

# The National Data Guardian for Health and Social Care

**Annual report  
2021-2022**

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## 2 Foreword from the National Data Guardian



**Dr Nicola Byrne, National Data Guardian for Health and Social Care**

This has undoubtedly been an eventful and tumultuous year for our sector. The publication of multiple influential reviews, strategies and legislation has occupied much of our time, and continues to introduce significant change: both to the operational structure of health and social care, and also its relationship with data and digital.

Whilst navigating this uncertain landscape has understandably been challenging at times, I have been grateful for the multiple opportunities I've had to further the National Data Guardian's mission: that of safeguarding trust in the confidentiality of our health and social care services. It is clear to me that only by securing people's confidence and support can we do all of the ambitious, innovative, life-changing things with data that are part of the system's future vision for how health and care will be delivered.

As a new National Data Guardian, I know that people have been keen to understand what I'm 'all about'. Experience over this first year has brought home to me the importance of the high value I place on leadership that supports the integrity, maturity and healthy functioning of our day-to-day working relationships – whether that is across organisations, professionally or with patients and the public. Ultimately, it is only through these relationships that the benefits of data and digital can be realised.

This means listening and responding to what you hear, learning from when things don't go right, and being honest and transparent with people. It also means leadership that is realistic. I want to advocate for a balanced approach to data use that engages with its complexity, both opportunities and risks, whilst resisting unhelpful polarised thinking – whether that is about initiatives, organisations, or indeed people.

I also intend to remain focused on the impact of the role, rather than its profile. For me this entails being trusted personally. Whilst at times my advice to decision-makers has been public, at other times it has been private, to give those I'm advising room to reflect and act without external judgement. Navigating between the two approaches is a challenge that I was lucky to have the opportunity to discuss with Dame Fiona Caldicott prior to my appointment, and her advice continues to ground my actions: that is, to act first and foremost in the interests of the public at all times.

The body of my work this year has fallen into three broad strands: NDG projects, work to support government data policy, and general advice given to the system. This report has been structured to reflect this, but for those who don't have the time to read the full report, I have highlighted below some of our key achievements. Whilst this report covers the financial year 2021-22, wherever it makes sense to do so I have referenced key events that have taken place during the report's drafting stage.

### **NDG projects**

We have made good progress on some of our own projects this year, and those we have delivered in partnership.

A key achievement was the publication of guidance on Caldicott Guardians<sup>1</sup>, issued under the National Data Guardian's statutory powers. This guidance introduces a formal requirement that widens the type and number of organisations which need to appoint a Caldicott Guardian, whether by appointing a member of their own staff or making other arrangements. This is a role that I once performed in tandem with my medical responsibilities at South London and Maudsley NHS Foundation Trust, and so I am keenly aware of the vital part that Caldicott Guardians play in ensuring people's data is used responsibly to support the delivery of better care. Having more staff in the system to advise on the ethical and legal aspects of data sharing benefits us all. To support those implementing the guidance, we collaborated with the UK Caldicott Guardian Council (UKCGC) to develop an elearning programme: *The Role of the Caldicott Guardian*. We have always been proud of our strong ties with the UKCGC, and earlier this year I was glad to help them recruit a new chair. Dr Arjun Dhillon brings a wealth of experience, and picks up the baton from Dr Chris Bunch, who

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<sup>1</sup> <https://www.gov.uk/government/publications/national-data-guardian-guidance-on-the-appointment-of-caldicott-guardians-their-role-and-responsibilities>

during his tenure provided thoughtful counsel to me, my team, and Caldicott Guardians everywhere.

We have also published a report detailing the findings of a dialogue with more than 100 members of the public about how to make sure that health and care data is used in ways that benefit people and society<sup>2</sup>. This report is the first outcome of the *Putting Good into Practice* project, which was co-funded by Understanding Patient Data and UK Research and Innovation's Sciencewise programme. Previous research has shown that the demonstration of public benefit is a crucial condition for most members of the public to support the use of health and care data for purposes beyond their own individual care. However, what exactly is meant by public benefit is often not clear. So we engaged with members of the public to find out more, with a view to producing practical guidance from the National Data Guardian to help organisations tasked with making decisions about data use. We are currently working on this guidance, with a view to publishing later this year.

In addition, we shared the findings from a citizens' juries public deliberation project we co-commissioned with the National Institute for Health Research Applied Research Collaboration Greater Manchester and NHSX<sup>3</sup>. The project's focus was data sharing in a pandemic. Three juries deliberated on three national data sharing initiatives which were introduced to tackle the pandemic. The juries concluded that the government was right to use emergency measures to ensure that data was used to manage the pandemic, but greater transparency is needed. A notable finding was that the juries strongly supported the concept of trusted research environments – soon to be the principal data access method for health and social care data – because of the increased transparency they provide.

The term 'emergency measures' refers to the Control of Patient Information (COPI) notices made under the Health Service (Control of Patient Information) Regulations 2002. The regulations provide the legal basis for sharing confidential patient information (CPI) in support of managing communicable diseases and other risks to public health; the notices required the sharing of CPI for the response to the COVID-19 pandemic.

The notices expired on 30 June 2022, but it was my view, and that of the citizens' juries, that it may be beneficial for some data sharing initiatives to continue beyond this date. Given this, I was glad to support and feed into the step-by-step guidance<sup>4</sup> drafted by NHS England to help organisations ensure that they have a sustainable legal basis for their ongoing processing of CPI for COVID-19 purposes (or that processing ends where it is no longer justified). During the coming year I will be looking to better understand how the step-by-

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<sup>2</sup> <https://www.gov.uk/government/publications/putting-good-into-practice-a-public-dialogue-on-making-public-benefit-assessments-when-using-health-and-care-data>

<sup>3</sup> <https://arc-gm.nihr.ac.uk/projects/Citizens-Juries-on-Health-Data-Sharing-in-a-Pandemic>

<sup>4</sup> <https://digital.nhs.uk/services/data-access-request-service-dars/copi-guidance>

step guidance has been applied, and its impact on data sharing initiatives that began under emergency measures in the pandemic.

### **Advising the system**

In tandem with the delivery of our own projects, my team, advisory panel, and I have met – or corresponded with – a multitude of different organisations and programmes: whether to advise and guide on the specifics of their work, or just to better understand the fantastic data and digital initiatives that are changing the way people’s care is delivered. I am grateful to have met so many welcoming, inspiring people, all of whom spoke with encouraging enthusiasm about both their work and improving outcomes for people. I won’t single out any of those encounters here, but I have hopefully given a flavour of some of those interactions in chapter 7, *Advising the system*.

### **Influencing data policy**

This year, my team, my panel, and I have worked steadfastly to advise the government and influence decisions about key policies and draft legislation pertaining to data confidentiality. This strand of work is described in full in chapter 6, *Influencing Data Policy*, and the key interventions are described below.

The General Practice Data for Planning and Research (GPDPR) programme, and its impact on public trust, appeared on my radar not long after I arrived in post. I am a great supporter of what the programme is intending to achieve, but whilst it stands to deliver much, prior to launch it didn’t do enough to talk to the public and professionals about what was happening and why. As a consequence, it was criticised in the press and on social media, leading many to lose trust in the system’s handling of their data. This resulted in many people exercising their right to opt out. In private, I advised the government to delay the collection of data from GP records until safeguards had been strengthened and people had been spoken with, and I was grateful that they listened. I was also invited to share my views publicly about this with the government’s Health and Social Care Committee. Allowing time to do this properly was the right thing to do. It is vital that data is used in research that benefits the public, and to improve the way that our health and social care services are run. But there is a risk of losing people’s support for this ambition if they feel decisions that affect them are being made without their knowledge.

GPDPR stands as a sobering reminder that despite all the visible good that data did during the pandemic, we cannot presume to know what the public will and won’t support. People still want and need to be consulted about information sharing and advised of their choices. The government cannot afford to take risks when the outcome of getting it wrong is broken trust and increased opt-out rates. Therefore, it was helpful to see an acknowledgement in its data strategy *Data saves lives; reshaping health and social care with data* that it needed to do better to rebuild and strengthen that trust.

Feeding back on the draft data strategy was an important strand of work for us during the year. I advised that the creation of public trust needed a much greater emphasis and was pleased by the strong focus it was given in the final version. I also advised that it should provide a more balanced view of the benefits and risks of data use and say how these will be addressed. Our full consultation response is available on the NDG GOV.UK webpages<sup>5</sup>; following the strategy's publication, I wrote a blog in which I explore to what degree the strategy's commitments provide a blueprint for the evolution of a trustworthy data system<sup>6</sup>. I am hopeful for the future as outlined in *Data Saves Lives*, and one of our big work priorities for 2022-23 is supporting and advising those implementing the strategy's commitments, within the bounds of my remit.

We also fed into Professor Ben Goldacre's review: *Better, broader, safer: using health data for research and analysis*, and strongly support the recommendation he made about the implementation of trusted research environments (TREs). Moving away from data dissemination towards transparent, controlled, safer access in a TRE will have a big impact on public trust. I look forward to supporting those who are implementing TREs by inputting into the development of the 'service wrapper' that shapes and defines how TREs will operate; it is crucial that the system gets this right.

The government's consultation *Data: a new direction: reform of UK data protection law*, and its related House of Commons Science and Technology Committee inquiry: *The right to privacy: digital data*, provided us with further important opportunities to ensure that changes to data legislation do not have the effect of harming the confidentiality of people's health and care information. We published our consultation response<sup>7</sup>, and our written evidence to the inquiry<sup>8</sup>, online.

In November 2021, the Laura Wade-Gery review *Putting data, digital and tech at the heart of transforming the NHS* recommended the merger of NHS Digital – health and care's 'digital safe haven' – into NHS England, and this was formalised in the Health and Care Act 2022. As this reconfiguration comes to pass, it is essential that the utmost care and attention is given to ensuring that the data safe haven for health and social care data becomes no less safe.

If the merger is to meet its aim of accelerating digital transformation and improving the ways in which data and technology are used and handled, we must acknowledge key successes and achievements and build upon them. This includes the good information governance practice established by NHS Digital over the years. As organisations change and reconfigure,

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<sup>5</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1015989/NDG\\_Data\\_Strategy\\_Response\\_v1.0\\_-\\_08.09.21.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1015989/NDG_Data_Strategy_Response_v1.0_-_08.09.21.pdf)

<sup>6</sup> <https://www.gov.uk/government/news/the-data-strategy-a-blueprint-for-the-evolution-of-a-trustworthy-data-system>

<sup>7</sup> <https://www.gov.uk/government/publications/national-data-guardian-feedback-on-data-a-new-direction-proposed-government-reforms-to-the-uk-data-protection-regime>

<sup>8</sup> <https://www.gov.uk/government/publications/the-national-data-guardians-written-evidence-to-the-science-and-technology-committees-inquiry-the-right-to-privacy-digital-data>



and people move on, the system needs to remain vigilant, so that vital expertise and important knowledge and learning is not lost.

It is not yet fully clear what the implications of the merger will be for access to data and the safeguards that will be set in place to protect it; this is something that I will continue to work through with those responsible during 2022-23. I have already spoken with system leaders in the affected organisations, and to government and relevant peers in the House of Lords, to ensure that the tried and tested checks and balances currently protecting access to people's data within NHS Digital are maintained, and even strengthened. I will be strongly advocating for independent and lay input into decision making. The Data Access Release Service (DARS) and the Independent Group Advising on the Release of Data (IGARD) have a wealth of specialist and legacy expertise and have played an integral part in ensuring that people's data is only used appropriately, for public benefit; their knowledge can continue to offer much in the way of decision-making that bolsters trust.

This year will also see work to implement a new federated data platform (FDP) to support the better management and use of health and social care data. It has been described by some as a new 'operating system' for the NHS and is being built to support five use cases: population health and person insight; care-coordination; elective recovery; vaccines and immunisation and supply chain. This is an incredibly ambitious project which will have a considerable impact on our data ecosystem. It stands to deliver many benefits, but as with all programmes of this size and consequence, there will be much to do to explain what is happening and why if the NHS is to earn people's trust and support. As such, there needs to be a strong commitment to transparency and engagement; this is advice that I have given to the programme team. As the plans for the FDP progress, I will continue to engage with the programme on a number of key areas, including the essential requirement that the programme develops in a way which aligns with NHS values.

Without a doubt there are some great challenges in the year ahead for our sector as a whole, and for those who work so hard in data and digital. But whatever the next year brings, I will continue to fulfil my mission by listening to patients, professionals, and the public, and endeavouring to act on what I hear. The *Priorities* section of this report, chapter 9, outlines our planned work for 2022-23 – although much of what we do is reactive and cannot be anticipated in advance, only reported upon thereafter.

Finally, I would like to thank all of the people who help me to keep the plates spinning as we work together to deliver our priorities. I am endlessly grateful for the support and wisdom of my team, my advisory panel, and my colleagues in the UKCGC.



**Dr Nicola Byrne**  
**National Data Guardian for Health and Social Care**

## 3 Introduction

The Health and Social Care (National Data Guardian) Act 2018 requires the NDG to produce an annual report that includes information about advice given, guidance published in the previous financial year, and the priorities for the forthcoming year. These responsibilities are being discharged in this report.

The report provides an account of work carried out by the NDG during the 12 months to the end of March 2022; however, wherever it makes sense to do so, select notable activities that have happened subsequently (during the report's drafting period) have also been included.

During the reporting period, the NDG has been supported in the delivery of her duties by a small team of officials and a panel of independent advisers (Appendix A). The panel's terms of reference and the minutes of its monthly meetings are available on the NDG's webpages<sup>9</sup>.

## 4 What the NDG does

### 4.1 Vision

The NDG's vision is for improved health and care outcomes through the safe, appropriate, and ethical use of people's health and social care information.

### 4.2 Mission

The NDG's mission is to help preserve trust in the confidentiality of our health and social care services. If people are to support the collection and use of their health and care data, they need to be confident that information about their care will remain private – and only be used in ways which benefit the public.

To support the development and maintenance of trustworthy systems and practices, the NDG, her team and panel provide advice, encouragement, and challenge on the safe, appropriate, and ethical use of people's confidential health and social care information. They do so in line with the eight Caldicott Principles and findings from public attitudes research.

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<sup>9</sup> <https://www.gov.uk/government/organisations/national-data-guardian/about#who-we-are>

### 4.3 Strategic objectives

The NDG's mission is supported by four long-term strategic objectives:

1. Safeguard trust in the confidentiality of our health and social care system
2. Encourage safe and appropriate information sharing for individual care
3. Support understanding and engagement about how and why data is used
4. Encourage the safe, appropriate, and ethical use of data in system planning, research and innovation that benefits the public.

## 5 Projects: NDG led and with partners

During 2021-22, the NDG and her team made progress on three key projects, two of which were in collaboration with partners. Work with citizens' juries provided some of the rationale for moving to protect people's data through secure data environments. The first piece of guidance issued under the NDG's statutory powers provided that more health and social care organisations should be required to appoint a Caldicott Guardian. Work is also underway to develop guidance intended to help organisations evaluating whether an intended use of health and care data is for public benefit, so that they can make their evaluation in line with public views and values.

### 5.1 Learning from the pandemic: citizens' juries

The NDG co-commissioned research that provided important evidence about public reactions to the emergency measures that enabled greater sharing of people's health and care data during the COVID-19 pandemic. A series of three citizens' juries<sup>10</sup> investigated whether people found these measures to be acceptable and whether they should be allowed to continue beyond the pandemic emergency period.

The juries operated online between March and May 2021. Each jury of 18 adult members met for eight afternoon sessions to hear evidence from experts about the merits and drawbacks of three data initiatives. The first jury was a representative group of adults from across England; the second was drawn from Greater Manchester; and the third from West and East Sussex. The project was initially funded by the National Institute for Health

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<sup>10</sup> The juries were designed and run by Citizens Juries c.i.c., a UK social enterprise, in partnership with the Center for New Democratic Processes (formerly the Jefferson Center), a non-profit civic engagement organisation based in the United States. The events were designed according to strict rules to minimise bias, and to enable jurors to become well informed and work co-operatively to reach reasoned conclusions.

Research's Applied Research Collaboration<sup>11</sup> (NIHR ARC) in Greater Manchester; it expanded after additional funding was provided by the NDG and NHSX.

Each jury heard the same evidence and was asked to answer the same questions about the three pandemic data sharing initiatives described below:

### **Summary Care Record Additional Information (SCRAI)**

The SCR is an electronic record containing important information from the patient's GP medical record. During the COVID-19 emergency period, additional information<sup>12</sup> was included in patients' Summary Care Records (unless they had opted out of having a SCR).

### **NHS COVID-19 Data Store and Data Platform<sup>13</sup>**

The NHS COVID-19 Data Store and Data Platform is a central store of patient-related data created by NHS England in response to the pandemic. It has a wide range of software tools including two which were specifically considered by the juries:

- The Early Warning System used for planning and monitoring the pandemic response (e.g. of COVID-19 admissions, bed usage etc.)
- The Immunisation and Vaccination Management Capability used to manage the delivery of the COVID-19 vaccination programme.

### **OpenSAFELY<sup>14</sup>**

OpenSAFELY is a software platform created at the start of the pandemic by a consortium including the University of Oxford and with the backing of NHS England for pandemic-related research. It uses de-identified (pseudonymised) patient data drawn from GP patient records within the boundaries of a trusted research environment (TRE), which enables researchers to analyse the data, but not to download, copy or export it.

Most jurors supported OpenSAFELY (77% of jurors very much in support) because they considered it to be the most transparent, trustworthy, and secure of the three data sharing initiatives. Jurors were least supportive of the NHS COVID-19 Data Store and Platform (38% of jurors very much in support) because of concerns about lack of transparency.

The three juries were asked to give reasons for supporting OpenSAFELY and commented:

"It is a software platform that doesn't require the moving or downloading of data, so data cannot be edited or copied and researchers do not need to access the data in order to

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<sup>11</sup> <https://arc-gm.nihr.ac.uk/>

<sup>12</sup> <https://www.nhs.uk/NHSEngland/thenhs/records/healthrecords/Documents/2016/SCR-additional-information-leaflet.pdf>

<sup>13</sup> <https://www.england.nhs.uk/contact-us/privacy-notice/how-we-use-your-information/covid-19-response/nhs-covid-19-data-store/>

<sup>14</sup> <https://www.opensafely.org/>

analyse it, ensuring confidentiality and minimising usage of sensitive information and maximising safety and security.”

“The initiative does not transfer or store data, meaning we do not have another platform holding vast quantities of data and the accompanying risk of it being leaked.”

“OpenSAFELY protects against misuse of the retrieved data via multi-level access, audit trails, publishing of code and no direct downloading or accessing of the data and publishing outputs (all of which is reviewed every three months).”

These results were quoted by Professor Ben Goldacre in the report of his review for the government on how to facilitate access to NHS data by researchers, commissioners, and innovators, while preserving patient privacy<sup>15</sup>. He said the citizens’ juries showed public understanding and support for what became one of the key recommendations of his review, namely that secure data environments should become the norm for analysis of NHS patient records data.<sup>16</sup> This recommendation was adopted in the commitments made in the Department of Health and Social Care’s data strategy<sup>17</sup>, which promises to establish secure data environments as the default for NHS and adult social care organisations to provide access to their de-identified data for research and analysis. It says: “Secure data environments – a subset of which are known as trusted research environments – are a big step forward in how data can be accessed securely in a virtual setting. Analysis takes place within a secure online platform rather than data being shared and distributed.”

The citizens’ juries also investigated whether people thought that initiatives introduced during the COVID-19 emergency period should continue after it. Most jurors were in favour of all the data sharing initiatives continuing for as long as they were valuable (potentially beyond the pandemic and for non-COVID-19 uses). However, very few jurors wanted decisions about the future of these initiatives to be taken by the minister or organisation accountable for them. Most believed that an independent body of experts and lay people should assess the data sharing initiatives. The juries thought that the main lesson to learn for future pandemics was to better inform and engage the public in the actions taken under emergency measures.

After speaking at the launch of the report<sup>18</sup> on these citizens’ juries in July 2021, the NDG said in a blog<sup>19</sup>: “One of the key findings was that members of the public should not just be

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<sup>15</sup> <https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis/better-broader-safer-using-health-data-for-research-and-analysis>

<sup>16</sup> Prof Goldacre leads an academic team at Oxford University that uses large health datasets to deliver research papers and tools, including OpenSAFELY. It should be emphasised that the NDG’s citizens’ jury work was entirely independent and the juries’ support for the OpenSAFELY model can be taken at face value.

<sup>17</sup> <https://www.gov.uk/government/publications/data-saves-lives-reshaping-health-and-social-care-with-data/data-saves-lives-reshaping-health-and-social-care-with-data>

<sup>18</sup> [https://arc-gm.nihr.ac.uk/media/Resources/ARC/Digital Health/Citizen Juries/12621 NIHR Juries Report ELECTRONIC.pdf](https://arc-gm.nihr.ac.uk/media/Resources/ARC/Digital%20Health/Citizen%20Juries/12621_NIHR_Juries_Report_ELECTRONIC.pdf)

<sup>19</sup> <https://www.gov.uk/government/news/the-importance-of-listening-and-changing>

informed about, but also involved in, decisions about data sharing, in partnership with data experts. The jurors thought this was preferable to those decisions being made by the organisations using the data or by politicians.”

## 5.2 Guidance on Caldicott Guardians

During 2021-22, the NDG made the first use of statutory powers in the National Data Guardian Act 2018 to issue formal guidance on the appointment of Caldicott Guardians, their role and responsibilities<sup>20</sup>. The guidance requires all public bodies within the health service, adult social care or adult carer support sector in England that handle confidential information about patients and service users to appoint a Caldicott Guardian.

A Caldicott Guardian is a senior person within a health or social care organisation who makes sure that confidential information about those who use its services is used legally, ethically, and appropriately, and that confidentiality is maintained. They play a vital role in ensuring that health and social care data is used responsibly to support the delivery of better care.

After public consultations during 2020-21, the NDG issued the new guidance in August 2021; it covers the following areas:

- which organisations should appoint a Caldicott Guardian
- advice on how to appoint them
- the way the role should be supported by organisations
- the role and responsibilities of a Caldicott Guardian
- the competencies and knowledge that will assist a Caldicott Guardian.

Public bodies exercising functions that relate to the health service, adult social care or adult carer support sector in England and organisations contracted by public bodies to deliver health or adult social care services must have regard to this guidance when processing health and adult social care data.

In preparation for this work, the NDG’s team helped the UK Caldicott Guardian Council (UKCGC) to redesign its website<sup>21</sup> and develop a new elearning programme for those wanting to find out more about what Caldicott Guardians do to keep people’s data safe and ensure that wise decisions are made about its use. Working in partnership with Health Education England elearning for healthcare (HEE elfh)<sup>22</sup> the NDG and UKCGC produced three audience specific elearning modules.

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<sup>20</sup> <https://www.gov.uk/government/publications/national-data-guardian-guidance-on-the-appointment-of-caldicott-guardians-their-role-and-responsibilities>

<sup>21</sup> <https://www.ukcgc.uk/>

<sup>22</sup> <https://portal.e-elfh.org.uk/>

The first module<sup>23</sup> is designed to raise awareness and inform a broad range of staff from across health and social care of the importance of Caldicott Guardians and confidentiality in their setting, organisation, or sector.

The second module is a starting point for newly appointed Caldicott Guardians and a supportive reference for those more experienced. It explains how the role fits into the wider information governance assurance framework and will help Caldicott Guardians arrive at lawful and practical decisions regarding the protection and sharing of patient and service user information. It also looks at what sources of support and resources are available.

The third module is for members of senior leadership teams who may need to appoint, work alongside, or otherwise support a Caldicott Guardian. It explains the importance of the role, including how a Caldicott Guardian's work represents the best interests of patients and service users, and how they impact the decision-making processes of the organisation. This material is available through the HEE elfh website.<sup>24</sup> Initial feedback from people who have completed the elearning modules was overwhelmingly positive.

In support of the guidance, the NDG wrote a blog<sup>25</sup> drawing on her personal experience as a Caldicott Guardian, to illustrate the importance of the role.

### **5.3 Supporting better public benefit assessments**

During 2021-22, the NDG commissioned and led a public dialogue to understand how people assess public benefit in the use of health and social care data when it is used for reasons beyond individual care. Drawing on these findings, the NDG is writing guidance to help organisations across the sector to carry out public benefit evaluations. People are more likely to support data sharing for purposes beyond their individual care if it can be shown to produce public benefit. However, what is meant by the term public benefit is not clear. To aid understanding, the NDG commissioned this public dialogue project with Understanding Patient Data<sup>26</sup> to help inform thinking about the content of the term public benefit. It is hoped that by following this guidance, organisations will be able to evaluate public benefit in a way that accurately reflects public views and values. The project was made possible with support from Sciencewise<sup>27</sup> and UK Research and Innovation<sup>28</sup>. It was designed and delivered by the deliberative engagement specialists Hopkins Van Mil<sup>29</sup>.

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<sup>23</sup> <https://www.ukcgcc.uk/news/2zvl7w2td2t8iydi21qo9ti5blqvwf>

<sup>24</sup> <https://www.e-elfh.org.uk/programmes/the-role-of-the-caldicott-guardian/>

<sup>25</sup> <https://www.gov.uk/government/news/in-praise-of-the-uk-caldicott-guardian-council-and-caldicott-guardians>

<sup>26</sup> <https://understandingpatientdata.org.uk/>

<sup>27</sup> <https://sciencewise.org.uk/>

<sup>28</sup> <https://www.ukri.org/>

<sup>29</sup> <http://www.hopkinsvanmil.co.uk/>

A report of this deliberative engagement<sup>30</sup> was published in April 2021. It found a fundamental link between public benefit and transparency. It said: “Transparency cannot be separated from public benefit. It is not an add-on or nice to have. Health and social care data use requests only demonstrate public benefit if they have integrated communications within their application including activity which demonstrates the value of data use to society.”

The report found that the concept of fairness was particularly important to dialogue participants. People felt that the benefits of data use should be distributed fairly, with safeguards to protect against discrimination and unjustified geographic disparities. They also thought that the scale of benefits was not a significant factor, seeing inherent value in data use which produces an impact, even if only for a small number of people.

The NDG’s work during 2021-22 focused on translating this research into guidance that will help organisations to carry out public benefit evaluations in a way that aligns with public views and values, and which provides an interpretation of public benefit rooted in public dialogue. The NDG continues to refine this guidance and aims to publish during 2022-23.

## 6 Influencing data policy

The NDG and her team spent a large part of their time responding to inquiries, reviews and consultations that directly impact data decisions at policy level, and to intervening in key national data policy matters. Below we describe the key interventions made during 2021-22.

### 6.1 Data saves lives: reshaping health and social care with data

An important strand of work during the year was the NDG’s contribution to the development of the NHS data strategy: *Data saves lives: reshaping health and care with data*<sup>31</sup>.

The urgency of the COVID-19 pandemic had given a strong impetus to digital transformation, powering research into new treatments and helping people to access advice and care remotely in unprecedented numbers. To build on these developments, the DHSC published a draft data strategy in June 2021.<sup>32</sup> The strategy aims to embrace the opportunities that data-driven technologies provide. In its mission to encourage a digital NHS, the strategy prioritised commitments to improve transparency about how health and social care data is used and to give the public more control over this.

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<sup>30</sup> <https://www.gov.uk/government/publications/putting-good-into-practice-a-public-dialogue-on-making-public-benefit-assessments-when-using-health-and-care-data>

<sup>31</sup> <https://www.nhs.uk/key-tools-and-info/data-saves-lives/>

<sup>32</sup> <https://www.gov.uk/government/publications/data-saves-lives-reshaping-health-and-social-care-with-data-draft/data-saves-lives-reshaping-health-and-social-care-with-data-draft>



Officials from NHSX attended a meeting of the NDG's panel in June 2021 to discuss the draft strategy. There was a broad welcome from panel members for the aim of the initiative, but reservations about some of the detail. This discussion helped to inform the NDG's formal written response to the consultation on the draft strategy published in September 2021.<sup>33</sup>

The response called for a reconsideration of whether the strategy's language of enabling increased 'control' for the public was appropriate, if what was meant in practice was enabling greater transparency and / or access to their own data. The NDG proposed that more authentic commitments to giving the public more control might be maintaining the choice to opt out (the mention of opt-out was missing from the draft strategy), and a wider consideration of how the public might, by design, be more routinely involved in decisions about how data is used for public benefit.

The NDG's response suggested that a clear plan for public engagement and communication was necessary, with more specific information about how public trust would be built and maintained. It also called for a more balanced view of the benefits and risks of data use and how these will be addressed. She suggested that the government needed to have honest conversations with the public about the fact that innovating with health and social care data often involves providing data access to commercial companies (such as those developing new treatments) who stand to make a profit from its use.

The NDG's team contributed to NHSX's data strategy workshop in December 2021 and worked with the Ada Lovelace Institute and Understanding Patient Data to develop constructive suggestions to help the NHS to improve the final version of the strategy.

The strategy was published in June 2022, and the NDG was pleased to see her recommendations on trust and control taken into account. She published a blog on her website<sup>34</sup> in which she gave her views on some of the strategy's commitments, in particular those intended to improve trust in data use.

## **6.2 *Better, broader, safer: using health data for research and analysis: The Goldacre review***

During 2021-22, the NDG was interviewed by Professor Ben Goldacre to inform his review into ways to deliver better, broader, safer use of health data for research and analysis<sup>35</sup>.

Prof Goldacre attended a meeting of the NDG's panel in November 2021 to give an overview of his committee's work and to discuss draft findings. Panellists agreed with his view that

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<sup>33</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1015989/NDG\\_Data\\_Strategy\\_Response\\_v1.0\\_-\\_08.09.21.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1015989/NDG_Data_Strategy_Response_v1.0_-_08.09.21.pdf)

<sup>34</sup> <https://www.gov.uk/government/news/the-data-strategy-a-blueprint-for-the-evolution-of-a-trustworthy-data-system>

<sup>35</sup> <https://www.goldacreview.org/>

implementing data access in trusted research environments (TREs) and moving away from data dissemination will help to develop a trustworthy system. Panellists also agreed that TREs and an accompanying standard 'service wrapper' would facilitate the development of a more transparent system of access to health and care data by supporting better audits of what data has been accessed by whom and the analysis they conducted.

The NDG is keen to support the development of this 'service wrapper'. A properly resourced centralised approach presents the opportunity to ensure that the key aspects that the public have told us should govern access to their data such as transparency and trust, proportionality, diversity and inclusion in design and oversight and ongoing learning are prioritised.

Prof Goldacre's report and recommendations<sup>36</sup> to government were published on 7 April 2022 and the government provided its formal response in the final version of the NHS data strategy. The NDG was pleased to see references to some of her office's outputs: the citizens' jury report on data sharing during a pandemic<sup>37</sup>, and the deliberative engagement report on public benefits: *Putting Good into Practice*<sup>38</sup>.

### **6.3 ICO call for views: Anonymisation, pseudonymisation and privacy enhancing technologies guidance**

The NDG welcomed draft guidance published for consultation from the Information Commissioner's Office (ICO) on anonymisation, pseudonymisation and privacy enhancing technologies<sup>39</sup>. This guidance will fill a significant gap in the available advice on ensuring that anonymisation is effective.

In 2013, the Information Governance Review<sup>40</sup> urged NHS and social care organisations to, wherever possible, use information rendered anonymous in line with the ICO's Code of Practice on Anonymisation. As technology and the regulatory landscape have developed with the introduction of new data protection legislation, the 2013 Code has become outdated, leading to the ICO's current suite of draft guidance. During the consultation period, the ICO's new draft guidance is being published incrementally as a series of chapters.

The NDG is collaborating with other stakeholders represented on the Health and Care Information Governance Panel (HCIGP) to provide joint responses to the guidance. The NDG and her team will continue to work with the HCIGP and its working group to provide advice

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<sup>36</sup> <https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis>

<sup>37</sup> [https://arc-gm.nihr.ac.uk/media/Resources/ARC/Digital%20Health/Citizen%20Juries/12621\\_NIHR\\_Juries\\_Report\\_ELECTRONIC.pdf](https://arc-gm.nihr.ac.uk/media/Resources/ARC/Digital%20Health/Citizen%20Juries/12621_NIHR_Juries_Report_ELECTRONIC.pdf)

<sup>38</sup> <https://www.gov.uk/government/publications/putting-good-into-practice-a-public-dialogue-on-making-public-benefit-assessments-when-using-health-and-care-data>

<sup>39</sup> <https://ico.org.uk/about-the-ico/ico-and-stakeholder-consultations/ico-call-for-views-anonymisation-pseudonymisation-and-privacy-enhancing-technologies-guidance/>

<sup>40</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/192572/2900774\\_InfoGovernance\\_accv2.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf)

and guidance specific to the health and care sector on the processing of confidential patient information in the context of the ICO's guidance on personal data.

## 6.4 General Practice Data for Planning and Research

The NDG supports the intention behind the GDPR programme – in so far as it was designed to replace the outdated General Practice Extraction Service (GPES) with a new system that strengthens privacy safeguards, reduces the administrative burden on GP practices and provides more reliable data for planning and research.

Along with other stakeholders, the NDG has been involved in discussions relating to the development of the GDPR programme since 2018. In these discussions, the importance of learning from previous data initiatives, including the failure of the care.data programme in 2014-15<sup>41</sup> was emphasised. The GDPR programme had been advised that, to earn public trust, it must adopt appropriate safeguards, involve the public in its development, and ensure effective communication with professionals and the public. In early 2021, during Dame Fiona Caldicott's tenure, the NDG expressly warned that the programme must not risk being perceived as trying to introduce changes 'under the radar'. The programme leads were encouraged to speak clearly and with confidence about the programme's aims, and what would and would not be done with the data, to secure trust and understanding.

On 12 May 2021, NHS Digital issued a Data Provision Notice to GPs to enable the new data collection process to begin from 1 July 2021 under the authority of a legal direction from the Secretary of State for Health and Social Care. This provoked a considerable amount of hostile media coverage suggesting that the NHS was engaged in a 'data grab' driven by motivations of commercial profit. The purpose of GDPR and the fact that it would replace other, less secure data collections were not well explained in these critical articles. As a result, the NHS lost control of the narrative, and debate about the programme became mired in risk and anxiety around concerns about both privacy and data use. As such, more positive, balancing messages about protective safeguards and benefits to the population from better research and planning, were drowned out.

Many people were alarmed by reports that they had to act quickly to prevent their data from being uploaded to NHS Digital because it could not be recalled thereafter. This led to a reported significant increase in the number of people registering type 1 opt-outs and also national data opt-outs. Whilst individuals choose to opt out for their own reasons, including specific privacy concerns related to their own circumstances, at a population level rising numbers of opt-outs can be taken as a proxy measure for falling levels of overall public trust around how data is being secured and used. Consequently, the increase in opt-outs seen

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<sup>41</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/389219/IIGOP\\_care.data.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/389219/IIGOP_care.data.pdf)

after the initial GDPR announcement strongly suggests more needs to be done by the system to demonstrate it is trustworthy to the public and professionals alike.

Addressing high levels of opt-out is essential, not only to ensure high quality data for research purposes into better care and treatments. It is also important to ensure that higher levels of opt-out amongst some communities, including those historically most disadvantaged, do not lead to the experience of people in those communities being lost from data used for resource planning purposes.

The NDG provided advice to the DHSC about the need for a pause in the launch of GDPR to allow for better engagement and communication with the public. The NDG also helped to inform ministers in discussions that led to a letter to GPs from Jo Churchill MP on 19 July 2021 announcing a further programme of work that would have to be completed before any target date could be set for the collection of data. The letter promised that data would only be collected once four key conditions had been met:

- the ability for patients to opt out or back in to sharing their GP data with NHS Digital, with data being deleted even if it has been uploaded
- a trusted research environment is available where approved researchers can work securely on de-identified patient data which does not leave the environment
- a campaign of engagement and communication has increased public awareness of the programme, explaining how data is used and patient choices
- the backlog of opt-outs has been fully cleared

The letter also committed to ensuring that patients would be able to change their type 1 opt-out status at any time, thereby ensuring that people could still choose to have data previously uploaded to GDPR deleted.

Appearing before the House of Commons cross-party Health and Social Care Committee<sup>42</sup> on 20 July 2021, the NDG said: "I am satisfied that my advice, not only on the pause but on some of the specifics that the letter that came out yesterday to GPs addresses, has been listened to and taken very seriously."<sup>43</sup>

The NDG and her representatives continue to engage with the programme via its three formal oversight groups: the GDPR Advisory Group (overseeing the programme's progress against the commitments made in the letter to GPs); the GDPR IG Expert Liaison Group (providing advice and feedback on the IG elements of the programme); and the GP Data Patient and Public Engagement and Communications Advisory Panel (advising on public engagement).

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<sup>42</sup> <https://committees.parliament.uk/committee/81/health-and-social-care-committee/>

<sup>43</sup> <https://committees.parliament.uk/oralevidence/2615/pdf/>

## 6.5 Police, Crime, Sentencing and Courts Bill

The NDG joined with the British Medical Association (BMA)<sup>44</sup>, the General Medical Council (GMC)<sup>45</sup> and other stakeholders to warn the government about a threat to confidentiality contained in the Police, Crime, Sentencing and Courts Bill<sup>46</sup> that could damage the relationship of trust between people and their care providers.

As initially drafted, the Bill imposed a duty on Clinical Commissioning Groups (CCGs) to disclose information to the police, and other specified authorities, for the purposes of the duty to collaborate to prevent and reduce serious violence in their local areas. This duty would have overridden the obligation of confidence that health and social care providers owe to patients and service users.

The NDG wrote to the Home Secretary explaining the damage this could do to public trust. She said: "I am concerned with provisions in Part 2, Chapter 1 of the Bill that allow for the 'setting aside' of the duty of confidentiality relating to health and social care data collected when providing care ... [The Bill] gives police forces the power to obtain confidential health information for planning to prevent and reduce serious violence, without demonstrating that planning to reduce serious violence requires that confidential health information be shared. This risks significant harm to public trust in sharing their information, and as a result potentially compromises government plans to better engage people with their health and care data to drive innovation and improvement across the health and care system."

The NDG expanded on her concerns in a blog on her website, published on 4 October 2021.<sup>47</sup> She said: "If people feel that their information may be used in unexpected ways, for purposes they may not support, this greatly undermines the fundamental relationship of trust. The effect may be to deter patients from seeking treatment, or, when seeking treatment, to only disclose partial or false details, thereby denying clinicians the information they need to deliver safe and effective care. Incomplete and inadequate health and care records are to the detriment of both the safe care of individuals now, and of system wide planning, research, and innovation for the future."

Jointly with the BMA and the GMC, the NDG briefed both the Department of Health and Social Care and engaged members of the House of Lords regarding the above concerns and potential amendments to the Bill. The suggested amendments would have had the effect of preserving confidentiality and trust in health and care settings without undermining the drive to combat serious violence. In the House of Lords on 8 December 2021, Baroness Williams of Trafford, the Home Office Minister of State, said: "I have listened to the particular concerns in

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<sup>44</sup> <https://www.bma.org.uk/>

<sup>45</sup> <https://www.gmc-uk.org/>

<sup>46</sup> <https://bills.parliament.uk/bills/2839>

<sup>47</sup> <https://www.gov.uk/government/news/data-driven-innovation-why-confidentiality-and-transparency-must-underpin-the-nations-bright-vision-for-the-future-of-health-and-care>

respect of patient information, which is why I have tabled these amendments.... As a result, excluding patient information will mean that no authority can share that information under the provisions in this Bill and will instead need to rely on existing legal gateways should they need to do so.”<sup>48</sup>

The government responded by tabling its own amendments, which the NDG reviewed and agreed would provide adequate protection for the duty of confidence owed to patients and service users. In a letter to DHSC officials responsible for drafting the government’s revised position, the NDG said: “We were pleased to see that the amendment to the Bill provides that regulations must not authorise the disclosure of patient information, or the disclosure of personal information by a specified authority which is a health or social care authority.”

The Bill received Royal Assent on 28 April 2022.

## 6.6 Health and Care Act 2022 and the statutory data safe haven

The NDG and her team followed the passage of the Health and Care Bill<sup>49</sup> through the Houses of Parliament, and members of the NDG’s team met with peers to discuss their concerns around data processing provisions in the Bill, in particular arrangements concerning the data safe haven for health and social care.

In November 2021, the Laura Wade-Gery review, *Putting data, digital and tech at the heart of transforming the NHS*<sup>50</sup>, recommended the merger of NHS Digital and NHSX into NHS England and NHS Improvement (NHSE&I), which the government accepted and immediately moved to action. Part 9 of the Health and Social Care Act 2012 describes the functions and obligations of the safe haven for health and social care data, NHS Digital. It provides the powers for NHS Digital to collect, maintain and disseminate health and social care data. This legislative framework is accompanied by a robust Data Access Request Service (DARS)<sup>51</sup> and an advisory body to NHS Digital: the Independent Group Advising on the Release of Data (IGARD)<sup>52</sup>. This process and oversight mean that strong safeguards are in place to ensure that the principles of transparency, accountability, quality, and consistency are central to any collection and dissemination of data by NHS Digital.

Concerns were shared by stakeholders and peers regarding how this safe haven would be sustained when NHS Digital is merged with NHSE&I and the data arm of health and social care is not as clearly separated from the operational arm of the NHS who may seek to use it.

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<sup>48</sup> <https://hansard.parliament.uk/lords/2021-12-08/debates/655C3E8B-EECF-4A5F-B29D-8F46C621EE7A/PoliceCrimeSentencingAndCourtsBill#contribution-1F133BB1-6370-4242-B928-FA066CF461AA>

<sup>49</sup> <https://bills.parliament.uk/bills/3022>

<sup>50</sup> <https://www.gov.uk/government/publications/putting-data-digital-and-tech-at-the-heart-of-transforming-the-nhs/putting-data-digital-and-tech-at-the-heart-of-transforming-the-nhs>

<sup>51</sup> <https://digital.nhs.uk/services/data-access-request-service-dars>

<sup>52</sup> <https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/independent-group-advising-on-the-release-of-data>

An amendment was put forward in the House of Lords which sought to confirm that the Regulations in the Act may not transfer a function as defined in Part 9 of the Health and Social Care Act 2012. The aim was to ensure that NHSE&I do not take on this responsibility because of a potential conflict of interest in their role.

Although the amendment was defeated in the House of Commons, the NDG was assured by DHSC that it is committed to ensuring there is no erosion of safeguards around the national safe haven for data when this moves from NHS Digital to NHSE&I.

Lord Kamall, Parliamentary Under Secretary of State for Technology, Innovation and Life Sciences at the Department of Health and Social Care, stated the intention to “use the regulations which affect the transfer to provide as much statutory protection as possible for the continuation of a data safe haven in NHS England—particularly to retain the confidence of the public in how we make best use of their data, and to improve outcomes.”<sup>53</sup> He also committed in the House of Lords, regarding the merger, to “...continue to involve and consult her [the NDG], formally and informally, on these regulations”.

The DHSC has committed to ensure arrangements for independent scrutiny of NHS England’s exercise of its data functions, including all data requests, and the governance of data handling within the organisation and, furthermore, the strengthening of safeguards on a statutory basis, a proposal the NDG strongly supported. The NDG will continue to engage with the DHSC about how these protections will be established in practice, including seeking assurance that the group providing independent scrutiny will be sufficiently resourced with the requisite expertise and authority to function effectively.

Another aspect of the Bill, clause 96, contained provisions relating to the sharing of anonymous information. In evidence given to the House of Commons Science and Technology Committee, the NDG voiced her support for provisions to allow health and social care bodies to share data that has already been rendered anonymous with other health and social care bodies to support the provision of health and social care services.

The Health and Care Act 2022 received Royal Assent on 28 April 2022.

## **6.7 *Data: a new direction*: Department for Digital, Culture, Media and Sport consultation on UK data protection law reforms**

The NDG gave a formal response to the Department for Digital, Culture, Media and Sport (DDCMS) on its consultation document, *Data: a new direction*<sup>54</sup>, which proposed reforms to data protection law in the UK. She supported the government’s aim of building an improved

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<sup>53</sup> <https://hansard.parliament.uk/lords/2022-04-05/debates/520A99EA-2F2F-4526-B719-892D67CE4E8C/HealthAndCareBill>

<sup>54</sup> <https://www.gov.uk/government/consultations/data-a-new-direction>

data protection regime but raised a series of caveats about how its proposals would affect the health and care sector.

The NDG's response, published on her website on 22 September 2021<sup>55</sup>, asked the Department to provide evidence to back up statements that elements of the existing regime are creating barriers to responsible innovation and research.

The NDG urged DDCMS to consider whether the stated aims of legislative proposals could be better achieved through engagement with stakeholders and the provision of guidance from relevant regulatory authorities and sector specific bodies.

Legislative changes in this area must be considered in the broader context of the European Commission's adequacy decisions regarding the UK allowing personal data to safely flow from the EU to the UK. If the Commission were to conclude that data protection legislation in the UK was inadequate, this would pose a significant burden for UK organisations, which would have to make significant changes to their data protection practices in order to continue to receive personal data from the EU.

The NDG felt that a case had not been sufficiently made to explain and justify why many of the issues identified in this consultation required new legislative initiatives, especially when a risk of this is that the UK may no longer be deemed to provide adequate protection of personal data by the European Commission. Furthermore, information regarding the real-world impact of the government proposals was sparse, and the benefits of these changes had not been sufficiently quantified.

The NDG was particularly concerned by the government proposal to "clarify that public and private bodies may lawfully process health data...irrespective of whether the processing is overseen by healthcare professionals or undertaken under a duty of confidentiality." Upholding the common law duty of confidence is an irreducible minimum in ensuring that a trustworthy confidential health and care system is safeguarded.

The outcome of the consultation<sup>56</sup> was published on the 17 June 2022.

## **6.8 *The right to privacy: digital data: House of Commons Science and Technology Committee inquiry***

The NDG sent written evidence to the House of Commons Science and Technology Committee in February 2022 for consideration as part of its inquiry into the right to privacy

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<sup>55</sup> <https://www.gov.uk/government/publications/national-data-guardian-feedback-on-data-a-new-direction-proposed-government-reforms-to-the-uk-data-protection-regime>

<sup>56</sup> <https://www.gov.uk/government/consultations/data-a-new-direction/outcome/data-a-new-direction-government-response-to-consultation>



for digital data.<sup>57</sup> Her evidence<sup>58</sup> provided a wide-ranging analysis of why health and care data must be treated differently from other personal data because of the common law duty of confidentiality attaching to it. The NDG said that improving the collection and use of health and care data will unlock further opportunities to benefit people's health and wellbeing, and to ensure the sustainability of the health and care system.

She concluded: "Achieving this will require a deep understanding of the uniquely sensitive, confidential nature of health and care data, provided by patients and service users within the context of a reciprocal relationship with the health and care system that is based on trust. The public should not be asked to simply trust how their data is subsequently used. Rather the onus should be on the system to demonstrate its trustworthiness through a commitment to good governance, engagement and transparency, data security, the provision of authentic public choice, and ensuring that the public are represented through involvement in decision making."

The NDG subsequently gave oral evidence to the committee on 20 April 2022.<sup>59</sup>

## **6.9 Medicines and Healthcare products Regulatory Agency consultation on the future regulation of medical devices in the United Kingdom (software and AI as a medical device)**

The NDG responded to a consultation by the Medicines and Healthcare products Regulatory Agency (MHRA)<sup>60</sup> inviting comment on possible changes to the regulatory framework for medical devices in the UK. These proposals were intended to improve patient and public safety, increase the transparency of regulatory decision making, align with international best practice, and achieve more flexible, responsive, and proportionate regulation of medical devices. Of particular relevance to the NDG were sections of the consultation that classify certain types of software and AI as medical devices subject to regulation.

During 2020-21, the NDG had become aware of a need for stronger protection for the public using health and social care related software and apps, whether prescribed by a care professional or downloaded on the user's own initiative. Members of her panel were interested to establish what safeguards are required to protect the confidentiality of people providing their data into this rapidly evolving sector. They expressed particular concern after hearing a case study about an app developed by an NHS trust to help patients record their vital signs, which was subsequently sold to a commercial third party. It appeared that

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<sup>57</sup> <https://committees.parliament.uk/work/1733/the-right-to-privacy-digital-data/publications/>

<sup>58</sup>

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1064577/NDG\\_STC\\_privacy\\_inquiry\\_response\\_V2.0\\_CORRECTED\\_-\\_30.03.22.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1064577/NDG_STC_privacy_inquiry_response_V2.0_CORRECTED_-_30.03.22.pdf)

<sup>59</sup> <https://committees.parliament.uk/oralevidence/10115/pdf/>

<sup>60</sup> <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

changes in terms and conditions introduced by this commercial entity did not respect patients' privacy. Such problems seemed particularly unacceptable when patients had been encouraged by clinicians who were effectively 'prescribing' use of the app.

The NDG was represented at a regulatory CEO roundtable in January 2021 attended by a wide range of sector leaders. Among other topics, they discussed the future regulatory framework for software as a medical device, including use of artificial intelligence.

In her response to the consultation, the NDG fed back to the MHRA that it was important for the regulatory framework advice to include content on data protection, security, and confidentiality. She suggested that manufacturers should be required to demonstrate a sound and defensible position with regard to data security and protection. This could be implemented by requiring manufacturers of software that is classed as a medical device to satisfy the requirements of NHS Digital's Data Security and Protection Toolkit<sup>61</sup>, which monitors the performance of health and social care organisations.

## **6.10 Cabinet Office consultation on the expansion of the National Fraud Initiative Data Matching Powers and the new Code of Data Matching Practice**

The NDG responded in May 2021 to a Cabinet Office consultation about the expansion of the National Fraud Initiative (NFI) Data Matching Powers and the new Code of Data Matching Practice.<sup>62</sup> Under legislation passed in 2014, public authorities could be given access to records to assist in the prevention and detection of crime, in the recovery of debt owed to public bodies and for various other limited purposes. The Cabinet Office was consulting on implementing these rights of access via affirmative votes in both Houses of Parliament.

The Office of the NDG understood from discussions with Cabinet Office officials that patient data is not currently used for matching and there is no expectation that it will be. Nonetheless, as the legislation allows for this, it advised that the code of practice sets out safeguards around patient data in order to provide reassurance to the public that patient data will be treated appropriately.

The Cabinet Office was reminded that the common law duty of confidentiality is owed to all information collected for the provision of health and social care where patients and service users would have a reasonable expectation that it be kept private.

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<sup>61</sup> <https://www.dsptoolkit.nhs.uk/>

<sup>62</sup> <https://www.gov.uk/government/consultations/consultation-on-the-expansion-of-the-national-fraud-initiative-nfi-data-matching-powers-and-the-new-code-of-data-matching-practice>

The NDG's response noted that the powers could require patient data to be used for matching if that was mandated by a relevant minister or person acting on behalf of a minister. "However, we would advise that the Code of Practice should nonetheless contain safeguards for patient data to reflect the importance of maintaining public trust in the confidentiality of health and care services." This could be achieved, for instance, by the Code requiring consultation with the relevant NHS organisation's Caldicott Guardian before a requirement for data is issued. If in the future there are plans to require patient data as part of data matching, it would be important for patients and service users to be made aware in line with the UK GDPR transparency requirements and the 8th Caldicott Principle.

## 6.11 All-Party Parliamentary Group for Longevity consultation on the Open Life Data Framework

The Open Life Data Framework was developed following a recommendation of The Health of the Nation Strategy published in February 2020 by the All-Party Parliamentary Group (APPG) for Longevity<sup>63</sup>. This strategy was designed to deliver the government's goal of five extra years of healthy life expectancy, while reducing health inequalities. Representatives of the APPG attended the NDG's panel in August 2021 to discuss how the data framework could build and maintain public trust.

Panel members highlighted the importance of ensuring the APPG group is clear on the guiding principles underpinning the framework and communicating these effectively to the general public by using plain English and language that is clear and accessible. Panel members also suggested consideration should be given to the fundamental importance of doctor-patient confidentiality, the right to privacy, the importance of informed consent and the need for transparency. This would help to reassure the general public that their data is being managed properly with the appropriate safeguards in place.

The Office of the NDG responded to the APPG's formal consultation on the Open Life Data Framework in October 2021. The framework was published in November 2021.<sup>64</sup>

# 7 Advising the system

The Health and Social Care (National Data Guardian) Act 2018<sup>65</sup> provides statutory authority for the NDG to "give advice and information about, and assistance in relation to, the

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<sup>63</sup> <https://appg-longevity.org/>

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<https://static1.squarespace.com/static/5d349e15bf59a30001efeaeab/t/619a82bf919e361f933c4fd7/1637515987580/Open+Life+Data+Framework+Report+18+November+2021+v3+final.pdf>

<sup>65</sup> <https://www.legislation.gov.uk/ukpga/2018/31/contents/enacted>

processing of health and adult social care data in England.” In 2021-22, that advice-giving role formed a large part of the workload of the NDG, her team and her panel of advisors. Over the last year, data protection legislation and the common law duty of confidentiality, combined with application of the Caldicott Principles, provided the basis for a wide range of advice given to the system. This section provides a summary of some of that advice, and details of the organisations, projects, and programmes that the NDG engaged with.

## **7.1 CQC report on care home deaths involving COVID-19**

The Care Quality Commission (CQC)<sup>66</sup> approached the NDG in July 2021 when it wanted to publish data about deaths of residents of individual care homes involving COVID-19.

Because of the small number of deaths on an individual care home basis, CQC identified a small risk that the published data could identify individuals if combined with other information. As the common law duty of confidentiality continues to apply after death, publishing these small numbers, which might permit identification, could breach confidentiality. The CQC asked for advice as to whether the obligation of confidence could be overridden due to the public interest in disclosure, and the low chance of reidentification.

The NDG advised the CQC to make a clearer case to establish the public interest in publication, as the initial case focussed on the low risk of identification in the balancing of competing interests. The NDG advised that the balancing exercise needed to focus on whether the duty of confidence could be set aside because there is a public interest in disclosure that outweighs the individual’s interest in confidentiality. Within this context, the perceived low risk of identification and perceived low risk of significant harm could be considered. In response to NDG advice, the CQC revised its balancing test setting out the public interest justification factors more clearly, which led it to publish its report<sup>67</sup>.

## **7.2 GP Connect: sharing clinical information with adult social care**

Senior officials from DHSC wrote to the NDG in February 2022 about plans to give non-clinical staff in Care Quality Commission (CQC) registered social care settings greater access to essential medical information about people in their care.

They explained that CQC-registered managers and other non-clinical staff would be able to view a partial version of the GP record including allergies, medications, immunisations and the last three interactions with the GP. This filtered summary of the GP record would be available through GP Connect<sup>68</sup> to adult social care staff who needed it for direct care

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<sup>66</sup> <https://www.cqc.org.uk/>

<sup>67</sup> <https://www.cqc.org.uk/news/releases/care-quality-commission-publishes-data-showing-death-notifications-involving-covid-19>

<sup>68</sup> <https://digital.nhs.uk/services/gp-connect>

purposes. Access to this data would be limited to staff with appropriate training and where there is appropriate technology and data security requirements in place. Data would remain stored on NHS approved systems, and transmitted via secure NHS maintained infrastructure, then viewed on a read-only basis within local assured digital social care record (DSCR) supplier systems with role-based access controls in place.

The NDG welcomed the proposals as good progress in data sharing, which respected the Caldicott Principles. She said: "Providing staff with the information that they require to provide direct care sits well within people's expectations. It is also necessary to enable effective and coordinated care across the health and social care sectors. I believe the plans outlined in your letter to allow non-clinical social care staff to have access to limited information for care purposes only, are necessary."

Following this advice, DHSC began implementing the scheme from March 2022, and the GP Connect team subsequently shared feedback on its use. As of July 2022, approved staff across 524 CQC-registered care providers have been able to access GP Connect, with summaries, medications and the last three encounters with a GP being the top items viewed.

A manager at Peverel Court care home, Kefas Jeshua, said, "Accessing the GP record helps us to understand the 'what' and the 'why' around an individual's needs. If there are concerns regarding medication, we can review the record and make more informed decisions. GP Connect is particularly helpful when admitting a new resident, by having this information at hand we can provide the best possible care from the start. Before GP Connect, we would wait for an email or phone call from the GP. Now we can access the relevant information instantly, which is great!"

The programme is on continuous roll-out and at the time of writing this report, 22,000 people's records were available to their social care settings via GP Connect.

### **7.3 Record sharing programmes and information governance**

NHSX<sup>69</sup> consulted the NDG before writing to all NHS data protection officers (DPOs) about the need for local shared care record systems to respect the common law duty of confidentiality. In September 2021, Simon Madden, Director of Data Policy at NHSX, wrote to remind DPOs that sharing information about patients and service users for purposes other than direct care requires careful consideration, since people may not expect that their information will be shared for such purposes. He said:

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<sup>69</sup> A joint unit of DHSC and NHS England, which has now become the NHS Transformation Directorate

“It is a responsibility of the joint data controllers within your Integrated Care System or partnership to ensure that there is a robust legal justification for processing data for secondary health and care purposes ... If you are sharing information from your local record sharing system for purposes other than direct care then you are required to consider how you will satisfy or set aside the common law duty of confidentiality as implied consent will not be appropriate.”

The letter set out the legal bases that organisations could rely on to lift the obligation of confidence and advised data controllers to document the basis that they rely on. The NDG supported this letter and hopes that shared care record programmes will follow it to facilitate compliance with the common law duty of confidentiality.

## 7.4 Integrated Care Systems and Caldicott Guardians

Key changes introduced by the Health and Care Act 2022<sup>70</sup> include the statutory establishment of integrated care systems (ICSs), the retirement of clinical commissioning groups (CCGs), and the introduction of integrated care boards (ICBs) to replace their functions, and integrated care partnerships (ICPs) to bring together a broad alliance of partners concerned with improving the health and wellbeing of the population. While this legislation was going through Parliament the NDG gave advice about relevant sections.

As ICBs have “the function of arranging for the provision of services for the purposes of the health service in England” they fall within scope of those required to have regard to the NDG’s guidance on Caldicott Guardians<sup>71</sup>. This means that they should put in place a Caldicott Guardian, whether by appointing a member of their own staff or making other arrangements. The NDG and the UK Caldicott Guardian Council met with the NHS England System Transformation team to talk about Caldicott Guardian representation within ICBs, and the information sharing challenges the system faces as it reconfigures in accordance with the Act and delivers on the four core purposes of ICSs<sup>72</sup>.

They explored how best to work together to engage and support the Caldicott Guardian community to transition effectively – including how to ensure the Caldicott Guardian function is appropriately implemented in an integrated system to support the legal, ethical, and appropriate use of confidential information.

From 1 July 2022, all 42 ICBs had put in place a nominated Caldicott Guardian.

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<sup>70</sup> <https://www.legislation.gov.uk/ukpga/2022/31/contents/enacted>

<sup>71</sup> <https://www.gov.uk/government/publications/national-data-guardian-guidance-on-the-appointment-of-caldicott-guardians-their-role-and-responsibilities>

<sup>72</sup> <https://www.england.nhs.uk/integratedcare/what-is-integrated-care/>

## 7.5 Future-proofing existing GP data uses

The NDG advised the General Practice Extraction Service (GPES)<sup>73</sup> programme about the potential to implement a new, more efficient system for ensuring that GP practices are paid accurately for the work they have done. The NDG was advised that the present payment system is 10 years old and is struggling to cope with the volume of data requests going through it and the complexity of some of those requests. The programme team discussed the potential of moving from using anonymous aggregate data to using pseudonymised patient information for the purposes of invoice validation. The NDG was reassured that only the codes currently processed in GPES (those relevant to the activity requiring payment) would flow to NHS Digital under this proposal. Should this model be implemented, it would also change the current arrangement wherein three private providers are processing GP data for payments to one where the NHS does so instead.

The team asked for advice about whether, in principle, it would be reasonable to waive type 1 opt-outs to allow NHS Digital to process data from general practice for the purposes of invoice validation, since the processing of patient information for the purpose of invoice validation does not fit within the definition of direct care. The issue came before the NDG's panel in July 2021 and January 2022. Panel members noted that data being processed for payments is a necessary consequence of direct care. They agreed it was right that providers of care or services should receive payment, and that evidence suggests that it may be within patients' reasonable expectations that practices get paid accurately for the services they deliver. But the panel did emphasise the need for transparency about the role people's data plays in the payment process.

The NDG's subsequent advice was that allowing the pseudonymised information about patients with a type 1 opt-out to flow to NHS Digital for the very narrow invoice validation purposes proposed would be analogous to the current arrangement, wherein the national data opt-out is waived under section 251 support to allow Controlled Environments for Finance to process information from NHS Digital for invoice validation. The NDG also recommended that should this proposal go ahead, the programme should consider working with GP practices to update their public-facing information to make it clear that people's type 1 objection will not prevent the processing of pseudonymised information by NHS Digital for the purpose of invoice validation.

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<sup>73</sup> <https://digital.nhs.uk/services/general-practice-extraction-service>

## 7.6 Accelerating citizen access to GP data

The NDG gave advice to NHS England (NHSE) about its plans to accelerate patients' access to their prospective medical record by automatically enabling access through the NHS App<sup>74</sup> and GP online services<sup>75</sup>. These plans accord with the NDG's long-standing priorities for removing barriers to people's access to their record and providing them with information about how their data has been used.<sup>76</sup> Better access to health information enables patients to better manage their health.

According to NHSE's original timetable, patients using the NHS App and other GP online services would have gained access to new entries in their record from December 2021. However, the NDG was mindful of concerns raised by the Royal College of General Practitioners (RCGP) and the British Medical Association (BMA) regarding the burden on the GP workforce and the potential for some patients to be put at risk of serious physical or mental harm if the programme proceeded without adequate workforce preparation. NHSE committed to RCGP's recommendation of providing GP teams with a minimum preparation time of two months for this change.

Following further engagement, including with patients, patient groups, the RCGP and the system more widely, and building on learning from early adopter sites, NHSE confirmed the change will take place on 1 November 2022. Additional time and supporting guidance will help practices to prepare, by identifying individuals potentially at risk, informing staff and patients of the change, and building confidence in record access. Patients will be able to view their online data in their GP record, as it is entered, from 1 November 2022.

The NDG noted that empowering patients through direct access to records is important. Healthcare providers and partnership organisations should continue to share important information with general practice. Good record keeping is critical for clinicians – even more so now that records will be valuable to both clinicians and patients. Given the time pressures on our health and care staff, in making these changes it is important that the right balance is struck between usefulness for clinicians and patients, with both benefiting from safe and effective record access.

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<sup>74</sup> <https://digital.nhs.uk/services/nhs-app>

<sup>75</sup> <https://www.england.nhs.uk/gp-online-services/>

<sup>76</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/192572/2900774\\_InfoGovernance\\_accv2.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf)



## 7.7 Data Security and Protection Toolkit

The Data Security and Protection Toolkit (DSPT)<sup>77</sup> is an online self-assessment tool developed and managed by NHS Digital that allows organisations to measure their performance against the National Data Guardian's 10 data security standards<sup>78</sup>.

All organisations that have access to NHS patient data and systems must use this toolkit to provide assurance that they are practising good data security and that personal information is handled correctly. The NDG engages regularly with the DSPT team and has an interest in the findings from the DSPT annual returns.

The team visited panel in August 2021 to discuss the results of the 2020-21 submissions. Over 42,000 organisations completed DSPT in 2020-21, an 18% rise compared to 2019-20. This was mainly due to an increase in social care organisations completing the DSPT toolkit as a result of a DHSC programme to support data security in social care called Better Security Better Care<sup>79</sup>.

Panel members were not surprised to see that the target for 95% of staff to receive appropriate training remains one of the most challenging requirements. However, they understood that it is right to keep this target high, as it emphasises the importance of training and encourages a higher attainment level.

The NDG was encouraged by the development of the DSPT audit and assurance regime<sup>80</sup>. This implements a recommendation that was made in both the Caldicott review, 'Review of Data Security, Consent and Opt-Outs'<sup>81</sup> and the Care Quality Commission report, 'Safe data, safe care'<sup>82</sup>: "Arrangements for internal data security audit and external validation should be reviewed and strengthened to a level similar to those assuring financial integrity and accountability"<sup>83</sup>. Connected medical devices were also introduced into the scope of the DSPT during 2021-22; this developing area of data security presents new challenges, and the NDG was pleased to see this recognised in the DSPT.

During 2021-22, the NDG's team was involved in discussions about the key changes to DSPT requirements, and about the new DSPT purpose/mission statement. The NDG was pleased to hear that the DSPT team plan to signpost to the new Caldicott Guardian elearning modules through the DSPT, its website and other products.

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<sup>77</sup> <https://www.dsptoolkit.nhs.uk/>

<sup>78</sup> <https://digital.nhs.uk/cyber-and-data-security/guidance-and-assurance/data-security-and-protection-toolkit-assessment-guides>

<sup>79</sup> <https://www.digitalsocialcare.co.uk/data-security-protecting-my-information/better-security-better-care/>

<sup>80</sup> <https://www.dsptoolkit.nhs.uk/News/auditnews>

<sup>81</sup> <https://www.gov.uk/government/publications/review-of-data-security-consent-and-opt-outs>

<sup>82</sup> <https://www.cqc.org.uk/publications/themed-work/safe-data-safe-care>

<sup>83</sup> p. 9, Review of Data Security, Consent and Opt-Outs, June 2016; p. 29, Safe data, safe care, July 2016

The DSPT team fed back that the NDG's support has been very useful this year, acting as a critical friend for the development of the DSPT, particularly on training requirements for Caldicott Guardians and the wider discussions about staff training.

## 7.8 Screening Quality Assurance Service (SQAS)

The Screening Quality Assurance Service (SQAS) attended panel in October 2021 to discuss the legal basis regarding the processing of confidential patient information to undertake its work relating to clinical safety, screening programme service specifications and quality assurance audits of local service providers.

SQAS auditing of quality of *local* screening programmes is considered to be direct care, in line with advice provided by the Information Governance Review<sup>84</sup>. The NDG was asked to consider whether *national* quality assurance audits undertaken by SQAS could also be considered direct care and, if so, whether the data sharing within SQAS could be permitted on the basis of implied consent. Alternatively, the NDG was asked to consider if it would be within patients' reasonable expectations for their data to be shared to SQAS to improve the screening purposes.

Processing of confidential patient information for national screening quality assurance within SQAS is currently undertaken with support under section 251 of the National Health Service Act 2006<sup>85</sup>, which allows it to process the relevant confidential patient information for these purposes without breaching the duty of confidentiality. The NDG advised that this remains the most suitable legal basis on which SQAS can continue its current operations. However, she felt that their work raised interesting questions around direct care and reasonable expectations.

As the effectiveness of screening services is fundamental to the delivery of safe and high-quality direct care, the NDG felt that there was potential for considering whether auditing direct care services can be considered within the reasonable expectations of patients and the public. Creating such an expectation would depend on the development of information and communication with patients and the public to ensure compliance with the longstanding NDG principle of 'no surprises' for patients about how their data is used.

## 7.9 Ada Lovelace Institute: digital inequalities research

Reema Patel, then Associate Director for Public Engagement at the Ada Lovelace Institute<sup>86</sup>, attended the NDG's panel in August 2021 to discuss the institute's research, which considers

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<sup>84</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/192572/2900774\\_InfoGovernance\\_accv2.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf)

<sup>85</sup> <https://www.legislation.gov.uk/ukpga/2006/41/section/251>

<sup>86</sup> <https://www.adalovelaceinstitute.org/>

how digital inequalities can be addressed when approaches to digital technologies are designed well. Reema explained how technologies such as symptom trackers, digital contact tracing apps and vaccine passports have challenged us to think through how to make data and artificial intelligence work equitably for everyone. Panel considered the risk that digital technology may exacerbate health inequalities because some people do not have the skills, equipment, or inclination to access digital services.

Panel members welcomed this research initiative. They suggested it may be helpful to engage with the voluntary and community sector, which has close links with communities who both do and do not have access to digital technologies, to inform their research and develop case studies.

## 7.10 UK Health Security Agency

The UK Health Security Agency (UKHSA)<sup>87</sup> was launched in October 2021 with responsibility for protecting the community from the impact of infectious diseases, chemical, biological, radiological and nuclear incidents and other health threats. It took over work previously done by Public Health England, NHS Test and Trace and the Joint Biosecurity Centre.

Before the launch, the NDG had an introductory meeting in July 2021 with Dr Jenny Harries, the UKHSA's chief executive. UKHSA officials then attended panel in February 2022. The NDG gave wide-ranging advice about how the UKHSA could build on the public support that its predecessor organisations earned during the pandemic. She emphasised that legal compliance is a necessary, but not a sufficient condition for building public trust. It is essential that any organisation handling data on a large scale should “hard bake” transparency and public involvement into every relevant aspect of its work.

The UKHSA said it was considering the development of an oversight group to advise it on any proposals for novel, nuanced or contentious uses of data. The NDG encouraged this, saying that independent, transparent advisory groups with lay membership are a strong safeguard and a well-proven route to building trust. Their role in the data access process provides vital reassurances to the public. The NDG pointed to NHS Digital's Independent Group Advising on the Release of Data (IGARD)<sup>88</sup> as an example of what good, independent oversight looks like. The NDG welcomes that the UKHSA:

- is exploring options for the inclusion of independent voices in governance
- plans to set out an ethical framework for the use of data that it holds
- has appointed a Caldicott Guardian.

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<sup>87</sup> <https://www.gov.uk/government/organisations/uk-health-security-agency>

<sup>88</sup> <https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/independent-group-advising-on-the-release-of-data>

## 7.11 NHS DigiTrials: data services to support clinical trials

NHS DigiTrials<sup>89</sup> is an NHS Digital programme that offers data services to support clinical trials. It has been working with the NHS-Galleri Trial<sup>90</sup> as a pilot to help identify suitable people to invite to participate in the trial. The trial obtained support from the Health Research Authority (HRA) under section 251 of the NHS Act 2006, for NHS Digital to process data on its behalf for the purposes of identifying and contacting people who might be eligible to participate in the trial. A condition of this support was that people should be offered a specific opportunity to opt out of being contacted to participate in the trial.

NHS DigiTrials asked the NDG for advice on whether it was appropriate to offer people a trial specific opt-out (prior to being invited to trial) for the NHS DigiTrials service, in addition to the national data opt-out. The concern was that the creation of multiple different opt-outs would be confusing, and conflict with the aim of the national data opt-out, which was introduced to simplify the opt-out landscape. The NDG noted the potential complexity and subsequent burden on people if they have to opt out of being contacted for each individual NHS DigiTrials project and discussed whether the option of a general opt-out from receiving contact from NHS DigiTrials might be worth considering.

NHS DigiTrials is undertaking further research with the public, building on a public survey, focus groups and testing with their patient panel around clinical trial invitations and opt-outs. The NDG and her office have engaged with the NHS DigiTrials team as they undertake this research, making suggestions on the language used for people to register their choices.

The NDG will continue to engage with the programme in 2022-23 as they progress their dialogue with the public to understand how opting out of being approached to participate in clinical trials can best sit within the wider opt-out landscape without causing confusion.

## 7.12 NHS Secure Data Environments

The NDG and her panel are following with great interest the design and development of secure data environments (SDEs) for research, in particular the Data for R&D Programme's national and sub-national investments, announced in March 2022<sup>91</sup>. SDEs aim to provide approved researchers from verified organisations with secure access to health and care data, while ensuring that only approved data can leave the platform.

The NDG strongly supports the move away from data dissemination towards data access in SDEs given the much stronger privacy, oversight, and security protections they enable. The

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<sup>89</sup> <https://digital.nhs.uk/services/nhs-digital-trials>

<sup>90</sup> The NHS-Galleri trial is looking into the use of a new blood test to see if it can help the NHS to detect cancer early and if successful this will form part of the cancer screening programme.

<sup>91</sup> <https://www.gov.uk/government/news/260-million-to-boost-healthcare-research-and-manufacturing>

transition to SDEs was committed to in the recent data strategy *Data saves lives: reshaping health and care with data*<sup>92</sup>, with 11 draft guidelines for their implementation. It also included commitments to develop technical guidance for the system and an accreditation framework to ensure that all SDEs meet minimum requirements, for instance information governance, training and patient and public involvement and engagement.

The NDG has valued engagement so far on the underlying policy approach to delivering SDEs in the NHS. She invited the programme team to panel in March 2022 to discuss their work to develop the policy, processes, and infrastructure for the national and sub-national investments. She commended their work to establish these in a demonstrably safe and trustworthy manner, and suggested areas for consideration, with the principal theme being that they should make every effort to build into their policies, systems, and processes all of the elements that research tells us are the key ingredients for earning public trust.

A key discussion point was the importance of communications and demonstrating a commitment to transparency, and the bearing that this has on public trust. Here, the NDG and her panel noted the risk of using multiple terms to describe similar data access platforms, with a confusing use of terms for both research platforms (e.g., TRE) and separate terms for platforms to support NHS planning and management. She understands the term 'secure data environment' is now being used as it captures the use of these platforms beyond 'research' to include planning and population health management too.

Another significant area of interest for the NDG was the assurance process for data applications and the importance of robust safeguards around this, including independent oversight and scrutiny for internal as well as external applications. She also advised that it would be important to minimise exceptions to the use of SDEs, even if a particular data access scenario is challenging. She further emphasised that getting public transparency and communication right around these exceptions will be crucial to avoid undermining public trust in the data access system.

NDG acknowledged the significant challenge of developing an offering and supporting policies that are scalable and work at both a national and sub-national level when the development is complex and subject to many variables, interdependencies and moving parts. She intends to stay in communication with the team throughout 2022-23 as they develop and implement policy and guidance around SDEs.

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<sup>92</sup> <https://www.gov.uk/government/publications/data-saves-lives-reshaping-health-and-social-care-with-data/data-saves-lives-reshaping-health-and-social-care-with-data>

## 7.13 Centre for Improving Data Collaboration

In the 2020 Life Sciences Industrial Strategy update<sup>93</sup>, the Office for Life Sciences<sup>94</sup> committed to establishing the Centre for Improving Data Collaboration (CIDC)<sup>95</sup> previously referred to as the Centre for Expertise. CIDC sits within NHS England and provides specialist advice to health sector organisations entering into data partnerships to ensure these align with DHSC's five guiding principles for data sharing partnerships<sup>96</sup>.

A CIDC representative attended panel in May 2021 to discuss its Value Sharing Framework (VSF): guidance to the NHS on operationalising the five principles, as well as building strong and fair health data partnerships. Ongoing work to explore mechanisms for value redistribution was discussed and CIDC took several of the panel's suggestions on board, including that it would be helpful to provide template contracts.

CIDC made commitments in *Data saves lives: reshaping health and care with data*<sup>97</sup> to publish the VSF by March 2023, and to develop commercial principles to ensure that partnerships for access to data for research and development have appropriate safeguards and benefit the public and the NHS by December 2023.

## 7.14 Acute Data Alignment Programme

The Acute Data Alignment Programme (ADAPT)<sup>98</sup> is run jointly by NHS Digital and the Private Healthcare Information Network (PHIN). It seeks to adopt common standards for data collections and performance measures across the NHS and private healthcare.

ADAPT's representatives attended the NDG's panel in March 2022 to discuss their work. The NDG welcomed the programme's vision to improve the consistency, transparency, quality, and safety of care through the alignment of data and data standards across the NHS and private healthcare. Providing visibility of a person's entire care pathway, regardless of where their care was delivered, will benefit both those receiving and delivering care, as well as helping researchers and service planners.

The national data opt-out does not apply to private patients at private providers<sup>99</sup>. The NDG noted that people may find it difficult to understand why private patients cannot opt out of the sharing of their confidential patient information (CPI) for planning and research via the

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<sup>93</sup> <https://www.gov.uk/government/publications/life-sciences-industrial-strategy-update>

<sup>94</sup> <https://www.gov.uk/government/organisations/office-for-life-sciences>

<sup>95</sup> <https://transform.england.nhs.uk/key-tools-and-info/centre-improving-data-collaboration/>

<sup>96</sup> <https://www.gov.uk/government/publications/creating-the-right-framework-to-realise-the-benefits-of-health-data/creating-the-right-framework-to-realise-the-benefits-for-patients-and-the-nhs-where-data-underpins-innovation#guiding-principles>

<sup>97</sup> <https://www.gov.uk/government/publications/data-saves-lives-reshaping-health-and-social-care-with-data/data-saves-lives-reshaping-health-and-social-care-with-data>

<sup>98</sup> <https://www.phin.org.uk/about/acute-data-alignment-programme-adapt->

<sup>99</sup> Where NHS Digital receive this data and links it to NHS data, if an opt applies to that individual then NHS Digital will apply the opt-out where the legal basis requires it.

national data opt-out in the same way that patients whose treatment is publicly funded can. The distinction between sectors should be carefully considered by private providers when policies with regard to use of data beyond individual care are determined, as public trust will be affected if a lower level of protection for CPI is perceived in the private sector.

It was also discussed that in private healthcare, privacy notices and consent forms vary considerably between providers. The NDG provided feedback that this would be a good opportunity for the private sector to take account of good information governance practice in the NHS and align information governance in privately funded health care. Regarding this variation, the programme noted that pilot participants were provided with IG guidance on requirements for privacy and consent, and that future submitters would be too.

Unlike NHS providers and local authorities, private healthcare providers are not required to appoint a Caldicott Guardian unless they are contracted to deliver publicly funded services. However, many organisations choose to appoint one because they recognise the value of having a dedicated individual with responsibility for the ethical and legal aspects of safeguarding the confidentiality of people's information. Further to this, the long-standing Caldicott Principles<sup>100</sup> are a set of eight good practice guidelines that any organisation which handles patient data should seek to observe. The NDG suggested that the programme may consider discussing these safeguards with private healthcare providers.

The NDG was pleased to hear that the project has taken public engagement and consultation seriously since its inception. It was reassuring to know that a public consultation will take place before any formal recommendations are made.

The ADAPt programme welcomed the NDG's input, emphasising that it is committed to continuing engagement with the public and private providers to ensure that data collection, sharing and use is transparent and aligns with best practice.

## **7.15 NHS COVID-19 Data Store and Data Platform**

The team at NHS England responsible for managing the NHS COVID-19 Data Store and Data Platform (which is powered by Palantir's Foundry operating system) met with the NDG to update her on both the publication of its COVID-19 data dissemination register and the benefits they were realising by using the data platform (and applying lessons learned from their COVID-19 response) to address the elective backlog caused by COVID-19.

They informed her about the pilot scheme at Chelsea and Westminster Foundation Trust in which the Trust is using its own instance of the data platform to manage its waiting lists and optimise theatre utilisation. The pilot aims to reduce inpatient waiting lists and prioritise care

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<sup>100</sup> <https://www.ukcgic.uk/the-caldicott-principles>

more efficiently, ensuring that patients are seen faster and in the right order. The team reported that at Chelsea and Westminster, theatre productivity has increased significantly, and no-show rates have fallen to below 1% as the lead time for informing patients on appointment details has increased. The solution was initially piloted in four specialities but is now being used in every department. Following the success of this proof of concept, NHS England is funding the deployment of the solution in 38 more Trusts in 2022.

During these discussions, the important role that transparency in data use plays in the building of public trust was also discussed. Beyond simply meeting legal obligation, the public should be able to easily find information in an accessible format about who has been permitted access to their data and why, including where access is granted to commercial organisations. The NDG advised that empirical evidence suggests that the public are not necessarily against the involvement of commercial companies in data driven innovation. However, their support is conditional: the rationale for their involvement needs to be made clear; the organisation needs to demonstrate it is trustworthy to the public; private profit should not outweigh public benefit; and adequate safeguards against improper use must be in place.

The team advised that the NDG's advice would inform their planning for the future, national federated data platform (FDP). The NDG will continue to engage with the programme during 2022-23 as its plans for the development and implementation of the FDP take shape.

## **7.16 Control of Patient Information notice exit guidance**

Four Control of Patient Information (COPI) notices<sup>101</sup> were issued at the start of the COVID-19 pandemic to require the processing and sharing of confidential patient information (CPI) amongst health organisations and other bodies where it was needed to support the COVID-19 pandemic response.

The notices were initially issued for a period of six months. However, they were extended a number of times due to the ongoing nature of the pandemic and the continuing need to process CPI to help with the response. They remained in force throughout 2021-22.

The Office of the National Data Guardian (ONDG) engaged with the NHS Transformation Directorate to provide advice to organisations processing CPI under COPI notices about the sustainable legal bases for any processing that needed to continue when the notices expired. The ONDG fed into the development of a step-by-step guide to help organisations relying on the notice to prepare for the 30 June 2022 expiration date.

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<sup>101</sup> <https://www.gov.uk/government/publications/coronavirus-covid-19-notification-of-data-controllers-to-share-information>



# 8 Supporting the system through board and panel membership

Much of the NDG's advice and guidance is delivered through regular meetings and input at various boards, panels, and groups. During 2021-22, these were the forums that the NDG and her representatives attended.

1. Public Service Delivery Review Board
2. Digital Economy Act - Early help and prevention subgroup
3. NHS Digital Research Advisory Group
4. Data & Cyber Security Programme Board
5. The Data Security and Protection Toolkit Working Group
6. Article 40 Code of Conduct Health and Care Information Governance Panel (HCIGP) Workshops
7. Health Data Research UK's UK Data Research Alliance Board
8. Data and Analytics Research Environments UK's Public Dialogue Oversight Group
9. Health and Care Information Governance Panel
10. Information Commissioners Office (ICO) anonymisation guidance
11. Digital Social Care Advisory Group
12. Health and Care Information Governance Working Group
13. Digital Health and Care Plan engagement sessions
14. NDG engagement with Test and Trace Caldicott Guardian
15. Cyber Security Leadership Board
16. NDG engagement with the ICO and COVID-19 app team
17. NHS AI Lab Advisory Group
18. EU Joint Action on Data and Health
19. Open Life Data Task Group for All Parliamentary Advisory Group on Longevity and National Data Strategy
20. IG Policy Key Messages Webinars
21. Professional Record Standards Body advisory board
22. GP Data for Planning and Research Advisory Group
23. GP Data Patient and Public Engagement and Communications Advisory Panel
24. GP Data for Planning and Research IG Expert Liaison Group
25. National Information Governance Templates Task and Finish Group
26. Accelerating Citizen Access to GP Data Senior Responsible Owner (SRO) Steering Group
27. AI Lab Stewardship and AI Oversight Group
28. ICO Privacy Enhancing Technologies workshop series
29. NHS DigiTrials workshop group

## 9 Priorities 2022-2023

The work priorities set out below describe the projects and other practical actions we will take to deliver against our strategic objectives. The NDG has three priorities for 2022-23:

### 9.1 Advising, supporting, and overseeing system change

There is much to be done in 2022-23 to support and advise the health and social care system regarding its use of confidential patient information, especially as the system is entering a period of significant legislative and operational structural change. Given the breadth and scale of the changes introduced by the data strategy and system restructure, the NDG and her panel will be looking to ensure that confidentiality and public trust remain a high priority, and that the processes and safeguards essential to a confidential health and care system are maintained.

#### Areas of interest for the NDG:

These key areas will require ongoing NDG involvement and oversight. This is not an exclusive list; the NDG will continue to respond to requests for advice and react to developments.

- The transition to Integrated Care Systems
- The merger of the NHS Digital 'data safe haven' into NHS England
- The use of data in a post COPI notices landscape
- Implementation of *Data saves lives: reshaping health and care with data*
- Data Protection and Digital Information Bill
- Health and Care Information Governance Panel / Working Group
- General Practice Data for Planning and Research programme
- Accelerated Access to GP Records programme
- The Data Security and Protection Toolkit
- Implementation of secure data environments / trusted research environments
- Implementation of the NHS federated data platform
- The Information Commissioner's Office's anonymisation, pseudonymisation and privacy enhancing technologies guidance
- Implementation of opt outs
- The definition of direct care in a collaborative and digitised health and social care system

## **9.2 Publishing guidance to help the system interpret what is meant by the term ‘public benefit’ when health and care data is used for secondary purposes**

The need for secondary uses of health and care data to deliver a public benefit is an essential criterion in establishing public support for access to that data. But what constitutes ‘public benefit’ in a data sharing context is an ill-defined concept. And so the NDG’s ‘Putting Good into Practice’ deliberative engagement project explored how people evaluate public benefit where health and care data is used for secondary purposes. The dialogue was carried out with the intention of informing NDG policy advice or guidance that will provide an interpretation of the term ‘public benefit’ that is rooted in empirical research. This will help organisations conduct public benefit evaluations that are consistent with public thinking.

### **Work and outputs**

We are developing a guidance document that will help any organisation that processes confidential or personal health and adult social care data (for reasons other than the provision of direct care) to evaluate whether their intended use of the data can be considered to deliver a public benefit. We have been refining this guidance throughout 2021-22. During 2022-23, we intend to finalise it and obtain reassurances from stakeholders that it: a) sufficiently fulfils the unmet need, b) and adds value for the sector, c) is workable and practical. Following this, we will communicate the guidance widely across the sector.

## **9.3 Reasonable expectations research project**

Previous work by the NDG has explored the concept of reasonable expectations and whether it could offer an appropriate legal basis for the disclosure and use of confidential patient information in specific circumstances. We now want to undertake a research project with the aim of better understanding whether clear expectations can be created regarding uses of data collected in the context of providing health and care – and what actions might be required to create those expectations.

### **Work and outputs**

Together with academic partners and research and insight specialists, we will aim to carry out both qualitative and quantitative investigations. We plan to work in partnership with specific programmes that use data to develop communications products relevant to their work and audiences, and together we will test whether particular methods can practically create and maintain people’s expectations.

We expect our academic partners to publish a peer reviewed paper reporting on the work, methods, and findings. This report will identify and describe whether there are high-level principles that enable expectations to be established and maintained, also whether there are

factors that might prevent the creation of reasonable expectations. Based on the findings, the NDG may then decide to develop guidance on creating reasonable expectations.

## 10 Financial statement

The National Data Guardian (NDG) is a non-incorporated office holder who does not employ staff, hold a budget, or produce accounts. The Department of Health and Social Care (DHSC) holds the budget and reports expenditure through the DHSC Annual Report and Accounts.

The budget meets the costs of:

- The Office of the NDG, hosted by NHS Digital
- The work of the NDG and the advisory panel
- The work of the associated UK Caldicott Guardian Council
- Events, public engagement, and legal advice
- The remuneration of the NDG

Except for the NDG's remuneration (the NDG is paid as a public appointee), the NDG has the flexibility to determine the allocation of the available budget according to in-year priorities.

For 2021-22 the budget was £745,269.

## 11 Appendix A: NDG panel members

The NDG was supported by the following panel members during 2021-2022:

- **Dr Joanne Bailey** (former GP, tribunal member (Social Entitlements), clinical ethics tutor)
- **Dr Chris Bunch** (vice chair of the UK Caldicott Guardian Council and former consultant physician and Caldicott Guardian at Oxford University Hospitals NHS Foundation Trust)
- **Sam Bergin Goncalves** (patient and public involvement representative)
- **John Carvel** (freelance writer, formerly social affairs editor of The Guardian)
- **Professor Ian Craddock** (professor in the Faculty of Engineering at the University of Bristol)
- **Dr Arjun Dhillon** (GP, clinical director and Caldicott Guardian at NHS Digital, UK Caldicott Guardian Council chair)
- **Dr Edward Dove** (lecturer in health law and regulation at the Law School, University of Edinburgh)
- **Dr Fiona Head** (GP, public health consultant and chief medical officer at Cambridgeshire and Peterborough Integrated Care System)

- **Andrew Hughes** (Local Government Association's director of health and wellbeing systems improvement)
- **Mr Adrian Marchbank** (consultant cardiothoracic surgeon and Caldicott Guardian, University Hospitals Plymouth NHS Trust)
- **Rakesh Marwaha** (former commissioning accountable officer)
- **Maisie McKenzie** (patient and public involvement representative)
- **Eileen Phillips** (freelance writer, communications consultant)
- **Rob Shaw** (managing director at Mercury Technology Ltd; former deputy chief executive, NHS Digital)
- **Professor James Wilson** (professor in the Department of Philosophy at University College London)

Panel members who left part-way through this financial year:

- **Dr Geoff Schrecker** (former GP, PRSB clinical adviser and specialist member of IGARD)
- **Professor Martin Severs** (Chief Medical Officer at Zesty; former Caldicott Guardian / Lead Clinician, NHS Digital)
- **David Watts** (Director of Adult Services (DASS) North Northamptonshire Council)

The NDG extends her most sincere thanks to those who left her advisory panel this year for the time they dedicated to supporting both her and Dame Fiona Caldicott before her.