Medicines Safety Assurance From GP Practices

Background

Medication has a huge potential to do good, but errors can occur at many points in the medication cycle – prescribing, dispensing, administering, monitoring and use. The World Health Organisation (WHO) identified 'Medication Without Harm' as the theme for their third Global Patient Safety Challenge which aims to reduce severe avoidable medication-related harm by 50% globally in five years by targeting health care provider's behaviour, systems and practices of medication, medicines, and the public.(1) In response to this challenge, the DH commissioned a report on the prevalence and cost of medication errors which reported that an estimated 66 million potentially clinically significant errors occur per year, 71% of which are in primary care.(2) While the majority of these errors are spotted (and corrected) at the point of error or do not threaten patient safety, a drastic reduction in the number of errors is now being called for. There is a need to develop and implement interventions to reduce medication errors associated with avoidable harm.

The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, medical devices and blood components for transfusion in the UK. Our Medicines Management Teams supports the cascade of messages from MHRA to prescribers, support prescribers to develop action plans and ensure they have acted on any relevant safety alerts.

Patient Safety Alerts have been published since 2002, previously by the National Patient Safety Agency (NPSA), and since 2012 by the national patient safety team at NHS England and NHS Improvement. Since 2019, organisations issuing patient safety alerts through the Central Alerting System need to gain accreditation to issue new National Patient Safety Alerts (NatPSA). Our MMTs support the cascade of these Alerts and ensure GP Practices have appropriate action plans relating to these Alerts.

The CCGs also share an ongoing Medicines Safety Programme of regular 'known' medicines safety issues. Examples include:

- Valproate pregnancy prevention programme
- Prescribing errors associated with drugs that require regular blood test monitoring e.g., clozapine, digoxin, gentamicin, lithium and methotrexate.

- Prescribing errors related to anticoagulants – warfarin, DOACs, injected heparin and low molecular weight heparins.
- Prescriptions for medicines being omitted or delayed
- Prescribing errors relating to opioid analgesics
- Prescribing errors related to insulin
- Paraffin based skin products – the risk of fire

GP Practices are expected to implement any changes required, as per GMC Good Medical Practice – Domain 2 – safety and quality – 'Contribute to and comply with systems to protect patients' [3] and as per Care Quality Commission (CQC) expectations that GP Practices provide safe care, S4, medicines management.[4]

Practices need to monitor updates and alerts and act upon these in a timely manner.[5] They need:

- systems in place to identify, recall and follow-up affected patients and to follow-up on these when required
- a process to recall a medicine or device
- 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.

What is the responsibility of CCGs to audit/oversee the implementation of CAS alerts in GP practices?

The NHS Standard Contract has a provision that 'The Provider must have in place arrangements to ensure that it can receive and respond appropriately to National Patient Safety Alerts' – see section 33.5.

As a commissioner, CCGs have a responsibility to ensure that Providers are compliant with all elements of the National Standard Contract, including the section outlined above.

NatPSAs are disseminated via CAS; in relation to alerts aimed at general practice this has historically been through regional teams to cascade down to providers in primary care. More recently, GP practices should have signed up directly to CAS, as this fulfils their requirement in the contract to 'receive' NatPSAs; although the regions may still play a role in dissemination. Therefore, CCGs have responsibility to ensure Providers can receive NatPSAs.

In addition, CCGs have a responsibility to ensure Providers can 'respond appropriately' to a NatPSA. To fulfil this responsibility, they not only have to ensure that Providers have a process in place but to check that the process is being used and Providers are responding appropriately when NatPSAs are issued.

Role of CCG MMT & PCN Pharmacists

The CCGs' MMTs share a Medicines Safety Team who will support and facilitate the implementation of medicine safety alerts but the responsibility lies with the GP Practice.

The MMT send out information/updates/alerts regularly and each will focus on a specific medicine safety area. These will be sent to all GP Practices if the issue affects all GP Practices, or to specific GP Practices if only a few are affected. ePACT2 prescribing data is often used to inform which GP Practices are affected.

Historically some of this medicine safety work may have been completed directly by the CCG MMT practice pharmacists and pharmacy technicians. However, in recent years the CCG MMT has moved to focus on strategic roles and functions, with a significant reduction in the number of CCG MMT practice pharmacists and technicians and GP Practices and PCNs starting to employ in-house clinical pharmacists and technicians.

The MMT will also flag any ad-hoc medicine safety issues, for example, a significant MHRA alert, as and when they arise and ensure that GP Practices are aware and have taken any relevant action.

The MMTs works with their CCG Quality Teams to support the investigation of medicines-related safety incidents and develop systems and processes, as appropriate, to share learning from medicines-related safety incidents to our providers and partners and prevent them from recurring.

Assurance

From time to time, the CCGs' MMTs will seek assurance from GP Practices that they have completed any actions required following a significant medicines safety alert. The usual mechanism for this will be to reply via email to confirm the appropriate action(s) have been taken.

This will help practices ensure compliance with The Care Quality Commissions (CQC) Outcome 11D. "Ensure relevant alerts from an expert, professional body or manufacturer are acted."

The usual mechanism for this will be:

- Receiving and assessing reports of suspected safety issues relating to medicinal products
- Communicating the details of this action to relevant parties as necessary**.**

to reply via email to confirm the appropriate action(s) has/have been taken.

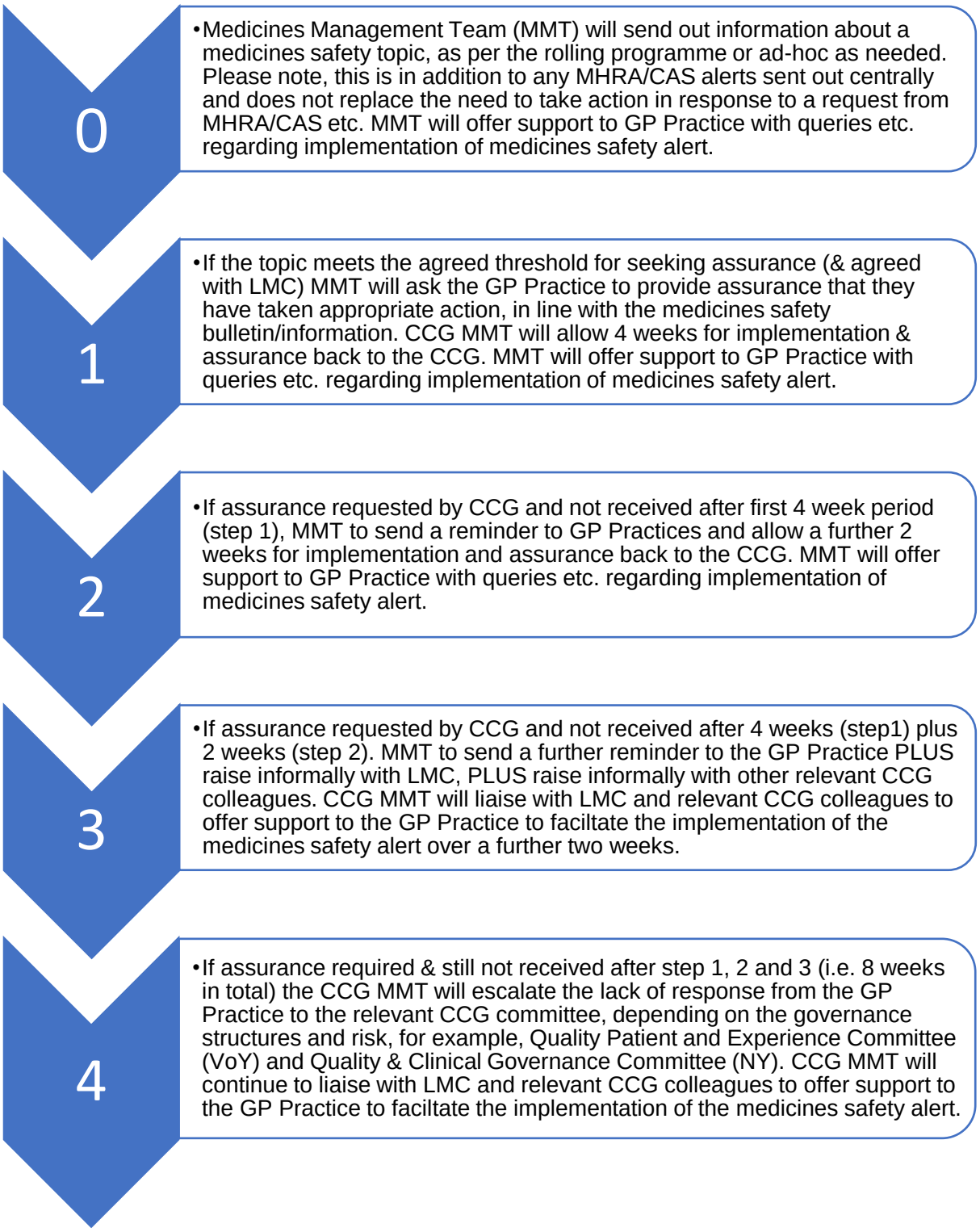
This guidance and support are intended to develop over time. Some examples are given below but this list is not exhaustive. Future actions requiring assurance will be considered at regular MMT meetings as and when new alerts arise via the MHRA / CAS system / National Patient safety Alert programme.

The CCG MMT will determine a threshold for when they seek assurance and this will be agreed with the LMC.

Examples of why assurance may be needed:

- All NatPSAs (relevant to primary care)
- They are related to the NHSE/I 'Never Events' list for medication - https://www.england.nhs.uk/wp-content/uploads/2020/11/2018-Never-Events-List-updated-February-2021.pdf
- In line with a national focus regarding patient safety focus.
- 'MHRA Class 1 drug alert' or medicine recall: presents a life-threatening or serious risk to health (MHRA Class 1 drug alerts are now issued by NatPSA).
- High-level National Patient Safety Alerts and safety critical guidance. Individual organisations that are accredited by the National Patient Safety Alert Committee issue NatPSAs. Currently, the NHSE/I National Patient Safety Team, MHRA, and PHE are accredited.
- When an alert poses a significant risk to a large proportion of the population, such as concerns over the inaccuracy of DOAC dosing.
- When an alert poses significant risk and irreversible fetal harm, such as phenytoin in pregnancy.

  The flowchart below details the expectations of the CCG MMT when it seeks assurance from GP Practices on a significant medicine-related safety issue. The request for assurance will be sent to the GP Practice Pharmacist, Practice Manager & GP Prescribing Lead. It is for each practice to determine who is best placed to respond to the alert and provide assurance.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•Medicines Management Team (MMT) will send out information about a medicines safety topic, as per the rolling programme or ad-hoc as needed. Please note, this is in addition to any MHRA/CAS alerts sent out centrally and does not replace the need to take action in response to a request from MHRA/CAS etc. MMT will offer support to GP Practice with queries etc. regarding implementation of medicines safety alert.
1
•If the topic meets the agreed threshold for seeking assurance (& agreed with LMC) MMT will ask the GP Practice to provide assurance that they have taken appropriate action, in line with the medicines safety bulletin/information. CCG MMT will allow 4 weeks for implementation & assurance back to the CCG. MMT will offer support to GP Practice with queries etc. regarding implementation of medicines safety alert.
2
•If assurance requested by CCG and not received after first 4 week period (step 1), MMT to send a reminder to GP Practices and allow a further 2 weeks for implementation and assurance back to the CCG. MMT will offer support to GP Practice with queries etc. regarding implementation of medicines safety alert.
3
•If assurance requested by CCG and not received after 4 weeks (step1) plus 2 weeks (step 2). MMT to send a further reminder to the GP Practice PLUS raise informally with LMC, PLUS raise informally with other relevant CCG colleagues. CCG MMT will liaise with LMC and relevant CCG colleagues to offer support to the GP Practice to faciltate the implementation of the medicines safety alert over a further two weeks.
4
•If assurance required & still not received after step 1, 2 and 3 (i.e. 8 weeks in total) the CCG MMT will escalate the lack of response from the GP Practice to the relevant CCG committee, depending on the governance structures and risk, for example, Quality Patient and Experience Committee (VoY) and Quality & Clinical Governance Committee (NY). CCG MMT will continue to liaise with LMC and relevant CCG colleagues to offer support to the GP Practice to faciltate the implementation of the medicines safety alert.

References

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2. Department of Health and Social Care. The Report of the Short Life Working Group on reducing medication related harm. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/683430/short-life-working-group-report-on-medication-errors.pdf. [Online] Feb 2018.

3. GMC Good Medical Practice Domain 2 - https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice/domain-2----safety-and-quality

4. CQC S4 Medicines Management - https://www.cqc.org.uk/guidance-providers/healthcare/medicines-management-healthcare-services

5. CQC Nigel's Surgery – Patient Safety Alerts https://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-91-patient-safety-alerts

6.https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/403210/A_guide_to_defective_medicines.pdf

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