

GDPR GUIDANCE FOR CLINICAL AUDIT
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1. One Year On Since GDPR

Since the introduction of the GDPR one year ago, there has been increasing confusion about what this means for clinical audit and research. There have been varying interpretations and application of the new regulations in practice. In some instances, the GDPR requirements for research are being transposed on to clinical audit, such as requiring ethical approval for clinical audit, restricting who can collect data for clinical audit. In some instances, this has resulted in clinicians and hospitals ceasing clinical audit work.

2. Keep Auditing

We strongly urge all healthcare providers to review their interpretation of the GDPR with regard to clinical audit and issue updated guidance to their staff where appropriate, so that clinical audit can continue to support improved patient care and outcomes.

3. Clinical audit and research are not the same

The purpose of **research** is to generate new knowledge and find out what treatments, interventions or practices are the most effective. The purpose of **clinical audit** is to find out if best practice is being adhered to for quality assurance and improvement purposes. The Commission on Patient Safety and Quality Assurance established by the Department of Health recognised clinical audit as a key and essential component of clinical governance stating that it: '...constitutes the single most important method which any healthcare organisation can use to understand and ensure the quality of the service that it provides'

4. GDPR is needed

GDPR exists to protect the individual's fundamental rights to privacy.

From a healthcare perspective, the application of the GDPR is a balancing act between the privacy of a single individual against the benefits to public health as a whole.

Many other European countries have recognised this and have implemented the new regulations in a way that respects the right of the individual but also respects the benefits to public health.

Information collected from individual medical records, when collated and analysed at a population level, is the most essential element when it comes to improving and advancing healthcare.

Without access to this information, essential quality improvement activities, that are core elements of every modern healthcare system, will cease or be greatly diminished in Ireland. Impacted areas include clinical audit, peer reviews, mortality and morbidity meetings.

5. GDPR Guidelines for Clinical Audit

Recognising the current uncertainty with regard to GDPR and how it applies to clinical audit both locally and nationally, the National Office of Clinical Audit (NOCA) is providing the following guidance in order to ensure continuation of clinical audit for the betterment of public health.

NOCA fully supports the need for legislation and standards and welcomes the GDPR. GDPR, if interpreted and applied appropriately, supports those working to improve healthcare using clinical audit and also increases trust between patients, clinicians and organisations in regard to ensuring that their data is used and managed appropriately.

5.1 Understanding the GDPR Definitions

- 5.1.1** Personal data includes identifiable and pseudonymised data.
- 5.1.2** Pseudonymised data is data that has a link back to enable identification. This link is usually retained for use by the Data Controller and not by the Data Processor.
- 5.1.3** Processing of personal data can include gathering, processing and use of personal data.
- 5.1.4** If the data in question can no longer be linked back to any identifiable individual, then it will constitute anonymised data, is not personal data and is not subject to the GDPR. For example, if NOCA has received data for clinical audit purposes but does not have access to any other information which would enable it to identify the underlying individuals, then this data will not constitute personal data.

6. Clinical Audit – the Lawful Basis

GDPR requires that processing of personal data is **fair, lawful and transparent**. It clearly sets out conditions for lawful processing of personal data (Article 6) and further conditions for processing special categories of personal data (Article 9) which must be met if processing this category of data. This means under the GDPR that for healthcare data:

- an Article 6 condition needs to be satisfied (for personal data); and
- an Article 9 condition needs to be satisfied (as health data is a special category of data).

Currently there is nothing in the legislation that prevents clinical audit being carried out locally or nationally. Health data is defined under the GDPR as a special category of personal data and can be processed in situations where it is necessary to do so for reasons of public health:

- Article 6(1)(c) GDPR “processing necessary for performance of contract” with the data subject, or Article 6(1)(e) – ‘processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller, or Article 6(1)(f) – processing is necessary for the purposes of legitimate interests.
- Article 9(2)(h) GDPR– ‘processing is necessary for the purpose of preventative...medicine...the provision of health or social care or treatment or the management of health or social care systems and services...’ or Article 9(2)(i) – ‘processing is necessary for reasons of public interest in the area of public health, such as...ensuring high standards of quality and safety of health care...’
- *Data Protection Act 2018, Section 52(1) (a)* – ‘for the purposes of preventative or occupational medicine’, *Section 52(1) (d)* ‘for the provision of medical care, treatment or social care’ and/or *Section 52(1) (e)* for the management of health or social care systems and services’ which allows patient information to be used for clinical audit provided that appropriate measures are taken to safeguard the fundamental rights of the data subject.
- *Data Protection Act 2018, Section 53(b)* – ‘ensuring high standards of quality and safety of health care...’

6.1 Example – Rationale to determine the appropriate lawful basis

- For National Clinical Audit, all patients meeting the criteria of the audit should be included, so that a full national picture can be collected.
- Consent would not be appropriate because the patient could decline to give their consent or subsequently withdraw their consent at any time. Both of these individual rights would prevent a full national picture can be collected.
- Therefore National Clinical Audit should not rely on consent as the lawful basis but should instead justify such audit on the public health lawful basis as applicable e.g. Articles 6(1)(e), 6(1)(f), 9(2)(h) and 9(2)(i).
- For clarity, the collection of data, validation of data, review of outliers for national clinical audit does not require consent.
- Patients should, however, be informed that their data may be used as part of a national clinical audit e.g. Information leaflets

6.2 Example where informed written patient consent is appropriate

NOCA Irish National Orthopaedic Register (INOR)

- Identifiable patient data is collected locally and transferred to NOCA. This data is to support a national recall of implants.
- Therefore consent is sought from each patient to allow their personal data to transfer to NOCA. This is informed written consent with the option to withdraw consent for personal data at any stage, in compliance with GDPR standards for consent.
 - This consent only applies to the identifiable personal data collected in INOR. There is also additional, anonymised clinical audit data collected for INOR but informed written consent does not apply to this data., The lawful basis for the clinical data is Article 9(2)(h) – ‘processing is necessary for the purpose of preventative...medicine...the provision of health or social care or treatment or the management of health or social care systems and services...’

7. Clinical Audit – Compliance with GDPR

To comply with the GPDR when carrying out clinical audit the following apply:

7.1 Collection

- 7.1.1 Collecting Identifiable Data from a patient's record for clinical audit requires a lawful basis. Provided that another lawful basis exists and has been deemed appropriate consent may not be required.
- 7.1.2 Patients should be notified of the collection of data for clinical audit purposes as part of a Fair Processing notice (included as part of admissions).
- 7.1.3 Clinical audit data can be collected by employees of the data controller other than those who provided direct care to the patient.
- 7.1.4 For clarity, collecting Data that is already anonymised does not require consent.

7.2 Processing

- 7.2.1 Processing Identifiable Data for the purpose anonymisation and or pseudonymisation for clinical audit does not need to rely on consent as the lawful basis:
 - Where another lawful basis exists e.g. processing for the purpose of preventative medicine or for the management of health or social care systems and services or to ensure high standards of quality and safety of healthcare.
 - Patient has been informed prior to the audit that you may use their data for audit e.g. as part of a Fair Processing notice (included as part of admission)
- 7.2.2 It is recommended that data is either anonymised and pseudonymised for all clinical audits
- 7.2.3 We recommend the following should be in place to inform patients about clinical audit. This information should be publicly available e.g. providers website, admission pack etc.:
 - Fair processing notice made available to patients advising that their data may be used for quality improvement activities such as clinical audit
 - Information leaflets and notices about how patient data is used to improve and advance healthcare.

7.3 Clinical Audit Data for Oral Presentations, Posters and Publications

Presentation and/or publication of clinical audit results/ findings are not Research. Providing that audit findings are aggregated and do not identify individuals, there should be no issues presenting clinical audit data externally e.g. poster,

conference or in journal. If a journal requires ethical approval for all articles then this is a decision for your local Research Ethics Committee.

7.4 Ethical Approval for Clinical Audit

Clinical audit does not require ethical approval but, as always and in line with best practice, ethical issues should still be considered while also adhering to data protection principles.

7.5 Using National Clinical Audit data for Research

Currently data collected for clinical audit is commonly also used for research studies, where more detailed analysis and linking with other data collections can help create new knowledge to advance healthcare. The new Health Research Regulations 2018 require explicit consent (GDPR consent) as the lawful basis to use a patient's personal data in research, unless a consent exemption is sought.

NOCA has considered the extent to which the new Health Research Regulations apply to NOCA's national clinical audit data. This data was pseudonymised by hospitals prior to disclosure to NOCA and NOCA cannot identify individual patients. In addition, when NOCA provides that data to third parties for research studies, those third parties cannot identify any individuals from the data, and have no means of re-identifying individuals from any other data or sources. This means that, in the possession of NOCA or third party researchers, this data is not personal data.

As the Health Research Regulations only apply to personal data, NOCA does not believe that the Health Research Regulations apply to this data. NOCA has therefore decided to continue to provide National Clinical Audit Data for research purposes as long as the third party researchers agree not to do anything with the data which could result in individuals becoming identifiable.

7.6 Using Local Clinical Audit data for Research

If you have access to a link to identify the patient in your clinical audit data that you are intending to use for the secondary purpose of research, then your relevant local research access policy will apply as well as the Health Research Regulations 2018.

If the clinical audit data is fully **anonymised** so that you **can no longer link back to identify** the individual, this data is no longer personal data and can be used for Research and the Health Research Regulations 2018 do not apply.

8. About NOCA

NOCA was established in 2012 to create sustainable clinical audit programmes at national level. NOCA enables those who manage and deliver healthcare to improve the quality of care through national clinical audit. NOCA is funded by the Health Service Executive Quality Improvement Division, is governed by an independent voluntary board and is operationally supported by the Royal College of Surgeons in Ireland.

Disclaimer

This guidance has been prepared by NOCA to assist those carrying out Clinical Audit to understand and comply with GDPR requirements. It has been reviewed by our legal advisors. The guidance is for educational and informational purposes only.

