Pre-loading of insulin syringes for people with diabetes to administer at home: New solution to an old practice

Samantha Rosindale

There remains a small minority of people with diabetes who, for a range of reasons, have difficulty self-administering insulin using a syringe and are unable to use insulin pen devices despite the wide range available. To overcome this problem and in order to maintain the independence of the person with diabetes, some community nurses have been involved in drawing up insulin from a vial into a standard insulin syringe in advance of it being administered by the individual. The preparation of pre-loaded insulin syringes presents a medico-legal problem as this activity falls outside the bounds of the Medicines Act 1968 and creates an unlicensed use of the medicine (sometimes referred to as "secondary dispensing"). This article seeks to explore the legalities of the practice and how the Torbay & Southern Devon Health and Care NHS Trust have developed an NHS Trust clinical policy to continue to support people with diabetes who use pre-loaded insulin syringes and to provide vicarious liability for registered nurses who follow the policy.

Anecdotally, the pre-loading of insulin syringes (see *Box 1* for a definition) by community nurses for people with diabetes to self-administer in their own homes has been an established practice for many years. The main reasons for this practice have been to help people with problems of manual dexterity, to maintain people's independence and to improve their quality of life as laid out in Domain 2 in the NHS Outcome Framework (NHS England, 2013). This practice began before insulin pens were available, and not only preserves the individual's independence, but also reduces the risk of hypoglycaemia and releases nursing time because each person can administer their insulin at the correct time in relation to their meals.

Over the past few years, with the improvement of innovative insulin delivery devices, more people with diabetes have been able to find a pen device that suits their needs, and the number of people requiring pre-loaded insulin syringes has reduced. However, there still remains a small number of people with diabetes who require this practice as there is no insulin pen device suitable for their individual circumstances. There are currently no guidelines to support this practice, so the Torbay & Southern Devon Health and Care NHS Trust (TSDHCT) established their own policy to follow that would ensure safe practice and provide vicarious liability for nurses following this practice.

What are the important considerations surrounding the use of pre-loaded insulin syringes?

Legal and pharmaceutical

There are many potential legal and pharmaceutical issues associated with healthcare professionals pre-loading insulin syringes. Preparing pre-loaded insulin syringes for a person with diabetes to administer at home at a later time or date is commonly referred to as "secondary dispensing". There is no statutory definition of secondary dispensing, but, briefly, secondary dispensing is when a person who is not a pharmacist transfers drugs from the pharmacy container into a "secondary" container to hand to the individual requiring the medication. Secondary dispensing is not covered in the Medicines Act 1968 and, in legal terms, moving a drug to a secondary container forms a new medicine, which is the definition of drug manufacture. Another problem with secondary dispensing is that the secondary

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Article points

1. Pre-loaded insulin syringes are syringes of insulin that have been pre-prepared by a healthcare professional for a person with diabetes to use at a later time or date.
2. There are currently no recognised guidelines for healthcare professionals to follow when using pre-loaded insulin syringes.
3. The Torbay & Southern Devon Health and Care NHS Trust have developed an NHS Trust clinical policy with their solicitors to continue to provide support for people who require pre-loaded insulin syringes and to provide vicarious liability for those registered nurses who follow the policy.

Key words

- Care in the community
- Policy
- Pre-loaded insulin syringes

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Box 1. What does "pre-loading insulin syringes" mean?

A registered nurse drawing up insulin into a syringe from a vial and leaving the syringe in a suitable place for the person with diabetes to administer themselves at home at a later time or date.

container is usually not clearly labelled with the proper dose instructions, warning instructions or safe storage instructions for the individual they have been prescribed for. The act of pre-loading insulin into a syringe is a form of secondary dispensing and is an unlicensed activity; the pre-loaded insulin syringe itself also becomes an unlicensed product. Futhermore, the nurse preparing the pre-loaded insulin syringe is going outside the bounds of the Medicines Act 1968 so, if something were to go wrong, they would be potentially liable.

A second issue to be aware of surrounding the use of pre-loaded insulin syringes is the time between preparing of the syringe and the administration by the individual with diabetes. The Nursing and Midwifery Council (NMC) advises that dispensing drugs should include the following:

> "[...] checking the validity of the prescription, the appropriateness of the medicine for an individual patient, assembly of the product, labelling in accordance with legal requirements and providing information leaflets for the patient." (NMC, 2010)

It also states that:

> "Registrants must not prepare substances for injection in advance of their immediate use." (NMC, 2010)

The second point is important when considering the safety of individuals using pre-loaded insulin syringes, as well as the storage, stability and sterility of the insulin once drawn up in the syringe.

The safety of the individual with diabetes

Of course, insulin is used safely thousands of times a day. However, insulin as a drug is associated with the potential to cause serious harm if it is not prescribed, handled and administered properly.

In 2010, the National Patient Safety Agency (NPSA) issued two Rapid Response Reports (RRRs) entitled *Reducing harm from omitted and delayed medicines in hospital* (2010a) and *Safer administration of insulin* (2010b). The publishing of both RRRs highlighted the potential errors that could occur in relation to insulin administration: omitted doses, delayed doses, inappropriate use of non-insulin syringes (e.g. intravenous syringes, which are marked in mL not in units) and use of abbreviations such as "U" or "IU" for units. In the worst case scenario, these errors led to severe harm or death (NPSA, 2010b).

The common theme that surrounded all of the incidents that led to the NPSA reports (2010a; 2010b) was that every reported incident was as a result of an error made by a registered healthcare professional, who was involved with prescribing, preparing or administering the insulin. So whilst it remains a high-risk situation for the patient if the healthcare professional does not adhere to the RRRs, none of the reported errors were associated with the pre-loading of insulin into syringes. It could be suggested that people with diabetes who require pre-loaded insulin syringes have a lower risk of harm than someone who does not use insulin-prepared syringes because they are fully involved with what is prescribed, they can observe the preparation of insulin into the syringe, they can check accuracy and they self-administer their insulin.

As a result of the publication of the RRRs, NHS Diabetes and Virtual College have developed a suite of e-learning modules on the safer use of insulin to help healthcare professionals reduce insulin administration errors and save lives. NHS Diabetes has now merged with NHS Improving Quality and the insulin safety suite can be found at the following web address: http://www.healthcareea.co.uk/nhsdiabetes.

Storage, stability and sterility of pre-loaded insulin syringes in the home

Once the decision has been made to manage the diabetes of an individual with pre-loaded insulin syringes, an important consideration is how they will be stored in the homes of people with diabetes. It could be suggested that leaving pre-loaded insulin syringes in a domestic fridge could be associated with a risk of microbial contamination due to air entering the syringe through the needle and leading to possible infection (Kasmer et al, 1986; Jackson and Gallo, 1990).

Another consideration to keep in mind if the insulin syringe is not used immediately, is the stability of the syringe material. It is possible that constituents of the syringe (e.g. plasticising agents or lubricants) may migrate into the insulin preparation (Tarr et al, 1991). In essence, factors outside of the

Page points

1. Secondary dispensing is an important legality to consider when preparing pre-loaded insulin syringes.
2. Once in the home of the individual with diabetes, the storage, stability and sterility of the pre-loaded insulin syringes should not be forgotten.

insulin manufacturers' control will prevent them guaranteeing the stability of insulin stored in a syringe when it is not used immediately*.

Searches of the Cochrane and PubMed databases for published literature on the stability and sterility of pre-loaded insulin syringes were completed by me using terms related to "sterility" and "stability" of "insulin prefilled syringes" and "patient safety" of prefilled syringes. Overall, there was little research found on the sterility and stability of pre-loaded insulin in a syringe; the articles found were old and the methodology used for sterility testing was out-dated compared to modern standards. However, there were some finding of note: Kasmer et al (1986) showed that there was a low incidence (0.5%) of bacterial colonies forming after 28 days in animal and neutral protamine Hagedorn (NPH) insulin when pre-loaded insulin syringes were not refrigerated.

This was in contrast to articles published some years later. Jackson and Gallo (1990) and Koffler et al (1992) found no bacterial growth in refrigerated NPH insulin syringes between 10 and 28 days, although the numbers in these studies were a lot smaller than Kasmer et al (1986). Tarr et al (1991) also found that NPH insulin (both isophane and in a 30/70 mixture) would remain stable and sterile after 28 days of storage both at room and refrigerator temperatures in plastic insulin syringes. Nonetheless, one of their recommendations was that pre-filled syringes should be stored in the refrigerator because the concentration of the preservative in the insulin decreased more rapidly when stored at room temperature compared to refrigerator temperature. To date and to the best of my knowledge, the only analogue insulin that has been investigated for its stability in this way is Lantus® (insulin glargine; Sanofi, Guildford)†. The manufacturer, Sanofi, has found that insulin glargine becomes turbid (cloudy) within 7 days of room (5–25°C) and refrigerator (2–8°C) temperature, and, therefore, only recommends that it is drawn into a syringe and administered as soon as possible. Sterility has so far not been tested.

Prescribing and preparing syringes

When prescribing pre-loaded insulin syringes, an important consideration must be to inform the prescriber, usually the GP, that they are prescribing the administration of insulin in an unlicensed way, the decision for which is usually agreed by the patient and community nurse.

It is also important to consider when preparing the insulin into a syringe that it is done so from a 10-mL vial and not a 3-mL pre-filled pen or cartridge as they are designed differently. Insulin vials have an air space to reduce the pressure difference between the inside and outside of the vial when withdrawing insulin; pre-filled pens and cartridges do not. If air is injected into the cartridge in order to withdraw the insulin, in the same manner as when using a vial, the pressure inside the cartridge will increase and may cause the cartridge to crack. If air is not injected into the cartridge, the pressure will decrease and, once again, increase the potential to crack the cartridge. Cartridges, on the other hand, have been designed for the insulin to be pushed out by a pen plunger, rather than drawn out with a syringe.

As cartridges are not designed or intended for use with insulin syringes, there are no data to support this practice and it is not recommended by insulin manufacturers‡. The only situation where the practice may be advised is in an emergency‡. If this situation occurred, the pre-filled pen or cartridge should be disposed of immediately after use and the insulin cartridges should never be put back into an insulin delivery device or be re-filled.

The safety of pre-loaded insulin syringes use in the UK

The preparation of pre-loaded insulin syringes is not covered by the Medicines Act 1968 and insulin manufacturers are unwilling to support the practice. However, despite the lack of updated research on sterility and stability, the use of pre-loaded insulin syringes has continued among small groups of people with diabetes across the UK without any harm to patients to date, as discovered in the response to a Freedom of Information request issued by me in October 2013 to NHS England.

*Based on medical information letters sent from Eli Lilly (October and November 2013), Novo Nordisk (November 2013) and Sanofi (October 2013) to the author.

†Based on a medical information letter sent from Sanofi (October 2013) to the author.

‡Based on medical information letters sent from Novo Nordisk (October 2007) and Eli Lilly (November 2011) to the author.

Page points

1. An insulin cartridge should not be used to draw up insulin into a syringe.
2. Pre-loaded insulin syringes continue to be used by small numbers of people with diabetes across the UK.

Page points

1. Data released after a Freedom of Information request showed that NHS England had no record of any patient safety incidents caused by pre-loaded insulin syringes that caused serious harm, or of any incidents caused by contamination or infection.
2. Torbay & Southern Devon Health and Care NHS Trust developed a policy with their solicitors to continue providing pre-loaded insulin syringes for people with diabetes who were most in need of the extra support to maintain their independence and quality of life.
3. In the trust, the eight people who received pre-loaded insulin syringes had an average age of 80 years, stable diabetes control and HbA_{1c} between 58 mmol/mol (7.5%) and 76 mmol/mol (9.1%).

I requested information on any recorded reports of patient safety incidents relating to the use of pre-loaded insulin syringes in the last 12 months, but ideally also in the past 5 to 10 years. NHS England searched through the National Reporting and Learning System and found 30 reported patient safety incidents over 8 years (between 2005 and 2013)*. Twenty-six of these instances had caused "no harm" to the individual (defined as "impact prevented: any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to the person(s) receiving NHS-funded care."). The remaining four instances had caused "low harm" (defined as "any patient safety incident that required extra observation or minor treatment, and caused minimal harm to the person(s) receiving NHS-funded care"). NHS England had no record of any patient safety incident causing "moderate harm", "serious harm" or "death", or of any incidents caused by contamination or infection.

The situation at Torbay & Southern Devon Health and Care NHS Trust

Despite the potential legal and professional complexities surrounding the practice of pre-loading insulin syringes, TSDHCT wanted to continue providing the service for people with diabetes who were most in need of the extra support to maintain their independence and quality of life.

As an NHS care trust with unique integrated health and social care services and a drive to enhance independent living, it was decided to pursue a policy to support the practice of pre-loaded insulin syringes with tight parameters for patient inclusion and clear practice standards and guidelines for healthcare professionals.

The Royal College of Nursing (RCN) produced definitive guidance for community nurses to support this practice (RCN, 2006), which the trust felt could be referenced to support its case to continue with the practice. The RCN guidance would also help to underpin any subsequent corporate clinical policy that the TSDHCT produced.

Review of pre-loaded insulin syringe use in the trust

In 2010, when the trust first reviewed the practice of pre-loading insulin syringes for people with diabetes to administer themselves, it found that there were eight people in its care who were supported by a community nurse preparing pre-loaded insulin syringes (0.05% of the diabetes population).

Four of these eight individuals needed weekly visits by a community nurse who would leave 7 days' worth of pre-loaded insulin syringes for the individual to administer for the week. The other four people required morning visits from a nurse who would prepare the syringe and watch them administer their morning dose. The nurse would then leave the evening dose of insulin pre-loaded in a syringe ready for the individual to administer later that day.

The eight people who received pre-loaded insulin syringes had an average age of 80 years, stable diabetes control and HbA_{1c} between 58 mmol/mol (7.5%) and 76 mmol/mol (9.1%). The reasons why their diabetes was managed in this way included the following: they were registered blind, they were unable to count, they had a lack of confidence drawing up the insulin into the syringe and they had reduced dexterity in both hands.

Pre-loaded insulin syringe policy

After a period of consultation, the trust developed a policy for the use of pre-loaded insulin syringes that was approved by TSDHCT solicitors. It would not be possible to reverse the Medicines Act 1968, but the legal constraints could be satisfied under vicarious liability (legal doctrine that assigns liability to the employer [TSDHCT] not the employee). The policy set clear and tight parameters of where and when the use of pre-loaded insulin syringes was considered necessary and offered support and training to staff involved in the process.

Policy "must haves"

To satisfy the legalities of the pre-loaded insulin syringe policy, the trust solicitors stipulated that a thorough risk assessment was to be completed for every individual with diabetes that required the use of pre-loaded insulin syringes and that it was updated every 3 months by the community nurse. Every 6 months the Diabetes Lead Champion

*The following information is taken from email correspondence between the author and NHS England.

would visit the individual at home to ensure patient satisfaction with the service, strict policy adherence and quality assurance (QA) of the whole process. It was also stipulated that the GP and community nurse, who prepared the syringes, needed training and guidance for their own responsibilities and accountability in prescribing and preparing the syringes for this practice. Each individual involved in the practice had specific elements in the policy that they had to adhere to.

Essential elements for the person with diabetes who requires pre-loaded insulin syringes

For the person with diabetes the essential elements that need to be included and checked in the risk assessment are the following:

- They must have a Mental Capacity at Level 3, which is defined by the Mental Capacity Act 2005 as "the patient accepts full responsibility for the storage and administration of the medicinal products."
- They must understand, consent and agree to receive treatment for diabetes with the use of pre-loaded insulin syringes.
- They must have been assessed to confirm that they cannot use any of the other first-line licensed alternatives that are currently available (e.g. other insulin pen devices).
- They must understand the name of the insulin, why they are taking it, the insulin time action profile and the dose and frequency of injections that they need.
- They must be able to demonstrate competence and understanding in the correct injection technique and site rotation.
- They must be able to discuss the signs, symptoms and treatment of a hypoglycaemic event.
- They must know how to store and obtain further supplies of insulin and syringes (pre-loaded insulin syringes must be labelled individually and stored in a wipeable, labelled, sealable, hinge-lidded container in the door or top shelf of the fridge).
- They must be able to correctly dispose of used sharps.
- They must know the frequency of visits by the community nurses and have a contact number for any problems between visits.

Essential elements for the registered community nurse

The essential elements that the registered community nurse must adhere to are the following:

- They must involve the Diabetes Lead Champion in each case (essential to ensure that all other first line-licensed alternatives had been considered, e.g. other pen devices).
- They must update the risk assessment every 3 months (essential to ensure that the person with diabetes maintains full mental capacity and agreement to take an active part in the use of pre-loaded insulin syringes).
- They must NOT delegate administration to a healthcare assistant.
- They must prepare the minimum number of syringes that have been assigned to each person with diabetes (to a maximum of 7 days).
- They must label each syringe with content, time and date of preparation.
- They must label each storage box with the individual's name, insulin type, number of syringes prepared, time and date.
- They must not mix different types of insulin together.

Working in this way ensures that each nurse will take the same approach in the way they perform the preparation of the syringes (e.g. appropriateness of the patient, labelling and storage). Once all of these steps are complete, vicarious liability protection can be afforded to nursing staff who adhere to the policy.

Essential elements for the GP

The essential elements that the GP of the individual with diabetes must adhere to are the following:

- They must be aware, understand and be in agreement that prescribing the pre-loaded insulin syringes has medico-legal issues attached, and that there is a policy that exists to support this process in the trust.
- There is a patient-specific letter from the Diabetes Lead Champion and Head of Medicines Management at TSDHCT to the GP that is to be kept on the individual's medical notes. It outlines the legalities of the situation and QA processes.

Page points

1. To satisfy the legalities of the pre-loaded insulin syringe policy, the trust solicitors stipulated that a thorough risk assessment was to be completed for every individual with diabetes that required the use of pre-loaded insulin syringes and that it was updated every 3 months by the community nurse.
2. People with diabetes who required this practice were required to understand their treatment, how to manage their diabetes and how to store and dispose of the insulin syringes.
3. Having the policy in place ensures that each nurse takes the same approach in the way they performed the preparation of the syringes so that they are afforded vicarious liability protection.

"The policy also seeks to promote patient safety and ensures that registered nurses are aware of the potential risks of pre-loading insulin syringes for later use by a person with diabetes."

Essential elements for the diabetes specialist nurse

The responsibilities of the diabetes specialist nurse (DSN) are the following:

- They must identify the legal complexities and risks to nursing staff, and relay them to the employing organisation's Trust Board.
- They must develop a clinical policy that sets out a clear framework of roles and responsibilities, principles of practice and contraindications.
- They must monitor, audit, review and evaluate all individuals with diabetes and staff who are involved in the preparing of pre-loaded insulin syringes on a 6-monthly basis.
- They must provide training and ongoing clinical advice and support as required.

Outcomes since the policy was implemented

Since the development and implementation of the policy in 2010, the number of people receiving diabetes care by pre-loaded insulin syringes in the trust and the reasons for its use have remained similar. The policy has continued to evolve and has been updated and peer reviewed; feedback from staff is that it is easy to follow and implement into practice. It has been successful in continuing to enable people to self-manage their diabetes, in spite of physical and emotional difficulties. It also continues to uphold the TSDHCT corporate ethos of enhancing independent living.

Final remarks

In the current economic climate where community nurse workloads are increasing in both number and clinical complexity, there is the potential for the use of pre-loaded insulin syringes to be abused as a way of merely saving community nurse visits and time. Having a policy and standard operating procedure provides a clear and consistent framework across the TSDHCT for the appropriate assessment and management of a person with diabetes who cannot safely prepare their own insulin dose. It also seeks to promote patient safety and ensures that registered nurses are aware of the potential risks of pre-loading insulin syringes for later use by a person with diabetes. Strong leadership from a DSN ensures policy adherence and that quality is maintained at all times.

The RCN withdrew its guidelines *Advanced preparation of insulin syringes for patients to administer at home* (2006) in 2012 because it did not address all the legal issues and was declared not fit for purpose. As a new committee member for the RCN Diabetes Forum, I am now actively involved with the RCN to provide practice guidance to replace this document by the end of Autumn 2014. ■

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