ROYAL PHARMACEUTICAL SOCIETY

# Patient safety professional standards

# Responding to patient safety incidents

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# Contents



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# 1 Introduction

These patient safety professional standards support you when responding to patient safety incidents. The definition of the term 'patient safety incidents' used in this document only applies to the context of this standards.

These standards replace the 2016 version of the RPS 'Professional standards for the reporting, learning, sharing, taking action and review of incidents'.[1] The 2016 version was developed to describe good practice and systems of care for reporting, learning, sharing, taking action and review as part of a patient safety culture. Until the introduction of a legal defence for dispensing errors for registered pharmacies in 2018, the 2016 version bridged the gap by removing the fear of the reporting system and resulted in a greater level of reporting, providing more insight to improve quality and patient safety. The 2018 legal defence was further extended to hospitals and other pharmacy services in 2022.[2]

These standards provide a broad framework to support you to continually improve services, shape future services and roles and deliver high-quality care across all settings and sectors. They describe clear expectations and outcomes to help you demonstrate good professional practice, patient safety, systems of care and effective working practices. While they are not mandatory, they are developed and owned by the profession and describe quality pharmacy services or what 'good' looks like. The RPS and General Pharmaceutical Council (GPhC) joint statement on the position of professional standards describes the relationship between a GPhC regulatory standard with an RPS professional standard.[3] **Figure 1** illustrates where RPS professional standards fit in relation to legislation, regulatory standards, other standards, policies and procedures.

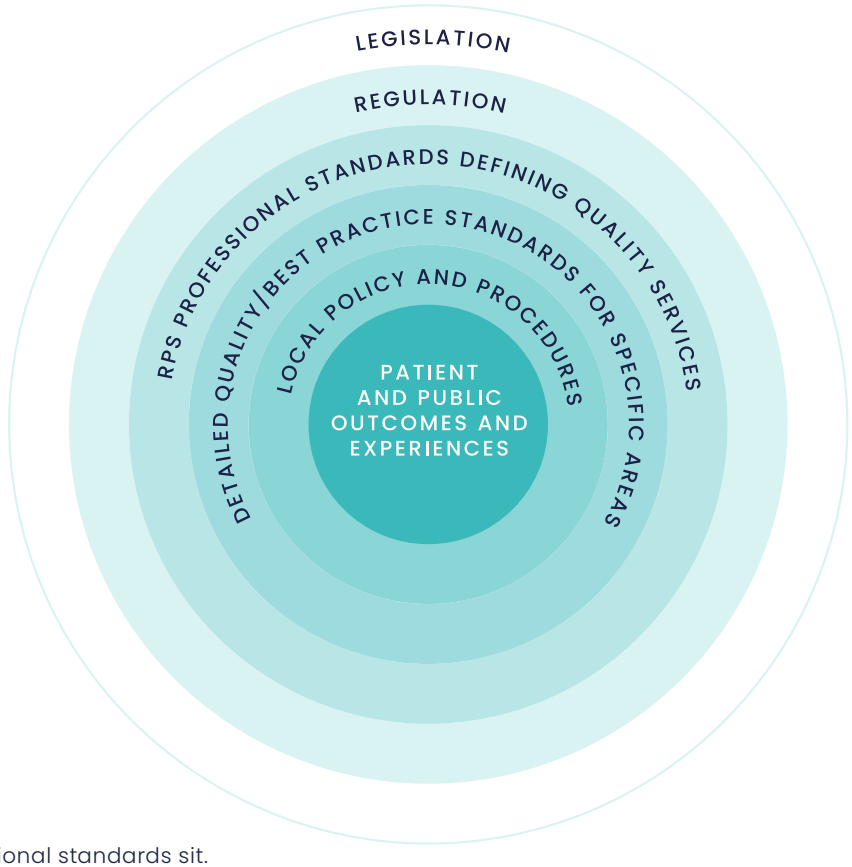


**Figure 1:**
Where RPS professional standards sit.

# 2 Purpose

These standards improve patient safety by helping you meet the expectations and outcomes when responding to patient safety incidents. Patient safety is built on a just culture to enable individuals involved to feel confident when responding to patient safety incidents. It is supported by:

- Proactive and regular reflection on current practice
- Being open and honest
- Active review of patient safety incidents in line with organisational policy
- Recording and reporting to communicate to the relevant individuals and organisations using the right mechanisms
- Preventative action to minimise recurrence and manage risk
- Sharing learning with others
- Evaluating any changes made for improvement.

All individuals involved in delivering pharmacy services are equally responsible and accountable for contributing to a culture that supports patient safety, regardless of their role, registration status or professional body.

All registered pharmacy professionals are expected to apply all relevant standards, both regulatory and professional, to support them in their work.

People who use pharmacy services expect a proactive, engaged, systems-based[4,5] and person-centred approach to patient safety improvement.

Following the standards can help to protect people who use pharmacy services by supporting every-one involved in delivering pharmacy services to:

- Deliver safe and effective person-centred care
- Develop and improve professional practice and services
- Promote health equality and equity
- Build a patient safety culture
- Empower people to make informed decisions about their care
- Ensure that people are placed at the core of the design and delivery of pharmacy services
- Meet contractual obligations, relevant regulations, NHS frameworks and the NHS constitution if they are NHS funded
- Meet the overarching regulatory standards and professional guidance set by their regulators and demonstrate professionalism
- Meet regulatory inspections for pharmacy, hospital or healthcare organisation premises
- Adopt systems of work and strong strategic, operational, personal and clinical leadership methods that ensure the right skill mix, capacity and capability to deliver pharmacy services
- Use relevant systems and processes to promote reflection, being open and honest, review, recording, reporting, acting, sharing learning and evaluating.

# 3
# Scope

**These standards can be used by various groups.**

These standards cover pharmacy services, whether provided internally or outsourced, and are applicable across the full range of service providers in the NHS and independent sector.

These standards apply equally to anyone delivering pharmacy services, pharmacy professionals working in other healthcare settings and anyone working within the pharmacy including (but not limited to):

- Pharmacists (including superintendents and chief pharmacists)
- Pharmacist prescribers
- Pharmacy technicians
- Pharmacy assistant technical officer
- All pharmacy trainees and students (foundation pharmacists, technicians and assistants)
- Pharmacy managers.

The standards apply to the above in all sectors across the United Kingdom, regardless of their professional background or setting.

Pharmacy employers, regulators, commissioners of pharmacy services, pharmacy leadership teams, those accountable for procuring a pharmacy service and NHS organisations may find these standards useful to improve the systems and working environments that enable and encourage a just reporting culture and shared learning.

The standards may also be of interest to the public, people who use pharmacy and healthcare services and healthcare professionals working with pharmacy teams to understand how people who use pharmacy services are protected.

### GENERAL SCOPE OF THE STANDARDS:

- It is a generic set of standards; therefore, it does not contain statements that relate to specific areas
- The standards must be contextualised to reflect different areas of practice, levels of expertise and settings.

### USING THE STANDARDS:

- These standards should be used in conjunction with relevant regulatory standards, statutory and professional duty of candour requirements, employer's, organisational and national policies, your indemnity insurance arrangements and legal reporting arrangements in place in each of the home nations
- The standards should be used within your scope and remit and escalated where relevant and appropriate
    - Clarity of roles and responsibilities for actions and decisions for meeting each standard should be delegated by organisations, i.e., at an individual or leadership level (where relevant and appropriate).
- The standards can be used to inform, develop and implement local and organisational policies and services
    - These standards should be applied when risk assessing new services and when using new and evolving technology.
- The supporting resources page here can be used to facilitate the implementation of the standards.

# 4
# The standards

## STRUCTURE OF THE STANDARDS:

**STANDARD**

Outcome and expectation.

↓

**DESCRIPTOR OUTCOME**

Under each standard is a sentence that supports attainment of the standard by describing the outcome that should be actively and routinely demonstrated.

↓

**SUPPORTING STATEMENTS**

Under the descriptor outcomes are supporting statements explaining how a standard and descriptor could be demonstrated.

↓

**FURTHER INFORMATION**

The further information sections under each supporting statement provide information and examples (list not exhaustive or definitive), which provide clarity and meaning to the supporting statements. The recommendation is to use the standards alongside any relevant further information sections to support their implementation into your practice.

Figure 2:
Structure of the standards.

**PLEASE NOTE:**

- The standards and supporting statements are inter-dependent and are not in any particular order. The numbering is mainly to support mapping purposes and does not reflect the level of importance of the statement. They are not designed to be used as a script or in isolation

- Due to the generic nature of the standards, it may be that not every standard, descriptor outcome or supporting statement is relevant to your practice or setting. However, you should still be able to consider how it could be demonstrated.


Figure 3:
Professional standards for responding to patient safety incidents adapted from Community Pharmacy Patient Safety Group.[6]

**PLEASE NOTE:**

- You can start anywhere depending on the individual circumstances, concern, incident or need
- Figure 3 is interactive. Click on any standard to be directed to that standard.

# STANDARD 1: REFLECT

## DESCRIPTOR OUTCOME

Proactively and regularly reflect on existing knowledge, understanding, safety culture and systems to identify gaps around responding to patient safety incidents and improve the delivery of safe and effective person-centred care.

## SUPPORTING STATEMENTS

1.1. Understand your own and others' roles[a] and responsibilities when responding to patient safety incidents, and encourage others to do the same

1.2. Understand work system-based factors[b] and approaches[c] when responding to patient safety incidents

1.3. Identify learning needs through individual reflection and continuous professional development,[d] and encourage and support others to do the same

1.4. Review and address issues and concerns[e] about responding to and escalating patient safety incidents

1.5. Develop,[f] review, understand and implement appropriate processes and policies[g] for identifying and responding to patient safety incidents using relevant national, local and regulatory guidelines

1.6. Ensure there are sufficient resources,[h] and access and training to relevant IT tools and systems to support the process[i] of responding to patient safety incidents.

## FURTHER INFORMATION

a. E.g., roles may include those outside the immediate team

b. E.g., work system-based factors (or socio-technical systems) may include tools, technology, tasks, people, organisations and internal and external environments[4]

c. E.g., system-based approaches may include looking at interrelationships and patterns, and using a structured process to deliver a socio-technical system (looking at needs, requirements, design, delivery)[5] that impacts on process (work done) and desired outcomes (related to performance and well-being)[4]

d. E.g., continuous professional development may include staying up to date with the latest emerging safety information on medicines for improving patient safety outcomes through safety alerts (such as the MHRA Drug Safety Updates[7])

e. E.g., issues and concerns may include fears, barriers and consequences

f. E.g., develop process and policies by involving the relevant people including end users, experts, managers and staff

g. E.g., processes and policies may include what, how and where to record and report, how to raise a patient safety incident, who to raise concerns with, how to learn from patient safety incidents, risk management systems, understanding the risk tolerance of organisations and how to identify and respond to patient safety incidents

h. E.g., resources may include staff, time, investigation and analytical skills, technology, standard operating procedures, supporting networks, education, training and guidance

i. E.g., process may include recording, reporting, incident analysis, risk identification, risk assessments and thematic review.

## STANDARD 2: **BE OPEN AND HONEST**

### DESCRIPTOR OUTCOME

Be open, honest and responsive when a patient safety incident occurs to support professional accountability and the individuals affected[a] by the incident.

### SUPPORTING STATEMENTS

2.1. Create and promote a just culture[b] in the workplace with an environment that supports psychological safety and enables individuals to feel confident, supported and empowered[8] to speak up and raise patient safety incidents without fear

2.2. Follow any relevant regulatory guidance[c] as well as any relevant national, workplace or local policies and procedures

2.3. Open lines of communication[d] with individuals affected,[a] your employer, relevant organisations[e] and anyone involved in the incident and the person's care

2.4. Actively listen to the individuals affected[a] by the patient safety incident in a respectful, compassionate, non-judgemental and non-defensive way, and check their immediate safety and wellbeing

2.5. Engage with individuals affected[a] by the patient safety incident (where relevant and appropriate) by providing information[f] and support[g]

2.6. Involve individuals affected[a] by understanding their expectations regarding how they would like the patient safety incident to be resolved[8] and how they would like to be kept informed of developments.

### FURTHER INFORMATION

a. E.g., individuals affected include the person affected, their family, carers, the person who raised or reported the incident, colleagues or pharmacy team members

b. E.g., just culture considers wider system issues and a fair evaluation of why incidents occurred to enable openness and learning without fear of blame[9]

c. E.g., guidance, policies and procedures may include statutory and professional duty of candour, raising concerns, or the NHS standard contract

d. E.g., adapt to the communication needs of the person (where relevant and appropriate), e.g., language, age, capacity, learning disability and physical or sensory impairments, providing digital or paper formats

e. E.g., communicating with organisations may include informing your regulator or your indemnity provider

f. E.g., information may include answering questions, making the person affected, their families and/or carers aware of complaint management procedures, informing individuals affected about how the patient safety incident will be managed, who will be involved, timescales and how the response will be escalated (where relevant and appropriate), providing regular feedback to individuals affected and the person who raised the patient safety incident

g. E.g., support may include self-reporting suspected side effects to medicines, vaccines and medical devices via the MHRA Yellow Card scheme[10] and signposting to bereavement, advocacy services, charities and mental health services.[11]

## STANDARD 3: **REVIEW**

### DESCRIPTOR OUTCOME

Review all patient safety incidents in a timely manner to identify an appropriate response or action, identify contributing factors, manage risk and support safety interventions and learning.

### SUPPORTING STATEMENTS

3.1. Review all patient safety incidents to determine an appropriate response or action[a]

3.2. Gather relevant data[b] from available sources to understand what happened

3.3. Analyse data[b] to provide insight and highlight patient safety incidents that require a systems-based[c] investigation

3.4. Investigate patient safety incidents (where relevant and appropriate) using the appropriate incident-investigation methodologies and tools

3.5. Undertake thematic reviews of reported patient safety incidents to identify underlying patient safety issues, rather than purely responding to individual incidents

3.6. Identify system-based[c] interventions, or solutions for improvement using the appropriate improvement methodologies and mechanisms

3.7. Understand why the patient safety incidents occurred by identifying the learning, contributory factors,[d] risks, themes, trends, patterns, behaviours and frequency, and document these (even if none are identified).

### FURTHER INFORMATION

a. E.g., an appropriate response or action may include making enquires, investigating, reporting externally, an independent investigation, delegating roles, a review on the patient safety incident, identifying problems, making recommendations, taking any corrective or preventative measures

b. E.g., data may include taking details of the patient safety incident from the individuals affected, reported patient safety incidents, audits, complaints, compliments, peer discussions or near miss logs

c. E.g., system-based may include tools, technology, tasks, people, organisations, internal and external environment[4] and the interrelationships[5] between these

d. E.g., contributory factors may include elements of work systems (or socio-technical systems) (including tools, technology, tasks, people, organisations, internal and external environment),[4] human factors or complex factors.

## STANDARD 4: **RECORD AND REPORT**

### DESCRIPTOR OUTCOME

Record and report in a timely manner using the appropriate internal, local and national reporting mechanisms, regardless of where the patient safety incident originated, to improve patient safety by monitoring and identifying issues that need escalating, enable learning and facilitate the development of local, regional and national solutions.

### SUPPORTING STATEMENTS

4.1. Record and report information[a] and patient safety incidents (where relevant and appropriate) using the appropriate mechanisms and reporting systems[b]

4.2. Effectively and securely communicate information,[a] ensuring that private and personal data is protected and communicated securely in line with relevant legislation/regulations

4.3. Communicate information[a] with individuals[c] and organisations (where relevant and appropriate) for the purpose of discussion, advice, collaboration, learning and/or to involve them.

### FURTHER INFORMATION

a. E.g., information may include good practice, culture, service quality excellence, information given or received, discussions had, advice given, updates or who you involved and having open discussions among teams about patient safety incidents to help generate new ideas

b. E.g., reporting systems may include internal, local and national

c. E.g., individuals may include healthcare professionals, the wider healthcare team, colleagues or people affected by the patient safety incident, their families and/or carers.

## STANDARD 5: **ACT**

### DESCRIPTOR OUTCOME

Take relevant action in a timely manner to manage risk, strengthen, change or improve the quality of practice or systems of care (including e-Systems) in a sustainable way,[a] and minimise recurrence by addressing contributory factors (where relevant and appropriate).

### SUPPORTING STATEMENTS

5.1. Identify and actively manage the contributory factors, system weaknesses and latent hazards using a systems-based[b] and risk-management approach to understand why the patient safety incident occurred

5.2. Assess, develop[c] and implement the required immediate corrective measures

5.3. Assess, develop[c] and implement the required proactive preventative measures

5.4. Measure impact and monitor effectiveness of existing processes and new interventions and changes made to practice using appropriate data collection tools and improvement methodologies

5.5. Recognise and acknowledge good practice and behaviours when responding to patient safety incidents

5.6. Implement any learning from patient safety incidents and relevant actions with relevant individuals

5.7. Provide feedback and support[d] to the person that raised the patient safety incident and to colleagues involved in the patient safety incident.[8]

### FURTHER INFORMATION

a. E.g., sustainability includes the longevity to continue processes and to maintain the environmental needs of the future

b. E.g., systems-based includes tools, technology, tasks, people, organisations and internal and external environments[4,5]

c. E.g., develop includes collaborating with colleagues and teams to identify needs and requirements, and to design, deliver and test new ways of working or any interventions

d. E.g., support may include employee support on how and where to seek confidential advice and mental health first aid.[8]

## STANDARD 6: **SHARE LEARNING**

### DESCRIPTOR OUTCOME

Share learning from appropriate patient safety incidents with relevant individuals and organisations to improve patient safety, promote a learning culture and minimise future risks where relevant and appropriate.

### SUPPORTING STATEMENTS

6.1. Create and encourage a supportive learning culture and environment to inform improvement

6.2. Share relevant learning[a] from patient safety incidents and thematic reviews in a timely manner with relevant individuals[b] and organisations[c] using available sharing mechanisms[d] so that information can be cascaded internally, locally and nationally

6.3. Raise awareness of the benefit and impact of recording, reporting, learning, sharing or acting in response to patient safety incidents to embed this as good practice

6.4. Create regular opportunities to learn together – explore case studies, examine topical patient safety incidents and consider professional, clinical and legal responsibilities.[8]

### FURTHER INFORMATION

a. E.g., learning may include best practice, positive outcomes to interventions, changes to practice, learning from others, information, advice, what went well, what could have gone better, feedback, future prevention, types of errors, risks or the benefits of staff time spent reporting and recording

b. E.g., individuals may include the person who raised the patient safety incident, staff, internal teams, wider healthcare team, medication safety officers or controlled drugs accountable officers

c. E.g., organisations may include patient safety teams, the MHRA, NHS England (including national patient safety team, and regional safety leads), manufacturers, system vendors, the integrated care system, adverse event review groups or regulators

d. E.g., sharing mechanisms may include incident reporting systems, internal communications, serious adverse event reviews, adverse event bulletins, good practice guides, updates, education and training events, prescribing bulletins, MHRA Yellow Card reporting,[10] local, regional and national networks and practice forums or GPhC notable practice examples.

## STANDARD 7: **EVALUATE**

### DESCRIPTOR OUTCOME

Regularly evaluate systems, interventions and changes made to practice to assess outcomes of mitigating or preventing future risks and patient safety incidents.

### SUPPORTING STATEMENTS

7.1. Follow up[a] on interventions and changes made to practice after an appropriate timeframe and at appropriate intervals (where relevant)

7.2. Interpret available data to assess the impact and effectiveness of interventions and changes made

7.3. Use a risk management approach early and regularly to evaluate if outcomes have been met or if new interventions and changes to practice have been identified that need actioning to mitigate future risk

7.4. Assess current systems used, including IT systems,[b] and update where relevant and appropriate

7.5. Assess risk management procedures and update where relevant and appropriate to promote safety management.

### FURTHER INFORMATION

a. E.g., follow up may include what is going well and what could be improved

b. E.g., IT systems may include prescribing and management systems.

# 5 Glossary

The definitions in the glossary only apply to the context of this standard.

### PATIENT SAFETY INCIDENT

In relation to people's care and/or their medicines, something that has happened, or something that failed to happen and could have, or did, lead to harm.[12] For example:

- Medicine-related incidents involving:
  - Preparation
  - Dispensing, supply or administration – e.g., the wrong dose, wrong frequency or strength, omission of the medicine, the wrong medicine, the wrong quantity or the wrong patient
  - Counselling and medicines advice
  - Storage
  - Procurement.
- Medicine-related incidents involving prescribing, e.g., diagnostics, clinical skills, monitoring, prescribing the wrong dose, wrong frequency or strength, omission of the medicine, the wrong medicine, the wrong quantity or the wrong patient
- Adverse events/side effects from taking medicines, vaccines or radiopharmaceuticals
- Medical device adverse incidents and events
- Defective medicines, defective radiopharmaceuticals, faulty products and counterfeit medicines
- Incidents identified by another organisation
- Incidents involving controlled drugs
- Incidents occurring within aseptic preparation services
- Incidents that cause 'no harm'
- Incidents that cause harm
- Incidents relating to the provision of services
- Concerns about treatment pathways and existing processes
- Concerns about actions of other healthcare staff resulting in a patient safety incident
- Risks identified that could cause potential harm unless addressed
- Near misses.

### HARM

The definitions of harm may vary between national reporting systems, organisations and countries. You should follow the definition used by your respective system, organisation and country. However, for the purpose of this document, we will use the definition of harm as defined by the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20.[13] Harm includes:

- Moderate harm – Harm that requires a moderate increase in treatment and significant, but not permanent, harm
  - Moderate increase in treatment – An unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment or transfer to another treatment area (such as intensive care).
- Severe harm – A permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition
- Prolonged pain – Pain that a service user has experienced, or is likely to experience, for a continuous period of at least 28 days
- Prolonged psychological harm – Psychological harm that a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

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