Adopters guidance

Monitoring the safety and effectiveness of digital technologies (real-world monitoring)

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This is required guidance

It is legally required and it is an essential activity.

This Guide covers:

- Great Britain (England, Scotland, Wales)

From:

- Medicines and Healthcare products Regulatory Agency (MHRA)

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It is important to monitor digital technologies used in health or care. This is because their safety and effectiveness can reduce over time, leading to poor outcomes for patients or service users.

Why monitoring is important

AI and data-driven technologies contain algorithmic systems and models. These models may be affected by changes in the external environment, which can result in changes to product performance, outside of previously validated safety and value criteria. An AI specific example of this is drift, in which the model's performance and accuracy decays (reduces) over time.

There are 2 main types of drift:

- Data drift - the input data differs from the data originally used to train the model. For example, demographic data for the local patient population can change because of an increase in age or arrival of new ethnic groups
- Concept drift - the relationship between the target variable and the input features changes.

For example, a technology developed to diagnose Covid-19 from symptoms can drift when new variants arise with a different set of symptoms

Note that internal processes in a model also cause drift, even if there are no changes in the external environment.

The performance of the technology may reduce because of drift. This can result in poorer or harmful outcomes for patients and service users. It may also increase the risk of algorithmic bias, meaning some groups of individuals are more affected than others. So, you should continuously monitor the technology to detect model drift.

Your responsibilities as an adopter

The developer has a legal responsibility to maintain the safety of medical devices. This includes doing 'post-market surveillance'. You have a responsibility to help the developer do this. For more information see post-market surveillance of medical devices.

Whilst the legal responsibility to identify, report and address post market medical device failures falls upon the developer as outlined above; there is a direct route for users and adopters of medical devices (including software and AI) to report

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concerns. We encourage anyone with concerns or direct evidence of failures to report this to the MHRA via our Yellow Card reporting system.

The developer may want to make updates to the model or introduce new features to the technology. You have a responsibility to assess the impact of these changes. You should work with the developer to make sure the changes are safe and effective. See managing change to medical devices after adoption for more information. If you are in England or Wales such monitoring is legally required by the standard DCB0160.

Technologies that are no longer supported by developers (legacy systems) have higher risk of reduced performance. They require careful monitoring and management. See managing legacy systems for more information.

Your monitoring processes may identify concerns about the safety and effectiveness of the technology. You should report such concerns through your internal risk-management processes, directly to the developer and to the MHRA's Yellow Card system.

What happens if you do not do continuous monitoring?

Reduced technology performance can result in harm to patients. For example, if a condition is diagnosed incorrectly the wrong treatment may be prescribed.

Drift can result in unwanted biases in the algorithmic processing. These biases accumulate over time. If you do not have due diligence in monitoring and mitigating such bias, there may be discriminatory outcomes for patients.

Note that liability has not been established for harmful outcomes related to healthcare technologies. So, you should not assume that full liability will fall on the developer. Your organisation may face reputational damage and legal action for breaches of the Equality Act 2010.

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