Document Type:	Policy	
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Title:	**Diabetes – Pre Loading Of Insulin Syringes For Adult Patients To Administer At Home**	
Document Author:	Diabetes Specialist Nurse	
Applicability:	All registered nurses and prescribers	

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1 Purpose

There are potential legal and safety complexities associated with the practice of pre-loading insulin syringes in order to enable people to self-administer in their own homes that health care practitioners MUST be aware of.

Firstly, the preparation of pre-loaded syringes represents a form of secondary dispensing which, under the terms of the Medicines Act (1968), is classified as an 'unlicensed' activity in all four UK countries. Consequently, health care organisations and practitioners must take full responsibility for the safety of this activity.

Secondly, the safety of individuals using pre-loaded insulin syringes, as well as the storage, stability and sterility of insulin once drawn up in the syringe, is of paramount importance (Rosindale, 2014).

For this reason Torbay & South Devon NHS Foundation Trust and the Royal College of Nursing (2015) recommends nurses should operate within the framework of this pre-loaded insulin syringe clinical policy which details the responsibilities of every individual involved in the practice (employing organisation/patient/GP/community nurse) and standardises how nurses perform the preparation of syringes (essential to assure vicarious liability protection for nurses undertaking this practice). Practitioners are also directed to review the recently updated Nursing & Midwifery Council '*Standards for medicines management'* (NMC, 2015b)

The purpose of this policy is to:

1.1 To promote patient safety.

1.2 To ensure that Registered Nurses (RN's) are aware of the potential risks of pre-loading insulin syringes for later use by a patient.

1.3 To provide a clear and consistent framework across Torbay & South Devon NHS Foundation Trust or the appropriate assessment and management of a person with diabetes who cannot safely prepare their own insulin dose.

1.4 The NMC standards for medicines management 14 (2015b) state that 'registrants must not prepare substances for injection in advance of their immediate use'.

The Department of Health (DoH)/Medicines & Healthcare products Regulatory Agency (MHRA) advise 'against pre-loading medication for injection at a later time' (Rosindale 2014).

1.5 To support RN's 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 (2015) 'Advance preparation of insulin syringes for adult patients to administer at home'.

1.6 The NHS commissioning board special health authority previously known as National Patient Safety Agency '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).

2 Introduction

2.1 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.

2.2 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.

2.3 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).

2.4 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.

2.5 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 8 mm needles be used when using an insulin syringe.

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

3 Roles and Responsibilities

3.1 This policy covers all RN's employed by Torbay and South Devon NHS Foundation Trust who are required to treat patients with diabetes mellitus within their own home. It is important to note that the delegation of the task to skilled not registered staff is inappropriate due to the nature of the task.

3.2 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.

3.3 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.

3.4 RN to positively identify the patient (obtaining confirmation of name and DOB) and establish allergy status.

3.5 All 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 'Safe use of Insulin' is a mandatory requirement every 2 years with a pass mark of 80%.
If a nurse fails the exam they must resit the exam as soon as possible or at the same sitting. If the nurse fails after the second attempt they should complete further studies and resit within one month of the last failed attempt. If failure occurs after the 3rd attempt then the nurse should be suspended from insulin administration immediately. The community Diabetes Specialist Nurse team should be contacted by the line manager to offer 1-2-1 education and support to the RN concerned.

3.6 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 & Midwifery Council (NMC 2015b) & 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 as "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 Standards for medicines management 2015b).

3.7 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.

3.8 RN's in administering any medicines, in assisting with administration or over-seeing any self-administration must assess the patient's suitability and understanding of how to use an appropriate compliance aid safely (Standard 16 NMC 2015b).

3.9 RN's are accountable to ensure that the patient/carer is competent to carry out administration of the insulin. This will require education, training and assessment of the patient, carer or care assistant and further support if necessary. The competence of the person to whom the administration of insulin has been delegated should be assessed and reviewed periodically. Records of the training received and outcome of any assessment should be clearly made and be available.
(Standard 17 NMC 2015b).

3.10 RN's are responsible for implementing this policy. Pre-loading insulin syringes must not be delegated to non-registered staff.

3.11 Pre-loaded syringes may not be prepared by one registered nurse for another health professional or skilled not registered person to administer.

3.12 Under no circumstances may RN's 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).

3.13 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 2015b).

4 Principles of Practice for the Pre-loading of insulin in syringes

4.1 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 A, B & C.

4.2 RN's should be aware of the alternative injection devices available and discuss the patient's needs and preferred options with the Senior Diabetes Specialist Nurse (SDSN) and General Practitioner.

4.3 Pre-loading of insulin for injection must only begin following a full written risk assessment, involving the SDSN, 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. Followed by completion of Appendix C: 'Risk Assessment Form – Advanced Preparation of Insulin into syringes for a patient to administer at a later date'.

4.4 The risk assessment form in Appendix C should be undertaken every 3 months, or sooner if the patient's condition changes.

4.5 The patient should always be consulted about their insulin administration and informed consent obtained regarding the care provided.

4.6 On completion of the risk assessment the RN should decide on the appropriate number of days that the insulin syringes that can be prepared for and left with the patient. It is important that the RN considers all aspects of social and healthcare for their patient in this decision. This number and 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 SDSN. Each time a nurse pre-loads syringes Appendix D 'Documentation Form for the advanced preparation of insulin in syringes' should be completed.

4.7 Pre-loaded insulin syringes must be labelled individually and stored in a wipe-able, 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 colours or shapes.

4.8 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.

4.9 It is recommended that insulin is most stable when stored at a temperature of between 2 and 8° Celsius. Never allow insulin to freeze. If insulin is frozen or not stored at the correct temperature the insulin should be discarded and a new vial used.

4.10 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.

4.11 Patients in residential care must have their pre-loaded insulin syringes stored as outlined in 4.6 – 4.10 but in a locked fridge.

4.12 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/friend using their own glucometer. A full written assessment should be undertaken to check patient or family member 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 3 months is also required to evaluate the level of diabetes control.

4.13 Liaise with SDSN as required for advice if circumstances change.

4.14 The SDSN will quality assure that the risk assessment & 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.

4.15 An overview of the processes involved in points 4.1 – 4.14 is outlined in Appendix A.

5 Contraindications

5.1 Insulin Glargine Lantus, Abasaglar & Toujeo must not be pre-loaded into insulin syringes.

5.2 Very variable capillary blood sugar recordings.

5.3 Lack of satisfactory storage conditions in the patient's home.

5.4 Unpredictable mental state or declining cognitive ability.

5.5 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.

5.6 If any of the points 5.1 – 5.5 are found, then this is to be reported to the GP or Devon 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. A clinical incident form should be completed.

6 Training

6.1 All staff involved with the care of these patients will receive a training session delivered through the SDSN. 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 Optimisation Team within the CCG.

6.2 There will be annual training offered to the staff concerned by the SDSN to update staff and feedback any observations from the 6 monthly Quality Assurance assessments.

6.3 All clinical staff should be made aware of this policy at induction (new staff) by their Locality community nurse leads and specific medicines management training where appropriate.

6.4 All 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 'Safe use of Insulin' is a mandatory requirement every 2 years with a pass mark of 80%.

6.5 All community nurses involved in this practice of preloading insulin syringes will undertake the MERIT 1 day module – 'helping people with diabetes to continue insulin therapy'. **(Insulin management in type 2 diabetes)**

7 Monitoring & Auditing

7.1 The SDSN will quality assure that the risk assessment & 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.

7.2 All patients receiving insulin by this methodology will be recorded and held on a register by the SDSN. This should be available to the Provider Safety Group at their request.

7.3 This policy will be reviewed in two years through the Torbay and South Devon NHS Foundation Trust Health Care and Clinical Policies Sub Group.

8 References

Nursing and Midwifery Council (2015a) The Code. Professional standards of practice and behaviour for nurses and midwives. www.nmc-uk.org. Accessed 16/04/2018

Nursing and Midwifery Council (NMC) (2015b) Standards for medicines management. https://www.nmc.org.uk/globalassets/sitedocuments/standards/nmc-standards-for-medicines-management.pdf Accessed 16/4/18

National Patient Safety Agency (2010) Rapid response Report. Safer Administration of Insulin. NPSA/2010/RRR013

Parliament (1968) *Medicines Act 1968*, London: Stationery Office.

Parliament (2005) Mental Capacity Act 2005, London: Stationery Office.

Rosindale S (2014) Pre-loading of insulin syringes for people with diabetes to administer at home: new solution to an old practice*, Diabetes and Primary Care,* 16 (3), pp.137-142.

Royal College of Nursing (2015) Advance preparation of insulin syringes for adult patients to administer at home.2nd Edition. https://www.rcn.org.uk/professional-development/publications/pub-004805 Accessed 16/04/2018

9 Equality and Diversity

9.1 This document complies with the Torbay and South Devon NHS Foundation Trust Equality and Diversity statements.

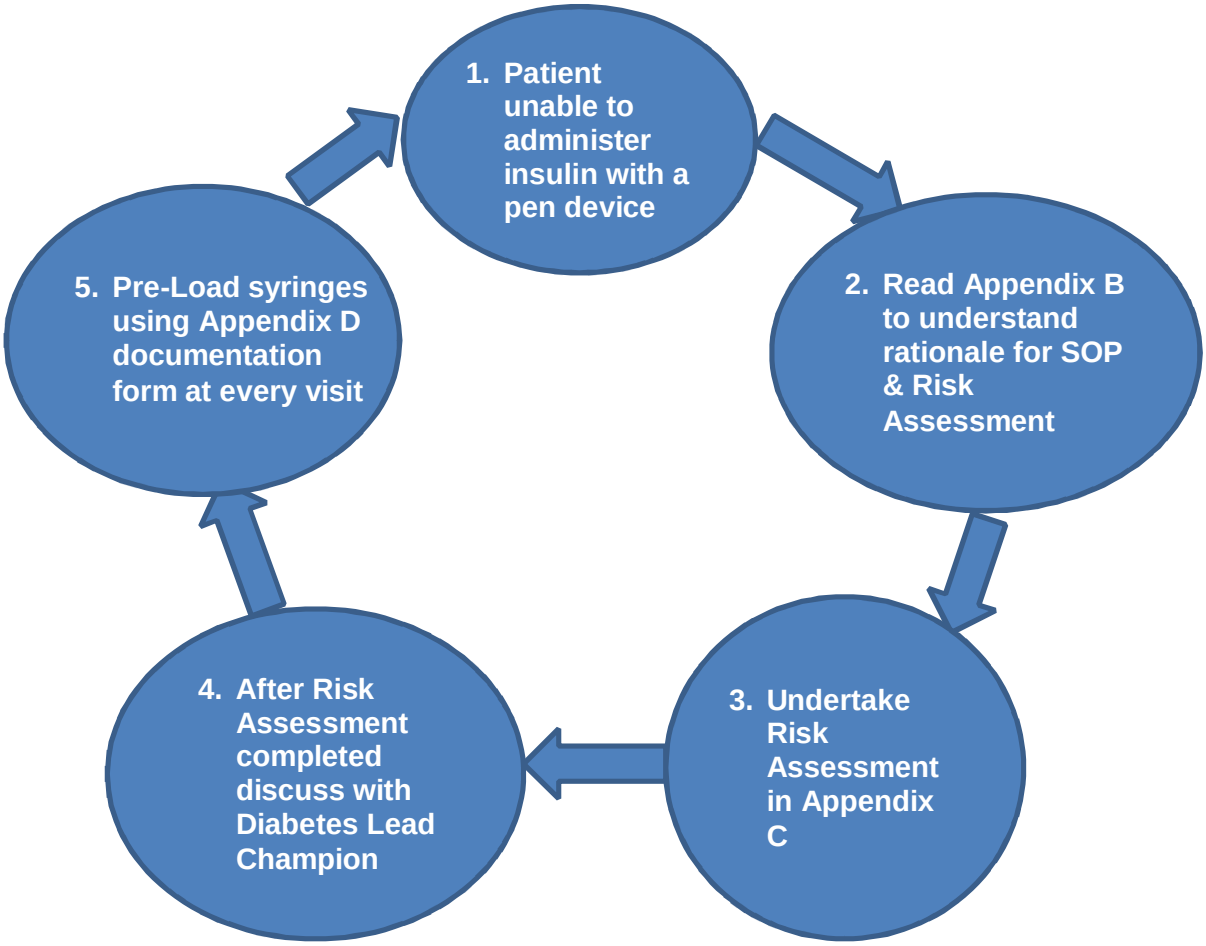
10 Further Information

10.1 Links to Administration of Insulin Ref 1929

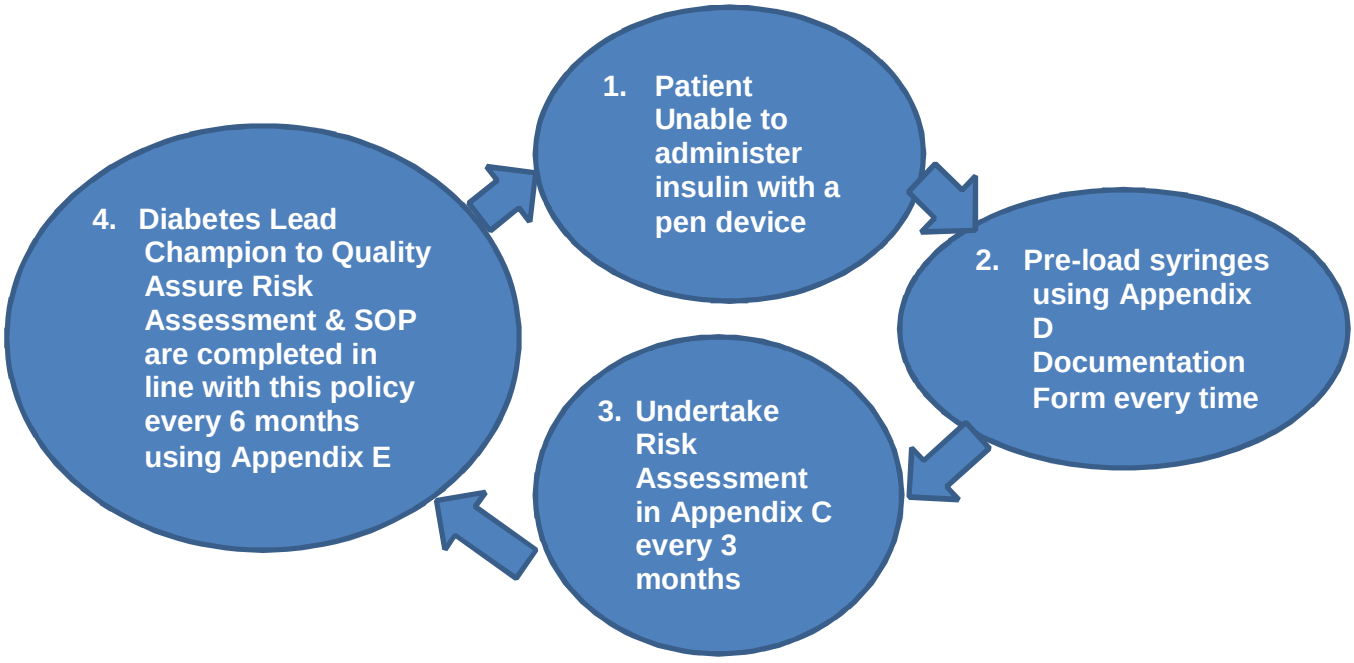
10.2 This policy has referenced as an example of best practice in the RCN national guidance document 'Advance preparation of insulin syringes for adult patients to administer at home. 2nd Edition'. www.rcn.org.uk/publications Accessed 16/04/2018

Appendix A

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



On-going 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 as "the patient accepts full responsibility for the storage and administration of the medicinal products".	Reduce the risk of medication error NMC Standards for Medicines Management (2015b)	Locality Community Nurse Lead/registered nurse
The level should be documented in the patient's records	Care Plan must be updated as a minimum every 3 months to meet needs of patient	Registered Nurse
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	

2. Consent		
Activity	**Rationale**	**Responsibility**
Discuss risks and benefits of self-administration with the patient. Support available between community nurse visits.	To gain informed consent and document in patient's record	Locality Community Nurse Lead/registered nurse
Where patients consent to self-administration of their medicines the following points 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 child proof fridge lock is in situ, Patients can withdraw consent at any time.	Patients are empowered to make informed choices Safeguarding of Children Patients retain right to withdraw consent.	Locality Community Nurse Lead/registered nurse

3. Ensure most appropriate product has been prescribed		
Activity	**Rationale**	**Responsibility**
Have you discussed a potential alternative insulin preparation/device with a Senior Diabetes Specialist Nurse (SDSN) in order to avoid this situation? **Note: This discussion must have taken place before the assessment can continue further to ensure only the most appropriate patients are involved with this way of insulin self-administration.**	Unable to preload/use pen devices due to manual dexterity, poor vision, peripheral neuropathy, physical weakness to deliver insulin dose in insulin pen device, patient preference or reluctance to change.	Locality Community Nurse Lead/registered nurse

4. Contra-indications		
Activity	**Rationale**	**Responsibility**
Are there any contra-indications for the pre-loading of insulin syringes: 4.1 Insulin glargine, Lantus, Abasaglar or Toujeo must not be pre-loaded for later administration as it becomes cloudy. 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 these need to be reported to the GP or Devon Doctors (when out of hours) and the advances 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 There would be a risk to patient safety.	Locality Community Nurse Lead/registered nurse
5. Education of patient		
Activity	**Rationale**	**Responsibility**
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	Locality community nurse lead/Registered Nurse

The following information should be provided to the patient <u>before</u> commencing self-administration: 5.1 The name of the medicine 5.2 Why they are taking it, dose and frequency. 5.3 Re-suspending each pre-loaded syringe by rocking back and forth between the hands to warm the insulin, at least 20 times prior to injection, if using cloudy insulin. 5.4 Injection at a 90o 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 e.g. hypoglycaemia. 5.7 Any special instructions 5.8 How to obtain further supplies 5.9 How to store the medication 5.10 Frequency of visits & 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.	To comply with NMC Standards for medicines management (2015b) Injecting cold insulin can be painful and it is not absorbed so effectively.	Locality community nurse lead/Registered Nurse
Plan of care documented and agreed with patient and nurse to ensure adequate support, monitoring of diabetes control and wellbeing.	To demonstrate partnership working.	One lead/registered nurse.

6. Preparation of insulin and pre-loading insulin into syringe		
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 manufacturers preparations)	To reduce the risk of administration errors	All Registered Nurses
Pre-loaded insulin should be left up to a maximum of seven days.	RCN and NMC policy	All Registered Nurses
Document the advanced preparation of insulin of 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 Torbay and South Devon NHS Foundation Trust documentation record keeping.	All Registered Nurses

Equipment required: 6.1 Plan of care 6.2 Sharps box (obtained from local 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 8 millimetres (8mm). 6.4 Relevant insulin vial. 6.5 Wipe-able, 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 SDHCT incident form should be completed to investigate why the syringes had not been used.	To reduce risk of administration errors.	
6.9 Explain procedure to patient, ensuring consent obtained.		
6.10 Prepare clean working surface and wipe with a antibacterial wipe.	To risk of cross infection.	
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.	To ensure safe administration of insulin.	

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. 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 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, name 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.	To comply with NMC Standards for medicines management (2015b) To ensure best practice in the preparation of insulin prior to injection.	

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 degrees 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 degrees. The container should be clearly labelled with the following information. • Date • Name of patient • Pre-loaded dose • Number of Syringes • Name of insulin preparation • Time of insulin administration e.g. before breakfast, before evening meal • Route (subcutaneous) • Instructions for administration e.g. just before or 30 minutes before food at times agreed with the patient and documented in the nursing notes. • Who has prepared the syringes	Needle blockage by suspended insulin. To promote safe storage of pre-loaded insulin To ensure best practice in the administration of medicines. To reduce the risk of medication errors To reduce medication error. To meet patients individual needs.	All Registered Nurses

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)	To promote standardisation of labels used.	All Registered Nurses
7.4 When each new insulin vial is opened, the date and time must be recorded on the vial and in the patient notes.		
7.5 Any insulin remaining in the vial after 28 days should be discarded.		All Registered Nurses
7.6 Patients should have a vial in use and a backup vial at all times to ensure that vials are used methodically.	To promote safe storage of insulin.	Patient/Carer
7.7 The patient should be advised of the correct storage (as above) and advised to notify the community nurse team ASAP if their fridge stops working or the fridge freezes.		

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 patients' 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) Has a fridge lock been purchased and in situ? e) Provided information about support available between community nurse visits? f) Is the patient happy to receive this service?					
3. Ensure the most appropriate product has been prescribed?	**Yes**	**No**	**Potential Risk**	**Not Known**	**Seek Advice**
Have you discussed a potential alternative insulin preparation/device with a Senior Diabetes Specialist Nurse (SDSN) in order to avoid this situation? **Note: this discussion must have taken place before the assessment can continue further.**					

4. CONTRA-INDICTATIONS	Yes	No	Potential Risk	Not Known	Seek Advice
Are there any contra-indications for the pre-loading of insulin syringes:- a) Is the patient on Insulin glargine, Lantus, Abasaglar or 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 Devon 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.					

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) Shown how to re-suspend each pre-loaded syringe, by rocking back and forth between their hands to warm the insulin, at least 20 times prior to injection, if using a cloudy insulin? e) 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) Shown how to rotate within an injection site or between different injection sites? g) Educated 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 & 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.					
	Yes	**No**	**Potential Risk**	**Not Known**	**Seek Advice**
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 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 registered nurse who has prepared the syringes:	
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 • Insulin Name • Date of Preparation • Initials of Registered Nurse	 **Yes/No** **Yes/No** **Yes/No** **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** • **Insulin Name** • **Insulin Dose** • **Time of Administration** • **Number of Syringes** • **Date** • **Name and Signature of Registered Nurse**	**Yes/No** **Yes/No** **Yes/No** **Yes/No** **Yes/No** **Yes/No** **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**
Documented in the nursing notes?	**Yes/No**
Anymore 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

Senior Diabetes Specialist Nurse 6 month quality assurance for policy Implementation

1. Assessment of patients' suitability for self-administration of insulin	**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. CONTR-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 Insulin glargine (Lantus, Abasaglar or Toujeo)? • Is the fridge in working order? • Is the fridge visibly clean? • 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?					

Issues/ comments back to RN's involved	
Date of next 6 month quality assurance visit	
Signature of Senior Diabetes Specialist Nurse	
Date and time	

Document Control Information

This is a controlled document and should not be altered in any way without the express permission of the author or their representative.

Please note this document is only valid from the date approved below, and checks should be made that it is the most up to date version available.

If printed, this document is only valid for the day of printing.

This guidance has been registered with the Trust. The interpretation and application of guidance will remain the responsibility of the individual clinician. If in doubt contact a senior colleague or expert. Caution is advised when using clinical guidance after the review date, or outside of the Trust.

Ref No:	1917		
Document title:	Diabetes – Pre loading of Insulin Syringes for Adult Patients to administer at Home		
Purpose of document:	Please see page 2		
Date of issue:	31 May 2019	**Next review date:**	31 May 2022
Version:	3	**Last review date:**	
Author:	Diabetes Specialist Nurse		
Directorate:	Community		
Equality Impact:	The guidance contained in this document is intended to be inclusive for all patients within the clinical group specified, regardless of age, disability, gender, gender identity, sexual orientation, race and ethnicity & religion or belief		
Committee(s) approving the document:	Care and Clinical Policies Group Meeting Clinical Director of Pharmacy		
Date approved:	21 May 2019		
Links or overlaps with other policies:			

Have you identified any issues on the Rapid (E)quality Impact Assessment. If so please detail on Rapid (E)QIA form.	Yes ☐	
	Please select *Yes*	*No*
Does this document have implications regarding the Care Act? *If yes please state:*	☐	☐
Does this document have training implications? *If yes please state:*	☐	☐
Does this document have financial implications? *If yes please state:*	☐	☐

Is this document a direct replacement for another? *If yes please state which documents are being replaced:*	☐	☐

Document Amendment History

Date	Version no.	Amendment summary	Ratified by:
October 2010	1	New	Care and Clinical Policies
November 2021	1	Re-Badged	Care and Clinical Policies
April 2015	2	Revised	Care and Clinical Policies
30 June 2017	2	Review date extended	Care and Clinical Policy Group
20 October 2017	2	Review date extended	Care and Clinical Policy Group
31 May 2019	3	Revised	Care and Clinical Policies Group Clinical Director of Pharmacy

The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person's ability to make a decision due to 'an impairment of or disturbance in the functioning of the mind or brain' the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

"The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual's right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves". (3)

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on iCare

http://icare/Operations/mental_capacity_act/Pages/default.aspx

Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the work place. All staff will attend Infection Control Training annually as part of their mandatory training programme.

NHS South Devon and Torbay Clinical Commissioning Group Torbay and South Devon NHS NHS Foundation Trust

Rapid (E)quality Impact Assessment (EqIA) *(for use when writing policies)*

Policy Title (and number)		**Version and Date**	
Policy Author			

An (e)quality impact assessment is a process designed to ensure that policies do not discriminate or disadvantage people whilst advancing equality. Consider the nature and extent of the impact, not the number of people affected.

Who may be affected by this document?

Patients/ Service Users ☐	Staff ☐	Other, please state… ☐

Could the policy treat people from protected groups less favorably than the general population?
PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below

Age	Yes ☐ No☐	Gender Reassignment	Yes ☐ No☐	Sexual Orientation	Yes ☐ No☐
Race	Yes ☐ No☐	Disability	Yes ☐ No☐	Religion/Belief (non)	Yes ☐ No☐
Gender	Yes ☐ No☐	Pregnancy/Maternity	Yes ☐ No☐	Marriage/ Civil Partnership	Yes ☐ No☐

Is it likely that the policy could affect particular 'Inclusion Health' groups less favourably than the general population? (substance misuse; teenage mums; carers[1]; travellers[2]; homeless[3]; convictions; social isolation[4]; refugees)	Yes ☐ No☐
Please provide details for each protected group where you have indicated 'Yes'.	

VISION AND VALUES: Policies must aim to remove unintentional barriers and promote inclusion

Is inclusive language[5] used throughout?	Yes ☐ No☐ NA ☐
Are the services outlined in the policy fully accessible[6]?	Yes ☐ No☐ NA ☐
Does the policy encourage individualised and person-centred care?	Yes ☐ No☐ NA ☐
Could there be an adverse impact on an individual's independence or autonomy[7]?	Yes ☐ No☐ NA ☐

EXTERNAL FACTORS

Is the policy a result of national legislation which cannot be modified in any way?	Yes ☐ No☐

What is the reason for writing this policy? (Is it a result in a change of legislation/ national research?)

Who was consulted when drafting this policy?

Patients/ Service Users ☐	Trade Unions ☐	Protected Groups (including Trust Equality Groups) ☐
Staff ☐	General Public ☐	Other, please state… ☐

What were the recommendations/suggestions?

Does this document require a service redesign or substantial amendments to an existing process? ***PLEASE NOTE: 'Yes' may trigger a full EIA, please refer to the equality leads below***	Yes ☐ No☐

ACTION PLAN: Please list all actions identified to address any impacts

Action	Person responsible	Completion date

AUTHORISATION:
By signing below, I confirm that the named person responsible above is aware of the actions assigned to them

Name of person completing the form		**Signature**	
Validated by (line manager)		**Signature**	

Please contact the Equalities team for guidance:
For South Devon & Torbay CCG, please call 01803 652476 or email marisa.cockfield@nhs.net
For Torbay and South Devon NHS Trusts, please call 01803 656676 or email pfd.sdhct@nhs.net
This form should be published with the policy and a signed copy sent to your relevant organisation.

[1] Consider any additional needs of carers/ parents/ advocates etc, in addition to the service user
[2] Travelers may not be registered with a GP - consider how they may access/ be aware of services available to them
[3] Consider any provisions for those with no fixed abode, particularly relating to impact on discharge
[4] Consider how someone will be aware of (or access) a service if socially or geographically isolated
[5] Language must be relevant and appropriate, for example referring to partners, not husbands or wives
[6] Consider both physical access to services and how information/ communication in available in an accessible format
[7] Example: a telephone-based service may discriminate against people who are d/Deaf. Whilst someone may be able to act on their behalf, this does not promote independence or autonomy

Clinical and Non-Clinical Policies – Data Protection

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU General Data Protection Regulation (GDPR) and Data Protection Act 2018 (DPA 18) in mind, and therefore provides the reader with assurance of effective information governance practice.

The UK data protection regime intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy. Furthermore, data protection legislation requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data.

Does this policy impact on how personal data is used, stored, shared or processed in your department? Yes ☐ No ☐

If yes has been ticked above it is assured that you must complete a data mapping exercise and possibly a Data Protection Impact Assessment (DPIA). You can find more information on our GDPR page on ICON (intranet)

For more information:

- Contact the Data Access and Disclosure Office on dataprotection.tsdft@nhs.net,
- See TSDFT's Data Protection & Access Policy,
- Visit our Data Protection site on the public internet.