PrescQIPP Community Interest Company

Medicines safety

This bulletin offers guidance and background information on medicines safety for England, Scotland, Wales and Northern Ireland. This includes the role of the Medicines Safety Officer (MSO) and the Medical Devices Safety Officer (MDSO). The MSO/MDSO can be the same person. It describes how the NHS will continuously improve patient safety, building on the foundations of a safer culture and safer systems.

The bulletin includes a range of resources to support healthcare professionals to promote and improve patient safety issues.

Recommendations

The NHS England and the Medicines and Healthcare products Regulatory Agency (MHRA) Patient Safety Alert

- All large healthcare providers and commissioners should have a MSO/MDSO. One of their key roles is to promote the safe use of medicines/medical devices across their organisations and be the main experts in this area.

Reporting of safety incidents

- Currently both healthcare staff and the general public are encouraged to report any Patient Safety Incident (PSI), whether they result in harm or not, to the National Reporting and Learning System (NRLS).
- A new Patient Safety Incident Management System (PSIMS), now known as the Learning from Patient Safety Event Service (LFPSE) began its public beta testing phase in summer 2021, with a planned national transition from late 2021/early 2022.
- Near-miss incidents that have not caused harm but have the potential to do so and those involving errors of omission should also be reported to the NRLS or via the LFPSE when available.
- Currently all Serious Incidents must also be reported on the Strategic Executive Information System (StEIS) as well as the NRLS for national learning.
- When the new LFPSE service goes live in late 2021/22, all PSIs and Serious Incidents will be recorded via the new service and will no longer be required separately on both the NRLS and the StEIS.
- An Adverse Drug Reaction (ADR) (actual or suspected) should be reported using the Yellow Card Scheme.

Patient Safety Alerts

- The National Patient Safety Alerting Committee (NaPSAC) requires healthcare providers to introduce systems for planning and co-ordinating the actions required by any National Patient Safety Alert across their organisation, and must include executive oversight.
- Failure to take the actions required under any National Patient Safety Alert may lead to the CQC taking regulatory action. Declared compliance with National Patient Safety Alerts is a key safety indicator, and a focus of CQC inspection.

Medicines are the most widely used intervention in health. Research evidence shows that medication errors and adverse drug reactions are common at all stages of the medicines use process and are associated with a high cost in terms of patient outcomes as well as financial consequences due to additional treatment or litigation.[1,2] A review published in 2018 and conducted by the UK Policy Research Unit in economic evaluation (EEPRU), found that an estimated 237 million medication errors occur at some point in the medication process in England per year, but 72% have little or no potential for harm. It is likely that many errors are picked up before they reach the patient. An estimated 66 million potentially clinically significant errors occur per year, 71% of these in primary care. As there is little evidence about how medication errors lead to patient harm, studies that measure harm from adverse drug reactions were used in the review to estimate burden. The estimated NHS costs of definitely avoidable ADRs are £98.5 million per year, consuming 181,626 bed days, causing 712 deaths, and contributing to 1,708 deaths.[3] This can be divided into:

- Primary care ADRs leading to a hospital admission (£83.7 million; causing 627 deaths)
- Secondary care ADRs leading to a longer hospital stay (£14.8 million; causing 85 deaths and contributing to 1,081 deaths).[3]

Non-steroidal anti-inflammatory drugs (NSAIDs), anticoagulants and antiplatelets cause over a third of admissions due to avoidable ADRs. Gastrointestinal (GI) bleeds are implicated in half of the deaths from primary care ADRs. Older people are more likely to suffer avoidable ADRs.[3]

Progress has been made over the last decade to detect, report and learn from patient safety incidents. However, further improvements are needed to increase the number of incident reports, improve data quality and maximise what is learned from medication errors.[2] Organisations should support a person-centred, 'fair blame' culture that encourages reporting and learning from medicines-related patient safety incidents. 'Fair blame' culture enables open and honest reporting of mistakes that are treated as an opportunity to learn to improve care. Health and social care practitioners should explain to patients, and their family members or carers where appropriate, how to identify and report medicines-related patient safety incidents.[4]

In 2014, NHS England and the Medicines and Healthcare products Regulatory Agency (MHRA) jointly issued two Stage 3 Directive Patient Safety Alerts, to improve medication error and medical device incident reporting and learning. The alerts recommend that all large healthcare providers (NHS Trusts, community pharmacy multiples, home healthcare companies and those in the independent sector) should identify:

- A board level director or superintendent pharmacist to be responsible for and to oversee medication errors/medical device incident reporting and learning.
- A Medication Safety Officer (MSO) and Medical Devices Safety Officer (MDSO) and inform the Central Alerting System (CAS) team of their contact details. One of their key roles is to promote the safe use of medicines/medical devices across their organisations and be the main experts in this area.
- A multi-professional group to regularly review medication errors/medical device incident reports, improve reporting and learning and take local action to improve medication safety/safety of medical devices.[2,5-7]

Small healthcare providers including general practices, dental practices, community pharmacies and small organisations in the independent sector should:

- Continue to report medication error incidents and incidents involving medical devices to the National Reporting and Learning System (NRLS) using the e-form on the NRLS website, or other methods. Also report incidents involving medical devices to the MHRA's online reporting system. Take action to improve reporting, learning and medication safety locally.[2,5-7]

A new reporting system has recently been made available for use across England, Wales and Northern Ireland for a public beta testing phase, prior to a formal national transition from recording incidents on NRLS to the new system in late 2021/early 2022. The Learn From Patient Safety Events (LFPSE) service,

formerly known as the Patient Safety Incident Management system (PSIMS) during its development, is now available for reporting from both healthcare organisations and anonymous reports from the general public. Some organisations may still opt to use the NRLS for the time being and individuals should check with local safety teams, which reporting system is currently being used and timescales for transition to the new reporting system for their locality Learn From Patient Safety Events (LFPSE).[8-10] In Scotland there are different reporting mechanisms available for Medical Devices.[11]

Healthcare commissioners including the former NHS Area Teams (now Regional Teams) and Clinical Commissioning Groups (soon to be Integrated Care Systems (ICS)) were also invited by the 2014 alert to:

- Identify a MSO/MDSO and email their contact details to the CAS team. This person will be a member of the National Medication Safety network/ National Medical Device Safety Network, to support reporting and learning and take local actions to improve medication safety.
- The MSO/MDSO can also use learning to influence policy, planning and commissioning as part of clinical governance in the organisation.
- Regularly review information from the NRLS and the MHRA to support improvements in reporting and learning, and to take local action to improve medication safety/safety of medical devices.[5,6]

Part of the service requirements for primary care as described in the Network Contract Directed Enhanced Service Contract specification is to provide Structured Medication Reviews (SMRs) and Medicines Optimisation for patient who would benefit. This must include patients:[12]

- In care homes.
- With complex and problematic polypharmacy, specifically those on ten or more medications.
- On medicines commonly associated with medication errors.
- With severe frailty, who are particularly isolated or housebound patients, or who have had recent hospital admissions and/or falls.
- Using one or more potentially addictive medications from the following groups: opioids, gabapentinoids, benzodiazepines and z-drugs.

In 2017, the World Health Organisation (WHO) launched its third Global Patient Safety Challenge 'Medication Without Harm', which aims to reduce the global burden of severe and avoidable medication-related harm by 50% over five years.[13] A set of medication safety indicators have been developed as a response to the WHO challenge as part of a programme of work to reduce medication error and promote safer use of medicines, including prescribing, dispensing, administration and monitoring. The purpose of the indicators is to identify hospital admissions that may be associated with prescribing that potentially increases the risk of harm, and to quantify patients at potentially increased risk. The indicators include patients admitted due to gastro-intestinal bleeds, acute kidney injury, pain, fractures, respiratory issues and the anticholinergic burden of medication.[14] The NHS Patient Safety Strategy describes how the NHS will continuously improve patient safety, building on the foundations of patient safety culture and a patient safety system.[15] A key part of the strategy is the Safety Improvement Programmes (SIPS) and includes the Medicines Safety Improvement Programme (MedSIP). This programme aims to reduce avoidable medication related harm in the NHS and is focused on high risk drugs, situations and vulnerable patients to achieve the following specific objectives:[16]

- Reduce medicine administration errors in care homes.
- Reduce harm from opioid medicines by reducing high dose prescribing of opioids.
- Reduce harm by reducing the prescription and supply of oral methotrexate 10mg.
- Develop a programme to reduce severe harms associated with anticoagulants.
- Develop a programme to reduce problematic polypharmacy for the most at-risk populations.

The Scottish Patient Safety Programme (SPSP) is a national quality improvement programme that aims to improve the safety and reliability of care and reduce harm. One of the programmes of work is the SPSP Medicines Collaborative and the key themes of this programme are:[17,18]

- Pharmacotherapy level 1 services' collaborative
- Reducing harm across transitions of care
- High risk situations involving medicines
- Omitted medicines
- Pharmacy in primary care

NHS Wales Delivery Unit aims to achieve sustainable improvement in NHS Wales through a whole system approach to health and care, by delivering the vision of, 'A Healthier Wales: our Plan for Health and Social Care'. Patient Safety assurance and improvements are the priority across the whole Delivery Unit and a dedicated Quality and Safety Team provide leadership and support on incident reporting, learning from incidents and never events, compliance with patient safety solutions and, where required, assurance reviews in NHS Health Boards and Trusts.[19]

Transforming medication safety in Northern Ireland is a five-year plan which was produced collaboratively with healthcare professionals and service users from across Northern Ireland in response to the WHO's Third Global Patient Safety Challenge 'Medication without Harm'. Part of the plan is to ensure the safer use of medicines where published evidence and our incident reporting data shows are associated with a risk of significant harm if used incorrectly:[20]

- Reduce the burden of avoidable harm from high-risk medicines
- Build good practice in medication safety into the supply of all medicines
- Support improvements in adherence to medication

The roles and responsibilities of the MSO and MDSO

MSOs/MDSOs are the essential link between local actions to improve medication/medicine device safety and implementation of national initiatives. One of the key roles is to promote the safe use of medicines/ medical devices across their organisation(s). Responsibilities are defined and include:[1,2,7]

- Being an active member of the National Medication Safety Network/National Medical Devices Safety Network.
- Managing medication/medical device incident reporting, and to improve the reporting and learning from these.
- Authorising the release of medication error reports to the NRLS each week or to make sure that medical device incidents are sent to the NRLS as soon as possible at least weekly.
- Receiving and responding to requests for more information about medication errors/medical device incident reports from NHS England and the MHRA.
- Working as a member of the medication/medical device safety committee - a multi-professional committee to support the safe use of medicines in the organisation. The committee should include medical staff; nursing staff; pharmacy staff; those in risk management and general management; and, a patient representative.[1,2]
- Supporting the dissemination of medication/medical device safety communications.[7]
- Acting as an additional point of contact for manufacturers on Field Safety Notices and support local actions arising from these.[7]

Independent Patient Safety Commissioner

One of the principle recommendations from the report of the Independent Medicines and Medical Devices Safety Review (First Do No Harm) is the appointment of an independent Patient Safety Commissioner (PSC), a person of standing who sits outside the healthcare system, accountable to Parliament through the Health and Social Care Select Committee. The Commissioner would be the patients' port of call, listener and advocate, who holds the system to account, monitors trends, encourages and requires the system to act. The Medicines and Medical Devices Act 2021 has legislated for the establishment of a Patient Safety Commissioner in England.[21-23] Consultations on the Patient Safety Commissioner role are underway in England and Scotland.

Medicines safety definitions

Patient Safety Incidents (PSI)

A PSI is defined as 'any unintended or unexpected incident, which could have or did, lead to harm for one or more patients receiving NHS care'.[2]

Medication errors

Medication errors are PSIs where there has been an error in the process of prescribing, preparing, dispensing, administering, monitoring or providing advice on medicines. These PSIs can be divided into two categories; errors of commission or errors of omission. The former include, for example, wrong medicine or wrong dose. The latter include, for example, omitted dose or a failure to monitor, such as international normalised ratio (INR) for anticoagulant therapy.[2]

Medical devices

The term 'medical device' covers a broad range of products, used every day throughout the health economy to support the diagnosis, treatment and care of patients. The definition of a medical device in European and UK law is, 'any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:[7]

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.
- Investigation, replacement or modification of the anatomy or of a physiological process.
- Control of conception.

It does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.[7]

Medical devices - adverse incidents

The MHRA defines a reportable 'adverse incident' concerning a medical device as 'any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health'.[7]

Any event that meets these three basic reporting criteria should be reported to MHRA:

- An event has occurred.
- A medical device is suspected, or cannot be rule out, as a contributory cause of the adverse incident.
- The event led, or might have led, to one of the following outcomes:
  - » Death of a patient, user or other person.
  - » Serious deterioration in state of health of a patient, user or other person.[7]

Adverse Drug Reactions (ADR)

An ADR is defined as, 'a response to a medicinal product that is noxious and unintended effects resulting not only from the authorised use of a medicinal product at normal doses, but also from medication errors and uses outside the terms of the marketing authorisation, including the misuse, off-label use and abuse of the medicinal product'.[2]

Current reporting of PSIs, ADRs, medication errors and medical device incidents

When a PSI, ADR, medication error or medical device incident occurs then reporting them supports the NHS to learn from mistakes and to take action to keep patients safe.[24] Guidance produced by the National Institute for Health and Care Excellence (NICE) specifically recommends the following actions:[4]

- Health and social care practitioners should explain to patients, and their family members or carers where appropriate, how to identify and report medicines-related patient safety incidents.
- Organisations should ensure that robust and transparent processes are in place to identify, report, prioritise, investigate and learn from medicines-related patient safety incidents, in line with national patient safety reporting systems – for example, the NRLS.
- Organisations should consider using multiple methods to identify medicines-related patient safety incidents – for example, health record review, patient surveys and direct observation of medicines administration. They should agree the approach locally and review arrangements regularly to reflect local and national learning.
- Organisations should ensure that national medicines safety guidance, such as patient safety alerts, are actioned within a specified or locally agreed timeframe.
- Organisations should consider assessing the training and education needs of health and social care practitioners to help patients and practitioners to identify and report medicines-related patient safety incidents.
- Health and social care practitioners should report all identified medicines-related patient safety incidents consistently and in a timely manner, in line with local and national patient safety reporting systems, to ensure that patient safety is not compromised.

Currently both healthcare staff and the general public are encouraged to report any PSIs, whether they result in harm or not, to the NRLS.[24] This includes near-miss incidents that have not caused harm but have the potential to do so and those involving errors of omission.[2] The NRLS is a central database of patient safety incident reports regarding many types of incidents which may include falls, diagnosis, surgery, medication and medical devices.[7,25] Since it was set up in 2003, the culture of reporting incidents to improve safety in healthcare has developed substantially. All information submitted is analysed to identify hazards, risks and opportunities to continuously improve the safety of patient care.[25] Healthcare staff are encouraged where possible to record all PSIs on their local risk management systems. These reports will then be routinely uploaded to the NRLS to support national learning. Health care staff unable to use a local risk management system can also record incidents directly on the NRLS or the new national system LFPSE, when available.[26]

Serious Incidents (SI) in health care are adverse events, where the consequences to patients, families and carers, staff or organisations are so significant or the potential for learning is so great, that a heightened level of response is justified. The Serious Incident Framework describes the circumstances in which such a response may be required and the process and procedures for achieving it, to ensure that serious incidents are identified correctly, investigated thoroughly and, most importantly, learned from to prevent the likelihood of similar incidents happening again.[27] Reporting a serious incident must be done by recording the incident on the Strategic Executive Information System (StEIS) or eventually its successor system the LFPSE.[27]

N.B. Currently the NRLS and StEIS are not linked and separate reporting of serious incidents is required in both systems, however the new LFPSE will eventually combined both functions and only one reporting mechanism will be required.[26,27]

In Scotland, adverse events that do, or could have, a major effect on the people involved are regarded as an opportunity to learn and to improve in order to increase the safety of the care system for everyone. The Scottish national framework, "Learning from adverse events through reporting and review", is intended to provide an overarching approach and was developed from best practice to support care providers to effectively manage adverse events. The updated fourth edition of the framework document was created to integrate the instruction from the Scottish Government that NHS boards must notify Healthcare Improvement Scotland of all significant adverse event reviews (SAERs) from January 2020.[28] There are different reporting mechanisms for reporting adverse incidents and near-misses involving medical devices, in-vitro diagnostic medical devices, estates, facilities, social care equipment and personal protective equipment (PPE).[11]

In Wales, PSIs are managed locally under "Putting Things Right" which was established to review the existing processes for the raising, investigation of, and learning from concerns. Concerns are issues identified from patient safety incidents, complaints and, in respect of Welsh NHS bodies, claims about services provided by a responsible body in Wales. The aim is to provide a single, more integrated and supportive process for people to raise concerns. From June 2021, national incident reporting in NHS Wales has changed as phase 1 of the National Patient Safety Incident Reporting Policy (Welsh Government, May 2021) comes into effect, relating to the individual reporting of the most serious incidents which occur in healthcare. Phase 2 of the policy will focus on new ways of national reporting, including thematic reporting of healthcare incidents.[29]

Adverse incidents in Northern Ireland are reported to the Northern Ireland Adverse Incident Centre (NIAIC) which operates as part of the Chief Medical Officers (CMO) Group within the Department of Health (DoH). The key aim of the NIAIC is to seek learning from investigations into reported adverse incidents involving medical devices, non-medical equipment, plant and buildings used within the healthcare environment across Northern Ireland and to issue safety information and guidance to help prevent recurrence.[30]

The Yellow Card Scheme run by the MHRA is the UK system for collecting and monitoring information on suspected safety concerns or incidents involving medicines and medical devices. The scheme relies on voluntary reporting of suspected ADRs or medical device incidents to be reported by health professionals and the public, including patients, carers and parents. The purpose of the scheme is to provide an early warning that the safety of a product may require further investigation. Reports can be made online for all medicines including vaccines, blood factors and immunoglobulins, herbal medicines and homeopathic remedies, all medical devices available on the UK market and safety concerns associated with e-cigarette products. The scheme collects information on suspected problems or incidents involving:[31]

- ADRs
- Medical device adverse incidents
- Defective medicines (those that are not of an acceptable quality)
- Counterfeit or fake medicines or medical devices
- Safety concerns for e-cigarettes or their refill containers (e-liquids).

The MHRA asks for Yellow Card reports to be submitted online for all suspected ADRs to medicines and vaccines marked with a black triangle which indicates they are subject to additional monitoring requirements. Reports of all serious ADRs are requested for established medicines and vaccines. These should be reported even if the effect is well recognised. Serious reactions include those that are:[2]

- Fatal
- Life-threatening

- Disabling
- Incapacitating
- Results in congenital abnormalities
- Results in or prolongs hospitalisation.

ADRs reported on Yellow Cards are evaluated, together with additional sources of information such as clinical trial data, medical literature or data from international medicines regulators, to identify previously unknown safety issues. These reports are assessed by medicine safety experts made up of doctors, pharmacists and scientists who study the benefits and risks of medicines. If a new side effect is identified, the safety profile of the medicine in question is carefully looked at, as well as the side effects of other medicines used to treat the same condition.[31] There is also Yellow Card Centre Scotland which aims to increase and improve the quality of ADR reporting in Scotland using the Yellow Card Scheme. Through its network of medicines information services throughout Scotland, Yellow Card Centre Scotland aims to provide local contact points to assist reporters when they are uncertain about the correct steps to take in this process.[32]

For medical devices, products reportable to the Yellow Card Scheme will have a CE mark. Examples of adverse events that should be reported include:[31]

- Faulty brakes on a wheelchair.
- Faulty ear thermometer giving a low reading.
- Faulty batch of test strips for a blood glucose meter giving wrong readings.
- Labelling or instructions on the device are not clear.

The reporting of adverse incidents including near misses should also be in line with the organisation's local policy and procedures. Staff should know who the healthcare organisation's Medical Device Safety Officer (MDSO) is and how they can be contacted. However, reports from individuals will be received by MHRA and investigated as appropriate. If you are in England or Wales, any problems with medical devices should be reported online using the Yellow Card website. There are different ways for healthcare professionals to report a problem with a medical device if you're in Scotland or Northern Ireland.[33]

The future of the patient safety incident reporting

As outlined in the NHS patient safety strategy, NHS England are in the process of developing a new Patient Safety Incident Response Framework (PSIRF) to replace the current Serious Incident Framework. To ensure successful implementation of the PSIRF when rolled out in 2022, they are working with a small number of early adopters using an introductory version of the framework. Learning from the early adopters will inform the final version of the PSIRF which is anticipated to be published in Spring 2022. It is anticipated that at that point, all other organisations will be encouraged to begin the transition to the PSIRF, with an expectation that all parts of the NHS in England will be using the new framework by Autumn 2022.[34,35]

A new adverse incident service, LFPSE, (previously called the patient safety incident management system – PSIMS – during development) is in the final stages of development as a central service for the recording and analysis of patient safety events that occur in healthcare. This system is replacing the current NRLS and StEIS, to offer better support for staff from all health and care sectors.[9]

The new LFPSE service is a major upgrade, creating a single national NHS system for recording patient safety events and it is being rolled out across England, Wales and Northern Ireland.[9,10] Further information on the roll out of the LFPSE service is available on the NHS England website.[9] It introduces improved capabilities for the analysis of patient safety events occurring across healthcare, and enables better use of the latest technology, such as machine learning, to create outputs that offer a greater depth of insight and learning that are more relevant to the current NHS environment.[9]

LFPSE will:[9]

- Make it easier for staff across all healthcare settings to record safety events, with automated uploads from local systems to save time and effort, and introducing new tools for non-hospital care where reporting levels have historically been lower.
- Collect information that is better suited to learning for improvement than what is currently gathered by existing systems.
- Make data on safety events easier to access, to support local and specialty-specific improvement work.
- Utilise new technology to support higher quality and more timely data, machine learning, and provide better feedback for staff and organisations.

Around three quarters of reporting to the NRLS and StEIS was from the hospital sector. LFPSE will make recording safety events easier in other care settings, including primary care, through the introduction of simple online forms, and a dedicated portal to access, review and update previously recorded incidents. This supports good incident response practice, by allowing smaller organisations to see all their safety events through one dashboard.[9,10]

Reporting medicine-related incidents in care homes and social care in the community

NICE have produced a social care guideline on managing medicines in care homes. This guidance makes the following recommendations for identifying, reporting and reviewing medicines-related problems and safeguarding:[36]

- Commissioners and providers of health or social care services should ensure that a robust process is in place for identifying, reporting, reviewing and learning from medicines errors involving residents.
- Health and social care practitioners should consider working with all relevant stakeholders to develop a locally agreed action plan, in line with other local and national strategies and governance arrangements, for improving the safety of residents and reducing medication errors in care homes.
- Care home staff (registered nurses and social care practitioners working in care homes) should report all suspected adverse effects from medicines to the health professional who prescribed the medicine or another health professional as soon as possible; this would usually be the GP or out-of-hours service. Staff should record the details in the resident's care plan and tell the supplying pharmacy (if the resident agrees that this information can be shared).
- Commissioners and providers of health or social care services should all be aware of local arrangements for notifying suspected or confirmed medicines-related safeguarding incidents.
- Care home providers should have a clear process for reporting medicines-related safeguarding incidents under local safeguarding processes and to the Care Quality Commission (CQC), or other appropriate regulator. The process should be recorded in the care home medicines policy.

Separate NICE guidance regarding managing medicines in adults receiving social care in the community recommends:[37]

- Health and social care commissioners and providers should review local governance arrangements and ensure it is clear who is accountable and responsible for providing medicines support to adults receiving social care in the community. When social care providers have responsibilities for medicines support, they must have robust processes for medicines-related safeguarding incidents, in line with Regulation 13 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, and they should have robust processes for identifying, reporting, reviewing and learning from medicines-related problems.
- Care workers should raise any concerns about a person's medicines (including medication errors and near misses) with the social care provider.

Generally the CQC do not need to be notified about medicines errors except in the following circumstances:[38]

- Death
- Injury
- Abuse, or allegation of abuse
- Incident reported to or investigated by the police

The registered person should record the action taken on the relevant notification form and make it clear that a medicine error was a known or possible cause or effect of the incidents or events being notified.[38]

National Patient Safety Alerts

In November 2019, the NHS England and NHS Improvement (NHSEI) national patient safety team began issuing alerts as 'National Patient Safety Alerts'. This was the first national body accredited to issue these alerts by the National Patient Safety Alerting Committee (NaPSAC). All National Patient Safety Alerts are required to meet NaPSAC's thresholds and standards, which include working with patients, frontline staff and experts to ensure alerts provide clear, effective actions to reduce the risk of death or disability.[39]

Any new or under-recognised patient safety issues that require national action are identified through a clinical review of incidents reported to the national reporting system NRLS (or LFPSE from mid-2022) and other sources. NHSEI will then work with frontline staff, patients, professional bodies and partner organisations to decide if they can influence or support others to act and if needed issue a National Patient Safety Alert that sets out actions healthcare organisations must take to reduce the risk.[39]

The NaPSAC requires healthcare providers to introduce systems for planning and co-ordinating the actions required by any National Patient Safety Alert across their organisation, including having executive oversight. This is essential for effective delivery of systematic actions to protect staff from error and protect patients from risk of death or disability.[39]

Failure to take the actions required under any National Patient Safety Alert may lead to CQC taking regulatory action and declared compliance with alerts is a key safety indicator, assessed through CQC inspection.[39]

Summary

The NHS Patient Safety Strategy describes how the NHS will continuously improve patient safety, building on the foundations of patient safety culture and a patient safety system.[15] The strategy includes the Medicines Safety Improvement Programme (MedSIP). This aims to reduce medication related harm in the NHS, focusing on high risk drugs, situations and vulnerable patients.[16] The Scottish Patient Safety Programme (SPSP) is a national quality improvement programme that aims to improve the safety and reliability of care and reduce harm. One of the programmes of work is the SPSP Medicines Collaborative.[17,18] Patient Safety assurance and improvements are the main priority across the whole NHS Wales Delivery Unit and there is a dedicated Quality and Safety Team to provide leadership and support on incident reporting, learning from incidents and never events, compliance with patient safety solutions and, where required, assurance reviews in NHS Health Boards and Trusts.[19] Transforming medication safety in Northern Ireland is a five-year plan. Part of the plan is to ensure the safer use of medicines where published evidence and our incident reporting data shows are associated with a risk of significant harm if used incorrectly.[20] These programmes will contribute to the WHO Challenge target to reduce severe avoidable medication-related harm globally by 50% over five years.[13]

Summary

The NRLS and StEIS are being replaced by LFPSE (previously known as PSIMS) a new reporting system made available for use across England, Wales and Northern Ireland. The LFPSE is currently in a public Beta testing phase, prior to a formal national transition from recording incidents on NRLS to the new system in late 2021/early 2022.[9,10] In Scotland there are different reporting mechanisms available for Medical Devices.[11] ADRs (actual or suspected) should be reported using the Yellow Card Scheme.[31] There is also Yellow Card Centre Scotland which aims to increase and improve the quality of ADR reporting in Scotland.[32]

All healthcare providers must introduce systems for planning and co-ordinating the actions required by any National Patient Safety Alert across their organisation, and this must include executive oversight. Failure to take the actions required may lead to CQC taking regulatory action. Compliance with alerts is a key safety indicator assessed through CQC inspection.[39]

The appendices includes signposting to information and a range of resources to support MSOs/ MDSOs and other healthcare professionals to promote and improve patient safety issues. There are also medicine safety audits and guides to support medicines safety in practice.

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Additional PrescQIPP resources

Briefing	https://www.prescqipp.info/our-resources/bulletins/bulletin-288-medicines-safety/
Implementation tools	

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Support with any queries or comments related to the content of this document is available through the PrescQIPP help centre https://help.prescqipp.info

This document represents the view of PrescQIPP CIC at the time of publication, which was arrived at after careful consideration of the referenced evidence, and in accordance with PrescQIPP's quality assurance framework.

The use and application of this guidance does not override the individual responsibility of health and social care professionals to make decisions appropriate to local need and the circumstances of individual patients (in consultation with the patient and/or guardian or carer). Terms and conditions

Appendix 1 – PrescQIPP resources to support MSOs/MDSOs and other healthcare professionals to promote and improve patient safety

The following are examples of PrescQIPP resources available to support medicines safety. These examples are not exhaustive, as aspects of medicines safety are considered in all resources.

Webkits

PrescQIPP has a number of webkits which are information hubs pulling together all of the information you need around key therapeutic or strategic areas. Any medicines safety information relating to these therapeutic areas can be found in the individual webkit (e.g. Medicines Safety, Pain, Antimicrobial stewardship, Diabetes, Respiratory care webkits).

Polypharmacy and deprescribing webkit

This webkit includes various resources including bulletins and an e-learning course. There is a section on high risk medicines which would be appropriate to prioritise for medication review. The materials below help support appropriate identification and review of patients taking these medicines.

Bulletin 254: Polypharmacy and deprescribing

Antimicrobial Stewardship

Bulletin 253: Anticholinergic burden

Anticholinergic burden e-learning course

Bulletin 272: Constipation

Bulletin 256: Dependence forming medications

Bulletin 285: Fentanyl

Bulletin 258: Hypnotics

Bulletin 268: Improving Medicines and Polypharmacy Appropriateness Clinical Tool - IMPACT

Bulletin 252: Medicines without harm

Bulletin 265: NSAIDs

Bulletin 215: Opioid patches

Bulletin 199: Oxycodone/naloxone (Targinact®)

Bulletin 267: PPIs - Long term safety and gastroprotection

Toolkit 7: Reducing antipsychotic prescribing in dementia

Reducing antipsychotics in dementia webinar

Bulletin 208: Paracetamol and tramadol combination products

Bulletin 228: Emollients, paraffin content and fire risk

This bulletin aims to highlight the fire risk associated with emollient products and measures which need to be taken to reduce this risk. The resource will support healthcare professionals who are optimising emollient treatment in line with the NPSA and MHRA alerts and for patients on oxygen therapy.

Bulletin 266: Tapentadol

This bulletin reviews the place in therapy of tapentadol and offers guidance and support materials for organisations considering reviewing tapentadol prescribing as a medicines optimisation project.

Bulletin 260: Acute Kidney Injury (AKI) - Sick day guidance

This bulletin provides information on offering individualised sick day guidance to patients when they are well, so that they are able to proactively manage medication known to impair renal function during illness or fever and reduce the risk of AKI.

Bulletin 139: CKD - Implementing NICE guidance

NB. Currently updating – the new bulletin is written in two parts. The CKD resource covers the new classifications of CKD and drugs which are likely to cause kidney damage. The AKI part of the bulletin covers current advice around sick day rules and signposts to the Think Kidneys resources.

Bulletin 250: Modafinil

This bulletin and support materials review the place in therapy for modafinil in light of the MHRA restrictions on prescribing indications due to safety concerns. Implementation support resources include an audit, patient review and switch letters, data pack, shared care guideline template and presentation.

Bulletin 242: Appropriately switching anti-epileptic drugs

This is an updated bulletin which includes new information on patient factors to consider before switching antiepileptic drugs, updated cost comparison charts and switch savings, new safety warnings for sodium valproate, pregabalin updated controlled drug scheduling and use of generic pregabalin for all indications.

Bulletin 213: Oxycodone

This bulletin supports the review of oxycodone treatment. It looks at cost effectiveness as well as opioid use overall, the rationale to stop treatment and also suggests alternative treatment options.

Bulletin 218: Reducing opioid prescribing in chronic pain

This resource discusses the risks of prescribing high dose opioids (above 120mg morphine equivalent) for chronic pain.

Bulletin 277: Prevention, recognition and management of UTIs

This bulletin supports the recognition, management and prevention of UTIs and provides advice for a range of patient groups including those over 65, men, women and catheterised individuals.

Advice on diagnosis and treatment is provided and in line with the Public Health England guidance. Prescribing information sheets on fosfomycin and pivmecillinam have been produced for those unfamiliar with these treatments.

Bulletin 278: Transfer of care around medicines

This bulletin covers good practice for safe and effective transfer of care between different care settings. It offers advice on the required information around medicines and changes in medicines as well as using support services available through community pharmacists. Tools to support the implementation of transfer of care around medicines are also available.

PrescQIPP Hot Topics - Implementing the NHS Steroid Emergency Card National Patient Safety Alert (NatPSA)

NHS England and Improvement recently issued a NatPSA about recognising and treating adrenal crisis in adults which included guidance on a new NHS Steroid Emergency Card and who to issue it to. This Hot topic covers the groups of patients needing an NHS Steroid Emergency Card. Searches and a full bulletin are available.

Clinical webinars

PrescQIPP have a number of webinars recorded which can be viewed, or sign up to take part in a live session in the future. These include:

Developing pragmatic, evidence based strategies to help people safely and calmly taper off and stop antidepressant therapy

Opioid reduction: Motivational Interviewing blended with Acceptance and Commitment Therapy (ACT) to achieve lasting change

Opioid prescribing in chronic pain webinar

PINCER - A proven pharmacist-led IT-based intervention to reduce clinically important medication errors in primary care

Reducing opioid prescribing in chronic pain e-learning

Opioids aware audit webinar

Safer Use of Controlled Drugs

How to avoid inappropriate prescribing of controlled drugs webinar

Steroid Emergency Card

Data and analysis

PrescQIPP have a number of data and analysis resources available in this section to support medicines safety which includes, but is not limited to; clinical snapshots (e.g. controlled drugs and pain), scorecards (including medicine safety scorecards) and individual bulletin data packs.

High dose opioids audits

This set of audit tools were developed by the NHS England East of England CDAO network to support practices and community pharmacists review and tackle high dose opioid prescribing.

PrescQIPP has numerous community resources which are initiatives and projects that have been shared by the community, for the community.

Some of the most recent examples of Innovation and Shared Good Practice case studies relating to medicines safety include:

Cambridgeshire and Peterborough CCG: Gold Award Winner - Using Emollients Safely (2020)

Health and Social Care Board (HSCB) Northern Ireland: Silver Award Winner - Pain Support Programmes in Healthy Living Centres across Northern Ireland (2020)

South West London CCG: Highly commended - Embedding Medicines optimisation and Holistic review of Learning Disability care home residents across South West London (2020)

Sheffield CCG: Highly commended - Improving pre-pregnancy care for women with diabetes: a community focused strategy (2020)

Nottingham and Nottinghamshire CCG: Highly commended - Safe Prescribing Of Direct Oral Anticoagulation: A Collaborative Approach To Minimising Harm From Interacting Medicines (2020)

East Norfolk Medical Practice: Silver Award Winner - 'Blue-folder clinics to facilitate reduction of inappropriate opioid, pregabalin, hypnotic and benzodiazepine prescribing to improve patient outcomes' (2019)

Great Yarmouth and Waveney CCG: High dose opiate reduction in Great Yarmouth and Waveney (2019)

Eastbourne Hailsham and Seaford and Hastings and Rother CCGs: Appropriately reducing opioid prescribing for chronic non-malignant pain in primary care (2019)

Sheffield CCG: Controlled Drug Monitoring Across The Integrated Care System (2019)

Mid Essex CCG: 3TT project (2019)

Herefordshire CCG: Optimising Transfer of Care to improve safety in diabetes care (2019)

Bedfordshire CCG: Primary Care Atrial Fibrillation (2019)

Hywel Dda University Health Board: Safety Review in GP practice of DOAC patients by a pharmacy technician (2019)

Swale CCG: EPIC (Enhancing Patient outcomes In COPD) (2019)

Camden CCG: Prescribing Quality Scheme Risk Reduction Review (2019)

University Hospitals Birmingham NHS Trust: Medication Safety Audit Assessment Tool in Care Homes (2019)

Coastal West Sussex CCG: Improving the Quality and Safety of Medication Dispensing Processes within GP Dispensing Practices (2019)

Barnet, Enfield and Haringey MH Trust: "Keeping Tabs"- Our Medicines Safety Newsletter (2019)

Midlands and Lancashire CSU: Medicines Safety Assurance Tool (MSAT™) (2019)

Appendix 2 – Other resources to support MSOs/MDSOs and other healthcare professionals to promote and improve patient safety.

NHS England's Medication safety dashboard can be accessed through ePACT2 if registered, or if not the indicators can be viewed through Catalyst - public insight portal.

A set of medicine safety indicators have been developed as part of a programme of work to reduce medication error and promote safer use of medicines, including prescribing, dispensing, administration and monitoring. The programme of work is in response to the World Health Organisation (WHO) global challenge – 'Medication Without Harm'.

The WHO have several resources as part of the 'Medication Without Harm' Global Patient Safety Challenge. These include:

Medication Without Harm brochure

This brochure outlines the vision and strategic direction of this global initiative aiming to reduce the level of severe, avoidable harm related to medications by 50% over the next five years, globally. It provides an overview of the key components of the challenge including the local, national and global action to be taken.

Patient Safety: Making health care safer brochure

This brochure illustrates the importance of safe care for everyone, what the burden and impact of unsafe care is, and WHO's approach to tackling the issue of unsafe care. The brochure also contains a comprehensive collation of key WHO materials and activities to generate improvements at the front line.

10 facts on patient safety

Patient safety is a serious global public health concern. It is estimated that there is a 1 in 3 million risk of dying while travelling by airplane. In comparison, the risk of patient death occurring due to a preventable medical accident, while receiving health care, is estimated to be 1 in 300. Industries with a perceived higher risk, such as the aviation and nuclear industries, have a much better safety record than health care does.

Medication safety in key action areas

As part of the Global Patient Safety Challenge: Medication Without Harm, WHO has asked countries and key stakeholders to prioritize three areas for strong commitment, early action and effective management to protect patients from harm while maximizing the benefit from medication. WHO is presenting a set of three technical reports to facilitate early priority actions and planning to address each of these areas:

Medication Safety in Transitions of Care - Technical Report

Medication Safety in Polypharmacy - Technical Report

Medication Safety in High-risk Situations - Technical Report

5 Moments for medication safety

The 5 Moments for Medication Safety is a patient engagement tool focuses on 5 key moments where action by the patient or caregiver can reduce the risk of harm associated with the use of medications. This tool aims to engage and empower patients to be involved in their own care. The 5 Moments for Medication Safety tool can be applied at different levels of care and in different settings and contexts. Resources include a booklet, flyer, infographic poster, pamphlet and a mobile application. The tool can be used when patients:

- Visit a primary health care facility
- Are referred to another health care facility or to another health care professional

- Visit a pharmacy
- Are admitted to a health care facility
- Are transferred to another health care facility
- Are discharged from a health care facility
- Receive treatment and care at home or nursing home.

Medication Without Harm: Real-life stories

This collection of stories from patients, families and health care providers shows how they have been affected by medication errors and harm, as well as other stories on what they have done to prevent such errors and harm from reoccurring.

Patient safety education and training

WHO have a range of training materials and tools have been developed to help individuals and organisations improve their understanding and knowledge of patient safety.

There are also links to related medicines safety topics:

Antimicrobial resistance

Blood transfusion safety

Health workforce

Infection prevention and control

Maternal health

Medical devices

Coronavirus disease (COVID-19) : Vaccines safety