

National Data Opt-out - Questions and Answers for Health and Care Professionals – Final v1.0

The following list contains frequently asked questions from health and care professionals. Some of the answers may reference further information sources on www.digital.nhs.uk/national-data-opt-out, such as factsheets and operational policy guidance.

Public-facing information can be found at www.nhs.uk/your-nhs-data-matters

| Question | Answer |
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| Consent | |
| <p>1) If a patient doesn't opt out, does this implicitly mean they have opted in or given consent to a data use?</p> | <p>No – lack of a national data opt-out does not equate to an opt-in or to giving consent. If a patient has not opted out it does mean that their confidential patient information can be used for purposes beyond their individual care if there is a legal basis to do so, such as s251 approval under the NHS Act 2006.</p> <p>Any processing of personal data still needs to be lawful, fair and transparent, including meeting the requirements of data protection legislation and considering the Common Law Duty of Confidentiality which relates to the disclosure of information that is given in circumstances where it is expected that a duty of confidence applies.</p> <p>Under data protection legislation any organisations collecting, or processing health and care data will need to identify a condition both under Article 6¹ (for personal data) and under Article 9² (special category of data) that provides a legal basis.</p> <p>To meet the Common Law Duty of Confidentiality there must be either:</p> <ul style="list-style-type: none"> • Consent, • A mandatory legal requirement, • An overriding public interest, or • Section 251 (NHS Act 2006) approval. <p><i>For further information see Factsheet 1B.</i></p> <p>Patients may provide explicit consent for a specific use of their data for purposes beyond their individual care e.g. for a specific research study, and in such cases the national data opt-out will not apply to that specific data use.</p> <p>(1) http://www.privacy-regulation.eu/en/article-6-lawfulness-of-processing-GDPR.htm (2) http://www.privacy-regulation.eu/en/article-9-processing-of-special-categories-of-personal-data-GDPR.htm</p> |
| <p>2) How will the national data opt-out apply to use/disclosure of data where consent has been given?</p> | <p>Where a patient has given consent for a specific purpose this will override the national data opt-out for that specific purpose. This includes where the consent was given before the patient has set their national data opt-out.</p> <p>This enables someone with a national data opt-out set, to still take part or continue to take part in a specific piece of research for which they have given consent.</p> <p><i>For further information see Factsheet 1A.</i></p> |

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| | <p>Where researchers need to identify people to participate in research studies, the national data opt-out may apply to this process depending on the mechanism that the researcher uses to identify potential research subjects. There are a number of established mechanisms available to researchers for identifying potential research subjects which are set-out in the 2013 IG Review (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf).</p> <p><i>Further information on 'consent for consent' is summarised in the National Data Opt-out Operational Policy Guidance.</i></p> |
| <p>3) Is there an opportunity to embed a consent to contact for research opportunities into the national data opt-out process?</p> | <p>No. The national data opt-out programme was established to deliver the opt-out model that was accepted by the Government in their response to the recommendations made by the National Data Guardian as set out in the "Review of Data Security, Consent and Opt-Outs". The aim of this work, in line with the review and Government response, is to improve understanding and information available to patients, public and the workforce on the use of health and care data for purposes beyond individual care and to put in place a system to allow patients to opt-out of their confidential patient information being used in this way. It has been determined that at this time to introduce additional functionality to allow the recording of 'consent to contact' would not be appropriate and would detract from the objective of ensuring that patients and the public are clear and understand how their data are used by health and care organisations and that they have a choice to opt-out for uses beyond individual care.</p> <p><i>For more information on 'Consent for Consent' see the National Data Opt-out Operational Policy Guidance.</i></p> |
| General Policy | |
| <p>4) What is meant by 'Confidential Patient Information'?</p> | <p>Confidential patient information is defined in section 251 (11) of the National Health Service Act 2006. Broadly it is information that meets the following requirements:</p> <ol style="list-style-type: none"> 1. Identifiable, or likely identifiable (e.g. from other data in possession of the recipient), 2. Given in circumstances where the individual is owed a duty of confidence; and 3. Conveys some information about the physical or mental health or condition of an individual <p><i>For further information see Factsheet 3.</i></p> |
| <p>5) How do the new General Data Protection Regulation (GDPR) affect the National Data Opt-out?</p> | <p>The national data opt-out will sit alongside the new General Data Protection Regulation and Data Protection legislation and is not replaced or changed by it. It is policy offer that is over and above the legal rights and protections of the GDPR/data protection legislation.</p> <p><i>For further information see Factsheet 6.</i></p> <p>The Information Governance Alliance (IGA) have developed materials to support organisations in understanding compliance with GDPR and meeting the requirements of the new data protection legislation. The IGA guidance can be found at: https://digital.nhs.uk/information-governance-alliance/General-Data-Protection-Regulation-guidance.</p> |
| <p>6) What is meant by "beyond individual care"? How does this relate to "indirect care" and "secondary uses"?</p> | <p>The terms 'indirect care' and 'secondary uses' are used interchangeably and have the same general meaning as 'beyond individual care'.</p> <p>The term 'beyond individual care' is adopted in line with recommendations made as part of the Understanding Patient Data initiative (https://understandingpatientdata.org.uk/) which tested public and patient understanding of health and care terminology.</p> |

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| | <i>For further information see Factsheet 1A and Factsheet 2 for how the National Data Guardian defined individual care.</i> |
| 7) What is the definition of “Health & Social Care” in relation to the opt-out? Does this only affect public sector organisations, or does it also include the voluntary and private sectors? | <p>The national data opt-out will apply to data that is generated and processed within the health social care system in England.</p> <p>It applies to publicly funded or publicly co-ordinated care – typically this is care or treatment organised or provided by an NHS organisation, or adult social care services coordinated by a local authority.</p> <p><i>The organisations and categories of organisations that must comply with the national data opt-out policy are described in further detail in Factsheet 3 and the Operational Policy Guidance.</i></p> |
| 8) How is invoice validation affected by the national data opt-out? | <p>The NDG review was clear that wherever possible, anonymised data should be used for payment and invoice validation purposes. The national data opt-out will apply to the disclosure of confidential patient information for payment and invoice validation purposes, however it will <u>not</u> apply to use of data for invoice validation for <u>non-contracted activity</u>.</p> <p><i>For further information see Factsheet 2 and the National Data Opt-out Operational Policy Guidance.</i></p> |
| 9) Do the Secondary Uses Service (SUS) Commissioning Data Sets (CDS) fall under the national data opt-out? | <p>The National Data Guardian in her review was very clear that the national data opt-out should not apply to existing national flows into NHS Digital where NHS Digital have a Direction from the Secretary of State or NHS England or receive a Mandatory Request to establish a system. This would include submissions of Commissioning Data Sets (CDS) data into the Secondary Uses Service (SUS).</p> <p>National data opt-outs would apply to any onward data release of CDS or SUS data by NHS Digital, in line with the national data opt-out policy unless the data is anonymised in line with the ICO Code of Practice on anonymisation.</p> <p><i>For further information see Factsheet 2.</i></p> |
| 10) How does the national data opt-out apply to risk stratification? | <p>The national data opt-out will not apply to data disclosures for risk stratification for case finding, where carried out by a provider involved in an individual’s care¹ as this should be treated as direct care for the purpose of the opt out.</p> <p>It will not apply where the data for risk stratification is anonymised in line with the ICO code of practice on anonymisation.</p> <p>National data opt-outs will apply to data disclosures for risk stratification which rely on S.251 support for use of confidential patient information.</p> <p><i>For further information see Factsheet 2 and the National Data Opt-out Operational Policy Guidance.</i></p> |
| 11) Do national data opt-outs apply to clinical audits? | <p>Local clinical audit is part of the definition of individual (direct) care used within the National Data Guardian Review and therefore local clinical audit would not be in scope for the national data opt-out.</p> <p>National clinical audit is in scope, so national data opt-outs would apply to any release of national clinical audit data in line with the national data opt-out policy. For example, they would apply where the legal basis for the release of the data is under s251(NHS Act 2006), but would not apply to the following national clinical audits for which patients have given consent:</p> |

¹ or by a data processor acting under contract with such a provider.

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| | <ul style="list-style-type: none"> ▪ Community-Based Surgery Audit (CBSA) ▪ National Diabetes Audit - Footcare ▪ National Pregnancy in Diabetes Audit (NPID) ▪ National Third Molar Audit (N3MA) |
| Setting Opt-outs | |
| 12) Will GP practice staff have to do anything to record the national data opt-out? (they had to specifically code Type 1 & 2 opt-outs) | <p>No. Patients who wish to set a national data opt-out will do so themselves via the online or telephone service. <i>See Factsheet 5.</i></p> <p>If a patient approaches their GP practice, they can be signposted to further information. This will include patient communications materials provided to GP practices, including a poster and handout, along with information available online at www.nhs.uk/your-nhs-data-matters and via the national telephone service, including how to register a national data opt-out themselves.</p> <p>Patients may ask GP practices to check their mobile phone number or email address is up to date in their patient record (and is synchronised with the Personal Demographics Service). Patients may also ask GP Practices for their NHS number, if they do not already know it, as these are key to enabling patients to use the online service effectively.</p> |
| 13) Can the opt-out be set on behalf of another person (by proxy)? | <p>Individuals who have a formal, legal relationship to act on behalf of another (i.e. somebody with parental responsibility for a child under 13, a legal power of attorney or a court appointed deputy) will be able to set an opt-out on their behalf by proxy. This will only be possible via the non-digital channel.</p> <p><i>For further information see Factsheet 5.</i></p> |
| 14) Can patients set an opt-out via their GP online service? | <p>Patients will NOT be able to set a national data opt-out via the GP Online service. If a patient approaches their GP practice about this they should be signposted to information on how to register a national data opt-out by using the online or telephone service to review, set or change their national data opt-out choice.</p> <p><i>For further information see Factsheet 5.</i></p> |
| Applying Opt-outs | |
| 15) Will I have to check the national data opt-out Spine repository every time I want to use or disclose data for a new purpose that requires national data opt-outs to be applied? | <p>Yes, as the online service for setting opt-outs is available 24 hours a day and 7 days a week, patients can set or change their opt-out at any time. So, it is important that the latest set of national data opt-outs are accessed in real time</p> <p>NHS Digital is developing and testing a system to enable health and care organisations to do this, known as the 'external upholding solution'.</p> |
| 16) How will Local Government apply the national data opt-out? | <p>Local government are required to uphold the national data opt-out for adult social care data flows in the same way as other healthcare organisations by March 2020 in line with the NDG recommendation and Government commitment.</p> |

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| <p>17) Will my organisation be monitored against delivery of the national data opt-out? And what are the penalties?</p> | <p>Your organisation will be asked to set out whether the national data opt-out applies to specific uses of data through the Data Security and Protection Toolkit. The implementation of the national data opt-out is an information standard and as such all health and care organisations must have due regard to it. Further mechanisms for monitoring the implementation of the national data opt-out will be considered as it is rolled out.</p> <p><i>For further information see Factsheet 1B.</i></p> |
| <p>Technical Solutions – Setting Opt-outs</p> | |
| <p>18) Will a patient’s national data opt-out status be flagged on the Personal Demographics Service (PDS) or Summary Care Record (SCR) and therefore also be visible to clinicians?</p> | <p>The national data opt-out will be stored in a dedicated repository on the NHS Spine. It will not be directly accessible via the Personal Demographics Service (PDS) or Summary Care Record (SCR). As a result, it would not be visible to healthcare professionals within patient records.</p> <p>A patient can use the national data opt-out online or telephone service to review, set or change their choice at any point.</p> <p>Health and care organisations will not be expected to view individual records to see if a national data opt-out exists but will be provided with a separate solution for applying national data opt-outs.</p> |
| <p>19) When a patient sets their opt-out, how will their identity be verified?</p> | <p>To set a national data opt-out preference, patients will first need to verify their identity – we match information provided by them with information we already hold on our system. What we need depends on how the patient accesses the service:</p> <ul style="list-style-type: none"> • Digital or assisted digital - we ask for name, date of birth and NHS number. • Non-digital - we ask for name, address, postcode and NHS number. If someone is unable to provide NHS number they will need to provide copies of two identification documents (one confirming name and the other confirming address). <p><i>For further information see Factsheet 5.</i></p> |
| <p>20) How secure will the system be for setting an opt-out?</p> | <p>The process for verifying identity and setting a national data opt-out meets the security standards set out in the following:</p> <ul style="list-style-type: none"> • Authentication and Credentials for use with HMG Online Services https://www.ncsc.gov.uk/guidance/authentication-and-credentials-use-hmg-online-services-gpg-44 • Identity proofing and verification of an individual https://www.gov.uk/government/publications/identity-proofing-and-verification-of-an-individual • Digital Identity Guidelines https://pages.nist.gov/800-63-3/sp800-63b.html |
| <p>Technical solutions – Applying Opt-outs</p> | |
| <p>21) What solution will be provided to organisations so that they can apply the national data opt-out?</p> | <p>Health and care organisations will be required to put in place the processes and systems to apply national data opt-outs by March 2020.</p> <p>NHS Digital is developing and testing a system to enable health and care organisations to apply national data opt-outs, known as the ‘external upholding solution’.</p> <p>This system will enable organisations to submit a list of NHS numbers relating to the patient records in a proposed data disclosure.</p> |

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| | <p>The list will be returned with NHS numbers removed for those patients with a national data opt-out. The returned list will then need to be matched by the organisation to the NHS numbers in the data to be disclosed and those that are not found should be removed before disclosure to ensure national data opt-outs are applied.</p> <p>Please contact newoptoutenquiries@nhs.net, if your organisation would be willing to be involved in piloting the external upholding solution.</p> <p>Other upholding solution options may also be considered following testing and evaluation.</p> |
| <p>22) Are you working with system suppliers so that the necessary changes to their systems can be made? Our legacy technical systems might struggle to cope with upholding the national data opt-out.</p> | <p>Local systems do not require changes to be made to allow national data opt-outs to be set or changed. The system used to set and change a patient's national data opt-out is made available directly to patients via an online or telephone service.</p> <p>NHS Digital are developing a solution (known as the external upholding solution) to provide access to national data opt-outs by organisations needing to apply the opt-outs. This solution should meet the requirements of all health and care organisations' processes for disseminating data. We will be testing this with local organisations to verify the service will be suitable.</p> <p>Please contact newoptoutenquiries@nhs.net, if your organisation would be willing to be involved in piloting the external upholding solution.</p> |
| Communications | |
| <p>23) When will information about the national data opt-out be available for patients and the public? How do I access them?</p> | <p>Information on the national data opt-out will be available to the public, aligned with the introduction of the new General Data Protection Regulation (GDPR) on 25 May 2018.</p> <p>Materials for patients will be sent to organisations from June 2018 and electronic versions of these are available at: https://digital.nhs.uk/national-data-opt-out</p> |
| <p>24) How will patients know which organisations are applying national data opt-outs?</p> | <p>Information is available at www.nhs.uk/your-nhs-data-matters which includes information about data uses and allows patients and public to set or change their national data opt-out choice.</p> <p>This will make it clear that a patient's decision to opt out will be respected and applied by NHS Digital in the first instance; and by all other organisations that use and disclose health and care information by March 2020.</p> |
| Other Opt-outs | |
| <p>25) Do patients have the right under law (e.g. Human Rights Act) to opt out of the sharing of their confidential patient information for individual care between, for example, primary</p> | <p>The national data opt-out does not apply to use of information for individual care purposes.</p> <p>Patients can ask the organisation providing their care for their confidential information not to be shared, however the potential consequences should be explained to them by an appropriate practitioner. The GMC provides detailed guidance https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/confidentiality/using-and-disclosing-patient-information-for-direct-care#paragraph-26</p> |

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| <p>and secondary care organisations?</p> | <p>The Human Rights Act 1998 gives effect to the rights set out in the European Convention of Human Rights. Article 8 gives individuals a right to respect for their private and family life, however this does not make it unlawful for organisations to process personal data where there is otherwise a lawful basis to do so.</p> |
| <p>26) Is this the same as the existing “Type 1” or “Type 2” opt-outs?</p> | <p>No.</p> <p>“Type 2” opt-outs were coded in the patient record at the GP practice to prevent <u>NHS Digital</u> disclosing confidential patient information for purposes beyond individual care whereas, by March 2020, all <u>health and care organisations</u> will be required to apply the new national data opt-out. Type 2 opt-outs will be converted to national data opt-outs, and those patients with a Type 2 opt-out will be notified.</p> <p>“Type 1” opt-outs apply to confidential patient information being released by a GP Practice and these opt-outs can still be set in the patient record held at the GP practice by coding “dissent from secondary use of GP patient identifiable data”. As set out in the Government response to the National Data Guardian (NDG) Review, Type 1 opt-outs will continue to be respected until 2020, when the National Data Guardian will be consulted on their removal.</p> <p>For further information on “Type 1” and “Type 2” opt-outs (including Type 2 conversions) please view the NHS Digital web page.</p> |
| <p>Data Sharing</p> | |
| <p>27) Is this another version of care.data?</p> | <p>No. The care.data programme closed in 2016.</p> <p>The national data opt-out programme was established to deliver the opt-out model that was accepted by the Government in their response to the recommendations made by the National Data Guardian as set out in the “Review of Data Security, Consent and Opt-Outs”. The aim of this work, in line with the review and Government response, is to improve understanding and information available to patients, public and the workforce on the use of health and care data for purposes beyond individual care and to put in place a system to allow patients to opt-out of their confidential patient information being used in this way, and to establish the detailed policy to support this.</p> |
| <p>28) What about other forms of data sharing for health purposes, how are they affected?</p> | <p>Local data sharing schemes also operate in many regions, usually to promote data sharing for individual care. These schemes typically have their own opt-out processes. If confidential patient information is to be shared for purposes beyond individual care as part of such schemes, then the national data opt-out may apply in line with the wider policy i.e. depending on the legal basis for the data sharing.</p> <p><i>For further information see Factsheet 1B.</i></p> |
| <p>29) Why is there a need to use confidential patient information for purposes beyond individual care?</p> | <p>The National Data Guardian set out in her “Review of Data Security, Consent and Opt-Outs” that “Information is essential for high quality health and care, to support the provision of excellent care and for the running of the health and social care system. It is also essential to improve the safety of care, including through research, to protect public health, and support innovation. It can be beneficial to join health data with other types of information, to provide better services to people. “</p> <p><i>For further information see Factsheet 1A.</i></p> |