Board Meeting – Public Session

Title of paper:	**National Data Opt-out Programme Directions**
Board meeting date:	6 September 2017
Agenda item no:	NHSD 17 03 04 b iii
Paper presented by:	Nic Fox Director of Provider Digitisation and Programmes
Paper prepared by:	Tim Magor Programme Head, National Data Opt-out Programme
Paper approved by: (Sponsor Director)	Nic Fox Director of Provider Digitisation and Programmes
Purpose of the paper:	To seek NHS Digital Board acceptance of the Directions for the implementation of the National Data Opt-Out Programme issued by the Department of Health.
Additional Documents and or Supporting Information:	Draft Directions dated 23 August 2017
Please specify the key risks and issues:	Key risks are timing of remaining policy decisions to support implementation and the timing and approach for the wider public communications and engagement. These are both key to building public trust and confidence in support of the Government's response to the National Data Guardian (NDG) Review of Data Security, Consent and Opt-Outs
Patient/public interest:	Direct – NDOP is developing a service that will be directly available to patients/public.
Supplementary papers:	No supplementary papers
Actions required by the Board:	To accept Directions for the National Data Opt-out Programme.

Official

National Data Opt-out Programme Directions

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Information and technology
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Contents

Executive Summary

The National Data Opt-out Programme (NDOP) is part of the Personalised Health and Care 2020 portfolio. It is tasked with creating, testing, consulting upon and implementing a national opt-out (on-line and in person) across the health and care system in England, which respects patients' preferences about how their personal confidential data is used for purposes beyond individual care. The Department of Health is now seeking to direct NHS Digital to undertake this work which will include collecting and processing data on patients' national opt-out preference.

The Board is asked to consider and accept the Directions (Annex A).

Background

The National Data Guardian (NDG) Review of Data Security, Consent and Opt-Outs was commissioned by the Secretary of State for Health and published on 6 July 2016. Following public consultation, the Government response Your Data: Better Security, Better Choice, Better Care was published on the 12 July 2017. It endorsed the NDG recommendation to provide a new national opt-out to give people a clear choice about how their personal confidential data is used for purposes beyond their individual care.

A patient should be able to state their preference once (on-line or in person) and be assured that this will be applied across the health and care system. NHS Digital has been commissioned to deliver the NDOP to implement the national opt-out, including designing and implementing a digital and non-digital mechanism for the public to record opt-outs, a system to hold these preferences centrally, and making these available for use across all health and care organisations. The Government response states that members of the public will start to set national opt-outs, and NHS Digital will start to uphold these from March 2018. All health and care organisations will be upholding the national opt-outs by March 2020.

NHS Digital currently collects and upholds type 2 patient opt-outs which prevent an individual's confidential patient information[1] being shared by NHS Digital for purposes beyond their individual care. The Government response sets out there will be a managed transition of type 2 opt-outs as part of the introduction of the national opt-out.

Recommendation

The proposed Directions provide a legal basis for NHS Digital to:

- collect, hold, and process data on patients' national opt-out status;
- conduct analysis of national opt-out data to enable NHS Digital to publish non patient identifiable information which enables data recipients to understand and manage the impact of national opt-outs; and
- use of the existing type 2 objections data for communication of the retirement of type 2 opt-outs and the transition arrangements to the national opt-out.

Following review and acceptance by the NHS Digital Board, the directions can be formally issued by the Department of Health.

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[1] This has the same meaning as "confidential patient information" defined in section 251 (11) of the National Health Service Act 2006.

Implications

Strategy Implications

This Direction supports the NHS Digital strategic vision as follows:

- Ensuring that every citizen's data is protected.
- Making better use of health and social care information.

Ensuring that NHS Digital is acting in accordance with individual's wishes will help in building public trust in the organisation's role as the national provider of information, data and IT systems for patients and service users in health and social care. This will in turn enable NHS Digital to fulfil its statutory functions to be the trusted 'safe haven' for health and care data in England.

Financial Implications

The NDOP programme has business case approval for the cost related to these Directions.

The Programme Business Case (PBC) for NDOP was approved on the 17 February 2017 by the Personalised Health and Care 2020 Technology and Data Investment Board (TDIB). The first tranche of the Outline Business Case was assured by the NHS Digital Investment Committee on 9 August 2017 and will be considered by TDIB on 15 September 2017.

Stakeholder Implications

Implementation of national opt-out is of significant interest to a wide range of stakeholders:

- **Patients across England** - Will need to be aware of the national opt-out and how they can set their national opt-out if they so choose. Those that have previously expressed type 2 opt-outs will need to be aware of the change, and potentially take further action;
- **Health and care professionals** - Will need to understand the national opt-out so that they can respond to patient queries, and reflect in their working practices;
- **Professional bodies** - Will need to fully understand the national opt-out, and support their membership in its adoption;
- **Health and care providers** - The national opt-out will need to be upheld across all health and care settings in England. This will therefore affect all local providers and public bodies that disseminate data for secondary uses across England (not anonymised in line with Information Commissions Office (ICO) guidance);
- **NHS Digital and other Arm's Length Bodies** - Will need uphold the national opt-out;
- **Bodies conducting analysis** will need to take account that national opt-outs may apply to the data they are using for research or other purposes;
- **Information Commissioner's Office (ICO)** – Will be interested in the progress of the implementation of the national opt-out;
- **Research bodies, third sector and patient representative groups** – Will support the implementation of the national opt-out by providing advice to the programme.

Handling

The impact of the publication of the Government response was limited but it is anticipated that as more detailed engagement commences there will be significant further interest. The programme has established processes to respond to general enquiries, freedom of information requests and media enquiries.

Risks and Issues

A risk register has been set up and is monitored and managed by NDOP. The highest rating risks are presented to the Programme Board every month. The key risks and issues to highlight to the NHS Digital Board are:

- risk that remaining key policy decisions are not made in a timely way - this will impact on the service being delivered to published timescales; and
- risk of the timing of wider communications on the benefits of data use in health and care – this will impact on public understanding of the national opt-out.

Corporate Governance and Compliance

NDOP is commissioned by the Department of Health through the Personalised Health and Care 2020 Portfolio on behalf of the health and social care system. The Senior Responsible Owner (SRO) is Katie Farrington, Director of Primary Care, Digital and Data, Department of Health. In carrying out the SRO function, the Department of Health will oversee the delivery of the Programme.

The Programme delivery is led by NHS Digital and reporting through the Programme Governance into the Personalised Health and Care 2020 Digital Delivery Board and NHS Digital Operations Board. External scrutiny is provided by the Infrastructure and Projects Authority and the NDOP Advisory Group.

Management Responsibility

The responsible Executive Director is Nic Fox, Director of Provider Digitisation and Programmes. The Programme Head for the National Data Opt-out Programme is Tim Magor.

Actions Required of the Board

The NHS Digital Board is asked to consider and accept the Directions set out in Annex A.

Annex A: Draft Directions as at 23 August 2017

Department
of Health

Sarah Wilkinson
Chief Executive,
NHS Digital
Trevelyan Square
Leeds
LS1 6AE

XX August 2017

Dear Sarah,

Thank you for NHS Digital’s work supporting the development of the Government response to, and delivery of the recommendations in, the National Data Guardian’s (NDG) Review of Data Security, Consent and Opt-Outs.

The review sets out recommendations for new data security standards and a national opt-out for data sharing which makes it clear to individuals when health and care data about them will be used; and, in what circumstances they can opt-out. The Government response accepts all of the NDG review’s recommendations and describes how we intend to deliver those recommendations.

NHS Digital has a critical role to play in continuing to support this programme, developing the implementation plan for the national opt-out and in preparing the national IT infrastructure that will allow the opt-out to be delivered in practice.

I am writing on behalf of the Secretary of State to provide a Direction to NHS Digital, formerly known as the Health and Social Care Information Centre and hereafter referred to as NHS Digital, to establish and operate a system for the collection and analysis of information, and to exercise such systems delivery functions, in respect of the new national opt-out model and the activities specified and described in this letter.

In accordance with section 254(2)(a) of the Act, the Secretary of State considers that the information is necessary or expedient to have in relation to his functions in connection with the provision of health services or of adult social care in England.

This Direction is given to NHS Digital in exercise of the powers of the Secretary of State for Health under section 254(1) and (6) and section 274(2) of the Health and Social Care Act 2012 (“the Act”) and regulation 32 of the National Institute for Health and Social Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 (the Regulations).

In accordance with the activities specified and described in this letter, and under section 254 of the Act and regulation 32 of the Regulations, NHS Digital is directed to:

(1) Collect the ‘patient opt-out data’, namely the record of those individuals who have registered an opt-out and store these against an individual’s NHS number, as well as relevant technical (or meta) data related to the setting of that opt-out e.g. time and date etc. for audit purposes.

(2) Establish a national repository for central storage of the patient opt-out data.

(3) Establish a new national opt-out system to enable health and care organisations to access the patient opt out data from the national repository, for the purposes of applying patient opt-outs to the patient data that they disseminate in accordance with the opt-out policy.

(4) In establishing the new system to write to all patients with a current type 2 objection to inform them of the transition to the new national opt-out and that their type 2 objection will be withdrawn. This should make clear any actions needed in line with the policy agreed by the Department of Health.

Analysis on the impact of national opt outs

As part of the system to be established and operated pursuant to paragraphs (1) to (3) above, NHS Digital is directed to:

(1) Undertake analysis of the patient opt-out data, in order to inform health and care organisations to aid their understanding of how the application of patient opt-outs may impact on the patient data being disseminated, for the purposes of their own analysis, research findings and performance measurement. This may include linking the patient opt-out data to other patient data held by NHS Digital. Any such analysis must be undertaken in such a way as to ensure that individuals are not identified and no confidential patient information is disseminated by NHS Digital.

(2) Apply NHS Digital Disclosure Control Procedures[2] before data resulting from analysis of patient opt-out data are shared or published.

Handling Type 2 objections with the new National Opt-Out system

Further to the Directions from the Secretary of State for Health dated 8th October 2015 [3] and the Directions dated 15th April 2016[4], and as part of the transition from type 2 objections pursuant to paragraph (4) above, NHS Digital is directed to:

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[2] http://content.digital.nhs.uk/media/23395/Disclosure-Control-Procedure/pdf/Disclosure_Control_Procedure.pdf

[3] [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/468439/patientobjectionsdirections.pdf] NHS Digital was directed, under Section 254 of the Health and Social Care Act 2012, by the Secretary of State for Health in October 2015 to collect Type 2 objection information from GP practices

[4] [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/517522/type2objections.pdf] NHS Digital was further directed, in April 2016, to uphold patients’ preferences to opt out of their data being disseminated from NHS Digital. The upholding of these directions commenced in April 2016.

(1) Use the list of NHS Numbers of all Type 2 objectors held within its Patient Objections Management System (POMS) data asset.

(2) Use the Personal Demographic System (PDS) which holds NHS Numbers, names and address details of all patients, to process the NHS Numbers held in POMS in order to obtain a match of NHS Numbers in the Personal Demographic System (PDS).

(3) Use the matched data, i.e. demographic data from PDS and Type 2 objectors NHS Numbers, to write to patients to inform them of the new opt-out. For the purposes of writing to individuals here, no confidential patient information will be accessed and no patient data will be processed for any other purpose.

(4) Further directions will be issued to NHS Digital setting out the agreed transition arrangements and date to commence upholding national opt-outs. NHS Digital will continue to operate the current process to collect and uphold Type 2 objections, as per the Direction issued on 15 April 2016 until further directed to stop doing so.

Notification of changes

NHS Digital is further directed to use the patient opt out data to contact patients with a registered opt-out if there are significant changes to the opt-out policy or if it is withdrawn.

In accordance with section 260 of the Act, NHS Digital will publish the information collected or analysed by complying with this Direction in a form which does not identify any individual or enable any individual to be identified, and may disseminate (other than by way of publication) the information to any persons it considers appropriate.

In exercising the functions under this Direction, NHS Digital must have regard to such priorities, policies, advice or guidance of the Secretary of State as the Secretary of State may notify in writing to NHS Digital.

This Direction supplements the following Directions:

- On the 8th October 2015, NHS Digital was directed by the Secretary of State for Health to collect Type 2 objection information from GP practices.
- On the 15th April 2016, NHS Digital was directed by the Secretary of State for Health to uphold Type 2 objections.

In accordance with regulation 32(2)(a) of the Regulations, the Secretary of State may make payments to NHS Digital for things done in the exercise of the function described in this direction.

In accordance with section 254(5) of the Act, NHS Digital has been consulted before this direction has been given.

Yours sincerely,

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