

The safe use of infusion devices

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Infusion devices are used extensively in all clinical areas and are an essential tool for providing perioperative care, critical care and pain management. Concern has been raised about the high incidence of critical incidents related to these devices. The majority of these incidents reported to the Medical Devices Agency (now part of Medicines and Healthcare products Regulatory Agency (MHRA)) is attributable to human error. The National Patient Safety Agency has therefore initiated a project in an attempt to reduce the number of these errors. Plans include standardization of devices, evaluation of user experience, possible development of equipment libraries and internet-based training. Whilst there is a bewildering choice of equipment available, they are essentially either syringe drivers or volumetric pumps. This review will consider three areas: starting the infusion, delivery of the infusion, and organizational structure.

Starting the infusion

Choice of device

When a clinical situation requires an infusion, the most appropriate device should be chosen for the intended therapy. The MHRA have recently drawn up three categories which are defined by features of the therapy and performance parameters of the device (Table 1).

Critical incidents have occurred because of an incorrect choice of giving set, connector, valve or syringe. Volumetric pumps should only be used with the set provided by the manufacturer and syringe compatibility should be checked with syringe drivers. The syringe driver infusion rate (ml h^{-1}) is the product of the drive rate (mm h^{-1}) and the internal cross-sectional area of the syringe barrel. Different syringe manufacturers use different bore sizes for the same size of syringe. In addition, volumetric pump accuracy is sensitive to the internal diameter of the giving set tubing.

Anti-siphon valves

Anti-siphon valves are usually used with syringe drivers to reduce the risk of inadvertent

free flow. This can occur if the syringe barrel or plunger is not engaged firmly in the pump mechanism. If the pump is more than 100 cm above the patient, a gravitational pressure can be generated that overcomes the friction between a non-secured plunger and barrel. Siphoning can also occur at a minimal height difference if there is a crack in the syringe allowing air entry. Syringe drivers should therefore not be positioned above the level of the patient. Some modern pumps have a function called 'back-off', which protects against post-occlusion bolus (see below). This function may preclude the use of anti-siphon valves.

Anti-reflux valve

An anti-reflux valve should be inserted in any other line that is connected to the infusion line. This will prevent back-flow up the secondary and often lower pressure line should a distal occlusion occur and avoid a subsequent inadvertent bolus.

Priming the system

The priming volume of the set and any connectors may be significant and could lead to a delay in onset of therapy. For this reason, the drug concentration in the infused solution should be such that the resultant infusion rate is not very low. A rate $>10 \text{ ml h}^{-1}$ is appropriate. Low infusion rates result in delays in both the initial onset and in the onset of effects from subsequent rate alterations. For example, if it were necessary to infuse a drug at 10 mg h^{-1} , it would be preferable to run a 0.5 mg ml^{-1} solution at 20 ml h^{-1} , rather than a 5 mg ml^{-1} solution at 2 ml h^{-1} . These considerations are important in the perioperative setting but lower infusion rates will be indicated for patients at risk of fluid overload or receiving long-term steady-state infusions.

Infusion sets with large priming volumes increase the risk of inadvertent, delayed bolus effects, for example remifentanyl remaining in an infusion line after intraoperative use may suddenly be infused some time later when the patient is in recovery.

Key points

Three therapy categories have recently been described for infusion devices.

The use of pre-filled syringes and infusion bags significantly reduces risk.

Infusion lines should be purged after connection to a pump to 'take up mechanical slack' and minimize delay in onset.

A significant inadvertent infusion bolus can follow the release of a line occlusion.

A multidisciplinary group should be set up in every hospital to establish a standard approach to procurement, training, maintenance and storage of infusion devices.

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Table 1 Therapy categories and performance parameters. Medical Devices Agency. Infusion Systems. *MDA Device Bulletin DB2003 (02)*. London: Department of Health, 2003

Therapy category	Therapy description	Patient group	Performance parameters
A	Drugs with narrow therapeutic margin	Any	Good long-term accuracy
	Drugs with short half-life	Any	Good short-term accuracy
	Any infusion given to neonates	Neonates	Rapid alarm after occlusion Small occlusion bolus Able to detect very small air embolus (volumetric pumps only) Small flow rate increments Good bolus accuracy Rapid start-up time (syringe pumps only)
B	Drugs, other than those with a short half-life	Any except neonates	Good long-term accuracy
	TPN	Volume sensitive* except neonates	Alarm after occlusion
	Fluid maintenance		Small occlusion bolus
	Transfusions		Able to detect small air embolus (volumetric pumps only)
C	Diamorphine	Any except neonates	Small flow rate increments only Bolus accuracy
	TPN	Any except volume sensitive* or neonates	Long-term accuracy
	Fluid maintenance		Alarm after occlusion
	Transfusions		Small occlusion bolus Able to detect air embolus (volumetric pumps only) Incremental flow rates

*Volume sensitive patients include those with renal failure, cardiac failure, pre-eclampsia, etc.

Connections

Several high profile cases have highlighted the catastrophic results that can follow misconnections between epidural, intrathecal, i.v. and enteral infusions. These have arisen because of the standard luer lock connection system. Alternative, physically different systems are proposed, but do not appear to be available imminently.

Documentation

Infusions must always be labelled clearly. Confusion arises if different containers appear superficially similar. The use of bag systems for epidural infusions has been associated with cases of fatal inadvertent i.v. infusion. The recently introduced national standard for the colour coding of syringe labels may help reduce such risks. Accurate and clear prescriptions are essential, as are regular written records of the progress of the infusion. Fatalities have occurred when basic documentation and associated monitoring have been overlooked and inappropriate pump settings have led to prolonged over-infusion. Modern pumps provide patient history logs and volume infused displays.

Dosage calculations

Estimates should be made before complex calculations are carried out. Any gross discrepancy may then be apparent. Medical staff should adopt the nursing practice of having a second person repeat the calculation. It is vital to double-check all conversions between different descriptions of concentration, for example a 1:1,000 solution can be 0.1% or 1 mg ml⁻¹. The use of pre-filled syringes and infusion bags significantly reduces risk.

Correct settings

The setting up of modern infusion devices is often far less intuitive than with earlier, simpler models. The need for training and assessment has never been greater. There are several potential pitfalls. Details should not be entered from behind the pump (e.g. 5 ml h⁻¹ entered upside down is 0.5 ml h⁻¹). It should also be remembered that displays usually extend to only one decimal place, for example 2.25 forced into such a display may become 22.5. Finally, it is crucial to double-check the units (e.g. mg and µg). Most modern devices can have a default standard configuration. This is particularly useful in situations where the great majority of patients receive an identical regimen such as patient-controlled analgesia.

Activating the device

After syringe or bag preparation, the pump can be set up. Lines attached to a syringe must be primed and all air removed. The syringe is then fitted into the pump. Most infusion devices have alarm sensors which detect whether or not the set or syringe is properly engaged. With syringe drivers, the pumps purge mechanism must be used once the syringe is in place. Purging removes the mechanical slack ('backlash') in the system and minimizes onset delays that would otherwise occur. Not purging a syringe pump, particularly at low rates, can delay infusion onset by over an hour.

Infusion sets with volumetric pumps must be carefully primed, ensuring that no air bubbles remain. Abiding by the manufacturer's priming instructions will reduce the incidence of air bubbles in areas of the set with joins, ports or sensor devices. Once the set is fitted into the pump and the door or mechanisms closed, the roller

clamp should be fully opened. This must be done before the pump is attached to the patient. This important check confirms no flow from the infusion bag when the pump is not running. Any visible flow suggests that the set is not properly engaged or that the set or pump is faulty. There is then a high probability of dangerous free flow from the infusion. Such events are well documented, for example free-flow of a syntocinon infusion causing profound fetal distress necessitating emergency Caesarean section.

Ten minutes after starting an infusion, a final basic check should be carried out. The expected volume should have been infused and settings should be unchanged. This simple check would have prevented many of the critical incidents that have been reported with infusion devices.

Delivery of the infusion

A careful set-up procedure will prevent the majority of errors; however, major problems can still occur after the onset of an infusion. This is particularly the case when patient care is transferred to different staff or clinical area. A proper hand-over with complete documentation is necessary. Good communication is the most important factor in reducing infusion risks. Checklists, which direct practice, increase compliance with correct procedures.

Inadvertent bolus

A syringe that is placed into a pump whilst connected to the patient is highly likely to deliver an infusion bolus. Syringes should always be inserted into pump mechanisms before being attached to patients. The infusion line should also be temporarily disconnected from the patient if a pump is changed during a procedure. During patient transfers, it is bad practice to have syringes removed from pumps and yet still attached to the patient. Lifting the syringe up will inevitably cause an inadvertent bolus. Even if the infusion set is left connected to the syringe driver or volumetric pump during transfers, large alterations in the device height relative to the patient may lead to over or under-infusion because of tubing compliance.

Siphonage or free-flow

Life-threatening siphonage or free-flow of an infusion should be unlikely if the simple precautions described above have been taken. Volumetric pump sets should be loaded correctly, the door closed and the absence of free-flow checked by opening the roller-clamp before connecting to the patient. Syringe pumps should be placed at the level of the patient with the syringe securely located in the mechanism and with an anti-siphon valve in the line.

Occlusion

The occlusion of an infusion may result in patient harm caused by cessation of therapy. Even in the absence of an occlusion, significant pressures have to be overcome to deliver infusions. Resistance

arises because of filters, anti-siphon and anti-reflux valves, administration sets and, in particular, the cannula. Together with the venous pressure, this results in a need for normal infusion pressures of at least 150 mm Hg in adults. An infusion through a long epidural cannula will need even higher pressures. Conversely, in neonates, pressures of 50 mm Hg are typical because of lower flow rates and shorter cannulae.

It is important to appreciate the pressures generated by infusion devices. Modern pumps have alarms that detect unacceptable rises in infusion pressure at the time of occlusion. Clamped-off or blocked lines and cannulae set off occlusion alarms but they are not the only triggers. Infusion pressures also rise significantly with very long or small bore cannulae, higher infusion rates and more viscous solutions (e.g. propofol). These factors are brought together in the Hagen-Poiseuille equation for laminar flow:

$$\text{Pressure drop} = \frac{128 \times \text{viscosity} \times \text{flow rate} \times \text{cannula length}}{\pi \times \text{cannula diameter}^4}$$

Occlusion alarms are set to activate if inappropriately high infusion pressures are reached; however, settings should be at the lowest appropriate pressure. Adult alarm settings should be ~150 mm Hg above working pressure. A default setting of 300 mm Hg is therefore usual. Neonatal default settings are much lower (100 mm Hg). Devices that have specific clinical uses (e.g. PCAs, epidural and anaesthesia pumps) have appropriate default alarm settings at their initial configuration. For this reason, anaesthetists will not usually have cause to alter the alarm setting. However, generic devices may need resetting to deal with different clinical situations.

It is dangerous if the pressure alarm limit is set too high. The higher the alarm setting, the longer it will take for the infusion pressure to reach the limit and activate the alarm. The patient will then inevitably suffer a significant period without the intended therapy. This is particularly the case if the line is already occluded at the commencement of the infusion, as the pump will always take a certain time to build-up to normal working pressures. A clamped-off line is perhaps the commonest cause of occlusion. Infusions running at low rates will take proportionately longer to reach the pressure alarm limit in the case of an occlusion. This is another reason for using solutions at lower concentrations that will run at higher rates (see above).

Extravasation results in cessation of therapy but may only cause a slight increase in infusion pressures. For this reason, occlusion alarms cannot be totally relied upon to alert staff to the problem. Regular, direct visualization of the infusion site is necessary. Unfortunately, this is not always possible during major surgical cases and critical incidents have occurred.

Post-occlusion bolus

After release of an occlusion, a sudden bolus can occur because of the increased pressure generated by the pump whilst the line is occluded. Although fluid cannot be compressed, other components of the infusion line are compliant and a significant increase

Table 2 Infusion Device Problems, their causes and prevention

Problems	Causes	Preventative checklist
Setting-up errors	Calculation error in concentration or rate Error in drawing up solution Incorrect settings on pump	Check calculations with second person Use pre-filled syringe/infusion bag or carry out solution preparation with second person Double check correct units to be entered e.g. ml h ⁻¹ or mg h ⁻¹ and confirm with second person
Under-infusion	Faulty device Delayed onset because of mechanical slack Air in line Occlusion	Ensure device and cable have been safety tested and are in date Check that delivery and clamping mechanism move smoothly Check alarm sounds when device switched on Check that device completes self-check Purge line after attaching to device Fully prime line before use Ensure clamps and connections are open Check for tissue or obstructed i.v. site Check need for increased occlusion alarm pressure settings if appropriate
Over-infusion	Faulty device Siphonage from a syringe driver Free-flow from a volumetric pump Post-occlusion bolus Inadvertent bolus during patient transfer	As above Check for cracks in syringe Ensure syringe barrel and plunger firmly engaged in mechanism Position device at same level as patient Ensure presence of anti-siphon valve in line (unless precluded by back-off facility) Ensure line properly fitted in pump Ensure no free-flow after full opening of roller clamp Ensure release of increased line pressure before relieving obstruction if device has no back-off facility Ensure presence of anti-reflux valve in secondary line so as to avoid risk of back-flow and subsequent bolus Keep pump at level of patient Disconnect infusion line from patient if syringe is to be removed from pump
Communication errors	Absent or incorrect record Label absence or error Absent or incorrect information during transfer/handover	Detail starting volume with regular volume and monitoring checks thereafter Ensure correct labelling with colour coding where appropriate Ensure correct information passed over and understood during transfer/handover

in the volume of the system can occur. The post-occlusion bolus will be larger with inappropriately high occlusion pressure alarm settings because the pump will continue running for longer after the start of the occlusion. To prevent this bolus occurring, the pressure in the system should be reduced. This can be done by temporarily opening the system to air or disengaging the clamp on the syringe plunger. The infusion line should be disconnected from the patient if the syringe has to be reinserted in the drive mechanism. Some modern syringe drivers have a ‘back-off’ facility. This briefly draws back on the plunger if the occlusion alarm is activated reducing the size of any bolus. Unfortunately, this feature may preclude the use of anti-siphon valves because their presence damages the pump mechanism during the back-off manoeuvre.

Air entrainment

The problem of air entrainment and embolus is restricted to volumetric pumps. The clinical problem of air entrainment relates to the risk of air embolus. Most modern volumetric pumps are designed to minimize this problem and should have in-line air detectors. Single bubbles of 0.1 ml can be detected.

Tampering

Physical and software locking systems are important to avoid accidental or malicious tampering with infusion devices.

Organizational structure

The safe use of infusion devices is dependent upon a robust organizational structure to deal with procurement, training and maintenance. A dedicated medical device co-ordinator should be appointed to work in conjunction with a multidisciplinary medical devices group, which includes clinical, engineering, technical and purchasing staff.

Procurement

In our view, device standardization is essential: one type of syringe driver and one type of volumetric pump. Individual departments should not have more than one type of each device. Procurement considerations include fitness for purpose, characteristics of disposables and training and maintenance requirements.

Training

Health and Safety law places an obligation on employers to provide training in the use of infusion devices. All members of staff should have appropriate training in existing, as well as newly introduced equipment. New staff should have induction programmes. Competency-based training and assessment is now recommended, with 3-year refresher courses. Checklists to prevent common problems should be used (Table 2).

Accurate records of staff training should be maintained to ensure full coverage of relevant personnel and for medicolegal reasons.

Maintenance

Device faults will be minimized with efficient, regular maintenance programmes. Equipment libraries have been recommended to facilitate this process, as well as to enable the effective use of limited equipment stocks.

Key references

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See multiple choice questions 58–60.