



Department
of Health &
Social Care

From the Rt Hon Jeremy Hunt MP
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Dr Sarah Wollaston MP
Chair, Health and Social Care Committee
House of Commons
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- 3 JUL 2018

Dr Sarah,

I am writing to respond to the concerns raised by Dr Margaret McCartney regarding the Babylon Health app, specifically that:

- The app was found to miss symptoms which could represent meningitis or MI
- The app also generates false positives at a high rate which has implications for demand
- The regulators, CQC, MHRA and ASA, feel as though the regulation of the app is outside of their remit

As you and Dr McCartney will be aware, adoption and accelerated use of digital services is part of our wider vision for primary care. However, we recognise that as new models are delivered we also need to examine any issues that they present so that we can support such innovation whilst at the same time safeguarding patients, general practice and the wider system.

Hammersmith and Fulham CCG, with support from NHS England, have commissioned an independent evaluation of GP at Hand. This will commence imminently and will provide robust analysis of the impacts of the service. An interim report will be available in October and a final report in March 2019.

This independent evaluation will build on the clinical review of GP at Hand which was carried out in August 2017 (available here: <http://www.hammersmithfulhamccg.nhs.uk/news.-publications-policies/publications-policies.aspx?n=6137> (item 6, appendix C)) and a further clinical review that is currently being undertaken to assess clinical safety and safeguarding aspects of the

service in response to the recommendations from the initial clinical review. It is the intention of NHS England and the commissioners that this will be an on-going process of assurance in which all parties can collectively deepen their understanding of how clinical quality can be maintained and enhanced using digital technology as the service scales.

Furthermore, NHS England's Operational Research and Evaluation Unit is undertaking a programme of analysis and evaluation to understand how the service is developing, its patients and their use of services, and financial impacts.

The findings from this analysis, the Independent Evaluation and the clinical reviews will be reviewed by the NHS England working group that has been set up to develop future policy on novel service models such as GP at Hand. This work includes exploring potential alternative contracting and financial models as well as the safety and compliance of the technology being utilised.

This is just one small part of an overarching programme of work being led by the Department of Health and Social Care and NHS England to ensure that the regulatory environment for technological innovations in health and care strikes a balance between ensuring the delivery of safe and effective care and not stifling innovation:

1. A Code of Conduct for more 'intelligent' platforms is being developed as a starting point for assurance. This will include a range of standards that innovators are expected to achieve before their product can be used to provide care in the NHS, including standards regarding evidence of safety and effectiveness. This will include looking at model management for clinical decision support in partnership with MHRA, FDA, BSI and others.
2. A range of potential scenarios presented by emerging models of care, such as that presented by GP at Hand, are being tested with the cross-government legal team to assess how, if these scenarios were to arise, the current regulatory system would deal with the issue. Where it is found that there is a gap in the regulatory model, risk-based 'fixes' are being evaluated. Such scenarios include where diagnostic support software misses symptoms.
3. NHS England has developed a series of Digital Assessment Questions which must be answered by developers looking to receive an 'NHS approved tick' on the NHS Apps Library. These questions include clinical safety questions and indicators. These are regularly reviewed and revised by the Clinical Digital Council which is a group of experts convened from across government to support digital innovation and clinical safety.

4. Public Health England and NHS England, in partnership with NICE, are working on a method of classifying digital health tools based on an assessment of risk of harm against function and evidence.

I hope that this has allayed your immediate concerns.

*Yours ever
Jery*

JEREMY HUNT