

BOARD PAPER - NHS ENGLAND

Title: Care.data Programme Update

From: Tim Kelsey, National Director for Patients and Information
care.data Senior Responsible Owner (SRO)

Purpose of Paper:

- To provide an update on the status of the care.data programme.

Rationale for this Paper Being Discussed in the Private Session:

- The programme is at a delicate stage awaiting advice on next steps from various stakeholders, not least the Information Governance Oversight Panel (IIGOP) chaired by Dame Fiona Caldicott.

The Board is invited to:

- note the current status of the programme
- consider next steps, particularly in relation to how lessons learnt from the care.data programme pathfinder stage can inform future strategy on broader areas such as patient ownership of data; patient consent models and supporting GPs with fair processing.

Care.data Programme Update

Purpose

1. The purpose of this paper is to provide an update to NHS England Board members on the status of the care.data programme.

Background

2. Care.data is a programme of work, which aims to securely connect information together and make it available to those who plan NHS services, researchers, medical charities and businesses that support the NHS to improve services. The first phase of the care.data programme is to securely collect and connect information from hospitals and GP practices.
3. Linking fully representative whole population hospital data with comprehensive coded general practice data will bring significant benefits. In addition, the programme is exploring the challenges associated with fair processing in general practice. This provides an important opportunity to describe and implement best practice with the aim of ensuring that all citizens understand how valuable their data is to the health and social care system and the choices available to them. The National Data Guardian will scrutinise and evaluate key aspects of the pathfinder stage prior to further roll out, which will form a key part of informing best practice.
4. These lessons are not only important for the care.data programme but also for NHS England and the National Information Board in terms of informing future strategy in relation to areas such as patient ownership of their data; patient consent models and supporting GPs with fair processing.
5. Significant progress has been made with the care.data programme. The programme has engaged with almost 3,000 people at over 180 meetings and events and as a result new safeguards for data sharing have been introduced including new legislation to strengthen controls around the use of data. A summary of what we heard during this listening phase is at Annex A.
6. Over 100 GP practices have volunteered to work with us to develop the care.data programme in a 'pathfinder stage'. The pathfinder Clinical Commissioning Groups (CCGs) are: Blackburn with Darwen, Leeds North, Leeds West, Leeds South and East, West Hampshire and Somerset.
7. Core public facing communication materials have been co-produced with the pathfinder areas and with national stakeholders and these are at Annex B (to be tabled). In addition a GP practice toolkit and a community toolkit have been specifically designed to support practices, and local community partners with local implementation.
8. The programme has appointed a GP clinical lead, Dr Lisa Harrod-Rothwell, who is providing valuable clinical input into the programme.
9. This briefing note provides an update for the NHS England Board on the general status of the programme and the specific status of the pathfinder project.

Pathfinder Project

10. The pathfinder project is a partnership between NHS England and the Health and Social Care Information Centre (HSCIC), with NHS England taking the lead on Policy, Communications and Engagement and on local implementation. Regional Heads of Intelligence and local NHS England resources have played and continue to play a key role in working with pathfinder

CCGs. The care.data programme presents an example of successful collaboration with local CCGs to improve support for GP practices and patients.

Quote from Dr Sarah Schofield, Chairman of the CCG and project sponsor:

11. "The sharing of patient information across the NHS helps to ensure that the quality and safety of services is consistent and provides valuable insight on diseases and conditions. It is essential that this is done in an appropriate and secure way. We are therefore extremely pleased to have the opportunity to work with our patients to test communications on care.data and ensure GPs are equipped to manage this locally and are able to support patients with making informed choices."

Pathfinder Sign Up

12. Across the West Hampshire, Somerset, and Blackburn with Darwen CCGs 104 practices have signed up to participate which represents just short of 70% of practices. Leeds is following a different timeline to the other CCGs to accommodate their two-staged approach to communications with the public, which will see CCG led local public engagement activity undertaken, ahead of the main public facing materials landing with patients and in practices. However, a number of practices within the Leeds CCGs have signed up and further practices are expected to volunteer to participate.

Pathfinder Support

13. As well as the core public facing communication materials (see below) the programme is developing a number of support tools for pathfinder practices including:
 - i) A comprehensive Practice Toolkit to support GPs, clinicians, practice managers and front line staff in pathfinder practices. This has been co-produced with NHS England Regional Heads of Intelligence and pathfinder CCGs and will be shared with GPs and Patient Participation Groups/Patient Reference Groups post-election. It will be available as an interactive resource and will support and enable practices to tailor their practice knowledge sessions appropriately.
 - ii) A Readiness Checklist for practices to use to self-assess their readiness to begin fair processing and for data extraction to take place. This will prompt practices to ensure that a) relevant processes are in place; b) that relevant guidance has been made available and is understood; and c) that necessary learning has taken place.
14. The care.data programme has also been working with national and local Healthwatch, patient groups, charities, voluntary sector organisations, and other groups to help inform the pathfinder stage. A community engagement toolkit has been designed with voluntary sector organisations and is aimed at local and national community organisations such as patient groups. This toolkit includes briefing materials and information to support responses to questions from networks and members.

Communication Materials

15. Pathfinder CCGs have been developing local project and delivery plans together with communication approaches to be implemented during the pathfinder stage. There have been a series of CCG led meetings with representatives from the CCGs, GP practices, and wider local

community groups (e.g. Healthwatch, Health & Wellbeing boards, councils, patient participation groups). Local media activity has been ongoing and Local Medical Committee (LMC) and locality engagement has taken place in order to support local awareness raising and to secure local buy-in.

16. A set of core patient-facing materials has been finalised (subject to one outstanding point being considered by the National Data Guardian and the Chief Medical Officer). The materials were developed taking into account the combined feedback gleaned throughout the care.data 'listening period', such as from local and national events/meetings about the care.data programme and formal research (conducted by Ipsos MORI) with both members of the public and GPs/GP practice managers. The programme has also completed a period of co-production to further develop these materials with key stakeholders. A central editorial review panel was established to consider all feedback received both nationally and locally on the communication materials.
17. The materials include:
 - i. Patient Letter;
 - ii. Opt out form (to be included with the letter);
 - iii. Introductory booklet (to be included with the letter but also available in practices);
 - iv. Poster;
 - v. Patient FAQs and
 - vi. GP toolkit including FAQs

Data Access and Analysis

18. During the pathfinder stage, access to the information collected from GP practices will only be available through a Secure Data Facility at the Health & Social Care Information Centre (HSCIC) offices in Leeds and will only be accessed by approved analysts from the HSCIC, NHS England, Public Health England and the Care Quality Commission. Consideration will be given as to how and when access should be extended to wider range of organisations as part of the evaluation of the pathfinder stage.
19. After the pathfinder stage we will carry out a consultation on plans to increase the scope of the GP dataset. Views will be sought on the benefits of increasing the scope of the dataset, for example to extend it to cover the following:
 - Collecting information that is more than four months old.
 - Collecting additional medical conditions/interventions.
 - Linking the data to other datasets.

Approvals and Evaluation

20. On 24 March 2015 a paper was approved at the care.data Programme Board, which outlines the full assurance, approvals and evaluation process. In terms of future approvals and evaluation there are two milestones:
 - i. Approval to commence extraction from pathfinders
 - ii. Approval to proceed beyond the pathfinder stage
21. The 'Approval to Commence Extraction from Pathfinders' will be informed by advice provided by the National Data Guardian, (Dame Fiona Caldicott) to the Secretary of State following her assessment of the programme proposals and safeguards in place to extract data. If the National Data Guardian's advice is favourable confirmation will be sought from NHS England to

confirm that it is content that all necessary obligations have been met to support the programme to proceed with extraction as Joint Data Controller with HSCIC.

22. The 'Approval to Proceed Beyond the Pathfinder Stage' will be informed by a full programme led evaluation of the pathfinder stage, and resulting report which will be prepared by the programme team, with input from colleagues across the pathfinder areas. The report will assess whether the success criteria for the pathfinder stage has been met, and will help to shape the approach to wider rollout beyond the pathfinder stage. A proposed approach to the evaluation, along with a proposed report structure, timeframe and approvals process is in development. The report will include any advice given by the National Data Guardian during the pathfinder stage and findings of formal research with patients and professionals, which will be conducted by Ipsos MORI.

Timescales

23. The intention is for the programme to start communicating with GP practices in May 2015. Pathfinder practices in Blackburn with Darwen CCG will begin communicating with their patients in late June 2015 with the extraction of data in early autumn. This is subject to final agreement with the pathfinder this week. The remaining CCGs are expected to follow with communications slightly later with an evaluation in the winter. Further rollout of the programme is dependent on the evaluation of the pathfinder stage.

Next steps after the pathfinder stage

24. The programme is considering next steps after the pathfinder stage including preparing for national rollout, expanding the GP dataset and increasing the organisations that can have access to the data.
25. As outlined in the background section, consideration needs to be given to how we ensure that the valuable lessons learnt from the care.data programme are applied to other areas of work and inform future strategy.
26. A number of different programmes are approaching the care.data programme team to understand the plans for informing members of the public about the programme and how GP practices have been supported with fair processing. This includes for example, the Integrated Care Pioneer Programme.
27. The cost of each data sharing initiative across the country writing to every patient would be exorbitant therefore consideration should be given to adopting a strategic approach to supporting GP practices with fair processing. The costs of a patient mailing together with public facing publicity materials would be £18 million. However as the communications do not mention the care.data programme they can be used to support fair processing for a range of local and national data sharing programmes.
28. Without delivering direct communications to patients the fair processing obligations of the Data Protection Act 1998 may not be met, which could result in a challenge to the legality of the extraction as people may not have been fully and appropriately informed about the introduction in the way that we have been advised to do so by the Information Commissioner. In addition, a centrally funded direct communication will be fundamental to retaining the support of key stakeholders such as the British Medical Association, Royal College of General Practitioners, Healthwatch England and local GP practices.

29. The programme has also heard views from stakeholders and members of the public about consent issues for example, delivering more granularity of patient choice and a two-tier model with implied consent for sharing data within the NHS and explicit consent for sharing with organisations outside of the NHS. The care.data pathfinder stage could inform the National Information Board (NIB) work in this area and be viewed as a pathfinder for consent policy. Joining up the lessons learnt in the pathfinder stage with the wider digital agenda could also present an exciting opportunity to explore patient ownership and consent models further.

Programme Governance

Business Case

30. It is anticipated that the Programme Business Case will be submitted to Cabinet Office and HM Treasury for approval along with the Outline Business Case for Phase 1 of the programme (the national rollout of the GP dataset and linkage with existing national datasets) after the General Election. The Programme Business Case has received the following endorsements and approvals to date:
- i. Endorsed by the care.data programme board on 14 January 2015
 - ii. Approved in terms of strategic fit, scope, ambition and agreement to commence development of the Outline Business Case (OBC) for Phase 1 of the programme by the Informatics Portfolio Management Board (IPMB) on 26 February 2015
31. The development of the OBC for Phase 1 of the programme has now commenced. This will include a wide stakeholder consultation on the approach to national collection, along with detailed costings, funding and affordability statements, and quantified benefits.

Programme Assurance Review

32. From 29 April – 1 May 2014 a Project Validation Review (PVR) took place for the care.data programme followed by a Programme Assurance Review (PAR) in February 2015. The PAR assessed the programme status as red/amber which was an improvement from the Project Validation Review which rated the programme as red.
33. This reflected the significant amount of progress made by the programme team. In particular, the strong direction and leadership of the SRO and the tightening in rigour of the overall Programme were noted. Progress on the development of the Programme Business Case (PBC) and the pathfinder stage of the programme was also welcomed. However, the programme still has significant issues to overcome to ensure successful delivery, hence the rating of red/amber. An action plan has been developed to address recommendations from the PAR.

Advisory Group

34. An Advisory Group for the care.data programme of work was established in March 2014 with the purpose of guiding the development of the care.data programme. The advisory group make recommendations to the care.data programme board. This independent group is chaired by Ciaran Devane, Chief Executive of British Council and NHS England Non-Executive Director.
35. The Advisory Group, expertly led by Ciaran, has provided invaluable constructive challenge, which has helped shape the pathfinder stage and the programme more generally. The group

continues to engage and is expected to play an important role in shaping and supporting the approach beyond pathfinders.

Risks

36. The care.data programme has a detailed risk register. It is important that the programme retains pace following the election particularly in the pathfinder areas where there has been a significant amount of time and resource invested.
37. Whilst all political parties are supportive of data sharing to improve health outcomes, some politicians in the newly formed government may be anxious about pressing ahead, which may impact upon momentum at a critical time.

Recommendation

38. The Board is invited to:
 - note the current status of the programme
 - consider next steps, particularly in relation to how lessons learnt from the care.data programme pathfinder stage can inform future strategy on broader areas such as patient ownership of data; patient consent models and supporting GPs with fair processing.

Tim Kelsey, National Director for Patients and Information and care.data Senior Responsible Owner

THE CARE.DATA LISTENING EXERCISE & ACTION PLAN

December 2014 Version 1 Final

IF WE CAN SEE WHAT'S HAPPENING, WE CAN MAKE THINGS BETTER

Contents

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- Using linked data – a case study
- Listening events
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What is care.data?

- care.data is the plan to join up patient information to improve health outcomes for all
- By joining up GP information with hospital information we will be able to:
 - Map diseases more quickly
 - Understand patients' journeys through the health system
 - See the outcomes of their treatments and address variations in care across the country
 - Improve the quality of care by monitoring adherence to national treatment guidelines
 - Plan where investment and changes are needed in NHS services
 - If you decide to opt out it won't affect the care and treatment you receive however, if significant amounts of people do opt out, we won't be able to collect enough information to help us improve NHS services across the nation.

Using linked data to improve patient care

This example shows how linked information can be used to improve patient care.

This type of analysis can be done locally but care.data would enable this kind of research to be done nationally and much more routinely.

Colorectal cancer is the third most common cancer and a major cause of mortality. Early diagnosis improves survival rates to 93%, versus 6% for those diagnosed late.

25% of colorectal cancer cases are diagnosed during emergency admissions via A&E.

In a project in North East London, GP information linked to hospital information is being used to examine variations in routes to diagnosis among patients with colorectal cancer. The project is exploring existing diagnostic pathways and aims to identify those pathways that give the best outcomes for patients, including the fewest avoidable healthcare episodes.

In this scenario, care.data would guide national development and implementation of care pathways, and support patients and clinicians in making shared, informed decisions about treatment options.

care.data listening events

- NHS England agreed to listen to and work with professionals and patients to get their feedback and reconsider how to implement care.data.
- Over 180 listening events and meetings were held across the country.
- Engagement involved GPs, practice managers, patient groups, other health professionals, patients and data experts.
- More than 3000 people shared comments and concerns.
- A care.data advisory group was set up, chaired by Ciaran Devane, chief executive of Macmillan Cancer Support and a non-executive director of NHS England and includes health and data security experts.
- Our listening is ongoing

You told us your concerns:



Who will have access to information and how will information be used?



Possible risks of disclosure of medical records.



Confusion about how this differs from other NHS information collection.



What about the communications with patients on their right to opt out?



Lack of clarity on the benefits of care.data



What about support for GPs to inform patient's about care.data?

What we have done

Established pathfinders - we are now working with a small number of GP practices to ensure we get this absolutely right. We are:

- working with CCGs in four areas (Leeds North, Leeds West and Leeds South and East, Somerset, West Hampshire, and Blackburn with Darwen), which represent around 265 GP practices and 2m patients.
- developing communication materials and approaches with GPs and patients to explain care.data.
- planning to send a letter to every patient in each pathfinder GP practice, explaining care.data and their right to opt-out.
- testing other methods - such as email and texts.
- The pathfinder stage will be scrutinised by the Independent Information Governance Oversight Panel, chaired by Dame Fiona Caldicott.
- There will be a full evaluation before deciding to roll-out care.data nationally.


You said: present the benefits




Support programme and understand need for big data




Want clear examples how care.data will specifically benefit patients and public health




More work needs to be done to show benefits



Why can't claimed benefits be gained without care.data?



Confusion between Summary Care Record and care.data




Show examples how big data has or will improve the quality of healthcare


Response: the benefits case

- We have developed a range of case studies to illustrate the expected benefits of care.data.
- These include:
 - Medical research and outcomes of treatments
 - Improving services and planning
 - Benchmarking care provision, treatments and outcomes across the country
 - Improving the NHS ability to predict and plan for demand
 - Analysis of treatment pathways
 - Quality assurance.
- Communications with patients will explain clearly the difference between care.data and Summary Care Records, which are used to improve patients' direct care.



You said: keep information safe





NHS has poor track record on data security





Why can't you remove any risk of identification?




Why do we need full postcode, date of birth, NHS number?



Need strong administrative controls and assurance



Health & Social Care Information Centre (HSCIC) must be a secure repository

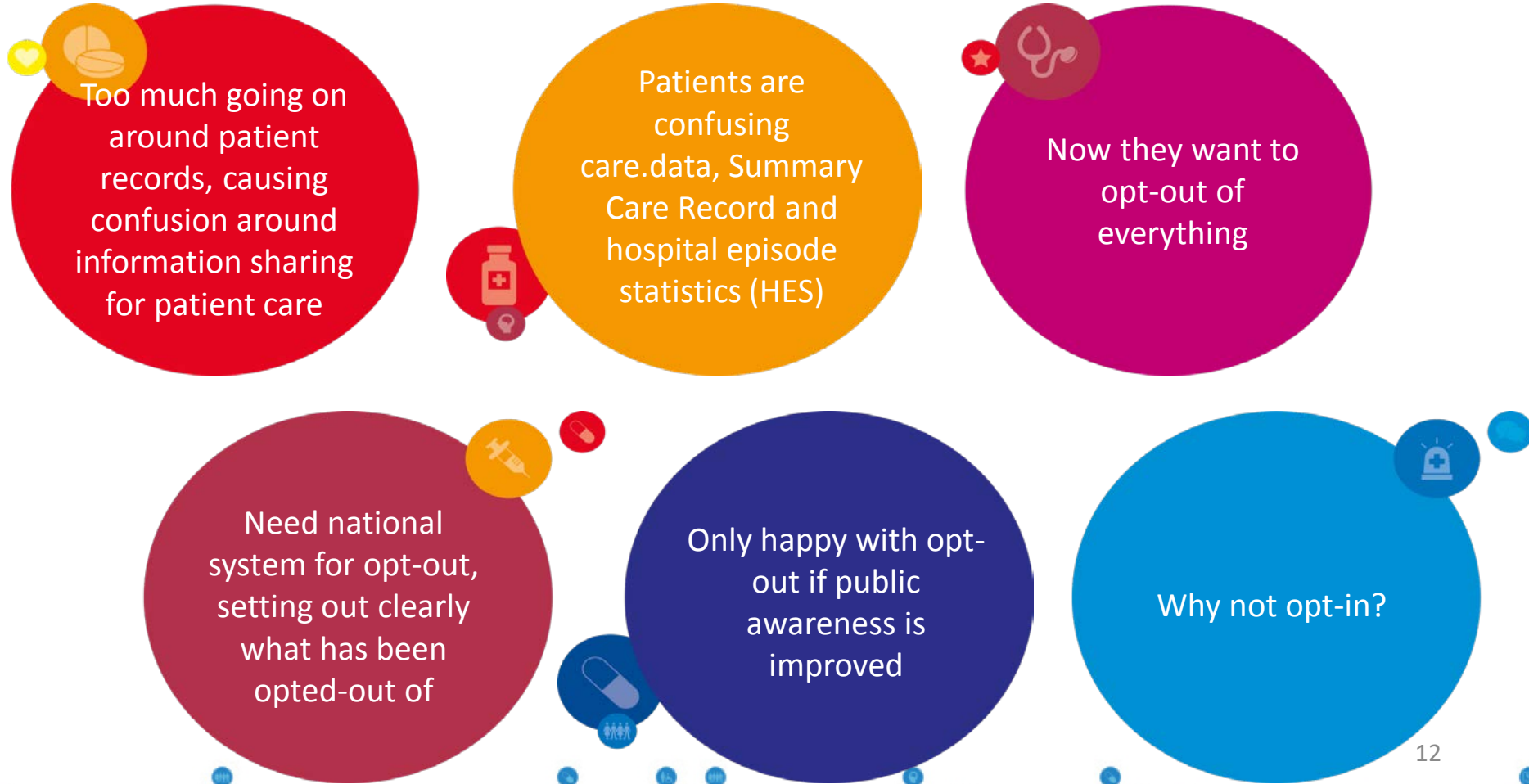


HSCIC must be transparent on who uses the data

Response: protecting privacy

- The rules around how information will be shared by the NHS's Health and Social Care Information Centre (HSCIC) will be clearly stated before coded information is collected from pathfinder GP practices.
- The HSCIC will implement these rules before any of the collected information is made available to any organisations outside the HSCIC.
- NHS numbers, dates of birth, postcode and gender are needed to link information to hospital information.
- As a patient's coded information from their GP reaches the HSCIC and is linked with hospital information, information that could identify them, like their NHS number, will be automatically replaced with a reference number.
- During the pathfinder stage of care.data, access to the information collected will only be given to a limited number of approved analysts who will have to travel to a new secure data facility that the HSCIC is setting up.
- The HSCIC will publish details on who is given access to the information and why.

You said: explain the opt-out clearly



Response: opt-out approach

- An opt-in approach won't provide the universal information needed to achieve health benefits and it would exclude more of those who most need health and care services, worsening health inequalities.
- We are committed to an opt-out approach and to raising patients' awareness of:
 - Our care.data vision
 - The reasons for the opt-out approach
 - How they can (easily) opt-out if they want.
- The Department of Health is commissioning work on how people's preferences for sharing information should be handled more broadly across the whole health and care system.
- We are testing communications messages during the pathfinder stage so that we can better understand how to take this forward.
- You can opt out at any time. Just talk to your GP Practice.

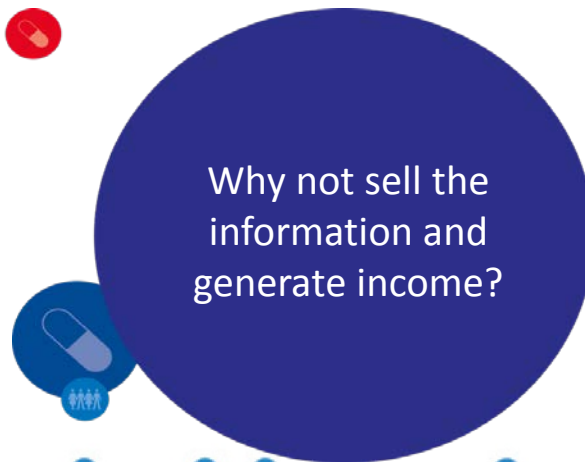
You said: improve legal protection




Response: legislative changes

- Law changed so information can only be shared if there is a clear purpose to provide health care, adult social care or to promote health.
- This clarifies that information may be made available for a wide range of health and care related purposes including for:
 - Commissioning health and care services
 - Public health
 - Research relating to health and care provision, for example, the epidemiological research that is needed at the earlier stages of developing new treatments.
- The law prohibits information sharing for solely commercial purposes, such as marketing.
- Further secondary legislation will specify the factors that will govern decisions to share information and the controls on the release of information.



You said: restrict access to data



Response: access safeguards

- The Confidentiality Advisory Group will be placed on a statutory footing and have a future role in advising HSCIC on their publication or dissemination of information.
- The Independent Information Governance Oversight Panel (IIGOP), chaired by Dame Fiona Caldicott, has scrutinised care.data and will evaluate the pathfinder stage.
- Dame Fiona Caldicott has been appointed National Data Guardian for health and care, where she will become the “the patients’ champion on security of personal medical information”.
- We are committed to transparency and laying a clear audit trail on who is granted access to the information, for what purpose and to what outcome.
- The HSCIC will not sell the information. It will only charge a fee to cover its costs and will not profit from providing information to other organisations.
- An applicant’s track record in handling confidential information will influence our decisions to share information with them.



You said: more support for GPs





Any mention of GP
information
controller role
creates conflict





Provide free toolkit
to GP practices




Greater burden on
staff, asking them
to do something
they don't have
capacity to do



Be clear about role
of GPs in care.data
and NHS
expectations



Some GPs feel the
scheme conflicts
with their ethical
stance




NHS England
should fund all
extra work


Response: building GP support

- We will test all communication materials with patients during the pathfinder stage to understand what methods work best with different population groups.
- We are already working with CCGs, local patient groups including Healthwatch organisations and GP practices to co-produce materials to ensure each patient makes an informed decision about the future of their information.
- We will also use the pathfinder stage to assess the burden on GPs and practices, including:
 - The provision of information to patients for fair processing
 - The management of the opt out process
 - The management of the data transfer process.


You said: inform patients properly




GPs not happy with information controller duty to communicate with patients



Communications with patients on care.data should not be GP job




Be clear about purposes, risks and benefits in honest language




National initiative, so NHS England should liaise with patients



Test materials with clinicians and other groups



Want guidance from Information Commissioner on information protection duties



Materials in easy read and accessible formats

Response: talking to patients

- We are working with CCGs, local Healthwatch organisations and GP practices to co-produce the public facing communication materials.
- Dame Fiona Caldicott's Independent Information Governance Oversight Panel (IIGOP) has agreed to advise us on implementing the first stage of the programme.
- We are working with Mencap and other charities to ensure we produce accessible materials alongside the mainstream materials so that as many people as possible understand our plans for information sharing.
- We are working with research agency Ipsos MORI to get feedback from the public on our communications materials.
- We are working with the Information Commissioner's Office (ICO) to develop guidance for practices to be tested in the pathfinder stage.

care.data : addressing risks

- As a patient's coded information is matched with hospital records as it arrives with the HSCIC, the information that could identify a patient will be removed and a reference number will be allocated instead. This is called pseudonymisation.
- It could be possible to track back to individuals in some cases using other information held for another valid reason (where you received treatment at hospital).
- The HSCIC is minimising these risks with its secure data area and applying strict rules about who can access the information and for what purposes.
- Information collected during the pathfinder stage will go to the HSCIC, will be linked to hospital information and be kept securely by the HSCIC.
- The HSCIC is responsible for the security of personal information and has secure systems in place for storing and processing information that are fully compliant with the latest UK and European standards.

care.data : next steps

- The pathfinder stage will inform the next stage of care.data including:
 - Testing communications with patients
 - Testing the collection and joining up of coded information from GPs with hospital information.
- The next stage of care.data will be informed by a full evaluation of the pathfinder stage and will only go ahead when we are confident it is right.
- We will continue our work with Ipsos MORI, the care.data advisory group, and engagement events to ensure we listen to feedback.
- NHS England is committed to consulting publicly and widely on future options.
- Future options include:
 - Expanding the set of information codes collected from GPs to cover more conditions and over a longer time period
 - Expanding the sources of information to include other health and social care settings, not just GPs and hospitals.

THANK YOU

We welcome your feedback on the care.data programme and this presentation, so please share your comments with us.

For more information on NHS England or Health and Social Care Information Centre support or speakers about the care.data programme, email:

Care.data@nhs.net

Or look online:

<http://www.england.nhs.uk/ourwork/tsd/care-data/>

<http://www.hscic.gov.uk/gpes/caredata>

