

# Verantwoording literatuuronderzoek

## Module Bewaarcondities van parenterale medicatie

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## Uitgangsvraag

Onder welke omstandigheden dienen aangebroken flacons, infuuszakken en voor toediening gereedgemaakte medicatie bewaard te worden?

## Methode

### Onderzoeksvraag

A systematic review of the literature was performed to answer the following question:  
What is the effect of storage conditions of prepared parenteral medication on healthcare related infections and contamination of the product?

P	Prepared parenteral medication
I	Storing with needle: with (different types of) caps, open system
C	Storing with needle: without (different types of) caps, closed system
O	Healthcare related infections, contamination of the product

### Relevant outcome measures

The guideline development group considered healthcare related infections and contamination of the product as critical outcome measures for decision making.

A priori, the working group did not define the health care related infection and contamination but used the definitions used in the studies.

The working group defined a 25% difference for dichotomous outcomes (RR < 0.8 or > 1.25), and 10% for continuous outcomes as a minimal clinically (patient) important difference.

### Search and select (Methods)

The databases Medline (via OVID), Embase (via [embase.com](http://embase.com)(externe link)) and CINAHL were searched with relevant search terms until 5-12-2022. The detailed search strategy is available upon reasonable request via [info@sri-richtlijnen.nl](mailto:info@sri-richtlijnen.nl). The systematic literature search resulted in 493 hits. Studies were selected based on the following criteria: systematic review, trial or observational study, adhering to our PICO. 28 studies were initially selected based on title and abstract screening. After reading the full text, all studies were excluded.

### Results

No studies met the inclusion criteria and were excluded in the analysis of the literature.

### Conclusions

No GRADE	Because of the absence of events, no conclusions could be drawn about the effect of storage conditions on the prevalence of healthcare related infections or contamination. Source: -
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Bijlage bij Richtlijn SRI Toediening medicatie in de langdurige zorg ([www.richtlijnenlangdurigezorg.nl](http://www.richtlijnenlangdurigezorg.nl))

## Referenties

Alharbi M. Review of sterility of reused stored dermal filler. J Cosmet Dermatol. 2019 Oct;18(5):1202-1205. doi: 10.1111/jocd.12932. Epub 2019 Apr 9. PMID: 30964239.

Bawden JC, Jacobson JA, Jackson JC, Anderson RK, Burke JP. Sterility and use patterns of multiple-dose vials. Am J Hosp Pharm. 1982 Feb;39(2):294-7. PMID: 6800255.

Das T, Volety S, Ahsan SM, Thakur AK, Sharma S, Padhi TR, Basu S, Rao ChM. Safety, sterility and stability of direct-from-vial multiple dosing intravitreal injection of bevacizumab. Clin Exp Ophthalmol. 2015 Jul;43(5):466-73. doi: 10.1111/ceo.12489. Epub 2015 Apr 14. PMID: 25545882.

Dolan SA, Arias KM, Felizardo G, Barnes S, Kraska S, Patrick M, Bumsted A. APIC position paper: Safe injection, infusion, and medication vial practices in health care. Am J Infect Control. 2016 Jul 1;44(7):750-7. doi: 10.1016/j.ajic.2016.02.033. Epub 2016 May 13. PMID: 27184207.

McNeil MM, Lasker BA, Lott TJ, Jarvis WR. Postsurgical Candida albicans infections associated with an extrinsically contaminated intravenous anesthetic agent. J Clin Microbiol. 1999 May;37(5):1398-403. doi: 10.1128/JCM.37.5.1398-1403.1999. PMID: 10203494; PMCID: PMC84784.

Nederlandse vereniging van ziekenhuisapothekers (NVZA(Nederlandse Vereniging van Ziekenhuisapothekers)). GMP-ziekenhuisfarmacie, hoofdstuk Z3 Aseptische handelingen 2022.

Ornek K, Karahan ZC, Ergin A, Tekeli A, Tekeli O. Bevacizumab sterility in multiple doses from a single-use vial. Ann Pharmacother. 2008 Oct;42(10):1425-8. doi: 10.1345/aph.1L270. Epub 2008 Sep 2. PMID: 18765834.

[RICHTLIJN 2010/32/EU VAN DE RAAD van 10 mei 2010: tot uitvoering van de door HOSPEEM en EPSU gesloten kaderovereenkomst inzake de preventie van scherpe letsels in de ziekenhuis- en gezondheidszorgbranche\(externe link\)](#)

Rueangchira-Urai R, Rujirojindakul P, Geater AF, McNeil E. Bacterial Contamination of Anaesthetic and Vasopressor Drugs in the Operating Theatres: Ameliyathanelerde Anestetik ve Vazopressör İlaçların Bakteriyel Kontaminasyonu. Turk J Anaesthesiol Reanim. 2017 Feb;45(1):47-52. doi: 10.5152/TJAR.2017.21703. Epub 2017 Feb 1. PMID: 28377840; PMCID: PMC5367725.

Stucki C, Sautter AM, Favet J, Bonnabry P. Microbial contamination of syringes during preparation: the direct influence of environmental cleanliness and risk manipulations on **Bijlage bij Richtlijn SRI Toediening medicatie in de langdurige zorg** ([www.richtlijnenlangdurigezorg.nl](http://www.richtlijnenlangdurigezorg.nl))

end-product quality. Am J Health Syst Pharm. 2009 Nov 15;66(22):2032-6. doi: 10.2146/ajhp070681. PMID: 19890087.

Weinbacher FM, Littlejohn CE, Conley PF. Growth of bacteria in prefilled syringes stored in home refrigerators. Appl Nurs Res. 1990 May;3(2):63-7. doi: 10.1016/s0897-1897(05)80160-0. PMID: 2192687.

V&VN(Verpleegkundigen en Verzorgenden Nederland ), Handreiking Voor Toediening Gereed Maken (VTGM) van geneesmiddelen, 2022.

#### Excusie-tabel

Reference	Reason for exclusion
Alam, M. and Yoo, S. S. and Wrone, D. A. and White, L. E. and Kim, J. Y. S. Sterility assessment of multiple use botulinum A exotoxin vials: A prospective simulation. Journal of the American Academy of Dermatology. 2006; 55 (2) :272-275	No comparison
Alessandro Rigotti, Marcelo and Menis Ferreira, Adriano and de Andrade, Denise and Watanabe, Evandro DISINFECTION OF AMPULES FOR INTRAVENOUS ADMINISTRATION: AN INTEGRATIVE REVIEW. Journal of Nursing UFPE / Revista de Enfermagem UFPE. 2013; 7 (7) :4899-4909	Wrong publication type (integrative review)
Alharbi, M. Review of sterility of reused stored dermal filler. Journal of Cosmetic Dermatology. 2019; 18 (5) :1202-1205	No comparison
André, P. and Cisternino, S. and Chiadmi, F. and Toledano, A. and Schlatter, J. and Fain, O. and Fontan, J. Stability of bortezomib 1-mg/ml solution in plastic syringe and glass vial. Annals of Pharmacotherapy. 2005; 39 (9) :1462-1466	Wrong outcome (chemical stability)
Baker J, Dickman A, Mason S, Ellershaw J. The current evidence base for the feasibility of 48-hour continuous subcutaneous infusions (CSCIs): A systematically-structured review. PLoS One. 2018 Mar 14;13(3):e0194236. doi: 10.1371/journal.pone.0194236. PMID: 29538455; PMCID: PMC5851608.	Wrong outcome (administration of drugs)
Denholm, Bonnie and Spruce, Lisa Clinical Issues. AORN Journal. 2015; 101 (3) :379-386	Wrong publication type (no research article)
Diggle, Jane HOW TO SUPPORT BEST PRACTICE INJECTION TECHNIQUE. Diabetes & Primary Care. 2019; 21 (4) :123-124	Wrong publication type (no research article)
Driver Jr, R. P. and Snyder, I. S. and North, F. P. and Fife, T. J. Sterility of anesthetic and resuscitative drug syringes used in the	No comparison

obstetric operating room. Anesthesia and Analgesia. 1998; 86 (5) :994-997	
Driver, R. P., Jr. and Brula, J. M. and Bezouska, C. A. The stability of atropine sulfate solutions stored in plastic syringes in the operating room. Anesthesia and analgesia. 1999; 89 (4) :1056-8	Wrong publication type (technical communication)
Husna, Muftihatul and Munawiroh, Siti Z. and Ekawati, Ratna Puji and Hanifah, Suci Systematic review of the stability and compatibility of propofol injection. Anaesthesiology Intensive Therapy. 2021; 53 (1) :79-88	Wrong outcome (chemical stability)
King, L. Continuing professional development: injection management. Subcutaneous insulin injection technique. Nursing Standard. 2003; 17 (34) :45-55	wrong publication type (no research article)
Milla, Paola and Viterbo, Maria Luisa and Mosca, Sabino and Arpicco, Silvia Chemical and microbiological stability, anticoagulant efficacy and toxicity of 35 and 90 mM trisodium citrate solutions stored in plastic syringes. European journal of hospital pharmacy : science and practice. 2018; 25 :e83-e87	No comparison
Moran, Katherine and Burson, Rosanne Insulin. Home Healthcare Nurse. 2014; 32 (6) :372-372	Wrong publication type (no research article)
Örnek, K. and Karahan, Z. C. and Ergin, A. and Tekeli, A. and Tekeli, O. Bevacizumab sterility in multiple doses from a single-use vial. Annals of Pharmacotherapy. 2008; 42 (10) :1425-1428	Wrong outcome (single use vials multiple use)
Parish HG, Morton JR, Brown JC. A systematic review of epinephrine stability and sterility with storage in a syringe. Allergy Asthma Clin Immunol. 2019 Feb 21;15:7. doi: 10.1186/s13223-019-0324-7. PMID: 30828350; PMCID: PMC6383228.	Wrong outcome (chemical stability)
Pearce, Lynne Diabetes: preparation of insulin syringes for home use. Primary Health Care. 2021; 31 (3) :9-9	Wrong intervention (preparation)
Puertos, E. Extended stability of intravenous 0.9% sodium chloride solution after prolonged heating or cooling. Hospital Pharmacy. 2014; 49 (3) :269-272	Wrong outcome (chemical stability)
Q & A... resheath needles... wash and store equipment dry. Nursing Times. 1990; 86 (13) :75-75	Wrong publication type (no research article)
Reid, Anna Changing practice for safe insulin administration. Nursing Times. 2012; 108 (10) :22-26	Wrong study design (survey)

Ripoll Gallardo, A. and Meneghetti, G. and Ragazzoni, L. and Kroumova, V. and Ferrante, D. and Ingrassia, P. L. and Ruzza, P. and Dell'Era, A. and Boniolo, E. and Koraje, G. and Faggiano, F. and Della Corte, F. Multiple withdrawals from single-use vials: A study on sterility. <i>International Journal of Pharmaceutics</i> . 2015; 485 (1) :160-163	Wrong comparison (single use vials for multiple use)
Shah, Harsh S. and Rubin, Rochelle F. and Lakhwani, Gargi R. and DiGregorio, Robert and Dave, Rutesh H. Stability of Insulin Detemir Injection in Different Primary Packaging Systems at Room Temperature. <i>Journal of Pharmacy Practice</i> . 2021; 32 (2) :253-258	Wrong outcome (chemical stability)
Stone, J. P. and Fenner, L. B. and Christmas, T. R. The preparation and storage of anaesthetic drugs for obstetric emergencies: a survey of UK practice. <i>International journal of obstetric anaesthesia</i> . 2009; 18 (3) :242-8	Wrong study design (survey)
Syringe and needle storage units. <i>Nursing Times</i> . 1978; 74 :64-64	Article not found
Takagi, J. and Khalidi, N. and Wolk, R. A. and Tjolsen, E. and de Leon, R. and Wesley, J. R. Sterility of total parenteral nutrient solutions stored at room temperature for seven days. <i>American journal of hospital pharmacy</i> . 1989; 46 (5) :973-977	No comparison
Trissel, L. A. and Spadoni, V. T. Comment: filgrastim sterility in syringes. <i>Annals of Pharmacotherapy</i> . 1997; 31 :500-501	Wrong publication type (comment)
Wagner, D. S. and Naughton, N. N. and Pierson, C. and Michel, T. Potency and sterility of anesthetic drugs in obstetric anesthesia. <i>International Journal of Obstetric Anesthesia</i> . 2002; 11 (4) :252-254	No comparison
Weinbacher, F. M. and Littlejohn, C. E. and Conley, P. F. Growth of bacteria in prefilled syringes stored in home refrigerators. <i>Applied Nursing Research</i> . 1990; 3 (2) :63-67	Wrong setting (homes)
Yoon, Seung-Yil and Sagi, Hemi and Goldhammer, Craig and Li, Lei Mass extraction container closure integrity physical testing method development for parenteral container closure systems. <i>PDA journal of pharmaceutical science and technology</i> . 2012; 66 (5) :403-19	Wrong outcome (performance of mass extraction system)