E-mail Message

From:	Rodgers, Catherine [EX:/O=NIGOV/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1398393]
To:	Dillon, Anne [EX:/O=NIGOV/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Ihrdadillon]
Cc:	Conlon, Bernie (IHRD) [EX:/O=NIGOV/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1318908]
Sent:	01/03/2013 at 16:26
Received:	01/03/2013 at 16:27
Subject:	Request for Departmental papers dated 15 February 2013 re SAIs
Attachments:	microsoft_word_-_hss__sqsd__18-07_lookback_guidance.pdf microsoft_word_-_hss__sqsd__18-07_patient_service_review_guidelines_-_fi....pdf hsc__sqsd__34-07.pdf hsc_sqsd__34-07_guidance.pdf

Anne

Please find attached copies of guidance on conducting patient service reviews/look back exercises. I am instructed that these documents relate to the documents previously provided to the Inquiry on the SAI process.

Should you require any further details please do not hesitate to contact me.

Kind regards

Catherine

Safety, Quality & Standards Directorate

Department of
Health, Social Services and Public Safety

An Roinn
Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

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Your Ref:
Our Ref: HSS(SQSD) 18/2007
Date: 08 March 2007

Chief Executives, HSS Boards:
For cascade to –
- Directors of Public Health
- Chief Nursing Officers
- Directors of Social Services
- Directors of Pharmaceutical Services
- Directors of Primary Care
- Directors of Dental Services

Chief Executives, HSS Trusts (existing & new):
For cascade to –
- Medical Directors
- Directors of Nursing
- Directors of Pharmacy
- Directors of Social Care

Chief Executive Designate, Health & Social Services Authority
Chief Executives, HSS Agencies
General Medical, Community Pharmacy
General Dental & Ophthalmic Practices

Dear Colleagues

Conducting Patient Service Reviews/Lookback Exercises

A number of Patient Service Reviews have had to be conducted in recent years, most notably the review of endoscopes in 2004 and the review of breast screening in 2005.

Following these events the HPSS Regional Governance Network recognised the need to share the learning from these exercises and established a subgroup to develop guidance based on the experience of members.

The subgroup has now produced *A Practical Guide to Conducting Patient Service Reviews or Look Back Exercises*.

The subgroup members have harnessed their collective experience to advise on:

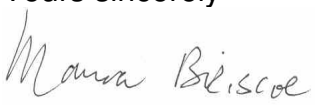
- Initiating a service review;
- Initial planning;
- Establishing patient helplines (staffing, training, record keeping and location);
- Establishing a patient database;

- The role of the Service Review Team; and
- The process of the Review (including sample documentation).

This is a fine example of the HPSS sharing best practice and I commend the Guide to you as an extremely useful source of reference material should the need for such an exercise occur in the future.

I would also like to thank the HPSS Regional Governance Network and, particularly the subgroup members, for their efforts and commitment in producing this Practical Guide.

Yours sincerely



Maura Briscoe
Safety, Quality and Standards Directorate
Office of the Chief Medical Officer

cc. Chief Executive, Regulation & Quality Improvement Authority
Chief Executive, Health Estates Agency
Chief Officers, HSS Councils
Chief Executive, NI Social Care Council
Chief Executive, NI Practice & Education Council
Chief Executive, NI Medical & Dental Training Agency
Chief Executive, Mental Health Commission
Director, NI Centre for Post Graduate Pharmaceutical Education and Training
Sub-Group members
Risk Managers/CSCG Leads
CSCG Support Team, Director
Regional Governance Adviser
Chief Professional Officers- DHSSPS
Policy Directorate leads- Primary, Secondary Care and Social Policy Group

A PRACTICAL GUIDE TO CONDUCTING PATIENT SERVICE REVIEWS OR LOOK BACK EXERCISES

REGIONAL GOVERNANCE NETWORK
NORTHERN IRELAND SUB GROUP

February 2007

Index

Introduction

A number of patient reviews have taken place in Northern Ireland in recent years, including the review of contaminated endoscopes in 2004 and Breast Radiology review in 2005.

Trusts involved in these reviews felt there was benefit in sharing experiences and offering a practical guide for others who may need to take part in similar exercises in the future. This guide does not offer an in-depth dialogue into this area, however suggests the practical steps that might be considered by future review teams in facing comparable circumstances.

1.0 What or Who initiates a service review or look back exercise?

1.1 The decision that an exercise is required usually occurs by chance after a patient or staff member has reported concerns about a healthcare worker or the healthcare environment. It may be that a healthcare worker is found to be infected and is involved in exposure-prone procedures which place patients at risk.

1.2 It may be that equipment is found to be faulty or contaminated and there is the potential that patients may have been placed at unacceptable risk.

1.3 Another healthcare worker may feel that he/she must report or whistleblow on a colleague who is placing unnecessary risk to patients as a result of clinical incompetence or outdated practice.

1.4 The decision to conduct a look back exercise will be taken by the Health & Social Services Board /Health & Social Services Authority (HSSA) and Department of Health, Social Services and Public Safety (DHSSPS). There may be occasions when the Trust initiates a look back review and it is undertaken internally. Look back reviews would, by their nature, be reported as a serious adverse incident to the relevant authorities.

1.5 Once a decision is taken to conduct a look back exercise a series of high level meetings with the Trusts involved and HSS Board/HSSA and DHSSPS will be convened to plan the nature and scope of the review.

1.6 While the public will need to be reassured that every effort is being made to conduct a full and thorough review, it is essential that the health care worker is protected and supported during this time. He/she needs to be kept fully informed at all times during the exercise. Support from a peer and counselling should be offered by the employer. This is particularly important during the early stages of the look back exercise when there will be intense media interest. One point of contact, such as the Director of Human Resources should be identified to lead on this aspect throughout the process.

1.7 It is vital to advise the Communications Manager at an early stage so that proactive or reactive media responses can be prepared.

2.0 Initial Planning

2.1 An incident planning meeting needs to be convened as soon as possible after the disclosure of the issue of concern. If the issue straddles a number

of organisations, it may be necessary for the HSS Board/HSSA to convene the meeting with senior officers from each organisation. This will usually include the Chief Executive, Executive Directors of Medicine and Nursing, Director of Public Health, Head of Division or speciality concerned and Public Relations lead. It would also be important to include the appropriate professional lead should the review involve a specific speciality or professional grouping.

It would also be advisable to convene an expert group at this stage who would develop the evidence base for the scope or limits of the recall. There needs to be clarity on the level of risk so to minimise unnecessary public anxiety by agreeing the at risk population.

2.2 The purpose of the meetings will be to co-ordinate and steer the process and ensure a regional approach to conducting the exercise. Meetings will usually need to take place daily at this level in the initial stages. A clear agenda with concise minutes are essential so that everyone is fully conversant with what action is required. Meetings should be time limited so that Trust staff have time to return to the front line and implement the review process.

2.3 Background briefing papers should be prepared by the HSS Board/HSSA to ensure that a consistent and clear message is being cascaded through the service. These may then be used by Trusts to brief staff at base.

2.4 Scheduling of the Look Back needs to be agreed, as does the launch of the press release and handling of Public Relations. Ideally one individual should co-ordinate all PR on behalf of the service and agree when and who is interviewed.

2.5 Protocols need to be agreed for the review process.ie. which patients should be recalled.

2.6 There needs to be agreement as to who will bear the financial risks associated with the Look Back. Many staff will be required to work substantially long, additional hours to conduct the exercise as speedily and effectively as possible.

3.0 Setting Up a Patient Helpline

3.1 Once it has been agreed that the Look Back exercise is to be publicly announced, organisations need to have in place a system to deal with potentially large numbers of calls from patients and their families.

3.2 Planning at this stage is vital to ensure public confidence in the service is not further eroded.

3.3 An individual, such as an Executive Director should be identified to co-ordinate and implement the Telephone Help Line.

3.4 A meeting needs to be convened with a small number of individuals, with the necessary knowledge of the speciality, to establish the necessary systems. It may be that Lead and Specialist Nurses are ideally placed to

assist at this crucial stage of planning.

3.5 Information Technology staff are essential members of this team to assist in establishing databases and the necessary technology. A senior member of staff from the Telephone Exchange is invaluable at this stage in planning.

3.6 Tasks need to be identified and allocated to this team eg.

- Identification of a suitable venue for the Telephone Helpline. This includes appropriate cabling for additional telephones and PC's. Identification of dedicated telephone numbers. (Support from IT and Telephone Exchange staff is vital).
- Identification of patient database and sizing the scope of the exercise
- Preparation of Background papers for those who will be manning the helpline.
- Production of simple algorithms which those manning the Helpline will use to assist in giving reliable and accurate information.
- Production of "key messages" for Helpline staff.
- Production of proforma to collect data on those calling the Helpline so that follow-up is streamlined.
- Production of Rotas.
- Open/Closing Time of Helpline.
- Staff briefing.

3.7 Identification of Venue

3.7.1 Ideally the Helpline should not be isolated from the main hub of the organisation. Staff need to be able to access others to seek advice while the Helpline is operational. However it does need to allow confidential conversations to take place and requires a dedicated space.

3.7.2 Cabling to allow sufficient telephones is required. Once the media report on the issue then there is likely to be a influx of calls. Each telephone line will realistically only be able to handle 100 calls in a 12 hour period. Additional capacity is required during the initial days, with surges of activity following each news bulletin.

3.7.3 Free phone telephone numbers need to be agreed with Telephone Exchange staff or relevant department.

3.7.4 It is advisable to have a fail safe system to capture additional calls if the telephone lines become blocked with calls. This may involve agreeing with the Telephone Exchange staff to take details from those callers who are unable to get through quickly and ensure one of the Helpline staff return the call within an acceptable timeframe.

3.7.5 Once the number of Helpline stations are agreed, personal computers are required for each to facilitate easy access to patient information. IT staff will assist in accessing the necessary cabling and hardware.

3.8 Establishing the Patient Database

3.8.1 It is essential to have a database of patient details that are involved in the Look Back exercise. This may already exist on one of the Trust's IT systems. Crucial however at this stage is the checking of this patient details data with the Central Services Agency database which will identify if any of these patients have since deceased. Clerical Administrative support is essential to facilitate this.

3.8.2 Letters will usually be sent to patients affected by the issue of concern using this database, simultaneously with the public announcement. **Validating of this data is therefore essential and cannot be over emphasised.** Patients and their families will be alarmed at this stage and increasing stress should be tolerated.

3.8.3 As the Look Back exercise progresses it will be necessary to continuously update the database. This will ensure that patients are given the most up-to-date and reliable information.

3.8.4 A database of patient details may already exist in one of the Trusts IT systems however if one does not exist a suggested core dataset for patients at risk is outlined below: -

- Unique patient identifier number
- Surname
- Forename
- Title
- Date of birth
- Sex
- Address line one (House name, number and road name)
- Address line two (town)
- Address line three (county)
- Postcode

- GP name
- GP address line one
- GP address line two
- GP address line three
- GP postcode

- Named consultant
- Date of appointment/procedure 1
- Date of appointment/procedure 2
- Date of appointment/procedure 3
- Procedure one description
- Procedure two description
- Procedure three description

- Reviewer 1 identification

- Reviewer 2 identification
- Data entered by - identification
- Data updated 1 by – identification
- Data updated 2 by – identification
- Data updated 3 by – identification

The data above is a suggested minimum dataset it is however subject to change depending on the individual situation. Ideally, the use of an existing database is preferred.

3.8.5 It is important to consider the output from the patient notification database at the outset. The list of patients will be needed to: -

- generate letters to patients
- check that patients at risk have made contact
- keep track of who requires further review/testing
- record who has had results back
- at the end of the exercise generate information on numbers of patients identified, further assessed and outcomes

3.8.6 Progress Reports - It is essential that the Incident Planning Team meet on a daily basis to ensure a co-ordinated approach continues to steer the process. Minutes should be shared with appropriate parties to ensure helpline and other key staff are kept informed. Briefing papers/key messages, for helpline operators, should be updated on a regular basis.

3.9 Preparation of Background Papers

3.9.1 It is important that those manning the Helpline should be trained and briefed. They should be provided with training and background information on the circumstances surrounding the Look Back exercise.

3.9.2 Files should be prepared and updated daily with the initial press release and briefing notes on the subject (see below).

3.10 Production of Algorithms

3.10.1 Staff manning the Helpline will find it useful to have simple algorithms which assist in giving accurate information to callers. It may be that the caller has no reason to be alarmed when they are informed they are not within the affected group of patients.

3.11 Production of Key Messages

3.11.1 Helpline staff need to be confident in the messages they are giving to callers. To assist this “key messages” should be agreed with the clinical teams and these are read to callers in response to specific questions. **Helpline staff must not deviate from these messages.**

Some anxious callers will ring on many occasions and it is vital

that if they speak to different Helpline staff they are being given a consistent message.

3.11.2 Key messages will change as the review progresses. These then require to be updated in the individual files for Helpline staff.

3.12 Production of Proforma

3.12.1 As each call is received it is important to maintain a record. A proforma should be designed to capture the relevant information. It should not be so detailed that the caller feels annoyed, however there needs to be sufficient to ascertain if follow up action is required.

3.12.2 If the Helpline staff believe that follow up is required then a system needs to be agreed to segregate proformas, perhaps by identifying follow up calls with a red dot. By the following day these need to have been actively followed up, probably by clinical staff in the speciality being reviewed.

3.12.3 For completeness and post Look Back audit purposes a database of Helpline calls might be helpful.

3.13 Production of Rotas

3.13.1 The Helpline opening times need to be agreed at the outset so that rotas can be produced. However as stated earlier the extent to which the matter is covered in the media will largely dictate when the calls might be made and some flexibility might be required. There is a strong correlation between media reports and number of calls made.

3.13.2 In the early stages it will be essential to have staff with good communication skills. Staff will need to be released very quickly from their “normal” duties to assist with this work. There may need to be back filling of these posts to release these staff to assist.

3.13.3 While staff should not be asked to work more than 6 hours at any one time on the Helpline, it is recognised that in the first few days resources may be stretched. On occasion some normal hospital business may need to be suspended temporarily.

3.13.4 Ideally if new staff are coming onto the rota there should always be one member of staff who is familiar with the system and can advise others and co-ordinate overall. As far as possible the help lines should be staffed by experienced people with an understanding of the governance and duty of care responsibilities. Briefing on this area is helpful to understand the corporate responsibility.

3.14 Staff Briefing

3.14.1 Briefing of staff, particularly in the early stages of the exercise is

vital. A leader needs to be identified to take this role. This would normally be an Executive Director.

3.14.2 Staff need to feel they are being listened to during the exercise. If they believe that the system could be improved they should have that opportunity to discuss their views at a daily staff briefing session.

3.14.3 Catering arrangements should be in place for staff who assist in this work. Regular coffee breaks should be accommodated.

4.0 Communication with Patients

4.1 One of the most important areas of managing any Look Back Exercise is Communication with all the relevant patients, while at the same time maintaining confidentiality.

4.2 Patients need to be informed of the Look Back Exercise simultaneously. The method of doing this will be dictated by the numbers of patients involved and must be co-ordinated with public announcements from the Public Relations Department within the organisation

4.3 Dependent on the nature of the review the organisation may need to review the notes of all patients who may be affected/involved. However those patients affected may have already been previously identified. (Refer to Appendix 1: Process for Service Review).

4.4 In an ideal situation patients should be contacted before a media announcement is made. However this is not always possible given the nature/scale of some Look Back Exercises.

4.5 The Department of Health's publication " Practical Guidance on Notifying Patients" in 1993 advises on communication methods.

4.6 Patients should be notified by letter, signed by the Chief Executive or a Director of the Trust. It is advisable for patient letters to be approved by the legal advisors representing the Trust/HSS Board/HSSA. (Refer to Appendix 5: Patient Letters)

4.7 Patient letters should be sent by first class post in an envelope marked "Private and Confidential -To be opened by addressee only" and "If undelivered return to...(*the relevant Trust*)..."

4.8 **Continuous validation of the database is essential and cannot be over emphasised. It is essential to check with the CSA database/General Practitioner to ensure letters are not sent to deceased patients.** There is no obligation to contact relatives of patients who have died, however there may need to be consideration given to the handling of relatives of deceased patients. This will be unique to each individual Look Back Exercise and legal advice should be sought.

4.9 Letter to the patient should include the following if appropriate: -

- Unique patient identifier number
- Patient fact sheet
- The freephone helpline number(s) and hours of opening
- Location map with details of public transport routes
- Free access to parking facilities
- Arrangements for reimbursement of travelling expenses

It can be helpful to include a reply slip with a pre-paid envelope to confirm that patients have received the letter and will or will not be contacting the helpline. This identifies those patients contacted successfully but who do not wish any follow-up.

4.10 Depending on the individual Service Review the Trust may need to identify any patients under 16 and other vulnerable groups to write to their parent/guardian/ representative.

4.11 "Every reasonable effort" should be made to contact all patients at risk. Patients may have moved out of the district, to Great Britain or abroad.

5.0 Setting up a Service Review

5.1 Service Review Team

5.1.1 The purpose of the Service Review Team is to identify those patients/clients that may be affected as a result of the review. This will involve clinical staff with necessary knowledge of the specialty.

5.1.2 The team will initially be required to screen the patients' notes/x-rays/test results etc to establish if they are in the affected cohort.

5.1.3 Following initial screening and identification of patients affected, further clinical assessment may be required.

5.1.4 If further clinical assessment is required, organisations must have systems in place to manage this process. In doing so it is vital to consider the following:-

- Identify venue for the duration of the review
- Secure administrative support
- Establish an appointment system
- Secure clinical support i.e. laboratory/x-ray etc
- Arrange transportation of samples and results
- Agree a system for recording of results
- Agree a communication strategy with the Incident Planning Team, public health medicine, commissioners etc.

5.2 Initial Identification of Patients involved in the Service Review (Refer to Appendix 1: Process for Service Review)

5.2.1 The retrieval of notes/x-rays/test results must be co-ordinated with the support from Medical Records staff.

5.2.2 A Service Review Pro Forma (Appendix 2) is attached to each set of notes.

5.2.3 The patient database needs to be updated after completion of this pro forma.

5.2.4 A quality assurance check is provided by Administration which is essential to ensure that the correct letter is sent to the correct patient.

5.2.5 The Service Review Pro forma should be transferred from the front of the notes and filed into the patient records.

5.3 Conducting Further Assessment (Notes/X-rays/Test Results etc.)

5.3.1 A Notes/X-ray/Test Results Review Pro Forma (Appendix 3) is attached to the front of each set of patient notes.

5.3.2 The service review team will undertake a further detailed audit of the patient notes to review the outcomes of previous assessment/scans/tests

5.3.3 The service review team will then decide if previous outcomes/diagnosis were accurate.

5.3.4 The proforma will be completed by the Service Review Team.

- A green or red sticker is placed on the pro forma. The **green** sticker identifies a positive outcome and that no further follow up is required - Letter D is sent to patient.
- A **red** sticker identifies a negative outcome that requires a further assessment – Letter E is sent to patient

5.3.5 The patient database needs to be updated after completion of this pro forma.

5.3.6 A quality assurance check is provided by Administration which is essential to ensure that the correct letter is sent to the correct patient.

5.3.7 The Notes Review Pro forma should be removed from the front of the notes and filed into the patient records.

5.4 Conducting Further Assessment (Clinical)

5.4.1 A Clinical Review Pro Forma (Appendix 4) is attached to the front of each set of patient notes.

5.4.2 The service review team will undertake a clinical examination/test/scan etc as appropriate to determine a positive or negative outcome. One must bear in mind that timescales for test/scan results may differ depending on individual situations.

5.4.3 The pro forma is then completed by the Service Review Team. A

green or **red** sticker is placed on the pro forma.

- The **green** sticker identifies a positive outcome and that no further follow up is required - Letter F is sent to patient.
- A **red** sticker identifies a negative outcome that requires further treatment which should be managed within normal clinical arrangements – Letter G is sent to patient

5.4.4 The patient database needs to be updated after completion of this pro forma.

5.4.5 A quality assurance check is provided by Administration which is essential to ensure that the correct letter is sent to the correct patient.

5.4.6 The Clinical Review Pro Forma should be transferred from the front of the notes.

If it has a **green** sticker attached: file into patient notes.

If it has a **red** sticker attached: return patient notes and pro forma to admin support for processing within normal clinical arrangements.

6.0 Patient Cohort Database

6.1 It is essential to have a database of patient details who are involved in the review process.

6.2 As referenced in 3.8.4 a database of patient details may already exist in one of the Trusts IT systems however if one does not exist a suggested core dataset for patients at risk is outlined below: -

- Unique patient identifier number
- Surname
- Forename
- Title
- Date of birth
- Sex
- Address line one (House name, number and road name)
- Address line two (town)
- Address line three (county)
- Postcode

- GP name
- GP address line one
- GP address line two
- GP address line three
- GP postcode

- Named consultant
- Date of appointment/procedure 1
- Date of appointment/procedure 2
- Date of appointment/procedure 3

- Procedure one description
- Procedure two description
- Procedure three description

- Reviewer 1identification
- Reviewer 2 identification
- Data entered by - identification
- Data updated 1 by – identification
- Data updated 2 by – identification
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The data above is a suggested minimum dataset it is however subject to change depending on the individual situation. Ideally, the use of an existing database is preferred.

6.3 It is important to consider the output from the patient notification database at the outset. The list of patients will be needed to: -

- generate letters to patients
- check that patients at risk have made contact
- keep track of who requires further review/testing
- record who has had results back
- at the end of the exercise generate information on numbers of patients identified, further assessed and outcomes

6.4 The database needs to be updated, by administration staff, on a regular, at least daily basis. This will ensure the information held is the most up to date and reliable.

6.5 Progress Reports
It is essential that the incident planning team meet on a daily basis to ensure a co-ordinated approach continues to steer the process. Minutes should be shared with appropriate parties to ensure helpline and other key staff are kept informed. Briefing papers/key messages, for helpline operators, should be updated on a regular basis.

7.0 Look Back Review

At the end of any Look Back exercise it is the responsibility of the Lead Director to ensure that an appraisal meeting is held, lessons learned and areas for improvement are identified and are documented. These findings should be included in a Look Back Review Report. The content will be unique to each Look Back Review. An audit of the review process may be beneficial.

This report should be shared with all relevant stakeholders.

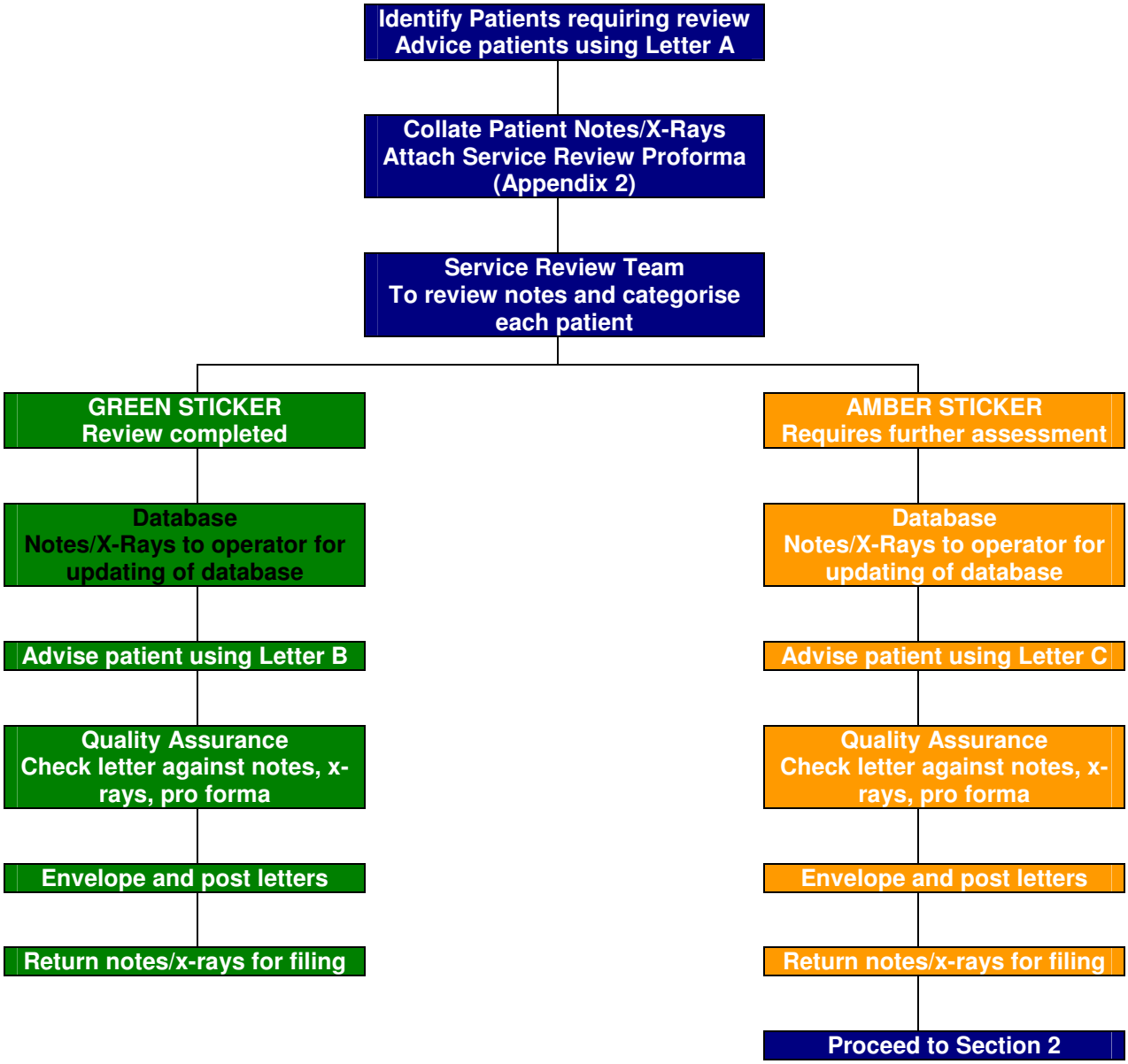
Glossary

Clinical Review	A re-examination of a medical and or clinical process(es) or individual(s) which has delivered results that were not to the expected quality standard.
Cohort	A sub-group selected by predetermined criteria.

Database	The ability to record information for retrieval at a later date. In this instance in may be on paper if the numbers involved are small. If the numbers are large, I.T. equipment and competent administration staff may be required.
Look Back Review	A re-examination of a process(es) or individual(s) which has delivered results that were not to the expected quality standard.
Pro Forma	A page on which data is recorded. The page has predefined prompts and questions which require completing.
Quality Assurance	A check performed and recorded that a certain function has been completed. Negative outcomes must be reported and actioned.
Service Review Team	A specially selected group of individuals, competent in the required field of expertise, to perform the Look Back Review.

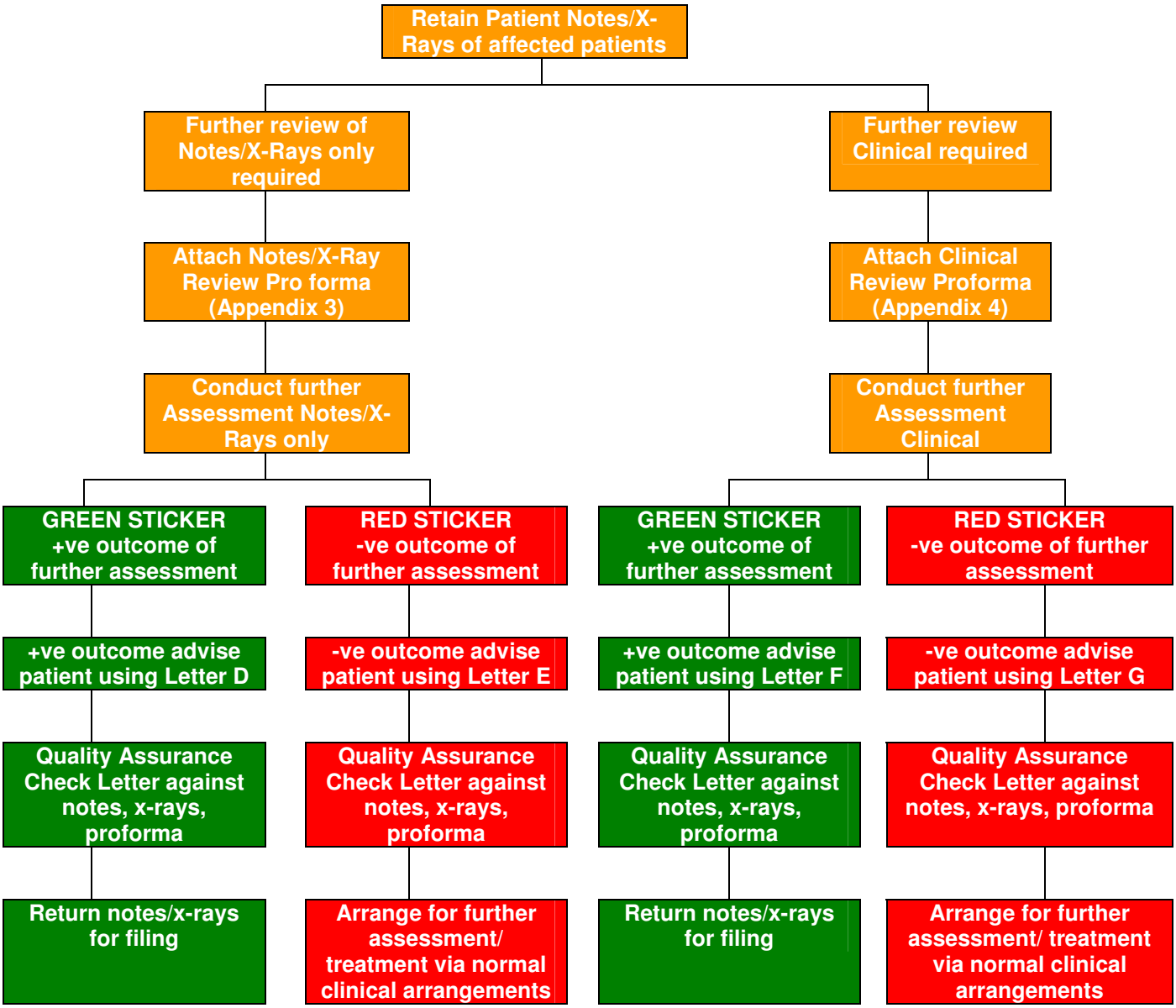
Appendix 1

Process for Service Review
Section 1: Advising all patients who may have been affected



Appendix 1

Process for Service Review
Section 2: Advising patients known to be affected



APPENDIX 2

SERVICE REVIEW PROFORMA

PATIENT DETAILS (ATTACH LABEL)

CASENOTES REVIEWED ☐

X RAYS REVIEWED ☐

OTHER MEDICAL DIAGNOSTIC/DATA REVIEWED ☐
(Give details)

_____

DATE OF APPOINTMENT/SCAN/EXAMINATION REVIEWED ☐

REVIEWER 1
Signature & date

REVIEWER 2
Signature & date

GREEN STICKER- REVIEW COMPLETED

AMBER STICKER - FURTHER FOLLOW UP REQUIRED ◯

DATABASE UPDATED ☐ **(Signature & date)**

ADMIN QA CHECK ☐ **(Signature & date)**

LETTER SENT ☐ **(Signature & date)**

APPENDIX 3

NOTES/X RAY REVIEW PROFORMA

PATIENT DETAILS (ATTACH LABEL)

ADDITIONAL INFORMATION

CASENOTES REVIEWED ☐

X RAYS/SCANS REVIEWED ☐

OTHER MEDICAL DIAGNOSTIC/DATA REVIEWED ☐
(Give details)

_____

ADDITIONAL TESTS/SCANS/X RAYS REQUIRED ☐

CLINICAL REVIEW REQUIRED ☐

REVIEWER 1
Signature & date

REVIEWER 2
Signature & date

GREEN STICKER- REVIEW COMPLETED

RED STICKER - FURTHER FOLLOW UP REQUIRED

DATABASE UPDATED	☐	**(Signature & date)**	
ADMIN QA CHECK	☐	**(Signature & date)**	
LETTER SENT	☐	**(Signature & date)**	

APPENDIX 4

CLINICAL REVIEW PROFORMA

PATIENT DETAILS (ATTACH LABEL)

	OUTCOME +VE	OUTCOME -VE
CLINICAL EXAMINATION	☐	☐
TEST	☐	☐
SCAN/X RAY	☐	☐
BIOPSY	☐	☐
OTHER MEDICAL DIAGNOSTIC/DATA REVIEWED (Give details)	☐	☐

_____

	YES	NO
FURTHER FOLLOW UP REQUIRED: PROCESS INTO NORMAL CLINICAL ARRANGEMENTS	☐	☐

CONSULTANTS SIGNATURE: _____ DATE: _____

GREEN STICKER - REVIEW COMPLETED

RED STICKER - FURTHER FOLLOW UP REQUIRED
PROCESS INTO NORMAL CLINICAL ARRANGEMENTS

DATABASE UPDATED	☐	**(Signature & date)**	
ADMIN QA CHECK	☐	**(Signature & date)**	
LETTER SENT	☐	**(Signature & date)**	

DRAFT LETTERS

APPENDIX 5

Although there will be one "master" letter, you will need to generate several variants from it for different circumstances e.g. when the patient is a child. The following are provided for suggested content.

LETTER A: Advising of a service review/look back exercise
LETTER B: No further follow up required
LETTER C (version 1): Further follow up is required – Notes only
LETTER C (version 2): Further follow up is required – Clinical
LETTER D: Positive outcome of further assessment – Notes only
LETTER E: Negative outcome of further assessment –Notes only
LETTER F: Positive outcome of further assessment – Clinical
LETTER G: Negative outcome of further assessment – Clinical

LETTER A: Advising of a service review/look back exercise

Patient Reference Number

Confidential Addressee Only

DD Month Year

Dear Patient

<***xxxxxxxx Service Review***>

It has come to the attention of <*Trust or Board*> that < *a health care worker/system*> has <brief outline of the incident>.

We have decided as a precautionary measure to review each of the cases with which this <*health care worker/system*> has been involved since <*date range*>.

Your case will be included in this review, which will be a substantial process <*involving…..*>. We have initiated a Service Review Process and will endeavor to deal with this as timely as possible.

I wanted to inform you directly about this rather than letting you hear it through another source and I believe it is important that you are kept fully informed of the review process. We will write to you immediately after your case has been reviewed to advise you whether or not it will be necessary for you to have <*a follow up appointment/test*>.

If in the interim you have any queries, a special telephone helpline has been set up on <*freephone/Tel:xxxxxxxx*> so that you can discuss any concerns. It is staffed from <*date and time to date and time*>. This line is completely confidential and operated by professional staff who are trained to answer your questions.

Although there are a large number of call handlers, there will be times of peak activity and there may be occasions where you may not get through. In this event I would ask you to please call again at another time.

<*Enclosed is a factsheet with more detailed information, which you may find helpful*>.

Please have your letter when you call the helpline, as you will be asked to quote the patient reference number from the top of the page.

Yours faithfully

(Chief Executive/Director of Trust)

LETTER B: No further follow up required

Patient Reference Number

Confidential Addressee Only

DD Month Year

Dear Patient

<***xxxxxxxx Service Review***>

We had previously written to advise you that <*Trust or Board*> had decided, as a precautionary measure, to review your individual case.

Your case was reviewed <*by xx / using the protocol*> and I am pleased to inform you that your <*case notes/assessment/test*> has now been reviewed and that **no further follow up is required.**

I fully appreciate that this has been a worrying time for you and I apologise for any upset this may have caused. However, I am sure you will understand that, although the risk <*of missed diagnosis/contracting xx*> was thought to be very low, we had an obligation to remove any uncertainty.

Yours faithfully

(Chief Executive/Director of Trust)

LETTER C (version 1): Further follow up is required – Notes only

Patient Reference Number

Confidential Addressee Only

DD Month Year

Dear Patient

<***xxxxxxxx Service Review***>

We had previously written to advise you that <*Trust or Board*> had decided, as a precautionary measure, to review your individual case.

Your case was reviewed <*by xx/using the protocol*> and the <clinician/consultant> has advised that **further follow up is required.** I must emphasis that this does not necessarily mean that <*illness/infection*> has been detected but that more investigation is required to reach a definite diagnosis.

I fully appreciate that this has been a worrying time for you and I deeply regret that your previous <*assessment/test/treatment*> has been found to be inadequate.

We have made special arrangements for <*name and grade of person*> to <*review patient notes/assessment*> and we will contact you again as soon as this is complete.

Yours faithfully

(Chief Executive/Director of Trust)

LETTER C (version 2): Further follow up is required – Clinical

Patient Reference Number

Confidential Addressee Only

DD Month Year

Dear Patient

<***xxxxxxxx Service Review***>

We had previously written to advise you that <*Trust or Board*> had decided, as a precautionary measure, to review your individual case.

Your case was reviewed <*by xx/using the protocol*> and the <clinician/consultant> has advised that **further follow up is required.** I must emphasis that this does not necessarily mean that <*illness/infection*> has been detected but that more investigation is required to reach a definite diagnosis.

I fully appreciate that this has been a worrying time for you and I deeply regret that your previous <*assessment/test/treatment*> has been found to be inadequate.

We have made special arrangements for you to be seen in <*where*> on <*date & time of appointment*>.

Our service review team will be available at this appointment to discuss the clinical aspects of your case. I have enclosed directions to <*xxxxxxx*> and information on parking arrangements.

If you are unable to attend this appointment please contact <*Tel xxxxxx*> to allow us to reorganise this for you.

Yours faithfully

(Chief Executive/Director of Trust)

LETTER D: Positive outcome of further assessment – Notes only

Patient Reference Number

Confidential Addressee Only

DD Month Year

Dear Patient

<***xxxxxxxx Service Review***>

Further to our letter dated <*date*> regarding the need for further assessment of your individual case.

I am pleased to advise you that your case has been reviewed by <*name and grade of person*> and we would wish to reassure you that <*he/she*> is satisfied with the quality of your original <*assessment/investigation/test*>.

We would however wish to offer you the opportunity to be reviewed by <*whomever*> at a forthcoming clinic. This will give us the opportunity to examine you and to help reassure you of the outcome of the Service Review Process we have undertaken.

If you wish us to arrange an appointment please contact <*Tel xxxxx*> quoting the patient reference number at the top of this letter.

Once again I would take this opportunity to apologise for the distress and anxiety caused by conducting this review. However, I am sure you will understand that, although the risk <*of missed diagnosis/contracting xx*> was thought to be very low, we had an obligation to remove any uncertainty.

Yours faithfully

(Chief Executive/Director of Trust)

LETTER E: Negative outcome of further assessment – Notes only

Patient Reference Number

Confidential Addressee Only

DD Month Year

Dear Patient

<***xxxxxxxx Service Review***>

Further to our letter dated <*date*> regarding the need for further assessment of your individual case.

Your case has been reviewed by <*name and grade of person*> and we are sorry to advise you that <*he/she*> has confirmed that the quality of your original <*assessment/investigation/test*> was unsatisfactory.

As a result of this we have arranged for you to be seen by <*whomever*> at <*where*> on <*date and time*>. This will give us the opportunity to examine you and to assess what further treatment you may require.

If the appointment above is unsuitable, please contact <*Tel xxxxx*> quoting the patient reference number at the top of this letter, so that we may reorganise it for you.

I would take this opportunity to apologise for the distress and anxiety caused by this letter, I have enclosed a fact sheet which may help answer any further queries you may have ahead of your appointment.

Yours faithfully

(Chief Executive/Director of Trust)

LETTER F: Positive outcome of further assessment – Clinical

Patient Reference Number

Confidential Addressee Only

DD Month Year

Dear Patient

<***xxxxxxxx Service Review***>

Thank you for attending <*special clinic*> on <*date*> for follow up assessment.

Your results have been reviewed by <*name and grade of person*> and we are pleased to advise you that <*he/she*> has confirmed that your <*investigation/test*> result was **NEGATIVE**. This indicates that you have not been exposed to <*infection/illness*>.

We would however wish to offer you the opportunity to be reviewed by <*whomever*> at a forthcoming clinic. This will give us the opportunity to examine you and to help reassure you of the outcome of the Service Review Process we have undertaken.

If you wish us to arrange an appointment please contact <*Tel xxxxx*> quoting the patient reference number at the top of this letter.

Once again I would take this opportunity to apologise for the distress and anxiety caused by conducting this review. However, I am sure you will understand that, although the risk <*of missed diagnosis/contracting xx*> was thought to be very low, we had an obligation to remove any uncertainty.

Yours faithfully

(Chief Executive/Director of Trust)

LETTER G: Negative outcome of further assessment – Clinical

Patient Reference Number

Confidential Addressee Only

DD Month Year

Dear Patient

<***xxxxxxxx Service Review***>

Thank you for attending <*special clinic*> on <*date*> for follow up assessment.

Your results have been reviewed by <*name and grade of person*> and we are sorry to advise you that <*he/she*> has confirmed that your <*investigation/test*> result was **POSITIVE**. This indicates that you have been exposed to <*infection/illness*>.

As a result of this we have arranged for you to be seen by <*whomever*> at <*where*> on <*date and time*>. This will give us the opportunity to examine you and to assess what further treatment you may require.

If the appointment above is unsuitable, please contact <*Tel xxxxx*> quoting the patient reference number at the top of this letter, so that we may reorganise it for you.

I would take this opportunity to apologise for the distress and anxiety caused by this letter, I have enclosed a fact sheet which may help answer any further queries you may have ahead of your appointment.

Yours faithfully

(Chief Executive/Director of Trust)

Membership of Sub-Group

Eleanor Hayes (Chair)	Director of Nursing, Belfast City Hospital Trust
Martine McNally	Clinical Governance Manager, United Hospitals Trust
Helen Hamilton	Governance & Risk Management Co-ordinator, Eastern Health & Social Services Board
Nigel McClelland	Senior Risk Manager, Armagh & Dungannon HSS Trust
Alan Finn	Director of Nursing, Down & Lisburn Trust

Safety, Quality and Standards Directorate
Office of the Chief Medical Officer

Department of
Health, Social Services and Public Safety

An Roinn
Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

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Chief Executives of Boards and Trusts for cascade to
- Governance/CSCG leads
- Risk managers

Mr David Sissling – Chief Ex. Designate, HSCA
Dr Anne-Marie Telford, Regional Director of Public Health & Care Standards Designate, HSCA
Medical Directors of HSC Trusts
Directors of Nursing -Boards and Trusts
Pharmacy Directors -Boards and Trusts
Directors of Public Health- HSS Boards
Directors of Primary Care -HSS Boards
Directors of Social Services -Boards and Trusts
Chair and Chief Executive RQIA (for cascade to independent hospitals, hospices, clinics and establishments)
Office of the Ombudsman
Chief Executive NISCC
Chief Executive NIPEC
Director, NI CSCG Support Team
Chief Executive, Mental Health Commission

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Our Ref: HSS(SQSD) 34/2007
Date: 12 September 2007

Dear Colleague

HSC REGIONAL TEMPLATE AND GUIDANCE FOR INCIDENT REVIEW REPORTS

This HSC Regional Template and Guidance for Incident Review Reports has been developed on behalf of the Department's Safety in Health and Social Care Steering Group. This work represents part of an on-going process to develop clarity and consistency when conducting reviews as outlined in *Safety First: A Framework for Sustainable Improvement in the HPSS* (March 2006).

This template and guidance notes should be used, in as far as possible, for the drafting of all HSC incident review reports whether internal or external to the organisation. However, it is not intended that the template be used without adaptation as it is recognised that certain incident review reports may require a greater level of

detail appropriate to the specialist nature of the incident. In such circumstances, the template may be tailored to suit the specific requirements of each HSC organisation.

The attached guidance makes reference to the importance of independence in investigations/ reviews particularly in relation to incidents involving suicide and of the need to have corporate systems in place to ensure learning and effective closure of the incident within a HSC organisation.

Further recommended reading is provided within the bibliography and in particular I would draw your attention to the principles outlined in the NPSA policy document *Being Open: Communicating Patient Safety Incidents with Patients and their Carers* http://www.npsa.nhs.uk/site/media/documents/1456_Beingopenpolicy1_11.pdf and to the guidance contained in *A Practical Guide to Conducting Patient Service Reviews or Look Back Exercises* *http://www.dhsspsni.gov.uk/microsoft_word_-_hss_sqsd_18-07_patient_service_review_guidelines_-_final_feb07.pdf*

The Department will evaluate the impact of this guidance over the coming year through the incident reports received via the SAI Review Group. It is hoped that the standardisation of Incident Review Reports will facilitate the future collation and dissemination of regional learning.

I would like to take this opportunity to thank Mrs Heather O'Neill, Regional Governance & Risk Management Advisor and her Project Team for their contribution.

Yours sincerely

DR MAURA BRISCOE
Safety, Quality and Standards Directorate
Office of the Chief Medical Officer

cc: Departmental Board Members & Directors
Safety in Health & Social Care Group

Department of
Health, Social Services and Public Safety

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Health and Social Care Regional Template and Guidance for Incident Investigation/Review Reports

September 2007

Working for a Healthier People

Departmental Solicitors Office

323-021d-037

Introduction

This work has been commissioned by the DHSSPS Safety in Health and Social Care Steering Group as part of the action plan contained within "*Safety First: A Framework for Sustainable Improvement in the HPSS*" (under 5.1.2 Agreeing Common systems for Data Collection, Analysis and Management of Adverse Events). The following work forms part of an on-going process to develop clarity and consistency in conducting investigations and reviews. This is an important aspect of the safety agenda.

This template and guidance notes should be used, in as far as possible, for drafting all HSC incident investigation/review reports. It is intended as a guide in order to standardise all such reports across the HSC including both internal and external reports. It should assist in ensuring the completeness and readability of such reports. The headings and report content should follow as far as possible the order that they appear within the template. Composition of reports to a standardised format will facilitate the collation and dissemination of any regional learning.

All investigations/reviews within the HSC should follow the principles contained within the National Patient Safety Agency (NPSA) Policy documents on "*Being Open – Communicating Patient Safety Incidents with Patients and their Carers*".
http://www.npsa.nhs.uk/site/media/documents/1456_Beingopenpolicy1_11.pdf

It is also suggested that users of this template read the guidance document "*A Practical Guide to Conducting Patient Service Reviews or Look Back Exercises*" – Regional Governance Network – February 2007.
http://www.dhsspsni.gov.uk/microsoft_word_-_hss__sqsd__18-07_patient_service_review_guidelines_-_final_feb07.pdf

This template was designed primarily for incident investigation/review however it may also be used to examine complaints and claims.

The suggested template can be found in the following pages.

Template Title Page

Date of Incident/Event

Organisation's Unique Case Identifier (for tracking purposes)

Introduction

The introduction should outline the purpose of the report and include details of the commissioning Executive or Trust Committee.

Team Membership

List names and designation of the members of the Investigation team. Investigation teams should be multidisciplinary and should have an independent Chair. The degree of independence of the membership of the team needs careful consideration and depends on the severity / sensitivity of the incident. However, best practice would indicate that investigation / review teams should incorporate at least one informed professional from another area of practice, best practice would also indicate that the chair of the team should be appointed from outside the area of practice. In the case of more high impact incidents (i.e. categorised as catastrophic or major) inclusion of lay / patient / service user or carer representation should be considered. There may be specific guidance for certain categories of adverse incidents, such as, the Mental Health Commission guidance
http://www.dhsspsni.gov.uk/mhc_guidance_on_monitoring_untoward_events.pdf

Terms of Reference of Investigation/Review Team

The following is a sample list of statements of purpose that should be included in the terms of reference:

- To undertake an initial investigation/review of the incident
- To consider any other relevant factors raised by the incident
- To agree the remit of the investigation/review
- To review the outcome of the investigation/review, agreeing recommendations, actions and lessons learned.
- To ensure sensitivity to the needs of the patient/ service user/ carer/ family member, where appropriate

Methodology to be used should be agreed at the outset and kept under regular review throughout the course of the investigation.

Clear documentation should be made of the time-line for completion of the work.

This list is not exhaustive

Summary of Incident/Case

Write a summary of the incident including consequences. The following can provide a useful focus but please note this section is not solely a chronology of events

- Brief factual description of the adverse incident
- People, equipment and circumstances involved
- Any intervention / immediate action taken to reduce consequences
- Chronology of events
- Relevant past history
- Outcome / consequences / action taken

This list is not exhaustive

Methodology for Investigation

This section should provide an outline of the methods used to gather information within the investigation process. The NPSA's "Seven Steps to Patient Safety" is a useful guide for deciding on methodology.

- Review of patient/ service user records (if relevant)
- Review of staff/witness statements (if available)
- Interviews with relevant staff concerned e.g.
  - Organisation-wide
  - Directorate Team
  - Ward/Team Managers and front line staff
  - Other staff involved
  - Other professionals (including Primary Care)
- Specific reports requested from and provided by staff
- Engagement with patients/service users / carers / family members
- Review of Trust and local departmental policies and procedures
- Review of documentation e.g. consent form(s), risk assessments, care plan(s), training records, service/maintenance records, including specific reports requested from and provided by staff etc.

This list is not exhaustive

Analysis

This section should clearly outline how the information has been analysed so that it is clear how conclusions have been arrived at from the raw data, events and treatment/care provided.

Analysis can include the use of root cause and other analysis techniques such as fault tree analysis, etc. The section below is a useful guide particularly when root cause techniques are used. It is based on the NPSA's "Seven Steps to Patient Safety" and "Root Cause Analysis Toolkit".

(i) Care Delivery Problems (CDP) and/or Service Delivery Problems (SDP) Identified

CDP is a problem related to the direct provision of care, usually actions or omissions by staff (active failures) or absence of guidance to enable action to take place (latent failure) e.g. failure to monitor, observe or act; incorrect (with hindsight) decision, NOT seeking help when necessary.

SDP are acts and omissions identified during the analysis of incident not associated with direct care provision. They are generally associated with decisions, procedures and systems that are part of the whole process of service delivery e.g. failure to undertake risk assessment, equipment failure.

(ii) Contributory Factors

Record the influencing factors that have been identified as root causes or fundamental issues.

- Individual Factors
- Team and Social Factors
- Communication Factors
- Task Factors
- Education and Training Factors
- Equipment and Resource Factors
- Working Condition Factors
- Organisational and Management Factors
- Patient / Client Factors

This list is not exhaustive

As a framework for organising the contributory factors investigated and recorded the table in the NPSA's "Seven Steps to Patient Safety" document (and associated Root Cause Analysis Toolkit) is useful.
www.npsa.nhs.uk/health/resources/7steps

Where appropriate and where possible careful consideration should be made to facilitate the involvement of patients/service users / carers / family members within this process.

Conclusions

Following analysis identified above, list issues that need to be addressed. Include discussion of good practice identified as well as actions to be taken. Where appropriate include details of any ongoing engagement / contact with family members or carers.

Involvement with Patients/Service Users/ Carers and Family Members

Where possible and appropriate careful consideration should be made to facilitate the involvement of patients/service users / carers / family members.

Recommendations

List the improvement strategies or recommendations for addressing the issues above. Recommendations should be grouped into the following headings and cross-referenced to the relevant conclusions. Recommendations should be graded to take account of the strengths and weaknesses of the proposed improvement strategies/actions.

- Local recommendations
- Regional recommendations
- National recommendations

Learning

In this final section it is important that any learning is clearly identified. Reports should indicate to whom learning should be communicated and copied to the Committee with responsibility for governance.

Further Reading

A Protocol for the Investigation and Analysis of Clinical Incidents. Clinical Risk Unit, University College London and ALARM (September 1999).

A Practical Guide to Conducting Patient Service Reviews or Look Back Exercises – Regional Governance Network – February 2007
http://www.dhsspsni.gov.uk/microsoft_word_-_hss__sqsd__18-07_patient_service_review_guidelines_-_final_feb07.pdf

Being Open. Communicating Patient Safety Incidents with Patients and their Carers. The National Patient Safety Agency, 2005.
http://www.npsa.nhs.uk/site/media/documents/1456_Beingopenpolicy1_11.pdf

Circular HSS (PPM) 06/2004 -Reporting and Follow-up on Serious Adverse Incidents: Interim Guidance

Circular HSS (PPM) 05/2005 – Reporting of Serious Adverse Incidents

Circular HSS (PPM) 2/2006 – Reporting and Follow-up on Serious Adverse Incidents.

Circular HSS (MD) 12/2006 – Guidance Document – How to classify Incidents and Risk

SAI Reporting Template from 1st April 2007 (PDF 20 KB) - Reporting and Follow-up on Serious Adverse Incidents
http://www.dhsspsni.gov.uk/index/phealth/sqs/sqsd-circulars.htm

Confidentiality: Protecting and Providing Information. General Medical Council 2004

Decision making tool to reduce unnecessary suspensions and support a safety culture – The National Patient Safety Agency
www.npsa.NHS.uk/idt

Dineen, M 2002, Six Steps to Root Cause Analysis, *Consequence UK Ltd.* Oxford.

Doing Less Harm; Improving the Safety and Quality of Care through Reporting, Analysing and Learning from Adverse Incidents, Department of Health and The National Patient Safety Agency, 2001

Mental Health Commission for Northern Ireland: Monitoring of Untoward Events by the Mental Health Commission (Revised Guidance) S6/2006 April 2006.

Managing risk and minimising mistakes in services to children and families, (SCIE: Children and Families' Services Report 6) 2005, http://www.scie.org.uk/publications/children.asp

Memorandum of Understanding Investigating patient or client safety incidents (Unexpected death or serious untoward harm) DHSSPS, PSNI, Coroners Service and HSENI, February 2006

Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults DHSSPS & PSNI 2003

Protocol for Joint Investigation by Social Workers and Police Officers of Alleged and Suspected Cases of Child Abuse – NI September 2004

Root Cause Analysis: Simplified Tools and Techniques, Anderson B, Fagerhaug T Quality Press, Milwaukee, 2000.

Seven Steps to Patient Safety A guide for NHS staff SSG/2003/01 - The National Patient Safety Agency, April 2004 (including the RCA tool kit) www.npsa.nhs.uk/health/resources/7steps

Managing risk and minimising mistakes in services to children and families, (SCIE: Children and Families' Services Report 6) 2005, http://www.scie.org.uk/publications/children.asp

Milne R and Bull R (2000) Investigative Interviewing, Psychology and Practice, Wiley J and Sons, Chichester, 1999

Taylor-Adams S.E et al*, Long Version of the CRU/ALARM Protocol: Successful Systems Event Analysis* (2002)