Patient safety incident response plan (PSIRP)

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Reviewed by: UK Medical Lead (Dr Thomas Curtis) & PSIRF Executive Lead (Emma Elstead)
Authorised by: Steven McEwen (Quality Manager - NHS Mid & South Essex ICB)
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Contents

Introduction

This patient safety incident response plan sets out how Oviva intends to respond to patient safety incidents over a period of 12 to 18 months. The plan is not a permanent rule that cannot be changed. We will remain flexible and consider the specific circumstances in which patient safety issues and incidents occurred and the needs of those affected.

Our services

Oviva is a provider of NHS services for people living with obesity, diabetes, malnutrition, cows' protein allergy and home enteral feeding requirements. Our dedicated team of dietitians, nutritionists, nurses, and psychologists use technology to safely and effectively support behaviour change, nutritional care and prescribing. Oviva is committed to developing and maintaining effective systems and processes for responding to patient safety incidents to ensure learnings are captured and patient safety improved.

To ensure our PSIRF reflects patient safety concerns for the variety of services Oviva offers, we have retrospectively analysed incident data and trends, patient and employee feedback and patient safety incident reporting, triage, learning and quality improvement. As a result, we have aimed to create a PSIRP proportionate to service requirements and patient needs to ensure we provide safe, effective, responsive and evidence-based care.

Defining our patient safety incident profile

A thematic review of Oviva's incident profile was conducted in the scoping and preparation phase of our PSIRF transition. In doing so we were able to identify the most commonly reported incidents in the past 2 years, and analyse the underlying and interlinking system issues that must be acted on to reduce risk. In this time period, no serious incidents or never events were reported or identified. The review firmly suggested that Oviva's current programmes had a low risk profile.

Stakeholder engagement included Oviva clinicians, patient support staff, senior clinical team members and function leads. Patient feedback over the past 6 months was also reviewed for safety concerns. Patient safety themes enabled us to prioritise what patient safety risks must be focused on over the next 12-18 months to inform our patient safety incident response. Including, how expected patient safety incidents will be addressed to minimise risk (i.e. risk mitigation).

Defining our patient safety improvement profile

Through our analysis of our patient safety insights, we have determined 5 patient safety priorities we will focus on for the next 12-18 months.

Table 1: Patient safety priorities and themes

Theme	**Key risk(s)**
Identification of emergent incidents	For the past 2 years, Oviva has implemented an internal patient safety incident criteria to guide incident reporting alongside the NHSE Serious Incident Framework. Internal criteria included, hyperglycaemia (raised blood glucose levels), hypotension (low blood pressure) and hospital admissions. However, reporting guidance did not distinguish between events that had coincidently occurred whilst the patient was on an Oviva programme, versus those potentially linked with Oviva care. As a result: ● The senior clinical team who reviewed and validated the severity of incidents, reported, due to the expected nature of the majority of the incidents, limited learnings were available ● Oviva employees fed back that reporting incidents is simple and easy to do, but some internal incident criteria did not feel relevant to care provision ● The great majority of reported incidents were either expected side-effects of the programme intervention and showed mild harm (minimal discomfort or inconvenience) and/or no evidence of inappropriate care. ○ Retrospective analysis found less than 2% of all reported incidents were identified as being clearly attributable to Oviva's care or unintended / unexpected. ○ Of these incidents, appropriate action had been taken to support patient care and had not led to patient harm. ● Reporting of emergent incidents (i.e. incidents which were not prepared or planned for) was rare outside of Oviva's internal reporting criteria (as above).
Patient safety risks associated with medication and clinical situation changes	Patient medication and clinical situation changes were identified as themes via near miss and adverse event reporting. These primarily related to increased risk of treatment advice being inappropriate / contraindicated. For example: ● Changes to medication resulting in dietary advice no longer being safe ● New onset, or disclosure of an eating disorder resulting in dietary intervention no longer being appropriate Patient feedback also identified a complaint theme regarding appropriate care planning.
Adverse glycaemia and blood pressure identification	Oviva has a relatively low risk profile, as evidenced by the 2 year data review, largely as a result of providing nutrition-based interventions with very limited and specific medication prescribing. The most commonly reported incidents were raised and low blood glucose and pressure readings self-reported by patients.

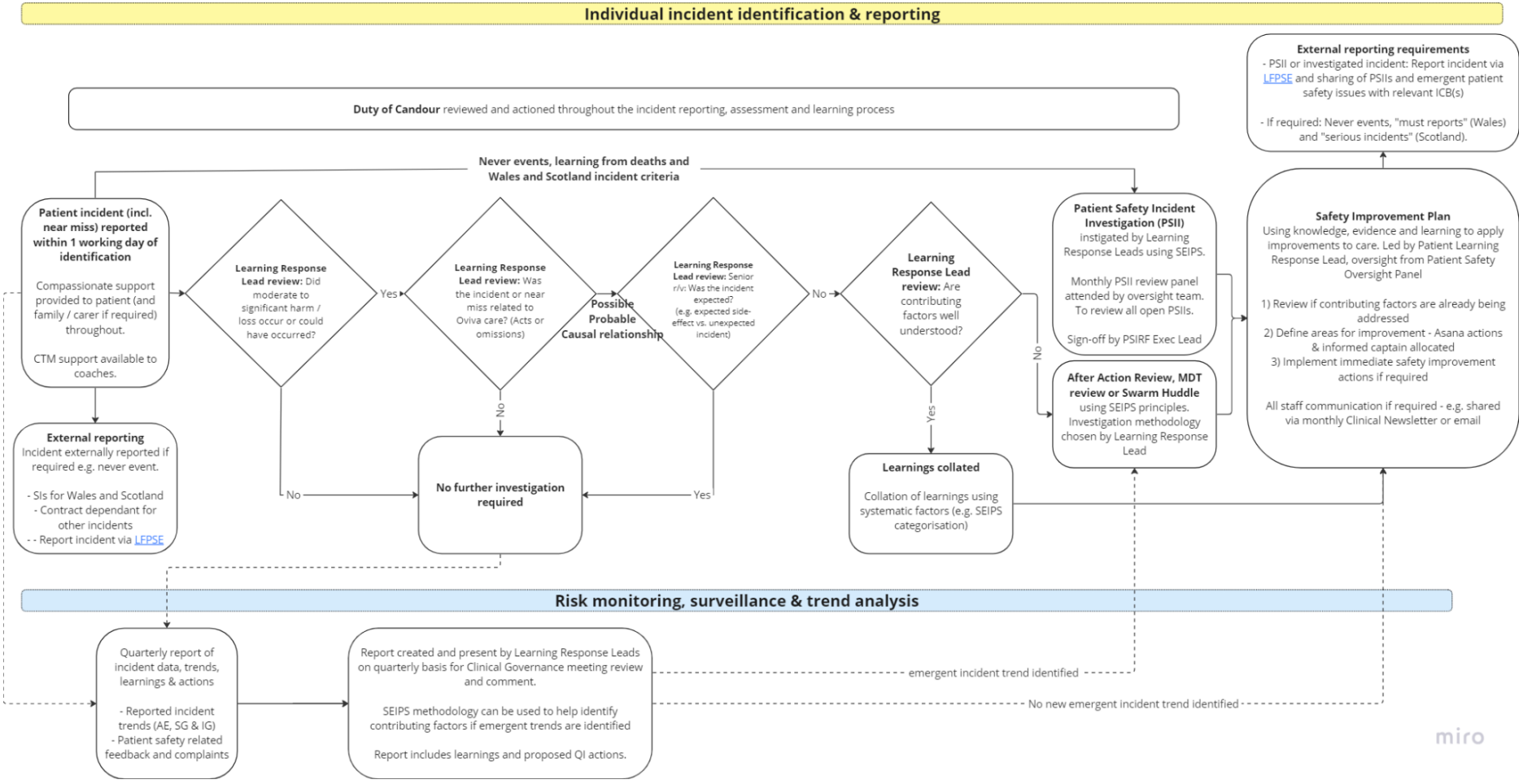
and management	In the majority of cases, incidents were not untoward and appropriate action had taken place by Oviva staff to support patients. This thematic review highlighted the need to rationalise how such incidents are reported, as well as ensure consistent guidance is in place to reduce risk.
Missed appointments and patient risk	Near misses were rare, however one theme was identified regarding clinicians missed appointments, and risk of missing a patient safety incident (e.g. high blood pressure). Issues regarding appointments not being honoured were also identified via patient feedback and complaints.

Deciding when to initiate a formal learning response through a Patient Safety Incident Investigation (PSII) or other learning response methodologies (e.g. Swarm, MDT Huddle) is informed by the local and national priorities and guidelines (as per figure 1). In response to the above patient safety priorities, a number of improvement actions are planned and underway.

Table 2: Improvement work

Theme	**Improvement work**
Identification of emergent incidents	A renewed focus on Oviva staff reporting untoward and emergent incidents potentially linked with Oviva care. Training and guidance to be provided alongside PSIRF launch.
	Review and amend of internal incident criteria and management guidance to ensure patients are supported when expected incidents occur. Reporting only required when something untoward is identified.
	Explore means of triangulating incidents trends with health inequalities data
	Scope and test a formalised proactive risk monitoring system to support patient safety
Patient safety risks associated with medication and clinical situation changes	Project underway to review how Oviva medication records can automatically highlight clinical risks and contraindications to clinicians, including medication prescribing risks.
Adverse glycaemia and blood pressure	Automated identification of adverse glycaemia and blood pressure (according to internal, evidence-based thresholds) to help identify trends, learning response needs and reduce the risk of patient safety incidents being missed (as below).
Missed appointments and patient risk	Automated identification and coach notification regarding patients appointments that have been missed as well as patients who have reported patient safety risk (see above)
	Develop plans for setting clear patient expectations regarding the care they can expect - including number and frequency of appointments.

Figure 1: Oviva incident response overview



Our patient safety incident response plan: national requirements

The following nationally defined incidents will require an internal PSII:

- Never events
- Incidents that meet the 'Learning from Deaths' criteria - untoward or unexpected deaths clinically assessed as more likely than not due to problems in care.
- Wales - 'Must reports' - Including never events
- Scotland - Serious incidents Category I – events that may have contributed to or resulted in permanent harm, for example unexpected death, intervention required to sustain life, severe financial loss (£>1m), ongoing national adverse publicity (likely to be graded as major or extreme impact on NHS Scotland risk assessment matrix, or Category G, H or I on National Coordinating Council for Medical Error Reporting and Prevention (NCC MERP) index).
- National priorities for investigations

The anticipated improvement route for nationally defined incidents will follow the process outlined in figure 1.

Oviva provides a number of NHSE services which require the reporting of specific incident criteria (typically referred to as adverse events). These incidents must be reported by Oviva staff as per contractual agreement and reviewed by Learning Response Leads, as per figure 1. Incidents which meet the above national criteria will be reported externally via the NHS Learn from Patient Safety Events (LFPSE) platform by Learning Response Leads.

Our patient safety incident response plan: local focus

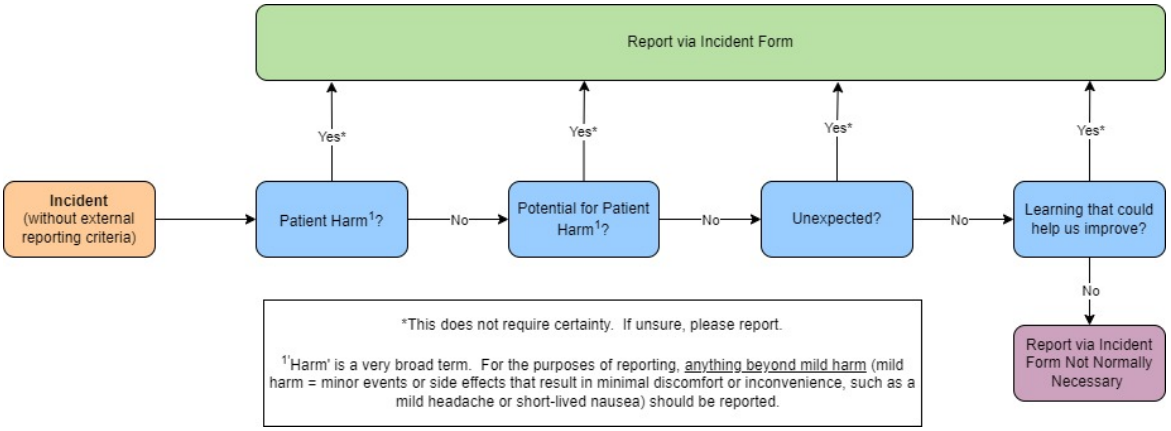
In addition to the national response requirements outlined above, the decision to carry out a learning response (e.g. Swarm, After action review (AAR), MDT review) is based on the following internal guidance:

- An unexpected patient safety incident which caused or could have caused moderate to significant harm, potentially linked with Oviva care, and the contributing factors not understood
- An emergent area of risk is identified. For example, a cluster of patient safety incidents of a similar type or theme is identified via quarterly analysis (figure 1), which may indicate a new safety priority emerging. In this situation, proactive investigation can be commenced, using a single or group of incidents as index cases. SEIPS methodology may be used to help identify contributing factors in such cases.
- Please note - Expected programme side-effects and incidents do not require individual assessment or reporting, instead, a risk mitigation plan has been put in place to support appropriate patient support / coach action should such an incident take place.

Senior Clinical Team support (including Clinical Service Managers and Clinical Leads) are available to assist and advise an incident reporter during working hours. Following 2 years of incident data, we have clear insights into expected programme side-effects. As a result, a risk mitigation plan is in place to ensure appropriate management of these expected incidents without the need for repeated incident investigation.

Oviva staff must report any incident that is unexpected or unintended, had the potential to cause harm (e.g. near miss), caused harm, or may offer an opportunity for learning or improvement. If staff are uncertain regarding the need to report an incident, they are encouraged to do so. All reported incidents are reviewed individually by the Learning Response Leads as per figure 1.

Figure 2 - Incident reporting guidance for Oviva staff



The following summarises the patient safety incident response processes in place:

- All reported incidents should be assessed (figure 1) within 5 working days of reporting by a Learning Response Lead. Incident assessments will be documented and tracked on Oviva's internal incident log.
- Learning Response Lead decisions and comments regarding a reported incident will be logged on a secure database for auditing purposes. To ensure objectivity, the Learning Response Lead cannot be a Line Manager of any Oviva staff involved.
- To maximise learnings and support appropriate resource allocation, incidents which caused or could have caused moderate to significant harm, are unexpected / untoward incidents and potentially linked to Oviva care will be eligible for a learning response if contributing factors are not understood:
    - The learning response methodology used is at the discretion of the Learning Response Lead (e.g. Swarm, MDT huddle, AAR)
    - Where an incident does not meet the requirement for a learning response, the Learning Response Lead can confirm closure of the incident, with appropriate consideration of Duty of Candour requirements (see PSIRF policy), and any existing learning and improvement plans.
- Quarterly surveillance and thematic analysis of incidents which are deemed to be low harm, not linked to Oviva care or expected will be conducted by a Learning Response Lead:
    - Such patient safety incidents will be reviewed on a quarterly basis to identify trends (thematic review) and contributing factors (via SEIPS if required) to

feed into improvement actions (if required). Including, identification of emergent incidents / patient safety themes and cross-organisational findings which will be shared with ICB partners accordingly.
    - This quarterly audit will be conducted by the Learning Response Leads and presented at Oviva's quarterly Clinical Governance meeting for review and comment.

The following systems-based principles will be followed by the Learning Response Leads when reviewing incidents and conducting a learning response if required (including PSIIs):

1. To ensure a systems-based approach, the SEIPS methodology will be used by Learning Response Leads to ascertain contributing factors and potential areas for learning and improvement.
    - Just culture principles will be used by the Learning Response Lead to ensure appropriate response work and reduce the risk of an individual blame culture.
    - SEIPS methodology will be used to identify the circumstances and systemic, interconnected causal factors that result in patient safety incidents
2. Compassionate engagement with staff, patients and their families and carers (if appropriate) impacted or relevant to the patient safety incident. Engagement is key to ensuring their perspective and questions are accounted for and prioritised as well as informing system-based interactions, learnings and improvement actions.
    - When a PSII is indicated, Terms of Reference (ToR) should be agreed with key stakeholders facilitated by the Learning Response Lead. This approach can help manage expectations, ensure a comprehensive investigation with the correct focus and boundaries that enable an achievable outcome within a practical timeframe.
    - Relevant stakeholders will be engaged throughout a learning response, including the incident reporter, employees involved and relevant Oviva function leads if required. To support this process, stakeholder interviews may be conducted
    - During an incident investigation, due consideration will be given to engaging Patient Support Partners (PSPs) by the Learning Response Lead(s) and/or Engagement Lead(s). PSPs may have unique insights during the investigation itself, and/or support action plan development and prioritisation to ensure actions address the needs of the patient
    - Improvement actions will be identified, rationalised & sense-checked via stakeholder engagement, review of contributing and interlinking factors (via SEIPS) and the hierarchy of intervention effectiveness, respectively. Additional tools to support improvement prioritisation and value assessment, such as iFACES, can be used at the discretion of the Learnings Response Lead.
3. Incident responses will be saved securely to support audit, response tracking and oversight to ensure a system-based approach is being taken.
    - PSIIs: The Learning Response Lead will complete the NHSE PSII template which will be securely saved on the Oviva shared drive for review and sign-off.
    - On incident response completion, key findings, improvement actions and priorities should be shared with key stakeholders to ensure transparency.

Appendix 1 - Harm definitions

No harm (two sub-categories):

- No harm (impact prevented) – Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care. This may be termed a 'near miss'.
- No harm (impact not prevented) - Any patient safety incident that ran to completion but no harm occurred to people receiving NHS funded care.

Low harm or loss

- Any unexpected or unintended incident that required or could have required (e.g. near miss) extra observation or minor treatment and caused minimal harm to one or more persons receiving NHS-funded care.

Moderate harm or loss

- Any unexpected or unintended incident that resulted or could have resulted in (e.g. near miss) in a moderate increase in treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.

Serious harm or significant loss

- Any unexpected or unintended incident that resulted in or could have resulted in (e.g. near miss) permanent harm to one or more persons.

Death

- Any unexpected or unintended incident that directly resulted in the death of one or more persons.

Appendix 2 - Related to Oviva care definitions

Not related: No relationship to the programme intervention or service found

Possible: The relationship with the programme intervention or service is weak but cannot be ruled out completely. Alternative causes are also possible (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment). Cases where relatedness cannot be assessed, or no information has been obtained should also be classified as possible.

Probable: The relationship with the programme intervention or service seems relevant and/or the event cannot be reasonably explained by another cause.

Causal relationship: the incident is associated with the programme intervention or service beyond reasonable doubt.