

Praxiject™, Saline Prefilled Syringes

Clinical evidence compendium

A summary of the Uses, Benefits & Risks of Saline prefilled syringes for locking/flushing VAD

Dear Readers,

Millions of prefilled flush syringes (PFS) are used in hospitals and offer safety benefits over manually-prepared flush syringes by reducing occlusions, and complications, including catheter-related bloodstream infections (CRBSI). These are important advantages and have made PFS a standard commodity for hospitals.

Prefilled Flush Syringes are perceived as low-risk, and procurement departments may place orders or change suppliers for PFS based on device cost alone, assuming that all prefilled saline syringes are the same, that is, sterile and safe. Unfortunately, this assumption is tragically false. A contaminated PFS can inject contaminants directly into the bloodstream, potentially producing significant morbidity and mortality.

This evidence summary was compiled in order to facilitate the reader's ease of accessing the literature pertinent to saline flush/lock solution. All studies in this compendium were found via a literature search and are provided as a courtesy to you, the reader.

All information in this summary was current as of September 2019 and MedXL is not liable for any inaccuracies therein.

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Table 1 | Studies examining the Benefits of Normal Saline flushes solutions for HD Catheters



Date of Publication	2018	2015	2014
First Author	Massoomi ¹	Schreiber ²	Keogh ³
Study Name	A closer look at Prefilled Flush Syringe Safety	Normal saline flushes performed once daily maintain peripheral intravenous catheter patency: a randomised controlled trial	A Time and Motion Study of Peripheral Venous Catheter Flushing Practice Using Manually Prepared and Prefilled Flush Syringes
Method	This article describes a 3-step process that pharmacy, nursing and procurement personnel can use to ensure that the PFS purchase and use are not putting patients and institutions at increased risk.	This was an open, non-inferiority, randomised controlled trial. Children with IVLs, aged 1–17 years, were randomly assigned to receive saline flushing every 12 h (group A) or every 24 h (group B). The main outcome was the maintenance of catheter patency.	The study used an observational design and involved a laboratory-based time and motion study of preparation and use of manually prepared flushes versus prefilled flush syringes
Results	Reputation is hard to quantify but is an important consideration. Ask these questions: How many years has the manufacturer been in the business of producing PFS? When the manufacturing facility was last updated? What kind of support services are offered along with PFS? Answers to these questions and the criteria presented in table 2 can help teams perform due diligence and get the evidence needed to make an informed selection of safe PFS.	Four hundred patients were randomised; 198 subjects were analysed in the 12 h group and 199 in the 24 h group (three patients were lost at follow-up). Occlusion occurred in 15 children (7.6%) in group A versus 9 (4.5%) in group B (p=0.21). The difference in catheter patency was +3.1% in favour of the 24 h group (95% CI -1.6% to 7.7%), showing the non-inferiority of the 24 h procedure (the non-inferiority margin was set at -4%). Catheter-related complications were not different between the two groups (12.1% in group A vs 9.5% in group B; p=0.42)	The mean total flushing time was 169 seconds for manually prepared flushes and 120 seconds for prefilled flushes, with a mean difference of 49 seconds (95% CI, 35–64, P > .001). Preparation time constituted the largest individual task time. The mean preparation time for manual flushes was 75 seconds versus 44 seconds for prefilled flushes, with a mean difference of 31 seconds (95% CI, 22–39, P < .001)
Conclusions	Don't let PFS be the weakest link in the protective chain of intravenous safety.	A flushing procedure with one flush per day allows maintenance of catheter patency without an increase in catheter-related complications. We propose a simplification of the flushing procedure with only one flush per day, thereby reducing costs (materials use and nursing time), labour and unnecessary manipulation of the catheters which can cause distress in younger children and their parents.	The results from this study demonstrate that using a prefilled flush is associated with a significant reduction in the time required to prepare the equipment for a PVC flush and, therefore, in overall time. A prefilled flush syringe also has the potential to promote adherence to some key principles of ANTT.
Journal Name	Pharmacy Practice News	Arch Dis Child	Journal of infusion nursing

Table 1

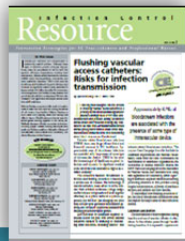
Studies examining the Benefits of Normal Saline flushes solutions for HD Catheters



Date of Publication	2014	2013	2013
First Author	Kordzadeh ⁴	Bertoglio ⁵	Zhong ⁶
Study Name	Efficacy of normal saline in the maintenance of the arterial lines in comparison to heparin flush: a comprehensive review of the literature	Pre-filled normal saline syringes to reduce totally implantable venous access device-associated bloodstream infection: a single institution pilot study	Normal saline versus heparin for patency of central venous catheters in adult patients - a systematic review and meta-analysis
Method	A comprehensive review of the literature from 1951 to 2012. An electronic search of OVID, Medline, Embase, Cochrane, Scopus and CINAHL database in English language was conducted. The search was limited to adult subjects only. The following keywords were used: heparin flush, saline flush, 0.9% sodium chloride flush, arterial line and indwelling vascular line. A total of ten papers (n=10) were found eligible.	This was a retrospective observational cohort study of 718 TIVADs implanted in adult cancer patients at the National Institute for Cancer Research, Genova, between September 2009 and August 2011	We searched PubMed, Embase and the Cochrane library databases. Randomized controlled trials (RCTs) evaluating the use of NS vs. HS to maintain the permeability of CVCs among adult patients were included in our meta-analysis. References of relevant papers were reviewed manually. No language restriction was applied. Nonhuman studies were excluded. Pooled relative risk (RR) was calculated using a Mantel-Haenszel random-effects model. We also performed subgroup analysis examining the effect of the duration of catheter placement on the outcome. All statistical tests were two-sided using a significance level of 0.05
Results	The evidence suggests patency is feasible with both solutions but if longer duration of use (arterial line) is advocated, heparin is superior in the long term. Furthermore, heparin flush effects are dose dependent and require fewer numbers of flushes. In addition, no adverse effects were found with heparin flush solution	Standardized nursing care protocols for TIVAD management are crucial for minimizing CRBSI. Guidelines for skin cleaning, the use of 'no-touch' technique, timing for non-coring needle substitution and procedures for flushing and locking devices have been extensively reported. Flushing and locking with pre-filled syringes to maintain catheter patency, ease nursing staff work, reduce medication errors and decrease risk of nosocomial transmission of infection has not so far been considered in these guidelines. To our knowledge, this is the first study of the effectiveness of pre-filled syringes in reducing TIVAD-associated CRBS	Ten RCTs involving 7875 subjects (with analysis at patient, catheter, lumen and line access level) were included in this meta-analysis. Whether in terms of pooled or local analysis (RR with 95% confidence interval spans 1), NS can be equally, if not more effective, in keeping the CVCs open. Of studies reporting secondary outcomes (maneuver needed, heparin-induced thrombocytopenia, haemorrhage, central venous thrombosis and catheter-related bloodstream infection), heparinised saline was shown not to be superior to non-heparinised solution.
Conclusions	There is level 1 evidence to support heparin as a flush solution once the time frame exceeds 48 hours. In addition, there is level 1 evidence to suggest that heparin at higher doses and in continuous infusion has better patency incidence with no reports of HIT type II or I.	The study suggests that switching from manually filled to pre-filled syringes for flushing and locking of TIVADs reduces the incidence of CRBSI. This finding, together with other possible advantages such as improved nursing work flow and reduced nursing time, needs to be confirmed by randomized controlled trial	Based on the results of this meta-analysis, HS is not superior to NS in reducing CVCs occlusion. But in the short term, the use of HS is slightly superior to NS for flushing catheters from a statistical point of view.
Journal Name	J Vasc Access	Journal of Hospital Infection	Critical Care

Table 1

Studies examining the Benefits of Normal Saline flushes solutions for HD Catheters



Date of Publication	2013	2012	2012
First Author	Hadaway ⁷	Bertoglio ⁸	Celetti ⁹
Study Name	Flushing vascular access catheters: Risks for infection transmission	Efficacy of normal saline versus heparinized saline solution for locking catheters of totally implantable long-term central vascular access devices in adult cancer patients	Taste and/or Odour Disturbances in Pediatric Patients Undergoing IV Flush with Normal Saline Administered by Prefilled Syringe.
Method	In her article, Ms. Hadaway discusses infection prevention techniques, including proper catheter flushing techniques with single-use flushing containers, adequate cleaning of the needleless surface before each connection, and careful attention to hand hygiene	This is a retrospective observational cohort study of 610 implanted ports receiving 2 different locking solutions conducted at the National Institute for Cancer Research, IST Genova, Italy, from January 2007 to August 2009. Group A (n = 297) received heparinized solution (10 mL/500 U heparin), whereas group B (n = 313), 10 mL normal saline. Primary endpoint was irreversible port occlusion. Minimum follow-up was 12 months. The role of age, type of tumor, disease stage, access site, access body side, catheter tip position, and concomitant use of parenteral nutrition and chemotherapy was evaluated in secondary aim	Inpatients aged 5–18 years who had undergone routine flushing of central or peripheral IV tubing with commercially available prefilled NS syringes were interviewed. Children aged 5–10 years used a visual hedonic scale to rate taste and odour sensations, and those aged 11–18 years used a numeric rating scale
Results	Current recommendations, guidelines, and national standards of practice strongly favor the use of single-dose containers for flush solutions.	Results fail to show statistically significant differences in implanted ports survival free from failure for occlusive events between the use of heparinized solution and that of normal saline for the maintenance of port patency, both in univariate (P = .9) and in multivariate analyses (P = .7).	Taste and/or odour disturbances were reported by 76 (73%) of the patients. Twelve patients described more than one taste or odour sensation. Taste and odour disturbances were detected by children in both age groups
Conclusions	When all aspects are considered, catheter flushing is much more than injecting some fluid through the catheter lumen. Clinical outcomes depend upon the entire system working together. The flushing technique must match the needleless injection system design, yet many times the bedside nurse does not know what type of needleless device is being used. All brands look similar, and it is very hard to distinguish the types because they are not labeled by their fluid-displacement characteristics. Changing the type of needleless system may not produce the desired catheter patency if the syringe design is not considered. needleless surface	Normal saline solution seems to be as effective as heparinized solution for keeping patent implanted ports in adult cancer patients.	Flushing of IV tubing with prefilled NS syringes resulted in taste and/or odour disturbances in a pediatric population
Journal Name	Infection Control Resource	Cancer nurses.	Canadian Journal Hospital Pharm.

Table 1 | Studies examining the Benefits of Normal Saline flushes solutions for HD Catheters



Date of Publication	2012	2010	2010
First Author	Wang ¹⁰	Hadaway ¹¹	Kongsgaard ¹²
Study Name	Preservative-free 0.9% sodium chloride for flushing and locking peripheral intravenous access device: a prospective controlled trial	Misuse of prefilled flush syringes Implications for medication errors and contamination	Experience of unpleasant sensations in the mouth after injection of saline from prefilled syringes
Method	Prospective controlled trial to compare the effectiveness and safety of preservative-free 0.9% sodium chloride solution versus heparin saline solution as flushing and locking solution for peripheral intravenous access devices	In her article Ms. Hadaway discusses these inappropriate uses that could put patients at risk for serious complications.	A randomised, blinded, crossover study comparing commercial available prefilled saline 9 mg/ml syringes to saline 9 mg/ml for injection in polyethylene package was performed in 10 healthy volunteers. The volunteers were given intravenous injections of varying volume and speed. Data were analysed using descriptive statistics, and also Wilcoxon Signed Rank Test to compare groups.
Results	Totally, 181 and 178 peripheral intravenous access devices in the sodium chloride solution and heparin saline solution groups were included and analyzed. Results indicated that sodium chloride solution did not increase the risks of occlusion (7.7% vs. 7.9%) and other adverse events of peripheral intravenous access devices (P = 0.163). Sodium chloride solution neither shortened the duration of peripheral intravenous access devices maintenance (3.6 ± 1.1 days vs. 3.7 ± 1.2 days, P = 0.651), nor increased the proportion of abnormal withdrawal (29.3% vs. 31.5%, P = 0.654)	One critical factor for transmission of a Micro-organism from a patient or healthcare worker to the environment and then to another person is the ability of that microbe to survive on that environmental surface. If the Micro-organism dies on the surface, then the transfer cannot occur	After intravenous injection, 2 of 15 recordings demonstrated any sensation of smell or taste after injection of saline from polyethylene package, while 14 of 15 recordings noted a sensation after injection of saline from prefilled syringes. The intensity of the unpleasant sensation was rated significantly higher after injection of saline from prefilled syringes compared to saline from polyethylene (p = 0.001).
Conclusions	Sodium chloride solution is as effective and safe as conventional heparin saline solution for flushing and locking peripheral intravenous access devices	Some microbes can survive on surfaces for long times. These environmental surfaces can be involved in the transfer of microorganisms to patients and subsequently in the development of hospital-associated infections. Following the suggestions above to reduce microbial transfer will help to protect you, your patients, your fellow HCWs, and your family.	Injection of saline from prefilled syringes in healthy volunteers resulted in an experience of bad taste or smell. It is important that nurses and health workers are aware of the phenomenon as described in this article in order to choose the preferred product for a given patient.
Journal Name	Journal of Evidence Based Med.	Infection Control Resource	BMC Nursing

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