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To all Members of the Health and Social Care Scrutiny Board (5)

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Date: 26th March, 2014

Our ref: C/EMK

Dear Member,

Supplementary Agenda – Meeting of the Health and Social Care Scrutiny Board (5) - Wednesday, 2nd April, 2014

The purpose of this letter is to provide you with some additional information for an item already on the agenda for the above meeting.

5. Local Care Data Programme (Pages 3 - 24)

The officers will report at the meeting

Richard Hancox, Associate Director, Clinical Strategy at Arden, Hereford and Worcestershire Area Team has been invited to the meeting for the consideration of this item.

If you have any queries, please do not hesitate to contact me on the telephone number shown above.

Yours sincerely

Liz Knight
Governance Services Officer



INVESTOR IN PEOPLE

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Coventry City Council

Briefing note

To: Health and Social Care Scrutiny Board (5)

Date: 2nd April 2014.

Subject: 'Care Data' – NHS England Plan to Share Patient Data

1 Purpose of the Note

- 1.1 NHS England has been developing a plan to share patient data with a view to making improvements in the quality of patient care. This introduction of this proposal - 'Care Data', has recently paused to allow further time for information to be shared and to create more public support. NHS England will be attending the meeting to discuss the matter.

2 Recommendations

- 2.1 To note this briefing note, and to consider providing NHS England with appropriate feedback following the meeting.

3 Information/Background

- 3.1 Members will note the attached information leaflet prepared by NHS England (Appendix 1) which outlines the perceived benefits of the NHS sharing patient data to help improve patient care and health outcomes.
- 3.2 The proposals are to share date of birth, postcode, NHS number and gender along with certain care records with the intention being that the new care record does not allow identification of individuals, with the sharing of this being controlled by both law and strict confidentiality rules. Information would be held by the Health and Social Care Information Centre.
- 3.3 The proposed benefits of sharing this anatomised data have been contrasted with the potential impact on privacy. A number of patient groups have raised concerns about people with more unusual conditions being identified by the data, and for the potential for this to be used in a potentially detrimental way by private sector companies for example insurance providers. Other concerns relate to the safety of data and who would be able to hold it.
- 3.4 In response to this the Health Secretary announced on February 25th that he was introducing a six month pause in the implementation of Care Data, with the intention being that there would be more publicity regarding the case for sharing the data and the safeguards which would be in place. GPs have been urged to encourage patients to support this proposal and there has also been discussion of a patient opt-in policy. This would however fall some considerable way short of the Governments original vision.
- 3.5 Frequently Asked Questions sheets for both GPs and patients are attached as Appendices 2 and 3.
- 3.6 The Scrutiny Board meeting will be attended by Richard Hancox Assistant Director – Clinical Strategy at the NHS England Arden, Herefordshire and Worcestershire Area Team.

Briefing Note Author:

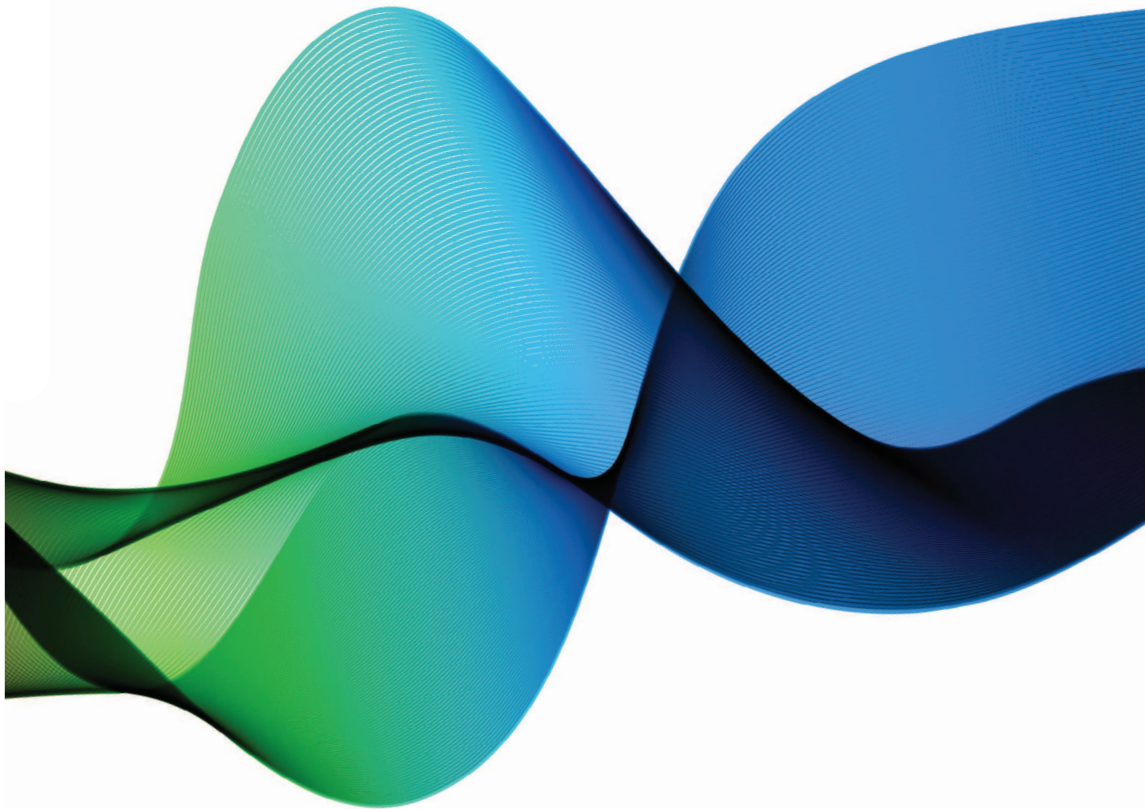
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Better information means better care



**This leaflet contains important information
about your health records.**

You, and everyone who lives with you, should read this leaflet carefully. It is important that everyone knows how we share, protect and use information about their health.

You have a choice.

Introduction

We want to improve the quality of care and health services for all. By using information about the care you have received, those involved in providing care and health services can see how well they are doing, and where improvements need to be made.

NHS organisations share information about the care you receive with those who plan health and social care services, as well as with approved researchers and organisations outside the NHS, if this will benefit patient care. As a patient, you may receive care and treatment from a number of places such as your GP practice, hospitals and community services. By bringing this information together from

all the different places, we can compare the care provided in one area with the care provided in another, so we can see what worked best.

We will use information such as your postcode and NHS number to link your records from these different places. Records are linked in a secure system so your identity is protected. Details that could identify you will be removed before your information is made available to others, such as those planning NHS services and approved researchers.

We sometimes release confidential information to approved researchers, if this is allowed by law and meets the strict rules that are in place to protect your privacy.

What are the **benefits** of sharing my information?

Sharing information about the care you have received helps us understand the health needs of everyone and the quality of the treatment and care provided.

It also helps researchers by supporting studies that identify patterns in diseases, responses to different treatments, and the effectiveness of different services.

Your choice will not affect the care you receive.

Information will also **help** us to:

- find more effective ways of preventing, treating and managing illnesses
 - make sure that any changes or improvements to services reflect the needs of local patients
 - understand who is most at risk of particular diseases and conditions, so those who plan care can provide preventative services
 - improve your understanding of the outcomes of care, giving you greater confidence in health and social care services
 - guide decisions about how to manage NHS resources so that they can best support the treatment and care of all patients
 - identify who could be at risk of a condition or would benefit from a particular treatment
 - make sure that NHS organisations receive the correct payments for the services they provide.
-

What will we do with the **information**?

We will only use the minimum information needed to improve patient care and services.

We are very careful with the information and we follow strict rules about how it is stored and used, and have a thorough process that must

be followed before any information can be shared.

When we share information we will make sure we do so in line with the law, national guidance and best practice.

Information that we publish will never identify a particular person.

What **choice** do I have?

We have explained how useful information about you is, and the steps that we take to protect your privacy. However, you may want to prevent confidential information

about you from being shared or used for any purpose other than providing your care (except in special circumstances allowed by law, such as when there is a public-health emergency).



continued

If you do not want information that identifies you to be shared outside your GP practice, please ask the practice to make a note of this in your medical record. This note will prevent your confidential information from being used other than in special circumstances.

Information from other places where you receive care, such as hospitals and community services, is collected nationally. You should also let your GP practice know if you want to

prevent the information from those places being shared.

The practice will make a separate note of this in your medical record.

You may have already asked for information about you not to be shared with others, such as your medical record being shared for your care. You still need to let your GP practice know if you have concerns about your information being shared for the purposes described in this leaflet.

Do I need to **do anything?**

If you are happy for your information to be shared you do not need to do anything. There is no form to fill in and nothing to sign. And you can change your mind at any time.

If you have any questions or are not happy for information about you to be shared, speak to your GP practice.

Where can I get **more information?**



Visit the NHS Choices website at:

www.nhs.uk/caredata

for more information, a list of common questions, or another format of this leaflet.



Speak to staff at your GP practice.



Call our dedicated patient information line on:

0300 456 3531

This line also offers translation and text phone services.

More details about how we look after confidential information and how it may be used can be found on the website at:

www.hscic.gov.uk/patientconf

FREQUENTLY ASKED QUESTIONS – CARE.DATA GUIDE FOR GP PRACTICES

JANUARY 2014

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Understanding key terms

1. What is the Health and Social Care Information Centre?

The **Health and Social Care Information Centre (HSCIC)** is England's central, authoritative source of health and social care information. The Health and Social Care Act 2012 empowered the HSCIC to require providers of NHS care to send it confidential data in limited circumstances i.e. when directed to do so by the Secretary of State for Health, NHS England or when receiving a mandatory request from the Care Quality Commission (CQC), NICE or Monitor.

The role of the HSCIC is to ensure that high quality information is used appropriately to improve patient care. The HSCIC is the guardian of nationally collected information. It publishes key statistics and shares information to support important research and commissioning. Its predecessor the NHS Information Centre had been carrying out that activity for some time.

The HSCIC is committed, and legally bound, to the very highest standards of privacy and confidentiality to ensure that confidential information is protected at all times. The HSCIC processes confidential data in a secure environment and can only release personal confidential data where there is a legal basis to do so.

2. What is care.data?

The NHS has some of the best information systems in the world. Since the 1980s, we have been collecting information about every hospital admission, nationwide. This information is brought together at the Health and Social Care Information Centre, where it is anonymised (see FAQ 15). The information has been invaluable for monitoring the quality of hospital care, for planning NHS services, and for conducting research into new treatments. However, the information collected is incomplete, with areas such as prescribing and test results not currently included. Additionally, while we have this type of information already for some care provided outside hospitals, there are significant gaps and as a result, it is not currently possible to see a complete picture of the care that individuals receive.

NHS England has therefore commissioned a programme on behalf of the NHS, public health and social care services to address these gaps. Known as the care.data programme, this initiative has been designed to ensure that there is more rounded information available to citizens, patients, clinicians, researchers and the people that plan health and care services. Our aim is to ensure that the best possible evidence is available to improve the quality of care for all.

3. What is the General Practice Extraction Service (GPES)?

GPES is the national primary care data extraction service managed by the HSCIC. GPES is capable of obtaining information from all GP practices in England for specific and approved purposes. GPES is the tool used by the HSCIC to extract data and therefore will be the default system by which GPs disclose data to the HSCIC for care.data. GPs can choose to use another system provided it is acceptable to the HSCIC.

4. What is Personal Confidential Data (PCD)?

This term describes personal information about identifiable individuals who are owed a duty of confidentiality i.e. the information was given 'in confidence' and should be kept private or secret unless there is a legal basis or overriding public interest for disclosure. It includes information about deceased as well as living individuals.

The data to be extracted

5. What data will GP practices be required to provide for care.data?

The data to be extracted from GP systems for care.data includes information such as family history, vaccinations, diagnoses, referrals, biological values (such as blood pressure, BMI and cholesterol with QOF exceptions codes) and all NHS prescriptions. Identifiers (DOB, postcode, NHS number and gender) are required to link the GP data with PCD from other care settings in order to analyse patient care across pathways. Free text will not be included in the care.data extract.

A full list of the data to be extracted is available in the **care.data GP extract – technical specification** document. The dataset has been considered by a clinical informatics expert group, which included representatives from the British Medical Association (BMA) and the Royal College of General Practitioners (RCGP). Any future changes to the dataset or to scope will be subject to review by the group and GP practices will be informed of any alterations. In addition, the GPES Independent Advisory Group (IAG) has recommended that the requirement should proceed to extraction. Further information on the IAG, including its membership, is available on the **HSCIC website**.

6. Will data from the records of deceased patients be extracted for care.data?

Once the status of a record is changed to 'deceased', no further data will be extracted.

The HSCIC will continue to process data that have been extracted prior to the status of the record being changed to deceased.

Raising awareness

7. What do I need to do to ensure patients know about care.data and have the chance to object before their data are extracted?

As data controllers, GPs have *fair processing* responsibilities under the Data Protection Act 1998. In practice, this responsibility means ensuring that a person's personal data are handled in ways that are transparent and that they would reasonably expect. It is important that patients are aware that the HSCIC has powers to extract personal confidential data and that they understand what they need to do if they wish to object. NHS England has provided guidance for GP practices on these fair processing responsibilities, which is available [here](#).

GP practices should also have received posters and leaflets about information sharing. It is important that GPs continue to communicate actively to patients and that these materials are easily accessible. Other routine communications to patients can also be used to raise awareness (e.g. by providing the leaflet with repeat prescriptions, including information in mailings for screening programmes or sending copies out with routine practice communications to patients). Practices should ensure they use the materials provided to them to ensure consistency of messages. These may be supplemented with other materials providing they only convey the same messages.

GPs should ensure that practice staff are aware of these materials because staff should be able to respond to queries from patients and direct them to the patient FAQs or the leaflet for further information. Again, this is important in terms of meeting fair processing responsibilities under the Data Protection Act 1998 (DPA).

8. Where can I get extra copies of leaflets and materials from?

Visit <http://www.england.nhs.uk/ourwork/tsd/care-data/> where you can order extra copies to be delivered to your practices directly. You can also download a pdf of the leaflet to put on your practice website.

9. What other awareness raising activities are taking place to ensure patients are aware?

Additional awareness-raising is taking place, led by NHS England and the HSCIC.

At a national level, awareness raising includes:

- A patient leaflet about information sharing sent to every household in England during January 2014
- A dedicated patient information line, which will be available from 6th January until 31st March 2014 to respond to questions from patients. Please note that the patient line will not be able to record objections
- Resources and guidance that we have developed nationally including patient materials and FAQs
- If required, arrangements for GPs to receive additional materials including Braille and easy read and audio versions
- Social media activities
- Digital media. For example, there are dedicated patient support pages on the NHS Choices website, including a lead article on the front page that signposts citizens to information (<http://www.nhs.uk/NHSEngland/thenhs/records/healthrecords/Pages/care-data.aspx>). The site receives over 20 million hits a month. There are also dedicated pages on the HSCIC website (<http://www.hscic.gov.uk/patientconf>)
- Discussion with national patient groups, charity and voluntary sector organisations to enable cascade of messages through their regular and social media channels
- Information about care.data provided to 350,000 charities and voluntary groups who have been asked to cascade the information to their members
- National media coverage for example articles in the Observer, the Guardian, and the Independent and radio interviews

Regional awareness raising

- Extensive regional media coverage with over 100 articles on regional news websites
- Proactive focus on specialist regional events aimed at area teams, CCGs and others who helped provide local support to practices
- Additional awareness raising with the public through regional communications teams

10. How long do patients have to read the leaflet sent to households?

Patients will have a minimum of four weeks from the time they received the leaflet to register any objections before the first extract begins. The first extraction is planned for spring 2014. Patients can, however, object at any time after this time (see FAQ 21 and 25) and it is important to remember that awareness raising began in September 2013.

We have discussed this timetable with the Information Commissioner's Office, which has agreed that this is an appropriate timescale.

11. How will patients who live in Wales or Scotland but are receiving care in England be informed about information sharing?

Patients who live in Scotland or Wales but receive care through the English NHS will have their data included in the extractions. These patients have the same right to object as those patients who are resident in England. The same guidelines apply in making these patients aware as all patients in the practice. In addition, we are currently exploring how best we can provide the same leaflet to these patients as we are sending to every household in England.

The extraction and linkage process

12. When will the data extract begin?

The extraction is scheduled to begin in spring 2014. You will be notified by your system supplier in advance of the exact date for your extraction.

All staff in your practice authorised to use GPES must have completed the online training package before running the extraction. Details of the training are available at: <http://www.hscic.gov.uk/gpestraining>

13. I understand that GPs can view the data extract before it is sent to the HSCIC – how long will we have to view the proposed extract?

GPs will be able to view the extract before it is sent to the HSCIC. Discussions are taking place to determine how long GPs will be given for this process and an update will be provided before the request for the extract.

14. Can practices opt out of care.data extractions?

No. The HSCIC has been directed by NHS England under the **Health and Social Care Act 2012** to make this collection. These Directions give the HSCIC the power to require the information and GPs are legally obliged to comply with that requirement. However, if a GP practice does not wish to provide this data extract through GPES, they should contact the HSCIC to agree an alternative method of providing the required data that is acceptable to the HSCIC.

15. How will PCD be linked in the HSCIC?

The information collected nationally by the HSCIC is from different care settings and care providers. As a result, the quality of that information varies and it does not always include the NHS number. The HSCIC has developed a way of matching records that takes into account this variability. The information used for matching includes the NHS number, postcode, gender and date of birth. Once a patient's record has been matched, the information that could identify a patient is removed and a reference number for the record is allocated instead.

16. We are having technical difficulties with our N3 connection, can we postpone the data extract until these are fixed?

You must contact the N3 technical team now to ensure that your practice is ready by the time the first extract takes place in spring 2014.

The Data Protection Act

17. How do these extractions comply with the Data Protection Act/GMC guidance?

The Health and Social Care Act 2012 creates a statutory obligation for GP practices to disclose information to the HSCIC in certain circumstances, for example to comply with a direction for PCD from NHS England. Where there is a rule of law that requires a person to provide information (as the direction under the Health and Social Care Act 2012 does), data controllers do not have discretion as to whether or not to comply with that requirement (section 35(1) of the DPA).

Although the duty to disclose is a legal requirement, GPs have collected the data and as data controllers retain some responsibilities under the DPA; most relevant for the extraction of primary care data is the need to comply with the fair processing requirements. This means you need to inform patients of the data you are required to

share with the HSCIC and you should also provide details of how patients can raise objections (i.e. by speaking to practice staff and having the objection recorded on their medical record). See FAQ 21 and 25.

Guidance on confidentiality from the GMC is clear and confirms that doctors must disclose information to satisfy a statutory requirement. GPs will not be in breach of GMC guidance for disclosing PCD in this case. They will be in breach of the statutory requirement if they don't disclose PCD.

18. Is the GP the data controller once the data has been disclosed to the HSCIC?

The GP remains the data controller for the data they hold but are not responsible for the data once it is disclosed to the HSCIC.

The ICO has advised that the HSCIC and NHS England become joint data controllers for the primary care data once data have been disclosed to the HSCIC. As data controllers, the HSCIC and NHS England will be obliged to comply with the Data Protection Act.

NHS England and the HSCIC are considered to be joint data controllers because NHS England will determine the purpose for the collection and the HSCIC will determine the manner of the processing. NHS England will not be processing personal confidential data; the HSCIC can only disseminate personal confidential data where permitted by law (see FAQ 43).

19. If the practice is the data controller why can't they prevent disclosure if they feel they are unable to fulfil their obligations under the Data Protection Act?

GPs as data controllers are required to fulfil their obligations under the DPA. GP practices have dual responsibilities; under the Health and Social Care Act there is a statutory obligation to disclose the data and under the DPA there is a statutory obligation to process personal data fairly. GP practices must meet both obligations.

20. If a patient complained that they were not aware their data had been extracted would the GP practice be fined under the Data Protection Act 1998?

As data controllers, GPs must meet fair processing obligations under the DPA. They must ensure that patients are aware of how personal confidential data about them are shared and their right to object. If a patient complained to the ICO that they were not aware that identifiable information had been extracted then the ICO would consider the extent to which the GP, as data controller, had made patients aware in order to meet their fair processing obligations of the DPA. The ICO has issued guidance, which states:

'As the organisation with primary responsibility for their patients' data, GP surgeries have an obligation to ensure that information about the use of their data is actively communicated to patients. They should satisfy themselves that the national and regional communications campaigns organised by NHS England, along with their proactive communication at a local level, ensures that, as far as practically possible, all patients are aware of these changes'.

Further guidance on fair processing is available at <http://www.england.nhs.uk/wp-content/uploads/2013/11/cd-fair-pro-guid.pdf>

Patient Objections

21. Can patients object to the disclosure of PCD from GP practices to the HSCIC?

Yes. As set out in the **NHS Constitution**, individuals have a right to object to the disclosure of personal confidential data about them and they have a right to have any reasonable objections respected. In addition, the Secretary of State for Health has given a commitment that in relation to data held in GP records, individuals' objections to disclosure to the HSCIC will be respected in all but exceptional circumstances (e.g. in the event of a civil emergency – see FAQ 23). A patient can inform their GP of their wishes to object and they do not need to give a reason for their objection. The right to object has been implemented as a constitutional rather than legal right.

22. What Read code do I need to use to stop the PCD of a patient who has objected from leaving the practice?

Where a patient objects to PCD leaving the GP practice for purposes beyond direct care, you should use the **'Dissent from secondary use of GP patient identifiable data'** code (Read v2: 9Nu0 or CTV3: XaZ89 or SNOMED CT 827241000000103).

23. Will recording an objection prevent all PCD for that patient from leaving the GP practice for purposes beyond direct care?

No, but the circumstances when an objection would be overridden are very rare and relate to specific legal requirements. See also FAQ 22 in relation to implementing the objection.

In relation to disclosures to and from the HSCIC, there may be exceptional circumstances, in accordance with the law, where patients' objections are overridden. There is a limited number of circumstances when the law requires disclosure of certain PCD, regardless of whether a patient has objected. An example of a legal requirement to disclose PCD is public health legislation, which is designed to control the spread of infectious diseases. A court order could also require disclosure of PCD.

In addition to the legal requirements to disclose PCD, doctors are permitted to make disclosures, without patient consent and even where a patient has objected, when it is in the public interest. For example, when the police are investigating a murder and may require information about an individual patient. These decisions are made on a case-by-case basis and must balance the duty of confidentiality owed to the patient and the broader public interest in a confidential health service versus the benefits that may arise from the disclosure.

Disclosures in the public interest are made where it is judged that the disclosure is essential to prevent a serious and imminent threat to public health or to national security, to protect individuals or society from serious harm, or to prevent or detect a serious crime.

These exceptions mean that it would be misleading to tell a patient that entering a code in their GP record will prevent all PCD leaving the GP practice.

24. Can patients prevent data from other healthcare settings flowing to the HSCIC?

Patients should talk to their care provider if they do not want information that identifies them being disclosed for purposes beyond their direct care. However, not all the systems we use in the NHS and in social care allow this. Currently, some information, which may identify a patient will flow to the HSCIC from hospitals and other places where patients receive care and treatment.

Patients can object to any data that identifies them from leaving the HSCIC secure environment for research and planning. They should let their GP practice know if they want to do this so that their objection can be recorded. In the future, it should be possible to stop information that identifies individuals from flowing to the HSCIC from wherever NHS care or treatment is received.

25. Can patients object to PCD leaving the HSCIC?

Yes. Where a patient objects to PCD leaving the HSCIC for purposes beyond direct care, the GP should enter the relevant code (see FAQ 26) into the GP record. This code will prevent PCD collected from any setting from leaving the HSCIC.

26. What Read code do I need to use to stop PCD leaving the HSCIC for a patient who has objected to this?

Where a patient wishes to prevent PCD gathered by the HSCIC from any health and social care setting from leaving the HSCIC for purposes other than direct care, you should use the **'Dissent from disclosure of personal confidential data by Health and Social Care Information Centre'** code (Read v2: 9Nu4 or CTV3: XaaVL or SNOMED CT 8815610 00000100).

27. Do I have to enter a reason for an objection?

No. GP practices should record patients' objections using the appropriate code as detailed in the [care.data guide for GP practices](#) and in FAQs 22 and 26. It is important that patients' wishes are respected both in terms of those who wish to object and those who wish for data to be used to benefit future healthcare. The BMA and NHS England will review data on the number of patient objections per practice.

28. Shouldn't patients opt-in to care.data?

The Health and Social Care Act 2012 empowers the HSCIC to require providers to send it personal confidential data when it is directed to do so. The Act also overrides the requirement under the common law duty of confidentiality to seek patient consent. This was because parliament recognised the importance of linking data to deliver high quality health and care services, for the benefit of all. The Secretary of State has, however, allowed patients to object and have this objection respected (see FAQ 21).

29. Why isn't there a form for patients to fill in?

GP practices are free to choose how they wish to work with their patients to capture their objections and can use a form if they wish.

However, practices must not use the Summary Care Record (SCR) 'opt out' form to capture this information as this is a dissent to sharing data for direct care rather than an objection to sharing data for uses beyond direct care. We are aware that some GP practices have given patients the SCR form and this is causing confusion with patients telephoning the wrong information line for assistance. The two programmes of work are different and GP practices should make this as clear as possible to their patients (see FAQ 37).

30. Shouldn't patients have a greater number of choices to allow them to object to specific uses of their GP data?

Ideally the BMA, RCGP, NHS England and the HSCIC would like patients to have more choices. However, we see the agreement for a patient to be able to object as an important first step. We hope that this arrangement will raise awareness amongst both healthcare professionals and patients about how personal confidential data are used for purposes other than direct care. Before introducing any additional options for patients, the BMA, RCGP, NHS England and the HSCIC will assess the impact upon GP practices, patients and the wider health service.

31. If a patient does not object does this mean that their personal confidential data will be freely available to researchers and commissioners?

No. The HSCIC will only ever disclose personal confidential data where there is a legal basis for doing so (e.g. where a patient has provided explicit consent or there is support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 (anecdotally 'section 251 support')).

32. If a patient objects to PCD from being shared by the HSCIC but there is approval under Regulation 5 (anecdotally known as section 251 approval), what would happen?

It is a standard condition of support under these Regulations that patient objections be respected. Therefore, if a patient has objected to their PCD being shared by the HSCIC, then the standard conditions of support under Regulation 5 would require that objection to be upheld.

Decisions to override a recorded objection would only be made in the most exceptional circumstances (e.g. serious public safety concerns).

33. Will the HSCIC and NHS England be monitoring the number of patient objections?

Yes. Once the data extracts begin, NHS England and the HSCIC will work with the BMA and the RCGP to monitor objection rates for each practice to ensure that objections are being implemented fairly.

34. Why can't patients object to anonymised data flows?

Data which are anonymised are not considered to be personal data for the terms of the DPA. Such data are not subject to a duty of confidentiality because they do not allow the individual to be identified.

35. What is the guidance for patients who have no capacity to make decisions for themselves, can carers decide on their behalf?

An individual with a Lasting Power of Attorney for health and welfare can object on behalf of a patient who lacks capacity. If a carer or relative who does not hold a Lasting Power of Attorney raises specific concerns with you, then you should make a decision based on an assessment of the patient's best interests, taking into account the views of the carer/relative.

36. Can a parent/guardian of a child make the decision on their behalf?

Where a child lacks competence an individual with parental responsibility may make a decision on behalf of the child. If the child is competent then they should make the decision.

The Summary Care Record

37. How does care.data relate to the Summary Care Record?

We are aware that there has been some confusion about the Summary Care Record (SCR) and the primary care data extract for care.data. The two initiatives are quite different.

The SCR is an electronic health record that provides healthcare staff with rapid access to essential information about an individual patient in order to provide them with direct care and treatment. In contrast, the care.data programme will use data for purposes other than direct care. The programme will extract coded data from all care settings to ensure that commissioners and providers obtain a more complete and balanced picture of the care being delivered to patients and service users. Without joined-up information it is impossible to commission joined-up care or to address variations in the quality, efficiency and equity of health and social care service provision.

It is important to note that if a patient has opted out of having a SCR then this preference will NOT automatically apply to care.data extractions. To make this clearer we have included a sentence in the patient leaflet, which will be sent to households in January.

Consent sought for the SCR was for that specific purpose only. If a patient wishes both to opt out of the SCR and to prevent personal confidential data from being used for wider purposes beyond their care, then GPs should apply both the SCR dissent code and the objection code(s) detailed in the care.data guidance.

Research

38. What is CPRD and will the objection codes apply to CPRD?

The Clinical Practice Research Datalink (CPRD) is the English NHS observational data and interventional research service, jointly funded by the NHS National Institute for Health Research (NIHR) and the Medicines and Healthcare products Regulatory Agency (MHRA). CPRD services are designed to maximise the way anonymised NHS clinical data can be linked to enable many types of observational research and deliver research outputs that are beneficial to improving and safeguarding public health. Further information is available [here](#).

The objection codes will apply to any flows of PCD from GP practices for secondary purposes so they will apply to CPRD.

Disclosures of data by the HSCIC

39. Will data be made available to organisations outside the NHS?

Yes. However, no identifiable data will be made available to organisations outside the NHS unless there is a legal basis to do so. There are three types of outputs from the HSCIC:

- **Anonymised data** – data are anonymised in accordance the HSCICs de-identification standard which is consistent with the Information Commissioner's Office guidance¹, e.g. in public reports produced by the HSCIC where small numbers are suppressed. Such data are made available on websites and other publications. They are therefore accessible to anyone.
- **Potentially identifiable data** – these data do not include identifiers but may be considered identifiable (e.g. due to a patient in an area having a rare disease or a rare combination of characteristics). There are strict controls around the limited release of such data. For example, there must be a contract in place, the data are only released to approved organisations, and restricted to a specific purposes that will benefit the health and social care system.
- **Identifiable data** – Such data can only be disclosed by the HSCIC where there is a legal basis for doing so (e.g. support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 (commonly known as 'section 251 support) or explicit patient consent). The Confidentiality Advisory Group (CAG) is an independent group that considers applications for support under Regulation 5. The use of data under Regulation 5 is not new. However, if a patient has objected then their confidential data will not be disclosed even under Regulation 5.

40. Which organisations will the HSCIC make the linked GP and hospital data available to?

Initially the linked data will only be made available for commissioning purposes. The data will be made available to them in anonymised or pseudonymised form (i.e., the data will not contain identifiers). In the future, we may make such data available to approved organisations outside of the NHS (e.g. medical charities, think tanks and universities). We would only ever do so under the same strict controls that govern our other data sets and where the data will be used to benefit the health and social care system (please see FAQ 39).

1 http://www.ico.org.uk/for_organisations/data_protection/topic_guides/anonymisation

41. What is Regulation 5 support?

Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 (commonly known as 'section 251') allows the common law duty of confidentiality to be set aside for specific medical purposes when it is

- in the interests of patients or the wider public to do so; and
- impractical to obtain consent; and
- not possible to use anonymised or pseudonymised data.

In certain circumstances, approval under Regulation 5 may be granted to cover essential NHS activity and important medical research. Further information is available on the [Health Research Authority](#) website, which includes a register of approved applications.

42. Which organisations will be able to access PCD under the new system? Is there a list?

Currently, no organisation other than the HSCIC will have access to personal confidential data in the primary care extract for care.data. In the future, PCD may be made available to approved researchers but only where there is approval under Regulation 5 (please see FAQ 41).

43. Will NHS England be able to access PCD?

NHS England does not have powers itself to collect personal confidential data from providers, only to direct the HSCIC to do so. NHS England would need to seek approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 (commonly known as 'section 251') if it wished to obtain personal confidential data without explicit patient consent.

As with any Regulation 5 application, such a request would be considered by the independent Confidentiality Advisory Group (CAG).

44. Will patient data be sold to private companies?

While the Health and Social Care Information Centre charges a fee to cover its costs, it does not make profits from providing data to other organisations, nor does it subsidise any applicants to receive it.

Any organisation can make an application for data but must go through an application process and meet the conditions for the release of that information (see FAQ 39).

45. Who do I contact if I have further questions?

If you have any remaining questions you can contact the HSCIC Contact Centre, which is acting as a helpline for GPs, by calling 0845 300 6016 or by emailing enquiries@hscic.gov.uk. Please quote 'care.data – GP' in the subject line.

Patients with queries can contact the separate patient information line. The number is on the back of the leaflet that will be sent to all households in January 2014.

NHS England Publications Gateway Reference 00969

Frequently asked questions for patients

1. Why do I need to read the leaflet ‘Better information means better care’?

The leaflet contains important information about your health records. It explains that NHS organisations share information about the care that you receive with those who plan health and social care services, as well as with approved researchers and organisations outside the NHS, if this may benefit patient care.

It is important you know how information about your health is used, shared and protected and what choices you have.

2. Why is information collected?

By using information about the care you have received, those involved in providing health and care services can see how well different services are performing and where improvements need to be made.

Sharing information about the care you have received helps us understand the health needs of everyone and the quality of the treatment and care being provided. It also helps researchers by supporting studies that identify patterns in diseases, responses to treatments, and the effectiveness of different services.

3. What is the “secure environment” mentioned in the leaflet?

The secure environment is called the Health and Social Care Information Centre, which is a public body based in Leeds. The Health and Social Care Information Centre was set up in April 2013 as the central source of health and social care information in England.

The role of the Health and Social Care Information Centre is to ensure that high quality information is used appropriately to improve patient care. The organisation has legal powers to collect and analyse information from all providers of NHS care. It is committed, and legally bound to the very highest standards of privacy, security and confidentiality to ensure that your confidential information is protected at all times. Access to information is strictly controlled. Further information about the Health and Social Care Information Centre is available at www.hscic.gov.uk/patientconf

4. What is changing?

For decades, the NHS has been using information from health records for purposes other than providing your direct care, for example to support research and to help plan new health services. However, we need to upgrade our information systems and collect information from more places where you may receive care. Doing so will make sure that we have joined-up information about all parts of the NHS, as well as public health and social care services.

5. Why are these changes needed?

The NHS has some of the best information systems in the world. Since the 1980s, we have been collecting information about every hospital admission, nationwide. This information is brought together at the Health and Social Care Information Centre, where it is anonymised (see FAQ 7 below). The information has been invaluable for monitoring the quality of hospital care, for planning NHS services, and for conducting research into new treatments. However, the information collected is incomplete, with areas such as prescribing and test results not currently included. Additionally, while we have this type of information already for some of the care provided outside hospitals, there are significant gaps. As a result, it is not currently possible for us to see a complete picture of the care that patients receive.

NHS England has therefore commissioned a programme of work on behalf of the NHS, public health and social care services to address these gaps. Known as the care.data programme, this initiative has been designed to ensure that there is more rounded information available to citizens, patients, clinicians, researchers and the people that plan health and care services. Our aim is to ensure that the best possible evidence is available to improve the quality of care for all.

6. When will these changes occur?

The first change is that information from GP practices will be brought in to the Health and Social Care Information Centre in spring 2014. This information will be joined to the hospital information that is already held by the Health and Social Care Information Centre. In the future, we will also collect information from different parts of the health and social care system to create a joined up picture of all the care delivered.

7. Will confidential information be shared?

The Health and Social Care Information Centre collects information from a range of places such as your GP practice, hospitals and community services. This information includes postcodes and dates of birth so that the information about an individual can be joined together accurately. However, there are very strict rules about what information the Health and Social Care Information Centre can release to the NHS and outside organisations. Information can be released in three ways:

- Anonymised information – this information does not identify any individuals, nor small numbers of patients with rare characteristics or diseases. Anonymous information may be published in public reports produced by the HSCIC.
- Potentially identifiable information – this is information about individual patients but it does not include any identifiers (i.e., there are no personal details such as your date of birth and postcode included). We would never publish this type of information because there is a risk that you might be identified. For example, if you were the only person in an area who had a rare disease then someone may work out that it was you even though your identifiers were not included. As a result, there are strict controls about how we release potentially identifiable information. For example, we would only ever release this type of information to approved organisations for approved purposes, and there must be a legal contract in place with penalties for any misuse of the information.
- Identifiable information – information that identifies you can only be disclosed where you have given your explicit consent (such as where you have agreed

to participate in a research study) or there is a legal basis for doing so (please see FAQ 22).

8. What kinds of information sharing can I object to?

There are two types of information sharing you can object to:

- You can object to information containing data that identifies you from leaving your GP practice. This type of objection will prevent the identifiable information held in your GP record from being sent to the Health and Social Care Information Centre's secure environment. It will also prevent researchers who have gained legal approval (see FAQ 22) from receiving your health information.
- Information from other places where you receive care, such as hospitals and community services is collected nationally by the Health and Social Care Information Centre. The Health and Social Care Information Centre only releases this information in identifiable form where there is legal approval for doing so such as for medical research (please see FAQ 22).

This legal approval is only granted where:

- in the interests of patients or the wider public to do so; and
- it is impractical to obtain each individual patient's consent; and
- it is not possible to use anonymised data.

If you object, this type of information will not leave the Health and Social Care Information Centre to researchers with approval. The only exceptions are very rare circumstances such as a civil emergency or a public health emergency.

9. Will my whole GP record be used?

No. Only the agreed amount of information required will be used. GP representatives and an independent advisory group have been involved in deciding which health, care and treatment information should be extracted. Your date of birth, postcode, NHS number, and gender (but not your name or full address) will be used to link your records in a secure environment at the Health and Social Care Information Centre but will then be removed (see FAQ 3). Once this information has been linked, a new record will be created with a reference number that does not identify you. This new record will not contain any information that identifies you.

10. I can't get in to my GP Practice to object, what should I do?

Please contact your GP Practice by telephone or email to discuss with them what arrangement would work best. If you have a query or a question about the leaflet you received through your letterbox, you can call our Patient Information line on 0300 4563531.

11. How long have I got to decide if I want to object?

You can decide to object at any time. If you would like to object before any information is extracted from your GP practice then we recommend you do so within four weeks of receiving the leaflet through your letterbox. The first extraction of information is planned for spring 2014. You can change your mind at any time (please see FAQ 12),

12. Can I change my mind?

Yes. You can change your mind at any time and as many times as you wish. If you object but then change your mind then you will need to speak to your GP practice to ensure your preferences are kept up-to-date. Likewise, if you do not object now but your later decide you wish to object, then just speak to your GP practice and ask them to record your wishes in your health record.

13. What should I do if I have concerns?

We have produced a leaflet called “Better information means better care”, which provides information about how your information is stored and used. There is also information on the Health and Social Care Information Centre website about how we look after confidential information www.hscic.gov.uk/patientconf

If you still have questions or concerns, you can call the patient information line on xxx or talk to staff at your GP practice. If you want to object you should speak to your GP Practice (please see FAQ 8)

14. I have opted out of the Summary Care Record (SCR). Do I still need to talk to my GP practice if I have any concerns?

Yes, you should still talk to your GP practice. There are important differences between allowing the NHS to use your information for planning and research and the Summary Care Record (SCR).

The SCR may be used by authorised health professionals to support your care. It would be wrong for us to assume that just because you have chosen not to have an SCR that this automatically means you also wish to stop the use of your information being used to improve health and care services. So you still need to let your GP practice know if you have concerns about sharing your information for improvements to services, planning and research.

15. Will information about me be safe and secure?

Yes. The Health and Social Care Information Centre maintains the highest levels of confidentiality both within the organisation itself and in the systems and services that we provide for the wider health and care system, in order to protect all information. We are continually testing, reviewing, and improving our security systems.

16. Can I stop information that does not identify me being used?

No. Information that does not identify you is neither personal nor private and the law says that it can therefore be used much more freely. Because this information does not identify you and because it can be so helpful to the NHS, public health and social care, it is important that we make the best possible use of it for the benefit of all.

17. Do I need to do anything if I am happy for my information to be used?

No. If you are happy for your information to be shared to help improve health services, then you do not need to do anything. Your information will continue to be used for that purpose and to benefit all patients.

18. I am a carer for someone who lacks capacity to decide whether to allow their information to be shared. Can I decide on their behalf?

It depends. If you have *Lasting Power of Attorney for health and welfare* then you can object on behalf of the patient who lacks capacity. If you are a carer or relative who does not hold a Lasting Power of Attorney then you can raise your specific concerns

with the patient's GP. The GP will make a decision based on an assessment of the patient's best interests, taking your views into account.

19. I am a parent/guardian of a child. Can I make the decision on their behalf?

It depends. If you have parental responsibility and your child is not able to make an informed decision for themselves, then you can make a decision about information sharing on behalf of your child. If your child is able to understand and make an informed decision, then the decision must be theirs.

20. Will you sell data?

No. While the Health and Social Care Information Centre charges a fee to cover our costs, we do not make profits from providing data to other organisations, nor do we subsidise any applicants to receive it.

21. What research will be carried out on information that identifies me?

Examples of approved projects are:

- a national study of people who have had a heart attack, and
- a study of the time that people had to wait for treatment for cancer and the effect of these waiting times on survival.
- Details of approved studies can be found at <http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/cag-advice-and-approval-decisions/>
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22. When does the HSCIC allow researchers to access confidential information about me?

In most cases, researchers can carry out their studies using information that does not identify you. Occasionally, however, medical researchers need to use information that does identify you.

Only researchers who have obtained your permission or who have been granted legal approval are allowed to access confidential information that identifies individuals. Only the Secretary of State for Health or the Health Research Authority (HRA) can grant this legal approval and they do so following independent advice from the *Confidentiality Advisory Group* (CAG).

CAG considers each application in great detail against the legal framework, and recommends whether approval should be provided together with any conditions. Applicants must demonstrate (i) that the research is in the public interest and for the benefit of the health service; (ii) that it is not possible to use information that does not identify you; and (iii) it is not possible to ask your permission. There are a variety of reasons why it might not be possible to ask people; for example, where there are extremely large numbers of patients. Access to the information is restricted to the specific information necessary for the research. All approvals must demonstrate compliance to with the Data Protection Act 1998.

23. Will information that identifies me be used by commercial organisations?

Please see FAQ 7 about the different ways in which the HSCIC shares information.

Any organisation can make an application to the HSCIC for identifiable or potentially-identifiable information and each application is considered individually.

An organisation making an application would only be allowed confidential information that identifies individuals if they have:

- already obtained your permission (i.e. patient consent); or
- have been granted legal approval by the Secretary of State for Health or the Health Research Authority (HRA) following independent advice from the Confidentiality Advisory Group (CAG) (please see FAQ 22); or
- where we are legally required to provide it for a public health emergency such as an epidemic.

So that we can ensure that confidential information about you remains protected, the organisation making an application must sign a data sharing contract and a data sharing agreement with the Health and Social Care Information Centre. This contract sets out the terms of how the information is shared, what it can and cannot be used for (its purpose), security requirements on how it is stored, and restrictions on onward sharing or publication.

For case studies and examples of how customers have used information from the Health and Social Care information Centre, please see <http://www.hscic.gov.uk/dlescst>

For clinical trials, pharmaceutical companies may work with your GP practice who will contact you first to ask if you are willing for a researcher to contact you about a particular trial for which you may be eligible. You will not be contacted by a pharmaceutical company or any other third party unless you have specifically agreed.

The Health and Social Care Information Centre will not share information about you with insurance companies or solicitors. If an insurance company or solicitor wanted information about you, they would need to approach your GP practice directly and you would need to give your explicit consent before any of your information could be shared with them. If you do not agree to their specific request for your information then it will not be shared with them.

Data will not be shared or used for marketing purposes

24. Can I have a greater number of choices and allow information to be used for some but not other research projects?

No. Currently, you have the right to say yes or no to your information leaving your GP practice or being shared by the Health and Social Care Information Centre. Our systems do not let you say yes or no to your information being used for specific projects. However, if a researcher is working directly with your GP practice for their study then, unless they have approval (please see FAQ 22), your GP will check with you first to see if you are happy for your information to be shared as part of the study.