



Risk Management

Adverse Event Management Policy (AEM)

Policy Manager Clinical Governance and Risk	Policy Group Clinical Quality Forum / Improvement and Quality Committee
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This policy does / ~~does not~~ apply to Medical/Dental Staff
(delete as appropriate)

UNCONTROLLED WHEN PRINTED

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ADVERSE EVENT MANAGEMENT POLICY (AEM)

1. Introduction

NHS Tayside recognises and accepts that it has legal and other requirements for managing all incidents and near misses. The organisation seeks to establish a balance of proactive and reactive risk management processes to enable early identification of potential problems thus creating prevention cycles to enhance patient and staff safety.

Many incident reporting systems rely on data capture, recording trends, in particular events/near misses, followed by investigations to determine the cause or blame of particular incidents. While the focus of counting numbers is important, changes in practice will only occur where there are established systems to learn from adverse events/near misses to prevent them recurring.

Emphasis on error prevention in healthcare is a National priority demonstrated in the publications; An Organisation with a Memory (Department of Health (DoH), 2000), Doing Less Harm (DoH, 2001) and Building a Safer NHS (DoH, 2001), Safety First: A Report for Patients, Clinicians and Healthcare Managers (DoH, 2006), Better Health, Better Care Action plan: What it Means for you (Scottish Government, 2008). These documents provide structure and direction for the development of local incident reporting systems **focused on learning**.

Research has been conducted in NHSScotland to establish a coherent framework for risk assessment. Following the consultation paper "Learning from Experience: How to Improve Safety for Patients in Scotland" (Scottish Executive, 2004) a framework document¹ has been published, by NHS Quality Improvement Scotland (NHS QIS) to address the key themes identified. Improving the safety of patients and staff in NHSScotland through incident reporting was highlighted as a priority within this publication.

1.1 Definitions

The following definitions apply to this document:

Individual/s refers to the person/s directly or indirectly involved in service provision, including employees, bank, locum or agency staff, contractors and volunteers. All health care staff are covered by this definition.

The term incident refers to an unplanned or unexpected occurrence or event arising during NHS service provision where there is loss of life, harm, injury, loss or damage to persons or property. It can include any event that may give rise to physical, emotional or psychological harm.

Harm is defined as 'injury' (physical or psychological), suffering, disability or death which was unexpected.

A near miss is any incident that had the potential to cause harm but was prevented, resulting in no harm **but could** have resulted in harm, loss or damage in other circumstances.

RIDDOR means the Reporting of Injuries, Diseases and Dangerous Occurrences Regulation 1995.

¹ NHS Quality Improvement Scotland (2006) *Safer Today – Safer Tomorrow Patient Safety Review of Incident and Near Miss Reporting*. NHS Quality Improvement Scotland. [http:// www.nhshealthquality.org](http://www.nhshealthquality.org)

2. Aims and Objectives

The NHS Tayside Adverse Event Management Framework covers all accidents, incidents, near misses and system failures which, either caused, or could have caused, injury or death to individuals or damage or loss to NHS Tayside property.

This document sets out a policy framework for recognising, reporting and reviewing all incidents and near misses within the organisation. Our **aim** in NHS Tayside is to **minimise** the risk of incidents occurring and **maximise** our opportunities to learn to keep patients safe and support staff.

The primary purpose of our significant event management framework is to improve systems, practice and care and NOT to apportion blame. All staff have a responsibility to report incidents and take appropriate remedial action where relevant. However, in the event of negligence, intended harm and professional mal-practice the reporting framework will convert to a disciplinary procedure where appropriate. It is important to remember that Incident Reporting /Investigation are distinct from disciplinary procedures. The purpose of this is to encourage staff to recognise a '**just**' reporting culture as the bedrock for sustained changes in practice to improve patient care and services.

2.1 NHS Tayside Fair and Just Culture

NHS Tayside recognises the complexity and interdependence of the work environment in all aspects of its operations. When events occur that cause harm or have the potential to cause harm to patients or staff members or place NHS Tayside at legal, financial or ethical risk, a choice exists: to learn or to blame. Within NHS Tayside we are committed to creating a work environment that emphasises learning rather than blame. We want all workplaces across NHS Tayside to be environments where respect and fairness are obvious from the moment staff walk into work. We want staff to feel safe in putting their hands up to report mistakes, speak up about flaws in our systems and not be party to inappropriate or risk-taking behaviours. Most errors, whether or not they cause harm, are due to breakdowns in the organisations systems: however when error takes place, individual culprits are often sought. Blaming individuals creates a culture of fear and defensiveness that diminishes both learning and the capacity to improve our systems.

Promoting and living a fair and just culture within NHS Tayside means giving constructive feedback and critical analysis in skilful ways, doing assessments based on facts whilst having respect for the potential complexity of the situation. It also means providing fair-minded treatment, having productive conversations and creating effective structures that help staff reveal their errors and help NHS Tayside learn from them. A fair and just culture does not mean non-accountable, nor does it mean an avoidance of assessment of competence. Rather, when incompetence or sub-standard performance is revealed after careful collection of facts, and or there is reckless or wilful violation of policies or neglectful behaviour, disciplinary action may be appropriate. However, in order to have the greatest impact and achieve the highest level of excellence, staff must be able to speak up in an environment where it is the shared goal to identify and discuss problems with curiosity and respect.

3. Roles and Responsibilities

3.1 All Staff

All staff are accountable for following the procedures defined within this Policy. However, accountability for managing the process lies with local management teams, i.e General Manager, Associate Medical Director, Associate Nurse Director, Head of Nursing, Clinical Service Manager and Director of Public Health through local Safety, Governance and Risk structures.

All staff have a professional responsibility to report incidents and near misses and taking appropriate remedial action where relevant. Responsibility for raising an incident report within Datix lies with the first person/s to recognise/become involved in the incident or near

miss irrespective/regardless of their domain, department or position within the organisation or area in which the incident occurs.

Further information on individual roles and responsibilities please refer to flowchart 1 at the rear of this policy where this information is defined.

4. Incident Reporting - The Datix Incident Reporting System

The board currently use the Datix web-based system for incident reporting. This system allows prompt, thorough reporting and requires line manager review/verification and recording of action taken, so learning from the incident can be disseminated.

Datix incident and near miss reports can be made by anyone with access to Staffnet.

Datix **must** be utilised to record all accidents, incidents and near misses which, either caused, or could have caused, injury to individuals or damage or loss to NHS Tayside property. The system is designed to be confidential but not anonymous thus supporting the ethos of the organisation that our aim in NHS Tayside is to minimise the risk of incidents occurring and maximise our opportunities to learn; to improve systems and practice, care and outcomes and NOT to apportion blame.

4.1 Reporting

The first person to recognise or become involved in the incident, irrespective of domain, department or position within the organisation or areas in which the incident occurs, is responsible for completing the incident reporting form within Datix as soon as possible but **within 24 hours of occurrence** for all incidents and near misses. However, if the incident features on the list for Significant Clinical Event Analysis (SCEA) or is a Never Event, the General Manager or Head of Nursing must be advised immediately and they will escalate to the relevant Executive Director **within 1 hour**. Datix will send an alert to the Chief Executive, Deputy Chief Executive, Chief Operating Officer, Nurse and Medical Directors and Head of Clinical Governance and Risk Management for every red incident reported.

4.2 Verification

The electronic Datix incident form must be sent in the first instance to the immediate line manager. The line manager will verify incidents **within 72 hours of receipt**, manage and report the adverse event in accordance with the grade and type of incident/near miss. Discussion with colleagues may be necessary to confirm the type, grade and impact of the incident/near miss.

The Datix Reporting System will record the following as a **Minimum Data Set**:

- What happened? Near miss or actual incident
- What time incident happened
- Consequence calculation (What is the impact of this incident? Red, Amber or Green. This is the 'actual' consequences and not the potential consequences. This grade will give guidance regarding reporting arrangements (see flow chart 1). The Red, Amber and Green selection will enable "forward reporting" (see flow chart 1).
- Location.
- How it happened? Immediate or proximal causes.
- Why did it happen (if known)? Underlying causes.
- What action was taken/proposed? (Immediate and longer term).
- What impact did the incident have? (Harm to the organisation, the patient /others).
- What factors did or could have minimised the event?
- Is this event likely to recur? (Red, Amber or Green risk based on potential likelihood x potential consequences)
- Identified Lead/Responsible Managers
- Local Incident Review Report and Action Plan

4.3 Grading The Harm Caused In This Incident/ Near Miss

What has happened and what is the impact?

Check Table 1 and determine the severity of the incident/near miss. Choose a score from 1-5 to describe the harm caused i.e 1=Negligible, 5=Catastrophic and report forward (see flow chart 2) accordingly. This can also be described as a Red, Amber or Green Incident. Near misses will always be graded Category Green.

1	2	3	4	5
Green	Green	Amber	Red	Red

Table 1
Consequence Score

Descriptor	CONSEQUENCES				
	Objectives	Cost	Physical Harm	Schedule	Reputation
Negligible (Green)	Minimal Impact. No service disruption	Minimal financial loss, <£50k	No obvious harm/ injury	Minimal	No interest to the press.
Minor (Green)	Minor impact on service provision.	Moderate financial loss £50-250k	First aid treatment. Non-permanent harm up to 1 month	Increased level of care /length of stay 1-7 days	Some public embarrassment. No damage to reputation or standing in the community.
Moderate (Amber)	Service objectives partially achievable.	Significant financial loss £250-1M	Medical treatment required. Semi - permanent harm up to 1 year.	Increased level of care /length of stay 8-15 days. Pressure on service provision	Local adverse public embarrassment leading to limited damage.
Major (Red)	Significant impact on service provision	Major financial loss £1M-2.5M	Extensive Injury. Major permanent harm.	Increased level of care /length of stay >15 days. Temporary service closure	National adverse publicity. Major loss of confidence in organisation.
Extreme (Red)	Unable to function. Inability to fulfil corporate obligations	Severe financial loss >£2.5M	Death	Extended service closure	Highly Damaging International adverse publicity. Severe loss of public confidence

The immediate impact of the incident must be categorised as Red, Amber or Green and reported in accordance with the local organisational Incident Reporting Mechanism (see flow chart 1).

4.4 Could This Incident Recur?

Following the initial impact consider if this incident were to happen again how frequently do you believe it will happen (likelihood) and what could the outcome be (consequence). Consider Tables 1, 2 and 3. The risk of recurrence will result in a Potential Risk Exposure Rating (see Table 3) of red, amber or green which will also help to identify those incidents which have not caused harm but potentially could in the future. For example, a near miss incident which has had minor consequences this time (GREEN) may have a significantly more serious outcome should it recur. Re-evaluation of this incident with a potentially more serious outcome will result in a RED risk exposure rating requiring a local incident review to minimise the possibility of recurrence. The information gained from local incident review will

be shared across the organisation through the Clinical Governance and Risk Management structures.

4.5 Likelihood Score

Table 2
Likelihood Score

Descriptor	Frequency of event occurring	Timescales (Guide Only)
Rare	Can't believe this event would happen	5-10 years or more
Unlikely	Not expected to happen but might	2-5 years
Possible	May occur occasionally	Annually
Likely	Could occur several times	Quarterly
Almost certain	Could occur frequently	Daily / Weekly / Monthly

Table 3
Potential Risk Exposure Rating

		CONSEQUENCE				
		Negligible	Minor	Moderate	Major	Extreme
LIKELIHOOD	Almost Certain	Medium	High	High	Very High	Very High
	Likely	Medium	Medium	High	High	Very High
	Possible	Low	Medium	Medium	High	High
	Unlikely	Low	Medium	Medium	Medium	High
	Rare	Low	Low	Low	Medium	Medium

The level of incident review required for actual events should not be solely dependent upon the incident grading but must include consideration of the Potential Risk Exposure Rating for both incidents and near misses. Please refer to Appendix 1 – Flow Chart 1 for further information and guidance.

4.6 Incident Reporting – RIDDOR Reporting

In addition to the electronic incident reporting noted above, certain incidents require to be notified to the HSE under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995.

This requires to be made separately from the NHS Tayside electronic incident report form. The NHS Tayside electronic incident reporting system does not automatically generate RIDDOR Reports.

The RIDDOR Report should be made by the Incident Verifier and the appropriate information then added to the electronic incident reporting form. RIDDOR Reports are made online at www.hse.gov.uk/riddor

Typical incidents which need to be reported include work related fatalities, major injuries, certain dangerous occurrences and incidents where a staff member is unable to attend work or perform their normal duties due to injury for more than 7 days (These are 7 consecutive days, not including the day of the incident but including any days which would normally not be worked (e.g. weekend)). Any work related fatality will also need to be reported directly to the HSE on line at www.hse.gov.uk/riddor. Reports must be made to the HSE within 15 days of the incident.

Some incidents involving patients may also need to be reported, but these are generally less straightforward to define. If in doubt, please contact the OHSAS H&S Team on 01382 346036.

For a full explanation of reportable incidents and examples, please see Healthcare guidance or full regulations. Links can be found in the “External Publications” section of the OHSAS webpages on Staffnet.

5. Types of Incident Reviews

5.1 Local Incident Review

Local Reviews must be held for **all** red incidents and if local teams feel appropriate for amber incidents and clusters of green incidents. They should also be held for all unexpected deaths in hospital or complaints. These should:

- Be Chaired/Facilitated locally within Directorates where possible preferably by Head of Nursing or Clinical Service Manager. If this is not appropriate support should be sought from the Clinical Governance and Risk Management Team.
- Be held within 7 days of the incident where it is identified as on the list for Significant Clinical Event Analysis (SCEA) or is a Never Event otherwise to take place within 28 days of occurrence of the event.
- Assign all persons directly involved in the event a coded reference;
- Determine the human and other factors most directly associated with the event, and the processes and systems related to its occurrence
- Consider analysis of the underlying systems and processes through a series of ‘why’ questions to determine where redesign might reduce the risk
- Identification of the risks points and their potential contribution to the event
- Formal recommendations for change and improvement in process or systems must be recorded in an action plan with a designated timescale for completion
- Have draft reports and associated action plans confidentially issued to all attendees for amendments or approval and thereafter once agreed have a confidential final version issued.
- Be reported, monitored and followed up through local Clinical Governance and Risk Groups/Committees in order that assurances can be provided that improvements have been achieved and the learning can be shared throughout organisation.

Examples of tools which can be utilised during the incident review process are provided in Appendix 5.

5.2 Significant Clinical Event Analysis (SCEA)

These focus on significant clinical incidents which have an impact of permanent psychological and/or physical harm or death on one or many patient(s).

A Significant Clinical Event Analysis must be held for:

- All suicides of patients currently receiving a Mental Health Service or having done so within 12 months prior to their death
- Any medication incident which causes death
- Missing Patient
- Maternal Death
- Unexpected Still Birth
- Inadvertent intrathecal administration of parenteral medications
- Serious Assault of staff and/or patients
- Breach of any Policy or Procedure resulting in harm (actual or potential) to patients, staff or the organisation.
- Ward Closure
- HAI Death
- Any hospital/healthcare acquired notifiable infection
- Death in Custody

- Any Drug Related Death
- Child/Adult Protection Incidents
- An IT failure or other external event that impacts on service delivery

A Significant Clinical Event Analysis must also be held for the following Never Events:

- Wrong Site Surgery
- Retained Instrument Post Operation
- Misplaced Naso or Orogastric tube not detected prior to use
- Wrong Route Administration of Chemotherapy
- Escape from within the secure perimeter of medium or high secure mental health services by patients who are transferred prisoners
- In hospital maternal death from post partum haemorrhage after elective caesarean section
- Intravenous administration of mis-selected concentrated potassium chloride
- In patient suicide using non-collapsible rails

Local teams can also request a SCEA in the following circumstances:

- Where the incident is likely to result in highly damaging adverse publicity/defamation
- Where the incident is likely to result in a claim being pursued against the organisation
- Where the incident could result in any of our hospitals being incapable of operating normally and whereby “shut down” is imminent.
- Where there is system wide learning.

The purpose of an SCEA is primarily to understand and learn from events and share any learning, changes or improvements to systems and processes with other appropriate stakeholders.

All incidents requiring SCEA must be reported to the General Manager or Head of Nursing immediately and they will escalate to the relevant Executive Director **within 1 hour**. Thereafter it must be recorded in the Electronic Incident Reporting System within 24 hours of the event and have a local review and analysis undertaken within 7 days of the event. This local review must contain a recommendation to proceed to a SCEA. The request for consideration for a SCEA must be submitted by the General Manager/Clinical Service Manager/Head of Service to the SCEA Team (Tay-UHB.SCEATeam@nhs.net) via email using the Proforma attached in Appendix 6. The Medical and Nurse Director will agree whether a review is required and will contact the SCEA Team, who will provide administrative support to the process.

Those present at the Significant Clinical Event Analysis will include:

Board Nurse Director (or nominated deputy)

Medical Director (or nominated deputy)

Associate Medical Director for Service

Associate Nurse Director for Service

Relevant Head of Service/Service Manager

Head of Safety, Governance and Risk

Other staff appropriate to the Incident – This can and should include, for example, relevant Mental Health Staff, Primary Care Staff, General Hospital Staff, Police, Local Authority, Voluntary Sector staff, Prison Healthcare Staff and Scottish Prison Service Operational Staff.

Patients/Families/Carers are given the opportunity to contribute to the SCEA. They are contacted in advance by a member of the SCEA Team to determine the questions they would like asked at the SCEA. Where Patients/Families/Carers have indicated they wish to receive feedback following a SCEA. This will be done through a meeting with the Chair supported by the appropriate service manager or known clinician. The SCEA Report will be discussed and a copy passed to the Patients/Families/Carers. In addition, learning from the

review will be shared and advice given regarding who they can approach if they are dissatisfied e.g Mental Welfare Commission, NHS Complaints and Advice Team.

The SCEA should be held within 3 months (90 days) of the event and will be Chaired by either the Board Nurse or Medical Director as they have the appropriate independence, organisational authority, skills and knowledge to carry out an effective review. If necessary the Chair will be supported by other relevant experienced personnel independent from the service subject to the SCEA. The final report should be completed within 5 months of the SCEA being held.

Following a SCEA where there is significant organisational learning or a failure to identify a cause of death, if deemed appropriate by the Nurse and/or Medical Director an Independent Review will be requested and undertaken.

The SCEA process will be managed by a member of Clinical Governance and Risk Management Administration Staff. This will include ensuring all necessary information, inclusive of relevant written records, third party information, any relevant policies and procedures and any relevant good practice guidance, is available to the review team in advance of the meeting.

The member of Clinical Governance and Risk Management Administration Staff will also record the SCEA using the template attached in Appendix 7 with all action points assigned an identified lead and a timeframe for completion. In the first instance, the report will be issued to all attendees confidentially in draft form for amendments or approval. Once agreed by the panel the confidential final report will be sent to attendees of the review; Health Improvement Scotland for Suicides; Mental Health Safety, Governance and Risk Committee; Relevant Directorate Clinical Governance and Risk Committees. The identified leads and relevant committees will be responsible for ensuring the follow up, completion and feedback of action points. In addition regular update reports from local Clinical Governance and Risk Groups/Committees will be provided to the Clinical Quality Forum.

5.3 HSE Incident Review

Where HSE involvement with an incident is known, or suspected to be likely, then the OHSAS H&S Team can lead or assist managers in a review of the incident. This will be conducted prior to and alongside any review by the HSE. OHSAS will also act as liaison between NHS Tayside and HSE for any such incidents. This review will be separate from any SIR that may be conducted.

6. Types of Incidents

6.1 Equipment Related Incidents

All incidents involving health, social care, estates and facilities equipment including those from JELS must be recorded within the NHS Tayside Electronic Incident Reporting System as soon as possible but within 24 hours of occurrence. The Incident Report Form must highlight the type of equipment involved in the heading.

All such incidents should be notified to the NHS Tayside Equipment Co-ordinator, who is the Head of Instrumentation in Medical Physics and include details of the electronic incident reporting system reference number.

Equipment involved or suspected to have been involved in an incident must be removed from use if at all possible. It should be quarantined (secured out of use) along with any consumables and patients leads etc. In the interest of infection control all equipment and consumables should be bagged as appropriate and labelled with details of the incident. Settings on the equipment must not be altered and no attempt should be made to replicate the incident or diagnose a fault. It is essential to capture the equipment before it is put back into service or settings and other evidence lost.

If the equipment is to be sent to Medical Physics:

- v do attach an equipment repair requisition to the equipment,
- v do note a summary of the incident on the requisition.

Medical Physics are tasked with the review of all medical equipment related incidents and their remit is to investigate what happened and ascertain if there is a fault in the equipment or use.

Medical Physics are also responsible for escalating such incidents to Health Facilities Scotland (HFS), and the Medicines and Healthcare products Regulatory Agency (MHRA). This is necessary where an equipment fault may affect equipment out with NHS Tayside.

6.2 Controlled Drug Incidents

All incidents involving Controlled Drugs (CDs) must be reported via the NHS Tayside Electronic Incident Reporting System. Examples include:

- Unexplained losses/discrepancies in CD Registers against actual stock.
- Any discrepancy in CD stock which, although resolved, raises concerns.
- All significant events or near misses involving prescribing, administration, supply, dispensing or destruction of CDs.
- Any suspected or actual illegal activity relating to CDs, e.g. theft, fraud or attempting to take CDs by deception.

There is a requirement for the NHS Tayside Accountable Officer (AO) for CDs to be notified of all incidents and concerns involving CDs. To achieve this, such incidents must be tagged as a CD Incident on the Incident Reporting System to ensure that the report is forwarded automatically to the AO Team.

All CD incident reports must include details of the actions taken, including immediate steps to prevent or reduce harm to patients, any investigations undertaken and actions taken to prevent recurrence to provide assurance to the AO that the incident has been thoroughly investigated. In the case of serious incidents, appropriate support will be provided to any investigation.

In the event of a serious incident or a concern, the AO or Head of CD Governance must be notified directly via (01382) 835153 (internal **CAT C**) or cdteam.tayside@nhs.net.

6.3 Child Protection Incidents

Incidents relating to the protection of children require to be reported via the NHS Tayside electronic Incident Reporting System in addition to recording in the patient/child's case record. The local manager (verifier) is responsible for ensuring that their service area lead for child protection is fully informed of the incident. The service area lead will then be responsible for ensuring appropriate action is taken in line with NHS Tayside child protection policies and procedures and will also communicate this with the relevant agencies/individuals required. Where incidents require to be escalated within the organisation, the service line manager in collaboration with the service area lead for child protection will require to complete an SBAR in accordance with the guidance for the use of an SBAR in cases of child protection.

6.4 Adult Protection

Incidents relating to support and protection of adults should be reported in accordance with the NHS Tayside Operational Procedures for the Support & Protection of Adults At Risk of Harm. These operational procedures should be applied to the extent required to satisfy compliance with the Adult Support and Protection (Scotland) Act 2007. They do not replace the need for effective professional practice in the treatment and care of those who use NHS Tayside services and apply to all staff employed by NHS Tayside, including those who work in integrated care services.

6.5 Prisoner Healthcare Incidents

For all incidents relating to Prisoner Healthcare, the flowchart in Appendix 2 should be followed. All Deaths in Custody will require a Significant Clinical Event Analysis to be undertaken. However, if it is a Self Inflicted Death in Custody e.g. Prisoner Suicide the incident will also require compliance with the Scottish Prison Service Self Inflicted Death in Custody: Audit, Audit & Review (SIDCAAR) Guidance.

Copies of all Scottish Prison Service SIDCAARs will be provided to NHS Tayside Nurse and Medical Directors, Central Legal Office, and NHS Tayside Claims Manager.

6.6 Drug Related Death Incidents

A drug death is defined as *“Where there is prima facie evidence of a fatal overdose of controlled drugs. Such evidence may be recent drug misuse, for example controlled drugs and/or a hypodermic syringe found in close proximity to the body and /or the person is known to the police as a drug misuser although not necessarily a notified addict.”*

Tayside Drug Deaths Review Group (DDRG) is a multi-agency group which undertakes reviews of all suspected drugs deaths notified by the police, regardless of whether the deceased had contact with NHS, local authority or other services. Through its case reviews, the DDRG brings a multi-agency perspective that adds to local incident review undertaken within NHS services for relevant cases.

The drug deaths review group will meet at intervals of approximately 6-8 weeks. The number of cases to be reviewed at each meeting will vary but is generally between 6 and 10.

All suspected drug deaths where the individual is an existing client, or has been a client in the 12 months prior to death, will be classified as a RED incidents and will be reviewed internally by the relevant service through Local Incident Review procedures. In all cases, a DATIX report will be raised.

Following local incident review, a drug death may be referred directly for SCEA. NHS Services and /or DDRG may also request SCEA if a series of drug deaths which individually may not warrant SCEA, but as a group raise similar issues that may point to systems failings.

7. Communication

In the event of an incident involving a patient, the incident should be noted in the patient case record. In addition, an incident report (form) must be completed in the Electronic Incident Reporting System **as soon as possible but within 24 hours of occurrence**. As all Incident Reports are legal documents the information recorded must be factual. **On advice from the Central Legal Office staff must not file a paper copy of the incident review form or the significant event analysis report in the patient case record.**

7.1 Patient/Family/Carer

A full, frank and factual explanation must be shared with the patient at the time of the incident. For particular patient groups, e.g. children, ventilated patients or vulnerable adults, this may not be possible. In these circumstances discussion with carer, guardian or relative is appropriate. In all other circumstances incidents should not be disclosed to the next of kin, carer or GP etc without the patient's consent.

This should be done by a team of at least 2 staff members including a clinician who has a pre-established relationship with them with a clear team leader identified. State what happened, why it happened and what is being done to prevent it from happening again (IHI, 2010). Address any concerns the patient and/or family have as soon as possible. This team should inform the patient and family as soon as the organisation has any new information pertaining to the event.

Essential messages can, when appropriate, include the following:

- The hospital apologises and regrets that the incident happened (See table 1 for language to use in such communication)
- We will disclose to the patient and family everything we know, keeping them informed as a priority
- We will work with appropriate authorities and use this as an opportunity to make the organisation a better and safer place for our patients, family and staff.

Table 1: Communicating after an adverse event: Words of Compassion, Concerns, Empathy and Remorse

Alarmed	Tragic	Let you down
Unfortunate	Concerned	Unhappy
Regret	Unintended	Disappointed
Sad / Saddened	Unnecessary	Unsatisfactory
Empathised	Sorrowful / Sorrow	Failed / Failure
Sympathetic		

7.2 External Enquiries

External enquires regarding any incident must be referred to the NHS Tayside Communications Team in all instances. The Communications Manager and the relevant Executive Director will agree a response to media enquiries. In the event of possible media interest, the Board Secretary will inform the Executive Management and the Non-Executive Directors of NHS Tayside and will share the media response.

The communication team provides communication support and advice across NHS Tayside to any emergency situation. This includes:

- Crisis Management
- Internal Communications
- Issuing of proactive Press Release
- Responding to and dealing with multiple media enquiries

There is one telephone number for all calls including media calls – 01382 424138. The communications team also operate an out of hours rota to ensure cover 24 hours a day, 365 days a year. Out of hours – anyone calling 01382 424138 will be redirected to the on call Communications Manager. The switchboard at Ninewells Hospital will also hold out of hours contact numbers.

7.3 Release of Incident Report Forms/Significant Event Analysis Reports

Individuals who are the subject of Incident

Copies of Incident Report Forms and Incident Review Reports will be provided as part of a Data Protection Subject Access request. However, the individual will be only be provided with personal information relating to them. All personal information relating to other individuals (i.e. verifiers, witnesses etc) within the documentation will be removed.

An individual's legal representative

Those holding, for example, Power of Attorney or Parental Responsibility can apply on behalf of the individuals and will be provided with information as outlined in the paragraph above.

Solicitors and Other Third Parties

Can apply for access with express permission of the data subject, however, any such request will require a signed mandate.

External Partner Organisations

Requests received from, for example, the Health and Safety Executive, the Police, The Procurator Fiscal, the Mental Welfare Commissions or Healthcare Improvement Scotland in

respect of suicides will be honoured as we have a duty to provide them with the requested information.

Freedom of Information Requests

Copies of incident report forms and incident review reports will not be released as part of any such request. Any person seeking such information will be advised that all they may be entitled to is a summarised version of information relating to the review.

Any requests for information in relation to Adverse Event Management should be directed to the Clinical Governance and Risk Management Department who will liaise with the Chief Executive as Accountable Officer, Board Nurse and/or Medical Director, Information Governance Team and OHSAS.

8. Support for Staff following an Incident

NHS Tayside has a duty of care to all employees following a critical incident which has occurred within the workplace. In such instances managers should refer to and where appropriate follow the [NHS Tayside Critical Incident – Employee Support Policy](#). Contact should also be established with the Employee Director's Office to ensure the associated staff side representatives can be alerted and actively provide support. In addition, the Manager can contact the Occupational Health and Safety Advisory Service (OHSAS) and the Department of Spiritual Care is also supportive and offers a drop in service at the Wellbeing Centre, Royal Victoria Hospital, Dundee on a Monday between 1200 and 2000 hours.

9. Feedback/Closing the Loop

As demonstrated in flow chart 1, feedback to frontline staff is a key element of the Incident Reporting Mechanism. All clinical groups have a Safety, Clinical Governance and Risk Management structure which should be used as a forum for discussing adverse events, sharing learning and follow up of actions/changes in practice.

10. National Patient Safety Agency's (NPSA) Incident Decision Tree

The [Incident Decision Tree](#) ²(click to launch Incident Decision Tree) is a key component of the National Patient Safety Agency's (NPSA²) drive to help the NHS move away from asking "Who was to blame?" to "Why did the individual act in this way?" when things go wrong.

This tool has been utilised to aid the decision making to determine whether or not the incident was deliberate harm or malpractice and thus handled via a disciplinary route, or unintended harm or system error and thus handles via the Incident Reporting Mechanism.

It has been created to help NHS Managers and Senior Clinicians decide whether to suspend (exclude) staff involved in a serious patient safety incident and to identify appropriate management action. The aim is to provide fair and consistent staff treatment within and between healthcare organisations.

The Incident Decision Tree is a web-based tool and is simple to use. Depending on the nature of the incident and the amount of information gathered, it usually takes 30 to 60 minutes to work through.

It helps NHS managers and senior clinicians decide initial action to take with staff involved in a patient safety incident. It is intended to promote a consistent and fair approach, avoiding unnecessary and costly suspensions and exclusions.

10.1 How the Incident Decision Tree works

The Incident Decision Tree is based on a flowchart (Appendix 8), and takes you through a series of structured questions about the individual's actions, motives and behaviour at the time of the incident.

² National Patient Safety Agency 2005². Incident Decision Tree:
[http://www.msnpa.nhs.uk/idt2/\(pl3iytbeavxkh445p525xc45\)/index.aspx](http://www.msnpa.nhs.uk/idt2/(pl3iytbeavxkh445p525xc45)/index.aspx) (April 2009)

These questions move through four sequential 'tests':

the Deliberate Harm Test;

the Physical/Mental Health Test;

the Foresight Test;

the Substitution Test.

In the majority of cases system failure turns out to be the cause of the incident.

11 Summary

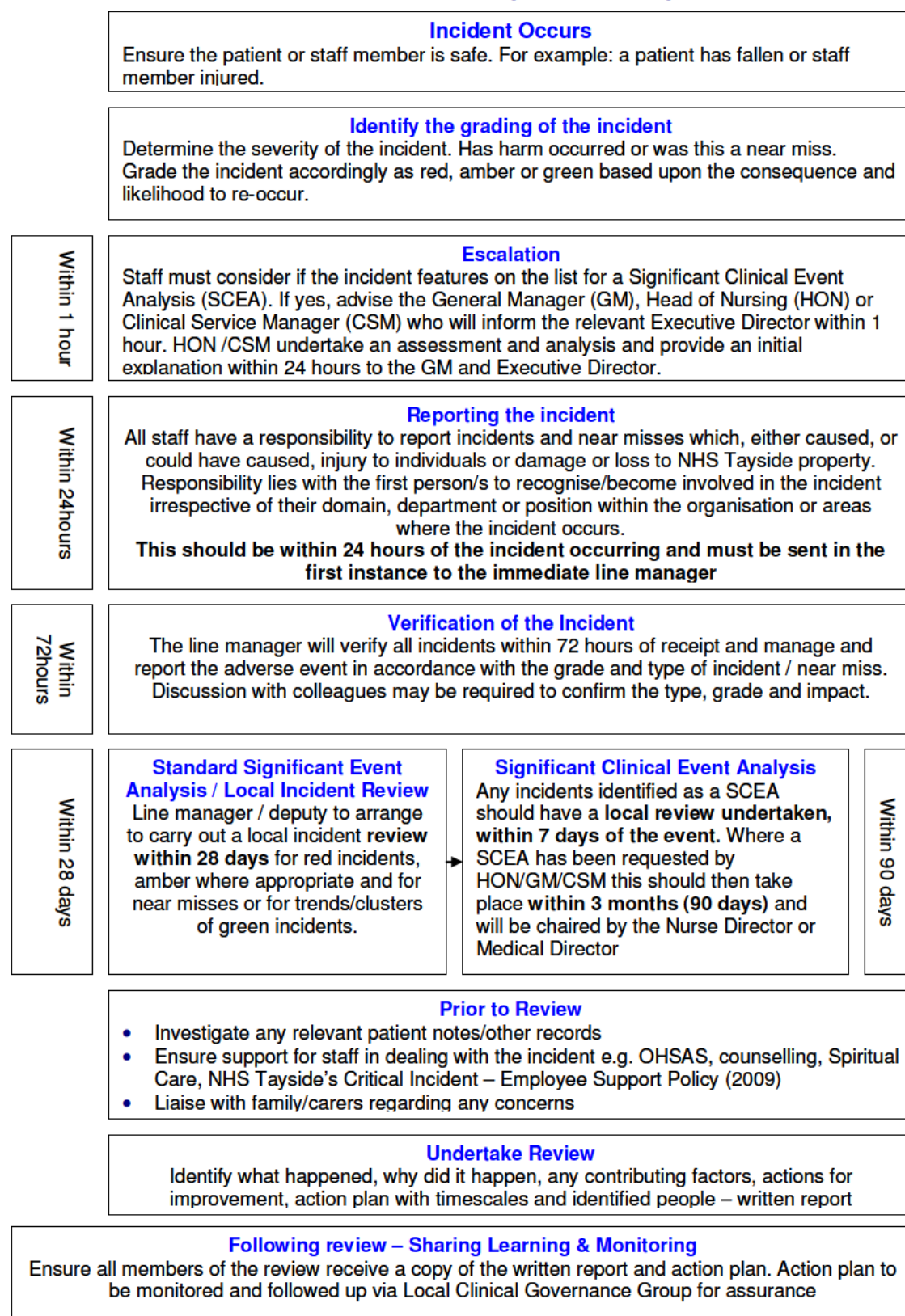
The NHS Tayside Significant Event Management Policy aims to provide clarity around the systems and processes in existence to report, investigate and share learning from adverse events.

The Safety, Governance and Risk Department may be contacted for further advice or guidance on any of the issues discussed above.

APPENDIX 1 - FLOW CHART 1

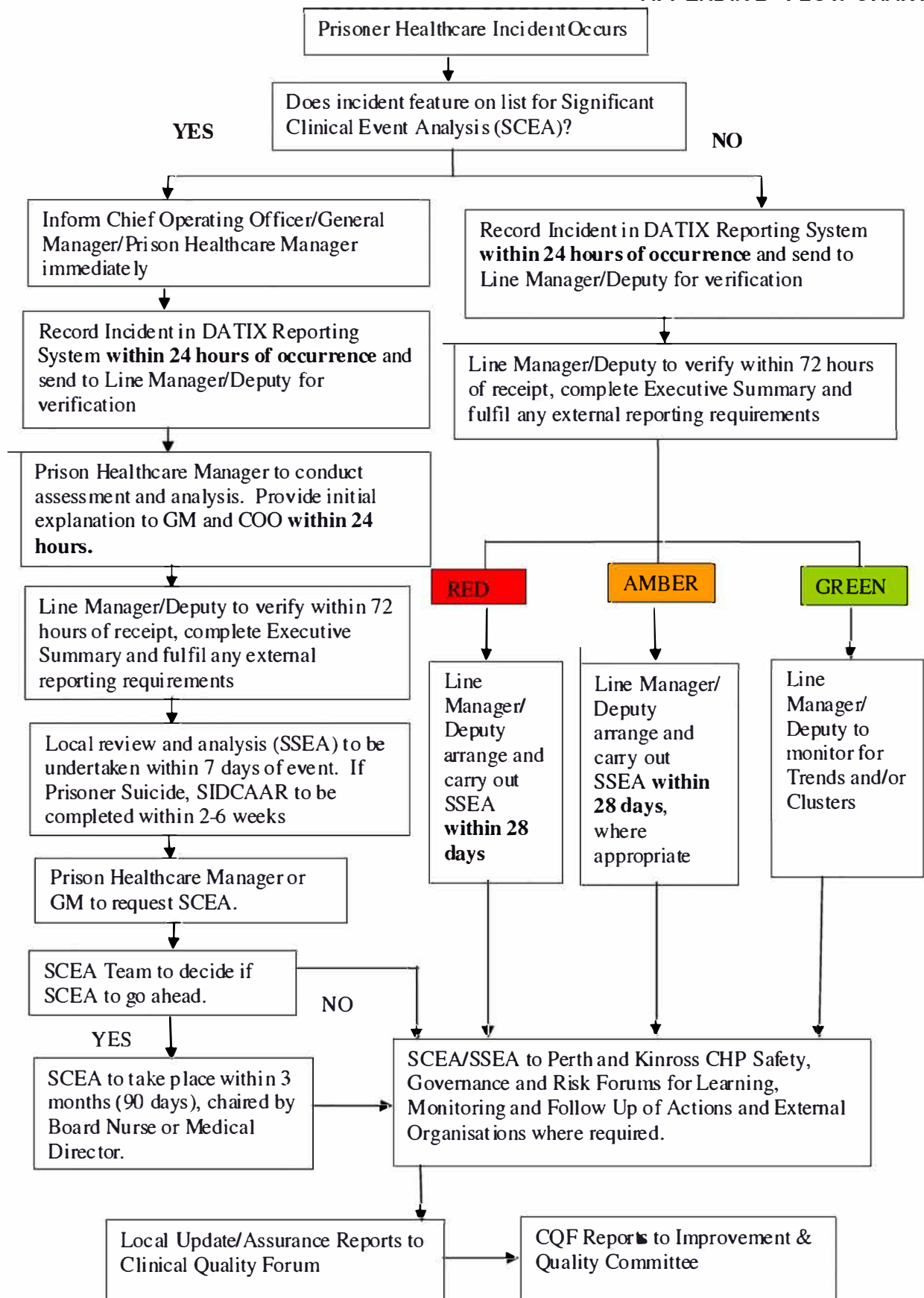
APPENDIX 1 – FLOWCHART 1

Adverse Events - Flowchart



Note: Please ensure the patient/family have been informed when an adverse event occurs during an episode of care

APPENDIX 2 - FLOW CHART 2



APPENDIX 3 - FORM 2

EXECUTIVE SUMMARY OF A RED INCIDENT

Incident (include date of incident)			
Location			
Incident Grade Score 1 – 5	Recurrence – Red / Amber / Green		
What was the actual and potential impact of the incident			
How did it happen			
Why did it happen			
What initial action was taken or proposed			
What factors could have minimised or did minimise the incident?			
Persons informed:	Name:	Yes	No
• Exec Director / General/Service Manager			
• Safety, Governance and Risk Department (Mandatory)			
• Specialist Adviser i.e. Pharmacist, Health & Safety, Medical Physics etc			
• Chief Executive			
Local Contacts:			
• Clinical Service Manager			
• Clinical Leader			
• Clinical Team Manager/Supervisor			
• Lead Consultant For Care			
Person identified to lead Significant Event Analysis			

Date _____

Manager's Signature _____

APPENDIX 4 - FORM 3

LOCAL INCIDENT REVIEW REPORT

Introduction (include Datix reference number)		
1. Contributors (Anonymised)	<i>Identify the individuals participating in the incident review. Assign all persons involved a coded reference e.g. Cons A which must be used throughout the report</i>	
2. Details the facilitation tools used in the SEA	<i>E.g. Fishbone Diagram, Five Whys, Tabular Timeline, Cause and Effect Chart, Brain Storming, Nominal Group Technique etc</i>	
3. Provide a factual account/summary of the incident and its consequences	<i>Include a synopsis of the incident, its consequences and the stage in the care process that it occurred. If incident spans over a number of days, where possible refer to these as Day 1, Day 2 etc</i>	
4. Identify the human and system factors which contributed to the incident.	Good Practice	Areas for Improvement
Patient		
Individual		
Task		
Equipment		
Team and Social Skills		
Working Conditions		

Communication		
5. Was the incident avoidable?	Yes	No
6. Give details of improvements to be made to reduce risk of incident recurring	By When?	By Whom?
7. Give details of how the learning (including good practice) will be shared across the organisation		
8. Give details of how improvements will be communicated to the patient, carer/significant other.		
9. Provide details of any media coverage relating to the incident		

Report led by: **Name** _____

Designation _____

Location _____

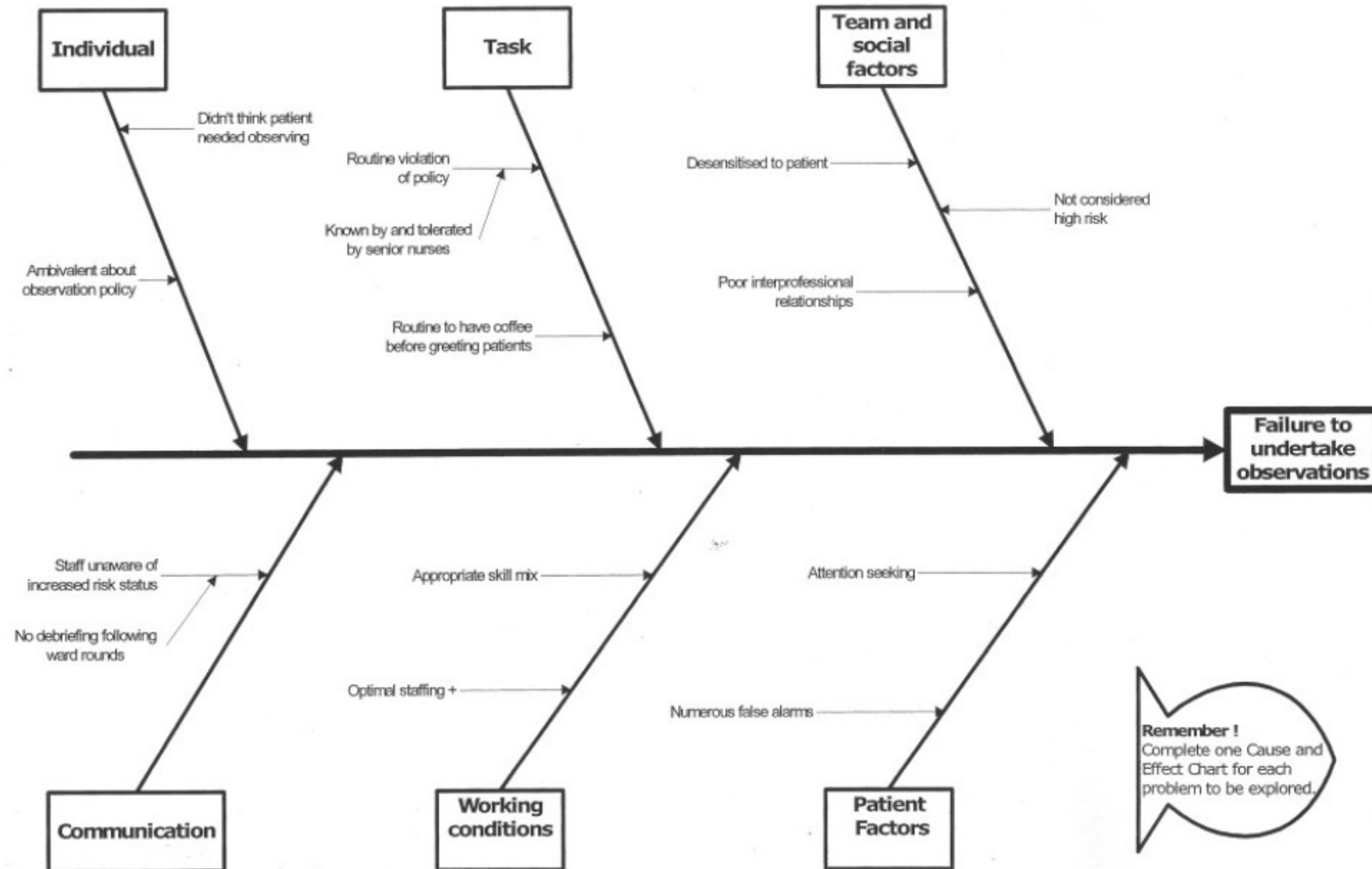
Persons Notified: _____

Date: _____

EXAMPLE OF TABULAR TIMELINE TEMPLATE

Event date and time				
Event				
Supplementary Information				
Good Practice				
Care Delivery/Service Delivery Problem				
Additional Information Required				
Areas for Improvement				

Worked example of causal analysis using the Fishbone diagram



SIGNIFICANT CLINICAL EVENT ANALYSIS (SCEA) REQUESTPlease complete Sections A and send request via email to: Tav-UHB.SCEATeam@nhs.net**Section A**

Patient Name/Incident Identifier	
Patient CHI:	
Adverse Incident/Complaint Reference Number:	
Brief Summary of Incident:	
Rationale for SCEA Request: (Please refer to Adverse Event Management Policy – Section 5.2)	

The following information <u>MUST</u> be provided <u>AT THE TIME OF REQUEST</u>	If Not Provided , please detail the reason
DATIX Incident Report	
Local Incident Review Report (inclusive of Staff Statements, Timeline and Action Plan)	
Relevant Copies of Case Notes/Letters	
Risk Assessments	
Copy of Care Plans	
Copy of Correspondence to NHS HIS (Suicide only)/	
Post Mortem Report/Procurator Fiscal Report	

Contact details for patient/family/carer:	Name	
	Address	
	Relationship	
Has contact previously been made with the patient/family/carer	Yes ☐	No ☐ Unknown ☐

Is this case subject to an ongoing <u>complaint</u>?:	Yes ☐	No ☐	Unknown ☐
Is this case subject to an ongoing <u>legal claim</u>?	Yes ☐	No ☐	Unknown ☐
Is the patient over 75 years of age?	Yes ☐	No ☐	Unknown ☐

Associate Nurse Director(s) Please ensure that AND(s) are invited to SCEA	Name:	
	Name:	

Associate Medical Director(s) Please ensure that AMD(s) are invited to SCEA	Name:	
	Name:	

General Manager of the Service (s) Please ensure that GM(s) are invited to SCEA	Name:	
	Name:	

General Practitioner of the Patient Please ensure that GP is invited to SCEA	Name:	
	Address:	

Section A Continued

Name of SCEA Requester:	
Designation of SCEA Requester:	
Date of Request:	

KEY PERSONNEL TO BE INVOLVED IN SCEA

[illegible]

Section B – Official use only

Section B – Official use only		
Clinical Risk Management Group:	Date:	
Agreement to hold SCEA Review (please tick)	Yes ☐	Terms of Reference to hold SCEA Review:
	No ☐	Reason for SCEA Review Refusal:

Panel Members:	Nurse Director/Associate Nurse Director Medical Director/Associate Medical Director Head of Clinical Governance and Risk Clinical Governance and Risk Team Leader Independent Reviewer(s) (<i>To be agreed at CRM Meeting</i>)
----------------	---

Family/Carer(s) to be contacted to arrange meeting pre-SCEA?	Yes ☐ No ☐ Name of person responsible: <i>(To be agreed at CRM Meeting)</i>
--	--

SCEA IDENTIFICATION NUMBER:	
-----------------------------	--

SCEA DATE, TIME & VENUE:	
--------------------------	--

SCEA CO-ORDINATOR:	
--------------------	--

LOCAL INCIDENT REVIEW REQUEST FORM

Please complete Sections A and send to: clinicalgovernanceriskdept.tayside@nhs.net

Section A

Patient Name/Incident Identifier	
Datix Incident Reference Number:	
Brief Summary of Incident:	
Local Review Date:	
Name of Requester:	
Designation of Requester:	
Scribe will be provided:	Yes ☐ No ☐ Why?.....
Date of Request:	

Section B

[illegible]

Clinical Governance & Risk Use Only

[illegible]



Significant Clinical Event Analysis Review Case ID:

Draft Version (Date)

HIGHLY CONFIDENTIAL

Commissioner(s) of the Report:

Nurse Director, NHS Tayside

Chair of the Report:

Nurse Director, NHS Tayside

Report Submission Date: Insert before submitting
--

REPORT INDEX	PAGE
1. INTRODUCTION-----	
2. CONTEXT OF THE REVIEW -----	
2.1 Terms of Reference -----	
2.2 Membership of Significant Adverse Event Review Team -----	
2.3 Methodology -----	
3. SUMMARY OF THE EVENT-----	
4. FINDINGS OF THE INVESTIGATION-----	
5. CONCLUSIONS-----	
6. ACTIONS-----	
APPENDICES -----	
Appendix 1 Significant Adverse Event Review Action Plan and Update Position -----	

INTRODUCTION

This Significant Clinical Event Analysis (SCEA), held on **Date** at **Time** hours in **Venue**, was requested to discuss **Brief Summary of Event**.

CONTEXT OF THE REVIEW

2.1 Terms of Reference

The aims of a significant clinical event analysis are:

- To establish the background and sequence of events that led up to the incident.
- To identify underlying contributing factors in management and organisational systems.
- To identify lessons learned and develop a list of recommendations that may prevent similar incidents occurring in the future.
- To communicate any findings and recommendations across the organisation including those individuals directly affected or involved.

***It is important to note** that whilst acknowledging the professional responsibility and accountability of all staff and departments involved in this incident, it is **NOT** the purpose of this report to apportion blame.*

This report has been compiled based on information obtained from the SCEA review and includes evidence from the case notes and the local incident review.

This report remains confidential and is not retained as part of the medical notes of the person involved.

Whilst family members have not been asked to attend this review, if there are any requests from family members to view the report produced from this review, an abbreviated report will be provided.

2.2 Membership of Significant Adverse Event Review Team

Panel

Staff

External Agency

In attendance

Apologies

2.3 **Methodology**

The Incident Report Form (IR1) raised on the ***date*** and pertinent Medical case notes and documentation in relation to ***Patient Reference*** care were circulated to the Review Group members for review prior to the SCEA Review being held.

SUMMARY OF THE EVENT

FINDINGS OF THE INVESTIGATION

CONCLUSIONS

ACTIONS

Responsible Person:

Timeframe:

Responsible Person:

Timeframe:

APPENDIX 1: SIGNIFICANT ADVERSE EVENT REVIEW ACTION PLAN AND UPDATE POSITION: REFERENCE

No.	Action	Responsible Officer(s)	Review Date	Measures of Implementation	Measures of Effectiveness	Position to Date	Status

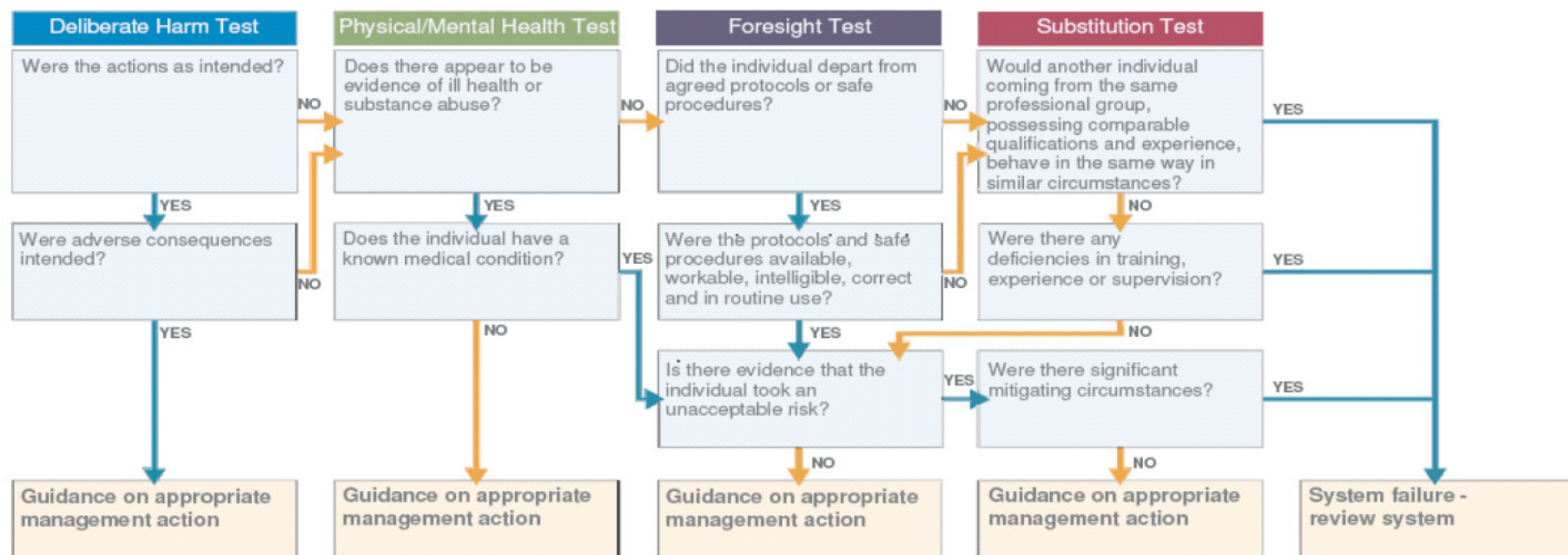
Appendix 2: Incident Report Form

Appendix 3: Local Event Review



Incident Decision Tree

National Patient Safety Agency



SIGNIFICANT EVENT ANALYSIS MANAGEMENT – DO’S AND DON’T’S

DO

In the event of an incident involving a patient, the incident should be noted in the patient case record and recorded in the electronic incident reporting system.
Share a full, frank and factual explanation with the patient as soon as practical after the incident occurs
Complete the electronic incident form within 24 hours of occurrence
Ensure that all narrative is and factual.
Complete any Standard Significant Event Analysis (SSEA) within 28 days of occurrence of the event
Verify incidents within 72 hours of receipt.
Escalate initial red incidents to Executive Team within 24 hours of verification
Refer any external enquiries to the Communications Team
Follow the advice given in section 7.3 in relation to the Release of Information

DO NOT

File a copy of the Incident Report or the Significant Event Analysis Report in the Patients Case Record
Name individuals as contributors in the Significant Event Analysis Report. However, a key should be retained as part of the incident file.
Release the final report until it has been proof read for accuracy and spelling by all involved in the review.

REFERENCES AND BIBLIOGRAPHY

Department of Health, 2000. *An Organisation With a Memory*. Crown Copyright: London

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National Patient Safety Agency 2003. *Root Cause Analysis Toolkit*. <http://www.npsa.nhs.uk> (accessed September 2011).

National Patient Safety Agency 2005¹. *Being open. Communicating patient safety incidents with patients and their carers*. <http://www.npsa.nhs.uk> (accessed September 2011).

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NHS Quality Improvement Scotland (2006) *Safer Today – Safer tomorrow Patient Safety Review of Incident and Near Miss Reporting*. NHS Quality Improvement Scotland. <http://www.nhshealthquality.org> (accessed September 2011)

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GLOSSARY OF TERMS

AO	Accountable Officer
CD	Controlled Drug/s
CQF	Clinical Quality Forum
CSM	Clinical Service Manager
DoH	Department of Health
GM	General Manager
HAI	Healthcare Acquired Infection
HFS	Health Facilities Scotland
HON	Head of Nursing
HSE	Health and Safety Executive
IR1	Incident Reporting Form
IT	Information Technology
JELS	Joint Equipment Loan Store
MHRA	Medicines and Healthcare Products Regulatory Agency
NPSA	National Patient Safety Agency
OHSAS	Occupational Health and Safety Advisory Service
RIDDOR	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995
SCEA	Significant Clinical Event Analysis
SEM	Significant Event Management
SIDCAAR	Self Inflicted Death in Custody: Audit, Analysis & Review
LIR	Local Incident Review

NHS TAYSIDE - POLICY APPROVAL CHECKLIST

This checklist must be completed and forwarded with policy to the appropriate forum/committee for approval.

POLICY AREA: Risk Management

POLICY TITLE: Significant Event Management (SEM)

LEAD OFFICER Arlene Napier, Head of Governance Safety and Risk

Why has this policy been developed?		To advise staff on the arrangements within the organisation for incident management.	
Has the policy been developed in accordance with or related to legislation? – Please give details of applicable legislation.		No – but developed to conform with Scottish Executive Recommendations & NHS QIS Clinical Governance & Risk Management Standards	
Has a risk control plan been developed? Who is the owner of the risk?		Yes. Safety, Governance and Risk Co-ordinator/Lead for Risk Management	
Who has been involved/consulted in the development of the policy?		Clinical Quality Forum. Improvement and Quality Committee. Information Governance. Nurse and Medical Director.	
Has The policy been assessed for Equality and diversity in relation to:-		Has the policy been assessed For Equality and Diversity not to disadvantage the following groups:-	
Race/Ethnicity Gender Age Religion/Faith Disability Sexual Orientation	Yes Yes Yes Yes Yes Yes	Minority Ethnic Communities (includes Gypsy/Travellers, Refugees & Asylum Seekers) Women and Men Religious & Faith Groups Disabled People Children and Young People Lesbian, Gay, Bisexual & Transgender Community	Yes Yes Yes Yes Yes Yes
Does the policy contain evidence of the Equality & Diversity Impact Assessment Process?		YES	
Is there an implementation plan?		YES	
Which officers are responsible for implementation?		Safety, Clinical Governance and Risk Department/Local Managers	
When will the policy take effect?		Replaces Adverse Incident Management Policy which has been in effect from 30 th November 2002	
Who must comply with the policy?		All Staff	
How will they be informed of their responsibilities?		Vital Signs and Implementation Plan	
Is any training required?		YES	
If yes, has any been arranged?		YES	
Are there any cost implications?		NO	
If yes, please detail costs and note source of funding		Not Applicable	
Who is responsible for auditing the implementation of the policy?		Safety, Governance and Risk Department	
What is the audit interval?		Annual	
Who will receive the audit reports?		Adverse Incident Management Group and Risk Management Groups	
When will the policy be reviewed and by whom? (please give designation)		May 2013 by Head of Governance, Safety & Risk	

Name: Arlene Napier

Date: May 2012

1. Rapid Impact Checklist (RIC)

Each policy must include a completed and signed template of assessment

Which groups of the population do you think will be affected by this proposal? • minority ethnic people (incl. gypsy/travellers, refugees & asylum seekers) • women and men • people in religious/faith groups • disabled people • older people, children and young people • lesbian, gay, bisexual and transgender people • people of low income • people with mental health problems • homeless people • people involved in criminal justice system • staff Other Groups: ALL GROUPS	
N.B. The word proposal is used below as shorthand for any policy, procedure, strategy or proposal that might be assessed.	
What impact will the proposal have on lifestyles? For example, will the changes affect: • Diet and nutrition? • Exercise and physical activity? • Substance use: tobacco, alcohol or drugs? • Risk taking behaviour? • Education and learning, or skills?	What positive and negative impacts do you think there may be? Which groups will be affected by these impacts? Risk Taking behaviour will be positively effected. By analysing risks, near misses and incidents looking at potential risk exposure ratings and the Incident Review process, learning from experience can take place and shared throughout NHS Tayside. This will in-turn will have a positive impact on the safety of patients and staff.
Will the proposal have any impact on the social environment? Things that might be affected include • Social status • Employment (paid or unpaid) • Social/family support • Stress • Income	The Incident Review process is designed to be a positive experience for all concerned, thereby reducing stress caused by incidents or near misses.
Will the proposal have any impact on • Discrimination? • Equality of opportunity? • Relations between groups?	No Impact
Will the proposal have an impact on the physical environment? For example, will there be impacts on: • Living conditions? • Working conditions? • Accidental injuries or public safety? • Transmission of infectious disease?	Positive impact, as reporting of incidents, incident review and learning from experience will promote a safer physical environment for staff and patients.
Will the proposal affect access to and experience of services? For example, • Health care • Transport • Social services • Housing services • Education	No

Rapid Impact Checklist (RIC): Summary Sheet Each policy must include a completed and signed template of assessment	
1. Positive Impacts (Note the groups affected) All groups will experience a positive impact: Risk Taking behaviour will be positively effected. By analysing risks, near misses and incidents looking at potential risk exposure ratings and the Incident Review process, learning from experience can take place and shared throughout NHS Tayside. This will in-turn will have a positive impact on the safety of patients and staff. The Incident Review process is designed to be a positive experience for all concerned, thereby reducing stress caused by incidents or near misses Reporting of incidents, incident review and learning from experience will promote a safer physical environment for staff and patients.	2. Negative Impacts (Note the groups affected) None identified. AIM Policy provides all groups with guidance on incident reporting.
3. Additional Information and Evidence Required None	
4. Recommendations None	
5. From the outcome of the RIC, have negative impacts been identified for race or other equality groups? Has a full EQIA process been recommended? If not, why not? Not recommended as no adverse impacts identified.	

Manager's Signature: Arlene Napier, Acting Head of Safety, Governance and Risk
 Date: May 2011