Medicines safety

Medicines are the most widely used intervention in health. Research evidence shows that medication errors and Adverse Drug Reactions (ADRs) are common and associated with a high cost in terms of patient outcomes as well as financial consequences due to additional treatment or litigation.[1,2]

Recommendations

Medicines Safety Officer/Medical Devices Safety Officer

- 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.

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.

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).
- 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. A new Patient Safety Incident Management System (PSIMS), now known as the Learning from Patient Safety Events (LFPSE) service began its public beta testing phase in summer 2021.
- Currently all Serious Incidents (SI) must also be reported on the Strategic Executive Information System (StEIS) as well as the NRLS for national learning.
- When the LFPSE service goes live with a national-scale transition in late 2021/early 2022 all PSIs and Serious Incidents will be recorded on the LFPSE service and not the NRLS and/or the StEIS.
- An Adverse Drug Reaction (ADR) (actual or suspected), which is not a result of human error, should be reported using the Yellow Card Scheme.

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.[3] 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.[4]

Medicines safety definitions

A **Patient Safety Incident** (PSI) is 'any unintended or unexpected incident, which could have or did, lead to harm'.[2] **Medication errors** are PSIs where there was an error in prescribing, preparing, dispensing, administering, monitoring or providing advice on medicines.[2]

The Medicines and Healthcare products Regulatory Agency 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'.[5]

An **ADR** is '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]

ADRs (actual or suspected) should be reported using the Yellow Card Scheme.[6] There is Yellow Card Centre Scotland which aims to increase and improve the quality of ADR reporting.[7] 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.[8]

References

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Additional resources available	Bulletin	https://www.prescqipp.info/our-resources/bulletins/bulletin-288-medicines-safety/
	Tools	

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