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Passive or active delivery devices in diabetes administration?

New evidence on the balance between healthcare worker safety and patient well-being

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Abstract

Anecdotal evidence came to the attention of **MindMetre Research** regarding instances of mis-dosage or non-delivery of insulin to patients when passive devices were being used. The organisation decided to investigate whether this anecdotal evidence was also being experienced by a significant number of NHS Trusts. An enquiry was launched under the terms of the Freedom of Information Act (2000). The resulting evidence revealed: around one third of Trusts were experiencing this phenomenon; a significant proportion of Trusts either gave indefinite answers to the questions posed or were unable to answer the questions; and a handful of Trusts reported that they had switched from passive to active delivery devices because of concerns over patient well-being and the avoidance of mis-dosage.

The background to safety-engineered devices

In 2010, after much public debate throughout Europe, the EU Directive on Sharps Safety was adopted[1]. The Directive legislates a framework agreement on the prevention of sharps injuries in hospitals and the healthcare sector by the Social Partners – the European Hospital and Healthcare Employers' Association (HOSPEEM) and the European Federation of Public Service Unions (EPSU).

Transposed into national law in all countries by the deadline of 11th May 2013, the legislation has now been in force for almost ten years. Its requirements are neatly summarised in an article from the Journal of Nursing Care, which says, "This includes eliminating the unnecessary use of sharps by implementing changes in practice and, on the basis of the results of the risk assessment, providing medical devices incorporating safety engineered protection mechanisms, as well as banning the recapping of needles[2]."

What safety legislation does, and does not, require

While the legislation is mandatory, in that it (along with regulatory guidance) requires safety devices to be used "wherever is reasonably practicable[3]" (or similar phrases), it does not proscribe the type of safety devices to be used. As guidance from the Royal College of Nursing (RCN) notes, "Safety engineered devices have a built in feature to reduce the risk of a sharps injury before, during and after use. Devices can be passive or active. For example, passive devices have an automatic safety mechanism that is activated after use…. An active device needs to be manually activated by the member of staff[4]."

Procedural standards are in place; for instance, BS EN ISO 23908:2013, ***Sharps Injury Protection***, lists test methods for evaluating the performance of sharps safety equipment and systems. It covers active and passive designs for medical devices containing needles for single use. The freedom for clinical and care specifiers to choose active or passive devices based on

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their judgement is underlined in many guidance documents, such as that from the Swansea Bay University Health Board: "Though passive devices will operate automatically and the sharp is protected even if staff fail to deploy the safety feature, the legislation does not require organisations to specifically provide a passive device rather than an active device[5]." The importance of training is widely emphasized, for instance by the RCN, which notes research showing that "25% [of nurses] had no training on safe sharps use. 21% had no education on reporting SI [Sharps Injuries]. 38% had no training on all the safer sharps they used[6]."

Why the bias towards passive devices?

However, despite the freedom of choice between active or passive delivery mechanisms that is carefully underlined in the legislations and professional association documents, a strange bias towards the use of passive devices in **all** contexts has arisen. The origins of this bias – which is clearly not contained in the legislation – are unknown. It may be the result of stringent healthcare worker safety protocols. And from that single isolated perspective, this is a good thing. However, it is the contention of this short research note that in some situations, an active device may be preferable and should at least be considered. This research note presents evidence from the diabetes field to illustrate one significant instance where blanket use of passive devices is not always in the patient's best interests and may lead to adverse patient outcomes – an unacceptable situation.

Delivery devices in diabetes – passive or active?

Evidence of recommendations for the blanket use of passive devices is widespread. One document from NHS Scotland says, "devices requiring no additional action to trigger the safety mechanism (i.e. Passive Devices) are preferable, as the safety mechanism is triggered automatically through 'normal' use of the device[7]." Another example can be found in outputs from the Health & Safety Executive, saying, "In general passive devices are preferable."[8] A typical example of an academic paper on needlestick injury tells us that, "We included passive but not active devices given the evidence showing the higher efficacy of the former over the latter in reducing NSI…[9]". In the field of diabetes administration, we find best practice groups making statements such as, "Where possible safety-engineered devices with passive activation should be used[10]."

Such blanket advice may – in some significant healthcare settings – be misleading. A recent clinical study conducted in Poland provides potent evidence of this, concluding that, "Surprisingly there were no significant differences between the risk of injuries with active and passive safety needles[11]."

Real-world evidence

In the context of diabetes administration, the authors of this research note had received anecdotal evidence from diabetes specialist nurses in NHS Trusts where two phenomena had taken place:-

1. Insulin pooling on the skin of patients after using passive injection devices, suggesting that the dose had either been under-delivered or not delivered at all

2. Instances of diabetics experiencing an adverse event related to misdosage while still in the Unit or on Trust premises

While these anecdotes were of great concern, a scan of official records indicated that there was an absence of precise data around the issue of insulin pooling or adverse events following insulin administration specifically with a passive device.

MindMetre Research therefore made an enquiry to all NHS Trusts in England and Wales, to gain a picture of how widespread these anecdotal experiences might be. The purpose of the enquiry was to provide some initial evidence as to whether diabetes specialist units might need to assess – or re-assess – which type of safety-engineered delivery device is most appropriate for insulin administration to diabetics attending their units.

The research was conducted under the terms of the Freedom of Information Act 2000. Trusts were asked whether:

A. They had experienced insulin pooling when using a passive delivery device

B. Their diabetic patients had experienced adverse events following insulin administration with a passive device, as a result of suspected misdosage

36.4%

of Trusts said they had experienced insulin pooling when using passive devices to administer insulin.

25%

of respondents reported that they had experience of misdosage of insulin when using passive devices, evidenced by an adverse related patient event on-premises.

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On the issue of insulin pooling, 36.4% of Trusts said they had indeed experienced this when using passive devices to administer insulin. 11.4% of Trusts said they were unable to answer the question.

While 56.8% of Trusts responded that they had not experienced skin pooling of insulin when using passive devices, just over half of these respondents gave indirect or prevaricating answers such as: "With the appropriate training put in place following introduction we have no evidence of insulin pooling"; "A Datix search over the past 5 years has shown there were 0 reported incidents of insulin pooling on the patient's skin when using passive safety needles on the Trust's diabetes wards"; "From the data that was searched, no records matching the specific criteria of the question were found"; "The Trust has found no evidence to reflect such instances during the noted period."

This enquiry was composed of extremely simple, straightforward questions, around an issue of potential patient well-being, that could have been processed simply by asking the specialist diabetes unit in the Trust. Therefore the authors of this research note are minded to highlight these indeterminate and vague answers, leaving readers to draw their own conclusions about their validity or otherwise.

On the issue of possible misdosage of insulin when using passive devices, evidenced by an adverse related patient event on-premises, **25% of respondents reported that they had experience of this occurring**. 56.8% reported no knowledge of such events occurring and 18.2% of respondents were unable to answer the question. Again, just under half of the negative answers were somewhat vague and indefinite, as with the skin pooling issue reported above.

Some NHS Trusts have switched from passive to active

Equally revealing were the additional comments offered by a selection of respondents. They described how one or both phenomena had been observed, leading staff to become concerned for the well-being of diabetic patients over and above healthcare worker safety issues, and this had then resulted in a policy change.

For instance, one northern Trust noted that, "Inaccurate insulin dosage was seen as a result of passive safety needles, due to this [we] moved to active safety needles." They added, "pooling of insulin was observed when using passive safety needles... again [we] moved to active safety needles for this reason." Another Trust in the North noted that, "Prior to using active safety needles ward staff complained of inaccurate dosing. We have only changed to an active safety needle in 2022."

Other Trusts had established policies one the issue, with one stating, "We stopped using passive safety needles more than 5yrs ago (approx. 2016) because we had previously experienced these problems..." And in a detailed response, one further Trust explained, "We have had occasional near misses where it was unknown if the insulin had been given from a passive safety needle... if the needle retracted before the insulin was fully administered, this was noted. This was one of the reasons to remove it from our local formulary... therefore the Quality and Safety team at the hospital decided to remove these and we moved to an alternative [active] device."

Conclusions and next steps

The result of this short research exercise have raised a warning flag – specifically over insulin administration in diabetes units.

While legislation allows practitioners to choose whether an active or passive safety-engineered device is used, a somewhat strange zeitgeist seems to have arisen promoting passive safety devices in **the majority of** clinical and care contexts. We suggest that this may not always be in the best interests of patients.

This short paper has provided research evidence that blanket recommendation of passive safety devices may in some cases be undermining the clear clinical duties of patient well-being, through inaccurate insulin dosage.

The authors of this paper recommend that diabetes units are supported by their NHS Trusts to make an objective enquiry into possible incidents of skin pooling and adverse incidents from possible misdosage. This recommendation is partly inspired by the level of vague or indefinite answers received as a result of MindMetre's Freedom of Information enquiry on the subject.

If there is any resulting evidence that either of these phenomena may be occurring, even in a minority of instances, Trusts may wish to take a fresh look at their delivery device policy. They may consider whether the balance between healthcare worker safety and patient well-being is best served by the continued use of passive devices, or whether a switch to active devices (in line with existing policy change at a number of Trusts) should be evaluated.

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