

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

**REGIONAL GOVERNANCE NETWORK
NORTHERN IRELAND SUB GROUP**

February 2007

Index

	Page No
Introduction	1
1.0 What or Who Initiates a Service Review or Look Back Exercise	1
2.0 Initial Planning	1-2
3.0 Setting up a Patient Helpline	2-7
<ul style="list-style-type: none">• Identification of Venue• Establishing the Patient Database• Preparation of Background Papers• Production of Algorithms• Production of Key Messages• Production of Proforma• Production of Rotas• Staff Briefing	
4.0 Communication with Patients	7-8
5.0 Setting up a Service Review	8-10
<ul style="list-style-type: none">• Service Review Team• Initial Identification of Patients• Conducting Further Assessment (Notes/X-Ray/Test Results etc)• Conducting Further Assessment (Clinical)	
6.0 Patient Cohort Database	10-11
7.0 Look Back Review	11-12
<ul style="list-style-type: none">• Glossary	
Appendix 1 Section 1 – Process for Service Review (Advising all patients who may have been affected)	13
Appendix 1 Section 2 – Process for Service Review (Advising patients known to be affected)	14
Appendix 2 Service Review Proforma	15
Appendix 3 Notes/X-Ray Review Proforma	16

Appendix 4	Clinical Review Proforma	17
Appendix 5	Draft Letters	18
Letter A	Advising of a Service Review or Look Back Exercise	19
Letter B	No Further Follow-up Required	20
Letter C	Version 1 – Further Follow-up is Required – Notes Only	21
Letter C	Version 2 – Further Follow-up is Required – Clinical	22
Letter D	Positive Outcome of Further Assessment – Notes Only	23
Letter E	Negative Outcome of Further Assessment – Notes Only	24
Letter F	Positive Outcome of Further Assessment – Clinical	25
Letter G	Negative Outcome of Further Assessment – Clinical	26
Membership of Sub-Group		27

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 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.

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

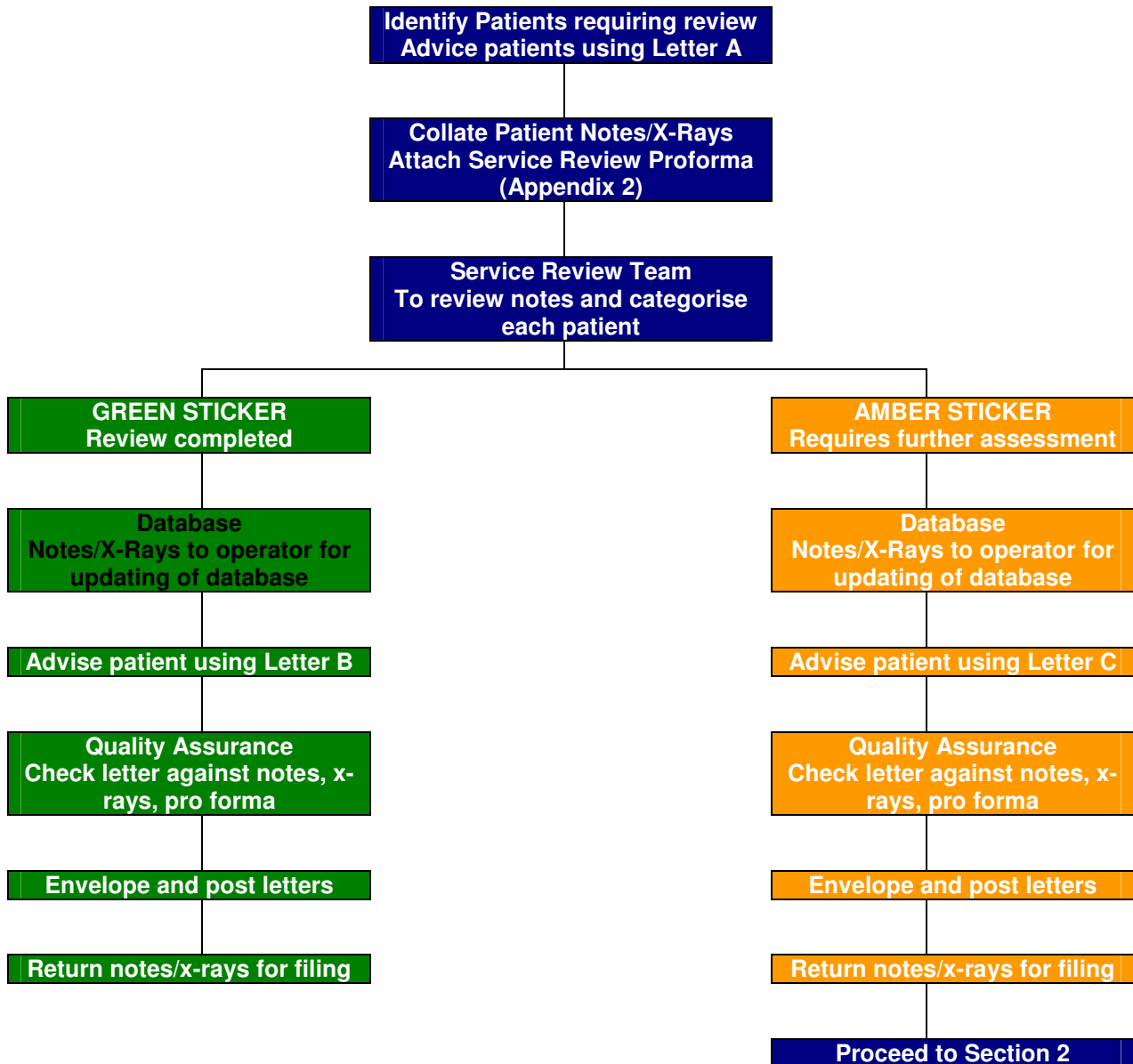
Clinical Review A re-examination of a medical and or clinical process(es) or individual(s) which has delivered results that were not to the expected quality standard.

Cohort A sub-group selected by predetermined criteria.

Database	The ability to record information for retrieval at a later date. In this instance it 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



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)

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

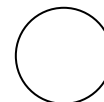
CLINICAL REVIEW REQUIRED

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)

CLINICAL REVIEW PROFORMA

PATIENT DETAILS (ATTACH LABEL)

OUTCOME

+VE -VE

CLINICAL EXAMINATION

--	--

TEST

--	--

SCAN/X RAY

--	--

BIOPSY

--	--

OTHER MEDICAL DIAGNOSTIC/DATA REVIEWED
(Give details)

--	--

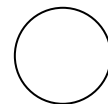
YES NO

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)

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

<xxxxxxx 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:xxxxxxx> 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

<xxxxxxx 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

<xxxxxxx 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 emphasize 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

<xxxxxxx 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 emphasize 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

<xxxxxxx 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

<xxxxxxx 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

<xxxxxxx 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