Welcome

Thank you for participating in this online citizens' jury about data sharing in a pandemic

We hope you find it an interesting and stimulating experience.

Malcolm Oswald Director,
Citizens' Juries CIC

Kyle Bozentko
Director, Center for New Democratic Processes

Online Citizens' Jury Event Information

When: 13.00 – 17.30 for eight days: 1 –19, 22-25 March 2021 (jury 1); 6-9, 12-15 April 2021 (jury 2); 27-30, 27-30 April, 3-6 May (jury 3). There will be break(s) in the middle each day. **Please connect to Zoom by 12.30 on day 1 and at 12.45 every other day**.

Where: Please connect to the online event using a computer. You will be provided with a different weblink to connect to Zoom each day.

Loss of connection to the meeting: If you are unable for any reason to connect to the meeting (for technical or personal reasons), please email info@citizensjuries.org and/or ring Malcolm Oswald on 07986 221381 as soon as possible. If no immediate response, ring Chris Barnes on 07790 634632.

Your appearance: Please keep your video on throughout the sessions unless asked to do otherwise or you need a short interruption (e.g. to respond to your doorbell). Dress comfortably. Please don't wear clothing with messages or pictures that may be offensive to others.

PARTICIPANT CONDUCT

Respectful body language: Please use respectful body language toward everyone. Match your body language with your intent of listening and learning, and be aware that eye rolling, crossing arms, or turning away from someone while they are speaking may inadvertently send a message of disrespect.

Respectful verbal language: Do not use language that disrespects anyone's religion, culture, racial group, appearance, etc.

Minimise distractions: Wherever possible, please connect to the meeting in a quiet room on your own. Keep other electronic devices such as mobile phones turned off/ silent during the sessions (unless asked to use them). Though others in your household may be interested in the jury, we ask that they do not observe or otherwise participate in the process.

Attend all sessions and be attentive: It is very important that participants hear all the information presented. Please refrain from multi-tasking (i.e. cooking, folding laundry, walking around your home, etc.) unless we are on a break. There will be breaks to give you time to visit the toilet and/or take care of other needs and we ask you to remain in the "room" when the group is in session. To maintain the legitimacy and fairness of the process, anyone who misses a significant amount of time (i.e. 2 hours or more) will likely not be able to stay for the remainder of the jury process, even if their absence is due to a medical emergency.

Citizens' Jury Questions: Pandemic Data Sharing Juries

The three citizens' juries will all consider the same questions.

The juries will consider three pandemic data initiatives which were introduced or substantially changed in response to Covid-19::

- Summary Care Record (which was extended to include more data about patients during the pandemic)
- NHS Covid-19 Data Store (which was created in response to the pandemic)
- OpenSAFELY (which uses primary care data for research).

For each initiative, the jury will address the following questions:

1. a) How supportive are you of the decision to introduce this data sharing initiative in 2020 as part of tackling the COVID-19 outbreak?
   Very much in support/ Broadly supportive/ Neutral/ Broadly opposed/ Very much opposed

   b) "What are the most important reasons to be supportive?"
   c) "What are the most important reasons to oppose the initiative?"

2. What should the future of the data sharing initiative be?
   a) For how long should the initiative continue
      i. As short a time as possible
      ii. Only as long as the Covid pandemic continues and emergency powers[1] are in place
      iii. As long as it is valuable (potentially beyond the pandemic and for Covid and non-Covid uses)
      iv. Something else

   b) By whom should these decisions be made?
      i. An independent advisory group of experts and lay people
      ii. The minister or organisation accountable for the data initiative
      iii. Parliament
      iv. Someone else

   c) How could or should the initiative and its uses be usefully changed in the future (if at all)?
   d) What actions, if any, could be taken to engender greater public trust in the initiative?
   e) What are the main reasons for these answers?

[Note that there are many questions above, each for several case studies, and to fit the process design into the time available may require that some or all of the answers to Q2c), d) and e) will be given by individuals rather than by the jury as a group.]

[1] Emergency powers are in place to deal with the pandemic, see: https://www.instituteforgovernment.org.uk/explainers/emergency-powers

At the end of each jury, the jury will be asked:

3. What lessons can we learn from how these pandemic data initiatives were introduced
    - which could be useful for future pandemics?
    - which could be useful outside of pandemics?

There are also two NHS Covid-19 Data Store case studies for the juries to consider. These are systems reliant on the Data Store:

- The Early Warning System
- The Immunisation and Vaccination Management (I&V) Capability.

The juries will answer two of the above questions about each of these sub-case studies: 1 a) and 2a).

Data Sharing in a Pandemic Citizens' Jury – Planned Schedule

Jury Day 1, Week 1, Tuesday, 13:00-17:30

Activities	**Topic**	**Witness**
-Introductions & Welcome -Guidelines & Process -Simulation exercise		
-Witness Presentation & Q&A	What are patient and care records and how are they used?	Dr Alan Hassey, GP (retired)
-Jury deliberation		

Jury Day 2, Week 1, Wednesday, 13:00-17:30

Activities	**Topic**	**Witness**
-Witness Presentation & Q&A	What are the normal rules for using and protecting patient records?	Peter Singleton, Cambridge Health Informatics
-Witness Presentation & Q&A	How did the normal rules change for the pandemic?	Peter Singleton, Cambridge Health Informatics
-Witness Presentation & Q&A	Planning for pandemics	Prof David Harper, Chatham House
-Jury deliberation		

Jury Day 3, Week 1, Thursday, 13:00-17:30

Activities	**Topic**	**Witness**
-Witness Presentation & Q&A	Summary Care Record Additional Information	Dr Robert Jeeves, GP Clinical Lead, NHS Digital (part 1) and John Farenden, Senior Programme Lead, Shared Records Programme, NHSX (part 2)
-Witness Presentation & Q&A	Summary Care Record Additional Information	Phil Booth, Co-ordinator, medConfidential
-Jury deliberation		

Jury Day 4, Week 1, Friday, 13:00-17:30

Activities	**Topic**	**Witness**
-Witness Presentation & Q&A	NHS Covid-19 Data Store	Ming Tang, Chief Data and Analytics Officer, NHS England and NHS

Data Sharing in a Pandemic Citizens' Jury – Planned Schedule

		Improvement (parts 1 & 2)
-Witness Presentation & Q&A	NHS Covid-19 Data Store	Phil Booth, Co-ordinator, medConfidential
-Jury deliberation		

Jury Day 5, Week 2, Monday, 13:00-17:30

Activities	**Topic**	**Witness**
-Witness Presentation & Q&A	Early Warning System	Ed Kendall, Deputy Director for Economics (part 1) and Dr Harrison Carter, National Medical Director's Clinical Fellow (part 2), NHS England and NHS Improvement
-Witness Presentation & Q&A	Early Warning System	Phil Booth, Co-ordinator, medConfidential
-Witness Presentation & Q&A	Immunisation and Vaccination Management Capability	Ayub Bhayat, Director of Insights and Data Platform Capability, NHS England and NHS Improvement (parts 1,2)
-Witness Presentation & Q&A	Immunisation and Vaccination Management Capability	Phil Booth, Co-ordinator, medConfidential
-Jury deliberation		

Jury Day 6, Week 2, Tuesday, 13:00-17:30

Activities	**Topic**	**Witness**
-Witness Presentation & Q&A	OpenSAFELY	Jess Morley, Policy Lead, University of Oxford's DataLab (parts 1&2)
-Witness Presentation & Q&A	OpenSAFELY	Phil Booth, Co-ordinator, medConfidential
-Jury deliberation		

Jury Day 7, Week 2, Wednesday, 13:00-17:30

-Jury Deliberation & Voting

Jury Day 8, Week 2, Thursday, 13:00-17:30

-Jury Deliberation & Voting -Finalise Jurors' Report

What are patient & care records and how are they used?

(neutral presentation)

Dr Alan Hassey

(Ack. David Riley)

Former GP & retired member of the National Data Guardian Panel
Currently working as a
Covid-19 vaccinator

My brief

My brief

- What are patient records?
- Why are patient / care records needed?
- Who makes them and where are they held?
- What sort of information is in them?
- How do social care records differ from patient records?
- How are they used?
  - In patient care?
  - Outside of patient care?
- What does anonymisation of patient records mean?
- When would you use patient records that identify people and when would you use anonymised records?

What is a patient record?

A document of your medical care and history created over time.

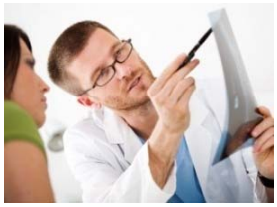
Could have one writer … or many

Could have one reader … or many

Might stay just at one organisation (eg GP) …. or be shared with many

Might be paper or electronic

Why are patient records needed?



First and foremost - so you get good care
Doctors/nurses/carers use your record to:

- Record what you tell them
- Structure their thoughts
- Make sure other professionals know what you need
- Make the right decisions with you, using the relevant information

Plus for your…

- Medico-legal reports
- Benefits claims
- Wearable devices

Plus other reasons not to do with your own direct care

- For example, research
- More on this later

Who makes patient records and where are they held?



- Health care professionals (HCPs) make records about you
- Normally there are separate records at your GP, hospital etc – often records in one place cannot be seen by HCPs in another


They could be paper or electronic

They might be held locally, nationally, internationally, in a cloud



What sort of information is in patient records?

Name, address, NHS number, information about appointments and tests

Codes
73211009 = Diabetes
38907003 – Chickenpox
14760008 = Constipation
400200009 = Ingrown toenail

- Can be read by a computer
- Codes make it easy to search groups of records and find patient with particular condition/drug/need

- Often used to record what the patient says
- Or to record the clinician's thoughts

Free text narrative
Patient says she feels very low
The patient presents a clear case
Might be the early stages of X disease

How might patient records be used?

Mrs X visits the GP
"I have found a lump in my breast"
GP agrees

Electronic fast track referral goes to local hospital breast unit
Includes free text and codes about Mrs X's case plus her name and address

Breast unit sends appointment letter to patient
Using the information from the GP, an appointment letter is sent

What sort of information is in a local authority (adult) social care record?

Name, address, (NHS No.) information about social care assessments, care plans, and (in some cases) financial information.

- The record usually has standard headings (e.g. around needs assessments)
- Used to plan, arrange, deliver & monitor services
- Includes key persons, relationships & carers
- Much of the information will be in free text
- Less likely to be computerized or linked
- It will include what you say & what the social care practitioner advises

Social care providers will have their own records (public & private providers)

To identify a package of care to meet your requirements

To help you to manage your own care

How might a social care record be used?

What is anonymised data?

Anonymised data

- Should be used wherever possible,
- Legally does not need patient consent
- Involves removing or scrambling details which identify individuals
- Can be aggregated or individual level

After this is done, re-identification is very hard…but the risk is not zero
The Information Commissioner's Office has a code that sets standards and gives guidance on anonymisation

KC53 PartB - Women invited

		Women invited in the year as a result of:		Women invited in the year as a result of repeat in < 3 years for reasons of:		
PCT	Age	Call	Recall	Surveillance	Abnormality	Inadequate
5AN	70-74	0	8	1	1	0
5LN	50-54	110	1329	413	98	76

When would you use anonymised records (e.g. in a pandemic)?

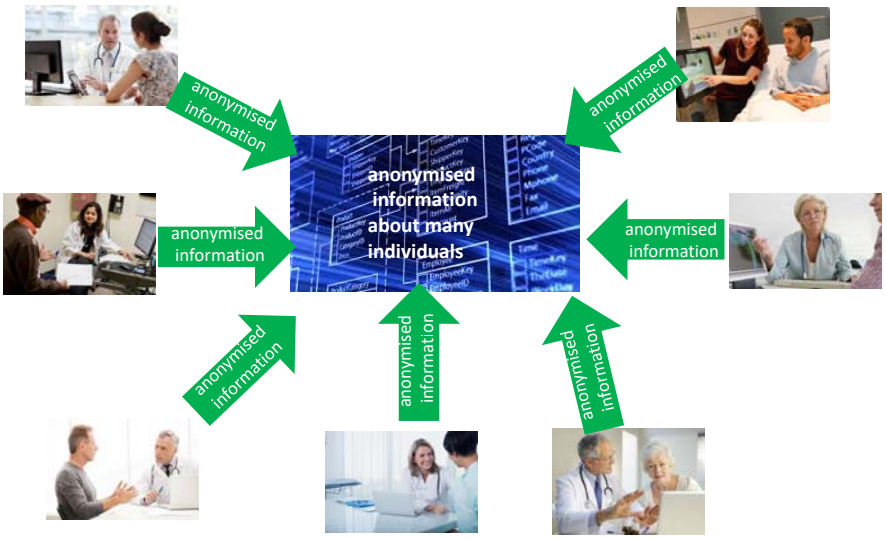
To spot patterns, scientists, analysts and planners need information

Without accurate information, they might be working in the dark

Controls can reduce the risk to privacy & confidentiality

- Approval and scrutiny committees
- Law
- Transparency
- Data contracts
- Fines and penalties
- More detail later in the jury process

Your information can be joined up with other peoples'…

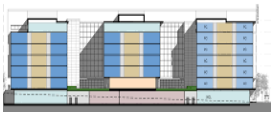


…and then used for purposes beyond your own direct care

Research

- Understanding diseases
- Finding new cures
- Checking medicines

Running the NHS and care system



- Spotting health trends
- Planning how to meet current needs
- Checking quality of care

Summary of key points

- A patient (care) record is a document of your care created over time
- It can be on paper or on computers (or both)
- It contains codes and “free text narrative”
- There are many records held in different places – GP, hospitals, mental health trusts, care homes, social services etc (public & private).
- The main purpose of patient (care) records is to make sure you get good care. They can be shared between organisations to make this happen
- We can anonymise patient records and use and share them for other purposes, such as research and planning (without needing consent)

What are the normal rules for using and protecting patient records?

PETER SINGLETON

CAMBRIDGE HEALTH INFORMATICS

My brief: - neutral presentation

- Where does a patient record fit within the law, including data protection law and common law of confidence?
- How does the common law of confidence protect patients and patient records?
- When does the NHS believe it is reasonable to disclose confidential information held in patient and social care records without explicit consent, and when is explicit consent required?
- Which records are caught by data protection law, and which are not, and how easy is it to determine?
- What rights do patients have under data protection law to access and control access to personal data in patient records?
- What national choices do patients have to opt in and out of data sharing?
- Under, data protection law, what are the main responsibilities of organisations that store and otherwise process patient records?
- How might organisations protect patient data (e.g. anonymisation)?
- In law, does anyone “own” the patient record?

Where does a patient record fit within the law, including data protection law and common law duty of confidence? (part I)

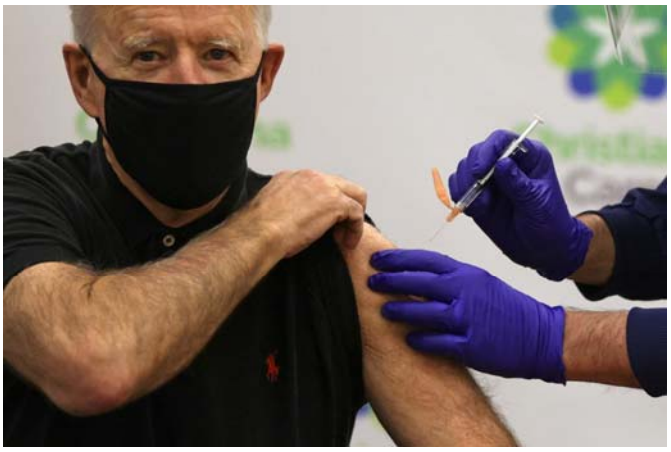
- **The General Data Protection Regulation (GDPR)/Data Protection Act 2018**: a patient record would be considered as 'special category' 'personal data' – so is subject to additional requirements over and above other 'personal data', requiring
  - explicit consent to use your records or other more restrictive legal bases
  - a Data Protection Impact Assessment (DPIA) to show how the organisation meets the data protection principles and complies with the law.
- **Common law**: based on 'case law' – what judges have thought is 'reasonable' so few explicit 'rules' and depends on the circumstances – using public expectations of 'medical confidentiality'
- Perhaps a distinction between 'laws' and 'justice' – 'rules' versus 'accepted practice'

Where does a patient record fit within the law, including data protection law and common law duty of confidence? (part II)

- **Common law duty of confidence**: if you felt a doctor had misused information about you, perhaps by sharing inappropriately, you could get lawyers to sue them for any harm that this may have caused. In legal terms, this is called 'tort' – you are seeking redress or compensation – this is different from being prosecuted for a breach of statutory law as laid down by Parliament (a 'crime').
- A judge would hear your case (and the case for the defence) and would make a judgement based on the facts – and also on previous cases (case law or precedents) and award damages and costs
- There is some statutory law in England & Wales which can 'set aside' the right to bring such a suit – or rather that the defendant (if they met the statutory requirements) would be judged not to have breached their duty of confidence

When does the NHS believe it is reasonable to disclose confidential information held in patient and social care records without explicit consent, and when is explicit consent required?

- Perhaps you appeared willing to receive a vaccination jab, so explicit consent was not needed. The act of rolling up ones sleeve was a sufficient positive response to be considered 'implied consent': 'consent is implied by your actions' as a nod would be considered positive, even though not a clear stated 'Yes'.
- A lot of life is 'implied consent'!



When does the NHS believe it is reasonable to disclose confidential information held in patient records **without explicit consent**?

- Your explicit consent will not be sought where it is for **your 'direct care'** – so within a clinical team, when referred to other care providers, when blood or tissue samples are sent for analysis. It is taken that your information or information that you have given is to be used to help determine the care you will receive
- It will not be sought where data about your treatment is being used for finance (e.g. paying your GP for treating you), public health surveillance, monitoring of the safety of care or medicines, etc., managing clinic diaries, bed availability, keeping you safe in hospital (e.g. which bed/ward you are in) – **basically, for running the NHS**
- It will **not be sought** if the information **does not explicitly identify yo**u
- It will **not be sought** where the **costs of seeking consent are too great** in relation to the likely risks
- For most other cases, unless the law requires or allows it, your consent is needed

How do Social care records differ from medical records?

- Many similarities, but also historic differences
  - In 1948, National Health Service created, but social care was local authority responsibility; social care is 'structurally' less complicated
  - Not all of Europe has same sort of social care, so GDPR considers 'data concerning health' only as a 'special category' of 'personal data'
- However, need to provide holistic care in all care settings – health and social care
- In Northern Ireland, there is no difference at all!
  Health and Social Care is the norm!

Which records are caught by data protection law, and which are not, and how easy is it to determine?

- Quick answer is 'all health records' except for deceased persons (but then may be 'confidential') – unless they are 'anonymised' but no absolute definition
- The Information Commissioner's Office (ICO) produced the 'Anonymisation: managing data protection risk Code of Practice' in 2012 to describe how data might be anonymised, but that was before GDPR came into force
- GDPR Recital 26 recognises that data can be anonymised, but requires a risk assessment that the data cannot be re-identified after considering '*all the means reasonably likely to be used*'
- 'How easy to determine this?' – pretty difficult!

What rights do patients have under data protection law to access and control access to personal data in patient records?

GDPR gives 9 data subject rights:

- **Right to information about the processing** – 'transparency' principle
- **Right of access to own personal data** – 'fairness' principle
- **Right to rectification** – 'accuracy' principle
- **Right to erasure** ('right to be forgotten') – 'purpose limitation' & 'storage limitation' principles
- **Right to restrict processing** – 'data minimisation' principle
- **Right to data portability** – where data provided by data subject
- **Right to object to processing** – 'purpose limitation' & 'storage limitation' principles
- **Right not to be subject to 'automated decision-making**, including profiling'
- **Right to complain to Supervisory Authority** – The Information Commissioner's Office in UK

These are generally not 'absolute' rights – there are a number of exemptions

What national choices do patients have to opt in and out of data sharing?

In England, there is a 'National Data Opt-out' (NDO)

- Individuals can choose not to have their 'confidential patient information' used for 'research and planning' at https://digital.nhs.uk/services/national-data-opt-out - or by post or phone
- This is still being implemented throughout NHS systems

What national choices do patients have to opt in and out of data sharing?

- In England, the Summary Care Record (which you will hear more about later) has these choices:
  - Not to have an SCR at all – but must actively 'opt out'
  - To have an SCR – but at the minimum level (current conditions, medications, and allergies, e.g. to penicillin) – this is the default
  - To have an 'enhanced' SCR with 'additional information' about significant medical history (past and present), reasons for medications, care plan information and immunisations – but you must ask for this
- Medical staff are supposed to ask for your permission to view your SCR – except in an emergency – so you could choose to say 'No'

Under DP law, what are the main responsibilities of organisations that store and otherwise process patient records?

- To hold them securely and confidentially, lawfully and fairly, but no longer than necessary
- To ensure the records are accurate and up-to-date – appropriate for the 'purpose' – there are also legal obligations on doctors to keep 'adequate records'
- To perform an impact assessment (DPIA) to justify what data is held, how it is used and protected, and that the processing is or is not 'high-risk'
- To inform likely data subjects, either when data first recorded or within one month of receipt of the data

How might organisations protect patient data (e.g. anonymisation)?

- First: **good design** – there is a legal requirement (Article 25) for 'privacy by design and by default', so
  - separate tables for a person's contact details and external identifiers – this also means they only have to change your address or telephone details in one place
  - separating where they need to know who you are from knowing about your 'case' or your 'order' – for example, where data is needed for planning or research purposes
  - Restricting access to the 'personal' data
- Using **encryption** to store the data in case it gets stolen
- Making it hard/impossible to identify you (anonymising/de-identifying/de-personalising):
  - Removing identifiers: name, address, NHS Number, Nat Ins Number, telephone numbers, IP Addresses
  - Altering combinations of information, such as full date of birth and postcode – restricting the detail
  - Using only a 'pseudonym' or 'token' to specify the record about your 'case' (as distinct from others)

In law, does anyone "own" the patient record?

A question which is often asked, but not very helpful, so the answer is:

No one person has total 'ownership' – if we say 'your record' then we mean a 'record about you' – not that 'you' 'own' it

People have different rights, obligations or calls on the records (which may be held in different places), for example:

- You have rights under DP law and also to sue for any harm through misuse
- The doctor or hospital have rights to use the record for defence against malpractice
- Hospitals or clinics use the records to be paid for the costs of providing their medical services
- Hospitals and medical regulators should use the records to monitor and improve the care they provide
- We need research to understand disease, to improve and discover new treatments.

Summary:

- Patient records need to be used for different purposes across the NHS in order to provide safe high-quality care services – this means that no-one really 'owns' the patient records
- The patient as a data subject has specific DP rights to be informed, to be allowed a copy, and to seek corrections or possibly to prevent processing
- There are a range of things that can be done to protect your privacy interests (e.g. anonymising) while also protecting your medical interests (and those of the wider public)
- Asking for your consent at every point isn't always workable or required by law, but should be if anything unusual is about to happen – except in an emergency …
- … but there are some things you can choose not to happen

How did the normal rules change for the pandemic?

PETER SINGLETON

CAMBRIDGE HEALTH INFORMATICS

My brief: - neutral presentation

- What temporary change(s) were there to the normal data sharing **rules** in response to the pandemic, and did they rely on emergency powers for tackling pandemics?
- When and how were the rule changes made and how long were they originally intended to last?
- Why were the changes made, and could the data initiatives we are considering in this jury have been done without the rule changes?
- How and when have these temporary rule changes been extended (explaining “COPI Notices”)?
- Could the rules be extended in this way indefinitely (or e.g. is legislation required)?

What temporary change(s) were there to the normal data sharing rules in response to the pandemic, and did they rely on emergency powers for tackling pandemics ? (PtI)

NHS England used powers under The Health Service (Control of Patient Information) Regulations 2002 to:

- Issue 'COPI Notices' to different parts of the NHS to permit the sharing of confidential patient information for the purposes of responses to the pandemic; for example, sharing of data such as:
  - COVID tests results, COVID vaccinations
  - death registrations (where COVID-related)
  - Other healthcare data, even if not specifically COVID-related, but needed for COVID tracking or planning
- Used mainly for statistics used by SAGE and the Government to determine lockdown and other measures
- Previously, NHS could seek special permission to use patient information without consent, COPI Notices were a blanket approval for dealing with the COVID emergency
- These were not 'pandemic-specific' rules, but were rules to cover the unexpected

What temporary change(s) were there to the normal data sharing rules in response to the pandemic, and did they rely on emergency powers for tackling pandemics ? (PtII)

For Summary Care Record (SCR), there was a change in practice, so perhaps a 'rule change', though not a legal requirement:

- All SCR records were 'enhanced' - including COVID-19 specific codes in relation to suspected, confirmed, Shielded Patient List and other COVID-19 related information – so the 'opt-in' was suspended
- The additional information (for those patients that had not requested it) may be removed once pandemic has passed – subject to a review (so perhaps not)

Not clear how this information was subsequently used, but likely that used to identify people 'at risk' and who should be 'shielded', to determine 'categories' or priorities for vaccination

When and how were the rule changes made and how long were they originally intended to last?

The 'COPI Notices':

- limited initially for 6 months to 30th Sept 2020
- Since extended twice by six months at a time to 30th Sept 2021
- The choice of 'six months' as a time limit is not set in law, but perhaps based on early optimistic view of pandemic – or that pressure on formal processes would ease in the meantime, so normal approval processes could be used instead

SCR 'additional data':

- No obvious timescale – likely to be until all vaccinations complete (if ever) and infections reduced to nil (or accepted as now 'background' infection like flu)

Why were the changes made, and could the data initiatives we are considering in this jury have been done without the rule changes?

Main effect was to enable NHS to '**just do it**' to address pandemic problems without delay.

Some of the operational changes were about getting the data to the right place as soon as possible.

There was probably no formal need to have any legal changes, but would have needed to get everyone to agree that they weren't needed.

NHS Scotland seems to have operated perfectly well without either these 'rules' or the need to change them

How and when have these temporary rule changes been extended (explaining "COPI Notices")?

As previously noted:

The 'COPI Notices':

- limited initially for 6 months to 30th Sept 2020
- Since extended twice by six months at a time to 30th Sept 2021
- The choice of 'six months' as a time limit is not set in law, but perhaps based on early optimistic view of pandemic – or that pressure on formal processes would ease in the meantime, so normal approval processes could be used instead

SCR 'additional data':

- No obvious timescale – likely to be until all vaccinations complete (if ever) and infections reduced to nil (or accepted as now 'background' infection like flu)

Could the rules be extended in this way indefinitely (or e.g. is legislation required)?

- Yes – they could just keep extending, but perhaps not just say 'forever'
- … but Secretary of State needs to report to Parliament, where the extension of COPI Notices might be challenged if felt to be excessive

Summary:

- Some of the changes were 'enabling' – to get things done quickly and to have one decision rather than many thousands of individual decisions across the NHS
  - e.g. COPI Notices … but only designed to be temporary
- Others were 'expedient',– using existing mechanisms to get the data to solve the immediate problem
  - e.g. change to Summary Care Record – the original vision of the SCR was to provide this sort of information routinely for patients in a personal emergency, for the public in wider emergency, or for all of us in improving healthcare technology and delivery

CHATHAM HOUSE

Planning for pandemics
Neutral Presentation

Professor David R Harper
Senior Consulting Fellow

Citizens' Juries – 17 March 2021, 7 April 2021, 28 April 2021

Planning for pandemics – the brief

CHATHAM HOUSE

- When might we reasonably predict the COVID-19 pandemic to come to a clear end (if at all)?
- Can we expect future pandemics to become more frequent?
- Are there pre-defined plans and guidance globally and in the UK for what should happen:
  - going into a pandemic?
  - coming out of a pandemic?
- Is there general good practice or steps that always apply when coming out of a pandemic back to "peace time rules" or does it depend largely on circumstances?

When might we reasonably predict the COVID-19 pandemic to come to a clear end (if at all)?

CHATHAM HOUSE

We cannot reasonably predict a clear end to the pandemic

- *Differences between countries – unpredictable policy outcomes and course of disease*
- *Differences in response strategies - mitigation, suppression, elimination….*
- *Uncertainties – virus and host characteristics, impact of interventions….*
- *What does the 'end' look like? – global eradication, national elimination, 'living with virus'….*

Can we expect future pandemics to become more frequent?

CHATHAM HOUSE

On basis of current megatrends, we could expect epidemics and pandemics to become more frequent

- *Increasing opportunities for viruses and bacteria to jump from animals into humans*
- *Increasing urbanization*
- *Climate change – impact on environments and habitats*
- *Population displacement and migration*
- *Increasing globalization, connectedness, international travel*

Are there pre-defined plans and guidance for pandemics globally and in the UK?

There are plans and guidance for pandemics globally and in the UK

- *International Health Regulations (2005)*

- *World Health Organization guidance for pandemic influenza*
- *WHO COVID-19 specific guidance*

- *UK guidance for pandemic influenza*
- *UK COVID-19 specific guidance*

Is there general good practice or steps that always apply when coming out of a pandemic, or does it depend largely on circumstances?

There are good practices that apply when coming out of a pandemic, but steps and timing depend on circumstances and assessment of the risks

- *Globally, WHO provides a framework for decision-making*
- *General approach is to tailor the steps taken and the timing according to an assessment of risks nationally/locally*
- *Decisions will vary from country to country, for example according to culture, society, politics, health system capacity and capability, availability of vaccines, therapeutics, testing….*

Summary of main points

- We cannot reasonably predict a clear end to the COVID-19 pandemic
- On basis of current megatrends, we could expect epidemics and pandemics to become more frequent
- There are plans and guidance for pandemics globally and in the UK
- There are good practices that apply when coming out of a pandemic, but steps and timing depend on circumstances and assessment of the risks
- Moving away from any special measures introduced during the pandemic depends on circumstances and assessment of the risks

Citizens' Juries Summary on Summary Care Record (SCR) Additional Information

What is the Summary Care Record, and where is it stored?

Summary Care Record (SCR) is a summary of key information from the patient's GP record which is sent from the GP Practice and then stored on the national NHS record database called the NHS Spine. SCR holds important 'core' information about, current medication, allergies and details of any previous bad reactions to medicines and the name, address, date of birth and your NHS number. All patients registered with a GP have a SCR unless they have chosen not to have one. Patients can choose whether to add Additional Information to their SCR beyond the core content or not.

How and when did the core data get into the Summary Care Record, and was that contentious?

Starting in 2007, letters were sent out to patients and SCRs started to be created from patients' GP records. At this point in time there was some variability in the content of a patient's SCR between different areas and GP practices which created confusion. This was contentious and raised concern about who would have access to this information, what purposes it would be used for and patients' ability to control who could access the information. A lot of GPs were also concerned as they are responsible for protecting the confidentiality of their patient's data feared that sharing information about their patients may cause them to breach data protection legislation. This prompted the government to call a ministerial review in 2010. The review recommended that the 'core' record should only contain a patient's demographic details, medications, allergies and adverse reactions. And this should continue to be copied from the patient's GP record and should be uploaded under what we considered implied consent. This means unless you have told your GP practice you didn't want an SCR, one would be created for you.

NHS Digital has a policy that any change to the scope of the record must be driven by citizens and patients, with appropriate advice from professional bodies and tempered by knowledge of the Information Technology capability. This is important for building trust in the system. Further records were uploaded until 2014 to cover the population of England who had a GP record and new ones have been created for new babies and people registering for a GP practice ever since.

How and where is the Summary Care Record typically used (e.g. in what context, for direct care alone)?

SCRs are only used to support a patient's direct care and not for any other purposes. Only authorised registered and regulated health and care professionals, or those who support them, working as a part of a wider clinical team can access a patient's SCR. They can only access this information after seeking and obtaining a patient's Permission to View their SCR, unless the patient is in a state where they cannot provide their permission in which case the information can be accessed at the discretion of the clinician in the patient's best interests. The SCR was initially designed to support patients who attend for an unscheduled or unplanned care episode – such as an acute illness requiring attendance at A+E. However, over time, it has been recognized that the same information can support the safe delivery of patient care across a much wider range of care settings away from your usual GP practice. SCR is now widely available across a range of care settings providing both planned and unplanned care should those settings choose to use the service. These include settings such as GP Out of Hours, 111, A+E, hospital admission teams and community pharmacists.

What is the "Additional Information" in the Summary Care Record, and what new types of information were introduced in Spring 2020?

Additional Information includes extra information from your GP record, including:

- significant medical history (past and present) - health problems like dementia or diabetes.
- communication needs, for example if you have hearing difficulties or need an interpreter.
- your treatment preferences.
- details for a carer or other health professionals involved in your care.

- reason for why you take a particular medication.
- information about the management of your long-term health conditions and planning ahead for your future care needs.
- vaccinations you have received in the past – now including COVID-19 vaccines.
- information to help you and those involved in your care to plan ahead for those people who are approaching the end of life.

In Spring 2020, there was a temporary change introduced to include COVID-19 specific information within the Additional Information. This included information regarding suspected and confirmed cases of COVID-19, Shielded Patient List, test results and vaccinations.

What changed in Spring 2020 to increase the number of people with "Additional Information" in the SCR, and to what extent was this enabled through the 2020 COPI regulations?

Before the pandemic, in order to have Additional Information included in your SCR, a patient would need to have agreed this in consultation with their GP practice. Many patients were never asked if they wanted this service and so the Additional Information was not available in their SCR to support interactions with the health and care service away from their GP practice. Due to pressures faced by General Practice, there often would not have been time to discuss this with millions of patients.
To help the NHS to respond to the COVID-19 pandemic, Additional Information was temporarily included in Summary Care Records for COVID-19 purposes for patients by default, unless patients had previously told the NHS that they did not want this information to be shared.
Patients can be reassured, that if you have previously chosen not to have a SCR or you have expressly declined to share the Additional Information in your Summary Care Record, your preferences will have been respected and applied.

This change of requirement was directed by the COPI Notice which the Secretary of State for Health and Social Care applied on a temporary basis in response to the COVID-19 pandemic in Spring 2020. The COPI regulations are applied for a temporary period and the change will be reviewed before these regulations expire (currently due to end in September 2021).

How many of the people with a Summary Care Record had "Additional Information": Before Spring 2020? After Spring 2020*?*

Before the change was introduced, there were approximately 3 million patients who had Additional Information included on their SCR. This number had been gradually rising since Additional Information was introduced around 2014. Since the change was introduced to include Additional Information by default on a patient's Summary Care Record, there are now over 55 million patients who have this information included on their SCR and available to support their care.

Summary Care Record Additional Information

Expert Witness Presentations

Jury Day 3

Introduction & Speakers

Today's session on SCR is split into two parts;

- Part 1: A Neutral and Information based presentation
- Part 2: A Persuasive presentation

Speakers:

- Dr Robert Jeeves – GP & SCR Clinical Safety Officer, NHS Digital (Part 1)
- John Farenden – Senior Programme Lead, Shared Records Programme, NHSX (Part 2)

Robert is a GP and member of the SCR Team at NHS Digital and has actively supported the SCR work for over 10 years. John has been working in the field of health informatics for 30 years, including working for the late Dame Fiona Caldicott on her first review of patient identifiable information in 1997.

Presentation duration: 30 minutes followed by 25 minutes for questions and answers from members of the jury.

2

Summary Care Record Additional Information

Part 1: Neutral

Dr Robert Jeeves

GP and SCR Clinical Safety Officer, NHS Digital

Part 1: Neutral - Brief

- What is the Summary Care Record, and where is it stored?
- How and when did the core data get into the Summary Care Record, and was that contentious?
- Briefly, how and where is the Summary Care Record typically used (e.g. in what context, for direct care alone?)?
- What is the “Additional Information” in the Summary Care Record, and what new types of information were introduced in Spring 2020?
- How many of the people with a Summary Care Record had “Additional Information”:
  - Before Spring 2020?
  - After Spring 2020?
- What changed in Spring 2020 to increase the number of people with “Additional Information” in the SCR, and to what extent was this enabled through the 2020 COPI regulations?

4

RJ1
RJ26

What is the Summary Care Record, and where is it stored?

- Summary Care Record (SCR) is a summary of key information from the patient's GP record which is sent from the GP Practice and then stored on the national NHS Spine database.
- All patients registered with a GP have a SCR unless they have chosen not to have one.
- SCR holds important 'core' information about, current medication, allergies and details of any previous bad reactions and the name, address, date of birth and your NHS number.
- Patients can choose whether to allow Additional Information to be added to their SCR beyond the core content.
- SCRs can then be made available to support direct care particularly unscheduled care encounters such as Walk in Centres/A&E.
- Your GP Practice is the author of the SCR content but it often contains detail of other relevant interactions with healthcare services.
- GP practices are responsible for your patient data on your patient record in their role as data controllers for information which is stored on their systems.
- NHS Digital are responsible for the patient data on your SCR in their role as data controllers for information which is stored on the NHS Spine.

MO3
RJ28

5

How and when did the core data get into the Summary Care Record, and was that contentious? (1)

- Starting in 2007, letters were sent out to patients and SCRs started to be created from patients' GP records.
- At this point in time there was some variability in the content of a patient's SCR between different areas and GP practices which created confusion.
- This was contentious and raised concern about who would have access to this information, what purposes it would be used for and patients' ability to control who could access the information.
- GPs were also concerned as they are responsible for protecting the confidentiality of their patient's data feared that by sharing information about their patients may cause them to breach data protection legislation.
- This prompted the government to call a ministerial review in 2010. The review recommended that the 'core' record should only contain a patient's demographic details, medications, allergies and adverse reactions only and should be uploaded to Spine under what we consider implied consent.

6

How and when did the core data get into the Summary Care Record, and was that contentious? (2)

- NHS Digital has a policy that, any change to the scope of the record must be driven by citizens and patients, with appropriate advice from professional bodies. This is important for building trust in the system.
- Further records were uploaded until 2014 to cover the **population of England** who had a GP record (any patient who had not opted out).
- New SCRs have been created for new babies and people registering for a GP practice ever since.

7

How and where is the Summary Care Record typically used (e.g. in what context, for direct care alone?)? (1)

- SCRs are only used to support a patient's direct care and not for any other purposes.
- Only authorised registered and regulated health and care professionals, or those who support them, working as a part of a wider clinical team can access a patient's SCR.
- They can only access this information after seeking and obtaining a patient's Permission to View their SCR, unless the patient is in a state where they cannot provide their permission (e.g. emergency access, if the patient is unconscious).
- The SCR was initially designed to support patients who attend for an unscheduled or unplanned care. However, over time, it has been recognised that the SCR can support the safe delivery of patient care across a much wider range of care settings away from your usual GP practice.
- The SCR team have worked with the Expert Advisory Committee (EAC) to consider and agree whether proposed new care settings should be allowed to access the SCR.

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How and where is the Summary Care Record typically used (e.g. in what context, for direct care alone?)? (2)

- SCR is now widely available across a range of care settings providing both planned and unplanned care should those settings choose to use the service.
- For transparency, NHS Digital publish a list on our website of the care settings that can access SCR. These include settings such as;

111	Accident and Emergency	Acute Assessment	Ambulance	Community Care
GP Out of Hours	GP (for temporary or non-registered patients)	Hospital Pharmacy	Minor Injury Units/Walk in Centres/Urgent Treatment Centres	Scheduled Care
Mental Health	Health & Justice (Custody Suites)	Hospices	Primary Care	Community Pharmacy

- Further care settings in new emerging areas such as Care Homes and Adult Social care are also included in the published list, demonstrating how SCR is available to supporting patients and staff across a wider range of care settings many years after it was introduced.

9

What is the "Additional Information" in the Summary Care Record, and what new types of information were introduced in Spring 2020?

Additional Information may include extra information from your GP record:

- significant medical history (past and present) - health problems like dementia or diabetes.
- communication needs, for example if you have hearing difficulties or need an interpreter.
- your treatment preferences.
- details for a carer or other health professionals involved in your care.
- reasons why you take a particular medication.
- information about the management of your long-term health conditions and planning ahead for your future care needs.
- vaccinations you have received in the past – now including COVID-19 vaccines.
- information to help you and those involved in your care to plan ahead for those people who are approaching the end of life.

In Spring 2020, there was a temporary change introduced to include **COVID-19 specific information** within the Additional Information. This included information regarding suspected and confirmed cases of COVID-19, Shielded Patient List, test results and vaccinations.

10

What changed in Spring 2020 to increase the number of people with "Additional Information" in the SCR, and to what extent was this enabled through the 2020 COPI regulations? (1)

- Before the pandemic, in order to have Additional Information included in your SCR, a patient would need to have agreed this in consultation with their GP practice. Many patients were never asked if they wanted this service and so the Additional Information was not available in their SCR.
- Due to pressures faced by General Practice, there often would not have been time to discuss this with millions of patients.
- To help the NHS to respond to the COVID-19 pandemic, Additional Information was temporarily included in Summary Care Records for COVID-19 purposes for patients by default, unless patients had previously told the NHS that they did not want this information to be shared.
- However, if you have previously chosen not to have a SCR or you have expressly declined to share the Additional Information in your Summary Care Record, your preferences will have been respected and applied.

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What changed in Spring 2020 to increase the number of people with "Additional Information" in the SCR, and to what extent was this enabled through the 2020 COPI regulations? (2)

- This change of requirement was directed by legislation called the Health Service Control of Patient Information (COPI) Regulations 2002 which allowed the Secretary of State for Health and Social Care to issue Notices to require health and care organisations to share people's information on a temporary basis to support the response to COVID-19.
- The COPI Notices are due to expire on 30 September 2021 and will be extended if they are necessary for the national response to COVID-19.

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How many of the people with a Summary Care Record had "Additional Information": Before & after Spring 2020?

- Before the change was introduced, approximately **3 million people** had Additional Information included on their SCR. This number had been gradually rising since Additional Information functionality was introduced around 2014.
- Since the change was introduced **55 million people** now have an SCR with the Additional Information available to support their care.
- The usage of SCR has increased by **over 25%** from **181,000 views per week** at the start of the pandemic to over **230,000 views per week** currently.

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NHS

Summary Care Record Additional Information

Part 2: Persuasive

John Farenden – Senior Programme Lead, Shared Records Programme, NHSX

Part 2: Persuasive – Brief (1)

- Why was this change made in Spring 2020?
- What uses have been made of the “Additional Information” and are there plans for this to change in future?
- What benefits have there been from the change?
- Could this same outcome have been achieved by getting explicit consent from everyone with a Summary Care Record?
- Is this something that you believe would have been valuable outside of the pandemic?
- What should the future of the Summary Care Record “Additional Information” be?
  - Have any decisions been made about its future?

15

Part 2: Persuasive – Brief (2)

- For how long should the Summary Care Record continue with the “Additional Information” introduced in Spring 2020?
  i. As short a time as possible
  ii. Only as long as the Covid pandemic continues and emergency powers are in place
  iii. As long as it is valuable (potentially beyond the pandemic and for Covid and non-Covid uses)
  iv. Something else
  - By whom should these decisions be made?
    i. An independent advisory group of experts and lay people
    ii. The minister or organisation accountable for the data initiative
    iii. Parliament
    iv. Someone else
- What, how and when could the public have found out about the change to Additional Information, and has it attracted significant public attention?
- What actions have been taken to engender public trust?

16

Why was this change made in Spring 2020?

- This change was required by the National Health Service Control Of Patient Information (COPI Notice).
- The regulation change ensured information was available to support the care of patients and service users during the COVID-19 period, helping provide wider coverage of a more comprehensive medical summary from an individual's GP record being made available to other GP practices, NHS 111 and other health and care services.
- This means that GP practices which provide care to new patients in the event that a nearby practice temporarily closes due to an infection, or health and care professionals who provide advice to people contacting NHS 111, will have the information they need.

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What uses have been made of the "Additional Information" and are there plans for this to change in future?

Significant medical history and significant previous procedures are often vitally important to inform care decisions across health and care. Additional Information provides a context for the patient's current problem(s) which often has significant influence regarding the next steps for management decisions and treatment, for example:

- a patient with breathlessness may be managed differently if they are already known to have heart failure or COPD.
- Medication being considered to treat a patient's current problem can have important interactions with their existing conditions e.g. beta-blockers and asthma.
- Looking forward, the central SCR Team regularly reviews further content. For the pandemic we specifically included items related to testing, diagnosis, vaccination and other COVID-19 codes.
- The SCR Team are also working to extend access to further care settings such as Care Homes and Adult Social care and other NHS and private sector other cases.
- In addition, a review is being undertaken of all the initiatives which involve record wider sharing, including Summary Care Records.

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What benefits have there been from the change? (1)

Since the change has taken place, positive feedback has been received from a wide range of health and care professionals across multiple care settings, about how these changes provide much greater access to Additional Information that can help health and care professional to provide safer and more effective care.

Comments include the following:

"Switching on Additional Information in the Summary Care Record for the population of England was a bold and brilliant step that will impact the health of the nation and save lives. We must not undo that".

Pharmacist

"SCR access allows me to see a patient's history and medication, rather than relying on their often imperfect recollection. The SCR Additional Information over the last few months has been a real boon, particularly dealing with older patients and their complex co-morbidities. It would be a real loss for OOHs GPs to go back to limited SCR access this winter [2020]".

Out of hours GP

19

What benefits have there been from the change? (2)

"I think it would really be helpful if this became an opt-out process long-term. When [patients] are unable to communicate for reasons of acute ill health, communication problems, cognitive problems and importantly learning disability, seeing this information can make the life and death difference".
Community Doctor

"The Additional Information really helps us even more than the basic details. From our perspective it fills in a lot of blanks, where the patient either doesn't know, doesn't want to know, or can't remember their past medical history, and is a good time saver on each job when we can access it there and then. I really hope it continues".

Paramedic, London Ambulance Service.

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Could this same outcome have been achieved by getting explicit consent from everyone with a Summary Care Record?

- Yes, albeit Additional Information coverage would have been significantly slower to increase.
- This would be mainly due to pressures faced by General Practice, there would not have been enough time or resources available in General practice to discuss this with millions of patients via the normal consultation or telephone approaches, to ensure information was available on SCR during the pandemic period.
- History demonstrates that an opt in model is much less likely to yield high results, regardless of how targeted the campaign to patients is.
- Before the pandemic, some areas of the country had developed specific communication campaigns for frail and elderly patients regarding Summary Care Record with Additional Information and had good opt in levels, but this activity did not happen everywhere so coverage was limited nationally.

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Is this something that you believe would have been valuable outside of the pandemic?

- Most definitely, SCR Additional Information supports better communication and decisions from health and care professionals which helps reduce delays to treatments and supports more personalised, patient-centred and safer care, all of which leads to improved patient care and health outcomes.
- It is the view of the SCR team, SCR Clinical Safety Officer, Live Services Clinical Team and Primary Care Technology clinical leads that there are significant safety risks should a decision be made to remove SCR Additional Information for patients who have had Additional Information added, after the end of the temporary COPI legal notice in September 2021.
- It is the strong recommendation of this group that consideration be given to how the current temporary changes can be made **permanent in a legal, ethical and transparent way.**

22

What should the future of the Summary Care Record "Additional Information" be? (1)

Have any decisions been made about its future?

- We have advised health organisations that the changes under the COPI notice are temporary.
- However, there is a risk that where services have incorporated SCR and Additional Information into their processes, particularly where they do not have an effective alternative, they will have introduced a new dependency on this information.
- Decisions have yet to be made on post-pandemic availability of Additional Information.

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What should the future of the Summary Care Record "Additional Information" be? (2)

- For how long should the Summary Care Record continue with the "Additional Information" introduced in Spring 2020?
  i. As short a time as possible
  ii. Only as long as the Covid pandemic continues and emergency powers are in place
  iii. As long as it is valuable (potentially beyond the pandemic and for Covid and non-Covid uses)
  iv. Something else

Ans. We believe, as long as it is valuable.

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What should the future of the Summary Care Record "Additional Information" be? (3)

- By whom should these decisions be made?
  i. An independent advisory group of experts and lay people
  ii. The minister or organisation accountable for the data initiative
  iii. Parliament
  iv. Someone else

Ans. We believe, the organisation accountable for the data initiative, but the decision should be informed by patients and other stakeholders.

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What, how and when could the public have found out about the change to Additional Information, and has it attracted significant public attention?

- Following the release of the Control of Patient Information (COPI) notice on 1st April 2020, NHSX updated their website here:
  - **On how data is supporting the COVID-19 response -** *Information is critical to the response to COVID-19. Key pieces of data extracted from health and care settings, combined with information provided by patients themselves, will be used in new ways to care for people and help the NHS and social care to better understand and respond to the virus*.
- The NHS Digital website was then updated to also hold key information for patients around the changes. NHS Digital and NHSX also distributed press releases to all mainstream news outlets to communicate the change.
- There has been **little public attention** on the changes to SCR Additional Information, however some practices have seen an increase in opt out queries from some patients asking further questions on the above public facing website content.

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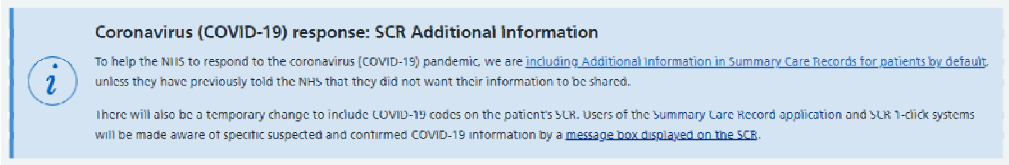
What actions have been taken to engender public trust?

- The National Data Guardian (NDG), Information Commissioner's Office (ICO), British Medical Association (BMA) and Royal College of General Practitioners (RCGP) consulted from the outset.
- Communications and social media messaging has been widely shared on external websites and social channels.
- Local Clinical Commissioning Groups (CCGs), Local sustainability and transformation partnerships (STPs) and practices have been fully informed of the changes, also enabling them to answer any patient queries or complaints.
- The NHSX & NHS Digital, NHS.UK websites also update and hold key information for patients around the changes as previously mentioned.



27

Summary of main points

- Making SCR with Additional Information available has undoubtedly improved care, saved time and potentially saved lives.
- There has been no evidence of harm to date.
- Protections have been put in place for individuals both to express their wish to have a SCR record at all, and ensuring that they are asked before it is accessed, whenever possible.
- The value has been in making this information more readily available to those who have a clear need to know.
- SCR with Additional Information has been a means to achieve this to date.

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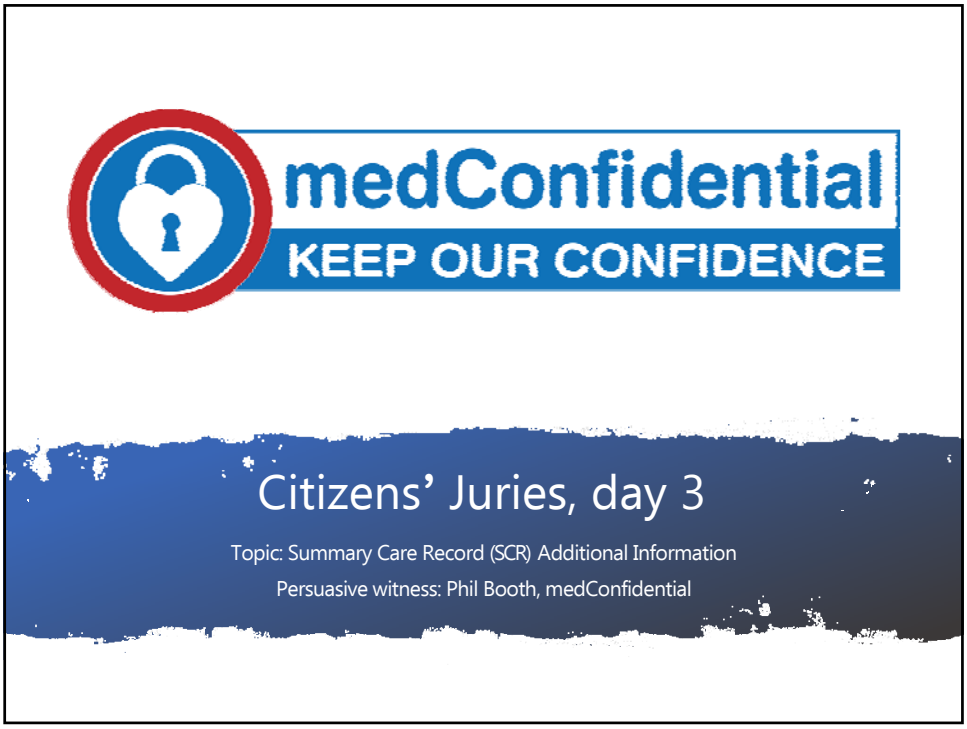
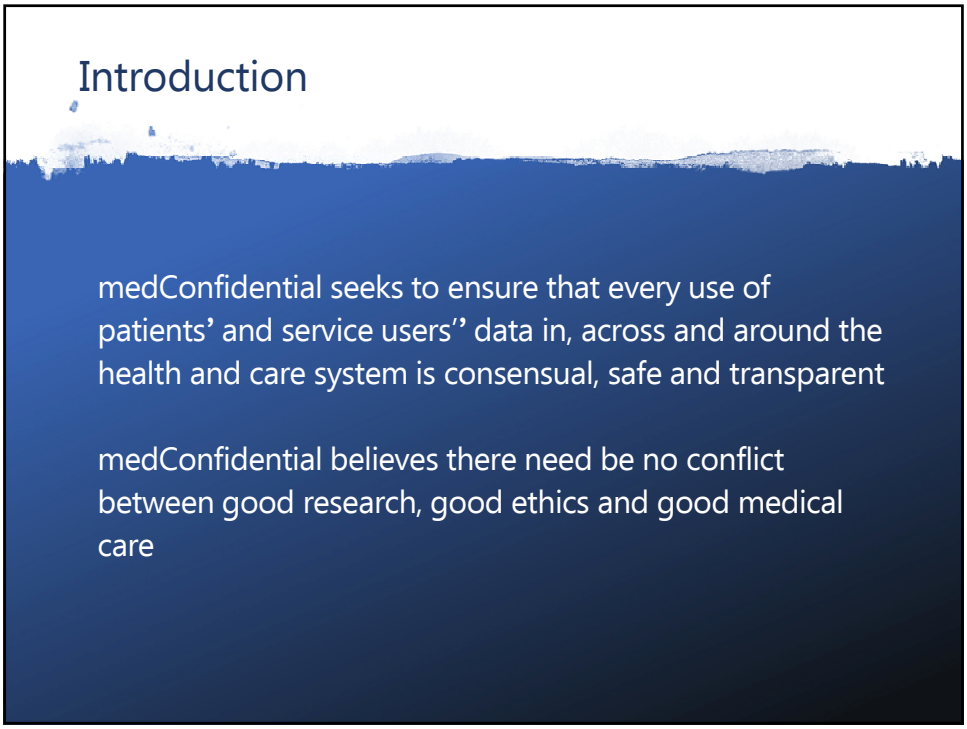
Thank you

Connect with us:

NHS Digital
www.digital.nhs.uk | @nhsdigital | www.linkedin.com/company/nhs-digital

NHSX
www.nhsx.nhs.uk | @NHSX | www.linkedin.com/company/nhsx


medConfidential
KEEP OUR CONFIDENCE
Citizens' Juries, day 3
Topic: Summary Care Record (SCR) Additional Information
Persuasive witness: Phil Booth, medConfidential


Introduction
medConfidential seeks to ensure that every use of patients' and service users'' data in, across and around the health and care system is consensual, safe and transparent
medConfidential believes there need be no conflict between good research, good ethics and good medical care

My brief

Why is it important to use patient data for the individual and the wider public?

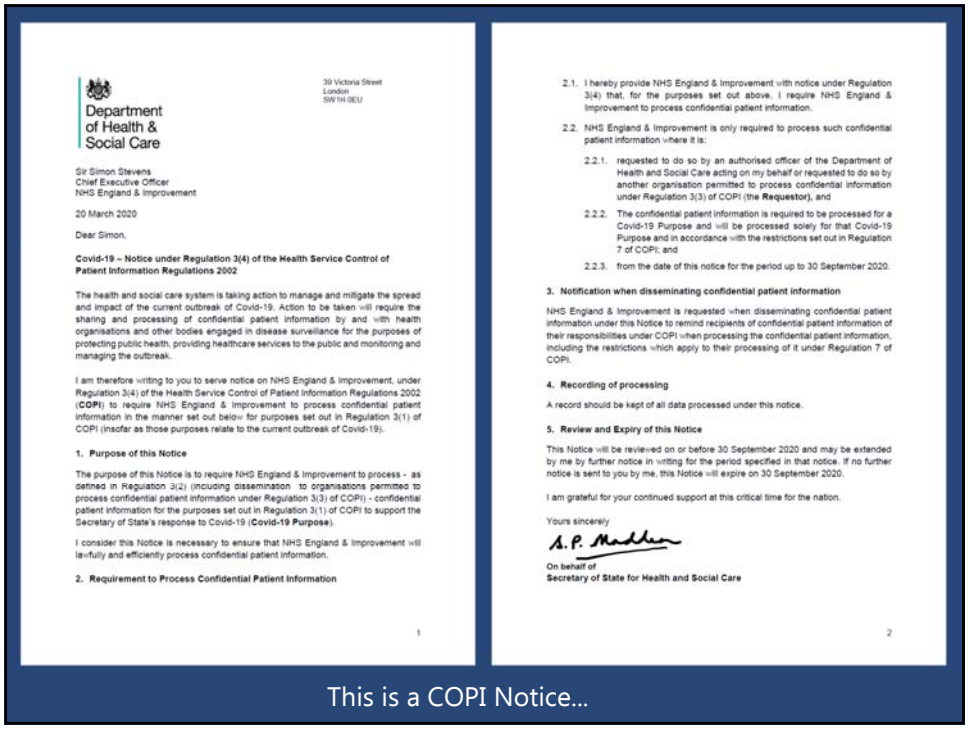
- Direct care;; planning and commissioning; research; commercial exploitation

Why is it important to protect patient data, and what should the public expect?

- That every use is legal - also consensual, safe and transparent

Should the public be prepared to accept a different level of protection of patient data during a pandemic?

- No



Department of Health & Social Care

39 Victoria Street
London
SW1H 0EU

Sir Simon Stevens
Chief Executive Officer
NHS England & Improvement

20 March 2020

Dear Simon,

Covid-19 – Notice under Regulation 3(4) of the Health Service Control of Patient Information Regulations 2002

The health and social care system is taking action to manage and mitigate the spread and impact of the current outbreak of Covid-19. Action to be taken will require the sharing and processing of confidential patient information by and with health organisations and other bodies engaged in disease surveillance for the purposes of protecting public health, providing healthcare services to the public and monitoring and managing the outbreak.

I am therefore writing to you to serve notice on NHS England & Improvement, under Regulation 3(4) of the Health Service Control of Patient Information Regulations 2002 (**COPI**) to require NHS England & Improvement to process confidential patient information in the manner set out below for purposes set out in Regulation 3(1) of COPI (insofar as those purposes relate to the current outbreak of Covid-19).

1. Purpose of this Notice

The purpose of this Notice is to require NHS England & Improvement to process - as defined in Regulation 3(2) (including dissemination to organisations permitted to process confidential patient information under Regulation 3(3) of COPI) - confidential patient information for the purposes set out in Regulation 3(1) of COPI to support the Secretary of State's response to Covid-19 (**Covid-19 Purpose**).

I consider this Notice is necessary to ensure that NHS England & Improvement will lawfully and efficiently process confidential patient information.

2. Requirement to Process Confidential Patient Information

1

2.1. I hereby provide NHS England & Improvement with notice under Regulation 3(4) that, for the purposes set out above, I require NHS England & Improvement to process confidential patient information.

2.2. NHS England & Improvement is only required to process such confidential patient information where it is:

2.2.1. requested to do so by an authorised officer of the Department of Health and Social Care acting on my behalf or requested to do so by another organisation permitted to process confidential information under Regulation 3(3) of COPI (the **Requestor**), and

2.2.2. The confidential patient information is required to be processed for a Covid-19 Purpose and will be processed solely for that Covid-19 Purpose and in accordance with the restrictions set out in Regulation 7 of COPI; and

2.2.3. from the date of this notice for the period up to 30 September 2020.

3. Notification when disseminating confidential patient information

NHS England & Improvement is requested when disseminating confidential patient information under this Notice to remind recipients of confidential patient information of their responsibilities under COPI when processing the confidential patient information, including the restrictions which apply to their processing of it under Regulation 7 of COPI.

4. Recording of processing

A record should be kept of all data processed under this notice.

5. Review and Expiry of this Notice

This Notice will be reviewed on or before 30 September 2020 and may be extended by me by further notice in writing for the period specified in that notice. If no further notice is sent to you by me, this Notice will expire on 30 September 2020.

I am grateful for your continued support at this critical time for the nation.

Yours sincerely

S. P. Madden

On behalf of
Secretary of State for Health and Social Care

2

This is a COPI Notice…

National Health Service Act 2006

UK Public General Acts ▸ 2006 c. 41 ▸ Part 13 ▸ Patient Information ▸ **Section 251**

251 Control of patient information

(1) The Secretary of State may by regulations make such provision for and in connection with requiring or regulating the processing of prescribed patient information for medical purposes as he considers necessary or expedient—

(a) in the interests of improving patient care, or

(b) in the public interest.

(4) Regulations under subsection (1) may not make provision requiring the processing of confidential patient information for any purpose if it would be reasonably practicable to achieve that purpose otherwise than pursuant to such regulations, having regard to the cost of and the technology available for achieving that purpose.

(7) Regulations under this section may not make provision for or in connection with the processing of prescribed patient information in a manner inconsistent with any provision [F2of the data protection legislation].

(13) In this section—

[F4"the data protection legislation" has the same meaning as in the Data Protection Act 2018 (see section 3 of that Act);]

...and this is the Law

My brief

To what extent does medConfidential support the regulations that were introduced in Spring 2020 to enable greater patient data sharing?

- Consensual, Safe and Transparent builds trust
- Lawful, Fair and Transparent is the law!
- What may be necessary in a public health emergency is not 'business as usual'

Concerns

Why was this change made?

- So more people can access more information about you, for your direct care, in different care contexts

Why might it be considered contentious?

- Lack of public awareness of the information added and SCR opt-out

How, when and what could the public have found out about the change and has it attracted significant public attention?

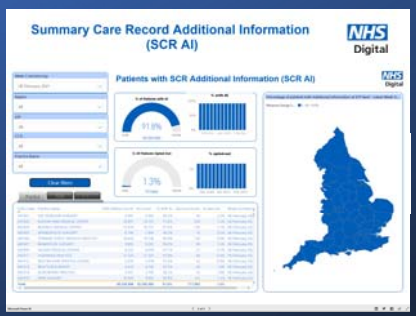
- GP practice website privacy policies, NHS Digital website. . . and no

What actions have been taken to engender public trust?

- Very few, if any (and it shows)

Concerns

- This change affects 55 million people, yet there' has been no discernable increase in opt-outs
- The projected number of views suggests over three-quarters of SCRs will simply not be used



- This is a huge amount of sensitive information to leave open on a system with so many entry points
- NHS Digital still doesn''t report to patients when their SCR has been accessed, and from where

What is SCR 'Additional Information'?

Pre-COVID, 'additional information' may have included:

- reason for medication
- immunisations
- significant medical history (past and present)
- significant procedures (past and present)
- anticipatory care information, e.g. management of long-term conditions
- end of life care information
- communication preferences, including contact details
- accessible information requirements
- carers' details
- lasting power of attorney
- information to help provide reasonable adjustments required under the Equality Act 2010
- specific information from the GP record that the patient and GP agree should be included

During COVID, 'additional information' includes ***any & all of the above for everyone who has not specifically opted out***, and:

- COVID-19 specific codes in relation to suspected COVID-19, confirmed COVID-19, the Shielded Patient List and other COVID-19 related information
- Noting that "information to help provide reasonable adjustments required under the Equality Act" will include protected characteristics like ethnicity and learning disabilities

Does this look like a 'summary' to you?

Concerns

What uses have been made of the "additional information," and are there plans for this to change in future?

- We know little about actual uses; the plan appears to be to keep the data

Could this same outcome have been achieved by getting explicit consent from everyone with a Summary Care Record?

- Not in the time available, but that doesn't justify not raising awareness and thereby offering patients the chance to dissent (i.e. opt out)

Is the addition of this additional information something that would have been valuable outside of the pandemic?

- Yes, for those who chose to have it added and where it was actually used. (N.B. the COVID-related information will be useful beyond the pandemic.)

Concerns

What could have been done differently?

- Patients could have been consulted
- Patients should have been properly informed
- Patients should have been given the opportunity to opt out before the additional data was uploaded
- More attention should have been paid to data retention & data minimization

- A missed opportunity to launch Data Usage Reports, and to build public trust

The future of SCR additional information

Have any decisions been made about its future?

- Hopefully not! This was an emergency measure, not a permanent one

How could or should SCR and its uses be changed in the future?

- This is a long-running debate. Whatever is done must be done with proper consultation and active engagement that has been sorely lacking thus far
- There are also potential downsides…

What actions could be taken to engender greater public trust in the initiative?

- Ensure that every use of patients' data is consensual, safe, and transparent

How long?

For how long should the Summary Care Record continue with the additional information introduced in Spring 2020?

(ii) Only as long as the COVID pandemic continues

- The legal basis for processing the SCR additional data beyond the pandemic / COPI notices is shaky at best
- The case must be made for each category of data, and each new use, especially in light of the Shared Care Record
- The lack of consultation and transparency about what has been done is a trust time-bomb

Who decides?

By whom should these decisions be made?

(i) An independent advisory group of experts and lay people

- If the purpose of SCR is for care, why would you not involve those being cared for? Who is the information about? And to whose treatment does it relate?
- Parliament should be involved in making the opt-out statutory, but not in (clinical) decisions about retaining data
- Ultimately, the Secretary of State is accountable but...

The decision about what is in their own SCR, and who gets to see it, must be decided by patients themselves.

In summary

CONSENSUAL?

Clearly not! Significant amounts of sensitive information has been added to 55 million patients' SCRs without fair notice, and without offering people a choice before it happened. Respecting an opt-out tens of millions of people were not told about is not consent.

SAFE?

How can we be sure? 'Number of views' is insufficient evidence, and the 'creepy doctor' problem is already well known.

TRANSPARENT?

All data processing must be lawful, fair and transparent. The NHS has a poor history of communicating data changes at scale; it must now do so for SCR opt-outs and, to maintain public trust into the future, it should introduce Data Usage Reports.

Summary - NHS COVID-19 Data Store & Data Platform

The NHS COVID-19 Data Store & Data Platform form a Data ecosystem.

NHS COVID-19 Data Store

- The Data Store is a single repository of COVID-19 datasets created to inform an effective COVID-19 response.
- The Data Store brings together multiple data sources from across the health and care in a single secure location.

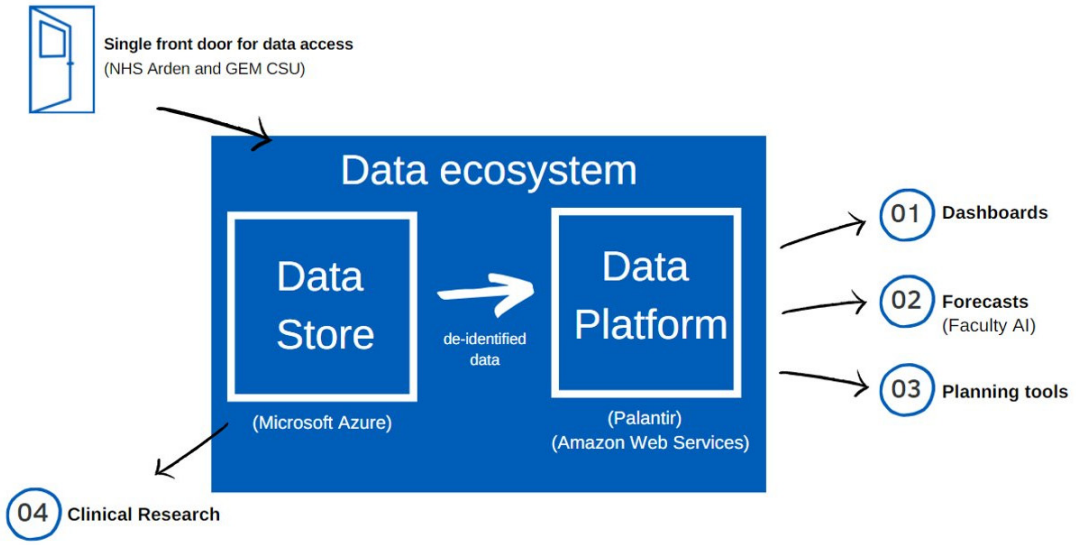
NHS COVID-19 Data Platform Aims

- The aim is to provide a single version of the truth about the rapidly evolving situation, data from the data store needs to be analysed to make it meaningful – this is where the data platform comes in.
- Analysing datasets in the Data Platform allows the NHS to understand what is happening to people.
- A suite of reporting tools including dashboards have been developed to provide senior decision-makers with an accurate picture of the evolving COVID-19 situation.
- The tools and products developed will be covered in more detail during the juries.

Data from the "Data ecosystem" is then used for two key purposes:

1. To support the organisations in charge of the COVID-19 response to make effective data-led decisions.
2. For clinical research – to help understand the virus better and develop potential treatments / vaccines.

When and by what organisation(s) were the NHS COVID-19 Data Store & Data Platform created, where is it stored and what organisations are involved?



NHS England and NHS Improvement and **NHSX** established the NHS COVID-19 Data Store & Data Platform in April 2020.

The Data Store is 'housed' on **Microsoft Azure** (a secure online storage solution or "cloud").

Palantir were contracted to provide NHS England and NHS Improvement with a data platform. Within the data platform numerous dashboards, planning tools and forecasts have been developed. These give a live view of the metrics needed to track and understand the current spread of COVID-19, and the capacity in the healthcare system to deal with it.

The Data Platform (provided by Palantir) is 'housed' on AWS - Amazon Web Services (a cloud solution for platforms).

Faculty AI have helped to develop some of the models and forecasts within the data platform.

NHS Arden and GEM CSU (on NHS England and NHS Improvements behalf) operate a "single front door" for data access requests. Via this process people can request access to the datasets within the Data Store for clinical research purposes and/or tools developed within the Data Platform.

How are decisions made about who can access data within the NHS COVID-19 Data Store & Data Platform?

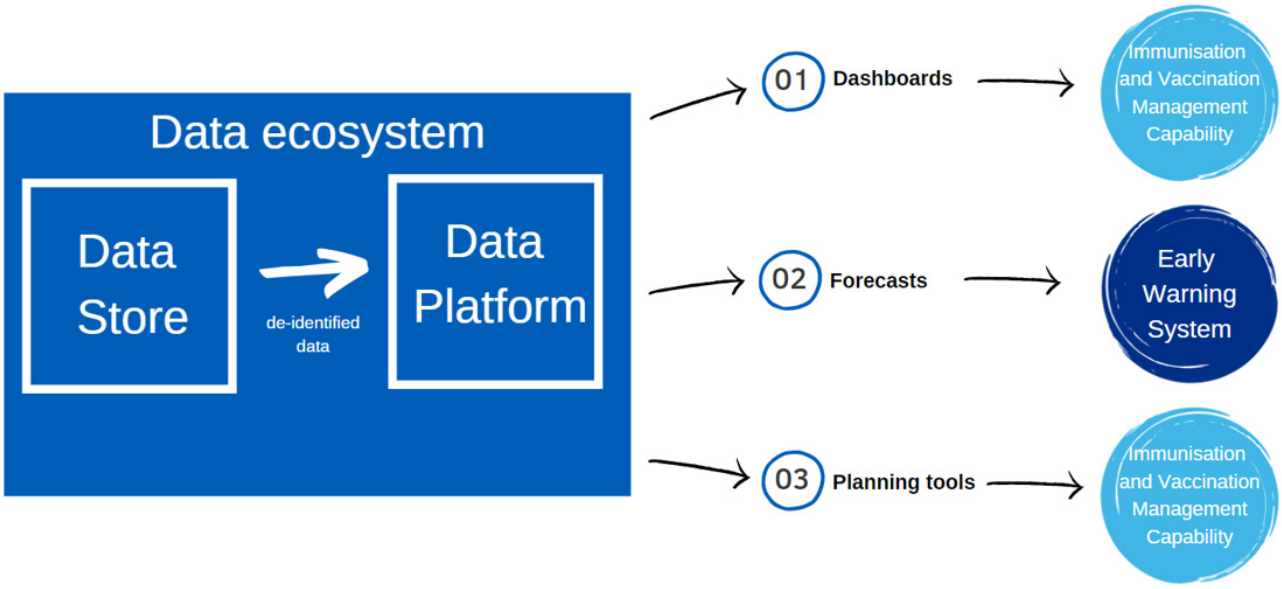
Requests for access to data are managed via a single front door. In line with COPI notices requesters must demonstrate an involvement in the COVID-19 response to be approved for access to data.

Each application for access to data is considered on a case-by-case basis. Considerations include:

- **The purpose** – which must be for COVID-19 purposes.
- **The type and amount of data requested** – any request for data will need to be justified e.g. if requesting record level data, the requestor will need to explain why.
- **Transparency** – how the requestor will be transparent about the data requested for COVID-19.
- **Legal Basis** – the legal basis which supports the applicant to process the data.

What is the legal basis for the NHS COVID-19 Data Store & Data Platform?

- Currently the legal basis for the NHS COVID-19 Data Store & Data Platform is Control of Patient Information (COPI) notices.
- NHSX worked with the Secretary of State for Health and Social Care to implement COPI notices to allow them to share COVID-19 data to support the response to the pandemic.
- The COPI notices require that data is shared for purposes of COVID-19.
- The vision was to collect data and information once to reduce duplication and burden on already over stretched systems and enable sharing between national bodies.
- The aim was for the COPI notices to achieve this in a way that protects the privacy of citizens.
- The COPI notices reduced the need for data sharing agreements with multiple individual organisations.



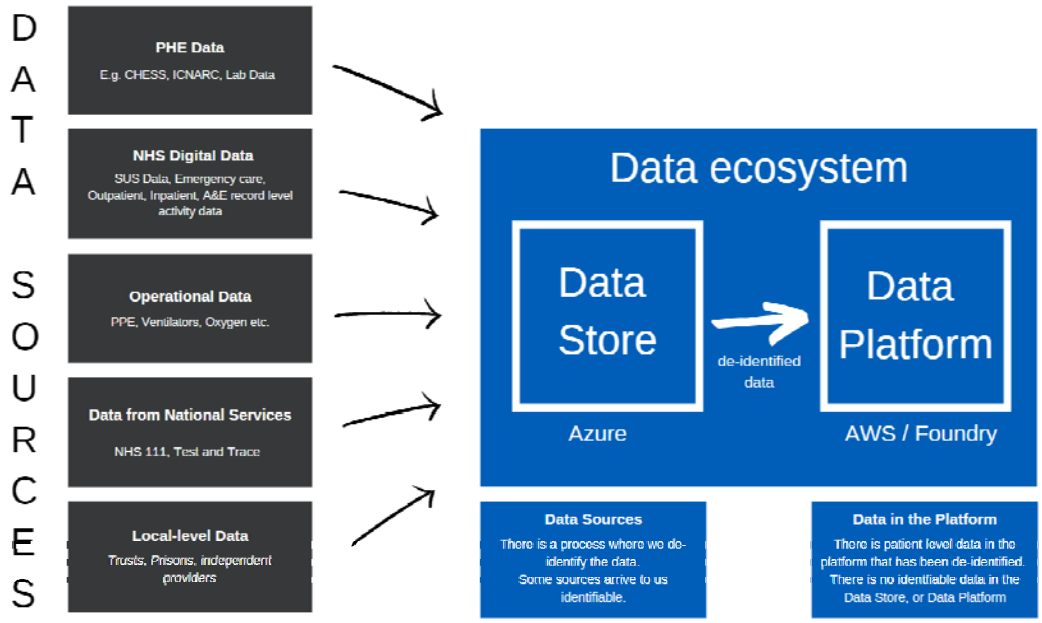
NHS COVID-19 Data Store & Data Platform

Ming Tang, Chief Data and Analysis Officer (Interim)
NHS England and NHS Improvement

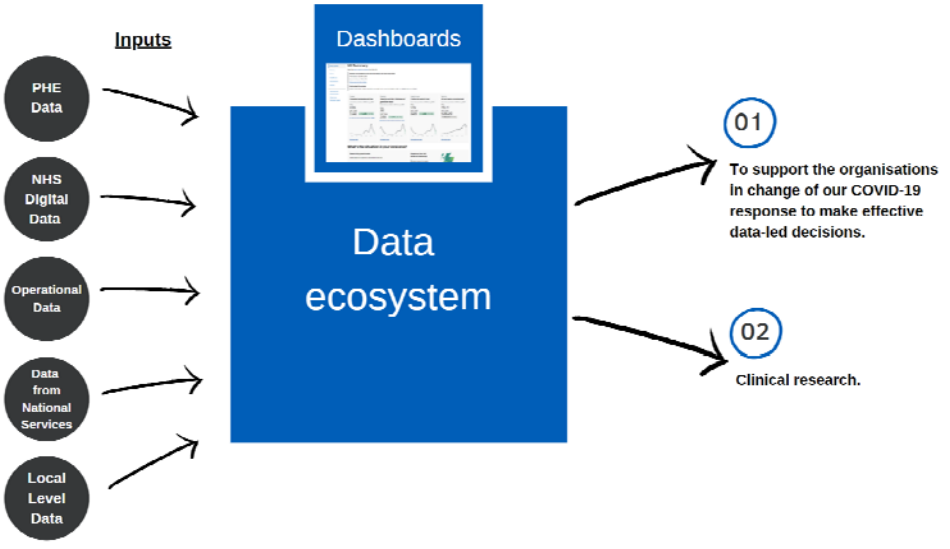
Part 1 – Summary (Neutral Presentation)

- What is the NHS COVID-19 Data Store and Data Platform (both Azure database, and Palantir's AWS), where is it stored, what data does it comprise, and how did the data get there?
- When and by what organisation(s) were the NHS COVID-19 Data Store and Data Platform created, and what organisations are involved in running them?
- Were the NHS COVID-19 Data Store and Data Platform enabled through the 2020 COPI regulations, and if so, how?
- How are decisions made about which applications are granted access to the COVID-19 Data Store and Data Platform, and when approved how do systems access the data?
- Briefly, how many approved applications of the NHS COVID-19 Data Store and Data Platform there are currently, and very briefly describe 3 examples (excluding those being considered on jury day 5)?

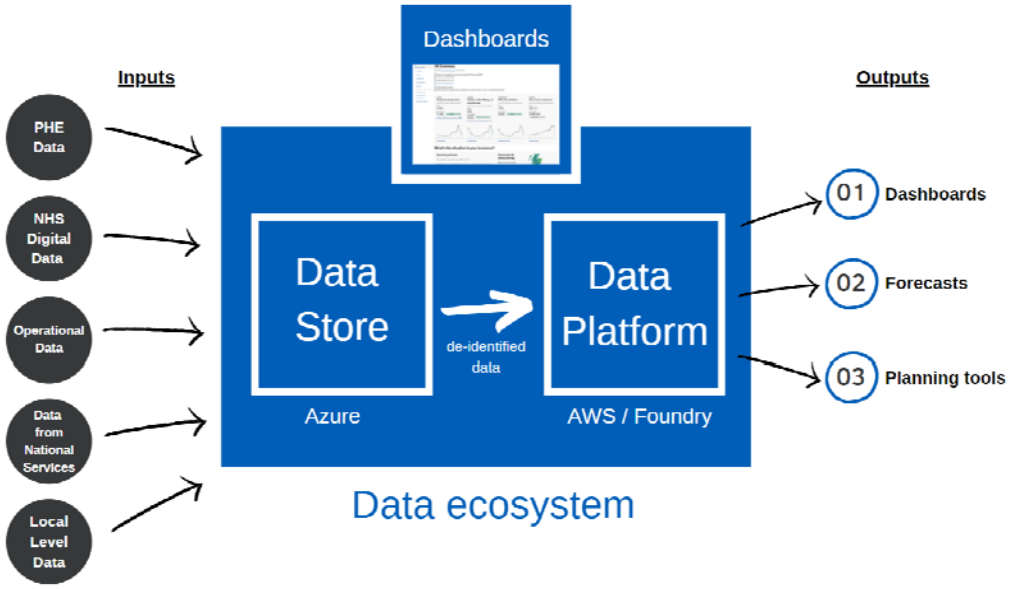
What is the NHS COVID-19 Data Store & Data Platform?



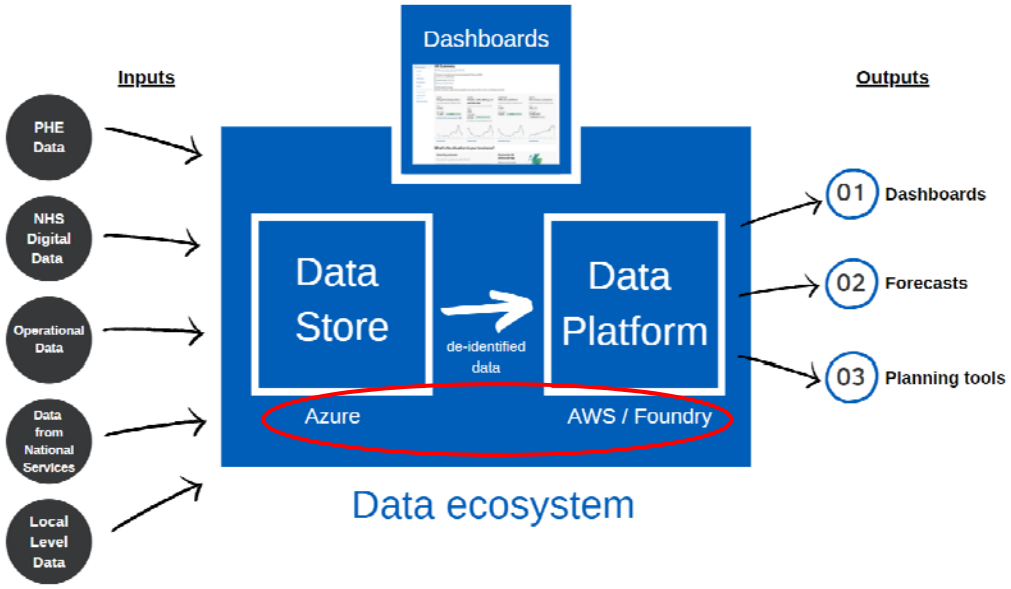
Data from the NHS COVID-19 Data ecosystem is then used for two key purposes:



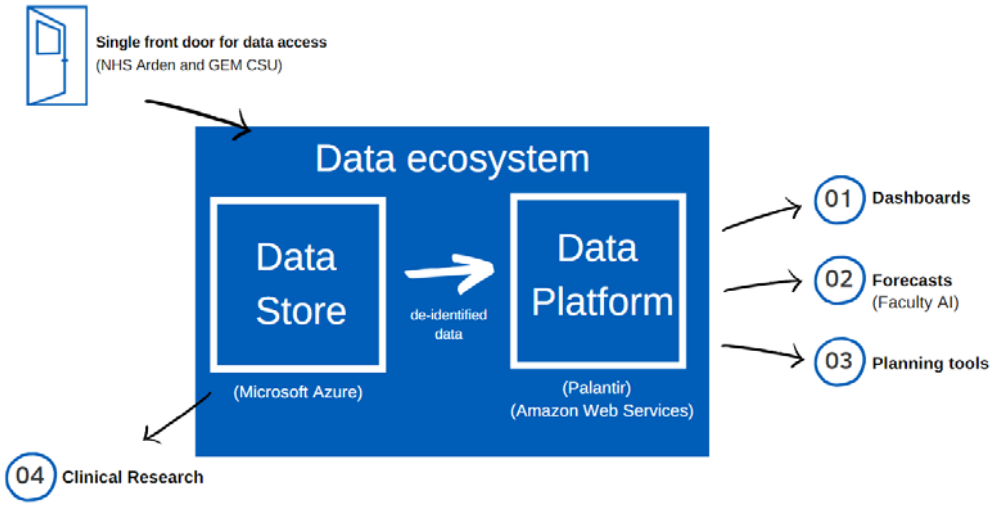
Enabling the organisations in charge of our COVID-19 response to make effective data-led decisions:



Where are the NHS COVID-19 Data Store & Data Platform stored?

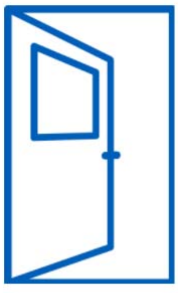


NHS England and NHS Improvement and NHSX established the NHS COVID-19 Data Store & Data Platform in April 2020.



How are decisions made about who can access data within the NHS COVID-19 Data Store & Data Platform?

Data access single front door



(NHS Arden and GEM CSU)

Requests for access to data are managed via a single front door.

Requesters must demonstrate an involvement in the COVID-19 response to be approved for access to data.

Each application for access to data is considered on a case-by-case basis. Considerations include:

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- The COPI notices require that data is shared for purposes of COVID-19.
- The COPI notices reduced the need for data sharing agreements with multiple individual organisations.
- Without the COPI notices we wouldn't have had access to the data needed to inform our COVID-19 response.

How many approved use cases of the NHS COVID-19 Data Platform are there currently, and very briefly describe 3 examples?

There are currently 6 approved use cases that fall into 3 categories.

- Operational Tracking and Reporting
- Operational Planning
- Data Collection

Below are 3 examples of products which we will look at in more detail in the next presentation.

Strategic Decision Makers Dashboard

- Provides senior decision-makers with an accurate picture of the evolving situation

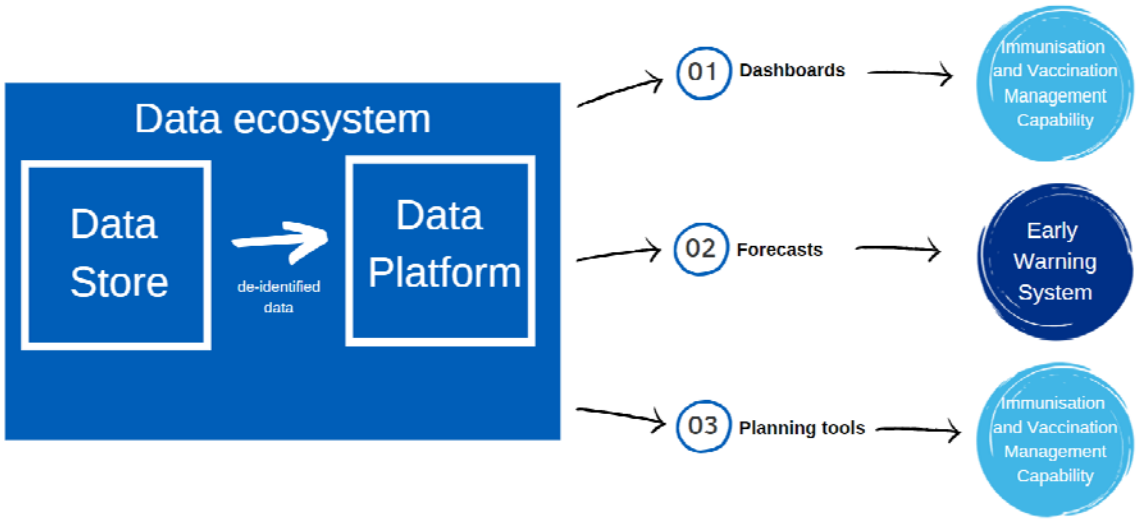
Integrated Planning Tool

- The Integrated Planning Tool (IPT) Capability is a tool configured to support planning between national, regional and local systems. It enables service planning, as well as national and local models for supply and demand.

PPE Supply Management Tool

- Using the portal, trusts submit a daily stocktake and burn rate. This is fed into the national dashboard, showing resource capacities and stockpiles across the UK

On Monday, you will hear more detail about 2 of the tools on the Data Platform



Part 2 – Summary (Persuasive Presentation)

- Why was the NHS COVID-19 Data Store & Data Platform introduced?
- What direct benefits, if any, have there been from the NHS COVID-19 Data Store itself (excluding the benefits from the approved applications)?
- What benefits have there been from the 3 example applications outlined earlier?
- Could similar outcomes have been achieved without creating the NHS COVID-19 Data Store & Data Platform?
- Is the NHS COVID-19 Data Store & Data Platform something that you believe would have been valuable outside of the pandemic?
- What should the future of the NHS COVID-19 Data Store & Data Platform be?
  - Have any decisions been made about its future?
  - For how long should the NHS COVID-19 Data Store & Data Platform continue with the additional information introduced in Spring 2020?
    - I. As short a time as possible
    - II. Only as long as the COVID pandemic continues and emergency powers are in place
    - III. As long as it is valuable (potentially beyond the pandemic and for COVID and non-COVID uses)
    - IV. Something else
  - By whom should these decisions be made?
    - I. An independent advisory group of experts and lay people
    - II. The organisation accountable for the data initiative
    - III. Ministers or parliament
    - IV. Someone else

Part 2 – Brief Cont'd

- What, how and when could the public have found out about the NHS COVID-19 Data Store & Data Platform, and has it attracted significant public attention?
- What information is available about all the NHS COVID-19 Data Store & Data Platform applications, and how long has that been available?
- What actions have been taken to engender public trust?
- A summary of your main points

Why was the NHS COVID-19 Data Store introduced?

•In a crisis response, inconsistencies in data can cost lives. Different parts of the NHS were already capturing much of the information we needed, however without a single place to gather and analyse this data, **decision-makers were unable to move as quickly** as the response demanded.

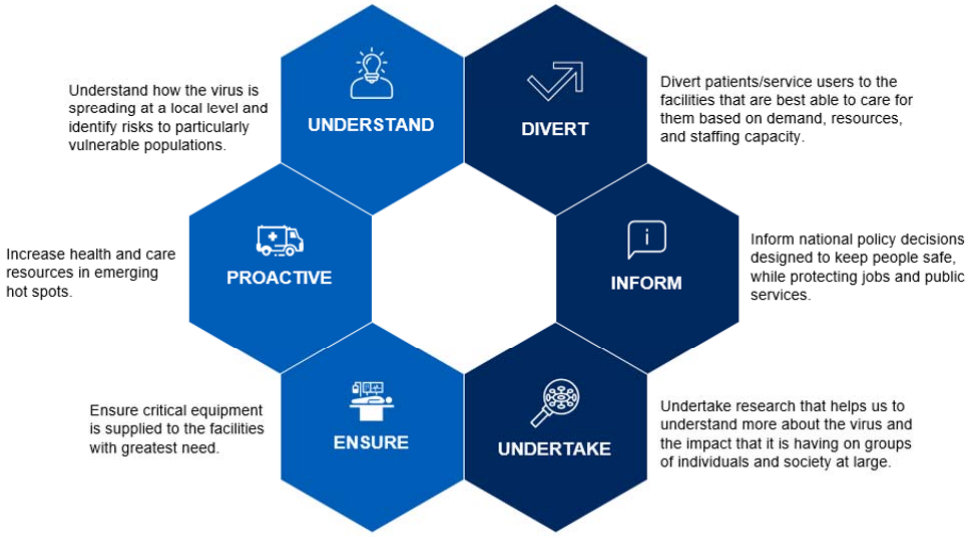
Information in spreadsheets held by disparate organisations was at risk of being duplicated and rapidly became outdated, leading to **inaccurate or incomplete understanding of the situation.**

Therefore, the **data was not timely enough** to create near-real time 'single version of the truth' needed to respond to the pandemic.

In addition, we needed to collect a lot of specific datasets in relation to COVID-19 such as **positive test results/ no. of cases** as well as administrative and activity data from NHS services such as no. of admissions.

The **NHS COVID-19 Data Store** enabled us to bring all of these datasets together in one place.

The NHS COVID-19 Data Store & Data Platform have been instrumental in giving decision-makers access to accurate real-time information to make informed, effective decisions.



What direct benefits, if any, have there been from the NHS COVID-19 Data Store?

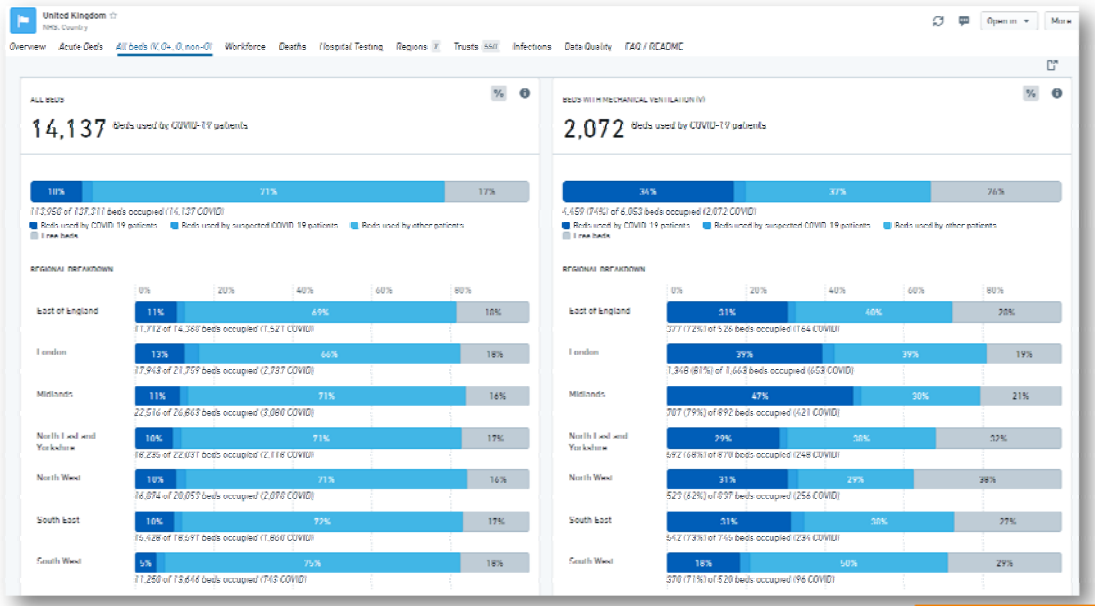
- •Having all the information in **one secure place** allowed us to make the **asset** available to those national organisations responsible for coordinating the COVID-19 response.
- •**Reduced duplication** as data is collected once and made available for multiple purposes through automated extraction; this also reduces the burden on trusts.
- •**Improved data quality** and a **single version of the truth** in near real time gives a consistent operating picture from which we can be assured that the data used is fit for purpose for decisions.
- •**Time savings** for users, especially frontline workers, due to the reduced effort needed in inputting, cleansing, disseminating and interpreting data.
- •**Cost savings** derived from current expenditure on data processing, storage and visualisation solutions being reduced.
- **Legacy -** capturing near real time data to **enable people to make effective operational decisions** is a great legacy to leave behind.

What direct benefits, if any, have there been from the NHS COVID-19 Data Platform?

Product Example	Type of Product	Benefits	Screenshots
Strategic Decision Makers Dashboard	Operational Tracking & Reporting	• Provide senior decision-makers with an **accurate picture of the evolving COVID-19 situation**	
Integrated Planning Tool	Operational Planning	• Supports Local Planning • Users can apply scenarios to see what knock on effect that would have on their services and then **plan services and workforce** accordingly	
PPE Supply Management Tool	Data Collection	• Used to manage the **national demand, supply and allocation** of PPE items • Over ***6 billion* PPE items** have been allocated through the PPE Supply Management Tool in the Data Platform	

Click on the icons to view screenshots

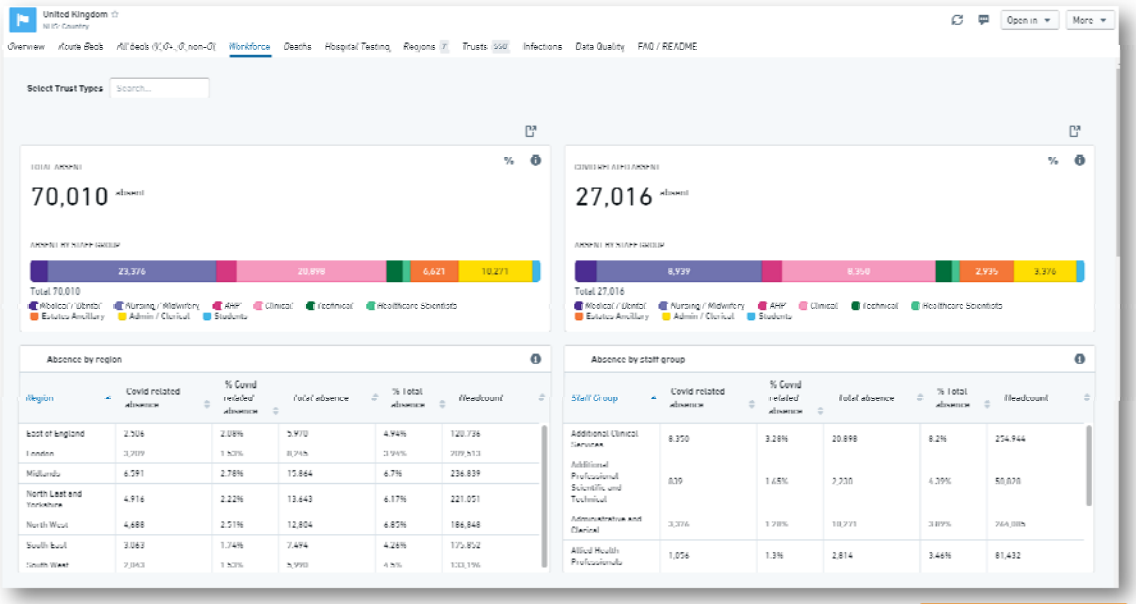
Strategic Decision Makers' Dashboard – Bed Capacity (1/3)



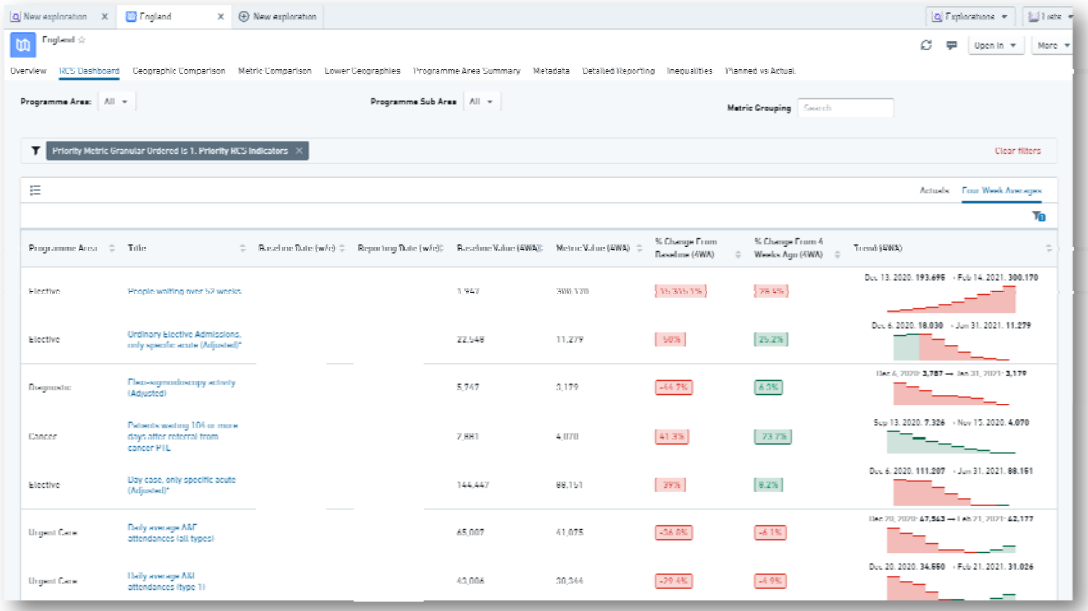
Return to 'Benefits' slide

SDMD– Estimated Admissions (2/3)

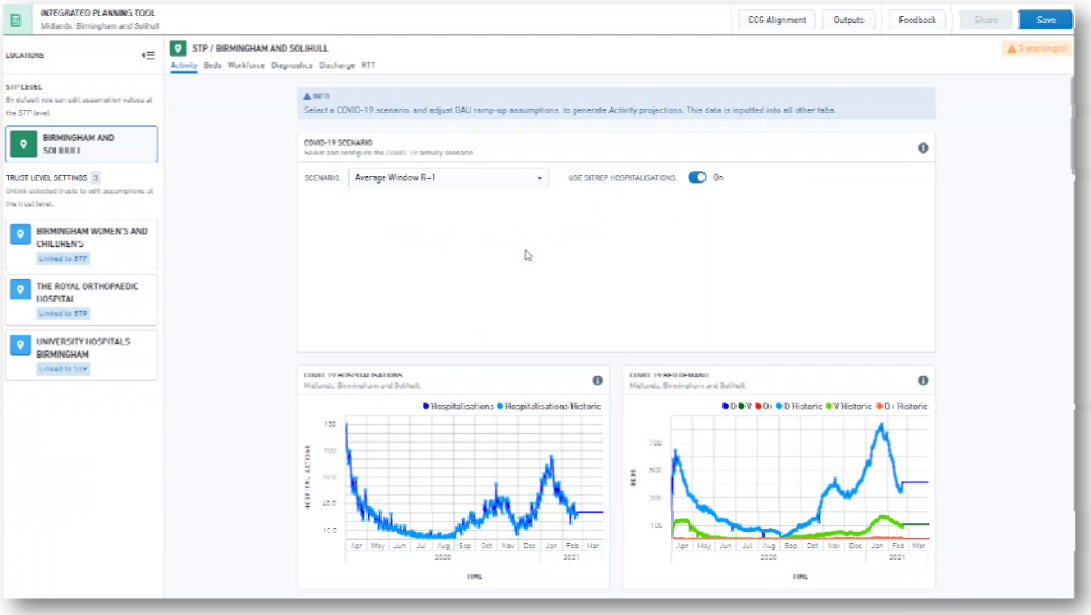
SDMD – Workforce (3/3)



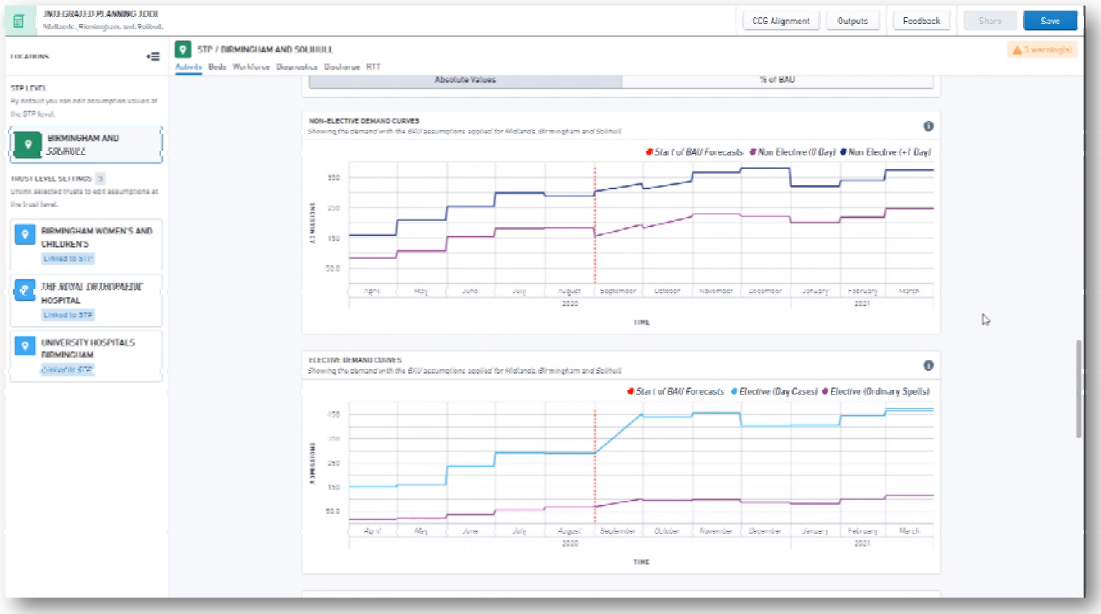
Recovery of Critical Services (1/1)



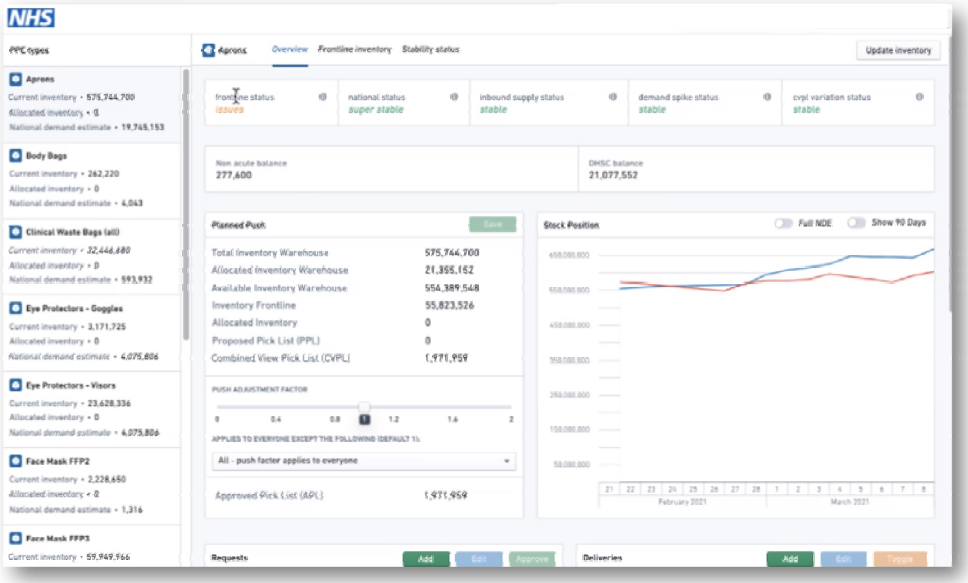
Integrated Planning Tool – (1/2)



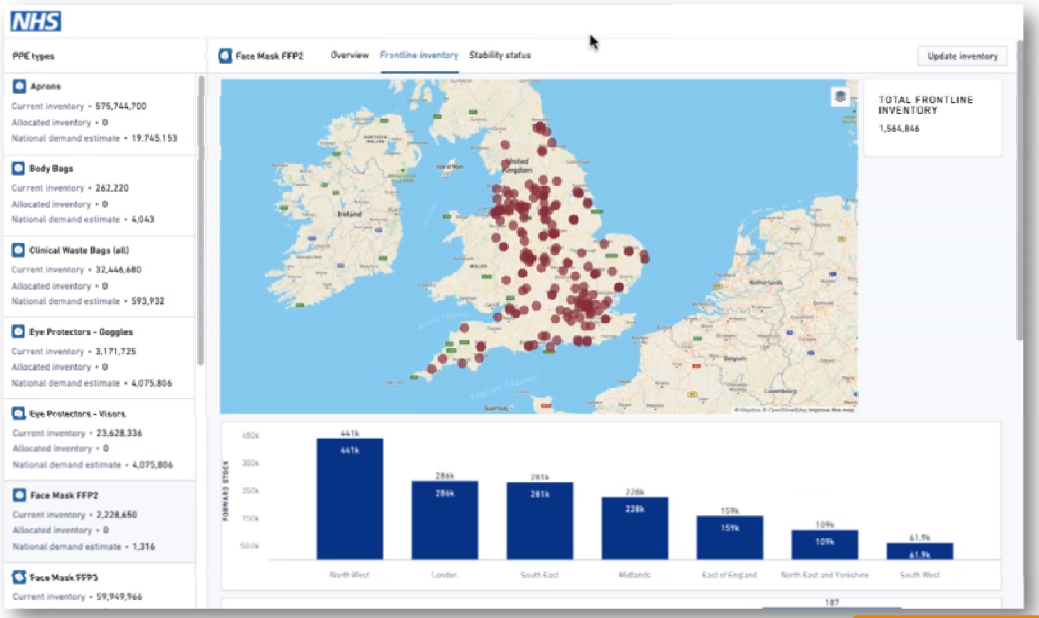
Integrated Planning Tool - (2/2)



PPE Supply Management Tool – (1/2)



PPE Supply Management Tool (2/2)



Data and Analytics

Return to 'Benefits' slide

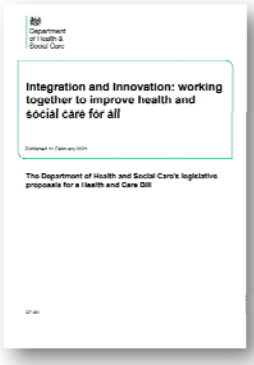
Could similar outcomes have been achieved without creating the NHS COVID-19 Data Store & Data Platform?

We wouldn't have been able to respond quickly enough.

We wouldn't have been able to provide data accurate enough to inform an effective response.

There would have been duplication across the system.

There would be no near-real time version of the truth.


Integration and innovation: working together to improve health and social care for all

The Department of Health and Social Care's legislative proposals for a Health and Care Bill

The government recently published a White Paper which shines a light on the NHS COVID-19 Data Store as a key achievement of the nation's response to Coronavirus.

- **Covid-19 response**. As of 9 February 2021, the UK has vaccinated 12.6 million people. In the early stages of the response, the NHS COVID-19 Data Store was established, which safely brought together accurate, real-time information necessary to inform decisions in response to the current pandemic in England.

Reference: Integration and innovation: working together to improve health and social care for all (web version), page 16

Data and Analytics

Is the NHS COVID-19 Data Store & Data Platform something that you believe would have been valuable outside of the pandemic?

Improved data sharing would enable us to **join up disparate NHS organisations** to provide **better care** for our patients and to plan services **using insights from data**.

Our ambition is to use better data to **enhance our understanding** and enable informed decision making to **reduce inequalities** and support people to **live longer, healthier and more independent lives**.

We must be smart and **start looking forward** – we need to be **more predictive** and **start proactively addressing issues** which we know will have a significant impact on services in the future if we don't put preventative measures in place.

What should the future of the NHS COVID-19 Data Store & Data Platform be?

- **Have any decisions been made about its future?**
  - The future of the Data Store & Data Platform is still being decided. Activities like the Citizens' Juries and other engagements can help influence its future.
- **For how long should the NHS COVID-19 Data Store & Data Platform continue?**
  I. As short a time as possible
  II. Only as long as the COVID pandemic continues
  III. As long as it is valuable (potentially beyond the pandemic and for COVID and non-COVID uses)
  IV. Something else
- **By whom should these decisions be made?**
  I. An independent advisory group of experts and lay people
  II. The minister or organisation accountable for the data initiative
  III. Parliament
  IV. Someone else
  - **Ministers** will ultimately be the group that decides the future of the NHS COVID-19 Data Store. Before that decision is made, ministers and NHS leaders will be working closely with stakeholder groups to ensure that the Data Store and Data Platform delivers the best possible outcomes for patients.
  - The NHS are currently developing a Data Strategy, which will help to define how the NHS is able to use data in the future.

What should the future of the NHS COVID-19 Data Store & Data Platform be?

NHS Data Strategy

The strategy will set out how the NHS in England plans to use, store and process patient and other types of data. It will describe our aspirations to continue to share data in a legal, beneficial way after the COPI notices expire.

The strategy will address key questions around information governance.

It is being developed in partnership with key Arms' Length Bodies & the National Data Guardian.

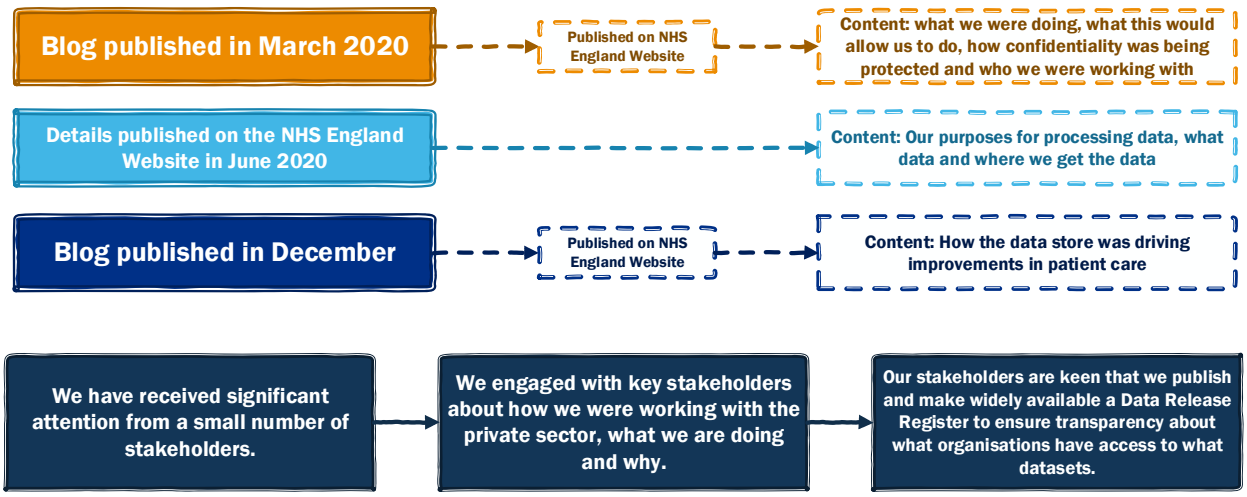
NHSX has also worked with key workforce and patient representative groups.

The NHS Data Strategy will set the strategic direction for how we continue to use data for improved outcomes for patients.

What information is available about all the NHS COVID-19 Data Store & Data Platform. How long has that been available?

Control of Patient Information Notices	The NHS COVID-19 Reference Library	Data Protection Impact assessment	Privacy Notice
March 2020	June 2020	June 2020	June 2020
Notification to healthcare organisations, GPs, local authorities and arm's length bodies that they should share information to support efforts against coronavirus	Describes the datasets being used in the NHS COVID-19 Data Store, and the sources of those datasets	A Data Protection Impact Assessment (DPIA) is a process to help organisations to identify and minimise the data protection risks of a project	Explains what the sharing of data means for patients

What, how and when could the public have found out about the NHS COVID-19 Data Store & Data Platform and has it attracted significant public attention? (1/2)



What, how and when could the public have found out about the NHS COVID-19 Data Store & Data Platform and has it attracted significant public attention? (2/2)

The majority of our dashboards, forecasts and planning tools are NHS facing.

They are designed to enable staff to make effective operational decisions.

Only those who need access to the data to inform our COVID-19 response are granted access.

The Data Store and Data Platform did not attract much public attention, despite the publications mentioned on the previous page.

However, data from the Data Store and Data platform powers the public-facing dashboard. The public facing dashboard gives an accurate, daily view of the situation across the country. This dashboard includes elements of the NHS facing dashboards we have developed such as heat maps which display cases data for specific areas within the UK.

What actions have been taken to engender public trust?

We are working closely with the National Data Guardians office, use MY data, and Understanding Patient Data.

use MY data

use MY data supports and promotes the protection of individual choice, freedom and privacy in the sharing of healthcare data to improve patient treatments and outcomes. **use MY data** aims to educate and harness the patient voice to understand aspirations and concerns around the use of data in healthcare delivery, in service improvement and in research, aimed at improving patient decision making, treatment and experience.

Understanding Patient Data

Understanding Patient Data aims to make uses of patient data more visible, understandable and trustworthy, for patients, the public and health professionals. They work with patient groups, charities, NHS organisations and policymakers to bring transparency, accountability and public involvement to the way patient data is used.

National Data Guardian: 8 Caldicott Principles

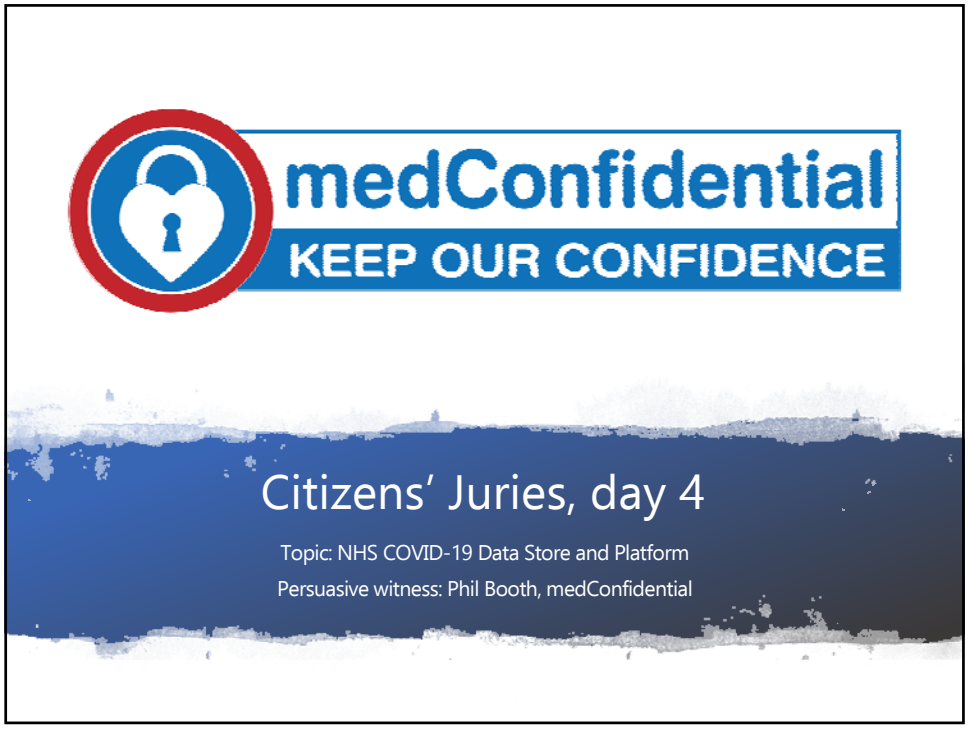
1. Justify the purpose(s) for using confidential information
2. Use confidential information only when it is necessary
3. Use the minimum necessary confidential information
4. Access to confidential information should be on a strict need-to-know basis
5. Everyone with access to confidential information should be aware of their responsibilities
6. Comply with the law
7. The duty to share information for individual care is as important as the duty to protect patient confidentiality
8. Inform patients and service users about how their confidential information is used

A summary of your main points

What is it?	How can it help?	Working in partnership
NHS England and NHS Improvement and NHSX established the NHS COVID-19 Data Store in March 2020.	Data from the NHS COVID-19 Data Store has enabled world first research	Decisions about the future should be made in partnership with all stakeholders
The Data Store collects all COVID-19 data in a single-secure location to reduce duplication	Data is used for situational awareness and pandemic management purposes	We are working with the National Data Guardian and patient data stakeholder groups
Data is de-identified before it is fed through to the NHS COVID-19 Data Store	Continued data sharing would enable use to apply our learning to future challenges	We publish as much data as we can publicly

Good data saves lives – data is used to inform effective decision making and to drive improvements

We need to retain beneficial change and apply our learning to address other health inequalities to ensure health and high quality care for all, now and for future generations



Quick recap

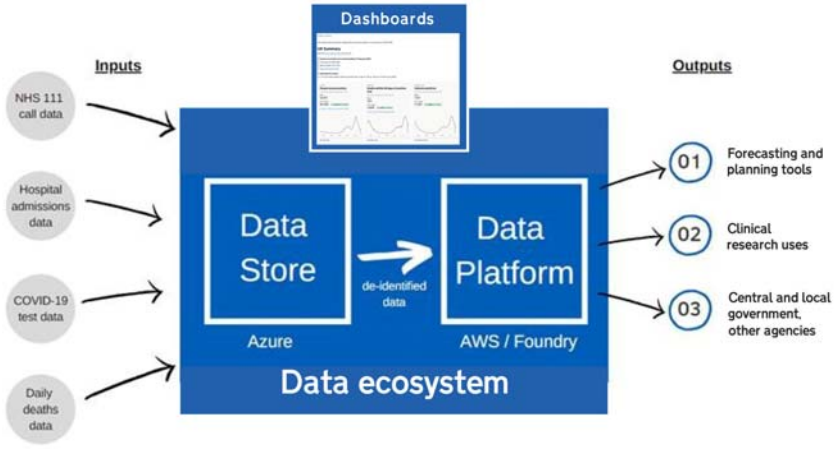
- Why is it important to use patient data for the individual and the wider public?
  - Direct care;; planning and commissioning; research; commercial exploitation
- Why is it important to protect patient data, and what should the public expect?
  - That every use is legal - also consensual, safe and transparent.
- Should the public be prepared to accept a different level of protection of patient data during a pandemic?
  - No.
- To what extent does medConfidential support the regulations introduced in 2020 to enable greater patient data sharing?
  - To the extent that what is done under them is necessary and proportionate - also lawful, fair and transparent!

NHS COVID-19 Data Store and Platform

The Data Store and Platform was introduced to collect real-time information necessary to inform decisions in response to the pandemic in a Microsoft Azure 'Bastion' controlled by NHS England

This consolidated data was then used to develop tools, build forecasting models and provide dashboards for decision-makers within a single integrated data platform, Palantir' Foundry, which runs on Amazon Web Services

Other companies, notably Faculty Science Ltd, helped develop models for such things as predicting the spread of the virus, and for hospital bed and workforce capacity, as well as for critical equipment capacity (PPE, ventilators, oxygen, etc.)



NHS Covid-19 Data Store and Platform

What, how and when could the public have found out about the NHS Covid-19 Data Store and Platform, and has it attracted significant public attention?

- A couple of blog posts, a privacy notice on the web, and coverage in the media (quite often confused, frequently negative).

What information is available about all the NHS Covid-19 Data Store and Platform applications, and how long has that been available?

- Much of the information is rather vague and high level, though there is some more detail in the contracts - only some of which have been published.

What actions have been taken to engender public trust?

- Very few. Indeed, lack of transparency, the reputation of some of the companies involved, and poor communications have been corrosive of trust.

NHS COVID-19 Data Store and Platform

Unfortunately, what was actually being done with patients' data was not explained well…

All the data in the data store is anonymous, subject to strict controls that meet the requirements of data protection legislation and ensure that individuals cannot be re-identified. The controls include removing identifiers such as name and address and replacing these with a pseudonym. GDPR principles will be followed, for example the data will only be used for Covid-19 and not for any other purpose and only relevant information will be collected. Any request to access data will be reviewed through a single process controlled solely by NHS England and NHS Improvement and NHSX.

28th March 2020

All the data held in the platform is subject to strict controls that meet the requirements of data protection legislation. GDPR principles will be followed, for example the data will only be used for Covid-19 and not for any other purpose and only relevant information will be collected. Any request to access data will be reviewed through a single process controlled solely by NHS England and NHS Improvement and NHSX.

9th April 2020

From 'The power of data in a pandemic' by Matthew Gould, Dr Indra Joshi and Ming Tang

NHS Covid-19 Data Store and Platform

What have we been able to find out about the applications of the NHS Covid-19 Data Store?

From just the Palantir and Faculty Science contracts:

1) 'Self-Service' Integration and Analytics Capability
2) Dashboard to manage resources used by projects using Foundry
3) Strategic Decision-Makers Dashboard
4) Recovery of Critical Services tool
5) Early Warning System (day 5)
6) Supply Management Capability
7) Immunisation and Vaccination Management Capability (day 5)
8) Workforce Analytics Capability
9) Adult Social Care Dashboard Capability
10) Integrated Planning Tool

NHS COVID-19 Data Store

What direct benefits, if any, have there been from the NHS Covid-19 Data Store itself (excluding the benefits from the approved applications)?

- The benefits are largely unknown. That is not to say there have not been any, but if NHS England is not transparent and fails to provide evidence, people are left to draw their own conclusions.
- What NHS England has built is basically an old-fashioned 'Data Lake'.
- What NHS England hasn't done is to publish all of the uses and users of the Data Store, their approvals and the outcomes.

What benefits have there been from the 3 example applications outlined earlier?

- Your guess is as good as mine...

NHS COVID-19 Data Store and Platform

Could similar outcomes have been achieved without creating the NHS Covid-19 Data Store and Platform?

- Some yes, some no - e.g. Public Health England was doing fine with the public dashboard until late August.
- Of course it was much easier for Palantir to integrate the disparate datasets in Foundry once NHS England had collected them into one place.

Is the NHS Covid-19 Data Store and Platform something you believe would have been valuable outside of the pandemic?

- Valuable to who? NHS England has been trying to build something like this for most of its existence. That it has used the extraordinary COPI powers to do so under COVID does not mean it even has a lawful basis to keep using it outside the pandemic.
- Rather than taking ever more copies, the NHS should invest in making its systems properly **interoperable**.

Concerns

What specific concerns do you have about the introduction of the NHS Covid-19 Data Store and Platform itself?

- Lack of transparency, e.g. no approvals / release register
- Outright secrecy;, sometimes concealing information
- Mass copying of data: where will it all end up?
- Poor public communication

Concerns

Why might the introduction of the NHS Covid-19 Data Store and Platform or any of its specific applications be considered contentious?

- It is not necessarily the applications as much as the secrecy around exactly who is being allowed to do what
- It seems like a giant data grab, despite promises given at the start
- Problematic reputations / political connections of some of the companies involved, e.g. Palantir, Faculty Science Ltd, Deloittes and McKinsey

What could have been done differently?

- Proper transparency, such as publishing the information that the COPI regulations require NHS England to keep anyway
- NHS England should have known and been able to explain its exit strategy from the first contracts, definitely before signing the second set

The future of the NHS Covid-19 Data Store and Platform

What should the future of the NHS Covid-19 Data Store and Platform be?

- It should become the Covid-19 Disease Register, under the control of NHS Digital - as per the Cancer Registry, etc.

How could or should the Data Store and Platform and its applications be usefully changed in the future (if at all)?

- If it is to persist, the Data Store and Platform must have a clear legal basis

What actions, if any, could be taken to engender greater public trust in the initiative?

- Respect patient opt-outs! N.B. the National Data Opt-out covers both research and planning
- Move it to a Trusted Research Environment, e.g. at NHS Digital, under well-established Information Governance and other procedures
- Transparency – data release registers, minutes & approvals, etc.

How long?

For how long should the NHS Covid-19 Data Store and Platform continue?

(ii) Only as long as the Covid pandemic continues

- The Data Store and Platform was created under the COPI Notices. When they expire, the legal basis for it expires - as does the legal basis for NHS Eng;land to be the data controller of much of the data in it
- If it is retained, the data should become the COVID-19 Disease Register

Who decides?

By whom should these decisions be made?

(iii) Parliament

- For anything to do with new lawful bases, the UK's law-making body must be involved. Parliament should also provide the necessary scrutiny.
- In practice, once the decision has been made, it is the Secretary of State who Directs the relevant bodies.

In summary

CONSENSUAL?

Clearly not! Data was copied under the COPI powers, public notification was minimal and patients' existing opt-outs (e.g. National Data Opt-out) were 'ignored.

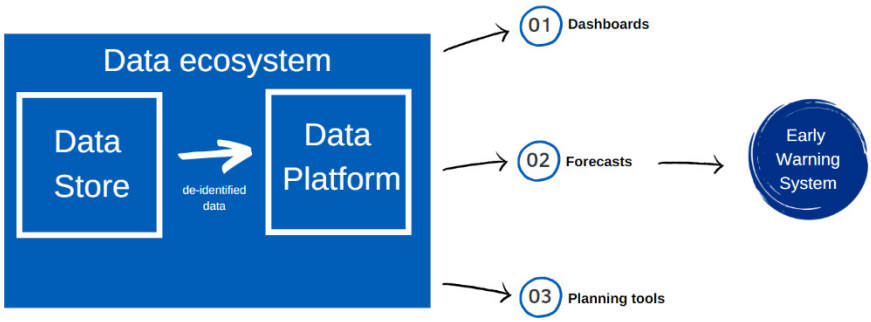
SAFE?

We must hope so. There's no reason to assume the platforms are not secure but, with so many unknowns and unknown people involved, the Data Store is not even close to a Safe Setting.

TRANSPARENT?

Not so far. People must know what data is being processed, for what purposes and by who - which requires not just (redacted) contracts and a DPIA but at least a comprehensive list of all of the data in the Data Store, publication of all applications, deliberations and approvals, and a 'release register' of every use.

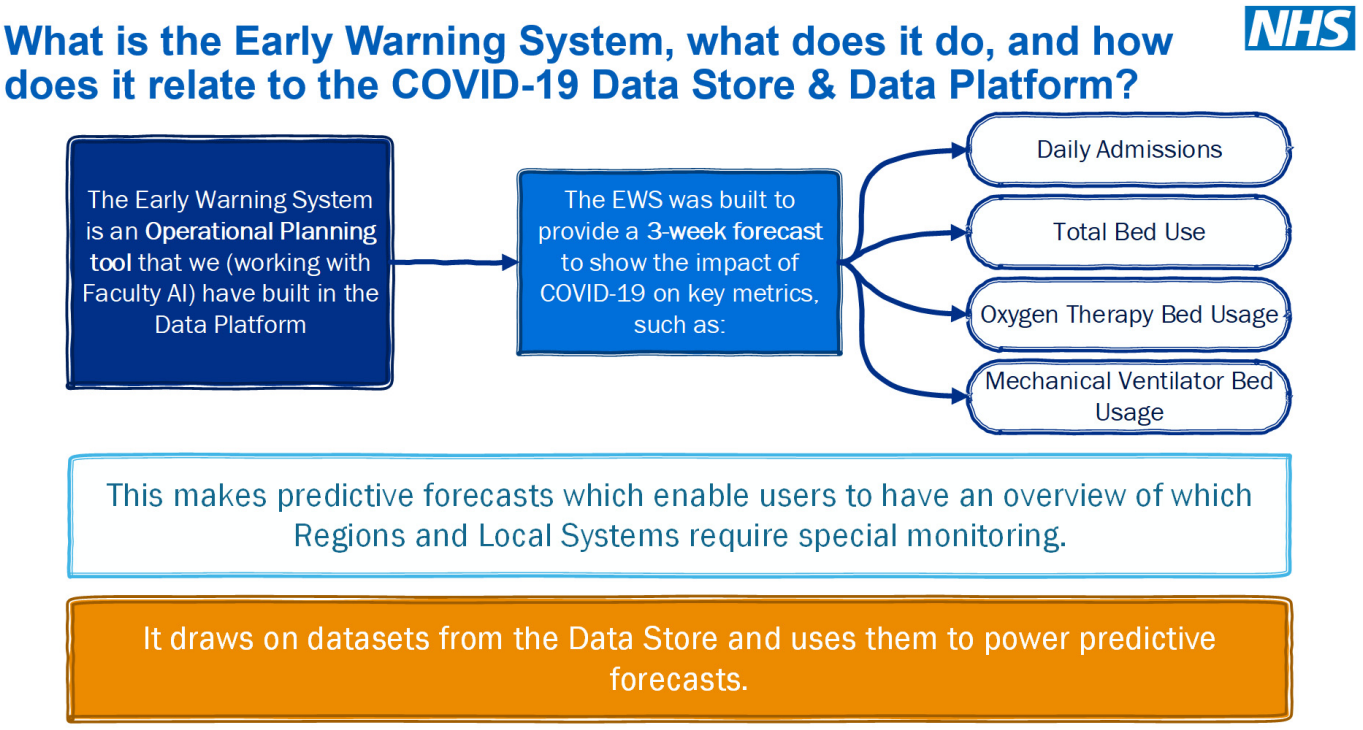
Case study 1: Early Warning System



The Early Warning System (EWS) is an operational planning tool (model) that we (working with Faculty AI) have built in the Data Platform.

The EWS was built to provide an up to three-week forecast to show the impact of COVID-19 on key system metrics (such as daily admissions, total bed usage, oxygen therapy bed usage and mechanical ventilator bed usage), enabling users to have an overview of which Regions and Local Systems require special monitoring.

It draws on datasets from the Data Store and uses them to power predictive forecasts.



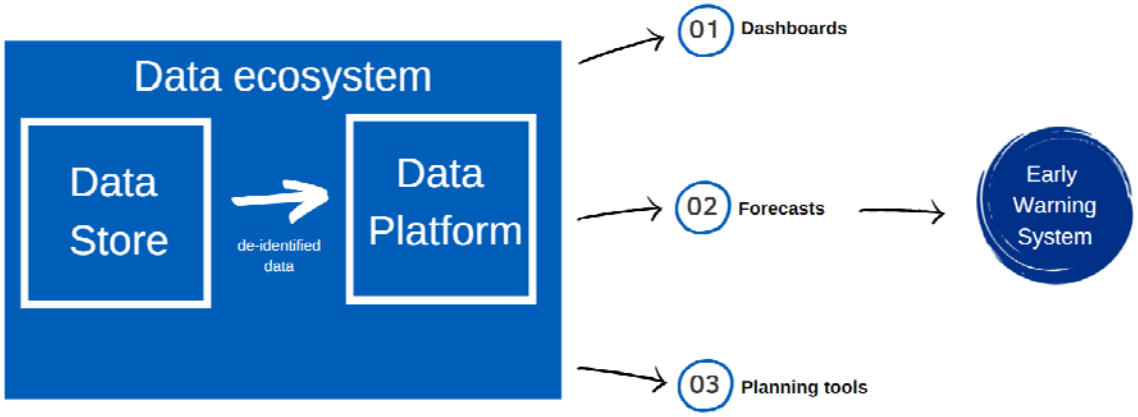
NHS COVID-19 Data Store Case Study 1: The Early Warning System

Ed Kendall – Deputy Director, Economics
NHS England and NHS Improvement

Part 1 - Summary (Neutral Presentation)

- What is the Early Warning System, what does it do, and how does it relate to the COVID-19 Data Store?
- Was this enabled through the 2020 COPI regulations?

Reminder from last time…



What is the Early Warning System, what does it do, and how does it relate to the COVID-19 Data Store & Data Platform?

The Early Warning System is an **Operational Planning tool** that we (working with Faculty AI) have built in the Data Platform

The EWS was built to provide a **3-week forecast** to show the impact of COVID-19 on key metrics, such as:

- Daily Admissions
- Total Bed Use
- Oxygen Therapy Bed Usage
- Mechanical Ventilator Bed Usage

This makes predictive forecasts which enable users to have an overview of which Regions and Local Systems require special monitoring.

It draws on datasets from the Data Store and uses them to power predictive forecasts.

Was this enabled through the 2020 COPI regulations?

- Yes – as the EWS uses data from the Data Store, and COPI notices enable the sharing of data to the Data Store, COPI notices enable the EWS.

NHS COVID-19 Data Store Case Study 1: The Early Warning System

Dr Harrison Carter - National Medical Director's Clinical Fellow
NHS England and NHS Improvement

Part 2 - Summary (Persuasive Presentation)

- When was the Early Warning System introduced, and why?
- What benefits have there been from the Early Warning System?
- Is this something that you believe would have been valuable without the pandemic?
- Could similar outcomes for the Early Warning System have been achieved without creating the NHS COVID-19 Data Store & Data Platform?
- What should the future of the Early Warning System be?
  - Have any decisions been made about its future?
  - For how long should the Early Warning System continue?
    I. As short a time as possible
    II. Only as long as the COVID pandemic continues
    III. As long as it is valuable (potentially beyond the pandemic and for COVID and non-COVID uses)
    IV. Something else
- What, how and when could the public have found out about the Early Warning System, and has it attracted significant public attention?
- What actions have been taken to engender public trust?
- A summary of our main points

When was the Early Warning System introduced, and why?

When?

EWS was set up at the very start of the Pandemic, shortly after the Data Store was established.

Initially, forecasts were included for senior leaders in charge of the COVID response.

Over time, as the demand for forecasts has grown, they were shared with National and Regional Senior NHS Leaders, and with local trusts.

Why?

We needed to forecast where the virus might spread next and how that would affect health and social care services.

The purpose of the forecasts is to help us to understand where the NHS is likely to face strain, so that we can put plans in place to mitigate the risk.

How?

The forecasts work by learning from the data from previous outbreaks that could happen again in the future.

As more people started to use forecasts, we began to house other useful tools within EWS.

For example, EWS includes explanations which help users who are new to using forecasts to understand and interpret them.

What benefits have there been from the Early Warning System?

- **Supports the NHS to plan** at a National, Regional and Local level to enable proactive decision making.
- Using forecasts in EWS, **users can see a 3-week forecast** for predicted COVID-19 Admissions.
- This allows us to **plan and put mitigations in place** e.g. it has helped national supply chain leads secure ventilators and oxygen supply.
- EWS supports the **recovery of non-COVID critical services** such as cancer screening, and mental health support
- Locally, NHS trusts are using EWS to **plan how to use their available bed capacity** for both COVID-19 patients and routine care patients.

Is this something that you believe would have been valuable without the pandemic?

The Early Warning System and its forecasts are COVID-19 specific...

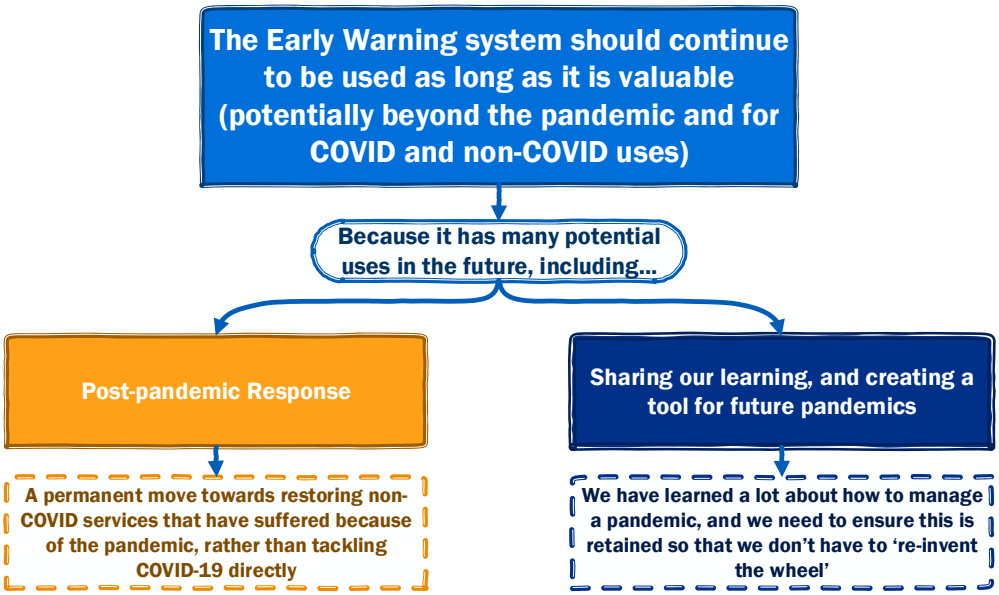
But, a 3-week forward view that supports key decisions about what care could be planned and maintained could be useful for many other non-elective things...

e.g. Post-COVID waitlists, winter/seasonal flu admissions, A&E attendance, broader infectious diseases

What should the future of the Early Warning System be?

- Have any decisions been made about its future?
  - No decisions have been made about the Early Warning System specifically.
- For how long should the Early Warning System continue in it's current form?
  I. As short a time as possible
  II. Only as long as the COVID pandemic continues
  III. As long as it is valuable (potentially beyond the pandemic and for COVID and non-COVID uses)
  IV. Something else

Why?



Could similar outcomes for the Early Warning System have been achieved without creating the NHS COVID-19 Data Store & Data Platform?

- No, without the Data Store we wouldn't have had the data we needed to power the forecasts and without the Data Platform we wouldn't have had the infrastructure we needed to build them.

What, how and when could the public have found out about the Early Warning System, and has it attracted significant public attention?

- NHS and the government are using forecasts to predict the increase of COVID-19 cases – this is very much in the public domain.
- When we first rolled the forecasts out to trusts it was briefed to the media, it didn't attract significant media or public attention.
- NHS England share our forecasts with the Scientific Pandemic Influenza Group on Modelling (SPI-M) who give expert advice to the Department of Health and Social Care and wider UK government on scientific matters relating to the UK's response to COVID-19.
- The Early Warning System itself is not widely publicised, but the outputs and findings from it are used to support the Governments Decisions.
- However, we do not directly publish our forecasts as there is sensitivity about sharing too widely.
- It would not be appropriate for us to publicly publish which trusts we are expecting to see an increased number of COVID-19 admissions as this could lead to panic or a knock-on effect on other services such as people not seeking medical attention when its needed or travelling further to visit a service in a different area.

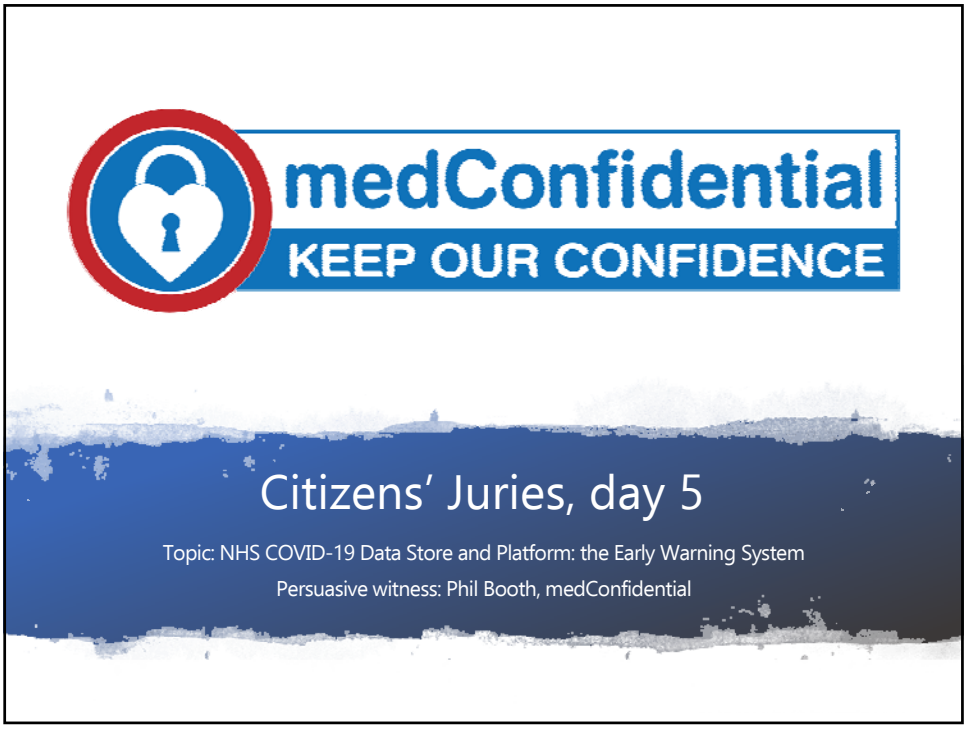
What actions have been taken to engender public trust?

- As with all of the tools on the NHS Data Platform, we have worked closely with groups such as ***use MY data***, ***Understanding Patient Data*** and other expert organisations to ensure that we are protecting patient data.
- All the data powering the EWS is aggregate, and non-patient identifiable information.

A summary of your main points

What is it?	How can it help?	Future of EWS
The **Early Warning System** is an Operational Planning tool that provides a **3-week forecast** to show the impact of key metrics.	Forecasts help National, Regional and Local NHS leaders to understand **where COVID might spread next**, so that they can better **plan their services**.	EWS has taught us a lot about how to manage **future pandemics**
The forecasts work by learning from **the data of previous outbreaks** to inform what happens in the future.	The **EWS** helps the NHS to plan and prepare for impacts of COVID-19, and helps with the **recovery of Critical Services.**	**EWS** would be helpful for other types of non-elective care such as **seasonal flu** and **A&E Attendance.**

The **Early Warning System** has been **crucial to our pandemic response**, and has helped us to **prepare the NHS in advance of outbreaks.**



Quick recap

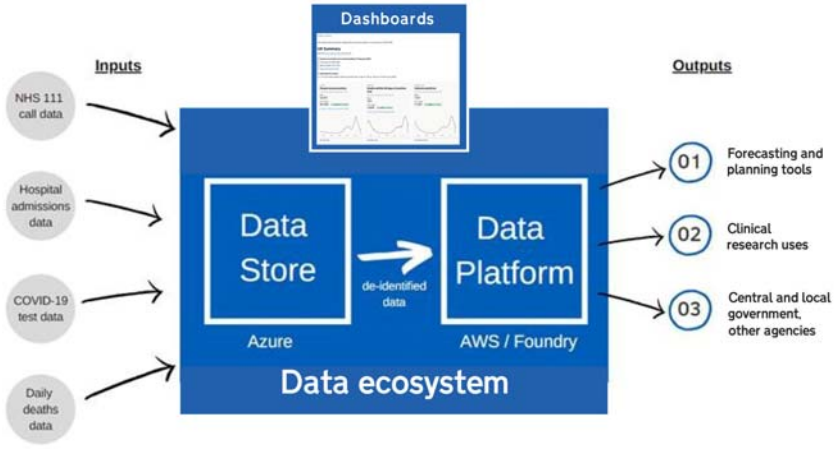
- Why is it important to use patient data for the individual and the wider public?
  - Direct care;; planning and commissioning; research; commercial exploitation
- Why is it important to protect patient data, and what should the public expect?
  - That every use is legal - also consensual, safe and transparent.
- Should the public be prepared to accept a different level of protection of patient data during a pandemic?
  - No.
- To what extent does medConfidential support the regulations introduced in 2020 to enable greater patient data sharing?
  - To the extent that what is done under them is necessary and proportionate - also lawful, fair and transparent!

COVID-19 Data Store and Platform: Early Warning System

The Early Warning System developed out of a bunch of ad hoc modelling done in the early stages of the pandemic. EWS was not mentioned in the original contract with Palantir, though some of the models now in EWS do appear in the first Faculty contract.

In essence, the Early Warning System is a three-week forecasting tool for several critical NHS capacities - e.g. ICU beds, ventilators, oxygen - but not all, e.g. care homes.

Some of the outputs were available to key decision-makers in late March, others became available more widely / locally later in the year. They are not published as similar information has been in Germany and some US states.



Concerns

What specific concerns if any do you have about the introduction of the Early Warning System itself?

- Raises questions about pandemic preparedness, especially after Exercise Cygnus in 2016
- EWS forecasts are based on models - which ones? Published where?

Why might the Early Warning System be considered contentious?

- How were the models tested / validated?
- Who (else) can use the models created for EWS? Do Faculty, Deloitte, McKinsey or anyone else have any commercial rights?

What could have been done differently?

- Far more transparency and clear communications

The future of the Early Warning System

What should the future of the Early Warning System be?

- Retain the code for pandemic preparedness
- The Early Warning System relies on COVID-19 data so when the COPI Notices expire, EWS is done

What actions, if any, could be taken to engender greater public trust in the initiative?

- Publish everything done during the pandemic, including the DPIA and all of the models and assumptions (not necessarily the data)
- Consult on / publish the requirements for any future use of an EWS
- Run an open procurement process
- Proper transparency: contracts, DPIAs, public dashboards, etc.

How long?

For how long should the Early Warning System continue?

(ii) Only as long as the Covid pandemic continues

- The EWS was built for the pandemic, using pandemic powers, and operates on data NHS England receives under the COPI Notices. When the pandemic ends, so does the lawful basis for EWS.
- If NHS England wants to build other models for forecasting, surely it has now learned enough to do so without Palantir and Faculty?

In summary

CONSENSUAL?

Clearly not. Data was copied under the COPI powers, public notification was minimal, and patients' existing opt-outs (e.g. NDOP for planning) were 'ignored.

SAFE?

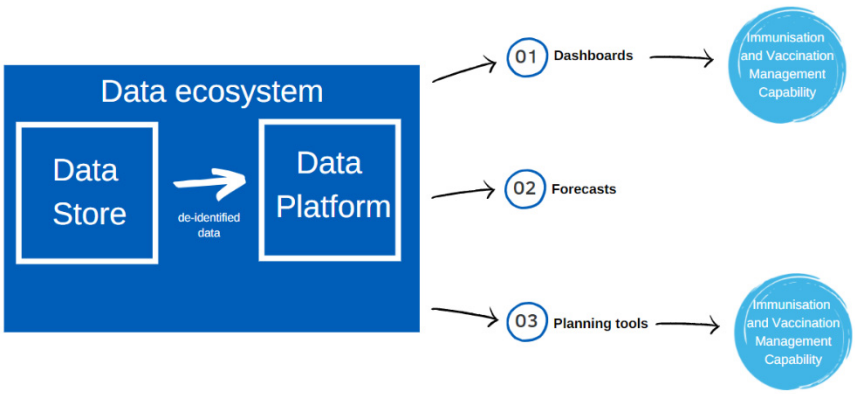
We can only hope so. There's no reason to assume the platforms are not secure, but with so many unknowns, including precisely what data was used to train the models, the EWS does not meet the standard of the Five Safes.

TRANSPARENT?

Nowhere close. Where is the DPIA for the Early Warning System, a description of how it works and a complete list of what data it uses / has used? If NHS England wants to build further EWSs, it must first model trustworthy behaviour.

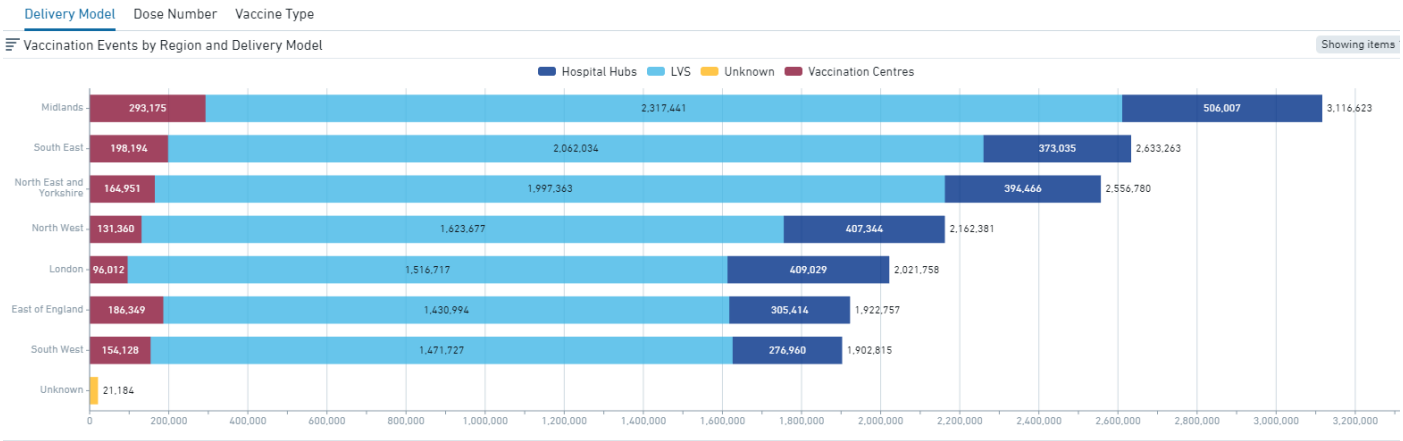
Summary: Case study 2: Immunisation and Vaccination Management Capability

The Immunisation and Vaccination Management Capability is a broad term for a suite of tools and products developed in the Data Platform to manage the delivery of the COVID-19 vaccination programme (the largest in NHS history).



Using these tools users can:

- Access vaccination data in near real time including tracking and organisation of vaccinations administered across delivery models, geographies and cohorts in order to report up to date statistics on how many vaccines have been delivered and the degree of uptake across cohort categories.
- Highlight inequitable access and uptake by geography, gender, ethnicity, disability and deprivation so the programme can act quickly to close the gap.
- Manage the national vaccine supply chain and enable operational allocation decisions based on need.
- Monitor expected vaccine supply to plan workforce and estates accordingly.
- Set ambitions for the programme, compare performance vs plan and adjust supply, policy and delivery levers in order to create an 8-week plan that meets the ambitions of the programme.
- Know the impact of decisions quickly and make adjustments for continuous improvement.



Glossary of terms

NHS COVID-19 Data Store	A single repository of COVID-19 datasets needed to inform an effective COVID-19 response.
NHS COVID-19 Data Platform (Foundry)	A platform used by the NHS to analyse data from the data store. Foundry is the name of this platform and some witnesses may therefore refer to Foundry or NHS Foundry.
Palantir	Are a data software company – they provide NHS England and NHS Improvement with the data platform (Foundry).
Single front door	The single front door is a team that manages data access requests.
Faculty AI	Are a company that specialise in data science and have helped us to develop some of the models and forecasts within the data platform.
Data Science	Data science is a field that uses scientific methods, processes, algorithms and systems to extract knowledge and insights from data.
Data model	A data model organises elements of data and standardises how they relate to one another and to the properties of real-world entities.
NHS Arden and GEM CSU	Run the single front door for data access requests on behalf of NHS England and NHS Improvement.

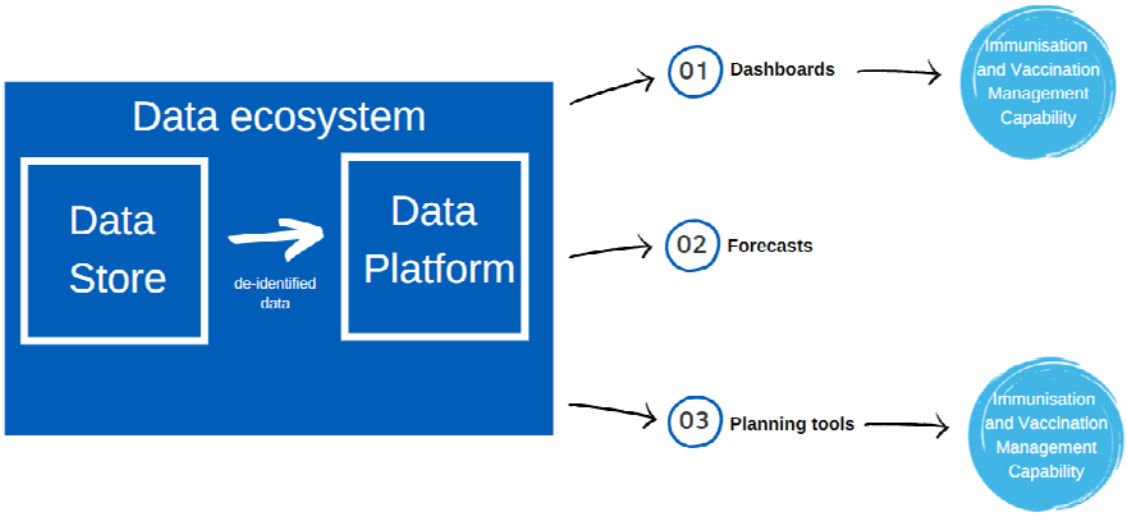
NHS COVID-19 Data Store Case Study 2: Immunisation & Vaccination Management Capability

Ayub Bhayat – Director for Insights and Data Platform
NHS England and NHS Improvement

Part 1 - Neutral

- What is the Immunisation and Vaccination Management Capability, what does it do, and how does it relate to the COVID-19 Data Store & Data Platform?
- Was this enabled through the 2020 COPI regulations?

Reminder from last time…



What is the Immunisation and Vaccination Management Capability, what does it do, and how does it relate to the COVID-19 Data Store & Data Platform? Was this enabled through the 2020 COPI regulations?

What is it?	The Immunisation and Vaccination Management capability is a suite of tools and products developed in the Data Platform to manage the delivery of the largest vaccination programme in NHS history.
What does it do?	The tool supports a number of areas of the vaccines programme, providing different views depending on your priorities, location and role. E.g. Managers can see which vaccine centres need vaccines, and when
Was it enabled by the COPI notices?	Yes – as datasets from the Data Store are fed into these tools, COPI notices have enabled the tool.

Part 2 - Persuasive

- When was the Immunisation and Vaccination Management Capability introduced, and why?
- What benefits have there been from the Immunisation and Vaccination Management Capability?
- Is this something that you believe would have been valuable without the pandemic?
- Could similar outcomes for the Immunisation and Vaccination Management Capability have been achieved without creating the NHS COVID-19 Data Store & Data Platform?
- What should the future of the Immunisation and Vaccination Management Capability be?
  - Have any decisions been made about its future?
  - For how long should the Immunisation and Vaccination Management Capability continue?
    I. As short a time as possible
    II. Only as long as the COVID pandemic continues
    III. As long as it is valuable (potentially beyond the pandemic and for COVID and non-COVID uses)
    IV. Something else
- What, how and when could the public have found out about the Immunisation and Vaccination Management Capability, and has it attracted significant public attention?
- What actions have been taken to engender public trust?
- A summary of our main points

When was the Immunisation and Vaccination Management Capability introduced, and why?

When?

The Immunisation and Vaccination Management Capability was introduced at the end of 2020.

Why?

Staff needed a set of tools to support them to make data-led decisions.

The tool supports planning vaccines delivery, who should get the vaccine, as well as monitoring the success of the vaccines rollout.

How?

The tool takes data from a range of sources from the Data Store.

It then displays this information through a variety of different views, depending on your focus.

E.g. Near-real-time vaccination data, inequitable access and uptake by a variety of factors, supply chain, and many more.

What benefits have there been from the Immunisation and Vaccination Management Capability?

- •Track how many vaccinations are being administered, and compare sites to identify best practice, and where to target support
- •Estimate maximum capacity for vaccinating and confirm the number of vaccination sites needed
- •Highlight inequitable access and uptake by geography, gender, ethnicity, disability and deprivation
- •Understand vaccine stock in the system with the ability to move vaccines to where they're needed most
- •Assess when Priority Groups should become eligible for rollout, determine which Priority Groups can go to which delivery models (GPs, Vaccination centres etc.) and assess which delivery models should be prioritised
- •One system for everything – delivery sites confirm that their site is ready for delivery, monitor vaccine supply, and ensure they have enough staff for a safe rollout
- •The NHS has used data from the Social Care sector to support the rollout of vaccines, such as identifying social care workers, unpaid carers and care home residents

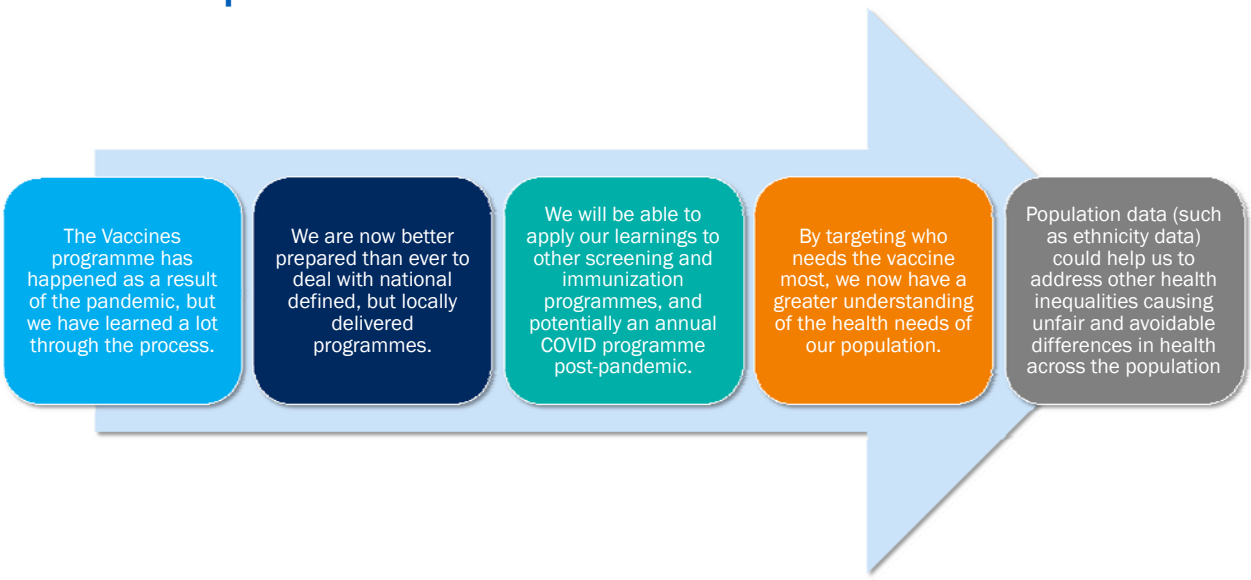
Linking up Social Care Data has strengthened the Vaccine Response

Because we had the care homes data, we were able to ensure that **all care homes received a vaccination visit**

And Care Homes that missed out initially because of a COVID outbreak, were able to be reallocated vaccinations **once it was safe to do so**

Which means that we were able to vaccinate 90.68% of Care Home Residents and 71.28% of Care Home Workers as of the 2nd March 2021

Is this something that you believe would have been valuable without the pandemic?



What should the future of the Immunisation and Vaccination Management Capability be?

- Have any decisions been made about its future?
  - No decisions have been made specifically about the future of the Immunisation and Vaccination Management Capability
- For how long should the Immunisation and Vaccination Management Capability continue?
  I. As short a time as possible
  II. Only as long as the COVID pandemic continues
  III. As long as it is valuable (potentially beyond the pandemic and for COVID and non-COVID uses)
  IV. Something else

Why?

The Immunisation and Vaccination Management Capability **should continue to be used as long as it is valuable** (potentially beyond the pandemic and for COVID and non-COVID uses)

Because the lasting legacy should be that **we are prepared for future pandemics…**

Once the current COVID-19 vaccination programme is over, we will need to take a step back and **look at what we have learned.**

We know that there may need to be future programmes to **protect us against other variants of the virus**, as well as **seasonal flus.**

We need to share our learning to understand how this capability could **support other key NHS and social care programmes.**

Could similar outcomes for the Immunisation and Vaccination Management Capability have been achieved without creating the NHS COVID-19 Data Store & Data Platform?

- No. Without the Data Store we wouldn't have had access to the data we needed.
- Without the Data Platform we wouldn't have had the infrastructure we needed to build the various tools and products we need to manage the end-to-end delivery of the vaccination programme.

What, how and when could the public have found out about the Immunisation and Vaccination Management Capability, and has it attracted significant public attention?

- We haven't publicised the Immunisation and Vaccinations Management Capability, but the outputs from the tool are used for many public facing products.
- It is no secret that we are nationally coordinating the largest vaccination programme in NHS History.
- The outputs from the I&V Capability contribute to public-facing information.
- From the outset of the vaccination programme information has been updated daily on the COVID-19 public dashboard.
- Data is also published on the NHS England and NHS Improvement website weekly so that the public can see how the programme is progressing.
- The NHS facing dashboards use the same data as the public dashboard however we can also drill deeper.

Top left: COVID-19 Public Dashboard
Bottom right: NHS vaccination Statistics

What actions have been taken to engender public trust?

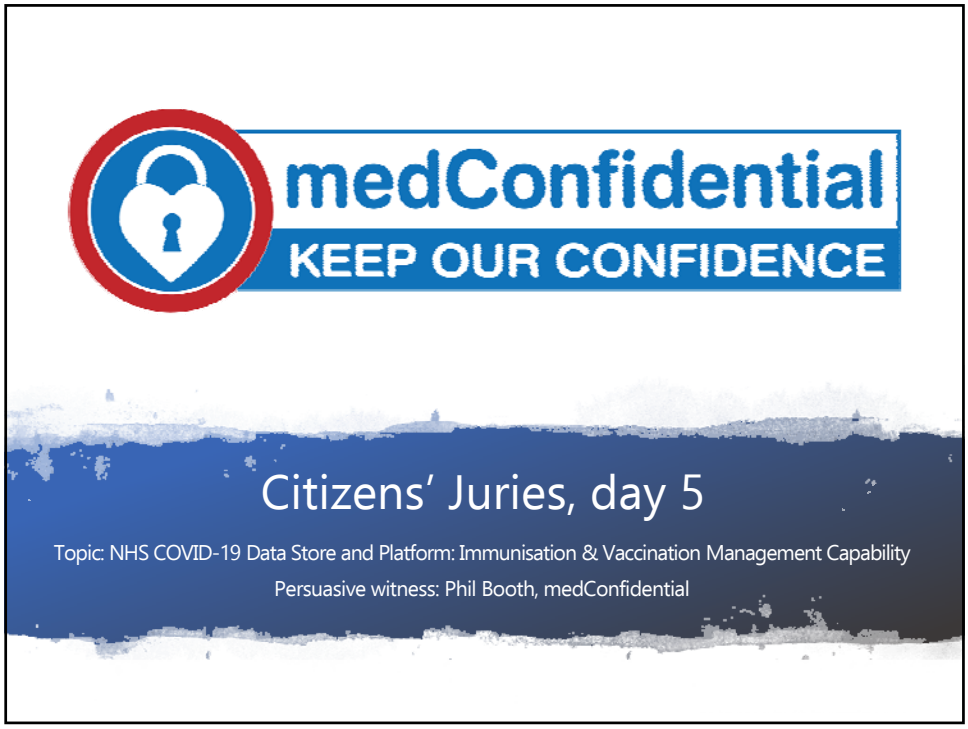
- As with all of the tools on the NHS Data Platform, we have worked closely with groups such as **use My data**, **Understanding Patient Data** and other expert organisations to ensure that we are protecting patient data and delivering the best outcomes for patients.
- We do not analyse patient identifiable information; we only see a total of vaccinations not who has been vaccinated.
- The record of vaccination is entered onto GP records so that it can be seen by medical professionals involved in the individual's care where needed and is also shared with the National Booking Service, so that those who have been vaccinated already are not sent additional invitations to make an appointment.
- This is done via the National Immunisation Management Service (NIMS) which is the system of Record for the NHS COVID-19 Vaccination Programme.

A summary of your main points

NHS

What is it?	How can it help?	Public Trust and the Future
The Immunisations and Vaccination Management Capability is a suite of tools that supports the NHS COVID-19 Vaccination programme	The tool has been essential in coordinating the distribution, planning and delivery of the COVID-19 Vaccine.	Data from the tool contributes to many of the public facing dashboards available online
The tool supports vaccine rollout by allowing staff to see **near real time vaccination data**	The tool helps with where to target the vaccine to **ensure equitable distribution**	The I&V tool would be helpful to deal with future immunisation and vaccination programmes, such as **seasonal flu**

The Immunisation and Vaccinations Management Capability has been **invaluable in our response to the Pandemic.**
We have learned a great deal throughout the programme – including a much **greater understanding of the health needs of the population.**



Quick recap

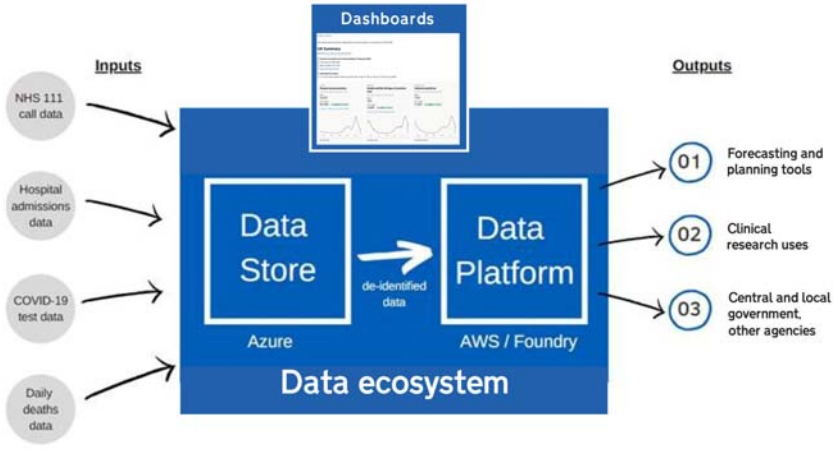
- Why is it important to use patient data for the individual and the wider public?
  - Direct care;; planning and commissioning; research; commercial exploitation
- Why is it important to protect patient data, and what should the public expect?
  - That every use is legal - also consensual, safe and transparent.
- Should the public be prepared to accept a different level of protection of patient data during a pandemic?
  - No.
- To what extent does medConfidential support the regulations introduced in 2020 to enable greater patient data sharing?
  - To the extent that what is done under them is necessary and proportionate - also lawful, fair and transparent!

COVID-19 Data Store and Platform: Immunisation and Vaccination Management Capability

The Immunisation and Vaccination Management Capability was commissioned late last year to help administer the COVID-19 and flu vaccination programmes. It is not the only system involved.

I&VMC does demand modelling based on (near real-time) data collected under COPI powers, and can be used to order or allocate supplies of the vaccines across England.

Everyone knows there is a massive vaccination programme going on. Far fewer are aware of how it is being done. Most don't care. But with the collection and centralised retention of information like ethnicity data, many probably will.



Concerns

What specific concerns, if any, do you have about the introduction of the Immunisation and Vaccination Management Capability itself?

- Lack of transparency on the models / forecasts and data used

Why might the Immunisation and Vaccination Management Capability be considered contentious?

- The "allocation" of vaccines without showing what that allocation is
- Centralised collection and retention of ethnicity data

What could have been done differently?

- Could have built upon existing vaccination capability?

The future of the Immunisation and Vaccination Management Capability

What should the future of the Immunisation and Vaccination Management Capability System be?

- Similar outcomes should be entirely possible without the Data Store and Platform, as part of a 'business as usual' pandemic-prepared NHS.
- Data collection relies on emergency COPI powers, so after the pandemic I&VMC as is ends.

What actions, if any, could be taken to engender greater public trust in the initiative?

- Publish everything done during the pandemic, including the I&VMC DPIA, all models and assumptions (not all the data)
- Consult on / publish the requirements for future I&V capability
- Run an open procurement process
- Proper transparency: contracts, DPIAs, public dashboards, etc.

How long?

For how long should the Immunisation and Vaccination Management Capability continue?

(ii) Only as long as the Covid pandemic continues

- This capacity is just one of several systems involved in immunisation and vaccination, and was set up in a hurry for COVID. For COVID / flu there are also NIMS & NIVS, as well as other well-established immunisation programmes.
- There is no reason for NHS England to retain IVMC, given it is a **public health** function and should in time become as routine as, e.g. annual flu vaccinations.

In summary

CONSENSUAL?

Clearly not. Data was copied under the COPI powers, public notification was minimal, and patients' existing opt-outs (e.g. NDOP for planning) were 'ignored.

SAFE?

We can only hope so. There's no reason to assume the platforms are not secure, but the very fact that individual-leve;l ethnicity data was collected raises serious questions about proper protections - both now and in the future.

TRANSPARENT?

Nowhere close. Where is the DPIA, where is the privacy notice? Where is the complete list of what data I&VMC uses / has used? Having taken so much sensitive personal data, NHS England must show it can be trusted to act lawfully within its regular powers.

One-Page Summary on OpenSafely

1. What is OpenSAFELY, what data does it make accessible, where is it stored, and how does the data get there?

OpenSAFELY is a software platform designed to provide secure access to any health dataset for analysis purposes. Currently it is used to enable access to full GP patient records stored by GP system suppliers TPP and EMIS. The patient records are stored by TPP and EMIS separately. The two sets of records are not aggregated and stored in the same place. In total they can cover up to 95% of England's GP records.

The records stay in the secure environments where they are kept for use by GPs as part of routine care. OpenSAFELY never moves the GP records it enables access to. Sometimes other datasets are linked with the GP records inside the secure environment. For example, sometimes records are linked to ONS death record data to understand which patients have died.

It is important to understand that because OpenSAFELY is a software platform it is not actually necessary for researchers to 'see' the data in order to analyse it. Researchers write code which instructs the software to run a query against the identifiable records and return summary data which is reviewed by the researcher e.g., X% of people with this condition had this outcome from covid.

2. What organisations created and run OpenSAFELY?

OpenSAFELY is a collaboration between: The research group known as "The DataLab" at the University of Oxford, the London School of Hygiene and Tropical Medicine, GP electronic records providers TPP and EMIS. OpenSAFELY currently conducts analysis on behalf of NHS England. NHS England makes all decisions regarding the data to which OpenSAFELY provides access.

3. What relationship does it have with the Covid-19 Data Store?

OpenSAFELY is not currently part of the COVID-19 data store. Some of the processes used to grant access to the COVID-19 data store by NHS England are the same as those used to grant external access to OpenSAFELY.

4. "What is the legal basis for the NHS Covid-19 Data Store (e.g. is it reliant on the 2020 COPI Notices)?

COPI 2020 Notices required GP practices to share data with NHS England. OpenSAFELY enables NHS England secure access to the GP data. OpenSAFELY as a software platform is not reliant on the 2020 COPI Notices but its current access to the GP data does rely on those COPI Notices.

5. How are decisions made about which applications are granted access to the Covid-19 Data Store, and when approved how do systems access the data?

Currently OpenSAFELY is primarily accessed by internal researchers from the University of Oxford and London School of Hygiene and Tropical Medicine. Access by other external researchers must be approved by NHS England from the perspective of Information Governance, and by the OpenSAFELY team who approve research access from the perspective of technical capability and feasibility.

OpenSAFELY

CITIZENS JURY PRESENTATIONS

Jess Morley, Policy Lead, University of Oxford's DataLab

MY BRIEF

- Part 1: Neutral
  - What is OpenSAFELY, what data does it make accessible, where is it stored, and how does the data get there?
  - What organisations created and run OpenSAFELY?
  - What relationship does it have with the Covid-19 Data Store?
  - Was OpenSAFELY enabled through the 2020 COPI regulations, and if so, how?
  - How are decisions made about which applications are granted access to the Covid-19 Data Store, and when approved how do systems access the data?
  - Briefly, how many approved applications of OpenSAFELY are there currently, and very briefly describe 3 examples?
  - What information is available about OpenSAFELY applications, and how long has that been available?
  - What actions have been taken to engender public trust?
  - Summary

What is OpenSAFELY?

- OpenSAFELY is a software platform designed to provide secure access to any health dataset for analysis purposes.
- Currently it is used to enable access to full GP patient records stored by GP system suppliers TPP and EMIS. The patient records are stored by TPP and EMIS separately. The two sets of records are not aggregated and stored in the same place. In total they cover 95% of England's GP records.
- This is because the records stay in the secure environments where they are kept for use by GPs as part of routine care. OpenSAFELY **never** moves the GP records it enables access to.
- Sometimes other datasets are linked with the GP records inside the secure environment. For example, sometimes we link ONS death record data so that we know which patients have died.
- It is important to understand that because OpenSAFELY is a software platform it is not actually necessary for researchers to 'see' the data in order to analyse it. Researchers write code which instructs the software to run a query against the identifiable records and return summary data which is reviewed by the researcher e.g., X% of people with this condition had this outcome from covid.

Who runs OpenSAFELY?

- OpenSAFELY is a collaboration between:
  - The research group known as "The DataLab" within the Nuffield Department of Primary Care Health Sciences, at the University of Oxfrod
  - The electronic health record research group at the London School of Hygiene and Tropical Medicine
  - Electronic health records providers: TPP and EMIS
- OpenSAFELY currently conducts analysis on behalf of NHS England. NHS England makes all decisions regarding what the data OpenSAFELY provides access to is used for.
- OpenSAFELY is funded by:
  - Wellcome Trust
  - UK Research and Innovation /Medical Research Council
  - National Core Studies funding

The COVID-19 Data Store & COPI

- OpenSAFELY is not currently part of the COVID-19 data store.
- Some of the processes used to grant access to the COVID-19 data store by NHS England are the same as those used to grant external access to OpenSAFELY.
- Currently OpenSAFELY conducts COVID-19 analysis using patient records on behalf of NHS England. The necessary access to patient records is enabled by the 2020 COPI regulations.
- COPI 2020 regulations required GP practices to share data with NHS England. OpenSAFELY enables NHS England access to the data without requiring it to be downloaded and shared in an insecure manner. All OpenSAFELY researchers with direct access to the patient records have contracts with NHS England. These arrangements are subject to change.
- OpenSAFELY as a software platform is not reliant on the 2020 COPI regulations.

Accessing OpenSAFELY

- OpenSAFELY is not part of the COVID-19 data store so applications are not granted through that process.
- Currently OpenSAFELY is primarily accessed by internal researchers from the University of Oxford and London School of Hygiene and Tropical Medicine. Within this group, different researchers have different levels of access. Those who have access to the data with the highest risk of identifying someone have contracts approved by NHS England.
- We are starting to enable external researchers to use the platform to answer specific research questions.
- Access to these researchers is approved by a two-step process also used to approve research conducted by Oxford and LSHTM.
  - Application reviewed by NHS England who approve from the perspective of Information Governance
  - Application reviewed by OpenSAFELY who approve from the perspective of technical capability and feasibility
- We are working on making this process public here: http://jobs.opensafely.org/

Approved Applications

- Three examples of research conducted using OpenSAFELY:
  - Factors associated with COVID-19 - related hospital death
  - Association between living with children and outcomes from COVID-19 infection
  - Trends, regional variation, and clinical characteristics of COVID-19 vaccine recipients
- All research outputs are published here: https://opensafely.org/research/. There are currently 11 research outputs.

Public Trust

- OpenSAFELY tries to be 'provably trustworthy'
- All applications to use the OpenSAFELY platform in order to analyse the GP patient records held by TPP and EMIS will be in the public domain. This is work in progress.
- It is not possible to use OpenSAFELY without working in the open. All analytical code has to be written in the public domain.
- The OpenSAFELY jobs runner logs all requests sent to the platform: http://jobs.opensafely.org/ including who made the request and when. We plan to make this more user-friendly in coming months. It is effectively an audit trail which anyone can review. It is reviewed regularly by the OpenSAFELY team and we plan to discuss it regularly with the OpenSAFELY Oversight Board.
- We have a public-facing website opensafely.org which we are currently redesigning, are currently making an animated explainer video, and have presented at multiple engagement events over the past 6 months.

Summary

- OpenSAFELY is a software platform designed to provide secure access to any health dataset for analysis purposes
- The records stay in the secure environments where they are kept for use by GPs as part of routine care. OpenSAFELY **never** moves the primary care records it enables access to.
- It is important to understand that because OpenSAFELY is a software platform it is not actually necessary for researchers to 'see' the data in order to analyse it. Researchers write code which instructs the software to run a query against the identifiable records and return summary data which is reviewed by the researcher e.g., X% of people with this condition had this outcome from covid.
- OpenSAFELY is not currently part of the COVID-19 data store. Currently it is used by researchers from the Oxford DataLab and the LSHTM. The process for enabling external researchers to use the platform is currently being piloted and involves legal (NHSE) and technical (OpenSAFELY) approval.
- OpenSAFELY is currently used to access GP patient records stored by GP system suppliers TPP and EMIS to conduct COVID-related analysis on behalf of NHS England. This access relies on the 2020 COPI Notices. OpenSAFELY as a standalone software platform does not rely on these notices.

MY BRIEF

- Part 2: Persuasive
  - When was OpenSAFELY introduced, and why?
  - What direct benefits, if any, have there been from OpenSAFELY itself (excluding benefits from applications that access it)?
    - What benefits have there been from the 3 example applications outlined earlier?
    - Is this something that you believe would have been valuable without the pandemic?
  - Could similar outcomes have been achieved without creating OpenSAFELY and/or without the NHS Covid-19 Data Store?
  - What should the future access to GP records provided by OpenSAFELY be?
    - Have any decisions been made about this?
    - By whom should these decisions be made?
  - What, how and when could the public have found out about OpenSAFELY, and has it attracted significant public attention?
  - Summary

When & Why Was OpenSAFELY Introduced?

- Work on developing OpenSAFELY as a software platform began in March 2020 as a response to the global COVID-19 pandemic
- OpenSAFELY produced its first research output using the GP patient records it enables access to in May 2020, just 5 weeks after project instigation
- OpenSAFELY as a software platform was developed to enable safe access to large volumes of data, such as the GP patient records it currently provides access to.
- Access to large volumes of data was essential for answering urgent research questions related to COVID-19 such as: who is most at risk? What are the factors associated with death?
- Large volumes of data means researchers can be more confident in the results.

Benefits Of OpenSAFELY

- Research conducted on GP patient records by using the OpenSAFELY platform has been used directly to inform NHS England and Public Health England Policy regarding:
  - The vaccine prioritisation programme
  - The NHS shielding list
- The OpenSAFELY platform is currently being used to analyse GP patient records for the purpose of monitoring vaccine uptake and vaccine effectiveness.
- The OpenSAFELY platform has also been used to conduct research which has provided essential insight into appropriateness and safety of treatments, for example: answering questions about painkillers.
- The OpenSAFELY platform will continued to be used for research that monitors the ongoing impact of COVID-19 related policy interventions

Outcomes Without OpenSAFELY

- It would not have been possible to achieve the same outcomes without researchers using the OpenSAFELY platform:
  - To achieve these outcomes, it has been necessary to have access to large volumes of near real-time data
  - It is only possible to access such large volumes of data via OpenSAFELY because its design is significantly more secure than alternatives.
  - In addition, because the OpenSAFELY platform enables access to the GP patient records in situ – i.e. they don't have to be extracted and transported from one location to another – the data is near real time. Researchers can analyse data as recent as last week. only has 1-2 weeks latency. Most of the time researchers have to rely on historic data because there are very big delays (as well as security risks) associated with the extraction model.
- It would still be useful to use the OpenSAFELY research platform to provide researchers access to the GP patient records – currently enabled by the COPI Notices - outside the context of the pandemic because this would enable researchers to conduct valuable medical research with a high-degree of accuracy, as well as 'operational research' such as identifying variation in care. But the legal basis for this would need to be reviewed.

The Future Of OpenSAFELY-enabled access to GP patient records

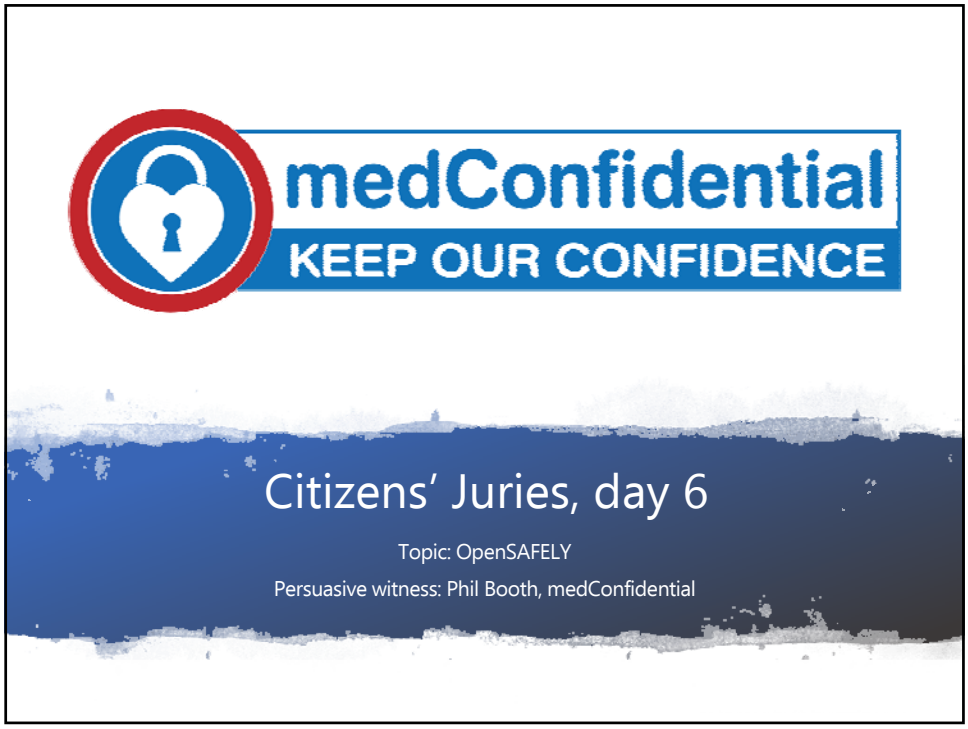
- As a member of the team responsible for the OpenSAFELY software platform, I cannot answer the question 'what the future access to GP records provided by OpenSAFELY be?' This is a question for NHS England.
- NHS England have expressed a view that they want access to GP data for research to continue via the OpenSAFELY platform in the future, but on a more secure legal footing. It is worth noting that TPP and EMIS currently provide support for access via OpenSAFELY for free. This might not be the case outside the context of the pandemic.
- To inform decisions about the future access to GP patient records enabled by OpenSAFELY, NHS England want to hear the views of the juries.
- Ultimately, the decision should be made by NHSE, and TPP and EMIS, in consultation with data controllers (GPs) and the public. Public consultation should not be conducted by OpenSAFELY but by independent groups, such as Understanding Patient Data.
-

Public Awareness

- The public can find out about OpenSAFELY from the website, from Twitter, and from public talks given by various members of the team.
- OpenSAFELY as a platform has also been covered by The Economist.
- Research produced using OpenSAFELY has been covered extensively in the popular press, including by the BBC, the New York Times and the Telegraph.
- Most press coverage is captured here: https://opensafely.org/press/
- We also have a public email inbox which anybody can use to contact the OpenSAFELY team.
- We are developing an animated explainer video, and are planning some open co-design sessions for the public in the coming months.

Summary

- Work on OpenSAFELY began in March 2020 as a response to the global COVID-19 pandemic.
- OpenSAFELY has been used to conduct research that has directly influenced the national response to COVID-19, most notably the vaccine roll-out.
- OpenSAFELY as a platform will continue to exist for, at least, the next three years. No decisions about the future of its current instances (i.e. OpenSAFELY-TPP and OpenSAFELY-EMIS) have yet been made.
- OpenSAFELY would still be useful outside the context of the pandemic because it enables safe access to large volumes of near real-time data that is useful for both medical and operational research.
- OpenSAFELY has been well documented in the public domain. There are plans in place to conduct more engagement over the next 6-12 months.
- Ultimately decisions about the future of OpenSAFELY need to be made collaboratively by data subjects and data controllers.



Quick recap

- Why is it important to use patient data for the individual and the wider public?
  - Direct care;; planning and commissioning; research; commercial exploitation
- Why is it important to protect patient data, and what should the public expect?
  - That every use is legal - also consensual, safe and transparent.
- Should the public be prepared to accept a different level of protection of patient data during a pandemic?
  - No.
- To what extent does medConfidential support the regulations introduced in 2020 to enable greater patient data sharing?
  - To the extent that what is done under them is necessary and proportionate - also lawful, fair and transparent!

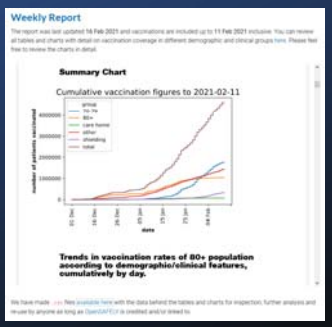
OpenSAFELY

When was OpenSAFELY introduced, and why?

- Built in 5 weeks, launched last May, commissioned to provide a secure statistical analytics platform for COVID-related research in GP data
- Performs rapid, large-scale analyses, commissioned by the Chief Medical Officer, to answer key clinical and public health questions

What benefits, if any, have there been from OpenSAFELY?

- Research papers
- Also monitoring, with weekly statistical reports
- Validation of risk prediction models, e.g. QCovid
- Informing policies and decision-makers



OpenSAFELY

What, how and when could the public have found out about OpenSAFELY and the access to GP data, and has it attracted significant public attention?

- Its website / online, social media, mention in some media reports?

•What information is available about OpenSAFELY uses and access to GP data, and how long has that been available?

- Some information on its website since May 2020, but no notification to patients, no DPIA, nor have we seen any GP practice information

What actions have been taken to engender public trust in OpenSAFELY?

- Consensual: it respects opt-outs recorded in patients' GP records
- Safe: it meets most of the 'Five Safes', but NHSE falls badly short on IG
- Transparent: good on outputs, not so much on informing patients

OpenSAFELY

Is this something that you believe would have been valuable without the pandemic?

- Potentially, yes. But OpenSAFELY could never have been built without the pandemic, and specifically the COPI powers.
- Last time NHS England tried doing this with GP data, it was found to be illegal; its work-around resulted in the care.data scandal

Could similar outcomes have been achieved without creating OpenSAFELY and providing access to the GP data?

- Yes, of course. NHS Digital has been doing a fortnightly 'extraction' of COVID-related GP data since last year
- The two approaches may complement each other, if a lawful basis can be found to persist OpenSAFELY beyond the end of the COPI Notices.

Concerns

What specific concerns, if any, do you have about the introduction of OpenSAFELY?

- Its lawful basis beyond the COPI Notices is unclear, and the distinct lack of required Information Governance (IG) by NHSE

Why might OpenSAFELY, and particularly the access it provides to GP data, be considered contentious?

- Patients were neither informed, nor provided with an opportunity to opt out. People might be content for their GP data to be used for COVID-19 research, but not other types of research (or planning) in future

What could have been done differently?

- Better public communications, proper Information Governance

The future of OpenSAFELY

What should the future provided by OpenSAFELY to GP data be?

- Rapid production of statistics and urgent research, alongside more complex research and linkage done in NHS Digital's Safe Setting
- OpenSAFELY makes dissemination of patient-level data unnecessary

How could or should OpenSAFELY and its applications be usefully changed in the future (if at all)?

- OpenSAFELY needs functional IG and transparency processes, and to be under the data controllership of the statutory safe haven, i.e. NHS Digital
- Once useful statistics have been developed and validated, they can be published regularly - –thus eliminating the need for, e.g. policy-makers to have access to patient-level data

The future of OpenSAFELY

Have any decisions been made about its future?

- Not yet, but the OpenSAFELY team are aware of the governance and post-pandemic lawfulness issues

What actions, if any, could be taken to engender greater public trust in the initiative?

- A comprehensive public communication, explaining ALL of the significant data changes during the pandemic, and giving people a chance to exercise their rights, e.g. to opt out of post-pandemic secondary uses
- Greater transparency, much of which could come from a move to NHS Digital data controllership[and IG processes

How long?

For how long should OpenSAFELY continue to provide access to GP data?

(iii) As long as it is valuable - potentially beyond the pandemic, and for COVID and non-COVID uses

- But ONLY if a legitimate lawful basis can be found
- And ONLY if it operates under effective Information Governance and transparency processes like those used by NHS Digital
- Beyond the pandemic, once the COPI Notices expire and NHS England is no longer data controller for GP data, the appropriate controller will be the statutory safe haven, i.e. NHS Digital

Who decides?

By whom should these decisions be made?

(iii) Parliament

- OpenSAFELY is for research. It is an example of 'secondary use' and should therefore also respect the National Data Opt-out (NDOP), which has been largely ignored during the pandemic.
- Opt-outs do not significantly affect effective statistical analysis so, to avoid patients' consent choices being ignored in future, the Government –- through Parliament - should make NDOP statutory and require that every health and care body respect it.

Patients must be able to decide if they want their data to be used for purposes beyond their direct care.

In summary

CONSENSUAL?

Up to a point. Existing opt-outs are respected, but people must be informed and be able to make a choice

SAFE?

Yes, with caveats. Not least that, at present, it is only the Chief Medical Officer who decides which projects are done

TRANSPARENT?

On outputs, yes - they are all published. Not so much on legal requirements like a DPIA, published IG and oversight