

# 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 guidance<sup>1</sup>, 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](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](mailto: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.