



INFORMATION
to **share** or
not to share

**The Independent Information Governance Oversight
Panel's report to the care.data Programme Board on
the care.data Pathfinder stage**

1. Introduction

Earlier this year, Dame Fiona Caldicott agreed that the Independent Information Governance Oversight Panel (IIGOP) would advise the care.data Programme Board and Senior Responsible Owner on the first stage of the implementation of the Programme. This was to be done as part of IIGOP's role in advising, challenging and reporting on the state of information governance across the health and care system in England. IIGOP's particular focus would be to provide quality assurance of the processes being developed to identify, work with and monitor Pathfinder practices that would be trialing care.data. IIGOP would also inform the Programme Board's decision to move to the next stage of rollout. Advice and scrutiny would be provided on an ongoing basis by regular interactions between IIGOP and the care.data Programme. It would be formalised in a report to the Programme Board before the care.data Pathfinder data extraction would commence.

During the course of this work the Secretary of State announced that Dame Fiona would become the first National Data Guardian for health and care¹. He confirmed that; *“No data will be extracted from GP practice systems - including during the ‘pathfinder’ pilot phase of the programme - until she has advised me that she is satisfied with the programme’s proposals and safeguards².”*

2. Background

a. The rights of the individual

On 26th April 2013, in the Government's response to the Caldicott2 Report³, Jeremy Hunt, the Secretary of State for Health, announced that *“any patient that does not want personal data held in their GP record to be shared with the Health and Social Care Information Centre will have their objection respected and where personal data has already been shared from a GP practice to the Information Centre, a patient will still be able to have the identifiable information removed.”* On 12th September 2013, Mr. Hunt, confirmed his commitment⁴ to balance patient safety and privacy. *“... But if someone has an objection to their information being shared beyond their own care, it will be respected. All they have to do in that case is speak to their GP and their information won't leave the GP surgery.”* This is now commonly known as a “type 1” objection.

¹ <https://www.gov.uk/government/news/national-data-guardian-appointed-to-safeguard-patients-healthcare-information>

² https://www.gov.uk/government/speeches/innovation-and-efficiency?utm_source=twitter&utm_medium=social

³ <https://www.gov.uk/government/news/health-secretary-to-strengthen-patient-privacy-on-confidential-data-use>

⁴ <https://www.gov.uk/government/news/jeremy-hunt-confirms-commitment-to-balance-patient-safety-and-privacy--2>

In September 2013 the HSCIC launched “A guide to confidentiality in health and social care” which set out in Section B, Rule 4, further clarification with regard to respecting a patient’s wishes to object. This, in addition to recognising that a patient may object to confidential information about them being sent from a GP practice, went further to confirm that a patient could also tell their GP if they objected to any confidential information about them leaving the HSCIC in identifiable form. This is now commonly referred to as a “type 2” objection⁵.

A citizens’ right to object is firmly embedded in the NHS Constitution⁶. The legal origins of this lie in both Article 8 of the European Convention on Human Rights and the European Data Protection Directive⁷, which require reasonable objections to the disclosure of personal confidential data to be respected.

The Pathfinder stage is dependent upon having agreed the position and wording around objections with the Secretary of State in order that draft communications materials can be finalised and used in the Pathfinder stage.

As a matter of policy the Secretary of State directed that he did not want the HSCIC to collect data in the case of citizens who had raised an objection. This was given effect by the bodies able to direct the HSCIC to use its power, limiting what they directed the HSCIC to collect, i.e. they would direct the HSCIC to collect only data where there was no flag indicating an objection (as reflected in Directions issued by NHS England to the HSCIC in December 2013 in relation to the collection and linkage of primary care data.) Only in exceptional circumstances (e.g. public health emergencies) would a broader direction be given.

This is consistent with the prevailing conditions set by the Confidentiality Advisory Group when it approves data flows as part of its recommendations under powers in section 251 of the NHS Act 2006.

⁵ <http://www.hscic.gov.uk/gpes/pom>

⁶ **You have the right** to request that your confidential data is not used beyond your own care and treatment and to have your objections considered, and where your wishes cannot be followed, to be told the reasons including the legal basis.

⁷ Both Article 8 of the European Convention on Human Rights (ECHR) and the European Data Protection Directive were enacted in UK law through the Human Rights Act 1998 and Data Protection Act 1998.

b. Pathfinder stage

In May 2014, the care.data Programme Board agreed that the Programme would work with two to four CCGs and up to 500 GP practice Pathfinders in order to test, evaluate and refine all aspects of the communication and technical processes. The Pathfinder stage was developed in consultation with stakeholders including the BMA, RCGP and Healthwatch England and a subgroup of the care.data Advisory Group. After approval by the care.data Programme Board, the Pathfinder proposal document was published in October 2014.

The CCG areas of Somerset, West Hampshire, Blackburn with Darwen, Leeds North, Leeds West and Leeds South and East were selected as Pathfinders.

The Programme is developing a “co-production” approach to initial GP and patient-facing material, based on feedback from the care.data “listening period” and from local events and formal research. The intent is to ensure that there is local ownership of material used to communicate with professionals and patients in the Pathfinder stage. The Programme commissioned Ipsos MORI to conduct research with practices and patients before and after receipt of communication material in the Pathfinders to provide insights into the level of understanding and opinions of the target audiences.

Patients in Pathfinder GP practices will receive a letter and an opt-out form with a pre-paid envelope, paid for by the Programme. Completed opt-out forms will be collated centrally and sent to practices in batches.

The Pathfinders are operating on the basis of an opt-out approach to care.data. The opt-out will affect all patient confidential data leaving the practice and not just care.data. The wording to be tested in the care.data Pathfinder stage to describe the opt-out is below:

“Information about your health and care can help to improve NHS services for all patients. For example, it can help the NHS to improve early diagnosis and treatment of illnesses, including cancer and heart disease. It can also help the NHS to check that health and social care services are doing a good job, to provide the right services at the right time and to support researchers to develop new medicines and treatments.

To achieve these benefits for everyone, the health and social care system is planning to make better use of this information.

You have the right to opt-out of allowing information about you to be used in this way. If you do not want your information to leave your GP practice please tell the practice that you wish to “opt out”. Opting out will not in any way affect the care or treatment that you receive as a patient.

We remain absolutely committed to keeping your data safe and secure and will take every step to protect your confidentiality. We will put strict

controls around access to the data so that it is only used for the benefit of health and care services.”

The Programme has already identified the following issues as being essential for demonstrating the success of the Pathfinder stage:

- *Use of the data* - the purposes for which the data will be used will be explained to patients;
- *Security* - a secure data facility will allow approved applicants to use and analyse the data;
- *Transparency* - HSCIC is taking action to update and maintain its register of data releases;
- *Confidentiality* - The Code of Practice for confidentiality will be published before data is extracted from GP practices and fair-processing information provided on the HSCIC website;
- *Control of data* - NHS England and HSCIC will be Joint Data Controllers for care.data;
- *Business case development* - the Programme Board will endorse this before data extraction commences from the Pathfinder practices;
- *Evaluation* - a full evaluation at the end of the Pathfinder stage will inform the wider rollout of care.data.

c. Review of process

IIGOP's interaction with the care.data Programme has been through regular conference calls with nominated members of both groups; attendance at boards or other meetings; and document reviews. IIGOP has received weekly update reports from the Programme, which are circulated to the Panel. The care.data Programme has been a standing item on agendas for meetings of the IIGOP Steering Group and Panel throughout this period. In November 2014, the Panel held a joint workshop with the care.data Steering Group and representatives of other key stakeholders with the aim of receiving feedback on the care.data Pathfinder process. This was done to inform IIGOP's report to the care.data Programme Board, due to be delivered by 22nd December 2014. The objectives for the day included:

- Assessing the extent to which key questions and concerns have been addressed in the Pathfinder stage, particularly in relation to clear and consistent communications to the public about the care.data Programme generally and objections and the opt-out specifically;
- Identifying any outstanding issues that might affect the timetable for data extraction from practices (e.g. technological readiness to go live);
- Identifying wider matters that should be addressed before national rollout of care.data.

3. National Data Guardian's Questions and Tests

After this period of research the National Data Guardian and IIGOP were left with a number of questions and concerns. Some were matters that the care.data Programme Board and other national organisations will have to clarify at national level before they can be confident that the Pathfinder stage is ready to go ahead. For ease of reference, these issues that are thus far unresolved are described below in section 4 as the National Data Guardian's Questions for care.data. It is possible that the Programme Board has considered many or all of these questions and can clarify matters by communicating the answers. The National Data Guardian looks forward to them doing so.

However, there were other matters that cannot be resolved at national board level because they depend on the actual progress made in each Pathfinder area. Evidence of that progress will have to be substantiated before a Pathfinder can be declared ready to proceed to data extraction. These tests of local readiness are described below in section 5 as the National Data Guardian's tests for care.data Pathfinders.

4. The National Data Guardian's Questions for the care.data Programme Board.

Clarity of policy and clarity of communications are both absolutely essential for gaining public and professional trust in the care.data Programme. This seems to be the area of most concern. The public, patients and care professionals must receive clear messages about care.data. The key questions and concerns that we heard are explored below, beginning with patient concerns.

a. Patients

1. *How do I know my data is safe?* Individuals are concerned about where their data will go, how it will be stored, how it will be shared, with whom, in what form and for how long it will be held and accessible.
2. *What is care.data exactly and what are Care Episode Statistics?* Individuals want to understand the purpose of care.data, what data will be extracted and why it is important for both themselves and for the NHS.
3. *What data will be extracted as part of care.data?* Is there an up-to-date list? (See also governance below)
4. *What about issues of age, competence and capacity?* Concerns were expressed that the law about age, competence and capacity was not reflected in the choices that patients and their representatives are able to make in relation to care.data.
5. *How can patients check, update or change their preferences and see that their choices have been respected?* (See also GP system suppliers below)

6. *When patient objections are not upheld, how are patients to be informed?*
7. *What are the implications of opting-out? Will it have any effects on the individual's care? Can this be absolutely guaranteed?*
8. *What are the implications of opting-out for other data flows? (e.g. a patient may previously have given explicit consent to participate in a research study using data extracted from the GP record.)*
9. *What does the opt-out not cover? What are the exceptions? What data will still flow if I opt out?*
10. *How will patient objections be managed in other care settings? (e.g. HES data opt out).*

b. GPs

Gaining the confidence of the GP community is going to be a crucial test of the Pathfinder stage.

1. *How are GPs meeting their legal responsibilities as data controllers?* GPs must meet their fair-processing responsibilities under the Data Protection Act (DPA).
2. *How is the Programme supporting GPs to meet these legal requirements?* A key test of success for the Pathfinders will be demonstration that participating GPs feel they have met their responsibilities under the DPA.
3. *Can GPs opt out of care.data?* GPs need to understand the legal and ethical implications if they are considering opting their practices and patients out of care.data.

c. Governance

1. *Is the content and governance of the data set that is to be extracted understood and clear?* What exactly is a “rolling extraction” of data? This may have important implications for statements about anticipated benefits.
2. *Why have some data items been excluded from the care.data extraction?* The fact that some medical conditions are excluded from the care.data set was thought to undermine the message that care.data is safe. While this measure was meant to reassure the public about care.data, some felt it might have the opposite effect and also adversely affect the completeness of the data set.
3. *Are the purposes of the care.data Programme and the care.data extraction clear and the processes open and transparent?*
4. *Do public bodies, commercial organisations and others understand their duties as data controllers for data they obtain from GPs? Can they uphold patient objections or decide if they are applicable? How will they tell patients when their objections are not being upheld?*
5. *What safeguards are there to hold HSCIC to account and assure the governance around its data publications and disseminations? What are the rules about dissemination? Who will get the data? Who will decide who gets the data? How will HSCIC enact the provisions of the Care Act 2014, particularly in relation to commercial uses of data?*

More generally, there seems to be no explicit statement that data extracted by the Pathfinders cannot be shared offshore. Is this deliberate, or an oversight?

6. *How will the HSCIC communicate and inform individuals?* How will it communicate to patients whether it will uphold their objection or not, now and in the future? How will it deal with “type 2” objections? How will the commitment that opting-out does not damage direct patient care be honoured? For example, can patients be assured that flows of data through HSCIC for direct care purposes - such as pathology results - will not be affected? How are the HSCIC going to deal with people who have filled in their objection form online?

d. GP system suppliers

1. *Have GP systems suppliers effectively understood and implemented patient objections?*
2. *How will systems manage explicit consent for some purposes and the opt-out for others?*
3. *Are systems designed in such a way that the information needed to support a patient’s direct care is not compromised, even if the patient has opted out of allowing their data to be used for secondary purposes?*

e. Pathfinders

1. *How far back does the data go?* Is the relevant starting point the date of onset of a condition or the date of entry in the record? As the extract will be time limited, is it right that we encourage patients not to opt-out on the basis of benefits from long-term research that cannot be realised over a short span?
2. *What are the implications of using locally developed communications material (“co-production”) for subsequent national rollout?*
3. *How will the Secure Data Facility work during and after the Pathfinder stage?* (Purposes and access.)
4. *How will this be made generalisable / extensible with full national rollout?* This was described to us as the “air-gap” question (e.g. will HSCIC be expected to delete the data after Pathfinder stage? Will patients have to be informed again if the purpose(s) change?)
5. *What are the success criteria for the Pathfinders?* How will we know what has worked and what has not? How will the Programme ensure the results are generalisable and scalable?

5. The National Data Guardian’s Tests for care.data Pathfinders

As explained above in section 3, there are some questions that cannot be resolved at national board level because the answers depend on the actual progress made in each Pathfinder area. To demonstrate that the Pathfinder

stage of the care.data programme is ready to go ahead the following conditions will apply:

1. Each Pathfinder CCG will be able to demonstrate that people in the area have a sufficient understanding of the choices on offer and the implications of making those choices.

This will require evidence of communications materials that are accurate, written in plain English, easily understood and acceptable to local stakeholders including GPs and the local Healthwatch. It will also require evidence of a properly conducted survey showing whether people received appropriate information and how they understood it. IIGOP would like to explore with the Programme Board how public understanding of this material might be tested.

2. Each Pathfinder CCG will be able to demonstrate equality of access to choice.

This will require evidence that GPs' lists of homes to which letters are sent are as up to date and comprehensive as possible. Practices will have considered how to get information to patients who are hard to reach. Suitable arrangements will be in place for people who have recently moved or are about to move during the Pathfinder period into another Pathfinder area so that any opt-out decision may travel with them to their new address. Parents, who will be expected to decide whether or not to opt out their children, will have the number of forms necessary for this purpose. Suitable arrangements will have been made for local authorities as the "corporate parent" of children in care to make decisions on behalf of those children. Children will be informed of decisions made on their behalf and given an opportunity to change that decision when they become old enough to do so. Support will be available to help people who do not or cannot understand the communications material to make their decisions. Arrangements will also have been made for legal guardians, who have a right to make decisions on behalf of those without capacity, to make those decisions as regards the opt-out. In each case the CCG will be able to provide evidence.

3. Each Pathfinder CCG will be able to demonstrate that participant GP practices are satisfied that they have met their fair processing obligations.

This will require evidence that GPs know where data flows from their practice for secondary purposes. Patients opting out of care.data will also automatically opt out of flows of data for secondary purposes, both national and local, including data flowing for CCG / CSU purposes, research and national audits. To satisfy the fair processing requirement, the GPs need to know about all these flows and to be able to offer conversations with patients about the implications of opting out. To demonstrate this, each participant practice will certify

its compliance publicly. Supporting evidence will include copies of material used by the practice for training doctors and staff, and material used to inform patients directly and indirectly, e.g. notices, leaflets and practice websites.

4. Each Pathfinder CCG will be able to demonstrate that patients understand what data will flow and for what purposes.

This will require evidence that patients have been informed about the secondary uses to which their data might be put. This may include local data flows as well as national ones. Patients will have a place to go to discover which of their data has been extracted and for what secondary purposes. They will be able to access that information in plain English and given help to understand it, if required. It is important to note that decisions to sign up to particular data flows (such as to CPRD, ResearchOne and QResearch) are often taken at practice level and so evidence will have to be supplied practice by practice and made known to patients. In addition, it is to be expected that the Pathfinder programme is likely to generate questions from patients about how their data is shared for direct care purposes, including referral information, laboratory tests, prescriptions and summary care records. To demonstrate readiness and to avoid confusion among patients, practices will be able to provide evidence that they are able to answer such questions.

5. Each Pathfinder CCG will be able to demonstrate that patients are given confirmation that their decisions have been acknowledged and implemented.

This will require evidence that some form of acknowledgement or receipt is given whenever a patient communicates a decision to opt out, whether that is done in the GP surgery or in another place such as a local Healthwatch, Citizen's Advice, a booth in a station or supermarket, or online. There will also be evidence that people requesting written confirmation that their opt-out has been implemented receive it by the means requested, for instance by letter, email or text.

6. Each Pathfinder CCG will be able to demonstrate that it has worked out procedures for measuring the outcome of its distinctive approach to the programme.

It is anticipated that each Pathfinder will test out and trial different approaches to communicating with patients and the public, including an evaluation of costs and effectiveness. Given these differences, each Pathfinder will show its readiness by providing evidence of the criteria for measuring outcomes. IIGOP will be glad to explore with the Programme Board what outcome measures are appropriate and to discuss other issues that arise as the programme progresses.

7. Each Pathfinder will be able to demonstrate that its GP system suppliers have provided the systems needed to deliver the functionality required.

This will require evidence that systems can handle the process for patients to make objections and have the technical capability to implement those objections. This should be the case not only for care.data extractions but also other national and local extractions to which the opt out also applies e.g. local data flows agreed with CCGs / CSUs to support commissioning, research and national audits. This will demonstrate that what goes on “under the bonnet” of Pathfinder practice systems operates in the same way that patients are being told it does.

6. Conclusion

The National Data Guardian and IIGOP thinks that it would be reasonable to proceed to a data extraction in the Pathfinder areas once the care.data Programme Board and other national organisations have provided satisfactory answers to the questions in section 4 and once the Pathfinders have satisfied the tests in section 5. We believe that this will provide a sufficiently robust framework within which we can be confident that patients have been reasonably informed about care.data and other uses of their health information and are able to make choices about sharing which can be evidenced from and effected in their GP records.

GP practices will be confident that they can meet their fair-processing responsibilities and be confident they can inform their patients on an equitable basis about the flows of data from their records.

In these circumstances we feel it is right and proper that the data extraction should proceed on an opt-out basis. We believe that this approach is consistent with the mandatory direction under the Health and Social Care Act 2012 for the HSCIC to collect the care.data extract and the provisions and principles of the Data Protection Act 1998.

IIGOP stands ready to explore with the care.data Programme Board how practical arrangements can be made for responding well to the questions and tests in this report, but the Panel does not anticipate any changes of principle.