# Patient Group Directions Policy

<table>
<thead>
<tr>
<th>Category:</th>
<th>Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary:</td>
<td>This policy outlines standards required for the development, review and on-going monitoring of Patient Group Directions at the Oxford University Hospitals NHS Foundation Trust.</td>
</tr>
<tr>
<td>Equality Analysis undertaken:</td>
<td>April 2017</td>
</tr>
<tr>
<td>Valid From:</td>
<td>April 2017</td>
</tr>
<tr>
<td>Date of Next Review:</td>
<td>April 2020</td>
</tr>
<tr>
<td>Approval Date/ Via:</td>
<td>Medicines Administration, Prescribing &amp; Supply Standards Group (MAPSS) 05/04/2017 Clinical Policies Group 03/05/2017</td>
</tr>
<tr>
<td>Distribution:</td>
<td>Trust-wide</td>
</tr>
<tr>
<td>Related Documents:</td>
<td>Medicines Policy and associated procedures</td>
</tr>
<tr>
<td>Author(s):</td>
<td>Governance Support Pharmacist</td>
</tr>
<tr>
<td>Further Information:</td>
<td><a href="mailto:Pharmacy.governance@ouh.nhs.uk">Pharmacy.governance@ouh.nhs.uk</a></td>
</tr>
<tr>
<td>This Document replaces:</td>
<td>Patient Group Directions Policy version 2.0</td>
</tr>
</tbody>
</table>

**Lead Director:** Medical Director  
**Issue Date:** April 2017
Document History

<table>
<thead>
<tr>
<th>Date of revision</th>
<th>Version number</th>
<th>Author</th>
<th>Reason for review or update</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 2015</td>
<td>1</td>
<td>Governance Support Pharmacist</td>
<td>New document</td>
</tr>
<tr>
<td>October 2015</td>
<td>2</td>
<td>Governance Support Pharmacist</td>
<td>Clarifications to ePMA requirements</td>
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</table>

Consultation Schedule

<table>
<thead>
<tr>
<th>Who? Individuals or Committees</th>
<th>Rationale and/or Method of Involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicines Administration, Prescribing &amp; Supply Standards group (MAPSS)</td>
<td>Review of document and approving committee</td>
</tr>
<tr>
<td>Medicines Management and Therapeutics Committee (MMTC)</td>
<td>Ratification</td>
</tr>
</tbody>
</table>

Endorsement

<table>
<thead>
<tr>
<th>Endorsee Name:</th>
<th>Endorsee Job Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Victoria Mott</td>
<td>Lead Pharmacy &amp; Medications Governance Pharmacist (Co-chair of MAPSS)</td>
</tr>
<tr>
<td>Liz Wright</td>
<td>Deputy Chief Nurse (Chair of MAPSS)</td>
</tr>
</tbody>
</table>
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Who should read this document?
1. All clinical staff across the Trust that are involved in the development of Patient Group Directions (PGDs) or use PGDs must read this policy.
2. Patient Group Directions (PGDs) are written instructions for the supply and/or administration of a medicine or medicines to patients who may or may not be individually identified before presentation for treatment.

Key Standards/Messages
3. All PGDs will be developed, written and monitored in line with this policy and in accordance with the Trust Medicines Policy.
4. A PGD is not a form of prescribing and where possible, medication should be provided on an individual, patient-specific basis.

Background/Scope
5. This policy outlines standards that must be adhered to when the need for a PGD is being considered, when it is being developed and reviewed and when its use is being monitored.
6. The policy outlines legal requirements and good practice guidance that must be considered when developing a PGD.
7. This document applies to all areas of the Trust, and all employees of the Trust, including individuals employed by a third party, by external contractors, as voluntary workers, as students, as locums or as agency staff.

Key Updates
8. The PGD proposal form and PGD templates can now be found on the MAPSS PGD Intranet Page.
9. Previously, this policy stated that some medical devices used as medicines supplied or administered could be considered for inclusion under a PGD at OUHFT. Clarification of the legislation supporting the use of PGDs has identified that medical devices must not be included in PGDs regardless of their indication.
10. NICE PGD guidance states that PGDs should not be used for medicines where exemptions in legislation allow for their supply/and or administration.

Aim
11. The purpose of this policy is to ensure that processes for developing and reviewing PGDs and monitoring their on-going use are clearly defined.
11.1. To ensure PGDs are only developed in appropriate circumstances
11.2. To support practitioners to develop and use PGDs
11.3. To support practitioners in their understanding of the legal framework governing PGDs
11.4. To support training and competency development for practitioners using PGDs
What is a PGD?
12. Patient Group Directions (PGDs) are written instructions for the supply and/or administration of a medicine or medicines to patients who may or may not be individually identified before presentation for treatment.

13. PGDs were first established in 2000. Current legislation governing PGDs is included in the Human Medicines Regulations 2012.

14. PGDs provide a legal framework that allows the supply and/or administration of a specified medicine(s), by named, authorised, registered health professionals, to a pre-defined group of patients needing prophylaxis or treatment for a condition described in the PGD, without the need for a prescription or an instruction from a prescriber.

15. A PGD is not a form of prescribing and where possible, medication should be provided on an individual, patient-specific basis. It is recognised that this may not always be possible and the supply and administration of medicines under PGDs should be reserved for those limited situations where this offers an advantage for patient care without compromising patient safety and where it is consistent with appropriate professional relationships and accountability.

16. With many healthcare professionals extending their professional and clinical practice by completing a non-medical prescribing course, the use of PGDs will be reviewed continuously at OUHFT to ensure that wherever possible, patients will be individually assessed by an appropriate prescriber.

17. The person operating under the PGD must be the person who administers the medicine or supplies the medicine to the patient or carer for the patient or carer to take themselves. This cannot be delegated to another person.

18. The benefits to patient care include:
   18.1. Delivering effective patient care that is appropriate in a pre-defined clinical situation, without compromising patient safety
   18.2. Offering a significant advantage to patient care by improving access to appropriate medicines
   18.3. Providing equity in the availability and quality of services when other options for supplying and/or administering medicines are not available
   18.4. Providing a safe legal framework to protect patients
   18.5. Reducing delays in treatment
   18.6. Maximising the use of the skills of a range of healthcare professionals.
**PGD Development Flowchart**

1. **Idea for PGD identified.**
2. Lead author completes PGD proposal form and sends to Pharmacy Governance Team.
3. Proposal reviewed by Pharmacy Governance Team who liaises with the lead clinician if further information required.
4. Proposal presented to MAPSS by lead author. If a PGD is not considered appropriate to develop, alternative recommendations will be offered by MAPSS to support the clinical service.
5. PGD lead author completes PGD template with support from PGD working group and sends to Pharmacy Governance Team.
6. Pharmacy governance team checks document and liaises with PGD author(s) to make any amendments.
7. **Document submitted to MAPSS for review**
   - PGD approved or rejected pending further amendments to the PGD. Conditions placed on whether the PGD must return MAPSS for final approval.
   - Audit results presented to MAPSS and decision made to agree or reject renewal. If renewal agreed, PGD updated as appropriate
8. Final document prepared for electronic signatures and signatures collated by the Pharmacy Governance Team for final sign off.
   - PGD audit and update tool reviewed by Pharmacy Governance Team. Actions agreed with PGD lead clinician if necessary.
9. Pharmacy governance team feeds back to PGD author(s) that the PGD may be used.
   - Renewal due six months before expiry – PGD lead clinical completes audit and update tool.
10. **On-going use of PGD**
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PGD Development Process

Stage 1: PGD Proposal and PGD Working Group
19. The PGD working group, i.e. the group writing/developing the PGD, must include representation from the following healthcare professionals in the clinical area in which the PGD is to be used:

19.1. Doctor and/or dentist
19.2. A lead practitioner representing the group of healthcare professionals using the PGD
19.3. A specialist pharmacist in the clinical area

20. Any PGD working group for a PGD involving an antimicrobial must include a local specialist in Microbiology from the Trust.

21. A PGD Proposal Form must be completed and submitted to MAPSS for review prior to development of the full PGD document.

22. Use the national PGD website tools to help to decide whether a PGD is necessary or not.

Stage 2: PGD Writing and Ratification
23. PGDs must be written using the Trust approved PGD template that outlines the information legally required and a generic PGD competency framework.

24. The Pharmacy Governance Team will provide an editable version to the lead author once the PGD has been approved for development.

25. Every section of the template must be completed. If a section is not applicable, it must be made clear why that is the case.

26. Abbreviations must not be used.

27. References used must be clinically accurate and up-to-date.


29. Where possible, include the BNF as a reference.

30. References must be updated when a PGD is renewed.

Stage 3: PGD Authorisation
31. Legally, all PGDs must be signed by a doctor or dentist and a pharmacist, who accept accountability for the clinical accuracy and pharmaceutical content of the PGD supported by the PGD working group.

32. PGDs must be electronically signed by all authors and all organisational leads as shown in the PGD template.

33. A member of the pharmacy governance team will contact the lead clinician to advise when all signatures have been collated. The PGD must not be used until all signatures have been received. The lead clinician is responsible for disseminating the PGD appropriately.

Stage 4: PGD Renewal, Update and Audit
34. All versions of PGDs will be given a review date of three years from authorisation.

35. Before a PGD can be renewed, evidence of audit will be required to enable a full review of the PGD and to determine if a PGD is still the best option for supporting the clinical service.

36. See the MAPSS PGD Intranet page for the generic recommended audit tools for areas not auditing via Cerner EPR. Contact the Pharmacy Governance Team for support with auditing via
37. If there is no evidence of audit, renewal will only be considered in exceptional circumstances.

37.1. Any PGD falling into this category will be extended for a maximum of 6 months. Following this extension, the decision to renew the PGD or to reject its use will be considered by MAPSS on a case-by-case basis.

Which medicines can be included in a PGD?

38. In order to ensure PGDs are clear and legally robust, ideally one PGD per medication should be developed, unless otherwise authorised by MAPSS.

39. Only medicines that are available on the Trust medicines formulary may be included in a PGD.

40. PGDs must only include medicines with a UK Marketing Authorisation.

41. Special consideration for inclusion will be required for the following medicines:

41.1. Off-label medicines (i.e. a licensed medicine being used for an unlicensed indication)

41.1.1. Off-label use of a licensed medicine will only be considered when such use is clearly justified and supported by best clinical practice and national guidance.

41.2. Black triangle medicines (medicines under close monitoring by regulatory authorities in the European Union)

41.2.1. Black triangle medicines must only be included when such use is clearly justified and supported by best clinical practice, such as NICE guidance.

41.3. Controlled drugs

41.3.1. Inclusion of controlled drugs in PGDs is governed by the Misuse of Drugs Regulations (2001).

41.3.2. Only certain controlled drugs may be considered for inclusion in PGDs if clinically appropriate:

<table>
<thead>
<tr>
<th>Schedule 2</th>
<th>Morphine and Diamorphine (Use by registered nurses and pharmacists only, for the immediate necessary treatment of a sick or injured person (except for treating addiction)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schedule 3</td>
<td>Midazolam</td>
</tr>
<tr>
<td>Schedule 4</td>
<td>All drugs excluding anabolic steroids and any injectable preparation used for treating addiction</td>
</tr>
<tr>
<td>Schedule 5</td>
<td>All drugs including codeine</td>
</tr>
</tbody>
</table>

41.4. Antimicrobials – only include in a PGD when clinically essential and clearly justified

41.5. Injectables for self-administration

41.6. Medicines being used in a small number of patients or a specific patient group, because the appropriate resources and expertise may not be available

41.7. Supplying and/or administering a range of medicines to the same patient (this may be appropriate in some cases when a discrete episode of care involves treatment with more than one medicine).

42. The following medicines are not permitted for inclusion in PGDs:
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42.1. Unlicensed medicines
42.2. Dressings, appliances and devices
42.3. Radiopharmaceuticals
42.4. Abortifacients
42.5. Where dose adjustment is required to a medicine already in the patient’s possession
42.6. Medicines requiring frequent dose adjustments or complex monitoring
42.7. Used for the management of long term conditions

Practitioners permitted to use PGDs
43. The following practitioners are permitted to supply and/or administer medicines under PGDs once all competencies have been met in the relevant PGD and the practitioner has been authorised to use the PGD by the clinical lead:
43.1. Chiropodists and podiatrists
43.2. Dental hygienists
43.3. Dental therapists
43.4. Dieticians
43.5. Midwives
43.6. Nurses
43.7. Occupational therapists
43.8. Optometrists
43.9. Orthoptists
43.10. Orthotists and prosthetists
43.11. Paramedics
43.12. Pharmacists
43.13. Physiotherapists
43.14. Radiographers
43.15. Speech and language therapists

44. Practitioners must be registered with their relevant professional body and employed by OUHFT.
45. Temporary/locum staff without an OUHFT contract are not permitted to supply or administer medicines under an OUHFT-approved PGD.

Accountability
46. Responsibility and accountability for the supply and/or administration of a medicine under a PGD lies with the individual practitioner using the PGD.
47. A practitioner is not permitted to supply/administer a medicine in any way other than that stated in the PGD.
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48. The practitioner takes full responsibility for any deviations from the PGD. They must take into account any other clinical qualifications they have e.g. if they are suitably qualified as an independent prescriber and make it clear in which capacity they are acting through documentation in the patient's records.

49. The PGD lead author must keep an up to date list of authorised practitioners who are competent to use the PGD.

**Competency Framework**

50. Any individual administering or supplying a medicine by a PGD must be authorised by name and assessed as competent based on the competency framework/assessments outlined in the PGD.

51. This policy outlines a set of generic competencies that any user of a PGD must meet as shown in the PGD Competency Framework (see PGD template). The PGD working group must agree any additional competencies that must be met or consider if any are not applicable relating to the PGD and the practitioners that use the PGD.

52. Competencies should be assessed by a suitable clinical lead (not necessarily the PGD lead) or a nominated deputy.

53. The frequency/method and accountability for competency assessments must be included in the main PGD document.

54. If there are major changes to the PGD when it is updated, it is good practice to reassess whether the competency framework will also require updating.

55. Records of competency assessments must be kept by the lead practitioner who has overall accountability for the PGD and the authorised user of the PGD.

**Record Keeping and Retention**

56. Accurate records must be made of the consultation that results in the use of the PGD, as outlined in the PGD template.

57. All PGD documentation must be retained as per the OUHFT Health Records Policy. The same rules that apply to the retention of patient records apply to PGDs.

58. In addition to following trust standards for record keeping and retention, the PGD lead clinician is responsible for keeping and storing the following records:

58.1. Authorised practitioners assessed as competent to use the PGD

58.2. Competency assessments and training records

59. The Pharmacy Governance Team is responsible for monitoring and updating a database of PGDs in use at OUH.

60. Approved versions of PGDs will be stored on a centralised electronic database with limited access to ensure PGD documents are used appropriately by authorised and competent users in the relevant clinical area. If a PGD is required for information, contact the Pharmacy team via pharmacy.governance@ouh.nhs.uk.

61. All supplies and administration carried out under a PGD must be clearly documented as outlined in each PGD document.

62. If a clinical area is using Cerner EPR, any documentation must occur on EPR. Additionally, medicines supplied or administered may be documented on any approved documents used to support the clinical service. Please contact the pharmacy governance team if a PGD is to be used for supply or administration of a medicine in an area using EPR, as individual orders may need to be designed.
Review
63. This policy will be reviewed every 3 years, as set out in the Policy for the Development and Implementation of Procedural Documents.

References

65. Specialist Pharmacy Service. To PGD or not to PGD? That is the Question. A guide to choosing the best option for individual situations. Link available at https://www.sps.nhs.uk/articles/to-pgd-or-not-to-pgd-that-is-the-question/ (Accessed 10/04/2017)


Appendix 1: Responsibilities
69. The Chief Executive has overall responsibility has overall statutory responsibility for the safe and secure handling of medicines.

70. The Medical Director is the lead Executive Director for medicines management and is responsible for being the most senior member of the group that will authorise every PGD in use at OUHFT.

71. The Clinical Director of Pharmacy and Medicines Management has lead responsibility for safe medicines practice throughout the Trust and reports to the Trust and Executive Boards. They have direct access to the Chief Executive for medicines management issues as required.

72. The Chief Nurse has responsibility for authorising every PGD in use at OUHFT and ensuring trust governance processes are followed.

73. Divisional Directors are responsible for authorising PGDs in their division and ensuring trust governance processes are followed.

74. The Medicines Administration, Prescribing & Supply Standards group (MAPSS) supports the development of new approaches to prescribing, administration and the supply of medicines. It considers all PGD proposals to ensure their safety, legality and appropriateness and supports development.

75. Lead clinicians for individual PGDs are responsible for the overall implementation of the PGD, ensuring only authorised practitioners competent to operate under the PGD do so and that training needs and audit requirements are met as outlined in this policy. They will also be
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responsible for ensuring the PGD document is kept up to date and will continually review whether a PGD remains the best method of supporting services in the clinical area.

76. Clinical practitioners operating under a PGD will be responsible for following guidance issued in this policy and only operating under the terms of the valid and approved PGD where they have been assessed as competent to do so.

Appendix 2: Definitions

77. EPR – Electronic Patient Record
78. MAPSS – Medicines Administration, Prescribing & Supply Standards Group
79. PGD – Patient Group Direction

Appendix 3: Training

80. There is no mandatory training associated with this policy. Clinical leads for PGDs and those accountable for competency assessments must ensure practitioners are adequately trained as outlined in the competency appendix of each PGD.

81. It is strongly encouraged that all healthcare professionals involved in developing, reviewing and using a PGD complete the CPPE e-learning package available at https://www.cppe.ac.uk/programmes/l/ptgpdir-e-01/.

Appendix 4: Monitoring Compliance

<table>
<thead>
<tr>
<th>What is being monitored:</th>
<th>How is it monitored:</th>
<th>By who, and when:</th>
<th>Minimum standard</th>
<th>Reporting to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance of Trust PGD Database</td>
<td>Review of database to identify those that are close to expiry and require updating</td>
<td>Pharmacy Governance Team</td>
<td>Annual review</td>
<td>MAPSS Committee</td>
</tr>
</tbody>
</table>
### Appendix 5: Equality Analysis

<table>
<thead>
<tr>
<th>Have you considered how the Policy will affect people:</th>
<th>Yes</th>
<th>No</th>
<th>How have these groups been included in the development of the Policy?</th>
<th>How will the Policy affect them?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who have a physical or sensory impairment? Have you consulted with them?</td>
<td>☐</td>
<td></td>
<td>This group has not been consulted with directly.</td>
<td>This policy will not affect those with this characteristic. The Trust expects all staff to adhere to the Equality and Diversity Policy including consideration of the nine protected characteristics.</td>
</tr>
<tr>
<td>With a disability?</td>
<td>☐</td>
<td></td>
<td>As above</td>
<td></td>
</tr>
<tr>
<td>Of different gender?</td>
<td>☐</td>
<td></td>
<td></td>
<td>This policy does not discriminate based on gender.</td>
</tr>
<tr>
<td>Of different ages?</td>
<td>☐</td>
<td></td>
<td></td>
<td>This policy does not discriminate based on age.</td>
</tr>
<tr>
<td>With different racial heritages?</td>
<td>☐</td>
<td></td>
<td></td>
<td>This policy does not discriminate based on race.</td>
</tr>
<tr>
<td>With different sexual orientations?</td>
<td>☐</td>
<td></td>
<td></td>
<td>This policy does not discriminate based on sexual orientation.</td>
</tr>
<tr>
<td>Who are pregnant or recently had a baby?</td>
<td>☐</td>
<td></td>
<td></td>
<td>This policy does not discriminate based on this.</td>
</tr>
<tr>
<td>With different religions or beliefs?</td>
<td>☐</td>
<td></td>
<td></td>
<td>This policy does not discriminate based on this.</td>
</tr>
<tr>
<td>Who are going through gender re-assignment or have transitioned?</td>
<td>☐</td>
<td></td>
<td></td>
<td>This policy does not discriminate based on this.</td>
</tr>
<tr>
<td>Of different marital/partnership status?</td>
<td>☐</td>
<td></td>
<td></td>
<td>This policy does not discriminate based on this.</td>
</tr>
<tr>
<td>Who are carers?</td>
<td>☐</td>
<td></td>
<td></td>
<td>This policy does not discriminate based on this.</td>
</tr>
<tr>
<td>Any other group who may be affected by this policy</td>
<td>☐</td>
<td></td>
<td></td>
<td>n/a</td>
</tr>
</tbody>
</table>

#### Summary of Analysis

<table>
<thead>
<tr>
<th>Does the analysis show evidence of:</th>
<th>Yes</th>
<th>No</th>
<th>Please explain your answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>The potential to discriminate?</td>
<td>☐</td>
<td>☐</td>
<td>This policy is to ensure medicines are stored safely and securely throughout the trust.</td>
</tr>
<tr>
<td>The advancement of equality of opportunity?</td>
<td>☐</td>
<td>☐</td>
<td>This policy does not aim to advance equal opportunities.</td>
</tr>
<tr>
<td>The promotion of good relations between groups?</td>
<td>☐</td>
<td>☐</td>
<td>This policy does not aim to promote good relations between groups.</td>
</tr>
</tbody>
</table>