



## **Information Governance Procedures for NELA**

### **Title**

National Emergency Laparotomy Audit

### **Description of proposal**

The National Emergency Laparotomy Audit (NELA) is part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP), overseen by the Healthcare Quality Improvement Partnership (HQIP). NCAPOP is a closely linked set of centrally-funded national clinical audit projects that collect data on compliance with evidence based standards, and provide local trusts with benchmarked reports on the compliance and performance. They also measure and report patient outcomes.

NELA was commissioned following evidence of a high incidence of death, and a wide variation in the provision of care and mortality, for patients undergoing emergency laparotomy in hospitals across England and Wales. The aim of the audit is to enable the improvement of the quality of care for patients undergoing emergency laparotomy through the provision of high quality comparative data from all providers of emergency laparotomy.

The contract for the provision of the NELA was awarded to the Royal College of Anaesthetists (RCoA) in June 2012. The Clinical Effectiveness Unit of the Royal College of Surgeons of England are partners and provide important methodological and technical input.

### **Overview of the audit**

The contract commenced in December 2012 with an organisational audit performed in year 1. Individual patient data collection commenced in Year 2 and is ongoing. All patients aged 18 and over, having a general surgical emergency laparotomy in all NHS hospitals in England and Wales are being enrolled on a prospective basis.

NELA looks at structure, process and risk-adjusted outcome measures for the quality of care received by patients undergoing emergency laparotomy. NELA compares against evidenced-based standards, a list of which can be found [here](#). The aim of the audit is to generate data that drives Quality Improvement (QI). QI will be facilitated through dissemination of collected data as well as workshops and seminars to drive specific QI projects alongside data collection.

NELA data will be linked to other sources of routine data including Critical Care Data (ICNARC case mix programme), Bowel Cancer Data (National Bowel Cancer Audit/Upper Gastro-intestinal Cancer Audit) and NHS Digital (Hospital Episode Statistics and ONS data).

NELA is delivered by a central project team from the National Institute of Academic Anaesthesia's Health Services Research Centre based at the RCoA. Formal oversight will be provided by a Project Board consisting of key stakeholders. Scientific input will be provided by a Clinical Reference Group consisting of representatives from all relevant clinical professional and speciality stakeholders (including patient groups).

### **Reporting**

NELA is on the list of mandatory national audits for inclusion in Trusts' Quality Accounts. NELA will issue annual reports that will include key outcome data, at named hospital level. These will be adjusted for risk. NELA will also provide comments on whether relevant standards are being met. A



Lay summary will be made available to accompany the Annual reports. There will be the capability for hospitals to access their data outside of the official reporting periods.

### **Governance**

NELA is delivered by a project team that meets on a monthly basis. It is overseen by a Project Board consisting of representation from key funding and stakeholder organisations.

### **Identify purpose**

1. Healthcare Medical Purpose (Primary)
2. Non-Healthcare Medical Purpose (Secondary)

### **Data items requested**

- 1) Demographic data: Date of birth, sex, postcode of place of residence
- 2) Patient identifiers: NHS number, name
- 3) Procedure data: Date & time of admission, date & time of surgery, procedure type, record of medical interventions performed, personnel involved in delivery of care, processes of care
- 4) Physiological data to enable risk adjustment
- 5) Outcome data: Date of hospital discharge, date of death

### **Time period for data required**

The audit will collect data on a continual basis from December 2013. The audit is delivered under contract to HQIP and the data will be retained for the duration of time that a contract remains in place and where there is no change in data controller or data processors. Data is collected contemporaneously via web-based data collection platform.

### **Receiving Organisation/individual**

**Organisation Name:** Royal College of Anaesthetists

**Address:** Churchill House, 35 Red Lion Square London WC1R 4SG

**Appointed person responsible for data:** Ms Sharon Drake

**Contact details:** 020 7092 1681

**Email address:** sdrake@rcoa.ac.uk

**Recipient's location for receiving and processing Trust data:** UK, Non-NHS organisation



### **Who else will have access to the data?**

The RCoA will oversee the collection of patient level data for patients undergoing emergency laparotomy. The source data will be collected from hospitals via a NELA webtool hosted by Netsolving. The NELA webtool will house the full dataset in a secure environment, including the patient identifiers.

The full identifiable dataset will be retained in its original format within the NELA webtool. Only the registered Data Protection Controller for NELA will have access to the full dataset. The project team and its subcontractors will not have access to the full set of patient identifiers. Pseudonymised data will be used for data analysis by the RCoA and its approved sub-contractors (The Clinical Effectiveness Unit of the Royal College of Surgeons of England). In the pseudonymised dataset, patients will be identified by a computer-generated label. It will not contain name, NHS number, date of birth or full postcode. The local hospital users will only have access to their own hospital's data.

Members of the NELA project team employed by the NHS will be subject to standard NHS confidentiality agreements.

Non-NHS members of the NELA project team are aware of their responsibilities and obligations to respect patient confidentiality. It is a condition of employment that all employees abide by their organisation's Data Protection Policy and confidentiality clause within their contract of employment.

All RCoA staff associated with NELA undertake mandatory information governance training on a yearly basis and receive regular updates on data protection and cyber security at the Staff Town Hall meetings.

The contract between HQIP and RCoA stipulates that appropriate security and audit mechanisms be in place for the management of all project and audit related information. This contract also governs the management of data by third parties sub-contracted to deliver different elements of the project/audit. All third parties and sub-contractors involved by NELA have been appointed following approval by HQIP as the NELA funding body. HQIP oversee delivery of NELA by the RCoA via Contract Review Meetings that occur at least every 6 months.

### **Method of secure information / data transfer**

Electronic File Transfer

### **Applicable security arrangements for the transfer**

Data will be collected by a web-based data collection tool (NELA webtool). This will be accessible via a secure website using SSL encryption (<https://data.nela.org>). The Project Team will have access to data via data exports from the online data collection web tool.

The organisation responsible for maintaining the data collection platform is NetSolving with data held in UKFast servers. UKFast has attained ISO-27001:2005 certification for their Information Security Management System and ISO 9001:2008 for their Quality Management System. UKFast have ISO-Certified Tier 3 data centres and hold the following certification: G-Cloud 12, Cyber essentials + and attained ISO 27018:2019

Further information about protection of data is given below.



Netsolving have been contracted to the Project due to their track record in managing audit and patient data. The hardware service provider (UKFast) has a track record in delivery to many private and public sector clients, including the NHS and is a G-Cloud supplier. The contract with UKFast mandates stringent security processes in terms of the back-up and protection of data, including subsequent deletion of audit data.



## **Service Users**

### **How will the service users be contacted?**

Patients will be informed about the audit via leaflets and posters produced by the NELA project team and made available when patients require an emergency laparotomy.

### **What information will be given to the service user about the purpose of the audit?**

Patient and public information will be made available via specific patient and public information leaflets. These will be made available for download from the NELA website, and also for distribution in paper format at hospital sites.

### **Will the service users' consent be obtained?**

No, see below.

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

Exemption has been obtained under Section 251 of the NHS Act 2006. NELA holds Health Research Authority (HRA), Clinical Advisory Group (CAG) exemption to process patient identifiable information without consent (CAG Ref: CAG 5-07(d)/2013). The nature of patients undergoing emergency laparotomy means that a high proportion of the highest risk patients will be unable to give consent due to the severity of their clinical illness.

### **How long will the data be stored?**

The audit will collect data on a continual basis from December 2013. The audit is delivered under contract to HQIP and the data will be retained for the duration of time that a contract remains in place and where there is no change in data controller or data processors.

Individuals will be pseudonymised by assigning a unique identifier at the time of data entry; however data linkage to external databases will require provision of patient identifiable data. Linked data will be requested periodically during the duration of the audit and therefore it is anticipated that personally identifiable data will be retained for the duration of NELA.

### **Where will the data be physically stored?**

On a server hosted by UKFast in a secure data centre. See below for additional details.

### **If the data is on a computer is there access via a local network or the internet?**

Information for analysis will be exported from the NELA data collection web tool as a pseudonymised dataset and held on a local network held within the RCoA. Access to this network is controlled by unique usernames and passwords. Furthermore, the exported files will be stored on parts of the network that are only accessible to the project team. Patient identifiable data will not be stored on the local network. A secure area on the RCoA servers has been set up that only allows RCoA substantive employees and contracted employees of RCoA to access. To add further separation of Research Data from the rest of our network filing, we have built a new server which will control access to the Research data.

NELA will require linkage of project Patient Identifiable Data (PID) to NHS Digital data for the purposes of additional research. The Royal College of Anaesthetists (RCoA) maintains a current **Data Sharing Framework** (with NHS Digital), which allows for the holding of NHS Digital data at



the RCoA headquarters: RCoA Churchill House, 35 Red Lion Square, London WC1R 4SG). This will be linked data that does not include any Patient Identifiers.

To obtain this linked data NELA is required to carry out a submission of an NHS Digital Application to obtain permission to carry out this linkage. Once this linkage is approved NELA will be able to go ahead and link the data. The data shared with NHS Digital will be the patient records submitted to NELA from participating hospital sites.

The RCoA will send the file of patient identifiers, (NHS Number, date of birth and postcode, and the NELA ID) to NHS Digital for linkage to HES and Mortality Data fields. The linked data will be returned as a new non-PID dataset to the RCoA and will need to be held, stored and processed in a secure manner, adhering to NHS Digital requirements and in accordance with NELA Information Governance requirements.

Only the registered Data Protection Controller for the NELA will have access to the full dataset. The project team and its subcontractors will not have access to a dataset that contains both a full set of patient identifiers and patients' clinical information.

### **How will data be protected?**

The server is hosted by UKFast in a secure Tier 3 datacentre based in the UK. All traffic passes through Cisco equipment including Anomaly Detection Systems (ADS), Intrusion Detection Systems (IDS) and Intrusion Prevention Systems (IPS). This is clustered across multiple locations. The hardware is protected by a Cisco Firewall with full access controls enabled. UKFast will carry out an annual security audit. These audits will inspect the system for any vulnerabilities or threats that could allow hackers to destroy or damage the system. Each UKFast datacentre is fully powered, secure, resilient and equipped to meet the project demands.

The company has a track record in delivering to many private and public sector clients including the NHS and has demonstrated a strong awareness of the need to protect systems and data from both physical and virtual threats. UKFast has attained ISO-27001:2005 certification for their Information Security Management System and ISO 9001:2008 for their Quality Management System. They are PCI compliant for all client transactions.

1. System Security
  - Full Security patching;
  - Dedicated firewall;
  - Risk assessment and security consultation and auditing;
  - Programmed evaluation and testing of all systems;
  
2. Physical and site security
  - Unassuming facilities, unmarked and inauspicious;
  - On site security 24/7/365;
  - Electronic surveillance with continual monitoring/recording;
  - Electronic access;
  - Client access by appointment only;
  - Dual power supply, UPS and onsite generator backup;
  - Fire, power, weather, temperature and humidity monitoring systems;



- Diverse fibre routing via multiple carriers;
- Cross connection to a number of tier 1 carriers;
- 24 hour security patrol (NSI accredited security).

### **At the end of this period how will the data be disposed of?**

Hard drives are removed by UKFast and stored in a secure storage facility on site for 30 days. After 30 days the drives are wiped to HMG standard. Once wiped they are physically destroyed. A Certificate of Destruction is provided.

Printed copies will be securely shredded. Files will be securely deleted from computer systems (including any copies held on backup or archive media).

## **Caldicott Principles**

### **Principle 1 - Justify the purpose(s)**

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

The National Emergency Laparotomy Audit is collecting data to improve the quality of care delivered to patients undergoing emergency laparotomy. It will collect only that data required for the published process and outcome measures. These have been specifically linked to evidence based published standards of care. It will also collect sufficient data to risk adjust cases in order to produce meaningful comparisons between hospitals. The data required for risk adjustment has also been subject to an evidence based review process. Documents will be produced that explain the explicit links between the data being collected and the process and outcome measures, and published standards of care. These documents will be in the public domain via the NELA website (<https://www.nela.org.uk/reports>)

All process and outcome measures, and related data has been subject to peer review by a Clinical Reference Group that meets every 6 months, consisting of key stakeholders including patient and public representation.

The data will be analysed at least annually by the project team to ensure that the dataset is fit for purpose.

NELA has approval from the Confidentiality Advisory Group (CAG), which is renewed annually.

### **Principle 2 - Don't use personal confidential data unless it is absolutely necessary**

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



In accordance with the requirements of nationally funded HQIP audits, NELA will not duplicate data collection where it is already being collected elsewhere, in order to minimise the burden of data collection on participants.

Linkage will be made with additional databases such as:

Hospital Episode Statistics (HES) for data validation

Patient Episode Database for Wales (PEDW) for data validation

Intensive Care National Audit & Research Centre (ICNARC) for intensive care data

Office of National Statistics (ONS) for mortality outcomes

National Bowel Cancer Audit and Upper Gastro-intestinal Cancer Audit for data validation

In order to successfully link with these databases, personal confidential data is required. The only personal confidential data being requested is the minimum required in order to successfully link with these databases. Data flows will be kept segregated wherever possible by using pseudonymised identifiers.

Among the patient identifiers, only sex is used for analysis. A pseudonymised dataset will be used by the RCoA and the CEU for analysis. In this dataset:

- The NHS number will be replaced by a unique Audit patient identifier.
- Date of Birth will be converted to age at diagnosis, and trimmed to month and year of birth
- Postcode will be converted to PCT, SHA of residence, and the Office for National Statistics Lower Super Output Area, which allows the allocation of the Index of Multiple Deprivation.

### **Principle 3 - Use the minimum necessary personal confidential data**

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

Each individual item within the dataset has been peer reviewed by the Clinical Reference Group, and the minimum data necessary to draw adequate conclusions about the care provided is being collected. The dataset has been informed by evidence based reviews carried out by the National Institute of Academic Anaesthesia's Health Services Research Centre.

In order to successfully link with the relevant databases listed above, personal confidential data is required. The only personal confidential data being requested is the minimum required in order to successfully link with these databases.

### **Principle 4 - Access to personal confidential data should be on a strictly need-to-know basis**

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

Each hospital will be assigned a lead user who will administer the user rights for staff within their hospital. Access will be via unique usernames and passwords issued to each user. This will ensure that only users who have a legitimate reason to use the data collection tool will be granted access. A database of users will be maintained by the Project Team. Local hospital users will only have access to their own hospital's data.



Only the registered Data Protection Controller for NELA will have access to the full dataset.

Data flows will be kept segregated wherever possible by using pseudonymised identifiers, in order to limit the number of people who have access to patient confidential data.

The following paragraphs describe the process of linkage, using the English Hospital Episode Statistics (HES) database as the example of the national database to which the NELA dataset will be linked.

A file (P) containing patient identifiers only will be extracted from the full dataset hosted in the webtool, and will be sent securely to a trusted Data Linkage Service. For HES data, this would be NHS Digital. File (P) will contain the following identifiers:

- NELA anonymised identifier
- NHS number
- Date of Birth
- Sex
- Postcode

Data Protection Controller for NELA and RCoA Data Analyst to carry out the process for linkage to take place following an agreed process:

- Day and time are scheduled to access the online data collection Webtool in the scheduled time (this should take no longer than 1-2 hours),
- Data Protection Controller for NELA and RCoA Data Analyst to securely carry out an export of NELA data including PID and save this file in the secure RCoA server.
- RCoA Data Analyst will carry out any data cleaning required to prepare data for submission to NHS Digital.
- Once this spreadsheet is ready to be submitted the original download of PID data will be deleted from the secure servers.
- The file to be submitted to NHS Digital is saved in the secure area of the RCoA servers and RCoA Data Analyst works with Head of Research to upload this data to NHS Digital via their secure portal.
- Any data not required will be deleted from the secure area of the RCoA servers.

For each patient in the file, NHS digital will identify the matching HES ID. NHS Digital will then return to the RCoA a 'look-up' file (L) containing only the NELA identifier and the HES ID identifiers. An extract of anonymised HES data will then be requested from NHS Digital for all the list of HES IDs contained in file (L).

The file (L) will be placed in the secure RCoA server. It will then be used to link the anonymised HES data to the anonymised extract of audit data from the NELA webtool for analysis. The anonymised NELA extract will not contain NHS number, postcode or date of birth. All datasets used for analysis will have patients identified with the NELA identifier only.

**Principle 5 - Everyone with access to personal confidential data should be aware of their responsibilities**

**Action should be taken to ensure that those handling personal confidential data - both clinical and**



**non-clinical staff - are made fully aware of their responsibilities and obligations to respect patient confidentiality.**

Members of the NELA project team employed by the NHS will have completed Information Governance training in accordance with their own Trusts requirements.

Non-NHS members of the NELA project team are aware of their responsibilities and obligations to respect patient confidentiality. It is a condition of employment that all employees abide by their organisation's Data Protection Policy and confidentiality clause within their contract of employment.

Clinical and non-clinical staff entering data will be reminded of their obligations surrounding the use of confidential data when registering to use the data collection tool and when signing in. These obligations will also be explicitly stated on a separate area of the data collection website.

### **Principle 6 - Comply with the law**

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

Users submitting data will be subject to Information Governance training in accordance with their own Trusts requirements, which will set out their legal responsibilities and requirements.

Each hospital has a designated lead from the Clinical Audit Department who will be familiar with the legal requirements due to the nature of their role within an NHS Clinical Audit Department

Members of the Project Team are aware of their obligations and legal requirements regarding personal confidential data. It is a condition of employment that all employees abide by their organisation's Data Protection Policy and confidentiality clause within their contract of employment. The Director of Clinical Quality and Research is the Data Protection Controller for NELA. In lieu of a Caldicott Guardian for the RCoA, the Director of Clinical Quality and Research will act as the Caldicott Guardian. The Data Protection Controller has undergone Data Protection Training and Information Governance Training. This role is supported by the Royal College of Anaesthetists' Information Governance Partner.

The Royal College of Surgeons of England and The Royal College of Anaesthetists both have Data Protection Registration.

RCS Eng	ICO Registration	Z5948910	Expires 24/10/21
RCoA	ICO Registration	Z7495398	Expires 22/12/21

The Royal College of Surgeons of England (RCS) has completed the Data Security and Protection Toolkit (organisation code 8HM21).

The Royal College of Anaesthetists has completed the Data Security and Protection Toolkit (Organisation code 8J277).

**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.**

All NHS employees are appropriately supported in this way.

Medical staff will be aware of their responsibilities as part of the General Medical Council's guidance on Good Medical Practice and Duties of a Doctor. This will be augmented by specific Trust policies. Other healthcare professionals will also be supported by their respective professional bodies (eg Nursing and Midwifery Council) and Trust policies.

RCoA staff are aware of their responsibilities as set out in the RCoA's Data Protection Policy

**Principle 8: Inform patients and service users about how their confidential information is used**

**A range of steps should be taken to ensure no surprises for patients and service users, so they can have clear expectations about how and why their confidential information is used, and what choices they have about this. These steps will vary depending on the use: as a minimum, this should include providing accessible, relevant and appropriate information - in some cases, greater engagement will be required.**

The NELA team provide patient information both to participating hospital sites and on the NELA website - [Patient Information - National Emergency Laparotomy Audit \(nela.org.uk\)](https://nela.org.uk)

**If you require any further clarification please contact the  
NELA project team – [info@nela.org.uk](mailto:info@nela.org.uk)**