

Definition of a significant risk

National Safety and Quality Primary and Community Healthcare Standards

This fact sheet clarifies the definition of a significant risk for the purposes of [Advisory PCHS26/03: Notification of significant risk](#).

Significant risk

Primary and community healthcare services (healthcare services) generally do not pose a significant risk of harm to patients. However, from time to time, lapses and errors may occur that result in an increased risk of harm to patients accessing care from a healthcare service.

Definition of a significant risk

A 'significant risk' is one where there is a high or an extreme probability of a substantial and demonstrable serious adverse impact for patients who access care from the healthcare service.

In each case, a significant risk will be sufficiently serious to warrant an immediate response to reduce the risk to patients (see [Table 1](#) for examples). This may include interventions or changes to the following:

- management systems, policies and procedures
- clinical care environment
- clinical practice.

Risks that have already been identified by the healthcare service, such as those identified through the review of a near miss or critical incident, and which are subject to existing quality improvement plans and effectively mitigated, would not be considered a significant risk.

A significant risk is a risk that, at the time of the assessment:

- has not previously been identified by the healthcare service
- is systemic in their origin
- is not currently controlled
- has not been sufficiently mitigated to prevent the possibility of serious patient harm.

Risk analysis matrix

Assessors and/or accrediting agencies can use the Risk analysis matrix¹ (Figure 1) to help determine if an identified risk of patient harm constitutes a significant risk.

Figure 1 Risk analysis matrix

Likelihood	Consequences				
	Insignificant	Minor	Moderate	Major	Catastrophic
Almost certain	Medium	High	High	Extreme	Extreme
Likely	Medium	Medium	High	High	Extreme
Possible	Low	Medium	Medium	High	High
Unlikely	Low	Low	Medium	Medium	High
Rare	Low	Low	Low	Medium	Medium

Low risk	Manage by routine procedures.
Medium risk	Manage by specific monitoring or audit procedures.
High risk	This is serious and must be addressed immediately. The magnitude of the consequences of an event, should it occur, and the likelihood of that event occurring, are assessed in the context of the effectiveness of existing strategies and controls.
Extreme risk	

¹ National Health and Medical Research Council (AU). Australian Guidelines for the Prevention and Control of Infection in Healthcare [Internet]. Canberra: Commonwealth of Australia, 2019. <https://app.magicapp.org/#/guideline/Jn37kn> (accessed 16 Oct 2025).



Examples of a significant risk

Table 1 provides some examples of significant risks for healthcare services. They are intended to be examples only. This list is not exhaustive and should not be exclusively used to identify significant risks.

Table 1 Examples of significant risks

Risk	Impact
Staff do not reprocess critical and semi-critical reusable equipment, instruments and devices to the required standard	Patients are exposed to microorganisms through direct contact, significantly increasing the risk of infection and transmission
The equipment used to reprocess reusable equipment, instruments and devices no longer complies with the manufacturer's guidelines	Patients are exposed to microorganisms through direct contact, significantly increasing the risk of infection and transmission
Staff do not manage temperature-sensitive medications and vaccines to the required standard	Patients are given ineffective medications or vaccines, increasing the risk of treatment failure and potentially requiring re-administration
Health providers do not follow processes to recall patients for follow-up health care when critical information, alerts and risks are identified	Patients fail to receive critical information promptly, leading to delays in care and deterioration in their health

The Health Practitioner Regulation National Law 2009 (the National Law) requires registered health practitioners, employers and education providers to report to the Australian Health Practitioner Regulation Agency (Ahpra) any instances of 'notifiable conduct' by individual registered health practitioners. Notifiable conduct by individual registered health practitioners does not fall under the definition of significant risk for the purposes of the relevant advisories and is not required to be reported to the Commission or the relevant state or territory health care complaints body.

Assessors and/or accrediting agencies that observe any conduct by individual registered health practitioners that constitutes notifiable conduct during an assessment are required to follow the mandatory reporting processes as outlined by Ahpra.

Questions?

Contact the Safety and Quality Advice Centre at AdviceCentre@safetyandquality.gov.au or call 1800 304 056.

For more information

Please visit: safetyandquality.gov.au/pchs

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