المركز السعودي لسلامة المرضى
SAUDI PATIENT SAFETY CENTER

Saudi Patient Safety Centre (SPSC)

national dose error reduction software and smart pump position paper. A component paper of the SPSC's national position on intravenous medication safety in the Kingdom of Saudi Arabia

Acknowledgement: This white paper was developed by the Saudi Patient Safety Center (SPSC) in collaboration with subject matter experts and stakeholders. SPSC acknowledges the technical contribution of Becton Dickinson (BD) in sharing data and insights on infusion safety practices. The analysis, recommendations, and conclusions represent the independent position of the Saudi Patient Safety Center

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About the Saudi Patient Safety Center.

The Saudi Patient Safety Center's mission is to eliminate preventable harm in the Saudi healthcare system by empowering patients and supporting healthcare professionals through building capacity, partnering with all stakeholders, i.e. regulators, healthcare providers, patients, and patients' families, and in developing national policies creating evidence-based guidelines and executing and implementing programs.

Executive Summary:

Across the Kingdom of Saudi Arabia many millions of intravenous infusions are given every year, these include intravenous fluids, blood product transfusions, antibiotic infusions, sedation and analgesia, and critical vasoactive medications.

There has been a strong drive through individual hospital tenders and the oversight of national bodies to ensure that hospitals are supplied with, and have purchased, so-called intravenous smart pumps. However, the use of all the features of these pumps to protect patients, including how to create comprehensive drug libraries to protect patients and healthcare workers from error may not be optimal. Surveys of the use of Dose Error Reduction Software (DERS) in smart pumps across hospitals in the Kingdom of Saudi Arabia (KSA) indicate that there is still much to be done, though there are a good groundwork and examples of excellence across the healthcare system of KSA.

The purpose of this National Medication Safety Position Paper (NMSPP) is to provide guidance and standards for good practice in intravenous medication management and administration, and to provide tools and standardized processes and protocols which may be applied by clinicians and facilities, and to put in place an ongoing apparatus of monitoring to assess the effectiveness of change. This initiative supports the Kingdom of Saudi Arabia's Vision 2030 Health Sector Transformation Program (HSTP) goals for safer, digitally transformed care, leveraging the Ministry of Health's Digital Health Strategy. [1] and its intention is to align with other regional initiatives and health quality improvement drives such as those undertaken by the Saudi Food and Drug Authority (SFDA) medical device safety communications, and Ministry of Health directives. A national standardization of DERS drug

libraries can be advanced, with progress benchmarked against WHO and other respected bodies' targets and insights shared through voluntary reporting via the SPSC.

Overall, the evidence supports a national policy that requires wireless DERS-enabled pumps, standardized drug libraries for high-alert IV medications, clear governance for DERS library updates and compliance monitoring, and phased interoperability with the electronic health record to reduce preventable IV medication harm.

This NMSPP has four component parts:

1. An assessment of the current international and regional evidence for the need for change, what is likely to bring success, and what success looks like in terms of safe intravenous therapy management and administration.
2. Provision of a standardized and best practice data set or DERS library which may be applied for patient groups and the units commonly found in facilities across KSA.
3. Provision of a standardized training plan both for the initial installation or rollout of smart pumps across a facility, and for ongoing in service and orientation training.
4. Provision of a recognized evaluation tool for failure mode effect analysis to accelerate the process of risk assessment and mitigation for intravenous therapy administration across organizations and to allow for a metric that may be measured pre- and post-interventions.

This position paper is designed to set a baseline standard for IV-therapy risk management in the Kingdom of Saudi Arabia upon which more specialist care areas and issues, both at facility and at a national level, may be addressed in forthcoming papers. These include:

- Specialist areas such as pediatrics and neonates.
- Specialist infusions such as Patient Controlled Analgesia (PCA).
- Issues of 'alarm fatigue' and its implications for critical short half-life infusions.
- Oncology medication is safe for both practitioners and patients.
- Advanced techniques of intravenous therapy safety such as Barcode Medication Administration (BCMA) and smart pump interoperability with Electronic Medical Record (EMR) systems.
- Compounding of IV-therapy, both within the pharmacy and in care areas.

- The provision of administration systems and disposables for medications affected by light, filter, and line-material type, and for medications requiring filtration at the point of administration.
- The creation of national-level governance programs to issue standard IV medication concentrations and curated reference DERS libraries, along with phased compliance targets with transparent performance metrics.
- Pilot-site studies to be learnt from and applied to nationwide rollouts, for the building of super-user networks and best-practice sharing.

Definitions:

Smart Pump:

An intravenous (IV) smart pump is equipped with Dose-Error Reduction Software (DERS) that detects and prevents programming errors. [2] This system has a predefined DERS library contained within software in the pump programming module. The DERS library allows upper and lower dosage limits to be set for each medication and a distinct DERS library or profile for designated patient-care areas of a hospital (i.e., intensive care unit [ICU] or operating room) or patient type (i.e., adult, pediatric, or neonate). When a pump is programmed above or below a medication dosage limit, audio and visual alerts provide feedback that an error may have occurred. The user can override a soft alert to continue with the administration at the programmed rate. A hard alert does not allow an override and requires reprogramming within the defined medication limits for delivery of the medication.

Medication Error:

For the purposes of this paper the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) definition and classification of medication error and resulting harm has been taken. [3] The categories of harm according to the NCC MERP are shown in Appendix 1. NCC MERP defines medication error as 'any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.'

Introduction: The Size of the problem: Risk of Harm from intravenous therapy in the Kingdom of Saudi Arabia.

The World Health organization's third global patient safety challenge 'medication without harm' aimed to reduce severe avoidable medication related harm by 50% globally in the 5 years following its launch in 2017, and it estimated that avoiding medication-related harm could save the global economy about 42 billion USD per year [4] This WHO initiative aimed to make improvements at each stage of the medication process including prescribing, dispensing, administering, monitoring, and use. That work continued with a new policy brief being produced in 2024. [5]

Patient harm due to unsafe care is a leading cause of death and disability worldwide, and most of such harm is avoidable. [6] Harm due to medicines and therapeutic options accounted for 50% of the overall preventable harm in medical care [7] and 18.3% of notified adverse events. [8] The pooled prevalence of preventable medication-related harm was 5% (1 in 20 patients) and one fourth of the harm was severe or potentially life-threatening. [9] Of this total harm intravenous medication (IV) administration is associated with a far greater risk of medication error than oral administration. [10]

During IV-therapy the evidence suggests that 39% of medication errors occur during prescription, [11] and 38% occur during administration. [12]. The international literature also suggests that medication errors occur in approximately 10% of intravenous doses, with the most common error (≈50%) being due to the drug being having been given at the wrong rate. [13]

Much of what we know about 'wrong rate-wrong does' errors come from the study of near-miss incidents from smart pumps with comprehensive DERS drug libraries. [14] This is important, as a major issue with all IV-therapy administration errors is the difficulty of their detection. Among all the parts of the medication chain (from prescription to administration), IV-medication administration errors consistently score as high-risk in Failure Mode Effective Analysis (FMEA) [15], and error detectability during administration has been suggested to be as low as a 2%, [16,17] and The UK National Reporting and Learning Services (NRLS) suggests that self-reporting only accounts for between 5-15% of actual events. [18] Furthermore, observational studies, chart reviews and reviews of sentinel events suggest that the magnitude of all medication error types is far greater than 'routine' reporting would suggest. [19,20] This phenomenon of under-reporting has also been identified in a KSA study, where 37.7% of surveyed health care practitioners stated that they believed that 'legal implications are a major barrier to the reporting of medication errors.' 53.5% of the survey participants also stated 'that no clear electronic system is available for the reporting of medication errors in their hospitals.' [21]

A great deal of the literature pertaining to IV-therapy medication error has focused on critical care, however, one whole-hospital study found a DERS medication error prevention rate of 0.31%. This said, DERS was only deployed in 65.4% of the infusions studied, so the potential for a higher error capture rate of 0.46% is possible. [22] In several studies medications and fluids likely to be given across facilities, and with therapeutic and safety implications, have been identified as common DERS 'good catches.' [22,23,24] In one study these included: Potassium Chloride 40mmol in 100ml/500ml/1L, Blood Products, and Gentamicin and Vancomycin, with doses exceeding 5 to 50 times the therapeutic limit. These errors would have resulted in severe consequences and/or death if they had not been intercepted by DERS limits. [22]

A recent, and extensive study in the United Kingdom of whole-hospital effectiveness of DERS, the categorization of magnitude of error, and expert opinion (via Delphi Panel) on the likely consequences of each 'good catch' in the catastrophic bracket had it not been caught has suggested that the ratio of these types of error that could lead to serious patient harm requiring critical care and 'rescue' is 1.886% of all hard-limit events. [25]

DERS may also impact on the risk of Transfusion Associated Circulatory Overload (TACO) as it can provide hard rate limits for the administration of blood products. TACO related 'major morbidity' [26] has an incidence of between 1-8% [27,28,29] for Red Blood Cell (RBC) transfusions, Fresh Frozen Plasma (FFP), and Platelet (PLT) transfusions [30,31]. Over-rapid infusion may induce TACO, and a controlled rate of delivery of <1ml/min is suggested for high-risk patients. [28,31]. High-risk patients for TACO have been identified as those under the age of three or over sixty years of age, and those with renal or heart failure. [28,29,30].

Serious IV-medication errors have been estimated to cost 7,300 USD per event [32] and to extend Length of Stay (LOS) by 4.8 days. [17] A recent evaluation of the costs of intensive care beds and medical beds in the Kingdom of Saudi Arabia place these costs as USD 2082.65 ± 345.04 USD and 1384.57 ± 166.04 USD per day, respectively. [33]

Evidence creation at a national level of the rate of intravenous medication error, and its possible underlying causes, has been undertaken. A national review undertaken by the Saudi Food and Drug Administration (SFDA) in 2020 of 140 facilities revealed high compliance with medical device maintenance (including smart pumps), but evidence of comprehensive staff training was weaker at 59.2% compliance with mandated requirements. This was noticeably worse in private hospitals and small hospitals. [34]

National systematic reviews published in 2024-2025 have reported rates of between 13-56 errors per one hundred medication orders (including intravenous medications), with the highest risk points being the prescribing and administration phases [35] and wrong dose and improperly titrated dose errors being among the most frequently reported errors across multiple studies. [36]

A meta-analysis of sixteen earlier papers found the total incidence of medication error in the Kingdom of Saudia Arabia to be 44.4% of all medication transactions, with administration being responsible for 34.5% of the total errors. [37]

A 2022 review of 3,025,414 DERS protected infusions from adult units outside of critical care across the Kingdom of Saudi Arabia assessed the volume of averted dose/duration errors achieved by the deployment of DERS smart pumps. [38] The study identified a prevented error incidence rate above those in many published studies, and this may be because the study was completed on wireless networked pumps which allowed data to be gathered from more diverse areas of the hospital and to allow for the deployment of up-to-date DERS datasets across entire facilities. The authors suggest that DERS was able to support clinicians who had limited experience of administration of some medications. The presence of insulin, potassium preparations, and cytotoxic medications in the study's good-saving results is in line with other studies.

Table 1: IV-Therapy harm averted by hard limit with multiples of dose during attempted programming of rate/dose by therapy type in adult care units outside of critical care. [32]

Therapy Type	Moderate Totals n. (% vs. DERS Infusions) Magnitude: Times Maximum Rate/Dose	Catastrophic Totals n. Magnitude: Times Maximum Rate/Dose				All Catastrophic Totals n. (% vs. DERS Infusions)
	1.5 - 9.999	10	10 - 99.999	100	100+	
IV Fluids	35,572 (1.1758)	23	259	4	9	295 (0.0098)
Simple Analgesia	10,844 (0.3584)	62	641	4	53	760 (0.0251)
Antivirals, General Antibiotics and Antifungals	20,277 (0.6702)	84	950	33	67	1,134 (0.0375)
Blood Products	35,830 (1.1843)	325	20	0	4	349 (0.0115)
Chemotherapy and Cytotoxic	11,422 (0.3775)	37	166	4	31	238 (0.0079)
Anticoagulants	2,688 (0.0888)	12	305	24	60	401 (0.0133)
Insulin	313 (0.0103)	31	77	6	37	151 (0.0050)
Electrolytes (K^+ and Mg^{2+})	17,918 (0.5922)	114	725	0	18	857 (0.0283)
GI System	5,688 (0.1880)	153	1,187	5	11	1,356 (0.0448)
Labor and Delivery Meds	111 (0.0037)	6	33	0	5	44 (0.0015)
Aminoglycosides	2,286 (0.0756)	13	179	0	5	197 (0.0065)
Diuretics	549 (0.0181)	34	63	4	38	139 (0.0046)
Steroids	24 (0.0008)	0	0	2	0	2 (0.0001)
Total all Adult	143,522 (4.7439)	894	4,605	86	338	5,923 (0.1958)

A similar situation was also described in a 2022 Saudi Arabian study of 2,347,951 infusions from pediatric units inside and outside of critical care assessing the volume of averted dose/duration errors. [39] The study compared the prevented intravenous therapy administration error rates of pediatric and neonatal critical care units with those in general and oncology pediatric care. The frequency of averted moderate and catastrophic error was found to be higher *outside* of the critical care areas.

Table 2: IV-Therapy harm averted by hard limit with multiples of dose during attempted programming of rate/dose by therapy type in pediatric and neonatal care units in critical care and general care areas. [33]

Medication group	Moderate Totals Magnitude: 2.5-9.999 Times Maximum Rate/Dose n. (% vs. DERS Infusions)			Catastrophic Totals Magnitude: 10-100+ Times Maximum Rate/Dose n. (% vs. DERS Infusions)			Totals Magnitude: 2.5-100+ Times Maximum Rate/Dose n. (% vs. DERS Infusions)		
	Pediatric Critical Care	Neonatal	Pediatric General Care and Oncology	Pediatric Critical Care	Neonatal	Pediatric General Care and Oncology	Pediatric Critical Care	Neonatal	Pediatric General Care and Oncology
Aminoglycosides	67 (0.0135)	313 (0.1328)	22 (0.0093)	29 (0.0058)	70 (0.0296)	0 (0)	96 (0.0193)	383 (0.1625)	22 (0.0095)
Antivirals, General Antibiotics and Antifungals	104 (0.021)	105 (0.0446)	668 (0.2895)	74 (0.0149)	17 (0.0072)	303 (0.1313)	179 (0.0361)	123 (0.0522)	971 (0.4208)
Blood Products	0 (0)	0 (0)	108 (0.0468)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	108 (0.0468)
Diuretics	0 (0)	279 (0.1184)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	279 (0.1184)	0 (0)
Electrolytes (K^+ and Mg^{2+})	0 (0)	0 (0)	882 (0.3822)	0 (0)	0 (0)	355 (0.1539)	0 (0)	0 (0)	1,237 (0.5361)
GI System	717 (0.1445)	0 (0)	0 (0)	37 (0.0075)	0 (0)	0 (0)	754 (0.1519)	123 (0.0522)	0 (0)
Insulin	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	32 (0.0139)	0 (0)	0 (0)	32 (0.0139)
IV Fluids	0 (0)	0 (0)	6,657 (2.8851)	0 (0)	523 (0.2219)	570 (0.2470)	0 (0)	523 (0.2219)	7,228 (3.1325)
Opiate/Opioid	90 (0.0181)	105 (0.0444)	0 (0)	7 (0.0015)	35 (0.0148)	0 (0)	97 (0.0196)	139 (0.0592)	0 (0)
Parental Nutrition	1,411 (0.2843)	349 (0.148)	0 (0)	7 (0.0015)	0 (0)	0 (0)	1,418 (0.2857)	349 (0.1480)	0 (0)
Sedative, Hypnotic, Stimulant	434 (0.0874)	453 -0.1922	43 (0.0186)	22 (0.0045)	0 (0)	0 (0)	456 (0.0919)	453 (0.1922)	43 (0.0186)
Simple Analgesia	7 (0.0015)	0 (0)	205 (0.0888)	0 (0)	0 (0)	183 (0.0793)	7 (0.0015)	0 (0)	388 (0.1682)
Steroids	37 (0.0075)	0 (0)	333 (0.1443)	0 (0)	0 (0)	11 (0.0048)	37 (0.0075)	0 (0)	344 (0.1491)
Vasoactive	493 (0.0993)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	493 (0.0993)	0 (0)	0 (0)
Total	3,360 (0.677)	1,603 (0.684)	8,918 (3.8647)	178 (0.0358)	645 (0.2736)	1,454 (0.6301)	3,538 (0.7128)	2,372 (1.0067)	10,373 (4.4955)
	Total All Hard Limit Events			Total DERS Infusions			Total Infusions		

Infusion Events, DERS, and Infusions	19,905	9,451	10,690	496,355	235,642	230,741	1,079,262	351,560	917,129
% DERS Compliance	Pediatric Critical Care		38.82	Neonatal		48.64	Pediatric General Care and Oncology		30.82

The conclusion from both these studies seems to be that DERS is a solution that needs to be applied in all care areas and not only limited to critical care.

A Saudia Arabian study of DERS smart pumps [40] showed how data collected over long periods of time from smart pumps is useful as it gets as close as possible to 'normal behavior' of users and can be expected to show 'day-to-day' fallibility more accurately than observational and self-reporting studies where the Hawthorne effect is a very tangible danger. The same study indicated the need for IV-therapy risk management strategies to be interconnected and to look beyond the pump to issues of compliance and training, medication dispensing and preparation, the standardization of the brand and type of smart pumps deployed, and simplification wherever possible to create a culture of medication safety. The use of data to support further changes and enhancements to IV-therapy safety beyond DERS was also a conclusion of this study. [40]

In the United States, national surveys, primarily undertaken by the American Society of Health-System Pharmacists (ASHP) show that acute care hospitals have universally adopted smart infusion pumps with DERS. Despite this, the Emergency Care Research Institute (ECRI) continues to list infusion pump issues, especially programming and interoperability risks, among its annual Top 10 Health Technology Hazards.

The Institute for Safe Medication Practices (ISMP) 2020 guidelines for optimizing smart pump safety [41] stress the importance of robust drug libraries, hard limits for high-alert medications, and continuous monitoring of compliance and overrides. ISMP Research has linked these measures to meaningful reductions in programming errors and high-alert IV medication events, particularly in pediatric and ICU settings. Real-world rollouts at large academic and children's hospitals report fewer wrong-does and wrong-rate errors after implementing strong DERS library governance and audit-feedback cycles. [41] Health systems that integrate pumps with electronic medication administration records and/or barcode medication administration also see fewer manual entry steps and more consistent infusion parameters. [42]

Recommendations based on the literature: What success looks like in terms of safe intravenous therapy management and administration.

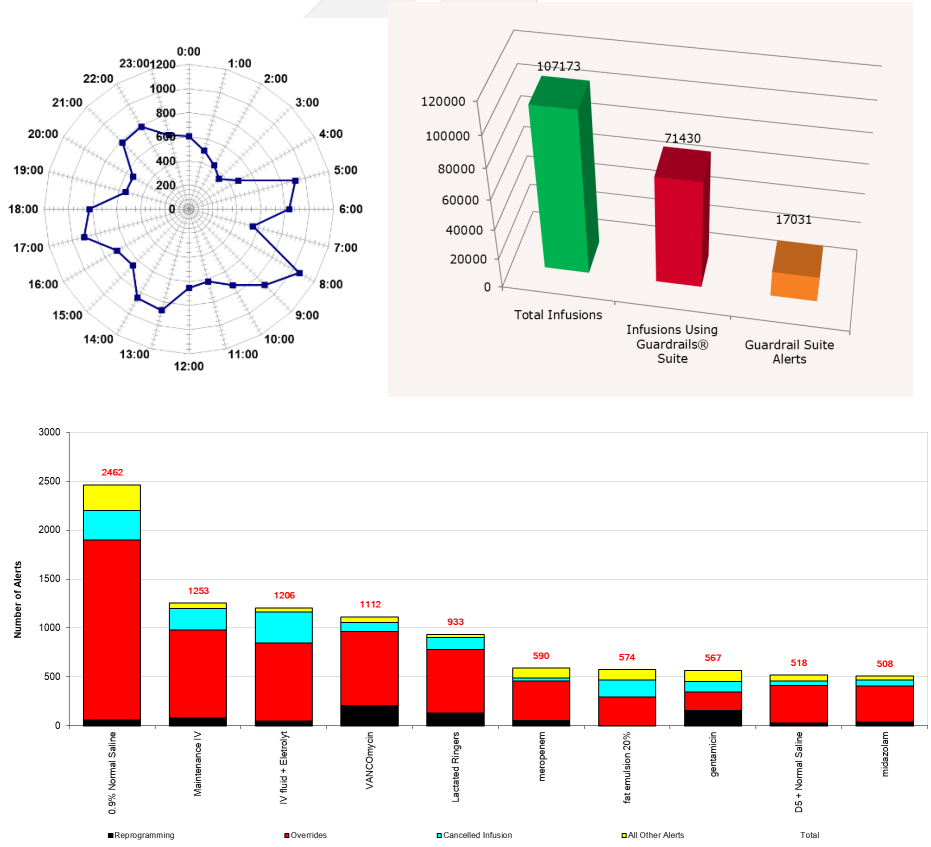
- Identify an executive sponsor. Without an executive sponsor, no attempt to drive the increased use of smart pumps will succeed.
- Identify a leader and champion. Leadership remains a challenge as patient safety falls between many different departments and environments.
- Identify a small group with authority. The group should include a doctor, a pharmacist, and a nurse. Ideally, a medication safety practitioner and a member of the quality department should join the team.)
- Standardize infusion practices.
- Share expertise and experience locally and nationally.
- IV-therapy safety requires more than just the presence of DERS pumps. Training, teamwork, a just culture, and above all compliance is required to optimize medication safety.
- Adequate compliance is suggested to be at least 75%, and it has been suggested that with 'free text' concentration entries, and the addition of blood products and intravenous fluids to the DERS library this can be driven to 90% of all intravenous therapy being given via the DERS library. [14] ISMP 'Targeted Medication Safety Best Practices for Hospitals' 2022 guide stretches this target further to 95%. [43] Trending for the stability of compliance should be assessed and maintained over 6–12-month periods, with monthly audit-feedback to demonstrate sustained effectiveness.
- Compliance can be driven through the process by which DERS libraries are built, with multi-disciplinary team involvement and rapid response to end-user requests being central to making the DERS dataset valued by end-users.
- Drug libraries should be segmented by population/service line but be centrally managed. Libraries should be created for all populations of patients: adult/general units, critical care (adult, pediatric and neonatal), general pediatrics, labor and delivery, oncology, and pediatric oncology. These libraries should have standard drug concentrations and hard and

soft dosing, patient weight, and medication concentration limits, which may be weight-based for certain patient groups such as pediatric patients and neonates. [41]

- Compliance and competency are also built on knowledge, skills, and attitude [44] and are dependent on training, engagement with staff, role-modelling, and celebration of achievements. A deep commitment to partnering and training by the smart pump vendor to achieve this optimization is required. As noted above, organizational expectations for the use of DERS should be established with the goal of achieving practitioner compliance of 95% or greater for the administration of medication infusions (This should include epidural and nerve block infusions). [43] Initial targets of 90% may be set for adult general care wards, but in critical care areas and pediatric units, the initial and maintenance target should be for 95–98% DERS use.
- Hard-limit overrides should be monitored with a target of less than 1% for medications that the organization has designated as high-alert medications.
- The literature suggests that there is a rate of approximately 0.48% 'Good Catches' by DERS hard limits that could have led to harm within all DERS infusions and 0.28% of all infusions in large facilities with multiple disciplines. This is a useful benchmark for judging the initial effectiveness of a chosen IV-therapy risk management strategy and can be used to judge progress according to the philosophy developed by the Institute for Healthcare Improvement (www.ihi.org) for the Failure Mode Effect Analysis (FMEA) process. 'That the target for any FMEA process is that the Risk Priority number (RPN) should be halved within the review period following fundamental redesign of the process; this is usually stated as one year.' [45]
- Initial selection of technology, which may be scalable later when the organization is ready to move to a higher level of risk management, is vital at the outset. In some facilities the use of DERS has been limited by the fact that updating DERS medication libraries across facilities is difficult when the pumps are not networked, and even in wired-connected environments networking of pumps is commonly limited to intensive care units.
- As per the study cited above, which identified a prevented error incidence rate above those in many published studies, wireless networked smart pumps allow for data to be gathered from more diverse areas of the hospital and to allow for the deployment of up-to-date DERS datasets across entire facilities. [38] A robust wireless infrastructure and smart pumps capable of secure data transmission across it is required.

- Much of what we know about IV-therapy is gathered from smart pumps. The data they generate can help shape decisions as well as create evidence for monitoring compliance, error hotspots within facilities, possible educational deficits, variability in clinical practice, and workflow failures.
- Continuous monitoring should be linked to learning and compliance. Near miss errors, and good catch data can be used to refine protocols, training, and device usage over time.
- The IV-medication safety team should run automatic monthly audits, provide feedback, and review outliers using a just-culture approach.
- Engage all stakeholders, including patients, staff, leadership, and vendors to foster a just culture, reporting systems, and continuous improvement, consistent with WHO Medication Without Harm guidance. DERS data collected over long periods of time from smart pumps is useful as it gets as close as possible to the 'normal day-to-day behavior' of users.
- The IV-medication safety team should track unit-level metrics and adjust individual drug libraries against the DERS data generated by the smart pumps over time to balance safety, compliance, and the risk of alert fatigue arising from inappropriate or unhelpful soft-limit settings. This review must include monitoring DERS library compliance rates, soft and hard limit alerts, and override rates, and near-misses from mis-programming. High override rates in individual medications and/or units need further investigation. Each medication in the DERS library requires periodic review and refining of limits, and special attention should be paid to pediatric dosage variability and to critical short half-life medications that are commonly titrated.
- The organization should plan competency-based training. (See Appendix 4). The recommended minimum level of super-users (10% of all users) should be managed to ensure round-the-clock availability. Quick Reference Guides (QRG) should be available in each work area. Annual revalidation of skills should be in place, and these should cover DERS library updates, provide targeted refreshers after any formulary changes, establish clear procedures for patient transfers, and reinforce human factors such as the continuing requirement for independent double-checks for high-risk infusions.

Figure 1: A sample of DERS derived data as an 'Executive dashboard' for high-level review, showing compliance across the facility, good saves, and the top ten medications causing DERS alerts.



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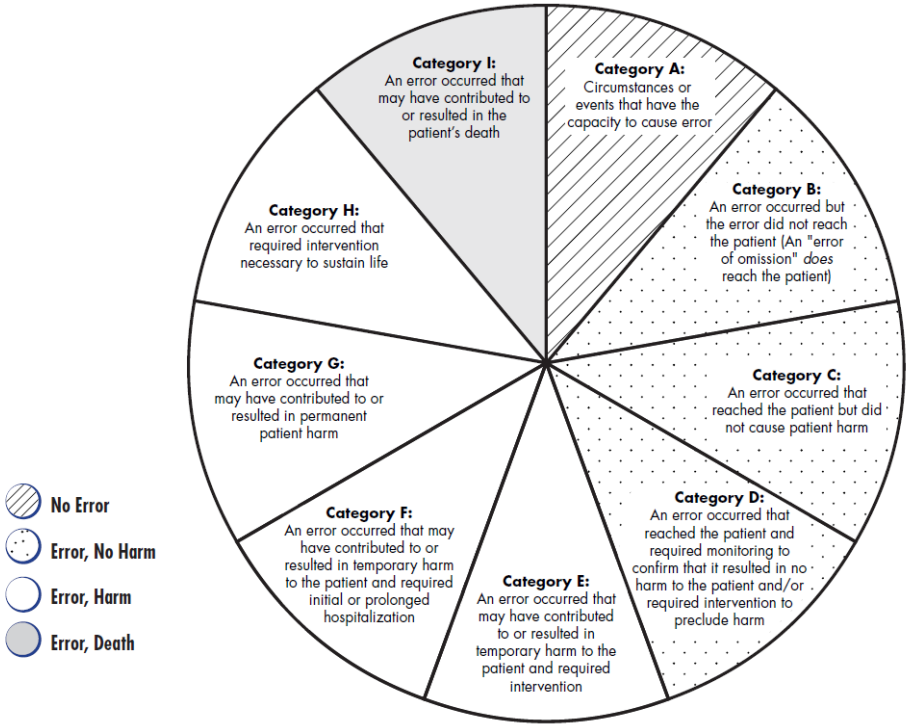
Appendices:

Appendix 1:

The NCCMERP Index for Categorizing Medication Errors.



Definitions

Harm
Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring
To observe or record relevant physiological or psychological signs.

Intervention
May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life
Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

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Appendix 2:

Failure Mode Effect Analysis: Suggested Components for Mitigation. See Also Separate Files (PDF and XL).

Step in the Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (O) 1-10	Likelihood of Detection (D) 1-10	Severity (S) 1-10	Risk Profile Number RPN (OxDxS)	Actions to Reduce Occurrence of Failure	Responsible Persons
1	Non-use of smart pump library	Bypassing medication library either accidently or intentionally due to lack of training, 'automaticity', unusable or insufficient safeguards in medication library and profile configurations.	No dose/rate/concentration limit protection for patient	5	10	7	350	Pump defaults to medication library. DERS log data can monitor compliance and usage of medication library. It can also identify areas where the library is not being used and targeted education to assist in improving compliance and raising issues.	IV pharmacy lead to share DERS data with nursing. nursing education can be given. Limits alteration in negotiation between pharmacy IV. leadership and nursing. DERS log data review for compliance. altering of limits if legitimate use restriction is too severe
2	Use of medication Calculator function on smart pump	Manual entry of new medication leading to incorrect calculation of medication (dose over time 'versus volume over time) Lack of training, 'automaticity', insufficient safeguards in medication library and profile configurations, medication missing from smart pump medication library	Potential overdose, decimal point error, duration, or rate, if medication details incorrectly selected.	5	10	7	350	Regular review of compliance level via DERS log data and consistent contact with nursing staff/anesthesia over need to use calculator/missing med. Research medications to be added as free text by profile. Smart pump library built against hospital formulary. Networked delivery to all pumps in the facility of new DERS library allows for consistent medication library complete- no omissions, including fluids and blood products. DERS log data monitoring to note compliance and usage of medication library. Reporting system for 'medication missing' reporting by nursing staff needs to be shown to be quarterly minimum.	DERS log data and reporting system Nursing to Pharmacy
3	Incorrect Profile selection	Incorrect Profile Selection. Lack of training, 'automaticity', insufficient safeguards in medication library and profile configurations. Induction training, monitoring of DERS log data profile usage, minimalization of profiles to reduce confusion, 10% super-user presence in nursing units.	Potential duration/rate loss of limits protection if profile incorrectly selected.	5	10	7	350	Education given on Smart Pump usage during medication library expansion across the facility. Each unit has a profile. Pump requires user to confirm new patient and new profile at each start up.	Nursing Education for super-user presence and messaging. pharmacy to monitor via DERS log data.
4	Incorrect programming of medication delivery on smart pump	Wrong entry of Medication, Dose of medication, Concentration (Volume of delivery), Patient weight, due to lack of training, 'automaticity', insufficient safeguards in medication library and profile configurations. 'Free entry' dose/volume without concentration limits.	Potential dose/rate loss of limits protection if medication incorrectly selected.	5	10	7	350	Full medication name, dose and volume on medication labels, standardized concentrations in smart pump library, minimal 'free entry' medications. Every pump has the TALLman system of medication 'look-alike' error reduction. Education for staff on medication selection. Ensure that vulnerable patient groups such as NICU and oncology patients have weight limits set on their configurations in the medication library. Application of medication limits and concentration limits for all medications in the medication library.	Pharmacy and Therapeutics Committee medication Error reduction Software introduced in 2016. Wireless communication with smart pumps to allow for regular audit and update with
RPN Total Score									1400

Appendix 3: Optimized for Best Practice Standardized Dose Error Reduction Software Library. See Separate Files (Document and XL).

Appendix 4: Standardized Installation and Training and Competency Plans with Metrics.

Executive Summary.

The implementation of smart pumps across a facility is expected to bring the following benefits:

- Reduction in risk to patients of serious preventable intravenous drug error through the application of Drug Error Reduction Software (DERS) and a tailor-made DERS Library.
- Implementation of measures and technology capable of reducing risk in terms of extravasation injuries through appropriate setting of occlusion pressure limits and alarms.
- The creation of data that identifies improvement and/or areas requiring further attention.
- To create a baseline for infusion therapy and technology with the capability for integration with other industry standard health information systems to further enhance intravenous therapy safety.
- Allow for evaluation of infusion product 'specialist' accessories such as disposables and applications that would improve the quality of infusion therapy across facilities.

Smart Pump Implementation following Institute for Safe Medication Practices (ISMP) Guidelines.

The following guide is not prescriptive; it is a series of recommendations and is not intended to be followed 'to the letter.' It is based on previous successful smart pump installations in the Middle East and in other regions.

Smart infusion pumps are used across organizations and multiple stakeholders have an interest and responsibility for their effective and safe use. These include:

Pharmacists who commonly lead in developing and maintaining DERS libraries, ensuring accurate and up-to-date medication information. They are critical of providing clinical guidance to the care team.

Nurses who are the primary users of smart pumps at the point of care. They are responsible for accurate drug administration, promptly reporting medication errors and near misses, and participating in continuous training.

Physicians must lead in safe prescribing practices and are responsible for validating drug orders against the DERS library. They must collaborate with pharmacists and nurses to clarify orders and ensure patient safety.

IT, biomedical and technical Professionals provide the technical infrastructure and support necessary for DERS implementation and smart pump integration with electronic medical records (EMR). They are responsible for system security, data management, proactive and regular inspections, services, and repairs to prevent smart pumps failures before they occur and troubleshooting.

Medical Device Manufacturers and Suppliers are vital partners for technical support, device maintenance, and training on new features and updates. Their collaboration ensures the pumps are functioning optimally and are configured to meet local clinical needs.

The smart pump task group must therefore be multidisciplinary, and comprise at a minimum of:

Clinical: pharmacy, nursing, anesthesia, and intensivists.

Technical: biomedical engineering and IT/EMR representation.

Operational: materials management, supply chain, and vendor and hospital project management.

The group should convene regularly, at least monthly, to review progress, address barriers, and ensure alignment across clinical, technical, and operational domains.

Smart Pump Installation Project Team Members:

The following key profiles are helpful to successful project completion. Selection of team members should be based on skill set, willingness, and availability to complete the project.

The roles are detailed below. Time commitments are variable, but members marked [*] will have the largest commitment.

Executive Sponsors:

A designated senior executive should be informed of the project and project requirements. The executive sponsor may be the chief medical officer, the chief nurse, chief pharmacist, or hospital CEO. They will be responsible for the following activities:

- Commit resources and effort to the implementation process to ensure timely and successful project completion.
- Attend the kick-off meeting to launch the project.
- Consult as part of the issue escalation process and as needed remove barriers.

Lead Pharmacist*:

- Responsible for the development of the DERS Library/Dataset software.
- Has clinical knowledge of intravenous therapy modalities and processes used throughout the facility.
- Consults with the appropriate clinical and medical personnel for DERS dataset optimization.
- Responsible for the release and sign off for the DERS dataset 4 weeks prior to the initiation of the facility's staff education and 8 weeks prior to technology conversion date.
- Undergoes training in and takes on-going responsibility for DERS dataset editor software and DERS Quality Logs Data Management.

Hospital Project Manager*:

- Has experience in the organization that can coordinate the project throughout the facility. A Products Coordination Lead Nurse would be a suitable candidate.
- It is recommended that the employee has strong clinical experience.

Hospital Nursing Education Lead*: A nurse educator who is experienced with scheduling and coordinating clinical staff training:

- Works with the pump vendor's Clinical Consultant to plan and coordinate User and Super User training. [See Training Plan].
- Responsible for establishing and maintaining a Super Users' network throughout the hospital to act as experts after Go-Live. This should ideally be 10% of all users by headcount.
- Schedules training in locations and at times convenient for trainees to attend.
- Responsible for developing staff communication of specific practice changes related to the changeover.
- Arrange annual revalidation sessions.

Clinical Profile Leads: Intensivist/neonatologist and nursing clinical leaders from the facility are required to provide input and approval of:

- Profile specific configurations under the guidance of the vendor Clinical Consultant.
- Clinical review of the Dataset.

Anesthesia Lead:

- A senior anesthesiologist should represent the specialty needs of anesthesia and consult on the DERS dataset and liaise with the Nursing Education Led to ensure that anesthesia training needs are met.

Materials Management and Central Supply Processing*: A supervisor who has decision making capability in their area will be responsible for the following:

- Completes an analysis of what disposables/infusion supplies will need to be distributed prior to Go-Live day and completes a distribution plan prior to Go-Live day.
- Works with the vendor Accounts Manager to assess needs for smart pump IV disposables.
- Works with the vendor Accounts Manager to ensure that supplies of tubing, extensions and other components are available and inventories before the Go-Live date.
- Helps coordinate the implementation of Technology Conversion activities and is responsible for the availability of disposables during the conversion.

Biomedical Engineer*: A Supervisor with decision making responsibility for their area, will be responsible for:

- Transferring maintenance logs, maintaining the software and hardware of the devices.

- Organizing with the vendor Biomedical Engineer team training in all aspects of transferring maintenance logs, maintaining the software and hardware of the devices as well as the DERS dataset upload and DERS quality logs download.
- Securing adequate space and location for smart pump device check-in.
- Works with vendor service engineers during installation to ensure a smooth flow of new modules into service if applicable.

Information Technology Department*:

- Approves the installation of smart pump editor software on specific facility computers.

Quality Management Officer:

- Liaises to set KPIs for DERS library compliance, hard-limit override rates, near-miss limit breaches.
- Conducts monthly audit-and-feedback.
- Liaises with educators for activities such as staff knowledge and satisfaction surveys.
- Leads just-culture reviews.

Standard Dataset Development Sub-committee:

Objective:

Collaborate with appropriate medical and clinical personnel to develop a DERS dataset that incorporates the needs of all users' profiles while adhering to best practice standards.

Participants:

- Lead Pharmacist and Team.
- Anesthesia Lead.
- Nursing Profile Leads for impacted departments.

Education Sub-committee:

Objective:

Collaborate on roll-out training. Responsible for implementation, review of education plan, scheduling training plan, collaborating with unit managers for Super User participation and resources, monitoring compliance with training.

Participants:

- Nurse Educator
- Anesthesia Lead

Vendor Support Team:

Vendor Clinical Consultant/Project Manager:

- Facilitates the implementation process and ensures that major milestones are met.
- Provides regular progress updates to facility management team.
- Help define DERS dataset for specific configurations.
- Provides multifaceted staff education around the DERS dataset.
- Manages clinical transition from current IV-therapy solution to smart pumps.

Vendor Technical Service Support Engineer:

- Tests, tags and documents pumps, perform system upgrades, uploads the initial DERS dataset.
- Conducts biomedical training on the basic maintenance and repair of pumps for facility Biomed Engineers.

Vendor Accounts Manager:

- Liaises with Materials Management and Central Supply Processing to ensure smooth delivery of pumps and disposables.

Installation Overview:

The process has three stages: Preparation, Performance, and Partnering.

Preparation:

- The Kick-Off meeting begins at this stage of the process.

- After independent work by all parties, the team along with unit-based nursing representation will come together to review the Dataset both on paper and on the device.

Performance:

- During the Performance phase the Dataset is completed, signed off, and loaded onto devices, users are educated on the device, and the device is rolled out for patient use.
- Education includes User and Super User education.
- Prior to Go-Live, all implementation participants will come together to review the plan and finalize Go-Live logistics in a Pre-Technology Conversion meeting.
- The following day the facility converts its technology and Go-Live to the new devices.
- After a minimum of 24 hours post Go-Live the vendor and facility team will conduct compliance rounds to assess unit use of the devices.
- At the conclusion of this stage of the project the implementation team will meet formally to review the implementation process and Technology Conversion.

Partnering:

Following implementation, the facility and vendor will transition from the implementation team to local vendor resources designated to provide on-going support.

Implementation Meetings Overview [For multiple participant meetings only]:

The meetings detailed below require pre-planning that may include advanced invitations, room reservations and internet access, projector and conference phone facilities.

The Vendor Clinical Consultant will work with the facility core team and facility Project Manager to determine date, time, and location for each of these key meetings:

Meeting Name	Date, Location	Attendees	Purpose
Kick Off Meeting		Executive Sponsor Hospital Project Manager Pharmacy Lead Nursing Leads Biomedical Nursing Education Infection Control Quality Management Officer Materials Management Vendor Clinical Consultant Vendor Accounts Manager Vendor Technical Service Support Engineer	To present an overview of the smart pump implementation process, milestones, and timeline review. Identify profiles, profile leads and sub-committee team members.
Nursing Configurations Meeting		Profile Leads Pharmacy Lead Vendor Clinical Consultant	Determine profile configurations.
Education Planning Meeting		Nurse Educator Vendor Clinical Consultant	Determine education plan and review basic supplies for clinical training.
Dataset review Meeting		Nursing Profile Leads Staff Nurses [Some facilities use Clinical Resource Nurses for this role] Pharmacy Lead	Clinical representatives from each profile will be scheduled to review the first draft of the Dataset. The first portion of the Dataset development meeting is a paper-based review of the Dataset.

			The second portion is a review of the Dataset on the device.
Managing the Software Presentation		Hospital Administration Biomed Quality Management Officer Nursing Admin Nurse Managers Pharmacy Hospital IT Nursing Education	Presentation to review roles and responsibilities for using DERS software and DERS Quality Logs Data.
Go-Live Planning Meeting		Hospital Project Manager Pharmacy Lead Nursing Leads Super Users Biomedical Materials Management Nursing Education IV Nurse Specialist Vendor Clinical Consultant Vendor Technical Service Support Engineer	Begin the development of the Technology Conversion plan and review the details of the Go-live.
Pre-Go-Live Meeting		Hospital Project Manager Pharmacy Lead Nursing Leads Super Users	Review the plan the day before conversion to confirm that all personnel and plans are in place for the following day.

		Biomedical Materials Management Nursing Education IV Nurse Specialist Vendor Clinical Consultant Vendor Technical Service Support Engineer	
Post Go-Live-Meeting		Project Team Vendor Clinical Consultant	Follow up to Go-Live. Resolve any outstanding issues. Obtain feedback on the implementation process.

Hospital Project Manager and Vendor Project Manager Timeline and Guide.

The chart below reflects a typical implementation process. The project managers will collaborate to set target dates and record completed actions:

Milestone	Date
Initial Equipment Delivery	
Kick Off Meeting	
Preliminary Nursing Configurations Meeting	
Preliminary Education Planning Meeting	
Bi-weekly Project Status Calls ▪ Finalize Profiles	
Dataset review Meeting ▪ Finalize Profile Configurations ▪ Education plan Finalized	
Go-Live Planning Meeting	
Managing the Software Presentation	
Dataset Sign Off	
Final Device Shipment Arrival	
Device Check In	
Super User Education	
End User Education	
Pre-Go-Live Preparation Meeting	
Go-Live	
Confirmation Sign-Off	

Agenda for Kick-Off Meeting.

1.	Welcome.	Project Managers.
1.1	Review Meeting Agenda.	
2.	Introductions.	Project Managers.
2.1	Implementation team Introduction.	
2.2	Project History/Objectives.	
2.3	Medication Safety Overview.	
2.3.1	Smart pumps review.	
2.3.2	DERS Software review.	
2.3.3	Implementation Process.	
2.3.4	Scope of Project.	
3.	Implementation overview and Roles.	Project Managers.
3.1	Project Management.	
3.2	Pharmacy Consulting.	
3.3	Educational Opportunities and Options.	
3.4	Technical Team.	
3.5	Accounts Manager/Disposables Management and ordering.	
4.	Review Implementation Milestones and Timeline.	Project Managers.
4.1	Profile names and clinical leads for each profile.	
4.2	Configurations.	

4.3 Dataset approval [Pharmacy, Therapeutics committee].

4.4 Dataset development meeting [Hard copy/paper and device review of each profile].

4.5 Dataset completion.

4.6 Verification and Validation of Dataset.

4.7 Training/Education plan.

4.8 Communication and dissemination of information plan for facility staff.

4.9 Biomedical checking-in and uploading of Dataset to devices.

4.10 Go-Live

5. Sub-Committee Formation. Project Managers.

5.1 Discuss Sub-Committees and Roles.

5.1.1 Pharmacy Dataset Development.

5.1.1.1 Profile Configurations.

5.1.1.2 Dataset Approval.

5.1.1.3 Interface Testing.

5.1.2 Clinical education.

5.1.3 Biomedical/Technical Details.

5.1.4 Internal Policy and Procedure review.

5.1.5 Disposables.

5.1.6 Go-Live.

5.1.7 Software/Hardware Management.

6. Assignment of Tasks and Follow up. Project Managers.

7. Questions. Project Managers.

Introduction to the DERS dataset build process.

The Dataset will be built around a defined list of drugs, concentrations, therapies, and limits specific to each clinical profile. DERS provides protection for:

- Dose.
- Duration/Rate.
- Drug Concentration.
- Patient Weight/BSA entry.

As both hard limits which cannot be overridden by clinicians and soft-limits which can be overridden but remain event-recorded in the pump's (DERS) Quality Logs Data.

Initial DERS software Editor Training includes:

- How to develop a customized DERS dataset.
- Hands on experience building a DERS dataset.
- Access to sample and standardized DERS datasets.
- DERS dataset transfers from and to devices.
- Consensus building during the approval process.
- Developing and programming Configuration Settings.
- Establishing a process for on-going management of DERS datasets.

Preparation:

The following items are required to be ready prior to training:

- Desktop or laptop loaded with Editor software.
- List of profile areas to be included in the DERS dataset as determined by the multi-disciplinary team tasked with this work at the Kick-off meeting.
- A Master Drugs list consisting of the names of the drugs used at the facility with the appropriate concentrations used by each unit.
- IV compound list, central supply pre-mixed IV list, formulary list.
- List of dosing units in each care area for each medication.
- Pre-printed physician order forms, protocols, therapies, IV policies and procedures.

IV-Therapy Needs Analysis.

A unit-by-unit assessment of IV-therapy needs and practice will be made by the Vendor Clinical Consultant with Nursing Clinical Leads.

The assessment will review areas such as:

- Are secondary infusions delivered via mini bags, syringe, or both?
- Is back priming utilized?
- Is concurrent flow presently utilized?
- Are blood products delivered via the IV infusion device?
- Is a valve system used on disposables?
- Does practice vary from unit to unit?

The report is presented in a table to succinctly highlight practice variation and/or uniformity.

The Clinical Consultant will also summarize opportunities and options to consider in the Dataset build process and disposable solutions selected.

Configuration Meeting:

- The settings for programmable smart pump configurations will be determined by clinicians with representation from each Dataset Profile.
- The purpose of the Configuration Meeting is to ensure that each Profile has clinically appropriate configurations.
- The Vendor Clinical Consultant will walk through the Profile leads through an explanation of the configurations, the available settings, and consult on the clinical implication of each setting.
- Alarm volumes, air in line tolerances, and pressure settings are all examples of configurable settings that will be determined during this meeting.
- The Configurations can be determined by each Profile to meet the unique needs of each patient population.

Education Overview and Planning:

During the Education Overview Meeting the vendor Clinical Consultant will give an in-depth overview of the education process and work with the Hospital Educator to set preliminary education plans.

Education consists of:

- Super User Training with a >10% of users trained target.
- End User Training with >80% of users trained target.
- Super Users should be selected as early as possible in the process.
- Super Users will be able to train End Users going forward.
- Class scheduling is determined during the meeting.

The Hospital Educator should review the following items prior to the meeting:

- Verify the number and times of shifts for all units/facilities.
- The number of nurses and anesthesia department trainees.
- Decide on dates per implementation timeline.

Dataset Review Meeting:

- The Lead Pharmacist will facilitate a Dataset Development Meeting during the implementation. The goal of the Dataset Development Meeting is to finalize the Dataset through a multi-disciplinary review by Profile area.
- The Review provides nursing representatives from Profile areas with the opportunity to review a printed draft of the Dataset.
- The feedback generated from this meeting will be used by the Pharmacist to modify the Dataset in preparation for the final technical review. This will be the last opportunity to make changes to the Dataset prior to upload by Biomedical Engineering during smart pump check-in.

Managing the Software:

- The purpose of Managing the Software training is to review the DERS software and begin building a comprehensive plan for DERS software management, and (DERS) Quality Logs Data Management.

- The meeting participants will also be tasked with forming an IV Data Management Committee that will formally review and modify the Dataset. It is recommended that this committee have cross functional representation, regularly scheduled reviews, a formal method for coordinating and communicating Dataset changes and clearly defined objectives for what they will accomplish as a team.

Technology Conversion Planning Meeting:

- Plan for the day of Go-Live.
- Begin dialogue around on-going support of the project.
- As part of the conversion planning, the team will discuss how they will swap out the devices, the number of Go-Live teams, change-over starting points and timing, disposable implementation logistics, ancillary area swap-out timing, and Crash Cart swap-out.

Biomed Training:

The vendor Technical Engineer will provide system training for facility Biomedical Engineers as appropriate including but not limited to:

- Introduction to the system.
- Performing preventative maintenance using Maintenance Software.
- Troubleshooting faults and performing repairs.
- Verifying and updating module software versions.
- Performing check-in verification on instruments.
- Downloading (DERS) Quality Logs Data from smart pumps.
- Transferring released Datasets to smart pumps.

Pre-Go-Live Phase Overview:

- Following Dataset Development, the project will enter Pre-Go-Live.
- The Lead Pharmacist will verify that the Dataset is in final form and ready for device upload.
- The final Dataset must be approved and signed to that effect for the facility by a designated responsible employee; this is usually the Head Pharmacist of the institution.

- During Device Check-In, all the devices will be unboxed, tagged, tested and uploaded with the signed version of the Dataset.
- Before the meeting, all devices should be staged for rollout as determined by the plan.
- Once the teams have been confirmed, each team will be assigned a route for device conversion.

Go-Live Performance:

- End Users will be educated on the devices and associated practice changes (See Standard Training Plan below), and the facility will then go-live with the new technology.
- The teams will divide and begin going unit to unit to assist clinicians with the device changeover.
- The conversion process will start at the points of patient entry such as OR/PACU, Cardiac Cath lab, ED, ICU and then roll out through the rest of the Hospital based on acuity starting with the highest acuity patients first.
- As the devices arrive on each unit, Hospital clinicians will be responsible for programming the devices and switching them out for patient use, implementation team members can offer guidance and support.
- Super Users are recommended to be staffed without patient assignment during Go-Live to assist their floor with the changeover as well as staff the Go-Live teams.
- Post Conversion Support.
- Immediately following Go-Live, the Vendor Clinical Consultant will make rounds to answer questions, troubleshoot, respond to any issues with the device, and support users on the transition.
- The rounds will check for the use of DERS software, proper set loading, correct patient Profile, and device handling.
- Compliance Rounds will be conducted at least 24 hours after implementation. At that point, end users will have had the opportunity to program the device on their own without the support of a Super User or Vendor Clinical Consultant giving a more accurate picture of actual practice.

Post Conversion Meeting:

Once the Hospital has started using the devices, the entire team will meet to review the implementation process. The goal of the meeting is to:

- Identify areas of strength and weaknesses in the implementation process.
- Recognize the accomplishments of the team.
- Review Compliance Rounds data and transition to on-going vendor support.

Training Processes and Standard teaching Plan for End Users:

General Preparation:

- Upload demo Dataset to training pumps.
- Verify that 'Not for Human Use' stickers are on the devices.
- Deliver to each teaching room or care unit.
- Track location of each training device.
- Announce availability of practice devices.

Standard User Training: [2 Hours].

Training Devices and supplies:

5 Large Volume Pumps (LVP) per room.

5 Syringe Pumps per room.

1 Pump Docking Station per room.

5 LVP Dummy sets.

250 ml IV bags x 10.

100 ml IV bags X 5.

5 LVP standard Primary sets

5 Secondary sets: Optional depends on local policy.

5 X 50 ml syringe

5 Syringe Pump lines

Five dump water bottles 500 ml

Tape

5 IV stands

1 X Samples of all other dedicated lines [light sensitive, Low sorb, in-line filters]

Process:

D1: Disposables.

- Needleless connector line access in dedicated pump lines.
- Cleaning Needleless connector pre-access.
- Needleless connector tolerances and emergent procedures.
- Specialist Line Usage.

LVP: Operation.

General overview of Pump:

- Rate, Volume to Be infused (VTBI), Volume Infused (VI) and Time to complete infusion indicators.
- Micro and Secondary mode indicators.
- Keypad.
- Door Latch.
- Flow Stop.
- Pole and Bar Clamps.

Pump use:

- Turning the Unit on.
- Door and flow stop mechanism.
- Inserting sets.
- Gravity and on-pump priming procedures.
- Rate setting.
- VTBI setting.
- Clearing VI.
- Starting an infusion.

- Stopping an infusion.
- Titrating a rate. (Without interrupting flow).
- Giving a Bolus. (Noting fluid infused will be added to the VI)
- Setting up a secondary infusion. (Note back-check valve in primary set)

Options:

- Setting alarm volume.
- Locking and unlocking the keypad.
- Setting the Occlusion level.

Alarms:

- Door Open.
- Callback/Time-out.
- Upstream Flow Occlusion.
- Keep Vein Open.
- Air-In-Line.
- Downstream Occlusion.

Operating with the DERS Library:

- Selecting the Profile.
- Selecting a drug from the DERS library.
- Default does/rates.
- Hard and soft dose/rate limits.
- Bolus and no bolus drugs.
- Entering patient weight and limits by profile.
- Custom and standardized concentrations, concentration limits.

Syringe Pump:

- Selecting the appropriate Profile.

- Loading the syringe and administration set.
- Confirming correct syringe type.
- Priming the line manually and via the pump.
- Selecting a basic infusion. (With warning over 'no safety')
- Selecting medication from the DERS library.
- Starting the pump and titrating. Soft and Hard limit breaches.
- Adjusting the pressure limit using manual and automatic pressure features.
- Bolus Hands-Free and Hands-On (Bolus available / not available)
- Back-off and Post Occlusion Bolus reduction.
- Restoring Infusions.
- Standby Mode.
- Cleaning

Cleaning & storage.

Per local policy and according to pump directions for use.

Training Plan Super Users:

1 Hour + Previous Attendance at Basic [2 Hours]

Drug Calculator:

Drug not available in DERS library or specialist infusion outside of limits set up in Drug Calculation/dosing units. (reiterate warning over lack of safety)

Use 21 mg/50 ml.

42 mg in 100 ml.

Mcg/kg/min.

70 kg patient.

Double Pumping and Vasoactive Switch Over.

Syringe Pump: Purge.

Downstream Occlusion Line Pressure Monitoring

- Soft and Hard occlusions.
- Setting alarms dynamically.

Promoting an infusion from ml/hr to DERS library.

Super Users to Demo and instruct another user:

IV-primary therapy Normal Saline with Ciprofloxacin Secondary.

DERS Library via Syringe Midazolam: Continuous infusion and Bolus- hands on and hands free.

Sample Competency Based Training Guide (May be adapted to local needs).

This task checklist is designed to be a practice tool for clinical personnel but can also serve as a verification of hands-on training for new products.

Task and description	Pump Type	Performed Correctly Y/N
Clinician sets the correct Infusion bag above Pump Height for Large Volume Pump / Set up	Large Volume	
Clinician identifies the safety clamp on the pumping mechanism of the administration set and verbalizes its deployment for preventing inadvertent free flow when the set is removed from the pump. Clinician shows understanding that to prevent free-flow the roller clamp must also be closed before removing a set from the pump.	Large Volume	
Clinician undertakes a gravity or pump driven prime of the administration set and verbalizes why the prime should be undertaken slowly to reduce the risk of micro-bubbles entering the administration set. Clinicians appropriately fill the drip chamber and when the administration set is fully primed, they ensure that the roller clamp is fully closed.	Large Volume	
The clinician understands the protocol for air-in-line removal and ensures that the access line to the patient is clamped during the removal of air at the lower needle-free IV access point.	Large Volume	
Clinician demonstrates priming the set using the feature 'Prime Set with Syringe' to decrease potential start-up delays and delivery inaccuracies. Clinician verbalizes the need to clamp the line after the administration set is primed to prevent uncontrolled flow.	Syringe Driver	
Clinician clamps the administration set before loading or unloading a syringe and verbalizes the requirement to not connect a patient until after loading the syringe into the pump.	Syringe Driver	

Clinician verbalizes the requirement to always ensure the selected syringe manufacturer/size is correctly identified by the pump. Clinician verbalizes the risk of over- or under-infusion to the patient if a syringe mismatch is confirmed incorrectly.	Syringe Driver	
Clinician sets the device as close to the level of the patient's heart as possible. Clinicians understand that vertical pump displacements may affect flow rates for a period.	Large Volume and Syringe Driver	
Clinician demonstrates how to place an infusion on pause, and how to restart the infusion.	Large Volume and Syringe Driver	
Clinicians show understanding of how to restore or clear a previous DERS infusion.	Large Volume and Syringe Driver	
Clinician successfully programs a DERS protected infusion.	Large Volume and Syringe Driver	
Clinician verbalizes the meaning and significance of DERS Hard and Soft Limits. Clinicians show appropriate response to encountering Soft Limit and Hard Limit alerts.	Large Volume and Syringe Driver	
Clinician programs an infusion order over a designated time frame using Volume/Duration features.	Large Volume and Syringe Driver	
Clinician recognizes the visual display on the pump seen whenever an infusion is programmed above a Soft Limit.	Large Volume and Syringe Driver	
Clinician delivers a DERS limited bolus from a running infusion, using hands-on and hands-free options.	Large Volume and Syringe Driver	
Clinician verbalizes understanding that a Basic Infusion does not offer the safety of DERS limits, and that Basic Infusion programming should only be utilized if a fluid or medication is not included within any of the hospitals developed DERS libraries.	Large Volume and Syringe Driver	
Clinician correctly accesses the pump's administration line via a needle-free valve. Clinician swabs site with a sterile 70% isopropyl alcohol wipe and allows to dry prior to accessing.	Large Volume and Syringe Driver	

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