of health warnings and incident reports for Materials Vigilance in the Marseille Public Hospitals

Informatisation de alertes sanitaires et des incidents de matériovigilance à l'Assistance publique hôpitaux de Marseille

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Health vigilance is defined as a "Method consisting of the collection and assessment of information relating to unexpected and adverse effects resulting from the use of medical goods and health products, in order to prevent them" [1]. The two main tasks of vigilance are issuing health warnings and recording and analyzing unexpected events.

Materials vigilance (MV) aims to monitor incidents or incident risks resulting from the use of medical devices (MD). A medical device is an instrument, apparatus, appliance or even software intended by the manufacturer to be used for human beings, particularly for the purpose(s) of diagnosis, prevention, monitoring, treatment, alleviation of a disease or an injury [2].

MV originates from European Union Medical Devices Directives [3,4]. Initially under the DHOS (French Hospitalisation and Care Organisation Division), it was, however, marked by the "sanctions" provided in the regulations, and the system was focused on the technical aspect of MD by biomedical engineers, regarding events observed in patients, and this led to a certain "disaffection" of the carers.

The new European Union Regulation [5] has brought about a new approach to MV. This text deals mainly with MD and reinforces their post-market surveillance. An electronic system for data processing is strongly recommended for operators, and patients in health institutions must be clearly informed in order to improve health and safety.

MD management in a health institute contributes to the specific complexity of this materials vigilance, since three different activities are involved in the separate management of MD: the Departments of Pharmaceutics, Biomedical Engineering and Economics departments.

1. Materials Vigilance Organisation in the Marseille Public Hospitals (AP–HM)

The MV correspondent is appointed by the president of the Medical Commission of the Institute to carry out vigilance assignments in accordance with Articles R. 5212-1 to R. 5212-35 of the *Code de la santé publique* (French Public Health Code) [6]. The law provides for the creation of a position but with no associated budget or dedicated time. In our institute, the Haemovigilance correspondent, with a full-time position, is also appointed to carry out assignments for MV [7].

Many health institutes have set up a vigilance coordination system given the large quantities of data sent by the different health authorities. Decree No. 2010-1408 from 12th November 2010 introduced the task of risk management related to care coordinator. In the AP–HM, this mission is carried out by ViGeRiS which is a functional unit of our institution in charge of risk management related to care. The resources for this structure help the MV correspondent to accomplish his tasks.

In the AP–HM adverse events are filed via an electronic system (BlueMedi®) [8], which ViGeRiS and the MV correspondent have adapted to MV needs. A partnership between the different vigilances and ViGeRiS improves data exchange [9].

The MV correspondent relies on central referrers and on-site referrers for each of the 3 activities included in MV:

- pharmaceutics: the Central Service of Pharmaceutical Operations and the Pharmacies of sites which manage implantable devices, single-use material, medical gases, . . .;

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- biomedical Engineering: the Central Biomedical Engineering department and sites which handle medical equipment (ventilator, dialysis, scanner, . . .);
- economics department: central economics departments and sites with non-sterile medical apparatus, beds, chairs, . . .

All of these professionals must communicate with each other to manage MV health warnings and incident reporting: the participation of carers remains crucial.

2. Management of health warnings and incidents

2.1. Management of top-down MV health warnings

Vigilance coordination receives all of the MV health warnings (on average 680 per year), 90% from the national agency and 10% from manufacturers. Distributing these to all of the professionals involved in MV has made us consider pre-sorting, in order to avoid mass transmission of information to referrers who may not even be concerned by it.

Each warning is referenced: M–YEAR–CHRONOLOGICAL ARRIVAL (e.g. M-17-048 is the 48th warning received in 2017 for MV).

The heads of central Pharmacy, central Biomedical Engineering and the central Economics department agree to receive the warnings first, via a workflow alert, and to carry out the pre-sorting. The central referrer analyses the warning and has to answer two questions:

- Have we got this MD?
- If so, are we concerned with the incriminated batches?
- If not, the information is used in a second phase for purchases that have or have not already been programmed, or for patients transferred from another health institute with this MD.

If the central referrer answers YES to the first question, the warning will be transmitted to the relevant network (on-site pharmacists, on-site biomedical engineers or on-site economics department) to check for incriminated batches.

The on-site referrer will then take action according to the health warning demands: batch recall, software change, inform users, . . . Their response will be computerized in the form of a response slip, which states the action taken. An automatic e-mail is sent for each response, which then gives the total number of actions taken. In this database, the MV correspondent can easily retrieve all of the actions taken within the institute: he can rapidly answer the suppliers' requests (Fig. 1).

Retrieval and/or searches are possible at any given time to determine the responses to the warnings or to see which actions have been, or are being, taken.

2.2. Management of MV incidents

All of the professionals in the institute use the adverse incident reporting software. In 2016, out of 300 reports, 299 were filed electronically. For our health vigilance system there are 2 possible accesses:

- either direct access to file a MV report, preferred when the incident is easy to report and particularly when it is without proven impact on the patient;
- or access to report an adverse incident related to care, which allows connection with a vigilance report.

The professional must fill in all of the mandatory fields (name of MD, batch number, serial number, product reference, manufacturer). If one of the items is not filled in, the report cannot be saved and an alert comes up on the screen asking to complete the fields.

Whatever the choice of access, if MV is involved and a report is filed, the MV correspondent, the on-site referrer and the central referrer all receive an electronic message.

The MV correspondent analyses all of the reports and can, if necessary, contact the declarer and the on-site referrer (by phone or e-mail) to assess the severity of the incident as well as impact on the patient. Following this analysis and moderation, he rates the incident (from A to N) before sending it to the health authorities [8]. Incidents are split into 3 groups:

- *without delay*: death, life-threatening, disability, prolonged hospitalization, medical or surgical intervention;
- *optional*: malfunctions, a noxious unintended reaction, insufficient information on the instructions for use, . . .;
- *quarterly*: recurring optional alerts which are analyzed quarterly and can lead to a report.

Without delay and quarterly (recurring) incidents are systematically transmitted to the *Agence nationale de sécurité du médicament et des produits de santé* (French National Agency for the Safety of Drugs and Health Products, ANSM) [11]. The software edits a message including all of the mandatory information from the CERFA form No. 10246*05 [10] for the national agency which sometimes requests supplementary information from the local MV correspondent. Response history is archived (Fig. 2).

The central departments are in charge of informing the manufacturer if one of their MD is involved in a report filed by the institute. When the incident is based on a manufacturer's report, it is inserted into the electronic incident file.

3. Plus points of electronic management of materials vigilance

Prior to electronic management, we sent out health warnings by e-mail without having any quick or simple way of knowing which actions had been taken. The correspondent had to question the on-site referrers and wait for them to reply. All of the referrers received all of the warnings, and some of them complained about the quantity, especially since in most cases the warning did not concern them.

A close link between risk management related to care and health vigilance correspondents [9] led to the adaptation of a

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