Rapid Response Report NPSA/2010/RRR015:
Prevention of over infusion of intravenous fluid and medicines in neonates

August 2010

Supporting Information

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1. Background

The administration of intravenous fluids and medicines to neonates is often an integral part of their care. However, there is a risk of the inadvertent over infusion of these solutions associated with specific intravenous infusion set up procedures or where the safety mechanisms associated with the administration of intravenous fluids using infusion pumps have been overridden. This risk has the potential to result in death. Weight and size and the often critical nature of the neonate’s condition are additional risk factors within this process. For the purpose of this report the definition of a neonate is taken as any infant aged 0-28 days, who may or may not require care on a neonatal unit, or any infant aged over 28 days who is an in-patient on a neonatal unit.

The NPSA received a report of a neonatal death following an accidental intravenous dextrose overdose. A 500 ml bag of intravenous 12.5% dextrose had been used to fill a 50 ml syringe which was then administered via a syringe pump. A 3 way tap was used to connect the 500ml bag to the syringe pump and the baby. It is likely that the overdose occurred as a result of the clamp being left open from the 500 ml bag of dextrose and the 3 way tap positioned so that the patient was receiving dextrose from both the bag and the syringe. An alternative explanation is that the tap was closed to the syringe pump and the solution infused directly from the 500ml bag. Following an inquest by HM Coroner a Coroners Rule 43 report endorsed the recommendations for shared learning made by the Court by way of a Patient Safety communication to prevent similar fatalities.

2. Review of the evidence of harm

A search of the NPSA’s National Reporting and Learning System (NRLS) was undertaken to search for similar incidents. A further incident where an identical intravenous infusion set up to that of the trigger incident was identified in the NRLS. However, due to the positioning of the 3 way tap and the closure of the administration set clamp, this did not result in an over infusion of fluid. In addition to this a further five ‘near miss’ incidents were identified where the safety mechanisms associated with the administration of intravenous fluids using volumetric pumps had been overridden. These included instances where intravenous fluids were removed from the infusion device and remained attached to the baby with the clamps open.

Incident data from NPSA’s National Reporting & Learning System (NRLS)

Search carried out on 20th January 2010.

A search of the NRLS was undertaken to identify all babies under 28 days and those over 28 days and under care of a neonatal unit. The following free text search terms were used in this search ; ‘fluid’ or ‘bag’ and ‘clamp’, ‘overload’, ‘overfill’, ‘overdose’, ‘too much’, ‘excess.’

All incidents reported from 1st November 2003 to 20th January 2010 were reviewed. From this search strategy, 120 incidents were obtained and all were reviewed. There were 7 relevant incidents identified.
<table>
<thead>
<tr>
<th>Themes</th>
<th>Incidents</th>
<th>Degree of harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syringe pump used to administer IV fluids with bag of fluids left connected to the syringe via a 3 way tap.</td>
<td>2</td>
<td>Death (1) No Harm (1)</td>
</tr>
<tr>
<td>Infusion fluid freely flowing with clamp open and not going through a pump.</td>
<td>3</td>
<td>Low Harm (1) No Harm (2)</td>
</tr>
<tr>
<td>Infusion fluid running through a pump that was switched off.</td>
<td>1</td>
<td>No Harm</td>
</tr>
<tr>
<td>Infusion fluid attached to baby and not in pump but clamped off.</td>
<td>1</td>
<td>Low Harm</td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td><strong>7</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Examples of incidents include:**

**Syringe pump used to administer IV fluids with bag of fluids left connected to the syringe and the baby via a 3 way tap**

> During the handover from night staff I noted that patient’s 50ml syringe had a 3 way tap attached and a giving set attached to a 500ml bag turnable to 50ml syringe to be filled as required. The 3 way tap was closed and so was clamp on giving set attached to 500ml bag of Dextrose so no additional fluid had been given in the end.

Lab test identified extremely high levels of blood glucose (153mmols) in patient. Not possible to explain such high levels medically. Analysis has concluded that the equipment set up which meant that the bag of fluids remained connected to the syringe pump and the patient is one of the root causes of this incident.

**Infusion fluid freely flowing with clamp open and not going through a pump**

> 1.8% saline infusion fluid found attached to long line, clamp open and not in IVAC 572 pump.

Found newly administered IV Fluid bag connected to baby, not enclosed in IVAC pump, giving set not clamped and UVC not clamped. 10% Dextrose running in to baby. Infusion and UVC clamped immediately, IV bag assessed. Blood glucose checked. Dr informed.

On removal of UVC (umbilical venous catheter) by medical team. Previous IVI fluids found to be freely running through the line. On examination giving set found not to be clamped off at appropriate site at patient end or at site near bag. Baby weighed. Blood sugar taken. Estimation made off amount of fluids given. IVI fluids via long line reduced to 0.5 mls / hr. Lipids stopped. Plan made to rpt BM every 30 mins. Parents informed.
Infusion fluid running through a pump that was switched off

On changing bag of Vamin it was noticed that the vamin line was running through a pump that was switched off and 5% Dextrose was running through the pump that was switched on. The 5% Dextrose had been discontinued the previous evening but along with the morphine had been left attached and not clamped off at either the bag or patient end. Vancomycin had also been given via the Long Line that afternoon and the pump switched off during the infusion.

Infusion fluid attached to baby and not in pump but clamped off

Alaris pump alarming "air in line". On checking line the IV fluid from x-xx-200x remained in pump and was infusing although disconnected from infant and found to be on floor. IV fluids from x-xx-200x connected to infant but clamped off and giving set had not been loaded into Alaris pump. Giving set loaded into pump and infusion commenced.

Data from NHS Litigation Authority

Search carried out 5th January 2010.

A search was undertaken of NHSLA data using the same search terms as for the search of NRLS data and no relevant incidents were identified.

Clinical network feedback

Eight neonatal units were contacted to give details of their current practice in relation to the administration of intravenous fluids or medicines via infusion devices. All eight units said that they used both volumetric and syringe pumps to administer intravenous fluids. A variety of reasons were given as to why each was used, and in which circumstances one would be chosen rather than the other. Generally volumetric pumps were used to administer larger volumes of fluid, and syringe pumps used to administer smaller volumes of fluid, medicines and blood. All of the neonatal units questioned said that they did not attach a bag of fluid to a syringe when using a syringe pump and all stated that they felt this was unsafe practice.

The British Committee for Standards in Haematology (BCSH) were contacted in relation to their guidelines on neonatal blood transfusion. These state that "Neonatal blood administration systems are available which allow blood components to be delivered via a syringe driver. These systems should incorporate an integral three-way system allowing the blood component bag to remain attached throughout the transfusion. The transfer of patient and blood component details to a syringe label is not advised due to the risk of transcribing errors. If this system is not used and the blood component bag not left attached to the syringe via a three way tap it would necessitate the transcription of patient and blood component information from the blood component bag to the syringe. BCSH guidelines state that this could lead to a risk of transcription errors which could result in the wrong blood being given, or difficulty in identifying the unit if an adverse reaction to the blood component occurred."
**Literature review**

A literature review of adverse events associated with the administration of intravenous fluids using intravenous infusion pumps was carried out in Pubmed and CINAHL databases using the following search terms.

**Pubmed**: "Infusion Pumps" AND "Infusions, Intravenous" AND "adverse effects"

**CINAHL**: Administration, intravenous, intravenous/AND exp infusion pumps/AND exp adverse health care event.

The abstracts were reviewed and key articles accessed. A search was also undertaken for guidelines (UK and international) that related to potential risk reduction strategies in the administration of intravenous fluids. In addition, the NPSA Human Factors Lead advised on relevant key studies on human error in the published literature.

In the five years between 2005 and 2010 there were 1,085 reports of incidents to the Medicines and Healthcare products Regulatory Agency (MHRA) involving infusing devices. In 68% of the reports no cause was established, 21% were attributed to user error while 11% were device related issues. MHRA produced an Infusion Systems Device Bulletin in 2003, which includes recommendations on the management of intravenous infusion systems.² There are also a number of other strategies that exist to reduce the risk associated with the administration of intravenous fluids. In 2004 the NPSA published a patient safety notice with recommendations on how to reduce the risk of patient safety incidents involving infusion devices³ and in 2010 produced guidance on the safe design of infusion pumps and syringe drivers.⁴ In addition, literature suggests that ‘smart pumps’ programmed with unchangeable limits can significantly reduce drug errors at the point of administration, particularly in the intensive care environment.⁵

However, guidance on infusion pump use or smart pumps could not have prevented the incident which triggered this report where a bag of fluid was left connected to the syringe via a 3 way tap and the fluids from the bag were inadvertently administered to the neonate due to the positioning of this tap. They also could not have prevented the reported near miss incidents where the safety mechanisms associated with the administration of intravenous fluids by volumetric pumps had been overridden. Applying Reason’s four stage model of human error theory⁶ to these incidents would suggest that organisational processes and management factors resulted in violation producing conditions. This in turn may have led to violations of local intravenous policies, such as the use of a non policy based intravenous set up procedure and the overriding of safety mechanisms, which resulted in the reported medication errors. A study of 483 intravenous drug preparations and 447 administrations identified a number of key causes of violation. These include a lack of appropriate intravenous administration training for nurses together with a lack of guidance regarding the quality and content of training, poor supervision, a lack of direct pharmacist support, poor practice going unchecked and becoming custom and practice within the environment and frequent interruptions and distractions during preparation and administration of intravenous drugs.⁷ The actions within this rapid response report have therefore focused on addressing the latent conditions which can lead to these violations.

### 3. Potential risk reduction strategies

A local neonatal intravenous administration policy which includes the action points detailed in the Rapid Response Report together with education, training and assessment for staff
involved in the administration and monitoring of intravenous infusions will assist in reducing the risk of inadvertent fluid overload in neonates. In addition, regular audit of practice against local policy should be undertaken.** A clinical briefing document also accompanies this Report. This provides guidance on checks to be carried out prior to and during an intravenous infusion, as well as at the handover of care which aim to reduce the risk of neonatal intravenous fluid overload. This includes advice regarding blood glucose monitoring which is recommended for neonates requiring additional energy provision via dextrose infusions.

A number of design solutions have been suggested to further improve the safety of neonatal blood administration systems. These systems currently incorporate an integral 3 way tap allowing the blood component bag to remain attached throughout the transfusion as the transfer of patient and blood component details to a syringe label is not advised due to the risk of transcribing errors. The replacement of the integral 3 way tap used in this system with a 2 way tap would mean that none of the possible tap positions could result in over infusion of fluid to the baby. In addition, the possibility of the use of volumetric pumps to administer blood components to neonates has been suggested by some networks. This would eliminate the use of an infusion system which necessitates the use of an integral tap.

** The National Patient Safety Agency’s Patient Safety Alert 20; *Promoting safer use of injectable medicines* (2007) recommends that NHS organisations provide training and audit for all healthcare staff involved in the administering and monitoring of injectable medicines and should audit medication practice with injectable medicines.

4. Summary and conclusion

Due to a neonate’s weight and size and the often critical nature of their condition, fluid overload can prove fatal. There is evidence that the majority of cases of fluid overload are associated with user error of the infusion device. The NPSA and MHRA have produced a range of guidance to assist in addressing these issues. In addition smart pumps have been demonstrated to be effective in reducing medication errors associated with infusion pump user error. However this guidance does not address the underlying cause of the incidents which triggered this rapid response report or meet the advice of the Coroners Rule 43 letter. The actions within this rapid response report aim to address the latent conditions which could result in the inadvertent over infusion of fluid to a neonate and specifically to reduce the risk associated with specific intravenous infusion set up procedures or where the safety mechanisms associated with the administration of intravenous fluids using volumetric pumps have been overridden.
References


3) National Patient Safety Agency. *Improving infusion device safety*. Patient Safety Notice 01. NPSA. 2004. Available at: [www.nrls.npsa.nhs.uk/resources/?EntryId45=59788](http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59788)


Appendices

Appendix 1

Suggested compliance checklist
The table below gives suggested evidence that organisations may wish to use locally as assurance of compliance with this Rapid Response Report.

<table>
<thead>
<tr>
<th>Number</th>
<th>Action</th>
<th>Suggested evidence of compliance</th>
</tr>
</thead>
</table>
| 1      | Ensure that a local neonatal intravenous administration policy is available that specifies:  
   a) When using a syringe pump to administer intravenous fluids or medicines to neonates, a bag of fluid should not be left connected to the syringe. **This action does not apply to the administration of blood components to neonates**  
   b) All clamps on the intravenous administration set must be closed before removing the administration set from the pump, or switching the pump off. This is required regardless of whether the administration set has an anti free flow device.  
   c) The frequency and responsibility for monitoring:  
      i. the intravenous infusion device  
      ii. the infusion administration equipment  
      iii. the patient receiving intravenous infusion | A copy of the policy, procedure or protocol approved by the appropriate governance committee and with the inclusion of points a to c highlighted.  
NOTE that this action does not apply to the administration of blood components to neonates.  
These should continue to be administered as per The British Committee for Standards in Haematology ‘Guidelines on the Administration of Blood Components (2009) Appendix 6 / Technical Aspects of Blood Component Administration / Administration Equipment / Paediatric Administration. |
| 2      | The above points should all be included in local standards for education, training, assessment and subject to audit to ensure clinical practice is in accordance with the local policy | A copy of training slides, workbooks or competency checklists with the inclusion of points a to c highlighted.  
A schedule or plan of ongoing training for new and existing staff.  
Meeting minutes or training records that indicate the proportion of staff achieving competency in neonatal intravenous administration is monitored and any lapses acted on, and that only staff who have achieved the required competencies administer intravenous infusions  
A copy of an audit programme or observational checklist demonstrating that points a to c have been built into existing audits of documentation and observation of clinical practice  
A schedule or plan of ongoing audit and observation of clinical practice  
Meeting minutes that indicate audit findings are discussed and any lapses acted on. |
## Appendix 2

### Summary of rationale for recommended actions

This table provides a summary of how the incident reports, local policy review, and literature explored informed our recommended actions.

NHS organisations should ensure that:

<table>
<thead>
<tr>
<th>Number</th>
<th>Action</th>
<th>Summary of rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>Ensure that a local neonatal intravenous administration policy is available that specifies:</td>
<td>Where bags of fluid are left connected to a syringe via a 3 way tap during the administration of intravenous fluids to neonates, there is a risk of unintentional over infusion. There are four possible positioning options of the 3 way tap. In conjunction with the clamp from the fluid bag being left open, 2 of these positions will cause over infusion of fluid to the patient. In one the patient would be receiving fluid from both the bag of fluid and the syringe and in the other the patient would be receiving fluid directly from the bag.</td>
</tr>
<tr>
<td></td>
<td>When using a syringe pump to administer intravenous fluids or medicines to neonates, a bag of fluid should not be left connected to the syringe</td>
<td>This action does not apply to the administration of blood components to neonates.</td>
</tr>
<tr>
<td></td>
<td><strong>This action does not apply to the administration of blood components to neonates.</strong></td>
<td></td>
</tr>
<tr>
<td>1b</td>
<td>Ensure that a local neonatal intravenous administration policy is available that specifies:</td>
<td>Over infusion of fluid can occur if an intravenous administration set is removed from an infusion pump or the pump switched off and the clamp not turned off. This risk applies even if the administration set contains an anti free flow device.</td>
</tr>
<tr>
<td>Number</td>
<td>Action</td>
<td>Summary of rationale</td>
</tr>
<tr>
<td>--------</td>
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<td>----------------------</td>
</tr>
</tbody>
</table>
| 1c     | Ensure that a local neonatal intravenous administration policy is available that specifies: The frequency and responsibility for monitoring:  
  i. the intravenous infusion device  
  ii. the infusion administration equipment  
  iii. the patient receiving intravenous infusion | Regular monitoring of the infusion pump, intravenous administration set and the patient during infusions, using the guidance on checks provided in the clinical briefing sheet will reduce the risk of fluid overload. |
| 2      | The above points should all be included in local standards for education, training, assessment and subject to audit to ensure clinical practice is in accordance with the local policy. | A policy alone is unlikely to change practice; the actions of the policy need to be embedded in training for all relevant staff. Only through audit of documentation and observation of clinical practice can the organisation assure itself that policy and training are being applied in practice. |