SCOTTISH EXECUTIVE

Health Department

Dear Colleague

Guidance on the Safe Handling of Intrathecal and Intraventricular I njections

Introduction

This letter alerts you to the publication of guidance prepared by a multi-disciplinary Working Group of the National Pharmaceutical Forum and the Scottish Medical and Scientific Advisory Committee on the safe handling of intrathecal and intraventricular injections. It complements but does not replace earlier guidance on the safe administration of intrathecal cytotoxic chemotherapy, issued under HDL (2004)30 and the Clinical Resource and Audit Group Good Practice Statement on the Preparation of Injections in Near-Patient Areas, including Clinical and Home Environments, published in 2002.

The guidance, which includes arrangements for intrathecal spinal anaesthesia and analgesia, recognises that anaesthetists have specialist skills and have developed safe systems of work that support the complex nature of their practice.

Action

NHS Boards and Operating Divisions where intrathecal and intraventricular injections are administered, must ensure full implementation of this national guidance with immediate effect.

This is a risk management issue and accords with the high priority which the Scottish Executive places on patient safety and clinical governance.

Further copies of the guidance are available on the Scottish Executive website: http://www.scotland.gov.uk/Home

Yours sincerely

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Guidance on the Safe Handling of Intrathecal and Intraventricular Injections

[separate guidance is available for intrathecal cytotoxic chemotherapy and should be followed]

BACKGROUND

The Scottish Executive Health Department issued HDL(2004)30 'Safe Administration of Intrathecal Cytotoxic Chemotherapy' in May 2004. Much of the guidance contained in the document applies equally to non-cytotoxic intrathecal and intraventricular injections. However, whereas all cytotoxic injections must be prepared in pharmacy aseptic departments, intrathecal spinal anaesthetics and analgesics are also prepared in operating departments. Restricting this practice would not be justified in view of the excellent safety record, and would result in operational problems.

The Clinical Resource and Audit Group (CRAG) 'Good Practice Statement on the Preparation of Injections in Near Patient Areas, including Clinical and Home Environments', December 2002, provides a risk assessment system that may be applied to identify and address hazards involved in the preparation of injections. The preparation and administration of intrathecal and intraventricular injections are hazardous processes, and suitable and sufficient control measures are necessary to minimise risk.

To help inform the work of this group, the current situation in Scotland was reviewed. The information gathered indicates that the range of medicines prepared for intrathecal and intraventricular administration is limited, and that preparation mainly takes place either in pharmacy aseptic units, or in operating departments.

This guidance is based on the recommendations in the documents previously mentioned, and recognises that anaesthetists have specialist skills, and have developed safe systems of work that support the complex nature of their practice.

All references to intrathecal medicines in the following paragraphs should be read as equally applicable to intraventricular medicines.

1.0 GENERAL GOOD PRACTICE

1.1 The intrathecal route should be used only where there is a clear body of evidence of efficacy in the particular clinical situation.

Education and training

1.2 Practitioners involved in the prescribing, preparation and administration of intrathecal injections must receive education and training appropriate to their roles. Formal induction programmes for all practitioners must cover, at the very minimum, all potential clinical hazards associated with intrathecal medicines. There should be a formal local assessment to ensure that all practitioners, including locums, have read and understood this guideline and all the organisation's relevant guidelines and protocols.

1.3 A written local protocol for the prescribing, preparation and administration of intrathecal medicines should be produced, and be readily accessible to all practitioners involved in the process. The local protocol should cover all aspects of this guidance – from training, through prescribing, preparation, transportation, storage, checking and administration. It should include the following local information:

- who can do what
- where things should be done
- where to find key documents such as national guidance and local protocols
- a list of medicines and specific formulations licensed to be administered by the intrathecal route
- doses licensed to be used for intrathecal administration
- procedures to eliminate or minimise the hazards associated with the preparation and administration of intrathecal injections

Use of medicines and doses not licensed for intrathecal administration should only be permitted in line with the local policy for the use of unlicensed and off-label medicines.

1.4 The provision of local information should complement this national guidance. It should not change the principles described in this guidance.

1.5 A system must be in place to ensure that only the latest editions of this guidance and local protocols are available to staff. Copies should be lodged in appropriate locations to ensure ease of access. Regular reviews of protocols should be carried out and documented.

1.6 All practitioners involved with the care and treatment of patients receiving intrathecal injections must be encouraged to challenge colleagues if, in their judgement, protocols are not being adhered to or when the actions of an individual may cause potential risk to a patient. Challenging a colleague should not be seen as adversarial, but as an additional check to improve patient safety and reduce risk.

Labelling, packaging and storage

1.7 Injections must be clearly identifiable at all stages during preparation and administration. This may be achieved by labelling the injection, or by another agreed safe system to meet local circumstances and situations. For example, if the prepared injection is to be supervised at all times during preparation and completion of administration, the original container and final preparation could be kept in an individual tray between preparation and administration.

1.8 If labels are added, the route of administration must be printed clearly in the largest font size possible and emboldened. Negative labelling (for example, 'Not for intrathecal use') must never be used.

1.9 Once prepared, intrathecal injections must be kept in designated areas separate from injections that are to be given by a different route. They should never be kept as ward or theatre stock.

2.0 ARRANGEMENTS FOR INTRATHECAL SPINAL ANAESTHESIA AND ANALGESIA

Personnel

2.1 Anaesthetists recognised as such by the Royal Colleges of Anaesthetists or equivalent professional regulator, or delegated by the Clinical Director of Anaesthesia, are authorised to prescribe, prepare and administer intrathecal spinal anaesthetics and analgesics in operating departments.

2.2 Practitioners in training under the supervision of an anaesthetist may prepare and administer intrathecal spinal anaesthetics and analgesics when they have achieved a suitable level of skill. The anaesthetist will determine the level of supervision required, depending on the experience of the trainee.

2.3 A local register of trainees that are authorised to prepare and administer intrathecal spinal anaesthetics and analgesics must be held in operating departments where intrathecal injections are prepared and administered.

2.4 Practitioners moving from one hospital to another must take with them proof of their competence before being placed on the register of their new employer. Additionally, it will be the responsibility of lead professionals to ensure that these practitioners are provided with a formal period of induction. This should include the provision of copies of the organisation's protocols and guidelines relevant to the prescribing, dispensing, checking and administering of intrathecal medicines. Practitioners should confirm in writing that they have received and read the correct protocols and guidelines before being placed on the intrathecal register of their new employer.

2.5 There must be a system in place to ensure that the local register is always up-to-date.

Preparation and administration

2.6 Intrathecal injections should be prepared and administered by the same person.

2.7 Practitioners preparing to administer an intrathecal injection must verify details to ensure that the correct medicine and the correct dose are given to the correct patient by the correct route.

2.8 Checks must be made at relevant stages throughout the preparation process. The responsibility for checking remains with the anaesthetist or trainee who administers the dose. A second person should check the ingredients to ensure that they are correct.

2.9 Intrathecal injections should be administered immediately following preparation.

2.10 Intrathecal injections should be prepared and administered at a different time from injections to be given by the intravenous or other injection route. Where this is not possible, intrathecal injections must be kept clearly separate from injections to be given by a different route to avoid the risk of selecting the wrong preparation.

2.11 Administration of intrathecal injections must be recorded on the anaesthetic record by the anaesthetist who administers the dose.

2.12 Scheduling of administration of intrathecal medicines must take account of the availability of anaesthetists, or trainees named on the local register. The intrathecal procedure should not be undertaken if they are not available.

3.0 ARRANGEMENTS FOR INTRATHECAL INJECTIONS OTHER THAN SPINAL ANAESTHESIA AND ANALGESIA

Personnel

3.1 All NHS organisations providing intrathecal therapy must establish and maintain an intrathecal register that names practitioners who have been trained and certified competent in the prescribing, preparation and/or administration of medicines given by the intrathecal route.

3.2 The intrathecal register must include, for each individual practitioner, the specific medicines, or category of medicines where appropriate, and the clinical indication for which they may be prescribed, prepared or administered. The intrathecal register must also include the activity (that is prescribing, preparation or administration), for which the practitioner is authorised.

3.3 The intrathecal register should be held by the Chief Operating Officer and a copy held by the Medical Director, Chief Pharmacist, and Director of Nursing.

3.4 Practitioners named on the intrathecal register will have to demonstrate that they are competent to fulfil their designated roles and that they have been certified as such by the appropriate lead professional. For doctors, it will be the responsibility of the Medical or Clinical Director to ensure that the intrathecal register is maintained and kept up to date. For nurses, the responsibility will rest with the Director of Nursing, and for pharmacists and pharmacy technicians, the Chief Pharmacist.

3.5 Practitioners named on the intrathecal register will be provided with a certificate confirming their status.

3.6 Practitioners, including locums, moving from one hospital to another must take with them their certificate along with their training logbook or other training record as proof of their competence before being placed on the register of their new employer. Additionally, it will be the responsibility of lead professionals to ensure that these practitioners are provided with a formal period of induction. This should include the provision of copies of the organisation's protocols and guidelines relevant to the prescribing, dispensing, checking and administering of intrathecal medicines. Practitioners should confirm in writing that they have received and read the correct protocols and guidelines before being placed on the intrathecal register of their new employer.

3.7 In order to remain on the intrathecal register, practitioners must demonstrate every two years that they are up-to-date on policies for the administration of intrathecal medicines.

Prescribing

3.8 Intrathecal medicines used for treatment and diagnostic imaging may only be prescribed by registered prescribers that are named on the intrathecal register.

3.9 Prescribing and administration of intrathecal medicines should be recorded on the main prescribing chart. However, where it is not possible to record prescribing or administration to the required level of detail on the main chart, a separate supplementary chart should be used.

3.10 Wherever possible, intrathecal doses should be prescribed and/or administered at different times from intravenous bolus doses. Where this is not possible, intrathecal injections must be kept separate from injections to be given by a different route to avoid the risk of selecting the wrong preparation.

Preparation

3.11 Intrathecal doses of medicines used for treatment and diagnostic imaging must only be prepared in pharmacy aseptic departments.

3.12 Only practitioners named on the intrathecal register, or trainees under the supervision of a person named on the intrathecal register as authorised to prepare, and who have achieved a suitable level of skill, may prepare intrathecal injections.

3.13 A copy of the intrathecal register, naming practitioners authorised to prepare intrathecal medicines, and of the local protocol, naming the medicines licensed to be administered by the intrathecal route and the doses to be used, must be held in pharmacies where intrathecal injections are prepared.

3.14 There must be a system in place to ensure that the copy of the intrathecal register and the local protocol is always up-to-date.

Issue and transportation from the pharmacy

3.15 Medicines for intrathecal administration should only be issued from the pharmacy by and to practitioners designated in the local protocol. If the medicines are taken to the near-patient area they must be either issued directly to the person who will be administering the intrathecal medicine or placed in the designated area for the storage of intrathecal injections. The pharmacy practitioner should sign for the release of the medicines, identifying to whom the medicines were released or that they have been placed in the designated area. Where the person who will be administering the intrathecal medicine does not take direct receipt of the medicines, she/he must check the medicines and sign for them on retrieval from the designated area.

3.16 Intrathecal injections must always be packed and transported separately from treatments for administration by other routes. Intrathecal doses should be packed in such a way as to highlight that the product is different from intravenous drugs. For example, the transport containers could be clearly labelled for intrathecal use. The packaging of intrathecal injections must comply with the manufacturer's recommendations. Colour coding of containers and syringes alone is unreliable and could result in error.

Timing of issue from the pharmacy

3.17 If injections to be administered by intravenous bolus, and injections to be administered by intrathecal injection are prepared in the pharmacy for the same patient, they must be issued from the pharmacy at different times. Injections to be administered by intravenous bolus must be issued first. The only exception that can be made to the sequencing is when it is essential that intrathecal injections, and injections to be administered by intravenous bolus, are given in one episode of treatment.

Storage

3.18 Prepared intrathecal medicines should not be stored in the clinical area. Intrathecal medicines issued from the pharmacy should be delivered immediately before the planned administration time, and those prepared in operating departments should be used immediately following preparation. Where this is not possible, intrathecal injections must be stored in the designated area, separate from injections to be given by a different route, to avoid the risk of selecting the wrong preparation.

3.19 The designated area must be a lockable area. The key should be kept with the nurse-in-charge. The area must be locked at all times.

3.20 Only a practitioner on the intrathecal register should remove the intrathecal injection from the designated area. Only one dose should ever be removed at any one time.

Administration

3.21 Practitioners preparing to administer an intrathecal injection must verify details to ensure that the correct medicine and the correct dose are given to the correct patient by the correct route. These details must be verified by a second person, and the checks made must be recorded on the prescription chart.

3.22 Intrathecal medicines should be administered at a different time from injections to be given by the intravenous or other injection route. Where this is not possible, intrathecal injections must be kept clearly separate from injections to be given by a different route, to avoid the risk of selecting the wrong preparation. Wherever possible, the intrathecal and the intravenous bolus injection should be administered by different practitioners

3.23 A technically difficult lumbar puncture may occasionally need the assistance of staff not on the intrathecal register, for example a radiologist to position the needle under imaging control. This is acceptable – however, these staff must never be involved in any other aspect of the process and, specifically, must never administer the intrathecal injection.

3.24 Intrathecal injections must be prepared and administered within normal working hours whenever possible. The intrathecal procedure should not be undertaken if practitioners named on the intrathecal register are not available.

Annex A

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