Medicines Management Pre-Checklist for CQC Inspection

Introduction

The pre-inspection checklist is intended to provide guidance to GP practices to ensure that medicines management processes are in place and up-to-date and identify any areas that may require improvement. This will support the management for the safe prescribing, administration, storage, optimisation of medicines and patient safety.

Resources:
GP mythbusters - Care Quality Commission (cqc.org.uk)
Bulletin 332. Preparing GP practices for a regulatory inspection (prescqipp.info)
GP mythbuster 12: Accessing medical records and carrying out clinical searches - Care Quality Commission (cqc.org.uk)
Ardens - CQC Searches
https://practiceindex.co.uk/gp/blog/how-to-manage-ardens-searches-by-cqc-chris/

Please note: if links are broken, please go to the website homepage and search for the topic.

Ardens CQC searches are based on national guidance, good practice and safety advice from MHRA. The Royal College of GPs and the British Medical Association have agreed on the content and focus of the searches, although this is subject to change in response to new guidance or safety alerts.

- CQC searches are not intended to be an alternative to practices own monitoring and recall protocols.
- Some searches are not intended to show as zero, even after work has been undertaken as they are to identify particular groups for random review e.g teratogenic, SGLT2i searches to ensure documentation of communication and management of potential risks.
- Standard searches are used to identify risk and allow a degree of tolerance to monitoring intervals but should not be used as the main governance searches for practices.
- Enhanced searches show more detail in terms of monitoring at recommended intervals in line with national guidance.

It is recommended that practices have protocols for each search area that requires monitoring, stating frequency the searches are to be run, who is responsible and the recall communication method(s) to the patient (e.g. text, email, phone call, letter), relevant time-periods for follow- up and an escalation process. Practices should keep records of any recall or monitoring audits that are undertaken.

NB: Practices should ensure protocols are followed to maintain standards and help ensure patients are not missed from monitoring or follow-up.

Index

1. Patient Group Directions (PGDs)

Resources:

GP mythbuster 19: Patient Group Directions (PGDs)/Patient Specific Directions (PSDs)
Specialist Pharmacy Services (SPS) website (register to access content).
National minimum standards and core curriculum for immunisation training for registered healthcare practitioners (publishing.service.gov.uk)
NHS England — South East » South East Patient Group Direction downloads

Registered nurses, registered paramedics, pharmacists and registered pharmacy technicians are included in the list of Registered Professions who may supply and/or administer medicines under a patient group direction (PGD), as per the Human Medicines Regulations 2012. The Human Medicines Regulations 2012 (legislation.gov.uk)

- The HCP working under the PGD must sign and date the PGD first.
- The PGD authoriser then signs and dates to declare named professional may work under the PGD. (CQC have identified examples where nurses have signed the authorisation sheet after the GP).

- If an HCP signs the PGD after already signed by the authoriser, the PGD authoriser must also re-sign the PGD.
- Where additional staff are added at a subsequent date the correct procedure is to start a new "Practitioner Authorisation Form" (as there isn't space for the authorising manager to sign twice).
- Staff authorisation records should be kept for 8 years after the expiry date of the PGD if it relates to adults only (10 years if relates to an implant) and 25 years after the expiry date of the PGD if it relates to children.

NB: Healthcare assistants, nurse associates or physician associates *cannot* work under a PGD, although they may work under a Patient Specific Direction (PSD).

Checklist	Yes/No	Comments
Are all PGDs up-to-date using the current version? (see link above for current PGDs)	Yes/No	
Has every HCP working under each PGD, completed the form(s) (Name, signature and date)?	Yes/No	

Has the authorising manager signed and dated each PGD **after** the HCP? The authorising manager is responsible for ensuring that only fully competent, qualified and trained health professionals are authorised to use the most recently approved version of the PGD. Although this does not need to be a clinical member of staff, the authoriser needs to understand and fulfil their responsibilities in this role and be able to assess competence.	Yes/No	
Is immunisation training current and up-to-date for each HCP working under the PGD?	Yes/No	

2. Patient Specific Directions (PSDs)

Resources:

GP mythbuster 19: Patient Group Directions (PGDs)/Patient Specific Directions (PSDs)
Specialist Pharmacy Services (SPS) website (register to access content).

A PSD is prescribing and is a written instruction and must be signed by a prescriber for medicines to be supplied and/or administered to a named individual after the prescriber has assessed that individual on a one-to-one basis.

Any suitably trained and competent person, including nurses, healthcare assistants and physicians associates may follow a PSD.

A person who supplies or administers a medicine is accountable for their own practice and it is the employer's responsibility to ensure to ensure staff have been trained and are competent to undertake such tasks in line with their agreed job description. Local guidelines on correct administration and monitoring should be followed.

Where a PSD is for the administration of more than one dose this must be clearly indicated including the total number of doses to be given and the dosage intervals as appropriate.

We would suggest incorporating an appropriate review date for patients receiving long term therapy via PSD. The review date would be influenced by the treatment, frequency of administration etc, and for local agreement.

PSDs may be created in Ardens, the link takes you to instructions on how to do with associated video.
Ardens recording template for immunisations, allows to record if you have given the vaccine under PSD or PGD.

Checklist	**Yes/No**	**Comments**
Are all PSDs completed using the relevant form?	Yes/No	
Are all PSDs signed by an authorised prescriber?	Yes/No	
Is the following information included in all completed PSDs? • name(s) of patient(s) and/or other individual patient identifiers including age if a child • name, form and strength of medicine • route of administration • dose • frequency • date of treatment/number of doses/frequency/date treatment ends, as applicable • signature of prescriber	Yes/No	
Have non-eligible healthcare staff administered medicines via a PSD? If yes, then ensure that this is documented and addressed.	Yes/No	
Is training current and up-to-date for each HCP/HCA working under a PSD?	Yes/No	

3. Emergency Drugs

Resources:

GP mythbuster 9: Emergency medicines for GP practices
Medical emergencies in the community | Treatment summaries | BNF | NICE
Emergency drug doses | Prescribing information | Angio-oedema and anaphylaxis | CKS | NICE

The CQC list of emergency medicines is not exhaustive and additional medicines marked with a * have been included in the list for the practice to consider. CQC expect to see evidence that an appropriate risk assessment has been carried out to identify a list of medicines that are not suitable for a practice to stock, and how this is kept under review. Any assessment of risk should include the reasons why a particular medicine on the suggested list is not required or a substitute used, including opiates and naloxone.

- Drugs and Therapeutics Bulletin Drugs for the Doctors Bag:1 Adults Volume 53 Issue 5
- Drugs and Therapeutics Bulletin Drugs for the Doctors Bag:2 Children Volume 53 Issue 6
- Anaphylaxis guidance (Resuscitation Council UK)
- Faculty of Sexual and Reproductive Healthcare: service standards for resuscitation

Consider using tamper-proof seals on emergency drug boxes or trolleys to reduce the need to check all contents. It can be helpful to visually display the shortest expiry date on the drug box or trolley.

Practices with access to Teamnet may wish to consider using QR codes to help record monitoring checks.

Checklist	Yes/No	Comments
Is there a process and system in place to check that emergency drugs are in date?	Yes/No	
How often are the emergency drugs checked? Weekly is recommended	N/A	
Is there a record of emergency drugs checks?	Yes/No	
What is the date emergency drugs were last checked?	N/A	
Are stocks of emergency drugs up-to-date as per list?	Yes/No	
Are all the emergency drugs in drug cupboard/trolley in date?	Yes/No	
Are all the emergency drugs in doctor's bag(s) in date?	Yes/No	
Do medicines have the date opened on them if needed?	Yes/No	
Do all patient's own drugs have the patient's name on?	Yes/No	
Are there any loose tablets/ strips?	Yes/No	
How are emergency drugs kept secure? e.g trolley secured to a wall	Yes/No	

Do clinicians have ease of access to emergency drugs?	Yes/No	
Is there a process and system in place to check that equipment is well maintained and calibrated where required?	Yes/No	
Are all equipment checks up-to-date?	Yes/No	
Have emergency drug risk assessments been carried out where necessary	Yes/No	
Emergency Medicines- list		
• Adrenaline 1:1000 injection, mandatory if vaccines being administered	Yes/No	
• Cyclizine, ondansetron, metoclopramide or prochlorperazine - antiemetic	Yes/No	
• Aspirin soluble tablets (75mg,300mg) – suspected MI	Yes/No	
• Atropine 500micrograms/ml, if fitting & removal of intrauterine devices or minor surgery performed*- symptomatic bradycardia	Yes/No	
• Benzylpenicillin for injection 600mg -suspected bacterial meningitis	Yes/No	
• Dexamethasone 5mg/2.5ml oral solution for croup in children (requires date opened sticker and new expiry once seal broken) or soluble prednisolone – off-label use	Yes/No	
• * Diazepam rectal tubes 5mg – epileptic seizure	Yes/No	
• Diclofenac (intramuscular injection)- analgesia	Yes/No	
• Glucagon (**needs refrigeration**). GlucaGen Hypokit (may be stored **out of a refrigerator** below 25°C for up to 18 months within the shelf life period - label with new expiry date) or alternative medicines to treat hypoglycaemia	Yes/No	
• Glyceryl trinitrate (GTN) spray or alternative unopened in date GTN sublingual tablets- possible cardiac chest pain	Yes/No	
• Ipratropium bromide nebules 250mcg for asthma in children • *Or 500mcg for adults	Yes/No	
• Midazolam (buccal) 5mg/1ml or 10mg/2ml - licensed 3m-18 yrs Over 18 years of age off-label use- epileptic seizure	Yes/No	
• Naloxone Injection 400mcg – opioid overdose or toxicity	Yes/No	
• Opiates-diamorphine, morphine or pethidine ampoules for injection (water for injection may be required for reconstitute) should also stock naloxone otherwise assess need	Yes/No	

• *Prednisolone 5mg tablets or soluble tablets- for asthma attack	Yes/No	
• Salbutamol nebules 2.5mg & 5mg with a nebuliser or salbutamol inhaler 100mcg with Volumatic for asthma attack	Yes/No	
• *Water for Injection	Yes/No	
• *Oxygen must be available for fitting & removal of intrauterine devices	Yes/No	
• Are sundries, e.g syringes & needles in date	Yes/No	

4.Security Controlled Drugs

Resources:

GP mythbuster 28: Management of controlled drugs - Care Quality Commission (cqc.org.uk)
The Misuse of Drugs Regulations 2001
Overview | Controlled drugs: safe use and management | Guidance | NICE

GP practices should have systems in place to ensure the safe management of controlled drugs. Staff should know what to do and who to contact if they have a concern about an incident or the performance or practice of other healthcare professionals /staff.

Controlled Drug Register

Any movement of a Schedule 2 CD into and out of the practice must be recorded in a CD register. This should be done as soon as possible but must be done within 24 hours. It is recommended that two people do this together and check stock levels at the same time. Also, practices are recommended to keep a running balance of the stock levels of each CD preparation as this makes it much easier to spot and track discrepancies. Whilst the task of making the register entries can be delegated, the GP retains full responsibility.

Controlled Drugs Accountable Officer (CDAO) : Julie McCann, Head of Pharmacy, Medication Safety Officer
NHS England and NHS Improvement South West (covering Bath and North East Somerset, Gloucestershire, Swindon and Wiltshire) and South East (covering Berkshire, Buckinghamshire and Oxfordshire). Email: julie.mccann3@nhs.net

Self-assessment for controlled drugs:

20190114_controlleddrugs_selfassessment-primary.xlsx (live.com)		
Checklist	**Yes/No**	**Comments**
Does the practice stock controlled drugs?	Yes/No	
If yes, does the practice have a written SOP in place?	Yes/No	
If yes, does the SOP cover the ordering, storing, administering, recording, and destruction of CDs?	Yes/No	
If yes, have staff been trained to ensure they have the relevant knowledge and skills to undertake CD related tasks?	Yes/No	
If yes, do staff should know what to do and who to contact if they have a concern about an incident or the performance or practice of other healthcare professionals / staff?	Yes/No	
Is the CD register on the premises and available for inspection?	Yes/No	
Are controlled drugs stored in a CD cupboard as per regulations?	Yes/No	
Are the keys to the CD cupboard stored separately?	Yes/No	
Does the practice store unwanted patient's own controlled drugs?	Yes/No	
Are patient's own controlled drugs stored segregated in the CD cupboard?	Yes/No	
Does the doctor's bag hold controlled drugs?	Yes/No	
Is there a separate record for controlled drugs held in the doctor's bag?	Yes/No	
Are expired/obsolete/unwanted controlled drugs disposed of according to regulations?	Yes/No	
If the practice does not stock controlled drugs, does the practice provide services for patients with addiction or opiate related problems?	Yes/No	
If yes to stocking controlled drugs or providing services for patients with addiction or opiate related problems, does the practice stock Naloxone to reverse the effects of opiates?	Yes/No	

5. Security of Blank Prescription Forms

Resources:

GP mythbuster 23: Security of blank prescription forms - Care Quality Commission (cqc.org.uk)

NHS Counter Fraud Authority guidance (2018)Management and control of prescription forms (cfa.nhs.uk)

A prescription form is an asset that has a financial value. It is in effect a blank cheque open to potential misuse. Theft of prescription forms and their resulting fraudulent misuse is a serious concern. It can lead to loss of valuable NHS resources and potentially result in serious harm. Forms can be used to illegally get controlled drugs (CDs) and other medicines. This can be for illegitimate personal use or to sell on. Fraud or thefts are not always complex or on a large scale; single forms can be stolen from the prescriber's bag, car, home or desk.

The CQC expects GPs (including locums), other practice prescribers, and all staff involved in the management of prescription forms to be able to explain how the practice manages and secures blank prescription forms and paper. This should be in line with national guidance unless the practice can justify, with risk assessment and mitigation, why this is not the case.

The practice should have a policy outlining roles and responsibilities, secure storage, and the controlling and recording of prescription form movement, including recording serial numbers.

Checklist	Yes/No	Comments
Does the practice have a policy on the security of prescriptions?	Yes/No	
Is a predetermined day arranged for receipt of prescription forms?	Yes/No	
Does the practice keep clear records of blank prescriptions received?	Yes/No	
Are barcodes recorded and checked against the delivery note?	Yes/No	
Are blank prescriptions stored securely in a locked cabinets within a lockable room or area?	Yes/No	
Is access to blank forms restricted to authorised individuals?	Yes/No	
Are serial numbers, quantity, date/time and where distributed recorded?	Yes/No	
Has a risk assessment been undertaken for printers used for computerised prescribing?	Yes/No	
Do all prescribers (including locums) know the practice policy for security of blank prescription forms for printers?	Yes/No	

Do all prescribers (including locums) know the practice policy for security of blank prescription pads (for home visits)?	Yes/No	
Do all other staff involved in the management of prescription forms know the practice policy for security of blank prescription forms and pads?	Yes/No	
Is the serial number of the first remaining form is made at the end of each patient session? (this may include the quantity remaining)	Yes/No	
Are all prescriptions removed from printers trays and locked securely when not in use/overnight?	Yes/No	
Do printers used for computerised prescribing have lockable printer covers?	Yes/No	
If not, are prescriptions in the printer secured if the clinician needs to leave the room during a clinic session?	Yes/No	
Do staff know what to do if they suspect that prescription forms have gone missing?	Yes/No	
Are records kept of prescription forms that are returned to stock or destroyed, and the reasons for destruction?	Yes/No	
Does the practice send any prescriptions by post? If yes, has a risk assessment been undertaken?	Yes/No	
Does the practice policy include dealing with lost prescriptions?	Yes/No	
Does the practice know how to report incidents relating to prescription security or fraud?	Yes/No	

6.Medicines Significant Events

Resources:

GP mythbuster 3: Significant event analysis (SEA) - Care Quality Commission (cqc.org.uk)
GP mythbuster 21: Statutory notifications to CQC - Care Quality Commission
GP mythbuster 24: Recording patient safety events with the Learn from patient safety events (LFPSE) service | Care Quality Commission (cqc.org.uk)
NHS England » The NHS Patient Safety Strategy

Significant event analysis(SEA) can be used to show quality improvement in the 'safety' key question of CQC inspections- this checklist focuses on medicines.

SEA uses case analysis to encourage the whole healthcare team involved in a case or incident to have a supportive discussion. The aim is to use this as a process to allow reflection and learning from the incident and so improve care. Examples can reflect good as well as poor practice.

Does the practice have a significant events policy?	Yes/No	
Number of medicines significant events in the last 12 months?	--------	
How often are medicines significant events discussed?	--------	
Does the practice use the national Learn from Patient Safety Events (LFPSE) to report patient medication safety incidents?	Yes/No	
Does the practice have evidence to show medicines significant events are recorded?	Yes/No	
Does the practice have evidence to show medicines significant events are discussed and are minutes available?	Yes/No	
Does the practice have evidence to show medicines significant events learning is implemented and any changes made?	Yes/No	
Who is responsible for ensuring actions are achieved?	--------	
Have any associated clinical audits been undertaken	Yes/No	
Does the practice have a process to ensure medicines significant events and learning are communicated throughout the practice?	Yes/No	
How often during the year are significant events communicated throughout the practice?	---------	
How is learning embedded in practice?	--------	

7. Prescribing Policy

Resources:

GP mythbuster 95: Non-medical prescribing - Care Quality Commission (cqc.org.uk)
Repeat Prescribing Toolkit
NHS England » Stopping over medication of people with a learning disability and autistic people (STOMP) and supporting treatment and appropriate medication in paediatrics (STAMP)
NHS England » Antimicrobial resistance (AMR)

Practices should have a prescribing policy in place and preferably reviewed annually and updated if new processes or procedures are implemented. All staff involved in prescribing or prescription management should have read the policy and work within the recommended guidance.

Non-medical prescribers may carry out a number of roles within GP practice and must have adequate professional indemnity to cover core as well as additional roles e.g. administration of vaccines or triage.

Clinical audits may be undertaken to demonstrate good prescribing practice as well as identifying areas for improvement and learning.

Checklist	Yes/No	Comments
Does the practice have a prescribing policy in place?	Yes/No	
When was the prescribing policy last reviewed updated?	-------	
Does the policy include a list of medication not routinely suitable for repeat prescribing?	Yes/No	
Does the policy include a process for reauthorisation of repeat prescriptions?	Yes/No	
Does the policy include a process for recording medicine supplied by the hospital?	Yes/No	
Does the policy include a process for recording medicine supplied over the counter?	Yes/No	
Does the policy include a process for recording medicine supplied privately?	Yes/No	
Does the policy include the number of days turnaround for issuing repeat prescriptions?	Yes/No	
Does the policy include a protocol for prescribing high-risk medicines?	Yes/No	

Does the policy include a protocol for prescribing to high-risk patients?	Yes/No	
Does the policy include a protocol for over-use of medication?	Yes/No	
Does the policy allow prescription requests over the telephone?	Yes/No	
Does the policy include a protocol for prescribing for patients who fail to attend for monitoring or review?	Yes/No	
Do only qualified prescribers authorise and sign prescriptions?	Yes/No	
Do prescribers follow appropriate national and local guidance?	Yes/No	
Do prescribers follow OptimiseRx messaging where appropriate?	Yes/No	
Do supplementary prescribers work to an agreed clinical management plan(CMP) agreed with an independent prescriber?	Yes/No or N/A	
Have HCPs who are non-prescribers and add medication to the clinical system from discharge and clinic letters been assessed as competent?	Yes/No	
Does the policy include guidance on prescribing and monitoring of medicines for patients with learning disability and/or autism.	Yes/No	
Does the policy include a whole team approach to antibiotic prescribing strategy to support local and national antimicrobial strategies?	Yes/No	

8. Non-Medical Prescribing

Resources:

GP mythbuster 95: Non-medical prescribing - Care Quality Commission (cqc.org.uk)

GP mythbuster 81: Pharmacy professionals in general practice - Care Quality Commission

In general practice, most NMPs are pharmacists or nurses, but could also be paramedics or physiotherapists and can be either independent or supplementary prescribers.

Supplementary prescribing is where an independent prescriber and a supplementary prescriber agree a clinical management plan (CMP) for a specific patient with the patient's consent and patients specific details of the illness, medicine dose/strength and limitations.

Independent prescribing is where the prescriber takes responsibility for clinical assessment, diagnosis, clinical management & prescribing as well as appropriate follow up, investigations and monitoring.

Non-medical prescribers may carry out a number of roles within GP practice and must have adequate professional indemnity to cover core as well as additional roles e.g. administration of vaccines or triage.

Checklist	Yes/No	Comments
Does the practice employ NMPs?	Yes/No	
If yes, how many?	--------	
What are their roles?	-------	
Does the practice have a clinical supervision policy with named supervisor(s)?	Yes/No	
Are all NMPs on the appropriate professional register?	Yes/No	
Do all NMPs have the prescribing qualification annotated on the register?	Yes/No	
Do non-medical prescribers (NMPs) prescribe within their competencies?	Yes/No	
Do all NMPs have adequate professional indemnity to cover their roles in primary care?	Yes/No	
Do supplementary prescribers work to an agreed clinical management plan(CMP) agreed with an independent prescriber?	Yes/No or N/A	
Do prescribers follow appropriate national and local guidance?	Yes/No	
Does the practice have any audits or reviews done by NMPs?	Yes/No	

9. Medication Reviews

Resources:

GP mythbuster 12: Accessing medical records and carrying out clinical searches - Care Quality Commission
https://www.rpharms.com/resources/repeat-prescribing-toolkit/medication-safety#2.4
Recommendations | Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes | Guidance | NICE
Ardens - CQC Searches – see 'What is the purpose of medication reviews'

CQC will assess the quality of a sample of medication reviews undertaken in the previous 3months from in 3 different categories by undertaking clinical reviews. (see Arends CQC standard searches)

- Medication review in last 3m - age >75y
- Medication review in last 3m - any age
- Polypharmacy - on >10 drugs + no medication review in last 18m

Medication review is a holistic clinical review of a patient's medications, including monitoring, concordance, concerns with the aim to optimise treatment and allow the patient an opportunity to ask questions and discuss treatment options and these should be scheduled at regular intervals.

Structured medication review (SMR), according to NICE, is *'a structured, critical examination of a person's medicines with the objective of reaching an agreement with the person about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste'.* It should be evidence-based, comprehensive and person-centred and carried out by a clinical pharmacist or other suitably qualified healthcare professional. It is not a review of some specific medicines in a long-term condition review.

Repeat medication check (clinical reauthorisation) is a clinical check and authorisation or re-authorisation of repeat medication for one or more conditions for a set amount of time.

CQC have come across instances where 'medication review' has been coded but the records do not show any evidence of a review having been undertaken. It is understood that in some cases a medication review is coded to consolidate previous consultations demonstrating evidence of review and patient care outcomes.

The frequency of medication reviews is not specified and should be based on an individual's needs, e.g. frailty, high-risk medication or poor control of a long-term condition.

Checklist	Yes/No	Comments
Does the practice have recall protocol for medication reviews?		

Does the practice have a protocol for patient who do not attend a medication review?		
Medication review in last 3m - age >75y -check reviews are complete	Yes/No	
Medication review in last 3m -– any age - check reviews are complete	Yes/No	
Has the practice identified any patients coded as medication review but not undertaken? If yes, has action been undertaken to resolve this and learning shared within the clinical team ?	Yes/No	
Polypharmacy - on >10 drugs + no medication review in last 18m – check if coding issue, if not prioritise for review	Yes/No	
Is advice about medicines given in line with current national guidance or evidence?	Yes/No	
Do medication reviews include the use of 'when required' medication?	Yes/No	
Are allergies reviewed and documented?	Yes/No	
Are prescribing instructions updated e.g. titration instructions changed when stable ?	Yes/No	
Are prescribing instructions actioned e.g. stop after 12m?	Yes/No	
Are medicines reconciled in line with current national guidance when transferring between locations or changing levels of care?	Yes/No	

10. MHRA and Medicines Safety Alerts

Resources:

GP mythbuster 91: Patient safety alerts - Care Quality Commission
Alerts, recalls and safety information: drugs and medical devices - GOV.UK
CAS - Home
A Guide to Defective Medicinal Products
2.15 Prescribing CAS Alerts : Ardens EMIS Web
How to Identify the Ardens EMIS Clinical Safety Alerts : Ardens EMIS Web

Spironolactone and renin-angiotensin system drugs in heart failure: risk of potentially fatal hyperkalaemia—February 2016 article - GOV.UK
https://www.gov.uk/drug-safety-update/citalopram-and-escitalopram-qt-interval-prolongation
Clopidogrel and proton pump inhibitors: interaction—updated advice - GOV.UK
NHS England » National Patient Safety Alert – Inappropriate anticoagulation of patients with a mechanical heart valve
Febuxostat: updated advice for the treatment of patients with a history of major cardiovascular disease - GOV.UK
Mirabegron (Betmiga▼): risk of severe hypertension and associated cerebrovascular and cardiac events - GOV.UK
Transdermal fentanyl patches for non-cancer pain: do not use in opioid-naive patients - GOV.UK
Hydrochlorothiazide: risk of non-melanoma skin cancer, particularly in long-term use - GOV.UK
Combination use of medicines from different classes of renin-angiotensin system blocking agents: risk of hyperkalaemia, hypotension, and impaired renal function—new warnings - GOV.UK
SGLT2 inhibitors: reports of Fournier's gangrene (necrotising fasciitis of the genitalia or perineum) - GOV.UK
SGLT2 inhibitors: updated advice on the risk of diabetic ketoacidosis - GOV.UK
Simvastatin: updated advice on drug interactions - GOV.UK
Carbimazole: increased risk of congenital malformations; strengthened advice on contraception - GOV.UK
Modafinil (Provigil): increased risk of congenital malformations if used during pregnancy - GOV.UK
Pregabalin (Lyrica): findings of safety study on risks during pregnancy - GOV.UK
Topiramate (Topamax): introduction of new safety measures, including a Pregnancy Prevention Programme - GOV.UK
Valproate (Belvo, Convulex, Depakote, Dyzantil, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell▼): new safety and educational materials to support regulatory measures in men and women under 55 years of age - GOV.UK

Appendix 1: Receiving, disseminating, responding to and acting upon MHRA/ national patient safety alerts

Medicines and Healthcare products Regulatory Agency (MHRA) alerts. MHRA produces alerts and recalls for medicines and medical devices, including:

- drug alerts

- medical device alerts
- drug safety updates
- field safety notices
- recalls

Central Alerting System (CAS) is a web-based cascading system for issuing:

- national patient safety alerts
- important public health messages
- other safety critical information and guidance.

Medicines Safety Alerts may also be issued locally.
Healthcare providers also have a duty to report any adverse incidents relating to medicines and devices using the Yellow Card Scheme.

Ardens has searches under CQC Safety Alerts and practices may also wish to review the Ardens Prescribing -Alerts and Prescribing CAS alerts (Note: there will be some duplication of searches)

CQC may check if relevant practice staff are aware of any recent alerts.
Checks may be undertaken to ensure affected patients have been identified with clear documentation in the patient notes, of communication or discussion of risks highlighted in the alert and actions undertaken.

Note: patients may not always be excluded from a search once action has been taken as CQC are looking to identify patients in order to undertake checks, except where monitoring is subsequently undertaken.

Checklist	**Yes/No**	**Comments**
Does the practice have a written protocol to manage or action medicines safety alerts within the practice?	Yes/No	
Name and role of person responsible for receiving medicines safety alerts	-------	
Are medicines safety alerts disseminated to all prescribers?	Yes/No	
Does the practice keep a log of medicines safety alerts?	Yes/No	
Does the log include action taken?	Yes/No	
Does the practice routinely run medicines safety searches to identify patients affected by the alert?	Yes/No	
Who is responsible for running medicines safety searches?	Yes/No	

Does the practice have evidence of incorporating medicines safety alert prescribing advice into routine practice?	Yes/No	
Has the practice undertaken any medicines safety audits in the last 12m?	Yes/No	
Have checks been made to ensure no new patients affected have joined the practice? How often is this done?	Yes/No	
Does the practice have any evidence of shared learning from MHRA alerts?(optional)	Yes/No	
Aldosterone Antagonist & ACEI /ARB - check U&E done in last 6m	Yes/No	
Citalopram 40mg or escitalopram 20mg & >65yrs -review to reduce dose	Yes/No	
Clopidogrel & omeprazole/esomeprazole -caution to review for reduced antiplatelet effect	Yes/No	
DOAC & mechanical cardiac valve -review to switch to warfarin	Yes/No	
Febuxostat & CVD – review as increased risk gout flares & inflammation	Yes/No	
Fentanyl patch started last 12m -review as no previous opiates	Yes/No	
Hydrochlorothiazide -check if informed risk of non-melanoma skin cancer	Yes/No	
Mirabegron – check no BP in last 12m (severe hypertension risk)	Yes/No	
Renin-angiotensin (ACEI, ARB,RI) -review for hypokalaemia, hypotension and impaired renal function	Yes/No	
SGLT-2i -review as no advice coded for ketoacidosis or Fournier's gangrene	Yes/No	
Simvastatin 40mg/80mg – review as on amlodipine, diltiazem or verapamil & increased risk of myopathy	Yes/No	
Teratogenic drugs in childbearing age (8-55yrs) – review as per guidance	Yes/No	
• **Carbimazole**	Yes/No	
• **Modafinil**	Yes/No	
• **Pregabalin**	Yes/No	
• **Topiramate**	Yes/No	
• **Valproate (sodium valproate & valproic acid)- females**	Yes/No	
• **Valproate (sodium valproate & valproic acid)- males**	Yes/No	

11. High Risk Medicines

Resources:

GP mythbuster 12: Accessing medical records and carrying out clinical searches - Care Quality Commission (cqc.org.uk)
GP mythbuster 92: Anticoagulant monitoring in primary care - Care Quality Commission (cqc.org.uk)
Medicines Monitoring – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
DMARDs | Health topics A to Z | CKS | NICE
Bulletin 332. Preparing GP practices for a regulatory inspection (prescqipp.info)
Ardens - CQC Searches
Frimley ICS Medicines Optimisation Board Formulary (frimleyhealthformulary.nhs.uk)
NHS Frimley - Shared Care

High risk medicines require regular monitoring and some may be subject to a shared care agreement (see links above). The practice should have recall and monitoring management processes in place including managing and prescribing for patients who do not attend for monitoring or reviews.

CQC will check that patients have been reviewed to ensure appropriate therapeutic drug and physical health monitoring with appropriate follow-up in accordance with current national guidance or evidence. Ensure safety-netting is documented and patients understand when to seek further help and advised what to do if their condition deteriorates.

The following high risk medicines are currently included in the Ardens CQC inspection searches:

- ACE (angiotensin converting enzyme) inhibitor or ARB (angiotensin receptor blocker)
- Aldosterone Antagonist in patients with heart failure
- Amiodarone
- Direct oral anticoagulants (DOAC)
- DMARDS (Disease-modifying antirheumatic drugs); azathioprine, leflunomide, methotrexate (ciclosporin, leflunomide, mercaptopurine, mycophenolate and sulfasalazine are not currently included in the CQC searches)
- Lithium
- Metformin if eGFR <30
- Warfarin

The Arden's CQC searches can be used to identify patients who may be at risk and are not designed to replace the practice recall and monitoring searches and processes. The standard searches have wider parameters to allow CQC to identify outliers, it is recommended the practice also runs the enhanced searches which have the recommended monitoring intervals.

The prescriber should ensure results undertaken by the hospital are downloaded prior to issuing a prescription for high-risk medication or document in the record that monitoring has been checked on ICE or clinical correspondence.

Checklist	**Yes/No**	**Comments**
Does the practice have a protocol in place for monitoring & recall of patients prescribed high risk medication?	Yes/No	
How often are high risk medication searches run?	-------	
Who is responsible for running the searches?	--------	
How often are the searches run?	--------	
Does the protocol include a failsafe for patients who fail to attend for monitoring or review?	Yes/No	
Does the practice have evidence of action for patients who fail to attend monitoring or review and is this be recorded in the patient record?	Yes/No	
Does the prescriber check that monitoring is not overdue prior to issuing a prescription for high risk medication?	Yes/No	
Does the prescriber check that all results are within safe parameters prior issuing a prescription for high risk medication?	Yes/No	
Does the prescriber ensure the quantity of medication does not exceed when monitoring is next due?	Yes/No	
Is the recall for monitoring up-to-date?	Yes/No	
ACEi or ARB - check U&E done in last 18m (should be every 12m)	Yes/No	
Aldosterone Antagonist in heart failure- check U+E done in last 6m	Yes/No	
Amiodarone – check U&E/LFT/TFT done in last 6m	Yes/No	
DMARDs- check bloods done in last 6m	---------	
Azathioprine (should be every 3m)	Yes/No	
Leflunomide (should be every 3m- include BP & weight)	Yes/No	
Methotrexate (should be every 3m)	Yes/No	
DOAC- **Direct oral anticoagulants -**check CrCl done in last 12m	Yes/No	
DOAC- check for contraindicated if CrCl <30 or <15	Yes/No	
DOAC – CrCl 30-59- check U&E in last 6m	Yes/No	

DOAC – CrCl<30- check U&E in last 3m	Yes/No	
DOAC- check FBC & LFT in last 15m (should be every12m)	Yes/No	
DOAC- review if Hb <9g/dl in last 12m	Yes/No	
Lithium - check levels done in last 6m (should be every 3m)	Yes/No	
Lithium - are levels within range?	Yes/No	
Lithium - check U&E/TFT/Ca in last 9m (should be every 6m)	Yes/No	
Lithium - are levels within range?	Yes/No	
Metformin – review if eGFR <30	Yes/No	
Warfarin – check if no INR in last 3m	Yes/No	
Warfarin – review if 2 x INR > 5 or 1 x INR> 8	Yes/No	

12. Medicines Management/Optimisation

Resources:

GP mythbuster 4: Quality improvement activity - Care Quality Commission

CQC will expect to see evidence of clinical prescribing audits; practices should be able to provide 2 examples of audits of prescribing to demonstrate medicines are appropriately prescribed in line with relevant legislation, current national guidance or best available evidence.
Audits should be within the last 12 months.

The medicines optimisation pharmacist may be able to provide advice and support for undertaking clinical audits.

Checklist	**Yes/No**	**Comments**
Has the practice undertaken prescribing audits within the last 12m	Yes/No	
How many prescribing audits has the practice undertaken in the last 12m?	--------	
Can the practice show evidence that any learning has been shared and discussed ?	Yes/No	
Can the practice show evidence that any agreed actions have been implemented?	Yes/No	
Has the practice re-audited to demonstrate that learning has been embedded into practice?	Yes/No	

13. Potential Missed Diagnosis

Resources: GP mythbuster 12: Accessing medical records and carrying out clinical searches - Care Quality Commission
Assessment | Diagnosis | Chronic kidney disease | CKS | NICE
Position statement defines remission of diabetes - PCDS
Ardens - CQC Searches – see 'Potential missed diagnosis of diabetes'

CQC will expect to see that the practice regularly runs searches to identify people who may have a missed diagnosis.
Ardens CQC standard searches include CKD and Diabetes.

The diabetes potential missed diagnosis search excludes people with gestational diabetes or steroid-induced diabetes in the last year or haemoglobinopathies but have a history of 2 or more HbA1c readings that are equal to or above 48. If 2 consecutive reading in the diabetic range, then the patient should be coded as diabetic. If HbA1c improves below 48, then code as 'diabetes in remission' in order to ensure the patient remains on recall for monitoring and eye screening.

Checklist	Yes/No	Comments
Does the practice have a protocol to manage potential missed diagnoses?	Yes/No	
Does the practice run searches to identify potential missed diagnosis?	Yes/No	
How often are these run?	Yes/No	
Who is responsible for running these searches?	Yes/No	
Does the practice have a process for managing potential missed diagnosis?	Yes/No	
Chronic Kidney Disease (CKD) stage 3-5- check coding if repeated eGFR <60 in last 2yrs, including latest. Check correct stage recorded.	Yes/No	
Diabetes - check coding if HbA1c greater or equal to 48 on 2 or more occasions? (may have non-diabetic hyperglycaemia coding)	Yes/No	

14. Monitoring of Long Term Conditions

Resources: GP mythbuster 12: Accessing medical records and carrying out clinical searches - Care Quality Commission

CQC will expect to see that the practice regularly runs searches to identify people with long-term conditions and monitoring is overdue
The Ardens standard searches have wider parameters to allow CQC to identify outliers and it is recommended the practice also runs the enhanced searches which have the recommended monitoring intervals.

The practice should ensure that patients are followed up for management of long-term conditions and escalated if fail to attend.

Checklist	Yes/No	Comments
Does the practice have a protocol to manage monitoring of long term conditions?	Yes/No	
Does the practice follow the protocol for management, follow up and escalation?	Yes/No	
Asthma -prescribed 2 or more courses of high dose oral steroids in the last 12 months- review for adherence and asthma control	Yes/No	
Chronic kidney disease (CKD) stage 4 or 5 and no U&Es in the last 9 months- recall for monitoring	Yes/No	
Diabetic retinopathy coded and latest HbA1c greater than 74mmol/l- review for control of diabetes, monitoring and education	Yes/No	
Hypothyroidism and no thyroid stimulating hormone (TSH) in the last 18m – recall for monitoring	Yes/No	
Pneumococcal vaccination for patients with hyposplenism or asplenia (including patients with coeliac disease and sickle cell anaemia) in patients over 10 years of age- recall for vaccination	Yes/No	

15. Medicines Usage

Resources:

GP mythbuster 12: Accessing medical records and carrying out clinical searches - Care Quality Commission
Why asthma still kills | RCP London
Hypnotics and anxiolytics | Treatment summaries | BNF | NICE
Overview | Atrial fibrillation: diagnosis and management | Guidance | NICE
Ethinylestradiol with levonorgestrel | Drugs | BNF | NICE
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/385791/PHE-NHS_England_pregabalin_and_gabapentin_advice_Dec_2014.pdf
Scenario: NSAIDs prescribing issues | Management | NSAIDs - prescribing issues | CKS | NICE

CQC will expect to see that the practice regularly runs searches to identify people who require review for medicines usage.
See Ardens CQC standard searches.

Checklist	Yes/No	Comments
Does the practice have a protocol to manage medicines usage?	Yes/No	
Does the practice run searches to identify medication overuse?	Yes/No	
How often are these run?	Yes/No	
Who is responsible for running these searches?	Yes/No	
Does the practice a process for managing medication overuse (as part of repeat prescribing policy)?	Yes/No	
Asthma - more than 12 Short Acting Beta 2 Agonist (SABA) inhalers issued in the last 12 months?	Yes/No	
Asthma – prescribed long-acting beta agonist (LABA) inhaler (excluding COPD) in the past 6 months with no inhaled corticosteroid?	Yes/No	
Atrial Fibrillation and no anticoagulant prescribed	Yes/No	
• In males with CHADSVASC2 equal or great than 1?	Yes/No	
• In females with CHADSVASC2 equal or great than 2?	Yes/No	
Benzodiazepine and z-drugs- where frequency requires review?	Yes/No	
Combined oral contraceptive pill – history of VTE or thrombophilia?	Yes/No	
Gabapentinoids – consider review as 3 or more issues in last 6m?	Yes/No	
On NSAID + >=65y or on antiplatelet + >=75y - Consider PPI as not coded declined/not tolerated?	Yes/No	

16. OpenPrescribing.net (Bennett Institute for Applied Data Science, University of Oxford, 2024)

Resources:

Prescribing measures for NHS FRIMLEY | OpenPrescribing

Every month, the NHS in England publishes anonymised data about the drugs prescribed by GPs. Openprescribing.net allows GPs, managers and everyone to explore the 77 standard and 24 NHS low priority measures at practice, PCN, ICB and nationally level to support safer and more efficient prescribing.

CQC may view how the practice compares on these prescribing measures.

Note: there is a 2-3month lag time on the prescribing data.

Have the Openprescribing measures been checked recently?	Yes/No	
Are there any outliers that need to be addressed ? (If yes, consider undertaking an audit which can be used as evidence)	Yes/No	

Appendix 1

Receiving, disseminating, responding to and acting upon MHRA/ national patient safety alerts

(Produced by Frimley Medicines Optimisation Team June 2023. Review due June 2025)

Practices need systems and processes to disseminate and act on information. This includes information from external sources which could affect patient safety. This is mainly patient safety alerts but could include local or national clinical guidance. There should be a system in place for cascading alerts to appropriate staff and checking that alerts are actioned and, where necessary, for collating information about practice rationale for not following the recommendation in the alert. There should be a Standard Operating Procedure (SOP) detailing the action to take in the event of a medication safety alert. (see Appendix A for a sample SOP).Please refer to GP mythbuster 91: GP mythbuster 91: Patient safety alerts - Care Quality Commission (cqc.org.uk)

To ensure there is appropriate clinical involvement and oversight, practices should:

- consider who should receive alerts and information within the practice
- make sure there are effective processes in place to act upon alerts received
- arrange cover for annual leave or staff absences.

For example, a practice could keep a log of alerts (see Appendix B for a sample log) They could document action taken in response to these. There should be clinical involvement and oversight of the process.

All GP practices in England are required to register to receive CAS alerts directly and register a practice email address with the CAS and monitor the email account to act on CAS alerts where appropriate. They must notify the MHRA if the email address changes to ensure MHRA distribution list is updated and register a mobile phone number (or several numbers) with the MHRA CAS which will only be used as an emergency back up to email for text alerts when e-mail systems are down. It is important to ensure that the email address used for the CAS alerts is one that can be accessed via a number of staff members e.g. GP practice generic email address, in the event of unexpected absences etc.

Key sources of information

MHRA alerts and newsletter

MHRA produces alerts and recalls for medicines and medical devices, including:

- drug alerts
- medical device alerts
- drug safety updates
- field safety notices.

Providers can sign up for email notifications of these MRHA alerts and updates.

Central Alerting System (CAS)

CAS is a web-based cascading system for issuing:

- national patient safety alerts
- important public health messages
- other safety critical information and guidance.

Alerts include:

- NHS Improvement Patient Safety Alerts (PSA) and Estates Alerts
- MHRA Dear Doctor letters
- Medical Device Alerts (MDA) and Drug Alerts
- Chief Medical Officer (CMO) Alerts, and
- Department of Health & Social Care Supply Disruption alerts.
  Register for email notifications of to receive all CAS alerts.

Acting on Alerts

Practices need to monitor updates and alerts and act upon these in a timely manner. They need:

- systems in place to identify, recall and follow-up affected patients and to follow-up on these where required
- a process to recall a medicine or device – especially in dispensing practices
- to incorporate prescribing advice into routine clinical practice, in the same way as any other prescribing guidance. This could be through medication reviews or as part of the practice audit programme.

The use of technology to monitor and raise alerts is used by many practices to facilitate ongoing safe prescribing.

As well as acting on alerts healthcare providers also have a duty to report any adverse incidents relating to medicines and devices using the Yellow Card Scheme.

Appendix A

Sample SOP for a Practice to Receive, Disseminate, Act upon MHRA/ National Patient Safety Alerts

Purpose

The purpose of the SOP is to set out the procedure for sharing national/local clinical guidance and acting on drug and safety alerts at **[insert name of practice]**. This protocol is relevant to anyone who works at the practice.

The individual responsible for the dissemination of guidance/alerts at **[insert name of practice]** is **[Insert job title]**. In their absence, the following staff members will be responsible in order of priority **[Insert job titles].** This protocol will be reviewed **[insert time scale]** to ensure that it remains effective and relevant.

Procedure

1) The responsible individual will ensure that the practice is signed up, with a generic practice address, to MHRA/CAS alert cascades

2) The responsible individual will determine who to send the guidance/alerts to, depending on nature of the alert.

- Appropriate clinical alerts/guidance will be shared with healthcare professionals at the practice;

- A plan of action (or no action if alert not relevant) must be decided on the basis of the alert. This could be straightforward or require discussion eg. at the next practice meeting or sooner if urgent/complex. Depending on the alert, this could also require multi-organisation responses

3) A record log will be kept of the above actions, noting initiation dates, responsible persons, review/update dates.

4) There should be a regular review of alerts received and acted upon with the practice prescribing lead or designated deputy, to ensure professional oversight and to pick up any anomalies or missed actions – regular review of the record log, would be an ideal way to do this.

Date of last Practice review xxxxx

Date of next Practice review xxxxxx

Appendix B

Sample Log Sheet

2023-2024 LOG OF MEDICINES/DEVICES SAFETY ALERTS/ RECALLS

Date	Alert (include hyperlink)	Relevant to primary care?	Relevant to practice?	No of patients affected	Action(s) taken	Name and job title of person responsible	Comments