Public Health England

Protecting and improving the nation's health

National Cancer Diagnosis Audit (NCDA) 2019

Privacy Impact Assessment (PIA)

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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This version produced January 2016

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Introduction

A Privacy Impact Assessment (PIA) is a process which helps assess privacy risks to individuals in the collection, use and disclosure of personal information. A failure to properly embed appropriate privacy protection measures may result in a breach of privacy laws, a declaration of incompatibility with the Human Rights Act, or prohibitive costs in retro-fitting a system to ensure legal compliance or address community concerns about privacy.

This document will help identify and address the data protection and privacy concerns both at the design and critical development stage of a project

What is the National Cancer Diagnosis Audit 2019?

The NCDA 2019 is an extension of the successful NCDA 2017, which collected data on approximately 6% of patients diagnosed in 2014. The NCDA 2019 aims to collect primary care data from 10% or more of GP surgeries in England, Scotland and Wales from patients who were diagnosed with cancer, and combine this with their cancer registry held secondary care data. The audit intends to demonstrate an approach that can support a sustained programme of clinical audit of cancer diagnosis

For the audit in England and Wales, the cancer registry will provide demographic data on patients through an online data portal managed by the National Cancer Registration and Analysis Service (NCRAS). For the audit in Scotland, Information Services Division (ISD) Scotland will provide demographic data on patients via Excel spreadsheets sent securely via nhs.net email. These initial data will comprise the sampling frame/platform for starting the data collection process at practice level. The GP will then input primary care data on patient characteristics such as language barriers and co-morbidities, consultations, intervals, referrals, delays in the patient's journey, symptoms and investigations.

When compared to data gathered in the previous round of the NCDA, the NCDA 2019 audit will allow assessment of the impact of major government and health service initiatives, as well as changes in referral guidelines, such as the NICE referral guidelines. It will answer questions on cancer diagnosis, specifically including the interval length from patient presentation to diagnosis and the use of primary care led investigations and further our knowledge on cancer diagnosis across the cancer pathway. The audit will also allow comparison of the referral pathways recorded in cancer registries and in the practice.

Local and national comparisons will be used to identify areas of best practice and highlight diagnostic challenges; this will be taken forward into the early diagnosis agenda and will lead to care pathway or influence policy changes. The analyses will allow the impact of clinical guideline changes to be measured. Participation in the audit will help identify cases for further in-depth review (learning events), support GP practice CQC inspection, demonstrate quality improvement for GP appraisal and re-validation and support NHS trusts in demonstrating their involvement in audits, along with facilitating self-assessment in GP practices and quality improvements. At a CCG, Health Board and Cancer Alliance level, the audit will produce valuable local and regional cancer intelligence and support local implementation initiatives, such as implementation of optimal cancer pathways in England or the single cancer pathway in Wales.

Who does the assessment apply to?

The NCDA audit involves direct activity of the following organisations and this assessment primarily focuses on their activity:

- National Cancer Registration and Analysis Service (within Public Health England) (as supplier of secondary care data for England, as owner of the NCDA online portal and as data controller)
- Wales Cancer Intelligence and Surveillance Unit (within Public Health Wales) (as supplier of secondary care data for Wales and joint data controller for the Welsh data)
- Users of the front-end services, including: General Practice clinicians, and GP practice staff specifically authorised by a GP at the practice to verify the data on their behalf
- NHS England

Why is this project needed?

Early diagnosis of cancer is a priority for all the stakeholders involved in the Programme (Cancer Research UK, Macmillan Cancer Support, NHS England, NHS Scotland, Public Health England, Public Health Wales, Scottish government, the Royal College of GPs, and academic partners). Diagnosing cancer earlier can increase survival, reduce mortality and improve quality of life and patient experience.

In 2015, the Cancer Taskforce recommended that "NHS England should commission a rolling programme of national clinical audits for critical cancer services, e.g. annually for lung cancer, and oversee an annual audit of cancer diagnosis". The Department of Health and Social care announce in October 2018 that 75% of cases should be diagnosed at early stage by 2028. The governments of other UK nations have also made earlier diagnosis of cancer a priority and a number of initiatives are ongoing to improve cancer waiting times and drive early diagnosis.

The first National Audit of Cancer Diagnosis in Primary Care was performed in England in 2010 and involved 1,170 practices who contributed data on 18,879 patients from 20 Cancer Networks. Following the Taskforce recommendation, the second National Cancer Diagnosis Audit (NCDA), which collected data in 2016/17 on patients diagnosed in 2014 involved 439 English practices who contributed data on 17,042 patients from 139 CCGs. Furthermore, the NCDA also took place in Scotland in 2017 where 73 practices from 13 NHS Health Boards submitted data on 2,014 patients. A smaller pilot study was conducted in North Wales.

These previous audits resulted in outstanding benefits in terms of motivating quality improvement in primary care and generating critical data to help understand patient pathways to cancer diagnosis. More specifically, they resulted in:

- Repeatable cycles of self-sustaining quality improvement activities in primary care, such as learning events centred on cancer diagnosis
- Strengthened local cancer intelligence and evidence to support local initiatives, such as optimal lung cancer pathway implementation and public awareness work
- Influential evidence about the size and nature of the challenge of cancer diagnosis in primary care (e.g. in respect of frequency of multiple pre-referral consultations and intervals, investigation and referral patterns, etc.)
- Opportunities to confirm and improve the accuracy of Cancer Registry data
- A suite of tools that can be employed to support ongoing service improvement initiatives

Previous audits have provided an in-depth picture of pathways to cancer diagnosis and supported quality and service improvements, as well as allowing review of the accuracy of cancer registration data.

The recommendation in the English Cancer Strategy was for 'an annual audit of cancer diagnosis'. Continuous audit of cancer diagnosis in primary care is critical to allow assessment of the impact of national initiatives, such as:

- Referral guideline changes (e.g. NICE, SCRG)
- Cancer Waiting Times standards (e.g. 28 day Faster Diagnosis Standard for England, Single Cancer Pathway for Wales)
- Optimal referral pathways (England)

They are also helpful in the evaluation of the continued investments in the early diagnosis agenda (e.g. Multi-Disciplinary Diagnostics Centres (England) and Rapid Diagnostic Clinics (Wales), Be Clear On Cancer campaigns, the introduction of Risk Assessment Tools etc.).

1 Privacy Impact Assessment Screening Questions

The following questions are intended to help organisations decide whether a PIA is necessary. Answering 'yes' to any of these questions is an indication that a PIA would be a useful exercise. Answers can be expanded as the project develops if needed:

1.1 **Will the project involve the collection of new information about individuals?**
Yes

1.2 **Will the project compel individuals to provide information about themselves?**
No

1.3 **Will information about individuals be disclosed to organisations or people who have not previously had routine access to the information?**
Yes
Primary care data will be sent to NCRAS that normally only receives secondary care data on patients.

1.4 **Are you using information about individuals for a purpose it is not currently used for, or in a way it is not currently used?**
Yes
Primary care data will be used to measure/benchmark cancer diagnosis process in England, where it is currently only used to inform that patient's care.

1.5 **Does the project involve you using new technology which might be perceived as being privacy intrusive? For example, the use of biometrics or facial recognition.**
No

1.6 **Will the project result in you making decisions or taking action against individuals in ways which can have a significant impact on them?**
No

1.7 **Is the information about individuals of a kind particularly likely to raise privacy concerns or expectations? For example, health records, criminal records or other information that people would consider to be particularly private.**
Yes
The audit will be using primary care health records.

1.8 **Will the project require you to contact individuals in ways which they may find intrusive?**
No

2 Data Submission

2.1 **General**

In England and Wales, data will be transferred and submitted via an online portal behind the N3 network developed and hosted by NCRAS. The portal will show GPs some demographic data on their patients. It will ask them a series of questions about each patient to be answered with primary care data.

In Scotland, data will be transferred and submitted in Excel files via secure nhs.net email. As an additional precaution, data submitted from GP practices to ISD will have all CHI numbers removed. A separate PIA has been completed for Scotland due to the differences in data collection method.

2.2 **Contact details collected as part of the audit**

When GPs and other professionals register for access to the online data collection portal, they will be asked to submit the following data items:

- Full name
- Email (nhs.net/wales.nhs.uk)
- Mobile phone
- GMC number

- Smartcard number (England only)
- Practice name
- Practice code
- Practice address

2.3 **Data items submitted as part of the audit**

GPs will be provided with the following data items:

- First name
- Surname
- NHS number
- Age at diagnosis
- Gender
- Cancer type
- Diagnosis date
- Date of death (if applicable)

The GP will be asked to provide the following data items

- Screen-detected cancer
- Language
- Communication difficulty
- Housebound status
- Living arrangement
- Co-morbidity
- Place of 1st presentation
- Date of 1st presentation
- Date patient first observed signs or symptoms
- Number of consultations before referral
- Why did multiple (3 or more) consultations occur?
- Safety netting
- Date of first primary care referral
- Date of ultimate primary care referral (if different)
- Number of referrals made judged relevant to eventual diagnosis
- Date first seen by specialist
- Date patient was informed they had cancer by specialist (recorded in letter the GP received from secondary or tertiary care services)
- Presenting symptoms
- Presenting signs and abnormal investigations that led to a suspicion of cancer
- Primary care led (ordered) investigations
- Type of referral
- Type of emergency referral (including patient self-referral)
- Avoidable delay to patient journey (yes/no)
- Was there any avoidable delay between presentation and referral?
- Was there any avoidable delay after referral?

The GP will also be able to add additional comments in free text at the end of the form.

2.4 **Technical**

Data will be collected from GPs via drop down menus and tick boxes (in the online portal or in Excel form for Scotland). A small number of free text fields to collect dates are available with field validation to control the formatting of the data.

2.5 Information Governance

All data transfers must operate within the principles of:

- The Law - these are mandatory requirements; specifically the Data Protection Act 1998[1] and Common Law Duty of Confidentiality[2];
- Department of Health Information Governance policies and standards[3].
- The General Data Protection Regulations (GDPR)[4]

In order that personal data (including sensitive personal data) may be processed fairly by the National Cancer Registration and Analysis Service, the data subjects must be able to access a 'fair processing notice' (previously called a privacy notice). The Cancer Registration Patient Information Leaflet[5] (and accompanying FAQs) has been designed to give patients information on what cancer registration is and why it is done.

2.6 **Provider responsibilities**

All Providers must ensure that the Cancer Registration Patient Information Leaflet is available for patients within their Organisation.

2.7 National Cancer Registration and Analysis Service responsibilities

The National Cancer Registration and Analysis Service will ensure that the leaflet is kept up to date and fit for the intended purpose by updating the leaflet when appropriate. Any updates will be notified to all Providers.

The National Cancer Registration and Analysis Service processes data with exemption to common law duty of confidentiality through legal support under Section 251 of the NHS Act 2006 and subsequent Health Service (Control of Patient Information) Regulations 2002 (Statutory Instrument 1438).

Since the support given to the National Cancer Registration and Analysis Service under Section 251 is subject to annual review by the Ethics & Confidentiality Committee (ECC) of the National Information Governance Board (NIGB), the NCRAS will ensure that any changes to this support are immediately disseminated to all data Providers.

The IG Toolkit[6] is an online system which allows NHS organisations and partners to assess themselves against Department of Health Information Governance policies and standards. It also allows members of the public to view participating organisations' IG Toolkit assessments. All Cancer Registration Services are required to carry out self-assessments of their compliance against the IG requirements through the IG Toolkit and are annually assessed.

3 Quality and completeness

3.1 **General standards**

Cancer registration of data is performed to the highest standards, as detailed in section 9.2.

In England, Cancer Waiting Times data "*has been subject to a process aimed at ensuring that the published data provide as accurate as possible a picture of the delivery of cancer services within the English NHS.*"[7]

3.2 **Specific standards**

Cancer staging data is complete to at least 70% across all malignant cancer types (excluding non-melanoma skin cancer) following the Public Accounts Committee's report: *Delivering the Cancer Reform Strategy*[8].

Allocation of newly diagnosed tumours to the practice of the patients is complete to above 95%.

[1] http://www.legislation.gov.uk/ukpga/1998/29/data.pdf
[2] https://www.dhsspsni.gov.uk/articles/common-law-duty-confidentiality
[3] http://systems.hscic.gov.uk/infogov
[4] https://www.gov.uk/government/publications/guide-to-the-general-data-protection-regulation
[5] http://www.ncr.nhs.uk/patientinfo/
[6] https://www.igtt.hscic.gov.uk/igte/index.cfm
[7] http://webarchive.nationalarchives.gov.uk/20130402145952/http://media.dh.gov.uk/network/261/files/2012/03/download-summary-of-data-quality-september-2010-pdf-41k.pdf
[8] http://www.publications.parliament.uk/pa/cm201012/cmselect/cmhealth/1048/1048we14.htm

3.3 **Conformance**

The majority of data items will be collected via drop down menus and tick boxes, to control attributes. The small number of free text boxes set up to collect dates will have field validation to control the formatting of the data. If data input does not follow the validations the portal shows an error on the data item when the GP uses the save button. There is a single free text box where GPs are invited to give extra information on, for example, the cause of avoidable delay.

4 Security

From a security perspective, the relevant organisations have taken a number of precautions to ensure all data is secure:

4.1 **Registration on online portal**

GPs will have to register their details before being created an account to access their patient registry data via the portal. During registration, GPs will be asked for some contact details, as well as their GMC number and Smartcard number (England only) and practice association, which will be stored securely by PHE within the portal system.

During registration GPs will be asked to provide specific, GDPR-compliant consent for future contact and use of their details. The three consent questions relate to (i) consent that PHE can keep details on record, create an account and contact the user about NCDA, (ii) consent that PHE can share name, email and practice association with CRUK as part of the monitoring and follow-up for the NCDA, and (iii) consent that CRUK can keep name, email and practice association on record for the purposes of NCDA follow-up. A link to CRUK's privacy policy, as well as clear information of how to withdraw consent, are provided with the questions.

Before an account is created a GP must have their email address verified, the fact they are a GP with the ability to practice medicine verified and the fact they are at the practice they have told us verified. A full SOP is available for this process.

Users who are not GPs (Practice Managers, Advanced Nurse Practitioners etc.) can also be created an account on the portal, but such users do not have a GMC number to verify. It is therefore recommended that a GP is the first to register from a practice and then later requests to add additional users from inside the portal system (via the 'add another user for this practice' function), which will speed up verification of the additional user. They will still have their email address verified before being created an account.

4.2 Continuous access to online portal

Access to data on the NCDA portal will be monitored. At twelve months intervals from data collection start all registered GPs will have their fitness to practice confirmed again via the GMC register and checks will be undertaken to confirm they still work at the practice at which they were registered on the portal system. Any GPs found to be no longer allowed to practice medicine will have their accounts deleted immediately. For any GPs who are found to have changed practice, the account will be locked. The user will be contacted to ascertain which practice (if any) they are now associated with and if they still use their NCDA portal account. The practice their account was associated with originally will also be contacted to enquire whether the user should no longer be associated with this practice on the portal system. Depending on the responses, the user may be removed from the practice and may be linked to another practice (after appropriate verification), the account may be deleted, or the account may be unlocked to allow continued access if expressed permission for this is given by the practice (e.g. a GP registrar may have moved practice during the audit but may still be allowed to access the portal so they can look at the data they inputted / practice report for the original practice for their development and appraisal).

4.3 **Data transfer from practice via online portal**

All data entry and submissions of patient data will take place within the secure N3 network via the portal hosted and managed by PHE.

Access for users to individual patient records will be converted to a read-only basis (for registered users only) a year after the case is first sent to the practice, or when data collection closes. This will allow us

to make local practice feedback reports available securely via the portal and will allow users to revisit and review individual cases during the feedback phase. Read-only access will close at the end of the project if the audit runs only for a finite amount of time (after data feedback has been provided), if the audit does continue (depending on available funding) read-only access to older patient records will continue.

Internal verification will be completed again in following years to re-open accounts for future audits if required.

There will be no function on the portal for GPs to export their data.

4.4 **Monitoring data transfer from PHE to CRUK**

On a weekly basis, PHE will provide the NCDA Programme Manager with an Excel spreadsheet which will list all registered users on the portal that have consented for their details to be shared with CRUK as part of audit monitoring, as well as the number of patients on the practice list and number of data submissions received (no patient identifiable data will be included in these spreadsheets). The transfer of the Excel spreadsheet will be via secure nhs.net email to the Programme Manager's nhs.net email account. Data will be stored by CRUK in line with its policies for personal data storage and only be used for monitoring and follow-up of NCDA.

4.5 **Servers**

The data is stored on servers at a secure data centre on the N3 network, in the same way as the NCRAS encore cancer registration system, and protected in line with the NHS Information Governance Toolkit. All identifiable data is encrypted on disk.

4.6 **Patient demographics**:

GPs will be asked to collect primary care data on all patients diagnosed with malignant cancer over the specified timeframe, excluding non-melanoma skin cancer.

4.7 **Security vulnerabilities**:

The NCRAS IT team maintains active awareness of security vulnerabilities, and the front-end servers are updated and patched regularly against known vulnerabilities.

5 Patient Consent

Patient consent is not required as the NCRAS has an exception under the under Section 251 of the NHS Act 2006 and subsequent Health Service (Control of Patient Information) Regulations 2002 (Statutory Instrument 1438). However, participating practices will be provided with posters to display in the surgery so that patients are aware the practice is participating and can tell their GP is they do not wish for their data to be shared.

6 Privacy Policy and Data Protection

The NCRAS have been granted authority to collect this information about patients and their tumour(s) under Section 251 of the NHS Act 2006 (and formerly under Section 60 of the Health and Social Care Act 2001) and regulation 2 of Health Service (Control of Patient Information) Regulations 2002 (Statutory Instrument 1438). The NCRAS complies with the requirements of the Data Protection Act 1998 regarding the receipt, storage and transfer of personal data.

The NCRAS also follow UK and Ireland Association of Cancer Registries policies for the use of potentially personally identifiable information. The NCRAS security policy complies with the current Information Governance arrangements for the NHS.

Data is only released with the permission of the Caldicott Guardian and in compliance with the policies agreed with the Ethics and Confidentiality Committee of the National Information Governance Board (now replaced by the Health Research Agency's Confidentiality Advisory Group).

In addition, there is a department within PHE called the Office of Data Release[9] (ODR). The ODR, as a pan-PHE service, manages the release of explicitly or potentially identifiable information from PHE, and is responsible for scrutinising applications for data. The ODR ensures that all releases are conducted in accordance with the rights of data subject, the legislative framework including the principles set out in the Data Protection Act 1998 and the seven Caldicott Principles.

Both the ODR and the Caldicott Guardian within PHE with direct responsibility for cancer data have scrutinized and accepted the audit protocol.

7 Patient Opt-Out

The benefits of the data collected by the cancer registry have been considerable and the NCRAS are grateful that nearly everyone with cancer is prepared to share their data with the cancer registry. However, patients can ask the NCRAS to remove all of their details from the cancer registry. These requests won't affect any treatment or care.

If patients wish to make such a request, they can either:

- Download a document to complete and return from the NCRAS website[10]
- Or complete an online form if they would rather have these details posted to them.

In England and Wales, patients who have opted out of their data being used for purposes other than their own care, including National Opt-Outs and Cancer Registry Opt-Outs, will be applied through PHE, so that such patients will not be shown on the online portal and no data will be collected for such patients.

Type 1 opt-outs for English patients will be applied through the GP surgery. If a patient has a type 1 opt out in place, GPs completing the audit will be asked to note this and no data from the GP medical record will be collected as part of the audit. There is a pop-up question built into the portal system that will prompt GPs to confirm whether or not a patient has a Type 1 Opt Out in place.

8 Caldicott Guardian Review and Sign-Off

The current Caldicott Guardian agreement has been reviewed and signed off to ensure all Information Governance and Data Protection/Security measures are in place and legally binding.

9 Privacy Risk

9.1 Physical Privacy

'The ability of a person to maintain their own physical space or solitude'

There is no physical risk to a patient or any person whose data is collected and submitted to the NCDA.

9.2 Informal Privacy

'The ability of a person to control, edit, manage and delete information about themselves and to decide how and what extent such information is communicated to other'

Data collected for Cancer Registration, is used to provide local, national and international analyses of cancer and treatment outcomes. These data are a vital part of healthcare and provide evidence to improve the diagnosis and ensure patients are treated with the most effective treatments possible.

The following risks are mitigated as follows:

- *Inaccurate, insufficient or out-of-date data*
  - The NCRAS employs around 200 cancer registrars across England, who undergo two years of initial training, and ongoing training as required to ensure that their professional abilities and skills are always up-to-date
  - These registrars use information provided to them, to ensure (through cross-referencing), that the data provided is accurate and complete.

[9] http://www.ncin.org.uk/collecting_and_using_data/odr
[10] http://www.ncr.nhs.uk/removal-request/

- If more information is required, these registrars will access patient records (though local honorary contracts) at the Trust to ensure the data is correct.
- All data is sent off for tracing to ensure it is correct and then cross referenced against the national cancer registration dataset (EnCORE/Catrin), to ensure the data is for the correct patient and no mistakes have been made in the collection and submission of data from the Hospital Trust to the NCRAS.
- Doctor's registrations and other key data (such as procedures or staging) are cross referenced against national datasets to ensure they are correct and not out-of-date.

- *Excessive or irrelevant data*
  - Data is strictly controlled, to ensure that only the data absolutely needed is collected. Only information on patients (who have a registrable cancer) is collected and only data within the dataset used.
  - This prevents excessive or irrelevant data being collected and submitted to the NCRAS. Any data submitted and not required is securely deleted on import or through the registration process.
  - Any errors identified are reported back to the submitting Trust.
- *Data kept for too long*
  - Data on cancer patients is kept indefinitely. This is a vital part of monitoring the nation's health and providing information about the survival and mortality of cancer.
  - These data are kept on a secure server and are not accessible by members of the public, private organisations or sold on.
  - Data required for analyses and international benchmarking or for medical papers, have to go through a series of legally binding requests, signed off by Caldicott Guardians and approved by the Office of Data Release, within PHE.
- *Data Disclosed to those who the person it is about does not want to have it*
  - Data required for analyses and international benchmarking or for medical papers, have to go through a series of legally binding requests, signed off by Caldicott Guardians and approved by the Office of Data Release, within PHE.
  - No data is released in' patient form' to the public on request.
  - No relatives can contact the NCRAS to request information on any of their relatives or people they may know.
  - The NCRAS is monitored annually by the Confidentiality Advisory Group (CAG).
- *Data used in ways that are unacceptable to or unexpected by the person it is about*
  - Hospitals are expected to provide a copy of the Registration 'Patient Leaflet' to all patients diagnosed with a registrable tumour.
  - This has details of how a patient may ask for their data to be excluded from data collection and submission to the NCRAS and any data already collected to be deleted.
  - Please refer to section 7 above (Patient Opt-Out)
- *Data not kept securely*
  - Cancer data is collected by clinicians or specially trained staff within the local Cancer Services Departments at each hospital Trust.
  - Data is collected at Hospital Trusts using secure datasets on hospital secure servers.
  - Local IG policies are expected to be in place to ensure that only people with the correct training and IG clearance are allowed to see, add and/or amend these data
  - Staff are required to have CRB checks and undergo IG training (including annual refresher courses).

10 Recommendations

10.1 Formal sign-off of the project by the NCRAS Caldicott Guardian

A formal sign-off of the project by the NCRAS Caldicott Guardian is required to ensure all Information Governance, Data Protection and Security issues have been mitigated, and effective measures in place to ensure the continued safe transfer and protection of confidential patient identifiable data.

10.2 Review of the project by the Public Health Wales Caldicott Guardian

Review of the project by the Public Health Wales Caldicott Guardian will be sought in addition to formal sign-off from the NCRAS Caldicott Guardian.

10.3 Annual CAG Review

The NCRAS must ensure that the annual Confidentiality Advisory Group (CAG) is up-to-date and maintained.

10.4 Annual IG Training

It is the responsibility of all hospitals and NCRAS management to ensure that annual training records are be kept up-to-date and all staff using, collecting or processing data are correctly trained.

10.5 Cancer Registration Patient Leaflet

The NCRAS must ensure that all hospital Trusts have a sufficient supply of Cancer Registration Leaflets, so that patients understand what their data is used for and why it is collected. Hospital Trusts are responsible for the circulation and delivery of these leaflets and request more as and when required from the NCRAS.