



Department of Health & Social Care

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

13 July 2020

Dear Sarah

1. **Surgical Devices and Implants Directions 2020**

- 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) and section 304(9), (10) and (12) of the Health and Social Care Act 2012¹ (**the 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

¹ 2012 c.7

² S.I. 2013/259

the Secretary of State as the Secretary of State may notify in writing from time to time to NHS Digital.

1.4 These Directions are to be known as the **Surgical Devices and Implants Directions 2020** and come into force on 13 July 2020.

1.5 These Directions replace the Surgical Devices and Implants Directions 2019, which are hereby revoked.

2. Purpose

The purpose of these Directions (**Purpose**) is to enable NHS Digital to collect and analyse information that NHS Digital does not already collect under separate directions regarding surgical devices and implants; and to collect and analyse information regarding alternative procedures³ (**Alternative Procedures**) for the same medical conditions which do not result in a surgical device or implant, in order to enable comparison of patient outcomes associated with surgical devices and implants.

3. Establishing and operating information systems for the Surgical Devices and Implants Directions data collection

3.1 In accordance with sections 254(1) and 254(6) of the Act, the Secretary of State directs NHS Digital to establish and operate such systems for the collection and analysis of information described in the Surgical Devices and Implants Requirements and Technical Specifications (**the Specification**) issued with these Directions, such system to be known as **Surgical Devices and Implants Information System**.

3.2 The information to be collected and analysed will be collected from providers of NHS funded care including NHS Providers and Independent Sector Healthcare Providers in England and from private healthcare providers in England.

3.3 Under section 254(1) and (6) of the Act, NHS Digital is directed to:

- collect and analyse patient information relating to surgical devices and implants. This will include reference data about manufacturers of devices and implants, e.g. batch number, serial number;
- collect and analyse information regarding Alternative Procedures for the same medical conditions which do not result in a surgical device or implant, in order to enable comparison of patient outcomes associated with surgical devices and implants;

³ An alternative procedure is any procedure undertaken that did not involve a surgical device or implant which was carried out as an alternative to a procedure involving a surgical device or implant, e.g. use of a coronary artery bypass graft (CABG) instead of a coronary angioplasty involving an insertion of a stent

- trace NHS numbers, where not available, and where possible to trace for those patients whose NHS number was not initially supplied to allow unique identification and linkage;
- track latest known patient address in the event of a product failure;
- monitor the outcomes achieved by ‘brand’ of device or implant, hospital and surgeon, and highlight where these fall below an expected performance in order to allow prompt investigation and to support follow-up action.

3.4 NHS Digital is directed to carry out the activities above in accordance with the Specification and generally in such a way as to enable and facilitate the Purpose described above. The Specification may be updated periodically and agreed in writing (within the confines of the scope set out in these Directions) by NHS Digital and the Department for Health and Social Care on behalf of the Secretary of State.

4. **Analysis and linkage**

4.1 Pursuant to the Secretary of State’s powers under 254(1) and 254(6) of the Act, NHS Digital is further directed to analyse the information collected pursuant to these Directions, including by such reference or linkage to other data obtained by NHS Digital under the Act or on any other lawful basis where NHS Digital is a controller⁴ of the data either now or in the future, as NHS Digital determines is necessary to achieve the Purpose.

4.2 The information to be collected for the Surgical Devices and Implants Directions 2020 may also be analysed by NHS Digital in the manner described and provided for in the **Life Sciences Directions 2019** issued to NHS Digital by the Secretary of State on 21 October 2019 (as the same may be amended from time to time), for as long as those Directions remain in force.

5. **Systems delivery functions for the Surgical Devices and Implants Directions data collection**

5.1 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 **Surgical Devices and Implants Information System**.

5.2 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

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

these Directions come into force, or as those requirements are amended and notified by the Secretary of State in writing to NHS Digital from time to time.

6. Requirement for these Directions

- 6.1 In accordance with section 254(2)(b) of the Act, the Secretary of State considers it to be 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.
- 6.2 In accordance with section 254(5) of the Act, NHS Digital has been consulted before these Directions have been given.

7. Publication

In accordance with section 260(2)(d) of the Act, NHS Digital is directed not to publish information that is specified as not for publication in the Specification. Any other information must be published in line with NHS Digital's duty under section 260(1) of the Act.

8. Dissemination

- 8.1 In accordance with section 261(2)(e) of the Act, despite the prohibition on publication above, NHS Digital may disseminate the information it has obtained by complying with these Directions, under section 261(1) of the Act, where it would be lawful for NHS Digital to do so ..
- 8.2 NHS Digital is further directed under section 262(3)(a) to exercise its powers under section 261(4) to disseminate, in such form and manner and at such times as it considers appropriate, the information it collects pursuant to these Directions to any person to whom the information could have been lawfully disclosed by the person from whom NHS Digital collected the information.
- 8.3 Any information collected and/or obtained as a result of these Directions may also be disseminated by NHS Digital in accordance with its powers under section 261 of the 2012 Act. This may include dissemination of information to the Department of Health and Social Care, NHS England, the Care Quality Commission and the Medicines and Healthcare products Regulatory Agency, to support the Purpose of these Directions, and where it would be lawful for NHS Digital to do so. The information disseminated will be subject to appropriate data sharing agreements.

9. Fees and Accounts

- 9.1 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.

9.2 NHS Digital must keep proper accounts, and proper records in relation to the accounts, in connection with the **Surgical Devices and Implants Directions 2020**.

10. **Duration**

NHS Digital is directed to operate the Surgical Devices and Implants Information System and undertake the systems delivery function referred to above (the **Directed Functions**) unless and until instructed in writing by an authorised officer of the Department of Health on behalf of the Secretary of State on reasonable notice to suspend and/or permanently cease the Directed Functions. Where a Directed Function is 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.

11. **Review of these Directions**

These Directions will be reviewed when the Specification is amended. This review will include consultation with NHS Digital as required by section 254(5) of the Act.

Yours sincerely



Helen Beazer

Head of Policy, Acute Care and Provider Policy