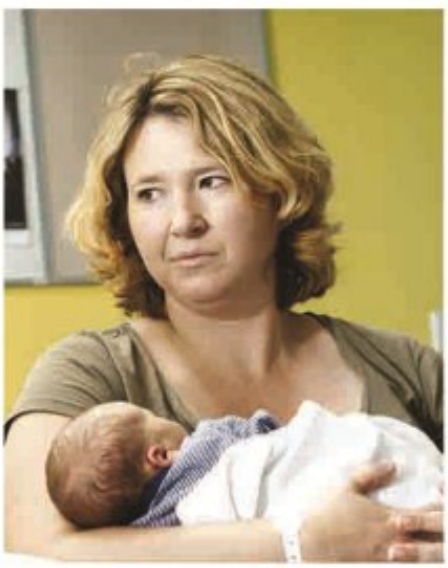
NHS England

Advice on the legal basis for processing of patient confidential data for Home Oxygen Services



THE NHS CONSTITUTION
the NHS belongs to us all

NHS England INFORMATION READER BOX		
Directorate		
Medical	Operations	**Patients and Information**
Nursing	Policy	Commissioning Development
Finance	Human Resources	

Publications Gateway Reference:	**01180**
Document Purpose	Guidance
Document Name	Advice on the legal basis for processing of patient confidential data for Home Oxygen Services
Author	South London CSU and Karen Thomson
Publication Date	Feb 2014
Target Audience	CCG Clinical Leaders, Medical Directors, Directors of Nursing, GPs, Emergency Care Leads, CLINICIANS
Additional Circulation List	NHS England Regional Directors, Department of Health, Home Oxygen Service Providers, NHS England Area Directors, Allied Health Professionals, GPs, NHS Trust CEs
Description	Advice on the legal basis for processing of patient confidential data for Home Oxygen Services (HOS) and template consent form
Cross Reference	N/A
Superseded Docs (if applicable)	N/A
Action Required	
Timing / Deadlines (if applicable)	
Contact Details for further information	Karen Thomson Strategic Information Governance Lead Patients and Information DirectorateNHS England 7E11 | Quarry House | Quarry Hill | Leeds | LS2 7UE england.information-governance@nhs.net

Document Status

This is a controlled document. Whilst this document may be printed, the electronic version posted on the intranet is the controlled copy. Any printed copies of this document are not controlled. As a controlled document, this document should not be saved onto local or network drives but should always be accessed from the intranet

Gateway publication number 01180

Acknowledgement: NHS England is grateful to South London CSU for the primary development of this advice.

Key Points:

- The provision of Home Oxygen Services is for a direct health care purpose.
- This activity is a separate purpose to those other secondary use purposes covered by the 13 June 2013 NHS England letter (Gateway Ref. No. 168) concerning section 251 approval for outbound data flows from the HSCIC to commissioning organisations.
- Section 251 does not apply to the sharing of personal confidential data (PCD) for direct care purposes.
- The provision of care and the safety of the patient are of paramount importance and information should flow between the care team where it is clinically necessary and/or to avoid a risk of harm.
- When an individual provides consent for sharing information about them for a particular purpose this consent provides a legal basis for sharing.
- Clinical staff of the commissioning organisations require access to personal confidential data to ensure patient safety and the delivery of a quality personalised service to patients, which is done on a basis of implied consent and provision of information to patients and is therefore lawful.
- The disclosure of patient confidential data by providers of Home Oxygen Services to Commissioners for a commissioning purpose is done on the basis of explicit consent and the provision of information to patients and is therefore lawful.
- Patient consent needs to be renewed at the next assessment visit to ensure patients have been provided with all necessary information and their consent adequately covers the new NHS organisations.

1. Audience

This document is intended primarily for Health Care Providers (HCPs) and providers of Home Oxygen Services (HOS). It provides clarification on the lawful basis for sharing personal confidential data for the care team and others involved in the provision of those services, including commissioning organisations.

2. Purpose and Scope

|This document provides advice to HOS, the direct care team, Clinical Commissioning Groups (CCGs) and Commissioning Support Units (CSUs) about their use of patient confidential data for the provision of the service. It sets out the lawful basis to support the necessary flow of PCD for the provision of direct patient care, and for the management of the contract, and is consistent with the Health and Social Care Information Centre's Guide to Confidentiality[1] .

3. Background

The supply of HOS is contracted under a NHS National Framework Agreement (the NFA). Each former SHA region appointed a Lead PCT to procure their local contract (the Contract) supplier against the NFA. Following the closure of PCTs on 31 March 2013, local responsibility for the Contract transferred to the relevant lead CCG.

On the 13 June 2013 NHS England issued a letter to explain the section 251[2] arrangements to support the transfer personal confidential data from the Health and Social Care Information Centre (HSCIC) to commissioning organisations[3].

Unfortunately this has led to some confusion about what data can flow between HOS Providers and Commissioners and clarification was requested.

The particular concern is that information flows have been suspended, which compromises patient safety and puts them at risk.

The Section 251 support only applies to data flowing from the HSCIC to commissioning organisations for specific secondary use purposes as set out in the letter and supporting guidance published by the HSCIC. [4]

---

[1] HSCIC Guide to Confidentiality http://www.hscic.gov.uk/media/12822/Guide-to-confidentiality-in-health-and-social-care/pdf/HSCIC-guide-to-confidentiality.pdf

[2] Section 251 NHS Act 2006 These regulations empower the Secretary of State for Health to approve applications for the common law duty of confidence to be set aside under certain circumstances for specified medical purposes that are not related to direct care

[3] Conditional Approval for Commissioning Data Flows under section 251 Gateway Ref. No. 168 http://www.england.nhs.uk/wp-content/uploads/2013/06/130614-s251conditions.pdf

[4] http://www.hscic.gov.uk/dataflowstransitionmanual

Section 251 does not apply to the processing of confidential patient data for direct care purposes. HOS is direct care purpose. Therefore it is neither necessary nor appropriate to consider applying for s251 approval to support the data flows to commissioners.

It is, however, necessary to establish a lawful basis for that data flow. This document sets out how to process data lawfully where HOS services are contracted to support the provision of direct care and treatment.

4. Sharing personal confidential data for direct care purposes

The definition of direct care is –

"*A clinical, social or public health activity concerned with the prevention, investigation and treatment of illness and the alleviation of suffering of individuals. It 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, the management of untoward or adverse incidents, person satisfaction including measurement of outcomes undertaken by one or more registered and regulated health or social care professionals and their team with whom the individual has a legitimate relationship for their care*".[5]

In the recent Information Governance Review, the Review Panel identified concerns about the detriment and/or risk to the patient when information necessary for the safe and effective delivery of their health care was not being shared appropriately.[6] The Government's response to the Review said: "Sharing information to support care is essential. It is not acceptable that the care a patient or service user receives might be undermined because the different organisations providing health and care to an individual do not share information effectively[7]".

The Review established a new seventh Caldicott principle – the duty to share information can be as important as the duty to protect personal confidential data[8], meaning those providing health (and social) care should have the confidence to share information in the best interests of the patient. However, there is still a requirement to treat information confidentially and respectfully in compliance with the

[5] Information Governance Review - Glossary

[6] Information Governance Review: To Share or Not to Share (Caldicott 2) (at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf

[7] Information: To Share or Not to Share? The Government's response to the Caldicott Review (at 3.5) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/239273/9731-2901141-TSO-Caldicott-Government_Response_ACCESSIBLE.pdf

[8] Information Governance Review – The Caldicott Principles 14.2

law.

5. Legal Requirements

All processing of confidential patient information must be lawful. Where personal and private information is confided in a confidential relationship, or the information is clearly confidential in nature, the common law duty of confidentiality requires that it should not be further used or disclosed except as originally understood and agreed by the individual concerned, or with their subsequent consent, or where another basis in law applies. The common law duty can also be overridden in certain case-by-case circumstances where there is a strong public interest in the benefit of disclosing information that outweighs the corresponding public interest in the provision of confidential services.

When an individual provides consent for sharing information about them for a particular purpose (either for direct care or for other purposes), their consent provides the legal basis for information sharing[9].

In addition to the common law duty of confidentiality, the principles of the Data Protection Act 1998 (DPA) and Human Rights Act 1998 (HRA) also need to be met.

6. Implied Consent

Registered and regulated professionals[10] (who are a part of the care team providing direct care through the care pathway) rely on a patient's implied consent to share information as an integral part of their consent to examination and treatment. This is based on the patient's reasonable understanding of who is included in the care team and why their information is being used and shared. Unless they have otherwise objected, information should be shared on the basis of trust that those professionals will protect their confidential data and share it in the interests of their care.

The reliance of implied consent however is only applicable within the context of direct care, and where it may not be obvious to a patient who exactly may be a part of that team (i.e. where it is not reasonable to expect them to know) then it is good practice to explain to them who else is involved and ensure they understand and have no objections. An example would be where information is shared across organisational boundaries with health and social care professionals who are not necessarily visible to the patient, but are an important part of the care team. An example would be clinicians who work for the CCG or a hospital and are responsible for ensuring patient safety in their use of home oxygen services and the quality of

[9] HSCIC Guide to Confidentiality References Page 9

[10] Registered and regulated professionals answerable to a regulatory body e.g. General Medical Council, Nursing and Midwifery Council etc.

that care[11].

When that confidential information needs to be shared with a third party who are not a registered or regulated member of the care team, or with anyone for a purpose that is not directly connected with the provision of direct care, then the patient's explicit consent is required.[12]

7. Obtaining explicit consent

When a patient is diagnosed as requiring home oxygen services, the prescribing Health Care Professional is responsible for obtaining the patient's explicit consent to share their personal confidential information with the HOS provider, relevant Commissioning organisation[13] for commissioning related (non-health care) medical purposes and other essential services.

In addition to being a common law duty of confidentiality requirement, explicit consent is the only condition in the DPA that can be met to provide the basis in law to share personal data with those additional services (See section 14 Data Protection).

All consent, whether it is implied or explicit, should be informed. It is unusual for people to express a concern about their information being shared where they see it as necessary to provide their care, however, even when it is obviously in their best interests it is still important to ensure they make fully informed choices and their decisions are respected.

Explicit consent is unmistakeable. It can be given in writing or verbally, or conveyed through another form of communication such as using sign language. A patient may have capacity to give consent, but may not be able to write or speak. Explicit consent is required when sharing information with someone who is not a part of the team caring for the individual. It may also be required for a use other than that for which the information was originally collected, or when sharing is not related to an individual's direct health and social care.[14]

Explicit consent should be obtained once, preferably at the same time the Home Oxygen Order Form (HOOF)[15] is completed and before information is shared. It should be comprehensive to support all subsequent information sharing between the

[11] Or whoever is designated within local area arrangements

[12] HSCIC Guide to confidentiality in health and social care: references Section 7 http://www.hscic.gov.uk/media/12823/Confidentiality-guide-References/pdf/confidentiality-guide-references.pdf

[13] As determined in NHS England "Who pays" Determining responsibility to payments to providers http://www.england.nhs.uk/wp-content/uploads/2012/12/who-pays.pdf

[14] HSCIC Guide to confidentiality: references Section 2

[15] See Appendix B for the NHS England HOOF template

HOS supplier, the electricity supplier, the emergency services, and the lead commissioning organisation for commissioning specific purposes. It should not be necessary for those services to obtain separate explicit consent to share information with those already listed as this risks causing confusion. It is therefore important to ensure that all those concerned are included in the process and that the patient fully understands why those services need to know their personal information and the likely consequences to their care if they choose to decline.

The following summarises the reasons why it is necessary to share information:

> The HOS Supplier will provide all of the equipment, supplies and support that a patient will need to receive the service. The HOS Supplier will need to share information with the following services to ensure the provision of an integrated service, safety standards, payment for those services and reimbursement of electricity costs.
>
> The electricity supplier is informed that the patient is an essential user of electricity and is to be given priority in the event of a breakdown in the electricity supply. The electricity supplier is responsible for informing the HOS supplier of any power outage in the area so they can respond and ensure the provision of service and patient safety is not compromised.
>
> The fire and rescue services are informed that a patient is a HOS service user to ensure they are aware of potential risks and are prepared to respond in the event of an emergency.
>
> The lead commissioning organisation is responsible for overseeing the provision and quality of the service; for ensuring patient safety, risk management and assurance as well as for co-ordinating payment.

Patients should also be provided with details of who to contact for further information in case the patient has further questions or subsequent concerns.

The recommendations within the NICE Guidance: Patient experience in adult NHS services: improving the experience of care for people using adult NHS services[16] should be followed.

A patient's explicit informed consent should be obtained and documented in accordance with the Department of Health's guidelines[17]. Where an individual's

[16] http://www.nice.org.uk/nicemedia/live/13668/58284/58284.pdf

[17] Department of Health Reference Guide to Consent for Examination or Treatment (second edition) (section 34) for further information https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatmen-second-edition

capacity to give consent is in doubt, their capacity should be assessed using the principles in the Mental Capacity Act 2005[18]

8. The Home Oxygen Consent Form

The prescribing HCP is responsible for obtaining the patient's explicit consent to share their personal information for the provision of home oxygen services. Unless the patient's personal circumstances require an alternative arrangement to be made, written consent should be obtained by the completion of the Home Oxygen Consent Form (HOCF)[19] at the same time the Home Oxygen Order Form (HOOF) is completed and before information is shared.

The HOCF is designed to obtain the patient's written consent to transfer the personal confidential data to:

- The HOS Supplier;
- The fire and rescue services;
- The patient's electricity provider;
- The Commissioning organisation; and
- Any other person or organisation as necessary.

The HOCF will be reviewed periodically by NHS England. It should be accompanied by local fair processing information that includes

- information about all of the organisations that will be processing their personal data;
- the purposes for which that data will be processed;
- their right to opt-out from having their information used for any of these purposes and the implication that would have on their care
- anything else they might not reasonably be expected to know and should be told about (also see Fairness and Transparency).

If other persons or organisations are also included in the provision of HOS not already listed on the form, then they should be added by the prescribing HCP at this stage.

The prescribing HCP is also responsible for ensuring all of the organisations are informed that patient consent to share information has been obtained. This can be achieved by providing them with a copy of the signed consent form. It is good practice to also provide the patient with a copy.

[18] Further guidance is available in the Mental Capacity Act (2005) Code of Practice http://www.justice.gov.uk/protecting-the-vulnerable/mental-capacity-act

[19] See Appendix C for the NHS England HOCF template

9. Fairness and Transparency

For consent to be valid it has to be informed. In addition, the DPA (first principle) requires that personal data is processed fairly, which means that as well as informing patients about which organisations are sharing their personal data and why, fairness also requires that information is shared in a way that people would reasonably expect and would not ordinarily object to if provided with a clear explanation and assurance that their confidentiality will be protected. In DPA terms this is referred to as a "privacy" or "fair processing" notice.

The Information Commissioner's Office (ICO) Privacy Notices Code of Practice[20] says that the need to communicate a privacy notice actively is strongest where:

- Sensitive personal data is being shared; or
- The data sharing is likely to be unexpected; or
- Sharing the data, or not sharing it will have a significant effect on the individual; or
- The sharing is particularly widespread and involves organisations individuals might not expect; or
- The sharing is for a different range of purposes.

The primary responsibility for ensuring that the patient understands what they are being asked to consent to lies with the prescribing HCP, however, each organisation is separately responsible under the DPA to ensure that individuals are aware that they hold their personal data, what they are using it for and who they should contact should they require access to their data or for further information.
It is therefore good practice for the organisations to work together to design a HOS fair processing notice as a supplement to the HOCF, that can be provided to patients as their record of what they have agreed.

10. Delays in obtaining consent

Professional judgement based on the patient's best interests will apply in circumstances where waiting for explicit consent to be obtained would cause an unacceptable delay and there is a specific safety concern regarding the individual, (i.e. where they would be at risk of harm if care is not provided immediately) If these circumstances can be resolved or mitigated by sharing some confidential information, then the appropriate information can be shared..

20

http://www.ico.org.uk/for_organisations/guidance_index/data_protection_and_privacy_and_electronic_communications#sharing

The ICO's Data Sharing Code of Practice gives the following guidance:

Sometimes there may be a need to share very sensitive information, even without the individual's knowledge. Acting appropriately in situations like this depends primarily on the exercise of professional judgement. However, disclosures of personal data in situations like this are still subject to the DPA. The ICO will give due weight to compliance with authoritative professional guidance in determining whether there has been a breach of the DPA. Therefore it is very much in the interests of organisations and individual employees to be aware of any professional guidance or ethical rules that are likely to be relevant to the type of decisions about disclosing personal data that they may be asked to make. It may not always be possible to document the sharing in an emergency or time dependent situation, however it is good practice to make a record as soon as possible, detailing the circumstances, what information was shared and explaining why the disclosure took place.[21]

The disclosure of information should be proportionate, relevant, not excessive to need, and restricted to those who need to know to provide essential immediate care. It should be supported by a verbal explanation and reassurance to the patient and documented in the medical record. The standard consent procedure should be followed a soon as it is practical to do so.

[21] ICO Data Sharing Code of Practice "Ad hoc or "one off" sharing Page 20
http://www.ico.org.uk/for_organisations/guidance_index/~/media/documents/library/Data_Protection/Detailed_specialist_guides/data_sharing_code_of_practice.ashx

11. Renewing consent

The duration of consent generally lasts until the circumstances under which it was given changes, or consent is withdrawn.

Due to the replacement of PCTs by CCGs, it is possible that some services will still be operating under the previous HOCF that will not have included the new arrangements. It is therefore necessary to review the HOCF to ensure that it incorporates the organisational changes and includes an explanation as to the purpose(s) for sharing information (as opposed to just a list of services).

Patient consent should be renewed using the revised HOCF at the next assessment visit, or when there are changes to the service. It is important to explain to the patient why it is necessary to do so and ensure they understand.

In the meantime, data should continue to be shared with the CCG to address issues of quality of care and ensure patient safety on a basis of implied consent. It is reasonable to assume that patients expect this and unreasonable to disrupt the service provisions and put them at risk by not sharing data until new consent is obtained.

The Health & Social Care Information Centre's Guide to confidentiality – Rule 2 says "members of a care team should share confidential information when it is needed for the safe and effective care of the individual". [22]

It is advisable to document the interim decision to share patient confidential data on best interests grounds of patient safety and implied consent, and gain agreement from the Commissioning organisation's Caldicott Guardian, in accordance with the Caldicott principles.[23]

Commissioning organisations should now implement these arrangements by introducing the revised HOCF and consent procedures for all new patients and ensuring consent is renewed progressively at the next assessment visit for all existing users of HOS.

The Health & Social Care Information Centre's Confidentiality Guide and reference document provides further information.

---

[22] http://www.hscic.gov.uk/media/12822/Guide-to-confidentiality-in-health-and-social-care/pdf/HSCIC-guide-to-confidentiality.pdf

[23] Information: To share or Not to Share? Government response to the Caldicott review https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/239273/9731-2901141-TSO-Caldicott-Government_Response_ACCESSIBLE.pdf

12. Clinical Audit

Clinical audit is important for providing assurance that care and treatment is safe and of high quality. Local clinical audits can be regarded as an integral part of direct care and therefore may be conducted with implied consent, provided the following criteria are met:

- the audit is conducted by healthcare professionals, with a legitimate relationship with the patient in one of the organisations that has delivered the patient's care or treatment; and
- the audit is carried out in accordance with clinical governance guidelines; and
- it has been approved by the NHS Trust's medical director and Caldicott Guardian

The use of de-identified data should be considered first, for national and regional clinical audits, or where third party organisations are used to conduct a clinical audit. If it is not possible to use de-identified data then patient consent must be sought, or if this is not feasible, Section 251 approval will be required. [24].

13. Information Sharing Agreements

When confidential personal information that can identify an individual is shared, both the disclosing and receiving organisations should have procedures that meet the requirements of law and guidance and make clear to staff the appropriate working practices.

The Information Governance Toolkit (IGT) guidance specifies a requirement for an Information Sharing Agreement where confidential information is shared between organisations where there is no requirement to carry out IG assessments or which do not provide IG assurance in the same way as health care providers i.e. the electricity supplier and fire and rescue services.

The Information Sharing Agreement should specify the required information governance standards in the recipient organisation, the legal principles that apply and the additional standards associated with the secondary uses in question, i.e. the purpose, constraints on re-use of information, retention periods and destruction.

For further information see the IGT standard 11-207 requirement description and

[24] Initially Patient Information Advisory Group (PIAG) policy published 5th August 2004 now published in the Health Research Authority – Confidentiality Advisory Group s251 FAQ
http://www.hra.nhs.uk/documents/2013/08/cag-frequently-asked-questions.pdf

guidance. [25]

See also the Information Commissioner's Data Sharing Code of Practice section 8 – Governance and 14 – Data Sharing Agreements.[26]

14. Data Protection

The supply of HOS is contracted under a NHS National Framework Agreement (the NFA). Each former SHA region appointed a Lead PCT to procure their local contract (the Contract) supplier against the NFA. Following the closure of PCTs on 31 March 2013, local responsibility for the Contract transferred to the relevant lead CCG.

The Contract (at 30.3) establishes the CCG[27] as the Data Controller and the HOS Supplier as the Data Processor acting on the CCG's behalf in respect of any Personal Data processed under the Contract.

Under the terms of the DPA, it is the duty of the Data Controller to ensure that all personal data they are responsible for is processed in accordance with the data protection principles.[28]

The Data Processor is responsible for ensuring their technical and organisational security measures are adequate and personal data is only processed in accordance with the instructions of the Data Controller[29].

Compliance with the first DPA principle

The first DPA principle requires personal data to be processed fairly and lawfully and at least one condition in Schedule 2 should be met. Where sensitive personal data is processed at least one condition in both Schedule 2 and Schedule 3 should be met.

Fair processing is addressed in section 9 and will be satisfied through the provision of a fair processing notice.

Lawfulness refers to both statute and common law. Processing would be unlawful if it results in a breach of:

---

[25] HSCIC Information Governance Toolkit 11-207
https://www.igt.hscic.gov.uk/RequirementQuestionNew.aspx?tk=415535452512376&lnv=2&cb=e52ffe5c-a266-4979-93fe-ca6af6558397&sViewOrgType=2&reqid=2386

[26] http://www.ico.org.uk/for_organisations/guidance_index/~/media/documents/library/Data_Protection/Detailed_specialist_guides/data_sharing_code_of_practice.ashx

[27] Although it may still state the PCT

[28] Section 4(4) Data Protection Act 1998

[29] Schedule 1 Part II Section 12 (a) (ii)

- a duty of confidence
- an enforceable contractual agreement;
- industry specific regulations;

It would also be unlawful if an organisation exceeding its lawful powers or infringed of the Human Rights Act 1998[30].

The NHS and other public authorities derive their legal powers from statute. Private sector organisations have a general ability to share information provided this does not breach the DPA or any other law. The sharing of personal data for the purposes of the provision of HOS outlined in this document will be consistent with the legal powers of each organisation involved in the care pathway.

A Schedule 2 condition for processing personal data must be met to satisfy the first principle.

The NHS and fire and rescue services, as public sector organisations, will meet the condition in Schedule 2 paragraph 5(d), where the processing is necessary for the exercise of public functions in the public interest.

The private sector organisations will meet Schedule 2 section 2 (a) and (b) as the processing is necessary for the performance of a contract which the data subject (patient) is a party to.

In addition, a Schedule 3 condition for processing sensitive personal data must also be met. Sensitive data processed for the purpose of HOS services will include information relating to the physical and/or mental health condition of the patient.

The only two conditions that apply are either section 1 – Explicit consent or section 8 Medical Purposes.

Section 8 applies to the processing of sensitive personal data where it is necessary for a medical purpose[31] and undertaken by a health professional or a person who owes and equivalent duty of confidentiality.

Section 8 will therefore apply to the sharing of sensitive personal data between the health care team and HOS suppliers where that sharing is necessary for the provision of care and treatment.

---

[30] Public authorities must comply with the Human Rights Act 1998 (HRA) in the performance of their functions. The HRA also applies to organisations in the private sector insofar as they carry out functions of a public nature. Compliance with the DPA and common law duty of confidentiality will satisfy the HRA.

[31] Medical Purposes includes the purposes of preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services. DPA 1998 Schedule 3 section 8 (2).

However, it would not apply to the sharing of that data between the fire and rescue teams, electricity supplier or the commissioning organisations for non-health care related purposes because they are not processing the data for a medical purpose. Therefore the only Schedule 3 condition that can legitimise the sharing of patient confidential data is with their explicit consent.

Each organisation is a Data Controller and separately responsible for ensuring that their processing of personal data about a HOS service user complies with the data protection principles. It is the legal duty of each organisation to make their own arrangements to ensure compliance with the DPA for any further use of the personal data they have been provided with under this HOS arrangement that is not covered by the patient's explicit consent.

15. HSCIC Guide to Confidentiality

The HSCIC has produced the Guide to Confidentiality in Health and Social Care and accompanying references under section 265 of the Health and Social Care Act 2012. Under the Act health or social care bodies or anyone working with them and processing confidential information to provide health services or adult social care must have regard to that advice or guidance.

The guidance and references are available on the HSCIC website at http://www.hscic.gov.uk/confguideorg.

The Caldicott Principles are listed in Appendix A.

16. Equality assurance

Equality and diversity are at the heart of the NHS strategy. Due regard to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited in under the Equality Act 2010) and those who do not share it, has therefore been given throughout the development of the policies and processes cited in this document.

17. Summary of recommendations

Ref	Description	Organisation	Section
1	Sharing information to support care is essential. It is not acceptable that the care a patient or service user receives might be undermined because the different organisations providing health and care to an individual do not share information effectively	All	4
2	All information sharing must be lawful. When an individual provides consent for sharing information about them for a particular purpose (either for direct care or for other purposes), their consent provides the legal basis for information sharing	All	5
3	The care team providing direct care through the care pathway can rely on a patient's implied consent to share information providing that the patient is aware of who is included in the care team, why their information is being shared, and have not raised any objection.	Care team	6
4	The prescribing health care provider is responsible for obtaining and recording the patient's explicit consent to share their personal confidential information with the HOS provider, relevant commissioning organisation (for commissioning related non-health care medical purposes) the electricity supplier and fire and rescue services.	Prescribing health care provider.	7
5	Issues concerning diversity and capacity should be managed when obtaining and recording consent	Prescribing health care provider	7
6	Written consent should be obtained by the completion of the Home Oxygen Consent Form (HOCF) at the same time the HOOF is completed and before information is shared.	Prescribing health care provider	8

7	The HOCF should be reviewed and updated to ensure that it includes information about all of the organisations that will be processing their personal data	NHS England to co-ordinate	8
8	All organisations should work together to develop a HOS fair processing notice as a supplement to the HOCF, that can be provided to patients as their record of what they have agreed to.	NHS England to co-ordinate	9
9	Where waiting for explicit consent to be obtained would cause an unacceptable delay and there is a specific safety concern regarding the individual i.e. where they would be at risk of harm if care is not provided immediately, which can be resolved or mitigated by sharing some confidential information, and then professional judgement and the patient's best interests apply.	Care team	10
10	Patient consent should be renewed using the revised HOCF at the next assessment visit, and it is important to explain to the patient why it is necessary to do so and ensure they understand. In the meantime, data should continue to be shared with the CCG to address issues of quality of care and ensure patient safety on a basis of implied consent	Lead commissioning organisation should co-ordinate Care team to renew consent	11
11	Clinical audit can be conducted under a basis of implied consent providing: the audit is conducted by one of the organisations that has delivered the patient's care or treatment; and the audit is carried out in accordance with clinical governance guidelines; and it has been approved by the NHS Trust's medical director and Caldicott Guardian	All	12

12	An Information Sharing Agreement is required to specify the information governance standards in the recipient organisation, the legal principles that apply and the additional standards associated with the secondary uses in question, i.e. the purpose, constraints on re-use of information, retention periods and destruction.	Lead commissioning organisation should co-ordinate	13
13	Each organisation is a Data Controller and separately responsible for ensuring that their processing of personal data about a HOS service user complies with the data protection principles. It is the legal duty of each organisation to make their own arrangements to ensure compliance with the DPA for any further use of the personal data they have been provided with under this HOS arrangement that is not covered by the patient's explicit consent.	All	14

18. Glossary

Anonymisation: The process of removing identifiers from a set of data so that there is little or no risk of the individual being identified from that data or by matching it to other data (identification is not likely to take place)

Caldicott Guardian: A senior person within an organisation who is responsible for ensuring the protection of confidentiality of patient and service user information and enabling appropriate information sharing.

Care pathway: A care pathway is anticipated care placed in an appropriate time frame, written and agreed by a multi-disciplinary team. It has locally agreed standards based on evidence, where available, to help a patient with a specific condition or diagnosis move progressively through the clinical treatment.

Care team: The health and/or social care professionals and staff that directly provide or support care to an individual.

Clinical audit: Clinical audit is a tool for improving practice, patient care or services provided. It is used to measure current practice and care against a set of explicit standards or criteria, identify areas for improvement, make changes to practice and re-audit to ensure that improvement has been achieved. The findings of the clinical audit provide evidence of the quality of practice and care.

Consent: The approval or agreement for something to happen after consideration. For consent to be legally valid, the individual must be informed, must have the capacity to make the decision in question and must give consent voluntarily. This means individuals should know and understand how their information is to be used and shared (there should be ‘no surprises’) and they should understand the implications of their decision, particularly where refusing to allow information to be shared is likely to affect the care they receive. This applies to both explicit and implied consent. For explicit consent there additionally needs to be a positive indication of the individual's wishes.

Data controller: (DPA Part 1 Section 1**) A** person (individual or organisation) who determines the purposes for which and the manner in which any personal confidential data are or will be processed. Data controllers must ensure that any processing of personal data for which they are responsible complies with the DPA.

Data processor: (DPA Part 1 Section 1**)** In relation to personal data, means any person (other than an employee of the data controller) who processes the data on behalf of the data controller. Data processors are not directly subject to the Data Protection Act. But the Information Commissioner recommends that organisations should choose data processors carefully and have in place effective means of monitoring, reviewing and auditing their processing and a written contract (detailing the information governance requirements) must be in place to ensure compliance with principle 7 of the Data Protection Act.

Direct care: A clinical, social or public health activity concerned with the prevention, investigation and treatment of illness and the alleviation of suffering of individuals. It 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, the management of untoward or adverse incidents, person satisfaction including measurement of outcomes undertaken by one or more registered and regulated health or social care professionals and their team with whom the individual has a legitimate relationship for their care.

Identifiable information: See 'Personal confidential data'.

Legitimate relationship: The legal relationship that exists between an individual and the health and social care professionals and staff providing or supporting their care

Personal confidential data: This term describes personal information about identified or identifiable individuals, which should be kept private or secret. For the purposes of this guide 'personal' includes the DPA definition of personal data, but it is adapted to include dead as well as living people. 'Confidential' includes both information 'given in confidence' and 'that which is owed a duty of confidence' and is adapted to include 'sensitive' as defined in the Data Protection Act. Used interchangeably with 'confidential' in this document.

Personal data: (DPA Part 1 Section 1**)** Data which relate to a living individual who can be identified from those data, or from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual.

Processing: (DPA Part 1 Section 1**)** Processing in relation to information or data means obtaining, recording or holding the information or data or carrying out any operation or set of operations on the information or data, including:

- organisation, adaptation or alteration of the information or data;
- retrieval, consultation or use of the information or data;
- disclosure of the information or data by transmission, dissemination or otherwise making available; or
- alignment, combination, blocking, erasure or destruction of the information or data.

Pseudonym: Individuals are distinguished in a data set through the use of a unique identifier, which does not reveal their 'real world' identity.

Public interest (test): This applies when the holder of the information believes that the public good that would be served by sharing the information outweighs both the obligation of confidentiality owed to the individual and the public good of protecting trust in a confidential service.

Sensitive personal data/information: (DPA Part 1 Section 2**)** Data that identifies a living individual consisting of information as to his or her: racial or ethnic origin, political opinions, religious beliefs or other beliefs of a similar nature, membership of a trade union, physical or mental health or condition, sexual life, convictions, legal proceedings against the individual or allegations of offences committed by the individual. See also 'Personal confidential data'

Appendix A: The Caldicott principles

1. Justify the purpose(s)

Every proposed use or transfer of personal confidential data within or from an organisation should be clearly defined, scrutinised and documented, with continuing uses regularly reviewed, by an appropriate guardian.

2. Don’t use personal confidential data unless it is absolutely necessary

Personal confidential data items should not be included unless it is essential for the specified purpose(s) of that flow. The need for patients to be identified should be considered at each stage of satisfying the purpose(s).

3. Use the minimum necessary personal confidential data

Where use of personal confidential data is considered to be essential, the inclusion of each individual item of data should be considered and justified so that the minimum amount of personal confidential data is transferred or accessible as is necessary for a given function to be carried out.

4. Access to personal confidential data should be on a strict need-to-know basis

Only those individuals who need access to personal confidential data should have access to it, and they should only have access to the data items that they need to see. This may mean introducing access controls or splitting data flows where one data flow is used for several purposes.

5. Everyone with access to personal confidential data should be aware of their responsibilities

Action should be taken to ensure that those handling personal confidential data — both clinical and non-clinical staff — are made fully aware of their responsibilities and obligations to respect patient confidentiality.

6. Comply with the law

Every use of personal confidential data must be lawful. Someone in each organisation handling personal confidential data should be responsible for ensuring that the organisation complies with legal requirements.

7. The duty to share information can be as important as the duty to protect patient confidentiality

Health and social care professionals should have the confidence to share information in the best interests of their patients within the framework set out by these principles. They should be supported by the policies of their employers, regulators and professional bodies.

Appendix B: Home Oxygen Order Form Template

Home Oxygen Order Form (HOOF)

Part A (Before Oxygen Assessment – Non-Specialist or Temporary Order)

All fields marked with a '*' are mandatory and the HOOF will be rejected if not completed

1. Patient Details

1.1 NHS Number*		1.7 Permanent address*	1.9 Tel no.
1.2 Title			1.10 Mobile no.
1.3 Surname*			**2. Carer Details (if applicable)**
1.4 First name*			2.1 Name
1.5 DoB*			2.2 Tel no.
1.6 Gender	☐ Male ☐ Female	1.8 Postcode*	2.3 Mobile no.

3. Clinical Details

3.1 Clinical Code(s)		
3.2 Patient on NIV/CPAP	☐ Yes	☐ No
3.3 Paediatric Order	☐ Yes	☐ No

4. Patient's Registered GP Information

4.1 Main Practice name:*

4.2 Practice address:

4.3 Postcode*

4.4 Telephone no.

5. Assessment Service (Hospital or Clinical Service)

5.1 Hospital or Clinic Name:

5.2 Address

5.3 Postcode:

5.4 Tel no:

6. Ward Details (if applicable)

6.1 Name:

6.2 Tel no.:

6.3 Discharge date: / /

7. Order* / 8. Equipment* / 9. Consumables*

For more than 2 hours/day it is advisable to select a static concentrator

(select one for each equipment type)

Litres / Min	Hours / Day	Type	Quantity	Nasal Canulae	Mask % and Type
		8.1 Static Concentrator Back up static cylinder(s) will be supplied as appropriate			
		8.2 Static Cylinder(s) A single cylinder will last for approximately 8hrs at 4l/min			

10. Delivery Details*

10.1 Standard (3 Business Days) ☐ 10.2 Next (Calendar) Day ☐ 10.3 Urgent (4 Hours) ☐

11. Additional Patient Information

12. Clinical Contact (if applicable)

12.1 Name:

12.2 Tel no. 12.3 Mobile no.

13. Declaration*

I declare that the information given on this form for NHS treatment is correct and complete. I understand that if I knowingly provide false information, I may be liable to prosecution or civil proceedings. I confirm that I am the registered healthcare professional responsible for the information provided. I also confirm that the patient has read and signed the Home Oxygen Consent Form.

Name:	Profession:	
Signature:	Date:	Referred for assessment: ☐ Yes ☐ No

Fax back no. or NHS email address for confirmation / corrections:

14. Clinical Code

CODE	Condition	CODE	Condition
1	Chronic obstructive pulmonary disease (COPD)	12	Neurodisability
2	Pulmonary vascular disease	13	Obstructive sleep apnoea syndrome
3	Severe chronic asthma	14	Chronic heart failure
4	Interstitial lung disease	15	Paediatric interstitial lung disease
5	Cystic fibrosis	16	Chronic neonatal lung disease
6	Bronchiectasis (not cystic fibrosis)	17	Paediatric cardiac disease
7	Pulmonary malignancy	18	Cluster headache
8	Palliative care	19	Other primary respiratory disorder
9	Non-pulmonary palliative care	20	Other
10	Chest wall disease	21	Not known
11	Neuromuscular disease		

Home Oxygen Order Form (HOOF)

Part B (After Specialist / Paediatric Oxygen Assessment)

All fields marked with a '*' are mandatory and the HOOF will be rejected if not completed

1. Patient Details

1.1 NHS Number*		1.7 Permanent address*		1.9 Tel no.
1.2 Title				1.10 Mobile no.
1.3 Surname*				**2. Carer Details (if applicable)**
1.4 First name*				2.1 Name
1.5 DoB*				2.2 Tel no.
1.6 Gender	☐ Male ☐ Female	1.8 Postcode*		2.3 Mobile no.

3. Clinical Details

3.1 Clinical Code(s)		
3.2 Patient on NIV/CPAP	☐ Yes	☐ No
3.3 Paediatric Order	☐ Yes	☐ No

4. Patient's Registered GP Information

4.1 Main Practice name:*	
4.2 Practice address:	
4.3 Postcode*	4.4 Telephone no.

5. Assessment Service (Hospital or Clinical Service)

5.1 Hospital or Clinic Name:	
5.2 Address	
5.3 Postcode:	5.4 Tel no:

6. Ward Details (if applicable)

6.1 Name:
6.2 Tel no.:
6.3 Discharge date: / /

7. Order* / 8. Equipment* / 9. Consumables*

For more than 2 hours/day it is advisable to select a static concentrator

(select one for each equipment type)

Litres/Min	Hours/Day	Type	Quantity	Conserving Device	Nasal Canulae	Mask % and Type
		8.1 Static Concentrator Back up static cylinder(s) will be supplied as appropriate				
		8.2 Static Cylinder(s) A single cylinder will last for approximately 8hrs at 4l/min				
		8.3 Self Fill Concentrator Same as static concentrator and can fill ambulatory cylinder(s) (8.5/8.6)				
		8.4 Transportable Concentrator (trolley based) Can be used in place of a static concentrator and / or for ambulatory use				
		8.5 Standard Ambulatory Cylinder(s) Cylinders for use outside of a home setting				
		8.6 Lightweight Ambulatory Cylinder(s) Lighter than the standard ambulatory cylinder				
		8.7 Portable Concentrator (carry over shoulder) Lighter weight than transportable concentrator and limited to pulse dose				
		8.8 Liquid Oxygen (LOX) Dewar Please select number of flasks required below				
		8.9 Liquid Oxygen (LOX) Flask To be used in conjunction with the LOX Dewar				

10. Additional Equipment

10.1 Humidification (not usually indicated for less than 4l/min) ☐ Yes ☐ No	10.2 Tracheostomy (mask only) ☐ Yes ☐ No

11. Delivery Details*

11.1 Standard (3 Business Days) ☐	11.2 Next (Calendar) Day ☐	11.3 Urgent (4 Hours) ☐

12. Temporary Secondary Supply

(e.g. Holiday Order with different modality)

12.1 Address:
Postcode:

13. Contact Details

(if applicable)

13.1 Name:
13.2 Tel no.

14. Additional Patient Information

15. Clinical Contact (if applicable)

15.1 Name:	
15.2 Tel no.	15.3 Mobile no.

16. Declaration*

I declare that the information given on this form for NHS treatment is correct and complete. I understand that if I knowingly provide false information, I may be liable to prosecution or civil proceedings. I confirm that I am the registered healthcare professional responsible for the information provided. I also confirm that the patient has read and signed the Home Oxygen Consent Form.

Name:	Profession:
Signature:	Date:
Fax back no. or NHS email address for confirmation / corrections:	

Appendix C: Home Oxygen Consent Form Template

Form issued by:			
Unit/Surgery		**Address**	
Contact name			
Tel no.			
			Postcode

Patient			
Name		**Address**	
D.O.B.			
NHS number			
Tel/mobile no.			**Postcode**
E-mail		(only include if the patient agrees to email contact)	

My doctor or a member of my care team has explained the arrangements for supplying Oxygen at my premises, that my personal information will be managed and shared in line with the Data Protection Act 1998, Human Rights Act 1998, and common law duty of confidentiality and I understand these arrangements, such that:

1. information about my condition/condition of the patient named above* will be provided to the Home Oxygen Service (HOS) Supplier to enable them to deliver the Oxygen treatment as per the Home Oxygen Order Form (HOOF),

2. the HOS Supplier will be granted reasonable access to my premises, so that the Oxygen equipment can be installed, serviced, refilled and removed (as appropriate),

3. information will be exchanged between my hospital care team, my doctor, the home care team and other teams (e.g. NHS administration) as necessary related to the provision, usage, and review, of my Oxygen treatment, and safety,

4. information will also be shared with the local Fire Rescue Services team to allow them to offer safety advice at my premises and where appropriate install/deliver suitable equipment for safety,

5. information will also be shared with my electricity supplier/distributer where electrical devices have been installed.

6. From time to time, I may be contacted to participate in a patient satisfaction survey/audit.

* Delete as applicable

Patient's signature		**Date**	

(see note 4 where signed and witnessed on patient's behalf)

I confirm that I have responsibility for the above-named patient.

Carer's signature		**Name**	
Relationship to patient		**Date**	

I confirm that I am the healthcare professional responsible for the care of this patient and I have completed this form on his/her behalf as s/he is unable to provide/withhold consent. The patient has been given a copy of this form.

Clinician's signature		**Date**	
Name			

GUIDANCE NOTES

Who may give consent?

1. It is presumed that anyone aged 16 or over is competent to give consent for her/himself unless the opposite is demonstrated. If a child under the age of 16 has 'sufficient understanding and intelligence to enable him or her to understand fully what is proposed', then he or she will be competent to give consent for him/herself. Young people aged 16 and 17, and legally 'competent' younger children, may therefore sign this form for themselves, but may like a parent to countersign as well.

2. If a child is unable to give consent him/herself, person(s) with parental responsibility for the child may provide information about their wishes in relation to the child. However, the final decision to disclose information lies with the healthcare professional in charge of caring for the child. Any decisions taken must be in the best interests of the child. Even where a child is able to give consent him/herself, a healthcare professional with responsibility for caring for the child should involve those with parental responsibility for the child's care, unless the child specifically asks the healthcare professional not to do so.

3. If a patient is mentally competent to give consent but is physically unable to sign a form, this form should be completed and signed by an independent witness as confirmation that the patient concerned gave consent orally or non-verbally.

4. Where an adult patient (aged 16 or over) lacks capacity to give or withhold consent, decisions must be taken by the healthcare professional in charge of the care of the patient. Decisions must be made in the best interests of the patient, taking into account any wishes that may have been previously expressed by the patient (for example, before he loss of capacity) and any views or wishes expressed by the patient's family or friends.

Guidance on Confidentiality and Consent

The NHS Confidentiality Code of Practice published by the Department of Health 2003 https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice

The HSCIC Guide to Confidentiality http://www.hscic.gov.uk/confguideorg

The Department of Health guidance on consent to treatment
https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition