PMA

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CQC Fundamentals for Pharmacists and Clinical Leads

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Welcome to the PMA

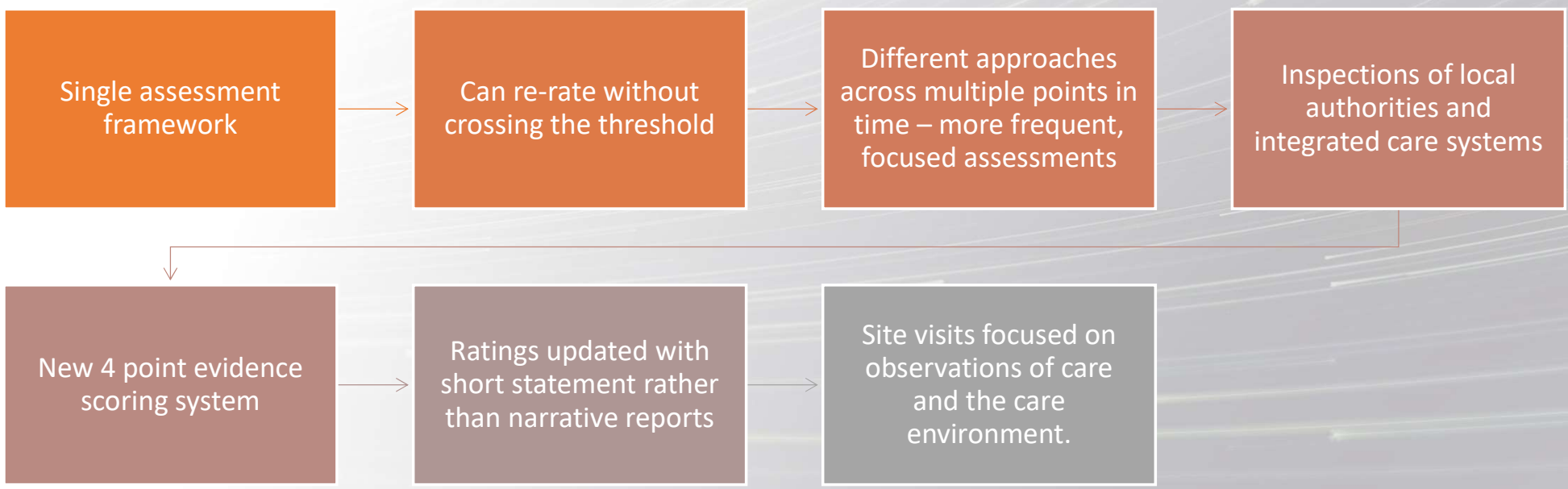
The **PMA** is the leading professional membership body for the healthcare sector (UK-wide). We provide insight, training, education and interaction opportunities for those involved in General Practice and the wider Health & Care sector. Our membership comprises Practice Managers, GPs and other Clinicians, Practice Business Managers, PCN Managers, Personalised Care workers, ICS, ICB and Training Hub members – all working in partnership. We seek to facilitate and promote best practice amongst its members.

The PMA offers education, support and career development to all those involved in the Health & Care sector. When you join you get 12 months for the price of 11 and you'll benefit from all we have to offer *(and there's plenty)* to find out more, please visit: www.pma-uk.org/pma-professional-membership/

Introduction

- CQC Background
- Inspection methodology
- Clinical searches focus
- Top tips
- Q&A

New Approach



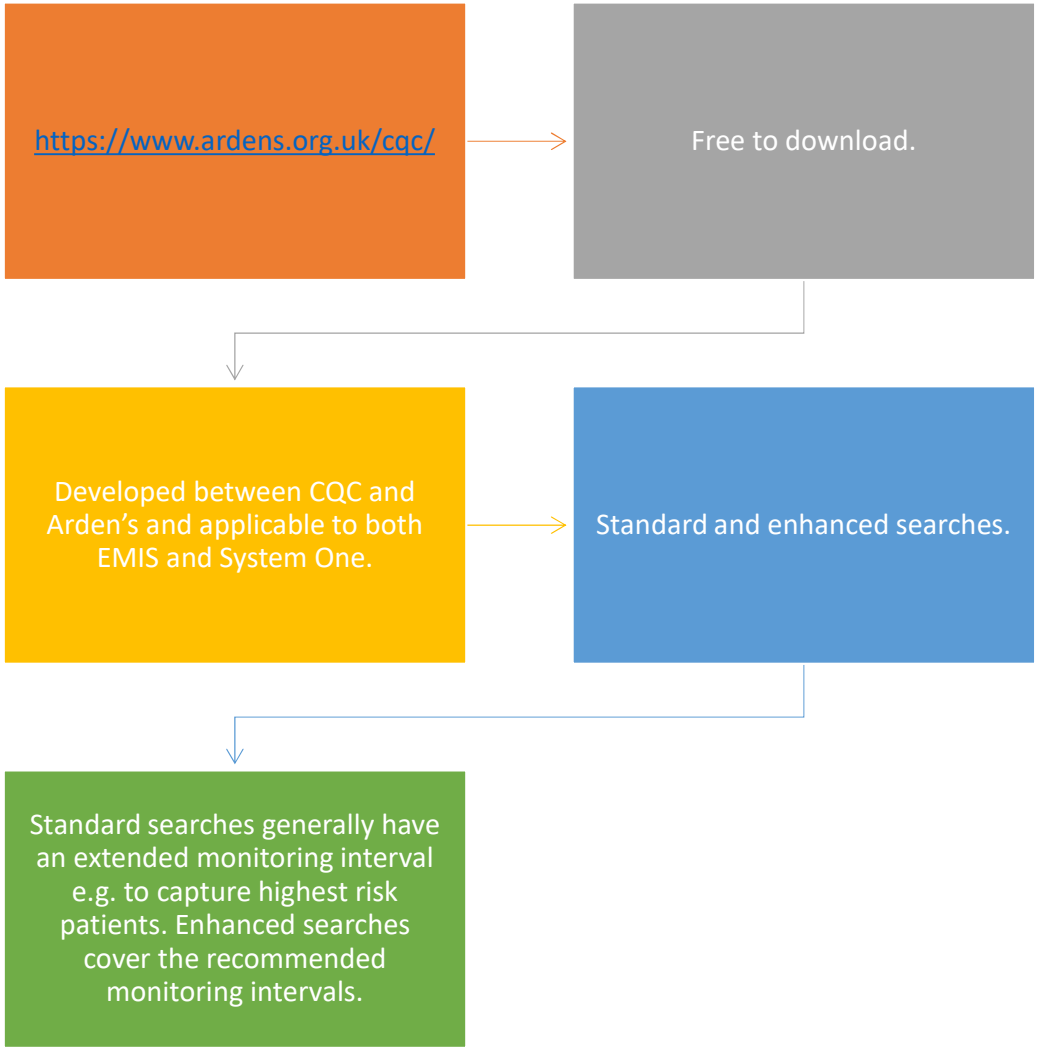
Quality Statements

Key Question	Quality statements
Safe	**Learning culture**; Safe systems, pathways and transitions; Safeguarding; Involving people to manage risks; Safe environments; Safe and effective staffing; Infection prevention and control; **Medicines optimisation**.
Effective	**Assessing needs; Delivering evidence-based care and treatment**; How staff, teams and services work together; Supporting people to live healthier lives; **Monitoring and improving outcomes;** Consent to care and treatment.
Caring	Kindness, compassion and dignity; Treating people as individuals; Independence, choice and control; Responding to people's immediate needs; Workforce wellbeing and enablement.
Responsive	Person-centred care; Care provision, integration and continuity; Providing information; Listening to and involving people; **Equity in access; Equity in experiences and outcomes; Planning for the future.**
Well-led	Shared direction and culture; Capable, compassionate and inclusive leaders; Freedom to speak up; Workforce equality, diversity and inclusion; Governance, management and sustainability; Partnerships and communities; **Learning, improvement and innovation**; Environmental sustainability – sustainable development.

Evidence categories

Evidence category	
People's experience of health and care services	Evidence from patients, families, carers and advocates for people who use services. Phone calls, emails and give feedback on care forms. Survey results. Interviews with people and local organisations who represent the patient population and those more likely to have a poorer experience/outcomes.
Feedback from staff and leaders	Staff surveys, individual interviews or focus groups, feedback through give feedback on care service, whistleblowing.
Feedback from partners	Commissioners, other local providers, professional regulators, accreditation bodies, royal colleges, multi-agency bodies.
Observations	Observing care and the care environment; Healthwatch reports; infection prevention and control, medicines management, emergency drugs, premises management, interactions
Processes	Audits, findings and learning from safety incidents, access times, case note reviews, policies etc.
Outcomes	Vaccination and prescribing data, mortality rates, emergency admissions and re-admission rates to hospital; infection control rates.

Arden's CQC Clinical searches



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Accessing medical records

- Health and Social Care Act 2008 gives inspectors powers to access medical records
- Code of practice dictates access when it is necessary and where intruding on patients' privacy is justified and proportionate
- Check that notes are contemporaneous and demonstrate that staff are working within their competencies.
- Records contain enough information – clinical findings; investigation requests, clinical assessment, management plans, safety netting, referrals and follow-up.
- Medicines are appropriately prescribed and monitored.

High Risk Medicines Monitoring

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Detailed in CQC mythbuster 12 – Accessing medical records during inspection

High risk medicine – patient monitoring and review

DMARDs	Lithium	Spironolactone	ACEi or ARB	Amiodorone	Warfarin	NOAC	Mirabegron

DMARDs

Used to treat autoimmune conditions

Require regular monitoring to ensure complications are identified early

More serious side effects include anemia, bone marrow suppression – leading to increased risk of infection and bleeding.

Increased risk of developing cancer and cause liver damage.

Methotrexate can cause respiratory disorders and lung fibrosis.

Leflunomide can cause neurological problems, weight loss and hypertension.

DMARD monitoring

Check FBC, U&Es and LFTs every 2 weeks until on stable dose for 6 weeks. Then monthly for 3 months, then at least every 12 weeks. More frequent monitoring is appropriate in patients at higher risk of toxicity.

Dose increases should be monitored every 2 weeks until on a stable dose for 6 weeks then revert to previous schedule.

Patients on Leflunomide also require BP and weight checks at every monitoring visit.

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DMARD searches

- Methotrexate, Leflunomide and Azathioprine prescribed in the last 6 months with no FBC, U&E or LFT checks in that time.
- The standard search is for 6 months but the monitoring is required every 12 weeks. The enhanced search looks for patients who have fallen outside of the 12 week monitoring – these are the ones generally used on inspection.
- Inspectors also look for evidence that Methotrexate is prescribed on a specific day of the week due to an MHRA alert relating to inadvertent overdose.
- Where there is a shared care agreement and monitoring is done in secondary care but prescribing in primary care, there must be evidence in the patient record that the prescriber has checked that it is safe to prescribe e.g. download results or record that results have been checked.

DMARD monitoring

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	**Methotrexate monitoring**														
2															
3				**Date of last Monitoring**				**Date Monitoring due**				**Recall date**		**Appt Date**	**Comment**
4	Patient ID	Signed Shared care agreement?	Nominated day on Px	FBC	U&E	LFT		FBC	U&E	LFT		3 weeks ahead			
5															
6	4234	Yes	Yes	06/05/2023	06/05/2023	06/05/2023		29/07/2023	29/07/2023	29/07/2023		08/07/2023			Texted x3. Called pt 30/6 no reply. Escalated to Dr LG 1/7 and reduced to weekly script. Patient away on holiday will book on return on 10/8
7	97226	Yes	Yes	01/08/2023	01/08/2023	09/05/2023		24/10/2023	24/10/2023	01/08/2023		01/08/2023		07/08/2023	LFT missed off last bloods, phoned 1/8 and appt booked
8	61883	Yes	Yes	01/06/2023	01/06/2023	01/06/2023		24/08/2023	24/08/2023	24/08/2023		03/08/2023		09/08/2023	Text message sent, appt booked
9	68432	Yes	Yes	07/07/2023	07/07/2023	07/07/2023		29/09/2023	29/09/2023	29/09/2023		08/09/2023			
10	86522	Yes	Yes	27/07/2023	27/07/2023	27/07/2023		19/10/2023	19/10/2023	19/10/2023		28/09/2023			
11	4325	Yes	Yes	29/07/2023	29/07/2023	29/07/2023		21/10/2023	21/10/2023	21/10/2023		30/09/2023			
12	2234	Yes	Yes	07/08/2023	07/08/2023	07/08/2023		30/10/2023	30/10/2023	30/10/2023		09/10/2023			
13															

Lithium

- Measure the person's plasma lithium level every 6 months. However, this should continue to be every 3 months in people in higher risk groups e.g. elderly, impaired renal or thyroid function, raised calcium etc.
- Weight or BMI, U&E (+calcium), eGFR and thyroid function every 6 months – more frequent if abnormal.
- CQC searches identify patients who have not had a lithium level in 6 months and those with no U&E, calcium or TFT in 9 months.
- Most commonly it is calcium monitoring that is forgotten.

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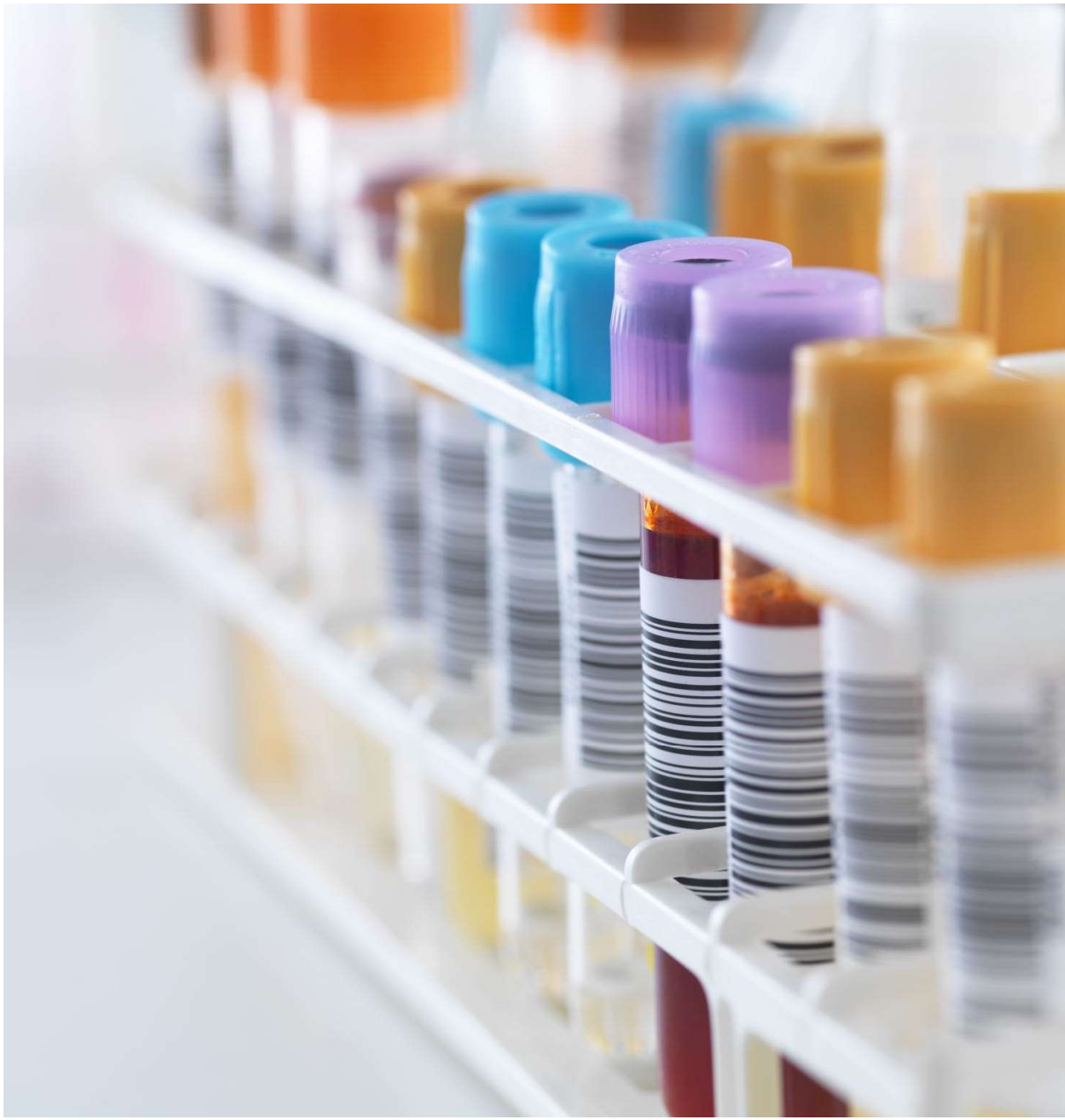
DOAC

- DOAC – Apixaban, dabigatran, edoxoban and rivaroxaban.
- Search for creatinine clearance in the last 12 months (and ever).
- FBC and U&E every 12 months.
- If CrCl >=60 annual bloods and CrCl
- If CrCl<30 bloods every 3 months.
- If CrCl<30-59 bloods every 6 months.
- If Hb<9g/dl in last year – should have evidence of review in relation to DOAC.



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ACE-I, ARBs and Aldosterone Antagonists

Check renal function and serum electrolytes annually unless clinical judgement or abnormal blood results indicate more frequent monitoring.

CQCs standard searches extend to 18 months but monitoring should be annually.

When patients are on an Aldosterone Antagonist with heart failure – monitoring every 6 months when stable. More frequent monitoring at the start of treatment.

OPTIMISE HEALTHCARE MANAGEMENT

QUALITY, COMPLIANCE AND IMPROVEMENT SPECIALISTS

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Other monitoring searches

Amiodarone – check U&E, LFT and TFT every 6 months. ECG annually.

Mirabegron – MHRA drug safety alert in October 2015 reported cases of severe hypertension. Not to be used if systolic BP >180mm Hg or dialstolic BP >110mm Hg. Clinical searches identify if BP not monitored in the last 12 months.

Metformin – patients with an egfr < 30 – should be stopped

Warfarin - record of INR in last 3 months

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Safety alerts

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Single alerts

- Teratogenic drugs – valproate, carbimazole and modafinil
- Hydrochlorothiazide
- SGLT-2 inhibitors
- Epipens
- Febuxostat
- Citalopram
- Fentanyl patches

Teratogenic Drugs (risk of birth defects)

- Valproate –
  - pregnancy prevention plan,
  - annual risk acknowledgement form signed and stored in patient record,
  - evidence that acknowledgement form checked and in date prior to each prescription issue,
  - annual review to ensure conditions of PPP in place,
  - referral back to specialist for annual review,
  - evidence of discussion of risks with patient and information given,
  - highly effective contraception (ideally intrauterine device or implant) or two complementary forms of contraception including barrier method.

Teratogenic drugs cont'd

Carbimazole and Pregabalin

- Evidence of discussion of risks with patient and patient guide given
- Effective contraception.

Modafinil

- Evidence of discussion of risks with patient and patient guide given
- Effective contraception.
- If possible highly effective contraception e.g. intrauterine device or implant as Modafinil reduces the effectiveness of oral contraception.

Topiramate

- Evidence of discussion of risks with patient and patient guide given
- Effective contraception.
- Topiramate may reduce the effectiveness of steroidal contraceptives.

Safety alerts (1)

Hydrochlorothiazide (diuretic)

- Linked to increased risk of skin cancers
- Patients should be advised of the risk of skin cancer
- Advised to regularly check for new or changed skin lesions or moles
- Reconsider use if previous skin cancer
- Advise to limit exposure to sunlight and UV rays
- CQC check there is evidence of the above discussions in the patient record.

SGLT-2-inhibitors (diabetes, heart failure or CKD treatment)

- Risk of Fournier's gangrene
- Evidence that patients have been informed to seek urgent medical attention if they experience severe pain, tenderness, erythema or swelling n the genital or perineal area – accompanied by fever or malaise.
- Patients should also have been informed of the increased risk of diabetic ketoacidosis.
- CQC look for evidence of these discussions in the patient record and that these have been incorporated into diabetic reviews etc.

Safety alerts (2)

Adrenaline auto-injectors (anaphylaxis)

- Various alerts in the last few years.
- Patients should have two, in date autoinjectors available at all times.

Febuxostat (gout)

- MHRA alert in July 2019 identified increased risk of cardiovascular death and other mortality causes where patients have a history of major cardiovascular disease.
- CQC will review patient records to understand if the risk has been considered by the prescriber. They will also look for evidence that the risk has been discussed with the patient.

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Safety alerts (3)

- Citalopram and Escitalopram (depression)
  - Can casue a potentially fatal arrhythmia. The risk increases with age.
  - December 2014 MHRA alert advised of increased risk when citalopram 40mg or higher or escitalopram 20mg or higher were used in patients over the age of 65.
  - New maximum doses for patients over 65 and adults with hepatic impairment.
  - CQC will review patient records to identify any patients at increased risk to ensure the risks have been considered and discussed with the patient.
- Fentanyl
  - September 2020 MHRA alert that fentanyl should not be used for non-cancer pain relief in opioid-naïve patients.
  - The search identifies patients who have received fentanyl in the last 6 months to identify if patients are affected by this alert.

Combination alerts

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- Simvastatin 40mg in combination with Amlodipine, Diltiazem, Verapamil – increased risk of muscle pain/damage (myopathy) - maximum dose of simvastatin should be 20mg – consider alternative statin.
- Clopidogrel and omeprozole or esomeprazole – reduced antiplatelet effect and increased risk of heart attack or stroke – consider alternative PPI
- Aldosterone antagonist and ACE or ARB - monitoring
- Renin-angiotensin system drugs – on 2 or more = increase renal risk

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Governance of safety alerts

Monitoring system

Centralised system for receiving and monitoring new safety alerts.

While the day to day management of this can be delegated e.g. to practice or PCN pharmacists, the leadership of this remains with the GP partners.

A log of all alerts received should be maintained.

Evidence of action taken should be linked to the log e.g. evidence of searches to identify patients at risk and actions to address the risks.

Evidence of all prescribers being made aware of alerts e.g. meeting minutes demonstrating discussions etc.

Evidence of regular searches of new and existing alerts to prevent patients falling through the net eg. When transferring from other practices.

Regularly running Arden's CQC searches as a 'safety net'.

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Potential missed diagnosis

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Missed diabetes diagnosis

CQC search to identify patients who have had two or more HbA1c readings of 48 or above without diabetes being coded.

CQC will review records to determine if diabetes, pre-diabetes etc. should be coded.

The CQC clinician will review patient records to determine if there is evidence of actual or potential patient harm.

Potential harm may be evidenced if there is an ongoing lack of monitoring and the impact of no coding to trigger a review.

Actual harm may be evidenced if the patient is symptomatic of diabetes but has not been subject to regular review.

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Missed chronic kidney disease diagnosis

The CQC search identifies patients with two reduced eGFR readings of less than 60.

The CQC clinician reviews records to determine if the patient is correctly coded or not.

The CQC clinician reviews records to determine if there is evidence of actual or potential patient harm.

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Long term condition monitoring

Asthma

- A search to identify patients who have received more than 12 SABA inhalers in the last 12 months.
- This is a sign that asthma may be poorly controlled.
- The National Report on Asthma Deaths recommended that all asthma patients on more than 12 SABA in the previous 12 months should be invited for urgent asthma review of their control, providing education and change of treatment as required.
- The CQC clinician reviews patient records to determine risk of asthma exacerbation. This includes a review of prescribed preventer inhalers and whether a review has taken place.

Asthma cont’d

- A second search is undertaken to identify patients with asthma who have had two or more courses of oral steroids in the last 12 months.
- They will determine if the patient had a review within 48 hours of the exacerbation (in line with NICE guidance) and look at evidence of treatment being adjusted accordingly.
- They also look to see if patients admitted to hospital with exacerbation have been reviewed within two days of discharge.
- They check that an adequate assessment including history and examination has been carried out (plus appropriate type of appointment e.g. face to face).
- Patients on repeated courses of oral steroids are at risk of developing adrenal suppression if steroids are stopped suddenly or they become unwell. These patients should be issued with an emergency steroid warning card.
- A further search identifies patients prescribed a long acting beta agonist inhaler and no inhaled corticosteroid – risk of progressively worsening inflammation and increased sensitivity to asthma triggers.

Diabetes

- A search of patients with diabetic retinopathy and an Hba1c >74.
- This identifies the most poorly controlled patients.
- A sample of patient records will be reviewed to determine appropriate monitoring and review.
- CQC expect to see regular diabetic and medication reviews, monitoring of BP and cardiovascular risk and albumin:creatinine ratio.
- They will review the action taken to improve diabetic control and determine if there is risk of harm relating to poor diabetes control.
- A further search of patients receiving Metformin and an eGFR<30 as the use of Metformin is contraindicated in this situation.

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Hypothyroidism

- A search of patients with hypothyroidism who have not had a thyroid function test in 18 months (should be annual).
- A search of patients who have been prescribed thyroxine in the last 6. months with no thyroid stimulating hormone check in 18 months and last TSH was outside of the normal range (>7).
- Patients with TSH levels outside of the normal range should have their dose reviewed and repeat monitoring after 3 months.

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CKD 4 or 5

- A search of patients with CKD 4 or 5 with no BP or U&E check in the last 9 months.
- NICE guidance advises between 2 and 4 checks annually (U&E and ACR).
- The search identifies patients at risk of poor management and deteriorating renal function.
- CQCs review of patient records includes evidence of signs or symptoms of reduced renal function and the use of medication that may further impair renal function.

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Benzodiazepines and Z drugs

- The search identifies patients who have had more than 10 prescriptions for benzodiazepines in the last 12 months. CQC will review patient records to identify if the risk of dependence has been identified and if there have been attempts to reduce doses.
- In addition, inspectors will review prescribing data relating to the ‘average daily quantity of hypnotics prescribed..’ (STAR PU).

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Gabapentinoids

- Gabapentin and pregabalin – neuropathic pain and epilepsy.
- Schedule 3 controlled drug since 2019.
- Prescribed for a maximum of 30 days at a time.
- Risk of misuse.
- Caution in respiratory, neurological and renal impairment.
- CQC focus on identifying patients receiving these medicines without evidence of a long term review.

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Additional searches

NSAID, anticoagulant or antiplatelet prescribed to patients > 65 with no proton pump inhibitor (PPI) – risk of gastric irritation.

Atrial fibrillation with an appropriate clotting risk score but no anticoagulant prescription – increased risk of stroke. Males with a CHA2DS2-VASC score >1 and females with a score >2.

Combined oral contraceptive pill and a history of venous thromboembolism – 2014 MHRA guidance not to prescribe. Unacceptable health risk.

DNACPR / ReSPECT forms in the last 2 years

Results, Correspondence, tasks and workflow

- CQC will look at the process for dealing with test results.
- They will ask to access global view and identify the oldest results waiting for review in order to establish any risk.
- They will do the same for correspondence and tasks to identify that follow up is appropriate and timely.
- They will follow up areas such as two week wait referrals to ensure appropriate monitoring e.g. have patients received an appointment and have they attended?
- Is there a result recorded for every smear taken?

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Hints and Tips

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Poor patient compliance with monitoring

- Ensure there is a policy/protocol in place
- Consider reducing the frequency of prescriptions
- Work in partnership with other providers e.g. secondary and community care specialists
- Balance of risk between continuing to prescribe and stopping medication if monitoring compliance is poor
- Ensure evidence of these discussions and considerations are recorded in the patient record.

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Clinical lead Inspection Questions

- Focus on clinical search findings
- Access questions
- Leadership
- Safeguarding
- Incidents
- Strategy
- Quality improvement
- Innovation
- Collaboration
- Tackling health inequalities

Pharmacist Inspection Questions

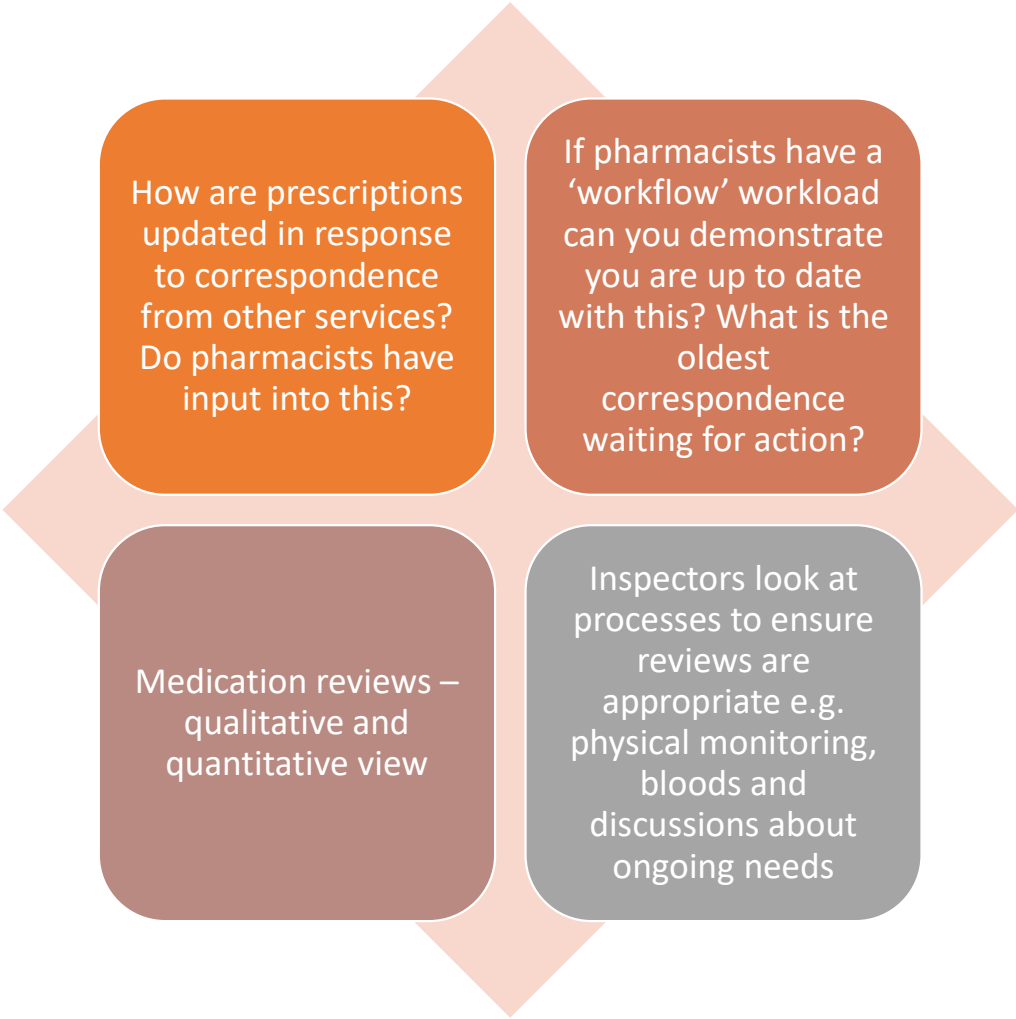
What is your role? Chronic disease management? Acute care? Medication review?

Are you a prescriber?

What is your scope of practice?

Where does your clinical supervision come from? Practice? PCN? Pharmacist? GP? (clinical supervision needs to cover the whole of your scope of practice)

Prescribing and medication reviews



Leadership responsibilities

OVERSIGHT OF CLINICAL GOVERNANCE

ASSURANCE THAT PROCESSES ARE FUNCTIONING APPROPRIATELY

INSPECTORS WILL EXPECT PARTNERS TO BE ABLE TO DESCRIBE THE SYSTEMS IN PLACE INCLUDING WHERE RESPONSIBILITY HAS BEEN DELEGATED