SPECIAL ARTICLE

# EVALUATION CRITERIA ON THE UTILITY AND EFFICACY OF SMART PUMP TECHNOLOGY IN A HOSPITAL SETTING

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**ABSTRACT**

The implementation of new technologies in each and every stage of the medication use cycle has become a key strategy aimed at diminishing the incidence of medication errors that may take place during the prescription, transcription, dispensing and administration process.

Using smart pumps to guarantee the safe administration of intravenous drugs is an initiative that has gained increasing importance in our hospital settings in recent years.

When implementing a new technology, it is necessary to establish criteria that will allow for an objective evaluation of its efficacy and safety in intercepting errors, in order to, finally, estimate the cost-effectiveness of its implementation.

The objective of this manuscript is to describe the criteria that should be taken into account when analyzing and evaluating the global process of implementation of smart pump technology within a hospital.

EVALUATION CRITERIA – INFUSION PUMPS – INTRAVENOUS INFUSIONS – ADMINISTRATION – PATIENT SAFETY – SMART PUMPS – TECHNOLOGY ASSESSMENT

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***RESUMEN***

*La integración de las nuevas tecnologías en todas y cada una de las etapas del ciclo de medicamentos se ha convertido en un elemento clave en la estrategia dirigida a reducir la incidencia de errores de medicación que puede tener lugar en el proceso de la prescripción, transcripción, dispensación y administración.*

*La utilización de las bombas inteligentes para garantizar la seguridad en la administración de los medicamentos vía intravenosa es una iniciativa que ha ido adquiriendo cada vez mayor importancia en nuestro hospital en los últimos años.*

*Al implementar una nueva tecnología, es necesario establecer los criterios que permitan una evaluación objetiva de la eficacia y seguridad para interceptar los errores, y así poder estimar el coste-efectividad de su aplicación.*

*El objetivo de este documento es describir los criterios que deben tenerse en cuenta al analizar y evaluar el proceso global de la aplicación de tecnología de la bomba inteligente dentro de un hospital.*

*CRITERIOS DE EVALUACIÓN – BOMBAS DE INFUSIÓN – INFUSIONES INTRAVENOSAS – ADMINISTRACIÓN – SEGURIDAD DEL PACIENTE – BOMBAS INTELIGENTES – EVALUACIÓN DE LA TECNOLOGÍA*

## BACKGROUND

The concept of safety regarding drug therapy has changed in recent years due to the associated high morbidity and mortality, attributable, in many instances to medication errors.[1-3]

The development and implementation of new technologies throughout the different stages of the drug use circuit, such as prescription, transcription, dispensing and administration, has contributed in reducing the incidence of errors and has increased safety in each of these phases.[4, 5]

Medication errors occurring during the administration phase are the most difficult to intercept and the con-

sequences for the patient depend on the drug itself, the administration route and the patient characteristics, such as age and clinical state.[6-8]

60% of life-threatening adverse effects are related to drugs that are delivered intravenously. Many of these drugs have a narrow therapeutic range and are considered to be high risk drugs. This fact, along with the intrinsic characteristics of intravenous administration, where the drug is directly delivered into blood stream, increases the risk of causing an adverse effect in the patient in the event of an error.[9, 10]

Nevertheless, the practice of medicine cannot be conceived without the use of highly effective drugs administrated intravenously, so guaranteeing safety in their management should be a priority for different health institutions to encourage development of new systems for drug administration, minimizing errors and increasing the confidence of the health staff involved in their daily use.[11-13]

The use of infusion pumps for intravenous administration of drugs that require an exhaustive monitoring of the infusion rate sparked a revolution in the administration of intravenous therapy, at the time of their development.

## WHAT IS AN INFUSION PUMP?

Infusion pumps are electromechanical devices which generate a positive pressure that allows the movement of the fluid to be administrated from its container to the vascular access in the patient at a constant, precise and controllable flow rate. These systems allow the programming of a very broad range of infusion rates, from 0.1 mL/h to 1,200 mL/h.[14]

However, despite the fact that the use of these devices increases safety in intravenous drug administration when compared to the conventional systems of infusion flow control by gravity, most medication errors associated with infusion systems occur due to pump programming errors which can lead to incorrect dosage in a specific patient simply by pushing the wrong key on the infusion pump at the moment of programming.[15]

## WHAT IS A «SMART» INFUSION PUMP?

The severe consequences these (relatively frequent) human errors have on patient health and the lack of means for intercepting these errors, have given rise to the second generation infusion systems known as «smart pumps». These systems include security software with a drug library specifically designed for each hospital unit.[16]

A drug library is a list of drugs for each of which a series of parameters are defined, such as concentrations, maximum and minimum infusion rates which determine the so-called upper and lower hard and soft limits, (UHL, LHL, USL, LSL). These limits are designed to avoid administration of drugs at excessively fast or slow rates, respectively. Therefore, if a user attempts to exceed a soft limit by mistake, an alarm will be triggered warning the user that the programmed infusion rate might not be adequate for a determined patient but allows the continuation of the infusion once the programming has been verified. On the other hand, if due to a programming error a hard limit is exceeded, an alarm will sound leading the user to cancel the infusion and re-programme the administration.[17, 18]

The information on every programmed infusion is stored in the device's internal memory, so that access to this gives data on the time, day and month of programming, the use of the drug library, the drug selection, the programmed rate and the consequent user action in case of an alarm.[19]

The ease and method of access to the stored information varies according to vendors and this is an important factor when considering the system for implementation.[20-22]

Likewise, the availability of the required connectivity to integrate these devices with the technology already implemented in a hospital, such as computerized physician order entry, automatic dispensing systems and bar code administration is an added value. This is important for closing the error interception circuit, as, in the five stages to be completed in error-free administration (right patient, right drug, right dose, right route and right time), smart pumps only guarantee the third stage, right dosage.[23]

## SYSTEM EVALUATION

Currently, there are several vendors offering smart pump technology. The differential features amongst each infusion system may condition the implementation process.

When evaluating smart pumps, several factors must be considered. On the one hand, technical characteristics, merely related to conventional use of the pump for intravenous drug administration, and on the other, those related to smart technology. Both should be studied in depth and analysed to be able to select the system which best adapts to units' requirements and expectations. (Annex I).

## MULTIDISCIPLINARY TEAM

For successful implementation and to achieve the desired results with this technology, the training of a multidisciplinary team comprised of physicians, pharmacists, nursing staff and computer technicians is mandatory.

The nursing staff and computer technicians must be actively committed to the development of the project, from the selection of the manufacturer and the development of the drug library to the analysis and continuous evaluation of the end results.[24]

Thus, physicians and pharmacists develop the drug libraries and define, based on existing sources of information, all the necessary parameters for a drug.

Nursing staff, the main users, play an important role when it comes to evaluating the characteristics of the infusion systems and selecting the most suitable, supported at all times by the physician and pharmacist, also involved in this task.

The technological integration, the last link in the chain, is carried out by the computer technicians, coordinated by physicians and pharmacists.[25]

The leading role of the pharmacist must be highlighted, who, besides participating in the different stages of implementation, also acts as coordinator in these stages and as the link amongst the different professionals involved.

## CONTINUOUS EVALUATION OF THE TECHNOLOGY

To guarantee the contribution of this technology to safer medication use, a programme for continuous evaluation must be developed allowing identification of areas for improvement to be carried out with the aim of optimising each stage of the process.[26]

The systematic analysis of the alarms triggered during the infusion pump use in habitual clinical practice is crucial as it gives information allowing us to perfect the technology refining the established limits and identifying users' training needs. Both aspects are fundamental for staff compliance with the drug library.[27]

Consequently, the connectivity characteristics of these systems play an important role when accessing the stored data.

Establishing methods for communication amongst the different health professionals involved in the project is key for the success of the implementation process. Periodical information on the changes introduced to the drug library, flaws and successes achieved in the safe management of intravenous medication encourages active commitment and participation from staff.

As indicators for continuous evaluation we can see those in Annex II.

## DISCUSSION

Implementation of smart pump technology in a hospital can play a vital role in error interception as well as in the reduction of associated costs.

To be able to evaluate the usefulness and efficacy of these devices in daily clinical practice, it is important to establish criteria allowing objective analysis of the appropriateness of the system from those available on the market, degree of use in a hospital setting and the efficacy in intercepting errors.

The right choice of vendor as regards characteristics, the possibilities and requirements of a unit, as well as the design of an implementation process alongside the reality of daily clinical practice in a hospital unit are key for the success of this technology.

One of the main limitations of this technology is the possibility of programming infusions without the drug library, as well as the inability to detect other administration errors when smart pumps work in an isolated environment.

Due to this, constant and fluid communication amongst the different health professionals involved in the implementation process, continuous evaluation of results and, in the future, technological integration, will help to achieve adherence to the technology and minimise the incidence of errors.

Collaboration between the different health professionals, physicians, pharmacists, nursing staff and computer teams is essential in guaranteeing the success of the project and in making this technology an easy tool to use as well as effective in avoiding errors. CP

**ANNEX I. Characteristics of the infusion systems.**

*Technical characteristics*

- Difference between syringe pump and great volume pump according to differential characteristics
- Specification of number of infusion channels
- Range of infusion speed that can be programmed
- Range of priming speed
- Facility for priming the infusion line
- Facility for eliminating air bubbles
- Security connections luer-lock type
- Variable work pressure
- Free flow control
- Connection type: mains, battery
- On screen: administered accumulated volume, infusion start finish, stand by, infusion time
- Options for stopping infusion and maintenance of vein open
- Types of visual and acoustic alarms: changes in pressure, occlusion, end of infusion, low battery, badly placed syringe, empty recipient (volumetric), excess of solution in drip chamber (volumetric), badly placed sensor
- Dimensions: reduced size (volumetric), space optimization (stackable syringe pumps, wheeled poles)
- Facility for programming
- Facility for solving triggered alarms

*Characteristics related to smart technology*

**General**

- Facility for programming
- Access levels according to user profile
- Easy access to drug library
- Easy resolution of triggered alarms
- Repercussion on workload
- Technical support: training, technical backup, user manual, training materials, incident resolution
- Purchase method or migration of conventional to smart systems: leasing/renting, payment for consumables

## ANNEX I. (Continuation)

*Characteristics related to smart technology*

**Drug library editor software**

- Intuitive programme for entering data
- Requisites for accessing editor: Internet access, administrator rights
- Capacity: total number of lines
- Capacity distribution: number of profiles and lines per profile
- Possibility of establishing concentration limits
- Possibility of establishing dosage limits in intermittent perfusions and bolus
- Possibility of establishing limits for intermittent perfusion and bolus administration times
- Possibility of establishing limits by default for protocol infusion start
- Possibility of establishing limits on patient weight by profile
- Types of available limits: default, absolute and relative, maximum and minimum
- Number and types of obligatory parameters to enter in the programme
- Definition of accuracy in concentration limits: number of permitted decimals
- Definition of accuracy in infusion speed limits: number of decimals, total number of characters (including commas and numbers)
- Limits in agreement with maximum speed of infusion pump (999 mL/h; 1,200 mL/h, variable according to supplier)
- Types of available units
- Type and maximum number of characters in the definition of each profile or line: upper case letters or symbols
- Possibility of changing order of each profile line
- Possibility of activating controlled bolus within a determined perfusion
- Programme language Spanish

**Event reporter software**

- Intuitive programme
- Capacity for data storage, according to pump internal memory
- Requisites for access to download programme: administrator rights, Internet access
- Types of reports and characteristics
- Possibility of editing reports and exporting to different formats (Excel, Word, PDF)
- Spanish language

**Connectivity**

- Wireless data updating and download
- Possibility of integrating with computerized physician order entry
- Possibility of integrating with automatic dispensing systems
- Possibility of integrating with bar code administration systems
- Possibility of integrating with electronic medication administration record
- Possibility of integrating with patient monitoring systems
- Possibility of integrating with medical records

## ANNEX II. Indicators of continuous evaluation.

*Technology use quality indicators*

- Adherence to drug library (1):
  (number of infusions programmed using drug library × 100 / total number of programmed infusions)
- Ratio number triggered alarms: number of infusions using drug library (2):
  (total number of alarms for drug × 100 / total number of infusions programmed with drug library)
- Percentage of ignored alarms (3)
  (total number of ignored alarms for drug × 100 / total number of alarms for soft limit)
- Percentage of alarms involving immediate infusion reprogramming (3)
  (total number of reprogrammed alarms × 100 / total number of alarms for drug)
- Percentage of alarms involving infusion cancellation (3)
  (total number of cancelled infusions × 100 / total number of alarms for drug)

*Health care setting indicators (4)*

- Distribution of alarms by time of day
  (total number of alarms for drug by time × 100 / total number of alarms for drug)
- Distribution of alarms by weekday
  (total number of alarms for drug by weekday × 100 / total number of alarms for drug)
- Distribution of alarms by month
  (total number of alarms for drug by month × 100 / total number of alarms for drug)

**ANNEX II. (Continuation)**

*Technology efficacy indicators (5)*

- Total number of avoided programming errors by detected alarms
- Percentage of potential fast infusion and/or overdose infusion errors
  (total number of alarms for drug exceeding USL and/or UHL × 100 / total number of alarms for drug)
- Percentage of potential slow infusion and/or underdose infusion errors
  (total number of alarms for drug lower than LSL and/or LHL × 100 / total number of alarms for drug)
- Percentage of nil potential severity errors
  (total number of nil potential severity errors × 100 / total number of intercepted errors)
- Percentage of minor potential severity errors
  (total number of minor potential severity errors × 100 / total number of intercepted errors)
- Percentage of moderate potential severity errors
  (total number of moderate potential severity errors × 100 / total number of intercepted errors)
- Percentage of severe potential errors
  (total number of severe potential errors × 100 / total number of intercepted errors)
- Percentage of catastrophic potential severity errors
  (total number of catastrophic potential severity errors × 100 / total number of intercepted errors)

(1): This is a determining aspect for the technology efficacy analysis when intercepting errors, as the incorporation of a drug library does not necessarily mean that infusions are programmed via the library. For this reason, user involvement and awareness is key to achieve high adherence rates and to draw conclusions on its use.[27]
(2): With this indicator we are able to follow the evolution in the total number of alarms throughout the complete implementation process, which is representative of the improvements in the reduction of unnecessary alarms.[28]
(3): These last indicators shows the real usefulness of established soft limits, the greater usefulness the lower the percentage of ignored alarms and the higher the number of immediately reprogrammed alarms.[29]
(4): The analysis of these three indicators gives information on the time periods with more alarms, which may help in identifying training requirements in specific user groups.[30]
(5): This analysis gives information on the intelligent infusion system's capacity for intercepting errors and therefore allows us to establish the real impact of this technology regarding avoided potentially severe errors as well as reduction in associated costs.[32]

## REFERENCES

1. Otero López MJ. Errores de medicación y gestión de riesgos. Rev Esp Salud Pública 2003; 77: 527-40.
2. Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, Servi D, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. JAMA 1995; 274: 29-34.
3. Leape LL, Bates DW, Cullen DJ, Cooper J, Demonaco HJ, Gallivan T, et al. Systems analysis of adverse drug events. ADE Prevention Study Group. JAMA 1995; 274: 35-43.
4. Bates DW. Preventing medication errors: a summary. Am J Health Syst Pharm 2007; 64 (14 Suppl 9): S3-9; quiz S24-6.
5. Pasto Cardona L, Masuet Aumatell C, Bara Olivan B, Castro Cels I, Clopes Estela A, Páez Vives F, et al. Incident study of medication errors in drug use processes: prescription, transcription, validation, preparation, dispensing and administering in the hospital environment. Farm Hosp 2009; 33: 257-68.
6. Kaushal R, Bates DW, Landrigan C, McKenna KJ, Clapp MD, Federico F, et al. Medication errors and adverse drug events in pediatric inpatients. JAMA 2001; 285: 2114-20.
7. Sullivan JE, Buchino JJ. Medication errors in pediatrics –the octopus evading defeat. J Surg Oncol 2004; 88: 182-8.
8. Otero López MJ, Castaño Rodríguez B, Pérez Encinas M, Codina Jane C, Tames Alonso MJ, Sánchez Munoz T, et al. Updated classification for medication errors by the Ruiz-Jarabo 2000 Group. Farm Hosp 2008; 32: 38-52.
9. Pepper GA. Errors in drug administration by nurses. Am J Health Syst Pharm 1995; 52: 390-5.
10. ISMP España [monografía en Internet]. Available at: <http://www.ismp-espana.org/> [Consulted: 3rd August 2012].
11. American Society of Health-System Pharmacists. ASHP guidelines on preventing medication errors in hospitals. Am J Health Syst Pharm 1993; 50: 305-14.
12. Oren E, Shaffer ER, Guglielmo BJ. Impact of emerging technologies on medication errors and adverse drug events. Am J Health Syst Pharm 2003; 60: 1447-58.
13. Grupo de trabajo nuevas tecnologías de la SEFH (TECNO). Bermejo Vicedo T, Pérez Menéndez Conde C, Álvarez A, Codina C, Delgado O, et al. The application of new technologies to hospital pharmacy in Spain. Farm Hosp 2007; 31: 17-22.
14. Jiménez ME, López M. Sistemas automáticos para infusión: Bombas, perfusores y sus accesorios específicos. In: Consejo General de Colegios Oficiales de Farmacéuticos, editor. Productos Sanitarios. Módulo III. 1ª ed. Madrid: Acción Médica, S.A.; 2004. p. 81-90.
15. KLAS. Smart pumps: In an area where decimal-point medication errors can be fatal, smart infusion pumps are adding a line of defense. Healthc Inform 2008; 25: 20.
16. Giannopoulos HT. Smart pump technology. In: Dumitru D, editor. The Pharmacy Informatics Primer. Bethesda, Md: American Society oh Health System Pharmacists 2008: p. 119-27.
17. Wilson K, Sullivan M. Preventing medication errors with smart infusion technology. Am J Health Syst Pharm 2004; 61: 177-83.
18. Proceedings from the ISMP summit on the use of smart infusion pumps. Guidelines for safe implementation and use [monografía en Internet]. Available at: <http://www.ismp.org/Tools/guidelines/smartpumps/comments/default.asp> [Consulted:16th October 2012].
19. Starenkyj E, Wolfe P, Hoh T, Mamer N, Soliven Llaguno J. What does your IV smart pump infusion data tell you about IV clinical practice and patient safety? Stud Health Technol Inform 2009; 146: 803-4.
20. Manrique Rodríguez S, Fernández Llamazares CM, Herranz Alonso A, Sanjurjo Saez M. Smart infusion pumps: lights and shades of an emerging technology. Med Clin (Barc) 2011; 137: 361-5.
21. Siv Lee L, Morgan L. Implementation of wireless «intelligent» pump IV infusion technology in a not-for-profit academic hospital. Hosp Pharm 2007; 42: 832-40.

22. Poppe LB, Eckel SF. Evaluating an approach to improving the adoption rate of wireless drug library updates for smart pumps. Am J Health Syst Pharm 2011; 68: 170-5.

23. Schaeffer R. Closing the medication safety loop. Health Manag Technol 2009; 30: 30-2.

24. Birk S. Smart pumps need OK from clinicians. Mater Manag Health Care 2008; 17: 38-40.

25. Dusing Wiest M, Longshore L, Harger N. Implementation of intelligent infusion technology in a multihospital setting. Am J Health Syst Pharm 2010; 67: 878-83.

26. Breland BD. Continuous quality improvement using intelligent infusion pump data analysis. Am J Health Syst Pharm 2010; 67: 1446-55.

27. Carayon P, Hundt AS, Wetterneck TB. Nurses' acceptance of smart IV pump technology. Int J Med Inform 2010; 79: 401-11.

28. Cassano AT. Iv medication safety software implementation in a multihospital health system. Hosp Pharm 2006; 41: 151-6.

29. Trbovich PL, Pinkney S, Cafazzo JA, Easty AC. The impact of traditional and smart pump infusion technology on nurse medication administration performance in a simulated inpatient unit. Qual Saf Health Care 2010; 19: 430-4.

30. Fanikos J, Fiumara K, Baroletti S, Luppi C, Saniuk C, Mehta A, et al. Impact of smart infusion technology on administration of anticoagulants (unfractionated heparin, argatroban, lepirudin, and bivalirudin). Am J Cardiol 2007; 99: 1002-5.

31. Naranjo CA, Busto U, Sellers EM, Sandor P, Ruiz I, Roberts EA, et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther 1981; 30: 239-45.

32. Sakowski J, Newman JM, Dozier K. Severity of medication administration errors detected by a bar-code medication administration system. Am J Health Syst Pharm 2008; 65: 1661-6.