Cambridgeshire NHS
Primary Care Trust

Patient Group Direction Policy

Approval Process

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Developed by	Sarah Woodley, Gillian Ascough, Ann Darvill	
Approved by	Medicines Safety and Governance Group	05/07/2007
Ratified by	Policy Ratification Group	
Version	1	
Latest Revision Date		
Review Date	**July 2009**	
Valid on	23/05/2008	

Signatures for Ratification

1. **Name** Julia Sirett **Title** Clinical & Practice Quality Manager

Date Signed 23 July 2007

2. **Name** David Wood **Title** Senior Clinical Audit & Effectiveness Manager

Date Signed 19 July 2007

Document Control Sheet

Development and Consultation:	This policy was developed by Sarah Woodley, Community Health Services Pharmacist in consultation with: • Gillian Ascough, Community Health Services Pharmacist • Ann Darvill, Pharmacist, Out of Hospital Care and Provider Liaison • Members of the Medicines Management Team • Medication Safety and Governance Group
Dissemination	This policy will be added to the PCT website, policy index and policy folder This policy will be sent to all healthcare professionals who are eligible to act under Patient Group Directions (see Purpose and Scope) This policy will be sent to managers and clinical governance leads responsible for ratifying Patient Group Directions within Cambridgeshire PCT.
Implementation	This policy will be implemented by clinical leads and service managers with advice where necessary from the Medicines Management Team.
Training	This policy will be highlighted to all appropriate healthcare practitioners. New healthcare practitioners to whom it applies will be advised to read the policy on induction. Individuals must read the policy and identify their own training needs using the NPC Competency Framework and must sign to say they have read and understood it. All practitioners should seek further advice from the Medicines Management Team or clinical lead if there are any aspects of the policy that they do not fully understand. Training required for individual Patient Group Directions (PGDs) will be specified in the individual PGD document.
Audit	The Medicines Safety and Governance Group (MSGG) will audit this policy. A completed copy of the PGD ratification checklist will be kept for audit purposes as evidence that PGDs submitted to the MSGGfor approval comply with this policy.
Review	This policy will be reviewed by the Medicines Safety and Governance Group
Links with other Documents that guide Practice	The Policy should be read in conjunction with the Policy and Procedures for Management and Administration of Medicines in Inpatient Settings or the Management and Administration of Medicines in Clinics, Community and Home Settings if applicable.
Equality and Diversity	The Medicines Safety and Governance Group has carried out a Rapid Equality & Diversity Impact Assessment and concluded the document is compliant with the PCT Equality and Diversity Policy.

Standards for Better Health This document supports the PCT in its compliance with the DH [2004] Standards for Better Health in reference to:	
Domain	**How?**
Safety	This purpose of this policy is to establish safe and consistent practice, to reduce risks, minimise errors and maintain the safety of patients and staff at all times. The policy reflects current legislation and national and local guidance and seeks to ensure that PGDs are only used in appropriate settings and situations by appropriately qualified and authorised staff.
Clinical and Cost Effectiveness	This policy will ensure that PGDs are evidence based and allow patients to be treated by the most appropriate health professional at the first point of contact.
Governance	PGD ensures standardisation of care. PGDs are a legal requirement for healthcare professionals (who are not independent prescribers) to be able to administer or supply medicines without a prescription. Practitioners working under the PGD must sign up to it and keep the specified records, thus providing an audit trail and accountability. This policy ensures that PGDs comply with the law and are used appropriately and it outlines responsibilities of individuals and the organisation.
Patient Focus	This policy allows Healthcare professionals to develop PGDs to allow them to respond to patients' needs in an appropriate and timely manner. It is specified that all aspects of the patient's treatment, including any medicines supplied or administered are discussed with the patient Every patient is treated as an individual.
Accessible and Responsive Care	This policy allows Healthcare professionals to develop PGDs to allow them to respond to patients' needs in an appropriate and timely manner. The documentation allows specified healthcare professionals to supply or administer medicines without a prescription.
Care Environment and Amenities	This policy ensures that PGDs are developed in areas that have the appropriate facilities and supplies available.
Public Health	The policy ensures that the PGD specifies that appropriate advice and information must be given to patients regarding the medicine they receive under the PGD. The policy enables PGDs to be developed safely and consistently in certain areas e.g. family planning and immunisation to promote Public Health.

Revisions

Version	Page/Para No	Description of Change	Date Approved

Contents

1. Introduction

This policy has been developed for individuals **using** Patient Group Directions for administration or supply of medicines, and for those involved in **developing** Patient Group Directions.

This policy has been developed to ensure that Cambridgeshire PCT complies with the requirements of HSC 2000/026, 9 August 2000, Patient Group Directions (England Only) and to ensure a safe, effective and consistent approach to development, implementation and use of Patient Group Directions throughout Cambridgeshire PCT.

This policy supersedes the Huntingdonshire PCT Policy for Patient Group Directions.

This policy should be read in conjunction with the Policy and Procedure for Management and Administration of Medicines in Inpatient Settings and The Policy and Procedure for Management and Administration of Medicines in Clinics, Community and Home Settings.

1.1 What is a Patient Group Direction?

A Patient Group Direction (PGD) is a specific written instruction that provides legal authorisation for the **supply** and / or **administration** of named medicines in identified clinical situations to groups of patients who may not be individually identified before presentation for treatment. It is NOT an authorisation to prescribe.

A PGD is drawn up locally by doctors, pharmacists and other appropriate healthcare professionals. It must be approved for use by the employer, advised by the relevant professional advisory committees.

The preferred way for patients to receive medicines is for an appropriately qualified healthcare professional to prescribe the medicine on an individual basis.

The supply and administration of medicines under patient group directions should be reserved for those limited situations where it is cost effective and offers an advantage for patient care without compromising patient safety, and where it is consistent with appropriate professional relationships and accountability. Health professionals must act within their own expertise and competence and are responsible for keeping themselves up to date. Patient choice and convenience must also be considered.

1.2 When can Patient Group Directions be used?

PGDs can be used in all areas in which NHS healthcare is directly provided and where services in the private, voluntary or charitable sector are NHS funded. PGDs do not extend to independent and public sector care homes or independent sector schools that provide healthcare entirely outside the NHS.

PGDs **cannot** be used for unlicensed medicines and Controlled Drugs (except Diamorphine for treating cardiac pain following myocardial infarction, schedule 5 CDs and part 1 schedule 4 CDs). Consultation proposing to extend the range of controlled drugs that can be included in PGDs is being undertaken; those wishing to develop PGDs that include CDs should seek advice from the Medicines Management Team.

Legally, a PGD is unnecessary in the following circumstances; however, individual local areas may require them:

- An exemption exists under the Medicines Act for podiatrists (chiropodists), paramedics or midwives to administer or supply certain specified medicines without directions from a doctor.
- The medicine to be **administered** is available over the counter (classified as P or GSL) or the medicine to be **supplied** is a GSL. (P medicines can only be sold or supplied through registered pharmacies). See To PGD or not to PGD.
- The medicine is exempt under the Medicines Act when used in an emergency and no prescription is required e.g. Adrenaline (epinephrine). The Medicines Safety and Governance Group will make a decision individual situations such as these.
- Medical gases that are not usually classified as prescription-only medicines
- Dressings, medical devices or chemical agents that are not legally classed as medicines.
- By practitioners authorised to prescribe the medicine in question.

2. Purpose and Scope of the Patient Group Direction Policy

2.1 Target Group

- Health professionals who wish to supply or administer medicines under a Patient Group Direction.
- Health professionals who wish to develop Patient Group Direction for use in their own area of work.
- Managers and Clinical Governance Leads who are responsible for authorising the use of a Patient Group Directions within the PCT.
- Currently, the following health care professionals are permitted to supply or administer medicines under a Patient Group Direction:

  Pharmacists
  Registered nurses
  Registered health visitors
  Registered midwives
  Registered dieticians
  Registered physiotherapists
  Registered occupational therapists
  Registered speech & language therapists
  Registered optometrists
  Registered orthoptists
  Registered orthotists and prosthetists
  State registered chiropodists (podiatrists)
  State registered physiotherapists
  State registered radiographers
  State registered paramedics or qualified ambulance paramedics

- Health professionals can only act under a Patient Group Direction as named individuals and must act within their appropriate Code of Professional Conduct.

2.2 Aims and Objectives

- To outline responsibilities of health professionals with regard to their role in the supply and administration of medicines using Patient Group Directions.

- To outline the responsibilities of health professionals and the PCT with regard to their role in developing and implementing Patient Group Directions.
- To ensure a safe, effective and consistent approach to development, implementation and use of Patient Group Directions.
- To provide a quick reference guide to the stages of development of a PGD, including when and how to seek guidance and approval.

2.3 Intended outcomes

- Patient Group Directions are only used in appropriate settings and situations by appropriately qualified and authorised staff.
- Patient Group Directions are written in a consistent way in accordance with legislation, local and national guidance and the PCT's policy and procedure by using the Patient Group Direction template.

3. Duties and Responsibilities

All staff involved in using, developing or approving Patient Group Directions must ensure that they have read and understood the Patient Group Direction Policy.

Each Patient Group Direction must be developed and signed by a multidisciplinary group involving a doctor (or dentist), a pharmacist and a representative of the professional group expected to operate within the Patient Group Direction, who will normally act as the clinical lead. Development of the PGD is the responsibility of the **clinical lead** with support from the multidisciplinary group.

The following specific duties and responsibilities apply within the PCT:

3.1 The PCT Clinical Audit and Effectiveness Team

- Organise the ratification process
- Ensure that new and updated PGDs are added to the PCT website, policy index and policy folder
- Ensure that the signed PGD is filed for safekeeping.
- Ensure signed originals of expired and superseded PGDs are kept as for all other patient records. PGDs that apply to adults must be kept for a minimum of 8 years and those that apply to children must be kept for 25 years.

3.2 Clinical Lead Developing the Patient Group Direction

- Ensure that a PGD is the most appropriate method for supply or administration of medicines to the defined group of patients in that clinical area.
- Ensure that all PGDs that are developed for use comply with legislation, national and local guidance and the PCT's Patient Group Direction Policy and Template (Appendix 2), seeking advice when necessary.
- Ensure that the PGD is approved, ratified and implemented.
- Ensure that supply and administration is audited in accordance with the PGD.
- Ensure that the PGD review is initiated 3 months before the expiry date unless a review is required more urgently in response to a change to the medicine(s) covered by the PGD.

3.3 Team leaders implementing the Patient Group Direction

- Ensure that staff are aware of any PGD which applies to their clinical area.
- Ensure that the most recent version of the PGD is available for use and any previous versions are removed from use.
- Ensure that copies of expired PGDs that were signed by authorised staff are kept as for other patient records. I.e. those applying to adults must be kept for a minimum of 8 years, and those applying to children, 25 years.
- Ensure that staff authorised to act under a PGD have the necessary qualifications, training and competencies.
- Ensure that all staff acting under the PGD are authorised to do so and have read, understood and signed the current version of the PGD and completed the agreement to practice form before attempting to work according to it.
- Keep a copy of the signed agreement forms of staff authorised to act under the PGD.
- Ensure that incidents and near misses in supply or administration under the PGD are reported using the Cambridgeshire PCT Incident Reporting form (DATIX) and/or Employer's own critical incident reporting system.
- Ensure that any suspected adverse drug reactions (ADR) are reported to the MHRA via the yellow card scheme www.yellowcard.gov.uk
- Ensure that the records specified within the PGD are maintained for audit purposes and provide audit information to the clinical lead if requested.
- Ensure that medicines are handled in accordance with the PGD and PCT medicines management policies, and that the necessary facilities and supplies are available.

3.4 Qualified Healthcare Professionals working under the Patient Group Direction

- Acting under a Patient Group Direction is not compulsory. Practitioners should exercise their professional judgement as to whether to accept the responsibility that this role will place upon them. No authorised practitioner should undertake any aspect of patient care for which they are not trained and which is beyond their professional competence. If the authorised practitioner is in any doubt about their competency they should not administer or supply in accordance with the PGDs and should seek advice.

- A practitioner authorised to work under a PGD cannot delegate the responsibility to another person.

- The PCT does not accept responsibility for anyone who operates within a Patient Group Direction that is not approved or has been superseded, or for anyone who attempts to operate within a PGD in an area of practice to which the PGD does not apply.

All healthcare professionals working under PGDs must:

- Ensure that they have read, understood and signed the current PGD and completed the agreement to practice form (Appendix 2) before attempting to work according to it. The original is kept in the health professional's personal file and the team leader holds a copy.
- Work in strict accordance with the current PGD ensuring that the necessary records are kept.
- Recognise the need for a medical opinion and make the appropriate referrals.

- Ensure that any medicine supplied is appropriately labelled in the original pack and the patient is given the appropriate advice and information as specified in the PGD.
- Ensure that the necessary records are kept and made available for audit purposes.
- Understand they are professionally accountable for their practice and must work within their competence.
- Ensure that they have received the necessary training.
- Ensure that they maintain and update their professional knowledge and skills in the relevant area of practice and keeps up to date with the medicines listed in the PGD. A record of CPD must be maintained as evidence.

It must be acknowledged by **all** members of staff that the interests and safety of every patient are paramount.

3.5 Independent Contractors

- PGDs prepared by the PCT for use in GP practices or by independent contractors, including out of hours service providers, must be authorised by the employer before the PGD becomes lawful. The employer must sign the "Authorisation of Employer" section on the front page of PGD before it can be used. Within a GP practice, one GP is asked to sign.
- At all times the employing organisation is accountable for ensuring appropriate and legal implementation of each PGD.
- Independent Contractors are at liberty to develop their own PGDs. They must be in accordance with HSC2000/026, and current regulations, and they must be approved by the PCT. Contractors should be aware that the Documents that Guide Practice Ratification checklist (Appendix 4) will be applied to any documents so submitted. The PGD Template (Appendix 2) may be used by independent contractors as a guide to ensure they meet all the requirements.
- The PGD Template (Appendix 2) must be used to develop PGDs for employees of the PCT.

4. Developing a Patient Group Direction (flowchart)

Before starting consider:
Is a Patient Group Direction the most appropriate option for the **supply or administration** of medicines in this situation? Follow the "To PGD or not to PGD" flowchart.
Consideration of the Special Circumstances for Development of PGD must be made before deciding on the most appropriate option (Appendix 1)
PGDs cannot be used for unlicensed medicines and Controlled drugs (except Diamorphine for treating cardiac pain following MI, schedule 5 CDs and part 1 schedule 4 CDs).

Essential reading:
HSC 2000/026
NPC Competency Framework
So you think you need a PGD
Examples of PCT approved PGDs can be obtained from the Medicines management team
Sample PGDs can be viewed at http://www.portal.nelm.nhs.uk/PGD/flowchart.aspx

Discuss with Cambridgeshire PCT Medicines Management team (MMT) to check if there is already a PGD for this medicine/ situation

Medicines Management Team contacts:
Cambridge 01223 885713
East Cambs & Fenland 01354 644254
Huntingdon 01480 354377

Community Health Services Pharmacists:
Gillian Ascough (ECF) 01353 652078
Sarah Woodley (Cambridge) 01223 723053

New Patient Group Direction definitely needed:
Obtain PGD template from PCT website or MMT.
Set up a multidisciplinary group that must include a pharmacist, a doctor (or dentist) and a representative of the professional group expected to operate within the PGD.
Decide who is the **clinical lead** with responsibility for the PGD.
If the PGD is for an antibiotic support is needed from a microbiologist.

Appendix 2 – Patient Group Direction Template

Is there any national or local guidance relating to the medicine(s) or situations covered by the PGD?
Is the medicine to be used outside the Summary of Product Characteristics (SPC)?

The SPCs can usually be found at http://emc.medicines.org.uk/

Consider:
Arrangements for how the medicines will be supplied, transported, stored, labelled and audited.

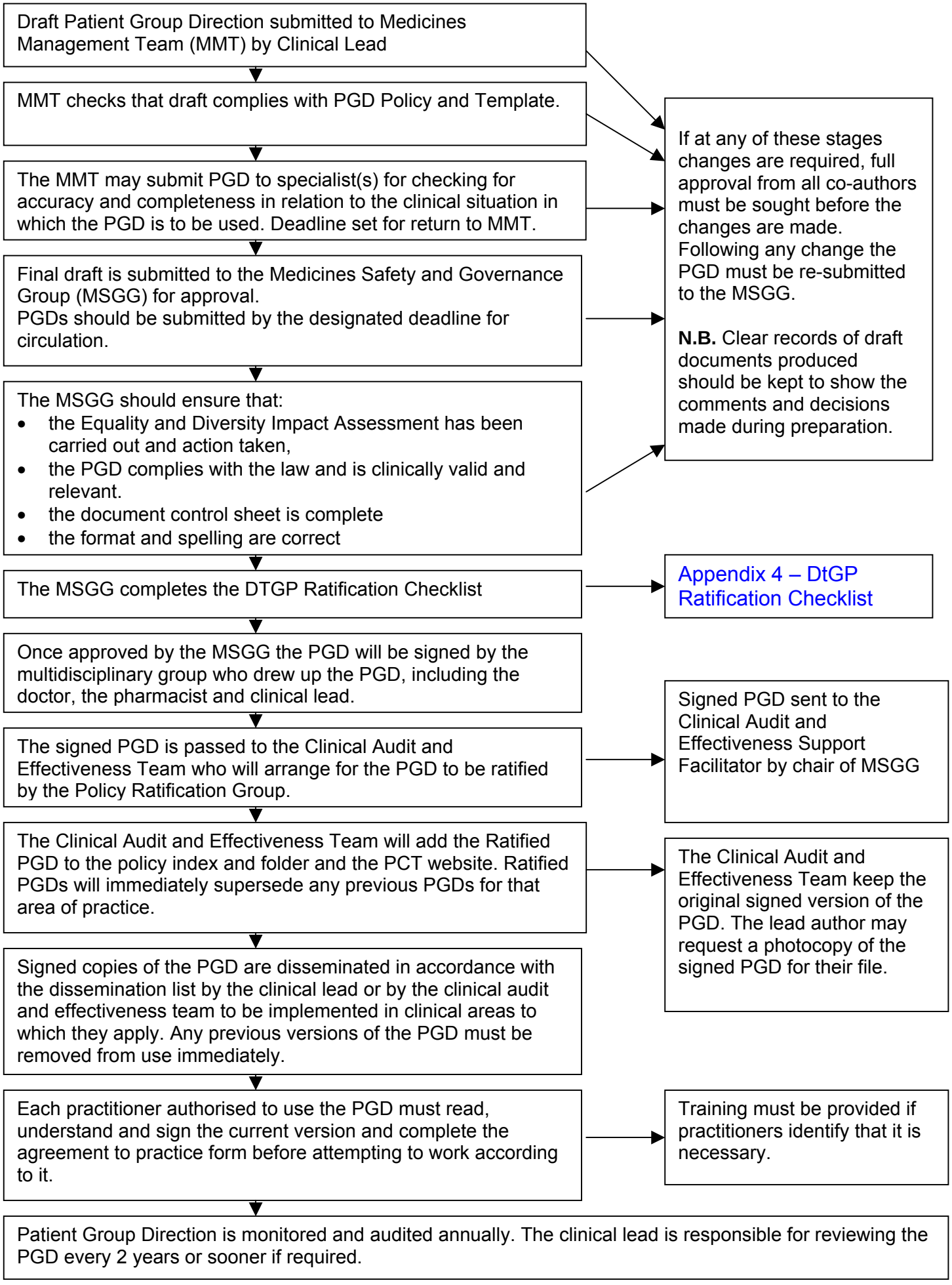
Are the necessary facilities available?

All **medicines supplied for patients to take away** should be available in pre-packs made up by a pharmacist.
There must be a secure system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and outgoings on a patient-by-patient basis.
The EC Labelling and Leaflet Directive applies to all medicines supplied under the PGD.
There must be a system in place for collection of prescription charges or confirmation of exemption status, where necessary.

Using the PGD Template

- Clarify if the Patient Group Direction is for administration **and / or** supply of medicine
- All sections of the template must be completed in full to ensure the PGD complies with the law.
- The ***italic*** text is for guidance and should be deleted as the document is completed.
- The **normal** text is standard to all PGDs and should be left in if applicable to the medicine/ situation.
- Additional information can be added if required or attached as appendices.
- Checklists or consent forms may be added if appropriate to assist with the patient consultation.
- Do not use abbreviations or Latin terms.
- List any statutory, national or other relevant guidance that has been used to develop the PGD
- Reference any documents referred to within the PGD, giving the author[s], title, publication source and date. If accessed electronically include date accessed.
- It is a legal requirement to keep records of administration / supply under PGD for audit purposes – specify in the PGD specific records to be maintained and the mechanism and frequency of audit.
- Consider the training and competencies required and how these will be accessed and maintained.

5. Approval and Endorsement process (flowchart)



6. Statutory and other Relevant Guidance

HSC 2000/026, 9th August 2000 Patient Group Directions (England only) HSC 2000/026

The relevant modifications to the provisions in and under the Medicines Act 1968 are contained in:

- The Medicines (Pharmacy and General Sale - Exemption) Amendment Order 2000 - SI 2000/1919
- The Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment (No. 2) Regulations 2000 - SI 200/1918
- The Prescription Only Medicines (Human Use) Amendment Order 2000 - SI 2000/1917
- http://www.legislation.hmso.gov.uk/si/si2003/20030696.htm
- http://www.legislation.hmso.gov.uk/si/si2003/20030697.htm
- http://www.legislation.hmso.gov.uk/si/si2003/20032429.htm
- http://www.legislation.hmso.gov.uk/si/si2003/20030697.htm
- http://www.legislation.hmso.gov.uk/si/si2004/20041189.htm
- http://www.legislation.hmso.gov.uk/si/si2004/20041190.htm

7. References

- Patient Group Directions in the NHS, Medicines Healthcare Products Regulatory Agency (MRHA) http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=148
- A practical guide and framework of competencies for all professionals using patient group directions, National Prescribing Centre, March 2004 http://www.npc.co.uk/publications/pgd/pgd.pdf
- Patient Group Direction Flowchart to aid decision making http://www.portal.nelm.nhs.uk/PGD/flowchart.aspx
- "To PGD or not to PGD" flowchart, Pharmacy Community Care Liaison Group/Beth Taylor and Leigh Machell, February 2004
- http://www.portal.nelm.nhs.uk/PGD/viewRecord.aspx?recordID=422
- PGD Website -Examples of good practice http://www.portal.nelm.nhs.uk/PGD/flowchart.aspx
- Reporting Suspected Adverse Drug Reactions, MHRA http://www.yellowcard.gov.uk/
- Royal Pharmaceutical Society of Great Britain, Patient Group Direction Resource Pack for Pharmacists, January 2004 http://www.rpsgb.org.uk/pdfs/pgdpack.pdf
- Royal College of Nursing, PGDs- Guidance and Information for Nurses http://www2.rcn.org.uk/pcph/resources/a-z_of_resources/administration_of_medicines_-_patient_group_directions

Appendix 1 - Special Circumstances for Development of Patient Group Directions

Antimicrobials

Particular caution should be exercised in any decision to draw up PGDs relating to antibiotics. Microbial resistance is a public health matter of major importance and great care should be taken to ensure that their inclusion in a direction is absolutely necessary and will not jeopardise strategies to combat increasing resistance.

A local microbiologist should be involved in drawing up the PGD. Should ensure that any such directions are consistent with local policies and subject to regular external audit.

Black Triangle Drugs and Medicines used outside the terms of the Summary of Product Characteristics

Black triangle drugs (i.e., those recently licensed and subject to special reporting arrangements for adverse reactions) and medicines used outside the terms of the Summary of Product Characteristics (SPC), e.g. as used in some areas of specialist paediatric care, may be included in PGDs provided such use is exceptional, justified by current best clinical practice (e.g. NICE guidance) and the direction clearly describes the status of the product.

PGDs may be used for Black triangle vaccines, and vaccines used outside the terms of their SPC in immunisation programmes, provided this is in accordance with the schedules recommended by the Joint Committee on Vaccination and Immunisation.

Where the medicine is for children, particular attention will be needed to specify any restrictions on the age, size and maturity of the child.

Each PGD should clearly state when the product is being used outside the terms of the SPC and the documentation should include the reasons why, exceptionally, such use is necessary.

Unlicensed Medicines

Medicines that do not have a marketing authorisation in the UK may NOT be supplied or administered under a PGD. They must be prescribed by a doctor by means of a prescription or a Patient Specific Direction, or by a supplementary prescriber as part of a supplementary prescribing arrangement if agreed within a clinical management plan.

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Appendix 2 – Patient Group Direction Template

PATIENT GROUP DIRECTION

For Administration *and/or* Supply of
Enter generic name of medicine(s)and setting in which it applies

Issue Date: *Leave blank to be completed by ratification group*

PGD expiry date: *Enter date (usually 2 years from the date ratified)*

Please check with the clinical lead, medicines management team or PCT website www.cambridgeshirepct.nhs.uk for the most recent version of the PGD before proceeding.

Names and signatures of the multidisciplinary group which drew up this PGD

NAME	DESIGNATION/TITLE	SIGNATURE	DATE
	**Doctor (enter title in full)*		
	**Pharmacist (enter title in full)*		
	**Representative of Professional Group working under PGD (enter title in full)*		
	Other (e.g. microbiologist)		

* *Mandatory Fields*

Approved by	**Cambridgeshire Primary Care Trust Medication Safety and Governance Group**	

Signatures for Ratification

NAME	DESIGNATION/TITLE	SIGNATURE	DATE
1.	Chairman/ Deputy of PCT Policy Ratification Group		
2.	Assistant Director, Clinical and Practice Governance		

Authorisation of Employer (if not employed by Cambridgeshire PCT)

NAME	DESIGNATION/TITLE	SIGNATURE	DATE

Each registered practitioner authorised to supply and/or administer medication under this PGD must have read, understood and signed this version of the PGD and completed the agreement to practice form before attempting to work according to it

NB. Italic text is for guidance and should be deleted as document is completed

Document Control Sheet

NB. Italic text is for guidance and should be deleted as document is completed

Rationale	A Patient Group Direction (PGD) is a specific, written instruction for the supply or administration of a named medicine in an identified clinical situation to patients who may not be individually identified before presentation for treatment. *Enter the reason why this specific PGD was developed*
Documents replaced or superseded by this PGD.	The following Patient Group Directions should no longer be used. Any signed-up copies should be archived: *List any previous patient group directions, together with their issue and expiry dates, and NHS area to which they applied, which this document replaces or supersedes.*
Development and Consultation:	*Give details of the team that developed the PGD and those consulted*
Dissemination	*Give details of who the PGD will be disseminated to and how this will happen*
Accessibility	Cambridgeshire PCT website www.cambridgeshirepct.nhs.uk
Implementation	*Give details of how this PGD will be implemented and by whom.* Each registered practitioner authorised to supply and/or administer medication under this PGD must have read, understood and signed it and completed the agreement to practice form before attempting to work according to it
Training	See PGD
Audit	See PGD
Review	*Enter name of clinical lead responsible for reviewing the PGD* Review should be initiated 3 months before the expiry date unless a review is required in response to a change to the medicine(s) covered by this PGD
Equality and Diversity	The Medicine Safety and Governance Group has carried out a Rapid Equality & Diversity Impact Assessment and concluded the document is compliant with the PCT Equality and Diversity Policy. *Enter details of any actions taken*

Standards for Better Health

Domain	How?
Safety	PGD documentation provides consistent approach to patient care This document sets out the information specified in law as that required for a Patient Group Direction.
Clinical and Cost Effectiveness	PGDs are evidence based. They allow the patient to be treated by the most appropriate health professional at the first point of contact.
Governance	PGD ensures standardisation of care. PGDs are a legal requirement for healthcare professionals (who are not independent prescribers) to be able to administer or supply medicines without a prescription. Practitioners working under the PGD must sign up to it and keep the specified records, thus providing an audit trail and accountability.
Patient Focus	Healthcare professionals respond to patients' needs in an appropriate and timely manner. It is specified that all aspects of the patients treatment, including any medicines supplied or administered are discussed with the patient Every patient is treated as an individual
Accessible and Responsive Care	Healthcare professionals respond to patients' needs in an appropriate and timely manner. The documentation allows specified healthcare professionals to supply or administer medicines without a prescription.
Care Environment and Amenities	
Public Health	Health promotion is an integral part of the consultation

1. Staff Authorised to *administer / supply* *(delete as required)* the medicine under the PGD	
Professional qualification	*Enter the Health Professional's qualification (e.g. Registered Nurse) and current role*
Specialist qualifications, training, experience and competence that must be achieved relevant to the clinical conditions and medicines used	*Enter details of specified additional qualifications or training courses required* *Enter details of PGD specific experience, training or competencies required to be undertaken before being authorised to act under **this** PGD and frequency of review/reassessment e.g. attendance at a training session and/or assessment by a senior health professional* In addition all authorised staff must demonstrate an appropriate level of understanding and knowledge with regards to: • Assessment of patient, *diagnosis and treatment of the clinical condition* • The medication, therapeutic use, side-effects, interactions and storage and handling requirements • Have undertaken basic life support and anaphylaxis training and receive annual updates • Be familiar with the relevant PCT medicines policies • The nurse must have read, understood and signed up to this PGD
Continuing Professional Development requirements (CPD)	• All registered professionals are professionally accountable and must work within their competence. • A record of training and competence must be maintained in the individual's personal file. • A signed copy of 'The agreement to practice form for this PGD is kept in the individual's personal file and a copy retained by the clinical lead. • The practitioner should be aware of any changes to the recommendations for the medicines listed and changes to national guidance. • It is the responsibility of the individual to maintain and improve their professional knowledge and skills in this area of practice. *Continued updating of relevant knowledge from current edition of any specific, necessary reference source, e.g. Immunisation against Infectious Disease (Green Book) when appropriate*
Documents to be read in conjunction with this PGD	• Cambridgeshire PCT Patient Group Direction Policy

2.Clinical condition or situation to which this Patient Group Direction applies	
Clinical condition/ situation	*Define the actual clinical condition or situation*
Inclusion criteria	*Use bullet points to list inclusions* • *Who is eligible e.g. age, sex, national/ local guidelines* • *Clinical criteria* • *The patient/client understands and agrees to treatment within the PGD*
Exclusion criteria	*Use bullet points to list exclusions and explain reason where necessary* *Who is not eligible to receive medicine e.g.* • *National/local guidelines* • *Age restrictions* • *Concurrent medical conditions* • *Contra-indications to medicine or exclusions specified in SPC* • *Cautions/concerns requiring medical assessment and advice* • *Concurrent medication or treatments* • *Previous adverse reactions or hypersensitivity reactions to medicine or ingredients* • *Consider pregnancy and breast feeding*
Actions to be taken regarding care of excluded patients	• *Offer alternative treatment where possible* • Refer *or transfer to the appropriate prescriber/service* as soon as appropriate • Discuss with patient/client and document the reasons for exclusion from treatment under the PGD.

Consent	• The proposed treatment including the risks, benefits and side effects must be explained to the patient /client/guardian and verbal consent obtained and recorded in the notes.
Actions for patients who do not wish to receive care under this PGD	• Document refusal in notes. • Seek medical advice if necessary • Refer/transfer to *the appropriate prescriber/ service* if necessary
Reasons for referral or for seeking medical advice	• Exclusions or patient preference as above • If there are any concerns or cautions/interactions relating to the medicine to be given, practitioners should seek medical advice or refer/transfer to the appropriate prescriber/ service if necessary

3. Medicine to be *administered/ supplied* *(delete as required)* under this Patient Group Direction	
Name, strength and form of medicine(s)	*Use BNF style format to express generic name, form and strength e.g. Aspirin soluble tablets 300mg, Amoxicillin Suspension 125mg/5ml*
Legal Status	
▼Black triangle	YES/NO *(delete)* • Black triangle drugs (see BNF) are newly licensed medicines that are closely monitored by the MHRA. All suspected reactions should be reported using yellow cards (see below Adverse Drug Reactions)
PGD covering use outside terms of Summary of Product Characteristics (SPC)?	YES/NO *(delete) (If YES - enter details of specific use outside SPC and reference guidance followed.)* *Note: PGDs must not include **unlicensed** medicine.* If YES, Explain to patient/client that advice differs from patient information leaflet and the reason for this
Route /Method of administration	*In full e.g. oral, inject subcutaneously (Do not use Latin or abbreviations) State practical information such as "after food", "dissolve in water"* *Specify preferred site of injection*
Dose	*Enter dose or dose range in full - if dose is outside SPC see above. Do not use Latin or abbreviations.*
Frequency	*Enter in full. Do not use Latin or abbreviations*
Maximum dose, duration or treatment period	*As per SPC or local/ national guidelines and clinical lead*
Cautions	*As per SPC or local/ national guidelines*
Interactions with other medicines See also any interactions listed as exclusions	*Use bullet points to list important/significant interactions where clinically relevant to this PGD and enter details of action to be taken where appropriate if interacting medicines are to be co-administered/supplied e.g. spacing of EC tablets and antacids or vaccination at different sites.* • See SPC or current BNF Appendix 1
Potential adverse reactions/ side effects	*Use bullet points to list important side effects as common, rare and very rare*
Instructions on identifying and managing Adverse Drug Reactions	• Advise patient on management of the adverse effect • Report any suspected ADR to a medical practitioner as soon as possible if clinically relevant. • Use the Yellow Card System to report adverse drug reactions directly to the Committee on Safety of Medicines (MHRA). Guidance on the use of the Yellow Card System and Yellow Cards are available in the current BNF
Advice to patient/ client	*Enter specific counselling points* *Enter storage and handling information e.g. expiry of eye drops* • Always provide the manufacturers Patient Information Leaflet and any specific local/ national service leaflets • Explain treatment and any further instructions to aid compliance

	• Advise patient to seek medical advice in case of severe or unexpected adverse effects, *or if treatment fails or condition worsens*
Follow up	*Enter any details of follow up required* *Enter details required for transferring or referring patient to another practitioner/service*
Storage and Handling	*Enter specific storage and handling requirements e.g. cool dark place, refrigerator*
Advice on Concurrent Medication (imms &vacs)	*Enter details of other medication commonly given concurrently*

Please note:
Listed above are the interactions with commonly used medicines and the main side effects. If the patient/client is taking a medicine not listed above or reports other possible side effects refer to the current BNF, Patient Information Leaflet or electronic medicines compendium http://www.medicines.org or seek advice from pharmacist or medicines information department.

4. Facilities and supplies that must be available	
Medicine to be stocked	*Enter generic name, form, strength and pack size of medicine to be stocked and whether it is stock for administration only or a pre-pack/ "TTO" pack to be supplied* ***PGD's for supply should also state the points below. If for administration only, please delete.*** • All medicines supplied to take away must meet the EC Labelling and Leaflet Directive. Minimum requirements include: Patient Name, Date, Name and address of clinic and "Keep out of children's reach" • Only original packs may be supplied, medicines must not be decanted into another container or removed from the original pack before supplying. • All medicines must be supplied with the manufacturer's Patient Information Leaflet.
Storage	*Enter storage requirements for department e.g. locked medicine cupboard, monitored medicines refrigerator* *Storage and handling of medicines must comply with the current guidelines and local policy.*
Reporting incidents	• Incidents and near misses must be reported using the Cambridgeshire PCT Incident Reporting form (DATIX) which should be forwarded to the Risk Manager as soon as possible OR via employer's critical incident reporting system.
Other requirements	• Anaphylaxis policy • Immediate access to adrenaline 1:1000 (1mg/1ml) injection • Current BNF • National guidance e.g. Immunisation Against Infectious Disease • Supplies of relevant Patient Information Leaflets • *Any necessary equipment, e.g. syringes (latex free), needles*

5. Records to be kept for audit purposes	
Patient details	• Patient identifiers • Allergies • Any reason for exclusion and action taken • Document patient consent or refusal • Advice sought from medical/specialist service • Details of any adverse reactions experienced by the patient and action taken • Verbal and written advice given to patient • Follow up and referral details
Records of administration *(delete whole row if not administering medicines)*	• Name of Medicine • Administration, date, time, route (including site of injection) and dose administered • Reason for administration • Full name, signature and registration of practitioner supplying treatment or

	record in patient's notes on clinical system • *Record batch numbers and expiry dates where pharmaceutically appropriate, in particular immunisations and vaccinations*
Records of supply *(delete whole row if not supplying medicines)*	• Medicine supplied, dose, route, frequency and quantity • Date and time of supply • Reason for supply • Full name, signature and registration of practitioner supplying treatment
Audit	• Annual audit must be carried out by the clinical lead • *Antibiotic use under PGD must be audited by an external reviewer* • Records of patients who have received treatment under the PGD must be accessible for audit purposes • Regulations require that there is a secure system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and out-goings on a patient-by-patient basis. • Audit may include evidence of authorised practitioners signatures, appropriate supply, standards of documentation, follow up arrangements, advice and information given to patients, reporting of adverse effects and incidents.

6. References

Enter full reference, include BNF, SPC, local and national guidelines, journals and other references

- http://emc.medicines.org.uk/ Summary of Product Characteristics *Medicine, Manufacturer, Date of revision, Date accessed*
- Mehta DK Ed. British National Formulary *Number ….., Date*, BMA and RPSGB Pharmaceutical Press
- HSC 2000/026, 9th August 2000 Patient Group Directions (England)

7. Authorisation

Individuals working under this patient group direction

NAME	DESIGNATION/TITLE	SIGNATURE	Date

Each registered practitioner authorised to supply and/or administer medication under this PGD must have read, understood and signed this version of the PGD and completed the agreement to practice form before attempting to work according to it

AGREEMENT BY HEALTH PROFESSIONAL TO ACT UNDER THE PATIENT GROUP DIRECTION

I have read and fully understand the following documents:

1. The Patient Group Direction:
2. Dated: ……Expiry date: ……..
3. BNF and SPC monographs for all drugs included in this PGD.
4. The Cambridgeshire PCT Patient Group Direction Policy

I agree to act within the terms of the Patient Group Direction and administer and/or supply medicines in accordance with the documents listed above.

I understand that my employer e.g. GP practice or Cambridgeshire PCT, is vicariously liable for acts and omissions by me during my employment with them.

I understand that failure to comply with the terms and conditions of the PGD, including the expiry date and limitations on practitioners, patients, drugs and indications may render me liable to disciplinary action by my employer e.g. GP practice or PCT under their performance and conduct arrangements.

NAME: *(block capitals)* ..... (Health Professional)

SIGNATURE: ..... (Health Professional)

POSITION: .....

EMPLOYER: .....

SITE/PRACTICE: .....

DATE SIGNED: .....

The original must be filed in the health professional's personal file and a copy held by their manager or employer for the purposes of ensuring practice occurs only in accordance with the PGD and is only undertaken by approved practitioners.

Appendix 3 - Glossary

Administer	To give a medicine either by introduction into the body, whether by direct contact with the body or not, (e.g. orally or by injection) or by external application (e.g. application of an impregnated dressing) [q.v. “administer” in section 130 Medicines Act 1968].
Authorised Practitioner	A healthcare professional who has been given authorisation to work under a PGD
Black Triangle Drugs ▼	Newly introduced drugs, still subject to special monitoring for potential side effects by the Medicines and Healthcare products Regulatory Agency (MHRA) (so called because they are identified by a black triangle symbol in the British National Formulary).
Clinical Assessment	Assessment of a patient’s conditions leading, in consultation with the patient, to a decision on treatment and/or on further diagnostic tests and/or on referral to another clinician.
Clinical Guideline	A summary of best clinical practice for a particular condition or disease area.
Clinical Responsibility	Accountability for a particular aspect of the clinical assessment or management of a patient’s condition.
Controlled Drugs	Narcotic drugs or other drugs liable to misuse, which are subject to special controls under the Misuse of drugs Act 1971.
Dispense*	To make up or give out a clinically appropriate medicine to a patient for self-administration or administration by another, often another professional. In the case of prescription only (POM) medicines, dispensing must be in response to a legally valid prescription. The act of dispensing is combined with advice on safe and effective use.
General Sales List (GSL) Medicine	A medicinal product which can be sold or supplied direct to the public in an unopened manufacturer’s pack from any lockable business premises. Such products are listed in the Medicines (Products Other than Veterinary Drugs) (General Sales List) Order 1984.
Licensed Indication	Treatment purpose for which a product may be used under the terms of the marketing authorisation granted by the Licensing Authority.
Licensed Medicine	A medicine which falls within the definition of a medicinal product and which is granted a marketing authorisation by the Licensing Authority when the safety, quality and efficacy of the product have been satisfactorily demonstrated by the License Holder (holder of marketing authorisation) in accordance with EC Directives 65/65.
Medicinal Product	Any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances, which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product (Article 1.2 EC Directive 65/65).

Glossary continued

Over the Counter (OTC) Medicines	Medicines legally classified P (Pharmacy) or GSL (General Sales List).
Patient Group Direction	Specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by doctors, pharmacists and other appropriate professionals, and authorised by the employer, advised by the relevant professional advisory committees. It applies to groups of patients or other service users who may not be individually identified before presentation for treatment.
Patient Specific Direction	**A patient specific direction** is used once a **patient has been assessed by a prescriber** and that prescriber, (doctor, dentist or supplementary/independent prescriber) supplies or administers, or instructs another health care professional in writing to supply or administer a medicine directly to that named patient or to several named patients (e.g. patients on a clinic list). NB: Independent non-medical prescribers may NOT prescribe or issue Patient Specific Directions for unlicensed medicines.
Pharmacy (P) Medicine	Any medicinal product other than those designated as GSL or POM products. Pharmacy medicines can be sold or supplied only from a registered pharmacy by or under the supervision of a pharmacist, subject to certain exceptions (e.g. where the sale or supply is in the course of business of a hospital as defined in the Medicines Act 1968 or health centre as defined in the NHS Act 1977 and related legislation).
Prescribe	To authorise in writing the supply or administration of a medicine (usually, but not necessarily, a prescription-only medicine) for a named patient
Prescription Only Medicine (POM)	A medicinal product which may only be sold or supplied against the signed prescription of an appropriate practitioner i.e. doctors, dentists and certain nurses (in respect of a specified list of POMs) specified in the prescription Only medicines (Human Use) order 1997. POMs may also be supplied or administered under a Patient Group Direction.
Supply*	To provide a medicine directly to a patient or carer for administration.
Treatment	Broadly, the management and care of a patient to prevent or cure disease or ameliorate suffering and disability or a substance or method used in treating a patient.
Unlicensed Medicine	A medicinal product which does not have a UK marketing authorisation
*	There is no legal distinction between “dispense” and “supply” although there are considerable differences in practice. The act of dispensing includes supply and also encompasses a number of other cognitive functions (e.g. checking the validity of the prescription, the appropriateness of the medicines for an individual patient, assembly of the product). In common usage “dispense” is usually reserved to the activity of pharmacists and “supply” can be used to describe that of other healthcare professionals e.g. nurses.

Appendix 4 – DtGP Ratification Checklist

DtGP APPROVAL CHECKLIST

This form should be completed by the Approval Group.
This should then be forwarded to the Clinical Audit & Effectiveness Team before the DtGP is accepted for review by the Policy Ratification Group.

Title of Document _____

_____

Date of Check _____

	Yes	No	N/A	Comments
1. Basic Details				
Is the title clear and unambiguous?				
Is it clear if it is a guideline, policy, protocol or procedure?				
Is the authorship clear?				
Is the document clearly dated?				
Is the document control sheet complete?				
2. Rationale				
Are reasons for developing the document clearly stated?				
3. Development Process				
Is the method described in brief?				
Are the people involved in the development identified?				
Were all relevant parties involved in the development?				
Is document county-wide? [if not state why area specific]				
Is there evidence of consultation with stakeholders and users – if appropriate?				
4. Content				
Is the objective of the document clearly stated?				
Is the scope identified e.g. patients and/or staff?				
Are the intended outcomes described?				
Is the guidance clear, relevant and unambiguous?				
Has a Rapid Equality and Diversity Impact Assessment been completed and returned to the Clinical Audit & Effectiveness Team?				

	Yes	No	N/A	Comments
5. Evidence Base				
Is evidence to support the document identified?				
Are key references given?				
Are links with SFBH and national guidance given?				
Are appendices relevant?				
6. Summary of Guidance				
Is there a quick reference guide, key recommendations or flowchart summarising the document – if appropriate?				
7. Format				
Is the document in an easily readable font?				
Is there an appropriate header or footer on each page?				
Is it easy to find sections within the document?				
8. Dissemination and Implementation				
Is there a dissemination list?				
Is there an implementation plan, including training and audit?				
9. Approval				
Does it identify the clinical or professional group that has approved this DtGP prior to submission to the PRG?				
10. Review				
Is the date of review stated?				

Clinical Audit & Effectiveness Team Decision	✓
DtGP not in accepted format – **return to author**	
Impact assessment not received – **request from author**	
DtGP in accepted format and all 'Yes' or 'N/A' responses – **add to PRG agenda**	
At least one 'No' response – **refer to Senior Clinical Audit & Effectiveness Manager**	
Senior Clinical Audit & Effectiveness Manager - **action and decision**	