Patient Group Direction (PGD) Audit Tool

A – Governance – process oversight   
To be completed at organisational level

|  | **Questions** | | **Yes/No** |
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| **A1** | Does the organisation have a PGD oversight group or similar? | |  |
| **A2** | Are there records of terms of reference and minutes or notes by the group? | |  |
| **A3** | Does the PGD oversight group or similar report into the organisation’s clinical governance framework? | |  |
| **A4** | Is there a current PGD policy? | |  |
| **A5** | Does the current PGD policy include: | | |
| **A5.1** | Considering the need for a PGD and obtaining agreement to develop a PGD |  |
| **A5.2** | Developing and submitting a PGD including review of need for a PGD/alternative mechanisms for administration/supply |  |
| **A5.3** | Authorising a PGD |  |
| **A5.4** | Authorising named, registered health professionals to use a PGD |  |
| **A5.5** | Training and competency |  |
| **A5.6** | Audit, review and updating a PGD (including in life amendments and review of continued need for PGD) |  |
| **A6** | Is there a current and up-to-date list of all the PGDs in use within the organisation, including their review/expiry dates? | |  |
| **A7** | Are all master authorised copies of all current PGDs held by the organisation (and where applicable the authorising commissioning organisation)? | |  |
| **A8** | Are master copies of all expired versions of the PGDs held by the organisation (and where applicable the authorising commissioning organisation)? | |  |
| **A9** | Is there an audit timetable for PGD audits within each service (see sections C and D)? | |  |
| **A10** | Are there any PGD related risks on the risk register? | |  |
| **A11** | Does the organisation have a policy on prescription charge collection for a supply made under a PGD for patients who are not exempt from NHS prescription charges? | |  |

B – Governance – PGD content  
Overarching review of all PGDs in use within an organisation/PGDs in use within a defined clinical area or service

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|  | **Questions** | | **Yes/No** |
| **B1** | Number of PGDs currently in use within the organisation |  |  |
| **B2** | Do all medicines administered/supplied under a PGD have a UK Marketing Authorisation? | |  |
| **B3** | Have all medicines which have a current "black triangle" status been clearly indicated on the relevant PGD? | |  |
| **B4** | Is any off-label use clearly indicated on the relevant PGD? | |  |
| **B5** | Is there evidence that all antimicrobial PGDs have had an input from the local microbiology specialist? | |  |
| **B6** | Are there any PGDs in the trust that have been developed and used for the management of long-term conditions? | |  |
| **B7** | Are any of the medications included in PGDs for **administration** of a GSL, P or medicines exempt under schedule 17 or 19 of the Human Medicines Regulations (HMR) 2012? | |  |
| **B8** | Are any of the medications included in PGDs for **supply** of a GSL, (P if only from a registered pharmacy) or medicines exempt under schedule 17 of the HMR 2012? | |  |
| **B9** | Are all medicine packs supplied in their original pack (or a licensed pre pack) when supplied under a PGD? (i.e. packs not split) | |  |
| **B10** | Do all medicines supplied under any PGD have appropriate instruction labels on the pack including the Trust's name, address and contact details? | |  |

C – Operational  
Staff factors/service level factors (to complete for each service using PGDs)

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|  | **Questions** | **Yes/No** |
| **C1** | Do staff always have access to a copy of the latest version of the PGD they are working under available for reference at the time of the consultation? |  |
| **C2** | Have all staff working under the PGD signed the latest version of that PGD? |  |
| **C3** | Are all staff working under the PGD competent to work under that PGD? (Either signed off by their senior clinician/manager or self-certified.) |  |
| **C4** | Are all staff authorised to work under the PGD employed as one of the registered health professions listed in the PGD? |  |
| **C5** | Is there an up-to-date list held within the service, of all staff authorised to work under each PGD in use? |  |
| **C6** | Have all staff completed the necessary training and continuing professional development specified in the PGD/s they are authorised to work under? |  |
| **C7** | Is there an up-to-date record within the service of all staff who have attended any required specific PGD training? |  |

D – Clinical patient factors/clinician decision factors  
To complete at individual PGD level either in a single service/clinical area or across all services/areas using the named PGD

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|  | **Questions**  (to be answered by retrospective review of clinical records – state number of records reviewed and rationale for sample size) | **Yes/No** |
| **D1** | Is the clinical indication (which is listed in the PGD’s inclusion criteria) stated in the patient's record? |  |
| **D2** | Is there a record of all of the following: patient's full name, date of birth, registered GP (where applicable) |  |
| **D3** | Is there a statement in the patient’s record that supply and/or administration of the medicine was made using a PGD? |  |
| **D4** | Is there a record of any written or verbal information/advice that was given to the patient when supplying/administering any medicine under any given PGD? |  |
| **D5** | Is there a record of the patient’s consent? |  |
| **D6** | If the patient was excluded, is the reason recorded? |  |
| **D7** | If the patient was excluded, is there a record of action taken? |  |
| **D8** | If the patient refused treatment, is there a record of advice provided on alternatives/risk of no treatment? |  |
| **D9** | Is there a register or other record of stock received and issued to patients under this PGD? |  |
| **D10** | Does the Patient Record contain details of the medicine supplied or administered (name, strength, dose, quantity, route)? |  |
| **D11** | For vaccines, (or other medicines in line with local procedure) is both the batch number and expiry date recorded? |  |
| **D12** | For injectable or topical medicines and implants is the site of administration recorded? |  |
| **D13** | Is the date of supply or administration recorded? |  |