Professional Record Standards Body

Better records for better care

EPILEPSY INFORMATION STANDARD CLINICAL SAFETY CASE

DECEMBER 2025

Document Management

Revision History

Version	Date	Summary of Changes
0.1	11/12/25	First draft
0.2	15/12/25	Updated following feedback from project team and CSO

Reviewers

Reviewer name	Date	Version
Clinical Safety Officer – Steve Bentley	12/12/25	0.1
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Approved by

Name	Date	Version
Clinical Safety Officer – Steve Bentley		
NHS England Clinical Safety Group		

Related Documents

Ref no	Title
[1]	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
[2]	DCB0160: Clinical Risk Management: its Application in the Deployment and Use 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

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1 Introduction

1.1 Background

Epilepsy12 (E12) was established in 2009 with the aim of supporting epilepsy services and those who commission health services to measure and improve the quality of care for children and young people with seizures and epilepsies. The audit is commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP) and is delivered by the Royal College of Paediatrics and Child Health (RCPCH).

Epilepsy is the most common significant long-term neurological condition of childhood, affecting an estimated 112,000 children and young people in the United Kingdom. Epilepsy12 seeks to improve the quality and consistency of care for these children and young people across England and Wales by collecting and analysing patient-level data to identify areas of good practice and highlight opportunities for improvement.

In 2022, a further contract was awarded to the RCPCH to continue delivering Epilepsy12 audit until 31 March 2025, with a further 2-year extension awarded until 31 March 2027. However, there continues to be considerable variation in the ability of different Health Boards and NHS Trusts in England and Wales to provide the necessary workforce capacity and resources to participate fully in the national audit. These challenges have been compounded by the impact of the COVID-19 pandemic.

1.2 The Structure of Epilepsy12

Epilepsy12 audit is comprised of three main components, which are reflected in its annual report:

1. Clinical Audit – Describing the care provided to children and young people newly diagnosed with epilepsy during their first year of care. Patients are grouped into cohorts based on the date of their first paediatric assessment and are followed for the subsequent 12 months.
2. Organisational Audit – Assessing paediatric epilepsy services and workforce provision at Trust or Health Board level, as they stand in November each year.
3. Quality Improvement Activities – Showcasing examples of local and national quality improvement initiatives, including case studies from NHS Trusts and Health Boards, outputs from the Epilepsy Quality Improvement Programme (EQIP), and activities led by the Epilepsy12 Youth Advocates.

1.3 The Case for an Epilepsy Information Standard

Through delivery of the audit, the Epilepsy12 team identified the need for an agreed national epilepsy information standard to facilitate the consistent recording and secure sharing of epilepsy-related data across health and care settings. This standard would also enable the use of routine clinical data for secondary purposes, such as national audit and research.

While Epilepsy12 focuses on children and young people, it is recognised that any information standard must also meet the needs of adults with epilepsy, ensuring interoperability and continuity across the life course.

There are multiple drivers across the epilepsy community for developing and embedding standardised data for epilepsy. For example, the RCPCH Epilepsy Passport, published in 2015, was designed to help families maintain up-to-date copies of their child's epilepsy-related

health information. However, implementation proved challenging due to the absence of standardised routes to derive and update this information directly from Electronic Health Records (EHRs). Similar barriers persist across epilepsy care planning, where maintaining accurate and consistent diagnostic information remains critical.

The Epilepsy12 (2024) report found that 55.3% (63/114) of Trusts and Health Boards maintain some form of local database or registry for epilepsy patients. However, there is no evidence that diagnoses, or care data are recorded in a consistent, standardised way, nor are these datasets routinely linked to EHR systems. The multiaxial, complex, and evolving nature of epilepsy, its associations with co-morbidities, and variations in disease progression further compound challenges in ensuring interoperability and data aggregation.

Within primary care and across Trust or Health Board EHRs, epilepsy diagnoses are not consistently coded or recorded. This lack of standardisation limits system-wide visibility of patients with epilepsy and constrains several key activities, including:

- Accurate coding of hospital admissions and emergency department attendances related to epilepsy within Hospital Episode Statistics (HES) data.
- Development of national activity and outcome dashboards to inform commissioning, which currently rely heavily on admission data and lack comprehensive epilepsy-specific indicators.
- Research and innovation, which increasingly depend on large, multi-centre population cohorts. The ability to identify and recruit specific subgroups or to undertake approved research using routinely collected clinical data is essential to drive the advances needed to improve outcomes. Epilepsy Research UK (ERUK) has identified *big data analysis* as one of its ten key research priorities.

Furthermore, the Core20PLUS5 framework for Children identifies epilepsy, particularly in children with learning disabilities and/or autism, as a key priority for reducing health inequalities.

1.4 Purpose of the Epilepsy Information Standard

The Epilepsy Information Standard (EIS) aims to establish a consistent, structured approach to recording and sharing information about the diagnosis, treatment, and ongoing management of epilepsy across all health and care settings. By defining a common set of data items and terminologies, the standard seeks to improve communication between professionals, enhance patient safety, and support more coordinated, person-centred care. The EIS will enable interoperability between systems, ensuring that essential information about an individual's epilepsy, such as seizure history, medication, and comorbidities, can be accurately and efficiently shared between clinicians, services, and digital platforms. This will facilitate timely decision-making, reduce duplication, and minimise the risk of errors.
In addition to improving clinical care, the EIS will provide a robust foundation for secondary uses of data, including national audit, research, and service improvement. By ensuring that information is recorded in a consistent and standardised way, the EIS will strengthen the evidence base for policy, commissioning, and quality improvement initiatives, ultimately contributing to better outcomes for people living with epilepsy.

1.5 Purpose of the Clinical Safety Case Report

This Clinical Safety Case Report (CSCR) for the Epilepsy Information Standard addresses the requirements of DCB0129 V2.0 Clinical Risk Management: it's Application in the Manufacture of Health IT Systems [Ref.1].

The full application of DCB0129 cannot be applied, as the professional standard itself is not a manufactured health IT system. However, the guidance within DCB0129 concerning clinical risk management and appropriately governed hazard assessment has been considered. The hazards identified here, along with proposed mitigations, are for system suppliers and providers implementing the standards to pick up and consider when implementing the standard and doing their own assurance.

2 Scope

2.1 In scope

The scope of the project covers both children and adults with epilepsy. Scope includes data relating to epilepsy which:

- might be required at point of care.
- might be shared between different settings.
- a patient might wish to share.
- might be required for national audit and approved research purposes.
- might be required to support care planning.

2.2 Out of scope

The use of artificial intelligence (AI) technologies including tools or systems designed to automatically generate, populate, or summarise patient records are out of scope for this project.

3 Clinical risk management system

The NHS England Clinical Safety Group (CSG) operates a full Clinical Safety Management System (CSMS) that encompasses integration with health organisations and professional bodies. The CSMS considers the integration with the Data Alliance Partnership Board (DAPB) and the process in which professional standards are developed in the CSMS framework. The essential structures of a CSMS have been implemented in this project through the consultation with healthcare professionals, patients, informaticians and clinical system suppliers, during the development of the standard. Governance structures, project methodology and stakeholder engagement are described in the Epilepsy Information Standard final report. The PRSB remit, organisational structure, roles and responsibilities of key personnel are fully described on the PRSB website.

It should be noted that this clinical safety report is necessarily limited in its scope because it is neither directly related to software development nor to deployment. Suppliers developing software to implement these standards will therefore still be expected to fully apply DCB0129 [Ref. 1]. Organisations involved in the deployment of such software will still be expected to fully apply DCB0160 [Ref.2].

The role of a Clinical Safety Officer (CSO) was to review the Clinical Safety Case using his/her clinical experience to judge the appropriateness and effectiveness of the risk management strategies and mitigating actions. The CSO monitored the execution of the Clinical Safety Case and ensured that clinical safety obligations were discharged.

The clinical safety case documentation is reviewed and approved by the NHS England Clinical Safety Group. The clinical safety case report is published on the PRSB website. Updates to the clinical safety case is the responsibility of PRSB.

4 Hazard identification & Clinical Risk Analysis

Activities that have been carried out to clarify and address the potential risks to patients include:

- Potential clinical safety issues identified during consultation events and other activities during the development of the standard.
- Safety issues identified by a team of the clinical and patient leads, informaticians and clinicians participating in a series of 3 hazard workshops run using 1 hour team meetings over a period of about 3 weeks (See Table A).
- Production and review of a hazard log for the standard.
- Review of the hazard log and any associated safety risks.
- Review of mitigation of risks.
- Clinical safety mitigation and confirmation of risks to be passed to implementation / maintenance stages identified.
- Drafting of safety case (approaches to mitigating the risks identified).
- Final draft of hazard log and clinical safety report.

Workshop	Date	Attendees
Clinical safety workshop 1	06/11/2025	CSO, Clinical lead, Business Analyst, Project Manager
Clinical safety workshop 2	13/12/2025	CSO, Clinical lead, Standard Assessor, Business Analyst, Project Manager
Clinical safety workshop 3	27/11/2025	CSO, Clinical lead, Project Manager, Business Analyst

Table A. Clinical safety workshop details.

5 Clinical risk evaluation and clinical risk control

5.1 Patient safety risk assessment approach

The patient safety risk assessment approach followed the new approach and template for hazard logs from the NHSE Clinical Safety Group and was as follows:

- Identify the hazard effect.
- Identify the actual hazard and the potential harm.
- Detail the possible causes.
- Assess the severity and likelihood and overall initial risk score for each possible cause. Derive an overall risk score for the hazard based on the worst case of the individual causes.
- Consider the mitigation controls which could be applied to reduce the risk for each possible cause.
- Consider the residual risk score based on revised severity and likelihood for each possible cause, and overall for the hazard based on the worst-case cause.

5.2 Hazard log composition

The Hazard log is contained in an Excel Spreadsheet which follows the NHSE Clinical Safety Group template.

5.3 Risk assessment methodology

Risk assessment was undertaken using the risk matrix and scoring tool shown in Appendix A. Note that severities were interpreted in terms of impact on outcomes including the person's experience of care.

The current way of working and template means that each effect, hazard and harm can have multiple possible causes. The approach used was to risk assess and consider controls for each possible cause.

6 Hazard log

The full hazard log is attached as a separate Excel document.

In total there are 5 hazards, but with each having up to 48 possible causes which are risk assessed with additional controls at the cause level. In addition, each hazard has an overall risk score based on the worst-case cause.

3 hazards have an initial risk of 4, all reduced to 3 after additional controls.
1 hazard with an initial risk score of 5 reduced to 3 with additional controls.
And 1 hazard with initial risk of 2, with 1 possible cause, remains at 2 and status left as open while awaiting national guidance on how to manage.

Below is a summary of each hazard. Full details of the hazards and causes are in the hazard log which can be found on the PRSB website.

6.1 Hazard 1 – Important Information is Not Available

If important information is not available to a clinician, then inappropriate/delayed/wrong care may be given to the patient. This could lead to varying levels of harm to the patient, including death. There are 8 possible causes.

Possible Causes	Existing controls	Severity	Likelihood	Risk	Additional controls	Severity	Likelihood	Risk
An information standard is designed for a specific use case; it is not the design for a complete health care record. If a system only implements the data items included in the information standard, then it will not contain a complete record of a patient.	In guidance documentation accompanying the standard it is made clear that the standard does not define the whole of a clinical record - but part of the record defined by the scope of the standard.	Major	Low	**3**	Suppliers/implementors should read the guidance before implementing a standard	Major	Medium	**3**
In development of the information standard, critical	In development of a standard, the PRSB goes through	Major	Very Low	2	Suppliers/implementors are responsible for the safety of the systems	Major	Very Low	2

information for the scenario was not identified and therefore not included in the standard.	extensive consultation with stakeholders including open consultations.				being used. Any critical deficits should be identified and reported to PRSB.			
When implementing the standard, local implementors do not implement support for all of the data elements in a standard. This may be due to a local decision on the importance of certain data items.	The standard uses compliance statements - specifying which data items are mandatory, required or optional. Compliance testing process. PRSB develops a minimum viable product specification for each standard.	Major	Medium	**3**	Suppliers could put their system through the PRSB standards conformance process. Suppliers/implementors are responsible for the safety of the systems being used	Major	Low	**3**
The standards are complex and are misunderstood and therefore not fully implemented.	PRSB provides implementation guidance and example scenarios to explain the standard. Simulations. ISN description. Presentations - targeted campaigns. Engaging suppliers and clinical staff, patients.	Major	Medium	**3**	Suppliers/implementors should read the guidance before implementing a standard	Major	Low	**3**
Healthcare professionals may require detailed rather than summary information set out in the standard e.g. an assessment performed by a local authority may be shown as completed without details of how that decision was made	PRSB specifies the essential information requirements. Additional information is allowable	Major	Low	**3**	Suppliers/implementors are responsible for the safety of the systems being used organisation should have standard operating procedures to define the information required to be documented.	Major	Low	**3**
The information as defined in the standard is not able to be recorded in the source systems, is recorded in a different way, or not structured. So, the information may not be available to the user.	The PRSB standard defines the information which should be collect and be available to the user. By defining this information systems will be able to be developed to include this information	Major	Low	**3**	Suppliers/implementors should implement the standard as defined. Suppliers could put their system through the PRSB standards conformance process.	Major	Low	**3**
The user chooses not to view information which is held in multimedia files e.g. About me.	The standard defines that particular information such as About Me is important to be understood by any care professional involved in a person's care.	Major	Medium	**3**	The IT system should be designed to promote important information and provide ready access to it.	Major	Very Low	2
Network bandwidth issues prevent or delays large files being shared or viewed.	When large file is pulled from a database this can lead to delay. Some systems inform the user that this is occurring, rather than just freezing the screen.	Major	Low	**3**	IT systems should have the ability of notifying users when a large file is downloading. Potentially downloading as a background operation, displaying an alert to users when the file is available.	Major	Very Low	2

6.2 Hazard 2 - Poor data quality

Information captured in the information system is of poor quality, due to it being incomplete, incorrect, out of date, or inconsistent. Inappropriate/delayed/wrong care may then be given to the patient. This could lead to varying levels of harm to the patient, including death. There are 11 possible causes.

Possible Causes	Existing controls	Severity	Likelihood	Risk	Additional controls	Severity	Likelihood	Risk
Information in the system is not updated and therefore becomes outdated and potentially contradictory	All data items included in the standard have associated dates. Information of the same type can be identified using the data structures in the standard. Thus, allowing sorting of the data to allow users to interpret the information appropriately	Major	Medium	**3**	IT systems should be designed to enable searching and sorting of data elements to enable the viewing of similar information types together. Elements of the record - such as Medications, Allergies and the Problem list should be managed as a single list. User training should include view the information in sortable/searchable lists. Training should include the management of Medications, Allergies, and the Problem list.	Major	Very Low	2
Lack of context and provenance of data items may make them appear contradictory	The standards include definition of context and provenance information	Major	Medium	**3**	IT systems should maintain the context of data elements wherever possible	Major	Very Low	2
Inconsistency in recording of information by different care professionals in different systems.	The standard aims to minimise this by introduction standard data items	Major	Medium	**3**	Providing standardised templates with constrained vocabularies for data entry User training and understanding of the information being recorded. With regular reviews	Major	Very Low	2
Information recorded against the wrong patient.	The standard mandates the use of patient identifying information.	Major	Medium	**3**	Clear display of the patient banner in the clinical system. Alerting the system that more than one patient is open. Clear patient searching mechanisms. Means to correct errors - remove the wrong patient recordings from view Users to check patient against patient using date of birth rather than name.	Major	Low	**3**
Incorrect information recorded in the patient's record.	The standard defines repeatable data items which should be familiar to users - decreasing the likelihood	Major	Low	**3**	Data validation Clear labels for data items Constrained vocabularies Training to help users understand how data is defined.	Major	Low	**3**

					Feedback audits of data quality			
Too many mandatory data items may adversely affect data quality by increasing the burden on care professionals.	PRSB defines data items which are Mandatory/Required/optional for users to populate. Mandatory items are kept to a minimum to deliver safe care.	Major	Low	**3**	IT Systems should be designed to auto-populate data fields whenever appropriate. Local implementors can define mandatory fields	Major	Low	**3**
Using a standard in a use case which is out of scope for the standard.	The standard clear defines the scope in which is to be used.	Major	Low	**3**	IT Systems MUST only implement the standards within areas of scope	Major	Very Low	2
Change in information requirement of a standard. E.g. change in statutory requirements, change in policy.	The PRSB will, wherever possible review its standards in response to a change in the requirements. Updating the standards where appropriate.	Major	High	**4**	Handover of the support and maintenance of the Epilepsy Information standard to NHSE.	Major	Medium	**3**
Failure to adopt PRSB information standards	The PRSB takes its standards through the information standards process (DAPB). The outcome of which is an ISN which mandates the implementation of a standard. PRSB supports the implementation of the standards with implementation guidance. PRSB supports the implementation of standards via the Standards Partnership Scheme and conformance process	Major	High	**4**	Suppliers should implement PRSB standards. Implementors of IT systems should ensure that the systems they deploy are compliant with PRSB standards.	Major	Very Low	2
PRSB standards are updated periodically which may result in changes to the structure or name of sections or elements	PRSB standards are updated in response to changes in requirements - these changes are clearly recorded and distributed to suppliers and implementors	Major	Low	**3**	suppliers and implementors should update to the latest version of the standard as soon as possible.	Major	Low	**3**
Recording of Assessments including scored assessments. An assessment can be recorded by just the score or result from an assessment or the score and the components which made up that score. If just the score is recorded, then there is a risk that the clinician may make assumptions which are incorrect.	The PRSB standard requires that the score of an assessment and the components which make up that assessment are recorded.	Major	Low	**3**	Suppliers should implement PRSB standards. Implementors of IT systems should ensure that the systems they deploy are compliant with PRSB standards.	Major	Low	**3**

6.3 Hazard 3 - Important data not found or incorrectly interpreted

If critical data in the system is hard to locate, missed, misinterpreted or represented incorrectly, then inappropriate/delayed/wrong care may be given to the patient. This could lead to varying levels of harm to the patient, including death. There are 19 possible causes.

Possible Causes	Existing controls	Severity	Likelihood	Risk	Additional controls	Severity	Likelihood	Risk
Unclear which sections should contain specific information e.g. observations and investigations result and therefore it may not be presented where a healthcare professional expects to see it on the screen and what the sections or elements mean e.g. misinterpretation of ' acute' verses repeat prescription medications in system- acute has no end date so the system interprets it as ongoing medication.	PRSB standards contain descriptions and definitions of the information to be included in specific data elements. Examples and use cases further help to specify these. Specific vocabularies - SNOMED CT or NHS Data dictionary further guide.	Major	Medium	**3**	Suppliers/implementors are responsible for the safety of the systems being used. System suppliers should use good user interface design principles to help users to find the information they need.	Major	Low	**3**
The data may have been entered into the wrong section of the record by mistake e.g. Reasonable adjustments or allergy information inappropriately included in the About Me, or not correctly populated.	PRSB standards contain descriptions and definitions of the information to be included in specific data elements. Examples and use cases further help to specify these. Specific vocabularies - SNOMED CT or NHS Data dictionary further guide.	Major	Medium	**3**	Users should be adequately trained in the safe use of the systems they use to provide care to patients	Major	Medium	**3**
Blank fields may be misinterpreted. There is a lack of clarity over what a blank field signifies (i.e. not recorded, not assessed, not present, etc).	PRSB guidance states that for mandatory data item, this data item must be included and a null entry included if there is no information. For required or optional data items, if there is no information then these data items should not be recorded.	Major	Medium	**3**	Suppliers/implementors should implement the standard as defined. Users should be adequately trained in the safe use of the systems they use to provide care to patients. Including the interpretation of missing information.	Major	Low	**3**
Multiple different systems and data structures, semantics and language and processes across different settings and users which may lead to incorrect interpretation / translation of clinical information	The standard aims to bring together a common representation of the data across the many systems involved. Including data definitions	Major	Medium	**3**	Suppliers/implementors should implement the standard as defined.	Major	Low	**3**
When using diagnosis qualifiers to indicate the certainty of a diagnosis, separation of diagnosis qualifier from diagnosis SNOMED CT code - Data is sent as post-	Specific guidance for this is included in the standards. Suspected diagnoses are to be populated into text. This will potentially be	Major	Medium	**3**	Suppliers/implementors should implement the standard as defined.	Major	Very Low	2

coordinated terms and the receiving system cannot interpret this.	updated when national guidance on the handling of suspected diagnoses is defined and agreed.							
Data badly presented in the system (GUI).	The PRSB does not specify system display in it standards	Major	Medium	**3**	Good user interface design is essential for systems supporting the care of patients. Users should be adequately trained in the safe use of the systems they use to provide care to patients	Major	Low	**3**
End user not able to use the system effectively potentially through lack of training.	The standard does not address user training.	Major	Medium	**3**	Users should be adequately trained in the safe use of the systems they use to provide care to patients	Major	Low	**3**
Information not found because of volume of data / information overload - critical data such as significant problems or allergies could be missed.	The standard produces a familiar picture of the data The standard is designed to contain a small essential dataset for recording.	Major	Low	**3**	Good user interface design. Local deployment template design Users should be adequately trained in the safe use of the systems they use to provide care to patients	Major	Low	**3**
Losing the link to a source document, for example the discharge summary means the context is lost.	[some words will be provided]	Major	Very Low	2	PRSB provenance data support the recording of the where when and who - which can support the linkage of documents/pictures to the record.	Major	Very Low	2
Inability to determine where, when and by whom clinical information was recorded means the context is lost	PRSB provenance data support the recording of the where when and who - which can support the linkage of documents/pictures to the record.	Major	Low	**3**	PRSB provenance data support the recording of the where when and who - which can support the linkage of documents/pictures to the record. Systems to record information at point of care by the person giving care.	Major	Very Low	2
Clinician unclear about the purpose of some of the information e.g. in About Me	The standard has data definitions. The standard links to national policies. Extensive consultation - high level of user recognition and understanding of approach.	Major	Low	**3**	Users should be adequately trained in the safe use of the systems they use to provide care to patients	Major	Very Low	2
Sections with unstructured data such as 'About Me' or 'problem list' not be easily found in searches and therefore not reviewed in a timely manner	Text sections such as "About me" can be indexed using Record Artifact SNOMED CT codes. This will allow this section to be retrieved and displayed in IT systems. These are currently not available for all text sections.	Major	Medium	**3**	Implement the usage of these Record Artifact SNOMED CT codes. Where not available local codes could be used.	Major	Low	**3**
Alerts are not viewed because professionals are unaware where to	System behaviours not part of the standard. PRSB standards define	Major	Low	**3**	Supplier and implementors of IT systems should ensure that information defined as alerts is clearly	Major	Low	**3**

look for them or are used to pop-ups	the content for alerts				displayed to users. users should be trained where to look in their systems to find important information which they should be alerted to. Policy regarding the population and management of important alerts should be developed on organisations.			
Unfamiliar context/terminology to patients/ service users used in populating the information.	The standard has data definitions. The standard links to national policies. Extensive consultation - high level of user recognition and understanding of approach.	Major	Low	**3**	Users should be trained to understand the terminology used in their IT systems. Users should be given support in understanding the use of terminology in their systems.	Major	Low	**3**
Including OTC medication in the same section as prescribed medication and flag not clear or not understood.	N/A	Significant	Medium	2	Suppliers and implementors of systems should ensure that medication obtained "over the counter" is clearly labelled as such User should be trained in the entering of over the counter (OTC) medications. And the identifying of OTC meds in a medication record.	Significant	Low	2
Different statutory and legal requirements across the four UK countries that may lead to confusion by clinicians about which sections are relevant to the country in which they work.	N/A	Significant	Medium	2	Suppliers and implementors of the standards should ensure that the systems are compliant with the statutory and legal requirements of the country which the system is deployed	Significant	Low	2
Patient/clinician expects to see epilepsy diagnosis in a diagnosis field (under a heading diagnosis). Instead, it appears under a heading problem	The standard defines the information structure of the epilepsy formulation. This describes the epilepsy problems and diagnoses.	Major	Medium	**3**	Providence information - where the information has come from. Always show problems and diagnoses together. clear labelling on systems of where information will be found	Major	Low	**3**
The model includes the ability to include certainty of a diagnosis (procedure verification status - confirmed/unconfirmed refuted). Some systems will not be able to interpret/display this information correctly. A refuted diagnosis may be recorded as a confirmed one.		Major	Very High	**5**	Systems need to be aware that when receiving information from other systems that qualifiers may be present and process this information appropriately. Users need to be aware that qualifiers may be used Clinical coders need to be aware that qualifiers may be used	Major	Low	**3**
The end user system does not allow for information to be displayed in accessibility formats. E.g. screen readers,	PRSB standards do not specifically design user interface and accessibility	Major	Medium	3	Suppliers and implementors must ensure that they comply with mandated	Major	Low	**3**

textual rendering of voice files, or video subtitles etc…					accessibility requirements			

6.4 Hazard 4 - Poor data quality - SNOMED CT and other vocabulary content.

If important information is not available to a clinician, then inappropriate/delayed/wrong care may be given to the patient. This could lead to varying levels of harm to the patient, including death. There are 9 possible causes.

Possible Causes	Existing controls	Severity	Likelihood	Risk	Additional controls	Severity	Likelihood	Risk
There is not an appropriate code/ term available for the information that needs to be expressed so local codes are developed.	The standard includes appropriate codes. These have been consulted on so the chances that codes are not available should be reduced. SNOMED CT content can be updated in response to requests for change.	Major	High	**3**	PRSB has support and maintenance service to log issues. Local systems running data quality searches. Many systems use standard templates which help users find the appropriate SNOMED CT codes. Users should be adequately trained in the safe use of the systems they use to provide care to patients	Major	Medium	**3**
Process for creating nationally agreed codes is difficult.	PRSB works closely with the UK Terminology service to ensure that all the terminology content required to implement the standards are available. If required terminology is not available then the standard will not be released for implementation.	Major	Low	**3**	Suppliers and implementors of standards should assure that the required SNOMED CT codes are available in their systems. As new standards will always require new Terminology content to be created, suppliers and implementors must ensure that they have the latest releases of SNOMED CT available.	Major	Very Low	2
Some suppliers and care providers systems make extensive use of their own namespace.	PRSB attempts to include all the SNOMED CT concepts required for suppliers to implement the standards. Thus, minimising the use of local codes	Major	Low	**3**	Suppliers and implementors of standards should notify the PRSB if there are codes which they require to implement the standards. PRSB can then ensure that these codes are available in the national UK release	Major	Low	**3**
SNOMED CT is dynamic with frequent updates. PRSB may not be up to date with the latest changes to SNOMED CT.	PRSB will review the SNOMED CT content of standards regularly. Some SNOMED CT vocabularies will be identified as SNOMED CT reference sets - these will be updated as part of the SNOMED CT release process.	Major	Medium	**3**	Suppliers and implementors of standards should assure; They are able to process concepts which are retired - (i.e. were part of the standard at some time in the past). That they update to the latest version of SNOMED CT as soon as possible.	Major	Low	**3**
Some providers are not updating to the latest versions of SNOMED CT;	PRSB recommends that suppliers update to the latest version of SNOMED CT as soon as possible	Major	Medium	**3**	Suppliers and implementors of standards should assure that they update their systems to the latest version of SNOMED CT as soon as possible.	Major	Low	**3**

Codes can become inactive and moved or not retained creating difficulty in retrieving historic information.	PRSB will review the SNOMED CT content of standards regularly. Some SNOMED CT vocabularies will be identified as SNOMED CT reference sets - theses will be updated as part of the SNOMED CT release process.	Major	Low	**3**	Suppliers and implementors of standards should assure that they are able to process SNOMED CT content which becomes inactive in an appropriate manner.	Major	Low	**3**
A Value set/reference set belongs to third party who no longer updates it. No identified owner for a value set or reference set.	The SNOMED CT refset management process identifies owners for reference sets - when reference sets are no longer owned these are then retired. As part of the standards management process the SNOMED CT content is reviewed and updated with active content including reference sets.	Major	Low	**3**		Major	Low	**3**
Medications which have been discontinued due to ineffectiveness or not being tolerated (allergies or severe adverse reaction would normally be recorded) not being recorded in the health record. Leading to these medications being re-prescribed inappropriately.	The standard defines how this should be achieved	Significant	Low	2	System suppliers need to develop functionality to record and display that a medication has been tried but discontinued due to ineffectiveness clinicians need to record in systems when medications are discontinued	Significant	Very Low	1
The standard will mandate the new seizure types - released by the ILEA in Feb 2025. Clinicians will be required t use these seizure types when recording information about seizures. A patient record may have the incorrect/outdate seizure types recorded in their record or have new ones which other clinicians/or the patient may not understand.	updates the standard when ILAE guidance changes	Minor	Very High	**3**	Updating systems in line with the standard	Minor	Low	1

6.5 Hazard 5 - Disclosure of information/images without the patients consent or knowledge

If confidential patient information or clinical images are disclosed without the patient's explicit consent or awareness, this may constitute a breach of privacy and professional duty of care. Such disclosure could enable unauthorised access to sensitive data, resulting in reputational harm, psychological distress, or discrimination.

Possible Causes	Existing controls	Severity	Likelihood	Risk	Additional controls	Severity	Likelihood	Risk
The display of patient 'sex' and 'gender' information, in person demographics, which do not match e.g. one states 'male' and the other states 'female'.	PRSB standards do not define specific access to information requirements	Considerable	Low	2	This is an ongoing issue which requires national guidance	Considerable	Low	2

7 Training

Training of the end users of the systems implementing the Epilepsy information standard is offered as a mitigation for a number of the possible causes of the hazards identified. This should be considered, when developing these systems. Users should understand the limitations of any system and how to use them to best understand the context and provenance of data. They should also understand that they are not designed to replace consulting the patient, which is an important mitigation in any clinical system.

Implementation guidance is provided as a part of the Epilepsy Information Standard and PRSB provide a support service (support@theprsb.org) where implementors can get advice about implementing the standard.

8 Test Issues

As the information standard is a conceptual model and, as yet, has not been implemented in any systems, it has not been possible to test the model in vivo. It is therefore dependent on those developing systems doing full end to end clinical safety testing. Any issues with the standard identified during testing should be raised with the PRSB through the support service (or by email to support@theprsb.org). All enquiries will be responded to, and issues requiring changes to the standard will be put on the maintenance log and the standard updated at times in accordance with the urgency of the issues identified as detailed in PRSB's release policy.

9 Summary safety statement

Five (5) potential hazards were identified with a total of 48 possible causes. All hazards were identified through the consultation processes carried out to develop and assure the standard and specific hazard workshops. The consultation process is described in detail in the project final report. It included patient and carer representatives as well as professionals from Royal

Colleges, specialist societies, allied health professions, health informatics professionals, social care professionals and system suppliers.

During the consultations, hazards were identified, reviewed and mitigations/actions considered. Nevertheless, some risks are inherent in the standard, but most have been:

(A) mitigated by the development of the standard (residual risk of 2 or less)

(B) or the residual risk (level 3) has been transferred (with guidance) to the implementors.

The hazard log (a separate document) provides guidance for system developers and implementors. It is important that this guidance in relation to those hazards, regarded as system issues, become requirements for implementation.

The residual risk of the hazards and their possible causes after additional controls are all level 3 or 2. There are 3 hazards and 30 possible causes at residual risk level 3 and the mitigations for the level 3 risks are outside the control of PRSB and these risks are therefore handed on to the implementors and deployers of this standard. There is 1 hazard, and 6 possible causes rated at level 2 and considered acceptable.

10 Quality Assurance and Document Approval

The hazard log and clinical safety case have followed the DCB0129 Risk Management standard and approach. The overall development of the information standard has followed the PRSB methodology, proven and trusted by our members and stakeholders, overseen by a project board and the PRSB's independent assurance committee. Both the project board and the assurance committee have reviewed the hazard log and safety case with final approval residing with the NHSE Clinical Safety Group.

11 Configuration Control / Management

The hazard log and clinical safety case are both version-controlled documents held in the PRSB project files and managed under the PRSB information management policy.
Future governance of the development and maintenance of the Epilepsy Information Standard is the responsibility of the PRSB.

12 Appendix A – 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
		Severity				

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

Severity 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 consequence	Single

	Risk Acceptability
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 the hazard or implement control measures 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 or where further risk reduction is impractical
1	Acceptable, no further action required