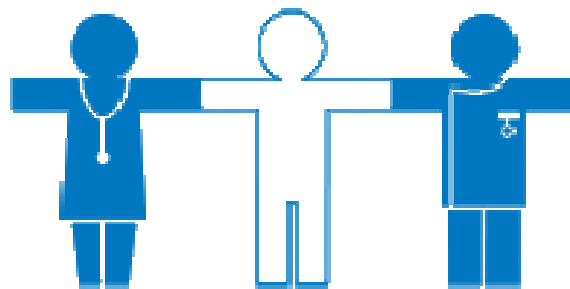


DNV

Sealed Envelopes Risk Assessment Project:

Report for NHS Connecting for Health
Revision 2
29th September 2006



Connecting for Health



MANAGING RISK

Sealed Envelopes Risk Assessment Project

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Executive Summary

DNV were engaged to support the NHS Connecting for Health (NHS CFH) project to identify and assess the “patient safety” and “breaches of confidentiality” risks associated with the sealing of confidential information within a patient’s medical record using Sealed Envelopes. Sealed Envelopes are one of several mechanisms for ensuring the confidentiality of patient information within the NHS Care Records Service. They restrict access to information a patient has requested be maintained as confidential between themselves and their care team.

The initial assignment was a comparative risk review aimed at identifying the change in perceived risk levels between:

- The current Sealed Envelopes (SE) design (where confidential information is held on the Spine in sealed envelopes), and;
- A situation where SEs are not available.

During the assignment an alternative sealing approach was suggested. This was included in the comparative review:

- The Alternative Sealed Envelope (ASE) design (where confidential information is held locally).

Three different types of risk were identified for consideration, these were” fear of breach of confidentiality”, “patient safety” and “breaches of confidentiality”. Initially the fear of breach was considered integral to the other types but was separated out during the process as it was felt it differed significantly to the others.

The review therefore considered three solutions and three types of risk:

Three Solutions	Three Types of Risk
1. The current “Sealed Envelope” (SE) solution.	4. Patient Safety risks.
2. The “Alternative Sealed Envelope” (ASE) solution.	5. Breach of Confidentiality risks.
3. A “without sealing” solution.	6. Fear of Breach of Confidentiality risks

Using a risk matrix, the risk level for each identified risk was classed as:

- “Low”,
- “Medium”, or
- “High”.

The review results are presented using these risk classes. The definitions of these and the development process followed in producing the risk matrix is presented in the main report.

Findings – Patient Safety

1. Overall the identified patient safety risks were assessed to be “Low” or “Medium”.
2. The patient safety risks were found to be higher with sealing (either with SEs or with ASEs) than without sealing. This is because the potential for error (e.g. in diagnosis) is lower when all information is available. In the sealing solutions, there is an increased likelihood that not all information will be available and, hence increases the risk of an incorrect diagnosis being made and / or inappropriate treatment being provided.
3. The majority of the significant patient safety risks identified related to the sealing of medication during one care episode with medication being provided in a subsequent care episode without knowledge of the medication from previous treatments. The risk lies with the interactions between the medications from the two care episodes, resulting in adverse consequences for the patient.
4. Another identified risk of concern is where the patient’s allergy information has been sealed in respect of a previous clinical episode. In this case, the concern relates to a future treatment which brings on a similar allergic reaction (which could have been avoided) if the information had been known.

Recommendations¹ were made which would successfully mitigate the patient safety risk for the two sealing solutions. It must be noted, however, that the recommendations increase the breach of confidentiality risk and the fear of breach of confidentiality risk. This is discussed further below.

Findings – Breach of Confidentiality

1. The majority of identified breach of confidentiality risks were assessed to be “low” or “medium”.
2. The most significant breach of confidentiality risk for the SE solution is a breach due to all the confidential information being held in a single envelope. The risk is that information being kept confidential in one healthcare setting is accidentally seen in another. (For example: A patient with a mental illness wishes to keep their related patient records confidential. When the patient visits a GUM (Genito-Urinary Medicine) clinic, a clinician could access their envelope for the purpose of inputting details of their GUM healthcare episode in a confidential manner. They may then inadvertently see information in the sealed envelope which reveals the patient’s mental illness.)
3. Another significant risk identified relates to the confidential filing of clinical information received from another healthcare provider relating to a “confidential” care episode, e.g. test results, if the original reason for the test results is sealed then the results should also be sealed, this may not always happen as prospective sealing is not available. This risk is significant for both the SE and ASE solutions.

¹ For the details of the recommendations see the list in Section 7.6.

The ASE solution mitigates the first of these by storing sealed information in local settings only. As such it is not possible for clinicians in different settings to see the data stored outside their own setting. Recommendations to address the second significant risk described (discussed later) were developed and these successfully reduce the breach of confidentiality risks.

Findings – Fear of Breach of Confidentiality

1. The national electronic method of sharing healthcare records could increase fear for some people in that their information will be seen by others from whom they wish to keep it confidential. A patient may then avoid or delay seeking treatment because their belief is that their information will not / can not be held in a confidential manner. This may impact greatly on their health and the treatment they receive or don't receive, and in turn their clinical safety. The perception of the patient and their level of fear of a breach of confidentiality may be raised by any negative headlines in the media. The potential risks of this type were identified and assessed and the risk was found to be highest without sealing.

The two sealing options are effective in mitigating this risk type. The ASE solution provides the lowest "fear of breach of confidentiality" risk. This is because the patient knows that the information is stored locally and can not be accessed in another healthcare setting or via Healthspace. One recommendation was made to mitigate this risk type further. This recommendation is detailed in the main report.

Summing the Risks

The assessment, for the three risk types, was undertaken using a common risk matrix. It is therefore possible to consider the combined risk results, although this must be done with care. The combined results show that the SE and ASE solutions posed a lower summed risk² than without sealing. It is therefore beneficial, from a risk view, to have some form of sealing. The ASE solution poses the lowest risk of the two sealing solutions.

Impact of Recommendations

The confidentiality recommendations developed reduce the summed risk, however, the patient safety recommendations (while reducing the patient safety risks) result in an increased summed risk. This is because two of these recommendations drive an increase in the breach and the fear of breach of confidentiality risks.

With confidentiality recommendations the risk for the SE and ASE solutions are comparable. This indicates, on a risk basis for the three types of risk considered, that there is little to choose between the two sealing solutions.

² Summed risk is the sum of the "patient safety" plus "breach of confidentiality" plus "fear of breach of confidentiality" risks.

However, the remaining “high” risk for the ASE solution relates to a limited population group; “habitual seekers of medication”³. Subsequent to the risk workshops, the report makes a recommendation for addressing this risk.

Conclusions:

From a risk perspective the ASE solution with recommendations R3 to R12 (as listed in the main report) was assessed to provide the lowest summed patient safety and confidentiality risk.

In this situation, two of the patient safety recommendations made, are not included. The reduction in patient safety risk they deliver is less than the increase the confidentiality risks which they cause.

³ A habitual seeker of medication is a person who continually goes to healthcare locations with the aim of receiving prescription for drugs in excess of what they need for their state of health.

1.0 Introduction

In March 2006 NHS Connecting for Health (NHS CFH) requested that DNV propose a process for, and initiate a risk assessment of the impact of the Sealed Envelopes project on patient safety. Within the proposal DNV highlighted the need to understand the balance between “patient safety” and “breaches in confidentiality” risks relating to the patient records within the NHS CFH project. DNV were engaged by NHS CFH and in this document the risk assessment process, its results and conclusions are reported.

NHS CFH arranged a Steering Group to provide guidance to the DNV team throughout the project. The Steering Group was formed of people who had knowledge of the Sealed Envelopes (SE) solution. They advised on the patient groups and specific individuals to be interviewed and to involve in the assessment. The Steering Group supported and reviewed the risk approach and all the deliverables.

The initial assignment was a comparative risk review aimed at identifying the change in perceived risk levels between:

- The current Sealed Envelopes (SE) design (where confidential information is held on the Spine in sealed envelopes), and;
- A situation where SEs are not available.

During the assignment an alternative sealing approach was suggested. This was included in the comparative review:

- The Alternative Sealed Envelope (ASE) design (where confidential information is held locally, e.g. within a GP practice).

A description of the sealing processes can be found in the NHS CFH documents presented in Appendix I.

Three different types of risk were identified for consideration, these were” fear of breach of confidentiality”, “patient safety” and “breaches of confidentiality”. Initially the fear of breach was considered integral to the other types but was separated out during the process as it was felt it differed significantly to the others.

The assessment therefore considers three solutions and three types of risk:

Three Solutions	Three Types of Risk
1. The current “Sealed Envelope” (SE) solution.	1. Patient Safety risks.
2. The “Alternative Sealed Envelope” (ASE) solution.	2. Breach of Confidentiality risks.
3. A “without sealing” solution.	3. Fear of Breach of Confidentiality risks

Using a risk matrix, the risk level for each identified risk was classed as:

- “Low”.
- “Medium”.
- “High”.

The results are presented using these risk classes. The definitions and development of the risk matrix is presented in Section 4.2 and Appendix II.

In addition to Sealed Envelopes it should be recognised that there are other mechanisms in place within the Programme products to maintain confidentiality of data (see Box 1.1). The assessment was made on the basis that these mechanisms are in place for all three sealing solutions studied.

Mechanisms for Ensuring the Confidentiality of Patient Information

“Sealed Envelopes” are one of several mechanisms for ensuring the confidentiality of patient information within the NHS Care Records Service. Confidentiality mechanisms include:

- Smart cards will ensure that only the card holder has authority permission levels of access to the records.
- Legitimate Relationships (LRs), which allow only those users with a direct patient relationship (such as the patient’s care team) to access that patient’s NHS CRS clinical records.
- Role Based Access Controls (RBACs), where a person’s job role and other attributes determine the NHS CRS system functions they can use and thus the type of data they can access (preventing, for example, an NHS manager from accessing identifiable clinical data).
- Sealed Envelopes are an access restriction information governance control. There are patient sealed envelopes which store information the patient says they want kept confidential, and there are clinician sealed envelopes which store information the clinician wishes to maintain as confidential prior to sharing it with a patient.
- Patient consent or dissent to NHS CRS information sharing – patient dissent prevents identifiable clinical information being accessible across organisational boundaries.

To help maintain and monitor the robustness of these controls, there are:

- Alerts: alerting a privacy officer where there is a question about the appropriateness of user access.
- Audit trails: records are made every time a patient’s record is accessed, which are available to patients on request.

Box 1.1

2.0 Objective and Scope

The initial objective of the risk assessment work was to assess the “patient safety” risks and the “breach of confidentiality” risks for the NHS CFH deliverables with and without SEs. During the project, and following the initial scoping, the ASE solution was developed. The project objective was therefore revised to consider risks associated with and without either of the sealing approaches. During the latter stages of the project it emerged that “fear of a breach of confidentiality” risks should be assessed and presented separately. “Fear of breach of confidentiality” overlaps both “patient safety” and “breach of confidentiality”; by treating it separately all implications were fully considered.

This risk assessment was designed to assist NHS CFH in deciding the most appropriate way forward with sealing. This was achieved by identifying the associated levels of risk with the various suggested approaches. The risk results allow NHS CFH to compare the summed “patient safety”, “breach of confidentiality” and “fear of breach of confidentiality” risks for electronic patient records with and without sealing, and for both sealing solutions.

The risk assessment reported here is for the Sealed Envelopes project only and does not consider or address the risks associated with the technology supporting the project.

DNV used a two stream approach in this risk assessment:

- Assessing the patient safety risks.
- Assessing the confidentiality (breach and fear of breach) risks.

The work streams were run in parallel.

3.0 Consulted Parties

Throughout the project relevant parties were consulted. The project was overseen by a Steering Group, interviews were undertaken with experts recommended by (amongst others) the steering group, and a range of people from within NHS CFH and various external/voluntary organisations participated in the risk assessment workshops. The names of those who contributed as Steering Group members and interviewees are detailed below. Sections 4.4.2 and 4.6.2 list the names of those involved in the risk assessment workshops.

3.1 Steering Group

The Steering Group met at regular intervals throughout the assignment with their level of participation being determined by their existing workload. The Steering Group was comprised of the following members:

- Maureen Baker – NHS CFH and National Patient Safety Agency (NPSA) – Clinical Safety Officer and Special Clinical Adviser.
- Steve Bentley – NHS CFH – Senior Clinical Consultant.
- Sarah Bronsdon – NHS CFH – Senior Public Engagement Officer.
- Ian Johnstone – NHS CFH – Head of External Resources.
- Joanne Nash – NHS CFH – Sealed Envelope Project Manager.
- Laurie Slater – NHS CFH – Clinical Advisor, GP National Clinical Leads.
- Jim Shannon – Department of Health – Policy Development, CRAG Chairman and Confidentiality Policy Manager
- Michael Thick – NHS CFH – Chief Clinical Officer / Medical Director.
- Phil Walker – Department of Health - Deputy Head of Digital Information Policy Digital & Health Information Policy Directorate.
- Richard Wild – NHS CFH – Technical Advisor.

DNV project team members were:

- Gavin Astin – DNV – Risk Expert / Facilitator.
- Mark Boulton – DNV – Risk Expert / Facilitator.
- Ken Garnett – DNV – Risk Expert / Facilitator.

3.2 Interviewees

During the assignment, interviews with identified expert participants were arranged and undertaken to gain opinions on patient safety and confidentiality issues when applying a Sealed Envelope process. Interviews were primarily held face to face, and a limited number were held by phone to accommodate the work schedules of the individual. Members of the Confidentiality Requirements Advisory Group (CRAG) held an open discussion with DNV as part of one of their meetings.

Interviewees (for both this task and Task 4.5) were:

- Maureen Baker – NHS CFH / NPSA – NHS CFH and National Patient Safety Agency (NPSA) – Clinical Safety Officer and Special Clinical Adviser.
- Dr Gillian Braunold – NHS CFH – National Clinical Lead.
- Sarah Bronsdon – NHS CFH – Senior Public Engagement Officer.
- Anne Cooper – NHS CFH – Clinical Advisor.
- Tim Donohoe – NHS CFH – Group Programme Director Electronic Prescribing.
- Nicola Doyle – Department of Education & Skills.
- Simon Eccles – NHS CFH – National Clinical Lead, Hospital Doctors.
- Karen Foy – NHS CFH - Senior Public Engagement Officer.
- Susan Grieve – Department of Health – Pharmacist.
- Alison Hadley – Teenage Pregnancy Unit.
- Christine Mead – Terrence Higgins Trust.
- Peter Murphy – NHS CFH – Clinical Advisor.
- Malcolm Oswald – NHS CFH – Information Governance Advisor.
- Sara Wilcox – Alzheimer’s Society.
- Marline Winfield – NHS CFH - Head of Public Engagement.
- CRAG (Confidentiality Requirements Advisory Group):
 - Caroline Harrison – BMA – Ethics.
 - Jim Shannon – Department of Health – Policy Development, CRAG Chairman and Confidentiality Policy Manager.
 - Connie Smith – GUM.
 - Karen Thompson - Patient Information Advisory Group - Head of Operations.

4.0 Process Applied

The overall approach to the project is presented in Figure 4.1. After the initial meeting (Task 4.1), the process commenced with the identification of the patient safety and confidentiality risk scenarios. These scenarios were developed through one to one interviews with personnel from a range of healthcare settings, and then refined by the Steering Group (Tasks 4.3 and 4.5). The risk matrix for assessing the identified risks was developed in parallel (Task 4.2). Two workshops were then facilitated by DNV, to analyse the patient safety and confidentiality (breach and fear of breach) risk scenarios (Tasks 4.4 and 4.6). Within the workshops recommendations were created and the risks ranked again, to determine the risk profile with the recommendations in place. All of the information was captured by a DNV consultant, (see Appendix IV). Each of the tasks (4.1 to 4.7) is described in the following sections.

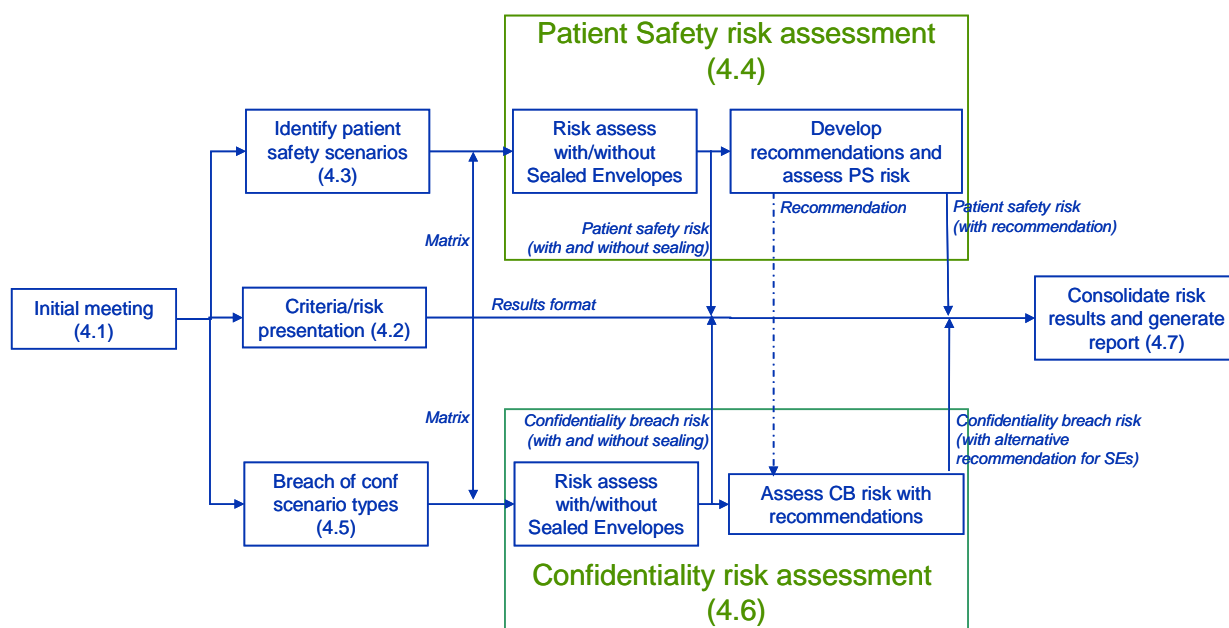


Figure 4.1 DNV Approach (Numbers in Drawing Relate to Sections in Report)

4.1 Initial Meeting

NHS CFH representatives and the DNV project team met to ensure a satisfactory and achievable approach to the project. The way forward, including the interactions between the project activities and the Steering Group, was agreed. The Steering Group had an essential guidance role throughout the assignment.

Initial dates were agreed for Steering Group meetings and a list of names of people to interview was developed. It was agreed that the NHS CFH would take the lead in setting-up and scheduling the meetings, interviews and the risk workshops. (During the project additional names were added to the list of people to interview, the full list of people interviewed is presented in Section 3.2).

4.2 Criteria and Risk Presentation

To allow risks (both patient safety risks and confidentiality risks) to be assessed, a risk matrix covering relevant potential adverse outcomes was developed. Its development drew on:

- The current NHS CFH risk matrix guidance document.
- Learning from the interviews.
- Discussions at the Steering Group.
- Learning gained in its application during the risk workshops.

DNV presented, to the Steering Group, proposals for the different aspects of the risk matrix at various stages during its development to gain their input and agreement on its structure and details.

4.3 Initial Identification of Patient Safety Risks

To identify the patient safety risks DNV undertook a series of interviews with a range of people from different organisations (identified with the help of the Steering Group, see Section 4.1) and a variety of healthcare backgrounds, (clinical, patient representatives, policy makers, etc.). Based on the discussions, a series of patient safety risk scenarios were developed.

The scenarios developed from the interviews were shared with the Steering Group. The scenarios were refined and used as the basis for the patient safety risk assessment workshop.

4.4 Patient Safety Risk Assessment Workshop

4.4.1 Preparation

Workshop preparation included:

- Refinement of the initial scenarios (see Section 4.3).
- Ranking the scenarios (to assure that the risk workshops focused their time on the risk scenarios of greatest significance).
- Preparation of the risk assessment record sheet.
- Pre-population of the risk assessment record sheet (based on the learning from the interviews and with input on specific medication issues from Dr Laurie Slater, a member of the Steering Group). Note that pre-populating was also aimed at efficiency, to cover as much ground as possible in the risk assessment workshop.

4.4.2 Workshop Attendees

The following personnel attended the workshop, their contribution is very much appreciated:

- Martin Baggaley – NHS CFH – Clinical Lead (London) / Consultant Psychiatrist.
- Katherine Henderson – St Thomas' Hospital – A&E.
- Sara Johnson – NPSA – Patient Safety Women's Services.
- Christine Mead – Terence Higgins Trust.
- Laurie Slater – NHS CFH – Clinical Advisor, GP National Clinical Leads.
- Sara Wilcox – Alzheimer's Society.
- Richard Wild – NHS CFH – Technical Advisor.
- Mark Boulton – DNV – Risk Expert / Facilitator.
- Gavin Astin – DNV – Risk Expert / Facilitator.

4.4.3 Risk Assessment Workshop Meetings

The process in the workshop was as follows:

- NHS CFH presented the Sealed Envelope (SE) and the Alternative Sealed Envelope (ASE) confidentiality solutions to everyone so they all had the same understanding.
- DNV presented the risk matrix and the risk assessment process being followed and the record sheet that would be used to capture the information.
- The workshop members reviewed the pre-populated worksheets; they were given the opportunity to propose additional scenarios and concealed information categories for the analysis (drawing on their own background and experience, and on the types of information they felt could potentially be sealed by a patient). They also added their ranking of scenarios to the prioritisation undertaken during preparation.
- Starting with the most important scenario from the ranking, the workshop team went through and further developed the risk assessment, updating the risk record sheets. This involved:
 - Specifying, at a second level of detail, the scenarios of greatest risk.
 - Defining the potential adverse outcomes.

- Risk ranking the scenarios using the risk matrix for:
 - The SE solution.
 - The ASE solution.
 - Having full sharing and no sealing of information.
- During the process, relevant causes and safeguards raised in the discussion, were captured in the record sheets.
- Making recommendations to mitigate the medium and high risks identified.
- The risks were ranked again with the recommendations in place.
- Each scenario was ranked within the workshop to give an understanding of which would produce the greatest risk to the patient's safety.
- Due to time factors in the workshop, the two most important scenarios were analysed in detail, these were:
 - Diagnosis and treatment of a patient who lacks capacity when details of a current or past care episode are unavailable (e.g. an unconscious patient arrives in A&E).
 - Prescribing when details of a current or past care episode (including medication details, adverse reactions, etc.) are unavailable.

The other scenarios were initially assessed by the DNV team based on their learning from the interviews and workshop. They were then shared with the workshop members, and all comments received were incorporated into the worksheets.

4.5 Initial identification Breach of confidentiality risks

To identify the breach of confidentiality risks, DNV undertook a series of interviews with a range of people (identified with the help of the Steering Group, see Section 4.1) from different organisations and different healthcare backgrounds, (clinical, patient representatives, policy makers, etc.). Based on the discussions a series of "breach of confidentiality" risk scenarios were developed along with a "fear of breach of confidentiality" scenario.

The scenarios developed from the interviews were shared with the Steering Group. The scenarios were refined and used as the basis for the confidentiality risk workshops.

The interview activity included meeting with the CRAG (Confidentiality Requirements Advisory Group) to discuss the aspects of confidentiality already identified and their associated risks. Additional people were identified from patient representatives group; these were Terence Higgins Trust, MIND, Teenage Pregnancy Unit and Alzheimer's Society.

4.6 Breach of Confidentiality and Fear of Breach of Confidentiality Risk Workshop

4.6.1 Preparation

Preparation for this workshop included:

- Refinement of the initial scenarios (see Section 4.5).
- Ranking the scenarios (to assure that the risk workshops focused their time on the risk scenarios of greatest significance).
- Preparation of the risk assessment record sheet.
- Partial pre-population of the risk assessment record sheet (based on the learning from the interviews). Note that pre-populating was also aimed at helping facilitate covering as much ground as possible in the risk assessment workshop.

4.6.2 Workshop attendees

The following people attended the workshop and their contribution is very much appreciated:

- Sarah Bronsdon – NHS CFH – Senior Public Engagement Officer.
- Sheila Davies – Contact a Family - Paediatrics Project Officer.
- Mark Hegarty – Terrence Higgins Trust - Counselling Placements Manager.
- Mark Leveson – CSIP London Development Centre - Head of User Participation & Development.
- Joanne Nash – NHS CFH – Sealed Envelopes Project Manager.
- Mary Norowzian – RNIB - Head of Emotional Support Service.
- Jim Shannon – Department of Health – Policy Development, CRAG Chairman and Confidentiality Policy Manager.
- Catherine Whitehouse – The Lilith Project - Sexual Violence Resource Worker.
- Sara Wilcox – Alzheimer's Society.
- Mark Boulton – DNV – Risk Expert / Facilitator.
- Ken Garnett – DNV – Risk Expert / Facilitator.

4.6.3 Risk Assessment Workshop Meetings

The Breach of Confidentiality Workshop was held on 9th August 2006 (an earlier selected date for the workshop was cancelled due to unavailability of delegates).

The process in the workshop was as follows (and is consistent with the Task 4.4 workshop approach):

- NHS CFH presented the SE and ASE confidentiality solutions to everyone so they had the same level of understanding.
- DNV presented the risk matrix, the risk assessment process being followed and the record sheet that would be used to capture information.
- The workshop members reviewed the pre-populated worksheets and proposed additional scenarios and concealed information categories for the analysis. They also added their ranking of scenarios to the prioritisation undertaken during the preparation.
- Starting with the most important situations from the ranking, the workshop team went through and further developed the risk assessment, updating the risk record sheets. This involved:
 - Specifying, at a second level of detail, the scenarios of greatest risk.
 - Defining causes, adverse outcomes and safeguards for each risk scenario.
 - Risk ranking the scenarios using the risk matrix for:
 - The SE solution, without and with patient safety recommendations.
 - The ASE solution, without and with patient safety recommendations.
 - Having full sharing and no sealing of information.
 - Making recommendations to mitigate medium and high risks identified.
 - The risks were ranked again with the recommendations in place.
- Each scenario was ranked within the workshop to give an understanding of which scenario would produce the greatest risk to the patient.
- Due to time constraints the attendees did not have sufficient time to populate the entire worksheet. The workshop therefore analysed the highest ranked scenarios in the workshop. The sheets from the workshop were shared with the attendees. DNV and NHS CFH personnel reviewed the feedback from the workshop attendees. The record sheet was revised and finalised, and then circulated to the attendees for further comments.

4.7 Reporting

This document (the project's report) was drafted and submitted firstly to NHS CFH for their review and comment and subsequently to the Steering Group. The comments received were incorporated in the subsequent revisions of the report.

5.0 Intermediate Outputs and Deliverables

5.1 Initial Meeting and Steering Group Meetings

Notes on the discussions which took place during the initial and subsequent Steering Group meetings were produced. These are not presented in this report, but have been provided to NHS CFH and distributed to all Steering Group Members.

5.2 Interviews

Notes were taken by hand during the interviews. These notes have been scanned and are compiled into a single document which has been provided to NHS CFH as part of the record of the project.

The interviews were fundamental to DNV gaining an understanding of the potential sealed envelope design and its implication with regard to patient safety and breach of confidentiality risks. They also formed the basis for the “patient safety”, “breach of confidentiality” and “fear of breach of confidentiality” risk scenarios which created the starting point for the risk analysis (see Section 5.4).

One major result of the interviews was to start NHS CFH thinking of alternative solutions that would provide the desired confidentiality in a practical and effective manner without adversely impacting on patient safety. As a result of the DNV interviews an additional potential solution was brought into the project, namely to assess both patient safety and confidentiality risks for an “Alternative Sealed Envelope” approach (ASE). The description of this approach is presented in Appendix I along with a description of the Sealed Envelope (SE) solution.

5.3 Risk Criteria and Risk Matrix

The risk matrix used in the analysis is presented in Figure 5.1 and Appendix II (where the definitions for the likelihood and consequence classes are stated). It should be noted that the matrix draws on the current NHS CFH risk matrix guidance document (NPSA, 2006) and was reviewed during its development by the project’s Steering Committee. It has been structured to allow patient safety risks and confidentiality risks to be assessed using the same matrix. To achieve this, consequence class definitions for both patient safety and confidentiality outcomes have been created.

Likelihood	Very Often	7	Medium	High	High	High	High	High
	Often	6	Medium	Medium	High	High	High	High
	Frequent	5	Low	Medium	Medium	High	High	High
	Occasionally	4	Low	Low	Medium	Medium	High	High
	Infrequently	3	Low	Low	Low	Medium	Medium	High
	Rare	2	Low	Low	Low	Low	Medium	Medium
	Very Rare	1	Low	Low	Low	Low	Low	Medium
Sealed Envelopes Risk Matrix			A	B	C	D	E	F
			Negligible / Very Low	Low	Moderate	Severe	Major / Fatal	Catastrophic
		Consequence						

Figure 5.1 Risk Matrix

5.4 Risk Scenarios

5.4.1 Patient Safety Risk Scenario

For the patient safety risk assessment, a set of healthcare situations and potentially concealed information (i.e. information which is unavailable during a healthcare situation) were used as the starting point (initial patient safety risk scenarios) for the risk workshops. These are presented in Table 5.1.

Table 5.1 Initial Patient Safety Risk Assessment Scenarios

Healthcare Situation	Combined with	Concealed Information
PA. Consultation when details of a current or past care episode are unavailable	}	HIV and AIDS
PB. Diagnosis and treatment of a patient who lacks capacity when details of a current or past care episode are unavailable (e.g. an unconscious patient arrives in A&E)		Sexual health (including TOP)
PC. Prescribing when details of a current or past care episode (including medication details, adverse reactions, etc.) are unavailable		Mental health
PD. Screening / diagnosis based on scans, tests, etc. when details of a current or past care episode are unavailable		Family history - hereditary illness
PE. Pre-assessment for surgery when details of a current or past care episode are unavailable		At risk of harm (children or vulnerable adults)
PF. Elective surgery when details of a current or past care episode are unavailable		Malignant disease
		Violent patient
		Drug addiction
		Other current clinical episode
		Other previous clinical episode

5.4.2 Breach of Confidentiality

In a similar manner to the patient safety risk assessment, for the breach of confidentiality risk assessment, a set of situations and potential concealed information were used as the starting point (initial breach of confidentiality risk scenarios) for the risk workshops. These are presented in Table 5.2.

Table 5.2 Initial Breach of Confidentiality Scenarios

Healthcare Situation	Combined with	Concealed Information
CA. Accessing confidential information for treatment when there is other confidential information on another care episode in the patient's record	}	HIV and AIDS
CB. Patient requests information on care episode be kept confidential. Healthcare professional does not file information in a confidential manner – primary entry, (e.g. after a GP consultation)		Sexual health (including TOP)
CC. Patient requests information on care episode be kept confidential. Healthcare professional does not file information in a confidential manner – secondary entry, (e.g. when test results received after consultation at a GP's office)		Mental health
CD. "Deduction" from information of contents of confidential information. (For example: the diagnosis is held in a confidential area of the record, but medication is not and the drugs give away contents, context sensitive field display reveals contents, search by clinician reveals contents)		Family history - hereditary illness
CE. Inappropriate revealing (unsealing) by second clinician of information marked as confidential to original clinician		At risk of harm (children or vulnerable adults)
CF. Family, friends or neighbours working in healthcare access patient confidential information through normal and natural work activities (including shoulder surfing and work groups)		Malignant disease
CG. Healthcare worker gains unauthorised access (unethical behaviour)		Violent patient
CH. External party gains unauthorised access (e.g. hacker)		Drug addiction
		Other current clinical episode
		Other previous clinical episode

5.4.3 Fear of Breach of Confidentiality

If a patient or a group of patients lose confidence in the confidentiality aspects of the records they may be very concerned about accessing healthcare professionals. This scenario is not a breach of confidentiality or a patient safety issue. This perceived "Fear" could deter the patient(s) from seeking advice / medication, which may be detrimental to their long term health or to their family / community if they have a communicable disease. The scenario is found in Table 5.3

Table 5.3 Fear of Breach of Confidentiality

Healthcare Situation	Combined with	Concealed Information
FA. Treatment not sought due to fear of breach of confidentiality	}	HIV and AIDS
		Sexual health (including TOP)
		Mental health
		Family history - hereditary illness
		At risk of harm (children or vulnerable adults)
		Malignant disease
		Violent patient
		Drug addiction
		Other current clinical episode
		Other previous clinical episode

6.0 Findings

6.1 Patient Safety Risk Assessment

The patient safety risk assessment record sheets are presented in Appendix IV. From the sheets the following results / findings can be drawn:

- The majority of the risks identified and discussed where sealed information could have an impact on patient safety were assessed to be “low”, see Figure 6.1.

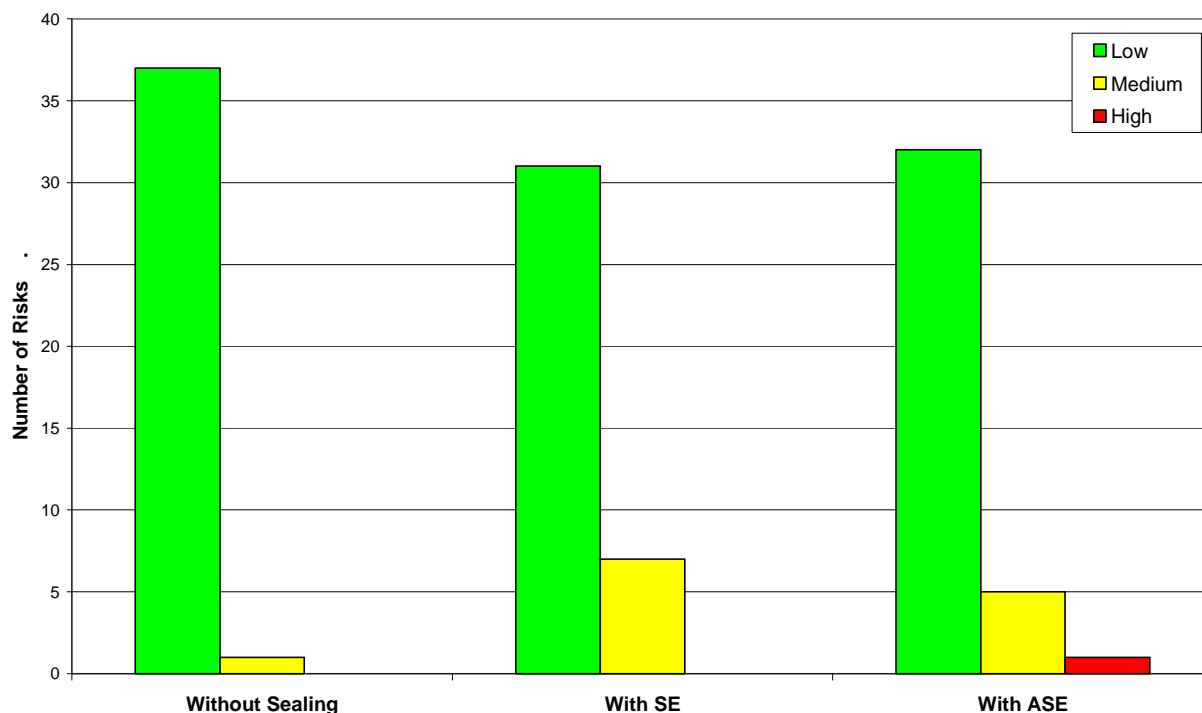


Figure 6.1 Bar Chart Showing Assessed Patient Safety Risks for the Two Sealing Options and Without Sealing

- The patient safety risks are higher with sealing (either with SEs or with the ASE) than without, see Figure 6.1 and Figure 6.2. This is because, in comparison with having all information shared, sealing is more likely to allow healthcare to be provided based on incomplete information. As such the decisions and treatment have a greater potential to be made / provided incorrectly with resulting adverse consequences for a patient.

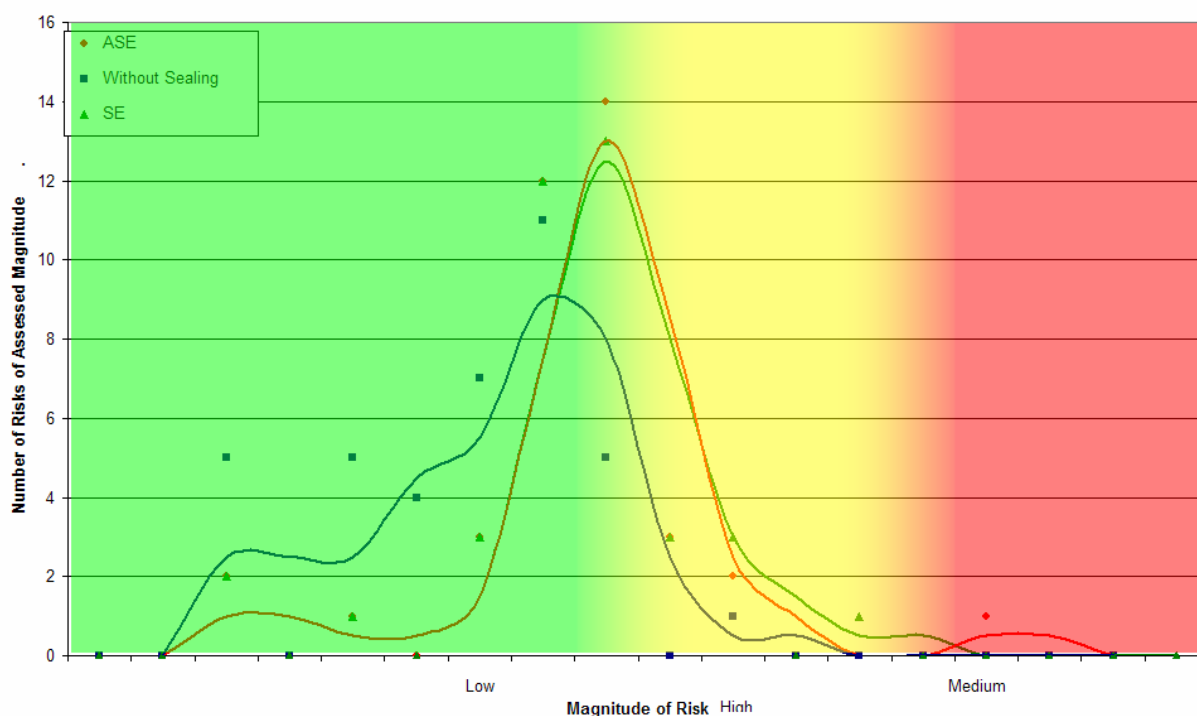


Figure 6.2 Distribution of Assessed Patient Safety Risks Comparing the Two Sealing Options and Without Sealing

- Between the two sealing options, discussions concluded that the likelihood of patient safety incidents is generally lower with the SE option than the ASE option. The reasons are:
 - The SE approach is a more involved process to implement (i.e. has more steps in it) , hence it was felt that there will be more occasions where data that should have been sealed is openly shared (in error). Although this is a breach of confidentiality it reduced the potential for errors in diagnosis and treatment due to healthcare workers having incomplete information.
 - Generally healthcare providers treat patients in a manner which assumes that not all information is available. This is the current way of working. In the future the system may create an expectation that all information is available, and there may be greater reliance on, and belief in, decision support. With the SE option the healthcare provider’s screen will show that the patient’s record contains sealed information. In effect this is a reminder. This will reduce the potential for the provider to fail to seek other information or to ask for access to the sealed information.
 - With the SE solution it is possible in exceptional circumstances (with strict guidelines on when it is appropriate) for envelopes to be opened in the "Public Interest". This is not possible in the ASE solution.

Although on a general basis it was judged that SE would be less likely to result in patient safety incidents than the ASE solution, the relative difference was judged to be such that it

was not sufficient to allocate the risk to a different likelihood class. (Note that the likelihood classes are a factor of 10 different from their neighbours).

- There was just one situation where the ASE solution was assessed to be significantly safer than the SE solution. This is where treatments occur solely within one healthcare organisation. In the ASE solution the information will be presented in an unsealed manner to users with legitimate access (e.g. with RBAC/LR controls in place). Full information is therefore visible to the provider, as well as being automatically accessed by decision support functions. In contrast, the SE requires additional interaction to see the sealed information. This difference came up explicitly when considering the scenario where a woman on oral contraceptives is treated with a broad range antibiotic (although standard medical practice would be to check this interaction).
- There was also one scenario where the risk with the SE solution was judged to be significantly safer than with the ASE solution. This related to a “habitual seeker of medication”. Such a patient would typically move from healthcare within one location to another location seeking prescriptions / drugs. In the ASE solution there will be a facility to keep their past receipt of medication confidential locally. With the SE solution if they request their treatment be “Sealed” then the sealing action reveals all past medications (as there is only one envelope with all sealed information within it). For this reason the potential of the habitual seeker to overdose is reduced in the SE solution relative to the ASE solution.
- The majority of the more significant risks identified related to the sealing of medication for one treatment followed by a subsequent treatment with that treatment being given without knowledge of the sealed medication. The medications interact with adverse consequences for the patient.
- Another risk type identified is where allergy information has been sealed (e.g. where an allergic reaction occurred with a previous treatment and the whole treatment episode has been sealed). In this case the concern relates to a treatment which brings on a second allergic reaction (which could have been avoided).
- From a patient safety point of view it is clear that if medication and allergy information “can not” be sealed, then patient safety will be improved. It is understood that this may not be acceptable from other view points. Without any constraints the risk assessment makes the following two patient safety recommendations:
 - **R1** - Medication details are not allowed to be sealed and are automatically shared.
 - **R2** - Allergy details are not allowed to be sealed and are automatically shared. For example allergy information is recoded in a manner such that it cannot and is not allowed to be sealed. It is treated to some extent like demographic data; NHS No 123456789, is for Mr Smith of London, he has blue eyes and an allergy to penicillin, etc.

- It is recognised that recommendations for variations in the ability to seal information (R1 and R2) will have an impact on breaches of confidentiality.
- In addition the assessment makes one other procedural patient safety recommendation unrelated to sealing:
 - **R3** - Doctors should continue to ask if the patient is taking an oral contraceptive (or other medication) before prescribing antibiotics. They should not rely upon the information presented on the computer screen, the human interaction is vital.

Recommendation R3 is currently standard practice, but was raised by the team because it was judged that in the future healthcare professionals could rely heavily on the decision support weakening this current control. Consideration should be given to broadening this recommendation to other checks undertaken today where potentially sealed information will influence diagnoses and treatments.

- The impact of the recommendations is to change the risk profile for the different sealing options as shown in Figure 6.3.

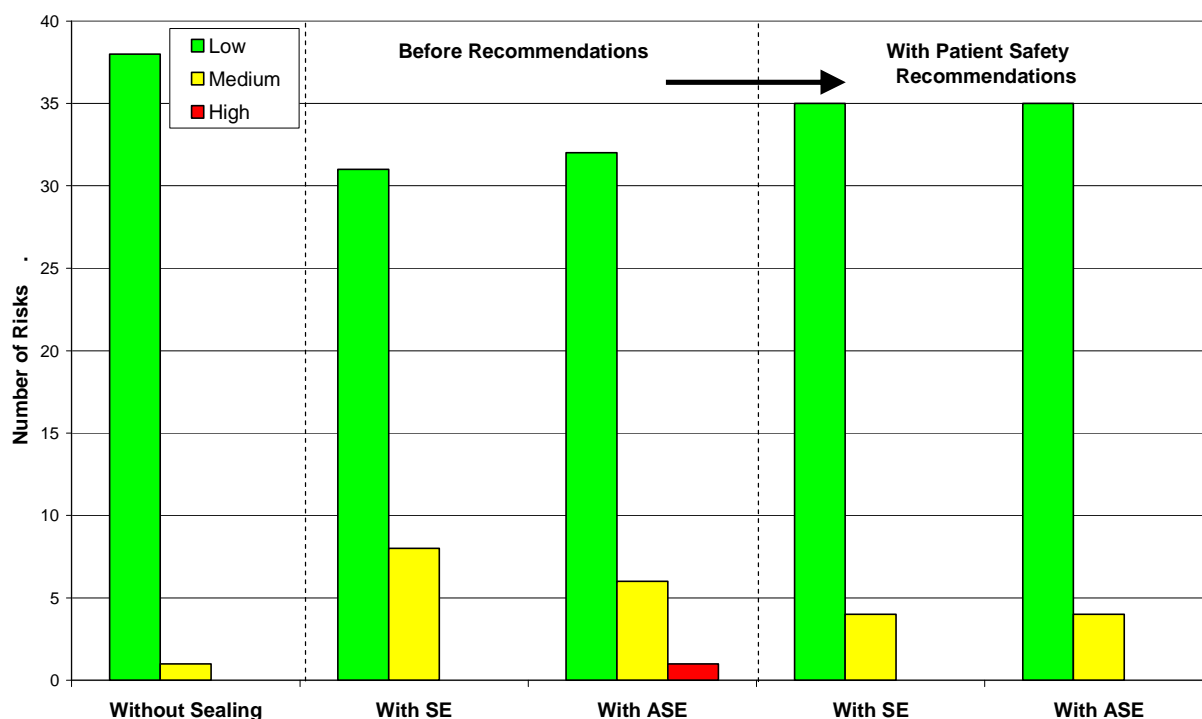


Figure 6.3 Impact of Recommendations on Patient Safety Risk Profile for Risk Identified as Being Impacted by the Sealed Envelope Solution

6.2 Breach of Confidentiality Risk Assessment

The breach of confidentiality risk assessment record sheet is presented in Appendix IV. From the record sheet the following results / findings can be drawn:

- The majority of the risks identified and discussed where sealing / not sealing information could have an impact on breach of confidentiality risk were assessed to be “low” or “medium”, see Figure 6.4.

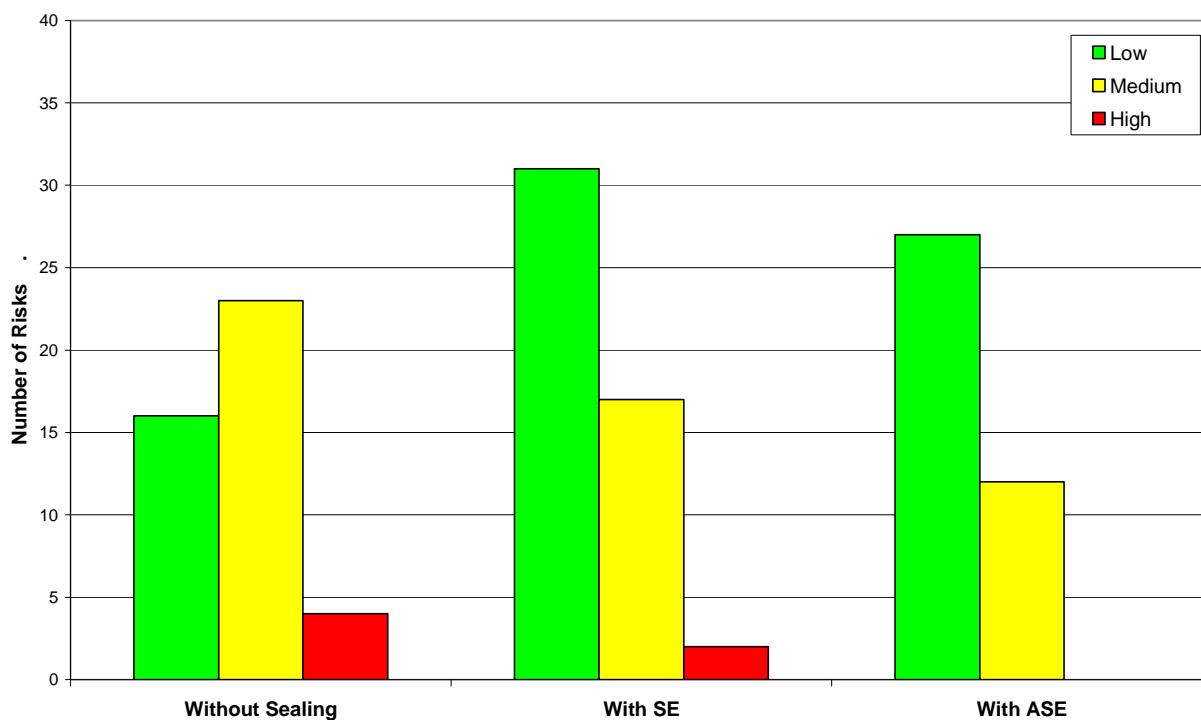


Figure 6.4 Bar Chart Showing Assessed Breach of Confidentiality Risks for the Two Sealing Options and Without Sealing

- As would be expected the breach of confidentiality risks are higher without sealing than with (either with SEs or with the ASE), see Figure 6.4 and Figure 6.5.

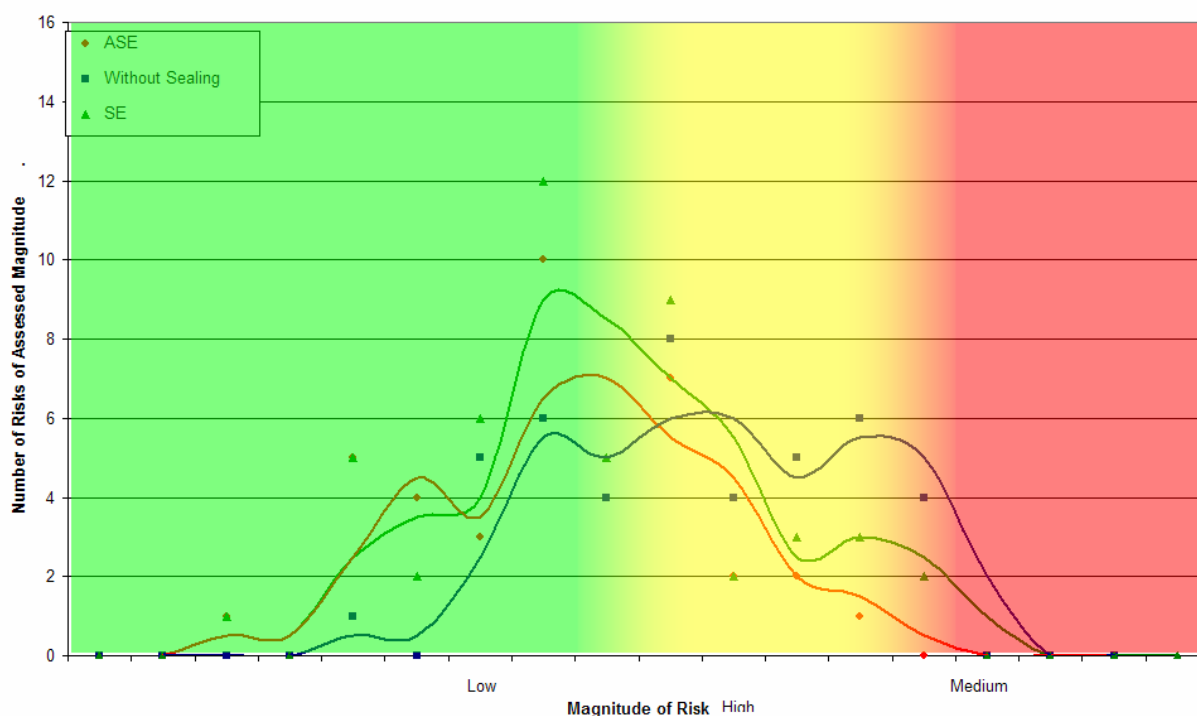


Figure 6.5 Distribution of Assessed Breach of Confidentiality Risks Comparing the Two Sealing Options and Without Sealing

- Between the two sealing options, discussions concluded that the likelihood of confidentiality incidents is generally lower with the ASE solution than the SE solution. The reasons for this are:
 - Confidential information is not held on the spine for the ASE option.
 - Breaches of spine held information in clinical settings are therefore not possible with the ASE option.
 - Confidential information will not be available on Healthspace with the ASE solution. Breaches via Healthspace are therefore not possible with the ASE option.
 - Less people will have access to the confidential information.
 - Patients will know that information is held locally and will be visible to all in a work group (e.g. a GPs practice). If a second person from a work group mentions the confidential information to the patient, they will know that person, as today, has access to their notes. Although they may be embarrassed they will not be as surprised and upset as they would if they had been told that the information was sealed from that person.

- There was a situation where the SE solution was assessed to pose a lower confidentiality breach risk than the ASE solution. This related to the information being automatically presented (on the screen) in a local setting with the ASE solution. With the SE solution it will be in the Sealed Envelope and as such not immediately viewable. For example a person “shoulder surfing” could see the locally held confidential information with the ASE solution. The added action to open a seal means that their viewing confidential information when “shoulder surfing” is reduced with the SE solution.
- There were “high” risks identified for the SE option. These were due to:
 - Having all confidential information in a single sealed envelope. This leads to the potential for information being kept confidential in one healthcare setting to be accidentally seen in another environment. (Example: A patient with a mental illness wishes to keep their patient records related to the illness confidential. When the patient visits a GUM clinic, a clinician accesses their envelope for the purpose of inputting details of their GUM healthcare episode into the patient record in a confidential manner. They see information in the sealed envelope which reveals the patient’s mental illness, for example the drugs the patient is taking.)
 - A failure to confidentially file the results or clinical information received from other healthcare providers relating to a specific care episode, which the patient has requested be kept confidential.
- The following recommendations were developed to reduce the risk of failure to file confidential information when received outside a consultation:
 - **R5** - If the clinical event (consultation or test result) to which it is linked, is sealed, this should be highlighted in the return record to the clinician.
 - **R9** - Make standard practice that test results remain under the clinician seal until the patient has attended a consultation and agreed they can be moved however long this may take.
- The following recommendations were developed to reduce the risk to confidentiality via Healthspace:
 - **R7** - If items are in a sealed envelope, they should not be available via Healthspace.
 - **R8** - The ability to change a password should be via a GP or other service to be decided (not via Healthspace or a perpetrator may prohibit patients access).
 - **R10** - Sealed envelopes are not accessible via Healthspace, or clinician and patient seals should be used in conjunction with each other to keep confidential information off Healthspace.
 - **R11** - Youth sexual health services information should not be included in care records or seen on Healthspace.
- Two procedural recommendations were developed to reduce the risk of breaches of confidentiality:

- **R4** - To create confidence in the process, Patients need understanding of how confidentiality is handled. Simple but clear information at GPs, clinics and information directed at particular groups should be available. For example, sexual health / contraceptives in schools. Very careful communication is required to reassure vulnerable groups.
- **R6** - With the ASE's, the transfer of information to another healthcare provider should generally be discussed with the patient before being actioned.
- The impact of the recommendations is to change the risk profile for the different sealing options as shown in Figure 6.6.

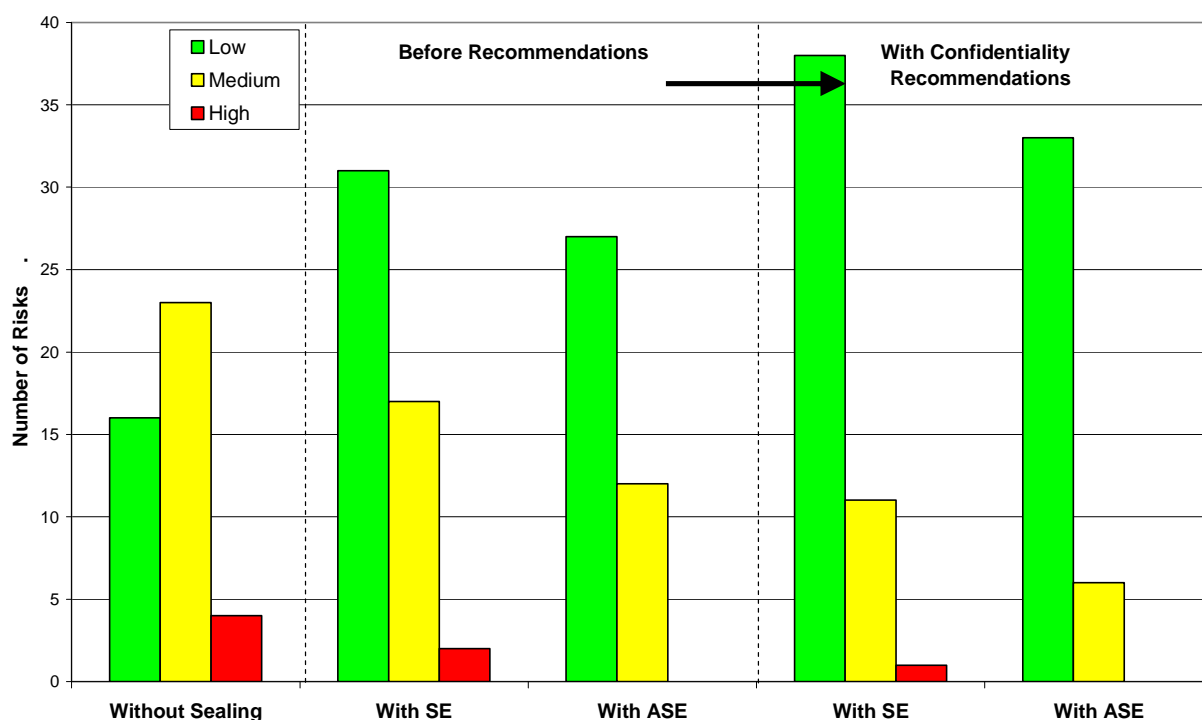


Figure 6.6 Impact of Recommendations on Breach of Confidentiality Risk Profile for Risk Identified as Being Impacted by the Sealed Envelope Solution

6.3 Fear of Breach of Confidentiality Risk Assessment

The fear of breach of confidentiality risk assessment record sheet is presented in Appendix IV. Note that these risks were separated from the patient safety and breach of confidentiality risks as they did not fall naturally into either group. The graphical results are presented using the same y-axis scale as for the equivalent graphs developed during the workshops, to allow comparison. From the record sheet the following results / findings can be drawn:

- The primary concern is that the fear of a breach of confidentiality will lead to patients delaying or not seeking treatment.
- As would be expected, the breach of confidentiality risks are higher without sealing than with (either with SEs or with the ASE), as demonstrated in Figure 6.7 and Figure 6.8.

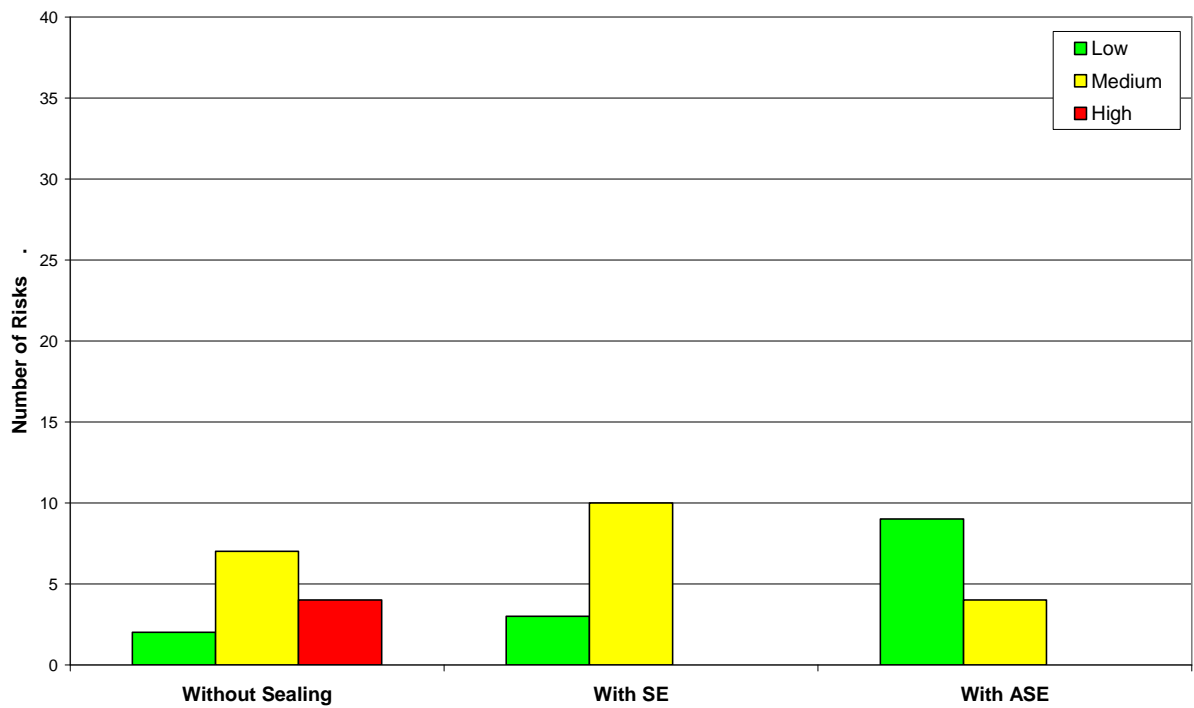


Figure 6.7 Bar Chart Showing Assessed Fear of Breach of Confidentiality Risks for the Two Sealing Options and Without Sealing

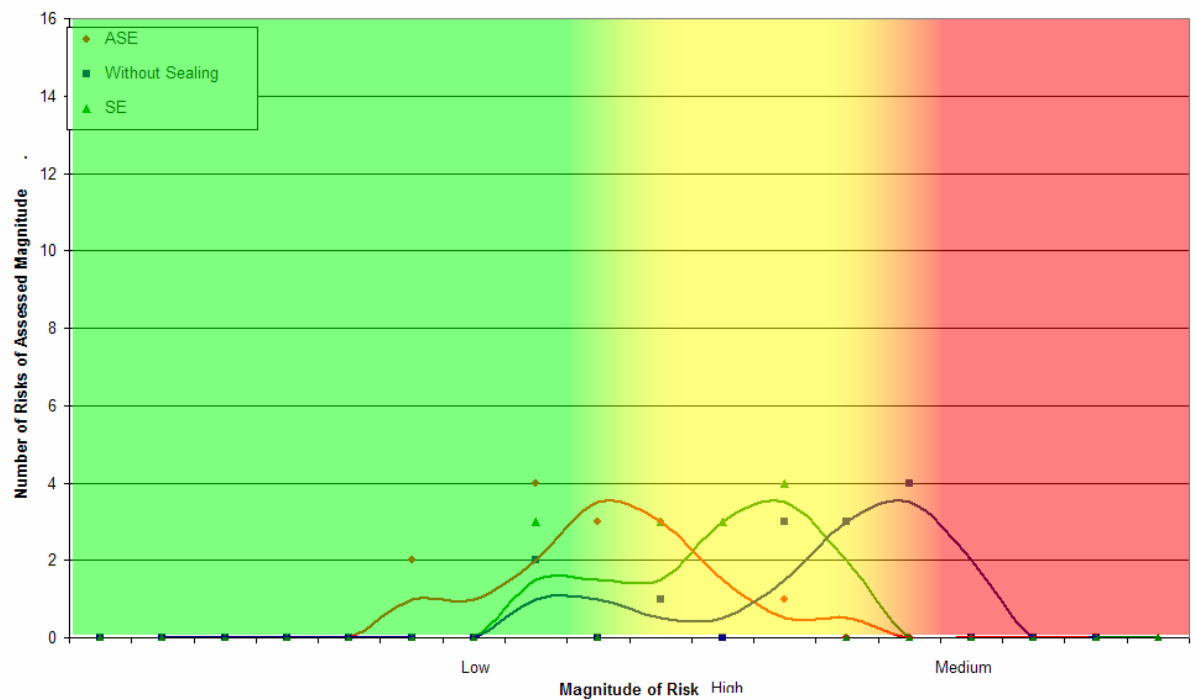


Figure 6.8 Distribution of Assessed Fear of Breach of Confidentiality Risks Comparing the Two Sealing Options and Without Sealing

- Between the two sealing options, discussions concluded that the risk due to breaches of confidentiality is generally lower with the ASE solution than the SE solution. The reason is the patient knows that the information is stored locally and cannot be accessed in another healthcare setting or via Healthspace.
- The SE and ASE solutions mitigate the fear of breach of confidentiality risks for without sealing.
- A procedural recommendation was developed to reduce the risk of fear of breach of confidentiality:
 - **R4** – To create confidence in the process, patients need understanding of how confidentiality is handled. Simple but clear information at GPs, clinics and information directed at particular groups should be available. For example, sexual health / contraceptives in schools. Very careful communication is required to reassure vulnerable groups.

6.4 Impact of Patient Safety Recommendations on Breach of Confidentiality Risks and Fear of Breach of Confidentiality

The impact of the patient safety recommendations (R1 to R3), as would be expected, increase the breach of confidentiality and fear of breach of confidentiality risks. This is the overall result and can be seen by considering both Figure 6.9 and Figure 6.10 together.

Interestingly, it can also be seen that the picture for the breach of confidentiality risk with the SE solution is more balanced. This relates to consequences being less for some risks, this is because it was felt that the patient's confidentiality expectations are reduced, and hence the breach consequences were assessed to be less severe by the workshop team.

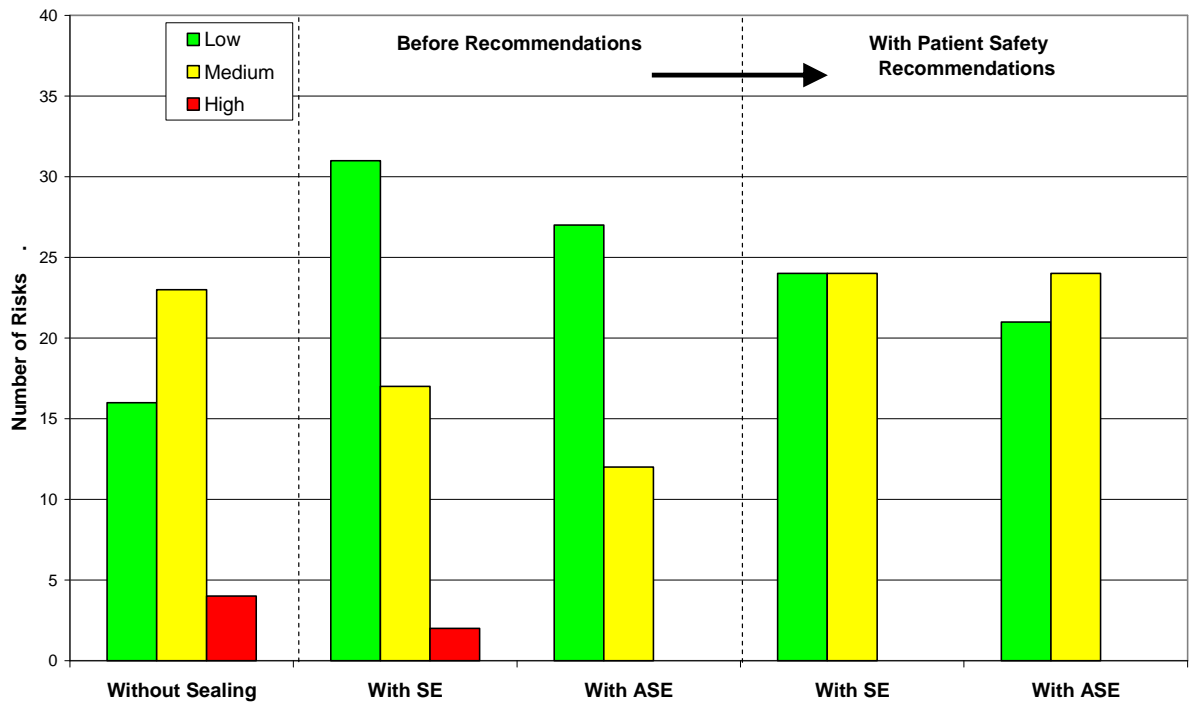


Figure 6.9 Impact of Patient Safety Recommendations (R1 to R3) on Breach of Confidentiality Risks

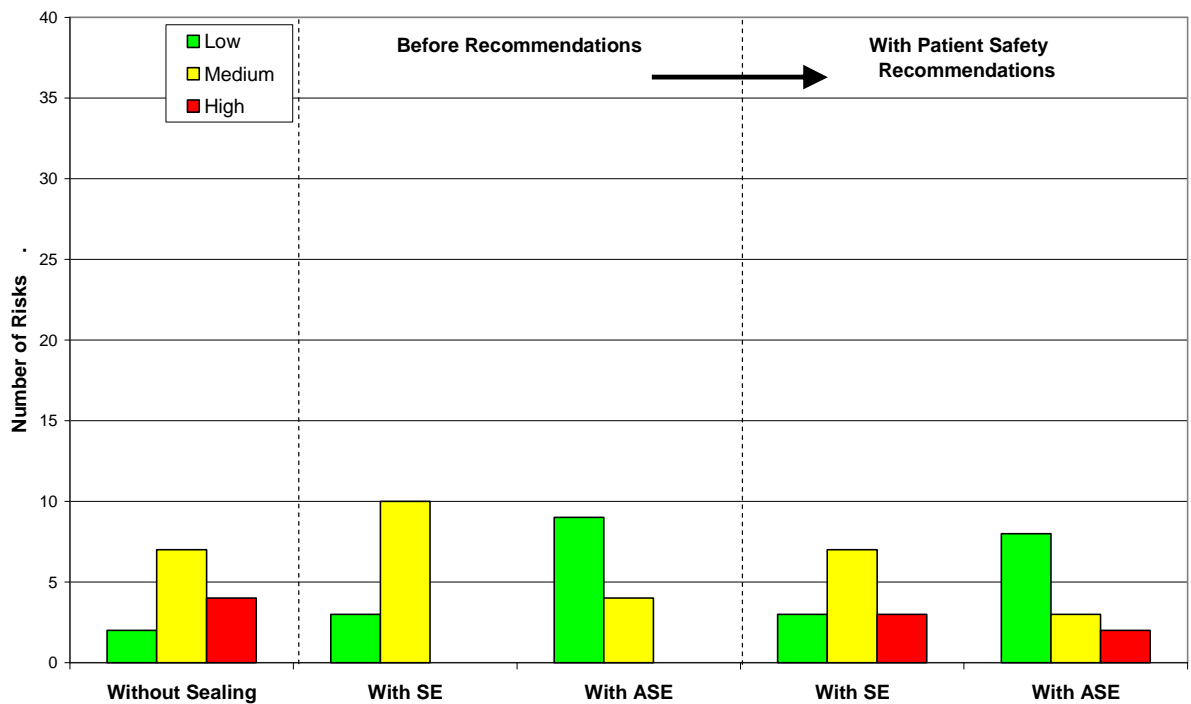


Figure 6.10 Impact of Patient Safety Recommendations (R1 to R3) on Fear of Breach of Confidentiality Risks

6.5 Combined Risk Results

The risk assessments were undertaken using a common risk matrix. It is therefore possible to consider the combined risk results, although this must be done with care. The combined results show that the SE and ASE solutions posed a lower summed risk (patient safety plus breach of confidentiality plus fear of breach of confidentiality) than the without sealing option, see Figure 6.11. It also shows that the ASE solution poses the lowest risk.

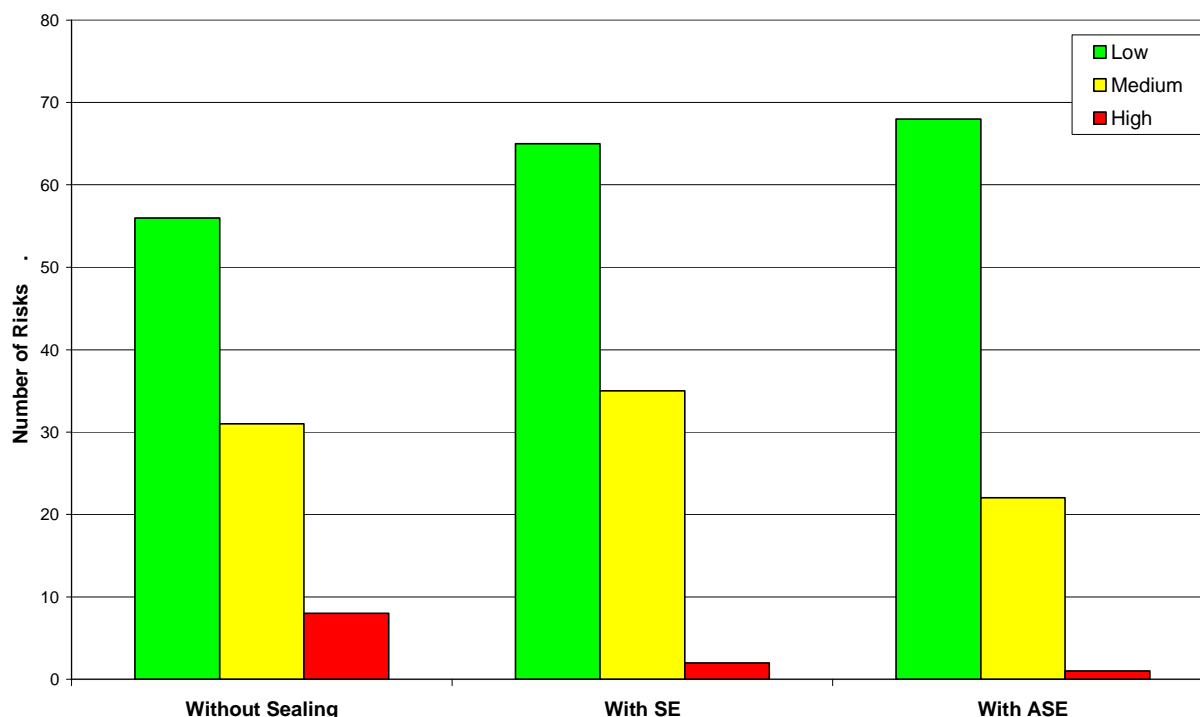


Figure 6.11 Bar Chart Showing Summed Risks for the Two Sealing solutions and Without Sealing

The confidentiality recommendations developed reduce the summed risk (see Figure 6.12). However, the figure also shows that the patient safety recommendation (while reducing the patient safety risks, see Figure 6.3) result in an increased risk because they result in increased breach and fear of breach of confidentiality risk.

The minimum summed risk comes with “confidentiality recommendations” only.

Note that, with the confidentiality recommendations, the risk for the SE and ASE solutions is comparable. This indicates, on a risk basis (for the three types of risk considered), there is little to choose between the two sealing solutions.

The remaining “high” risk for the ASE solution relates to a limited population group; “habitual seekers of medication”. If a way to address this risk is developed the results would favour ASE solution, see Figure 6.13. For example if, once an “habitual seekers of medication” has been diagnosed, their record is marked, then in future encounters the healthcare professional will be aware of this diagnosis and can provide care accordingly.

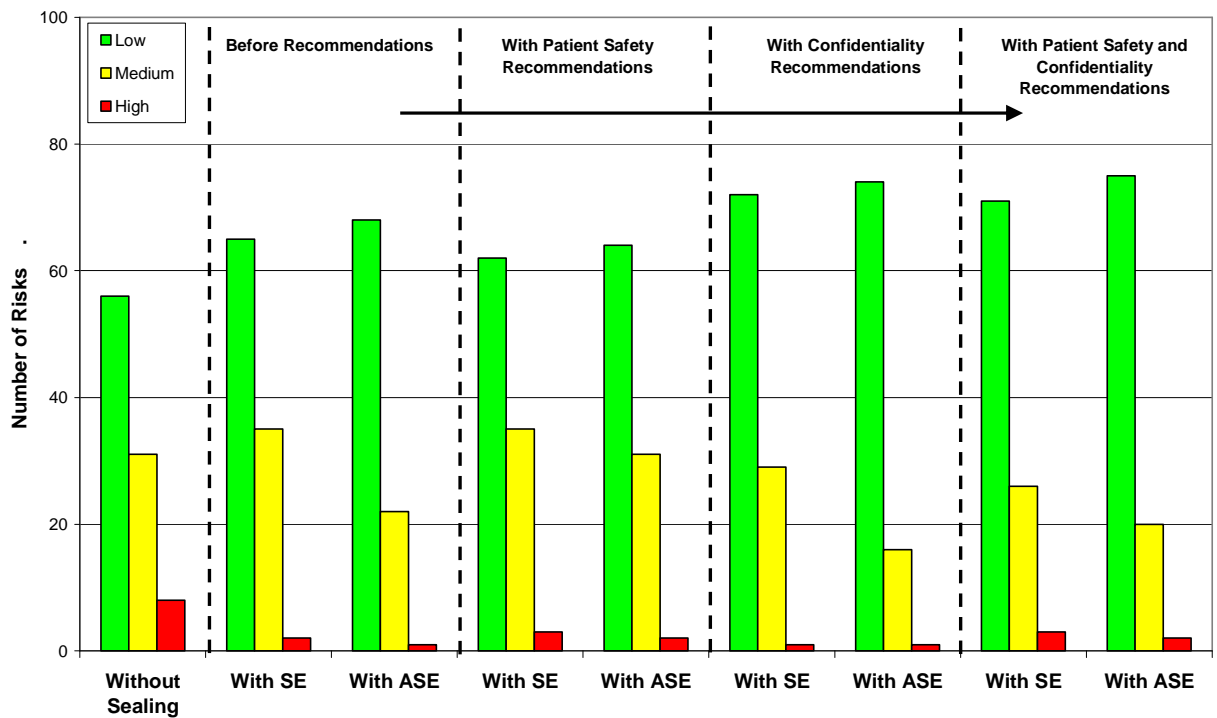


Figure 6.12 Impact of Recommendations Risk Profile

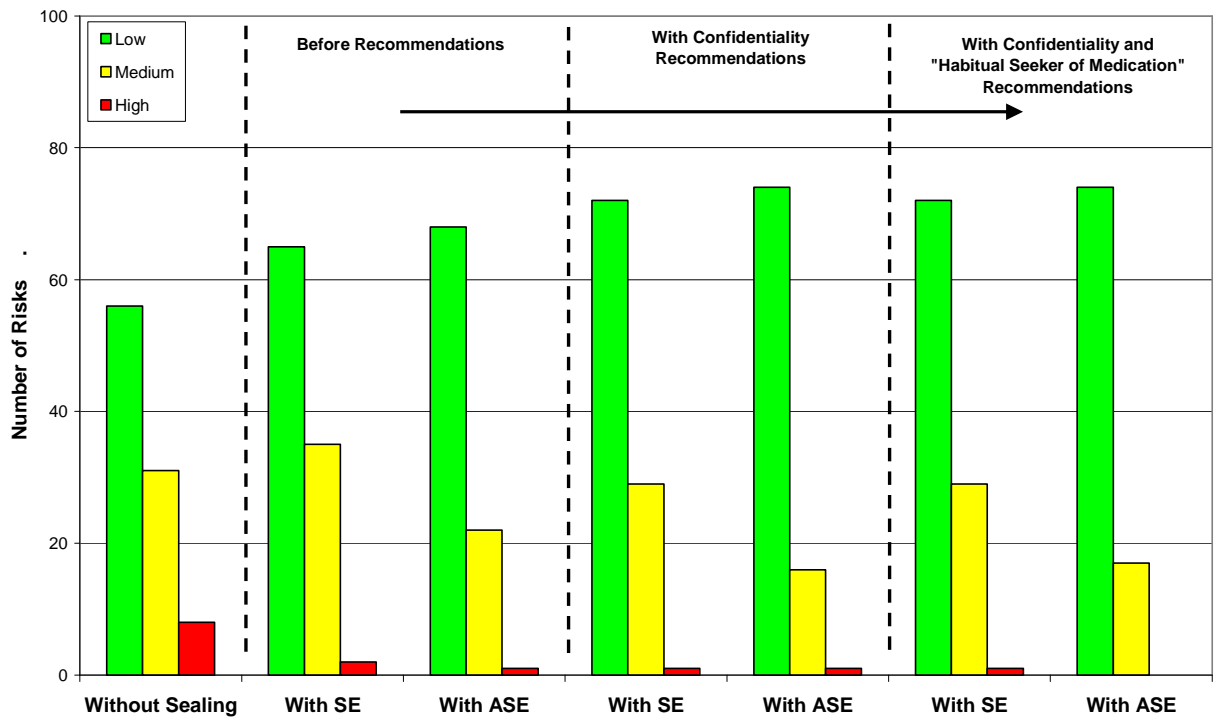


Figure 6.13 Bar Chart of Summed Risks without the Habitual Seeker of Treatment Removed

7.0 Discussion and Conclusions

7.1 General

Using the Pareto principle, the discussion in this section is focused on the most significant risks, controls, recommendations and issues which drive / manage the three types of risks assessed. The workshop record sheets (see Appendix IV) provide the record of the risk assessment session, including identified risks which were assessed to be less significant.

The risk assessment process has allowed the important risks, for the three types of risk in the scope, to be identified and assessed for the different sealing solutions. It has allowed a conclusion to be developed indicating which sealing / non-sealing solution(s) deliver the lowest risks. Recommendations to mitigate the overall risk have been proposed for further consideration by NHS CFH.

The inclusion of experts from the programme, clinical practices and patient representatives has been critical to the success of the project. It must be recognised that the risks identified and the assessment of their significance is the output from the contributions made by these experts. Their contributions have been made drawing on their knowledge of the programme, clinical practices and the expectations and concerns of patients. The process was developed and facilitated by DNV risk experts.

7.2 Patient Safety

Most of the patient safety risks identified were assessed to be “low”. When compared to having no sealing, the sealed solutions resulted in higher patient safety risk.

The key patient safety risks identified relate to medication. These generally are scenarios where a patient receives a drug which interacts with another drug they are taking, or have recently ceased taking. In the scenarios the healthcare staff providing the treatment, are unaware of the potential drug interaction as the medication information is unavailable to them. This could occur if information has been sealed, or the patient is unable or unwilling to tell them of the other drugs they are taking or to give them access to the sealed information.

When information is not sealed the healthcare professional prescribing a drug will be able to see other drugs the patient is taking, and the decision support software will be able to use the information to provide a warning that there is a conflict. The sealing options reduce / prevent the visibility of the previous drugs to the healthcare professional so stop the decision support software from providing guidance / warnings.

It is patient choice to divulge information which is not available to the healthcare professional (so long as the patient has the mental capability to understand the question and the capacity to answer correctly). Some patients do not realise that the effects of a medication can remain in their body for a period of time after the course is completed. If the recent medication details are unavailable (sealed), then the healthcare professional may be getting a true answer to their question; e.g. “I am not currently taking any other medication”. The patient is unintentionally retaining the information relevant for their treatment without any knowledge of the potential adverse consequences.

In a similar manner risks related to allergic reactions were raised. Here the concern was a repeat of an allergic reaction because the same drug, which caused the previous allergic reaction, is given again. The cause identified was having the details of the previous allergic event sealed with all information on the previous care episode.

A primary control today for these risks is the standard practice for a healthcare professional to check with the patient if they have allergies or are taking any medication. This is a valid control to maintain for the future. The risk assessment team did note that with decision support the healthcare professionals may rely less on this check, weakening it as a control. Recommendation R3 is a reflection of this concern.

Although today's situation was not assessed as a comparator in this project, it was noted in discussions that records are held locally, therefore, the full patient record is not accessible to all healthcare professionals when providing care. The risks described above are, therefore true for the present day situation. Sharing information helps mitigate risks where the unavailability of information is a contributing factor, therefore the NHS CFH solutions help mitigate such risks for the current situation.

The plans are that patients will be told of the patient safety risks associated with sealing information. Healthcare professionals will be prompted to do this by the systems. From a patient safety view point this is an important control as patients need to understand the risks they are accepting when they choose to seal information. If they understand these risks they will make informed decision to seal or not to seal information.

The risk above can be mitigated by not allowing medication and allergies to be "sealed". These restrictions were recommended by the patient safety risk assessment workshop team for further consideration. As can be seen from the confidentiality workshop results these recommendation increase the confidentiality risks. This is because the recommendations mean that allergies and medication are visible across the Spine. From details of medication it is possible for illnesses and treatments to be deduced. This effectively negates the objectives of the sealing solutions, and consequently, the confidentiality risks increase towards those for "without sealing".

Unexpectedly the patient safety risk scenario identified and assessed to be of greatest significance relates to a "habitual seeker of medication and overdose". In this scenario the "habitual seeker", moves from location to location seeking repeat medication, and asks for their treatment information to be sealed each time they receive a drug. For the ASE solution this risk was assessed as being high, as confidential information is stored locally, so there is no way one healthcare location will see drugs recently prescribed by another. With the SE solution all information is in the envelope, so it is possible for a healthcare professional to identify a "habitual seeker" who is getting their prescriptions sealed.

If the patient safety and confidentiality risks are summed there is a net increase in the total risk with these recommendations in place.

7.3 Breach of Confidentiality

Most of the breach of confidentiality risks identified were assessed to be "low" or "medium". Compared to not having sealing, the sealed solutions resulted in lower breach of confidentiality risk.

The fundamental designs of the SE and ASE solutions determine which of the breach of confidentiality risks are most significant for each solution. The SE solution has:

- Only one patient sealed envelope per patient for all confidential information.
- Places all confidential information for a patient in their patient “envelope”.
- Stores the envelope on the Spine.
- Makes the sealed information accessible through Healthspace.

In comparison the ASE solution:

- Holds confidential information locally.
- Marks it as confidential.
- Keeps the confidential information off Healthspace.

By having one envelope and placing it on the spine, the SE solution has the potential for information being kept confidential for one care episode (and one set of healthcare professionals) to be accidentally seen in another environment when the patient is seeking treatment for another confidential illness. This is not the case for the ASE solution.

Risk of breaches via Healthspace are only possible for the SE solution as the sealed information is presented openly (un-sealed). In the ASE solution, confidential information is stored locally and can not be accessed from Healthspace.

In the SE solution, having the confidential information in an “envelope” means it is not automatically visible. To display the information the envelope has to be opened. This mitigates the risk of a person without a LR seeing the information when viewing a record on a screen inappropriately, for example through shoulder surfing. This risk is judged to be greater with the ASE solution as the confidential information is automatically presented on the screen in the healthcare location to which it is being kept confidential.

For the SE solution, where the sealed information is held nationally on the Spine, there is uncertainty on the frequency the confidential information will be accessed without permission (e.g. by a healthcare professional who judges accessing the information is in the public interest). There is a concern the “Cauldicott Guardians” could be overwhelmed with alerts, especially during the period when users are becoming familiar with the system.

Relevant to both sealing solutions is the risk of not sealing information received outside a consultation. Healthcare professionals need to be aware that information received outside a consultation, e.g. a test result, may be part of a confidential care episode and therefore should be electronically stored with a seal. The recommendation to tag information requests and to prompt healthcare professionals to file such information confidentiality will help mitigate this risk.

The assessment considered the risk consequences taking into account patient's likely expectations on confidentiality. The assessment team judged that their confidentiality expectations would be less where sealing of information is not allowed. Based on this some "breach of confidentiality" risks are assessed with lower consequences without sealing compared to the SE and ASE sealing solutions. (Note that this is balanced with an increased "fear of breach of confidentiality" risk).

The planned overall education of the patients, the medical staff and those in a support role is going to be fundamental to the implementation of a confidentiality solution. Users need to follow the planned protocols, which are supported by system prompts, to minimise breach of confidentiality risks. These protocols and prompts are recognised as breach risk controls in the assessment, along with the security aspects listed in Box 1.1 (see Section 1.0), and ethical behaviour.

Having a local solution for retaining confidential information (e.g. the ASE solution) will help ensure that information is only shared with other healthcare professionals if the patient consents to the process through proactive action. This would require clear guidance from the Sealed Envelopes project team so the task is easy to apply. This would encourage healthcare professionals to use the system and not to bypass it in a manner that may result in breach of confidentiality.

Considerations and concerns on the practicality of sealing information were raised. This concern will influence the way healthcare professionals work and how they may portray / communicate confidentiality options to patients. If operating the sealing options is difficult, then the healthcare professionals may tend to influence patients against sealing or not ask them if they would like information sealed. The workshop attendees perceived that the SE solution would be more time consuming and involved to operate and the assessed risk levels reflect this consideration.

7.4 Fear of Breach of Confidentiality

A main concern throughout the interviews and the workshop was the situation that may arise if patients have a lack of confidence in the process applied to ensure confidentiality is maintained. As stated previously there are a number of patient groups who request a high degree of confidentiality due to their current condition or previous medical history. Some of these patients may not seek medical help if they cannot ensure that confidentiality is maintained, the obvious consequence of this is that their condition could deteriorate or they could infect others within the family or community. A loss of confidence in the NHS CFH system could be highlighted by groups to the media, who would then exert pressure to change the system. Patient expectation is, therefore, a big factor and the Sealed Envelopes project must ensure that patients have the correct information given to them regarding the level of confidentiality the process can achieve. As noted above, sealing is one of several methods for maintaining the confidentiality of patients' records (see Box 1.1 in Section 1.0). All information needs to be communicated to patients in "sealing" discussions.

Patients may have a fear of breach for various reasons, including for example:

- Insurance being declined or a job application rejected due to a release of information.
- Domestic disruption or domestic violence if family members see information (e.g. a patient taking a contraceptive may be in conflict with the beliefs of others in their family with potential severe consequences if this becomes known).
- Their children being taken into care if their treatment or condition became known to other parties.

The sealing solutions, especially the ASE solution, provide lower fear of breach of confidentiality risk than not being able to seal information.

7.5 The Summed Risk Picture

The summed risk for the sealed solutions (SE or ASE) are lower than “without sealing”. This is because the confidentiality risks (breach and fear of breach) out-weigh the patient safety risks. (Note, that for the sealed solutions compared to without sealing, the confidentiality risk has been assessed to be lower and the patient safety risk higher).

The risk for the SE solution and the ASE solution are comparable with the confidentiality recommendations and it is difficult to prioritise one over the other with confidence. However, if the patient safety risk related to habitual seekers of medication is mitigated, then the ASE solution would be preferred to the SE solution from a risk view point. A recommendation to mitigate this risk with the ASE solution was not made in the risk assessment workshop sessions. Subsequently developing a recommendation has been discussed within the project. The recommendation of not being able to seal a “habitual seeking of medication” diagnosis is made in this report (**R12**). Including this recommendation, or a recommendation with a similar mitigating effect, leaves the ASE solution with only “low” and “medium” identified risks.

7.6 Recommendations

Through the assessment twelve recommendations were developed. These are presented in Table 7.1. Of these recommendations R3 to R12 produce the lowest assessed summed risk when applied with the ASE solution. Recommendations R1 and R2 are effective in reducing the patient safety risks, but increase the confidentiality risks.

Table 7.1 Recommendations

No	Recommendation
R1	Medication details are not allowed to be sealed and are automatically shared.
R2	Allergy details are not allowed to be sealed and are automatically shared.
R3	Doctors should continue to ask if the patient is taking an oral contraceptive (or other medication) before prescribing antibiotics. They should not rely upon the information presented on the computer screen, the human interaction is vital.
R4	To create confidence, patients need understanding of how confidentiality is handled. Simple but clear information at GPs, clinics and information directed at particular groups should be available. For example, sexual health/contraceptives in schools. Very careful communication to reassure vulnerable groups.
R5	If the clinical event (consultation or test result) to which it is linked is sealed, this should be highlighted in the return record to the clinician.
R6	With the ASE's, the transfer of information to another healthcare provider should generally be discussed with the patient before being actioned.
R7	If items are in a sealed envelope, they should not be available via Healthspace.
R8	The ability to change a password should be via a GP or other service to be decided (not via Healthspace or a perpetrator may prohibit patient access).
R9	Make standard practice that test results remain under clinician seal until the patient has attended a consultation and agreed they can be moved however long this may take.
R10	Sealed envelopes are not accessible via Healthspace, or clinician and patient seals should be used in conjunction with each other to keep confidential information off Healthspace
R11	Youth sexual health services information should not be included in care records or seen on Healthspace.
R12	Do not allow a "habitual seeking of medication" diagnosis to be sealed.

7.7 Sensitivities

The primary sensitivities to consider when reading this report and making a decision based on the results are:

- The likelihood of risks were assessed for the population of England. Where a risk is applicable to a specific population group (e.g. people with a mental health condition), the likelihood, and hence the risk level, would be higher if assessed for the specific population group. By assessing the risks for the total population, all risks are assessed consistently, but a person from a specific group may not view the assessed risk level for a specific risk as accurate for themselves, they may feel it should be higher as, for them the risk is more likely.
- The risk assessment has been undertaken with a limited number of clinical staff and patient representatives. However, in the time available, it was not possible to involve staff from all clinical areas.
- It must be recognised that the risks identified and the assessment of their significance is the output from the contributions made by the experts who participated. The experts included NHS CFH programme personnel, clinicians and patient representatives. They have drawn on their knowledge of the programme, clinical practices and the expectations and concerns of patients in making their contributions.

- During the project we had evidence (NHS Information Authority, 2002) from research which suggested, that patients with HIV are more likely to accept sharing their records than compared to Mental Health patients. Evidence, of which the experts who contributed were aware, now suggests that this opinion has changed. This is due in part to allegations in the media and court proceedings stating that HIV patients have deliberately infected other people. Therefore this group of patients now have an increased concern over confidentiality of their records.
- The ASE option was only suggested approximately half way through the assignment. This solution and its potential risks were, therefore, not canvassed in the early interviews.
- When considering the findings of this report the NHS CFH team should consider the percentage of the population who will use the SE or ASE facility. Based on current information (a survey, NHS Information Authority, 2002) the percentage saying they would remove sensitive information from their shared record was; 4% for removing “all”, 4% for removing “a lot” and 24% for removing a little, 8% “don’t know” and 60% chose “none”. Although the initial take-up may be low, it is likely to increase with time as more education of patients gives them the choice to “seal” information out of the record shared nationally.
- During the assignment many issues were raised regarding patient safety and confidentiality. It is difficult to differentiate between the two from the patient perspective as to which they consider would have the greatest impact upon themselves.
- The risk ranking is based upon the perception of those attending the workshops and is judgemental.

Although patient safety and confidentiality risks are a main factor in the Sealed Envelopes project, there are many other aspects that need to be considered when taking a decision on the way forward. These include, for example; cost, usability, practicality and acceptability within the user community as well as legal constraints. Also, consideration should be given to the sensitivities in the assessment (see Section 7.7).

8.0 Conclusions

- The summed risk for the sealed solutions (SE or ASE) are lower than “without sealing”.
- The patient safety risks can be mitigated through the patient safety recommendations made, but this results in the summed risk being greater. The patient safety recommendations **R1** and **R2** (see Section 6.0) increase the breach of confidentiality risks more than they decrease the patient safety risks.
- The third patient safety recommendation does not adversely impact the confidentiality risks. It should also be considered if the recommendation should be broadened to all of today’s checks (i.e. beyond checks in prescribing antibiotics), where potentially unavailable information influences diagnosis and treatment.
 - **R3** - Doctors should continue to ask if the patient is taking an oral contraceptive (or other medication) before prescribing antibiotics. They should not rely upon the information presented on the computer screen, the human interaction is vital.
- The confidentiality (breach and fear of breach) recommendations reduce the summed risk. The confidentiality recommendations which have the greatest impact on the risk are:
 - **R5** - If the clinical event (consultation or test result) to which it is linked is sealed, this should be highlighted in the return record to the clinician.
 - **R9** - Make standard practice that test results remain under clinician seal until the patient has attended a consultation and agreed they can be moved however long this may take.

Other confidentiality recommendations are:

- **R4** – To create confidence patients need understanding of how confidentiality is handled. Simple but clear information at GPs, clinics and information directed at particular groups should be available. For example, sexual health/contraceptives in schools. Very careful communication is required to reassure vulnerable groups.
 - **R6** - With the ASE's, the transfer of information to another healthcare provider should generally be discussed with the patient before being actioned.
 - **R7** - If items are in a sealed envelope, they should not be available via Healthspace.
 - **R8** - The ability to change a password should be via a GP or other service to be decided (not via Healthspace or a perpetrator may prohibit patients access).
 - **R10** - Sealed envelopes are not accessible via Healthspace, or clinician and patient seals should be used in conjunction with each other to keep confidential information off Healthspace.
 - **R11** - Youth sexual health services information should not be included in care records or seen on Healthspace.
- The risk for the SE solution and the ASE solution are comparable with the above recommendations and it is difficult to priorities one over the other with confidence.

- The assessment would prefer the ASE solution to the SE solution if the patient safety risk related to habitual seekers of medication is addressed, for example by:
 - **R12** - not being able to seal a “habitual seeking of medication” diagnosis.

Although patient safety and confidentiality risks are a major issue in the Sealed Envelopes project, there are many other aspects that need to be considered when taking the decision on the best way forward, including; cost, usability, practicality and acceptability within the user community.

From a risk perspective the ASE solution with the recommendations above has the lowest risk profile of the solutions assessed.

Appendix I Descriptions of Sealed Envelopes and the Alternative Sealed Envelope Approach Assessed in the Risk Assessment

This appendix presents descriptions of the sealed envelopes and the alternative sealed envelope approaches to providing confidentiality as provided by NHS CFH.

I.1 Sealed Envelopes

Descriptive Text from NHS Connecting for Health:

Sealed Envelopes (2007B) – on-a-page

WITHOUT PREJUDICE

Virtual 'sealed envelopes' is an access restriction information governance control, that is additional to Consent, LRs, and RBAC.

A patient may have one virtual 'sealed envelope' (or in the future possibly several) associated with their record.

- The patient can request that only nominated care professionals can obtain access to the contents of an envelope. Nominations can be by User Id or workgroup membership. However, authors retain access to their authored information.
- The sealed envelope may contain multiple decision notes (which are themselves sealed), and carry a single expiry date or be unlimited.
- Restrictions cease after the patient's death.

Care professionals may have any number of virtual 'sealed envelopes' associated with a patient's record.

- The patient, or representative, does not have access to the contents of the envelope via HealthSpace, and generally not via a subject access request. They may or may not know that information has been withheld.
- All care professionals, subject to other controls, have access to their contents.
- Each envelope, must contain one or more reasons, may contain a free-text reason for sealing, and can be time limited or unlimited.

Administration of sealed envelopes is controlled by LRs and RBAC:

- A care professional can, at the patient's request: add to, or remove from, the patient's envelope, some or all of the sealable or sealed items in their record; change envelope access nominations; or change its time restriction.
- A care professional can set or change clinicians' envelope restrictions.
- Changes are audited. Some changes generate an alert.

When a care professional makes an enquiry and information in any sealed envelope meets the selection criteria, then:

- If they have access, patient sealed information is shown and its 'sealed' status indicated;
- If they do not have access: an indicator is shown in place of the patient sealed information; a competent patient may be asked, and may agree, to grant them permission. *(In future, authenticated consent is required.)*
- clinician sealed information is not initially shown, but is accessible on request.

A care professional can 'break the seal' of the patient's envelope and access all its content:

- if a non-competent (e.g. unconscious) patient is unable to agree and access is in their best interests; etc.; or
- for legal reasons (in the public interest, by statute, by court order).

When the seal of an envelope is broken:

- The reason must be selected, and a free-text reason may be recorded.
- An alert is sent to the user's organisation's privacy officer(s); and will be investigated.
- Details, including alert details, are audited.

Individual items or groups of items can be 'sealed' either at the time of recording, or retrospectively. Sealing must apply to directly derived information or copies.

- The smallest unit of information that can be sealed is a Clinical Statement, a similar local system unit of information, a single image, etc..
- Some inappropriate, or if agreed 'old', information may not be sealable.
- Information cannot be both in the patient's envelope, and the clinicians' envelope.

Martin Tallis – NHS CFH Page 1 of 2 Version 1.7 – 17 May 2006

Sealed Envelopes (2007B) – on-a-page

WITHOUT PREJUDICE

DETAIL AND OTHER POINTS NOT INCLUDED IN ABOVE DESCRIPTION

- Procedural aspects are not covered.
- Non-functional requirements are not covered.

Further detail required to support the 2007B functionality:

1. Reasons for refusing a patient's sealing request (730.48.6) and notes associated with this (730.48.9).
2. Warnings to users about to break seal (730.48.22).
3. Reasons for clinician sealing. (730.51.4/5/6).
4. Recording who made each decision. (730.55.7)
5. Noting whether the patient has been effectively informed (730.48.33).
6. Noting that clinician screening has taken place (730.59.2).
7. Patient sealing on behalf of a patient (e.g. on Gender Reassignment)
8. Reviews of clinicians sealed envelope (730.51.11/15).
9. Processing without triggering an alert for legal reasons (730.48.19), or other processing (730.48.20).
10. Feedback to Patient, via HealthSpace or else by letter², whenever sealing instructions change (730.48.22, 370.8.3).
11. Distinguishing and withholding third party information (730.51.3, 730.51.7)

(This list should not be considered to be complete.)

Possible future extensions beyond 2007B:

12. Patients submitting sealing requests through HealthSpace (730.48.2)
13. Electronic authentication - patient 'passwords' (730.48.4).
14. Prospective sealing of well understood logical groups of information (730.48.2).
15. Multiple patient's sealed envelopes.
16. 'Locking' of patient's sealed envelopes.

Being considered for withdrawal:

17. Privacy officer granting access to that sealed data within their organisation only (730.48.18).
18. Patient sealing by the patient themselves through HealthSpace (730.48.2).

¹ Only that data normally output by the system function they are using will be displayed, but the access to further information within the user session will not require a seal to be broken again.

² The possible use of letters for this communication is to be confirmed.

I.2 Alternative Sealing Approach

Descriptive Text from NHS Connecting for Health:

Three Hypothetical Scenarios for Sealed Envelopes

- 1 Do not have Sealed Envelopes
- 2 Take SE forward with the solution as per the briefing paper – i.e. nationally stored
- 3 Take SE forward with a more localized solution. This solution suggests that instead of information being stored centrally in PSIS it will be stored locally and not shared with PSIS.
So:
 - It would be possible to label as sensitive any items recorded in a patients detailed record as with option 2 but items marked would only be viewable within that organization by people with access to the patient's record, but only when a specific request to view sensitive data is made (by using a tab or button) i.e. no sensitive information is ever sent to the spine.
 - In some settings such as GUM the entire record could be marked as sensitive as a default unless the clinician and patient agree otherwise
 - **When a patient record is shared with another organization the default is that no data marked as sensitive would be shared. If the patient and clinician expressly decide that a "sensitive marker" should be included in the record when it moves between organizations, this can be included.**
 - If the patient changes their mind in another other setting, there would be no ability to reveal the sensitive electronic record there and then – the patient would have to convey the sensitive information verbally.
 - There would be a full audit trail available of who had viewed sensitive information as with option 2.

Appendix II Risk Matrix

The risk matrix developed for use in this assessment is presented in this appendix. It draws on the NHS CFH Risk Matrix guidance document (NPSA, 2006) and was reviewed at various stages though its development by the project's steering group.

The Risk Matrix is presented in Figure II.1 with the definitions for its consequence and frequency classes presented in Table II.1 and Table II.2. In addition examples of the meanings for the patient safety classes can be seen in Table II.3.

Note that the consequence classes draw on the NPSA's national reporting and learning system patient safety incident consequence classes. The patient safety consequence classes are therefore consistent with what is used nationally in the NHS for incident reporting and incident data analysis.

Likelihood	Very Often	7	Medium	High	High	High	High	High
	Often	6	Medium	Medium	High	High	High	High
	Frequent	5	Low	Medium	Medium	High	High	High
	Occasionally	4	Low	Low	Medium	Medium	High	High
	Infrequently	3	Low	Low	Low	Medium	Medium	High
	Rare	2	Low	Low	Low	Low	Medium	Medium
	Very Rare	1	Low	Low	Low	Low	Low	Medium
Sealed Envelopes Risk Matrix			A	B	C	D	E	F
			Negligible / Very Low	Low	Moderate	Severe	Major / Fatal	Catastrophic
Consequence								

Figure II.1 Risk Matrix

Table II.1 Risk Matrix Consequence Classes

Class		Definition Patient Safety Outcomes		Definition Information Governance / Confidentiality Breaches	
No	Name	Single patient impact	Multiple patient impact	Lack of Confidence Outcomes	Direct Harm Outcomes
A	Negligible / Very Low	This is an unexpected or unintended incident, which results in: <ul style="list-style-type: none"> Minimal extra observation or very minor treatment, and causes minimal harm to a patient. 		Loss of confidence by a single patient. Patient changes service provider.	This is an unexpected or unintended release of confidential information which results in: <ul style="list-style-type: none"> Acute embarrassment, no continuing harm.
B	Low	This is an unexpected or unintended incident, which results in: <ul style="list-style-type: none"> Extra observation or minor treatment, and causes minimal harm to a patient. 	This is an unexpected or unintended incident, which results in: <ul style="list-style-type: none"> Of the order of ten patients receiving "negligible/very minor" harm. 	Loss of confidence by a single patient. Patient stops / delays seeking future treatment. Loss of confidence by a single patient who then spreads an infectious disease to partner.	This is an unexpected or unintended release of confidential information which results in: <ul style="list-style-type: none"> Anxiety. Domestic argument.
C	Moderate	This is an unexpected or unintended incident, which results in: <ul style="list-style-type: none"> Further treatment, possible surgical intervention, cancelled treatment, or transfer to another area, and which causes short-term harm to a patient. 	This is an unexpected or unintended incident, which results in: <ul style="list-style-type: none"> Of the order of ten patients receiving "Low" harm. Of the order of 100 patients receiving "negligible/very minor" harm. 	Loss of confidence by multiple patient (e.g. the family and friends of the person immediately impacted). Patients stop / delay seeking future treatments. Loss of confidence by a single patient who then spreads an infectious disease to family and friends.	This is an unexpected or unintended release of confidential information which results in: <ul style="list-style-type: none"> ○ Patient requires treatment for depression. ○ Domestic argument with violence.
D	Severe	This is an unexpected or unintended incident, which results in: <ul style="list-style-type: none"> Permanent or long-term harm to a patient. 	This is an unexpected or unintended incident, which results in: <ul style="list-style-type: none"> Of the order of ten patients receiving "Moderate" harm. Of the order of 100 patients receiving "Low" harm. Of the order of 1,000 patients receiving "negligible/very minor" harm. 	Loss of public confidence in a local area regarding the NHS care records system. NHS CFH able to recover the situation. Expenditure required (less than £1 million). Loss of confidence by a single patient who then spreads an infectious disease to the local community.	This is an unexpected or unintended release of confidential information which results in: <ul style="list-style-type: none"> ○ Patient requires sustained treatment for depression. • Serious domestic violence continuing over a long period and / or causing permanent harm.

Class		Definition Patient Safety Outcomes		Definition Information Governance / Confidentiality Breaches	
No	Name	Single patient impact	Multiple patient impact	Lack of Confidence Outcomes	Direct Harm Outcomes
E	Major / Fatal	This is an unexpected or unintended incident, which results in: <ul style="list-style-type: none"> A patient fatality. 	This is an unexpected or unintended incident, which results in <ul style="list-style-type: none"> Of the order of 3 patients receiving "Severe" harm. Of the order of 30 patients receiving "Moderate" harm. Of the order of 300 patients receiving "Low" harm. Of the order of 3,000 patients receiving "negligible/very minor" harm. 	Loss of public confidence in the NHS care records system on a regional basis or, by an national patient group. NHS CFH able to recover the situation. Significant expenditure required (£1 million to £10 million). Loss of confidence by a single patient who then spreads an infectious disease to a large population.	This is an unexpected or unintended release of confidential information which results in: <ul style="list-style-type: none"> Suicide. Domestic violence death.
F	Catastrophic		This is an unexpected or unintended incident, which results in: <ul style="list-style-type: none"> More than 3 fatalities. More than 10 patients receiving "Severe" harm. More than 100 patients receiving "Moderate" harm. More than 1,000 patients receiving "Low" harm. More than 10,000 patients receiving "negligible/very minor" harm. 	Complete loss of public confidence in the NHS care records system. NHS CFH unable to recover the situation. Loss of confidence by a single patient who then spreads a fatal infectious disease to others.	This is an unexpected or unintended release of confidential information which results in: <ul style="list-style-type: none"> Multiple violent death.

Table II.2 Risk Matrix Likelihood Classes

Class		Per patient year	For a GP	For an A&E
No	Name			
7	Very Often	Greater than one in ten per patient year	Greater than one a day for a GP	More than three times per 8 hour A&E shift or more than 500,000 a year in A&Es in the NHS
6	Often	One in ten to one in a hundred per patient year	Once a week to once a month for a GP	Of the order of once per 8 hour A&E shift or 200,000 a year in A&Es in the NHS (3 time per shift to once per A&E day once or 50,000 to 500,000 per year in A&Es in the NHS)
5	Frequent	One in a hundred to one in a thousand per patient year	Once a month to once per year for a GP	Of the order of twice a week for an A&E or 20,000 a year in A&Es in the NHS (once per A&E day to once per A&E week or 5,000 to 50,000 per year in A&Es in the NHS)
4	Occasionally	One in a thousand to one in ten thousand per patient year	Once a year to one in ten per year for a GP	Of the order of once every 1 month for an A&E or 2,000 a year in A&Es in the NHS (once per A&E week to 1:4 per A&E month or 500 to 5,000 per year in A&Es in the NHS)
3	Infrequently	One in ten thousand to one in a hundred thousand per patient year	One in ten to one in a hundred per year for a GP	Of the order of once every 1 years for an A&E or 200 a year in A&Es in the NHS (1:4 per A&E month to 1:4 per A&E year or 50 to 500 per year in A&Es in the NHS)
2	Rare	One in a hundred thousand to one in a million per patient year	One in a hundred to one in a thousand per year for a GP	Of the order of once every 10 years for an A&E or 20 a year in A&Es in the NHS (1:4 to 1:40 per A&E year or 5 to 50 per year in A&Es in the NHS)
1	Very Rare	Less than one in a million per patient year	Less than one in a thousand per year for a GP	Less than once in 40 years for an A&E or less than 5 a year in A&Es in the NHS

Table II.3 Example consequence for Patient Safety Consequence Classes

Class		Single patient impact	Examples of single patient consequences.
No	Name		
1	Negligible / Very Low	This is an unexpected or unintended incident, which results in: <ul style="list-style-type: none"> Minimal extra observation or very minor treatment, and causes minimal harm to a patient. 	<ul style="list-style-type: none"> The patient's treatment is delayed by an hour. A patient cuts a finger and needs a plaster. A patient receives their prescribed drug an hour late, but with no other adverse consequences.
2	Low	This is an unexpected or unintended incident, which results in: <ul style="list-style-type: none"> Extra observation or minor treatment, and causes minimal harm to a patient. 	<ul style="list-style-type: none"> Perforation of the bowel during surgery, repaired at the time and area appropriately washed out so that only antibiotic treatment was required; Continuing treatment with Warfarin without monitoring clotting levels, which resulted in prolonged clotting times, which in turn caused bruising; Blood given to the wrong patient, which caused a minor rash and a temporary rise in temperature; An ambulance patient in a chair is wheeled against the ambulance door and sustains a minor abrasion. Patient requires multiple attempts to secure venous access, causing bruising & discomfort.
3	Moderate	This is an unexpected or unintended incident, which results in: <ul style="list-style-type: none"> Further treatment, possible surgical intervention, cancelled treatment, or transfer to another area, and which causes short-term harm to a patient. 	<ul style="list-style-type: none"> Perforation of the bowel during surgery, not picked up at the time, which resulted in septicaemia and a return to theatre for repair; Continuing treatment with Warfarin without monitoring clotting levels, which resulted in an overdose and bleeding problems; Wrong blood given resulting in temporary renal failure; An ambulance patient tips out of a wheel chair and bumps their head. They suffer short-term loss of consciousness and are admitted to hospital for observation. Inadvertent over insertion of an airway causing temporary collapse of one lung. Patient needs physiotherapy / additional treatment. Pneumothorax from central line insertion requiring fitting of a chest drain.
4	Severe	This is an unexpected or unintended incident, which results in: <ul style="list-style-type: none"> Permanent or long-term harm to a patient. 	<ul style="list-style-type: none"> Perforation of the bowel during surgery, requiring a temporary colostomy and subsequent major operations; Continuing treatment with warfarin without monitoring clotting levels, which resulted in a brain haemorrhage and brain damage; Wrong blood given to a young woman, who then develops anti-D antibodies that affect any future pregnancy; An ambulance patient tips out of a wheel chair and bumps their head. This results in a subarachnoid haemorrhage causing left-sided weakness. Anaphylactic reaction to a drug causing ITU treatment for more than two months. IV administration of local anaesthetic causing cardiac arrest requiring full resuscitation.

Class		Single patient impact	Examples of single patient consequences.
No	Name		
5	Major / Fatal	This is an unexpected or unintended incident, which results in: A patient fatality.	<ul style="list-style-type: none"> • Death as a direct consequence of perforation of the bowel during surgery; • Continuing treatment with Warfarin without monitoring clotting levels, which resulted in a brain haemorrhage and death; • Wrong blood given resulting in multi-organ failure and death; An ambulance patient tips out of a wheel chair and bumps their head. This results in a subarachnoid hæmorrhage causing death.

Appendix III References and Abbreviations

III.1 References

NHS Connecting for Health, 2006, *Sealed Envelopes (2007B) – on-a-page. Version 1.7.*

NHS Connecting for Health 2006, *Three Hypothetical Scenarios for Sealed Envelopes*

NHS Information Authority, 2002, *Share with Care! People's Views on Consent and Confidentiality of Patient Information.* Document Reference No: 2002-IA-1099.

National Patient Safety Agency, 2006, *Risk Matrix Guidance for Patient Safety Risk Assessments.* Produced for NHS Connecting for Health, Version 1

III.2 Abbreviations

A&E	Accident and Emergency
ASE	Alternative Sealed Envelope
BMA	British Medical Association
CRAG	Confidentiality Requirements Advisory Group
CRS	Care Records Service
DNV	Det Norske Veritas
GP	General Practitioner
LR	Legitimate Relationship
MIND	The National Association for Mental Health
NHS	National Health Service
NHS CFH	NHS Connecting for Health
NPSA	National Patient Safety Agency
RBAC	Role Based Access Control
SE	Sealed Envelope
TOP	Termination of Pregnancy

Appendix IV Risk Assessment Record Sheets

In this appendix the risk assessment record sheets for patient safety, breaches of confidentiality and fear of breach, are presented.

Patient Safety Risk Assessment Record Logsheet

Hazardous Situation	Concealed Information (diagnosis, treatment, medication etc.)	Healthcare Risk Scenario of Greatest Concern	Consequence	Risk Ranking Current Options									Discussion on Differences in Rankings for Current Options	No.	Recommendations	Risk Ranking Current Options with									
				With SE			With ASE			Without						With SE			With ASE			Without			
				C	L	R	C	L	R	C	L	R				C	L	R	C	L	R	C	L	R	
PA1	Consultation when details of a current or past care episode are unavailable	Family history - hereditary illness	The patient's diagnosis is made incorrectly, or is severely delayed.	The treatment provided is in appropriate and the patient develops Huntington's disease	D	2	L	D	2	L	D	1	L	Probability is low considering rareness of illness. It is more likely with sealing. Hence selected rankings for likelihood.			D	2	L	D	2	L	D	1	L
PA2		At risk of harm (children or vulnerable adults)	The person making the diagnosis is unaware of the patient being at risk of abuse. They treat the injuries they are shown based on the reasons given. Hidden injuries from the abuse are not identified.	The hidden injuries are not addressed and the patient fails to recover. They eventually return and are correctly treated and recover.	C	3	L	C	3	L	C	3	L	Information is likely to be sealed in the Clinicians sealed envelope for the SE solution. Sealed information could be opened. In the ASE solution it is not available. In the full sharing without sealing there may be a reluctance to record at harm information in an open record. There is therefore judged to be a differences in the likelihood for the different solutions. However the difference is not considered significant enough for the likelihood class to differ.			C	3	L	C	3	L	C	3	L
PA3					The hidden injuries are not addressed and the patient fails to recover and dies from their injuries.	E	1	L	E	1	L	E	1		L	Rare outcome which, as discussed above, is more likely with ASE but difference is expected to be small hence the same likelihood class is selected.			E	1	L	E	1	L	E
PA4		The person making the diagnosis is unaware of the patient being at risk of abuse. They treat the injuries and the patient recovers.	The patient continues to suffer abuse and no action to remove the patient for the abusive environment is taken. The patient is further injured.	B	4	L	B	4	L	B	4	L	Assessment made relative to above two scenarios.			B	4	L	B	4	L	B	4	L	
PA5		At risk or harm (health care professional)	Indicators that a patient may have violent tendencies not available during consultation	Patient becomes violent and assaults person(s) providing consultation	B	3	L	B	3	L	B	3	L	Note that risk is assessed for the patient. This scenario could result in harm for healthcare personnel. Assessing such risks is outside the scope of work.			B	3	L	B	3	L	B	3	L

Patient Safety Risk Assessment Record Logsheet

Hazardous Situation	Concealed Information (diagnosis, treatment, medication etc.)	Healthcare Risk Scenario of Greatest Concern	Consequence	Risk Ranking Current Options									Discussion on Differences in Rankings for Current Options	No.	Recommendations	Risk Ranking Current Options with											
				With SE			With ASE			Without						With SE			With ASE			Without					
				C	L	R	C	L	R	C	L	R				C	L	R	C	L	R	C	L	R			
PB1	Diagnosis and treatment of a patient who lacks capacity when details of a current or past care episode are unavailable (e.g. an unconscious patient arrives in A&E)	HIV and AIDS	The patient is given a drug that interacts in an adverse manner with a drug they are already on. Patient unable to give informed consent to access content	Adverse reaction of medication given with concealed medication (liver failure, etc) or toxicity leading to patient harm / death (possibly decrease or increase of level of drug effectiveness)	E	2	M	E	2	M	E	1	L		A1	This risk needs to be validated with clinician knowledgeable in HIV drugs.	E	1	L	E	1	L	E	1	L		
PB2				Reaction that leads to discomfort / minor harm	B	4	L	B	4	L	B	3	L				R1	Medication details are not allowed to be sealed and are automatically shared.	B	3	L	B	3	L	B	3	L
PB3			Diagnostic delay of time critical information (septicaemia, etc)	Escalation of serious medical condition			C	3	L	C	3	L	C		2	L			C	3	L	C	3	L	C	2	L
PB4																											
PB5	Pregnancy	Diagnostic delay of time critical information (sceptisimia, pregnancy, TOP, etc.)	Escalation of serious medical condition, increased mortality. Possible mental traumas for the mother	Possible miscarriage, death of unborn child moderate harm to mother	B	1	L	B	1	L	B	1	L				B	1	L	B	1	L	B	1	L		
PB6				TOP of previous pregnancy with complications, and complication sealed with this record	Escalation of previous complications from the TOP	C	2	L	C	2	L	C	1	L				C	2	L	C	2	L	C	1	L	
PB7				Mental Health	Diagnostic delay of time critical information (overdose, etc.)	Fail to address overdose toxicity and harm results (patient has overdosed)		B	4	L	B	4	L	B	4	L	It is possible that a healthcare worker may decide to open a SE opened in the "Public Interest". It is judged that there is a small difference in the frequency between the scenario with SEs and ASEs. With the potential to see the sealed information is not available. The change in likelihood is judged to be small, hence the same frequency class is assigned to the SE and ASE assessed risk levels.			B	4	L	B	4	L	B	4
PB8	Overdose may routinely be considered during treatment.																										
PB9	Malignant disease	Diagnostic delay of time critical information (sceptisimia say)	Escalation of serious medical condition, increased mortality	Bring on hypertension, parkinsonian type disease etc (outcome likely to be reversible and short term)	A	2	L	A	2	L	A	2	L	Probably no change as this may be the course of action for all violent patients?			A	2	L	A	2	L	A	2	L		
PB10				Futile treatment given, lead to patient discomfort and/or harm	B	2	L	B	2	L	B	1	L			B	2	L	B	2	L	B	1	L			
PB11	The patient is given a drug that interacts in an adverse manner with a drug they are already on. Patient unable to give informed consent to access content	Adverse reaction of medication given with concealed medication (liver failure, etc.) - possible death	Adverse reaction of medication given with concealed medication		E	1	L	E	1	L	E	1	L		R1	Medication details are not allowed to be sealed and are automatically shared.	E	1	L	E	1	L	E	1	L		
PB12																											
PB13	Drug addiction	Diagnostic delay of time critical information	Escalation of serious medical condition, increased mortality - possibly more susceptible / likely to have severe consequences but easy to identify		D	2	L	D	2	L	D	1	L				D	2	L	D	2	L	D	1	L		
PB14																											

Patient Safety Risk Assessment Record Logsheet

Hazardous Situation	Concealed Information (diagnosis, treatment, medication etc.)	Healthcare Risk Scenario of Greatest Concern	Consequence	Risk Ranking Current Options									Discussion on Differences in Rankings for Current Options	No.	Recommendations	Risk Ranking Current Options with									
				With SE			With ASE			Without						With SE			With ASE			Without			
				C	L	R	C	L	R	C	L	R				C	L	R	C	L	R	C	L	R	
PB15		Other previous clinical episode	The previous clinical episode included the patient having an allergic reaction to a drug. Because the previous episode was sealed the allergy to the drug was hidden from the clinicians. The patient is given the same drug and reacts in an allergic manner to it. Patient unable to give informed consent to access content (primary concerns relate to anaesthesia or penicillin)	The allergic reaction lead to patient harm/fatality	E	1	L	E	1	L	E	1	L		R2	Allergy details are not allowed to be sealed and are automatically shared.	E	1	L	E	1	L	E	1	L
														A2	Check with JS if it is possible not to seal allergy details										
PC1	Prescribing when details of a current or past care episode (including medication details, adverse reactions, etc.) are unavailable	HIV and AIDS	The patient is given a drug that interacts in an adverse manner with a drug they are already on. (For example, the patient is prescribed OMEPRAZOLE for dypepsia which he thinks might be alcohol related. The patient is unwilling to give informed consent to access content and so the clinician is unaware that	Adverse reaction of medication given with concealed medication (liver failure, etc) or toxicity leading to patient harm/death (possibly decrease or increase of level of drug effectiveness). (For example, Q & A	D	2	L	D	2	L	D	1	L		A1	This risk needs to be validated with clinician knowledgeable in HIV drugs.	D	1	L	D	1	L	D	1	L
				Reaction that leads to discomfort/ minor harm	B	4	L	B	4	L	B	3	L		R1	Medication details are not allowed to be sealed and are automatically shared.	B	3	L	B	3	L	B	3	L
PC2																R1	Medication details are not allowed to be sealed and are automatically shared.								
PC3		Malignant disease	The patient is given a drug that interacts in an adverse manner with a drug they are already on. Patient unable to give informed consent to access content	Adverse reaction of medication given with concealed medication (liver failure, etc) - possible death	E	1	L	E	1	L	E	1	L		R1	Medication details are not allowed to be sealed and are automatically shared.	E	1	L	E	1	L	E	1	L
PC4				Adverse reaction of medication given with concealed medication	C	3	L	C	3	L	C	2	L		R1	Medication details are not allowed to be sealed and are automatically shared.	C	2	L	C	2	L	C	2	L
PC5		Sexual health (including TOP)	A lady is on the pill and is given a broad spectrum antibiotic which causes diarrhoea which makes the pill ineffective. The lady becomes pregnant with the two events in the same organisation	Unwanted pregnancy	C	4	M	C	3	L	C	3	L		R1	Medication details are not allowed to be sealed and are automatically shared.	C	3	L	C	3	L	C	3	L
														R3	Doctors should ask if person on the pill before prescribing anti-biotics										
PC6			A lady is on the pill and is given a broad spectrum antibiotic which causes diarrhoea which makes the pill ineffective. The lady becomes pregnant with the two events in different organisations	Unwanted pregnancy	C	4	M	C	4	M	C	3	L		R1	Medication details are not allowed to be sealed and are automatically shared.	C	3	L	C	3	L	C	3	L
														R3	Doctors should ask if person on the pill before prescribing anti-biotics										
PC7		Mental health	Details for the treatment of depression with Lithium are not available when a patient presents with hypertension. One of the medications prescribed is a diuretic which has an interaction with Lithium	Patient is aware that he is taking antidepressants but not familiar with the different types. Tells doctor about Fluoxetine, but does not think to mention the Lithium. As a result of the interaction the patient develops Lithium toxicity, renal impairment, seizures and dies.	E	1	L	E	1	L	E	1	L		R1	Medication details are not allowed to be sealed and are automatically shared.	E	1	L	E	1	L	E	1	L
PC8			Patient on mood stabiliser that has significant interactions with other medication which are then prescribed (e.g warforin)	Toxicity	C	3	L	C	3	L	C	2	L		R1	Medication details are not allowed to be sealed and are automatically shared.	C	2	L	C	2	L	C	2	L
PC9				Lack of efficacy	B	3	L	B	3	L	B	2	L		R1	Medication details are not allowed to be sealed and are automatically shared.	B	2	L	B	2	L	B	2	L
PC10		Medication	Patient on medication which should not be stopped, but is stopped	Deterioration in health condition, recurrence of treated symptoms	C	4	M	C	4	M	C	1	L	General comment: May be a greater level of sealing in SIS case because it is easier to "seal" and to manage the process??	R1	Medication details are not allowed to be sealed and are automatically shared.	C	1	L	C	1	L	C	1	L
PC11			Habitual seeker of medication/attention approaches health service for repeated care / prescriptions	Unintentional drug overdose or unnecessary surgery.	C	5	M	C	6	H	C	4	M	If medication were not in SE then this could not be hidden - unsure whether this can be sealed. Issue of people with multiple "identities" may negate the potential gains of SE vs SIS	R1	Medication details are not allowed to be sealed and are automatically shared.	C	4	M	C	4	M	C	4	M
														A3	Check if habitual seekers are allowed to have their medication and treatment history sealed.										

Patient Safety Risk Assessment Record Logsheet

Hazardous Situation	Concealed Information (diagnosis, treatment, medication etc.)	Healthcare Risk Scenario of Greatest Concern	Consequence	Risk Ranking Current Options									Discussion on Differences in Rankings for Current Options	No.	Recommendations	Risk Ranking Current Options with									
				With SE			With ASE			Without						With SE			With ASE			Without			
				C	L	R	C	L	R	C	L	R				C	L	R	C	L	R	C	L	R	
PD1	Screening / diagnosis based on scans, tests, etc. when details of a current or past care episode are unavailable	Family history - hereditary illness Glucose-6-Phosphate-Dehydrogenase deficiency (G6PD)	The patient's family history of G6PD deficiency is not known when he present in casualty with a pneumonia.	They are admitted to hospital and treated with intravenous Sulphonamide antibiotics. They subsequently gets a severe reaction to this treatment (which is contraindicated in G6PD deficiency) develops a haemolytic crisis, is treated and slowly recovers	C	3	L	C	3	L	C	1	L	Outcome is more likely than for a fatal outcome, but is seen as a relatively rare event given it is specific to Glucose-6-Phosphate-Dehydrogenase deficiency (G6PD). With sealing the likelihood is greater than without. Without sealing the likelihood is judged to be very rare.			C	3	L	C	3	L	C	1	L
			He is admitted to hospital and treated with intravenous Sulphonamide antibiotics. He subsequently gets a severe reaction to this treatment (which is contraindicated in G6PD deficiency) develops a haemolytic crisis and dies from internal haemorrhage.	E	1	L	E	1	L	E	1	L	Very rare outcome which is more likely with sealing.			E	1	L	E	1	L	E	1	L	
PE1	Pre-assessment for surgery when details of a current or past care episode are unavailable	Previous reaction to anaesthetic	Records not available and anaesthetist unaware of the fact that the patient had a respiratory arrest in response to opiates given whilst under anaesthetic for an appendicectomy 10 years earlier	Fentanyl (opiate based medication) given under anaesthetic. Patient recovers from procedure but goes into respiratory arrest in recovery room, is treated and recovers.	B	4	L	B	4	L	B	1	L	Outcome is more likely than for a fatal outcome. It is judged to be more likely than for the PD equivalent scenarios given the number of people with allergies. With sealing the likelihood is greater than without.			B	4	L	B	4	L	B	1	L
			Fentanyl (opiate based medication) given under anaesthetic. Patient recovers from procedure but goes into unnoticed respiratory arrest in recovery room and dies.	E	2	L	E	2	L	E	1	L	Very rare outcome which is more likely with sealing.			E	2	L	E	2	L	E	1	L	
PF1	Elective surgery when details of a current or past care episode are unavailable	Confidential information known to exist in patient records	Operation refusal due to clinician's concern for the patient. For example, a total hip replacement is refused by doctors because of fear of consequences of adverse reaction in an elderly patient with multiple pathology who declines to disclose relevant medical intervention.	Multiple cancelled operations, patients left waiting for operation, and adverse public / media reaction. May also result in damage clinician patient relationship and a loss of trust.	C	3	L	C	3	L	C	1	L	Frequency based on number of operations with similar characteristics and expectations on levels of sealing.			C	3	L	C	3	L	C	1	L
Patient becomes depressed as a result of worsening pain and takes and takes fatal overdose				E	1	L	E	1	L	E	1	L	Judged to be a rare outcome with sealing			E	1	L	E	1	L	E	1	L	
PF2			Relatively minor operation refusal due to clinician's concern for the patient. For example, a clinically benign pigmented skin lesion not removed by doctors because of fear of consequences of adverse reaction in an elderly patient with multiple pathology who declines to disclose relevant medical. Skin lesion enlarges and later develops into malignant melanoma.	Due to delay patient has to undergo more invasive and severe treatment than should have taken place. May also result in damage clinician patient relationship and a loss of trust.	B	4	L	B	4	L	B	1	L	Frequency based on number of operations with similar characteristics and expectations on levels of sealing.			B	4	L	B	4	L	B	1	L
PF3				Patient dies due to metastatic spread	E	2	L	E	2	L	E	1	L	Judged to be a rare outcome with sealing			E	2	L	E	2	L	E	1	L
PF4				Patient dies due to metastatic spread	E	2	L	E	2	L	E	1	L	Judged to be a rare outcome with sealing			E	2	L	E	2	L	E	1	L
PF5			Patient dies due to metastatic spread	E	2	L	E	2	L	E	1	L	Judged to be a rare outcome with sealing			E	2	L	E	2	L	E	1	L	

Breach of Confidentiality Risk Assessment Record Logsheet

Hazardous Situation	Concealed Information / Context	Confidentiality Risk Scenario of Greatest Concerns	Causes	Consequence	Safeguard	Risk Ranking Current Options										Discussion on Differences in Rankings for Current Options	No.	Recommendations	Risk Ranking Current Options with Recommendations																																		
						With SE		With ASE		Without Sealing		With SE, With PS RA Recs.		With ASE, With PS RA Recs.					With SE		With ASE		Without Sealing		With SE, With PS RA Recs.		With ASE, With PS RA Recs.																										
						C	L	R	C	L	R	C	L	R	C				L	R	C	L	R	C	L	R	C	L	R	C	L	R	C	L	R																		
CG1	People who work in health care environments gain unauthorised access (unethical behaviour). Sensitive information - Mental Illness / Drug Addiction / Malignant Disease/ Vulnerable patients/ Patients who have experienced violence.	Healthcare professional accesses information through covert means.	"Shoulder surfing", use of other clinicians smartcard etc.	Information used for personal gain causing severe trauma to patients) and damage to care records system possibly difficult to identify offender for some time.	Clear guidelines on confidentiality and consequence of breaching confidentiality to all people who have access.	D	3	M	D	2	L	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M			
CG2		Health care professional changes patient confidential record.	Record changed through use of other clinicians Smartcard.	Burden on NHS to identify person and to correct records changed. Loss of confidence in care records system.		D	2	L	D	1	L	D	2	L	D	2	L	D	2	L	D	2	L	D	2	L	D	2	L	D	2	L	D	2	L	D	2	L	D	2	L	D	2	L	D	2	L						
CG3		Widespread release of confidential information to the media or published on the internet.	Additional interest in specific patient or orchestrated effort to embarrass government project (CIH).	Complete loss of trust in care records system Major political uproar.		F	1	M	F	1	M	F	1	M	F	1	M	F	1	M	F	1	M	F	1	M	F	1	M	F	1	M	F	1	M	F	1	M	F	1	M	F	1	M	F	1	M						
CG4		Release of confidential information of a public figure to the media or published on the internet.	Financial gain or public recognition, sabotage.	Confidential information printed in the media. Temporary or short-term loss of trust in care records system.		E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L			
CG5		Perpetrator of violence asks healthcare worker to check record, or perpetrator works in healthcare environment and gains access.	Inadequate CRB checking of staff. Temporary staff with 'less to lose' or who can be bribed. 'Legitimate relationship' system breakdown. Unethical behaviour by one or more staff or Caldecott guardian.	Woman's whereabouts/ medical details/ disclosure of abuse revealed possibly giving rise to further violence or abuse, resulting in depression, hardship, injury or death. Loss of patient faith in service and reluctance to seek future treatment from any part of health service for her or any children.		D	3	M	D	2	L	D	3	M	D	3	M	D	3	M	D	2	L	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M			
CG6				Information used to undermine legal proceedings For example requesting access to medical evidence or asking to use sexual history in court on basis of what's been seen.		D	2	L	D	1	L	D	2	L	D	2	L	D	2	L	D	1	L	D	2	L	D	2	L	D	2	L	D	2	L	D	2	L	D	2	L	D	2	L	D	2	L	D	2	L			
CG7			Opportunity for befriending of health care worker by a person with intent to use patient information for fraudulent purposes.	Vulnerable health care worker targeted by malicious person.	Patient is victim of fraud.		C	2	L	C	2	L	C	3	L	C	2	L	C	2	L	C	2	L	C	2	L	C	2	L	C	2	L	C	2	L	C	2	L	C	2	L	C	2	L	C	2	L	C	2	L		
CH1	External party gains unauthorised access, for example, a hacker. Sensitive information - Mental Illness / Drug Addiction / Malignant Disease/ Vulnerable patients/ Patients who have experienced violence.	External party "hacks" into records for a GP practice.	Malicious intent.	Information used for personal gain causing severe trauma to patients) and damage to care records system.	Security management arrangements.	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M	D	3	M
CH2		External party "hacks" into records at a regional level.	Malicious intent.	Information used for personal gain causing severe trauma to patients) and significant damage to care records system. Loss of trust n care records system.	Security management arrangements.	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L	E	1	L						
CH3		External party "hacks" into records at a national level.	Malicious intent.	Complete loss of trust in care records system.	Security management arrangements.	F	1	M				F	1	M	F	1	M	F	1	M	F	1	M	F	1	M	F	1	M	F	1	M	F	1	M	F	1	M	F	1	M	F	1	M	F	1	M						
CH4		Hacking via Healthspace.	Desire for information about patient. For example control /violence, lack of trust/anxiety or concern about patient's health.	Loss of trust in system, possible violence, possible breakdown of relationships, infringement of vulnerable persons dignity/wish for independence.	Security management arrangements.	B	4	L				B	4	L	B	4	L	B	3	L	B	3	L	B	4	L	B	4	L	B	4	L	B	4	L	B	4	L	B	4	L	B	4	L	B	4	L	B	4	L	B	4	L

Breach of Confidentiality Risk Assessment Record Logsheet

Hazardous Situation	Concealed Information / Context	Confidentiality Risk Scenario of Greatest Concerns	Causes	Consequence	Safeguard	Risk Ranking Current Options										Discussion on Differences in Rankings for Current Options	No.	Recommendations	Risk Ranking Current Options with Recommendations																														
						With SE			With ASE			Without Sealing			With SE, With PS RA Recs.				With ASE, With PS RA Recs.			With SE			With ASE			Without Sealing			With SE, With PS RA Recs.			With ASE, With PS RA Recs.															
						C	L	R	C	L	R	C	L	R	C				L	R	C	L	R	C	L	R	C	L	R	C	L	R	C	L	R	C	L	R	C	L	R								
CI1	Confidential information shown on Healthspace.	Sensitive information - Mental Illness / Drug Addiction / Malignant Disease/ Vulnerable patients/ Patients who have experienced violence.	Sensitive information seen on Healthspace by abusive parent, partner or trafficker through 'shoulder surfing'. (For example, a person living with domestic violence, abusive parent, non-abusive parent, trafficker, pimp gives password to them. Does not disclose abuse because she fears violence/abuse/other repercussions/being removed from Healthspace.)	Information not being double sealed. Patient not realising information can be seen from Healthspace. Standard procedure (if it is agreed test results will always be placed in visible section). Clinician not checking content of results or circumstances around test. Doctor not aware of abuse taking place. Accidentally or misfile of confidential information not being double sealed. Patient not realising information can be seen from Healthspace.	Woman's whereabouts/medical details/disclosure of abuse revealed. Abuser inflicts further Partner causes harm to vulnerable patient, resulting in depression, hardship, injury or death. Loss of patient faith in service and Care Records and reluctance to seek future treatment. Risk that perpetrator forces wishes on woman (For example forced termination or not allowed to have termination).	Contents of sealed envelopes not visible on Healthspace. Information about sealed envelopes and double sealing being given to patients. The clinician should seek the permission from the patient before releasing their records.	D	4	M				D	4	M	D	4	M	D	3	M	D	3	M	ASE not applicable as content could not be viewed over Healthspace. This makes the ASE a much safer option.	R5	If the clinical event (consultation) to which the test is linked is sealed, this should be highlighted in the return record to the clinician. If items are in a sealed envelope, they should not be available from Healthspace. Only able to change password via GP or other service (not via Healthspace or perpetrator may prohibit her access).	D	1	L				D	4	M	D	2	L	D	2	L							
CI2																																																	
CI3																																																	
CI4													B	6	M				B	6	M	B	6	M	B	5		M	B	4	M	Sealed envelope risk are dependent on procedure decided - i.e. whether it will be standard practice to release results from clinician seal to patient seal after 7 days, or only after consultation.	R5		B	3	L				B	6	M	B	5	M	B	4	M
CI5																																																	
CI6																																																	
CI7																			C	2	L				C	2		L				Confidential information is not on Healthspace with the AES option.			C	2	L				C	2	L	C	2	L			
CI8																			B	4	L				B	4		L	B	3	L	Confidential information is not on Healthspace with the AES option.	R8		B	1	L				B	4	L	B	3	L	B	2	L
CI9																																																	
CI10																			A	4	L				A	4		L	A	4	L	Confidential information is not on Healthspace with the AES option.	R8		A	1	L				A	4	L	A	3	L	A	2	L
CI11																																																	
CI12																			D	4	M				D	4		M	D	4	M	The likelihood in both of these cases without sealing is a 5 - abusive parties frequently retain identification documents, financial records and money in order to control women. Parents frequently retain documents for children to prevent them losing them.	R5		D	1	L				D	4	M	D	2	L	D	2	L
CI13																																																	
CI14																																The risk is lower where women	R11																

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