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Getting started with development and implementation of Patient Group Directions

June 2021

The first stop for professional medicines advice

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Outline of today's webinar

- Overview of PGDs
- SPS Medicines Governance Do Once Programme – national PGD templates
- Real life scenarios – PGD use in practice
- SPS website and PGD resources
- Questions – session on 30th June

An overview of Patient Group Directions (PGDs)

Jo Jenkins
Specialist Pharmacist SPS MUS
Patient Group Directions

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Before we start – what is a Patient Specific Direction (PSD)?

Take two minutes to think about this and jot down your ideas before we move on

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What is a 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.

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What is a PGD?

Again take two minutes to think about this and jot down your ideas before we move on

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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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Background to PGDs

1999 Final Crown Report

2000 Changes in legislation PGDs established

2002/3 Supplementary prescribing

2006 Independent prescribing

2008 Health and Social Care Act

2012 The Human Medicines Regulations

2020 The Human Medicines Regulations amendments due to pandemic

What has recently changed in the legislation?

- Oct 2020 The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020
- Dec 2020 The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020
- Both amend the Human Medicines Regulations 2012
- Some cease to have effect on 1 April 2022 – HMR 2012 review due

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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.

Quick quiz

Who can work under a PGD?

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Who can supply or administer under a PGD

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

2021/22…ODPs, clinical scientists, biomedical scientists….

20??…Physician Associates/ Nursing Associates/Pharmacy Technicians….

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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.

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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

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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.

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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
- Reproductive and sexual health services
- Urgent Care Centres/Minor Injury Units
- Ambulance services

Considering the need for a PGD

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

- Is a PGD necessary for or the best way of delivering a service? Are there opportunities within the pathway to prescribe? Have more NMPs been trained/employed since PGD last reviewed?
- Is a PGD legal?
- Is a PGD appropriate?
- **PGDs should not be used to address inefficiencies within a service.**

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Is a PGD legal?

- PGDs must only include medicines with a UK marketing authorisation but can include off label use and black triangle medicines. **2020 legislation change to include Reg.174 authorised 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

Quick quiz

Which medicines could be supplied/administered under a PGD?

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PGDs cannot be used

- Where there is delegation of responsibility to supply or administer the medicine
- When 2 or more licensed medicines 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

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When should PGDs not be used?

- 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 individual's possession.

When is a PGD not necessary?

NICE Medicines Practice Guideline Patient Group Directions (2017) states:

- Provide the majority of clinical care involving supplying and/or administering medicines on an individual, patient-specific basis. Reserve patient group directions for limited situations in which this offers an advantage for patient care, without compromising patient safety, and where there are clear governance arrangements and accountability.
- **Explore all the available options for supplying and/or administering medicines in a specific clinical situation.**
- **Do not use PGDs for medicines when exemptions in legislation allow their supply and/or administration without the need for a PGD.**

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So what does this mean in practice?

Take two minutes to think about when PGDs aren't required and jot down your ideas before we move on

What does this mean in practice?

PGDs should not be used for the following:

- Where there is an opportunity in the pathway to prescribe
- Supply or administration of GSLs
- Administration of Ps (or supply if from a registered pharmacy/midwife/exemptions exists)
- Administration of Schedule 19 medicines
- Administration of Schedule 17 medicines by the listed professionals
- Administration of medical gases (if GSL/P)

If you have PGDs in place for any of the above they should be reviewed.

GSL&P medicines & medical gases

GSL medications

- A PGD is not necessary and should not be used where the medicines to be supplied or administered are General Sales List (GSL) medicines. A locally approved protocol or similar could be used to support administration/supply of GSL medications.

P medications

- A PGD is not necessary and should not be used where the medicines to be administered are Pharmacy Only (P) medicines. A PGD or prescription is needed for supply of P medications unless the supply is made from a registered pharmacy premises/by midwives/exemption. A locally approved protocol could be used to support administration.

Exemptions

Human Medicines Regulations exemptions:

- Exemptions for paramedics, midwives, optometrists, orthoptists and podiatrists allowing these registered health professionals to administer or supply certain specified medicines within their scope of practice and competency without the directions of a prescriber. (Schedule 17)
- Exemptions for administration of certain parenteral medicines by anyone for the purpose of saving life in an emergency e.g. adrenaline (Schedule 19).
- Occupational Health Schemes – Q&A available
- Naloxone supply by Drug Treatment Services

Occupational Health Services

- Advice issued by SPS on PGDs in OHS – updated for legislation changes in 2020.
- OHS within NHS organisations can use PGDs for **own staff only.** However as alternative mechanism exists in legation written instructions should be used unless reason not to.
- OHS within private or non-NHS/publically funded services **cannot use** PGDs and should use written instructions as allowed under legislation.
- This also applies to NHS/publically funded services providing private OHS services (e.g. to neighbouring NHS organisation or local police force).

Written Instructions for OHS

- A written instruction must be signed by a doctor and detail the medicine/vaccine to be supplied/administered and list who can work under it by name.
- Who can work under a WI now depends on the organisation type and medicine/vaccine to be supplied/ administered.
- If for anything other than a ‘flu or coronavirus vaccine only registered nurses can work under a WI, signed by a doctor whatever organisation they work for.

Written Instructions for OHS – ‘flu and coronavirus vaccines

For flu and coronavirus vaccines **only AND** for an NHS body or Local Authority **only**:

- Additional registered staff can act as an **occupational health vaccinator** - this is a new term introduced in this new legislation
- Staff must be employed or engaged
- Cease to have effect 1st April 2022
- Note 2020/21 COVID vaccination of health and social care staff NOT OHS so not under WI

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Who can work as an occupational health vaccinator?

- Registered nurse
- Registered midwife
- Registered nursing associate (in England)
- Registered operating department practitioner
- Registered paramedic
- Registered physiotherapist
- Registered pharmacist

Protocols relating to coronavirus and influenza vaccinations (Reg 247A)

- This is a new mechanism for coronavirus and flu only
- National protocol - needs to be authorised by the secretary of state. No local authorisation allowed.
- Allows trained, competent and authorised persons (registered and non registered) to participate in delivering the programme
- Some stages of protocol limited to certain registered health care professionals

Protocols relating to coronavirus and influenza vaccinations (Reg 247A)

- The protocol can be used by a single registered HCP undertaking the whole vaccination process, or by multiple persons undertaking the appropriate stages.
- These are clearly outlined in the protocol.
- All activity under protocol must be under a Clinical Supervisor (doctor, nurse or pharmacist).

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Controlled Drugs and PGDs

Currently, the following CDs **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 listed medicines except anabolic steroids and injectables used for treating addiction.
- Schedule 5: All listed medicines

2019 update on CDs and PGDs

- We became aware in the summer of 2019 that when the following professions were added to the PGD legislation the Misuse of Drugs Regulations were not also amended:
  - Dietitians
  - Speech and Language Therapists
  - Dental Hygienists
  - Dental Therapists
- As a result the above professions cannot supply or administer controlled drugs under a PGD.

PGDs for antimicrobials

NICE MPG2 2017 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 NICE/PHE 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

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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.**

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Delegation

- Cannot delegate responsibility for any part of PGD process including making the clinical review, supply/administration and record keeping
- 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 an individual 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.

Developing, authorising and reviewing PGDS

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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/administer medicines under the PGD ('PGD working group')
- Collaborate with stakeholders
- Consistent presentation
- Must contain legally required information
- Must be written against best available evidence

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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

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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 or one can represent a wider group)

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Quick quiz

Which bodies can authorise PGDs for NHS/Local Authority commissioned/provided services?

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Which bodies can authorise PGDs?

Those organisation 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.

Independent Healthcare Providers (IHPs)

- Human Medicines Regulations 2012 resulted in PGDs for non-NHS providers (e.g. independent medical agencies/CICs) commissioned by NHS or public health commissioned services requiring authorisation 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.

See Q&A https://www.sps.nhs.uk/articles/authorisation-of-independent-healthcare-provider-ihp-pgds-for-nhs-and-public-health-commissioned-services/

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Complex commissioning and PGDs

- NHS and non-NHS commissioner/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 up’ 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.

https://www.sps.nhs.uk/articles/patient-group-directions-in-complex-commissioning-scenarios/

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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.
- See Q&A https://www.sps.nhs.uk/articles/questions-electronic-systems-and-pgds/

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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.

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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 and communicated.

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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.

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Other things to consider

- Need for robust and transparent processes – PGD policy. Share with others if cross organisational working for assurance.
- 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

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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 including e systems
- Drugs with associated Risk Minimisation Materials (RMM)
- Local medicines policy/professional standards
- Training and competency of everyone involved
- Implementation including audit
- Mergers

PGD Record Retention

- Advice updated in August 2018 following a review of the advice with an NHSE data specialist.
- All PGD records need to be retained for 8 years (adults) and 25 years (children) or for 8 years after a child's death.
- This includes the final authorised copy of the PGD, staff authorisation records and patient records.
- Main amendment is any records relating to an implant must be kept for 10 years so may affect record retention in reproductive service PGDs.

PGD Record Retention

- Additional advice around retaining copies of final PGDs which contain no identifiable data. These can be retained for up to 20 years for business continuity/ planning purposes.
- Commonly not all parts of the PGD record will be held by the same organisation - if service operating under PGDs is commissioned/provided by different organisations then details of records keeping should be included in the MOU.
- Organisations should have an up to date log of all PGDs – CQC will expect this to be in place.

https://www.sps.nhs.uk/articles/retaining-pgd-documentation/

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Remember…..

- Do not work in isolation - engagement is key
- Engage stakeholders/commissioners at an early stage.
- Consider need for MOUs or similar.
- 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!

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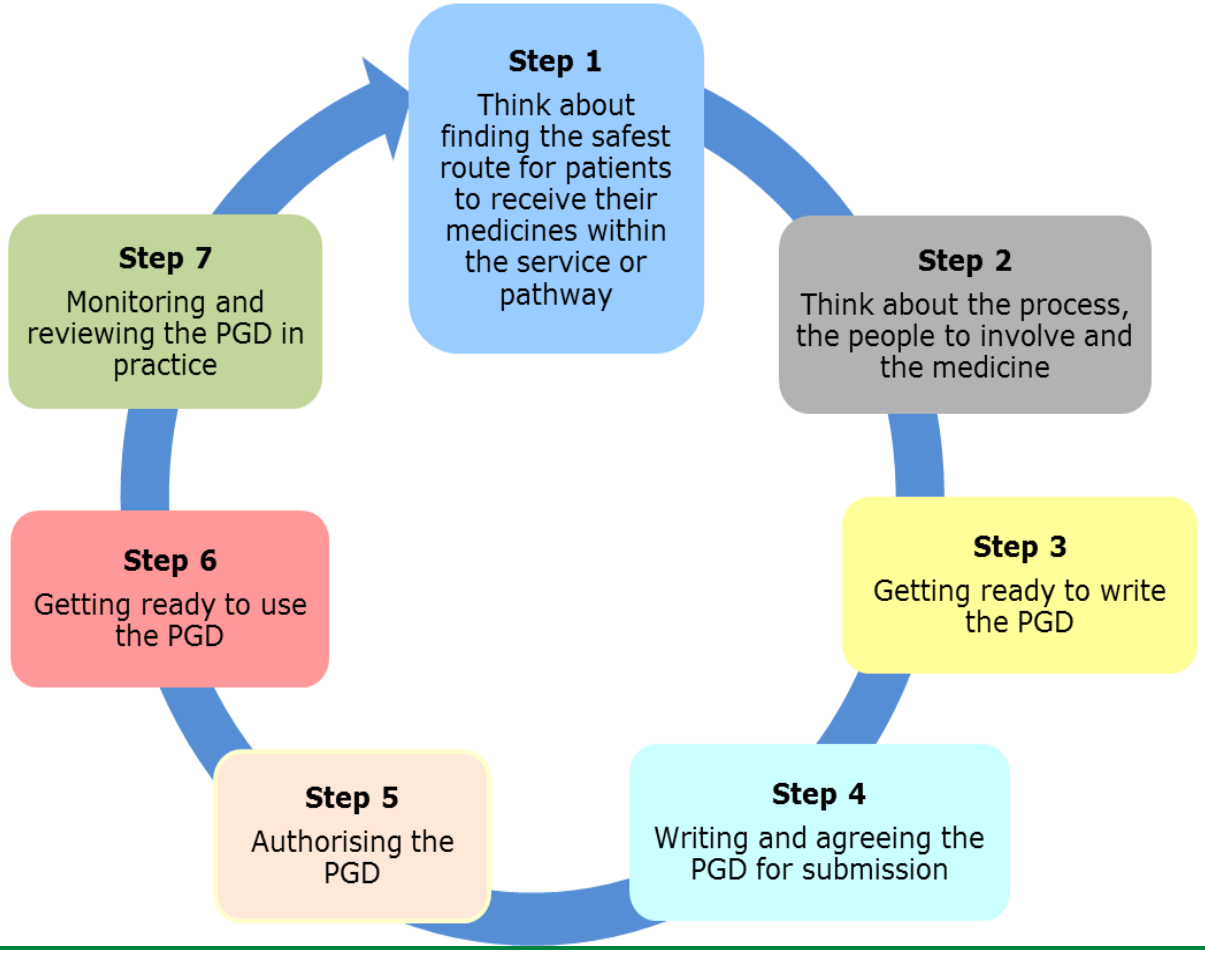
Quality PGDs – 7 steps to success



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Tools and resources

Specialist Pharmacy Services PGD resources – Q&As, decision tools, support documents, example policies and 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.

10 minute comfort break

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Medicines Governance Do Once Programme

Tracy Rogers

Director SPS MUS

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Key Drivers

- Carter reviews
  - Recommendations based around efficiency and productivity
  - Specific recommendation on developing a do once system that includes PGDs
- NHS Long term plan
  - boost ‘out-of-hospital’ care
  - prevent unnecessary admissions to hospitals

Before COVID-19

- When PGDs are not required
- Established a process
  - There must be published national guidance
  - Work with appropriate stakeholder (nationally recognised groups)
  - Work Subject Matter Experts
  - Sign off by RMOC
- Ambulance trusts
- Sexual Health
- Reproductive Health

During COVID-19

- Moved to producing template PGDs
  - RMOC was not meeting
  - The work we had done would assist organsiations
- Successfully developed suites of PGD templates for
  - Sexual health
  - Reproductive health

During COVID-19

- Future areas of work:
  - Maternal Health
  - Radiology PGDs – contrast
  - Antimicrobial PGDs

Post COVID-19

- There are advantages and disadvantages of template PGDs versus nationally signed off PGDs
  - COVID-19 has changed things e.g national sign off of PHE developed COVID-19 vaccine PGD
  - Working closer with National Clinical Directors and National Specialty Advisers
  - Currently exploring what the best model is

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Benefits

- Deliver consistent care across England
- Reduce variability in PGDs
- Reflect national guidance
- Deliver increased organisational capacity
- Release significant local resource to be redeployed on optimising outcomes from medicines use
- Support organisational Governance arrangements

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Challenges

- Stakeholder engagement critical
- Everyone is committed to the process but they do have a “day job”
- Changes to national guidance
- National PGDs will only be considered for development where there is national guidance
- National priorities

Constraints

- The programme will not develop PGDs for everything
- Local PGDs will still be necessary
- It takes time and resources to develop national PGDs

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Where to find more information

When Patient Group Directions (PGDs) are not required. Guidance on when PGDs should not be used and advice on alternative mechanisms for supply and administration of medicines

Medicines Governance Do Once Programme

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PGD Scenarios

Sandra Wolper

Associate Director

SPS MUS

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How this will work

It's interactive !

- Each scenario will end with questions for you (in purple)
- Instructions will be included with each scenario
- Please either
  - Use tools on Webex to indicate your answers OR
  - Write down brief notes for yourself
- Some answers are not so straightforward!
- We'll look at the feedback together; then Sandra will go through the answers

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Open the feedback box with the megaphone at the bottom of the participant panel.

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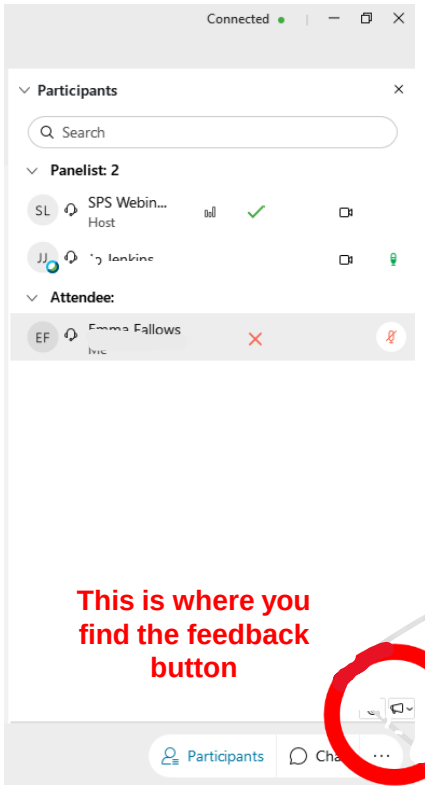
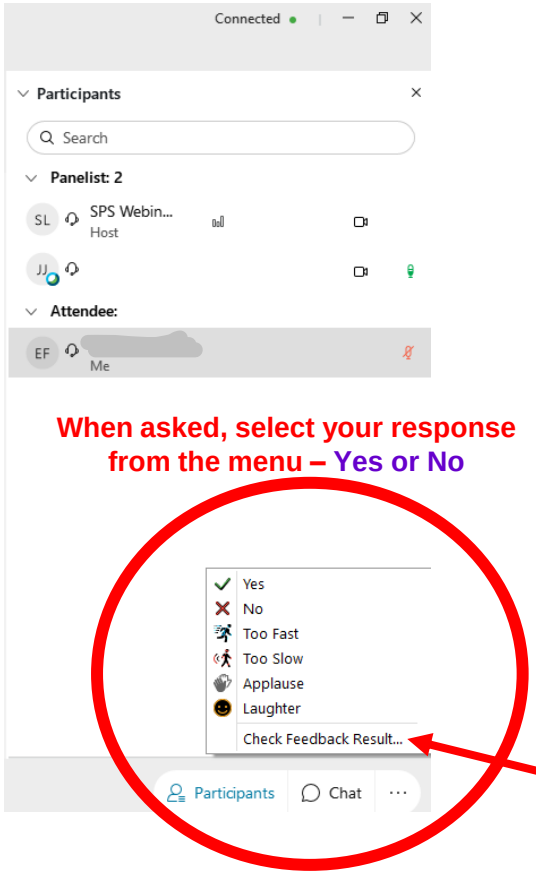
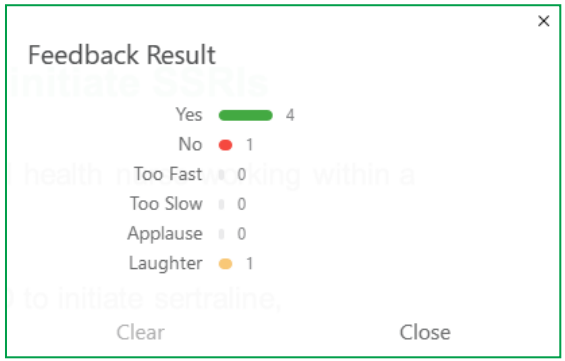


Select this megaphone to open the feedback menu

This is where you find the feedback button



When asked, select your response from the menu – Yes or No



Use this option to see the results of all attendees' votes

All answers are anonymous – this is just for fun!

Scenario - Administering medicines under PGDs – two questions

A nurse works in a community clinic using PGDs to administer Depo-Medrone® injections.

A new nurse is recruited.

1. Can the new nurse be supervised administering an injection under a PGD as part of their training and assessment of competency?

INSTRUCTIONS: Please use Webex to say ‘yes’ or ‘no’

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Scenario - Administering medicines under PGDs

A nurse works in a community clinic using PGDs to administer Depo-Medrone® injections.

A new nurse is recruited.

2.Would the new nurse be allowed to work under the PGD if she had undertaken the same role under a PGD in another Trust and thought herself to be fully competent?

INSTRUCTIONS: Please use Webex to say ‘yes’ or ‘no’

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Scenario – PGDs to initiate SSRIs

We have a specialist mental health nurse working within a GP practice.

She would like to have PGD to initiate sertraline, citalopram and mirtazapine.

Would this be an appropriate use of PGDs?

(Prompt – think about legislation vs. guidance)

INSTRUCTIONS: Write down one or two points to consider, then Sandra will give some answers

Scenario - PGD for a clinical trial

There is a meningitis B vaccine clinical trial being undertaken by a Trust where a PGD is proposed to allow nurses to supply and administer to individuals aged 16-19 in school. This vaccine is part of a clinical trial and black triangle vaccine

Would this be appropriate for administration under a PGD?

INSTRUCTIONS: Please use Webex to say ‘yes’ or ‘no’
AND write down a reason for your answer

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Scenario – Authorising PGDs

An Independent Healthcare Provider (IHP) is commissioned by a CCG to provide an urgent care service and PGDs are required to provide medications. Who should write the PGDs and who should authorise them?

Consider:

- Who commissions the service?
- Who provides the service?
- Which organisations can authorise PGDs?
- What should each organisation be responsible for?
- Who in the organisation should authorise?

INSTRUCTIONS: Nothing to do! Sandra will explain the answers

Scenario - PGD for NRT

PGD has been proposed for Trust wide supply of NRT.

All appropriately registered healthcare professionals deemed competent to work under the PGD would be permitted to supply nicotine replacement therapy to any inpatient or outpatient in any area of the trust.

Is this acceptable under a PGD?

INSTRUCTIONS: Please use Webex to say ‘yes’ or ‘no’

Scenario - Labelling of COCs supplied under a PGD

This query was submitted (*it takes a bit of digesting!*):

"Can COCs supplied under a PGD be labelled at the time of supply with a label stating the patient name, date of supply and supplying clinic address if the dosage instructions are included on the packaging?"

INSTRUCTIONS: Please use Webex to say 'yes' or 'no'

Caution: it takes a bit of thinking about….

Scenario – PGDs when services integrate

PGDs were authorised for use by an NHS organisation providing sexual health clinic services. The organisation is to be integrated into another provider from August 2021.

1. What options are available for this PGD?
2. What are the possible risks and benefits of each of these options?
3. Who is responsible for ensuring the PGD remains valid and appropriate when the provider is integrated?

INSTRUCTIONS: Nothing to do! Sandra will explain the answers

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New email address for SPS PGD query support

lnwh-tr.sps-pgd@nhs.net

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SPS website

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POLL: A SHORT INTERLUDE……

We would be really pleased if you could complete a short poll which will appear on your screen. This will help us know how we are doing!

The questions are:

To what extent was this event useful to you?

If this webinar was repeated, would you recommend it to your colleagues?

THANK YOU FOR JOINING US! WE HOPE YOU HAVE ENJOYED THE WEBINAR!