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Parenteral products: in-use shelf life after preparation on the ward

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What was done?

A practical framework for the determination of retention time of manipulated parenteral medication was developed, as economic and ecological perspectives stand in contrast to the hygienic ideal.

Why was it done?

The preparation of parenteral medication on wards poses a hygienic challenge. The bioburden of non-preserved parenteral medications after manipulation depends on the setting. Therefore, manufacturers cannot provide guidelines on microbial stability after manipulation and hence limit the retention period to use. National recommendations concerning this issue range from cautious to restrictive, but often allow exceptions e.g. for emergency medication [1, 2]. These recommendations are difficult to implement universally due to the non-transferable framework conditions from one hospital to another.

What has been achieved?

Cornerstones for the assessment of microbial stability of in-use parenteral drugs were identified that enable an assessment to adapt to individual clinical setting.

Categories	Parameters	Effect on Stability
Primary Packaging	Infusion Bags	↑
	Vials	↓
	Ampoules	↓↓
Type and Complexity of Manipulation	No Manipulation	↑↑
	Withdrawal	↑
	Reconstitution	↓
	Mixture	↓↓
Physico-Chemical Properties	Water-Based	↑
	Lipid-Based	↓
Storage Temperature	Refrigerator	↑
	Room Temperature	↓

Table 1: Cornerstones and their general effect on microbial stability

These parameters influence the retention period in which the parenteral medication may be safely used and are strongly influenced by one another. Therefore the microbial stability should not be assessed solely on one parameter, but all of the mentioned factors should be considered.

How was it done?

International recommendations were sighted. Recommendations of the German Commission for Hospital Hygiene and Infection Prevention, as well as the American Society of Anesthesiologists and The Society for Healthcare Epidemiology of America were used as references, as well as stated sources.

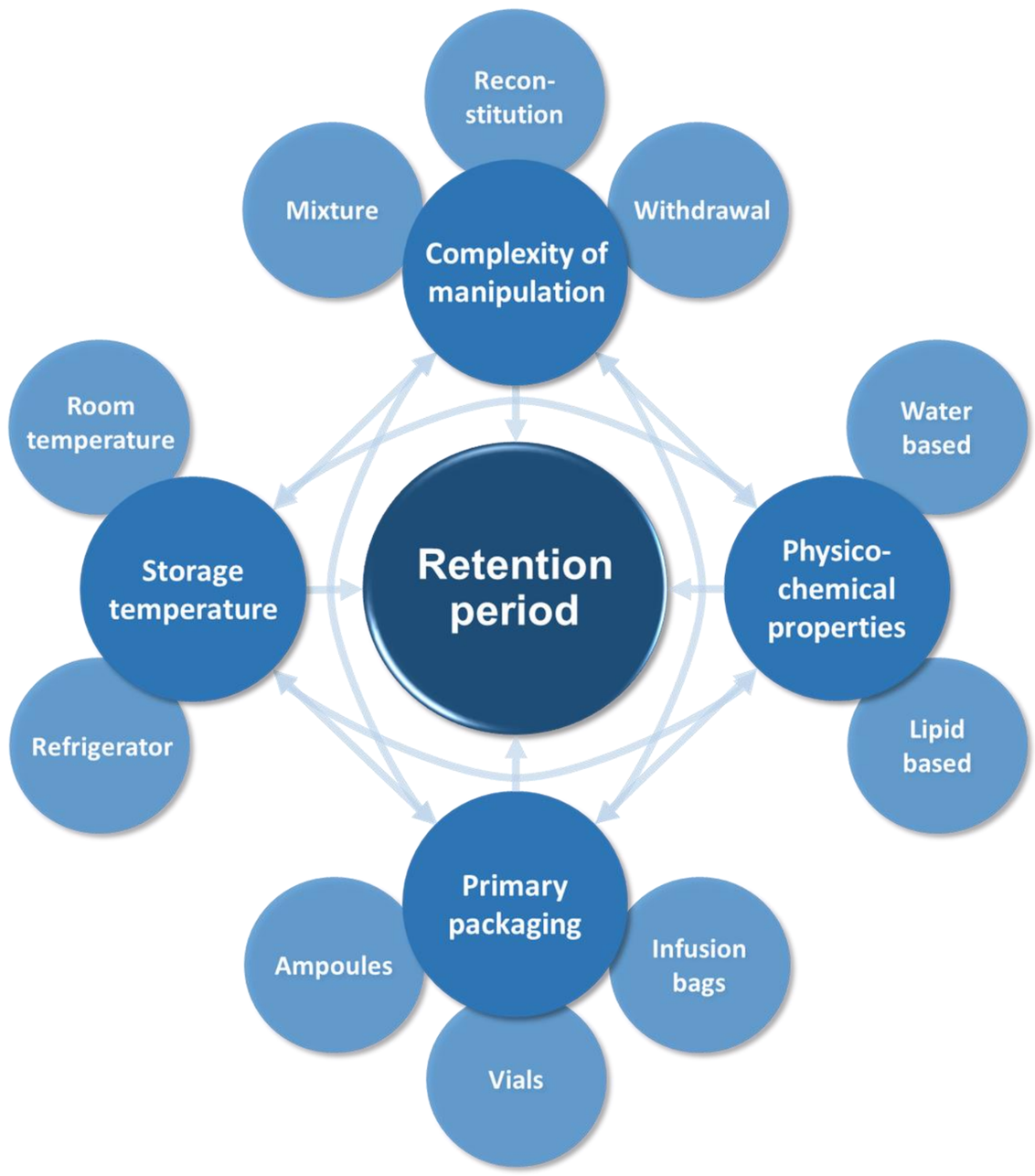

Figure 1: Influence factors have on another and therefore on microbial stability

What's next?

A collaboration with the Department of Infectious Diseases and Hospital Epidemiology of the University Hospital of Zurich was established to record the hospital specific conditions and to subsequently adapt the clinical practice and evaluate patient safety, cost-effectiveness and ecological impact.
Further collaborations with Swiss hospitals are being sought.

1. Anforderungen an die Hygiene bei Punktionen und Injektionen. Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz, 2011. 54(9): p. 1135-1144.
2. Koch-Institut, R., Zu spezifischen Fragen bezüglich Rekonstitution, Zubereitung und Applikation von Arzneimitteln und Infusionslösungen sowie zur Hautantiseptik. 2016, Robert Koch-Institut, Epidemiologie und Gesundheitsberichterstattung.