Data Provision Notice

Equality, Diversity and Inclusion (EDI) in Health and Care Research

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Background

The Health and Social Care Act 2012 (the 2012 Act) gives NHS England statutory powers, under section 259(1)(a), to require data from health or social care bodies, or organisations that provide publicly funded health or adult social care in England, where it has been directed to establish an information system by the Secretary of State for Health and Social Care.

The data, as specified by NHS England in this published Data Provision Notice, is required to support a direction from the Secretary of State for Health and Social Care to NHS England. Therefore, organisations that are in scope of the notice are legally required, under section 259(5) of the Act, to provide the data in the form and manner specified below.

Purpose

The purpose of the EDI data collection is to understand inclusion, representation and participation in health and care research, identify variation in participation in health and care research, based on demographics, to assess and improve equality, diversity and inclusion in such research, to ultimately improve access to good quality, evidence-based health and care.

(EDI Directions) issued to NHS England by the Secretary of State for Health and Social Care which is published here: https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notices/secretary-of-state-directions/equality-diversity-and-inclusion-in-health-and-care-research-pilot-directions-2025, require the collection of data from participating Health Care Organisations in England, linkage and analysis of data, the development and implementation of a dashboard and the provision of analytics and data products around equality, diversity, and inclusion in health and care research.

The provision of analytics and data products around equality, diversity, and inclusion in health and care research will help funders, researchers, and the healthcare system to address these issues, and ultimately ensure their health research studies, (including clinical trials), are representative and inclusive.

In addition, this pilot will support funders and studies to identify variation of participation in research - initially based on age, gender (*recorded in Patient Demographics Services (PDS) as administrative gender. Also provided by the General Register Office and as gender is written on the birth certificate*), geographic location and deprivation.

Benefits

Patient/public benefits

- Give patients and the public confidence that the National Institute for Health and Care Research (NIHR) is serious about its commitments to EDI policy.
- Help to identify and reduce inequalities in access to health research and ensure that research takes place where the need is greatest.
- Help to ensure that research is representative and therefore applicable to the patient population, thereby ensuring that patients only receive treatment where there is robust evidence of the benefit versus risk for them.

NHS Benefits

- Help ensure that research is representative and therefore provide healthcare professionals with the evidence they need to make the best clinical decisions.
- Help ensure that research is representative and provide evidence that interventions will be work in practice in the healthcare system.
- Provide NHS research and development (R&D) teams with the data they need to understand the demographics of participants in their research compared with their local population and thereby enable targeted EDI improvement activity where needed.

User Benefits

- Department of Health and Social Care (DHSC) - Fulfils DHSC's duty under the Equality Act 2010 and enable NIHR corporately to achieve public accountability.
- National Institute for Health and Care Research (NIHR) - Help ensure that the evidence generated by NIHR supported research is robust and therefore best value for money.
- NIHR - Provide NIHR with the data it needs to understand inequalities in access to research across the portfolio and Regional Research Delivery Networks (RRDNs) and thereby support implementation of the EDI strategy, activity to improve the diversity and inclusivity of research and target research to areas of greatest need.
- RRDNs - RRDNs are a major customer of the outputs of this data collection as it gives them a means of baseline equity of access, track performance, drive local EDI strategies and measure impact.

Legal basis for collection, analysis, publication and dissemination

NHS England has been directed by the Secretary of State for Health and Social Care under the EDI Pilot Directions 2025 under section 254 of the 2012 Act to establish and operate a system for the collection and analysis of the information specified in the Direction and the associated Requirements Specification. The direction and accompanying requirements specification are published on this web page: Equality, Diversity and Inclusion in Health and Care Research Pilot Directions 2025.

The information NHS England is required to collect under the EDI Directions is required by NHS England from the organisations within the scope of this Data Provision Notice under section 259(1)(a) of the 2012 Act.

In line with section 259(5) of the Act, all organisations in scope of this Data Provision Notice in England, must comply with the requirement and provide information to NHS England in the form, manner and period specified in this Data Provision Notice.

This Notice is issued in accordance with the procedure published as part of an NHS England duty under section 259(8) of the 2012 Act.

Limitation on publication

NHS England is directed not to publish the data obtained by virtue of the EDI Directions under section 260(2)(d) of the 2012 Act.

Legal basis for disclosure:

NHS England is directed under section 261(3) of the Act to provide data to:

- DHSC, in the form of aggregate, with small number suppressed data through the EDI Dashboard
- NIHR, in the form of aggregate, small number suppressed, tabulated summary tables and through the EDI Dashboard.

Data will not otherwise be made available by NHS England.

Persons consulted

NHS England has, as required under section 258 of the Act, carried out consultation including:

a. NHS England has consulted with the issuing organisation the Department of Health and Social Care (DHSC) on behalf of Secretary of State (SoS) for Health and Social Care and this consultation is ongoing
b. NHS England/DHSC has consulted and will continue to consult with the prime users of the information including DHSC, National Institute for Health and Care Research (NIHR) and Local Clinical Research Networks (now known as RRDNs)
c. The Department of Health has engaged with nine NHS Trusts and all 12 Local Clinical Research Networks who have a representative role in this context
d. NHS England has consulted with members of the public, this involved:
    - Eight online discussion groups involving around eight people per group were held on the topics of Equality, Diversity, Inclusion in health and care research and data collection by the NHS
    - People representative of the target user group population were recruited, with a mix of attitudes towards the NHS and data sharing
    - Outcome measures included attitude and opinion in terms of their non-identifiable data being collected to monitor and improve the inclusivity of health and care research participation
    - These discussion groups were run by an external agency and held with participants who had given their informed, opt-in consent to participate in the research.

Scope of the collection

Under section 259(1)(a) of the 2012 Act, this Notice is served in accordance with the procedure published as part of the NHS England duty under section 259(8) on the following persons:

- publicly funded health organisations in England which have been funded by NIHR to deliver health research studies who have agreed to participate in the collection. These may include NHS Trusts, General Practices or organisations commissioned by these to deliver clinical trial functions (HCOs).
- All HCOs will initially be asked if they agree to participate in the collection; those which agree to participate will then be sent this Notice. This will inform them of the legal basis for the collection.

- A list of the participating HCOs is maintained on the published alongside this DPN here: NHS England website

Under section 259(5) of the 2012 Act the participating HCOs must comply with the Form, Manner and Period requirements below.

The list of volunteering organisation that must comply with the Notice is published in this NHS England website.

Form of the collection

NHS England will be collecting patient level, identifiable data for the purposes of the EDI Pilot. The data items to be collected are identified in the EDI Technical Data Specification published alongside this DPN.

Data to be collected includes:

- participant NHS number
- name of study and study identification code
- physical/mental health or condition (as part of the 'Project_ Speciality' data item in the Project file. These are the clinical groupings: https://www.nihr.ac.uk/support-and-services/find-expert-or-specialist/support-for-delivering-research/specialties-and-settings by which NIHR Clinical Research Network (CRN) manages its portfolio of clinical studies and is at a high level e.g., Dermatology
- study funding type

The EDI Technical Data Specification is published alongside this DPN.

Manner of the collection

Two files of data, Project and Participant are to be provided by University of Southampton, as a processor for the participating HCOs, monthly into the NHS England DPS MESH mailbox from EDGE.

Message Exchange for Social Care and Health (MESH) is a standard NHS England tool which meets security standards. More information can be found here: https://digital.nhs.uk/services/message-exchange-for-social-care-and-health-mesh

The University of Southampton will submit the following two record level csv files from its EDGE system as set out in the EDI Data Specification:

- Project file: 9 fields of data on research study (clinical trial) projects, a full refresh each month.
- Participant file: 5 fields of data which relate an individual (clinical trial participant) to the research study (clinical trial) projects; this file contains personal data (NHS Number), this will be appended with a monthly update of data.

The expected volumes are about 100,000 participants per year. Project data will accumulate but is unlikely to exceed 10,000 records for the foreseeable future. This is because the participants will be collated from the latest month, whereas the project file will contain all projects submitted since the outset.

These will be automatically ingested into the DPS database via generic data pipelines (GDPs) into two tables participant raw and project raw.

No validation steps are conducted. Anything that is submitted by the University of Southampton via EDGE will be ingested. Any DQ issues arising from this will need to be manually fixed by the HCO or the University of Southampton.

Period of the collection

Files will be received monthly from the first submission date which will be 7th November 2025 and then monthly updates on [5th] until 28 February 2027.

Full Directions will be sought for the continuation of this project continuous beyond the pilot phase, subject to evaluation of the Pilot.

Burden of the collection

Steps taken by NHS England to minimise the burden of collection

NHS England has a statutory duty under section 253(2) of the Act to seek to minimise the burden it imposes on others. In seeking to meet these obligations in relation to this collection, NHS England has:

- Worked closely with DHSC, NIHR and the University of Southampton to ensure that the data specification is implementable.
- Sought to only collect the necessary items required to meet NIHR and DHSC requirement and minimise the collection of personal identifiable data

In addition, in support of its obligation under 265(3) of the Act, NHS England has an assessment process to validate and challenge the level of burden incurred through introducing new information standards, collections and extractions.

This process is carried out by the Data Assurance Service (DAS) which assures burden assessment evidence as part of the overarching Data Assurance Board (DAB) approval process. The DAB, acting under authority of the Secretary of State, oversees the assurance, approval and publication of information standards and data collections. for the health and social care system. in England.

At the time of publishing this Data Provision Notice, the assurance process, undertaken by DAS, agreed that a more accurate assessment of Burden would be easier to complete as part of the Post Implementation Review (PIR) of the data collection, after it had been operating for an agreed period, (normally 12 months).

This recommendation was included in the report sent to DAB requesting approval of the data collection. DAB has set a PIR date to be completed no later than 12 months after approval of the collection, this will include the assessment of burden on the health and care system.