How should insulin preparations and insulin pens be stored?

27 November 2021



How should insulin preparations, insulin pens and pre-drawn syringe be stored?

Storage of insulin	**Insulin should be stored according to the manufacturer's instructions.[2,30]**	**IIIA**

How should insulin preparations, insulin pens and pre-drawn syringe be stored?

Insulin pen/ pre-filled syringe	1. Pre-filled syringes of single formulation (except Lantus) should be stored in refrigerator at 2 to 8°C at the most 28 days. [2,65,78]	IIIB
	2. Insulin glargine should not be mixed with other forms of insulin.[2,30]	IIIA

How should insulin preparations, insulin pens and pre-drawn syringe be stored?

Insulin pen/ pre-filled syringe	1. The practice of pre-loading insulin in the syringe is not recommended.	IIIB
	2. Insulin glargine and determir should not be mixed with other forms of insulin.	IIIA
	3. Insulin should not extracted from pen devices or penfill.	IIIB

The practice of pre-loading insulin in the syringe is not recommended

#66
Advances preparation of insulin syringes for adult patients to administer at home: Guidance for nurses
2018 3rd Ed. RCN



Replaced & Withdrew

- This guidance has been updated and replaces previous guidance in 2006 [1] and 2015 [2]
- "The RCN **withdrew** its guidelines *Advanced preparation of insulin syringes for patients to administer at home* (2006) in 2012 because it did not address all the legal issues and was declared not fit for purpose" (Rosindale, 2014).
- there are no national guidelines currently in place to support this practice (Rosindale, 2014).

(1) RCN. Advances preparation of insulin syringes for patients to administer at home: RNC guidance of community nurses. 2006
(2) RCN. Advances preparation of insulin syringes for adult patients to administer at home: Guidance for nurses. 2nd Ed. 2015



Royal College of Nursing

Advanced Preparation of Insulin Syringes for Adult Patients to Administer at Home

Guidance for nurses

Third edition

CLINICAL PROFESSIONAL RESOURCE



2018

Royal College of Nursing

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2015

The practice of pre-loading insulin in the syringe is not recommended

RCN believes

- the practice of pre-loading insulin syringes should only be considered when all other options to enable patients to self-manage have been **exhausted**

RCN recommends

- for their own legal protection, nurses must operate within the requirements of a **local policy/protocol** for the pre-loading of insulin syringes for patients to administer at home
- The pre-loading of insulin syringes should only be undertaken by **registered nurses**

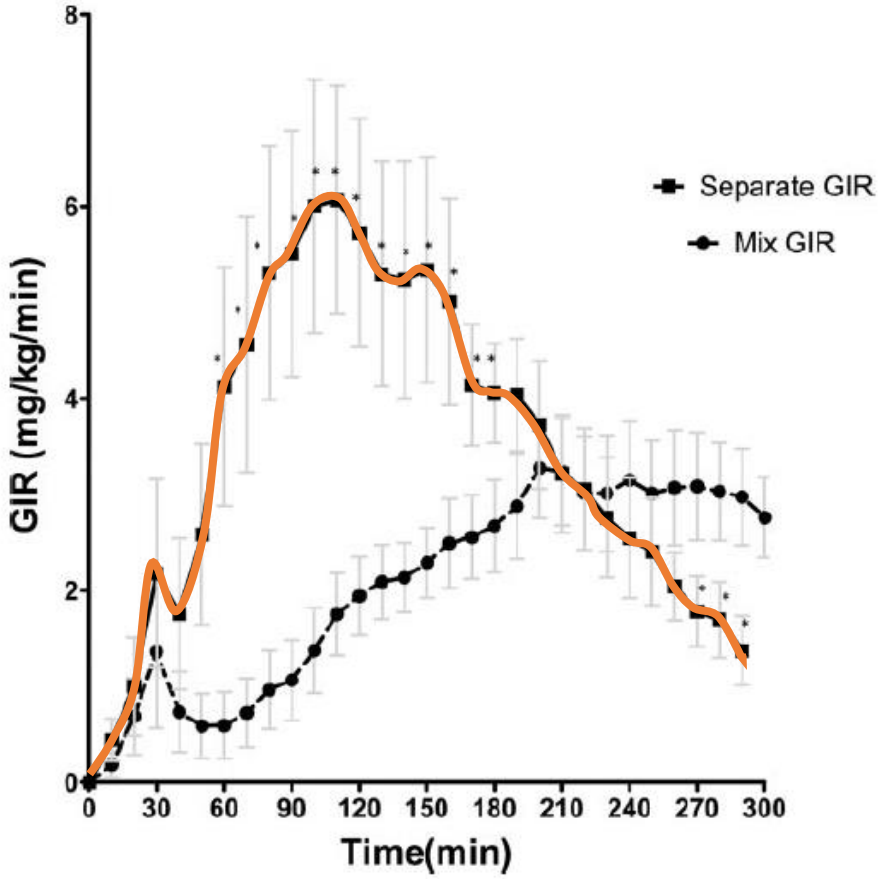
RCN recommends the following:

	**Ensuring that there is an organisation-wide policy in place covering the use of pre-loaded insulin syringes**
	Patients must be assessed and have **full capacity for this practice** to be considered and patient capacity must be routinely and frequently re-assessed (as per local policy).
	A **senior diabetes specialist nurse** (SDSN) must be involved in the initial patient assessment; this risk assessment should be updated on a regular basis (as per local policy).
	**Comprehensive training** on pre-drawn insulin for self-administration must have been undertaken
	A **patient care plan** must be in place
	A **quality assurance plan** must be in place (as per local policy) which is overseen by your local SDSN
	The patient's **GP is aware**, understands and is in agreement that prescribing pre-loaded insulin syringes has associated medical-legal issues, and that there is a policy in place to support this process

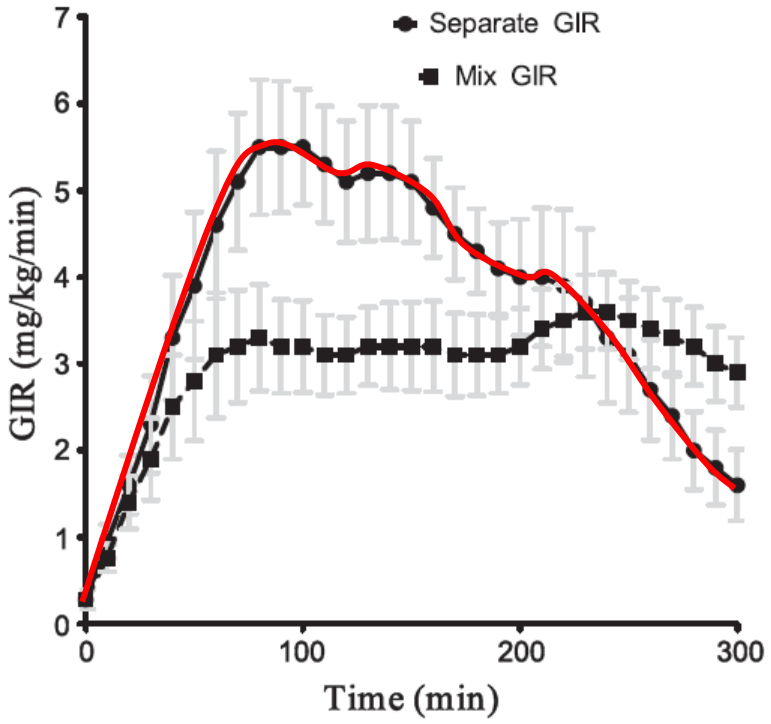
Insulin glargine and detemir should not be mixed with other forms of insulin in the same syringe

Bibliographic Citation	Design	Sample size & characteristics	Intervention	Findings	Limitations	Evidence level and quality
#18 Cengiz E et al, 2010	Crossover, randomize	n= 11 Youth with at least one year diagnosis of type 1 diabetes, age ranging from 11 to 21 years (age 15.1± 3 years, A1c 7.6 ± 0.6%)	• Euglycemic glucose clamps were performed twice, in random order • 0.2 units/kg lispro and 0.4 units/kg glargine, given either as separate or as a single mixed injection	• Significantly lower glucose infusion rate (GIR) values after the mixed injection between 60 and 190 min and significantly higher values between 270 and 300 min, lowered the GIR_{max}, and markedly delayed the time to reach GIR_{max}	The study does not delineate the PKPD of insulin glargine due to the low specificity of this assay for insulin glargine and the confined 5-hr duration of the clamp procedure.	II
#24 Eda C et al, 2012	Crossover, randomize	N= 8 Adolescents with type 1 diabetes (age 17.3±0.6 years and A1c 7.3± 0.3%)	• Two euglycemic glucose clamps during which 0.2 units/kg aspart and 0.4 units/kg detemir insulin were injected either as a separate or single mixed injection in random order	• Mixing the 2 insulins diminished the peak and overall early aspart insulin action with significantly lower maximum glucose infusion rate values and the area under curve for GIR during the first 3hr of the insulin action study	• Small sample size to detect statistically significant differences • Detemir does not reach 50% maximum action until 4-14 h after injection	II

Finding



Significantly lower GIR values after the mixed injections between 60 and 190 min and significantly higher values between 270 and 300 mins. (Cengiz et al, 2010)



For mixed injection, early rise in GIR was blunted, but late insulin action was increased following the mixed compared with separate injections (Eda et al, 2012)

Insulin should not be extracted from pen devices or penfill

Classification: Official

NHS Improvement



Patient Safety Alert

Risk of severe harm and death due to withdrawing insulin from pen devices

16 November 2016

Alert reference number: NHS/PSA/W/2016/011

Warning Alert

Pen-shaped devices are commonly used by patients for subcutaneously injecting insulin. Compared to insulin syringes, the use of these devices has increased as they make it easier for patients to self-inject.

Although the strength of insulin was previously standardised at 100 units/mL, this can vary in pen devices, currently by multiples of 100 units/mL. Pen devices

Actions

Who: All organisations providing NHS-funded care where insulin is prescribed, dispensed or administered



NHS Improvement

Patient Safety Alert issued by NHS Improvement on 16 Nov 2016

"… If insulin extracted from a pen or cartridge is of higher strength, and that is not considered in determining the volume required, it can lead to a significant and potentially fatal overdose…."

"… extracting insulin from pen devices or cartridges is dangerous and should not happen. Organizations should ensure staff are **trained and competent** in using insulin pens … Staff, … should be routinely provided with **safety needles** and access to equipment capable of **safely removing and disposing** of used insulin pen needles…"



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Medication Safety Bulletin

The Medication Safety Bulletin (MSB) is published by the Medication Safety Committee HAHO (MSC) biannually (May and Nov) as an educational publication to share issues related to medication safety. Please refer to the HA Risk Alert (HARA) for sharing of medication incident cases reported in HA.

Parenteral medications with different concentrations



For oral medications, there are many examples of preparations of same medications, with multiple strengths available. For example, amlodipine, a calcium channel blocker, could be available in HA institutions as 5mg and 10mg tablets. For parenteral medications, the situation could be more complicated when there are preparations with multiple concentrations, where potential risk would be imposed.

Case: 3-fold of prescribed dose of penfill insulin was administered to an in-patient

- Patient was admitted for poor Diabetes control
- Patient's own insulin preparation was brought by relatives for administration
- The medication was drawn from the prefilled insulin pen device into an ordinary insulin syringe after checked by two nurses and administered to patient
- One day later, it was found that the concentration of the prefilled insulin preparation was **300 units/mL instead of 100 units/mL** *(Note: Currently, all insulin preparations in HA Drug Formulary are 100 units/mL)*
- The dose administered to patient was 3-fold of the prescribed dose

Points to consider The design of prefilled insulin pen devices (penfill cartridge or prefilled pen) is not intended for direct extraction of insulin by insulin syringe. The penfill device's mechanism could be damaged by such practice, which may result to inaccurate dosing in future use. Also, while there are insulin preparations with different concentrations available, the drug concentration on the label should be checked before administration.



Insulin pen needles

To ensure a safe and proper use of insulin pen preparations, the pen devices should be used directly for administration, with the aid of appropriate insulin pen needle.



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Advice sought

Thank you