

**Ref:** care.data/Programme Board – Main session/Paper 03

**Title:** care.data Assurance, Approval and Evaluation for Pathfinders

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**Purpose:** The purpose of this document is to set out the approval process for decision to commence testing of communications and extraction of primary care data, and to proceed to further roll-out beyond the pathfinder stage. This approval will be gained from the Programme Board in three stages.

1. Documentation and evidence which will be provided to gain the approval to commence the testing of communications.
2. National Data Guardian will provide advice to the SofS to make an assessment as to whether she is satisfied with the programme proposals and safe guards before extraction.
3. Evidence and evaluation which will be provided to measure success following the pathfinder stage in order to make a further decision to proceed beyond the pathfinder stage.

**Background:** In February 2014, the decision was taken to delay the start of the extraction of primary care data from general practice following concerns raised by key stakeholders, in the media and across social media. Since then the programme has been listening to the views of patients, the public, GPs and stakeholders on how best to build trust and confidence in the programme.

The first phase of the programme is defined as the delivery of a dataset which links data from GP systems with Hospital Episode Statistics (HES) to support clinicians, commissioners, researchers, charities and patients, to improve quality, safety and effectiveness of local care services

The following papers have previously been presented to the board:

- Documentation and Evidence to inform decision for Extraction (26 August 2014)
- Pathfinder Success Criteria (23 September 2014)

The documents have been merged and extended into this version in order to present to the Programme Board one comprehensive document encompassing assurance, approval processes and evaluation for the pathfinder stage.

**Key Points:** The planning principles document outlined dependencies and pre-requisites for moving through and beyond the pathfinder stage. Documentary evidence which will be used to inform decisions taken by the programme board through the pathfinder stage is set out in this paper.

**Desired outcome(s):** For the programme board to approve this document at their meeting on 24 March 2015.

**Circulation:** Programme Board attendees only

**Dates considered by Programme Board:**

- 15 October 2014 (v 0.1)
- 17 November 2014 (v 0.2)
- 14 January 2015 (v 0.3)
- 11 February 2015 (v 0.4)
- 24 March 2015 (v 1.0)

## **Purpose**

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## **Background**

2. In February, GPs, Healthwatch England, professional bodies and patient groups made their views clear that more needed to be done to ensure that patients and the public have a clear understanding of NHS England's intention to use patient data held by GP practices for purposes beyond direct health care.
3. In light of feedback from patients, the public, GPs and stakeholders since February 2014, the programme agreed to a phased implementation of care.data and to work with between 100 and 500 GP practices within 2-4 CCG areas in the 'pathfinder stage'.
4. The National Data Guardian and Independent Information Governance Oversight Panel (IIGOP), chaired by Dame Fiona Caldicott, agreed to advise the care.data Programme Board and Senior Responsible Owner on the first phase of the implementation of the programme in its role of advising, challenging and reporting on the state of information governance across the health and care system in England.
5. The programme has been progressing with a selection process to identify which CCGs should go forward as pathfinders. The selection panel, which consisted of representatives from the programme, Royal College of General Practitioners, National Association of Voluntary and Community Action, British Medical Association and Healthwatch England, assessed four CCG areas that had nominated themselves and recommended all four to go forward. The pathfinder CCG areas are Somerset, West Hampshire, Blackburn with Darwen and Leeds (with Leeds being a collective of the three CCGs in that area, North, West and South East). Following Programme Board approval, and agreement with ministers, these CCG areas were subsequently confirmed as pathfinders on Tuesday 7 October 2014.
6. The CCGs and constituent GP practices that participate in the pathfinder stage will be involved in testing all aspects of the communications and data extraction process so they can be refined before any decision is made on widening participation.
7. The objectives of the pathfinder stage were agreed as part of the pathfinder proposals document, which was developed with the Advisory Group and approved by the Programme Board. The objectives are included here in box 1 for reference:

## Box 1:

1. *Test and refine resource packages so that GP practices understand how they can meet their fair processing requirements and have materials which support them in doing so. This will include materials which support GP practice staff in:*
  - a. *understanding care.data e.g. the benefits/risks; the available choices for patients, what these choices mean; the difference between care.data and other data sharing etc.*
  - b. *awareness raising e.g. materials within the practice; template text for websites/repeat prescriptions etc.*
  - c. *administering the opt out process for example opt out forms*
  - d. *responding to patients who have questions/concerns e.g. by providing or signposting patients to further information*
  - e. *understanding how the extraction process works.*
2. *Assess existing national materials and identify changes that may need to be made to these e.g. existing FAQs, fair processing information materials that NHS England and HSCIC have available.*
3. *Test out and trial different approaches to communicating with patients and the public, including evaluation in terms of their costs and effectiveness. This will include materials which enable patients and the public to understand:*
  - a. *how data will be used;*
  - b. *their choices;*
  - c. *objections and how they can opt out;*
  - d. *what happens if they have already opted out; and,*
  - e. *their rights to change their mind at any time.*
4. *Assess the impact on resources and services looking in particular at GP practices and Clinical Commissioning Groups while considering the effect on other parts of the overall service, this will specifically look at:*
  - a. *any additional burden on GPs and practice staff;*
  - b. *any additional burden on Clinical Commissioning Groups;*
5. *Provide and test enhanced guidance and resources specifically in relation to opt out processes.*
6. *Assess the level of patient awareness across a broad and diverse demographic group in discharging their rights and choices for data sharing.*
7. *Consider how local and regional structures/organisations can support awareness raising e.g. local Healthwatch/ Local Medical Committees (LMCs).*
8. *Explore how whole communities e.g. through Third Sector organisations such as charities and volunteer groups can be consulted and involved at the regional level to support awareness raising.*
9. *Establish if there are other potential routes to get information across to patients and the public.*
10. *Provide assurance of the technical aspects of the data extracts through the GP Extraction Service, demonstrating that the GP system suppliers have interpreted and implemented the extraction specification correctly.*
11. *Provide assurance regards process and controls in place to regulate and restrict the onward dissemination of the data that is extracted*
12. *Act as a key decision point to determine whether the care.data programme can proceed to the next stage in rollout to a wider selection of practices.*
13. *Identify how data collected from practices can be best utilised to feedback information and analysis that will support the pathfinder practices and CCGs, e.g. providing analysis such as comparator data and data quality analysis.*
14. *Explore with a limited number of research organisations using a secure data environment how the data may be used for research purposes and the potential for benefits to be realised (assuming General Practice Extraction Service Independent Advisory Group approval is given to enable access to data beyond commissioning purposes).*

### **Decisions Required**

8. The Programme Board confirm they are content with the proposed evidence and associated documentation that will be provided to enable them to approve the start of testing the communications.
9. The Programme Board confirm they are content with the measures to enable evaluation of the success of the pathfinder stage to inform the decision on further rollout (anticipated August 2015).

### **Important Notes regarding Approval**

10. The programme will work closely with National Data Guardian and IIGOP before and during the testing of communications to ensure that the programme is well placed to meet the questions and conditions set out in the IIGOP report published on 18 December 2014.

**Table A: Documentation and evidence to assist decision for approval to commence testing of communications.**

Ref	Outcome	Description	Deliverable	Owner	Approver	Date of Approval
1	Achievement of Planning Principles	Evidence for board to consider achievement of the planning principles including: <ul style="list-style-type: none"> <li>• HSCIC Code of Practice published</li> <li>• HSCIC fair processing pages live on the website</li> <li>• Joint data controller agreement in place</li> <li>• Business case endorsed by the programme board to enter HSCIC/NHS England/Government Department assurance and approvals</li> <li>• Position statement regarding care bill secondary legislation</li> <li>• Revised Privacy Impact Assessment for NHSE</li> </ul>	An evidence based board paper from the programme confirming that the other dependencies as listed in the Planning Principles document have been achieved and adhered to	Eve Roodhouse	Programme Board	13/05/2015
2	CCG View	Each pathfinder CCG to provide a summary statement which are expected to include: <ul style="list-style-type: none"> <li>• GPs are content with the communication activities/materials that are to be delivered, and with the approach that is to be followed</li> <li>• The CCGs and practices understand the process for data extraction.</li> <li>• A statement from the local Healthwatch group(s)</li> </ul>	CCG View Board Paper	David Corbett	Programme Board	13/05/2015
3	Independent Assurance	Summary report produced by National Data Guardian and IIGOP and presented to care.data programme board covering: <ul style="list-style-type: none"> <li>• Introduction</li> <li>• Role of National Data Guardian and IIGOP (including development of the proposals for the pathfinder stage, the role leading up-to testing of communications, and planned role through to the end of the pathfinder stage, and evidence considered in informing the report and its conclusions, signed off by National Data Guardian and IIGOP).</li> <li>• Summary of the planned process followed for the pathfinder stage including assurances National Data Guardian and IIGOP are content with the communication materials that are prepared and planned approach.</li> </ul>	IIGOP Report	Alan Hassey	IIGOP (Alan Hassey in attendance at the Programme Board)	22/12/2014
4	Programme Team Assurance	Programme team assessment of the position against the questions and conditions set out in the IIGOP report published on 18 December 2014.	Response to IIGOP report	Eve Roodhouse	Programme Board	13/05/2015
5	Communication Materials	Programme Board to review and approve the communication materials to be used by pathfinders.	Approval of communication materials	Phil Bastable	Programme Board	31/03/2015

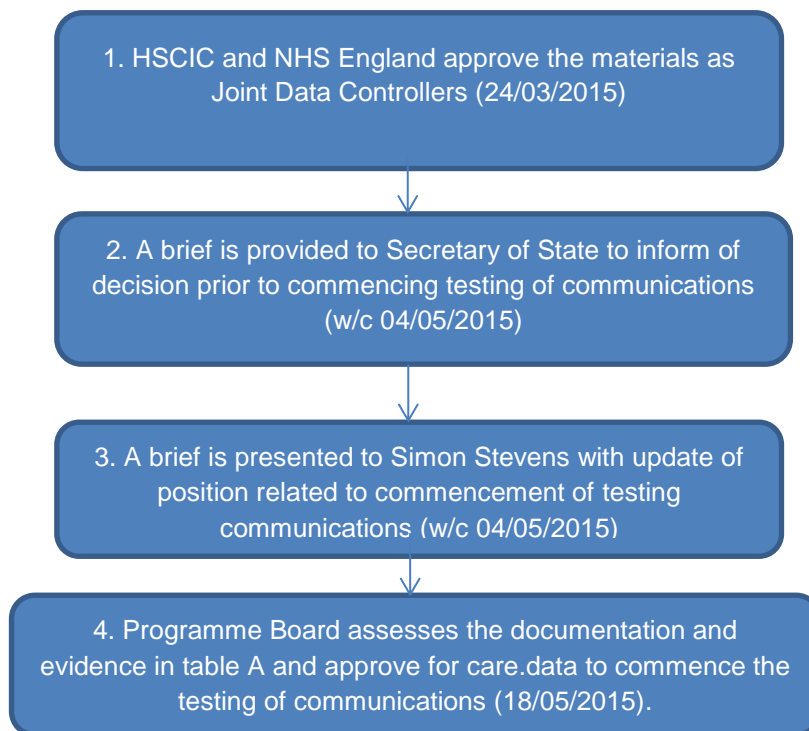
**Table B: Documentation and evidence to assist decision for approval to commence extraction.**

Ref	Outcome	Description	Deliverable	Owner	Approver	Date of Approval
1	National Data Guardian assurance	National Data Guardian to provide advice to the SofS as to whether she is satisfied with the programme proposals and safe guards before extraction.	Written advice	Richard Wild	National Data Guardian	TBC
2	Technical assurance	Status report confirming technical readiness that will include delivery dates for when the technical infrastructure will be in place and fully tested, and when the Secure Data Facility will be available for use.	Technical Readiness Paper	David Ibbotson	Programme Board	TBC
3	HSCIC Board assurance	Note from HSCIC Board to confirm they have been sighted on Dame Fiona's advice and are content to proceed.	Written note	Eve Roodhouse	CEO HSCIC	TBC

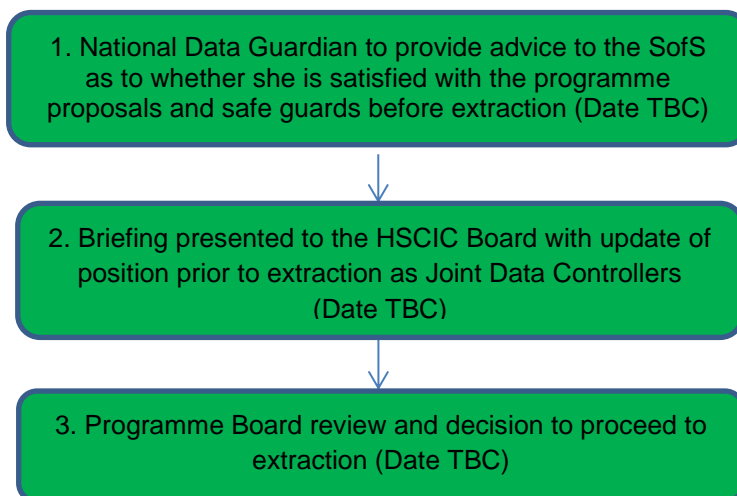
**Table C: Approval Process**

Ref	Description	Advisor/ Information Provider	Approver	Date
<b>Approval for Testing of Communications</b>				
1	HSCIC and NHS England approve the materials as Joint Data Controllers.	N/A	HSCIC & NHS England	24/03/2015
2	A brief is provided to Secretary of State to inform of decision prior to commencing testing of communications.	N/A	SofS	TBC
3	A brief is presented to Simon Stevens and Andy Williams with update of position related to commencement of testing of communications.	Programme Team	N/A	TBC
4	Programme Board assesses the documentation and evidence in table A and approve for care.data to commence the testing of communications.	N/A	Programme Board	13/05/2015
<b>Approval for Extraction</b>				
1	National Data Guardian to provide advice to the SofS as to whether she is satisfied with the programme proposals and safe guards before extraction.	N/A	National Data Guardian and IIGOP & SofS	TBC
2	Briefing presented to the HSCIC Board with update of position prior to extraction as Joint Data Controllers.	HSCIC Board	HSCIC Board	TBC
3	Programme Board review and decision to proceed to extraction.	N/A	Programme Board	12/08/2015
<b>Approval for National Rollout</b>				
1	Programme Board to assess evaluation documents in table C.	N/A	Programme Board	27/11/2015
2	Other briefings as required.	N/A	N/A	TBC

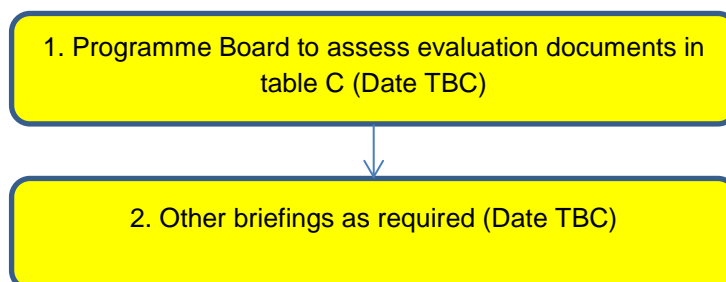
### Flow Chart 1: Approval for commencement of testing communications



### Flow Chart 2: Approval for Extraction



### Flow Chart 3: Approval for National Rollout





**Table D: Evaluation of the success of the Pathfinder Stage for approval to proceed beyond pathfinders.**

Ref	Outcome	Description/Evidence	Deliverable	Owner	Approver	Date of Approval
1	There is a package of communications materials and tools which is endorsed by GPs and practice managers for the next stage(s) of roll out (with an acceptable level of improvements which may be identified).	Each pathfinder CCG to provide a summary statement incorporating the views of GPs and practice managers It is expected to include: <ul style="list-style-type: none"> <li>• They were supported in delivering their fair processing responsibilities with high quality communication materials for their patients and for them.</li> <li>• They knew what support was available to them and were able to access communications materials as required.</li> <li>• They could confidently answer questions raised by patients.</li> <li>• They understood how the extraction process would work.</li> <li>• The burden on GP practices is understood and there are approaches in place to reduce the burden (Ipsos MORI research)</li> </ul>	TBC	David Corbett	Programme Board	27 November 2015
2	There is a package of communications materials and tools which reaches all patients in the pathfinder areas. The communications material needs to be clear that the purpose and nature of intended data sharing is beyond direct care. Further this package is endorsed by practice participation groups for use in the next stage(s) of roll out (with an acceptable level of improvements which may be identified).	<ul style="list-style-type: none"> <li>• All patients registered at a pathfinder practice received a personalised communication e.g. letter/text/email.</li> <li>• Materials are accessible e.g. available in easy read and braille and supported by local and national voluntary groups. Any requirements for additional accessible materials or improvements have been identified.</li> <li>• Detailed information is available to those who want to access it, i.e. the exact details of what will be extracted and how data will be stored.</li> <li>• Local communities and stakeholders feel the communications were effective.</li> </ul>		David Corbett	Programme Board	27 November 2015
3	Awareness, understanding, and sentiment towards the communication materials supporting care.data (Public and GPs/ Practice Managers)	Research among these groups to test the approach This is expected to include: <ul style="list-style-type: none"> <li>• Questions on the suitability and relevance of pathfinder communication materials</li> </ul>	Report from Ipsos MORI to include baseline and final polling findings	Laurence Bruce	Programme Board	27 November 2015
4	The technical solution has worked as planned with no issues requiring resolution before the next stage(s) of roll	The GPES extraction process and the subsequent landing, linking and presentation of data in the Secure Data Facility work to specification.	Technical Delivery Board Paper	David Ibbotson	Programme Board	27 November 2015

Ref	Outcome	Description/Evidence	Deliverable	Owner	Approver	Date of Approval
	out (dependant on further IT investment).					
5	There is a good understanding of the effort required by CCGs, GPs and Practice Manager to support data sharing for care.data	The effort required in terms of: burden on GPs and practice managers; cost of producing communications materials and tools; and, local engagement, is understood to ensure that an informed decision as to the next stage(s) of roll out can be made.	Report from Ipsos MORI to include consultation sessions with CCGs, GPs and Practice managers	Eve Roodhouse & Laurence Bruce	Programme Board	27 November 2015
6	There is some initial analysis of the linked dataset including an indication of the quality of the data.	Early view of the potential benefits of the dataset as well as any limitations to inform next stage(s) of roll out.	Analysis Board Paper (including feedback from Advisory Group)	Richard Irvine	Programme Board (in conjunction with Advisory Group)	27 November 2015
7	The options for the next steps are clear and defined in order to make an informed decision	Overarching summary document which reports on the pathfinder stage referencing the evidence points and options for next steps.	Option paper for next steps	Eve Roodhouse	Programme Board	27 November 2015