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BOARD PAPER - NHS ENGLAND

Title: The Health and Social Care Information Centre (Establishment of Information Systems for NHS Services: Collection and Analysis of Primary Care Data) Directions 2015
From: Tim Kelsey, National Director for Patients and Information
Purpose of paper: • The purpose of this paper is to present the Health and Social Care Information Centre (Establishment of Information Systems for NHS Services: Collection and Analysis of Primary Care Data) Directions 2015.
The Board is invited to: • review and comment on the Directions to the Health and Social Care Information Centre for the collection of Primary Care Data; and • approve the Directions.

Purpose

1. The purpose of this paper is to present the Health and Social Care Information Centre (Establishment of Information Systems for NHS Services: Collection and Analysis of Primary Care Data) Directions 2015 for comment and approval.

2. The Directions will be issued to the Health and Social Care Information Centre (HSCIC) by NHS England only when the National Data Guardian (Dame Fiona Caldicott) has provided advice to the Secretary of State to confirm that she is satisfied with the proposals and safeguards; the HSCIC Board has considered that advice; and the care.data Programme Board have confirmed the decision to extract.

3. The 2013 Directions that these new Directions replace will be withdrawn by NHS England at the same time as the new Directions are issued.

Background

4. In February 2014, 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.

5. 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'.

6. 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.

7. The programme progressed 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.

8. 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.

9. The 2013 Directions now need to be withdrawn and new Directions issued to reflect these changes.

Directions to the HSCIC for the collection of primary care data

10. The Directions appended in Annex 1 have been developed by NHS England in consultation with the HSCIC, as required by the Act, and also with input from the Department of Health. They have also been reviewed by lawyers from NHS England and HSCIC.

11. These Directions will replace the previous version, Health and Social Care Information Centre (Establishment of Information Systems for NHS Services: Collection and Analysis of Primary Care Data) Directions 2013. The existing Directions are provided for reference in Annex 2.

12. The Directions establish a legal basis to facilitate the collection, analysis and dissemination of data from pathfinder practices as defined in the care.data GP data specification v1.1 published by HSCIC on 12 February 2014. The key features of this specification that are explicitly addressed are:
    i. collection and analysis of data from primary care systems and linkage to Hospital Episodes Statistics;
    ii. data items to be collected;
    iii. fees to cover the cost of implementing these directions;
    iv. provisions for review of the directions.

Changes introduced in these directions

13. In September 2014, the programme's application to the General Practice Extraction Service (GPES) Independent Advisory Group (IAG) for extending access to the linked GP-hospital dataset for research and health intelligence purposes was recommended to proceed subject to changes (e.g. greater clarity around controls, IIGOP involvement). This has been reflected in the 2015 Directions.

14. The organisations that the HSCIC will disseminate information to in support of these purposes have been limited to NHS England, Public Health England, the Care Quality Commission and the Pathfinder CCGs and GP Practices in the pathfinder stage.

15. Direction on dissemination is removed as these directions apply to the collection and analysis rather than the dissemination of primary care data. HSCIC's power to disseminate data is set out in the Health and Social Care Act 2012.

16. Detailed direction on the management of patient objections has been removed and will be replaced by a direction to be issued by the Secretary of State. This is because patient objections are broader than the care.data programme so the Department of Health expressed a wish for this to be dealt with separately.

17. The scope of these Directions is limited to the pathfinder stage of the programme. Further Directions will be required should it be agreed that the scope of the collection be extended e.g. beyond the pathfinders or to a wider range of data.

18. These directions will be reviewed and updated as required, including where new collections are agreed, or annually if this is earlier.

Decisions Required

19. The Board is asked to review and comment on the Directions to the Health and Social Care Information Centre for the collection of primary care data.

20. The desired outcome is that the Board will approve the Directions.

Tim Kelsey
National Director for Patients and Information

DIRECTIONS

NATIONAL HEALTH SERVICE, ENGLAND

The Health and Social Care Information Centre (Establishment of Information Systems for NHS Services: Collection and Analysis of Primary Care Data) Directions 2015

The National Health Service Commissioning Board hereby gives the following Directions to the Health and Social Care Information Centre in exercise of the powers conferred by sections 254(1), (3) and (6), 304(9), (10) and (13) of the Health and Social Care Act 2012.

In accordance with section 254(5) of the Health and Social Care Act 2012, the National Health Service Commissioning Board has consulted the Health and Social Care Information Centre before giving these Directions.

Citation, commencement and repeal of existing directions

1. (1) These Directions may be cited as The Health and Social Care Information Centre (Establishment of Information Systems for NHS Services: Collection and Analysis of Primary Care Data) Directions 2015 and shall come into force on **[insert date]**.

   (2) These Directions are given to the Health and Social Care Information Centre by the National Health Service Commissioning Board.

   (3) The Health and Social Care Information Centre (Establishment of Information Systems for NHS Services: Collection and Analysis of Primary Care Data) Directions 2013 are hereby repealed.

Interpretation

2. In these Directions:-

“The 2012 Act”	means the Health and Social Care Act 2012;

“the Board”	means the National Health Service Commissioning Board[1];
“care.data Programme Board”	means the group chaired by the Board’s National Director for Patients and Information that is responsible for the ensuring that the care.data programme is managed and resourced well, that it delivers the benefits required, manages costs and risks, and operates lawfully;
“Care Quality Commission”	means the body corporate established by section 1 of the Health and Social Care Act 2008;
“CCG”	means Clinical Commissioning Group;
“General Medical Practitioner”	means a medical practitioner whose name is included in the General Practitioner Register kept by the General Medical Council;
“General Practice”	means the business operated by one or more General Medical Practitioners for the purpose of delivering services under a General Medical Services Contract, Personal Medical Services or Alternative Provider Medical Services contract;
“The Health and Social Care Information Centre”	means the body corporate established by section 252 of the 2012 Act;
“the HSCIC”	means The Health and Social Care Information Centre;
“HES”	means the Hospital Episodes Statistics database held by the HSCIC;
“Primary Care Data”	means data collected or generated by systems operated in support of general medical services, personal medical services or alternative provider medical services;
“the Pathfinder CCGs”	means the CCGs listed in the schedule to these Directions, of whom the Pathfinder General Practices are members and any additions to or removals from this list as may be notified to the HSCIC by the Board in writing following the approval of the care.data Programme Board;
“the Pathfinder General Practices”	means the General Practices listed in the schedule to these Directions and any additions to or removals from this list as may be notified to the HSCIC by the Board in writing following the approval of the care.data Programme Board.
"Public Health	means the unit within the Department of Health which has that title and has operational responsibility for fulfilling the

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[1] The National Health Service Commissioning Board was established by section 1H of the National Health Service Act 2006 (2006 c 41.), and operates as NHS England.

England"	Secretary of State's functions under the 2012 Act with regard to public health

Establishment of Information Systems: primary care data

3. (1) In exercise of its powers in section 254(1) and Section 254(6) of the 2012 Act the Board hereby directs the HSCIC to establish and operate systems for the collection and analysis of information as further described and specified in sub-paragraph 3(2) and paragraph 4.

(2) The HSCIC is directed to establish and operate systems pursuant to sub-paragraph 3(1) to collect Primary Care Data from the Pathfinder General Practices and to analyse that data to enable the activities described in paragraph 3(4). The description of the Primary Care Data to be collected and of the actions to be taken by HSCIC to analyse the data is specified in paragraph 4.

(3) In accordance with section 254(3) of the 2012 Act, the Board confirms that it is necessary and expedient for it to have the information which will be obtained through the HSCIC complying with these Directions in relation to the Board’s exercise of functions in connection with the provision of NHS services, and in particular to enable the purposes further described in sub-paragraph 3(4).

(4) The collection and analysis of Primary Care Data by the HSCIC pursuant to these Directions will enable the Board to develop and test the processes required to support the effective future collection and analysis of certain Primary Care Data from General Practices as part of the care.data programme generally including analysis of data as described in paragraph 4 of these Directions. It is necessary and expedient to work towards and facilitate such future data collection and analysis as this will enable the Board to carry out the following activities or to facilitate the carrying out of such activities by other bodies including Public Health England, the Care Quality Commission, CCGs and General Practices through the sharing of information with those bodies in accordance with the Board's statutory functions and powers:

(a) identification, evaluation and improvement of NHS care pathways across primary and secondary care;
(b) design or commissioning of services tailored for individuals and communities;
(c) conduct of research; and
(d) analysis of data for health intelligence purposes, including for public health and healthcare regulatory purposes]

Data to be collected and analysed

4. (1) The HSCIC is directed by the Board pursuant to paragraph 3 of these Directions to:

    (a) collect from Pathfinder General Practices the Primary Care Data items listed in the Care.data GP data specification v1.1 published by HSCIC on 12th February 2014 attached at Annex 1 of these Directions;

    (b) de-select at the point of collection, those clinical data entries that contain codes listed in the Care.data GP data specification v1.1 published by HSCIC on 12th February 2014 under the heading "Do not extract terms from this set".

    (3) The HSCIC is further directed by the Board pursuant to paragraph 3 of these Directions to analyse the Primary Care Data collected in accordance with sub-paragraphs 4(1) and 4(2) through:

    (a) linking it to data held in HES; and

    (b) carrying out such other forms of data analysis in relation to the data, including data manipulation and report-generation, as the HSCIC determines to be reasonable or as are reasonably requested by the Board or the other organisations listed in sub-paragraph 3(4) for the purposes set out in sub-paragraph 3(4).

Managing patient objections

6. For the avoidance of doubt or ambiguity, the Board notes that in complying with these Directions the HSCIC will also need to comply with such other directions as the Secretary of State may give to HSCIC under section 254 of the 2012 Act with regard to recognising and respecting patient objections to the collection, analysis and dissemination of their data by the HSCIC. These Directions shall be interpreted and applied in a manner which is consistent with such other Directions from the Secretary of State and in the event of any conflict between these Directions and such other directions of the Secretary of State with regard to the requirements on the HSCIC as to management of patient objections, such other directions of the Secretary of State shall have precedence.

Fees and accounts

7. Pursuant to sub-section 254(7) of the 2012 Act, HSCIC is entitled to charge the Board a reasonable fee in respect of the cost of HSCIC complying with these Directions and the

Board acknowledges such right and agrees to meet such reasonable fee charged by HSCIC.

Review of these Directions

8. These directions will be reviewed and updated as required, including where new collections are agreed, or annually if this is earlier. This review will include consultation with the HSCIC as required by section 254(5) of the 2012 Act (powers to direction Information Centre to establish information systems).

Signed by authority of the NHS Commissioning Board

Sir Bruce Keogh
Caldicott Guardian

[INSERT DATE]

SCHEDULE

Pathfinder CCGs

ODS Code	**CCG Name**
11X	NHS Somerset CCG
00Q	NHS Blackburn with Darwen CCG
11A	NHS West Hampshire CCG

Pathfinder General Practices

DN - To be confirmed

Annex 1

CareData Clinical Code specification v1

caredata-gp-data-spec v1.1.xls

DN – This specification will be replaced with updated version before the Directions are issued. HSCIC expect publication in June 2015.

DIRECTIONS

NATIONAL HEALTH SERVICE, ENGLAND

The Health and Social Care Information Centre (Establishment of Information Systems for NHS Services: Collection and Analysis of Primary Care Data) Directions 2013

The National Health Service Commissioning Board hereby gives the following Directions to the Health and Social Care Information Centre in exercise of the powers conferred by sections 254(1), (3) and (6), 260 (4)(a), 262(1), (3)(a), (5),(7)and 304(9), (10) and (13) of the Health and Social Care Act 2012.

In accordance with section 254(5) of the Health and Social Care Act 2012, the National Health Service Commissioning Board has consulted the Health and Social Care Information Centre before giving these Directions.

Citation and commencement

1. (1) These Directions may be cited as The Health and Social Care Information Centre (Establishment of Information Systems for NHS Services: Collection and Analysis of Primary Care Data) Directions 2013 and shall come into force on [insert date].

   (2) These Directions are given to the Health and Social Care Information Centre by the National Health Service Commissioning Board.

Interpretation

2. In these Directions:-
   “the Act” means the Health and Social Care Act 2012;
   “the Board” means the National Health Service Commissioning Board established by section 1H(1) of the National Health Service Act 2006;
   “the Health and Social Care Information Centre” means the body corporate established by section 252 of the Act;
   “the HSCIC” means the Health and Social Care Information Centre;
   “HES” means the Hospital Episodes Statistics database held by the HSCIC;

"identifiable data" means information which is in a form which identifies any individual to whom the information relates or enables the identity of such an individual to be ascertained;
“primary care data” means data collected or generated by systems operated in support of general medical services, personal medical services or alternative provider medical services;
“pseudonymised” has the meaning given in Appendix C of Care Episode Statistics: Technical Specification of the GP Extract published by the Board on 29th May 2013 and attached at Annex 1 of these Directions; and
"re-identification" has the meaning given in Appendix C of Care Episode Statistics: Technical Specification of the GP Extract published by the Board on 29th May 2013 and attached at Annex 1 of these Directions and "re-identify" shall be interpreted accordingly.

Establishment of Information Systems: primary care data

3. (1) In exercise of its powers in section 254(1) and Section 254(6) of the Act the Board hereby directs the HSCIC to establish and operate systems for the collection and analysis of information as further described and specified in sub-paragraph 3(2) and paragraph 4.

   (2) The HSCIC is directed to establish and operate systems pursuant to sub-paragraph 3(1) to collect primary care data and to analyse that data, including analysis through linking that data to HES data held by the HSCIC, to enable the activities described in paragraph 3(4). The detailed description of the primary care data to be collected and of the actions to be taken by HSCIC to analyse the data is further specified in paragraph 4.

   (3) In accordance with section 254(3) of the Act, the Board confirms that it is necessary and expedient for it to have the information which will be obtained through the HSCIC complying with these Directions in relation to the exercise of functions in connection with the provision of NHS services, and in particular to enable the effective and appropriate commissioning of NHS services by the Board and other NHS commissioners as further described in sub-paragraph 3(4).

   (4) The collection and analysis of primary care data by the HSCIC pursuant to these Directions, including the linking of primary care data to the HES, will enable the Board and other NHS commissioning organisations or others acting on their behalf to identify and evaluate the overall NHS care pathway, across primary and secondary care, in relation to particular categories of patient or condition, resulting in the following benefits in relation to the exercise of commissioning and other health service functions:

For communities

(a) enabling the design of health services according to comprehensive needs assessment;
(b) enabling communities to become more active in the planning, redesign and prioritisation of local care services through the provision of information that reflects the end-to-end process of care;
(c) enabling the provision of integrated care through the use of linked data;

For patients

(d) accommodating patients' right to know that unexplained variations in how care is provided will be identified and addressed swiftly;
(e) providing confidence that services are planned in a coordinated way, and that planning is centred on patient pathways;
(f) ensuring that clinical outcomes are measured in transparent ways, based on an appropriate set of data;

For GPs and other primary care clinicians

(g) improved monitoring of outcomes through linkage between primary and secondary care;
(h) improved monitoring of performance through linkage between primary and secondary care;
(i) earlier diagnosis of illness;
(j) improving the contribution of primary care to wider Clinical Commissioning Group outcomes;
(k) improved data quality;
(l) monitoring and understanding trends;
(m) predictive modelling;
(n) evaluation of preventive services and interventions;
(o) exploring patient pathways;
(p) detecting unwarranted variation.

Data to be collected and analysed

4. (1) The HSCIC is directed by the Board pursuant to paragraph 3 of these Directions to collect from General Practitioner practices the data items listed in Appendix A of Care Episode Statistics: Technical Specification of the GP Extract published by the Board on 29th May 2013 attached at Annex 1 of these Directions.

(2) However the HSCIC is directed to de-select at the point of collection, those clinical data entries that contain any of the "sensitive" codes listed in Appendix B of Care Episode Statistics: Technical Specification of the GP Extract published by the Board on 29th May 2013 attached at Annex 1 of these Directions.

(3) The HSCIC is further directed by the Board pursuant to paragraph 3 of these Directions to analyse the primary care data collected in accordance with sub-paragraphs 4(1) and 4(2) through:

(a) linking it to data held in HES in accordance with Care Episode Statistics: Technical Specification of the GP Extract published by the Board on 29th May 2013 attached at Annex 1 of these Directions; and

(b) carrying out such other forms of data analysis in relation to the data, including data manipulation and report-generation, as the HSCIC determines to be reasonable or as are reasonably requested by the Board or other NHS commissioning organisations.

Publication and dissemination

5. In exercise of its powers under section 260(4)(a) the Board hereby directs the HSCIC that publication of any information which was obtained by complying with these Directions shall only be made in a form which complies with:

(1) the guidance published by the Information Commissioner's Office: Anonymisation: managing data protection risk code of practice attached at Annex 2 of these Directions (or as the same may be updated from time to time) ; and

(2) the Anonymisation Standard for Publishing Health and Social Care Data Specification published by the Information Standards Board dated 21 February 2013 attached at Annex 3 of these Directions (or as the same may be updated from time to time),

including the approach to small number suppression set out in those documents.

6. In exercise of its powers under section 262(1) and 262(3)(a) and 262(7) of the Act, the Board makes the following directions to the HSCIC:

(1) The Board directs the HSCIC to disseminate information obtained by complying with these Directions (including the primary care data, any information obtained through analysis of that data as required by these Directions and any sub-set of that data or information) pursuant to section 262(1) of the Act and by exercising its power under sections 261 (4) of the Act to the NHS Commissioning Board, other NHS commissioning organisations and other bodies to the extent that the HSCIC considers such a request to be reasonable, where the conditions set out in sub-paragraph (2) are met;

(2) The HSCIC may only disseminate the data under paragraph 6(1) if:

(a) The recipient is a health service body, a provider of NHS-funded services or a local authority engaged in joint commissioning with an NHS organisation, or a person acting on behalf of any such body, and the information is to be used by that person or body for purposes relating to the exercise of public functions;

(b) The data are pseudonymised and the HSCIC is appropriately assured that the recipient would not be able to re-identify individuals from the information to be provided when linked to other information held by or likely to come into the possession of the recipient; and

(c) The recipient has signed a written agreement with the HSCIC which specifies the data to be made available, the purpose for which the recipient will use the data and the terms on which that data may be shared and re-used.

7. In exercise of its powers under section 262(5) of the Act the Board hereby directs the HSCIC not to exercise its power under section 261(1) or (4) in relation to information that it obtains by complying with these Directions to disseminate:

(1) identifiable data; or

(2) pseudonymised data to the extent that the HSCIC reasonably considers that the proposed recipient of the data would be able to re-identify individuals from the information to be provided when linked to other information held by or likely to come into the possession of the recipient.

Managing patient objections

8. The HSCIC is directed by the Board pursuant to paragraph 3 of these Directions to put measures in place as part of the establishment and operation of the information systems which are the subject of these Directions to ensure that where any primary care data are coded to indicate a patient's objection to disclosure of their identifiable primary care data to the HSCIC or any third party, to the extent that the HSCIC is acting in pursuance of these Directions in relation to that patient the HSCIC will only collect non-identifiable primary care data and those data items necessary to enable the HSCIC to record the fact of the patient's objection and that the data items necessary to record the fact of the patient's objection shall be collected and stored separately from other information to be collected in order to prevent any possibility of identification or re-identification of the patient within the HSCIC.

Review of these Directions

9. These directions will be reviewed and updated as required, including where new collections are agreed, or annually if this is earlier. This review will include consultation with the HSCIC as required by section 254(5) of the Act (powers to direction Information Centre to establish information systems).

Signed by authority of the NHS Commissioning Board

Sir Bruce Keogh
Caldicott Guardian

[INSERT DATE]

Annex 1

Care Episode Statistics: Technical Specification of the GP Extract

ces-tech-spec-gp-extract.pdf

Annex 2

Anonymisation: managing data protection risk code of practice

anonymisation_code.pdf

Annex 3

Anonymisation Standard for Publishing Health and Social Care Data Specification

1523202010spec.pdf

EXPLANATORY NOTE

(This note is not part of the Directions)

These Directions are published by the NHS Commissioning Board (which operates as NHS England) in exercise of its powers under section 254 of the Health and Social Care Act 2012 to direct the Health and Social Care Information Centre (the Information Centre) to establish information systems.

The rationale behind the Directions is to facilitate the information system defined in the Care Episodes Statistics: Technical Specification of the GP Extract published in May 2013 by NHS England[1]. This defines release 1 of the care.data system, which includes linkage of primary care data to data on hospital activity. Analysis of the resulting data will provide NHS Commissioners and the public with information better to understand the overall NHS care pathway, and to facilitate commissioning of services and improvement of services.

The key components of the Directions are:

- direction to the Information Centre to collect primary care data and link this to Hospital Episodes Statistics as the first stage of analysis (sub-paragraphs 3(1)-3(3) and sub-paragraph 4(3)(a));
- direction to the Information Centre to carry out further analysis including data manipulation and report generation as may be requested by commissioners (sub-paragraph 3(4) and sub-paragraph 4(3)(b);
- explanation of benefits for communities, patients, GPs and other clinicians (sub-paragraph 3(4));
- specification of the data items to be collected – with reference to the Technical Specification (sub-paragraph 4(1));
- specification of “sensitive” data items to be excluded – also with reference to the Technical Specification (sub-paragraph 4(2));
- direction to the Information Centre to comply with the guidance published by the Information Commissioner’s Office: Anonymisation: managing data protection risk code of practice[2], and the Anonymisation Standard for Publishing Health and Social Care Data Specification published by the HSCIC[3] (paragraph (5));
- direction to the Information Centre is to disseminate record level data to NHS Commissioners – with specified controls in place to ensure confidentiality is maintained (paragraph (6));
- direction to the Information centre not to disseminate identifiable data (paragraph (7));
- management of patient objections (paragraph (8)).

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[1] http://www.england.nhs.uk/ourwork/tsd/data-info/

[2] http://www.ico.org.uk/for_organisations/data_protection/topic_guides/anonymisation

[3] http://www.isb.nhs.uk/library/standard/128

Patients are able to record an objection either to the collection of identifiable data from their GP records by the Information Centre, or to onward disclosure of *any* identifiable data held by the Information Centre, or both. They can do this by telling their GP, who will record the objection(s) in the practice information system using pre-determined codes. The Information Centre will respect a recorded objection to the collection of identifiable data from the practice system by collecting only the items necessary to record the fact of this objection, which will be held for statistical purposes. This will be held separately to non-identifiable data from the same records.

Objection to the onward disclosure of primary care data by the Information Centre is not covered, as it is directed not to disseminate identifiable data collected under these Directions anyway. Onward disclosure of data originating from other organisations is beyond the scope of these Directions.

Further Directions will be issued for further data to be collected and where the methodology is to be changed.