NHS Confederation and Understanding Patient Data (UPD) – Written Evidence (DAT0017)

NHS Confederation and Understanding Patient Data (UPD) submission to House of Lords European Affairs Committee inquiry on UK-EU data adequacy

May 2024

About us

The NHS Confederation is the membership organisation that brings together, supports and speaks for the whole healthcare system in England, Wales and Northern Ireland. The members we represent employ 1.5 million staff, care for more than 1 million patients a day and control £150 billion of public expenditure. We promote collaboration and partnership working as the key to improving population health, delivering high quality-care, and reducing health inequalities.

Our international health programme represents NHS expertise and interests in the UK's international strategy and policy and provides the essential link between European policy and legislation and NHS organisations.

The NHS Confederation hosts Understanding Patient Data (UPD). UPD is a small initiative focused on making the use of health data more visible, understandable and trustworthy. Whilst we are independent from each other, our views on this issue align and so this is a joint submission on behalf of both organisations.

What implications, if any, would a no or disrupted UK-EU data adequacy scenario have?

1. The inquiry places an exclusive emphasis on EU:UK data exchange for commercial and criminal investigation-related personal data. Whilst we fully recognise the importance of data adequacy for these purposes, these are not the only sectors where data adequacy has considerable salience for the UK.

2. As we will address in this submission, the EU renewal of the UK's data adequacy is fundamental to numerous NHS endeavours, too. From cross border health and social care to NHS-led research and innovation, and from pandemic preparedness to global disease

surveillance, the NHS relies on the free flow of personal data, currently enabled by long-established safeguards, to expediently and effectively deliver numerous functions.

3. Whilst the full and exact impact of lost adequacy is not known, the uncertainty created and necessity for additional protections would undermine the UK's ambition to be a 'science superpower' and, of more immediate concern, place significant additional burdens on NHS services already facing significantly strained financial and human resources.

The impact of lost adequacy

4. In December 2023, the UK government secured association to the EU's flagship research and innovation fund, Horizon Europe. Association comes 3 years after the start of the 7-year programme, (2021-2028) and has resulted in UK participation falling in the first years of the programme compared to the predecessor programme, Horizon 2020, where UK researchers and institutions were one of leading partners in the programme.

5. This decline was partly due to practical constraints placed on our third country access and partly due to a perception among the UK and EU research communities about the challenges and uncertainties associated with participation.

6. Loss of data adequacy would have an impact on the UK's participation in Horizon from a practical and perceptive point of view. Lost adequacy would require the use of alternative data sharing arrangements (commonly Standard Contractual Clauses) that would require the NHS members of Horizon consortia to spend additional time and effort approving all transfers of personal data between UK and European partners. This could have the effect of UK researchers becoming less attractive partners in multinational consortia, as human and financial resources are stretched.

7. Furthermore, the NHS is not siloed from the wider sectors that will be impacted by a loss of adequacy. As the Committee has heard during oral evidence, the loss of data adequacy would place significant strain on small and medium-sized enterprises (SMEs) (1).

8. As NHS England set out earlier this year in the Small and Medium Enterprises (SME) action plan: "SMEs contribute hugely to the creation of novel and disruptive innovations that can dramatically enhance both the patient outcomes and our operational efficiency..." (2)

9. Any impact upon the SMEs would therefore be felt by the NHS too. This is because a loss of adequacy would potentially place an unstainable requirement on SMEs to straddle two diverging regulatory regimes. These SME's may be forced to decide between either the UK or European market as a result. Were the EU to become the market of choice for existing and future SME's this could have a negative impact upon NHS access to new innovation and therefore a knock on to patient care, as well as the UK economy.

10. Through our engagements with Cancer Research UK (CRUK) we know that cancer clinical trials are contingent on the free flow of data between the UK and EU, with 61% of published CRUK research involving international collaboration and 80% of cancer researchers involved in international collaborations. Were the UK to lose data adequacy, these trials would become harder to conduct, as demonstrated by a 2023 CRUK survey of cancer researchers reporting that 89% of cancer researchers said it is important for scientists to share personal health data across borders. These statistics only represent the scale of cancer clinical trials; clinical trials conducted in the NHS across multiple disease pathways would also be affected.

11. Moving into a future where the UK does not have an adequacy agreement established with the EU, where no alternatives are developed and SCCs are increasingly relied upon, the cost of conducting all forms of clinical trials where UK and European researchers are involved will become more expensive and the UK a less attractive partner to work with as a result. This would hamper the government's ambition for establishing the UK as a global leader in life sciences.

12. In conclusion, the combined effect of losing adequacy would have negative impact upon the NHS both directly and indirectly. This will make it more costly to conduct research in the UK and make the UK a less attractive place to work and invest. As ABPI research shows (3), the UK is still yet to recover the 2015 peak in

commercial clinical trials. The loss of adequacy would make it harder still to recover as we face more barriers to accessing data, skilled professionals, and the investment that follows.

Implications of no or an interrupted UK-EU data adequacy regime

13. Cross border healthcare requiring the sharing of sensitive data between parties in the EU and UK occurs at a significant scale in the NHS. Foreign individuals requiring treatment by the NHS and the transfer of health records from the EU to the UK may include short term visitors such as students and holiday makers, or EU citizens living permanently in the UK. Under the current data adequacy agreement, data can flow freely between the UK and the EU but were data adequacy to be lost and alternative mechanisms required, the necessary sharing of data between UK and EU countries could result in significant additional costs and administrative complexity and hindrances to timely treatment.

14. The NHS already has a culture of risk aversion to the sharing of data between domestic parties, which has recently been recognised as a factor in the death of a HMG prisoner, Finlay Finlayson, during the Prevention of Future Death report (4). It would not be unreasonable then to assume that any increased challenges in sharing data associated with a loss of adequacy could add to to this aversion to data sharing. This could have potentially negative outcomes for the treatment of patients requiring the sharing of data from hospitals in the EU and those in the NHS, and vice versa.

15. As the EU develops the European Health Data Space (EHDS), and the associated MyHealth@EU (the common infrastructure designed to facilitate cross border exchange of health data for the purposes of treatment abroad) for the sharing of health data for primary and secondary purposes across member states and third countries, the implications for the future treatment of EU patients in the event UK loses adequacy becomes more uncertain as it remains unclear whether the UK will be able to participate in this infrastructure.

16. If the UK were to lose data adequacy, it would be faced with a requirement for more stringent safeguards for onward transfers of data to the UK from the EU. One such example can be seen from the excerpt from the draft EHDS below: "Connection of national contact points for digital health of third countries or interoperability with digital systems established at international level should be

subject to a check ensuring the compliance of the national contact point with the technical specifications, data protection rules and other requirements of MyHealth@EU. A decision to connect a national contact point of a third country should be taken by data controllers in the joint controllership group for MyHealth@EU."

17. As set out in the NHS Long Term Plan (NHS England, 2019) NHS organisations, where it is appropriate, are encouraged to export their expertise to international markets as a means of generating additional revenue for investment in frontline NHS services, the development of research partnerships and diversification of professional experience.

18. Any loss of adequacy will make NHS organisations potentially unattractive to prospective European partners due to the associated costs and complexity of delivery already discussed. In a competitive international market, this has potential to cause the UK to lose out on part of the European market share it has established.

19. In respect of the upcoming review of the UK:EU Trade and Co-operation Agreement, or in relation to any future Memoranda of Understanding between the UK and the EU on health matters, it is important that data adequacy is not a barrier to successful negotiation or change. This could relate to supply chains of medicines and medical devices including where there are global shortages in supply; to collaboration and innovation on novel drugs and medicines including in light of any global health crises; to other matters that a future UK Government may wish to engage or collaborate on with EU providers, customers or at Commission level.

20. It is hard to place an exact figure on the administrative costs to the NHS as this will vary from organisation to organisation and will be dependent on the degree of disruption to international collaborations. Research conducted by University College London and commissioned by the SMF (5) estimates that a conservative estimate for the average compliance costs would be:

- £3000 – for a micro business
- £10,000 – for a small business
- £19,555 – for a medium business
- £162,790 – for a large business

21. The UK government defines a large business as any business employing over 250 people. There are over 200 NHS Trusts in England, all of which will far surpass this threshold. It should be a

reasonable assumption then that loss of data adequacy could run into the £10s millions cumulatively across the NHS. This is to say nothing of the more than 6000 GP practices providing NHS primary care, the VCSE organisations contracted by NHS providers, or the independent sector increasing being relied upon to augment stretched NHS capacity.

22. The advent of Integrated Care Systems (ICS) and other forms of organisational collaboration in the NHS is only likely to make this more complex and costly still, as statutory independent organisations inside and outside of the NHS are expected to collaborate on the delivery and improvement of services.

Alternatives to Data Adequacy will create more costs than benefits for the NHS.

23. As we have discussed above, if the UK were to lose data adequacy it would be required to ensure the safe cross border exchange of personal health data by alternative mechanisms. The committee heard during oral evidence about several existing and future mechanisms by which the UK could share data. The most common will be the use of standard contractual clauses (SCCs).

24. There are examples where data can be shared without the need for an SCC, but this must be used under specific circumstances. Given the scale at which the NHS participates in data sharing with the EU, and the immediacy of data need in some cases, this seems unlikely to be an appropriate option for the NHS, in the vast majority of cases.

25. The NHS will therefore be required to make use of SCCs until an alternative arrangement can be agreed between the UK and the EU.

26. In light of the Schrems II decision, the use of SCCs has been updated under EU and UK GDPR. Where no data adequacy agreement is in place, any transfer of personal data, the laws of the country would need to be considered in the context of the transfer. Given the variety of reasons we have outlined for the use of data by the NHS, this will add to the complexity of conducting research in, and for, the NHS.

27. In addition, if adequacy is lost, the NHS will be required to undertake many of additional assurance steps to ensure the continued flow of data, as the government and ICO recommended back in 2020. This includes identifying where data is stored by EU/EEA data processors and gaining assurances that data will continue to flow freely, and auditing all personal data sets to ensure all relevant meta data is held and in compliance with legal basis for transfer (6).

References

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