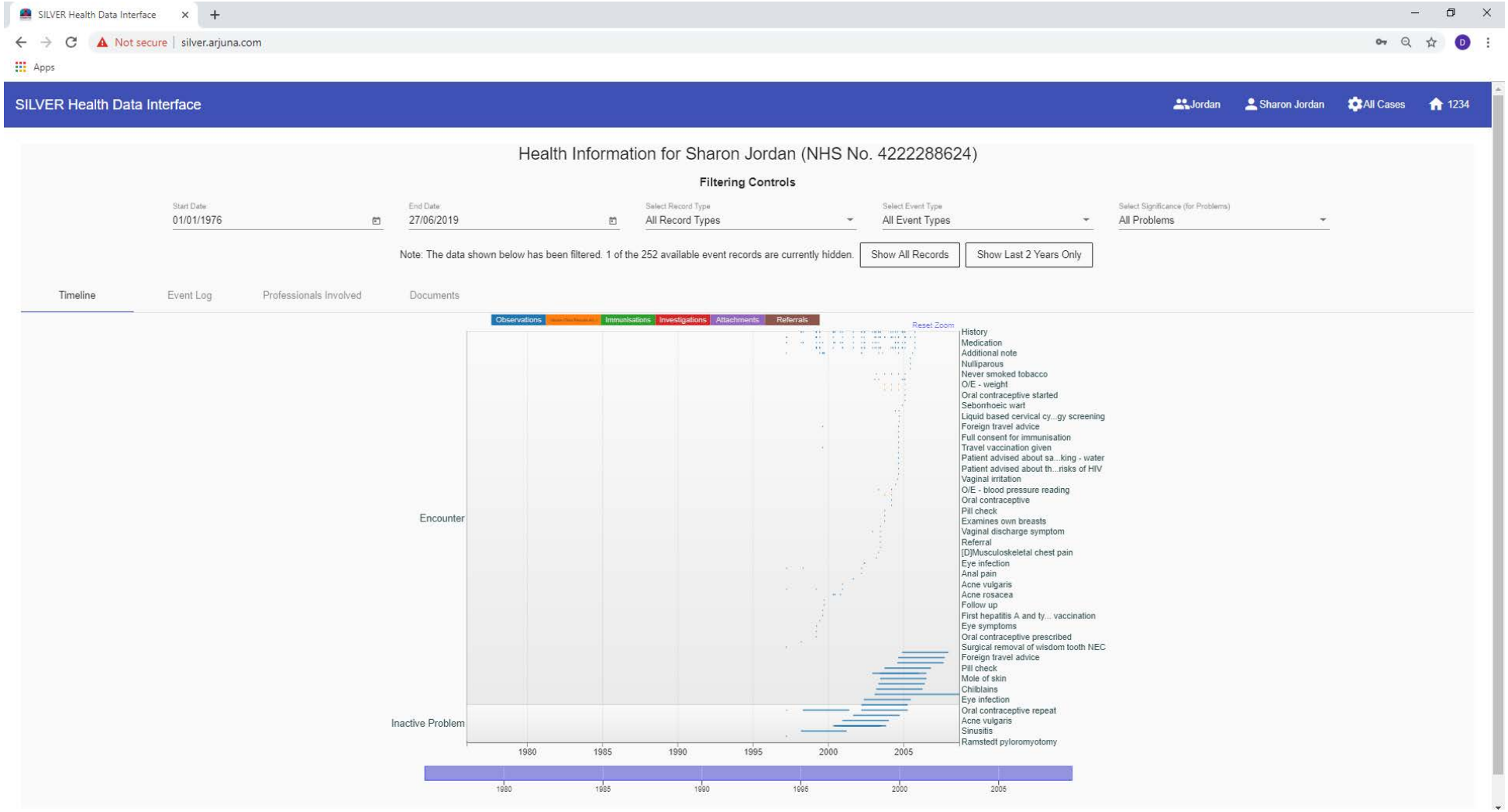
Appendices

SILVER Project; end of project report

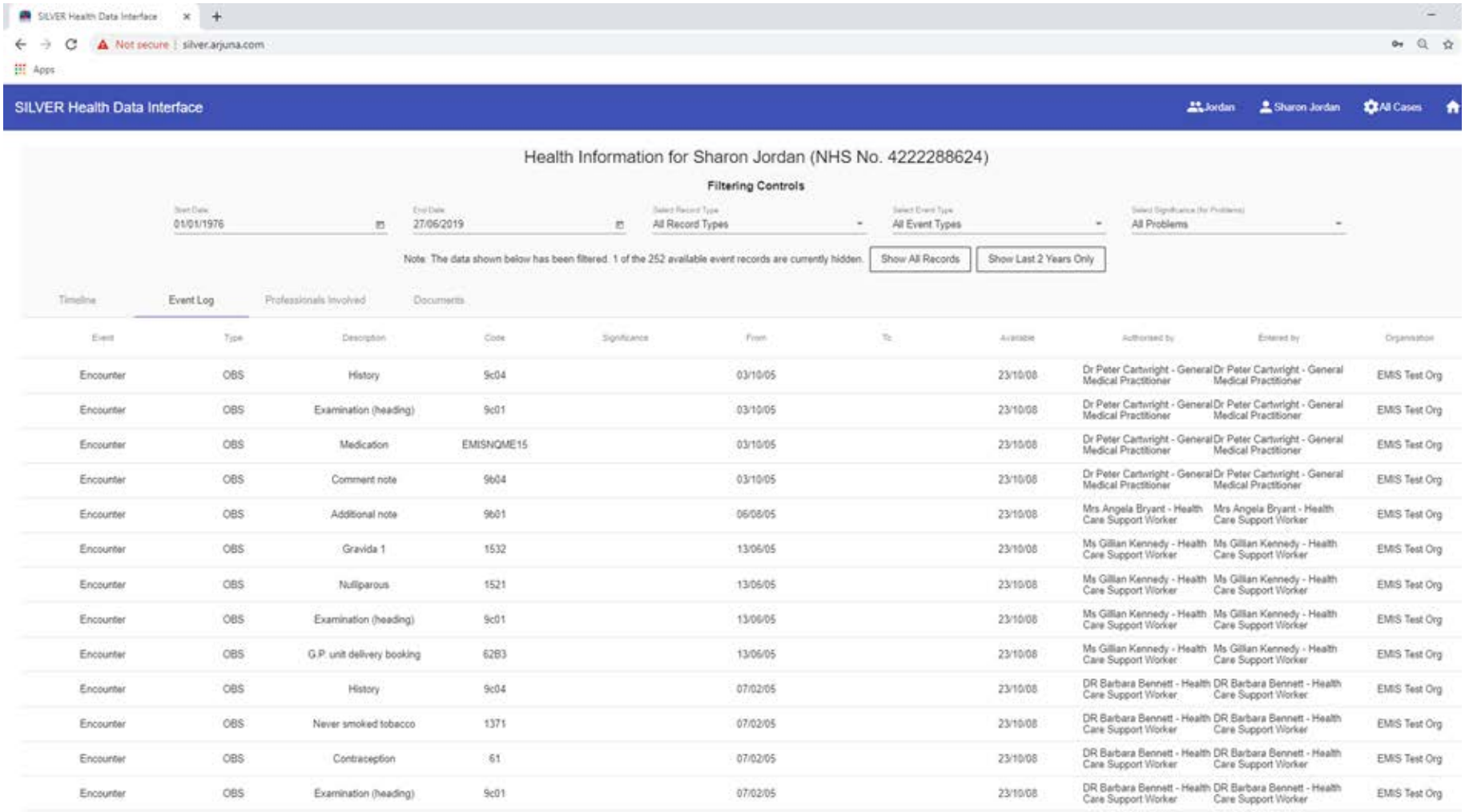
June 2019

Appendix 1

SILVER timeline of health events



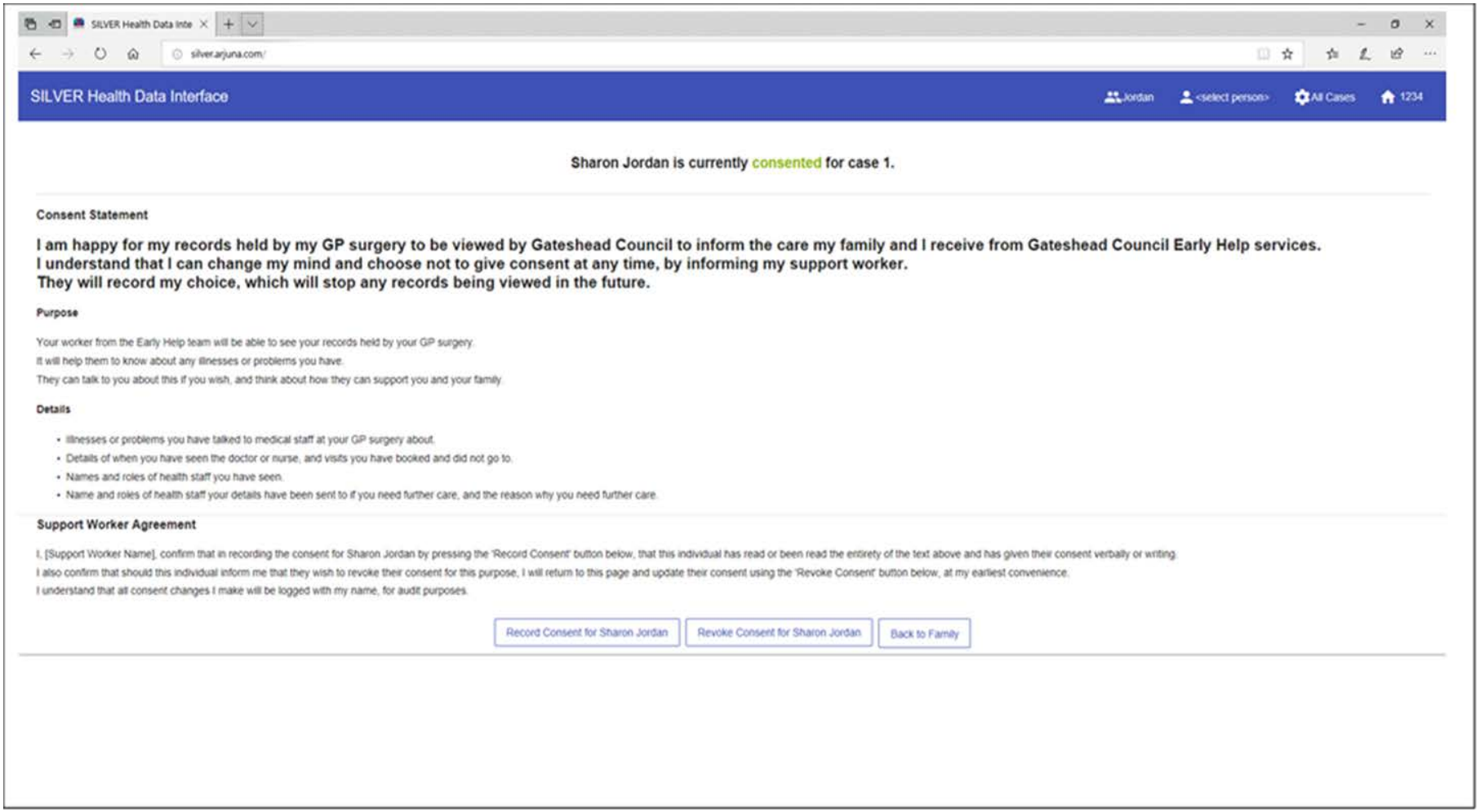
SILVER Event log



Event	Type	Description	Code	Significance	From	To	Available	Authorised by	Entered by	Organisation
Encounter	OBS	History	9c04		03/10/05		23/10/08	Dr Peter Cartwright - General Medical Practitioner	Dr Peter Cartwright - General Medical Practitioner	EMIS Test Org
Encounter	OBS	Examination (heading)	9c01		03/10/05		23/10/08	Dr Peter Cartwright - General Medical Practitioner	Dr Peter Cartwright - General Medical Practitioner	EMIS Test Org
Encounter	OBS	Medication	EMISNQME15		03/10/05		23/10/08	Dr Peter Cartwright - General Medical Practitioner	Dr Peter Cartwright - General Medical Practitioner	EMIS Test Org
Encounter	OBS	Comment note	9b04		03/10/05		23/10/08	Dr Peter Cartwright - General Medical Practitioner	Dr Peter Cartwright - General Medical Practitioner	EMIS Test Org
Encounter	OBS	Additional note	9b01		06/08/05		23/10/08	Mrs Angela Bryant - Health Care Support Worker	Mrs Angela Bryant - Health Care Support Worker	EMIS Test Org
Encounter	OBS	Gravida 1	1532		13/06/05		23/10/08	Ms Gillian Kennedy - Health Care Support Worker	Ms Gillian Kennedy - Health Care Support Worker	EMIS Test Org
Encounter	OBS	Nulliparous	1521		13/06/05		23/10/08	Ms Gillian Kennedy - Health Care Support Worker	Ms Gillian Kennedy - Health Care Support Worker	EMIS Test Org
Encounter	OBS	Examination (heading)	9c01		13/06/05		23/10/08	Ms Gillian Kennedy - Health Care Support Worker	Ms Gillian Kennedy - Health Care Support Worker	EMIS Test Org
Encounter	OBS	G.P. unit delivery booking	62B3		13/06/05		23/10/08	Ms Gillian Kennedy - Health Care Support Worker	Ms Gillian Kennedy - Health Care Support Worker	EMIS Test Org
Encounter	OBS	History	9c04		07/02/05		23/10/08	DR Barbara Bennett - Health Care Support Worker	DR Barbara Bennett - Health Care Support Worker	EMIS Test Org
Encounter	OBS	Never smoked tobacco	1371		07/02/05		23/10/08	DR Barbara Bennett - Health Care Support Worker	DR Barbara Bennett - Health Care Support Worker	EMIS Test Org
Encounter	OBS	Contraception	61		07/02/05		23/10/08	DR Barbara Bennett - Health Care Support Worker	DR Barbara Bennett - Health Care Support Worker	EMIS Test Org
Encounter	OBS	Examination (heading)	9c01		07/02/05		23/10/08	DR Barbara Bennett - Health Care Support Worker	DR Barbara Bennett - Health Care Support Worker	EMIS Test Org

Appendix 2

SILVER consent portal



Appendix 3

SILVER source list

SILVER-ConstellationOfCare: Front-end: Family Support Worker Web Portal - https://github.com/arjuna-technologies/SILVER-ConstellationOfCare (Open Source)

SILVER-ConsentEngine: Back-end: Consent Service & MIG Data Service - https://github.com/arjuna-technologies/SILVER-ConsentEngine (No-public - contain Heathcare Gateway IP)

SILVER-ConsentPortal: Front-end: Generic Consent Portal - https://github.com/arjuna-technologies/SILVER-ConsentPortal (Open Source)

SILVER-FamilyDataService: Back-end: Experimental Data Service - https://github.com/arjuna-technologies/SILVER-FamilyDataService (Open Source)

SILVER-AdminPortal: Front-end: Consent Authoring Portal - https://github.com/arjuna-technologies/SILVER-AdminPortal (Open Source)

SILVER-DataPortal: Front-end: Data Exploration Portal - https://github.com/arjuna-technologies/SILVER-DataPortal (Open Source)

SILVER-APIs: Early test data & API related to Troubled Families Program - https://github.com/arjuna-technologies/SILVER-APIs (Open Source)

Appendix 4

Data sharing agreements

Multi agency data sharing agreement
SILVER Project

1. Introduction

1.1. The Multi Agency SILVER Project Information Sharing Protocol (the Protocol) has been developed to ensure that information is being shared lawfully, appropriately, and in compliance with best practice.

1.2. The Protocol aims to improve the care that vulnerable families receive from social care professionals when accessing early help services by sharing personal and non-personal information appropriately between GP's and Partner Agencies.

1.3. The purpose of the Protocol is to provide information from (medical practice) GP systems via a healthcare gateway to social care professionals who have a legitimate professional relationship in providing direct care to the patient/service user. This is an overarching Protocol designed to provide a framework for all operating procedures and practices regarding information sharing for the project.

1.4. Each Signatory has their own procedures for information sharing and maintaining confidentiality and it is important to note that the Protocol does not supersede these.

1.5. The ethos of the Protocol is for Partner Agencies to share information in all situations to improve service delivery, where service users/patients have consented, except where it would be unlawful to do so.

1.6. A list of signatories to the Protocol can be found at Appendix A.

2. Objectives of the Protocol

Partner Agencies and their employees need to feel confident of their obligations when requested, or requesting, to share information. This Protocol aims to ensure compliance and consistency across the region by achieving the following objectives:

- To agree standards that each organisation will follow, govern working practices and create greater transparency, data security and improved services for users;
- By offering guidance on how to share information lawfully;
- Increasing understanding of Data Sharing principles and legislation;
- To protect Partner Organisations from allegations of wrongful use of data;
- To monitor and review information flows.

3. Signatory Responsibilities

It will be the responsibility of the signatories to commit to:

- That they are registered with the Information Commissioners Office in accordance; with current Data Protection Legislation

- Apply the standards that are prescribed in guidance and Codes of Practice issued by

the Information Commissioner's Office and https://ico.org.uk/for-organisations/

- Comply with the provisions of Data Protection legislation which includes, but not limited to:
    - The General Data Protection Regulation (GDPR)
    - Data Protection Act 2018 (DPA)
    - Privacy and Electronic Communications Regulations (PECR)
    - Digital Economy Act 2017 (DEA)
    - Human Rights Act 1998
    - Common Law Duty of Confidence
    - Health and Social Care Act 2012

Please note this list is not exhaustive and, accordingly, each Signatory has a duty to refer to appropriate legislation when making decisions regarding information sharing:

- All organisations that are signatories to the Protocol are expected to have a Data Protection Officer. If a Partner Organisation is not required to have a Data Protection Officer, by statute, then they are expected to have a designated information governance lead.

- Ethical standards must be maintained;

- All organisations must ensure any data processors are under contract and on approval of the appropriate agency.

- All Partner Organisations agree to be responsible for ensuring measures are in place to guarantee the security and integrity of data and that staff are sufficiently trained to understands their responsibilities and comply with the law.
- Appropriate arrangements exist to monitor the adherence to this protocol. This document shall be reviewed every two years unless significant new legislation or guidance from central government makes it necessary to have an earlier review.

4. Requirements for access to GP systems

Partner organisations will be provided with a logon to the Data portal to request access to a patient record. If the patient has consented to their record being shared with the agency requesting access to it, access will be granted via the medical interoperability gateway (MIG). No medical data obtained via the portal access is to be downloaded or stored on the Partner organisation's system.

4.1. Power to Disclose

Express consent will be the basis for processing 99% of data sharing under the terms of this protocol. In the limited circumstances where consent is not the lawful basis for processing, signatories must ensure that they have an express obligation, express power or implied power to access the information requested. They must also ensure that they have consent to share information with any third parties involved in the care of the patient (unless a statutory provision requires the data to be shared), and must

also ensure that there are no statutory prohibitions on disclosure.

4.2. Data Processing

4.2.1. Any disclosure of personal data must have regard to both common and statute law, for example: defamation, the common law duty of confidence, the principles of the Data Protection legislation, the Human Rights Act 1998 and the Freedom of Information Act 2000, to ensure that confidential information should be exchanged, as defined within operating procedures, of each agency.

Partner organisations are required to process personal data to ensure they have a valid condition for processing under the relevant legislation.

4.3. Restrictions

Partner organisations should ensure that they only use the information, that they have received, as a consequence of this Information Sharing Agreement, for the purposes stipulated in the agreement documentation, i.e to improve the care that vulnerable families receive from the responsible social care professional when they access local authority early help services. Contravention of this may result in the termination of an arrangement. This does not apply if Partner organisations are required to process the data if compelled by a statutory obligation (i,e Court Order).

Where a Partner organisation receives a request for information, which could involve the disclosure of information that originated from the (medical practice) GP systems via the portal, then the originating organisation should be consulted prior to disclosure. It should be noted that the decision to disclose rests with the receiving organisation and that the originating organisation does not have an automatic veto. The deciding authority must take another organisation's concerns seriously and if disclosure takes place against the wishes of that organisation then a sufficient explanation must be provided to that organisation.

Signatories will ensure that any restriction of rights is proportionate to the purpose for which the information is shared. In assessing proportionality Signatories will consider the impact on the data subject against the wider benefits of sharing the information.

4.4. Confidentiality

4.4.1. Before sharing information, Signatories will consider whether a duty of confidence is owed to the data subject or any other person.

4.4.2. If a duty of confidence does exist, Signatories will consider whether disclosure is lawful.

- Consent – confidentiality cannot be breached in circumstances where the person to whom the duty of confidence is owed consents to disclosure
- Public interest – there is a general public interest is preserving confidentiality, however, the law recognises that there may be instances where there is a countervailing public interest in disclosure
- The reason the information came into existence – if information was brought into existence for a particular purpose, it is generally accepted that the information can be disclosed for that purpose
- Court order or legal obligation – if there is a court order for disclosure or the disclosure is in pursuance of a legal obligation then you should satisfy yourself that any disclosure sought is required by law or can be justified in the public interest. (Confidentiality is not to be considered separately)

5. Security

5.1. Security

5.1.1. Controls are in place to ensure that no medical information can be downloaded from the (medical practice) GP system or stored by Local Authorities or other third parties. The data is stored on the (medical practice) GP System and accessed via a portal where access is controlled to only designated staff from each Local Authority and /or partner agency.

5.2. Retention and Destruction

5.2.1. Signatories will comply with the relevant Data Protection legislation and relevant government standards / best practice. To this end, Signatories will ensure that Information Sharing Agreements contain arrangements for the retention and destruction or return of information.

5.3. Issues and/or Non-Compliance in relation to the Application to this Protocol

5.3.1 In the first instance issues will be directed to (name & role)

5.3.2 Issues and or non-compliance in relation to the protocol regarding processing of personal data will be referred to the data controller, and will be investigated in accordance with the data protection legislation, regulation and relevant organisational procedures.

5.3.3 Responsibility for dealing with persistent non-compliance with the Protocol lies with the Chief Executive or signatory for the relevant organisation.

5.4. Refusal to share

5.4.1. Signatories will record any refusal to share information and will include the reasons for that decision. Specific Information Sharing Agreements will define procedures for a senior member of staff within the organisation to review information sharing decisions. Where necessary this may involve liaison with the Signatory's Designated Officer.

6. Monitoring and Review

6.1. Policy Management

This policy will be revised every two years in accordance with any significant changes to relevant legislation.

6.2. Specific Procedures

6.2.1. All procedures, including Information Sharing Agreements, devised as a result of the Protocol will state who is responsible for the monitoring and review process in relation to them.

Appendices

Appendix A: Signatories list

Appendix A: List of Signatories

Health Bodies
Name Signature Date
Local Authority
Name Signature Date

Detailed Care Record - data sharing information

Purpose of this document

The purpose of this document is to provide HGL customers and potential customers an overview of the information required by HGL in order to enable data sharing between different health organisations.

Introduction

Prior to the technical activation of the MIG in any given locality, Healthcare Gateway Limited require evidence of the signed data provider sharing agreements. These sharing agreements will have been defined and agreed by the data providers e.g. GPs to determine which consuming organisations have access to which elements of the clinical record.

Information required

As a minimum the following information is required by Healthcare Gateway before enabling data sharing between a provider (sharer) and consuming (viewing) organisation.

- Details of the organisation sharing the data (name of organisation, data controller, NACS/ODS code, supplier reference code).
- What information is being shared? Please note that all practices must agree to share the same level of data with any one organisation.
- Details of the organisation who will be viewing the data (name of organisation, data controller, NACS/ODS code, supplier reference code).

The agreement must be signed by the data controller of the data from each sharing organisation e.g. the GP practice.

Information sharing agreement

HGL have produced an example information sharing agreement that can be used to ensure the above items are covered sufficiently, please see appendix A of this document

It should be noted whilst this agreement cover the minimum information required by HGL to enable data sharing, HGL strongly recommend that customers liaise with their Information Governance Department and Caldecott Guardian to discuss the information governance requirements for projects involving the sharing of patient data.

Information to be shared

The Detailed Care Record caters for the real time retrieval and display of GP held patient record detailed information. The service provides fully embedded, integrated access to Primary Care patient records from trusted third party applications. Subject

to appropriate enabled sharing agreements, data is presented as a common HTML read only view. Information is displayed in 10 view based on a fixed content model (see appendix) consisting of all or a subset of the following:

- Summary
- Procedures
- Problems
- Investigations
- Diagnosis
- Examinations (BPs only)
- Medications
- Events (Encounters, Referrals and Admissions)
- Risks and Warnings
- Demographic

Agreement name	(Council name) Medical Interoperability Gateway Information Sharing Agreement
Purpose of sharing agreement	
The purpose of this Information Sharing Agreement (ISA) is to provide integration of the GP Detailed Care Record (DCR) service from (Medical Practice) to (Council name) Healthcare Gateway will provide the MIG technology and hosting infrastructure to support the interoperability between provider (sharing) organisations and consumer (viewing) organisations.	
We (Medical Practice) agree to share the following patient information via MIG.	
MIG Detailed Care Record	
Patient demographics	
Summary, including current problems, current medication, allergies, and recent tests	
Problem view	
Diagnosis view	
Medication including current, past and issues	
Risks and warnings	
Procedures	
Investigations	
Examination (blood pressure only)	

Events consisting of encounters, admissions and referrals	
Provider (sharing) organisation	
Practice/organisation name	
Address	
NACS/ODS code	
Supplier reference number	
Name and role	
Signed (on behalf of the practice/organisation)	
Date	
Consumer (viewing) organisation	
Organisation	
Address	
NACS/ODS code	
Name and role	
Signed (on behalf of the organisation)	

Please note for further information on the data items included in the above views please refer to HGQM009 - Healthcare Gateway MIG Content Model Read Code Mappings to Record Elements and EXT584- TPP Implementation of the content model.

1. Record sharing

The GP practice is the data guardian and controls access to the records therefore no data is shared via the MIG unless the practice has agreed to do so via the data sharing agreement. This details the data to be shared. Each organisation must agree to the sharing agreement before the data can be shared or viewed.

Please note that all sharing organisations must agree to share the same level of data with an individual organisation.

No data is ‘sent’ anywhere with data sharing via MIG, it remains within the organisation and the ‘sharing’ only enables others to view the data. Data cannot be changed or amended in any way be the viewing organisation.

2. Purpose of agreement

This agreement has been developed to document the flow of information between the named organisations to enable monitoring of patients being cared for and to provide accurate data for patient service delivery. Through this agreement all parties agree to ensure that staff are made aware of their responsibilities and comply with

the law and demonstrate compliance with the Data Protection Act 1998 and the Department of Health Code of Confidentiality.

3. Scope of agreement

The agreement covers the flow of information between the named organisations as to assist service delivery. This agreement is limited to information shared between the parties that are defined in this agreement and does not include any information sharing outside of the scope of this agreement

4. Approval

This agreement can only be signed by the organisation's Caldecott Guardian or an appropriate senior officer, nominated by an organisations' Caldecott Guardian/Information Governance Lead.

5. Monitoring of Agreement

Each organisation signed up to this agreement is responsible for ensuring full compliance of all staff within their organisation to the terms and conditions of this agreement. Any identified areas of non-compliance must be forwarded to the Nominated Senior Professional for resolution.

Please note that once the information has been extracted by the consuming system HGL shall not be held liable for the data recipient's use and governance of such information.

6. Access to patient information

Clinical and personal details will only be available to any person who is involved with the care of the individual on a need- to-know basis. Professionals must be able to justify fully the reasons for their obtaining any particular detail about an individual. Before anyone can view the shared record there must be a legitimate relationship with the patient and permission from the patient to view the shared record or stated that there was an emergency override.

Associated documentation

- HGQM009 Healthcare Gateway MIG Content Model Read Code Mappings to Record Elements.
- EXT584 TPP Implementation of the MIG DCRV1 Content Model.
- HGIF003 MIG Detailed Care Record (V1) Data Sharing and Security.

Disclaimer

Contact information

Healthcare Gateway, Fulford Grange, Micklefield Lane, Rawdon, Leeds, LS19 6BA.
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0845 601 2642

Appendix 5

Clinical Risk Management Plan

SILVER Project

Published XX June 2019

Document filename: SILVER CRMP v1	
Directorate / Programme	**Project**
Document Reference SILVER CRMP v1	
Director	**Status**
Owner	**Version 1**
Authors	**Version issue date**

Document Management

Revision History

Version	Date	Summary of Changes
1	June 2019	Document produced

Reviewers

This document must be reviewed by the following people:

Reviewer name	Title / Responsibility	Date	Version
	Clinical Safety Officer, SILVER Project		
	Clinical Safety Officer, Newcastle Gateshead CCG		

Approved by

This document must be approved by the following people:

Name	Title	Date	Version
	Clinical Safety Officer, SILVER Project		
	Clinical Safety Officer, Newcastle Gateshead CCG		

Related Documents

These documents provide additional information and are specifically referenced within this document.

Ref	Title	Version
1	DCB 0129 Clinical Risk Management: its application in the manufacture of health IT systems https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0129-clinical-risk-management-its-application-in-the-manufacture-of-health-it-systems	
2	DCB0160 Clinical Risk Management: its application in the deployment of health IT systems https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0160-clinical-risk-management-its-application-in-the-deployment-and-use-of-health-it-systems	

Ref	Title	Version
3	SILVER Clinical Risk Safety Case Report	2
4	SILVER Hazard log	

Contents

Introduction

Purpose of Document

The purpose of the Clinical Risk Management Plan (CRMP) is to define the implementation of the SILVER system. It describes how the SILVER Clinical Risk Management sub-group will conduct clinical risk management to ensure patient safety with respect to services provided and the interrelated and interactive activities that will occur to ensure that SILVER meets the requirements of DCB 0129[1] and DCB 0160[2].

This CRMP identifies the means by which SILVER shall be controlled to ensure that the safety work is of high quality, conforms to requirements and any specific programme requirements.

This document will be updated when the plan changes in any way as to deviate from what has been committed to deliver. This will be decided by the SILVER Clinical Risk Management sub-group.

Background to clinical safety standards and requirements

Information standards provide the mechanism for introducing requirements to the NHS, those with whom it commissions services and its IT system suppliers. There are two Information Standards related to patient safety described below.

DCB 0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems

This standard sets clinical risk management standards for manufacturers of Health IT systems. It requires the manufacturer to establish a structure within which clinical risks associated with the design and development of a new Health IT system or the modification of an existing system are properly managed. It also ensures that outputs are clearly documented to provide evidence of compliance. Compliance with the standard ensures that the manufacturer has instigated a best practice clinical safety programme during the manufacture of the health IT system.

DCB 0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems

This standard requires health organisations deploying and using new or modified health IT systems to have a structure to manage clinical risks associated with that deployment. Many of the requirements in DCB 0129 are repeated in DCB 0160 for the health organisations.

SILVER Overview & Clinical Safety

The SILVER project aims to improve care for vulnerable families by sharing parents' health data recorded by their GP with Local Authority Early Help Services. Early Help Services aim to assist families to overcome challenges, seek support and work towards improving outcomes for children, young people and families. Engagement with early help services is voluntary, and as such parents will be required to provide explicit consent for their Early Help practitioner to access data from their GP health record. Access to parents' health data will better inform support plans and improve direct care.

The SILVER clinical risk management process sets out the safety related activities being carried out for this release, in line with standards DCB0129 and DCB0160. Those aspects of

clinical functionality that have the potential to introduce clinical hazards have been assessed and added to the hazard register.

This is an additional system and will not replace any existing systems accessed by Local Authority Early Help practitioners. This document is intended for health and social care organisations involved in the deployment of SILVER; (health/social care organisations).

This revised documentation will be agreed with the SILVER Clinical Risk Management sub group and Clinical Safety Officer to ensure the correct governance and control are in place.

Impact of DCB 0129 and DCB 0160 on SILVER

Whilst SILVER may not physically be manufacturing the service itself, it may classify as a 'Manufacturer' as defined in DCB 0129:

'Person or organisation with responsibility for the design, manufacture, packaging or labelling of a Health IT System, assembling a system, or adapting a Health IT System before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party.'

Within the safety standard DCB 0160 we can also assume partial responsibility in the role of a Health Organisation. This standard is addressed to those persons in Health Organisations who are responsible for ensuring clinical safety in the deployment of Health IT Systems through the application of clinical risk management.

SILVER will therefore adhere to all applicable requirements of DCB 0129 and DCB 0160 in this regard.

Note: this section provides guidance for those organisations who may fall within the scope of both safety standards. If this does not apply then please delete this section.

Clinical Risk Management File

The SILVER file is located at (electronic file location) and contains all relevant clinical safety documentation and will perform the function of the Clinical Risk Management File. This folder will be managed by the Clinical Risk Management sub group.

Resources / Personnel

The Clinical Safety Officer is responsible for ensuring the clinical safety of SILVER through the application of clinical risk management. The Clinical Safety Officer is a suitably qualified and experienced clinician who holds current registration with their relevant professional body and has had appropriate training for this role.

Key responsibilities include:

- approval of the Clinical Risk Management Plan to confirm that the plan is appropriate and achievable in the context of the Health IT System development and modification;
- ensuring that clinical risk management activities are completed in accordance with the Clinical Risk Management Plan (this document);
- reviewing and approving of all safety documentation including Clinical Safety Case Reports and Hazard Logs;
- reviewing evidence in the Clinical Risk Management File to ensure it is complete and supports the Clinical Safety Case Report;
- providing recommendation to Newcastle Gateshead Clinical Safety Officer whether the Service is safe to release; and
- escalating any unacceptable safety risks.

Table 1 Roles and responsibilities

Development Team		Assurance Team	
Safety Engineer		Safety Engineers	
Clinical Safety Officer		Clinical Safety Officer	

Note: This is an example of where roles and responsibilities can be summarised simply or referenced out to more suitable and detailed documentation if available.

Clinical Risk Evaluation and Management

The clinical risk matrix, evaluation and management process used is defined below and can also be found in more detail within the appendix.

Hazards may be identified in other ways during the development and use of SILVER such as:

- Discovery during design of a solution by supplier;
- Testing of amended functionality;
- Ad hoc testing of live service functionality;
- Reporting of an incident or problem within the live service; and
- Identification by a member of staff within the supplier or receiving organisation (LA)

For each identified hazard, the following information will be defined and recorded on the Hazard Sheet and summarised on the Hazard Log:

- Hazard number;
- Hazard name;
- Hazard description;
- Potential clinical impact – this will describe the effect of the hazard in the care setting and potential impact on the patient;
- Possible causes – these may be technical, human, error etc. A hazard may have a number of causes; and
- Existing controls – these are identified existing controls or measures that are currently in place and will remain in place post implementation that provide mitigation again the hazard, i.e. will be used as part of the initial Hazard Risk Assessment.

Each Hazard will be discussed by the SILVER steering group and Clinical Safety Officer and any other appropriate people. They will perform the following tasks and record the outcome in the Hazard Sheet and a summary in the Hazard Log:

- Estimation of clinical risks;
- Clinical risk evaluation; and
- Clinical risk control option management.

Estimation of clinical risks.

For each identified hazard estimation will be made of the clinical risk. This will include the severity of the hazard, the likelihood of the hazard and the resulting clinical risk. The estimation process will follow that established by the safety processes defined in DCB 0129. A copy of the risk assessment matrix is provided in the appendix.

Note: Any valid approach to hazard assessment and associated risk assessment matrices can be used. The sample provided in this document is to highlight documentation requirements only and does not provide a recommendation on any specific methodology to be used. This decision must be made by the organisation and its clinical safety team.

Appendix – Risk Classification Matrix

Clinical Risk Management Risk Matrix

Likelihood						
	Very High	3	4	4	5	5
	High	2	3	3	4	5
	Medium	2	2	3	3	4
	Low	1	2	2	3	4
	Very Low	1	1	2	2	3
		Minor	Significant	Considerable	Major	Catastrophic
		Consequence				

Risk Matrix key - Severity

5	Unacceptable level of risk.
4	Mandatory elimination or control to reduce risk to an acceptable level
3	Undesirable level of risk Attempts should be made to eliminate or control to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical.
2	Acceptable where cost of further reduction outweighs benefits gained.
1	Acceptable, no further action required

Hazard likelihood definitions

Likelihood Category	Interpretation
Very high	Certain or almost certain; highly likely to occur
High	Not certain but very possible; reasonably expected to occur in the majority of cases
Medium	Possible
Low	Could occur but in the great majority of occasions will not
Very low	Negligible or nearly negligible possibility of occurring

Hazard Consequence definitions

Consequence Classification	Interpretation	Number of Patients Affected
Catastrophic	Death	Multiple
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Multiple
Major	Death	Single
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Single
	Severe injury or severe incapacity from which recovery is expected in the short term	Multiple
	Severe psychological trauma	Multiple
Considerable	Severe injury or severe incapacity from which recovery is expected in the short term	Single
	Severe psychological trauma	Single
	Minor injury or injuries from which recovery is not expected in the short term.	Multiple
	Significant psychological trauma.	Multiple
Significant	Minor injury or injuries from which recovery is not expected in the short term.	Single
	Significant psychological trauma	Single
	Minor injury from which recovery is expected in the short term	Multiple
	Minor psychological upset; inconvenience	Multiple
Minor	Minor injury from which recovery is expected in the short term; minor psychological upset; inconvenience; any negligible severity	Single

Appendix 5

Clinical Safety Case Report

SILVER – Newcastle University

Published XX June 2019

Document filename: SILVER v2	
Directorate / Programme CHC care pathway	**Project SILVER**
Document Reference	
Director	**Status**
Owner	**Version 2**
Authors	**Version issue date** **June 2019**

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Version	Date	Summary of Changes
1	June 2019	Revised following comments from CSO's
2	June 2019	

Reviewers

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SILVER Project Clinical Risk Management sub-group	Produce clinical risk management documents	June 2019	
	Clinical Safety Officer, SILVER Project	June 2019	
	Clinical Safety Officer Newcastle Gateshead CCG	June 2019	

Approved by

This document must be approved by the following people:

Name	Title	Date	Version
	Clinical Safety Officer, SILVER Project		
	Clinical Safety Officer Newcastle Gateshead CCG		

Related Documents

These documents provide additional information and are specifically referenced within this document.

Ref	Title	Version
1	SILVER Clinical Risk Management Plan	
2	SILVER Hazard Register	
3	DCB0129 Clinical Risk Management: its application in the manufacture of health IT systems https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0129-clinical-risk-management-its-application-in-the-manufacture-of-health-it-systems	

Ref	Title	Version
	DCB0160 Clinical Risk Management: its application in the deployment of health IT systems https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0160-clinical-risk-management-its-application-in-the-deployment-and-use-of-health-it-systems	
	Data sharing agreement – MIG	
	Data sharing agreement – Local Authority	

Contents

Introduction

This document represents the Clinical Safety Case Report (CSCR) for SILVER; this is a new product.

This document includes the results of the hazard assessment, a review of mitigation procedures defined and undertaken, and confirmation that all hazards have been addressed and mitigated.

System Definition / Overview

The SILVER project aims to improve care for vulnerable families by sharing parents' health data recorded by their GP with Local Authority Early Help Services. Early Help Services aim to assist families to overcome challenges, seek support and work towards improving outcomes for children, young people and families. Engagement with early help services is voluntary, and as such parents will be required to provide explicit consent for their Early Help practitioner to access data from their GP health record. Access to parents' health data will better inform support plans and improve direct care.

The SILVER clinical risk management process sets out the safety related activities being carried out for this release, in line with standards DCB0129[3] and DCB0160[4]. Those aspects of clinical functionality that have the potential to introduce clinical hazards have been assessed and added to the hazard register.

This is an additional system and will not replace any existing systems accessed by Local Authority Early Help practitioners. This document is intended for health and social care organisations involved in the deployment of SILVER; Teams Medical Practice, Newcastle Gateshead Clinical Commissioning Group and Gateshead Council.

Clinical Risk Management System

SILVER takes seriously its responsibility to ensure that all releases of functionality contained within the systems are assessed for their potential impact upon clinical safety. SILVER has published a Clinical Risk Management Plan[1] that is followed for each release which describes the safety activities that will be conducted in support of safety acceptance into service.

1.1 Assessment Process

The SILVER Clinical Risk Management (CRM) sub-group provide an initial analysis of the proposed functionality associated with a release. In addition to considering new hazards that may arise as a result of new, changed, or enhanced functionality; they also consider if hazards associated with previous releases of this software may affect the service differently after each release is implemented.

Where new functionality requires it, the SILVER CRM sub-group will organise workshops, using relevant technical and clinical expertise, to further consider the impact of functionality on the service.

Hazard assessments for each release are not undertaken in isolation or in ignorance of previous functionality and reviews. Each assessment is an extension of previous assessments, where considerations are assessed understanding that changes to both functional and non-functional parts of the system can have clinical impact.

Any new or revised hazards as documented in this report, together with any that are unchanged, are recorded in the Hazard Register[2]

Clinical hazard assessment for a change, enhancement or minor release involves the following steps:

- Identification of the functional deltas between the last release and this release;
- Consideration of the potential for any new functionality to introduce new hazards;
- Review of any existing hazards from previous releases to ensure that new functionality does not alter deleteriously any mitigations in place;
- Consideration of test evidence to provide evidence supporting the assessment conclusions.

Any hazards are assessed by the use of hazard classification and likelihood matrices to assess the level of risk associated with a hazard. The risk is classified from the two scales as seen below:

- A Consequence (or Severity/Impact) scale; and,
- A Likelihood (or Probability/Frequency) scale.

The process of assessment is as follows:

SILVER assesses the changes to the system via requirements catalogue and functional description. Each change has a unique identifier. These changes are assessed for clinical impact and potential risk to the patient, and any associated clinical hazard is assessed and recorded.

Each change with associated clinical risk is then mapped to a test log and script ensuring it has been adequately tested and has passed.

All changes within the release will be examined for potential clinical impact on those changes which may impact clinical safety and the approach taken to mitigate them OR any changes that require further details or explanation.

Clinical Risk Analysis

Likelihood

Classification	Criteria
Very High	Certain or almost certain, highly likely to occur
High	Not certain but very possible, reasonably expected to occur in the majority of cases
Medium	Possible
Low	Could occur but in the great majority of occasions will not
Very Low	Negligible or nearly negligible possibility of occurring

Consequences

Consequence Category	Interpretation Consequence	Number of Patients affected
Catastrophic	Death	Multiple
	Permanent life changing incapacity and any condition for which prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Multiple
Major	Death	Single
	Permanent life changing incapacity and any condition for which prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Single
	Severe injury or severe incapacity from which recovery is expected in the short term	Multiple
	Severe psychological trauma	Multiple
Considerable	Severe injury or severe incapacity from which recovery is expected in the short term	Single
	Severe psychological trauma	Single
	Minor injury or injuries from which recovery is not expected in the short term	Multiple
	Significant psychological trauma	Multiple
Significant	Minor injury or injuries from which recovery is not expected in the short term	Single
	Significant psychological trauma	Single
	Minor injury from which recovery is expected in the short term	Multiple
	Minor psychological upset; inconvenience	Multiple
Minor	Minor injury from which recovery is expected in the short term: Minor psychological upset; inconvenience; any negligible consequence	Single

Clinical Risk Evaluation

Risk Matrix

The risk for a given hazard is determined from the intersection of the selected consequence and likelihood in the following table:

Likelihood	Consequence				
	Minor	Significant	Considerable	Major	Catastrophic
Very High	3	4	4	5	5
High	2	3	3	4	5
Medium	2	2	3	3	4
Low	1	2	2	3	4
Very Low	1	1	2	2	3

Acceptability

5	Unacceptable level of risk
4	Mandatory elimination or control to reduce risk to an acceptable level
3	Undesirable level of risk
2	Acceptable where cost of further reduction outweighs gained or where further risk reduction is impractical (ALARP)
1	Acceptable, no further action required

The general acceptability of the derived risk is shown in the table above.
Risks that are unacceptable shall be subject to suitable risk reduction measures.

Clinical Risk Control

Identification, justification, implementation and verification of adequate risk controls; residual clinical risk evaluation and completion of controls.

Hazards during safety assessments conducted by the organisations can be controlled by:

- Appropriate local governance ensuring all parties are aware of the intended function of SILVER and associated procedures for use.

- Training to understand the configuration requirement and impact on the business process; and,
- Local testing of the content/configuration at deployment.

Any issues occurring once the system is in live service will be dealt with in accordance with the procedures outlined in the data sharing agreement[6]. Procedures outlined in Gateshead Councils policy regarding data breach will be adhered to.

Once an incident is raised, and assuming that it has been explicitly flagged as having a clinical risk, a clinical risk assessment process will be undertaken by the SILVER CRM sub group.

If system faults are exposed and mitigation activities are agreed between the supplier and the customer, then it is expected that these activities will be undertaken.

Where a system is not used as agreed it cannot assumed to be safe.

Hazard Log

Hazard ID	Hazard name	Hazard description	Hazard causes	Initial risk rating	Potential clinical impact	Mitigation	Residual risk rating
1	Misidentification of patient	Early Help Workers (LA) do not have access to patient NHS numbers.	Early Help Workers (LA) select the wrong patient to participate in SILVER.	2	Medical information that does not belong to the patient is accessed. The illnesses/conditions of the patient intended to be traced are unknown to the Early Help Worker and may affect the discussions about care they initiate with the patient.	SILVER will be linked to the Patient Demographic Service (PDS) via the MIG to obtain the NHS number.	1
2	User authentication	Unauthorised users access SILVER	Insufficient user authorisation process	2	Medical information belonging to patients may be accessed without authorisation.	Use of Keycloak* as an authentication and authorisation service.	1
3	Unfamiliar medical terminology	Early Help Workers do not understand the medical terminology presented in patient data in SILVER.	Early Help Workers are not medically trained.	3	If Early Help Workers misunderstand the terminology there is the possibility that this may affect the discussions about care they initiate with the patient. It also has the potential to damage the relationship between the Early Help Worker and the patient, and disrupt care if the Early Help Worker presents the patient with incorrect information.	Early Help Workers will participate in training prior to using SILVER. Advise to be cautious and apply usual practice when understanding and acting on medical information.	2
4	Access to raw and filtered data	Early Help Workers may build a picture of the patients' medical history from the filtered data only. The raw data view provides all of the patient data available via MIG.	Early Help Workers do not look at raw data view and rely purely on filtered view.	3	If the Early Help Workers only look at the filtered data about the health problems experienced by the family, the health of the family may be mis-presented to them. They may miss a health problem which is important to the family but is not shown in the raw data view.	Early Help Workers will participate in training prior to using SILVER. During the training we will ensure they are aware of the need to check both the raw and filtered data views.	1

Hazard ID	Hazard name	Hazard description	Hazard causes	Initial risk rating	Potential clinical impact	Mitigation	Residual risk rating
		Early Help Workers have access to too much medical information and cannot access information that will influence care.	Early Help Workers do not filter raw data.			Timeline, contact type, and event type can be filtered to reduce the amount of available data in view.	
5	Verbal disclosure of medical information	Early Help Workers may verbally share medical information about a family member (from SILVER) with another family member who is not aware of that information.	Early Help Workers are unaware that an aspect of an individual's medical history is unknown in families.	1	It has the potential to damage the relationship between the Early Help Worker and the patient if the Early Help Worker discloses information they should not be sharing. This may disrupt the care that can be offered in this relationship. It has the potential to cause difficulties within the patient's family.	Early Help workers should be advised in training to only discuss health information in private with patients until they can be sure which other family members are aware of the circumstances. Advise to be cautious and apply usual practice when understanding and acting on medical information.	1
6	Patient disagrees with medical information in their record	Patient disagrees with the health information that the Early Help Worker has accessed through the SILVER system.	Possible inaccurate recording of health information.	3	It has the potential to damage the relationship between the patient and their GP and disrupt the care that is offered.	Early Help Worker or patient contact the GP to discuss and possibly revise the information recorded about their health.	1
7	Selected patient data is	Gaps in medical information available.	MIG does not record all medical information about	2	The information included in SILVER is not all of the patient's medical records. If the Early Help Worker only relies on the information in SILVER they will	This information will be included in the training provided to users of SILVER.	1

Hazard ID	Hazard name	Hazard description	Hazard causes	Initial risk rating	Potential clinical impact	Mitigation	Residual risk rating
	available via the MIG		a patient, exclusions apply.		have an incomplete picture of the patient's medical history (e.g. it will exclude sexual health). This will limit the care they can offer the family.	Early Help Workers will need to continue to ensure they talk to families about their medical history.	
8	Third party software components	The SILVER front-end and back-end are dependent on numerous third party software components, which SILVER members don't have influence/control over.	The continued availability and maintenance of these third party software components can't be guaranteed. This leads to issues with ongoing maintenance and support of the SILVER system.	2	Requested changes and issues may not be possible to support.	A list of third party software components has been created, and each component's individual hazard evaluated. Refer to SILVER 3rd party components document	2
9	Records for patients under 18 are accessed	Medical records for patients under the age of 18 are accessed wrongly. SILVER is only for consenting adults over the age of 18.	Practitioner wrongly requests access for a patient under the age of 18	2		Staff know that SILVER is only for over 18 year olds. Access to SILVER is restricted to patients over the age of 18. If a request for a patient under the age of 18 is made, the request will be denied.	1
10	Medical data accessed without consent	The SILVER system allows access to health data for an individual once the user clicks "Record	Accidental or deliberate misuse of the "Record consent" / "Revoke consent"	2	The Early Help Worker may have access to information about the individual's health to which they should not be party. This information may	Firstly staff will be trained about the importance of ensuring that the consent status in	1

Hazard ID	Hazard name	Hazard description	Hazard causes	Initial risk rating	Potential clinical impact	Mitigation	Residual risk rating
		consent." If this is clicked without having actually having sought and obtained consent from the data subject (or, if the data subject has revoked consent but this has not been recorded in the system) then the data can be viewed and accessed without consent. This could happen by accident or maliciously.	buttons to enable/disable access to an individual's medical data.		affect the staff member's judgements or decisions in the care they provide.	SILVER always reflects the very latest consent status from consent conversations with the family and is consistent with paper consent records held by the local authority. Secondly, all changes to consent status are recorded with a staff member name who made the change. This ensures that any misuse is logged and as it would be a disciplinary offence this should serve as a deterrent. Each local authority should have their own procedures for regularly reviewing consent, and these should be updated to include checking that consent status is correct in SILVER, and updating it where it is not. The processors will adhere to their	

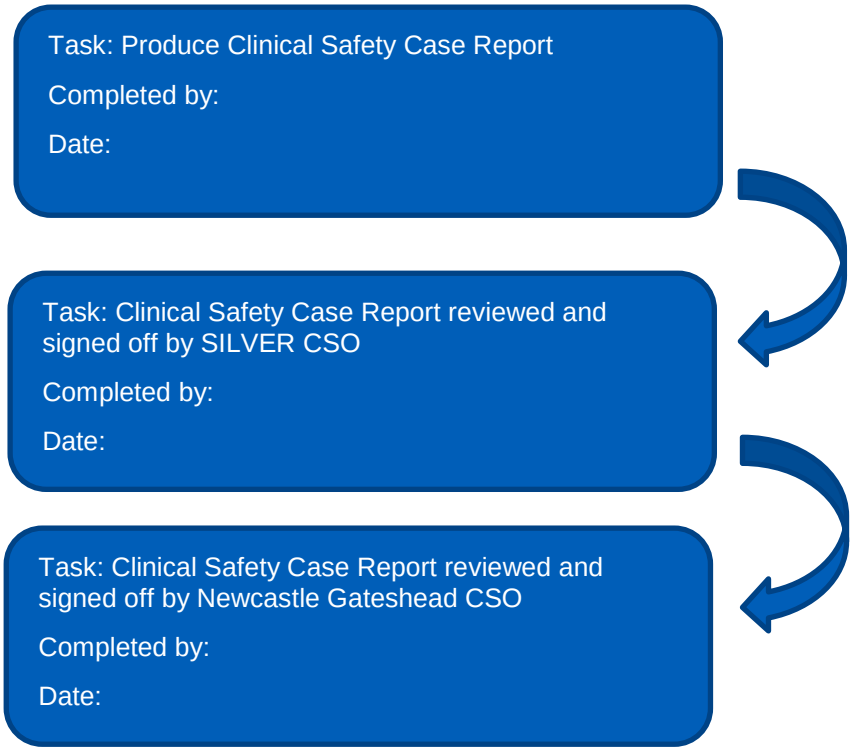
Hazard ID	Hazard name	Hazard description	Hazard causes	Initial risk rating	Potential clinical impact	Mitigation	Residual risk rating
						usual data protection policy.	
11	MIG system goes down	Health data is not accessible from the MIG because of a technical issue with retrieving the data.	Planned monthly 1 hour scheduled maintenance. Unplanned service interruption.	2	Early Help Workers are unable to access health information for a patient.	Direct care to patients is not wholly dependent upon the function of SILVER Dates for scheduled maintenance are published and can be shared with Early Help Workers. Healthcare Gateway log unscheduled interruptions online to advise customers of progress in resolving interruptions.	1

*Keycloak - Users authenticate with Keycloak rather than individual applications. Applications don't have to deal with login forms, authenticating users, and storing users. Once logged-in to Keycloak, users don't have to login again to access a different application, this also applies to logout. Keycloak provides single-sign out, which means users only have to logout once to be logged-out of all applications that use Keycloak.

Test Issues

There are no outstanding test issues.

Quality Assurance and Document Approval



This Clinical Safety Case Report demonstrates that SILVER has made all reasonable efforts to identify, assess and, where appropriate, mitigate hazards associated with SILVER.

This document is the Clinical Safety Case Report for SILVER. It demonstrates that SILVER has made all reasonable efforts to identify, assess and, where appropriate, mitigate hazards associated with this product. The Clinical Safety Officer confirms that this product, as released and where used as specified, does not include any clinical hazards or functionality which could give rise to unacceptable clinical risk to patients.	
Signed	
Name	
Role	
Date	

Configuration Control / Management

Documents have been prepared which describe the overall structure of the deployment of the SILVER system, and detailed instructions on how to deploy the components software subsystems. There are four sets of detailed instructions one for each of the virtual machines on which the SILVER system is deployed: silver_kc, silver_web, silver_db and silver_mig.

These documents will be maintained, and updated as changes to the deployment are approved.

The virtual machines on which the SILVER system will be deployed is based on Ubuntu 16. The Ubuntu operation system receives continues updates, including security updates. There updates will routinely be applied to all the virtual machine on which the SILVER system is deployed.