Department of
Health, Social Services and Public Safety

An Roinn
Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

www.dhsspsni.gov.uk

Noel McCann
Director of
Planning & Performance Management

Room D4.13, Castle Buildings
Stormont Estate
Belfast, BT4 3SQ

Tel: [redacted]
Fax:
Email:
noel.mccann[redacted]

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For action:

Chief Executives of HSS Trusts
Chief Executives of HSS Boards
Chief Executives of Special Agencies
General Medical, Community Pharmacy,
General Dental & Ophthalmic Practices

For information:

Chief Officers, HSS Councils
Directors of Public Health in HSS Boards
Directors of Social Services in HSS Boards and Trusts
Directors of Dentistry in HSS Boards and Trusts
Directors of Pharmacy in HSS Boards and Trusts
Directors of Nursing in HSS Boards and Trusts
Directors of Primary Care in HSS Boards
Medical Directors in HSS Trusts
Chairs, Local Health and Social Care Groups

Circular HSS (PPM) 06/04

Dear Colleague

REPORTING AND FOLLOW-UP ON SERIOUS ADVERSE INCIDENTS: INTERIM GUIDANCE

Introduction

1. The purpose of this guidance is to provide interim advice for HPSS organisations and Special Agencies on the reporting and management of serious adverse incidents and near misses, pending the issue of more comprehensive guidance on safety. This will be issued once the work currently being undertaken by the Department on the strategic review of the reporting, recording and investigation of adverse incidents and near misses has been concluded.

2. This interim guidance highlights, in particular, the need for the Department to be informed immediately about incidents which are regarded as serious enough for regional action to be taken to ensure improved care or safety for patients, clients or staff. It also draws attention to the need for the Department to be informed where a Trust, Board or Special Agency considers that an event is of such seriousness that it is likely to be of public concern. In addition, the guidance requires Trusts, Boards or Special Agencies to inform the Department where they consider that an incident requires independent review.

3. The guidance complements existing local and national reporting systems, both mandatory and voluntary, which have been established over the years. These provide for specific incidents relating, for example, to medical devices and equipment, medicines, mental illness, child protection, communicable disease and the safety of staff to be reported to various points in the Department. **These systems should continue to be used in addition to the action required by this interim guidance**. In the context of contractual arrangements for the independent family practitioner services, practices should report serious incidents, in the first instance, to the relevant HSS Board, which will communicate with the Department as appropriate.

Background

4. The consultation paper *Best Practice Best Care*, published by the Department in April 2001, recognised the need for more effective arrangements for monitoring adverse incidents. As a result, a Safety in Health and Social Care Steering Group was established by the Department, with a remit to develop a strategic approach to the reporting, recording and investigation of adverse incidents and near misses and the promotion of good practice to minimise risk.

5. As part of its work, the Steering Group is also undertaking an evaluation of the effectiveness of systems used to identify and manage adverse incidents and near misses, including the Northern Ireland Adverse Incident Centre (NIAIC). NIAIC operates a voluntary system for reporting and investigating adverse incidents in the HPSS and issues alerts and other material on the safety of devices and equipment.

6. It is hoped that the Steering Group will conclude its work later this year, following which comprehensive guidance on safety and the promotion of learning will be brought forward. This may include links, where appropriate, with the National Patient Safety Agency in the NHS.

Defining Serious Adverse Incidents

7. Preliminary feedback from the Steering Group's work highlights a lack of uniformity in incident reporting and management in the HPSS. This also applies to the definition of what constitutes a serious adverse incident.

8. In line with the action required by this Circular, the Department considers that a serious adverse incident should be defined as "*any event or circumstance arising during the course of the business of a HSS organisation/Special Agency or commissioned service that led, or could have led, to serious unintended or unexpected harm, loss or damage*". This may be because:

- it involves a large number of patients;
- there is a question of poor clinical or management judgement;
- a service or piece of equipment has failed;
- a patient has died under unusual circumstances; or
- there is the possibility or perception that any of these might have occurred.

9. Examples of serious adverse incidents include:

- any incident involving serious harm or potentially serious harm to a patient, service user or the public. This could include disease outbreaks, apparent clinical errors or lapses in care;
- any incident which has serious implications for patient or staff safety – involving potential or actual risk to patients or staff;
- any incident involving serious compromises or allegations of serious compromises in the proper delivery of health and social care services.

10. The above list is not exhaustive and Annex A provides a more comprehensive list.

Key Issues for HPSS Organisations

11. HPSS organisations and Special Agencies should be developing a culture of openness. Policies should be in place to raise awareness and to

actively encourage the reporting, assessment, management and learning from adverse incidents and near misses. If they have not already done so, all HPSS organisations and Special Agencies should nominate a senior manager at board level who will have overall responsibility for the reporting and management of adverse incidents within the organisation.

12. All HPSS organisations and Special Agencies should have developed, or be developing, centralised systems which facilitate the collection, analysis and reporting of adverse incidents and near misses relating to patients, clients, staff and others. These systems should be capable of supporting an analysis of the type, frequency and severity of the incident or near miss and, where appropriate, should record the action taken.

13. In those situations where a body considers that an independent review is appropriate, it is important that those who will be conducting it are seen to be completely independent. In addition, such reviews should normally be conducted by a multi-professional team, rather than by one individual. It is also important that the Department is made aware of the review at the outset.

Action

14. HPSS organisations and Special Agencies should continue to use established local or national reporting and investigation mechanisms to manage adverse incidents. This will include, where appropriate, notifying other agencies such as the Police Service, the Health and Safety Executive, professional regulatory bodies or the Coroner. Where there is any doubt as to which agencies should be notified, advice should be sought from the Department.

15. The Department will expect urgent local action to be taken to investigate and manage adverse incidents.

16. In addition, where a **serious** adverse incident occurs, it should be reported immediately to the senior manager with responsibility for the reporting and management of adverse incidents within the organisation. If the senior manager considers that the incident is likely to:

    - **be serious enough to warrant regional action to improve safety or care within the broader HPSS;**
    - **be of public concern; or**
    - **require an independent review,**

he/she should provide the Department with a brief report, using the proforma attached at Annex B, within 72 hours of the incident being discovered. The report should be e-mailed to adverse.incidents[redacted]. In cases where e-mail cannot be used, the report should be faxed on [redacted]

Action by the Department

17. The Department:

- will collate information on incidents reported to it through this mechanism and provide relevant analysis to the HPSS;
- may also, where appropriate, seek feedback from the relevant organisation on the outcome of the incident to determine whether regional guidance is needed;
- may, in independent reviews, provide guidance in relation to determining specialist input into such reviews.

Enquiries

18. Any enquiries about this Circular from the nominated senior manager should be made, in the first place, to Jonathan Bill, Planning & Performance Management Directorate, on [redacted] or by e-mail at Jonathan.Bill@[redacted]

19. This guidance will be reviewed once the Safety in Health and Social Care Steering Group has concluded its work, at which point further, comprehensive, guidance will be issued. In the meantime, the Department will welcome feedback on the issues covered in this guidance. This should be addressed to Jonathan Bill on the e-mail address above, or to Room D2.3, Castle Buildings, Stormont, Belfast, BT4 3SQ.

Yours sincerely

NOEL McCANN
Director of Planning & Performance Management

ANNEX A

SERIOUS ADVERSE INCIDENTS - EXAMPLES

The following are examples of serious adverse incidents. It is not an exhaustive list and is intended as a guide only. Where there are any doubts about an incident it should be reported.

Major Incidents

- Any circumstance which necessitates the activation of an HSS Trust, HSS Board or wider community Emergency Plan

Clinical incidents

- Any clinical incident whose consequences would be regarded as severe
- Serious drug events which might require regional or national guidance, to prevent occurrence or reoccurrence within HPSS/NHS organisations, e.g. maladministration of a spinal medicine, major prescription error causing, or with the potential to cause, serious damage or death of a patient

Court Proceedings

- Any incident which might give rise to serious criminal charges
- Impending court hearing, including Coroners' Inquests, or out of court settlement in cases of large scale litigation
- Legal challenges to the HSS Trust or HSS Board

Incidents involving staff

- Serious complaints about a member of staff or primary care contractor
- Serious error or errors by a member of staff or primary care contractor
- Significant disciplinary matters (e.g. suspensions of staff)
- A serious breach of confidentiality
- Serious verbal and/or physical aggression towards staff

Mortality/morbidity incidents

- Clusters of unexpected or unexplained deaths
- The suicide of any person currently in receipt of health and personal social services on or off HPSS premises, or who has been discharged within the last twelve months.
- Death or injury where foul play is suspected
- Situations when a patient or patients require(s) additional intervention(s) as a result of serious failures in diagnostic processes

- The accidental death of, or serious injury to, a patient, a member of staff, or visitor to HPSS or primary care premises, or involving HPSS or primary care staff or equipment
- Significant harm to children where reported under child protection arrangements
- Vulnerable adult abuse

Premises/equipment incidents

- Serious damage which occurs on HPSS premises or premises on which primary care services are delivered, or to HPSS property or property on which primary care services are delivered, or any incident which results in serious injury to any individual or serious disruption to services (e.g. evacuation of patients due to fire)
- Failure of equipment so serious as to endanger life, whether or not injury results
- Suspicion of malicious activity e.g. tampering with equipment
- Circumstances that lead to the provider no longer being able to provide an element of service

Mental Health or Learning Disability incidents (including substance misuse services)

- The disappearance, absence without leave or absconding of a patient (whether or not detained under the Mental Health Order 1986) where there is serious cause for concern
- Escapes by patients (whether or not detained under the Mental Health Order 1986) from secure accommodation/area
- Homicide, or suspected homicide, by any patient who has received mental health services
- Unexpected death
- All deaths within secure settings
- All deaths of persons who are subject to the Mental Health Order or equivalent legal restriction who has or is receiving mental health service care and treatment
- Any serious criminal acts involving patients, or staff
- An incident that causes serious harm that places life in jeopardy
- Serious injury, resulting in the need for emergency medical treatment via an A&E department, sustained by patient, staff or visitor on HPSS property
- Where a member of staff is suspected of harming patients or serious fraud
- Hostage taking, mass / organised disturbance
- Any omissions/failings of security systems/procedures that jeopardise security
- All incidents reported to or involving the police

ANNEX B

SERIOUS ADVERSE INCIDENT REPORT
1. Organisation:
2. Brief summary (and date) of incident:
3. Why incident considered serious:
4. Action taken:
5. Is any regional action recommended? (if so, full details should be submitted) Y/N -
6. Is an Independent Review being considered? (if so, full details should be submitted) Y/N -
7. Other Organisations informed **PSNI** Y/N - **Coroner** Y/N - **NIHSE** Y/N - **HSS Board** Y/N - **Other** (please specify) Y/N -
8. Report submitted by (name and contact details of nominated senior manager or Chief Executive)

Completed proforma should be sent, by email, to:

adverse.incidents [redacted]

If e-mail cannot be used, fax to [redacted]