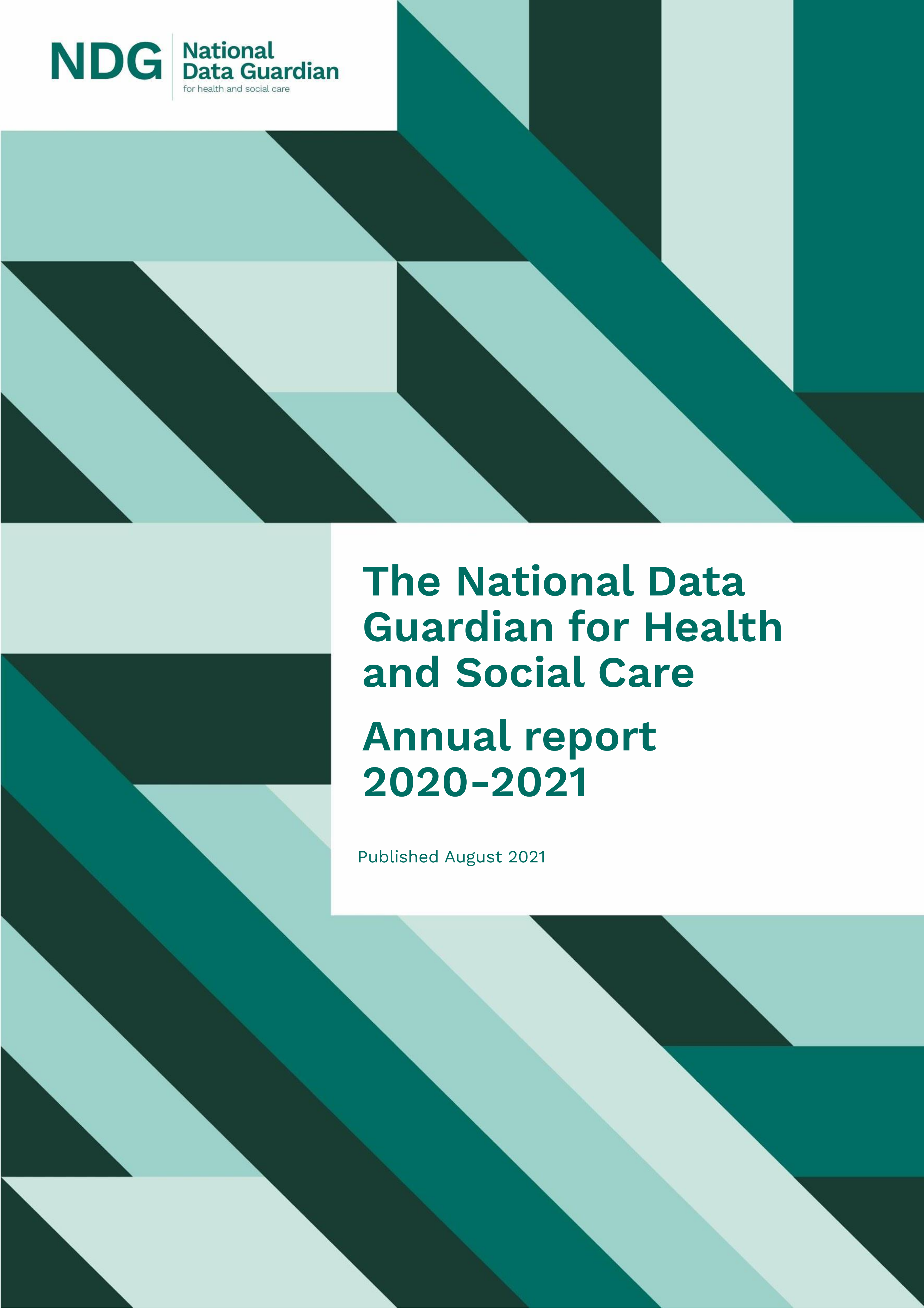
NDG National Data Guardian
for health and social care



The National Data Guardian for Health and Social Care

Annual report 2020-2021

Published August 2021

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Foreword from the National Data Guardian

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

I am pleased to present this report on the work of the National Data Guardian for Health and Social Care (NDG) in 2020-21, but I can take no credit for the achievements it chronicles. Throughout most of the year the position was held with great distinction by Dame Fiona Caldicott. Sadly, her untimely death on 15 February 2021 came just before her planned retirement. The heartfelt tribute from her colleagues on the NDG panel and staff is included at the end of this report. I was fortunate enough to have spent time talking with Dame Fiona during the process of applying to succeed her.

My admiration for her wisdom and diligence has become even greater as a result of everything I have learned since taking over the title in mid-March and stepping fully into the role in April.

The Health and Social Care (National Data Guardian) Act 2018 requires the NDG to set out priorities for the year ahead in an annual report. I have done that here in Chapter 5. Given their continued relevance, I have adopted much the same priority headings as Dame Fiona, but have refreshed them with new work programmes in response to the needs of a rapidly changing data environment.

I approach this work as a practising doctor. I continue to work part-time as a consultant psychiatrist in South London, not least to remain grounded in the often-complex reality of frontline clinical care. Working in mental health, I'm acutely aware of the importance of maintaining confidentiality as the basis of trust within a doctor-patient relationship. That is essential for anyone to feel able to disclose what may be highly sensitive personal information.

I am also very aware from both professional and personal experience, of the frustration, anxiety and sometimes distress that can be experienced by patients and carers when critical healthcare information isn’t readily available when needed. As a former chief clinical information officer, I’ve been involved in bringing data-driven digital innovations into frontline patient care. I’m firmly convinced of the potential benefits to patient safety, experience and outcomes of using data for research and innovation. To realise any of these benefits however, we need to ensure our systems for data use are trustworthy.

I see my role as championing the importance of building and maintaining trustworthy data systems across health and social care. This requires being clear about what the foundations of a trustworthy data system are. The public trust that is needed by the health and care system is not a blind trust, but a trust that is informed, strong and sustained. As the evidence shows, including the findings of our public attitudes research projects over the last year, which you will read about in this report, transparency is the founding principle of a trustworthy system. Through transparency, it can be demonstrated to the public that certain conditions necessary to earn trust in data use are met. These include: clear purpose, secure infrastructure, privacy safeguards, strong governance and processes, independent oversight of decision making about data access, easily accessible outcomes and, crucially, simple and straightforward mechanisms for patients to exercise choice about how information about them is used.

A data system can be designed behind closed doors, by well-meaning experts of great integrity, working hard to do the right thing for patients and the public. But without transparency and active public involvement such projects risk being compromised by untested assumptions about what matters most to people using or impacted by the system, unconscious bias and potential vested interests of varying kinds. Public involvement not only helps to demonstrate trustworthiness by opening up the system to scrutiny by the people whose data it will use. It also improves the integrity and strength of the system itself.

Over the next year I intend to work with organisations across health and social care to learn from what is currently working, and what isn’t, in the safeguarding and use of data. Ongoing improvement requires diligence, curiosity and humility. This starts with us listening to each other – and above all to the public. This is the goal I will seek to achieve over the coming months.

Dr Nicola Byrne, August 2021

Introduction and background

The Health and Social Care (National Data Guardian) Act 2018 gives the National Data Guardian for Health and Social Care (NDG) the ability to issue guidance about the processing of health and adult social care data in England. Public bodies, such as hospitals, general practices, care homes, planners, and commissioners of services, have to take note of guidance that is relevant to them. So do organisations such as private companies or charities which are delivering services for the NHS or publicly funded adult social care. The Act also 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. It is these responsibilities that are being discharged in this report.

The report provides an account of work done by the NDG during the 12 months to the end of March 2021. For most of that period, the position was held by Dame Fiona Caldicott, who had been appointed as the first NDG in November 2014 and continued to hold the office after its authority was enhanced by the Health and Social Care (National Data Guardian) Act 2018. Dame Fiona's term had been due to last until the end of September 2020 but was extended by six months when the Cabinet Office postponed making fresh appointments during the COVID-19 emergency.

It was with huge sadness that the team supporting Dame Fiona heard that she had passed away on 15 February 2021, just six weeks before she had been due to step down. Their heartfelt tribute to her is included in this report as Appendix C.

Before Dame Fiona died, an open public appointment process had already selected Dr Nicola Byrne, a consultant psychiatrist, to be the next NDG. Her appointment by the Secretary of State for Health and Social Care was subsequently scrutinised and endorsed by the Health and Social Care Committee of the House of Commons. Dr Byrne's three-year term began in mid-March, a little earlier than might have been the case under happier circumstances.

Dr Byrne said in her statement to the committee that she intended to build on progress towards the NDG's existing priorities. Her plans for developing the role are set out in Chapter 5 of this document. However, the account of the NDG's work in 2020-21 that is given in this report is one of seamless transition.

The report is structured to examine progress in each of the three priority areas, which were defined after a public consultation in 2019. These priorities – each broken down into a number of work areas – were:

- Supporting public knowledge and understanding
- Encouraging information sharing for individual care
- Safeguarding a confidential health and care system

It should be stressed that it was never anticipated that these complex priorities would be completed in a single year. It should also be noted that the three priorities are not ranked in order of importance: they are of equal significance.

In this report there are separate chapters on each of these priorities. They are preceded by a chapter on the work that has been of huge importance in 2020-21. The NDG provided support for emergency measures to assist the response of health and social care services to the COVID-19 pandemic. She did so without losing sight of the need to maintain the trust of patients and service users that their confidentiality must be protected. The importance of this balance between encouraging information sharing to promote safe care and protecting confidentiality to maintain people's trust is the basis of the NDG's approach to planning for the post-pandemic period.

During the period covered by this report the NDG has been supported by a small team of officials and a panel of independent advisers, listed in Appendix B. The panel's terms of reference and the minutes of its deliberations are available on the NDG's webpages.

The NDG's own engagement with the public and patients was enhanced by the appointment of an additional member of her panel, who was recruited specifically as a patient and public involvement representative. Maisie McKenzie came to the NDG from use MY data, which is a movement of patients, carers and relatives. It promotes the benefits of sharing and using data to improve patient outcomes, with sensible safeguards against misuse. Her role on the panel is to further concentrate attention on the patient, service user and carer perspective by providing feedback and constructive challenge.

1. The response to COVID-19

When the pandemic struck in the spring of 2020 the NDG acted quickly to ensure that health and social care data would be used to save lives. Working in concert with the Information Commissioner, she gave a clear signal to frontline staff that they could share information with confidence in the interests of patients, service users and the population at large. They jointly endorsed a message from NHSX which aimed to reassure health and care professionals that they should use information to support individual care[1].

It said: “In the current circumstances it could be more harmful not to share health and care information than to share it.”

This was not a radical departure. In 2013 the Information Governance Review[2] led by Dame Fiona Caldicott had established a seventh Caldicott Principle to encourage the judicious sharing of confidential information among all the professionals involved in an individual’s care. However, the COVID-19 emergency required information to be shared more quickly and widely than normal across organisations; and different types of information needed to be collected and used. This did not require long-standing and valued concepts such as privacy, confidentiality and respect for individual choices to be abandoned. Indeed, the NDG observed that the pandemic illustrated how well our information governance framework is able to flex in a time of public health emergency to serve as an enabler to the rapid sharing of information while maintaining proportionate safeguards.

She wrote in April 2020:

“It is inspiring and humbling to see the levels of devotion from our health and care staff, including all those working alongside clinicians to deliver other key roles on the frontline and behind the scenes. As a former NHS doctor, I recognise their steadfast dedication to saving lives. And as a patient and service user, I share with my fellow citizens the admiration and gratitude for their bravery and professionalism. We are right to be proud of them. To protect them, and all of us, the health and care system must now work together to manage the outbreak successfully: monitoring and responding to COVID-19 as effectively as possible. Data plays a vital role in this in so many ways.”

COPI notices

The NDG supported a decision by the Department of Health and Social Care (DHSC) to invoke powers under the Health Service Control of Patient Information

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[1] https://www.nhsx.nhs.uk/information-governance/guidance/covid-19-ig-advice/

[2] https://www.gov.uk/government/publications/the-information-governance-review

Regulations (COPI) of 2002[3] to assist the flow of confidential data in a public health emergency. The Secretary of State issued notices under these powers on 22 March 2020 to instruct healthcare organisations, GPs, local authorities, and arm's length bodies to share and use data to support the provision of healthcare services, for disease surveillance to protect public health, and for monitoring the response to the COVID-19 emergency. These notices, known as the COPI notices[4], required the organisations in scope to process confidential patient information for COVID-19 purposes.

The notices were limited to COVID-19 purposes and for a time-limited period, initially until September 2020, now extended to September 2021.

In a blog in April 2020, Dame Fiona wrote supporting this approach. She said:

> "One of the many wonderful things about our NHS is the unrivalled dataset that it gifts us. As our universal health care system covers almost every person in the country, we have the potential to have consistent, coherent information about patients and the effectiveness of their treatment. And because the knowledge contained within this information is key to the management of the pandemic, it has never been more important to get the right information, to the right people, at the right time."

The COPI notices provided access to health data to inform crucial work to respond to the COVID-19 pandemic. Such as the whole-population study that examined the risk of in-hospital death with COVID-19 for people with diabetes[5]. Another example was a partnership between NHSX, the British Society of Thoracic Imaging (BSTI) and Royal Surrey NHS Foundation Trust to create a national database of chest X-ray, CT computerised tomography (CT) and magnetic resonance imaging (MRI) scans to understand more about the disease and support patients better.

NHSX COVID-19 Data Store and Data Platform

NHS COVID-19 Data Store

In the response to the pandemic, the decision-makers needed accurate, real-time information to understand and anticipate demand on services. And so in an important early use of the COPI notice powers, the government commissioned NHS England and Improvement and NHSX to establish the NHS COVID-19 Data Store. This brought together data from a wide range of sources from across the NHS, social care and partner organisations into a single, secure location.

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[3] https://www.legislation.gov.uk/uksi/2002/1438/contents/made

[4] https://www.gov.uk/government/publications/coronavirus-covid-19-notification-of-data-controllers-to-share-information

[5] https://www.thelancet.com/journals/landia/article/PIIS2213-8587(20)30272-2/fulltext

The aim was to provide the national organisations responsible for coordinating the response to the pandemic with secure, reliable and timely information.

Data Platform

To provide a ‘single version of the truth’ about the rapidly evolving situation, data from the store needed to be analysed and interpreted. The data platform (provided by Palantir) was designed to give decision-makers access to real-time, accurate insights to help them understand things such as how the virus was spreading and where the ‘hot spots’ were that may require increased health and care resources.

A ‘single front door’ process was established to manage requests to access data held in the data store, as well as requests to use analytical tools and dashboards NHS analysts have built in the platform. The NDG provided advice to the organisations involved, such as the Health Research Authority’s Confidentiality Advisory Group, NHSX, NHS England and NHS Improvement, and NHS Digital, to ensure that the process and communications were clear.

When the data store was established at the beginning of the pandemic, the original plan was for the initiative to end in September 2020, at which point the data was to be destroyed or returned to the source organisations. However, as the pandemic was still ongoing, COPI notices were extended until 30 September 2021 and the data store and data platform continued to be used to support the response effort.

The initial contract with Palantir for use of their data platform software was a short-term contract. In December 2020, NHS England and NHS Improvement procured a longer-term solution, signing and publishing a new contract with Palantir until December 2022.

The NDG’s advice was sought at a meeting with her panel, particularly on how to demonstrate trustworthiness to the public of arrangements with commercial partners. She emphasised the importance of communicating openly with the public about what the plans were for the data store and data platform, what organisations would be involved, how the data was being used and released, and what current and future uses were envisaged for the data. Subsequently the contract for the re-procurement was published, alongside communications from NHS England and NHS Improvement and NHSX about this.

The NDG noted that NHS England and NHS Improvement had committed to publish a full register of releases of data from the data store to promote transparency in how information is used and shared, and provide assurance that disseminations are considered carefully to ensure that they are lawful. It was disappointing that by the end of the period this report covers the register had not yet been published. The NDG was informed that NHS England and NHS Improvement would continue to work with others to develop the data dissemination register.

Systems for data sharing

To support people's individual care during the pandemic, the NDG offered advice on a number of rapid changes to the systems used for data sharing.

Summary Care Record with Additional Information

The NDG gave strong support for an initiative to include additional information in patients' Summary Care Records (SCRs) without having to seek each individual's explicit consent. The SCR had been introduced in 2010 to provide a limited set of basic information that might help medical staff to treat patients in an emergency. This standard data was limited to: current medication; allergies and details of any previous bad reactions to medicines; and the name, address, date of birth and NHS number of the patient. Moves to provide additional information on the SCR were made in some parts of England, but these depended on patients giving their consent and geographical coverage was partial.

In response to the pandemic the NDG was asked to review plans to include additional information in the SCR by default. This would allow the SCR to include details of long-term conditions, significant medical history, medication prescribed by a clinician other than a GP, or specific communications needs. Such information could be critical to support both patients and health and social care staff during a pandemic.

The NDG enthusiastically agreed with the plan. Her previous consultations with patients had demonstrated strong public support for such information to be available wherever they seek care. If a patient provides information to one hospital department and then attends for treatment in another, they do expect their information to flow across smoothly. In the NDG's view, the pandemic provided an opportunity to implement a change that should have come anyway. The SCR was a useful vehicle for sharing data because it already had national coverage and was widely available across health and social care, covering a significant percentage of the population.

56 million people (92.2% of the registered population) now have a SCR with additional information, compared with 3.5 million pre pandemic.

SCR in care homes

In a further move, the NDG supported an initiative by NHSX to make the SCR available to authorised staff in care homes and other adult social care service providers. This gave professionals in the care sector prompt access to healthcare information about the people in their care.

The NDG encouraged NHSX to consider a strategy for giving adult social care providers access to GP level information after the pandemic emergency has passed.

GP Connect

To further encourage the sharing of information for health and social care, the NDG also supported the introduction of the GP Connect system by NHSX and NHS Digital to GP practices in England. This makes patient medical information available to all appropriate clinicians when and where they need it to support individual patient care. 97% of GP practices can now view a read-only version of the patient's detailed GP practice record and have the ability to share and manage people's appointments to support joined up patient care. The service regularly delivers half a million record views a week, and over 1.5 million appointments have been made through its appointment booking function.

General Practice Extraction Service

In April 2020, NHS Digital asked the NDG for advice about proposals to use the General Practice Extraction Service[6] (GPES) to collect patient data centrally, within NHS Digital, to support the COVID-19 response. The data was to be used for planning services and supporting research on the cause, effects, treatments and outcomes for patients of the virus. One of the intended benefits of the central collection of this data was to relieve pressure on general practices, which were experiencing a large number of requests to provide patient data for COVID-19 planning and research. The initiative was to be authorised under the COPI notice issued to NHS Digital[7].

After consulting with the Royal College of GPs, the British Medical Association and other stakeholders, the NDG supported the proposals in principle, but recommended doing more to build public trust. She emphasised the need for transparency and engagement with the public about the collection and the dissemination of the data. The NHS Digital GP data team took on board all her suggestions and engaged with relevant stakeholders around timings, delivery and implementation of the scheme. Data is currently collected on a fortnightly basis with six-monthly reviews as to whether there is still a COVID-19 need. The GP data team continued to update the NDG by giving evidence at meetings of her panel.

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[6] The General Practice Extraction Service (GPES) collects information for a wide range of purposes, including providing GP payments. It works with the Calculating Quality Reporting Service (CQRS) and GP clinical systems as part of the GP Collections service. https://digital.nhs.uk/services/general-practice-extraction-service

[7] https://www.gov.uk/government/publications/coronavirus-covid-19-notification-of-data-controllers-to-share-information/coronavirus-covid-19-notice-under-regulation-34-of-the-health-service-control-of-patient-information-regulations-2002-nhs-digital

National data opt-out

One consequence of the pandemic was a delay in the timetable for implementing the national data opt-out (NDOO)[8] that the government introduced in 2018 after it was recommended by the NDG in 2016.[9] The opt-out was designed to give patients and service users a right to decide whether their confidential patient information could be used for purposes beyond their individual care, such as service planning and research.

The deadline for all health and social care organisations to uphold this opt-out was 31 March 2020. But, as the scale of the pandemic and the pressure on services became clear, there was agreement that this should be postponed until September 2020. The NDOO deadline has since been postponed again and is now set as September 2021. Organisations that were already implementing the opt-out were able to continue to do so, and those that were not could continue to move towards full implementation. Following discussions with the government, the NDG agreed that the NDOO would not normally apply to data being used for COVID-19 purposes due to the overriding public interest.

The reasons for the opt-out remain as important as ever. Dame Fiona, as a keen advocate of data use, said she herself would not opt out. But providing people with a mechanism to do so shows that people's autonomy is respected. Upholding the choices that have been made is vital in order to demonstrate trustworthiness.

Data sharing for managing the spread of the disease

As the response to the pandemic developed, the NDG's focus moved from encouraging the sharing of data for individual care to advising on how data could be used for public health purposes in managing the spread of the disease.

NHS Test and Trace

An important aspect was advice to the NHS Test and Trace programme. Dame Fiona and her panel engaged several times with the programme about how the public could be helped to feel confident about sharing their health and social care information and what they needed to be able to trust that it would be used and safeguarded appropriately.

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[8] https://digital.nhs.uk/services/national-data-opt-out

[9] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/535024/data-security-review.PDF

In a letter to Baroness Dido Harding, the head of the NHS Test and Trace programme, Dame Fiona said:

> "As citizens we all have a stake in the success of NHS Test and Trace and it is clear that the willingness of the public to participate is critical to its effectiveness. Building and maintaining public trust about data usage is an essential element of maximising that participation. Individuals engaging with the programme are being asked to confide information that is private and may even be embarrassing or incriminating. If they fear that such information might be insecure or not treated in confidence, they may choose not to engage with the programme and its public benefit will be reduced."

The NDG and her panel were particularly keen to see that clear, accessible, reliable and timely information would be provided to the public about the way that NHS Test and Trace uses and shares data. As the NDG observed, the public's levels of awareness about how the health and care system uses patient and service user data is generally very low. For instance, relatively few people understand that commercial organisations may be involved in processing information for the NHS and so it would be important to explain how data will be used, who will see it and for what purposes.

The NDG also recommended that the programme should build strong information governance structures and provide independent scrutiny. As part of this, she recommended that appointing a Caldicott Guardian would enable NHS Test and Trace to draw on advice about the ethical, legal and proportionate use of data and work alongside the programme's Senior Information Risk Owner (SIRO).

She emphasised the importance of independent advice and scrutiny, whether this would be by a dedicated group or other means. The NDG was pleased to see the appointment in December 2020 of a Caldicott Guardian to DHSC, with a particular remit to advise on NHS Test and Trace. Since January 2021, members of the NDG office and panel have met regularly with the programme's Caldicott Guardian and SIRO team to discuss current and future data decisions and use.

The NDG also advised on particular elements of data use for NHS Test and Trace activities, notably the development of a contact tracing app. Two members of the NDG panel joined the NHS COVID-19 App Data Ethics Advisory Board (EAB). This group advised NHSX on the development of the first version of the contact tracing app. The EAB presented a set of six principles to the Secretary of State in April 2020[10] and a final report in September 2020[11]. These principles were adopted in a second version of the app and so proved influential.

The NDG and her panellists continued to take a keen interest in how the app was being developed and were encouraged by the emphasis that was laid on privacy in the development of its second version. The team developing the app showed a

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[10] https://nhsbsa-socialtracking.powerappsportals.com/EAB Letter to NHSx.pdf

[11] https://covid19.nhs.uk/pdf/ethic-advisory-group-report.pdf

determination to engage fully and openly with the NDG and listen to her advice and concerns, and she was pleased to see that pledges about anonymity and privacy were kept. The number of people who chose to download the app exceeded expectations, with more than 22 million downloads by the end of March 2021[12]. The number of people using the app is one of the factors that has helped in its efficacy, with a peer-reviewed paper[13] estimating that the app had averted between 284,000 and 594,000 COVID-19 cases – roughly one case for each time a person who has been in close contact with someone who has shared a positive test result receives an alert instructing them to self-isolate.

An area that caused the NDG initial concern was the passing of information about citizens from NHS Test and Trace to the police. Parliament created new criminal offences in the summer of 2020 which made it illegal for someone to breach an instruction to self-isolate, either because they had had a positive coronavirus test or because they had been in contact with somebody who had the virus. Police tasked with enforcing the new offences argued, reasonably, that if they received a complaint about somebody breaching isolation, they would need a way to check whether that person was supposed to be isolating. Therefore, regulations were introduced to allow NHS Test and Trace to give some limited information to police, which they could use solely for the purpose of enforcing the isolation rules. A memorandum was put in place to describe and govern how the requests could be made and how the data would be handled.

In early 2021, the NDG was asked about extending the amount of information that NHS Test and Trace could share with the police. Regulations agreed by Parliament had originally set out that where police were investigating allegations that an individual had failed to obey an instruction to isolate, they could ask NHS Test and Trace for confirmation of the individual's name and home address and that they had been instructed to isolate. It was proposed to amend the regulations to allow police to ask for more, the additional detail being: the individual's date of birth; whether the isolation instruction was the result of them testing positive or being a contact of someone who had tested positive; the form of the notification to isolate (eg email, text message, verbal); and a copy if possible.

This proposal was to ensure that police could be reasonably certain that they had identified the correct person and that they had received notification to isolate because they had tested positive for the virus, these being the most urgent cases. NDG panellists advised that this was proportionate, given the existence of these offences on the statute book. They provided advice on the safeguards be put into an updated memorandum of understanding to underpin how information could and could not be shared with the police. They also encouraged publication of the

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[12] https://stats.app.covid19.nhs.uk/#app-downloads

[13] https://www.nature.com/articles/s41586-021-03606-z

memorandum. The regulations were subsequently updated[14] and the memorandum was published[15].

The NDG had long emphasised that maintaining trust in a confidential health service required that a high threshold should be set for the disclosure of data from people's health and care records for the purpose of law enforcement. It is vital that people feel they can share information in confidence with those treating them; if they do not, there is a danger that people, in particular vulnerable people, may be deterred from seeking healthcare or may not be frank with their care professionals, which could endanger clinical safety.

It is for this reason that the medical profession has long set a high public interest bar for disclosing confidential data without the person's consent[16]. Where a crime is suspected, it has normally been the case that the crime would have to be serious in order to justify the release of confidential data. The NHS Confidentiality Code of Practice[17] says this will include crimes that cause serious physical or psychological harm to individuals, such as murder, manslaughter, rape, treason, kidnapping, and child abuse or neglect causing significant harm and likely include other crimes which carry a five-year minimum prison sentence. These were principles emphasised by the NDG and others during the Health and Social Care Committee's inquiry into the now defunct memorandum of understanding which underpinned NHS Digital releasing demographic data to the Home Office for the purpose of immigration enforcement[18].

In the case of the releases of information by NHS Test and Trace to the police for the enforcement of the isolation offences, the context was clearly different. The regulations that had been approved by Parliament expressly set aside the duty of confidence. So it was not necessary to show that the release of this data was in the public interest; and for that reason the serious crime test did not apply. The NDG acknowledged that it is vital that we all obey the rules to control the spread of the virus and that this was the purpose of the new offences. While she was glad to hear that a memorandum of understanding restricted the information that could be passed to the police, she still expressed concerns[19]: that the current arrangement may have the unintended consequence of reducing people's readiness to seek care. She was clear that she would not want this arrangement to set a precedent for sharing health and social care information for law enforcement beyond the pandemic.

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[14] https://www.legislation.gov.uk/uksi/2020/1045/regulation/14/made

[15] https://www.gov.uk/government/publications/umbrella-memorandum-of-understanding-umou-between-dhsc-and-npcc

[16] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/confidentiality/disclosures-for-the-protection-of-patients-and-others

[17] https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice

[18] http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/health-and-social-care-committee/memorandum-of-understanding-on-datasharing-between-nhs-digital-and-the-home-office/written/77475.html

[19] https://www.gov.uk/government/news/why-caldicott-principles-and-caldicott-guardians-are-still-relevant-in-2020

Data sharing for vaccinations and vaccine research

The NDG has been pleased to offer advice on some elements of the efforts to develop and distribute vaccines against COVID-19.

NHS Digital requested the NDG's advice about a web portal that members of the public could use to volunteer to participate in COVID-19 vaccine studies[20]. By registering, people were agreeing to their details being passed on to researchers as potential participants. Subsequent stages would ask participants to agree to take part in a trial and give permission for their health records to be accessed (with a further consent process for the trial itself). The NDG offered advice on the proposed consent wording so that it would be clear what people were and were not signing up to at each stage of the process. The service went live in July 2020 and was hugely popular, with more than 250,000 people registering for it between July and September[21].

The NDG welcomed this initiative – and not only for the contribution it made to identifying willing volunteers to develop a COVID vaccine. The approach developed in collaboration between the National Institute of Health Research and NHS Digital for this project has potential to help with a longstanding barrier to identifying clinical trial participants in general, which she described in her Information Governance Review published in 2013:

> "In some cases, researchers may need to access personal records to identify people with particular characteristics to invite them to take part in clinical trials and other interventional studies. The researcher must first establish a clear legal basis before they can access the data. This process is often referred to as 'consent for consent' and can present a barrier for researchers…"

Historically, this barrier has been addressed in two main ways – either by a member of the care team undertaking searches through records to identify potential participants or by a special legal permission being granted for the search (known as section 251[22]). By building a national platform to allow individuals to come forward of their own volition, it has been demonstrated that other viable options are possible to harness the altruism of citizens wishing to participate in research that could help others. Dame Fiona hoped that this could be developed and taken forward in the future.

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[20] https://www.nhs.uk/sign-up-to-be-contacted-for-research

[21] https://digital.nhs.uk/news-and-events/latest-news/nhs-vaccine-research-registry

[22] By Section 251 of the National Health Service Act 2006 allows the common law duty of confidentiality to be temporarily lifted so that confidential patient information can be transferred to an applicant without the discloser being in breach of the common law duty of confidentiality.

QCovid® and the Shielded Patient List

The NDG joined a group advising NHS Digital on the use of a risk prediction model to identify individuals who could be at high risk of serious illness as a consequence of COVID-19 and who should therefore be advised to shield and be prioritised for vaccination. The model had been developed as the result of a rapid research study commissioned by the Chief Medical Officer for England (CMO) and undertaken by Oxford University Innovations. The recommendations from that research fed into a risk prediction calculator developed by Oxford University Innovations, called QCovid®[23]. The calculator estimates the risk of someone catching COVID-19 and being admitted to hospital, or catching COVID-19 and dying, and generates risk assessment results for individuals. The calculator is based on risk factors such as: age, sex assigned at birth, ethnic group, medical conditions, and current or recent treatment.

At the beginning of the pandemic, a Shielded Patient List (SPL)[24] was created based on the best clinical understanding at the time of who might be at high risk of complications from COVID-19. The Chief Medical Office (CMO) for England commissioned NHS Digital to produce the list of vulnerable people at 'high risk' of complications from COVID-19 using a set of clinical conditions and agreed with the devolved administrations. Individuals were identified either by NHS Digital from the central data it holds or by their local NHS and social care organisations based upon the conditions identified by the CMO. These patients were then sent a letter with advice on how to protect themselves and what additional NHS and government services would be available to them.

The QCovid® research brought additional understanding about others who could be at higher risk. In February 2021, the CMO charged NHS Digital with using this algorithm to identify those individuals so that they, too, could be added to the model. One of the important consequences for these people would be that they would be prioritised for vaccination earlier than they might otherwise have been. The NDG supported this worthwhile aim. As members of an expert advisory group, NDG representatives helped NHS Digital to ensure that the minimum data necessary was run through the model; that the limitations of the model were clearly understood and mitigated; and that GPs and other clinicians were involved as far as possible in reviewing the results produced by the model. Most importantly, communications to the public had to be clear, so that individuals understood the process that had led them to being added to the list; what they could do if they disagreed with being added to the list; and, equally importantly,

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[23] https://digital.nhs.uk/coronavirus/risk-assessment

[24] https://digital.nhs.uk/coronavirus/shielded-patient-list

what they could do if they felt they should have been added to the list, but were not.

Looking ahead

As demonstrated above, the NDG did her utmost to encourage the use of data to save lives during the emergency. However, she did not lose sight of the longer term. In a foreword to her 2019-20 annual report published in July 2020 she said:

> "We must not allow the pandemic to become an excuse for permanently abandoning limits on the use of confidential information that are essential for maintaining the public's trust. There is a danger that some people and organisations might seek to take advantage of this situation. However, the rules approved that require scrutiny of applications to use confidential information remain important to secure the confidence of patients and those using social care. They are important to maintain public trust."

Towards the end of 2020 she set in train work to inform thinking about how the data environment should develop after the pandemic.

Clearly it would not be necessary to restore every aspect of the pre-pandemic status quo if perhaps people's reasonable expectations of confidentiality had changed during the pandemic. However, it would not be appropriate to persist with emergency powers merely because health and social care organisations found them convenient if that would jeopardise trust. To make a start on gauging public opinion, the NDG added questions to her regular polling of public attitudes and jointly funded three citizens' juries to explore the issues in depth.

An online survey was conducted by the research company Kantar in February 2021 as part of an omnibus poll of 2,228 adults in England aged 16+. Results were weighted. Respondents were asked whether they agreed or disagreed with a series of propositions about health and social care data. Responses showed 73%[25] agreed with the statement: "It is OK for the data to be collected and used more freely than usual during the pandemic, but we should go back to the stricter data sharing rules once the pandemic has gone away." And 64%[26] agreed that: "We should reinstate the original data sharing rules as soon as possible." However, 62%[27] agreed that: "This valuable data should be used as long as it is useful, whether we are still in a pandemic or not." The lesson to be drawn from these apparently inconsistent views was that complex issues about confidentiality and trust are not easily decided by polling. There is a danger that the outcome would be determined by whoever chooses the question.

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[25] 73% breakdown: strongly agree – 24%, agree – 29%, somewhat agree – 20%

[26] 64% breakdown: strongly agree – 18%, agree – 24%, somewhat agree – 24%

[27] 62% breakdown: strongly agree – 15%, agree – 25%, somewhat agree – 22%

To probe public attitudes more deeply, the NDG joined with others to commission three citizens' juries – one with jurors drawn from a representative sample of adults aged 18+ from across England, one with jurors from Greater Manchester and one with jurors from West and East Sussex. The project was initially funded by the National Institute for Health Research's Applied Research Collaboration (NIHR ARC) in Greater Manchester; it expanded after additional funding was provided by the NDG and NHSX. 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.

Operating online and spread over eight afternoon sessions, each jury of 18 members heard evidence from experts about the merits and drawbacks of various initiatives that were introduced under the pandemic emergency powers[28]. Overall, the juries supported these initiatives, but many jurors were concerned that there was a lack of transparency about how some of the initiatives had been introduced, and considered this the main reason to oppose them. A majority 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 review 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 powers.

The first of the juries completed its work in March 2021, while the second and third juries deliberated in April and May 2021 and a report of the exercise was published in June 2021[29] providing important evidence about the reasons why the juries were more or less enthusiastic about particular initiatives. Clearly this came

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[28] Each jury heard the same evidence and was asked to answer the same questions about three pandemic data sharing initiatives that were enabled through the 2020 COPI Notices:

- **Summary Care Record (SCR) Additional Information** which was extended to include additional information for over 50 million people in England without explicit patient consent (which had been the basis for uploading additional information from GP patient records to the Summary Care Record before the pandemic)
- **NHS Covid-19 Data Store and Data Platform** – a new central store of patient-related data created by NHS England in response to the pandemic with 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** - a tool 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 patient data accessed from GP patient records but outputs aggregate data.

[29] https://www.arc-gm.nihr.ac.uk/media/Resources/ARC/Digital%20Health/Citizen%20Juries/12621_NIHR_Juries_Report_ELECTRONIC.pdf

after the end of the period of this annual review, but it is mentioned here as the foundation for the NDG’s work on post-pandemic planning that will be an important theme for 2021-22. The new NDG is as eager as her predecessor to ensure that the post-pandemic data regime maximises public trust.

2. *Priority:* Supporting public knowledge and understanding

Patient access to health and care records

What we said we would do:

“We will work with the relevant bodies to explore the barriers to improving patient access to their records and to information about how data about them has been used.”

What we did:

The origins of this work lay in one of the recommendations of the Information Governance Review that Dame Fiona Caldicott chaired in 2012-13. It said that people must have the fullest possible access to all the electronic care records about them, across the whole health and social care system, without charge. It also called for an audit trail to inform patients about everyone who had accessed their records. Dame Fiona’s Review of Data Security, Consent and Opt-outs in 2016 added a further ambition. She wanted the Health and Social Care Information Centre (the precursor of NHS Digital) to develop a tool to help people understand how sharing their data has benefited others. All these recommendations were accepted by the government.

The NDG commissioned a series of opinion polls including questions about what the public thought about access to records. As was detailed in her annual report for 2019-20[30], a poll conducted by the research company Kantar in April 2019[31] found strong support for access to a fuller online GP record. Nearly two thirds of those polled (65%[32]) said it was important to them to have full access to their GP patient record online, including detailed information about their health, such as diagnoses, illnesses, referral letters, test results, operations etc. Among those who already had access to a basic version of their GP record, 78%[33] said full access was important to them. The most common reasons that people gave for wanting better

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[30] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/908066/NDG_progress_report_2019-20_v1.0_FINAL_30.07.20.pdf

[31] This was conducted by research company Kantar as part of an omnibus poll of 2,221 English adults aged 16+. Results were weighted.

[32] 65% breakdown: very important – 32%, important – 33%

[33] 78% breakdown: very important – 45%, important – 32%

access were the ability to check for accuracy and greater opportunity for managing their own health.

A subsequent poll in February 2020[34] found that 81%[35] said they would want to find out when a project using NHS patient data had used information about them; and 70%[36] said that they would register with an online service where they could find out whether any projects have used their data.

This insight into the public's desire for more information about their medical records was confirmed by another poll that the NDG commissioned from Kantar in July-August 2020[37]. Nearly eight in ten people (78%[38]) agreed that during a public health emergency such as coronavirus, it is more important than usual that health and social care data is shared with all those involved in the emergency response. When asked if they would like to know more about how information about them can be used to tackle the coronavirus pandemic, 71%[39] of respondents said they would. Among people working in health and care, 81%[40] said they would like more information.

During 2019-20, the NDG asked NHSX to consider doing more to enable members of the public to see how their own data has been used for purposes other than their individual care. In discussions with NHSX about the development of its data strategy, the NDG was pleased to note a commitment to enable members of the public to see what research data about them has informed, and who has had access to it.

Once implemented, these commitments will go a long way to satisfying the objectives of this NDG priority.

The NDG was also pleased to note the work done by many GP practices and their system suppliers to improve patients' access to their online medical records as well as repeat prescriptions and other services. In addition, uptake of the NHS App (which allows people to view their GP record and access a range of NHS services) has been considerable over this twelve-month reporting period. In March 2020, 1,491,961 people had downloaded the app and 425,388 had registered to use it. By March 2021, this stood at 5,205,789 downloads and 1,995,092 registrations.

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[34] Research conducted by Kantar as part of an omnibus poll of 2,222 English adults aged 16+. Results were weighted.

[35] 81% breakdown: strongly agree – 32%, agree – 33%, and somewhat agree – 16%

[36] 70% breakdown: strongly agree – 23%, agree – 29%, somewhat agree – 19%

[37] This was again conducted by research company Kantar as part of an omnibus poll of 2,114 English adults aged 16+. Results were weighted. Read a fuller report of these findings: https://www.gov.uk/government/news/polling-indicates-growing-public-understanding-about-importance-of-using-health-and-care-data

[38] 78% breakdown: strongly agree – 25%, agree – 32%, somewhat agree – 21%

[39] 71% breakdown: strongly agree – 19%, agree – 30%, somewhat agree – 22%

[40] 81% breakdown: strongly agree – 30%, agree – 28%, somewhat agree – 23%

Transparency and public engagement

What we said we would do:

"We will continue to champion the NDG's long-standing principle that those using and sharing data must be transparent and that they must engage with the public and patients so that the case for data sharing is made."

What we did:

A great deal of the NDG's work under this heading has been described above in the chapter on her response to COVID-19. That work included her advice on the transparency aspects of the NHS Test and Trace programme and vaccination roll-out, as well as the procurement arrangements for the NHS Data Store and development of the General Practice Extraction Service.

In addition, the NDG encouraged other organisations to be transparent and engage with the public, as outlined below.

Healthcare Quality Improvement Partnership

The Healthcare Quality Improvement Partnership (HQIP)[41] invited the NDG to review an information governance guide that it was preparing to disseminate across the sector. The HQIP is an independent organisation led by the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices; it aims to improve health outcomes by enabling those who commission, deliver and receive healthcare to measure and improve our healthcare services. The NDG reviewed the information governance guide and facilitated contact between HQIP and NHSX so that HQIP could take advantage of NHSX's information governance portal as a route for disseminating their guidance across the sector.

HQIP then invited the NDG to review the messaging across a broader project focussing on how data is shared for secondary uses – Understanding Health Data Access[42]. This work is intended to help data applicants, patients and the public understand how and why health data is shared, explaining and demystifying the rules under which the data sharing is permitted and showing how individuals and organisations make sure the rules are followed. The NDG shared the resources with all UK Caldicott Guardians and encouraged HQIP to take them for review by the NHS Health and Care Information Governance Panel (HCIGP), which was set up by NHSX to advise on guidance that could be shared through the portal.

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[41] https://www.hqip.org.uk/

[42] https://www.hqip.org.uk/understanding-health-data-access/#:~:text=The%20Understanding%20Health%20Data%20Access,privacy%20and%20meet%20legal%20requirements

This led to the resources being published on the portal, as well as actively disseminated by NHSX to data protection officers across health and care.

Health Data Research UK

The NDG also engaged with Health Data Research UK (HDR UK)[43], the national institute for health data science, which aims to increase understanding of diseases and discover ways to prevent, treat and cure them by making health and social care data available to researchers and innovators.

Caroline Cake, its chief executive, with some of her senior colleagues, attended a meeting of the NDG's panel in November 2020 to update the NDG on their involvement in work being led by Sir Patrick Vallance, the government's chief scientific adviser, to support and accelerate the UK's research response to COVID-19. HDR UK and the Office for National Statistics (ONS) are leading the national COVID-19 data and connectivity study[44]. This programme is making COVID-19 datasets securely available for research and has already supported many urgent research projects; including linking vaccination, primary care, testing, and admission records for all 5.4 million people in Scotland (approx. 99% of the population), showing that 1st dose of the Pfizer-BioNTech and the Oxford-AstraZeneca vaccines are 91% and 88% effective at reducing COVID-19 hospitalisation[45].

Panel members encouraged ongoing engagement and communication with the public and patient groups to support the development of this study, saying it would be particularly important as the nation moves towards the recovery/vaccination phase of the pandemic. Panel members were also keen to understand more about the health data research infrastructure and how storing more linked data in trusted research environments (TREs)[46] would work in practice. HDR UK continues to involve patients and the public in its work to support the pandemic response and in the data and connectivity study. Examples include a consultation to prioritise research questions on COVID-19 vaccines, which received input from more than 800 people, and public involvement in the development of the PRINCIPLE trial[47] which shaped the approach to increase recruitment to this important trial.

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[43] https://www.hdruk.ac.uk/

[44] https://www.hdruk.ac.uk/covid-19-data-and-connectivity/

[45] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00677-2/fulltext

[46] https://understandingpatientdata.org.uk/news/putting-trust-trusted-research-environments

[47] https://www.hdruk.ac.uk/case-studies/accelerated-recruitment-for-clinical-trials-through-rapid-access-to-large-linked-datasets-and-integrated-patient-engagement/

National Health and Social Care Strategic Information Governance Network

During 2020-21, there continued to be a close working relationship between the UK Caldicott Guardian Council and the National Health and Social Care Strategic Information Governance Network (National SIGN). This relationship helped to ensure that the NDG was kept informed about frontline information governance issues that might require her attention; for example, SIGN presented an overview of key issues to the NDG pertaining to their work, including the national data opt-out, the Data Security and Protection Toolkit and the Shielded Patient List. When appropriate, the NDG was able to raise such issues on their behalf at a national level with the DHSC or its arm's length bodies.

Ada Lovelace Institute and the Health Foundation

The NDG was pleased to hear about a partnership between the Ada Lovelace Institute and the Health Foundation to explore how the accelerated adoption of data driven technologies and systems during the pandemic may have affected inequalities. The NDG was particularly interested in how people's experiences might affect the extent to which they can benefit equally from digital advances and how far data that is used to drive technology is representative of all groups – with associated implications for people's trust in the use of that data. She invited the partnership to speak to the panel, which they did in December 2020. In March 2021 a nationally representative survey took place and highlighted a 'data divide' of inequalities in access, knowledge and awareness of digital health technologies used in the pandemic[48].

General Practice Data for Planning and Research

The NDG also gave advice about the work to develop a new system of collecting (pseudonymised) patient data from GP systems to support health and care research and planning. Dame Fiona and her panel discussed plans for a new GP Data for Planning and Research programme (GPDPR) to replace the old General Practice Extraction Service that NHS Digital has used since 2014 to collect GP data. GPES had been found by the National Audit Office and the Parliamentary Public Accounts Committee to be failing to provide what it had been designed to do in 2009: ensure a reliable and comprehensive picture of GP data in England to monitor quality, plan and pay for health services and help medical research. The NDG agreed that GPES should be replaced and that a new system of GP data collection would be of benefit for research and planning for health and care, would relieve the burden of multiple requests for data from GP practices, and could represent a step forward in terms of privacy safeguards moving towards all releases of GP data being subject to a strong system of independent oversight.

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[48] https://www.health.org.uk/news-and-comment/news/public-lacks-access-to-and-has-concerns-about-discriminator

However, Dame Fiona felt it was important to learn the lessons from the care.data programme, which did not earn the trust of some GPs and the public and was delayed and subsequently abandoned. This led to the NDG underlining the need for effective communications and engagement about GPDPR. She advised that it was vital to have the understanding and support of the GP community, as doctors needed to understand enough to be open and transparent with patients and recommended a communications campaign to practices. The NDG expressly warned that the programme must not risk being perceived as trying to introduce changes 'under the radar' and encouraged the programme to speak clearly and with confidence about the purpose of the programme, and what would and would not be done with the data, to secure trust and understanding.

Benefits of health and care data

What we said we would do:

"We will examine what additional public engagement would be most useful on the subject of the benefits from the use of health and care data. We will continue to support the work to develop a framework to realise the benefits for patients and the NHS where health and care data is being used to underpin innovation."

What we did:

During 2020-21, the NDG jointly commissioned research to explore in greater depth the public's attitudes to sharing their health and social care data. Previous studies had already established that people are more likely to support data sharing for purposes beyond their individual care if it can be shown to produce public benefit. However, many questions remained about the amount and timing of the benefit that people would expect in return for allowing their data to be used by academics, charities, and profit-making companies.

The need for there to be a public benefit is reflected in a range of frameworks and duties. However, our project scoping work found there were still gaps in our understanding of what the public thinks about how benefits and risks might be weighted and whether attitudes towards the use of social care data would be the same as attitudes to the use of health data.

To investigate these questions, the NDG joined forces with Understanding Patient Data[49] and UK Research and Innovation's (UKRI) Sciencewise programme[50] to deliver a public dialogue project. Following an open competition, the project

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[49] A report by https://understandingpatientdata.org.uk/ in March 2020 laid much of the groundwork for this project with the NDG in 2020-21: *Foundations of Fairness Where next for NHS health data partnerships?*

[50] Sciencewise is an internationally recognised public engagement programme which enables policy makers to develop socially informed policy with a particular emphasis on science and technology. It is led and funded by (UKRI) with support from The Department of Business, Energy and Industrial Strategy. Involve, the UK's leading public participation charity, provides expert advice, assurance and support to the programme. https://www.involve.org.uk/

partners appointed the public engagement specialists Hopkins Van Mil[51] to design and manage the dialogue process. The dialogues engaged 114 participants, recruited in a 50-mile radius from four locations: Great Yarmouth, Stockport, Plymouth and Reading. Each participant attended five dialogue events, a webinar plus four workshops.

A report by Hopkins Van Mil, published in April 2021[52], 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.”

One of the issues that mattered most to participants in the dialogues included fairness. They thought that benefits of data use in health and social care should be equitably distributed, with safeguards to protect against discrimination and unjustified geographic disparities. However, they found it acceptable for data to be used for purposes beyond the primary purpose for which it was originally collected if there was a clear public benefit for the secondary purpose. Moreover, they thought the scale of benefits was not a significant factor; participants saw inherent value in data use which produces an impact, even if only for a small number of people.

Staff in the NDG’s Office have begun work on turning what we heard from our public dialogues into guidance that will help organisations to carry out public benefit evaluations with greater consistency and confidence across the health and social care sector. The guidance will go to consultation and may be issued under the NDG’s statutory powers in the next financial year. It would help a range of bodies to ensure and demonstrate that data is being used for public benefit. As well as being the clear expectation and desire of the participants in our dialogue and many previous pieces of empirical research, this will also help organisations comply with various requirements and pieces of guidance, such as the Department of Health and Social Care’s framework for realising the benefits of health data[53].

A further major piece of public engagement by the NDG was the citizens’ juries that were held to explore the people’s attitudes toward data sharing during the pandemic; this is covered in the chapter on her response to COVID-19.

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[51] http://www.hopkinsvanmil.co.uk/home

[52] https://www.gov.uk/government/publications/putting-good-into-practice-a-public-dialogue-on-making-public-benefit-assessments-when-using-health-and-care-data

[53] https://www.gov.uk/government/publications/creating-the-right-framework-to-realise-the-benefits-of-health-data

3. *Priority:* Encouraging information sharing for individual care

Guidance for Health and care staff

What we said we would do:

"We will work with others to develop advice and guidance for health and care staff with the aim of improving information sharing for individual care. This will include work to address the interplay between the requirements of common law and statutory data protection law. We will work with relevant bodies to do this, in particular the Information Commissioner's Office (ICO)."

What we did:

Barriers to sharing for individual care

In August 2020, the NDG published the conclusions of work by Dr Alan Hassey, one of her panel members, to identify barriers that were preventing health and social care professionals from sharing information appropriately for individual care[54].

As Dr Hassey explained in a blog[55] on the day of publication, his research was conducted before the pandemic, during which information sharing improved. However, his report revealed fundamental problems that require long-term solutions to improve the safety and quality of care.

On the basis of Dr Hassey's work, the NDG made four recommendations for action. In outline, she called for:

- an education and training strategy to encourage information sharing for individual care
- greater clarity about what falls within individual care and what does not
- development of an approach to ensure that patients, carers and service users can access important information about their health and care

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[54] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/906788/NDG_survey_report_v1.4.pdf

[55] https://www.gov.uk/government/news/exploring-the-barriers-to-information-sharing-for-direct-care

- a better understanding of what specific data and information is required by the health and care system to meet the different demands of care provision, research and planning

To help frontline health and care professionals make decisions about whether an activity falls under individual care, the NDG developed a draft decision-support algorithm[56]. She received positive and helpful feedback, and was particularly grateful to the Royal College of Physicians, the Faculty of Clinical Informatics, and the Strategic Information Governance Networks for their suggestions about how the algorithm could be refined and developed into a practical tool.

The NDG was pleased to hear from NHSX that it is keen to take forward the recommendations as it develops its data strategy. During the autumn of 2020 NHSX informed the NDG that it would begin work to develop the algorithm further into a tool. This may complement the existing secondary uses data governance tool[57].

The Health and Care Information Governance Panel

Dr Hassey's survey report also went to the Health and Care Information Governance Panel (HCIGP)[58], which had been convened by NHSX during 2019 to bring strategic policymaking on information governance into one place, to avoid conflicting guidance. Its members included representatives from the Information Commissioner's Office, NHS Digital, Health Research Authority, Care Quality Commission, Public Health England, and others. The HCIGP accepted all the findings and recommendations in Dr Hassey's report.

Dame Fiona Caldicott was a member of the HCIGP and staff from her office joined a small working group which met regularly to review and feed back on guidance before it was made available to health and social care staff through a new online Information Governance portal.[59] Dame Fiona helped NHSX to promote the launch of the portal in October 2020 and collaborated with Ian Hulme, Director of Regulatory Assurance in the Information Commissioner's Office to write a joint blog in support of it.[60] They said the portal would provide "a one stop shop of national information governance guidance for frontline staff, information governance professionals and the public." The organisations involved would retain individual responsibilities and independence, "but we hope this approach will help to provide more clarity, consistency and simplicity."

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[56] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/906534/Direct_care_decision_support_tool.xlsx

[57] https://data.england.nhs.uk/sudgt/

[58] https://www.nhsx.nhs.uk/information-governance/health-and-care-information-governance-panel/

[59] Information governance - NHSX

[60] https://www.nhsx.nhs.uk/blogs/making-information-work-everyone/

Examples of material that was reviewed by the HCIGP working group before publication on the portal included guidance on: records management; consent; volunteers; bring your own device (BYOD); subject access requests; mobile messaging; sharing with the voluntary sector; multidisciplinary teams; using health data in data driven technologies; video conferencing; and email/text messages with patients.

Local Health and Care Record programme

The Local Health and Care Record (LHCR) programme was set up to support regional collaborations of NHS organisations and local authority social care departments. They were supported centrally by NHS England with the aim of encouraging information sharing to improve the quality of care and people's experience of it. During 2019-20 the NDG provided feedback on several iterations of an information governance (IG) framework for the LHCR programme, which was expected to be issued in the spring of 2020. It was hoped that the framework would benefit not only the record sharing schemes that had been chosen by NHS England to take part in the programme, but other areas that would follow their lead. The aim was to ensure that data is shared in the best interests of citizens in a way that respects confidentiality and choice and demonstrates transparency.

As a consequence of the pandemic, work on the IG framework was paused for several months, but in the autumn of 2020, NHSX produced a new version that was reviewed by the NDG. It focused exclusively on sharing for individual care and did not include sharing for other purposes such as population health management and research, which had featured in earlier iterations.

NHSX subsequently confirmed to Dame Fiona that the LHCR programme would close and be replaced by the Shared Care Records programme, which will emphasise sharing for individual care. The aim is to achieve a minimum shared care record nationwide by September 2021. The NDG welcomed this shift in emphasis. Her public consultation in 2019 found that most respondents thought improvement in information sharing for individual care should come before work on data for research and planning.

Template Data Sharing Agreement

The distinctive contribution that the NDG and her panel were often able to make in discussion with other health and social care organisations centred around her understanding of the common law duty of confidentiality. A duty of confidentiality arises in circumstances where it is reasonable for the person disclosing the information to expect that it will be held in confidence by the recipient. It is separate from, but complementary to, their data protection rights under statute law, as enshrined in the EU's General Data Protection Regulation (GDPR), the UK's Data Protection Act of 2018, and other legislation.

For example, the NDG helped to improve a template Data Sharing Agreement[61] (DSA), which NHSX published in December 2020 for use across the whole of health and social care. She requested changes to the introduction so that the common law duty of confidentiality was given greater emphasis. Her other recommendations included amendments to ensure that the DSA was appropriate for use by social care as well as health. These suggestions were accepted and mentions of Caldicott Guardians and the national data opt-out were also added.

The ICO's Data Sharing Code of Practice

Similarly, the NDG gave advice to improve the ICO's Data Sharing Code of Practice. During 2019-20 she responded to an ICO consultation on the code, recognising that its purpose was to provide guidance that was compliant with GDPR for organisations across every sector. She said:

> "However, we are concerned that the common law duty of confidentiality which forms a large part of the discussion for many health and social care organisations in the balancing of their duty to protect and share data may be lost within the code ... We feel that the current mention of the duty of confidentiality is hidden away and may escape the attention of many readers."

When the final version of the code was published in December 2020[62] it did indeed give the common law duty an earlier mention and explained it in a little more detail. More support will be needed for the system to understand the relationship between data sharing protection and confidentiality requirements. The NDG is involved in ongoing work that the HCIGP began in 2020 to outline this in relation to issues such as pseudonymisation and anonymisation.

Role Based Access Control

During 2019-20, members of the NDG's team were invited by NHSX to help develop a policy on role-based access control (RBAC). This was needed to allow professionals to access information about patients and service users with whom they have a legitimate relationship, while denying access to others. Access control should be simple to use, easy to understand and provide assurance to patients and the public. Professionals should be able to use the same credentials to access data wherever it is held, whether in local, regional or national systems. Work on the RBAC agenda was placed on hold during the early stages of the pandemic but resumed in October 2020 with a "deep dive" workshop attended by a member of the NDG's team. The outcomes were shared for consultation and the NDG

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[61] https://www.nhsx.nhs.uk/information-governance/guidance/data-sharing-agreement-template/

[62] https://ico.org.uk/for-organisations/data-sharing-a-code-of-practice/

responded in December 2020, highlighting some potential improvements around transparency and consent.

Training and education

What we said we would do:

“We will work with training and education bodies to ensure advice and guidance about information sharing is embedded into their programmes where possible.”

What we did:

British Medical Association’s confidentiality toolkit

The NDG’s contribution to advice and guidance given by the Health and Care Information Governance Panel has been reported in the previous section. In addition, the NDG’s team met regularly with representatives of the British Medical Association to provide advice and assistance. During 2020-21, the NDG was asked to review the BMA’s revised confidentiality toolkit[63], which remains an excellent resource for the medical profession and all those who handle confidential information.

Her feedback included encouragement for the BMA to stress that modern healthcare is delivered by teams. While technically the duty of confidentiality rests with the person with whom the patient shares their information (in the context of this toolkit, a doctor), the information will usually be shared with others involved in delivering individual care. Patients expect as much, and such sharing is a duty and not a breach of confidentiality. The NDG was also pleased to note the BMA’s recognition that demographic information provided in a health or care context should be treated as confidential.

The NDG’s team was also asked by NHSX to review guidance on sharing for individual care. This was published on the IG portal[64] with a banner noting that it had been reviewed by the NDG and the Information Commissioner’s Office.

UK Caldicott Guardian Council

The NDG supported a series of initiatives taken by the UK Caldicott Guardian Council (UKCGC), an organisation which exists to provide advice to the more than 22,000 Caldicott Guardians in organisations across the health and care sector. These organisations include NHS providers and commissioners, GPs, social care departments in local authorities, charities, hospices and other services for

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[63] https://www.bma.org.uk/advice-and-support/ethics/confidentiality-and-health-records/confidentiality-and-health-records-toolkit

[64] https://www.nhsx.nhs.uk/information-governance/guidance/use-and-share-information-confidence/

patients and service users. Dr Chris Bunch, chair of the UKCGC, attends the NDG's panel meetings and the Office of the NDG provides the secretariat and support for the UKCGC's work.

Caldicott Guardians help their organisations to ensure that confidential information about health and social care service users is used ethically, legally, and appropriately. They help to protect each patient and service user's right to confidentiality. They also support their welfare by helping to ensure that information about them is shared safely and appropriately among those caring for them, often across organisational boundaries. NHS organisations have been required to have a Caldicott Guardian since 1998, and local authorities providing social care in England have been required to do so since 2002. These requirements were issued via departmental circulars, but there was no statutory basis for the role or legal definition of its scope.

Guidance on Caldicott Guardians

An NDG public consultation that ran from June to September 2020 put forward a proposal to issue guidance that all public bodies within the health service, adult social care or adult carer support sector in England should have a Caldicott Guardian. The guidance would also apply to all organisations which contract with such public bodies to deliver health or adult social care services. The consultation explained that the key effect of such guidance would be to widen the range of organisations that should appoint a Caldicott Guardian. Once this guidance had been issued under the NDG's statutory powers, those it applied to must have regard to it.

More than 80% of respondents agreed or strongly agreed that the NDG should issue such guidance. We heard that the guidance should be flexible in order that it could be implemented by the wide range of organisations which would need to appoint a Caldicott Guardian, which are of different sizes, hold and share very different amounts of data and face different challenges around data use. We also heard organisations and individual Caldicott Guardians would like more support and resources, such as training, networking opportunities, case studies.

In response to the consultation[65], the NDG published draft guidance[66] in January 2021, which covers the appointment of Caldicott Guardians, their role, responsibilities, competencies, knowledge, training, and continuous professional development. Stakeholders were invited to provide feedback, and some were engaged with directly, over the following two months. The NDG received about 50

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[65] The feedback urged that the guidance: avoided disproportionate additional burden, particularly on small organisations; that it should provide flexibility for the large range of in-scope organisations about how to apply it; that it was particularly important that the guidance described the relationship of the Caldicott Guardian to other key roles; and that organisations wanted support to implement the guidance, e.g., e-learning. These key messages and the plans for drafting the guidance were brought to the NDG panel in October 2020, where it was agreed to accept these adjustments.

[66] https://www.gov.uk/government/news/national-data-guardian-invites-feedback-on-draft-caldicott-guardian-guidance

written responses, which included suggestions for how to improve the guidance. It was adjusted in response, to provide clarity about:

- how Caldicott Guardians and other information governance roles should work together (e.g. data protection officers, heads of information governance)
- which organisations are in scope of the guidance
- options for flexibility, where it would be disproportionate or not possible for an organisation to appoint a Caldicott Guardian from among its own staff

It had been anticipated that Dame Fiona Caldicott would issue a final version of the guidance before she completed her term as NDG at the end of March, but tragic personal events intervened. On coming into post late in March, her successor, Dr Nicola Byrne, reviewed all the material with a view to ensuring that this important piece of Dame Fiona's legacy could be published within the first months of her tenure.

Alongside this work to support the NDG to develop and establish the guidance, the UKCGC has been building enhanced training and support for Caldicott Guardians. It is planned to include e-learning modules; a refreshed online Caldicott Guardian manual; and a suite of supporting communications products, including a redesigned website. Preparations for these initiatives began in 2020-21 and they are expected to be delivered in 2021-22.

4. *Priority*: Safeguarding a confidential health and care system

Reasonable expectations

What we said we would do:

"We will progress the concept of reasonable expectations and provide an update on our next steps."

What we did:

Establishing the eighth Caldicott Principle

Although the year was dominated by supporting the pandemic response, the NDG's most significant achievement was perhaps the completion of work to establish an eighth Caldicott Principle.

Its purpose was to make clear that the expectations of patients and service users must be considered and informed when confidential information is used. It said that action should be taken to ensure there must be 'no surprises' about the handling or sharing of service users' data.

The NDG's work on reasonable expectations had originally been triggered by a growing concern that some organisations were claiming they had the implied consent of service users to use and share information about them, when in fact it was not reasonable to expect that those service users knew what was happening to their data. Starting in 2017, she embarked on a methodical examination of the issues in a series of seminars, articles, a citizens' jury and a workshop on 4 February 2020 attended by key regulators and stakeholders. Her thinking on this subject was also informed by academic work led by two of her panel members, Dr Mark J Taylor and Professor James Wilson, which resulted in the publication in April 2019 of *Reasonable Expectations of Privacy and Disclosure of Health Data*.[67]

The NDG and her panel decided to advance this work by consulting on the wording of an additional Caldicott Principle to establish that a range of steps should be taken to inform the expectations of patients and service users about how their

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[67] https://academic.oup.com/medlaw/article/27/3/432/5479980

confidential information is to be used. In doing so, she took the opportunity to consult on updating the wording of the existing seven principles[68] and also on a proposal that she should issue guidance about the role of Caldicott Guardians[69], using her statutory powers. The consultation ran from 25 June to 3 September 2020. An explanatory document[70] said:

> "We hope that by conducting our consultation now we can develop a new set of Caldicott Principles and guidance in time to inform decisions and discussions about data sharing after the pandemic is resolved."

The consultation was conducted by means of a written survey, which received 194 responses, and eight online focus groups involving 88 patients, social care service users and members of the public. These activities were supplemented by engagement with key individuals and organisations from across the health and social care system, before and during the consultation period.

The consultation elicited overwhelming support for a new principle to bring the expectations of patients and service users more explicitly into the foreground of decision making about how data is used and shared. The results showed 84% of respondents agreed that this new principle should be introduced.

The NDG made adjustments to the wording of the new principle 8 when she published her response to the consultation[71] on 8 December 2020. The final version read as follows:

Principle 8:

Inform patients and service users about how their confidential information is used

> A range of steps should be taken to ensure no surprises for patients and service users, so they can have clear expectations about how and why their confidential information is used, and what choices they have about this. These steps will vary depending on the use: as a minimum, this should include providing accessible, relevant and appropriate information - in some cases, greater engagement will be required.

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[68] A set of six principles was first published as part of The Caldicott Committee's Report on the Review of Patient-Identifiable Information published in 1997 to serve as good practice guidelines to be applied to the use of confidential information within the NHS. https://webarchive.nationalarchives.gov.uk/20130124064947/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4068404.pdf A further principle was added in 2013 as part of The Information Governance Review https://www.gov.uk/government/publications/the-information-governance-review.

[69] This aspect of the consultation was described in the previous chapter.

[70] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/894610/777_consultation_background_document_FINAL_FOR_WEBSITE.pdf

[71] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/941865/NDG_CP_and_CG_consultation_response_FINAL_08.12.20.pdf

The NDG did not envisage that this principle would establish reasonable expectations as a legal basis in its own right to meet the duty of confidentiality. However, given the influence of the Caldicott Principles, she did believe it would helpfully emphasise the perspective of patients and service users in decisions to use and share confidential information.

In a blog on the day of publication, the NDG said:

> “This new principle focuses on ensuring that expectations of patients and care users are considered and met when decisions about data sharing are made. Working with them and the public to ensure that data use aligns with expectations has been a mainstay of my work.”

Responding to the consultation, the NDG also revised the text of the first seven principles. The new version of all eight principles is included in the appendices. The results from the section of the consultation that was concerned with whether the NDG should use her statutory powers to publish guidance on Caldicott Guardians was given in a previous section.

Safeguarding confidentiality

What we said we would do:

> “We will continue other work under the broad ‘safeguarding confidentiality’ theme. This will include work to ensure confidential patient information is not inappropriately linked with other types of data and/or used for non-healthcare purposes in a manner that could undermine public trust and, potentially, discourage individuals from seeking healthcare.”

What we did:

A consistent finding of the five opinion polls that have been commissioned by the NDG since 2018 was a high level of public concern about people’s health and social care data falling into the wrong hands. The most recent poll in this series was conducted by the research company Kantar in February 2021 as part of an omnibus poll of 2,228 adults aged 16+ in England. It showed 67%[72] of the public, when thinking about their NHS patient data, were concerned about cyber-attacks; and 69%[73] were concerned about such data being shared unlawfully, or accidentally with organisations outside of the NHS and care system.

The NDG had led a review in 2016[74] that recommended 10 data security standards for all organisations holding health and care data. They were accepted by the

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[72] 67% breakdown: very concerned – 33%, quite concerned – 34%

[73] 69% breakdown: very concerned – 35%, quite concerned – 34%

[74] https://www.gov.uk/government/publications/review-of-data-security-consent-and-opt-outs

government as a comprehensive framework for addressing security under the three key themes of people, processes, and technology. The 10 standards continued to provide a framework for cyber security defences in 2020-21.

Membership of cyber security boards

The NDG does not have any executive responsibility for enforcing the standards, but she continued to provide support and monitor progress through membership of relevant boards. She was a member of the Cyber Security Leadership Board, at which senior officials of relevant departments and agencies provide strategic direction for this work. Its functions include agreeing the roles and responsibilities across the system in managing the cyber risk.

In addition, a member of her panel attended the Data and Cyber Security Programme Board (DCSPB), which is the operational and decision-making board for data and cyber security products and services across the health and social care system. It supervises the high-level integrated roadmap for the delivery of data and cyber security, ensuring that functions are operating to a central vision and that common objectives and synergies between functions are maximised. Membership of the DCSPB allowed the NDG to keep track of the operational implementation of the data security standards and understand how any issues in implementing them are being addressed. The NDG's team offered support in following up with organisations to advise on the importance of progressing various programme requests.

Monitoring compliance of data security standards

The NDG was also able to monitor progress in implementing the standards through the Data, Security and Protection Toolkit (DSPT), an online self-assessment that all health and care organisations with access to NHS patient data and systems are required to complete each year. The original deadline for completing the 2019-20 return had been the end of March 2020, but this was put back to the end of September in response to COVID-19 pressures. Results showed that more organisations than ever before were implementing key security measures to protect the data that they hold. This reduces the risk that these organisations will be subject to a data breach or cyber security incident and provides regulators with a source of intelligence to shape future support and investment.

A report from NHS Digital in October 2020 showed that more than 36,000 DSPT assessments had by then been published against the 2019-20 standard. This total was 8,000 more than in the previous year (a 30% increase in publications) and 13,000 more than in the predecessor system of self-assessments, known as the Information Governance Toolkit.

Results for NHS trusts showed more than 70% met the required standard or exceeded it. Most of the remainder were able to submit an improvement plan to NHS Digital setting out the outstanding actions necessary to meet the required standard. NHS Digital has kept these improvement plans under review.

The vast majority of organisations that complete the DSPT are smaller organisations. The largest sectors were pharmacy (10,800 assessments), GPs (6,400), dentists (5,800) and care homes (5,000). The NDG was pleased to note that the sector with most increased take-up was care homes / social care. Historically, many social care organisations have not been subject to a national requirement to complete an assessment. Thanks in large part to the work of the Social Care Data and Cyber Programme Board, there has been a sharp rise in the number of social care organisations engaging with this process. A similar picture applied for domiciliary care organisations. While some progress is being made, there still needs to be improvement in this important but vulnerable sector.

Monitoring national data opt-out implementation

The national data opt-out is a service that allows patients to opt out of their confidential patient information being used for service planning and research beyond their individual care.

Originally the opt-out was intended to be implemented across the system by March 2020. This is what the public were told when the opt-out service was launched in May 2018. The March 2020 compliance date was postponed originally by 6 months, and then to 30 September 2021[75], to enable health and social care organisations to focus their resources on the coronavirus outbreak.

When the deadline was extended, the system was given a clear message that this was only a temporary extension, and all organisations would be expected to uphold it in due course in line with promises made to the public when the opt-out was launched.

When developing the proposal for the national data opt-out, the NDG listened carefully to what people said they wanted and recommended an opt-out scheme, because she heard that an important element of building trust was to give people a real choice about the use of their data.

The Data Security and Protection Toolkit (DSPT) returns for March 2021 were originally expected to provide the first full year of intelligence about which organisations were upholding the national data opt-out. They now can’t give this picture, but some organisations had already implemented it before the deadline was extended, and some have done it during the year anyway. In February 2021, the DSPT team provided a snapshot from baseline submissions, which indicated

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[75] https://nhs-prod.global.ssl.fastly.net/binaries/content/assets/website-assets/services/national-data-opt-out/ndoo-compliance-letter-090221.pdf

that 107 out of 256 NHS trusts had actively selected ‘Yes’ to the compliance question. The default answer was ‘Not Provided’ therefore it is possible that the actual compliance rate is higher, and the remaining 149 organisations chose not to provide an answer at that time.

In September 2020, the NDG contributed to NHS Digital’s guidance[76] for auditors and independent assessors who are responsible for scrutinising the DSPT self-assessments of health and care organisations. She said:

> “The health and care sector holds some of the largest and most valuable data sets in the world, but with the repository of this important national asset comes great safeguarding responsibility. Recent examples of data security incidents in industry have seen vulnerabilities exposed and public confidence affected. There is a clear link between data and cyber security and the delivery of patient care. As such, we all have a responsibility to do everything we can to ensure that robust data security procedures, processes and behaviours are in place to protect against threats and maintain that all important public trust.”

During 2020-21, the ICO received more reports of data security breaches[77] in health than in any other sector of business or public service. There were 1,512 breaches in health, compared with a UK total for all breaches of 8,815. However, the disproportionately high figure for health was almost certainly due to more meticulous reporting by health organisations, which have an obligation to report that does not apply elsewhere. It is interesting to note that only 15.1% of the breaches in health concerned failures of cyber security; most of the breaches concerned non-cyber incidents such as posting or emailing data to the wrong address, loss of paperwork or unauthorised access to records. Data security breaches in social care were much fewer, with a total of 270 in 2020-21, of which only 16.7% related to cyber security. These statistics highlighted the need for continued vigilance by health and social care organisations in traditional aspects of data security as well as the cyber risk.

National Audit Office report

The National Audit Office (NAO) published a report[78] on digital transformation in the NHS after taking evidence from a wide range of organisations including the NDG. It found that the Department of Health and Social Care and its arm’s length bodies had taken steps to improve cyber security in response to the WannaCry cyber-attack in 2017. These included agreeing a Windows 10 licensing agreement (which includes the ‘advanced threat protection’ functionality, intended to reduce

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[76] https://www.dsptoolkit.nhs.uk/Help/Attachment/526

[77] The ICO’s statistics relate to data security incidents that are breaches of the seventh data protection principle or personal data breaches reported under the Privacy and Electronic Communications Regulations, Results for the four quarters of 2020-21 are available at: https://ico.org.uk/action-weve-taken/data-security-incident-trends/

[78] https://www.nao.org.uk/wp-content/uploads/2019/05/Digital-transformation-in-the-NHS.pdf

vulnerabilities and increase resilience) and setting up the NHS Digital Data Security Centre to help prevent, detect and respond to cyber-attacks.

The NAO noted: “However, while some attempts have been made to address underlying cyber security issues, and progress has been made, it remains an area of concern.”[79] A related review by the Public Accounts Committee echoed this concern and highlighted areas for focus. The NDG was pleased to see the emphasis on public trust in the NAO’s report, which observed that maintaining public trust is essential to achieving national ambitions for the use of data. The NAO noted that if large numbers of people have concerns and choose to opt out of their identifiable data being used for research and planning, then these activities will be less effective.

Supporting the safe and confidential use of data in software and apps

The NDG engaged with the Medicines and Healthcare products Regulatory Agency (MHRA), which regulates medicines and medical devices across the UK. She wanted to discuss 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.

The MHRA is in the process of drafting new regulations after the UK’s exit from the EU to replace CE marking. The aim is to ensure medical devices are regulated and acceptably safe to use and perform in the way the manufacturer/ developer intends.

Certain types of software are likely to be classified as medical devices under the new regulations. However, although the MHRA understands the importance of privacy, that is not within the scope of its remit. Its officials helpfully put the NDG in touch with groups that are working in this space, namely the Multi Agency Advisory Service[80] (MAAS), and the Digital Technology Assessment Criteria (DTAC)[81]. Despite not being within its strict remit, MHRA is committed to assisting partner

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[79] Ibid para 2.15

[80] MAAS is a multi-agency advice service developed with the CQC, MHRA and NICE to provide a ‘one stop shop’ for support, information and guidance on regulation and evaluation and give a clear overview of the regulatory pathway for AI technologies.

[81] NHSX established the Digital Technology Assessment Criteria for health and social care (DTAC) to give staff, patients and citizens confidence that the digital health tools they use meet clinical safety, data protection, technical security, interoperability and usability and accessibility standards. DTAC sets the baseline for the assessment of digital health and social care technologies before they can be considered for inclusion in the NHS App Library.

organisations to underline the importance of patient privacy and to highlight NDG or ICO guidance where appropriate.

Similar concerns were raised by a case that was brought for discussion at the NDG's panel involving an NHS trust that had developed a mobile phone app that could be used by patients to record vital signs and reduce their need to attend hospital appointments during the pandemic. The app was trusted by the patients, as it was, in effect, prescribed by their clinicians. The app was subsequently sold to a commercial third party, which — although acting as a data processor on behalf of the trust — required users to agree to extensive terms and conditions before they could use the app. These included using the data provided by users for reasons unconnected with their own individual care. In doing so, the supplier appeared to be acting as a data controller. Also, the supplier reserved the right to alter the terms and conditions at any time. This controller/processor ambiguity and the lack of transparency concerning the use of data concerned the trust.

The panel was concerned that some in-house developers and third-party operators needed to do more to ensure that people's privacy was being protected.

A thorough analysis of the complex issues raised by the proliferation of apps and wearables was prepared independently by Templar Executives, a cyber security training and consultancy organisation with substantial NHS experience, and presented to the NDG. Its senior representatives discussed the problem with the NDG's steering group in September 2020 and brought a revised version of their white paper back to her panel in February 2021. The paper considered gaps within existing regulatory and advisory structures and suggested means by which those gaps might be addressed. It included a range of scenarios showing how apps and wearables are blurring lines of accountability that are supposed to define who is responsible if patients are harmed. The paper raised concerns that the existing bodies and processes do not cover privacy considerations adequately, especially where clinicians may be prescribing an app. It is not clear what information assurance exists, or who is responsible for ensuring that an app not only works but is handling data appropriately.

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.

It is fair to say that the problems discussed in this section of the NDG's annual report were not resolved during 2020-21. They remain work in progress for the year ahead.

The Health and Care Information Governance Panel's role in tackling strategic data sharing issues

The Health and Care Information Governance Panel (HCIGP) was formed to bring strategic policymaking and advice into one place. During 2020-21, it inevitably focused on addressing the challenges brought about by the pandemic and much, but not all, of the new guidance focused on this and on ensuring information is shared appropriately for care.

However, the panel also has an important role to play in identifying strategic issues that are acting as barriers to good information sharing or endangering trust in a confidential health and care service. The NDG was pleased that even during the pandemic HCIGP agreed to look at some long-standing issues that needed to be clarified. Examples were:

- when pseudonymous data should be considered personal and/or confidential and when it can be considered anonymous
- how confidential information can be rendered anonymous for secondary uses in line with the common law duty of confidentiality
- what further guidance the sector needs on the sharing of information for purposes beyond individual care

The Information Commissioner's Office (ICO) is writing a suite of sector wide guidance on anonymisation, pseudonymisation and privacy enhancing technologies. Along with other health organisations on the HCIGP, the NDG will work closely with the ICO in determining how the standards on anonymisation and pseudonymisation of personal data relate to the standards on anonymisation and pseudonymisation of confidential patient information.

Supporting independent oversight

The NDG maintained dialogue during the year with a number of the bodies that have an important role to play in ensuring access to health and social care information is only granted where appropriate. This was particularly important during a year when the need to respond to the pandemic increased demand for rapid access to data. This dialogue included liaison with the Confidentiality Advisory Group (CAG), Health Data Research UK (HDR UK), the Independent Group Advising on the Release of Data (IGARD) and NHSX and NHSE/I in relation to access to the NHS COVID-19 data store.

In a noteworthy development, a memorandum of understanding (MoU) between the Information Commissioner's Office and the NDG was published in June 2020[82]. It set out the broad principles of collaboration between the two organisations,

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[82] https://www.gov.uk/government/publications/a-memorandum-of-understanding-between-the-information-commissioner-and-the-national-data-guardian-for-health-and-social-care

establishing a framework for the sharing of relevant information and intelligence. The purpose of the MoU was to enable closer working to help both parties discharge their regulatory and/or statutory functions. As mentioned in a previous chapter, the Information Commissioner and the NDG jointly endorsed a clear message from NHSX to frontline staff at the start of the pandemic encouraging the sharing of information to support individual care.

The NDG remained firm in her belief that independent oversight is essential to ensure that the health and social care system is using data in demonstrably trustworthy ways, with appropriate thoughtfulness and care. This will be a theme of work on evaluating public benefit that will continue in 2021-22.

The NDG was also represented on the Public Service Delivery Review Board[83], which was set up as a result of the Digital Economy Act (DEA) 2017 under the leadership of the Cabinet Office. This board oversees use of the public service delivery data sharing power in England and any non-devolved activities. It also considers potential new uses of the powers. As a result of public and stakeholder consultation at the time of the DEA passing through Parliament, health and adult social care bodies were not included in the list of specified persons permitted to use the powers. Any move to bring them into scope would first require public consultation, including with appropriate representative health bodies, adult health and social care bodies in England and the devolved administrations. Affirmative regulations would then need to be made in Parliament. During 2020-21, the board considered how the existing powers have been used. It discussed data sharing during the pandemic, in particular how health and social care data was effectively shared using the COPI notices.

The NDG responded to the consultation from the Department of Digital, Culture, Media and Sport on its UK National Data Strategy[84]. She advised that ‘maintaining a trusted data regime’ should be made into one of the strategy’s overarching missions to ensure there is an ongoing openness and transparency regarding the collection, uses and security of data and to encourage an active partnership with the public about how data is used. She observed that during the pandemic, there has been increased understanding among the public about how data about them can be used in ways that benefit themselves, their families and others both now and in the future.

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[83] https://www.gov.uk/government/groups/digital-economy-act-public-service-delivery-review-board

[84] https://www.gov.uk/government/consultations/uk-national-data-strategy-nds-consultation

5. Looking forward: NDG work priorities

Priorities for 2021 – 2022

The aim of the NDG is to provide advice and guidance to support the building and maintenance of trustworthy systems and practices for the collection and use of people's confidential information across health and social care in England.

The NDG's 2021 – 22 work priorities support this ambition. They will continue to progress the three NDG priority themes that have been the focus of the last two years, which are outlined below. However, the first priority has been expanded to stress the importance of supporting professional understanding as well as public understanding, and encouraging the active engagement of both.

These priorities represent a continuity of focus in the NDG's work and encourage a smooth transition from Dame Fiona Caldicott to Dr Nicola Byrne as NDG, with the NDG panel's advice and input providing further continuity.

We cannot deliver these priorities alone, as much of what we do depends upon collaborative working with other organisations both within the health and social care sector, and outside of it. It is also anticipated that due to their complex nature, some of our priorities are long term projects that will continue beyond this current year.

In addition to working on these priorities, the NDG will continue to respond to the many reactive requests for advice and guidance from members of the public and organisations, including government and its agencies, health and social care organisations, researchers, and professional bodies.

This statement complies with a requirement in the Health and Social Care (National Data Guardian) Act 2018 that the NDG should include a general description of her priorities in her annual report.

Supporting public and professional understanding and engagement

- Encourage organisations across health and social care to be more transparent about how they collect, safely manage, and use data.
- Promote the sharing of information about how data use has improved health and social care by encouraging those who share data to improve the availability and usability of data release registers.

- Issue guidance on evaluating public benefit where health and social care data is being used for purposes beyond individual care and encourage the adoption of that guidance across health and social care.

Encouraging safe and appropriate information sharing for individual care

- Continue to work with training and education bodies to ensure that advice and guidance about appropriate information sharing within health and social care is embedded into training.
- Promote the involvement of the public as active stakeholders in the collection and effective use of data about their health and social care. Encourage routine online access for patients and service users to records held about them, with people enabled to directly enter their own information when appropriate. This will improve the quality and utility of that information, both for professionals and the individuals themselves.
- Issue guidance on the appointment of Caldicott Guardians, including organisations that should appoint them, their role, responsibilities, competencies, knowledge, training and continuous professional development.

Safeguarding a confidential health and social care system

- Support work to strengthen the use of the Data Security Protection Toolkit, including across social care, to ensure the NDG’s Data Security Standards are routinely upheld.
- Promote the new Caldicott Principle 8 to inform patients and services users about how confidential information about them is used. Encourage organisations to take steps to ensure ‘no surprises’ for people when it comes to their data, designing these steps into systems for health and care data use. Promote active patient and public involvement in decisions about data access for research, system planning and health innovation, to ensure both use and safeguards are in keeping with people’s reasonable expectations.
- Reinforce the importance of patient and public choice in how data about them is used as a key foundation of a trustworthy confidential health and care system by advising on work to clarify i) how and when opt-outs to data use are applied, ii) how those choices are transparently and clearly communicated and iii) how those choices are enacted in a straightforward way.

6. Financial statement

2020-2021

The National Data Guardian (NDG) is a non-incorporated office holder, who does not, herself, employ staff, hold a budget, or produce accounts.

The Department of Health and Social Care (DHSC) holds the budget, which was £760,000 for 2020-21 to meet the costs of:

- the Office of the NDG (salaries, accommodation, IT equipment etc)
- the work of the NDG, her advisory panel, and the work of the associated UK Caldicott Guardian Council
- events, public engagement, additional staff training etc
- co-funding, with a matched contribution grant from Sciencewise (UK Research and Innovation), the engagement project "Good enough? Assessing public benefit in data-driven health and care research and innovation"

NDG staff breakdown

The Office of the National Data Guardian is hosted by NHS Digital.

For 2020-21, the staffing breakdown for National Data Guardian staff includes the below roles and their associated NHS Agenda for Change pay bands:

Head of the Office of the NDG	8c
Senior project manager	8b
Senior policy advisor	8b
Communications manager	8a
Business support manager	6

The NDG, as an independent post-holder, has the flexibility to allocate spending according to in-year priorities.

Expenditure is reported through the DHSC Annual Report and Accounts.

Appendix A: The eight Caldicott Principles

As revised and published on 8 December 2020[85]

Good information sharing is essential for providing safe and effective care. There are also important uses of information for purposes other than individual care, which contribute to the overall delivery of health and social care or serve wider public interests.

These principles apply to the use of confidential information within health and social care organisations and when such information is shared with other organisations and between individuals, both for individual care and for other purposes.

The principles are intended to apply to all data collected for the provision of health and social care services where patients and service users can be identified and would expect that it will be kept private. This may include for instance, details about symptoms, diagnosis, treatment, names and addresses. In some instances, the principles should also be applied to the processing of staff information.

They are primarily intended to guide organisations and their staff, but it should be remembered that patients, service users and/or their representatives should be included as active partners in the use of confidential information.

Where a novel and/or difficult judgment or decision is required, it is advisable to involve a Caldicott Guardian.

Principle 1: Justify the purpose(s) for using confidential information

Every proposed use or transfer of confidential information should be clearly defined, scrutinised and documented, with continuing uses regularly reviewed by an appropriate guardian.

Principle 2: Use confidential information only when it is necessary

Confidential information should not be included unless it is necessary for the specified purpose(s) for which the information is used or accessed. The need to

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[85] https://www.gov.uk/government/publications/the-caldicott-principles

identify individuals should be considered at each stage of satisfying the purpose(s) and alternatives used where possible.

Principle 3: Use the minimum necessary confidential information

Where use of confidential information is considered to be necessary, each item of information must be justified so that only the minimum amount of confidential information is included as necessary for a given function.

Principle 4: Access to confidential information should be on a strict need-to-know basis

Only those who need access to confidential information should have access to it, and then only to the items that they need to see. This may mean introducing access controls or splitting information flows where one flow is used for several purposes.

Principle 5: Everyone with access to confidential information should be aware of their responsibilities

Action should be taken to ensure that all those handling confidential information understand their responsibilities and obligations to respect the confidentiality of patient and service users.

Principle 6: Comply with the law

Every use of confidential information must be lawful. All those handling confidential information are responsible for ensuring that their use of and access to that information complies with legal requirements set out in statute and under the common law.

Principle 7: The duty to share information for individual care is as important as the duty to protect patient confidentiality

Health and social care professionals should have the confidence to share confidential information in the best interests of patients and service users within the framework set out by these principles. They should be supported by the policies of their employers, regulators and professional bodies.

Principle 8: Inform patients and service users about how their confidential information is used

A range of steps should be taken to ensure no surprises for patients and service users, so they can have clear expectations about how and why their confidential information is used, and what choices they have about this. These steps will vary depending on the use: as a minimum, this should include providing accessible, relevant and appropriate information - in some cases, greater engagement will be required.

Appendix B: NDG panel members

NDG panel members during 2020-2021:

- **Mike Adams** (Royal College of Nursing Director, England) – no longer on panel
- **Dr Joanne Bailey** (former GP, tribunal member (Social Entitlements), clinical ethics tutor)
- **John Carvel** (Freelance writer formerly Social Affairs Editor of The Guardian)
- **Dr Alan Hassey** (retired GP) – no longer on panel
- **Andrew Hughes** (Local Government Association's Director of Health and Wellbeing Systems Improvement)
- **Mr Adrian Marchbank** (Consultant Cardiothoracic Surgeon, University Hospitals Plymouth NHS Trust)
- **Rakesh Marwaha** (former commissioning accountable officer)
- **Maisie McKenzie** (patient and the public representative, mental health first aid associate and trainer with Mental Health First Aid England)
- **Eileen Phillips** (freelance writer, communications consultant)
- **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)
- **Rob Shaw** (Managing Director at Mercury Technology Ltd; former Deputy Chief Executive, NHS Digital)
- **David Watts** (Director of Adult Services (DASS) North Northamptonshire Council)
- **Professor James Wilson** (senior lecturer in the Department of Philosophy at University College London)

Appendix C: A tribute to Dame Fiona Caldicott

Published on the NDG website on 15 February 2021

In memory of Dame Fiona Caldicott, the first National Data Guardian, whose work over many years leaves a lasting legacy for patients and service users.

It is with great sadness that we learned today of the death of Dame Fiona Caldicott.

As members of the team who supported Dame Fiona in her work as National Data Guardian for Health and Social Care (NDG), we are full of sorrow at losing our inspirational colleague. She led us with unswerving integrity, modesty and a commitment to doing her best for patients and service users. Her name is well known across our sector and beyond, but we had the added privilege of knowing her personally and holding dear the thoughtful, compassionate person behind the public profile.

Dame Fiona's success as NDG owed a lot to her style of operation. She did not pontificate. She appointed a panel of advisers from across a range of disciplines and listened well to what they had to say before reaching a conclusion. Their loyalty to her was based on profound respect for her integrity. She empowered her staff by asking helpful questions and then trusted them to get on with the job. Her formidable intellect and exacting standards meant that she could sometimes seem stern. But behind the business-like approach she was caring towards members of her team and supportive at times of difficulty. She always took the time to express her thanks and demonstrate gratitude for a job well done or a kindness shown. Her longevity in office gave her an apparently unfailing sense of judgement about when and how to intervene most effectively in dealings with government departments and other organisations. She put patients and service users first. She knew outcomes were more important than headlines.

Dame Fiona was appointed to the office of NDG in November 2014 and was confirmed as the first statutory holder of the position in April 2019. However, her achievements are of much longer standing across a wide range of public life. In the field of medical confidentiality and public trust, she has been a towering presence for the past quarter of a century.

From the age of 10 she knew she wanted to be a doctor. After working initially in general practice, she took advantage of reforms that allowed part-time hospital-based training in clinical specialisms. This enabled her to combine parenting responsibilities with qualifying for membership of the Royal College of Psychiatrists and gaining appointment to senior clinical and teaching posts. She became the first woman president of the Royal College of Psychiatrists from 1993 to 1996 and was chair of the Academy of Medical Royal Colleges from 1995 to 1996.

In those roles she caught the attention of the Chief Medical Officer for England and Wales, who appointed her to lead a review of how patient information was protected. This was a time of widespread concern about how the development of IT systems might spread information about patients that had previously remained protected in doctors' local premises. When she undertook the review, she didn't profess any special expertise in information governance, although as a practising psychiatrist she had experience of the sensitivities of information handling. The task might have been a poisoned chalice because the Department of Health appointed 50 people to her committee with a wide range of conflicting views. But out of this complexity came a report that had a lasting influence on the theory and practice of medical confidentiality.

It established an enduring set of principles that became permanently associated with Dame Fiona's name. The six Caldicott Principles for sharing personal confidential data established that confidential information should only be used when absolutely necessary, for a justifiable purpose, within the law and on a strict need-to-know basis.

The Caldicott report in 1997 also recommended that NHS organisations should each appoint a "guardian" to uphold these principles. NHS bodies were instructed to do this by the Department of Health in 1998. Much to Dame Fiona's surprise, they became known as Caldicott Guardians. The role was subsequently implemented within social care and other sectors such as the police, prisons and the Ministry of Defence. There are now over 22,000 Caldicott Guardians, not only throughout Britain, but also overseas. Dame Fiona sometimes expressed mild bemusement that so many people should be called after the surname that she took from her husband.

Dame Fiona moved on from information governance to take senior positions across a wide range of public service. From 1996 until 2010 she was Principal of Somerville College, Oxford, also serving as a Pro Vice-Chancellor of Oxford University, responsible for personnel and equal opportunities. From 2009 until 2019 she was chair of Oxford University Hospitals NHS Trust, steering it to Foundation Trust status.

After stepping down from her role at Somerville, she moved back into the field of medical confidentiality in 2011, as chair of the National Information Governance Board. It was a brave thing to do since the NIGB had already been slated for abolition as part of a wider programme of Whitehall reform. When asked why she did it, she said: “I wanted to leave information governance in a good state.”

Except that she didn’t leave. In 2012-13 Dame Fiona was asked by the government to lead a second inquiry, known as the Information Governance Review. The government wanted this inquiry to find an appropriate balance between the protection of patient information and the sharing of information to improve care. Dame Fiona took evidence from patients, service users and a wide range of health and social care professionals, exploring the protections needed to allow information to be shared for individual care - and in anonymised form to benefit research, service planning and public health.

The main outcome was a seventh Caldicott principle to add to the other six. After hearing evidence that some over-anxious care providers were interpreting the confidentiality guidance too rigidly, she explained how the duty to share information can be as important as the duty to protect it.

The government accepted all the 26 recommendations in her report and the Secretary of State asked Dame Fiona to set up a new independent panel to monitor progress and provide independent advice and challenge to the whole health and care system. He strengthened this role in November 2015 when he appointed her National Data Guardian for Health and Social Care.

The highlight of her work during this period was a third formal review for the government: the Review of Data Security, Consent and Opt-outs, which was published in June 2016. This set 10 standards of data security for health and care organisations, which formed the basis for current work across these services to strengthen cyber defences. It also recommended a new consent/opt-out model to give people a clear choice about how their personal confidential data may be used for purposes beyond their individual care. Dame Fiona did not want to encourage people to opt out and she made it clear that she would not opt out herself, but she believed that providing the opportunity was an essential step towards maintaining public trust.

Dame Fiona was delighted when Parliament passed legislation in December 2018, with all-party support, to put the NDG role on a statutory basis. In the Bill debate, many Parliamentarians paid tribute to the extraordinary contribution that Dame Fiona had made as a staunch advocate for the public interest with regards to data, which had illustrated the need for this role. She was confirmed as the first holder of this statutory office in April 2019.

Her recent work as NDG has included advice to the government about temporary relaxation of the normal rules to permit more extensive data sharing to combat the coronavirus pandemic. Following research into people's expectations about data sharing, she has also added a new, eighth Caldicott principle, which makes clear that patients and service users should be informed about how their confidential information is used. This built on a theme that Dame Fiona had been developing in speeches and articles over recent years. She advocated that a range of steps should be taken to ensure no surprises for patients and service users, so they could have clear expectations about how and why their confidential information is used, and what choices they have about this. The wording of this eighth principle was finalised after consultation and published on 8 December 2020.

Dame Fiona had her 80th birthday in January 2021. Until the final days, when she became unwell, she maintained an energetic workload. She was preparing to complete her extended term as NDG at the end of March 2021 and wanted before then to make the first use of her statutory powers to enhance the authority of Caldicott Guardians. After public consultation, that work is far enough advanced to be implemented over the coming weeks as a permanent part of her legacy.

She concluded a blog posted on this site on 8 December by saying: "As we ... think about what data use should look like in a post coronavirus landscape, we must continue to listen to the public. We have already begun to see emerging evidence, which suggests that people are becoming more knowledgeable about the importance of health and care data, and more accepting of its use. We now have an opportunity to build on this growing awareness. And at this time, transparency will be key to providing the reassurance that earns confidence. We must make a concerted effort to engage with the people whose data we hold before making important decisions about it."

Dame Fiona is survived by her husband Robert Caldicott and daughter Lucy.

Written by John Carvel on behalf of the NDG panel and office team.