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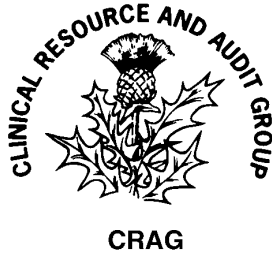


GOOD PRACTICE STATEMENT FOR THE PREPARATION
OF INJECTIONS IN NEAR-PATIENT AREAS,
INCLUDING CLINICAL AND HOME ENVIRONMENTS



SCOTTISH EXECUTIVE

Working together for a healthy, caring Scotland



"Bringing clinical effectiveness into practice"



Good Practice Statement for the Preparation of Injections in Near-Patient Areas, including Clinical and Home Environments

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‘Patients rightly expect that their stay in hospital will be as safe and comfortable as possible.’

*Our National Health: A Plan for Action, a Plan for Change.*¹

‘The promotion of a culture of patient safety within local services is an integral part of clinical governance.’

*Building a Safer NHS for patients.*²

The publication in July 2001 of the Report of the Bristol Royal Infirmary Inquiry³ reinforced the messages in our guidance on clinical governance⁴ that Trusts should have systems and policies in place to support all health professionals in their responsibilities for providing safe and effective care and driving up the quality of care. The consultation on the Quality and Standards Board for Health in Scotland⁵ in March 2002 emphasised the need to integrate patient safety issues with other aspects of the quality and clinical effectiveness agenda.

No therapeutic or diagnostic intervention is risk-free, but generally the benefits of medicines greatly outweigh the risks. The publication of *An Organisation with a Memory*⁶ in 2000 by the Department of Health in England, was followed by *Building a Safer NHS for Patients* in 2001, which identified targets for reducing key risks in healthcare. One of these was to reduce to zero the number of adverse events due to the maladministration of intrathecal drugs by the end of 2001. The Association of Scottish Trust Chief Pharmacists expressed concerns that the administration of all medicines by injection is associated with risk and there is a lack of consistency in the standard of practice for the preparation of injections. This concern was reinforced in the Audit Commission report *A Spoonful of Sugar*⁷ which drew attention to the risks to patients associated with preparation of intravenous medicines at ward level.

It was particularly timely therefore, when a proposal was put to the Clinical Resource and Audit Group (CRAG) to establish an Expert Group on the Preparation of Medicines for Injection. Dr John Browning agreed to chair the Expert Group which would be multi-professional and would include patients’ views. Injections are prepared in diverse settings including wards, theatres and people’s homes, as well as in pharmacies. They are prepared by medical, nursing, pharmacy and other healthcare staff, and sometimes by patients themselves when managing chronic conditions. It is important to ensure that the right method is followed in the right setting for the right circumstances in order to minimise the risks.

This Expert Group was established to develop good practice statements on:

- The principles for the prescribing of medicines for injection.
- The most appropriate location for the preparation of medicines for injection.
- The standard required for the environment, procedures, and operators involved in the preparation of medicines for injection.

FOREWORD

The good practice statements apply to all injections for patients, wherever they are prepared. This includes hospitals, community pharmacies, GP and dental surgeries, nursing homes and patients' homes.

The Expert Group has worked quickly and efficiently to produce this excellent, clear guidance which will have a significant impact on actual practice. Staff in our hospitals and in the community who prepare injections, and patients on long-term therapies involving injectable medication, will have clear guidance about how to minimise the associate risks.

I have recently consulted NHSScotland on proposals to improve patient safety in a publication entitled *Learning from Experience*, which refers to this important initiative. These good practice statements are sound recommendations which will improve the safety of patients in NHSScotland and I commend them to you.



Dr Mac Armstrong
Chief Medical Officer

December 2002

EXECUTIVE SUMMARY

The administration of medicines by injection is a hazardous process that should be avoided wherever possible. However, for some patients and medicines there are no alternatives, and these good practice statements have been developed to provide guidance on the standards of practice that should apply in the preparation of injections.

The individual statements are linked (see Appendix 3). Together, they provide a risk-assessment framework which supports the development of policies and procedures to take account of local needs and circumstances. Policies should be applicable to patient groups or categories of medicines, and also to specific situations to decide action in particular circumstances. The good practice statements can be applied by individual clinicians in their practice, by the clinical team and by the organisation.

Locally, Trust Chief Executives, Medical Directors, Directors of Nursing and Chief Pharmacists are responsible for implementing the good practice statements. Regular audit of the local action required that is clearly defined for each of the statements should be undertaken to monitor compliance. Action from national bodies and agencies including the Association of Scottish Trust Chief Pharmacists, NHS Education for Scotland, university schools of medicine, pharmacy and nursing, and further relevant education establishments is also recommended.

The good practice statements

- Medicines should only be given by injection when no other route is suitable.
- Wherever possible, injections that are available in a ready-to-use form should be used.
- When the injection is available in a ready-to-use form, and there are no health and safety risks to the operator or to the environment, it should be transferred to the administration device in near-patient areas, and used immediately.
- Where a ready-to-use form of an injection is not available, a multi-professional risk assessment should be completed to determine the most appropriate location for preparation, and any action required to eliminate or minimise hazards.
- Parenteral nutrition solutions that require to be prepared, and cytotoxic medicines, should be made available through a pharmacy in the final container or device for administration.
- The preparation of injections in near-patient areas should be carried out by suitably instructed patients, carers or healthcare staff, in a suitable environment, using safe procedures.
- Injections prepared in near-patient areas should be administered immediately.
- Regular planned audit of the preparation of injections in near-patient areas in healthcare premises should be undertaken.
- Where local aseptic dispensing services are required, they must comply with the national standards.

GLOSSARY OF TERMS

Aseptic dispensing	The preparation of a medicine that is appropriate for issue or administration to a patient, by a method of handling sterile material that employs techniques which minimise the risk of microbial contamination.
Bolus	Administration of a small volume of a solution of a medicine directly into a tissue, organ or vein by manual means using a syringe, as a single dose given over a relatively short period of time.
Hazard	A factor with the potential to cause harm.
High risk	Where the hazard associated with preparation is likely to have serious consequences for the patient or operator.
Infusion	Administration of a large volume of a fluid or solution of a medicine directly into a tissue, organ or vein, by means of gravity or a pump system, given over a relatively long period of time.
Licensed manufacturer	Possessing a licence from the Licensing Authority (the Medicines Control Agency) to operate as a manufacturer of pharmaceutical products.
Low risk	Where the hazard associated with preparation is unlikely to have serious consequences for the patient or operator.
Multi-professional	Doctor, pharmacist and nurse, and any other professional involved in the process.
Near-patient areas	The general area in which the patient is examined, treated and cared for e.g. the ward, the clinic or surgery, the patient's home.
Operator	The person undertaking the preparation.
Parenteral	Administered by injection, infusion or implantation into the body.
Preparation	The manipulation of ingredients and components to make a final product.
Ready-to-administer	Requiring no further dilution or reconstitution, and presented in the final container or device, ready for administration or connection to a needle or giving set, e.g. an infusion in a bag, with no additive required.
Ready-to-use	Requiring no further dilution or reconstitution before it is transferred to the administration device, e.g. a liquid in an ampoule, of the required concentration, that only requires to be drawn up into a syringe. Ready-to-administer injections are also ready-to-use.

1.1

Background

Medicines for injection are not always available from the manufacturer in a ready-to-use form. Therefore, many injections need to be prepared before they can be administered. For example, in NHSScotland, it is estimated that at least 650,000 antibiotic injections are prepared in near-patient areas each year, and 350,000 in pharmacies.⁸

The process of preparation may be straightforward, for example a simple dilution, or complicated, for example involving complex calculations, or several manipulations. There are the risks of error in the calculations and during the manipulations involved, and risks of microbial and particulate contamination. The nature of the medicine, and the clinical condition of the patient, affect the degree of the overall risk.

The Expert Group acknowledged at an early stage that the available evidence of error rates associated with the preparation of injections in scientific literature is limited. However, individual cases have resulted in serious outcome or even death to patients,^{9,10} and some have been the subject of litigation and media attention.

1.2

Hazards associated with the preparation of medicines for injection

The hazards associated with the preparation of injections may be summarised as follows:

- Incorrect dosage calculation
- Selection of the wrong drug or diluent
- Incorrect method of preparation
- Incompatibility of constituents
- Instability of the final product
- Microbial contamination
- Particulate contamination
- Health and safety risk to the operator or the environment.

Since 1990, data on errors in the injection preparation process have been systematically collected.⁹ Examples of serious medication errors that have been reported include:

- Error in the calculation of the dose, e.g. one hundred times the correct dose of morphine administered to a neonate, resulting in patient death.⁹
- Selection of the wrong drug, e.g. gentamicin instead of clindamycin, resulting in serious adverse reaction.⁹
- Selection of the wrong diluent, e.g. strong potassium chloride solution selected instead of 0.9% sodium chloride solution, resulting in patient death.¹⁰

Physical and chemical incompatibilities may result in loss of potency, or toxicity, e.g. precipitation due to pH changes, breakdown of fat emulsions when electrolytes are added.

Inadequate mixing during preparation of infusions may result in the formation of a concentrated layer of the additive. Strong potassium chloride solution is particularly prone to this effect, and administration of an infusion of this product that has not been thoroughly mixed may result in a serious adverse reaction for the patient.

Degradation of the final product due to instability may result in the formation of toxic substances, or in loss of potency.

The risks of microbiological contamination of the final product increase when injections are prepared in environments without suitable controls. Over the past thirty years, surveys on intravenous medicines prepared in near-patient areas have shown a range of microbiological contamination rates ranging from 2 to 15% (average 8%).¹¹⁻²⁰ Although most of the contamination does not lead to sepsis,²¹ the nature of the contaminating organism cannot be predicted. Therefore, the risk of serious sepsis cannot be discounted, particularly if the patient is immunocompromised, or if the injection solution supports bacterial growth.²² There are many possible sources of microbiological contamination,^{21,23,24} for example, dirty preparation areas, omission of handwashing, and failure to swab vial tops. It has been shown that a contamination rate of less than 0.1% is achievable in near-patient areas by an experienced operator using aseptic technique²⁵.

1.3

Current standards

Injections prepared in pharmacies are subject to a high level of control to comply with national standards.^{22,26-35} Integral to the standards is the requirement to undertake external audits of NHS pharmacy aseptic dispensing services. Progress has been made, however, deficiencies remain in premises and their maintenance. Investment is required in the aseptic facilities and in the support available from estates personnel to correct the deficiencies.

There is wide variation in practice in the preparation of injections in near-patient areas, and there are no national standards. This document aims to provide a standard for NHSScotland.

1.4

Improving practice

The standards currently in place for injection preparation^{22, 26-35} have been developed as a consequence of individual cases that resulted in serious patient harm or death, but the scope of these standards is limited to pharmacy aseptic dispensing services. It is desirable, therefore, to take a pro-active approach, and to review practice to further reduce the risk associated with the preparation of injections.

The good practice statements have been developed to raise awareness that the use of medicines by injection is hazardous, and should be avoided where possible, and to provide guidance on the standards of practice that should be adopted by all personnel involved in the supply and preparation of injections. They provide a framework for the development of policies and procedures to take account of local needs and circumstances. Risk assessments may be applied to patient groups or categories of medicines to decide broad policies, and also to individual patients and situations to decide action in particular circumstances.

The good practice statements are based on the following risk-management principles:

- Raise awareness of the existence of the hazard
- Eliminate the hazard at source, or substitute the hazard with something less hazardous
- Design and organise practices and processes to minimise risk
- Provide information, instruction, and training
- Implement suitable and sufficient control measures.

2.1

Medicines should only be given by injection when no other route is suitable

Reason for statement	Local action required
<p>The injection route is more hazardous than other routes of administration and should be reserved for the following circumstances.</p> <ul style="list-style-type: none"> • The clinical condition of the patient does not allow administration by another route, for example, oral, naso-gastric, rectal, etc. • The clinical condition of the patient requires the medicine to be administered by injection to achieve immediate effect and/or the required therapeutic levels. • The medicine, or a therapeutic equivalent, is unavailable for administration by any other route. • Administration by injection is in the best interests of the patient. 	<p>Policies and systems should be put in place to ensure the following.</p> <ul style="list-style-type: none"> • Medicines are only prescribed by injection when no other route is suitable. • Following local assessments of circumstances and hazards, practitioners who are allowed to prescribe injections are clearly identified. The policies reflect national guidance where available, for example, restrictions relating to the prescribing of cytotoxic chemotherapy.³⁶ • Prescriptions for injections have a specific finishing date or review date stated. If this is not appropriate, the prescription is reviewed regularly, preferably at least once every 24 hours, by a prescriber in the clinical team, and changed to a less hazardous route at the earliest stage possible. <p>Formularies and treatment protocols, for example, intravenous to oral step-down policies, should be developed to reflect the need to</p> <ul style="list-style-type: none"> • minimise the number of injections administered to patients • standardise doses or concentrations to avoid complex or unfamiliar preparation processes.

2.2

Wherever possible, injections that are available in a ready-to-use form should be used

Reason for statement	Local action required
<p>The risk to patients, staff, and the NHS is minimised by using an injection that is ready-to-use, that is, does not require to be further diluted or reconstituted before it is transferred to the administration device. An example would be an ampoule containing the medicine in a liquid form of the required concentration, which only needs to be drawn up into a syringe.</p>	<p>Formularies and treatment protocols should be put in place taking account of the recommendation that, if they are required, injections that are available in a ready-to-use form should be prescribed.</p>

National action recommended

- Standard doses or concentrations of commonly used injections should be identified. The NHS should explore whether they could be produced by licensed manufacturers.

2.3

When the injection is available in a ready-to-use form, and there are no health and safety risks to the operator or to the environment, it should be transferred to the administration device in near-patient areas, and used immediately

Reason for statement	Local action required
<p>Where injections are presented in a ready-to-use form, that is requiring no further dilution or reconstitution before being transferred to the administration device, and the solution presents no health and safety risks to the operator or to the environment, then the process is low risk and should be carried out in near-patient areas.</p> <p>This will ensure that the patient receives the medicine at the time that it is required.</p>	<p>Policies and systems should be put in place to ensure the following.</p> <ul style="list-style-type: none"> • All ready-to-use injections that pose no health and safety risk to the operator or environment, are transferred to the administration device in near-patient areas. • All injections transferred to the administration device in near-patient areas are administered immediately.

2.4

Where a ready-to-use form of an injection is not available, a multi-professional risk assessment should be completed to determine the most appropriate location for preparation, and any action required to eliminate or minimise hazards

Reason for statement	Local action required
<p>There are risks of error and contamination associated with the preparation of injections. If injections are not available in a ready-to-use form, or in a ready-to-administer form where required, a risk assessment should be undertaken.</p>	<p>Multi-professional risk assessments should be undertaken to decide the most appropriate location for the preparation of all injections that are not available in a ready-to-use form. The risk assessment process is shown in Appendix 4 and should be incorporated in the local risk management framework.</p> <p>Risk assessments should be undertaken by</p> <ul style="list-style-type: none"> • the organisation • clinical teams • individual clinicians in their practice for • patient groups • categories of medicines • specific situations and circumstances. <p>Risk assessments should be undertaken for patient groups or categories of medicines to decide general policies. The outcome will depend on local circumstances. For example, some paediatric injections might be assessed as being suitable for preparation in near-patient areas for patients in a paediatric hospital being treated by staff experienced in the calculation and preparation of paediatric doses. On the other hand, in general hospitals with few paediatric beds and fewer staff available with the necessary expertise, the assessment might result in a policy that paediatric injections are prepared in a pharmacy.</p>

Reason for statement	Local action required
	<p>Similarly, the preparation of intrathecal injections carries a high risk, and in most circumstances should be undertaken in a pharmacy. However, this may not be possible for operational reasons, for example, anaesthetic practice. In such situations, in environments where intrathecal injections are prepared routinely, it may be appropriate for them to be prepared in near-patient areas by suitably competent practitioners.</p> <p>Risk assessments should also be undertaken for specific situations and circumstances. For example, an individual patient who is immunocompromised may require injections normally assessed as being suitable for preparation in near-patient areas, to be prepared in a pharmacy.</p> <p>Policies and systems should be put in place to ensure that injections are prepared by a pharmacy aseptic dispensing service when the preparation of an injection carries a high risk to staff or patients, and it is unavailable from the manufacturer in a ready-to-use form.</p>

2.5

Parenteral nutrition solutions that require to be prepared and cytotoxic medicines, should be made available through a pharmacy in the final container or device for administration

Reason for statement	Local action required
<p>Parenteral nutrition solutions that require to be prepared involve complex calculations and manipulation, and have high potential for microbial growth in the final product.</p> <p>The preparation and/or drawing up of cytotoxic medicines present health and safety hazards to the operator.</p>	<p>Policies and systems should be put in place to ensure that the following injections are supplied from a pharmacy in the final container or device for administration.</p> <ul style="list-style-type: none"> • All parenteral nutrition solutions that require to be prepared. • All cytotoxic injections.

2.6

The preparation of injections in near-patient areas should be carried out by suitably instructed patients, carers or healthcare staff, in a suitable environment, using safe procedures

Reason for statement	Local action required
<p>Medication errors during injection preparation occur due to, for example calculation errors, selection of the wrong drug or diluent or, incorrect method of preparation.^{9,10}</p> <p>Contamination rates are reduced when an injection is prepared by an experienced operator using aseptic technique.²⁵</p>	<p>Policies and systems should be put in place to ensure the following.</p> <ul style="list-style-type: none"> • Patients and carers who prepare injections are given appropriate information and instruction (see Appendix 5). • Only healthcare staff who have completed a competency-based training programme prepare injections. Staff that have completed the training programme are subject to a regular re-assessment of competence. The training programme includes, as a minimum, instruction and practice in aseptic technique, in dosage calculation, and in the hazards associated with the preparation of injections. An example of the elements that should be included in a training programme is shown in Appendix 6. • All required information is available in areas where injections are prepared. The information is up to date, and must conform with the licence holder's Data Sheet, or Summary of Product Characteristics, or the manufacturer's package information. It includes, as a minimum where applicable, instruction for reconstitution, compatibility with infusion fluids and other medicines, limits on the concentration of the final solution, stability, and the administration rate.

Reason for statement	Local action required
	<ul style="list-style-type: none"> • Injections are 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. <p>Trusts should work towards introducing the following.</p> <ul style="list-style-type: none"> • Standard operating procedures for the preparation of injections by healthcare staff. An example is shown in Appendix 7. • Documentation to record all aspects of the preparation of individual injections that are prepared by healthcare staff.

National action recommended

- National training boards should develop a competency standard with a defined reassessment process. This will facilitate the continuing use of skills when staff transfer between Trusts.
- University schools of medicine, pharmacy, nursing and other providers of undergraduate education to relevant professionals should include in the syllabus, formal training in the preparation of medicines.
- Networks and representative bodies of relevant patient groups should develop information and instruction packages for patients and carers who require to prepare injections.
- Research should be undertaken to establish validated standards for environments and procedures used for the preparation of injections in near-patient areas.

2.7

Injections prepared in near-patient areas should be administered immediately

Reason for statement	Local action required
<p>The risk of contamination is far higher when injections are prepared in near-patient areas compared with pharmacy aseptic services facilities, and the risk increases with the complexity of the preparation. Injections prepared in such areas should be administered immediately to reduce the risk of infection. They should not be stored for future use.</p> <p>Medicines that have undergone reconstitution, dilution or addition may have limited stability, and therefore administration may require to be completed within a specific timescale.</p> <p>The British National Formulary recommends that the administration of infusions, and other injections requiring slow or intermittent administration, that have been prepared in near-patient areas, should be completed within 12 hours of preparation unless a shorter time period is required due to stability factors.</p>	<p>Policies should be put in place to ensure that administration of injections that have been prepared in near-patient areas</p> <ul style="list-style-type: none"> • is commenced immediately following preparation as far as possible • is completed within 12 hours of preparation unless a shorter period is required due to stability factors. <p>Medicines should be prescribed by bolus injection wherever possible, and only added to infusions in the following circumstances.</p> <ul style="list-style-type: none"> • Constant plasma concentrations are needed. • A minimum administration time is required. • A more concentrated solution would be harmful. • The volume required for a bolus, due to the dose required, is excessive. <p>Where the above recommendations cannot be adopted for practical or operational reasons, a risk assessment should be undertaken, and the action taken to minimise the risk should be documented.</p>

National action recommended

- Research should be undertaken to establish the time limit that should be imposed due to the risk of contamination, for the completion of administration of injections prepared in near-patient areas.

2.8

Regular, planned audit of the preparation of injections in near-patient areas in healthcare premises should be undertaken

Reason for statement	Local action required
<p>Regular, planned audit of personnel, environments and procedures involved in the preparation of injections in near-patient areas in healthcare premises must be undertaken to monitor the implementation of, and compliance with, the good practice statements.</p>	<p>The following system should be put in place to audit compliance with the good practice statements.</p> <ul style="list-style-type: none"> • Audits of the preparation of injections in near-patient areas in healthcare premises are undertaken every 12 to 18 months. • Auditors have completed a competency-based training programme, and are subject to regular re-assessment of competence. • The audits cover personnel, environment, and procedures. • Observations made during the audits are clearly recorded, and an action plan including timescales for rectifying any deficiencies is agreed. There is a system in place to ensure that any remedial work required is carried out. Contingency arrangements are agreed while deficiencies are being corrected.

National action recommended

- National training boards should develop competency standards for auditors with a defined reassessment process.
- Further education establishments should develop training programmes for auditors and include them in the syllabus.

2.9

Where local aseptic dispensing services are required, they must comply with the national standards

Reason for statement	Local action required
<p>Trusts are required³⁷ to ensure that aseptic dispensing services comply with the standards in the guidance document, Aseptic Dispensing for NHS Patients, 1995²⁷ and any subsequent revisions. The standards cover the following elements:</p> <ul style="list-style-type: none"> • Process • Personnel • Facilities and equipment • Protective clothing • Documentation • Starting materials and components • Storage and handling • Labelling • Product shelf-life • Quality assurance and release of finished products • Service audit. <p>Aseptic dispensing services must be externally audited at least every 12 to 18 months.²²</p> <p>The audits that have been undertaken have identified deficiencies in some aseptic dispensing service facilities, and a national problem with their maintenance.</p>	<p>The following system must be in place to ensure that aseptic dispensing services meet the national standards.</p> <ul style="list-style-type: none"> • A corrective action plan with timescales is agreed if the aseptic dispensing service does not meet the required standards. A risk assessment to determine the most appropriate course of action in the interim period is undertaken. • Auditors have completed a competency-based training programme, and are subject to regular re-assessment of competence. • Estates services personnel are adequately trained in the planned preventative maintenance of aseptic dispensing service facilities, and ensure that it is given the appropriate degree of priority.

National action recommended

- National training boards should develop competency standards for auditors with a defined reassessment process.
- Further education establishments should develop training programmes for auditors and estates services personnel and include them in the syllabus.

APPENDIX 1

REMIT AND SCOPE OF THE EXPERT GROUP

The remit of the Expert Group was to develop good practice statements on:

- the principles for the prescribing of medicines for injection;
- the most appropriate location for the preparation of medicines for injection; and
- the standards required for the environments, procedures, and operators involved in the preparation of medicines for injection.

The good practice statements apply to all injections for patients, wherever they are prepared. This includes hospitals, community pharmacies, GP and dental surgeries, nursing homes, and patients' homes.

The remit was concerned with the preparation of medicines for injection. Reference is made to prescribing and administration only where these associated functions impact on preparation. However, the Expert Group recommends that good practice statements on prescribing and administration also require to be developed in order to minimise the risk involved in the whole process.

APPENDIX 2

COMPOSITION AND MEMBERSHIP OF THE EXPERT GROUP

Chairman

Dr John Browning Medical Director
Lanarkshire Acute Hospitals NHS Trust

Members

Dr Angela Bowman Consultant Medical Oncologist
Edinburgh Cancer Centre

Dr Alison Bramley CRAG Secretariat
Scottish Executive Health Department

Dr Michael Cornbleet Senior Medical Adviser
Scottish Executive Health Department

Miss Irene Couper Area Quality Assurance Pharmacist
North Glasgow University Hospitals NHS Trust

Dr James Grant General Practitioner
St Margaret's Health Centre, Auchterader

Dr Michael Logan Consultant Anaesthetist
Lothian University Hospitals NHS Trust

Mrs Laura McIver Chief Pharmacist
Forth Valley Acute Hospitals NHS Trust

Ms Fiona McQueen Director of Nursing
Ayrshire and Arran Acute Hospitals NHS Trust

Dr Baxter Millar General Manager
Tayside Pharmaceuticals

Mr Stewart Miller Patient Representative

Mr John Milne Dispensing Service Manager
Hairmyres Hospital, East Kilbride

Dr John Schulga Consultant Paediatrician
Stirling Royal Infirmary

Ms Vivienne Simpson Practice Development Nurse
Victoria Infirmary, Glasgow

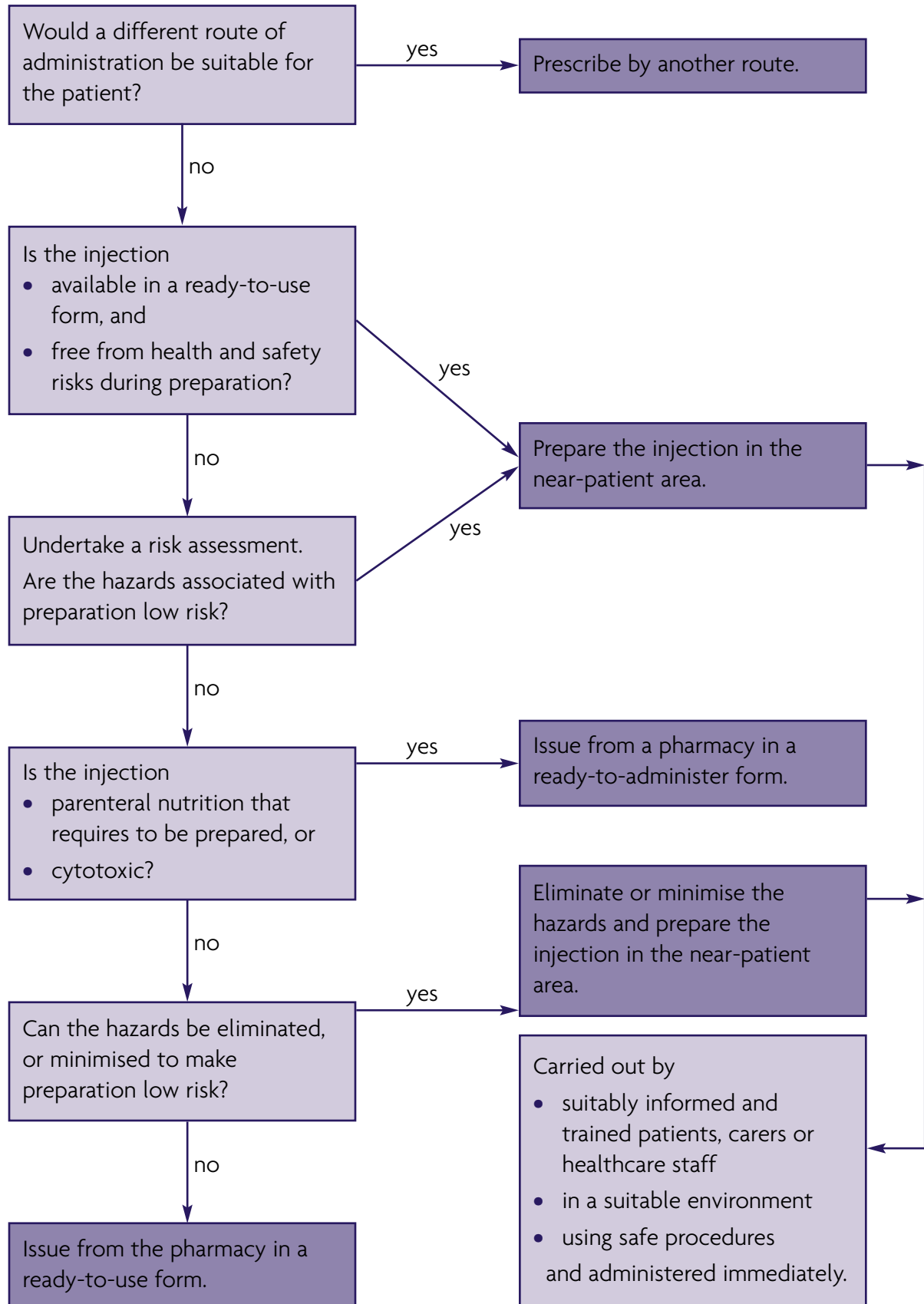
Mrs Pamela Warrington Deputy Chief Pharmaceutical Officer
Scottish Executive Health Department

Secretary

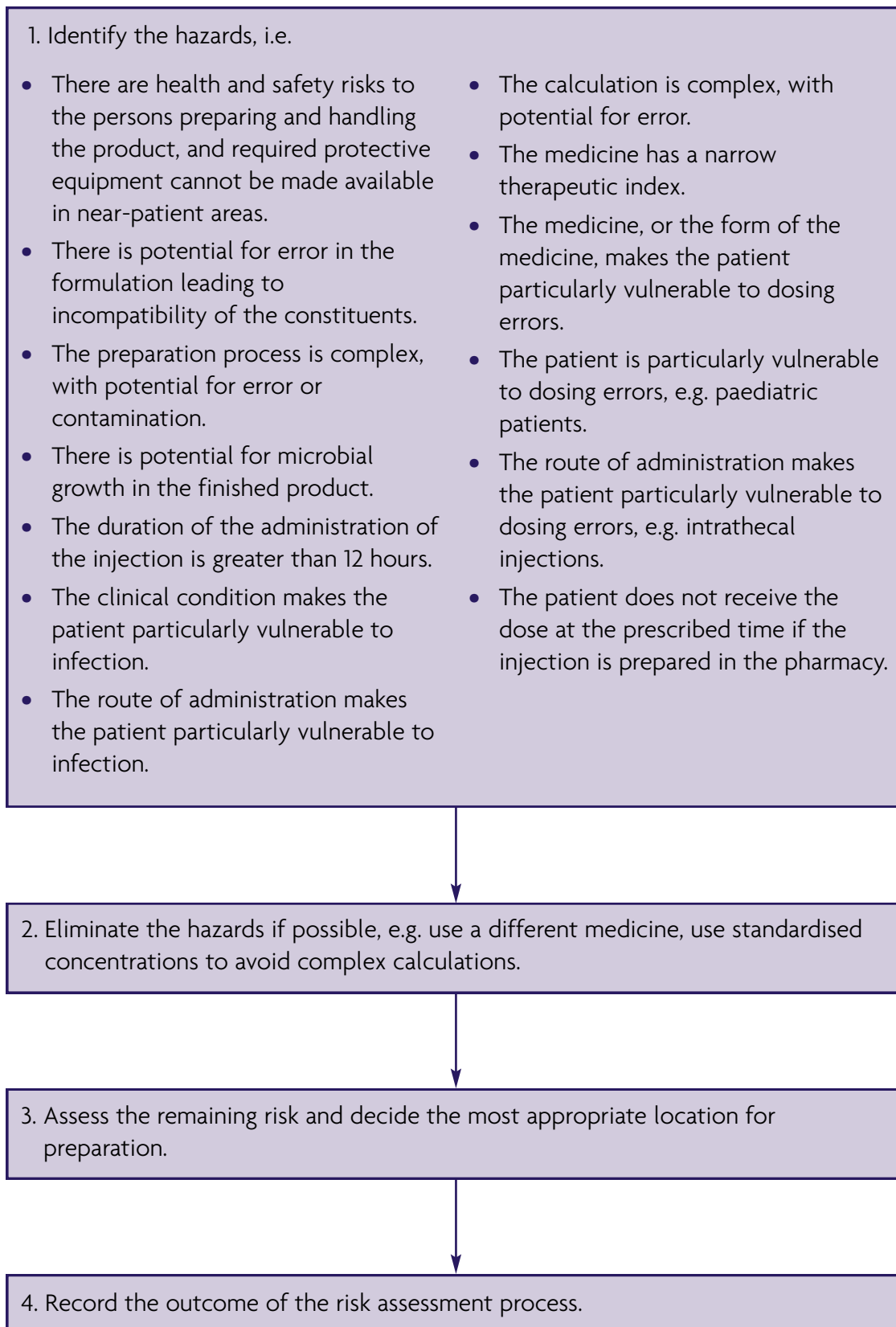
Mrs Dorothy Hughes Deputy Chief Pharmacist
Lothian University Hospitals NHS Trust

APPENDIX 3

DECISION PROCESS



RISK ASSESSMENT PROCESS



INFORMATION AND INSTRUCTIONS FOR PATIENTS AND CARERS ON THE PREPARATION OF INJECTIONS

1. The information and instructions provided to patients and carers must be tailored to their individual needs and circumstances. Healthcare staff who are involved in supporting patients and carers should consider home, work and social circumstances when advising on the suitability of environments for preparation.
2. Patients and carers should be shown how to prepare their injections, and given adequate opportunity to practise under supervision until they are familiar and confident with the procedure and have achieved the necessary competence. Healthcare staff should re-assess the patient's or carer's technique regularly. Records of initial instruction and re-assessment should be kept, signed by both the healthcare worker and the patient or carer.
3. Written information and instruction on the preparation of injections should include:
 - storage requirements for each product;
 - general guidance; and
 - specific step-by-step instruction on the preparation of each product.

The following general guidance is extracted from the leaflet provided to patients of the Scottish Adult Cystic Fibrosis Service, Western General Hospital, Edinburgh.

“How do I prepare IV antibiotics?”

1. When you are prescribed a course of IV antibiotics you will be supplied with:
 - a) **Vials of antibiotics** – either in powder form which has to be dissolved in water for injection or in liquid form ready to inject.
 - b) **Water for injection** – if needed to dissolve antibiotic powder in vial.
 - c) **Sodium chloride for injection (saline)** – for flushing the line and to separate antibiotics if two are prescribed together.
 - d) **Heparin (Hepflush®)** – which prevents blood clots from forming in injection devices.
2. It is important to check the names, doses and expiry dates of all drugs prior to their preparation and administration. Check that all sterile equipment to be used (e.g. syringes and needles) is intact.

APPENDIX 5 (continued)

3. It is important to **use a clean area** easily washed down with detergent and water (like a tray or kitchen work top) where you can prepare your antibiotic injections. Minimise sources of germs during the procedure by keeping pets out of the room and reduce the amount of dust in the air by closing windows and avoiding housework, such as dusting, prior to the injection.
4. Thoroughly **clean your hands** before you begin.
5. Always use '**no-touch**' technique when preparing the antibiotics:
 - **NEVER** touch the ends of needles, nozzle of syringes, necks of ampoules or rubber bungs.
 - **ALWAYS** put plastic covers back on needles even when expelling air (do not put cover back on needles once they've been used – put needles in cin-bin).
 - If you think you may have contaminated the needle, syringe or vial during the procedure (by touching or dropping) then discard and start again.

APPENDIX 6

EXAMPLE TRAINING PROGRAMME FOR THE PREPARATION OF INJECTIONS

Any training programme for the preparation of injections should include the following elements:

- 1.** Responsibilities of staff (e.g. nurses, doctors and pharmacists)
- 2.** Hazards involved in the preparation of injections
- 3.** Calculations and checking procedures
- 4.** Drug incompatibilities
- 5.** Stability of prepared injections
- 6.** Displacement values
- 7.** Aseptic technique
- 8.** Standard preparation methods
- 9.** Checking procedures
- 10.** Documentation
- 11.** Labelling
- 12.** Disposal of waste, including medicines, containers and sharps
- 13.** Product monographs
- 14.** Awareness of Control of Substances Hazardous to Health, and other health and safety considerations.

EXAMPLE STANDARD OPERATING PROCEDURE FOR THE PREPARATION OF INJECTIONS IN NEAR-PATIENT AREAS IN HEALTHCARE PREMISES

Note: This guidance has been endorsed by the Scottish Pharmaceutical Aseptic Services Specialist Interest Group as an example of ‘best practice’.

Introduction

The procedure detailed below recommends the steps that should be taken for the safe preparation of medicines in a ward or department.

It is intended for use with planned work only and is not necessarily relevant to emergency situations.

In all cases staff should refer to local policies, for example for handwashing techniques, where applicable.

Before starting the procedure, all relevant information leaflets should be read and any specific safety or handling/reconstitution instructions noted.

Any relevant labels should be prepared prior to preparation. Worksheets, where relevant, should be completed immediately after completion of the preparation process.

A new needle should always be used when administering to a patient.

1. General

- 1.1 Use aseptic technique throughout to keep the injection free from microbial contamination.
- 1.2 Use a ‘no-touch’ technique, i.e. avoid touching areas where bacterial contamination may be introduced, e.g. syringe tips, needles, vial tops, etc.
- 1.3 Gather all equipment required, ensure area is clear, quiet and uncluttered.
- 1.4 Clean the surface where preparation is to take place using an appropriate cleansing agent as recommended in local policy.
- 1.5 Check form, drug, dose and diluent against the prescription and the product information. (Note that some forms of medicines are similar, e.g. plastic ampoules and nebules.)
- 1.6 Check the expiry dates of all ingredients and equipment to be used.
- 1.7 Check the integrity of all packaging.
- 1.8 Peel wrappers from needles and syringes – do not push through wrappers as this will result in heavy particulate contamination.
- 1.9 Check route of administration against the prescription.
- 1.10 Check that the medicine has not already been given.

APPENDIX 7 (continued)

2. Handwashing

2.1 Wash hands with an antiseptic cleansing solution or with liquid soap and water followed by an antiseptic cleansing solution or as directed in local policy.

2.2 Do not use bars of soap as they are reservoirs for bacteria.

3. Gloves

3.1 Wear gloves recommended in local policies to avoid contamination of the injection being prepared and to protect the operator from inadvertent skin contamination.

4. Swabbing

4.1 Swab vial closures and infusion ports with alcohol wipes as recommended in local policy and allow to dry.

4.2 Note that where vials are protected by tamper-evident plastic or metal covers, this does not ensure sterility of the vial closure – swab all closures.

5. Withdrawing liquid from an ampoule into a syringe

5.1 Swab the neck of the ampoule using an alcohol wipe and allow to dry.

5.2 Snap open the neck of the ampoule using agreed local procedure.

5.3 Using a 'no-touch' technique, carefully withdraw required dose, filtering if applicable (e.g. when using glass ampoules) into a syringe. Tilt the ampoule if necessary so that all the required contents can be removed.

5.4 Tap the syringe lightly to concentrate any air bubbles.

5.5 Remove the needle and fit a sterile blind hub (sterile protective cap) to the syringe if required.

APPENDIX 7 (continued)

6. Withdrawing liquid from a vial into a syringe

- 6.1** Remove the tamper-evident seal if applicable and swab the top of the vial with an alcohol wipe. Allow to dry.
- 6.2** Keeping the needle cover on, draw the syringe plunger back to the desired volume.
- 6.3** Remove needle cover and insert the needle into the rubber bung.
- 6.4** Invert the vial and, keeping the needle in the liquid, gradually depress the plunger pushing air into the vial.
- 6.5** Note – if a large volume of liquid is required, use a ‘push and pull’ technique adding the liquid in aliquots of 5ml to avoid pressure building up with the risk of aerosol spray.
- 6.6** Release the plunger so that the liquid enters the syringe.
- 6.7** Tap the syringe lightly to concentrate any air bubbles and push them back into the vial. Ensure that the needle with syringe attached remains firmly in the vial during this process to avoid pulling atmospheric air into the syringe.
- 6.8** Fill syringe with desired volume of liquid, draw in a slight excess of air, then carefully remove the needle from the bung to prevent sprayback (or follow local procedure).
- 6.9** Expel any excess air, remove needle and fit a sterile blind hub if required.

7. Reconstitution of drug in powder form and removal from vial into a syringe

- 7.1** Swab vial top and/or ampoule neck with an alcohol wipe and allow to dry.
- 7.2** Using the procedures indicated in 5. (as shown on the previous page), draw up the required volume of diluent.
- 7.3** Inject this into the vial. The syringe will fill with air which has been displaced by the liquid added to the vial (unless the vial has been vacuum filled).
- 7.4** Note – if a large volume of liquid is required, use a ‘push and pull’ technique, adding the liquid in aliquots of 5ml to avoid pressure building up with the risk of aerosol spray.
- 7.5** With the needle and syringe attached to the vial, shake the contents of the vial carefully to dissolve the powder (unless otherwise indicated in the product information leaflet).
- 7.6** Fit new needle and draw up the required volume of liquid from vial using procedures indicated in 6.2 – 6.9 (as shown on this page).

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APPENDIX 8 (continued)

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