Paper: 8d

Date	Tuesday, 20 November 2018

Title of paper	**Update on GP at Hand Clinical Safety and Information Governance review**

Presenter	Name and Organisation
Author	Dr Phil Koczan – Clinical Safety Officer NHS England (London Region)
Responsible Director	Janet Cree Managing Director Approved report **Yes**
Clinical Lead	Name and Role

Confidential	**Yes**	☐	**No**	☑	Items are only confidential if it is in the public interest for them to be so
Assurance Level Agreed by Responsible Director	**Good** ☐	**Adequate** ☐	**Limited** ☐	**Unsatisfactory** ☐	

The Committee is asked to:
note

Summary of purpose and scope of report
This report updates the progress made by GP at Hand and Babylon to fulfil the requirements of the NHS standards DCB0129 and DCB0160. These are carried out to risk assess the product and ensure it has been developed to an acceptably safe level. **Clinical Risk Management Process** Clinical Risk Management and its application in health IT systems falls under two different standards, DCB0129 (formally SCCI0129) "Clinical Risk Management: its Application in the Manufacture of Health IT Systems" and DCB0160 (formally

SCCI0160) "Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems"

DCB 0129 is conducted by Babylon as the system suppliers and DCB0160 is undertaken by GP at Hand as the provider deploying the product.

In order to ensure that the process is undertaken to the required level and avoid any concerns over the relationship between GP at Hand and Babylon, this process has being overseen by the Clinical Safety Officer from NHS England (London) and a senior member of the NHS Digital Clinical Safety Team.

The formal clinical safety process has taken time because of the inevitable lack of clarity over the process that needed to be followed given the unique nature of the product and the relationship between Babylon and the GP at Hand practice. An interim report was completed in July 2018. This document updates on that process.

An initial Clinical Risk Management Workshop was held on 2nd July 2018 to review the draft Hazard Logs. It was agreed that, at this time, all hazards are associated with an acceptable or tolerable degree of clinical risk. The full Safety Cases have been produced and externally reviewed. A summary document has been produced by Babylon and GP at Hand that describes the process undertaken and the outcomes. The summary document is attached to this report.

The DCB 0129 safety cases submitted by Babylon and GP at hand for each of the Babylon technology products used in the GP at hand service have been considered. These are the Artificial Intelligence symptom checker, the Babylon clinical portal, and the Babylon HealthCheck service. Each safety case meets the standards required by the NHS and has been completed using a robust assessment methodology to a high standard.

There is a documented process for managing clinical risk during live service from the symptom checker component which is a class 1 medical device and has already been subject to a separate clinical safety assessment. This is also subject to post market surveillance, regulatory vigilance and risk management during live service.

Quality & Safety/ Patient Engagement/ Impact on patient services:

Not applicable for this report

Finance, resources and QIPP

List implications for the organisation in terms of:

Not applicable for this report

Equality / Human Rights / Privacy impact analysis

Not applicable for this report

Risk	Mitigating actions
No risks have been identified during the process of the review that have not already been mitigated	

Supporting documents

Include only what the meeting requires for decision making/ action, and list documents below. If documents are available online, please include the link.

- Babylon Safety Case summary
- 1

Governance and reporting

(list committees, groups, other bodies in your CCG or other CCGs that have discussed the paper)

Committee name	Date discussed	Outcome
Name	DD/MM/YYYY	