



National Review of Clinical Audit

November 2019

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MESSAGE FROM THE CHIEF CLINICAL OFFICER

Clinical audit is an integral component of safety in all modern healthcare systems. In its absence, there will be no measurement and no awareness of how we deviate from the standards we set for our services. When it is supported and prioritised, audit can be a powerful tool for continuous improvement and assurance. The 2008 report on Patient Safety and Quality Assurance recommended that all clinicians, both as individuals and as members of teams or networks, should actively participate in clinical audit. Rather than be viewed through the prism of individual responsibility alone, the report recommended that clinical audit should be a core activity of every healthcare facility and organisation, with coordinated activity linked to service plans and local and national priorities. Thus sponsored, supported and prioritised, clinical audit will be a key determinant of any organisation's self-awareness and continuous development.



This report on clinical audit is particularly welcome at a time when expectations around patient safety have never been higher. The report affirms the central role of clinical audit in meeting these expectations and describes the supports, structural and educational, that are required to support clinicians in fulfilling this critical function of their practice. These recommendations build on the work of the National Office of Clinical Audit (NOCA) and should act a template for the development of dynamic, responsive clinical audit systems in every healthcare delivery organisation.

I would like to thank Professor Sean Tierney and Dr Brian Creedon for their leadership and diligence in completing this report. I would also like to thank the various members of the Steering Committee and Working Group, external advisors and the frontline staff who gave up their valuable time to participate in the focus groups.

Finally, I would like to acknowledge the invaluable contribution of the public and patient interest representatives Iryna Pokhilo and Brian O'Mahony who ensured that the experience and needs of the patient influenced the outcomes of this review.

Dr Colm Henry
Chief Clinical Officer
HSE

FOREWORD: CLINICAL AUDIT – IMPROVING HEALTHCARE FOR ALL

Historically, the quality of healthcare provided in Ireland has largely rested on the assumption that healthcare is provided by (or supervised by) well-trained, regulated professionals and that this alone will ensure it is safe and effective. The emerging system of accreditation and licensing in healthcare also examines the facilities and the processes. However, modern healthcare is provided in a complex and complicated rapidly evolving environment in which many practitioners and others interact to provide care.

Health service providers have a responsibility to ensure and demonstrate that the quality of care provided is compared against known standards of best practice. Healthcare is a partnership between health service providers and patients. Patients and the public at large are equally interested in clinical audit, as it demonstrates a commitment to assuring and improving clinical care to those most affected by it.

This can be achieved in some cases through the establishment, maintenance and resourcing of appropriate national clinical audits. National clinical audits should be published and should identify performance against standards at health service provider level. Where a national clinical audit identifies that a health service provider is not meeting clinical standards, a quality improvement initiative should be commenced established locally to explain and address the issue. The National Review of Clinical Audit has identified measures that could enhance the use and effectiveness of national clinical audit.

In certain circumstances, local clinical audit may be a more appropriate measure, and in the National Review we have proposed standardisation of the approach used in local clinical audits. Training, resourcing and governance of these local clinical audit processes is of key importance, in order to ensure that such tools are appropriately and effectively used in improving patient care.

Transparency, through the publication of clinical audit reports, is of key importance in order to assure patients and the public that the quality of care provided meets defined standards. Ensuring the protection of patient confidentiality, and of their data, should not conflict with the need to conduct a clinical audit to determine the quality of care provided to patients. However, we have identified some concerns regarding the implementation of the General Data Protection Regulation (GDPR) and proposed legislation, and have suggested how these conflicts might be mitigated.

The expectations of patients, practitioners, health service provider organisations, healthcare commissioners and funders, government, and the public are diverse and are sometimes in conflict. Frequently, the public debate about healthcare is consumed by the conflicts that inevitably arise. However, we believe that all stakeholders will be better served by expanding the routine use of clinical audit to measure the care provided against defined standards, which will ultimately ensure improved outcomes for patients.

Prof. Sean Tierney
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In particular, we would like to thank the members of National Review of Clinical Audit Working Group and the National Review of Clinical Audit Steering Committee, for their invaluable input and work over the course of the National Review. The expertise they provided was invaluable in the production of this report.

We would also like to thank our Advisory Panel of national and international experts, as well as numerous additional experts who provided feedback and information during the course of the National Review.

A number of organisations and offices provided support during the National Review. The HSE National Quality Improvement Team, the HSE Quality Assurance and Verification Division, the Office of the Chief Clinical Officer at the HSE, the Department of Health, the Royal College of Physicians of Ireland, the Royal College of Surgeons in Ireland, the Health Information and Quality Authority, and the Irish Clinical Audit Network all provided inputs during the preparation of this report. Guidance was also received from international organisations; the Healthcare Quality Improvement Partnership (UK) and the Royal College of Physicians (UK).

We would like to say a special thank you to the National Office of Clinical Audit, who assisted with the coordination of this report and the National Review of Clinical Audit Project Manager.

Finally, we would like to acknowledge and thank the managers and participants in the four focus group sessions that were carried out. The insight gleaned from these sessions was invaluable and was a key source and resource for a number of chapters in this report.

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GLOSSARY OF TERMS AND ABBREVIATIONS

CCO	chief clinical officer
CEO	chief executive officer
CHO	community healthcare organisation
DOH	Department of Health
DOHC	Department of Health and Children (now DOH)
DPO	data protection officer
EU	European Union
EWS	early warning score
GDPR	General Data Protection Regulation
HCA	healthcare audit
healthcare professionals	clinicians, health service managers, policy-makers, and educators involved in healthcare
health services provider	any person, organisation or part of an organisation delivering healthcare services
health service provider organisation	any organisation delivering healthcare services
HIPE	Hospital In-Patient Enquiry
HIQA	Health Information and Quality Authority
HQIP	Healthcare Quality Improvement Partnership
HSCP	health and social care professionals
HSE	Health Service Executive
ICAN	Irish Clinical Audit Network
ICU	intensive care unit
IHFD	Irish Hip Fracture Database
IMEWS	Irish Maternal Early Warning Score
IT	Information technology
local clinical audit	clinical audit carried out at a local level e.g.in a hospital or primary care centre
MTA	Major Trauma Audit
NAHM	National Audit of Hospital Mortality
NCA	national clinical audit
NCEC	National Clinical Effectiveness Committee
NCHD	non-consultant hospital doctor

NCNM	National Council for the Professional Development of Nursing and Midwifery
NDTP	National Doctors Training and Planning
NEWS	National Early Warning Score
NHS	National Health Service (UK)
NOCA	National Office of Clinical Audit
NPEC	National Perinatal Epidemiology Centre
NPMR	National Paediatric Mortality Register
NQICAN	National Quality Improvement and Clinical Audit Network
ONMSD	Office of the Nursing and Midwifery Services Director
PPI	patient and public involvement
PROM	patient-reported outcome measure
QAV	Quality Assurance and Verification
QAVD	Quality Assurance and Verification Division
QI	quality improvement
QID	Quality Improvement Division
QIP	Quality Improvement Project
QIT	Quality Improvement Team (previously QID)
QPS	quality and patient safety
QPSD	Quality and Patient Safety Directorate (UK programme)
RCP	Royal College of Physicians (UK)
RCPI	Royal College of Physicians of Ireland
RCSI	Royal College of Surgeons in Ireland
REC	Research Ethics Committee
SCA	State Claims Agency
SMT	senior management team
SQI	specialty quality improvement
SRE	serious reportable event
TARN	Trauma Audit & Research Network
UK	United Kingdom
Unit	clinical setting in which care is delivered
WTE	whole time equivalent

EXECUTIVE SUMMARY

The National Review of Clinical Audit was commissioned by Dr Colm Henry, Chief Clinical Officer (CCO) of the Health Service Executive (HSE), to ensure the continued development of the essential role of clinical audit to protect patients and promote improved patient outcomes by fostering learning and improvement in healthcare. The need for effective local clinical audit has grown and the number of national clinical audits (NCAs) has expanded in a rapidly evolving regulatory, legislative and medico-legal environment. Perceived threats to the use of effective clinical audit include the controversy over the initial clinical audit and subsequent look-back reviews conducted within CervicalCheck, the potential implications of certain interpretations of the European Union (EU) General Data Protection Regulation (GDPR), and the implications of future legislation.

In modern healthcare systems, clinical audit is an essential tool for improving patient care. In a number of jurisdictions, clinical audit receives substantive national support, which facilitates both NCAs and local clinical audits. In the United Kingdom (UK), participation in NCAs is mandatory, whereas Denmark's advanced health IT system, and legislative confirmation that explicit consent is not required for clinical audit, ensure that clinical audit flourishes there. While the National Office of Clinical Audit (NOCA) has been established and resourced by the HSE National Quality Improvement Team (QIT), the scale of support and commitment to audit in Ireland lags behind that found in many other jurisdictions.

This report summarises the current state of clinical audit in Ireland. In addition, it provides guidance and recommendations to ensure that clinical audit can continue to be developed as an essential patient safety tool in Ireland promoting improved patient outcomes. To produce this report, terms of reference were drawn up in October 2018. Subsequently, the Project Manager, the Working Group, the Steering Committee, and the Advisory Panel were appointed in early November 2018. Membership of the Working Group and the Steering Committee included patient representatives, senior HSE leaders and clinicians, and individuals with clinical audit expertise. The Working Group and Steering Committee held six and five meetings, respectively; a number of subcommittees were also established and engaged in regular correspondence. Advisory Panel members were consulted as necessary, as were additional experts throughout the process. In addition to consultation with these experts, four focus group sessions were facilitated in three hospitals across Ireland. These focus groups provided invaluable feedback regarding the clinical audits under way at that time. They also highlighted the value of clinical audit, as well as the issues hindering its efficacy. A number of key findings were identified throughout the review process; these were based on feedback from the focus groups, consultation with experts, and an extensive review of national and international literature in the field of clinical audit.

A key finding of this National Review is that there are inconsistencies across the Irish health service regarding the nomenclature in the area of clinical audit, which leads to confusion. For this reason, a significant amount of the work carried out was to produce a taxonomy of agreed terms, including a standard definition of clinical audit, to be adopted across Ireland in general, and in the HSE in particular, with the aim of avoiding further confusion in the future.

The National Review also found that there are significant differences between the governance of, and support for, clinical audit in health service provider organisations across Ireland. Even within organisations, the governance of clinical audit can vary widely between departments. While there are well-defined governance structures for NCAs provided by national clinical audit organisations, the National Review concluded that a national senior structure within the HSE is needed in order to provide high-level support for all clinical audits being carried out, including NCAs and local clinical audits. Such a structure would ensure that adequate training, guidance, and resourcing are in place, and would assist those carrying out clinical audits within health service provider organisations. A number of other key recommendations have been made regarding both national and local governance of clinical audit, which will ensure that clinical audit can continue to flourish in Ireland.

The National Review also reviewed the existing available guidance for the design of clinical audits. Feedback from the focus groups identified the HSE publication *A Practical Guide to Clinical Audit* (2013) as a comprehensive and widely used resource which covers the design of clinical audits in great detail. However, some areas are excluded which would assist those who carry out clinical audit, such as consideration of governance at the planning stage and throughout the clinical audit process. To address this, a gap analysis was carried out to identify areas to be included in an updated version of the 2013 guide. Updating this 2013 guide is the key recommendation to support the design of clinical audits in the Irish healthcare system.

Up to end 2018, clinical audit training was delivered to HSE staff by the National QIT, and feedback received during the course of the National Review was that this training facility was hugely beneficial. However, the provision of this training finally ceased in September 2019. This report outlines a number of recommendations regarding the resourcing of clinical audit training, both at national and local level.

Finally, this National Review looked at the impact of recent and impending legislative changes that have affected, or will affect, clinical audit. The transposition into Irish law of the EU GDPR through the Data Protection Act 2018 and subsequent Health Research Regulations 2018 were identified as having the potential to detrimentally affect the use of clinical audit. Concern around this legislation has already led to the cessation of a number of clinical audits across Ireland. Health service provider organisations are erring on the side of caution due to a lack of clear guidance from the Department of Health, the Data Protection Commission, and the HSE. The forthcoming Patient Safety Bill 2019 represents an opportunity to protect and promote the value of clinical audit.

As part of the National Review, specific guidance has been developed, such as the nomenclature provided in Chapter 4. However, much of the guidance and supports required to ensure that clinical audit continues in Ireland should be developed by the HSE following the National Review. The recommendations included in this report will be reviewed by the HSE CCO and actions assigned to the relevant organisations and/or individuals. These recommendations are intended to strengthen clinical audit in Ireland and assist those carrying out clinical audits across Ireland through the provision of appropriate governance structures and resources.



DEFINITION OF CLINICAL AUDIT

“Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria, and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements.”

(DOHC, 2008, p. 152)

“Clinically-led” includes all health and social care professionals.

KEY RECOMMENDATIONS

The key recommendations identified by the Working Group and approved by the Steering Committee are summarised below, and repeated in the relevant chapters of this report.

Where possible, every effort should be made to fully utilise and build on existing resources. However, some of the recommendations contained within the report will require funding to be made available for the implementation and long-term maintenance of certain resources.

Nomenclature

The National Review extensively reviewed existing literature and subsequently agreed a number of definitions for clinical audit and related terms. The review group recommends that:

- | | |
|-----------|--|
| 1. | The agreed list of definitions in the nomenclature document produced as part of the National Review should be adopted by the HSE, and become the national standard for nomenclature for all agencies involved in clinical audit. |
|-----------|--|

National governance of clinical audit

Clinical audits provide vital information to the healthcare system – from policy-makers to healthcare managers, healthcare professionals, patients, and the public – allowing comparison with national and international standards. The review group recommends the following national governance supports to ensure that clinical audit continues to effect improved clinical outcomes for patients across the entire Irish healthcare system:

- | | |
|------------|---|
| 1. | The HSE, through the Office of the CCO, should put in place appropriate governance arrangements to provide senior leadership for clinical audit at a national level in the health service. This governance structure should establish and monitor a national strategy for clinical audit, promote and advocate for clinical audit, ensure that national structures are in place to provide clinical audit guidance and support, commission national reviews, and oversee the implementation of the recommendations from these reviews, including the National Review. |
| 2. | This HSE governance structure should be responsible for the commissioning of new NCAs, reviewing the value of existing NCAs, and ensuring that appropriate management and governance structures are in place. |
| 3. | The HSE should develop a dedicated clinical audit portal on the HSE website with an assigned manager. The portal should be the ‘home’ for clinical audit guidance and supporting material. It should be updated with advice resulting from new legislation or any policy changes which may affect clinical audit. |
| 4. | The HSE should publish and maintain a complete list of currently recognised NCAs on the new dedicated clinical audit web portal. |
| 5. | The HSE should compile, publish, and retain a list of recommended local clinical audits with associated tools, such as those based on National Clinical Effectiveness Committee (NCEC) guidelines and the Nursing and Midwifery Quality Care-Metrics, on the new dedicated clinical audit portal on the HSE website. |
| 6. | The HSE should assign appropriate resources to health service provider organisations to enable clinical audit, including a local clinical audit function, protected time for clinical audit, data analysis support, clinical audit templates, software, and training. |
| 7. | Clinical audit should be a management priority in line with financial and risk management reporting. |
| 8. | All NCAs should be managed and governed to agreed best practice standards that include governance structures, data quality, information governance, and reporting. |
| 9. | All NCAs should regularly publish aggregated data reports, with individual health service provider organisations identified. These reports should be made publicly available. |
| 10. | The HSE should support a national forum for clinical audit leads where knowledge and learnings can be shared and disseminated to individual health service provider organisations. |

Local governance of clinical audit

The following recommendations have been agreed through discussions of the Working Group and Steering Committee as supporting clinical audit and have incorporated focus group feedback. They should be adopted by all health service provider organisations which take part in clinical audit, including the proposed six new regional health areas (aligned with the recommendations made in the Sláintecare Report of the Oireachtas Committee on the Future of Healthcare (2017)).

<p>1. Every health service provider organisation should:</p> <ul style="list-style-type: none"> • Provide access to a clinical audit and/or a quality office with a dedicated audit manager responsible for ensuring that appropriate management and governance structures for clinical audit are in place. • Provide protected time and resources to carry out clinical audits, including implementation of improvements and re-audit. • Designate appropriate clinical leadership roles with responsibility for supporting clinical audit across the health service provider organisation. • When developing local guidance material and templates, ensure that it aligns to national standards, such as that in A Practical Guide to Clinical Audit (HSE, 2013). • Provide training on clinical audit, including design, data analysis, and using audit findings. • Include information regarding clinical audit and quality improvement structures and support as part of staff induction. • Maintain a register of all clinical audits carried out locally. 	<p>3. Clinical audit should be a strategic priority for the health service provider organisation's senior management team (SMT). It should be the cornerstone of the clinical governance function of the health service provider from the board, senior management meetings, Quality and Patient Safety (QPS) committees, through to clinical team committees. Key findings of all clinical audits must be reviewed by the SMT of the health service provider organisation. An explicit information flow should be established between the SMT/board and the audit team. The SMT should have responsibility for reviewing both the clinical audit programme and the outcomes of individual projects.</p>
<p>2. There should be a clear process in place for the submission, prioritisation, approval, and registration of clinical audits. The following factors should be considered when prioritising:</p> <ul style="list-style-type: none"> • External priorities, such as those highlighted by the outputs of NCAs, and those based on Health Information and Quality Authority (HIQA) standards • Internal priorities based on clinical risks, serious incidents and patient safety • Organisational priorities, including service redesign and development • Departmental, unit, specialty, or professional priority, for example, for professional revalidation, appraisal, and training needs. 	<p>4. Completed local clinical audits should be widely disseminated for the purposes of transparency. This can be achieved internally within the health service provider organisation at education meetings, practice meetings, posters, and local website or externally through posters/presentations at conferences and journal publications.</p>
	<p>5. Clinical audit and quality improvement activities should be visible – public information notices regarding the purposes of clinical audit should be displayed in health service provider organisations. Annual organisational-level clinical audit days are to be encouraged.</p>
	<p>6. The governance of clinical audit should be aligned with the HSE governance for quality and safety. There should be clear lines of reporting and accountability from the frontline delivery function to local and national management structures.</p>

Developing guidance for clinical audit

The review group has identified a number of actions and supports to improve the consistency and quality of clinical audits across the health service:

1.	<i>A Practical Guide to Clinical Audit</i> (HSE, 2013) should be updated by the HSE to reflect best practice in clinical audit. It should be available via a dedicated HSE web portal for all clinical audit resources.
2.	Healthcare professionals should use this new guidance to design and develop their clinical audit.

Clinical audit training

The review group agreed the following recommendations to support training in clinical audit:

1.	The undergraduate, postgraduate, and continuing professional development education programmes of healthcare professionals should continue to support competence in clinical audit.
2.	The HSE and health service provider organisations should develop and resource a blended approach to clinical audit training which includes face-to-face and virtual learning. This can be supported with a cascade approach to training and coaching programmes.
3.	Where such resources already exist, for example HSELand, these should be signposted on the new dedicated clinical audit portal and additionally at local level.

Legislative changes affecting clinical audit

The review group agreed the following recommendations to ensure that those involved in clinical audit are aware of, and supported in their efforts to be compliant with, any legislative changes affecting clinical audit:

1.	The HSE Data Protection Officer (DPO) should provide guidance regarding the interpretation of GDPR, which should include specific guidance related to the application of GDPR to clinical audit. The HSE should then advise that individual DPOs adopt this approach to ensure consistency across all health service provider organisations.
2.	The HSE should form a national healthcare DPO network to support the process of consistent guidance to the system.
3.	The HSE should provide timely guidance on any changes or updates to legislation and guidance which affect clinical audit. This should be published on a new dedicated clinical audit web portal that has been recommended by this National Review.



CHAPTER 1

INTRODUCTION



CHAPTER 1: INTRODUCTION

1.1 Background

Clinical audit is an essential aspect of modern healthcare and important to all healthcare professionals. Internationally, this recognition of the value of clinical audit is clear from a variety of supports and legislative protections in place in many countries. For example, in the United Kingdom (UK), participation in national clinical audits (NCAs) within the National Clinical Audit and Patient Outcome Programme relevant to the services in question is mandatory in every standard contract between the National Health Service (NHS) and hospitals (NHS, 2019). In Denmark, the efficacy of clinical audit is supported by the country's well-established national registries and advanced health IT data, as well as its interpretation of the European Union (EU) General Data Protection Regulation (GDPR) not requiring consent to carry out clinical audit.

Unfortunately, Ireland lags behind in terms of national supports and legislative protection. However, there has been growing support for clinical audit in Ireland in recent years. Indeed, the Commission on Patient Safety and Quality Assurance identified 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 assure the quality of the service that it provides” (DOHC, 2008, p. 12). It is equally important at the level of the health service provider organisation and at a national level.

The important role of clinical audit has been highlighted in recent reports and policy decisions from within the broader health service. Clinical audit findings from the National Office of Clinical Audit (NOCA) Major Trauma Audit (MTA) informed the recent report on the development of a national trauma system from the Department of Health (DOH) Trauma Steering Group (2018). The Scoping Inquiry into the CervicalCheck Screening Programme recommended that “audits should continue to be an important component of cervical screening, as this complies with all good clinical practice” (Scally, 2018, p. 91).

In 2018, the HSE Healthcare Pricing Office introduced a policy best practice tariff to incentivise improving quality through a payment system. It was introduced to minimise the variation between health service provider organisations and to support improvement in care delivery to patients with hip fractures. This replicates a similar approach implemented in the UK in 2012 (The Health Foundation, 2016; Gershlick, 2016). Information from the Irish Hip Fracture Database (IHFD) supports these payments and enables the enactment of this policy decision (NOCA, 2018b). The value of clinical audit is clearly evident through improvements in delivery of care. The following examples in Table 1.1 were identified in the *National Clinical Audit Review* (Appendix 10) as demonstrating improvements from NCAs.

Table 1.1 Examples of quality improvement arising from national clinical audits

Audit	Examples of improvement
Major Trauma Audit	<ul style="list-style-type: none"> • Contribution to policy on the development of a national trauma network • Development of a trauma document, currently disseminated through trauma-receiving hospitals. This initiative has received quality awards from both the Trauma Audit and Research Network (TARN) and NOCA
Irish Hip Fracture Database	<ul style="list-style-type: none"> • Contribution to the development of bypass protocols in hospitals without an orthopaedic service, with 92% of patients with hip fracture going directly to the operating hospital • Development in orthogeriatric service, which has led to reduced length of care and increased discharge back to patient's own home
Irish National Intensive Care Unit Audit	<ul style="list-style-type: none"> • Data quality reviews from sites shared back to facilitate data review on others • Shared solutions for similar issues occurring from site to site
National Audit of Hospital Mortality	<ul style="list-style-type: none"> • Local reviews leading to improvement in care with feedback of learnings in national reports
NPEC Perinatal Mortality in Ireland	<ul style="list-style-type: none"> • All 19 maternity units in Ireland contribute to the audit on perinatal mortality. With the support of the Faculty of Pathology at the Royal College of Physicians of Ireland (RCPI), the National Perinatal Epidemiology Centre (NPEC) has adapted the standardised terminology for presenting placental pathology as per the international consensus • In 2018, the HSE National Women and Infant's Health Programme adapted, with a view to implementing nationally, the following NPEC recommendations: establishment of a confidential inquiry into unexpected intrapartum-related deaths and the development of a national perinatal pathology service
NPEC Severe Maternal Morbidity in Ireland	<ul style="list-style-type: none"> • All 19 maternity units contribute to the audit on severe maternal morbidity • In 2018, the National Women and Infant's Health Programme adapted, with a view to implementing nationally, the following NPEC recommendations: national implementation of a specific proforma to improve management and documentation of obstetric haemorrhage; development of a toolkit to assist a standardised quantitative approach to estimate obstetric blood loss; equitable access for all pregnant women to the most appropriate critical care facility for her needs; and provision of a national maternal retrieval service
National Paediatric Mortality Register (NPMR)	<ul style="list-style-type: none"> • Reduction of sudden infant death rates via safe sleep guidelines • Accurate mortality estimates established for deaths due to infection/sepsis in the paediatric population. Coding issues have caused the burden of infection-related deaths among Irish children to be underestimated. This information is to be made available soon
National Stroke Register	<ul style="list-style-type: none"> • Decreased mortality • Improved door-to-imaging times/treatment • Reduction in nursing home admissions
Clinical audit carried out by National Sepsis Programme	<ul style="list-style-type: none"> • Process audit: hospital based and used to inform education programme and track sepsis guideline implementation • Outcome audit: national mortality trends; burden of acute healthcare usage; patient characteristics for improved recognition

However, while participation and support of clinical audit has grown in the past 10 years in Ireland, concerns have recently emerged regarding its viability. This was highlighted in 2018 during the CervicalCheck controversy when a series of look-back reviews (incorrectly described as clinical audit) were performed. This led to concerns that the identification of patient safety incidents, and subsequent open disclosure, would become a requirement of clinical audits. It also raised questions concerning the design, methodologies, and management of clinical audit:



“It is notable that, particularly in its earlier phases, the protocols were brief, and throughout there was minimal consultation with clinicians in designing the audit. Indeed, the lead colposcopists were very clear in their view to the Scoping Inquiry that they had no involvement, and felt that they should have....

Governance of the audit seems to have been weak. It was discussed in occasional meetings which were irregular and not well recorded. It appears that many of the decisions were made by a small number of senior staff at CervicalCheck in an informal way.... Audit results have never been published.”

(Scally, 2018, p. 84)

This would make carrying out clinical audit non-viable for most, if not all, healthcare professionals. The viability of clinical audit has been further questioned following the publication of the Health Research Regulations 2018 and the resulting concerns that a similarly strict interpretation of GDPR may become applicable to clinical audit. Numerous clinical audits have subsequently ceased across Ireland due to these concerns.

Should these concerns continue, more and more health service provider organisations across Ireland may cease carrying out clinical audits. This cessation would impede improvements in patient safety, which is the core purpose of clinical audit, to the detriment of all patients in the Irish healthcare service.

As a result of these concerns, the HSE CCO, Dr Colm Henry, and the National Director of the HSE Quality Improvement Team (QIT), Dr Philip Crowley, requested a review of 15 NCAs and one healthcare audit, which was coordinated by NOCA in May 2018 (see Appendix 10). The review identified a number of key findings relating to NCAs in Ireland, including:

- NCA is widely supported by clinicians and when properly resourced is producing reliable data to drive improvements.
- Locally, there is a lack of protected time, training, and resources.
- Nationally, there is a lack of a national governance and management structures.
- There is a need for investment in clinical audit infrastructure to ensure a sustainable future and high-quality clinical audit.

Following on from these findings, the HSE CCO established this in-depth National Review of Clinical Audit across the Irish healthcare system to ensure that suitable structures and supports are identified and implemented.

1.2 Purpose

The purpose of this National Review is to identify and make recommendations on the structures and supports required to ensure the continuation and development of effective clinical audit across the Irish healthcare system.

1.3 Intended audience

This National Review is relevant to anyone involved in clinical audit in the Irish healthcare system, from on-the-ground data collectors to those in senior management positions. Those involved include, but are not limited to, the following:

1. Healthcare professionals, including nurses, doctors, and health and social care professionals (HSCPs), carrying out local clinical audits, as well as those involved in NCAs
2. Clinical staff carrying out clinical audits as required by their professional competence schemes to maintain certification, or those for fulfilment of undergraduate and postgraduate education
3. Clinical audit managers, quality managers, and service managers
4. Clinical audit leads
5. Quality and Patient Safety (QPS) leads and managers
6. Health service provider organisation's senior management
7. Health service provider organisation's group management
8. HSE Directorate and senior management
9. Department of Health based policy-makers
10. Patients
11. Members of the public.

1.4 Scope

The following topics are included in this report, in line with the scope of this National Review, as outlined in the project terms of reference (see Appendix 1):

1. Nomenclature
2. Clinical audit in Ireland
3. Guidance for the design of clinical audits
4. Recommendations for governance structures and supports to improve clinical audit
5. Challenges faced when carrying out clinical audit
6. Recommendations for training supports
7. Impact of legislative and policy changes on clinical audit
8. List of NCAs and recommended local clinical audits
9. Exemplar templates
10. Review of recommendations from the Scoping Inquiry into the CervicalCheck Screening Programme (Scallly, 2018).



CHAPTER 2

APPROACH TO NATIONAL REVIEW



CHAPTER 2: APPROACH TO NATIONAL REVIEW

2.1 Governance of the National Review

As previously outlined, this National Review was commissioned by Dr Colm Henry, HSE CCO. The terms of reference were agreed in October 2018, with a Project Manager in place from the first week of November. Membership of the Working Group, Steering Committee, and Advisory Panel was confirmed and work began on the National Review with a planned completion date of May 2019. Membership of the Working Group and the Steering Committee included public and patient representatives, senior HSE leaders and clinicians, and individuals with clinical audit expertise. The purpose of the Steering Committee was to oversee the direction of the National Review in line with the established terms of reference. The function of the Working Group was to advise and support the development of the process. The Advisory Panel consisted of key national and international experts in clinical audit and related fields, who were available for consultation as required. Detailed terms of reference, including group memberships, are presented in Appendix 1.

2.2 Overview of approach

The work of the National Review was informed by the following key tasks and activities:

- Review of the scope and deliverables from the terms of reference to determine a plan of work
- Consultation with members of the Working Group, Steering Committee, and Advisory Panel
- Consultation with additional key experts
- Extensive review of clinical audit and related publications in Ireland, including legislative and policy documents
- Review of seminal and grey literature to ascertain best practice internationally in respect of clinical audit
- Review of documents supplied by health service provider organisations
- Review of the findings and recommendations of the Scoping Inquiry into the CervicalCheck Screening Programme (Scallan, 2018)
- Facilitation of focus group sessions at three Irish hospitals (Section 2.2.1)
- Comprehensive analysis of information to develop findings and evidence-based recommendations for consideration by the governance structures of this National Review.

2.2.1 Focus groups approach

Six key experts from the Working Group formed a subgroup to organise focus group meetings in three hospitals in different locations across Ireland, with the assistance of the local clinical audit or quality manager at each site. Two Model 4¹ hospitals and one Model 3¹ hospital were selected. Two focus groups were held at one of the Model 4 hospitals. Semi-structured questions were used as a basis to structure an open conversation with focus group participants. These can be seen in Appendix 4. A facilitator and note-taker attended all focus groups.

All focus group meetings were audio-taped for reference purposes and detailed notes were taken. All data, including consent forms, participant information leaflets, and transcripts, were stored on a secure IT server. Analysis of all focus group dialogue was carried out by the Project Manager to identify key themes and ideas, which have been incorporated throughout this National Review.

Participation in focus groups

Participation consisted of healthcare professionals who take part in clinical audit regularly, comprising nurses (including advanced nurse practitioners, clinical nurse managers, clinical nurse specialists, and assistant directors of nursing), HSCPs, consultants and non-hospital doctors (NCHDs), principally senior house officers, from a wide range of departments, as well as quality managers and specialists. This participation is presented in Table 2.1.

¹ **Model 1:** community hospitals where patients are under the care of resident medical officers. No surgery, emergency care, acute medicine (other than a select group of low-risk patients) or critical care are provided.

Model 2: hospitals providing most hospital activity including extended day surgery, selected acute medicine, local injuries, a large range of diagnostic services, specialist rehabilitation medicine and palliative care.

Model 3: hospitals providing 24/7 emergency medicine, acute surgery, acute medicine, and critical care.

Model 4: hospitals similar to Model 3 hospitals providing tertiary care and, in certain locations, supraregional care.

Table 2.1 Focus group participation by discipline

Hopital Type	No.	Consultants	NCHDs	Nurses	HSCPs	Healthcare quality professionals
Model 3	23	3		13	7	
Model 4 A1	15	7	3	2	1	2
Model 4 A2	20			15	4	1
Model 4 B	17	8		6	1	2

Participation was excellent, with participants in every group speaking multiple times. All participants worked in the acute hospital and hospital group sector during the course of the review. While this perspective may be limited, it does represent the experience of frontline and support healthcare staff, particularly those actively involved in local and national clinical audit.

2.3 Project management of the National Review

The Project Manager was responsible for the coordination of the activities of the Working Group and Steering Committee to produce the National Review report, including supporting appendices.

The Working Group was responsible for accomplishing the deliverables from the project terms of reference. This required an extensive review of the literature; analysis of the feedback from focus group discussions across a number of expert subgroups formed from the Working Group members, such as that detailed above; in addition to informed discussion and debate among the Working Group during the six official meetings held.

Five official meetings of the Steering Committee were held, where completed work was submitted for formal approval and any work in progress was also presented. Any issues that could not be resolved by the Working Group were discussed with the Steering Committee at these meetings. Any comments or concerns raised by Steering Committee members were brought back to the Working Group for incorporation into the report. The final report has received formal approval from the Steering Committee.

The anticipated timeline for completion of the report was six months from the appointment of the Project Manager on 5 November 2018. However, given the significant engagement necessary with stakeholders to ensure a full and complete consultation, and the time required to develop an informed report, it was necessary to extend the initial timescale to 13 June 2019. This was agreed in consultation with the Steering Committee and Dr Colm Henry.

In addition to the discussions from the Working Group, Steering Committee, and focus groups, extensive consultations were carried out with experts in clinical audit and related fields. These consultations consisted of numerous face-to-face meetings, in addition to telephone and email correspondence.

Those consulted in Ireland included experts from:

- Department of Health
- Royal College of Physicians of Ireland (RCPI)
- Royal College of Surgeons in Ireland (RCSI)
- National Office of Clinical Audit (NOCA)
- HSE Quality Assurance and Verification Division (QAVD)
- HSE National Quality Improvement Team (QIT)

-
- Legal counsel
 - RCSI Research Ethics Committee personnel
 - HSE Office of the National Clinical Advisor and Group Lead (Acute Hospitals Division)
 - Hospital Research Ethics Committee personnel
 - National Screening Service leads
 - Data protection officers (DPOs)
 - Quality experts.

There was broad consultation with international experts from the Advisory Panel and others recommended by Working Group and Steering Committee members. These included clinical audit experts from the Healthcare Quality Improvement Partnership (HQIP), the Royal College of Physicians (UK), and the Australian Trauma Registry. Screening programme experts from the Australian Cancer Research Foundation were also consulted.

2.4 Approval and handover to sponsor

The National Review report will be presented by the Chairs and members of both the Steering Committee and Working Group to the sponsor, the HSE CCO, at an official launch event in September 2019. The HSE CCO is responsible for the implementation of the recommendations.



CHAPTER 3 CLINICAL AUDIT IN IRELAND



CHAPTER 3: CLINICAL AUDIT IN IRELAND

3.1 Development of clinical audit in the Irish health service

Clinical audit has been part of the healthcare system in Ireland for many years. However, it is only since 2007 that the value of clinical audit has been recognised through legislation, such as the Medical Practitioners Act 2007, and through comprehensive national reports and policies, such as the *Report of the Commission on Patient Safety and Quality Assurance* (DOHC, 2008). The HSE has recognised the importance of clinical audit through the provision of national guidance and support. However, more legislative and guidance support is needed for clinical audit to continue successfully.

The seminal report from the Commission of Patient Safety and Quality Assurance (DOHC, 2008) signalled a new emphasis on safety and quality in the Irish health service. To build a culture of patient safety, that report targeted all healthcare professionals – clinicians, health service managers, policy-makers, educators – and the public. The recommendation that clinical audit become an essential and integral component of professional practice and thus contribute to improved patient outcomes prompted further growth of clinical audit (DOHC, 2008). This was set amid other national drivers at that time, which included the *Quality Framework for Mental Health Services in Ireland* (Mental Health Commission, 2007) followed by the launch of *National Standards for Safer Better Healthcare* (HIQA, 2012).

Clinical audit is further recognised as an important attribute of professional practice for clinical healthcare professionals. It features in undergraduate and postgraduate education for both doctors and nurses (DOHC, 2008). The Medical Practitioners Act 2007 provided a new legal framework under which the Medical Council ensured that all doctors maintained their professional competence. This commenced in 2009 and clinical audit was one of the first aspects of the new professional competence scheme to be enacted.² In nursing, with the development of clinical nurse specialist roles, led by the National Council for the Professional Development of Nursing and Midwifery (NCNM), clinical audit was included as a core concept of this new role (NCNM, 2008).

The launch of the Patient Safety First initiative in 2010 brought with it a framework to support clinical audit as an integral aspect of clinical effectiveness (HSE, 2013). The first national guidance for clinical audit was subsequently launched by the HSE in 2013 (HSE, 2013). There were further recommendations that a structured programme of clinical audit was to be included as a key component of clinical governance and continuous quality improvement for health service provider organisations (HSE, 2012; HSE, 2016a). This signalled a converging interest in clinical audit not only of clinicians and health managers but of policy-makers and regulators.

3.2 Local clinical audit

Clinical audit has continued to grow in health service provider organisations. Clinical audits are carried out within these organisations every year, from individual to unit to organisation-wide. Local clinical audits are selected and carried out based on local and clinical priorities and available resources in addition to areas of personal interest. They are also based on national clinical guidelines and standards from organisations such as the National Clinical Effectiveness Committee (NCEC), the Office of the Nursing and Midwifery Services Director (ONMSD), and the Health Information and Quality Authority (HIQA). A number of these audits are carried out by HSE QAVD. A list of these recommended local clinical audits can be found in Table 3.1.

² Available from <https://www.medicalcouncil.ie/News-and-Publications/News/2009/Items/An-Introduction-to-Professional-Competence-Schemes-.html>

Table 3.1 Recommended local audits based on national standards

No.	National Organisation	Standard
1	ONSMD	Nursing and Midwifery Quality Care-Metrics: Acute Care
2	ONSMD	Nursing and Midwifery Quality Care-Metrics: Children's Services
3	ONSMD	Nursing and Midwifery Quality Care-Metrics: Intellectual Disability Services
4	ONSMD	Nursing and Midwifery Quality Care-Metrics: Older Person Services
5	ONSMD	Nursing and Midwifery Quality Care-Metrics: Mental Health Services
6	ONSMD	Nursing and Midwifery Quality Care-Metrics: Public Health Nursing Services
7	ONSMD	Nursing and Midwifery Quality Care-Metrics: Midwifery Services
8	ONSMD	Nursing and Midwifery Quality Care-Metrics: Theatre
9	NCEC	National Early Warning Score (NEWS)
10	NCEC	Prevention and Control of Methicillin-Resistant Staphylococcus Aureus (MRSA)
11	NCEC	Irish Maternity Early Warning Score (IMEWS)
12	NCEC	Communication (Clinical Handover) in Maternity Services
13	NCEC	Sepsis Management
14	NCEC	Diagnosis, Staging and Treatment of Patients with Breast Cancer
15	NCEC	Diagnosis, Staging and Treatment of Patients with Prostate Cancer
16	NCEC	Pharmacological Management of Cancer Pain in Adults
17	NCEC	Management of Constipation in Adult Patients Receiving Palliative Care
18	NCEC	Communication (Clinical Handover) in Acute and Children's Hospital Services
19	NCEC	Irish Paediatric Early Warning System (PEWS)
20	NCEC	Diagnosis, Staging and Treatment of Patients with Gestational Trophoblastic Disease
21	NCEC	Management of an Acute Asthma Attack in Adults (aged 16 years and older)

ONSMD = Office of the Nursing and Midwifery Services Director; NCEC = National Clinical Effectiveness Committee

3.3 National clinical audits

From a national perspective, clinical audit has evolved to become a more integrated part of modern healthcare in Ireland with the development of NCAs. While health service provider organisations voluntarily participate in these NCAs, participation is recommended by the HSE corporate level and its clinical programmes, educators, and professional bodies. Clinical audit findings and reports are provided to the individual health service provider organisations, the HSE, and the public in published reports, with subsequent re-audit to close the clinical audit loop. These NCAs are implemented by national organisations on an ongoing basis. HSE-funded organisations govern and manage clinical audit in the acute health sector across 46 acute hospitals in Ireland, illustrating a commitment and belief in clinical audit as a mechanism for improving patient outcomes.

There are currently four main organisations involved in the governance and management of NCAs in Ireland – RCPI, NOCA, National Perinatal Epidemiology Centre (NPEC), and NCEC. Some of these delivery organisations also govern and manage other national data collections. This report includes a list of ongoing NCAs identified by this National Review, which can be found in Table 3.2.

Table 3.2 National clinical audits

No.	Management Organisation	National clinical audit
1	NOCA	Irish National Orthopaedic Register
2	NOCA	Irish National Intensive Care Unit (ICU) Audit
3	NOCA	Paediatric Intensive Care Audit Network
4	NOCA	Irish Hip Fracture Database
5	NOCA	Major Trauma Audit
6	NOCA	Heartbeat Audit (2019)
7	NOCA	Irish National Audit of Stroke (2019) (previously the National Stroke Register)
8	NPEC	Perinatal Mortality
9	NPEC	Serious Maternal Morbidity Audit
10	NPEC	Vermont Oxford Network
11	NPEC	Planned Homebirths in Ireland
12	RCPI	Histopathology National Quality Improvement Programme
13	RCPI	Gastrointestinal Endoscopy National Quality Improvement Programme
14	NUI Galway	Out of Hospital Cardiac Arrest Register
15	HSE	Sepsis Audit

NOCA = National Office of Clinical Audit; NPEC = National Perinatal Epidemiology Centre; RCPI = Royal College of Physicians of Ireland; NUI = National University of Ireland; HSE = Health Service Executive.

3.3.1 RCPI Specialty Quality Improvement Programmes

The Royal College of Physicians of Ireland (RCPI Specialty Quality Improvement (SQI) Programmes were jointly established with the HSE between 2009 and 2011.³ They are funded by the HSE National QIT. The aim of these programmes is to ensure a high-quality, consistent and accurate service nationally which translates into an improved patient experience with consistently high standards of quality care. RCPI manages two NCAs as follows:

- Histopathology
- Gastrointestinal Endoscopy

The SQI programmes collect data from hospitals which are analysed both locally and nationally. The data are currently published annually in National Data Reports for both the Histopathology National SQI Programme and the Gastrointestinal Endoscopy National SQI Programme.

³ For further information, visit <https://www.rcpi.ie/quality-improvement-programmes/>

There is a third SQI programme for Radiology. The definitions in the NCA Review for clinical audit, clinical registry and service evaluation have caused the SQI Radiology Programme and the Faculty of Radiologists to reflect on the data collected and the standards currently used for this programme. Work is now underway to clarify the scope of a national clinical audit in radiology services and therefore the SQI programme for Radiology is not currently included on the list of NCAs found in Table 3.2.

3.3.2 National Office of Clinical Audit (NOCA)

In 2012, NOCA was jointly established by the RCSI and HSE to carry out NCAs.⁴ NOCA governs the majority of NCAs currently running in the Irish healthcare system. Their current portfolio consists of the following NCAs, with a number of additional NCAs planned for the coming years:

- Irish Hip Fracture Database
- Major Trauma Audit
- Irish National ICU Audit (including Paediatric Intensive Care Audit Network)
- Irish National Orthopaedic Register
- Heartbeat Audit (2019)
- Irish National Audit of Stroke (2019)

NOCA also governs and manages a national data collection, the National Audit of Hospital Mortality (NAHM). This programme carries out a detailed analysis of mortality within the participating health service provider organisations, with an overall aim of healthcare improvement. It does not meet the definition of clinical audit as put forward by this review and is therefore not currently included on the list of NCAs found in Table 3.2.

3.3.3 National Perinatal Epidemiology Centre (NPEC)

Established in 2009, the NPEC undertakes clinical audit and research into pregnancy outcomes in the Irish maternity services and manages a portfolio of related NCAs. The governance structure of NPEC is aligned with that of NOCA's, with their audit governance committees, monitoring and escalation of statistical outliers, and national reporting governed by NOCA. NPEC manages the following five NCAs in Ireland.

- National Clinical Audit of Perinatal Mortality
- National Clinical Audit of Severe Maternal Morbidity
- Vermont Oxford Network
- National Clinical Audit of Planned Homebirths in Ireland
- National Clinical Audit of Neonatal Therapeutic Hypothermia

3.3.4 National Clinical Effectiveness Committee (NCEC)

The NCEC was established by the Minister for Health in September 2010 and provides strategic leadership for the national clinical effectiveness agenda and guidance for NCA (NCEC, 2015a; NCEC, 2015b). It can commission, prioritise, and quality assure NCAs. As of 2019, one clinical audit has been prioritised by the NCEC, which is the Major Trauma Audit, launched in December 2016 as the first NCEC NCA. This NCA is governed and managed by NOCA.

3.4 HSE healthcare audit

There are a number of audits known as healthcare audits carried out across the Irish healthcare system. These are currently

⁴ For further information, visit <https://www.noca.ie/>

managed by the HSE QAVD which was established in 2010. They include both clinical and non-clinical audits.

Healthcare audit, in line with the design and practice of internal audit, is an independent, objective assurance activity designed to add value and improve an organisation's operations. It helps an organisation accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes (Institute of Internal Auditors, 2017). Under the HSE's Code of Governance (HSE, 2015), healthcare audit sits alongside and mirrors the organisation's internal audit function. It does this by providing a:

“...third line of defence assurance in relation to risks and controls in care related activities in both clinical and non-clinical settings. The HSE's Healthcare auditors are members of the Chartered Institute of Internal Auditors (CIIA) and are required to comply with the professional and general standards set by the CIIA.”

HSE (2019a)

The majority of healthcare audits carried out to date are non-clinical audits. However, the QAV Healthcare Audit Team carries out audits related to both clinical and non-clinical standards.

3.5 National Screening Service audits

There are five national screening programmes in Ireland: the three cancer screening programmes, BreastCheck, CervicalCheck, and BowelScreen; the national diabetic retinal screening programme, Diabetic RetinaScreen; and the National Selective Ultrasound Screening Programme for Developmental Dysplasia of the Hip in Infant (HSE, 2017), which is in the final phase of implementation.

Screening programmes are population health measures which, by design, utilise rapid, inexpensive, low-technology investigations to detect early signs of disease in a large cohort. Their success is determined by measurements of population health outcome. This is in contrast to detailed investigations undertaken in a symptomatic or diagnostic setting where success or failure is determined by the clinical outcome of the individual patient.

The three national cancer screening programmes routinely audit their work, as is standard with screening programmes worldwide. These audits are carried out to investigate if required standards are being met, which are based on international best practice. To complete this audit work, cancer screening programmes need to look at interval cancer rates to assess if they are within acceptable error rates. This has raised many issues, including how to reconcile what constitutes harm in a process that has a known and accepted error rate.

In 2018, the HSE CCO commissioned an expert committee to review the interval cancers audit processes in Ireland and to compare this with other jurisdictions. Recommendations from this committee are awaited. It is therefore not part of the scope of this review.

3.6 Registries

Developed healthcare systems generally have clinical registries which aim to improve health outcomes of patients diagnosed with particular diseases or cared for in particular healthcare settings (Hoque *et al.*, 2017). National registries and registers can feed into quality improvement nationally and are invaluable to the system.

There are numerous registries and registers held in the Irish healthcare system, both local and national. They are managed

by health service provider organisations, educational institutions, and other organisations such as NOCA. This National Review has found that national registries can be mistaken for NCAs. Many national registries have improvement aims and are valuable in terms of patient safety and quality improvement. However, they do not meet the definition of clinical audit provided in this report or in other recognised definitions.

The purpose of many of these national registries is to provide information that can help to identify areas for improvement. They produce publicly available data, such as the published report of the National Audit of Hospital Mortality (NOCA, 2018c).

3.7 Conclusion

This all points to a developing culture where clinical audit is becoming “the norm in every healthcare facility and for every healthcare professional”, as envisaged by Prof. Deirdre Madden (DOHC, 2008, p. v). Indeed, this commitment has already demonstrated value at both local and national levels.



CHAPTER 4 NOMENCLATURE

4

CHAPTER 4: NOMENCLATURE

4.1 Background

This National Review found that there have been misunderstandings across the Irish healthcare system about the nomenclature for clinical audit, quality improvement, research, and day-to-day care of patients. This was raised on many occasions during the focus group sessions that were carried out, and in the discussions of both the Working Group and Steering Committee. A large portion of the work of these groups was dedicated to agreeing a list of definitions, including the adoption of the clinical audit definition from the *Report of the Commission on Patient Safety and Quality Assurance* (DOHC, 2008). The agreed definitions are recommended for adoption across the Irish healthcare system.

4.2 Key findings from consultation process

The consultation process carried out as part of this National Review highlighted that there is much confusion in relation to clinical audit in the Irish healthcare system. A number of definitions have been approved by the Working Group and Steering Committee for the terms that were identified as causing the most confusion. The full list can be found in Section 4.3.

Much of the confusion was around what is and is not a clinical audit. The consultation process made it clear that clinical audit, registries, and research are often confused. Across all three sites where the focus groups were facilitated, many participants used the terms clinical audit and research interchangeably. This confusion with research may result in the misapplication of the strict GDPR interpretation from the Health Research Regulations 2018 to clinical audit, to detrimental effect. This National Review also highlighted a number of national registries that have been incorrectly identified as NCAs. These are to be excluded from any published list of NCAs.

There are also a number of different definitions for clinical audit across the healthcare system, resulting in confusion around clinical audit design. The definitions provided in this chapter aim to provide clarity on these activities.

The controversy relating to the CervicalCheck Screening Programme in 2018 caused further confusion. The controversy arose from conduct associated with a number of look-back reviews. However, those look-back reviews were repeatedly misidentified as clinical audit, which has had a negative effect on the work of clinical audit. A definition for look-back reviews, consistent with the HSE Incident Management Framework (HSE, 2018), has been included in this report to provide clarity.

Finally, the consultation process found that the terms 'healthcare audit' and 'clinical audit' are not widely understood as distinct activities by many staff in health service provider organisations. Healthcare audits can include both clinical and non-clinical audits, which further confused some of those consulted. This potential for confusion was acknowledged by both the Working Group and Steering Committee. For this reason, a definition of healthcare audit, provided by the HSE QAVD is included in this chapter.

4.3 Agreed nomenclature

The following definitions have been agreed by both the Working Group and Steering Committee as part of the National Review. This was a lengthy process and reflects significant work from both groups.

4.3.1 What is clinical audit?

“Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements.”

DOHC (2008, p. 152)

“Clinically-led” includes all health and social care professionals.

4.3.2 What is service evaluation

“Service evaluation seeks to assess how well a service is achieving its intended aims. It is undertaken to benefit the people using a particular healthcare service and is designed and conducted with the sole purpose of defining or judging the current service.”

Twycross and Shorten (2014, p. 65)

Unlike clinical audit, it does not compare the service to a predefined standard.

4.3.3 What is a registry?

“A clinical registry is described as a system which collects a defined minimum data set from patients undergoing a particular procedure or therapy, diagnosed with a disease or using a healthcare resource.”

Hoque et al. (2019)

4.3.4 What is research?

“Research is designed and conducted to generate new generalisable or transferrable knowledge. It includes both quantitative and qualitative studies that aim to generate new hypotheses as well as studies that aim to test existing or new hypotheses.”

Health Research Board (2018)

4.3.5 What is a healthcare audit?



“Healthcare audit, in line with the design and practice of Internal Audit, is an independent, objective assurance activity designed to add value and improve an organisation’s operations. It helps an organisation accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.”

HSE (2019a, p. 2)

“Under the HSE’s Code of Governance, Healthcare Audit sits alongside and mirrors the organisation’s Internal Audit function by providing ‘third line of defence’⁵ assurance in relation to risks and controls in care related activities in both clinical and non-clinical settings. The HSE’s Healthcare auditors are members of the Chartered Institute of Internal Auditors (CIIA) and are required to comply with the professional and general standards set by the CIIA.”

HSE (2019a, p. 2)

4.3.6 What is the Maternal Death Enquiry (MDE) Confidential Enquiry?

In 2009, Ireland launched the Maternal Death Enquiry (MDE) Ireland. MDE Ireland was developed with the support of the Institute of Obstetricians and Gynaecologists, the HSE, the DOH, and the State Claims Agency. MDE Ireland is a stand-alone office, based in the National Perinatal Epidemiology Centre (NPEC) UK, and funded by the HSE. It uses the validated UK confidential enquiry methodology.



“A confidential enquiry is a systematic process of multi-disciplinary, anonymous review of all or a sample of defined cases occurring in a defined geographical area during a defined period of time. Where the numbers of a specific type of condition are few, for example maternal deaths, it is possible and generally necessary to review all the cases. Where numbers are large it is usual to take a sample of cases for review. The review can take place either by individual or paired reviewers or during a panel process. Comparisons of care are made against guidelines or best practice where guidelines have not been developed. The review aim is to assess the quality of care provided in each case so as to inform future practice and improvements in care which may make a difference to future outcomes.”

National Perinatal Epidemiology Unit UK (2018)

4.3.7 What is a Healthcare Record Review?

A Healthcare Record Review is where pre-recorded, person-centred data are used to answer one or more questions. The review is not part of direct patient care. It may be carried out for a number of purposes, including clinical audit, research, or incident review. The purpose will dictate the governance structures to be followed. It can also be referred to as a chart review or case review.

A Healthcare Record Review for the purposes of audit collects pre-agreed datasets from a cohort of charts without reviewing the overall care or looking at the context of that care. These datasets are used as inputs to a clinical audit which aims to provide learning and subsequent quality improvement.

⁵ According to the Institute of Internal Audit, the first line is operational management, the second line is internal corporate governance, the third line is internal audit assurance on the effectiveness of the first and second lines of defence. These levels are described in the *HSE Code of Governance* (2015), Section 9.6, HSE Controls Assurance Framework.

4.3.8 What is an Incident Review?



An Incident Review takes place after an individual patient safety incident has occurred. It

“involves a structured analysis and is conducted using best practice methods, to determine what happened, how it happened, why it happened, and whether there are learning points for the service, wider organisation, or nationally”

(HSE, 2018, p. 5).

4.3.9 What is a Look-Back Review?



“A Look Back Review is a process that is initiated where it has been determined that a number of people have been exposed to a specific hazard. The process seeks to identify if any of those exposed to the hazard have been harmed and what needs to be done to ameliorate the harm. This process consists of three key stages: Preliminary Risk Assessment, Audit and Recall.”

HSE (2018, p. 29)

4.3.10 What is peer review?



“Peer review is the professional assessment, against standards, of the organisation of healthcare processes and quality of work, with the objective of facilitating its improvement.”

McCormick (2012, p. 8)

4.3.11 What is a standard in healthcare?



“A standard is a definable measure against which existing structures, processes or outcomes can be compared.”

NCEC/HIQA (2015, p. 9)

4.3.12 What is a clinical guideline?



“Clinical guidelines are systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances, across the entire clinical spectrum.”

NCEC/HIQA (2015, p. 7)

4.3.13 What is Quality assurance?



“Quality assurance is defined as all those planned and systematic actions necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily and comply with agreed standards.”

HSE (2019b)

4.3.14 What is Quality improvement?



“Quality improvement (QI) is the combined and unceasing efforts of everyone – healthcare professionals, patients and their families, researchers, commissioners, providers and educators – to make the changes that will lead to:

- better patient outcomes
- better experience of care
- continued development and supporting of staff in delivering quality care.”

HSE (2016b, p. 4)

“All methods highlight the importance of accessing the unique knowledge that frontline staff possess and involving them in any change and improvement process. Improving the quality of care, and sustaining it, requires all programmes to have a theory of change that is based on the application of improvement science.”

HSE (2016b, p. 15)

4.4 Distinguishing clinical audit from other processes

There are a number of processes that are similar to clinical audit which can lead to confusion about which governance structures and guidance to follow. This section aims to provide clarity and highlight the key differences of these processes to clinical audit in tabular form and by using the Irish Hip Fracture Database (IHFD) as an example.

4.4.1 Differentiating clinical audit from other processes

Table 4.1 highlights the key differences of processes such as service evaluation, research, and registries to clinical audit.

Table 4.1 Differentiating clinical audit from other processes

Theme	Clinical audit	Service evaluation	Research	Registry
Definition	Clinical audit is a clinically led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and acting to improve care when standards are not met.	Service evaluation seeks to assess how well a service is achieving its intended aims. It is undertaken to benefit the people using a particular healthcare service and is designed and conducted with the sole purpose of defining or judging the current service.	Research is designed and conducted to generate new generalisable or transferrable knowledge. It includes both quantitative and qualitative studies that aim to generate new hypotheses as well as studies that aim to test existing or new hypotheses.	Registries are systems which collect a defined minimum dataset from patients with a particular disease, undergoing a particular procedure or therapy, or using a healthcare resource.
Answers question	Clinical audit demonstrates whether a predetermined standard is being met.	Service evaluation tells how well a service is working.	Research demonstrates what should be done.	Registries show the details of certain patient groups. They can be used to answer both clinical audit and research questions.
Purpose	To find out if best practice is being practised for quality assurance and improvement purposes	To evaluate current practices for information purposes. The information can inform management decisions.	To generate new knowledge and find out what treatments, interventions or practices are the most effective	To monitor a patient population or healthcare process A registry may have an improvement aim, a cost focus or form an epidemiological database used for research
Context	Carried out at local or national level	Carried out at local level only	Carried out at local or national level	Carried out at national level only
Methods	Measures practice against evidence-based clinical standards	Measures current service without comparison against standards	Has a systematic, quantitative or qualitative approach to investigation	Carries out data collection and analysis
REC Review	No, but ethical considerations should still be considered	No, but ethical considerations should still be considered	Yes	<ul style="list-style-type: none"> • Yes, if for research • No, if for others listed

4.4.2 Example from IHFD: distinguishing clinical audit, quality improvement, and research

Throughout this review, questions relating to the differences between clinical audit, quality improvement, and research have been raised. Clear definitions are now provided for all of these approaches to data collection (Section 4.3).

Clinical audit and quality improvement are inexorably linked, in that measuring clinical practice against agreed standards is likely to lead to the identification of areas and aspects of practice that could benefit from quality improvement methodologies. Where clinical audit findings identify a need to pursue new information or to reach a new understanding, which is unrelated to the clinical audit standards, research can be undertaken. Exemplars from the IHFD are used to distinguish these processes.

The following example from the IHFD demonstrates how clinical audit can be used for both quality improvement and research projects, which are not in themselves clinical audit, to provide further clarity.

Clinical audit

The IHFD audit assesses care of hip fracture patients across six standards of care, one of which relates to access to surgery. One of the determinants of early access to surgery is admission to a hospital where hip fracture surgery is carried out.

The IHFD Report showed that 84% of patients with a hip fracture were brought directly to a hospital that could operate on hip fractures in 2014. One clear recommendation coming from the IHFD audit was that all patients with a suspected hip fracture should be brought directly to a hospital where hip fracture surgery is carried out (NOCA, 2015).

Making improvements – clinical audit leading to change

In 2016, the HSE National Clinical Advisor and Group Lead for Acute Hospitals, Dr Colm Henry, working with key stakeholders, instituted a national hip fracture bypass policy implementing this recommendation. In 2017, 92% of patients with hip fractures were brought directly to an operating hospital, an improvement of 6% from 2015 (NOCA, 2018b).

Creating new knowledge – research arising from clinical audit

In 2015, Mr Andrew Hughes, an orthopaedic specialist registrar, undertook a research project using data from the IHFD. The aim of the study was to generate new knowledge on the impact of admission route on the time to surgery, length of stay, and pressure ulcer development in patients who sustained a hip fracture in Ireland during 2013–2014. It was found that interhospital transfers predisposed patients to a prolonged length of stay (six days longer than those admitted directly), but did not result in a longer time to surgery or a higher rate of pressure ulcer development. The significantly prolonged length of stay may have both personal, medical, and social repercussions for these patients, as well as financial and capacity implications for the health service (Hughes *et al.*, 2019).

4.5 Recommendations

The National Review recommends that:

1. The agreed list of definitions in the nomenclature document produced as part of this National Review should be adopted by the HSE, and become the national standard for nomenclature for all agencies involved in clinical audit.



CHAPTER 5

CLINICAL AUDIT AND PATIENT SAFETY



CHAPTER 5: CLINICAL AUDIT AND PATIENT SAFETY

5.1 Background

A key deliverable from the terms of reference of this National Review was to define the role of clinical audit in patient safety. This topic was discussed at length with the Working Group and Steering Committee. This chapter aims to provide some clarity on this topic.

5.2 Overview

Clinical audit ensures continuous quality improvement and invaluable learnings for clinicians to deliver the best care possible to their patients. In this way, clinical audit makes a key contribution to patient safety. It should not, however, become confused with other patient safety processes in healthcare such as incident management and open disclosure. This section seeks to clearly define the interfaces between clinical audit and these patient safety processes.

5.3 Clinical audit data collection and incident management

The purpose of all clinical audit is to identify variance from standards and therefore opportunities for improvement. It does not review the context of decision-making in patient management and as such cannot comment on the standard of care relating to an individual patient. If, however, during the collection of audit data, the audit data collector discovers information that indicates that an incident has or may have occurred, it is their responsibility to bring this information to the attention of the senior accountable person or clinician in the organisation. This information must then be reviewed and managed by the health service provider organisation via internal processes in accordance with the HSE Incident Management Framework and HSE Open Disclosure Policy (HSE, 2018; HSE, 2019c). The audit data collector is not involved in the incident management process or any subsequent open disclosure.

5.4 NCA findings and incident management

5.4.1 Context

NCA's analyse the findings from multiple health service provider organisations and use the aggregated results for comparison purposes. Clear evidence-based audit standards with defined targets and exceptions support the analysis of findings. On completion of this analysis, conclusions are drawn on how well the clinical audit standards were met and, if applicable, reasons identified as to why the standards were not met.

Example: Aggregated NCA findings⁶ can present:

- Conformance to clinical audit standards; for example, 100% of patients accessed surgery for a hip fracture in 48 hours.
- Non-conformance to the standards; for example, 50% of patients accessed surgery for a hip fracture in 48 hours.

Where the non-conforming findings are a statistically significant deviation from the expected comparator value, this is referred to as a statistical outlier.

There may be exceptions, however. These are justifiable reasons for not meeting the standard; for example, a patient chooses not to accept care or a patient is too unstable or unwell to access surgery in 48 hours. In some cases, it may be possible to agree on the list of exceptions before the start of an audit.

5.4.2 Non-conforming NCA findings

Where there is significant non-conformance or a statistical outlier, the local audit team should review the 'non-conforming' cases identified through the NCA to determine the reasons for not meeting the audit criteria. This review should determine

⁶ The examples used in this text do not represent actual findings from the Irish Hip Fracture Database.

if the findings are acceptable, for example, an exception or whether there is a systematic issue that should be addressed.

The reasons for non-conformance may be acceptable. For example, a patient with a hip fracture was not admitted to an orthopaedic ward within four hours of presentation as he was brought directly to theatre for surgery. These reasons may be potentially acceptable and therefore can be added to the exception criteria for the standard.

5.4.3 Non-conforming NCA findings and patient harm

NCA findings of non-conformance do not necessarily signify that harm has occurred to a patient. For example, the Irish Hip Fracture Standard 6 states that a patient with a hip fracture should have a specialist falls assessment during their hospital stay (NOCA, 2018b). Where this does not occur, it does not cause harm to a patient. However, it is not good practice and if it systematically occurs, it should be addressed as an area for improvement.

If during a review of the non-conforming cases, information indicating a potential patient safety incident has or may have occurred, the reviewer has a responsibility to bring this information to the attention of the senior accountable person or clinician in the organisation. This information must then be reviewed and managed by the health service provider organisation via internal processes in accordance with the HSE Incident Management Framework and HSE Open Disclosure Policy (HSE, 2018; HSE, 2019c). At this time, further actions are carried out under the Incident Management Framework (HSE, 2018) and not under the auspices of clinical audit. The interface between clinical audit findings and the potential for incident management is clearly illustrated in Figure 5.1.

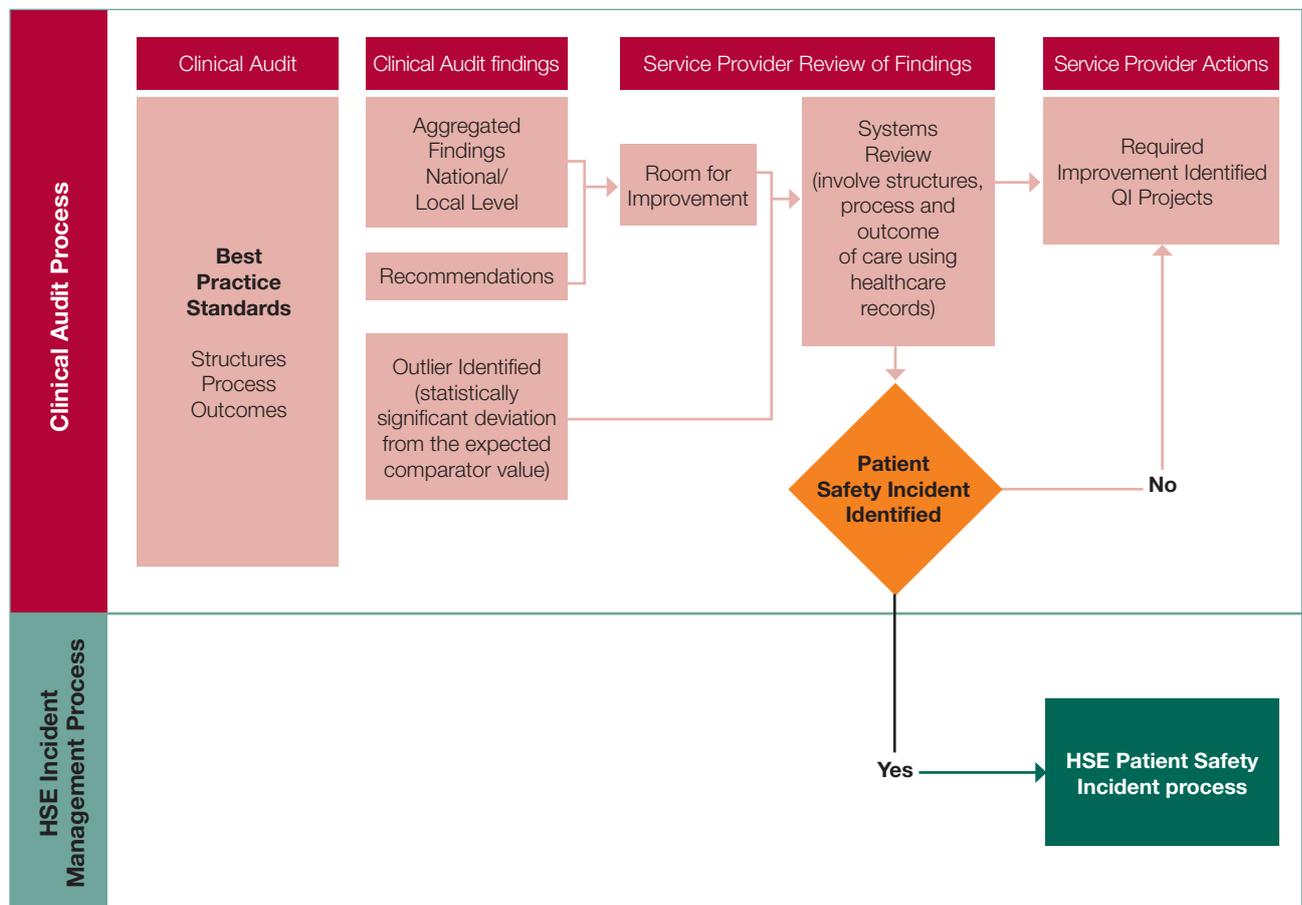


Figure 5.1 Interface of clinical audit with incident management and open disclosure



CHAPTER 6

NATIONAL GOVERNANCE OF CLINICAL AUDIT



CHAPTER 6: NATIONAL GOVERNANCE OF CLINICAL AUDIT

6.1 Background

In line with the deliverables outlined in the terms of reference of this review, this chapter will propose a set of governance recommendations at the national level for clinical audit. This will also include arrangements for identifying, prioritising, and maintaining a relevant portfolio of NCAs to ensure compliance with required clinical audit standards. Governance for clinical audit involves having the necessary structures, processes, and oversight in place to ensure that safe, person-centred and effective services are delivered.

6.2 Key findings

6.2.1 National governance support for local clinical audit

For local clinical audit to continue effectively, there needs to be support at a national level to ensure essential resources are made available, including but not limited to guidance materials, training, and IT support. Feedback from the focus groups and both the Working Group and Steering Committee of the National Review, in addition to consultation with experts involved in clinical audit from the frontline to national level, made evident that there is currently an insufficient level of such national support. This section outlines some of the key areas that would benefit from increased support for clinical audit at a national level.



“Audit is a powerful tool for change. It is a way you can make things happen for you in your department. It speaks to management in a way that other things don’t.”

Focus Group Participant

While quality improvement methods such as clinical audit are recognised as an essential component of high-quality healthcare, it is clear from the feedback of the focus groups that clinical audit is hugely under-resourced and perceived not to be a management priority when compared with financial issues, patient safety incidents, service delivery demands, and staffing retention. This is consistent with the findings of the preceding *National Clinical Audit Review* (see Appendix 10). However, research shows that a healthcare system that prioritises quality improvement and learning performs better. This includes improved patient outcomes, reduced costs, and higher staff satisfaction (King’s Fund, 2017).

Feedback from the focus groups highlighted that the quality of local clinical audit varies greatly between hospitals. The consistent message was that performing local clinical audit within the Irish healthcare system is challenging. The focus groups also highlighted that while there had been some national support for clinical audit that was very beneficial, it was a limited resource. Focus group participants consistently identified the national HSE Quality and Patient Safety Directorate’s *A Practical Guide to Clinical Audit* (2013) as a seminal resource for clinical audit practice. They also acknowledged the positive impact of external face-to-face training delivered nationally by HSE QID, which has now ceased. Currently, there is no national training resource available for health service provider organisations. This is discussed in more detail in Chapter 9.

Participants also noted that where national supports for local audit exist, such as standards with supporting templates, it was extremely beneficial. This includes the supports provided for a number of nationally recommended local audits (see Table 3.1) based on best practice clinical guidelines from organisations such as NCEC, ONMSD, and HIQA. Participants found the supports provided extremely useful and would welcome an expansion of these types of clinical audit templates and other supports, which could then become standardised across Ireland.

The lack of a national governance structure for clinical audit to communicate with and support the system during significant events was very evident in recent times with the introduction of the new EU General Data Protection Regulations (GDPR) transposed into Irish law by the Data Protection Act 2018, and the subsequent lack of any clear consistent national advice.

The opinions of focus group participants on the effects of GDPR were that:

“The whole system is heading for paralysis.”

“Audit has decreased since new legislation fears.”

“Healthcare professionals are ‘terrified’, ‘petrified’ and ‘scared’ to carry out clinical audit.”

Focus Group Participants

This void has been complicated by varying advice from DPOs regarding the collection and use of clinical audit data and the suspension of clinical audits in a number of hospitals. Further discussion on the impact of recent legislative changes is provided in Chapter 10.

Further feedback from the focus groups highlighting the difficulties in carrying out clinical audit locally are discussed in Chapter 7. This feedback is consistent with that received in the *National Clinical Audit Review 2018* (see Appendix 10), which identified the lack of national governance and management structures as a key concern. The 2018 Review also identified that there is a need for investment in audit infrastructure. This was repeated across all focus groups.

Clinical audit needs to be a priority for the senior management team (SMT) right up to the board of the HSE. This can thus support health service provider organisations and encourage provision-appropriate governance structures locally. The Steering Committee and Working Group concluded that there is a need for a national structure for the governance of clinical audit which should be put in place by the HSE.

This structure would support clinical audit, ensuring appropriate resources (e.g. training, IT, analytics, legislative, and policy support) are made available nationally, as well as providing and monitoring a national strategy for clinical audit. It is anticipated that this would provide governance and support for all clinical audits carried out, including those performed by HSE QAVD. However, any non-clinical audits carried out will not be governed by this structure.

6.2.2 Governance of NCAs

NCAs support those who plan, manage, and deliver healthcare to measure how they are performing against recognised best practice standards of care. In addition, NCAs allow local healthcare providers to compare their performance with national and international benchmarks and work to improve care when standards are not met.

There are a growing number of NCAs in the Irish healthcare system. These NCAs are funded by the HSE via the National QIT and in the main are managed and governed by NOCA and RCPI SQI Programmes. Feedback from the focus groups was in general very positive about the governance and support for NCAs. This was mainly due to the supports provided by the national clinical audit organisations, which included training, IT systems and support, data validation and reports, as well as a number of dedicated roles. The difference between this and the support for local clinical audits was repeatedly mentioned.

However, while this National Review has observed that NCAs are currently well governed, some gaps have been identified. Discussions with the national clinical audit organisations highlighted that there is a lack of transparent processes within the HSE to prioritise and develop new NCAs, including the provision of appropriate funding. There is also no publicly available list of recognised NCAs and registers, although a list of the known NCAs has been developed as part of this National Review (see Table 3.2) and is recommended for review and publication on a new dedicated HSE clinical audit web portal.

All NCAs should continue to be managed and governed to agreed best practice standards by the relevant national organisations. These standards include having the appropriate governance, data quality, information governance, and reporting structures in place to support every stage of the NCA, from design, through to data collection, and finally interpretation of the results and subsequent recommendations. The reports of all NCAs should be made publicly available, with health service provider organisations identified.

6.2.3 Irish Clinical Audit Network

With the changing quality landscape and the development of clinical audit in the health service, new clinical and professional roles have been created and evolved since 2010. Health service provider organisations have developed these roles to manage and facilitate local clinical audit and quality improvement. In Ireland, the evolution of clinical audit roles has been supported by the Irish Clinical Audit Network (ICAN). The purpose of ICAN is the development of a national network for healthcare staff with a working remit or an interest in clinical audit to enable a shared approach to clinical audit and offer support and advice to members. It is a peer support network, where clinical audit professionals can share knowledge and experience, as well as social and practical help. This can lead to collaboration across health service provider organisations.

ICAN mirrors a similar UK network, the National Quality Improvement and Clinical Audit Network (NQICAN), established in 2013. It is a recognised group with an independent voice advocating for clinical audit across the system, contributing to multiple agencies, such as NHS Improvement; HQIP; The Health Foundation; and the Falls and Fragility Fracture Audit Programme (Walker, 2018). NQICAN receives funding from HQIP, bringing the independent voice of clinical audit professionals to the NCA and quality improvement forum. In Ireland, ICAN is appropriately placed both as a peer support network and an independent voice to represent clinical audit professionals advocating for frontline clinical audit.

6.3 Recommendations

To ensure that clinical audit continues to deliver improved clinical outcomes across the entire Irish healthcare system, the following recommendations have been agreed by the Working Group and Steering Committee to be developed nationally:

1. The HSE, through the Office of the Chief Clinical Officer, should put in place appropriate governance arrangements to provide senior leadership for clinical audit at a national level in the health service. This governance structure should establish and monitor a national strategy for clinical audit, promote and advocate for clinical audit, ensure that national structures are in place to provide clinical audit guidance and support, commission national reviews, and oversee the implementation of the recommendations from these reviews, including the National Review.
2. This HSE governance structure should be responsible for the commissioning of new national clinical audits (NCAs), reviewing the value of existing NCAs, and ensuring that appropriate management and governance structures are in place.
3. The HSE should develop a dedicated clinical audit portal on the HSE website with an assigned manager. This portal should be the 'home' for clinical audit guidance and supporting material. It should be updated with advice resulting from new legislation or any policy changes which may affect clinical audit.
4. The HSE should publish and maintain a complete list of currently recognised NCAs on the new dedicated clinical audit web portal.
5. The HSE should compile, publish, and maintain a list of recommended local clinical audits with associated tools, such as those based on National Clinical Effectiveness Committee (NCEC) guidelines and the Nursing and Midwifery Quality Care-Metrics, on the new dedicated clinical audit portal on the HSE website.
6. The HSE should assign appropriate resources to health service provider organisations to enable clinical audit, including a local clinical audit function, protected time for clinical audit, data analysis support, clinical audit templates, software, and training.
7. Clinical audit should be a management priority in line with financial and risk management reporting.
8. All NCAs should be managed and governed to agreed best practice standards that include governance structures, data quality, information governance, and reporting.
9. All NCAs should regularly publish aggregated data reports, with individual health service provider organisations identified. These reports should be made publicly available.
10. The HSE should support a national forum for clinical audit leads where knowledge and learnings can be shared and disseminated to individual health service provider organisations.



CHAPTER 7

LOCAL GOVERNANCE OF CLINICAL AUDIT



CHAPTER 7: LOCAL GOVERNANCE OF CLINICAL AUDIT

7.1 Background

In line with the deliverables in the terms of reference of this review, this chapter will propose a set of governance recommendations to support effective local clinical audit.

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“Clinical governance is the system through which service providers are accountable for continuously improving the quality of their clinical practice and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. This includes mechanisms for monitoring clinical quality and safety through structured programmes, for example, clinical audit.”

HSE (2018, p. 3)

Governance for local clinical audit involves having the necessary structures, processes, standards, and oversight in place to ensure that safe, person-centred and effective services are delivered (HSE, 2016c).

”

“For health and social care staff this means: specifying the standards you are going to deliver and showing everyone the measurements you have made to demonstrate that you have done what you set out to do.”

HSE (2016c, p. 1)

Local clinical audits are chosen based on a number of priorities and interests; they can be decided anywhere from senior management level down to individual level. They are selected based on local priorities, clinical priorities, and available resources, in addition to areas of personal interest. Design of local clinical audits varies from person to person, and organisation to organisation, although those based on national standards have a level of consistency.

7.2 Key findings

Local clinical audit is a valuable and routine source of information for healthcare professionals and management to better understand the standards of care they are providing to their patient groups. It is acknowledged that there is a large amount of excellent clinical audit work being conducted at local level in the Irish healthcare system. This includes participation in NCAs as well as clinical audits carried out locally. This work should be supported and the sharing of learning and outcomes facilitated.

Feedback from various clinicians on the Steering Committee and Working Group advised that much of what clinicians think of as clinical audit is in fact a series of look-back reviews to see how patients were cared for and is not a structured assessment of care to recognised standards. For example, clinicians might choose a number of patient charts and review them in their entirety, without any preidentified standards being used. Local governance needs to address this by providing clear guidance on what constitutes clinical audit.

The focus group sessions highlighted huge variability among the governance structures in place and the resources available to staff. Where good management and governance structures for clinical audit were in place, participants acknowledged the benefits of this approach. The overarching feedback was that clinical audit is difficult to perform well due to a lack of time and access to basic supports that should be provided by a clinical audit office.

Focus group participants, noting the lack of time available to do a clinical audit, remarked:

“Finding time to do audit is tough.”

“[You] need time and people.”

“No protected time for the majority of people to carry out clinical audit. They have to squeeze it into the normal day’s work, and they are already strained.”

“No time for improvement or re-audit.”

Focus group participants

Participants further remarked on the lack of local governance support regarding the actioning of findings to implement improvements.

“[There is a] lack of any proper structured audit oversight.”

“Unless results are fed back to the people doing the audit, they’re going to lose interest as it’s just a tick-box exercise ... Results need to be fed back for it to be meaningful.”

“[It’s] soul-destroying identifying training you need and not being able to resource it.”

“Not sure why we do audits if we can’t get funding to make the improvements.”

Focus group participants

One participant based in a Model 4 hospital reported that no information was provided regarding clinical audit governance or support when they started their position at the hospital, and suggested that key information should be included during induction. Following the focus group feedback, one quality manager planned to produce clinical audit material for inclusion in induction packs.

Publishing the results of clinical audits was mentioned at two of the three hospitals as improving morale and interest in clinical audit generally. Both hospitals highlighted the success of annual ‘clinical audit days’, where the results of local clinical audits and their resultant improvements were displayed, encouraging others to undertake their own clinical audit work. Publication should ideally be done not only to encourage others to undertake clinical audit work but also for the purposes of transparency.

Consultation with an information governance expert stressed that the provision of general information regarding clinical audit being carried out should be done as part of best practice. This can be done by displaying information notices throughout health service provider organisations. There was also consistent feedback regarding the lack of IT and data analysis skills and training, with participants remarking:

”

“[They] don’t know where to get the information relevant to the audit they want to do. [They] spend a lot of time looking for the information. Huge barrier to people doing audits – feel it’s going to take too long.”

“[There is] confusion around the data. They’re clinicians not statisticians. [They] have to learn new skills. All the energy is gone to finding the data. All very highly trained people, wasting their time. Needs to be a resource/person to do a lot of this: pulling charts, getting data out of charts, etc.”

“Something like iPads for live data collection would be brilliant.”

“[There is a] need for audit templates and software to use with the templates.”

Focus group participants

This feedback is consistent with that received in the *National Clinical Audit Review* carried out in May 2018 (see Appendix 10), which identified a lack of protected time, a lack of formal training, and a lack of resources, such as a clinical audit lead, as key concerns of healthcare professionals.

Finally, participants expressed frustration that equivalent audits are started repeatedly by NCHDs moving between hospitals, and that there is limited information sharing about ongoing and completed audits within hospitals and hospital groups. One participant gave the real example of a situation where:

”

“[In] another location, there’s been a really good audit and really good outcome. We know it’s the same issue here but you can’t trust it, so you have to do it yourself. It’s disheartening. People are not even sharing the tool. [You] have to come up with your own tool all over again. This is a hospital in the same group.”

Focus group participant

For the above issues to improve, local governance structures need to be clearly defined and provide additional support for clinical audit, including dedicated time and resourcing for all stages of clinical audit, and commitment to making the recommended improvements. These local structures should be aligned with HSE governance for quality and safety to ensure consistency across the Irish healthcare system. An example of a local governance structure in a hospital that supports clinical audit is outlined in Figure 7.1.

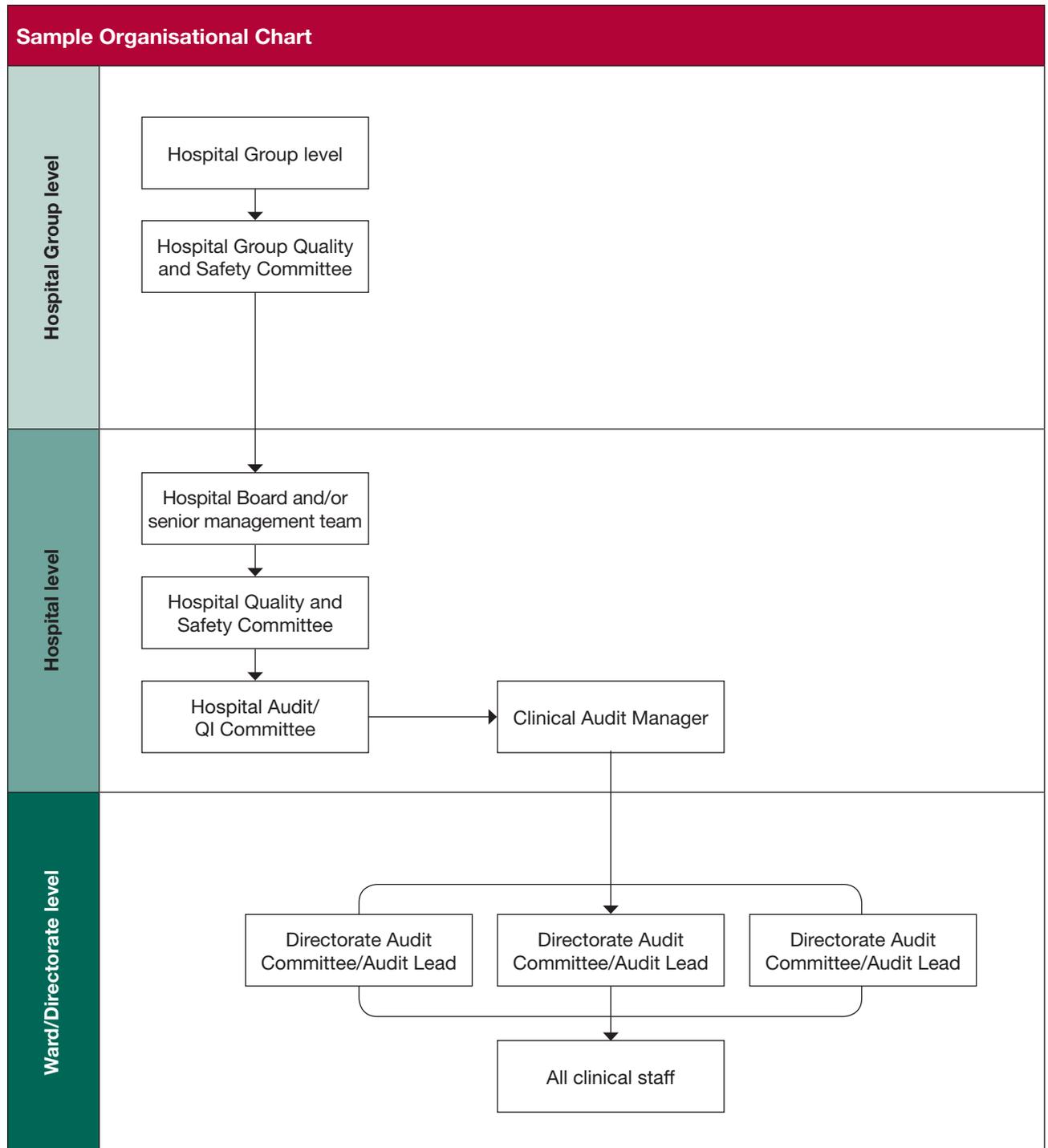


Figure 7.1 Sample organisational chart

7.3 Recommendations

The following recommendations have been agreed through discussions of the Working Group and Steering Committee as supporting clinical audit and have incorporated focus group feedback. They should be adopted by all health service provider organisations which take part in clinical audit, including the proposed six new regional health areas (aligned with the recommendations made in the Sláintecare Report of the Oireachtas Committee on the Future of Healthcare (2017)).

1. Every health service provider organisation should:
 - Provide access to a clinical audit and/or quality office with a dedicated audit manager responsible for ensuring that appropriate management and governance structures for clinical audit are in place.
 - Provide protected time and resources to carry out clinical audits, including implementation of improvements and re-audit.
 - Designate appropriate clinical leadership roles with responsibility for clinical audit across the health service provider organisation.
 - When developing local guidance material and templates, ensure that it aligns to national standards, such as that in *A Practical Guide to Clinical Audit* (HSE, 2013).
 - Provide training on clinical audit, including design, data analysis, and using audit findings.
 - Include information regarding clinical audit and quality improvement structures and support as part of staff induction.
 - Maintain a register of all clinical audits carried out locally.
2. There should be a clear process in place for the submission, prioritisation, approval, and registration of clinical audits. The following factors should be considered when prioritising:
 - External priorities, such as those highlighted by the outputs of NCAs, and those based on HIQA standards
 - Internal priorities based on clinical risks, serious incidents, and patient safety
 - Organisational priorities, including service redesign and development
 - Departmental, unit, specialty, or professional priority, for example, for professional revalidation, appraisal, and training needs.
3. Clinical audit should be a strategic priority for the health service provider organisation's SMT. It should be the cornerstone of the clinical governance function of the health service provider from the board, senior management meetings, Quality and Patient Safety (QPS) committees, through to clinical team committees. Key findings of all clinical audits must be reviewed by the SMT of the health service provider organisation. An explicit information flow should be established between the SMT/board and the audit team. The SMT should have responsibility for reviewing both the clinical audit programme and the outcomes of individual projects.
4. Completed local clinical audits should be widely disseminated for the purposes of transparency. This can be achieved internally within the health service provider organisation at education meetings, practice meetings, posters, and local website or externally through posters/presentations at conferences and journal publications.
5. Clinical audit and quality improvement activities should be visible – public information notices regarding the purposes of clinical audit should be displayed in health service provider organisations. Annual organisational-level clinical audit days are to be encouraged.
6. The governance of clinical audit should be aligned with the HSE governance for quality and safety. There should be clear lines of reporting and accountability from the frontline delivery function to local and national management structures.



CHAPTER 8

DEVELOPING GUIDANCE FOR CLINICAL AUDIT



CHAPTER 8: DEVELOPING GUIDANCE FOR CLINICAL AUDIT

8.1 Background

Guidance for the design of clinical audits was identified as one of the key deliverables of this National Review. The Working Group was tasked with reviewing the existing national and international guidance available for those involved in clinical audit, and making recommendations which would ensure that clinicians have the necessary support to carry out clinical audit effectively. This was achieved through a review of seminal and grey literature, consultation with key experts, as well as gaining valuable feedback from those carrying out clinical audit on the ground through a series of hospital-based focus groups.

8.2 Key findings from the focus groups

While numerous discussions with the National Review expert groups were held over the seven-month period and an extensive review of grey literature carried out, the majority of the key findings in relation to existing guidance for clinical audit design are based on discussions with the focus groups. A number of key themes relating to good audit design emerged during the focus groups. These occurred across all focus groups, but to varying degrees.

8.2.1 National guidance

Participants consistently referred to *A Practical Guide to Clinical Audit* (HSE, 2013) as the primary reference source for conducting clinical audit. Participants also voiced their confusion between clinical audit and research, which highlighted the need for guidance in this area.

8.2.2 Governance and management of local clinical audit

Guidance for clinical audit should include governance advice and support. It emerged that there was variance between the local governance of clinical audit across the hospitals. Some departments had clear structures with defined roles and responsibilities, but this was not the case in all sites. Where clear structures for clinical audit were not in place, focus group participants reported limited clinical audit planning taking place, as well as poor governance:

“[There is a] lack of any proper structured audit oversight.”

- Focus group participant

The focus groups also highlighted a lack of designated roles to support clinical audit in clinical practice. One of the Model 4 hospitals had one whole time equivalent (WTE) clinical audit manager. The other Model 4 hospital was resourced with only a 0.1 WTE (i.e. 0.5 days a week) clinical audit manager. Participants highlighted the value of this “on the ground” support role, but also that they need more support. Numerous focus group participants in one Model 4 hospital noted the vast difference in support for clinical audit since the appointment of the clinical audit manager for 0.5 days a week. However, this role is spread across an entire hospital group, so is a limited resource. Participants stressed that:

“[You] need time and people.”

- Focus group participant

Focus group participants also acknowledged the positive difference made to clinical audit where this support exists.

8.3 Reflection on focus groups findings

One key finding was that the HSE Quality and Patient Safety Directorate publication, *A Practical Guide to Clinical Audit* (2013), is the seminal resource for clinical audit practice used by clinicians. Since its publication in 2013, both clinical audit practice and the environment in which it is carried out continue to evolve. Structures around governance, management, and supports for clinical audit need to be addressed to support the design and development of effective clinical audit practice. This National Review is cognisant of the impact of the current *A Practical Guide to Clinical Audit* and recommends that it be updated. This recommendation was endorsed by the Working Group and approved by the Steering Committee for the National Review of Clinical Audit.

Engagement with hospitals showed variation in management and governance of clinical audit, highlighting the need for guidance in this area. Where good management and governance structures of clinical audit were in place, focus groups participants, primarily clinicians, acknowledged the benefits of this. Structures which include designated leadership and where governance for clinical audit is appropriately included at department, directorate and executive level need to evolve within the current healthcare system. While there is some guidance currently available on governance (HSE, 2016c), this can be further defined for clinical audit both at a local and national level. It is recommended that this be included in the update of *A Practical Guide to Clinical Audit*.

8.3.1 Update of *A Practical Guide to Clinical Audit*

Up-to-date and evidence-based guidance will support healthcare professionals to design, develop and manage effective clinical audit. From this perspective, the Working Group examined *A Practical Guide to Clinical Audit* (HSE, 2013). While it covers many of the key areas involved in clinical audit design in exceptional detail and is a key resource for those on the ground, there were a number of key areas identified that should be updated.

This should include the following updates and additions, with associated templates which can be adopted locally:

- Leadership and management of clinical audit, including the roles and responsibilities of healthcare professionals
- Governance and accountability for clinical audit
- Registration and prioritisation of clinical audit in health service provider organisations
- Ethical framework for clinical audit
- Requirements for information governance.

Further details on the proposed updates and additions can be found in Appendix 4.

8.4 Recommendations

This National Review recommends that:

1. *A Practical Guide to Clinical Audit* (HSE, 2013) should be updated by the HSE to reflect best practice in clinical audit. It should be available via a dedicated HSE web portal for all clinical audit resources.
2. Healthcare professionals should use this new guidance to design and develop clinical audit.



CHAPTER 9 TRAINING IN CLINICAL AUDIT



CHAPTER 9: TRAINING IN CLINICAL AUDIT

9.1 Background

One of the key deliverables of the National Review was to identify and recommend any training needs to support improved clinical audit.

9.2 Key findings from the focus groups

There is very little on-site face-to-face training on clinical audit provided at hospital level. All three sites had training provided by HSE QIT. However, this was a limited resource (no longer available), and participants felt more was needed. Participants had to resort to other methods, and reported having to:

“Figure it out yourself.”

“Learn as you go along.”

- Focus group participants

Doctors in attendance, who require annual clinical audit for their professional competence scheme, reported feeling unsupported in achieving this competency:

“[You are] told you have to do [an] audit every year but not told how.”

- Focus group participant

Some participants reported that they had had good clinical audit training for specific national audits, such as those from NOCA. Participants reported very limited IT training provided to support clinical audit:

“All of us [are] expected to use Excel and other programmes to interpret and present audit results.”

- Focus group participant

A number of participants also expressed confusion regarding the interpretation of HIPE (Hospital In-Patient Enquiry) data used for clinical audit, with one participant remarking:

“[I] don’t trust the HIPE data.”

- Focus group participant

9.3 Reflection on focus group findings

Focus group participants acknowledged the positive impact of external face-to-face training delivered by a HSE QIT Quality Specialist. However, this resource is no longer available. With one specialist trainer, this was not a sustainable approach to provide training across 44 acute hospitals and extending into other health and social care organisations.

Focus group participants did not refer to external training from professional organisations, or internally available online clinical audit modules, such as those available on HSE LanD. An inventory of currently available training opportunities should be developed and published on a new dedicated HSE clinical audit web portal, to ensure that healthcare professionals are aware of available resources. This could be carried out at a national level and promoted by hospital groups, local hospitals, and other health service provider organisations. It is recognised that there are possible associated costs with some of these training options.

In terms of the provision of training, the HSE should develop and resource a blended learning approach to clinical audit training which includes face-to-face and virtual learning. This can be supported with a cascade approach to training (previously called train-the-trainer) and mentorship programmes. Leadership and support of healthcare professionals will be key to the impact of these approaches.

Focus groups participants identified barriers to clinical audit, such as data collection and interpretation, e.g. HIPE data and poor IT skills and capacity. Clinical audit enablers identified primarily barriers related to additional training and resources. While some of this may be available and indeed similar to clinical audit training, an inventory of currently available training opportunities needs to be developed and disseminated to ensure that best use is made of available resources. The possibility of multidisciplinary teams utilising the skills and competencies of those across professional groups could be explored in a local context. This should include clinical audit team members from the HIPE office and persons with IT or data analytical skills. This will not only address the needs of clinical audit teams but will also promote cross-team and cross-organisational knowledge transfer and contribute to a culture of learning within an organisation.

9.4 Recommendations

The National Review agreed the following recommendations to support training in clinical audit:

1. The undergraduate, postgraduate, and continuing professional development (CPD) education programmes of healthcare professionals should continue to support competence in clinical audit.
2. The HSE and health service provider organisations should develop and resource a blended approach to clinical audit training which includes face-to-face and virtual learning. This can be supported with cascade approach to training and coaching programmes.
3. Where such resources already exist, for example HSE LanD, these should be signposted on the new dedicated clinical audit portal and additionally at local level.



CHAPTER 10

LEGISLATIVE CHANGES AFFECTING CLINICAL AUDIT

10

CHAPTER 10: LEGISLATIVE CHANGES AFFECTING CLINICAL AUDIT

10.1 Background

The importance of legislation that supports both patient safety as well as advancing and improving care has never been more important. However, here in Ireland, concern has been expressed that an apparent shift in legislation is placing the entire work of improving and advancing care at risk. This is clearly demonstrated with the following two major legislative changes.

10.1.1 General Data Protection Regulation

The first is the transposition into Irish law of the EU General Data Protection Regulation (GDPR) (EU 2016/679) through the Data Protection Act (2018). GDPR is a regulation intended to strengthen and unify privacy and data protection rights for all individuals in the EU. It aims to give control back to citizens and residents over the uses of their personal data and requires organisations to be more explicit and transparent about the legal basis and reason for which they hold, use, and process personal data. There must be a lawful basis for processing personal data and transparency in the use of that data. The data must be secure, accurate, and not excessive, and only held for the length of time that is necessary. Central to this is good information governance. The regulation relates to personal data and allows for member states to interpret certain aspects of the Regulation in different ways. Section 36(2) of the Data Protection Act allowed for further regulations to be enacted by the Irish Government on the processing of personal data. Subsequently, Ireland enacted the Health Research Regulations (2018) to expand on the application of GDPR for healthcare research in Ireland.

10.1.2 Patient Safety Bill 2019

The second legislative change is the proposed Patient Safety Bill, the general scheme of which was published in July 2018. The Bill covers a number of patient safety priorities, including mandatory open disclosure of serious reportable patient safety incidents, the notification of reportable incidents to the regulator, the use of clinical audit to improve patient care and outcomes, and the extension of HIQA's remit to private hospitals. While the final Bill is as yet unpublished and therefore the exact wording unknown, it is known that all the above areas will be included. A number of clinical audits have ceased across the Irish healthcare system as a result of concerns relating to these pieces of legislation.

10.2 Key findings from consultation process

The key findings from the consultation process undertaken as part of this National Review relating to the interpretation of GDPR for clinical audit and the application of the Patient Safety Bill are presented in this section. These findings are based on the four focus group sessions carried out across three hospitals, as well as discussions with experts from the Working Group, Steering Committee, Advisory Panel, and a number of other experts who were approached as part of the National Review.

10.2.1 General Data Protection Regulation

The Data Protection Act (2018), under Section 36(2), allowed for additional regulations to be developed by the Irish Government around the processing of personal data. Subsequently, Ireland enacted the Health Research Regulations 2018 (SI No. 314 of 2018). These regulations have taken a strict interpretation of GDPR with regard to healthcare research, requiring GDPR consent to be secured before carrying out healthcare research. This strict interpretation will “place a significant extra burden of work on Ireland's clinical researchers and at their worst will force individuals and institutions out of the clinical research field, which will result in significant loss to the Irish knowledge economy and lead to the detriment of patient care” (Clarke *et al.*, 2019). Indeed, some hospitals have incorrectly interpreted the aspects of the Health Research Regulations as being applicable to chart access for clinical audit and have suspended clinical audit entirely.

Participants across all four focus groups expressed concerns about the implications of the new GDPR. Participants reported how they felt about the situation:

”

“Terrified.”

“Petrified.”

“No-one is getting to grips with it.”

- Focus group participants

Concerns were expressed that hospitals are not being given consistent national advice and therefore have to seek their own legal advice, which varies from hospital to hospital.

Focus group participants revealed their concerns if a strict interpretation of GDPR, in line with that applied for the Health Research Regulations, is applied to clinical audit. One participant expressed their fears:

”

“[The] whole system is heading for paralysis.”

- Focus group participant

10.2.2 Patient Safety Bill 2018

Following the publication of the general scheme of the Patient Safety Bill 2018, there were concerns that many clinical audits will not be afforded appropriate protection, and that clinical audit may be subject to open disclosure, as outlined in the Bill. Participants from the focus groups expressed real concern about the lack of clarity on when to engage in open disclosure; for example, whether the identification of potential patient safety incidents, or clinical audit non-compliance, leads to open disclosure, and the implication of this for clinical audit. Participants reported on the current situation:

”

“[Clinical] audit has decreased since new legislation fears.”

- Focus group participant

10.3 Reflection on findings from the consultation process

The current information void on the legislative and practical implications of these topics on clinical audit has led to a discourse which lacks clarity and is often misleading. Clear and consistent information across the healthcare system is required. Further regulations and guidance from both the Office of the Data Protection Commissioner and the Department of Health on the interpretation of GDPR for both healthcare practice and clinical audit, anticipated to come later in 2019, are eagerly awaited. In the meantime, interim guidance is included in the following Section 10.4. Clinical audit, incident management, and open disclosure are separate and distinct processes, all of which relate to the quality and safety of care. Guidance on clinical audit and patient safety is provided in Chapter 5.

10.4 General Data Protection Regulation

The following section has been adapted from advice prepared by NOCA to assist those carrying out clinical audit to understand and comply with GDPR requirements. The guidance is for educational and informational purposes only and should not be considered as legal advice.

10.4.1 Data collection and processing

Under GDPR, there must be a lawful basis for collecting and processing personal data and special categories of data, for example, health data. Consent from individuals is only one of the several lawful bases for the collection and processing of both personal and special category data under GDPR. Where consent is used as the lawful basis to carry out clinical audit, its potential for withdrawal could have a real and detrimental impact on clinical audit and its contribution to healthcare clinical effectiveness and quality improvement.

To minimise this, the use of the term ‘public health’ may be a more appropriate rationale or legitimiser for the collection and processing of clinical audit data. This approach supports population-based clinical audit. The other lawful bases that may be more appropriate to apply to clinical audit are ‘performing a contract’, ‘legitimate interest’ or ‘public interest’. The relevant sections of GDPR that can be applied to clinical audit are presented in Table 10.1.

Table 10.1 Relevant sections of GDPR relating to data collection and processing

The following sections of the GDPR can be used to support access to medical records to collect and analyse data (processing) to use in a clinical audit, which can be at local or national level. There must be a minimum of one lawful basis from each of Article 6 and Article 9.

Lawful basis for processing and special categories of personal data

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”.

and/or

Article 6(1)(c) – “processing is necessary for the performance of a contract” and

Article 9(2)(h) – ‘processing is necessary for the purposes of preventative ... medicine ... the provision of health or social care or treatment or the management of health or social care systems and services...’

Source: Regulation (EU) 2016/679 of the European Parliament and of the Council of the European Union

10.4.2 Important notes

- The Health Research Regulations are applicable only to research and not to clinical audits, routine direct care, look-back reviews, case reviews, or service evaluation.
- Clinical audit data for sharing and transferring should be pseudonymised or anonymised.
- Data retention relates to the purpose of the clinical audit. For example, NOCA NCAs retain data for the audit lifetime for longitudinal analysis. For local clinical audits, the retention period would be much shorter.
- Other aspects of GDPR, including professional and ethical rules, continue to apply when dealing with personal and health data.

10.5 Recommendations

The National Review recommends that:

1. The HSE Data Protection Officer (DPO) should provide guidance regarding the interpretation of GDPR, which should include specific guidance related to the application of GDPR to clinical audit. The HSE should then advise that individual DPOs adopt this approach to ensure consistency across all health service provider organisations.
2. The HSE should form a national healthcare data protection officer (DPO) network to support the process of consistent guidance to the system.
3. The HSE should provide timely guidance on any changes or updates to legislation and guidance which affects clinical audit. This should be published on a new dedicated clinical audit web portal that has been recommended by this National Review.

The background is a photograph of a hospital room, including a bed with a control panel, medical equipment, and a hallway. The entire image is overlaid with a semi-transparent red filter. At the bottom of the page, there are three large, light-colored, stylized vertical bars that resemble the number '11' or a similar graphic element.

CHAPTER 11 CONCLUSION

CHAPTER 11: CONCLUSION

This report sets out the current state of clinical audit in Ireland and makes recommendations to ensure its sustainability into the future. With the uncertainty and challenges facing clinical audit in 2018, the HSE CCO commissioned this National Review. Through the Steering Committee, Working Group, and Advisory Panel, membership was drawn from healthcare professionals, including senior managers from both the operational and strategic arms of the health service. This clearly demonstrates a cross-disciplinary belief in, and commitment to, clinical audit at this time. With support from service delivery and policy-makers, clinical audit is poised to become more valuable in informing the health service.

11.1 Benefits and limitations of this report

In terms of the approach to developing this report, a broad consultation process was envisaged. However, focus groups were solely conducted in hospital settings. While this may be a limitation in terms of consultation design, it is likely that the clinical audit process has progressed further in this healthcare setting than in others, such as primary or community care. It is envisaged that this report can provide a roadmap for clinical audit across healthcare boundaries.

The terms of reference of this National Review aimed to develop guidance on good audit design as a key deliverable. This would incorporate design requirements for clinical audit, including the aim, standards, data collection and analysis, implementing change and re-auditing, and the inclusion of worked examples. While it may be viewed as a limitation of the National Review that this was not achieved, delivery of a complete guidance is a complex process. It requires time for systematic research combined with stakeholder consultation and engagement to develop informed guidance. Rather than extend the timescale further, the National Review called attention to important additions and updates to the seminal guidance publication, *A Practical Guide to Clinical Audit*. This work will be commissioned by the HSE on completion of this National Review.

11.2 Summary

This National Review has concluded that clinical audit is essential to the Irish healthcare system and must be supported in order to continue to achieve improvement in patient care. The recommendations made in this report are the result of extensive consultation and research and are approved by a Steering Committee of experts from across the health service. These recommendations, where actioned, will ensure that clinical audit continues effectively, to the benefit of all patients.



REFERENCES

REFERENCES

Clarke, N., Vale, G., Reeves, E.P., *et al.* (2019) GDPR: an impediment to research? *Irish Journal of Medical Science*. Available from: <https://doi.org/10.1007/s11845-019-01980-2> [Accessed 24 May 2019].

Data Protection Act 2018 (No. 7 of 2018). Available from: <http://www.irishstatutebook.ie/eli/2018/act/7/enacted/en/pdf> . [Accessed 24 May 2019].

Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018. Available from: <http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf> [Accessed 24 May 2019].

Department of Health and Children (DOHC) (2008) *Building a culture of patient safety: Report of the Commission on Patient Safety and Quality Assurance*: Dublin: Stationery Office. Available from: https://health.gov.ie/wp-content/uploads/2014/03/en_patientsafety.pdf [Accessed 24 May 2019].

Department of Health Trauma Steering Committee (2018) *A trauma system for Ireland: Report of the Trauma Steering Committee*. Dublin: Department of Health. Available from: <https://health.gov.ie/blog/publications/a-trauma-system-for-ireland-report-of-the-trauma-steering-group/> [Accessed 24 May 2019].

Gershlick, B. (2016) *Best practice tariffs. Country background note: United Kingdom (England)*. London: The Health Foundation. Available from: <https://www.oecd.org/els/health-systems/Better-Ways-to-Pay-for-Health-Care-Background-Note-England-Best-practice-tariffs.pdf> [Accessed 13 May 2019].

The Health Foundation (2016) *Quality improvement made simple: what everyone should know about health care quality improvement*. London: The Health Foundation. Available from: <https://www.health.org.uk/sites/default/files/QualityImprovementMadeSimple.pdf> [Accessed 13 May 2019].

Health Information and Quality Authority (HIQA) (2012) *National standards for safer better healthcare*. Dublin: HIQA. Available from: <https://www.hiqa.ie/reports-and-publications/standard/national-standards-safer-better-healthcare> [Accessed 14 May 2019].

Health Research Board (2018) *What is research?* Dublin: Health Research Board. Available from: <https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/what-is-research/#c607> [Accessed 13 May 2019].

Health Service Executive (HSE) (2012) *Quality and patient safety – clinical governance development: an assurance check for service providers*. Dublin: HSE. Available from: <https://www.hse.ie/eng/about/who/qid/governancequality/resourcespublications/> [Accessed 14 May 2019].

Health Service Executive (HSE) (2013) *A practical guide to clinical audit*. Dublin: Quality and Patient Safety Directorate, HSE. Available from: <https://www.hse.ie/eng/about/who/qid/measurementquality/clinical-audit/practicalguideclaudit.html> [Accessed 14 February 2019].

Health Service Executive (HSE) (2015) *Code of governance*. Dublin: HSE. Available from: <https://www.hse.ie/eng/about/who/directoratemembers/codeofgovernance/governance.html> [Accessed 23 May 2019].

Health Service Executive (HSE) (2016a) *Quality and safety committees: guidance and resources*. Dublin: HSE. Available from: <https://www.hse.ie/eng/about/who/qid/governancequality/resourcespublications/> [Accessed 14 May 2019].

Health Service Executive (HSE) (2016b) *Framework for improving quality in our health service*. Dublin: Quality Improvement Division (QID) HSE. Available from: <https://www.hse.ie/eng/about/who/qid/framework-for-quality-improvement/framework-for-improving-quality-2016.pdf> [Accessed 23 May 2019].

Health Service Executive (HSE) (2016c) *Overview: governance for quality and safety*. Dublin: Quality Improvement Division (QID), HSE. Available from: <https://www.hse.ie/eng/about/who/qid/governancequality/governance-for-quality-and-safety-overview.pdf> [Accessed 15 March 2019].

Health Service Executive (HSE) (2017) *National Selective Ultrasound Screening Programme for Developmental Dysplasia of the Hip in Infants: Implementation Pack*. Dublin: HSE. Available from: <https://www.hse.ie/eng/services/publications/clinical-strategy-and-programmes/radiologyddhimplementaionpack.pdf> [Accessed 23 May 2019].

Health Service Executive (HSE) (2018) *Incident management framework*. Dublin: HSE. Available from: <https://www.hse.ie/eng/about/qavd/incident-management/hse-2018-incident-management-framework-guidance-stories.pdf> [Accessed 11 May 2019].

Health Service Executive (HSE) (2019a) *Healthcare audit standards*. Dublin: Quality Assurance and Verification Division (QAVD), HSE. Available from: <https://www.hse.ie/eng/about/qavd/audit-service/healthcare-audit-standards-2019.pdf> [Accessed 23 May 2019].

Health Service Executive (HSE) (2019b) *Quality assurance and quality control*. Dublin: HSE. Available from: <https://www.hse.ie/eng/about/who/qualityandpatientsafety/safepatientcare/medexradiationunit/quality-assurance-and-quality-control.html> [Accessed 23 May 2019].

Health Service Executive (HSE) (2019c) *Open disclosure policy: communicating with patients following patient safety incidents*. Dublin: HSE. Available from: <https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/opensdisclosure/> [Accessed 14 June 2019].

Hoque, D.M.E, Kumari, V., Hoque, M., Ruseckaite, R., Romero, L. and Evans, S.M. (2017) Impact of clinical registries on quality of patient care and clinical outcomes: a systematic review. *PLOS One*, 12(9): e0183667. Available from: <https://doi.org/10.1371/journal.pone.0183667> [Accessed 14 June 2019].

Hughes, A.J., Brent, L., Biesma, R., Kenny, P.J. and Hurson, C.J. (2019) The effect of indirect admission via hospital transfer on hip fracture patients in Ireland. *Irish Journal of Medical Science*, 188(2): 517–24. Available from: <https://doi.org/10.1007/s11845-018-1854-6> [Accessed 9 May 2019].

Institute of Internal Auditors (2017) *Internal auditing: assurance, insight, and objectivity*. Altamonte Springs, FL: Institute of Internal Auditors. Available from: <https://na.theiia.org/about-ia/PublicDocuments/PR-Value Prop Bro-FNL-Lo.pdf> [Accessed 24 May 2019].

The King's Fund (2017) *Making the case for quality improvement: lessons for NHS boards and leaders*. London: The King's Fund. Available from: <https://www.kingsfund.org.uk/publications/making-case-quality-improvement>. [Accessed 24 May 2019].

Mental Health Commission (2007) *Quality framework for mental health services in Ireland*. Dublin: Mental Health Commission. Available from: https://www.mhcirl.ie/for_H_Prof/NSforMHS/Quality_Framework_2017.html [Accessed 14 May 2019].

McCormick, B. (2012) *Pathway peer review to improve quality*. London: The Health Foundation. Available from: <https://www.health.org.uk/publications/pathway-peer-review-to-improve-quality> [Accessed 14 May 2019].

National Council for the Professional Development of Nursing and Midwifery (NCNM) (2008) *Framework for the establishment of clinical nurse/midwife specialist posts*. 4th edn. Dublin: NCNM. Available from: <https://www.lenus.ie/handle/10147/565741> [Accessed 24 May 2019].

National Clinical Effectiveness Committee (NCEC) and Health Information and Quality Authority (HIQA) (2015) *National quality assurance criteria for clinical guidelines*. Version 2. Dublin: NCEC and HIQA. Available from: <https://health.gov.ie/wp-content/uploads/2015/07/HIQA-NCEC-National-Quality-Assurance-Criteria-NCG-v2-April-2015.pdf> [Accessed 14 May 2019].

National Clinical Effectiveness Committee (NCEC) (2015a) *Prioritisation and quality assurance for national clinical audit*. Dublin: Department of Health. Available from: <https://health.gov.ie/national-patient-safety-office/ncec/national-clinical-audit/> [Accessed 14 May 2019].

National Clinical Effectiveness Committee (2015b) *Framework for endorsement of national clinical audit*. Dublin: Department of Health. Available from: <https://health.gov.ie/national-patient-safety-office/ncec/national-clinical-audit/> [Accessed 14 May 2019].

National Health Service (NHS) (2019) *2019/20 NHS standard contract*. London: NHS. Available from: <https://www.england.nhs.uk/nhs-standard-contract/19-20/> [Accessed 14 June 2019].

National Office of Clinical Audit (NOCA) (2015) *Irish Hip Fracture Database national report 2014*. Dublin: NOCA. Available from: <https://www.noca.ie/publications/publications-listing/P12/category/3> [Accessed 9 May 2019].

National Office of Clinical Audit (2018b) *Irish Hip Fracture Database national report 2017*. Dublin: NOCA. Available from: <https://www.noca.ie/publications/publications-listing/P0/category/3> [Accessed 9 May 2019].

National Office of Clinical Audit (NOCA) (2018c) *National Audit of Hospital Mortality annual report 2017*. Dublin: National Office of Clinical Audit.

National Perinatal Epidemiology Unit (NPEU) (2018) *Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE) – confidential enquiry topics*. Oxford: NPEU, University of Oxford. Available from: <https://www.npeu.ox.ac.uk/mbrrace-uk/topics> [Accessed 14 May 2019].

Oireachtas Committee on the Future of Healthcare (2017) *Sláintecare report*. Dublin: Houses of the Oireachtas. Available from: https://data.oireachtas.ie/ie/oireachtas/committee/dail/32/committee_on_the_future_of_healthcare/reports/2017/2017-05-30_slaintecare-report_en.pdf [Accessed 14 May 2019].

Scally, G. (2018) *Scoping Inquiry into the CervicalCheck Screening Programme*. Dublin: Department of Health. Available from: <http://scallyreview.ie/wp-content/uploads/2018/09/Scoping-Inquiry-into-CervicalCheck-Final-Report.pdf> [Accessed 11 March 2019].

Twycross, A. and Shorten, A. (2014) Service evaluation, audit and research: what is the difference? *Evidence-Based Nursing*, 17(3): 65–66. Available from: <http://dx.doi.org/10.1136/eb-2014-101871> [Accessed 14 May 2019].

Walker (2018) National Quality Improvement & Clinical Audit Network (NQICAN) Annual Report 2017/18. Available from: http://www.nqican.org.uk/index.php?p=1_5_Annual-Report. [Accessed 25 May, 2019]



BIBLIOGRAPHY

BIBLIOGRAPHY

Agency for Health Research and Quality (AHRQ) (2018) Types of quality measures. Rockville, MD: AHRQ. Available from: <https://www.ahrq.gov/professionals/quality-patient-safety/talkingquality/create/types.html>

Australian Council for Safety and Quality in Health Care (2002) *National report on qualified privilege*. Canberra: Australian Council for Safety and Quality in Health Care.

Australian Commission on Safety and Quality in Health Care (ACSQHC) (2019) Clinical care standards. Sydney: ACSQHC. Available from: <http://www.safetyandquality.gov.au/our-work/clinical-care-standards/>

Brain, J., Schofield, J., Gerrish, K., Mawson, S., Mabbott, I., Patel, D. and Gerrish, P. (2011) A guide for clinical audit, research and service review. London: Healthcare Quality Improvement Partnership (HQIP). Available from: <https://www.hqip.org.uk/wp-content/uploads/2018/02/hqip-guide-for-clinical-audit-research-and-service-review.pdf>

Burgess, R. (2011) *New principles of best practice in clinical audit*. London: Radcliffe Publishing.

Civil Liability (Amendment) Act 2017 Number 30 of 2017. Available from: <http://www.irishstatutebook.ie/eli/2017/act/30/enacted/en/html>.

Department of Health (2018) *General scheme of the Patient Safety Bill 2018*. Dublin: Department of Health.

Department of Health (2019) National clinical guidelines. Dublin: Department of Health. Available from: <https://health.gov.ie/national-patient-safety-office/ncec/national-clinical-guidelines/>

Department of Health UK (2008) Guidance on the routine collection of patient reported outcome measures (PROMs). London: Department of Health. Available from: http://www.healthcare-today.co.uk/doclibrary/documents/pdf/152_guidance_on_routine_collection.pdf

Dixon, N. (2013) Proposed standards for the design and conduct of a national clinical audit or quality improvement study. *International Journal for Quality in Health Care*, 25(4): 357–65.

European Parliament (2016) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). Luxembourg: Publications Office of the European Union.

Great Ormond Street Hospital for Children (2016) Clinical outcomes. London: NHS Foundation Trust. Available from: <https://www.gosh.nhs.uk/conditions-and-treatments/conditions-we-treat-index-page-group/clinical-outcomes>

Healthcare Quality Improvement Partnership (HQIP) (2015) What is clinical audit? And other frequently asked questions. London: HQIP. Available from: <https://www.hqip.org.uk/resource/what-is-clinical-audit-and-other-frequently-asked-questions/>

Healthcare Quality Improvement Partnership (HQIP) (2016) *Best practice in clinical audit*. London: HQIP. Available from: <https://www.hqip.org.uk/resource/best-practice-in-clinical-audit/>

Healthcare Quality Improvement Partnership (HQIP) (2016) *Developing a clinical audit programme*. London: HQIP. Available from: <https://www.hqip.org.uk/resource/developing-a-clinical-audit-programme/>

Healthcare Quality Improvement Partnership (HQIP) (2017) Guide to managing ethical issues in quality improvement or clinical audit projects. London: HQIP. Available from: <https://www.hqip.org.uk/wp-content/uploads/2017/02/guide-to-managing-ethical-issues-in-quality-improvement-or-clinical-audit-projects.pdf>

Healthcare Quality Improvement Partnership (HQIP) (2017) *Clinical audit – statutory and mandatory requirements*. London: HQIP.

Healthcare Quality Improvement Partnership (HQIP) (2017) *Using clinical audit in commissioning healthcare services*. London: HQIP.

Healthcare Quality Improvement Partnership (HQIP) (2018) *National Maternity and Perinatal Audit: Clinical report 2017 – revised version*. London: HQIP.

Healthcare Quality Improvement Partnership (HQIP) and Information Governance Alliance (IGA) (2017) *Information governance in local quality improvement*. London: HQIP. Available from: <https://www.hqip.org.uk/wp-content/uploads/2018/02/information-governance-in-local-quality-improvement.pdf>

HealthKnowledge (2019) Confidential enquiry processes. Gerrards Cross, Bucks: Public Health Action Support Team. Available from: <https://www.healthknowledge.org.uk/public-health-textbook/research-methods/1c-health-care-evaluation-health-care-assessment/confidentiality-enquiry-processes>

Health Research Authority (2017) Defining research table. London: Health Research Authority. Available from: http://www.hra-decisiontools.org.uk/research/docs/definingresearchtable_oct2017-1.pdf

Health Service Executive (HSE) (2016) *HSE Quality Improvement Division & Acute Hospitals Division clinical audit plan – April 2016*. Dublin: HSE.

Health Service Executive (HSE) (2016) HSE National Framework for Developing Policies, Procedures, Protocols and Guidelines (PPPGs). Dublin: National Quality Improvement Division and National Clinical Strategy and Programmes Division, HSE. Available from: <https://www.hse.ie/eng/about/who/qid/use-of-improvement-methods/nationalframework-developingpolicies/hse-national-framework-for-developing-policies-procedures-protocols-and-guidelines-pppgs-2016.pdf>

Health Service Executive (HSE) (2017) *Rapid appraisal of the healthcare audit function*. Dublin: Quality Assurance and Verification Division, HSE.

Health Service Executive (HSE) (2018) *Healthcare audit plan 2018/2019*. Dublin: Quality Assurance and Verification Division, HSE.

Health Service Executive (HSE) (2019) *Annual reports*. Dublin: Quality Assurance and Verification Division, HSE. Available from: <https://www.hse.ie/eng/about/qavd/audit-service/qpsaaudit.html>

Lincolnshire Community Health Services NHS Trust (2018) *Clinical audit policy and procedures, 2018–2021*. Lincoln: Lincolnshire Community Health Services NHS Trust Available from: https://www.lincolnshirecommunityhealthservices.nhs.uk/application/files/5815/3960/7206/P_CIG_17_Clinical_Audit_Policy_and_Procedures.pdf

National Office of Clinical Audit (NOCA) (2017) *Monitoring and escalation policy*. Dublin: NOCA.

National Perinatal Epidemiology Centre (2018) *Perinatal mortality in Ireland: annual report 2016*. Cork: National Perinatal Epidemiology Centre.

O'Hare, M.F., Manning, E., Corcoran, P., Greene, R.A., on behalf of MDE Ireland (2017) *Confidential Maternal Death Enquiry in Ireland: Report for 2013–2015*. Cork: MDE Ireland.

Polit, D.F. and Beck, C.T. (2005) *Essentials of nursing research: methods, appraisal and utilization*. 6th edn. Philadelphia, PA: Lippincott Williams and Wilkins.

Sackett, D.L., Strauss S.E., Richardson W.S. et al. (2000) *Evidence-based medicine: how to practice and teach EBM*. 2nd ed. Edinburgh: Churchill Livingstone.

Swonell, C. (2010) *Clinical audit policy*. Bristol: University Hospitals Bristol, NHS.

University Hospitals Bristol (2009) *What is clinical audit?* Bristol: NHS Foundation Trust.

Vassar, M. and Holzmann, M. (2013) The retrospective chart review: important methodological considerations. *Journal of Educational Evaluation for Health Professionals*, 10: 12. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3853868/>

Vreugdenburg, T.D., Forel, D., Marlow, N., Maddern, G.J., Quinn, J., Lander, R. *et al.* (2018) Morbidity and mortality meetings: gold, silver or bronze? *ANZ Journal of Surgery*, 88(10): 996–74. Available from: <https://doi.org/10.1111/ans.14380>

Williams, K., Sansoni, J., Morris, D., Grootemaat, P. and Thompson, C. (2016) *Patient-reported outcome measures: literature review*. Sydney: Australian Commission on Safety and Quality in Health Care.



APPENDICES

APPENDIX 1: PROJECT TERMS OF REFERENCE

National Review of Clinical Audit in the Irish Healthcare System

Terms of Reference

1. Purpose of this review

The purpose of this review is to identify the structures and supports required to ensure the continuation and flourishing of clinical audit across the Irish healthcare system.

There is strong support from clinicians, patient representatives, healthcare management and policy-makers to strengthen clinical audit, while also recognising that deficits exist in terms of governance, legal, funding, training, and support.

For this review, clinical audit includes national, local, individual clinician and healthcare audits carried out by the HSE Quality Assurance and Verification (QAV) Division.

2. Scope of work

The detailed schedule of work, based on the following scope of work, will be developed by the Working Group and approved by the Steering Committee.

- Identify the opportunities, risks and issues impacting clinical audit in the Irish healthcare system.
- Review the following reports to understand the current 'As Is' status of clinical audit in the Irish healthcare system:
 - NOCA National Clinical Audit Review Report, commissioned by the Chief Clinical Officer (CCO) in May 2018
 - Rapid Appraisal of the Healthcare Audit Function, Quality Assurance and Verification (QAV) Division
 - HSE QAV Healthcare Audit Plan 2018/2019
 - HSE Quality Improvement Division (QID) Clinical Audit Guidance and Tools
 - NOCA Establishing a Central Structure to Manage National Clinical Audits, 2018
- Review existing terminology used in the system.
- Review list of national data collection systems to determine the full set of national clinical audits.
- Review current guidance in relation to:
 - Clinical audit including selection, design, governance, use of data
 - Case reviews
 - Incident management and open disclosure.
- Review existing training and supports available for those managing and using audit data.
- Consider the ethical requirements of audit.
- Review existing governance of audits at national and local levels.
- Legal Review:
 - Existing and upcoming legislation in Ireland and its impact on clinical audit, e.g. Civil Liability Act, Patient Safety Bill, data protection and consent, e.g. outcomes with patient identifiable data
 - International legislation regarding clinical audit.
- Review clinical audit approaches in other countries to include selection, design, governance, use of data, incident management, and open disclosure and legal requirements.
- Undertake consultation process to understand the issues facing those on the ground using clinical audit, raising patient safety incidents and holding open disclosure meetings with patients and or their families, ethical concerns for clinical audit, and the future of clinical audit process, especially in terms of patient outcomes.
- Review all findings and recommendations of the Scoping Inquiry into the CervicalCheck Screening Programme and reflect these in this Review, where appropriate, and also specifically address the clinical audit recommendations, numbers 26 and 27:
 - "Auditing Cervical Screening
 - 26) Audits should continue to be an important component of cervical screening, as this complies with all good clinical practice. Common, robust and externally validated approaches to the design, conduct, evaluation and oversight of audits should be developed across the screening services.
 - 27) There should be a minimum of two patient advocates involved in the oversight of clinical audits for the screening services."

-
- Establish a process to support alignment of work currently under way at the Department of Health (DOH):
 - Patient Safety legislation and related guidance to include governance framework, the methodology and decision-making in relation to the clinical standard/guideline for the audit
 - International practices (tender under way)
 - Identify or set clinical standards and clinical guidelines for clinical audit at national or other levels.
 - Provide guidance on ethical issues in clinical audit.
 - National Clinical Effectiveness Committee (NCEC) National Audit Subcommittee
 - Nomenclature (definitions and criteria in relation to clinical effectiveness) so as to provide for consistency of approach and utilisation in the Irish health system.

3. Key deliverables

- Complete a set of core clinical audit guidance to include but not limited to:
 - Definitions of the types of clinical audit in the Irish healthcare system
 - Purpose of clinical audit, when and how to use it
 - Define the role of clinical audit in patient safety
 - Difference between a clinical audit and case reviews that look at individual patient care
 - Understanding the outputs of an audit and who will be responsible
 - Good design requirements for clinical audit, including aim, standards, data collection and analysis, implementing change and re-auditing
 - Set of worked examples regarding audit design, outputs, outliers and associated reviews.
- Identify any required changes to guidance regarding the application of the HSE incident management and open disclosure policies to clinical audit.
- Propose a set of recommendations regarding what constitutes 'Good Governance' for national and local clinical audit, which should also look to include arrangements for identifying, prioritising and maintaining a relevant portfolio of national audits and an 'Audit of audits' process to ensure compliance to required audit standards.
- Establish a set of recommended core local audits with supporting audit templates.
- Recommend any new training needs to support better clinical audits and use of their data to drive improvement.
- Produce a final report, to include recommendations and agreed guidance material, including any agreed actions required with identified owners, timeline and governance structure for oversight of implementation.

4. Change control

Any changes to the scope of work/deliverables will be brought by the Working Group to the Steering Committee for review and approval.

5. Governance

Clinical Audit Review Steering Committee

The Clinical Audit Review Steering Committee will:

- Ensure that the scope of work outlined in this document is delivered within the agreed time frame and to required standards.
- Provide advice and feedback to the Working Group.
- Be the final approval point for all proposals from the Working Group.
- Approve the final report.

Clinical Audit Review Steering Committee	
Prof. Sean Tierney (Chair)	Dean of Professional Development and Practice, RSCI Surgical Affairs
Dr Brian Creedon (Project Lead)	National Clinical Lead for Palliative Care (HSE/RCPI)
Eda Martin	Consultant Project Manager
Dr Philip Crowley	National Director, National Quality Improvement Team, HSE
Prof. Mary Day	Group CEO, Ireland East Hospital Group
Prof. Fidelma Flanagan	Clinical Director, Eccles BreastCheck
Angela Fitzgerald	Deputy Director, Acute Operations, HSE
Dr Gerry Fitzpatrick	Chair, Quality and Risk Subcommittee, Forum of Irish Postgraduate Medical Training Bodies Vice President, College of Anaesthesiologists of Ireland
Dr Anne Gallen	Director, Nursing Midwifery Planning and Development, HSE West
Karen Greene	Director of Nursing, Beaumont Hospital
Dr Vida Hamilton	National Clinical Advisor and Group Lead, Acute Hospital Operations, HSE
Patrick Lynch	National Director, Quality Assurance and Verification, HSE
Deirdre McNamara	General Manager, Office of Chief Clinical Officer, HSE
Prof. Conor O'Keane	Director of Quality and Clinical Care, RCPI
Dr Cathal O'Keeffe	Head of Clinical Risk, State Claims Agency
Dr Stephanie O'Keeffe	National Director, Strategic Planning and Transformation, HSE
Brian O'Mahony	Chief Executive, Irish Haemophilia Society
Iryna Pokhilo	Cáirde
Collette Tully	Executive Director, NOCA

Clinical Audit Review Working Group

The Clinical Audit Review Working Group will be responsible for the following:

- Finalising the review scope and plan
- Delivering the agreed project deliverables within the specified time frame
- Presenting proposed solutions to the Steering Committee for review and approval
- Engaging with advisors as required.

Clinical Audit Review Working Group	
Dr Brian Creedon (Chair, Project Lead)	National Clinical Lead for Palliative Care (HSE/RCPI)
Eda Martin	Consultant Project Manager
Dr Emer Ahern	Geriatrician, St Luke's General Hospital, Kilkenny, Ireland East Hospital Group, HSE
Margaret Brennan	Assistant National Director, Quality and Patient Safety, Acute Operations, HSE
Gareth Clifford	Quality, Standards and Compliance, Quality and Patient Safety, Acute Operations, HSE
Marina Cronin	Head of Quality and Development, NOCA
Ms Christine Kiernan	National Fellow for Innovation and Change, NDTP
Gavin Maguire	Head of Operations, Quality Assurance and Verification Division, HSE
Cora McCaughan	Assistant National Director, Healthcare Audit, Quality Assurance and Verification Division, HSE
Linda McEvoy	Clinical Governance and Audit Manager, Beaumont Hospital
Caitriona McGrath	Manager, Specialty Quality Improvement Programmes, RCPI
J.P. Nolan	Head of Quality and Patient Safety, National Community Healthcare QPS Office, HSE
Nicola O'Grady	Quality Improvement Specialist, National Quality Improvement Team, HSE
Collette Tully	Executive Director, NOCA
Angela Tysall	Lead in Open Disclosure, National Quality Improvement Team, HSE

6. Advisory Panel

The following experts will provide independent advice and guidance to the Working Group and Steering Committee as required.

Clinical Audit Review Advisory Panel	
Teena Chowdhury	Royal College of Physicians, UK
Dr Eric Hans Eddes	Dutch Institute for Clinical Auditing, the Netherlands
Prof. Belinda Gabbe	Australian Trauma Registry, Monash University
Jenny Hogan	Clinical Effectiveness Officer, Clinical Effectiveness Unit, National Patient Safety Office, Department of Health
Jane Ingham	CEO, Healthcare Quality Improvement Partnership (HQIP)
Linda Kelly	Assistant Director of Nursing, Ulster Hospital, South Eastern Health and Social Care Trust, Northern Ireland
Kim Rezel	Patient and Public Involvement Lead, HQIP
Dr Suja Somanadhan	Chair, Irish Clinical Audit Network (ICAN)
Dr Suzanne Timmons	Community Audit Advisor, HSE

External legal advice will be sought on a needs basis only and in agreement with the Steering Committee and the Sponsor.

7. Reporting structure

The Clinical Audit Review Working Group will report, via the Chair, to the Steering Committee. The Steering Committee Chair and Sponsor will return any matters of national/institutional importance to the HSE Senior Leaders Group and or the Department of Health.

8. Duration

The duration of this review is six months from the date the project manager is in place. The Working Group will produce a detailed plan within one month of their first meeting for approval by the Steering Committee.

APPENDIX 2: MEMBERSHIP OF SUBGROUPS

Good Audit Design Subgroup	
Eda Martin	Consultant Project Manager
Marina Cronin	Head of Quality and Development, NOCA
Ms Christine Kiernan	National Fellow for Innovation and Change, NDTP
Linda McEvoy	Clinical Governance and Audit Manager, Beaumont Hospital
Caitriona McGrath	Manager, Specialty Quality Improvement Programmes, RCPI
Nicola O'Grady	Quality Improvement Specialist, HSE National Quality Improvement Team

Focus Group Subgroup	
Eda Martin	Consultant Project Manager
Margaret Brennan	Assistant National Director, Quality and Patient Safety, Acute Operations, HSE
Gareth Clifford	Quality, Standards and Compliance, Quality and Patient Safety, Acute Operations, HSE
Linda McEvoy	Clinical Governance and Audit Manager, Beaumont Hospital
Nicola O'Grady	Quality Improvement Specialist, HSE National Quality Improvement Team
Collette Tully	Executive Director, NOCA

Patient Safety Incident Subgroup	
Margaret Brennan	Assistant National Director, Quality and Patient Safety, Acute Operations, HSE
Angela Tysall	Lead in Open Disclosure, Quality Improvement Team, HSE

APPENDIX 3: QUESTIONS USED AT FOCUS GROUPS

1. Audit structures (planning, approval, design and governance)

Can you describe the audit structures in place (audit office, audit manager, clinical lead)?

- What works well?
- What do you think could be improved?
- What have you seen in other places that worked well?

2. Audit training

Can you describe what training and support you receive to carry out clinical audit?

- What works well?
- What do you think could be improved?
- What have you seen in other places that worked well?

3. Use of audit data

Can you describe how audit data is used to drive improvement?

- What works well?
- What do you think could be improved?
- What have you seen in other places that worked well?

4. Legislation

Have your audits been (or will they be) impacted by any new legislation (GDPR, Patient Safety, Civil Liability Bill)?

- Do you find the published guidance useful?
- Have your audits been impacted by data protection?
- Are you clear on what is not clinical audit?

5. Any other suggestions?

Please let us know if you have any other suggestions.

APPENDIX 4: UPDATE TO A PRACTICAL GUIDE TO CLINICAL AUDIT (2013)

The following additions have been identified by the Working Group as being necessary to ensure *A Practical Guide to Clinical Audit* (HSE, 2013) encompasses all the essential parts of good audit design. The majority of the recommendations relate to the pre-audit stage of clinical audit design, as this area is not currently addressed in the guidance. Consideration should also be given to including sample templates in the updated guidance which can be adapted and/or adopted at local level. Any template should also be available as a stand-alone document on a dedicated clinical audit web portal. A number of examples of useful templates are included in Appendices 5–10.

Pre-audit

1. Define the roles and responsibilities of:

- Clinical audit manager or quality and safety manager
- Hospital management responsibilities to include:
 - Approval of clinical audit strategy
 - Oversee the development of a clinical audit programme within a quality framework
 - Ensure resource availability – personnel, IT, data management.
- Hospital group management
- All healthcare professionals.

2. Registration and approval of clinical audit

- All health service provider organisations should maintain a register of clinical audits – proposed, current and closed.
- It should be highlighted that the clinical staff who register an audit hold the responsibility for its management, including timelines, completion, and follow-up.
- Individual audits should have a sign-off confirming they have handed their clinical audit work over to a consultant or appropriate clinical lead. This will allow others to take up the work and complete the clinical audit cycle.
- Plan for audit completion – contingency to be in place, especially for clinical audits led by NCHDs, who are likely to be rotated to another site. A multidisciplinary input and approach, where appropriate, should be considered and encouraged.

3. Prioritisation of clinical audit

- Clinical audit should be prioritised in health service provider organisations. Only those meeting prioritisation criteria are eligible for support from health service provider organisations.
- Consider a template to prioritise clinical audit, such as that outlined in Table A4.1. This should take immediate and prevalent risks as well as resources into consideration.

Table A4.1 Prioritisation of clinical audit in health service provider organisations

Audit	Category	Examples
National clinical audit	External	<ul style="list-style-type: none"> • NOCA and NPEC • RCPI • HIQA requirements (e.g. infection control monitoring)
Local clinical audit	Internal must do	<ul style="list-style-type: none"> • Clinical risk / serious incidents • Complaints • Re-audit
Local clinical audit	Organisational/ corporate priority	<ul style="list-style-type: none"> • Local topics important to the organisation, e.g. national clinical guidelines, healthcare audits such as consent, healthcare records, or corporate • Directorate-specific audits, e.g. return to theatre • Hospital service plan, e.g. pressure injuries; serious falls
Local clinical audit	Department, specialty or professional interest	<ul style="list-style-type: none"> • Department/specialty, e.g. surgical site infection, medication compliance or arising from HSE Clinical Programme • Professional interest – clinician/advanced nursing practice or clinical nurse specialist/health and social care professional

4. Ethical framework for clinical audit

- Ethical guidance should be included in clinical audit. While Research Ethics Council (REC) approval is not needed for clinical audit, there are still ethical considerations at the planning, data collection, and data review stages of the audit. The HQIP guidance, *Guide to Managing Ethical Issues in Quality Improvement or Clinical Audit Projects* (2017), is a useful resource for this aspect.
- A checklist should be developed and included to help identify whether a proposed project constitutes research or clinical audit, where confusion exists. This could be included in an audit proposal form, for example, the Beaumont Audit Registration Form in Appendix 5.

5. Information governance

- This section in the guidance should be strengthened by addressing the following: collection, processing, analysis, storage, and retention of data, as well as confidentiality, dissemination, and reporting.
- The section needs to briefly outline to whom requests should be submitted, as well as whom to consult with any queries (such as IT, data, and clinical specialists).
- It should include guidance on how to maintain anonymous and pseudonymous records.
- It should make clear that the data collected belongs to the hospital.
- It should consider if the work of any others should be cited.

6. Accountability

- Depending on the specialty and/or primary role of the auditor, accountability should rest with the most senior colleague.
- Selection of the most senior colleague should be realistic.
- The primary auditor should be identified, as well as any secondary or tertiary ones.
- Clinical audit findings should be reviewed at all management levels. Key findings should be submitted with the audit. The recommendations should then be agreed by appropriate senior management. Transparency is an integral aspect of well-designed clinical audit, promoting trust in clinical services and illustrating governance and accountability. Publishing or making public clinical audit results is key to this. Clinical audit findings should therefore be published. This can be in journals, at the local level (website with a brief summary of the key findings), posters at conferences, etc. Health service provider organisations may consider inclusion of quality information in annual reports. In England, NHS hospitals and trusts include clinical audit and quality information in an annually published Quality Account. This is a mandatory requirement to assure funding. (Available from: <https://www.nhs.uk/Services/UserControls/UploadHandlers/MediaServerHandler.ashx?id=23958&t=636882990020171639> [Accessed 5 April 2019]).

The five-stage approach to clinical audit

Stage 1: Planning for audit

- Clinical audit topics should be developed with quality improvement focused aim and objectives. Responsibility for achieving this should rest with the auditor.
- Quality impact assessments should be carried out.

Stage 2: Standard/criteria selection

- This is sufficiently covered in the guide.

Stage 3: Measuring performance

- Guidance on managing areas of concern identified by the audit should be included. See Chapter 5: Clinical audit and Patient Safety
- Local policy and associated templates should be developed. See Appendix 5 for an example of an audit registration form which can be adapted (Appendix 5: Audit Registration Form [Beaumont Hospital]).

Stage 4: Making improvements

- The use of quality improvement (QI) methodologies to implement changes should be highlighted.
- A basic Plan-Do-Study-Act (PDSA) example in the guidance should be included.

Stage 5: Sustaining improvements

- It should be highlighted clearly that closing the loop or a control phase will be key to fulfilling the function of clinical audit.
- Recommendations should be separated into short-term and long-term feasibility.

APPENDIX 5: AUDIT REGISTRATION FORM (BEAUMONT HOSPITAL)

CLINICAL AUDIT REGISTRATION FORM Beaumont Hospital & St. Joseph's Raheny



Audits, which have a **patient focus** and measure **multi-professional practice** across services, are encouraged.

AUDIT TITLE:

REASONS FOR CHOICE OF AUDIT:
National Priority –

Local Priority -

AUDIT OBJECTIVE(S)

AUDIT STANDARDS:
What standards will you be auditing against? *(Continue on separate sheet if necessary)*

CONSULTATION:
Will the audit involve patients?
Will the audit involve other health professionals?
Will the audit involve other organisations?

If yes to any of the above, has their agreement been obtained to carry out the audit?

CLINICAL AUDIT REGISTRATION FORM
Beaumont Hospital & St. Joseph's Raheny



AUDIT METHODOLOGY:

Please provide outline of proposed methodology:

Data Source:

- | | | | |
|----------------------------|--------------------------|---------------------------|--------------------------|
| Data collection Proforma | <input type="checkbox"/> | Healthcare Records | <input type="checkbox"/> |
| Integrated pathway of care | <input type="checkbox"/> | Computer held information | <input type="checkbox"/> |
| Questionnaire | <input type="checkbox"/> | Patient experience | <input type="checkbox"/> |
| Interview | <input type="checkbox"/> | Consumer group | <input type="checkbox"/> |
| HIPE/Coding | <input type="checkbox"/> | Other | <input type="checkbox"/> |

- | | | | |
|---------------|--------------------------|-----------------------|----------------------|
| Prospective | <input type="checkbox"/> | Proposed Sample Size: | <input type="text"/> |
| Retrospective | <input type="checkbox"/> | | |

Proposed Start Date: _____ Proposed End Date: _____

How do you intend to share the audit results?

PROJECT LEAD(S):	Directorate/Dept:
Position:	Tel/Ext/Bleep No:
[Digital] Signature of project lead:	
Date:	

CLINICAL AUDIT REGISTRATION FORM
Beaumont Hospital & St. Joseph's Raheny



GDPR Checklist:

GDPR's requirements do not apply to fully anonymous data or audits carried out on RIP patients.

Please ensure that all data Performa's are maintained in a safe locked office/desk/drawer – and ***shredded*** once uploaded onto Excel™ or equivalent.

All electronic data ***must*** be stored on secure encrypted computer – do not email via unsecured addresses or use non-encrypted USB keys.

IF POSSIBLE GET SIGNED CONSENT OFF PATIENTS IN YOUR PROPOSED AUDIT COHORT

Article 9 (2)(h): “Processing necessary for purposes of preventive or occupational medicine, for assessment of working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services”

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 and of medicinal products or medical devices.... “

Article 9 (2)(j): “processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.”

General Comments:

Article 9/2/h permits audit to be carried out, when the objective of the audit is to assess current practice with best practice / standard of care, to assess outcome from specific treatments, monitor current practices within Beaumont Hospital and in the interest of patient safety.

Article 9/2/i permits audits to be undertaken when ascertaining usage, complications, profile and /or effectiveness of medication and /or medical devices.

Only collect data that is pertinent to your objectives / aims - if data is not needed DON'T collect it.
“...adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed Article 5/1/c”

Data must be accurate and where possible kept up to date (Article 5/1/d)

Data can only be collected by employees of Beaumont Hospital (exceptions dealt with on individual basis).

Once your audit is completed shred all paper records and permanently delete all electronic data. “...data should be kept for no longer than necessary Article 5/1/e”

Treat your data like the PIN code of your ATM card...

CLINICAL AUDIT REGISTRATION FORM
Beaumont Hospital & St. Joseph's Raheny



OFFICE USE ONLY

CLINICAL AUDIT MANAGER

Date Reviewed: _____ Signed by: _____

Checklist

- | | |
|--|-----|
| 1. Is the audit in compliant in GDPR? | Y/N |
| 2. Infringe on any patient's rights? | Y/N |
| 3. Risk breaching any patient's confidentiality or privacy? | Y/N |
| 4. Place a burden on a patient beyond those of his or her routine care? | Y/N |
| 5. Involve any clinically significant departure from usual clinical care? | Y/N |
| 6. Involve a potential conflict of obligation? | Y/N |
| 7. Involve the use of any untested clinical or systems intervention? | Y/N |
| 8. Allocate any interventions differently among groups of patients or staff? | Y/N |
| 9. Provide no direct benefit to patient to patient care? | Y/N |

Approved: **Y/N**

Registration Number: **CA**_____

Other

CLINICAL AUDIT REGISTRATION FORM
Beaumont Hospital & St. Joseph's Raheny



**GUIDANCE NOTES FOR THE COMPLETION OF THE
CLINICAL AUDIT PROPOSAL FORM**

Please use these notes to help you complete the form. If you require any further assistance, contact your Clinical Governance/Audit Manager.

Audit Title: Describe the subject of the audit as completely as possible.

Reason for Audit: Explain why the audit subject was selected. Is it a National or Local priority? Do the reasons for undertaking the audit project include the high volume, cost or risk associated with the topic area; the existence of evidence of a serious quality problem in the topic area; evidence on effectiveness; or the likelihood of a significant and achievable quality improvement in the topic area.

Audit Objectives: These must be measurable and specific i.e. what are you trying to achieve by undertaking this audit. Clear objectives will enable you to focus project activity ("To ensure that...." To determine if...")

Audit Standards: A standard is the basis for measurement by which the accuracy or quality of something is judged. Please list the standards of care along with any exceptions. These are used to evaluate your care.

N.B. A **standard** of care is a statement describing what should be done or what should be happening. An **exception** is any clinically acceptable reason why the standard of care will not be met

Audit Support: The Clinical Governance /Audit Manager is available to assist with planning audits and facilitating the completion of the audit cycle.

Consultation: Indicate whether the audit involves patients or other professionals. You should **not** audit other people's work without their consent. Please indicate whether the agreement of other professionals has been obtained to carry out this audit. Audits have a greater chance of success if all staff likely to be affected by the audit process or the changes identified, are involved at the outset.

Audit Method: Indicate the audit method and the source(s) of the data to be used for the audit. Indicate the proposed sample size, an approximate start and end date for the audit project and specify how you intend to share the results of your audit.

Project Lead: Name of the person responsible for ensuring the audit is undertaken and completed.

APPENDIX 6: CLINICAL AUDIT PROPOSAL FORM (CORK UNIVERSITY HOSPITAL)



CUH
Ospidéal na hOllscoile Corcaigh
Cork University Hospital

Section A: Clinical Audit Proposal Form

Please complete in Full

This proposal form is for Clinical Audit & Service Evaluation only.

Name		Department	
Title		Contact Details	

Clinical Audit Service Evaluation
 Priority 1 Audit Priority 2 Audit Priority 3 Audit Priority 4 Audit

Clinical Audit title / Service Evaluation details

Why are you proposing to conduct this audit /service evaluation? Why was this topic chosen?

What standards will you be auditing against? Please attach a copy of the relevant standard(s) to the submission

**Describe the audit tool you intend to use? Please attach a copy of the audit tool to the submission
(for service evaluation, measurement should be prospective)
Contact the Quality office if you need assistance in designing an audit tool or service evaluation spread sheet.**

Outline the PDSA cycle indicating the improvement you plan to implement.

Clinical Audit – Quality Unit –Cork University Hospital

Please tick additional reasons (if any) for carrying out this audit:

- | | | | |
|---------------------------------|--------------------------|--|--------------------------|
| Patient centeredness | <input type="checkbox"/> | Professional development | <input type="checkbox"/> |
| High volume activity | <input type="checkbox"/> | Service improvement | <input type="checkbox"/> |
| High risk activity | <input type="checkbox"/> | Re-audit | <input type="checkbox"/> |
| High cost activity | <input type="checkbox"/> | Risk management | <input type="checkbox"/> |
| Policy/guideline recommendation | | Specify if: Local <input type="checkbox"/> National <input type="checkbox"/> | |

Other, please state: _____

Each audit should satisfy all of the following:

- Aim to improve patient care.
- Be multidisciplinary where possible.
- Have support within your department head, including a willingness to implement changes.
- Be compliant with GDPR.
- Be patient centred

Have all the potential stakeholders been identified? Yes

1

List relevant stakeholders by name

Are these stakeholders aware of this audit?

_____	<input type="checkbox"/>	<input type="checkbox"/>
_____	<input type="checkbox"/>	<input type="checkbox"/>
_____	<input type="checkbox"/>	<input type="checkbox"/>
_____	<input type="checkbox"/>	<input type="checkbox"/>

Has a literature search been undertaken?

Sample size:

Length of time to audit and target completion date: _____ date

Outline your data protection management plan:

By signing this document you undertake to handle all data in line with GDPR

Signed: _____ Signed: _____

Audit Lead

Head of Department / Clinical Service / CUH Consultant

Office Use only	Audit Number:		
Date Received:	Signature:	Date Reviewed:	Signature:
Date of Notification of Approval to Audit Lead:			Signature:

Clinical Audit – Quality Unit – Cork University Hospital Section A

APPENDIX 7:CLINICAL AUDIT REPORT TEMPLATE (BEAUMONT HOSPITAL)

Clinical Audit Report Beaumont Hospital



Submitted to:	Date:
Submitted by:	Date:

Title of Audit & Registration Number:

Author/Team/Clinician/Department/Directorate:

Aim:

Objectives:

Standards Referenced/ Evidence Base:

Clinical Audit Report

Beaumont Hospital



Criteria (Data points used to measure standards)

Methodology:

Findings:

Clinical Audit Report

Beaumont Hospital



Recommendations:

Clinical Audit Report
Beaumont Hospital



Quality Improvement Plan / Initiative

TITLE OF CLINICAL AUDIT:

AUDIT REGISTRATION NUMBER CA

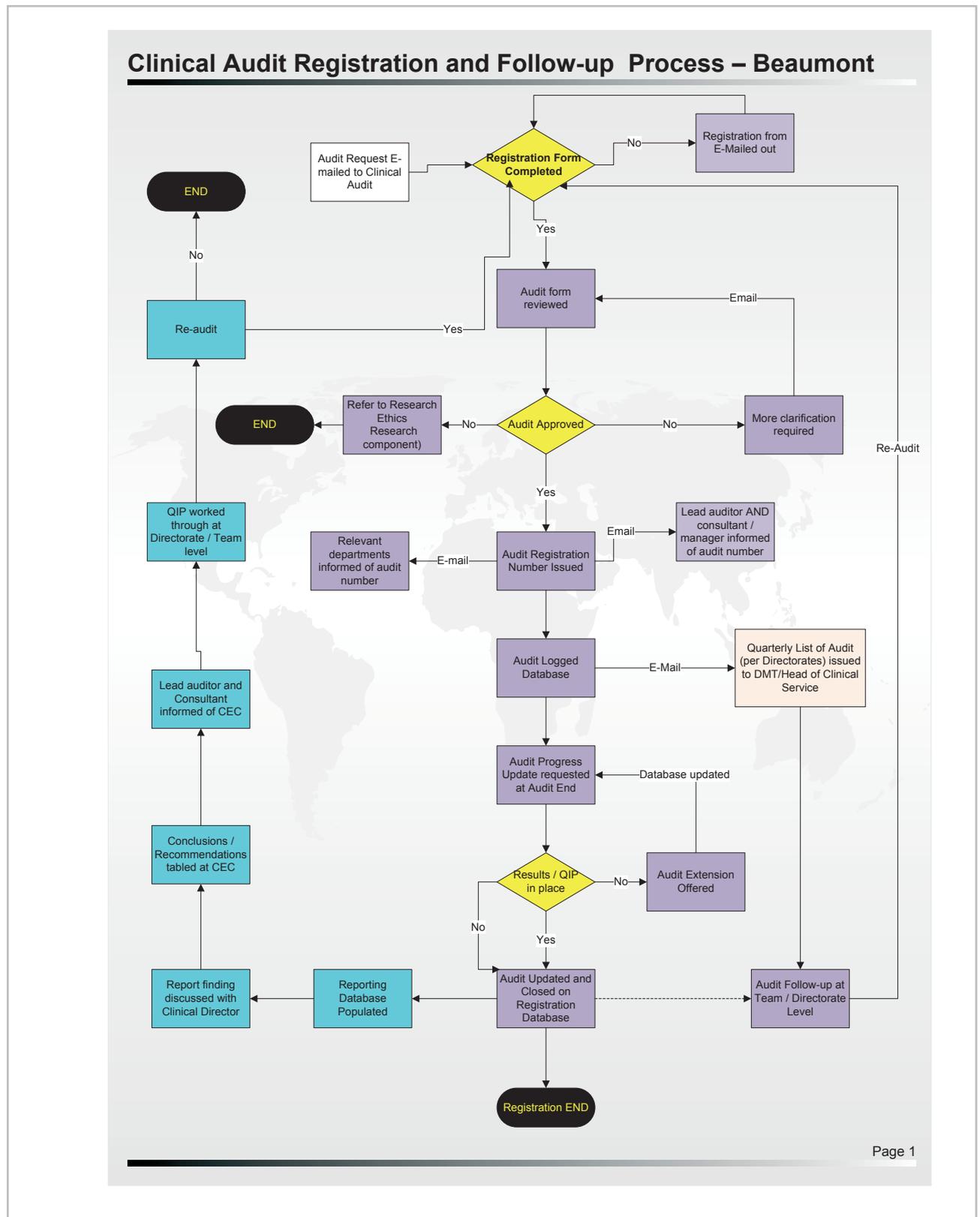
DIRECTORATE:

SPECIALITY/DEPT:

DATE:

Recommendation(s) for Improvement	Action to be Undertaken	By Whom (Will deliver action)	Completion Timescale (Date)	Has this been completed Yes/ No	Please ensure you state the Improvements/Outcomes/Changes in practice? (Have we made a sustainable improvement?)
1.					
2.					
3.					
4.					
5.					

APPENDIX 8: CLINICAL AUDIT PROCESS (BEAUMONT HOSPITAL)



APPENDIX 9: CLINICAL AUDIT INFORMATION LEAFLET (TALLAGHT UNIVERSITY HOSPITAL)

“Clinical audits give me a way to demonstrate that my service is meeting quality targets. It’s part of a culture that puts quality firmly on the agenda” Manager



Clinical Audit Cycle



Further Information

If you require any further information please contact

Clinical Audit Department

01 414 2855

Did you find this leaflet helpful?

Let us know if you have any suggestions as to how we could improve.

Return email suggestion to clinicalaudit@amnch.ie

Protection of your personal data is important. Clinical audits comply with the General Data Protection Regulations (GDPR)
Document reviewed 01/07/2018



PATIENT INFORMATION LEAFLET

Clinical Audit

Checking you receive safe evidence-based care

What is Clinical Audit

Clinical audit is one of the ways Healthcare Professionals check that the care they provide to Patients is safe and up to date. This is called evidence-based practice



Doctors, Nurses and other Healthcare Professionals conduct clinical audits as part of their professional responsibilities to ensure you receive the highest quality care.

A clinical audit involves selecting an area of practice that needs to be checked, identifying the latest best practice (evidence/standards) and then comparing care to the evidence. If the audit results show areas that could be improved then changes are made and the audit is repeated to monitor progress. This is called the clinical audit cycle.

“Clinical audits give me a way to check that the care I am providing is of a high standard. It helps with my education and training and keeps me up to date with best practice”
Lead Clinical Director

Confidentiality & Data Protection



We may use information contained in your healthcare record in order to carry out a clinical audit.

You will not be contacted directly and you do not need to give your consent if we use your healthcare information for a clinical audit.

This is because your name and personal details are either not used or kept confidential and are not included in the audit findings and audit report.

Sometimes a clinical audit involves patients taking an active part in the audit process and your personal details are an important part of the audit. In this type of audit you will be asked to give your consent.

Types of Clinical Audits

There are different types of clinical audits. Below are some examples.

- Hand hygiene audit
- Documentation audit
- Patient observations
- Medication prescribing

Some audits involve observing a healthcare professional’s practice. Other audits involve review of a patient’s healthcare record or talking to patients.

“I was asked to take part in a clinical audit. I was pleased to answer questions because it was good to know that my experience might help to improve the service and it is reassuring that they are looking at the care that they give” Patient

APPENDIX 10: NATIONAL CLINICAL AUDIT REVIEW - JUNE 2018



Title	National Clinical Audit Review – Open Disclosure: Final Report
Prepared for	Dr Colm Henry, HSE Interim Chief Clinical Officer Dr Philip Crowley, HSE National Director, Quality Improvement Division
Prepared by	Colette Tully, Executive Director, NOCA Marina Cronin, Head of Quality & Development, NOCA On behalf of the Short Life Working Group
Date	18 June 2018

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Background

Following on from the open disclosure issues raised regarding clinical audit in the Cervical Screening Programme, the HSE Chief Clinical Officer and the National Director of the HSE Quality Improvement Division have requested that each National Clinical Audit (NCA) Organisation carry out an assessment of their audits. The review was to be coordinated by NOCA.

Approach

To carry out this work, a short life working group was convened. This involved three face-to-face and web-based meetings between 22 May 2018 and 5 June 2018. Further consultation processes were undertaken to support this review. These included:

- NOCA Clinical Leads were consulted at a recent Clinical Lead Symposium held in RCSI on 23 May 2018.
- Key international contacts in the Royal College of Physicians, UK; Victorian State Trauma Outcomes Registry Monitoring Group (VSTORM); South Eastern Trust, Northern Ireland, and the Dutch Institute of Clinical Auditing.

A desktop review was undertaken, primarily focusing on grey literature from key organisations leading in clinical audit and open disclosure. This search resulted in policy documents, national standards, and references to legislation. NOCA provided the governance for this review.

National clinical audits in scope

- NOCA
 - Major Trauma Audit
 - Irish National ICU Audit
 - Irish Hip Fracture Database
 - National Audit of Hospital Mortality (NAHM)
 - Irish National Orthopaedic Register
- NPEC
 - Severe Maternal Morbidity in Ireland
 - Perinatal Mortality in Ireland
 - Very Low Birth Weight Infants in Ireland
- National Paediatric Mortality Register (NPMR) (Temple Street)
- RCPI Specialty Quality Improvement Programmes
 - Gastrointestinal Endoscopy
 - Histopathology
 - Radiology
- Stroke Register, National Stroke Programme
- Sepsis Audit, HSE Clinical Strategy and Programmes Division
- National Early Warning System (NEWS), Clinical Strategy and Programmes Division, HSE
- Heartbeat ACS Audit (HSE)

Key deliverables

- Establish a working group with representatives from:
 - Each audit organisation
 - HSE Open Disclosure Advisor
 - HSE Healthcare Audit, Quality Assurance and Verification Division.
- Carry out a review of international best practice for national clinical audit re outlier management, accountability and open disclosure.
- Prepare a checklist to aid each audit complete its review regarding:
 - Quality measures contained within audit data set
 - Reporting from audit
 - Management of outliers.
- Prepare a final presentation for the HSE Chief Clinical Officer and the National Director of the HSE Quality Improvement Divisions.

Findings

Aggregated findings are collated from 16 national audits; 15 national clinical audit and one compliance audit.

Table 1 Quality measures contained within audits N=16

Quality measure	Yes	No	Missing Data
Process Measures	11 (69%)	4 (25%)	1 (6%)
Clinical Outcomes	12 (75%)	4 (25%)	–

Table 2 Reporting from audit N=16

	Yes	No	Missing Data
Reports to hospitals	12 (75%)	3 (19%)	1 (6%)
National report	14 (88%)	1 (6%)	1 (6%)

Reports to hospitals range from locally user-generated reports to reports issued throughout the year from the national clinical audits. The latter ranges from one to at least four reports issued to the receiving hospitals. Nine NCAs send reports only to hospitals, while three include hospital groups. Three national clinical audits do not send hospital reports – one audit is currently developing reports and two audits only produce hospital-level reports.

Fourteen national clinical audits produce a national report. This review did not explore if presentation of these reports is included in a named group and or hospital-level information.

Table 3 Management of outliers N=16

	Yes	Yes with issues	No	In development	Missing Data
Policy on outlier management	8 (50%)	3 (19%)	2 (12%)	3 (19%)	–
Serious reportable events (SREs) identified following data validation process	2 (12%)	N/A	14 (88%)	N/A	–

The purpose of this is to ascertain if the national clinical audits have a process to identify statistical outliers and SREs. Two audits have the potential to identify SREs (HSE, 2015) following a data validation process; for example, the Irish National Orthopaedic Register has the potential to identify concerns about the site of surgery. Hospitals have to carry out a data quality assessment to confirm the site of surgery. If following this, a patient safety incident or specifically an SRE is identified, incident management and open disclosure is the responsibility of the hospital.

Structures for national clinical audit

This review highlighted a need for investment in audit infrastructure to ensure a sustainable future and high-quality audit.

Table 4 Concerns raised by national clinical audit organisations

Hospital level

- No protected time for staff to carry out audit – there is variation across hospitals depending on available resources.
- Lack of formal audit training for hospital staff – no national clinical audit staff.
- Clinical Leads are time and resource poor to address local clinical audit issues.

National clinical audit level

- Lack of national governance and management structures for audit. Some audits are run from HSE National Clinical Programmes, with lack of support for governance, resourcing and quality.
- No processes for measurement of statistical outliers. One national clinical audit has developed a statistical model but lacks resources to implement this.

Improvement examples from national clinical audit

The value of national clinical audit can be made visible through improvement in the delivery of care. Some examples are shared from some of the national clinical audits in this review. This is not a definitive list.

Table 5 Some examples of quality improvement arising from national clinical audits

Audit	Examples of Improvement
Major Trauma Audit	Contribution to policy on the development of a national trauma network. Development of a trauma document, currently disseminated through trauma-receiving hospitals. This initiative has received quality awards from both TARN and NOCA.
Irish Hip Fracture Database	Contribution to the development of bypass protocols in hospitals without an orthopaedic service, with 92% of patients with hip fracture going directly to the operating hospital. Development in orthogeriatric service, which has led to reduced length of care and increased discharge back to patient's own home.
Irish National Intensive Care Unit Audit	Data quality reviews from sites shared back to facilitate data review on others. Similar issues occurring from site to site with shared solutions.
National Audit of Hospital Mortality	Local reviews leading to improvement in care with feedback of learnings in national reports.
NPEC Perinatal Mortality	All 19 maternity units contribute to the audit on perinatal mortality. With the support of the Faculty of Pathology at RCPI, the NPEC has adapted the standardised terminology for presenting placental pathology as per the international consensus. In 2018, the National Women and Infant's Health Programme adapted, with a view to implementing nationally, the following NPEC recommendations: establishment of a confidential inquiry into unexpected intrapartum-related deaths and the development of a national perinatal pathology service.
NPEC Severe Maternal Morbidity	All 19 maternity units contribute to the audit on severe maternal morbidity. In 2018, the National Women and Infant's Health Programme has adapted, with a view to implementing nationally, the following NPEC recommendations: national implementation of a specific proforma to improve management and documentation of obstetric haemorrhage; development of a toolkit to assist a standardised quantitative approach to estimate obstetric blood loss; equitable access for all pregnant women to the most appropriate critical care facility for her needs; and provision of a national maternal retrieval service.

Audit	Examples of Improvement
National Paediatric Mortality Register (NPMR)	Reduction of sudden infant death rates via safe sleep guidelines. Accurate mortality estimates established for deaths due to infection/sepsis in the paediatric population. Coding issues have caused the burden of infection-related deaths among Irish children to be underestimated. This information is to be made available soon.
National Stroke Register	Decreased mortality. Improved door-to-imaging times/treatment. Reduction in nursing home admissions.
Clinical audit carried out by National Sepsis Programme	Process audit: hospital based and used to inform education programme and track sepsis guideline implementation. Outcome audit: national mortality trends; burden of acute healthcare usage; patient characteristics for improved recognition.

Conclusion

This high-level review of national audits has highlighted the following:

- National clinical audit is widely supported by clinicians and when properly resourced is producing reliable data to drive improvements.
- However, the Irish healthcare system would benefit if the following were in place:
 - A formal process to prioritise, fund and implement new national audits in the HSE to ensure that they are sustainable.
 - Standards for design and governance of national audits to include resourcing and ethical consideration.
 - A definitive list of recognised national clinical audits that require participation.
 - Clear accountability to implement audit recommendations.
 - Supports available to the healthcare system with regard to local audits, specialty registers, and using these data to drive improvements.
 - A healthcare system that invested in QI:
 - Time on meeting agendas for QI
 - Training – data analysis, designing clinical audits, QI approaches, change management
 - Time for staff to lead/take part in improvement projects
 - QI Office linked to National QI Network.

References

Health Service Executive (HSE) (2015) *Serious reportable events (SREs): HSE implementation guidance document*. Dublin: HSE. Available from: <https://www.hse.ie/eng/services/publications/performance-reports/srejan15.pdf>

Bibliography

Agency for Health Research and Quality (AHRQ) (2011) *Types of health care quality measures*. Available from: <https://www.ahrq.gov/professionals/quality-patient-safety/talkingquality/create/types.html>

Department of Health (UK) (2008) *Guidance on the routine collection of Patient Reported Outcome Measures (PROMs)*. Available from: http://www.healthcare-today.co.uk/doclibrary/documents/pdf/152_guidance_on_routine_collection.pdf [Accessed 11 May 2018].

Health Service Executive (HSE) (2013) *Open Disclosure: National Guidelines – Communicating with service users and their families following adverse events in healthcare*. Dublin: HSE. Available from: http://hdl.handle.net/10147/305968_re/ [Accessed 11 May 2018].

HSE (2018) *Incident management framework*. Dublin: HSE. Available from: <https://www.hse.ie/eng/about/qavd/incident-management/hse-2018-incident-management-framework-guidance-stories.pdf> [Accessed 11 May 2018].

Porter, M. (2010) What is value in health care? *New England Journal of Medicine*, 363: 2477–81. Available from: <https://www.nejm.org/doi/full/10.1056/nejmp1011024> [Accessed 11 May 2018].

Williams, K., Sansoni, J., Morris, D., Grootemaat, P. and Thompson, C. (2016) *Patient-reported outcome measures: literature review*. Sydney: Australian Commission on Safety and Quality in Health Care.

Appendix 1: Glossary of terms used for this review

Definition 1: Clinical outcome measures

Clinical outcomes are those which measure the outcomes of clinical interventions. Ideally, they should be outcomes that are important to patients (rather than solely reflect the hospital's or unit's perspective) and there should be evidence that the outcome measure is associated with the quality of care. Some examples of clinical outcome measures include, but are not limited to, the following:

- Hospital-acquired infection rates – outcome measure
- Unplanned readmission rates to hospital or unit – outcome measure
- Survival – outcome measure
- Rates of avoidable adverse events – outcome measure.

Definition 2: Process measure

Process measures can inform consumers about medical care they may expect to receive for a given condition or disease, and can contribute towards improving health outcomes. These measures typically reflect generally accepted recommendations for clinical practice, e.g. time to diagnostic procedure or treatment. The majority of healthcare quality measures used for public reporting are process measures.

Definition 3: Patient safety incident

As defined in the revised general scheme of the Health Information and Patient Safety Bill 2015, a 'patient safety incident' means:

- (a) an incident which has caused an unintended or unanticipated injury, or harm, to the patient and which occurred during the provision of a health service to that patient, or
- (b) an incident (i) which has occurred during the provision of a health service to the patient and did not result in actual injury or harm, and (ii) in respect of which the health service provider has reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm, or
- (c) the prevention, whether by timely intervention or by chance, of an unintended or unanticipated injury, or harm, to the patient during the provision, to him or her, of a health service, and in respect of which the health service provider has reasonable grounds for believing that, in the absence of such prevention, could have resulted in such injury, or harm, to the patient.

Definition 4: Serious reportable events

Serious reportable events (SREs) are a defined subset of incidents which are either serious or that should not occur if the available preventative measures have been effectively implemented by healthcare providers. Serious reportable events are mandatorily reportable by services to the Senior Accountable Officer.

Note: Clinical outcome and process measures are monitored using the statistical outlier process. During a hospital review, a patient safety incident or SRE may be identified. An SRE is a single event and the HSE has published a list of these events. There are often called sentinel events.

Appendix 2: Membership of the Short Life Working Group

Name	Role
Miriam Bell	Project Officer, National Deteriorating Patient Recognition and Response (EWS) Improvement Programme
Avilene Casey	Lead, National Deteriorating Patient Recognition & Response (EWS) Improvement Programme
Brendan Cavanagh	Programme Manager, National Acute Coronary Syndrome Programme
Dr Ronan Collins	Clinical Lead, National Clinical Programme for Stroke
Ann Coughlan	Manager, Specialty Quality Improvement Programmes, RCPI
Marina Cronin	Head of Quality and Development, NOCA
Dr Kieran Daly	Clinical Lead, National Acute Coronary Syndrome Programme
Christine Doyle	Programme Manager, National Clinical Programme for Sepsis
Kenny Franks	Operations Manager, NOCA
Dr Vida Hamilton	Clinical Lead, National Clinical Programme for Sepsis
Dr Joe Harbison	Clinical Lead, National Clinical Programme for Stroke
Cora McCaughan	Assistant National Director, Healthcare Audit, Quality Assurance and Verification Division
Joan McCormack	Programme Manager, National Clinical Programme for Stroke
Cliona McGarvey	Manager, National Paediatric Mortality Register
Brid Moran	Information Manager, NOCA
Iryna Pokhilo	Patient Representative, NOCA
Collette Tully	Executive Director, NOCA
Angela Tysall	Lead in Open Disclosure, National Open Disclosure Office, National Quality Improvement Team

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