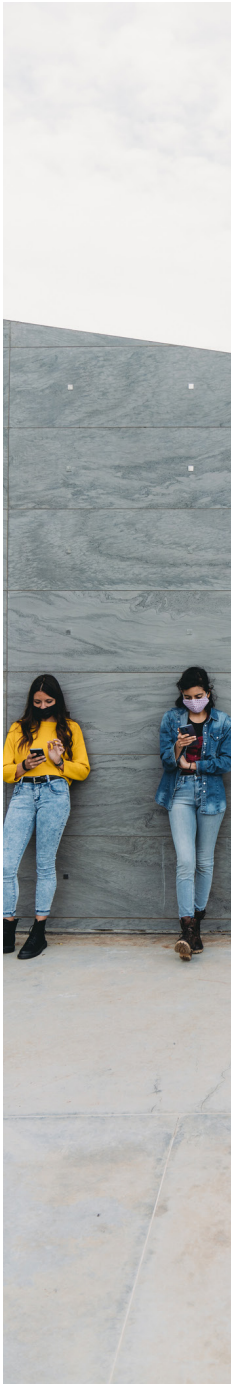
Executive summary

Regulation and use of confidential patient information for genomic and medical research during and post COVID-19



At the start of the COVID-19 pandemic, in March 2020, the government in England introduced measures to enable the use of confidential patient information (CPI) for COVID-19 purposes without consent or another form of approval that would normally be required. These measures, the 'COPI notices', set aside the common law duty of confidentiality for a range of purposes, including research into the disease and its impact on health and care. This report considers how these regulatory changes to the governance of confidential patient information have impacted genomic and medical research, and whether these changes should be integrated into the regulatory framework longer-term.

The significant impact of the COPI notices on genomic and medical research

To assess the impact of the COPI notices we reviewed the landscape of data use and linkage for genomic and medical research during the COVID-19 pandemic. We also interviewed key stakeholders from research, public health and population-level data initiatives. We identified a considerable range of data initiatives addressing COVID-19 that have relied (at least in part) on the COPI notices. Many have leveraged existing projects, infrastructures and organisations in order to address COVID-19. They include the COVID-19 Genomics UK (COG-UK) consortium, initiatives established by Public Health England for genomic surveillance, and large-scale genomic research initiatives, such as the GenOMICC study-with linkages to Genomics England and COG-UK, the HOCI study initiated by COG-UK, the SIREN study and research enabled by UK Biobank.

The evidence suggests that the COPI notices have had significant positive impacts in terms of the speed and efficiency of data access for research and also in improving access to sources of data, such as primary care data, which had been hard to obtain prior to the pandemic. The notices are likely to have had an impact in several ways: introducing a new regulatory pathway for research without consent or approval from the NHS Health Research Authority - to enable or mandate disclosure of CPI for COVID-19 purposes; development of new or streamlined processes to facilitate COPI notice-authorised data access and; the powerful signal they have sent about the importance of data sharing and access to combat COVID-19. Untangling these elements will

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be important in determining whether, and what manner of, changes should be taken forwards on a permanent basis.

Extension of the COPI notices or continued exceptions for COVID-19

COVID-19 still presents a major threat. Ongoing surveillance and research will be necessary to manage infection levels and assess the risk of new mutations or variants for some time. While this is necessary, it could be argued that measures to facilitate processing of confidential patient information for COVID-19 purposes should remain in place. However, the impact of vaccination may have altered the equation and it is clear from our focus group and from wider empirical research of public attitudes in England, that the public desire greater transparency about what is being done with CPI and justifications for any changes. The NHS Health Research Authority has published guidance for the transition of research reliant on the COPI notices to the conventional pathway for approval of research using CPI without consent based on a recommendation from the Confidentiality Advisory Group. This might signal a return to normal for most research but these measures could remain in place for specific forms of processing or flows of data between specific actors. If longer term exceptions are made, we recommend that greater transparency is provided about the scope of 'COVID-19 purposes' and the oversight of an independent body is considered.

Building on the COPI notices with further reforms

Our work has highlighted the need to build on the experience of facilitating fast and efficient access to confidential patient information for research in the public interest, while maintaining high levels of public and professional confidence. The COPI notices may already have catalysed improvements through streamlining of processes and the strong signal of support for health data sharing that they engendered, but calls for further regulatory changes could be envisaged. For example, the mandatory sharing of certain categories of data, such as primary care data, or mandatory sharing with specific recipients such as Trusted Research Environments, for research purposes. Further work and consultation is required to determine whether such reforms are necessary and proportionate. Our reviews of the legal framework and health data landscape, interviews with key stakeholders and research on public attitudes to data sharing do however, highlight a set of key ethical and legal considerations that should be taken into account in the development of any proposals for reform.

Ethical and legal considerations for changes to regulation of CPI for health research

The central pillar for the use of CPI for research and other secondary purposes is the trust and confidence of professionals, patients and publics in the institutions, processes and individuals involved. Our research highlights widespread agreement with Onora O'Neill's account, that those responsible must endeavour to demonstrate that they are worthy of patients' and publics' trust. A number of factors will be important in demonstrating such **trustworthiness**.

Transparency is crucial and a desire for greater transparency has been repeatedly emphasised in empirical work through the pandemic. This does not simply mean provision of information about the potential benefits of data sharing but there should be clarity about the scope of potential uses, the nature of the data involved, safeguards, residual risks and justifications, including the opportunity cost of not sharing data. However, although necessary, provision of information is not in itself sufficient. There is also an imperative for public **involvement and engagement** in decisions about CPI.

Our research identifies a desire from both the public and professionals that greater efforts are made to engage with communities and groups in both general and specific decisions about the use of CPI. The General Practice Data for Research and Planning initiative has provided a timely example that inadequate transparency and engagement can set-back plans to unlock the power of data for health. Millions of patients have subsequently exercised their National Data Opt-out (NDO) and opted-out entirely from the use of data for secondary purposes.

Consent and choice have an important role in the health data system. The NDO is a relatively blunt instrument because it does not allow individuals to set their preferences about specific forms of research or recipients they are comfortable with, the opt-out is all or nothing. However, as a policy it was felt to strike the right balance in supporting autonomy without placing a burden of myriad specific decisions on individuals or the development of complex systems to facilitate and maintain downstream commitments on the health service and researchers. The system is not perfect and there are challenges which would benefit from further consideration. In particular, developing consensus between healthcare professionals who owe a duty of confidentiality to their patients and researchers obtaining specific informed consent for use of their confidential patient information. This is likely to require agreement on the information required to demonstrate and communicate the scope and validity of such consents to data custodians.

It is no surprise that concerns of **privacy, data security and data protection** are foremost among the risks perceived by the public in the use of patient data for research. The development of Trusted Research Environments that enable highly secure and de-identified processing of data for research without sharing data is highly promising in this regard. Empirical work during the pandemic found high levels of approval for data

processing via OpenSAFELY, a platform developed by the DataLab at the University of Oxford for secure analysis of patient records.

A perennial challenge highlighted by our legal analysis and interviews is the complexity of the regulatory landscape. The interaction between different regulatory domains can be confusing and uncertain for professionals as well as the public. In particular, **data protection law and the common law duty of confidentiality** overlap significantly but they have important differences in terms of scope and legal requirements. Further guidance for professionals on this topic would be useful and there should be efforts to explain aspects, such as the nature of 'pseudonymised' data and how it differs from 'anonymised' data to patients and the public.

A second area of overlap is between **health research** and **public health surveillance**. Under the COPI notices certain activities may not have had to categorically differentiate between these fields and it may be appropriate that the requirements for each should be aligned where they overlap. However, it will be important to ensure that regulatory reforms do not inadvertently exclude certain actors or inappropriately incentivise the use of one route over another.

The social licence in a time of change

Finally, these considerations and decisions about reform are part of a broader dynamic context. Rapidly advancing technologies, including artificial intelligence, new models of healthcare, such as the learning healthcare system, the integration of diverse sources of data-from genomic and 'omic' data to data generated through wearable devices and apps-hold great promise and also significant challenges for regulation, governance and the relationship between the patient and the healthcare system. It may be time for a broad public dialogue, with engagement at local and national levels, about uses of health data and the social contract or licence that underpins it. New models of governance, such as data trusts or intermediaries, and continued technical developments may have an important role to play. Ultimately, unlocking the power of data for public benefit will only be achieved through commitments to transparency and consultation with the public about how data are used.

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