

Satellite Symposium

DRIVING EFFICIENCY AND IMPROVING SAFETY

September 2018



Funded by



Media partner



Executive summary

The implementation of technology and automation for the entire medication pathway has been shown to result in greater efficiencies and enhanced safety. Studies in Spain, France and the UK have confirmed the following:

- The use of BD PhaSeal™, when added to general awareness and cleaning procedures, significantly improves safety in the preparation of hazardous drugs by reducing surface and environmental contamination.
- Implementation of BD Cato™ software enhances patient safety, process productivity, regulatory compliance and cost optimisation.
- Introduction of the BD Rowa Vmax™ medication storage and dispensing robot positively impacts on employees' time, dispensing error rates, storage space and stocks, drugs management, team management, staff inclusiveness and financial aspects.
- A safer and more effective use of intravenous critical medicines in paediatric intensive care is achieved through the roll out of standard concentration infusions, the reconfiguring of dose limit ranges and the implementation of BD Alaris™ Plus Guardrails™ smart pumps.



© Cogora Limited 2018. The contents of this publication are protected by copyright. All rights reserved. No part of this publication may be produced, stored in a retrieval system or transmitted in any form or by any means without the written permission of the publisher. The views expressed in this publication are not necessarily those of the publisher or editorial advisors. While the publisher and editorial advisors have taken every care with regard to accuracy of editorial and advertisement contributions, they cannot be held responsible for any errors or omissions contained therein. Published in the United Kingdom by Cogora Limited, 140 London Wall, London EC2Y 5DN, UK.

Date of preparation: July 2018

The panel...



Dr Sara Arenas-López
Consultant Pharmacist
in the Paediatric
Intensive Care Unit
at the Evelina London
Children's Hospital,
Guy's and St Thomas'
Foundation Trust in
London



Dr Olivier Aujoulat
Director of Pharmacy
at the Mulhouse and
South Alsace Hospital
Group, France



Warren Poon
Lead Pharmacist
Aseptics and Quality
Assurance at the
Leaders in Oncology
Care Cancer Unit, UK



Dr Silvia Valero García
Hospital Pharmacist
from the University
Hospital in La Fe,
Valencia, Spain

The Chair...



Dr Theresa Saklatvala
Chair, Content Director,
Cogora

Driving efficiency and improving safety

On 22 March at the 23rd European Association of Hospital Pharmacists (EAHP) Congress in Göteborg, Sweden, BD sponsored a satellite symposium in which four speakers shared their real-world experiences of how medication management processes can optimise efficiencies and safety of drug delivery, from preparation to administration

A call for safety

Dr Silvia Valero Garcia, Hospital Pharmacist from the University Hospital in La Fe, Valencia, Spain, shared the hospital's experience in assessing the safety and efficiency of closed system transfer devices (CSTDs).

She noted that, three years ago, a workshop of scientific societies published a Consensus Statement that analysed the problems they saw with the manipulation of hazardous drugs, from a legal and clinical practice viewpoint. A number of recommendations for hazardous drug handling were proposed, including:

- The development of a list of hazardous drugs
- The definition of the technical specifications for a closed system, based on definitions already established by the National Institute for Occupational Safety and Health (NIOSH) and the International Society of Oncology Pharmacy Practitioners (ISOPP)
- The creation of a CSTD registry
- Review and analysis of critical points with the Ministry of Health for the prevention of exposure to hazardous drugs (preparation, transport and administration):

- Information on risks arising from exposure
- Registration and training of healthcare professionals involved
- Update and review of health surveillance programmes for exposed health professionals
- Preventive research, analysis and monitoring of contamination levels in health centres, epidemiology, etc.
- Information and training programme for patients and patients' families development on:
 - The risks of exposure to hazardous drugs
 - The forms of exposure during their stay in the healthcare centre as well as in their own homes, after having received hazardous drugs in the healthcare centre
 - Recommendations to prevent such exposure in the healthcare centre and in their own homes

Less than four months after the publication of the Consensus Statement, the Ministry of Labour and Social Security released Technical Note 1.051 confirming the presence of contamination on work surfaces in areas where cytotoxics are handled. One of the origins of this contamination was identified as the aerosols generated during the drug compounding process. They therefore officially recommended the use of CSTDs and/or robotic compounding to reduce the risk of contamination.

Technical Note 1.051 also officially adopted a definition of CSTDs: 'equipment that mechanically prevents the entry of pollutants into the system and the escape of hazardous active substances outside the system'. It also defined the

technical specifications with which all CSTDs should comply:

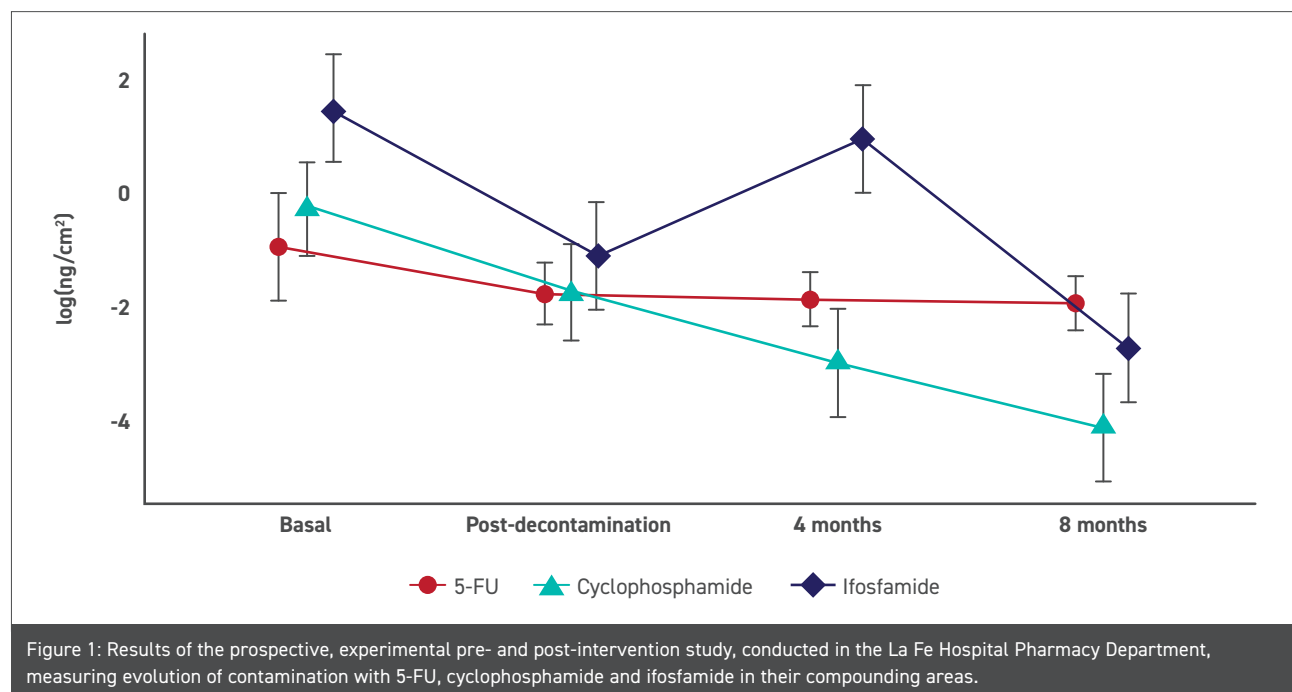
- Avoid aerosol formation
- Aseptic
- Safety and reliability in handling
- Transfer capacity avoiding product losses
- Universality of use
- No filters
- Transfer precision
- Equipment designed to suit the application, e.g. sealing conditions for transport, storage and administration

At the end of 2017, the Ministry of Employment and Social Security published *Medicamentos Peligrosos*, a hazardous drugs list (available online), compiled by Spanish hospital pharmacists, recommending protection measures for their handling.

Contamination studies

Confirmation of the presence of hazardous drugs on surfaces in drug preparation units prompted three studies. They included: a prospective, observational, multicentre study looking for the presence of hazardous drugs on the working surfaces of pharmacies in a number of hospitals; and two studies, conducted at La Fe Hospital, looking at the relative safety of different devices in terms of reducing hazardous drug contamination.

The multicentre study (DOI:10.7399/fh.10935) involved ten hospitals, each with preferably more than 700 beds, and tested for the presence of cyclophosphamide, ifosfamide and 5-fluorouracil (5-FU) – three chemotherapies selected for their frequency of use, the quantity in which they are used



and the ease with which contamination could be measured. To reflect actual levels of contamination, standard operation procedures applicable in participating hospitals were used in the study.

The primary objective of the study was to look for the presence of hazardous drugs on pharmacy work surfaces, with secondary objectives including: (1) quantification of contamination; (2) a comparison of contamination levels on different types of surface; and (3) a comparison of contamination between the different hospitals.

Sampling for contamination was done at the end of one Wednesday, using the CYTO Wipe Kit® (Exposure Control, Sweden AB), prior to the usual cleaning and decontamination process.

The results showed that: (1) of the three compounds tested, there was a significantly greater number of positive samples with cyclophosphamide, although (2) the median (ng/cm²) for 5-FU was far higher, owing to a tenfold higher detection rate; (3) there was significant variability between hospitals; and (4) there was significant variability depending on the location within the hospital.

The single institution studies at La Fe had different aims. One study was

designed to see whether the filter-vented devices (B Braun Mini-Spike 2®) allowed them to maintain their contamination levels, making them an optional alternative to CSTDs (in press).

This study measured contamination with cyclophosphamide and 5-FU at 30 locations in their compounding areas, with contamination readings taken at base level, after decontamination and after six months' use of B Braun Mini-Spike 2®. Results did not reveal any statistically significant differences between the three time points, and the study authors concluded that usability, time and cost are factors that should be further studied when choosing a compounding device.

The other La Fe study (also in press) sought to answer the question: can CSTDs confer improved safety over the use of spikes? It was a prospective, experimental pre- and post-intervention study, conducted in the compounding area of the La Fe Hospital Pharmacy Department.

The same three drugs as above were evaluated. The sampling points were identical to those of the other La Fe study, and the sampling times were: (1) base level, (2) post decontamination, (3) after four months' use of BD PhaSeal™ for cyclophosphamide and 5-FU, and

(4) after 8 months' use of PhaSeal™ for cyclophosphamide and 5-FU and 1 month for ifosfamide (i.e. last month of the study).

So as not to expose staff to contamination unnecessarily, a weekly decontamination process was introduced after analysis of the second time point.

The results showed that, compared with base level, there were (1) no significant decreases in any of the sampling points with 5-FU, (2) significant decreases in levels at 4 and 8 months, but not post-decontamination with cyclophosphamide, and (3) significant decreases post-decontamination and 8 months (1 month using BD PhaSeal™) for ifosfamide (Figure 1).

Study authors concluded:

- The absence of a 100% effective decontamination method
- The difficulty of cleaning certain points (e.g. airfoil)
- The persistence of contamination
- The lack of an effective means of cleaning spills
- A minimum 6-month training time for users of BD PhaSeal™
- High staff turnover results in variability of the management of reducing risk of contamination

In overall conclusion, the use of CSTDs added significantly to awareness and good spill-handling regimes to reduce the risk of contamination with hazardous drugs. International consensus is needed, however, on which tests are necessary to confirm the effectiveness of a CSTD. Evidence is needed on how processes affect personal exposure, and international standardisation is needed to avoid differences in compounding procedures.

Intravenous (IV) workflow compounding system

Driving greater efficiencies and enhancing patient safety is a process that extends along the drug management continuum. **Warren Poon**, Lead Pharmacist Aseptics and Quality Assurance at the Leaders in Oncology Care (LOC) Cancer Unit, UK, shared his experience with the new IV workflow compounding system – BD Cato™ – in improving patient safety, process efficiency and regulatory compliance.

The three pharmacy aseptic preparation units at the LOC consist of three separate facilities, with a maximum capacity for treating 90 patients and

aseptically preparing 225 ready-to-administer treatments per day (cytotoxics and monoclonal antibodies). They are under Section 10 exemption of the UK Medicines Act 1968, i.e. unlicensed facilities, each with two safety cabinets with built-in display screens.

The reasons for implementing the BD Cato™ system were fivefold:

1. To eliminate most paperwork (and the resulting transcription errors)
2. To increase compounding accuracy using the gravimetric method
3. To adopt barcoding technology to prevent compounding errors
4. To close the loop on the medicines management chain
5. To free up pharmacists' time to concentrate on clinical tasks

Implementation

Software verification followed Good Automated Manufacturing Practice 5 (a risk-based verification process), with which BD Cato™ is fully compliant. On the hot topic of data integrity, BD Cato™ is compliant with all elements of ALCOA – attributable, legible, contemporaneous, original and accurate – and is fully traceable.



Benefits

Figure 2 illustrates the improvements in efficacy and safety that the introduction of BD Cato™ has brought to LOC.

Although particular problems were encountered with powders, the manufacturer support team was able to work through any issues that were encountered.

Efficiency savings were realised in terms of a reduction in technician compounding time, a reduction in waste and a reduction in the time pharmacists spend on non-clinical tasks.

Non-cash benefits include increased capacity, compliance with the Falsified

Realised benefits			
	Pharmacist saving Time Minutes/Year		Technician Saving Time Minutes/Year
Total Worksheet Set Up, Ingredients, Labels	–		19,300
Transfer process and Labelling	–		38,600
Final Check of product and release	38,600		–
Total Saving per staff in minutes/year	38,600		57,900
FTE Saving	2.68 hrs/day		4 hrs/day

Expected benefits vs Realised benefits*			
	Pre-Cato™	Post-Cato™	Direct Benefit
Average turnaround time of each preparation (min)	45	22	Increasing Capacity
Barcode Adoption	0%	100%	Scan4Safety, GS1, FMD
Re-issuing	0%	Enabled	Reduce Wastage, Increase capacity
Volume Error Rate	6.5%	Completely Eliminated	Patient Safety

*Source: pilot gravimetric study of 40 doses of LOCs two most commonly compounded Systemic Anti-cancer Therapy (SACT) – paclitaxel (relatively low cost) and bevacizumab (relatively high cost) – was undertaken to assess the impact of gravimetric method at the LOC. The results are extrapolated over 12 months.

Figure 2: Improved safety and efficacy.

Medicines Directive, reduced wastage and increased patient safety.

In summary, BD Cato™ has enhanced patient safety, process productivity, regulatory compliance and cost optimisation at the LOC. Future projects will focus on closed loop status (including nurse administration), further upgrades and tighter control of aseptic preparations.

Introducing a medication storage and dispensing robot

Hospital growth brings with it unique challenges with respect to safety systems and overall quality of drug, but how is your hospital affected when a decision is made to buy a medication storage and dispensing robot?

Dr Olivier Aujoulat, Director of Pharmacy at the Mulhouse and South Alsace Hospital Group, France, shared the lessons of the impact of the adoption of BD Rowa Vmax™ on his hospital.

Driven by the need for new tools to cope with the massive growth of the Mulhouse hospitals activity, managerial aims were to reduce the time spent on dispensing, to reduce medication errors, to optimise medication stocks and storage space and, most importantly, to make a major improvement in the quality of drug management.

The question was: would BD Rowa Vmax™ help them to reach these goals, and would it prove cost effective?

The size and complexity of the project could not be overstated, including multidisciplinary meetings to organise the project, stock removal from rotating stores to shelves, the dismantling of rotating stores, restoration work in the pharmacy before BD Rowa Vmax™ could be moved in, determining which drugs could and could not be stored in BD Rowa Vmax™, a review of work processes and procedures, and training sessions. More than 1,000 working hours were dedicated to the preparation for installation.

Impact of installation of BD Rowa Vmax™ Workflow management

- Stock management carried out by storekeepers and not pharmacy

technician

- Dispensing for medical units concentrated in the morning
- Afternoons reserved for urgent requests

Employee time

- 59% decrease in time lost due to interruptions
- 29% time saving made on full dispensing activities, allowing 1.25 full time equivalent (~€47,000 annually) pharmacy technicians re-allocated to development projects with more added value

Dispensing error rate

- 75% decrease in error rate
- No more qualitative errors found for products stored in the robot
- Errors still remaining: qualitative errors because of human involvement at the time of open box dispensing; quantitative and qualitative errors for 'outside-robot' stored drugs

Storage space and stocks

- Freed up 80 m² of space, allowing installation of two new cold storage rooms
- Stock value reduction by 4.3% (equivalent of €175,000)
- Massive time reduction in stock levels assessment meaning that it no longer necessary to close down to assess stock levels

Quality drug management

- A completely new drug-related information flow available at any time for 1200 drugs, based on the drugs datamatrix information in the robot database
- No expired drug is delivered with a threshold of less than eight weeks
- Secure drug supply chain inside and outside the pharmacy

Financial

- Global savings of €443,000 over 15 years (return on investment within 4 years), resulting principally from staff savings and stock reduction

The successful implementation of BD Rowa Vmax™ was characterised by a team approach and change management

including all staff who were in any way connected with the project, a culture of participation and openness, and motivational communication across the team. All members of the team have been energised with the confidence that comes with success and with renewed levels of job satisfaction.

Safe implementation of standard concentration infusions

Nowhere in a hospital are the consequences of medication error more acute than in paediatric intensive care, a message brought home by **Dr Sara Arenas-López**, who is a Consultant Pharmacist in the Paediatric Intensive Care Unit (PICU) at the Evelina London Children's Hospital, Guy's and St Thomas' NHS Foundation Trust in London.

According to the PICANet 2017 Annual Report (Paediatric Intensive Care Audit Network Annual Report 2017, The University of Leeds, the University of Leicester and the Healthcare Quality Improvement Network), between January 2014 and December 2016, in the UK and Ireland, there were more than 60,000 admissions, 45.6% of whom were aged less than 12 months and 32.2% who were aged less than 1 month. A PICU is defined by the PIC Society as 'a service for children (0–18 years) with potential reversible diseases that benefit from more detailed observation, treatment and technological support than is available in standard wards'.

What are the general considerations for drugs administered in PICU?



- Lack of age-appropriate licensed formulations results in the use of unlicensed or off-label drugs, with consequential decreased therapeutic effect and increased risk of medication error and adverse reactions
- Adverse drug reactions can lead to a 40% increase in neonatal mortality

Administration of continuous IV infusion has the advantage of bedside dose adjustments and fluid value limits, but disadvantages including complex calculations, manipulation, no quality control of the final product and multiple-step drug programming. To overcome these potentially severe disadvantages, the PICU set out to identify a safer and more effective delivery of IV critical medicines, to identify deviations of morphine IV infusion concentrations made by nurses and pharmacy, to identify service development steps to introduce standardised concentrations and to extrapolate these findings to other drugs administered as IV infusions.

Dr Arenas-López shared with her audience the results of three studies: the first of these,¹ a prospective six-week study, reported on the accuracy of morphine infusions in relation to label strength and identified significant differences in deviation between the ward and the pharmacy.

Such results constituted an obvious driver for the adoption of standard concentrations of infusions.

Implementation of Alaris™ Guardrails™ Solutions

The second study² was a multidisciplinary (physician, pharmacist, nurse) service development study for quality improvement, comprised of a 6-month pilot and an 8-year evaluation. It looked at safety following the introduction of standard concentrations of morphine infusions in the PICU. Results of the 6-month study showed that, in a cohort of 419 preparations, banding was unsuccessful 19% of the time (reasons including fluid restriction,

the required doses exceeding the programmed limit, and inappropriate diluents in the ready-to-administer prefilled syringes). Smart pump data downloads (Alaris™ Plus Guardrails™) recorded 535 alerts, 44% of which was hard limit violation, and the majority of these were in patents weighing between 4 and 7 kg, in which the hard limit was too low for their clinical requirements. As a result, dose limit ranges were reconfigured and Alaris™ Plus Guardrails™ datasets were adjusted.

The third study³ looked at extrapolating the methodology developed with morphine to all standard infusion concentrations in the PICU: testing bands in extreme clinical cases, considering infusion pump accuracy in relation to syringe size and volume/rate to be delivered, comparing strengths to adult critical care, risk assessment of proposed concentrations and making final recommendations on standard concentrations for medication, including a requirement for barcoding, as an additional step to boost safety along the medication management process.

For the majority of the medicines used, three weight bands of standard concentrations were found to be sufficient to cover the children's weight ranges and keep within predefined fluid requirements and accuracy of delivery. The study was an example of a patient-focused, systematic approach for defining and evaluating standardised concentrations in an intensive care paediatric unit as well as implementing change in a multidisciplinary team.

As next steps, the PICU at the Evelina London Children's Hospital is rolling out all the standard concentrations throughout the hospital, enabling pump connectivity to the prescription system for maximum safety and uploading datasets to BD Alaris™ Plus Guardrails™ smart pumps. Finally, they are engaging with national interest groups and drug and device manufacturers to arrive at a National Consensus on Standardised Concentrations.

Conclusion

Despite day-to-day challenges, the implementation of technology and automation for the entire medication management pathway has been shown to result in greater efficiencies and enhanced safety, for patient and healthcare worker alike.

In this satellite symposium, a number of senior healthcare professionals from various European hospitals have shared details of their real-world experiences, their successes and lessons learned, and given us insight into how their institutions' drug management processes have been changed for the better.

References

1. Aguado-Lorenzo V et al. Accuracy of the concentration of morphine infusions prepared for patients in a neonatal intensive care unit. *Arch Dis Child* 2013;0:1-5. DOI:10.1136/archdischild-2013-304522
2. Arenas-Lopez S et al. Safe implementation of standard concentration infusions in paediatric intensive care. *J Pharm Pharmacol* 2016. DOI:10.1111/jphp.12580
3. Perkins J, Aguado-Lorenzo V, Arenas-Lopez S. Standard concentration infusions in paediatric intensive care: the clinical approach. *J Pharm Pharmacol* 2017;69:537-43. DOI: 10.1111/jphp.12604

For more information:

T 020 7214 0500
E info@cogora.com

cogora.com



Cogora

We know healthcare

© Cogora Limited 2018. The contents of this publication are protected by copyright. All rights reserved. No part of this publication may be produced, stored in a retrieval system or transmitted in any form or by any means without the written permission of the publisher. The views expressed in this publication are not necessarily those of the publisher or editorial advisors. While the publisher and editorial advisors have taken every care with regard to accuracy of editorial and advertisement contributions, they cannot be held responsible for any errors or omissions contained therein. Date of preparation: July 2018