

NHS Digital and MRC Researcher Roadshow



Information and technology
for better health and care

Presented by
Estelle Spence, Strategic Engagement Manager,
Research & Life Sciences

Today's Roadshow

- **Welcome**
- Agenda & key timings
- Our approach – 4 keys:
 - Working together
 - Open & transparent
 - Interaction to build understanding
 - Continually improve based on your feedback

Working together & improving communications

- **Research Advisory Group (RAG)**
- Membership & purpose
- Find out more:

<http://www.digital.nhs.uk/research-advisory-group>

Research Bulletin

Current & upcoming datasets

Data Access Request Service (DARS)



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Presented by
Garry Coleman, Head of Data Access

NHS Digital data products available via DARS

- Hospital Episode Statistics (HES)
- Primary Care Mortality Data (PCMD)
- Patient Reported Outcome Measures (PROMs)
- Secondary Uses Services Payments by Results (SUS PbR)
- Mental Health Data Sets (MHMDS, MHLDDS)
- Diagnostic Imaging Datasets (DIDS)
- Personal Demographics Services (PDS) Registration
- Public Health England (PHE) Cancer – for cohorts
- Office for National Statistics (ONS) Mortality (Civil Registration data)
- Linked local flows through DSCROs

...plus others to come...and linked data products

Health Data Interrogation Service (HDIS)

What?

- HDIS is an online service that allows registered users to securely access datasets; one can interrogate the data, perform aggregations, statistical analysis, & produce a range of different outputs.

Why?

- SAS Enterprise Guide is a powerful Microsoft Windows client application.
- There are no substantive data storage requirements to run the tool.

How?

- Users have secure access through a web browser or through VMware software.
- SAS Enterprise Guide provided for analysis.
- We are looking to expand the range of tools & data available.

Who?

- Access to HDIS is only provided to UK organisations where there is a sufficient purpose justifying access with clear benefits to health and social care.

Datasets becoming available through DARS on-line

- Civil Registration Data
 - Selectable December 2017, Available January 2018
- Mental Health Services Data Set (MHSDS)
 - Selectable 30th November 2017, Available from 20th December 2017
- Adult Psychiatric Morbidity Survey (APMS)
 - Selectable 24th November 2017, Available from Feb 2018
- National Diabetes Audit
 - Selectable Feb 2018
- Summary Hospital Mortality Indicator (SHMI)
 - Selectable Feb 2018
- Electronic Prescribing Service (EPS) & Pathology datasets
 - Further detail expected shortly

Datasets suggested for DARS

- National Child Measurement Programme (NCMP)
- Emergency Care Dataset (ECDS)
- Sexual and Reproductive Health Activity Dataset (SRHADS)
- Maternity Services Dataset
- Electronic Staff Record Dataset
- Children Services Dataset
- Updated Civil Registration Dataset

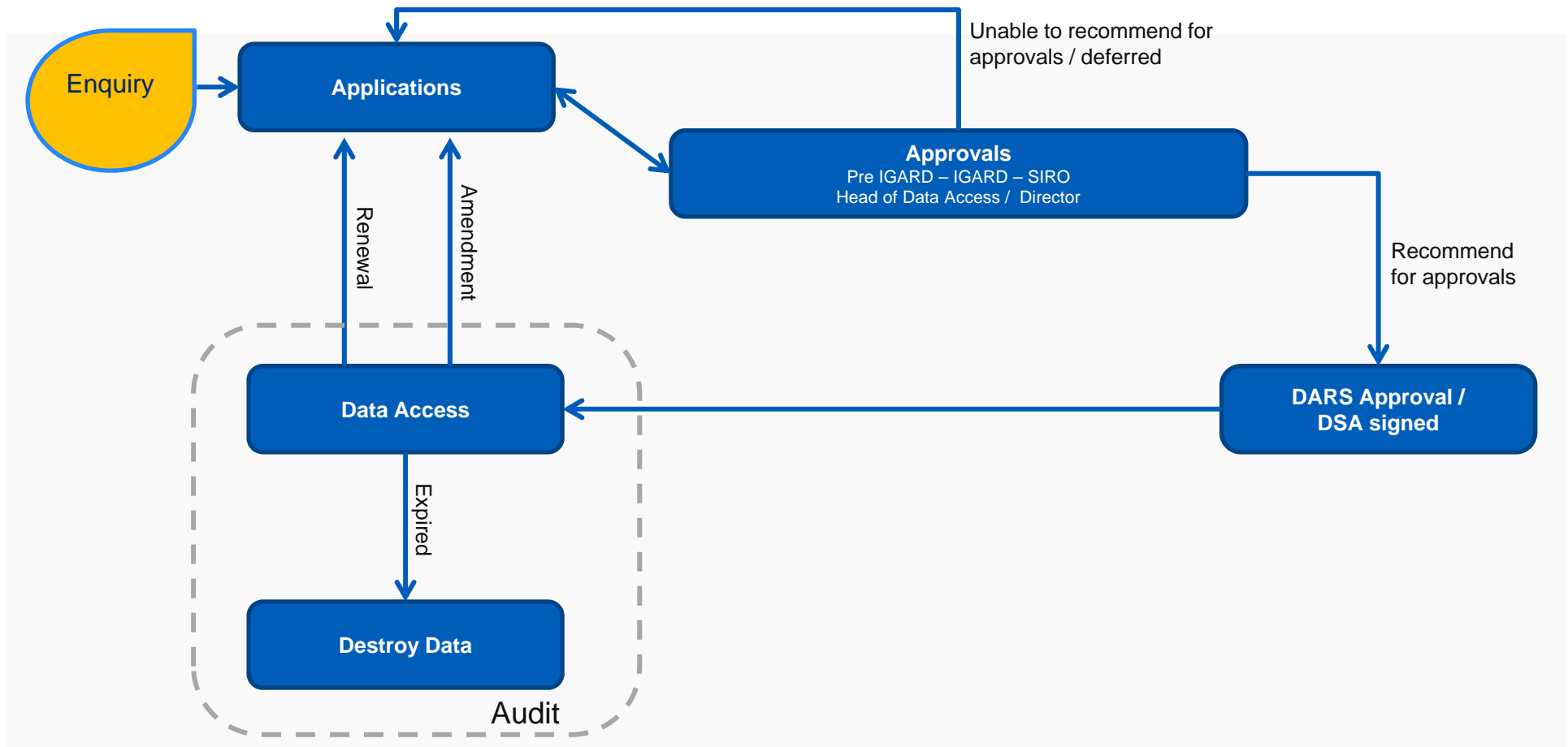
All datasets subject to governance considerations and assessment

How to apply for NHS Digital data



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Data Access Request Service



Data Access Request Service (DARS)

Over **538** active agreements managed through DARS Online



Over **10,000** data disseminations per year, including HES, mental health and PROMS



Over **1,000** applications for data received per year



Over **280** monthly data extract customers



Over **1,067** data releases for medical research disseminated each year



A range of data products, including HES which contains over



1.7bn records

Over **300** active medical research studies



What an application must have...

- All applicable sections of the form filled in
- Active Data Sharing Framework Contract(s) for all named Data Controller(s)
- Evidence that the proposed data processing (including each data flow) is lawful
- Security assurance for all Data Processors

Data Controller(s)

- Any organisation (or person representing an organisation) who can determine, alone or jointly, what will be done with the data should be named as a data controller
- Consider roles of committees, commissioners, funders, Principal Investigators, etc. in determining the above
- There may be multiple Data Controllers (Data Controllers in common or joint Data Controllers)

Data Processor(s)

- Name all organisations whose employees access the data for any reason
- Include organisations providing data storage/back up facilities
- Where employees of a third party organisation have an honorary contract with a named Data Processor, their substantive employer may not need to be named as a Data Processor, however:
 - provide evidence of contractual controls regarding the conduct of the individual and an agreement with the substantive employer in respect of disciplinary proceedings in the event of a data security breach

Security Assurance

- IG Toolkit
 - Provide organisation code
- ISO 27001 Certification
 - Provide certificate – must be in date and cover the specified location(s)
- System Level Security Policy
 - Provide relevant documents

Legal Basis

- Pseudonymised data
 - Typically data is disseminated under section 261(1) Health & Social Care Act 2012
- Identifiable data
 - It must meet the conditions for processing set out in Schedules 2 and 3 of the Data Protection Act
 - Typically Consent or Section 251
 - Otherwise supply evidence of an alternative legal basis
- Mortality can be provided by NHS Digital on behalf of ONS
 - Provided under Statistics & Registration Service Act 2007
 - Uses Informed Participant Consent, Section 42(4) or Approved Researcher Gateway
 - More on this shortly...

Mandatory Supporting Evidence

- For identifiable data
 - Evidence of favourable opinion by a Research Ethics Committee (REC) or evidence that REC review is not required
 - Any supporting documents associated with REC review – e.g. Study Protocol
 - To evidence informed consent
 - All iterations of participant information sheets and consent forms used.
 - If multiple iterations were used, provide details of what was used when and for how many participants

Mandatory Supporting Evidence

- For identifiable data
 - To evidence section 251 (NHS Act 2006) support
 - Copy of the application form submitted to HRA CAG (or predecessor)
 - Copies of all letters in response from CAG (e.g. Conditional Approval, Final Approval, Annual Reviews, amendments, etc.)
 - Copy of latest Annual Review report and evidence of timely submission to CAG
 - Evidence of Fair Processing notices
 - E.g. Participant newsletters, website notices, etc.
 - Detail how you pass the 9 point Fair Processing Check

Purpose Section

- Who/What is it for?
 - What data you require, why and what will be done with the data
 - This section is published if the application is approved
 - It forms the Data Sharing Agreement **as written**
 - Remember your audience - It needs to be clearly understood by:
 - The Data Applications team
 - The approvers within NHS Digital
 - The Independent Group Advising on the Release of Data (IGARD)
 - The public
 - Auditors
 - You

Purpose Section

- DO
 - Write in plain English
 - Avoid jargon and excessive acronyms
 - Write in third person style
 - Avoid “we” or “I” or “our”
 - Make clear unambiguous statements that are not open to interpretation
 - Focus on the data from NHS Digital for which you require access
- DO NOT
 - Provide excessive information about the wider purpose that is not directly relevant to the use of the NHS Digital data
 - Some background information may be necessary but be concise
 - Assume knowledge of your industry or subject matter by the reader

Purpose Section

- The Health & Social Care Act 2012 as amended by the Care Act 2014 dictates that NHS Digital may only release data for use for the benefit of health and social care and not for solely commercial purposes
- In the Purpose section you must explain how your proposed use of the data will benefit health and social care
- DO NOT presume it will be obvious how benefits will be achieved
 - E.g. It will not be assumed that publishing findings in a peer reviewed journal will benefit health. You need to elaborate on how doing this will logically lead to measurable benefits.

Purpose Section

- Ensure you provide a clear link between:
 - the data you are requesting,
 - the objectives for requesting the data,
 - the outputs to be produced and
 - the benefits to be achieved
- Remember this section will be reproduced in your Data Sharing Agreement and our Register of Data Releases where it will be detached from other information in the application and supporting documents
- It must convey sufficient detail in its own right: avoid statements such as “see supplied Protocol”

Objectives for Processing

- Explain why the data is required
- Explain the organisations involved and their roles
- Explain why the work is being undertaken (with reference to intended benefits to healthcare)

Processing Activities

- Describe what happens with the data
- Be clear about what data you are referring to including what identifiers are present if applicable
- At each stage of processing be clear:
 - Who has access to the data?
 - Where is the data?
 - In what form?
 - For what purpose?

Processing Activities

- Where it adds clarity, describe what will NOT happen with the data – e.g.
 - The data will not be linked with any record level data
 - The data will not be made available to any third parties other than those specified except in the form of aggregated outputs with small numbers suppressed in line with the HES Analysis Guide
- Remember – just because it doesn't state "no" doesn't mean it's a "yes"

Processing Activities

- Justify why the amount of data requested is the minimum required
- Types of data minimisation include filtering to:
 - Specific individuals – e.g. individuals with specific diagnoses and/or above, below or between specific ages
 - Specific geographical areas – e.g. selected regions rather than national data
 - Specific health conditions/diagnoses – e.g. select all hospital episodes involving x diagnosis
 - Specific time periods – e.g. episodes within a 5/10/15-year timeframe

Specific Outputs Expected

- What do we mean by outputs?
 - Anything you produce after processing the data such as:
 - Reports
 - Publications
 - Presentations
 - Information to the public
 - Tools
- What do we not mean by outputs?
 - Analyses – e.g. “The outputs will be mortality outcomes after 30 days” **x**

Specific Outputs Expected

- What do we need to know about the outputs?
 - Target date for completion
 - Target audience(s)
 - Purpose of the output(s)
 - “The output will be peer reviewed journal publications..” **x**
 - “An output will be a report outlining the project’s findings which, subject to acceptance, will be published in high impact peer review journals such as the Lancet” ✓
 - “An output will be a report of findings and recommendations to the Department for Health and NICE” ✓

Specific Outputs Expected

- If applicable state: “All outputs will contain only data that is aggregated with small numbers suppressed in line with the HES Analysis Guide.”
- If you are amending, extending or renewing a previous Data Sharing Agreement, have any outputs already been produced?

Specific Measurable Benefits

- Explain who will do what with the outputs to directly or indirectly achieve benefits to health and/or social care including:
 - What is the logical sequence of events to occur in order for such benefits to be achieved including actions/decisions by third parties?
 - Why is it reasonable to expect that the expected benefits will be realised (e.g. has there been prior engagement with key decision/policy makers?)?
 - What are the actual expected benefits and how do these benefit healthcare users (e.g. cost/efficiency savings enabling commissioners/care providers to reallocate funding to other areas of care benefitting care users; improved quality of care/reduced waiting times/improved ability of care providers to meet demand; improved survival rates; improved quality of life post-treatment/care, etc.).
 - Clarify the expected magnitude of the impact, eg: How many care users may benefit? What is the expected impact in terms of cost/efficiency savings?

Specific Measurable Benefits

- Reminder: DO NOT presume benefits to health will be obvious
 - “Findings will be published in high impact peer review journals...” **x**
 - “Findings will be directly fed back to NHS policy makers...” **x**
- For an extension/renewal/amendment request or a request related to a long-running programme of work, specify whether any benefits have been achieved to date
- Avoid listing publications; focus on the impact of published findings to date or expected impact of planned publications

Common Issues

- Inadequate information in the 'Outputs' and 'Benefits' sections to justify release of the data for the benefit of health/social care
- Data minimisation - Insufficient justification for the amount of data requested
- Lack of clarity over roles and involvement of other organisations
- Consent materials do not provide enough clarity about the data and organisations involved; the sharing of data with NHS Digital; of participants' right to withdraw, and of the process to withdraw

Tips

- Check out our Register of Approved Data Releases at:
<http://content.digital.nhs.uk/dataregister>
- It contains copies of the 'Purpose' statements of approved applications
- Remember your target audience!



Coffee Break

Data Access Request Service (DARS)

Improvements



Information and technology
for better health and care

Presented by
Garry Coleman, Head of Data Access

Everything

should be

made as

simple

as possible

but no simpler

Albert Einstein

Templating...

- **Benefits**

- Solve once, use many
- Easy renewal process

- **Already in place**

- Primary Care Mortality Data – Local Authority: Public Health purposes
- HES – Local Authority: Public Health purposes
- SUS using a CSU as a data processor - Public Health & Commissioning purposes

- **Willing to create more**

- Archiving – Researchers
- Investigating data (HDIS) - Researchers
- Linkage between HES and Social Care for Public Health ...?

Simplifying locally to NHS Digital...

- **Making it easier**
 - Improving support for applicants
 - Continual development of DARS on-line (e.g.: approvers)
 - DARS On-line to include Commissioning applications
- **Delivering efficiencies**
 - Additional datasets available via DARS on-line (incl. Civil Registration data)
 - Additional resources to handle increasing number & complexity of applications
 - Account Management
- **Reducing duplication**
 - Benefits – where stated as part of research funding

Simplifying the wider system ...

- **Working with HRA-CAG to align 251 approvals and DARS**
 - Overall timeline key
 - Initiative being extended to include PHE and CPRD
 - Separate work around service levels across system
- **Civil Registration Data**
 - Principles agreed, including data processing agreement
 - Clarification expected in December around Date of Death status
- **Migrating Data Services for Commissioners on to DARS On-line**
 - Significant reduction in time to renew

Webinars

- **Programme of webinars underway, including**

- Applying for data
- Using DARS on-line
- Local Authority access to data

To come:

- Fair Processing
- Consent
- Dataset changes – e.g. Civil Registration data
- Objections



**To date:
750+
customers
have joined 16
interactive
webinars**

We welcome suggestions on topics

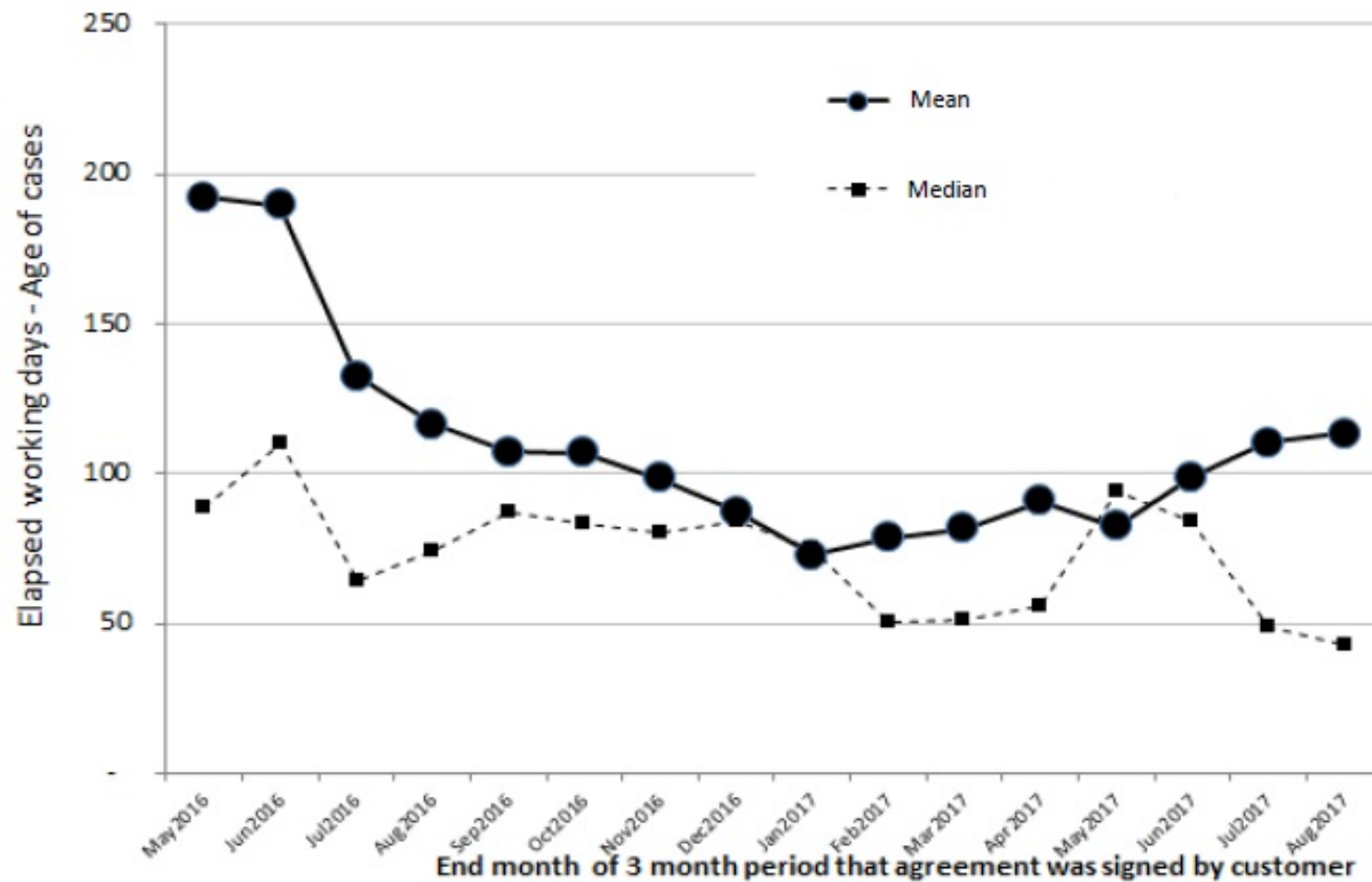
Transparency

- **NHS Digital publishes audit outcomes**
- **NHS Digital publishes details of all record level patient data releases, including:-**
 - Who
 - What
 - Why
 - Whether patient objections are upheld

There is always more to do...



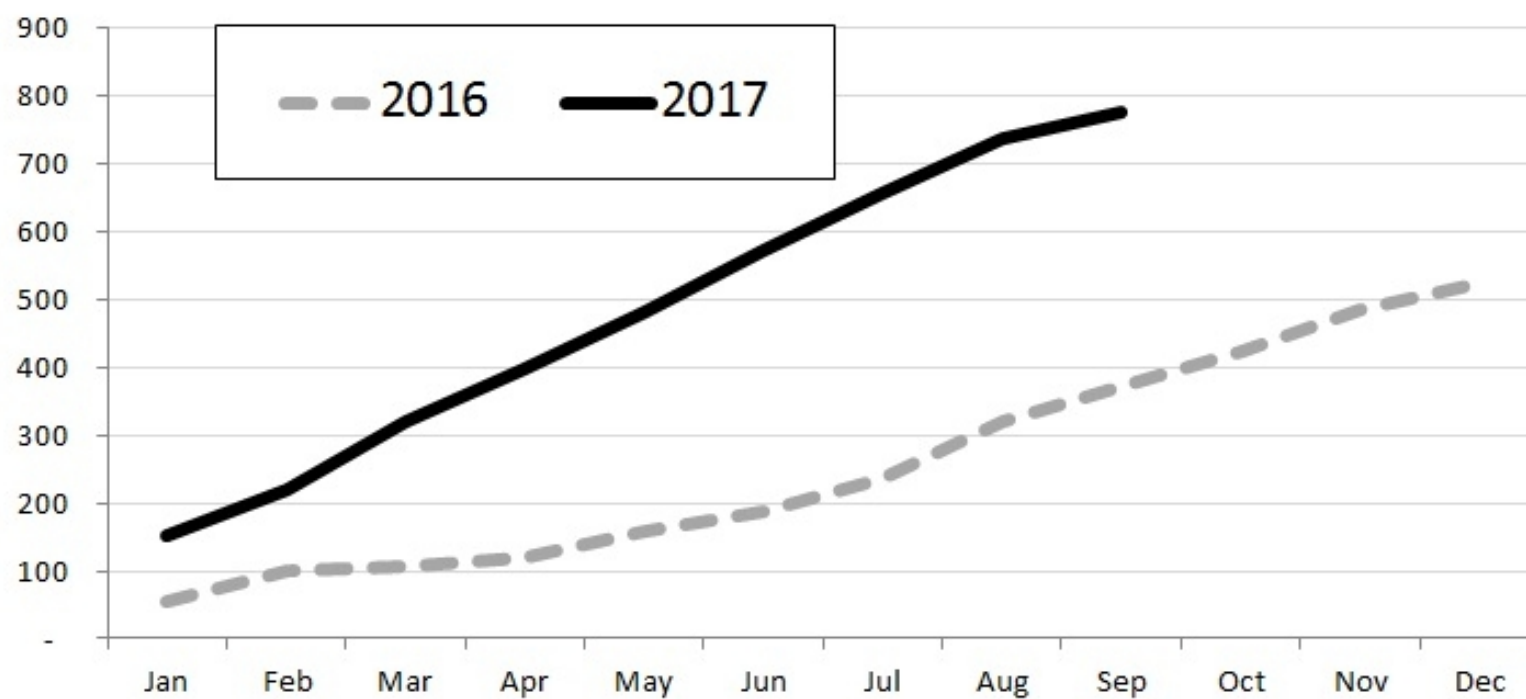
3 month rolling average length of closed research cases - based on END date of case



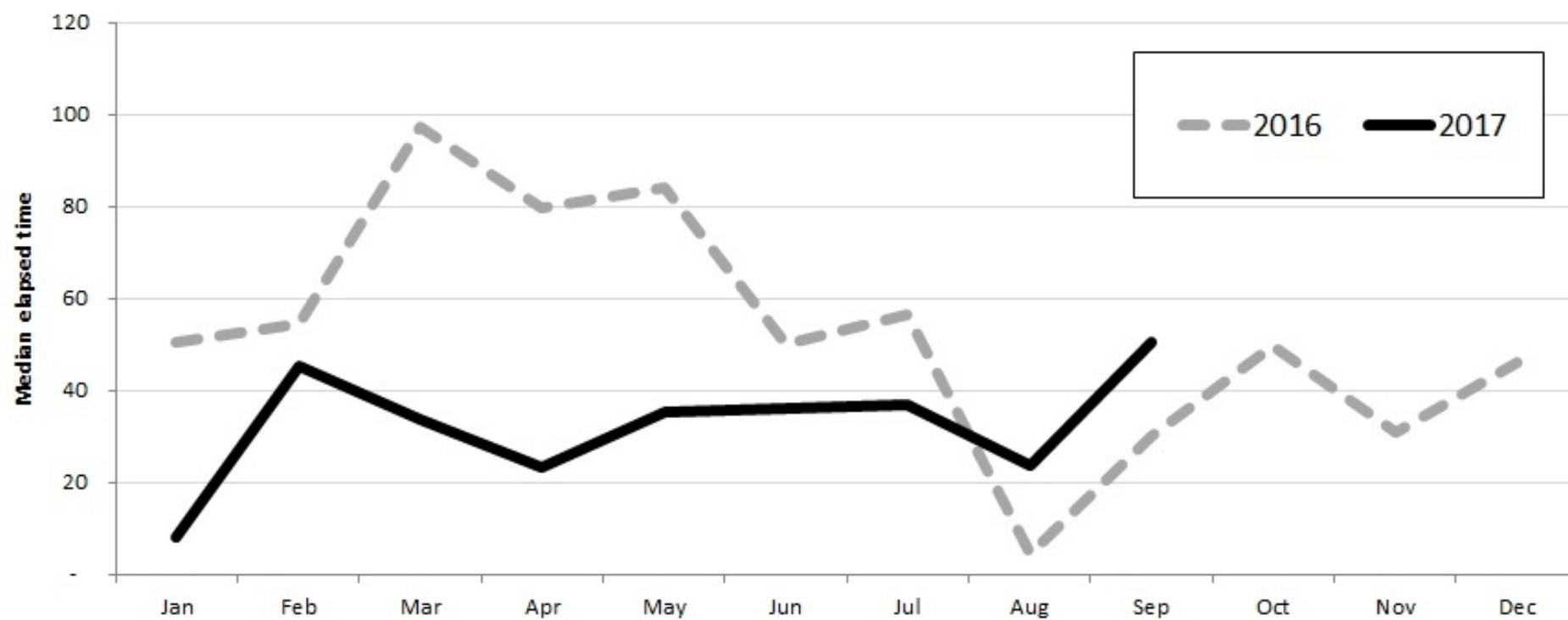
Covers all applications including research

Number of applications received - cumulative monthly total by year

Cumulative number of applications received



Elapsed time from application receipt to Data Sharing Agreement signature for closed applications





Data Protection, Consent and Transparency

Alex Bailey

Medical Research Council Regulatory Support Centre

alex.bailey@rsc.mrc.ac.uk

<https://www.mrc.ac.uk/research/facilities-and-resources-for-researchers/regulatory-support-centre/>

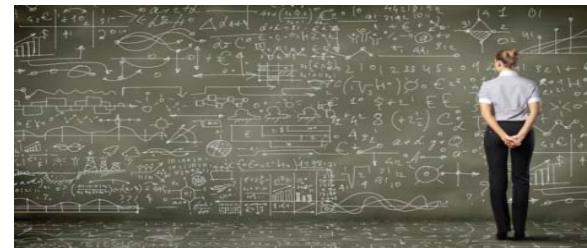
Research Advisory Group (RAG)

Set up as the 'intelligent customer' to NHS Digital
Has a number of sub-groups

Streamlining - reducing duplication in the application process

Harmonising language - consistency in the language used in the application process

Research Clarity Portal - advice about application processes



Researchers

Researchers complain about lack of clarity around

What approvals are required and why

How long the process will take

Questions asked

Interactions between different application processes



Approval bodies

Approval bodies complain about lack of clarity around

What approvals are required and why

Researchers expectations

Questions answered

Interactions between different application processes



Research Clarity Portal

Online tool aiming to provide guidance about

Language used in data applications

What approvals are required for using data in research in the UK

How long the approvals process will take and an approximate cost

General guidance about each approval process



Help!

What would you like to see in the portal and why?



Data Quality



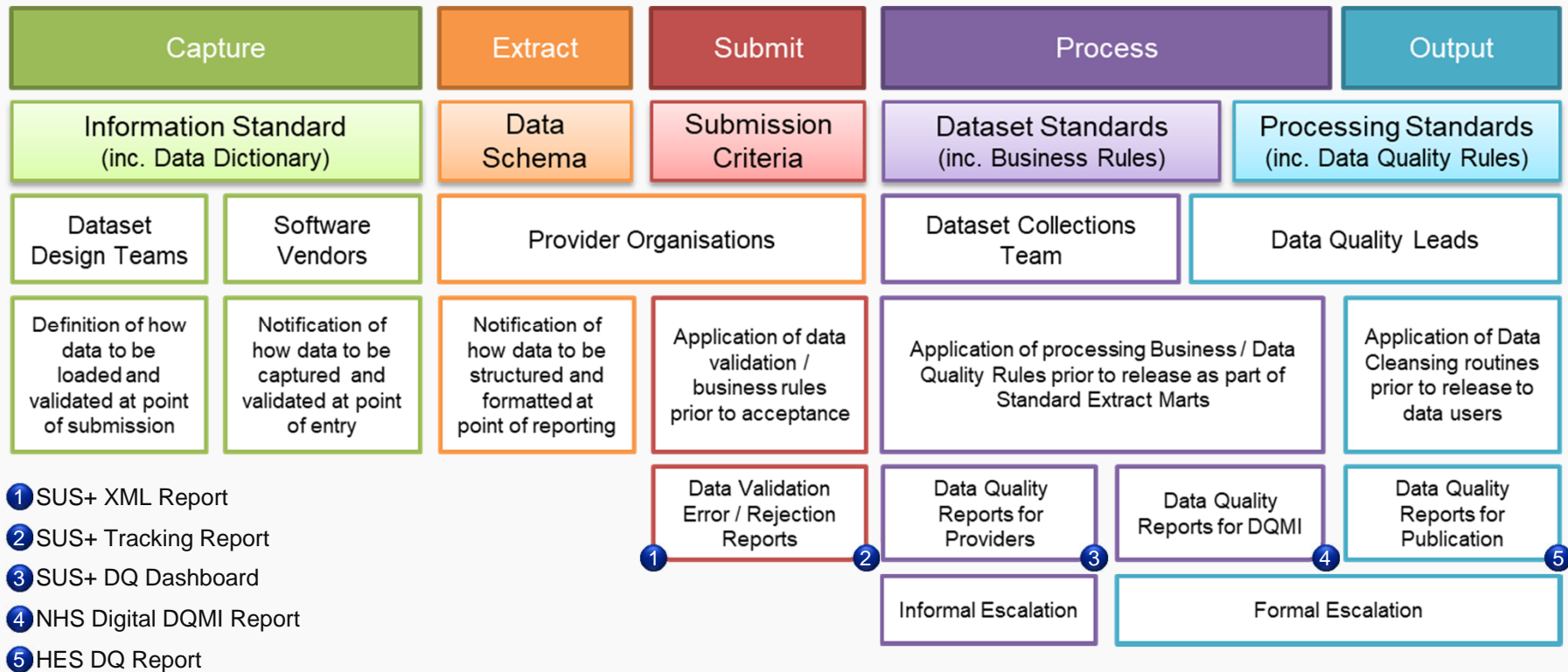
Information and technology
for better health and care

Presented by
Andrew Heggs, Head of Data Quality

Topics for Discussion

1. What we do now for Data Quality
 - a. Where we apply Data Quality
 - b. How we measure & report Data Quality
 - c. What we are doing to improve Data Quality
 - d. What data cleansing processes we apply
2. What will we do in the future
 - a. What are our DQ priorities going forward
 - b. How we will be changing our DQ structure
 - c. How we will be changing our DQ solutions

Where we apply Data Quality



How we measure Data Quality

Incentives and Levers Programme

The Data Quality Incentives and Levers programme sets out to ensure that national health bodies work collaboratively to drive up the quality of data submitted by provider organisations. The vision paper was approved by NHS Digital EMT on Thursday 18 August 2016, after which point the paper was circulated to a number of health ALBs for comment.

Feedback was collected, summarised and presented at the Data Quality Assurance Steering Group on Thursday 20 October 2016. This Steering Group has representation from DH, NHS England, NHS Improvement, PHE and CQC. A number of delivery work streams were agreed and meetings were set-up to develop an implementation plan for each part of the programme.



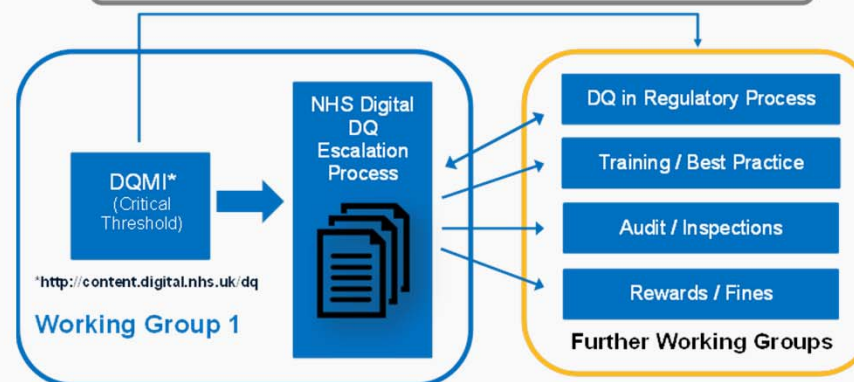
There was significant enthusiasm in the proposals at the Steering Group and acknowledgement that cross-organisation working is the only way to deliver this proposal effectively

The programme has five workstreams cover the five areas detailed above. The majority of work to date has focused on the development of a methodology for calculating the relative Data Quality Maturity Index (DQMI) score for each provider organisation across eight key national datasets. In conjunction with this an Escalation Process has been established to provide a formal contact mechanism with provider organisations for the resolution of data quality issues at dataset level.

Oversight of the programme is maintained through the Data Quality Assurance Steering Group where future development priorities are set.

A need was identified for national health bodies to work collaboratively to drive up the quality of data submitted by provider organisations and from this the Incentives & Levers Programme was established with representation from across NHS England, NHS Improvement, the CQC and Public Health England. The main aim of the programme is to develop a series of processes that measure and monitor the data quality of key national datasets and target areas of low data quality using various incentives and levers afforded by the regulatory powers of the constituent members.

Incentives & Levers Board Meeting



How we measure Data Quality

Characteristic	Description	Calculation
Coverage	The degree to which data have been received from all expected providers	$\frac{\text{\# of data suppliers that submitted data}}{\text{\# of data suppliers expected to submit data}}$
Completeness	The degree to which data items include all expected values	$\frac{\text{\# of data items holding a value}}{\text{\# of data items expected to hold a value}}$
Validity	The degree to which data collected satisfy the set of standards and business rules that govern the permitted values and formats at data item level (excludes defaults)	$\frac{\text{\# of complete data items holding a valid value*}}{\text{\# of complete data items}}$
Default	The degree to which the default values specified in applicable standards and business rules have been used in the data collected	$\frac{\text{\# of complete data items holding a default value}}{\text{\# of complete data items}}$

Other Dimensions under development / consideration

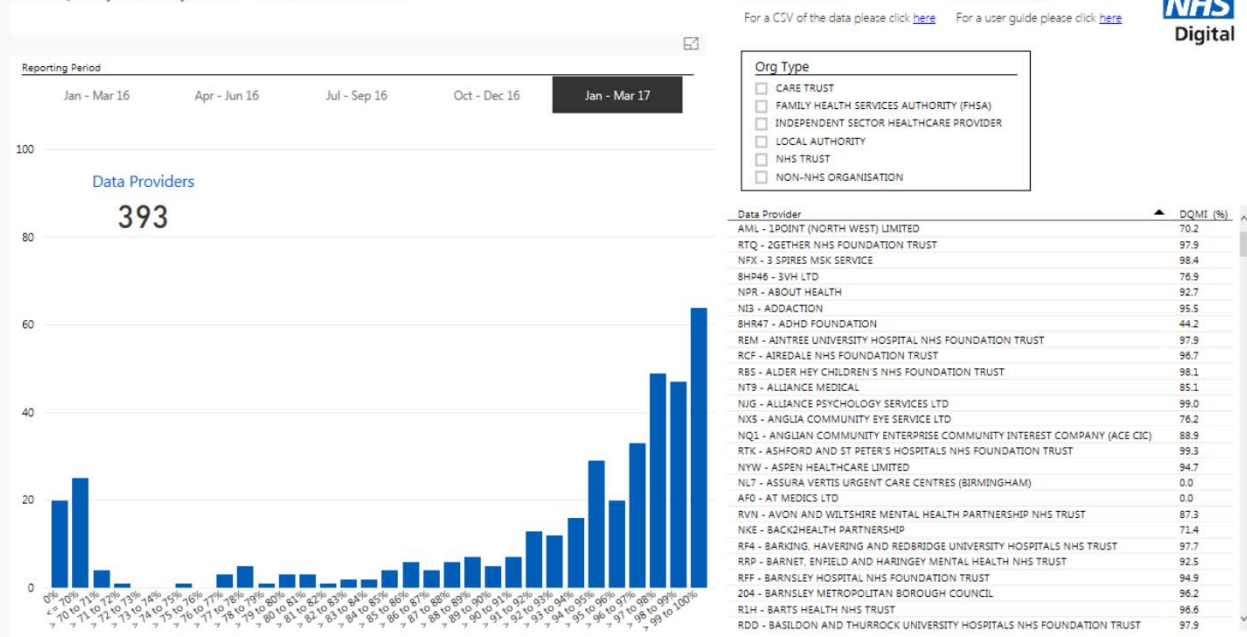
Timeliness (or Latency)	The degree to which data represent reality from a required point in time (or the degree to which customers have the data they need at the right time)
Consistency	The degree to which data conform to an equivalent set of data produced by the same process over time
Integrity	The degree to which data satisfy the set of business rules that govern the relationship between data items

How we report Data Quality

Each quarterly DQMI is publication includes the [DQMI Methodology](#) (click on link) which in turn is supported by the provision of both the raw data (as a CSV) and an interactive report using [PowerBI](#) (click on link)

Future enhancements to the PowerBI report are planned including the provision of time series data.

Data Quality Maturity Index - Score Distribution



What we are doing to improve Data Quality

The Data Quality Maturity Index (DQMI) is a quarterly publication intended to raise the profile and significance of data quality in the NHS.

The first DQMI was published in May 2016 for the period Jan-Dec 2015 covering the eight datasets listed below. Since then it has undergone a number of iterations and extensions to the dimensions. The table below shows the last 3 DQMI publications where the methodology has remained consistent.

Period	Overall	AE		APC		OP		DID		MHSDS		MSDS		IAPT		CYPHS	
Q2 16	91.7		91.3		91.9		90.6		92.3		94.1		94.9		90.8		N/A
Q3 16	↑ 92.1	↑	91.4	↑	92.0	↑	91.2	↑	93.4	↓	93.8	↓	94.2	↑	94.3	→	90.0
Q4 16	↑ 92.2	→	91.4	↓	91.9	↑	91.8	↑	93.9	→	93.8	↑	94.5	↓	93.7	↓	88.9

Established datasets: DQ activity
concentrating on all DQ dimensions

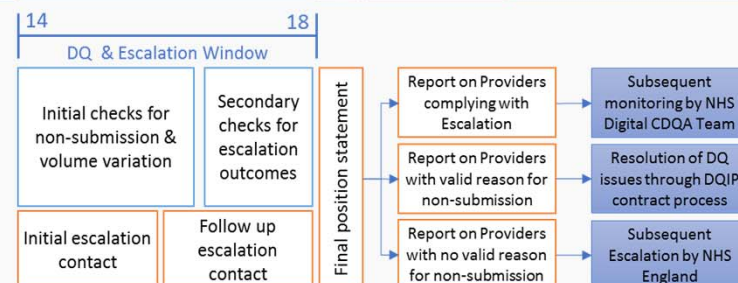
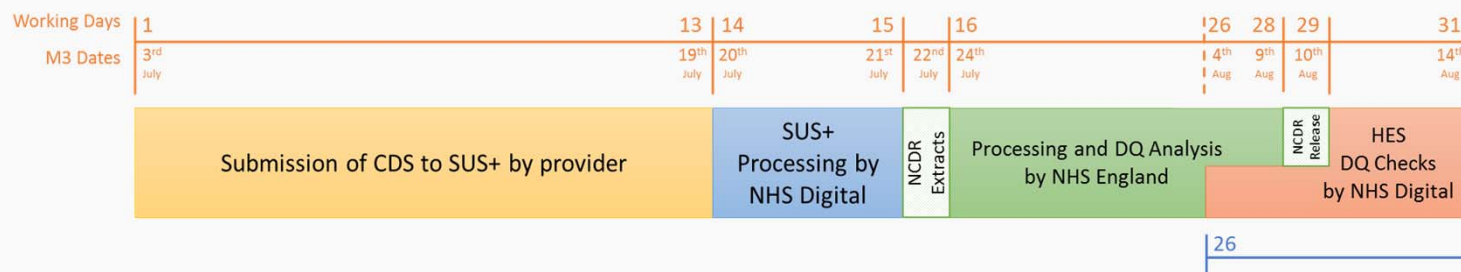
Newer datasets: DQ activity
concentrating on Coverage dimension

What we are doing to improve Data Quality

Work was recently undertaken for NHS England to improve coverage on or after after Inclusion Date.

For M4 A&E data this resulted in an increase over M3 coverage from 97.5% to 99.2%.

Work will now commence in applying the process to the APC and OP datasets. This work will further assist the intended move of HES DQ activity closer to the Inclusion Date and a potential move to near real time SUS+ DQ reporting.



What we are doing to improve Data Quality

An investigation undertaken at the end of 2016/17 into the number of default values present in key fields in HES, identified by the HES Analysis Team (opposite).

A default value is defined as a value that has either been submitted as blank or 'Not Known' by a provider. The report found that there had been a sharp increase in the number of default values submitted by approximately 8 Providers in AE, 30 in APC and 24 in OP.

NHS Data Dictionary Name	Dataset	Shortname
Attendance Category	Accident and Emergency	AEATTENDCAT
Source of Referral	Accident and Emergency	AEERESOURCE
Person Conducting Delivery	Admitted Patient Care	DELSTAT
Place of Delivery	Admitted Patient Care	DELPLAC
Method of Onset of Labour	Admitted Patient Care	DELONSET
Type of Anaesthetic	Admitted Patient Care	DELPREAN
Ethnicity	Admitted Patient Care	ETHNOS
Main Speciality Code	Outpatient Care	MAINSPEF

HES DQ Team contacted providers and developed further data quality checks in an attempt to reduce the number of default values being submitted.

The table to the left shows that there has been a decrease in the percentage of default values present in each of the majority of fields in the months immediately following the HES DQ Team's consultation

Dataset	Field	Percentage of Default Records					
		Pre Consultation				Post Consultation	
		2013/14 %	2014/15 %	2015/16 %	2016/17 %	2016/17 %	
AE	AEATTENDCAT	1.30	1.73	2.25	2.69	2.71	↑
AE	AERESOURCE	3.40	3.51	3.93	3.44	3.36	↓
APC	DELSTAT	18.02	18.71	18.57	22.97	19.85	↓
APC	DELPLAC	15.04	14.76	18.31	21.58	16.83	↓
APC	DELONSET	18.36	20.97	21.59	19.05	15.00	↓
APC	DELPREAN	13.99	14.83	15.13	25.03	20.32	↓
APC	ETHNOS	1.92	2.46	3.3	2.67	3.25	↑
OP	MAINSPEF	0.16	0.26	0.78	0.33	0.10	↓

What data cleansing processes we apply

Autocleans

- Existing fields are automatically cleaned as part of core processing e.g.
 - If a diagnosis or procedure code is submitted in an incorrect format, clean it to a default code
 - If a record is submitted with a birth date before 1 April 1890 clean to unknown age
 - Postcodes changed to 8 character format AANN NAA

Provider Mapping

- Records submitted with blank, invalid or historic provider code (PROCEDURE) are mapped to ensure that activity is attributed to correct provider as follows:
 - Check if there is a successor organisation to map to, else
 - Check if there is a valid Site Code of Treatment to map to, else
 - Check if there is a valid Sender to map to, else records will be deleted

Duplicate Detection

- Duplicates are records which failed to be overwritten by a subsequent submission into SUS. Records are initially grouped where certain fields are the same - Local Patient ID, NHS Number or (Postcode, DOB and Sex), but only deleted if reason is 'failed to overwrite'

What data cleansing processes we apply

Other tasks done by SUS+/HES DQ

- Regular feedback to providers on three main DQ issues: coverage, duplicate records & provider mapping
- Other feedback to providers on DQ issues as & when required
- Interactions direct with providers using SUS data through to end users of the HES data



395,411

records that would have been lost were mapped to the correct providers for 2016-2017 annual refresh publication.



Around **40** emails are sent out each month to highlight and assist with DQ Issues to providers

596

There are **596** fields in the HES data dictionary within the A&E, APC, and OP datasets.



220

There are approximately **220** business rules in HES that automatically cleanse the incoming data



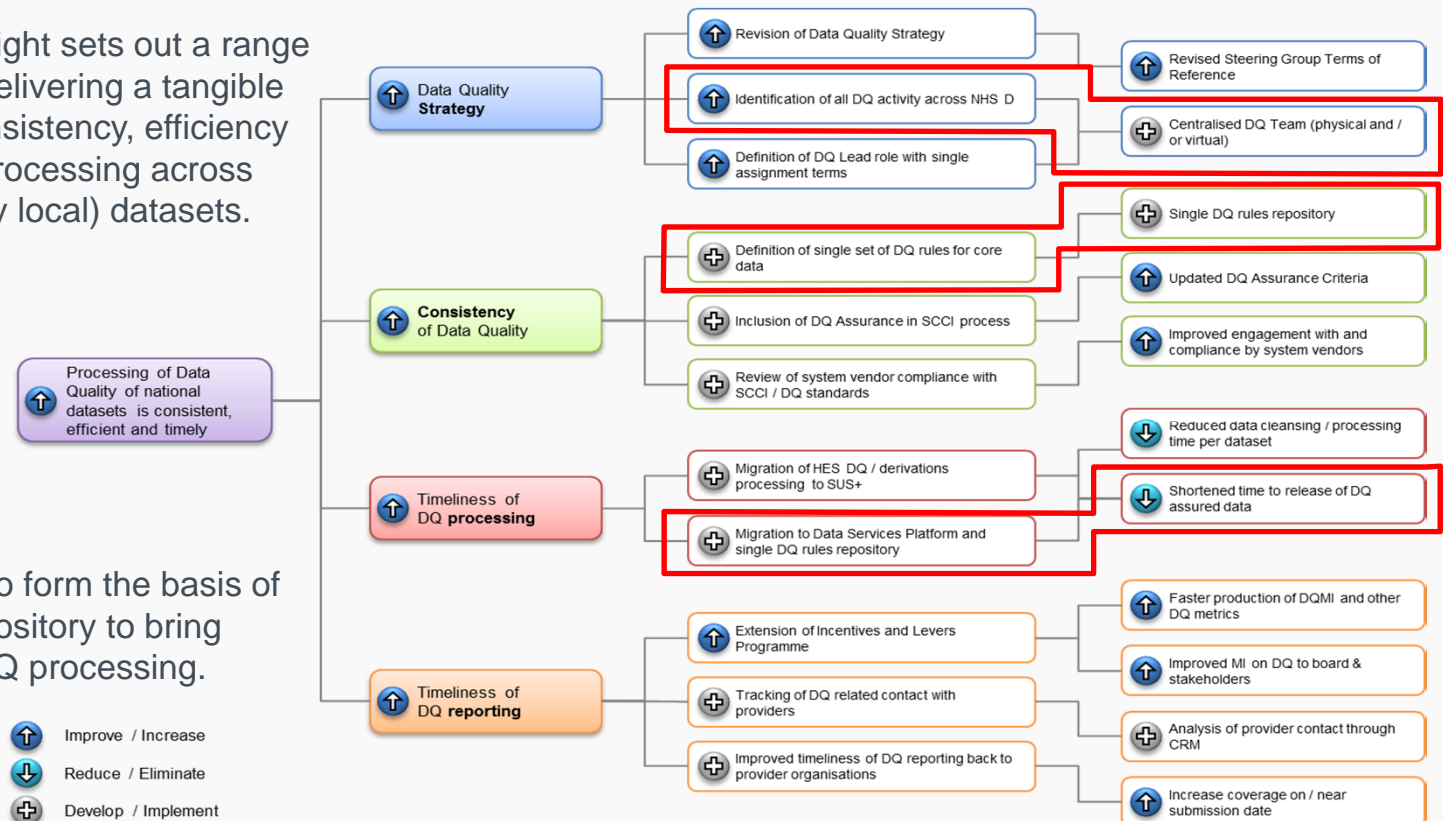
The business rules referenced on the right can be found in the HES Autocleans Dictionary [here](#)

What are our DQ priorities going forward

The driver tree on the right sets out a range of initiatives aimed at delivering a tangible improvement in the consistency, efficiency and timeliness of DQ processing across national (and potentially local) datasets.

Core to this will be better understanding the range and scope of DQ activities and the opportunities for resource centralisation that this offers.

This will then be used to form the basis of a single DQ Rules Repository to bring about consistency of DQ processing.

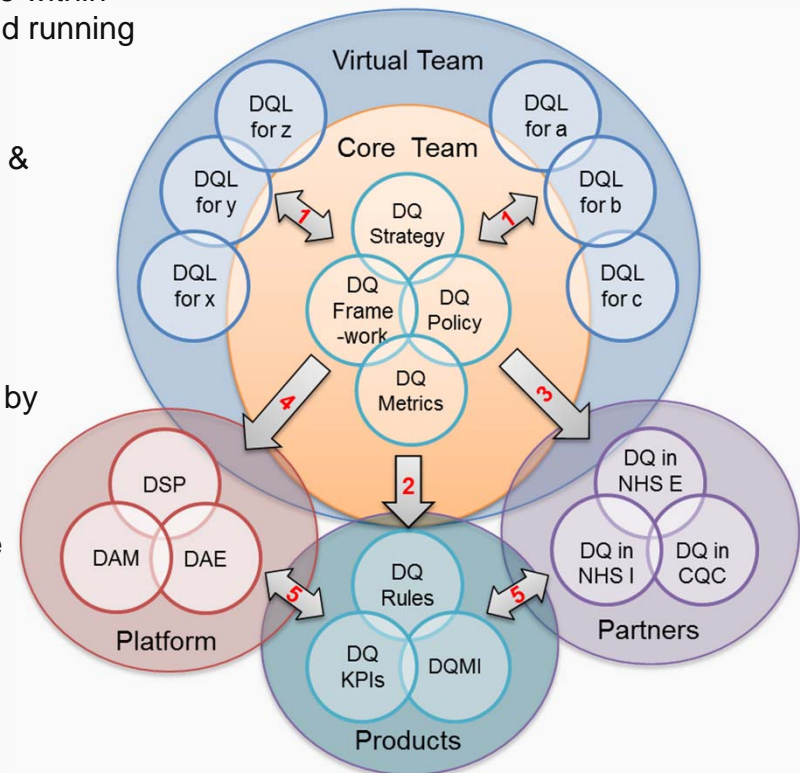


How we will be changing our DQ structure

Core Team: consists of all staff currently explicitly assigned to a DQ role within NHS Digital. Responsible for setting strategy, DQ Rules Framework and running DQ Steering Group and Incentives & Levers Programme

Virtual Team: consists of staff with explicit DQ responsibility within an assignment e.g. DQ Leads. Responsible for contributing to the strategy & DQ rules framework, applying DQ Rules against own datasets & completing the DQ Assessment

1. Collaborative working between core and virtual team to define and implement DQ rules and develop other DQ products as required
2. Core Team to develop and approve for use DQ products as required by NHS Digital and its partners.
3. Collaboration with other ALBs on DQ related topics through such forums as DQA Steering Group and Incentives & Levers Programme
4. Provide DQ representation on programmes such as DSP, providing SME input, ownership and governance of DQ elements
5. Provision of core DQ products to support internal developments and support DQ initiatives instigated by other health ALB partners.



What are the main DQ issues for researchers?



Lunch



Data Protection, Consent and Transparency

Alex Bailey

Medical Research Council Regulatory Support Centre

alex.bailey@rsc.mrc.ac.uk

<https://www.mrc.ac.uk/research/facilities-and-resources-for-researchers/regulatory-support-centre/>

The law

Common law

Data Protection law

Health Service (Control of Patient Information) Regulations

The Human Rights Act 1998

Statistics and Registration Service Act

The Health and Social Care Act

Human Fertilisation and Embryology Act



Common law - confidential information

Information not in public domain

Degree of sensitivity

Related to identifiable person (alive or dead)

Given to you (or someone) with the reasonable expectation that it won't be disclosed to anyone else



Common Law Duty of Confidence

A duty to hold and disclose information in ways that respect a patient's 'reasonable expectations of privacy'

No surprises

Reasonable expectations?



Common law - sharing confidential information

Consent

Or

Overwhelming public interest/legal reason

Or

Other legal avenue e.g. Section 251
(Confidentiality Advisory Group)



Personal data

Data i.e. structured information - electronically or manually filed

Relates to, or is about a living, **identifiable** person

Sensitive personal data - personal data with a degree of sensitivity associated with them (e.g. health data)



If you process personal data

You must comply with the Data Protection Act

- Must process lawfully -
- Includes having a legal basis to process (collect, store, use, etc.) personal data
- Must process fairly -
 - Transparent
 - Consider objections



Legitimate interests as a legal basis

Schedule 2 of the DPA provides the legal basis for supporting data processing

‘necessary for the purposes of legitimate interests’

What are the legitimate interests of your organisation (University / NHS / research organisation)?



Legal basis alternatives

If not processing data for legitimate reasons - other options available

Schedule 2 of Data Protection Act - defines legal basis

- Legitimate interests
- (Consent)
- ...others...



Sensitive personal data

Additional condition (Schedule 3) to be met if you hold sensitive personal data (e.g. personal data about health, sexual orientation, trade union membership etc.)

‘necessary for medical purposes’ (includes medical research)

or

Explicit consent (DPA does not define difference between consent and explicit consent)



Legal basis and conditions for processing sensitive data

Schedule 2

Legitimate interests

(Consent)

Schedule 3

- For medical purposes
- (Explicit Consent)



New Data Protection Law

- You must comply with the Data Protection Act
- Must process lawfully -
- Includes having a legal basis to process (collect, store, use, etc.) personal data
- Must process fairly and transparently
- New data protection law does not affect Common Law Duty of Confidence



New Data Protection Law - Legal basis

Article 6 (personal data)

Legitimate or public interest

(Explicit consent)

Public authorities (Universities, NHS etc.) cannot rely on legitimate interest, but can rely on 'task in the public interest'

No longer just 'medical research' but 'scientific research'

'Explicit consent' clearly defined and comes with limitations

Article 9 (sensitive data)

- Scientific Research

- (Explicit consent)

New Data Protection Law

Current law does not ask you to be explicit about your legal basis to process personal data

New law will require **organisations** to be explicit

Organisations required to be accountable and transparent about how they process personal data

Transparency

By law

Concise, transparent, intelligible and easily accessible

Written in clear and plain language, particularly if addressed to a child

Best practice

Layered approach to ensure appropriate transparency

Living documents



Intelligible?

Language understandable to the data subjects

Understanding Patient Data

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



Transparency for Research

Data controllers must take 'appropriate measures' to provide data processing information

How?

Website

Leaflets/Posters

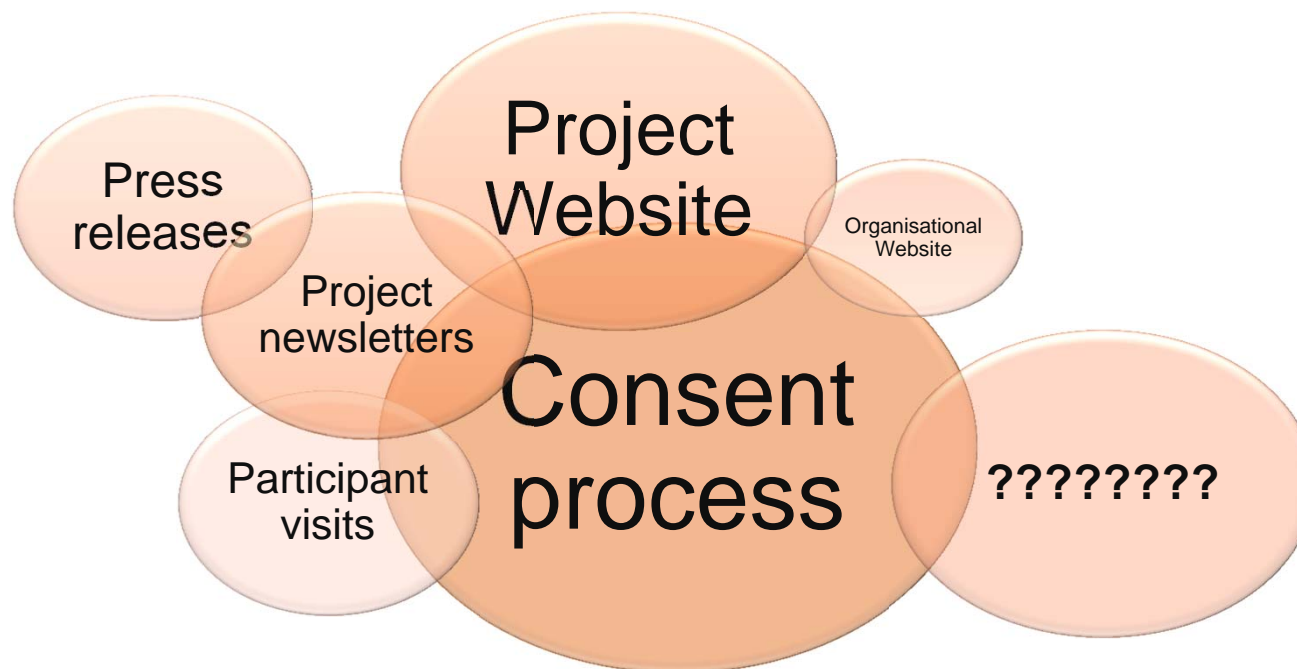
Newsletters/Media Campaign

Participant Information Sheet

Consent process



Transparency for Research

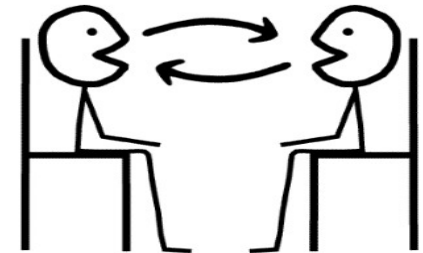


The consent process and transparency

Consent process isn't only about getting consent to participate or to share confidential information

Not just a tick-box exercise

Outstanding opportunity to discuss data processing



Things to do?

What research data are you processing?

Not identifiable?

Personal?

Sensitive?

What legal basis are you currently relying on?

What does your transparency look like?

Liaise with your DPO



Questions?



<https://www.mrc.ac.uk/research/facilities-and-resources-for-researchers/regulatory-support-centre/>

National Data Opt-out Programme



Information and technology
for better health and care

Presented by
Trevor Anders, Programme Manager

Agenda

- What is the national data opt-out
- Operational policies
- Implementation
- What will this mean to you?

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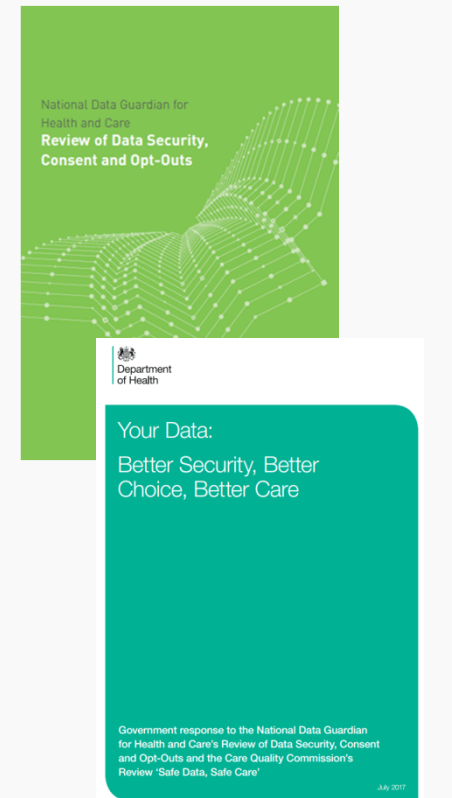
The national data opt-out

NDG Review and Government's response

National Data Guardian Review – Key Points & Recommendations

- You are protected by the law
- Information is essential for high quality care
- Information is essential for other beneficial purposes
- You have the right to opt out of your personal confidential information being used for these other purposes beyond your direct care:
 - Providing local services and running the NHS and social care
 - Supporting research and improving treatment and care
- This opt-out will be respected by all organisations that use health and care information
- Explicit consent will continue
- The opt-out will not apply to anonymised information
- Arrangements will continue to cover exceptional circumstances

The Government response to the National Data Guardian Review supports the recommendations



Implementation Timetable (Oct 2017 – Mar 2020)

Area	Oct – Dec 2017	Jan – Mar 2018	Apr – Jun 2018	Jul 2018 – Mar 2019	Apr 2019 – Mar 2020
Opt-out awareness raising	Awareness raising				
Opt-out service testing	Build opt-out service	Test opt-out service			
Setting opt outs			03/18 Opt-outs can start being set from this date		
Applying opt-outs			03/18 Opt-outs upheld by NHS Digital	Upholding of opt-outs phased in for all other health and care organisations	
New Data Protection Legislation (GDPR)			05/18 New data protection legislation comes into effect		
Overall data communications strategy	Develop strategy	Implement communications strategy			

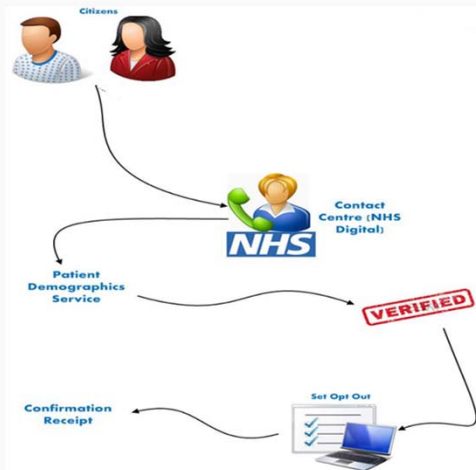
Solution approach

1) Setting preference(s) ...

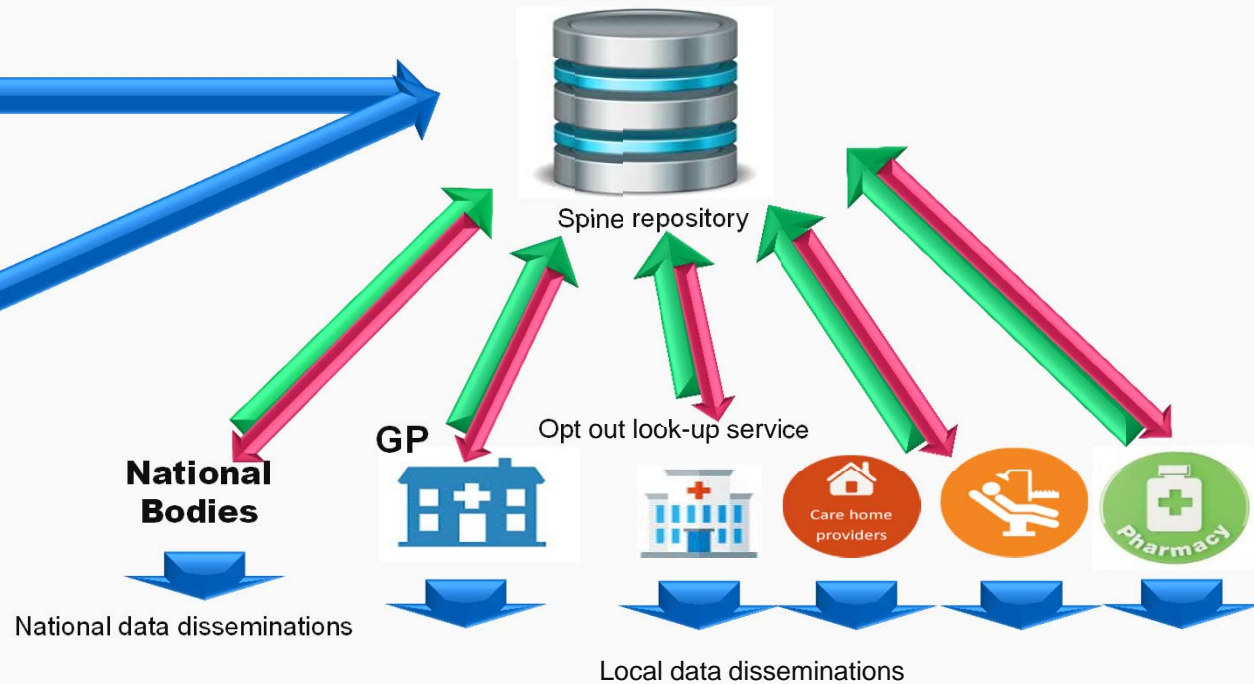
Patient-facing digital front-end



Non digital front-end



2) Storing preference(s) ...



3) Upholding preference(s) ...



Operational policy

Applying the national data opt-out

Data shared for planning and research purposes

Research – finding ways to improve treatments and identify causes of and cures for illnesses
Planning – to improve and enable the efficient and safe provision of health and care services



This identifies you personally

Data shared for an individual's care & treatment

E.g. where data is shared between the health and care professionals in a hospital and in a GP practice



This identifies you personally

Legal requirement / public interest / consent

E.g. There is a mandatory legal requirement such as a court order, to protect the greater interests of the general public or there is explicit consent



This identifies you personally

Data is anonymised

The data shared is determined to be compliant with the ICO Anonymisation: managing data protection risk code of practice



This does not identify you personally

When it applies

The national data opt-out will apply when:

- personally identifiable data is used for purposes beyond an individual's care and treatment—this includes
 - data being used for research purposes such as to identify the effectiveness of a new drug
 - data being used to provide information to support the safe and effective delivery of health and care services
- the legal bases to use the data is based on approvals made under:
 - regulation 2 (medical purposes related to the diagnosis or treatment of neoplasia i.e. cancer); or
 - regulation 5 (general medical purposes including medical research)

of the Control of Patient Information Regulations 2002 under the NHS Act 2006 s251

- The Confidentiality Advisory Group which provides independent expert advice on applications for data use under s251 can in some cases agree that opt-outs do not apply but have indicated that this would only be in exceptional circumstances

How/When/What

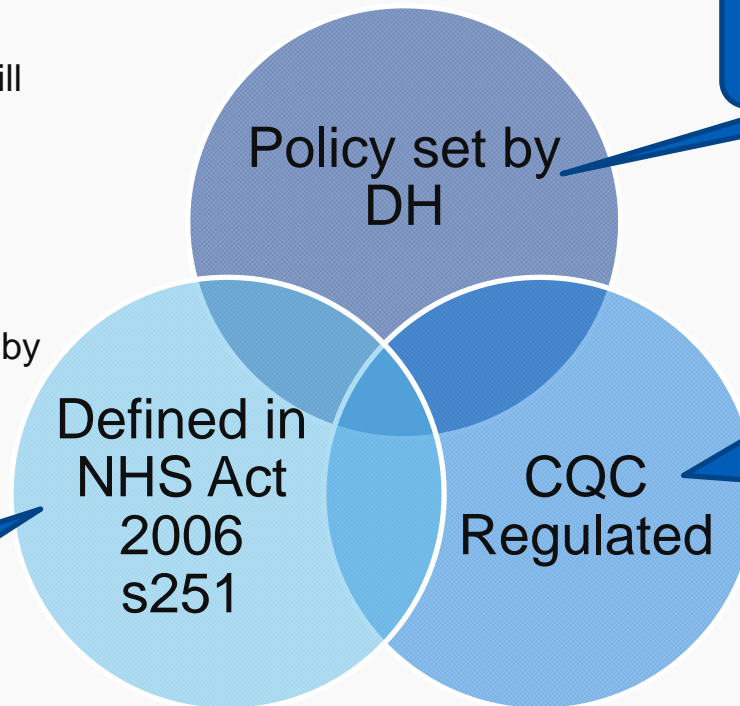
- the NHS number will be used to apply the opt-out
- continues to apply after a person has died
- applies to all data controllers
- is an opt-out for England only
- when applied the whole record must be removed – not just identifiers
- information on national data opt-out rates and some analysis of the characteristics of those patients that have chosen to opt out will be made available

Definition of health and social care - proposal

Information about patients generated or processed in the health and care organisations as defined on this slide will be considered as “in scope” for national data opt-outs when used for purposes beyond individual care in line with the wider policy.

This includes any subsequent releases by organisations acting as data controllers who use that data such as NHS Digital or Public Health England (PHE).

Health service bodies or relevant social care bodies as defined within s251 of the NHS Act 2006



As defined in DH Annual Accounts

or regulated by a health or care related professional body e.g. General Pharmaceutical Council

Public funding & independent providers

National data opt-out

The national data opt-out will apply to any publicly funded or publicly co-ordinated care or treatment

Will apply

- All NHS organisations (including private patients treated within such organisations)
- Adult social care which is funded or coordinated by a public body (typically a local authority)
- NHS funded care within independent providers (e.g. Nuffield, BMI Healthcare)
- Any release of data by NHS Digital which relates to private patients including that which is collected by a request under s259 of the Health and Social Care Act 2012

Will not apply

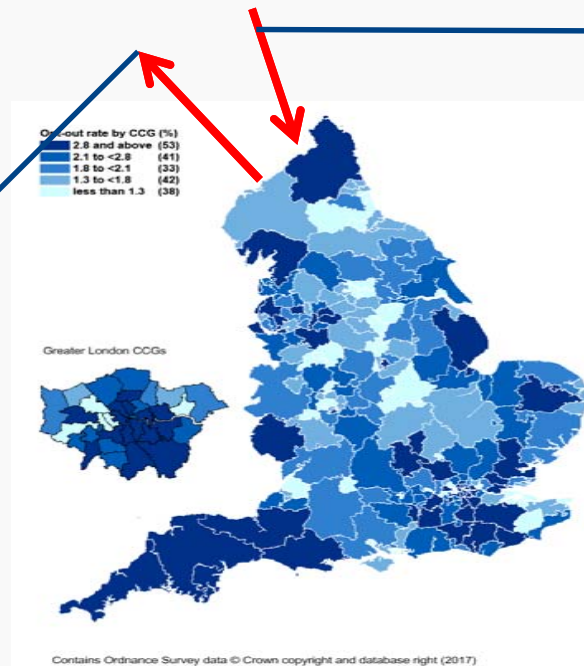
- Privately (non NHS) funded patients within independent providers unless the care is coordinated by a public body
- Care which is not funded or coordinated by a publicly funded - i.e. privately arranged/privately funded care

Data collected in England & cross border flows

National data opt-outs will continue to apply if a patient has opted out and then left England without changing their opt-out preference.

National data opt-outs will apply to information originating in England which is released outside of England.

Including to home countries, e.g. Wales, Scotland, Northern Ireland, or the Isle of Man or Channel Islands unless another exemption applies such as consent



National data opt-outs will not apply to information from providers of health or care in other home nations, i.e. where the patient receives treatment in another home country.

Key policy in development

- whether there will be single opt-out question that covers both research and planning purposes or whether a patient can choose to opt out of one or other or both
- what is classed as personally identifiable data
- age a young person can set a national data opt-out
- arrangements for proxies e.g. for those without capacity



National data opt-out – Fit with new Data Protection Legislation (General Data Protection Regulation)

Fit with General Data Protection Regulations

- The national data opt-out will sit alongside the new Data Protection Legislation coming into force in May 2018 due to the General Data Protection Regulations (Data Protection Bill 2017 currently going through Parliament)
- The national data opt-out is not replaced or changed by it
- Areas of overlap relate mainly to:
 - Understanding of consent
 - The 'right to object'
 - Potential changes to ICO Code of Practice on Anonymisation
 - Privacy Notices

GDPR and confidentiality

- GDPR requires that processing of personal data is **fair, lawful** and **transparent**
- To be **lawful** in UK law the common law duty of confidence (confidentiality) must also be satisfied
- This means under the GDPR that for health and care data:
 - an Article 6 condition needs to be satisfied (for personal data); **and**
 - an Article 9 condition needs to be satisfied (as health data is a special category of data) **and**
- To respect confidentiality
 - there is consent from a patient for the use of their data under common law **or** there is another legal basis which enables the common law duty to be set aside (i.e. there is a mandatory legal requirement or sec 251 support, or overriding public interest)

Consent

- 'Consent' to meet the common law is different to, and should not be confused with, consent to processing under GDPR.
- The Information Commissioner's Office has advised that using consent as the lawful basis for processing under GDPR should be avoided by public authorities because:
 - It is unlikely to be able to meet the strict requirements.
 - It cannot be freely given if access to a service is dependent on it.

Consent – two types

- For common law purposes there are two general types of consent:
 - **Implied consent** – assumed where the use of the information is to support direct delivery of care. If the patient agrees to the care – it is reasonable that their information for delivery of this care is shared (e.g. GP referral), provided the patient has been appropriately informed or the uses and disclosures are obvious
 - **Explicit consent** - a patient has agreed to the use of their data for a purpose:
 - This does not have to meet GDPR requirements.
 - It does need to be transparent and supported by appropriate information.
- Where an organisation does not use consent as its basis for lawful processing for GDPR purposes, professionals do not need to change consent practices that meet the common law requirement

Or you can think of it as a 3 legged stool...

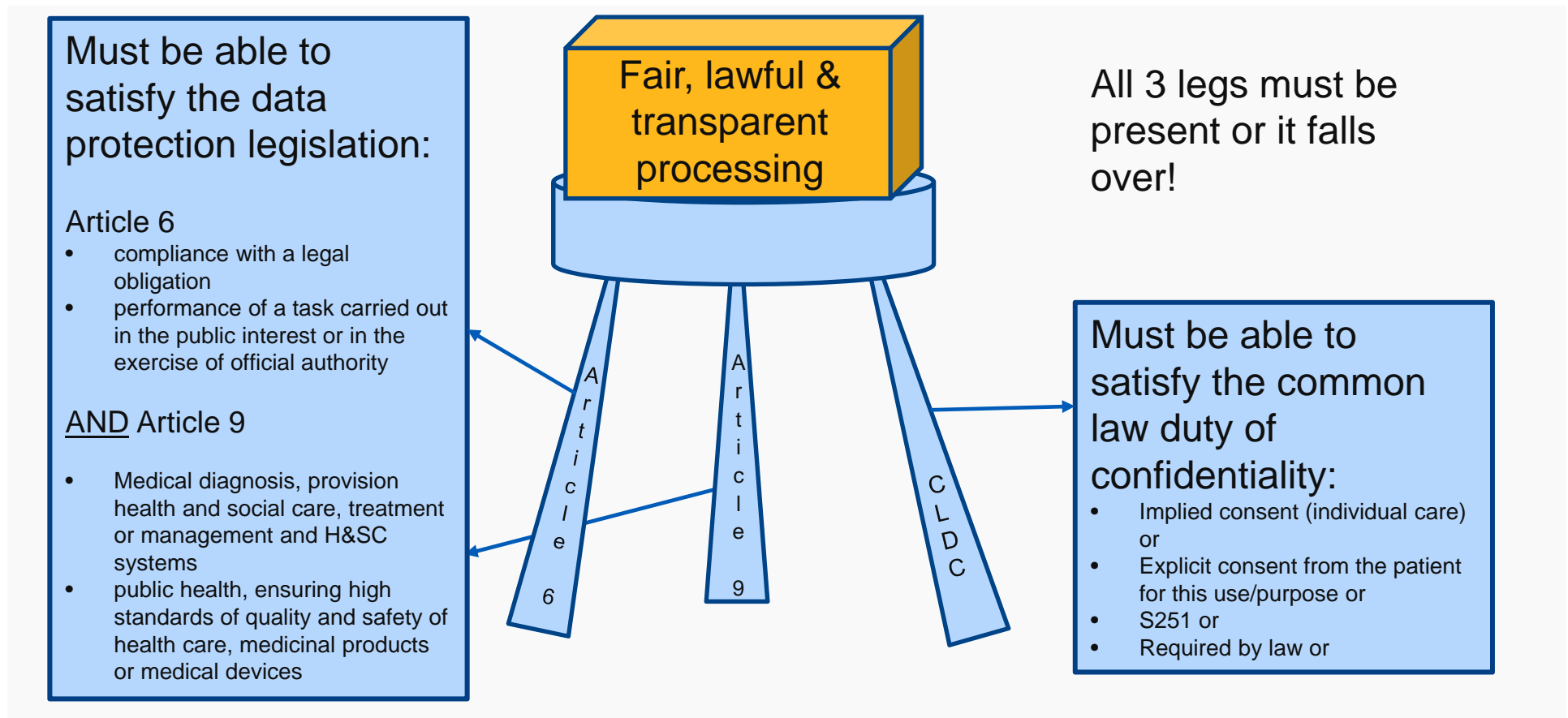


Illustration of how to be ‘lawful’ under GDPR

Purpose/Use data	Example	GDPR Lawful Processing Requirements			National data opt-out
		Article 6	Article 9	Common law duty of confidentiality	
Individual care	E-referrals	6(1)(e)	9(2)(h)	Implied consent	✗
Beyond individual care - flows to NHS Digital	Collection of mental health services data set	6(1)(c) (legal obligation for NHSD and provider)	9(2)(h) or (i)	Directions	✗
Beyond individual care – planning and running NHS (other mandatory flow)	CQC powers to require information and records	6(1)(e) for CQC 6(1)(c) for the provider	9(2)(h) or (i)	Legally required	✗
Beyond individual care – planning and running NHS (s251 – Reg 5)	National clinical audits	6(1)(e)	9(2)(h) or (i)	s251	✓
Beyond individual care – research (consented)	Clinical trial for new drug treatment	6(1)(e)	9(2)(j)	(explicit) Consent	✗

^[1] Article 6(1)(e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller

^[2] Article 9(2)(h) processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3;

^[3] Article 9(2)(i) processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy



Implementation approach

Stage 1 - Awareness and setting

- Raising awareness about the national data opt-out and how preferences can be recorded and changed
- Implemented a private on-line solution in September 2017 to enable testing of the digital and non digital solutions, processes and supporting materials for the setting of a national data opt-out
- Currently raising awareness across health and social care organisations to enable understanding of the national data opt-out
 - what it means,
 - when it applies;
- From 2018, engagement focus will be on preparing health and care organisations to be ready for the introduction of the national data opt-out and being able to handle queries from patients

Stage 2 - Upholding

- Providing information on how and when to uphold the national data opt-out (for those organisations that share personal identifiable information for purposes beyond an individuals care)
- The requirement for organisations to uphold the national data opt-out will be phased in through to 2020
- NHS Digital will be the first organisation ready to support the national data opt-out
- Phasing will be based on organisation types as this will provide a coherent way to explain to patients when their national data opt out will be applied
- The programme is working with organisations to help establish the organisation phases

Materials to support the national data opt-out

- Information materials will be made available with the expectation they can be adapted and tailored to suit local needs and be available through local channels as well as being hosted and available through national websites
- The national data opt-out will be communicated as part of communicating about data use and sharing in the health and care system to provide greater transparency and understanding
- A wider benefits of data sharing campaign strategy is being developed and delivery will take place outside of the National Data Opt-out Programme but timed to align with the launch of the national data opt-out

The background of the slide is an abstract image with a blue color scheme. It features numerous bright, out-of-focus light spots (bokeh) and thin, diagonal streaks of light that create a sense of motion and depth. The overall effect is reminiscent of light trails or data flow in a digital environment.

Preparing for implementation

What this could mean to you

- If you receive data from NHS Digital, national data opt-outs will be applied as per policy starting from March 2018
- If you already receive data and type 2 opt-outs are applied then likely no significant change as policies are broadly similar
- If you receive data from other health and care organisations for purposes beyond individual care at some stage through to 2020 those data will need to have national data opt-outs applied as per the policy
- If you receive health and care data and have agreements in place to then onwardly share those data that position will need to be reviewed to ensure national data opt-outs are applied at an appropriate point in the data journey

Things to consider

- What do you think your organisation will want to know about the introduction of the national data opt-out?
- Do you have any communication channels that you would want to use to share information with your organisation about the national data opt-out e.g. networks, user groups, bulletin/email distribution lists, websites?
- How can we work with you to help in shaping/reviewing any communications for your organisation?
- Is there any other support you think your organisation will need to help in understanding the national data opt-out e.g. do you have any specific user forums, conferences, scheduled meetings that you think it would be useful for the programme to attend?

Supporting the National Data Opt-out Programme

- Are there any ways that you think you may be able to help in ensuring there is awareness of the use of data and the national data opt-out across the health and care system?
- Do you want to be involved in helping to develop/review any of the content, products/materials that the programme develops for patients and the health and care workforce?

More information

National Data Opt-out Programme web pages & to join our mailing list

<https://digital.nhs.uk/national-data-opt-out>

Understanding Patient Data - Wellcome Trust

<https://understandingpatientdata.org.uk>

National data opt-out enquiries mailbox newoptoutenquiries@nhs.net

Information Governance Alliance (IGA) information on GDPR:

<https://digital.nhs.uk/information-governance-alliance/General-Data-Protection-Regulation-guidance>

The background of the slide is an abstract composition of numerous bright blue and white light streaks and bokeh circles, creating a sense of motion and depth. The streaks are mostly diagonal, running from the top-left towards the bottom-right. The bokeh circles are of various sizes and are scattered throughout the image, with a higher concentration in the upper half. The overall color palette is dominated by shades of blue, with the light streaks and bokeh providing a high-contrast, energetic feel.

Questions

Roadshow Close

- **Thank you for taking part**
- **More opportunities to participate**
- **Your feedback will help us improve**



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enquiries@nhsdigital.nhs.uk

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Information and technology
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Case officer teams with key research customers

Other applications allocated to teams as required

Team led by Jen Donald: Dan Goodwin, Denise Pine, Nichola Makin

Key customers: University of Oxford

Team led by Louise Dunn: Russell Heep, Emma Russell, Suzanne Shallcross

Key customers: University of Leeds, Imperial College London

Team led by Duncan Easton: Tracy Taylor, Belinda Garrow, Rick Jones

Key customers: University of Manchester, University of Bristol, University of York

Team led by Rachel Farrand: Matilda Korovesi, Frances Hancox, Fiona Dodsworth

Key customers: London School of Hygiene and Tropical Medicine, University of Newcastle, University of Nottingham

Team led by Dickie Langley: Katie Sheppard, Anna Weaver

Key customers: University of Birmingham, University of Sheffield, University of Dundee and Kings College London

Team led by Vicky May: Elizabeth Flaherty, Jonathan Smith, Anna Duggan

Key customers: University of Cambridge, University of Warwick and Queen Mary University

Team led by Kimberley Watson: Charlotte Skinner, Cath Day, Victoria Byrne Watts

Key customers: UCL and University of Liverpool

Fair processing – 9 point checklist

The new essential criteria would be less & are clearer, namely:-

The Privacy Notice must be:

- ✓ Published
- ✓ Visible to any member of the public when visiting the organisation's website
- ✓ Clear and truthful. Not include statements that may lead the public to believe that they can exercise choice over the collection and use of their personal information when they really cannot e.g. by using misleading or contradictory statements.

The Privacy Notice must specify:

- ✓ Who the data controller (DC) is
- ✓ What level of data is collected (whether the individual is directly identified, or could be indirectly identified if combined with other data, or whether the individual cannot be identified)
- ✓ Where data is collected from (e.g. one's GP records or hospital records, etc.)
- ✓ The purpose or purposes for which the data is processed
- ✓ Who the data is shared with
- ✓ The opt-out method and contact details