

Managing and Sharing Concerns

1. Introduction

In order to ensure the safer management of controlled drugs (CDs) in accordance with The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, and best practice, it is necessary to share information, including personal information, with other Designated Bodies¹ and Responsible Bodies² working within the Local Intelligence Network (LIN). The information or concern that you will consider sharing will have arisen from intelligence received or evidence obtained relating to the management and use of controlled drugs both within and outside your organisation.

Each organisation must have robust governance systems in place to ensure that the sharing of personal data (as defined by the Data Protection Act 1998), both internally and externally is in compliance with the legislative framework for information sharing.

2. What is a concern?

A concern could be something which has been reported or picked up by, for example:

- Routine monitoring
- Incident reporting systems
- Complaints
- Police intelligence
- Word of mouth
- Email, mail or fax
- Read or heard through the media

Some information can be considered as 'soft' information; "soft" information is a statement of concern about an identifiable healthcare professional which has not been articulated as a formal complaint or as part of a formal process such as the summary record of an appraisal interview.

Health and social care organisations should always take seriously – and act on – any soft information which, if true, implies a threat to patient/client safety. However, it is important that information on 'soft' concerns is tested for reasonableness. Such assessment will require some level of judgement about the degree of confidence in the information provided and an assessment of 'weight' of the information provided. An assessment of reasonableness will rely to a certain extent on the skill and experience of the senior health and social care professional to whom the concern is identified. Such information, while not having been obtained through formal routes should, nevertheless, be taken seriously, recorded and thoroughly investigated.

Where this information relates to controlled drugs the Accountable Officer will need to ensure that robust systems are in place to enable concerns to be raised, to log these concerns, to be alerted where appropriate and to initiate investigations (Regulations 15 and 16).

¹ Reg 3 of The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 prescribes the following as Designated Bodies: Regional Board, a HSC Trust, Northern Ireland Ambulance Services and Independent Hospitals

² Reg 22 of The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 identifies the following as Responsible Bodies: Designated Bodies, the Department, RQIA, RBSO, Police and a Regulatory Body

Wherever possible, established mechanisms for identifying and managing concerns about performance such as clinical governance and performance review, complaints and adverse incident reporting should be used.

3. Raising Concerns

To ensure that the opportunities to raise concerns are optimised organisations should ensure that mechanisms such as those listed below work effectively

- the complaints system - is this sensitive enough to identify and prioritise complaints relating to the performance, conduct or health of individual healthcare professionals?
- confidential arrangements – do these enable healthcare professionals and other colleagues, trainees or employers/employees to raise concerns about the performance, conduct or health of a colleague? Organisations should have a written policy³ which should include the option of raising concerns with a responsible person outside the normal work setting or line of command.
- systems for reporting patient safety incidents (errors leading to actual patient harm or 'near misses') and for analysing their 'root cause' in order to draw lessons to minimise the risk of recurrence in the future.
- monitoring routine indicators of service quality – are these adequate to draw attention to any clusters or trends which might give cause for concern?
- arrangements for objective investigation of any complaints or concerns relating to relevant persons.

For those individuals who have raised concerns, clear explanation of the processes involved should be provided at the outset and should be kept informed in broad terms about the progress of the investigation and in particular about its final outcome, e.g. whether the health/social care professional has been referred to the national regulator or made subject to local restrictions on practice.

Concerns should be treated with due seriousness and appropriately clarified and investigated as with formal complaints. Consideration must be given to informing the relevant person of concerns raised in relation to them at an appropriate time.

4. Investigating Concerns

Where concerns are serious, if for example patient safety is at risk or the professional's fitness to practise may be impaired, the concern(s) should be passed on to the appropriate Responsible Body at the earliest opportunity. Where concerns appear to be minor, further local investigation may be more appropriate.

Each healthcare organisation should draw up clear policies for local investigation in partnership with all stakeholders, signed off at board level. This should include an initial assessment of whether the case can be handled internally or should be referred externally to an appropriate Responsible Body; and whether there are any underlying health issues for the healthcare professional or systems issues for the organisation.

All decisions must be based on the best available evidence and thorough records must be kept.

³ HSC organisations are required to have Whistleblowing policies in place to meet the requirements of the Public Interest Disclosure (Northern Ireland) Order 1998.

5. Sharing Information

Confidence in Care “Guidance on Information Sharing to Support Tackling Concerns” set out some broad principles in respect of sharing information between organisations as follows:

The key principle is that a healthcare organisation, before sharing information or seeking information from another organisation, should apply the following general tests:

- i Is it possible that the information, once fully investigated, could indicate that the health/social care worker is likely to pose a risk to patients/clients or the general public?
- ii Does the information come from a source which the organisation has reason to believe is reliable, and/or which is supported by other information in the organisation’s possession?

(Note that these are essentially the same tests that a prudent organisation might reasonably apply in deciding whether to invoke their disciplinary procedure / take precautionary action within its own power, e.g. suspension of the health/social care worker or enhanced supervision or monitoring.)

Tests before sharing information

- iii Are there any other organisations which could also take action to reduce the risk to patients/clients from the health/social care worker in question?

Tests before seeking information

- iv Are there any other organisations which might have information which will help the health/social care organisation to investigate the original concern and take with greater certainty whatever action is needed to protect patients/clients and (where possible) to help the health/social care worker to remedy any weaknesses

These tests are most likely to be fulfilled when a healthcare professional is working simultaneously for two or more healthcare organisations (for instance, a GP who is also employed by an out of hours agency, or a nurse who also works for an agency). Slightly different considerations apply when a healthcare organisation becomes aware that one of its healthcare professionals is seeking to move to a new organisation. In these circumstances the guidance recommends that:-

The broad nature of the concern (not necessarily the details) should be disclosed if there is judged to be a sufficient risk to patients/clients to require placing special conditions on the professional’s practice or particularly close monitoring or supervision. If however it is judged that there is no immediate threat to patient/client safety, but there is a note on file about the concern in case similar concerns are raised in future, it is recommended that this information should not be shared at this stage.

Once the appointment process has been completed all the relevant clinical and social care governance information in its possession should be transferred to the new organisation. The health/social care professional should be made aware of the information being transferred and given the opportunity to add their comments to the record transferred.

6. Legal basis for data exchange

Each Responsible Body should be able to identify their lawful basis to exchange this data. This lawful basis may come from common law, statute or legal precedence, which may be supported by Home Office guidance, professional/executive bodies, e.g. the Department, Association of Chief Police Officers, Dept of Education, etc. This will enable partners to defend a challenge with regard to the Data Protection Act 1998 and/or the Human Rights Act 1998.

Relevant laws governing & enabling the sharing of personal data under this agreement. Please note that this is not a definitive list

Legislation	Relevant Section	Relevance
Data Protection Act 1998	s.35(1)	Personal data can be shared where an enactment requires disclosure. Regulation 25(8) of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 provides a statutory requirement to disclose personal data to certain specified bodies ⁴ for the safer management of controlled drugs.
Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009	Reg. 25	Duty to co-operate by disclosing information as regards relevant persons for the safer management of controlled drugs
The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009	Reg. 26	Power to request additional information from other Responsible Bodies for the safer management of controlled drugs
The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009	Reg. 30	Duty to make recommendations as to actions relating to the management of controlled drugs for the protection of patient safety or the safety of general public
Common Law Duty of Confidentiality	Public Interest	The public interest criteria includes (but is not limited to): <ul style="list-style-type: none"> • the administration of justice; • maintaining public safety; • the apprehension of offenders; • the prevention of Crime and Disorder; • the detection of Crime; and the protection of vulnerable members of the community.

⁴ The specified bodies include a designated body, Department, RQIA, RBSO, Police and a Regulatory Body.

Data Protection Act 1998

The purpose of the Act is to prevent personal information being used for purposes other than that for which it has been collected. Personal data can, however, be shared where an enactment requires disclosure. Regulation 25(8) of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 provides a statutory requirement to disclose personal data to certain specified bodies⁵ for the safer management of controlled drugs.

Human Rights Act 1998

Under the European Convention of Human Rights, every individual has the right to respect for his private and family life, his home and his correspondence. (Article 8). There should be no interference with this right by a public authority unless it is in accordance with the law and necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

Common Law Duty of Confidentiality

Patients' personal data are protected by the common law duty of confidentiality. This duty requires that confidential data may only be disclosed:

- with the consent of the individual to whom the information relates; OR
- if it is a legal requirement (eg required by a court order, Act of Parliament); OR
- if it is in the public interest (ie where the public interest in the specific circumstances of a case outweighs the individual's right to privacy).

Principle Exemption

The common law requires that information may not lawfully be disclosed when given in certain circumstances of confidentiality.

Disclosure may breach confidentiality where the information:-

- has a 'quality of confidence' ie should not already be in the public domain and has sensitivity and value
- is given in circumstances given rise to an 'obligation of confidence' on the part of the person to whom the information has been given eg the clinician
- is used in a way that was not authorised.

The duty of confidentiality is not absolute and should not be a bar to information sharing.

Disclosure can be justified if:-

- the information was not confidential in nature
- the person to whom the duty is owed has consented to the disclosure
- there is an overriding public interest in disclosing
- disclosure is required by a court order or other legal obligation.

Information held in confidence can still be disclosed without the individual's consent, where it can be demonstrated that:

- it needs to be shared by law
- it is needed to prevent, detect or prosecute crime
- there is a public interest
- there is a risk of death or harm

⁵ The specified bodies include a designated body, Department, RQIA, RBSO, Police and a Regulatory Body.

- there is a public health interest
- it is in the interests of the person's health
- it is in the interests of the person concerned

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 impose a duty on Responsible Bodies (as defined in the regulations) to co-operate by disclosing information as regards relevant persons (as defined in the regulations).

7. Purposes for which data is shared

Responsible Bodies may share identifiable personal data for the purposes of:

- Identifying cases in which action may need to be taken in respect of matters arising in relation to the management or use of controlled drugs by a relevant person
- Considering of issues relating to the taking of action in respect of such matters
- Taking action in respect of such matters

8. Information to be shared

Identifiable personal data of, and other information relating to, 'relevant persons' (as defined below) may be shared with appropriate members of the LIN for the purposes identified above and in accordance with Regulations 25 and 26 of The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.

The following information is the identifiable personal data of 'relevant persons' that may be disclosed by an organisation with other members of the LIN for the purposes identified above:

- Name
- Work Address (town)
- Home Address (town)
- Professional Registration number
- Date of birth

Not all information will be shared on all occasions.

Patient information will not be shared or disclosed without the consent of the patient unless it is not reasonably considered practical to do so e.g. where it would jeopardise an investigation. Patient information should only be held and shared if it relates to a problem with a practitioner or member of staff and is part of the evidence.

The Local Intelligence Network is currently chaired by the Department. All Occurrence Reports and details of relevant persons supplied to and distributed by the LIN is the responsibility of the Department and the Department is the Data Controller for this information for the purposes detailed above.

9. Disclosure of information to another Responsible Body

Responsible Bodies must also keep a record (either paper or electronic) of any requests received from another Responsible Body to disclose information, details of the nature of the information disclosed, details of the Responsible Body to which the information was disclosed and any other details considered to be relevant (Regulation 28).

10. Limitations to sharing/ disclosing information

Disclosures must only be made by or to the Accountable Officer or to a designated person in the Accountable Officer's staff.

No information will be shared where disclosure of the information would:

- prejudice or would be likely to prejudice an investigation being conducted by a Responsible Body, or
- prejudice or would be likely to prejudice any civil or criminal proceedings, or
- involve disproportionate cost

Patient information

Any information or data that relates to or can identify a patient will be removed where that information is not required for the purposes of identifying cases in which action may need to be taken in respect of matters arising in relation to the management or use of controlled drugs by a relevant person, or for considering or taking action in such a case.

Consent to disclose patient information

Where a Responsible Body is unable to remove any information or data that relates to or can identify a patient, or where it considers it necessary to disclose information which contains the confidential information that relates to and can identify a patient, consent of the patient must be sought unless it is not practicable to do so.

11. Processing of information

In accordance with the legislation Accountable Officers submit Occurrence Reports quarterly to the Chair of the Local Intelligence Network. Two weeks after the submission date the Local Intelligence Network meets and Occurrence Reports are shared with Responsible Bodies at this meeting and through subsequent minutes of the meeting.

Accountable Officers are required to ensure appropriate arrangements are in place within their organisation to:

- refer concerns that relate to controlled drug matters to a regulatory body
- refer concerns that relate to controlled drug matters to police
- in a case of possible fraud, refer the concerns to the Counter Fraud Unit of the Business Services Organisation.
- Ensuring that information shared within the Local Intelligence Network is appropriately managed within their organisation

(See The Code of Practice on Protecting the Confidentiality of Service User Information <http://www.dhsspsni.gov.uk/confidentiality-code-of-practice0109.pdf>)

12. Access, Storage, Retention and Security of Personal information

Information must be shared in a secure manner whether in person, by telephone, email, post or fax. Information must only be shared through encrypted email or by following safe-haven procedures.

'Safe Haven' is a term used to explain an agreed set of arrangements that are in place in an organisation to ensure confidential person identifiable information (e.g. patients and staff information) can be communicated safely and securely, whether this is by facsimile (fax), e-mail, post or other means

Information must not be shared with persons who are not required to be in possession of it.

Organisations receiving shared information must:

- ensure that their employees are able to access only the shared information necessary for their role
- ensure that their employees are appropriately trained so that they understand their responsibilities for confidentiality and privacy
- protect the physical security of the shared information

Information in the Department will be stored on a secure database which has access controls in place.

Retention of Records

The Chair of the LIN will retain paper records for 5 years and electronic records will be retained in accordance with Departmental guidelines.

Storage and Security

When information is disclosed it must be stored securely at all times by the recipient and destroyed when it is no longer required for the purpose for which it was provided

Each Responsible Body will ensure that they have mechanisms in place to enable them to address the issues of physical security of data, as well as undertaking training and raising staff awareness.

Each Responsible Body must take all reasonable care to safeguard and protect both the physical securities of information technology and the data contained within them.

All personal information systems must be effectively password protected and users must not divulge their password or leave systems active whilst absent from their workstations.

Off site working

Personal information, which is taken off site, must be protected in a secure manner according to good practice guidelines within the Responsible Body.

14. Guidance on Investigating Controlled Drugs Concerns

Guidance on investigating patient safety incidents involving unexpected death or serious untoward harm, and liaising between HPSS organisations, the Police Service of Northern Ireland and the Health and Safety Executive is available⁶.

Organisations must ensure that investigations, including interviews, are conducted appropriately.

Care should be taken to ensure that any evidence collected during the course of an investigation is preserved in an appropriate manner to ensure its integrity in case it is required at a later stage for proceedings instituted by the police, other enforcement agencies and/or regulatory bodies. In such circumstances, it is strongly recommended that early advice be sought from the police or another appropriate enforcement authority.

It will be an organisation's decision if they wish to make a formal complaint to the police. Criminal investigations will usually take precedence over other investigations. Organisations must, however, be aware that undue delay may constitute a potential 'Abuse of Process' which could be a challenge put forward at any subsequent court proceedings.

Accountable Officers should ensure that there is a clear separation between investigating and decision-making.

Well-founded concerns

There may be occasions where well-founded concerns come to light, either initially or through further investigation of a minor concern.

Depending on the nature of the well-founded concern, various options may apply (Regulation 17):

- Appropriate action to protect patients
- Requesting additional advice, support, mentoring or training
- Implementation of a serious adverse incident⁷ procedure
- Referral to a regulatory body, police or, if fraud is suspected, CFU
- Sharing or requesting information from other members of the network
- Requesting an incident panel be convened

Appropriate action may also include invoking the organisation's disciplinary procedure.

⁶ http://www.dhsspsni.gov.uk/mou_investigating_patient_or_client_safety_incidents.pdf "Promoting liaison and effective communications between the Health and Personal Social Services, Police Service of Northern Ireland, Coroners Service, and the Health and Safety Executive for Northern Ireland" February 2006.

⁷ The definition of a serious adverse incident in the context of Health and Social Services is: "*any event or circumstance arising during the course of the business of a health and social organisation, special agency or commissioned service that led, or could have led, to serious unintended or unexpected harm, loss or damage*".

Immediate action to protect patients

If patient safety is thought to be at risk, immediate action should be taken. Health and Social Care bodies should follow their local adverse incident procedures. In addition to this all organisations should consider if, on assessment of the degree of risk, the concern should be referred for the purpose of the issue of an alert letter. Prompt referral to the relevant regulatory body should be considered where there are well-founded concerns about an individual's fitness to practise.

Incident Panels

An Accountable Officer may request the Chair of the LIN to convene an Incident Panel to investigate a concern and make recommendations. The individual membership would depend on local circumstances and the nature of the concern but should include key members of the local network. The police would normally expect to be involved at this stage if they have not been previously.

Inspection

An Accountable Officer may decide to carry out an inspection of premises as part of their monitoring arrangements, as a direct result of a concern or following an Incident Panel. The inspection could be undertaken by any body with the power to inspect the management of controlled drugs: the Designated Body, the Department, RQIA, Police or a mixture of the above. The Health Act gives powers of entry and inspection to examine the arrangements for the safe management of controlled drugs to nominated groups, such as the police and Accountable Officers. Information-sharing between organisations will be necessary. Depending on the nature of the concern, inspection teams involving members of different organisations may be helpful to bring expertise and knowledge together.

Remedial actions: dealing at local level

Many concerns can be rectified at local level. Examples may be a 'false positive' where an apparent prescribing anomaly is due to the caseload of a particular prescriber. In other cases, a minor lapse may be put right locally, where for example an organisation's storage arrangements for controlled drugs could be improved. If there is a minor concern about a healthcare professional's performance, they may require support or training. Additional visits from a prescribing adviser or clinical governance lead may be sufficient to rectify any minor issues (see Regulation 17(2)).

15. Remedial actions: escalating concerns

However there may be cases where concerns can not be resolved satisfactorily at local level and need to be formally escalated or passed on to another organisation.

The NPSA incident decision tree offers help and support in deciding how to pass on issues. The table summarises where issues should normally be referred. There may well be occasions where a concern should be passed to more than one organisation.

Concern	Refer to:
Criminality suspected	Police
Fraud/ Theft suspected	Counter-Fraud Unit BSO and police
Individual fitness to practise issue	Professional regulatory body, or Local Supervising Authority Midwifery Officer for midwives
Organisational/systems issue	Regulatory body, RQIA (in case of an HSC Trust or any person registered with RQIA that provides healthcare).

16. Support for healthcare professionals

Individuals raising concerns should be supported in doing so. Free and confidential advice on how to raise a concern and the protections provided by the Public Interest Disclosure Act can be obtained from Public Concern at Work (an independent organisation on public interest whistleblowing)⁸. Regulatory bodies may also be able to provide advice.

Individuals should also be supported where concerns are raised about them, or where they wish to raise concerns about their own performance. The NCAS toolkit and maintaining high professional standards in the modern NHS provide some advice on supporting professionals and covers matters such as:⁹

- Managing
- Developing
- Alerting
- Supporting
- Documenting
- Investigating
- Rebuilding
- Disciplining

17. Closure of cases

Cases considered by an Accountable Officer or a Responsible Body should be recorded with a clear account of the findings and any action taken (regulation 28). Accountable Officers must ensure that in respect of concerns raised by them any new evidence or information which comes to light, including the outcome of any proceedings by the police, the civil courts, regulatory body, disciplinary proceedings as appropriate which confirms that concerns no longer exist must share this information with Responsible Bodies and the Chair of the LIN. Each organisation is responsible for ensuring that the record of concern is revoked within their organisation and all appropriate bodies or persons notified.

Where there has been serious systems failure, the inspecting/investigating body will wish to return to check that appropriate action has been taken.

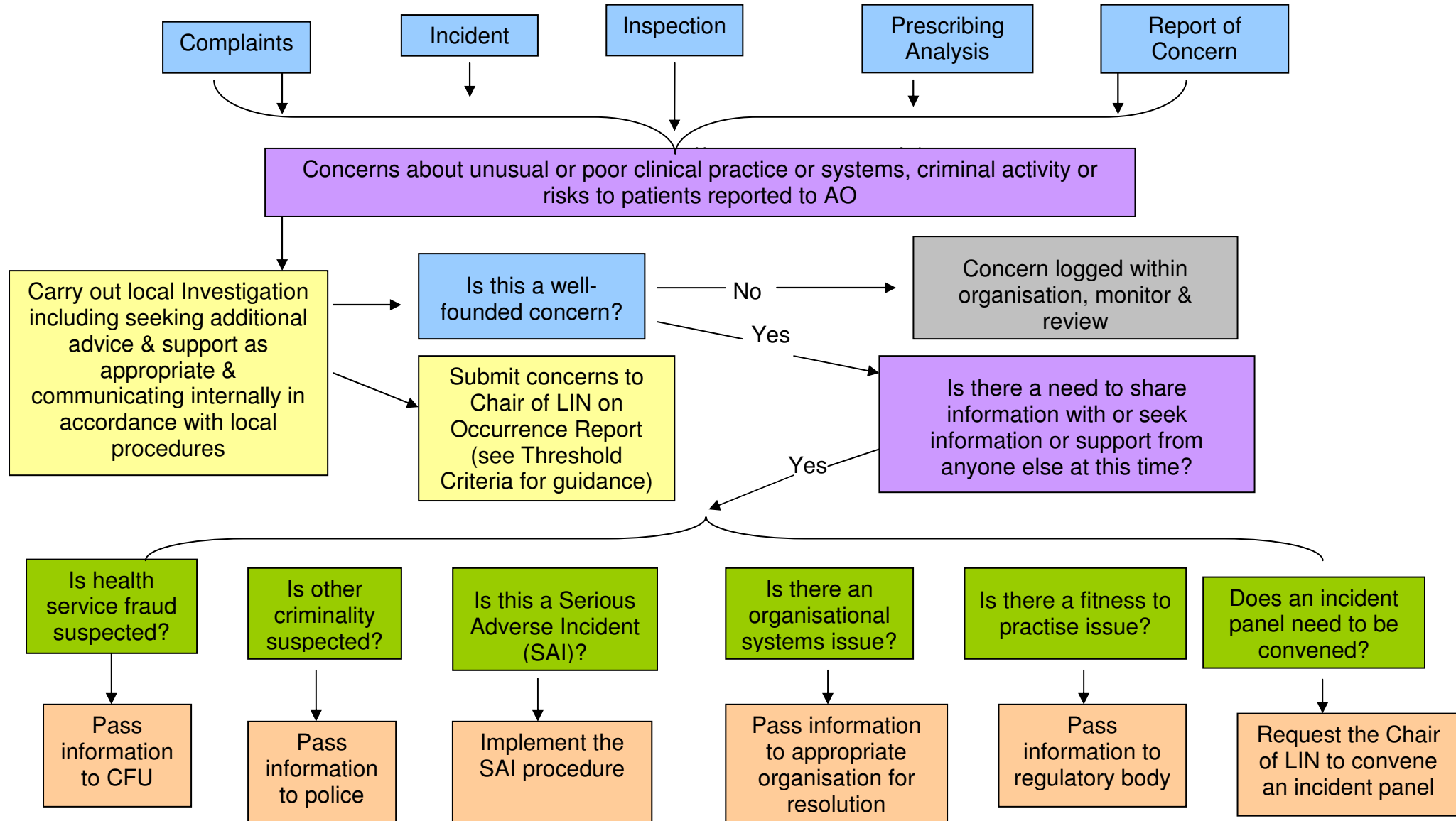
Learning points following investigations should be shared with other Responsible Bodies at the LIN. Where learning points are applicable to other administrations, these should be shared through the Cross Border Intelligence Group.

Reports containing information about the storage and movement of controlled drugs should not normally be disclosable under Freedom of Information legislation as they could aid criminal activity and so would come within the “law enforcement” exemption.

⁸ <http://www.pcaw.co.uk/> or telephone 020 7404 6609

⁹ See <http://www.ncas.npsa.nhs.uk/toolkit/toolkit/>

Investigating CD Concerns



Guidance on threshold criteria for reporting concerns on an Occurrence Report

Regulation 29 of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 requires all Accountable Officers to submit a quarterly Occurrence Report to the chair of the Local Intelligence Network (LIN).

The legislation however does not prescribe the type of concern or the level of detail that should be included in the Occurrence Report (OR).

This guidance has been prepared following a review of the concerns that have been recorded on ORs relating to the period from 1 October 2009 to 30 April 2010. The purpose of this guidance is to support Accountable Officers (AOs) in deciding whether a concern should be written in an Occurrence Report and shared at the LIN.

It must be emphasised that this document is for guidance only and it is for each AO to decide whether or not a concern is reported in an OR and subsequently shared at the LIN.

The AO has responsibility within their Designated Body for the safer management and use of controlled drugs which includes reporting concerns. It may be that an AO elects to err on the side of caution and reports matters which fall into the “No suspicion at present” and this is their prerogative.

As part of the review of the ORs, it was noted that some concerns are described with little detail and insufficient information to form a clear understanding of the exact nature of the concern. As Occurrence Reports are now attached to the Minutes, it is important that each OR is comprehensively and unambiguously completed to facilitate other AOs and Responsible Bodies to understand the concern.

Three categories of concern have been developed

- No suspicion at present
- Suspicion - not confirmed
- Suspicion – confirmed

No suspicion at present (not reported)

These would be matters that have either been successfully resolved or where incidents have been noted that appear to be one off matters, with no other associated concerns. All incidents in this section should be kept under review by the AO, and if further concerns are raised regarding a similar matter, the situation should be reviewed and where appropriate reported in the next quarterly occurrence report.

There may however be important learning points from these incidents which would be useful to other LIN attendees. These learning points should be included on the OR.

Suspicion - not confirmed (to be reported on OR)

These would be matters where concerns have been raised but the investigation is still ongoing/ the quantities are substantial but no individual has been identified.

Suspicion – confirmed (to be reported on OR)

These would be matters where concerns have been raised and an individual has been identified.

Examples of categories

No suspicion at present (not reported)
Any concern about a controlled drug where, in the opinion of the AO, there was no intent on the part of the relevant person to mislead/misuse controlled drugs e.g. a single incident of a nurse independent prescriber prescribing outside her scope of practice, a controlled drug being delivered to the incorrect patient address, failure to record the administration of a controlled drug, incorrect storage of a controlled drug.
Discrepancy of a small quantity of controlled drug in a ward register. One off incident.
Isolated overage/underage of controlled drug liquid where no other concerns or suspicions have been raised.
Loss of CD keys where it is a single occurrence and no other concerns are raised regarding individuals or system weaknesses and the stock is untouched/correct
Suspicion - not confirmed (to be reported on OR)
Missing quantities of controlled drugs on four separate wards. Investigation ongoing but no definite outcome.
Loss of one box of fentanyl injection where a patient was transferred from hospital to their home and the community pharmacist contacted the hospital the next day to say that the patient had been discharged with insufficient fentanyl injections.
Ordering of controlled drugs by a nurse on a ward requisition over a period of time where the ward does not use the ordered controlled drug. Investigation ongoing as nurse on sick leave.
Any unexplained high use of a controlled drug. Even if usage has reduced, the reduction may be as a result of the concern being brought to the attention of staff members.
Suspicion – confirmed (to be reported on OR)
Where a member of staff had admitted misusing controlled drugs (includes theft and abuse).
Where a member of staff is under supervision or prescribing restrictions in relation to controlled drugs.

This guidance shall be reviewed at least every 2 years.

Review Date: December 2012