An overview of Patient Group Directions (PGDs)

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Patient Group Directions
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The first stop for professional medicines advice

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Scope of SPS PGD service…where have you come from?

Commissioners (England)
- NHS England
- CCGs
- Local authorities

Providers (England)
- NHS organisations
- Non-NHS organisations providing public health or NHS-commissioned services

Arrangements vary:
- Local organisational structures
- How services are commissioned or provided
- What resources are available
Background to PGDs

1999

2000
Changes in legislation
PGDs established

2000
Health Service Circular (2000/026)

2002/3
Supplementary prescribing

2006
Independent prescribing

2012
The Human Medicines Regulations

2012
Health and Social Care Act

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Background

• Health and Social Care Act – 2012
• Human Medicines Regulations - 2012
• NHS reorganisation – April 2013
  – New organisations
  – New responsibilities
  – New governance structures
• NICE Medicines Practice Guidelines 2 2017
• CD legislation changes (November 2015)
• 5 Year Forward and Carter Report
What is a PGD?
But firstly what is a Patient Specific Direction (PSD)?

- A Patient Specific Direction (PSD) is the traditional written instruction, signed by a doctor, dentist, or non-medical prescriber for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis.
- Where a Patient Specific Direction exists, there is no need for a Patient Group Direction.
- In practice, a PSD is commonly referred to as a prescription by those who write and follow them because this indicates that it is written by a prescriber.
What is a PGD?

‘Written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.’

*(Health Service Circular (HSC 2000/026)*

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Who may act to supply and/or administer under PGD?

- only those qualified and registered health professionals listed in PGD legislation
- an individual health professional must be named and authorised to practice under each PGD
- the named, authorised health care professional working within the PGD is responsible for assessing that the patient fits the criteria set out in the PGD.
Who can supply or administer under a PGD

- chiropodists and podiatrists
- dental hygienists
- dental therapists
- dieticians
- midwives
- nurses
- occupational therapists
- optometrists
- orthoptists
- orthotists and prosthethists
- paramedics
- pharmacists
- physiotherapists
- radiographers
- speech and language therapists

2019…ODPs, clinical scientists, biomedical scientists….
Caution with professions listed v job title

As an example:

• PGD cannot refer to “Emergency Care Practitioner (ECP)” to cover a range of professionals employed in this role - ECP is not a protected title and is not within the PGD legislation.

• PGD must refer to those registered professionals who have the role of an ECPs e.g. registered nurse, registered paramedic.

• Employer must assure themselves that the person is currently registered and has declared that they are competent to carry out the provisions of the PGD.
Intention of PGD use

• The majority of clinical care should be provided on an individual, patient-specific basis

• PGDs should be reserved for those limited situations where this offers an advantage for patient care without compromising patient safety

• Use must be consistent with the law and professional accountability
A PGD is not a form of prescribing

- Patient must exactly fit the inclusion criteria in the PGD and not be excluded under criteria for exclusion

Prescribing is an all you can eat buffet       A PGD is a restricted set menu

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‘Patients who may not be individually identified before presentation for treatment’

The intended meaning is that patients may/or may not be identified, depending on the circumstances.

- May not be identified: Urgent Care, immunisation clinics

- May be identified: repeat supply of contraception where patients may be known to the service from a previous episode of care.
Established uses of PGDs

Use of PGDs is well established in services where assessment and treatment follows a clearly predictable pattern e.g.

- NHS immunisation clinics
- contraception and sexual health services
- Urgent care centres/minor injury units

But – always review the need....
Considering the need for a PGD

This applies whether this is a new service/new PGD or a review of an existing PGD:

• Is a PGD the best way of delivering the service?
• Is it legal?
• Is a PGD necessary?
• Is a PGD appropriate?
• Discuss and agree the need with a multi-disciplinary team
• Always remember individual patient basis preferred
Is using a PGD the best way to deliver the service?

Apply medicines optimisation principles
Is a PGD legal?

PGDs must only include medicines with a UK marketing authorisation (can be off label use and includes black triangle medicines)

Some restrictions on what can be included in a PGD

Controlled drug restrictions

Other legal requirements also apply to PGDs:

- labelling of medicines
- provision of a manufacturer’s patient information leaflet
- prescription charges and exemptions
Controlled Drugs and PGDs

Currently, the following controlled drugs can be included in PGDs:

- **Schedule 2**: Morphine and diamorphine (only registered nurses and pharmacists for the immediate necessary treatment of a sick or injured person (except for treating addiction)).
- **Schedule 2**: Ketamine
- **Schedule 3**: Midazolam
- **Schedule 4**: All drugs except anabolic steroids and injectables used for treating addiction.
- **Schedule 5**: All drugs.
PGDs cannot be used

- where there is delegation of responsibility to supply or administer the medicine
- when 2 or more injections are mixed together as this results in an unlicensed medicine
- Unlicensed medications
- Supply or administration of radiopharmaceuticals (Administration of Radioactive Substances) Regulations 1978
- Supply or administration of dressings and medical devices
- Supply or administer abortifacients (Abortion Act 1967)
- As part of training
Delegation

Supply and/or administration of the medicine cannot be delegated when working under a PGD. However....

• A PGD for an injectable must be supplied AND administered by the practitioner or supplied to patient for self administration only.

• A PGD for a non-injectable CAN be supplied by the practitioner for another person to administer to the person but this is NOT delegation if the PGD is only for supply.

• Advice different for prison services.
Is a PGD necessary?

- Consider and identify any opportunities in the care pathway for the medicine to be safely prescribed on an individual basis including prescribing by doctors, dentists or non-medical prescribers.
- Consider all the potential methods of supply and/or administration of medicines
- Consider and address inefficiencies in the care pathway if prescribers are not writing prescriptions in a timely manner.
Is a PGD necessary?

Human Medicines Regulations exemptions:

• Exemptions for paramedics, midwives, orthoptists and podiatrists. These exemptions allow these registered health professionals to administer or supply certain specified medicines within their scope of practice and competency without the directions of a doctor.

• Exemptions for administration of certain parenteral medicines by anyone for the purpose of saving life in an emergency e.g. adrenaline.

• Occupational Health Schemes

• Naloxone supply by Drug Treatment Services
When is a PGD not necessary?

- GSL medicines to be supplied or administered.
- P medicines to be administered (or supplied if from a registered pharmacy premises)
- Medical gases
Is a PGD appropriate?

- PGDs should not be used for managing long-term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis.
- PGDs should not be used for supply of medicines needing frequent dosage adjustments or frequent or complex monitoring.
- PGDs should not be used to make dose adjustments when the medicine is already in the patient's possession.
PGDs for antimicrobials

NICE MPG2 PGDs states: *in most circumstances, PGDs for antimicrobials are not appropriate*

Antimicrobials should be included in a PGD only when:

- clinically essential and clearly justified by best clinical practice, such as Public Health England guidance
- a **local specialist in microbiology** has agreed that a PGD is needed and this is clearly documented
- use of the PGD is monitored and reviewed regularly
Can more than one medicine be in a PGD?

- Local decision – what is safe and appropriate?
- Carefully consider the risks and benefits of including more than one medicine in a PGD on a case-by-case basis.
- Ensure all legal requirements are met for each medicine.
- If the PGD is for the same medicine but more than one indication or more than one preparation – again needs careful consideration.
- If difficult to write – it may be difficult to follow and possibly unsafe.
Expiry Dates

• NICE states:

  *Determine the expiry date for an individual PGD on a case-by-case basis, with patient safety paramount. Ensure that this date does not exceed 3 years from the date the PGD was authorised.*

• It is not acceptable or legal for an individual practitioner to decide to use a PGD that has expired.

• Within lifetime of a PGD changes may be required in cases of changes to SPC, supporting guidance etc. The PGD working group should make these changes as identified. All amendments require a PGD to be re-authorised.
Extending an expiry date of a PGD

- This should be exceptional practice e.g. during organisational or service transition and should be for an agreed and limited period of no longer than one year.
- Extension of expiry dates without review of a PGD is not without risk (e.g. license of medicine may have changed/national guidance may have changed).
- There may be a risk where withdrawing the PGD could result in significant service disruption and potential patient safety issues due to lack of access to medicines.
- If a period of extension is agreed, then this should be formally noted by the organisation alongside an agreed plan of action with timescales for review and re-approval of the PGD.
Developing, authorising and reviewing PGDS
Development of PGDs

- PGDs should be drawn up by a multi-disciplinary group involving a doctor, pharmacist and a representative of any professional group expected to supply medicines under the PGD (‘PGD working group’)
- Collaborate with stakeholders
- Consistent presentation
- Must contain legally required information
- Must be written against best available evidence
What a PGD must include

- the name of the organisation who owns the PGD
- the start and end date of the PGD
- a description of the medicine(s)
- the class of the health professional who can supply or administer the medicine
- a signature of a doctor or dentist (as appropriate) and a pharmacist
- authorisation by an appropriate organisation
- the clinical condition or situation to which the direction applies
- a description of patients excluded from treatment under the direction
- a description of when you should get more advice from a doctor/dentist
- arrangements for referral
- details of appropriate dosage, maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, minimum/maximum period to administer the medicine
- relevant warnings, including potential adverse reactions
- details of any necessary follow-up actions
- a statement of the records to be kept for audit purposes
Signatories for development of PGDs

- PGD must be signed by a senior doctor (or dentist) and a senior pharmacist
- PGD should be signed by a representative of any professional group expected to supply medicines under the PGD
- No limit of number of signatories (i.e. if several services work under PGD a professional representative from each service can sign)
Which bodies can authorise PGDs?

Those organisations listed in the legislation as able to authorise a PGD in England are:

- clinical commissioning groups (CCGs)
- local authorities
- NHS trusts or NHS foundation trusts
- Special health authorities
- NHS England
- Public Health England

An authorised signatory from the organisation must sign the PGD.
Unintended consequences of legislation

- Human Medicines Regulations 2012 resulted in PGDs for non-NHS providers (e.g. independent medical agencies) commissioned by NHS or public health commissioned services must be authorised by the relevant authorising body i.e. commissioner of the service.

- Be aware of this if you are commissioning services from an IHP or are a IHP being commissioned for a service using PGDs.

Complexities of arrangements....

- NHS and non-NHS provider arrangements are becoming increasingly complex and varied and sub-contracting/partnership working becoming more common.

- Increasingly **local decisions** will have to be made based on the ‘set ups’ in place and considered on a case by case basis when determining who authorises a PGD.

- Memorandums of Understanding need to be drawn up where multiple providers/commissioners are involved in services using PGDs.

- Clear line of sight required and understanding by all parties involved.
Reviewing PGDs

- Locally agreed process for reviewing PGDs.
- Full review of PGD required – don’t just change dates.
- Take this opportunity to review if a PGD is still required.
- Time consuming process so ensure plenty of time and adequate resources available.
- Engage all stakeholders.
- Ensure review well in advance of expiry/review date to prevent overrunning leading to PGD expiry.
- If a PGD expires consider the risks of extending a PGD versus withdrawing it from use.
Signatures

- Signatures on PGDs can be electronic – they do not need to be handwritten.
- If added by hand or using scanned/electronic signatures any final copies must prevent these being lifted.
- Alternatively electronic agreement can be used – particularly useful if cross organisational.
- Ensure an auditable trail is in place if electronic agreements used.
Other things to consider

- Need for robust and transparent processes
- Clear lines of accountability and governance e.g. formal agreements where more than one organisation is involved in the development and authorisation of PGDs (e.g. Memorandum of Understanding)
- Planning - workload and resources needed to review a large number of PGDs can be significant
Other things to consider

- Medicines management systems:
  - Labelling and packaging – associated costs for over labelling (including unnecessary over labelling)
  - Patient information leaflets
  - Prescription charges
  - Documentation
- Drugs with associated Risk Minimisation Materials (RMM)
- Local medicines policy/professional standards
- Training and competency of everyone involved
- Implementation including audit (more later today)
Developing challenges

• New models of care
• New organisational structures
• Joint commissioning arrangements
• Sub-contracting arrangements
• Transition of services after tendering – managing PGDs during and after change
• Carter Report/Carter 2 – reducing replication of work with ‘Do once and share’ principle
Remember

• Do not work in isolation - engagement is key
• Engage stakeholders/commissioners at an early stage
• Challenge the need for PGDs – they are not meant to be used to address inefficiencies in systems. Consider longer term solutions too such as need to train non medical prescribers.
• Have a step-wise approach……writing a PGD is not the first step!
Quality PGDs – 7 steps to success

1. **Step 1**: Think about finding the safest route for patients to receive their medicines within the service or pathway
2. **Step 2**: Think about the process, the people to involve and the medicine
3. **Step 3**: Getting ready to write the PGD
4. **Step 4**: Writing and agreeing the PGD for submission
5. **Step 5**: Authorising the PGD
6. **Step 6**: Getting ready to use the PGD
7. **Step 7**: Monitoring and reviewing the PGD in practice
Tools and resources

**Specialist Pharmacy Services PGD resources** – Q&As, decision tools, support documents, quality assured examples of PGDs, policies, audit tools

**NICE MPG2 PGDs** – guidance and support on PGD processes

**NICE Resources** – implementation tools, competency frameworks, case studies

**PGD e learning** – CPPE programme available not just for pharmacists but all staff involved in PGDs.