



# **Accessible Information: Clinical Safety Case**

OFFICIAL

**NHS England INFORMATION READER BOX**

**Directorate**

Medical  
Nursing  
Finance

Commissioning Operations  
Trans. & Corp. Ops.

**Patients and Information**  
Commissioning Strategy

**Publications Gateway Reference:**

**03574**

**Document Purpose**

Other (see Description)

**Document Name**

SCCI1605 Accessible Information Clinical Safety Case

**Author**

NHS England, Patients and Information

**Publication Date**

03 July 2015

**Target Audience**

CCG Clinical Leaders, CCG Accountable Officers, Care Trust CEs, Foundation Trust CEs, Medical Directors, Directors of Nursing, Directors of Adult SSs, NHS Trust Board Chairs, Allied Health Professionals, GPs, Communications Leads, NHS Trust CEs

**Additional Circulation List**

Voluntary and Community Sector Organisations, Professional Representative and Membership Bodies, Public Sector Partners

**Description**

SCCI1605 Accessible Information directs and defines a specific, consistent approach to identifying, recording, flagging, sharing and meeting the information and communication support needs of patients, service users, carers and parents, where those needs relate to a disability, impairment or sensory loss. This document is the Clinical Safety Case for SCCI1605 Accessible Information.

**Cross Reference**

N/A

**Superseded Docs (if applicable)**

ISB 1605 Accessible Information Clinical Safety Case Draft

**Action Required**

Applicable organisations are required to consider the Clinical Safety Case in implementing SCCI1605 Accessible Information.

**Timing / Deadlines (if applicable)**

**Applicable organisations are required to conform with SCCI1605 Accessible Information by 31/07/16**

**Contact Details for further information**

Accessible Information Standard  
Patient and Public Participation and Insight  
NHS England  
7E56, Quarry House, Quarry Hill, Leeds,  
LS2 7UE  
01138 253002  
  
<http://www.england.nhs.uk/accessibleinfo>

**Document Status**

This is a controlled document. Whilst this document may be printed, the electronic version posted on the intranet is the controlled copy. Any printed copies of this document are not controlled. As a controlled document, this document should not be saved onto local or network drives but should always be accessed from the intranet. **NB:** The National Health Service Commissioning Board was established on 1 October 2012 as an executive non-departmental public body. Since 1 April 2013, the National Health Service Commissioning Board has used the name NHS England for operational purposes.

## **SCCI1605 Accessible Information: Clinical Safety Case**

Version number: 1.0.

First published: 03.07.15.

Prepared by: Sarah Marsay, Public Engagement Account Manager, NHS England.

Classification: OFFICIAL

.

## Contents

Contents .....	4
1 Glossary of terms .....	5
2 Executive summary .....	8
3 Introduction.....	9
3.1 Purpose .....	9
3.2 Standard overview.....	9
3.3 Standard summary .....	10
4 Clinical Safety Management System.....	12
4.1 Clinical safety governance.....	12
4.2 Implementation.....	12
4.3 Maintenance.....	12
5 Hazard identification and assessment approach .....	13
6 Hazard workshop .....	14
7 Positive impact of the Standard on patient safety.....	15
8 Hazard log.....	16
9 Statement of closure of identified clinical safety hazards .....	21
10 Related Documents .....	22
Appendix A – Risk Matrix .....	23
Appendix B – Advisory Group Membership.....	25

## 1 Glossary of terms

Term / abbreviation	What it stands for
Advocate	A person who supports someone who may otherwise find it difficult to communicate or to express their point of view. Advocates can support people to make choices, ask questions and to say what they think.
Accessible information	Information which is able to be read or received and understood by the individual or group for which it is intended.
Alternative format	Information provided in an alternative to standard printed or handwritten English, for example large print, braille or email.
Braille	A tactile reading format used by people who are blind, deafblind or who have some visual loss. Readers use their fingers to 'read' or identify raised dots representing letters and numbers. Although originally intended (and still used) for the purpose of information being documented on paper, braille can now be used as a digital aid to conversation, with some smartphones offering braille displays. Refreshable braille displays for computers also enable braille users to read emails and documents.
British Sign Language (BSL)	BSL is a visual-gestural language that is the first or preferred language of many d/Deaf people and some deafblind people; it has its own grammar and principles, which differ from English.
BSL interpreter	A person skilled in interpreting between BSL and English. A type of communication support which may be needed by a person who is d/Deaf or deafblind.
Communication support	Support which is needed to enable effective, accurate dialogue between a professional and a service user to take place.
Communication tool / communication aid	A tool, device or document used to support effective communication with a disabled person. They may be generic or specific / bespoke to an individual. They often use symbols and / or pictures. They range from a simple paper chart to complex computer-aided or electronic devices.
d/Deaf	A person who identifies as being deaf with a lowercase d is indicating that they have a significant hearing impairment. Many deaf people have lost their hearing later in life and as such may be able to speak and / or read English to the same extent as a hearing person. A person who identifies as being Deaf with an uppercase D is indicating that they are culturally Deaf and belong to the Deaf community. Most Deaf people are sign language users who have been deaf all of their lives. For most Deaf people, English is a second language and as such they may have a limited ability to read, write or speak English.
Deafblind	The Policy guidance <a href="#">Care and Support for Deafblind Children and Adults (Department of Health, 2014)</a> states that, "The generally accepted definition of Deafblindness is that persons are regarded as Deafblind "if their combined sight and

OFFICIAL

	hearing impairment causes difficulties with communication, access to information and mobility. This includes people with a progressive sight and hearing loss” ( <a href="#">Think Dual Sensory, Department of Health, 1995</a> )."
Disability	The <a href="#">Equality Act 2010</a> defines disability as follows, “A person (P) has a disability if — (a) P has a physical or mental impairment, and (b) the impairment has a substantial and long-term adverse effect on P’s ability to carry out normal day-to-day activities.” This term also has an existing <a href="#">Data Dictionary definition</a> .
Disabled people	<a href="#">Article 1 of the United Nations Convention on the Rights of Persons with Disabilities</a> has the following definition, “Persons with disabilities include those who have long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others.”
Easy read	Written information in an ‘easy read’ format in which straightforward words and phrases are used supported by pictures, diagrams, symbols and / or photographs to aid understanding and to illustrate the text.
Impairment	The <a href="#">Equality and Human Rights Commission</a> defines impairment as, “A functional limitation which may lead to a person being defined as disabled...”
Interpreter	A person able to transfer meaning from one spoken or signed language into another signed or spoken language.
Large print	Printed information enlarged or otherwise reformatted to be provided in a larger font size. A form of accessible information or alternative format which may be needed by a person who is blind or has some visual loss. Different font sizes are needed by different people. Note it is the font or word size which needs to be larger and not the paper size.
Learning disability	This term has an existing <a href="#">Data Dictionary definition</a> and is also defined by the Department of Health in <a href="#">Valuing People (2001)</a> . People with learning disabilities have life-long development needs and have difficulty with certain cognitive skills, although this varies greatly among different individuals. Societal barriers continue to hinder the full and effective participation of people with learning disabilities on an equal basis with others.
Lipreading	A way of understanding or supporting understanding of speech by visually interpreting the lip and facial movements of the speaker. Lipreading is used by some people who are d/Deaf or have some hearing loss and by some deafblind people.
Notetaker	In the context of accessible information, a notetaker produces a set of notes for people who are able to read English but need communication support, for example because they are d/Deaf. Manual notetakers take handwritten notes and electronic notetakers type a summary of what is being said

OFFICIAL

	onto a laptop computer, which can then be read on screen.
Patient Administration System (PAS)	Mainly used in hospital settings, and especially by NHS Trusts and Foundation Trusts, Patient Administration Systems are IT systems used to record patients' contact / personal details and manage their interactions with the hospital, for example referrals and appointments.
Read Codes	A coded thesaurus of clinical terms representing the clinical terminology system used in general practice. Read Codes have two versions: version 2 (v2) and version 3 (CTV3 or v3), which are the basic means by which clinicians record patient findings and procedures.
Speech-to-text-reporter (STTR)	A STTR types a verbatim (word for word) account of what is being said and the information appears on screen in real time for users to read. A transcript may be available and typed text can also be presented in alternative formats. This is a type of communication support which may be needed by a person who is d/Deaf and able to read English.
SNOMED CT (Systematised Nomenclature of Medicine Clinical Terms)	Classification of medical terms and phrases, providing codes, terms, synonyms and definitions. SNOMED CT is managed and maintained internationally by the <a href="#">International Health Terminology Standards Development Organisation (IHTSDO)</a> and in the UK by the <a href="#">UK Terminology Centre (UKTC)</a> . SNOMED CT has been adopted as the <a href="#">standard clinical terminology for the NHS in England</a> .
Text Relay	Text Relay enables people with hearing loss or speech impairment to access the telephone network. A relay assistant acts as an intermediary to convert speech to text and vice versa. British Telecom (BT)'s <a href="#">'Next Generation Text' (NGT) service</a> extends access to the Text Relay service from a wider range of devices including via smartphone, laptop, tablet or computer, as well as through the traditional textphone.
Translator	A person able to translate the written word into a different signed, spoken or written language. For example a sign language translator is able to translate written documents into sign language.

Note: a more extensive 'glossary of terms' to assist organisations in effectively implementing the Standard is included as part of the Implementation Guidance.

## 2 Executive summary

This document constitutes the Clinical Safety Case for SCCI1605 Accessible Information – the ‘Accessible Information Standard’. As such, it:

- identifies hazards and potential hazards relating to the Standard;
- details the finding of a risk assessment; and
- includes the outcomes of a virtual Patient Safety Assessment Workshop.

In so doing, the Clinical Safety Case seeks to address the requirements of [ISB0129 Clinical Risk Management: its Application in the Manufacture of Health IT Systems](#) and to implement clinical safety management in accordance with the Clinical Safety Management System.

The Accessible Information Standard will require providers of NHS and adult social care to identify, record, flag and share the information and communication support needs of patients and service users (and where appropriate carers and parents) with a disability, impairment or sensory loss, and to take action to ensure that those needs are met.

Assessment has identified 3 hazards relating to the Standard, as follows:

1. Increase in information provided to patients, service users, carers and parents in alternative formats;
2. New / amended processes for recording the information and communication support needs of patients, service users, carers and parents;
3. Misidentification of patients, service users, carers or parents resulting in provision of information in inappropriate formats.

Draft version 0.1 and 0.2 of this Clinical Safety Case and the associated Hazard Log were reviewed by subject matter experts from the Health and Social Care Information Centre (HSCIC) Clinical Safety Team, including Clinical Safety Officers, and by members of the Standard Setting for Accessible Information Advisory Group via a virtual Patient Safety Assessment Workshop during May 2014. Version 0.7 was reviewed and endorsed by the Clinical Safety Group (CSG) of the HSCIC on 22 May 2015.



## 3 Introduction

### 3.1 Purpose

This document constitutes the Clinical Safety Case for the Accessible Information Standard.

As such, it considers the safety aspects of changes to be generated or directed by the Standard, including proposed changes to IT systems and administrative processes, and increases in the availability and provision of information in alternative formats and of communication support. It:

- Documents the hazard assessment process followed, presents a hazard list and associated risk assessment.
- Where required, defines the additional control measures to be used for each hazard and justifies how their implementation reduces clinical risk to acceptable levels.
- Assesses the residual clinical risk associated with each hazard post-implementation of the additional control measures.
- Documents any safety related activities (completed or otherwise), stating the impact and any mitigations associated with non-execution.

Note that the information governance and privacy impact of the Standard has been assessed separately, as outlined in the Specification, and in all instances organisations implementing and using the Standard are required to follow existing information governance protocols, including [ISB Information Governance baselines](#). This includes, for example, processes governing the sharing of patients' data with external third parties for the purposes of the production of alternative formats and / or the provision of communication support.

### 3.2 Standard overview

The Accessible Information Standard directs and defines a specific, consistent approach to identifying, recording, flagging, sharing and meeting individuals' information and communication support needs by NHS and adult social care service providers.

The aim of the Standard is to establish a framework and set a clear direction such that patients and service users (and where appropriate carers and parents) who have information or communication needs relating to a disability, impairment or sensory loss receive:

- 'Accessible information' ('information which is able to be read or received and understood by the individual or group for which it is intended'); and
- 'Communication support' ('support which is needed to enable effective, accurate dialogue between a professional and a service user to take place');

Such that they are not put “[at a substantial disadvantage...in comparison with persons who are not disabled](#)” when accessing NHS or adult social services. This includes accessible information and communication support to enable individuals to:

- Make decisions about their health and wellbeing, and about their care and treatment;
- Self-manage conditions;
- Access services appropriately and independently; and
- Make choices about treatments and procedures including the provision or withholding of consent.

### 3.3 Standard summary

<b>Standard</b>	
Standard Title	Accessible Information
Standard Number	<a href="#">SCCI1605 (ISB1605 - Amd 8/2013 Initial Standard)</a>
Description	<p>Accessible Information aims to ensure that people with a disability, impairment or sensory loss get information about their health and care which they can read and understand (for example in easy read, braille or via email) and communication support if they need it (for example British Sign Language (BSL) interpretation).</p> <p>The Standard will establish a clear and consistent framework and provide direction as to the identification, recording, flagging, sharing and meeting of disabled people’s information and communication needs. Implementation will require changes to recording practices (including electronic systems) and to processes for identifying and meeting people’s communication needs.</p> <p>Accessible Information will require providers of NHS and adult social care to:</p> <ul style="list-style-type: none"> <li>• Identify the information and communication support needs of patients, service users, carers and parents with a disability, impairment or sensory loss;</li> <li>• Record or input data using identified definitions / codes (including using relevant <a href="#">SNOMED CT®</a>, Read v2 or CTV3 codes where used in systems);</li> <li>• Refer to, act upon and share the recorded information and communication support needs of patients, service users, carers and parents with a disability, impairment or sensory loss (within existing information governance and data-sharing protocols);</li> <li>• Meet patients,’ service users,’ carers’ and parents’ information and communication support needs, wherever reasonably possible.</li> </ul>
Applies to	All providers of NHS and publicly-funded adult social care

OFFICIAL

	<p>services, including, but not limited to:</p> <ul style="list-style-type: none"> <li>• NHS Trusts including Foundation Trusts, Acute Trusts, Community Trusts, Care Trusts, Ambulance Trusts;</li> <li>• Independent contractors providing NHS services – GP practices, optometrists, pharmacists, dentists;</li> <li>• Non-NHS providers of NHS and social care services including organisations from the voluntary and independent sectors.</li> </ul> <p>Commissioners of NHS and publicly-funded adult social care must also have regard to this standard, in so much as they must ensure that contracts, frameworks and performance-management arrangements with provider bodies enable and promote the Standard's requirements.</p>
<b>Release</b>	
Release Number	SCCI1605
Release Title	Accessible Information
Description	The consistent identification, recording, flagging, sharing and meeting of the information and communication support needs of patients, service users, carers and parents with a disability, impairment or sensory loss.
Voluntary Implementation Date	Organisations MAY begin to implement the Standard immediately upon publication of the Information Standards Notice (ISN).
Mandatory Implementation Date	By 31 July 2016, all applicable organisations MUST comply with the Accessible Information Standard in full (date of full conformance).

## 4 Clinical Safety Management System

### 4.1 Clinical safety governance

This Clinical Safety Case intends to support clinically safe implementation of SCCI 1605 Accessible Information and should be read alongside the Specification, Implementation Plan and Implementation Guidance.

Clinical safety governance for the Accessible Information Standard is overseen by the Standard Setting for Accessible Information Advisory Group, managed at an operational level by the Business Lead and the responsibility of the Senior Responsible Officer (SRO) for the Standard, Giles Wilmore (Director of Patient and Public Participation and Information at NHS England). Ultimately, the SRO is accountable to the NHS England Board.

As part of the information standard development and assurance process, input has been sought from members of the Clinical Safety Team at the Health and Social Care Information Centre (HSCIC), and the Clinical Safety Case was reviewed and endorsed by the Clinical Safety Group (CSG) of the HSCIC on 22 May 2015.

### 4.2 Implementation

Clinical governance, social care governance and IT safety leads MUST consider and take mitigating action to address the identified hazards as outlined in the Clinical Safety Case and any other locally identified risks or hazards associated with implementation of the Standard such that they are as low as reasonably possible. The Standard requires that IT systems providers comply with [ISB0129 Clinical Risk Management: its Application in the Manufacture of Health IT Systems](#) to ensure they identify and mitigate clinical hazards.

The Standard also requires that health and care organisations follow [ISB0160 Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems](#). This is in concert with the safety handover from the IT system supplier.

### 4.3 Maintenance

NHS England will continue to have strategic oversight and operational ownership of the Standard, and will also provide governance for future developments including periodic review of the Standard, changes and future development.

As outlined in the Maintenance Plan, feedback received from users and stakeholders, and as a result of any monitoring or assessment of compliance, will be impact assessed and prioritised. Where appropriate, proposed changes will be taken forward for development, testing and consultation prior to submission to the Standardisation Committee for Care Information (SCCI) for formal approval.

If there is a safety implication, the person raising the issue must log the safety issue with the Health and Social Care Information Centre (HSCIC) Safety Helpdesk at [safety.incident@hscic.gov.uk](mailto:safety.incident@hscic.gov.uk)

## 5 Hazard identification and assessment approach

The first step in preventing harm to patients through the use of this Information Standard is to ensure a robust development process is followed in order that the Standard is fit for purpose.

The Standard has been coproduced by the multi-agency Standard Setting for Accessible Information Advisory Group and has been informed by engagement, consultation, testing and piloting – involving patients, service users, carers, health and care professionals and organisations, and support and supplier organisations. Further information is included in the Report of Engagement, Report of Consultation, Test Report and Pilot Report.

This document includes the outcome of assessment of the patient safety risks associated with SCCI1605 Accessible Information, and demonstrates compliance with relevant Information Standard development and assurance criteria with regards to clinical safety assurance. It has been reviewed and where appropriate amended following input from subject matter experts. This has included assessment of the Standard in accordance with [ISB0129 Clinical Risk Management: its Application in the Manufacture of Health IT Systems](#)

This assessment has also included:

- A Patient Safety Assessment Workshop to identify risks and hazards associated with the Standard, building upon the initial Patient Safety Assessment Report submitted at Requirements stage;
- Compilation and review of a Hazard Log;
- Compilation and review of a Clinical Safety Case (this report) including justification of risk control measures;
- Independent review and endorsement of the Clinical Safety Case by the Health and Social Care Information Centre (HSCIC) Clinical Safety Team;
- Review and endorsement of the Clinical Safety Case by the HSCIC Clinical Safety Group.

Safety assessment is following a stepwise approach:

- Identifying what could go wrong (likelihood and consequence);
- Identifying the main causes;
- Identifying controls and mitigations to reduce residual risk;
- Clarification of any outstanding actions.

Risk assessment was undertaken using the Health and Social Care Information Centre (HSCIC) risk matrix and scoring tool (Appendix A).

## 6 Hazard workshop

A Patient Safety Assessment Workshop took place virtually during May 2014. Members of the Standard Setting for Accessible Information Advisory Group and subject matter experts were invited to comment on and input into a draft of this Clinical Safety Case prior to submission. The aim of this activity was to review and expand upon the initial draft Safety Case.

The following were invited to participate:

- All members of the Standard Setting for Accessible Information Advisory Group (see Appendix B for details);
- Representatives from the Health and Social Care Information Centre (HSCIC) Clinical Safety Team.

## 7 Positive impact of the Standard on patient safety

The implementation of the Accessible Information Standard will make a significant contribution to patient safety, through directing the provision of information to patients, service users, carers and parents in formats which they can understand, and support to communicate if they need it.

The Standard will mean that individuals with information and communication support needs are able to understand and therefore follow advice or instruction from health and social care bodies. This will result in improvements in patient safety and clinical outcomes due to increasing the ability of patients, service users, carers and parents to:

- Understand and therefore to act upon screening and vaccination invitations, for example for cervical screening or a 'flu jab';
- Recognise the signs and symptoms of diseases and conditions, and therefore take appropriate action, for example skin cancer or stroke;
- Comply with pre- and post- operative advice;
- Take prescription medication appropriately.

It will also mean that clinicians are able to have effective dialogue with patients or service users (and where appropriate their carers or parents) with communication support needs, for example through having a British Sign Language interpreter present. This will enable the individual to explain symptoms, feelings and concerns to the clinician, and for the clinician to ask probing questions and thus improve the accuracy of his or her clinical advice and judgement.

## 8 Hazard log

A Hazard Log detailing the hazards identified to date is presented below. This includes input from Advisory Group members and the HSCIC Clinical Safety Team. Agreement has been reached that this represents the full set of clinical safety hazards associated with the Accessible Information Standard.

<b>Hazard</b>					
Hazard number	1				
Hazard name	Increase in information provided to patients, service users, carers and parents in alternative formats.				
Hazard description	This standard will result in an increase in the provision of correspondence and clinical advice in alternative formats – including braille and British Sign Language – the accuracy of which most health and social care staff will be unable to personally verify (as they would with correspondence or communication in standard written or verbal English).				
Potential Clinical Impact	Patients or service users (or their carers or parents) receive incorrect information or advice about their health or care, for example an incorrect diagnosis, prognosis, medicines or self-management guidance, resulting in poorer clinical outcomes / delays in receipt of treatment (for example due to incorrect pre-operative, follow-up or referral advice).				
Possible Causes	Inaccurate interpretation or translation of information into non-English formats by translator / interpreter / transcriber.				
Existing Controls	Variable. Some health and social care organisations have robust contracts in place with relevant organisations for the provision of interpretation / translation which include specifying industry-standard qualification / registration / conduct standards for interpreters / translators, others have no such safeguards (and / or no such contracts) in place.				
<b>Initial Hazard Risk Assessment</b>					
Consequence	<b>Considerable</b>	Likelihood	<b>Medium</b>	Risk Rating	<b>3</b>
<b>Additional Controls</b>					
Design	The Specification for the Standard and accompanying Implementation Guidance include requirements and advice (respectively) as to ensuring that suitably skilled and qualified communication professionals, interpreters and translators are used.				
Test	The draft accessible information standard was piloted by a range of health and social care provider organisations during January – March 2015. This followed a desk-based review exercise (or testing) during April – May 2014. Feedback from both of these phases has informed the Specification and Implementation Guidance, including with regard to reducing risks associated with data quality and clinical safety.				



OFFICIAL

	Feedback has also informed the suite of resources which will be provided to support safe, effective implementation of the Standard by organisations (as outlined in the Implementation Plan).				
Training	As part of resources to support implementation, NHS England will make an e-learning module available to organisations. This will cover safe, effective implementation of the Accessible Information Standard in health and social care settings. The Specification also requires organisations to identify the training needs of their workforce to enable implementation of the Standard, and to take steps to ensure that any identified needs are met.				
Business Process Change					
<b>Residual Hazard Risk Assessment</b>					
Consequence	<b>Considerable</b>	Likelihood	<b>Low</b>	Risk Rating	<b>2</b>
<b>Summary of Actions</b>	<ul style="list-style-type: none"> <li>Organisations implementing the Standard are responsible for ensuring accurate, reliable interpretation and translation of information. They must identify and mitigate information governance and clinical safety hazards, including with regards to accuracy of translated or interpreted information, such that the residual risks are as low as reasonably possible.</li> <li>The Specification for the Standard includes specific Requirements around quality assurance of translation and interpretation, and direction as to the qualification of interpreters and translators used.</li> <li>Further advice with regards to quality and governance has been included as part of Implementation Guidance.</li> </ul>				
Status	Closed.				

<b>Hazard</b>	
Hazard number	2
Hazard name	New / amended processes for identifying and recording the information and communication support needs of patients, service users, carers and parents.
Hazard description	Establishment of new identification and recording processes / amendments to existing IT and administrative systems for the recording of information and communication support needs.
Potential Clinical Impact	Communication to patient, service user, carer or parent delayed or disrupted, resulting in delay in receipt of advice or treatment.
Possible Causes	<ul style="list-style-type: none"> <li>Change to established recording processes and processes for communicating with patients, service users, carers and parents, which could lead to lack of clarity about how and where to record</li> </ul>

OFFICIAL

	<p>data about individuals' information or communication support needs, or errors in entry / action.</p> <ul style="list-style-type: none"> <li>Lack of processes for addressing individuals' information or communication support needs could delay communication.</li> </ul>				
Existing Controls	Existing guidelines for clinical record keeping.				
<b>Initial Hazard Risk Assessment</b>					
Consequence	<b>Significant</b>	Likelihood	<b>Medium</b>	Risk Rating	<b>2</b>
<b>Additional Controls</b>					
Design	<p>The Specification for the Standard clearly and precisely outlines how information and communication support needs must be identified and recorded, including specifying categories / data items to be used. The intention is to remove ambiguity and minimise errors caused by lack of clarity or confusion.</p>				
Test	<p>The draft accessible information standard was piloted by a range of health and social care provider organisations during January – March 2015. This followed a desk-based review exercise (or testing) during April – May 2014. Feedback from both of these phases has informed the Specification and Implementation Guidance, including with regard to reducing risks associated with data quality, information governance and clinical safety. Feedback has also informed the suite of resources which will be provided to support safe, effective implementation of the Standard by organisations (as outlined in the Implementation Plan).</p>				
Training	<p>As part of resources to support implementation, NHS England will make an e-learning module available to organisations. This will cover safe, effective implementation of the Accessible Information Standard in health and social care settings. The Specification also requires organisations to identify the training needs of their workforce to enable implementation of the Standard, and to take steps to ensure that any identified needs are met.</p>				
Business Process Change					
<b>Residual Hazard Risk Assessment</b>					
Consequence	<b>Significant</b>	Likelihood	<b>Low</b>	Risk Rating	<b>2</b>
<b>Summary of Actions</b>	<ul style="list-style-type: none"> <li>The Specification for the Standard includes defined processes and data items / categories for identification and recording of needs.</li> <li>The Implementation Guidance provides advice about effective implementation of the Standard into existing systems, and the changes which may be required.</li> </ul>				

OFFICIAL

	<ul style="list-style-type: none"> <li>The Implementation Plan includes commitments to provide resources to support implementation, including an e-learning module.</li> </ul>
Status	Closed.

Hazard	
Hazard number	3
Hazard name	Misidentification of patients, service users, carers or parents resulting in provision of information in inappropriate formats.
Hazard description	Individuals without any information or communication support needs – i.e. who read and speak standard English – receive personal correspondence or generic health information in an alternative format which is illegible to them, due to misidentification on patient / service user record systems.
Potential Clinical Impact	Patient, service user, carer or parent unable to understand correspondence / information and therefore does not follow advice / attend appointment, resulting in poorer clinical outcomes / delays in receipt of treatment.
Possible Causes	Human or system error resulting in misidentification of individuals / confusion of an individual without any information or communication support needs with an individual who has needs recorded.
Existing Controls	<a href="#">Use of the NHS number as the unique identifier</a> / existing processes followed to confirm patient identity / sending of automatic reminder and follow-up correspondence.
Initial Hazard Risk Assessment	
Consequence	<b>Significant</b>
Likelihood	<b>Low</b>
Risk Rating	<b>2</b>
Additional Controls	
Design	The Specification and Implementation Guidance for the Standard refer to existing controls (including existing Information Standards) to ensure accurate identification of patients, service users, carers and parents with information and / or communication support needs. The Specification and Implementation Guidance also provide specific direction around accurate identification and recording of individuals' needs.
Test	The draft accessible information standard was piloted by a range of health and social care provider organisations during January – March 2015. This followed a desk-based review exercise (or testing) during April – May 2014. Feedback from both of these phases has informed the Specification and Implementation Guidance, including with regard to reducing risks associated with data quality, information governance and clinical safety. Feedback has also informed the suite of resources which will be provided to support safe, effective implementation of the Standard by organisations (as outlined in the Implementation Plan).

OFFICIAL

	Specific feedback about this hazard was received from one of the pilot sites, and this has led to refinement of the Specification for the Standard and Implementation Guidance with regards to data management and quality / safe and effective recording of needs.				
Training	As part of resources to support implementation, NHS England will make an e-learning module available to organisations. This will cover safe, effective implementation of the Accessible Information Standard in health and social care settings. The Specification also requires organisations to identify the training needs of their workforce to enable implementation of the Standard, and to take steps to ensure that any identified needs are met.				
Business Process Change					
<b>Residual Hazard Risk Assessment</b>					
Consequence	<b>Significant</b>	Likelihood	<b>Very Low</b>	Risk Rating	<b>1</b>
<b>Summary of Actions</b>	<ul style="list-style-type: none"> <li>• The Specification and Implementation Guidance for the Standard include requirements and advice (respectively) about data management and quality / accurate recording of needs.</li> <li>• The Implementation Plan includes commitments to provide resources to support implementation, including an e-learning module.</li> </ul>				
Status	Closed.				

## **9 Statement of closure of identified clinical safety hazards**

Implementation of the Accessible Information Standard will make a significant positive contribution to patient safety, through directing the provision of information to patients, service users, carers and parents in formats which they can understand, and support to communicate if they need it. This will improve the accuracy of clinical diagnosis, support patients' adherence to clinical advice and enable individuals to access early intervention and screening opportunities.

3 potential hazards associated with the Accessible Information Standard were identified and subjected to review as part of a virtual Patient Safety Assessment workshop. Following feedback as part of engagement, consultation, testing and piloting, the hazards have been mitigated through the design of the Specification for the Standard and content of the accompanying Implementation Guidance.

All hazards have now been closed following completion of mitigating actions. This outcome was endorsed and levels of residual risk accepted by the HSCIC Clinical Safety Group at their meeting on 22 May 2015.

## 10 Related Documents

Ref	Doc Reference Number	Title	Version
1	SCCI1605	Accessible Information: Specification	0.3
2	ISB0129 Amd 39/2012	<a href="#">Clinical Risk Management: its Application in the Manufacture of Health IT Systems</a>	2.0
3	ISB0160 Amd 38/2012	<a href="#">Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems</a>	2.0

## Appendix A – Risk Matrix

<b>Likelihood</b>	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
<b>Consequence</b>						

5	Very High	Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level.
4	High	Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level
3	Significant	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	Moderate	Tolerable where cost of further reduction outweighs benefits gained.
1	Low	Acceptable, no further action required

### Likelihood

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

**Consequence**

Category	Interpretation	
	Consequence	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



## Appendix B – Advisory Group Membership

The members of the Standard Setting for Accessible Information Advisory Group are:

### NHS England

- Olivia Butterworth, Head of Public Participation
- Sarah Marsay, Public Engagement Account Manager
- Ian Townend, Enterprise Business Architect / Data Projects Lead
- Giles Wilmore, Director for Patient and Public Participation and Information (Chair and Senior Responsible Officer)

### Public sector partners

- Margaret Flaws, Senior Equality and Human Rights Officer, Care Quality Commission
- Toto Gronlund, Health Informatics Business Lead for Primary Care IT, Health and Social Care Information Centre (HSCIC)
- Dr Ira Laketic-Ljubojevic, Informatics Development Lead, Developing Informatics Skills and Capability, HSCIC
- A representative from the Association of Directors of Adult Social Services
- A representative from the Department of Health Directorate of Social Care

### Professional representative bodies

- Professor Iain Carpenter, Chair, Professional Records Standards Body (PRSB)

### Voluntary sector organisations working with affected groups

- Catherine Carter, Lead Trainer, CHANGE
- Erin Fahey, Projects Manager, CHANGE
- Hugh Huddy, Policy and Campaigns Manager, Royal National Institute of Blind people (RNIB)
- Sarah White, Policy Officer (Health), Sense
- Chris Wood, Senior Research and Policy Officer, Action on Hearing Loss (formerly the Royal National Institute for Deaf People (RNID))

### Patient and Public Involvement (PPI) Members

- Dr Howard Leicester
- John Taylor