



Department
of Health &
Social Care

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

21 October 2019

Dear Sarah,

Life Sciences Directions 2019

I am writing to provide directions to the Health and Social Care Information Centre, known as, and hereafter referred to in these Directions as, NHS Digital.

These Directions are given in exercise of the powers conferred by sections 254(1), 254(2)(b), 254(5) and (6), 260(2)(d) and 304(9), (10) and (12) of the Health and Social Care Act 2012 (**the Act**).

These Directions are to be known as the '**Life Sciences Directions 2019**' and come into force on the date signed. In exercising the functions described in these Directions, NHS Digital must have regard to such priorities, policies, advice or guidance of the Secretary of State for Health and Social Care as the Secretary of State may notify in writing from time to time to NHS Digital.

Purpose

The purpose of these Directions (**Purpose**) is to enable NHS Digital to support the Government's response¹ to the *National Data Guardian Report*² and the *Life Sciences: Industrial Strategy*³ by meeting the demand for anonymised and pseudonymised health and social care data and the analysis and dissemination of such data for research and innovation, planning, commissioning, population health, and policy

¹ <https://www.gov.uk/government/consultations/new-data-security-standards-for-health-and-social-care>

² <https://www.gov.uk/government/publications/review-of-data-security-consent-and-opt-outs>

³ <https://www.gov.uk/government/publications/life-sciences-industrial-strategy>

making. They will also contribute to meeting the WHO Global Patient Safety Challenge “*Medication without Harm*⁴”.

The Directions support these demands by enabling NHS Digital to convert the record level information it has currently obtained (under previous directions made under section 254 and mandatory requests made under section 255 of the Act) into anonymised and pseudonymised forms; to analyse that information, including through linkage of different datasets and to make that information available for dissemination in an anonymised and, where this is lawful, in pseudonymised form. The information would be pseudonymised in the sense that it will not be disseminated by any means which may lead to the identification of an individual, unless it would otherwise be lawful in the circumstances for NHS Digital to do so. In doing so the Directions will enable NHS Digital to meet the key objectives listed below (**Key Objectives**).

Key Objectives

The Key Objectives of these Directions is to generate pseudonymised and anonymised data which can be:

- used or further analysed to create insights that will deliver outputs to support a range of secondary uses, including but not limited to public health, health and social care commissioning, health and social care benchmarking, clinical trials, health and social care system operational performance, research, including medical research and development of new treatments, health and social care management planning, population health management, citizen and patient health improvement, health and social care policy development, and health and social care service improvement;
- examples of use of these types of data could include but are not limited to:
 - understanding patient outcomes variation by area to address inequalities in cancer care as identified in the NHS Long Term Plan;
 - creating more powerful emergency demand predictors to better support effective management of emergency demand flow across areas;
 - enhancing efficiency and improving patient safety through, for example, analysing data to reduce Did Not Attend rates in patients.
- used to improve and build new clinical tools and technology that will improve patient care and citizen health; and

⁴ <http://www.who.int/patientsafety/medication-safety/medication-without-harm-brochure/en/>

- disseminated to a variety of organisations to include commissioning organisations, arms' length bodies, providers (both health and social care, primary, secondary and tertiary), central government, the private sector, universities and to research & health organisations involved in the improvement of health and care.

Directions to establish an Information System

Pursuant to sections 254(1) and 254(6) of the Act, NHS Digital is directed to establish and operate a system for the analysis of information which has been obtained by NHS Digital complying with:

- the directions issued to NHS Digital under section 254(1) of the Act by either the Secretary of State for Health and Social Care or the NHS Commissioning Board (known as NHS England); and
- the mandatory requests made to NHS Digital under section 255 of the Act by a Principal Body,⁵

as described in the Specification entitled “**Life Sciences Information Assets**” attached as an Annex to these Directions.

Analysis

NHS Digital is directed to anonymise or pseudonymise the information to be analysed and to carry out such analysis on this information as NHS Digital considers appropriate and, in a manner, that NHS Digital considers appropriate, so as to enable and facilitate the achievement of the Purpose and Key Objectives. This includes but is not limited to linkage of the different information identified in the Specification and the production of analytical descriptive,⁶ predictive⁷ and prescriptive⁸ models.

Prohibition on Publication

⁵ Health and Social Care Act 2012 section 255(9) Principle Body means Monitor, the Care Quality Commission, the National Institute for Health and Care Excellence and such other persons as may be prescribed in regulations

⁶ Descriptive - describing a situation or circumstance. For example, clinical indicators which say 1000 in 100,000 people developed condition Z last year, which is known as a result of reviewing the historical data covering the past year, counting the number of cases, and dividing by the total population to get the condition Z rate.

⁷ Predictive - predicting what the value of something unknown will be. For example, observing that people who developed condition Z last year had X and Y in common, therefore it can be predicted that next year people who have X and Y are more likely to develop condition Z, while those who do not have X and Y are less likely to develop condition Z. A model can then be provided to predict the likelihood of different people developing condition Z.

⁸ Prescriptive - prescribing what should be done. For example, where we know that people with X and Y are more likely to develop condition Z, we could intervene in advance so as to reduce the level of risk of people developing condition Z where X and Y are present.

In accordance with section 260(1), NHS Digital must publish the information which it obtains by complying with this Direction. However, pursuant to section 260(2)(d) it is directed not to publish information that NHS Digital does not reasonably consider would support the achievement of the Purpose and Key Objectives above.

These Directions do not affect any existing direction made which cites section 260(2)(d) of the Act to prohibit the publication of information previously obtained by NHS Digital as a result of complying with a direction or mandatory request identified in the Specification. Therefore, pursuant to section 260(2)(d) of the Act, NHS Digital is directed not to publish any further information obtained by complying with these Directions which it was previously directed not to publish.

NHS Digital must take all reasonably practicable steps to ensure that no information processed under these Directions is disseminated or published by any means which may lead to the identification of an individual, unless it would otherwise be lawful in the circumstances for NHS Digital to do so.

In accordance with section 254(2)(b) of the Act, the Secretary of State considers that it is in the interests of the health service or of the recipients or providers of adult social care in England for these Directions to be given.

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

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Gary Cook', written over a horizontal line.

Gary Cook
Deputy Director, Life Sciences Industrial Strategy Projects and Genomics