Healthwatch Birmingham and Solihull's response to regulation of AI in Healthcare

Healthwatch Birmingham and Solihull responded to this online survey consultation regarding regulation of AI in a healthcare setting. As the independent champion for patient voice, our insight is grounded in the experiences of people who use health and social care. We therefore focus our response on ensuring transparency for patients and ensuring that patient feedback is used to drive improvements to these systems. Due to the more technical focus of several of the questions regarding implementation and liability, we have provided responses to questions 5, 7 and 9 as they were most relevant to our role.

Q5: How should the regulatory framework manage post-market surveillance for AI health technologies?

Patient feedback is essential in properly understanding the effectiveness of a treatment or procedure. We therefore strongly recommend that the regulatory framework includes a clear commitment to incorporating patient feedback in post-market surveillance measures. As such, we would expect that post-market surveillance not only focusses on critical incidents, but that the wider body of patient feedback is examined. Without the inclusion of patient feedback in long-term monitoring, it is impossible to build a clear picture of issues that patients may commonly face that have not led to harm. For example, Healthwatch England have identified several delays in treatment and medication changes due to AI not properly understanding or accommodating their needs (AI in NHS care: what's the impact, and what do people think? | Healthwatch). We would therefore expect the regulatory framework to include a clear pathway for patients to share feedback on AI health technologies, to ensure that changes can be made accordingly.

Transparency should also be ensured when implementing AI-enabled care and when sharing data as part of post-market surveillance. This includes

providing patients with clear details of how their data will be used. Whilst a patient may consent to AI-enabled treatment, they may not consent to having their data used to support a broader learning model. Patients should therefore be provided with clear information on how their data will be used to ensure proper understanding of the processes involved.

In addition, the adaptive nature of AI means it is unclear whether patients can truly provide informed consent in relation to all its capabilities. As detailed in Healthwatch England's overview of early public experiences with AI (AI in NHS care: what's the impact, and what do people think? | Healthwatch) there is a mixed consensus as to standardised procedures regarding patient consent. Some services are not disclosing the use of AI before an interaction, whereas others are explicit in their use of AI during each consultation. The regulatory framework should therefore include a consistent, national approach to gathering patient consent and explaining how data is going to be shared following the use of AI-enabled care. Staff should also be properly trained on how these AI models work so that they are properly equipped to answer questions from patients and obtain informed consent prior to the use of AI in their setting.

The regulatory framework should include clear mention of how feedback regarding a specific AI-enabled care system can help to shape improvement across the broader system. For example, we would like to see mention of how improvements made to bespoke in-house models based on patient feedback are reported to regulatory bodies. We would also like to understand how this data will then be used to drive national improvements to AI-enabled care.

Q7: How could manufacturers of AI health technologies, healthcare provider organisations, healthcare professionals, and other parties best share responsibility for ensuring AI is used safely and responsibly?

Whilst we do not have any specific comments regarding how responsibility should be shared, we again emphasise the importance of clear pathways for how data will be shared between professionals and other parties. We would like to see clear information on how providers will share patient feedback to drive improvements in AI enabled care across the wider system. This is to ensure transparency for patients in how their data will be used and provide clear information for providers on how this feedback can be used to drive system wide improvement in cases where AI falls short.

From a patient perspective, it is also important that accountability remains clear, even when responsibility is shared across multiple organisations. Patients should be able to understand who is ultimately responsible for decisions influenced by AI-enabled systems.

Q9: Any other comments/evidence

Whilst we do not have any specific written evidence to include, we have several points which fall outside of the questions provided elsewhere in this survey.

Alongside the findings from Healthwatch England, we support the recommended principle of human backstops when considering AI implementation. Our concern spans to specific instances within mental health support services where chat-bots or AI enabled triage systems may be implemented to reduce waiting times. We would like to see assurance that clinical safeguards are documented in the regulatory framework to consider all 'what-if' scenarios and outline how human backstops will be used to prevent errors. This is particularly important in higher-risk contexts

such as mental health, where errors or delays may have significant consequences.

Given that the use of AI in healthcare is a topic of major discussion, we feel the time-period in which to respond to this call for evidence has been shorter than expected. To accurately gather insight into the opinions of AI regulation in healthcare, we feel the release of this document fell at an inconvenient time, factoring in the Christmas and New Year period. We therefore feel that additional engagement with patients and the public should be undertaken prior to the implementation of this framework to properly understand the impact it is likely to have on them.