



Simon Bolton
Interim Chief Executive
NHS Digital
7 & 8 Wellington Place
Leeds
West Yorkshire
LS1 4AP

30 September 2021

Dear Simon,

1. National Disease Registries Directions 2021

- 1.1 I am writing on behalf of the Secretary of State for Health and Social Care (**the Secretary of State**) to provide Directions to the Health and Social Care Information Centre, known as and hereafter referred to in these Directions as **NHS Digital**.
- 1.2 These Directions are given in exercise of the powers conferred by sections 254(1) and (6), section 260(2)(d), section 261(2)(e) and section 304(9), (10) and (12) of the Health and Social Care Act 2012¹ (**the 2012 Act**) and Regulation 32 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013² (**the Regulations**).
- 1.3 In exercising the activities and functions described in these Directions, 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 from time to time to NHS Digital.

¹ 2012 c.7

² S.I. 2013/259

- 1.4 These Directions are to be known as the **National Disease Registries Directions 2021** and come into force on 1st October 2021.

2. Purpose

- 2.1 The purpose of these Directions (**Purpose**) is to support the transfer of responsibility for the operation and maintenance of the National Disease Registration Service, which comprises the National Cancer Registration and Analysis Service (**NCRAS**) and the National Congenital Anomaly and Rare Disease Registration Service (**NCARDS**), collectively the **National Disease Registries**, from Public Health England to NHS Digital as part of the closure of Public Health England and transfer of its functions.
- 2.2 The NCRAS aims to increase prevention and early diagnosis of cancer; and to improve the management of NHS cancer services, NHS cancer treatment and care, research and patient outcomes, including better quality of life and longer survival. The NCARDS aims to help the NHS in England, researchers, charities, people with congenital anomalies and rare diseases, and the public understand the prevalence of congenital anomaly and rare disease in England and to support wider understanding and treatment of these conditions.
- 2.3 The Directions enable NHS Digital to collect, analyse, publish and disseminate confidential patient information for medical purposes³ relating to:
- 2.3.1 Individuals referred for the diagnosis or treatment of cancer, and
 - 2.3.2 Individuals with suspected, confirmed, or high genetic risk of congenital anomalies and rare or inherited diseases, and appropriate members of their family, such as where relevant, the parents of a child or fetus with a congenital anomaly and younger siblings of a child with a rare or inherited disease.
- 2.4 Such purposes include but are not limited to:
- 2.4.1 the surveillance and analysis of health and disease;
 - 2.4.2 the monitoring and audit of health and health related care provision and outcomes where such provision has been made;
 - 2.4.3 the planning and administration of the provision made for health and health related care;
 - 2.4.4 medical research;

³ As defined in section 251(12) of the National Health Service Act 2006

2.4.5 the provision of information about individuals who have suffered from a particular disease or condition where:

2.4.5.1 that information supports an analysis of the risk of developing that disease or condition, and

2.4.5.2 it is required for counselling and support of a person who is concerned about the risk of developing that risk or condition or concerned about the risk of their child developing that risk or condition.

3. **Establishing and operating information systems for the National Disease Registries**

3.1 In accordance with sections 254(1) and 254(6) of the 2012 Act, the Secretary of State directs NHS Digital to establish and operate a system for the collection and analysis of information described in the National Disease Registries Requirements Specification version 1 issued with these Directions, which may be updated periodically (within the confines of the scope set out in these Directions) by NHS Digital and agreed in writing by the Secretary of State (the **Requirements Specification**). Such collection and analysis includes any operations, or set of operations which are undertaken in order to establish and maintain the National Disease Registries, including:

3.1.1 the recording and holding of information;

3.1.2 the retrieval, alignment and combination of information;

3.1.3 the organisation, adaption or alterations of information; and

3.1.4 the blocking, erasure and destruction of information.

3.2 The information system to be established under these Directions is to be known as the National Disease Registries Information System (the **Information System**).

3.3 For the avoidance of doubt, the collection referred to in paragraph 3.1 and further specified in the Requirements Specification includes:

3.3.1 collection of all historic data obtained from Public Health England pursuant to its operation and maintenance of the National Disease Registries, and

3.3.2 new information to be collected and obtained as a result of NHS Digital taking over the operation and maintenance of the National Disease Registries pursuant to these Directions.

3.4 Pursuant to the Secretary of State's powers under 254(1) and 254(6) of the 2012 Act, NHS Digital is directed to analyse the information collected pursuant to and/or obtained by NHS Digital under these Directions, as may

be requested by the Secretary of State or as NHS Digital determines is necessary to achieve the Purpose.

3.5 Such analysis referred to above includes:

3.5.1 analysis by reference or linkage to other data obtained by NHS Digital under any other direction to which it is subject under section 254 or a request made under section 255 of the 2012 Act, or any other lawful basis where NHS Digital is a controller⁴ of the other data, including but not limited to the data identified in the Requirements Specification;

3.5.2 analysis for data quality purposes, including undertaking comparison and consistency analysis of the same or similar information obtained through other information systems established by NHS Digital, and taking such steps as NHS Digital considers appropriate to maintain data quality, accuracy and consistency of information it has obtained under these Directions and across all information systems.

3.6 Under section 254(1) and (6) of the 2012 Act, NHS Digital is directed to put in place measures as part of the establishment and operation of the Information System:

3.6.1 to give effect to the specific National Disease Registries patient opt out for those individuals who opt out of their personal data being held in the Information System as further described in the Requirements Specification; and

3.6.2 to anonymise or pseudonymise confidential patient information where identifiable information is not necessary for the purposes for which it is to be disseminated.

3.7 The information held in the Information System may also be analysed by NHS Digital in the manner described and provided for in the **Covid-19 Public Health Directions 2020**⁵ issued to NHS Digital by the Secretary of State on 17th March 2020(as amended from time to time) for as long as those Directions remain in force.

3.8 NHS Digital is directed to carry out the activities above in accordance with the Requirements Specification and generally in such a way as to enable and facilitate the Purpose described above. The collection, dissemination and other use of data by NHS Digital under these Directions relating to the confidential patient information of patients referred for the diagnosis or treatment of cancer for the purposes set out in paragraph 2.4 above amounts to processing for medical purposes approved by the Secretary of State within Regulation 2(1) and 2(3) of the Health Service (Control of

⁴ As defined in Article 4(7) of the UK General Data Protection Regulation 2016

⁵ <https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notice/secretary-of-state-directions/covid-19-public-health-directions-2020>

Patient Information) Regulations 2002 (**COPI**). Section 261 of the Health and Social Care Act 2012 and Regulation 3 of COPI also applies.

4. Systems delivery functions for the National Disease Registries Directions

- 4.1 In accordance with Regulation 32 of the Regulations, the Secretary of State directs NHS Digital to exercise such systems delivery functions of the Secretary of State as are necessary for it to deliver the Information System.
- 4.2 The Secretary of State directs NHS Digital to exercise the functions described above in accordance with the service levels, support and monitoring requirements, and the reporting and governance requirements notified by the Secretary of State in writing to NHS Digital as at the date these Directions come into force, or as those requirements are amended and notified by an authorised officer of the Department for Health and Social Care on behalf of the Secretary of State in writing to NHS Digital from time to time.

5. Requirement for these Directions

- 5.1 In accordance with section 254(2)(b) of the 2012 Act, the Secretary of State considers that it is in the interests of the health service in England or of the recipients or providers of adult social care in England for these Directions to be given.
- 5.2 In accordance with section 254(5) of the 2012 Act, NHS Digital has been consulted before these Directions have been given.

6. Publication

In accordance with section 260(2)(d) of the 2012 Act, NHS Digital is directed not to publish information that is specified as not for publication in the Requirements Specification.

7. Dissemination

- 7.1 In accordance with section 261(2)(e) of the 2012 Act, NHS Digital may disseminate under section 261(1) of the 2012 Act the information it has obtained by complying with these Directions, where section 261(1) would otherwise not apply due to the restriction on publication in paragraph 6 above, and where it would be lawful for NHS Digital to do so.
- 7.2 Any information collected as a result of, or obtained by complying with, these Directions may also be disseminated by NHS Digital in accordance with its powers under section 261 of the 2012 Act or where otherwise it is lawful to do so.

8. Fees and Accounts

- 8.1 In accordance with regulation 32(2)(a) of the Regulations, the Secretary of State may make payments to NHS Digital for things done in connection with the exercise of the systems delivery functions referred to above.

8.2 NHS Digital must keep proper accounts, and proper records in relation to the accounts, in connection with the National Disease Registries Directions 2021.

9. **Duration**

NHS Digital is directed to operate the Information System and undertake the system delivery function referred to above (the **Directed Functions**) unless and until revoked by a further direction or instructed in writing by an authorised officer of the Department of Health and Social Care on behalf of the Secretary of State on reasonable notice to suspend and/or permanently cease the Directed Functions. Where the Directed Functions are to cease, such written request will also contain a direction to revoke these Directions in accordance with the timescales and arrangements to be agreed with NHS Digital.

10. **Review of these Directions**

These Directions will be reviewed when the Requirements Specification is amended. This review will include consultation with NHS Digital.

Yours sincerely,

A handwritten signature in black ink that reads "A. P. Madden". The signature is written in a cursive style with a large initial 'A' and 'M'.

Signed by authority of the Secretary of State

Date signed: 30 September 2021

ANNEXES - NATIONAL DISEASE REGISTRIES REQUIREMENTS SPECIFICATION

Published alongside the National Disease Registries Directions 2021 are:

- **Annex A** - Requirements Specification for the National Cancer Registration and Analysis Service (NCRAS)
- **Annex B** - Requirements Specification for the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS)