

Infusion systems

December 2013

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Revision history

This version	Date published	Changes
V2.1	Dec 2013	New MHRA logo

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1 Executive summary

The Medicines and Healthcare products Regulatory Agency (MHRA) receives many reports of incidents involving infusion pumps. These incidents are of concern as many result in patient harm or death, primarily from over-infusions.

This publication has been updated to take into account changes in devices and practices, as well as information gained from the investigation of adverse incidents and current trends in the use of infusion systems.

1.1 Aim

This document is designed to raise awareness of the nature of infusion systems, their advantages and risks, management and training issues, with a view to reducing the number of adverse incidents that arise from their use. It describes problems in the use and selection of infusion systems and the training of users.

The advice is intended particularly for:

- clinical managers
- hospital and community users of infusion devices
- medical engineering staff
- those in charge of procurement.

1.2 Scope

This document deals primarily with infusion pumps and infusion devices for fixed and ambulatory applications. This includes intravenous and enteral delivery. Gravity controllers are addressed in less detail. The document does not cover implantable infusion devices.

2 Introduction

2.1 What is an infusion system?

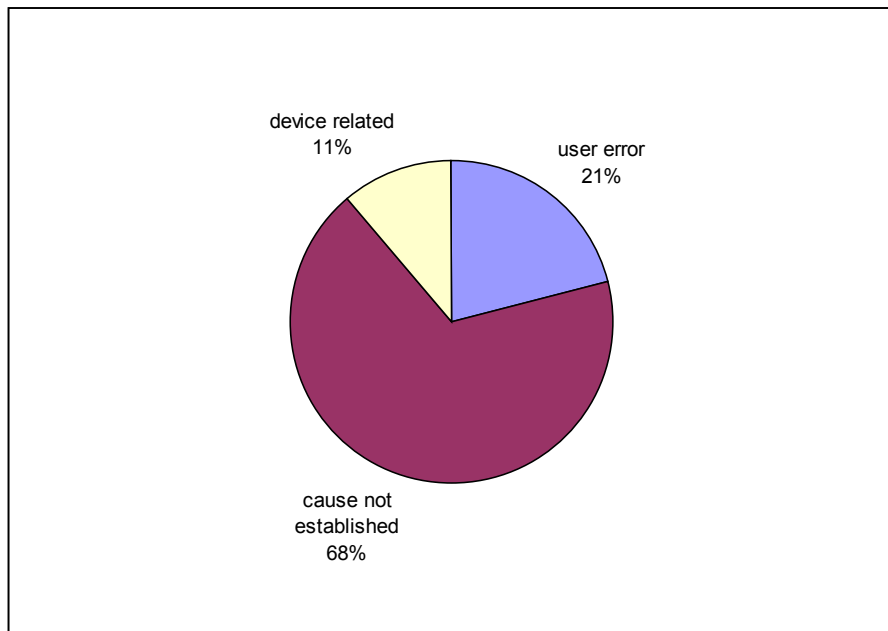
An infusion system is a device, and any associated disposables, used to deliver fluids or drugs in solution to the patient. The common routes are: intravenous, subcutaneous, epidural or enteral.

The simplest devices, gravity controllers, employ a clamping action to vary the flow of liquid under the force of gravity. More complex systems use a positive pumping action for infusion. The simplest of these is an elastomeric pump which has a balloon reservoir which contracts delivering the infusion at a constant rate. Powered volumetric infusion pumps, together with an appropriate administration set, are intended to provide an accurate flow of fluids over a prescribed period. Volumetric pumps may employ a linear peristaltic pumping mechanism applied to the infusion tubing ('giving set') or use a special cassette within the set. Powered syringe pumps work by pushing the plunger of a disposable syringe along at a predetermined rate. The type of pump used will depend on the required volume and speed of infusion. Appendix 1 gives more detailed descriptions of the different types of pumps.

2.2 What are the problems?

Many thousands of infusion devices are now in use in hospitals and in the community and there is an identifiable mortality and morbidity associated with their use. In the five years between 2005 and 2010 the MHRA investigated 1,085 incidents involving infusion pumps alone in the UK. Figure 1 summarises the causes of these incidents as percentages of the total number. In 68% of the reports no cause was established (either due to the reporter not providing enough information or reporting the incident incorrectly or the device was working as intended) and 21% were attributed to user error, including maintenance, damage and contamination problems. The remaining 11% of incidents were due to device-related issues such as performance problems, degradation, inadequate quality assurance and design and labelling. Table 1 gives examples of types of adverse incidents involving infusion pumps.

Figure 1 Outcomes of adverse incident investigations involving infusion pumps (2005 to 2010)



The majority of serious problems relate to over-infusion of drugs. In most fatal incidents no fault has been found with the infusion device, suggesting that use error is the most significant contributing factor or that some form of tampering could have taken place. Although in theory any infusion system can be misused, in practice syringe pumps have given rise to the most significant problems in terms of patient morbidity and mortality.

Table 1 Examples of types of incidents involving infusion pumps

Category of incident	Examples of incidents
Storage / packaging	<ul style="list-style-type: none"> ● Flat battery due to not charging the pump. ● Set packaging damaged – set contaminated.
Maintenance	<ul style="list-style-type: none"> ● Loss of battery capacity because battery not maintained according to manufacturer's instructions. ● Incorrectly replaced seal resulting in fluid ingress. ● Free-flow from volumetric pump because the door contacts were not checked during the pump's annual maintenance.
Contamination	<ul style="list-style-type: none"> ● Fluid ingress into infusion pump. ● Dried infusate on syringe size sensor resulting in incorrect syringe size being displayed by the pump.
Degradation	<ul style="list-style-type: none"> ● Set worn out – inaccurate infusion. ● Worn pumping mechanism leading to inaccurate infusion.
Damage	Pumping mechanism became loose because the pump was dropped. The loose mechanism could not hold the set against the door sufficiently to control the flow.
Performance	Infusion pump not performing to specification because the manufacturer had incorrectly set the pumping mechanism.
Design and labelling	A reprint of the user instructions specified a zero instead of the number one to set the KVO. Users following the new instructions could not set the pump to KVO.
Quality assurance (QA)	Spare components for detecting when the infusion was near its end were undersize. If fitted the pump would not signal 'near end of infusion'.
User errors	<ul style="list-style-type: none"> ● Misloading administration set. ● Misloading the syringe. ● Setting the wrong rate. ● Confusing primary and secondary rates. ● Not confirming the set rate. ● Not confirming the syringe size. ● Confusing the pump type. ● Not stopping the infusion correctly. ● Not confirming the pump mode. ● Not confirming the configuration of the pump.

3 Pump management

3.1 Introduction

This section outlines recommendations for the management of infusion systems.

A management system is essential to ensure resources are used efficiently and effectively and that the device performs in accordance with the manufacturer's specifications. This helps a trust meet the goal of patient care and safety.

3.2 Management

The organisational responsibilities involved in managing medical devices are outlined in the MHRA's document 'Managing Medical Devices', DB 2006(05) [1].

A medical device coordinator, usually a director or board member, should be appointed with overall responsibility for the management of infusion systems and operational matters among other devices. These responsibilities include the following aspects of infusion systems:

- selection and procurement
- development of a unit policy to determine appropriate use
- risk assessment
- installation and commissioning
- maintenance
- staff training
- operational documentation
- development of policies that identify spare infusion devices, control lending out, and facilitate recovery of devices both from hospital departments and the community
- ensuring that safety warnings have been acted upon.

There should be clear lines of accountability throughout the organisation leading to the board. These lines of accountability should be extended, where appropriate, to include general practitioners, residential and care homes, community-based services, independent hospitals providing services for NHS patients, managed care providers, PFI organisations and other independent contractors.

Since various groups of healthcare professionals (at different levels in an organisation) use infusion systems, the responsibilities of each group should be clearly defined. It is important to establish who is accountable, and where there is a need for joint accountability arrangements and to ensure that every member of staff using infusion systems fully understands who is responsible for what, and to whom, within the management system.

3.3 Selection and procurement

All units responsible for buying infusion devices should have an agreed and documented procurement policy. Clear specifications and requirements should be prepared, based on the therapy categories in Appendix 2.

Decisions on which infusion pumps should be purchased for each individual unit should be made in close consultation with the medical device co-ordinator and those responsible for their clinical use. In the primary care setting, the medical device co-ordinator may also wish to seek advice on procurement from a local, broad-based medical device group or other appropriate colleagues.

Advice given by the NPSA Safer practice notice 01 [2], the MHRA's Managing Medical Devices [1] and evaluation reports originally published by the Centre for Evidence-based Purchasing, now archived by the Department of Health (<http://www.cep.dh.gov.uk/CEPProducts/Catalogue.aspx?ReportType=Evaluation+report>), should be taken into account (see also Appendix 2).

3.4 Reporting adverse incidents

3.4.1 What is an adverse incident?

An adverse incident is an event which gives rise to, or has the potential to produce, unexpected or unwanted effects involving the safety of patients, users or other persons.

Adverse incidents can be caused by:

- shortcomings in the device itself
- inadequate instructions for use
- insufficient servicing and maintenance
- locally initiated modifications or adjustments
- inappropriate user practices, including inadequate training
- inappropriate management procedures
- the environment in which pumps are used or stored
- incorrect prescription

3.4.2 Reporting an adverse incident

It is essential that users know how and what to report as an adverse incident. Appendix 3 contains a poster that highlights examples of incidents to report and how to report.

Adverse incidents should be reported to the MHRA immediately, following local procedures, directly or via a medical device liaison officer who is responsible for prompt action in:

- reporting adverse incidents through agreed channels
- disseminating safety warnings for equipment.

Content of adverse incident report

The initial written report of the incident should include all relevant details immediately available. These include:

- make and model of pump and consumables
- serial number
- batch number of sets
- flow rate
- drug/feed
- syringe or bag size
- amount of drug/feed left in bag or syringe
- details of the incident, including times.

Reporting should not be delayed if any details are not immediately available.

Further details can be found in the MHRA's publication 'Reporting adverse incidents and disseminating medical device alerts' [3].

3.5 Preparation for use

3.5.1 Acceptance testing

When a new infusion system is delivered, the user organisation should check that it operates safely in accordance with DB 2006(05) Section 4 [1]. An organisation could be found negligent if harm occurs which could have been prevented by acceptance testing.

3.5.2 Medical device registers

All units should develop and maintain comprehensive device registers and resource information as soon as possible. These registers provide up-to-date information on the availability of devices and on important practical aspects of each infusion system, especially those related to patient safety. Such aspects include training requirements, maintenance records and safety warnings

All medical devices, including those on loan or donated, should be entered into a medical device register. All staff using infusion systems should have access to this register.

Note: Medical device registers should not be confused with asset registers, which are a simple list of equipment purchased, without the additional details included in the medical device register. To avoid duplication, asset registers could be amended to include the additional information relevant to the medical device register.

There should be standards for regular auditing of the register(s).

Information on an infusion device should be retained on a register for a minimum period of 11 years after the device has been removed from use [4].

3.5.2.2 Central and local registers

A large unit, such as a trust hospital, may require two types of register:

- a central register for the directorate or department
- separate local registers for each area or ward, allowing day-to-day supervision.

Smaller units, such as nursing homes and primary care practices, may only require one register, which combines the functions of both registers (described below).

3.5.2.3 Central medical device register

The central register is the responsibility of the medical device co-ordinator(s). For every infusion device it should record:

- date of receipt
- date placed into service
- location of operating instructions (master copy)
- training requirements
- calibration details/records
- maintenance carried out
- official location
- history of damage, malfunction, modification or repair
- procedures for withdrawal of device
- action taken in response to safety warnings
- software configuration.

It is recommended that the master copy of the manufacturer's instructions be kept with the central device register.

3.5.2.5 Local medical device register

The individual responsible for device management in that unit should maintain the local device register.

For every infusion device it should record:

- normal location or new location, if it has been moved
- calibration requirements
- maintenance requirements
- malfunctions and action taken
- software configuration
- procedures for withdrawal of device
- copies of relevant safety warnings
- reference to central medical device register.

Particular difficulties arise in the case of devices loaned between units. As noted above, details of any movement from the original location should be documented in the appropriate register. Arrangements should also be made to ensure that the device is returned when it is no longer required.

Example 1: Equipment libraries

Some trusts have centralised infusion pumps and other medical devices by setting up an equipment library. The concept of an equipment library is to 'provide an efficient service to clinical areas of commonly used equipment and to facilitate the safe and optimal usage of equipment for the benefits of patients and staff'. Although there can be challenges e.g. out of hours access.

Equipment libraries have many benefits:

- Equipment is cleaned and charged in the library, and devices are easily retrieved for repair and planned maintenance.
- Trusts are easily able to identify supply needs and replace old, unsafe and inappropriate devices.
- Training needs can be identified.
- Quality of service can be improved by:
 - reducing time wasted on finding equipment;
 - reducing the number of incidents due to poor maintenance and improving the tracking of devices.

3.6 Manufacturer's instructions

Manufacturers are required to provide operating and maintenance instructions. These instructions, supplemented by local material as required, should be used when preparing teaching packages for staff training.

Providing instruction summaries

Operating instructions are normally contained in a manual. They may also appear in an abbreviated form on, or attached to, the device itself. Where this is not possible, copies of the instructions should be issued to all wards where the equipment might be used.

If the manufacturer does not provide instruction summaries, the medical device co-ordinator should ensure that they are prepared by an experienced member of staff and approved by the manufacturer before use. If possible, they should also be attached to the device.

3.7 Maintenance and repair

Section 8 of DB 2006(05) [1] provides guidance on maintenance and repair.

3.7.1 Care of infusion systems in the community

In the community, patients and carers are responsible for the safe operation and day to day care of infusion systems.

It is important that an appropriately trained health professional makes sure that carers and patients are able to:

- check that devices are undamaged and functioning correctly
- carry out recommended inspection, functional and safety checks
- ensure devices are kept clean and, if necessary, decontaminated
- notify the appropriate people of device malfunctions.

In some cases, appropriate training may be required.

End users in the community should be assigned a named contact, by the healthcare supplier, who can provide technical and clinical support. An out-of-hours contact service should be arranged to offer clinical support and, if required, to replace faulty devices.

3.7.2 Routine maintenance

Requirements of the maintenance system

All devices should be maintained to the manufacturer's recommendations. A formal maintenance system is essential to ensure that devices remain safe and reliable. The system should include:

- regular checks and maintenance by users
- scheduled servicing
- defect reporting and correction.

All scheduled servicing and emergency repairs should be carried out by competent technicians.

The technical supervisor, in consultation with the medical device co-ordinator, should specify the frequency of servicing. This is particularly important in the case of heavy use, greater than usual wear and tear, or when pumps are returned from community or domiciliary use

Before putting a serviced device back into use the settings should be checked to ensure that they are appropriate.

Example 2 **Over-infusion incident following maintenance**

A patient suffered an over-infusion whilst using an infusion pump at home.

The infusion pump came from a special stock maintained for home applications. All pumps were set to a single, standard infusion rate. Following maintenance, the pump in question had been returned, set to its highest rate. The rate had not been checked and reset before issue.

Maintenance organisations must reset controls before returning devices. All newly serviced devices should be carefully checked before reissue. A label should be attached, stating the date on which maintenance was carried out.

Avoiding unauthorised modifications

It is potentially dangerous to modify an infusion pump without authorisation. All modifications should be authorised by the technical supervisor and medical device co-ordinator, together with the manufacturer, to ensure that safety is not compromised.

Example 3 **Unmodified pumps incompatible with giving sets**

A pump manufacturer offered, free of charge, to modify users' pumps to accept new giving sets, in order to standardise the sets. A trust had all its pumps modified, except in one hospital. When that hospital received new sets from the trust, it reported under-infusions. Furthermore, sets purchased from a third party manufacturer for these pumps were only compatible with the unmodified pumps. When these sets were used with modified pumps it resulted in over-infusions.

Service records should be kept and pumps should be labelled after servicing.

3.7.3 Breakdowns

In the case of breakdowns, the pump should be replaced with an equivalent device or rapidly repaired. Planning is required to ensure that suitable replacement devices are available and that maintenance contracts specify acceptable response times.

If an infusion pump has been accidentally damaged, perhaps dropped or subject to fluid ingress/spillage, it should be withdrawn from service immediately. The usual service department – EBME, manufacturer or supplier – should be contacted for advice.

Each unit should establish a clear system for notifying damage or malfunction to any device during use. This can be verbal or written. The medical device co-ordinator should notify the technical supervisor, to ensure prompt repair.

3.7.4 Record keeping

Within larger trusts, each unit should keep a service record of every device it holds, including infusion devices. This record is in addition to the central device register. The record should specify:

- servicing, repair and modification work carried out
- date of next service
- movements of devices to other units, including those outside the hospital.

3.8 Replacement and obsolescence

A system is required, in both hospital and community settings, to determine when an infusion pump needs replacing.

The expected life cycle of a pump should be held in the inventory record and regularly reviewed against the usage, maintenance and repair record to see if the end date needs to be adjusted. Heavy use or irregular maintenance may reduce the life cycle. A manufacturer recall of a pump will take precedence over other considerations.

Guidance on replacement and obsolescence can be found in section 10 of DB 2006(05) [1].

4 Training

This section provides general guidelines for operational and training standards required in the use of infusion systems. General guidance is available in DB 2006(05) section 5 [1].

4.1 Why is training needed?

There is a high frequency of human error in using infusion systems, particularly powered devices. This highlights the need for more formalised and validated competence-based training and assessment. Competence-based training is assessed on knowledge and skills.

Current health and safety law (RIDDOR 1995) [5] places an obligation on trusts to provide such training. Senior management should acknowledge the need for training programmes and standards of practice. Resources and time should be allocated to training in order to:

- ensure patient safety and minimise adverse incidents
- ensure the appropriate device is used with each therapy
- improve staff competence
- report any adverse incidents
- keep up with technological developments.

4.2 Who requires training and when is training needed?

The main users of infusion systems are nursing, medical and pharmacy staff. However, **all** staff likely to use these systems should receive training. Users should be given sufficient training, knowledge and supervision to be competent when operating infusion devices.

Induction training should include practical instruction for all potential users, regardless of their grade.

Anyone involved in the direct care of patients receiving therapy via infusion devices should also receive practical training, including the principles of operating infusion devices. Additional training for any other devices used locally should also be provided.

Organisations need to ensure that all professional staff, including bank, agency and locums, are trained in the local procedures and any pump configurations specific to a hospital or clinical area. Users who are not familiar with an infusion system should not operate it unless supervised or until they are considered competent in its use.

Users who feel they are not sufficiently trained, experienced or confident to use a particular device or perform a particular procedure should feel able to refuse to perform that task or procedure in the interests of patient safety.

Users should also be made aware that they are accountable for their own actions and may not be protected from the legal implications if their actions are inappropriate.

4.3 Organisation of training

4.3.1 Training policy

All organisations should have a formal training policy but arrangements will vary according to local circumstances.

The management system should ensure that:

- responsibility for training is delegated to a suitable individual in each unit
- adequate numbers of trainers are identified
- relevant skills are disseminated to other staff. Patient care should only be handed over to appropriately skilled individuals
- operating instructions are available
- operating practices are periodically audited to ensure they adhere to standards laid down by the trust.

4.3.2 Training programmes

When a new device is introduced, whether purchased, borrowed or donated, training sessions should be arranged for all relevant staff before it is used. The level of training required will depend on the complexity of the system and on the training needs of individual users.

Hospitals and primary care establishments should draw up formal training programmes for those instructing new staff. Written training plans are also required to ensure consistency among trainers.

When planning initial instruction in the use of a device, consideration should be given to training provided by the manufacturer to clinical engineering, medical, nursing and pharmacy staff, thereby developing a core of local expertise. Such initial instruction should be included in the contract conditions at the time of purchase.

Requirements of training programmes

Training programmes should be:

- multi-disciplinary
- ongoing
- documented
- included in staff induction programmes
- form part of continuous professional development
- designed to include assessment of practical competence in specific devices
- reviewed and updated to reflect changes in equipment or software.

Refresher training

Initial practical training should be supported by written instructions and reinforced by refresher courses. Refresher training is needed to:

- update the skills of regular users of infusion systems;

- maintain levels of expertise amongst those who use the systems less frequently.

4.3.3 Resources for training

Written operating instructions

Manufacturers must provide adequate operating and maintenance instructions. These instructions, supplemented where appropriate by locally prepared material, should be used when preparing teaching packages for staff training.

Instructions are usually contained in an operating manual. An abbreviated form of the instructions often appears on, or attached to, the device.

Copies of the instructions should be issued to all wards where the equipment might be used. This is especially important where abbreviated instructions do not appear on the device. If the manufacturer does not provide summaries, the medical device co-ordinator could arrange for an experienced staff member to prepare them, in consultation with the manufacturer. The summaries should be issued **before** the device is used.

Example 4 Training to train

A large trust has appointed a medical device trainer who runs a training programme for medical staff and nurses, involving many medical devices from different manufacturers. The training focuses on the operation, safety, maintenance and troubleshooting of medical devices. It also emphasises common user errors specific to each ward. A 'training for trainers' course has also been set up for infusion systems. Its aim is to appoint key trainers for each ward, responsible for cascading training to their ward staff in a consistent, documented manner. In addition, to measure competence, evaluation sheets are used to test each trainee.

Example 5 The National Infusion Devices Programme, Skills Academy for Health – Core Learning Unit

The aim of this programme is to:

- ensure that staff understand how to use infusion devices properly
- build competence and confidence amongst practitioners
- promote patient confidence
- reduce hospital acquired infections (HCAI)
- support organisations to deliver Risk Management and Care Quality commission (CQC) standards (The programme is matched to both CQC and to the NHS Knowledge Skills Framework).

The programme consists of:

- an introductory module
- a diagnostic test
- E-learning modules
- practical sessions using infusion devices and tutor support throughout

The programme is linked to a City & Guilds qualification accredited to FE Level 3.

National Infusion Devices Training Programme
Skills Academy for Health - Core Learning Unit
5th Floor, Don Valley House
Savile Street East
Sheffield S4 7UQ

Tel: 0845 330 6507 Email: clpu@sysha.nhs.uk
<http://www.corelearningunit.com>

4.3.4 Record keeping and assessment

Training log

All users of infusion systems should be given a training log, as part of their individual record of continuing professional development (CPD).

The training log should be used to monitor staff training, and to identify and remedy deficits. The log should detail, as a minimum:

- dates of initial and refresher training
- system(s) covered
- trainer's endorsement.

Assessing competence

An individual's competence to perform the required tasks should be checked and verified. Certification and assessment by local training procedures is an appropriate means of ascertaining whether individuals have undergone current and relevant training and achieved appropriate levels of competence.

4.4 Content of training

The areas covered in training should reflect local circumstances and the specific needs of different staff and/or user groups.

4.4.1 Training for hospital staff

Training should demonstrate competence and seek learning outcomes in the following areas:

Devices

- the principles of the main types of devices, including the advantages and disadvantages
- criteria for selecting and using infusion devices/associated disposables for any given therapy or location
- setting up, priming, loading and checking procedures for devices
- monitoring of devices in use and observational skills in assessing the observed flow rate compared with the rate displayed on the device
- free-flow, including siphoning
- preventing air entrainment
- configuration of the devices used in their clinical area
- using battery powered pumps
- security against tampering
- maintenance, storage and cleaning.

Drugs and solutions

- pharmacology of the most commonly used drugs/solutions and associated hazards
- dose calculation and checking
- pharmaceutical information – stability, incompatibilities, interactions

- preparation of solutions.

Procedures

- record-keeping, including training records, maintenance records, reporting and recording of adverse incidents, device registers, prescriptions and monitoring charts
- incident procedure
- rationale for regular maintenance
- reporting procedures for incidents and injuries, as well as feedback on repeated errors (RIDDOR)
- awareness of MHRA publications (Medical Device Alerts, One Liners and Device Bulletins), other relevant documentation, written protocols and reporting of adverse incidents.

4.4.2 Training for patients and carers

Training instruction should be provided for patients/carers who need to use infusion devices. Printed guidance, which could combine the manufacturer's instructions and local guidelines, should be issued. This could include:

- operation and control of the device, including known environmental hazards
- details of settings
- regime of necessary checks required (type, periodicity)
- care of the device (cleaning and battery changes etc.)
- recognition of a system failure
- what action to take in the event of system failure, extravasation or adverse effects
- nature of the treatment and the drug(s) to be infused
- expected results and side effects
- reasons for the choice of infusion system
- preparation of the infusion and connection to the infusion device (if required)
- free-flow and siphonage
- individual(s) to be contacted in emergencies
- potential consequences of tampering
- care of the infusion site.

4.4.3 Healthcare professionals working in primary care and the community

Healthcare professionals working in the community and primary care setting face different challenges to their colleagues in hospitals where services, patients and clinicians share the same geographical location.

Training for community nurses

Community nurses increasingly care for patients receiving drug treatment via infusion devices. Examples include parenteral nutrition, and drugs used in palliative care. Nurses may be faced with new equipment or work for long periods of time without direct contact with the hospital. In such situations, it can be difficult to maintain and acquire skills related to the devices. Special consideration should be given to the issues surrounding working in isolation, assessment and maintenance of competence.

The most effective way of training community nurses might be to provide training on specific equipment that is to be used in the community. This could be achieved through access training course provision at acute hospitals. Suitably trained nominated staff could provide such training. The training should cover understanding of the infusion device (settings, alarms, assembly etc.), together with any special precautions, safety or maintenance information.

Training for nursing home staff

Patients in private sector nursing homes often receive treatment via infusion devices. The nursing home may own infusion devices or borrow them from the Macmillan service or hospice.

It is essential that nursing home owners ensure that nurses working in this environment are adequately trained. Support for training is available from local hospices and/or trusts. Under current health and safety law [6] and CQC guidance (<http://www.cqc.org.uk>), homes are obliged to provide training for the safe use of medical devices and effective risk management.

4.4.1 Training on maintenance and repair

All users should be trained to:

- ensure that devices are undamaged and functioning correctly
- make sure that devices are kept clean and, if necessary, decontaminated
- carry out recommended inspection, functional and safety checks
- notify the appropriate people if a device malfunctions.

See Table 2 for a summary of actions.

Table 2 Action required by infusion pump users

When?	Action
Before use	<ul style="list-style-type: none"> • Check that leads, administration sets, bags and cassettes or syringes are in good working order and properly assembled/loaded. • Carry out relevant functional and calibration checks (start-up checks). • Note results. • Check control settings. • Check that correct flow rate has been set.
A problem occurs	<ul style="list-style-type: none"> • Stop the infusion. Make sure that all clamps on the giving sets are closed. • Seek technical advice. • Record problems and action taken. • If necessary, withdraw the device from service.
At specified intervals	<ul style="list-style-type: none"> • Check that the observed flow rate corresponds to the rate displayed on the infusion pump. • Inspect infusion site. • Note results. • If checks fail, withdraw the device from service if necessary.
After use	<ul style="list-style-type: none"> • Clean as recommended by the manufacturer. • Safely dispose of single-use devices and other accessories that cannot be reused.
When sending an infusion system to be repaired or serviced	<ul style="list-style-type: none"> • Include all the leads and accessories needed to operate the device. • Enclose a full account of any problems and faults. • Decontaminate. • Fill in decontamination form.
When an infusion device has undergone service	<ul style="list-style-type: none"> • Carry out all standard pre-use inspections. • Check the set-up of protocols and programs, as these may have been altered during servicing.
When an adverse incident has occurred (see section 3.4 for what should be reported to the MHRA)	<p>First take steps necessary for the well being of the patient and/or staff, then:</p> <ul style="list-style-type: none"> • Do not alter settings or remove administration sets. • Leave any fluids in the infusion system if possible. • Note details of all medical equipment attached to the patient. • Note details of device: type, make, model and serial number. • Retain packaging for details of consumables. • Note setting of controls and limits of alarms. • Note the content volume remaining in the bag, container, set or syringe. • If relevant, record the contents of computer memory logs of the infusion pump. Seek the assistance of the electrical biomedical engineering (EBME) department if necessary. • If possible, contact the MHRA before moving or dismantling the equipment.

Example 6 Over-infusion due to user not checking that the user's instructions were for the pump in use

A user followed the instructions in the quick reference guide for a particular pump which resulted in an over-infusion of heparin. The quick reference guide attached to the pump was for the wrong model. The user should have noted that these instructions identified clearly which pump they were for and that the pump display did not correspond to that indicated in the guide.

Example 7 Under-infusion due to users not taking up the backlash in syringe pumps

In the maternity ward of a hospital members of staff were allowing two hours from the start of an infusion of oxytocin to the onset of contractions. If contractions had not started by then, a caesarean delivery was undertaken. A higher than expected number of caesarean deliveries were being carried out until users started purging the 50ml syringes being used for the oxytocin infusion, which took up the mechanical backlash in the pumps. Without purging the pumps, the low infusion rate meant that the pumps were taking over an hour to take up the backlash and so patients received no drug during that time.

5 Operational documentation

Users should maintain careful documentation regarding all operational aspects of infusion systems. This applies whether the infusion is administered in a hospital or primary care setting.

5.1 Drug selection and dose calculation

Local drug and therapeutics committees at all levels should work together to produce clinical guidelines for the safe prescribing and administration of drugs using infusion systems in hospital and community settings. The guidelines should be widely disseminated and regularly reviewed and updated.

Users should seek additional advice from drug information departments, ward pharmacists, local drug and therapeutics committees and drug manufacturers, where appropriate.

Guidelines for safe prescribing and administration of drugs

The guidelines should include:

- intended infusion route
- choice of drug
- dosage calculations e.g. infusion rate
- standardised prescribing documentation
- standardised administration documentation.

The guidance on dosage calculations should draw particular attention to the potential for error where the units of prescription differ from units of administration. For example, a prescription might be written in ml, mg or units per hour, whilst the device is set at mm per hour.

5.2 Prescription of drugs

Prescription details to be recorded by the prescriber should include:

- the prescribed drug
- details of any diluent
- final concentration of drug e.g. mg per ml
- dose per unit of time
- administration route
- date and time (24 hour clock) to be started and completed
- signature of prescriber
- instructions for using 'bolus' facilities or variable dose regimens.

5.3 Preparation of the drug in solution

Every time a solution is freshly prepared, the relevant details should be recorded on the product label or appropriate unit document. Whenever possible, drugs or fluids should be prepared aseptically in the pharmacy.

Details recorded for prepared drug solutions should include:

- date and time (24 hour clock)
- total amount of drug used
- total volume of diluent used
- batch numbers of all ingredients
- names of persons preparing and checking solutions
- name of patient.

5.4 Administration

The following details should be recorded:

At start of infusion:

- type of model, serial number etc. of device
- date
- route
- time infusion started (24 hour clock)
- volume at start of infusion
- volume to be infused
- initial infusion rate setting
- expected completion time
- name(s) of person(s) setting and checking rates.

On each check:

- date
- time (24 hour clock) – actual time not a tick in a box
- volume remaining
- total volume infused
- infusion rate setting
- name of person carrying out the check.

In cases of variable prescribed dose regimens (e.g. heparin, insulin sliding scale) where the concentration of the drug is not altered:

- date
- time (24 hour clock)
- rate setting
- name(s) of person(s) setting and checking rates
- indication for alteration
- appropriate notification if completion/replacement time altered.

With variable prescribed dose regimens it is important to consider the need for replacement infusion solutions prior to the existing solution running out.

5.4.1 Non-variable dose regimens

In the case of dose alteration with non-variable dose regimens (fixed rate infusions), a new prescription is required as described in section 5.2. In instances where a new solution must be prepared, see section 5.3.

5.4.2 Rapid dose alterations in theatre and ICU

When alterations in doses are made in rapid succession, for example in the operating theatre or intensive care unit, it may not be practicable to document all changes. In such cases, procedures and protocols should be prepared by clinical managers to ensure that safe working practices are maintained.

5.5 Discharge or transfer

A discharge care plan is required for all patients who are discharged from hospital to continuing care in the community. This should be prepared in advance by hospital staff, together with the community staff and GP.

If a patient is still undergoing treatment involving an infusion device, the discharge care plan should detail all aspects of the therapy. This should be given to the patient and carer, and to anyone else involved in managing the patient.

Similar information should be given to hospital staff when patients are transferred between units, whether within the hospital or from the community or a hospice.

5.5.1 Discharge plan

The written discharge plan should include:

- details of therapy (drug and dose)
- details of settings
- regime of necessary checks to be made (type, periodicity)
- how to recognise an incident and what corrective action to take
- details of clinical and technical support – including a contact telephone number.

Example 8 **Good practice record keeping**

A hospital has found an improved way of recording details of infusion systems.

It designed a new form, which was monitored by a project team representing several directorates and reviewed by the trust's drugs and therapeutics committee.

The form is in two layers and is self-duplicating. The top layer has an adhesive edge that is attached to the patient's notes. The bottom layer is sticky backed and wraps around the syringe barrel or infusion line. This gives staff the extra security of a visible record of treatment, whilst avoiding extra form filling.

6 General safety recommendations

Users should ensure that they are familiar with the manufacturer's instructions and the organisation's practice policies. Appendix 1 gives details of the different types of pumps.

6.1 Safe use of volumetric pumps

6.1.1 Recommendations for using administration sets

- Always check that the administration set is compatible with the infusion pump. The correct pump should be specified on the administration set's packaging.
- Always inspect the administration set for damage before priming the line.
- Inspect the drop chamber, after loading the set and during infusion, to ensure the drip rate is as anticipated.
- Consider using an administration set fitted with an anti free-flow device.
- Always use the roller clamp to occlude the line when removing the administration set, regardless of whether the set has an anti free-flow device.
- Replace the administration set within the lifetime specified by the manufacturer, in order to maintain accurate delivery.

6.1.2 Preventing free-flow (siphonage)

Free-flow should not occur if the set is loaded correctly.

However, users should check that the roller clamp is closed before removing the administration set from the pump, as a primary means of occluding the line. If the administration set is fitted with a flow-stop mechanism, this should **not** be relied upon and the roller clamp should still be used.

6.1.3 Preventing air entrainment

The MHRA recommends that all volumetric pumps – whether mains powered, battery powered or ambulatory – be fitted with the means to prevent air embolism.

Even if there appears to be no air in the line, the action of pumping can often draw air out of solution and this can accumulate into significant sized bubbles. Furthermore, if there is a leak in the upstream part of the line, the pumping action may draw air into the line.

Air entrainment can be prevented by the intrinsic design of the pump or by using an air detector. Most air detectors can detect and stop the passage of single bubbles of around 100µl in volume. Some air detectors are more sensitive and can detect 'champagne bubbles', although this may give rise to nuisance alarms.

If an air detector is available as an optional extra, this should always be purchased.

6.2 Safe use of syringe pumps

6.2.1 Recommendations for using syringes in infusion pumps

- always check that the syringe is compatible with the pump
- check that the syringe barrel clamp is secured over the syringe; do not place tape on the syringe barrel where the barrel clamp is positioned
- make sure that the syringe plunger clamp is correctly secured
- check that the syringe finger grips are secure within the recess located on the pump body
- inspect the syringe before use, checking in particular for signs of damage around the syringe plunger. **NEVER** use a damaged or defective syringe
- Use the prime or purge facility on the pump to reduce mechanical backlash. **NEVER** prime or purge the line with the extension set attached to the patient.

6.2.2 Preventing free-flow (siphonage)

Free-flow will not occur with syringe pumps if:

- the syringe is loaded correctly and the plunger and barrel are correctly secured
- the syringe and administration line are intact and correctly connected.

The following safe practice should be followed:

- ensure that the syringe (plunger and barrel) is correctly located and secured
- position the syringe pump as close as possible to the infusion site height
- consider using an anti free-flow valve.

6.2.3 Preventing air entrainment

There is minimal risk of air entrainment into the system when using a syringe pump.

6.3 Correct configuration/application of pumps

It is essential that all pumps are configured correctly for their required application. Configuring means selecting the appropriate mode for the intended application. This is especially important since new generation pumps have a variety of features, which allow them to be used in more than one therapy category or application. (See Appendix 2)

6.3.1 User-adjustable facilities

Pumps may have facilities including variable pressure, maximum flow rate and flow rate increments.

When using such pumps, users should ensure that the level set is consistent with the appropriate pump therapy category (see Appendix 2). Note that the manufacturer's default settings may be initiated on start-up. Settings should therefore be checked or changed every time the pump is used.

6.3.2 Blood sets and solution sets

Blood sets and solution sets are not usually interchangeable. Always use the sets recommended by the manufacturer.

Hazards of using incorrect sets

The use of blood sets or solution sets with the incorrect pump has led to the following hazards:

- free-flow
- over/under-infusion (inaccurate delivery)
- malfunction of alarms.

In addition, incorrect use of blood sets can lead to air entrainment.

6.3.3 Battery powered pumps

Most mains powered pumps have an automatic backup. This gives a few hours of extra use if the mains supply fails or the pump is used during transportation. Batteries are generally rechargeable and are charged by connecting the pump to the mains supply.

Users should follow the manufacturer's instructions regarding battery type and frequency of charging. Rechargeable batteries should not be used in pumps designed to use disposable batteries only. This can result in poor performance and a fire risk.

6.3.4 Ambulatory pumps

Ambulatory pumps are usually powered by rechargeable or disposable batteries.

Users should follow the manufacturer's instructions regarding battery type and frequency of charging. Some manufacturers have particular recommendations regarding storage, for example removing the batteries.

7 Pressure in infusion systems

The following background information aims to give users a better understanding of pressure in infusion systems.

7.1 What pressures does the pump have to overcome in order to deliver the drug?

A pump uses pressure to overcome resistance to flow. In an infusion system, this resistance to flow is usually caused by:

- the relatively small diameter of the cannula
- filters for air or particulates
- additional components e.g. anti siphon valves
- infusion administration set tubing
- intravascular or intra-compartmental pressure at the infusion site, at a level substantially higher than atmospheric pressure
- length of the line.

See Appendix 4 for further details.

Examples

Adult infusions

To deliver simple electrolytes into an adult intravenous site through a 16G, 9cm long cannula at 100 ml/h the pressures caused by resistance are:

Maximum adult venous pressure	30 mmHg
Filter	10 mmHg
Cannula	100 mmHg
Administration set	1 mmHg
Total	141 mmHg

However, an infusion pump with an occlusion alarm configured to 140mmHg or less could not administer the fluid at this rate. An occlusion alarm would result, even without any blockage in the fluid pathway. Therefore, to administer this infusion the occlusion alarm pressure should be configured above 140mmHg.

Note: using a positive pressure device for this infusion does **not** raise the pressure in the vein to 140mmHg or more. A pressure of 111mmHg plus venous pressure will occur in the pumping chamber of the device. There will be a pressure gradient between the pumping chamber and the vein. Pressure in the vein will remain at normal physiological levels. In this example 141 mmHg is the pressure **drop** over the whole administration set plus cannula.

Neonatal infusions

Resistance is lower in neonatal infusions due to the reduced flow (typically 10ml/hr) and reduced venous pressure compared to an adult, leading to lower driving pressures being required.

For a neonatal infusion the rate selected is rarely greater than 10ml/h. Any catheter used would not be very long, although it would probably be narrow.

A typical example:

Maximum neonatal venous pressure	10 mmHg
Filter	1 mmHg
Cannula	10 mmHg
Administration set	<1 mmHg
Total	22 mmHg

Therefore the pressure required to sustain an infusion at typical neonatal rates is far less than that required for adult infusions. The occlusion alarm pressure can therefore be configured lower (see section 7.4 below). The advantage of configuring the lowest feasible occlusion pressure is that it minimises time to alarm and post-occlusion bolus.

7.2 Why do simple gravity drips slow down when the patient sits up in bed?

Pressure generated within a gravity system is limited by the height of the fluid container above the infusion site. The bag can be hung up to 1.5 metres above the infusion site. This height provides a hydrostatic pressure of around 110mmHg (see Appendix 4). If the bag is hung lower, or the patient moves upwards, the available driving pressure is decreased. This is why simple gravity drips slow down if the patient sits up in bed.

7.3 When is a higher pumping pressure needed?

If the administration is horizontal a higher pressure appears at the tubing inlet than at the outlet; the pressure 'drops' over the length of the tubing. For example, 100mmHg pressure within the pumping chamber does not appear as a pressure of 100mmHg at the infusion site. Therefore you need to increase the pressure.

Higher pumping pressures are needed for:

- narrower cannulae
- higher flow rates
- longer cannula, such as a PICC
- more viscous fluids e.g. 50% dextrose.

7.4 Occlusion pressures and alarms

An infusion pump attempts to maintain sufficient pressure on the fluid to cause it to flow through all restrictions, such as the cannula or filter, at the set rate. The pump detects any resistance to flow and increases the pumping pressure to maintain the set flow rate.

The same effect is achieved in gravity devices by opening the clamp to allow freer flow by reducing its resistance.

The occlusion pressure of a pump is the pressure in the tubing, registered at the pump, when the pump is still operating but cannot sustain the flow rate. The resultant build up of pressure sets off the occlusion alarm.

7.4.1 What triggers an occlusion alarm?

An occlusion alarm can be set off by:

- a blockage in the delivery tubing – often inadvertently caused by leaving a roller clamp or three-way tap closed
- a clotted-off cannula
- a partially occluded cannula, if it causes the required driving pressure to rise above the occlusion alarm level
- a very narrow or very long cannula.

NB Extravasation does not trigger an occlusion alarm.

7.4.2 What are the hazards to the patient caused by occlusion?

Occlusion causes two main hazards to the patient:

- interruption to therapy
- a potential sudden injection of an unwanted bolus, on release of the occlusion.

The parameters that most affect the patient's safety are:

- time to alarm from occlusion (rate dependant)
- stored bolus.

Both these parameters should be minimised for optimum safety. The recommended actions in Appendix 2 will ensure that pumps with the shortest time to alarm and bolus are used for critical applications where continuity and consistency of flow are most important.

7.4.3 Bolus at occlusion alarm and time to occlusion alarm

If an occlusion occurs, the feedback circuits of the pump cause the pumping mechanism to work harder to overcome the additional resistance. Although fluid is incompressible, the administration set and other components of the system have some 'give' (compliance). The tubing expands under the increasing pressure. Other components of the system, such as the bung of the syringe, become compressed. This expansion and compression takes some time to occur. If a high occlusion pressure limit is set, it may take some time for the occlusion pressure limit to be reached and the alarm to sound.

In the case of a complete occlusion, there is no flow to the patient whilst pressure in the system is increasing. When the occlusion is released, the build up of fluid in the tubing results in a large bolus being delivered to the patient. The lower the occlusion alarm pressure level is set, the more quickly the alarm will sound and the smaller the bolus will be on release of the occlusion.

7.4.4 Pressure at alarm

The presence of large pressures in the pumping chamber of an infusion device has not been shown to present a direct hazard to the patient. The venous system is a highly compliant reservoir and, in ordinary circumstances, the pump cannot cause the pressure in the venous or arterial system to rise to a higher level. The pump only develops enough pressure to deliver fluid from the end of the cannula at the set flow rate. The pressure usually drops before the vein is reached. As fluid is pumped into the vascular system, the vascular reservoir expands to accommodate it. As a result, local increases in pressure are negligible.

There are only two exceptions to this:

- when a vein is thrombosed and is therefore not connected to the rest of the venous system
- when flow rates far greater than the ordinary physiological flow rates in veins are delivered.

7.4.5 How can occlusion alarm time and bolus be reduced?

- use the highest flow rate clinically acceptable – this reduces the time to alarm
- use a smaller syringe size – this reduces both bolus and time to alarm
- use syringes requiring less force to move their plungers. This minimises 'stiction' and normal variability in driving force
- use a syringe pump with a 'backoff' feature. The pumping mechanism briefly runs backwards upon occlusion alarm, thereby reducing the potential bolus.

7.5 Why are infusion pump occlusion alarms not configured to run at the lowest possible level?

It would seem sensible to configure all infusion pump occlusion alarms at the lowest possible level. This would give rapid alarm and a tiny occlusion bolus.

Reasons why this is not done are:

- infusions need pressure to drive the fluid through components of the system which present resistance to flow
- pressure is needed to overcome the normal physiological pressure at the infusion site
- less sophisticated occlusion mechanisms, which estimate rather than measure the pressure in the fluid, are prone to error and require some leeway to allow for inaccurate estimates.

To ensure the system is as safe as possible, the following should be taken into account upon each use:

- the occlusion alarm pressure should be configured at the minimum level above the normal running pressure of the required infusion
- the configured pressure at alarm should allow for any miscalculation of pressure by the device
- lower alarm pressure should be configured for low flow rates, and higher alarm pressures for narrow cannulae.

It should be noted that the normal running pressure of every infusion is determined by many different factors (see section 7.1). Optimal occlusion alarm levels can only be achieved if the alarm level is set for each infusion.

7.6 What are the implications for patient safety of configuring a high occlusion pressure?

It is sometimes necessary to configure a relatively high occlusion pressure. An example is when epidural infusions are given, as epidural cannulae are comparatively narrow. If a high alarm pressure has to be configured to sustain a high running pressure, there will be unavoidable consequences for patient safety, which should be understood.

a) For the alarm time

- If the occlusion occurs after the pump has stabilised at its set flow rate, the alarm time will not be unusually long. The pressure in the pumping chamber increases from the already high running pressure up to the alarm level. This occurs relatively quickly.
- If the occlusion is present from the beginning of the infusion, the time to alarm will be increased. The pressure in the pumping chamber increases from zero at the start of the infusion up to the alarm level. This is the most likely situation, as leaving stopcocks closed is the most usual cause of occlusions. The patient's therapy will therefore be

interrupted for a lengthy period.

b) For the occlusion bolus

- The occlusion bolus will be greater for a higher configured pressure at alarm. This increases the hazard to the patient.

Summary

In general, the higher the value to which the occlusion alarm is configured, the longer it will take to activate the alarm and the greater will be the post-occlusion bolus.

The safest system is a pump that allows the user to assess the baseline infusion pressure early in the infusion. The user can then set an alarm pressure that exceeds this baseline pressure by a minimum amount.

Pumps with highly configurable pressure alarms are the most clinically flexible. This may be particularly useful when very low-pressure infusions are required, for instance the very low flow rates appropriate for neonates. Here the alarm pressure can be configured to very low values (10-50mmHg) so that alarm is reasonably rapid even at the lowest flow rates. The correct configuring of alarm pressure is vital to optimise patient safety.

7.7 How does raising or lowering an infusion pump relative to the infusion site affect flow?

Users should be aware that unplanned boluses or delays to therapy might occur if the infusion device is moved in relation to the level of the infusion site. It is good practice to minimise disturbance to the pumps and to maintain the pump at the same level throughout an infusion, so far as possible. Manufacturers usually design positive pressure infusion devices to operate optimally when positioned at the same level as the infusion site. This position should be adopted where possible.

Infusion devices are usually mounted on a pole at or just above the infusion site. If the pump is raised from this level whilst connected to the infusion site, a bolus will be delivered to the patient. This occurs because, when the pump is raised, the infusion tubing collapses slightly under the negative pressure developed. Similarly, as the pump is lowered, the infusion tubing acts like an elastic reservoir and fluid flows back into it, thus momentarily reducing the flow to the patient.

Syringe pumps are more vulnerable to this phenomenon than other types of pump. Not only does the elastic tubing flatten or expand in response to the sudden change in pressure, but the syringe can slide backwards in its mounting. Pushing the syringe body back to its normal position can cause a delay of several minutes before fluid delivery is resumed (see Appendix 4, [7], [8], [9]).

7.8 Extravasation

7.8.1 What is extravasation?

Extravasation occurs when fluid that should be delivered intravenously is inadvertently delivered into a tissue space. It can be caused by misplaced cannulae or if the cannula migrates and punctures the vessel wall or during infusion into a thrombosed vein.

7.8.2 What causes extravasation?

There are various theories as to why extravasations occur. Extravasations have been associated with:

- the occurrence of phlebitis
- the use of drugs that cause a local vasoconstrictive effect [10]
- the use of steel cannulae e.g. butterfly.

The actual mechanics of extravasation are still the subject of hypothesis. Suggested causes include:

- a blocked vein
- a misplaced cannula
- a fibrin sheath that develops around a long line, such as a peripherally inserted central catheter (PICC). The sheath prevents flow from the tip of the cannula into the vascular system, and can channel it backward between the sheath and the outside surface of the catheter. This can result in fluid leaking into the tissues where the cannula is inserted into the vein.

There is no published evidence to suggest that extravasation correlates with the use of positive pressure devices. On the contrary, there are reports that suggest no significant difference in the rate of occurrence of extravasations when positive pressure devices are used rather than gravity controllers [11]. A gravity controller can provide sufficient pressure to deliver fluid into the tissue spaces.

7.8.3 Can an infusion pump detect extravasation?

Studies monitoring pressure during infusions show that there is no significant rise in pressure at the infusion site when an extravasation occurs. Fluid continues to be delivered to the tissue space without alarm, since most tissue spaces present very little resistance to the flow of fluid. Occlusion alarm mechanisms on most current infusion devices cannot detect the small change in baseline pressure that may arise when an extravasation occurs.

This does not mean that pressure will never rise during an extravasation. In rare cases, extravasations may cause a rise in pressure – the fibrin sheath that forms around a PICC is one such case. In general, however, the body of evidence suggests that occlusion alarm mechanisms are unlikely to detect extravasation.

The most effective safeguard against extravasation is to visually inspect the infusion site regularly.

See Appendix 4 for more information on extravasation.

7.9 What are the risks of piggyback infusions?

Piggyback infusions, also known as secondary infusions, (using a single volumetric pump) allow delivery from a second source container at a rate and volume independent of the primary infusion. In order to successfully deliver two drugs or fluids through the same IV line, users need a firm understanding of the principles of pressure in infusion systems.

Pressure, not the pump, determines which bag is administered. The change over from piggyback to primary **rate** occurs after a set volume has been delivered. However the change over from piggyback to primary **bag** occurs only when the piggyback bag is exhausted.

The pump cannot determine which bag the flow is coming from. The volume of fluid in bags can only be estimated. There are risks associated with this procedure:

- the end of the piggyback infusion may be administered at the primary rate
- or, if the volume of the piggyback bag is overestimated, the primary fluid may be delivered for a limited period at the secondary rate. The volume should therefore be estimated carefully to avoid any hazard to the patient.

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Appendix 1 Infusion devices: types, features, functions and accessories

Classification

Infusion devices can be classified according to their power source as:

- gravity controllers
- infusion pumps (pneumatic, mechanical or electrically powered devices).

1 Gravity controllers

1.1 Application

Gravity controllers are most suited to lower risk applications, including fluid replacement therapy, provided the low delivery pressure is sufficient to sustain the set flow rate.

1.2 Types of gravity controllers

Drip rate controllers

Drip rate controllers look like a pump, but have no pumping mechanism. They rely instead on standard solution sets. The desired flow rate is set in drops per minute and controlled by battery or mains powered line occlusion valves. The controls tend to be few and simple to operate. All models have a drop sensor. More advanced models incorporate a flow status system, which gives a visual indication of resistance to flow.

1.3 Usage considerations

Gravity controllers rely solely on gravity to provide the infusion pressure. Therefore, the fluid container should be placed sufficiently high above the infusion site to achieve the desired flow. A drop sensor, attached to the drip chamber of the administration set, monitors the drip rate. A variable mechanical clamp within the device, acting on the delivery tube, controls the flow and thus the drip rate, to achieve the set rate.

Control against over-infusion is effective, but under-infusion can result from increased resistance to flow. This can be avoided by using a drip rate controller with a visible flow status system.

1.4 Accuracy of drop controlled devices

The drop counting mechanism used in gravity controllers is highly accurate in delivering the required number of drops. However, the accuracy of volume delivery depends on the accuracy of the conversion from drops to millilitres. The nominal drops/ml for a set, or conversion chart values, are approximate, so the actual drops/ml may differ considerably.

The volume of fluid in a drop depends on:

- the fluid's composition, temperature and surface tension;
- the drip rate set;
- the size, shape and condition of the drop-forming orifice.

Most simple aqueous solutions of electrolytes, lactates or dilute sugars give drop volumes fairly close to the expected nominal 20 drops/ml. However, the drop volume for total parenteral nutrition (TPN) mixtures, fat soluble vitamins and solutions containing alcohol will be lower than expected, increasing the infusion time. With all fluids, the drops/ml value falls and the drop volume rises as the delivery rate increases.

For the majority of infusions these variations are acceptable. **But where the volumetric accuracy is critical, an infusion pump (volumetric or syringe) should be used.**

1.5 Gravity controllers and extravasation

It is widely thought that gravity devices minimise the risk of extravasation. Yet it is difficult to find evidence in the literature to support this view and recent studies suggest there is no such link. For historical reasons, however, some types of vesicant are still given by gravity controller in the expectation that extravasation will be less likely to occur.

The following points should be noted:

- The link between pressure and extravasation is hypothetical. Not enough is known about the mechanisms by which extravasation occurs. Further research is therefore needed.
- 'Positive pressure' devices can often be configured to alarm at pressures less than that exerted by the column of fluid in a gravity method of administration. If minimal pressure is required, it is preferable to use a device with configurable alarm pressure and in-line pressure monitoring, not a controller.
- The use of a gravity controller inevitably reduces the volumetric accuracy with which a fluid can be administered.

2 Infusion pumps

These pumps use an active method to overcome resistance to flow by increased delivery pressure. Volumetric or syringe pumps are the most common. Other methods include elastomeric, pneumatic, clockwork or spring. Another option is drip rate, although this is not recommended for use in the UK.

See Appendix 2 for guidance on selecting the correct device for a specific application.

2.1 Elastomeric pumps

Application

Elastomeric pumps are non-electronic single use pumps. They are generally designed for use by a patient at home as they are small, lightweight, easy to use and are easily portable. They are primarily intended to deliver antibiotics, chemotherapy and analgesics where a high degree of accuracy is not required.

Mechanism

The pump contains an outer shell and an inner elastomeric balloon reservoir. When filled, the distended balloon forces the medication through a tube with a fixed resistance, allowing a constant rate infusion. The infusion rate remains constant regardless where the device is placed in relation to the body.

These pumps have no built in alarms or event log and temperature; under and over filling and storage conditions can affect their delivery rate. However, their fixed volume and flow-rate reduce the risk of user error.

2.2 Volumetric pumps

2.2.1 Application/usage considerations

These pumps are the preferred choice for medium and high flow rate and large volume intravenous or enteral infusions.

Their wide range of features makes them suitable for category A and B therapies, depending on the performance parameters, which can vary widely. However, volumetric pumps are most suited to administering fluids in categories B and C and at higher flow rates.

Most volumetric pumps will perform satisfactorily at rates down to 5 ml/h. Although the controls can set rates below 1 ml/h, these pumps are not considered appropriate for delivering drugs at such low rates.

2.2.2 Features

Volumetric pumps are powered by mains or battery. The rate is selected in millilitres per hour (ml/h) or micrograms per kilogram per hour ($\mu\text{g}/\text{kg}/\text{hr}$).

Most volumetric pumps have the following features:

- automatic alarm and shut-down: this is triggered if air enters the system, an occlusion is detected or the reservoir or bag is empty
- pre-set control of the total volume to be infused and digital read-out of volume infused
- automatic switching to keep the vein open (KVO) rate at the end of infusion
- automatic switch to internal battery operation if the mains supply fails. Battery power can also be used if no mains power is available e.g. during transportation.

Additional features can include:

- micro and macro delivery modes
- computer interface
- operator call alarm
- a drop sensor – used for monitoring and alarm purposes (such as an empty container) rather than as a control of the delivery rate;
- primary and secondary ('piggyback') infusion capability
- technical memory log for incident analysis – some can record the settings and alarms for operations over the past two days or a thousand data points
- set based anti free-flow mechanism.

Features such as air-in-line detection or a mechanism that cannot pump air and comprehensive alarm systems make intravenous (IV) infusion much safer.

2.2.3 Types of mechanisms

There are two types of volumetric pumps:

- peristaltic
- dedicated cassette.

Peristaltic mechanisms

The majority of peristaltic mechanisms:

- linear peristaltic
- rotary peristaltic.

Both mechanisms consist of fingers, cams or rollers that pinch off a section of the set.

In linear peristaltic mechanisms fingers or cams are located on a camshaft. As the shaft rotates, each 'pinched off' section delivers its volume to the patient. These mechanisms are the most common.

In rotary peristaltic mechanisms rollers are located on a hub which, as it rotates, delivers the volume in each 'pinched off' section.

The volume delivered varies according to:

- the size of the cams, fingers or rollers
- the tube or set they are gripping
- the speed at which they rotate or shuffle.

Owing to this variance, these mechanisms are usually designed for a particular administration set.

Dedicated cassette

Some dedicated sets or cassettes have a distal and proximal line attached to a collapsible chamber. The chamber may include channels and flexible membranes that align with pistons or rams in the pump. The rams or pistons close off or open the channels and chambers such that they are filled from the bag or reservoir and emptied into the proximal line to the patient.

2.2.4 Setting correct pressure levels

In common with all pumps, volumetric pumps can develop high pressures. Although the pressure is lower than in drip rate pumps, careful attention should be paid to this.

The pressure in most volumetric pumps is limited to a pre-set value, which can be configured far lower than the default. If this level is exceeded, an alarm is set off. The occlusion pressure should be set as low as possible in order to give early warning of genuine occlusions. The lowest feasible level will depend on what pressure raisers are present in the line (see Appendix 4).

2.2.5 Correct use of administration sets

Most volumetric infusion pumps are designed for use with a specific type of infusion set. Therefore, the accuracy of delivery and of the occlusion pressure detection system depends on the set.

Some volumetric pumps use low cost standard infusion sets but it is important to note that **the pump must be configured correctly for the specific set.**

Sets that are incorrect, or not recommended, might appear to operate satisfactorily. But the consequences for performance, particularly accuracy, can be severe. For example:

- under-infusion can result if the internal diameter is too small
- free-flow through the pump, over-infusion or leakage back into the bag or reservoir can result from tubing that is less flexible or has a larger outside diameter
- tubes can rupture if the construction materials are not sufficiently strong to withstand wear from the pumping action
- air-in-line and occlusion alarm mechanisms can be disabled through using the wrong set.

Air-in-line detectors on pumps use ultrasonics or optics to detect air bubbles in the line. Again, these detectors will have been designed for use with a particular set.

The action of the mechanism, which compresses and stretches the set during infusion, causes the set to wear out over time and this inevitably affects the accuracy of delivery. Recommended sets are designed in such a way that, except for large volume, high flow-rate infusions, wear and/or work hardening of the material will not adversely affect the accuracy. The current international standard for infusion devices (IEC 60601-2-24¹) does not specify the testing of pumps at maximum flow rates. Therefore some fall-off in performance at high flow rates should be expected.

2.3 Syringe pumps

2.3.1 Application

These pumps are the preferred choice for lower volume and low flow rate infusions. Users should be aware that the flow delivered at the start of an infusion may be considerably less than the set value. At low flow rates the backlash should be taken up before a steady flow rate is achieved. At low flows it can be some time before any fluid is delivered to the patient.

2.3.2 Mechanism

Syringe pumps drive the plunger of a syringe forward at a controlled rate to deliver the substance to the patient. The rate can be continuous or in steps, delivering a number of boluses in a given time.

The syringe is clamped or located in the pump with its plunger attached to a moving carriage. As the carriage moves forward the syringe is emptied. In most cases the carriage is driven forward by means of a nut attached to a lead screw. As the screw rotates, the nut moves along it, taking the carriage and the syringe plunger with it and so emptying the syringe.

¹ IEC 60601-2-24 Medical electrical equipment – Part 2-24: Particular requirements for the safety of infusion pumps and controllers, 1998. <http://www.iec.ch>

2.3.3 Features

The features of syringe pumps vary widely, so each model should be assessed separately. Some models have many features, including delivery pressure displays and in-line pressure monitoring.

In most modern pumps the default pressure is limited and there may be a facility to set very low occlusion alarm pressures. This benefits the patient by resulting in shorter times to alarm and reducing the chance of occlusion bolus hazard. It also avoids the delivery pressure rising to a high value, if a catheter becomes occluded or displaced

2.3.4 Usage considerations

Syringe pumps have been designed to give optimum performance when placed approximately level with the infusion site. It is not advisable to place the pump well above the infusion site as, even in modern designs, some siphoning can occur in this position.

NB: When the administration set has been connected to the infusion site, the vertical position of the device and giving set in relation to the site should be altered as little as possible. If the pump is raised above the infusion site whilst the liquid is being delivered, it can result in a large bolus being delivered to the patient. (See Section 7 and Appendix 4.)

2.4 PCA Pumps

2.4.1 Application

These pumps are designed specifically for use in patient controlled analgesia (PCA).

Unlike a general-purpose infusion pump, a PCA pump has the facility for patients to deliver a bolus dose themselves. This is achieved by operating a switch or pressure pad connected by a cord to the pump.

Protection against free-flow is especially important with PCA pumps, particularly if the patient may be unsupervised for some of the time.

Most PCA pumps have a memory log, accessed through a display or downloaded via a printer or a computer. This enables a clinician to determine when, and how often, the patient has made a demand and the total volume of drug infused over a given time.

2.4.2 Types of PCA Pumps

PCA pumps are typically syringe pumps, as the total volume of drug infused can usually be contained in a single-use syringe.

Some PCA pumps are based on volumetric designs. For example, there is a range of miniature battery powered volumetric pumps designed for PCA applications that have disposable internal fluid reservoirs.

PCA pumps can be:

- disposable: powered by battery or other means, including pneumatic and elastomeric
- non-disposable: powered by mains or battery.

2.4.3 Programming options

PCA pumps can be programmed by clinical staff in different ways. Options include:

- loading dose
- continuous infusion (basal rate)
- continuous infusion with bolus on demand
- bolus on demand only, with choice of units (ml or $\mu\text{g/ml}$, etc.) and variable lockout time
- drug concentration.

Once programmed, a key or software code is needed to access control of the pump. In some cases, patients are given limited access in order to change some parameters.

2.5 Anaesthesia pumps

2.5.1 Application

These are syringe pumps designed for anaesthesia or sedation and should be used **only** for this purpose. They should be clearly labelled 'ANAESTHESIA PUMP' and restricted to operating theatres and high dependency areas.

2.5.2 Features

Anaesthesia pumps are designed so that the rate can be adjusted, and other functions accessed, during infusion. These pumps infuse over a higher flow rate range than normal syringe pumps and have a high rate bolus facility. This means that the induction dose can be delivered quickly in a single operation.

Other features include:

- programming for body weight and drug concentration
- drug-specific smart card system. This automatically configures the pump for the drug being infused
- built-in drug libraries
- interface with computer control and monitoring.

Some anaesthesia pumps are for target controlled infusion (TCI) of anaesthetics. Target controlled infusion pumps calculate their infusion rates based on patient factors such as age and weight in order to maintain a user-defined drug concentration in the patients plasma or tissue site. The calculations are based on a model that determines an initial bolus dose to fill the central compartment, blood, then a continuous rate that is equal to the elimination rate of the drug and then an infusion that compensates for the transfer to peripheral tissues.

These facilities are software enabled, for example by programming and smart card, in a pump that is otherwise suitable for other applications. **It is vital that management initiates policies to ensure that these facilities are disabled before the pumps are used in other applications.** If this cannot be achieved, the pumps should not be used for other applications.

2.6 Ambulatory pumps

2.5.1 Application

Ambulatory pumps have been designed to allow patients to continue receiving treatment or therapy away from a hospital, thereby leading a normal life during treatment. The size and design of these pumps means patients can carry them around in a form of holster.

Therapies that can be administered by ambulatory pumps include: analgesia, continuous and PCA, antibiotic or antiviral infusions, chemotherapy and hormone delivery.

2.6.2 Accuracy

The accuracy of ambulatory pumps depends on factors including:

- back pressure
- temperature of the flow-limiting element
- temperature and viscosity of the fluid.

Figures for flow rate accuracy given in manufacturers' instructions do not take into account deviation from 'standard' conditions. In some circumstances a significant reduction in the flow rate may lead users to think that there is a defect in the system, although the remaining volume of fluid is often significantly higher than expected.

2.6.3 Electrical and non-electrical ambulatory pumps

Ambulatory pumps can be powered by electricity or by other means.

Pumps not powered by electricity may lack the accuracy and some of the features (such as alarms) of electrically powered pumps. However, they offer a cost advantage when used for non-critical infusions.

Electrically powered ambulatory pumps sometimes use smaller versions of the pumping mechanisms used in volumetric and syringe pumps. Depending on the pumping mechanism, rates of flow range between 0.01 and 1000ml/h. The features of different models vary widely. Delivery rates can be set in mm of syringe travel per hour or day, ml of fluid per hour or day or dose units. Some can also be programmed for different delivery modes.

2.6.4 Reusable and disposable ambulatory pumps

Reusable pumps consist of a container or syringe that is emptied by gas pressure or a spring that is compressed when the pump is primed. The gas, usually carbon dioxide, is produced from a chemical reaction at the start of the infusion. The delivery rate is determined by the rate at which gas is released, its pressure and/or a capillary line attached to the syringe or container. The container, bag, syringe and gas cartridges are thrown away when empty. The rest of the device is reused.

Disposable devices include infusers and bolus-only analgesia devices controlled by the patient. They consist of a calibrated bolus chamber, filled from an elastomeric reservoir or syringe by a capillary tube. The patient flushes the chamber to receive the bolus.

2.7 Drip rate pumps

This type of pump is **not** recommended. Although no manufacturer currently sells these pumps in the UK, their use in hospitals persists.

3 One-way valves

IV lines with one-way valves control the passage of fluid and can prevent backtracking. Examples of one-way valves are check, non-return or anti-reflux valves or anti-siphon/anti free-flow valves.

Stopcocks, Y-connectors, manifolds and needle free connectors are not one-way valves and will allow back-tracking when connected to IV devices.

Backtracking

Back-tracking can lead to under-infusion and/or bolus delivery of IV drugs when more than one IV line is connected to a single access point if one line has no flow or a slower flow of fluid running through it. The fluid will back-track as it will take the path of least resistance. This can also occur during a downstream occlusion as the occlusion alarm may not be activated. Bolus delivery can occur following backtracking when flow in the line is increased, the line is flushed or the occlusion is released. Application of clamps (where available) to lines not in use is recommended and can also prevent backtracking.

Occlusion alarm

In an infusion system, valves exhibit resistance to flow. Optimal occlusion alarm levels can only be achieved if the alarm level is set for each infusion (see Section 7).

Air entrainment

One-way valves (anti-reflux, non-return and check valves) will not necessarily prevent air entrainment. These valves should be capped with a non-vented cap when not in use and clamps applied prior to disconnecting IV devices from these one-way valves.

Appendix 2 Choosing infusion devices according to therapy category

Information about the technical performance of infusion devices can be found on the Department of Health website www.dh.gov.uk/CEP and the NHS evidence portal www.evidence.nhs.uk. These sites contain evaluation reports on infusion devices. Guidance on devices issued by NICE can be found on www.nice.org.uk. These reports are intended to supplement information already available to prospective purchasers, including that supplied by manufacturers.

1 Therapy categories, performance parameters and safety features

Pumps are designed for a variety of clinical applications and their performance characteristics will vary. The same level of technical performance of pumps is not necessary for every clinical therapy. We have divided therapies into three major categories according to the potential infusion risks to help purchasers and users select the pump(s) most appropriate to their needs.

These categories are shown in Table 4(a) with a list of the performance parameters critical to each, and the important safety features are given in Table 4(b). These have been selected on the principle that, in general, the greater the risks associated with therapies, the higher the performance needed and the more important are the safety features.

Table 4: Therapy categories and performance parameters

Therapy category	Therapy description	Patient group	Critical performance parameters
A	Drugs with narrow therapeutic margin	Any	Good long-term accuracy Good short-term accuracy (see below) 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)
	Drugs with short half-life ¹	Any	
	Any infusion given to neonates	Neonates	
B	Drugs, other than those with a short half-life ¹	Any except neonates	Good long-term accuracy Alarm after occlusion Small occlusion bolus Able to detect small air embolus (volumetric pumps only) Small flow rate increments Bolus accuracy
	TPN Fluid maintenance Transfusions	Volume sensitive except neonates	
	Diamorphine ²	Any except neonates	
C ³	TPN Fluid maintenance Transfusions	Any except volume sensitive or neonates	Long-term accuracy Alarm after occlusion Small occlusion bolus Able to detect air embolus (volumetric pumps only) Incremental flow rates

Notes on Table 4

¹ The half-life of a drug cannot usually be specified precisely, and may vary from patient to patient. As a rough guide, drugs with half-lives of the order of five minutes or less might be regarded as 'short' half-life drugs.

² Diamorphine is a special case. The injected agent (diamorphine) has a short half-life, whilst the active agent (the metabolite) has a very long half-life. It is safe to use a device with performance specifications appropriate to the half-life of the metabolite.

³ Not all infusions require a pump. Some category C infusions can appropriately be given by gravity.

Important safety features in descending order of importance

- Anti free-flow device in administration set
- Free-flow clamp in pump when door opened
- Provision against accidental modification of settings
- Two distinct actions to change rate
- Two distinct and/or simultaneous actions to initiate bolus
- Syringe barrel clamp alarm, door open alarm or equivalent
- Syringe plunger disengagement alarm or equivalent
- Patient history log
- Volume infused display
- Technical history back-up
- Battery back-up

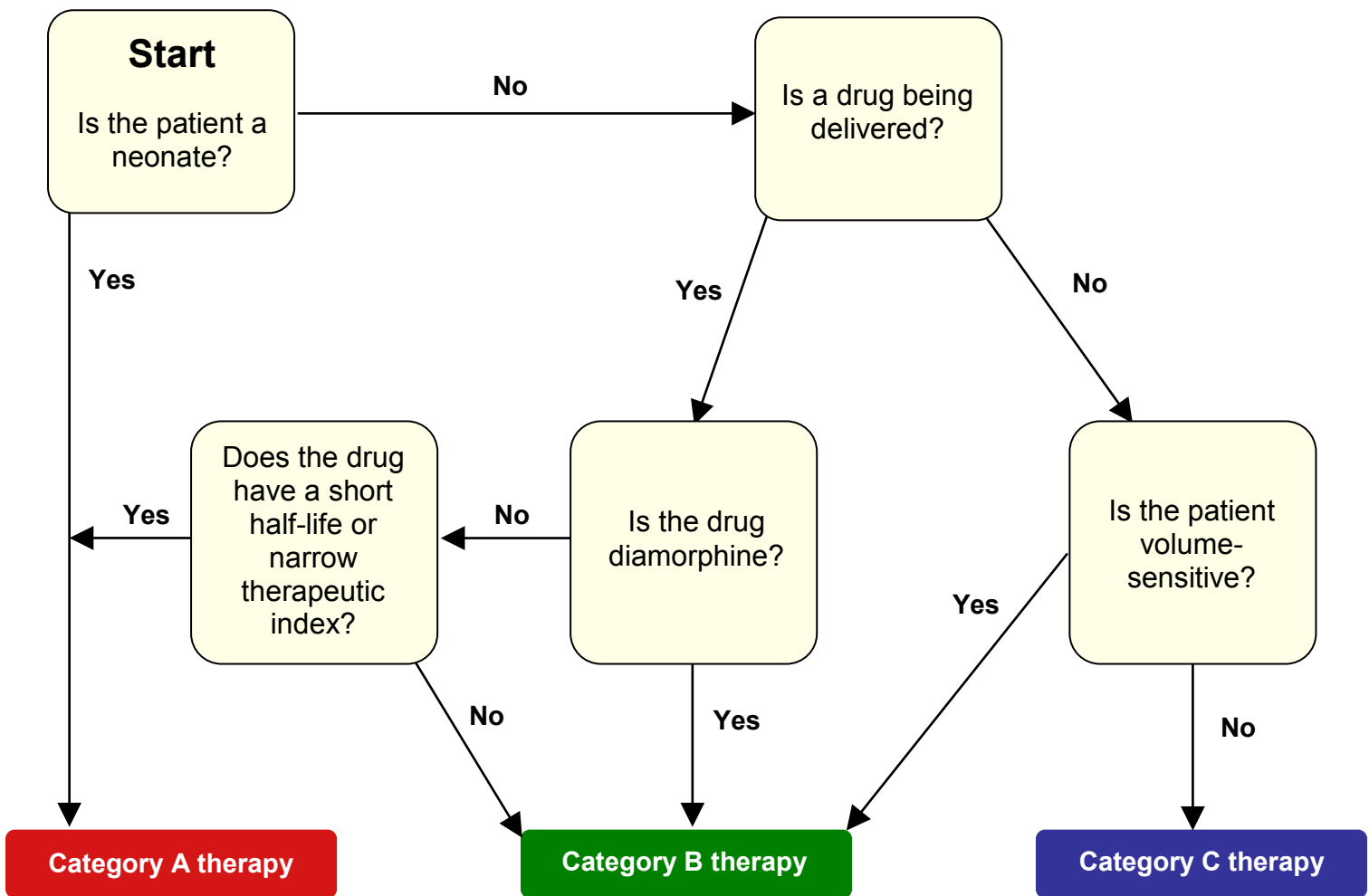
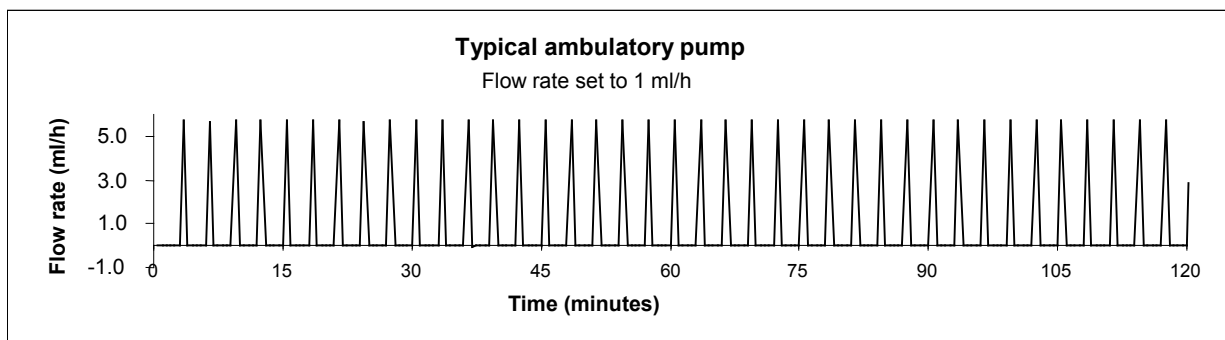
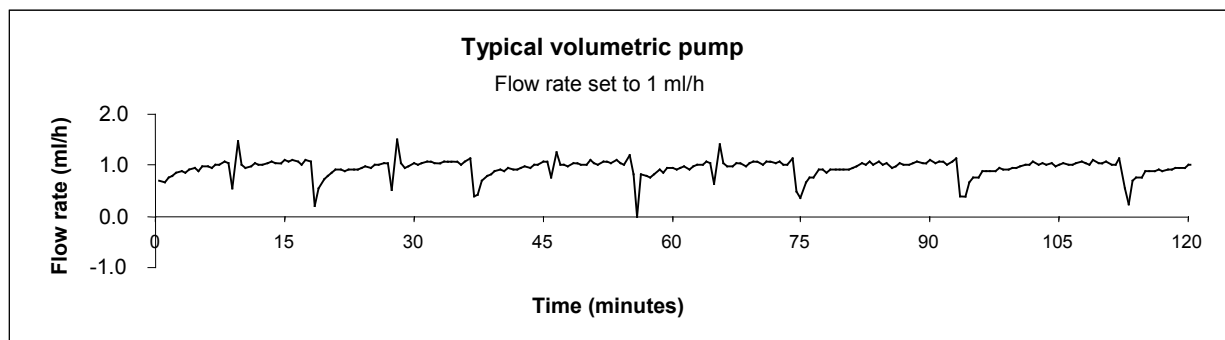
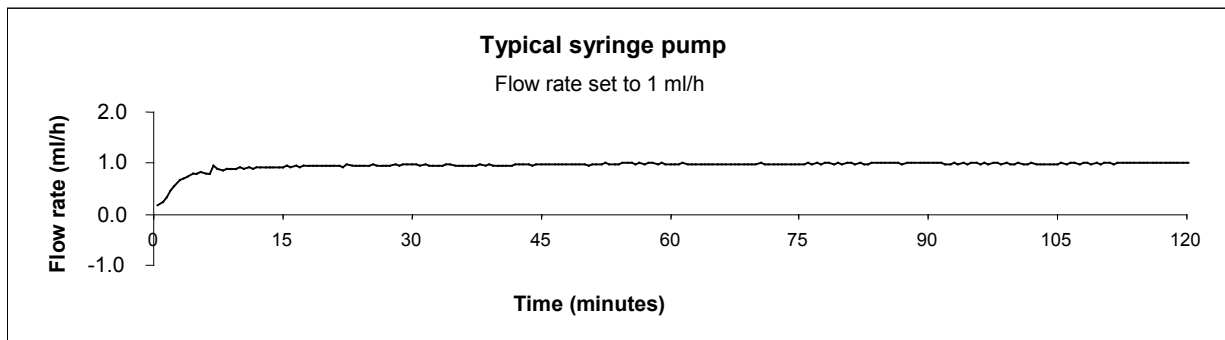


Figure 2 Decision tree for selecting the appropriate therapy category

2 The performance parameters explained

2.1 Accuracy

The pattern of delivery of fluid from an infusion pump is very dependent on the type of pump used. These three graphs show typical flow patterns from a syringe pump, a volumetric pump and an ambulatory pump. Each of these pumps delivers fluid accurately (better than $\pm 5\%$ of set rate) over long periods, but only the syringe pumps deliver fluid accurately over very short periods (a few minutes).



Long-term accuracy

Hour-to-hour variability of flow is particularly important for the more critical applications. For instance, overall accuracy is important with drugs whose therapeutic margin is narrow. Therapeutic margin is a property of the particular drug and is the ratio of the toxic dose (TD) to effective dose (ED). It is seldom less than 2. There is wide variability in the therapeutic margins and half-lives of some drugs between one individual patient and another.

Short-term accuracy

Minute-to-minute variability of flow becomes very important where drugs with short half-lives are being administered. The importance derives from the need to prevent undesirable fluctuation of effect-site concentration of the drug. There is documented evidence that minute-to-minute

variability of flow can cause variation of physiological parameters and consequent difficulties in management, in both adults and neonates, where the half-life of the drug is short.

Short-term accuracy can be expressed by the concept of **constancy index**. This is the shortest period during the pump's steady-state operation over which measurement of output consistently falls within $\pm 10\%$ of the mean rate. These data are derived from the flow tests performed over 24 hours at 1ml/h. Flow is recorded at 30 second intervals over the final 18 hour period. And the average rate compared with flow over each short period.

The principle is that the constancy index of the pump should be less than or equal to the half-life of the drug used. Syringe pumps have a shorter constancy index than volumetric pumps i.e. a low constancy index indicates good short-term flow rate accuracy. Battery operated ambulatory pumps frequently have a constancy index in excess of 31 minutes making these particular devices unsuitable for use with short half-life drugs.

For the purposes of this document the **half-life of a drug** is the time taken for the concentration of that drug to be reduced by 50 % either by metabolism or excretion.

2.2 Time to alarm following occlusion

The occlusion alarm is the response to a build-up of pressure of fluid in the line. Infusion pumps are positive pressure devices; that is the pumping mechanism will generate a pressure in the infusion line in order to maintain fluid delivery at the set rate. Under some circumstances the infusion line or catheter may become totally occluded therefore preventing fluid flow to the patient. The device will initially continue to pump, but with the line blocked, the fluid remains in the line and the line pressure increases. At some line pressure limit the pump will stop and alarm (see section 7).

From the onset of a total line occlusion the patient receives no infusion therapy. In some critical applications involving the use of drugs which have a short half-life and result in an immediate pharmacological or physiological response (e.g. adrenaline, dopamine, dobutamine, dopexamine, insulin) the plasma concentrations of drug may drop rapidly following cessation of delivery. In the case of short half-life vasoactive drugs used to maintain cardiac output it is known that if the infusion stops then the patient's condition can deteriorate rapidly.

2.3 Occlusion bolus – following release of occlusion

Occlusion bolus is the volume of fluid stored under pressure in the giving set following occlusion. The term has been introduced to try and eliminate confusion between desired, deliberately 'administered bolus' and undesired 'occlusion bolus'. There is a risk to the patient when this occlusion bolus is released after the occlusion is removed.

2.4 Air embolus detection (applies to volumetric pumps only)

Small volumes of air injected intravenously are considered a hazard by some clinicians. Volumetric pumps provide either a mechanism for preventing the pumping of air or an air detection system.

2.5 Bolus delivery accuracy

Elective bolus – There are circumstances when a bolus is deliberately given. This should be as accurate as practicable in order to avoid difficulties in patient management.

2.6 Start-up time

This is a newly defined performance parameter. It is the time taken for the flow to become established in a consistent pattern. This is negligible in volumetric pumps, but generally significant in syringe pumps.

The categories of therapy are intended to help users select an appropriate pump for their application. Hospitals will need to take steps to facilitate effective use of the scheme. Implementation methods may vary.

3 Syringes and administration sets

The brand of syringe used can significantly affect the performance of syringe pumps. Hospitals should be aware of the consequences of substituting a different disposable syringe. The use of administration sets which are not recommended by the pump manufacturer in volumetric pumps can also significantly affect pump performance.

4 Training, standardisation and configuration

Selection of the appropriate pumps can only be effective as part of a general policy for the safe use of devices. In view of the fact that many adverse incidents with infusion devices are due to user error:

4.1 Training

The greatest possible step towards safe operation of infusion devices is to require that all staff who use an infusion device have been specifically trained in its use.


4.2 Standardisation

Reducing the variety and number of different models that each user has to operate is also known to improve safety. A high degree of standardisation will minimise both training needs and the risks of user confusion or error. Ideally staff in any one clinical area should be trained in the use of and have access to only to a very small range of infusion devices (typically one type of syringe pump and one type of volumetric pump). Hospitals that operate an equipment store or pump library will have an advantage in implementing such standardisation.

4.3 Configuration

- It is safest and therefore strongly recommended that all devices in one clinical area are configured identically. Confusion and consequent errors can arise if apparently identical infusion devices behave differently. (A possible exception to this is occlusion alarm level, which may need to be matched to individual infusions e.g. higher occlusion alarm level if a very long narrow cannula is being used.)
- Configuration should be done centrally by technical staff and not at the bedside (again with the possible exception of occlusion alarm level).
- It should be remembered that local re-configuration of devices will not necessarily reproduce the settings used for the pump's published evaluation. This should be taken into account when managing risks. It may, for instance, be necessary to increase the occlusion alarm level if a long and narrow vascular access device is in use. This will also increase time to alarm and occlusion bolus above the levels published in the evaluations.

Appendix 3 Poster – reporting infusion device incidents

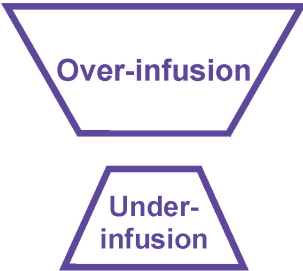


Infusion pumps

Reporting adverse incidents

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health. We enhance and safeguard the health of the public by ensuring that medicines and medical devices work and are acceptably safe.

What to report ?



Any incident that caused or had the potential to cause serious injury to the patient or user including those where an alarm is activated.

Examples include:

- false occlusion or air-in-line alarm
- air in line
- free flow or no flow
- fluid ingress
- battery/contact problems (e.g. during transportation)
- electric shock
- software problems -display irregularities, error codes
- user interface problems e.g. keypad failures
- maintenance issues – recurring problems
- poor instructions for use
- difficult to set up or use
- leakage
- suspected tampering.

Immediate action after an incident

Quarantine the pump and all accessories (including the administration set), noting serial/batch numbers. Where possible, leave the administration set in situ.

Note and record pump settings

Contact the manufacturer

Report to the MHRA using your local reporting mechanism

? Why should I report

Reporting adverse incidents helps the MHRA identify and address device related safety problems, preventing recurrence and therefore protecting public health.

How can I report ?

Online at www.mhra.gov.uk
 Email: aic@mhra.gsi.gov.uk
 Fax: 020 3118 9814

For further advice, call the Adverse Incident Centre hotline:
 020 3080 7080

Appendix 4 Pressure in infusion systems

3.1 Pressure delivery methods

Pressure developed within the infusion system is used to deliver fluid to the patient, using one of the following basic techniques:

- Gravity
- Positive pressure

Gravity devices

The hydrostatic pressure on a column of fluid delivers the fluid to the infusion site.

Pressure generated within a gravity system is limited by the height of the fluid container above the infusion site. The maximum pressure that can be exerted is derived from the equation

$$\text{Pressure } p = \rho gh \quad \text{Equation 1}$$

where g is the constant acceleration due to gravity, h is the height of the fluid container above the infusion site and ρ is the density of the fluid.

Positive pressure devices

These devices generate pressure by mechanical means. Force is applied to the fluid to drive it through the infusion tubing. Examples are a syringe pump, volumetric pump or elastomeric device.

In these devices, flow can be maintained whether the reservoir of fluid is level with or lower than the infusion site.

Pressure in a tube where flow is occurring can be modelled by the equation:

$$\text{Pressure drop } \propto \frac{\text{Flow rate} \times \text{Viscosity} \times \text{Cannula length}}{\text{Diameter}^4} \quad \text{Equation 2}$$

3.2 Pressure at infusion site

In a typical adult, venous pressure can vary between small negative values (-10 mmHg) in the large veins situated vertically above the heart, up to 80 mmHg in dependent peripheral veins. Since a column of liquid exerts pressure at its base, pressure in the leg veins can sometimes rise to quite high values. An ambulant patient with a cannula situated in a peripheral arm vein might present a baseline site pressure of up to 30 mmHg.

3.3 Occlusion alarm mechanisms

All powered infusion devices have mechanisms for detecting when the flow has ceased. These are based on measuring the increase in pressure, either directly or remotely.

Gravity devices register that no flow is occurring when drops cease to fall.

Positive pressure devices have several different means of detecting no flow. Their occlusion response is characterised in terms of three measurable parameters:

- pressure at alarm
- time to alarm
- bolus released when occlusion is resolved.

Minimising patient risk

Alarms are principally provided to minimise the hazard to the patient.

For some of the more critical drugs, current technology cannot provide alarms that activate sufficiently rapidly to provide 'safe' warning of the cessation of therapy. It is therefore essential that,

when short half-life drugs are used, there is additional monitoring of the patient. For less critical drugs, alarm within five minutes of the onset of occlusion is probably adequate.

High pressure at alarm may not directly place the patient at risk. However, placing a limit on pumping pressure ensures that the bolus and time to alarm are both minimised. This will remain the case while current mechanisms for detecting occlusions are used. There is more than one method of sensing the pumping pressure, however, and some methods are more effective than others.

Types of occlusion detection mechanisms

The two main types of mechanism are:

- in-line pressure monitoring
- indirect sensing of pressure within the pumping mechanism.

In-line pressure monitoring

In-line pressure monitoring measures the expansion of a compliant segment of the infusion tubing, downstream of the pumping mechanism.

It is a more accurate form of monitoring and is therefore the best option where the application requires continuity of therapy. It is more complex to achieve and usually requires the administration set to include a pressure disc, thereby increasing costs.

Indirect measurement of pressure

Indirect methods of sensing pressure are achieved by measuring the drive force, drive pressure or motor current.

Such methods can give false values. For example, where poor quality 'sticky' syringes are used in syringe pumps, a very high force is required to move the syringe plunger or bung from a stationary position. This is sometimes referred to as 'stiction'. This force can vastly exceed that required to sustain movement of the plunger during a running infusion. Although no pressure is exerted on the fluid whilst the bung sticks, the pump calculates the pressure as though the bung is free to move. As a result, the pressure in the fluid is overestimated.

When a sticky syringe is used, the occlusion alarm pressure will be required to be set at an appropriate level to allow for the high force at start-up.

Some more sophisticated indirect pressure measuring systems are introducing a feature that permits a large start-up force, but will alarm at lower running forces. However, this feature does little to reduce alarm time and bolus at alarm for the most common cause of occlusion, namely leaving a stopcock closed at the start of the infusion.

3.4 Bolus or cessation of flow due to raising or lowering of pump

The figure illustrates a test where a syringe pump running at 5 ml/h is first raised (note the bolus delivered) and then lowered (note the suckback and delay to therapy).

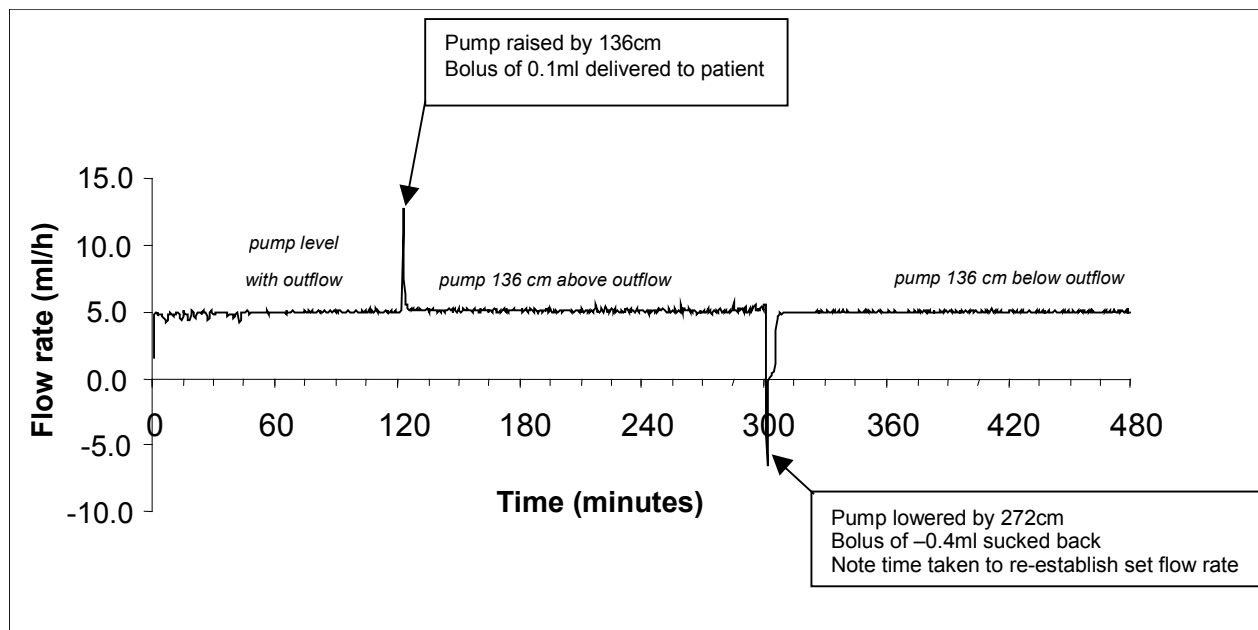


Figure 3 Example of bolus and delivery delay due to raising and lowering of a syringe pump

3.5 Extravasation and in-line pressure monitoring

Centres using in-line pressure monitoring have noted that pressure rising by a few mmHg is a possible predictor of a positional IV occurring. Positional IV means extravasation owing to displacement of the cannula. Such a small pressure rise only becomes apparent if in-line pressure is one of the parameters recorded at regular intervals on patient data sheets.

These centres claim that incidence of extravasation can be reduced by:

- monitoring in-line pressure
- inspecting and/or manipulating or re-positioning the cannula when small changes in baseline pressure occur.

However, no controlled study has been published that confirms these findings. Furthermore, reports in the literature seem to contradict this and suggest that no measurable increase in baseline pressure occurs during infiltrations [i]. Additional monitoring of the patient is, however, a common-sense approach and does not disadvantage the patient

Manufacturers are attempting to design infusion pumps with mechanisms that alert the user to potential extravasation [ii]. Only one manufacturer is currently marketing a device with this technology. In its current form, the mechanism for detecting extravasation adversely affects short-term flow rate variability. Users should decide whether the benefit outweighs the disadvantage.

- i Phelps SJ, Tolley EA and Cochran EB. Inability of inline pressure monitoring to predict or detect infiltration of peripheral intravenous catheters in infants. *Clinical Pharmacy* 9(4), 1990, p. 286-292.
- ii Scott DA, Fox JA, Philip BK et al. Detection of intravenous fluid extravasation using resistance measurements. *Journal of Clinical Monitoring* 12(4), 1996, p. 325-330.