A Guide for Family Practitioner Staff

- **General Medical Practices**
- **General Dental Practices**
- **General Ophthalmic Practices**
- **Community Pharmacies**

Reference Guide for FPS Practitioners regarding the Reporting of Adverse Incidents and Serious Adverse Incidents

Directorate of Integrate Care, HSCB

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1.0 Context

A true safety culture is one in which every person in the organisation recognises their responsibilities for patient safety and works to improve the care that they deliver; this is the essence of clinical governance. There is also a recognition that mistakes and incidents will happen and that healthcare is not without its risks. Evidence shows that if the culture of the organisation is safety conscious and people are encouraged to speak up about mistakes and incidents, then patient safety and care is improved.

2.0 Responsibilities of the HSCB in relation to Serious Adverse Incident (SAI) Reporting

The responsibility for the reporting and management of SAIs was devolved to the HSCB from the DoH in May 2010.
Under the revised HSC-wide SAI procedure introduced in October 2013, the HSCB has a number of responsibilities to fulfil including to:

- Promote the reporting and management of incidents
- Ensure investigation of such incidents using a method proportionate to the incident
- Ensure investigation report is completed in a timeframe appropriate to the incident
- Ensure that relevant parties are informed at all stages of the incident, investigation and follow-up
- Identify and ensure implementation of regional / local recommendations from adverse incidents / near misses
- Hold organisations to account
- Provide assurance to the DoH that requirements are being met

The reporting of SAIs to the HSCB works in conjunction with, and in some circumstances informs, the reporting requirements of other statutory agencies and external bodies (e.g. Professional Regulators, PSNI and Coroner). In that regard, all existing local or national reporting arrangements where there are statutory or mandatory reporting obligations continue to operate in tandem.

As a Primary Care Contractor, practices and their staff are well placed to assist in the management of SAIs, especially in terms of user / family engagement as they have:

- Knowledge of the patient / family
- Clinical information / records

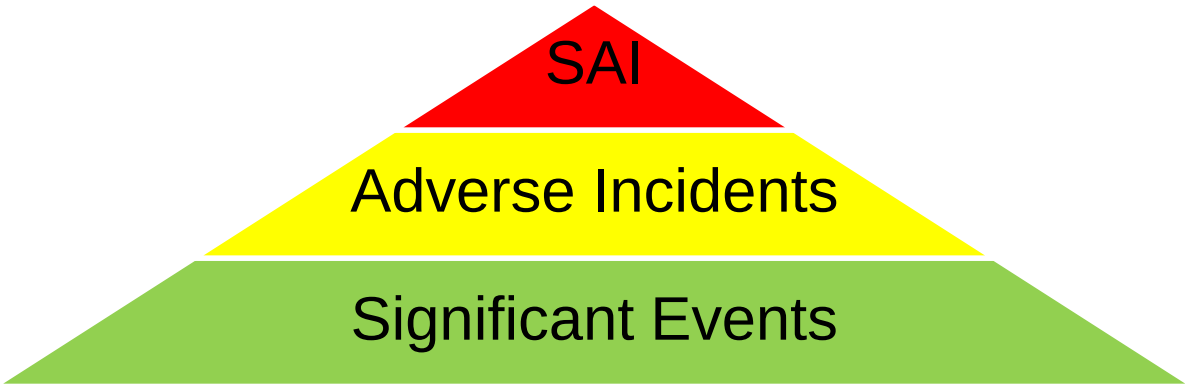
- The ability to respond to direct questions regarding clinical care
- A potentially reassuring presence for patient / family in times of difficulty / distress.

3.0 Overview of Event and Incident Reporting

Within Primary Care three levels of events occur: Significant Events, Adverse Incidents (AI) and Serious Adverse Incidents.

However it should be noted that while the term 'Significant Events' is commonplace within General Medical Practice, this does not tend to be the case within the other Primary Care services. Please refer to the definitions in Sections 4.0 for further information.

SAIs are a very small subset of Adverse Incidents which in turn are a subset of Significant Events.



Practices do not need to decide whether or not an incident meets the SAI criteria as onward notification, where appropriate, will be undertaken by a Board Officer.

Where incidents are assessed as being serious, the HSC wide Procedure for the Reporting and Follow Up of Serious Adverse Incidents is instigated. This has been in operation since October 2013. http://www.hscboard.hscni.net/publications/Policies/index.html#P-1_0

In addition to the SAI Procedure, and following a number of high profile cases which were reported in the media, a further document, 'A Guide for Health and Social Care Staff – Engagement / Communication with the Service User / Family / Carers Following a Serious Adviser Incident (January 2015) has been developed for use across the wider HSC. This can be accessed for reference purposes at the following links:

- **GMS:** http://primarycare.hscni.net/risk_management.htm
- **GDS:**http://www.hscbusiness.hscni.net/pdf/Guidance_on_communication_following_a_Serious_Adverse_Incident_23.02.15.pdf
- **GOS:**http://www.hscbusiness.hscni.net/pdf/Guidance_on_communication_following_a_Serious_Adverse_Incident_23.02.15.pdf
- **CP:** http://www.hscbusiness.hscni.net/services/2632.htm

However, given the unique position of FPS within the HSC, bespoke guidance has been developed specifically to assist FPS Contractors and Directorate of Integrated Care (DOIC) staff who assist in the investigation and management of SAIs within Primary Care and in particular regarding the family / user / carer elements of the SAI process. This can be accessed at:
http://primarycare.hscni.net/risk_management.htm

4.0 Definitions

4.1 What is a Significant Event?

Significant Event Review is a recognised methodology for reflecting on important events usually within general medical practices. It involves the discussion of cases and events and the learning obtained through reflection and is an extension of audit activity. For it to be effective, it needs to be practised in a culture that avoids allocating blame and involve all staff disciplines within the practice.

4.2 What is an Adverse Incident?

The definition of an AI is broad:
"any event or circumstance that could have or did lead to harm, loss or damage to people, property, environment or reputation."

Other terminology such as Patient Safety Incident, No Harm Event, Near Miss, Harm Events and Medication Errors may all be used to describe an adverse incident. Please refer to Appendix 1 for further definition of these terms.

4.3 What is the difference between a Significant Event and an Adverse Incident?

The simple answer is not a lot perhaps, as both are “significant” events. It is not an exact science, but an AI has the potential for implications beyond the practice, and/or wider learning for others.

Adverse Incident reporting is an important part of risk management within the clinical governance framework.

4.4 What is an SAI?

To be regarded as an SAI, an adverse incident must meet 1 or more of 6 criteria including, for example:

- Serious injury to, or the unexpected/unexplained death of:
  - a service user (including a Looked After Child or a child whose name is on the Child Protection Register and those events which should be reviewed through a significant event audit)
  - a staff member in the course of their work
  - a member of the public whilst visiting a HSC facility

- Unexpected serious risk to a service user and/or staff member and/or member of the public

- Unexpected or significant threat to provide service and/or maintain business continuity

- Serious self-harm or serious assault (*including attempted suicide, homicide and sexual assaults*) by a service user, a member of staff or a member of the public within any healthcare facility providing a commissioned service

- Serious self-harm or serious assault *(including homicide and sexual assaults*)
  - on other service users,
  - on staff or
  - on members of the public

by a service user in the community who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and known to/referred to mental health and related services *(including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident;

- Suspected suicide of a service user who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and known to/referred to mental health and related services *(including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident;

- Serious incidents of public interest or concern relating to:
  any of the criteria above
  - theft, fraud, information breaches or data losses
  - a member of HSC staff or independent practitioner.

5.0 What sorts of Incidents are deemed to be SAIs within FPS?

Below is a non-exhaustive list of some examples of SAIs that have been investigated to date:

- Prescription Fraud: Member of staff printed prescriptions in a number of separate patients' names, leaving for GP to sign, removed from Practice once signed & dispensed by pharmacy.

- Practice unaware that one of its patients had been in prison. A partner or relative of the patient was continuing to request medication - diazepam and pregabalin on his behalf over a 3 month period

- Member of staff obtained strong analgesics and CDs for her own use by fraudulently registering as a temporary resident and then deleting the scripts

- Sudden death on practice premises

- Patient was prescribed Depixol instead of clopixol, largely due to incorrect information having been passed from the Trust's psychiatric nurse to the patient's GP in the absence of a discharge summary.

- Information / data breaches containing identifiable patient information, accessible to external parties

- Dispensing error - Propranolol dispensed by community pharmacy instead of Prednisolone. Patient collapsed a few hours later at home and was deceased on arrival at hospital.

- Near Miss – Patient's medications were not checked properly prior to discharge. New diagnosis of AF. Aspirin should have been stopped when Clexane and Warfarin were started. All the internal checks had been carried out within the Health Centre and the appropriate action taken. It was the action of clinicians within the Health Centre that prevented the patient from taking the wrongly dispensed medication.

- Endodontic File Ingested By Patient - operator did not use appropriate securement devices while undertaking endodontic treatment

6.0 What is expected of a Practice/Pharmacy when it is notified of an SAI by the HSCB?

- Acknowledgement of the incident to the service user
- Involvement in investigation
- Writing / contributing to report
- Liaising with service user / family / carer and other agencies / bodies as appropriate. The practice/pharmacy needs to complete a checklist and return a checklist to the HSCB around this part of the SAI process (see App X)
- Identifying any local or regional actions / recommendations and implementing these in the practice / pharmacy

7.0 Why Report?

Practices are encouraged to report adverse incidents in order to:

- Alert the system so that any necessary, immediate action can be taken
- To allow others to learn from these incidents, share knowledge across practices and prevent reoccurrence.

8.0 How Do I Report?

The Adverse Incident reporting system is the same for all Family Practitioner Services

Complete an AI form (AIF1 Form) by using the following links:

- GMS: http://primarycare.hscni.net/risk_management.htm
- GDS: http://www.hscbusiness.hscni.net/services/2631.htm
- GOS: http://www.hscbusiness.hscni.net/services/2563.htm
- CP: http://www.hscbusiness.hscni.net/services/2632.htm

Email to your local office using the appropriate email address.

Remember: Practices do not need to decide whether or not an incident meets the SAI criteria as onward notification, where appropriate, will be undertaken by a Board Officer. Where an incident is confirmed as an SAI, the local office will advise the practice of such and the level at which the incident will be reviewed and managed. The practice will also be advised what further input / participation will be required among the parties / organisations involved in the incident. This may include for example the local Trust, Out of Hours Services or a community pharmacy.

9.0 Learning from Incidents

A key part of achieving robust clinical governance is recognising that it is not always possible to achieve the perfect clinical outcome and that lessons learned are an important and an integral part of a continuous programme for quality improvement.

The purpose is to learn from these incidents, share knowledge across practices and to prevent recurrence.

10.0 How is Learning Disseminated?

It is acknowledged that FPS practices will already have mechanisms in place for cascading local learning from AIs / SAIs internally within their own organisations. This should run in parallel with the dissemination of any regional learning.

Additionally, the HSCB, in conjunction with the PHA:

- Ensures that themes and learning from SAIs are identified and disseminated for implementation via:
    - Newsletters and professional letters – examples can be accessed at: http://primarycare.hscni.net/gms_newsletter_main.htm

http://primarycare.hscni.net/PharmMM_newsletters.htm
http://primarycare.hscni.net/optometry_update.htm
http://www.hscboard.hscni.net/publications/Learning%20Matters/index.html#P-1_0
http://www.hscbusiness.hscni.net/services/2670.htm
http://www.medicinesgovernance.hscni.net/primary-care/

- Learning letters and Best Practice Reminders – examples can be accessed at: http://primarycare.hscni.net/PMM_Learning_Letters.htm

- Thematic Reviews - these can be accessed at: http://intranet.hscb.hscni.net/documents/Governance/Information%20for%20DROs/index.html#P-1_0

  Please contact your local HSCB office for copies of the above documents if you are unable to access the website

- Seeks assurances from organisations and service providers that learning from SAIs has been disseminated and appropriate action taken by all relevant organisations

- Reviews and considers learning from external / independent reports relating to quality

Appendix 1: Other Terminology Which Falls Under the Adverse Incident Banner

Patient Safety Incident
The National Patient Safety Agency (NPSA) defines a **patient safety incident** as:
'Any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS funded healthcare'.
The term 'patient safety incident' is used to describe 'adverse incidents /events' or 'clinical errors', 'no harm events' and 'near misses'.

No Harm Event:
'A patient safety incident that caused no harm but was not prevented or a patient safety incident that was prevented' (NPSA).

Near Miss
'Any patient safety incident that had the potential to cause harm but was not prevented, resulting in no harm to patients' (NPSA).
An incident detected up to, and including the point, at which the medication was handed over to the patient.

Harm Events – e.g.
Medication Incident
'**Any preventable medication related event that could, or did lead to patient harm, loss or damage'**

Medication Error
This is a dispensing incident detected after the patient has taken possession of the medication.