Fit for purpose?
What the NHS needs to know about big data and health technology

Key points:

- **Steps are now being taken centrally to adopt a co-ordinated approach to using NHS data and new technologies to unlock improvements in health care.**
- **Guidance is still high level, but more detailed work is expected.**
- **A strong legal and ethical framework will form the core of these requirements.**
- **The commercial value of the data should not be underestimated – particularly bearing in mind the investment in NHS infrastructure that has made such projects feasible.**

As technology and innovation take an increasingly key role in the ability of the health and social care sector to deliver more efficient, flexible and higher quality services, we have seen 'Big Data' and machine learning-driven AI projects using NHS data, climb up the political agenda, as both the potential for healthcare improvement and the value of such projects have become more widely known and understood. In this article we take a look at the developments in this area and the changes we are likely to see in the future.

As anyone with more than a passing interest in the secondary uses of health data will be aware, there is an initially baffling number of official sources of advice and guidance on the information governance issues relevant to its use with new technologies. The fragmented nature of this guidance was exemplified by media coverage of a 'new' ban on exclusive data sharing arrangements in the NHS introduced in July 2019, despite this already being existing government policy. (Admittedly it was tucked away at page 46 of the December 2018 *'Industrial Strategy – Life Sciences Sector Deal 2'*!)

It is therefore not surprising that there is a lack of a common understanding of the principles to be applied, even within the NHS economy. These problems are magnified when dealing with the big tech, data and pharma companies who are not used to working with NHS data in this way and have little institutional experience or knowledge of the limitations on using patient data for purposes outside direct care. This can result in unintended consequences, such as those arising out of the Royal Free/Deep Mind "Streams" project.[1]

Everybody involved needs central, authoritative and accessible guidance to be produced. Thankfully some steps in this respect are being taken.

In July 2019, there was a flurry of activity from the Department of Health and Social Care which sets out a road map of how such data projects are likely to be governed in the future. As well as updating its Code of Conduct for Data Driven and Health and Care Technology, the DHSC published the guidance "Creating the right framework to realise the benefits for patients and the NHS where data underpins innovation". This outlines the plans for NHSX to take the lead on strategy and guidance in this area. Five guiding principles for NHS data projects are outlined.

In summary, these are:

1 Any use of NHS data must have the explicit aim to improve the health welfare and/or care of NHS patients, or improve the operation of the NHS.

2 The importance of NHS data as a resource must be reflected in ensuring fair terms for the use of NHS data for their own organisation and the NHS as a whole.

3 The arrangements should not inhibit or restrict the ability of the NHS as a whole, including a reiteration on the prohibition on exclusive data access deals.

4 Public trust is vital, so transparency and communication are necessary.

5 All existing national, legal, regulatory, privacy and security obligations should be met, including the National Data Guardian's standards.

The guidance also outlines plans for NHSX to set up a National Centre for Expertise for data agreements and projects, publishing guidance, standards and templates. Such work will undoubtedly be invaluable, but at present much of the published information is a high-level indication of future projects rather than

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[1] See, for example ICO press release 31 July 2019

direct practical solutions, and in relation to these data projects the devil is very much in the detail.

There is an increasing understanding of the value of NHS data in purely commercial terms as shown, for example, in the report by EY on 'Realising the value of health care data: a framework for the future'. A direct translation from commercial database sales to NHS data is not possible, as the protections for NHS data will mean that there will always have to be some purpose limitation and controls over data shared. Even within such constraints the commercial value of NHS data is potentially immense, with the ability to provide linkages between primary and secondary care over a lifetime, and at a scale and population diversity not currently replicable anywhere else in the world.

The datasets analysed in traditional assessments of efficacy and cost effective of pharmaceuticals and treatments will often be tiny in comparison to the information potentially available from NHS data, so there is a clear imperative for commissioners, suppliers and providers to work together to utilise the best evidence available.

Whether and how that value should be realised raises complex ethical and practical questions. For many the idea of commercial exploitation of NHS data will be redolent of selling patient data for profit or might be seen as impeding medical research. However, just as is the case with the pharmaceutical industry, progress may only realistically be possible within a commercial environment. With appropriate safeguards the benefits of interrogating mass de-identified data bases can be realised while still maintaining the core NHS principle of protecting individual privacy.

While making data available without charge may seem more in line with the spirit of the NHS, it is worth bearing in mind that this incredibly fruitful information source is only available to be analysed as a result of billions of pounds of investment of public funds. This may provide reassurance that there is a strong moral case that it is only fair and just that the NHS seeks a return on this investment, particularly when the data is used in commercial projects.

There may be lessons to be applied from the purchasing of medicines. Even the president of the United States is aware the NHS is able to secure a better deal from its medicines suppliers by bargaining on behalf of the NHS as a whole. Likewise, central negotiations for commercial data deals will result in better overall value for the NHS than individual local bespoke agreements.

We are still very much in the early days of what has the promise to revolutionise healthcare. However, there are clear indicators of how future guidance is likely to be shaped and so those responsible for planning Big Data projects should bear in mind the following points:

• Health data should not be commoditised – it should not and cannot simply be sold.

• Ensure there is a proper ethical and legal framework applied to the use of even de-identified data.

• Be transparent about who is working with your data and how it is being used. If the potential users of data are unknown, you need to have clear and transparent idea of types of user and types of project that will be involved.

• Regulation of this area is likely to be tightened in the future, so what is currently good practice is likely to be mandatory as time goes on. Similarly, previous projects may not necessarily meet current standards and so may have limited precedent value.

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