2022

Managing HSE National Patient Safety Alerts in your service: Guidance Document

QPSIM-PST 005

Contents

1. **Introduction** 2
2. **Key definition used** 3
3. **Acronyms used in this document** 3
4. **Purpose** 3
5. **Governance** 4
   5.1 - National Governance of HSE NPSAs 4
   Figure 1: HSE NPSA National Governance Structure 4
   5.2 - Local Governance of HSE NPSAs 4
6. **The HSE eAlert System** 5
   Figure 2: Closed Loop System 6
7. **Roles and Responsibilities** 6
   7.1 Role Descriptions for HSE National Patient Safety Alerts 7
   Figure 3. Communication flow chart for HSE NPSAs 7
   7.1.1 The role of the HSE NPSA Committee 8
   7.1.2 The role of the HSE NPSA Business Administrator 8
   7.1.3 The role of the HSE NPSA Co-ordinator 9
   7.1.4 The role of the HSE NPSA Officer 9
   7.1.5 The role of the HSE NPSA Responsible Person 10
   7.1.6 The role of the local Senior Accountable Officer 11
8 **Policies and Procedures linked to this guidance** 12
9 **References** 12
Appendix 1: Frequently Asked Questions 13
Appendix 2: Local NPSA Meeting Agenda 15
Appendix 3: New NPSA Response Form Template 16
Appendix 4: NPSA Quarterly Update Report Template 20
Appendix 5: NPSA Action Plan Template 22
Appendix 6: NPSA Selection and Inclusion Criteria 24
Appendix 7: Sample HSE NPSA 25
Appendix 8: Referral Template 27

DRAFT

Version Control

Doc Control	Date	Version	Created by	Reviewed By	Approved By
QPSIM-PST-005	November 2022	Version 1	PST Learning Team	Assistant National Director, QPSIM	Assistant National Director, QPSIM

1. Introduction

The vision of the HSE's Patient Safety Strategy[1] is that all patients will consistently receive the safest care possible and that patient safety is a key priority across our entire healthcare system. The majority of services provided by health and social care organisations within the HSE and its funded services are safe and result in good outcomes, both for those receiving and for those providing these services. Yet, healthcare is complex and sometimes, despite our best efforts, things can go wrong and patients may experience harm as a result.

The Quality and Patient Safety Incident Management Office (QPSIM) of the National Quality and Patient Safety Directorate (NQPSD) are actively working to embed a culture of learning across the healthcare system, and are supporting staff to identify, report, manage and learn from patient safety incidents as per the HSE's Incident Management Framework 2020[2]. Further resources to support staff manage and learn from patient safety incidents are available through the HSE Open Disclosure Policy 2019[3], the HSE's Just Culture Guide 2022[4]and An Introduction to Human Factors for Healthcare Workers 2021[5]. To support this priority, communication of critical safety information is facilitated through a National Quality and Patient Safety eAlert (QPS eAlert) system. This QPS eAlert system provides a means of disseminating HSE National Patient Safety Alerts (NPSAs) to named NPSA Officers in each service. NPSAs pertaining to services under the governance of the HSE's Chief Clinical Officer (CCO) are issued through this system.

As a closed loop system, named NPSA officers are required to disseminate NPSAs within their service and have a means of recording when necessary actions have been taken. In turn, the QPSIM will receive assurance through the eAlert system that each service has received and actioned the NPSA where applicable. A similar process is already in situ to disseminate medical device alerts and health and safety alerts using the same information and communications technology (ICT) system.

All NPSAs will also be available to all staff though the NQPSD sharing patient safety learning platform *Patient Safety Together: learning, sharing and improving* (Patient Safety Together). Patient Safety Together is a HSE patient safety platform developed in collaboration between multiple internal and external stakeholders who use and work in health services in Ireland. The platform is overseen by QPSIM and will provide up to date patient safety information for the purpose of sharing learning and

---

[1] Available at https://www.hse.ie/eng/about/who/nqpsd/patient-safety-strategy-2019-2024.pdf
[2] Available at https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/incident-management/hse-2020-incident-management-framework-guidance.pdf
[3] Available at https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/open-disclosure/hse-open-disclosure-full-policy.pdf
[4] Available at https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/just-culture-overview.pdf
[5] Available at https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/incident-management/a-guide-to-human-factors-in-healthcare-2021.pdf

DRAFT

supporting healthcare improvement. Through an agile and responsive approach, the platform will support collaboration to ensure that the information on the HSE NQPSD website is accurate, valid and informative.

2. Key definition used

HSE National Patient Safety Alerts

- HSE NPSAs are high priority communications in relation to patient safety issues, which requires HSE services and HSE funded agencies to take specific action(s) within an identified timeframe, in order to reduce the risk of occurrence or recurrence of patient safety incidents that have the potential to cause harm. HSE NPSAs are issued by the HSE in conjunction with relevant stakeholders (subject matter experts, patient representatives, clinical & academic experts).

3. Acronyms used in this document

BA – Business Administrator
CCO – Chief Clinical Officer
HSE – Health Service Executive
IMF – Incident Management Framework
NCD – National Clinical Director
NPSA – National Patient Safety Alert
NQPSD – National Quality and Patient Safety Directorate
PST- Patient Safety Together
QPS – Quality and Patient Safety
QPSIM – Quality and Patient Safety Incident Management Office
SAO – Senior Accountable Officer

4. Purpose

The purpose of this guidance document is to provide a practical support to assist HSE and HSE funded services to locally manage any HSE NPSA received.

A 'Frequently Asked Questions' section (Appendix 1) and some local resources to support the managing of HSE NPSAs at local level are included as appendices;

- Local NPSA Meeting Agenda (Appendix 2)
- New NPSA Response Form Template (Appendix 3)
- NPSA Quarterly Update Report Template (Appendix 4)
- NPSA Action Plan Template (Appendix 5)

DRAFT

The local resources are also available in word format on the Patient Safety Together website at https://healthservice.hse.ie/organisation/nqpsd/pst/

5. Governance

5.1 - National Governance of HSE NPSAs

Identification of potential learning content for HSE NPSAs will be supported through a QPSIM Learning Team. The QPSIM Learning Team will work with a multi-agency, multidisciplinary HSE NPSA Committee who will consult and advise on content, and engage Subject Matter Experts as required. A decision to proceed with developing a new HSE NPSA will be undertaken by the NPSA committee using the Selection and Inclusion criteria (Appendix 6). The HSE NPSA content will be developed using an agreed HSE NPSA template. An example of a HSE NPSA is included in Appendix 7. Initial review and sign-off of the content will be by the HSE NPSA Committee Chair/Co-Chair, followed by the NCD - NQPSD and finally from the CCO (Figure 1). Ownership of the HSE NPSA content remains with the CCO.

Figure 1: HSE NPSA National Governance Structure

QPSIM Learning Team
- Identify potential content
- Develop content into draft HSE NPSA on approval of NPSA Committee
- Coordiante content dissemiantion
- Content Quality Assurance

HSE NPSA Committee
-Consult on content
- Identify NPSAs for development and publication
- Provide specialist input
-Advise on content / dissemination route
-Test content locally
- Inital content sign-off

National Clinical Director- National Quality and Patient Safety Directorate
- Review
- Sign-off for dissemination and publication

Chief Clinical Officer
- Review
- Final Sign-off for dissemination and publication
- Ownership of Content

DRAFT

5.2 - Local Governance of HSE NPSAs

In line with the HSE's Performance and Accountability Framework (2020), Accountable Officers maintain the responsibility and accountability for managing the performance of the services they lead.

Therefore, oversight and management of HSE NPSAs should align with the local QPS Governance arrangements at service level. Applicable NPSA actions that cannot be implemented at local level should be included on the local Risk Register and managed accordingly.

6. The HSE eAlert System

The HSE eAlert system is a national 'closed loop' ICT system developed to manage HSE medical device, health and safety and national patient safety alerts pertaining to any of the locations within the HSE or HSE funded voluntary services. The eAlert system provides an easy and efficient method of monitoring the status of responses to issued alerts facilitating adherence to critical timelines via electronic reminders and alerts.

The benefits of the HSE eAlert system includes that it:

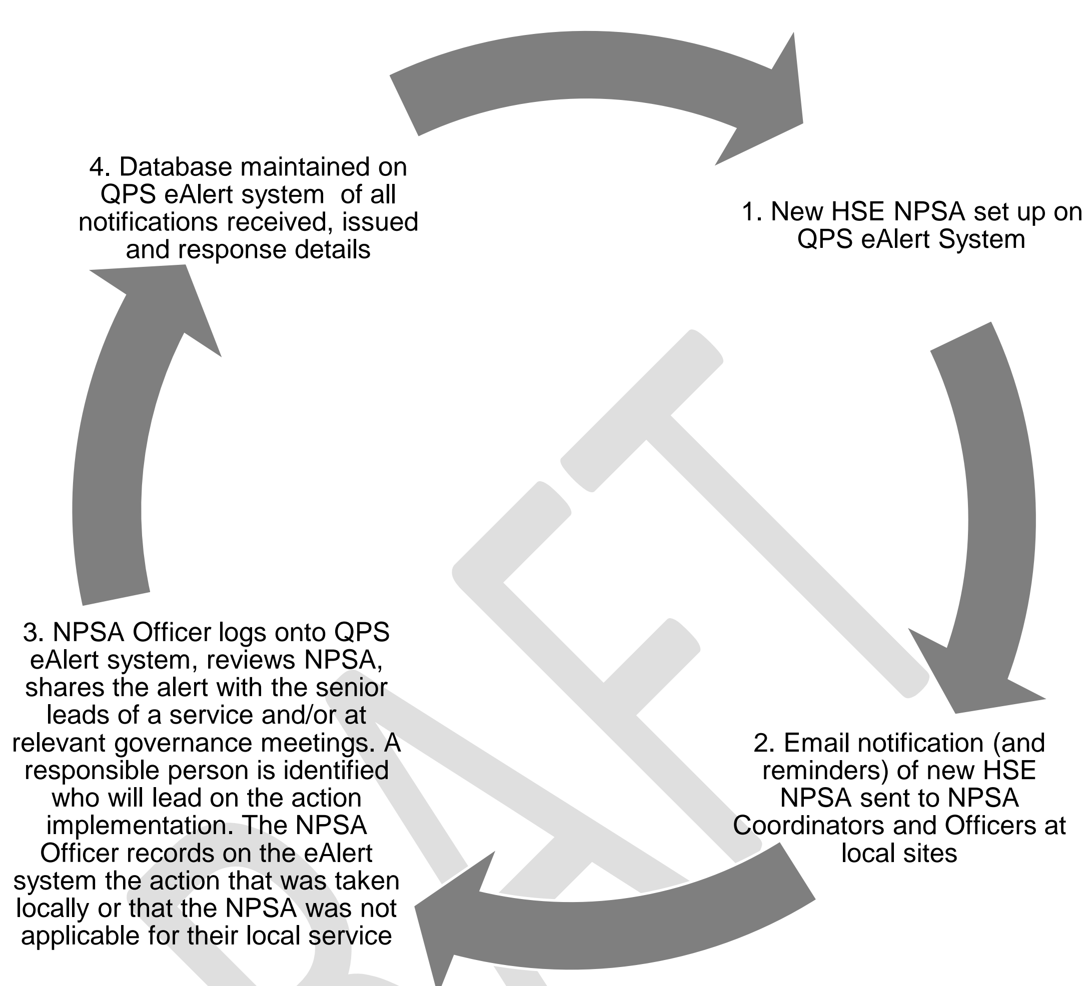
- Standardises processes for handling alerts issued within the HSE and HSE funded voluntary services
- Improves patient safety processes through the efficient handling of issued alerts
- Provides a central data repository from which statistical and management reports regarding alerts can be extracted

The QPS channel of the HSE eAlert system is used to facilitate the dissemination of HSE NPSAs which will be received by the local HSE NPSA officers (see section 6.1.3). Through the closed loop element, the HSE NPSA Officers can update the system with details of whether the NPSA was relevant to their service and/or if any NPSA actions have been completed. The notice is automatically closed on the national system when the NPSA Officer has completed the 'Response Details' screen and where notices are not closed an automatic reminder email is generated.

Local and corporate assurance that HSE NPSAs are being delivered to relevant services in a timely and standardised way is achieved through the "Closed Loop" communication system (Figure 2)

DRAFT

Figure 2: Closed Loop System



DRAFT

7. Roles and Responsibilities

HSE NPSAs will be developed and disseminated by the HSE NPSA Committee on authority of the CCO's office. However as per the HSE Performance and Accountability Framework (2020) the authority, responsibility and accountability for ensuring HSE NPSAs are acted upon and recommendations implemented where applicable remains with the appropriate accountable officer within each service through the operational line. The accountable officer has the responsibility to nominate a local staff member (HSE NPSA Co-ordinator) to oversee and coordinate the management of HSE NPSAs within their service.

The HSE NPSA Co-ordinator nominates HSE NPSA Officers within their service to receive, disseminate and track completion of actions of the safety information received in the HSE NPSA. This HSE NPSA Officer will have a responsibility to ensure that the communication reaches the most appropriate personnel within their organisation. QPSIM will seek and receive assurance on behalf of the CCO through the Quality and Patient Safety (QPS) eAlert system (See Section 5) that each service has

received and actioned the HSE NPSA where applicable. However, assurance that the issue outlined in the notice is considered, the risks assessed and the appropriate / recommended actions are completed remains with the senior accountable officer and the operational line of accountability of the service.

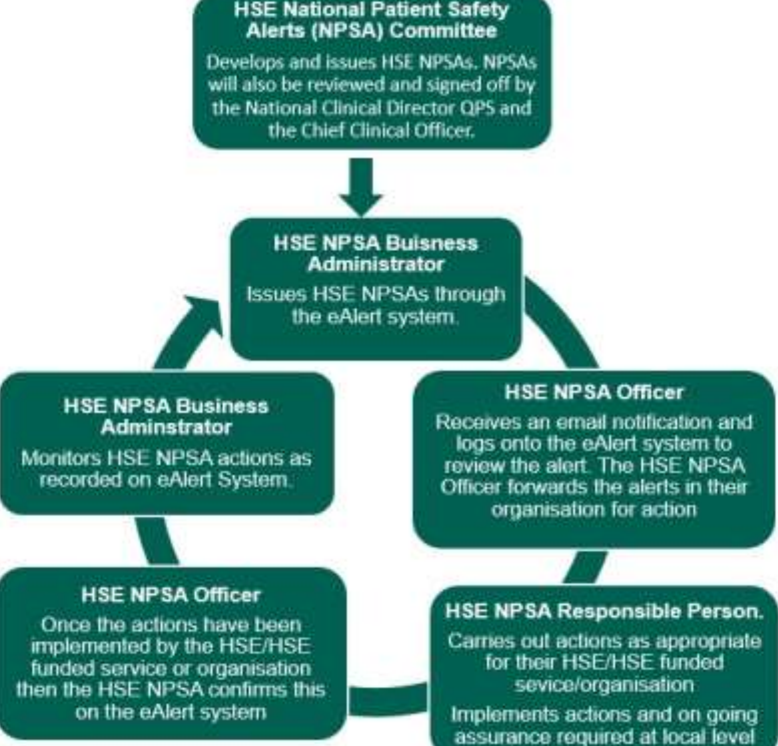
7.1 Role Descriptions for HSE National Patient Safety Alerts

The following section details the roles and responsibilities involved in the process of developing, disseminating and actioning HSE NPSAs. The six roles described are:

- 7.1.1 HSE NPSA Committee
- 7.1.2 HSE NPSA Business Administrator
- 7.1.3 Local HSE NPSA Co-ordinator
- 7.1.4 Local HSE NPSA Officer
- 7.1.5 Local HSE NPSA Responsible Person
- 7.1.6 Local Senior Accountable Officer

The communication flow pathway for HSE National Patient Safety Alerts is outlined in Figure 3

Figure 3. Communication flow chart for HSE NPSAs



7.1.1 The role of the HSE NPSA Committee

Under the governance of the CCO the role of the HSE NPSA Committee is to oversee the identification, development, publishing, dissemination and evaluation of critical safety information through HSE NPSAs and Patient Safety Supplements. These resources will be developed to support and improve patient safety within the HSE and its funded services by helping to reduce patient safety incidents and thus preventing patient harm.

Prior to publication all HSE NPSAs developed by the HSE NPSA Committee will be reviewed and approved by the National Clinical Director, National Quality and Patient Safety Directorate and the CCO.

7.1.2 The role of the HSE NPSA Business Administrator

The HSE NPSA Business Administrator (BA) is a national role and sits in QPSIM. The role of the HSE NPSA BA includes:

- to disseminate patient safety alerts via the QPS eAlert system on behalf of the HSE NPSA Committee.
  Patient Safety Alerts will be disseminated using the national eAlert ICT system.
- to monitor updates on the QPS eAlert system in relation to the completion of required actions.
  The eAlert system provides a facility for HSE NPSA Officers to record completion of actions relating to specific NPSAs.
- to ensure all new HSE NPSAs are entered on to Patient Safety Together; learning, sharing and improving.
  This online resource https://healthservice.hse.ie/organisation/nqpsd/pst/ *will act as a searchable repository for all HSE NPSAs issued*
- to manage change requests for the HSE NPSA eAlert system in conjunction with the overall BA for all HSE eAlerts
  Where feedback is received on the current functionality of the HSE eAlert system or where new change requests are submitted, the NPSA BA will maintain a log of requests and bring to the HSE eAlert BA for consideration for future development work.
- to validate the NPSA Officer list six-monthly with the local HSE NPSA Co-ordinator
  Local NPSA Officers lists are checked to ensure all details are correct including name and contact details and whether any changes over the previous six months have been updated
- to provide six monthly reports to NPSA Co-ordinators on the status of all NPSAs issued to their local services
  Six monthly reports detailing the status of all NPSAs issues to their services including details of all closed, due and pending NPSAs.

DRAFT

7.1.3 The role of the HSE NPSA Co-ordinator

The HSE NPSA Co-ordinator is identified for each Hospital Group and for each Community Healthcare Organisation. The role of the HSE NPSA Co-ordinator includes:

- to identify HSE National Patient Safety Alerts Officers for each service or location in their organisation
  The process of disseminating HSE NPSAs begins with a system generated e-mail to HSE NPSA Officers. The role of HSE NPSA officer is further described in the section 5.1.3.
- to provide a list of HSE NPSA Officers for their organisation to the HSE NPSA BA
  This list will include e-mail addresses. Every service or location must have an identified NPSA Officer. If deemed appropriate by the HSE NPSA Co-ordinator, an NPSA Officer may act for more than one service or location.*
- to update the NPSA BA if there is a change required to the NPSA Officer contact details for any service under their remit (e.g. following change of role of an Officer – retirement, resignation of post etc.)
- to validate their local NPSA officer list six monthly with the NPSA BA
- on receipt of the NPSA to update the QPS eAlert system that they have received the NPSA for information purposes

While HSE NPSA Co-ordinators do not have a role in disseminating individual NPSAs within their local service for action, they can forward the NPSA received to others for information purposes.

7.1.4 The role of the HSE NPSA Officer

*It is recommended that e-mail accounts that are monitored be included for HSE NPSA Officers. Where it is not possible to have a monitored e-mail account, local arrangements are recommended whereby cover is provided for planned and unexpected leave.

A nominated HSE NPSA Officer within each local service will take responsibility for the receipt of the NPSAs. The NPSA Officer will ensure the further internal facility distribution to the relevant responsible personnel for implementation of the recommended actions where applicable.

A HSE NPSA Officer is identified for each location or service. The role of the HSE NPSA Officer is three fold:

- to receive HSE National Patient Safety Alerts.
  The HSE NPSA Officer will be set up on and will receive an e-mail from the HSE NPSA eAlert system once a new HSE NPSA is issued. The HSE NPSA Officer will then log on to the QPS eAlert system to see the full detail of the new HSE NPSA.
- to review HSE National Patient Safety alerts and distribute the alerts within their area of responsibility.

DRAFT

Each new HSE NPSA will include details of staff roles for whom the HSE NPSA is relevant. The HSE NPSA Officer will review the new HSE NPSA and determine which staff within their area of responsibility should receive the HSE NPSA (these staff are known as HSE NPSA Responsible Persons – see section 6.1.5). Through the QPS eAlert system, the HSE NPSA Officer can then forward system generated e-mails to HSE NPSA responsible persons that may be required to take relevant actions.

- to update the QPS eAlert system as to the status of the HSE NPSA.
  Once HSE NPSA Responsible Persons have carried out actions or responded to the HSE NPSA Officer to indicate that no actions were required, or that the HSE NPSA is not relevant to their area, the HSE NPSA Officer will then update the QPS eAlert system to indicate that the HSE NPSA has been acted on. The HSE NPSA is deemed 'closed out' when all responsible persons in a specific service or location have responded as required to the HSE NPSA Officer

In the event that a HSE NPSA has not been closed off on the QPS eAlert system and the deadline has passed, the HSE NPSA Officer will receive automated reminders from the eAlert system.

7.1.5 The role of the HSE NPSA Responsible Person

The SAO (or designate) should nominate the HSE NPSA Responsible Person for each individual HSE NPSA Alert.

The HSE NPSA Responsible Person receives the HSE NPSA from the HSE NPSA Officer for their service. This role is not a fixed role as such and will depend on the content of the alert. It may be that an alert is issued in relation to the whole organisation, or is more specific and in relation to mental health or maternity care for example. It would then be appropriate then to nominate an NPSA Responsible Person who leads out on the specific service. A HSE NPSA Responsible Person may therefore not receive all NPSAs issued, but where a HSE NPSA is received they are required to respond to the HSE NPSA Officer for their service. The role of the HSE NPSA Responsible Person is:

- to review HSE NPSAs that are received and take action as appropriate.
  By reviewing the HSE NPSAs the HSE NPSA Responsible Person can make a decision on which course of action is the most appropriate:

  to inform the HSE NPSA Officer for their service that the HSE NPSA is not relevant to them

  or

  to inform the HSE NPSA Officer for their service that no action is required on their part

  or

  to take a specific action(s) as required.

DRAFT

- Where a specific action(s) has been taken, the HSE NPSA Responsible Person informs the HSE NPSA Officer that the actions required have been completed.

- Where possible, the NPSA Responsible Officer should build in on-going assurance of compliance with the alert.

7.1.6 The role of the local Senior Accountable Officer

As per the HSE Performance and Accountability Framework (2020) the authority, responsibility and accountability for ensuring HSE NPSAs are acted upon, and recommendations implemented where applicable remains with the SAO within each service through the operational line.

HSE NPSAs should be managed within the existing local QPS governance structure and the SAO should seek assurance that all HSE NPSAs issued have been actioned and closed out as appropriate. For the purpose of good governance, there should be robust mechanisms in place of being able to evidence that actions have been completed, closed and periodically reviewed for compliance purposes. Applicable HSE NPSAs that cannot be actioned locally should be managed as per the local Risk Register Process.

DRAFT

8 Policies and Procedures linked to this guidance

HSE Incident Management Framework 2020	https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/incident-management/hse-2020-incident-management-framework-guidance.pdf
HSE Just Culture Guide 2022	https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/just-culture-guide.pdf
An Introduction to Human Factors for Healthcare Workers 2021	https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/incident-management/a-guide-to-human-factors-in-healthcare-2021.pdf
HSE Patient Safety Strategy 2019-2024	https://www.hse.ie/eng/about/who/nqpsd/patient-safety-strategy-2019-2024.pdf
HSE Open Disclosure Policy 2019	https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/open-disclosure/hse-open-disclosure-full-policy.pdf
HSE Performance and Accountability Framework 2020	https://www.hse.ie/eng/services/publications/serviceplans/service-plan-2020/performance-and-accountability-framework-2020.pdf

9 References

1. Health Service Executive (2021) *An Introduction to Human Factors for Healthcare Workers.* Available at: https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/incident-management/hse-2020-incident-management-framework-guidance.pdf
2. Health Service Executive (2020) *Incident Management Framework.* Available at: https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/incident-management/hse-2020-incident-management-framework-guidance.pdf
3. Health Service Executive (2019) *Open Disclosure Policy*. Available at: https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/open-disclosure/hse-open-disclosure-full-policy.pdf
4. Health Service Executive (2019) *Patient Safety Strategy 2019-2024* Available at: https://www.hse.ie/eng/about/who/nqpsd/patient-safety-strategy-2019-2024.pdf
5. Health Service Executive (2020) *Performance and Accountability Framework*. Available at: https://www.hse.ie/eng/services/publications/serviceplans/service-plan-2020/performance-and-accountability-framework-2020.pdf
6. Health Service Executive (2022) *The Development of a Just Culture Guide in the HSE.* Available at: https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/just-culture-overview.pdf

DRAFT

Appendix 1: Frequently Asked Questions

Q1. What is the HSE QPS eAlert system?

The HSE QPS eAlert system disseminates published HSE NPSAs via on online platform on the HSE server to identified HSE NPSA Coordinators and NPSA Officers within each local service.

Q2. Who can be set up on the HSE QPS eAlert system?

Nominated HSE NPSA Coordinators and HSE NPSA Officers will be set up on the QPS eAlert System. All requests to be set up on the HSE QPS eAlert system should be sent vis the local HSE NPSA Coordinator to patientsafetytogether@hse.ie

Q3. How do I get set up on the QPS eAlert system?

HSE NPSA Coordinators send contact details of both HSE NPSA Coordinators and NPSA Officers to the HSE NPSA Business Administrator (BA) at patientsafetytogether@hse.ie The contact details should include, name, email address, service and the geographical area the NPSA Coordinator or NPSA Officer is covering. The NPSA Coordinator and NPSA Officers will then be set up on the QPS eAlert system by the HSE NPSA BA. HSE NPSA Coordinators and NPSA Officers will subsequently be issued a personalised user name and password by email.

Q4. How do I access the QPS eAlert system?

There are two ways you can access the HSE QPS eAlert system

1. You can access the system via an embedded link on the email you will receive with your user name and password. Once you click on the embedded link, save the page as a bookmark/favourite on your preferred website search engine (e.g. Google Chrome)
2. You can also access the system via an embedded link on the email you will receive notifying you of the issuing of a new HSE NPSA.

Q5. Who will receive HSE NPSAs?

HSE NPSAs will be issued to the HSE NPSA Officer in HSE and HSE funded services via the QPS eAlert system. However all published HSE NPSAs will also be freely available to access and download on https://healthservice.hse.ie/organisation/nqpsd/pst/

Q6. What happens if the HSE NPSA Officer is on leave?

Patientsafetytogether@hse.ie will receive an out of office response if any NPSA Officer has an "out of office" email set up. To guarantee that the local service receives the NPSA, the Patient Safety Together Learning Team will inform the local HSE NPSA Coordinator of receipt of the 'out of office'.

Q7. How will Section 38's and 39's be set up on the system?

Only organisations with a license to access the HSE Network can be set up on the HSE eAlert system. For more information, contact patientsafetytogether@hse.ie

DRAFT

Q8. When will HSE NPSAs be published?

HSE NPSAs will be issued for addressing critical patient safety issues once they have fulfilled the NPSA Committee selection and inclusion criteria for publication. Learning may also be shared through Patient Safety Supplements or Learning Notices via the Patient Safety Together website on https://healthservice.hse.ie/organisation/nqpsd/pst/

Q9. Can the QPS eAlert be forwarded to people not set up on the system?

Yes, it is possible for HSE NPSA coordinator or Officer to forward any HSE NPSA via e-mail from the QPS eAlert system to any e-mail address (including non HSE addresses) via the 'Forward' function.

Q10. Is there a limit to the number of "Forwarding Groups" or to the number of members within each Forwarding Group that can be set up on the QPS eAlert system?

No, there is no limit.

Q11. How long will local services have to implement actions defined in the HSE NPSA?

The priority level of the HSE NPSA will be decided by the HSE NPSA Committee and will dictate the deadline date for completion of actions. The specific deadline date will be clearly indicated on each individual HSE NPSA. Actions associated with a Priority 1 alert may need to be implemented within weeks, whereas actions associated with a Priority 3 alert may have months to be completed.

Q12. What should be done if there are actions from a HSE NPSA that cannot be implemented?

HSE NPSA Officers update the QPS eAlert system to indicate that actions have been implemented **OR** that the alert was not applicable to their services. Applicable HSE NPSAs that cannot be implemented should be monitored on the local Risk Register.

Q13. Will the NPSA Coordinator know how services under their remit are performing?

The HSE NPSA BA will forward a quarterly report to all HSE NPSA Coordinators for their area detailing the number of NPSAs issued, how many were closed on time, how many are overdue etc.

Q14. Can local services highlight patient safety issues to the HSE NPSA Committee for consideration as development as a HSE NPSA or Patient Safety Supplement?

Yes, local services can forward their suggestions to the HSE NPSA committee via patientsafetytogether@hse.ie via the approved referral template (see Appendix 8). Please ensure the local/executive QPS Governance committee (or equivalent) has been informed that the referral has been sent.

Q15. Can I provide feedback on the QPS eAlert system or any HSE NPSA received?

Yes, any feedback is welcome and can be send to the Patient Safety Together Learning Team at patientsafetytogether@hse.ie

DRAFT

Appendix 2: Local NPSA Meeting Agenda

SAMPLE HSE NATIONAL PATIENT SAFETY ALERTS MEETING AGENDA

Frequency of meeting; [Weekly /Fortnightly /Monthly - Delete as appropriate]

1) Apologies

2) Actions from last meeting:

3) New Alerts since last meeting:
    - Alert Title / Reference / Deadline / Action Required / Plan / Responsible Person

4) Overdue alerts
    - Alert Title / Reference / Deadline / Action Required / Update / Responsible Person

5) Alerts due for closure in the next month
    - Alert Title / Reference / Deadline / Action Required / Update / Responsible Person

6) Alerts for escalation:
    - Alert Title / Reference / Deadline / Action Required / Update / Why alert is being escalated / Who alert is being escalated to

7) Any other business

8) Date of next meeting:

DRAFT

Appendix 3: New NPSA Response Form Template

HSE NATIONAL PATIENT SAFETY ALERT RESPONSE FORM

Local Service: ______________________ HSE NPSA Officer: ___________________

Local Responsible Person: ______________________

<table>
<tr><th colspan="4">Notification:</th></tr>
<tr><td>HSE NPSA Title:</td><td></td><td>HSE NPSA Reference number:</td><td></td></tr>
<tr><td>Date HSE NPSA issued</td><td></td><td rowspan="5">Area(s) / Speciality(ies) HSE NPSA applies to (list all)
e.g. Obstetric Services, Stores, Pharmacy</td><td rowspan="5"></td></tr>
<tr><td>HSE NPSA Priority</td><td></td></tr>
<tr><td>Alert Deadline</td><td></td></tr>
<tr><td>Date HSE NPSA closed on QPS e-Alert system</td><td></td></tr>
<tr><td>Date HSE NPSA notified to local QPS Committee</td><td></td></tr>
<tr><td rowspan="4">Team/Individual HSE NPSA forwarded to for follow-up</td><td></td><td rowspan="4">Date</td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
</table>

Service Response					
Action Number	**Requirements**	**Statement of Compliance [Provide evidence where required]** (What has been done?) Or **Reason for Non-Compliance**	**Responsible Person(s)** (By Whom?)	**Completion Date**	**Assurance Compliance Yes/No** (If no, complete action plan below)
1.					
2.					

Where the HSE NPSA requires an action plan to be developed this action plan must be added below and monitored until completion of all actions.

Action plan required to complete compliance Where no compliance, fill in action plan below						
Action Plan required as part of alert which requires on-going monitoring:		**YES**	**NO**			
Action Number	**Requirements**	**Action (SMART)**	**Responsible Person(s)**	**Due Date**	**Completion Date**	**Evidence**
1.						
2.						
3.						.
4.						
5.						

DRAFT

Assurance Sign-off by Department	
Name	
Title	
Date	
Further recommendations	

Final Sign-off from Clinical Director (or Designate)	
Name	
Title	
Date	
Further recommendations	

Risk Management	
Was HSE NPSA notified to Risk Department:	
If Yes:	
Date of notification to Risk Department	
Who was HSE NPSA notified to?	
Is HSE NPSA included on Risk Register?	
If Yes: Please include Risk Register reference number.	
If No:	
Why?	

Ongoing Monitoring	
Does the HSE NPSA require ongoing monitoring?	Yes/No

DRAFT

If yes, please indicate if an audit or review will be undertaken?	
Sign off by relevant governance committee	Yes/No
If Yes: Please include name of committee	
Date signed off	

Appendix 4: NPSA Quarterly Update Report Template

Subject: HSE National Patient Safety Alert (NPSA) Updates

Report to: [Senior Accountable Officer / Clinical Director / Local Quality & Safety Committee (or equivalent)]

Timeframe: [Q1/Q2/Q3/Q4 Year]

Date:

Service Name:

Completed By:

1. Background

HSE NPSAs are high priority communications in relation to patient safety issues, which requires HSE services and HSE funded agencies to take specific action(s) within an identified timeframe, in order to reduce the risk of occurrence or recurrence of patient safety incidents that have the potential to cause harm. HSE NPSAs are issued by the HSE in conjunction with relevant stakeholders (subject matter experts, patient representatives, clinical and academic experts)

HSE NPSAs are disseminated to each service through the HSE QPS e-Alert System through HSE NPSA Officers. HSE NPSA will also be freely available to access and download through the online resource Patient Safety Together: learning, sharing and improving.

Each HSE and HSE funded service take the following steps:

1. Through the e-Alert system the HSE NPSA Officer acknowledges receipt of the alerts and signs off as required.
2. Disseminates the alerts within their service and monitors progress against completion
3. Records evidence of completion on an internal database (optional)

Overdue HSE NPSAs should receive internal oversight and management through local Quality and Safety Committee's (or equivalent) and as escalated as appropriate. It is essential that all areas respond appropriately and within the set timescales to HSE NPSAs.

2. HSE National Patient Safety Alerts Issued

During [Insert time frame] there were [insert no.] of HSE NPSAs issued

DRAFT

Number of HSE NPSAs closed:

Number of HSE NPSAs overdue for closure (see section 3):

Number of HSE NPSAs actions included on Risk Register (see section 4):

List of HSE NPSAs issued during [insert time frame here] including priority ranking, dates of issue, due date for completion and progress status:

Title of HSE NPSA	Priority ranking	Date of issue	Due date for completion	Progress status (open, closed)

3. HSE National Patient Safety Alerts Status

There are currently [insert number] open HSE NPSAs overdue.

Where overdue closure of HSE NPSAs exist within the service please give details here of reasons for delay, outstanding actions and current progress.

HSE NPSA reference	HSE NPSA title	Issue date	Deadline	Reason for delay in closure	Outstanding action	Progress	Estimated date of closure

4. HSE National Patient Safety Alerts monitored through the Risk Register

Where an action plan is in place to address HSE NPSAs recommendations but the deadline for the alert has expired, the action plan is tracked via the risk register.

Give details here of HSE NPSAs included on the Risk Register

Title of HSE NPSA	HSE NPSA recommendations	Risk Register reference number	Date added to Risk Register	Risk rating applied

DRAFT

Appendix 5: NPSA Action Plan Template

HSE National Patient Safety Alert (NPSA) Action Plan Template

Local Service:			
HSE NPSA Officer		**HSE Responsible Person**	
HSE NPSA Title:		**HSE NPSA Reference number:**	
Date HSE NPSA issued		**Area(s) / Speciality(ies) HSE NPSA applies to (list all) e.g. Obstetric Services, Stores, Pharmacy**	
HSE NPSA Priority			
HSE NPSA Deadline			
Date HSE NPSA closed on QPS e-Alert system			
Date HSE NPSA notified to local QPS Committee			

****Where the HSE NPSA requires an action please complete the following table and monitor at QPS committee until completion of all actions****

	Action Required	i) Evidence for compliance or ii) Reason(s) for non-compliance	Responsible person(s)	Completion date	How was change communicated to relevant stakeholders?
1.					
2.					
3.					.

4.					
5.					

Governance and Assurance sign-off	Outcome	Further recommendations	Date Completed and Signed Off
Local Quality & Patient Safety Committee			
Additional Committee oversight/lead (Medication Safety, Occupational Safety, etc.) Include Local and Regional Committees			
Has this HSE NPSA been added to a Risk Register?	Yes □	No □	
If Yes; please give details	Local Risk Register Yes □ Reference No: ____________________ Risk Rating: ___________ Area Risk Register Yes □ Reference No: ____________________ Risk Rating: ___________		

Closed Out – Date: ____

Signed: ____

Role: ____

DRAFT

Appendix 6: NPSA Selection and Inclusion Criteria

HSE National Patient Safety Alerts (NPSAs) are only to be issued when there is an identified and specific patient safety issue that without action being taken would cause harm or death. Before publication of a HSE NPSA by the HSE NPSA committee the following criteria must be met.
HSE NPSAs;

- Are only issued for new or under-recognised patient safety-critical issues (risk of harm, disability or death)
- Have been developed in consultation with the appropriate stakeholders both internal and external to the HSE
- Are within the authority of the CCO to publish
- Have an identified target audience
- Require target healthcare organisation / service to take an identified action
- Are within the control of the target recipient to action
- Fulfil the identified governance arrangements for developing and issuing of HSE National Patient Safety Alerts through the HSE NPSA committee
- Have a process available to respond to questions, concerns or requests for clarification after publication
- Have been properly catalogued. Documentation needs to be logged documenting supporting evidence, timelines, decision making processes and that correct procedures were followed in its identification and development. These records would be required if, for example, a manufacturer legally challenged the issuing of the HSE NPSA, or there was public concern on the timeliness of the response.

DRAFT

Appendix 7: Sample HSE NPSA

HSE National Patient Safety Alert

Date of Issue: **26 Sept 2022**

Unique ID: HSENPSA 0001/2022

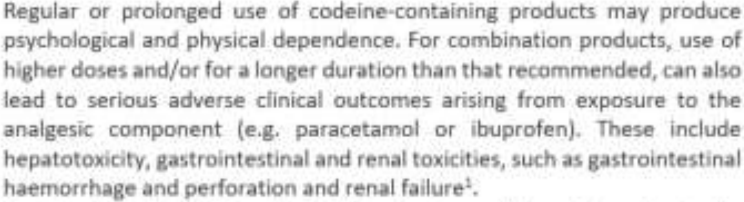
PRIORITY 2 –Warning

Risk of Harm from Codeine-Containing Products

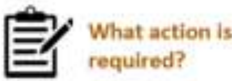
Who needs to take action on this safety issue?

This HSE National Patient Safety Alert (NPSA) is for action by all Health Service personnel involved in caring for patients suspected to have experienced harm arising from dependence on codeine-containing products, including toxicities associated with the analgesic component of combination products.

What is the safety issue?

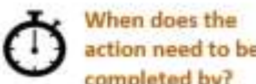


Regular or prolonged use of codeine-containing products may produce psychological and physical dependence. For combination products, use of higher doses and/or for a longer duration than that recommended, can also lead to serious adverse clinical outcomes arising from exposure to the analgesic component (e.g. paracetamol or ibuprofen). These include hepatotoxicity, gastrointestinal and renal toxicities, such as gastrointestinal haemorrhage and perforation and renal failure[1].



1. Circulate this NPSA to all clinical staff who provide care for patients who may be impacted by the use of codeine-containing products, particularly in the specialities of Gastroenterology, Nephrology, Gynaecology, General Practice, Pharmacy and Psychiatry and Addiction Services.

2. Staff should report cases of suspected harm (past or current) **to the Health Products Regulatory Authority (HPRA) via the HPRA's online adverse reaction report form available at:** *https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form* or by phone on 01 676 4971.
   - It is not necessary to complete all fields of the online form, however, as much information as is known should be provided. Include the brand name(s) of the suspect medicine(s), or if unknown, state all active ingredient(s) (e.g. ibuprofen codeine combination product). Provide a summary of available information on the circumstances of use (e.g. if use was prescribed and/or accessed over the counter 'OTC', duration and quantity), details of any suspected dependence or misuse, and any associated suspected reactions (i.e. adverse clinical outcomes).



Please circulate this HSE NPSA to relevant staff by 21 Oct 2022.

Why is this action required?

The HPRA are the competent authority in Ireland for pharmacovigilance and operate a system through which suspected adverse reactions can be reported by health care professionals. A small number of cases describing significant harm relating to the analgesic component of codeine-containing combination products, in the context of dependency to codeine, have recently been reported to the HPRA via the national adverse reaction reporting system. As the system is voluntary, there may be under-reporting of such cases. The HPRA are therefore encouraging reporting of any similar cases that you may be aware of for pharmacovigilance monitoring purposes.

HSE National Patient Safety Alert

Date of Issue: 26 Sept 2022

Unique ID: HSENPSA 0001/2022

PRIORITY 2 –Warning

Risk of Harm from Codeine-Containing Products

What evidence supports the issuing of this HSE NPSA?

Available data suggest regular usage of codeine-containing products in Ireland, including those available 'over-the-counter'.[1,2,3,4] Given the known risk of dependence as well as the potential for harm associated with the additional analgesic component in combination products (e.g. paracetamol or ibuprofen), it is important that relevant cases are reported to the HPRA.

The devastating personal impact of dependency cannot be overstated as is outlined in a recently reported Irish example[5], and a lived experience report on codeine dependency[6].

What stakeholders were involved in issuing this HSE NPSA?

A coordinated approach was undertaken to endorse reporting of relevant data to the HPRA to inform pharmacovigilance monitoring and risk management on this patient safety issue.

This alert has been developed collaboratively by the following groups:

- National Quality and Patient Safety Directorate, HSE
- National Clinical Advisors and Group Leads (NCAGL), HSE
- HSE Addiction Services
- Irish Medication Safety Network
- Health Products Regulatory Authority (HPRA)
- National Patient Safety Office (NPSO), Department of Health

Where can I get further information?

For queries on patient safety alerts in general please email patientsafetytogether@hse.ie

For any queries on reporting to the HPRA or to discuss any other potentially relevant data sources with the HPRA, please contact medsafety@hpra.ie

References

1. Carney et al., 2018. "A comparative analysis of pharmacists' perspectives on codeine use and misuse – a three country survey." Substance Abuse Treatment, Prevention, and Policy, 13 (12). https://doi.org/10.1186/s13011-018-0149-2
2. "Rates of reported codeine-related poisonings and codeine prescribing following new national guidance in Ireland" https://www.drugsandalcohol.ie/30636/
3. "Non-Prescription Medicinal Products containing Codeine: Guidance for pharmacists on safe supply to patients." PSI guidance document Version 4 2019.
4. Richards, et al., 2022. "Sales of Over-the-Counter Products Containing Codeine in 31 Countries, 2013-2019: A Retrospective Observational Study." Drug safety, 45(3) 237-247. https://doi.org/10.1007/s40264-021-01143-2
5. https://www.rte.ie/news/ireland/2022/0203/1277601-mother-medication-addiction/
6. Van Hout et al., 2018. "'Codeine is my companion': Misuse and dependence on codeine containing medicines in Ireland." Irish Journal of Psychological Medicine, 35(4), 275-288. https://doi.org/10.1017/ipm.2015.60

Appendix 8: Referral Template

Referral to Patient Safety Together Learning Team

**Please use this referral form to send patient safety learning suggestions to the Patient Safety Together (PST) Learning Team for consideration to develop and publish for sharing.

- Referred from: [insert name] on behalf of [insert team/service/committee]
- Referral Category:
    - Potential for National Patient Safety Alert □
    - Potential for Safety Supplement □
    - Potential for Patient/Service User or Staff Story □
    - Upcoming QPS Event □
    - QPS Journal Article □
    - Other □
- Detail:

____

____

____

____

____

- Please include evidence (National and International) to support:
  [Validated Data / Journal articles / Policy / Case Reviews etc.]

____

____

____

____

- Please include evidence for any actions or recommendations that are to be included:

____

____

____

____

The [insert Line Manager / QPS Governance Team] have been informed and consent for this referral to be forwarded to the PST Learning Team for further consideration, and if accepted to be disseminated nationally via the PST website and/or the HSE QPS eAlert system **Yes** □

Signature of Line Manager (General Manager or above) / QPS Lead (or designate)

____

Date Approval Given: ______________________________

Signed: ____________________ Date: ________________

DRAFT