



**Royal  
Pharmaceutical  
Society  
of Great Britain**

**Clinical Governance Framework for Pharmacist Prescribers and organisations commissioning or participating in pharmacist prescribing (GB wide)**

1. The quality and safety of health care provided to patients is a priority for all health care professionals. Pharmacists have a variety of opportunities to provide a broad range of services to patients and improve access and usage to medicines. Prescribing is a developing and expanding role for pharmacists and it is important that it is conducted in a safe and effective manner
2. The Health Departments across the UK have set out the steps NHS organisations have to put in place to ensure the implementation of clinical governance<sup>1 2 3</sup> These include:
  - Clear lines of responsibility and accountability for overall quality of clinical care
  - Development of quality improvement programmes i.e. clinical audit, supporting evidence-based practice, implementation of clinical standards, monitoring of clinical care, workforce planning and development, access to appropriate CPD programmes
  - Management of risk
  - Procedures to identify and remedy poor performance
3. Ensuring patient safety is an integral part of all healthcare providers' clinical governance programmes.<sup>4</sup> When healthcare organisations put pharmacists forward to undertake prescribing training (or if pharmacists already qualified as pharmacist prescribers join the organisation) they should ensure

<sup>1</sup> Clinical Governance: Quality in the new NHS. HSC 1999/065

<sup>2</sup> Clinical Governance Guidance WHC(99)54

<sup>3</sup> Clinical Governance MEL(98)75

<sup>4</sup> Building a safer NHS for patients: implementing an organisation with a memory. DoH 2001.

appropriate and robust systems are in place to incorporate prescribing into their organisation's existing and future clinical governance arrangements. There should also be systems in place to assess the competence of the potential pharmacist prescriber, including their clinical knowledge, before they are recommended for training. Chief Pharmacists / Senior Pharmaceutical Advisers of NHS Trusts and Primary Care Organisations (PCOs) should be proactive in this respect, liaise closely with local clinical governance leads, and ensure their participation in clinical governance arrangements for prescribing.

4. The Royal Pharmaceutical Society of Great Britain (RPSGB) Code of Ethics and Standards details specific professional obligations for pharmacist prescribers that require pharmacists to prescribe responsibly and in their patient's best interest (Annex A). The RPSGB has also produced this clinical governance framework to support the development of high quality care and patient safety in this particular area of practice. This clinical governance framework should be used in conjunction with the competency framework for pharmacist supplementary prescribers developed by the National Prescribing Centre (NPC)<sup>5</sup>. Whilst the NPC document mainly focuses on the competency requirements of pharmacist prescribers, its implementation will form only one part of the local clinical governance arrangements for prescribing.
5. This framework for pharmacist prescribing has been developed from two distinct viewpoints:
  - Firstly from an organisational perspective. This looks at the organisational components of clinical governance and what might need to be put in place within the organisation in order to support clinical governance of pharmacist prescribing. Such organisations include PCOs, NHS Trusts, the private and voluntary healthcare sector and all organisations who employ Pharmacist Prescribers (PP) providing care to both NHS and non-NHS patients.
  - Secondly from an individual PP point of view. This guideline provides some suggested indicators of good practice for pharmacist prescribing and examples of good clinical governance practice relating to prescribing.

Many of the recommendations in this framework need to be implemented as part of the wider organisational work on managing prescribing and medicines management.

Where we have identified additional / different requirements for Pharmacist Supplementary Prescribers (PSP), from Pharmacist Prescribers (PP) in general, these are highlighted in *italics*.

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<sup>5</sup> [http://www.npc.co.uk/publications/maint\\_compt\\_presc/outline\\_framework.pdf](http://www.npc.co.uk/publications/maint_compt_presc/outline_framework.pdf)

## 6. Recommendations for Organisations commissioning or participating in Pharmacist Prescribing

### 6.1 Recommendations for NHS Organisations

Component of Clinical Governance	Recommendation to NHS Organisations
Clear lines of responsibility and accountability for overall quality of clinical care	Pharmacist prescribing is included in reports on quality of clinical care to local Clinical Governance Committees or equivalent
	Pharmacist prescribing forms part of local organisational Clinical Governance Action Plans
Clinical audit	Clinical audit units incorporate PPs within their audit programmes
	Prescribing by <u>PPs</u> is monitored regularly (in line with other prescribers) using prescribing or medicines usage information systems (such as ePACT) as part of the wider monitoring of prescribing by all prescribers. The review should consider choice and range of medicines prescribed in relation to scope of practice. <i>In addition for <u>PSPs</u> only, prescribing is in line with clinical management plans (CMP).</i>
Evidence based practice	Ensure that information about national guidelines (e.g. NICE guidelines, NSFs), local guidelines, local agreements and formularies are disseminated to all PPs
Monitoring of clinical care	Patient's experience of pharmacist prescribing is included in surveys of patient's experience of health services
Workforce planning and development is integrated in organisations' service planning	Ensure that the ongoing Continuing Professional Development (CPD) needs of PPs, identified as part of PDP, are included in workforce development plans. Ensure succession planning and contingency plans are in place to ensure continuity of services. Ensure patients are involved in the development of these services and their opinions are taken into account
Risk management programmes	Pharmacist prescribing should be included in clinical risk management (including Root Cause Analysis), patient safety (including the NPSA National Reporting and Learning Scheme), confidentiality, handling complaints and controls assurance programmes

***All of the above recommendations are equally applicable to the private and voluntary health sectors.***

## 6.2 Recommendations for employers of pharmacist prescribers:

The table below highlights additional recommendations for all employers including non-NHS employers, e.g. pharmacy contractors, who employ PPs who are providing services to NHS and non-NHS patients.

Component of Clinical Governance	Recommendation to Employers
Monitoring of clinical care	Pharmacist prescribers should participate in clinical governance programmes for prescribing, and be supported to do this
Continuing professional development programmes are in place	The NPC competence framework for <i>PSPs</i> should be used to identify gaps and learning needs that will form the basis of the PPs personal development plans (PDP).
	PPs will need to satisfy RPSGB requirements for CPD and should have time to access programmes and resources to meet their CPD needs
	The development of peer review, support and mentoring, possibly through the development of learning sets <sup>6</sup> for pharmacist prescribers, should be supported. Peer review should be carried out within an agreed structure and should concentrate on appropriate elements and protect commercially sensitive information.
	Appropriate CPD should be undertaken to support the extension of prescribing practice into other clinical areas
	<i>PSP are required to have regular (normally at least annual) meetings with the independent prescribers to review CMPs</i>
Poor performance programme	All organisations employing pharmacist prescribers should have systems in place for identifying poor professional performance as for other prescribers. Prescribing responsibilities need to be considered as part of this process

<sup>6</sup> Learning set – a group of “like” minded individuals who choose to form a group in order to undertake some form of learning together

### **6.3 Recommendations to individual pharmacist prescribers**

The proposed indicators and examples of good clinical governance practice (Annex B) have been developed to help individual pharmacist prescribers (PP) ensure that their practice is safe and of a high standard. Patient safety is of paramount importance within all aspects of prescribing and medicines management.

It is also incumbent on pharmacists as health care professionals to practice within the law, to a high professional standard, and to ensure that they strive to continuously improve the quality of care that they offer to patients. Poor professional performance needs to be identified and rectified at an early stage. A clinical governance framework, used in association with the NPC competency framework for PSPs, can help to identify what is good practice by the use of indicators of good practice.

### **6.4 Suggested indicators of good practice for pharmacist prescribers**

The pharmacist prescriber:

1. Communicates with patients / carers in a way that allows the pharmacist prescriber to understand the patient's needs, concerns and expectations about their medicines and enables the patient to make an informed choice about their treatment (including the risks and benefits).
2. Prescribes within their own competence and within their own scope of practice
3. Prescribes safely, appropriately, clinically and cost effectively
4. Monitors responses to therapy and modifies treatment or refers appropriately
5. Does not prescribe for themselves or anyone else with whom they have a close personal relationship (e.g. family and friends), other than in an emergency. Further guidance on what constitutes an emergency will be issued in due course but it would need to be in exceptional circumstances where there are no other reasonable options available without compromising patient care.
6. Develops an effective relationship with the wider primary care team
7. Writes prescriptions clearly and legibly, and ensures that they are identifiable as the prescriber. (PPs should have their own prescription pad and preferably generate printed prescriptions)

8. Does not direct prescriptions they have written to their pharmacy or any other pharmacy in particular
9. Preferably prescribes only when they have access to an individual patient's main medical record at the time of prescribing. In the future this will be accessed via an individual patient's Electronic Patient Record. This may only be possible once IT allows sharing of records.
10. Makes a contemporaneous, comprehensive, clear record of their consultation and prescription for an individual patient in the main medical record. Where it is not possible for a PP to make a contemporaneous record in the main medical record, they should make a contemporaneous record, which is then added to the main medical record within 48 hours of the consultation.
11. Stores prescription pads safely and takes appropriate action if they are lost or stolen
12. Must not ask for or accept any inducement, gift or hospitality which may affect or be seen to affect their judgement when making a prescribing decision
13. Regularly participates in CPD relating to prescribing and maintains a record of their CPD activity within their CPD portfolio
14. Ensures separation of the prescribing and dispensing wherever possible. Where the pharmacist is both prescribing and dispensing for an individual patient, a suitably competent second person (as designated in the pharmacy Standard Operating Procedure) should be involved in accuracy checking of the dispensed medicine. If the pharmacist does both prescribe and dispense for the patient without the involvement of a suitably competent second person then records should be made to ensure good clinical governance and probity
15. Carries out any relevant physical examinations of patients competently and with regard to the patient's dignity and privacy.

Additional indicators for PSPs

16. *Prescribes according to the clinical management plan (CMP) agreed with the Independent Prescriber, for an individual patient.*
17. *Refers all individual patient circumstances that fall outside the clinical management plan, or outside the PSP's competency, to an Independent Prescriber who is responsible for that patient's care.*
18. *Develops an effective relationship with the independent prescriber and participates as a member of the wider primary care team*

## **Annex A Code of Ethics and standards Service Specification for Pharmacist Prescribers**

Before prescribing, pharmacists must successfully complete an education and training programme accredited by the Society and must register with the Society as a pharmacist prescriber. Pharmacists must only prescribe within the limits of their registration and must comply with the statutory requirements applicable to their prescribing. Pharmacists have an obligation to prescribe responsibly and in their patient's best interests and must:

- a) prescribe within the limits of their professional expertise and competence
- b) not prescribe for themselves, or for anyone with whom they have a close personal or emotional relationship, other than in an emergency
- c) make an appropriate assessment of the patient's condition and only prescribe to meet the patient's genuine clinical needs
- d) prescribe only where they have an adequate knowledge of the patient's health and medical history
- e) be aware of and give consideration to local and national prescribing guidelines
- f) keep accurate comprehensive records of their consultation and prescribing for an individual patient
- g) communicate effectively with other practitioners involved in the care of the patient
- h) refer the patient to another practitioner when it is necessary to do so
- i) prescribe in accordance with a patient's individual clinical management plan when prescribing as a supplementary prescriber. Refer the patient back to the independent prescriber when their circumstances fall outside the clinical management plan
- j) ensure separation of prescribing and dispensing whenever possible. Where a pharmacist is both prescribing and dispensing a patient's medication a second suitably competent person should normally be involved in the checking process.

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## Annex B Examples of Good Clinical Governance Practice

The final section of this framework has been developed using the "Standards for Better Health"<sup>7</sup> and from the main components of clinical governance identified in HSC 1999/065 (England)<sup>1</sup> WHC (99) 54 (Wales)<sup>2</sup> and MEL(98)75<sup>3</sup> (Scotland). In addition to indicators of good practice given above we have identified a number of examples of good clinical governance practice relating to prescribing which PPs and organisations may wish to aspire to. These examples are listed below.

Component of Clinical Governance	Exemplar clinical governance practice for pharmacist prescriber	Examples of Evidence
Clear lines of responsibility and accountability for overall quality of clinical care	<i>PSP agrees with the independent prescriber how continuity of patient care is maintained when they are not available (i.e. annual leave, sick leave)</i>	<i>Written procedure in place</i>
	PP is aware of, and complies with local, national and professional standards relating to dealing with the pharmaceutical industry	PP declaration of interests held by Trust or employer
Clinical audit	PP participates in local clinical audit activity relating to their scope and quality of prescribing practices e.g. asthma audit	Report of outcome of audit
	Audit / Clinical Governance arrangements should allow pharmacists to reflect on their prescribing practice. Use of the competency framework produced by the NPC is recommended	Reflective learning is recorded in CPD record
Clinical Guidelines and Evidence based practice	PP keep up to date with and prescribes according to local or national standards and guidelines, with reference to best evidence based practice	Results of procedures for monitoring and auditing prescribing patterns.  Reflective learning included in CPD portfolio
Clinical Guidelines and Evidence based practice continued	<i>Patient specific CMPs are developed and kept up to date. CMPs will refer to national and local guidelines where appropriate.</i>	<i>Within CMPs guidelines are referenced, and CMPs include date of development and date of review</i>

<sup>7</sup> Standards for Better Health

<sup>1</sup> Clinical Governance - Quality in the new NHS. HSC 1999/065

<sup>2</sup> Clinical Governance Guidance WHC(99)54

<sup>3</sup> Clinical Governance MEL(98)75



<b>Component of Clinical Governance</b>	<b>Exemplar clinical governance practice for pharmacist prescriber</b>	<b>Examples of Evidence</b>
Continuing professional development	PP maintains a CPD portfolio, including a review of prescribing related critical incidents and learning from them, although critical incidents may be recorded in a separate log	Reflective learning included in CPD portfolio
	PPs participates in local prescriber learning set or peer support group	Reflective learning included in CPD portfolio
	PPs, in conjunction with their line managers, identifies their training needs in relation to prescribing, and develops ways of meeting these needs	Training needs identified in CPD portfolio or PDP, and evidence of learning and development undertaken recorded
	<i>PSP participates in regular (normally at least annually) meeting with the independent prescriber to review CMP, discuss working arrangements and review patient care</i>	<i>Learning points from these meetings are included in the PSP's CPD portfolio</i> <i>Notes of the meeting are made and identify action required</i>
		<i>Where possible Independent prescriber contributes to the PSP annual appraisal by their line manager, although problems should be discussed as they arise</i>
Monitoring of clinical care	PPs participate in audits of clinical record keeping and medicines monitoring information.	Report of outcome of audit, reflective learning included in CPD portfolio
	PPs participates in audits of the communication pathways they use, to ensure the correct patient information (relating to prescribing) is included in a timely manner in patients medical notes, or when care is transferred to another prescriber	Report of outcome of audit
	PPs audits whether individual patients have received appropriate information about their prescribed medication	Report of outcome of audit using SIMS tool <sup>8</sup>

<sup>8</sup> Horne R, Hankins M, Jenkins R. The Satisfaction with Information about Medicines Scale (SIMS): a new measurement tool for audit and research. Qual Health Care 2001;10:135-140.

<b>Component of Clinical Governance</b>	<b>Exemplar clinical governance practice for pharmacist prescriber</b>	<b>Examples of Evidence</b>
Research and Development	PPs reviews their practice with a view to research potential	Outcome of research
Risk management	PPs participates in a local clinical risk assessment and management programmes	Copy of local policy held by PPs and systems are developed for formal recording of risks and evaluation of risk arising from prescribing decisions
	PPs report any relevant adverse drug reactions via the CSM scheme	Record of ADRs reported by PPs
	PPs participates in, and reports critical incidents as part of the local critical incident reporting system (including the NPSA National Reporting and Learning Scheme)	Record of critical incidents reported by PPs
	PPs are aware of local patient complaints procedures (organisational and individual pharmacies)	Copy of local complaints procedure held by PPs
	PPs ensure they have an appropriate level of professional indemnity insurance	Explicit confirmation that their insurance is commensurate with the service they provide
	PPs use complaints and compliments to identify learning needs and areas for improvement.	Reflective learning included in CPD portfolio

***Additional reading:***

The outline curriculum for training programmes to prepare pharmacist supplementary prescribers at [www.rpsgb.org.uk/pdfs/supplprescphoutlcurric.pdf](http://www.rpsgb.org.uk/pdfs/supplprescphoutlcurric.pdf)