

# **Patient Safety Alert NPSA/2011/PSA003**

## **The adult patient's passport to safer use of insulin**

March 2011

### **Supporting Information**

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## 1. About this document

This document provides additional information and guidance for the interpretation and implementation of the National Patient Safety Agency (NPSA) Patient Safety Alert *The adult patient's passport to safer use of insulin*.

In developing local policies and procedures, it is recommended that further advice is sought from subject experts in diabetes, and patients who have diabetes and use insulin.

## 2. Background

Use of insulin in diabetes is complex. It involves a large and growing healthcare population. The Association of Public Health Observatories Diabetes Prevalence Model update of 28 September 2010 estimated that there were 3,099,853 people in England with diabetes<sup>1</sup> and insulin is frequently included in lists of the top 10 high-alert medicines worldwide.<sup>2,3,4,5</sup> Fatal patient safety incidents involving patients with diabetes have been reported by the media.<sup>6</sup>

Incorrect insulin treatment has been identified as an important cause of hospital admissions.<sup>7,8,9</sup> This is commonly as a result of severe hypoglycaemia from administration of too much insulin in relation to food intake.<sup>10</sup> As well as hypoglycaemic events, treatment of diabetes with insulin needs to be carefully managed to avoid disease progression, hyperglycaemia and complications such as diabetic ketoacidosis.

Patient safety incidents reported to the NPSA's National Reporting and Learning System (NRLS) confirm the link between errors and hypoglycaemic or hyperglycaemic events. Errors associated with insulin therapy are avoidable, and the costs of managing severe hypoglycaemia are significant in the UK and Europe.<sup>11</sup> Patients with type 1 diabetes typically experience between 1.0 and 1.7 severe hypoglycaemic events per year.<sup>12</sup> In the UK in 2007, the average cost across all healthcare settings of treating a single event of severe hypoglycaemia was £208.<sup>13</sup> If a rough, rounded estimate of the number of people with type 1 diabetes in England and Wales is taken to be 250,000, then as a conservative estimate the annual cost of treating 1.35 severe hypoglycaemia events per year at a cost of £200 per event is £67,500,000.

Safety issues with insulin use arise from:

- a lack of vigilance to prevent medication errors, resulting in use of the wrong insulin products;
- poor systems for managing insulin therapy in hospitals;
- a lack of education and access to information about diabetes management including the safe use of insulin, injection technique, hypoglycaemia and hyperglycaemia;
- lack of patient awareness of the symptoms of hypoglycaemia and hyperglycaemia; and,
- poor monitoring and adjustment of insulin doses.

There is a well-developed system of support for patients who have diabetes. Mechanisms exist for blood glucose monitoring, recording of doses, notifying personal details and providing tracking of relevant laboratory data. Such resources are often specific to individual insulin products, and are provided free to the NHS by pharmaceutical companies.

Information on diabetes is provided by government to healthcare professionals and patients ([www.diabetes.nhs.uk](http://www.diabetes.nhs.uk)). Patients have a dedicated organisation providing a range of products and services (<http://www.diabetes.org.uk>, [www.iddtinternational.org](http://www.iddtinternational.org)) and there are specialist research organisations such as the Juvenile Diabetes Research Foundation ([www.jdrf.org.uk](http://www.jdrf.org.uk)).

Ensuring the insulin products that patients use are correct, that the dose is right and that patients self-administer insulin in hospital whenever appropriate, will go a long way towards improving the safety of patients with diabetes.

### 3. Scope

The Patient Safety Alert applies to patients who are 18 years or over. It does not apply to children and young persons under the age of 18. It aims to ensure that adult patients who are 18 years or over:

- are offered the use of an Insulin Passport to record information on the insulin products they use;
- are given a patient information booklet which describes known error-prone situations and actions that might minimise harm;
- receive support from healthcare professionals to put the risk of error in context and complete details in the Insulin Passport;
- are advised to self-administer their insulin as hospital inpatients when it is safe and practical to do so; and,
- benefit from greater vigilance by healthcare practitioners that the correct insulin products are prescribed and dispensed.

Situations outside the scope of this Patient Safety Alert are described in the following sections.

#### ***Identification of the need for an Insulin Passport and patient information booklet***

Patients who have diabetes, and healthcare professionals working with patients who have diabetes, advised the NPSA against duplicating the resources currently available. As a result of this advice and following a literature search, a decision was made to develop an insulin passport rather than a national diary.

The NPSA is only aware of one adult 'insulin passport' currently in existence in the UK. This is an A5 multiple-page document, developed specifically to facilitate transfer of information across the primary care/secondary care interface (the Hospital Passport is available from [www.iddtinternational.org](http://www.iddtinternational.org)). A new insulin passport was, therefore, developed with the objective of enabling patients and healthcare professionals to check the accuracy of prescribing, dispensing and administering of insulin as well as providing a mechanism for transferring patient safety information across all healthcare interfaces.

Research to date has only concerned insulin diaries or diabetic passports, which were not designed specifically to minimise insulin errors.

The nature of errors revealed by analysis of the NRLS was conveyed to subject experts and patients who have diabetes and use insulin. Following discussions, the NPSA also identified

the need to provide patients with an information booklet detailing the key error-prone situations.

## Children and young people

Patients under 18 who have diabetes and use insulin are not within the scope of this Patient Safety Alert, although the use of the adult Insulin Passport and information booklet is an option available to them and their healthcare professionals.

Children and young people with diabetes who use insulin are cared for by specialist secondary care teams and have extensive information given to them and their families at diagnosis and then at follow up thereafter. They are generally seen every three months in specialist clinics run by a paediatrician and specialist nurse who both have training in paediatric diabetes. The nurse will also have regular contact and input with the child or young person and their family. The information the patient needs and what they need to understand will change as the child grows older and their lifestyle changes. A variety of information booklets suitable for different ages is available. There is an Insulin Passport for children and young people with similar features to the adult Insulin Passport.

## The products

We have produced:

- an Insulin Passport; and,
- a patient information booklet, *Diabetes: insulin, use it safely*

An Insulin Passport has been designed as a single, double-sided sheet that folds up to credit-card size with cardboard covers for added resilience. It contains the necessary information for emergencies and safe use of insulin as patients transfer across healthcare providers.

Use of the Insulin Passport and further information to help patients use their insulin safely is fully explained in a dedicated patient information booklet '*Diabetes: insulin, use it safely*' specifically designed for adults who are 18 years or older.

Previous implementations of diabetes passports have failed to provide the necessary structural support within the healthcare delivery system.<sup>14</sup> The current initiative will benefit, through compliance with the Patient Safety Alert, from embedding local policies and procedures that engage healthcare practitioners. Tracking of implementation and the availability of the Insulin Passport and patient booklet will also be enabled.

Following requests from patients, the Insulin Passport includes an optional facility for patients to indicate their concurrent medication. It is for patients, in discussions with their healthcare professionals, to determine the risks and benefits of using this facility. One potential risk is that the information is not up-to-date and could be misleading. A benefit is that it signals to healthcare professionals what other medication(s) a patient should be taking. This can be used as a resource to avoid wrong product errors in the same way that the Insulin Passport focuses on insulin products. A further benefit is that it acts as an alert card in an emergency.

## ***Use of the NPSA developed products***

The NPSA recommends the use of the Insulin Passport and patient information booklet available from NHS non-secure forms (see the later section 'Obtaining the Insulin Passport and patient information booklet'). The Patient Safety Alert does not mandate use of the NPSA Insulin Passport or patient information booklet. Providers of diabetes services in conjunction with patients can develop their own versions, provided they comply with the principles of the NPSA products as stated below.

### **Essential core information**

The NPSA has evidence of specific error categories. Any alternative products must make these error-prone situations known. Any alternative to the Insulin Passport must facilitate patients receiving the correct insulin products and allow for details of concurrent medications. Full responsibility for alternatives to the Insulin Passport and patient information booklet rests with the developer.

### **The focus on specific types of error**

Adverse patient incidents with insulin reported to the NRLS indicated three main types of error.

- Getting the wrong insulin product(s).
- Having insulin omitted or delayed.
- Getting the wrong dose of insulin.

Existence of these error types has been independently confirmed. They accounted for 60 per cent of insulin adverse drug incidents reported in the UK and 67 per cent of insulin incidents reported in the USA.<sup>15</sup>

Given the evidence and extent of error, the Insulin Passport is designed to ensure information on each patient's insulin product(s) can be made readily available. A patient information booklet has been produced to explain the nature of error. This includes awareness of the need to ensure the correct dose is administered and to encourage self-administration of insulin whenever possible. As only four per cent of error was associated with children and young people with diabetes who use insulin, the NPSA was positive in its decision to focus on adults with this initiative.

While no patient safety incidents were received implicating the 500 unit per millilitre strength of insulin used by patients with type 2 diabetes and insulin resistance, healthcare professionals should be vigilant that these patients may require additional support to minimise potential errors and mistakes. Care must be taken in highlighting the strength of insulin products if such patients choose to adopt the Insulin Passport.

### **Patient self-administration**

Dosing errors and incidents of omission and delay were commonly reported from an in-patient environment where insulin was administered by healthcare staff. The NPSA has received reports of death and severe patient harm where basal insulin had been omitted for patients designated 'nil-by-mouth' or fasting. Empowering patients to self-administer was seen as a logical method of improving safety, particularly in relation to ensuring correct dosing and time of administration. The case for increased patient safety by empowering

patients to self-administer in hospital has been made and included as a recommendation for NHS hospitals.<sup>16</sup> Assuming that patients are motivated, assessed as safe to give their own insulin, willing to assume responsibility and empowered, then self-administration of insulin in hospitals is seen as a proactive way of minimising such error.

Hospital policies and procedures to allow patients the option of self-administration of insulin will need to take account of complex in-patient situations when patients will require short-term help with their insulin administration. Examples are when they are sedated, temporarily incapable of taking decisions or misunderstand situations such as 'nil-by-mouth'. Healthcare professionals should be vigilant for such error-prone situations. While the default scenario is that patients should be able to self-administer where feasible, policies and procedures should enable appropriate transfer of responsibilities for insulin administration between patients and healthcare staff. Policies and procedures for patient self-administration should also include the following:

- specified mechanisms for recording patients' self-administered doses;
- access to self-blood glucose monitoring and quality control equipment; and,
- access to insulin via bedside locker for storage.

### Professional responsibility

Healthcare professionals who prescribe insulin are responsible for issuing patients with a patient information booklet and an Insulin Passport. They are also responsible for issuing a replacement Insulin Passport when there is no space left for new information, it has been lost or it has become unreadable.

Changes in patients' circumstances, their insulin products, other drug therapy (if recorded) and information that needs to be communicated in order to help patients use their insulin safely should be reflected as soon as is practical in the Insulin Passport.

Healthcare professionals must be available to assist patients in completing the Insulin Passport, and specifically in how to describe their insulin products so that there is no ambiguity in what they are using.

The patient information booklet *Diabetes: insulin, use it safely* provides essential information that patients should be aware of in order to be safe with their insulin use. It directs patients to show the Insulin Passport to healthcare professionals in order that they are fully informed during the prescribing and dispensing process.

Local protocols and policies should describe clear processes and audit benchmarks for cross-checking information in the Insulin Passport during the prescribing and dispensing processes, and to identify and document if patients decide not to follow the recommendations in the Patient Safety Alert.

Factors beyond the control of patients or healthcare professionals may mean it is not possible to use a patient's Insulin Passport for the purposes of validating the correct insulin product(s). While every effort should be taken to confirm the accuracy of prescribing and dispensing, the risks in this situation should be acknowledged and all actions to promote patient safety recorded. Local protocols and policies should describe clear processes and audit benchmarks when it is not possible to cross-reference and confirm the accuracy of prescribing or dispensing.

Patients who have diabetes and use insulin should be offered the patient information booklet and given the opportunity to discuss its content with a healthcare professional. This is so

that they can better understand the nature of error with insulin, judge the relative risk of common errors and understand measures they can take to reduce the risk of error. Without professional advice the information may appear frightening and be taken out of context. This is because, although errors do on occasions happen, they are rare. Patients may need help to balance the risks of known errors with the necessary actions of carrying an up-to-date Insulin Passport and being vigilant as to error-prone situations.

Appendix two (page 15) provides further information to assist healthcare professionals to advise patients. It is not intended that the appendix is given to patients, rather that healthcare professionals read this material and then judge how best to use the material to complement the patient information booklet.

Healthcare professions play a pivotal role in making patients aware of the issues and reassuring them that, while errors do happen, they are very unlikely. In most situations, the benefits of using the passport should outweigh the risks.

The Insulin Passport will not suit all patients with diabetes. There may be circumstances where, in the judgement of the healthcare professional, patients are not able to develop a balanced approach to the inherent risks of insulin use. Such circumstances should be fully documented and alternative arrangements made to minimise the problems of errors with insulin use outlined in the Patient Safety Alert.

This Patient Safety Alert does not override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or carer.

## **Continuing professional development**

For healthcare staff an e-learning programme is available from NHS Diabetes: [www.diabetes.nhs.uk/safe\\_use\\_of\\_insulin](http://www.diabetes.nhs.uk/safe_use_of_insulin). For pharmacy staff the Centre for Postgraduate Pharmacy Education (CPPE) Safer use of insulin learning@lunch flex module is available.\*

## **Obtaining the Insulin Passport and patient information booklet**

Copies of the Insulin Passport and patient booklet are available in Microsoft Word format at [www.nrls.nhs.uk/alerts](http://www.nrls.nhs.uk/alerts) for information. Supplies of these new items in English and in Welsh will be available from April 2011, from the current NHS Non-Secure Contract held by 3M. Orders can be placed as follows:

Telephone: 0845 610 1112  
Email: [nhsforms@spsl.uk.com](mailto:nhsforms@spsl.uk.com)

If you have access to the electronic ordering system 'Astroweb', you can place your orders this way. This contract is currently managed by Kay Ellermeyer, National Programme Manager, NHS Non-Secure Forms. You can contact her on 01244 650458 or email [kay.ellermeyer@wcheshirepct.nhs.uk](mailto:kay.ellermeyer@wcheshirepct.nhs.uk)

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\* This is understood to be available from end March 2011. <http://www.cppe.ac.uk/learning@lunch>

## 4. Review of evidence of harm

All medication incident reports received by the NRLS between 1 November 2003 and 1 November 2009, which included the term 'insulin' or the proprietary names of current insulin products, were selected. Deaths and severe patient safety incidents were clinically validated using the current NPSA criteria (appendix one) and the results published.<sup>17</sup>

A total of 16,600 incidents involving insulin were identified and 24 per cent reported harm to the patient. There were 18 incidents with fatal and severe outcomes (Table 1).

**Table 1. The degree of harm from incidents involving insulin**

| Degree of harm <sup>†</sup> | Incidents     | Percentage  |
|-----------------------------|---------------|-------------|
| Death                       | 6             | <<1%        |
| Severe                      | 12            | <<1%        |
| Moderate                    | 1042          | 6%          |
| Low Harm                    | 2914          | 18%         |
| No Harm                     | 12,626        | 76%         |
| <b>Total</b>                | <b>16,600</b> | <b>100%</b> |

Incidents were reported at all stages of the medication process. The majority (61 per cent) occurred during insulin administration with a further 17 per cent caused by prescribing errors and 10 per cent at dispensing.

Qualitative analysis showed that the top three medication error types were wrong dose, omitted or delayed insulin and wrong insulin product. Quantitatively these accounted for over 60 per cent of all incidents reported (Table 2).

**Table 2. The medication error type involving incidents with insulin**

| Medication Error Type             | Incidents     | Percentage* |
|-----------------------------------|---------------|-------------|
| Wrong dose, strength or frequency | 4,256         | 26%         |
| Omitted or delayed doses          | 3,390         | 20%         |
| Wrong insulin product             | 2,390         | 14%         |
| Other                             | 6,564         | 40%         |
| <b>Total</b>                      | <b>16,600</b> | <b>100%</b> |

\* Note % value rounded up

<sup>†</sup> Note categories of harm are defined in Appendix one.

## Qualitative themes (with example incidents)

### Wrong dose, strength or frequency

*Patient found unresponsive at 06:40am. Assisted onto bed, crash team called. Highest blood glucose during arrest 1.2mmol. The previous day the patient had received 2 doses of long-acting insulin (glargine) instead of one at 11:50 and 21:00.*

*The patient received double doses of insulin due to insulin being prescribed on Diabetes Treatment Chart and drug inpatient medication chart. The patient had a hypoglycaemic attack, which led to arrest and unsuccessful resuscitation.*

### Omitted or delayed

*The patient had type 1 diabetes, 75 years old, on once daily insulin glargine. She was not eating, so insulin was not given for three days. She developed diabetic ketoacidosis (DKA) PH 7.19, BM sticks 22.6. She was treated but prognosis was poor and she failed to recover from her operation, C. Difficile and DKA.*

*The patient, who had type 1 diabetes had her Insulin omitted (not given) for 48hrs. Resultant DKA and cardiac arrest. Resuscitated successfully, however, remains critically ill.*

*[Similar patient experiences have been reported to Diabetes UK - On being admitted for an operation..., my insulins and syringes were removed and taken into the "Care" of the Sister. I was informed that I was not permitted to administer any "Medication" and this would be performed by a member of Staff. Guess what? No member of Staff had the required certification to deliver this.<sup>18</sup>]*

### Wrong insulin product

*The patient was given the wrong insulin by the pharmacist (Novorapid instead of Novomix), which resulted in significant hypoglycaemia associated with fall and confusion. Fortunately the patient was found by the daughter and brought to hospital.*

*The patient was prescribed and administered the wrong type of insulin. Prescribed and administered Humalog Rapid insulin twice a day and instead of Humalog Mix insulin twice a day. Episodes of severe and persistent hypoglycaemia.*

*The patient was an inpatient on [a ward]. She attended a drop in session at the diabetes clinic on [date]. Observations were stable. She returned a few days later. The insulin pen she had been given to taken home and which she had been using contained the wrong insulin. The pens were very similar in colour - grey/purple.*

## 5. Summary of rationale for recommended actions

This table provides a summary of how the incident reports and literature explored above informed our recommended actions.

An executive director, nominated by the chief executive, working with relevant medical and nursing staff, the lead pharmacist and patient groups should ensure, through reviewing policies, procedures and staff training, the following actions are taken:

| No | Actions                                                                                                                                                                                                                                 | Summary of rationale                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1  | Adult patients on insulin therapy receive a patient information booklet and an Insulin Passport, to help provide accurate identification of their current insulin products and provide essential information across healthcare sectors. | <p>The NPSA has evidence of three areas of patient safety incidents relating to insulin therapy. Patients are more likely to receive the correct insulin products if they carry a record of what they should be given. Patients should be vigilant that they are administered the correct dose of insulin. A patient information booklet with information on error-prone situations has been developed to empower patients with knowledge and ways of avoiding harm.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 2  | Healthcare professionals and patients are informed how the Insulin Passport and associated patient information can be used to improve safety.                                                                                           | <p>To be effective, adult patients who have diabetes and use insulin and their carers need to understand how and why their Insulin Passports can be used to minimise the risk of error.</p> <p>On occasions, patients and healthcare professionals will each have information relevant to the Insulin Passport. Both must understand how they can best work together to minimise the possibility of errors. It is a priority to ensure that the information on insulin held in an Insulin Passport is up-to-date.</p> <p>It must be recognised that the Insulin Passport is neither designed nor intended to be used for blood glucose monitoring or as a dosing diary.</p> <p>Healthcare professionals are asked to use the patient information booklet to discuss with patients error-prone situations and what can be done to make the use of insulin safer. Offering the booklets to patients as a resource should provide a reminder of such situations.</p> |

| No | Actions                                                                                                                                                                                      | Summary of rationale                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3  | When prescriptions of insulin are prescribed, dispensed or administered, healthcare professionals cross-reference available information to confirm the correct identity of insulin products. | <p>A preventable error is the prescribing and/or dispensing of incorrect insulin products.</p> <p>The likelihood of error is compounded by similarities in products and their names.</p> <p>The Insulin Passport is a record of the patient's current insulin products. It provides an additional check to make a patient's use of insulin safer. Where there is a discrepancy between the Insulin Passport, a patient's notes or current understanding of insulin therapy, it should be reconciled and the information in the Insulin Passport updated.</p>                               |
| 4  | Systems are in place to enable hospital inpatients to self-administer insulin where feasible and safe.                                                                                       | <p>The NHS recognises that patients are well placed to continue their own diabetes care in hospitals if it is feasible and safe to do so.</p> <p>The NPSA has evidence of dosing errors and omissions and delays in insulin administration leading to patient harm when responsibility for treatment is devolved to the healthcare system. This action facilitates patients maintaining their personal responsibility while in hospital.</p> <p>Healthcare practitioners are still responsible for the appropriate administration of insulin therapy while patients are in their care.</p> |

## 6. Suggested compliance checklist

This checklist gives examples of what needs to happen before the Central Alerting System (CAS) can be updated as 'Action Complete'.

| No | Action                                                                                                                                                                                                                                 | Compliance with Action                                                                                                                                                                                                                                                                                                                                                                                                                                               | Compliant Y/N                 |
|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| 1  | Adult patients on insulin therapy receive a patient information booklet and an Insulin Passport to help provide accurate identification of their current insulin products and provide essential information across healthcare sectors. | a) Local policies and procedures specify the requirement to issue and support the use of the Insulin Passport and information booklet.<br><br>b) Record that the above has been reviewed and approved by an organisational committee.<br><br>c) Local policies and procedures specify the actions and records required if the patient, carer or responsible healthcare professional makes an informed choice that the patient is not to engage with this initiative. | Y/N<br><br><br>Y/N<br><br>Y/N |
| 2  | Healthcare professionals and patients are informed how the Insulin Passport and associated patient information can be used to improve safety.                                                                                          | a) Policies and procedures describe mechanisms or systems to effectively communicate the necessary responsibilities to patients and healthcare professionals. The communication strategy should be formally recorded.                                                                                                                                                                                                                                                | Y/N                           |
| 3  | When prescriptions of insulin are prescribed, dispensed or administered, healthcare professionals cross-reference available information to confirm the correct identity of insulin products.                                           | a) Policies and procedures describe mechanisms or systems that confirm safe prescribing, dispensing and/or administration will be undertaken, and where available that this is with reference to the information in patients' Insulin Passport.                                                                                                                                                                                                                      | Y/N                           |
| 4  | Systems are in place to enable hospital inpatients to self-administer insulin where feasible and safe.                                                                                                                                 | a) Policies and procedures stipulate the mechanism whereby hospital inpatients who have diabetes and require insulin can be offered the option to self-administer.                                                                                                                                                                                                                                                                                                   | Y/N                           |



## Appendix one: categories of harm<sup>19</sup>

|                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>No harm</b>       | <p><b>Incident prevented</b> any patient safety incident that had the potential to cause harm but was prevented, and no harm was caused to patients receiving NHS-funded care.</p> <p><b>Incident not prevented</b> any patient safety incident that occurred but no harm was caused to patients receiving NHS-funded care.</p>                                                                                                                                                 |
| <b>Low harm</b>      | <p>Any patient safety incident that required extra observation or minor treatment and caused minimal harm to one or more patients receiving NHS-funded care.</p> <p>Minor treatment is defined as first aid, additional therapy, or additional medication. It does not include any extra stay in hospital or any extra time as an outpatient, or continued treatment over and above the treatment already planned; nor does it include a return to surgery or readmission.</p>  |
| <b>Moderate harm</b> | <p>Any patient safety incident that resulted in a moderate increase in treatment and that caused significant but not permanent harm to one or more patients receiving NHS-funded care.</p> <p>Moderate increase in treatment is defined as a return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another area such as intensive care as a result of the incident.</p> |
| <b>Severe harm</b>   | <p>Any patient safety incident that appears to have resulted in permanent harm to one or more patients receiving NHS-funded care.</p> <p>Permanent harm directly related to the incident and not related to the natural course of the patient's illness or underlying condition is defined as permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of the wrong limb or organ, or brain damage.</p>                        |
| <b>Death</b>         | <p>Any patient safety incident that directly resulted in the death of one or more patients receiving NHS-funded care.</p> <p>The death must be related to the incident rather than to the natural course of the patient's illness or underlying condition.</p>                                                                                                                                                                                                                  |

## **Appendix two: information to help healthcare professionals in advising patients**

The following information is an elaboration of the adult patient information booklet. It provides further actions and material in a manner that healthcare professionals may find helpful in discussions with adult patients who have diabetes and use insulin.

The material is not intended for patients, rather it is provided to give healthcare professionals greater insight into error-prone situations and possible safety actions that patients might take.

### ***Why healthcare professionals should read this information***

This information will explain known risks for patients' use of insulin. It gives simple actions that they can take to make their use safer. It supports the use of the Insulin Passport, which provides a concise up-to-date record of key information about the patient's use of insulin. In this Appendix the words 'insulin product(s)' refer to:

- all of the packaging in which insulin can be provided, such as vials, cartridges and pens; and,
- all the devices that are used to store, measure and inject insulins.

This information and the Insulin Passport have been developed following a review of patient safety incidents (or errors) involving insulin.<sup>17</sup> The following were most frequently reported:

- being prescribed the wrong insulin product(s);
- omitted or delayed insulin; and,
- being administered the wrong dose of insulin.

It is important that healthcare professionals convey to patients that these incidents are very rare. There are things healthcare professionals can do to reduce the possibility of problems. The next section provides key tips that healthcare professionals could use to help avoid such problems.

### ***Key tips to make the use of insulin safer***

Healthcare professionals should advise patients to:

- know the details of their insulin product(s) and to keep this information up-to-date in their Insulin Passports;
- carry their Insulin Passport with them so that the information is available in an emergency and to show it to health professionals to confirm details of their current insulin therapy;
- make sure that they receive the correct insulin product(s) and to check all prescriptions and dispensed items that they receive with the information in their Insulin Passport. Patients should question any changes, as the names of insulin products can look and sound very similar and that can result in errors;
- make sure that they know, and anyone administering insulin to them knows, the correct dose and frequency of their insulin therapy (this information is not kept in the Insulin Passport);

- be aware that the abbreviation 'u' for insulin 'units' is sometimes misread as a '0' resulting in a 10 times over dose of insulin;
- be aware that insulin should always be administered using a commercial insulin pen or insulin syringe. Intravenous syringes should never be used to administer insulin. They have the wrong calibration marks and this could lead to errors; and,
- avoid delays or omissions of their insulin doses. They should have their insulin products readily available and have reserve supplies. Patients should be told to inform healthcare staff when they are willing and able to self-administer their insulin as hospital inpatients and to remind healthcare staff when an insulin dose is due if they are not self-administering their insulin as hospital inpatients.

## *The Insulin Passport*

Patients can make a choice whether to use the Insulin Passport, or any suitable alternatives that may become available. The Patient Safety Alert directs healthcare professionals to have discussions with patients to decide what is best for them.

Healthcare professionals should advise adult patients with diabetes using insulin that they can be issued with a credit-card sized paper record, the Insulin Passport. It is a document that is used to record:

- accurate and up-to-date details of a patient's insulin product(s);
- emergency information informing others that a patient has diabetes and injects insulin;
- information for others that tells them what to do if a patient is found ill or has lost consciousness;
- contact names and telephone numbers; and,
- other medication that a patient is using.

The Insulin Passport has been pre-folded. Patients should unfold it and be advised to follow the steps below.

- Patients should complete the information in the boxes they feel are necessary. If the patient needs help healthcare professionals should not hesitate to provide appropriate advice. Specifically, it is possible that patients will ask healthcare professionals how best to describe their insulin products so that there is no ambiguity for prescribing or dispensing. Accurate descriptions are provided in the current British National Formulary.
- When information is updated, a single line should be drawn through old information, so that new information can be clearly seen and recognised.
- If this is a replacement Insulin Passport because a patient's current one is full, they should be advised to transfer information that is current and add in the new information.
- When patients need a new Insulin Passport, they should be advised to ask at their diabetes clinic, or see their diabetes nurse or GP for a replacement.
- Patients should fold the paper back to its credit-card size and keep it somewhere readily accessible in an emergency, like their wallet or purse.

Health professionals who prescribe insulin are responsible for issuing patients with a patient information booklet and Insulin Passports.

## Getting the right insulin product

### What are the potential problems?

Insulin can come in a vial, cartridge or pre-filled pen. It can have special equipment to store it and then measure how much is delivered for each injection. Depending on whether the patient's insulin is in current use or kept in reserve there are storage requirements. There are dedicated insulin syringes with measurements in units on the barrel for 30 unit (0.3 ml), 50 unit (0.5 ml) and 100 units (1 ml) of insulin.

There is a wide range of insulin products. Similar insulin products can be made by different manufacturers and there is a risk that patients may be given the wrong insulin product. Below are some incidents that have been received by the NRLS. They give healthcare professionals an idea of things that might go wrong. The descriptions are based on the actual incident reports.

Patients can get the wrong type of insulin.

A patient was given the wrong insulin (Novorapid™ instead of NovoMix™ 30) resulting in significant hypoglycaemia associated with a fall and confusion. Fortunately, the patient was found by her daughter and brought to hospital.

Patients can get the wrong insulin presentation or device.

The patient attended a drop-in session at her diabetes clinic. Her observations were stable. She returned a few days later, the insulin pen she had been given to take home and which she had been using contained the wrong insulin. Pens were very similar in colour - grey / purple.

A patient was discharged home with the wrong insulin pen, so was unable to administer the insulin dose as prescribed. The patient was given a HumaPen™ rather than a NovoPen™ and the cartridges are not interchangeable.

### When can problems occur?

Problems can arise at transfer of care from hospital to the community. Patients may have been prescribed insulin therapy for the first time in hospital, or their insulin therapy may have been changed in the hospital or in the clinic. This change must be communicated accurately or when patients eventually request prescriptions from their GPs and take it to their community pharmacists there is a risk that the insulin products will not be correct.

Problems can arise at transfer of care from the community to the hospital. When patients are admitted to hospital, the detail of their insulin therapy is recorded and the insulin and equipment prescribed on a hospital prescription form. Patients' insulin products may be available as ward stock or the hospital pharmacy may be asked to provide a supply. Unless everyone gets it right, there is a risk that the insulin products will not be correct.

Problems can arise when repeat supplies are provided. There are many variations of insulin products. There is a risk that during the normal repeat supply process the wrong product(s) will be prescribed or dispensed.

Problems can arise for hospital inpatients. Their insulins may be removed from their possession for safe custody. There is a risk that when it is time for insulin doses to be administered the wrong insulin products will be selected in the ward area and administered.

Problems can arise at home. If patients' insulin therapies change but they keep old insulin products at home there is always a risk that they may be used in error.

## The risks of getting the wrong insulin product

The risk of using the wrong insulin is that a patient's blood glucose becomes too low or too high. The time to act and length of action for different insulins can vary considerably. This may result in unwanted symptoms and even collapse, loss of consciousness and hospital admission. Patients must recognise the warning signs and act to be safe.

There are many different types of insulin and some are known by two names; a brand name (shown below with a capital letter) and a generic name (shown below in all lower case). Many of these names look and sound like one another. This creates a potential risk. Patient safety incidents involving confusion between the following brand name pairs or groups have been reported to the NRLS:

glulisine and glargine;  
Humalog™ and Humalog™ Mix;  
Humulin S™, Humulin I™ and Humulin M3™;  
Humalog™ and Humulin™ products;  
Hypurine products;  
Lantus™ and lente;  
Levemir™ and Lantus™; and,  
NovoRapid™ and NovoMix™.

There are usually two or more presentations of equipment for each type of insulin. A prescription and the entry in the Insulin Passport should identify both the type of insulin and the presentation that patients use.

There are safety checks. If the wrong insulin presentation is prescribed and/or dispensed then patients could find that they are unable to administer a dose of insulin because the cartridge or vial that they have been given will not fit in their insulin administration pen. Alternatively, they may have been given a pre-filled insulin pen that they have not been trained to use safely. Also, if their use of insulin is unclear, or the insulin product does not make sense, patients should be advised to seek advice from their healthcare professional.

Actions patients can take to minimise the risks of getting the wrong insulin product.

- Patients should know the details of the insulin product(s) that they use. This will include the type of insulin, the presentation and any devices used in administration.
- Patients should be advised to record this information in their Insulin Passport or request that their healthcare professional advises them how to do so. They should make sure that any time an insulin product is changed that this is recorded in the Insulin Passport.
- If a healthcare professional records the information they should sign the Insulin Passport in the far right hand column.
- If there is no room left in the Insulin Passport, patients should be advised to obtain another and fill in the details.

- Patients should check prescriptions with the information in their Insulin Passport to make sure that they receive the correct insulin product.
- Patients should be advised to show the information in their Insulin Passport to health professionals including community pharmacists to help them cross-reference with available information and check they have the right insulin therapy.
- If any patients' use of insulin products is unclear, or they have questions or uncertainties about their insulin products, they should be advised to seek advice from their healthcare professional.

## ***Having the patient's insulin delayed or omitted***

### **What are the potential problems?**

Insulin takes glucose circulating in a patient's blood and helps it get into cells. Patients need the energy from the glucose in cells in order to live. Insulin therapy is designed to cope with changing levels of glucose from the food eaten at meal times and the glucose the liver produces in-between meals to keep the body functioning.

The important points are that the insulin therapy is given at the right time in relation to meals, and patients always have some insulin working in their bodies. Here are some example incident reports where insulin therapy went badly wrong.

Patients might have their insulins omitted.

[In hospital] The patient had been without an intravenous insulin infusion since the afternoon. Blood glucose levels were climbing. Unable to establish if the patient was eating or drinking as no record charts were completed. Observations were only recorded once. No 'as required' quick acting insulin used. Patient deteriorated and died despite intervention.

Patients might have their insulin delayed.

The patient's morning insulin was missed due to low staff levels. Blood glucose 15.1mmols/L. Afternoon insulin was administered as normal. The following morning the blood glucose was 19.0mmols/L. Patient stated he felt fine. Normal insulin then administered.

### **When can problems occur?**

Problems can arise during prescribing and dispensing. If patients do not have ready access to a source for their insulin products, it may be another cause for omitted or delayed therapy. Few community pharmacies will keep stocks of every insulin product. Delays in obtaining a repeat prescription or dispensed supplies of insulin products can lead to delayed or omitted doses of insulin.

Problems can arise for hospital inpatients. Some hospitals have a policy of taking insulin supplies away from hospital inpatients and storing them in ward medicines refrigerators or cupboards. Insulin is administered from these supplies by the ward nurse as part of the regular medicine administration rounds. The problem with this system is that it is sometimes difficult for nurses to administer insulins in a timely way in relation to when meals are served on the ward. There is a risk that patient's insulin doses may be delayed or administered too early in relation to their food.

Problems can arise when inpatients are 'Nil-by-mouth', fasting or not eating. If this is the case, or for whatever reason they are not eating, remember the patient's body is constantly producing glucose, and it will need a constant low level of insulin. If patients usually inject a long-acting insulin and are self-administering, they may need to continue.

### **The risks of having insulin delayed or omitted**

Some insulins need to be taken at a mealtime, so the timing of insulin in relation to food can be critical. Patients should be advised that their healthcare professional can tell them when it is the right time to use their insulin product.

The risks occur when the patient's insulin is given too early or too late in relation to food.

If patients have their insulin too early before food, then they do not have enough glucose in the blood for the insulin to work on. This may cause a 'hypo'.

If patients have their insulin too late after food, then the food is absorbed by the body and glucose levels in the blood rise too high, a 'hyper'.

Finally, if a patient's insulin is omitted completely, then even without food blood glucose levels will actually rise. The risk is that, because there is no insulin, the patient's cells lack the necessary energy to survive, yet you have lots of glucose in your blood. Consider the following case.

|                                                                                                                                                                                                                                                                                                                                  |
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| An insulin dependent patient was admitted the day before surgery and not seen by a doctor the day before surgery so no sliding scale insulin was ordered. The patient was kept nil by mouth and allowed to have subcutaneous insulin on the morning of surgery. The nurse in charge was not aware that the patient had diabetes. |
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Actions that healthcare professionals can advise patients to minimise the risk of omitted and delayed doses of insulin:

- Ensure that patients have adequate supplies of insulin products. Ideally, they should have insulin products that they are using and additional insulin products in reserve, including spare pen devices. It may take two or three days to request prescription items from their GP and obtain new supplies of insulin products from their community pharmacies. This may take longer around holiday time. If they have 'regular' community pharmacies, make sure they are aware of all prescription needs with sufficient time to get in stocks of the necessary insulin product(s).
- Remind patients to have their insulin with them so that they can administer doses when required.
- If patients are going into hospital, remind them to take their insulin product(s) with them. Many hospitals have schemes to enable patients to self-administer their own insulin. If patients are happy to do so, they should be advised to inform hospital staff when they are admitted. If they are self-administering their own insulin, it is best if they have easy access to their insulin. Many hospitals have lockable bedside medicine lockers and it is best if patients medicines are stored in these lockers, rather than in the ward medicines refrigerator. It is unlikely that the insulin they are using will need to be stored in a refrigerator.
- Patients may be trained to count their carbohydrates and determine their own level of insulin, for example following the Dose adjustment for Normal Eating (DAFNE) regimen. Careful monitoring of food intake is essential. Patients should be advised to make staff in hospital aware of their needs and ensure ready access to their insulin if they are self-administering.
- If patients are unable to self-administer their own insulin in hospital and it is past the time for their insulin doses, they should be advised to remind the ward staff when their insulin dose needs to be given.
- Patients' insulin product(s) may be changed as part of their hospital stay. Patients should be advised to make sure that they are given adequate supplies of the new insulin, and know how to use it before they are discharged from hospital.

## ***Getting an incorrect dose of insulin***

### **What are the potential problems?**

The amount of insulin patients inject is measured in units. The standard insulin syringe is calibrated to deliver 100 units per ml (units/ml, or units per millilitre) of insulin. Fatal errors have occurred when no insulin syringe was immediately available and an intravenous (IV) syringe was used instead. There are many sizes of IV syringe, but they are all measure in millilitres (ml) not units. Converting from units to mls has led to patient safety incidents (errors) in insulin dosing.

A common error with insulin is the failure to read the prescribed dose correctly. Mistakes are then made by those administering insulin. Use of the abbreviation 'u' for insulin units is sometimes misread as a '0' resulting in a tenfold overdose of insulin.

Here are some example incident reports.

Unless patients are advised to be vigilant they could be given the wrong dose of insulin.

The patient was given 40 units of Mixtard™30 at 17.00 as prescribed. Later they had symptomatic hypoglycaemia, blood glucose 2.2mmol/L. The next evening a nurse discovered from the patient that the usual dose was 40 units am and 10 units pm, not 30 units am and 40 units pm as charted.

The closeness of the term 'unit' to the dose produced confusion.

The patient had been given 44units Mixtard™ 30 in the morning instead of 4units (written as '4u') as prescribed. The patient fitted and had a hypo - became aggressive and confused. The blood glucose was 3.1mmol/L.

A patient was prescribed '10units' of insulin glargine. At midday two qualified nurses checked the medication chart and both read it as 100 units; this dose was then administered. The patient became ill and was transferred to the acute trust where her blood glucose level was recorded as 0.5 mmol/L.

An IV syringe could be used instead of an insulin syringe or pen.

There was no means of administering insulin to the patient as cartridges had been delivered instead of the prescribed disposable pens. Insulin was drawn up from a cartridge and given by syringe and needle. After leaving the staff realised the amount of insulin given was too great. The GP was contacted and an ambulance was called. The patient was admitted to hospital overnight

## When can problems occur?

The wrong dose can be given at any time when administration takes place, which is why patients need to take special care.

Problems may arise when administration is undertaken by persons other than patients, whether in a care home, a hospital ward or the patient's own home. While others do not set out to get it wrong, it is a complicated process with many steps, so errors can happen.

Patients should be advised not to assume it will always be all right. They should make sure personally that anyone giving them insulin has got the dose correct.

Patients should use the Insulin Passport to confirm their insulin products but not their daily dose. The Insulin Passport is not a daily diary rather it has a specific safety purpose.

## The risks of getting an incorrect dose of insulin

The risk of giving the wrong dose is that patients have a 'hypo' or hyperglycaemia. Healthcare professionals should describe to patients the feelings that they might get when their bodies have too little or too much glucose respectively.

Patients should be advised that if they get these feelings they should tell someone. A simple test can confirm their blood glucose level and treatment is well known.

The Insulin Passport allows patient to provide basic instruction for what they want people to do in the event that they have a 'hypo' or hyperglycaemia. If they are unsure how to carry out their instructions, the healthcare professional should advise them accordingly.

As soon as patients realise an error has been made they can predict the effect of getting too much or too little insulin.

To minimise the risk of getting the wrong dose of insulin, healthcare professionals should advise patients to:

- check each time with the person administering their insulin that the dose is correct. They should use the Insulin Passport as a record to confirm exactly what type of insulin they should be receiving;
- note in the Insulin Passport if their dose is determined based on their food intake and therefore alters each time. Staff in hospital should be made aware that this is the case;
- make sure that they are informed of the dose on discharge and record the correct dose in the Insulin Passport. Patients' insulin doses may be changed as part of their hospital stay. If this varies from what they are used to or expect, they should be advised to ask for an explanation;
- inform the nurse exactly what dose they have administered if they self-administer in hospital. It will need to be recorded on their medication chart and in their notes; and,
- be aware of the actions they can take if the wrong dose is administered.

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