





Professional standards for the reporting, learning, sharing, taking action and review of incidents

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I. PROFESSIONAL STANDARDS

STANDARD I: OPEN AND HONEST

Be open and honest when things go wrong^{1,2,3}

STANDARD 2: REPORT

Report patient safety incidents to the appropriate local or national reporting programme

STANDARD 3: LEARN

Investigate and learn from all incidents, including those that cause harm and those that are "no harm" or "near-miss" ⁴

STANDARD 4: SHARE

Share what you have learnt to make local or national systems of care safer

STANDARD 5: ACT

Take action to change practice or improve local or national systems of care

STANDARD 6: REVIEW

Review changes to practice

2. SCOPE

WHAT THIS IS FOR

These professional standards describe good practice and good systems of care for reporting, learning, sharing, taking action and review as part of a patient safety culture. The accompanying guidance and information support the implementation of the standards.

WHO THIS IS FOR

These professional standards are for pharmacists, pharmacy technicians and the wider pharmacy team across the United Kingdom.

This may also be of interest to the public, to people who use pharmacy and healthcare services, healthcare professionals working with pharmacy teams, regulators and commissioners of pharmacy services.

WHAT THIS IS NOT

These professional standards and accompanying guidance do not include methodology for incident investigation and analysis. Signposting to existing published resources are available in section 5.

Harm or incidents arising from deliberate intended actions are also excluded from the scope of this document. These would be managed through disciplinary processes and/or referral to police and regulatory bodies.

3. HOW PATIENTS WHO USE PHARMACY SERVICES ARE PROTECTED

People who use pharmacy services are protected by:

THE PROFESSIONALISM OF PHARMACY TEAMS

Professionalism is the first-line of defence for patients using pharmacy services

REGISTERED PHARMACISTS AND PHARMACY TECHNICIANS*

Pharmacy teams include registered pharmacists and registered pharmacy technicians* who are regulated and held to account through standards for pharmacy professionals⁵ or code of ethics⁶

SUPERINTENDENT PHARMACISTS
AND CHIEF PHARMACISTS

Pharmacy teams are overseen by superintendent pharmacists, chief pharmacists or equivalent who are also registered and held accountable through standards for pharmacy professionals⁵ or code of ethics⁶

THE PHARMACY, HOSPITAL OR HEALTHCARE ORGANISATION

Pharmacies, hospitals and healthcare organisations are regulated. They need to meet regulatory standards^{7,8} and are inspected⁹

If they are funded by the NHS, they will also need to meet contractual obligations^{10,11,12,13}, NHS frameworks and the NHS constitution¹⁴

^{*} Pharmacy technicians practising in Northern Ireland are not registered by the Pharmaceutical Society of Northern Ireland.

4. HOW REPORTING, LEARNING, SHARING, TAKING ACTION AND REVIEW ARE FUNDAMENTAL TO PATIENT SAFETY

Patients always expect pharmacy teams to be pro-active and engaged in improving patient safety.

Patient safety is reliant on a patient safety culture that is open and honest and is supported by reporting, sharing, learning and taking action on patient safety incidents and review.

This is illustrated in the wheel diagram below¹⁵ which is reproduced with kind permission from Pharmacy Voice.

The standards are inter-dependent. For example, reporting incidents results in data being collected which can be analysed to identify the causes and the actions needed to avoid reoccurrence. The learnings can be shared to spread improvement across systems of care.



5. WHAT TO REPORT AND WHO TO REPORT TO

Different types of incidents are reported to different reporting programmes.

Table I below describes some examples. Definitions and terminology differ depending upon the reporting programme.

	WHAT TO REPORT			WHO TO REPORT	то
LOCAL	All incidents (including omissions)	In the first instance, report, learn and share from all incidents (including those that cause harm, "no harm" and "near-miss") with the people you work with i.e. your immediate team, line manager, clinical governance lead or local area team.			
	Side effects from taking medicines Medical device adverse incidents Defective medicines Counterfeit medicines	The Yellow Card Scheme (UK) ¹⁶			
MES	Patient Safety Incidents The most common medicines related incidents reported to NRLS ²⁴ relate		Registered pharmacy	NHS hospital or NHS healthcare organisation	Independent sector hospital or healthcare organisation
REGIONAL OR NATIONAL REPORTING PROGRAMMES	to incidents involving prescribing, administering or dispensing: the wrong dose, frequency or strength omission of the medicine	H	National Learning and Reporting System (NRLS) ^{17,10}	NRLS ¹⁷ and Care Quality Commission (CQC) ¹¹	Internal, CQC ^{II} and Private Healthcare Information Network (PHIN) ^{I8}
		×	Local reporting systems with a focus on quality improvement and learning is promoted in Scotland. The Healthcare Improvement Scotland Adverse Events National Framework ¹² provides useful context whilst learning summaries are available from the adverse events Community of Practice network. ³⁸		
			NRLS ^{17,13}	NRLS ^{17,7} and Health inspectorate Wales	Health inspectorate Wales
			Health and Social Care (HSC) medicines governance team via community pharmacy anonymous reporting system ¹⁹	HSC framework for serious adverse events ²⁰ The regulation and quality improvement authority (RQIA) ²¹	The regulation and quality improvement authority (RQIA) ²¹
	Adverse reactions with radiopharmaceuticals Defective radiopharmaceuticals	The <i>UK Radiopharmacy Group</i> collects data relating to defective radiopharmaceutical products and patient adverse reactions which are published on an annual basis in the European Journal of Nuclear Medicine and Molecular Imaging. ²²			
	Errors occurring within aseptic preparation services	The <i>pharmaceutical aseptic services group</i> ²³ operate a national scheme (open across the UK) to record errors occurring within aseptic preparation.			

6. WHAT STOPS PHARMACY TEAMS FROM REPORTING, LEARNING, SHARING AND TAKING ACTION

Different reasons discourage people from reporting, learning, sharing and taking action to improve patient safety. Themes include:

- Time needed to report, learn share and to take action
- Lack of knowledge or understanding the value of reporting, sharing, learning and taking action
- A range of fears and anxieties about reporting, learning, sharing and taking action.

The table below summarises in more detail, the reasons why people decide not to report, share, learn or act and identifies solutions which can help.

Some solutions cannot be implemented by pharmacy teams alone and need the involvement of government, regulators, commissioners, pharmacy and healthcare organisations or patient safety networks.

	Y PEOPLE DECIDE NOT TO RT, LEARN, SHARE OR ACT	POSSIBLE SOLUTIONS TO ENCOURAGE PEOPLE TO REPORT, LEARN, SHARE AND ACT
TIME	Time needed to report, learn, share and act Workload pressure	Design and improve reporting, learning and sharing systems to make them as easy as possible for pharmacy teams to use. ²⁵
		Make use of existing and new technology to improve systems. For example the "Yellow Card Scheme" is now accessible through a phone app in addition to online, and by post.
	How to report, Who can report, What should be reported	Raise awareness of local processes for incident reporting and the key messages contained within this standard.
DGE	The team do not know how to learn from incidents	Use of existing improvement methodology and incident investigation tools and templates to analyse incidents. ^{26,27,28,29,30,31,43} Encourage individual reflection and continuous professional development as an incident can be an indication of a learning need.
LACK OF KNOWLEDGE	The team are not aware of networks that can support	Make use of the leadership roles of patient safety networks across UK including: "Freedom to Speak Up Guardians" or Care Quality Commission National Guardians ³² Medication Safety Officers network ³³ Scottish Patient Safety programme networks ³⁴ HSC safety forum ³⁵ Patient Safety Wales Team ³⁶ Northern Ireland medicines Governance team ³⁷ Adverse Events Community of Practice Network (in Scotland) ³⁸

\A/L IV	A DECIDE NOT TO	POSSIBLE COLUTIONS TO ENCOLUDACE PEOPLE TO REPORT LEARNI
	PEOPLE DECIDE NOT TO RT, LEARN, SHARE OR ACT	POSSIBLE SOLUTIONS TO ENCOURAGE PEOPLE TO REPORT, LEARN, SHARE AND ACT
BENEFITS OF REPORTING	The pharmacy team cannot see the benefits/impact of reporting, learning, sharing or acting	Local and national reporting systems need to be able to provide feedback to pharmacy teams reporting to reinforce reporting habit.
		People need to see that reporting, learning, sharing and acting has made a difference.
		Encourage incident reporting behaviour by acting positively when teams and individuals report, share, learn and take action. Discourage non-reporting so that it is viewed as poor practice.
		Improve the effectiveness of communications about learning from incidents by:
		Highlighting key messagesPersonalising communications
BEN		 Personalising communications Describing positive case studies where reporting, sharing, learning and acting has made a difference
		Describing the impact of non-reporting.
	Involvement of the regulator	Safety culture and human factors ³⁹ principles are taken into account by regulators and regulatory frameworks.
	Criminal sanction or obtaining a criminal record	A defence to criminal sanction for inadvertent dispensing errors is implemented. ^{40,41}
	Public and media perception, impact on reputation and business	Educate the public and general media that:
		encouraging incident reporting improves patient safety healthy levels of reporting are positive and show that a pharmacy team is committed to
		 healthy levels of reporting are positive and show that a pharmacy team is committed to patient safety
		campaigns to encourage reporting will lead to a "good" increase in incidents of reporting and should not be viewed as a "sign of failure"
Ä		■ Increases in incidents of reporting should be described fairly and within context.
FEAR		Proportionate levels of anonymity for people or organisations reporting incidents should be built into local or national reporting systems.
		The Health Foundation hosts research on the merits of anonymous reporting systems. ⁴²
	Blame or reprimand by the employer	Safety culture and human factors ³⁸ principles are taken into account by employing organisations.
	Not wishing to get colleagues "into trouble" Negative attitudes from	Reporting, learning, sharing and taking action are actively promoted and supported by employing organisations.
	colleagues through giving negative feedback or perception of bullying	

7. ACKNOWLEDGEMENTS

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STEERING GROUP MEMBERS

Catherine Duggan	Director of Professional Development and Support, Royal Pharmaceutical Society
Tess Fenn	President, Association of Pharmacy Technicians UK
Helen Gordon	Chief Executive, Royal Pharmaceutical Society
Julie Greenfield	Pharmacy Manager, Pharmacy Forum NI
Karen Harrowing	Quality Systems and Pharmacy Consultant
Steve Howard	Quality and Regulatory Director & Superintendent pharmacist
Janice Perkins	Pharmacy Superintendent, Well and Chair of the Pharmacy Voice Patient Safety Group
Ruth Wakeman	Assistant Director for Professional Development and Support, Royal Pharmaceutical Society
Wing Tang	Lead author and senior professional support pharmacist, Royal Pharmaceutical Society
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Mary Agnew	Assistant Director, Standards and Education Policy, General Medical Council
Sarah Billington	Head of Medicines Optimisation, Care Quality Commission
Barry Corbett	Professional Secretary, Guild of Healthcare Pharmacists
Cathy Cooke	Medicines Management Consultant, Specialising in secure environments
Steven Eggleston	Community pharmacist
Danielle Fisher (responding on behalf of)	Pharmacy Schools Council
Carolynne Freeman	Superintendent pharmacist, Cox & Robinson (Chemists) Ltd
Charles Fulton	Diabetes UK
Dr David Gerrett	NHS Improvement, Senior Pharmacist Patient Safety
Sandra Gidley	Chair of the Royal Pharmaceutical Society English Pharmacy Board and Locum Pharmacist
Gerard Greene	Chief Executive, Community Pharmacy Northern Ireland (CPNI)
Dr Adrian Hall	UK Radiopharmacy Group
Dr William Harrop-Griffiths	Royal College of Anaesthetists
Vanessa Hunter	Pharmacy Technician
Dr Yogini Jani	National Medication Safety Officer Network Steering Group
Dr Carina Livingstone	Medicines Use and Safety Team, NHS Specialist Pharmacy Service

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Kate Livesey	Policy & Programmes Adviser, Pharmacy Voice
Steve Lutener	Pharmaceutical Services Negotiating Committee
Nigel Mathers	Honorary Secretary, Royal College of General Practitioners
Claire May	Senior Lecturer in Pharmacy Practice. University of Brighton.
Laura McEwen-Smith	Principal Pharmacy Technician, HEE Kent, Surrey and Sussex Pharmacy Education team
Annamarie McGregor	Practice Development Lead, Scottish Directorate
Laura McIver	Chief Pharmacist, Healthcare Improvement Scotland
Sam McIntyre	Quality Manager, Royal College of Emergency Medicine
Amanda Mclean	Specialist Pharmacist, Quality Risk and Governance Services; NHS Lothian
Sharon O'Donnell (responding on behalf of)	Northern Ireland Medicines Governance Team
Rose Marie Parr	Chief Pharmaceutical Officer, Scottish Government
Gill Risby	School of Medicines Optimisation, Health Education England, working across Yorkshire and the Humber
Gillian Robson	Pharmacy Technician
Tim Root	Specialist Pharmacist, NHS Specialist Pharmacy Service
Bernadette Sinclair-Jenkins	Enforcement & Standards Division, Medicines Healthcare Regulatory Agency
Joy Wingfield	Pharmacy Law and Ethics Consultant

8. REFERENCES

- I. Joint statement from the Chief Executives of statutory regulators of healthcare professionals. *Openness and honesty: the professional duty of candour.* http://www.pharmacyregulation.org/sites/default/files/joint_statement_on_the_professional_duty_of_candour.pdf (last accessed April 2016)
- 2. General Medical Council & Nursing and Midwifery Council Openess and honesty when things go wrong: the professional duty of candour. (2015). http://www.gmc-uk.org/DoC_guidance_englsih.pdf_61618688.pdf (last accessed April 2016)
- 3. NHS Litigation authority. *Guidance on candour.* (2014). http://www.nhsla.com/OtherServices/Documents/NHS%20LA%20-%20Duty%20of%20Candour.pdf (last accessed April 2016)
- 4. National Patient Safety Agency. What is a patient safety incident? http://www.npsa.nhs.uk/nrls/reporting/what-isa-patient-safety-incident/ (last accessed May 2016)
- 5. General Pharmaceutical Council. Standards of conduct, ethics and performance. (2012). https://www.pharmacyregulation.org/sites/default/files/standards_of_conduct_ethics_and_performance_july_2014.pdf (last accessed April 2016)
- 6. Pharmaceutical Society of Northern Ireland. *Code of ethics.* (2016). http://www.psni.org.uk/about/code-of-ethics-and-standards/ (last accessed May 2016)
- 7. Welsh Assembly Government. National minimum standards for independent health care services in Wales. http://www.hiw.org.uk/sitesplus/documents/1047/NMS%20IHC%20Services%20in%20Wales-e.pdf (last accessed April 2016)
- 8. General Pharmaceutical Council. Standards for pharmacy premises. https://www.pharmacyregulation.org/standards/standards-registered-pharmacies (last accessed April 2016)
- 9. General Pharmaceutical Council. *Inspection decision making framework.* http://www.pharmacyregulation.org/sites/default/files/Inspection%20Decision%20Making%20 Framework%20Nov%202013.pdf (last accessed April 2016)

- 10. Pharmaceutical Services Negotiating Committee. *Patient safety incident reporting FAQs.* http://psnc.org.uk/contract-it/essential-service-clinical-governance/patient-safety-incident-reporting/ (last accessed April 2016)
- II. Care Quality Commission. *Notifications web page*. http://www.cqc.org.uk/content/notifications-nhs-trusts (last accessed April 2016)
- 12. Healthcare Improvement Scotland. Learning from adverse events through reporting and review framework. http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/management_of_adverse_events/national_framework.aspx (last accessed April 2016)
- 13. NHS Wales. Clinical governance Essential Services Specifications. http://www.wales.nhs.uk/sites3/page.cfm?orgid=498&pid=11862 (last accessed April 2016)
- 14. Department of Health. *The NHS constitution for England.* https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england (last accessed April 2016)
- 15. PharmacyVoice. *Patient safety incident reporting principles*. http://pharmacyvoice.com/resource/patient-safety-incident-reporting-principles/ (last accessed August 2016)
- 16. Medicines Healthcare Regulatory Agency. *Yellow Card Scheme*. https://yellowcard.mhra.gov.uk/ (last accessed May 2016)
- 17. NHS. *National Reporting and Learning Service (NRLS)* web portal. http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/ (last accessed April 2016)
- 18. Private Healthcare Information Network (PHIN) website. https://www.phin.org.uk (last accessed May 2016)
- 19. HSC Medicines Governance Northern Ireland. Community pharmacy services anonymous reporting system. http://www.medicinesgovernance.hscni.net/primary-care/community-pharmacy/community-pharmacy-incidentsnear-misses/ (last accessed April 2016)

- 20. HSC health and social care board. *Procedure for the Reporting and follow up of Serious Adverse Incidents.*http://www.hscboard.hscni.net/publications/
 Policies/102%20Procedure_for_the_reporting_and_followup_of_Serious_Adverse_Incidents-Oct2013.pdf (last accessed April 2016)
- 21. The regulation and quality improvement authority. *Notifiable events web page.* http://www.rqia.org.uk/what_we_do/registration__inspection_and_reviews/notifiable_events.cfm (last accessed May 2016)
- 22. UK Radiopharmacy *Group Adverse* event reporting form. http://www.bnms.org.uk/adverse-event/defectreporting/adverse-event-reporting-information.html (last accessed May 2016)
- 23. National Aseptic Error Reporting Scheme webpage. http://www.civas.co.uk/error.htm (last accessed May 2016)
- 24. National Patient Safety Agency. Safety in doses: medication safety incidents in the NHS. (2007). http://www.nrls.npsa.nhs.uk/resources/?entryid45=61625 (last accessed April 2016)
- 25. Cabinet Office Behavioural Insights Team. (2012). Applying behavioural insights to reduce fraud, error and debt. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/60539/BIT_FraudErrorDebt_accessible.pdf (last accessed April 2016)
- 26. NHSScotland. *Quality Improvement hub.* http://www.qihub.scot.nhs.uk/
- 27. 1000 lives programme website and quality improvement tools. http://www.1000livesplus.wales.nhs.uk/home
- 28. NHS Improving Quality website. http://www.nhsiq.nhs.uk/
- 29. Health Foundation webpage, improvement tools and publications. http://www.health.org.uk/
- 30. Royal Pharmaceutical Society, Pharmacy Forum NI and APTUK. http://www.pharmacyqs.com/

- 31. NHS Education for Scotland. Significant event analysis: for pharmacy staff. http://www.nes.scot.nhs.uk/education-and-training/by-discipline/pharmacy/about-nes-pharmacy/audit,-cpd,-sea/significant-event-analysis-for-pharmacy-staff.aspx
- 32. Care Quality Commission. Freedom to speak up guardians web-page. http://www.cqc.org.uk/content/cqc-appoints-first-national-guardian-freedom-speak-nhs
- 33. NHS England Patient Safety Alert Improving medication and error incident reporting and learning. (2014). https://www.england.nhs.uk/wp-content/uploads/2014/03/psa-med-error.pdf (last accessed April 2016)
- 34. Scottish patient safety programme website. http://www.scottishpatientsafetyprogramme.scot.nhs.uk/contact-us
- 35. HSC Safety forum website. http://www.publichealth. hscni.net/directorate-nursing-and-allied-health-professions/hsc-safety-forum
- 36. Patient safety Wales website. http://www.patientsafety.wales.nhs.uk/about-us
- 37. HSC medicines governance team webpage. http://www.medicinesgovernance.hscni.net/contact-us/
- 38. Adverse Events Community of Practice Network (in Scotland). http://www.knowledge.scot.nhs.uk/adverseevents/sharing-learning.aspx (last accessed August 2016)
- 39. A Concordat from the National Quality Board. Human Factors in Healthcare. (2014). https://www.england.nhs.uk/wp-content/uploads/2013/II/nqb-humfact-concord.pdf (last accessed April 2016)
- 40. Royal Pharmaceutical Society. Consultation response to Department of Health Consultation on Rebalancing Medicines Legislation and Pharmacy Regulation: draft orders under section 60 of the Health Act 1999. http://www.rpharms.com/consultation-responses-pdfs/consdocl50527.pdf (last accessed April 2016)

- 41. Pharmacy Forum NI. Consultation response to Department of Health Consultation on Rebalancing Medicines Legislation and Pharmacy Regulation; draft orders under section 60 of the health Act 1999. http://forum.psni.org.uk/wp-content/uploads/2015/09/Consultation-Response-from-the-Pharmacy-Forum-NIto-Rebalancing-May-2015.pdf (last accessed April 2016)
- 42. http://www.health.org.uk/journal/anonymous-online-reporting-sparks-quality-improvement
- 43. NPSA patient safety resources. http://www.nrls.npsa.nhs.uk/resources/ (last accessed August 2016)



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