

Data Provision Notice

Data about medicines dispensed or supplied in the community, as held by NHS Business Services Authority

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Information and technology
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Background

The Health and Social Care Act 2012 (the Act) gives the Health and Social Care Information Centre, now known as [NHS Digital](#) and hereafter referred to by this name, 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 or NHS England.

The data, as specified by NHS Digital in this published Data Provision Notice (DPN), is required to support a direction from the Department of Health and Social Care to NHS Digital. 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 of the collection

The NHS Digital Medicines Data programme has been commissioned to provide better data about medicines. The programme will provide good quality medicines data, crucial to the successful delivery of commitments laid out in the following:

- [NHS Long Term Plan](#)
- [Next Steps on the Five Year Forward View](#)
- [Antimicrobial Resistance \(AMR\) Strategy](#)
- [Life Sciences Industrial Strategy](#)
- [World Health Organisation's 2017 3rd global challenge, 'Medication without Harm'](#)

Through monthly collections, NHS Digital will establish a set of data about medicines dispensed or supplied, as held by the NHS Business Services Authority (NHSBSA) to allow:

1. Analysis and linking of this data to other data sets by NHS Digital to provide richer information and improve intelligence about medicines safety, effectiveness and outcomes.
2. Data to be made available to a range of organisations for secondary uses such as to inform and support prescribing behaviour, decision making and research. This will include making the data available through the NHS Digital Data Access Request Service (DARS) and enhancing existing and developing new publications.

Data about dispensed and supplied medicines, as held by NHSBSA, is not currently available to be used for these purposes and there is genuine and significant demand which is supported by:

- NHS Digital;
- NHSBSA, the key delivery partner;
- a multi-agency Medicines Data Advisory Group, which includes NHS England and NHS Improvement, NHS Digital, National Institute for Health and Care Excellence, Clinical Commissioning Groups and Trusts;

- NHS England and NHS Improvement; and
- the Department of Health and Social Care.

Finally, since the outbreak of COVID-19, there is also significant demand for medicines data from the NHSBSA in relation to understanding and supporting the management of the pandemic. As such, medicines data collected from the NHSBSA data may now also be analysed and linked with other data for COVID-19 purposes under [COVID-19 Directions](#).

Note: Since the original version of this DPN was published on the NHS Digital website (October 2019) the document has been updated twice (May and August 2020) to:

- include reference to the use of medicines data from the NHSBSA in relation to understanding and supporting the management of the COVID-19 pandemic
- provide additional information governance information to the NHSBSA, particularly in respect of criteria where certain data must be excluded by NHSBSA, prior to transmission to NHS Digital (please refer to the 'Scope of the collection' and specifically the section entitled 'Legally restricted or sensitive data – data to be excluded from this collection by the NHSBSA, prior to transmission to NHS Digital')
- provide additional clarification and information to the NHSBSA in respect of the ongoing monthly provision of the data, including incident handling. The August 2020 update includes specific reference to the two separate MESH mailboxes that NHSBSA must use to supply each month's data (one for the provision of reference data files, the other for the main medicines data files)
- clarify wording in relation to the 'Assessed costs' table (August 2020 update).

Benefits of the collection

There is genuine and significant demand for this data from a range of organisations including NHS Digital, NHS England and NHS Improvement, the National Institute for Health and Care Excellence, Clinical Commissioning Groups and Trusts, the Department of Health and Social Care, research bodies, charities and other health organisations.

However, as this data is not currently available to be used in this way, it has been difficult for these organisations to identify the benefits they expect. Quality benefits have been identified and are summarised below. No monetised benefits have been identified at this stage.

NHS Digital will work closely with those requesting data to identify use cases, baseline before they use the data to make changes, then measure the outcomes of any benefits realised from their change initiatives. This will allow emergent benefits to be captured and the level of savings provided to the NHS as a result of using this data assessed.

The existing Medicines Safety Dashboard¹ which links limited dispensing and hospital episode data has identified monetised benefits as a result of de-prescribing of medication and avoided hospital stays. It is reasonable to assume the plan to continue adding more indicators will result in additional new monetised and qualitative benefits.

It is also expected that benefits will emerge in the following areas of work:

¹ <https://www.nhsbsa.nhs.uk/epact2/dashboards-and-specifications/medication-safety>

- Improved intelligence on the uptake of new innovative medicines.
- Support for pharmacovigilance (the collection, detection, assessment and monitoring) of medicine safety (serious and severe ADRs).
- Linkage to future secondary care patient level medicines data to allow measurement of medicine use across patient journeys.
- Impact of admission on polypharmacy (the concurrent use of multiple medications by a patient) and re-admission.
- Improved intelligence around the use of Sodium Valproate and other teratogenic medicines (which contain an agent that can disturb the development of the embryo or foetus) and maternity.
- Tracking patients and high-risk medicines post-discharge e.g. injectable anticoagulants which are used to reduce the ability of the blood to clot.

In addition, NHS Digital's Prescribing, Medicines & Estates Team and Innovative Uses of Data Team have provided a range of scenarios where they intend to investigate the use of this data including diabetes and long-term conditions.

Benefits are summarised below:

Benefit	Beneficiary
Potential to reduce harm including life-threatening, disabling, and incapacitating injury, and fatalities as a result of NHS Digital linking Hospital Episode Statistics and dispensed medicines data	Patients
Ability to compare patients with same conditions and different medication regimes as a result of NHS Digital linking dispensed medicines data, with general practice data set to understand treatment efficacy	Patients
Reputational benefit for NHS Digital as a result of linking prescribing data to hospital admissions at a national level and using data to highlight risks to patient safety	NHS Digital
Increased opportunities to make existing reporting richer as a result of the dispensed medicines data set including patient demographics enabling age and geographical breakdowns	Data users
Production of analytical descriptive, predictive and potentially prescriptive models is supported as a result of NHS Digital receiving dispensed medicines data and will support and fulfil the objectives of the Life Sciences agenda	Innovative Uses of Data Team
Ability to analyse patient journeys as a result of NHS Digital linking dispensed medicines and Hospital Episode Statistics data to NHS111 dispositions to see how advice and treatment influences subsequent A&E attendance	NHS Pathways

Legal basis for the collection, analysis, publication and dissemination

Pursuant to sections 254(1) and 254(6) of the Act, NHS Digital has been directed by the Department of Health and Social Care to establish and operate information systems for the collection and analysis of data about medicines dispensed or supplied, as currently held by NHSBSA:

NHS Business Services Authority (NHSBSA) Medicines Data Directions 2019

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 supporting technical specification(s). Any other information must be published in line with NHS Digital's duty under section 260(1) of the Act, unless it falls within section 260(2) of the Act.

Where a prohibition on publication is specified in the supporting technical specification(s), NHS Digital may disseminate that information under sections 261(1) and 261(2) of the Act, in such form and manner and at such times as it considers appropriate. Any other information may be disseminated in line with NHS Digital's powers under section 261 of the Act.

NHS Digital has been directed by the Secretary of State for Health and Social Care under section 254 of the Health and Social Care Act 2012; to establish and operate a system for the collection and analysis of the information specified for this service.

A copy of the Direction is published here:

<https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notices/secretary-of-state-directions/nhs-business-services-authority-nhsbsa-medicines-data-directions-2019>

This information is required by NHS Digital under section 259(1)(a) of the Health and Social Care Act 2012.

In line with section 259(5) of the Act, all organisations in scope, in England, must comply with the requirement and provide information to NHS Digital 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 NHS Digital duty under section 259(8).

Type 1 Opt Outs apply where a GP Practice shares confidential patient information directly with a third party for purposes other than the direct care of the individual. NHS Digital is satisfied that Type 1 Opt Outs do not legally apply to the data flow as neither NHSBSA nor NHS Digital collect the data directly from GP Practices.

Finally, and as stated earlier under 'Purpose of the collection', since the outbreak of COVID-19, there is significant demand for medicines data from the NHSBSA in relation to understanding and supporting the management of the pandemic. As such, medicines data collected from the NHSBSA may now also be analysed and linked with other data for COVID-19 purposes under [COVID-19 Directions](#).

Persons consulted

NHS Digital has, as required under section 258 of the Health and Social Care Act 2012, consulted with the following persons:

- NHS Business Services Authority (NHSBSA)
- Representatives of other organisations who NHS Digital considers are likely to use the information, for examples relevant Arm's Length Bodies through a Medicines Data Advisory Group. Membership of this group includes NHS England and NHS Improvement, NHS Business Services Authority, the National Institute for Health and Care Excellence and Trusts.
- The Data Coordination Board (DCB). DCB was established as part of a system-wide information and technology governance model, as a sub board of the Digital Delivery Board (DDB). The DCB acts with delegated authority from the DDB and directly from the Secretary of State as the main governance route through which all data collections and standards requirements are agreed and priorities assigned.

Scope of the collection

Under section 259(1)(a) of the Health and Social Care Act 2012, this Notice is served in accordance with the procedure published as part of the NHS Digital duty under section 259(8) on NHSBSA. NHSBSA has worked with NHS Digital to develop the collection.

The data being collected is obtained from NHS Primary Care Services (part of the NHSBSA). It is an extract of information captured during prescription processing to calculate reimbursement payments to community dispensers. It is taken from paper FP10 prescription forms and Electronic Prescription Service messages.

The data relates to medicines, which includes but is not limited to patient information, from the NHSBSA of all prescriptions issued by prescribers and dispensed or supplied in the community.

This includes prescriptions for medicines that are dispensed or supplied by community pharmacists, appliance contractors and dispensing doctors and prescriptions submitted by prescribing doctors in England for medicines personally administered in England. Included are prescriptions written in England but dispensed outside England, prescriptions written in Wales, Scotland, Northern Ireland and the Isle of Man but dispensed in England. Prescribers include GPs, hospital doctors, NHS dentists and non-medical prescribers e.g. nurses, pharmacists.

The NHS Digital collection will include ongoing monthly provision of data from the NHSBSA and historic data submitted to NHSBSA since April 2015 (also refer to 'Stage 3: Provision of historical data', below).

The following data is not collected by NHSBSA:

- Items dispensed or supplied within secondary care.
- Items on an issued prescription that has not been presented for dispensing.

- Items on a prescription that has been presented for dispensing but not submitted to NHS Prescription Services by the dispenser.

The full Input-Output Specification is available on the NHS Digital website:

<https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notices/data-provision-notices-dpns/nhs-bsa-medicines-data-provision-notice>

The Input-Output Specification also includes:

- details of reference data files to be provided monthly by NHSBSA (tab 'Input Ref Data Files')
- criteria to be applied by the NHSBA to exclude certain personal data, prior to transmission to NHS Digital (see more below on this)
- data validation rules (the validation rules to be applied by NHS Digital to the incoming data).

Legally restricted or sensitive data – data to be excluded by NHSBSA, prior to transmission to NHS Digital

The full Input-Output Specification contains a tab called 'Legally Restricted Sensitive' that sets out criteria where certain data must be excluded by NHSBSA, prior to its transmission to NHS Digital.

The criteria have been created in relation to:

- Human fertilisation and embryology
- Sexually transmitted diseases
- Gender recognition.

The Human Fertilisation and Embryology Act (HFEA) 1990 (as amended by the HFEA 2008) – legally restricted data

The Human Fertilisation and Embryology Authority (HFEA) keeps a register of information which contains identifiable patient information about IVF treatment provision as defined under section 31(2) of the above act. This provides that no person shall disclose any information falling within section 31(2) which the person obtained in the person's official capacity as outlined in section 33(1). This official capacity includes persons to whom a licence applies (licensed fertility clinics, which would apply to NHS Trusts who are licensed fertility clinics). The restriction on disclosure does not apply where the disclosure is made so that no individual can be identified from the information.

NHS Digital has concluded that certain actions must be taken to restrict personal data, in relation to human fertilisation and embryology, for certain records within the scope of the collection from the NHSBSA.

For a specific set of medicines or for a specific set of cost centres, the NHSBSA must remove (blank) NHS Number, Date of birth and Age from the data and change Gender to 0 (unknown).

Details of the criteria to be applied by the NHSBA, are set out in the tab 'Legally Restricted Sensitive' of the full Input-Output Specification.

NHS Digital has provided NHSBSA with a list of the specific medicines and cost centres, where actions are to be taken to restrict personal data.

NHS Digital and NHSBSA will discuss and agree the means and frequency for maintaining the list of in-scope medicines and costs centres, to ensure that they remain current and accurate.

Gender recognition (Gender Recognition Act 2004) – legally restricted data

NHS Digital has concluded that certain actions must be taken to restrict personal data, in relation to gender recognition, for certain records within the scope of the collection from the NHSBSA.

The NHSBSA must remove (blank) NHS Number, Date of birth and Age from the data and change Gender to 0 (unknown) for all medicines data for a specific set of cost centres

Details of the criteria to be applied by the NHSBA, are set out in the tab 'Legally Restricted Sensitive' of the full Input-Output Specification.

NHS Digital has provided NHSBSA with a list of the specific cost centres, where actions are to be taken to restrict personal data.

NHS Digital and NHSBSA will discuss and agree the means and frequency for maintaining the list of in-scope medicines and costs centres, to ensure that they remain current and accurate.

Sexually transmitted diseases (The NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000) – sensitive data

NHS Digital has concluded that certain actions must be taken to restrict personal data, in relation to sexually transmitted diseases, for certain records within the scope of the collection from the NHSBSA.

For a specific set of medicines (or certain quantities of specific medicines) or for a specific set of cost centres, the NHSBSA must remove (blank) NHS Number, Date of birth and Age from the data and change Gender to 0 (unknown).

Details of the criteria to be applied by the NHSBA, are set out in the tab 'Legally Restricted Sensitive' of the full Input-Output Specification

NHS Digital has provided NHSBSA with a list of the specific medicines and cost centres, where actions are to be taken to restrict personal data.

NHS Digital and NHSBSA will discuss and agree the means and frequency for maintaining the list of in-scope medicines and costs centres, to ensure that they remain current and accurate.

Under section 259(5) of the Health and Social Care Act 2012 the organisation types specified in the above scope must comply with the form, manner and period requirements below.

Form and manner of the collection

Data will be transferred monthly from NHSBSA to NHS Digital using MESH, the messaging service used across health and social care, allowing health and care organisations to communicate securely.

The data will be transferred as a flat CSV file. Each transfer will provide the most recent available month of processed data.

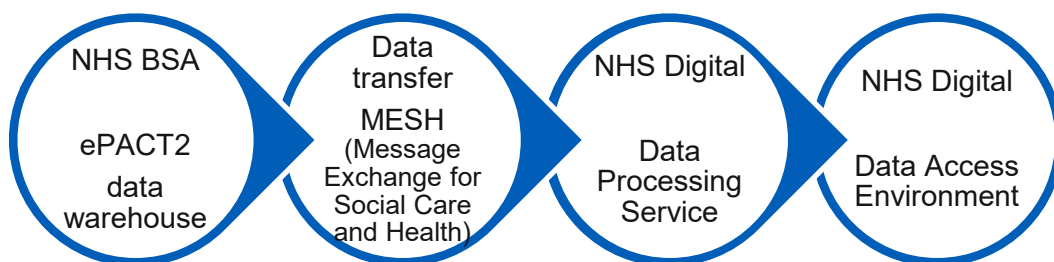


Figure 1 - Summary of the data transfer

The full Input-Output Specification contains a tab called 'MESH Ctl File' that provides the details of the **two** MESH mailboxes that NHSBSA must use to transfer data each month:

- one mailbox for the provision of reference data files (into NHS Digital's Corporate Reference Data Team)
- the other mailbox for the provision of the main medicines data files (to be ingested into NHS Digital's Data Processing Services (DPS)).

Period of the collection

The collection of the in-scope data can be divided into three stages:

Stage 1: Testing and assurance

As agreed between NHSBSA and NHS Digital, NHSBSA will initially provide subsets of live data to NHS Digital, purely for the purposes of testing and assurance. This will be available to a restricted group of users within NHS Digital.

The specifics of the subsets and the date of their provision will be discussed and agreed between NHSBSA and NHS Digital.

Stage 2: Regular monthly provision of data

Following successful completion of testing and assurance, the NHSBSA will start the regular monthly flow of data to NHS Digital (this will be considered as the start of the ongoing monthly data collection). The start of the regular monthly flow of data will be discussed and agreed between NHSBSA and NHS Digital.

Details of the ongoing provision of monthly data by NHSBSA, including incident handling, are outlined below.

Ongoing provision of monthly data

- NHSBSA must complete transfer of the in-scope data as soon as it is available each month and no later than the 20th of every month (where the NHSBSA is not able to meet the 20th of month, for whatever reason, please refer to the contact details set out below).
- Where the 20th of the month falls on a weekend, the file must be transferred no later than the final working day before the 20th (where the NHSBSA is not able to meet this, for whatever reason, please refer to the contact details set out below).
- Once data transfer has successfully completed, the NHSBSA must inform the NHS Digital Prescribing, Medicines & Estates Team, at the following email address:

prescribing@nhs.net

Incident handling in relation to the ongoing provision of monthly data

- Where the NHSBSA is unable to transmit data (as per the schedule above) due to *internal* NHSBSA issues, NHSBSA must log an incident with the [National Service Desk \(NSD\)](#) referencing the internal NHSBSA incident number and quoting the name of the NHS Digital service ('NHSBSA Medicines Data'):

ssd.nationalservicedesk@nhs.net

Telephone – 0300 303 5035

- Where the NHSBSA is unable to transmit data (as per the schedule above) due to MESH issues that require NHS Digital support, NHSBSA must log an incident with NSD (details above) and note the NHS Digital incident number.

If either of the above scenarios occur, NHSBSA should also inform the NHS Digital Prescribing, Medicines & Estates Team at the email address below and provide the NSD incident reference number:

prescribing@nhs.net

This will enable the NHS Digital Prescribing, Medicines & Estates Team to liaise with other internal NHS Digital teams, to inform customers who are regularly in receipt of the data that there may (or will) be a delay to them receiving it.

Stage 3: Provision of historical data

Historical data, from April* 2015 will also be provided by NHSBSA to NHS Digital (*data submitted to NHSBSA since April 2015). The start of transfer of historical data will be discussed and agreed between NHSBSA and NHS Digital (this is likely to be after the start of the provision of regular monthly data).

Review of this Data Provision Notice

This Data Provision Notice and data collection, will be reviewed on an annual basis starting from 31st March 2021.

Any mid-year changes required to this collection, will be discussed and agreed between NHS Digital and NHSBSA and reflected in an updated version of this Data Provision Notice (and/or an updated version of the Input-Output Specification associated with the Data Provision Notice, whichever is applicable).

Burden of the collection

Steps taken by NHS Digital to minimise the burden of collection

In discharging its statutory duty to seek to minimise the burden it imposes on others, NHS Digital is collecting the data from an existing source. NHSBSA has been involved in developing the operating model for the collection to ensure that existing technology can be used. The collection will replace a current flow of Medicines Safety data from NHSBSA to NHS Digital.

In seeking to minimise the burden it imposes on others, in line with sections 253 (2a) and 265(3) of the Health and Social Care Act 2012, NHS Digital has an assessment process to validate and challenge the level of burden incurred through introducing new information standards, collections and extractions.

This assurance is carried out by the Data Standards and Assurance Service (DSAS) which assures burden assessment evidence provided as part of the overarching Data Coordination Board (DCB) process. The DCB, acting under authority of the Secretary of State, oversees the development, assurance and acceptance of information standards, data collections and data extractions for the health and social care system in England.

Assessed costs

The associated burden of the data collection is:

Set up costs for the data collection	£45,000	One off cost to establish data flow and transfer historical data (to be paid from NHS Digital programme budgets).
Annual costs of the data collection	£15,000	Annual costs for NHSBSA to maintain the data flow (£15,000 per year) once the data collection is established as a service.

		<p>The 1st year, following establishment of the data collection (during 2020/21, £15,000) will be paid from NHS Digital programme budgets.</p> <p>Ongoing costs from 2021/22 financial year will be reviewed annually.</p>
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For further information

www.digital.nhs.uk

0300 303 5678

enquiries@nhsdigital.nhs.uk

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