Upwell Health Centre and Welle Ltd (Pharmacy)

National Data Opt Out Protocol

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| Version | Author | Owner | Notes |
| V1 | Primary Care DPO (Kafico) | Stephen Reeves | Original draft |
| V1 | Primary Care DPO (Kafico) | Stephen Reeves | Reviewed and no changes made March 23. |

INTRODUCTION

The National Data Opt Out (NDO) programme allows patients to express their wishes, at a national level, and ‘opt out’ of their confidential information being used for planning and research.

When they register their preferences via <https://www.nhs.uk/your-nhs-data-matters/>, it will be marked against their NHS Digital record at the [NHS Spine](https://digital.nhs.uk/services/spine).

Health and care providers are responsible for ensuring that planning and research activities locally, take account of the opt out wishes that have been registered at a national level.

These preferences must be applied before;

1. Disclosing confidential information outside the organisation for research and planning
2. Using confidential information internally for research and planning purposes (in certain circumstances)

SCOPE

The national data opt-out applies to data that originates within the health and adult

social care system in England. This includes private providers including Any Qualified Providers (AQPs) who provide health and adult social care services which are funded or under contract with a public body, for example NHS England, Clinical Commissioning Group (CCG) or local authority).

LEGISLATION / FRAMEWORK

* Common Law Duty of Confidentiality
* Data Protection Act 2018 / UK General Data Protection Regulations
* Human Rights Act 1998
* NHS Act 2006 s 251

DIRECT CARE

Activities performed for direct care purposes **are not in scope** for NDO and do not have to have the opt outs applied.

Direct Care is;

* activity concerned with the prevention, investigation and treatment of illness and the alleviation of suffering of individuals.
* Includes supporting individuals’ ability to function and improve their participation in life and society.
* It includes the assurance of safe and high-quality care and treatment through local audit,
* Incident Management
* Measurement of outcomes

As long as the activities are undertaken by, or under the oversight of, one or more registered and regulated health or social care professionals and their team with whom the patient has a legitimate relationship.

**Local Audit**

Audits performed with the participation of a health and social care professional who has a legitimate relationship with the patients, through implied consent (they either know about the activity or would reasonably expect the activity).

**If the above audits were happening across organisations (i.e. across the PCN) the data would need to be anonymised, consent obtained or the NDO opt outs applied before disclosure.**

NOT DIRECT CARE

Planning or research activities that are not direct care purposes are **in scope** for NDO and must have to have the opt outs applied.

These are “Activities that contribute to the overall provision of services to a population as a whole or a group of patients with a particular condition, but which fall outside the scope of direct care. It covers health services management, preventative medicine, and medical research.”[[1]](#footnote-1)

For example;

• [Risk Stratification](https://www.england.nhs.uk/ig/risk-stratification/)

• [Population Health Management](https://www.england.nhs.uk/integratedcare/what-is-integrated-care/phm/)

• Research

• Service Evaluations

• Predictive activities

• Financial Audits

NDO does not mean that the above activities cannot take place. If confidential data is involved, it can be anonymised, consent obtained or the NDO out outs applied.

DISCLOSURES TO PROVIDERS / SUPPLIERS

Before data is disclosed to outside organisations, the NDO **must** be considered. The opt outs must be applied before it leaves the organisation’s ‘controller boundary’.

Health and care providers will often use third parties to process data on their behalf, for example, they will engage a company to extract and analyse their data, to plan local capacity or identify cohorts of patients.

As long as these companies are engaged as “Processors”, this does not count as a disclosure to a third party.

This is because, companies engaged as Processors are **acting only** on the narrow instructions of the organisation who owns the data (the Controller). They act as a proxy for the Controller and so are not technically a third party.

If you are using a Processor to undertake local non care activities, you would not need to consider the NDO prior to disclosure.

INTERNAL ACTIVITIES

Even where processing of data happens internally, there are still some circumstances where NDO must be considered.

This might be where the activity is;

* Not direct care
* Not based on consent
* Not something the individual would reasonably expect or know about

Patients generally expect routine internal evaluations of the safety and efficacy of care[[2]](#footnote-2).

NOTED EXCLUSIONS

* **does not** apply to disclosures for direct care purposes.
* **does not** apply where explicit consent has been obtained
* **does not** apply to the disclosure of confidential patient information required for the monitoring and control of communicable disease and other risks to public health (i.e. COVID-19 disclosures)
* **does not** apply to the disclosure of confidential patient information where there is an overriding public interest in the disclosure (DVLA, guns etc)
* **does not** apply to the disclosure of confidential patient information where the information is required by law or a court order.
* **does not** apply to local case finding
* **does not** apply to confidential patient information flowing to Public Health England (PHE) under the following approvals:
  + i. National Cancer Register (PIAG 03(a)/2001);
  + ii. National Congenital Anomaly and Rare Diseases Register (CAG 10- 02(d)/2015).
* **does not** apply to data flowing into the Office for National Statistics (ONS) solely for the production of official statistics.
* **does not** apply to disclosures of confidential patient information for the purpose of allowing participation in National Screening Programmes endorsed by the UK National Screening Committee. For the avoidance of doubt national data opt-outs do not apply to confidential patient information flowing under the following approvals:
  + i. NHS Breast, Bowel and Cervical Cancer Screening Programmes (15/CAG/0207);
  + ii. NHS Abdominal Aortic Aneurysm Screening Programme (ECC 3-04(o)/2011).
* **does not** apply to confidential patient information about people with learning disabilities and/or autism who are in hospital for their mental health or due to challenging behaviour which is disclosed under the following approval:
  + Assuring Transformation: Enhanced Quality Assurance Process Data flow (CAG 8-02 (a-c)/2014).
* **does not** apply to the National Cancer Patient Experience Survey (CPES) and CQC NHS Patient Survey Programme, both of which will continue to run unaffected under their current arrangements.
* **does not** apply to flows of data into NHS Digital (NHS Digital is the operating name for the Health and Social Care Information Centre (HSCIC)) where these are required under S.259 of the Health and Social Care Act 2012 following a Direction from Secretary of State or NHS England or a mandatory request. DSCRO

APPLYING THE OPT OUTS

NHS Digital has set up a service that allows organisations to check a cohort or list of patients before it is disclosed or used for planning or research purposes.

1. Organisations can submit a list of NHS numbers that they need to disclose, and the service looks these up against the central repository of national data opt-outs. It returns a “cleaned list” of those that do not have a national data opt-out i.e. it removes the NHS numbers for those with a national data opt-out. This is most suitable for one-off and infrequent disclosures of data.
2. Organisations can submit the NHS numbers for all patients with whom they have a legitimate relationship and then store temporarily the list of patients who do not have an opt-out at the current time and whose data they may be able to disclose16. There are a number of policy rules around the storage and use of this “temporary cache” of data so flag with your DPO for advice if this is your preferred approach.

In order to use the above service, practices will need to be set up on the NHS Digital MESH service.

Contact your IT Provider to obtain support with the best version for you.

<https://digital.nhs.uk/services/national-data-opt-out/compliance-with-the-national-data-opt-out/check-for-national-data-opt-outs-service>

PREPARING FOR COMPLIANCE

This section will be removed from the protocol next year and focuses on preparing for the March 22 deadline for NDO compliance.

It is important that existing data flows, as well as any new data flows or disclosures are reviewed against NDO to ascertain if they are covered and required submission to the NHS Digital MESH service as above.

Below is a checklist of actions to be taken to ensure that the organisation is ready to comply with NDO.

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| Task / Action | Responsible | Status |
| DPO will send survey identifying the various activities performed by the organisation that may fall be covered by NDO | Data Protection Officer |  |
| Organisation to respond to survey, identifying the various activities performed by the organisation that may fall be covered by NDO | Organisation compliance lead |  |
| DPO and organisation to identify, against each activity, how it complies (i.e. consent, anonymisation, NDO applied) | Organisation compliance lead / Data Protection Officer |  |
| Check whether NDO transparency materials are live on organisation’s website | Organisation compliance lead |  |
| Contact IT provider to set the organisation up with the MESH service | Organisation compliance lead |  |
| Add NDO assessment to all DPIA and other risk assessments performed by DPO  (This means that new providers and projects will be assessed for NDO as long as they come to the DPO for review) | Data Protection Officer |  |
| Ensure that all new projects or initiatives continue to be passed to DPO for review | Organisation compliance lead |  |
| Check the clinical system for any pre-configured reports that run automatically, are not anonymised and are not used for direct care (flag with DPO as appropriate) | Organisation compliance lead |  |
| Removed any old or unused system reports to prevent accidental reporting where the opt outs have not been applied | Organisation compliance lead |  |

1. <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf> [↑](#footnote-ref-1)
2. <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf> [↑](#footnote-ref-2)