

Summary of Findings: Safe and secure handling of insulin on neonatal units




Introduction and Background

1. As a result of the actions of neonatal nurse Lucy Letby, including the misuse of insulin, at the Countess of Chester Hospital between June 2015-2016, there has been an increased interest in the safe and secure handling of medicines. In December 2023, NHS England (NHSE) received a request from Minister Caulfield, The Parliamentary Under Secretary of State (Minister for Women), to explore how the safe and secure handling of insulin on neonatal units could be improved; NHSE was asked to undertake work in the following three areas:
 - (a) An assessment of how frequently insulin is used in neonatal units and for what purpose.
 - (b) An assessment of the level of variation in NHS trusts' approaches to the safe and secure handling of insulin on neonatal units.
 - (c) Given (a) and (b), what action NHSE could take to increase safeguards of insulin on neonatal units. This should include options for:
 - (i) Additional safeguards that could be introduced on neonatal units for the use of insulin. Here, Minister Caulfield had previously cited the safeguards used for concentrated potassium as an example that could be explored, though she remains interested in other proposals.
 - (ii) Doing more to standardise approaches to safeguards across NHS trusts, ensuring that everyone adheres to best practice (including interventions identified under (i)).
2. In response to the above commission, an initial assessment of practice was carried out in November 2023 which assessed practice on a sample of twenty neonatal units in England including units at teaching hospitals, tertiary referral centres and district general hospitals. This assessment highlighted some variation in practice and identified a potential for standardisation to improve safety and control of insulin use in neonatal units. To consider appropriate actions and assess their expected impact, a wider investigation across a larger sample size was proposed and commissioned by Minister Caulfield to help inform any change in practice and/or guidance.

Method

3. A survey was developed using a multi-directorate group within NHSE (to include experts in patient safety, medication safety, neonatology, and pharmacy practice) to assess current practice; this was distributed to all neonatal units in England between January-February 2024.

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- 107 responses were received from teaching hospitals, tertiary referral centres and district general hospitals.

Findings


- This wider review of practice surrounding the safe and secure handling of insulin demonstrated results consistent with the initial assessment conducted in December 2023; a summary of findings in three focus areas is listed below.

An assessment of how frequently insulin is used on neonatal units and for what purpose.

- Insulin is used a few times per year or less in most neonatal units, with only 25% of units reporting to use insulin once per week or more; mostly in neonatal intensive care units. Of the units that report more frequent use, most (88%) will have one or two babies receiving insulin; only 4% of units reported having more than two babies receiving insulin at any one time.
- Two main indications for insulin administration by infusion were identified: all units using insulin used it for the treatment of hyperglycaemia (high blood glucose level) and just over half of the units also reported using insulin for the treatment of hyperkalaemia (high blood potassium level). Use of insulin in the treatment of hyperkalaemia is less frequent and was used mainly by the higher acuity units.
- Overall, insulin use in the neonatal patient population is infrequent; however, it remains a medicine that needs to be readily available on neonatal units for use in an emergency, i.e. accessible within minutes, to prevent patient harm arising from delay or omission.

An assessment of the level of variation in NHS trusts' approaches to the safeguards they implement around the use of insulin on neonatal units.

- This review identified some variation between the neonatal units in the following areas of practice:
 - use of digital management systems including electronic prescribing,
 - availability of neonatal specific policies, guidelines, and training,
 - pharmacy staffing levels,
 - the use of ready to administer and/or standard concentrations of insulin infusions.
- All units utilise a general medicines management policy that covers insulin use and 39% of the units reported having a policy that relates specifically to the use of insulin on the neonatal unit.
- There was consistency of practice in the following areas:
 - ordering of insulin,

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- (ii) storage and disposal of insulin,
 - (iii) preparation of insulin,
 - (iv) second checking of insulin at both preparation and administration stages.

12. Insulin vials are used by 94% of units prepare their insulin infusions, mainly supplied as ward stock, and 99% of units appropriately store their insulin in a locked cupboard or fridge.

13. Second checking at both the preparation and administration stage is mandated in policy for 90% of units and good adherence to this was reported. The effectiveness of a double-checking procedure on increasing safety was not explored as part of this survey.

Action NHSE could take to increase safe and secure handling of insulin on neonatal units.


Current safe and secure practice in use on neonatal units

14. Most trusts reported using a combination of measures (three or more) to ensure the safe and secure handling of insulin, for example policy restrictions on which staff groups can access insulin, insulin specific policies, and processes for ensuring the competency of staff prescribing and administering insulin. The most common strategies reported were (i) physical barriers to accessing insulin i.e. locked cupboards, fridges, or cabinets, and/or locked rooms with access restricted to healthcare professionals working on the neonatal units (87%) and (ii) clinical review of prescriptions by a pharmacist (76%).

15. Clinical pharmacy services in hospitals provide guidance and assurance on the safe and secure handling of medicines in hospital clinical areas. There was variation in the clinical pharmacy services on neonatal units reported in this review; 29% of units reported having a dedicated pharmacist, while 64% reported receiving a service from a pharmacist not solely allocated to the neonatal unit. 41% of those without a dedicated pharmacist reported between 0.1-0.3 whole time equivalent (WTE) pharmacist cover. It is not possible to draw any connections between the level of pharmacist input and the safety of insulin use on a neonatal unit from this survey.

16. A process for ensuring regularity of staff training and maintaining competency of staff handling insulin, i.e. preparing and administering insulin, was reported to be in place in 48% of neonatal units and 34% of units reported a process for ensuring the competency of staff prescribing insulin.

17. A few units reported using a combination of other strategies to ensure the safe and secure handling of insulin such as: (i) keeping records of staff who have accessed



insulin; (ii) use of automated medicines cabinets; (iii) controls on who can request stock of insulin; (iv) audits of insulin use and supply.

18. Incident reporting is used by neonatal units to help improve patient safety and prevent avoidable harm through identification of common themes and modifiable risk factors and helping teams learn from adverse events or near misses; 86% of neonatal units report insulin related incidents. There is no direct link between the frequency of incident reporting and safer handling of medicines, including for insulin, however, a positive learning culture and the improvements that result from incident reporting are key to controlling risks around medicines use and improving patient safety.

Potential actions to improve practice

19. This review focussed on current practice, based on the Royal Pharmaceutical Society's safe and secure handling of medicines standards, which apply to all medicines and patient settings, not just insulin and neonates.

20. It has identified overall good practice in the safe and secure handling of insulin in neonatal units in England, with some expected variation in practice based on the type and size of unit, patient acuity levels and the number of babies admitted at any one time.

21. The results have not demonstrated any systemic failures that require a change in practice; the survey has identified some areas that could be improved such as: (i) regularity of training and maintenance of competence; (ii) access to specialist clinical pharmacy services; (iii) use of electronic prescribing. No evidence could be found that such quality improvement actions would reduce or prevent the risk of deliberate misuse of insulin in this setting.

22. It is important to note that unintended consequences, including the impact on insulin use across paediatric and adult patients would need to be carefully considered if changes in practice were to be proposed, to avoid increasing risk from delaying access to insulin when needed urgently.

Conclusions

23. This review identified good processes and practice for the safe and secure handling of insulin in neonatal units in England. Whilst some expected variation in practice was noted, no changes to practice were identified that would reduce the risk of patient harm from deliberate misuse of insulin, without increasing the risk of harm from restricted or delayed access.

24. It is recommended that neonatal units continue to follow national and local policies and guidelines on the safe and secure handling of medicines, including insulin, and to
