JAG

Joint Advisory Group
on GI Endoscopy

NED | NATIONAL ENDOSCOPY DATABASE

National Endoscopy Database

Caldicott and data governance information

This document is aimed to help you obtain Caldicott approval for the NED project.

Hosted by

Royal College of Physicians

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1. Information for NED leads

Prior to commencing data uploading from your local endoscopy reporting system to the national database, you will need to obtain local approval. The minimum local approval required is Caldicott Approval. Further approval may be required according to local arrangements. In some organizations, the following approvals have been required and you should check with the appropriate departments if this is necessary in your organization:

- Audit department approval
- IT department approval
- Change control approval

Please use the information below and the specimen Caldicott application below to aid local application for Caldicott approval in your organization.

Please inform the NED project team (askjag@rcplondon.ac.uk) when you have obtained Caldicott approval or if you have any queries.

Formal agreement to engagement with the NED project should also be obtained from your endoscopy lead and endoscopists in the organization. Usually, this is best addressed via the Endoscopy User Group or equivalent.

All participating endoscopists will be required to be registered on the JAG Endoscopy Training System (JETS). Endoscopists may 'opt out' from having their GMC or NMC number linked to their performance data, though they should be reassured that there will be clear restrictions on who can see their data. Endoscopists should be made aware of this option by the NED lead. Sample emails to circulate to local endosocpists will be made available to NED leads to raise awareness.

Caldicott approval is needed to allow export of data from the trust/organization to the national database regardless of whether the data is patient identifiable or not. All NED data is patient non identifiable.

2. Supporting information for Caldicott Guardians of organizations participating in the National Endoscopy Database project (NED)

a. What is the purpose of the National Endoscopy Database (NED)?

The NED has been established in order to;

- pool endoscopy data from individual units around the UK
- enable quality assurance and benchmarking of standards
- deliver feedback to individual endoscopists and units with regards to their performance
- enable performance to be audited against current BSG and JAG quality standards
- act as a potential database for service evaluation and research
- automatically provide data for some of the current JAG audits

The aim is that by accurately measuring endoscopy performance and enabling benchmarking the quality of endoscopy will hopefully improve

b. Ownership of National Endoscopy Database Data and Systems

1. Data ownership
   The data collected by the National Endoscopy Database (NED) is owned by the JAG (Joint Advisory Group on GI Endoscopy).
2. Data collection
   The data collected will not contain patient identifiable data. It will be procedural and will link data to clinicians and to services.
3. Data use
   The data inputs and outputs of the NED are under the auspices of the NED working group.
4. Application for access to the data beyond use by the JAG will need to be made to and approved by the JAG Committee.
5. Data governance
   The data is to be collected and used in accordance with the RCP *Clinical Standards Department - Information Governance Policy.*
6. Roles and responsibilities

Data owner	The JAG (RCP Accreditation Unit)
Database supplier	Weblogik

The relationship between the data owner and the data supplier are set out in the contract between Weblogik and the RCP accreditation unit. Further information and the contact between Weblogik and the RCP accreditiation unit can be found in the NED Data Ownership and Management Policy v0.1 (available on request).

c. Scope and System of Data Collection for the National Endoscopy Database

The National Endoscopy Database has been developed by JAG in conjunction with other societies and colleges, in order to develop a national endoscopy database. The database will be populated by data extracted automatically from each participating hospital's endoscopy reporting system (ERS) to the national database. The expectation is that every endoscopic procedure performed in the UK will be accounted for in NED.

Minimum patient data will be used; only age and sex will be recorded, as this is clinically relevant data to enable quality assurance. Each procedure will be given a unique identifier in the National Endoscopy Database that will contain a string of information to allow the procedure to be identified in the local endoscopy database for data quality checking purposes and to facilitate further service evaluation. Individuals and units will receive feedback of their performance data.

d. Patient Consent

Patients will not be contacted or consented as data will not be made identifiable. Agreement with this arrangement has been obtained from NRES and the Confidentiality Advisory Group (CAG). Publicity posters will be made available to organizations for display in Endoscopy Unit waiting areas.

e. Access to data

Access to the data by the NED National Team and the Database supplier/ administers will be limited to individuals approved by the Chair of the NED National Team. This access will be for administrative purposes only.

A hierarchy of access to NED data will be set up to restrict access. Individual endoscopists will only be able to see their own performance data. They will also be able to see summary level data for their organization (anonymized by endoscopist). Clinical Leads will be able to view data for endoscopists within their organization only. Only data from within an organization will visible to users in the organization.

Users will view performance data via the NED web site. This will be similar in format to the existing JETS e-portfolio facility.

f. Data storage

The data storage and database systems will be run by Weblogik. The data storage details are described below:

Access to NED- Access to the NED/JETs site is via a username/password combination (stored as one way hash) and is over SSL (2048 bit). Access to the NED upload service is also over SSL and requires a username and password for each unit as well as a unique supplier identifier. Servers are running Windows Server 2008 software.

Hardware- The NED/JETS application is hosted on a multi-tier environment accessed via the public internet behind a CISCO firewall.

Hosting Environment- Weblogik has its own secured rack within the Equinix Group data centre at London Docklands, the NED application is hosted on multi-tier servers within this rack. The data centre offers high levels of data and network security, with electrical and mechanical systems engineered with multiple levels of redundancy, and 24x7 protection against fire and natural disasters.

Physical Security- The data centre has 24x7 security systems. Customers have the protection of security barriers, 24x7x365 monitoring by on-site personnel to include verification of all persons entering the building, CCTV video camera surveillance throughout, and security breach alarms.

Access- Access to the buildings, data floors and individual areas are via individually programmed access cards, and visual identification. Whenever you swipe your card tag over the sensors to gain access to the building, your digital photograph is displayed and on-site technicians verify the request before allowing access.

Standardised procedures ensure you and your nominated staff can gain access to your equipment whenever you require, day or night.

Power- Customers have access to a redundant high-capacity power supply, scalable for future expansion. Power is isolated between customers, and with Uninterruptible Power Supply (UPS) systems and stand-by diesel generators on site to ensure a resilient location for important infrastructure equipment.

Fire Detection/Suppression- Very Early Smoke Detection Apparatus (VESDA) is installed in every facility. These highly sensitive smoke detectors, which are linked to the Building Management System and monitored continually from a network operations centre, provide very early detection to help avoid fire, loss and business disruption. This is coupled with an environmentally-friendly gas-based or water mist fire suppression system to put out fires, with minimal damage to equipment.

Air Conditioning- To ensure performance and avoid equipment failure, all data floors are managed such that air entering customers' equipment is maintained at a controlled temperature and relative humidity.

Building Management System (BMS)- All Equinix Group facilities operate computerised Building Management Systems that monitor and remotely operate sensors covering electrical, mechanical, fire detection and leak detection systems.

Backups- The application is backed up each day to an onsite NAS (Network Attached Storage device), transaction level backups are taken every 15 minutes and full backups once a day to a separate off site NAS. These backups are performed over a VPN and are stored in a locked server cabinet within Weblogik's main office. The office is in a secure compound, protected by CCTV, requiring access cards to gain entry (at multiple points); the office itself is protected by a monitored alarm system.

g. Requests for external and research access to NED

Requests for external and research access to anonymized NED data will be overseen by the Research sub-committee of the NED national team.

h. Approval from Advisory Groups

1. National Research Ethics Service (NRES)
NRES was consulted in 2013 regarding the need for individual patient consent. They advised as follows: 'Provided that the proposed unique identifier cannot be used, either on its own or in conjunction with other identifiers, to re-identify individual patients by users of the national database and that sufficient controls are in place to ensure that this would not be possible, we would not recommend an application for support under the Health Service (Control of Patient Information) Regulations 2002 or any need for further advice from the Confidentiality Advisory Group, as it appears that identifiable data would not be disclosed outside the local care teams'.

2. Information Commissioner`s Office (ICO)
The ICO was contacted in September 2014. The NED project was outlined to a senior officer who made a number of recommendation to ensure that the NED project complied with the Data Protection Act. These measures have been fulfilled. Further details of communications with the ICO are available on request from the NED Team.

3. Confidentiality Advisory Group (CAG)
CAG were approached in December 2014. After review of the project they advised that formal application to the Confidentiality Advisory Group for approval by the Secretary of State for Health under section 251 is not necessary. Further details of communications with CAG are available on request from the NED Team.

Appendix 1. Specimen Caldicott Application form

Specimen Caldicott Approval Form

Use & Release of Personal Identifiable Data (Caldicott Approval Form)

Introduction

The purpose of the Request for Use or Release of Person-identifiable Data Form is to record the details of identifiable information sent from the Trust/organization to other partners/agencies. This will ensure that all data flows of personal and/or sensitive information, including healthcare, medical and non-medical, are conducted in a secure and confidential manner and approved by the Caldicott Guardian where necessary.

Division/Directorate: Medicine
Data Flow Title: National Endoscopy Database (NED)
Description of proposal: JAG, in conjunction with several other societies and colleges, is working to develop a National Endoscopy Database (NED). This will be populated by data extracted automatically from each hospital's endoscopy reporting system (ERS). The aim of the project is to enable better quality assurance of endoscopy by pooling data to allow benchmarking and offer potential for research by providing a central store of information.
Identify purpose: **Healthcare Medical Purpose (Primary)** ■ **Non-Healthcare Medical Purpose (Secondary)** ☐ **Non-Medical Purpose** ☐
Indicate which data items have been requested: **Forename:** ☐ **Surname:** ☐ **DoB:** ☐ **Age:** ■ **Sex:** ■ **Address:** ☐ **Postcode:** ☐ **NHS No.** ☐ **Ethnic Origin** ☐ **Other (please specify)**
Time period for data required: Start date: June 2015 End date: indefinite **Please state regularity – rolling upload**
Appointed person/Safe Haven responsible for release of data : **Name: Usually NED lead Title:** **Division: Department: Medicine** **Address:** **Telephone: xxxxxxx Email: xxxxxxxxxxxxx**

Receiving Organisation/individual

Organisation Name: National Endoscopy Database
Address: Royal College of Physicians London, 11 St Andrews Pl, London NW1 4LE

Appointed person responsible for data: Dr Tom Lee

Contact details: as above **Email address: askjets@rcplondon.ac.uk**

Recipients location for receiving and processing data:

NHS Organisation	☐	**Government Dept.**	☐	**UK x**	■
EEA Country	☐	**Non EEA Country**	☐		

Who else will have access to the data?
(*If data recipients are not employed by the NHS please state whether NHS honorary contracts are in place. If not – detail confidentiality agreements.)*

Method of secure information / data transfer (please tick):

NHSmail.net ☐ **Secure fax** ☐ **Removable media encryption AES 256** ☐

Email (secured) ☐ **Special Delivery / courier** ☐ **Electronic File Transfer** ■

Organization Safe Haven ……

Please describe the applicable security arrangements for the transfer:

Access to NED
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Physical Security
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Access
Access to the buildings, data floors and individual areas are via individually programmed access cards, and visual identification. Whenever you swipe your card tag over the sensors to gain access to the building, your digital photograph is displayed and on-site technicians verify the request before allowing access.
Standardised procedures ensure you and your nominated staff can gain access to your equipment whenever you require, day or night.
Power
Customers have access to a redundant high-capacity power supply, scalable for future expansion. Power is isolated between customers, and with Uninterruptible Power Supply (UPS) systems and stand-by diesel generators on site to ensure a resilient location for important infrastructure equipment.
Fire Detection/Suppression
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How will the service users be contacted? No contact will be made

What information will be given to the service user about the purpose? none

How will the service users consent be obtained?
As only non patient identifiable information wil be transferred, consent will not be obtained. Verification of this has been obtained from NRES- see below:

Dear Dr Dunckley,

Your query was reviewed by our Queries Line Advisers.

Thank you for your query regarding your proposed linkage study for endoscopy reports.

Provided that the proposed unique identifier cannot be used, either on its own or in conjunction with other identifiers, to re-identify individual patients by users of the national database and that sufficient controls are in place to ensure that this would not be possible, we would not recommend an application for support under the Health Service (Control of Patient Information) Regulations 2002 or any need for further advice from the Confidentiality Advisory Group, as it appears that identifiable data would not be disclosed outside the local care teams.

Regards
NRES Queries Line
Ref. 63/57

If no consent being obtained, please detail the reason why not e.g. exemption under Section 251 of the NHS Act 2006.

How long will the data be stored? indefinitely

Where will the data be physically stored: see above

If the data is on a computer is there access via a local network or the internet?
See above

How will data be protected? (Please detail security measures to be taken)
See above

At the end of this period how will the data be disposed?
No plans made to dispose of data.

You must address the 6 Caldicott Principles – please give a brief description under each of the following headings

Principle 1 - **Justify the purpose(s)** Every proposed use or transfer of service user-identifiable information within or from an organisation should be clearly defined and scrutinised, with continuing uses regularly reviewed, by an appropriate guardian. National collection of endoscopy data to improve quality assurance of endoscopy
Principle 2 - **Don't use service user-identifiable information unless it is absolutely necessary** Service user-identifiable information items should not be included unless it is essential for the specified purpose(s) of that flow. The need for service users to be identified should be considered at each stage of satisfying the purpose(s). Only age and gender will be uploaded. No other patient identifiable information will be retrieved. Each procedure will be given a unique identifier in the National Endoscopy Database that will contain a string of information to allow the procedure to be identified in the local endoscopy database for data quality checking purposes and to facilitate further service evaluation.
Principle 3 - **Use the minimum necessary service user-identifiable information** Where use of service user-identifiable information is considered to be essential, the inclusion of each individual item of information should be considered and justified so that the minimum amount of identifiable information is transferred or accessible as is necessary for a given function to be carried out. Only age and gender are required. These are clinically relevant data which will contribute to the quality assurance process.
Principle 4 - Access to service user-identifiable information should be on a strictly need-to-know basis Only those individuals who need access to service user-identifiable information should have access to it, and they should only have access to the information items that they need to see. This may mean introducing access controls or splitting information flows where one information flow is used for several purposes. Only national clinical leads, database managers and individuals approved by the chair of the National Endoscopy database Project Team will be permitted access to data.
Principle 5 - **Everyone with access to service user-identifiable information should be aware of their responsibilities** Action should be taken to ensure that those handling service user-identifiable information - both clinical and non-clinical staff - are made fully aware of their responsibilities and obligations to respect service user confidentiality. All individuals involved in the project will be aware of their responsibilities. Individual organizations providing data to the national database will be required to obtain local information governance and Caldicott approval where appropriate
Principle 6 - **Understand and comply with the law** Every use of service user-identifiable information must be lawful. Someone in each organisation handling service user information should be responsible for ensuring that the organisation complies with legal requirements. The Project team will be responsible for ensuring legal requirements are fulfilled.
Principle 7 - The duty to share information can be as important as the duty to protect patient confidentiality Health and social care professionals should have the confidence to share information in the best interests of their patients within the framework set out by these principles. They should be supported by the policies of their

employers, regulators and professional bodies

The National Endoscopy Database aims to contribute to improvements in the quality of endoscopy in the United Kingdom. This is facilitated by pooling anonymised endoscopy data to produce key performance indicators for benchmarking and quality improvement purposes. The information governance arrangements support Trusts uploading data to NED once Caldicott approval has been obtained locally. NED data will not be shared outside these arrangements.

Other supporting information e.g. Ethics approval, correspondence etc

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Regards
NRES Queries Line
Ref. 63/57

I confirm that the data will be held and used according to the conditions and information given as described within this approval from.

Name:…….. Title:…….……

Signature: …… Date:……

If the form has been completed by a Medical Student or other similar training posts a supervisory signature or equivalent is required below:

Name:…….. Title:…….……

Signature: …… Date:……..

Appendix 2. NRES advice document

ENQUIRY TO NRES

Dear Dr Dunckley,

Your query was reviewed by our Queries Line Advisers.

Thank you for your query regarding your proposed linkage study for endoscopy reports.

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Regards
NRES Queries Line
Ref. 63/57

PLEASE NOTE OUR NEW EMAIL ADDRESS: nres.queries@nhs.net

The NRES Queries Line is an email based service that provides advice from NRES senior management, including operations managers based in our regional offices throughout England. Providing your query in an email helps us to quickly direct your enquiry to the most appropriate member of our team who can provide you with an accurate written response. It also enables us to monitor the quality and timeliness of the advice given by NRES to ensure we can give you the best service possible, as well as use queries to continue to improve and to develop our processes.

Please note:

- If you have been asked to follow a particular course of action by a REC as part of a provisional or conditional opinion, then the REC requirements are mandatory to the opinion, unless specifically revised by that REC.
- Should you wish to query the REC requirements, this should either be through contacting the REC direct or, alternatively, the relevant local operational manager (details available from the NRES website NRES - NRES Office and Departmental Contact Details).

NRES Queries

Health Research Authority
National Research Ethics Service (NRES)
Ground Floor, Skipton House, 80 London Road, London SE1 6LH