NHS
South West London

CQC Inspections and Medicines Guidance for Primary Care

Contents

1. Introduction

The Care Quality Commission (CQC) is an independent regulator that monitors, inspects and regulates health and social care services in England. Five questions are at the heart of the way CQC regulate:

- Is a practice safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well led?

These help to focus on the things that matter to people.

Safe use of medicines and handling fall under the following questions:

- **Are they safe?** To protect people from abuse and avoidable harm from their medicines
- **Are they effective?** Does the care, treatment and support available achieve good outcomes to help people maintain quality of life and is it based on the best available evidence.

CQC considers how well health and care services meet the needs of people and includes how medicines can be optimised to ensure safe and effective use to deliver the best possible outcomes. CQC also looks at the value that medicines deliver, making sure that they are both clinically and cost effective, and that people get the right choice of medicines, at the right time, with clinicians engaging them in the process.

This document is to support GP practices on what to consider from CQC aspects of medicines use and to support safe use of medicines. The information and list of questions provided is not exhaustive.

Refer to the CQC Key Lines Of Enquiry (KLOE) guidance for detail.

Figure 1:*Shows the six most comment areas of risk with medicines across health and care which are: Prescribing, monitoring & review, Administration, Transfer of care, Reporting & learning from incidents, Supply storage & disposal, Staff competence & workforce capacity. Learning from risks and sharing good practice for better outcomes © Care Quality Commission 2019*

2. Prescribing, monitoring, and reviewing medicines

2.1 Prescribing, timely medicines reviews

- Are all practice patients' records and summary notes up to date?
- Does the practice have access to electronic or Lloyd George notes as a backup?
- Is coding within the clinical system adequate?
- Are allergies reviewed, confirmed and documented?
- When prescribing medicines consider the patient outcomes of treatment provided, how this is monitored, recorded and changed based on emerging evidence and the learning shared.

2.2 High risk drug monitoring (e.g., DOACs, azathioprine, methotrexate, lithium, ACE inhibitors, insulin, valproate, warfarin)

- Does the practice have a high-risk drug monitoring policy/process?
- How are patients identified for monitoring need? i.e. Does the practice use ARDENS searches to support identification and review of patients prescribed high risk medicines?
- Where are patients monitored? i.e., GP surgery or secondary care
- How are monitoring outcomes documented? Are subsequent monitoring follow up dates documented in the patients notes?
- Are results coded (not free text)?
- Are any risk assessments/discussions/changes made to the medication list documented in the patient's record?

- Is there a process to access and import pathology/blood results from the acute trusts?
- Are most recent blood results viewed prior to signing prescriptions?
- Is prescribing done remotely? Are relevant safeguards in place to ensure appropriate prescribing i.e., controlled drugs. Consider other medicines where additional safeguards may be required.
- Are prescription clerks/receptionists aware that patients on high-risk medicines require monitoring checks for every prescription issued?
- How and when are repeat prescriptions issued to patients without up-to-date monitoring?
- Are prescribing decision support tools given due consideration at the point of prescribing? i.e., Optimise Rx®, Scriptswitch®, EMIS pop-up messages
- Is there a proactive process supported with audit to identify gaps (e.g., EMIS search library) in monitoring?
- Does practice regularly audit prescribing of high-risk medicines in line with safety recommendations e.g., valproate audit and PREVENT programme. See CQC guidance (High risk medicines: valproate)
- How are actions documented in patient notes? e.g., valproate
- What actions are taken if patients do not attend for blood tests/follow up appointments and is this documented in patient notes?
- Are 'misses' related to monitoring recorded as significant events?

Note: medicine monitoring tools can be found under Specialist Pharmacy Services (SPS)

2.3 Medicines safety alerts

- Does the practice have a documented process, including identification of a practice lead, for receiving, discussing, actioning and documenting actions in response to MHRA drug/safety alerts?
    - Check how information is shared from the local Medicines Optimisation Team
    - Are the roles/responsibilities clearly defined for staff and are they aware of what this entails?
    - How are alerts received and actioned in the practice?
    - Are these discussed at practice meetings?
    - How are actions documented in patient notes?
    - Is there an audit of alerts?
- Practices are able to identify prescribing areas in which they are outliers in comparison to national trends to review the 'safety' elements in preparation for an inspection. This can be found using OpenPrescribing

2.4 Reviewing medicines – tailor to individual patient (suggest annual review as a minimum for patients on regular medicines)

- How are patients identified for Structured Medication Reviews (SMRs) and how are their outcomes recorded?
- How is it demonstrated that medicines (including when required medicines, addictive medicines) are regularly reviewed?

    - Are there ‘Stop dates’ on medicines where appropriate (e.g., antiplatelet medicines)?
    - Are repeat/ acute prescriptions used appropriately?
    - Are medicines which are no longer required/have not been issued for more than 1 year removed from current medicines record (moved to past drugs)?
    - Is duration of therapy given where appropriate? e.g., antibiotics, see SWLIMO clinical infection guidance
- Are prescribing decision support tools given due consideration at the point of prescribing? i.e., Optimise Rx®, Scriptswitch®, EMIS® pop-up
- Are clinicians, including locum GPs activated for Optimise Rx/Scriptswitch)?
- Does the practice have the EMIS® medicines formulary (if available for your Borough) installed on the system?
- Are medications linked to clinical conditions?
- Are any risk assessments/discussions/changes made to the medication list documented in the patient’s records?
- Is prescribing done remotely? If so, are relevant safeguards in place to ensure appropriate prescribing particularly for controlled drugs?
- Does the practice have a current repeat prescribing policy? Is this audited and how often?
- How does the practice receive, discuss, and action information received from the Medicines Optimisation Team e.g., drug alerts; drugs shortages; progress/achievement of engagement scheme or prescribing incentive scheme areas?
- If adverse effects have been identified/suspected – are these reported via the MHRA Yellow Card system?
- Does practice use Quality and Outcomes Framework (QOF) population reporting as evidence of how the practice is caring for their patients? Is there an assigned lead in the practice for specific QOF clinical parameters to be reviewed, discussed and agreed a practice plan with evidence of meeting notes?
- Non-attenders for appointments
    - Is there a process in place that clearly clarifies actions that have been taken to encourage the patient to attend their appointments?
    - Are the relevant staff members included in this process?
    - Are all actions documented in the patient’s consultation notes?
    - Have potential links to capacity/safeguarding vulnerable people and best interest decisions been considered?
    - Are exception codes for non-attenders for review/drug monitoring used for valid reasons?

2.5 Antimicrobial stewardship

- How does the practice support the national antimicrobial strategy?

    - Is there a whole team approach to improve effectiveness of antimicrobial stewardship strategies in the practice?
    - Are staff including locums aware of the most UpToDate local antibiotic guidance i.e. TARGET (Treat Antibiotics Responsibly, Guidance, Education and Tools) toolkit resources, PHE fingertips data

- Does the practice have an antibiotic champion to help ensure appropriate antibiotic prescribing is a clinical priority?
- Does practice have a clear action plan to address issues especially if identified as an outlier?
- How is prescribing of antibiotics reviewed to reduce inappropriate prescribing?
- Does the practice review and discuss antibiotic prescribing indicators if included in any local engagement scheme, PMS KPI scheme or equivalent? Is progress information available on local intranet?
- Does the practice audit antibiotic prescribing? Refer to toolkits on local intranet if available
- How are prescribing guidelines SWLIMO clinical infection guidance and prescribing data shared within the practice?

2.6 Stopping over-medication of people with a learning disability, autism, or both (STOMP)

- How are medicines for patients with learning disability and/or autism reviewed, refer to the STOMP / Supporting Treatment and Appropriate Medication in Paediatrics (STAMP)

3. Administration of medicines

- Are patient treatment/management plans in place as appropriate?
- Are staff administering medicines suitably qualified and assessed as competent?
- Are injectable medicines being administered, appropriate for administration in the GP practice/healthcare setting and is there guidance in place to support this? e.g., methotrexate subcutaneous injection should not be administered in primary care as this is not included in the SWL shared care guideline; however it can be prescribed (not administered) as long as the patient/carer is able to self-administer and waste disposal has been arranged in line with the guideline
- How is covert administration flagged up for patients on the clinical system? Does the practice have guidance in place to support covert administration of medicines?

4. Transfer of care between services

4.1 Review of discharge letters

- Is there a timely and robust medicines reconciliation process around hospital discharges? CQC checks for evidence that action has been taken from discharge notifications. Expectation is that this is done within a week of receipt
- Are medicines related recommendations flagged up at the point of prescribing e.g., Optimise Rx® messages/ Scriptswitch®?
- Are SWLIMO shared care guidelines and transfer of care documents received for medicines as appropriate and prescribing is in line with guidelines?
- Are SWL Hospital only medicines drug list recorded for information only on GP clinical system (not prescribed)?

    - Is there a process for communicating inappropriate requests back to hospital clinicians and making arrangements for the specialist to continue prescribing?
- How does the surgery document interventions made by the Community Pharmacist from the NHS Discharge Medicines Service?

4.2 Care Homes

- Care homes – refer to local care home guidance provided by the Medicines Optimisation Team (if available) and ensure staff are aware of this

5. Reporting and learning from incidents

5.1 Recording of incidents, Insight to investigate, Sharing the learning

- How does the practice Learn From Patient Safety Events (LFPSE), previously National Reporting and Learning System (NRLS)?
- Has the practice registered with LFPSE?
- Are medicines related incidents submitted to LFPSE?
- Is there a practice policy/ template for recording significant events?
- Is a root cause analysis done and the information shared with other clinicians/staff in the practice? Is this documented?
- How are Make a Difference Alerts (MKAD) raised and acted upon?
- Are LFPSE/MKAD alerts discussed at practice meetings for shared learning (consider these as standing agenda items)?
- Are you an immunisation service provider? If so, is there a process in place on reporting vaccine incidents?

5.2 Prescription stationary security

- Does practice have a clear system for ordering, transporting, storing (locked away), access to and monitoring use of prescription pads (including distribution and safe and secure disposal)?
- How are incidents reported, discussed and reviewed?
- Can the practice demonstrate steps that would be undertaken if fraudulent activity is suspected?

6. Storing, supplying and disposal

6.1 Fridge monitoring

Does the practice have a policy for this?

6.2 Cold chain policy

- Does practice have a cold chain policy which identifies how to handle vaccines to maintain the cold chain?
- How is temperature of medicines fridges monitored (how often and by who), recorded and temperature excursions managed? Refer to: SWL vaccines and immunisations clinical guidance
- Are expiry dates of refrigerated medicines checked, how often and by who? How is this recorded?
- Are staff aware of the process to follow if there is a UKHSA Vaccine incident guidance?

6.3 Controlled drugs

- If controlled drugs are stored in the practice/ doctors' bag, how is it ensured that this is in line with the legal framework?
- How is prescribing of controlled drugs reviewed/audited?

6.4 Other medicines (Emergency medicines, End of life care)

- Emergency drugs
  - Is there an appropriate schedule in place to regularly confirm that all recommended emergency drugs are in place? If the practice does not stock a particular medicine, has this been documented in the risk register stating review and rationale?
  - Is the expiry date checked regularly (includes needles and syringes, salbutamol nebules and oxygen)?
  - Is there a named responsible member of staff and a named deputy to check stocks and expiry of emergency drugs?
  - Are emergency medicines stored in a secure location in the practice? How readily are they accessible in an emergency?
  - Is there a system in place for signing medicines in and out of the practice, ensuring there is a clear audit trail of medicine movement?
- End of Life Care (EOLC) medicines
  - Is the practice aware of the local policy for obtaining EOLC medicines for their patients?
- Liquid nitrogen
  - If practice stores liquid nitrogen for cryotherapy procedures, has a risk assessment been carried out to protect staff and public from any potential hazards?

7. Staff competence and workforce capacity

7.1 Training, Assessing competency, Medicines reconciliation

- How is competency/scope of practice of non-medical prescribers assessed and reviewed? Is there evidence of this?
- How are non-medical prescribers/ Additional Roles Reimbursement Scheme (ARRS) clinicians supported in practice?

- Is there a named clinical supervisor for non-medical prescribers/ARRS clinicians and are there scheduled review dates with an associated case review process?
- Are staff aware of and trained to support the GP Community Pharmacy Consultation Service (CPCS)? Is the practice referring to CPCS? Has practice joined the CPCS Hub — NHS Networks to access collated resources and discussion forum?
- Is there a prescription collection facility at the practice - are these scripts regularly scrutinised to check collection compliance; is there a member of staff responsible for this?
- Does the practice demonstrate a 'working together' ethos working across teams e.g., part of multidisciplinary teams for palliative care/EOLC, virtual wards
- Are staff clear on their roles and been given the necessary training to perform their roles?
- Is the practice aware of the SWL Training Hub which provides access to clinical webinars as well as education and training resources for Additional Roles in Primary Care? These can be used to help support Primary Care Network (PCN)/practice-based pharmacists. Check with your local team if unsure how to access.

8. Other

8.1 Equipment

- Does the practice use electronic equipment to support monitoring and management of patient's health needs? e.g., 24-hour blood pressure machines? Are these checked and calibrated annually?
- Are patients trained on how to use equipment if necessary and is there a process in place for patients to report results back to the clinician?

8.2 Accessibility for patients

- Does the practice make provisions for patients with long term conditions (or for carers or people at end of life)? e.g., include double appointments, gym referrals, weight management
- How does the practice make adjustments for patients with hearing impaired, impaired sight or language impairment and what aids are available to support this?
- Does the practice have patient online medicines ordering facility?
- Are resources within the practice and on the practice website available in an accessible format?

8.3 CQC GP MythBusters

- GP mythbusters guidance for providers clear up some common myths about CQC inspections of GP services, independent doctors, and clinics and out-of-hours services and share agreed guidance to best practice

8.4 Mock Inspections

- Has your practice requested a mock CQC inspection organised by local PCN teams or other?
- Has practice received feedback from mock inspection and discussed to prioritise areas of focus?

8.5 Inadequate practice

- What does inadequate practice look like? Has the practice considered this in the above areas? Consider sharing examples from CQC GP inspections

8.6 Policy reviews

- Do practice policies have a review date and how are they flagged and actioned for review?
- If patient group directions (PGD) or patient specific direction (PSD) are used, are they the most up to date?

8.7 National health priorities

- How does the practice support national priorities? Examples include smoking cessation, dementia, cancer

References/resources

1. General Medical Council, Good practice in prescribing and managing medicines and devices
2. CQC Guidance (How we monitor GP practices)
3. Southwest London Prescribing: Interface policy
4. British Medical Association (How to prepare for a CQC inspection)

Document History

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Author: **SWL Medicines Optimisation Team (Sutton Borough)**
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