

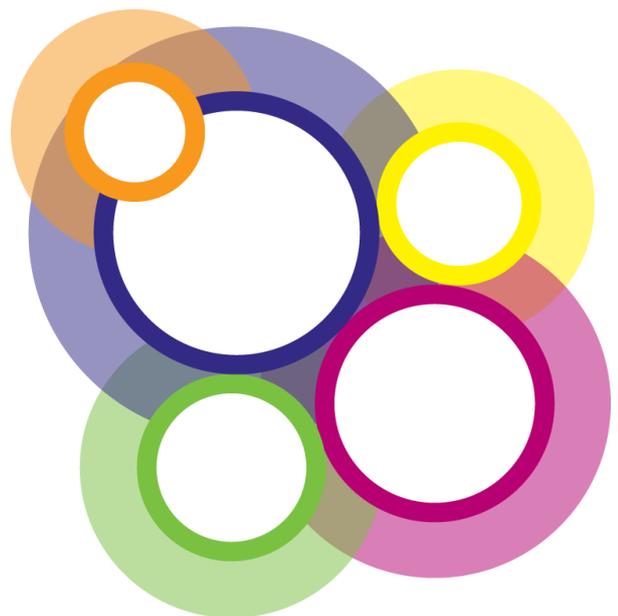


# Medicines Optimisation

## *Care Quality Commission Inspections – Managing Medicines in a GP Practice Resource*

<b>MO Reference Number</b>	MOPT- 002
<b>Version Number</b>	3
<b>Version issue date:</b>	24/04/18
<b>Date of MO Q&amp;G approval:</b>	24/04/18
<b>Date of review:</b>	April 2020

<b>Author Name</b>	<b>Email Address</b>
Katie Mellor	<a href="mailto:katie.mellor@cumbria.necsu.nhs.uk">katie.mellor@cumbria.necsu.nhs.uk</a>
Helena Gregory	<a href="mailto:helena.gregory@cumbria.necsu.nhs.uk">helena.gregory@cumbria.necsu.nhs.uk</a>



## 1. Introduction

This document is a resource for managing medicines in a GP practice to help you prepare for this aspect of a Care Quality Commission (CQC) inspection. The document also signposts to other sources of support, in order to implement best practice. Each section details the actions and resources supporting CQC inspection requirements and is linked to the relevant standards (key lines of enquiry (KLOE)) from the CQC website (see link in resources section). A template implementation plan that can be used to measure and improve practice performance in these areas is available on [Page 19](#). For further information and support please contact your Medicines Manager or Medicines Optimisation (MO) Pharmacist.

This document does not cover all areas of a CQC inspection.

### These are the key lines of enquiry that CQC inspectors use:

- Safe
- Effective
- Caring
- Responsive to needs
- Well-led

### Meeting the needs of these target patient groups:

- Elderly
- Long term conditions
- Families, children and young people
- People of working age
- Vulnerable people
- Poor mental health

## 2. General points for the inspection

### 2.1. Actions

- During the CQC inspection you will be asked to showcase your practice in a presentation. Try to cover as many as possible of the KLOE and target patient groups during the presentation, including examples. Identify any outstanding achievements or projects that worked well and produced results e.g. reduction in antibiotic prescribing. Also include audits that resulted in the need for change and any work planned or in progress, even if not complete.
- Practices should have Standard Operating Procedures (SOPs) covering all of the aspects of prescribing and medicines handling outlined in the table, including Controlled Drugs (CDs). All SOPs relating to medicines should have a review date. They should be reviewed annually (by a designated

---

MOPT-002 - V3 - Managing Medicines in General Practice a resource to support CQC inspection (2).docx	Status: Approved	Next Review April 2020
©NHS Commissioning Board. Developed by North of England Commissioning Support Unit 2018	Approved date: 24/04/18	Page 2 of 21

member of staff) or more often if changes in legislation, evidence, national or local guidance or best practice occur. Template SOPs are available from many sources, but these must be amended to reflect what happens in your practice and should name the person or role responsible (including deputies in case of absence) for any actions they may contain. It is advisable to have these SOPs (including CD documentation) easily available for staff and inspectors, either paper or electronically.

- CQC inspectors focus on use of information within the practice, including:
  - dissemination to relevant staff
  - opportunities for reflection
  - actions to be carried out
- This might take place via practice meetings, protected practice learning time (PLT), practice intranet, email, system tasks and noticeboards. The best method of communication for your practice should be utilised for each of the standards and kept up to date as necessary.

## 2.2. Resources

- The North of England Commissioning Support (NECS) MO website has a range of resources to support you with your CQC inspection, including CDs, local guidelines and repeat prescribing: <http://medicines.necsu.nhs.uk>
- The CQC updated their key lines of Enquiries in November 2017. The link below includes the changes:  
<http://www.cqc.org.uk/sites/default/files/20171020-healthcare-services-kloes-prompts-and-characteristics-showing-changes-final.pdf>
- The CQC website has helpful information (Guidance for Providers) and links (“Nigel’s Surgery” is especially helpful): <http://www.cqc.org.uk/guidance-providers/gps>
- Many of the CQC standards support the National Institute of Health and Care Excellence (NICE) Guideline NG5 on Medicines Optimisation. The guideline and supporting information can be found at:  
<https://www.nice.org.uk/guidance/ng5>

MOPT-002 - V3 - Managing Medicines in General Practice a resource to support CQC inspection (2).docx	<b>Status:</b> Approved	<b>Next Review April 2020</b>
©NHS Commissioning Board. Developed by North of England Commissioning Support Unit 2018	<b>Approved date:</b> 24/04/18	Page 3 of 21

### 3. CQC KLOE

The five key questions the inspectors ask (KLOE) are linked to each area of medicines management in the text below. This allows practice activities to be linked back to CQC requirements during preparation for the inspection, including the presentation. Details of the KLOE are available in the CQC provider handbook appendix.

#### 3.1. Secure storage and control of prescriptions

##### 3.1.1. Actions

- EPS2 and eRD systems provide enhanced security, reducing the risk of prescriptions being lost, missing or stolen. Electronic prescriptions can be traced using the NHS Digital Prescription Tracker.
- To ensure the practice adhere to information governance legislation, make sure stored paper prescriptions are locked away, personal data is made secure and doors to consulting rooms are locked when not in use.
- There must be a system in place to record blank paper prescriptions received and track them in the practice. This would ensure that the practice were able to identify the numbers involved should any go missing.
- Make sure there is a system in place for paper prescriptions that are not collected from reception (generally over 4 weeks old). Mark any uncollected scripts as such on the clinical system before disposing of them confidentially. In exceptional circumstances, e.g. a patient suffering from mental ill-health we would expect staff to task the patients usual GP to make them aware.

##### 3.1.2. Resources

- The Model Repeat Prescribing System is available on the NECS MO website <http://medicines.necsu.nhs.uk/download/model-repeat-prescribing-system/>
- Where a GP joins or leaves the practice:
  - NECS briefing: what to do when prescribers join or leave a GP practice: <http://medicines.necsu.nhs.uk/download/what-to-do-when-prescribers-join-or-leave-a-gp-practice-briefing-document/>
  - NHS Business Services Authority – GPs within a Clinical Commissioning Group (CCG): <http://www.nhsbsa.nhs.uk/PrescriptionServices/3973.aspx>
- CQC myth buster: <http://www.cqc.org.uk/content/nigels-surgery-23-security-blank-computer-prescription-forms>
- Guidance on CD prescriptions, requisition forms and private prescriptions for CDs. <http://medicines.necsu.nhs.uk/controlled-drugs/guidance-documents/>

---

MOPT-002 - V3 - Managing Medicines in General Practice a resource to support CQC inspection (2).docx	Status: Approved	Next Review April 2020
©NHS Commissioning Board. Developed by North of England Commissioning Support Unit 2018	Approved date: 24/04/18	Page 4 of 21

- NHS Counter Fraud Authority (NHSCFA) will use information from a wide range of sources to build a better understanding of the fraud risks faced by the NHS and develop creative, innovative and proportionate solutions to tackle fraud.
  - Guidance on security of prescriptions  
[https://cfa.nhs.uk/resources/downloads/guidance/Management%20and%20control%20of%20prescription%20forms\\_v1.0%20March%202018.pdf](https://cfa.nhs.uk/resources/downloads/guidance/Management%20and%20control%20of%20prescription%20forms_v1.0%20March%202018.pdf)
  - Aide memoires for practice managers and clinicians:  
<https://cfa.nhs.uk/resources/downloads/guidance/Aide-memoire%20for%20practice%20managers.pdf>  
<https://cfa.nhs.uk/resources/downloads/guidance/Aide-memoire%20for%20prescribers.pdf>

### 3.1.3. CQC KLOE

- Safe: S3, S4.1
- Caring: C3.3

## 3.2. Medicines safety information

### 3.2.1. Actions

- Have a robust system for checking that medicines safety and drug alert information is disseminated, actioned and collated, including any rationale for not following the recommendations.
- Have a SOP detailing the action to take in the event of a medication safety alert, including recording and communication to appropriate staff and follow up if necessary.
- An appropriate review of the affected patients should be undertaken and documented in their notes.
- Clinical codes should be used consistently to record interventions on patient records.

### 3.2.2. Resources

- Sign up with the Medicines and Healthcare Products Regulatory Agency (MHRA) to receive alerts directly: <https://www.gov.uk/drug-device-alerts>
- Use the Reporting Analysis and Intelligence Delivering Results (RAIDR) patient safety dashboard to identify patients who may be at risk of medicines safety incidents: <https://nww.raidr.nhs.uk/>
- Safeguard Incident and Risk Management System (SIRMS) to record any incidents where actions from an external clinician or provider have impacted on patient safety or care: <https://sirms.necsu.nhs.uk/>

MOPT-002 - V3 - Managing Medicines in General Practice a resource to support CQC inspection (2).docx	Status: Approved	Next Review April 2020
©NHS Commissioning Board. Developed by North of England Commissioning Support Unit 2018	Approved date: 24/04/18	Page 5 of 21

### 3.2.3. CQC KLOE

- Safe: S3, S4, S5, S6
- Effective: E1, E5
- Well-led: W1, W5

## 3.3. Learning from incidents

### 3.3.1. Actions

- Have a system and protocol in place to review incidents, including ensuring learning and reflection from incidents is shared within the practice and with affected patients (where applicable) as part of the resolution process.
- This applies to an incident involving prescribing or dispensing, just as much as any other patient safety incident or safeguarding concern.
- CQC state that within a 'good' practice all staff should be open and transparent and fully committed to reporting incidents and near misses.
- The Duty of Candour sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things go wrong.

### 3.3.2. Resources

- CQC recommend reflecting on incidents using Significant Event Analysis: <https://www.cqc.org.uk/content/nigels-surgery-3-significant-event-analysis-sea>
- Explanation of what is expected in the Duty of Candour Regulation
- <http://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-32-duty-candour-general-practice-regulation-20>
- National Reporting and Learning System reporting: <https://www.cqc.org.uk/content/nigels-surgery-24-reporting-patient-safety-incidents-national-reporting-and-learning-system>
- Use Safeguard Incident and Risk Management System (SIRMS) to record any incidents where actions from an external clinician or provider have impacted on patient safety or care: <https://sirms.necsu.nhs.uk/>

---

MOPT-002 - V3 - Managing Medicines in General Practice a resource to support CQC inspection (2).docx	Status: Approved	Next Review April 2020
©NHS Commissioning Board. Developed by North of England Commissioning Support Unit 2018	Approved date: 24/04/18	Page 6 of 21

## CQC KLOE

- Safe: S1, S3, S6
- Effective: E2, E5
- Caring: C2
- Responsive: R1, R4
- Well-led: W1, W2, W3, W4, W5

### 3.4. Transfer of care and medicines reconciliation

#### 3.4.1. Actions

- Have a system and SOP in place for a timely review of hospital discharge and advisory letters which contain information about medicines.
- Any changes to prescribed medication by a non-prescriber must be reviewed and checked by a GP or other appropriate prescriber before changes are made to a patient's record. If medication is updated by a non-prescriber, the changes must be checked by a GP or other appropriate prescriber before being issued. This check must be documented and be auditable.
- Clinical codes should be used consistently to record interventions on patient records.

#### 3.4.2. Resources

- NICE Quality Standards are one way for practices to demonstrate that the care they are delivering is high quality and evidence based. For example: Medicines Optimisation, Quality Statement 5: Medicines reconciliation in primary care: <https://www.nice.org.uk/guidance/qs120/chapter/Quality-statement-5-Medicines-reconciliation-in-primary-care>
- Guidance to help ensure safe and effective medicines optimisation. Medicines Optimisation: the safe and effective use of medicines to enable the best possible outcomes. NICE Guideline 5: <https://www.nice.org.uk/guidance/ng5/chapter/1-Recommendations>
- Royal College of General Practitioners (RCGP) Patient Safety Audit toolkits: medicines reconciliation tool: <http://www.rcgp.org.uk/clinical-and-research/toolkits/patient-safety.aspx>

#### 3.4.3. CQC KLOE

- Safe: S3 S4.5
- Effective: E4, E5, E6
- Responsive: R3
- Well-led: W2

---

MOPT-002 - V3 - Managing Medicines in General Practice a resource to support CQC inspection (2).docx	Status: Approved	Next Review April 2020
©NHS Commissioning Board. Developed by North of England Commissioning Support Unit 2018	Approved date: 24/04/18	Page 7 of 21

### 3.5. Repeat prescribing systems

#### 3.5.1. Actions

- Practices should have robust and safe systems for issuing repeat prescriptions for patients. The default choice should be electronic prescribing and if appropriate, electronic repeat dispensing. The GMS contract promotes the use of online ordering for patients.
- It is good practice to link medications to their indications on the patient records.
- Clinical codes should be used consistently to record interventions on patient records.
- Use shared decision making to involve patients in decisions about their care.
- When reviewing/auditing the repeat prescribing system involve patient participation groups to produce a system that is both convenient for the patient and the practice.

#### 3.5.2. Resources

- The Model Repeat Prescribing System is available on the NECS MO website: <http://medicines.necsu.nhs.uk/download/model-repeat-prescribing-system/>
- The Model Repeat Prescribing System contains an audit that can be used to identify areas that could be reviewed to improve the system. This should ideally be carried out annually.

#### 3.5.3. CQC KLOE

- Safe: S4, S5
- Effective: E1, E5
- Caring: C2, C3
- Responsive: R2, R3
- Well-led: W2, W7

### 3.6. Initiation of prescription or treatment

#### 3.6.1. Actions

- Demonstrate that patients/carers are involved in and understand decisions that are made about them. Shared decision-making is an essential part of evidence-based medicine, seeking to use the best available evidence to guide decisions about the care of the individual patient.
- Take a person-centred approach when reviewing/prescribing medicines for the patient:
  - Consider interlinked symptoms, co-morbidities and medication related side effects.
  - Discussion with the patient about the risks and benefits of the interventions, and their values and preferences, aims to help them to

---

MOPT-002 - V3 - Managing Medicines in General Practice a resource to support CQC inspection (2).docx	Status: Approved	Next Review April 2020
©NHS Commissioning Board. Developed by North of England Commissioning Support Unit 2018	Approved date: 24/04/18	Page 8 of 21

reach a fully informed decision taking into account their knowledge, beliefs, culture and values.

- Further information to aid the assessment of benefits versus risks is available from a variety of sources, including patient decision aids, number needed to treat and number needed to harm.
- When starting a medication, it should be considered as part of the overall management package for the condition, alongside appropriate lifestyle and non-medicinal interventions.

### 3.6.2. Resources

- NICE information on shared decision making: More information can be found at: <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/shared-decision-making>

### 3.6.3. CQC KLOE

- Safety: S4.2, S4.3, S4.4, S4.6, S4.7
- Effective: E5.1, E5.2, E5.3, E5.4, E5.5
- Caring: C1, C2, C3

## 3.7. Vulnerable Patients

### 3.7.1. Actions

- CQC will look at whether practices provide care that is safe, effective, caring, responsive and well-led for six different population groups including vulnerable people.
- GPs and their staff should have a good understanding of the Mental Capacity Act (MCA) 2005 and the Deprivation of Liberty Safeguards (DoLS) to ensure that they can act in a patient's best interest. For vulnerable patients lacking capacity, this might apply to choice of or covert medication.
- GP practices should have a palliative care register to support end of life care. This should include people with conditions other than cancer, and people with frailty and dementia who may be in the last year of life.
- Have early and ongoing conversations about end of life care in the last phase of life. Each patient should have a named care coordinator who is the lead professional who coordinates services around them.
- CQC will expect to see a plan as to how GPs are trying to find their 1% on the palliative care register and also how they are aiming to identify people with a non-cancer diagnosis. They would also expect there to be a plan as to how to improve end of life care for people from equality groups.
- Practices should engage with local initiatives around the STOMP agenda (stopping over-medication of people with a learning disability). Other examples of outstanding practice for patients with learning disabilities:

---

MOPT-002 - V3 - Managing Medicines in General Practice a resource to support CQC inspection (2).docx	Status: Approved	Next Review April 2020
©NHS Commissioning Board. Developed by North of England Commissioning Support Unit 2018	Approved date: 24/04/18	Page 9 of 21

- Adopting electronic templates for the annual health check to produce a Health Action Plan that is meaningful, easy to understand and is followed up.
- Including people with learning disability and their carers in patient forums.
- Pro-active systems to target people with learning disability for screening and immunisation.
- Consider innovative methods to support finding undiagnosed dementia patients. Patients with dementia may need support with their medication including: review of medication which contributes to cognitive impairment, simplified regimes and prompts to take medication.

### 3.7.2. Resources

- Nigel’s Surgery tips provides a summary:  
<http://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-10-gps-mental-capacity-act-2005-deprivation-liberty-safeguards>
- Five priorities for the care of a dying person:  
[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/323188/One\\_chance\\_to\\_get\\_it\\_right.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/323188/One_chance_to_get_it_right.pdf)
- What CQC expect to see with respect to patients with learning disabilities:  
<http://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-53-care-people-learning-disability-gp-practices>
- Good practice and tools for use in care homes:  
<http://medicines.necsu.nhs.uk/necs-good-practice-guidance-and-tools-for-care-homes/>
- North Cumbria CCG’s policy on deprivation of liberty safeguards:  
<http://northcumbriaccg.nhs.uk/about-us/key-policies-and-documents/cumbria-policy-deprivation-of-liberty-safeguards-quoc-approved.pdf>
- NHS England STOMP guidance and resources:  
<https://www.england.nhs.uk/learning-disabilities/improving-health/stomp/>

### 3.8. Medication review

#### 3.8.1. Actions

- Clinical staff should be responsible for clinical aspects of medicines re-authorisation and medication review.
- Relevant and current evidence-based guidance, standards, best practice and legislation should be identified, shared and used to develop how care and treatment are delivered.
- Include therapeutic drug and physical health monitoring in the medication review e.g. mental health review.

MOPT-002 - V3 - Managing Medicines in General Practice a resource to support CQC inspection (2).docx	<b>Status:</b> Approved	<b>Next Review April 2020</b>
©NHS Commissioning Board. Developed by North of England Commissioning Support Unit 2018	<b>Approved date:</b> 24/04/18	Page 10 of 21

- Prioritise patients over 75 years on 15 or more medicines. Take into account the patient's anticholinergic burden (see STOPP START booklet) and medicines that can cause acute kidney injury.
- Signpost to Community Pharmacists for a Medicines Use Review (MUR) and other relevant services, especially patients in the following target groups:
  - Patients taking high risk medicines;
  - Patients recently discharged from hospital with changes to their medicines.
  - Patients with respiratory disease
  - Patients at risk of or diagnosed with cardiovascular disease and prescribed at least four repeat medicines.
- See section 3.6 for actions on shared decision making.

### 3.8.2. Resources

- Medication review: a practice guide is available on the NECS MO website to support clinicians with the process of medication review:  
[http://medicines.necsu.nhs.uk/download/medication\\_review\\_practice\\_guide\\_2\\_013-pdf/](http://medicines.necsu.nhs.uk/download/medication_review_practice_guide_2_013-pdf/)
- To assist in carrying out medication reviews, the STOPP START 2 booklet is available on the NECS MO website:  
<http://medicines.necsu.nhs.uk/download/stopp-start-2-cumbria-screen-version/>
- NICE information on shared decision making: More information can be found at: <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/shared-decision-making>
- Suggestions for Therapeutic Drug Monitoring in adults:  
[https://www.sps.nhs.uk/wp-content/uploads/2017/12/Drug-monitoring\\_October-2017.pdf](https://www.sps.nhs.uk/wp-content/uploads/2017/12/Drug-monitoring_October-2017.pdf)
- The BMA have guidance on excessive prescribing that supports the GMS contract: <https://www.bma.org.uk/advice/employment/gp-practices/service-provision/prescribing/focus-on-excessive-prescribing>
- Advice and resources on acute kidney injury:  
<https://www.thinkkidneys.nhs.uk/>

### 3.8.3. CQC KLOE

- Caring: C1, C2, C3
- Safety: S4.2, S4.3, S4.4, S4.6, S4.7
- Effective: E5.1, E5.2, E5.3, E5.4, E5.5

MOPT-002 - V3 - Managing Medicines in General Practice a resource to support CQC inspection (2).docx	Status: Approved	Next Review April 2020
©NHS Commissioning Board. Developed by North of England Commissioning Support Unit 2018	Approved date: 24/04/18	Page 11 of 21

### 3.9. Stock control, storage and waste

#### 3.9.1. Actions

- All medication should be stored in appropriate conditions of temperature, light and humidity, in lockable cupboards (or fridge when appropriate), which are kept locked. Access to keys should be restricted to named personnel. All rooms where medication, including oxygen, is kept should be locked when not in use. Steps must be taken to ensure patients cannot access areas where medication is stored.
- Doctors' bags should be securely stored when not in use.
- Medication in all locations in the practice (treatment rooms, fridges, doctors' bags, emergency trolleys, and dispensary) should be regularly inspected; replenished and out of date stock removed and disposed of promptly in line with waste regulations.
- There should be stock lists in place for all locations where medication is stored to enable audit and stock control. Stock lists should be reviewed regularly to ensure the correct drugs are available.
- Medication should be stored in its original packaging. If it is removed from the packaging, it must be clearly identifiable and labelled with Name, Form, Strength, Quantity, Batch Number and Expiry Date.
- On receipt of new stock, stock should be rotated such that old stock is always used before new stock.
- Any movement of stock between locations should be recorded to ensure a robust audit trail. This will enable stock to be traced in the event of a safety alert or recall.
- SOPs should be in place for aspects of medicines storage and stock control, including the member(s) of the clinical team responsible for them.
- Medication in doctors' bags and on emergency trolleys should be in line with current recommendations to ensure the drugs needed in emergency situations are available. The practice should have a system in place to replenish items which have been used.

#### 3.9.2. Resources

- CQC myth buster article on emergency bags and trollies:  
<https://www.cqc.org.uk/content/nigels-surgery-9-emergency-drugs-gp-practices>
- The National Framework Agreement for Clinical Waste Services details the arrangements for clinical waste handling:  
<https://www.england.nhs.uk/commissioning/primary-care-comm/clinical-waste/>
- CQC have further information on waste:  
<https://www.cqc.org.uk/content/nigels-surgery-76-health-care-waste>

---

MOPT-002 - V3 - Managing Medicines in General Practice a resource to support CQC inspection (2).docx	Status: Approved	Next Review April 2020
©NHS Commissioning Board. Developed by North of England Commissioning Support Unit 2018	Approved date: 24/04/18	Page 12 of 21

### 3.9.3. CQC KLOE

- Safe: S3, S4.1
- Well-led: W1, W2

## 3.10. Storage of medication in fridge

### 3.10.1. Actions

- Specialised refrigerators are available for the storage of pharmaceutical products and must be used for vaccines and diluents. Ordinary domestic refrigerators must not be used.
- Fridges should be locked and access to keys controlled: see point 3.9
- If fridge stock is moved between locations e.g. to a branch surgery it must do so under conditions such that the cold chain is preserved using validated cool boxes from a recognised medical supplier.
- A record should be kept of any movement of stock between locations.
- Practices should have a SOP for daily fridge temperature monitoring and recording, including details on what action to take in the event that the temperature goes out of range.
- There should be an audit trail of temperature records (either paper based or a built-in memory function).
- The refrigerator should be regularly cleaned and defrosted and this should be recorded.

### 3.10.2. Resources

- The cold chain guidance for immunisation providers commissioned by NHS England Cumbria and North East Region has been reviewed and updated in April 2017.  
Safe and Secure Handling of Vaccines. Operational Good Practice Guidance. This can be found at <http://medicines.necsu.nhs.uk/cold-chain-guidance-2017/>
- More details can be found in the CQC myth buster on fridges:  
<https://www.cqc.org.uk/content/nigels-surgery-17-vaccine-storage-and-fridges-gp-practices>

### 3.10.3. CQC KLOE

- Safe: S3, S4.1, S5
- Well-led: W1, W2

## 3.11. Controlled Drugs

### 3.11.1. Actions

- Have systems and SOPs in place to ensure that CDs are ordered, stored, dispensed, supplied, recorded and disposed of in line with legislation and best practice.

---

MOPT-002 - V3 - Managing Medicines in General Practice a resource to support CQC inspection (2).docx	Status: Approved	Next Review April 2020
©NHS Commissioning Board. Developed by North of England Commissioning Support Unit 2018	Approved date: 24/04/18	Page 13 of 21

- Keep a local folder of CD resources, either in paper or electronic format for staff and inspectors to refer to e.g. Environment Agency T28 waste control certificate, CD bulletins, audits and destruction records.
- Keep a note of the local Controlled Drug lead contact and the name of the Accountable Officer for Controlled Drugs in case any CD Incidents need to be reported to them.
- For North Cumbria CCG:
  - Controlled Drugs lead contact: Phillip Utting  
[Phillip.utting@nhs.net](mailto:Phillip.utting@nhs.net)
  - Accountable officer: James Gosow  
[england.cumbrianortheast-cds@nhs.net](mailto:england.cumbrianortheast-cds@nhs.net)

### 3.11.2. Resources

- NECS MO website has links to a range of advice documents including destruction of CDs, reporting of incidents and CCG responsibilities: <http://medicines.necsu.nhs.uk/controlled-drugs/>
- CD governance self- assessment tool for primary care organisations, a useful tool to complete prior to the inspection and add to the CD folder: <http://www.cqc.org.uk/content/controlled-drugs>
- A summary of advice is also available as a CQC myth buster: <https://www.cqc.org.uk/content/nigels-surgery-28-management-controlled-drugs>
- Names of local CD lead contact and Accountable Officer: <http://medicines.necsu.nhs.uk/resources/cd-contact-details/>

### 3.11.3. CQC KLOE

- Safe: S4, S5
- Well-led: W1, W2

## 3.12. Patient Group Directions (PGDs)

### 3.12.1. Actions

- If PGDs are used to enable nurses to supply or administer Prescription Only Medication (POM) without a prescription, the PGD must be within date and signed by the practitioner working under it.
- There should be a clinical member of staff who has overall responsibility for PGDs within the practice e.g. monitoring expiry dates.

### 3.12.2. Resources

- More information on PGDs from CQC: <https://www.cqc.org.uk/content/nigels-surgery-19-patient-group-directions-pgds-patient-specific-directions-psds>
- NICE guidance on PGDs: <https://www.nice.org.uk/guidance/mpg2/resources>

MOPT-002 - V3 - Managing Medicines in General Practice a resource to support CQC inspection (2).docx	Status: Approved	Next Review April 2020
©NHS Commissioning Board. Developed by North of England Commissioning Support Unit 2018	Approved date: 24/04/18	Page 14 of 21

- Cumbria's PGDs are on the NECS MO website:  
<http://medicines.necsu.nhs.uk/resources/patient-group-directions/>

### 3.12.3. CQC KLOE

- Safe: S4, S5
- Effective: E1, E3
- Caring: C2
- Responsive: R1
- Well-led: W2

## 3.13. Infection control

### 3.13.1. Actions

- Areas of the practice where medication is stored, handled and administered must comply with current legislation and best practice standards of cleanliness.
- Relevant areas should be kept clean and free of clutter. Food and/or drink should not be consumed or stored in medicines storage areas (including the refrigerator) or areas where medicines are supplied from.
- There should be a source of drinking water available for the preparation of medicines. A separate sink area should be used for the preparation of medicines (for example, reconstituting oral paediatric antibiotic products). This should be in addition to sinks providing hand-washing facilities for staff. All sinks should be kept clean. Hot and cold water should be available.
- Surfaces and worktops should be smooth and impervious to dirt and moisture.
- Records should be kept of when each area is cleaned.
- Any area where spillage is possible e.g. treatment rooms, should have floor coverings and equipment that meets infection control standards.

### 3.13.2. Resources

- CQC follow the Health and Social Care Act 2008 Code of Practice:  
<https://www.gov.uk/government/publications/the-health-and-social-care-act-2008-code-of-practice-on-the-prevention-and-control-of-infections-and-related-guidance>
- NICE quality standard QS61 outlines other areas to consider, including antimicrobial stewardship: <https://www.nice.org.uk/guidance/qs61>
- For further advice please contact Paula Smith, Patient Safety Lead-  
[Paula.smith@northcumbriaCCG.nhs.uk](mailto:Paula.smith@northcumbriaCCG.nhs.uk)

### 3.13.3. CQC KLOE

- Safe: S1, S3
- Well-led: W1, W2

MOPT-002 - V3 - Managing Medicines in General Practice a resource to support CQC inspection (2).docx	Status: Approved	Next Review April 2020
©NHS Commissioning Board. Developed by North of England Commissioning Support Unit 2018	Approved date: 24/04/18	Page 15 of 21

### 3.14. Training

#### 3.14.1. Actions

- All practice staff should have access to training appropriate to their role; for clinical staff, this should include opportunities for clinical supervision.
- Information on prescribing should be made available to all new prescribers at the practice including locums and GP registrars.
- In addition to academic routes, training in medicines and prescribing might include: Cumbria Learning and Improvement Collaborative (CLIC), PLT sessions, Medicines Optimisation meetings, E-learning and opportunistic routes within the practice.
- Training should be multidisciplinary – your Medicines Optimisation Pharmacist is best placed to give training on medicines to all staff.
- A member of the practice team should take the lead on training.

#### 3.14.2. Resources

- Training suitable for all staff can be identified at:  
<https://www.cqc.org.uk/content/nigel%E2%80%99s-surgery-70-mandatory-training-considerations-general-practice>
- NECS hosts e-learning topics on the MO website:  
<http://medicines.necsu.nhs.uk/education-training/>

#### 3.14.3. CQC KLOE

- Effective: E1, E3
- Responsive: R1
- Well-led: W1, W2, W4, W5, W8
- Safe: S1, S3
- Caring: C2

### 3.15. Clinical audit

#### 3.15.1. Actions

- All audits should have clear action plans with designated staff given responsibility for each action within a timeframe.
- Re-audit should be completed to demonstrate that improvements identified as necessary have been implemented.
- CQC would like to see two examples of clinical audits that have completed the full audit cycle.
- Prescribing audits might include care bundles, PrescQIPP audits, RAIDR patient safety dashboard and NICE quality standards.
- Use the PDSA (Plan, do, study, act) cycle to test a change and assess its impact.

#### 3.15.2. Resources

- More information on the audit cycle can be found a

---

MOPT-002 - V3 - Managing Medicines in General Practice a resource to support CQC inspection (2).docx	Status: Approved	Next Review April 2020
©NHS Commissioning Board. Developed by North of England Commissioning Support Unit 2018	Approved date: 24/04/18	Page 16 of 21

<https://www.cqc.org.uk/content/nigels-surgery-4-clinical-audits>

- CQC have further information on the use of NICE quality standards:  
<https://www.cqc.org.uk/content/nigels-surgery-45-nice-quality-standards-general-practice>

### 3.15.3. CQC KLOE

- Effective: E1, E2, E5
- Responsive: R1
- Safe: S4, S5, S6
- Well-led: W1, W2, W5

## 3.16. Responding to outliers in prescribing

### 3.16.1. Actions

- CQC inspectors will check for any outlying areas of prescribing, including good antimicrobial stewardship.
- Use local prescribing indicators, for example PrescQIPP Priorities Report, QIS, RAIDR, ePACT and care bundles to identify outlying areas, monitor financial pressures, unplanned hospital admissions and areas of improvement and success. Share this information with relevant staff within your practice and invite them to participate in discussions e.g. during PLT.
- Use the PDSA (Plan, do, study, act) cycle to test a change and assess its impact.
- Add any work done on your prescribing outliers to your presentation, including audits as in point 3.15 above.

### 3.16.2. Resources

A wide range of resources to support work on prescribing can be found on the NECS MO website: <http://medicines.necsu.nhs.uk/>

### 3.16.3. CQC KLOE

- Effective: E1, E2, E5, E7
- Responsive: R1
- Safe: S4
- Well-led: W1, W2, W5, W6

## 3.17. Responding to new guidance

### 3.17.1. Actions

- Show that the practice has responded to new guidance i.e. disseminated information, conducted an audit if needed and has actions in place to ensure guidance is followed.
- Show that the practice responds to prescribing data using different resources for example: – RAIDR, local prescribing indicator data and ePACT2.

---

MOPT-002 - V3 - Managing Medicines in General Practice a resource to support CQC inspection (2).docx	Status: Approved	Next Review April 2020
©NHS Commissioning Board. Developed by North of England Commissioning Support Unit 2018	Approved date: 24/04/18	Page 17 of 21

### 3.17.2. Resources

- National Institute for Health and Care Excellence (NICE) guidelines: <http://www.nice.org.uk/guidance/conditions-and-diseases>
- NICE clinical knowledge summaries (CKS): <http://cks.nice.org.uk/>
- North Cumbria CCG local prescribing formulary, guidelines and resources: <http://medicines.necsu.nhs.uk/guidelines/cumbria-guidelines/>
- Cumbria Partnership Foundation Trust local prescribing guidelines: <https://www.cumbriapartnership.nhs.uk/health-professionals/policy-documents/category/medicines-management>
- The British National Formulary (BNF): <http://www.evidence.nhs.uk/formulary/bnf/current>
- Medicines and Healthcare Product Regulatory Agency services and information: <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

### 3.17.3. CQC KLOE

- Effective: E1, E2, E5
- Responsive: R1, R2
- Safe: S4, S6
- Well-led: W1, W2, W5

## 3.18. Dispensing practices

### 3.18.1. Actions

- All prescriptions should be checked and signed before dispensing.
- Dispensary stock checks which should be carried out every 3 months and a record of such made (DDA guidance).

### 3.18.2. Resources

- Further details can be found at: <https://www.cqc.org.uk/content/nigels-surgery-11-prescriptions-dispensing-practices>

### 3.18.3. CQC KLOE

- Effective: E1
- Caring: C1
- Responsive: R3
- Safe: S4, S5

---

MOPT-002 - V3 - Managing Medicines in General Practice a resource to support CQC inspection (2).docx	Status: Approved	Next Review April 2020
©NHS Commissioning Board. Developed by North of England Commissioning Support Unit 2018	Approved date: 24/04/18	Page 18 of 21

#### 4. Care Quality Commission Inspections: Managing Medicines in a GP Practice – Implementation plan

Area of medicines management	Pg	Actions to complete	Resources to use	People to involve	Deadline	Completed name/date
1. Secure storage and control of prescriptions	<a href="#">4</a>					
2. Medicines safety information	<a href="#">5</a>					
3. Learning from incidents	<a href="#">6</a>					
4. Transfer of care and medicines reconciliation	<a href="#">7</a>					
5. Repeat prescribing systems	<a href="#">8</a>					
6. Initiation of prescription or treatment	<a href="#">8</a>					
7. Vulnerable Patients	<a href="#">9</a>					
8. Medication review	<a href="#">10</a>					
9. Stock control, storage and waste	<a href="#">12</a>					

<b>10.Storage of medication in fridge</b>	<a href="#">13</a>					
<b>11.Controlled Drugs</b>	<a href="#">13</a>					
<b>12.Patient Group Directions (PGDs)</b>	<a href="#">14</a>					
<b>13.Infection control</b>	<a href="#">15</a>					
<b>14.Training</b>	<a href="#">16</a>					
<b>15.Clinical audit</b>	<a href="#">16</a>					
<b>16.Responding to outliers in prescribing</b>	<a href="#">17</a>					
<b>17.Responding to new guidance</b>	<a href="#">17</a>					
<b>18.Dispensing practices</b>	<a href="#">18</a>					
<b>Review completed by:</b>		<b>Date:</b>		<b>Re-audited by:</b>		<b>Date:</b>

## Appendix One: Abbreviations

Abbreviation	Definitions
DDA	Dispensing Doctors Association
MO	Medicines Optimisation
CQC	Care Quality Commission
KLOE	Key Lines of Enquiry
SOPs	Standard Operating Procedures
CDs	Controlled Drugs
PLT	Practice Learning Time
NECS	North of England Commissioning Support
NICE	National Institute of Health and Care Excellence
CCG	Clinical Commissioning Group
MHRA	Medicines and Healthcare Products Regulatory Agency
RAIDR	Reporting Analysis and Intelligence Delivering Results
SIRMS	Safeguard Incident and Risk Management System
PGDs	Patient Group Directions
ePACT2	Electronic Prescribing Analysis and Cost
NHSCFA	NHS Counter Fraud Authority