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Implementation Plan

1. Professional responsibilities

- **Professional leads**
Disseminate the protocol
- **Clinical Governance Department**
Support compliance with the protocol and audit compliance
- **Clinical Managers**
Implement the protocol in their area
Supervise compliance with the protocol, organise audits as required
Respond to audit results and take corrective action if required
- **Clinicians**
Will ensure their practice complies with the protocol
Will undertake training and demonstrate competency as required in compliance with the protocol

2. Audit

- The protocol will be audited as necessary
- The Clinical Audit Support Team will provide technical advice in relation to audit of the protocol

3. Review

A multi-disciplinary group will review the Protocol. Three years after issue or following any change in National Standards. The results of relevant Clinical Audits will be used to inform this review

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1.0 Intent

The aim of this protocol document is to provide guidance on the use of medical infusion devices within NHS Borders clinical areas, and applies to **ALL** staff working within or for NHS Borders, who operate or intend to operate a medical infusion device for diagnostic or therapeutic purposes.

This protocol will address the types of device in use, training required and supporting governance structure.

2.0 Introduction

Technological and scientific advances in healthcare have resulted in the increasing use and levels of sophistication of medical infusion devices.

Medical infusion devices are an important aspect of healthcare and as such it is essential for NHS Borders to have a policy in place in respect of these.

It is the responsibility of **ALL** staff to ensure that they are working to the most up to date and relevant policies, protocols and procedures.

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. MHRA 2010.

For the purpose of this protocol and in accordance with the NHS Borders code of practice for the control of medicines (2019), a *medicine is defined as a substance that is introduced into the body, or externally applied to the body, for the purpose of:*

- *treating disease*
- *preventing disease*
- *diagnosing disease*
- *ascertaining the existence, degree or extent of a physiological condition*
- *contraception*
- *inducing anaesthesia, or*
- *otherwise preventing or interfering with the normal operation of a physiological function and*

Please note that this includes all intravenous fluids, licensed medicines, unlicensed medicines, medical gases, medicines licensed as medical devices, aromatherapy oils, Herbal medicines, homeopathic remedies and other complementary medicine

2.1 Prescription of medicines for use in infusion devices

Medicines that are prescribed for administration by an infusion device are subject to the same rules as other medicines and prescribers should follow the guidance within the NHS Borders Code for the Control of Medicines when prescribing.

If prescribing multiple medicines which are then mixed within an infusion device prior to administration, prescribers must ensure that they follow best practice and are aware of any potential interactions between medicines.

When more than one medicine is mixed in this way their product licenses become invalid and the prescriber is accountable for 'manufacturing' the unlicensed treatment that the patient receives.

2.2 Preparation and administration of medicines via infusion devices

Only those NHS employees who have met the following criteria are eligible to prepare and/or administer via infusion devices within NHS Borders.

- Numeracy competence - Achieved 100% pass using the NHS Borders Numeracy Assessment Programme within the previous 3 year period
- Intravenous Therapy Competence – Achieved completion of the NHS Borders Intravenous Therapy/Cannulation Education programme, which includes theory preparation and practical competency assessment. Professional competence must be demonstrated every 2 years using the NHS Borders Intravenous Therapy CARS foundation and IV update programme
- All infusion pump users must complete the competency based training for each pump in use according to the manufacturer's instructions. Cascade trainers are available within all clinical areas to provide the training
- All cascade trainers and users must undertake competency update every 3 years

It is the responsibility of the cascade trainers to provide instruction and training, supervision and competency assessment for all Users within the clinical area.

- The cascade trainer oversees and participates in the discussion of training needs and competency attainment with supervisee staff member.
- The Cascade trainer will liaise with the course facilitator and manager if difficulties arise during the competency attainment and sign off period to ensure resolution or initiate an alternative action plan.
- It is recommended that a minimum of two cascade trainers are available within each clinical area to provide all staff with access to the competency based training.

Please see appendix 1. Intravenous Therapy and Infusion Devices Competency Algorithm

If an employee does not meet these criteria they must not use infusion devices.

3.0 Responsibilities

The NHS Borders Code of Practice for the Control of Medicines **must be adhered to at all times** for the prescription, dispensing and administration of medicines, no matter the route of administration. This is equally true when infusion devices are being used.

The Code of Practice for the Control of Medicines outlines the processes/procedures involved in the administration of parenteral medicines. Within this section, the code focuses on infusion pumps and drivers and identifies the roles of those that prepare solutions and medicines for administration via an infusion device.

Each Doctor, Nurse, Midwife, Allied Health Professional, Operating Department Practitioner and Pharmacist must ensure that they are fully aware of and understand their individual responsibility and accountability with regard to the prescription, dispensing, preparation, administration, monitoring and recording of medicines administered by infusion device. This includes calculating and setting the rate of infusion, setting up and reloading the device and monitoring administration of the fluid to the patient for diagnostic or therapeutic purpose.

Alongside the NHS Borders Code for the Control of Medicines each professional involved in the afore mentioned medicines processes should ensure that they follow the standards for medicines management set by their regulatory bodies. (i.e. RSPSG Guidelines, GMC guidelines).

Assistant Practitioners

Trained and competent Assistant Practitioners may check and monitor the Infusion device.

This specifically includes:

- 2nd check only where a registered nurse is making up and commencing the infusion
- 2nd check of drug, volume, diluent, route, dose and prescription
- 2nd check of patient
- 2nd check of rate and calculation

This excludes:

- 'high dose' controlled drugs (as labeled by pharmacy)
- Medicines that require blood investigations /interpretation
- Doses that are weight related
- Infusions requiring specific ongoing monitoring of the patient
- Patients with more than one concurrent infusion
- **Medications identified for Bolus infusion as high risk (identified during IV study day)**

They must undertake formal training, competency assessment and update every 2 years.

3.1 NHS Borders Organisational Responsibilities

- Support the provision of quality education and training as outlined in this policy to enable staff to deliver safe and effective care
- Ensure there is a robust process in place for the procurement of infusion/medical devices
- Ensure that all new infusion/medical devices introduced into NHS Borders are accompanied by approved training and education to support use
- Ensure robust policies are in place to facilitate new and existing staff in accessing appropriate education and training to provide safe and effective care to patients, on commencement of and throughout their employment.
- Endorse the use of the CARS foundation and IV Update programme system to support managers and staff members to decide upon and access appropriate training in line with service needs and

needs of individual staff members.

- Utilise the DATIX system to record, analyse and learn from incidents in relation to infusion/medical devices.

3.2 Senior Charge Nurses/Department managers

Senior Charge Nurses/ Department Managers retain overall responsibility and accountability for all aspects of medical infusion device training in relation to their staff and will:

- Ensure **ALL** staff within their ward/department who are required to operate a medical infusion device are competent to do so
- All students must be supervised if using a medical infusion device. Ensure appropriate numbers of cascade trainers are available within the clinical area to meet the training needs of staff
- Provide staff with access both medical infusion device training and refresher training, including face to face demonstrations of practice and competency assessment
- Monitor training records to ensure that competency standards are maintained
- Ensure all staff complete and update their competency as required following the initial assessment or sooner if there are concerns in relation to competency
- If competency issues arise with individual staff members in relation to the use of medical infusion devices the SCN must discuss this with the individual, and arrange for training update / competency re-assessment as applicable
- Encourage individual staff to record training and competency on CARS foundation and IV update programme, as part of the development review process and sign off to confirm completion
- Ensure any incidents or near misses in relation to medical infusion device usage in clinical practice are recorded on the DATIX system including the recording of the individual asset number of the device

3.3 Staff Member responsibilities

All healthcare professionals have a personal responsibility and accountability to ensure that they are trained in the safe and effective use of the infusion/medical devices they need to use within their role (MHRA 2010).

Individual assessment of competence is completed in stages:

- Competency standard for each medical infusion device is identified in accordance with the manufacturer instructions. Staff are required to record training and competency on CARS foundation and IV update programme as part of the development review process.
- All staff using medical infusion devices will follow the skills pathway to competence. Any elements not achieved as part of this will be referred to the manager to identify further training and support

Staff uncertain about the process or their own competence will discuss the issues with their manager.

Staff will not use equipment unless they are competent to do so. Any training will be followed by supervised practice until the user has been deemed competent by a qualified cascade trainer to use the equipment independently.

4.0 Infusion Devices

NHS Borders has standardized the majority of the pumps in use, and the most commonly seen pumps will be explored in more detail below, however within NHS Borders there are some medical infusion devices for which external specialist training **must** be undertaken, and users are referred to the manufacturer's instructions and guidelines for safe and effective use.

DO NOT USE ANY INFUSION DEVICES IF YOU HAVE NOT RECEIVED TRAINING AND HAVE BEEN DECLARED COMPETENT TO USE THEM BY AN APPROPRIATELY QUALIFIED ASSESSOR.

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.

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 1 with a list of the performance parameters critical to each, and the important safety features are also given. 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 1: 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) |
| | Drugs with short half-life ¹ | Any | Rapid alarm after occlusion Small occlusion bolus Able to detect very small air embolus (volumetric pumps only) |
| | Any infusion given to neonates | Neonates | Small flow rate increments Good bolus accuracy Rapid start-up time (syringe pumps only) |
| B | Drugs, other than those with a short half-life ¹ | Any except neonates | Good long-term accuracy Alarm after occlusion Small occlusion bolus |
| | TPN Fluid maintenance Transfusions | Volume sensitive except neonates | Able to detect small air embolus (volumetric pumps only) Small flow rate increments Bolus accuracy |
| | 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

4.1.1 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.

4.1.2 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.

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

4.1 Volumetric pumps

These pumps use an active method to overcome resistance to flow by increased delivery pressure. Volumetric or syringe pumps are the most common. See table 1a and 1b for guidance on selecting the correct device for a specific application.

Devices used within NHS Borders have been standardised to the:

Alaris GP Plus infusion Pump

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.

Infusion Systems DB 2003(02) v2.0 November 2010

42/56 Features

Volumetric pumps are powered by mains or battery. The rate is selected in milliliters per hour (mls/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:

- a drop sensor – used for monitoring and alarm purposes (such as an empty container) rather than as a control of the delivery rate;
- 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.

Drop Sensors

Drop sensors should be used when administering chemotherapy but are not required to be used in general administration of Intravenous infusions

Types of mechanisms

Dedicated
Administration lines.

Peristaltic mechanisms

Linear peristaltic

The Mechanism consists of 'fingers' 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.

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 table 1).

Air-in-line detectors on pumps use ultrasonic or optics to detect air bubbles in the line, 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.

4.2 Syringe pumps

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.

Device used within Borders Health Board has been standardised to

the: Asena group of syringe drivers. Models GH, 3 VP (SCBU only)

and CC,

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.

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/Infusion Systems DB 2003\(02\) v2.0 November 2010 44/56](http://www.iec.ch/Infusion%20Systems%20DB%202003(02)%20v2.0%20November%202010%2044/56)

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.

4.3 PCA Pumps

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.

Device used within Borders Health Board has been standardised to the:

Alaris PCAM

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.

Powered by mains or battery.

Programming options

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

- loading dose
- continuous infusion (basal rate) (In ITU only)
- continuous infusion with bolus on demand
- bolus on demand only, with choice of units (ml or µg/ml, etc.) and variable lockout time
- drug concentration.

Once programmed, a key or software code is needed to access control of the pump.

Infusion Systems DB 2003(02) v2.0 November 2010 45/56

4.4 Ambulatory pumps

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.

Device used within Borders Health Board has been standardised to the:

McKinley T34

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

4.5 Anaesthesia Pumps

Application

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

Device used within Borders Health Board has been standardised to the:

Alaris PK pumps

Features

Anesthesia 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 anesthesia pumps are for target controlled infusion (TCI) of anesthetics. 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.

4.6 Contrast Medium Pumps Application

These are pumps designed to introduce a contrast medium to facilitate diagnosis during CT or MRI scanning and should be used **only** for this purpose. They are integral to the Scanner and cannot be removed

Device used within Borders Health Board has been standardised to the:

Medrad Stellant, Medrad MR Experion and Ulrich CT motion injector.

Features

Contrast pumps are designed so that the rate can be adjusted and other functions accessed, once set the pump delivers the medium via computer control. This means that the dose can be delivered under the control of the scanner and Health care professional operating the device.

The pumps **should not be used** for any other applications.

5.0 Documentation and Record Keeping

It is the responsibility of **all** staff giving direct care, whether a registered practitioner or someone in a support role, to make a note of all encounters and interventions relating to the patient in the appropriate section of the patient's health record. NHS Borders Completion of Health Records Policy

All nursing, midwifery, AHP and medical staff responsible for the prescribing and/or administration of fluids to a patient through an infusion device will ensure that the appropriate documentation and recording is accurately completed. There will be accurate and timely

recording in the patient's health records of any fluid prescribed and/or administered via an infusion pump.

6.0 Cleaning Infusion Devices

Before transferring an infusion pump to a new patient, preparing the pump for storage, and periodically when in use, clean by wiping over with a lint free cloth dampened with warm water and a standard disinfectant/detergent solution compliant to NHS Borders Infection Control Policy.

All devices must be sent to Electro medical department for specialist cleaning/decontamination as required.

The following **must not** be used for cleaning Infusion Devices:

- Presept, Chlorasol or Cidex as these are known to be corrosive to any metal parts in the device
- Iodine as it causes surface discolouration
- Isopropyl Alcohol as it degrades plastic parts such as the drip sensor

Before cleaning **always** switch the pump off and disconnect from the mains.

7.0 Reporting an Incident or Near Miss

In the event of a near miss or actual untoward incident involving an infusion device staff must firstly ensure the patient is made safe and comfortable. The near miss or actual incident them must be reported using the Datix Incident Recording System. Please refer to Datix Full Guidance for Reporter which can be accessed through the Risk Health and Safety web page.

If the device has malfunctioned resulting in medication being incorrectly administered to a patient the event should be reported under the following categories:

- Type of Incident –Medication event
- Subcategory 1 – Infusion Error (Device under/ overdose)

This will allow the reporter to identify the medication involved in the specific medication section but also to enable identification of the medical device the asset number/serial number of the infusion device documented as the equipment section will also be present.

Where the event has not resulted in a medication error the Medical device should be reported via the equipment issues, and description of incident.

In the event of malfunction, the Infusion device **must be removed from use immediately and clearly labelled “not for use”**. The chief technician or his deputy **must** be informed to the incident as soon as possible in order that they can arrange for the device to be examined in order to identify any mechanical problems which have contributed to or resulted in the incident. Any disposable items i.e. administration set, syringe etc. in use at the time of the incident must be retained for examination by the Chief Technician. They **must not** under any circumstances be disposed of.

Any malfunctioning device must be clearly labelled to indicate that it is being retained for examination. All appropriate staff should be informed and the device made available to the Chief Technician as soon as possible after the incident.

Following examination of the device and any associated items the Chief Technician will report the findings and advise the relevant managers of the necessary course of action. This may if appropriate include alerting MDA and commencing the 'Hazard/SAB' process.

8.0 Competency attainment and maintenance

Within NHS Borders **ALL** Healthcare professionals who wish to use **ANY** medical infusion device **MUST** attend device specific training, and be verified as competent by an approved assessor.

Training for the most commonly used devices is arranged across the full calendar year, however bespoke training can be organised by ward managers (please contact Clinical and Professional Development if you would like further details). It is essential that staff engage in activities to ensure continued competence in an ever changing environment, and therefore Refresher training is required **ONCE EVERY TWO YEARS** to update the skills of regular users, and to maintain levels of expertise amongst those who use the system less frequently.

Managers are reminded of their responsibilities in ensuring that staff who have been out of clinical practice are supported to attend either a refresher or full formal training on the appropriate medical infusion device.

- If a staff member has not used a skill or piece of equipment for 1 year e.g. returning from maternity leave or long term sick
- If a skill competency / capability/ confidence issue is identified by a staff member, a peer and/or a manager on an ongoing basis or as part of the development review process then attendance on a refresher is recommended.

9.0 References

1. Infusion Systems DB 2003(02) v2.0 November 2010 42/56.
<http://www.mhra.gov.uk/home/groups/dts-iac/documents/publication/con007322.pdf>
2. NHS Borders: CODE OF PRACTICE FOR THE CONTROL OF MEDICINES
3. NHS Borders Completion of Health Records Policy

NHS Borders would like to recognize the invaluable assistance given by the Head of Professional Development at NHS Grampian in the development of this policy, from whom permission has been granted to utilise relevant sections of their own infusion device documentation.

Infusion Device Protocol Group

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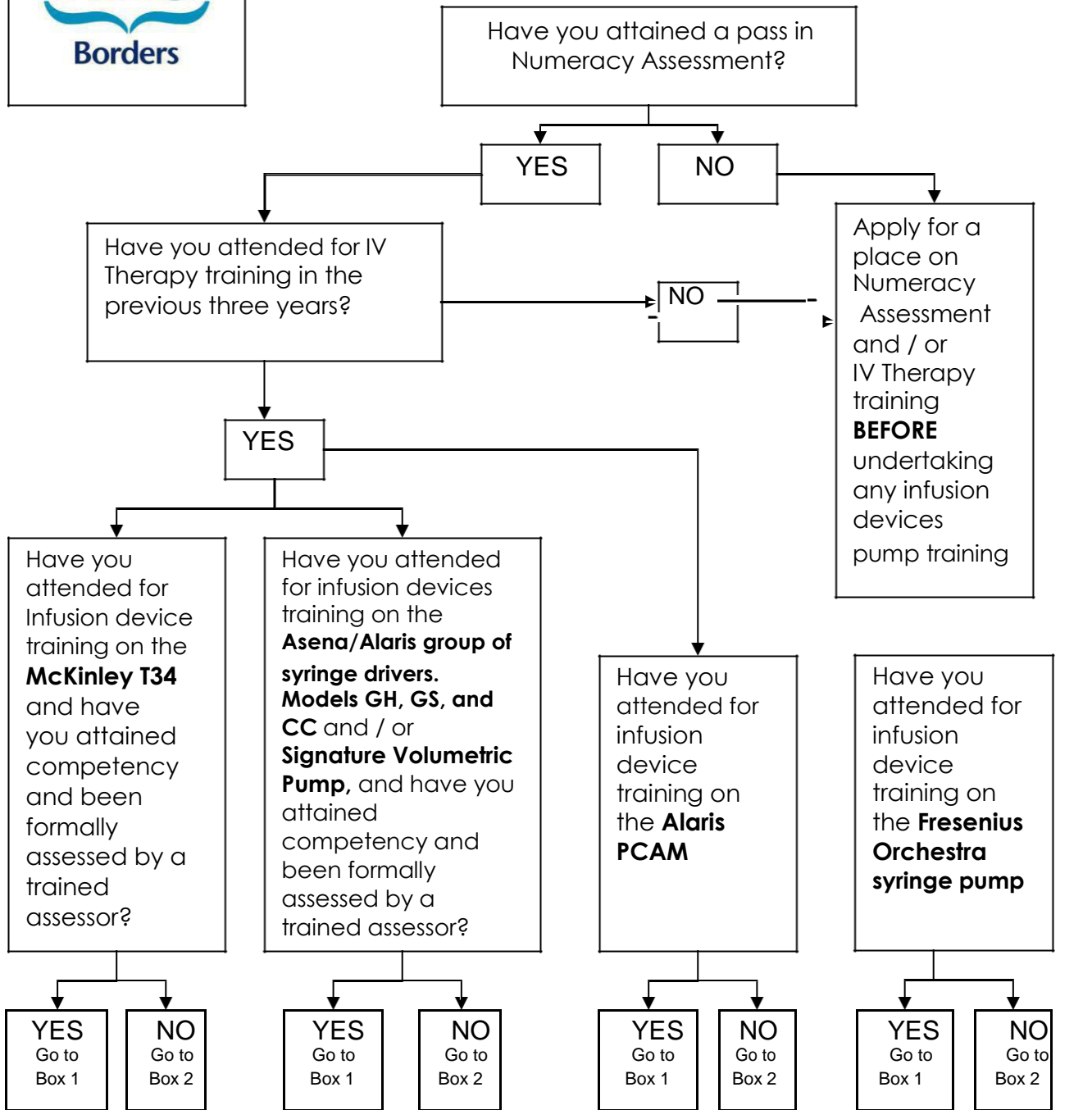
Christine Irving: Clinical Practice Lead

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Appendix 1



Intravenous Therapy and Infusion Devices Competency Algorithm



BOX 1
Please maintain competency by undertaking refresher once every two years and undertaking an annual peer review through the PDP process

BOX 2
Please arrange to attend for training or ensure that you are achieving competency standards but only if you are required to use this device in your clinical area

ARE YOU A CASCADE TRAINER?
Please ensure that you undertake the appropriate update for the devices on which you deliver training

