ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

PROCEDURE FOR DEVELOPMENT, REVIEW AND UPDATING OF PATIENT GROUP DIRECTIONS

1. INTRODUCTION

1.1. The preferred way for patients to receive the medicines they need is for a prescriber (Doctor, dentist or non-medical prescriber) to issue a prescription for a medicine for an individual patient. That prescription would then be dispensed by a pharmacist or dispensing doctor and the medicine issued to the patient.

1.2. Following the Crown Report (Review of prescribing, supply and administration of medicines) in 1999, Legal frameworks were developed that have allowed services to be redesigned and health professionals to work more flexibly for the benefit of patients. As a result of these changes, there are now several legal options for supplying and/or administering medicines, one of which is the use of Patient Group Directions (PGDs). Legislation establishing PGDs was introduced in 2000 and the Health Service Circular (HSC 2000/026) provided additional guidance. The current legislation for PGDs is included in The Human Medicines Regulations 2012 (amended 2013)

1.3. *PGDs provide a legal* framework that allows specified categories of registered health professionals to supply and/or administer a specified medicine(s) to a pre-defined group of patients, without them having to see a prescriber. However, supplying and/or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care, without compromising patient safety.

1.4. In August 2013 NICE produced guidance on the production, implementation and use of Patient Group Directions (NICE medicines practice guidelines: Patient Group Directions [MPG2}, August 2013). The purpose of this protocol is to ensure that the production and use of PGDs within the Trust complies with NICE MPG2 recommendations.

2. SCOPE

2.1. This procedure describes the processes required for the development, review, authorisation, and monitoring of new and existing PGDs. It also describes the competencies required of the people involved in the development and review of PGDs, the authorisation of PGDs and the healthcare professionals working under PGDs, within the Trust. It applies to all healthcare professionals developing and reviewing PGDs, all registered healthcare professionals working under PGDs, and all managers considering the need for PGDs when looking at service redesign, or the introduction of new services.

3. DEFINITION OF A PGD

3.1. A PGD is defined as 'Written instructions for the supply or administration of medicines to groups of patients who may or may not be individually identified before presentation for treatment.' This means that patients may either be known to a service, e.g. a list of children provided to an immunisation clinic for vaccination, or may not be known before they arrive, e.g. patients turning up at a no-appointment walk-in centre.

3.2. A PGD is NOT a form of prescribing

4. ASSESSING THE NEED FOR NEW PGDS

4.1. Approval from the Medicines Management Group must be obtained before any PGD can be developed, unless the PGD is necessary in order to provide a national service e.g. National Immunisation Programme.

4.2. A PGD Working Group consisting of a lead author, supported by a doctor (or dentist), a pharmacist and a representative of any other professional group who will practise under the PGD must be convened to develop the PGD proposal at service/ directorate level and make an initial assessment and recommendation to the Medicines Management Group. The proposal must demonstrate that:

- A PGD is the most appropriate method to supply and/or administer the medicine.
- Treatment cannot be delivered on an individual named basis either by prescription or Patient Specific Direction
- The PGD is a legal method for supply and/or administration of the medicine in the proposed care setting

4.3. The PGD Working Group will use the national PGD website tools to consider whether a PGD is necessary or appropriate. E.g. “To PGD or Not to PGD” (Annex 3) They will ensure that the health professional group being considered to practice under the PGD can legally do so, and also consider other options e.g. exemptions in legislation which may allow medicine supply and/or administration without the need for a PGD. The Group will consider the following:

- There must be a UK marketing authorisation for the medicine, in line with legislation.
- If the use is Off-label of a licensed medicine, it must be clearly justified by best clinical practice. (e.g. The Green Book recommendations for immunisation)
- Off-label use must have Trust approval. Refer to CLPG13 for further information
- Black triangle medicines should only be included in a PGD when clearly justified by best clinical practice.

- A controlled drug will only be included in a PGD when legally permitted and clearly justified by best clinical practice. The Trust CD Accountable Officer must be aware and agree in principle with the PGD Proposal
- Dose adjustments to a medicine supplied under a PGD cannot be made when the medicine is already in the patient's possession.
- A PGD should not normally include more than one medicine. The risks and benefits should be considered on a case-by-case basis.
- A PGD should not be used for managing long-term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis.
- The appropriate consultation with antimicrobial experts has taken place if the PGD is for an antimicrobial medicine.
- A PGD should not include a medicine needing frequent dosage adjustments or frequent or complex monitoring (for example, anticoagulants or insulin)
- If the medicine is to be supplied to a patient rather than administered, the availability and cost of prepacks.
- How and where the medicine will be stored

4.4. The PGD Working Group will submit the PGD Proposal using the PGD Proforma and Checklist (Annex1) to the MMG for approval once they are satisfied that the necessary criteria have been met and there is sufficient information to support the proposal.

4.5. The Medicines Management Group will consider the following in relation to the PGD Proposal:

- all legal requirements have been met
- robust local processes and clear governance arrangements are in place
- the risks and benefits of all options for supplying and/or administering the
- medicine(s) have been explored
- the PGD will deliver effective patient care that is appropriate in a pre-defined clinical situation, without compromising patient safety
- the views of stakeholders, such as clinical groups, patients and the public, and the commissioning organisation have been considered
- appropriate registered health professionals are available to use the PGD, and training and competency needs are addressed
- people who are developing, authorising, monitoring, reviewing and updating the PGD are identified, and their training and competency needs are addressed
- the need for appropriately labelled packs and safe storage can be met
- adequate resources, such as finance, training, medicines procurement and

- diagnostic equipment are available for service delivery
- adequate resources are available to ensure that processes are followed within any locally agreed timeframe
- decisions are aligned with local clinical commissioning frameworks.

5. DEVELOPING PGDS

5.1. Development of a PGD should not proceed until the Medicines Management Group has formally agreed that a PGD is needed.

5.2. The PGD will be developed by the PGD Working Group.

5.3. A named lead author as identified on the approved PGD Proposal has responsibility for developing a PGD, supported by the PGD working group, as specified in the approved PGD Proposal.

5.4. The lead author must not work in isolation. Members of the PGD working group should be regularly involved at each stage of the process.

5.5. The Working Group may communicate “virtually” rather than face-to-face.

5.6. When developing a PGD that includes an antimicrobial medicine, the Working Group must liaise with a local specialist in microbiology. Where the PGD is intended for use in more than one locality, the specialists for each locality must be consulted.

5.7. The Working Group must seek views on draft PGDs and agree final draft PGDs with relevant stakeholders, including clinicians and local medicines decision-making groups where applicable.

5.8. The Trust PGD Template (see Annex 2) must be used to write the PGD.

5.9. PGDs must be consistent with the relevant Summary of Product Characteristics (SPC), unless the medicine is being used off-label or relevant national guidance is being followed.

5.10. Where a medicine is to be used off-label, this must be clearly stated in the relevant section of the PGD. The best available up to date evidence must be used, such as NICE guidance and other sources of high-quality information when developing PGDs. References must be listed.

5.11. A senior responsible person who will authorise named registered health professionals to work under the PGD should be made known to the Working Group.

6. REVIEWING AND UPDATING PGDS

6.1. A structured work programme for reviewing, updating and re-authorising PGDs must be in place and regularly reviewed. PGDs should normally be scheduled to be reviewed and updated within 6 months of their expiry date.

Drug Details	
Name, form & strength of medicine	*References include: BNF/SPC/ Medicines for Children* *Use clear format to express strength and form e.g. BNF style: Amoxicillin Capsules 250 mg; Amoxicillin Suspension 250mg in 5mL*
Use outside of the terms of the Marketing Authorisation (i.e. unlicensed use)	
Storage requirements	*e.g. temperature restrictions e.g. 2-8C; protect from light etc.*
Route/Method	*References: BNF/SPC /Medicines for Children* *To avoid errors, state in full and do not use abbreviations e.g. oral not p.o.*
Dosage	*References: BNF/SPC/Medicines for Children* *Are dosages licensed – need to add reference / note to support use in unlicensed / off-label circumstances.* *Decide on format to express dosage, especially in children – will it be on weight-adjusted basis or would doses be rounded up to the nearest spoonful etc. Liaise with Community Health Services Pharmacy Lead on practical issues relating to dosage and quantity to supply.* *State in full and do not use abbreviations e.g. Take one capsule three times a day not 1 tds.*
Frequency	*References: BNF/SPC/ local and guidelines/ Medicines for Children*
Maximum or minimum treatment period	*State duration of treatment if applicable*
Quantity to supply/administer	*Depends on above i.e. dosage, frequency and duration.*
Side effects	*Useful references: SPC/BNF/Meyler/Medicines for Children.* *List common side effects and may need to refer to other sources for full details. Advisable to warn about potential adverse effects e.g. any CSM advice.*
Advice to patient/carer	• Manufacturer's Patient Information Leaflet • Any further instructions to aid compliance • Storage or expiry details • Practical advice on self-care if appropriate • Advice on recognising side effects and what to do • Advice on where to seek help if treatment fails or condition worsens
Audit Trail	
Records/audit trail	• *Patient's name, hospital unit number, date of birth* • *Diagnosis*

	☐ Can critically appraise and apply information in practice
The NHS in context	☐ Understands, and works with, local and national policies and services that impact on PGD use.
The team and individual context	☐ Works in partnership with colleagues for the benefit of patients. Is self-aware and confident in own ability to use PGDs

COMPETENCY APPROVAL AND INDIVIDUAL AUTHORISATION OF PRACTITIONER TO USE PGD

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Note to Authorising Managers: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation

Registered Healthcare Practitioner

I confirm that I:

- have read and understand this PGD
- am of the opinion I am competent to use this PGD effectively
- agree to supply and administer the medicine only in accordance with this PGD

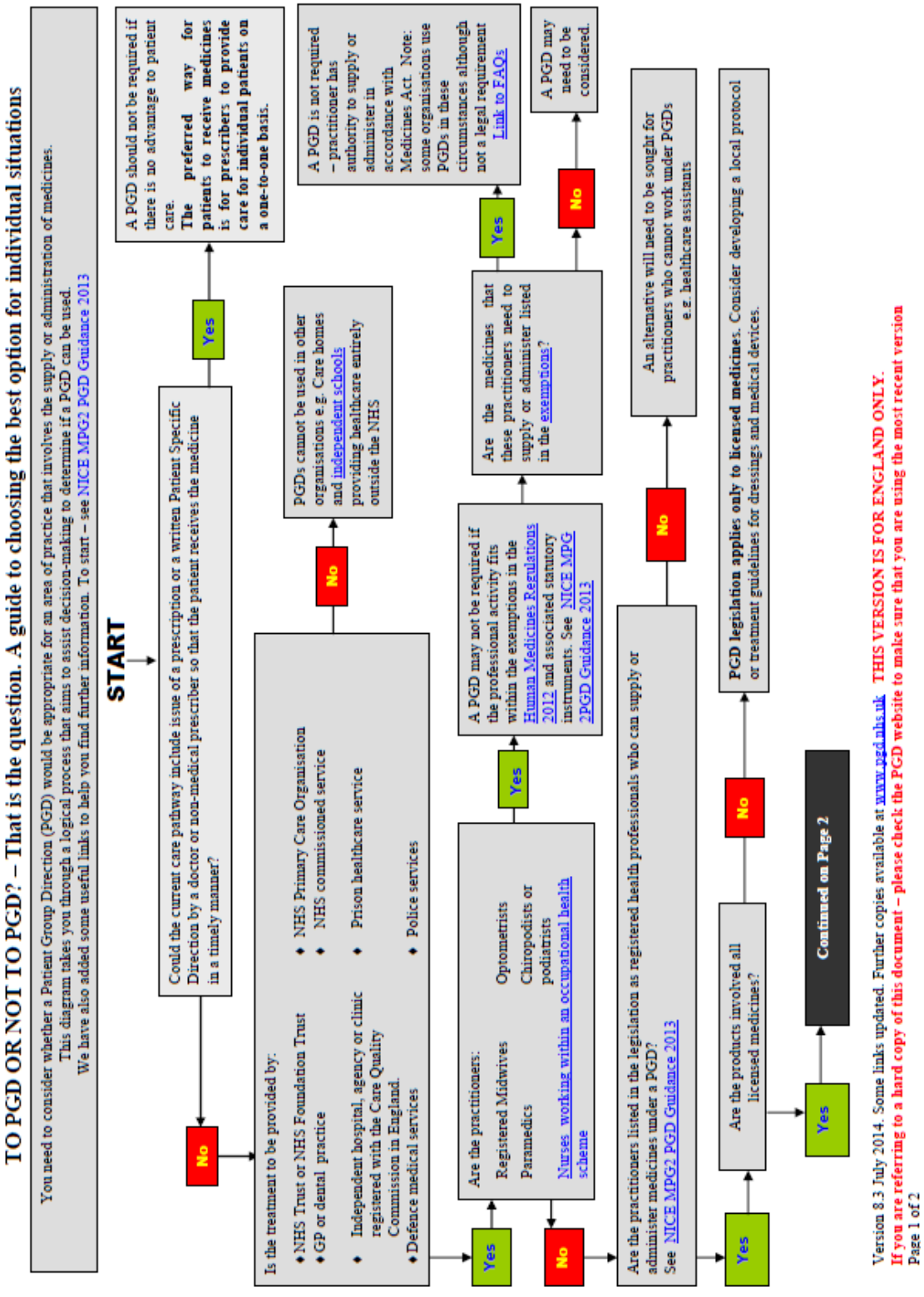
Name:	
Signature:	
Position:	
Date:	

Senior Clinician/manager authorising this PGD

The above-named practitioner is competent in all areas listed in the Competency Checklist, has achieved all the specialist competencies and qualifications required, and is authorised to use this PGD.

Name:	
Signature:	
Position:	
Date:	

Annex 3


TO PGD OR NOT TO PGD? – That is the question. A guide to choosing the best option for individual situations
You need to consider whether a Patient Group Direction (PGD) would be appropriate for an area of practice that involves the supply or administration of medicines.
This diagram takes you through a logical process that aims to assist decision-making to determine if a PGD can be used.
We have also added some useful links to help you find further information. To start – see NICE MPG2 PGD Guidance 2013
START
Could the current care pathway include issue of a prescription or a written Patient Specific Direction by a doctor or non-medical prescriber so that the patient receives the medicine in a timely manner?
Yes
A PGD should not be required if there is no advantage to patient care.
The preferred way for patients to receive medicines is for prescribers to provide care for individual patients on a one-to-one basis.
No
Is the treatment to be provided by:
NHS Trust or NHS Foundation Trust
GP or dental practice
Independent hospital, agency or clinic registered with the Care Quality Commission in England.
Defence medical services
NHS Primary Care Organisation
NHS commissioned service
Prison healthcare service
Police services
No
PGDs cannot be used in other organisations e.g. Care homes and independent schools providing healthcare entirely outside the NHS
Yes
Are the practitioners:
Registered Midwives
Paramedics
Optometrists
Chiropodists or podiatrists
Nurses working within an occupational health scheme
Yes
A PGD may not be required if the professional activity fits within the exemptions in the Human Medicines Regulations 2012 and associated statutory instruments. See NICE MPG 2PGD Guidance 2013
Yes
Are the medicines that these practitioners need to supply or administer listed in the exemptions?
Yes
A PGD is not required – practitioner has authority to supply or administer in accordance with Medicines Act. Note: some organisations use PGDs in these circumstances although not a legal requirement Link to FAQs
No
A PGD may need to be considered.
No
Are the practitioners listed in the legislation as registered health professionals who can supply or administer medicines under a PGD?
See NICE MPG2 PGD Guidance 2013
No
An alternative will need to be sought for practitioners who cannot work under PGDs e.g. healthcare assistants
Yes
Are the products involved all licensed medicines?
No
PGD legislation applies only to licensed medicines. Consider developing a local protocol or treatment guidelines for dressings and medical devices.
Yes
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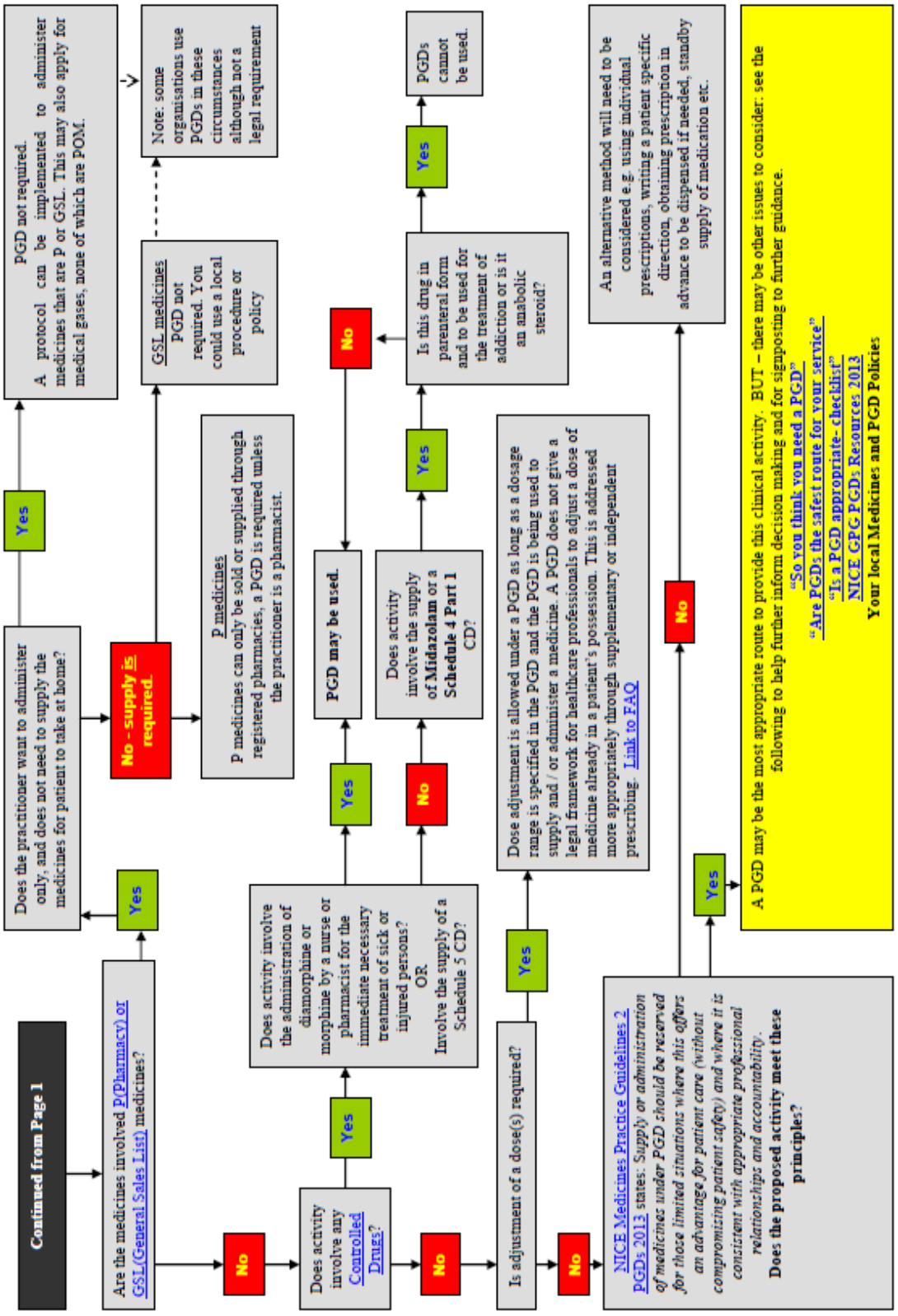

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