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Standardization for safety: a feasible challenge

Estandarizar por seguridad: un reto asumible

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There is increasing complexity and variability in the management of each stage of the drug use system, thus increasing the risk of incidents and adverse patient effects.

Drug-related incidents can occur at any stage of the medication use process, from prescription to administration; however, although many of these incidents are preventable[1], those that take place in the administration stage are the most difficult to intercept[2].

The impact of drug-administration incidents on patients depends on three fundamental factors: administration route, type of medicine administered, and patient characteristics. The intravenous route for the administration of high-risk drugs or those with a narrow therapeutic index in critically ill and/or pediatric patients are maximum-risk scenarios in which all available resources must be used to guarantee the safety of the process.

The intravenous route carries a high risk of harm in the event of an error. Some studies have found that 60% of life-threatening adverse effects are related to the intravenous administration of drugs[3]. However, the practice of medicine is inconceivable without the use of the intravenous route. For some patients and procedures, it is not only essential, but also the only available route for diagnosis, clinical monitoring or management of multiple therapeutic indications. Therefore, all health care centres should prioritize guaranteeing safety in the intravenous medication management process.

There is evidence that the implementation and integration of electronic systems in the different stages of the medication use process can contribute to reducing drug-related incidents[4]. National and international organizations recommend the adoption of these tools to improve the safety and quality standards of health institutions[5]. Technologies that have been found to increase safety in the drug-use process include the following: electronic prescription systems, automated drug dispensing machines, computerized medication administration records, bar code medication administration, and smart intravenous infusion pumps[6].

Although these new technologies have increased safety in the drug-use process, their use may lead to new types of errors. Some of these errors derive from the technology itself or from the tendency of users to bypass inbuilt safety circuits, thus compromising the ability of these tools to detect incidents. Michalek *et al.* found that despite the implementation of technologies such as barcode medication administration or smart infusion pumps, the lack of mandatory institutional standard procedures and low adherence to them can undermine the safety of these devices when used properly[7]. Therefore, developing standardized processes and promoting their incorporation in health care practice is crucial to guarantee safety within health care centres.

A key first step in the management of intravenous drugs would be to standardize their concentrations and dosage units within each health care centre and subsequently at the national level. This initiative would form the basis of further developments and actions in IV management. This strategy would also minimize variability in intravenous drug preparation and administration by health staff and would provide greater safety both within Pharmacy Services and in hospitalization units[8].

The scientific literature has shown that the risk of errors is increased by the lack of standardized intravenous drug concentrations and the lack of uniformity when selecting the dosage units of specific high-risk drugs[9]. It is a common observation that different units within the same hospital prepare intravenous mixtures of the same drug at different concentrations; unit doses of the same drug can be based on patient weight or just expressed as absolute units, such as miligrams or micrograms, or expressed as unit doses per hour or minute. These scenarios greatly increase the risk of error, especially during healthcare transition.

Several studies have shown that standard drug concentrations reduce administration errors without significantly modifying the effectiveness of treatment or total infused volumes. This aspect is of particular relevance in critically ill patients requiring the careful management of fluid volumes[10].

Although increasing numbers of national and international centres are beginning to address this issue, there is still great room for improvement. For this reason, prestigious organizations, such as the Institute for Safe Medication Practices (ISMP), recommend the standard management of high-risk

intravenous medication as an essential tool to increase safety in this area. Similarly, the American Society of Health-System Pharmacists (ASHP) was the first professional organization to promote a national initiative known as "Standardize 4 Safety", which focused on achieving the same objective[11]. This initiative was based on the results of a survey conducted in American hospitals in 2008, which found that the majority of health care centres did not use standard concentrations for the intravenous administration of high-risk drugs commonly used in the adult, pediatric, and neonatal population[12].

The purpose of this initiative was to reach a consensus among multidisciplinary work teams of doctors, pharmacists, and nursing staff on the standardization of intermittent and continuous intravenous therapy in adult and pediatric patients, and on the standardization of fluid formulations of orally administered drugs. The adoption of these recommendations throughout the entire nation would contribute to a reduction in medication errors and an increase in safety during healthcare transitions, particularly in high-risk areas such as critical care units, operating rooms, and emergency, pediatric, and neonatal care services.

The philosophy underlying this project, which is completely exportable to other health care systems, could be the cornerstone of the development and implementation of technologies used in the administration stage. These technologies include those mentioned previously, in which the frequent lack of standardised procedures compromises their ability to intercept drug-related incidents[13].

We are aware of regional experiences in different health care centres that have addressed this issue; however, the lack of leadership at the national level in relation to this issue means that we are still far from having consensus recommendations that are valid for all health care centres in Spain.

If it were possible to coordinate a project of this nature at a national level and to adopt the standardization proposal on a massive scale across all health care centres, we would not only increase safety in the administration stage, which is the main objective, but we would also lay the foundations for the centralized preparation of intravenous mixtures in Pharmacy Services[14]. A further possibility would be that the pharmaceutical industry would prepare ready-to-administer intravenous mixtures as their current preparations and related handling recommendations often do not meet the real needs of clinical care practice.

Other advantages derived from the process of standardization and adherence to the resulting proposals would include the following: the possibility of reducing dispensing and administration times of specific vital emergency medicines; the availability of predefined databases for direct upload into specific technological tools and information systems; and the possibility of better characterizing the physicochemical properties of the mixtures by determining their pH and osmolarity in the established diluents given their influence on the selection of the most appropriate type of vascular access (central or peripheral)[15] and the lack of information on this aspect in the summary of product characteristics.

Therefore, the standardization of intravenous medication is only one aspect, although fundamental, of a global strategy aimed at guaranteeing safety related to the administration of intravenous therapy.

The creation of local initiatives is a first step that can contribute to providing the needed impetus to form a group capable of assuming leadership at the national level. Such activity would facilitate the development of a valid consensus document in health care centres, leading to the definitive homogenization of criteria for the safe management of intravenous medication and gaining confidence in stating that our time has finally come.

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