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GP at hand Clinical Safety Case summary

1. Document Purpose

This document is a summary of the processes that have been followed by GP at Hand (the "deploying organisation") in relation to *DCB 0160 - Clinical Risk Management: its Application in the Deployment and Use of Health IT System* (13) demonstrating and ensuring that safety deliverables have been met for the technologies provided by Babylon to the GP at hand partnership.

These technologies are:

- "Checkbase" - an AI symptom checker triaging people to the right level of care
- "Healthcheck" - supporting people to understand how their physical and mental health may be affected by current and past lifestyle choices, as well as medical and family history.
- "Babylon portal" - supporting clinicians and administrative staff to provide care and coordinate activity
- "Workflow management tool" - supporting the standardisation of clinical pathways

Formal and structured clinical risk assessments of each technology have been carried out by Babylon, in compliance with UK safety standard DCB 0129 (2) - as required by the NHS Data Coordination Boards, and the EU Medical Device Directive (3). The GP at hand Partnership has received these safety cases and supporting hazard logs and GP at Hand were able to develop clinical safety cases and hazard logs as the recipient of the technology and NHS contract holder, in accordance with UK safety standard DCB 0160 (13).

The Clinical Safety Case is a structured argument which is supported by a body of relevant evidence that provides a compelling, comprehensible and valid case that a system is safe for a given application in a given operating environment. The Clinical Safety Case provides an explanation of how the supporting evidence can be interpreted as indicating that the Health IT System exhibits an adequate degree of safety, e.g. by demonstrating compliance with requirements or sufficient mitigation of identified hazards.

A Clinical Safety Case evolves during the lifecycle of the Health IT System and is to be reviewed to ensure that it continues to provide sufficient confidence in the safety of the Health IT System and this will continue with GP at hand. The safety cases demonstrate that all foreseeable hazards have been characterised, documented and evaluated, with each hazard being either judged to be acceptable or mitigated as far as possible, in line with NHS safety

requirements (13). This has been completed for both Babylon and GP at Hand which is in line with DCB 0129 and DCB 0160. (3,13).

The detailed documentation has been made available in full to NHS England, who have taken expert advice and confirmed that each safety case was completed to a high standard as required in the NHS.

2. Personnel and competency

In line with the DCB 0129 standard, both Babylon at GP at Hand have a Clinical Safety Officer (CSO) who oversees and approves the clinical risk management deliverables. The CSOs, as required by the standard, are registered clinicians, appropriately trained and experienced in clinical risk management. (7). Both Clinical Safety Officers have been working very closely in ensuring that both DCB 0129 and DCB 0160 (3,13) safety standards have been followed.

3. Process

GP at hand have followed the requirements for effective clinical risk management in undertaking the safety work in line with DCB 0160 (13). In the deployment of a Health IT System, clinical risk management is an essential activity in ensuring the system does not compromise patient safety. The following have been undertaken and considered:

- a complete understanding of the Health IT System to be deployed and used
- an appropriate awareness of clinical risk management
- an awareness of how clinical risk management aligns with any wider governance processes
- a fully defined clinical risk assessment process which incorporates the application of recognised and rigorous methodologies (for example, see Appendix B)
- a risk assessment, carried out completely and competently
- the implementation of any required clinical risk control measures
- any residual clinical risks appropriately documented
- appropriate lifecycle management is in place.

Additionally in the manufacture of a Health IT System, clinical risk management is an essential activity in ensuring the system does not compromise patient safety. The focus of Babylon as the Manufacturer has been ensuring that the Health IT System delivered does not introduce unnecessary clinical risk and wherever possible reduces existing clinical risk.

The following requirements for effective clinical risk management have been met and used as recommended by DCB 0129 (3):

- an understanding of the hardware/software and underlying development practices being used to implement the Health IT System a thorough understanding of:
    - the clinical functionality that the Health IT System is intending to provide or replicate
    - the business processes that the Health IT System is intending to support
    - usability issues which may result in unintended consequences to patients
- an assessment of any known deficiencies in existing systems or business processes
- an appropriate awareness of clinical risk management
- an awareness of how clinical risk management aligns with any wider governance processes
- a fully defined clinical risk assessment process which incorporates the application of recognised and rigorous methodologies)
- a risk assessment, carried out completely and competently
- the implementation and verification of any required clinical risk control measures
- any residual clinical risks appropriately documented
- appropriate lifecycle management is in place.

4. Hazard Logs

Hazard Logs have been completed by GP at Hand as recommended under DCB 0160. The Babylon Hazard logs have also been reviewed and taken under consideration during the process. The Hazard logs have been reviewed by a multi-disciplinary team.

As an example, the process for creating the Hazard Logs for Checkbase consisted of a dedicated Clinical Risk Management workshop for the product. Attendees included Babylon's CSO and Medical Director along with GP at Hand Partners and CSO, safety consultants from a third party, and representation from accredited safety experts within the NHS. At this session the scope of the Symptom Checker (Checkbase), its components, and its intended use were set out. Attendees confirmed that the assessment methodology was robust and in keeping with the relevant safety standards. The level of Clinical Risk against each of the identified hazards was agreed with the attendees. (8) Controls for each hazard were then discussed and the implementation of mitigations agreed. This process was agreed by all parties involved.

Safety Profile & Hazards identified

Given the controls set out in the detailed Hazard Log, the Clinical Risk associated with each hazard is deemed to have been mitigated as far as possible, is tolerable, and no further

mitigation of risk is required at this time. Babylon and GP at Hand will together continue to actively manage clinical risk and seek opportunities for continued risk reduction.

5. Test Assurance & Clinical Validation

Test Assurance is carried out as part of GP at Hand's risk management activities and includes clinical validation. Test assurance is carried out prior to any Babylon product release and involves the multidisciplinary team as well as Senior Clinicians and the CSO to ensure acceptance criteria are met. This is also true of the safety deliverables produced by Babylon.

Assurance activities

The following describes an example of the traceability and testing done as part of the clinical risk management process, again taking Checkbase as an example. This information is shared in detail with the GP at Hand CSO so that risk management activities can be planned and incorporated in order for the standards set out in DCB 0160 to be met.

Design assurance

Where features of the product had been included in the hazard log as mitigation, each was examined in detail to ensure that they were traceable back to a demonstrable design requirement, and the relevant features included within the coverage of the release test strategy.

Test approach & Outcome

Testing by GP at Hand occurs within a User Acceptance Testing environment and any issues are logged and shared with Babylon. These issues are risk assessed and fixed as appropriate before retesting.

Risk control measures reduce the likelihood of the hazard occurring or lessen the severity if the hazard arises. A reduction in risk can be achieved through the application of one or more mechanisms. The following mechanisms have been considered and followed during the assurance process:

- changes to the design or the inclusion of protective measures in the Health IT System
- product verification and validation (for example, testing). A testing programme should address each of the hazards and thus provide a practicable demonstration that the claimed risk reduction has been achieved
- administrative and implementation procedures reassessed and updated accordingly

- user, operator and clinical training and briefings
- information for patient safety, including warnings.

Risk management in live service

GP at hand has processes in place that are supported by DCB 0160 so that any safety incidents can be raised and tracked accordingly and, if required, safety communications can be shared with both clinical and appropriate administrative staff.

Within Babylon, where software bugs are reported, these are tracked and maintained within Babylon's internal systems, and the CSO or designated CRM assesses the level of clinical risk, escalates as appropriate, and documents further requirements and validation criteria to ensure that the fix is implemented in a safe manner. Babylon's CSO works closely with the GP at Hand CSO to ensure that information is shared promptly and fully. The GP at Hand CSO will then, if required, ensure safety communications are shared with both clinical and appropriate administrative staff.

Where it is identified that new requirements introduce or impact hazards, causes or controls, the Hazard Log is updated and communicated to relevant parties without delay. Where there are material changes to the product's overall safety profile, or in the instance of a significant product enhancement, the CSO will update and re-issue the Safety Case or create a suitable annex. If no updates are made to the Safety Case during a period of 12 months, a routine update of the document will be performed.

References

Ref.	Title	Description
1	Babylon Symptom Checker (Checkbase) - Clinical Safety Case - CB.RISK.03	Symptom Checker (Checkbase) - Clinical Safety Case. v1.0
2	DCB (SCCI) 0129 Standard Specification	DCB (SCCI) 0129 Clinical Risk Management: its Application in the Manufacture of Health IT Systems – Specification. NPFIT-FNT-TO-TOCLNSA-1792.06. 02/05/18. Version 4.2.
3	EU Medical Device Directive	EU Medical Devices Directive 93/42/EEC
4	Babylon Symptom Checker (Checkbase) Hazard Log - CB.RISK.01	Symptom Checker (Checkbase) - Clinical Risk Management Hazard Log. v1.0
5	Babylon Symptom Checker (Checkbase) Clinical Evaluation Report – CER.02	Clinical Evaluation Report for Babylon Symptom Checker (Checkbase). v 2.0
6	Babylon Clinical Risk Management Process	Babylon Clinical Risk Management Process. BAB.POL.11. v1.1. Acts as the Company's Clinical Risk Management System (CRMS).
7	CSO Competency Evidence Files	Competency Evidence for Dr Matt Noble & Maria Birkmyre
8	BAB.MIN.129	GP at Hand Risk Workshop Minutes
9	NHS England. 111 Online Evaluation. 2017	Url: https://askmygp.uk/wp-content/uploads/111-Online-Evaluation-DRAFT_.pdf Accessed 27/9/18
10	CB.TECH.04	Symptom Checker (Checkbase) - Technical and Clinical Validation Strategy. v1.0
11	Clinical AI Complaints Review Committee - Terms of Reference	Personnel and Responsibilities of the Clinical AI Complaints Review Committee
12	Checkbase Post-Market Surveillance Log	Documentation of all Post-Market incidents, concerns and complaints for the Symptom Checker (Checkbase) product.
13	DCB 0160 Standard Specification	DCB 0160 Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems – Specification. NPFIT-FNT-TO-TOCLNSA-1793.05. 02/05/18. Version 3.2.
14	GPAH.RISK.322	GP at Hand – Clinical Safety Case and Hazard Log – DCB 0160

Appendix A – Clinical risk matrix and acceptability criteria

The following risk matrix, has been used in the application of clinical risk assessment and is supported by the following safety standards DCB0129 and DCB 0160.

Severity classifications

Severity Classifications	Interpretation	
	Consequence	**Number 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

Likelihood classifications

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

Clinical 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				

Risk acceptability definitions

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 or impossible without introducing alternative risks.

2	Moderate	Tolerable where further risk reduction is not practical or is impossible without introducing alternative risks.
1	Low	Acceptable, no further action required.