Lincolnshire Community Health Services
NHS Trust

Policy for the pre-loading of insulin syringes for patients to administer at home

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Version Control Sheet

Version	Section / Para / Appendix	Version / Description of Amendments	Date	Author / Amended by
1	New policy	This policy replaces Policy G_CS_89 Guidance and Procedures for Pre Filling Insulin Syringes.	30th January 2020	The Diabetic Specialist Nurse Team
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1. Introduction

1.1 This policy is supported by a risk assessment and standard operating procedure (SOP) for the pre-loading of insulin for patients to self-administer later. It stresses the necessary principles of practice including patient assessment and review, ensures other methods of insulin administration have been considered, together with contra-indications, and details appropriate insulin storage requirements and record keeping.

1.2 Diabetes mellitus is a chronic condition. Patients require long-term medication to control blood glucose levels and reduce the risk of associated complications. For some patients the prescribed treatment is regular insulin injections.

1.3 There are a number of patients with diabetes who cannot convert to using an insulin pen for independent self-administration of insulin because of manual dexterity, lack of strength, personal preference or reluctance to change. As a result many patients are unable to draw up their own insulin and need community nurse support, although they are able to inject independently using a syringe once or twice a day. The preparation of insulin injections by community nurses for patients to administer in their own homes at a later time has been the practice for many years. In this way, each patient can administer their insulin at the correct time in relation to their meals. This preserves the individual's independence (Rosindale, 2014).

1.4 The pre-loading of insulin into syringes is an unlicensed activity that falls outside of the Medicines Act (Rosindale, 2014) and adherence to this policy protects the patient, and provides legal protection for the registered nurse and this organisation under vicarious liability. The Royal College of Nursing (RCN, 2015) advises that this activity must be seen as the final option, and only considered when all other options have been exhausted.

1.5 Within the context of this policy the definition of pre-loading an insulin syringe refers to insulin that has been withdrawn from a 10ml vial, using an insulin syringe that is marked in one or two unit graduations. It is recommended that 8mm needles be used when using an insulin syringe.

1.6 No other type of syringe should ever be used for insulin administration.

2. Summary of professional issues

The act of pre-loading an insulin syringe is considered a form of secondary dispensing which is not covered by the terms of the Medicines Act (1968). In essence, the act of pre-loading an insulin syringe creates an unlicensed product.

This is an important legal consideration that needs to be taken into account by health care professionals and employers. If something were to go wrong, it is the nurse who prepares a pre-loaded insulin syringe outside the bounds of the Medicines Act that would be liable (Rosindale, 2014).

A second key consideration relates to the lapse of time between preparation of the syringe and its administration by an individual with diabetes. The Nursing and Midwifery Council (NMC, 2010) advises registrants “must not prepare substances in advance of their immediate use” and that the dispensing of drugs should include: Anecdotally, the practice of pre-loading insulin syringes for people with diabetes to administer themselves has taken place satisfactorily for decades. However, there are no national guidelines currently in place to support this practice (Rosindale, 2014).

- Checking the validity of the prescription.
- The appropriateness of the medicine for an individual patient.
- The assembly of the product and labelling in accordance with legal requirements.
- The provision of information leaflets for patients.

These points have significant implications for community nurses. While the pre-loading of insulin syringes is considered to be common practice, ultimately, it is the nurse who is professionally accountable for this action.

For this reason the RCN recommends that, 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. Therefore, a local policy must be in place to ensure that nurses benefit from vicarious liability, in which the employer takes full responsibility for the safety of this activity.

The pre-loading of insulin syringes should only be undertaken by registered nurses; this activity cannot be devolved to health care assistants.

3. Statement/objective

1. To promote patient safety.
2. To ensure that registered nurses (RNs) are aware of the potential risks of pre-loading insulin syringes for later use by a patient.
3. To provide a clear and consistent framework across Lincolnshire Community Health Trust for the appropriate assessment and management of a person with diabetes who cannot safely prepare their own insulin dose.
4. The Nursing & Midwifery Council (NMC) Standards for medicines management 14 (2010a) state that 'registrants must not prepare substances for injection in advance of their immediate use'. The Department of Health (DH)/Medicines & Healthcare Products Regulatory Agency (MHRA) advise 'against pre-loading medication for injection at a later time' (Rosindale, 2014).
5. To support RNs to provide insulin therapy as detailed in this policy which is classified as secondary dispensing (and thus not covered in the Medicines Act 1968) however, takes note of RCN guidance Advance preparation of insulin syringes for adult patients to administer at home (RCN, 2015).
6. The National Patient Safety Agency (NPSA) 'are unaware of any reports where insulin syringes prepared in advance by nurses in the community and given expiry dates of greater than 24 hours have caused serious harm due to infection and contamination issues' (Rosindale, 2014). However, a Rapid Response Report has been issued for the safer prescribing and administration of insulin (2010).

4. Roles and responsibilities

1. This policy covers all RNs employed by Lincolnshire Community Health Services NHS Trust who are required to treat patients with diabetes mellitus within their own home.
2. It relates specifically to the patient who is able to safely administer the correct dose of insulin at the correct time, but is unable to draw up insulin or utilise standard commercially available insulin preparations.
3. It is the responsibility of every trust employed RN who is required to treat patients with diabetes mellitus to be familiar with this policy and procedure.
4. RN to positively identify the patient (by obtaining confirmation of name and DOB) and establish allergy status.

5. RNs involved in the administration of insulin, as in all other areas of their practice, will be responsible for maintaining and updating their knowledge and practice. The e-learning module on the ‘Six steps to insulin safety’ available here:
6. https://www.diabetesonthenet.com/course/the-six-steps-to-insulin-safety/details.
7. RNs are responsible for the initial and continued assessment of patients who are self-administering and have continued responsibility for recognising and acting upon changes in a patient’s condition with regards to safety of the patient and others. The Nursing and Midwifery Council (NMC) and Mental Capacity Act 2005 state that for a patient to be able to self-administer, the patient should be assessed as being at Level 3 which is defined: “the patient accepts full responsibility for the storage and administration of the medicinal products”. The level should be documented in the patient’s records (Standard 9 NMC, 2010a).
8. Patients must be allowed to decide whether they will agree to treatment in this way and this should be documented in the patient case notes.
9. RNs in administering any medicines, in assisting with administration, or in overseeing any self-administration must assess the patient’s suitability and understanding of how to use an appropriate compliance aid safely (Standard 16 NMC, 2010a).
10. RNs are accountable to ensure that the patient is competent to carry out the task (Standard 17 NMC, 2010a).
11. RNs are responsible for implementing this policy. Pre-loading insulin syringes must not be delegated to non-registered staff.
12. Pre-loaded syringes may not be prepared by one registered nurse for another health professional or skilled professional that is not registered to administer them.
13. Under no circumstances may RNs mix and pre-load different insulins in the same syringe for administration at a later time (there is no longer a need to mix insulins due to the availability of suitable manufacturer’s preparations).
14. Registered nurses are responsible for recognising any limitations in their knowledge and competence and declining any duties they do not feel able to perform in a skilled and safe manner (NMC, 2015).

5. Principles of practice for the pre-loading of insulin in syringes

1. Pre-loading of insulin should only be recommended when alternative methods of delivery are not possible and after appropriate risk assessment, as outlined in Appendices 2-4.
2. RNs should be aware of the alternative injection devices available and discuss the patient's needs and preferred options with the diabetes specialist nurse (DSN) and general practitioner.
3. Pre-loading of insulin for injection must only begin following a full written risk assessment, in discussion with DSN, and the ruling out of alternative methods of administration. A thorough assessment of the patients understanding of the insulin regime, their ability to manage it and the support available between community nurse visits, must be undertaken using Appendix B (Standard operating procedure (SOP)) for the assessment of a patient to have insulin prepared in advance of administration. This should be followed by completion of Appendix C (Risk assessment form – advanced preparation of insulin into syringes for a patient to administer at a later date).
4. The risk assessment form in Appendix C should be undertaken every three months, or sooner if the patient's condition changes.
5. The patient should always be consulted about their insulin administration and informed consent obtained regarding the care provided.
6. On completion of the risk assessment the RN should decide on the appropriate number of days that the insulin syringes can be prepared for and left with the patient. It is important that the RN considers all aspects of social and health care for their patient in this decision. This number and the reason for the decision should be recorded in Appendix C. The maximum number of days that insulin syringes can be left pre-loaded is seven (RCN, 2015; Rosindale, 2014). Advice may be sought from the DSN. Each time a nurse pre-loads a syringe, Appendix D (Documentation form for the advanced preparation of insulin in syringes) should be completed.
7. Pre-loaded insulin syringes must be labelled individually and stored in a wipeable, labelled, sealable, hinge-lidded container (see Appendix B). If the patient is having a different type of insulin or dose at another time of the day a different storage container should be used. To prevent any confusion the containers should be either different colors or shapes.

8. The patient's fridge should be visibly clean and free of debris. The insulin should be stored in the fridge door or top shelf to prevent cross-contamination from other food items.
9. It is recommended that insulin is most stable when stored at a temperature of between 2 and 8° Celsius. Never allow insulin to freeze.
10. Unopened insulin can be kept in these conditions until the expiry date. An opened vial of insulin kept in these conditions should be discarded after 28 days. The date that the vial was opened must be written on the vial and in Appendix D.
11. Patients in residential care must have their pre-loaded insulin syringes stored as outlined in 4.6-4.10 but in a locked fridge.
12. Arrangements must be made to ensure that the monitoring of diabetes control is undertaken. Capillary blood glucose monitoring may be undertaken by the patient themselves, a family member or friend using their own glucometer. A full written assessment should be undertaken to check that they are confident and competent to undertake this procedure. The meter should also be checked weekly with the relevant quality control solution that is provided by the relevant meter company to ensure that it is accurate. Accuracy can also be checked by comparing a capillary blood glucose result with a venous glucose sample on a weekly basis. An Hba1c every three months is also required to evaluate the level of diabetes control.
13. Liaise with DSN as required for advice if circumstances change.
14. The DSN will quality assure that the risk assessment and SOP are being completed as outlined in this policy in Appendices B, C and D, using Appendix E every six months to ensure that this type of care remains appropriate for the individual.
15. An overview of the processes involved in points 4.1-4.14 is outlined in Appendix A.

6. Contra-indications

1. Lantus , Abasglar , Tresiba & Toujeo must not be preloaded into a insulin syringe.
2. Very variable capillary blood sugar recordings.
3. Lack of satisfactory storage conditions in the patient's home.
4. Unpredictable mental state or declining cognitive ability.
5. Pre-filled insulin cartridges and commercially available pre-loaded pens must not be used to withdraw insulin in order to comply with this policy. Only 10ml vials are permissible to be used.

6. If any of the points 5.1-5.5 are found, then this is to be reported to the GP or out of hours service and the advanced preparation of insulin in syringes should cease and arrangements made for the community nursing team to visit at the required intervals. A clinical incident form should be completed.

7 Training

1. All RNs involved with the care of these patients will need to receive training sessions delivered through the DSN. This session will cover a detailed presentation of the policy, the responsibilities of the RN, completing the risk assessment and practical aspects of dispensing insulin into syringes. Support and advice may also be sought from the medicines management team.
2. There will be annual training offered to the staff concerned by the DSN to update staff and feedback any observations from the six monthly quality assurance assessments.
3. All clinical staff should be made aware of this policy at induction (new staff) by their zone leads and specific medicines management training where appropriate.

7. Monitoring, auditing, reviewing and evaluation

1. This policy will be reviewed in two years through the Lincolnshire Community Health Services NHS Trust Care and Clinical Policies Sub Group.
2. The assistant director of professional practice will report to the care and clinical policies and procedures sub-group any concerns over the implementation of this policy.
3. All patients receiving insulin by this methodology will be recorded and held on a register by the DSN. This should be available to the provider safety group at their request.

8. Contact details for any further Information

Diabetes specialist nurse (DSN): Helpline 01522 308838

Or local Community Diabetes Team

References

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5. Nursing and Midwifery Council (2018) Standards for medicines management, London: NMC.
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7. Parliament (1968) Medicines Act 1968, London: Stationery Office.
8. Parliament (2005) Mental Capacity Act 2005, London: Stationery Office.
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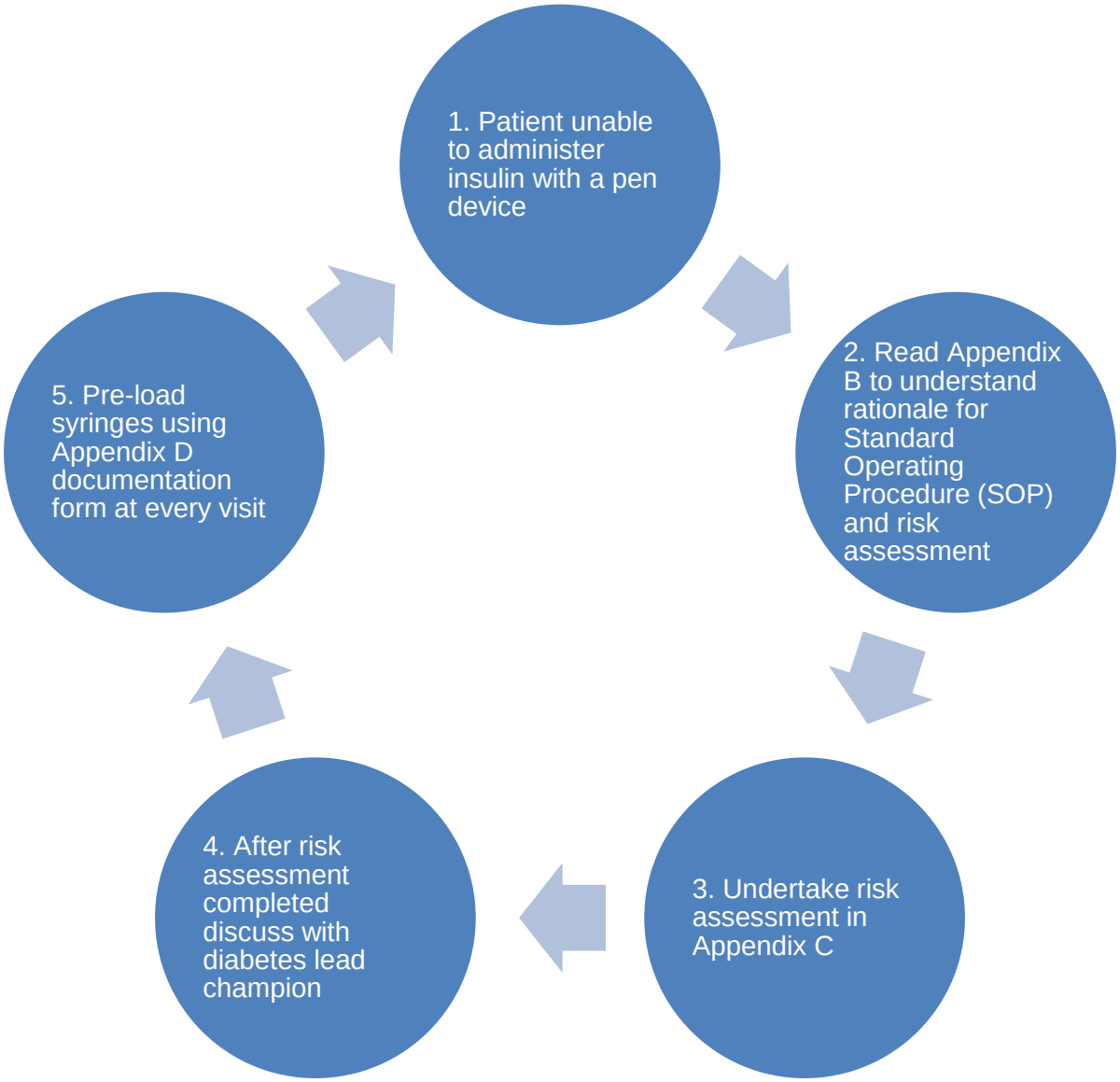
10. Training, Research and Education for Nurses on Diabetes (TREND-UK) (2018) Diabetes nurse competency assessment tool (WAND), London:
11. Orange juice Communications. Available at: http://trend-uk.org/resources (accessed 6 November 2018)

Appendices

Appendix A: Process of syringes being pre-loaded for the patient

Process of syringes being pre-loaded for the patient on the first occasion



Ongoing process of syringes being pre-loaded for the patient

Appendix B: Standard Operating Procedure (SOP) for the assessment of a patient to have insulin prepared in advance of administration

1. Mental capacity and physical capability		
Activity	**Rationale**	**Responsibility**
Assess the mental capacity and physical capability of the patient/carers to self-administer insulin. The patient should be at Level 3 which is defined: "the patient accepts full responsibility for the storage and administration of the medicinal products". The level should be documented in the patient's records. Registered nurses should be aware that the Mental Capacity Act 2005 requires all those working with potentially incapacitated people to assess the individual's capacity at a particular moment about a particular decision. Any change in the patient's condition would necessitate a review of their self-administration status; for example, risk of self-harm.	Reduce risk of medication error. NMC Standards for Medicines Management (2010). Care plan must be updated as a minimum every three months to meet needs of patient. Reduce risk of medication error.	Case Manager/ registered nurse
2. Consent		
Discuss risks and benefits of self-administration with the patient. Support available between community nurse visits. Where patients consent to self-administration of their medicines the following must be considered: Patients share the responsibility for their actions, relating to self-administration of their medicines. If children have access to the fridge that the patient ensures that the syringes are kept out of their reach and/or a childproof fridge lock is in situ. Patients can withdraw consent at any time	To gain informed consent and document in patient's record. Patients are empowered to make informed choices. Safeguarding of children. Patients retain right to withdraw consent.	Case Manager / registered nurse
3. Ensure most appropriate product has been prescribed		
Discuss and assess potential alternative insulin preparation with DSN or prescriber.	Unable to pre-load/use pen devices due to manual dexterity / poor vision / peripheral neuropathy / physical weakness to deliver insulin dose in insulin pen device / patient preference / reluctance to change	Case Manager / registered nurse

4. Contra-indications		
Activity	**Rationale**	**Responsibility**
Are there any contra-indications for the pre-loading of insulin syringes? 4.1 Lantus, Abasglar , Tresiba & Toujeo must not be preloaded into an insulin syringe. 4.2 Only use 10ml vials to withdraw insulin into syringes. Do not withdraw from pre-loaded pens or 3ml cartridges. 4.3 Is the fridge in working order? 4.4 Is the fridge visibly clean? 4.5 Is the fridge free from debris? 4.6 Patient suffers from an unpredictable mental state or declining cognitive ability. 4.7 Very variable capillary blood glucose readings. 4.8 If any of the above points are found, then this needs to be reported to the GP or doctors (when out of hours) and the advanced preparation of insulin in syringes should cease and arrangements made for the community nursing team to visit at the required intervals. Complete incident form.	Risk of deterioration of insulin. To ensure appropriate storage conditions. Risk to patient safety.	Case Manager / registered nurse
5. Education of patient		
Information/education given and supervision should be tailored to meet individual patient need, to enable the patient to administer the right dose, at the right time using the correct technique.	To ensure safe administration of insulin.	Case Manager/ registered nurse
The information below should be provided to the patient before commencing self-administration. 5.1 The name of the medicine. Injecting cold insulin can be painful and it is not absorbed so effectively. 5.2 Why they are taking it; dose and frequency. 5.3 Re-suspending each pre-loaded syringe, between the hands to warm the insulin, at least 20 times prior to injection, if using a cloudy insulin. 5.4 Inject at a 90° angle into sub-cutaneous tissue using a ‘pinch-up’ technique into abdomen, outer thigh or buttocks as decided in care plan. 5.5 Rotation within an injection site or between different injection sites. 5.6 Common side effects and what to do if they occur eg hypoglycaemia.	To comply with NMC Standards for medicines management (2010). Injecting cold insulin can be painful and it is not absorbed so effectively	Case Manager / registered nurse

5.7 Any special instructions. 5.8 How to obtain further supplies. 5.9 How to store the medication. 5.10 Frequency of visits and contact number for between visits. 5.11 Recognition of error and procedure to follow. 5.12 Correct disposal of sharps at the point of use.		
Plan of care documented and agreed with patient and nurse to ensure adequate support, monitoring of diabetes control and wellbeing.	To demonstrate partnership working.	Case Manager / registered nurse
6. Preparation of insulin		
Activity	**Rationale**	**Responsibility**
Nurses must not mix different insulins in the same syringe for administration at a later time. (There is no longer a need to mix insulins due to the availability of suitable manufacturer's preparations).	To reduce risk of administration errors.	All registered nurses
Pre–loaded insulin should be left up to a maximum of seven days.	RCN (2015) and Rosindale (2014).	All registered nurses
Document the advanced preparation of insulin on the PCT Community Nursing Record Sheets, ensuring full details are recorded, including batch number, type of insulin and expiry date are recorded.	To comply with Lincolnshire Community Health Services NHS Trust documentation record keeping.	All registered nurses
Required equipment. 6.1 Plan of care. 6.2 Sharps box (obtained from council). 6.3 Insulin syringes 30, 50 or 100 unit syringes (depending on which is most appropriate for the dose), needle length should be no more than 8mm. 6.4 Relevant insulin vial. 6.5 Wipeable, sealable, hinged, labelled container/s for storage of pre-filled syringes. 6.6 Alcohol swab. 6.7 Syringe labels.	To ensure adequate preparation of procedure.	All registered nurses

6.8 Read and check plan of care. Check all previous pre-loaded syringes have been administered and safely disposed of. An adverse event form should be completed to investigate why the syringes had not been used. 6.9 Explain procedure to patient, ensuring consent obtained. 6.10 Prepare clean working surface and wipe with a Clinell wipe. 6.11 Collect equipment required; check insulin for expiry date and against instructions of care plan. 6.12 Wash hands. 6.13 Prepare equipment and re-suspend (by rocking back and forth) insulin at least 20 times if using a cloudy insulin. Do not shake as you will damage the insulin suspension. If using a clear insulin there is no need to re-suspend. 6.14 Swab insulin vial with an alcohol wipe and allow to dry. 6.15 Draw up insulin in presence of patient as follows for each syringe using a clean procedure to prevent contamination. 6.16 Remove needle cover and pull back plunger to measure an amount of air equivalent to the amount of insulin prescribed. 6.17 With insulin vial standing upright, insert the needle through the centre of the rubber cap and push down plunger. 6.18 Invert the insulin vial.	To reduce risk of administration errors. To reduce risk of cross-infection. To ensure safe administration of insulin. To comply with NMC Standards for medicines management (2010).	All registered nurses
6.19 Pull back plunger until slightly more than correct dose is drawn up. 6.20 Expel any air bubbles back into vial. 6.21 Re-check correct prescribed dose has been drawn up and remove needle from vial. 6.22 Carefully re-sheath needle (there is no risk of	To ensure best practice in the preparation of insulin prior to injection.	All registered nurses

contaminated needle stick injury as needle is sterile – in event of a needle stick injury the syringe must be safely discarded). 6.23 Label each syringe with patient name, insulin name, date of preparation, initials of RN. 6.24 Label each container with patient name, insulin name, insulin dose, time of administration, number of syringes, date, mane and signature of registered nurse. 6.25 Store pre-filled syringes with needles slightly elevated, within a labelled container as described earlier in main body of the fridge (away from freezer section or the back of the fridge). 6.26 Dispose of clinical waste and wash hands. 6.27 Complete nursing notes ensuring date, time, insulin type/dose, batch number and number of syringes pre-filled are recorded. 6.28 If any pre-loaded syringes have not been used within the designated period, they must be disposed of.		
7. Safe storage of pre-drawn insulin		
Activity	**Rationale**	**Responsibility**
7.1 The needle should be stored approximately at 45° to prevent blockage by suspended substances in the insulin. 7.2 Pre-filled syringes should be labelled and stored in a protective container. If there are different doses then use more than one container. Store in the main body of the fridge (away from the freezer section or the back of the fridge) between 2-8°. The container should be clearly labelled with the following information: • date • name of patient • number of syringes • name of insulin preparation To meet patients individual needs. • time of insulin administration eg before breakfast, before evening meal.	Needle blockage by suspended insulin. To promote safe storage of pre-loaded insulin. To ensure best practice in the administration of medicines.	All registered nurses

• pre-loaded dose • route (subcutaneous) • instructions for administration eg just before or 30 minutes before food at times agreed with the patient and documented in the nursing notes • who has prepared the syringes. 7.3 Separate containers should be used for insulin to be delivered at different times of day, particularly if the syringe contains a different dosage or type of insulin (RCN, 2015). 7.4 When each new insulin vial is opened, the date and time must be recorded on the vial and in the patient's notes. 7.5 Any insulin remaining in the vial after 28 days should be discarded. 7.6 Patients should have a vial in use and a backup vial at all times to ensure that vials are used methodically. 7.7 The patient should be advised of the correct storage (as above) and advised to notify the district nurse team ASAP if their fridge stops working or the fridge freezes.	To reduce risk of medication errors. To reduce medication error. To promote standardisation of labels used. To promote safe storage of insulin.	Patient / carer

Appendix C: Risk assessment form – advanced preparation of insulin into syringes for a patient to administer at a later date

To be completed every three months.

Name of patient	
NHS number	
Date of birth	
GP	
Community nursing team	
Type of diabetes	
How long has the patient been insulin treated?	
Range of blood glucose readings	
Last Hba1c result and date	
Date risk assessment completed Date of review for risk assessment	
Full name of nurse completing risk assessment form	
Signature	

1. Assessment of patient's suitability for self administration of insulin	Yes	No	Potential risk	Not known	Seek advice
a) Have you assessed the mental and physical capability of the patient/carer to self-administer insulin?					
b) Is the patient at Level 1? = The registered nurse is responsible for the safe storage of the insulin and the supervision of the administration process ensuring that the patient understands the insulin product being administered.					
c) Is the patient at level 2? = The registered nurse is responsible for the storage of the insulin. At administration time the patient will ask the nurse to open the cabinet/locker. The patient will then self-administer the insulin under the supervision of the nurse.					
d) Is the patient at level 3? = The patient accepts full responsibility for the storage and administration of the medicinal products. Note: the patient should be at Level 3 for this assessment to continue further.					
e) Is the level documented in the patient's records?					
f) Risk associated with disability – sensory and/or physical?					
g) Risk of self-harm?					
2. Consent	Yes	No	Potential risk	Not known	Seek advice
a) Have you discussed the risks and benefits of self-administration with the patient?					
b) Do children have access the fridge?					
c) If yes, have you advised the patient to ensure that the syringes are kept out of the reach of children?					
d) Is a fridge lock in situ?					
e) Provided information about support available between community nurse visits?					
f) Is the patient happy to receive this service?					
3. Ensure most appropriate product has been prescribed					
Note: this discussion must have taken place before the assessment can continue further.					

4. Contra-indications	Yes	No	Potential risk	Not known	Seek advice
a) Is the patient on Lantus (Glargine), Abasglar (biosimilar Glargine), Tresiba & Toujeo?					
b) Is the fridge in working order?					
c) Is the fridge visibly clean?					
d) Is the fridge free from debris?					
e) Patient suffers from an unpredictable mental state or declining cognitive ability?					
f) Blood glucose showing wide variations?					
g) Is their current insulin in a pre-filled cartridge/pen?					
If any of the points a-g are found, then this needs to be reported to the SDSN, GP or out-of-hours service and the advanced preparation of insulin in syringes should cease and arrangements made for the community nursing team to visit at the required intervals.					
5. Education of patient	**Yes**	**No**	**Potential risk**	**Not known**	**Seek advice**
Has the patient received the following information before commencing self-administration:					
a) The name of the insulin?					
b) Why they are taking it?					
c) Dose and frequency?					
d) How to re-suspend each pre-loaded syringe, between their hands to warm the insulin, at least 20 times prior to injection, if using a cloudy insulin?					
e) How to inject at a 90° angle into sub-cutaneous tissue using a ‘pinch-up’ technique into abdomen, outer thigh or buttocks as documented in the care plan?					
f) How to rotate within an injection site or between different injection sites?					
g) How to manage hypoglycaemia and what to do if it occurs?					
h) How to obtain further supplies?					
i) How to store the insulin?					
j) Frequency of visits and contact number for between visits?					
k) Recognition of error and procedure to follow?					
l) Correct disposal of sharps at the point of use?					
m) Is the plan of care documented and agreed with patient?					
n) Nurse to ensure adequate support, monitoring of diabetes control and wellbeing.					

6. Summary of risks identified					
Summarise risks identified, including intuition and patient's awareness and experience of risk factors.					
7. Would pre-loading of insulin promote independence and meet patient need?					
8. Is there a need for any further assessments					

Appendix D: Documentation form for the advanced preparation of insulin in syringes

The needle should be stored approximately at 45 degrees to prevent blockage by suspended substances in the insulin.	
Pre-filled syringes should be stored in a labelled protective container in the main body of the fridge (away from the freezer section or the back of the fridge) between 2-8 ° Celsius.	
Date	
Name of patient	
NHS number	
Date of birth	
GP	
Community nursing team	
Name of insulin preparation (morning)	
Name of insulin preparation (evening)	
Pre-loaded dose – before breakfast	
Pre-loaded dose – before evening meal	
Number of syringes (maximum 7 days to be pre-loaded)	
Syringes labelled with:	
• patient name	Yes / no
• insulin name	Yes / no
• date of preparation	Yes / no
• initials of registered nurse	Yes / no
Number of containers – separate containers should be used for insulin to be delivered at different times of day, particularly if the syringe contains a different dosage or type of insulin (RCN, 2015)	
Container labelled with:	
• patient name	Yes / no
• insulin name	Yes / no
• insulin dose	Yes / no
• time of administration	Yes / no
• number of syringes	Yes / no
• date	Yes / no
• name and signature of registered nurse	Yes / no
Instructions for administration – for example, just before or 30 minutes before food at times agreed with the patient?	

Date vial of insulin opened (discard any unused insulin in vial after 28 days)	
Batch number of insulin vial	
Expiry date of insulin	
Does the fridge appear to be in good working order?	Yes / no
Name of registered nurse who has prepared the syringes	
Documented in the nursing notes?	Yes / no
Do any insulin/supplies need re-ordering? Patients should have a vial in use and a backup vial at all times to ensure that vials are used methodically.	Yes / no
Signature of registered nurse	
Date and time	
Date of next visit	

Appendix E: Diabetes Nurse Quality Assurance for Policy Implementation

5. Education of patient	Yes	No	Potential risk	Not known	Seek advice
Has an assessment of the mental and physical capability of the patient/carer to self-administer insulin been documented?					
Is the patient at level 3? = The patient accepts full responsibility for the storage and administration of the medicinal products.					
Is the level documented in the patient's records?					
Risk associated with disability: sensory and/or physical?					
2. Consent	**Yes**	**No**	**Potential risk**	**Not known**	**Seek advice**
Has the risks and benefits of self-administration been discussed with the patient?					
Provided information about support available between community nurse visits?					
Is the patient happy with this service?					
3. Contra-indications	**Yes**	**No**	**Potential risk**	**Not known**	**Seek advice**
Are there any contra-indications for the pre-loading of insulin syringes:					
• Is the patient on Lantus (Glargine), Abasglar (biosimilar Glargine), Tresiba & Toujeo?					
• Is the fridge in working order?					
• Is the fridge free from debris?					
• Protective container/s to store syringes?					
• Blood glucose showing wide variations?					
• Is the insulin being drawn from a pre-filled cartridge/pen?					
Incident form completed?					
Signature of diabetes Link Nurse					
Issues/comments back to RNs involved					
Date of feedback to RNs					
Date and time					
Date of quality assurance visit (maximum time allowed between visits is six months)					

Appendix F: Consensus statement and Methodology

The RCN Diabetes Forum Task and Finish Group undertook an exercise to understand the state of knowledge in regard to the practice of pre-loading insulin syringes and to source expert input in the development of these guidelines.
A consensus statement was developed and circulated to senior diabetes nurse specialists who were not associated with the Task and Finish Group guidelines development project.
Participants were asked to evaluate 12 statements, ranking the extent to which they agreed or disagreed with individual statements; a ranking of 1 indicated strongly disagreed, while a ranking of 9 indicated strongly agreed.
Scores from participants, whose responses were anonymised, were fed back to the Task and Finish group to support the development of this guidance.

Statement 1
Pre-loading of insulin syringes is not considered best practice
Disagree 0 1 2 3 4 5 6 7 8 9 Agree

Statement 2
Promoting self-management of diabetes. Why using available devices should be promoted to support independence
Disagree 0 1 2 3 4 5 6 7 8 9 Agree

Statement 3
Pre-filled insulin syringes sit outside the Medicines Act
Disagree 0 1 2 3 4 5 6 7 8 9 Agree

Statement 4
Only registered nurses should be involved in pre-loading syringes not HCAs
Disagree 0 1 2 3 4 5 6 7 8 9 Agree

Statement 5
Patient must have capacity in order for this practice to be considered
Disagree 0 1 2 3 4 5 6 7 8 9 Agree

Statement 6
Only an insulin syringe should be used
Disagree 0 1 2 3 4 5 6 7 8 9 Agree

Statement 7
The organisation or trust must have a policy in place
Disagree 0 1 2 3 4 5 6 7 8 9 Agree

Statement 8
Full patient training and education must be provided
Disagree 0 1 2 3 4 5 6 7 8 9 Agree

Statement 9
Specialist must be involved in ensuing only most appropriate patients are offered this
Disagree 0 1 2 3 4 5 6 7 8 9 Agree

Statement 10
DSN must be involved in quality assurance
Disagree 0 1 2 3 4 5 6 7 8 9 Agree

Statement 11
All nurses involved in insulin therapy must have appropriate training
Disagree 0 1 2 3 4 5 6 7 8 9 Agree

Statement 12
Risk assessment must be undertaken for all patients
Disagree 0 1 2 3 4 5 6 7 8 9 Agree

Appendix G - Equality Analysis

Name of Policy/Procedure/Function*

Equality Analysis Carried out by: Estelle Walden

Date: 16.04.2020

Equality & Human rights Lead: Rachel Higgins

Date:

Director\General Manager:

Date:

***In this template the term policy\service is used as shorthand for what needs to be analysed. Policy\Service needs to be understood broadly to embrace the full range of policies, practices, activities and decisions: essentially everything we do, whether it is formally written down or whether it is informal custom and practice. This includes existing policies and any new policies under development.**

Section 1 – to be completed for all policies

A.	Briefly give an outline of the key objectives of the policy; what it's intended outcome is and who the intended beneficiaries are expected to be	To outline good practice for all aspects of management of injectable medicines in clinical areas. To provide a clear and consistent framework for the appropriate assessment and management of a person with diabetes who cannot safely prepare their own insulin dose. Intended Outcome: To avoid harm to patients and ensure compliance with relevant legislation and best practice. Beneficiaries: Patients receiving subcutaneous injections in an LCHS setting. LCHS staff
B.	Does the policy have an impact on patients, carers or staff or the wider community that we have links with? **Please give details**	Non known
C.	Is there is any evidence that the policy\service relates to an area with known inequalities? **Please give details**	No

D.	Will/Does the implementation of the policy\service result in different impacts for protected?	No		
		Yes	No	
	Disability		**x**	
	Sexual Orientation		**x**	
	Sex		**x**	
	Gender Reassignment		**x**	
	Race		**x**	
	Marriage/Civil Partnership		**x**	
	Maternity/Pregnancy		**X**	
	Age		**x**	
	Religion or Belief		**x**	
	Carers		**x**	
	If you have answered 'Yes' to any of the questions then you are required to carry out a full Equality Analysis which should be approved by the Equality and Human Rights Lead – please go to section 2			
The above named policy has been considered and does not require a full equality analysis				
Equality Analysis Carried out by:		Estelle Walden		
Date:		16.04.2020		

NB - It is the responsibility of the author / reviewer of this document to complete / update the Equality Analysis each time it has a full review and to contact the Equality Diversity and Inclusion Lead if a full equality impact analysis is required