Safety and insulin: Implementation of national guidance at a local level

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Despite the many advantages of insulin, the development of different insulin preparations, along with varying times of action and similar product names, has undoubtedly increased the risk involved in its use. In recent years, various organisations have highlighted safety issues with insulin and national audits (National Patient Safety Agency [NPSA], 2010; 2011) have indicated that errors relating to wrong doses of insulin, omitted or delayed doses and wrong insulin product frequently occur. As a result of the 6-year audit which was reported in 2010, the NPSA issued strict guidelines on safe insulin use by healthcare professionals. This article discusses the problem of insulin error and highlights some national and local initiatives that are being carried out to reduce the number of patient safety incidents.

The development of insulin has come a long way since it was first discovered in 1922. Now, with over 20 different preparations, it can be used by and potentially transform the lives of approximately one third of all people with diabetes. At the time of discovery it was hailed as a modern miracle drug and this is still the case for many people.

Despite its many advantages, the development of different insulin preparations along with varying times of action and similar names, has undoubtedly increased the risk involved in its use. Insulin is labelled as a high-risk medication in many countries including the US and the UK (Institute of Safe Medication Practice, 2008; Patient Safety First, 2013) and errors in insulin use are common (National Patient Safety Agency [NPSA], 2010). A definition of error was given in the Department of Health (DH) report An organisation with a memory (2000):

"An event or omission arising during clinical care and causing physical or psychological injury to a patient"

In the past 3 years Government policy and organisations such as NICE, The never events policy framework (DH, 2012) and the NPSA have highlighted safety issues with insulin use. These are outlined below.

NICE quality standards

NICE quality standards are concise documents developed to drive and measure priority quality improvements within specific areas of care. The quality standard Diabetes in adults (NICE, 2011) includes a statement specifically about insulin therapy and states that

"Trained healthcare professionals initiate and manage therapy with insulin within a structured programme that includes dose titration by the person with diabetes".

This document also recommends that there should be: a) Evidence of local arrangements for a structured programme for initiating and managing insulin therapy, including training and support for the healthcare professionals and the patients and b) Evidence of local arrangements and locally agreed

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- National audit
- Patient safety incidents

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criteria for healthcare professionals to demonstrate and document training and competencies in initiating and managing insulin.

**DH: Never events**
In 2012, the DH produced a report and framework around “never events”, which are events that either cause direct harm or have the potential to cause harm. Such incidents are said to be intolerable, inexcusable, unacceptable and preventable. This framework aimed to reduce the risk of such incidents to zero and included insulin misuse as a separate category. This section states specific areas in insulin preparation and administration which would constitute a ‘never event’; this is shown in Box 1.

The maladministration of insulin criteria in the document, however, only relates to actual severe harm or death; the potential to cause harm through unsafe insulin use is excluded (DH, 2012). The never events policy framework on insulin misuse centres on previous NPSA reports.

**NPSA guidance**
In 2010, the NPSA issued a “rapid response report” in response to a 6-year audit, which reported that there were 16,600 patient safety incidents (PSIs) relating to insulin between 2003 and 2009. These included one death and one case of severe harm that occurred after abbreviation of the term “unit” was misinterpreted. Three deaths and 17 other incidents between January 2005 and July 2009 were also reported where an intravenous syringe was used to measure and administer insulin (NPSA, 2010).

The report highlighted the most common reported insulin errors as:

- The inappropriate use of non-insulin intravenous (IV) syringes, which are marked in mL and not in insulin units
- The use of abbreviations such as “U” or “IU” for units.

**The challenge of insulin error**
The NPSA report stated that errors in the administration of insulin by healthcare professionals (HCPs) were common and some cases were the result of insufficient training in the use of insulin. It made the recommendation that organisations should have training programmes in place for all healthcare staff expected to prescribe, prepare and administer insulin (see Box 2). At the same time NHS Diabetes (now part of NHS Improving Quality), working in partnership with the NPSA, drew up or administer insulin.

**Box 1. Maladministration of insulin: The Never Events List 2012/13 (DH, 2012).**
- Death or severe harm as a result of maladministration of insulin by a health professional.
- Maladministration refers to when a health professional:
  - Uses any abbreviation for the words “unit” or “units” when prescribing insulin in writing.
  - Issues an unclear or misinterpreted verbal instruction to a colleague.
  - Fails to use a specific insulin administration device, such as an insulin syringe or insulin pen to draw up or administer insulin.
  - Or fails to give insulin when correctly prescribed.

**Box 2. NPSA Rapid Response Report: Safer administration of insulin (NPSA, 2010).**
All organisations in the NHS and independent sector should ensure:
1. All regular and single insulin (bolus) doses are measured and administered using an insulin syringe or commercial insulin pen device. Intravenous syringes must never be used for insulin administration.
2. The term “units” is used in all contexts. Abbreviations, such as “U” or “IU”, are never used.
3. All clinical areas and community staff treating patients with insulin have adequate supplies of insulin syringes and subcutaneous needles.
4. An insulin syringe must always be used to measure and prepare insulin for an intravenous infusion. Insulin infusions are administered in 50 mL intravenous syringes or larger infusion bags. Consideration should be given to the supply and use of ready-to-administer infusion products (e.g. prefilled syringes of fast-acting insulin 50 units in 50 mL sodium chloride 0.9%).
5. A training programme should be put in place for all healthcare staff expected to prescribe, prepare and administer insulin.
6. Policies and procedures for the preparation and administration of insulin and insulin infusions in clinical areas are reviewed to ensure compliance.
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1. Local initiatives have evolved to meet the challenges of insulin use and patient safety. However, these initiatives have only been recently implemented so it is not yet clear if they have been successful.

2. In 2011, the National Patient Safety Agency issued a second rapid response report recommending that all insulin users over 18 years should be issued with a patient information booklet outlining specific risks associated with insulin use and an “insulin passport”, which clearly identifies their insulin and the device they should be using.

3. National recommendations and educational tools have been in place for some time and annual audits by the National Patient Safety Agency and the Health and Social Care Information Centre access improvements in prescription errors and insulin safety.

Issued an e-learning package that would meet the requirements of the NPSA and both hospital and community trusts where no insulin training was in place (NHS Diabetes, 2010). Since its launch the national e-learning programme on the safe use of insulin has attracted more than 100 000 users and three other modules have since been produced: the safe use intravenous insulin infusions (2011); the safe use of non-insulin therapies (2012) and the safe management of hypoglycaemia (2012).

Some teams have introduced the NHS “Think Glucose” programme for hospital teams and other local initiatives have evolved to meet the challenges of insulin use and patient safety. Some of these initiatives are listed below. These initiatives have all been recently implemented so it is not yet clear if they have been effective.

- The Plymouth Hospitals NHS Trust Diabetes Team set up an inpatient steering group to implement safety initiatives and guidance as did the University of Leicester NHS Trust Diabetes Team.

- The University Hospitals of North Tees and Hartlepool working in partnership with other hospital trusts has developed regional guidance on insulin safety, standardised diabetes prescribing charts and information on safe prescribing practice.

- The University of Southampton NHS Trust has developed a diabetes app to help junior medical staff with decision making when initiating insulin and following use of intravenous infusions. The app, “DiAppBetes” is available on Apple and Android devices. It has had around 2000 downloads on each platform and been identified as one of the top 5 medical apps in the UK (New Doctor, 2013).

In 2011, the NPSA issued a second rapid response report; this time it put the person with diabetes at the heart of patient safety by recommending that all insulin users over 18 years should be issued with a patient information booklet outlining specific risks associated with insulin use and an “insulin passport”, which clearly identifies their insulin and the device they should be using (NPSA, 2011). It was recommended that the booklet be discussed with the person with diabetes and all individuals should have received the booklet and passport by 31 August 2012. An expert working group, comprising nurse consultants, clinicians and representatives from the NPSA, NHS Diabetes and the RCN, also developed a shorter version of the NPSA information booklet; the Safe use of insulin and you booklet (NHS Diabetes, 2012) is available in eight languages and over 100 000 thousand copies have been distributed to HCPs across England and Wales.

Insulin-specific safety cards were designed and produced by pharmaceutical companies and, following NPSA approval, were distributed free of charge to GP surgeries and specialist diabetes teams. These additions to the insulin safety toolkit were approved and promoted by the NPSA.

Evaluation

National recommendations and educational tools have now been in place for some time and it is important to review and evaluate whether their existence has improved patient safety. Local initiatives, which have been recently implemented, have not yet been evaluated. There are two organisations which lead the way in this field, the NPSA, which is now part of the National Commissioning Board, and the National Diabetes Inpatient Audit (part of the National Diabetes Audit managed by the Health and Social Care Information Centre) who assess insulin and diabetes management error in inpatients annually.

NPSA audit

The NPSA re-audited insulin-related patient safety incidents in 2012 using the same search terms used in the initial alert in 2010. This time the audit included data from 2010 to 2012 over a 15-month period. They categorised the types of error into mild, moderate or severe harm (Cousins et al, 2011). The criteria for “wrong dose incidents” are shown in Box 3.

The number of reported events was

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Box 3. Wrong dose criteria (Cousins et al, 2011).

- Incorrect prescription on admission.
- Abbreviation of “units”. With poor handwriting “U” and “IU” may be misread as “0” or “10”.
- Incorrect monitoring of blood glucose and dose adjustment of insulin.
- Poor documentation of dose administration in inpatient medicine charts.
- Duplicate dose administration.
- Errors in calculation of insulin doses for intravenous infusion.
- Incorrect programming of electronic infusion devices.
proportionally higher compared with the previous analysis – 9382 in 15 months compared with 16,600 in 6 years (Table 1). When examining 24 serious harm PSIs, they found there was a significant reduction in the expected relative proportion of “wrong insulin product” PSIs after the rapid response report (14.4% before, compared with 13.25% after the report) and fewer severe harm episodes (one death and five severe harm PSIs.)

**National e-learning package**

There have been over 100,000 registrations for the national e-learning package since the NPSA rapid response report in 2010, with more than 71,000 completing the online assessment. About 50% of learners are based in primary care and as there is no annual national audit of community insulin prescribing, management and errors it is not possible to measure outcomes in this setting.

However, evaluation of mandatory e-learning training in hospital staff can be measured through the National Diabetes Inpatient Audit (NaDIA). This national audit was undertaken over a 3-year period and involves a case review and contact with all individual inpatients with diabetes during a single week in the year. The audit aims to review three elements of inpatient care:

1. Did diabetes management minimise the risk of avoidable complications?
2. Did harm result from the inpatient stay?
3. Was the patient experience of the inpatient stay favourable?

The use of insulin and diabetes management is examined to determine whether harm was caused to the patient and whether this relates to subcutaneous and intravenous use, as well as incidents of hypoglycaemia and development of diabetic ketoacidosis (DKA) in hospital.

The 2012 audit of 13,409 diabetes inpatients in England and Wales showed a mean bed occupancy rate of 15.3%. In people with diabetes, 39.6% experienced at least one medication error (either insulin, oral hypoglycaemic agents or both), 24% of charts had prescription errors and 21.6% had one or more insulin error. Of the patients included in the audit, 20.4% had mild hypoglycaemia (blood glucose of 3–4 mmol/L) and 10.5% had severe hypoglycaemia (blood glucose <3 mmol/L). Furthermore, 2.3% needed injectable treatment for hypoglycaemia and 0.5% developed DKA in hospital. Prescribing errors overall have reduced over time; Figure 1 shows the rate of prescribing error and Figure 2 shows the specific type of error over the 3-year period.

The audit also confirmed that 26.2% (31.9% in 2011) of audited sites had no specific diabetes inpatient specialist nurses and 38.3% (52.2% in 2011) had no inpatient DSNs. Whilst this was an improvement on the previous year, still only about a third of inpatients had been seen by a member of the diabetes team; so it was clear that the majority

<p>| Table 1. NPSA audit data (2010 and 2012). |
|----------------|----------------|----------------|</p>
<table>
<thead>
<tr>
<th>Events</th>
<th>2003–9</th>
<th>2012 (15-month data)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong doses, strength or frequency</td>
<td>4256</td>
<td>1782</td>
</tr>
<tr>
<td>Omitted and delayed doses</td>
<td>3390</td>
<td>2243</td>
</tr>
<tr>
<td>Wrong insulin product</td>
<td>2390</td>
<td>1241</td>
</tr>
<tr>
<td>Other</td>
<td>6564</td>
<td>4116</td>
</tr>
<tr>
<td>Total</td>
<td>16,600</td>
<td>9382</td>
</tr>
</tbody>
</table>

**Figure 1.** Percentage of prescription errors over the 3-year audit (2012 audit).
of diabetes inpatient management was done by non-diabetes specialist HCPs. A total of 107 trusts had made the national e-learning mandatory since its launch and some trusts had introduced other types of training including "Think Glucose". It was not possible to assess the relationship between the reduction of insulin errors and the national e-learning module, although trusts where the training was mandated did have a significantly lower rate of insulin management error.

Virtual College, the hosting organisation, has reviewed completion rates from 52 hospitals where training was mandatory and found that the mean number of HCPs completing the course was 124 (range 15–606) so the evaluation may have been performed too early to detect an effect as more HCPs need to complete their training.

Discussion

The evaluation has shown that various reports, audit and nationally implemented training have highlighted insulin errors and the importance of staff training. Raised awareness of the problem may have also increased the number of incidents being reported to the NPSA over the 15-month period of the 2012 audit. It is encouraging to see that hospital errors are reducing over time, as are PSIs. The inclusion of insulin safety as a “never event” goes some way to raising awareness of error but falls short as the inclusion of insulin-specific events is limited and the decision not to include potentially serious errors is disappointing. The more recent NPSA initiatives to assist adult insulin users to learn more about the safe use of insulin and empower them to take control of their medication is welcomed but it is too early to see if this will reduce error.

The national e-learning module has been well received and the significant reductions in diabetes management error is positive; however, as completion rates in trusts are still low it may be some time before it can demonstrate effectiveness in insulin error reduction. Other locally initiated programmes are welcomed and we await their evaluation. The NPSA rapid response reports and the NaDIA work has ensured that insulin safety is at the top of many trusts and individuals’ agenda but knowledge does not equate to competence; training must encompass both if patient safety is to be ensured.

I recently received an email from a consultant colleague saying whilst he thought that the NPSA recommendation that insulin training be provided for all HCPs was a positive step, many trusts were still not implementing any form of training. It is important for all trusts and organisations to ensure that training is implemented and undertaken.


Institute of Safe Medication Practice (2013) List of high-alert medications. Available at: http://bit.ly/13LDpru (accessed 01.05.13)


Online CPD activity
Visit www.diabetesonthenet.com/cpd to record your answers and gain a certificate of participation

Participants should read the preceding article before answering the multiple choice questions below. There is ONE correct answer to each question. After submitting your answers online, you will be immediately notified of your score. A pass mark of 70% is required to obtain a certificate of successful participation; however, it is possible to take the test a maximum of three times. A short explanation of the correct answer is provided. Before accessing your certificate, you will be given the opportunity to evaluate the activity and reflect on the module, stating how you will use what you have learnt in practice. The CPD centre keeps a record of your CPD activities and provides the option to add items to an action plan, which will help you to collate evidence for your annual appraisal.

1. All healthcare professionals (HCPs) initiating or managing insulin should complete a structured training programme that includes dose titration. What local evidence needs to be in place to support this recommendation?
   Select ONE option only.
   A. Evidence of a locally agreed criteria for HCPs to demonstrate and document training and competencies in initiating and managing insulin
   B. An identified structured programme for initiating and managing insulin including training for HCPs and patients
   C. None of the above
   D. Both of the above

2. Over 16 000 patient safety reports were identified in a 6-year audit by the National Patient Safety Agency in 2010. Which two were the most commonly reported errors?
   Select ONE option only.
   A. Insulin given at the wrong time and the use of abbreviations such as “U” or “IU”
   B. The use of abbreviations such as “U” or “IU” and the use of non-insulin intravenous syringes
   C. Insulin given at the wrong time and insulin given without prior blood glucose monitoring
   D. Insulin given at the wrong time and the inappropriate use of non-insulin syringes

3. What is a “Never Event”?
   Select ONE option only.
   A. A serious event
   B. An event that should never happen
   C. An event that is preventable
   D. All of the above

4. Which of these statements is accurate? Maladministration in this instance refers to:
   A. When an HCP issues an unclear or misinterpreted written instruction to a colleague
   B. When an HCP issues an unclear or misinterpreted verbal instruction to a colleague
   C. When the person with diabetes gives the injection in the wrong site

5. What percentage of prescribing errors were shown in the 2012 National Diabetes Inpatient Audit report?
   Select ONE option only.
   A. 10%
   B. 17%
   C. 24%
   D. 31%

6. What percentage of inpatients were recorded as having “mild hypoglycaemia” in the 2012 NaDIA report?
   Select ONE option only.
   A. 16%
   B. 18%
   C. 19%
   D. 20%

7. What percentage of insulin errors were recorded in the 2012 NaDIA Report?
   Select ONE option only.
   A. 21%
   B. 22%
   C. 24%
   D. 31%

8. What is an “insulin passport”?
   Select ONE option only.
   A. An information booklet
   B. A document used to identify the right to carry insulin when travelling abroad
   C. A document which identifies the type of insulin and delivery system used by the carrier
   D. A document that records the dose of insulin a patient is using

9. All staff who prepare, prescribe or administer insulin should undergo a training programme on the safe use of insulin.
   A. True
   B. False

10. Which of the following statements is true? Select ONE option only.
    A. Insulin safety is the HCP’s responsibility
    B. Insulin safety is the patient’s responsibility
    C. Insulin safety is everyone’s responsibility
    D. Insulin safety is the Government’s responsibility