Lincolnshire Community Health Services NHS Trust

Guidance and Procedures for Pre-filling Insulin Syringes 2017-2019

Reference No:	G_CS_89
Version	1
Ratified by:	LCHS Trust Board
Date ratified:	14th November 2017
Name of originator / author:	Diabetes Specialist Team/Jane Scrafton
Name of responsible committee / Individual	Effective Practice Assurance Group
Date issued:	November 2017
Review date:	October 2019
Target audience:	Clinical Staff
Distributed via	Website

Diabetes Management Guidelines and Policy

Version Control Sheet

Version	Section / Para / Appendix	Version / Description of Amendments	Date	Author / Amended by
1		New Policy	October 2017	Jane Scrafton
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				

Guidance and Procedures for Pre-filling Insulin Syringes Contents

Guidance and Procedures for Pre-filling Insulin Syringes

Procedural Document Statement

Statement:
Lincolnshire Community Health Service will develop policies to fulfil all statutory and organisational requirements. These will be comprehensive, formally approved and ratified, disseminated through approved channels and implemented.

Background	The purpose of this guidance is to implement a co-ordinated and uniform approach to the clinical management of pre-filled insulin syringes to support management of diabetes.
Statement	Lincolnshire Community Health Service will develop policies to fulfil all statutory and organisational requirements. These will be comprehensive, formally approved and ratified, disseminated through approved channels and implemented.
Responsibilities	Compliance with the policy will be the responsibility of all Lincolnshire Community Health Service staff involved in delivering direct patient care or responsible for supporting those to deliver patient care.
Training	Directors/Heads of Service are responsible for making policy authors aware of the development and management process of all policy documents to be adopted by Lincolnshire Community Health Service
Dissemination	Website Training Email Intranet Team Brief / Newsletter
Resource implication	The policy has been developed in line with the NHS Litigation Authority guidelines to provide a framework for staff within NHS Organisations to ensure the appropriate production, management and review of organisation wide policies.

Section One
Guidance and Procedures for Pre-filling Insulin Syringes

1. Policy for Pre-filling of Insulin Syringes

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. 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).

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

2. 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 Services NHS 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).

3. 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 (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 'Safe use of insulin' is a mandatory requirement every two years with a pass mark of 80 per cent.
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 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).
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.
8. 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).
9. RNs are accountable to ensure that the patient is competent to carry out the task (Standard 17 NMC, 2010a).
10. RNs are responsible for implementing this policy. Pre-loading insulin syringes must not be delegated to non-registered staff.
11. 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.
12. 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).
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, 2015).

4 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 senior diabetes Pre-loading of insulin for injection must only begin following a full written risk assessment, involving the DSN, and the ruling out of alternative methods of administration.
3. 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)f or 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. 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.
7. Each time a nurse pre-loads a syringe, Appendix D (Documentation form for the advanced preparation of insulin in syringes) should be completed.
8. 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 colours or shapes.
9. 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.
10. It is recommended that insulin is most stable when stored at a temperature of between 2 and 8° Celsius. Never allow insulin to freeze. 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.
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.

5 Contra-indications

1. Insulin Lantus (Glargine) must not be preloaded into insulin syringes.
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 DSN 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

1. All staff involved with the care of these patients will receive a training session 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 feed back 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 clinical leads and specific medicines management training where appropriate.
4. All community nurses involved in insulin administration will undertake training as defined in training matrix including safe administration of insulin and classroom education sessions relevant to role.

7 Monitoring, auditing, reviewing and evaluation

This policy will be reviewed in two years through the Lincolnshire Community Health Services NHS Trust Care and Clinical Governance and Quality and Scrutiny Groups who will raise and take action to alleviate any concerns over the implementation of this policy. All patients receiving insulin by this methodology will be recorded and held on a register by the DSN. This should be available to the Quality and Risk group at their request.

8 References relating to prefilling of insulin syringes

Nursing and Midwifery Council (NMC) (2010a) *Standards for medicines management*.

www.nmc-uk.org/publications

Nursing and Midwifery Council (2015) *The Code. Professional standards of conduct, performance and ethics for nurses and midwives*. www.nmc-uk.org

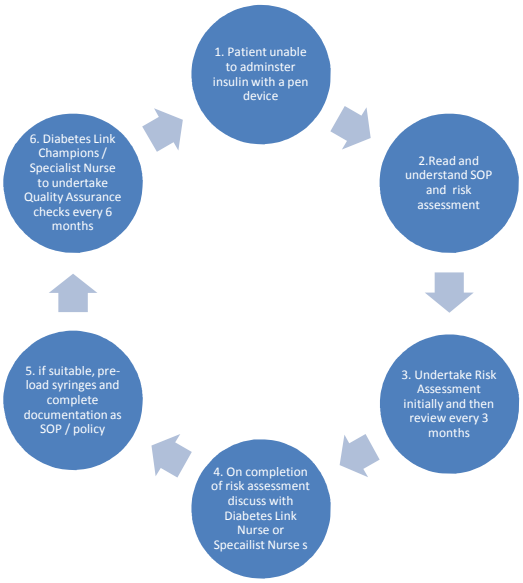
National Patient Safety Agency (2010) *Rapid response Report. Safer Administration of Insulin*. NPSA/2010/ RRR013.

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

Pre-filling Insulin Syringe Assessment	Pre-filling Insulin Syringe Assessment.(
Standard Operating Procedure for Pre-filling Insulin	Standard Operating Procedure for Prefillin
Risk assessment guide for the advanced preparation of insulin into syringes for a patient to administer at a later date	Risk assessment guide for the advanc
Documentation form for the advanced preparation of insulin in syringes	Documentation form for the advanced pre
Diabetes lead champion quality assurance for policy implementation	Diabetes lead champion quality assu



Adapted from RCN 2015

Monitoring Template

This template should be used to demonstrate compliance with NHSLA requirements for the procedural document where applicable and/or how compliance with the document will be monitored.

Minimum requirement to be monitored	Process for monitoring e.g. audit	Responsible individuals/group /committee	Frequency of monitoring /audit	Responsible individuals / group / committee (multidisciplinary) for review of results	Responsible individuals / group / committee for development of action plan	Responsible individuals / group / committee for monitoring of action plan
Bi-annual Review	Audit	Clinical Audit Group	Bi-annual	EPAG	CAG	EPAG
Incident Investigation	Datix Review	Adult Clinical Governance	Ongoing	Quality and Risk	Adult Clinical Governance	Quality and Risk
Training recorded ESR	ESR Audit	Clinical Audit Group	Annual	EPAG	Clinical Audit Group	EPAG

Equality Analysis

Introduction

The general equality duty that is set out in the Equality Act 2010 requires public authorities, in the exercise of their functions, to have due regard to the need to:

- Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Act.
- Advance equality of opportunity between people who share a protected characteristic and those who do not.
- Foster good relations between people who share a protected characteristic and those who do not.

The general equality duty does not specify how public authorities should analyse the effect of their existing and new policies and practices on equality, but doing so is an important part of complying with the general equality duty. It is up to each organisation to choose the most effective approach for them. This standard template is designed to help LCHS staff members to comply with the general duty.

Please complete the template by following the instructions in each box. Should you have any queries or suggestions on this template, please contact Equality and Human Rights Lead.

Name of Policy/Procedure/Function*
Diabetes Management Guidelines, Policy and Procedural Document 2017

Equality Analysis Carried out by: Jane Scrafton
Date: 19/07/2017
Equality & Human rights Lead:
Date: 13/10/2017
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	The purpose of this guidance is to implement a co-ordinated and uniform approach to the clinical management of Diabetes. This provides a clear expectations for staff and aims to ensure patient safety by providing best practice guidance.		
B.	Does the policy have an impact on patients, carers or staff, or the wider community that we have links with? **Please give details**	Sets standards and provides guidance to support high quality patient / carer interaction, information and care		
C.	Is there is any evidence that the policy\service relates to an area with known inequalities? **Please give details**	Diabetic population often include vulnerable people with multiple co-morbidities, functional and social difficulties. This policy is inclusive of all groups		
D.	Will/Does the implementation of the policy\service result in different impacts for protected?	This policy aims to ensure that no person receives less favourable treatment on the grounds of gender, sexual orientation, civil partnership/marital status, colour, race, nationality, ethnic or national origins, religion/belief, disability, age or caring responsibility.		
		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:		Jane Scrafton		
Date:		19/07/2017		

Section 2

Equality analysis

Title:
Relevant line in:

What are the intended outcomes of this work? *Include outline of objectives and function aims*
Who will be affected? *e.g. staff, patients, service users etc*

Evidence *The Government's commitment to transparency requires public bodies to be open about the information on which they base their decisions and the results. You must understand your responsibilities under the transparency agenda before completing this section of the assessment.*
What evidence have you considered? *List the main sources of data, research and other sources of evidence (including full references) reviewed to determine impact on each equality group (protected characteristic). This can include national research, surveys, reports, research interviews, focus groups, pilot activity evaluations etc. If there are gaps in evidence, state what you will do to close them in the Action Plan on the last page of this template.*
Disability *Consider and detail (including the source of any evidence) on attitudinal, physical and social barriers.*
Sex *Consider and detail (including the source of any evidence) on men and women (potential to link to carers below).*
Race *Consider and detail (including the source of any evidence) on difference ethnic groups, nationalities, Roma gypsies, Irish travellers, language barriers.*
Age *Consider and detail (including the source of any evidence) across age ranges on old and younger people. This can include safeguarding, consent and child welfare.*
Gender reassignment (including transgender) *Consider and detail (including the source of any evidence) on transgender and transsexual people. This can include issues such as privacy of data and harassment.*
Sexual orientation *Consider and detail (including the source of any evidence) on heterosexual people as well as lesbian, gay and bi-sexual people.*
Religion or belief *Consider and detail (including the source of any evidence) on people with different religions, beliefs or no belief.*
Pregnancy and maternity *Consider and detail (including the source of any evidence) on working arrangements, part-time working,*

infant caring responsibilities.
Carers *Consider and detail (including the source of any evidence) on part-time working, shift-patterns, general caring responsibilities.*
Other identified groups *Consider and detail and include the source of any evidence on different socio-economic groups, area inequality, income, resident status (migrants) and other groups experiencing disadvantage and barriers to access.*

• Engagement and involvement

Was this work subject to the requirements of the Equality Act and the NHS Act 2006 (Duty to involve) ? (Y/N)
How have you engaged stakeholders in gathering evidence or testing the evidence available?
How have you engaged stakeholders in testing the policy or programme proposals?
For each engagement activity, please state who was involved, how and when they were engaged, and the key outputs:

Summary of Analysis *Considering the evidence and engagement activity you listed above, please summarise the impact of your work. Consider whether the evidence shows potential for differential impact, if so state whether adverse or positive and for which groups. How you will mitigate any negative impacts. How you will include certain protected groups in services or expand their participation in public life.*

Now consider and detail below how the proposals impact on elimination of discrimination, harassment and victimisation, advance the equality of opportunity and promote good relations between groups.

Eliminate discrimination, harassment and victimisation *Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).*

Advance equality of opportunity *Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).*

Promote good relations between groups *Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).*

What is the overall impact? *Consider whether there are different levels of access experienced, needs or experiences, whether there are barriers to engagement, are there regional variations and what is the combined impact?*

Addressing the impact on equalities

Please give an outline of what broad action you or any other bodies are taking to address any inequalities identified through the evidence.

Action planning for improvement

Please give an outline of the key actions based on any gaps, challenges and opportunities you have identified. Actions to improve the policy/programmes need to be summarised (An action plan template is appended for specific action planning). Include here any general action to address specific equality issues and data gaps that need to be addressed through consultation or further research.

Please give an outline of your next steps based on the challenges and opportunities you have identified. Include here any or all of the following, based on your assessment

- **For the record**

Name of person who carried out this assessment:

Date assessment completed:

Name of responsible Director/ General Manager:

Date assessment was signed: