Public Health England

Protecting and improving the nation's health

Cancer Outcomes and Services Data set (COSD) Version 7.0

Specification

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

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Approvals:

This document MAY be approved by the following:

Name	Signature	Title / Responsibility	Date	Version
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COSD Governance Board	COSD Governance Board	COSD Governance Board	28.04.2016	7.0

SCCI Standardisation Committee for Care Information

This information standard (SCCI1521) has been approved for publication by the Department of Health under section 250 of the Health and Social Care Act 2012.

Assurance that this information standard meets the requirements of the Act and is appropriate for the use specified in the specification document has been provided by the Standardisation Committee for Care Information (SCCI), a sub-group of the National Information Board.

This information standard comprises the following documents:

- Specification
- Change Request
- Implementation Guide.

An Information Standards Notice (SCCI1521 Amd 1/2016) has been issued as a notification of use and implementation timescales. Please read this alongside the documents for the standard.

The controlled versions of these documents can be found on the NHS Digital website.

Date of publication 17 August 2016.

Glossary of terms:

Term	Acronym	Definition
Burden advice and assessment service	BAAS	The Burden Advice and Assessment Service (BAAS)[1] – previously the Review of Central Returns (ROCR)[2] programme offers advice, guidance and support for the health and social care system (both nationally and locally) on minimising the burden and bureaucracy of data collection, freeing up staff time to care, as well as recommendations to the Standardisation Committee for Care Information (SCCI)[3].
Cancer		For the purposes of this standard the term 'cancer' is used throughout the standard and related documents to cover all conditions defined as registerable by the UK and Ireland Association of Cancer Registries[4].
Cancer Centre		Organisations which help people to live with, through and beyond cancer by bringing together specialist clinical and professional staff and communities of support.
Cancer Outcomes and Services Data set	COSD	The COSD is the national standard for reporting cancer in the NHS in England. It replaced the previous National Cancer Data set and includes the former Cancer Registration data set and additional site specific data items relevant to the different tumour types.
Cancer Registration Data set	CRDS	The data set requirements for cancer registration now incorporated into the COSD.
Cancer Registries		Organisations which exist internationally to collect, process, analyse and disseminate data on cancer patients in their local regions.

[1] http://www.digital.nhs.uk/baas
[2] https://rocrsubmissions.ic.nhs.uk/Pages/HomePage.aspx
[3] http://www.digital.nhs.uk/isce
[4] http://www.ukiacr.org/

Care Quality Commission	CQC	One of the independent regulators of health and social care in England.
Term	**Acronym**	**Definition**
Commissioners		Organisations that plan, purchase and monitor services to meet the health needs of their local population.
Diagnostic Imaging Data set	DIDS	Data set containing diagnostic imaging test activity across the NHS, taken from Radiology Information Systems.(See SCCI Standard 1577)[5]
Extensible Markup Language	XML	Extensible Markup Language (XML) is a set of rules for encoding documents in machine-readable form.
Health and Social Care Information Centre *(now known as NHS Digital)*	HSCIC	The Health and Social Care Information Centre is the national provider of information, data and IT systems for commissioners, analysts and clinicians in health and social care. Note that from 1 August 2016 the HSCIC adopted a new trading name – NHS Digital (see www.digital.nhs.uk)
Improving Outcomes: A Strategy for Cancer	IOSC	The overarching strategy for cancer services in England[6].
Information Standard	IS	A measure that ensures that information is managed in a consistent manner across health and social care, both by the computers and the staff.
International Statistical Classification of Diseases and Related Health Problems	ICD	A medical classification list for the coding of diseases, signs and symptoms, abnormal findings, complaints, social circumstances and external causes of injury or diseases, as maintained by the World Health Organization (WHO). (The title is followed by the revision number, e.g. ICD-10 is the tenth revision.)

[5] http://www.digital.nhs.uk/did
[6] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/388160/fourth_annual_report.pdf

International Classification of Diseases for Oncology	ICD-O	An extension of the ICD coding system used principally in tumour or cancer registries for coding the site (topography) and the histology (morphology) of neoplasms. (The title is followed by the revision number, e.g. ICD-O-3 is the third revision.)
Term	**Acronym**	**Definition**
MDT Coordinator		The Multidisciplinary Team (MDT) coordinator is the person(s) responsible for facilitating the MDT meeting. They also have additional duties for collecting and recording information on patients as they pass through the Hospital Trust, whilst on a cancer pathway. Sometimes known as a Patient Pathway Coordinator.
National Cancer Data set	NCDS	The previous nationally approved reference standard for the collection of cancer data now incorporated into the COSD.
National Cancer Intelligence Network	NCIN	A UK-wide initiative, working to drive improvements in standards of cancer care and clinical outcomes by improving and using the information collected about cancer patients for analysis, publication and research. The NCIN is part of Public Health England[7].
National Cancer Registration and Analysis Service	NCRAS	The NCRAS is the National Cancer Registration and Analysis Service for England collecting cancer data from all NHS Providers of cancer care in England. The NCRAS is a function within the National Disease Registration Service within Public Health England
National Cancer Waiting Times Monitoring Data set	NCWTMDS	The Information Standard (SCCI0147) used to monitor the time that patients with suspected and diagnosed cancer have to wait for appointments, tests and treatments[8].
Office of National Statistics	ONS	The UK's largest independent producer of official statistics and the recognised national statistical institute of the UK.

[7] The NCIN is now part of the National Cancer Registration and Analysis Service.
[8] http://www.digital.nhs.uk/isce/publication/SCCI0147

Providers		Organisations that provide health services.
Public Health England	PHE	Public Health England is an executive agency of the Department of Health in the United Kingdom, taking up its full powers from 1 April 2013. Its role is protecting and improving the nation's health and wellbeing and to reduce inequalities.
Term	**Acronym**	**Definition**
Radiotherapy Data set	RTDS	A standard data set covering every patient treated with radiotherapy in the NHS in the England[9].
SNOMED CT	SNOMED CT	SNOMED CT is the information standard for clinical terminology[10].
Systemic Anti-Cancer Therapy Data set	SACT	The national collection of all cancer chemotherapy data in the NHS in England, which covers all solid tumour and hematological malignancies. This includes all adult and paediatric cancer patients, those in clinical trials, and covers acute inpatient, day case, outpatient and community settings.[11]
The Royal College of Pathologists	RC Path	A professional membership organisation committed to setting and maintaining professional standards and to promoting excellence in the practice of pathology.
United Kingdom and Ireland Association of Cancer Registries	UKIACR	The UKIACR brings together organisations with an interest in developing cancer registration as a resource for studying and controlling cancer in the UK and Ireland[12].
XML schema		The documentation, definitions and descriptions required to enable the production and transmission of data for a specific XML.

[9] http://digital.nhs.uk/isce/publication/SCCI0111
[10] http://digital.nhs.uk/isce/publication/scci0034
[11] http://www.datadictionary.nhs.uk/data_dictionary/messages/clinical_data_sets/data_sets/systemic_anti-cancer_therapy_data_set_fr.asp?shownav=1
[12] http://www.ukiacr.org/

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1. Overview

1.1 Summary

The table below contains a summary of the information standard.

Standard	
Standard Number	SCCI1521
Standard Title	Cancer Outcomes and Services Data set
Description	The Cancer Outcomes and Services Data set (COSD) is a compiled data set which provides the standard for secondary uses information required to support implementation and monitoring of Improving Outcomes: a Strategy for Cancer (IOSC)[6]. This standard consists of: • A set of individual data items, with their definitions. • The assemblage of these data items into collection areas. • The means of flowing the data items. • Compilation of the data items into a single reconciled and verified data set. The COSD has replaced the former National Cancer Data set (NCDS) (including the approved site specific data Items such as those for breast, colorectal, lung, head & neck, urological, upper gastrointestinal, gynaecological, sarcoma and skin cancers), and the former Cancer Registration Data set. It incorporates the National Cancer Waiting Times Monitoring Data set (NCWTMDS) and items from the Systemic Anti-Cancer Therapy Data set (SACT) and the Radiotherapy Data set (RTDS), all of which also remain as separate standards. This standard covers all patients diagnosed with or receiving cancer treatment in or funded by the NHS in England. This includes adult and paediatric cancer patients. Providers of cancer services are required to provide a monthly return on all cancer patients diagnosed from 1st January 2013 using this data set. Data are collated via the NCRAS local offices, and formal mechanisms for transmission of data from Providers to registries has been extended to carry the COSD data set
Applies to	• Cancer centres, cancer units and all other providers of NHS commissioned cancer services

	• Developers and suppliers of electronic systems for use in NHS commissioned cancer centres and NHS provider services • Organisations purchasing electronic systems for use in NHS commissioned cancer centres and NHS provider services • Users of secondary data about cancer at both national and local levels, including: At a national level: the Department of Health (DH), National Cancer Registration and Analysis Service (NCRAS) and other appropriate national information, research and service planning organisations, e.g. NHS Digital, the Care Quality Commission (CQC), NHS Improvement, Public Health England (PHE). At a local level: Strategic Clinical Networks (SCNs) and local Cancer Service Provider Networks, the local NCRAS offices, Commissioners and Provider Organisations will have data on cancer services based on this national standard. As COSD is for Secondary Care uses, there is no intention for this to be used by Primary Care or Private Hospitals. ** It is important to note that if a patient is on a NHS pathway, but the treatment is carried out in a private hospital (due to capacity issues or at the request of the NHS Trust), these data must be collected and reported (within COSD) by the NHS Trust, as if the treatment was carried out by them.
Release	
Release Number	Amd 1/2016
Release Title	Version 7.0
Description	This change to the Cancer Outcomes and Services Data set (COSD) standard introduces some amendments and re-alignments to the current data set, a formalised pathology specific data set (which is a subset of the COSD v7.0) and a revision of the current schema specification in order to continue to meet the business objectives of the standard. The Achieving World-Class Cancer Outcomes, A Strategy for England 2015-20 (Cancer Taskforce Report)[13], produced a series of recommendations which directly impact upon COSD. The strategy pointed out the need for changes – which have

[13] http://www.cancerresearchuk.org/about-us/cancer-taskforce

	been interpreted and applied to the data set and new data items have been included within v7.0 to support the recommendations. In addition there are new data items to help identify and analysis: • An unplanned return to theatre • The surgeon (or surgeons) who were responsible for each surgical episode • Molecular and biomarker testing. Many data items have been re-aligned across the data set into the correct higher level groupings. The data set can now be easily maintained within each Trust, by using one of two subsets (depending on the department responsible for each data collection process): • Pathology - This was part of the last standard and is now mandated across all Trusts to supply these data in COSD XML directly from their pathology departments. o This is different from COSD as there are unique linkages for pathology and therefore requires its own unique schema. • Patient Pathway – This is the data, excluding Pathology, which the Cancer Services Teams need to collect. By removing the pathology data from their workload, it reduces their burden of data collection by up-to 30% across the whole data set. o As these data are now collected and submitted by the pathology departments directly, it is a huge burden of duplication if we therefore ask the Cancer Services (non-clinical) teams to transcribe the same data into COSD via a Trust's Cancer Information Systems.
Implementation start and completion date	Implementation will be between 18/08/2016 and 31/03/2017 (Seven and a half months). Data collection will start from 01/04/2017 (with a three month roll-out period between 01/04/2017 and 30/06/2017). Full conformance from 01/07/2017 (back dated to 01/04/2017).

1.2 Supporting Documents

This Specification should be read in conjunction with the following documents:

Product	Document Reference	Title
Change Request	http://www.digital.nhs.uk/isce/publication/scci1521	Change Request – This document will be available from the NHS Digital website to the left, from 17th August 16.
Data set	http://www.ncin.org.uk/collecting_and_using_data/data_collection/cosd_downloads_v7	COSD data set v7.0 – This data set will be available from the website to the left, from 17th August 16.
Implementation Guide	http://www.digital.nhs.uk/isce/publication/scci1521	Implementation Guide – This document will be available from the NHS Digital website to the left, from 17th August 16.

1.3 Related Standards

This Specification should be read in conjunction with the following standards:

Ref #	Reference	Title
SCCI0147	http://www.digital.nhs.uk/isce/publication/SCCI0147	National Cancer Waiting Times Monitoring Data set
SCCI0111	http://www.digital.nhs.uk/isce/publication/SCCI0111	Radiotherapy Data set
ISB 1533	http://www.isb.nhs.uk/documents/isb-1533/amd-63-2010/index_html	Systemic Anti-Cancer Therapy Data set
SCCI1577	http://www.digital.nhs.uk/isce/publication/SCCI1577	Diagnostic Imaging Data set
SCCI0021	http://www.digital.nhs.uk/isce/publication/SCCI0021	International Classification of Diseases
SCCI0034	http://www.digital.nhs.uk/isce/publication/SCCI0034	SNOMED CT
n/a	https://www.rcpath.org/profession/publications/cancer-datasets.html	Royal College of Pathologists Standards and Data sets for Histopathology Reporting on Cancers and Tissue Pathways

1.4 Contacts

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2. Health and Care Organisations

2.1 Requirements

#	Requirement
1	NHS Providers of cancer services (hereinafter referred to as NHS providers) **SHOULD** read the Specification in conjunction with the Implementation Guide to identify how the standard is applicable to them.
2	NHS Providers **MUST** review their system compatibility against this standard to identify any changes required to current practice to ensure that all data items in COSD v7.0 can be flowed electronically by dates specified in the Implementation Guide. If there are compatibility gaps, then further development is required to meet the standard.
3	NHS Providers **MUST** submit the data using the XML format for extracts from MDT cancer information management systems.
4	NHS Providers **MUST** submit the data using the XML format for extracts from pathology systems.
5	NHS Providers **SHOULD NOT** utilise this data set primarily to support their clinical and operational data capture.

2.2 Conformance Criteria

Organisational Type	#	Criteria
Providers	1	NHS Providers **MUST** submit COSD v7.0 data items as specified in the implementation guidance within the defined time period and in the format specified in these documents.
	2	All submitted data files **MUST** contain the specified linkage items at record level to enable linkage of the relevant cancer registration records.
	3	NHS Providers **MUST** submit the agreed data items within 25 working days of the month end following diagnosis date.
	4	NHS Providers **MUST** submit the agreed data items within 25 working days of the month end following treatment start date.
	5	NHS Providers **MUST** submit further records for all cases within 25 working days of the month end following any additional or amendments to the data items.
	6	NHS Providers **MUST** agree methods of submission with the NCRAS for all items not flowed as part of the standard extract.

	7	NHS Providers **MUST** notify the NCRAS (as soon as possible after discovery) of any known reasons for significant variation in the number of new cases submitted monthly if applicable.
	8	NHS Providers **MUST** review monthly feedback from the NCRAS, using the CancerStats portal. This will allow cancer teams to assess if the data uploaded meets their expectation (if not), then these should be challenged with the Cancer Services Manager.
	9	NHS Providers **MUST** audit case ascertainment, quality and completeness on receipt of quarterly feedback reports from the NCRAS and notify the NCRAS of reasons for any discrepancies.
	10	Providers **MUST** report a minimum of 80% of all expected cases annually by Site specific Tumour Group as agreed with the NCRAS.
	11	NHS Providers **MUST** submit the data set extracted from their MDT cancer information management systems in XML
	12	NHS Providers **MUST** submit data from pathology systems in XML

Conformance is measured against the COSD Conformance Framework which has been published on the COSD webpage[14]. Basic feedback on conformance is provided to Providers through the NCRAS's COSD CancerStats portal[15].

Additional reporting for the National Prostate Cancer Audit (NPCA), National Lung Cancer Audit (NLCA), Incidence, Survival and Mortality data and Clinical Headline Indicators (CHI)[16] are now available with site specific CHI measures to follow later in 2016.

Feedback reports are provided to the COSD Governance Board in order to monitor and manage compliance to the Information Standard.

[14] http://www.ncin.org.uk/collecting_and_using_data/data_collection/cosd_downloads_v7
[15] https://nww.cancerstats.nhs.uk/users/sign_in
[16] www.ncin.org.uk/view?rid=2805

3. IT Systems Suppliers

The term IT system supplier can be either an external company (who provides either an off-the-shelf or bespoke system) or an in-house solution. It would be expected that all Trusts have a Service Level Agreement (SLA), with their system supplier to ensure future development needs are sufficient to meet changes to the standard.

3.1 Requirements

#	Requirement
1	In-house providers of Cancer IT & Pathology systems **MUST** implement changes in accordance with their local contractual arrangements, to enable all specified data items in COSD v7.0 to be captured and extracted in compliance with the Specification and Implementation Guidance. Commercial suppliers should work with their clients and within their Service Level Agreements to make the changes required within v7.0 as outlined above. There will be amendments to the existing COSD schema(s) to support this process and a new schema issued for Pathology data.

3.2 Conformance Criteria

#	Criteria
1	The requirement above **MUST** be met.

All Trusts are mandated to collect and report all data within COSD (if applicable), within 25 working days of the end of each month (in structured XML format). The SCCI standard provides all the documentation to support this process, including:

- Implementation Guide
- Change Request
- Specification
- Data Set v7.0
- Schema(s)
- Data Set User Guide.

Each regional NCRAS office has a nominated Cancer Improvement lead who will help and support any Trust struggling to meet the standard.

4. Scope

4.1 In scope

The data set relates to all cancer patients, both adult and paediatric, in acute inpatient and outpatient settings. The trigger for data collection is when a diagnosis or suspected diagnosis of cancer is confirmed. Primarily this diagnosis takes place within secondary care.

The standard covers neoplasms coded within ICD-10 diagnosis codes range C00 – C97, D00 – D48 and E85.9[17]. (See Appendix A for list of Mandatory Registerable Conditions (UKIACR Library of Recommendations)).

The Achieving World-Class Cancer Outcomes, A Strategy for England 2015-20 (Cancer Taskforce Report)[18], produced a series of recommendations which directly impacted upon COSD. The strategy pointed out the need for changes – which have been interpreted and applied to the data set and new data items have been included within v7.0 to support the recommendations.

In addition there are new data to help identify and analysis:

- An unplanned return to theatre
- The surgeon (or surgeons) who were responsible for each surgical episode
- Molecular and biomarker testing.

Many data items have been re-aligned across the data set into the correct higher level groupings.

The data set can now be easily maintained within each Trust, by using one of two subsets (depending on the department responsible for each data collection process):

- Pathology - This was part of the last standard and is now mandated across all Trusts to supply these data in COSD XML directly from their pathology departments.
    - This is different from the main COSD data set as there are unique linkages for pathology and therefore requires its own unique schema.
- Patient Pathway – This is the data, excluding Pathology, which the Cancer Services Teams need to collect. By removing the pathology data from their workload, it reduces their burden of data collection by up-to 30% across the whole data set.
    - Pathology consists of 151 data items which is 30% of the data set. As these data are now collected and submitted by the pathology departments directly, it is a huge burden of duplication if we therefore

[17] *Although Primary amyloidosis (E85.9) is listed as an E ICD code in the World Health Organisation (WHO) disease classification, amongst clinicians it is widely acknowledged and subsequently treated as a cancer, receiving Chemotherapy in cases. Whilst we await the WHO disease classification being updated to reflect this fact, we have extended the scope of the COSD to include this. The United Kingdom and Ireland Association of Cancer Registries (UKIACR) is currently considering its inclusion in the UKIACR Library of Recommendations, which we have referenced in Appendix A.*

[18] http://www.cancerresearchuk.org/about-us/cancer-taskforce

ask the Cancer Services (non-clinical) teams to transcribe the same data into COSD via a Trust's Cancer Information Systems.

Wherever possible duplication across the data set has now been removed and full explanations of how to collect these data within the new structure provided within the change log of the data set.

Finally, where there were data that are no longer part of a linked national data set (e.g. Royal College of Pathologists), these have also been removed from the data set.

4.2 Out of scope

As a Secondary Uses data set, this standard does not define record level data to be used in the delivery of care. The data for COSD should be derived from patient identifiable data which are already recorded for the purpose of care management.

- General Practice - developments in the extraction of data from general practice systems are the subject of other work by NHS Digital, specifically the General Practice Extraction Service (GPES).
    - There are no formal links at present but this is expected to be developed in the future.
- Radiotherapy - this is subject to an existing standard, the Radiotherapy Data set (RTDS) - SCCI0111. These data are now collected by the NCRAS and this standard was updated in September 2015.
- Chemotherapy - this is subject to an existing standard, the Systemic Anti-Cancer Therapy data set (SACT) - ISB 1533.
- Imaging - this is subject to an existing standard, the Diagnostic Imaging Data set (DIDS) - SCCI1577.

COSD has been carefully reviewed to support other major data sets to (wherever possible) reduce the duplication of data collection across data sets. In addition, discussions have taken place with other data sets to refine data-items where cross-over is possible to maximise the clinical relevance and prevent multiple (similar) data being created with different meanings. This work is supported by the NHS Digital Data Dictionary and Terminology teams.

5. Implementation and Use

5.1 Guidance

5.1.1 High Level View

This standard, together with the supporting COSD data set v7.0, defines the complete set of secondary uses cancer data for reporting and specifies the items which need to be returned directly by NHS Providers.

Other items are either subject to other Standards (such as RTDS), provided from other sources (such as ONS or Screening services) or derived (these are clearly distinguished in the data set documentation). Further details are provided in the User Guide and the following provides summary information only.

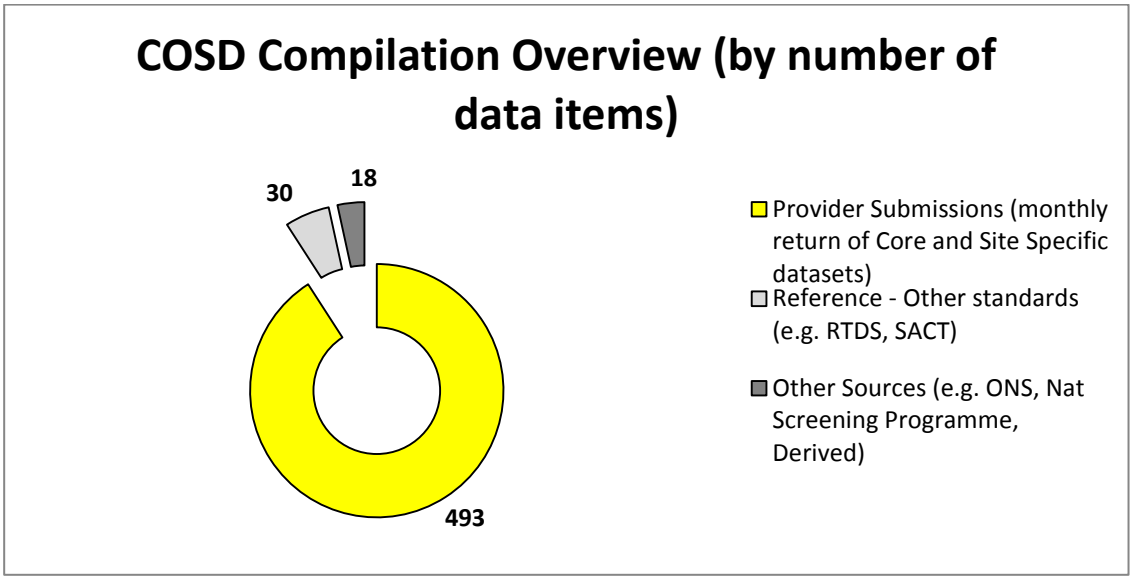


Fig 1: COSD compilation overview

Provider submissions: The 493 items shown above comprise the subset of the COSD to which the remainder of this specification refers unless otherwise stated. These are the items which are included in the XML schema and are expected to be flowed directly from NHS Providers to the local NCRAS Branch Office, from one or more electronic systems within the Provider organisation.

Reference - Other standards: Unless otherwise specified, these items are excluded from the remainder of this specification document and are identified separately within the full data set. These are items which are essential to compile the full data set but are covered by other information standards and therefore will not need to be included in the direct data flows for COSD. These items are flowed to the NCRAS from other national collection systems.

Other sources: Unless otherwise specified (within the data set), these items are excluded from the remainder of this specification document and are identified separately within the full data set. These are items which are essential to compile the

full data set but will be collected from other sources and therefore will not need to be included in the direct data flows for COSD.

5.1.2 Model data flow diagram

The following diagram demonstrates how the full COSD data set will be compiled centrally by local NCRAS offices from data flowing from a number of systems and sources. (This diagram includes Reference - Other Standards and Other Sources data items.)

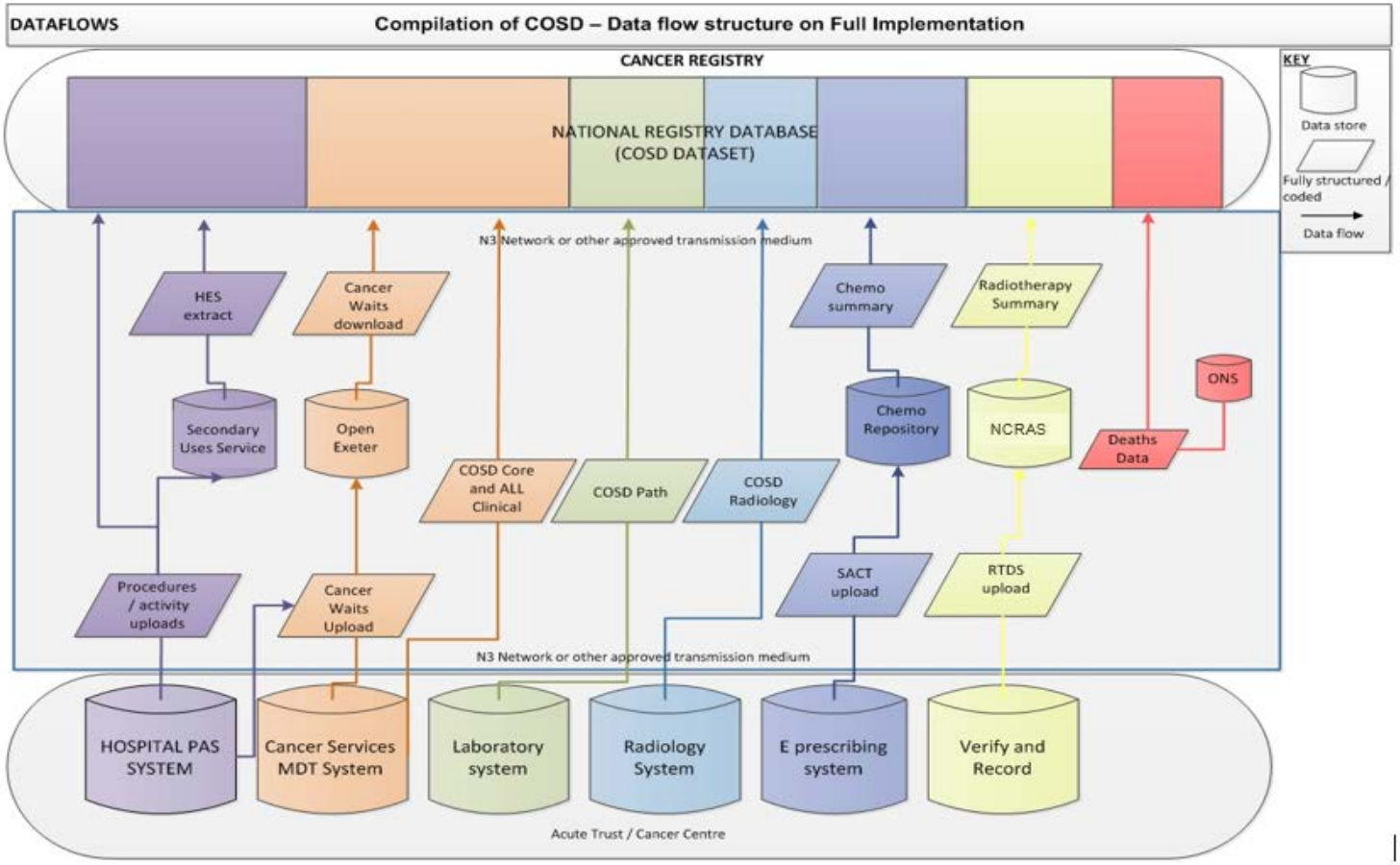


Fig 2: COSD compilation – Data flow structure on full implementation

5.1.3 Structure of data set – Provider Submissions

There is a core data set most of which is applicable to all cancers and an additional site specific data set for each of the twelve identified tumour groups. Some of these site specific data sets contain further subsets applicable to individual diseases. Each recorded case will therefore have a core and usually a site specific data set completed.

This would be the same for pathology, where you have a core and then eleven site specific pathology data sets, although you can submit pathology through both.

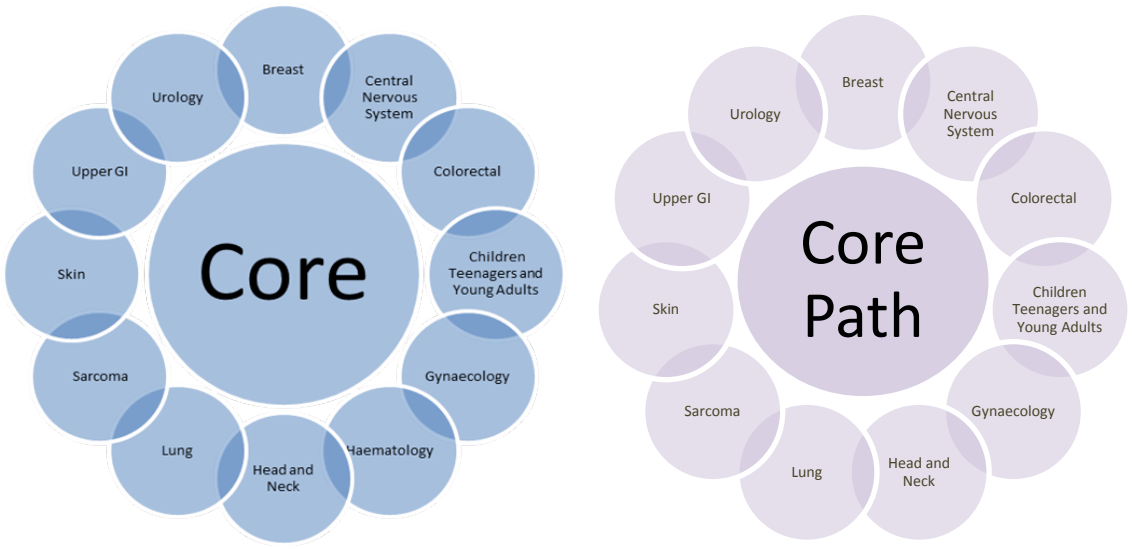


Fig 3: Structure of COSD

5.1.4 Data set subsections

Within each of the core and site specific data sets, the data items are further grouped according to their stage along the patient pathway as follows:

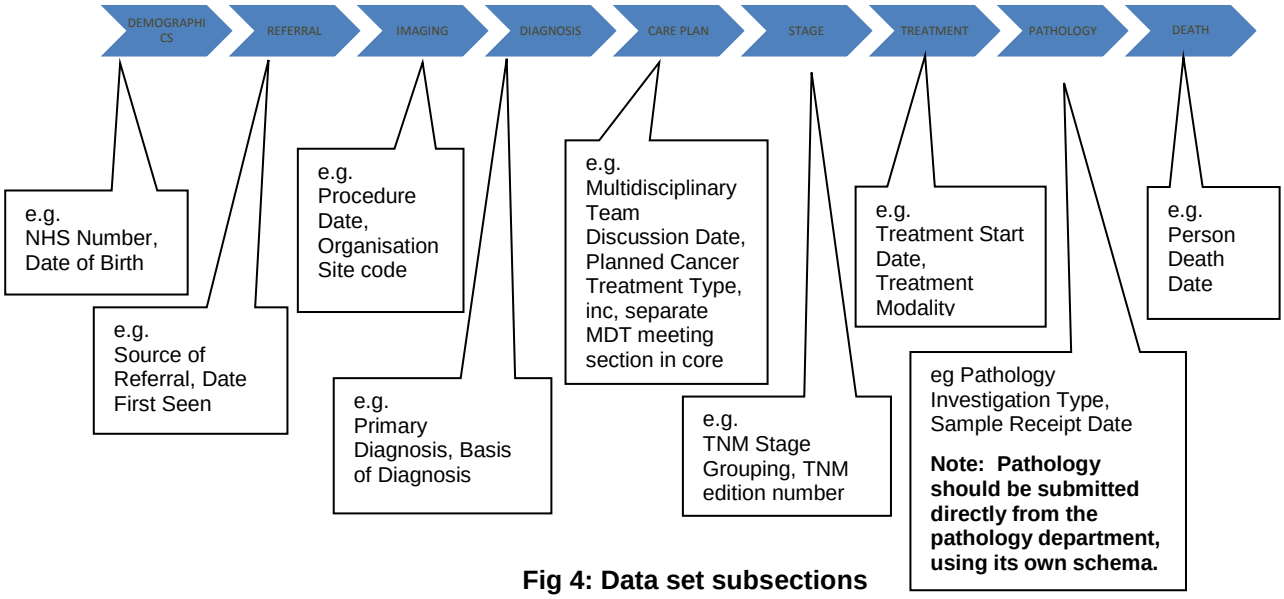


Fig 4: Data set subsections

From January 2016, Trusts were mandated to collect pathology directly from their pathology departments, although these data can also be submitted within COSD.

However the recommendation is that (non-clinical) MDT Coordinators should not be expected to transcribe free text reports into their local MDT system, if these data are already supplied direct from the pathologist.

5.2 Governance

5.2.1 Information governance

Data collection from all the new sources required to support the Cancer Registration Data set are covered by existing permissions granted by the Confidentiality Advisory Group (CAG) of the Health Research Authority (HRA).

The data set contains sensitive and patient-identifiable information items. The Confidentiality Advisory Group (CAG) of the Health Research Authority (HRA) has confirmed that reporting of patient identifiable data is covered by the NCRAS existing support under the Health Service (Control of Patient Information) Regulations 2002 (see Appendix H for details). Reported data will be managed by the NCRAS where there is long standing expertise in managing large volumes of confidential data.

Although the data items which are flowed to the NCRAS have changed, the data flows (i.e. which organisations will be receiving the data in identifiable form) remain unchanged. In compliance with the fair processing requirement within the Data Protection Act, Provider organisations are expected to inform patients of this purpose for reporting their information and of the potential use of the information for service development, analysis and statistical research[19].

The UKACR has expanded to include the Republic of Ireland Cancer Registry and consequently has changed its name to the United Kingdom and Ireland Association of Cancer Registries – UKIACR. The policies referred to below will be revised in due course.

The NCRAS and Cancer Research UK have developed a patient information leaflet (see Appendix B) that is a useful resource for organisations wanting to develop or revise local information materials. NCRAS, as part of PHE, will come under the Department of Health's Data Protection Act registration with the Information Commissioner's Office (ICO). The NCRAS is currently reviewing and harmonising its information governance policies to correlate them with those of PHE and maintain compliance with the NHS Digital information governance toolkit. These policies inform for example: access controls of data, server security, encryption and data transfer procedures.

[19] http://www.ncr.nhs.uk/patientinfo/

5.2.2 Consent process

Where patients have requested their data are not shared, the provider organisation must ensure that their records are not included in the data downloads submitted to the NCRAS. It is suggested that a dissent (i.e. the proactive expression of dissent by an individual from whom consent has not been obtained) or a similar flag is provided in the Provider organisations systems so that the record can then be omitted from the monthly upload.

The NCRAS has published an updated Patient Information Leaflet (Appendix B) which explains that individuals have the right to access and have their own data held in the NCRAS removed, and explains the process. If a patient discovers that their information has been uploaded to the NCRAS and they wish for this to be deleted, the requester must complete a Removal Request form (available from the weblink below) and send this to the NCRAS (instructions on the form) to action. The NCRAS will then, as far as is possible, remove the patient from the NCRAS database.

The NCRAS information for patients wishing to have their information removed as far as possible from the NCRAS database is available on the NCRAS website (http://www.ncr.nhs.uk/removal-request). See Appendix C for further information.

The NCRAS has Subject Access Request policies relating to requests for patients to view their own data. These will be standardised as part of the Registry Modernisation Programme. A sample policy is attached at Appendix E.

5.2.3 Data retention

The NCRAS holds data indefinitely, as without this facility accurate mortality and survival data cannot be calculated. If a patient wants their data removed at any point, then this facility is available via http://www.ncr.nhs.uk/removal-request See Appendix C for further information.

5.2.4 Data disclosure

The NCRAS adheres to the requirements of the Data Protection Act 1998 with regard to the receipt, storage and transfer of information relating to individuals. When releasing data to third parties, all NCRAS offices strictly comply with the approved UKIACR policies on the release of patient-identifiable and potentially identifiable information.

Recipients of such data are required to sign a declaration stating that they will protect the information they are entrusted with, use it only for the purpose for which it was supplied and make no attempt to identify information pertaining to particular individuals or to contact individuals. They are also prohibited from presenting any information that may identify an individual. This is also the case with publications produced by NCRAS, which present aggregated data only.

The UKIACR policy on Data Disclosure applies to this data and is available (see Appendix D for further information). As the NCRAS is part of PHE, all such requests must be approved by the Office of Data Release (ODR)[20].

5.2.5 Clinical governance

This is a secondary uses standard – no direct patient safety hazards were identified for the data set itself. Consultation, piloting, user guidance and validation processes address data quality issues that might have an indirect impact on services, patient care and treatment. The risk that patient identifiable data could be accessed or disclosed inappropriately is addressed in the Implementation Guide. The risk that the data set could be used to design primary use clinical systems is addressed at number 5 at Section 2.1 (Health and Care Organisations Requirements) of this document.

5.2.6 Data quality

The two areas for consideration are the quality of data submitted by Providers and the data quality processes at the NCRAS offices.

NHS Providers:

Each Provider is responsible for ensuring the data submitted to the NCRAS or submitted through other standard NHS routes is of the highest quality and completeness possible, and accurately represents the service provided.

The NCRAS will provide a dynamic feedback process from the ENCORE cancer registration system to Providers. This will allow data quality assurance at a field level – with clinical teams given secure access to the data (via the CancerStats portal) that their organisation has submitted.

National Cancer Registration and Analysis Service:

One of the main roles of the NCRAS is to ensure data quality and consistency. The eight NCRAS regional offices have now moved to a single online processing system (ENCORE). The working practices will be standardised with continuous performance monitoring and oversight of the entire NCRAS through Public Health England.

NCIN has now become part of the National Cancer Registration and Analysis Service (NCRAS), which is part of Public Health England (PHE). This will enable more efficient analysis of cancer data. Specific aspects of data quality are described in Appendix F.

CancerData[21] is the new portal to look at outcomes data for CCG and Provider Trusts. This has been specifically released for the public as well as NHS

[20] http://www.ncin.org.uk/collecting_and_using_data/odr
[21] https://www.cancerdata.nhs.uk/index.html

organisations, and is a vital step forward in improving data quality, whilst producing as near-to real-time data analysis from the NCRAS.

Although these data are not drawn exclusively from COSD (level two measures this in CancerStats), COSD does form part of the total data used within the NCRAS Cancer Registration record and is an important part of data collection across the NHS in England.

5.2.7 Demographic data

The cancer registration data set is dynamic and individual tumour records are updated from numerous disparate data sources. Data quality of these sources across the NHS is not sufficiently good to allow accurate mapping of new data to existing items without patient-identifiable data.

Even once linked, retaining addresses and names remains important; the address stored by the NCRAS is that at the time of diagnosis of the tumour and is essential for cancer cluster analyses possibly many years later, when the patient may have moved. Without patient name, registries could not support genetic and follow-up enquiries made by clinicians who often only have limited information on the index case and possible relatives.

Nevertheless it is registry practice to use pseudonymised or even anonymous (possibly still disclosive) data sets for analysis where patient identity is not needed. Access to identifiable and potentially disclosive data requires appropriate permissions from the Office of Data Release (ODR).

For details on how the cancer registry processes deal with linkage and data discrepancies please see Appendix G.

5.3 Technical architecture

5.3.1 Implementation overview

The COSD modifies and extends the pre COSD requirements on NHS Providers to submit monthly cancer data returns to the NCRAS by approved NHS secure methods. Providers should therefore have reviewed and revised their previous arrangements to submit monthly returns to their local NCRAS office in relation to the timeframe, content and format of those returns in order to conform to this Specification.

It is recognised that the data items may be recorded in different electronic systems and there is no requirement to send an integrated record of all data items in one file provided the rules for identifying and linking records are followed to enable the data to be recombined by the NCRAS.

The pre COSD cancer data returns to the NCRAS covered generic (core) data items only. However, in addition to revising this core data set, the COSD also includes twelve site specific data sets consisting of data items which have been identified by the Site Specific Clinical Reference Groups (SSCRGs) as essential for the analysis of

outcomes and services of the relevant tumour sites, which now only include clinical data items.

Pathology data have now been moved and re-aligned with Core pathology, keeping their site-specific identity and groupings. This has been necessary to enable to correct formatting of the pathology data set, which requires a different set of linkage data-items.

This data set was created in 2015 outside of NHS Digital but with SCCI acceptance. For v7.0, this has been brought back into SCCI and a separate schema has been created by a Technical Modeller within the NHS Digital Architecture Standards & Innovation team.

The COSD also defines a subset of data items within the Core and Breast data sets which should be completed for recurrent/secondary breast cancer.

There is a 7½ month implementation period to amend local systems to comply with the new standard (SCCI1521 Amd 1/2016). The full data set should be submitted using XML format for all new primary cancers, recurrent, metastatic and secondary cancers.

Providers are therefore expected to update their data extraction processes as per the defined standard. All new extracts should be developed using the XML schema provided as part of the standard. All extracts from MDT management systems should be submitted in XML. The original deadline for submissions in XML from pathology systems was extended to 1 January 2016.

It is recognised that some changes to pre-existing working practices may be required, particularly in relation to the electronic capture of site specific clinical data items by clinical Multidisciplinary Team (MDT) members in order to facilitate extraction for COSD. With the collection of pathology data submitted direct from the pathology labs, this reduces the burden of data collection by up-to 30%[22] on the MDT, thus making the collection of these non-pathological data easier to collect.

There are no changes to arrangements for submission of data under other approved standards as a result of implementing this standard.

5.3.2 Changes to prior data collection/data flows

About 45% of the data items to be submitted directly by NHS Providers under COSD are covered by pre-existing data collections. Most of these are collected either monthly or at point of care.

The following summarises the changes to the pre-existing collections and flows:

National Registration Data Set:

[22] Pathology consists of 151 data items which is 30% of the data set

- ***Previously:*** The National Cancer Registration Data Set was replaced by COSD monthly submission to NCRAS under national contract. This was extended to include site specific clinical and site specific pathology items, data has been submitted from cancer information management systems in XML from January 2015.
- ***New:*** Consolidation of the Pathology data set and subset within COSD, will make collecting data more logical and reduce the burden of data collection for (non pathological data items) by up-to 30% across the whole data set.

COSD Pathology Data Set:

- ***Previously:*** Data was submitted from (LIMS) laboratory information management systems in XML from January 2016.
- ***New:*** Revised pathology data set and schema, issued by NHS Digital's Architecture Standards & Innovation team.
- ***Previously:*** RCPath core pathology data sets (data items covered by professional standard minimum data sets (MDS)).
- ***New:*** All datasets within COSD have been aligned to RCPath core data sets and wherever required, out-of-date items removed.

Cancer Waiting Times:

- ***Previously:*** Cancer Waiting Times (available to Cancer Registries monthly, following local validation and central reporting).
- ***New:*** There are no new changes here, although better collaboration will be incorporated during future updates to both datasets. This is vital to reduce duplication and improve data collection.

National Cancer Audits:

- ***Previously:*** It is expected that data items shared with the national audits will continue to be dual flowed until the quality and completeness of these items through the COSD standard is considered adequate. At this time the audits will be able to obtain the items through the NCRAS service and will no longer need to collect them directly.
- ***New:*** The National Lung Cancer Audit (NLCA) is now completely collected within COSD, this has replaced LUCADA and was updated in v7.0. The National Prostate Cancer Audit (NPCA) uses 50% of its data set from COSD data items, however it is submitted to the NCRAS as a separate data set.

SACT and RTDS:

- ***Previously:*** There were no changes to the provision or collection of these data sets and/or data.
- ***New:*** RTDS is now submitted directly to the NCRAS and both RTDS and SACT have been integrated as direct feeds into the Cancer Registration Data Set.

5.3.3 Actions required

NHS Providers will need to:

- Identify items in COSD which were previously collected electronically and those that require changes to systems in order to collect them.
- Identify items in COSD which may be received by the NCRAS offices from other routes (e.g. Image Exchange Portal).
- Identify electronic sources for all data items. This may include Patient Administration Systems (PAS), MDT software systems, pathology and imaging systems etc.
- Identify the items that can be extracted in XML format and submitted by the current NHS compliant methods to the NCRAS.
- Identify data items which are not recorded in a structured format but could be submitted in other formats until appropriate electronic software is available. This is likely to be pathology/ imaging data items which are included in pathology/imaging reports.
- Agree the method of submission for all data items with the NCRAS and record this in a Data Transfer and Partnership Agreement (DTPA).

A range of supporting documents is available from the COSD pages on the NCIN website[23]. Additional support is available to Providers from the NCRAS Data Liaison Teams. The standard DTPA is held by the NCRAS and will be adapted if necessary for individual Providers.

NCIN has now become part of the National Cancer Registration and Analysis Service (NCRAS), which is part of Public Health England (PHE). The NCIN website will be re-branded shortly to reflect these changes but will continue to publish additional information and updates on the COSD webpages (see footnote 23 below).

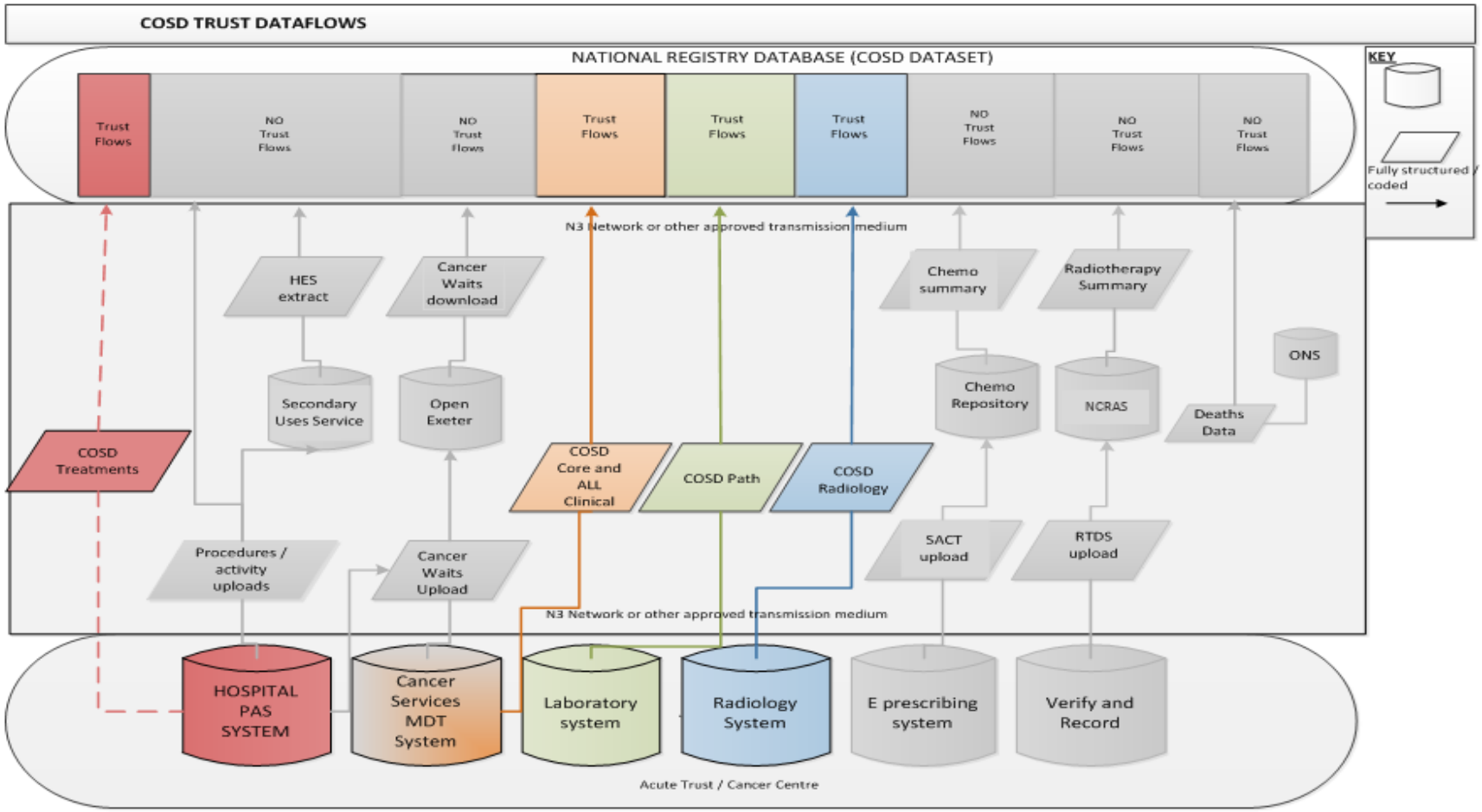
5.3.4 Data Sources

Data may be recorded in a variety of systems such as MDT software and Patient Administration Systems and therefore multiple data extract files may be submitted from a variety of sources.

The following diagram shows the data flows to complete the full COSD data set as of January 2016. (The grey shaded areas are data items in the Reference – Other Standards and Other Sources sections of the data set). This differs from Fig 2 (pg21) as it highlights the flow of data for COSD only.

[23] http://www.ncin.org.uk/collecting_and_using_data/data_collection/cosd

Fig 5:



Example of data flows to complete COSD

The coloured items show expected data sources for NHS Provider data extracts. There may be some variation in the data sources between providers as configurations of data collection systems are not uniform across the provider community.

Note that the structured flow of pathology and radiology items are subject to development of appropriate systems within NHS Providers.

5.3.5 Submission of data

Providers will submit the data to the NCRAS monthly in XML format, using the current NHS approved standards of submission (see Technical Guide for further details).

5.3.6 XML format for submissions

All Trusts have been required since January 2016 to submit data from MDT Cancer Information Management Systems and Pathology systems in the NHS prescribed XML format.

5.3.7 Phased approach to implementation for Data set v7.0

The original COSD data set (v1.0) was required to be submitted in full from January 2014, with v1.2 2014 refinements from April 2014. Data extracts from MDT management systems were originally required to be submitted in XML from January 2015, although this was extended to January 2016 on review. Compliance is monitored by the COSD Governance Board and quarterly reports will be made available to Clinical Commissioning Groups[24].

The revised data set v7.0 will have a 7 and a half month implementation period for Trusts and suppliers to make and test the changes required throughout the new standard.

Full Compliance of the standard must commence by July 2017 at the latest with a phased roll-out from April 2017 (for start of data collection). This is to make allowance for the varied timescales of different software suppliers and in-house developers. During this three month period, data can be submitted in accordance with either data set v6.0 (schema v6.0) or v7.0 (schema v7.0).

Data extracts from pathology systems should be submitted in XML and below is a table of compliance for the COSD data set for v7.0.

By Date	All Providers
17 August 2016	**SCCI1521 Amd 1/2016 ISN Publication**
18 August 2016	**Implementation period starts (7½ months)**
October 2016 - January 2017	**Supplier system testing (phase 2)**
January 2017 - February 2017	**Trust system testing (phase 3)**

[24] http://www.nhscc.org/ccgs/

31 March 2017	**Implementation period ends**
1 April 2017	**First submissions of the COSD data set (v7.0 Revisions)**
April 2017 - June 2017	**Three month roll-out period, to support system developers.**
1 July 2017	**Full Compliance of the COSD data set (v7.0 Revisions). All data submitted (wherever possible) to be back-dated to 1 April 2017 after upgrade.**

5.3.8 Working practices

The implications of the data standard to data providers are as follows:

- NHS Providers and system suppliers need to include the new and changed data items in their electronic systems.
- These organisations may need to amend their transmission methods to enable the new and changed data items to flow and be centrally collated by the NCRAS.
- There may be training implications for staff given changes to data item definitions or the implementation of new data items.
- Provider Multidisciplinary teams may need to adjust their previous processes for capturing data in order to include all the data items in the monthly extracts and ensure accuracy of clinical items.

5.3.9 Implementation guidance

Implementation guidance continues to be developed to support users, organisations and systems suppliers to implement the standard and updated versions of the documentation are available on the COSD pages of the NCIN website[25]. The previous cancer data set manuals have been replaced by the COSD User Guide v7.0. Supporting Information

6.1 Contact details

- Information including the COSD data set and COSD User Guide is available on the NCIN website at:
  - http://www.ncin.org.uk/collecting_and_using_data/default.aspx
- Queries regarding this document should be addressed to:
  - COSDenquiries@phe.gov.uk
- Queries regarding submissions should be discussed with the NCRAS Data Liaison Team.

[25] http://www.ncin.org.uk/collecting_and_using_data/data_collection/cosd

- Their contact details are available from the CancerStats webportal.

Appendix A – Mandatory Registerable Conditions (from the UKACR Library of Recommendations)

ICD 10	Description of neoplasm
C00-C97	All malignant neoplasms
D00-D09	All carcinoma in-situ
D32-D33 D35.2 & D35.3 D35.4	Benign neoplasms of brain & other parts of nervous system Benign neoplasms of pituitary gland & craniopharyngeal duct Benign neoplasms of pineal gland
D37-D48 (excluding D47.2)	All neoplasms of uncertain behaviour Neoplasms of unspecified nature of bladder Neoplasm of unspecified nature of brain Neoplasm of unspecified nature of other parts of nervous system & pituitary gland only (Excluding D47.2 Monoclonal gammopathy of undetermined significance (MGUS))
E85.9	Primary Amyloidosis *(Subject to confirmation by the UKIACR)*[26]

Please see COSD User Guide for full list of Mandatory Registerable Conditions.

[26] Although Primary amyloidosis (E85.9) is listed as an E ICD code in the World Health Organisation (WHO) disease classification, amongst clinicians it is widely acknowledged and subsequently treated as a cancer, receiving Chemotherapy in cases. Whilst we await the WHO disease classification being updated to reflect this, we have extended the scope of the COSD to include this.

Appendix B – NCRAS/CRUK Patient Information Leaflet

Registry information has shown that 1 in 2 people will now survive cancer for at least 10 years.

Achievements made possible by cancer registration information:

- research showing that there are at least **10** different types of breast cancer, which means treatments can be made more specific for each type
- monitoring whether cancers are becoming more or less common - for example spotting the rapid increase in skin cancer cases has led to prevention campaigns to promote staying safe in the sun and avoiding sun beds
- improvement of the breast cancer screening programme, and the decision to introduce flexible sigmoidoscopy (a technique for examining the bowel) as a method of screening for bowel cancer
- research **around when and where patients** are diagnosed with cancer, which showed that almost a quarter are diagnosed in an emergency. **This** has reinforced the importance of finding ways to get more patients diagnosed early

The more information we have in the registry, the easier it is to improve diagnosis and treatment.

What if I don't want my details on the cancer registry?

The benefits of the data collected by the cancer registry have been considerable and we are grateful that nearly everyone with cancer is prepared to share their data with the cancer registry. However, you can ask us to remove all of your details from the cancer registry at any time. These requests won't affect your treatment or care. If you wish to make such a request, you should email optout@ncr.nhs.uk or write to **Director**
National Cancer Registration Service
Public Health England
Wellington House
London SE1 8UG

If you have any questions about cancer registration, you can get more information by:

- asking your doctor
- visiting the Cancer Research UK website at www.cruk.org/cancer-registration or the cancer registration website at www.ncr.nhs.uk/patientinfo where you will find a longer booklet
- and for any questions on cancer, speak to one of Cancer Research UK's nurses on freephone **0808 800 4040** (9am-5pm, Monday to Friday)

Cancer registration is crucial for progress against cancer, and is supported by all the main UK cancer charities and cancer patient groups.

Against Breast Cancer
Bowel & Cancer Research
Bowel Cancer UK
Brain Tumour Research
Brain Tumour Research Campaign
Brainstrust
Breast Cancer Campaign
British Lung Foundation
Core - the Digestive Disorders Foundation
Cancer52
Cancer Research UK
GIST Support UK
It's in the Bag
James Whale Fund for Kidney Cancer
Jo's Cervical Cancer Trust
Skcin - The Karen Clifford Skin Cancer Charity
Leukaemia & Lymphoma Research
Lymphoma Association
Macmillan Cancer Support
Marie Curie Cancer Care
Melanoma Focus
My Name is NOT Cancer
Myeloma UK
Pancreatic Cancer Action
Rarer Cancers Foundation
Sarcoma UK
Shine Cancer Support
Skin Cancer Research Fund
Target Ovarian Cancer
Teenage Cancer Trust
The Pelican Cancer Foundation
The Pink Ribbon Foundation
WMUK

PHE publications gateway number: 2014449

Image source: Cancer Research UK

Public Health England

Protecting and improving the nation's health

Cancer Registration - what it is, the benefits of being on the register, and your options

NHS

CANCER RESEARCH UK

We've made great strides in recent years in our understanding of what causes cancer and how best to diagnose and treat it. But we can only continue this progress if we have information about the people who are developing cancer. We collect this information through a process called cancer registration.

Here, we explain why information about you and your cancer is recorded, how this information is used, and how, if you wish, you can see your information or have it removed from the registry.

What is cancer registration?

If you or your child has been diagnosed with cancer, or a condition that can lead to cancer, the medical staff looking after your health will pass information about you on to the National Cancer Registration Service.

This will include your name, address, age, sex and date of birth, as well as information about the type of cancer or condition you have, and your treatment.

The Registration Service has the government's permission to collect this information. To get a complete picture we will also link this information to your other health information and to patient surveys about your care, and may share it with the nurses and doctors who are looking after you.

Cancer registration helps scientists investigate possible causes of cancer and improve treatment options.

Your details drive progress in cancer prevention and treatment

Cancer registration is the only way we can keep track of how many people are getting cancer and what types of cancer they have. Healthcare teams use this information to continually evaluate and improve services and treatment options for patients.

Cancer registration also fuels research into cancer, helping scientists investigate possible causes of cancer and improve treatments for the disease. This information is crucial for progress against cancer, and is supported by all the main UK cancer charities and cancer patient groups.

Is my information confidential?

Making sure your personal information is private and confidential is very important. Without your consent or a strict approval process, information that can be used to identify you will only be released to those providing your care, such as your hospital and doctor.

If you would like to see the information we have about you on the registry, we can give this to your doctor for them to share with you.

How will it benefit me?

There is no guarantee that having your information on the cancer registry will directly benefit you. However, we know that registry information is continually leading to improvements and new information on the prevention, diagnosis and treatment of cancer and so can help future generations.

In order to give each person the best possible care, we need to know how different cancers respond to different treatments — this information is held in the registry.

The registry could also make it easier for your doctor to see whether you could enrol in any clinical trials. If you have a family history of cancer, doctors can use the registry to find out what treatments worked best for your relatives and tailor your care accordingly.

Registry information is sometimes also used to find out which patients have had a particular treatment. This helps doctors identify any patients they need to contact about the treatment.

- The Cancer Registration leaflet can be downloaded from the following website: http://www.ncr.nhs.uk/patientinfo/

Appendix C – Patient Opt Out Request Form

Patient Opt Out Request Form

This form is for use by patients to request that their personal information be excluded from processing onto the National Cancer Registration Service's cancer registration database.

The personal information collected on this form is needed so that we can process your request correctly. It will only be used in connection with carrying out this request.

To be completed by the patient. Please complete as fully as possible.

<table>
<tr><td>My Details</td><td></td></tr>
<tr><td>My name</td><td></td></tr>
<tr><td rowspan="6">My address</td><td>NHS number</td></tr>
<tr><td>Date of birth</td></tr>
<tr><td>Sex</td></tr>
<tr><td>Telephone number</td></tr>
<tr><td>Place last treated</td></tr>
<tr><td>Post code</td><td>Date last treated</td></tr>
</table>

My request

I wish the cancer registration system in England to stop adding information about me to the cancer registration database and either

☐ Delete everything except for 'My Details'

Remove, as far as possible all clinical information relating to me but **retain** my NHS number and the information I have provided in the 'My Details' section above in the 'watch list', so that any further information received about me will not be processed by the national cancer registration system.

Or:

☐ Delete everything

Remove, as far as possible all clinical and personal information relating to me **including** my NHS number and the information I have provided in the 'My Details' section above. I understand the registry will not keep any record of my details, so, will not know that any information received about me in the future should not be processed.

We will send you a copy of the leaflet, '*Cancer Registration – what it is, the benefits of being on the register, and your options*'', in the hope that you may change your

mind about opting out. If you do change your mind then please contact us as soon as you can.

Signed _____ Date _____

Please return to: Dr Jem Rashbass
Director,
National Cancer Registration Service
Public Health England
Wellington House
London
SE1 8UG

Patient advice

The Health Service (Control of Patient Information) Regulation 2002[27] permits the National Cancer Registration and Analysis Service (NCRAS) to collect information on all cancer patients in England.

The law also gives you, the patient the right to opt out of cancer registration. The first stage of opt out is usually a discussion with a clinician. The clinician will ensure that you are fully aware of the value of your information to research and for improving cancer treatments.

If you still want to opt out and have your details removed from the cancer registration data, you must apply in writing preferably by using the "Patient Opt-Out Request" form in Appendix 1.

The NCRAS will then add your NHS number to an 'exemption list'. By adding your details to this list, the NCRAS can ensure that it will not collect any incoming information about you.

The NCRAS will search all cancer registration files and records and as far as is practicable delete any existing information relating to you that it may already have.

The NCRAS will also check whether it has sent any identifiable information to other permitted organisations such as the Office for National Statistics, and if so as far as is practicable contact that organisation and instruct them to delete the information.

The NCRAS will complete its actions within 20 days of receiving the written request and will confirm this in writing to you.

You may also request removal from the exemption list and the NCRAS will act on this request. However if your details are removed from the exemption list, the NCRAS will not be able to guarantee that your data are not added in future.

[27] http://www.legislation.gov.uk/uksi/2002/1438/made

Appendix D – UKIACR policy on data disclosure

Home » UKACR Disclosure Policy

UKACR Disclosure Policy

UKACR Policy on disclosure of identifiable data by cancer registries – guidance on implementation within England and Wales

Background

Regulation 2 of the Statutory Instrument (SI) on confidentiality – No. 1438, The Health Service (Control of Patient Information) Regulations 2002 – permits cancer registries to receive patient identifiable data [note 1] without the need for informed consent and it permits registries to process said data for the medical purposes stipulated in regulation 2. The regulation was made under Section 60 of the Health and Social Care Act 2001 and continues to have effect under Section 251 of the NHS Act 2006. The approval has been subject to annual review by the Patient Information Advisory Group (PIAG). The functions of PIAG have now been taken over by the Ethics and Confidentiality Committee (ECC) of the National Information Governance Board (NIGB).

When dealing with requests for patient identifiable data registries must assess each request carefully and on merit, to ascertain whether or not patient identifiable data are really necessary. If not, anonymised data must be supplied, following the relevant UKACR guidelines. This is an important principle that registries must apply, even if patient identifiable data have been provided for similar requests in the past.

The UKACR guidance is informed by the Disclosure Review for Health Statistics (referred to as the Health Review) developed by the Office for National Statistics and approved by ministers as policy in England. The health review provides detailed guidance on how to decide whether or not data are identifiable, and is the standard reference for publishing health data.

Summary

Cancer registries in England and Wales can release patient identifiable data legally only to those organisations specified in items 1) a), 1) b), 1) c), 1)d) and 1) e. All other organisations or individuals need approval from the Ethics and Confidentiality Committee of the National Information Governance Board, unless they have informed consent from patients. This policy must be implemented by all organisations listed in Appendix 1. This policy will be subject to annual review.
All requests for patient identifiable data must be made using the UKACR request form for patient identifiable or potentially identifiable data or the registry's host organisation's standard request form for identifiable data [note 2].

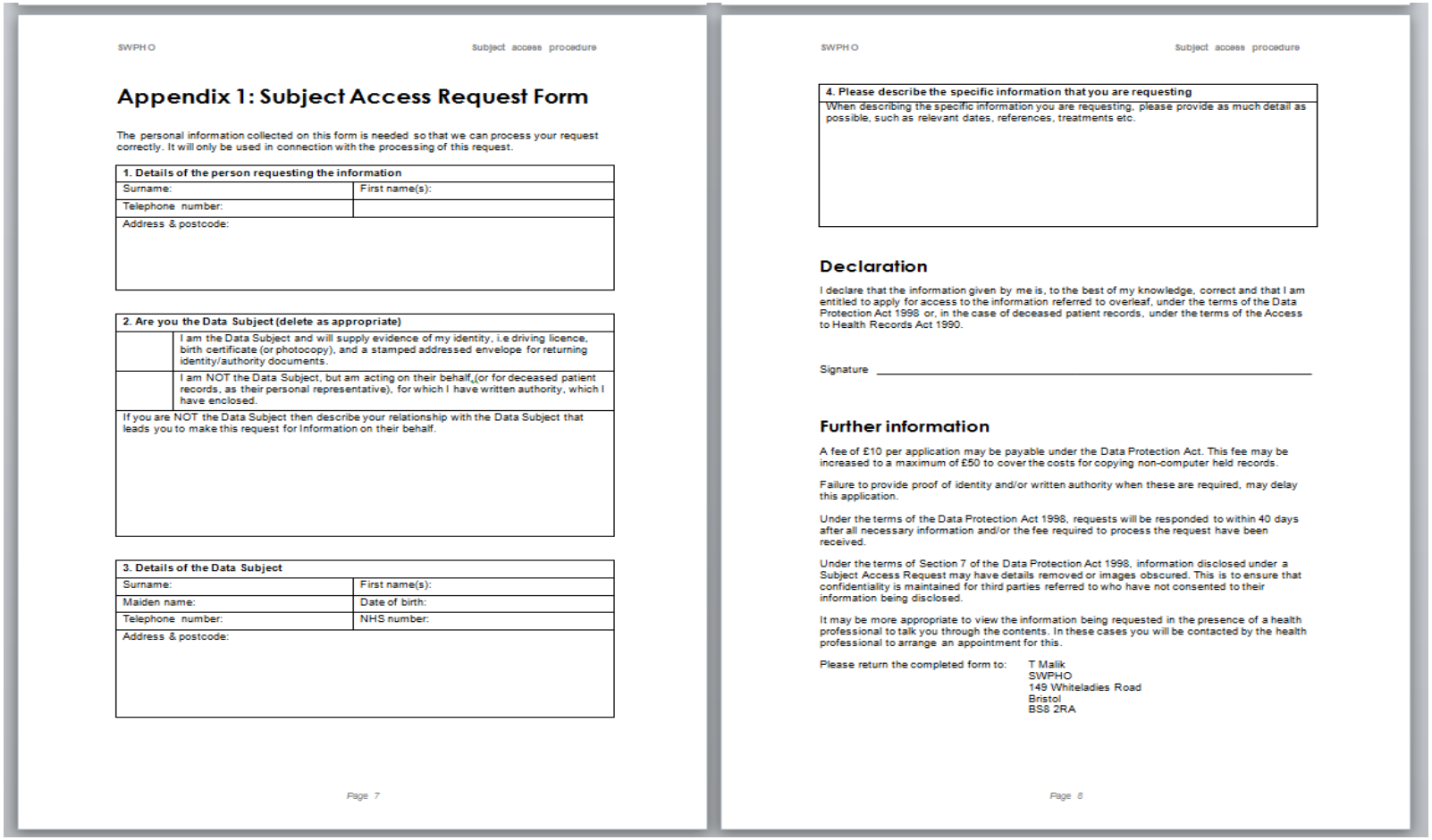
Chris Carrigan, National Cancer Registration Co-ordinator, England
Monica Roche, Co Chair, United Kingdom Association of Cancer Registries

[note 1] Defined in the Health and Social Care Act 2001 as "For the purposes of this section, patient information is "confidential patient information" where:
(a) the identity of the individual in question is ascertainable:
(i) from that information, or
(ii) from that information and other information which is in the possession of, or is likely to come into the possession of, the person processing that information, and
(b) that information was obtained or generated by a person who, in the circumstances, owed an obligation of confidence to that individual.
Data will be regarded as identifiable if it includes any of the following data items: name, address, postcode, date of birth, date of death, NHS number, hospital number.
[note 2] Registry specific versions of the UKACR request form for patient identifiable or potentially identifiable data are available at: (http://www.ukacr.org/confidentiality).

Reference documents

- Health and Social Care Act 2001
  (www.legislation.gov.uk/ukpga/2001/15/contents

Appendix E – A sample Subject Access Request policy from the SWPHO*



SWPHO Subject access procedure

Appendix 1: Subject Access Request Form

The personal information collected on this form is needed so that we can process your request correctly. It will only be used in connection with the processing of this request.

1. Details of the person requesting the information	
Surname:	First name(s):
Telephone number:	
Address & postcode:	

2. Are you the Data Subject (delete as appropriate)	
	I am the Data Subject and will supply evidence of my identity, i.e driving licence, birth certificate (or photocopy), and a stamped addressed envelope for returning identity/authority documents.
	I am NOT the Data Subject, but am acting on their behalf (or for deceased patient records, as their personal representative), for which I have written authority, which I have enclosed.
If you are NOT the Data Subject then describe your relationship with the Data Subject that leads you to make this request for information on their behalf.	

3. Details of the Data Subject	
Surname:	First name(s):
Maiden name:	Date of birth:
Telephone number:	NHS number:
Address & postcode:	

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SWPHO Subject access procedure

4. Please describe the specific information that you are requesting
When describing the specific information you are requesting, please provide as much detail as possible, such as relevant dates, references, treatments etc.

Declaration

I declare that the information given by me is, to the best of my knowledge, correct and that I am entitled to apply for access to the information referred to overleaf, under the terms of the Data Protection Act 1998 or, in the case of deceased patient records, under the terms of the Access to Health Records Act 1990.

Signature _____

Further information

A fee of £10 per application may be payable under the Data Protection Act. This fee may be increased to a maximum of £50 to cover the costs for copying non-computer held records.

Failure to provide proof of identity and/or written authority when these are required, may delay this application.

Under the terms of the Data Protection Act 1998, requests will be responded to within 40 days after all necessary information and/or the fee required to process the request have been received.

Under the terms of Section 7 of the Data Protection Act 1998, information disclosed under a Subject Access Request may have details removed or images obscured. This is to ensure that confidentiality is maintained for third parties referred to who have not consented to their information being disclosed.

It may be more appropriate to view the information being requested in the presence of a health professional to talk you through the contents. In these cases you will be contacted by the health professional to arrange an appointment for this.

Please return the completed form to:

T Malik
SWPHO
149 Whiteladies Road
Bristol
BS8 2RA

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South West Public Health Observatory is part of Public Health England from 1st April 2013

Appendix F – NCRAS Data Quality controls

Automated Quality Control.

The data files submitted through the NCRAS data clearing house are subject to a wide range of validation rules to ensure that the data files and data within fields is consistent, as follows:

- **Batch tracing of all cases**. All patient-identifiable electronic records are sent to the Demographics Batch Service, for tracing against the NHS Spine Discrepancies are identified, investigated and whenever possible reconciled.
- It is not anticipated that this will place any additional load on either the Personal Demographics Service (PDS) or Batch Tracing facilities. However, it is acknowledged that use of this service is within purchased volumetric limits as the Health and Social Care Information Centre does not support the creation of new databases using batch tracing. In this case the system should consider full PDS compliance. The impact will be monitored by the NCRAS as the project progresses with any significant increase being brought to the attention of the COSD Governance Board.

- **Use of multiple data sources**. The quality of cancer registration relies upon the use of multiple independent data sources to ensure high ascertainment and cross validation. The ENCORE system automates much of the data linkage between the disparate sources – highlighting inconsistencies that can be further investigated.

- **Cancer registration staff.** The National Cancer Registration and Analysis Service employs tumour registration staff at the local registries. These registration staff have considerable expertise in cancer coding and classification and spend much of their time quality assuring the electronic data sources and cases recorded at the registry. In some cases cancer registration officers work in a local provider organisation, but all registries maintain very close contacts with the clinical teams.

- **Data feedback to clinical teams.** Rapid feedback to the provider clinical teams, usually through the MDT or Cancer Programme Board provides an important process of data validation. The NCRAS uses secure web-based systems to deliver reports at a field-level on the completeness of individual data items.

- **Data quality audit.** The UKIACR has developed a large number of performance metrics covering the process of data collection by registries. These performance metrics have been integrated into the new ENCORE system and will, where appropriate form the basis of daily updates on the data quality and completeness of records held in the NCRAS.

Appendix G – Data Linkage and Data Discrepancies

Linkage

Linkage is a complex issue, which has become far simpler in recent years with the rollout in use of the NHS Number. Registries use different linkage methods according to the type of data which is available. In essence, the more data that is available, the more confidence the linkage is correct.

In fact linkage comprises two parts; blocking and weighting. Blocking takes an incoming record and uses a range of search criteria, determined by the incoming records content, to identify a series of possible matches in the database. Where the NHS Number is available, that is used, but other blocking is usually also applied. In a manual context, these blocks tend to be sequential, but in an automated setting they tend to run consecutively, with all potential matches passing to the second stage, weighting.

Weighting can be simple. Deterministic weighting is used for NHS Number matching, but this is always augmented with at least one other identifier. Probabilistic techniques use a wider set of data matches, and are usually used when the NHS Number is not available on either the source record or the blocked record. It looks for the ”commonness” of the data value in the overall database, and then uses that to weight up or down based on a series of random control matches. Probabilistic weighting is a well-defined science, with robust methodologies, however it is used far less than in past years.

Data Discrepancies

The fundamental principle of cancer registration is that it relies on multiple sources of data. When dealing with multiple sources, many of which may contain a common item, there is likelihood that two sources will give different values for a particular item of data.

The technical design of the registration schema is such that multiple sources and multiple data values are held against the summarised registration record. Registration clerks are trained to identify and deal with data discrepancy. This usually starts with some basic data checking with the source data supplier, but where conflicting data exists there are clear rules by which registry staff undertake this. At no stage is any source data overwritten or lost, and regular checks are included in the registration practice to examine random sets of records as part of the standard QA built into registration practice over many years.

Appendix H – Approval under Health Service (Control of Patient Information) Regulations 2002

Application Number	0001	
Reference	PIAG 03(a)/2001	
Other Refs		
Application Title	National Cancer Registry databases	
Application Summary	Application submission by United Kingdom Association of Cancer Registries (UKACR) represented several different registries with a common purpose, which is to use patient information on cancer registry databases.	
Applicant Organisation Name	United Kingdom Association of Cancer Registries (UKACR)	
Contact Name	Roger Hartley, Head of Cancer Registration, National Cancer Registration and Analysis Service (North West)	
Address	Public Health England, The Palatine Centre	
	63-65 Palatine Road, Withington	
	Manchester	
Postcode	M20 3LJ	
Telephone	0161 446 3584	
Email	roger.hartley@phe.gov.uk	
Medical Purposes	Y	preventative medicine
	□	medical diagnosis
	□	medical research, approved by a research ethics committee
	□	the provision of care and treatment
	□	the management of health and social care services
	□	informing individuals about their physical or mental health or condition, the diagnosis of their condition or their care and treatment
Cohort/Population	UK-wide patients diagnosed with cancer	
Description of confidential patient		

information used		
S251 Class(es)	Y	Specific Support
	□	Class I - making the person less readily identifiable
	□	Class II - present or past geographical locations of patients
	□	Class III - to identify and contact patients to obtain consent
	□	Class IV - linking multiple sources; validating quality and completeness; avoiding error
	□	Class V - audit, monitoring, & analysis of healthcare provision
	□	Class VI - granting of access to data for purposes I-V
Sponsor		
Status	Approved	
Outcome Date	26/11/2014	
Next Review Date	25/11/2016	
Notes	ECRIC, NWCIS, NYCRIS, OCIU, SWPHO, Thames, Trent and WMCIU registries transferred into PHE 01 April 2013 and collectively comprise the National Cancer Registration Service (NCRS). Following consideration and referral from the June and August 2014 meetings, a recommendation of continuing support was deferred while Public Health England seek advice from the Information Commissioner's Office on issues of fair processing. Progress on actions arising from these discussions in conjunction with a number of outstanding aspects are to be considered on 06 November 2014. Support continues while this consideration is ongoing. This application was approved by Parliament in Statutory Instrument 2002 No. 1438: The Health Service (Control of Patient Information) Regulations 2002	